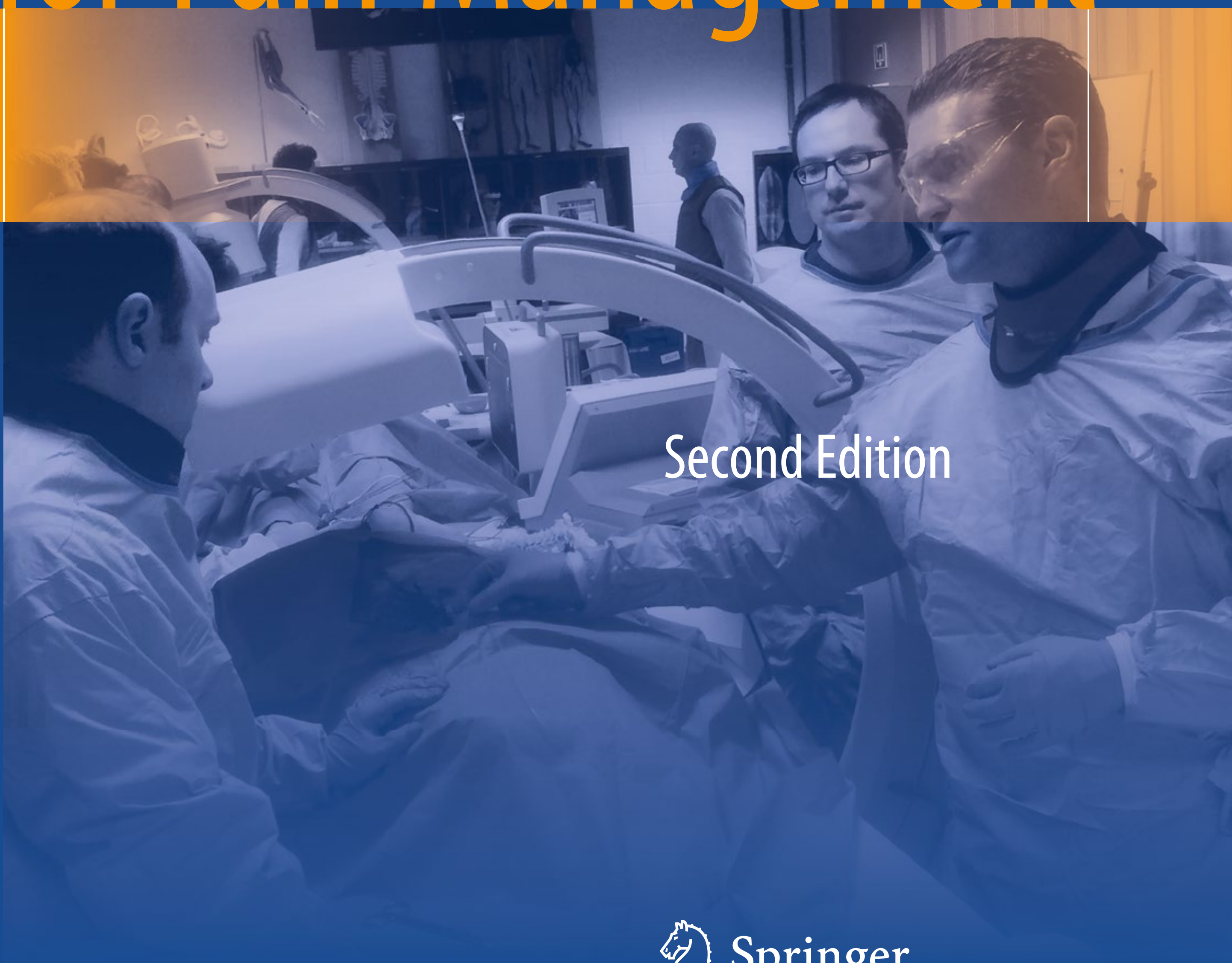
Timothy R. Deer
Jason E. Pope
Editors

Atlas of Implantable Therapies for Pain Management



Second Edition

Springer

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To Melissa Deer, my partner in all things and loving wife, who has inspired me for almost 30 years. I look forward to the next 30 years of love and success.

To my children, Morgan, Taylor, Reed, and Bailie, I also dedicate this book. They are my inspiration for life and daily reminders of the blessings I have been given.

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This book is dedicated to those who struggle against chronic pain and suffering. The patient–doctor relationship is a special one that touches the soul of the physician, who experiences the success and failure of achieving the desired result.

