

# Spinal Cord Stimulation: Using Technology To Solve Complex Pain Problems

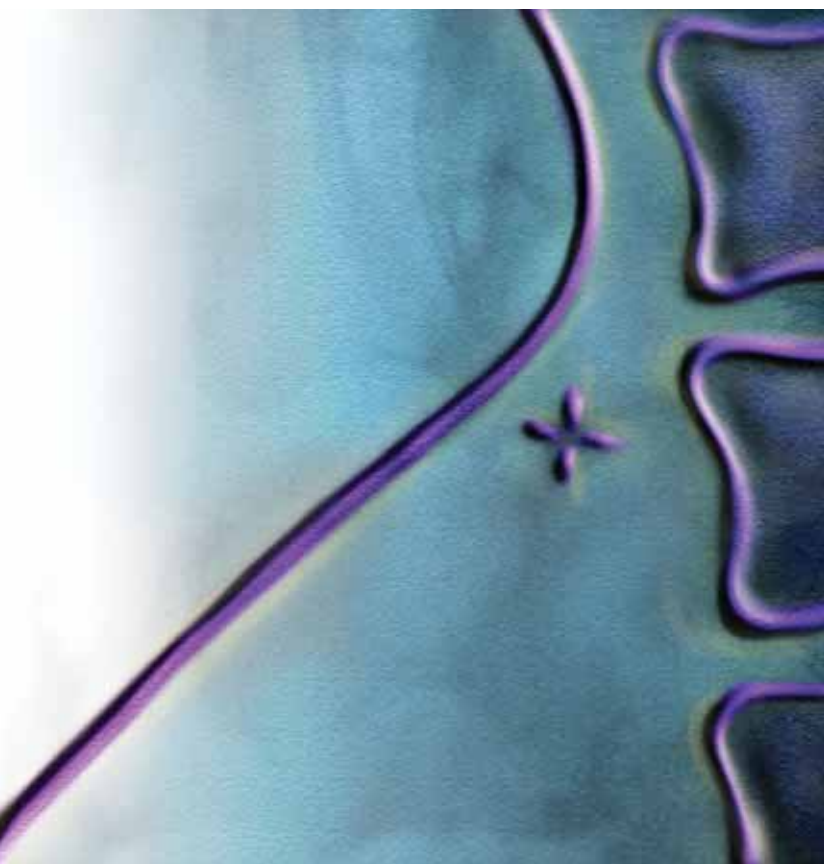
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Spinal cord stimulation (SCS) is a well-established treatment for neuropathic pain of the trunk or limbs. Formerly used later in the treatment algorithm, this intervention has moved up the treatment ladder. SCS shows positive outcomes in patients who receive it after spine surgery and before a second surgery. SCS also appears to be a much better solution for treating neuropathic and mixed pain syndromes, showing favorable end organ side effects, efficacy, and cost effectiveness over time compared with high-dose oral opioids and other drug combinations.

The pain syndromes most commonly treated with SCS include radiculitis, neuropathy, postherpetic neuralgia, ischemic pain, and failed back surgery syndrome with scarring around a nerve root. SCS also is an effective treatment option for visceral abdominal pain, pelvic pain, angina, and peripheral vascular disease.

This article presents new, breakthrough technology in SCS that allows the interventional pain physician to implant a paddle lead that previously required a surgical approach to bone removal and laminotomy. This truly is a step forward for the minimally invasive pain physician who strives to improve outcomes and reduce complications and costs.

## History and Background

In 1965, Ronald Melzack, PhD, and Patrick Wall, MD, both of the Massachusetts Institute of Technology, described the gate-control theory for the mechanism of pain transmission. The researchers proposed that pain was controlled by a complex circuitry of inhibitory and excitatory pathways. In 1967, data on the first SCS device implant were published.<sup>1</sup> The device was rudimentary and involved a bipolar system in the intrathecal space, as opposed to today's multichannel epidural systems. The device was thought to control the gate-control pathway and allow for pain relief.

