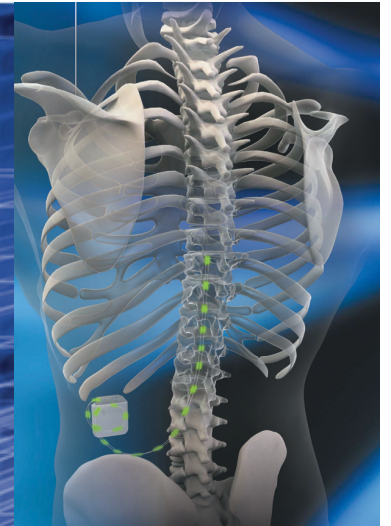


Neurostimulation



Mudit Sharma, MD
Prince William Pain Symposium
October 18th, 2008



Disclosure

I do not have any financial interest in any of the companies discussed, nor have I received any compensation from these companies for my presentation.

Overview / Objectives

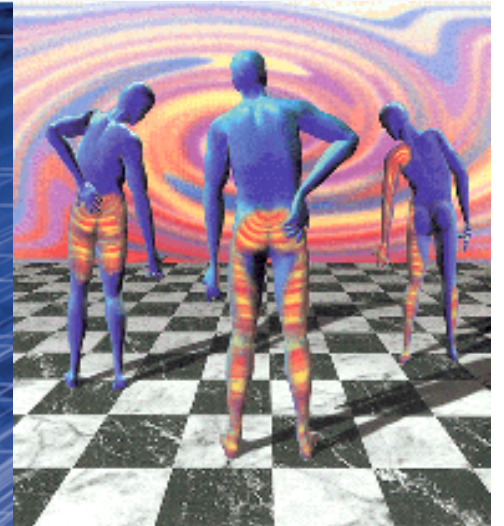
- Current and emerging chronic pain management algorithms
- Overview and treatment options:
 - Chronic back and/or leg pain
 - Complex regional pain syndrome (CRPS)
 - Failed back surgery syndrome (FBSS)
- Neurostimulation Therapy: Trial to implant
- Clinical evidence: Neurostimulation
- Multidisciplinary approach to chronic pain management

Pain Treatment Ladder



1. Stamatou JM. Live Your Life Pain Free. Magni Company. January 2005.

A Review of Chronic Back and Leg Pain



Chronic Back and Leg Pain Statistics

Chronic back and/or leg pain is a common medical condition:

- Up to 80% of the population experience an episode over a lifetime¹
- One of the leading causes of disability, with multiple etiologies²
- Between 10% and 40% of patients who have undergone lumbosacral spine surgery in the U.S. experience persistent or recurrent pain.³

Impact / burden of Chronic pain:

- Total costs exceed \$100 billion annually in the U.S. alone.⁴
- Cancer pain costs of care are estimated at \$12 billion per year.⁵
- Americans spend \$4 billion per year on medications for chronic, recurrent headaches.⁵
- The estimated cost for treating recurrent facial and neck pain is approximately \$1.9 billion per year.⁵

1. Miller B et al. *Pain Practice*. 2005;5:190-202. 2. Rozen D. *Pain Practice*. 2005;5:228-243. 3. North RB et al. *Neurosurgery*. 2005;56:98-107. 4. Katz JN. *J Bone Joint Surg Am*. 2006;88:21-24. 5. Medical Data International, Rep. 1260.

Treating Chronic Back and/or Leg Pain

Non-Interventional Approach

Encourage patients to engage in normal physical activity to maintain function as much as possible

- Rehabilitation
- Pharmacotherapy (e.g. nonsteroidal anti-inflammatory drugs [NSAIDs]; opioid analgesics; nonopioid analgesics)
- Behavioral therapy (eg, psychotherapy)
- Other therapies (eg, acupuncture)

Surgical Approach

May be used when there are degenerative changes at one or two levels and when non-interventional approaches fail

- Surgical resection of the disc herniation (discectomy)
- Laminectomy
- Intervertebral disk replacement
- Interbody infusion (intervertebral injury)

Interventional Approach


Optimize pain management through a balance of conservative treatments and less invasive interventional options

- Neuromodulation (therapeutic blocks/infusion; transcutaneous electrical nerve stimulation [TENS])
- Neurostimulation
- Intrathecal drug delivery (IDD)
- Neuroablation (radiofrequency; sympathectomy)

Potential Candidates for Neurostimulation



Chronic Pain Overview and Treatment Options



Complex Regional Pain Syndrome (CRPS)

Complex Regional Pain Syndrome (CRPS) Overview

CRPS I and II are chronic pain syndromes characterized by severe pain accompanied by autonomic changes in the painful region, including edema, temperature abnormalities, sudomotor activity and skin color changes. CRPS affects up to 1.2 million Americans^{1,2,3}

- CRPS develops in response to a traumatic physical event, such as an accident or medical procedure
 - Even “minor” accidents, such as a sprain, can be the cause of CRPS
- CRPS causes nerves to misfire, sending constant pain signals to the brain
- Typically, patients with CRPS see an average of 5 doctors before being accurately diagnosed

1. Stanton-Hicks MD, An update interdisciplinary clinical pathway for CRPS: report of an expert panel. Pain Practice. 2002; vol 2, no. 1, 1-16. 2. Reflex Sympathetic Dystrophy Syndrome Association (RSDA). CRPS Treatment Guidelines. June 2006. 3. RSDA. CRPS/RSD Fact Sheet, CRPS Treatment Guidelines. June 2006.

Complex Regional Pain Syndrome (CRPS) Overview

Original IASP Diagnostic Criteria for CRPS Types I and II ¹ * †:

- The presence of an initiating noxious event, or cause of immobilization
- Continuing pain, allodynia, or hyperalgesia with which the pain is disproportionate to any inciting event
- Evidence at some point in time of edema, changes in skin blood flow, or abnormal sudomotor activity in the region of pain
- This diagnosis is excluded by the existence of conditions that would otherwise account for the degree of pain and dysfunction

An international consensus group has reviewed validation studies of these diagnostic criteria and have proposed revised criteria.

1. RSDA. CRPS Treatment Guidelines. June 2006. 2. RSDA. CRPS/RSD Fact Sheet. CRPS Treatment Guidelines. June 2006. *CRPS Type I: without evidence of major nerve damage. †CRPS Type II: with evidence of major nerve damage.

Clinical Diagnostic Criteria for CRPS: Proposed by Budapest Consensus Group

Criteria	Sensory	Vasomotor	Sudomotor/ Edema	Motor/ Trophic
1. Continuing pain which is disproportionate to any inciting event	n/a	n/a	n/a	n/a
2. Must report at least one symptom in three of the four categories:	Reports of hyperesthesia and/or allodynia	Reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry	Reports of edema and/or sweating changes and/or sweating asymmetry	Reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
3. Must display at least one sign (a sign is counted only if it is observed at time of diagnosis) at time of evaluation or two or more of the following:	Evidence of hyperalgesia (to pinpoint) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)	Evidence of temperature asymmetry and/or skin color changes and/or asymmetry	Evidence of edema and/or sweating changes and/or sweating asymmetry	Evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
4. There is no other diagnosis that better explains the signs and symptoms	n/a	n/a	n/a	n/a

Source: Complex Regional Pain Syndrome: Treatment Guidelines. Reflex Sympathetic Dystrophy Syndrome Association. June 2006

Interventional Management of CRPS

Treatment may include medication, physical therapy, psychotherapy, sympathetic nerve blocks, sympathectomy, and/or neurostimulation

Interventional Pain Treatment Algorithm for CRPS Type I¹

Minimally Invasive Therapies

- Sympathetic Nerve Blocks
- IV Regional Blocks
- Somatic Nerve Blocks

More Invasive Therapies

- Epidural and Plexus Catheter Block(s)
- Neurostimulation
- Intrathecal Drug Infusion (eg, Baclofen)

Surgical and Experimental Therapies

- Sympathectomy
- Motor Cortex Stimulation

1. RSDA. CRPS Treatment Guidelines. June 2006.



Failed Back Surgery Syndrome (FBSS)

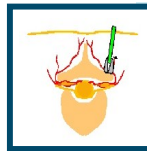
Overview of Failed Back Surgery Syndrome (FBSS)

Definition of FBSS: Chronic Pain That Persists After Surgery¹

Patients with FBSS have failed to obtain long-term pain relief, even after treatment with a variety of therapies, including¹:



