**Spinal Cord Stimulation**

### 1. Volume of evidence

Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.

A total of thirty-eight studies were identified for inclusion in this review.

Two guidelines, two health technology assessments (HTAs) and six systematic reviews (SRs) were identified for spinal cord stimulation (SCS) encompassing the last ten years (1995-2004): Manchikanti, 2003 (medium quality guideline); Sanders, 1999 (medium quality guideline); Jadad, 2001 (high quality HTA); McQuay, 1997 (medium to high quality HTA); Turner, 2004 (high quality SR); Grabow, 2003 (high quality SR); Stocks, 2001 (medium quality SR); Carter, 2004 (low quality SR); Spruce, 2003 (low quality SR); Kemler, 2001 (low quality SR). The low quality studies were only considered as part of the safety section.

One high quality randomised controlled trial (RCT) was identified and reported in Kemler, 2004 and Kemler, 2001. Three other RCTs were identified: North, 2003 (medium quality); North, 1994 (medium quality) for which only initial/interim results have been published; and North, 2002 (low quality). Fifteen case series studies were also identified, five of which were of medium or medium to high quality. The other ten case series provided low quality evidence of improvement of selected cases treated with SCS.

Eight additional reports were also considered for the review of safety and harm.

Outcomes varied greatly in the studies as shown in the evidence tables. Outcomes were measured by patient questionnaire, patient records, length of time of pain relief (variable), categorical measures of pain relief such as percentage pain relief (<50%, >50%) and binary pain relief, visual analogue scales, least and worse pain descriptors, analgesic medication use, disability/work status, mobility, improvement in leg function, improvement in sleep, improvement in psychometric measures, treadmill performance, Oswestry disability rating, Oswestry Pain Questionnaire, Euroquol 5D, Self-rating Depression Scale, Back Depression Index, Sickness Impact Profile, Nottingham Health Profile, Padilla Quality of Life Scale, McGill Pain Questionnaire, global perceived effect, internalisation of stimulation device or not, use of stimulation device and discontinuation of stimulation device. The timeframe for outcomes, in the appraised studies varied between within days of trial stimulation device (days) to time after implantation of stimulation device (13 years).

Co-interventions were not consistently reported in the appraised studies. Those reported were analgesic and medication use.

### 2. Consistency

Comment here on the degree of consistency demonstrated by the availability of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Failed back surgery – inconsistent evidence of effectiveness

Neuropathic pain following spinal cord injury – appears to be some evidence of effect from high quality secondary sources

Complex regional pain syndrome- appears to be consistent evidence of effectiveness from primary and secondary sources.

### 3. Applicability

Comment here on the extent to which the evidence is directly applicable in the New Zealand setting. Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.

Selection criteria are critical, follow-up involves reprogramming.

Few cases are carried out in Auckland and Christchurch

Cases in Auckland tend to be for debilitating angina.

### 4. Clinical Impact

Comment here on the potential clinical impact that the intervention in question might have – e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.

Three medium to high quality systematic reviews conclude that there is inadequate and insufficient evidence to make definitive conclusions regarding the effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome and complex regional pain syndrome. The two HTAs and one guideline (Sanders, 1999) came to similar conclusions. All agree that the quality of studies evaluating the effectiveness of spinal cord stimulation is generally poor as most studies are case series, lack randomisation and control or comparison groups, and have small sample sizes. Studies also lack consistency in outcome measurements.

Both the Turner and Grabow systematic reviews conclude, on the basis of the same high quality randomised controlled trial, that there is moderate evidence that spinal cord stimulation plus physical therapy is more effective than physical therapy alone in patients with complex regional pain syndrome type I. The Jadad health technology assessment also concludes that there may be a variable rate of early success and lower long-term success with spinal cord stimulation in patients with chronic
neuropathic pain due to traumatic spinal cord injury.

The second medium quality guideline (Manchikanti, 2003) concludes that the evidence for the long-term effectiveness of spinal cord stimulation in patients with neuropathic pain is moderate.