In the 40 years since the introduction of this device, the technology has moved forward and pushed SCS to new heights.<sup>2</sup> Current devices have complex programming platforms, miniaturized generators, rechargeable batteries, and new lead designs for both surgical and percutaneous placement. The past year has been especially encouraging for implantation devices, because new technology has given physicians the ability to reduce risks, improve outcomes, and make many surgeries more minimally invasive. This report examines some of those new advances.

## An Overview of SCS

### DEVICE OVERVIEW

The technology of SCS systems is derived from that of cardiac pacing devices and shares many of the same characteristics. All SCS systems involve placing a pacing-type lead into the neuroaxis to transmit electrical current to the neural tissue. The presence of electrodes on the lead provides a source for delivering the current, which can be closely controlled and modified. These leads are connected to a subcutaneous generator that contains a power source and a computer-programming platform, which controls current, pulse width, amplitude, rate, and electrode array. Interactions between the cathode (negatively charged) contacts and anode (positively charged) contacts shape the electric field.<sup>3</sup>

### PATIENT SELECTION

Patient selection is important for long-term outcomes

with SCS.<sup>4</sup> The patient should try more conservative approaches before SCS. He or she should have no contraindications, such as active infection at the site of implant or systemically, no untreated bleeding disorders, and no psychological contraindications, such as suicidal thoughts, delusions, or untreated psychosis. SCS is not a treatment for drug abuse. Addiction issues should be addressed prior to implant when possible.

It should be noted, however, that the definition of conservative care is evolving. Data show SCS to be more efficacious and to have a better safety profile than high-dose opioids, multiple drug class combinations, and surgical approaches to the spine. In many cases, SCS is preferable to spine surgery when pain is the primary complaint.

### TRIALING FOR SCS

Prior to placing a permanent device, the patient can undergo a trial of epidural stimulation. This is accomplished by placing 1, 2, or 3 leads into the space with a needle-based approach. The location of those leads is based on well-established targets and the leads are placed by laser-guided fluoroscopy. Once the leads are situated, the patient can talk with the implanter while the electrodes are activated. When the patient experiences paresthesia that covers the area of pain, the leads are left in this position while the needles and stylets are removed, and the leads are secured. The trial can be done without incisions, general anesthesia, or hospital admission. New technology has made it possible to use an introducer sheath to deliver paddle leads or multiple cylindrical leads in a percutaneous method using only one needle stick. Figures 1 through 11 give an overview of the procedure.<sup>5</sup> We focus on this technology in the Case section of this review.

## Clinical Use of the Therapy

The use of SCS has been well established in many disease settings. The most common reason for implantation in the United States is nerve pain after failed back surgery or progression of disease after previous spine surgery. Other common disease states have been well documented in the literature and are continuing to expand. The clinician who wishes to implant these devices should be familiar with lead targets (Table 1), disease states that are indicated for implantation (Table 2), and special issues associated with each patient who is considered for surgery. Wonderful advances in therapy are changing how we practice medicine in the arena of neuromodulation. Some of these are currently available as locking mechanical anchors, epidural access sheaths, steerable paddle leads, accelerometers, and limited MRI-compatible systems. Current research is evolving into dorsal root ganglion stimulation, high-frequency SCS, and new methods of changing nerve conduction. These

new technologies may signal new hope for patients who suffer from severe pain (Table 3).

### Specific Conditions for SCS

#### *FAILED BACK SURGERY SYNDROME AND OTHER SPINAL DISORDERS*

In many cases, when a spine surgery fails to provide pain relief, an additional spine surgery is recommended. There are few alternatives to this additional surgery when the goal is to relieve neurologic compromise, but the outcomes often are tenuous when it is performed primarily to reduce pain. Prospective randomized studies in patients who are candidates for a second spine surgery have shown that they do better with SCS with regard to pain reduction, health care use, crossover to additional therapies, and long-term costs.<sup>6,7</sup> Consequently, SCS should come before a second spine surgery when pain is the primary indication.<sup>8,9</sup> Considering that the cost of a primary complex spine surgery may exceed \$89,000 in initial expenses, it is reasonable to consider SCS as a primary treatment option for patients whose odds of a good outcome are uncertain.