Oral Meds



Nerve Blocks



Corticosteroid Injections



Physical Therapy



Chiropractic Care



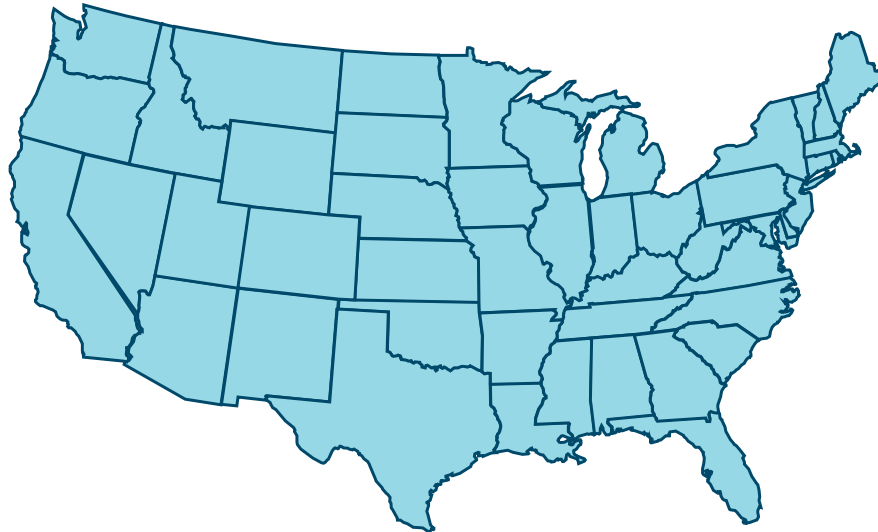
Fixation Surgeries



Repeated Surgeries

1. De Andrés J, Van Buyten J-P. *Pain Practice*. 2006;6:39-45.

Incidence and Economic Concerns



In the United States, FBSS affects **up to 40%** of patients who undergo spinal surgery each year^{1,2}

- Over 9,000 patients per year may be candidates for neurostimulation, based on predicted FBSS rates from failed surgeries³
- Over 5 years, treatment with conventional pain therapies can cost more than \$38,000 per patient^{4 *}

*Does not take into account indirect costs such as lost wages and reduced productivity.

1. North RB et al. *Neurosurgery*. 2005;56:98-107. 2. Stojanovic MP. *Curr Pain Head Rep*. 2001;5:130-137.

3. Segal R et al. *Neurol Res*. 1998;20:391-396. 4. Kumar K et al. *Neurosurgery*. 2002;51:106-116.

Diagnosing and Managing FBSS

- Structural causes can be identified post-operatively by CT scan, MRI, myelogram, or X-ray
- If no structural cause can be found, the persistent pain may be neuropathic—caused by the prolongation of the original condition
- A patient may be a candidate for neurostimulation

Managing FBSS Brings About Numerous Challenges for Patients and Clinicians¹:



1. De Andrés J, Van Buyten J-P. *Pain Practice*. 2006;6:39-45.

Common Treatments for FBSS

Non-Invasive / Minimally Invasive



Oral Meds



Nerve Blocks



Corticosteroid Injections



Physical Therapy



Chiropractic Care

Invasive



Fixation Surgeries



Repeated Surgeries

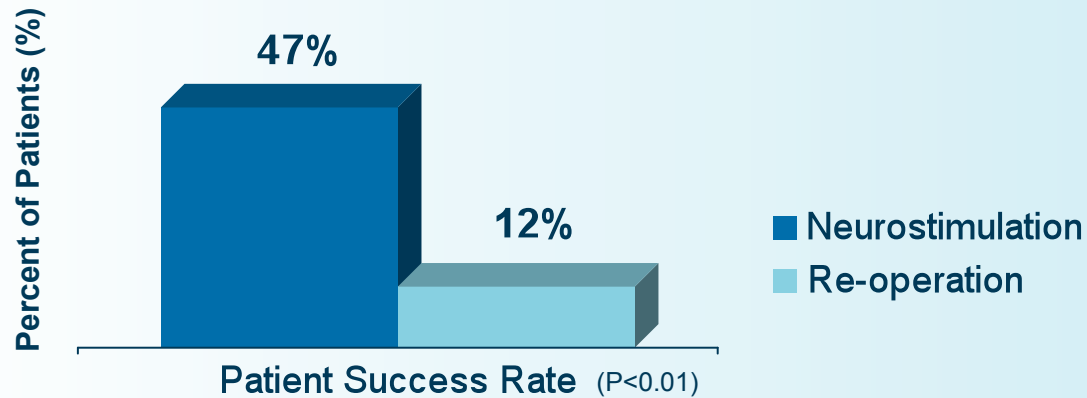
One retrospective study showed a success rate for 102 patients with repeat operation of only 34%.¹

If these treatments are unsuccessful, neurostimulation is an excellent alternative option.

1. North RB et al. *Neurosurgery*. 1991;28:685-691.

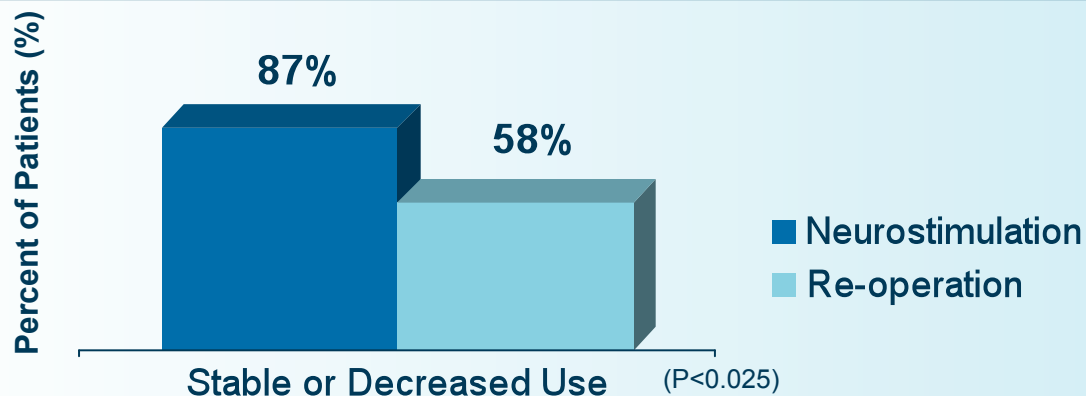
Neurostimulation vs Re-operation: A Single Center Study

Success Rate of Neurostimulation vs Re-operation



A randomized clinical study of patients with FBSS reported a 47% success rate with neurostimulation, but only a 12% success rate with re-operation.¹

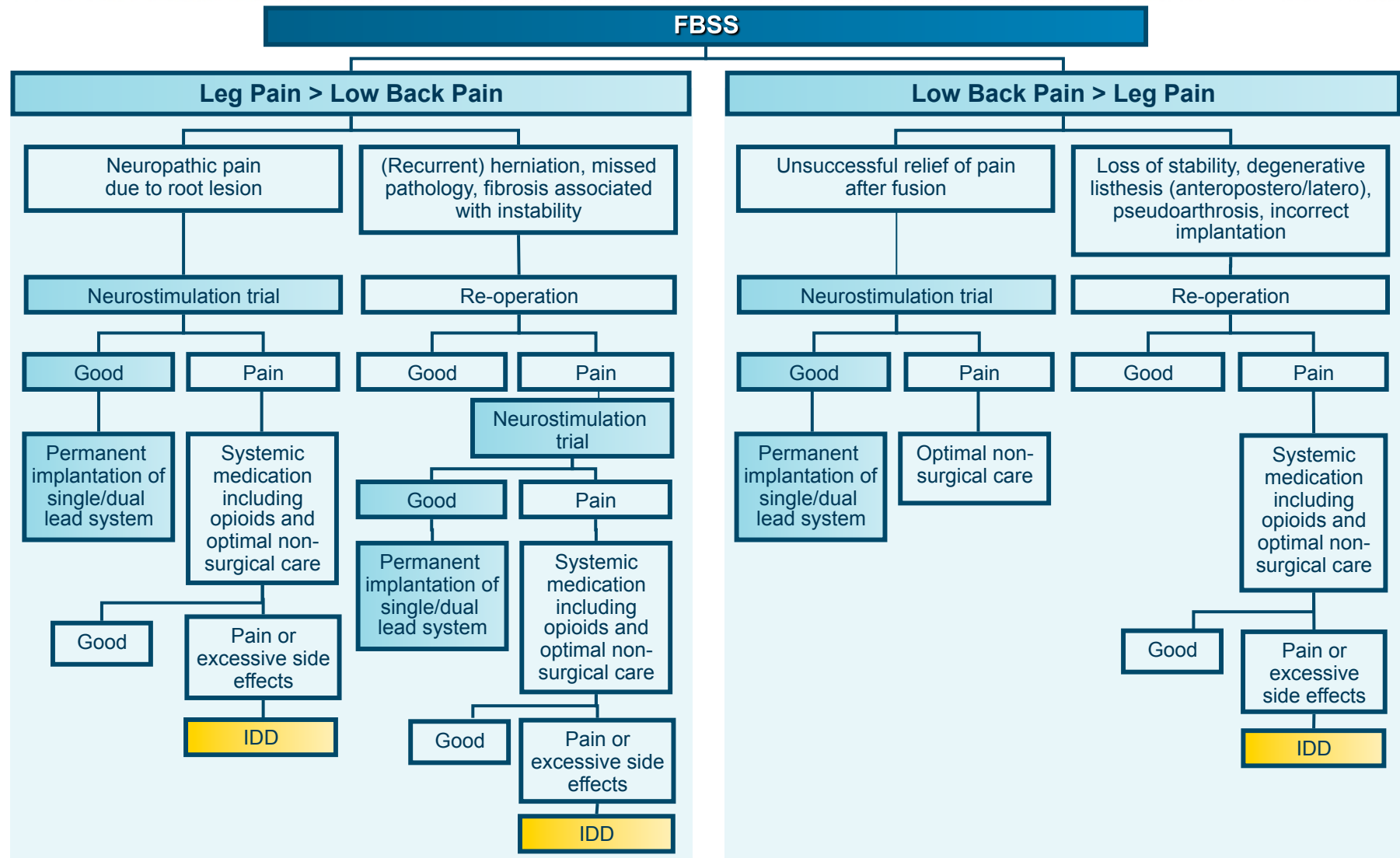
Chronic Opioid Use



Patients randomized to re-operation showed significantly more analgesic use

1. North RB et al. *Neurosurgery*. 2005;56:98-107. Success was defined as $\geq 50\%$ pain relief.

Consensus Algorithm for Treating FBSS: Neurostimulation Compared With Re-operation and/or Eventual Intrathecal Drug Delivery (IDD)



