

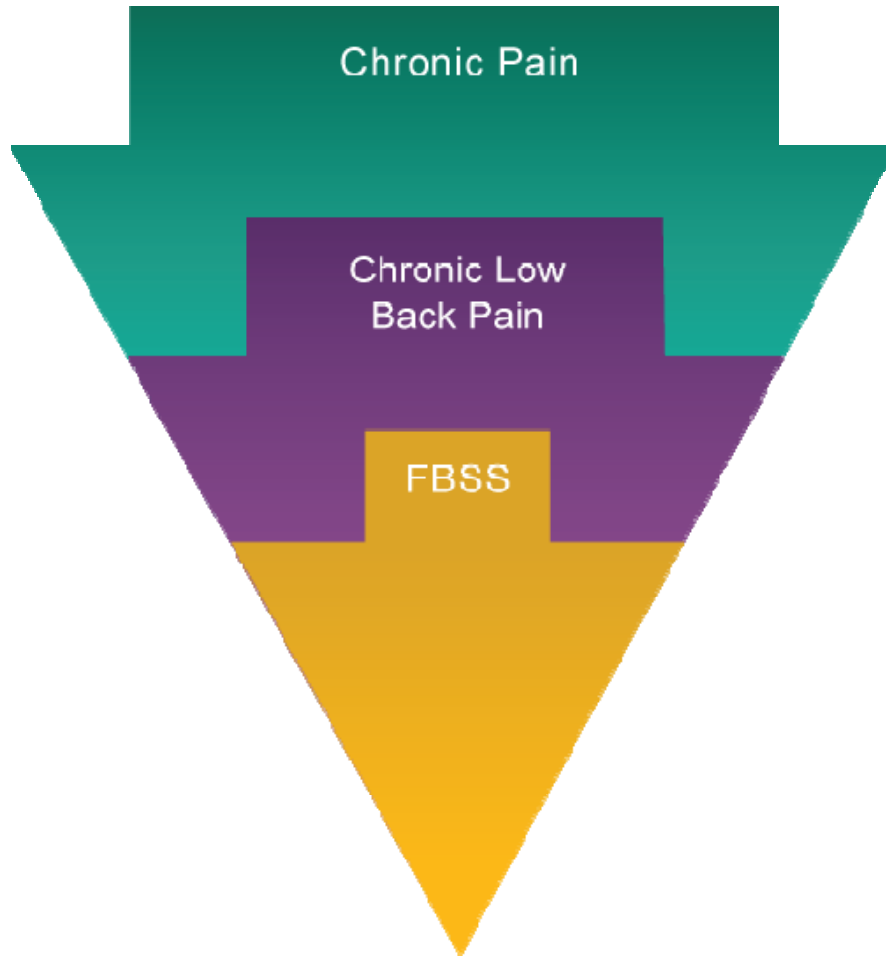
Spinal Cord Stimulation Business Case for Failed Back Surgery Syndrome



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Understanding How Various Stakeholders Gauge Success in Treating Chronic Pain



- FBSS is a subset of chronic low back pain, which is a type of chronic pain.

FBSS Comorbidities

Patients typically suffer many problems associated with FBSS, including the following¹:

- Sleeping problems
- Depression
- Family problems sometimes leading to divorce
- Economic problems because they are unable to remain employed
- High-dose opioid use or dependence
- Low probability that further surgery will relieve pain



