

Chronic Low Back Pain: Care Along the Continuum **Long-Term Benefits of Spinal Cord Stimulation**

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Objectives

At the conclusion of this presentation, the participant will be able to:

- Define spinal pain, historical perception, and its status along the continuum of care
- Describe the anatomy and physiology of spinal pain
- Identify current treatment options
- Describe the physiology of spinal cord stimulation (SCS)
- Assess long-term costs (and alternatives) of chronic pain treatment

Introduction

Each year, the healthcare system is barraged with an array of new technologies. Healthcare providers need to know about these technologies: what they are, what they do, where they fit into patient care, and how best to evaluate and utilize technology to address patient needs.

Utility value is based on the recipient's perspective. For example, patients seek relief from illness, injury, pain, and suffering. Physicians and healthcare providers are concerned about health economics and the ability to provide the best care in a cost-effective manner. Third-party payors are concerned with containing health care costs and reducing healthcare resource consumption. These values are not mutually exclusive.

Background

In the United States today, 9% of the population have moderate to severe non-cancer-related chronic pain. In addition to disability, impairment, suffering, and compromised quality of life (QOL), the presence of chronic pain presents an economic burden to patients and society. Annual economic loss associated with chronic pain exceeds \$100 billion,¹ exclusive of disability ("An alteration of an individual's capacity to meet personal, social, or occupational demands, because of an impairment"²) or societal costs.

"Pain is subjective. It is what the patient says it is. It is present when the patient says it is."³ It does not always correlate with diagnostic testing. Excluding mechanical defect does not necessarily decrease pain.

Chronic, intractable neuropathic pain is intense pain caused by injury to the nervous system that lasts several months or longer and is not relieved by medical or surgical intervention. It may result from an injury already healed or an ongoing condition (e.g., nerve damage, cancer, chronic infection). Chronic low back pain (LBP) may develop from alterations in the central nervous system (CNS), causing pain to be magnified and imprinted on sensory pathways to the CNS.

Chronic pain usually follows an injury and continues after healing. The trauma produces sympathetically (nervous system) maintained pain. Pain impacts overall health, including the:

1. Mekhail NA, Aeschbach A, Stanton-Hicks M. Cost benefit analysis of neurostimulation for chronic pain. *Clin J Pain*. 2004;20(6):462.

2. AMA Guidelines

3. Moreo K. *Managing Low Back Pain*. Unpublished Peer Review.

- Cardiovascular system (decreases myocardial oxygen supply, resulting in arrhythmias, angina, congestive heart failure and potentially, myocardial infarction),
- Endocrine system (increases the release of cortisol, ACTH, glucagons, epinephrine and can decrease testosterone and insulin levels),
- Gastrointestinal system (disrupts nutritional intake and increases sphincter tone),
- Pulmonary system (can increase skeletal muscle tension, impacting lung capacity and potentially lead to hypoxemia), and
- Mental well-being.

Psychologically, pain can produce inhibition and fear-avoidance behavior, further increasing the morbidity that occurs with chronic pain. Depressed patients report greater pain intensity, reduced life control, passive-avoidant coping, and poor surgical outcomes.

Ten percent of adults in the United States meet the criteria for depression and 25% are diagnosed with anxiety in any 12-month period. The prevalence of depression and anxiety is two to three times greater in the pain population.⁴

A Behavioral Pain Assessment can evaluate symptoms of depression associated with medical complaints, as well as emotional and behavioral factors that impact pain intensity or surgical recovery.

Chronic pain is a long-term process, and patients have developed anticipatory anxiety and fear-related activity restrictions and may have limited their lifestyle activities from feelings of hopelessness, anxiety, and inappropriate goals and timelines. A counselor can help patients identify realistic goals that are explicit and operationally defined.

A pain management counselor is part of the team dedicated to resolution of chronic pain. The behavioral assessment enhances the team's ability to treat depression/anxiety, set realistic goals, develop an effective rehabilitation program, and teach the patient to measure incremental success. The patient is empowered to take control of his/her pain by systematically eliminating anxiety, fear, and disability associated with chronic pain.

Pain

There are two categories of pain: 1) actual damage to peripheral nerves or the CNS and 2) nociceptor (neural) pain resulting from nerve irritation or tissue damage.

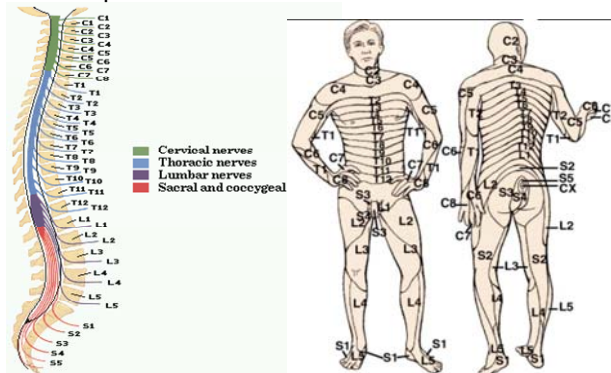
Neuropathic pain is the clinical manifestation of neural injury. It may involve peripheral mechanisms or become centralized, producing a clinical state of pain and impairment (a loss, loss of use, or derangement of any body part, organ system or organ function),⁵ not related to ongoing tissue damage. The tissues have healed, but the irritated nerves continue to send pain signals. It becomes a self-sustaining pain process. Nerves that carry persistent signals "learn" to carry signals more efficiently, transmitting signals without stimuli, while simultaneously recruiting other nerves. Damage to sensory or motor neurons in one dermatome (the area of skin supplied by cutaneous branches from a single spinal nerve) can produce spontaneous activity among nociceptors (peripheral nerves that that receive and transmit painful or injurious stimuli) in adjacent dermatomes.