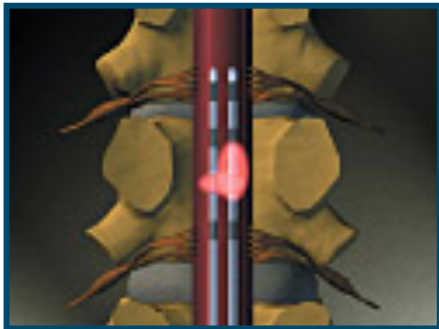


Neurostimulation: A Customized Alternative Treatment Option

Defining Neurostimulation

Neurostimulation is:

- A therapy that alleviates pain by sending electrical stimulation via implanted leads to electrodes in the epidural space



Neurostimulation activates pain-inhibiting neuronal circuits in the dorsal horn and induces a tingling sensation (paresthesia) that masks the sensations of pain.

Goal of Neurostimulation:

- Maintain at least a 50% reduction in pain at 1 year post-implant¹
- Improved HRQoL as assessed by the Short Form questionnaire (SF-36)
- Improved functionality as measured by the Oswestry Disability Index (ODI)

1. Kumar K et al. *Surg Neurol.* 1998;50:110-121.

Defining Neurostimulation: Neuropathic Pain

- Neuropathic pain is associated with injury to the peripheral nervous system or the spinal cord.
- This pain is perceived as shooting, shock-like pain with severe burning or aching sensations:
 - May have tingling, numbness, or itching
 - Severe cases have a ripping or tearing sensation
- Neuropathic pain is often responsive to neurostimulation.

Defining Neurostimulation: Nociceptive Pain

- Nociceptive pain is activated in response to tissue damage or inflammation arising from receptors sensitive to noxious stimuli.
- It can be perceived as
 - well localized, constant, aching, throbbing, dull, vague, or a pressured feeling
 - poorly localized and diffuse
- Nociceptive pain is often responsive to opioid treatment.

Indications for Neurostimulation

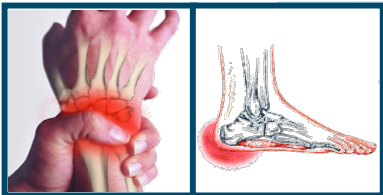
Most Common Indications for Neurostimulation¹⁻³



FBSS-associated chronic pain



Refractory neuropathic back and leg pain



**Sympathetically mediated pain,
specifically Complex Regional Pain
Syndrome (CRPS) Types I and II**

Neurostimulation is perhaps best utilized for the treatment of neuropathic pain of peripheral origin vs. nociceptive origin.^{1,2}

1. Meyerson BA, Linderöth B. *Neurol Res.* 2000;22:285-292.
2. Gybels J et al. *Eur J Pain.* 1998;2:203-209.
3. De Andrés J, Van Buyten J-P. *Pain Practice.* 2006;6:39-45.

Patient Selection

- Objective evidence of pathology
 - Use appropriate diagnostic studies to establish pain etiology; to rule out other causes such as a tumor
- Inadequate pain relief and/or intolerable side effects after treatment with more conservative therapies
- Psychological evaluation
 - Is the patient physically and mentally able to handle the procedure and associated maintenance and/or follow-up?
- Absence of drug-seeking behavior
- Patients with predominant nociceptive pain may not respond to treatment with neurostimulation
- Potentially adverse psychosocial factors should also be considered prior to treatment with neurostimulation:
 - Non-compliance to treatment
 - Severe depression
 - Untreated drug dependency

Factors Associated with Success

Clinical Factors:

- Pain etiology
- Treating as early as possible
 - Evidence suggests early intervention yields better efficacy¹
- In FBS, consider neurostimulation before re-operation¹⁻⁴
- Successful screening trial
- Matching patient energy demand and pain coverage needs with device selection

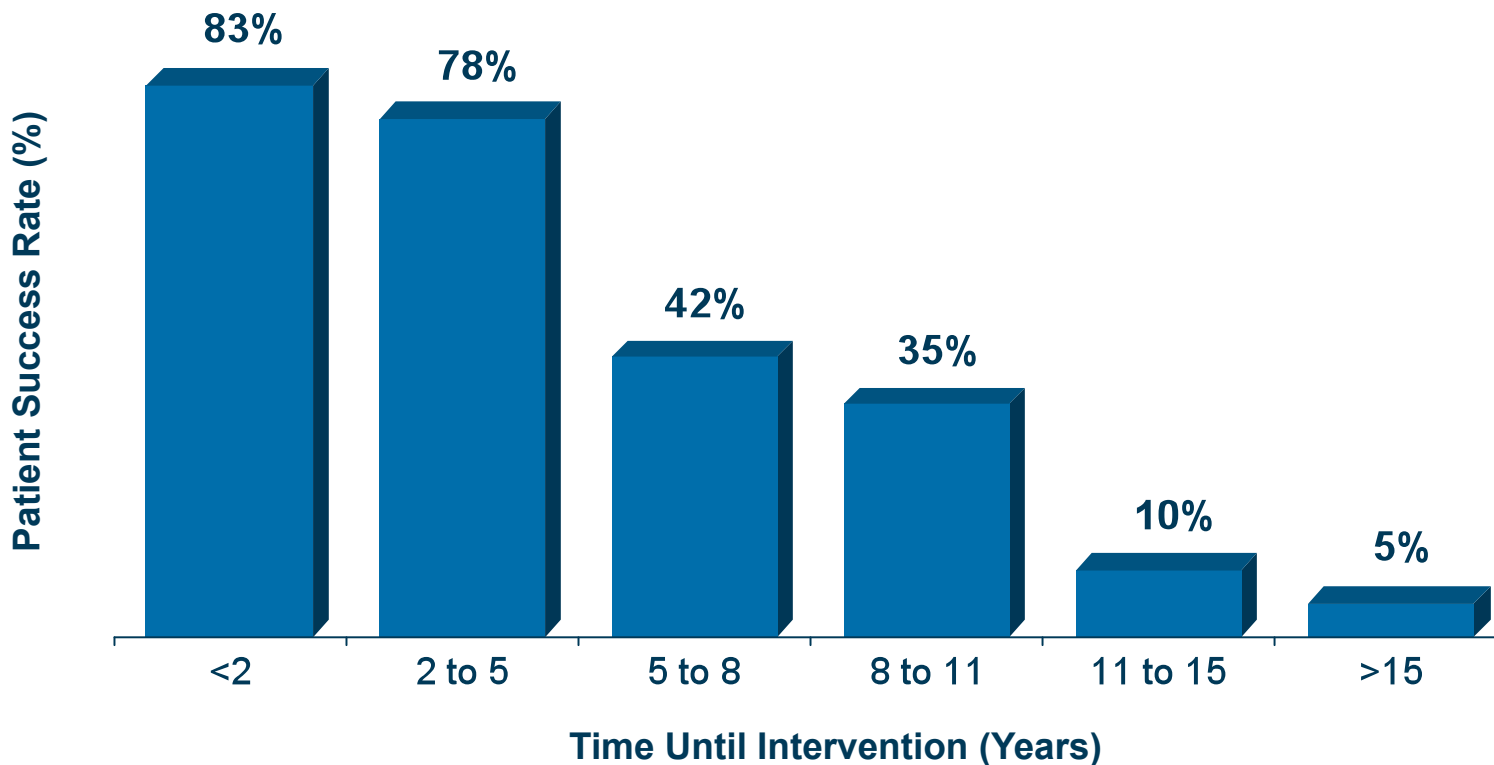
Individual Patient Attributes:

- Knowledge about neurostimulation and what to expect in terms of pain relief
- Support system (i.e., family, friends)
- Ability to operate implanted device (trialing, recharging, patient programmer, etc)

1. Kumar K et al. *Surg Neurol*. 1998;50:110-121. 2. De Andrés J, Van Buyten J-P. *Pain Practice*. 2006;6:39-45.
3. North RB et al. *Neurosurgery*. 2005;56:98-107. 4. Stojanovic MP, Abdi S. *Pain Physician*. Vol. 5, No. 2, 2002

Advantage of Earlier Intervention

A retrospective study showed an inverse relationship between the onset of the chronic pain syndrome and SCS therapy success.¹