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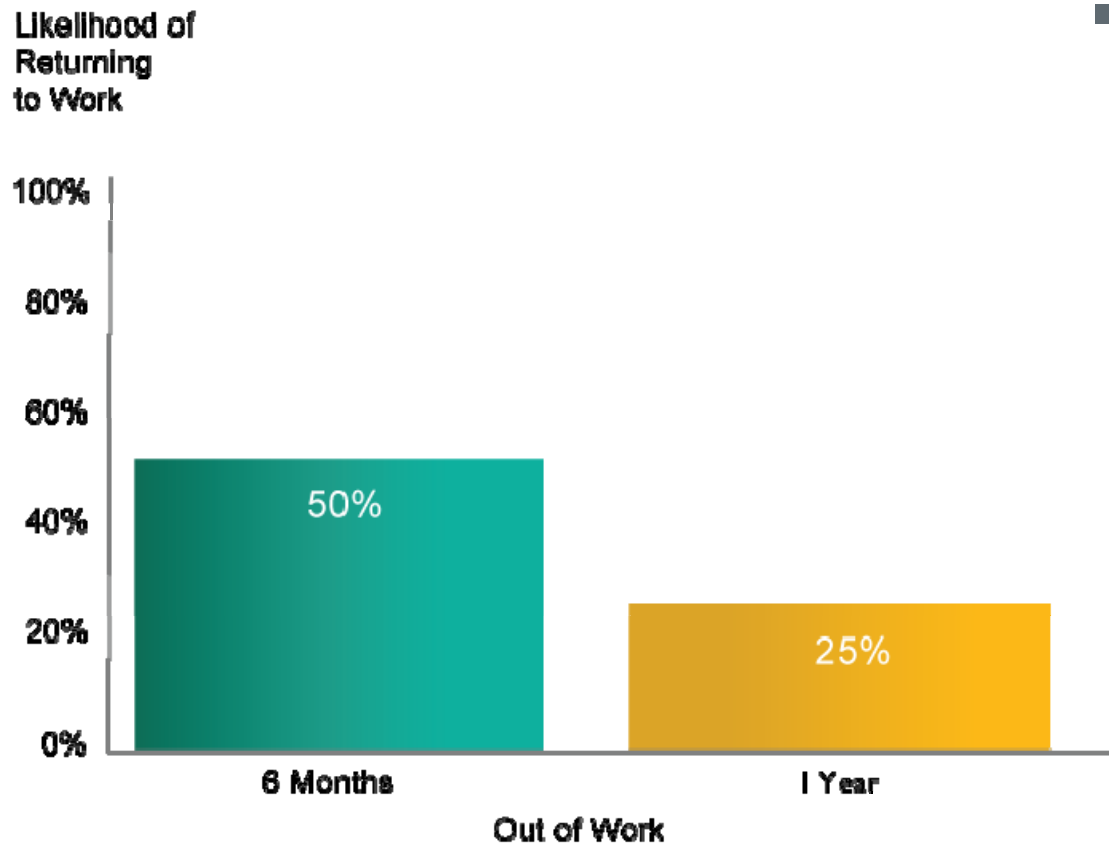
Understanding How Various Stakeholders Gauge Success in Treating Chronic Pain

Stakeholder Category	Criterion of Success
Individual	Receives pain relief
Healthcare provider	Satisfies needs of the patient
Managed care organization	Improves patient function
Worker's compensation	Reduces healthcare consumption
Society	Has patient returned to work



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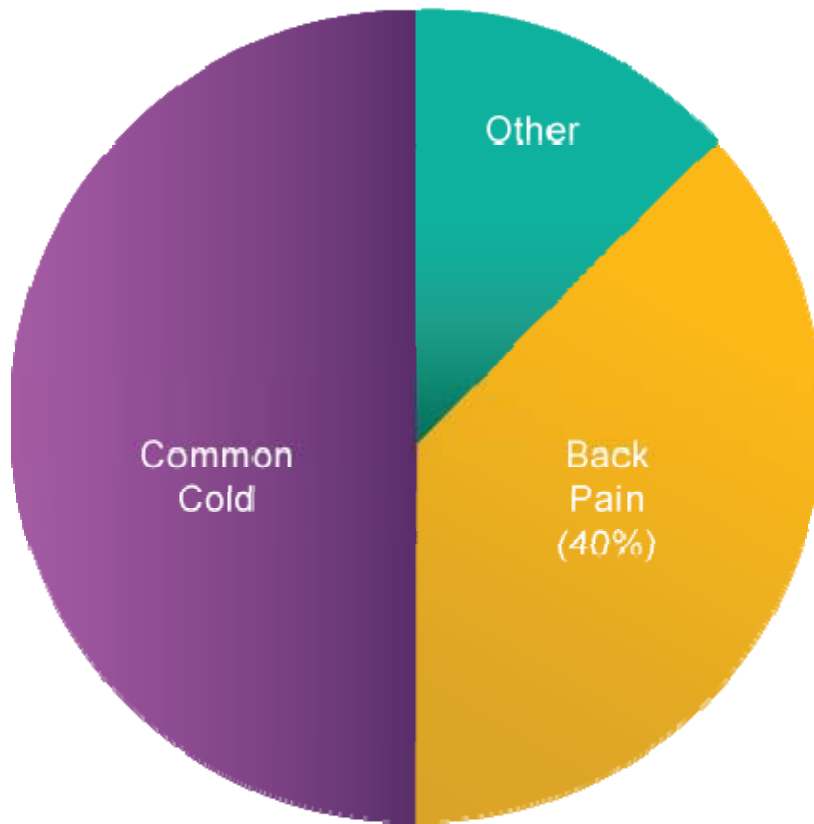
How Low Back Pain Impacts Society