4. Van Dorsten B. Psychological considerations in preparing patients for implantation procedures. *Pain Medicine*. 2006;7(S1):S51.

5. AMA Guidelines

Spinal Nerves & Dermatomes

- Spinal Nerves travel from Spinal Cord to innervate associated Dermatome
 - L5 Spinal Nerve innervates L5 Dermatome



Leriche defined pain disorders as: “Certain, little understood conditions, whose determinant factors run an unknown, but that are frequent and in which pain is the entire, or almost the entire, disorder itself.”⁶

Back pain is the most common and expensive cause of chronic pain. LBP is experienced by 15% to 20% (30-40 million people per year) in the United States. Sixty to ninety percent of adults will experience LBP at some time in their lives. It is a major cause of disability in people younger than age 45 and the third most common cause of disability in people of all ages. The direct medical cost of LBP is \$25 billion per year.⁷

Common causes of low back pain (LBP) include arachnoiditis, disc protrusion, pinched nerve, and failed back surgery syndrome (FBSS). It is crucial, when treating back pain, to rule out (and treat) any mechanical anomaly. This often involves surgery. In the United States, there are more surgeries for LBP and leg pain per capita than any other country.⁸ Unfortunately, “...There is little empirical evidence supporting efficacy of any surgical treatment for chronic low back pain.”⁹ The success rate following surgery is less than 25%.¹⁰ Many patients suffer from FBSS (“chronic back and leg pain after technically and anatomically adequate lumbo-sacral surgery”¹¹).

Studies by the Social Security Administration and the Institute of Medicine have led to the emerging consensus that treatment of chronic LBP is generally inappropriate, excessive, and expensive, requiring frequent office visits, expensive medication, emergency room visits, hospitalizations, radiology tests, interventional pain therapies, and repeat surgeries. Most patients begin treatment with surgery and carry a 10% probability of repeat surgery each succeeding year.¹²

6. Bennett DS, Brookoff D. Complex regional pain syndromes (reflex sympathetic dystrophy and causalgia) and spinal cord stimulation. *Pain Medicine*. 2006;7(S1):S67.

7. Moreo K, Hess C. *Managing Low Back Pain*. Unpublished peer review.

8. Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. *Pain*. 2004;108:24.

9. *Ibid.* page 24.

10. Moreo, page 5.

11. Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: A decision-analytic model and cost-effectiveness analysis. *Int J Technol Assess Health Care*. 2005;21(3):351.

12. Bell GK, Kidd D, North RB. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage*. 1997;13(3):289.

Treatment goals for chronic pain include reduction in pain, improved function, and restoration of psychological health.

Historical Perspective

Neuromodulation is defined by the International Neuromodulation Society (INS) as: “Field of science, medicine, and bioengineering that encompasses both nonimplantable and implantable technologies, electrical and chemical, that improve the life of humanity.”¹³ The INS exists to: “Promote, disseminate and advocate for the science, education, best practice and accessibility of all aspects of neuromodulation.”¹⁴ Physicians treating chronic pain agree that: “Neuromodulation therapies add immeasurably to the armamentarium of pain physicians and should be used when less invasive and less costly therapies fail to meet the goals of pain medicine.”¹⁵ The goal is consistent, time stable relief of LBP, reduced intensity of pain, and improved physical and emotional functioning.

The first SCS devices were implanted in 1967 for the treatment of FBSS, peripheral vascular disease (PVD), angina, and CPRS (formerly called reflex sympathetic dystrophy (RSD)).

Major improvements led to better results and widespread acceptance for neuropathic pain refractory to other therapies:

- Clearer definition of appropriate indications,
- Improved system component design resulting in decreased device failures,
- Refined patient selection criteria that screens out inappropriate patients, and
- Evolution of trial stimulation through percutaneous electrode stimulation to assess effectiveness for individual patients.

SCS received an approved Medicare national coverage decision on August 7, 1995.

Care Along the Continuum

Chronic LBP is typically treated by multiple providers using multiple modalities, resulting in fragmented care and delayed referral for pain management, thus allowing central sensitization of nociceptor pain to occur. Traumatized nerve endings begin to fire spontaneously.

The incidence of chronic pain can be diminished through early referral to a multidisciplinary pain center and a coordinated approach to pain management to prevent central sensitization. Early referral has been recognized by the North American Spine Society (NASS) and the American Academy of Orthopedic Surgeons (AAOS), who have included early intervention in their algorithm for the treatment of chronic LBP.

There are economic barriers to chronic care. Third-party payors measure cost in relation to their fiscal year, thus long term gain is sacrificed for immediate gratification (low cost per annum). Additionally, there are continuous changes in carrier medical necessity criteria for coverage. “It is easier to control the plans financial resources by constantly

13. Krames ES. Neuromodulatory devices are part of our “tools of the trade.” *Pain Medicine*. 2006;7(51):S3.

14. Ibid, P. S4

15. Ibid, P. S5

changing the eligibility rules of the plan.”¹⁶ Advanced technologies are used as a last resort, usually following an extensive list of other treatments.

There are multiple, conflicting reimbursement goals. Patients are seeking coverage for medical care and relief of pain and suffering. Physicians are looking for adequate payment. Hospitals are seeking revenues, carriers are trying to reduce cost, and society is seeking productivity. Treatment requires care that is coordinated, efficacious, affordable, and low risk. There is a need for outcome measures that meet the needs of the patient, the healthcare system and society.