1. Kumar K et al. *Neurosurgery*. 2006;58:481-496.



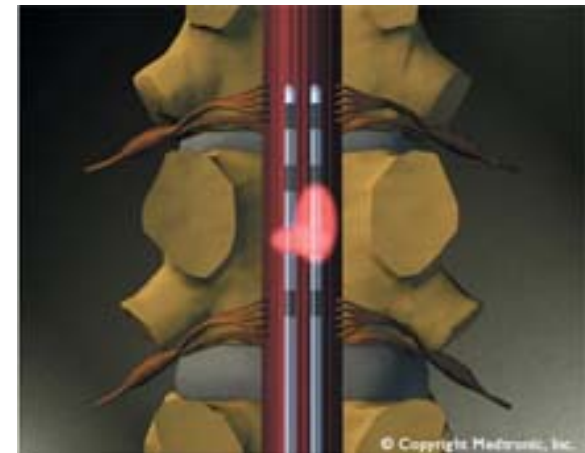
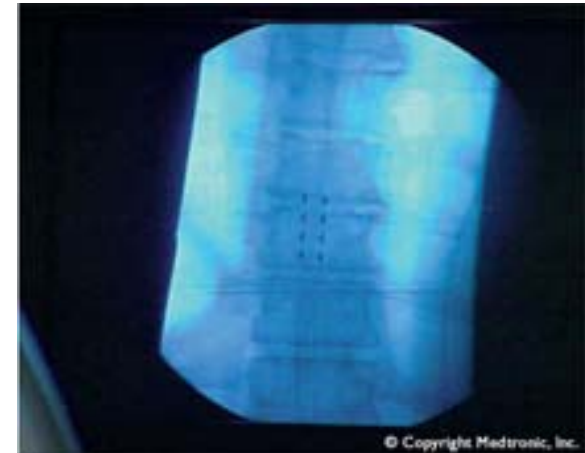
Neurostimulation: Trial to Implant

Neurostimulation

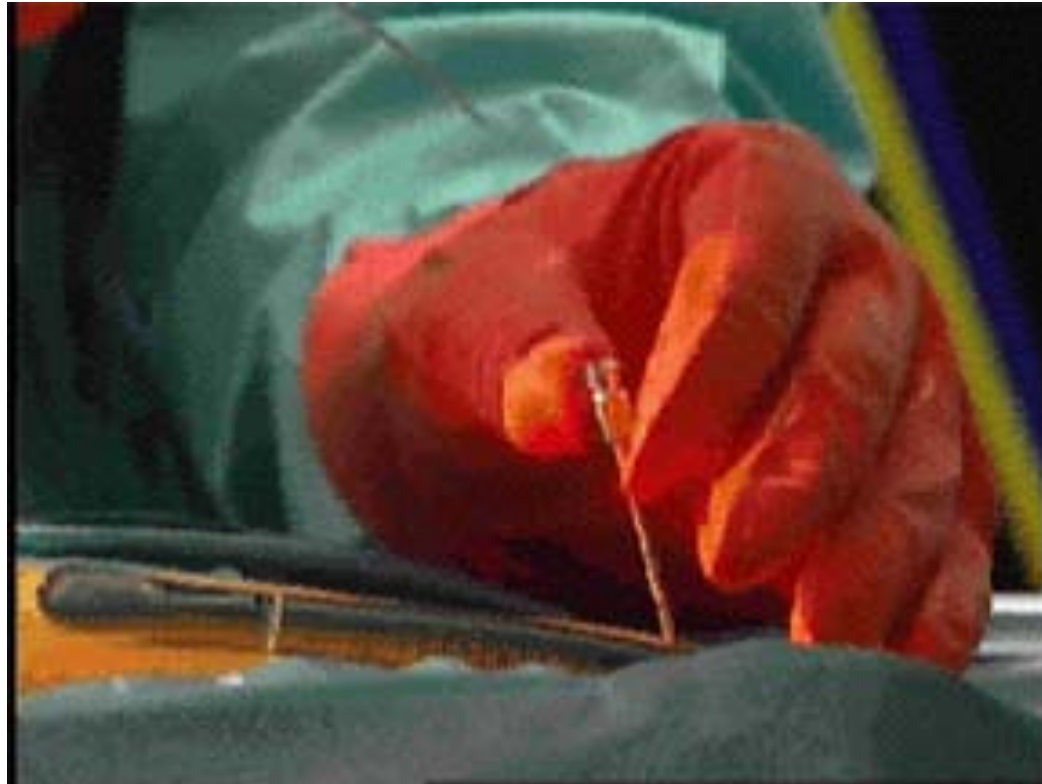
- Neurostimulation is a pain treatment that delivers low voltage electrical stimulation to the spinal cord to inhibit or block the sensation of pain
- Trial screening to evaluate patient response to neurostimulation is performed prior to committing to a full implant

Overview of Trial Procedure

- A percutaneous lead is positioned in the epidural space on the dorsal aspect of the spinal cord at the appropriate nerve root level(s).
- Electrical current from the lead generates paresthesias that can be adjusted in intensity and location to achieve the best pain coverage.
- Leads are attached to an external pulse generator (screener) which supplies the current.
- Patients can use the screener to adjust stimulation to meet pain management needs.



Percutaneous Lead Placement



Advantages of Implanted Neurostimulators for Pain

- Effective method of pain control¹
- Screening trial allows patient response to be tested before a full implant
- Systems reprogrammable without surgery
- Patient control within physician set limits
- Non-destructive procedure compared with surgical alternatives
- Reduction of pain medications²

Optimal Lead Positioning and Contact Options

Optimal lead position:

- Posterior epidural space
- Ipsilateral to the pain area
- Rostral to the highest corresponding dermatomal area of pain

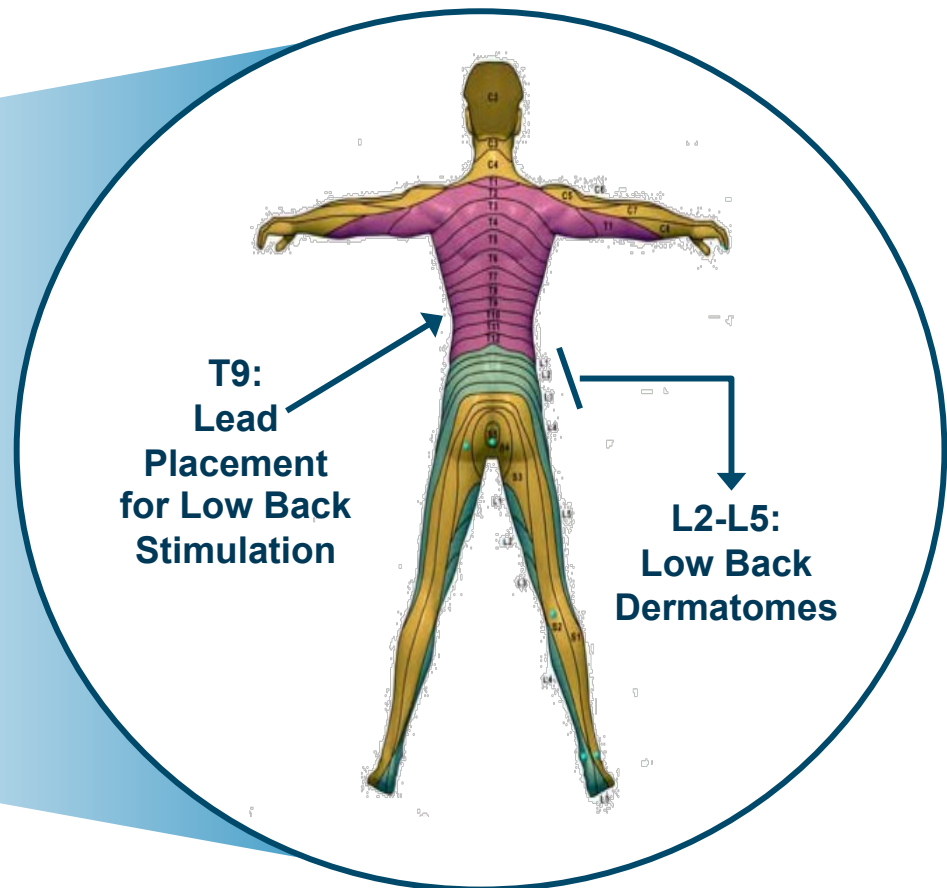
Number of contacts used and contact placement are dictated by the area of pain:

- Bilateral pain often requires 2 leads to cover all painful areas
- Pain from FBS may be best managed with multiple lead systems. Transverse tripolar lead configurations may also be considered.¹
- Leads should be placed as close to the physiological midline or the spinal cord as possible, so that contacts are closer to the dorsal column and stimulation gets where it is needed most²
 - Dual leads should be placed closely to the right and left of the midline²

Lower Back Stimulation: Lead Placement

Dermatomes—regions of the body where sensation may be felt relative to the spinal cord and spinal column—vary from person to person.¹

- In general, low back dermatomes are L2–L5¹
- Leads should be placed at approximately the T9 level of the spinal segment in order to stimulate low back dermatomes¹
- If a lead is placed off the midline at the T9 level, paresthesia may be felt in the chest wall¹

