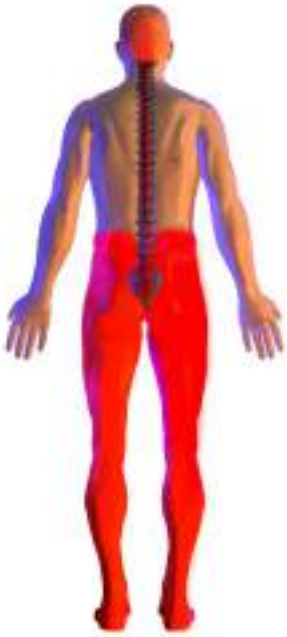
Spinal Cord Stimulation Overview

Definition of Neuromodulation

Neuromodulation is the electrical or chemical modulation of the central nervous system to manage chronic pain or improve neurologic function

Spinal Cord Stimulation (SCS)

Implanted medical device therapy that delivers electrical pulses to nerves in the dorsal aspect of the spinal cord that can interfere with the transmission of pain signals to the brain and replace them with a more pleasant sensation called paresthesia.



Pain

- Unpleasant sensory or emotional experience
- 2 types of pain: acute and chronic
- Chronic:
  - Nociceptive
    - Somatic
    - Visceral
  - Neuropathic
    - Central
    - Peripheral
  - Mixed Pain
    - Many patients have a combination of both because disease or trauma has damaged both nerve cells and other tissues

Nociceptive Pain

- Somatic pain arises from bone and joint, muscle, skin, and connective tissue
    - Aching or throbbing
    - Localized
- Visceral pain arises from visceral organs such as GI tract and pancreas
    - Tumor involvement
    - Obstructive

Neuropathic Pain

- Abnormal processing of sensory input by the peripheral or central nervous system
- Centrally generated pain
- Peripherally generated pain

Definition of Chronic Pain

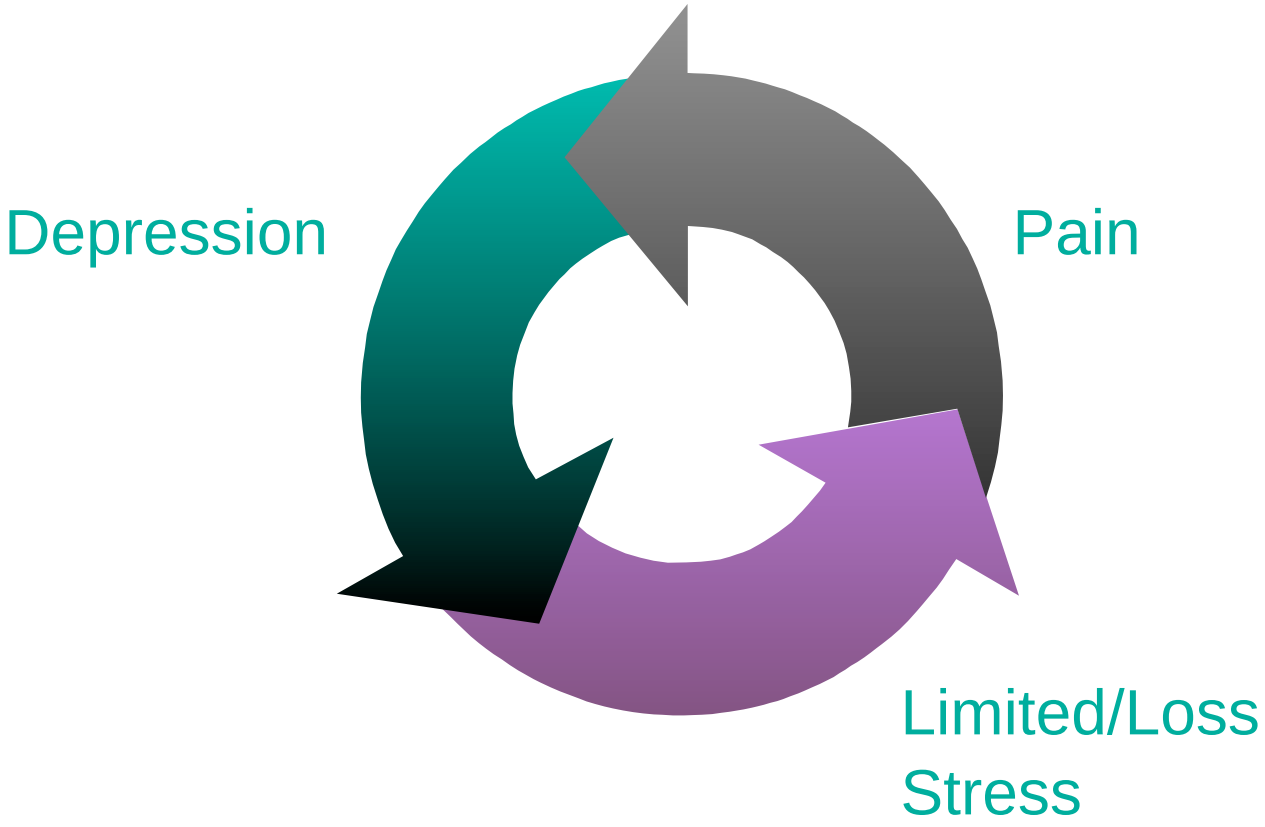
- Frequent or constant pain that does not respond to the usual treatments
- Unlike acute pain, which gets better and goes away in a short time, chronic pain persists for at least several months

Pain[1]