- For people who report low back pain, the longer they remain out of work, the less likely they are to return.²

How Low Back Pain Impacts Employers and Other Payers

Absences From Work



- Back pain accounted for 40 percent of absences from work, second only to the common cold.³

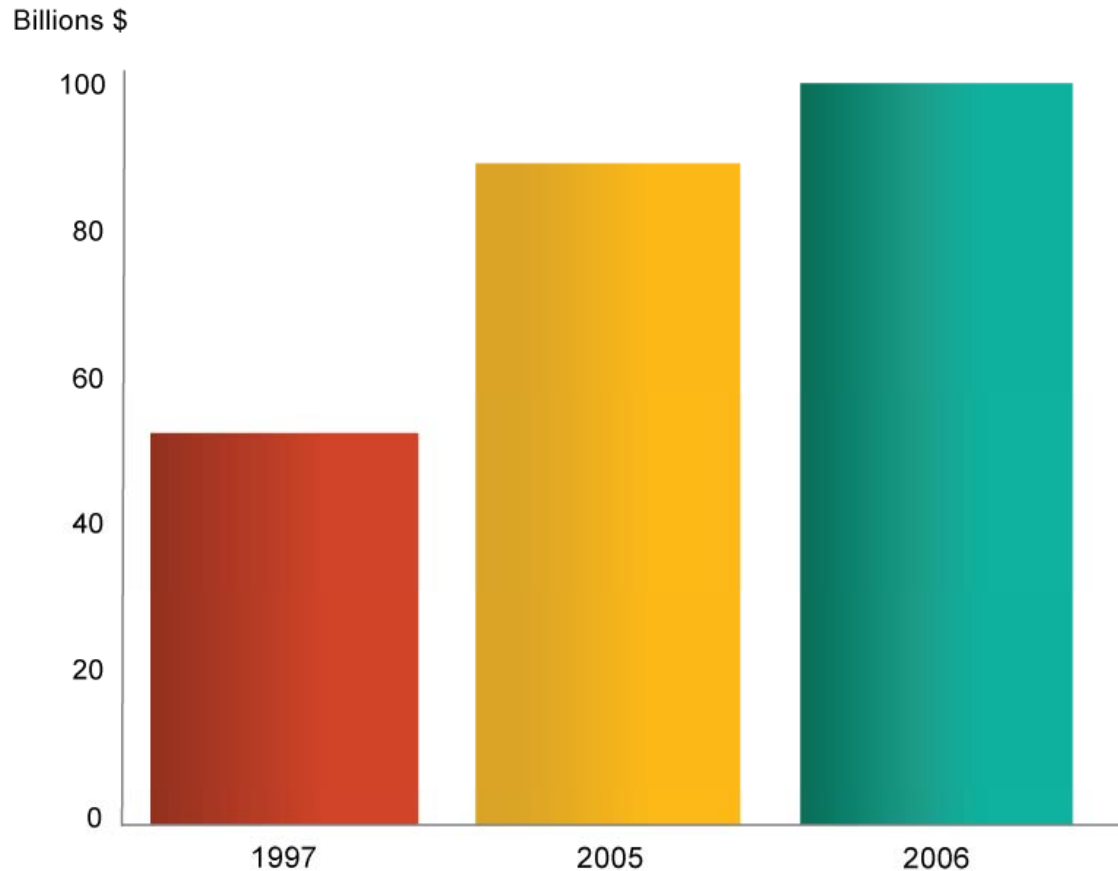


Costs to Disability and Workers' Compensation

“Back pain is the most common reason for filing workers' compensation claims.”³

From an economic perspective, the average cost of a workers' compensation claim for low back pain was \$8,300, which was more than twice the average cost (\$4,075) for all compensable claims combined.⁴

How Low Back Pain Impacts the Economy and Healthcare



- Total estimated costs to the U.S. economy for treating low back pain have continued to increase since 1997.⁵

How Low Back Pain Impacts the Economy and Healthcare

In 2008, the *Journal of the American Medical Association* reported

“Total estimated expenditures among respondents with spine problems increased 65 percent from 1997 to 2005. These spine-related expenditures have increased substantially, without evidence of corresponding improvement in self-assessed health status.”⁶

