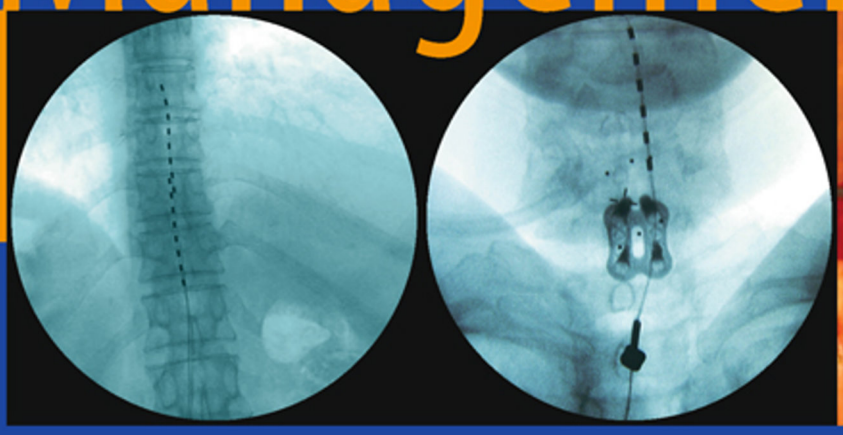
Timothy R. Deer

Atlas of Implantable Therapies for Pain Management



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Timothy R. Deer, MD

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Authors' Note: The United States Food And Drug Administration has labeled implantable devices for specific approved uses in the United States. This Atlas is not intended to promote or encourage any off-label use to any Physician practicing in the United States. The Atlas discusses currently used techniques, clinical research, and personal experiences as learning tools for the clinician. This is not intended to be promotional in any fashion. While this Atlas is intended for physicians in the International Pain Treatment community, it should not be read, used, quoted, or interpreted, in whole, or in part, as endorsing, recommending, or suggesting that any device be utilized or implanted for any purpose, which is not consistent with and authorized by the law, practice and regulations regarding the device and procedure where performed. No author of this Atlas, nor anything in this Atlas, shall be read as providing that authorization and nothing in this Atlas shall be interpreted or read to the contrary. At a minimum, it is imperative that any physician reviewing any portion of this Atlas confirm before implanting any device that: 1) he/she has the necessary and proper training, licensure, education, facilities, equipment and qualified personnel to implant the device safely in the specific manner contemplated and disclosed to the patient: 2) the specific use of the device in that prescribed manner is permissible under applicable law, regulation and practice; 3) the use of the device in that manner is in the patient's best interests; and 4) that all necessary disclosures have been made to the patient, or appropriate representative, so that informed consent for the specific device and procedure has been obtained prior to any use or implantation thereof.

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Foreword

I am honored to write this foreword to the *Atlas of Implantable Therapies for Pain Management*. While implantable devices for the treatment of intractable pain have been used for nearly half a century, never before has such a comprehensive atlas been available for the benefit of the pain practitioner. While several excellent texts have discussed the various aspects of neuromodulation for pain control, including patient, procedure and device selection, their complications, and outcomes, none have provided a detailed pictorial representation of what is a largely technical specialty. By being able to view the devices used for these neuromodulation procedures as well as the detailed procedures used for their implantation, the pain practitioner for the first time can gain access to this exposure that otherwise would require intense apprenticeship with an experienced and skilled mentor.

In this volume, Dr. Deer and his collaborators have provided a clear and instructive visual atlas that provides the pain practitioner not only with a step-by-step guide to these procedures but also instructive views of those procedural steps that require special attention or unique approaches. Nowhere in the history of pain medicine has this material been so lucid and readily available; as such, I expect that it will serve as the standard guide for students, fellows, and practitioners of interventional pain medicine.

Chicago, IL — Robert M. Levy

Dedications and Acknowledgements

This book is dedicated to the many who have impacted its creation.

It is dedicated to my patients who continue the struggle against chronic pain and suffering. The patient–doctor relationship is a special relationship that is touching to the soul of the physician who experiences the success and failure of achieving the desired result.

It is dedicated to my partners and colleagues in West Virginia who have joined me in the struggle to care for the infirm. Christopher Kim has been critical to my success in practice and in life. Rick Bowman has been a terrific partner who has brought innovative thought and wide-reaching knowledge. Matt Ranson has brought a new energy to our practice that is contagious and awesome in its scope.

Doug Stewart, my good friend, has been a critical part of our surgical success, and an advocate for excellence in patient care. Wil Tolentino has been a daily blessing in the care of our patients with his skills in problem solving, efficiency, and friendship. Michelle Miller has been a daily part of the success of my practice; her work allows me to do my work, and I am very appreciative. I thank my nurses and assistants and value their work and contribution to our success.

Jeff Peterson has been critical to the completion of this atlas, and to the success of our practice. Jeff has a sound business mind and is an ethical guide to our practice and a trusted friend.

This book is dedicated to Jane Deer, a single parent, who sacrificed to raise an aspiring physician in a small town of West Virginia. Her ability to persevere gave me a role model that is engrained in my life.

It is also dedicated to the memory of my father, Raymond Deer, a tough coal miner who taught me to keep a positive attitude regardless of the perils and to have discipline in thought and work.

I also dedicate to James Cottrell. As a physician, uncle, friend, and father figure, Dr. Cottrell has been a role model for me. His kindness and caring have affected me greatly, both personally and professionally. I will be forever grateful.

To my children, Morgan, Taylor, Reed, and Bailie, I also dedicate this book. They are my inspiration for life. Their presence in my life makes each day brighter, and makes me realize the blessings I have received. It is a wonderful thing to watch them evolve and develop into beautiful, bright, wonderful people. I am very proud of each of them.

I dedicate this book to my wife, Missy. She has been the critical part of my life that has led to all good things and has helped me through all troubled waters. She is my friend, advisor, and counselor when I am worried, and the love of my life forever. I cannot express how much I appreciate her every day and how much I look forward to sharing with her the many years to come.

Finally, this book is dedicated to my God from whom all blessings flow. I thank God for his presence and guidance.

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I

Neurostimulation: Spinal Cord Stimulation

1

History of Neurostimulation

Timothy R. Deer

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Introduction

The use of electrical current has been an area of human interest since ancient times, most notably in Greece, where the development of ideas concerning electricity was abundant. It was the ancient Greeks who coined the word *elektron* to describe amber, a fossilized resin used to create sparks, and later this term would become the modern root of the word *electricity*. The use of electrical current to treat pain was first described by Greek physicians. The first documented use involved the release of electrically charged torpedo fish in clinical footbaths to treat prolonged headache. The use of electricity continued to develop in both Greece and Rome, and was more common in some communities, than herbs and other medicinal treatments. After the classical age of electrical medicine, published accounts of successful use of electricity to improve symptoms of pain were limited for many centuries, and the dark age of electrical treatment persisted for several centuries.

Gilbert, a famous seventeenth century scientist who first used the term *electricity*, described the relationship of electromagnetism to the treatment of pain when he wrote the use of lodestone, a piece of magnetic iron ore possessing polarity like a magnetic needle. He published reports of using lodestone therapy for treatment for headache, mental disorders, and marital infidelity. The mechanisms for treating infidelity were never theorized and the

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use of electrical current was not well understood. In 1745, Von Kleist, the bishop of Pomerania, devised a revolutionary method of capturing electrical current from amber and cloth and storing it in a glass jar. Unfortunately, the credit for this advancement was not given to the bishop. The same year, Dutch physicist, Pieter van Musschenbroek, at the University of Leyden, was credited with the invention of a device to store electric charge known as the Leyden jar. The device was constructed by placing water in a metal container suspended by insulating silk cords, and placing a brass wire through a cork into the water. The process of harnessing electricity was critical to all future work in science and medicine. The work of Von Kleist and van Musschenbroek made the development of neuromodulation possible.

The Leyden jar was applied to critical experimental work when used by the scientist Jean Jallabert, who, in 1746, discovered how to use electricity to stimulate muscle fibers. Using a Leyden jar, Jallabert successfully treated a paralyzed limb, resulting in involuntary contractions, regeneration of muscle, and increased blood flow. Jallabert's success inspired many scientists, and over the following two decades there were several reports of successful treatment of neuromuscular disorders. This work, which seemed highly advanced for the time period, led to the theory that electricity was a fluid. This theory had been previously touted by Descartes, and reinforced when John Walsh dissected the torpedo fish and explained that the electrical organ of the animal was like the Leyden jar. The torpedo fish, lodestone, Leyden jar, and early muscle experiments were the foundation of Neuromodulation that led to the future use of our current therapies.

Neurostimulation First Used in the United States

Benjamin Franklin was the first American to use Neurostimulation. Franklin's interest in electrical current peaked in 1756, after learning about the work Leopaldo Caldani, who reported that a Leyden jar could be discharged in the vicinity of a mounted and dissected frog's leg and cause it to twitch. Many scientists touted electricity as a miracle cure for many diseases after the presentation of Caldani's work. Especially popular was the hypothesis that paralysis may be cured by this method. Franklin did his own experiments on painful conditions and concluded that these claims were inflated after discovering that his subjects experienced more discomfort than pain relief. Unfortunately for Franklin's volunteers, many of whom were desperate souls willing to try this new option, he used high voltage stimulation that caused injury, pain, and tissue burns. The first use of neurostimulation in the United States, as reported in Paris by Franklin to the French Academy of Sciences, was unsuccessful. This scientific report diminished the interest in electrical treatment in the United States for many years.

Batteries for Neurostimulation

In 1780, Galvani discovered that touching a frog's leg with a copper wire led to nerve discharge and muscle contraction. He concluded from this experiment that animals had natural electricity that led to movement. This work was predicated by the theory of Isaac Newton that animal fluids had a direct relationship to subtle electrical fields and caused movement.

Twenty years later, Volta published a paper that explained a chemical interaction in animals that led to "animal electricity." His work led to the development of batteries and low voltage capacitors. Over time, this low voltage electricity used by Volta was applied to humans, and was much better tolerated by research volunteers than the high voltage stimulation used by Franklin, and led to progress in pain treatment. Volta and Galvani did work that both led to modern batteries and improved the understanding of electrical current in animals.

Early Neurostimulation: Advances and Failures

Unfortunately, the path to modern use of electricity was not one of universal success and understanding. The famed Italian physicist Volta felt the use of electrical current in medicine had no scientific backing. After Jallabert's work became well known, a period of quackery followed. Franz Mesmer's work on magnetism theorized that the celestial bodies acted upon our bodies by "invisible fluid." He used magnets to channel this fluid and create an electrical field. This "mesmerism" was short lived in popular acceptance and gave rise to suspicion among the public and scientific community. Many years later magnets became a popular alternative treatment although their relationship to "mesmerism" is unclear. Another questionable scientist was Elisha Perkins, who theorized that he could use an electrically charged rod to cure yellow fever. His credibility was highly questioned when he died of the disease after treating himself with the device. After his death, the use of the electrically charged rod fell out of favor.

In 1801, electrical currents were used experimentally to resuscitate patients who had suffered cardiac arrest or drowning. In 1804, a publication titled "The Elements of Galvanism" recommended passing an electrical current through the skin by applying gold leaf to the skin's surface then attaching a battery source to create an intermittent charge through the body for short time intervals. This treatment was applied through the occiput when possible and was used to treat headache, tumors, and generalized pain. These concepts are strikingly similar to the current concepts of cardioversion and greater occipital nerve stimulation. Perhaps, these scientists were ahead of their time.

The next steps forward in this field were the result of the work of Andre Marie Ampere. Ampere researched the effect of electrical current on magnetic needles. This study led to the understanding that currents can attract or repel each other depending on the flow of current. Faraday advanced this work in 1831 when he described electromagnetic induction. His description was based on the observation that generation of electricity in one wire could "induce" magnetic and electrical effects in a separate wire. These descriptions of electromagnetic induction are the critical link to modern day neuromodulation in the treatment of pain and movement disorders. The initial development of a magnetic electrical machine by Clarke in 1835 was based on Faraday's work. This device provided a steady supply of induced electricity and led to all future developments in medicine and electrical therapy. The use of these therapies was difficult to apply to patients initially because of the strong sensitivity of tissue to direct current. Concepts such as insulation, amplitude, and pulse width were still many years away, but these early developments were critical.

In the mid-nineteenth century, Guillaume Duchenne du Boulogne used electropuncture, or application of electricity to small needles inserted directly into muscles, to observe that closing of the circuit caused contraction of specific muscles, thus allowing for exact mapping of muscle function. Duchenne summarized his thoughts on direct muscle stimulation and indirect nerve stimulation in the landmark book *De L'electrisation Localise*. This work led to the development of early prostheses that used surface electrodes to move the body part and eventually to modern rehab stimulation devices. Current conceptual devices are being used to improve motor rehabilitation by applying current to the brain, spinal cord, and nerves of the peripheral extremities.

High-Frequency Stimulation and Voltage Alterations

The French physiologist d'Arsonval found that the application of high frequency current caused less pain. He used 10,000 oscillations per second, which was increased further by Hertz in 1890 when he was able to achieve 1,000,000,000 oscillations per second without

stimulating tissue in a painful manner. This initial stimulation was at a low voltage that was eventually increased by Hertz's spark gap resonator, a device that allowed the use of a gap in the otherwise complete electrical circuit to discharge current at a prescribed voltage. This increase in voltage control along with high frequency led to successful treatment of arthritis, pain, and tumors. The developments of d'Arsonval and Hertz remain critical for modern day stimulation programming platforms.

Modern Neurostimulation: 1960 to the Present

The use of electrical stimulation in modern medicine had its origins in the 1960s. This work began with basic and bench science research. Woolsey used electrical stimulation to map the animal cortex and subcortex. Melzack and Wall further increased our understanding of Neurostimulation with the publication of the gate control theory that described inhibitory and excitatory relationships in the nervous system and, in particular, in pain pathways. These scientific efforts led the way to great clinical progress, and led to the building blocks of all future developmental work.

Norman Shealy, MD, at the University Hospitals of Cleveland, Case Western Reserve, described the use of electrical current to modulate the nervous system and change the perception of pain and suffering. Shealy worked with an engineering student, Thomas Mortimer, to develop a stimulating lead that would work on the dorsal columns of the spinal cord. This ambitious and innovative team used a crude platinum electrode design with a positive and negative electrode to treat a cancer patient at the end of life. The generator was an external cardiac device with the lead placed in the intrathecal space. The target was not ideal, the patient was not one that would be considered appropriate in modern selection thought, but still the outcome was excellent. This work excited the field, and led to multiple projects that stimulated advancement. Shealy and others such as William Sweet at Massachusetts General Hospital modified the technique over the next few years to stimulate the epidural space. In 1968, Medtronic (Minneapolis, Minnesota) obtained FDA approval to produce these devices for the treatment of pain. Early devices required radiofrequency communication between the electrodes and power source. In addition to the treatment of pain, these devices were also used to treat hypertension (targeting the carotid sinus), spasticity, and torticollis.

In 1973, Hosobuchi made another incredible observation that these devices could be used in the deep brain to treat facial pain. This was the birth of deep brain stimulation, and many patients were treated over the ensuing four years. The use of electrical delivery to the brain was restricted in 1977 when the FDA determined that the use of these devices for pain was safe and effective but that they should not be used for other indications until further blinded prospective research was performed. The work of Hosobuchi was built upon by Tsubokawa in 1991 when he showed stimulation of the motor cortex alleviated pain of central origin. This was the origin of motor cortex stimulation, which was less invasive, easier to apply, and had less apparent risks. Eventually, deep brain stimulation was approved for the treatment of movement disorders in Parkinson's disease and dystonia. Several studies are currently ongoing for deep brain and motor cortex stimulation including pain, depression, obsessive compulsive disorder, traumatic brain injury, and obesity.

After Shealy's initial work, stimulation had a slow developmental process for pain treatment. Significant work was done by Augustinsson in ischemic pain, North and Kumar in failed back surgery syndrome, Murphy in angina, and Kemler in complex regional pain syndrome. In addition to advances in clinical disease states the last three decades have shown amazing changes in technology. New developments have included advances from two contact leads made of platinum to eight contact leads made from titanium. Paddle leads have been advanced to many new configurations and choices to give more direct stimulation. Current paddle configurations now allow three to five rows of contacts to

program many spinal cord regions to apply current to neural targets. Other advances have included complex computer programming models, rechargeable batteries, new anchors that secure the lead, and lower profile wire connectors and wiring.

Selected Reading

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2

Spinal Cord Stimulation: Indications and Selection

Timothy R. Deer and Robert J. Masone

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Introduction

The selection of proper candidates for implantable spinal cord stimulation is a critical factor for producing acceptable outcomes for patients suffering from severe pain. A device in the proper location with the appropriate programming will not be helpful if the patient is a poor candidate for the therapy or if the disease process does not respond to the application of spinal cord stimulation. This chapter examines important factors for selecting patients who may need a device for the treatment of pain. The selection process can be narrowed into two specific areas – patient-specific characteristics and disease-specific characteristics – and each will be covered in detail in this chapter.

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Patient-Specific Characteristics

Analysis of patient outcomes has shown that some predictability of success can be made in advance of trialing the patient for a stimulation system. These criteria are helpful in determining who may benefit from these advanced techniques and include:

1. The patient should have no untreated drug addiction problems. This refers to the psychological problem of addiction and does not refer to a patient who is taking properly prescribed opioids under the care of a vigilant physician. If substance abuse and addiction are concerns, the patient should be seen by a health care provider with expertise in these areas and treated. After successful treatment, the patient may be reconsidered for the device.
2. The patient should be psychologically stable for the planned technique. Many patients who are afflicted with chronic pain also suffer from depression and anxiety. Outcome studies have shown that the presence of these problems does not adversely affect outcomes if they are treated and stable. Psychological interventions such as cognitive behavioral therapy may be helpful both before and after the placement of a spinal cord stimulation device although no definitive outcome studies exist. Once the patient has been successfully treated for the problem, the procedure can be performed. Screening for depression or anxiety can be difficult. Work by Doleys showed that the Minnesota Multiphasic Personality Inventory (MMPI) is not predictive of an adverse outcome even if the patient's scores indicated high levels of depression and anxiety. In this analysis, the patients with the worst scores on this inventory had excellent outcomes and showed a major improvement in repeat testing. Because of the complexity of this issue if the implanting doctor is concerned about the issue they should consult a psychologist or psychiatrist well versed in the relationship between pain and depression and familiar with spinal cord stimulation. While depression and anxiety may be controversial, the issue of the suicidal or homicidal patient is not an area of debate and should be considered inappropriate candidates for these devices. The other area of concern is that of personality disorders. While several personality disorders can lead to functional disabilities, the diagnosis of borderline personality disorder should be seen as a relative contraindication to moving forward with an implant. Antisocial personality disorder is another worrisome problem and should also be viewed with caution.
3. The patient should have appropriate cognitive ability to understand the procedure, the risks, and expectations of the therapy. The patient must also understand the use of the equipment and the technical responsibilities of having the device implanted. Cognitive functioning can be diminished because of neurological disease, medical illnesses, or from a baseline level of intelligence that does not allow for implanting. A psychologist or neurologist may be helpful in determining competence when the implanting doctor has doubts.
4. The patient should have no untreated bleeding disorders. Prior to implanting the device the patient should be questioned concerning diseases that affect clotting, liver function, and platelet activity. A preoperative workup would include a complete blood count including a platelet count. A bleeding analysis should be considered if a history of bleeding exists. INR appears to be the most helpful study. PT/PTT and bleeding times are not predictive of bleeding risks in these patients. Platelet function studies are a new test area that may lend information for patients on drugs that affect platelet function. Patients should be able to come off of drugs that effect bleeding for the appropriate length of time prior to invading the epidural space. The guidelines of the American Society of Regional Anesthesia on bleeding and medication should be considered when doing a patient evaluation. A new issue is the use of drugs that affect clotting such as clopidogrel, and similar drugs, which put the patient at risk of bleeding and epidural hematoma. Prior to moving forward with an implant, the physician prescribing of these medications should be involved in the decision making process to determine the safety of taking the patient off the medications prior to implant. The patient should be off clopidogrel and similar drugs for several days prior to the placement of spinal leads, and should remain off the drugs until the lead is removed in cases of stimulation trialing. In permanent implants, the

Table 2.1. Patient characteristics that predict success with spinal cord stimulation.

Absence of aberrant opioid-related drug use behavior suggesting opioid abuse or diversion
Dose escalation without practitioner's approval
Lost prescriptions
Requests for frequent refills
Loss of opioid medications
Obtaining opioids from multiple prescribers or other sources
Absence of psychiatric/psychological co-morbidities
Untreated mood disorders (anxiety, depression)
Untreated psychosis
Personality disorders
Appropriate understanding of the risks and benefits of spinal cord stimulation
Absence of bleeding diathesis
No history of bleeding disorders or platelet abnormalities
No history of nosebleeds, easy bruising, or difficulty controlling bleeding
Discontinue all medications affecting hemostasis (NSAIDs, antiplatelet drugs, anticoagulants)
Absence of infection at site of implant or signs of systemic infection

drugs may be restarted a few days after the leads are surgically secured. The number of days required off of these drugs is controversial with most experts agreeing that the proper time is between seven and fourteen days. New classes of drugs are being developed that are much more potent than the currently available products and may result in new risks for patients undergoing invasive procedures. The implanting physician should ask the prescribing physician to recommend a time course in which the blood clotting should be back to a normal baseline, but in many cases this may be difficult to determine.

5. The patient should be free of infection at the site of implant. Systemic infections should be treated and under good control prior to moving forward. If any evidence of potential bacteremia exists, the benefit of the stimulation system should be carefully weighed prior to moving forward. In the case of local infections such as cellulitis the case should be delayed until proper evaluation and treatment can be arranged. This danger should be considered when the patient has had a recent procedure in the area of needle insertion. This is not an uncommon concern when considering spinal cord stimulation is part of an algorithmic process for the treatment of intractable disorders.

Table 2.1 shows the common issues involved with patient selection.

Disease-Specific Characteristics

The second factor involved in the selection process is choosing the patient with the proper disease state and indication. Several factors have been shown to be helpful in choosing who we should select for this type of treatment and who may be a poor candidate. The indications for spinal cord stimulation that are best supported by published studies include burning, or shooting pain in the extremity after spinal surgery, complex regional pain syndrome, types I and II, peripheral nerve injury, painful neuropathies, refractory angina with no correctable lesions, ischemic pain, and pain related to peripheral vascular disease. Some disease processes may respond but are not as well supported in the literature. These include axial pain in the lumbar spine with or without a history of spinal surgery, intercostal neuralgia, spinal cord injury, and phantom pain or neuropathic pain after trauma, and

Table 2.2. Disease based selection for stimulation.

High probability of successful pain reduction
Chronic radicular pain (cervical and lumbar)
Complex regional pain syndrome (CRPS), types I and II
Painful peripheral neuropathies and mononeuropathies
Angina pectoris refractory to conventional drug therapy and not amenable to surgical bypass
Painful ischemic peripheral vascular disease not amenable to conventional drug therapy or surgical bypass
Low probability of successful pain reduction
Neuropathic pain following spinal cord injury
Central pain (e.g., poststroke pain)
Nerve root avulsion (e.g., brachial plexus avulsion)
Unknown probability of pain reduction (case reports of successful treatment)
Postherpetic neuralgia
Axial low back pain (improving with new lead arrays and programming)
Phantom limb pain

chest wall pain. In some patients, despite proper lead placement and proper stimulation coverage, no improvement is seen. Patients at high risk of failure include those with spinal cord injury, thalamic stroke pain, or pain of any origin within the brain, pain in the rectum and anus, complete nerve root avulsion and aching nociceptive pain of the limb. These generalizations are based on peer reviewed studies showing that SCS is more effective for radicular pain following spinal surgery of the cervical or lumbar spine. Emerging technology has allowed more effective treatment of axial disorders particularly with new dual and tripolar lead arrays and new computer models for driving current to deeper areas of the cord. Conclusions regarding ischemic pain are based on considerable data suggesting positive results on both flow and pain reduction in patients with diminished blood flow. Existing data are also strongly supportive of the use of spinal cord stimulation for the treatment of angina pectoris. Many of these publications are based on European cardiology evidence that show improved function, reduced pain and reduced need for nitrates. Complex regional pain syndrome has been shown to respond well to SCS when considering pain reduction and improved function. Recent outcome analysis has also shown improvements in costs of care and overall utilization of the health care system. Table 2.2 summarizes the disease states considered for spinal cord stimulation and the probability for success with each area of pain.

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3

Needle Placement for Percutaneous Spinal Cord Stimulation of the Back and Legs

Timothy R. Deer and Louis J. Raso

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Introduction

The introduction of a needle into the epidural space is a component of the procedure that must be completed in order to place a percutaneous lead. The needle placement is often viewed as a simple procedure, yet it is a technique that should be performed with vigilance and planning. Prior to placing the needle, the patient must be prepared, positioned, and a fluoroscopic scout film is taken to evaluate the best route to use when placing the needle.

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Technical Overview

After proper patient preparation, the physician should develop a strategy for needle placement. This should include level of entry, angle of entry, side of entry, and method of identifying the epidural space. The physician should also plan the site in relation to bony landmarks regarding the placement of the needle tip at the time of epidural space entry. Once the route of entry is determined a local anesthetic injection is given. At this point, a 15 blade is used to make a small stab wound to place the needle. This step allows for an easier entry into the tissues, and may reduce the risk of introducing infection into the epidural space from skin pathogens. The needle is then placed at an angle of 30–45° and advanced until it is seeded in the ligament. At this point, the stylet is removed and the needle is advanced carefully using the loss of resistance or hanging drop technique. The angle will determine the end point of the tip when entering the epidural space. In most cases, this will be just below the spinous process on anterior–posterior view, and it will be in the posterior epidural space on lateral view. At this point, the needle is ready for lead placement. The procedure is illustrated in Figures 3.1–3.8.

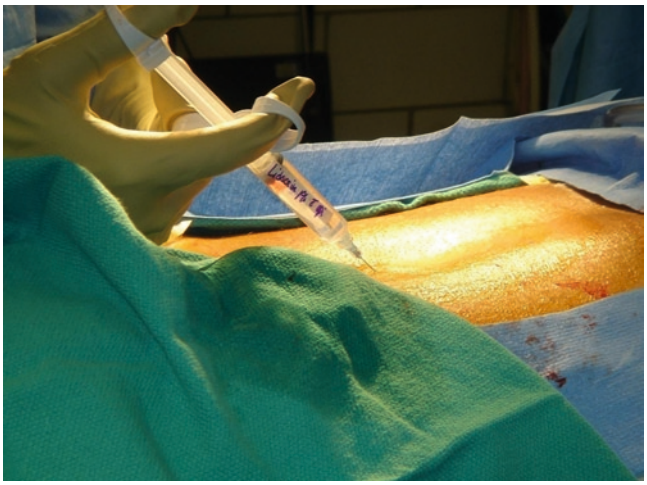

Figure 3.1. Local anesthetic should be applied in the same plane that is planned for the needle placement. The local anesthetic should be placed in the skin and subsequent tissues to the level of the supraspinous ligament. If the needle is advanced aggressively into the spine, injection of local anesthetic into the spinal fluid can lead to an accidental spinal block.

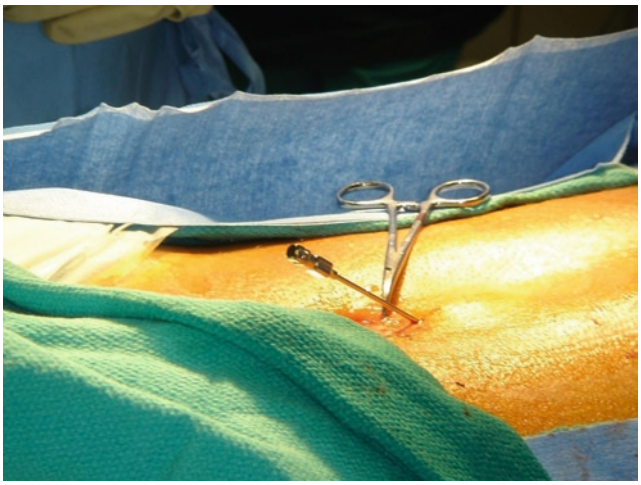

Figure 3.2. The angle of needle placement should be between 30 and 45° when possible. In some cases, the patient's anatomy will not lend to that angle and adjustments must be made accordingly.

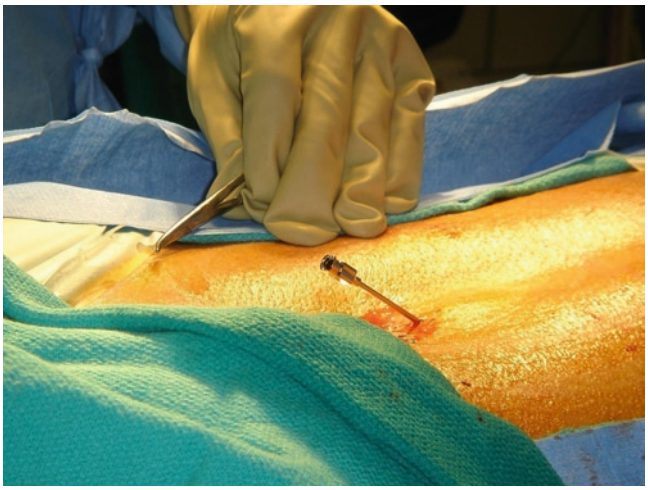

Figure 3.3. Ideal needle placement with stylet removed.

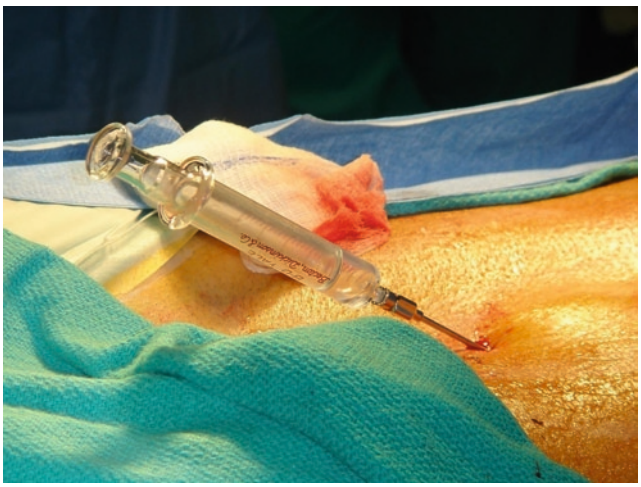

Figure 3.4. The confirmation of needle placement is performed by loss of resistance or hanging drop technique. In some cases, the placement of contrast is needed, but should be avoided if possible.

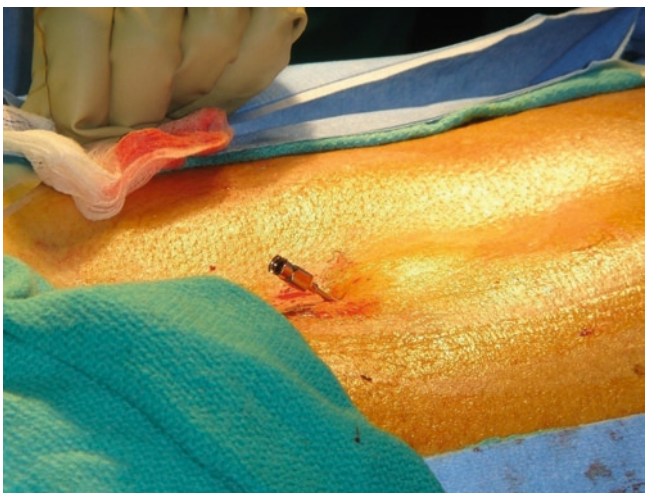

Figure 3.5. Needle placement in the epidural space.

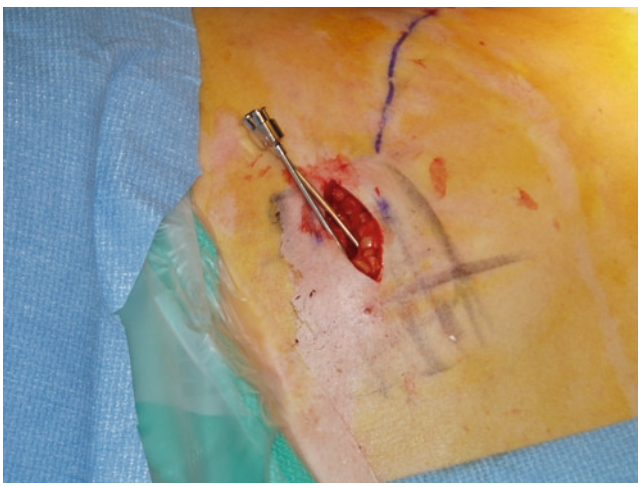

Figure 3.6. In morbidly obese patients, a cutdown may be needed to achieve a safe angle. The physician must weigh the risks of the cutdown with the risk of a sharper angle that can lead to wet tap or nerve injury.

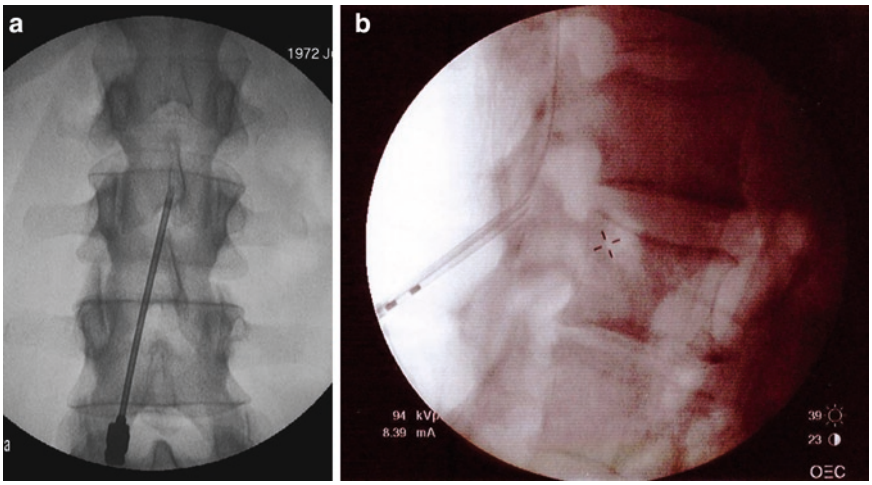

Figure 3.7. Fluoroscopic guidance is critical for placement. The use of anterior–posterior and lateral images are needed to confirm needle placement.

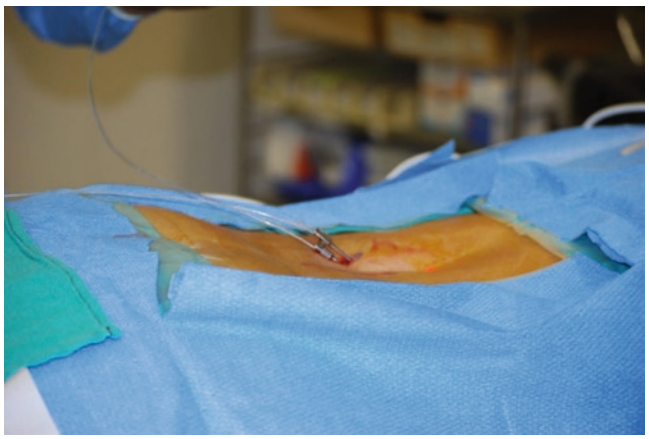

Figure 3.8. Once the needle position is acceptable, the leads are placed to the proper target.

Risk Assessment

1. Skin infection
2. Bleeding
3. Nerve injury
4. Postdural puncture

Risk Avoidance

1. Do a thorough presurgical workup of coexisting diseases that may increase patient risks and determine whether the risks are acceptable. Primary care and other specialists should be consulted to assure all systems are optimally controlled prior to implant. Choose a sterile operating area, prep widely, drape widely, use prophylactic antibiotics as directed, make a skin entry puncture, and use sterile dressings.

2. Assess preoperative risks of bleeding and determine whether the risks are acceptable. Consult with primary care or cardiovascular specialist regarding drugs that affect the platelet function, bleeding times, or other areas of hemostasis. Determine whether the patient can be removed from those medications for an acceptable time period prior to needle placement. Consult with primary care regarding disease states that effect bleeding such as leukemia or other diseases of the hematological system. If the platelet function is below fifty thousand, the physician should be hesitant to proceed without the written consent from the treating physician assessing the patient's bleeding status.
3. The ability to harm a patient by introducing a large needle into the neuroaxis is a substantial worry. Fortunately despite this potential harm, the occurrence of a significant injury is a rare event. The critical points to avoid nerve injury are: keep the patient alert and responsive during needle placement even when using monitored anesthesia care or conscious sedation, keep the needle angle at 45° or less, if paresthesia is elicited remove the needle immediately and enter the spine at a different location once the paresthesia dissipates, if a patient complains of a stabbing or lancinating pain during needle placement consider giving intravenous steroids as a method of reducing neuritis. The decision to give steroids such as decadron (dose ranges from 2 to 12 mg) should be weighed against the risks of steroids on other disease states.
4. The risks of dural puncture is low with the placement of a spinal cord stimulation leads. The risks can be reduced by: proper positioning, proper fluoroscopic imaging, needle angle of 45° or less, careful advancement of the needle through the ligaments with image guidance as the needle is advanced, confirmation of needle placement by X-ray, hanging drop, loss of resistance, and in rare cases use of contrast. Once a dural puncture has been identified, the patient's risk may be reduced by increasing intravenous fluids, using abdominal binders to change intraabdominal pressure, consuming caffeine, and limiting activity. The use of a blood patch should be reserved for situations in which the patient does not resolve a severe postdural headache even with conservative measures.

Conclusions

The placement of a needle into the epidural space is seen by many clinicians as a simple portion of the implant of a spinal cord stimulation device. The needle placement should be viewed as a critical portion of the procedure and should be carefully planned and executed. By following the recommendations of this chapter, the chance of a successful outcome should be enhanced.

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4

Physician Guided Lead Placement: Making the Lead go to the Target

Timothy R. Deer, Louis J. Raso, and Stanley Golovac

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Introduction

The successful placement of a lead has several components. The physician must choose a patient with acceptable anatomy for placement, properly insert a needle, and pick a target for desired lead location for proper stimulation. In many patients, the most difficult component of the procedure is guiding the lead from the needle to the end location. Multiple factors will influence the ease in which this task is completed. By modifying the technique, the physician can maximize the ease in which the lead is guided to the target.

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Technical Overview

In some clinical settings, guiding a lead is technically very simple. The needle is placed at a proper angle into an area of the spine with excellent anatomy and the lead advances to the posterior epidural space without any obstructions. Unfortunately, in some patients the lead placement and guidance is very difficult. In these settings, the clinician must make proper adjustments to technique to optimize the procedure and improve the chances for a good outcome. A proper checklist of variables should be reviewed by the implanter. The first component of the procedure to examine for modification is the needle. Is the angle of entry at forty five degrees or less on the axis of the ligamentum flavum? (Figure 4.1a). Is the open component of the needle bevel adjusted to allow the lead to exit cephalad or slightly to the right or left? (Figure 4.1b). Is the amount of space where the needle is entering the epidural space limited to the degree that the lead does not have adequate space to be safely passed? Does the needle cause paresthesia? Needle issues are reviewed in Table 4.1.

Once the needle has been addressed, the next component to examine should be the lead itself. Is the stylet ideal to advance in the space? In general, a curved stylet (Figure 4.2a)

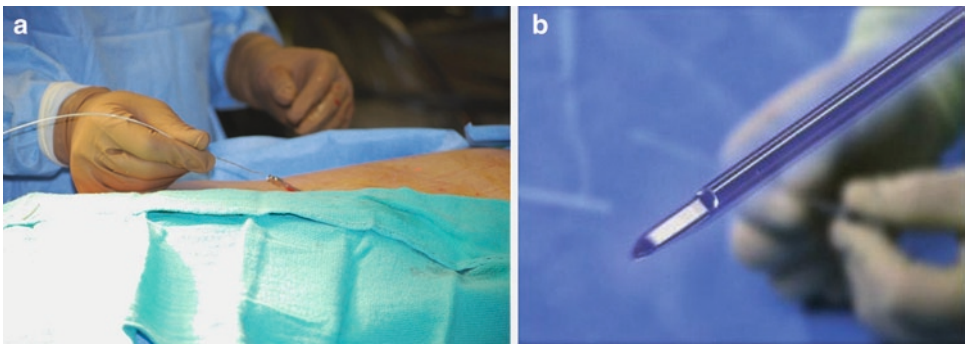


Figure 4.1. **(a)** Proper needle angle. **(b)** Typical epidural needle with bevel.

Table 4.1. Needle issues.

Needle issue	Recommendations
Angle of placement	45° or less
Bevel orientation	Rotate to allow easy lead exit
Tight exit for lead	Lower the needle angle and approach
Paresthesia	Immediately remove and replace the needle once the pain dissipates

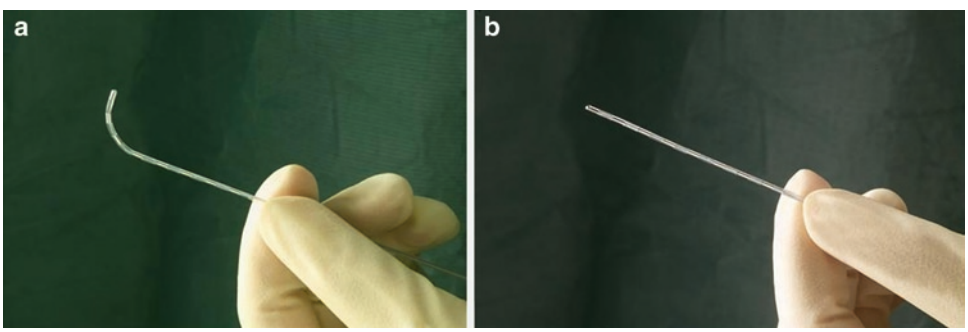


Figure 4.2. **(a)** Curved stylet. **(b)** Straight stylet.

Table 4.2. Lead issues.

Lead issue	Options
Lateral lead movement	Rotate the lead using a curved stylet
Obstruction to movement	Gently reposition the lead alternating the curved and straight stylet
	Gently tap the lead against the obstruction on multiple rapid attempts, withdrawing slightly each time
	Use the wire coil to pass the obstruction (use caution, and stop if pain occurs)
Failure to achieve stimulation despite optimal X-ray placement	Troll with the lead to find an area responsive to stimulation, try different programming arrays including a guarded cathode
High impedance of the lead	Reposition the lead cephalad or caudad

Table 4.3. Causes of obstructions.

Epidural fibrosis
Epidural vessels
Fascial bands
Spinal stenosis
Disc protrusions compressing the canal
Postsurgical scarring

is ideal for initial exit from the needle to start on a correct path toward the target. In situations where the lead is advancing too far laterally a change to a straight stylet (Figure 4.2b) may allow the lead to correct toward the midline. In some clinical settings the physician may need to alternate between a curved and straight stylet several times to maneuver the lead to the desired location. The need to exaggerate the curve in the stylet is rare, but in some cases the physician may create an exaggerated curve creating a "hockey stick" angle is needed to drive the lead toward midline when it is tracking laterally. In cases where an exaggerated stylet is used, the physician should reconfirm placement of the lead with both fluoroscopy and computer screening once the stylet is removed to detect a "rebound movement" that results in lead movement once the rigidity of the stylet is removed. Lead issues are reviewed in Table 4.2.

Epidural obstructions can be frustrating and potentially dangerous when attempting to successfully place a lead. These obstructions can be caused by several factors (see Table 4.3) and can lead to a failure of the procedure. All manufacturers include a wire coil in their typical lead deployment kit. This coil wire can be used to create a pathway or channel in the epidural space to help with lead advancement. These wire inserts can be helpful, but can also lead to complications and should be used with caution. The author prefers a different method for overcoming this issue. That is to use a technique of finesse, and a gentle approach to avoid trauma. In this method, the lead is advanced to the point of obstruction and then repeatedly advanced forward. Each time an obstruction is felt the lead is withdrawn, and then only advanced during exhalation. In many cases, this method will lead to an ability to advance the lead without traumatizing the tissue. Other options include using the curved and straight stylet to "drive" around the obstructive structure. In the event that these methods are unsuccessful, a different intralaminar level of entry should be considered. If difficulty persists past a reasonable number of attempts, the procedure should be aborted and a surgical laminotomy approach should be considered, even for the trial phase.

Once the lead is driven to the desired target hand held computer screening can be used to assure that the patient has the desired response. In the event the response is not optimal, additional modifications may be needed. Trolling of the lead can be used to

optimize placement. In this method, the lead is activated to the sensory threshold and then adjusted in the epidural space until optimal placement is achieved. When the clinician is satisfied with the placement, a fluoroscopic image should be taken on lateral and anterior–posterior views, and saved for future comparisons if there are any concerns about lead migration.

Risk Assessment

1. The risk of nerve injury should be considered when guiding a lead to the target zone. The lead may contact a nerve root or dorsal root entry zone and lead to an injury to the neural structures.
2. The lead can rent the dura and lead to a chronic CSF leak. This can produce a chronic post dural puncture headache.
3. The lead can dissect an epidural vessel and cause a bleed that may create an epidural hematoma, and subsequent neural injury.
4. The lead may be guided to the lateral or anterior position in the epidural space that can cause a motor nerve stimulation that can be very painful and stressful to the patient.

Risk Avoidance

1. To avoid nerve injury, the clinician should keep the patient conversant and alert during the time of lead placement. An alert patient can warn of paresthesia and result in a change in practice for the implanter.
2. To avoid the risk of dural tear or rent the lead should be advanced only when resistance is minimal and the lead should not be forced to advance past an obstruction. When using the wire coil device caution should be exercised to avoid excessive force.
3. Drugs that affect the bleeding function of the patient can lead to severe complications if not stopped prior to implant. The decision to stop warfarin, Plavix (Clopidogrel), and other drugs should be made by the treating physician for the affliction for which these drugs are being prescribed. The risk versus the benefit of stopping these drugs should be considered prior to moving forward. Proper laboratory values that may have an impact on bleeding should be considered prior to moving forward.
4. It is important to obtain an anterior posterior film and a lateral film to assure the lead is not positioned near a nerve root or ventral fiber area. The evaluation of only one view can lead to a miscalculation of lead placement.
5. The use of a shallow needle angle for entry into the epidural space is important for risk avoidance. This maneuver will improve the ease of passing the lead, help with directing the lead, and lower the incidence of lead migration over time.

Conclusions

The ability to drive a lead into a proper target zone can vary in difficulty. The physician can have a great impact on this process by making modifications noted in this chapter. The process of guiding a lead is essential to the procedure.

Supplemental Images

See Figures 4.3–4.9.

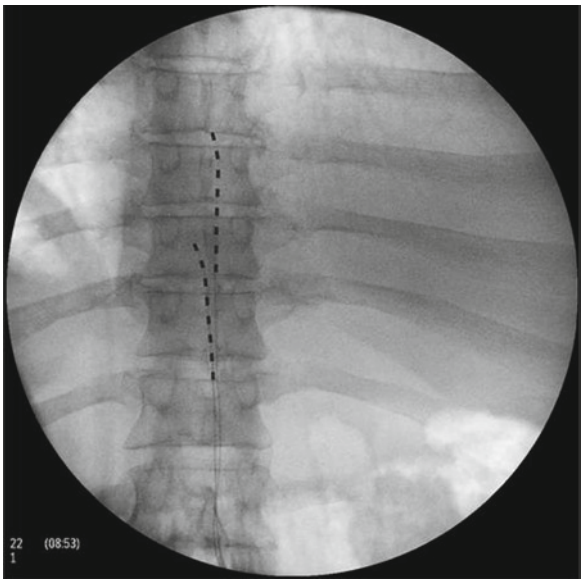


Figure 4.3. Percutaneous leads covering the T8–T10 vertebral bodies.

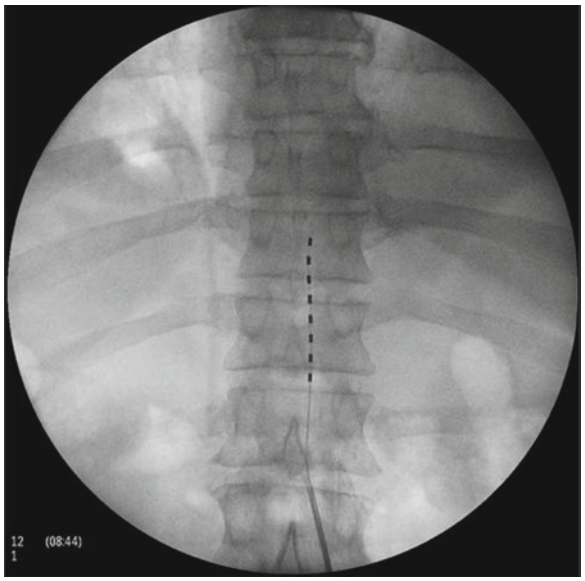


Figure 4.4. Percutaneous lead covering T10 and T11 off midline to provide unilateral coverage.

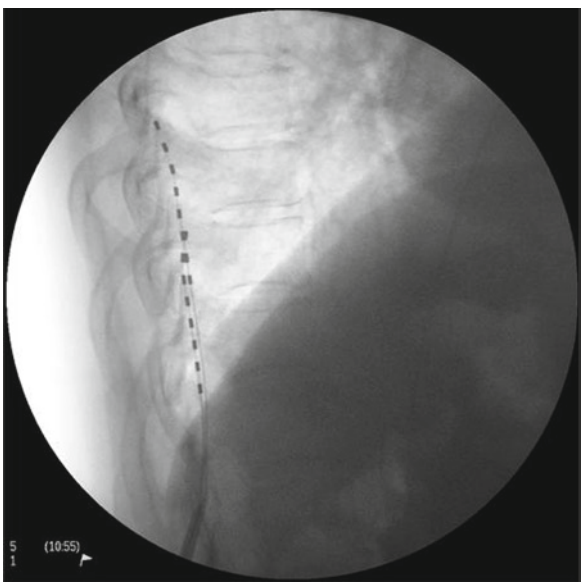


Figure 4.5. Lateral view showing correct lead placement for thoracic implantation of spinal cord stimulation systems.

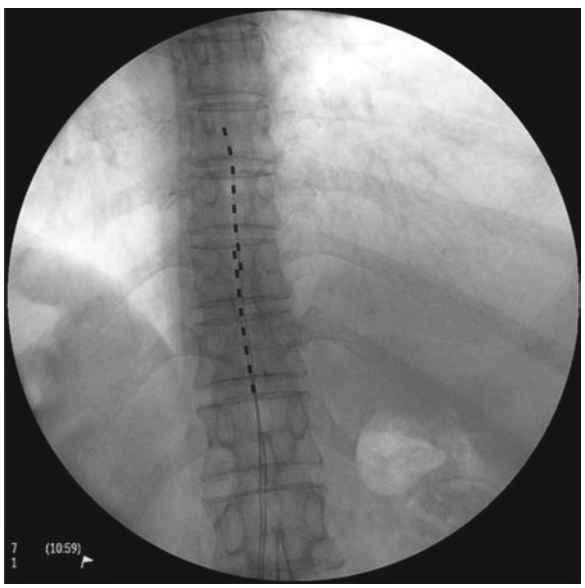


Figure 4.6. Staggered percutaneous array covering T8 to T11.

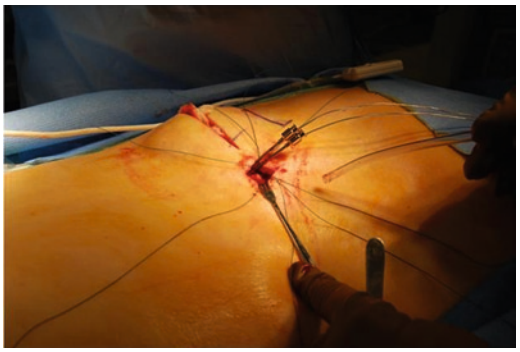


Figure 4.7. Once the leads are confirmed on X-ray, a cutdown is performed, anchoring stitches are placed and a pocket is made to implant the generator.

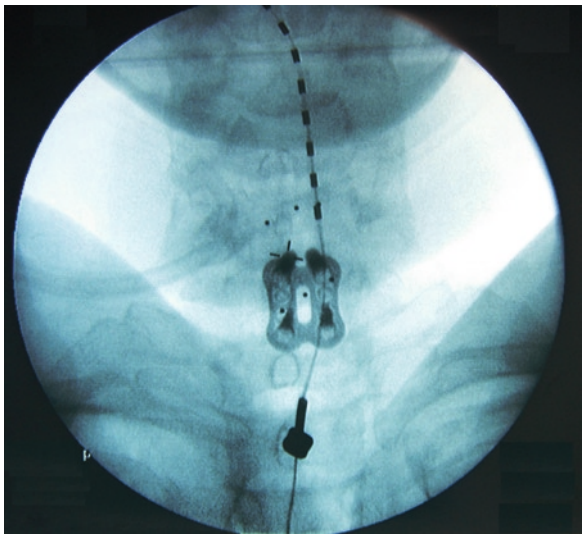
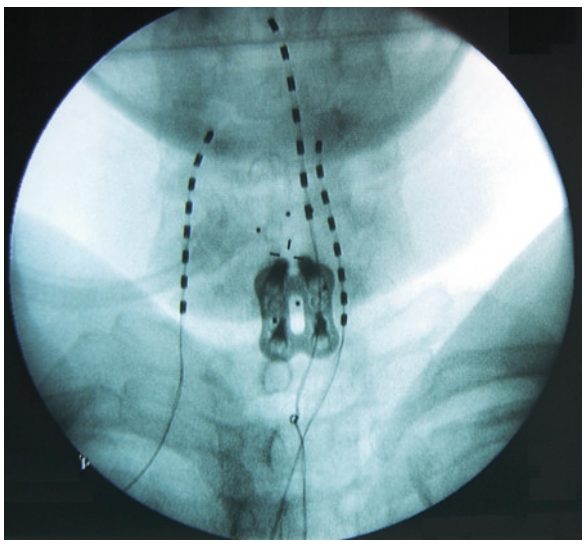


Figure 4.8. Percutaneous placement of cervical lead in patient with history of anterior fusion.

Figure 4.9. Combined stimulation of percutaneous and peripheral leads for the treatment of axial and radicular and cervical pain.



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5

Anchoring Percutaneous Leads During Permanent Device Placement

Timothy R. Deer and Stanley Golovac

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Introduction

Skillful needle placement, excellent lead guidance, and impeccable surgical technique are all technically critical parts of a good long-term outcome with spinal cord stimulation. In addition to these critical steps of implantation, the physician must properly anchor the lead. Even with meticulous attention to anchoring, lead migration can occur. This risk can be reduced by using proper anchoring procedures, and careful attention to tissue dissection.

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T.R. Deer, *Atlas of Implantable Therapies for Pain Management*,
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Technical Overview

Once the needle and lead have been successfully placed, the system must be prepared for anchoring. An incision must be made around the needle to the level of the fascia and ligament. The clinician should dissect the fatty tissue from the area surrounding the needle so that fascia and ligament are easily visible. The fascia has a "shiny" appearance that should be visualized around the lead entry, and the ligament has an appearance of leather. Anchoring sutures are then placed in the desired location prior to needle and stylet removal. When the needle and stylet are removed, careful attention should be given to maintain lead position. This portion of the procedure should be confirmed with fluoroscopic views taken before and after the needle and stylet have been removed to assure the position remains consistent. At this point, an anchor is moved over the lead to the entry point of the lead into the fascia or ligament. The amount of slack between the lead exit from the fascia and the anchor's most distal point should be minimal. Excessive amounts of exposed lead may allow migration distal to the anchor, between the anchor and the lead entry point into the superficial spinal structures. At this time, additional sutures may be placed based on the type and manufacturer of the anchor chosen. Some clinicians prefer a single suture while others prefer multiple sutures to avoid lead movement. New anchor technologies may allow for suture-free methods of anchoring. In addition to securing the anchor to the tissue, it is important to secure the lead to the anchor. This can be done by using surgical ties or anchors that lock to the lead. Some anchor models are equipped to lock down to the lead to avoid the problem of the lead moving despite a secure immovable anchor. When using these systems, attention must be paid to avoid tension on lead components which can lead to lead damage and eventual fracture. In these types of anchors, it is also important to carefully secure the anchor to the tissue so that the anchor itself will not shift (see Figure 5.1).

The physician should pay careful attention to the stimulation pattern of the lead(s) when obtaining optimal stimulation. The ideal lead orientation involves obtaining optimal stimulation patterns using electrodes in the center of the lead. This allows for correction of small lead distance migrations with programming changes rather than surgical revisions. Excellence in anchoring involves more than technical skill, but it also involves a good understanding of the concept of spinal neurostimulation programming.

Suturing and Anchoring Materials

The suture used to anchor the lead should be nonabsorbable and durable. In the past, many texts and articles have recommended silk as a mainstay of anchoring. Over time, the use of silk can lead to migration. This occurs because of silk degradation with time and eventual breakdown of the silk and potential movement of the lead. Ethibond and other similar sutures provide a sturdy nonabsorbable suture that will reduce the risk of long-term migration.

The type of anchor the clinician chooses may be less significant. Manufacturers often point out advantages of their anchoring systems and clinicians develop preferences based on individual experiences, but to date no long-term studies have been performed comparing anchors from competing companies. Regardless of the anchor chosen, it is important for the clinician to perform several safeguards to improve outcomes (Table 5.1).

The Deer–Stewart Anchoring Method

In our experience, the commitment to excellence in anchoring is worth adding a few minutes to the surgical procedure. To properly secure the lead that has been placed percutaneously, it is important to space the sutures properly. This can be achieved by using both strategically placed sutures that use the benefits of the anchor and figure-of-eight sutures that lead to tissue fibrosis around the anchor lead complex. Figure 5.1 illustrates the technique in

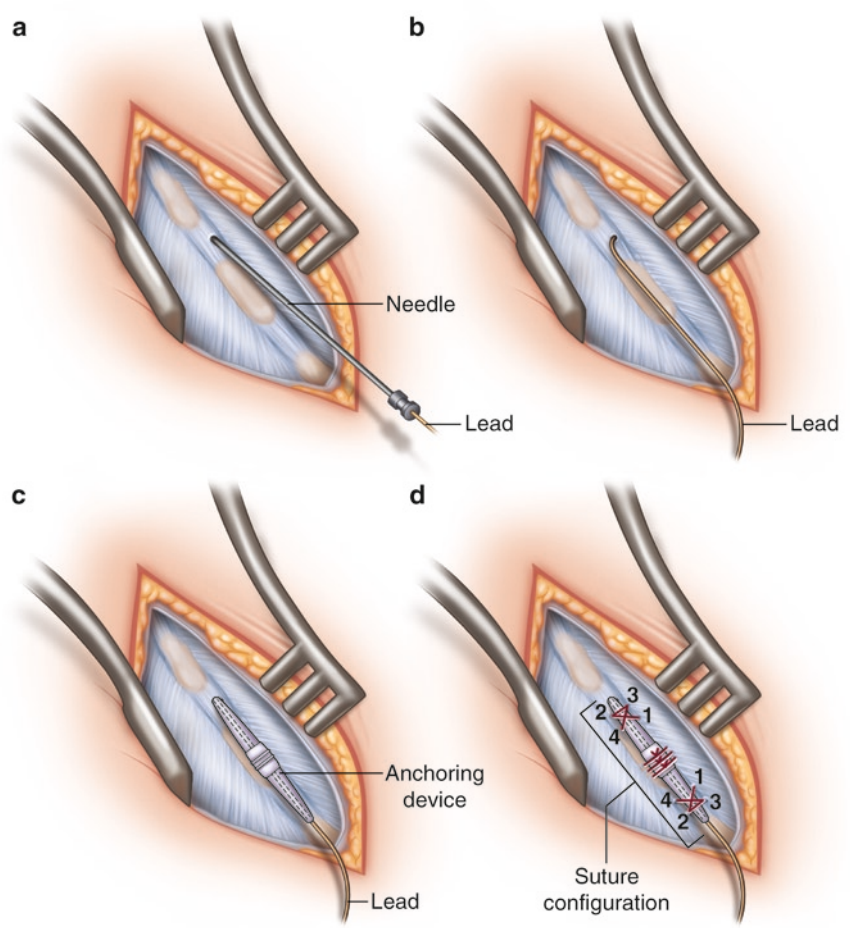

Figure 5.1. Anchoring and suturing technique. (**a**) Proper needle placement. (**b**) Proper placement of the surgical lead. (**c**) Proper placement of the anchoring device at the fascia entry point. (**d**) Suturing of the anchoring device employing the Deer–Stewart suturing technique showing three interrupted sutures in the middle of the anchor and figure-of-eight sutures at the distal and proximal anchor ends. The figure-of-eight sutures are numbered based on needle entry.