#### *NEUROPATHIC PAIN OF THE EXTREMITIES*

SCS for neuropathic pain of the extremities is effective and life changing for many patients. A prospective randomized study by Kumar et al has shown that SCS helps patients with burning leg pain compared with conventional medical management alone.<sup>10</sup> In this group of patients, the primary pathology was failed back surgery syndrome. Other studies and reports have shown SCS to be efficacious in treating diabetic peripheral neuropathy and nerve pain of other origins. In most studies, the chance of a good outcome with SCS in neuropathic limb pain is 85% or higher.

#### *COMPLEX REGIONAL PAIN SYNDROME*

SCS as a treatment for complex regional pain syndrome (CRPS) has been well documented. The level of evidence for utilizing SCS for neuropathic pain relief in CRPS is at the highest level, according to peer review criteria. In a prospective randomized trial of SCS plus physical therapy versus physical therapy alone, the group receiving SCS plus physical therapy had a significantly better outcome up to 2 years later.<sup>11</sup> In this study and similar evaluations, the use of SCS with other modalities such as physical medicine and anticonvulsants appears to result in the best outcome.

#### *ISCHEMIC PAIN*

Evidence shows that SCS can treat the neuropathic pain caused by ischemia as well as improve blood flow and tissue oxygenation and enhance wound healing. SCS is used in patients who have either severe

**Table 1. Targets for Spinal Cord Stimulation**

Cervical	C2: face C2 to C4: shoulder to hand C4 to C7: forearm to hand C7 to T1: anterior shoulder
Thoracic, Lumbar, Sacral	T1 to T2: chest wall T5 to T6: abdomen T7 to T9: back T10 to T12: limb L1: pelvis, limbs L1: foot L5,S1: foot, lower limb S2 to S4: pelvis, rectum Sacral hiatus: coccyx

**Table 2. Indications for Spinal Cord Stimulation and Probability of Success**

Indications for SCS	Probability of success
Failed back surgery syndrome	50%-60% with >50% pain relief
Complex regional pain syndrome (CRPS)	67%-84%
Chronic critical limb ischemia	70%-80% with >75% pain relief
Angina	Insufficient data
Abdominal/visceral pain syndromes	Insufficient data
Brachial plexus	Insufficient data
Phantom limb pain	Insufficient data
Intractable pain secondary to spinal cord injury	Insufficient data
Mediastinal pain	Insufficient data
Cervical neuritis	Insufficient data
Postherpetic neuralgia	Insufficient data

Adapted from Deer TR, series ed; Hayek S, Levy R, volume eds. *Neurostimulation for the Treatment of Chronic Pain*. Vol 1. Philadelphia, PA: Elsevier; 2012.

primary ischemic pain or mixed pain of both ischemic and neuropathic origins. The trial for ischemic pain involves evaluating pain relief and blood flow. This can be assessed by visualization or by complex tissue oxygenation measurements.

**Table 3. Recent Advances in Spinal Cord Stimulation (SCS)**

Recent advances in SCS	Improvement in care
Locking mechanical anchors	Reduced migration
Percutaneous lead introduction sheaths	Reduced trauma and complex lead arrays
Steerable paddle leads	Reduced need for laminotomy leads
Accelerometer additions	Reduced stimulation change with position
Magnetic resonance imaging compatibility	Expanded patient access to care
Future advances in SCS	Potential improvement in care
Dorsal root ganglion stimulation	Low energy requirements, specific nerve targeting, target of processing center for neural activity
High-frequency stimulation	Pain relief without the need for paresthesia

**OTHER NEUROPATHIC CONDITIONS**

Large multicenter studies of SCS have shown good clinical outcomes with pain relief and improved vascular outcomes. In a review of studies of both ischemic pain of the extremities and angina pectoris, Timothy Deer, MD, and Louis J. Raso, MD, found that the current evidence for both indications is very strong.<sup>12</sup>

Many patients with angina are successfully treated with cardiac stenting, coronary artery bypass graft surgery, or oral medications. In a subset of patients, angina persists despite other treatments. In this group, SCS can be used to improve quality of life, decrease pain, and improve function. Angina is caused by an imbalance between the supply of and demand for oxygen. The mechanism for changing this imbalance to a more favorable status using SCS is uncertain, but several theories exist.<sup>13</sup> Studies have shown that SCS improves tissue oxygenation, decreases pain, and does not mask anginal symptoms. The typical lead position is to place one lead at C7-T1 in the midline and a second lead off midline to the left side at T1-T2.