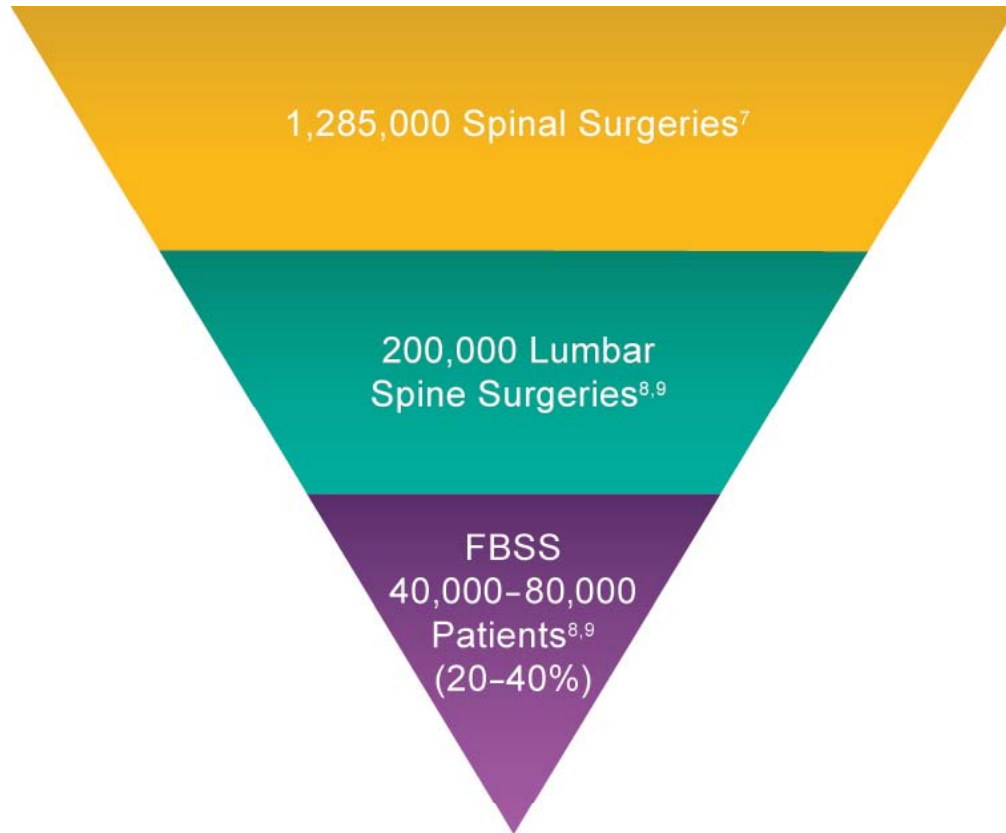
How Low Back Pain Impacts the Economy and Healthcare

According to a study by Katz,² the 5 percent of patients who have low back pain who do not return to work by 3 months account for 75 percent of total healthcare costs.

As of 2004, low back pain was the⁴

- Second leading symptomatic cause for physician visits
- Third most common cause for surgical procedures
- Fifth most common reason for hospitalizations

How Low Back Pain Impacts the Economy and Healthcare



- In 2005, between 20 and 40 percent of spine surgery patients were diagnosed with FBSS.

Complexities in Managing FBSS

Overall from 1997 to 2003¹⁰

- Cervical fusions increased by 433 percent.
- Thoracolumbar fusions increased by 52 percent.
- Lumbar fusions increased by 356 percent.