Table 5.1. Physician action to safeguard against risk.

Migration risk	Physician action
Needle angle	Needle angle of 30–45°
Needle entry	Paramedian approach
Fatty tissue at anchoring site	Debride fatty tissue around the needle entry site exposing fascia and ligament for proper anchoring
Anchoring to muscle	When using an exaggerated paramedian approach, the physician should dissect medially until approaching ligament or fascia, avoiding anchoring to muscle, which may lead to migration with contraction
Lead anchor gap	The anchor should be as close to the lead entry into the ligament or fascia as possible avoiding room for migration distal to the anchor
Suturing with silk	Avoid silk sutures when anchoring
Dependence on lock systems	When using anchor lock systems, the clinician should give attention to avoid tension on the lead and to properly secure the anchor
Hematoma below anchor	Hemostasis should be obtained prior to closing the wound
Minimal migration changes	Final lead placement should result in accommodation of small (less than 5 mm) migrations with reprogramming rather than reoperation

which three sutures are placed through the fascia and ligament (prior to needle removal), and two additional figure of eight sutures are placed at the proximal and distal ends of the anchor. This technique can be applied to any manufacturer's lead to secure better anchor to tissue fibrosis and subsequent reduction in anchor shifting (see Figure 5.1).

Risk Assessment

1. The incidence of migration for spinal cord stimulation systems have been reduced over the past decade. Despite this favorable development, migration still occurs and can lead to a need to reprogram the system, revise one or more leads, convert to a surgical lead, or remove the device. Since these systems are often therapies offered late in the algorithm, these occurrences are unfavorable.
2. When anchoring is performed to fatty tissue, necrosis of the adipose will occur leading to migration.
3. When anchoring is performed to the muscle tissue, migration can occur as the patient undergoes normal movement requiring muscle contraction.
4. Suture breakage can occur. This may lead to shifting of the lead or anchor.
5. The anchor can cause discomfort if it is superficial in the tissue.

Risk Avoidance

1. Migration can be reduced by using an angle of 45° or less for needle entry and by using a paramedian approach with needle placement.
2. Anchoring should occur only after all fatty tissue has been debrided from the area surrounding the needle.
3. When the paramedian approach is used in an extreme manner, the amount of fascia and ligament available for anchoring is unacceptable. The paramedian approach should be used in all cases of implantation; however, the needle entry point should remain in the area of the spine that allows for proper anchoring. If the paramedian approach is extreme, the tissue underlying the needle entry is muscle tissue.
4. Nonabsorbable suture should be used for anchoring. When possible, silk should be avoided since its long-term stability is worrisome.
5. In thin patients, it is important to use a double or triple layer closure to reduce the risk of discomfort at the anchor placement site. If an unacceptable tissue layer is present to cushion the anchor the surgeon can make a pocket in the muscle adjacent to the anchor to place any excess wiring or strain relief loops.
6. Attention to hemostasis should be given in the area of lead placement. Hematoma development in and around the lead can lead to movement of the anchor, fracture of the sutures, or movement of the leads.

Conclusions

Anchoring the lead is an important step in the long-term success of the procedure. Many clinicians focus on the placement of the lead, the creation of the pocket, and wound closure. Equal thought, planning and care should be given to the anchoring technique, and appropriate training should focus on this critical part of the procedure.

Supplemental Images

See Figures 5.2–5.6.

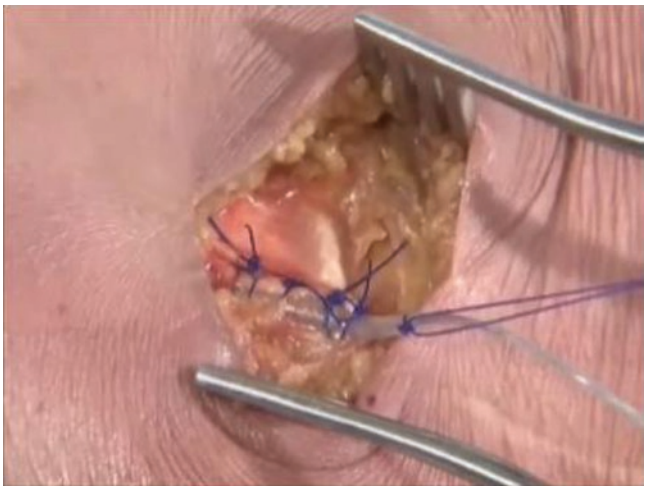

Figure 5.2. Anchoring to fascia and ligament.

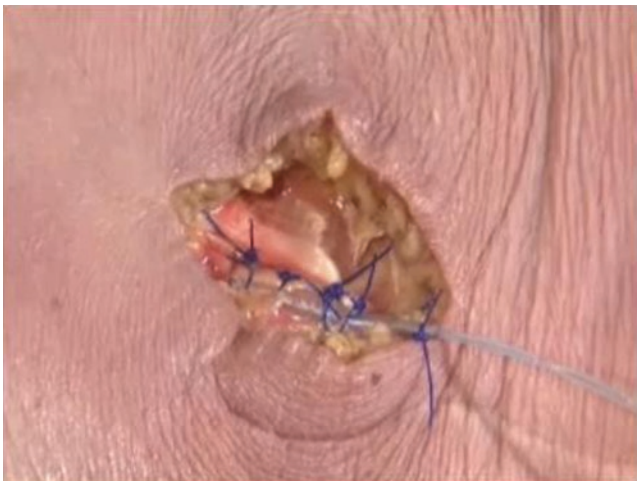

Figure 5.3. Anchoring to the fascia and ligament.

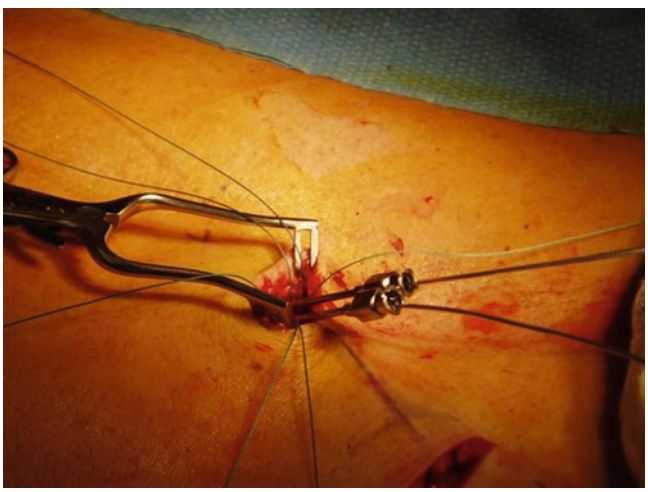

Figure 5.4. Sutures may be placed in the fascia and ligament prior to removing the needles in order to protect the leads.

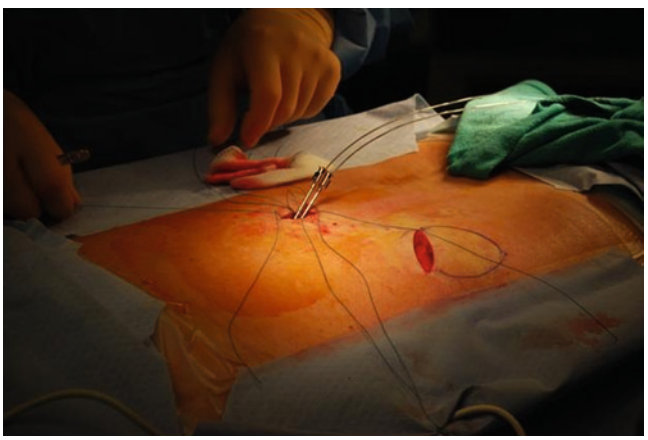

Figure 5.5. Dual needles are seen with a pocket created prior to anchoring to allow for observation of hemostasis prior to closure.

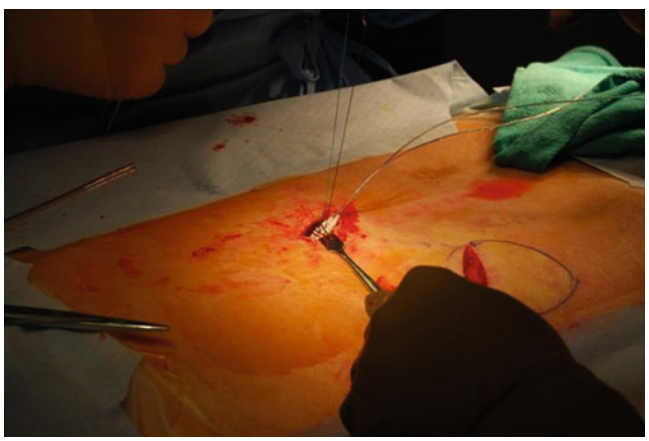

Figure 5.6. Anchors should be abutting the fascia prior to securing them to the spine.

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6

Tunneling Spinal Cord Stimulation Systems

Timothy R. Deer

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Introduction

The proper placement of a spinal cord stimulation lead is an accomplishment that is critical for a successful outcome. Likewise, the creation of a pocket to hold the internal programmable generator requires skill and planning. However, even if both of these steps are performed successfully, it still may not result in a competent system. The process of tunneling the lead or lead connectors is critical to allow communication of the electrode contacts and the desired neurological tissue. This chapter focuses on the procedure of tunneling for spinal cord stimulation.

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Technical Overview

The patient is positioned, prepped, and draped in a normal fashion. The leads are satisfactorily placed and a cutdown is performed to expose the fascia and ligament for anchoring. Anchoring should occur prior to tunneling, and the leads should be secured with a strain relief loop in the tissue to reduce the risk of migration. In addition to securing the lead, an incision is made to create a pocket for the generator. The pocket is sized to properly fit the desired device, and hemostasis is confirmed.

Once both incisions are sufficiently created and the leads are properly anchored, a course of planned tunneling is determined. The course of tunneling is based on landmarks, body habitus, and bony margins. Once the course is determined, a sterile skin marker is used to outline this pathway of planned tunneling. Local anesthesia is then placed along the marked path. The local anesthetic used can vary, but a common choice is lidocaine 1% with epinephrine. Bicarbonate can be added in a 1:9 ratio to the local anesthetic in order to buffer the pH. This can lead to a quicker onset of action and decreased sensation of burning. In addition to a local anesthetic, many physicians choose to supplement the tolerance of the procedure with intravenous opioids or anesthetics such as diprivan.

The tunneling direction is sometimes determined by the manufacturer's tool, but in general can be done in either direction. The author prefers to tunnel from the lead incision to the generator pocket. The implanter should palpate the tract as the tunneling tool is advanced to gauge the depth and course of the progress. The depth of the tunneling process should be in the subcutaneous adipose tissue. The tunneling can be painful and potentially dangerous if it occurs in the wrong tissue plain. The course of tunneling can be very painful and lead to skin erosion if it is too superficial. The course of tunneling can be dangerous and painful if it is too deep. This can occur with leads in the muscle, or in the abdominal cavity, or pleura, which can cause morbidity and potential mortality. Once the tunneling device has reached the exit point of the second incision, the tunneling procedure is at an end point. At this point, based on the tunneling tool for the chosen manufacture, the leads or extensions are passed through the issue to allow communication with the indwelling spinal leads and the programmable generator. See Figures 6.1–6.10.

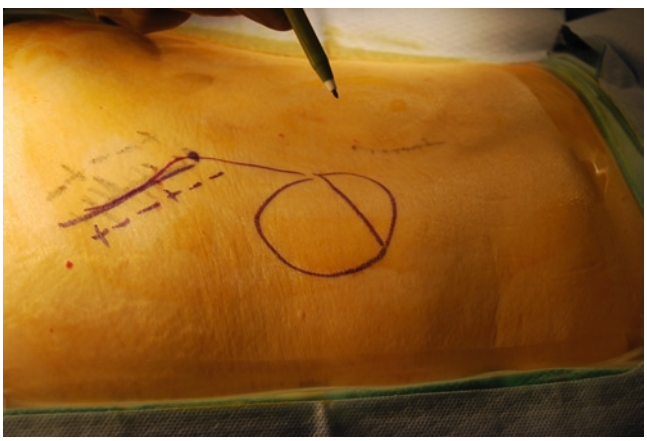


Figure 6.1. The course of tunneling is planned based on landmarks and the best direction for placing the tunneling tool.

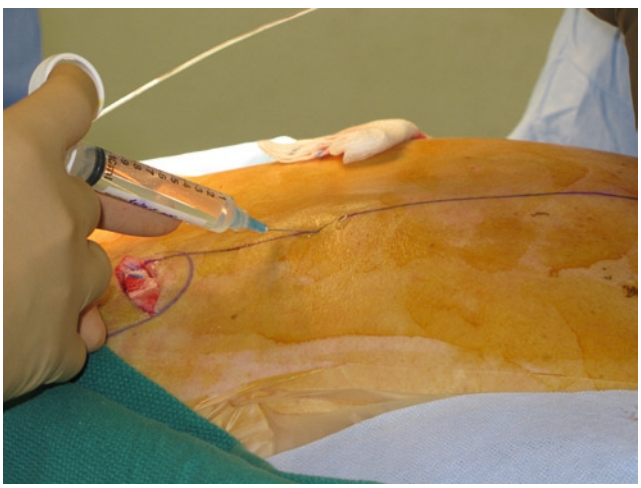


Figure 6.2. Local anesthetic placed along the tract for tunneling.

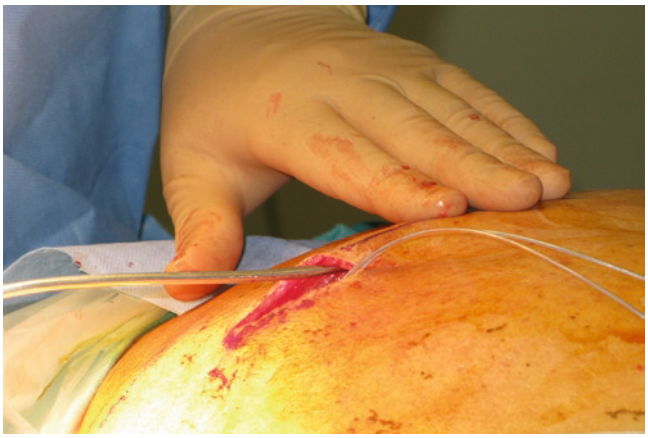


Figure 6.3. Initiation of tunneling at lead insertion site.

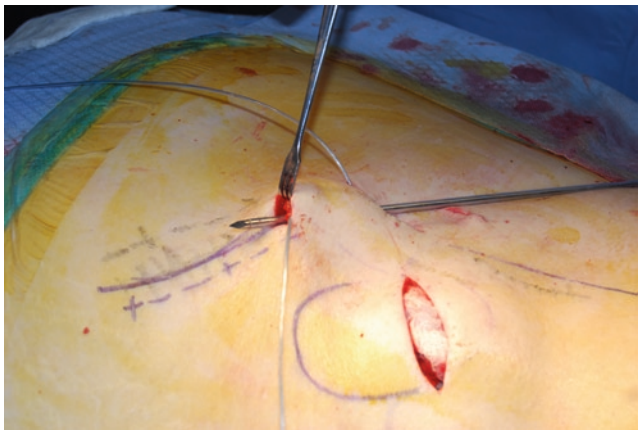


Figure 6.4. Angle of tunneling with attention to sterile technique.

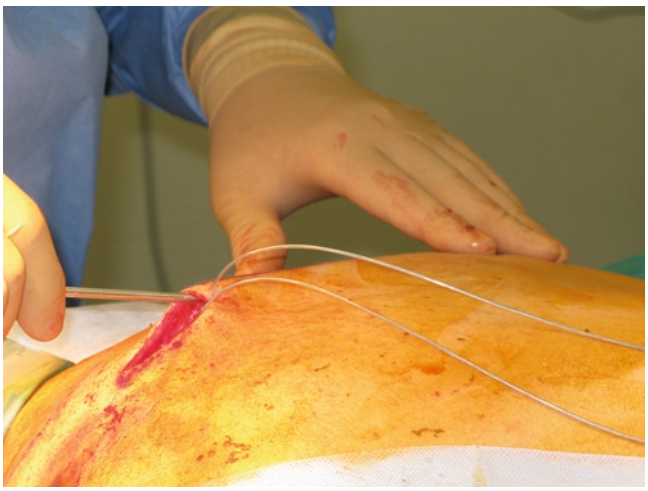


Figure 6.5. Palpation of the course of tunneling to assure adequate depth.

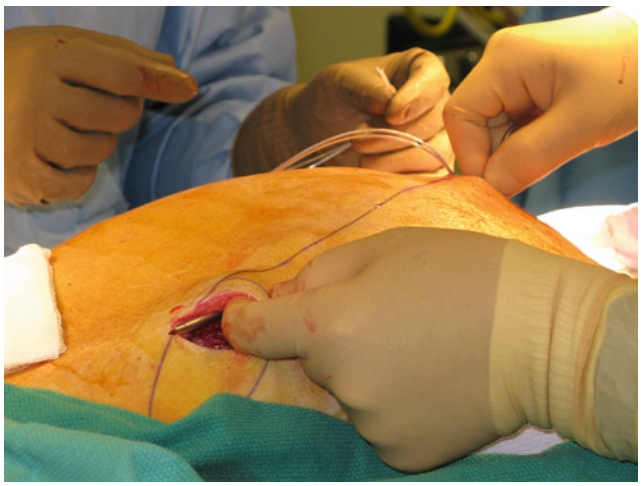
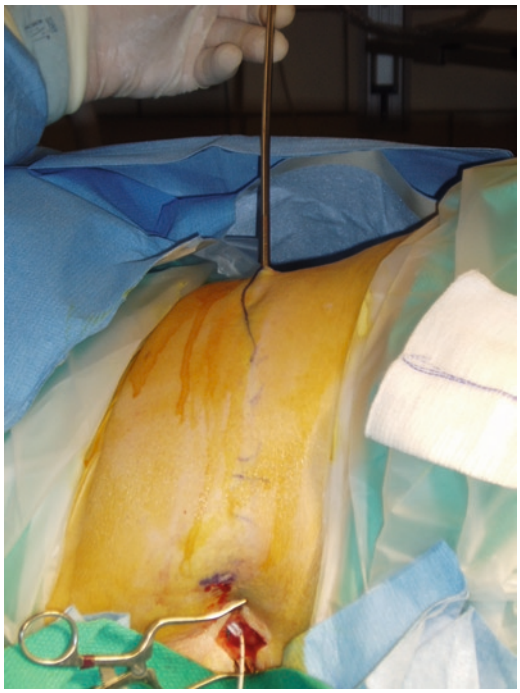


Figure 6.6. Continued progress of tunneling toward the pocket.

Figure 6.7. Final passing of the device through the tissue to complete the tunneling process.

Figure 6.8. Lateral decubitus representation of tunneling along a planned direction.



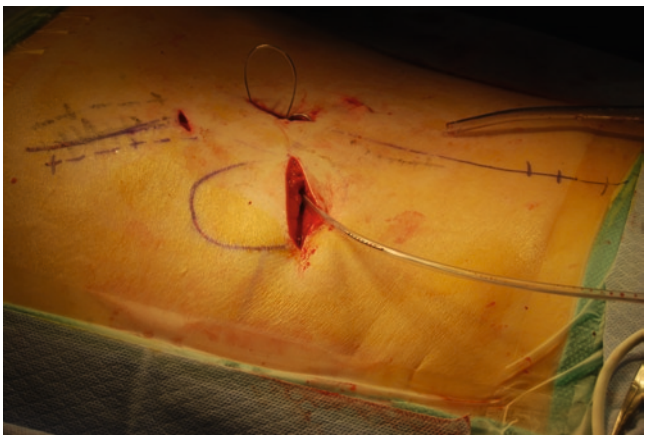


Figure 6.9. Depiction of tunneling from the posterior lead position to the generator pocket.

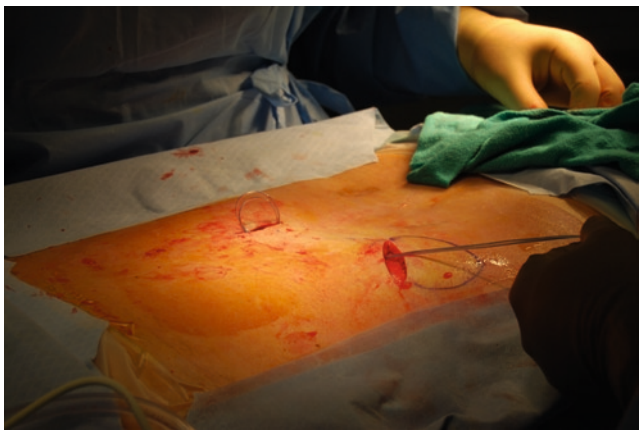


Figure 6.10. The completed tunneling procedure in lateral decubitus position.

Risk Assessment

1. The risk of depth of tunneling should be considered. The physician may tunnel in a superficial plane causing skin irritation or eventual erosion. The physician may tunnel too deep causing injury to muscle or more serious dilemmas such as visceral or pleural injury.
2. Tunneling can lead to hematoma formation, which can lead to pain and potential loss of the system.
3. Tunneling can place the physician in physically awkward positions requiring the rod to be placed well above the patients head, or below the table when tunneling from a lateral decubitus position. This positional challenge can lead to wound contamination or field contamination.
4. Tunneling can be traumatic and may cause severe pain, making the level of comfort difficult to control for the patient, and to those providing sedation. This is a common problem when tunneling from the head and neck to the lower flank or buttocks.

5. Tunneling can lead to tissue infection and eventual loss of the system.
6. Tunneling can result in an injury to components of the system since a sharp metallic object is placed in proximity to the leads, anchors, and wire loops.

Risk Avoidance

1. The physician should constantly monitor the depth of the tunneling path. This is accomplished by using the nontunneling hand to palpate the course of the tunneling tool as it is advanced toward the target incision. With adherence to this policy, the risk of injury is greatly reduced.
2. The patient should be evaluated preoperatively for bleeding disorders and medications that may affect clotting. If the area of tunneling appears to be swelling or expanding, tissue pressure should be applied until the situation has stabilized.
3. While prepping and draping for permanent stimulation implants, the physician should consider the course that will be used for tunneling and properly conduct the surgical field so that the physician's elbows, hands, and the tunneling rod itself will not come into proximity with any unsterile area.
4. Prior to tunneling the device, the physician should apply local anesthetics to the planned tract to reduce pain associated with the procedure. Additional local anesthetics can be added if tunneling is painful, with time allotted to allow the anesthetic effect to commence. In some instances, the anesthesia team will slightly increase sedation just prior to tunneling. Some clinicians advocate an epidural block prior to placing the leads to reduce the pain of tunneling. The author does not support this idea for several reasons, but the most convincing is the need to avoid high volumes of fluid in the epidural space at the time of implanting new leads.
5. The entire procedure requires vigilance to reduce the risk of infection. The skin should be prepped widely, draping should be extended to widen the surgical field, and the clinician should avoid contact with any unsterile area. The use of antibiotic solution to coat the tunneling tool, and to irrigate the tunneling tract may reduce the risk of infection.
6. When tunneling near components of the system, the physician should be able to clearly visualize the entire implant to and strive to avoid any contact with the tunneling tip. The use of an Army-Navy, or similar retractor, may be helpful in protecting the system.

Conclusions

The placement of a spinal cord stimulation system is a complicated procedure requiring technical skills, good clinical judgment, and vigilance to good outcomes. Many physicians have great concern regarding proper lead placement, and creation of a pocket, but do not give the tunneling process proper consideration. This chapter summarizes the potential pitfalls, and need for attention to this important part of the procedure. Competence in tunneling can lead to an improved cosmetic outcome, improved patient comfort, and improvements in the overall patient experience.

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7

Pocketing Techniques

Timothy R. Deer and C. Douglas Stewart

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Introduction

Creating a pocket to place the permanent generator is an important part of the procedure. The placement of the pocket can have an impact on the overall outcome in several ways. The physician must pay careful attention to the body site for the implant, to the pocket size, to hemostasis, and to wound closure. If the clinician does a poor job with the pocket component of the procedure, the entire outcome of the procedure can hang in the balance.

Technical Overview

The technical aspects of the spinal cord stimulation implant are often centered on lead placement and spinal interventions. The pocket is an equally important part of the procedure that deserves special attention. The decision making for pocketing begins prior to implant. The physician should consider the patient's body habitus, site of lead implant, likelihood of weight gain or weight loss, risk of migration, and impact on the sterile field when choosing the pocket site. The patient should be evaluated while sitting, standing,

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and laying down especially in individuals with very large body habitus to make sure that there is not a significant shift in the soft tissue that would adversely affect outcome. If the lead entry anchoring point is in the upper lumbar spine placing the pocket above, the beltline may resolve this issue in most cases, since significant tissue shifts have little impact on tissues in this body region.

It is important to carefully mark the site of implant preoperatively based on this decision process to assure the physician does not become distracted by other issues in the operating room (Figure 7.1). Once the pocket site is determined, the patient is positioned to expose the site for surgical intervention (Table 7.1).

The incision should be made with one distinct motion to assure an even cut for improving closure. The surgeon should retract the skin at the time of incision to allow for an even tissue plane for dissection. The incision depth varies based on the patient's body fat and adipose tissue. Routinely, the incision is made between 1.5 and 3.0 cm in depth. The depth should be deep enough to avoid generator erosion through the tissue, but superficial enough to allow for computer telemetry. When the proper tissue plane is achieved, the tissue is dissected by either blunt dissection, cutting electrocautery dissection, or sharp dissection. Clinicians differ based on their preference for dissection. The blunt dissection technique is often preferred since it is associated with less tissue trauma and bleeding; however, in some patients fibrous tissue is present and must be dissected by sharper and more aggressive techniques. The use of sharp scissors to separate rather than cut the tissue is a common way to combine both the sharp and the blunt tissue dissection techniques.

Figure 7.1. Anatomic pocketing sites.

Table 7.1. Site selection information.

Location	Advantage	Disadvantage	Ideal use for implant
Buttock	The generator is close to the implant site for the lumbar and thoracic spine. The patient does not require repositioning for patients with implants for back and leg pain. The amount of adipose is adequate in normal to obese patients	The generator can cause pain from irritation by the belt or clothing. In the immediate postoperative period, the patient can open the wound when sitting by putting pressure on the tissue. This is more of a concern in the obese patient. Bending at the waist can place pressure on the wiring and may cause concern regarding migration	Sacral and caudal implants. Lumbar and thoracic spine implants

(Continued)

Table 7.1. (Continued)

Location	Advantage	Disadvantage	Ideal use for implant
Abdomen	The generator is in an area of low pressure for sitting and lying. The generator is easily accessible for patient programming	The amount of wiring between the spine and the pocket may increase the risk of lead migration. In obese patients, the abdominal wall may have a contour that leads to generator discomfort. When the leads are implanted simultaneously with the generator, the patient must be repositioned, reprepped, and redraped, and this process can lead to increased risks of infection	The abdominal wall is an ideal place for patients who have discomfort from implants at other sites. It is ideal for staged implant procedures where the trial leads are surgically implanted for the trial. The site is ideal for peripheral nerve implants of the pelvis, abdomen, and chest wall
Posterior flank	This location is the ideal implant site for the majority of implants. The location above the beltline has less stress on the tissue than the buttock. The area is less contaminated due to the distance from the anus and pelvis. The stress on the leads is less when tunneling from the cervical spine and head and neck, as compared to the buttocks and abdomen. This may reduce the risk of migration. The distance from the site of lumbar incisions is in close proximity to the flank, which may improve the risks of migration	The area may be sensitive and may result in pain at the generator site (Figure 7.3)	Lumbar, thoracic, cervical, and head and neck implants
Spine implant site	This location is possible when using very small generators. The pocket is made through the same incision as the spinal lead implant. The distance between the spinal leads and the generator reduces the risk of migration. Only one incision is made so there is less sites to become infected	The wire length of the leads may result in excessive wire that may make it difficult to place it into the pocket. Discomfort may occur with sitting or reclining	Patients with adequate tissue to support a generator in the paravertebral tissue
Chest	The chest wall position puts minimal stress on implants in the occiput and facial nerves for peripheral implants	The area is sometimes difficult to reach by tunneling. When tunneling from the head and neck, it is important to be aware of the vessels of the neck, and the lung position. The tunneling must occur over the clavicle	Implants of the head and neck including peripheral nerve and intracranial nerve implants
Subpectoral	In children and in patients with very low body fat, the subpectoral position may avoid the risk of skin erosion	The procedure is technically difficult, and requires additional training	In children and very thin patients who do not have subcutaneous fat to support the metal under the dermis
Extremity	In peripheral nerve implants, the physician often has to tunnel the wiring over joints that can cause migration. When using small generators, it may be possible to implant the device in the subcutaneous tissue of the limb	The tissue may not support the device because of pain or erosion. This is not possible with larger internal programmable generators	
Axillary line at T4	The device can be placed in this position when implanting the cervical spine and head and neck. The position reduces the need for tunneling to the flank or buttock. The brassiere can be used to secure the antenna of a radiofrequency device	The tissue may be irritated by arm movement. It may be difficult to reach with the opposite arm for programming	

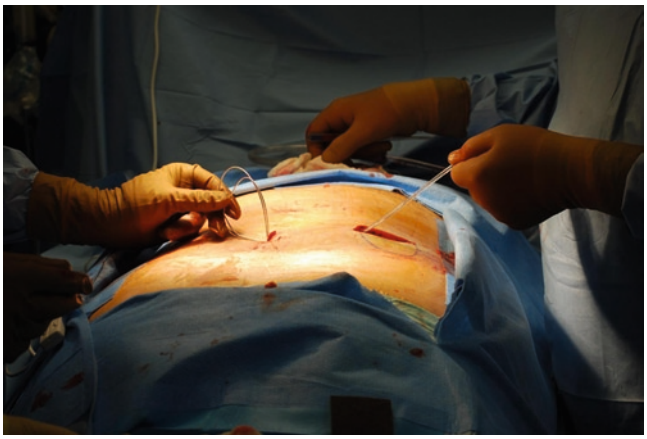

Figure 7.2. After the pocket is completed, a tunneling procedure is performed to bring the lead wiring to the pocket.

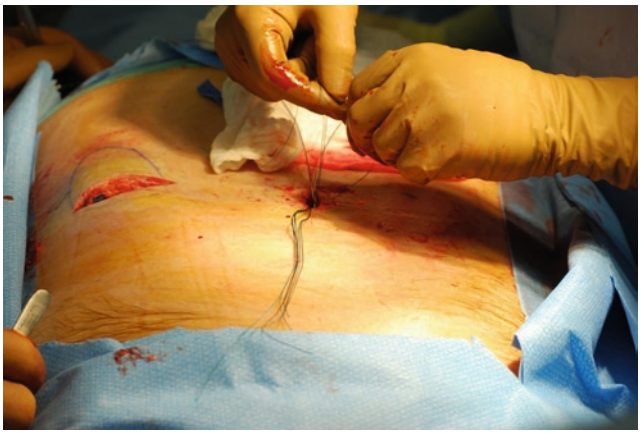

Figure 7.3. Posterior flank incision in close proximity to the site of l3 lumbar incision.

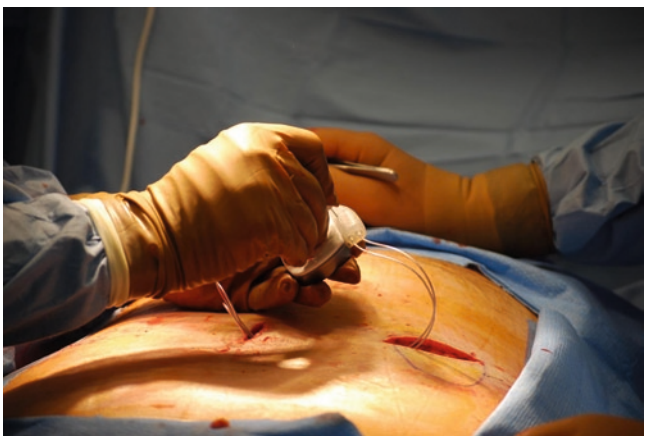

Figure 7.4. Wire for strain relief behind the generator which is being secured with a hex wrench.

The ideal pocket size should be 120–130% of the generator volume. This additional room will allow for tissue slack to avoid wound dehiscence and to decrease pain. If the pocket is larger than the recommended size, the patient may be prone to generator flipping, which can lead to a need for surgical revision.

Hemostasis is important since bleeding can lead to hematoma, seroma, wound dehiscence, and the need to explore the wound. When making the pocket, the clinician should carefully retract the tissue and examine the pocket for bleeding. Bleeding can be controlled by cautery or, in the case of pulsatile arterial bleeds by an absorbable ligature suture. Suture is used to ligate the bleeder when cautery is not successful. It is important to avoid cautery at the surface of the skin where wound closure occurs. Being too aggressive with the tissue heating can lead to necrosis and poor tissue healing.

Prior to closing the wound, the pocket should be irrigated aggressively with antibiotic such as bacitracin. The irrigation should be copious with a focus on using 500–1,000 ccs or more. The old surgery adage, "the solution for pollution is dilution," holds true in these cases.

After the pocket is completed, a tunneling procedure is performed to bring the lead wiring to the pocket (Figure 7.2). This wire should have a length that allows for a strain

relief loop to reduce the risk of migration. The loop of wire should fit smoothly behind the generator. The importance of making the pocket 20–30% larger than the generator is helpful with this step to assure that there is proper room for the wiring.

Wound closure of the pocket is often taken lightly with a focus on the more technical aspects of the procedure, but wound closure should be seen as a critical point in the process. The exact details of wound closure are covered elsewhere in the atlas. The critical points are to use a two- to three-layer closure technique, to assure proper skin alignment, and to avoid tension of the tissue, which can lead to necrosis.

Risk Assessment

1. The generator can cause pain and irritation if placed too superficially.
2. The generator may be unable to communicate with telemetry if it is placed too deeply.
3. The generator can cause pain if placed close to a bony prominence.
4. Seroma of the pocket can lead to wound dehiscence and pain.
5. Hematoma of the wound can lead to the need for surgical evacuation, and wound dehiscence or infection.
6. Cautery lesioning for hemostasis can lead to skin breakdown if done too near the surface.
7. Coiling the wire above the generator can lead to pain or erosion.

Risk Avoidance

1. The generator must be at a depth that is seeded in the subcutaneous tissue with appropriate adipose for cushioning.
2. The generator must be superficial enough to allow communication. Prior to leaving the operating room on permanent implant, the clinician should test the device for impedance which will help avoid this risk.
3. The bony prominences of the pocket region should be examined preoperatively and at the time of implant. The implant should avoid the rib, anterior superior iliac spine, posterior superior iliac spine, and sacrum.
4. Seroma can be reduced by using blunt dissection, limiting tissue trauma, and assuring good hemostasis of venous bleeders. This can be improved by packing the pocket with antibiotic soaked sponges for 5–10 min during the course of the procedure.
5. Hematoma can be avoided by close attention to preoperative medications that affect clotting or change platelet function. Careful attention to identifying and resolving bleeding is critical prior to wound closure. Bleeding can be resolved by cautery, suturing, and applying pressure.
6. When using cautery, the physician should avoid surface bleeders that border the skin margin.
7. The wire that is in excess of that needed for spine insertion and tunneling should be carefully secured in a strain relief loop at the spinal site of lead placement and at the pocket site with attention to placing the wire below the generator (Figures 7.4 and 7.5).

Conclusions

When creating a pocket, the physician should carefully plan its location based on factors such as lead target, body habitus, and patient function. The pocket should be made with careful surgical skill, and attention should be given to avoid risks. Wound closure and post

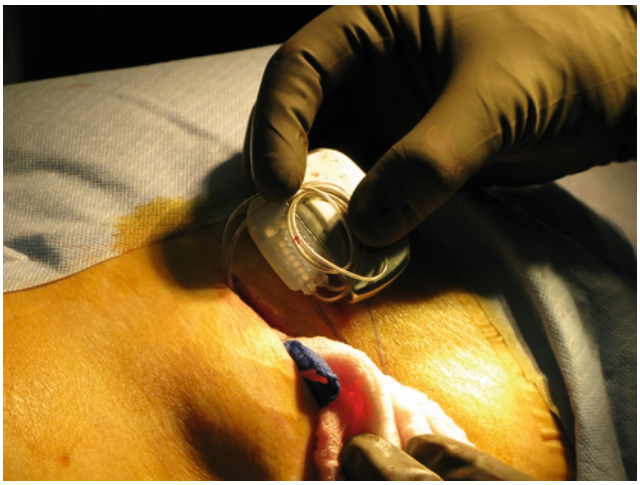

Figure 7.5. Wire strain relief loop.

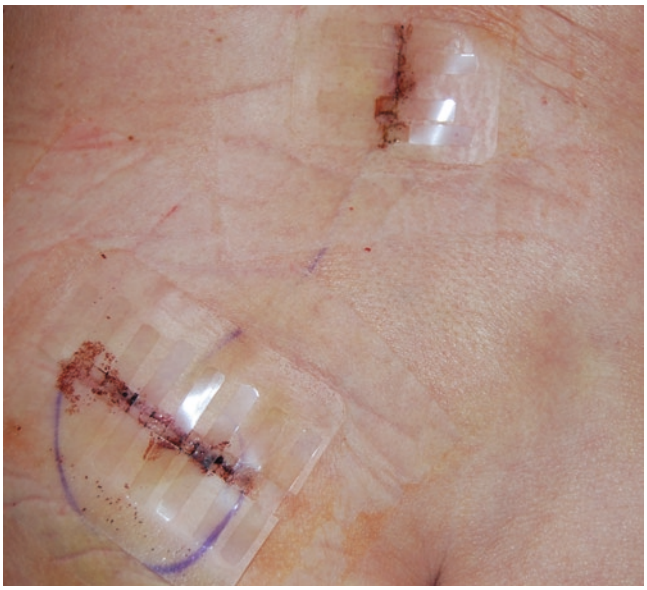

Figure 7.6. Example of a well-healed pocketing site.

operative follow up should be performed with a focus on reducing tissue trauma and optimizing wound healing (see Figure 7.6).

Suggested Reading

Scheepensa EHJ, Weila GA, van Koeveringea D, et al. Placement of the implantable pulse generator: a new implantation technique for sacral neuromodulation – a multicenter study. *Eur Neurol.* 2001;40(4):2001.

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8

Complications of Spinal Cord Stimulation

Timothy R. Deer

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Introduction

Spinal cord stimulation is a therapy that offers hope to thousands of patients who suffer from chronic pain. The therapy has undergone significant advancement in recent years including improved leads, more complex programmable generators, and different arrays for achieving nerve activation. Unfortunately, despite the amazing promise of these devices, the need to enter the spinal canal, make an incision, and perform invasive maneuvers leads to a risk of complications and potential patient injury. The incidence of complications with spinal cord stimulation varies based on the author reviewed. Systemic analyses have shown device complications in 17% of patients in chronic therapy. The risk of

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life-threatening complications appears to be less than 1%. Epidural fibrosis occurs in 19% of patients, but is not always seen as a complication since many patients are asymptomatic, and in some patients this development even stabilizes the lead and improves the outcome. The purpose of this chapter is to give an overview of important complications and to evaluate strategies to reduce the risk to the patient.

Overview of Complications of Spinal Cord Stimulation

See Tables 8.1 and 8.2. The physician must be vigilant to prevent, identify, and resolve complications. Even in the most talented hands, complications will occur and may lead to a poor outcome. By reducing the risks the patient faces, the overall outcomes of the physician practice will improve and the success of SCS will be ideal.

Complications of the Neuroaxis

Bleeding in the epidural space is common when needles and leads are introduced. In most patients, this bleeding is unnoticed and causes no sequelae. In rare patients, the bleeding progresses to the development of an epidural hematoma. If a developing epidural hematoma progresses, it can lead to numbness, back and leg pain, weakness, and eventual paraplegia. Treatment of clinically significant epidural hematoma is surgical evacuation. It is critical that this problem be identified early and treated within 24 h of the development of symptoms. Weakness in the postoperative period is a red flag warning that should raise the suspicion of this tragic complication.

Risk factors for developing an epidural hematoma include patients taking anticoagulants, platelet acting drugs, aspirin, and nonsteroidals. The other factors may include difficult percutaneous lead placement, laminotomy approach to lead placement, and revision

Table 8.1. Migration risk avoidance.

Migration risk	Physician action
Needle angle	Needle angle of 30–45°
Needle entry	Paramedian approach
Fatty tissue at anchoring site	Debride fatty tissue around the needle entry site exposing fascia and ligament for proper anchoring
Anchoring to muscle	When using an exaggerated paramedian approach the physician should dissect medially until approaching ligament or fascia, avoiding anchoring to muscle, which may lead to migration with contraction
Lead anchor gap	The anchor should be as close to the lead entry into the ligament or fascia as possible avoiding room for migration distal to the anchor
Suturing with silk	Avoid silk sutures when anchoring
Dependence on the anchor	The anchor should be seen as one component of securing the system. Total dependence on the anchor can lead to poor outcomes
Hematoma below anchor	Hemostasis should be obtained prior to closing the wound. Bleeding can lead to catheter movement due to hematoma compression placing pressure on the anchor
Minimal migration changes	The catheter should be placed in an area of the spine that will not be affected by minimal migration movements. If the catheter tip is in the spinal cerebral fluid, a good outcome may be preserved even in the presence of movement

Table 8.2. Complications of stimulation.

Complication of stimulation	Diagnosis of problem	Treatment of problem
Lead migration	Inability to program, X-rays	Reprogramming, surgical revision
Current leak	High impedance, pain at leak site	Revision of connectors, generator or leads
Neuroaxis complication		
Nerve injury	CT or MRI, EMG/NCS/physical exam	Steroid protocol, anticonvulsants, neurosurgery consult
Epidural fibrosis	Increased stimulation amplitude	Lead reprogramming, lead revision
Epidural hematoma	physical exam, CT or MRI	Surgical evacuation, steroid protocol
Epidural abscess	physical exam, CT or MRI, CBC, blood work	Surgical evacuation, IV antibiotics, ID consult
Postdural puncture headache	Positional headache, blurred vision, nausea	IV fluids, rest, blood patch
Device complication		
Unacceptable programming	Lack of stimulation in area of pain	Reprogramming of device, revision of leads
Lead migration	Inability to program, X-rays	Reprogramming, surgical revision
Current leak	High impedance, pain at leak site	Revision of connectors, generator, or leads
Generator failure	Inability to read device	Replacement of generator
Nonneurological tissue		
Seroma	Serosanguinous fluid in pocket	Aspiration, if no response surgical drainage
Hematoma	Blood in pocket	Pressure and aspiration, surgical revision
Pain at generator	Pain on palpation	Lidoderm patches, injection, revision
Wound infection	Fever, rubor, drainage	Antibiotics, incision and drainage, removal

of previously placed leads. The need to perform surgical instrumentation and to create bony insult dramatically increase the risk of a significant bleed.

The diagnosis of epidural hematoma is assisted by clinical suspicion, physical exam, and history, but the confirmatory diagnosis is made by CT scan. MRI can be obtained once the leads are removed.

Another major complication of the neuroaxis associated with spinal cord stimulation is epidural abscess. This is one of the infectious risks of implanting devices in the body. Other risks include incisional infection, cellulitis, meningitis, and discitis. The risks of a serious infection appear to be less than one in a thousand. Epidural abscess may present with severe pain in the area of the lead implant. This may be associated with fever with most patients experiencing temperatures over 101°F. Radicular pain may develop if the abscess extends to the canal or compresses the cord. Risk factors for abscess include immunocompromised state, history of chronic skin infections, history of methicillin resistant *Staphylococcal aureus* (MRSA) infection or colonization, chronic diseases such as poorly controlled diabetes mellitus, or local infection at the surgery site. Abscess is diagnosed by clinical suspicion, history, physical exam, and confirmed by CT. MRI may be performed once the device is explanted.

Neurological injury of the spinal cord or nerve roots are other potential risks of SCS. Injury may occur by needle trauma, lead placement or removal, or surgical manipulation during paddle lead placement.

In many patients, the injury is associated with deep sedation or general anesthesia. In the immediate postprocedure period, the injury may be difficult to diagnose. CT may not show an abnormality and MRI cannot be performed until the device is surgically removed. An electromyogram and nerve conduction may be helpful in determining the injury, but may not become abnormal for several days following the insult.

Less worrisome complications include inadvertent dural puncture with postdural puncture headache, which has been reported in up to 11% of cases, although that number appears much higher than clinical practice would suggest. This risk is increased by obesity, calcific ligaments, patient movement, and previous surgery at the level of needle entry. A paramedian approach with an angle of less than 40° appears to lower the risks of complications.

Spinal cord stenosis can develop over time in the vicinity of an implanted lead. This may result in new radicular symptoms and can progress to myelopathy over time. This problem requires revision or lead removal.

Complications Outside of the Neuroaxis

Wound infections involving the generator, tunneled area or lead incision site can occur in 0–4.5% of patients based on reported incidences. This problem is diagnosed by pain, swelling, rubor, and drainage of purulent material. An elevated white blood cell count, sedimentation rate, or C-reactive protein should create concern regarding the infectious status of the implant. Other causes of infection should also be considered.

In some cases, the patient may develop a swollen, irritated wound, which is not associated with infection. This complication, called a seroma, is caused by a buildup of serosanguinous fluid. Seroma is diagnosed by lack of fever, and a normal blood study evaluation of white blood count. If the diagnosis cannot be determined, incision and drainage with cultures may be required to make a conclusive diagnosis. In most cases, seroma can be treated without device removal. Careful dissection and attention to minimize tissue trauma may reduce the risk of this complication.

Bleeding can occur in the generator or lead incision site. This can lead to hematoma requiring drainage, or to wound dehiscence. The best treatment is prevention which consists of thoughtful tissue dissection, pressure to the area of bleeding, suturing of arterial bleeding, coagulation of ongoing small vessel hemorrhage, and careful inspection of the wound prior to closure.

Pain at the generator site may occur secondary to neuroma, tissue irritation, or bony contact with a rib or pelvic bones. Treatment can include topical local anesthetic patches, wound injection, or surgical revision.

Complications of the Device

See Figures 8.1–8.3. The most commonly reported complication of SCS devices is loss of paresthesia capture over time. This can occur because of lead migration, dead zone stimulation, tolerance to stimulation developing in the patient, or to fibrosis below the lead increasing impedance. Many of these problems can now be overcome by changing programming since modern systems allow for changes in activated cathodes which may

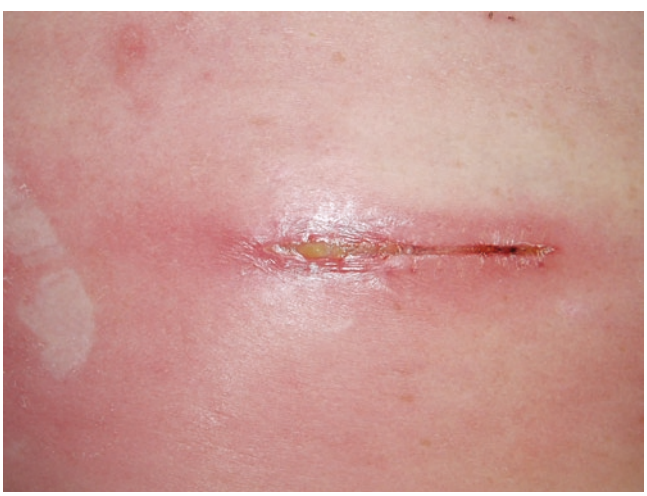

Figure 8.1. Postoperative cellulitis with early dehiscence.

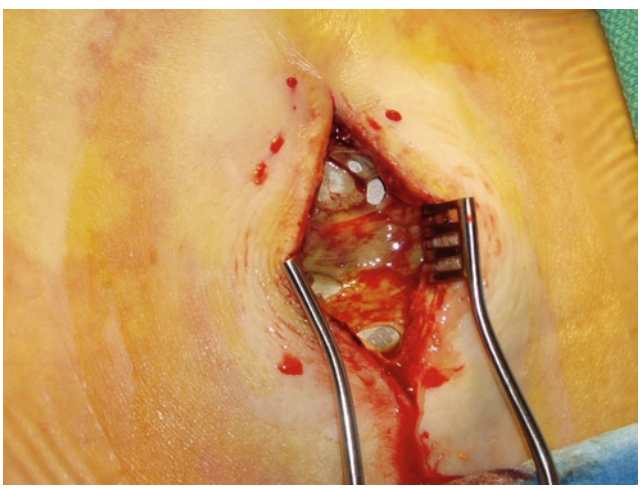

Figure 8.2. Gross infection present at generator site.

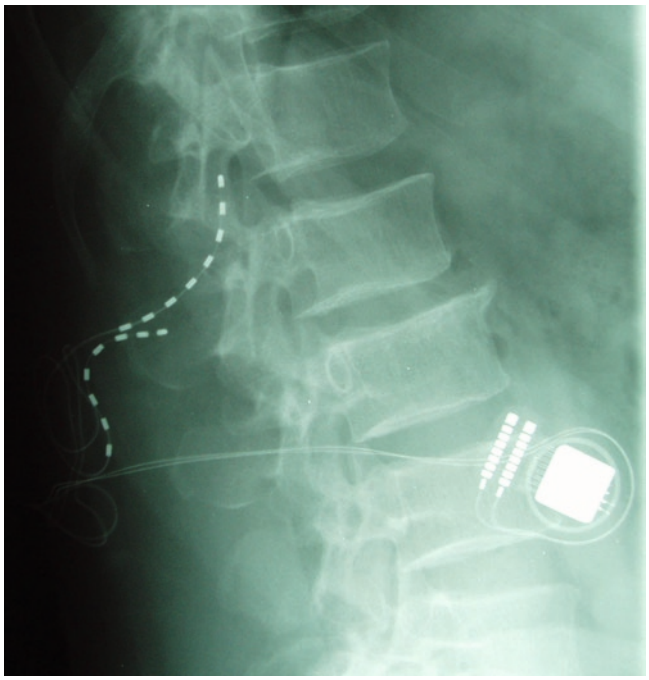

Figure 8.3. Migration of the lead.

change the electrical field. If reprogramming the system does not resolve the situation, plain films of the leads may be helpful in diagnosing migration. Eventual treatment may require lead revision or conversion to a paddle lead.

Lead migration is another complication that can lead to system failure. This problem is more common with percutaneous systems and has been reported in some studies to occur in up to 20% of cases over time. The author has experienced less than 1% migration based on X-ray evaluation, and recent studies have shown the number to be less than 5% in most evaluations. The problem is diagnosed by anterior–posterior and lateral films with comparison to original implant films. Treatment ranges from simple computer reprogramming to surgical lead revision. A careful attention to anchoring may reduce this complication risks, but cannot prevent it from occurring.

Painful stimulation or loss of stimulation can occur secondary to current leakage or loss of system integrity. This problem is often diagnosed by computer analysis showing high impedance compared to baseline. Possible causes include lead migration, poor conduction secondary to fluid in or around the contacts, or partial or total lead fracture.

Positional stimulation can occur due to poor lead to tissue contact with standing, lying, or bending. This problem will sometimes resolve over time, but may require revision to a paddle lead that takes up more volume in the epidural space.

Device flipping and generator pain may occur secondary to difficulties at the pocket. These complications can be reduced by anchoring the generator and securing the device in a pocket that is adequate to allow room for the device. In situations when the pocket is too small, it may lead to poor wound closure, pressure on the tissue, and even erosion over time. If the pocket is too large, it may lead to flipping of the device, pain secondary to device tissue irritation, or a seroma in the area of the pocket that is not involved in the implant. The physician should be careful to measure the pocket size intermittently as it is created. Some manufacturers are now supplying spacers that can be used to check pocket size without having to place the actual device into the pocket as it is created.

Erosion of device components through the skin can lead to loss of the system. This can occur secondary to poor tissue health from chronic disease, weight loss, and placement of anchors in the superficial tissues. This does occur more commonly at the generator site. When erythema occurs around a generator, the physician should consider surgical revision prior to the complete loss of tissue integrity, which leads to the need to remove the system.

In the placement of peripheral leads, the device should be placed below the dermis. In general, the physician should determine this depth by palpation, needle placement, and observation when making an incision to secure the lead. The use of suture for securing the device without the use of a formal anchor should be considered since many cases of device erosion occurs at the silastic anchor site. This problem may be worsened by new anchors containing harder substances such as titanium.

Risk Assessment

1. The patient should be assessed for bleeding risks prior to moving forward for an implant. A careful review of medications that effect bleeding, an evaluation of coexisting diseases, and an evaluation of the spinal anatomy and challenges should be undertaken prior to moving forward.
2. Infection risk assessment includes a review of coexisting diseases, an inspection of the patient's skin, and a review of preoperative laboratory studies. In patients with a history of such problems as advanced HIV disease, brittle diabetes mellitus, chronic systemic steroid use, and malignancy, caution should be exercised and implantable devices should be moved further down the treatment algorithm.
3. The patients who are at risk for neural injury during implant are hard to identify secondary to the low incidence of this problem. The patient with multiple spinal instrumentation procedures, the morbidly obese, the extremely anxious, and the patient with extensive spinal disease such as significant scoliosis should be approached with caution.
4. The occurrence of inadvertent dural puncture can lead to a headache that may impair the ability to assess the success of a stimulation trial or complicate the postoperative period during a permanent implant. The risk of this complication is increased with obesity, scoliosis, significant stenosis, ligament calcification, and previous surgery at the site of the planned implant. The risks are also increased in a patient with extensive movement and inability to cooperate with the implant approach.
5. The development of stenosis in the vicinity of a previously implanted lead can produce symptoms and lead to the ultimate removal of the device. Prior to placing a device in the cervical spine the doctor should consider an imaging study to assess preimplant spinal diameter. In cases of preexisting stenosis, the implant should be approached with caution.
6. Wound infections can vary from mild erythema to frank dehiscence. The implanter should use great care in wound closure to assure tissue alignment is ideal. It is important to evaluate the patient preoperatively for local skin abnormalities and evaluate disease states for possible increased risks of systemic infections. The history of previous MRSA infections should alarm the physician of potential difficulties.
7. Seroma development can occur in the wound surrounding the generator, and can lead to loss of the device because of wound breakdown. History of seroma development with other surgical procedures may alert the physician to potential risks of this complication. Patients with connective tissue disorders such as lupus, rheumatoid arthritis, and scleroderma may have more propensities to develop these problems.
8. Pain at the generator site is most commonly associated with patients having a history of complex regional pain syndrome or fibromyalgia. It is difficult to predict patients who will have problems with this issue.
9. Loss of proper stimulation paresthesia can occur leading to a reduction or complete loss of relief. This can be due to epidural fibrosis, migration, positional change, or other electrical stimulation factors. The physician should undergo a troubleshooting evaluation when loss of coverage occurs including a physical exam, plain film evaluation, and computer analysis of the system.

10. Lead migration can lead to an adverse outcome. The risk of migration is increased by movement in the early preoperative period including bending at the waist, lifting above the head, and carrying heavy objects. The techniques used for anchoring and suturing can reduce the risk of migration, but cannot eliminate the problem.
11. Lead fracture is more common with surgically placed paddle electrodes. The presence of tension on the wiring can increase this risk, as can trauma to the area of the spine where the implant is placed.
12. Device flipping can occur, which leads to inability to program or use the SCS system.
13. Erosion of the leads, anchors, or generators through the skin can lead to loss of the system or the need to do an extensive revision.
14. Loss of pain relief can occur in a system, where paresthesias are still felt in the proper region, impedance numbers are appropriate, and the leads and generator is functioning properly.

Risk Avoidance

1. Patients who are on clodripogel, warfarin, and other drugs that change the ability to perform a clot should be taken off these drugs prior to implant. This decision should be made by the physician prescribing the medications. If the patient is unable to be taken off of these agents, the procedure must be canceled. If the physician feels the procedure is critical, a possibility of admitting the patient for an infusion of heparin to allow for discontinuation of oral medications can be considered.
2. Preoperative antibiotics should be given prior to moving into the procedure area. The use of preoperative antibiotics is sometimes considered controversial, but it now has become standard of care for most implanters. Other risk avoidance techniques include extensive prepping and wide draping, and careful attention to sterile technique. Vigorous irrigation should be used to create tissue dilution of any potential infectious agents. Wound closure should be considered critical to reducing complications and should be taken very seriously. Postoperative follow-up is needed to detect any early signs of infection such as rubor, drainage, or painful incisions. In these cases, the consideration of an early intervention such as an incision and drainage should be considered.
3. The risk of neural injury can be reduced by proper patient education including the need for patient cooperation with maintaining a minimal of movement during the procedure. The physician should focus on proper patient positioning prior to moving forward. The use of fluoroscopy should be approached carefully with attention to aligning the spine to allow for a good approach to the spine. In difficult cases, the patient should remain alert during the implant to allow for early warning to the implanting doctor of impending nerve injury. The best form of risk avoidance in these cases is referral to a spine surgeon to allow for a surgical approach to the spine with direct visualization of the neural tissues.
4. Postdural puncture is a known complication that is unavoidable in some patients. The risk can be reduced by several factors: (1) Using a needle angle of 45° or less. (2) Using a paramedian approach. (3) Using both a hanging drop and loss of resistance technique. (4) Using contrast and lateral views if the depth of the needle is not clear to the implanter. (5) Being patient and using a careful and thoughtful approach to the space.
5. In patients with preimplant imaging that suggest moderate-to-severe stenosis, the doctor should be cautious with percutaneous implants. The alternative of a decompression with placement of a paddle lead is an attractive option when there is any doubt of a risk of disease progression causing nerve impingement. The use of small profile leads for trialing should be considered in these patients. When this approach is taken, the patient should be alert and responsive during lead and needle manipulation.

6. Wound infections are best avoided by careful preoperative screening, optimization of coexisting diseases, and evaluation of skin condition prior to making an incision. The patient should be prepped and draped widely, and careful attention should be given to wound closure. The physician should be vigilant regarding tissue approximation and the reduction of tension on the wound. The patient should be followed in the postoperative period with inspection of the wound. If a superficial infection develops, the author recommends an aggressive approach of excising the wound tissue with an elliptical incision with an incision and drainage of the wound prior to the infection extending. In cases where the infection involves the pocket or the posterior spinal incison, it is important to entirely remove the device and consult with infectious disease when appropriate.
7. Seroma formation can lead to devastating results including failure of the system. Some clinicians recommend aspiration of the fluid with analysis. This is a reasonable approach, but careful attention must be given to avoid contaminating a noninfected pocket. The best approach to seroma is to avoid the initial problem. This risk can be reduced with careful and gentle handling of the tissue, judicious use of cautery, and gentle and blunt dissection. Some clinicians have found a reduction in seroma by making the generator pocket prior to placing the leads, and packing the wound with antibiotic soaked sponges to tapenade venous and small arterial bleeders.
8. Pain at the generator site can lead to a bad outcome even in patients who have excellent stimulation and reduction of their primary problem. The device should be placed 1–2 cm below the dermis with attention to avoid placing the generator too superficially. The placement of the generator near the pubic bones, or the rib margin can also cause pain with movement. The other factor that is important is the distribution of the adipose in the patient's body habitus. In some patients, the placement of the device in the buttock leads to pain secondary to lack of adipose tissue in the region. The development of smaller implantable generators has allowed the pocket to be created closer to the spinal incision site, which may mitigate this risk.
9. Loss of paresthesia can be devastating to the patient who has experienced pain relief with SCS. The physician may find that this problem can be overcome by complex computer reprogramming with a change in lead arrays, pulse width, or amplitudes. If reprogramming fails to resolve the issue, the physician should review the impedance numbers at each contact. High impedance of the system or individual contacts may lead to the need to revise the leads, open the system and check the contacts, or revise the system to a surgical paddle lead system. A plain film showing a lead migration can sometimes give insight into a reprogramming strategy that may help avoid the need for more surgery. In cases where this is not possible, the treatment of this problem is with revision.
10. Lead migration can be reduced by using a paramedian approach, using a shallow needle angle of 45° or less, and dissecting the tissue to anchor to fascia and ligament rather than adipose. Anchoring techniques vary and this atlas reviews some options in detail, but the primary construct is to anchor the lead to the device and the device to the fascia and ligament. New anchors help the physician to more easily secure the lead to material, but even with these advances it is very important to secure the anchoring device to the body tissue. Bracing, limitation of activity, and restrictions on motion may help avoid this complication, but these recommendations have never been proven to be effective in a prospective fashion.
11. Lead fracture can be reduced by using a shallow angle to insert the device, by adding a strain relief loop to the spinal incision, and by adding a strain relief underneath the generator.
12. Device flipping can be reduced by using a nonabsorbable suture to anchor the device to the fascia in the pocket and by properly sizing the pocket to avoid excessive unoccupied volume surrounding the device.
13. Erosion cannot be avoided in some patients, but we can make observations that may reduce this risk. Change in body habitus over time due to weight loss or weight gain

may lead to new tissue pressures on the metal or silastic devices. In other settings, patients with poor skin integrity such as those caused by chronic diseases or medications may lead to erosion. The physician should place the initial generator in the fatty tissue below the dermis with adequate tissue to cushion the materials. If the patient starts to experience redness or pain over the device, the physician should consider device revision. This is a judgment call since the risk of revision including infection or mechanical problems may outweigh the potential benefit. Many physicians have begun to use nonabsorbable sutures to secure peripheral leads for nerve or nerve field stimulation. The risk of erosion around silastic anchors in the periphery appears to be substantial and requires chronic monitoring when anchors are used.