It is essential to consider long-term treatment of a long-term condition. Physicians should select treatment based on the best current efficacy, evidence, and likelihood of longitudinal effectiveness. They must consider the patient’s activity level, sleep pattern, and social functioning.

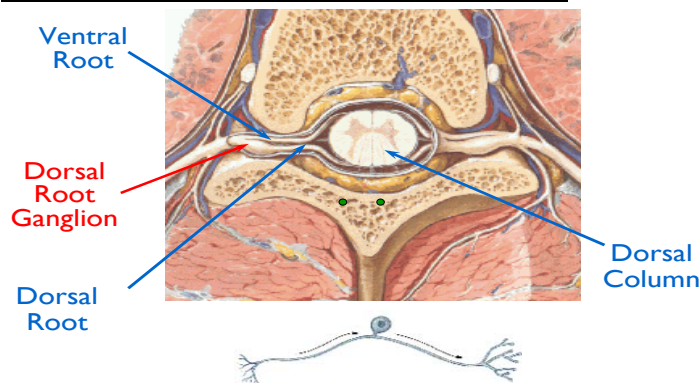
Current treatment has not demonstrated long-term benefit or pain relief. Surgery often results in FBSS, and implantable drug pumps (IDPs) are effective for only 40% of patients. Physical therapy may provide temporary relief, but has not been shown to improve physical, psychological, or occupational health.

There is a need for a better understanding of interventional pain technologies and their existing indication/application, as well as new indications. It is essential to understand the mechanism of action, case selection and assessment of outcomes.

Anatomy and Physiology

The spinal cord carries nerve fibers mediating sensation from receptors in specific areas (dermatomes). Each spinal nerve has a dorsal and ventral root. The dorsal root (DR) mediates sensory information. The ventral root (VR) mediates motor function. The DR and VR exit the spine and merge to form a (mixed) spinal nerve.

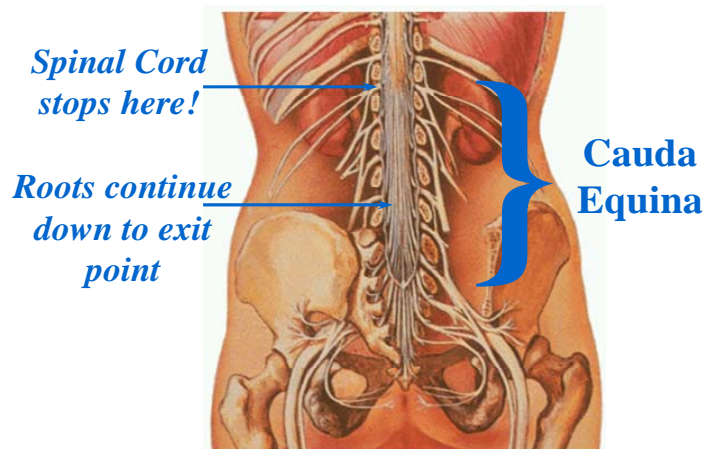
Dorsal Column and Dorsal Root



16. Sitzman TB, Gallagher RM. Effectiveness of neuromodulation: An economic paradigm. *Pain Medicine*. 2006;(S1):S186.

The dorsal root enters the dorsal column (DC). It carries pain sensation to stimulate pain, but the level of stimulation is low enough to avoid altering motor function. The DC contains representations of all body parts below the level of entry, thus the spinal segment for LBP is at T7. Dorsal root stimulation produces parasthesias in the distribution of a single dermatome at the level stimulated. More diffuse parasthesias must interact with the dorsal column.

Spinal Cord & Spinal Nerves



Early treatment for pain and inflammation is an influencing factor in the prevention of chronic pain. If severe pain persists, the CNS undergoes changes and begins generating signals that will maintain and escalate peripheral inflammatory response. This involves an *antidromic* (backward) transmission through sensory nerve fibers, called *dorsal root reflex*. Prolonged pain signals produce dorsal root reflex. Afferent cells in the dorsal horn release mediators that stimulate nociceptors to fire action potentials antidromically. This occurs only with prolonged and unsuppressed nociception. The concentration of neurotransmitters changes markedly and their function may be transformed after injury. A barrage of painful stimuli over time produces neural pathway changes. These changes alter how pain signals are processed, producing hyper sensitization, which results in severe, persistent pain—now the pain becomes the disease.

Continuous pain stimulation → neural pathway changes → changes how pain signals are processed → hyper sensitization → severe, persistent pain → pain becomes the disease.

The treatment goal is to bring neural activity into balance—to “unlearn” the pain response and return to more normal processing. Neuroplasticity is the CNS’ ability to adapt (rewire) in response to stimuli injury. It is essential to relieve pain enough to prevent progression. It is critical to prevent early central sensitization. If the third-party

payor requires conservative therapy for one month, pain has time to alter the CNS resulting in more pain and ever-increasing costs.