Most importantly, eternal thanks and glory for all things to God. My daily life is enhanced by my relationship with God, and I know that all success is by his grace.

Timothy R. Deer, MD

To Emily, my wife and partner. Thank you for your unwavering support, grace, and the selflessness you have demonstrated for our family and my career. We are together in all adventures, and I am humbled and thankful we can share this life together.

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To Springer for their continued precision and timeliness in making this second edition a reality.

To the many people who battle chronic pain: you are not alone in this fight—this atlas is an effort to arm your physician partners with more tools in their bag of tricks, improving outcomes and management of your needs.

And finally, thank you to God for making all things possible.

Jason E. Pope

Preface

In this second edition, we refine and expand our teaching in the area of pain treatment using neuromodulation, which we believe is critical to reduce the global epidemic of opioid abuse, societal dysfunction, and the malaise of suffering that so many experience.

Added improvements in this edition include new techniques, new targets, new waveforms, and new concepts in neurostimulation. We also update the brain and spine sections for the neurosurgical treatment of pain via neural bioelectric delivery. The use of intrathecal drug delivery is updated with a focus on safety. We add a section of infection control and reduction of bleeding risks. We have added new drawings, photographs, and tables to further make this a more comprehensive Atlas and to make it more applicable in daily use by our readers.

In the past 5 years, much has evolved in the field of neuromodulation. In addition to pain, we are making great advances in the area of urinary and gastrointestinal health, cardiovascular diseases, Parkinson's disease, inflammatory diseases of the body, and neurological diseases that are life altering and very expensive to society. We expect the third volume of this Atlas in a few years to focus on all of these areas of interest and neuromodulation for the treatment of pain to play a smaller yet important role in a vastly expanding field.

This book is intended to complement fellowship training, peer-to-peer experiences, and hands-on continuing medical education. By giving the visual description of each technique, we intend to improve physician practice and enhance outcomes. The physicians who have collaborated on this book are world class in their research, clinical acumen, and ethics of practice.

We are hopeful that this book becomes a daily reference for students, residents, fellows, and experienced physicians as they strive to help ease suffering.

Charleston, WV, USA — Timothy R. Deer

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Part I

Neurostimulation: Spinal Cord

1 History of Neurostimulation

Timothy R. Deer and Jimmy Mali

1.1 Introduction

When we discuss advances like dorsal root ganglion spinal cord stimulation, high frequency stimulation, burst delivery, MRI compatibility, Bluetooth innovation, and the potential of smart programming, one may ask whether we are already in the future. But Galvani, Volta, Franklin, and Gilbert may have posed the same question as they evolved the field. Interestingly, no matter what advances we see in our daily patient treatment, our phase of the advancement will be viewed as antiquated by those who follow. This is good news; we want to encourage innovation. But at the same time, we need to celebrate the history of the field. The purpose of this chapter is to examine, celebrate, and learn from past thinkers and scientists, and to apply what they have taught us to future thought.

1.2 The Ancient or Classical Age

Many of those involved in neuromodulation say that stimulation began in Mesopotamia with the use of the electric eel to treat foot pain and headache. The ancient history of this discipline is more complex and interesting than simplified version, however.

In Greece, the interest in currents and electrical properties was vast. The Greeks coined the word *elektron* to describe amber, a fossilized resin used to create sparks, and later this term became the modern root of the word *electricity*. Greek physicians were the initial users of current to treat illness, and along with the Mesopotamians, they were credited with the initial sparks that started what is now known as neurostimulation. The first documented use involved the release of electrically charged torpedo fish in clinical footbaths from the Nile to treat prolonged headache. Egyptian physicians called the electric fish "Thunderer of the Nile." The use of electricity continued to develop in both Greece and Rome, and in some communities it was more common than the use of herbs and other medicinal treatments.

1.3 The Dark Ages and Forward

After well-documented use of electrical current in the classical age, the stage went silent for innovation for many centuries. This period has been referred to as the "dark ages" of neuromodulation history. Some use of these concepts may have been made, but documentation was poor, so the ability to teach new pupils and pass on knowledge seemed to evaporate. As time progressed, however, some individuals stepped up to move the field forward:

William Gilbert: This famous seventeenth-century scientist first used the term *electricity* and described the relationship of electromagnetism to the treatment of pain. Gilbert wrote of the use of lodestone, a piece of magnetic iron ore possessing polarity like a magnetic needle. He published reports of using lodestone therapy to treat headache, mental disorders, and marital infidelity. The mechanisms for treating infidelity were never theorized, and the use of electrical current was not well understood.