14. The loss of pain relief in an area despite adequate stimulation patterns can be very frustrating to both the patient and the physician. In some settings, there is no option to resolve this problem and treatment may require device removal and movement down the treatment algorithm. The physician does have other options, however, which may include change in frequency, change in programming parameters such as rate and pulse width, or change in generator to alter current delivery. The revision to a surgical paddle lead may help salvage this outcome in some cases, particularly in those who have a problem with the development of fibrosis. In some cases, there is no physician action to salvage a good outcome.

Conclusions

SCS is a great option for many patients who suffer from chronic pain. While the success of these devices continues to improve in the areas of pain reduction, functional improvement, and quality of life, they are not without risks. It is critical for the physician to identify risks, reduce their occurrence, and treat them appropriately to reduce the numbers of permanent complications.

Supplemental Images

See Figures 8.4–8.10.

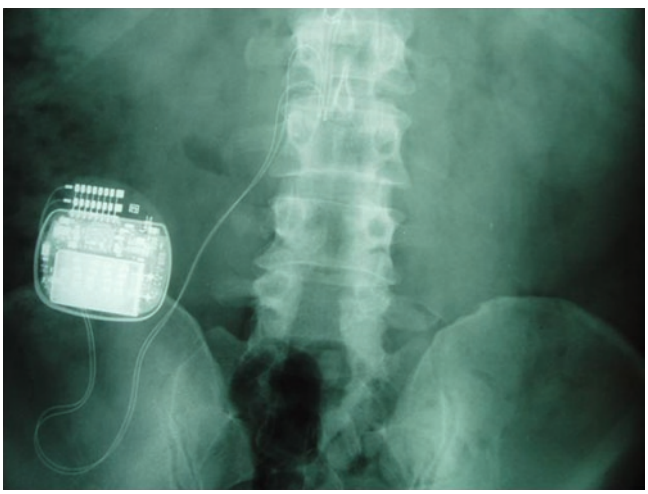

Figure 8.4. Lead fracture; anterior view.

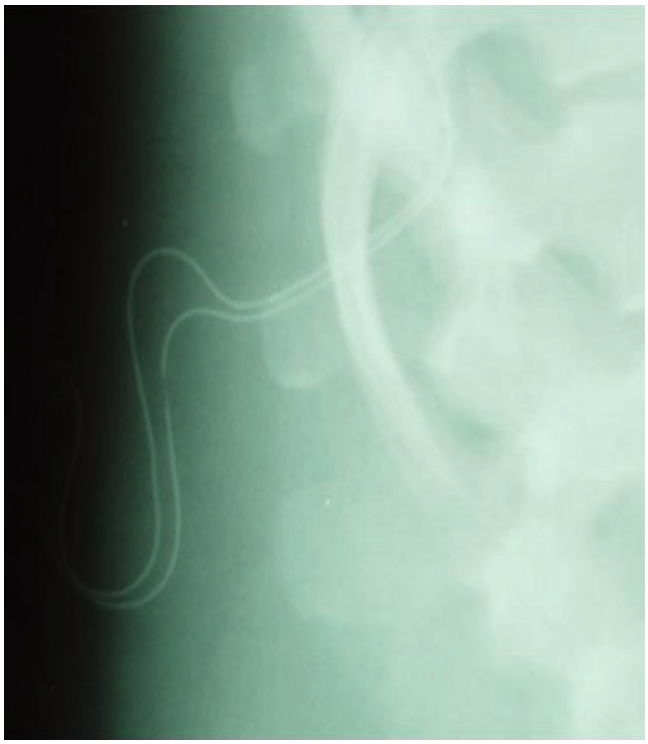

Figure 8.5. Lead fracture: lateral view.

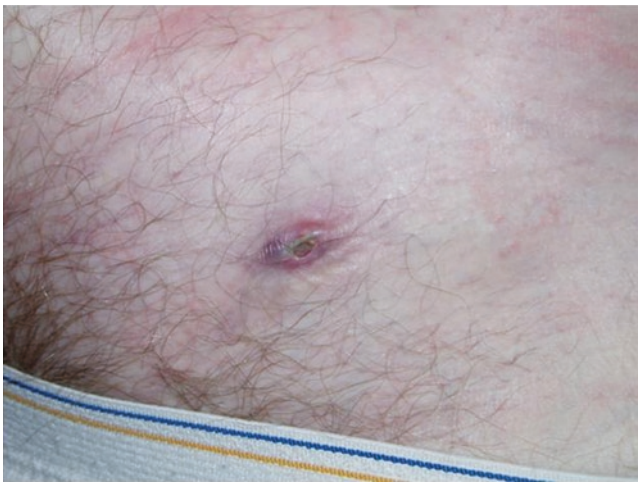

Figure 8.6. Suture abscess.

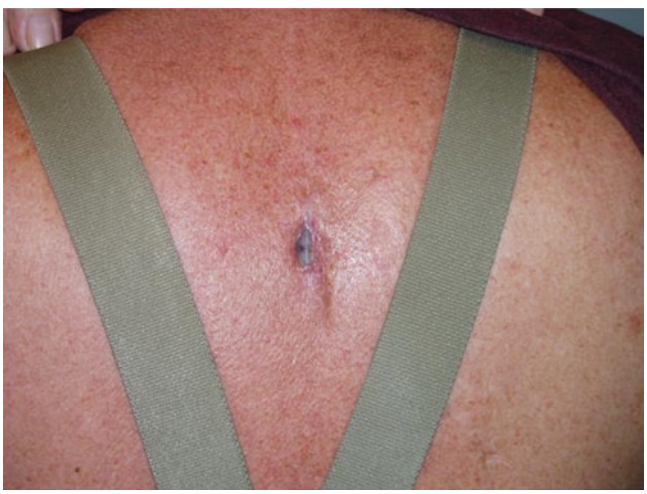

Figure 8.7. Erosion of an anchor through the tissue causing exposure of the device.

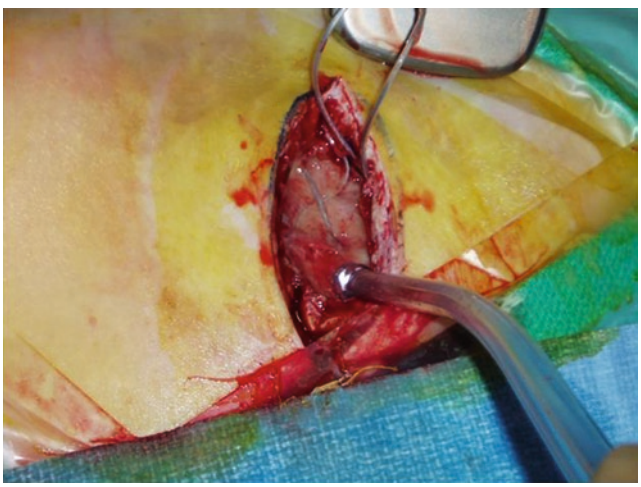

Figure 8.8. Infected pocket requiring SCS removal.

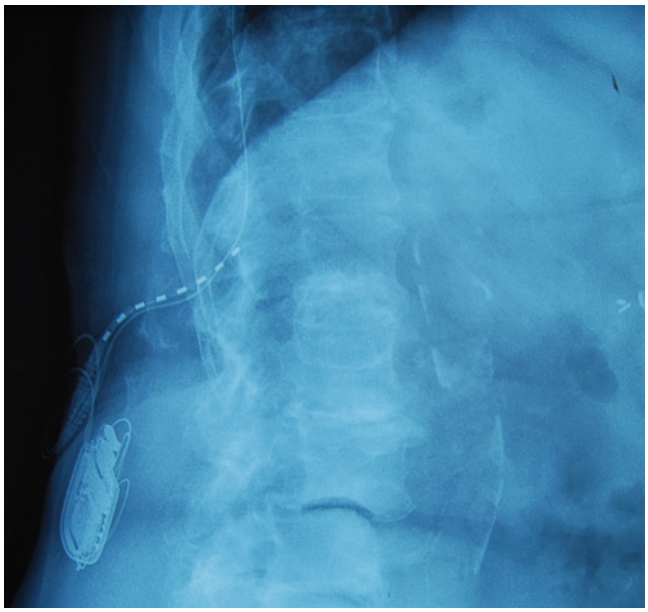

Figure 8.9. Example of caudad lead migration.

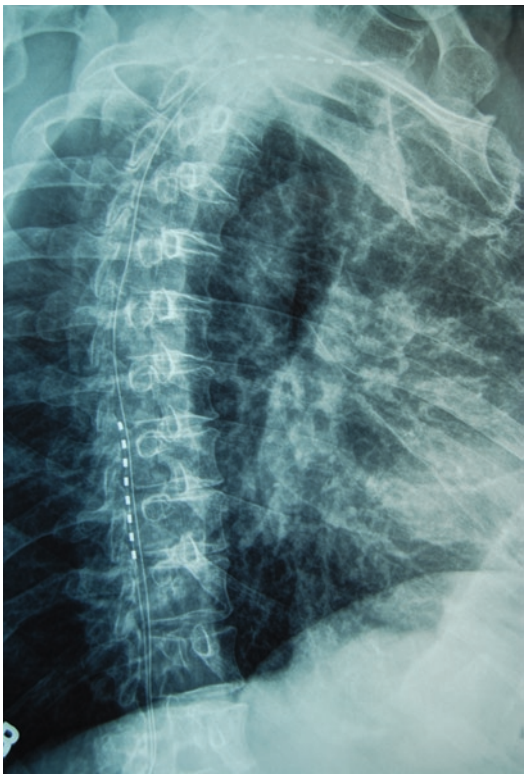

Figure 8.10. Example of cephalad migration into the cervical nerve root.

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9

Programming Spinal Cord Stimulation Systems

Timothy R. Deer

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Introduction

The placement of a lead into the epidural space is an accomplishment that is essential to performing spinal cord stimulation. Once the lead is in place, the clinician must program the device to deliver current to change the way the spine modulates neural signals. Each device manufacturer has significant intellectual property design that makes their programming unique. The goal of this chapter is to give a noncommercial look at general programming principles. The physician should have a good understanding of electrical properties that are critical in achieving an overall acceptable outcome. The first perception the physician must comprehend is the lead target for ideal stimulation (Table 9.1). The targets are a starting point for programming, but they may vary based on patient-specific anatomy. The basic concepts of programming involve the understanding of amplitude, pulse width, and frequency (Figure 9.1). Amplitude involves the intensity of the electrical field. Increasing the amplitude results in a change in the size of the electrical field.

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Table 9.1. Targets for lead placement.

Cervical	
C2	Face, below the maxillary region
C2 to C4	Neck, and shoulder to hand
C4 to C7	Forearm to hand
C7 to T1	Anterior shoulder
Thoracic	
T1 to T2	Chest wall
T5 to T6	Abdomen
T7 to T9	Back and legs
T10 to T12	Limb
L1	Pelvis
T12, L1	Foot
L5, S1	Foot, lower limb
S2 to S4	Pelvis, rectum
Sacral hiatus	Coccyx

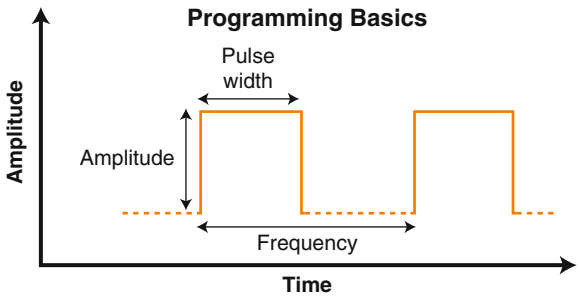


Figure 9.1. Programming basics.

Pulse width is the length of time the nerve target is exposed to an impulse. Frequency is the number of exposures that occur per minute of stimulation.

Technical Overview

The basic concept of using electrical current to modulate the neurotransmission of pain signals involves creating an electrical field that changes synaptic connections. This process involves using a negative and positive charge to create a change in the neural milieu. The negative charged contact, the cathode, is responsible for driving current into the neural tissue. The positive charged contact, the anode, is used to shape the field of stimulation delivered to spinal cord. This results in a cathode-driven depolarization, and an anode-driven hyperpolarization (Figure 9.2). With this understanding, the clinician can shape the field and corresponding patient response. Using a paddle lead configuration, we can illustrate the vertical and horizontal mapping that can shape the patient response that is created by changing the number and position of positive and negative contacts (Figure 9.3).

To summarize the points made above, in order to shape the field, the clinician must understand several components. They are:

1. Where is the lead position? The target location of the lead will determine the stimulation possibilities. The implanter should review the anterior–posterior view and the lateral view to determine the patient's response to changes in lead activation.

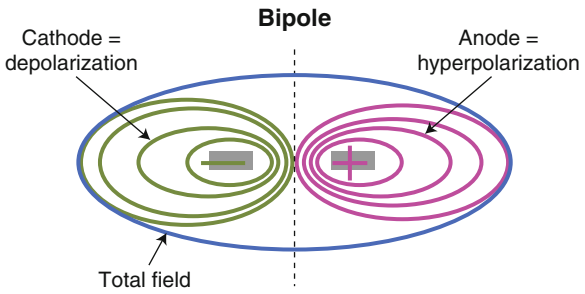
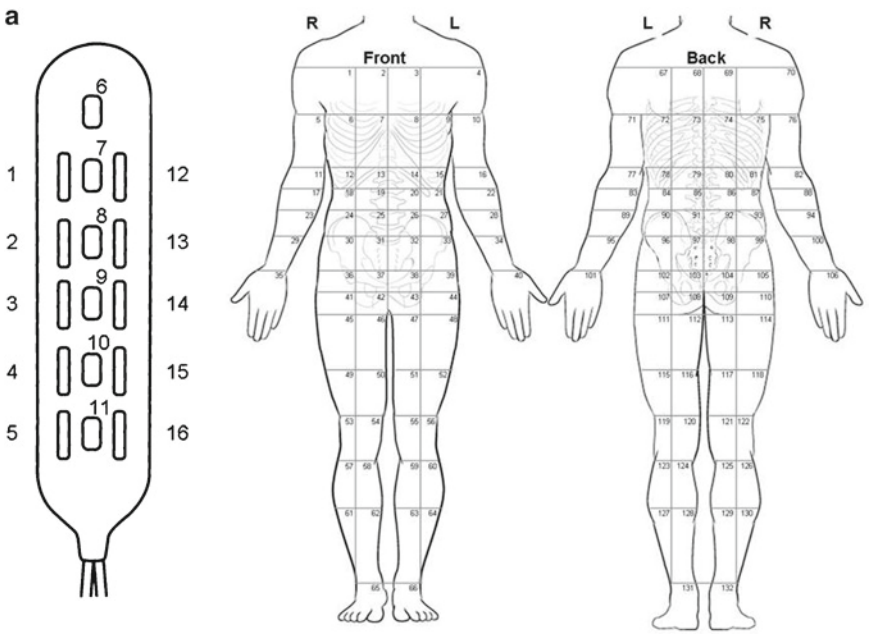


Figure 9.2. Depolarization/hyperpolarization.



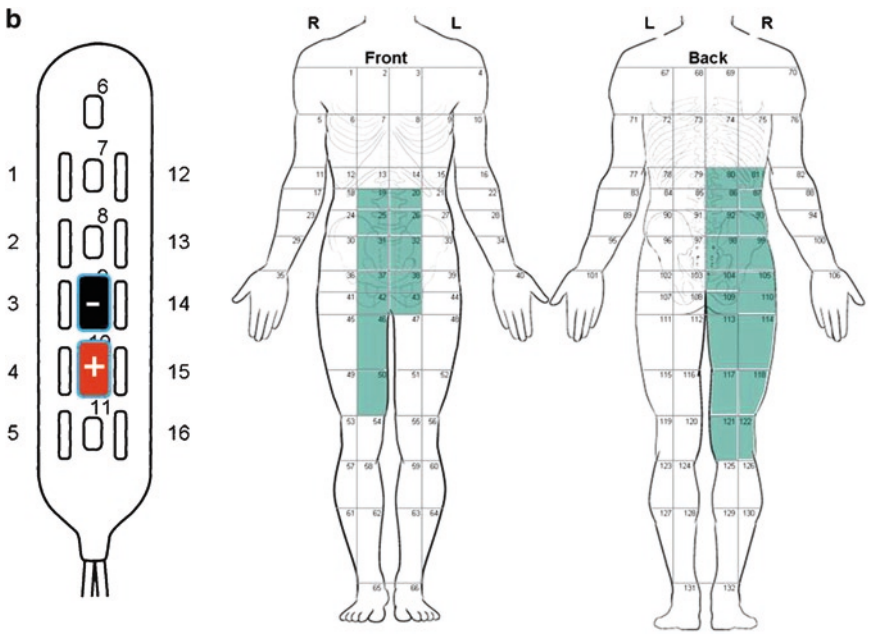


Figure 9.3. (**a**) Clinical example of programming, array off. (**b**) Bipolar array.

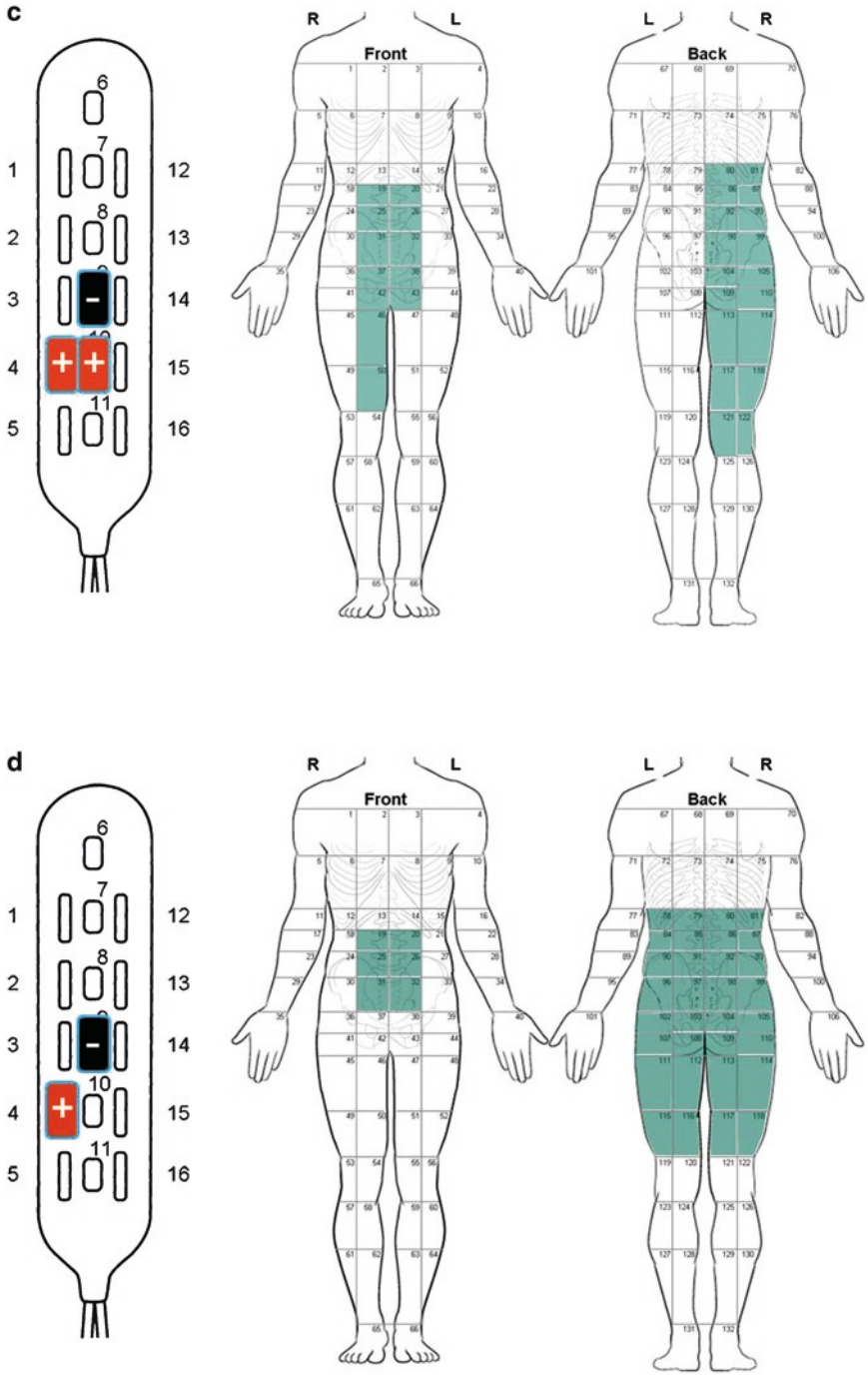


Figure 9.3. (Continued) (**c**) Dual anode with cathode. (**d**) Staggered array.

2. How many contacts are on the lead? An octipolar lead will allow many more possible combinations of programming than a quadripolar lead. A paddle lead with multiple contacts may allow lead screening in both vertical and horizontal orientations.
3. How many leads or contacts are in the spine? By adding a second or third percutaneous lead, the number of programming options will increase dramatically. This is also true for changing from a simple quadripolar surgical lead to a more complex tripolar or pentapolar paddle lead. These increased contact systems lead to an exponential improvement in possible electrode combinations to shape the field.

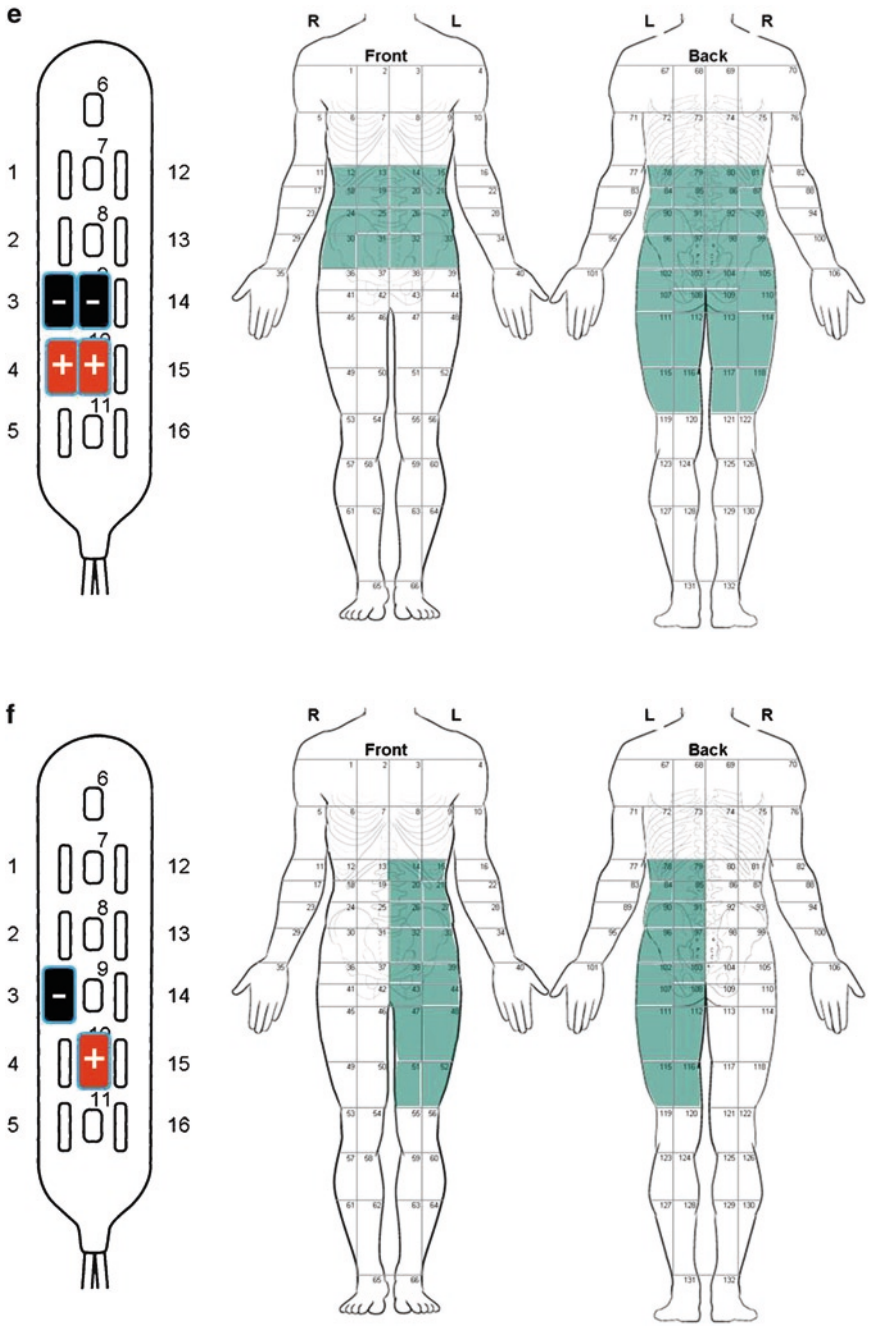


Figure 9.3. (Continued) (**e**) Dual matched cathode/anode. (**f**) Staggered array.

4. The system must contain one cathode to drive current. A single cathode drives current to that area of the system. The addition of cathodes to the system leads to dispersion of the current. A general rule is that the number of cathodes is directly proportional to the concentration of current in an area of neural tissue. In some peripheral nerve tissues, the addition of multiple cathodes will result in current being spread through the area increasing the number of small nerve fibers exposed to the current.
5. The system must contain one anode to create a field along with the cathode. Anodes may be used to guard a cathode to isolate the negative charge or may be used to shape current based on a combination of multiple cathode and anode combinations.

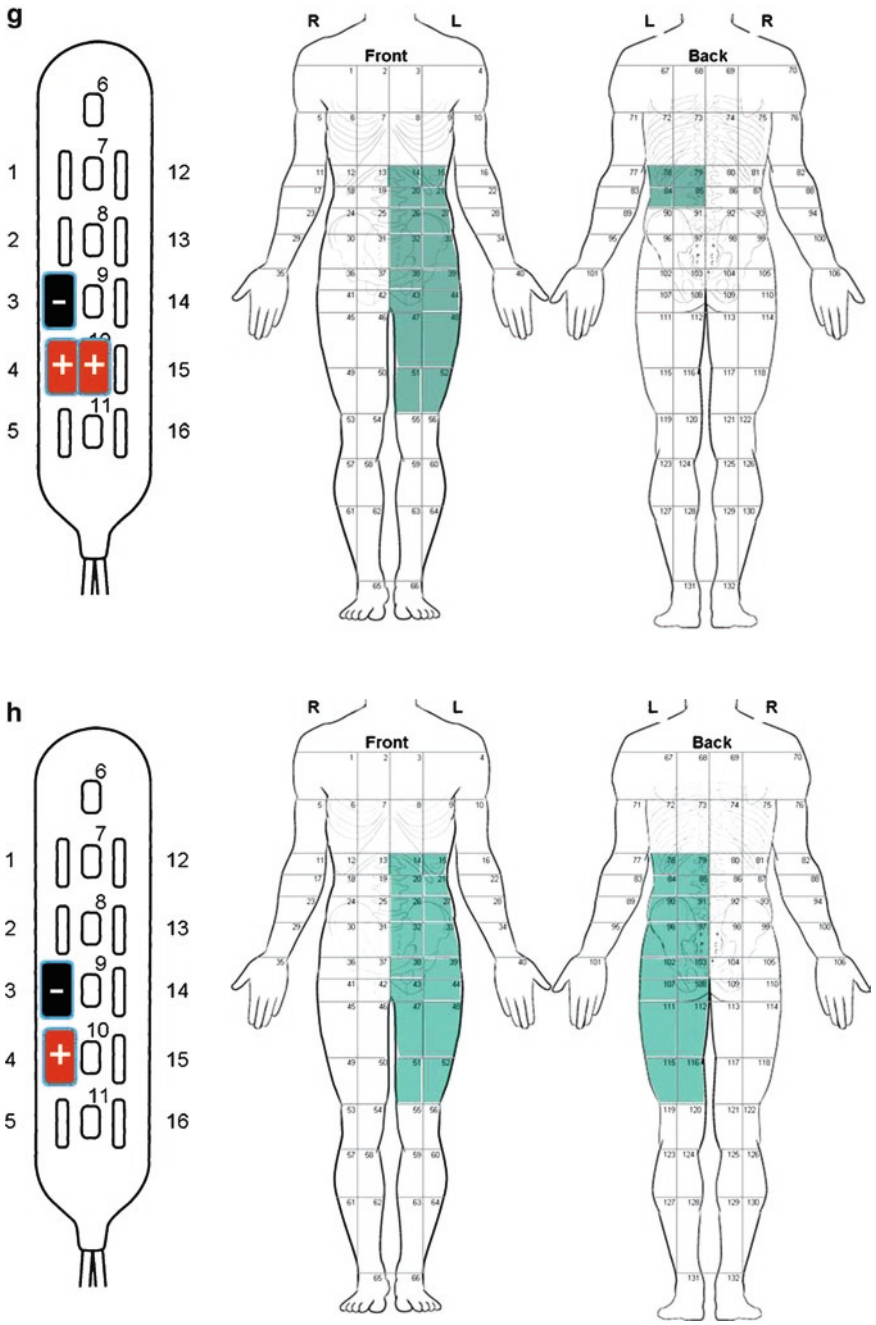


Figure 9.3. (Continued) (**g**) Shifting of the field. (**h**) Lateral array. (Image Copyright © St. Jude Medical, all rights reserved).

6. The amplitude of stimulation will determine the strength of the stimulation delivered to the patient. In some settings, increasing the amplitude will result in increased radicular fiber recruitment, and perception of spread of impulse to additional areas in the extremity or axial region.
7. The frequency of stimulation will determine the number of impulses provided to the nerve tissue per minute. Some patients prefer a low frequency, while others prefer the frequency to be very high. The use of high frequency stimulation has been found to be helpful in some conditions, such as complex regional pain syndrome, which may fail low frequency stimulation.

8. The pulse width determines the amount of time the nerve tissue is exposed to the current. Increasing pulse width can change the area of stimulation in a limb. In some settings, pulse width adjustment has no effect on the perception of stimulation.

Risk Assessment

1. The placement of leads into an improper anatomical location will make it difficult to achieve proper programming even in the best of hands or the ideal technology.
2. Prior to programming the system, the implanter and the programmer should identify the electrode contact position. Activating a contact that is in the wrong position can lead to painful paresthesias. Electrodes can be in the far lateral or anterior epidural space and can result in motor activation when programmed.
3. Improper understanding of programming can lead to a failed trial or permanent implant even in the setting of a proper candidate, good lead placement, and good surgical technique.
4. If the lead is positioned on top of epidural adipose, a large blood vessel or epidural scar or fibrosis, it may lead to poor lead to neural tissue conduction. This may lead to a failed system.
5. Improper contacts at the generator or at a connector location will lead to poor electrical current transfer and a failed or inefficient system.
6. Patients may require different programs based on activity, for example the patient may require low amplitudes and simple programming while at rest, but may require much different parameters with walking or activity.

Risk Avoidance

1. Prior to attempting to program the system, the clinician should assure the leads are in proper position based on the target of stimulation. Lateral views should also confirm the lead in the proper posterior epidural space.
2. The electrodes may vary in orientation with some contacts more lateral than others. The programming is based on the physician activating the proper contact and deciding on ideal anode and cathode positions.
3. During the implant of trial leads and the subsequent permanent implant the clinician should strive for lead placement that allows for ideal coverage at the center of the lead. This is true for single and dual percutaneous leads, and for surgical paddle leads.
4. "Dead zones," or areas of minimal or no stimulation, are identified by high impedance on attempted programming or failure to elicit a paresthesia despite high amplitudes. This problem can be avoided during the trial phase and at the time of permanent implant by repositioning the lead. Once in place, risk avoidance can be achieved by programming alternate contacts, increasing the ratio of cathodes to anodes to drive current, programming the other lead in dual lead systems or by surgical revision to change lead position. In cases of epidural fibrosis, a revision to a paddle lead may be necessary to increase current strength.
5. High impedance can be a sign of improper contacts within the system. This can occur at the generator or at extensions or connectors when used. At the time of surgery, it is important to clean the contacts and assure the system is dry with no fluid in the connections. Once the system is implanted, this problem usually will require programming of alternative contacts or in some cases reoperation to explore the connections for fluid or damage.
6. New advanced systems allow for multiple program selections that the patient may control when doing different activities. This can be helpful to stimulate different dermatomes, to cycle programs to give a sensation of broader coverage, or to treat patients who have pain pattern changes when varying activity such as those with spinal stenosis.

Conclusions

Many physicians spend hours training to implant leads, place generators, and connect systems. These surgical concerns must be addressed and competence must be obtained as part of the core skills of an implanter. It is also important for the physician to understand electrophysiology and how programming can impact success of a system. This understanding is important for lead placement, troubleshooting, changing pain patterns, and overall patient care. The competent implanter should have a good understanding of the concepts in this chapter and be prepared to give instruction to technicians and nurses who assist the doctor in programming.

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10

Stimulation of the Spinal Cord by the Placement of Surgical Based Paddle Leads

Timothy R. Deer, Robert M. Levy, and Claudio A. Feler

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Introduction

Spinal cord stimulation can be achieved by placing a needle into the epidural space and then passing a cylindrical lead into the proper place in the posterior section of that space to modulate the neurological function of the neuroaxis. This percutaneous method is favored by the majority of implanters and is the common method of doing trials and most permanent implants. The alternative method of placing a spinal cord stimulation lead is by an open surgical technique in which a small laminectomy is performed to allow a ribbon-type surgical or paddle lead to be placed in an antegrade or retrograde fashion. The paddle or plate lead allows for a more efficient, unidirectional, stable lead that has a different characteristic of stimulation than the percutaneous lead. Paddle leads are indicated based on surgeon preference or other clinical factors detailed in Table 10.1.

Technical Overview

The placement of a paddle electrode requires additional surgical skills as compared to percutaneous placement, but it does not require the ability to place a needle in the epidural space and to drive a lead. This different set of surgical skills requires a small surgical laminotomy, which allows for direct vision placement of a lead. The size and shape of the leads preclude them from being placed through a needle approach with current technology (Figure 10.1). The procedure is initiated by properly positioning the patient in the prone or in the semilateral position, and taking all precautions for prepping and infection prophylaxis. Once positioned, fluoroscopy is used to identify the desired level of surgery. At this time, a 3–4 cm long incision is made to allow proper exposure of the tissues. Once exposure is obtained, bony removal is accomplished depending on the planned surgical lead that will be placed. These leads vary in size and shape, but more significantly they can be modified based on patient needs. Options include single, dual, tripolar, or pentapolar configurations, variability in number of leads placed, spacing of electrodes, curve of the paddle, and overall shape of the lead(s). The complexity of the lead, variation in programming, and hours of stimulation result in a marked variability in the amount of energy required by the generator.

The surgical exposure is confirmed by direct vision and then a subperiosteal dissection is performed. In most cases, the dissection is performed with parts of the spinous process being slowly removed until the limamentum flavum is viewed, and dissected to allow visualization of the epidural space (Figure 10.2). Once a clear view of the space is obtained, an electrode spacer is placed to clear the path for the final lead placement (Figure 10.3). At this time, a lead or an array of leads is placed into the posterior epidural space under fluoroscopic guidance (Figure 10.4). At this point, the procedure varies with some surgeons doing an awake test stimulation with a goal of obtaining paresthesia in the desired area of pain, while other surgeons work under general anesthesia confirming placement by either X-ray guidance, or evoked potential stimulation. A typical stimulation occurs to 4–6-Hz at a pulse width of 300–350 with increases in amplitude until electromyographic signal

Table 10.1. Indications for paddle lead placement.

Surgeon prefers paddle lead
Surgeon not skilled in percutaneous technique
Difficult needle access to the spine because of anatomical characteristics
Epidural fibrosis
Revision because of lead migration
Inadequate power with percutaneous leads
Positional stimulation

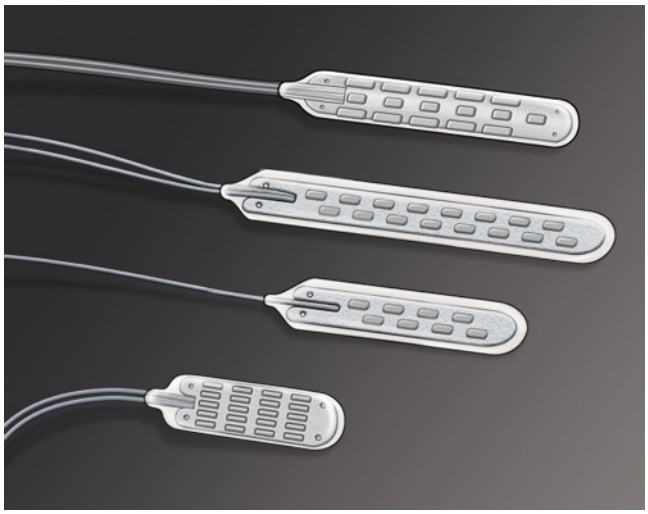

Figure 10.1. An example of paddle type leads.

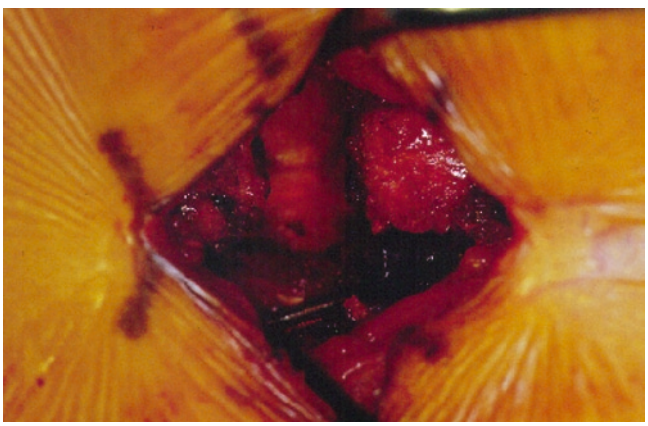

Figure 10.2. Exposure for lead placement.

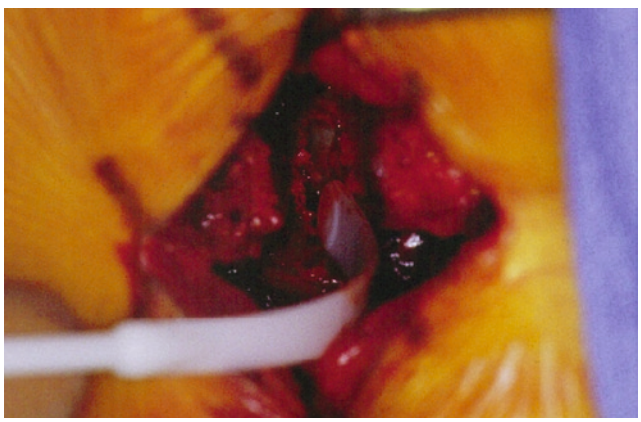

Figure 10.3. Preparation of the epidural space.

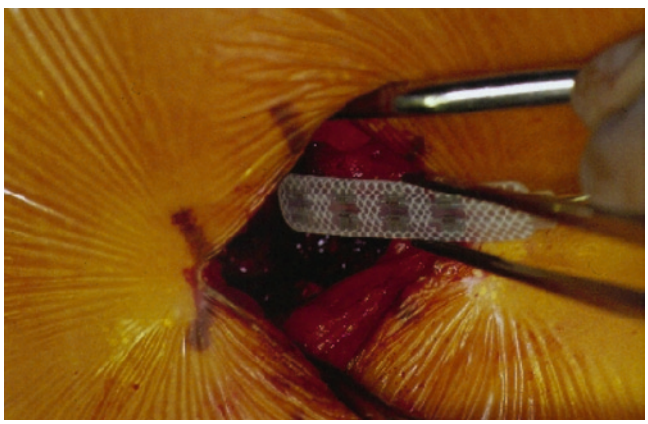

Figure 10.4. Lead placement into the epidural space.

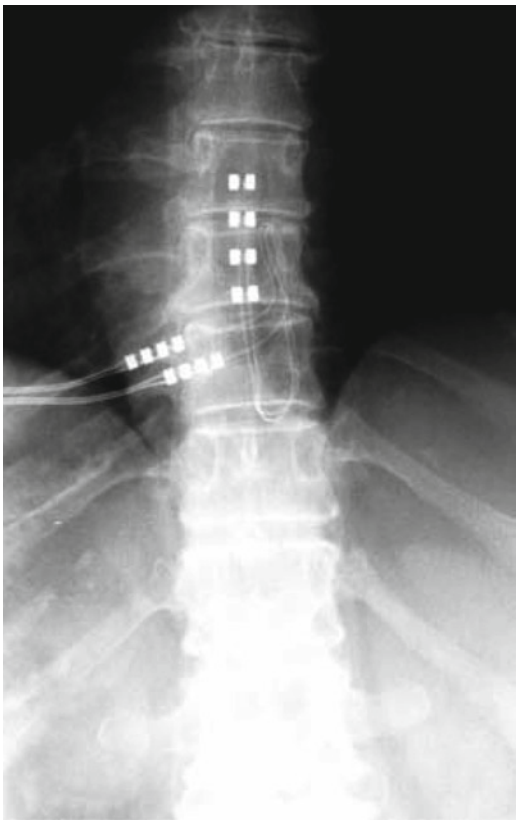

Figure 10.5. Fluoroscopic confirmation of lead placement.

changes are detected. To assure central lead placement, the goal is to achieve bilateral lower extremity stimulation. In some cases, the fluoroscopic and antatomical midline vary and the stimulation is more accurate. In cases of unilateral limb pain, the goal is to stimulate the midline and the area just off the midline to side of pain generation.

Once the surgeon is pleased with the position of the lead, it is secured and the system is tunneled to the pocket where it is connected to a programmable generator. At the conclusion of the lead placement, a final X-ray confirmation is made to document position for future reference (Figure 10.5).

Risk Assessment

1. The placement of a paddle lead requires bone removal and tissue disruption. This leads to the risk of epidural bleeding and possible epidural hematoma.
2. Infection is a concern and possible complications include osteomyelitis, epidural abscess, meningitis, sepsis, and death. The most common complication is superficial wound infection.
3. Paddle leads are considered much more stable than percutaneous leads, but possible system failures include lead fracture, lead migration, and current leak from abnormalities of the wire covering or insulation.

4. Paddle leads take up volume in the epidural space and can lead to a worsening of spinal stenosis and neurological compromise.
5. Epidural fibrosis develops below and around the leads and may cause a change in the stimulation parameters and could change the overall success of the procedure.

Risk Avoidance

1. The risk of bleeding can be minimized by optimizing the patient's health prior to implant. The physician should review lab values that have an impact on the bleeding function. Medications that affect bleeding function should be reviewed by the patient's family doctor or cardiologist and modified to reduce bleeding risk if possible. If the patient cannot come off drugs that affect platelets and bleeding function for an acceptable period of time prior to implant because of medical risks the procedure should not be performed. The patient and the caregivers should be informed to monitor postoperative symptoms to identify bleeding early and allow immediate treatment.
2. Prior to surgery, the physician should review the patient's tissue for infection or lesions in the surgical area. The surgery should be delayed if there is any doubt about the safety of moving forward.
3. Preoperative antibiotics, intraoperative antibiotic irrigation, and postoperative oral antibiotics may reduce the risk of infectious complications. This should be coupled with careful attention to detail of prepping, draping, wound closure, to reduce the risk of contamination. In patients with a history of immune system compromise such as HIV/AIDS, cancer, poorly controlled diabetes mellitus, and primary immune dysfunction, a consultation with an infectious disease specialist or primary care doctor should be considered.
4. Prior to placing a paddle lead, the surgeon should consider the amount of room in the spinal canal and determine whether there is adequate room for the volume of the lead. This can be determined by a preoperative MRI. The implanter may also decompress the spine at the time of implant.
5. Careful attention to lead position, strain relief loops in the incision, and avoidance of pressure on the lead wiring can reduce the risk of fracture and electrical system disruption. Over the past few years, the quality of lead manufacturing has also reduced this risk.

Conclusions

The paddle lead option is often a very good solution to treating difficult pain problems. This method can be chosen because of the preference of the surgeon or can be an option based on clinical scenarios that develop based on patient needs and anatomy. Unidirectional current, efficient energy delivery and enhanced lead stability are all reasons to consider the paddle lead approach in treating patients with difficult pain syndromes.

Supplemental Images

See Figures 10.6 and 10.7.

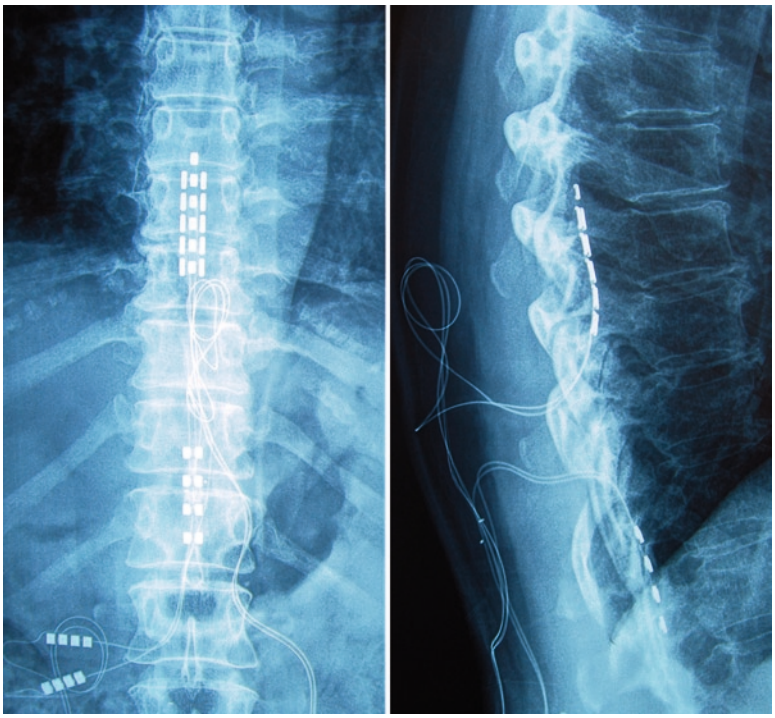

Figure 10.6. Dual paddle leads to treat axial and foot pain.

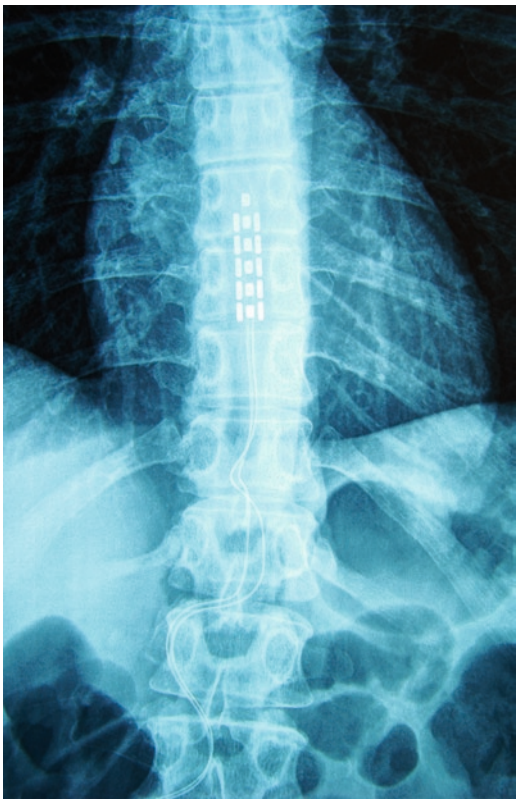

Figure 10.7. Proper placement of paddle for lumbar radiculopathy.

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II

Neurostimulation: Peripheral Nerve and Peripheral Nerve Field Stimulation

11

Stimulation of the Peripheral Nervous System

Timothy R. Deer, David Abejon, and Giancarlo Barolat

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Introduction

Peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNfS) are areas of neuromodulation that are growing in interest from both clinical and research standpoints. The increasing uses of these modalities are a reflection on the safety and increasing technical ease in which the devices can be delivered. This surgical technique has shown good potential in patients suffering from many severe pain conditions including intercostal neuralgia, ilioinguinal neuralgia, carpal tunnel syndrome, neuropathic facial pain, nerve entrapment syndromes, postsurgical nerve pain, and areas of specific neuropathic pain isolated to a small area of the body.

PNS and PNfS are not new options for patients suffering from pain involving the peripheral nervous system. Work by Wiener, Hassenbusch, Stanton-Hicks, and others showed that physicians could successfully implant devices around the peripheral nerve and create

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paresthesia in the innervation of the nerve. Over a decade ago, the placement of these devices required a careful surgical dissection, fascial graft debridement, and placement of the lead. This complicated procedure had relatively low reimbursement, required exceptional surgical skills, and was time consuming. The newer methods of placing leads percutaneously have led to an improved level of access to patients and have made stimulation of the peripheral nervous system a viable tool in the arsenal of the well-rounded interventionist.

This chapter focuses on the technical tasks associated with implant, selection of candidates, and potential pitfalls and solutions to implanting devices in the peripheral nervous system.

Selection of Candidates

Neurostimulation often involves finding a target in the spine or brain that can be influenced by electrical current application, which causes a change in the neural environment specific to the area of pain complaints. In selecting candidates for PNS and PNfS, the physician must consider the innervation of the specific area of complaint and resolve if there is an opportunity to influence that area by directly applying current to a nerve or nerve fibers. Table 11.1 outlines the selection criteria for implanting a percutaneous peripheral lead. The decision to implant a permanent lead is similar to that of spinal cord stimulation; specifically, does the patient experience significant pain reduction by visual analog scale? does the stimulation feel pleasant and acceptable? and is objective function improved during the temporary period? Contraindications include lack of significant relief from the trial phase, localized infection, uncorrected bleeding disorders, untreated depression or anxiety, and untreated drug abuse. Table 11.2 reviews the currently supported nerve targets for implanting a system for the peripheral nervous system.

Table 11.1. Selection criteria for implanting the peripheral nervous system stimulation system.

Characteristic	Establishing the characteristic
Pain is localized to a specific nerve distribution	Physical examination and history
Pain is burning or shooting in nature	History
Pain is relieved by injection of local anesthetic at the nerve innervation area	Resolution of 50% or more of the patients pain intensity with injection of local anesthetic on two occasions
Pain has not responded to or is not appropriate for other more conservative neuropathic treatments	Review of the records
No local infection at the implant site	Inspection of the skin
No allergies to the materials to be implanted	History of metal allergy
No major untreated psychological factors	History and appropriate psychological evaluation

Table 11.2. Established targets for PNS and PNfS placement.

Disease	Nerve target
Occipital neuralgia	C2 fibers at the occiput
Neuritis of the face	Supraorbital, infraorbital temporo-auricular, trigeminal divisions
Upper extremity pain	Median, ulnar, radial, axillary, suprascapular
Pain of torso	Intercostal, cluneal
Pain of pelvis	Ilioinguinal, iliohypogastric, genitofemoral
Pain of lower extremity	Common peroneal, superficial peroneal, lateral femoral cutaneous, tibial, saphenous, sciatic, femoral

Technical Overview

The use of PNS and PNfS is based on the concept that the delivery of electrical current in a controlled fashion to a specific nerve or nerve fibers will affect the transmission of pain by influencing the firing of the A delta and C fibers as well as potentially changing the neurotransmitters in the tissue. To make these important modifications of the nervous system the physician must place a system in the appropriate tissue plane.

Percutaneous Trialing

The lead placement through a percutaneous needle has revolutionized the care of patients with specific pain patterns that are isolated to an area of 4 cm or less in pain topography. Once the surgeon determines the pain is appropriate for this modality, the patient is properly prepared preoperatively, antibiotics are given based on physician preference, and the tissue is prepped and draped widely. Prior to going to the procedure room, the patient should be mapped with a permanent marker based on examination. This marking will guide the needle approach. The estimated area of the pain pattern is evaluated and the longest length being vertical or horizontal guides the needle approach. This technique allows the lead or leads to cover the most numerous number of fibers in the area of pain. Once the target and approach are planned, the physician uses fluoroscopy to identify landmarks and to document both the needle and lead placement so the procedure can be replicated on the permanent implant. A small stab wound is made in the skin to allow easy and appropriate needle placement to the appropriate depth. Anesthesia varies based on physician preference. Options include the use of local anesthetic only at the needle entry site, local anesthetic at the entire area of invasion, or absence of local anesthetic with a small dose of propofol or other short-acting anesthetic during the time of needle placement. Avoiding local anesthetic has the advantage of allowing trialing of the lead immediately without having to wait for resolution of numbness. The author uses local only at the initial stab wound site.

The needle depth has been debated among implanters, but the tissue response helps determine the appropriateness. If the lead is too superficial, the patient will experience burning on activation of the system. If the lead is too deep, the patient will experience involuntary muscle spasm, which is uncomfortable. In most cases, the lead is 0.5–1.0 cm deep in the subcutaneous adipose. In most cases, the physician can palpate the needle as it is placed into the target zone, but is unable to palpate the lead once it is disengaged from the needle. In some newer devices, the use of a nerve stimulator can help identify the exact target prior to depositing the lead.

The needle is advanced based on preoperative marking and fluoroscopic imaging, and when appropriate the lead is passed in the needle to the tip. The needle is then withdrawn while maintaining lead placement in the target zone. At this point, the appropriate manufacturers hand held programming device activates the lead. The programming may vary, but in our experience the use of multiple cathodes spread widely over an octipolar lead with minimal anodes appears to have the best chance of nerve capture.

Once the nerve or nerve fibers are appropriately stimulated and pleasant paresthesias are achieved over the target area, the lead is secured to the skin. Options include the use of a conventional silastic anchor with sutures, the use of adhesive tape, or a combination of the two.

The patient is then taken to recovery for a short observation period prior to discharge for an outpatient trial.

Percutaneous Permanent Implant

Once the trial has been completed with acceptable pain relief, the patient is offered a permanent implant. The physician should carefully evaluate any cosmetic or structural issues that may impact lead choice, device choice, pocket placement, and incision location.

The patient is returned to the operating theater and the percutaneous lead is replaced based on mapping, fluoroscopy, and review of the previous films with landmarks. Once the lead is in good position, an incision is made to the fascia at the area of the lead proximal to the electrodes. This allows an opportunity to secure the lead without affecting the electrical fields. Homeostasis is achieved, and the fascia is identified by dissection and debridement of fatty tissue.

Anchoring methods vary and include use of a conventional anchor, use of a suture(s) without a formal anchor or in some practices avoidance of an anchoring technique. If an anchor is chosen, it is imperative that the implanter closes the tissue in two to three planes to protect the anchor from erosion. The use of a nonabsorbable suture such as ethibond or similar materials can be modified to secure the lead without using a formal anchor. In this technique, the suture is placed through the fascia and tied with a surgeons knot. The suture is then looped around the lead in a method similar to that used for securing central lines. This allows the lead to move slightly with patient motion, but still maintains the location. This method also avoids the risk of anchor erosion. Once the lead is secured, a pocket is made in the appropriate location. For example, the pocket should be in close proximity to the lead to reduce the risk of migration. This is illustrated by placing the pocket for head and neck implants in the chest wall, placing the pocket for cluneal nerve implants in the area above the beltline, and placing the pocket for the ilioinguinal or intercostal nerves in the abdominal wall or flank. Smaller batteries from each of the manufacturers have lead to more options for the patient. Like any pocket, the implanting doctor should consider the bony margins, skin condition, and body habitus before selecting the appropriate location. All wounds should be irrigated with copious amounts of antibiotic solution or saline prior to closure to follow the surgical rule "dilution is the solution to the pollution." Programming of the device will stabilize over 6 weeks, with many patients receiving improved stimulation as fibrosis develops around the lead.

Paddle Lead Implantations of the Peripheral Nerve

In some cases due to lead migration, or failure to capture appropriate coverage, it is still advisable to place a paddle-type lead in or around the peripheral nerve. This is most commonly done in the occipital region or in the limb targeting nerves such as the common peroneal or the median nerve. This technique is more difficult and should not be attempted without proper training. In the occiptut, the tissue is expanded to allow for placement of the paddle lead after removal of the previously implanted percutaneous system. The main issues are controlling bleeding and appropriate tissue depth. The placement of a paddle lead is much more difficult in the extremity. In these cases, the surgeon must carefully dissect to the nerve target and expose the nerve. Once the nerve is exposed, a careful graft of fascia must be performed. The fascia is placed over the nerve and the lead is placed superior to the fascia. The entire complex is secured with small nonabsorbable suture. Since paddle leads are unidirectional in the delivery of current, it is very important to have the active portion of the lead positioned to deliver current toward the nerve. Once the lead is secured, a pocket is created and the lead is tunneled to the pocket site. In many cases, the pocket must be placed in a location that requires crossing one or more joints in the tunneling process. This is not optimal and with newer systems the pocket may be placed closer to the nerve since the smaller generator may allow the pocket to be placed in areas such as the thigh or upper arm. Again careful consideration of comfort must be considered prior to making this decision.

Common Nerve Targets for PNS and PNfS

Any peripheral nerve or nerve fibers could theoretically be treated by electrical stimulation of the neural tissue. Any tissue in which the nervous innervation can be reached by a needle could be stimulated to induce a modulatory change. The use of PNS and PNfS

is more common in certain regions of the body. The most common nerve targets are noted below.

Occipital: Occipital targets are well defined and have been addressed in several reports and articles over the past decade. The use of PNS for the occipital nerve was originally described in 1990s by Wiener, and has evolved. The initial description involved placing the lead horizontal to the C1 vertebrae in the midline, but over time the technique has evolved to be placed through a midline incision just above the nuchal line. By placing leads bilateral in the more superior location, it is possible to maintain a better long-term contact with the nerve fibers and to reduce the risks of significant migration. Occipital leads are placed for C2 radiculitis, transformed migraine, and cervicogenic headache.

Supraorbital: Stimulation of the supraorbital nerve, a nerve derived from the trigeminal nerve, is important in the treatment of pain just above the eyebrow that is of a burning or stabbing nature. The most common causes of disease in this nerve include trauma and infection. The most common infectious cause is viral in the form of herpes zoster. The lead is placed 0.5 cm above the brow in most cases. The approach is most commonly laterally with a mapping of the nerve occurring prior to implant. In some cases, the patient cannot tolerate the weight of the lead because of allodynia. In these cases, an approach with a very small lead may be indicated. The advantage of small leads is their atraumatic nature, but the disadvantage is that it does not cover as much area, and the leads may be more prone to fracture.

Infraorbital: Stimulation of the infraorbital nerve, a nerve derived from the trigeminal nerve, is important in the treatment of pain just below the eye that is of a burning and stabbing nature. The most common causes of disease in this nerve are trauma and disease. The lead is placed 0.5–1.0 cm below the eye with the exact placement based on preoperative skin mapping with a semi-permanent marker. The lead is placed from the lateral approach and is left in place for 3–7 days in most cases.

Divisions of the trigeminal nerve: Trigeminal neuralgia is a painful condition of the face that involves one to three divisions of the nerve. The divisions, ophthalmic, mandibular, and maxillary, may become abnormal and cause severe burning pain of the face. In many cases, this problem is treated with oral anticonvulsants or by neurosurgical adventures, such as brainstem vascular decompression, or by nerve destruction. When these options do not give appropriate relief or are not acceptable, the interventional pain specialist may place a peripheral lead over the involved division(s). This involves mapping by history and exam, careful placement with mapping by landmarks and fluoroscopic guidance, and attention to proper tissue depth and anchoring techniques. The leads are often anchored behind the ear, with the pocket in the chest wall or trapezius area or upper flank.