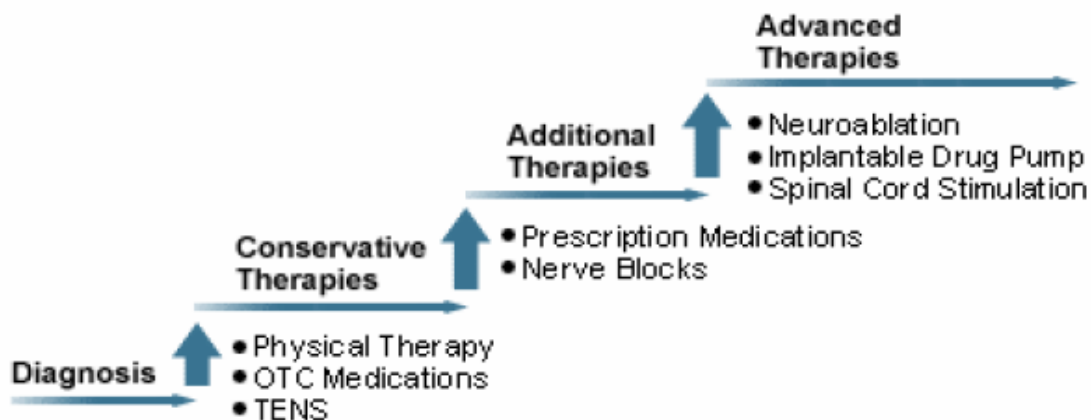
Gate Control Theory

The dorsal horn of the spinal cord receives nociceptor (painful) stimuli via small diameter nerve fibers. Stimulation of large nerve fibers inhibits reception of painful small diameter fibers (theory behind SCS). There is a normal path to transmit pain and multiple paths to mediate pain. Pain is an alarm system that causes the individual to react to pain to reduce pain and thus stop the danger. For example, rubbing a sore leg stimulates the large nerve fibers that inhibit the transmission of pain impulses across the small nerve fibers. This replaces the pain sensation through stimulation of non-nociceptor fibers.

Normally, nociceptors do not generate pain, but develop heightened sensitivity to catecholamines (chemicals, such as epinephrine and norepinephrine, secreted in response to stress) after injury. The process that promotes pain also damages tissues and organs, thus prolonged pain has lost its purpose.

Treatment Options

Medical. Treatment for LBP begins conservatively with physical therapy (PT) and medication, such as nonsteroidal antiinflammatory drugs (NSAIDs), then progresses to muscle relaxants, antidepressants, and activity modification. Many patients independently seek massage therapy and spinal manipulation. When these efforts fail, treatment may progress to opioids (neuropathic pain is resistant to opioids) steroid injections, and finally surgery.



Surgical. There are multiple surgical options: discectomy, laminectomy, spinal fusion, and foraminotomy. Patients may also choose intradiscal electrothermal therapy (IDET). This procedure uses heat to shrink a single, specific disc, thus reducing pressure on a nerve. It is best used for young patients with a single disc and no complications. Patients may also choose an IDP, with specific doses of analgesic delivered directly into the spinal column to relieve pain.

When conservative measures have failed, the next phase of treatment begins with surgery. The success rate after surgery is less than 25%. Many patients develop scar

tissue and adhesions at the surgical site, necessitating additional surgery to remove the scar tissue and adhesions and reduce pain from the previous surgery. Patients carry a 10% chance of repeat surgery every year thereafter.

Removal of a mechanical defect may not reduce pain or improve mobility. Patients continue to have chronic LBP. The diagnosis becomes FBSS. Pain has become neuropathic, often with a vascular component. Neuropathic pain must be treated neuropathically.

One option for treating neuropathic pain is with SCS. This procedure involves placing metal electrodes—arrayed on a lead or leads—in the dorsal epidural space. The lead(s) are then connected to an implantable pulse generator (IPG). The contacts are programmed in a combination of anode (negative charges) and cathodes (positive charges) that generate an electric field that stimulates axons in the dorsal root and dorsal column. Stimulation of the leads inhibits activity in the spinothalamic tract (pain pathology) and increases activity in the antinociceptors (anti-pain) pathways, producing parasthesia. Stimulation of the non-pain receptors closes the gate to pain receptors, thus altering the perception.

Effective treatment of the painful area mandates that parasthesias cover 100% of the affected (painful) area. If they do not, the leads must be reprogrammed.

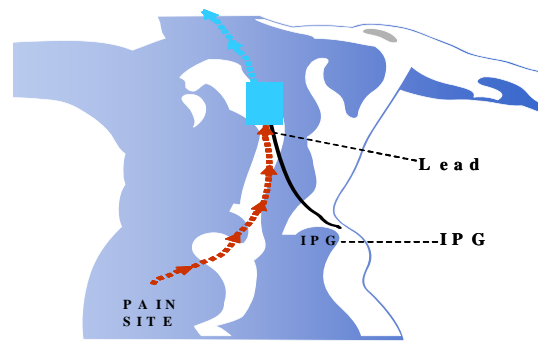
SCS suppresses efferent sympathetic activity, thus reducing peripheral vasoconstriction and providing secondary relief of pain of both vascular and neural etiology.

Slight movement or dislocation of the leads may alter the area covered by parasthesia resulting in other motor or sensory signals. For this reason, patients must be involved with their therapy and be able to verbalize change in sensation and comfort level and work with the physician to reprogram as necessary.

Mechanism of Action. Chronic pain is a pathological condition in which the pain sensory and pain relieving system is out of balance. It is essential to either reduce abnormal pain signals or reinforce the body's natural pain-relieving mechanism. SCS must achieve maximum control over stimulation of targeted nerves while avoiding non-targeted nerves (neural selectivity). The intent of neurostimulation is to activate only those nerves that create therapeutic effect.

The benefit of SCS is proportional to the number of targeted nerves stimulated and inversely related to the number of undesired nerves stimulated. Pain relief with SCS is strongly correlated with ratings of overlap by parasthesia. Sensory nerves cluster in the dorsal aspect of the spinal canal, therefore the spinal canal is the preferred region for SCS. Leads are placed dorsal to the target structure and outside the dura to avoid motor stimulation and maintain the integrity of the dural membrane.