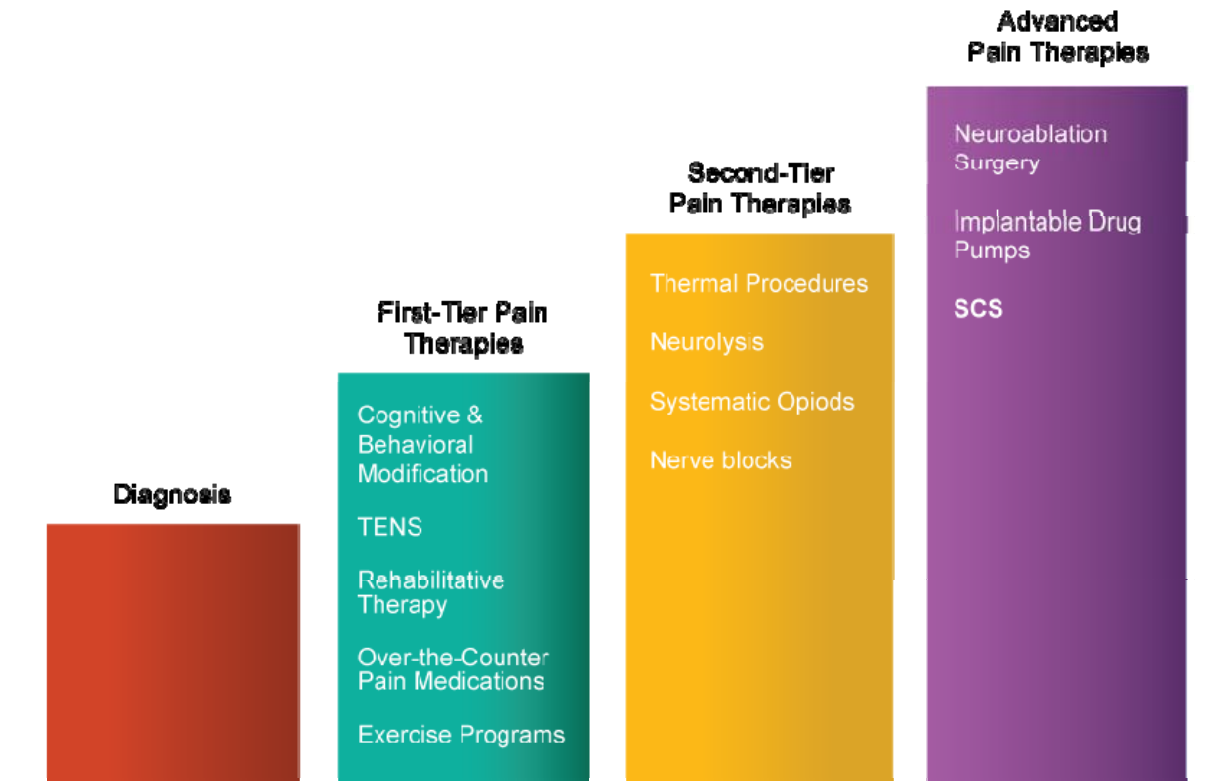
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Current Medicare Criteria for Evaluating Spinal Cord Stimulation Candidates

Currently, Medicare requires the following criteria to be met in order to reimburse costs for SCS¹¹:

- Pharmacological, surgical, physical, or psychological therapies have been tried and have not satisfactorily treated the patient; or they are considered unsuitable or contraindicated for the given patient.
- Patient must undergo screening including a physical and psychological evaluation.
- All facilities, equipment, and professional and support personnel are available to properly diagnose, treat, train, and follow up with the patient.
- Before permanently implanting an SCS system, physicians must demonstrate that implanted electrodes relieved pain during an SCS trial.
- Stimulator is implanted only as a late resort for patients with chronic intractable pain.

Current Continuum of Care for Failed Back Surgery Syndrome



- As part of the continuum of care for patients who suffer from FBSS, proper diagnosis is the first phase, followed by first- and second-tier therapies. SCS, among other advanced pain therapies, is considered a late resort.



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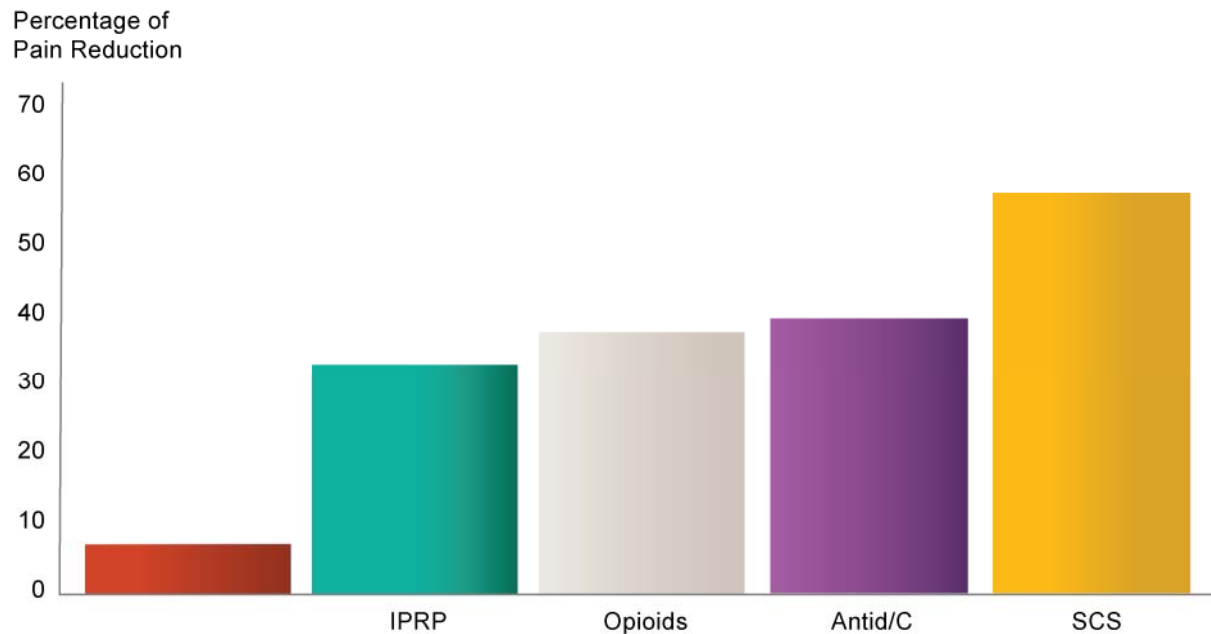
The Clinical and Economic Case For SCS