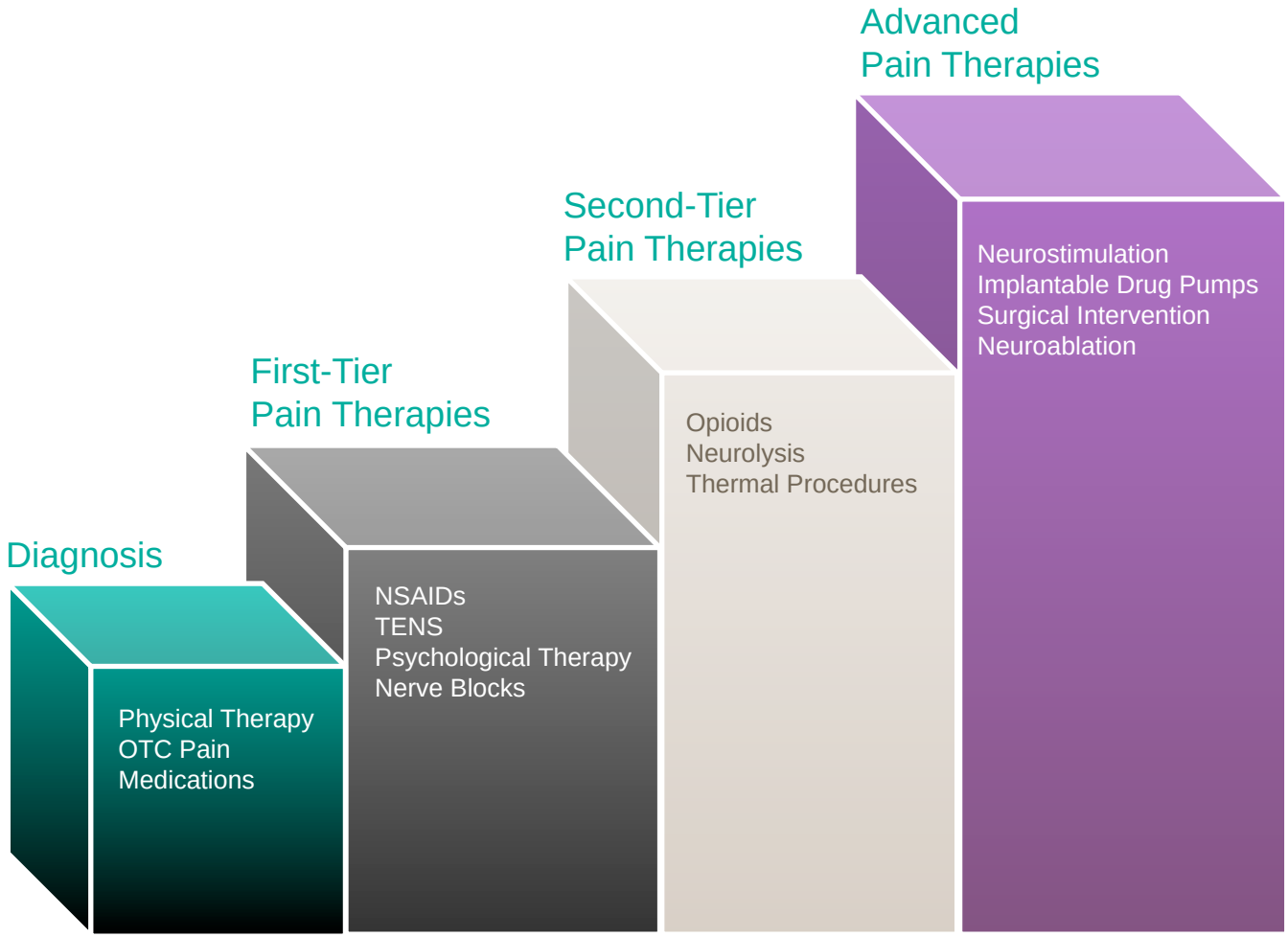
Huge, Growing, and Expensive Problem

- Pain costs more than $100 billion in lost productivity
  - More than $3 billion in lost wages
  - More than $50 million lost workdays
- More than 75 million American suffer from persistent, debilitating pain
- One in four people in the United States suffers from chronic pain
- Pain accounts for more than 80 percent of all physician visits