**OTHER DISEASE STATES**

SCS has been used to treat patients with many pain origins, including postherpetic neuralgia, traumatic nerve injury, post-amputation syndromes, brachial plexopathy, and facial pain in the mandibular nerve distribution.<sup>14</sup> Many studies are ongoing to evaluate SCS efficacy in these patient groups.

For the future of neuromodulation, the role of implant systems in the peripheral nervous system is a growing area of research and clinical application. Peripheral targets include the occipital nerve, ilioinguinal nerve, intercostal nerve, and nerves of the face. A recent multicenter study examined occipital stimulation for the treatment of migraine. The results should be complete in the near future and may lead to a new approved indication.

**Risks, Side Effects, and Complications**

SCS involves the placement of a needle into the epidural space, a lead into a targeted region on the spinal cord, and an incision to stabilize the leads and create a pocket for an internal programmable generator. With this complex array of procedures, there are accompanying risks, including epidural bleeding, epidural infection, postdural puncture headache, wound infection, and other complications.

**Conclusion**

SCS is a reversible, minimally invasive approach to treating pain with the goals of reducing suffering, health care resource utilization, and opioid use, and improving function and quality of life. SCS has been shown to be efficacious and cost-effective versus comparative therapies and should be considered as a viable option in the treatment continuum before a second back surgery, high-dose oral opioids, or an intrathecal pump. It is important for patients to be educated about SCS as a treatment option before moving on to more invasive and irreversible treatments.

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## Case 1

### HISTORY OF PRESENT ILLNESS

The patient is a 45-year-old man who began to complain of pain in the back and both legs after lifting a piece of equipment at work. He later became weak, had severe pain in his legs, and underwent a laminectomy with nerve decompression for acute herniation. He did well for 3 months, but then his pain worsened. A workup was performed with magnetic resonance imaging (MRI) with gadolinium, which showed epidural fibrosis, nerve compression, and disk bulging. He underwent a second surgery with an anterior and posterior fusion. Unfortunately, his condition worsened, and he presented with pain in his axial spine and both lower limbs.

After attempts at conservative measures, he opted for a stimulation trial. This trial was performed with 2 percutaneous cylindrical leads at T9 to T11, which provided him with excellent relief for his leg and buttock pain. He wished to move forward with a permanent implant. The patient and the neurosurgeon who had done his spine interventions discussed his low back pain, and they agreed that a paddle-type plate electrode might be more successful because of the unidirectional electrical flow, energy efficiency, and stability. The patient did not wish to undergo another laminotomy to have the paddle placed and asked the pain team for additional options. At this time, the team decided to place a percutaneous paddle system with a hybrid tripolar array to avoid the need for laminotomy and to reduce trauma, potential complications, and cost.

The patient was prepared for surgery, and an epidural needle was placed at L1/2 via a paramedian approach at a 30-degree angle. A guide wire was placed to the lower thoracic spine, and an introducer sheath was put in the epidural space (Epiducer, St. Jude Neuromodulation (SJNI)). This sheath was used to position a steerable styletted paddle lead into the thoracic target zone (S-8 paddle, SJNI). The paddle lead was used to achieve

coverage of the axial back and lower extremities. At this time, the system was supplemented by two 4-contact cylindrical leads to create a tripolar system. When all leads were activated, a neuromodulatory effect was created, giving paresthesia coverage from the L2 vertebral level to the feet. The sheath was removed, and an incision was made to anchor the leads to the fascia and ligament. A subcutaneous pocket was created, and the leads were connected to a rechargeable generator (Eon Mini, SJNI).