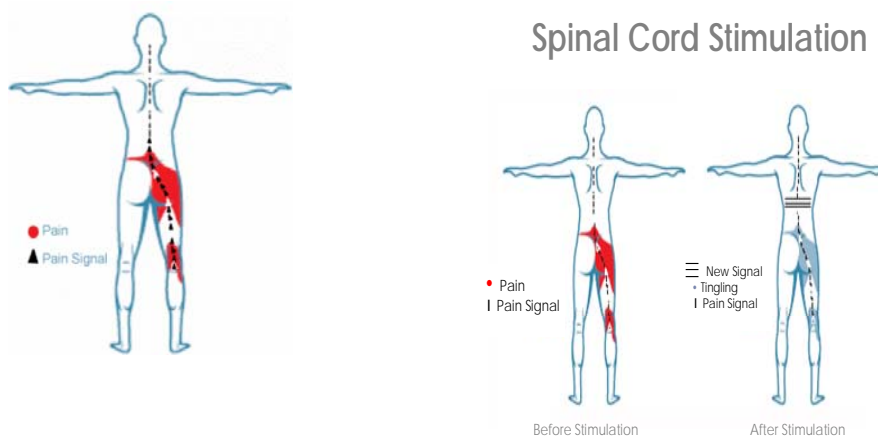
Electrical stimulation of the spinal cord replaces the pain sensation with a tingling sensation called parasthesia. The clinical objective is to match the parasthesia to the regions(s) of pain by activating specific dorsal column fibers using a localized electrical stimulation field. SCS uses a multi-contact lead placed along the spinal cord, attached to a programmable IPG.



Activation of special pain receptors in the skin and tissue (dermatomes) sends an impulse along the nerves to the *spinal cord* and upward to the brain, which registers the message as the sensation of pain. The SCS alters that sensation by replacing it with parasthesia, thus registering the sensation of tingling.

The optimal parasthesia-pain overlap depends upon activation of specific spinal cord sensory fibers. These are primarily determined by the shape of the stimulation field. The shape of the stimulation field is determined by the anode-cathode current distribution. The anode-cathode produces many possible contact combinations. Sixteen contacts can produce more than 63 million combinations—clearly an overwhelming task.

New SCS systems can manage this task and allow the patient to self-direct the stimulation field to achieve parasthesia-pain overlap. Under physician supervision, the patient increases stimulation amplitude until a comfortable threshold is reached. The goal is to optimize parasthesia-pain overlap. Patients should adjust the level of stimulation so that they always feel parasthesia. Patients select the current contact distributions that provide the best parasthesia coverage of painful areas. When patients find good contact distribution, they should save that program. Patients then assemble four of the best contact distributions into a program. The program can be changed as needed.



Outcomes. “SCS has been so effective for intractable chronic pain syndrome, that every pain center should be able to offer this therapy in its treatment program”¹⁷

17. Brookoff D. Neurophysiological underpinnings of electronic analgesic neuromodulation for dummies. *Pain Medicine*. 2006;7(S1):S116.

Success is based on the patient's tolerance of parasthesia, greater than 50% reduction in pain perception and patient satisfaction. Measured outcomes should include LBP, physical functioning, drug use, work status, health care utilization and QOL.

The 100 mm visual analog scale (VAS) is an established measurement in clinical pain practice to measure and record patient pain perception. On a scale of 1 (no pain) to 10 (unbearable pain), patients are asked to designate a number corresponding to their perception of pain. The accepted standard for pain relief is *equal to, or greater than, 50%* reduction in pain.

A study by Kemler¹⁸ reporting one-year outcomes of patients treated with SCS, describes a reduction in VAS rating from an average of 7.1 mm before SCS to 4.4 mm after SCS and compares this to patients treated with conservative medical management (CMM) that included physical therapy and medication. The CMM group reported an *increase* in VAS rating from 6.7 mm before CMM to 7.1 mm after CMM.

Both Kemler¹⁹ and Ohnmeiss²⁰ reported significantly improved quality of life. Kumar²¹ in a study of 104 patients concluded SCS patients reported 27% improvement in quality of life (QOL) and 15% return to work (RTW). He reported patient satisfaction: 60% very satisfied, 28% satisfied, 12% unsure; 88% would recommend the procedure to a friend. The control group reported 12% increase in pain. This is consistent with other QOL and RTW studies (Appendix A).

Recent systematic reviews of many trials with thousands of patients also verify the benefits of SCS. A 2005 review²² of 74 studies of 3300 patients with chronic leg and back pain and FBSS found that:

- 62% of implanted patients achieved at least 50% pain relief.
- 53% needed no analgesics post-SCS.
- 40% returned to work.
- 70% were satisfied with SCS.

Another review of 3679 patients²³ with mixed diagnoses demonstrated that SCS is safe and effective for treating a variety of chronic neuropathic conditions. Specifically:

- Overall success rate was 67% in patients followed for more than 6 months.
- Success rate was 83% for CRPS and 62% for FBSS.
- SCS is safe. Most complications were not life threatening and could usually be resolved by removing the device. The most common complication was lead migration.