Cycle of Pain



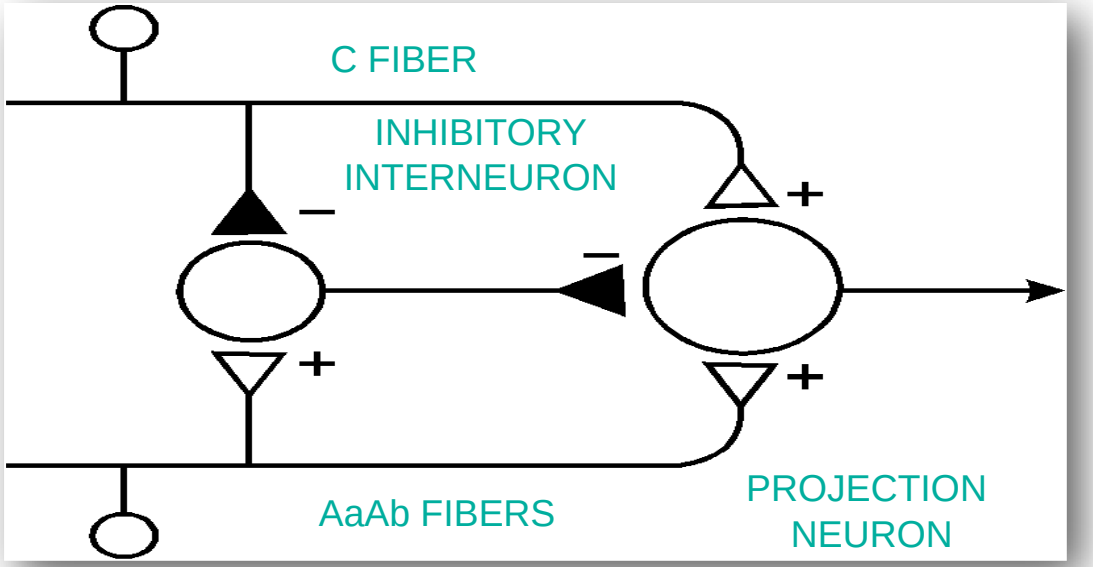
Chronic Pain Treatment Continuum



CNS Pain Management

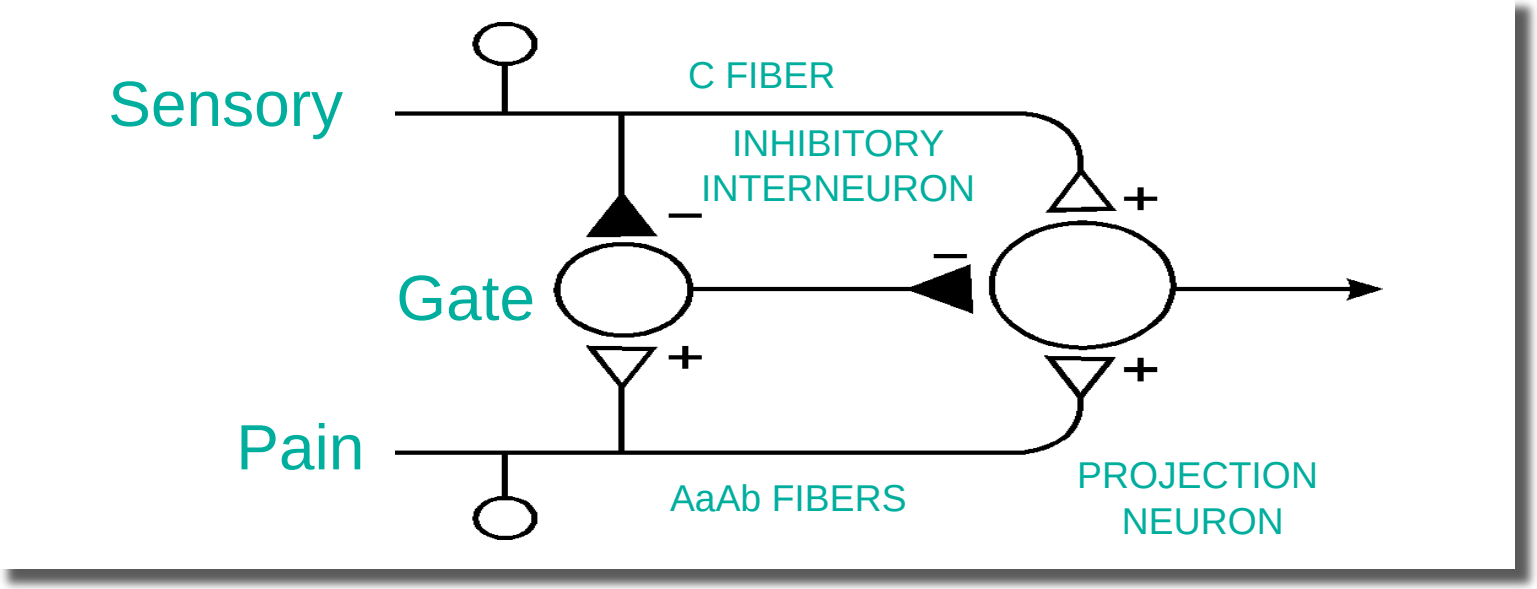
(Theory)

- Gate Control Theory
- Melzack and Wall, 1965[2]



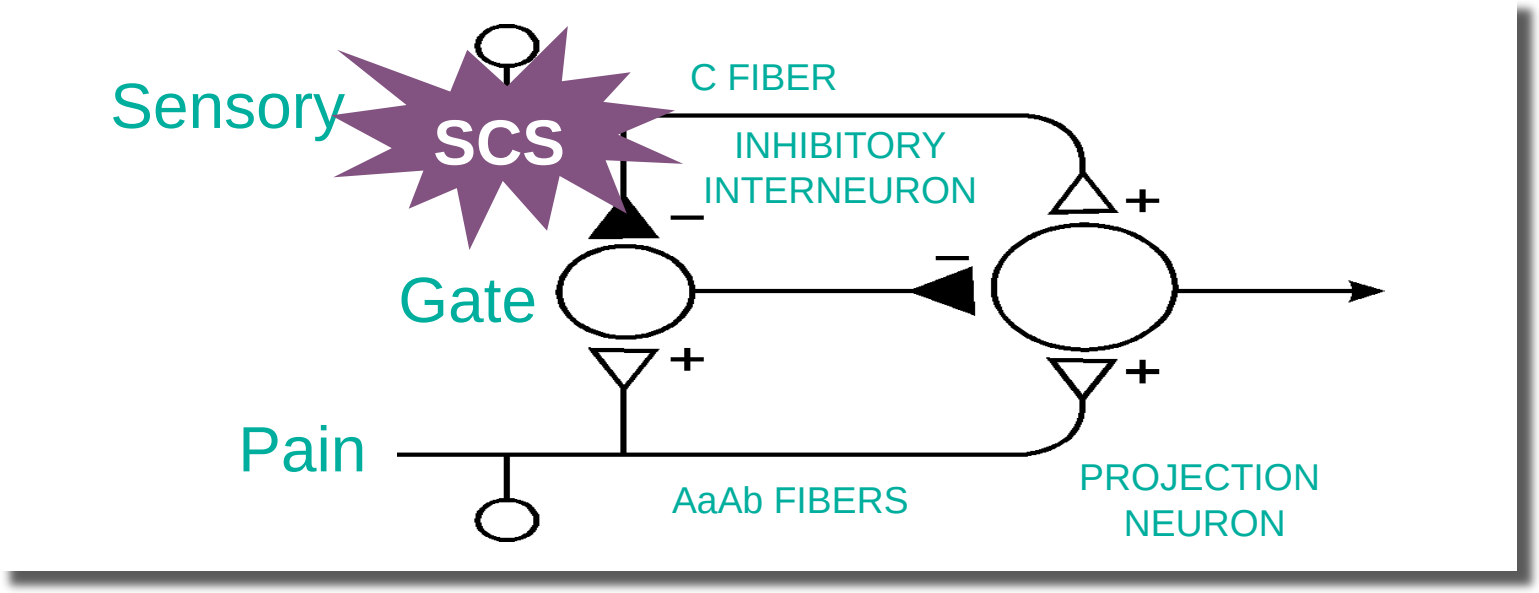
Gate Control Theory

- When sensory impulses are greater than pain impulses
- “Gate” in the spinal cord closes preventing the pain signal from reaching the brain



Gate Theory and SCS

SCS system implanted in the epidural space stimulates the pain-inhibiting nerve fibers masking painful sensation with a tingling sensation (paresthesia)



Overall Goals of SCS Therapy

- Position electrode in area of specific neural target
- Create paresthesia that overlaps painful area(s)
- Program for effectiveness, patient comfort, and energy efficiency
- Reduce medication, restore function and improve quality of life

Tenets of SCS

- Comprehensive trial
- Customizable system components
- Optimized efficiency in programs and design
- Team approach to patient care

Clinical Factors Influencing Therapy Success

- Indications—Responsive to SCS
- Disease etiology—Disease likely to progress should have device with "extra capacity"
- Pain distribution—Multi site and broad pain patterns often require more leads and electrodes
- Patient factors—Anatomy, physiology, and patient selection

How Are Clinical Factors Evaluated?