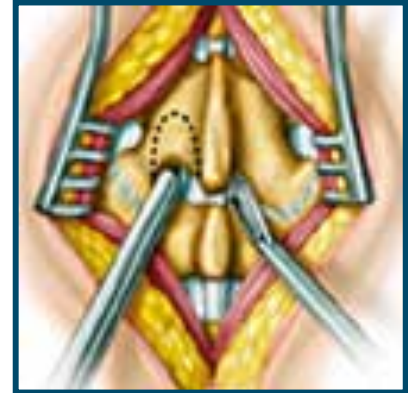


1. Oakley JC. *Pain Medicine*. 2006;7:S58-S63.
Dermatome Chart © Apparelyzed.com.

Lead Options: Laminectomy vs Percutaneous

Surgical Leads

- More invasive than percutaneous, thus may cause patient discomfort¹
- May have less chance of migration after encapsulation due to their shape¹



Percutaneous Leads

- May reduce patients' insertion-related discomfort²
- May improve implanters' ability to obtain accurate results during trialing²
- Offer longitudinal access to multiple levels of the spine²
- A small amount of silicone elastomer adhesive between the inner surface of the anchoring sleeve and the outer surface of the lead may reduce lead migration²



Neurostimulation: Clinical Evidence

Neurostimulation: Clinical Evidence

Several studies and numerous case series have been reported in patients with FBSS who have received SCS.

After 10 to 15 years of follow-up, the following was reported:

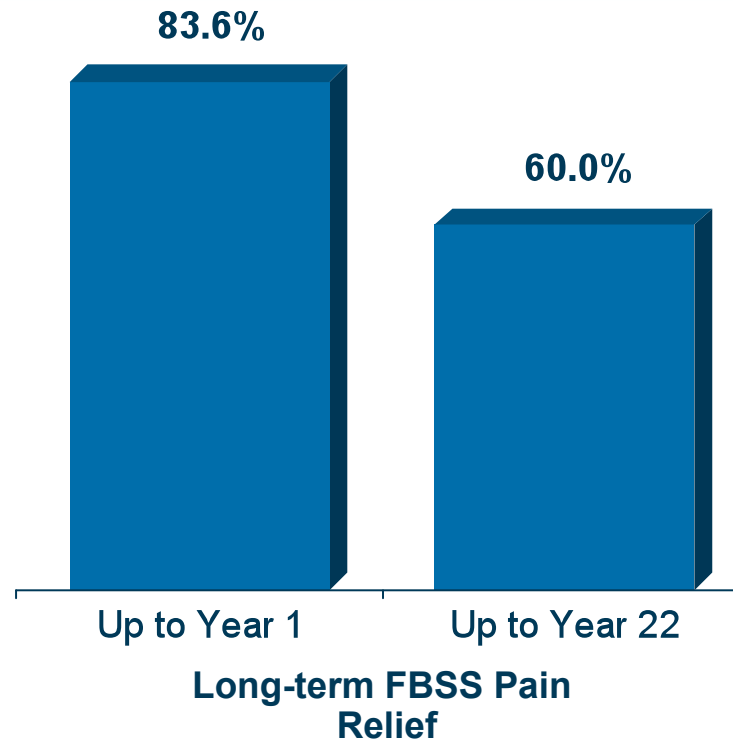
- Good to excellent response in 68% of patients¹
 - Average pain VAS significantly improved¹
 - Reduction in concomitant pain meds¹
 - Improved effect of medication (greater pain reduction after neurostimulation than before neurostimulation)¹
- Sustained pain relief²



1. Van Buyten J-P et al. *Eur J Pain*. 2001;5:299-307. 2. Kumar K et al. *Neurosurgery*. 2006;56:481-496.

Neurostimulation: Clinical Evidence - Pain Relief

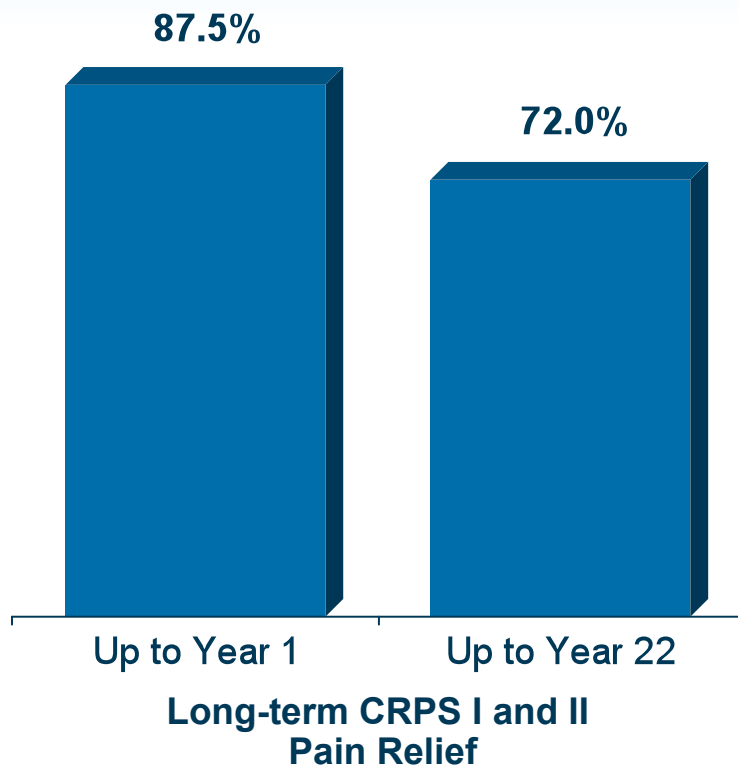
Failed Back Surgery Syndrome: Percentage of patients receiving satisfactory pain relief up to 1 Year and 22 Years (n=220)¹



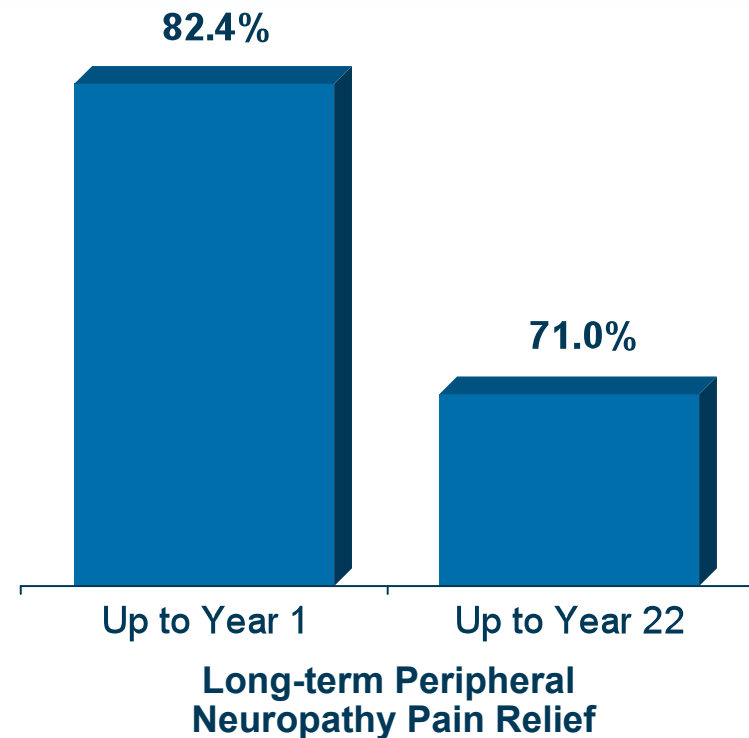
1. Kumar K et al. *Neurosurgery*. 2006;58:481-496.

Pain Relief (cont'd)

CRPS I / II: Percentage of internalized patients receiving satisfactory pain relief up to 1 year and 22 Years (n=22)¹