Auriculotemporal: The auriculotemporal nerve is a branch of the mandibular nerve that runs with the superficial temporal artery and vein, and provides sensory innervation to the face and jaw. The sensory portion of the nerve is often injured by trauma, surgery of the temporomandibular joint, or surgery of the parotid gland. Placement of the lead is often simple, with an understanding of the pain pattern in the anterior face, jaw, and temporal region. The lead is anchored behind the ear and tunneled to the chest wall, trapezius region, or upper flank.

Superficial cervical plexus: The superficial cervical plexus has been described as a source of pain after trauma, radiation, or surgery. The approach of placing a lead in this region is based on pain topography, since it would be very difficult to isolate the nerves without direct tissue dissection.

Intercostal: The intercostal nerves are the anterior divisions (rami anteriores; ventral divisions) of the thoracic spinal nerves from T1 to T11. The intercostal nerves are common causes of pain and disease involving neuropathic pain of the chest wall. The most common causes of pain in this region are postherpetic neuralgia, and post surgical nerve entrapment such as that seen with postmastectomy syndrome, and postthoracotomy syndrome. The treatment of this problem is often successful with oral medications. It is sometimes treated with epidural lead placement, but the success rates are not as successful as with failed back surgery or neuropathic limb pain. In these cases where other options fail,

a PNS is indicated prior to placing a pump. The patient should be carefully examined, the pain topography should be well mapped, and a lead should be placed in the long axis of the pain mapping. If the trial gives appropriate relief, the patient undergoes a permanent system. The pocket should be placed in close proximity of the leads, but with caution to avoid contact with the rib margin.

Ilioinguinal: The presence of burning groin pain can be very disabling and cause decreased quality of life, inability to work, and decreased overall function. The most common cause of pain in this region is posthernia nerve entrapment. A peripheral lead can be placed by first confirming the diagnosis with exam, history, and in most cases a temporary response to nerve injection. The pain after hernia repair can be from either nerve entrapment or direct nerve injury. The lead is placed in the tissue parallel to the longest axis of pain on mapping of the tissue. If the trial gives successful pain relief, a permanent device is placed in the nerve distribution. In the past, we often dissected down to the actual nerve to place the lead under direct vision, but the use of a percutaneous nerve approach appears to be equally successful for the patient with reduced trauma overall. The generator should be near the area of the leads to reduce the risk of migration.

Genitofemoral and iliohypogastric: The genitofemoral and iliohypogastric nerves are often involved in chronic pain. The use of PNS has been described for these nerves, but is difficult to achieve. The anatomical location and course makes it difficult to achieve good, sustained relief in these pain syndromes. The most common causes of injury to these nerves are blunt trauma and surgical scarring.

Cluneal and nerves of the paravertebral region: The low back is a common cause of pain in patients suffering from intractable problems. The innervation is complicated and involves the cluneal nerve, branches of the sinu-vertebral nerve, and branches of the medial branch nerves. The branches of the cluneal nerves, particularly the superior cluneal nerves, are often involved in severe burning pain of the low back. This problem often occurs after lumbar surgery. In many cases, the patient has successful stimulation with epidural leads, but the stimulation misses a very specific area of the lower back and buttocks. Placement of a PNfS lead in this area is based on pain mapping. The lead is placed in the subcutaneous tissue in the subdermal adipose tissue being careful not to place it too deep causing muscle recruitment or too superficial causing skin erosion or burning pain on stimulation. The lead(s) is often combined with epidural leads to create a mixed stimulation pattern.

Lateral femoral cutaneous: The lateral femoral cutaneous nerve of the thigh is a nerve that arises from the dorsal divisions of the second and third lumbar nerves. It emerges from the lateral border of the psoas major muscle, and crosses the iliacus muscle obliquely, toward the anterior superior iliac spine. It then passes under the inguinal ligament and over the muscles of the upper thigh. This nerve is often diseased when traumatized, injured by pressure and resulting ischemia, or injured by diabetes mellitus or other metabolic syndromes. The nerve can also be injured by compression from excessive weight gain or weight loss. The problem may be successfully managed by oral medications, steroid injections, or topical patches or gels. In cases where the pain remains severe, the patient may be a candidate for spinal cord stimulation, which is often successful. The use of PNS has been successful in some cases including those with specific areas of burning pain. The lead is placed based on tissue mapping, and when placed permanently, anchored to the fascia with the generator placed in the closest approximation to the leads.

Axillary, suprascapular, brachial plexus, and other mixed nerves: The possibility of achieving pain relief and improved muscle function in nerves that contain both motor and sensory fibers has been discussed and current studies are examining viability. These issues remain experimental and the use in these arenas, although exciting, remains inconclusive.

Median, ulnar, and radial nerves: The use of PNS to treat the sensory components of the nerves of the forearm and hand is a concept that is showing promise. The author has

completed a pilot study that showed the stimulation of the median nerve could create substantial pain relief in the patient who has failed carpal tunnel surgery. The stimulation of the ulnar and radial nerves is conceptually possible, easily accessed with a needle, and may be a great option. Additional studies are needed to evaluate treatment possibilities.

Saphenous, sural, peroneal, and tibial: Treatment of nerves of the lower legs is possible to improve burning pain. The saphenous nerve is often involved in nerve entrapment syndromes after knee surgery. The peroneal nerves are often injured during lower extremity trauma. The superficial peroneal nerve can be stimulated at the dorsum of the foot. The common peroneal nerve can be stimulated just below the popliteal fossa, and requires extensive tissue dissection. Smaller generators have made it possible to stimulate in the lower extremity and place the generator near the lead to avoid crossing over the joint at the knee or hip.

Risk Assessment

1. The patient who may be high risk for epidural lead placement or major neurosurgical interventions may be a candidate for peripheral nerve placement. The risks are limited, but careful preoperative planning is still necessary.
2. Skin infection is the most common problem with PNS and PNfS.
3. Nerve injury of the peripheral nerve or its fibers is possible and may lead to continued or worsened pain.
4. Skin erosion may occur when the lead, anchor, or generator irritates the skin causing a cellulitis and potential skin breakdown.
5. Pain at a component of the device may lead to a decreased use of the device, decreased function, and a need to revise the system.

Risk Avoidance

1. The risk of PNS and PNfS is limited, but it is still important to evaluate comorbidities prior to moving forward with the device. Diseases such as diabetes and those involving the skin should be optimized prior to moving forward.
2. The skin should be examined and inspected for infection or other high risk conditions prior to implant. If those conditions exist, the primary care specialist or a dermatologist should be consulted prior to moving forward.
3. Nerve injury is very rare with the newer percutaneous techniques of lead placements. The lead is placed in the proximity of the nerve rather than in direct contact in most cases. The patient should be kept alert during lead placement and the needle or lead should be redirected if the patient complains of paresthesia.
4. The lead should be placed into the subcutaneous tissue at a level below the dermis. The physician should palpate the skin while placing the needle and it is helpful to direct the bevel downward prior to engaging the lead. The use of leads with plastic stylets may allow for easier tissue plane identification and placement. Many implanters have gone to a technique that eliminates the use of the anchor with a loop suture of nonabsorbable suture being used to secure the lead placement near the target nerve.
5. Pain at the device can be minimized by carefully examining the bony structure of the patient prior to implant. The pocket should be in a location that receives the least amount of tissue pressure during the patient's daily activities. If pain persists, options include the use of topical anesthetics, padding, and if other methods surgical revision.

Conclusions

The interest in stimulating the peripheral nervous system to treat chronic pain has seen resurgence in recent years. New areas of research also include stimulation of the motor nerves to improve function. The number of patients who are candidates for neuromodulation will increase exponentially if these methods are proven to be successful. New prospective research is needed going forward, and a careful attention to patient selection is needed in current clinical practice.

Supplemental Images

See Figures 11.1–11.13.

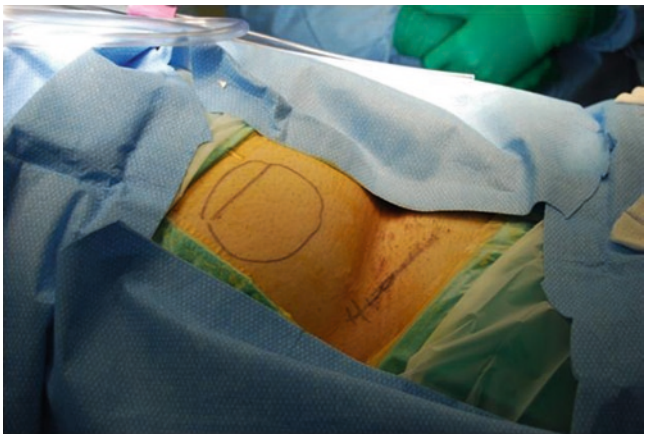

Figure 11.1. Patient marking for peripheral nerve pocket and lead target.

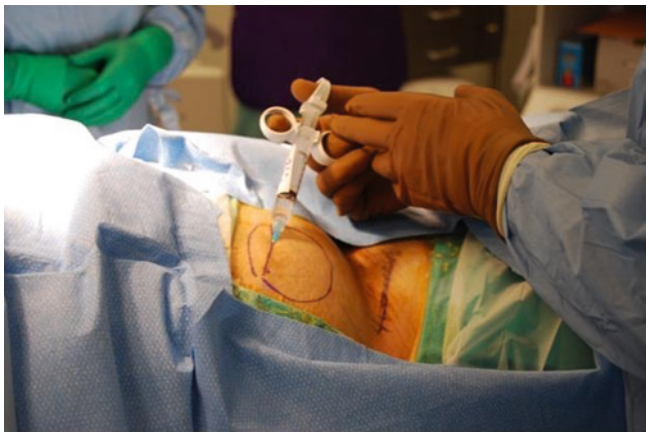

Figure 11.2. Local anesthetic placement.

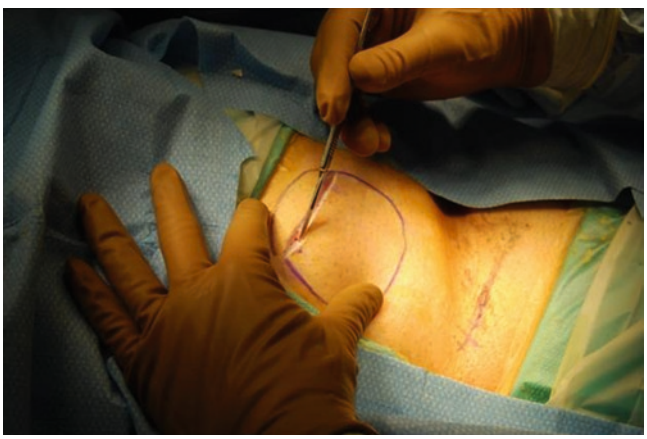

Figure 11.3. PNS pocket creation.

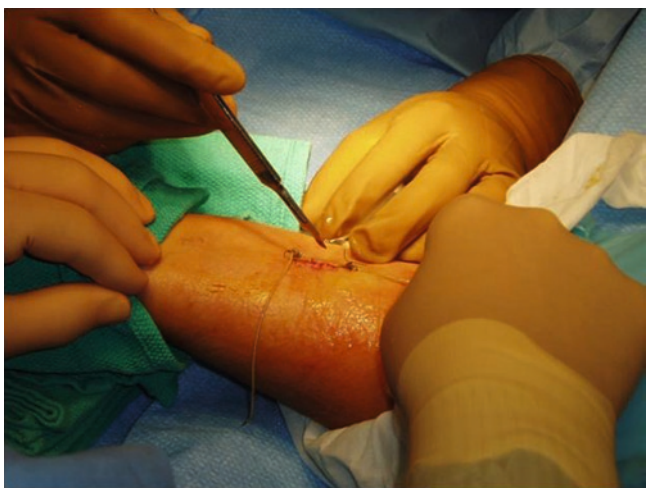

Figure 11.4. Insertion of percutaneous leads in the area of the median nerve.

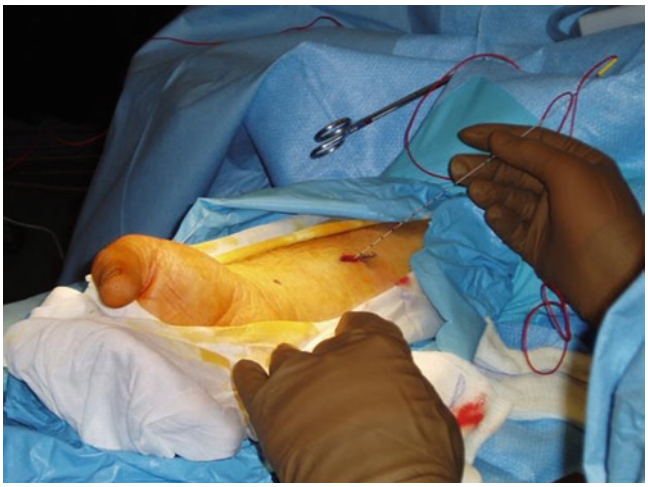

Figure 11.5. Peripheral nerve stimulation can be facilitated by identifying the nerve with a nerve stimulator. This can be used to guide the final lead placement.

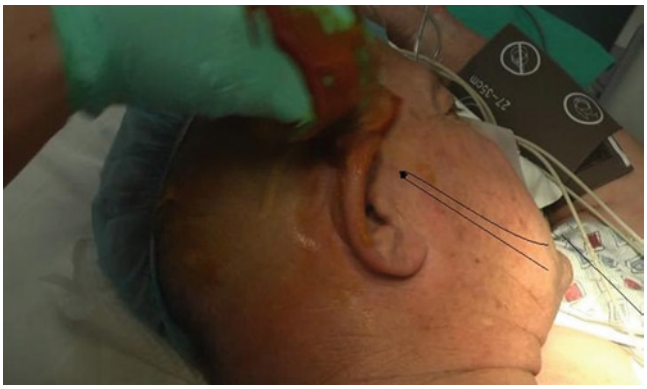

Figure 11.6. Mapping of the neuropathic pain is helpful prior to peripheral nerve implant.

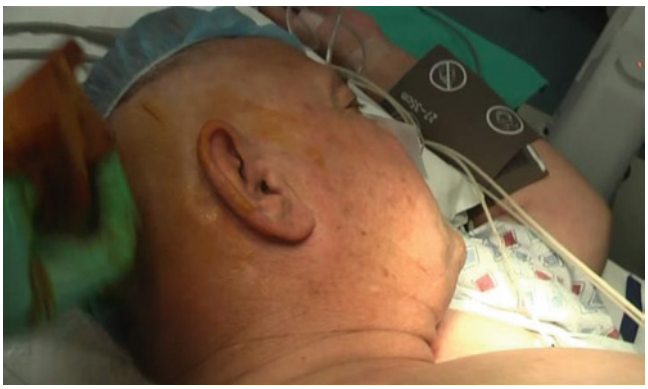

Figure. 11.7. Prepping should be well outside of the target area for the peripheral nerve implant.

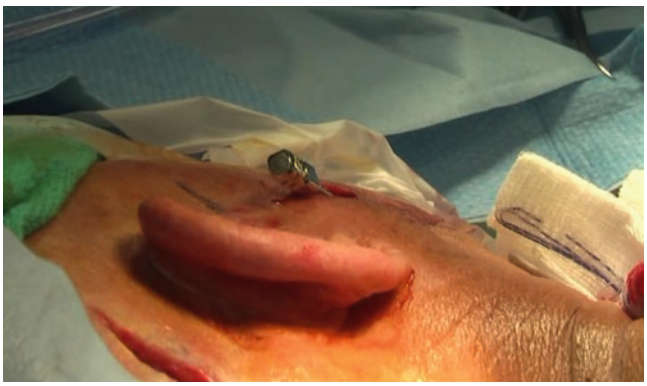

Figure 11.8. Lateral orientation of the needle placement prior to lead delivery.

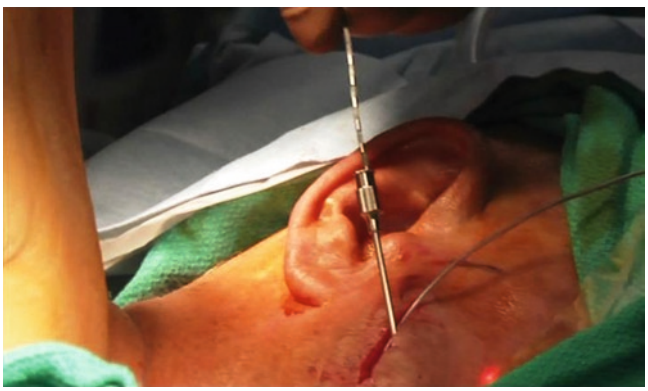

Figure. 11.9. Needle orientation and targeting is an essential part of the head and neck implant.

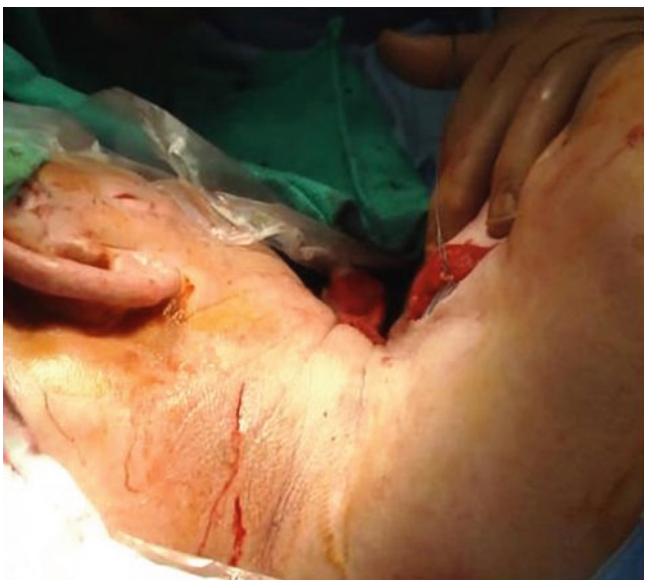

Figure 11.10. Pectoral pocketing for head and neck implants is often desirable to reduce the risks of lead migration.

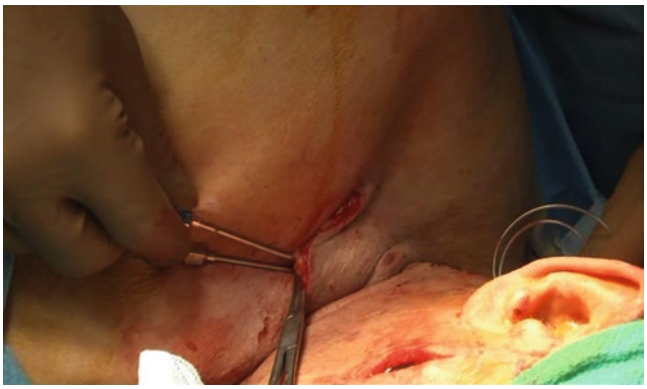

Figure 11.11. Tunneling of the peripheral lead of the head and neck must be performed with caution to avoid the vessels in the area of the implant.

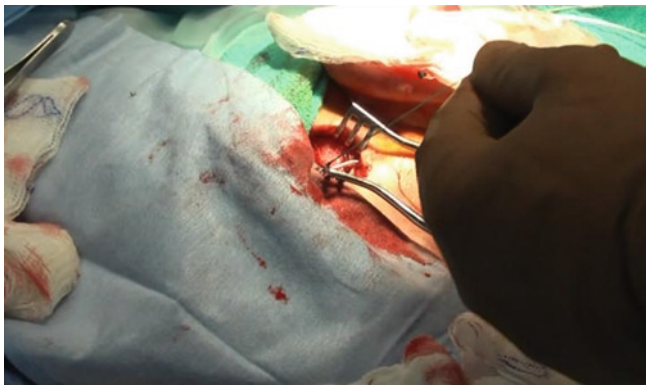

Figure 11.12. Anchoring of the leads to the fascia behind the ear can lend extra stability to the system and be cosmetically desirable to the patient.

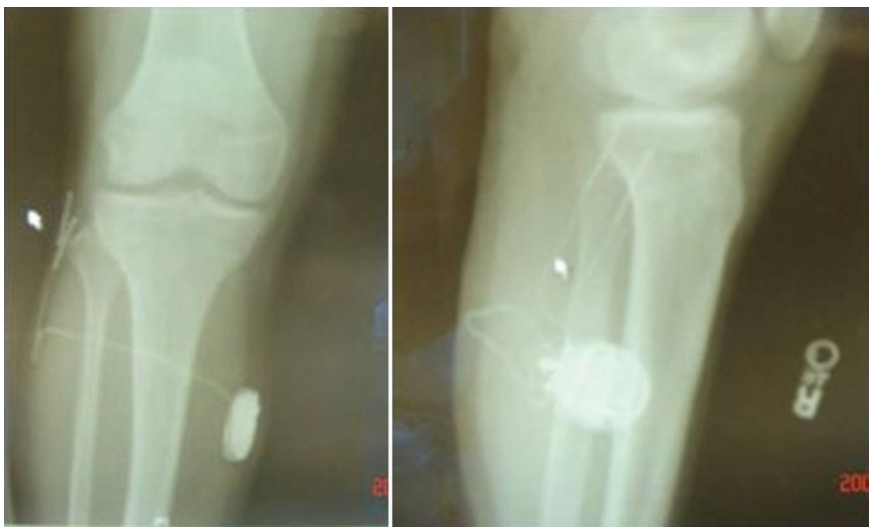

Figure 11.13. Pocketing in the extremity.

Suggested Reading

Davis G. Peripheral nerve stimulation for the treatment of chronic pain. *J Clin Neurosci*. 2007; 14(3):222–223.

Henderson J. Peripheral nerve stimulation for chronic pain. *Curr Pain Headache Rep*. 2008;12(1): 28–31.

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12 Stimulation of the Nervous System to Treat Neuropathic Pain of the Foot

Timothy R. Deer and Giancarlo Barolat

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Introduction

Neuropathic foot pain is a common disease state that affects more than 200 million people globally. The pain may vary from a mild tingling to an excruciating, constant burning pain with exacerbation often seen in the evening hours. Neuropathic pain is often difficult to treat with conservative measures and more advanced techniques are required. This problem comes to light in those suffering from primary peripheral nerve problems, neuropathies, nerve entrapment, spinal nerve root injury or scar entrapment, and complex regional pain syndrome.

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Spinal cord stimulation can be successful in treating this troubling problem. Conventional methods involve routine placement at the common locations in the spinal canal (T8–T12), but in some cases stimulation is required at the level of the nerve root, or peripheral nerve. This chapter discusses possible strategies to successfully control neuropathic foot pain.

Technical Overview

Other sections of this Atlas have covered many of the pearls of this section. Needle placement, lead placement, and techniques such as anchoring and pocketing are consistent with other sections described in the text. Nerve root stimulation, paddle lead placement, and peripheral nerve placement is also covered elsewhere in the atlas. The primary technical decision in this pain disorder is a cerebral exercise. The decision of where to target the nervous system to achieve the desired result is the most critical decision in this process (see Tables 12.1 and 12.2).

The Percutaneous Method of Epidural Stimulation

Once the epidural needle is in place, the lead is targeted to the nerve that is involved in the generation of pain. The traditional approach involves placing the lead at the level of T8–T12. This is often done in parallel or a staggered array (Figure 12.1). If these lead arrays are successful, no further adaptations are needed, and in some cases, this treats both foot pain and other dermatomal patterns. Some physicians prefer to cross the midline with the leads used in a guarded array with two cathodes in the center of the lead to drive the current deeper (Figure 12.2). This pattern often leads to total coverage of the entire leg including the feet. In selected patients, the paresthesia in the foot is troubling and not desired. In these cases, the epidural approach is not the ideal treatment option.

In cases where the foot is not stimulated by the epidural approach, a nerve root approach is an option. This can be performed by either a percutaneous or paddle approach.

Table 12.1. Common disease states causing neuropathic foot pain.

Neuropathies: diabetic, alcohol induced, metabolic, nutritional deficiency, heavy metal, chemotherapy induced, idiopathic, infectious (HIV, Syphilis)
Spine-induced pain: disc impingement of the nerve, foraminal narrowing, central stenosis, epidural fibrosis, arachnoiditis, mechanical entrapment of the nerve, nerve trauma, iatrogenic, bone impingement on the nerve, failed back surgery syndrome
Complex regional pain syndromes types I and Ii, Raynaud's syndrome, vasculitis, ischemic pain secondary to peripheral vascular disease, vasospasm
Peripheral nerve pain: nerve injury, nerve entrapment, tarsal tunnel syndrome, post surgical scarring, neuroma, bony deformity causing nerve pain

Table 12.2. Lead placement options.

Approach	Location
Traditional approach	T8–T12
Modified approach	Crossing midline AT T10–T11
Conus approach	Crossing midline AT T12–L1
Nerve root approach	Lead capturing the nerve root in lower lumbar spine
Nerve root approach	Lead capturing the nerve root at Foramen L4,5, or S1
Peripheral nerve approach	Lead placed at the peripheral nerve pain site

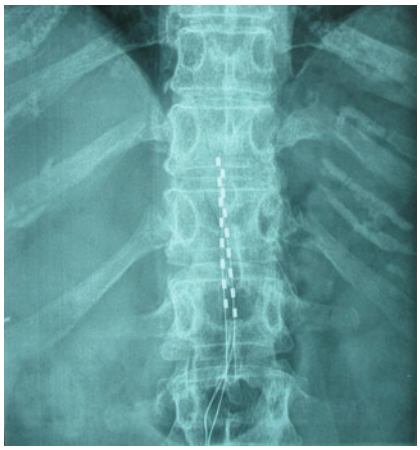

Figure 12.1. Traditional lead placement.

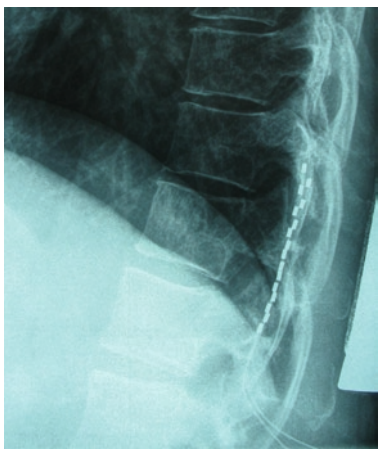

Figure 12.2. Guarded array placement.

The Nerve Root Method of Stimulation

The lead can be placed in the area of the L5 or S1 nerve root by the percutaneous approach. This can be performed by the retrograde approach or the sacral hiatus route. The retrograde approach involves entering the epidural space in a caudad approach via the intralaminar space two to three levels above the target nerve. This approach requires the physician to stand at the opposite side of the table than baseline. Once the epidural needed has been successfully placed by fluoroscopic guidance, the lead is driven down the middle of the epidural space until one level above the desired level and then using an appropriate stylet the lead is directed under X-ray to the nerve target. The alternative approach is to use a percutaneous approach to enter the sacral hiatus with an epidural Tuohy needle and then place the lead antegrade to the desired nerve foramen. The lead is placed at the foramen or adjacent to the foramen for stimulation (Figures 12.3 and 12.4). This approach can be very helpful, but the size of conventional leads makes it difficult to stabilize this lead placement. Current research is working on developing new technology to improve outcomes for these issues, but there are no currently approved leads specific to the foramen or these neurological structures.

In some patients, it is not possible or desirable to place the nerve root leads via the percutaneous approach. In these cases, a paddle approach is a possible solution. The lead can capture the nerve at the foramen or in the spinal canal as it travels to the foramen. These two lead placements are depicted in Figures 12.5–12.7).

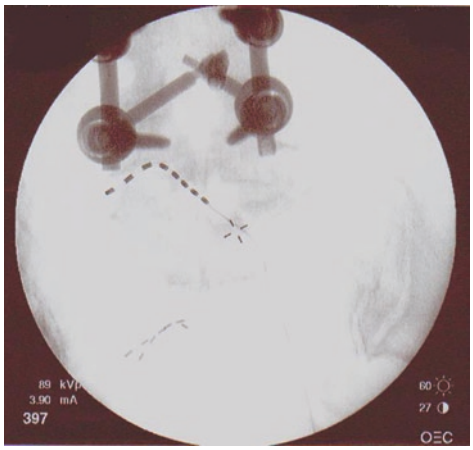

Figure 12.3. Nerve root placement.

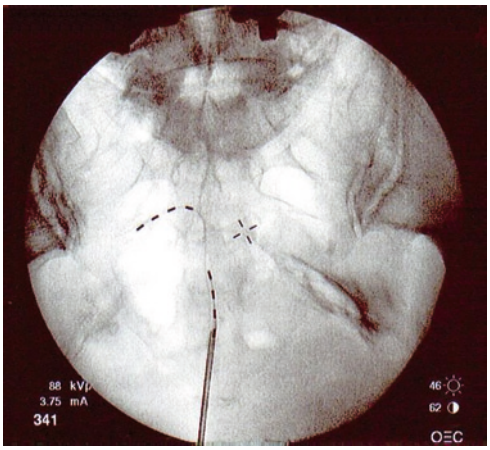

Figure 12.4. Nerve root placement via caudal approach.

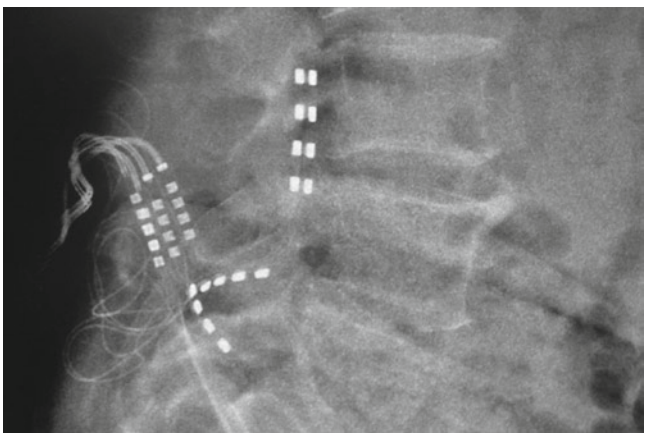

Figure 12.5. Mixed paddle approach (courtesy of Giancarlo Barolat, MD).

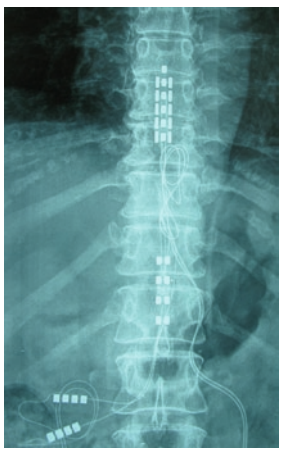

Figure 12.6. Epidural paddle approach (courtesy of Giancarlo Barolat, MD).

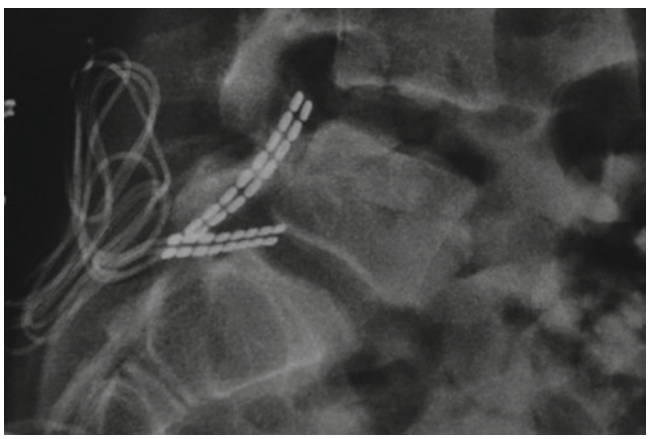

Figure 12.7. Lateral view paddle approach (courtesy of Giancarlo Barolat, MD).

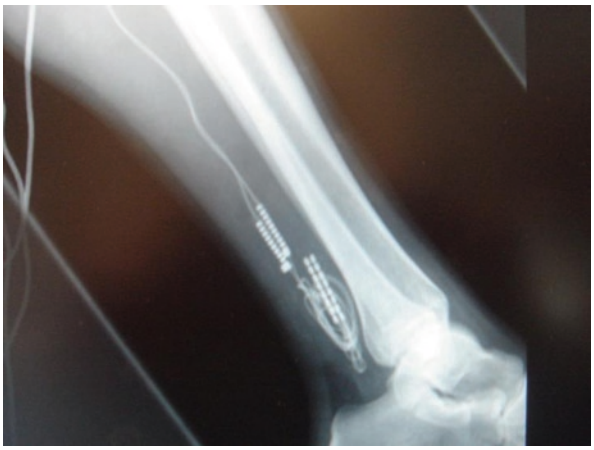

Figure 12.8. A possible stimulation location for a patient with isolated foot pain (courtesy of Giancarlo Barolat, MD).

In the chapter on peripheral nerve discussion, we covered the possibility of placing a lead on the peripheral nerve. The target for this nerve stimulation is based on exam, pain pattern, and when available an electromyogram or nerve conduction study. The technique can be performed by either a percutaneous approach, or a paddle lead approach based on surgical preference and patient characteristics. A possible location for stimulation for a patient with isolated foot pain is shown below (Fig. 12.8).

Risk Assessment

1. The foot innervation can lead to a challenging problem with spinal cord stimulation. The lead can be placed too high in the spine resulting in a failure to achieve proper target stimulation.
2. Stimulation in the upper lumbar spine, such as at the level of the conus, can lead to an unstable lead location, and can lead to a varying degree of stimulation, which may be unpleasant.
3. Nerve root stimulation may be felt as an intense paresthesia that is so powerful the patient gets motor recruitment.
4. Stimulation of the peripheral nerve can lead to the development of scar tissue reducing the long-term success of the device.

Risk Avoidance

1. Crossing the midline in the thoracic spine may result in a more uniform stimulation pattern leading to coverage of the back down to the feet. This is often achieved by using a "double guarded" cathode array. That involves a (+ − − +) programming of the portion of the lead crossing the midline. This may require two leads in a staggered orientation.

2. The placement of the lead over the conus can be very helpful in achieving stimulation of the foot, but unfortunately the lateral movement of the lead is an issue, as well as movement of the conus with positional changes. This can be reduced by crossing the midline with the center of the configuration of programming at the conus. This can be done with a single lead, or dual leads.
3. When placing a stimulation lead in the vicinity of the nerve root, the programming should be started initially to capture threshold, and then backed off to a subthreshold level. The patient should be offered several programs that cover different contacts on the lead, and have a variety of pulse width options.
4. Peripheral nerve stimulation leads can be placed percutaneously in the vicinity of the nerve to avoid direct nerve contact that in some cases can reduce the impact of scar. In cases where the lead must be placed directly on the nerve a fascial graft may be helpful in stabilizing the stimulation pattern, although this technique is difficult to perform and has questionable long-term outcomes.

Conclusions

A successful outcome with patients suffering from neuropathic foot pain can be achieved with spinal cord stimulation. The method of lead placement, neuropathic pain target, and lead programming may all play a critical role in the long-term efficacy of the device. The clinician must be an active problem solver in these situations, and must adapt to the patients response.

Supplemental Images

See Figure 12.9.

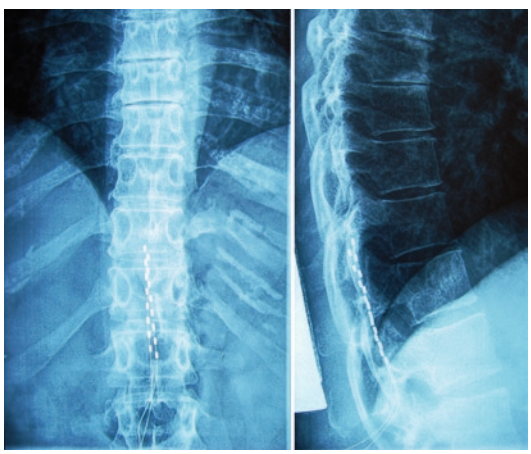

Figure 12.9. Percutaneous lead placement for foot pain.

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13

EMG/SSEP Monitoring During Thoracolumbar Spinal Cord Stimulation

Erich O. Richter, Marina V. Abramova, and Kenneth M. Alò

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General Uses of Neurological Monitoring in Spine Surgery

Intraoperative neurophysiological monitoring has become a routine procedure in complex spine surgery. Somatosensory-evoked potential (SSEP) recording has been advocated to monitor the functional integrity of the nervous system during surgical manipulation.[1–4] When stimulated, sensory afferents give rise to signals carried via the dorsal columns (DCs) within the spinal cord to the medial lemniscus and spinocerebellar tracts, ending in the primary somatosensory cortex.[5] SSEP monitoring does not involve the motor pathways,

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which in some clinical situations can lead to false-negative results and postoperative neurological deficits undetected intraoperatively.[6–12] Dermatomal SSEP testing allows for assessment of individual nerve roots during surgery and has been shown to be more sensitive.[11,13] However, the sensitivity and specificity of this method varies and is inferior to electromyographic (EMG) monitoring.[13,14] EMG has become the standard of practice in complex spine surgery, providing surgeons with accurate feedback about individual nerve root activity during surgical manipulation of neural structures.[12,15–18]

Neurological Testing to Implant Spinal Cord Stimulation Devices

We devote this chapter to a technique, which allows the comfort, and safety of general anesthetic while determining the physiological midline (PM) by objective neurophysiological testing.[19]

The identification of PM using evoked potentials was introduced by Claudio Feler, who obtained a patent for a device to perform the mapping [US 6,027,456]. While the device did not gain widespread usage, a few centers adopted this methodology using standard intraoperative electrophysiologic monitoring equipment. To obtain the optimal coverage over painful areas, two major criteria must be met: the applied stimulation should be positioned longitudinally along the DC and the PM must be identified. When general anesthesia is used, intraoperative neurophysiological monitoring with evoked potentials becomes the only way to determine the PM. Stimulation of various portions of the dorsal spinal cord produces paresthesia in a given distribution in the awake patient, and produces a reliable pattern of sensory (SSEP) and motor unit action potentials (MUAPs) of the EMG in the patient under anesthesia. In addition, the output data may include interpolations between specific measured points for optimal assessment of applied stimulation between evaluated lateral positions [US 6,027,456].

These fundamental findings have been implemented in practice by the senior author (KA) who began using this approach in 1999, noting a marked outcome improvement over the previous fluoroscopically guided technique. In this technique, MUAPs via EMG activation are used to determine the PM by examining the symmetry of the evoked potentials with presumed midline stimulation. In addition, it became clear that objective MUAPs via EMG activation of specific muscles corresponded with postoperative induced paresthesia in particular regions depending on laminectomy level. For example, EMG activation of the external oblique muscle from a T9 to T10 thoracic paddle consistently correlates with low back paresthesia (Figure 13.1). These correlations are summarized in Table 13.1. These concepts can be readily employed as a basis for cervical and sacral placement of electrodes. The application of EMG/SSEP for cervical and sacral SCS will be further explored in later chapters.

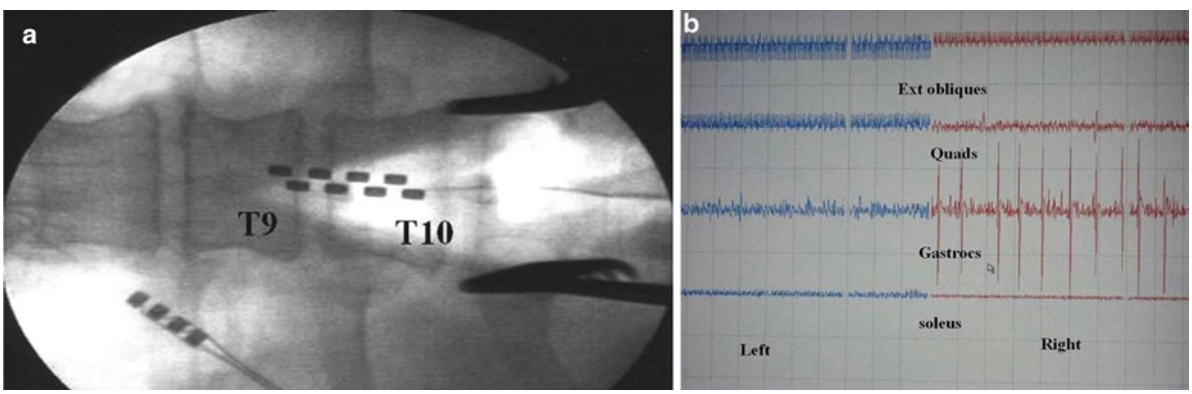

Figure 13.1. Intraoperative view of thoracic paddle lead implantation. (**a**) The electrode is behind the body of T9 and T10. Stimulation is right sided with the cathode at the second position and the anode at the third. (**b**) With right-sided stimulation, there is right-side gastrocnemius activation, which will correlate with an S1 dermatomal paresthesia.

Table 13.1. Correlations between EMG activation of specific muscles with postoperative-induced paresthesia – thoracic paddle electrode at T9-10 (laminectomy T10/11).

EMG activation, muscle group	Induced paresthesia
External oblique	Low back
Tibialis anterior	L4
Vastus lateralis	L5
Gastrocnemius	S1

The general concept of using intraoperative EMG in the placement of the SCS on the PM of the spinal cord is similar with respect to the 2- and 3-column paddle configuration and differs in terms of whether the "expected" pattern should be symmetric (the middle column of a 3-column array) or "equally asymmetric" (a 2-column array). We have just begun PM evaluation with this technique using the newest 5-column array (Penta, St. Jude Medical, Plano, TX).

Technique of Midline Positioning of the Spinal Cord Stimulator: Tripolar Paddle

Once the 3-column paddle is placed in the dorsal epidural space, the superior midline contact is stimulated at minimal settings and the EMG trace recording associated with the dermatomal level of stimulation is monitored. The stimulus intensity is gradually increased until MUAPs are seen on EMG. The lowest stimulus intensity needed to elicit a motor response is referred to as the threshold stimulus. MUAPs will be seen bilaterally at the threshold stimulus if the midline contact of the SCS is in line with the PM of the spinal cord. If MUAPs are seen unilaterally, the threshold intensity for that side is recorded and the stimulus is further increased to elicit a response on the other side. A difference in threshold stimulus intensity between the left and right side indicates that the SCS is lateral to the PM. Medial/lateral repositioning of the SCS is only necessary, however, if the difference in threshold intensity between the two sides is greater than 2 mA. In this case the paddle may not be perfectly flat on the lateral X-ray (Figure 13.2a), thus dissection of the lateral recesses or proximal/superior lamina is further performed until the electrode is perfectly aligned with vertebrae on a lateral view (Figure 13.2b). This assures optimal electrode column symmetry and programmability relative to the PM. Of course, as a last resort, the laminotomy can be extended to a full laminectomy to allow perfect alignment of the paddle on the PM. In this case, tissue must typically be identified to suture the electrode in place to prevent migration. These tenants hold true for all paddle (1, 2, 3 and 5 column) array configurations.

New Frontiers of Intraoperative EMG Application

There appears to be a correlation between the muscles with objective EMG activation during intraoperative monitoring, and the subjective paresthesia obtained postoperatively as described in Table 13.1. Thus, this may be explored to generate a precise model of paresthesia coverage and create a functional dermatomal mapping of perceived stimulation

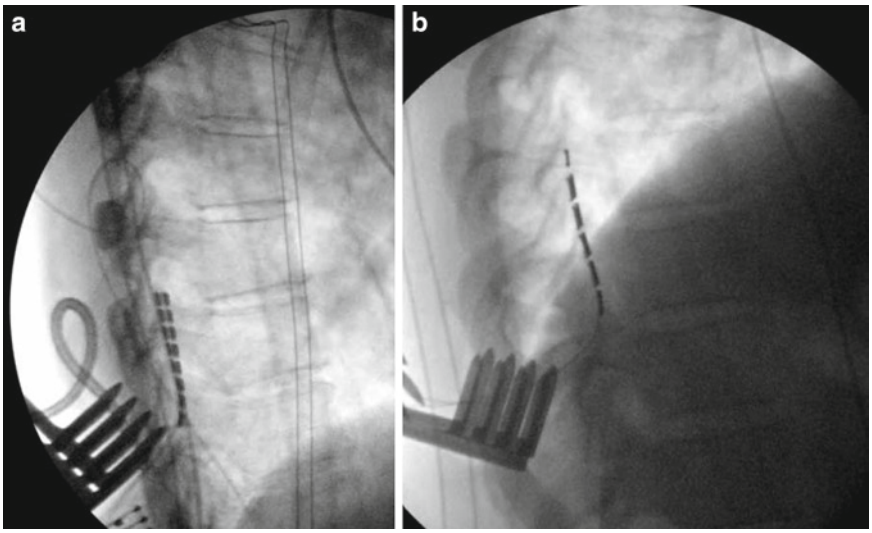

Figure 13.2. Lateral intraoperative views. (**a**) Lead placed off the midline. (**b**) Perfect alignment on the midline.

threshold after the surgery. Furthermore, the EMG activation threshold may be a reliable predictor of the patient's perceived paresthesia threshold. It has been the author's experience that EMG activation correlated with pain control at amplitudes lower than the paresthesia threshold (i.e., subthreshold stimulation), and that occasionally persistent EMG activation intra- and postoperatively may be seen lasting as long as 15 min after the stimulation is discontinued. These patients typically respond extremely well to the stimulation therapy. It seems likely that these patients are the occasional patients who use their stimulation only intermittently, often having effective long term pain relief while only using their system for a portion of each day.

Conclusions

EMG and SSEP monitoring are well accepted modalities of neurophysiologic testing in traditional spine surgery, but their application relative to implantation of neuromodulatory systems, in particular epidural paddle electrode systems is comparatively new. Given the limitations associated with other methods of implantation however, we expect that the techniques described in this chapter will continue to gain acceptance and improve outcomes by objectively localizing neurophysiologic stimulation targets.

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14

Sacral Nerve Root Stimulation for the Treatment of Pelvic and Rectal Pain

Timothy R. Deer

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Introduction

Sacral nerve root stimulation has been recognized as a treatment of pain of the pelvis, rectum, and perineum. It has been described for the treatment of intractable pain of the bladder for interstitial cystitis, and for pain after radiation to the pelvis and rectum, and for post surgical nerve entrapment. The sacral nerve targets are normally at S2, S3, and S4. This chapter focuses on the methods of obtaining lead placement and achieving an optimal outcome in this complicated patient population.

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Selection of Candidates

Pelvic and rectal pain is a complicated patient complaint that is experienced by an eclectic group of individuals. Some of these patients are excellent candidates for stimulation while other patient populations have a poor prognosis. Table 14.1 identifies the important factors to consider when selecting patients for this procedure and their predictive impact on outcome.

Technical Overview

There are four methods used to percutaneously access the sacral nerve roots, and one surgical method to stimulate the nerves.

Method 1. The retrograde technique. The retrograde approach became very popular over the past 10 years. This method involves the placement of the needle into the spine directing the bevel from a cephalad to a caudal position. The needle is placed under fluoroscopic guidance and then a lead is directed from the epidural entry zone downward until secured in the area of the S2, 3, and 4 nerve roots unilaterally or bilaterally. The leads are then secured at the fascia and ligament at the needle entry site. The approach is usually attempted with a needle entry at L2/3 or L3/4. Entry at the L5/S1 level is difficult and may lead to difficulty in passing the lead. The disadvantage of the technique is the risk of wet tap, nerve irritation with lead placement, and potential inability to pass the lead.

Method 2. The lumbar transforaminal technique: The lumbar transforaminal approach involves placing a needle in the superior aspect of the lumbar nerve foramen and then passing the lead inferiorly until the sacral targets are obtained. This approach is technically difficult, may result in dorsal root entry zone injury, and may produce and angle that is hard to create an inferior course with the lead. This method is covered in detail elsewhere in this Atlas.

Method 3. The sacral transforaminal technique: The sacral transforaminal approach involves placing the lead directly through the sacral foramen to the target nerve. This approach has been used to treat incontinence by direct nerve stimulation, and has been used to treat chronic pain. This approach is simple, but has complication risks. The approach may lead to nerve injury and is difficult to anchor once the device is in place.

Method 4. The sacral hiatus approach technique: The sacral hiatus can be entered by placing an epidural introducer needle into the caudal space and then driving the lead laterally to stimulate the sacral nerve targets. The target may be in the midline if the pain is in the rectum or in the coccyx. The advantage of this technique is the simple approach and ease of driving the lead. The disadvantage of the technique is the difficulty

Table 14.1. Important factors to consider when selecting patients.

Factor	Consideration	Predictor
Pain generator is understood	Diagnostic workup has shown an objective abnormality	Positive
History of sexual or mental abuse	Psychological evaluation and workup	Negative
Disease is stable	No progressive condition is present	Positive
Previous treatment	History suggests some relief from other treatments	Positive
Coexisting disease	History of fibromyalgia, irritable bowel, fatigue	Negative
Pain character	Pain is burning or stabbing in nature	Positive
Drug abuse	Active drug abuse behavior	Negative
Bleeding disorders	History of active coagulopathy	Negative

of anchoring the lead in the region if the body fat is not appropriate to give adequate coverage over the lead an anchor. If erosion is a risk, the permanent lead must be placed by the neurosurgical technique.

Method 5. The neurosurgical laminotomy approach: In some cases the lead cannot be placed via one of the percutaneous methods because of anatomical challenges. This approach is also used for patients who have inadequate tissue to place a permanent lead at the sacral hiatus. The approach requires the creation of a small laminotomy on the involved side or sides to place a lead over the target nerve roots.

Pocket placement: The pocket for the sacral nerve stimulation should be as close in proximity to the lead insertion site as possible. This may involve placing the pocket into the buttock or just above the beltline. The physician should consider the patients body habitus, bony landmarks, and skin condition prior to creating the pocket.

Risk Assessment

1. The retrograde approach can lead to a very steep angle and may increase the risk of a wet tap or direct nerve root insult.
2. The retrograde approach can lead to difficulty passing the lead. The most common area of difficulty is at the L5/S1 level.
3. The lumbar transforaminal approach can lead to nerve root injury, and an increase in the pain level. It is also difficult to anchor the lead, which may lead to migration.
4. The sacral transforaminal approach can lead to nerve root injury and increased pain. It is also difficult to anchor the lead, which may lead to migration.
5. The sacral hiatus approach may lead to infection based on the relative location to the rectum. This concern is more worrisome for the permanent device.
6. The sacral hiatus approach can cause nerve irritation that may lead to increased pain. In some cases, it is difficult to place the lead because of stenosis in the canal blocking the path. An epidurogram is often helpful to identify proper needle placement and the size of the canal.
7. The neurosurgical approach can lead to bleeding, and the potential for nerve damage when entering the sacrum.
8. The history of mental, physical, or sexual abuse may lead to psychological disorders that affect the long-term outcome of the device.

Risk Avoidance

1. The risk of the retrograde approach can be reduced by using a needle with a curved bevel to enter the epidural space. This risk can also be reduced by positioning the pelvis with a total elimination of the baseline lumbar lordosis.
2. Lead placement by the retrograde approach and by the lumbar transforaminal technique can be assisted by driving the lead in the midline until the lead crosses the L5/S1 junction at which time the lead may be directed to the desired side of capture.
3. The lumbar transforaminal approach can be difficult to achieve and should only be attempted in those who are an expert at the procedure of transforaminal injection. The risk can be reduced if the patient is kept conversant and alert during lead placement and lead movement.
4. The sacral transforaminal approach can be improved by placing several pillows below the pelvis to reduce the amount of lordosis. The procedure can be improved by keeping the patient alert, and by carefully adjusting the fluoroscopic beam to improve the view of the foramen.

5. When using the sacral hiatus approach, the patient should be widely prepped and draped with a potent cleanser on at least six occasions. The prep should involve the buttocks, anal region, and perineum.
6. The reduction of space in the sacral hiatus can lead to difficulty in passing the lead. The use of smaller leads and 17 gauge needles may help to overcome this issue. If the obstruction continues, the physician should consider an alternative route of lead placement.
7. The neurosurgical approach should be approached with caution and the surgeon should carefully expose the nerve roots as they enter the foramen. If there is any structural anomalies that are known prior to moving forward, the surgeon should consider placing the leads under sedation to ensure ongoing communication and warning of any paresthesia.
8. In pelvic and rectal pain patients, it is important for the patient to be given a full psychological evaluation prior to moving forward. Psychological comorbidity is not an absolute contraindication, but the treatment and counseling may improve the long-term outcome with the device.

Conclusions

Stimulation of the sacral nerve roots can lead to decreased pain, improved function, and improved quality of life. The nerves are technically difficult to access by conventional percutaneous methods. The patients should be carefully selected, the anatomy should be carefully reviewed in the sacrum and pelvis, and the patient should be educated regarding expectations and risks.

Supplemental Images

See Figures 14.1–14.5.

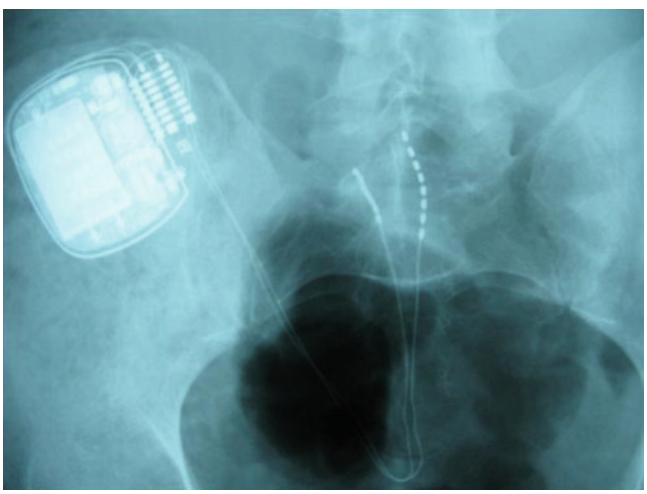

Figure 14.1. Caudal approach for the sacral nerve roots.

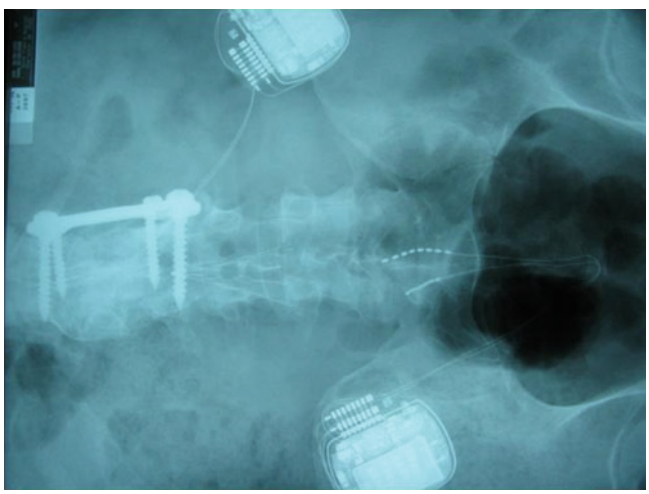

Figure 14.2. Combined thoracic and sacral stimulation for a complicated patient with a traumatic spine injury.

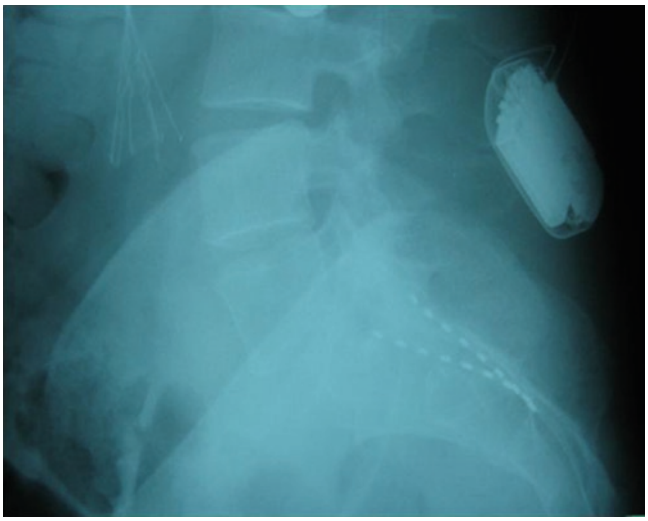

Figure 14.3. Sacral nerve root stimulation (lateral view).

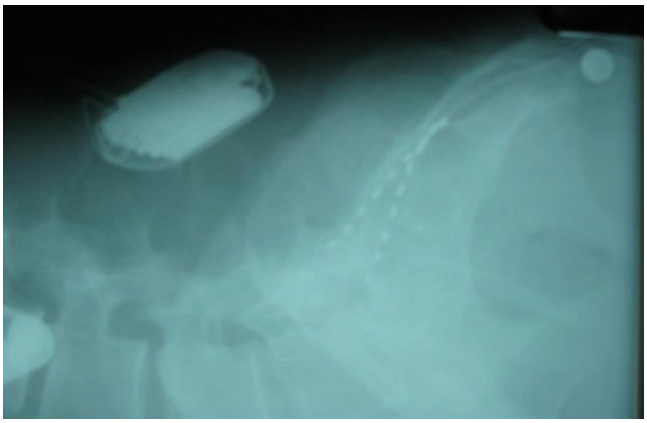

Figure 14.4. Lateral view of sacral leads in the treatment of neuropathic pain secondary to pelvic disease.

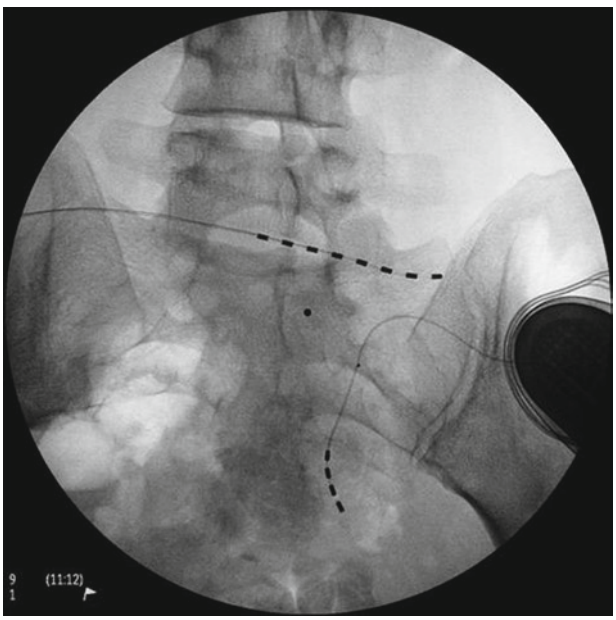

Figure 14.5. Combined sacral nerve root and peripheral nerve stimulation.

Suggested Reading

1. Feler C, Whitworth L, Brookoff D, et al. Recent advances: sacral nerve root stimulation using a retrograde method of lead insertion for the treatment of pelvic pain due to interstitial cystitis. *Neuromodulation*. 1999;2(3):211–216.
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15

EMG/SSEP Monitoring During Sacral Neuromodulation

Erich O. Richter, Marina V. Abramova, and Kenneth M. Alò

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Introduction

Sacral root neuromodulation has been employed for the treatment of idiopathic overactive bladder, urgency-frequency syndromes, interstitial cystitis, pudendal neuralgia, vulvodynia, coccygodynia, and a variety of chronic pelvic pain (CPP) syndromes.[1–12] A direct, single root stimulation device received FDA approval for the treatment of urinary urgency and frequency, urinary incontinence in 1997, and urinary retention in 1999,[6] but many centers have had more success with retrograde longitudinal placement within the spinal canal. The ventral rami of S2–S4 provide innervation of the pelvis. The S3 sacral level contributes to the innervation of the anterior perineal muscles,[13] making it the most frequent target in treatment of pelvic dysfunction, and a typical target for the single root

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percutaneous device. These portions of the nervous system have traditionally been very difficult to target with traditional methods over the dorsal columns in the spinal cord. The conus medullaris is a highly mobile structure, which is nearly enveloped in the nerve roots of the cauda equina. Accordingly, placement of epidural stimulating electrodes over the conus has traditionally been plagued by extreme variability in the effects of stimulation, not only from patient to patient, but also in the same patient over time. At the conus level, the dorsal cerebrospinal fluid layer is relatively thick and serves as an insulator for the spinal cord; the conus is very mobile which increases the risk of lead migration, and finally, due to the presence of large afferent fibers, the sacral stimulation may produce undesired paresthesia in additional regions.[13]

Intraoperative neurophysiological monitoring with somatosensory-evoked potential (SSEP) and electromyographic (EMG) monitoring are widely used in traditional spinal neurosurgery.[14–22] In this chapter, we focus on the use of neuromonitoring techniques for placement of sacral root stimulation electrodes. These techniques of implantation are specific to the anatomy of sacral root stimulator implantation within the epidural space of the spinal canal, and are not specific to the clinical indication for the electrode placement although the targeting of individual electrodes will have characteristic patterns for each disorder. The radiology of the sacral region is often difficult to reliably interpret, and the depth of muscle dissection to approach the lumbosacral junction makes direct surgical approaches under strict local anesthetics impractical at most centers. Accordingly, techniques to reliably identify the stimulation of individual sacral nerve roots by neurophysiologic methods in a patient under general anesthetic are particularly helpful.