The use of the minimally invasive approach to the paddle placement led to a rapid recovery with minimal trauma and risk for epidural bleeding and less time needed in the operating room. The patient returned to work just 10 days following the procedure. At postoperative week 12, the patient's axial stimulation was maintained and he had weaned off his opioids, increased his function, and rated his quality of life as very high.

## Case 2

### HISTORY OF PRESENT ILLNESS

The patient is a 34-year-old white man with a history of severe pain, particularly in the feet. He was diagnosed with diabetes at the age of 15 years and has had difficulty controlling his blood sugar since. His electromyogram and nerve conduction trial revealed severe peripheral neuropathy. He did not respond to a variety of medications, including anticonvulsants, opioids, and tricyclic antidepressants. After undergoing an SCS trial with a single midline lead at the T9 to T10 level, he obtained 30% relief in the right leg and 10% relief in the left leg. His case was deemed a "failed trial," and he was referred to our center for placement of an intrathecal pump.

### TREATMENT PLANNING

After evaluating the patient, we determined that he was a candidate for a pump trial using ziconotide (Prialt, Azur Pharma). Before proceeding, the SCS trial records were reviewed, and our team determined that the

patient had not received an adequate trial. The patient consented to a repeat trial, and the team obtained approval for the procedure from his insurer.

### ***THE PROCEDURE***

The usual preoperative assessment and preparation were performed. The patient received aggressive treatment from diabetic management professionals, and his hemoglobin A<sub>1c</sub> was optimized. The patient underwent a Hibiclens bath on the morning of surgery, was prepped widely on 6 occasions with Betadine, and was draped widely. A Seldinger approach was used to implant the epidural sheath (Epiducer, SJN), and 3 percutaneous leads were implanted through that device over 5 minutes. The device was removed, and the leads were left in place at T11 to L1. The resulting coverage, new vertebral location, and ability to create a cross-midline tripolar configuration led to a 90% reduction in pain. The trial leads were left in place for 3 days and then discontinued. Two weeks later, the same lead configuration was implanted using the epidural introducer sheath. The patient did well, experiencing excellent pain relief at the 3-month follow-up.

### **Case 3**

#### ***HISTORY OF PRESENT ILLNESS***

A 56-year-old male self-employed farmer presented in 2006 to the pain clinic with a 3-year history of severe lower lumbar pain and bilateral buttock and proximal posterior-lateral thigh pain. He had no discernible numbness, weakness, or atrophy of the lower extremities. His reflexes were normal in the lower extremities, and he had intact bowel and bladder function. He had tried to achieve pain relief without success using a variety of treatments, including 8 weeks of physical therapy, nonsteroidal anti-inflammatory drugs, 2 antiepileptic medications, 3 antidepressant medications, and 4 short-acting opioid medications. His lumbar x-ray revealed spondylosis and loss of disk height at L3/4, L4/5, and L5/S1. An MRI revealed severe loss of disk height with disk protrusions at L3/4, L4/5, and L5/S1, as well as disk bulging at L2/3 and L1/2. Spondylosis was pronounced bilaterally at L3/4, L4/5, and L5/S1.

#### ***TREATMENT PLANNING***

After discussing his options, physicians ordered epidural steroid injections. With 3 sequential epidural injections, the patient achieved 60% subjective pain relief and marked perceived improvement in lifting tolerance, but sustained relief only for about 60 days. Three months after the injections, the pain had fully returned, and a neurosurgical consultation was obtained. The neurosurgeon did not feel that surgical intervention was prudent or feasible because of the patient's multiple-level involvements. Instead,

he recommended further diagnostic workup of the facet and the sacroiliac joints because of the axial component to the pain.

Diagnostic and therapeutic bilateral facet blocks were performed and revealed 15% axial pain relief for 6 hours after the anesthetic phase of the block, where bupivacaine was the anesthetic used. Further injections or radiofrequency ablation of the joints was deferred because the patient perceived that this amount of relief was negligible. The bilateral sacroiliac joints were then injected with 1 to 2 cc of bupivacaine injected into each joint, revealing no discernible relief.