According to a 2007 analysis, “In spite of the apparent clinical success of SCS reported in the literature and the data presented by the authors, there continues to be concern, particularly among third-party payers, that SCS is an expensive and even ineffective therapy.”¹²

Percentage of Pain Reduction for Different Treatments

- More patients receiving SCS achieved 50 percent or more pain relief compared with those who underwent reoperation.^{1,13}
- According to a study conducted by North et al. in 2005,¹⁴ 47 percent of patients who received SCS found that it relieved their pain by 50 percent or more; this is significantly more than the 12 percent who achieved the same effect through reoperation.

The Clinical and Economic Case for SCS



- SCS relieves more pain overall compared to other treatment modalities.¹⁵

In the figure to the left,

IPRP = interdisciplinary pain rehabilitation program

AntiD/C = antidepressants/anticonvulsants

SCS = spinal cord stimulation

The Clinical and Economic Case for SCS

In 2007, Kumar et al. published a study on the largest trial of SCS for managing neuropathic pain. Called the PROCESS study, it was a randomized controlled trial that showed SCS' positive effect on FBSS. Key results from this study are as follows¹⁶:

- Compared with conventional medical management (CMM) alone, SCS improved pain relief, quality of life, function capacity, and patient satisfaction in selected patients with neuropathic pain related to FBSS.
- At 6 months, 24 SCS patients (48 percent) and 4 CMM patients (9 percent) achieved at least 50 percent or more pain relief in the legs.
- Compared to CMM, treatment with SCS resulted in greater improvement in all SF-36 domains, which evaluate quality of life.

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 ¹⁷	410	8 years	74% had \geq 50% relief
North ¹⁴	19	3 years	47% had \geq 50% relief
Barolat ⁹	41	1 year	50%-65% had good to excellent relief
Van Buyten ¹⁸	123	3 years	68% had good to excellent relief
Cameron ¹⁹	747	Up to 59 months (4.9 years)	62% had \geq 50% relief or significantly reduced pain scores

Reduction in Medication

Reference	Number of Patients	Follow Up	Results
North ¹⁴	19	3 years	~50% reduced their medications
Van Buyten ¹⁸	123	3 years	As a group, reduced medication use by >50%
Cameron ¹⁹	766	Up to 84 months	45% reduced their medications
Taylor ²⁰	681	n/a	68% no longer needed analgesics

Improvements in Daily Activities

Reference	Number of Patients	Follow Up	Results
Barolat ⁹	41	1 year	As a group, significantly improved function and mobility
North ¹⁴	19	3 years	As a group, improved in a range of activities

Return to Work

Reference	Number of Patients	Follow Up	Results
Van Buyten ¹⁸	123	3 years	31% returned to work
Taylor ²⁰	1,133	n/a	40% returned to work
Dario ²¹	23	3 years	35% returned to work

Cost-Effectiveness of SCS

SCS is cost-effective, as several experts have shown:

- Based on a randomized controlled SCS trial, North reported in 2007, “At a mean 3 years of follow-up, SCS is dominant [less expensive and more effective] than reoperation.”¹² In this study, the mean cost per success was \$177,901 for patients who crossed over to SCS. No crossovers to reoperation were successful, despite a mean per-patient cost of \$260,584.