Ewald Georg von Kleist and *Pieter van Musschenbroek:* These two scientists were both instrumental in inventing the initial methods of harnessing energy via electrical current storage. Eventually their device become known as a Leyden jar, named after the University of Leyden (van Mussenchenbroek's home town). Von Kleist, the bishop of Pomerania, tried to name the device the Kleistian jar, but this name was not adopted. The device was constructed

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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.

Jean Jallabert: The work of von Kleist and van Musschenbroek was critical to the next major development. In 1746, Jallabert used electricity to stimulate muscle fibers. This advancement was used to successfully treat 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 that time, led to the theory that electricity was a fluid.

John Walsh: The theory of electricity as a fluid was evaluated by Walsh, who 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 current therapies.

Henry Cavendish: In 1771, Cavendish explained the relationship between electrical force and distance in mathematical theory. This mathematical equation established the groundwork for many future electrical engineering advances.

Alessandro Giuseppe Antonio Anastasio Volta: Volta invented the first battery about 1800. His invention led to the ability to create modern devices.

Luigi Galvani: Galvani may be considered the father of modern neuromodulation. He created what we may term bioelectrics when he first used sparks to move the muscles of frog legs. This simple concept led to the first step of connecting electricity to an animal.

1.4 Neurostimulation First Used in the United States

Benjamin Franklin is important to neuromodulation for two reasons: The development of the lightening rod was an early practical use of electricity, and Franklin was also the first American to use neurostimulation. Franklin's interest in electrical current peaked in 1756, after he learned about the work of Leopoldo Caldani, who reported that discharging a Leyden jar in the vicinity of a mounted and dissected frog's leg could 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 might be cured by this method. Franklin did his own experiments on painful conditions. After discovering that his subjects experienced more discomfort than pain relief, he concluded that these claims were inflated. Unfortunately for Franklin's volunteers, many of whom were desperate and hopeless people, he used high-voltage stimulation that caused injury, pain, and tissue burns.

The first use of neurostimulation in the United States, as Franklin reported to the French Academy of Sciences in Paris, was unsuccessful. This scientific report diminished the interest in electrical treatment in the United States for many years. Considering these issues, Franklin may have harmed the advancement of neurostimulation in the United States, but it is hard to lay blame on such a marvelous figure, who had the type of inquisitive mind that we all strive for. It also makes one wonder which of our current ideas may be off base, harmful, or in need of redirection. Time will tell, as we move forward and seek Food and Drug Administration (FDA) approval for new devices and methods.

1.5 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 on 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, the low-voltage electricity used by Volta was applied to humans; it was much better tolerated by research volunteers than the high-voltage stimulation used by Franklin, and led to progress in pain treatment. The work of both Volta and Galvani led to modern batteries and improved the understanding of electrical current in animals.

1.6 Early Neurostimulation: Failures and Advances

1.6.1 Failures

Unfortunately, the path to the modern use of electricity has not been one of universal success and understanding. Volta felt that the use of electrical current in medicine had no scientific backing. After Jallabert's work became well known, a period of quackery followed, including these misguided efforts:

Magnetism: 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 the scientific community. Many years later, magnets became a popular alternative treatment, but their relationship to "mesmerism" is unclear.

Infectious disease cures: Elisha Perkins was a questionable scientist 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 infectious disease treatment.

1.6.2 Advances

Too early for their time: In 1801, electrical currents were used experimentally to resuscitate patients who had suffered cardiac arrest or drowning. This crude technique was an early form of cardioversion. 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 and then attaching a battery source to create an intermittent charge through the body for short intervals. This treatment was applied through the occiput when possible and was used to treat headache, tumors, and generalized pain. Currently occipital nerve stimulation has been found to be successful in treating migraine, headache, and potentially chronic pain.

André-Marie Ampère and *Michael Faraday:* The next steps forward in this field were the result of the work of André-Marie Ampère, who 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, a noted British scientist, 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, based on Ampère's work and his own observations. These descriptions of electromagnetic induction are the critical link to modern neuromodulation in the treatment of pain and movement disorders.

The Magnetic Electrical Machine: E. M. Clarke advanced the field based largely by building on Faraday's work. The Clarke Magnetic Electrical Machine provided a steady supply of induced electricity and led to all future developments in medicine that needed electrical therapy. Initially, it was difficult to apply these therapies to patients 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.