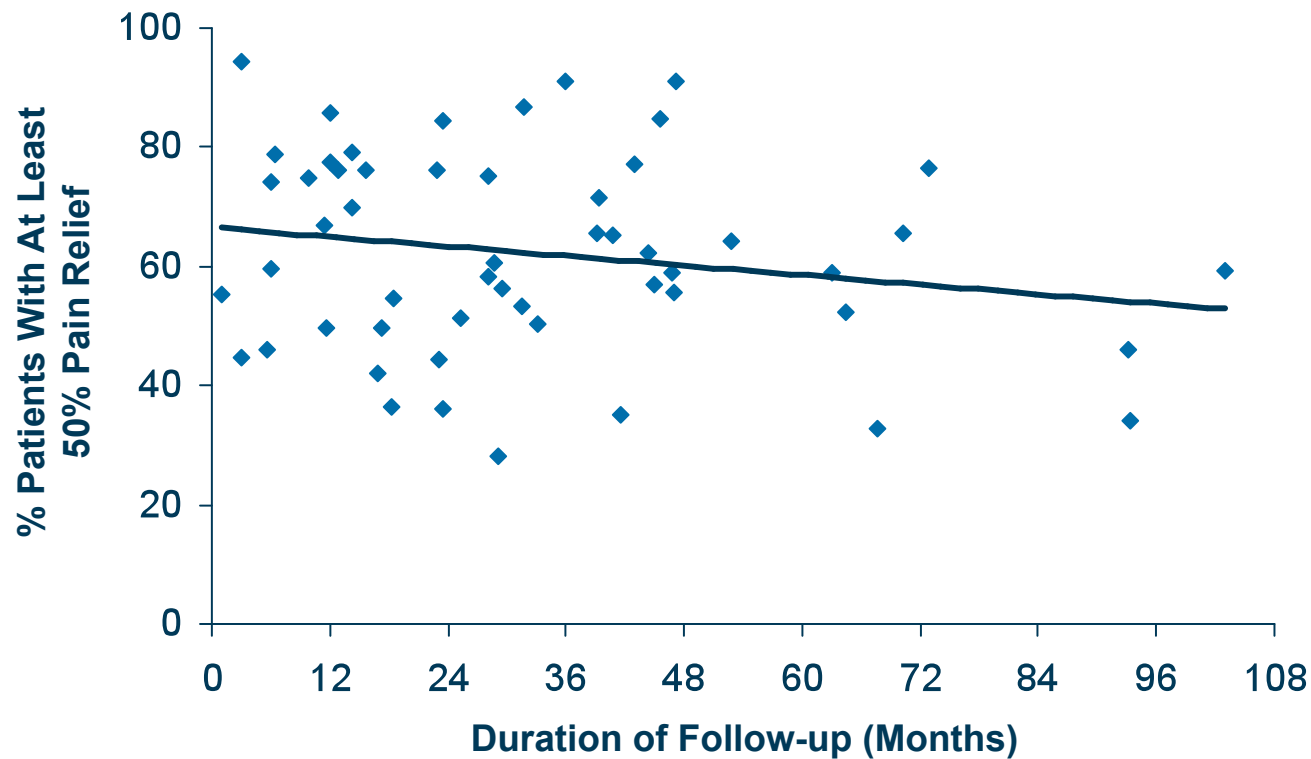
Peripheral Neuropathy: Percentage of internalized patients receiving satisfactory pain relief up to 1 Year and 22 Years (n=17)¹



1. Kumar K et al. *Neurosurgery*. 2006;58:481-496.

Pain Relief (cont'd)

Sustained Pain Relief Over Time With Neurostimulation¹



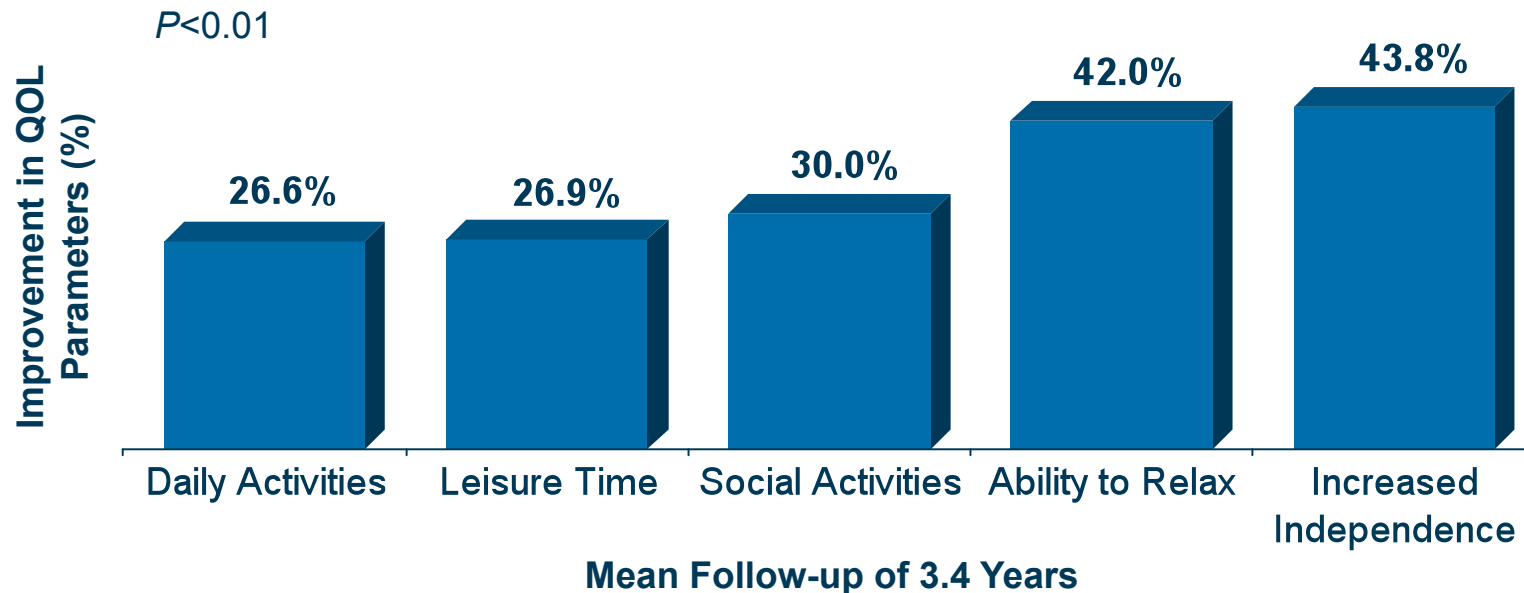
Sixty-two Percent (62%) of Patients With FBSS Achieve at Least 50% Sustained Long-term Pain Relief With Neurostimulation.¹

1. Taylor R. *Spine*. 2005;30:152-160.

Quality of Life

- Evidence indicates neurostimulation improves quality of life (QOL) in patients with FBSS^{1,2}
 - Improved QOL reported in 27% of patients treated with neurostimulation (n=60) versus only 12% of patients treated with conventional pain therapy (n=44)²

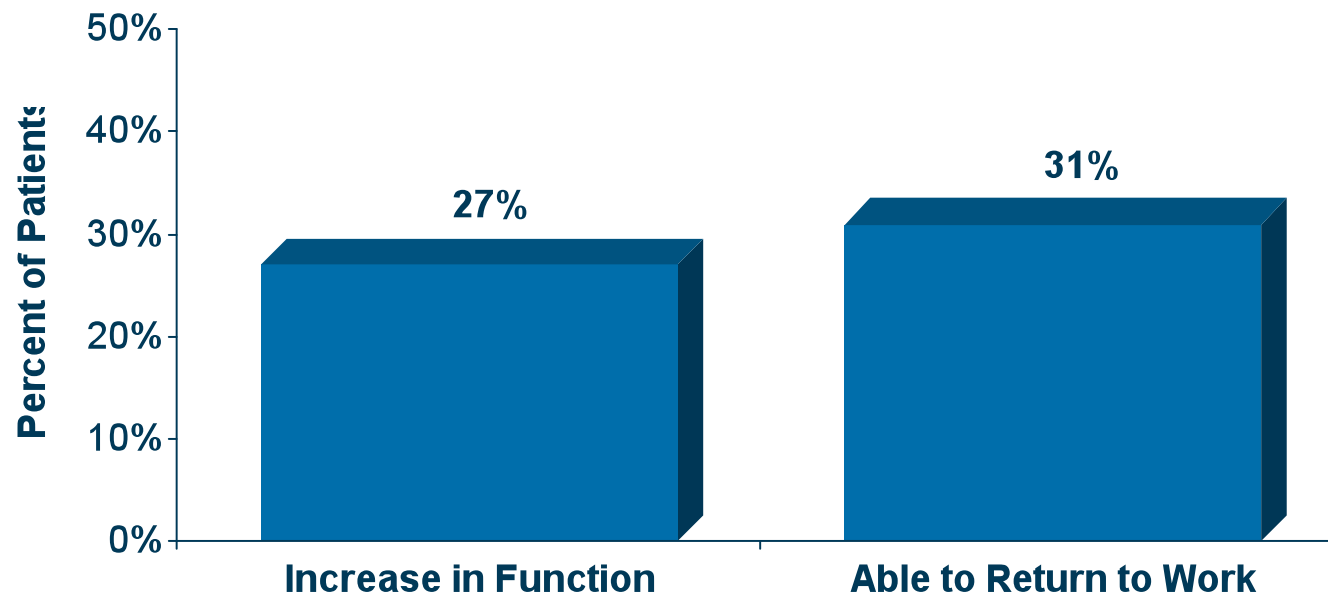
Neurostimulation Improves QoL in Patients With FBSS¹



