In patients with chronic radicular leg pain refractory to traditional surgical management (the Failed Back Surgery Syndrome), an implantable spinal cord stimulator in conjunction with conservative medical management was more effective in reducing pain than medical management alone.

Clinical Problem: *A 48yo male presents with classic symptoms of L5 radiculopathy. He undergoes uncomplicated surgical decompression. One month later, despite normal MRI and EMG and a lack of abnormalities in lower extremity strength, sensation, or reflexes, his pain persists. Six months later, he has still been unable to return to work, despite escalating analgesic requirements and participation in an exercise regimen. He returns dissatisfied, requesting a new option for management.*

Clinical Question:
In patients with chronic radicular leg pain refractory to surgery (failed back surgery syndrome), is implantation of a spinal cord stimulator in addition to conservative medical management more effective in reducing pain compared to medical management alone?

Search Strategy:
A medline (ovidSP) search for Back Pain (keyword and exploded MeSH) and Spinal Cord Stimulation (keyword and exploded MeSH), limited to English, last 10 years, and all meta-analyses. Three articles were found but were either reviews or did not address our clinical question.
Limiting to randomized control trials using the same search terms above yielded 12 results. Of these, 3 were relevant to the clinical question. These 3 trials included separate publications describing aspects the PROCESS trial (1-3). The article (Kumar 2007) was chosen given the relevance to the clinical question and the stringent design.

Clinical Bottom Lines:

1. In patients with chronic predominantly radicular leg pain, unresponsive to surgical treatment, spinal cord stimulation in conjunction with conventional medical therapy, was more effective in reducing pain (NNT 3 (95% CI 2 to 4) and resulted in greater patient satisfaction (NNT 2 (95% CI 1.5 to 3) than conventional medical therapy alone.

2. The risk of complication was 32% at 12 months, among patients receiving an implanted device. These events included electrode migration, infection or wound breakdown, and loss of paresthesia.

The Evidence:
Design: PROCESS was a prospective, randomized, controlled, multicentre trial comparing spinal cord stimulation (SCS) in addition to conservative medical treatment (CMT) (analgesia, exercise, etc.) versus CMT alone in patients suffering from Failed Back Pain Syndrome with a lower leg pain predominance.
Patients: 100 patients in a total of 12 multi-national centres recruited between April 2003 and June 2005.
Inclusion Criteria: Patients 18 or older with neuropathic pain of radicular origin (L4 and/or L5 and/or S1) predominantly in the legs (exceeding back pain), of an intensity of at least 50 mm on a visual analogue scale, for at least 6 months, after a minimum of one anatomically successful surgery for a herniated disc.
Intervention and Comparison: Patients were randomly assigned to receive SCS plus CMT or CMT alone.
Outcomes: The primary outcome measured was a >50% reduction in leg pain as recorded on a visual analog scale. Secondary outcomes assessed included back and leg pain severities (VAS), quality of life (7/8 dimensions of SF-36), functionality (ODI), and patient satisfaction with treatment.

Data:

	CMT group (n=44)	SCS group (n=50)	Absolute Risk Reduction (95% CI)	Number Needed to Treat (95% CI)
Primary outcome measure at 6 months				
>50% leg pain relief *n* (%)	4 (9%)	24 (48%)	39% (23 to 55%)	2.54 (1.81 to 4.39)
Secondary outcome measures at 6 months				
Leg pain relief (>30%) *n* (%)	8 (18%)	32 (64%)	46% (29 to 63%)	2.17 (1.58 to 3.51)
Satisfaction with pain relief *n* (%)	8 (18%)	33 (66%)	48% (31 to 65%)	2.08 (1.53 to 3.26)
Complications				
Electrode Slippage		8(10%)		
Infection or wound breakdown		7(8%)		
Loss of paresthesia		6(7%)		

CMT – Conventional Medical Treatment, SCS – Spinal Cord Stimulation

Comments:

1. The authors conducted intention-to-treat analyses and showed significant improvement even though 10% of patients randomized to receive SCS failed the screening trial and failed to receive an implantable device.
2. At 6 months, patients were allowed to cross over. An asymmetrical flux of subjects was noted into the SCS/CMT group. This impacted analysis of the 12 month follow up study (not assessed here), but did not impact results as above detailed. Analysis of the 12 month follow up data suggested a similar pattern of findings, taking both intention to treat and as-treated approaches.
3. Favourable effects of SCS on neuropathic pain are consistent with the results of previously reported trials conducted by North et al. (2005), Kemler et al. (2006), and Tesfaye et al. (1996).
4. Nature of the study and intervention made it impossible to blind patients, and difficult to blind investigators over the course of the study.

References:

1. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomized controlled trial in patients with failed back surgery syndrome. Pain 2007; 132 (1-2): 179-188.
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Key Words: Chronic Pain, Failed Back Surgery Syndrome, Spinal Cord Stimulation, Neuromodulation.
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