Guillaume-Benjamin-Amand Duchenne (de Boulogne): Duchenne was important in our field because of electropuncture. He used small needles to apply current to the muscle to cause contraction and to assist in muscle mapping, and published these findings in his book, *De l'Electrisation Localisée*. This work led to the development of early prostheses that used surface electrodes to move the body part and eventually to modern rehabilitation 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.

The first United States patented device: Charles Willie Kent patented the "Electreat" in 1919. This was an early version of transcutaneous electrical stimulation. The work was based largely on an 1871 publication by Beard and Rockwell, which explained how the Faradic current principles might be applied to pain relief.

1.7 High-Frequency Stimulation and Voltage Alterations

The focus now is on the potential for high-frequency stimulation to treat patients in a paresthesia-free method of current delivery. This seems to be a new concept, but high frequency has a long history, at least in theory. 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 stimulation programming platforms. As we review these historical figures, the reader can put together each step and the impact it has had on current devices and delivery.

1.8 Modern Neurostimulation: 1960 to the Present

The use of neurostimulation as we clinically know it today really had its start in the 1960s. Critical developments included basic and bench science research. Woolsey used electrical stimulation to map the animal cortex and subcortex. Melzack and Wall further increased our understanding of pain perception with a 1965 publication in *Science*, which provided the basic groundwork for the clinical application of neurostimulation. The gate control theory described inhibitory and excitatory relationships in the nervous system, particularly in pain pathways.

At the University Hospitals of Cleveland, Case Western Reserve, Norman Shealy described the use of electrical current to modulate the nervous system and change the perception of pain and suffering. Dr. Shealy worked with an engineering student, Thomas Mortimer, to develop a stimulating lead that would work on the dorsal columns of the spinal cord. They used a crude platinum electrode design with a positive and negative electrode to treat a 70-year-old man with thoracic pain from inoperable bronchogenic carcinoma. The generator was an external cardiac device with the lead placed in the intrathecal space. Although the target was not ideal and the patient was not one that would be considered appropriate today, the outcome was excellent during the test stimulation, which lasted 1½ days. An account of this landmark achievement was published as a case report in 1967.

This work ignited 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. Sweet and Wepsic applied the concept of neurostimulation to the peripheral nervous system in a 1968 paper, "Treatment of chronic pain by stimulation of fibers of primary afferent neuron." This work was an early example of taking work in the central nervous system and applying it to different targets.

The first device company to achieve FDA approval for an implantable neuromodulation device was Medtronic (Minneapolis, Minnesota) in 1968. These early devices required radiofrequency communication between the electrodes and power source. Earl Bakken, the founder of Medtronic and inventor of the wearable pacemaker, became a critical figure in neurostimulation, committed to advancing the field.

Yoshio Hosobuchi was another great pioneer in this field. He discovered that these devices could be used in the deep brain to treat facial pain. His 1973 paper, "Chronic thalamic stimulation for the control of facial anesthesia dolorosa," was the birth of deep brain stimulation. Many patients were treated over the ensuing 4 years, but 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.

Takashi Tsubokawa advanced this work further in 1991, when he showed that 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 fewer apparent risks. Eventually, deep brain stimulation was approved for the treatment of movement disorders in Parkinson's disease and dystonia. Several studies of deep brain and motor cortex stimulation are currently ongoing, involving pain, depression, obsessive compulsive disorder, traumatic brain injury, Alzheimer's disease, and obesity.

The past 5 years have shown more promising advances than the previous 20. Significant advances have included dorsal root ganglion spinal cord stimulation, high-frequency stimulation, burst stimulation, MRI compatibility, and new lead and programming platforms that could change the field and enhance people's lives for many years forward.

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2 Patient Selection

Corey W. Hunter, Eric T. Lee, Robert Masone, and Timothy R. Deer

2.1 Introduction

When contemplating neuromodulation as the next potential step, the treatment paradigm in the pain care algorithm, careful attention must be paid to the patient's potential to respond to the therapy. There are a number of factors (both disease- and patient-specific) one must consider when selecting patients for this treatment modality to maximize the change of a successful outcome. Data suggest that particular disease states are more likely to respond to spinal cord stimulation (SCS) than others (*e.g.*, radicular pain versus phantom limb).

This chapter delineates the criteria to consider when assessing a patient's candidacy for an implantable SCS system. Importantly, the goal of this chapter is not to dogmatically and inclusively describe selection criteria, but rather to give guidance and insight for potential refinement of patient selection.