Of the four randomised controlled trials, two high quality studies (Kemler, 2004 and Kemler, 2001) report on the results coming out of one clinical trial in patients with reflex sympathetic dystrophy (complex regional pain syndrome type I) with pain unresponsive to conventional treatments. The 2004 report concludes that, after two years, spinal cord stimulation reduces pain intensity in patients with reflex sympathetic dystrophy. The 2001 report concludes that, after one year, spinal cord stimulation does not reduce painful sensory symptoms, decrease sensitivity, improve pain thresholds or reduce hyperalgesia. Although pain thresholds for pressure, warmth and cold increased in all patients, the changes were not significantly different for patients receiving spinal cord stimulation. Mechanical hyperalgesia was the only sensory characteristic that remained reduced at 12 months, although the reduction was slight and not statistically significant.

One medium quality randomised controlled trial (North, 1994) reports ambiguous interim results of a comparison of the effectiveness of spinal cord stimulation with re-operation in patients with persistent radicular pain after lumbosacral surgery. The fourth medium quality trial is a technical report comparing two methods of determining the appropriate level of stimulation required for effective pain control (North, 2003).

The five observational studies varied considerably in their emphasis, outcomes and quality. Two concluded that spinal cord stimulation provides pain relief in a portion of patients with a variety of conditions (Devulder, 1997; Burchiel, 1996). Of particular note is a large reasonable quality case series by Kumar, 1998, that found that after an average of 5.6 years, 47% of 111 patients experienced 50% or greater pain relief with spinal cord stimulation, although there was variability of response with different pain syndromes. Another more recent medium quality study by Chandler, 2003, found that analgesia improved in 67% of 21 patients receiving spinal cord stimulation for management of lumbar spinal stenosis after failure of conservative care. Chandler concludes that spinal cord stimulation warrants further investigation. The fifth good quality study concluded that somatosensory evoked potentials predict outcomes of spinal cord stimulation in patients (Sindow, 1993).

Adverse Events and Complications

Adverse effects and complications were reported in one of the guidelines (Manchikanti), both health technology assessments, two of the systematic reviews (Turner, Stocks), two of the Experimental studies (Kemler 2004 and North 2003) and one of the observational studies (Burchiel) described above. Six poor quality studies (Carter, 2004; Kumar, 2003; van Buyten, 2001; Lang, 1997; van de Kelft, 1994; North, 1993; de la Porte, 1983; Siegfried, 1982; Kainnick, 1980) and eight additional studies (Aldrete, 1994; Barolat, 1993; Eisenberg, 1997; Ferrante, 2004; Long, 1981; Sanchez-Ledesma, 1989; Vogel, 1986; Zdanowicz, 1999) provided additional information on safety and harm of spinal cord stimulation.

Complications were generally described as frequent but minor. Additional surgeries were frequently required. Complication rates ranged from 20-75% in patients with chronic low back pain and failed back surgery syndrome (Stocks). Kemler 2004 reported complications in 38% of patients, with the frequency of complications decreasing after the first year, and side effects in all patients. Mechanical complications include lead migration or breakage, over- or under- or intermittent stimulation, hardware malfunction, loose connections, electrical short out, failure of electrode lead, and battery failure. Other adverse events include infection (subcutaneous, wound and epidural abscess), seroma, haematoma and epidural haemorrhage, pain over the implant site, allergic reaction, paralysis, central spinal fluid (CSF) leakage or fistula, skin erosion, fibrosis at electrode points, urinary hesitancy, muscle spasm, radicular muscle twitches, and failure of pain relief.

There are also individual case reports of spinal cord stimulator activation by an antitheft device (Eisenberg), conversion disorder mimicking Dejerine-Roussy syndrome (thalamic stroke) (Ferrante), paraplegia (Aldrete) and induction of a schizophreniform disorder (Zdanowicz).

Tends to be used as a last resort and trial stimulation is required first.

5. Other Factors

Indicate here any other factors that you took into account when assessing the evidence base.