1. Van Buyten J-P et al. *Eur J Pain*. 2001;5:299-307. 2. Kumar K et al. *Neurosurgery*. 2002;51:106-116.

Functional Improvement

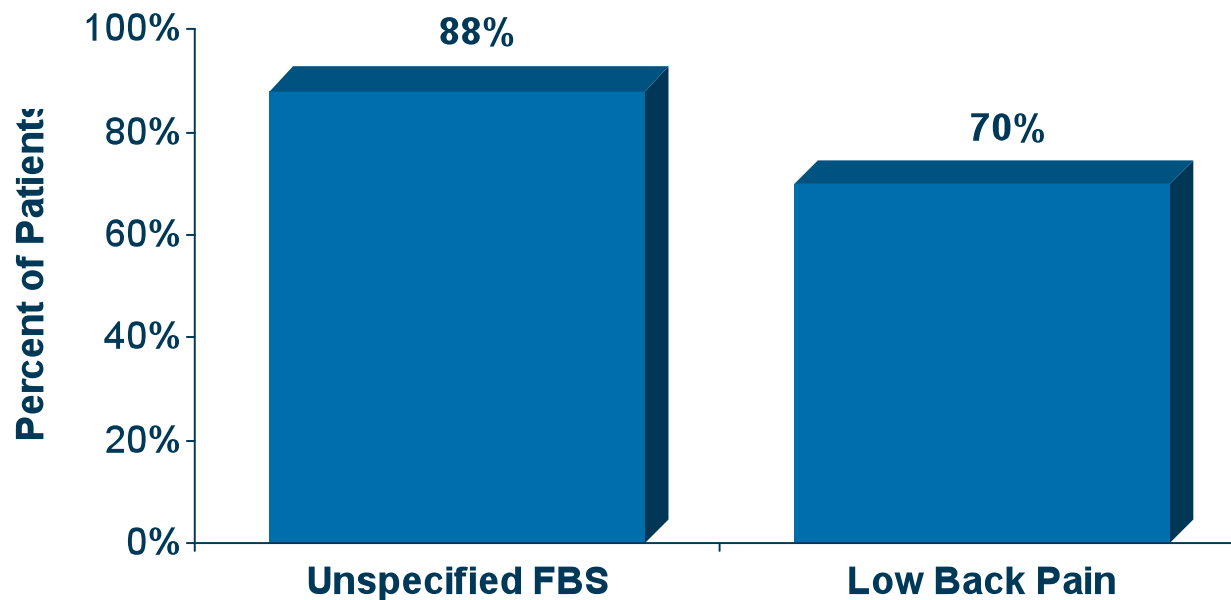
Percentage of Patients Experiencing Increased Function and Ability to Return to Work¹⁻³



- Patients (41%) with FBSS experienced an increase in function after treatment with neurostimulation¹
- Up to 31% of active patients treated with neurostimulation were able to return to work, resulting from improved pain control and less oral med intake^{2,3}

Patient Satisfaction

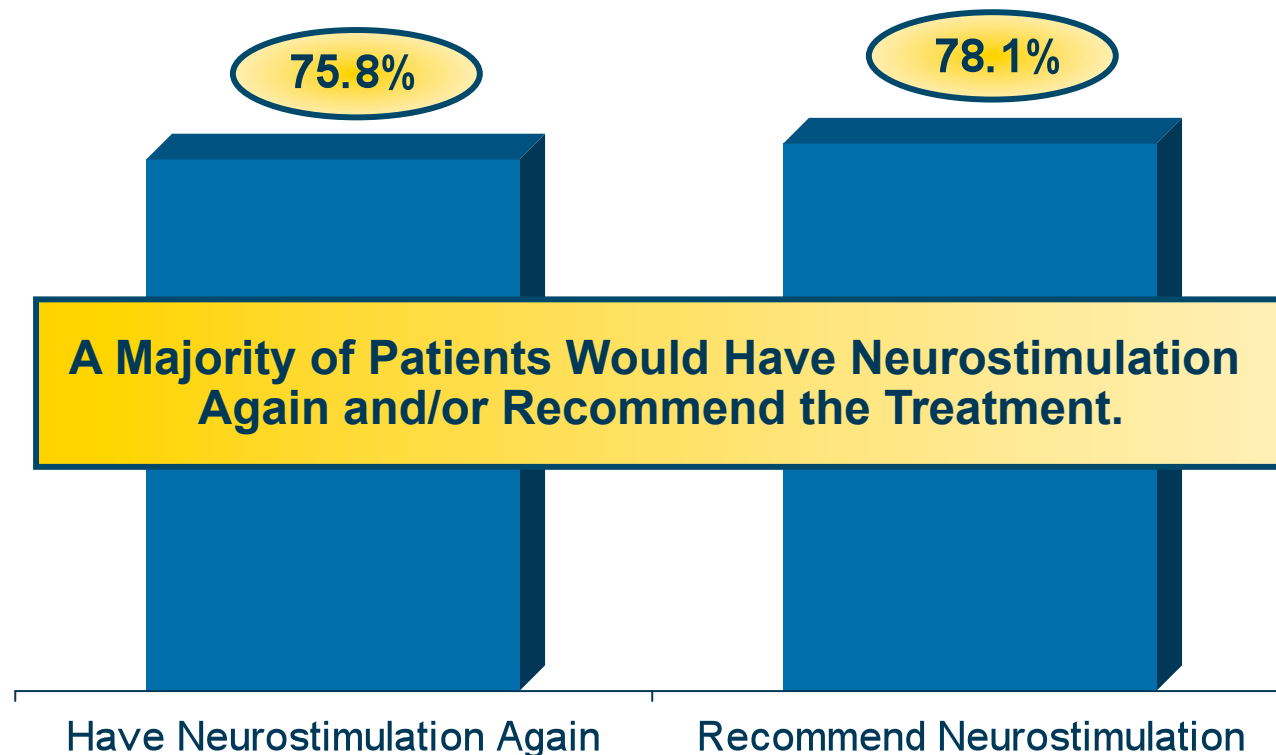
Patient Satisfaction With Neurostimulation^{1,2}



- Eighty-eight percent (88%) of patients with unspecified FBSS were satisfied with neurostimulation treatment¹
- Seventy percent (70%) of patients with predominantly axial low back pain were satisfied with neurostimulation treatment²

Patient Satisfaction (cont'd)

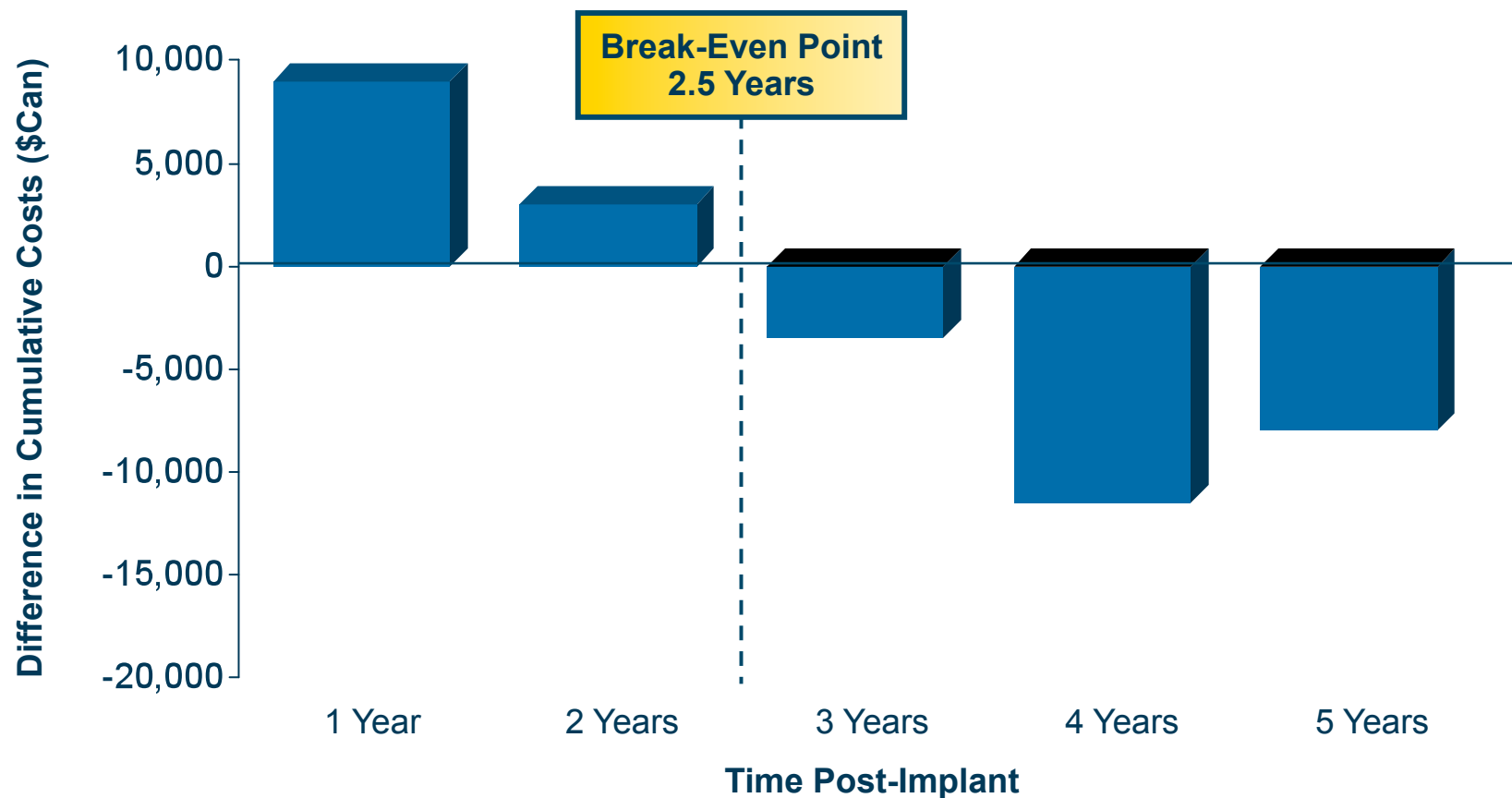
**Patient Satisfaction With Neurostimulation for Predominant Complaints of Chronic Intractable Low Back Pain
(% of Patients)¹**