2.2 Indications

The indications for neuromodulation through SCS are growing every day, owing in large part to steadily improving technology, new devices, and the devoted efforts by clinicians to responsibly explore novel uses for this modality, thus expanding its seemingly limitless utility. Particular disease states that were once considered "low probability for success," such as those that may contribute to axial low back pain, are now showing great promise. The same is true for groin pain, phantom limb pain, and chest wall pain. This improvement in outcomes may change the entire thought process for patient selection. The advent of new lead arrays, new structural targets, and new waveform and frequency delivery has paved the way for continued successes. At the time of this writing, multiple prospective randomized studies are now ongoing in both the United States and abroad that will further define these candidates.

Analysis of available data regarding potentially successful outcomes lends a degree of predictability when selecting candidates. This section outlines which criteria tend to predict a greater likelihood of sustainable positive results.

The indications for SCS that are best supported by the literature include radicular pain after spinal surgery, Complex Regional Pain Syndrome (CRPS) types I and II, peripheral nerve injury, painful neuropathies, lumbar radiculopathy, and cervical radiculopathy (Table 2.1). Vascular diseases, such as refractory angina with no correctable lesions, ischemic pain, and pain related to other peripheral vascular diseases, also appear to have a great potential for response.

A number of studies over the past 30 years suggest that SCS has preferential success for common pain characteristics. In 1998, Kumar et al. reported that the five most common etiologies for treatment with SCS were Failed Back Surgery Syndrome (FBSS), peripheral vascular disease, peripheral neuropathy, multiple sclerosis (MS), and CRPS. The largest percentage of successful response to SCS was noted in peripheral neuropathy (73 %) and reflex sympathetic dystrophy (100 %). FBSS had a success rate of 52 %, likely secondary to its mixed neuropathic and nociceptive nature. Kumar went on to say that patients without surgical procedures prior to implant typically responded better, and if a surgical history was present, having a shorter transition time to implant improved the outcome. In summary, he found SCS most successful in intractable angina and ischemic pain, as well as CRPS and neuropathic pain after spinal surgery.

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North et al. reported that SCS was successful in producing pain relief in up to 60 % of patients with arachnoiditis secondary to failed back surgery. Additional work showed that SCS could be superior to reoperation in patients randomized to one of these treatment arms.

In the past two decades, significant advances in both hardware and software for these devices appear to have significantly improved the outcome for FBSS (Table 2.2). Specifically, data for new, advanced multicolumn paddle leads, percutaneous paddle lead arrays, high-frequency 10,000 kHz stimulation, and burst stimulation offer new promise to these patients that may reduce the burden of failed treatment and, if successful, may offer alternatives to additional back surgery or increasing opioids.

It has been suggested that SCS is most effective in the setting of sympathetically mediated pain states, with success rates approaching 70 %. Kemler and colleagues produced peer-reviewed, high-level evidence that SCS was superior to conservative treatment for CRPS. In addition to sympathetic pain, evidence of effectiveness for pain of vasculopathic origin is also mounting. Many studies have shown improved pain, better function, and, perhaps most importantly, improved limb salvage in settings where the distal extremity ischemic lesion measures less than 3 cm.

The development of novel systems to perform dorsal root ganglion (DRG) stimulation within the neuroaxis may result in improved outcomes in neuropathic groin and extremity pain owing to the ability to target specific abnormal pain fibers that were traditionally very challenging with SCS.

Table 2.1 Likelihood of success with spinal cord stimulation

High probability
Chronic radicular pain
Neuropathic pain
Peripheral neuropathy
Ischemic pain
Refractory angina pectoris (not amenable to surgery)
Sympathetically mediated pain
Peripheral vascular disease
Failed Back Surgery Syndrome with radicular components
Complex Regional Pain Syndrome (CRPS), types I & II
Moderate probability
Visceral pain
Multiple sclerosis–induced nerve pain
Cancer-related pain syndromes such as radiation neuritis, chemotherapy-induced neuropathy
Low probability
Deafferentation pain
Spinal cord injury pain
Central/post-stroke pain
Cancer pain without nerve component
Nociceptive pain
Nerve root avulsion

Table 2.2 New technology producing outcome changes

New technology	Technical aspect	Disease states impacted
High-frequency 10 kHz	Similar to current systems Technical software advancement	Axial back pain, patients who do not like or respond to paresthesia, salvage for failed SCS
Burst stimulation	Similar to current systems, different waveform Technical software advancement	Axial back pain, patients who do not like or respond to paresthesia, salvage for failed SCS
Percutaneous paddles	Requires epidural sheath Technical hardware advancement	Axial back pain, complex pain patterns
Dorsal root ganglion spinal cord stimulation (DRG-SCS)	Technical advancement of both hardware and software	Expands the field: phantom pain, chest wall pain, groin pain, foot pain
MRI compatibility	Hardware advancement	Expands the field for those who need serial MRI

2.3 Exclusion

Even as SCS has preferential success for some pain types, its failure in others has been reported in a number of studies. It should be noted that many of the unsuccessful outcomes previously reported may have been a product of shortcomings of the technology employed, and in its current form, may be more responsive. That being stated, the following data reference the disease states and pain states that have been shown to be historically resistant to SCS.