- Patient Selection Process
  - Correctly diagnosed
  - Failed lower level therapies
  - Successfully passed psychological evaluation
  - Patient is motivated
  - Patient is educated

Device Factors Influencing Therapy Success

- Stimulation Coverage—Paresthesia is delivered to entire painful segment(s)
- Precision of Stimulation—Not delivered to extraneous sites but masks the pain with a tolerable sensation
- Sustainability of Therapy—Sustained over the painful anatomical segment

How Are Device Factors Evaluated?

- During a Temporary SCS Trial
  - Leads are implanted
  - External power source is used to evaluate
    - Pain relief
    - Paresthesia coverage
    - Power requirements
    - Programming needs
    - System requirements (IPG)

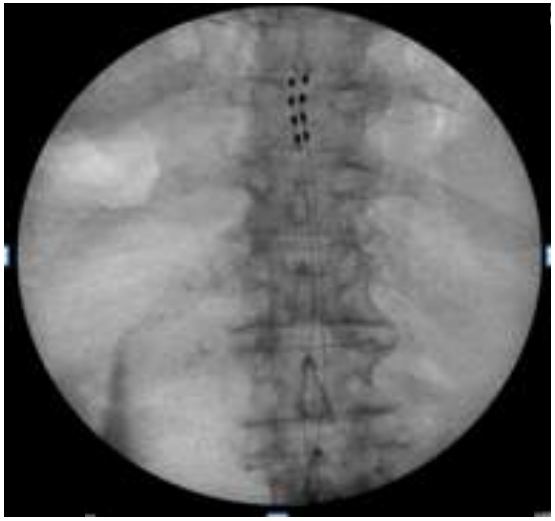
Right Device for Particular Patients

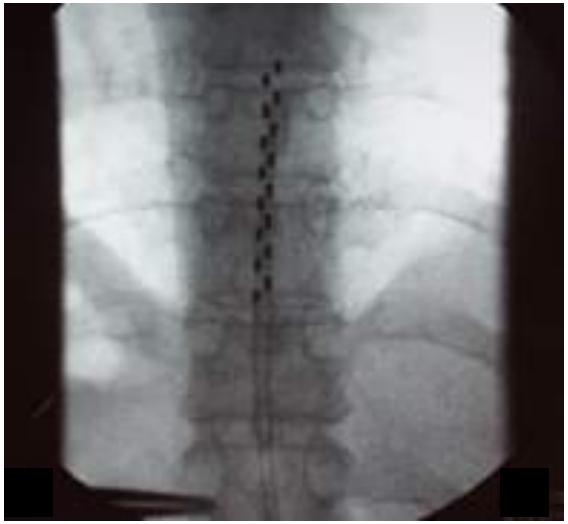
- **Primary Cell IPGs**
  - Simple/unilateral pain
  - Lower power requirements
  - Less patient compliance necessary
- **Rechargeable IPGs**
  - Complex/multifocal pain
  - Higher power requirements
  - More patient compliance necessary

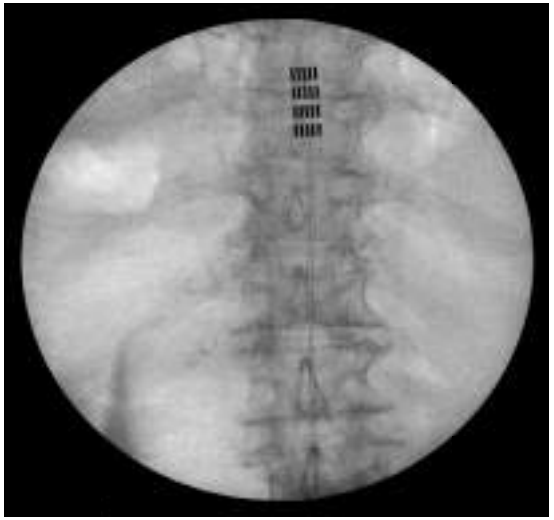
Patient/Device Criteria

	Conventional IPG	Rechargeable IPG
Power requirements	Low to moderate	Moderate to high
Frequency requirements	Low	Low to moderate
Pain	Stable	Likely to progress
Coverage needs (contacts/leads)	8 or 16 contacts on 1-4 leads	8 or 16 contacts on 1-4 leads
Compliance (motivation and ability)	Requires very little interaction	High—due to recharging protocol
Competence (physical or mental)	Appropriate for most levels	Higher level required
Skin sensitivity	Patients with high sensitivity	Patients with moderate to low sensitivity
Implant size	Moderate to large sizes	Small to moderate size
Implant longevity	2-7 years	5-10 years
Patient interface	Easier to use	Requires management

More Electrodes = More Coverage







Fewer electrodes
cover smaller area
(fewer nerve fiber targets)

More electrodes
cover larger area
(more nerve fiber targets)