Cost-Effectiveness of SCS

SCS is cost-effective, as several experts have shown:

- Bell et al.²² showed that SCS pays for itself within 2.1 years with patients who have clinically effective SCS.
- Another study by Kumar²³ determined the average cumulative cost for SCS therapy for 5 years was \$29,123 per patient, less than the per-patient cost of \$38,029 for conventional pain therapy.

Cost-Effectiveness of SCS

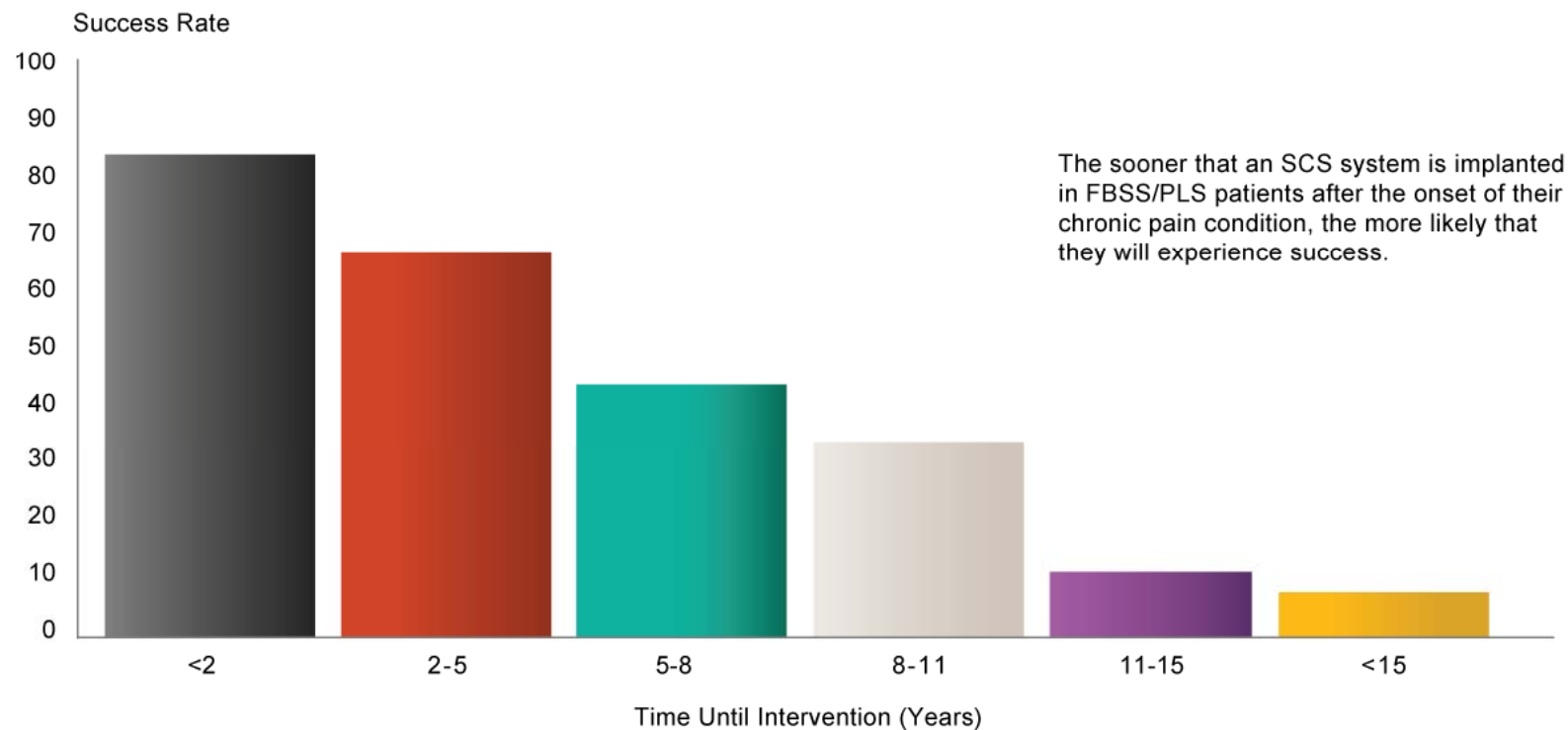
SCS is cost-effective, as several experts have shown:

- A cost-benefit analysis by Mekhail et al. in the *Clinical Journal of Pain* revealed that the cost savings associated with SCS was \$30,221 per patient per year.²⁴
- Mekhail attributed this savings largely to patients dramatically reducing nerve blocks, emergency department visits, and hospitalizations.