Patients at higher risk of failure include those with spinal cord injury, thalamic stroke pain or pain of any origin within the brain, complete nerve root avulsion, and aching nociceptive pain of the limb secondary to arthritis. Other factors that may have negative predictive value includes cauda equina syndrome, paraplegia, primary bone pain, deafferentation syndrome, and cancer pain secondary to tissue invasion.

2.4 On the Horizon

Traditionally, pelvic, rectal, or anal pain has been characterized as somewhat resistant to SCS with a risk for failure, but a number of studies referencing retrograde and sacral lead placements report promising results. In 2011, Hunter et al. published their successes in treating these regions of pain with lead placements over the conus and the high thoracic region (Table 2.3).

Another pain syndrome that has shown resistance to traditional tonic SCS is discogenic low back pain. Conventionally placed leads over the dorsal columns in the epidural space have met with disappointing results. In recent European and Australian studies, Deer et al. have described some success in treating discogenic low back pain with a radicular component by placing leads over the dorsal root ganglion at various levels, most commonly at L2.

The need for neuroaxial imaging after placement of SCS is very rare, but recent MRI compatibility advancements have broadened the scope of neuromodulation to include patients who require serial MRIs for disease surveillance. Among these patients are those with MS, intracranial tumors or malignancy, and neurodegenerative diseases.

Table 2.3 Novel lead placements with reports of success for pain states traditionally resistant to spinal cord stimulation

Disease type	Lead placements with reported success
Pelvic pain	High thoracic (T6-7), over the conus, or sacrally via hiatus or retrograde approach
Discogenic pain	Dorsal root ganglion
Postherpetic neuralgia	Dorsal root ganglion, dorsal column at corresponding level with or without peripheral nerve lead
Axial low back pain	Newer paddle arrays via laminotomy or percutaneous approach New current delivery
Phantom limb pain	Dorsal root ganglion
Groin pain	Dorsal root ganglion at T12 or L1

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Disease Indications

3

Corey W. Hunter, Eric T. Lee, Robert Masone, and Timothy R. Deer

3.1 Introduction

Treating the proper patient with the proper device at the proper time is the essential key to medicine and extends to a successful neurostimulation experience. This chapter focuses on disease states that best lend themselves to a good outcome.

An analysis of peer-reviewed data suggests that particular disease states are more likely to be responsive to spinal cord stimulation (SCS) than others. An example may be a patient with chronic lumbar or cervical radicular pain who in general is an excellent candidate for conventional tonic SCS, as compared to a patient with phantom limb pain who has been traditionally unlikely to respond. Interestingly, success has been seen recently in this complex phantom and stump pain group with the use of dorsal root ganglion spinal cord stimulation (DRG-SCS).

3.2 Indications

The appropriate indications for neurostimulation are expanding rapidly. This is due in large part to steadily improving technology, a rapid innovation cadence, new devices, and devoted efforts by clinicians to explore new and novel uses for this modality, thus expanding its seemingly limitless utility. Particular disease states that were once considered "low probability for success," such as those that may contribute to axial low back pain, are now considered viable candidates. The advent of new lead arrays, new programming software, and enhanced screening has paved the way to continued successes.

Analysis of available data regarding potentially successful outcomes lends a degree of predictability when selecting candidates. This section outlines what criteria tend to predict a greater likelihood of sustainable positive outcomes.

The indications for SCS that are best supported by the literature include burning or shooting pain in the extremity after lumbar or cervical spinal surgery, Reflex Sympathetic Dystrophy (RSD)/Complex Regional Pain Syndrome (CRPS), types I and II, peripheral nerve injury, painful neuropathies, refractory angina with no correctable lesions, ischemic pain, and pain related to peripheral vascular disease.