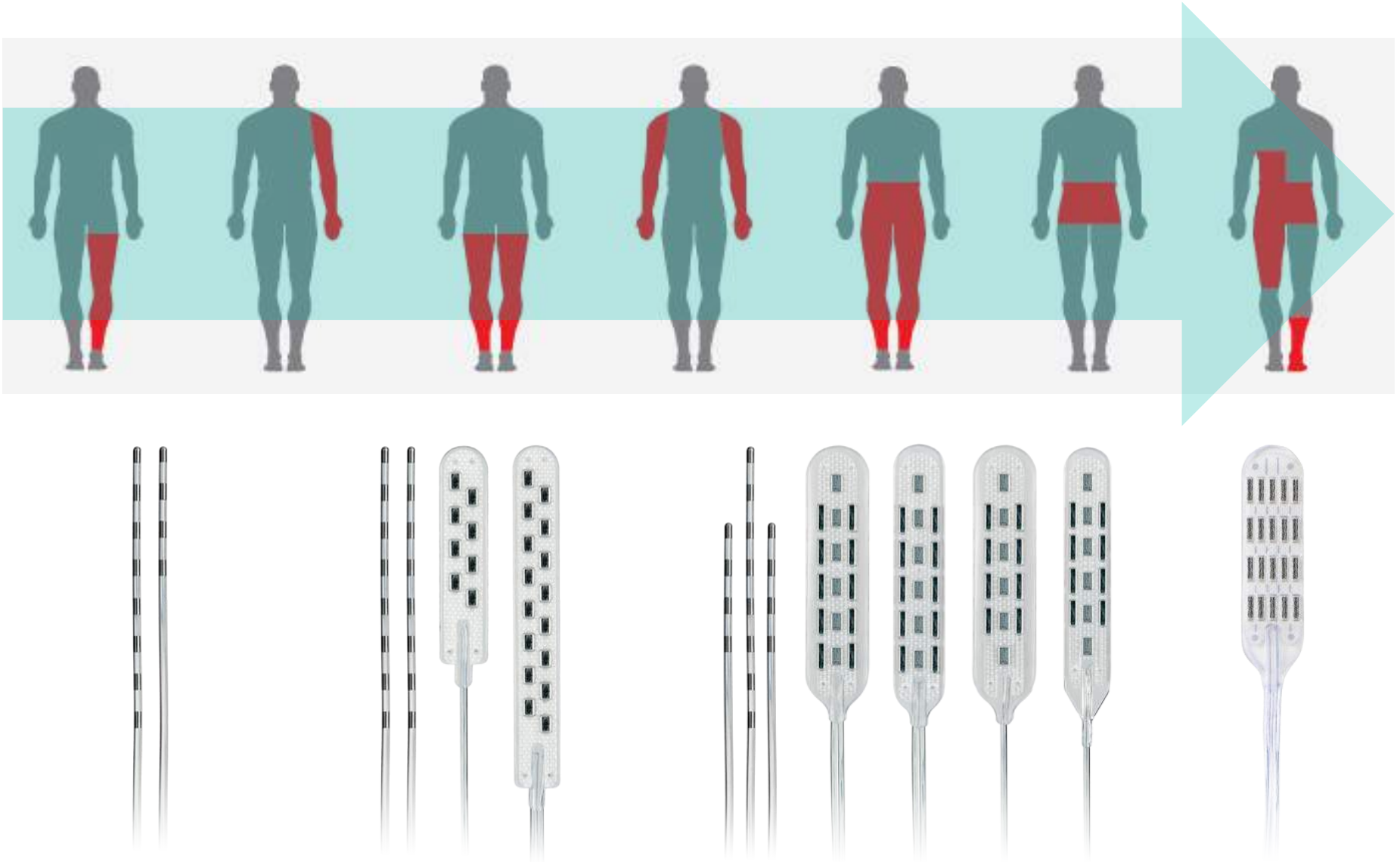
Programming Cannot Overcome...

- Out of position leads
  1. Poor placement location
  2. Leads that have migrated below original vertebral level location

- Selection of wrong system
  1. Not enough electrodes—reduced targeting flexibility and electronic repositioning capabilities for lead migration

  2. Inadequate power outputs—cannot activate necessary electrodes or provide sustainable power to optimize pain relief

Lead Options for Various Pain Patterns



Reduction of Pain

Clinical studies on SCS continue to support the effectiveness of this therapy. The following charts summarize studies of SCS and its effects on the quality of life of patients.

Reference	Number of Patients	Follow-Up	Results
Kumar[3]	410	8 years	74% had ≥50% relief
North[4]	19	3 years	47% had ≥50% relief
Barolat[5]	41	1 year	50%–65% had good to excellent relief
Van Buyten[6]	123	3 years	68% had good to excellent relief
Cameron[7]	747	Up to 59 months (4.9 years)	62% had ≥50% relief or significantly reduced pain scores
Alò[8]	80	30 months (2.5 years)	Mean pain scores declined from 8.2 at baseline to 4.8