18. Kemler M, Furnee C. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology*. 2002;59:1205.

19. Ibid.

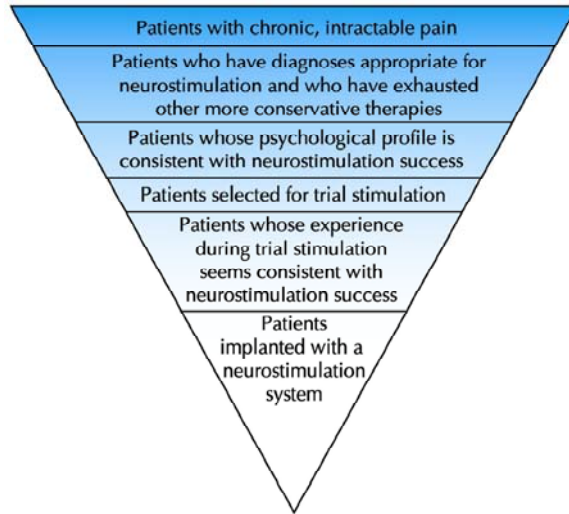
20. Ohnmeiss D, Rashbaum R, Bogdanffy G. Prospective evaluation of spinal cord stimulation in patients with intractable leg pain. *Spine*. 2001;21(11):1347.

21. Kumar K, Malik S, Demeria D. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: Cost-effectiveness analysis. *Neurosurgery*. 2002;51(1):106-115.

22. Taylor RS, Van Buyten JP, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: A systematic review and analysis of prognostic factors. *Spine*. 2005;30:152-60.

23. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: A 20-year literature review. *J Neurosurg (Spine 3)*. 2004;100:254-267.

Screening Paradigm for SCS



There are four basic steps.

1. **Candidate Evaluation:** The physician determines if the patient is likely to be an appropriate candidate for SCS.
2. **Trial Stimulation:** Minor reversible procedure where trial leads are placed along the spinal cord and attached to an external trial stimulator (ETS), programmed to deliver stimulation that covers the pain areas at the necessary level. Over a trial period of two days to two weeks, the patient experiences SCS to evaluate whether it relieves pain.
3. **Permanent Implantation:** If the trial is successful, the patient will undergo another surgical procedure to implant the stimulator (IPG).
4. **Fine Tuning Pain Coverage:** Over time, the stimulation settings can be routinely fine-tuned for more precise pain coverage.

Process. There are specific patient selection criteria. Not all patients are candidates for SCS. Prior to implanting a stimulator, patients should have a thorough medical evaluation (history and physical, x-ray, CT, MRI, myelogram) to rule out any potential pathology such as tumor, fracture, dislocated disc, etc. If a treatable pathology exists, this should be addressed, and the patient reevaluated (if necessary) after treatment.

Patients considering SCS should have a presurgical psychological evaluation. The presence of clinical psychosis or substance abuse is a contraindication for SCS treatment. Many patients with chronic LBP have an element of depression present (it is part of the chronic pain syndrome). This can be treated preoperatively.

The patient's chronic pain has been present for a long time. Patients have developed anticipatory anxiety related to fear of pain with increased activity. Patients may also have developed subjective disabilities. These can be addressed prior to implant. An experienced counselor can help the patient define expectations and set goals. There may always be some pain present, but the majority of the pain will be replaced with paresthesia. This is an opportunity to identify QOL improvements and set goals. Patients need to be made aware that they may not assume their pre-morbid activity.

Patients can benefit from meeting with the rehabilitation team (physician, physical therapist, neuromodulation nurse, and psychologist). Rehabilitation is focused on function, not pain. Education for goal-setting, exercise to target levels with gradual increase, and gradual expansion to painful activity, are essential. Patients need to know pain will increase initially. This is not dangerous and exercise should continue. This will help to increase muscle strength and manage pain. Both will improve QOL.

Following the medical evaluation, psychological screening, and rehabilitation evaluation, patients who are appropriate candidates for SCS begin *trial stimulation*. That is, a minor surgical procedure in which electrodes are implanted in the dorsal column, connected to an external pulse generator and programmed so that parasthesia covers the painful area. If patients experience 50% (or greater) reduction in pain and chooses to continue, they may undergo a second procedure to implant a permanent SCS system, comprised of an IPG and new leads. A patient programmer and charging system (for rechargeable IPGs) is also necessary. Patients are followed by their physician and neuromodulation specialist to program and reprogram as necessary the IPG to ensure parasthesia coverage of the affected area.

Complications. Life-threatening complications (including spinal cord infection) are rare. A costly complication is IPG replacement due to earlier-than-expected battery depletion, but that incidence may be reduced with rechargeable IPG technology. The most frequent complications reported in the literature²⁴ include:

Complication	Incidence (%)
Lead migration	13.2
Lead breakage	9.1
Infection	3.4
Hardware malfunction	2.9
Unwanted stimulation	2.4
Battery failure*	1.6
Pain over implant	0.9

* Failure = Battery replacement before expected failure date

Contraindications for SCS, in addition to clinical psychosis and substance abuse, include patients who are unable to operate the SCS system, have failed trial stimulation by failing to receive effective pain relief, and are poor surgical risks or are pregnant.

Cost. “The best medical care may not be the cheapest.”²⁵ SCS has a high initial cost, followed by a long-term stream of benefits.²⁶ Initial costs are those of the implant, surgery, devices, programming and physical therapy. (Appendix D)

Maintenance treatment of chronic LBP usually begins with surgery and carries a 10% probability of repeat surgery each succeeding year. The Medicare cost of one year of nonsurgical chronic care is \$8,850.²⁷ The average patient will have 3.3 surgeries before being referred for SCS. Operative costs include revision and instrumentation, revision and fusion, microdiscectomy, drugs, physical therapy, hospitalization, and complications.