Technical Overview

Technique for Sacral Placement

Stimulation of multiple specific nerve roots of the cauda equine is best accomplished through an intraspinal, epidural, "retrograde" technique. The details of retrograde access have been addressed in other publications.[1–12] In this chapter, we focus on the use of intraoperative monitoring techniques to verify effective placement.[23] Most centers place temporary trial electrodes with the patient awake under local anesthetic, and accordingly, these techniques are seldom used for trial implantations. For open placement of permanent electrodes, the patient is positioned prone, on some form of soft support that allows the abdomen to remain free of compression to minimize epidural bleeding. We use gel chest rolls, but some centers use the Wilson frame or similar equipment. It is critical that whatever equipment is used not obstruct the ability to obtain high-quality fluoroscopic visualization from all angles. In the direct open approach, the lumbosacral junction is identified on lateral imaging, and a midline incision is used to create a subperiosteal dissection to expose the superior edge of the S1 lamina, and the L5–S1 interspace. The ligamentum flavum is released from the S1 lamina, and frequently a small laminotomy is created to define these planes and expose the dura. A small, blunt, angled dissector is used to free the initial portion of the epidural space, and then a single column electrode is passed into the epidural space, and turned laterally toward the foramen of interest distally, usually the S2 or S3 foramen. The marked angle of the sacral canal back toward the surgeon can make this placement difficult, and a curved instrument such as a Penfield #3 is often indispensable in helping the electrode transition into an appropriate trajectory (Figure 15.1). The Penfield is placed into the epidural space, and the single column paddle is passed over it and directed by it into the epidural space.

For pelvic pain, the electrode is typically rotated off the midline toward the S2 foramen. For coccygodynia, generally remains midline, but stops at the S3 level (more caudal placements frequently produce painful stimulation). Other disorders may require

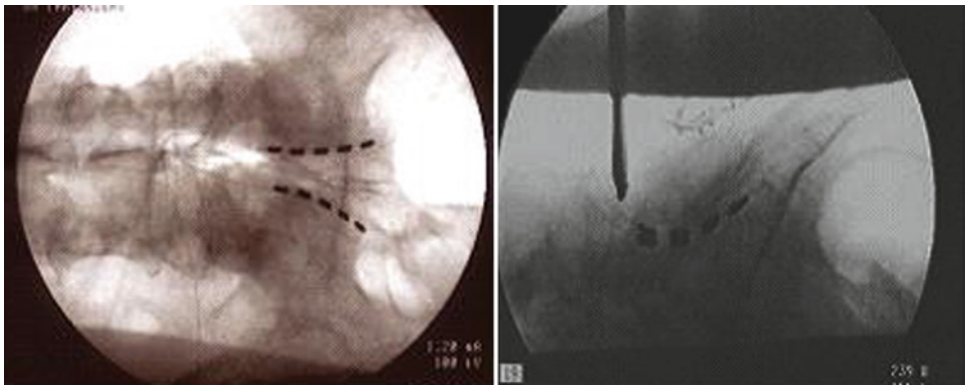

Figure 15.1. (**a**) Bilateral pelvic stimulation with 3.8 mm quadripolar, selective, cephalocaudal paddles (S1 laminotomy). Distal contacts are anodes at each S2 foramen, and proximal 3 contacts are each cathodes. (**b**) Lateral radiograph. Penfield 3 elevating tool assisting with placement of 3.8 mm paddles toward the S2 foramen.

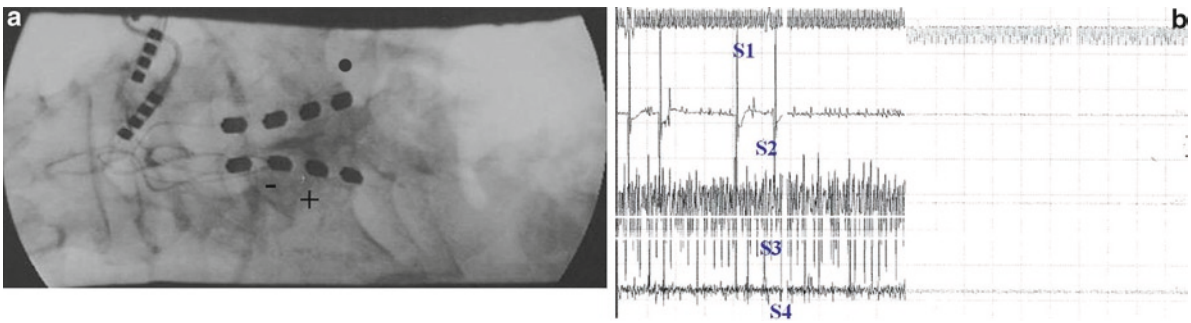

Figure 15.2. Permanent retrograde implantation of sacral root paddle leads. (**a**) Stimulation is left sided, with the cathode at the second position and the anode at the third. (**b**) In this older tracing, the stimulation in the second left contact produces primarily adductor hallucis activation, solely on the left side. This correlated with the postoperative paresthesia felt in the S3 perineal region.

Table 15.1. Correlation between EMG activation of specific muscles with postoperative induced paresthesia – sacral paddle(s) S2–3 (laminectomy S1).

EMG activation, muscle group	Induced paresthesia
Gastrocnemius	S1 (undesired)
Adductor hallucis	S2–3
Perianal	S4

other targeting. When the electrodes appear appropriately positioned on AP and lateral fluoroscopy, attention is turned to the physiologic assessment of electrode position. When the nerve roots are stimulated, SSEP or motor unit action potentials (MUAPs) via EMG serve as the main monitoring tool used to verify accurate position of the electrodes over the roots of interest. The dermatomal distribution of postoperative paresthesia can be predicted from the pattern of intraoperative stimulation activation, and is clearly associated with the specific pattern of responses coming from the muscles of the lower extremities. For example, the placement of an S2–3 paddle may result in EMG activation in adductor hallucis muscle (Figure 15.2), which will correlate with an S2–3 paresthesia. The typical correlation pattern between muscles in the lower extremity and induced postoperative paresthesia is represented in Table 15.1.

Conclusions

With the accumulation of knowledge and experience on intraoperative neuromonitoring with SSEP and EMG techniques, new applications such as intraoperative verification of neuromodulatory electrode placement under general anesthesia have emerged. In this chapter, we have reviewed the use of such techniques to determine effective stimulation of individual sacral roots when placing electrodes in the intraspinal, epidural space from a retrograde or open approach. As an objective method, SSEP/EMG monitoring is an attractive alternative to awake methods in open cases due to the significant muscle mass at the lumbosacral junction which makes such awake cases quite uncomfortable and relatively impractical. With the increasing prominence of sacral root neuromodulation as an important treatment modality across a number of prevalent conditions, we expect that these techniques will become more widespread over coming years.

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16

Selective Nerve Root Stimulation: Facilitating the Cephalocaudal "Retrograde" Method of Electrode Insertion

Kenneth M. Alò

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Conclusions 113

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Introduction

Selective nerve root stimulation (SNRS) as a method was first presented in 1998[1–3] and was published in 1999.[4,5] Despite advances at that time in dual electrode technology and patient controlled programming, "anterograde" spinal cord stimulators (SCSs) were unable to consistently produce and maintain paresthesia in the neck, pelvic, and foot dermatomes.[6,7] As well, some individual lower extremity dermatomes lacked SCS paresthesia coverage. Thus, selective, cephalocaudal, "retrograde" electrode placement was developed to improve capture in these targets.[4] Safety concerns limited cervical in vivo application;[3,5] however, lumbosacral placement gained interest in the evaluation of many difficult-to-treat conditions.[8–17] Despite initial enthusiasm and success, many encountered technical difficulty entering the lumbar intralaminar space from the superior to inferior or cephalocaudal, "retrograde" direction.[17,18] Subsequently, this author began teaching a needle entry technique utilizing a lateral intralaminar approach (Figures 1–10). This mimics the "single shot epidural" needle placement applied commonly by interventional practitioners. This facilitates entry of the stimulation electrode into the epidural midline, and standardizes entry of the needle below the conus at L2/3.

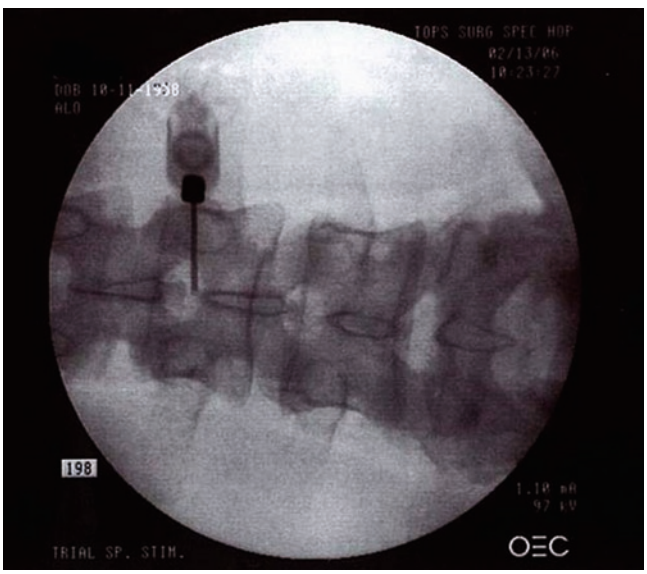

Figure 16.1. S2/3 Retrograde: L2/3 epidural "lateral" approach (AP view).

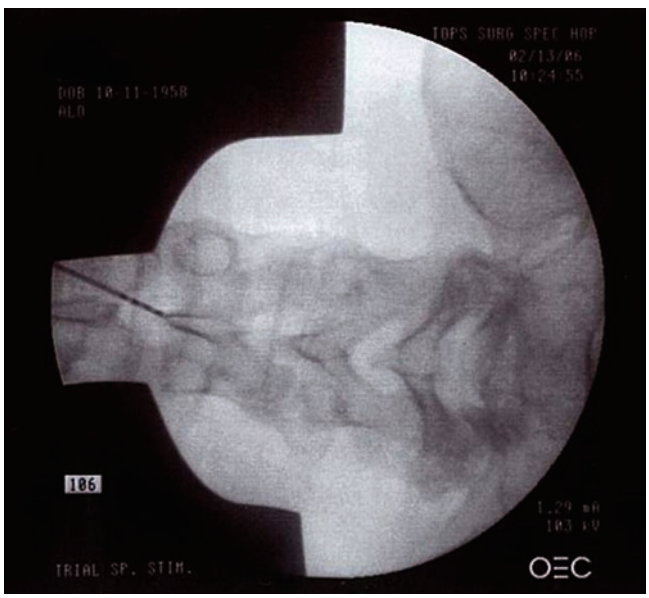

Figure 16.2. S2/3 Retrograde: L2/3 needle tip in steep caudal view to limit hand exposure.

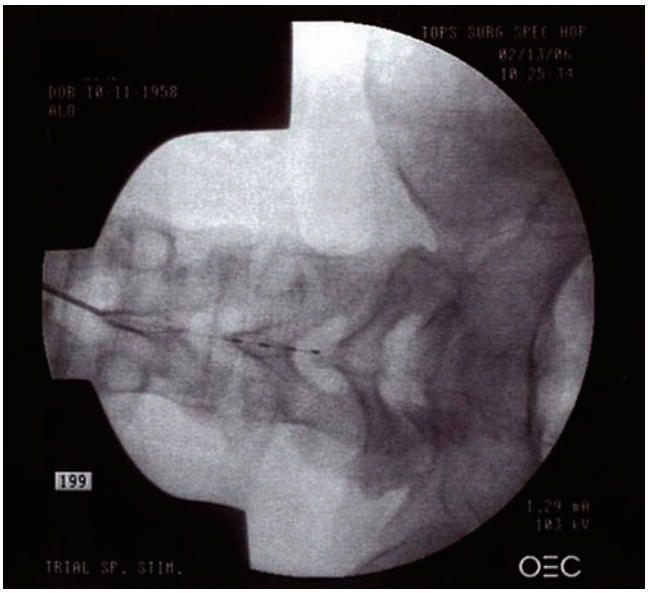

Figure 16.3. S2/3 Retrograde: electrode directed caudally in the midline.

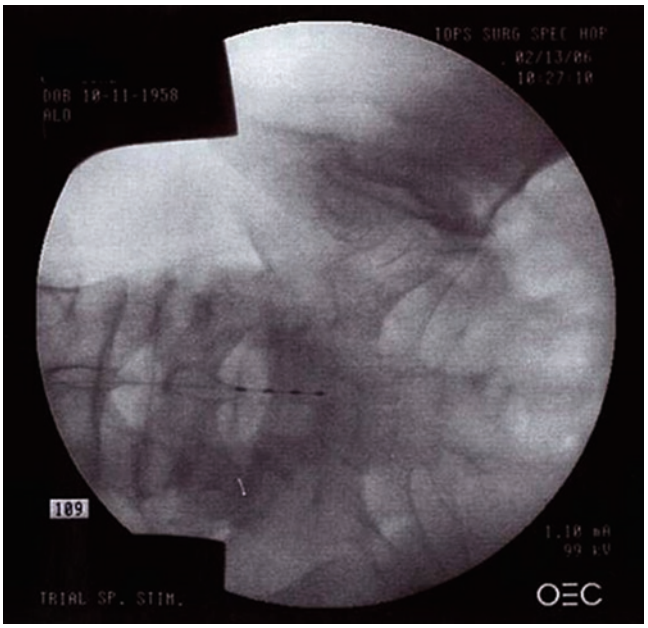

Figure 16.4. S2/3 Retrograde: electrode crossing S1 level in midline.

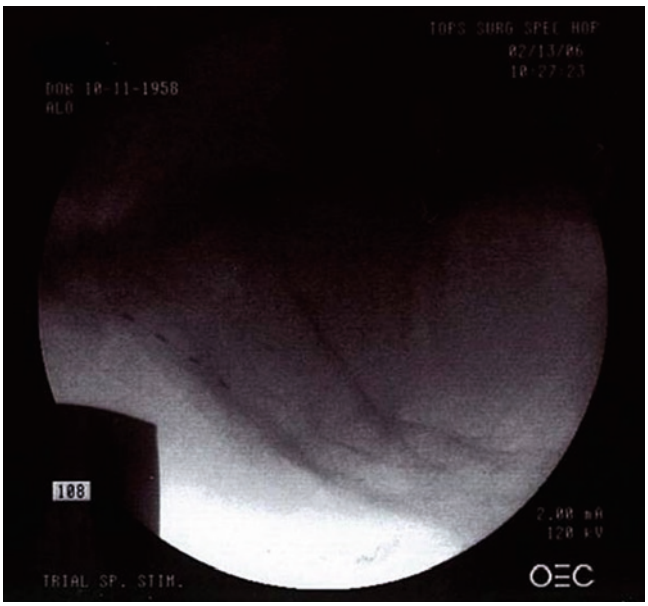

Figure 16.5. S2/3 Retrograde: S1 level electrode posterior on lateral view.

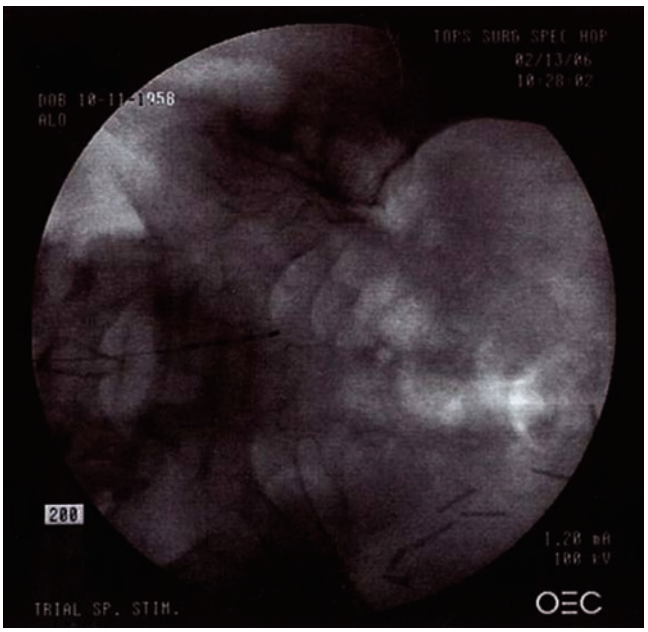

Figure 16.6. S2/3 Retrograde: electrode rotated to right S2/3 foramen: stimulating right S2-3-4 roots.

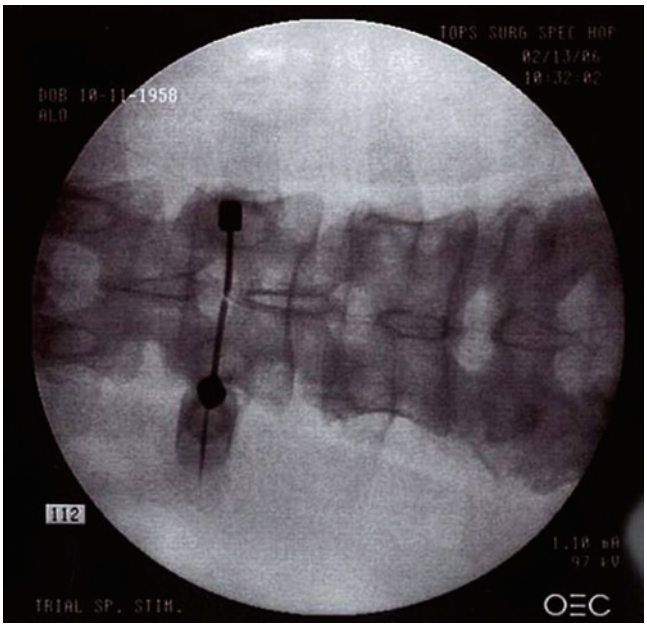

Figure 16.7. S2/3 Retrograde: dual L2/3 epidural "lateral" approach (AP view).

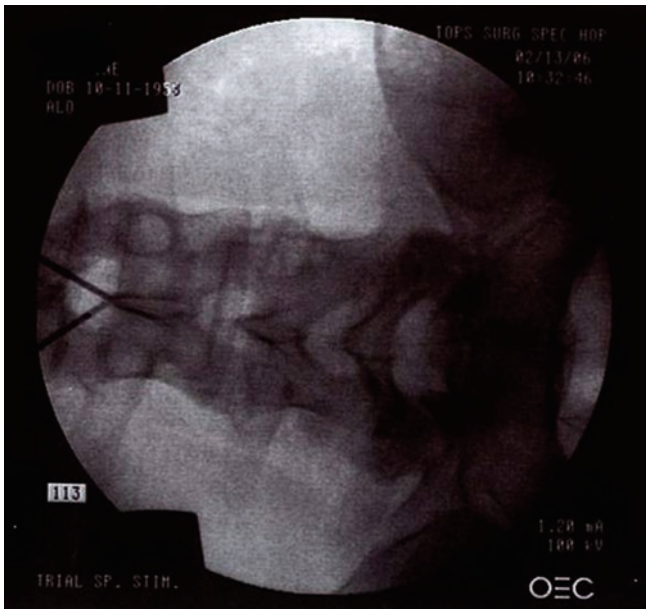

Figure 16.8. S2/3 Retrograde: dual L2/3 needle tips in steep caudal view to limit hand exposure.

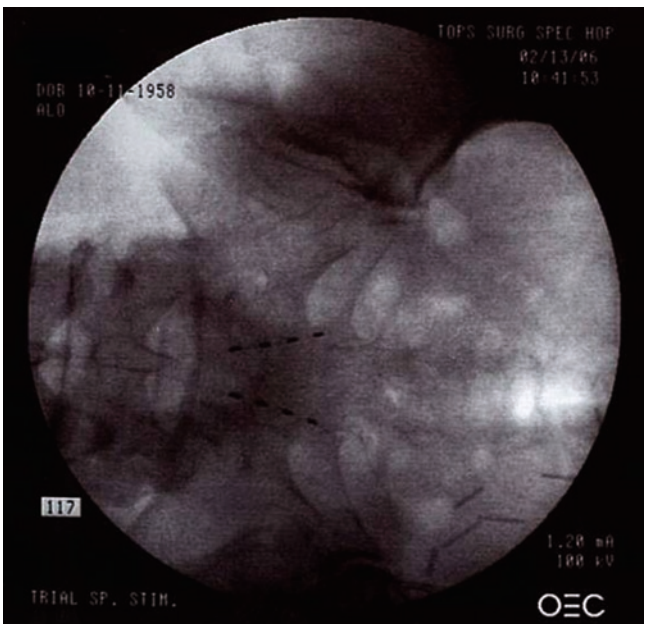

Figure 16.9. S2/3 Retrograde: dual electrodes at final S2/3 foramen stimulating S2-3-4 roots.

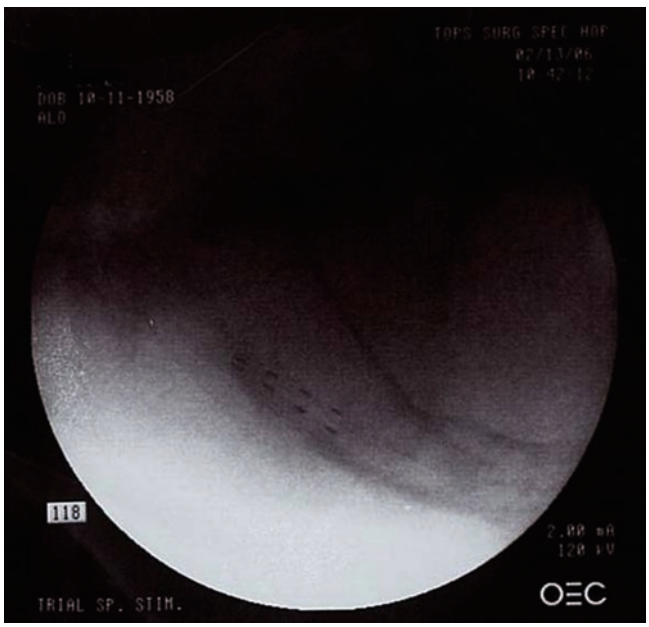

Figure 16.10. S2/3 Retrograde: dual electrodes at S2/3 stimulating S2-3-4 roots (lateral view).

Technical Overview

Cephalocaudal Lumbosacral Electrode Placement: Foot and Pelvic Root Placement

To stimulate the foot, a quadrapolar electrode enters the midline at L2/3 crossing over the L3/4 disc space before it is then rotated to, but not through the L4 foramen (Figures 16.11 and 16.15). This positioning allows the electrode to remain "in line" with the ipsilateral L4, 5, and S1 roots. It is then programmed at the foramen with an anode, and up to three proximal contacts as cathodes. This allows depolarization of all three roots as they course cephalad lateral to medial. A second electrode can be applied if needed depending on the stimulation pattern obtained (Figure 16.11). Given the reduced cerebrospinal fluid and proximity to the root, most patients feel initial paresthesia at low thresholds (1.0–1.5 V), with maximal tolerable intensity approximately 1.5× that level (1.5–2.5 V).

To stimulate the pelvic roots, a quadrapolar electrode enters the midline at L2/3 and remains there until it crosses S1 before it is rotated to, but not through the ipsilateral S2 foramen. A second electrode is positioned in the same fashion contralaterally for bilateral pathology (Figures 16.1–16.10). These electrodes are also programmed with a distal anode at the foramen, and up to three cathodes over the proximal S2-3-4 roots, respectively. This allows an anatomical placement for stimulating all of the following conditions: urge incontinence, urgency-frequency syndromes (including detrusor dysfunction), pudendal neuralgia, vulvadynia, and interstitial cystitis. This may be done as well with small paddle style electrodes through a small S1 laminotomy (Figure 16.12). To ease placement of the paddle toward the S2 foramen, a Penfield 3 can be used at the laminotomy to elevate the

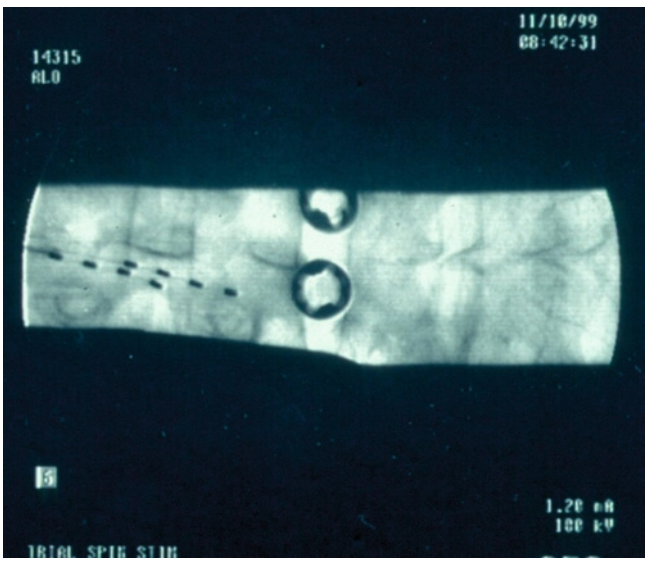

Figure 16.11. Unilateral left leg/foot stimulation with two quadrapolar, selective, cephalocaudal electrodes. Distal electrode terminates at the L4 foramen stimulating the L4-5-S1 roots with an anode at the foramen, and three proximal cathodes. The proximal electrode stimulates the L3 and 4 roots programmed the same way. As pulse width is increased, geographic paresthesia coverage is increased in the left L3-4-5-S1 dermatomes.

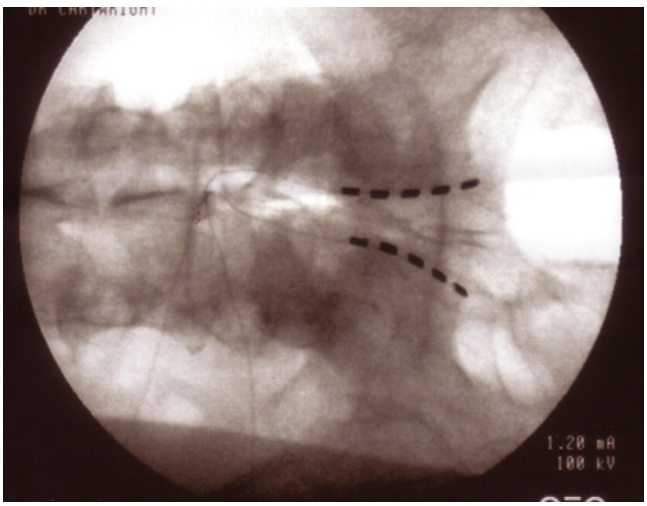

Figure 16.12. Bilateral pelvic stimulation with 3.8 mm quadrapolar, selective, cephalocaudal paddles (S1 laminotomy). Distal contacts are anodes at each S2 foramen, and proximal 3 contacts are each cathodes.

electrode into position (Figure 16.13). Given the relative lack of cerebrospinal fluid at the S2 level, most patients feel initial paresthesia at low thresholds (0.7–1.2 V) with maximal tolerable intensity approximately 1.5× that level (1.2–1.7 V).

When programming both foot and pelvic electrode placements, varying pulse width is perceived as increasing or decreasing regional paresthesia coverage, and varying frequency as altering character and intensity of paresthesia. The clinical parameter effects and thresholds of these electrodes are physiologically those of intraspinal, epidural, peripheral nerve stimulators.

Cephalocaudal Lumbosacral Electrode Placement: Coccygeal Root Placement

To stimulate the coccyx, a quadrapolar electrode enters the midline at L2/3 and remains there until the tip rests at S3 (Figure 16.14). If the tip of the electrode is advanced to close to the sacral hiatus, painful stimulation may be seen, in particular if scarring from a previous coccygectomy is encountered. Programming follows the same distal anode, proximal cathode configuration to achieve paresthesia into the distal S4 and S5 dermatomes. Wide pulse widths assist in recruiting both the left and the right S4 and S5 roots, which are close to the midline at this level (with single or dual quadrapolar electrodes).

Cephalocaudal Lumbosacral Electrode Placement: Individual Lower Extremity Root Placement

To stimulate the individual lower extremity roots, a quadapolar electrode enters the midline at L2/3 and is rotated to but not through the foramen at the root level(s) of interest

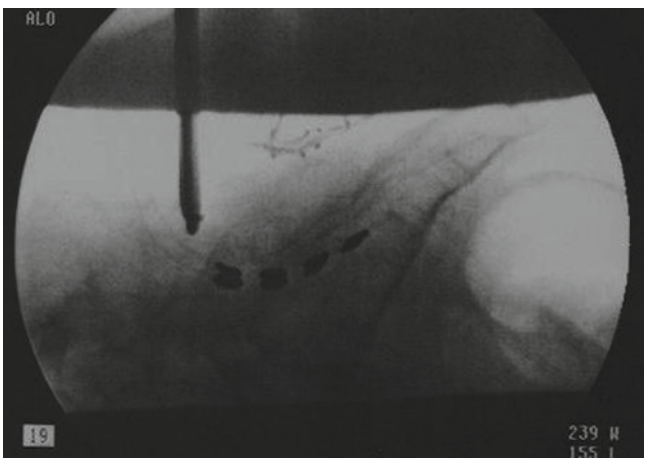

Figure 16.13. Lateral radiograph of Figure 12. Penfield 3 elevating tool assisting with placement of 3.8 mm paddles toward the S2 foramen.

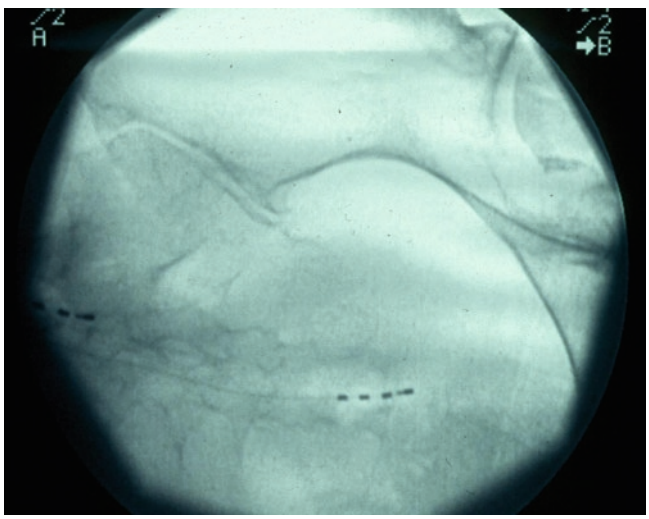

Figure 16.14. Midline quadrapolar, selective, cephalocaudal electrode for coccygodynia. Programming a distal anode, and up to three proximal cathodes with a wide pulse width (>200) provided paresthesia capture of the bilateral S4 and S5 roots.

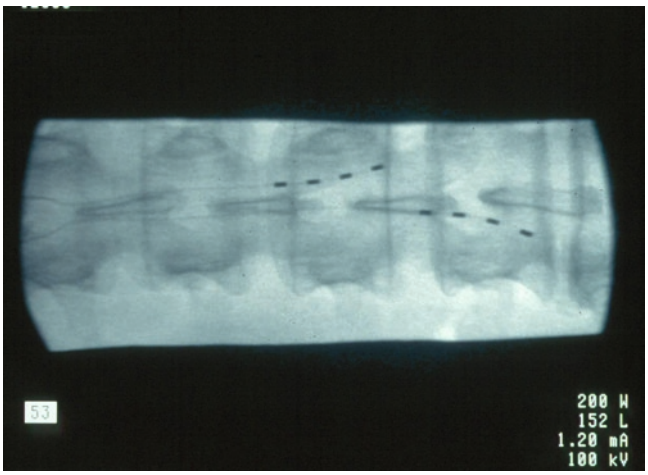

Figure 16.15. Individual quadrapolar, selective, cephalocaudal root electrodes for lower extremity radicular pain. Right electrode at the foramen of L3 (capturing the L3-4-5 roots), and left at the foramen of L4 (capturing the L4-5-S1 roots). Both programmed with a distal anode at the foramen, and up to three cathodes proximally.

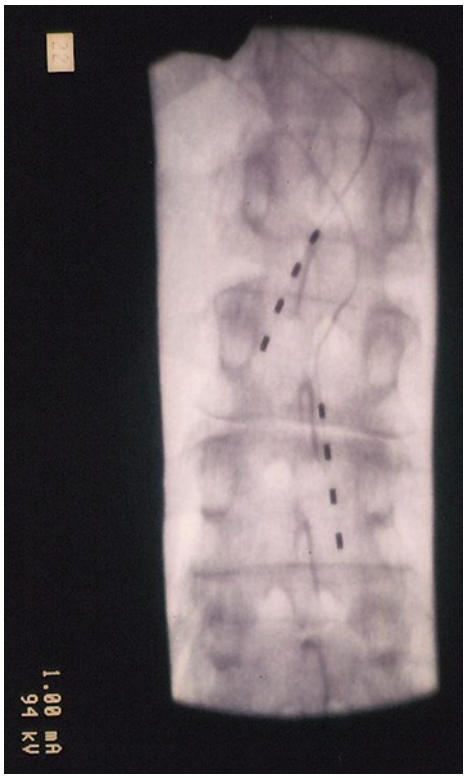

Figure 16.16. Individual quadrapolar, selective, cephalocaudal root electrodes for lower extremity radicular pain. Right electrode just medial to the foramen of L3 (capturing L3-4-5-S1), and left at the foramen of L2 (capturing L2 and L3 roots). Both programmed with a distal anode at the foramen, and up to three proximal cathodes.

(Figures 16.15 and 16.16). Programming and activation thresholds are much like those for foot placement, with the possibility of slightly increased activation and maximal intensity thresholds, due to the relative increase of cerebrospinal fluid above L5. When programming individual lower extremity root electrodes (just as coccygeal, pelvic, and foot), varying pulse width is perceived as increasing or decreasing regional paresthesia coverage, and varying frequency as altering character and intensity of paresthesia.

Contraindications

Relative contraindications to perform cephalocaudal electrode insertion include previous spinal epidural operation, spondylolisthesis, spina bifida, and epidural lipomatosis. Absolute contraindications include lack of informed consent, coagulopathy, lack of adequate training, and infection. Experienced interventionalists, noting that in vivo cephalocaudal cervicothoracic placements have not been routinely performed to date, should carefully consider needle or electrode placements above L2/3.

Conclusions

The cephalocaudal, "retrograde" method of electrode insertion remains an important technique for the interventional neuromodulation specialist. With prudent application of the modified placement and programming approach described, this strategy can facilitate SNRS of many conditions involving the L2-S5 anatomy.

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III

Neurostimulation: Stimulation of the Cranium and Head

17

Stimulation of the Deep Brain for the Treatment of Chronic Pain

Timothy R. Deer and Robert M. Levy

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Introduction

Deep brain stimulation is a therapy that has been used for more than half a century to treat chronic pain. The first use of these treatments occurred in the 1950s when neurosurgeons stimulated the septal region nuclei in patients with psychiatric diseases who also suffered from chronic pain. Over the next twenty years, the therapy evolved to include the sensory thalamic nuclei to treat pain of neuropathic origin. Other targets have included the periaqueductal gray and periventricular gray, and several new targets are under current investigation. Outcomes for both facial and extremity pain have been positive and the use of

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this modality in the neuromodulation algorithm is increasingly helpful to those who have severe pain.

The use of deep brain stimulation is based on a thorough knowledge of the brain targets involved in the pain process. In order to understand the technical aspects of the procedure, the implanter must adhere to the theory of target-based implantation focusing on the pain pattern and the neuroanatomy. Many patients have mixed pain syndromes of neuropathic and nociceptive character, such as failed back surgery syndrome or spinal stenosis. In most cases, the candidates for deep brain stimulation have pain that is primarily neuropathic in nature.

Technical Overview

Deep brain electrodes are implanted to the target using frame-based stereotactic guidance. A frame is applied prior to sending the patient for a high-resolution stereotactic MRI (Figure 17.1). The patient is taken to the operating theater and local anesthesia and mild intravenous sedation is given. A parasagittal frontal burr hole is created to assist in delivering the lead to the target. Once exposure is achieved, physiological stimulation is achieved to identify the target that has been suggested by the stereotactic MRI. It is a key point to remember that the stereotactic coordinates represent the starting point for target identification, but that the end target is identified in the operating room.

Electrophysiological activity can be used to identify exact targets. This is done by microelectrode recording, microelectrode stimulation, and macro stimulation. Once the implanter is satisfied with the target, the permanent lead is deployed (Figure 17.2). The permanent lead is then externalized with a connector through a stab wound in the scalp to allow a temporary stimulation period.

In the postoperative period, the brain is assessed with postoperative CT scans to confirm electrode placement and to rule out any evidence of intracerebral bleeding. In some cases, edema is found around the lead and may impact the ability to stimulate the first few days after implant. Once the edema has resolved, the lead is used for a trial of stimulation usually lasting 5–10 days using different computer programs. If appropriate and acceptable pain relief is achieved, the patient is taken back to the operating room

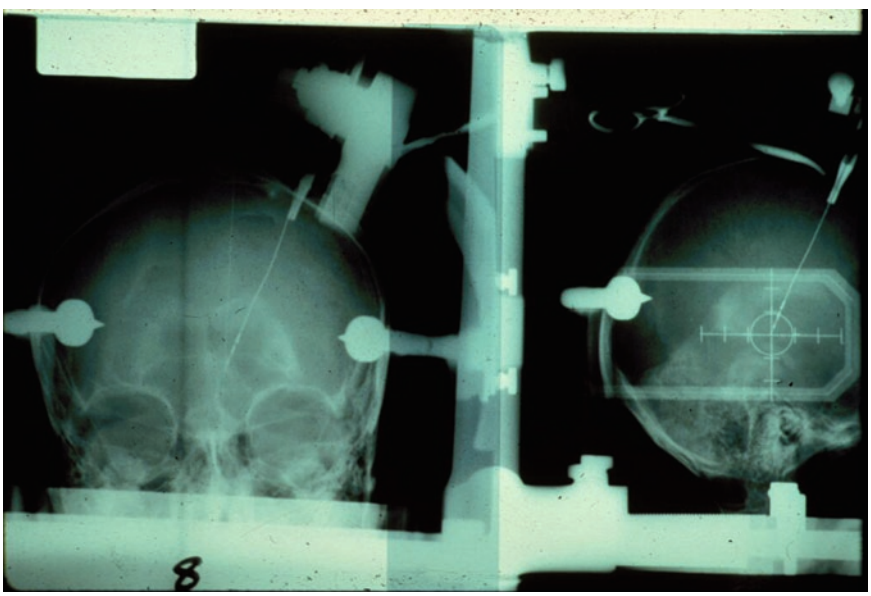

Figure 17.1. Stereotactic guidance for deep brain lead placement.

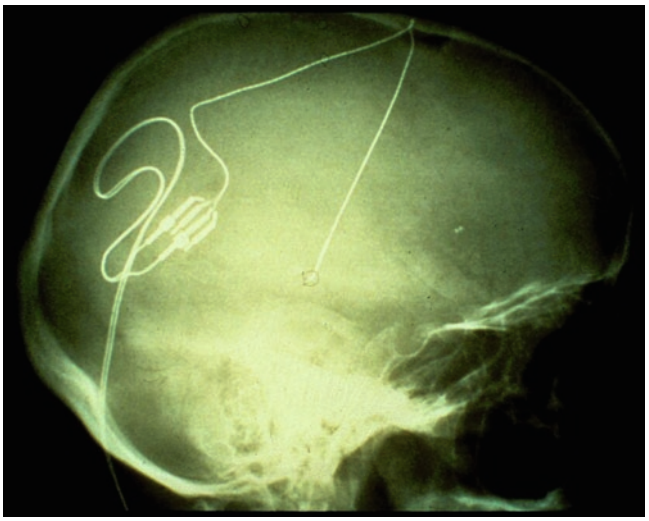

Figure 17.2. Final lead placement for deep brain pain target.

and the temporary connector is removed and a permanent connection wire is used to connect to the lead. A subcutaneous pocket is prepared for the internal generator and the wiring is passed by a tunneling tool through the subcutaneous tissue to connect the system. If the system fails to provide relief, the lead is explanted and the patient is not a candidate for a permanent device.

Risk Assessment

1. Mortality from deep brain stimulation is a rare complication that occurs in less than 1.7% of patients. Neurological compromise occurs in less than 2% of patients on a permanent basis.
2. The most common and devastating risk of deep brain stimulation is intracranial hemorrhage. This problem occurs in 2–4% of patients receiving deep brain stimulation and can occur at the time of implant or at the time of removal.
3. Infection rates vary among institutions and have been reported between 3 and 13%. Infectious complications include meningitis, encephalitis, skin infection, sepsis, and death.
4. Less serious but troubling complications include diplopia, nausea, vertical gaze palsies, nystagmus, oscillopsia, and blurred vision.

Risk Avoidance

1. Preoperative screening for deep brain stimulation should be similar to other neurosurgical techniques including preadmission testing, a focus on comorbidities, and an evaluation of current medications. Preoperative anesthesia consultation is a necessity to improve overall outcomes.
2. Prior to surgery the physician should review the patient's medications and assure that all medical conditions are under adequate control prior to moving forward. Drugs that effect bleeding should be discussed with the proper medical specialist and discontinued when safe and advisable.
3. Preoperative and intraoperative antibiotics are recommended. It is advisable to vigorously irrigate the wound prior to closure. Most infections with deep brain implants resolve with proper antibiotics, wound debridement, and removal of all hardware.

4. It is critical to have the patient keep a good diary of the pain level and patterns prior to the implant and during the course of the trial. The patient should experience significant relief of the pain and be educated about the system prior to the permanent generator placement.
5. When tunneling the permanent system, the clinician must be careful to avoid blood vessels along the path of the procedure. The carotid and jugular vessels are of particular concern.
6. The position of the generator pocket should be carefully planned to allow patient comfort and to avoid tissue irritation skin erosion. Most of these devices are placed in the subclavicular tissue.

Conclusions

Deep brain stimulation is an area of neuromodulation that is evolving and being defined in studies regarding proper patient selection. The use of deep brain stimulation offers hope to those who have failed other pain treatment modalities for severe neuropathic pain. When possible the use of deep brain stimulation should be used as a last resort when spinal cord stimulation and peripheral nerve stimulation is not a reasonable option.

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18 Stimulation of the Motor Cortex to Treat Chronic Pain

Timothy R. Deer and Robert M. Levy

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Introduction

Motor cortex stimulation (MCS) is a technique that allows physicians to offer treatment to many individuals who would otherwise have no treatment options. The increasing use of this modality is a reflection on the safety, perceived good outcome, and surprisingly long history of human use. This surgical technique has shown good potential in patients suffering from many severe pain conditions including trigeminal neuralgia, poststroke central pain syndromes, phantom limb pain, facial pain, pain from injury to the spinal cord, and postherpetic neuralgia.

Intracranial stimulation, which includes deep brain and MCS targets, is not a new option for patients. These techniques were first used experimentally in the deep brain in 1954 and were actually described prior to the much more accepted method of spinal cord stimulation. While many consider MCS a new or novel treatment option clinically, the procedure was first reported in 1991 by Tsubowkawa. His work and that of other pioneers

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showed that stimulation of the sensory cortex gave equivocal results, and was not as helpful as direct stimulation to the motor cortex. Modern outcome studies have shown success with this treatment option in more than 60% of those suffering from poststroke pain, and greater than 75% in those with trigeminal neuralgia.

Current studies are ongoing to evaluate the use of MCS for other diseases of the neurological system such as traumatic brain disorders, obsessive compulsive disorder, depression, and dystonia.

Technical Overview

Once the patient has been determined to be an acceptable candidate for the procedure, a functional MRI (fMRI) is performed to successfully locate the site in which the motor cortex should be activated to treat the specific pain pattern. In some settings, the implanter may prefer to use a conventional MRI to provide anatomic information without adding the functional component. The patient is taken to the operating room once these steps have been satisfactorily completed. At this time, careful attention is given to prepping, draping, and preparing the patient (Figures 18.1 and 18.2). Different surgical approaches are possible, but most commonly a small craniotomy is performed for electrode placement. The location of the circular craniotomy is determined by image-guided neuronavigation to make the electrode placement as precise as possible (Figure 18.3). Once the target is marked, a 10-cm linear incision is made, the tissue is separated and then a 5-cm diameter craniotomy is performed, which is used for the implant (Figures 18.4–18.9). Once the tissue is exposed, the physician performs a different type of mapping, electrophysiologic monitoring and stimulation is used to identify the central sulcus based on electrical activity on the brain surface. This anatomic mapping is performed by monitoring the brain waveforms in the region. The central sulcus is identified by an inflection of the waveform from negative to positive, which is called the N20/P20 waveform phase reversal. The complexity and exactness of the procedure is further enhanced by using somatosensory-evoked potentials and EMG to match the motor cortex area with the pain pattern.

When the clinician is happy with the mapping, electrode strips are then placed into the epidural space. Options for placement include horizontal over the precentral gyrus, and longitudinal over the entire central sulcus. Lead selection varies between two four contact leads, but the possibility of using leads with more contacts, or specially designed

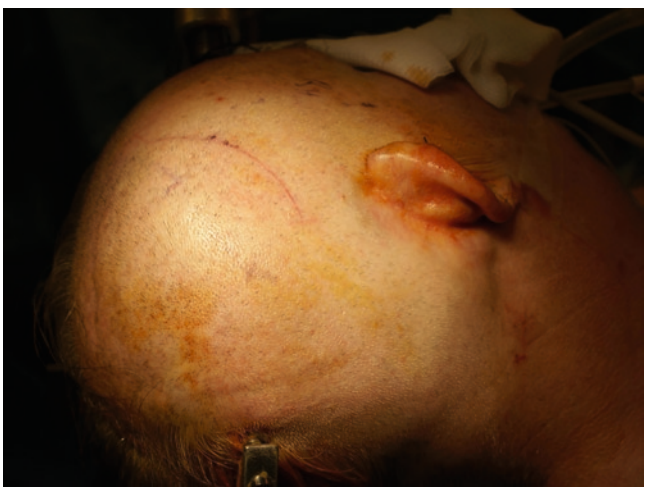

Figure 18.1. Positioning the patient.

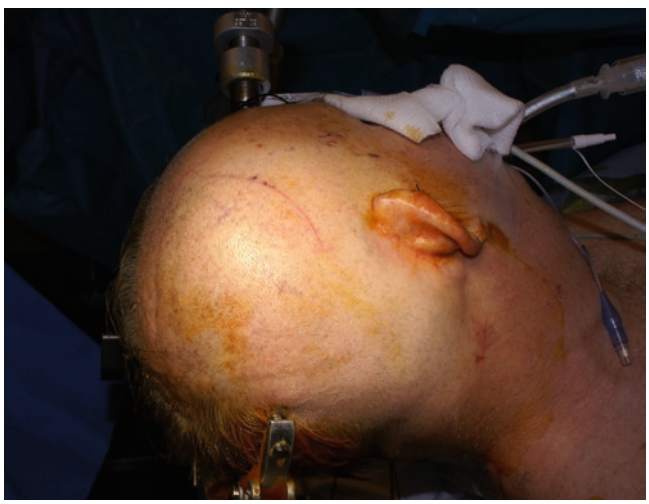

Figure 18.2. Prepping and preparing the patient.

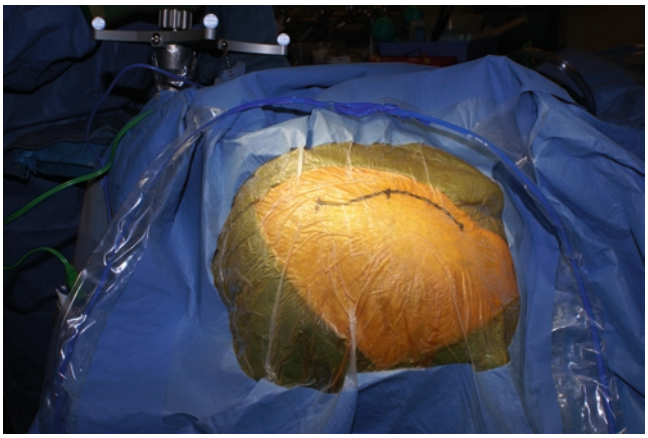

Figure 18.3. Draping and planning the incision for craniotomy approach.

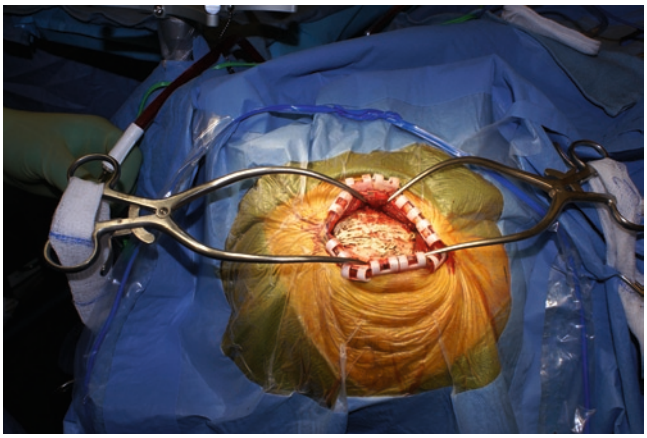

Figure 18.4. Incision for exposure for craniotomy.

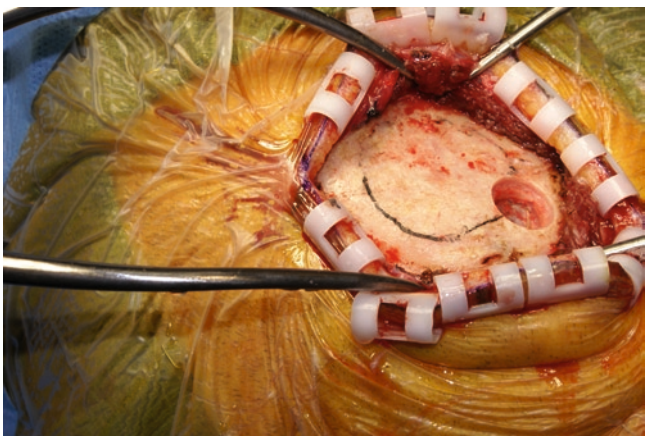

Figure 18.5. Skull exposure with initiation of craniotomy.

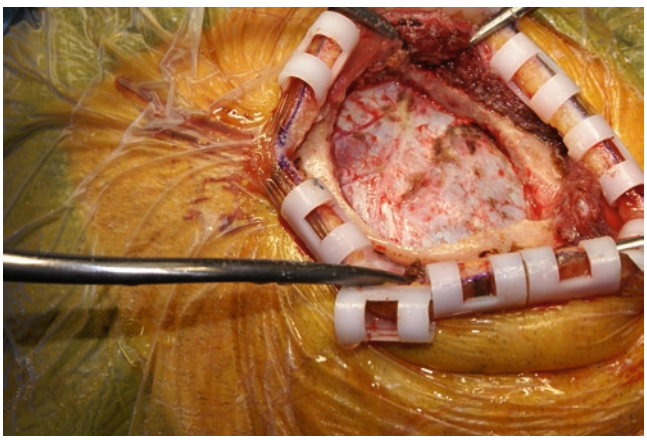

Figure 18.6. Craniotomy with proper exposure over the central sulcus based on preoperative mapping.

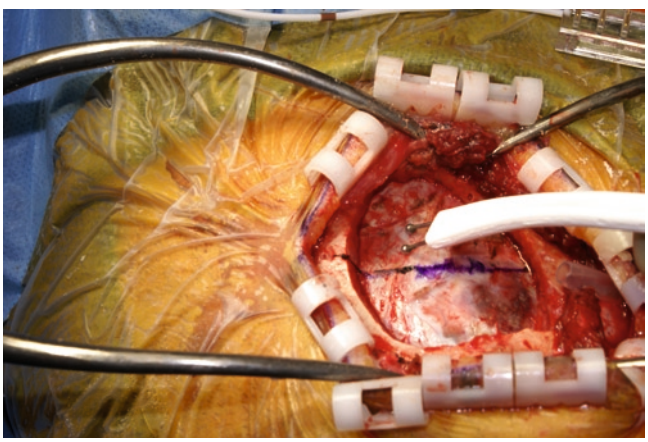

Figure 18.7. Electrophysiological mapping for lead placement.

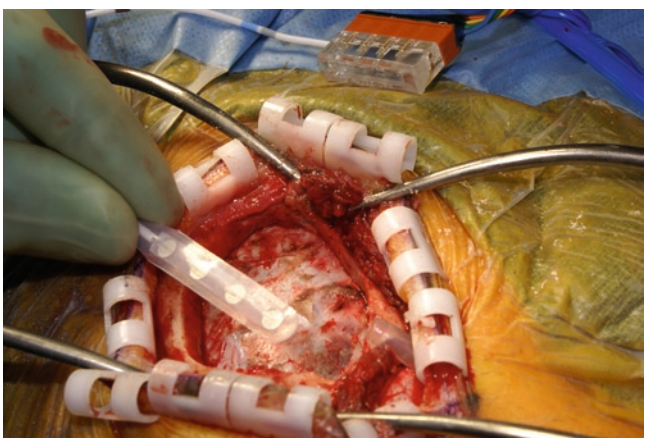

Figure 18.8. Epidural exposure lead placement.

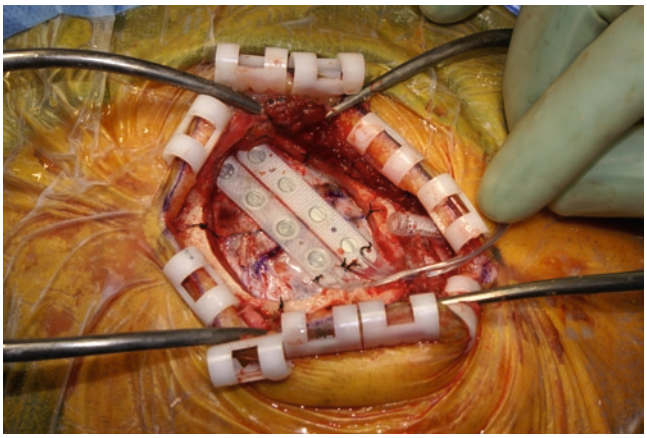

Figure 18.9. Leads in proper position for MCS.

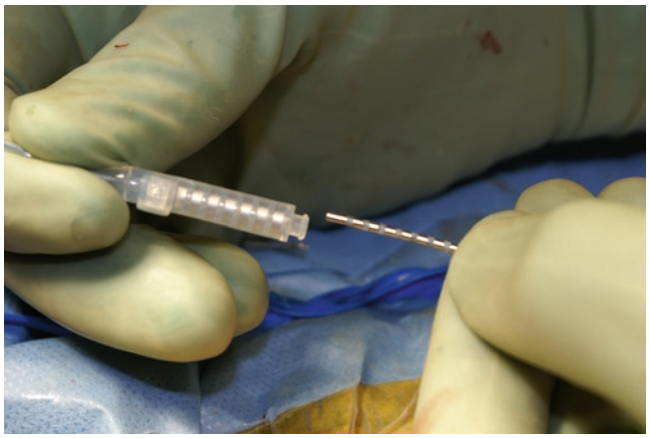

Figure 18.10. Securing the connections.

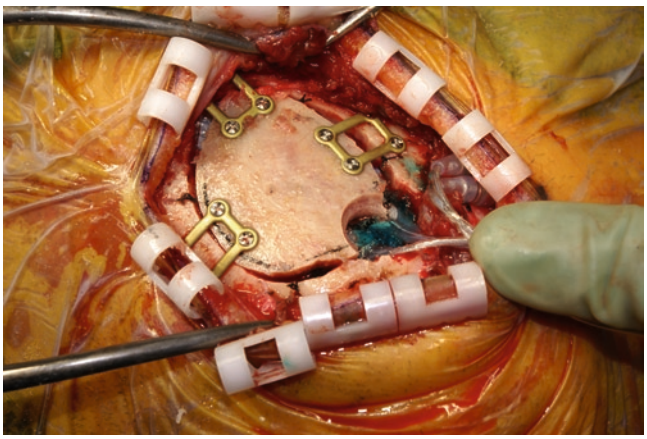

Figure 18.11. Replacing the bone from the craniotomy prior to closure.

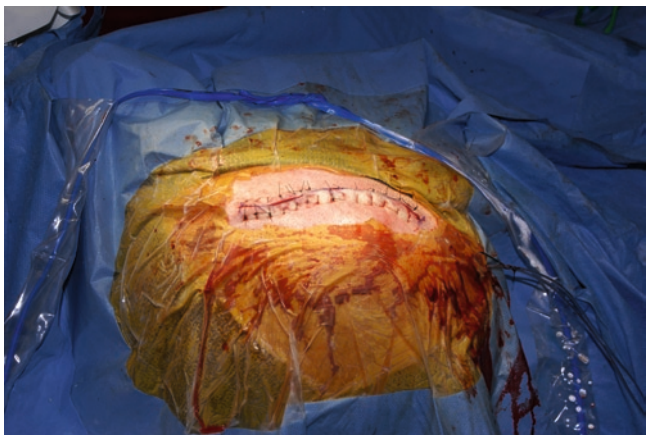

Figure 18.12. Closure of the wound.

investigational grid leads exists. Motor threshold testing can be done in the operating room, and in patients who remain responsive it is possible to test pain reduction during the initial placement.

Once the leads are in place, the electrode is connected to a trialing wire and a trial of 3–7 days is performed. During the trial period, the patient must keep a log for pain reduction since paresthesia is not elicited as it is with spinal cord or peripheral nerve stimulation. Amplitudes for stimulation vary between 0.5 and 10 V, rate varies from 5 to 130 Hz, and pulse widths vary from 50 to 450 ms. The intensity of stimulation is compared to the motor threshold, with a starting value of 15–20% of the energy needed to activate the motor components. The upper level of stimulation is 80% of the motor threshold.

Once the trial is deemed successful, the patient is brought back to the operating room, and the temporary lead connectors are removed. Most implanters prefer pocketing in the chest wall and permanent connectors are tunneled between the two incisions. It is often less traumatic to tunnel from the chest to the head, although both directions have been described. Once the connections are secured and tested, both wounds are irrigated vigorously and a careful closure is performed (Figures 18.9–18.12).

Risk Assessment

1. Surprisingly, the majority of studies involving MCS have had no reported complications or adverse outcomes. It should be considered that these initial studies have been performed with great care, and may not be representative of the overall experience with this therapy once it becomes more commonly used in mainstream pain medicine.
2. One of the most disastrous events that have occurred during placement of MCS is intracranial bleeding. These complications can lead to severe neurological dysfunction and even death.
3. Infection risks are very serious when implanting MCS leads. Infection may result in meningitis, osteomyelitis, sepsis, and death.
4. Reported neurological deficits have included stroke, hemiparesis, confusion, abnormal involuntary movements, and development of motor loss in one or more limbs.
5. The most commonly reported complication is seizure. This event can occur in the immediate postoperative period or may develop over long-term use.

Risk Avoidance

1. Prior to surgery, the physician should review the patient's tissue for infection or lesions in the surgical area. The surgery should be delayed if there is any doubt about the safety of moving forward.
2. Prior to surgery, the physician should review the patient's medications and assure that all medical conditions are under adequate control prior to moving forward. Drugs that effect bleeding should be discussed with the proper medical specialist and discontinued when safe and advisable.
3. Preoperative and intraoperative antibiotics are recommended. It is advisable to vigorously irrigate the wound prior to closure.
4. It is critical to have the patient keep a good diary of the pain level and patterns prior to the implant, and during the course of the trial. Since the patient cannot feel a sensory change during the trial, the ability to keep proper records is critical in determining the success of the trial.
5. When tunneling the permanent system, the clinician must be careful to avoid blood vessels along the path of the procedure. The carotid and jugular vessels are of particular concern.
6. The position of the generator pocket should be carefully planned to allow patient comfort and to avoid tissue irritation skin erosion.

Conclusions

MCS stimulation is an important component of the pain treatment continuum. It is a technologically advanced procedure that requires great skill and training. With additional study, it will likely become a more widespread tool in the fight against difficult pain syndromes.

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19

Stimulation of the Peripheral Nervous System: Occipital Techniques for the Treatment of Occipital Neuritis and Transformed Migraine

Timothy R. Deer

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Introduction

The occipital nerve is involved in pain syndromes originating from nerve trauma, myofascial spasm around the nerve fibers, cervicogenic diseases, posterior fossa surgery, and transformed migraine. Inflammation of the C2 nerve root will also cause severe symptoms in this region, consistent with a cervical radiculitis. The transformed migraine begins with pain in the occipital nerve distribution and then evolves into a full migraine headache.