### ***THE PROCEDURE***

At this point, because conservative treatment had failed and surgical intervention was not an option, SCS was scheduled on a trial basis. Two 8-contact percutaneous leads were introduced into the epidural space with needle introduction. The T12/L1 level was the point of introduction, and both leads were steered cephalad until the superior end of each lead ended at the T7/8 disc space. Both leads were placed in parallel near the midline, covering the right and left sides with contacts overlying T8 and T9. Intraoperative testing revealed paresthesia overlap in both buttocks and thighs. After a 4-day trial and 2 intra-trial reprogrammings, the patient chose to defer permanent stimulator placement because he felt very little relief of his low back pain, even though his leg pain was well controlled with the stimulator.

The physicians attempted to maximize pain control for 26 months with medication. The patient tried multiple regimens, and his final regimen, which included timed-release oxymorphone, gabapentin, and baclofen, relieved 40% to 50% of his overall pain if he avoided lifting around the farm; however, his farm and income continued to suffer as a result of his reduced activity.

In August 2011, he underwent a repeat trial of SCS. A percutaneous placement of 3 leads was performed through a new introduction device known as the Epiducer. Using the Seldinger technique, a spinal needle was placed in the epidural space at L1/2, and then a guide wire was placed through it. The surgeon made a half-inch cut in the skin and introduced the Epiducer with careful fluoroscopic visualization, guiding it down to the epidural space. The guide wire and the inner sheath of the Epiducer were removed before steering an 8-contact paddle lead into the epidural space, which was placed cephalad to the T8 level. Two additional 4-contact leads were steered through the same Epiducer to flank the centrally placed paddle, creating a tripole array. The leads were then internalized by creating a small incision, attaching extension leads, and tunneling laterally to the posterior flank. Intraoperative programming revealed excellent low back and leg pain

coverage with stimulator-induced paresthesias.

After a 3-day trial, which successfully relieved 70% of low back pain and 90% of leg pain and eliminated the perceived need for opioids, physicians implanted a permanent stimulator system with a rechargeable generator placed in the left buttock and attached to the 3 implanted leads. At the 4-week follow-up visit,

the patient continued on gabapentin and baclofen, was completely weaned off oxymorphone, and reported about 70% overall pain relief. Six weeks after the operation, he was released to physical therapy. He reported improved range of motion after 4 weeks and has started helping other family members with light to medium lifting on the farm over the last 2 weeks.

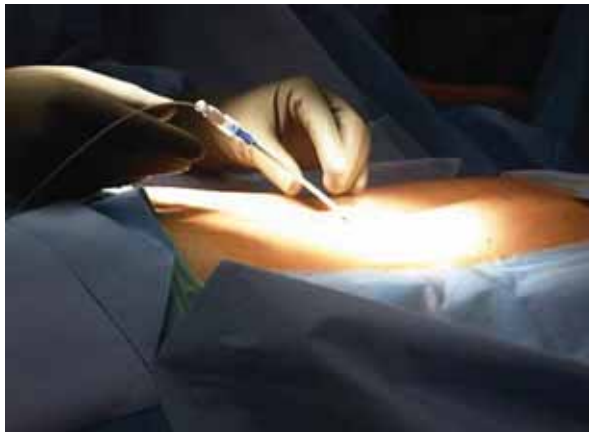
## STEPS INVOLVED IN USE OF EPIDUCER EPIDURAL SYSTEM



**Figure 1.** The Seldinger approach to sheath placement.



**Figure 3.** The system is advanced forward.



**Figure 2.** An Epiducer introduction system placed over a guide wire.



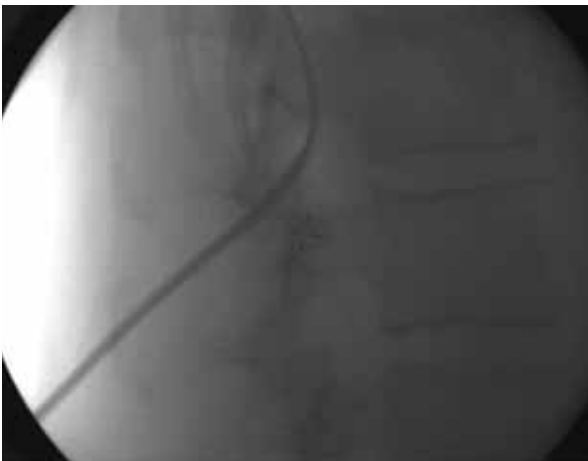
**Figure 4.** Once the Epiducer is placed into the epidural space, the guide wire and introducer are removed.