24. Cameron T. Twenty Year Literature Review of SCS. *J Neurosurgery (Spine)*. 2004;100:264.

25. Schofferman J. Restoration of function: The missing link in pain medicine? *Pain Medicine*. 2006;7(S1):S164.

26. Bell GK, Kidd D, North RB. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage*. 1997;13(3):289.

27. *Ibid*, p 290.

Costs for SCS, including replacement cost every five years and an annual complication rate of 30%, include; hardware, professional fees, radiology, hospitalization, medication, nursing contacts, electrode or pulse generator replacement during the five-year follow up.

Costs for chronic care after surgery include physician fees, medication, radiology, alternative therapy, and hospital admissions.

There are multiple studies (Appendix B) comparing the cost of SCS to CMM. All demonstrate cost savings via long-term reduction in healthcare resource consumption.

Bell²⁸ discusses a European study²⁹ that concluded the expense of SCS therapy was more than compensated by the relief of pain, ability to return to work, and reduction in analgesic use. In that European study, the authors estimate “payback” at 2.1 years. Kumar³⁰ estimated the costs of SCS over five years at \$29,123 per patient, while those of CMM are at \$38,029 per patient. Kemler³¹ estimates an average saving per life with SCS at over \$60,000 versus the control therapy. Additionally, the effectiveness of SCS is superior to CMM, thus the true utility is underestimated.

Based on his literature review, Taylor concluded: “The initial healthcare acquisition costs of implantation are consistently offset by a reduction in post implant healthcare resource demands and costs.”³²

Cost neutrality can be achieved at five years, even with a high complication rate, and at 3.4 years without complications. SCS requires fewer physician visits, nerve blocks, imaging studies, emergency room visits, and hospitalizations. Estimated savings from surgery is \$30,221 or \$93,685 over three years.³³

Mekhail³⁴ postulates that the ideal cost-benefit should be based on third-party payor actual reimbursement. Appendix B uses the Medicare fee schedule to compare five-year costs of SCS with PT to CMM over a five-year period to find the cost per pain-free day. Appendix B also uses the Medicare national average reimbursement for 2007. Number and type of interventions for chronic pain are identified by Kumar³⁵. He describes emergency visits at level III (including assessment and evaluation, lab work), radiology, a three-day hospitalization, nerve block. Facility costs are based on ICD-9 codes.

As shown in Appendix B, based on the actual Medicare national unadjusted average payment for 2007, amortized over five years, the cost per pain-free day for SCS is \$31.97. The cost per day for CMM is \$39.36. This represents a savings of 18.8% with

28. Bell GK, Kidd D, North RB. Cost-effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage.* 1997;13(3):288

29. Bel S, Bauer BL. Dorsal column stimulation (DCS): Cost to benefit analysis. *Acta Neurochirurgica Suppl.* 1991;52:121-123.

30. Kumar K, Malik S, Demeria D. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: Cost-effectiveness analysis. *Neurosurgery.* 2002;51(1):106-115.

31. Kemler M, Furnee C. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology.* 2002;59:1208.

32. Taylor R, Taylor RJ, Van Buyten JP, Buchser E, North R, Bayliss S. The cost effectiveness of spinal cord stimulation in the treatment of pain: A systematic review of the literature. *Pain Symptom Manage.* 2004;27(4):370.

33. Mekhail NA, Aeschbach A, Stanton-Hicks M. Cost benefit analysis of neurostimulation for chronic pain. *Clin J Pain.* 2004;20(6):467.

34. Ibid

35. Kumar K, Malik S, Demeria D. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: Cost-effectiveness analysis. *Neurosurgery.* 2002;51(1):106-115.

SCS. This is exclusive of psychosocial factors such as diminished suffering and depression, improved QOL and RTW.

Evaluating Technology. One function of the International Neuromodulation Society (INS) is to educate healthcare professionals, identify best practices, and promote accessibility of neuromodulation. Part of the education process is to develop a mechanism to identify the best options and apply them appropriately. Any new device must be effective, comfortable, easy to use, acceptable to patients, and cost-effective. There are three variables to be considered: clinical efficacy, complication rates, and cost savings through advanced technology.

There is clinical efficacy for SCS. Previous studies with original technology demonstrated that SCS provides, on average, 50% reduction in pain for at least 62% of patients.^{36,37} Though the primary objective of SCS is to reduce pain, outcomes have shown an improvement in RTW. The literature validates improved QOL and reduction in healthcare costs. Complications are minimal, and those that do occur are non-life-threatening.

We now need to know how to evaluate *advanced technology alternatives*. Some issues to consider include:

- Generator life: A longer generator life equals fewer replacements.
 - What is the longevity of the IPG?
 - Does it address multiple afferents?
 - Can it change stimulation patterns to meet the patients' needs?
- Battery life: A longer battery life means fewer surgeries
 - Is it rechargeable—repeatedly—without loss of function?
 - Can it be drained to zero volts without loss of function?
 - Is it backed by a warranty?
- Leads control current: More electrodes equal more combinations.
 - Is there tight spacing for more control?
 - Are there multiple contacts within the leads designed to allow precise targeting?
 - Are there multiple combinations?
 - Is there a constant flow of current (voltage)?
- Software: After the SCS is implanted, the patient must identify painful areas.
 - Is the software easy to use for both patient and provider?
 - Can it be programmed to stimulate the identified pathways?
 - Is the patient able to evaluate, respond to, and control stimulation?
- Size: Smaller generator size means more placement options and greater patient acceptance
 - Is the generator small enough to be acceptable to the patient?

