



Contents lists available at ScienceDirect

## Journal of Clinical Neuroscience

journal homepage: [www.elsevier.com/locate/jocn](http://www.elsevier.com/locate/jocn)

## Review

## Recommendations for patient selection in spinal cord stimulation

L. Atkinson<sup>a,\*</sup>, S.R. Sundaraj<sup>b</sup>, C. Brooker<sup>c</sup>, J. O'Callaghan<sup>d</sup>, P. Teddy<sup>e</sup>, J. Salmon<sup>f</sup>, T. Semple<sup>g</sup>, P.M. Majedi<sup>h</sup><sup>a</sup> Department of Neurosurgery, 2nd Floor, Princess Alexandra Hospital, 201 Wickham Terrace, Brisbane, Queensland 4102, Australia<sup>b</sup> Nepean Hospital, Penrith, New South Wales, Australia<sup>c</sup> Royal North Shore Hospital, St Leonards, New South Wales, Australia<sup>d</sup> Axxon Pain Medicine, Brisbane, Queensland, Australia<sup>e</sup> Royal Melbourne Hospital, Parkville, Victoria, Australia<sup>f</sup> Bethesda Hospital, Claremont, Western Australia, Australia<sup>g</sup> Royal Adelaide Hospital, North Terrace, South Australia, Australia<sup>h</sup> Sir Charles Gairdner Hospital, Nedlands, Western Australia, Australia

## ARTICLE INFO

## Article history:

Received 23 November 2010

Accepted 22 February 2011

Available online xxxx

## Keywords:

Chronic pain management

Referral

Spinal cord stimulation

## ABSTRACT

Studies have shown that spinal cord stimulation (SCS) can reduce chronic pain by at least 50% over prolonged periods, improve function and quality-of-life, reduce requirements for healthcare resources and enable return to work in appropriately selected patients. However, SCS does not provide pain relief in all patients and is an expensive, labor intensive and invasive procedure with complications and ongoing management that requires specialists with specific skills and judgment. Multidisciplinary selection of appropriate patients for SCS is essential to achieve maximal benefit from the procedure. The aim of the article is to provide a clinical practice guide to the likely effectiveness of SCS in treating various types of chronic pain, as supported by the literature. The article will summarize indications and contraindications for SCS, provide guidance on the selection and timing for referral, and highlight the benefits and complications associated with the procedure.

© 2011 Elsevier Ltd. All rights reserved.

## 1. Introduction

Spinal cord stimulation (SCS) is a widely used technique that delivers electricity via implanted electrodes to treat chronic pain that is unresponsive to other treatments.<sup>1,2</sup> SCS is a sophisticated, reversible therapeutic technique to relieve pain and reduce medication use. Unlike surgical pain relief procedures, it does not ablate pain pathways or change anatomy.<sup>3</sup>

SCS has come a long way in the last 40 years, with more than 14,000 SCS implantations performed worldwide each year for a range of indications.<sup>4</sup> In 1965, Melzac and Wall announced the "gate theory", proposing that activating large, myelinated afferent nerve fibers would inhibit transmission in small, unmyelinated primary afferent nerves in the dorsal horn of the spinal cord.<sup>5</sup> In 1967, Shealy and colleagues were the first to test this theory, experimenting with surgically implanted electrodes to stimulate the dorsal columns for the treatment of chronic, intractable pain.<sup>6</sup> It became clear that SCS activates dorsal horn neurons and spinal roots as well as dorsal columns, thus the name SCS was coined. Current research suggests that SCS may actually inhibit transmission in the spinothalamic tract through activation of central inhib-

itory mechanisms that influence sympathetic afferent neurons and through the release of various inhibitory neurotransmitters.<sup>7–9</sup>

Today, the technique of SCS can be minimally invasive, with electrodes placed percutaneously under local anesthesia during a day surgery procedure.

This SCS clinical practice guide was developed by the Australasian Neurostimulation Working Group. The aim of the article is to provide information and guidance to clinicians on the appropriate referral of patients for SCS by indicating the likely effectiveness of SCS as supported by the literature. It is not intended as a review of the technique of neurostimulation; however, it will cover the benefits and complications associated with SCS as well as selection of patients and timing of referral.

## 2. Chronic pain

Chronic pain affects over 15% of the Australian population (about one in every six Australians).<sup>10</sup> Defined as pain persisting beyond a period of normal tissue healing, and/or experienced every day for 3 months or more, chronic pain can have a profound impact not only on the individual who is suffering pain, but also on their family and society in general.<sup>10</sup> Chronic pain may be ongoing or intermittent, and is always accompanied by physiological and psychological changes including sleep disturbance, frequent medication dependence, and emotional changes such as irritability,

\* Corresponding author. Tel.: +61 7 3839 3393.

E-mail address: [leighatkinson@optusnet.com.au](mailto:leighatkinson@optusnet.com.au) (L. Atkinson).

withdrawal and depression.<sup>2</sup> It has a substantial economic impact, much of which is borne by the individual, with an estimated total cost in 2007 of A\$34.3 billion per annum (\$10,847 per person).<sup>10</sup> The pathology of chronic pain may not always be well defined and therefore treatment outcomes may be unpredictable.