Importance of Timing With SCS in the Treatment of FBSS

- SCS is more effective in treating FBSS if considered earlier.
- In 2006, Van Buyten¹ found that early treatment with SCS yields the best results—the shorter the time between the previous surgery to implantation of an SCS system, the greater the rate of success.

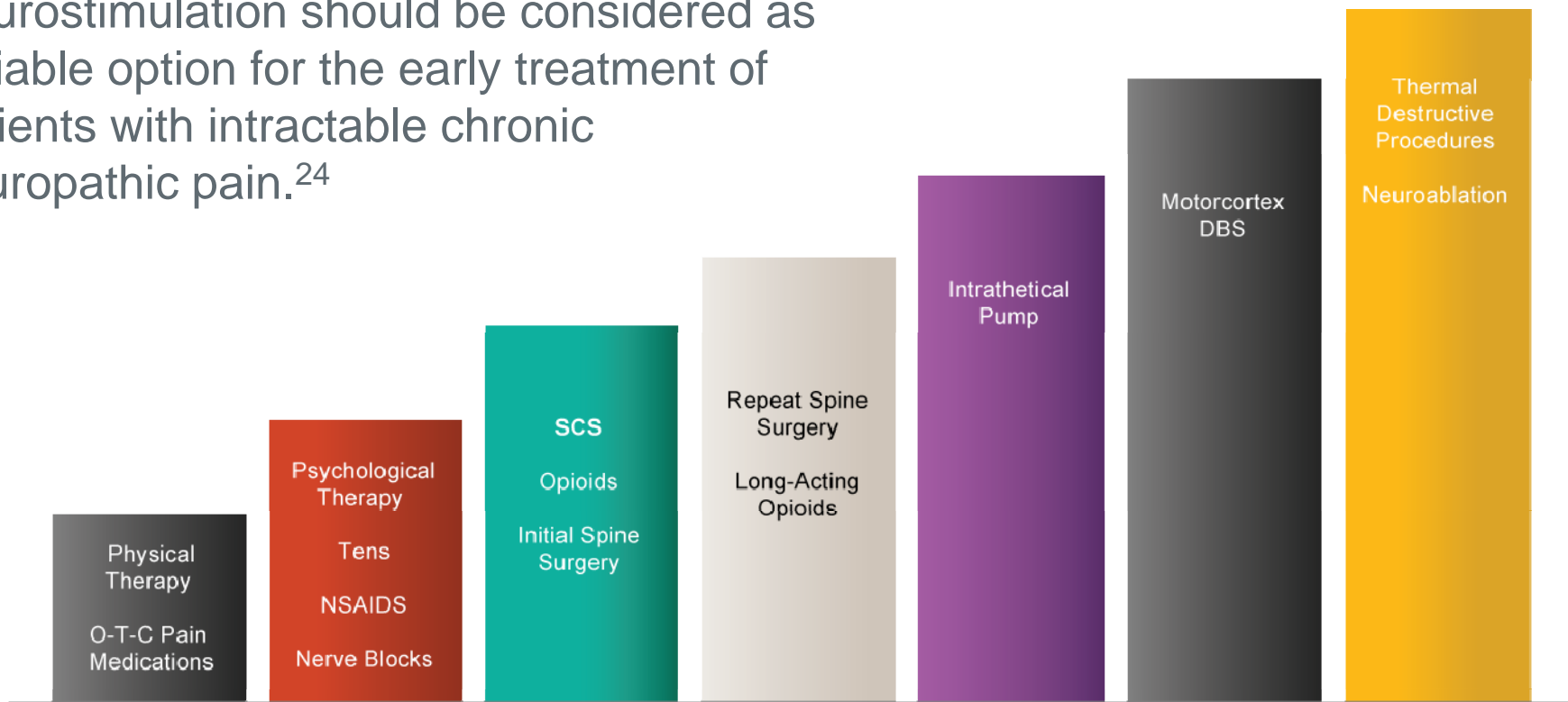
Importance of Timing With SCS in the Treatment of FBSS



- SCS for patients with FBSS is more effective the sooner an SCS system is implanted from the date of the previous failed surgery.¹⁷

Proposed New Chronic Pain Treatment Continuum

Neurostimulation should be considered as a viable option for the early treatment of patients with intractable chronic neuropathic pain.²⁴



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