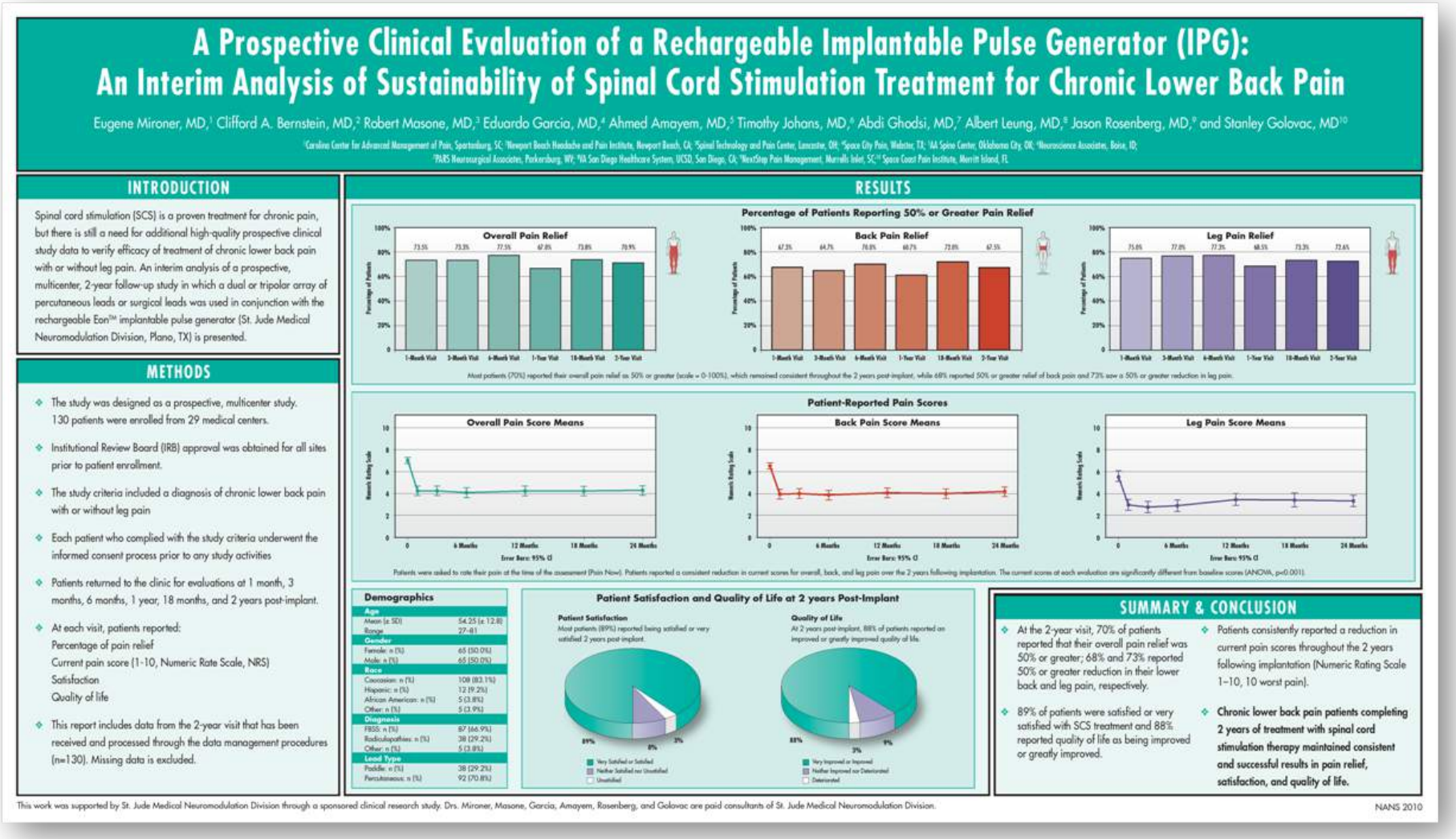
Reduction of Medications

Reference	Number of Patients	Follow-Up	Results
North[4]	19	3 years	50% reduced their medications
Van Buyten[6]	123	3 years	As a group, reduced medication use by >50%
Cameron[7]	766	up to 84 months	45% reduced their medications
Taylor[9]	681	n/a	53% no longer needed analgesics

Improvements in Daily Activities

Reference	Number of Patients	Follow-Up	Results
Barolat[5]	41	1 year	As a group, significantly improved function and mobility
North[4]	19	3 years	As a group, improved in a range of activities

Leading Pain Research and Outcomes[10]



A Prospective Clinical Evaluation of a Rechargeable Implantable Pulse Generator (IPG): An Interim Analysis of Sustainability of Spinal Cord Stimulation Treatment for Chronic Lower Back Pain

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INTRODUCTION

Spinal cord stimulation (SCS) is a proven treatment for chronic pain, but there is still a need for additional high-quality prospective clinical study data to verify efficacy of treatment of chronic lower back pain with or without leg pain. An interim analysis of a prospective, multicenter, 2-year follow-up study in which a dual or tripolar array of percutaneous leads or surgical leads was used in conjunction with the rechargeable Eon™ implantable pulse generator (St. Jude Medical Neuromodulation Division, Plano, TX) is presented.

METHODS

- The study was designed as a prospective, multicenter study. 130 patients were enrolled from 29 medical centers.
- Institutional Review Board (IRB) approval was obtained for all sites prior to patient enrollment.
- The study criteria included a diagnosis of chronic lower back pain with or without leg pain
- Each patient who complied with the study criteria underwent the informed consent process prior to any study activities
- Patients returned to the clinic for evaluations at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post-implant.
- At each visit, patients reported:
  Percentage of pain relief
  Current pain score (1-10, Numeric Rate Scale, NRS)
  Satisfaction
  Quality of life
- This report includes data from the 2-year visit that has been received and processed through the data management procedures (n=130). Missing data is excluded.

RESULTS

Percentage of Patients Reporting 50% or Greater Pain Relief

Most patients (70%) reported their overall pain relief as 50% or greater (scale = 0-100%), which remained consistent throughout the 2 years post-implant, while 68% reported 50% or greater relief of back pain and 73% saw a 50% or greater reduction in leg pain.

Patient-Reported Pain Scores

Patients were asked to rate their pain at the time of the assessment (Pain Now). Patients reported a consistent reduction in current scores for overall, back, and leg pain over the 2 years following implantation. The current scores at each evaluation are significantly different from baseline scores (ANOVA, $p<0.001$).

Demographics

Age	
Mean (± SD)	54.25 (± 12.8)
Range	27-81
Gender	
Female: n (%)	65 (50.0%)
Male: n (%)	65 (50.0%)
Race	
Caucasian: n (%)	108 (83.1%)
Hispanic: n (%)	12 (9.2%)
African American: n (%)	5 (3.8%)
Other: n (%)	5 (3.9%)
Diagnosis	
FBSS: n (%)	87 (66.9%)
Radiculopathies: n (%)	38 (29.2%)
Other: n (%)	5 (3.8%)
Lead Type	
Paddle: n (%)	38 (29.2%)
Percutaneous: n (%)	92 (70.8%)

Patient Satisfaction and Quality of Life at 2 years Post-Implant

Patient Satisfaction
Most patients (89%) reported being satisfied or very satisfied 2 years post-implant.

Quality of Life
At 2 years post-implant, 88% of patients reported an improved or greatly improved quality of life.