The treatments of occipital-induced pain syndromes include oral medications, nerve blocks, physical therapy, and pulsed radiofrequency ablation. In the past, occipital neurectomy, which involved the destruction of the nerve, was performed by Neurosurgery, but this fell out of favor because of deafferentation syndrome and the overall long-term worsening of the pain syndrome. Cryotherapy and pulsed radiofrequency appear to have some efficacy, but unfortunately are very short lived in duration, have not been shown to have cost effectiveness, and require the patient to undergo multiple procedures over time. Stimulation of the nerve has evolved over the past decade and has become a standard treatment of occipital nerve pain that does not respond to conservative measures.

Technical Overview

Prior to considering the technical aspects of the implantation of occipital leads, the clinician must confirm the diagnosis of occipital neuralgia. The clinician should have a clear mental picture of the occipital anatomy including the branches of the occipital nerves. This diagnostic workup includes a history of pain originating or ending in the occipital area; a physical exam that includes tenderness of the occipital notch, and nerve root distribution, and a temporary response to injection of local anesthetic that give relief for the duration of the medication used.

Once the patient is felt to be an appropriate candidate for occipital stimulation, the occipital anatomy is reexamined and the skin is evaluated for lesions, texture, and bony prominences. The occipital nerves branch into multiple fibers and the leads must cover a wide area to obtain appropriate stimulation. The occipital region is shaved to remove hair, which can be a nidus for infection. The trial leads are often placed via a single needle stick on the affected side(s), and the permanent leads are most commonly placed via a midline incision. The targets for the leads vary based on physician preference and can range from a lateral C1 approach to a perpendicular greater occipital nerve approach. The most common area for placement for the leads is at an angle from the midline to the lateral edge of the occipital bone (Figures 19.1–19.4). This placement allows for proper stimulation even in the event of mild-to-moderate migration. By using an octipolar array bilaterally, the amount of coverage increases covering the multiple branches of the nerve. With temporary leads, once the implant is place by X-ray, the leads are secured to the skin by a suture or tape. In permanent implants, the surgical process begins by making an incision at the midline just below or above the occipital prominence. Tissue separation can be achieved with the blunt use of a surgical scissor to minimize trauma. Once the fascia is visualized, a cautery tool is used to achieve hemostasis. Once hemostasis is acceptable, a needle is placed in the desired path of the planned lead placement. Local should be placed only at the midline location. If local is placed in the path of the needle, it will be difficult to confirm stimulation on the operating room table. Fluoroscopy is important to guide and confirm the needle path. In many cases, the needle must be slightly bent to achieve the desired depth and course of the lead implant. Needles with a plastic stylet are often easier to use since the metal stylet may be difficult to remove once the needle is bent. The depth of the needle should be just below the dermis in the subcutaneous tissue. Once the stylet is removed, the lead is placed to the tip of the needle using fluoroscopy to confirm placement. The needle is then pulled distally while the lead is held in position using X-ray confirmation, while the tissue is stabilized by holding pressure above the lead. Once the

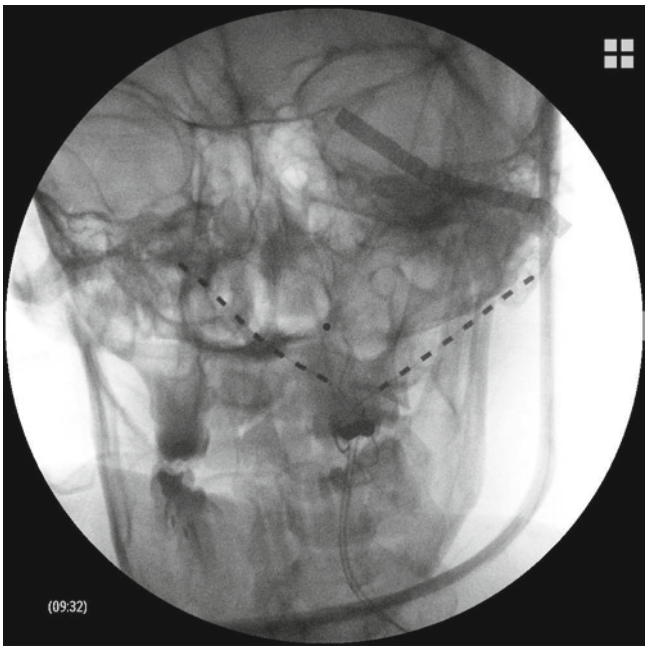

Figure 19.1. Bilateral occipital leads.

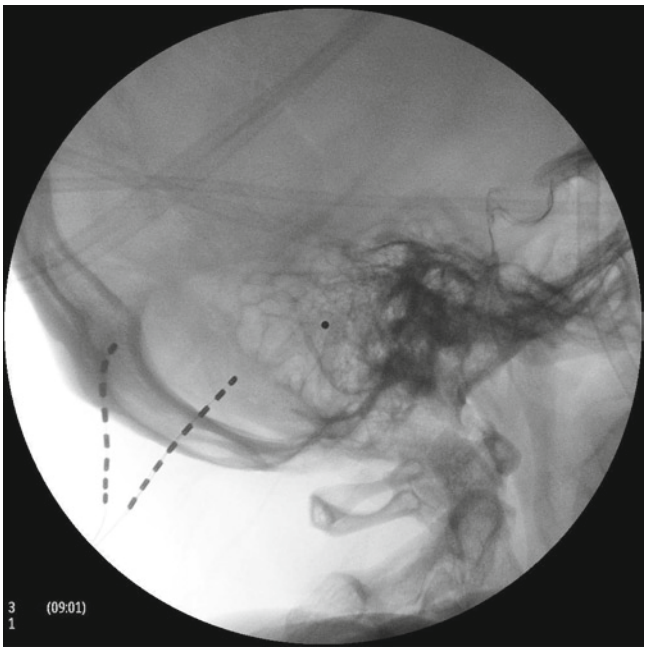

Figure 19.2. Lateral lead position for occipital nerve stimulation.

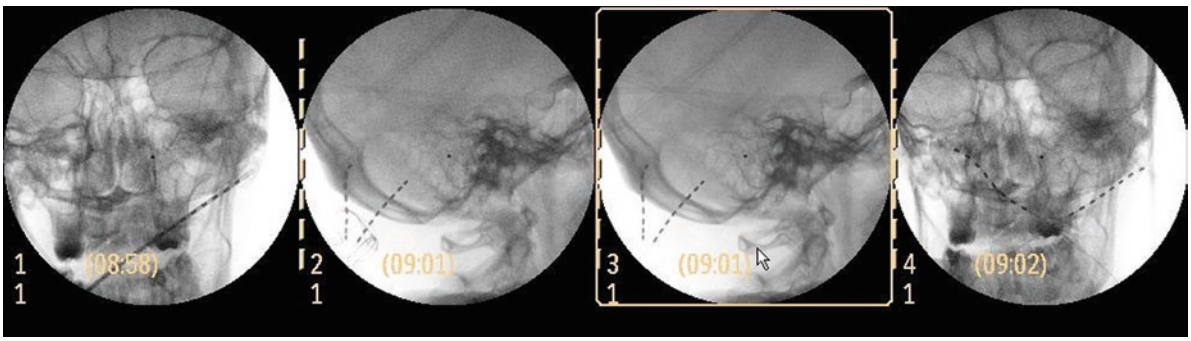

Figure 19.3. Multiple position view.

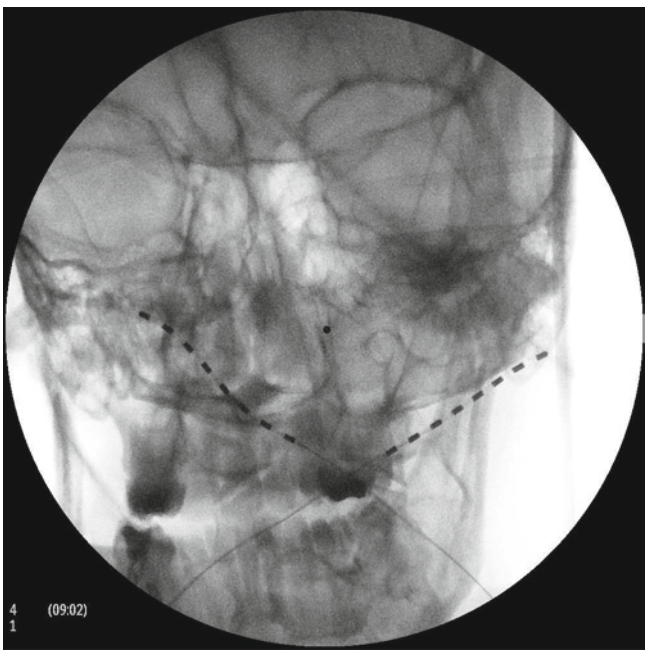

Figure 19.4. Lead position with occipital octipolar leads, with one lead driven to obtain proper stimulation.

lead is in the desired location, a handheld programmer is used to activate the leads and to achieve stimulation. In many cases, an array with multiple cathodes is successful, which will help spread the current. When the patient's stimulation is acceptable, the lead is anchored to the fascia with nonabsorbable suture and silastic anchors. A coil is then made as a form of strain relief and the lead is tunneled to the pocket. Pocketing options include the chest wall in the subclavicular region, buttock, and flank. Figures 19.5–19.8 demonstrate lead and generator placement techniques.

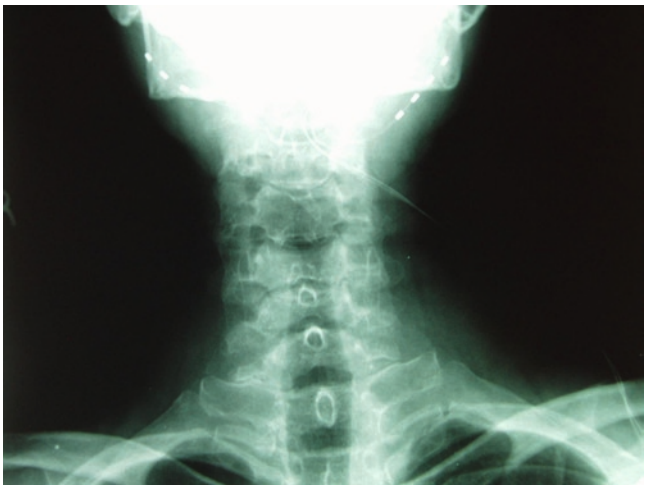

Figure 19.5. Bilateral quadripolar lead placement.

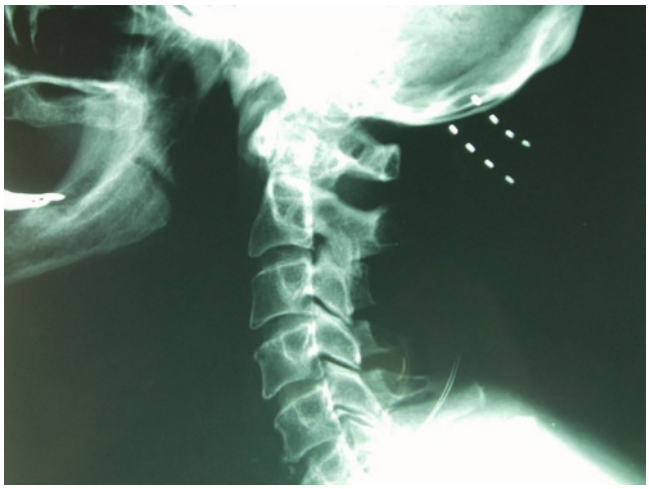

Figure 19.6. Bilateral quadripolar leads in the lateral position.

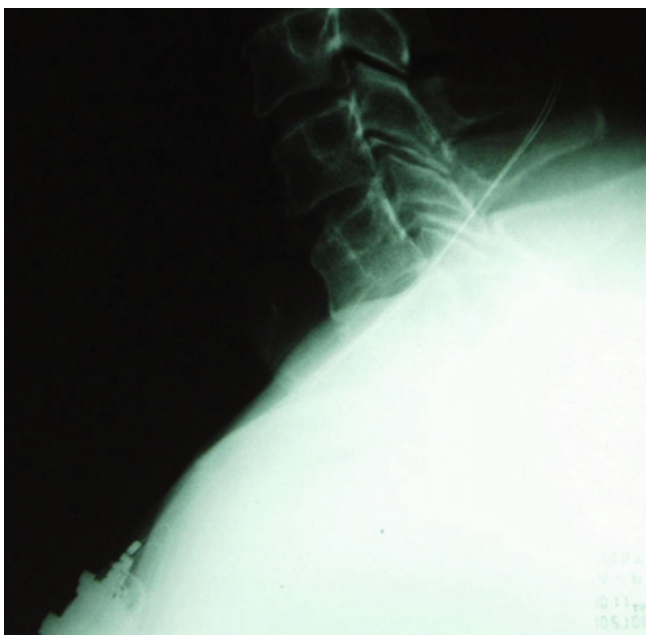

Figure 19.7. Subclavicular generator placement on lateral view.

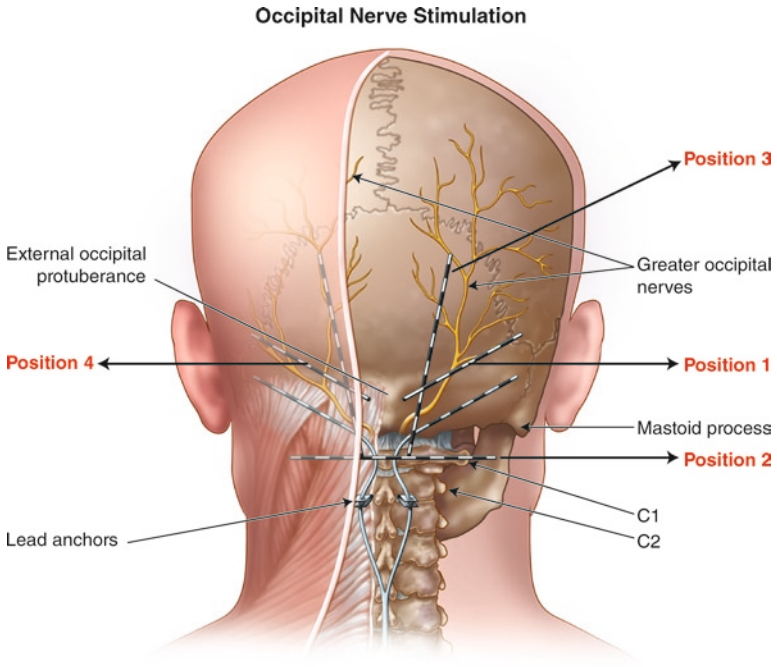

Figure 19.8. Locations for stimulation. Position 1 = high nucale placement. Position 2 = transverse placement. Position 3 = parallel placement.

Risk Assessment

1. The depth of the leads and generator should be carefully considered. The ideal lead placement is in the tissue just below the dermis. If the lead is over a pressure point, the depth should be slightly increased. The generator depth should be 1.5–3.0 cm.
2. The tissue of the planned surgery should be evaluated for lesions or infection. If an area of irritation exists, surgery should be delayed.
3. The lead may be prone to erosion through the skin. Diabetics and those with a history of skin disorders should be approached carefully.
4. The patient's postoperative movement is a fine balance. If you allow the patient to have unrestricted movement, it may cause lead migration, but if too restricted fibrosis can occur which may cause restricted movement of the neck and pain with palpation, over the wiring.
5. Injection and surgical manipulation of the occipital region could lead to extensive bleeding of the occipital artery, or to arterial clotting. Either process could lead to tissue sloughing or a need to reoperate on the patient.

Risk Avoidance

1. Prior to surgery, the physician should review the patient's tissue for infection or lesions in the surgical area. The surgery should be delayed if there is any doubt about the safety of moving forward.
2. Prior to surgery, the physician should review the patient's medications and assure that all medical conditions are under adequate control prior to moving forward. Drugs that affect bleeding should be discussed with the proper medical specialist and discontinued when safe and advisable.
3. Preoperative and intraoperative antibiotics are recommended. It is advisable to vigorously irrigate the wound prior to closure.

4. Prepping and draping of the occipital region can be difficult because of the need to operate in the region of the patients head where there is also a need for airway access. This issue is very important when tunneling the leads. In positioning the patient, the pocket location is important. The options for pocketing can be the chest wall, which requires a lateral decubitus position, or the back or buttock which can be done in the supine position.
5. It is critical to adequately measure the lead length and try to match it to the insertion and pocket location. There should be adequate length to allow for a stress relief loop at both the lead anchoring site and the generator location. This will reduce both the risk of migration and fibrosis.
6. The tissue in the area of the occipital region should be handled gently. It is important to separate the tissue with care and to minimize bleeding. The tissue should close evenly and without stress to maximize tissue circulation.
7. Postimplant, the patient's movement should be restricted for the first 6 weeks. At the end of 6 weeks, the patient may benefit from musculoskeletal treatment by a certified physical therapist.

Conclusions

Occipital nerve stimulation is becoming a common procedure to treat pain in the occipital nerve distribution. It is an alternative to more destructive procedures, and to high-dose oral medications that may cause systemic side effects and complications as well as rebound headaches, and addictive disorders. Occipital nerve stimulation is a valuable low-risk procedure that will continue to improve as lead technology and programming is enhanced by future research and development.

Supplemental Images

See Figures 19.9–19.24.

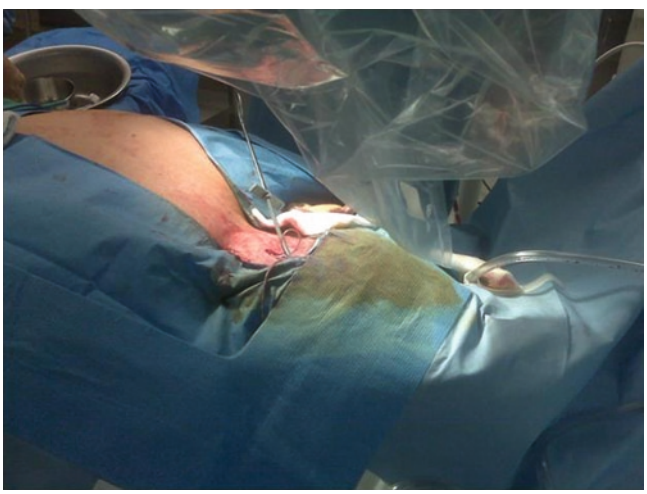

Figure 19.9. Proper positioning to access the occipital nerve for implant.

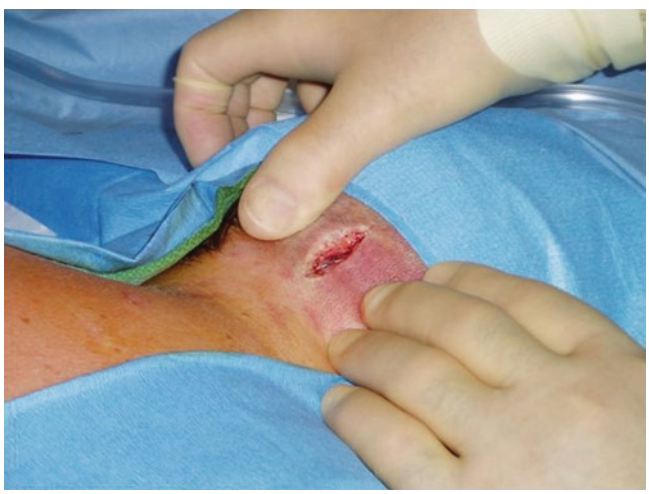

Figure 19.10. Proper incision site for implant of occipital leads just below the nuchal line.

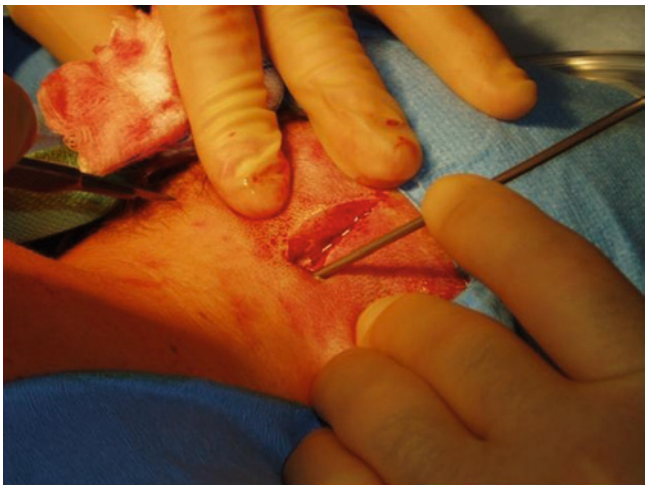

Figure 19.11. Proper tunneling initiation in the occipital region.

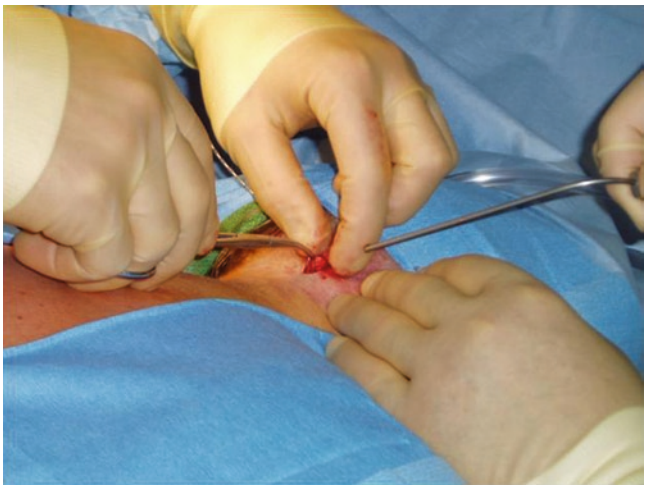

Figure 19.12. Creation of strain relief loop for occipital nerve implant.

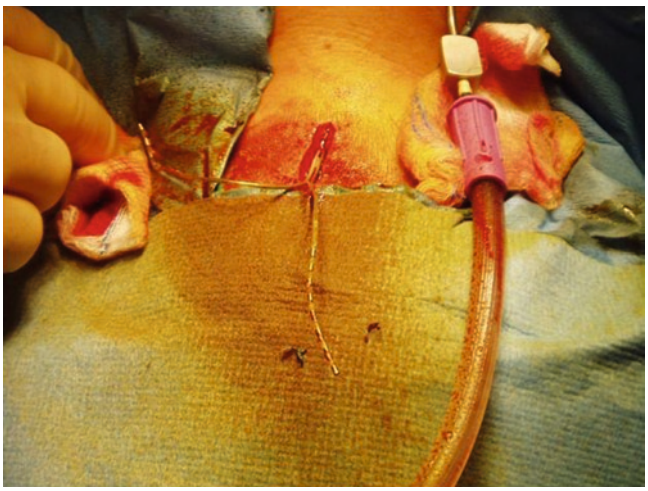

Figure 19.13. These short occipital leads require a connector in the implant area. Lubricant jelly has been used to move the hair out of the wound prior to prepping and draping.

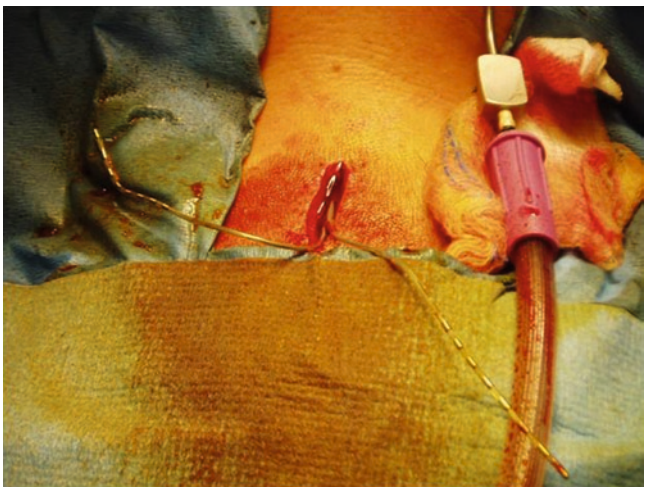

Figure 19.14. Cephalad view of the occipital nerve incision site.

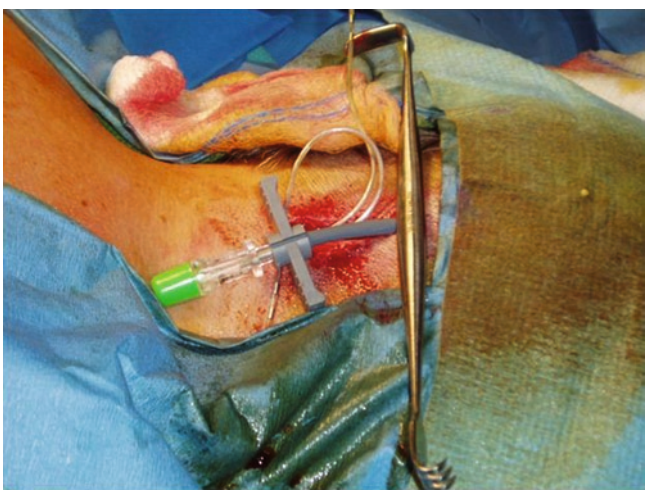

Figure 19.15. Needles with plastic stylets may be optimal to allow contour of the lead to the proper tissue plane.

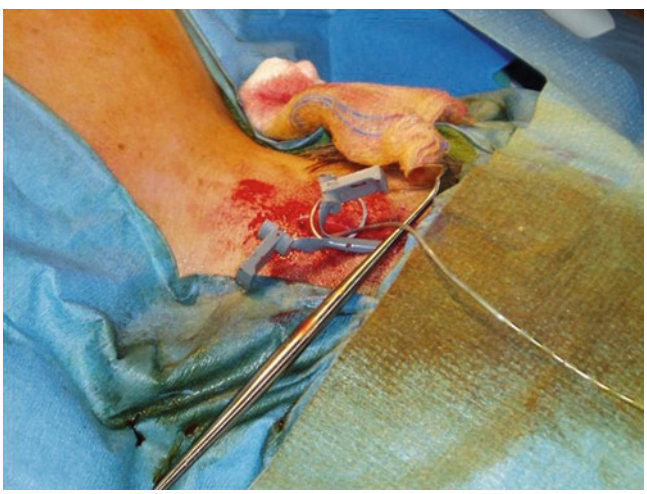

Figure 19.16. Seldinger technique to occipital lead placement.

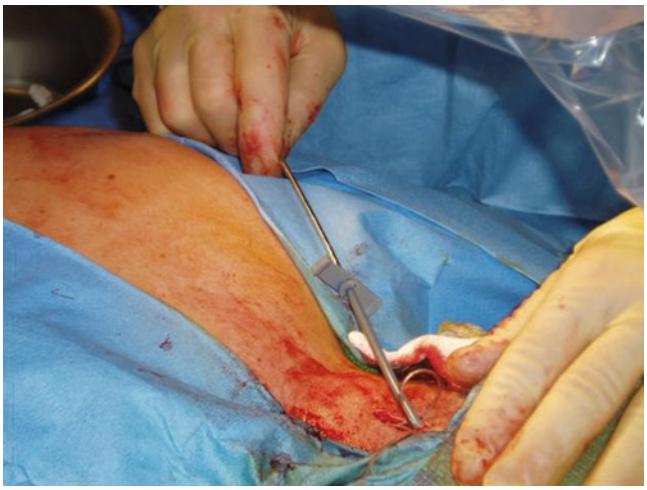

Figure 19.17. Lead placement under fluoroscopic guidance with needle and Seldinger technique.

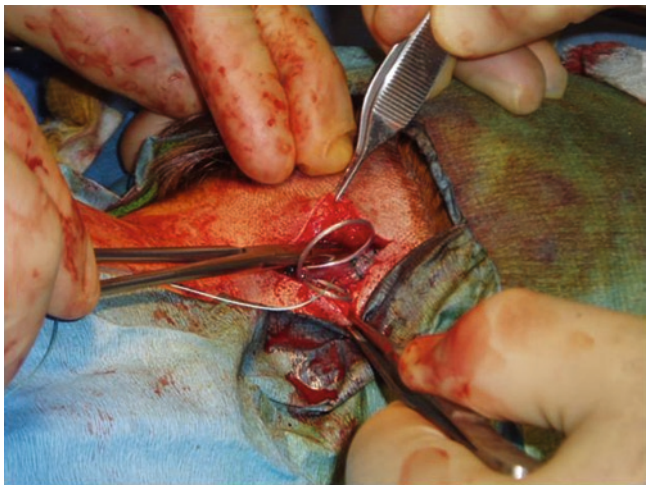

Figure 19.18. Anchoring of the lead to the fascia may be accomplished with nonabsorbable suture with or without an anchor.

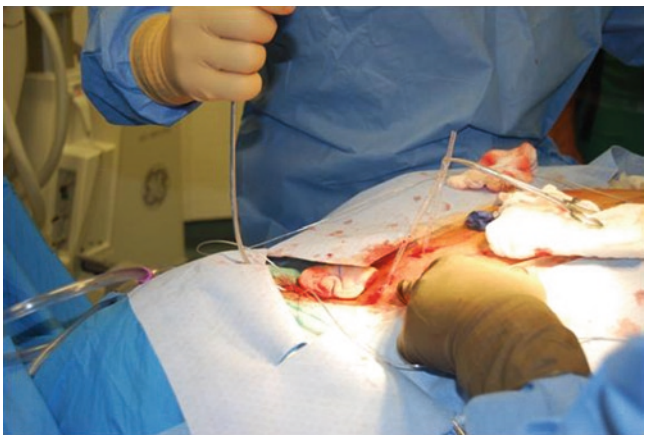

Figure 19.19. Tunneling from the head and neck may require a multistep approach due to body contour and habitus.

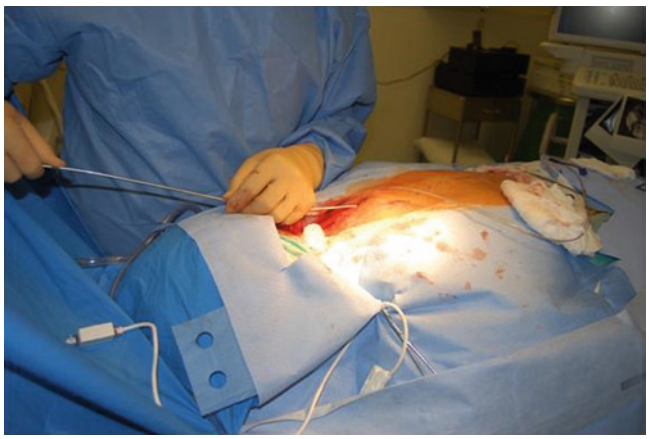

Figure 19.20. The angle of the tunneling should be planned prior to initiating the procedure.

Figure 19.21. When tunneling, care should be used to avoid the leads.

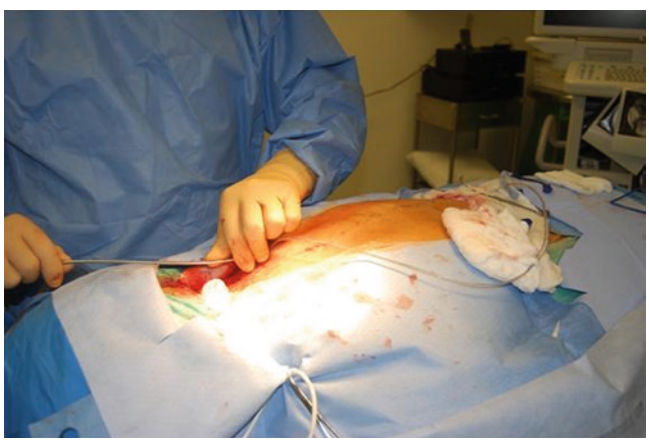

Figure 19.22. Proper tissue planes should be monitored while advancing the tunneling device.

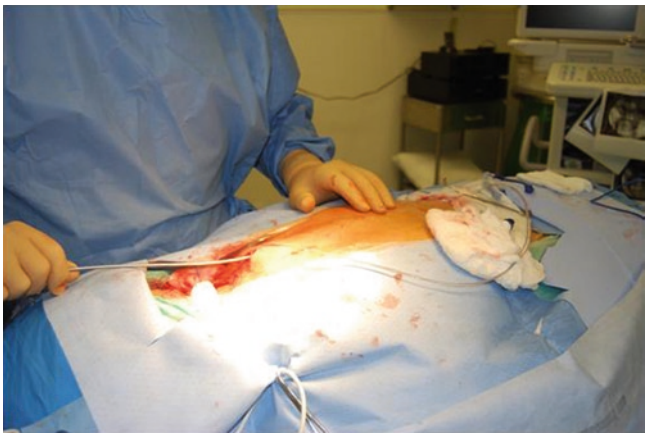

Figure 19.23. Palpation can assist in assessing depth.

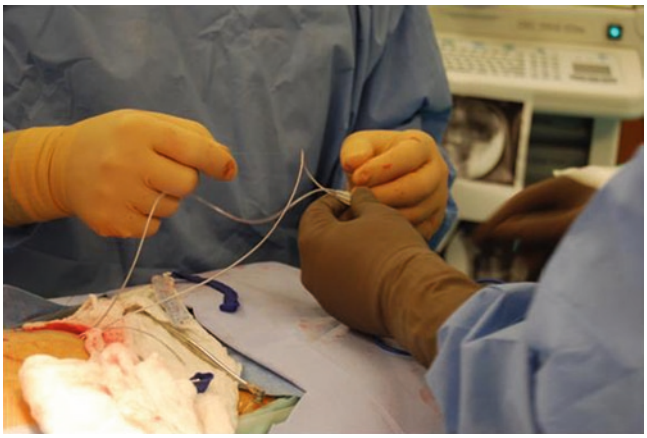

Figure 19.24. When using more than two leads, a connector may be necessary to configure the system.

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IV

Drug Delivery

20

History of Intrathecal Drug Delivery

Timothy R. Deer

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Introduction

Intrathecal infusions of analgesics have been utilized increasingly since the late 1980s for the treatment of persistent pain. Early credit goes to Leonard Corning, who administered neuraxial local anesthetic in 1885. Corning's work led to an interest in using this method to treat pain during surgery, with chronic pain being of little interest in initial development of these methods. Morphine may have been administered spinally as early as 1901. The use of opioids in the spine then underwent a long void in advancement. A breakthrough came in 1971 with the discovery of specific opioid receptors in the spinal cord. Yaksh and Rudy demonstrated the efficacy of analgesia from intrathecal opioids in animal models in 1976, and Wang and colleagues reported the treatment of cancer pain with morphine in 1979. With the development of implantable, programmable, continuous drug

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delivery systems in the 1980s, the use of intraspinal opioids became part of the modern treatment algorithm. The availability of these devices led to interest in using pumps to treat cancer pain, noncancer pain, and intractable spasticity.

Delivery Systems

Although many clinicians recognized the value of spinal anesthetics in these early studies, the short duration of action led to the search for methods of lengthening the period of effectiveness. Continuous catheter access was first proposed by Grafton Love, a neurosurgeon at the Mayo Clinic in 1935. Dr. Love had an extensive background in the treatment of hydrocephalus utilizing continuously draining ureteral catheters placed in lateral ventricles. His treatment of meningitis patients prompted him to attempt the same technique by introducing an intrathecal catheter into the lumbar space.

The first clinical application of continuous spinal anesthesia was described in a 1940 report by Dr. William Leonard, a Philadelphia surgeon, who administered procaine to approximately 200 patients. Dr. Leonard utilized a control syringe attached to a malleable needle, which had been placed presurgically in the lumbar spine. This method was quickly adopted by other physicians in the field, and used primarily in patients who were felt to be of high risk for the use of systemic approaches to anesthesia.

The next major advancement was in the form of a flexible epidural or intrathecal catheter. Manalan, an obstetrician from Indianapolis, Indiana, is credited with the first administration of a caudal anesthesia using an antiquated nylon catheter. This catheter was placed through a 14 gauge needle into the sacral canal. These catheters were placed for varying time periods and in some cases were left indwelling for as much as 18 hours. The catheters were left indwelling, but were not used continuously. The method of anesthesia was based on a strategy of intermittent bolus injections.

The development of continuous intrathecal and lumbar catheter techniques was further advanced in 1944 by Edward Tuohy's introduction of a new Catheter into the spinal interspace for the purpose of repeated delivery of the surgical anesthetic Procaine. The Tuohy needle and catheter was the first of its kind because of the ability to direct its course to a predictable location in the spine. The technique was later enhanced by the development of a needle with a side exit deployment access area designed by Hubor.

The final major advancement in the development of the delivery technique was the permanent implantation of the intrathecal and epidural catheter in combination with internal or external ports, reservoirs and programmable pumps for the continuous injection or infusion of a wide variety of therapeutic agents. These catheters were implanted in the spine, and the drug was infused by accessing the port, which were implanted in most cases in the subcutaneous tissue.

The first human clinical implant of an intrathecal, programmable, pump occurred in 1982, with a widespread release of the system in the United States in 1991. (Medtronic Neurological, Minneapolis, Minnesota.) The approved drug at that time was preservative-free Morphine Sulfate. Over the past two decades, the pump and catheter have remained similar in appearance and function. This decade will most likely see major changes in pump therapy for chronic diseases. Delivery tools continue to evolve, with several companies working on new technologies that may impact the size of the programmable pump, internal mechanisms, accuracy, safety, and catheter materials used to deliver the drug. The other area of interest in the intrathecal space is the development of new drugs to deliver to treat specific ailments. These drug developments have been slow to progress, but many clinicians remain hopeful that we will eventually be able to treat many new patients for diseases causing pain and other areas of human affliction.

Table 20.1. Important milestones in intrathecal drug delivery.

1885	Leonard Corning: administration of neuraxial local anesthetic
1901	First reported use of intraspinal morphine
1935	Continuous catheter access was first proposed by Dr. Grafton Love
1940	The first practical application of continuous spinal anesthesia was described by Dr. William Leonard, a Philadelphia surgeon, who administered procaine to approximately 200 patients
1944	Edward Tuohy introduces of a catheter into the spinal interspace for the purpose of repeated delivery of the surgical anesthetic Procaine
1976	Yaksh and Rudy demonstrate the efficacy of analgesia from intrathecal opioids in animal models
1979	Wang and colleagues report the treatment of cancer pain with morphine
1982	Medtronic Neurological (Minneapolis, Minnesota) reported their first clinical implant of an intrathecal, programmable, intrathecal pump
1991	Medtronic Neurological (Minneapolis, Minnesota) releases their programmable intrathecal pump in the United States

Please see Table 20.1 for a summary of these significant events.

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21

Selection and Indications for Intrathecal Pump Placement

Timothy R. Deer

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Introduction

The placement of an intrathecal catheter, tunneling of the catheter, pocketing for pump placement, and connection of the system is a complex process of interventions requiring great technical skill. The selection of the patient who will receive the pump is as important as each step in the procedural process. Selection considers patient characteristics, while indications consider the disease state being treated. This chapter focuses on proper patient selection for intrathecal drug infusion implantation.

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Factors to Determine Proper Selection for Pump Implantation

Intrathecal pumps are approved by the Food and Drug Administration for chronic use in patients with moderate-to-severe pain from cancer or noncancer causes. The implantation of a pump should be seen as part of a treatment continuum based on very specific selection criteria. In many cases, the implanting physician will have a long-term relationship with the patient, but in other situations, the physician may be seen in consultation to determine whether pump implantation is appropriate. In both these situations, a list of criteria is helpful when considering implantation. The patient does not have to meet all criteria for implant, but these criteria should be considered. Table 21.1 outlines these issues.

Factors to Determine Proper Indications for Pump Implantation

Intrathecal pumps are indicated for chronic use in patients with moderate-to-severe pain of cancer and noncancer origin. The indications for these devices vary based on the disease process, and the effect of the disease on the source of pain generation. Some of the more common indications are seen in Table 21.2.

Conclusions

The decision to place an intrathecal device is a serious medical matter. The physician and patient should discuss the details of pump placement, risks of the procedure, and alternatives. In patients who have an acceptable indication for device placement, and meet acceptable selection criteria the procedure is performed. In some patients, the indication may be uncommon or they may not meet all selection criteria, and these situations should be considered on an individual basis. In cases where the options are limited, a pump may be considered as a last resort, even when the selection criteria may be in question.

Table 21.1. Selection criteria for intrathecal pumps.

The patient has failed more conservative options for the treatment of their condition or other options are unacceptable or not indicated
A trial of neuraxial medications provide acceptable pain relief, tolerable side effects, and functional improvement when indicated
The patient has unacceptable side effects or unacceptable relief from oral or transdermal medications
The patient has spinal anatomy that will allow for the placement of a spinal catheter
The patient is medically stable with no untreated bleeding disorders
The patient is medically stable with no untreated infectious processes
The patient has no skin disorders that would preclude the implantation of a foreign body
The patient is mentally stable having no untreated severe depression or anxiety disorders
The patient does not suffer from a significant personality disorder such as the diagnosis of borderline or antisocial personality disorders

Table 21.2. Selection criteria for intrathecal pumps.

Cancer indications
Primary tumors causing pain from tissue invasion
Metastatic lesions causing pain from tissue invasion
Neuropathy from chemotherapy treatments
Nerve irritation or injury from radiation
Noncancer indications
Failed back surgery syndrome
Spinal canal stenosis
Foraminal stenosis
Compression fracture
Spondylolisthesis
Peripheral neuropathy
Complex regional pain syndrome
Severe osteoarthritis
Rheumatoid arthritis
Connective tissue disorders

Suggested Reading

Deer T, Winkelmüller W, Erdine S, et al. Intrathecal therapy for cancer and nonmalignant pain: patient selection and patient management. *Neuromodulation*. 1999;2(2):55–66.

Deer T, Krames E, Hassenbusch S, et al. Polyanalgesic consensus conference 2007: recommendations for the management of pain by intrathecal (intraspinal) drug delivery: report of an Interdisciplinary Expert Panel. *Neuromodulation*. 2007;10(4):300–328.

Hassenbusch S, Portenoy R, Cousins M, Buchser E, Deer T, et al. Polyanalgesic consensus conference 2003, an update on the management of pain, by intraspinal drug delivery–report of an expert panel. *J Pain Symptom Manage*. 2004;27:540–563.

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22

Placement of Intrathecal Needle and Catheter for Chronic Infusion

Timothy R. Deer

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Introduction

The decision to place a pump is a complicated medical matter that requires careful evaluation, planning, and technical skill. The catheter is the portion of the procedure that allows direct delivery of drugs to the intrathecal space so it is very important that it be placed in a manner that leads to a satisfactory long-term outcome. This section reviews the essentials for placing and securing an intrathecal catheter for chronic infusion.

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Technical Overview

The patient is positioned to establish the best possible path to successfully place the needle and catheter. The most common position is the lateral decubitus with flexion of the hips and cervical spine. The patient should be aligned with both shoulders at equal tilt to avoid torsion of the trunk. The patient is prepped widely to encompass both the planned area of invasion and the surrounding tissues. Fluoroscopic imagery is used to assess the bony anatomy and to determine the level in which the needle will be placed. Once the clinician is pleased with the positioning, prepping, draping, and X-ray imaging, the procedure is initiated. In some cases, the position is less than optimal because of the patient's pain being too great to be placed in the lateral decubitus position, or because of body habitus and spinal abnormalities. In these cases, the position can be modified to the prone orientation realizing that if the plan is to place the pocket into the abdominal wall, repositioning will be required.

The fluoroscopic image is visualized to place local anesthetic one to two vertebral bodies below the planned site of entry. A paramedian approach is recommended to allow the catheter to avoid the constant wear and tear of the spinous processes (Figure 22.1). The needle is positioned to walk off the laminae and enter the intrathecal space at an ideal angle of 30° (Figure 22.2). In some cases, the angle can be increased to 60° because of

Figure 22.1. Paramedian approach to needle placement.

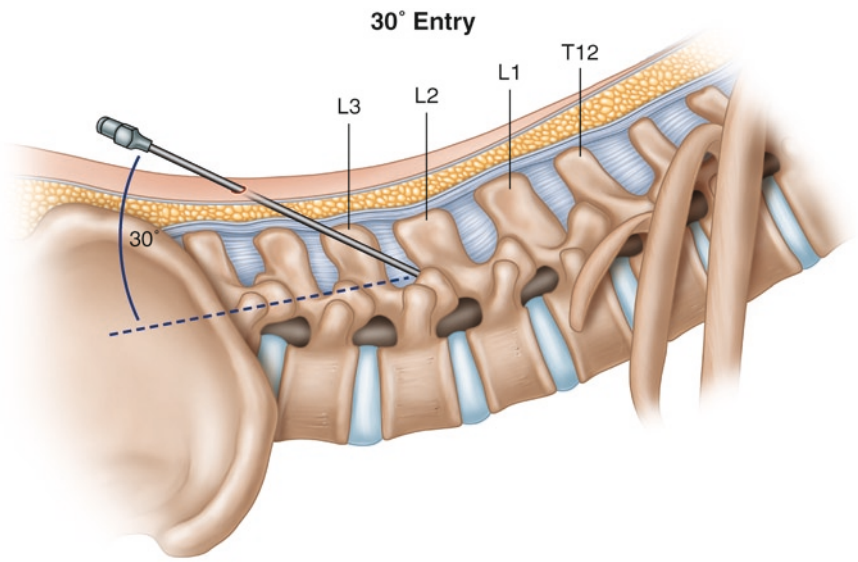

Figure 22.2. Proper needle angle placement at 30°.

anatomical variation, but angles that exceed this mark may lead to excessive pressure on the catheter and subsequent catheter failure (Figure 22.3). Once the needle is positioned into the space, the implanter should visualize unobstructed flow of cerebral spinal fluid. At this point, the needle stylet is removed and the catheter is advanced. In ideal situations, the catheter is advanced in the dorsal intrathecal space to the desired vertebral level. The level of tip placement varies on physician preference and the decision process is outlined in Table 22.1. Once the catheter is ideally placed, a cutdown is made to the ligament and fascia, at which time the fatty tissue is debrided and a purse string suture is placed along with an anchoring suture. The purse string suture should be placed while the needle remains in place, and secured prior to needle removal. The same suture may also be used to secure the anchor, but this is a decision based on physician preference. Once the catheter is anchored, a strain relief loop is created and the catheter is then ready to tunnel to the desired pocket location for connection to the pump. A final film is taken to document the final catheter course once it is attached to the intact system (Figure 22.4).

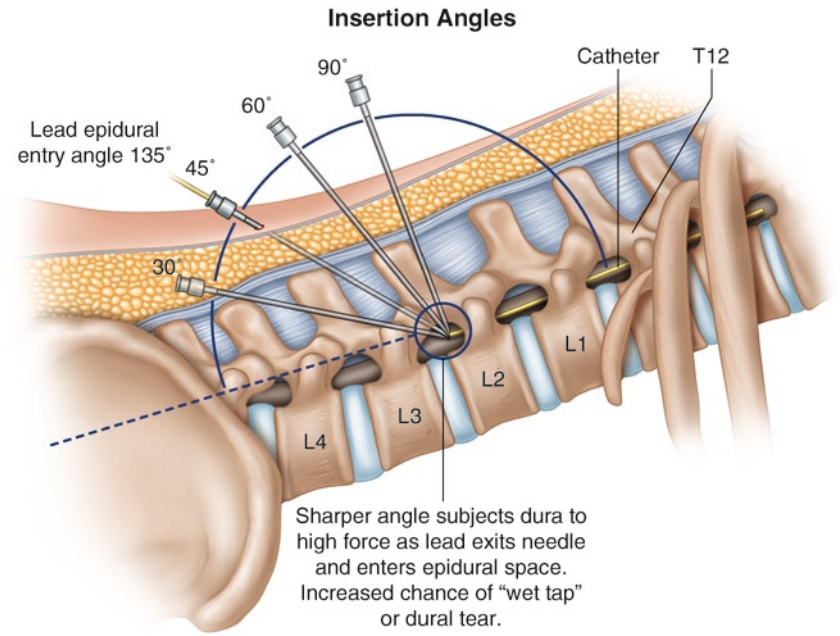

Figure 22.3. Alternative needle placement for difficult access.

Table 22.1. Preferred level of catheter tip placement.

Location	Clinical theory
Site of pain	Lipophilic drugs delivered to site
T10	Failed back fibers
Sacrum	Pelvic and rectal pain
Below conus	Reduced risks of inflammatory mass
Upper cervical spine	Head and neck pain

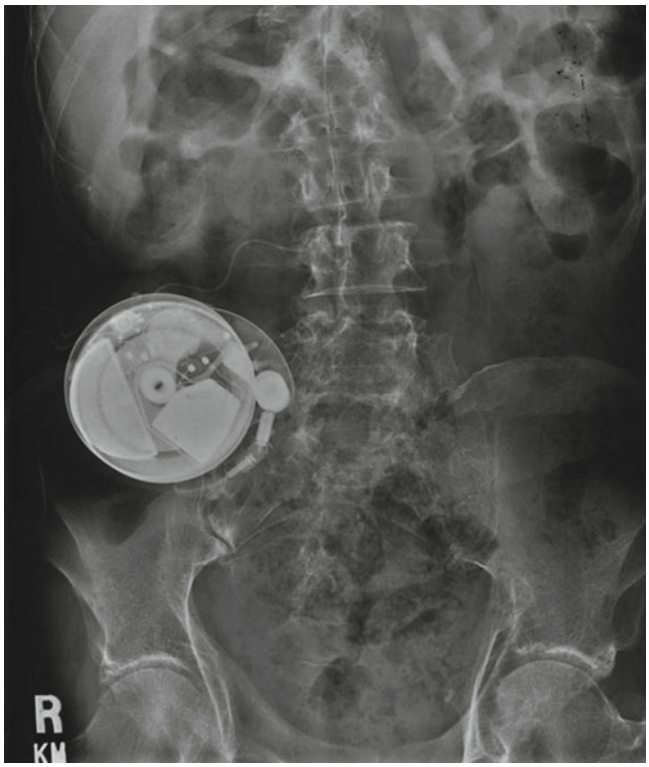

Figure 22.4. Final position of catheter.

Risk Assessment

1. The most significant risk of catheter placement is injury to the spinal cord or nerve roots. The injuries can range from nerve inflammation to serious cord injury resulting in paraplegia.
2. The catheter angle required to achieve intrathecal placement may be very steep, in some cases approaching 90°. This angle may allow easy entry into the space and subsequently may increase the torque on the catheter. This steep angle may increase the risk of tissue injury, may lead to increased difficulty passing the catheter, and may increase catheter movement or failure over time.
3. Multiple entries into the intrathecal space may lead to a significant loss of cerebral spinal fluid.
4. Ventral placement of the catheter is sometimes the only option when placement is performed. This may lead to significant risk of motor compromise should an inflammatory mass develop.
5. Catheter damage including tearing or fracture may occur during needle or stylet removal.
6. The purse string catheter may lead to catheter occlusion or obstructed flow.
7. The anchor and anchoring suture may lead to catheter kinking or obstruction.
8. The catheter wall may be insulted with a needle when suturing the anchor or during tissue closure.

Risk Avoidance

1. To avoid nerve or spinal cord injury, the physician can take several precautions. Attention should be paid to proper and aligned positioning to optimize the ability to place the needle easily. The fluoroscopic image should be modified by changing the

beam to correct for patient rotation, spinal kyphosis, or scoliosis or abnormal body habitus. This will allow needle placement in a gun barrel approach. When possible, a laser-guided imaging technique can be helpful. The choice of anesthesia technique is based on surgeon and anesthesiologist preference; however, the use of monitored sedation with direct patient communication can provide an early warning for the implanter of impending nerve injury or spinal cord damage. An alternative would be a wakeup test in patients undergoing general anesthesia. The entry of the needle below the level of the conus will also reduce the risk of cord injury, although the cord can still be invaded with forceful catheter advancement. In some cases, general anesthesia is required to allow the patient to tolerate the procedure.

2. The angle of entry for the needle can be optimized by proper positioning, paramedian approach, careful anatomical observation, and in some cases by making a cutdown to improve the ability to drop the hub of the needle and therefore lowering the angle. A cutdown approach is very helpful in obese patients. In patients with a large body habitus, the use of a longer (6 in.) needle may also be of value.
3. Proper needle angle, positioning and attention to cerebral spinal flow will reduce the need to make multiple entries into the intrathecal space.
4. Using a shallow angle and paramedian approach leads to easier catheter placement and tends to encourage lead placement to the posterior intrathecal space.
5. Careful attention should be given to resistance to withdrawing the needle or stylet. When significant resistance occurs, the implanter should remove the entire system and reinitiate the procedure. Pulling the needle out against significant resistance can lead to catheter damage or fracture and should be avoided.
6. It is important to secure the purse string around the needle and tie the suture prior to removing the needle. Tying the suture after removing the needle can lead to occlusion of the catheter and failure of the system.
7. The anchor should be carefully placed against the fascia to assure that the catheter does not have the tendency to occlude or kink. The catheter should have a smooth course through the anchor and into a strain relief loop prior to being tunneled to the pocket.
8. When closing the tissues and skin of the area of the catheter careful attention must be paid to avoid hitting the catheter with the needle. This can lead to fluid leak and failure of the system. Avoidance methods include careful vigilance to the catheter and the use of blunt instruments to retract the catheter to avoid injury to the device.

Conclusions

Intrathecal catheter placement is a very important part of the implant procedure since the overall success of the implant depends on a patent conduit to the spinal fluid. The planning and execution of the catheter implant is successful when the patient is properly positioned, the radiological anatomy is properly identified, and the needle and catheter placement is properly executed.

Supplemental Images

See Figures 22.5–22.11.

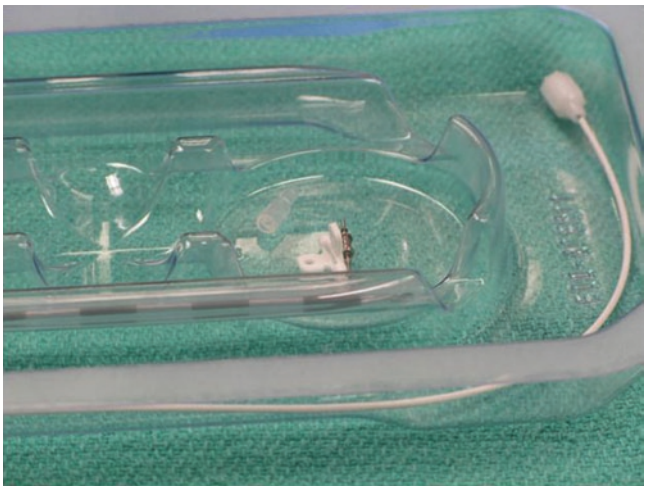

Figure 22.5. Example of an intrathecal catheter with stylet, needle, anchor, and titanium connector.

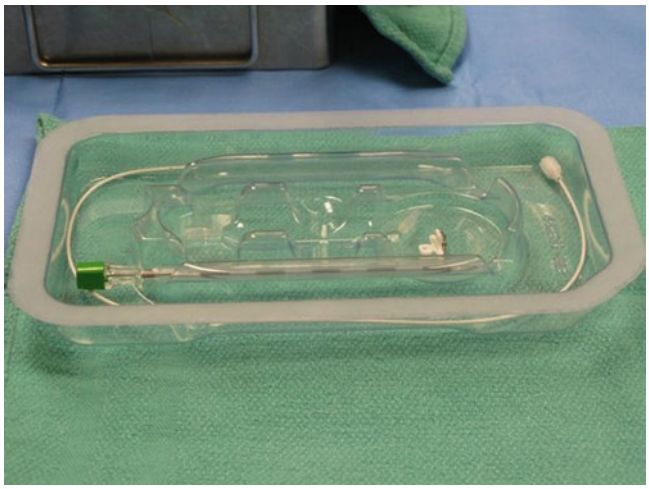

Figure 22.6. Intrathecal catheter with needle and accessories.

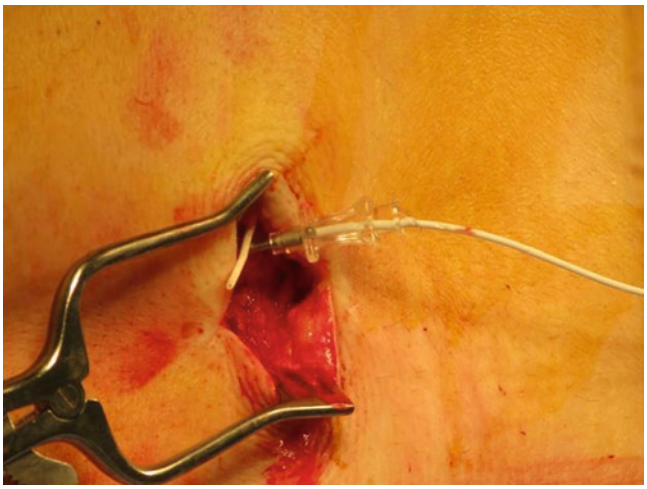

Figure 22.7. After a distal catheter malfunction, the catheter is explanted from the spine. A new catheter is implanted and then spliced to the existing tubing, which is traveling to the pump.

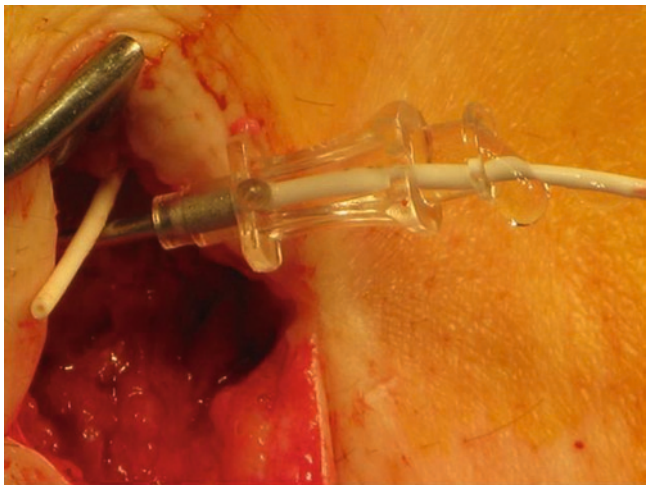

Figure 22.8. Excellent cerebral spinal fluid flow should be seen prior to connecting the system to the intrathecal device.

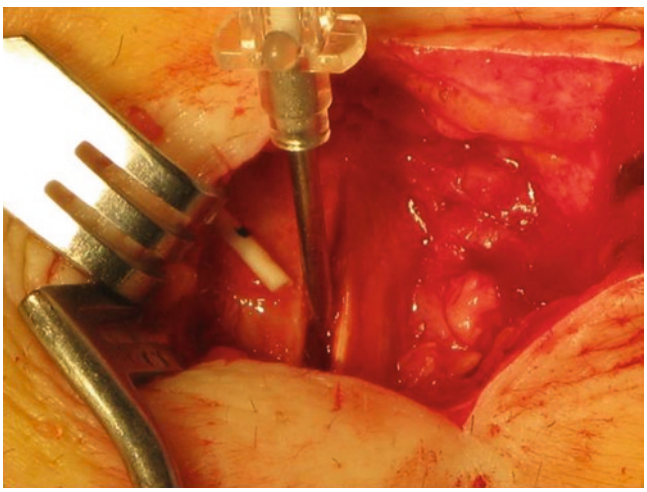

Figure 22.9. Fascia should be exposed prior to placing the purse string suture around the needle at the ligament entry.

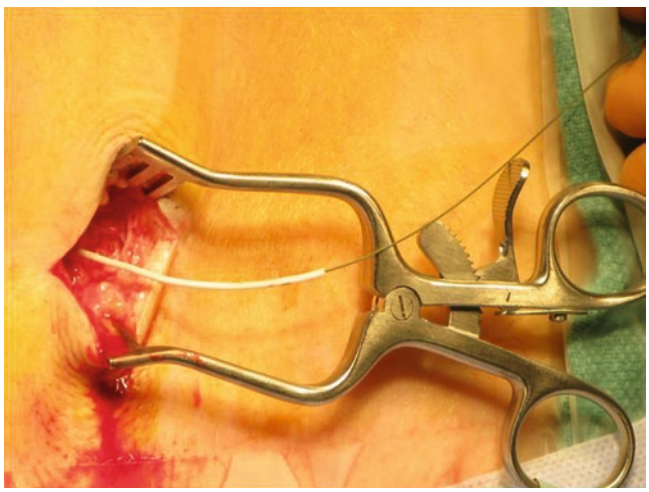

Figure 22.10. The catheter stylet is removed prior to tunneling the catheter.