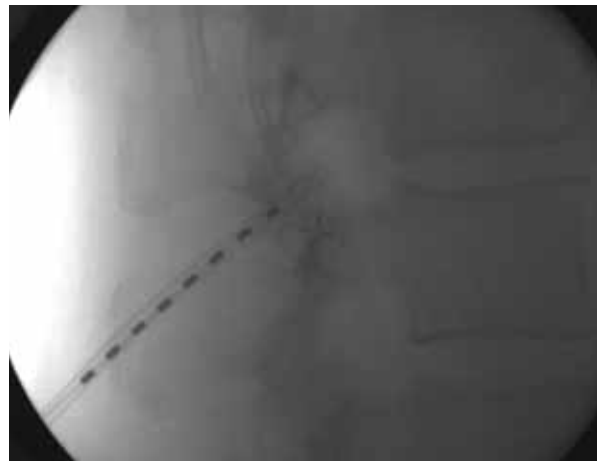
**Figure 5.** Placement of leads via the Epiducer.



**Figure 7.** The guide wire in the epidural space.

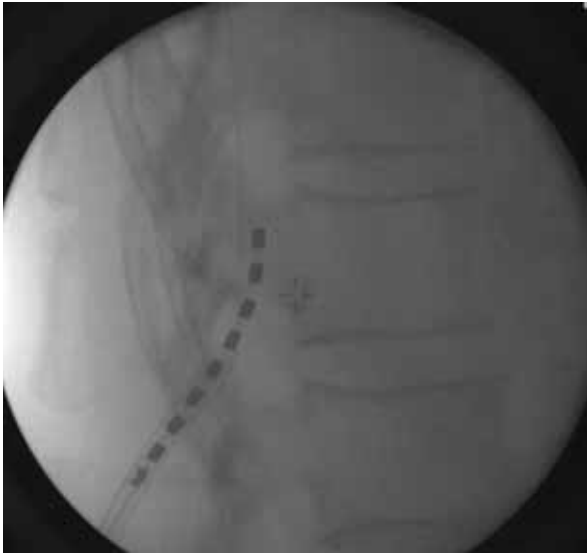


**Figure 6.** The guide wire is placed through the Epiducer.



**Figure 8.** The paddle lead is visualized on the lateral view.

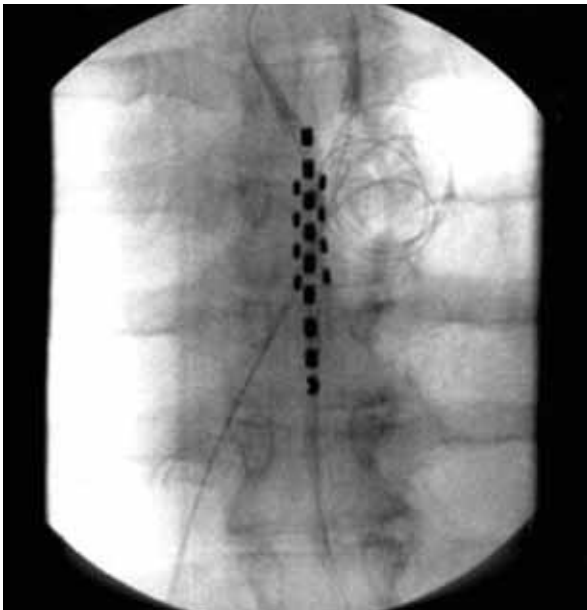




**Figure 9.** A second paddle lead is placed with an indwelling lead in position.



**Figure 11.** Lateral view of permanent paddle lead placed without laminotomy.



**Figure 10.** Percutaneous paddle hybrid tripolar system.