SUMMARY & CONCLUSION

- At the 2-year visit, 70% of patients reported that their overall pain relief was 50% or greater; 68% and 73% reported 50% or greater reduction in their lower back and leg pain, respectively.
- 89% of patients were satisfied or very satisfied with SCS treatment and 88% reported quality of life as being improved or greatly improved.
- Patients consistently reported a reduction in current pain scores throughout the 2 years following implantation (Numeric Rating Scale 1–10, 10 worst pain).
- **Chronic lower back pain patients completing 2 years of treatment with spinal cord stimulation therapy maintained consistent and successful results in pain relief, satisfaction, and quality of life.**

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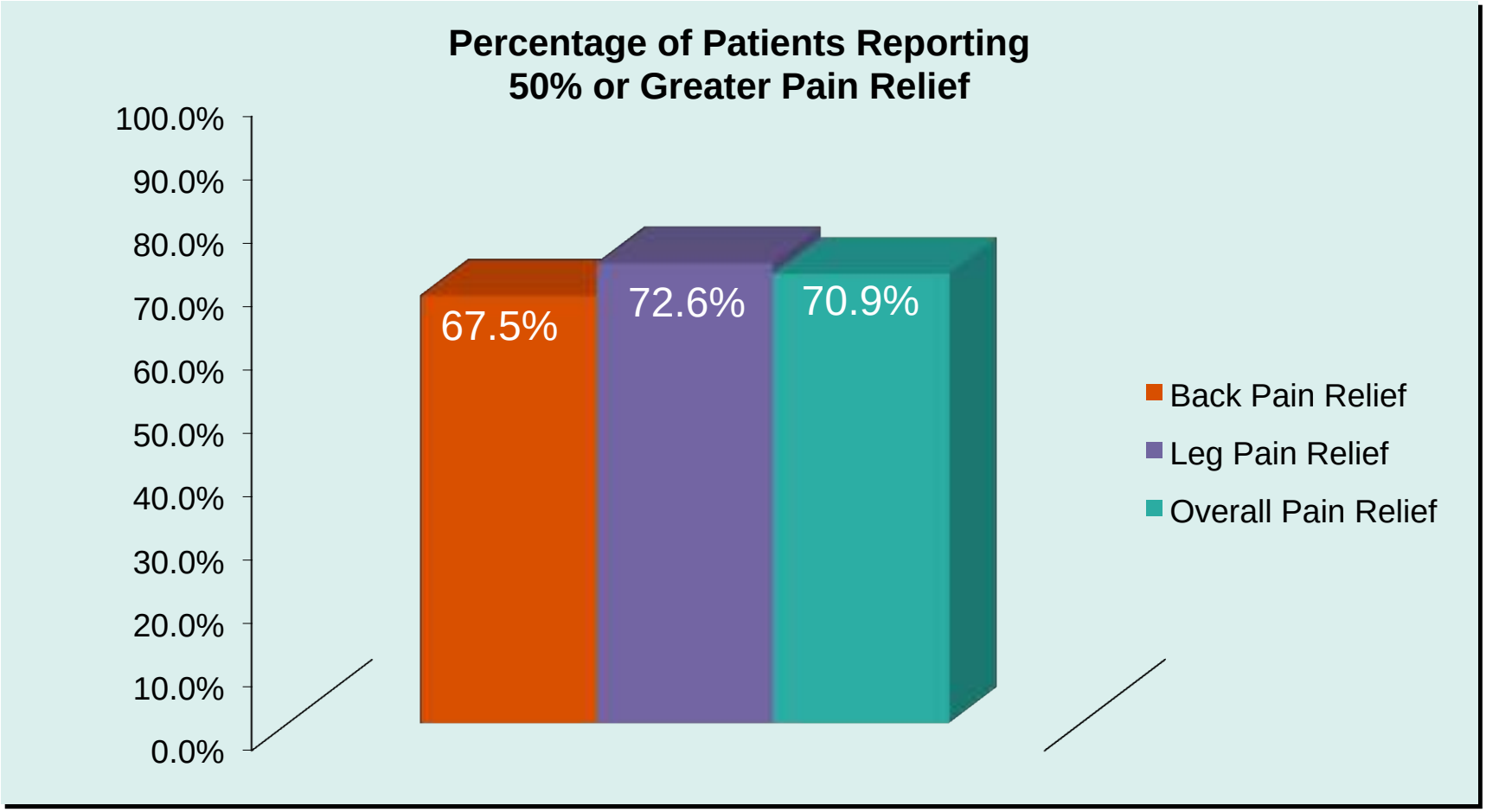
Leading Pain Research and Outcomes[10]