A number of studies over the past 30 years suggest that SCS has preferential success for common pain characteristics. In 1998, Kumar et al. [1] reported the five most common etiologies for treatment with SCS were failed back surgery syndrome (FBSS), peripheral vascular disease, peripheral neuropathy, multiple sclerosis (MS), and CRPS. The largest percentage of successful response to SCS was noted in peripheral neuropathy (73 %) and reflex sympathetic dystrophy (100 %). FBSS had a success rate of 52 %, likely secondary to its mixed neuropathic and nociceptive nature. Kumar et al. [1] went on to describe that patients without surgical procedures prior to implant typically respond better and, if a surgical history was present, having a shorter transition time to implant improved the outcome.

It has been suggested that SCS is very efficacious in the setting of sympathetically driven pain states, with success rates approaching 70 %. In 1989, Meglio et al. [2] reported that SCS was most effective in vasculopathic pain, low-back pain, and post-herpetic neuralgia. North et al. [3] reported that SCS was successful in producing pain relief in up to 60 % of patients with arachnoiditis. He further proposed that

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SCS had success rates as high as 88 % in FBSS, suggesting it may even be superior to reoperation. He found it most successful in intractable angina and ischemic pain, as well as CRPS and neuropathic pain after spinal surgery.

With the advent of new technology and ideas, peer-reviewed publications are now reporting successes in treating axial low back pain. Some of these advances include DRG-SCS at L2, high frequency SCS at 10 kHz, hybrid systems with epidural and peripheral leads, and burst SCS. In addition to enhancing outcomes with axial back pain, these new therapies have expanded the chance of success with chest wall pain, groin pain, visceral pain, and other conditions once thought unlikely to be successful.

3.3 Exclusion

Whereas SCS has preferential success for some pain types, its failure in others has been reported in a number of studies. It should be noted that many of the unsuccessful outcomes previously reported may have been a product of technological shortcomings of the time or possibly resulting from a lack of accessibility to the more advanced product lines currently available. Notwithstanding, the following data reference those disease/pain states that have been shown to be historically resistant to SCS.

Patients at higher risk of failure include those with spinal cord injury, thalamic stroke pain, or pain of any origin within the brain, complete nerve root avulsion, and aching nociceptive pain of the limb. With additional analysis of some of the longest-standing prospective data sources, one can surmise that other areas of potentially increased failure rates include cauda equina syndrome, primary bone pain, pain from dystonia and paraplegia, extensive arachnoiditis, deafferentation pain, and cancer pain

3.4 On the Horizon

Traditionally, pelvic, rectal, and anal pain has been characterized as somewhat resistant to SCS with a risk for failure; however, a number of studies referencing retrograde and sacral lead placements report promising results. More recently in 2011, Hunter et al. [4] published their successes in treating these regions of pain with lead placements over the conus and the high thoracic region. This work is encouraging, as is work by Kapural et al. [5] on SCS to treat abdominal pain and diseases of the viscera.

Congestive heart failure is another exciting area in development and shows great promise in both animal models and human pilots. The next decade could prove to be a time of digital medicine that changes and saves patient lives.

Another pain syndrome that has shown resiliency to SCS is discogenic low back pain, as conventionally placed leads over the dorsal columns in epidural space have met with disappointing results. Recently, Liong et al. described some success in treating discogenic low back pain with a radicular component by placing leads over the dorsal root ganglion at the affected levels.

Table 3.1 shows the probability of success with conventional SCS. Table 3.2. shows common lead targets for pain distributions and potential enhanced outcomes with new technology.

Table 3.1 Disease bias With SCS

High probability	Chronic radicular pain Neuropathic pain Peripheral neuropathy Visceral pain Ischemic pain Sympathetically driven pain Peripheral vascular disease Multiple sclerosis Refractory angina pectoris (not amenable to surgery) Painful ischemic peripheral vascular disease Failed back surgery syndrome Complex regional pain syndrome (CRPS), types I and II
Low probability	Deafferentation pain Spinal cord injury pain Central/post-stroke pain Cancer pain Nociceptive pain Nerve root injury

Table 3.2 Novel lead placements with reports of success for pain states traditionally resilient to SCS

Disease type	Lead placements with reported success
Pelvic pain	High thoracic (T6-7), over the conus, or sacrally at S1, S2, S3 via hiatus or retrograde approach
Discogenic pain	Dorsal root ganglion, multi-contact paddles at T8, T9, HF 10 kHz at T8, T9. Burst SCS at T8, T9, T10
Post-herpetic neuralgia	Dorsal root ganglion, or hybrid with epidural and subcutaneous leads
Axial low back pain	Dorsal root ganglion, multi-contact paddles at T8, T9, HF 10 kHz at T8, T9. Burst SCS at T8, T9, T10
Phantom limb pain	Dorsal root ganglion
Groin pain after hernia repair	Dorsal root ganglion or hybrid SCS plus PNS
Congestive heart failure	T1, T2, T3