ACC’s current purchasing option is on a case by case basis in those centres (Auckland and Christchurch) where protocols are currently in place and which collect procedural data that is available to guide ACC in future purchasing decisions.

Replacement of existing devices for which ACC has liability is funded without delay.

6. Evidence Statement

Please summarise the development group’s synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level which applies.

<table>
<thead>
<tr>
<th>Weight and consistency of evidence*</th>
<th>Evidence Level**</th>
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</thead>
</table>
**Initial Statements**

There is insufficient evidence of effectiveness of spinal cord stimulation for the treatment of pain in failed back surgery syndrome.

There is insufficient evidence of effectiveness of spinal cord stimulation for the treatment of chronic neuropathic pain following traumatic spinal cord injury.

There is limited evidence of the effectiveness of spinal cord stimulation for pain relief without improvement in function in the treatment of complex regional pain syndrome type I.

Updated May 05

There is conflicting evidence about the effectiveness of spinal cord stimulation for the treatment of adults with pain due to failed back surgery syndrome or chronic neuropathic pain following traumatic spinal cord injury.

There is medium quality evidence about the effectiveness of spinal cord stimulation in the treatment of adults with complex regional pain syndrome type I.

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**Recommendation**

What recommendation(s) does the guideline development group draw from this evidence? Please indicate the grade of recommendation(s) and any dissenting opinion within the group.

<table>
<thead>
<tr>
<th>Initial Statements</th>
<th>Grade of Recommendation***</th>
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<tbody>
<tr>
<td>We recommend that spinal cord stimulation should not be used for the treatment of failed back surgery syndrome.</td>
<td>C</td>
</tr>
<tr>
<td>We recommend that spinal cord stimulation not be used for the treatment of chronic neuropathic pain following traumatic spinal cord injury.</td>
<td>C</td>
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<tr>
<td>Spinal cord stimulation may be indicated in highly selected patients with complex regional pain syndrome type I.</td>
<td>B</td>
</tr>
<tr>
<td>Updated May 05 We do not recommend spinal cord stimulation for the treatment of adults with pain due to failed back surgery syndrome or chronic neuropathic pain following traumatic spinal cord injury.</td>
<td>C</td>
</tr>
<tr>
<td>We recommend spinal cord stimulation should be used in highly selected patients with complex regional pain syndrome type I.</td>
<td>B</td>
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**Good practice point**

**Initial Statement**

Spinal cord stimulation should be carried out in the multimodal setting where adequate assessment and long term follow up are carried out, preferably in the research setting.

**Update May 05**

Spinal cord stimulation may be indicated in adults with complex regional pain syndrome type I following a positive response to test stimulation. It should be carried out in a multi-disciplinary (medical, functional and psychosocial) pain clinic setting where adequate assessment and long term follow up are carried out.

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*Weight and Consistency of Evidence:

+ good

~ moderate

- poor

**Evidence level:

+ strong studies where all or most of the validity criteria are met

~ studies where not all of the criteria are met but the results of the study are not likely to be affected

- weak studies where very few of the validity criteria are met and there is a high risk of bias

***Grade of recommendation:
Considered Judgement Form: Neuromodulation-Spinal Cord Stimulation

A = The recommendation (course of action) is supported by good evidence
The evidence consists of results from studies of strong design for answering the question addressed

B = The recommendation (course of action) is supported by fair evidence
The evidence consists of results from studies of strong design for answering the question addressed but there is some uncertainty attached to the conclusion either because of inconsistencies among the results from the studies or because of minor flaws; or the evidence consists of results from weaker study designs for the question addressed but the results have been confirmed in separate studies are reasonably consistent. There is fair evidence that the benefits of the course of action being proposed outweigh the harms.

C = The recommendation (course of action) is supported by expert opinion only
For some outcomes, trials or studies cannot be or have not been performed and practice is informed by only expert opinion

I = No recommendation can be made because the evidence is insufficient
Evidence for a course of action is lacking, of poor quality or conflicting and the balance of benefits and harms cannot be determined.