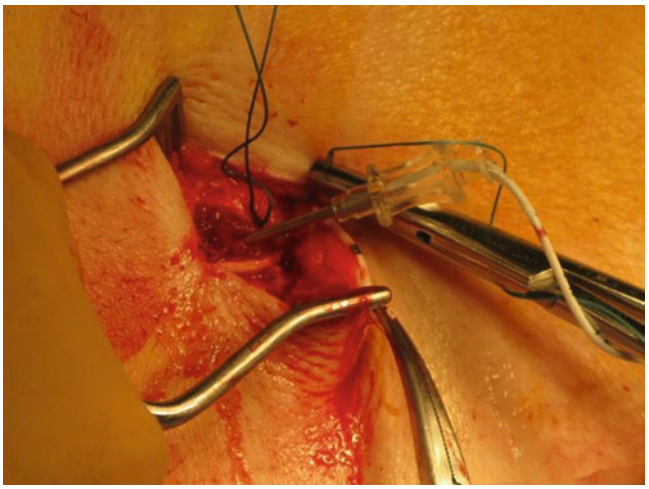

Figure 22.11. A purse string suture may promote fibrosis around the catheter and reduce cerebral spinal fluid leaks and hygroma formation.

Suggested Reading

1. Deer T, Krames E, Hassenbusch S, et al. Polyanalgesic Consensus Conference 2007: Recommendations for the Management of Pain by Intrathecal (Intraspinal) Drug Delivery: Report of an Interdisciplinary Expert Panel. *Neuromodulation*. 2007;10:300–328.
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23

Securing and Anchoring Permanent Intrathecal Catheters

Timothy R. Deer

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Introduction

Catheter migration is an important problem when considering complications of intrathecal drug infusion systems. Catheter migration can result in loss of efficacy, drug withdrawal, and the need for surgical revision. The methods of securing the catheter vary due to physician preference. Options include placing a purse string to secure the tissue surrounding the catheter, and the placement of a variety of silastic anchors to secure the catheter to the ligament or fascia. This chapter examines both the options of securing the catheter and the associated problems with catheter movement.

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Technical Overview

The process of securing and anchoring the catheter involves several steps that help ensure a good outcome (Table 23.1).

Once the needle and catheter are in good position, the physician must debride all fatty tissue from the area surrounding the needle exposing the fascia and ligament. At this point, the physician must decide whether they wish to place a purse-string suture around the needle. The purpose of a purse-string suture is often misunderstood by the clinician. If the suture is tied tightly around the catheter, it will result in catheter occlusion and a poor outcome. The goal of a purse-string suture is to secure the tissue that surrounds the catheter to reduce the short-term risk of cerebral spinal fluid lead around the catheter, and to reduce the risks of catheter migration in the long term by allowing the tissue to fibrose around the catheter. The purse string is placed by using a nonabsorbable suture around the catheter while it is still in the needle. The suture is placed in the fascia and ligament in a purse string orientation with at least four entries and exists is a circular pattern encompassing the needle. The suture is then tied while the needle is in place. This allows for a tight occlusion of the tissue without worry of damaging the catheter, which can result in catheter fracture or occlusion (Figure 23.1).

Once the catheter is placed in an acceptable fashion, the purse string is placed around the needle and catheter, and the needle and stylet are removed and the catheter can be anchored. Anchoring involves the placement of a suture in secure tissue such as fascia or ligament that is positioned so that the angle of spinal exit does not place any undue stress on the catheter.

Anchoring can be performed with a variety of anchors depending on manufacturer, but there are only a few basic anchor types.

1. These include a "butterfly" anchor, which secures the catheter by wrapping around the catheter. A suture is placed through a singular suture hole to lay the catheter and anchor down against the fascia. An advantage of this type of anchor is the ability to use the same suture used for the purse string to also secure the catheter and anchor. To accomplish this task, the suture must exit the fascia caudad to the needle entry site (Figure 23.2).

Table 23.1. Risks and action to ensure successful anchoring.

Migration risk	Physician action
Fatty tissue at anchoring site	Debride fatty tissue around the needle entry site exposing fascia and ligament for proper anchoring
Anchoring to muscle	When using an exaggerated paramedian approach, the physician should dissect medially until approaching ligament or fascia, avoiding anchoring to muscle, which may lead to migration with contraction
Lead anchor gap	The anchor should be as close to the lead entry into the ligament or fascia as possible avoiding room for migration distal to the anchor
Suturing with silk	Avoid silk sutures when anchoring
Dependence on the anchor	The anchor should be seen as one component of securing the system. Total dependence on the anchor can lead to poor outcomes
Hematoma below anchor	Hemostasis should be obtained prior to closing the wound. Bleeding can lead to catheter movement due to hematoma compression placing pressure on the anchor
Minimal migration changes	The catheter should be placed in an area of the spine that will not be affected by minimal migration movements. If the catheter tip is in the spinal cerebral fluid, a good outcome may be preserved even in the presence of movement

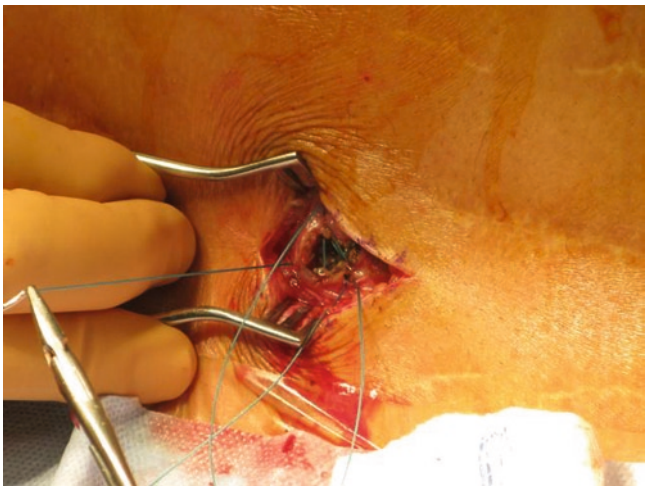

Figure 23.1. Purse-string suture.

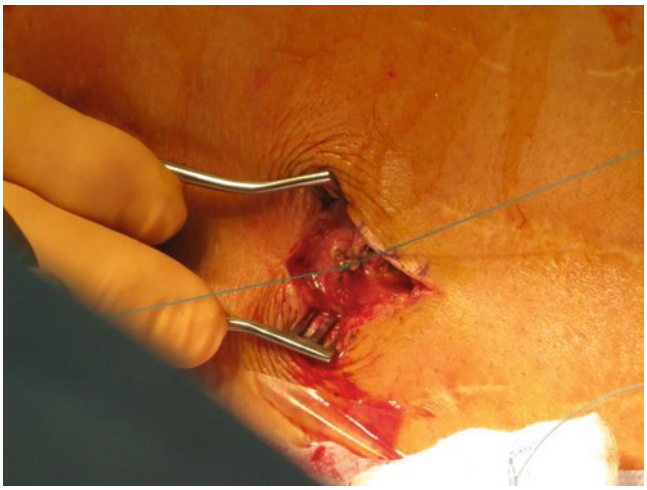

Figure 23.2. "Butterfly" anchor on the catheter.

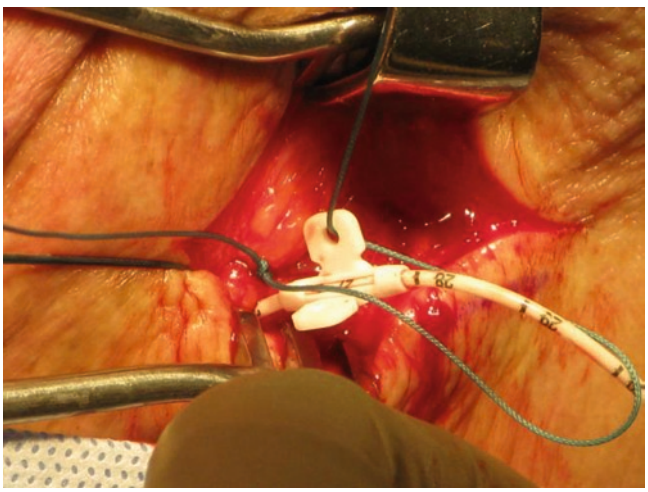

Figure 23.3. "Long tubular" anchor on the catheter.

Figure 23.4. Common "Macaroni" anchor.

2. The "long tubular" anchor is placed over the catheter at the proximal tip and is slid downward to the spinal entry site to abut the fascia or ligament. This type of anchor may have one, two, or three suture holes, and it is important to assure that sutures are placed that work well in concert so that there is no strain on the catheter materials that can lead to kinking or catheter trauma (Figure 23.3).
3. The "macaroni" anchor (Figure 23.4) is a curved anchor with grooves in which the catheter rests. This anchor requires a stabilizing suture to hold down the anchor, and an additional suture or two to hold the catheter in place in the anchor. The advantage of the macaroni anchor is that it directs the catheter in a subtle angle as it exits the anchor to avoid strain on the material. The disadvantage is the need to align the sutures in an exact location to reduce kinking. In some patients, the ability to place the sutures in the exact location needed is difficult.

Suturing and Anchoring Materials

The suture used to anchor the catheter should be nonabsorbable and durable. In the past, many texts and articles have recommended silk as a mainstay of anchoring. Over time the use of silk can lead to migration. This occurs because of silk degradation and eventually a

high risk of suture breakdown. Ethibond and other similar sutures provide a sturdy nonabsorbable suture that will reduce the risk of long term migration.

The type of anchor the clinician chooses may be of minimal significance. Manufacturers often point out advantages to their anchoring systems and clinicians develop preferences based on individual experiences, but to date, no long-term studies have been performed comparing anchors from competing companies, or for anchors made from the same company.

The Deer–Stewart Anchoring Method

In our experience, the commitment to excellence in anchoring is worth adding a few minutes to the surgical procedure. To properly secure the catheter that has been placed percutaneously, it is important to space the sutures properly. This requires a purse string that is initiated 0.5 cm distal to the needle entry into the ligament and fascia. The exit of the purse string should be a 0.1-cm from the entry point. The suture is then secured with a surgeons knot and left uncut. The needle and stylet are then removed and an anchor is placed. The author prefers the butterfly anchor, which is placed over the catheter and advanced to the entry point to the ligament. The purse-string suture is then used to secure the anchor and catheter. This method avoids the need to place a suture while the vulnerable catheter material is exposed to the risk of puncture. Once the anchor is secured, a strain relief loop of 2–3 cm is placed in the incision prior to tunneling.

Risk Assessment

1. The incidence of migration for intrathecal catheters is low, but can be problematic leading to loss of efficacy, withdrawal, or mechanical failure of the device. In some cases, the catheter can totally exit the spine and move into the abdominal pocket (Figures 23.5 and 23.6).
2. Failure to create a proper purse-string suture can lead to cerebral spinal leak around the catheter, and the development of a hygroma in the posterior incision or into the abdominal pocket (Figures 23.7–23.9).
3. Failure to properly remove adipose tissue can lead to anchoring to a necrotic area of tissue that will lead to migration.
4. When anchoring occurs to the muscle tissue migration can occur as the patient undergoes normal movement requiring muscle contraction.
5. Suture breakage can occur. This may lead to shifting of the catheter or anchor.
6. The purse-string suture can lead to catheter occlusion.
7. Kinking of the catheter can lead to fracture or kinking. This can occur at the spine exit point or the catheter entry or exit into the anchor. This can occur even with ideal needle entry, optimal catheter placement, and superb anchoring technique.

Risk Avoidance

1. Migration can be reduced by using an angle of 45° or less for needle entry and by using a paramedian approach with needle placement.
2. Anchoring should occur only after all fatty tissue has been debrided from the area surrounding the needle. The implanter should view a shiny fascial layer with the ligament and fascia in view prior to anchoring.

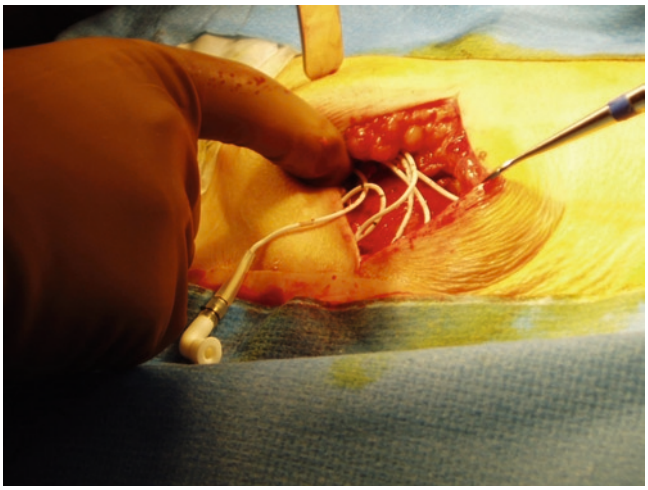

Figure 23.5. Migration of the catheter into the pocket.

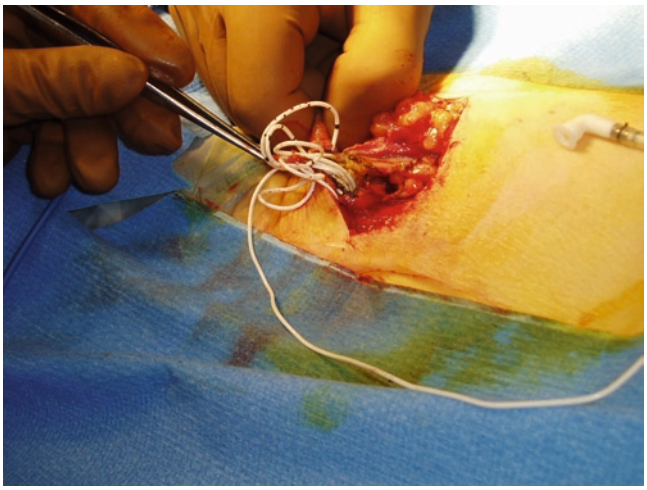

Figure 23.6. Fibrosis of tissue around the catheter in the pocket that may have contributed to migration of the catheter into the pocket.

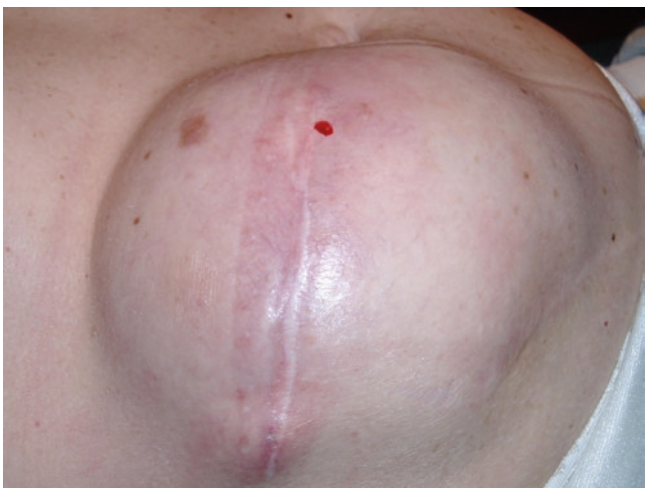

Figure 23.7. Hygroma of pocket.

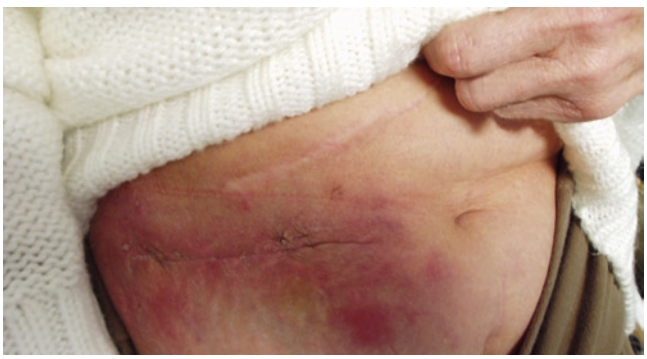

Figure 23.8. Large hygroma of pocket.

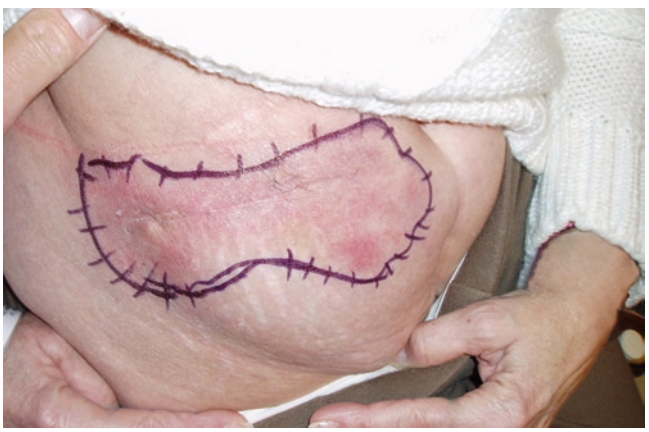

Figure 23.9. Large hygroma of pocket after healing.

3. When the paramedian approach is used in an extreme manner, the amount of fascia and ligament available for anchoring is unacceptable. This can lead to anchoring to muscle or adipose. The paramedian approach should be used in all cases of implantation; however, the needle entry point should remain in the area of the spine that allows for proper anchoring.
4. A proper purse string should pull the tissue surrounding the needle entry site around the catheter to help with fibrosis to reduce the risk of cerebral spinal fluid leak or hygroma.
5. Nonabsorbable suture should be used for anchoring. When possible, silk should be avoided since its long-term stability is worrisome.
6. In thin patients, it is important to use a double or triple layer closure to reduce the risk of discomfort at the anchor placement site. If an unacceptable tissue layer is present to cushion the anchor, the surgeon can make a pocket in the muscle adjacent to the anchor to place any excess catheter. Trimming the catheter in the pocket should be able to reduce this risk. The catheter should have a strain relief loop at both the anchor site and at the area beneath the pump.

Conclusions

A successful outcome with an intrathecal drug infusion system requires several successful processes. Anchoring of the catheter is a very important component, particularly in regard to the long-term stability of the system. It is very important to create a smooth transition for the catheter out of the spine, entering and exiting the anchor, and leaving the dorsal incision in the tunneling path. Attention to securing the catheter can improve outcomes, patient satisfaction, and reduce the need for revisions.

Supplemental Images

See Figures 23.10–23.17.

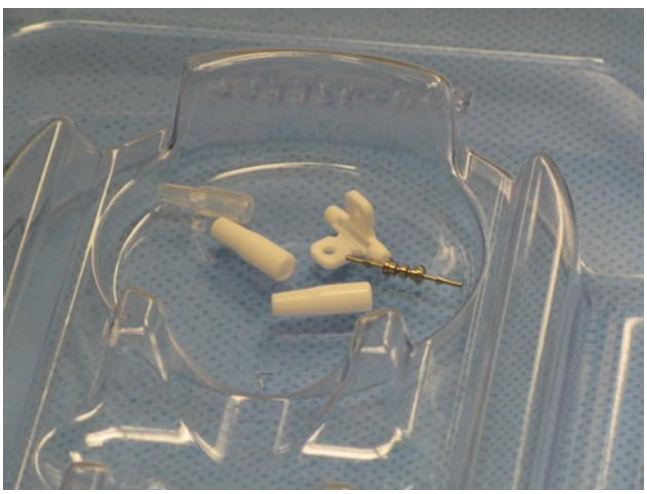

Figure 23.10. Examples of connectors and anchors used for intrathecal drug delivery.

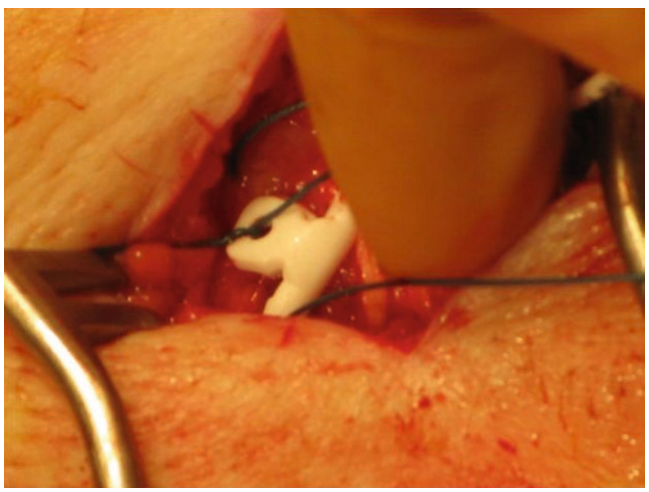

Figure 23.11. The catheter is anchored to the fascia with a nonabsorbable suture and anchor.

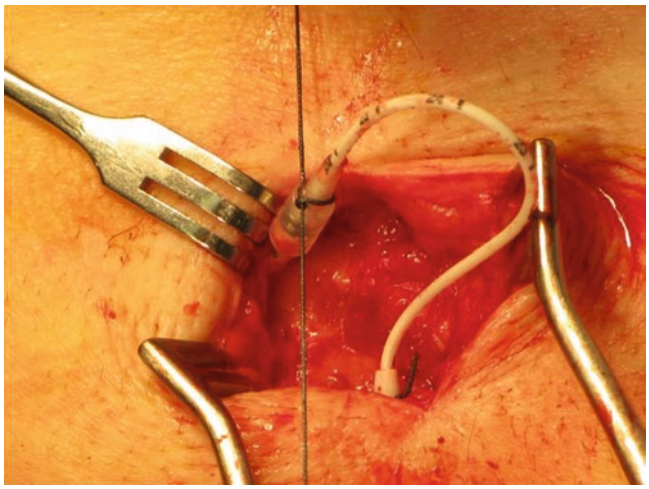

Figure 23.12. A two-piece catheter is secured with a boot and suture.

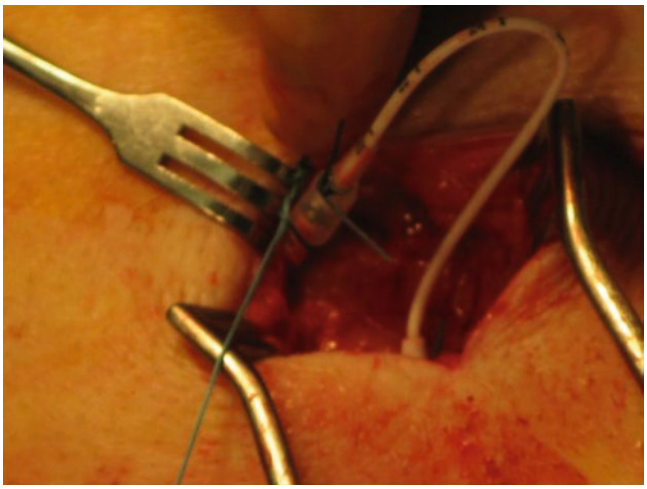

Figure 23.13. A two-piece catheter is secured with a boot and sutures.

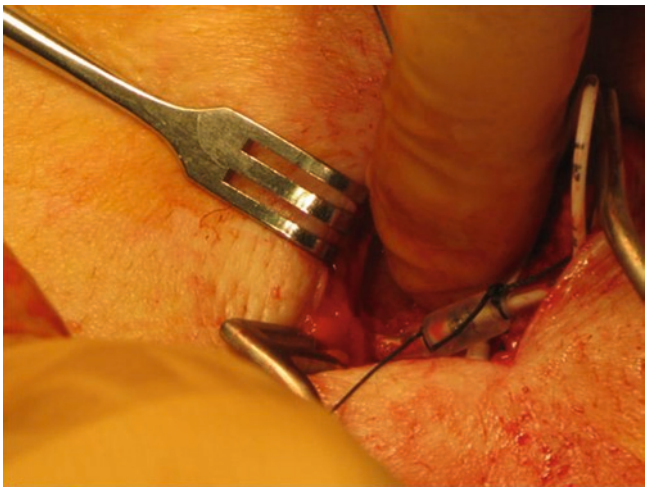

Figure 23.14. A small area of tissue dissection will improve patient comfort when a connector is in place.

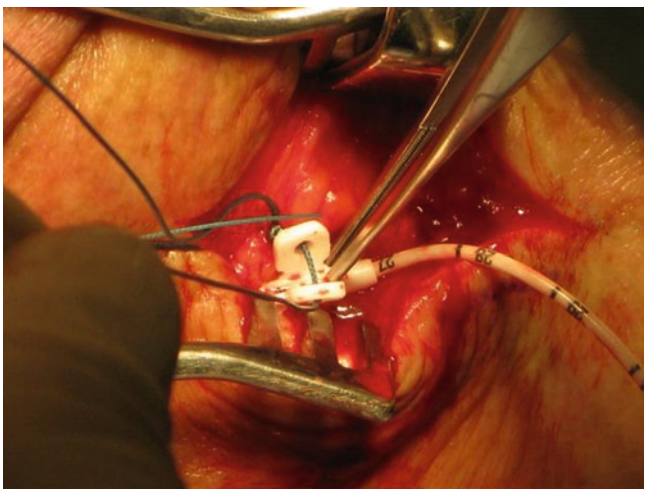

Figure 23.15. A purse-string suture may have a dual use. In this picture, a purse string nonabsorbable suture is being used to anchor an intrathecal catheter.

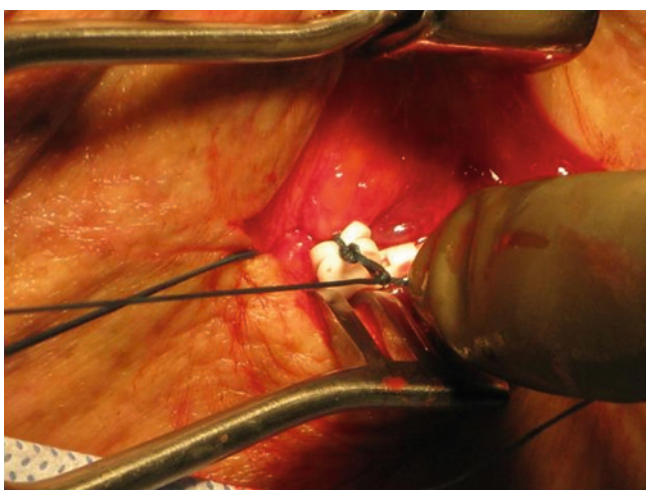

Figure 23.16. The anchor should have a smooth flowing course to avoid stress fractures and kinking, which can result in catheter failure.

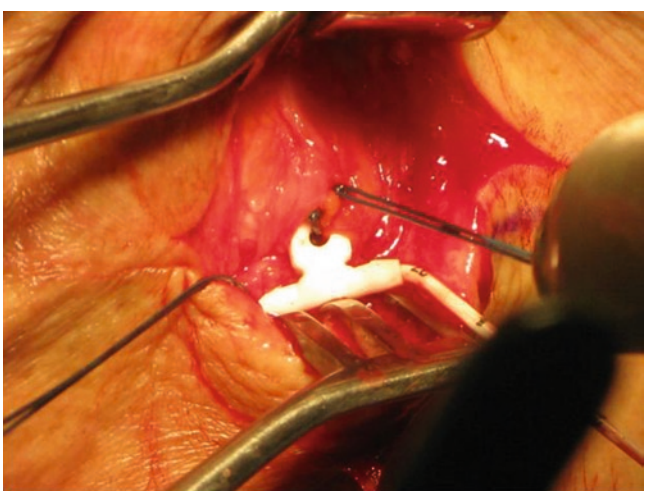

Figure 23.17. This picture shows the final position of the anchor and anchoring stitch. The catheter will then be looped to create a strain relief for the system.

Suggested Reading

1. Follett K, Burchiel K, Deer T, et al. Prevention of intrathecal drug delivery catheter-related complications. *Neuromodulation*. 2003;6(1):3–41.
2. McIntyre P, Deer T, Hayek S. Complications of spinal infusion therapies. *Tech Reg Anesth Pain Manag*. 2007;11(3):183–192.

24

Tunneling Permanent Intrathecal Catheters

Timothy R. Deer

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Introduction

Once the catheter is successfully placed in the spinal canal, the stylet and needle are removed, the purse-string suture is secured, and the anchor is successfully placed, the physician must pass the catheter from the dorsal incision at the spine to the pocket that has been created for the intrathecal pump. The process of tunneling can be simplified as a simple "passage" of the catheter, but the technique is important and when done improperly can lead to a poor outcome.

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Technical Overview

Prior to going into the operating theater, it is important to evaluate the patient's body habitus and to determine the ideal location for pocket placement. Once the pump pocket site has been located and the pocket has been made, the physician can determine the best path for tunneling the catheter. When making this determination, the physician should consider the patients bony structure including the rib margin and the bones of the sacrum. The pathway of tunneling should be finalized and a permanent marker should be utilized to mark the course for local anesthetic placement as shown in Figure 24.1. The ideal local anesthetic varies based on physician selection with lidocaine and bupivacaine being the most common selections. When using lidocaine, the addition of a small amount of bicarbonate may lead to less pain on injection with a normal dilution ratio of 9:1 (lidocaine:bicarbonate). The addition of epinephrine may lead to decreased bleeding at the time of tunneling. The local anesthetic placement should be accompanied by intermittent aspiration to avoid intravascular injection, and an attention to depth to avoid puncture of inadvertent structures. Local anesthetic placement is depicted in Figure 24.2.

Once the patient has been properly anesthetized by using local anesthesia or intravenous sedation, the physician is ready to tunnel. Conventional tunneling rods are of fairly large diameter and require passage over a distance that may lead to improper depth. This can be managed by bending the tunneling device to the contours of the body, or by making a two-pass tunneling approach. In this method, the physician makes an incision along the course of the tunneling path and tunnels to the incision, and then tunnels in a second step to complete the catheter pass. Figures 24.3 and 24.4 show the options for the one-pass and two-pass methods. Figure 24.5 demonstrates the placement of the catheter into the tunneling rod.

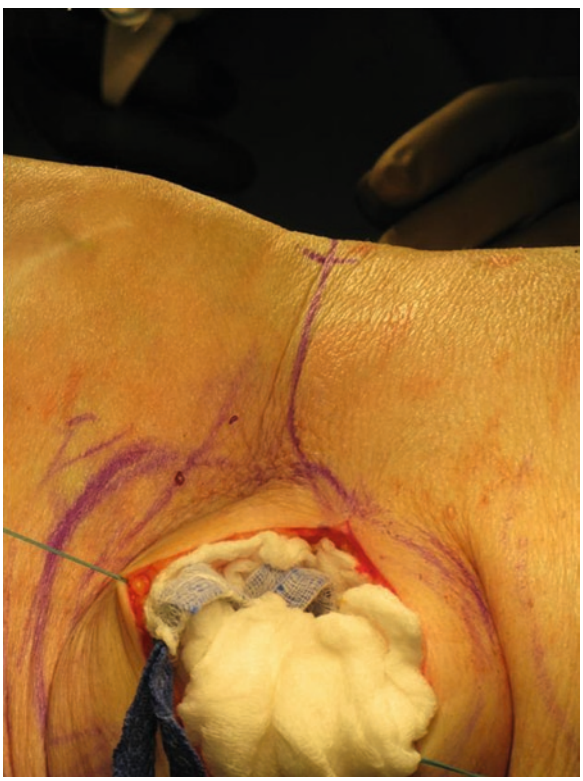

Figure 24.1. Marking the skin for the tunneling course using the two-step technique.

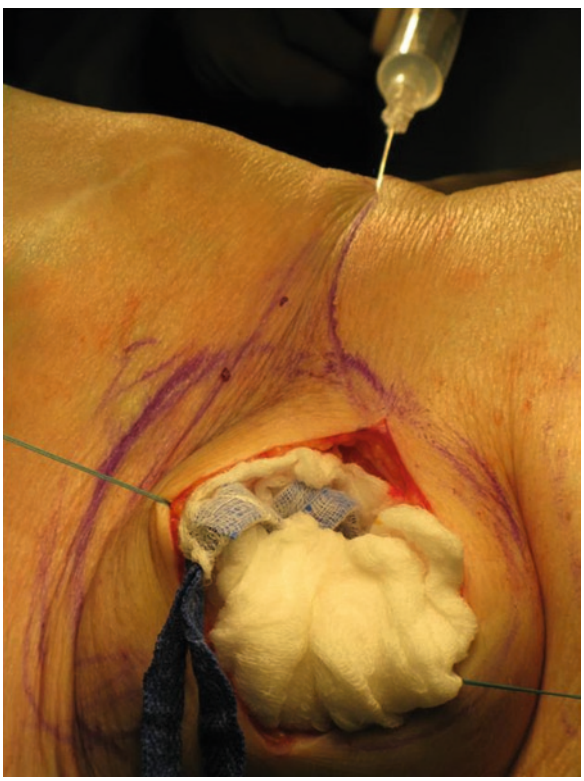

Figure 24.2. Local anesthesia for tunneling.

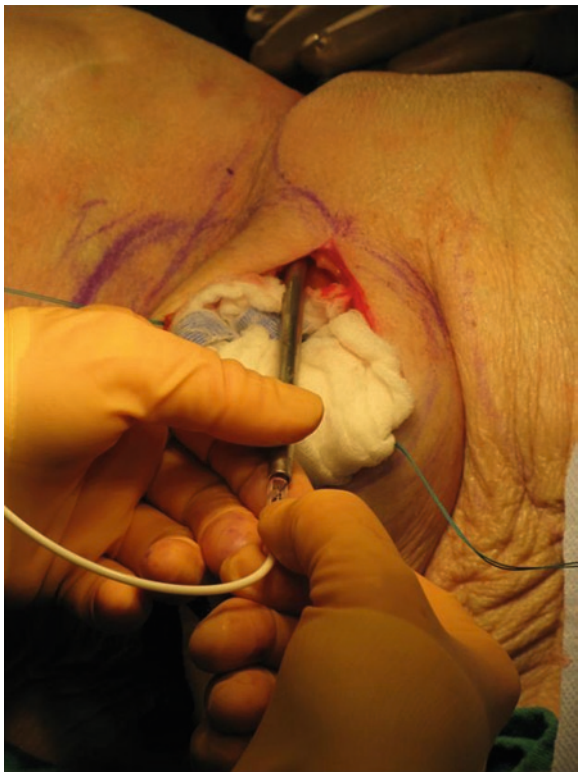

Figure 24.3. Completion of step one with the tunneling rod in the spinal incision.

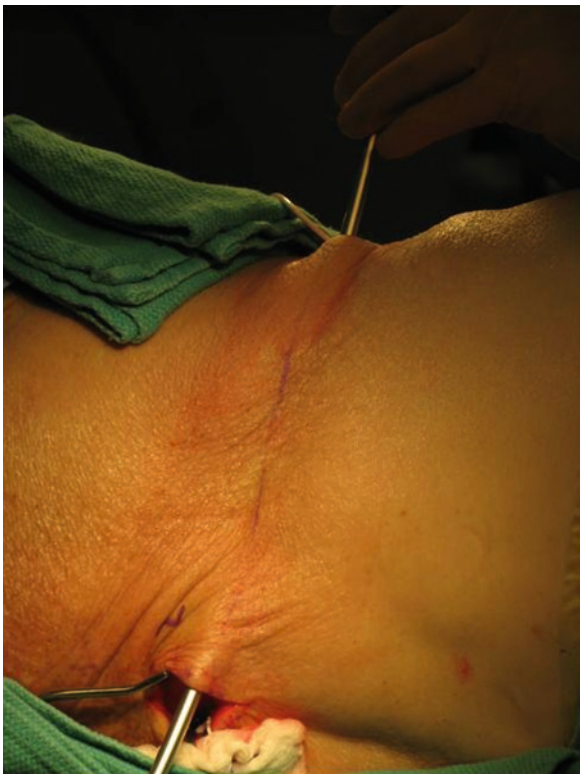

Figure 24.4. Two-pass tunneling approach.

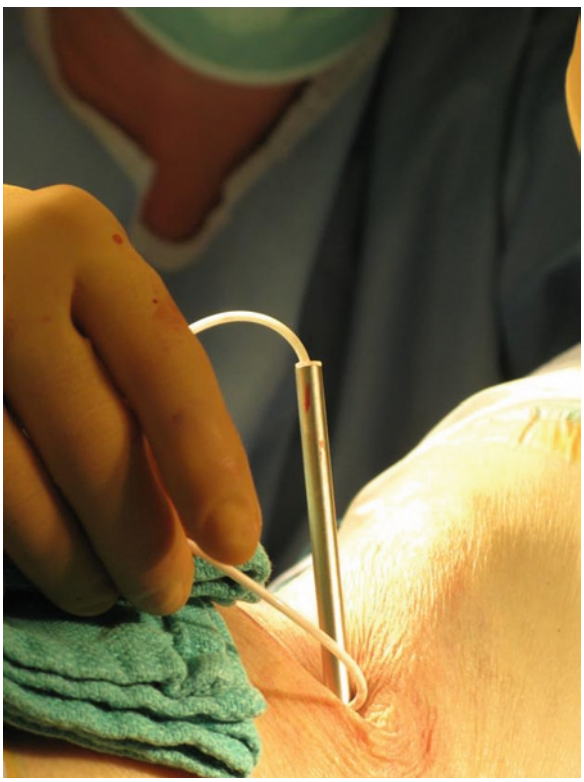

Figure 24.5. Placement of the catheter into the tunneling rod.

During the course of tunneling, the physician should use palpation to determine that they are staying at proper depth. Ideally, the tunneling rod should be palpable in the subcutaneous tissue with proper depth to avoid invading the dermis, but superficial enough to avoid penetration of unintentional structures.

The physician may tunnel from the spinal incision to the pocket or from the opposite direction. Regardless of the direction chosen the physician must be aware of the risk of injuring the catheter as it enters the spinal structures, and should be vigilant in avoiding the catheter on either entry or exit of the tissues with the rigid tunneling device.

Once tunneling is completed, the catheter should be prepared in the pocket for attachment to the pump with proper trimming and confirmation of proper flow of cerebral spinal flow. In the spinal incision, a strain relief loop should be created prior to wound closure to help avoid catheter migration.

Risk Assessment

1. Complications from the tunneling component of the procedure are rare in the overall consideration of pump morbidity. Table 24.1 reviews some of the more common problems seen in clinical settings.
2. A hematoma can develop when the tunneling rod disrupts a vessel during passage.
3. Tunneling too superficially can lead to discomfort and in some cases erosion through the tissue.
4. Tunneling too deep can lead to the puncture of the bowel, lung, or other vital structures.
5. Infection can develop in the tract if the tunneling rod or catheter becomes contaminated.
6. In obese patients, the ability to tunnel may be limited due to inadequate length of tunneling tools.
7. In emaciated patients, tunneling may be difficult secondary to lack of subcutaneous fat.

Risk Avoidance

1. Even though complications of tunneling are rare, they still may occur and the clinician should take all possible steps to avoid risks to the patient.
2. In patients with a high risk of bleeding, preoperative laboratory evaluation should be carefully reviewed with a focus on platelet function and clotting indices. If any sign of swelling develops in the tunneling course, pressure should be applied in the postoperative period with compression dressings and ice packs.

Table 24.1. Reducing risks of tunneling for intrathecal pumps.

Tunneling risk	Physician action
Too deep; may puncture viscera	Enter tissue in the subcutaneous tissue and palpate the tunneling rod as it is advanced
Too shallow: may erode	Enter tissue in the subcutaneous tissue and palpate the tunneling rod as it is advanced
Large body habitus	Use a two-pass technique
High risk of infection	Use a one-pass technique
Hematoma along the tract	Check preoperative clotting factors, apply pressure if swelling develops, surgical drainage if needed
Emaciated patients	Avoid tunneling in the dermis

3. When advancing the tunneling rod, the physician should palpate the tunneling rod with a focus on avoiding the dermis. In severely protein-deficient patients, this may be difficult to accomplish.
4. The clinician should be able to palpate the tunneling rod through its entire passage. By accomplishing this goal, the doctor can avoid the risk of tunneling at depths that may lead to tissue damage.
5. Tunneling may require the physician to be placed in physically uncomfortable positions to achieve the proper angle to place the rod. This can lead to getting outside of the sterile field and contamination of the tunneling tool or the catheter. This problem highlights the need to prep and drape widely in the patient undergoing an intrathecal device. Other helpful factors would be vigorous irrigation of the tunneling tract with antibiotic solution.
6. In obese patients, the measurement of the tunneling distance required at the time of marking the course should be accomplished. This distance should be compared to the length of the tunneling tool. In cases where the distance is longer than the available tunneling device, a two-step technique should be used. This alteration in technique will lead to a successful procedure and reduce the risk of improper depth of tunneling.

Conclusions

The placement of a permanent intrathecal device requires attention to detail and vigilance at each step of the procedure. Much of the physician's attention is placed on the placement of the catheter and the creation of a pocket. It is very important to give adequate consideration to the tunneling element of the process since it has a profound impact on achieving a successful outcome.

Supplemental Images

See Figures 24.6–24.8.

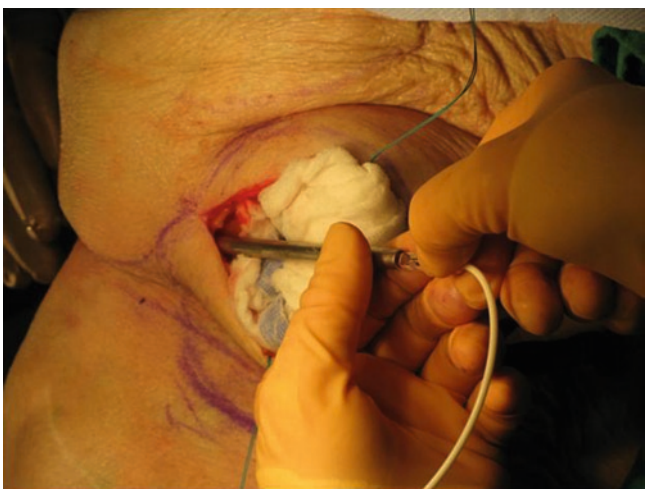

Figure 24.6. The tunneling rod must stay in the proper tissue plane to assure the catheter is not superficial, which can lead to erosion or deep, which can result in patient injury.

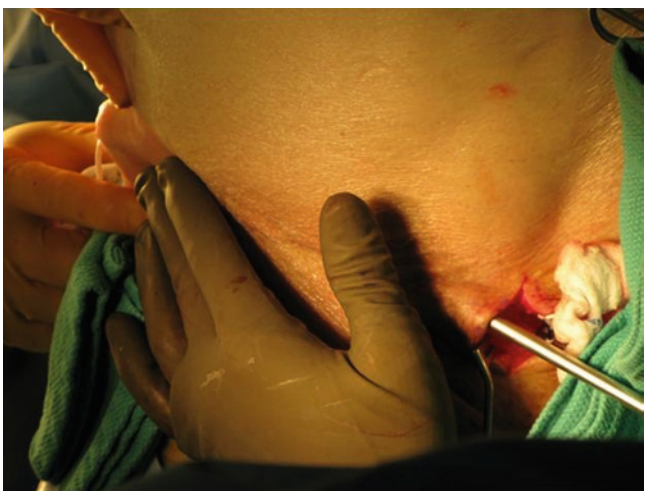

Figure 24.7. The tunneling rod should be palpable as it is passed in the tissue to monitor depth.

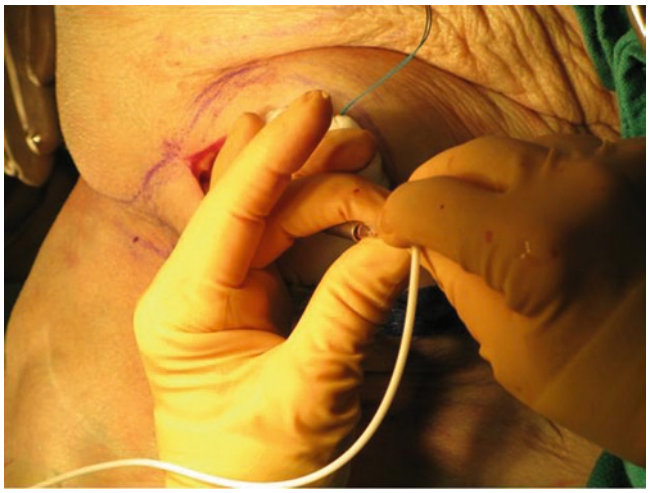

Figure 24.8. The tunneling process is completed when the catheter is secured to the pump connection mechanism.

Suggested Reading

1. Follett K, Burchiel K, Deer T, et al. Prevention of intrathecal drug delivery catheter complications. *Neuromodulation*. 2003;6(1):32–41.
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Pocketing for Intrathecal Drug Delivery Systems

Timothy R. Deer and C. Douglas Stewart

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Introduction

The focus of much of the implantation of the intrathecal pump is on the proper delivery of the catheter to the spinal fluid and the subsequent anchoring and tunneling. Many critical aspects also exist for creating a pump pocket. These points will be examined in this chapter.

Technical Overview

The incision of skin, separation of tissue planes, and hemostasis of the wound are factors we must focus on when creating a pump pocket. There are several steps that must be taken into consideration prior to doing the surgical components of the procedure. The physician

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should closely evaluate the patient's bony structure to evaluate the location of the most inferior rib margin and the anatomy of the anterior iliac spine. Attention should also be given to the patients existing scars and skin lesions that may affect pocket creation. Evaluation of local infection should be performed on the skin with the pocket location being altered based on any infectious appearing areas. An evaluation should be performed to determine whether the patient has acceptable nutrition to tolerate the placement of the device in the subcutaneous tissue or whether a need exists to place the device below the fascia. Finally, an evaluation should be done to determine whether the patient has skin viability to handle the procedure. This point may be important in patients on long-term high-dose steroids, renal disease, or with chronic skin diseases.

Once the preoperative assessment is completed, the patient is taken to the operating theater and positioned. When positioning the patient, the placement of the pocket must be given consideration. The abdomen must be properly exposed and draping should allow for easy visual inspection of the surgical field, rib margin, pelvis, and umbilicus. This exposure will allow the physician to properly utilize the information obtained in the preoperative period.

Another area of concern is the need to maintain a sterile field on the abdomen while placing the catheter, using fluoroscopy, and anchoring the catheter. This often requires manipulating the fluoroscopy machine from an anterior–posterior view to a lateral view with close contact above the abdomen. The author recommends using a three-quarter sheet over the abdomen until it is time to make the pocket. This will reduce the risk of secondary contamination.

Once the patient has been properly prepared, the surgeon makes the skin incision to initiate pocket formation. Prior to incision, the patient must be properly anesthetized with either local anesthesia, intravenous sedation, or both. The incision should be made with the skin retracted to a taut orientation. A #11 or #15 blade is the most commonly used instruments for incision. The incision can be made to the desired depth, which can be used as an entry point for pocket dissection, or the incision can be made just below the dermis and the depth can be achieved with cutting electrothermal dissection. The normal depth of the pocket ranges from 1 to 3 cm based on physician preference. The pocket can be made by sharp dissection with surgical scissors, or by blunt dissection with the surgeon's hand, or with the blunt portion of an instrument. The method of pocket dissection chosen is based on physician preference and training. The pocket should be 110–120% of the total volume of the pump. The physician may use the pump to measure the pocket size as dissection is carried out. If the pocket is too large, it may lead to pump movement and even result in the pump flipping. If the pocket is too small, it may lead to tissue pressure and possible discomfort, or in worse case scenarios tissue erosion with loss of the device.

Regardless of dissection technique, the tissue should be manipulated gently to avoid the later complication of seroma. If epinephrine is placed in the local anesthetic, it may retard some small vessel bleeding, but can also cause a delay that can lead to bleeding after wound closure. The physician must be aware of this issue. Hemostasis can be achieved by electrocautery, suturing of the vessel, and by applying pressure by packing the wound with antibiotic-soaked surgical tapes.

Once the pocket has been properly sized, the pump has been tested for proper fit, and the catheter has been tunneled to the pocket, the physician can connect the pump to the catheter and secure the connection to avoid disruption of the system. Prior to placing the pump into the pocket for the final time, the nonabsorbable suture is placed into the tissue. The suture can then be applied to suture loops on the pump, which will secure its position. The author prefers suture loop pumps, but an alternative is to use a Dacron pouch, which allows suturing of the pouch to hold to the pump in place. The downside of the pouch is scarring over time that may make future revisions difficult. As the pump is placed in the pocket, the implanting doctor needs to pay attention to the location of the side port and pump catheter connector. The shape of this part of the pump can irritate the tissue and potentially cause pain. The patient's body habitus should be considered when placing the

side port and the connector and the position should be noted in the operative note if it varies in individual patients.

Once the clinician is pleased with the pump pocket and device placement, the pocket must be closed. The pocket should be irrigated vigorously with antibiotic solution and then the tissue brought together with a two- to three-layer closure. The choice of suture is at the discretion of the implanter. The author prefers absorbable monofilament suture such as monocryl. Sterile surgical tapes can be applied on the skin surface, or staples may be used in some cases. An abdominal binder can be helpful in reducing postoperative pain, and may help in the reduction of pocket seroma or hematoma.

Risk Assessment

1. The pocket may become infected. This can be superficial or involve the deeper tissues and the device.
2. Bleeding within the pocket can cause a hematoma resulting in wound dehiscence and breakdown and ultimate loss of the device.
3. Seroma occurs when the tissue seeps serosanguinous fluid that results in pocket pressure and potential pain, wound dehiscence, and loss of the device.
4. A pocket that is too large can lead to pocket flipping, seroma formation, and eventual catheter complications.
5. A pocket that is too small may lead to pain, tissue necrosis, and erosion of the metal through the skin.
6. A pocket that is created close to the rib or anterior superior iliac spine can lead to discomfort when sitting, lying, or changing positions.

Risk Avoidance

1. Careful attention to detail is critical in preventing infection. This involves preoperative assessment, prophylactic antibiotics, proper prepping and draping, tissue irrigation, and attention to wound closure.
2. The avoidance of pocket bleeding can be achieved by attention to preoperative clotting indices, careful handling of the tissue during dissection, and hemostasis by electrocautery, suturing of vessels and tissue pressure to clot small bleeding vessels that may not be initially obvious.
3. Seroma cannot always be avoided, but the likelihood of seroma can be reduced by using careful attention to detail when dissecting the pocket. The tissue should be handled carefully, electrocautery should be used judiciously, and bleeding vessels should be controlled prior to wound closure. It is also important to size the pocket properly for the device. Tissue pressure in the postoperative period may be helpful in reducing seroma. This can be achieved by abdominal binders, elastic wraps, or by pressure dressings.
4. Pocket sizing should be done carefully, checking the pocket with the actual device when the size of the pocket is felt to be adequate. In this method, the pocket can slowly increase in size until it is ten to twenty percent bigger than the volume of the pump. In the future, sizing templates would be helpful in achieving proper size, and depth of the pump.
5. The physician should assure that there is 5 cm or more between the pump location and the bony landmarks of the ribs and the bones of the pelvis. This should allow for enough room when standing, sitting, and lying avoiding bony irritation of the pump site. In cases of scoliosis, kyphosis, small stature, and other body habitus irregularities, the placement of the pump may be in contact with the bone even with the best effort to avoid such contact.

Conclusions

Successful pump placement requires attention to detail and execution of several critical steps. The placement of the pocket is more than simply making and incision and separating tissue. It involves the use of strategy, careful planning, and surgical skill to create a pocket that results in a good initial outcome and reduces the need for future revisions and reoperations. The other issue is patient satisfaction and comfort, which can be enhanced by following the edicts noted in this chapter.

Supplemental Images

See Figures 25.1–25.4.

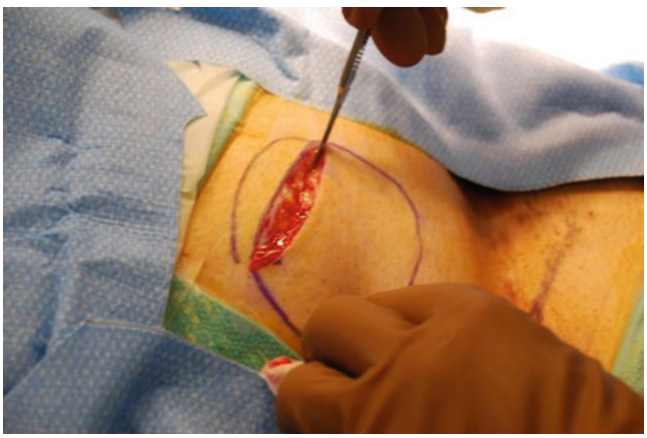

Figure 25.1. Appropriate pocket incision length and location.

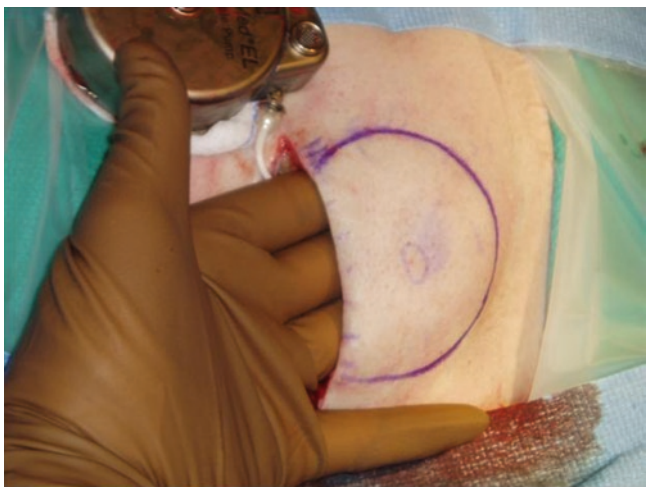

Figure 25.2. The physician should evaluate pocket depth and size prior to pump implant.

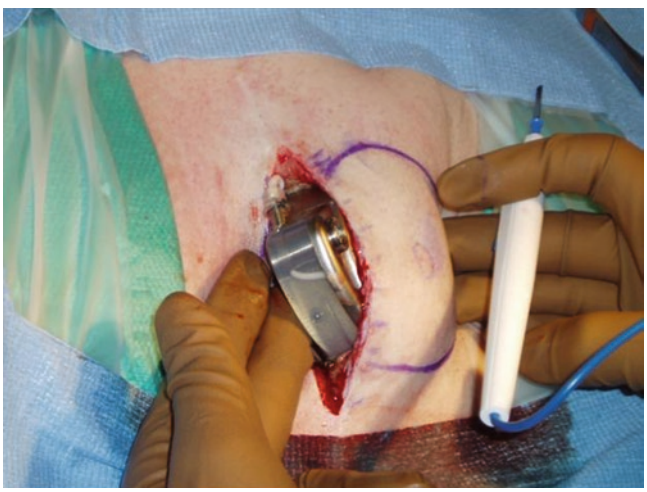

Figure 25.3. Proper orientation of the pump in the pocket with the side port at the 1 o'clock orientation.

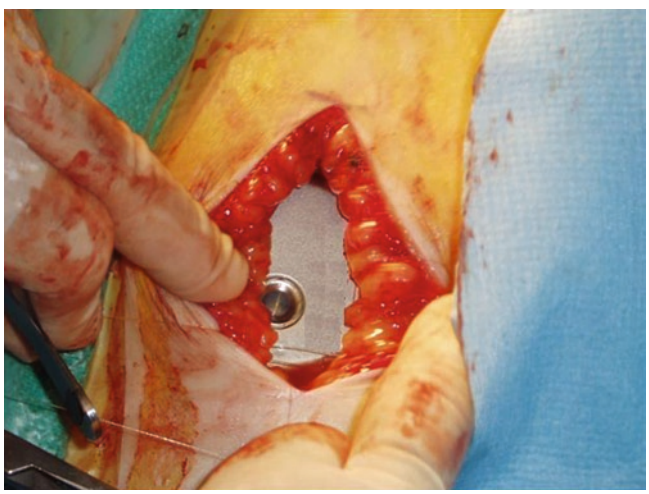

Figure 25.4. The tissue must be loose enough to close without pressure on the tissue edges.

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26

Drug Selection for Intrathecal Drug Delivery

Timothy R. Deer

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Introduction

The use of intrathecal agents to treat pain and other diseases such as spasticity is based on the principle that delivering drugs directly to the cerebral spinal fluid (CSF) bypasses the first-pass effect and results in a higher degree of effectiveness when compared with other routes of delivery such as the oral or transdermal approach. The result of this improvement in delivery is a favorable equipotent dosing comparison. It also results in less impact on the end organs and overall reduced systemic drug exposure.

The selection of the proper drug to use in an individual patient is complicated by disease state, patient characteristics, and the character of the pain which afflicts the patient. This chapter examines the options for drug delivery in the intrathecal space. These principles can be applied when managing the trial to see whether someone is a candidate for implant or in the setting of managing a permanent implant.

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Technical Overview

In the United States, the Food and Drug Administration (FDA) has approved three drugs for chronic continuous intrathecal use. These agents are morphine and ziconotide for the treatment of pain, and baclofen for the treatment of spasticity. It has become common practice in the United States and throughout the world to use other agents in patients who have unacceptable relief or unacceptable side effects from the use of these three standard substances. The author does not recommend or endorse the use of off-label medications, and the decision to use drugs in an off-label fashion is a case-to-case decision made by the managing physician. In the event, the doctor does choose to use off-label medications, several safety factors should be considered. Medications are often used off-label when three conditions are met; (1) Animal and human safety data support the use of the agent. (2) Other clinicians in the field use the drug in a similar fashion. (3) The literature supports the use of off-label medications in the form of studies or consensus guidelines. As a guide to clinical practice and an effort to improve patient safety, algorithms have been created by well-published experts on the proper selection and dosing of both labeled and off-labeled medications based on patient response. These algorithmic selections are based on animal safety data, human safety data, clinical efficacy publications, and clinical experience. These consensus algorithms shape current practices on drug selection and continue to evolve, with new studies and clinical experience.

The first well-developed and peer reviewed consensus paper was published in 2000 by Portenoy and Hassenbusch. This paper was preceded by a survey that involved physicians from the United States, Europe, and Australia. This survey found that more than 35% of patients failed to achieve therapy goals with morphine as a solo agent. The survey was used in addition to an extensive literature review of animal and human studies on intrathecal agents for safety and efficacy. The resulting analysis led to a consensus meeting and subsequent publication. This paper, published in the *Journal of Pain and Symptom Management*, recommended morphine as the only first-line agent for the treatment of pain, with an algorithm for alternatives once morphine failed or had unacceptable side effects. The second line of therapy based on established criteria included hydromorphone as an alternative opioid, or the addition of a nonopioid adjuvant such as bupivacaine or clonidine to morphine in neuropathic states. Figure 26.1 presents the algorithm from 2000.

In 2003, the authors felt compelled to reexamine the process and the clinical information that may impact the treatment recommendations. The process of reviewing the bench and clinical research was repeated adding new information and clinical investigations. This review led to changes in the recommendations. In this publication from 2003, hydromorphone was advanced to a first-line agent equal to morphine. The reasoning included equivalent efficacy data, equivalent or superior safety data, and the possibility of reduced risk of intrathecal granuloma with hydromorphone. The algorithm from 2003 is presented in Figure 26.2.

The most recent algorithm for intrathecal drug selection was published in the journal, *Neuromodulation: Technology at the Neural Interface*, in 2007. This updated algorithm, seen in Figure 26.3, involved a review of all literature published from 2003 to 2007 that had not been considered in the 2003 publication. The consensus of experts determined that first-line therapies should include morphine, hydromorphone, and ziconotide (which was FDA approved for primary use during the 4-year period). Other significant changes includes adding fentanyl as a solo agent as a second-line option, and adding combination therapies including opioids with bupivacaine or clonidine, but also with ziconotide. As the algorithm is followed, we see clonidine as a solo agent for neuropathic pain and sufentanil as an alternative opioid. These changes in the algorithm may result in salvage of potentially poor outcome due to disease progression, change in pain characteristics, drug tolerance, or unacceptable side effects from the previously selected drug. The other major change seen in the currently accepted algorithm is recommendations to lower opioid concentrations and dosing in an effort to reduce the risk of inflammatory masses or granulomas. These new drug concentration and dosing recommendations are seen in Table 26.1.