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Preoperative Evaluation for Spinal Cord Stimulation

4

Corey W. Hunter, Eric T. Lee, and Timothy R. Deer

4.1 Introduction

Preoperative evaluation and clearance is imperative to any surgical procedure. Due diligence must be paid to ensure the lowest chance of complication and the highest likelihood of success. This includes managing the patient's expectations of the device and managing the procedure for its safe implementation. Tonic stimulation therapies require lead placement location optimization and intraoperative cogent patient feedback, highlighting the importance of optimizing preoperative education and expectations. In addition, optimization of disease comorbidities and procedural hematological and infectious risk avoidance are of equal importance. Given this unique set of considerations, one can see the preoperative assessment for spinal cord stimulation (SCS) has several distinctive components.

This chapter reviews the preoperative evaluation for SCS as it pertains to (1) ensuring patient safety by minimizing risks (known and theoretical), (2) identifying the intended entry point, pathway, and position for final lead placement while safeguarding that these are feasible and impose minimal risk, and (3) maximizing the possibility for a positive outcome (pain relief).

4.2 Procedural Considerations

Before any surgical procedure, a proper history and physical examination should always be performed. This will be the time to identify any comorbidities that may impact the procedure itself and give the physician time to follow through on any suboptimal health concerns. It is equally important to elucidate any new information—especially changes or appearance of new symptoms—that may adversely affect the procedure itself such as neurological changes, fevers, skin lesions, or other significant health changes.

4.3 History

4.3.1 Infection

Despite the minimally invasive nature of SCS, infection is still a concern. Any type of infection can pose a serious risk to the patient; however, an epidural abscess can be a particularly devastating complication in even the healthiest of patients (Fig. 4.1). Therefore, careful attention should be paid to any perioperative illnesses or conditions that may suppress the immune system. The skin in and around the intended entry point(s) should be carefully inspected for any signs of recent infection. Even with diligent skin sterilization technique, if pathogens are present within the skin from a lesion of some sort, the needle has potential to carry these pathogens directly into the epidural space leading to infection. One should inquire about any history of methicillin-resistant *Staphylococcus aureus*. If so, the physician may wish to take additional precautions such as preoperative bathing with chlorhexidine, intranasal bactobran, and preoperative vancomycin. In complex cases, additional consultation may be needed.

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 infection in the area of needle insertion. This is not an uncommon concern when considering SCS as part

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of an algorithmic process for the treatment of intractable disorders. It is for these reasons, the authors advocate getting a basic complete blood count (CBC) prior to implant. Urinalysis may also be helpful in those patients with a history of urinary tract diseases or risks.

Fig. 4.1 Sagittal T2-weighted MRI of an epidural abscess (*arrows*, *arrowheads*) from an SCS trial

4.3.2 Coagulopathy

Bleeding is a concern in any surgical procedure, but probably none more so than in any case in which epidural access is involved. An epidural hematoma is a tragic and catastrophic complication. In a healthy, uncomplicated patient, the incidence is as low as 1 in 40,000. Given the plethora of data as they pertain to epidural hematomas, there is a predictability of sorts as to when the risk may be higher at certain points than others (Fig. 4.2). As a result, guidelines are now in place that give some safeguards to lower the risk.

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 CBC including a platelet count.

- **International Normalized Ratio (INR)**—the most predictive of potential complication
- **Prothrombin time/partial thromboplastin time (PT/PTT) and bleeding times**—not as reliable, but may be helpful as general sources of information.
- **Platelet function assay studies**—a new test area that may lend information for patients on drugs that affect platelet function.

Special attention should be paid to assess whether the patient is taking any medication that may put she or he at risk for increased bleeding. The guidelines of the American Society of Regional Anesthesia (ASRA) on bleeding and medication should be reviewed when doing a patient evaluation (Table 4.1). If it is discovered the patient is taking a medication listed on the ASRA guidelines that may affect bleeding, the prescribing physician should be consulted to determine if he or she can safely discontinue those medications for the appropriate length of time prior to invading the epidural space. At this point, this is the best available guidance, but it was not designed for neuromodulation devices. It would be preferable in the future to have guidance directly applicable to this field.

In permanent implants, the drugs may be restarted a few days after the leads are surgically secured. The number of days required off of these drugs is controversial and will vary from one medication to the next. 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.