1. Ohnmeiss DD, Rashbaum RF. *Spine J.* 2001;1:358-363.

Cost-Effectiveness

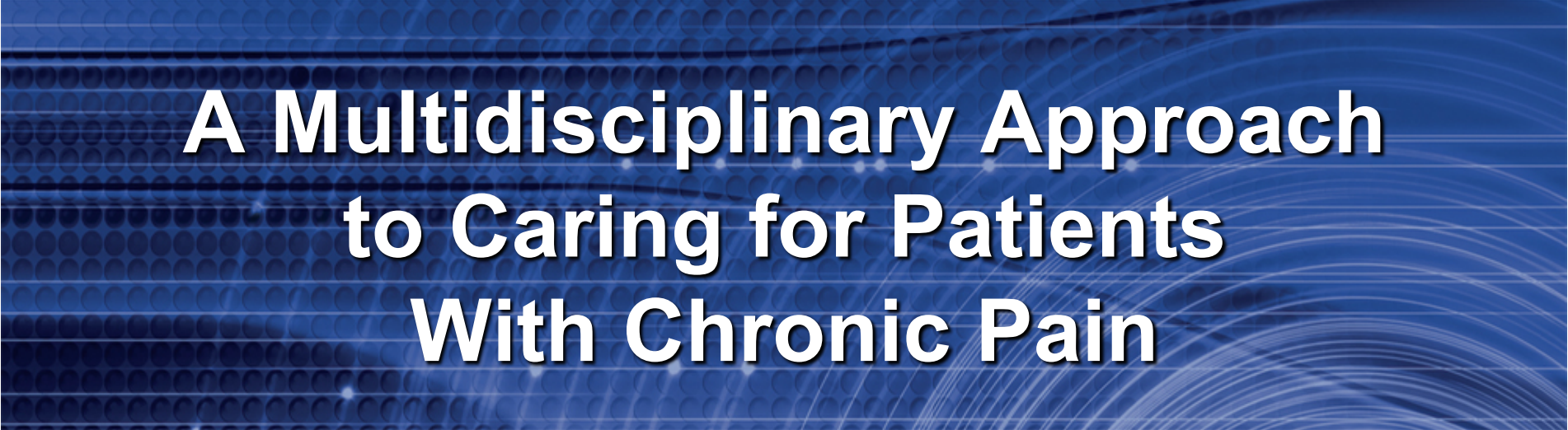
Neurostimulation for FBSS Resulted in a Cost Savings After 2.5 Years Compared With Conventional Medical Management¹



1. Kumar K et al. *Neurosurgery*. 2002;51:106-116.

Benefits of Neurostimulation

- Provides pain reduction/relief
- Trial conducted before fully implanted
- Reversible procedure
- Nondestructive (vs neuroablation)
- Minimally invasive
- May reduce the use of narcotics
- Improves patient ability to perform activities of daily living
- Cost-effective



A Multidisciplinary Approach to Caring for Patients With Chronic Pain

Multiple Risk Factors for Chronic Pain

Individual

- Increasing age
- Smoking
- Poor general health
- Health care provider attitudes
- Unemployment
- Obesity
- Low education level
- High birth weight (males)
- High levels of pain/disability

Psychosocial

- Stress
- Pain behavior
- Depressive mood
- Cognitive functioning
- Distress
- Somatization
- Baseline long duration of pain
- Fear-avoidance behavior

Occupational

- Manual handling of materials
- Monotonous tasks
- Job dissatisfaction
- Social support/work relations
- Lifting for more than $\frac{3}{4}$ of the day
- Night shifts
- Bending and twisting
- Whole-body vibration
- Unavailability of light duty

1. Manek N., MacGregor A.J., Epidemiology of back disorders: prevalence, risk factors, and prognosis, Current Opinion in Rheumatology. 2005; 17:134-140.

Chronic Pain Management

Patients With Chronic Pain Often Seek a Myriad of Opinions and See Numerous Physicians of Varying Disciplines for Treatment



Oral Meds



Nerve Blocks



Corticosteroid Injections



Physical Therapy



Chiropractic Care



Fixation Surgery



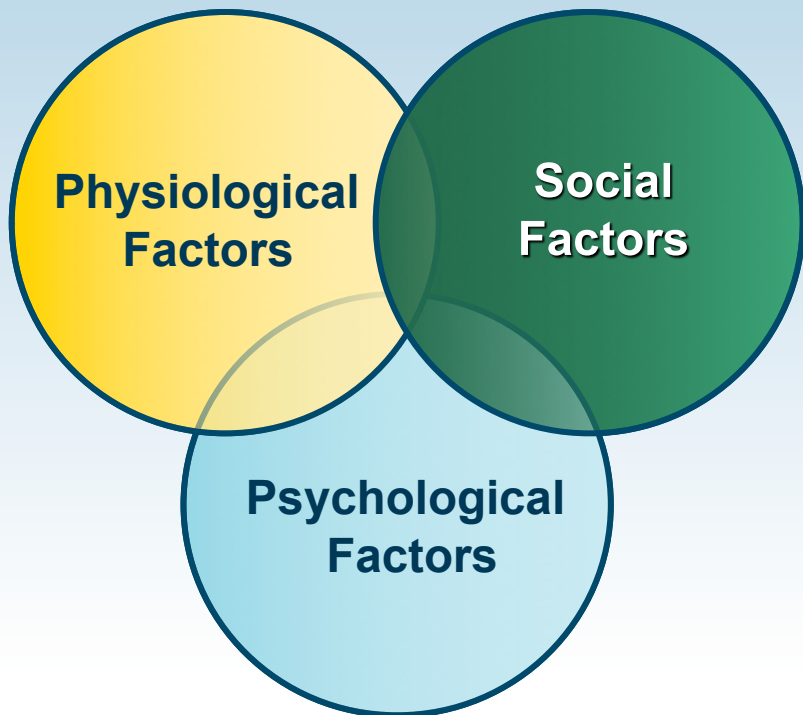
Repeated Surgeries

- Therefore, an open dialogue among managing physicians is needed for:
 - Sharing pertinent patient information
 - Coordination of treatment plan
 - Enable roundtable of multidisciplinary expertise for considering treatment options
 - Provide timely, appropriate, cost-effective treatment, thus increasing the quality of health care and quality of life for patients with chronic pain¹

1. De Andrés J, Van Buyten J-P. *Pain Practice*. 2006;6:39-45.

A Multidisciplinary Team Approach

Complex Patient Problem = Interdisciplinary Management



- Spine Surgeons
- Neurosurgeons
- Pain Specialists
- Psychiatrists/ Psychologists
- Physiatrists/PM&R
- Neurologists
- Radiologists

**Cross-Dialogue Is Imperative for
Successful Pain Management**

Neurostimulation Referral Checklist¹

- ☒ More conservative therapies have failed
- ☒ An observable pathology exists that is concordant with the pain complaint
- ☒ Further surgical intervention is not indicated
- ☐ No serious untreated drug habituation exists
- ☐ Psychological evaluation and clearance for implantation has been obtained
- ☐ No contraindications to implantation exist



☒ **Refer Patient for a Neurostimulation Trial**



Neurostimulation Summary

Neurostimulation: Clinical Summary

- Neurostimulation provides a treatment option that is:
 - Less invasive than surgery
 - Reversible
 - Customizable
 - Cost-effective
- Screening trials allow evaluation of patient response prior to an implant
- Neurostimulation provides $\geq 50\%$ sustained pain relief in 62% of patients with persistent or recurrent FBSS¹
- Improved functional capacity and reduced use of analgesics¹
- Multipolar and multichannel electrode systems may have significant advantages in providing long-term pain relief²

1. Taylor R. *Spine*. 2005;30:152-160. 2. Kumar K et al. *Neurosurgery*. 2006;58:481-496.
3. Kumar K et al. *Surg Neurol*. 1998;50:110-121.

Combining Advancements for Successful Outcomes With Neurostimulation

- The percentage change of patients with long-term successful pain relief has increased in the past decade ¹
 - Improved patient selection criteria, improved accuracy in contact placement, and improvements made to the multipolar and multichannel devices¹
 - Neurostimulation is safe, effective, and reversible³
- Additional ways to improve outcomes:
 - Work as a multidisciplinary team: health care professionals can make decisions that may change the course of a patient's life
 - Utilize advanced treatment options: to improve the quality of life for patients with chronic pain²

1. Kumar K et al. *Neurosurgery*. 2006;58:481-496. 2. De Andrés J, Van Buyten J-P. *Pain Practice*. 2006;6:39-45.
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