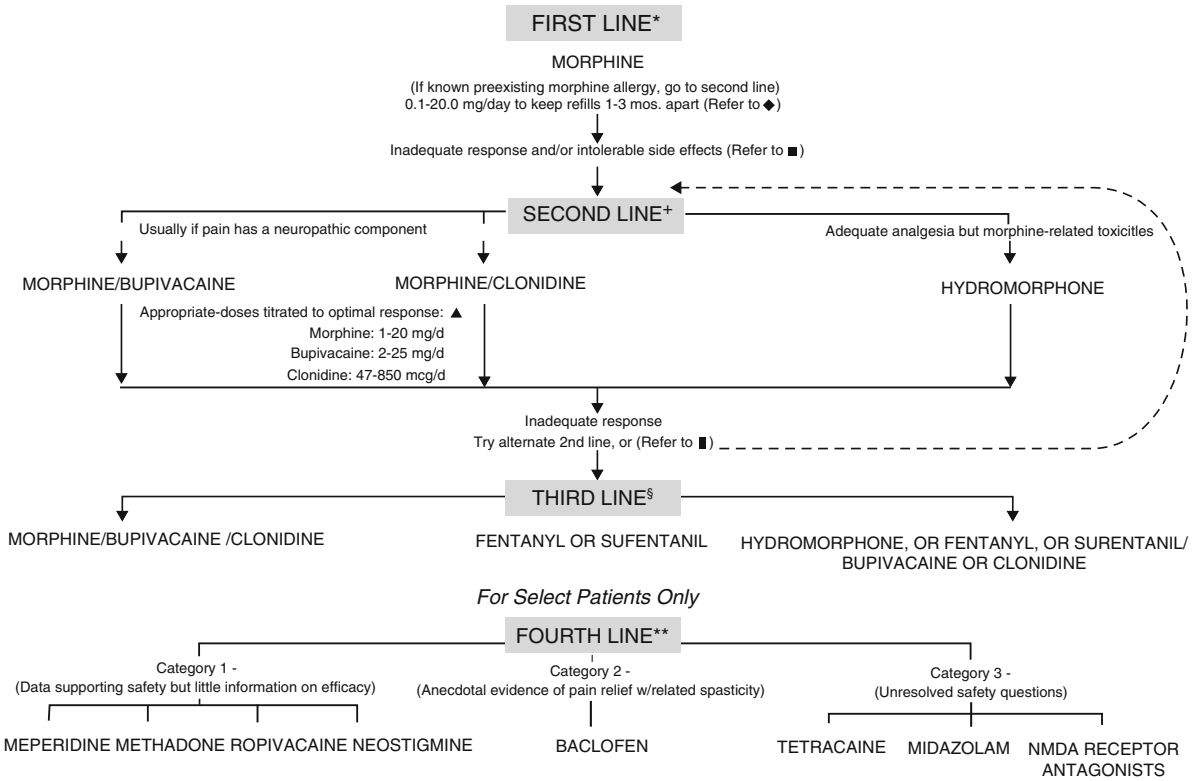
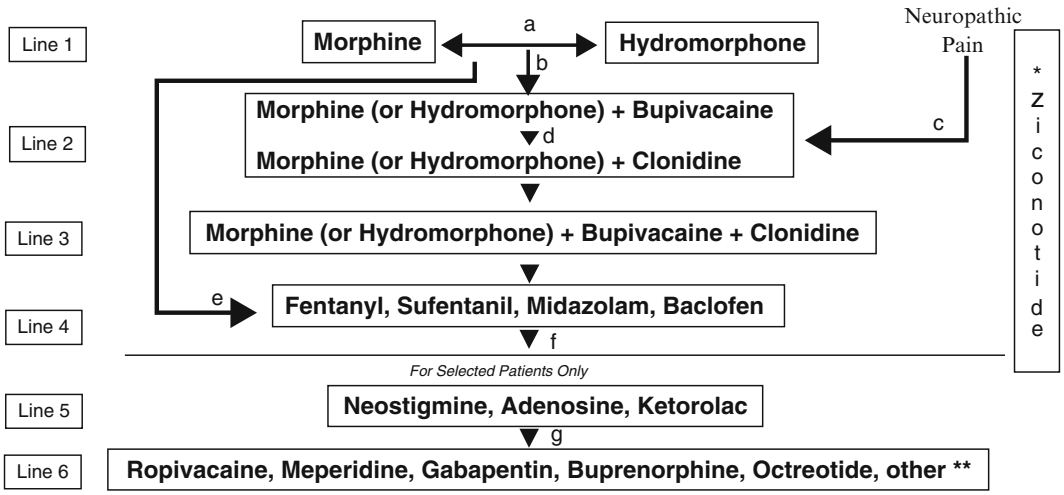


Figure 26.1. 2000 Polyanalgesic Consensus Conference Guidelines. (Reprinted from Journal of Pain and Symptom Management, Vol 20, Portenoy, RK et al, PolyAnalgesic Consensus Conference 2000 © 2000 U.S. Cancer Pain Committee).



*The specific line to be determined after FDA review
**Potential spinal analgesics: Methadone, Oxymorphone, NMDA antagonists

a. If side effects occur, switch to other opioid.
b. If maximum dosage is reached without adequate analgesia, add adjuvant medication (Line 2).
c. If patient has neuropathic pain, consider starting with opioid monotherapy (morohine or hydromorphone) or, in selected patients with pure or predominant neuropathic pain, consider opioid plus adjuvant medication (bupivacaine or clonidine), (Line 2).
d. Some of the panel advocated the use of bupivacaine first because of concern about clonidine-induced hypotension.
e. If side effects or lack of analgesia on second first-line opioid, may switch to fentanyl (Line 4).
f. There are limited preclinical data and limited clinical experience; therefore, caution in the use of these agents should be considered.
g. There are insufficient preclinical data and limited clinical experience; therefore, extreme caution in the use of these agents should be considered.

Figure 26.2. 2003 Polyanalgesic Consensus Conference Guidelines. (Reprinted from Journal of Pain and Symptom Management, Vol 27 / Issue 6, Hassenbusch, SJ et al, PolyAnalgesic Consensus Conference 2003, pp 540–563 © 2004 U.S. Cancer Pain Committee).

Line #1:	(a) Morphine	↔	(b) Hydromorphone	↔	(c) Ziconotide
Line #2:	(d) Fentanyl	↔	(e) Morphine/hydromorphone + ziconotide	↔	(f) Morphine/hydromorphone + bupivacaine/clonidine
Line #3:	(g) Clonidine	↔	(h) Morphine/hydromorphone/fentanyl bupivacaine + clonidine + ziconotide		
Line #4:	(i) Sufentanil	↔	(j) Sufentanil + bupivacaine + clonidine + ziconotide		
Line #5:			(k) Ropivacaine, buprenorphine, midazolam, meperidine, ketorolac		
Line #6:			**Experimental Drugs** Gabapentin, octreotide, conopeptide, neostigmine, adenosine XEN2174, AM338, XEN, XGX180		

Figure 26.3. 2007 Polyanalgesic Consensus Conference Guidelines. (Reprinted from Neuromodulation: Technology at the Neural Interface, Vol 10 / Issue 4, Deer, T et al., Polyanalgesic Consensus Conference 2007: Recommendations for the Management of Pain by Intrathecal (Intraspinal) Drug Delivery: Report of an Interdisciplinary Expert Panel © 2007 International Neuromodulation Society).

Table 26.1. 2007 recommendations for drug concentrations and dosing.

Drug maximum concentration	Maximum dose/day
Morphine 20 mg/mL	15 mg
Hydromorphone 10 mg/mL	4 mg
Fentanyl 2 mg/mL	No known upper limit
Sufentanil 50 μg/mL (not available for compounding)	No known upper limit
Bupivacaine 40 mg/mL	30 mg
Clonidine 2 mg/mL	1.0 mg
Ziconotide 100 μg/mL	19.2 μg

In selecting the proper drug for the patient, the physician should attempt to determine the type of pain. Neuropathic pain syndromes respond less frequently to solo opioid therapies, as opposed to pure nociceptive pain syndromes, which respond well to opioids. The occurrence of side effects may also have a profound effect on making adjustments to infusion combinations.

Drug algorithm selection is not only used during continuous chronic intrathecal infusion, but also by many physicians during patient screening. When the patient fails to respond to opioid alone during the trial, many physicians will change to ziconotide, or add an adjuvant such as bupivacaine or clonidine.

End of Life

The 2007 consensus group realized the use of intrathecal agents in the terminally ill patient may be different than that of someone expected to use the therapy for long-term use. Higher concentrations of agents, and the use of agents that are not normally recommended, may be appropriate in these cases. Some of the drugs listed in this category are tetracaine, ropivacaine, and meperidine. A frank discussion of risks and benefits should occur with the health care team, patient, and the patient's significant others.

Future Research and Development

The future use of these devices may include new drugs that are not currently available. These drugs include gabapentin, adenosine, octreotide, and new conopeptides. Practitioners should pay careful attention to the peer reviewed literature in the next few years to analyze the potential of these agents that may change the way intrathecal drugs infusion systems are used. Unfortunately, the numbers of new agents in recent years have been very limited, and this scarcity of drugs has limited the options for many patients who have failed the currently available drugs.

Risk Assessment

1. Intrathecal opioids may cause tolerance and the drug effect may be lost over time. This lack of efficacy may create the need to alter drug infusions or to abandon the therapy.
2. Intrathecal opioids may impact the hormonal axis causing changes in antidiuretic hormone, and testosterone. A common complication is peripheral edema, which may occur early in the course of therapy, and be difficult to control with ongoing opioid therapy.
3. Intrathecal opioids have been associated with inflammatory masses, also called granulomas, which can result in failure of the system and may possibly lead to significant neurological injury.
4. Intrathecal clonidine has been seen to have an impact on blood pressure and may cause sedation.
5. Intrathecal bupivacaine may cause numbness, edema, urinary retention, and change in proprioception.
6. Intrathecal ziconotide may cause drowsiness, dizziness, hallucinations, and other side effects.
7. Allergies can develop to intrathecal agents. This is characterized by systemic symptoms of allergy usually developing soon after initiating the drug infusion.

Risk Avoidance

1. Some practitioners believe that tolerance can be avoided or slowed by either making dose increases at prolonged intervals of several months or by adding synergistic drugs to lessen the need for opioids.
2. Patients with long-term opioid therapy may require hormone replacement and testing. This is a problem not only with intrathecal opioids, but also with other routes of opioid administration and with chronic pain in general. The most commonly replaced drug is testosterone, but other hormones may also be affected. The development of pedal edema may be directly related to intrathecal opioid and can be treated with mild antidiuretics, compression stockings, and leg elevation. If this does not resolve the problem, the patient may benefit from drug substitution. The primary care doctor should also evaluate the patient to rule out other causes of fluid retention.
3. The formation of intrathecal inflammatory masses has been shown to be directly related to high concentrations of opioids. In particular, morphine and hydormorphone have been implicated. The polyanalgesic consensus conference in 2007 set recommended concentrations for drug infusion. These concentrations should be followed in newly implanted patients, but in patients with ongoing intrathecal therapy the use of higher concentrations may be worth the risk of granuloma formation. The treating doctor must weigh the risks and determine whether the drug should be changed, the concentration reduced, or a second drug added to the admixture. Inflammatory mass is a problem diagnosed by MRI or CT myelogram. Warning signs include loss of analgesic effect, changes in proprioception, changes in sensation, or changes in motor function.

4. Intrathecal clonidine is well tolerated by most patients with no change in blood pressure or consciousness. The dose should be initiated at low levels such as 10–30 μg/day, and interval changes should be small. The patients are at higher risk of complication when the catheter is in the high thoracic or cervical region.
5. Intrathecal bupivacaine has been shown to improve efficacy and reduce the needs of opioids for equianalgesic effect. To reduce the risk of complications and side effects, the dose should be initiated at a low level of 1–3 mg, with any change being made at very small intervals.
6. The use of ziconotide has a long history of both efficacy and side effects. Studies have been performed that compare a rapid to a slow titration when increasing the dose. These studies have shown that a slow titration markedly reduces the number and severity of complications.
7. Allergies are rare with intrathecal drugs. Most are identified during trialing. Itching may occur during trialing without the presence of a rash. In these situations, the itching often dissipates without stopping the drug. This is not an allergy, but a transient reaction to the opioid. In cases of true allergy, the drug should be immediately discontinued and allergy treatment should be initiated. Pruritus is a side effect that usually dissipates over time in the setting of a permanent intrathecal pump.

Conclusions

Intrathecal drug delivery provides hope to thousands of patients who would otherwise have no chance of achieving an acceptable quality of life. In some patients, the initial use of morphine or ziconotide leads to acceptable pain relief. Unfortunately, in a large number of patients the outcome is not acceptable and adjustments are initiated by the treating physician. In instances where drugs are used that are not approved for first-line use, the physician should use a scientific approach centered on patient safety. The previous use of agents based on physician preference, anecdotal reports, and off-label marketing is not acceptable. Algorithmic thought, vigilance, and an attention to both a good outcome and safety must be used when using intrathecal therapies.

Suggested Reading

1. Deer T, Krames E, Hassenbusch S, et al. Polyanalgesic consensus conference 2007: recommendations for the management of pain by intrathecal (intraspinal) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2007;10(4):300–328.
2. Hassenbusch S, Portenoy R, Cousins M, et al. Polyanalgesic consensus conference 2003: an update on the management of pain by intraspinal drug delivery – report of an expert panel. *J Pain Symptom Manage*. 2004;27(6):540–563.
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27 Intrathecal Pump Refills

Timothy R. Deer

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Introduction

Physicians spend a great deal of time and effort in training and continuing education to learn how to place intrathecal catheters and intrathecal pumps. In a perfect setting, the pump is placed without incident, the patient does well on a continuing basis, and the pump must be refilled at regular intervals. Many implanting doctors spend little or no time in training to learn the refill technique. While this procedure seems limited in technical difficulty, and lacking in excitement, it is very important for the continued desired outcome of acceptable pain relief and absence of complications. Vigilance is an essential part of this simple, but essential part of intrathecal drug delivery and care.

Technical Overview

Once the patient has been implanted with the intrathecal pump, telemetry is performed to establish an initial starting dose and alarm date. The patients initially are seen frequently in the physician's office to monitor for postoperative infection, assess their response to the intrathecal drug therapy, and identify the need for dosage adjustments.

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During most office evaluations, the patient's pump is interrogated, an alarm date is established, and office appointments are scheduled at least a week prior to the alarm date to ensure the pump will be refilled prior to the depletion of medication from the pump reservoir.

Prior to refilling the pump, the patient is assessed by the physician with regard to pain relief, neurological function, and any potential complications. The prescribed drug is evaluated for proper concentration, volume, and dosing. The procedure is explained to the patient and informed consent documents are completed. The patient is placed on the exam table in the supine position and pump telemetry is performed based on manufacturer's recommendations. The pump telemetry informs the physician of the patient's demographic information and the pump and catheter specifications including model number, serial number, and catheter length. Pump telemetry also informs the physician of the medication settings of the pump including drug concentration and dosage, pump reservoir volume, and alarm date. Currently available programmable pumps have information on the calculated volume of the pump, but actual volumes are not determined by the reading of the device. In pumps that are constant flow and "nonprogrammable," the volume is based on timing and the number of days between refill events. These pumps cannot be interrogated by telemetry, and give no computerized information to the managing physician. The number of nonprogrammable pumps in the United States is limited and physicians who are not familiar with the devices should consult with the manufacturer's insert and technical support prior to moving forward. Programmable pumps are the most common type of implant in both the United States and most International settings where pump therapies are offered.

The pump refill kit should include sterile drapes; a pump template; proper noncoring Huber needles for intrathecal pump port access; syringes; micropore filters to reduce the risk of introduction of contaminants; and tubing with proper stop cocks that allow change in flow direction, stoppage of flow, and evaluation of pump pressure. The prepping process should be performed with a solution that is proper for local pathogens and should be done widely outside the area of planned pump refill. The prep should be initiated at the center of the pump site and then moved outward in a circular motion until the entire pump area is cleansed. This process should be repeated on at least three occasions. Once the pump is properly prepped, the field should be covered with a fenestrated drape. While maintaining a sterile field, the central port of the pump is accessed by using a template and inserting the noncoring Huber needle of the appropriate gauge perfectly parallel with the center port in the pump. The pump lumen is secured when the physician or nurse feels the needle contact a metal surface, after passing through a rubbery port structure. The medication remaining in the pump is withdrawn and measured, comparing the actual volume with the programmer reservoir volume found upon the initial pump telemetry. After rechecking and verifying the new medication concentration with the concentration noted on the initial telemetry, the new medication is injected into the pump, aspirating every 5 mL to verify continued needle placement in the pump. Once all of the medication is injected into the pump, the needle is withdrawn from the pump and a bandage is applied to the puncture site. The pump programmer is then used to verify the drug concentration, make dosage adjustments, and reset the reservoir volume to reflect the amount of medication placed in the pump. The new alarm date is noted and the patient is given an appointment for at least 1 week prior to the alarm date. All tracings should be confirmed by at least two members of the clinical team including the physician.

Risk Assessment

1. The greatest risk to the patient during the refill process is placing the wrong drug or concentration into the device. This can lead to death or serious injury.
2. Infection is a risk of pump refill. This can lead to meningitis, abscess, or death.

3. The patient can develop sensitivity to the prepping solution leading to a rash over the refill site.
4. The catheter can be damaged with the placement of the needle for pump refill.
5. Pump programming is an essential part of every refill. Improper programming can lead to overdose, under dose, withdrawal, serious neurological injury, or death.
6. Overfilling of the pump can lead to damage to the bellows and pump failure.
7. Inadvertent placement of the drug into the subcutaneous area can lead to abnormal reactions to the drug in the immediate period after pump refill.

Risk Avoidance

1. Prior to refilling the pump, the physician and nurse should review the prescribed drug, concentration, and dose and double check it against the drug delivered by the pharmacy provider.
2. Careful attention to sterile technique, use of micropore filters, and sterile handling of the drug solutions are critical in reducing infection. Any redness or swelling of the pump pocket should lead to close observation, and may necessitate incision and drainage of the pump.
3. The patient's skin should be evaluated prior to each refill. If a rash develops, the cleaning solution should be changed, and if necessary, a dermatologist should be consulted.
4. The catheter should be placed below the pump at the time of implant. If the catheter moves to an area in front of the device, it may be injured. This is why it is critical to aspirate after every 5 ml is injected.
5. All programming should be prescribed by the physician and confirmed by at least two members of the clinical team including the physician.
6. The pump volume to be replaced should be reviewed at the time of each refill. The volume should never be exceeded. Excessive filling of the pump could lead to injury of the internal pump mechanics, and failure of the device.
7. It is important to place the needle through the rubber port and then to feel it stop at the metal back portion of the lumen. Once it is in proper position, the existing drug should be aspirated and compared to the calculated volume. If the volumes are within 25%, it considered reasonable for refill. In cases where the aspirated volume is more than 25% of the expected volume, the physician should do additional workup on the integrity of the pump. Once the refill process is started, the drug should be aspirated at 5 cc intervals.

Conclusions

The procedure of refilling a pump appears simplistic to the casual observer. The serious nature of this process may be undervalued by many practices and physicians. The pump refill process is very important and should be taken very seriously with attention given to prerefill preparation, vigilance during refill , and follow-up afterward to access any potential complications.

Supplemental Images

See Figures 27.1–27.11.

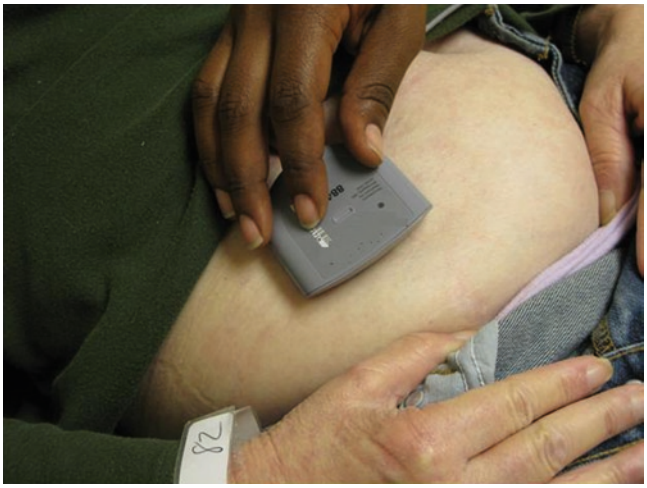

Figure 27.1. Computer telemetry to access the status of the pump prior to pump refill.

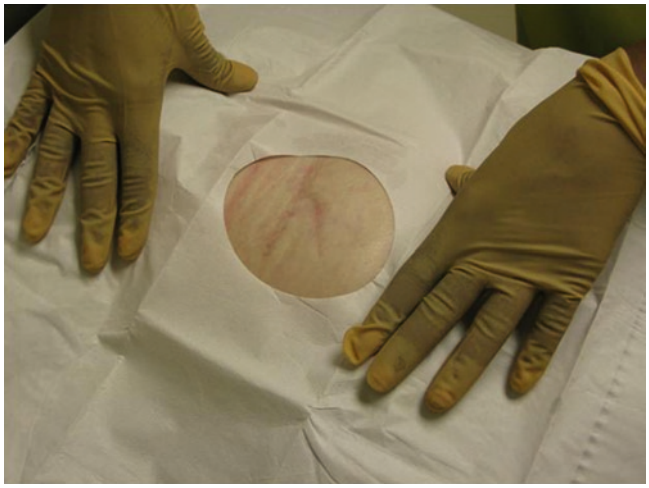

Figure 27.2. After carefully prepping the abdomen on multiple occasions, sterile drapes are placed.

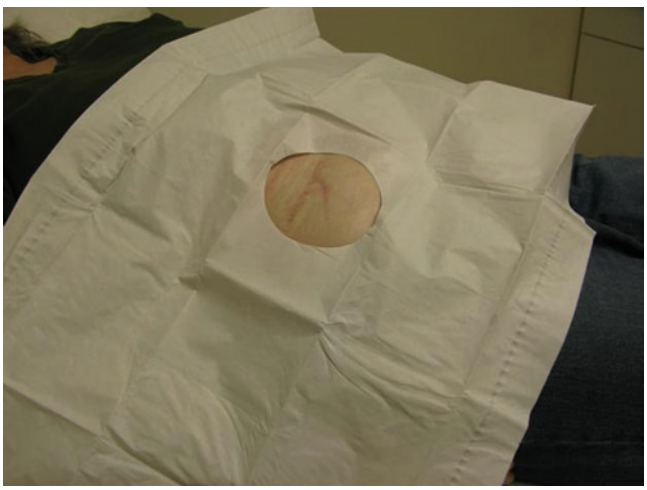

Figure 27.3. The patient should be assessed to orientation of the pump, and as to evidence of any skin abnormalities.

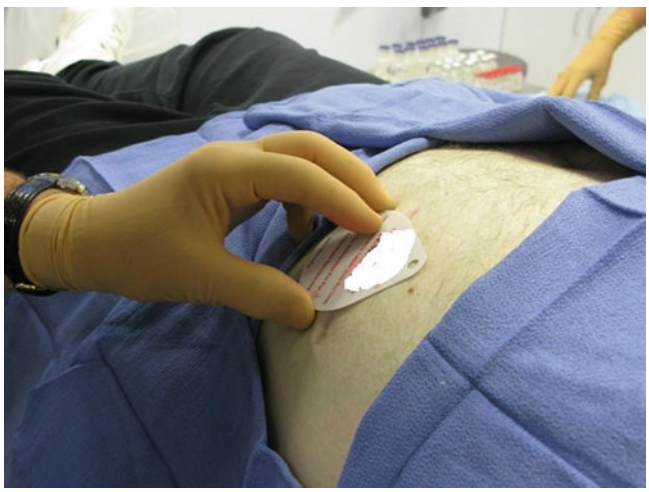

Figure 27.4. In some cases, laser-guided fluoroscopy can be used to refill the pump. This may be very helpful in the obese patient or in a patient with an abnormal abdominal wall secondary to scar or poor tissue integrity.

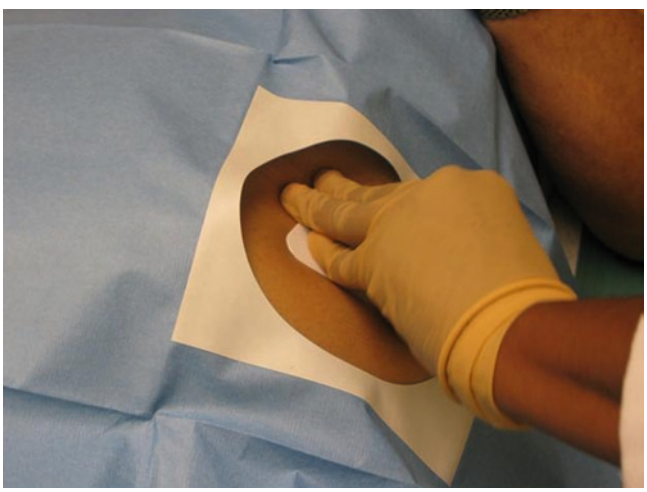

Figure 27.5. Sterile dressings are placed once the pump is refilled.

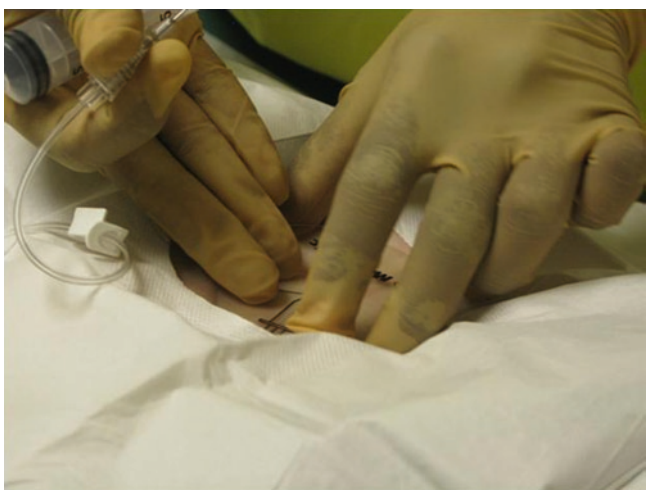

Figure 27.6. A template can be used to help identify the port of the intrathecal pump.

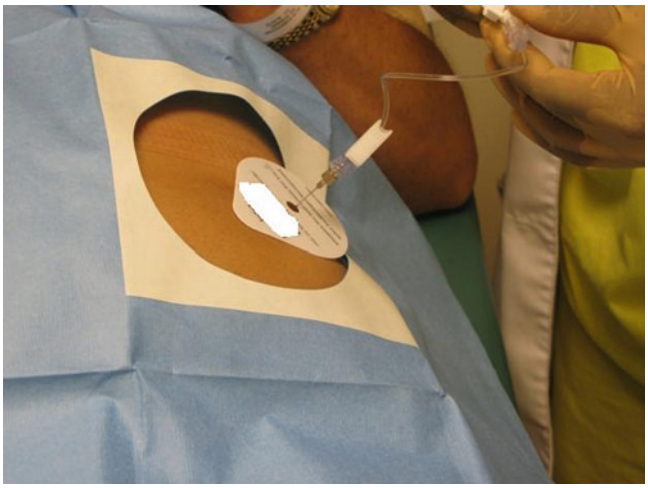

Figure 27.7. After securing the needle in the lumen, the pump should be aspirated and compared to the expected volume.

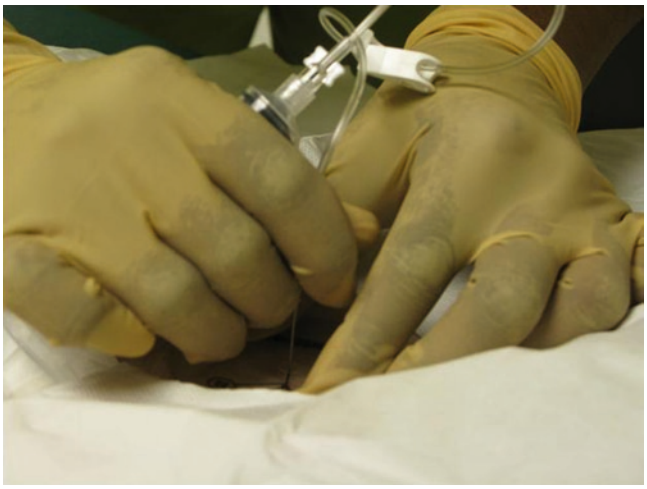

Figure 27.8. The needle should be secured in the pump lumen and secured based on landmarks and successful aspiration.

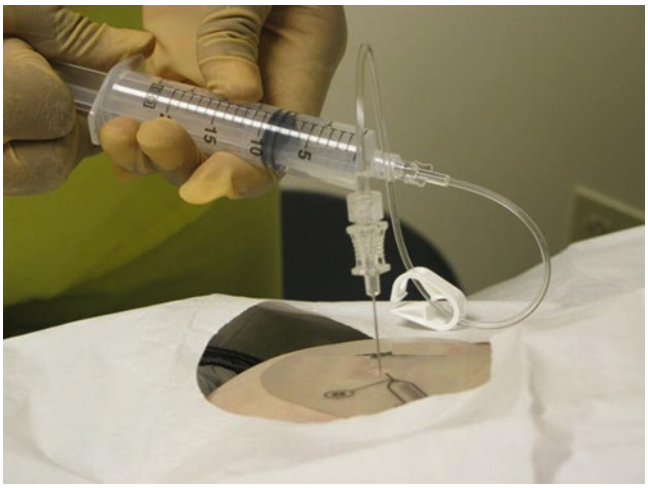

Figure 27.9. The infusate should be delivered in small increments with frequent aspiration to assure that the needle does not slip outside of the lumen.

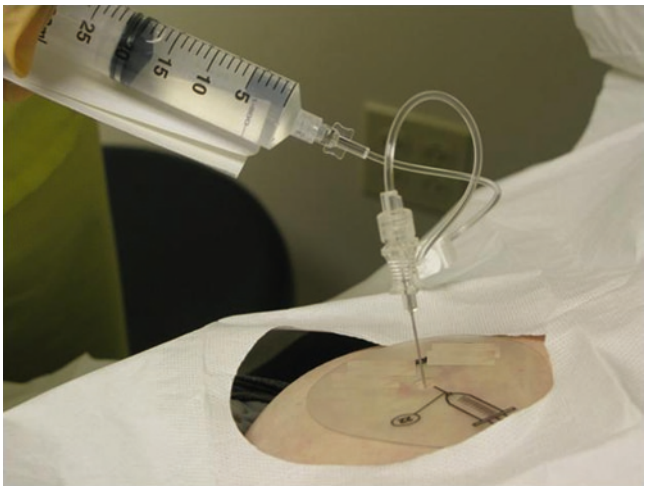

Figure 27.10. An example of pump refill using sterile morphine with intermittent aspiration and filling.

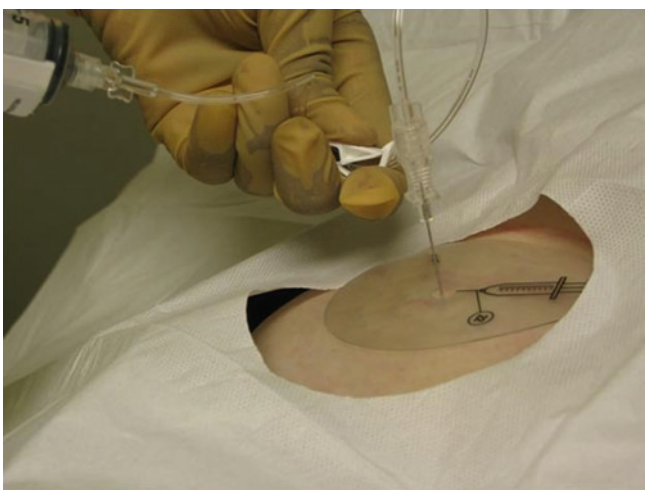

Figure 27.11. The tubing should be clamped off prior to removing the needle to avoid drug leaking into the surrounding tissue.

Suggested Reading

1. Medtronic Synchromed II Manual http://professional.medtronic.com/downloads/itb/M221311A_a_014.pdf
2. Codman 3000 http://www.codman.com/DePuy/products/Products/neuromodulation/pumpfeatures/index.html

28

Complications of Intrathecal Drug Delivery

Timothy R. Deer

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Introduction

Intrathecal pumps are an option that allows patients who suffer from moderate-to-severe pain to have an improvement in quality of life, reduction in pain, and change in function. They also are an option for patients who are at the end of life to improve alertness, reduce fatigue and nausea, and improve survival. Unfortunately, despite the many positive attributes of these devices, they are not without risks. The complications can be classified as surgical,

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device related or drug related. This chapter focuses on the complications of intrathecal drug delivery, and on options to assess and reduce risks.

The reported incidence of adverse events range from 3 to 24%, most of which are minor and related to the drug infused. The risks of serious events such as neural injury appear to be markedly less than 1%. The majority of device complications occurs with the pump at the time of implant, but may also occur with the catheter over months or years of use. Drug-related complications could occur at any time including immediately after implant.

Complications Associated with the Neuroaxis

Intrathecal drug delivery involves the placement of a needle and catheter into the thecal sac. This can lead to an injury to the spinal cord, nerve root, or other neuroaxial tissue. The risk of needle injury is much more likely when the needle entry is above the conus medullaris, which is usually located at L1. Direct needle injury below this level is highly unlikely since the nerves float in the cerebral spinal fluid (CSF) and are usually pushed away by the needle approach. Spinal cord or nerve injury is more likely to occur due to catheter trauma to the tissues. This can occur from the catheter being thread into the conus medullaris or other portions of the spinal cord, or can occur secondary to impingement of the nerve by the catheter invading the foramen.

Infectious complications are uncommon and include meningitis. Reports of viral-induced transverse myelitis have been reported with pump catheters, but these reports are difficult to differentiate from chemical injury to the tissue.

Reports of granuloma or inflammatory mass have become a concern among those who implant and manage intrathecal drug delivery systems. The granuloma, or inflammatory mass, appears to be a chronic fibrotic, noninfectious mass that develops at the tip of the intrathecal catheter that can range from an asymptomatic problem to a major insult that can cause paraplegia. Fortunately, inflammatory masses develop slowly over time and in many cases are detected early. The most common presentations are loss of effect, sensory changes, pain in the distribution of the catheter tip, and loss of proprioception. Motor loss usually occurs late in the progression and can lead to an immediate need to intervene.

The cause of granuloma appears to occur from the long-term use of high concentration opioids. The most commonly reported opioids are morphine and hydromorphone. In a recent analysis of the published and reported data, a consensus panel recommended reducing the drug concentrations when possible to a concentration of morphine not greater than 30 mg/cc and the concentration of hydromorphone not greater than 20 mg/cc. In addition to reducing the concentration of opioids, other theories have been developed including using smaller more lipophilic molecules such as fentanyl and sufentanil, or adding bupivacaine to reduce the dose of opioid required. Some have theorized a protective effect of clonidine in reducing the formation of granuloma, but this has not been proven prospectively. There have been no confirmed cases of granuloma with ziconotide. The diagnosis is confirmed by MRI, but physical exam and history are very important in making the initial diagnosis. The MRI may be diagnostic with or without gadolinium depending on the size and location of the mass. CT myelogram is an option if the patient is contraindicated for an MRI.

Complications Involving Nonspinal Tissues

Infection of the pump or catheter can lead to explant of the device. The rate of infection varies from practice to practice but is reported from 0 to 4.5%. Infection is obvious in some cases with redness, purulent drainage, and swelling, but in some cases it may be difficult to

differentiate from postoperative skin irritation. The presence of a fever, elevated white blood count, elevated C-reactive protein and elevated erythrocyte sedimentation rate raises the index of suspicion toward an infectious process. The diagnosis is confirmed by gram stain and culture. The diagnosis can be confusing in the immunocompromised patient since the tissue reaction and blood marker elevations may be blunted. In addition to device infection, the clinician should consider other sources of fever, such as atelectasis, urinary tract infection, and drug reaction.

The noninfectious buildup of serosanguineous fluid in the pocket can lead to a seroma that may impede the ability of the wound to heal. This may be very similar to an infection in tissue appearance, and may be associated with an elevation of the white blood count. Diagnosis is confirmed by aspiration of straw colored noninfectious fluid. Treatment may include surgical drainage, simple aspiration, or conservative management.

Bleeding of the pocket or spinal incision can lead to wound dehiscence, pain, and the need for surgical drainage. Diagnosis is made by an expanding wound with pain or by frank bleeding.

The pump can cause pain because of flipping in the tissues, contact with bony landmarks, or by erosion of the device through the skin. Erosion is most commonly caused by significant weight loss and a diminished subcutaneous adipose layer. This may develop from an overall decrease in body mass index or by redistribution of fat with aging or diseases.

Complications Involving the Catheter

The most common cause of complications in intrathecal drug delivery systems are catheter related. Possible problems seen with intrathecal catheters include kinking, fracture, leak, and migration. Migration of the catheter is rare if proper anchoring and purse-string suturing is utilized. The movement of the catheter out of the spinal canal can lead to loss of pain relief or withdrawal from the infused drug. Subdural migration has been reported and can lead to decreased efficacy or in some cases overdose. Transverse myelitis has been associated with intrathecal catheters in very rare situations. If a progressive myelopathy develops in the presence of a normal MRI, a neurology consult should be obtained.

Catheter kinking, scarring, and leakage can lead to multiple clinical problems. The problem is suspected with the loss of clinical efficacy, or a higher than suspected volume of the pump reservoir at the time of refill. The diagnosis is confirmed by surgical exploration with catheter splicing of the affected area or in less severe cases by a side port dye study to evaluate flow. If the side port cannot be aspirated, a surgical exploration and potential catheter replacement should be considered.

Complications Involving the Implanted Device

Intrathecal pump patients require intermittent refills to continue to deliver drugs. This process requires access to the silastic port. The risks of refill include infection, seroma formation, inadvertent catheter access, inadvertent deposit of drugs outside the pump, and inability to access the pump. The risk of infection can be reduced by appropriate sterile technique, use of a bactereostatic filter, and antibacterial effects of local anesthetics when included in the infused agent. Infections appear to be less than one in a thousand when proper technique is used.

In a normal patient, the body creates a fibrous pocket around the pump that holds it in place and stabilizes the device. In patients with poor tissue integrity, the formation of this pocket may not develop and the device may be prone to flipping and to creating discomfort. These patients may require a Dacron pouch around the pump to establish a localized tissue reaction.

Rotor failure is a risk of currently approved programmable pumps. The problem can be diagnosed by an X-ray after the pump is programmed to give a bolus that will result in a turn of the rotor on films if it is functioning correctly. Newly developed devices that may soon be approved for use have different mechanisms of action that do not involve rotors. The newer technology will allow the care team to access the actual volume in the computer without aspirating the pump. The complications of these new pump mechanisms are not currently known, and careful observation will be necessary when these products become commercially available.

The pump side port and the main pump access port are entered by noncoring needles that reduces trauma to the materials. These needles are specific to the port of intended refill to reduce the risk of inadvertent refill into the wrong port. Unfortunately, the pump can experience failure of the lumen or side port over time that leads to a leakage of drug and a need for a revision.

Patients with drug abuse histories can sometimes be treated successfully with a pump. In some cases, the pump can be accessed by a patient or associate for the cause of drug diversion. This can lead to poor outcomes, major complications, disease transmission, and illegal activity.

Complications Involving Administered Agents

Long-term opioid infusions can lead to complications (Table 28.1–28.2). A multicenter analysis of complications has shown that these complications can impact several body systems. Intrathecally administered opioids cause multiple side effects including nausea and vomiting (25.2%), pruritus (13.3%), edema (11.7%), diaphoresis (7.2%), weakness (7.2%), weight gain (5.4%), and diminished libido (4.9%).

Peripheral edema is a rare, but bothersome side effect from opioid infusions. The mechanism appears to be related to a direct effect on the pituitary from intrathecal opioids involving antidiuretic hormone.

Clonidine is active at the alpha receptors. This drug can cause hypotension and somnolence. It can be rarely associated with severe rebound hypertension with the sudden withdrawal or reduction.

Ziconotide (SNX-111) is a synthetic analog of an N-type voltage-dependent calcium channel blocker that first isolated from the marine snail, *Conus magnus*. Ziconotide was approved for intrathecal use by the United States Food and Drug Administration in late 2004 and has shown some promise in treating refractory pain associated with cancer and acquired immunodeficiency syndrome. Common adverse events include dizziness,

Table 28.1. Frequency of complications associated with intrathecal drug delivery.

Complication	Reported frequency (%)
Constipation	50
Difficulty urinating	42.7
Nausea and vomiting	24.4–36.6
Impotence	26.8
Nightmares	23.2
Pruritus	13.3–14.6
Edema	6.1–11.7
Diaphoresis	7.2–8.5
Weakness	7.2
Weight gain	5.4
Diminished libido	4.9

Table 28.2. Complications reported with short-term intrathecal infusion of ziconotide (SNX-111).

Complication	No. of patients (%)	
	Ziconotide ($N = 72$)	Placebo ($N = 40$)
Patients with any adverse event	70 (97.2)	29 (72.5)
Patients with any serious adverse event	22 (30.6)	4 (10.0)
Cardiovascular system	24 (33.3)	4 (10.0)
Postural hypotension	17 (23.6)	2 (5.0)
Hypotension	6 (8.3)	2 (5.0)
Nervous system	60 (83.3)	14 (35.0)
Dizziness	36 (50.0)	4 (10.0)
Nystagmus	33 (45.8)	4 (10.0)
Somnolence	17 (23.6)	3 (7.5)
Confusion	15 (20.8)	2 (5.0)
Abnormal gait	9 (12.5)	0
Urogenital system	23 (31.9)	0
Urinary retention	13 (18.1)	0
Urinary tract infection	7 (9.7)	0

Adapted from: Staats PS, Yearwood T, Charapata SG et al. Intrathecal ziconotide in the treatment of refractory pain in patients with cancer and AIDS. JAMA. 2003; 291:62–70

drowsiness, psychosis, tinnitus, nausea, and fatigue. Using a slow titration protocol may dramatically reduce the adverse event incidence with this drug.

When refilling the pump, the physician and the nursing staff must be vigilant in assuring the drug placed is the intended drug at the intended concentration and dose. A policy should be in place that reduces the risk of this problem occurring.

Treatment of Complications Associated with Implanted Intrathecal Drug Delivery Systems

Treatment of Complications Involving the Neuraxis

Direct trauma to the spine or nerve roots is confirmed by MRI or CT. Once the problem is suspected, immediate neurosurgical consultation and intravenous steroids should be considered. If the catheter is in a location that may cause ongoing trauma, it should be removed when the patient is stable for surgical explants.

Ongoing CSF leak may lead to chronic headache, diplopia, and tinnitus. Treatment includes bedrest, fluids, and caffeine. If the problem persists, a blood patch should be considered, but attention should be given to sterile technique, atraumatic needle placement, and avoidance of hitting the catheter with the blood patch needle.

Once a neuroaxial infection is suspected, a workup must be rapidly initiated. Physical examination should be in detail and with great vigilance. Additional workup includes a sample of CSF, an analysis of the white blood count, and sedimentation rate. Meningitis should be treated by infectious disease in accordance with the documented pathogen. Epidural abscess requires immediate surgical decompression.

Inflammatory mass varies in its presentation and required intervention. In small granulomas, the management can consist of rotation to a different intrathecal agent and continued observation. As the mass size and clinical presentation becomes more worrisome, the options for treatment include catheter removal, catheter repositioning, and catheter revision to a new catheter. The need for neurosurgical debridement is rare and is generally only needed when motor symptoms develop.

Treatment of Complications Involving Nonspinal Tissues

The most common reason to replace an intrathecal pump is the battery being at the end of life. The procedure seems simple, but if great care and attention is not taken the outcome can be disastrous. The patient is at risk for drug overdose or withdrawal. In most reported cases of postoperative death, the cause has been a poor estimate of drug dosing. Caution should be given to postoperative monitoring, neurological checks and monitoring of oxygen saturation. Baclofen withdrawal and opioid overdose are the two most common causes of significant problems in this patient group. Both of these problems can be limited with proper monitoring and patient evaluation.

The use of routine antimicrobial prophylaxis is controversial, but it has become standard clinical practice in most treatment centers (Table 28.3). Treatment of superficial infections may be oral antibiotics, incision and drainage, and observation. The more extensive infection involving the pocket requires device removal.

Seroma treatment includes attention to reducing tissue trauma at the time of the implant. Once a seroma develops treatment includes pressure to the wound, aspiration of the fluid, or in severe or recurrent cases tissue exploration and drainage.

Postoperative bleeding can be reduced by preoperative evaluation and management of drugs that may effect blood clotting. Once a bleed occurs treatment includes pressure to the wound, aspiration of the hematoma, or surgical exploration and evacuation.

Skin irritation from the device can lead to pain, swelling, cellulitis, and eventual loss of the device. Treatment should be aggressive and involves wound exploration, pocket revision, and the consideration of a smaller pump if available.

Treatment of Complications Involving the Catheter

Treatments of catheter complications are dependent on the cause of the problem. In most cases, the catheter has to be revised, but the scope of revision may vary based on the problem. In the event that the problem is at the spinal incision or in the spine, revision can be performed at that level with a splicing of the catheter from the spine to the existing catheter to the pump. In cases where the problem is less certain, the revision must involve the entire catheter. In some instances, the problem occurs at the pump connector. This problem is suggested when the pump pocket has swelling in the setting of reduced efficacy. The clinician should open the pocket and if the problem is at the connector a revision can occur at the area within the pocket. A dye study may be necessary once the revision is completed to assure not problems exist downstream in the distal catheter.

Treatment of Complications Involving the Implanted Device

Excessive tension on the margins of the wound created during implantation can lead to skin breakdown, cellulitis, and loss of the device. To prevent this complication, the size of

Table 28.3. Recommended antibiotic prophylaxis prior to implantation of an implanted intrathecal drug delivery system.

Antibiotic	Dose and administration
Cefazolin	1–2 g iv 30 min prior to incision
Clindamycin [β-lactam allergic patients]	600 mg iv 30 min prior to incision
Vancomycin [Methicillin-Resistant *Staphylococcus aureus* (MRSA) carriers]	1 g iv over 60 min prior to incision

Adapted from: Rathmell JP, Lake TL. Infectious complications associated with chronic pain treatment. Reg Anesth Pain Med. 2006 (in press)

the pocket should be adequate to avoid tissue tension. The wound should be brought together without the need for any forced skin movement. The wound margins should have apposition that is uniform. If proper wound planning and management is performed, a pump can be placed in patients with low body mass index without complications. This group includes patients with malignancy, children with spasticity, and patients with conditions that cause a low protein balance. In this select group, the pump may need to be placed in the area under the fascia.

Flipping of the pump can occur resulting in difficulty filling the pump and failure of the catheter. The problem can be reduced by proper pocket sizing, anchoring of the pump with suture loops, or by sewing in a Dacron pouch. Treatment includes revision of the device and pocket. The most common causes of these problems include weight gain, and poor tissue integrity secondary to chronic disease.

Mechanical failure of the pump is a complication that is resolved by pump replacement. Pump replacement is also required if the pump develops a leak from the side port or main port.

Treatment of Complications Involving Administered Agents

The use of intrathecal agents can be very helpful in the majority of patients. As with any route of delivery, a side effect profile exists with drugs even when used properly. This problem cannot be avoided in the patient receiving intrathecal agents, but by using thoughtful algorithmic approaches the risks can be reduced. When problems develop, the clinician should use techniques to reduce the number of side effects. These techniques include testosterone replacement, diet changes to treat constipation, antidiuretics, and compression stockings for edema, and medications to treat disruptions of sleep.

When the patient experiences side effects from an agent, options include dose reduction, addition of an adjuvant drug to produce synergistic effects, drug rotation to an alternative agent, or reduction and removal of all intrathecally administered drugs.

When to Seek Consultation

Consultation should be considered in the preoperative period to optimize coexisting disease states. Consultation should be considered with an infectious disease specialist in the high-risk patient, or postoperatively should a problem develop. Neurosurgical or Neurology consultation should be considered when any change occurs in the neurological function in the postoperative period or over time with continued therapy.

Risk Assessment

1. Complications are more common in patients with coexisting diseases, such as diabetes, connective tissue disorders, and cancer.
2. Drugs that affect blood clotting can result in neuroaxial bleeding or bleeding of the pocket and should be evaluated. Diseases that can affect bleeding should be evaluated with proper laboratory evaluations.
3. Skin diseases can lead to a propensity to develop superficial infection, wound dehiscence, and loss of device.
4. Patients with a history of pedal edema, venous varicosities, or vascular disease may be at a higher risk of developing complications of lower extremity swelling from intrathecal drug infusions.
5. Patients who have an equivocal trial are at a high risk of eventual failure. Likewise, patients who are psychologically unstable should be approached with caution.

6. Obese patients are at a higher risk of developing problems with the pocket, and are more difficult to place catheters into the spinal canal.
7. In emaciated patients, the risk of skin irritation and eventual erosion through the tissue is a high risk.

Risk Avoidance

1. Any coexisting disease should be optimized prior to moving forward with the device. Since many patients have significant problems, the time to move forward should be decided by the physician managing the disease. In some very ill patients such as those with advanced malignancy, the ability to optimize the disease process may be limited.
2. In patients with a high risk of bleeding, preoperative laboratory evaluation should be carefully reviewed with a focus on platelet function and clotting indices. The primary care physician or cardiologist should be consulted to optimize any disease states and to give an opinion on the management of drugs that may increase the risk of bleeding.
3. When the skin is abnormal in the area of the planned surgery, the procedure should be delayed until proper skin treatment is performed. In some cases, the pocket is placed in an area other than the abdomen in order to find a place for an implant.
4. Intrathecal drug delivery has been associated with pedal edema in a small percentage of patients. The patient should be managed closely with limb elevation, compression stockings, and antidiuretics. The eventual treatment is drug dose reduction or drug change.
5. The trial should produce 50% relief of pain based on the visual analog scale, should produce side effects that are acceptable and manageable, and in noncancer patients should produce an improvement in function. The patient should be cleared by a psychologist or psychiatrist prior to implant. Patients should be delayed or canceled if they have significant untreated depression, anxiety, drug abuse, or if they have a borderline personality disorder.
6. The obese patient may require longer needles, extended tunneling rods, and may require pocket modification. The best method of risk avoidance is to plan ahead to prepare for these changes in the procedure. The pocket location may be modified to an area that will be less likely to cause flipping with patient sitting and movement.
7. The patient with low body fat is a challenge for both initial implant and long-term management. The surgeon should consider placement of the device under the fascial plane if the amount of adipose is not sufficient to provide padding for the pump.

Conclusions

Intrathecal drug delivery is a viable alternative treatment to long-term pharmacologic management with oral agents and has proven superior to repeat spinal surgery in many circumstances. Like spinal cord stimulation, intrathecal drug delivery has proven efficacious, cost-effective, and satisfying to many patients with chronic and cancer-related pain. The prevention, recognition, and treatment of complications are a vital part of the successful use of these devices. With proper vigilance, the implanting physician can provide advanced care with outcomes that are acceptable both to the patient and to the society.

Supplemental Images

See Figures 28.1–28.8.

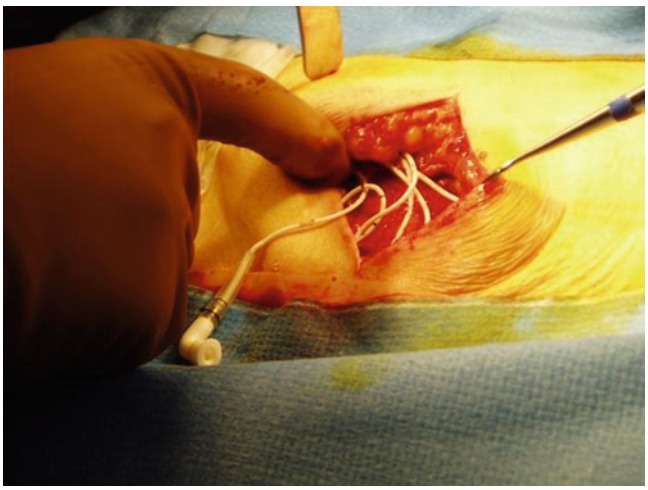

Figure 28.1. Catheter migration can lead to a malfunction of the system.

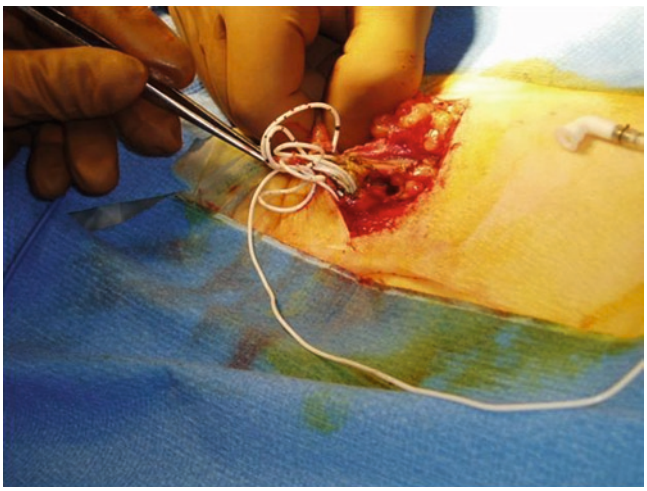

Figure 28.2. Catheter revision can be difficult when fibrosis develops in the pocket. This may be more extreme in those cases where a Dacron pouch is implanted to add stability to the pump location.

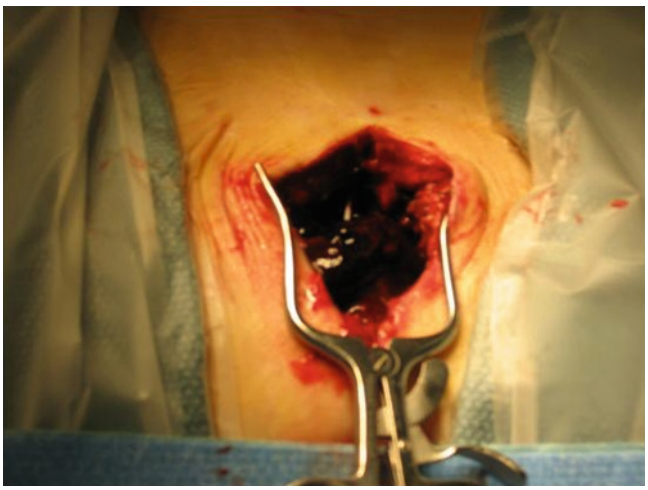

Figure 28.3. Pocket hematoma can lead to wound swelling and dehiscence. Surgical incision and drainage may lessen the impact of this complication.

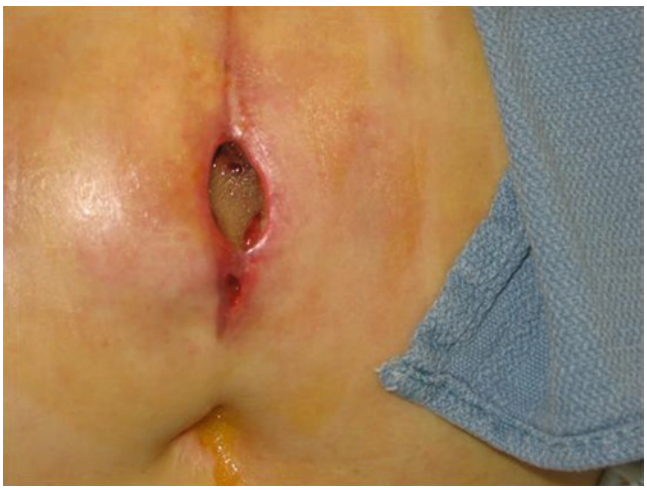

Figure 28.4. Seroma of a wound can be a subtle finding and may be self-limiting, but if it increases in volume it may lead to wound separation and lead to a secondary infection.

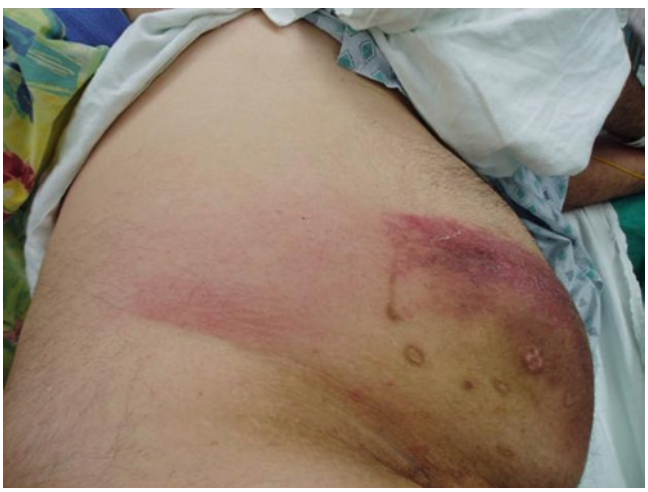

Figure 28.5. Hematoma is a common occurrence after pump insertion and is normally self-limiting and does not cause long-standing complications.

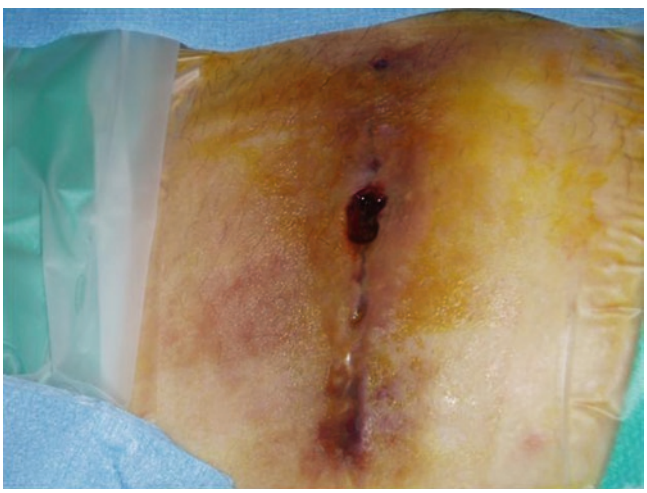

Figure 28.6. Superficial hematoma may be treated with incision and drainage with preservation of the pump. Once the pump materials are exposed to the environment, the device should be removed.

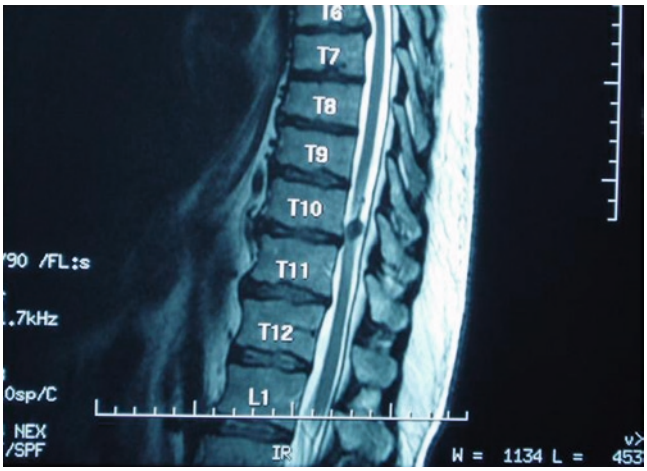

Figure 28.7. Intrathecal granuloma at T10 creating a space-occupying lesion.

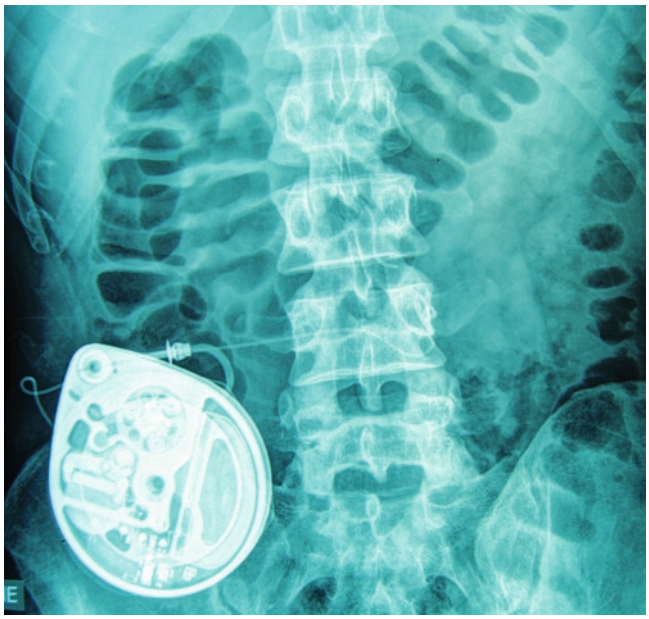

Figure 28.8. Example of a catheter fracture.

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Author Queries

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Queries	Details Required	Author's Response
AU1	We have arranged these below entries under Array. Please check if this is ok.	
AU2	Found as Leopaldo Caldani in page 4	
AU3	We have arranged these below entries under Dissection. Please check if this is ok.	
AU4	Found as Hygroma formation in the text	
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