Conclusion. Neuropathic pain precipitates pain and suffering, diminishes QOL, and turns impairment into disability. It is expensive for society, government, employers, payors, and patients. Early referral to a multidisciplinary pain center and more coordinated approach is essential to prevent central sensitization. Early referral has been put forth in an algorithm by NASS and AAOS. There is a need to educate primary care physicians

36. Taylor RS, Van Buyten JP, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: A systematic review and analysis of prognostic factors. *Spine*. 2005;30:152-60.

37. Cameron T. Twenty-year literature review of SCS. *J Neurosurgery (Spine)*. 2004;100:264.

(PCP) and other healthcare professionals to build an awareness of this disease entity and options available for treatment.

Spinal cord stimulation has existed for many years. It has been proven clinically effective in multiple studies. It also has been proven cost effective. There have been technical advances (small IPG, rechargeable batteries, etc). Patient selection criteria have been identified. The availability of trial stimulation ensures that SCS is performed only in patients with a high likelihood of success. Pain management providers advocate early intervention and use of SCS. Complications are few and non-life-threatening. SCS is a very viable option that diminishes pain and suffering, reduces dependence on medication, and provides return to work.

Utility value is based on the recipient's perspective. SCS offers utility value to all recipients. Patients obtain relief from pain, suffering, and disability, and can begin to restore psychological health. Providers can offer lasting relief of LBP, reduced intensity of pain, and improved physical and emotional functioning. Third-party payors are able to lower health care costs and reduce consumption of healthcare resources. Society benefits from improved productivity.

Spinal cord stimulation, appropriately implanted, is recognized as a successful option in the treatment of chronic pain.

APPENDIX A

Quality of Life and Return to Work After Spinal Cord Stimulation

Study	Improved QOL	RTW
Taylor 2005	70% satisfied with SCS	40% returned to work
Kumar 2002	SCS: 27% ↑ Control: 12% ↑ 88% satisfied w/SCS	SCS: 15% returned to work Control: no RTW
Kemler 2000	QOL improved 11%	No change in functional status
Ohnmeiss 1996	Significantly improved QOL	Before SCS: 0 patients 2 years after SCS: 4 patients

APPENDIX B

Comparison of costs per day: SCS implant versus conservative medical management

- Meklar states that the best economic evaluation is based on third-party actual reimbursement
- Kumar suggests an analysis based on cost/day over 5 years

The following is based on:

- 1) The Medicare national average payment (unadjusted) for 2007
- 2) Each element (CMM and SCS) is calculated for 5yrs.
- 3) Costs (actually, Medicare payment rates) are amortized over 5 years to yield a cost/day.

Results of analysis:

Average cost/day over 5 yrs:

- SCS: \$31.97
- CMM: \$39.36

18.8% reduction in costs with SCS

GLOSSARY

ACTH (adrenocorticotrophic hormone): A steroid secreted by the adrenal cortex that facilitates the chemical transfer of nerve impulses across the synapse.

Afferent: Inflowing—nerve fibers that transfer impulses from the periphery to the spinal cord or CNS.

Anode: An electrode to which negatively charged ions (anions) migrate.

Antidromic: The propagation of an impulse along a conduction system (ie, nerve fiber) in the direction opposite to which it usually travels.

Arrhythmia: Loss or abnormality of rhythm, especially an irregularity of heartbeat.

Catecholamines: Chemicals, such as epinephrine and norepinephrine, secreted in response to stress.

Cathode: The electrode to which positively charged ions (cations) migrate.

Dermatome: The area of skin supplied by cutaneous branches from a single spinal nerve.

Disability: An alteration of an individual's capacity to meet personal, social, or occupational demands, because of an impairment.

Efferent: Conducting (fluid or nerve impulse) outward from a given organ.

Epinephrine: A catecholamine that is the chief neurohormone of the adrenal medulla.

Failed back surgery syndrome (FBSS): Chronic back and leg pain after technically and anatomically adequate lumbosacral surgery.

Glucagons: Substance of intestinal origin, secreted into the blood following ingestion of Glucose.

Hypoxemia: Subnormal oxygenation of arterial blood.

Impairment: A loss, loss of use, or derangement of any body part, organ system, or organ function.

Intradiscal Electrothermal Therapy (IDET): Procedure that uses heat to shrink a single, specific disc, reducing pressure on a nerve.

Intrathecal Drug Pump (IDP): Implantable pump, placed within the dura, that releases specific doses of medication directly into the spinal column.

Metaanalysis: Systematic, organized, structured evaluation using information from a number of different studies of a problem.

Neural selectivity: Ability to act on targeted nerves, while avoiding non-targeted nerves.

Neuromodulation: Field of science, medicine, and bioengineering that encompasses both nonimplantable and implantable technologies—electrical, and chemical—that improve the life of humanity.

Neuropathic pain: Clinical manifestation of neural injury.

Neuroplasticity: The central nervous system's (CNS's) ability to adapt in response to stimuli injury.

Nociceptor: A peripheral nerve organ or mechanism for the reception and transmission of painful or injurious stimuli.

Paresthesia: An abnormal sensation such as tingling.

Pay back: Length of time before the savings due to effective treatment results are sufficient to compensate for greater initial costs.

Sympathetic: Denoting the sympathetic part of the autonomic nervous system.

Trial stimulation: Minor reversible procedure where trial leads are placed along the spinal cord and attached to an external trial stimulator (ETS), which is programmed to deliver stimulation that covers the pain areas at the necessary level. Over a trial period of 2 days to 2 weeks, the patient experiences SCS to evaluate whether it relieves pain.

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