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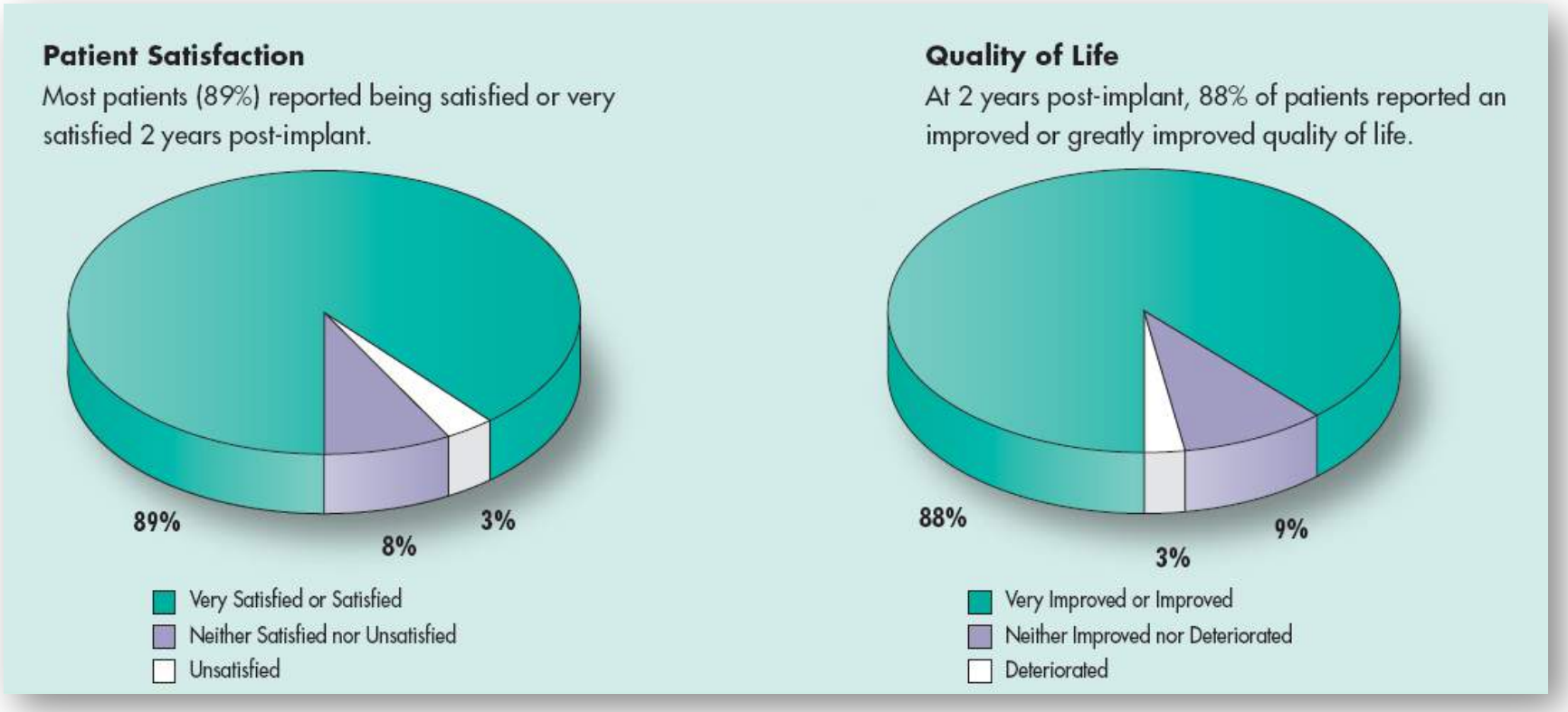
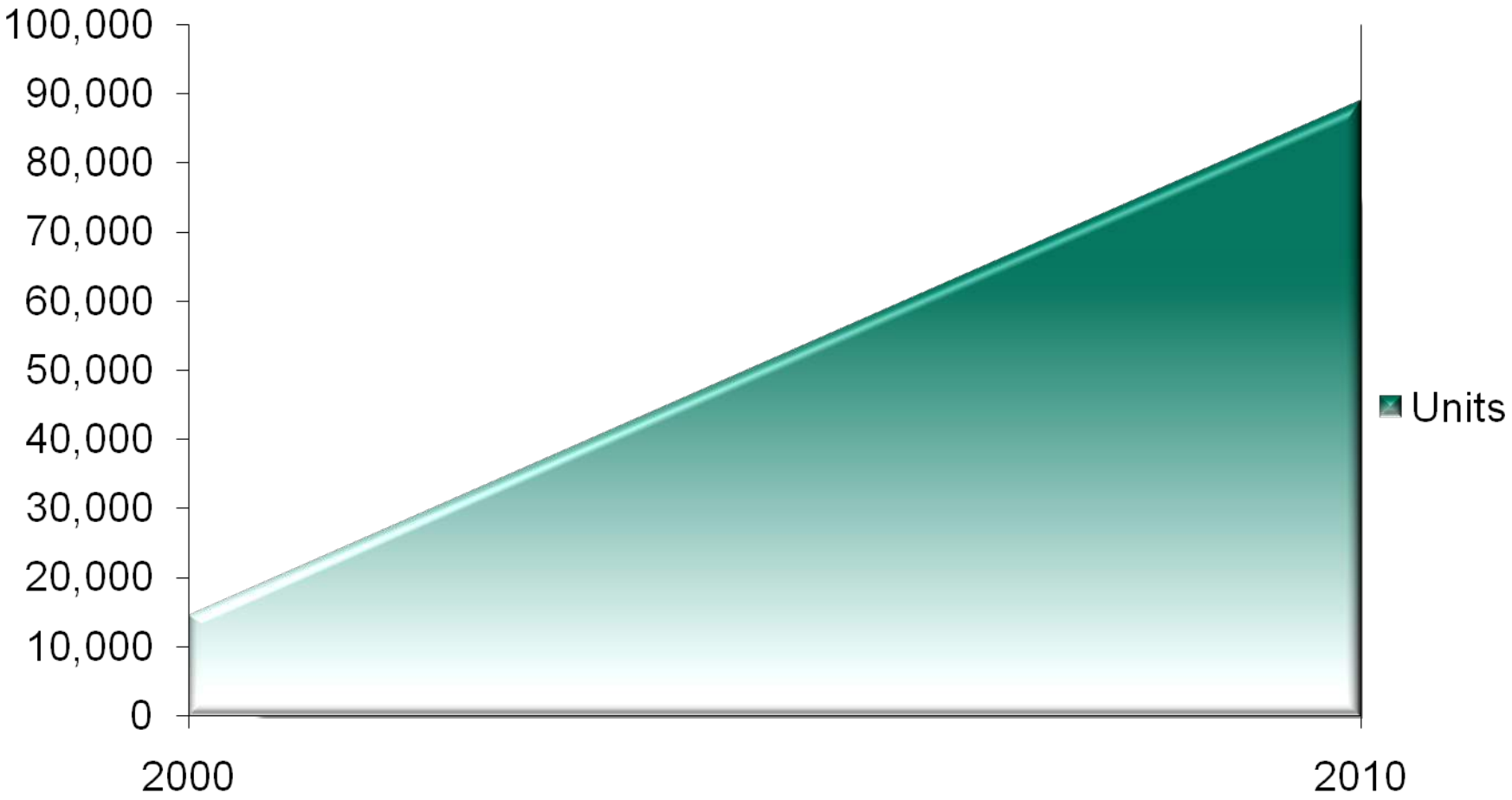


Industry Growth–Spinal Cord Stimulators[11]



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