The aims of chronic pain management are to control pain to a tolerable level (it is rarely possible to eliminate pain), to enhance physical, psychological and social function, and to improve quality-of-life.<sup>2</sup>

Chronic pain has been typically categorized into nociceptive (pain arising from mechanical, chemical or thermal irritation via peripheral sensory nerves) and/or neuropathic (pain caused by a lesion or disease of the somatosensory nervous system), and their management approach differs.<sup>11</sup>

Neuropathic pain is caused by a primary lesion or dysfunction of the peripheral or central nervous systems. The pain is often described as burning, shooting or tingling and is often associated with allodynia. Pharmacotherapy of this type of pain is difficult as there is a lack of efficacy of conventional opioid analgesics.<sup>12</sup>

Nociceptive pain is due to tissue damage that results in somatic or visceral stimuli being sensed by peripheral nociceptors and transmitted by functional afferent sensory pathways. Nociceptive pain is often localized and described as aching, cramping or sharp. Unlike neuropathic pain, nociceptive pain is more responsive to conventional analgesics and has little evidence for effective relief with SCS.<sup>12</sup> Indeed, the question of whether SCS alleviates nociceptive pain, at least to some extent, is still controversial.

There are numerous internationally recognized guidelines for the pharmacological management of chronic pain, and treatment algorithms have been developed for managing neuropathic pain.<sup>1,13–15</sup> Few guidelines or algorithms include non-pharmacological management techniques. Interestingly, a recent American practice guideline makes recommendations for the use of techniques such as ablation, blocks, electrical nerve stimulation, epidural steroids, intrathecal drug therapies, physical or restorative therapy, psychological treatment and acupuncture, as well as pharmacological therapy.<sup>16</sup> SCS is one option for the management of selected patients with certain types of chronic (neuropathic) pain.

The British Pain Society's recommendations for best clinical practice provides a concise guide to the use of SCS in the management of pain, and was used as a basis for consensus within the Australasian Neurostimulation Working Group to produce this guide.<sup>1</sup>

All guidelines on chronic pain management stress the importance of multidisciplinary care for the patient and utilize several different approaches in a planned, long-term treatment program. Patients who do not obtain adequate pain relief and functional restoration from initial management should ideally be referred to multidisciplinary pain clinics (Fig. 1). These clinics provide overall assessments of the medical, psychological and social/environmental characteristics of patients, and develop multidisciplinary management plans that may include further investigations. They also identify goals, optimize medication and provide education/reassurance, physiotherapy, cognitive behavioral therapy or other psychological support, and provide interventions such as nerve blocks.<sup>17</sup> The Australian Pain Society has also developed minimum requirements for pain management services and multidisciplinary pain clinics (Table 1).

### 3. What is spinal cord stimulation?

#### 3.1. Mechanism of pain relief in spinal cord stimulation

The theory behind pain mechanisms and transmission through the nervous system proposed by Melzack and Wall in 1967 has been significantly modified over the years, with increased under-

standing of the molecular changes that occur with neurotransmission.<sup>5</sup> The "gate control" theory proposed that activating large, myelinated afferent fibers of peripheral nerves which carry non-nociceptive, non-painful touch sensations inhibits transmission of nociceptive projections in small, unmyelinated primary afferent nerve fibers (A- $\delta$  and C) in the dorsal horn.<sup>9</sup> Therefore, strategically placed epidural electrodes would stimulate the dorsal columns to inhibit or modulate incoming nociceptive input through the smaller fibers.<sup>9</sup> However, this theory does not fully explain why all types of pain (particularly nociceptive) are not modulated uniformly, with SCS primarily affecting neuropathic and non-nociceptive pain.

It is known that the SCS device stimulates several structures: the dorsal column, lateral funicular and dorsal root fibers. It is believed that both anti- and orthodromic activation modulates pain through spinal and supraspinal circuits.<sup>18</sup> Stimulation of these fibers results in inhibition of pain transmission in the ascending nociceptive pathways and increased activity in descending anti-nociceptive pathways.

Advances in understanding of the mode-of-action since the "gate control" theory have moved towards direct modulation of neurotransmitters themselves. Animal studies suggest SCS promotes the release of an array of neurotransmitters including substance P, serotonin, noradrenalin, glycin and gamma-aminobutyric acid (GABA). Modulating the GABA-B receptor may be associated with a reduction of glutamate and other excitatory amino acids being released, leading to pain modulation.<sup>9</sup> An additional putative mechanism includes modulation of the adenosine-A receptor which has been shown to potentiate SCS in both human and animal studies.<sup>19</sup> SCS may also abolish peripheral ischemic pain by rebalancing the oxygen supply through the alteration of sympathetic tone and possibly stimulating the release of vasodilatory neurotransmitters.<sup>20</sup>

#### 3.2. Components of spinal cord stimulation

Spinal cord stimulator systems are designed to apply low voltage electrical pulses to afferent nerve fibers, usually within the dorsal column. Pulses are delivered via an epidural electrode that is implanted surgically or percutaneously, near the spinal cord. This electrode is connected to and powered by a neurostimulator device, which generates the electrical pulses and is surgically implanted under the skin. Stimulation of the spinal cord modifies patient experience of neuropathic pain; it can replace painful sensations with a paraesthesia (tingling sensation) that may be considered pleasurable. The electrode must be carefully positioned so that the paraesthesia overlaps the area where pain is experienced. The patient can turn the stimulator on or off and may vary the stimulation parameters within physician-set limits as required using a hand-held remote control.

Neurostimulators may be battery-powered (non-rechargeable or rechargeable) implanted pulse generators (IPG), or radio frequency devices that receive energy in the form of radio-wave pulses from an external source.<sup>1,2</sup> Batteries used in IPG devices are now mainly rechargeable (used for patients with high-current use). Selection of the type of device used and the neurostimulator parameters applied are the responsibility of specialist SCS clinical teams, and depend on the type, intensity and location of pain.<sup>1,2</sup>

### 4. Historical use of spinal cord stimulation

SCS has been used in many thousands of patients worldwide, although few randomized clinical trials have been conducted over the full range of different indications. Trials have been performed in failed back surgery syndrome (FBSS) or leg pain despite

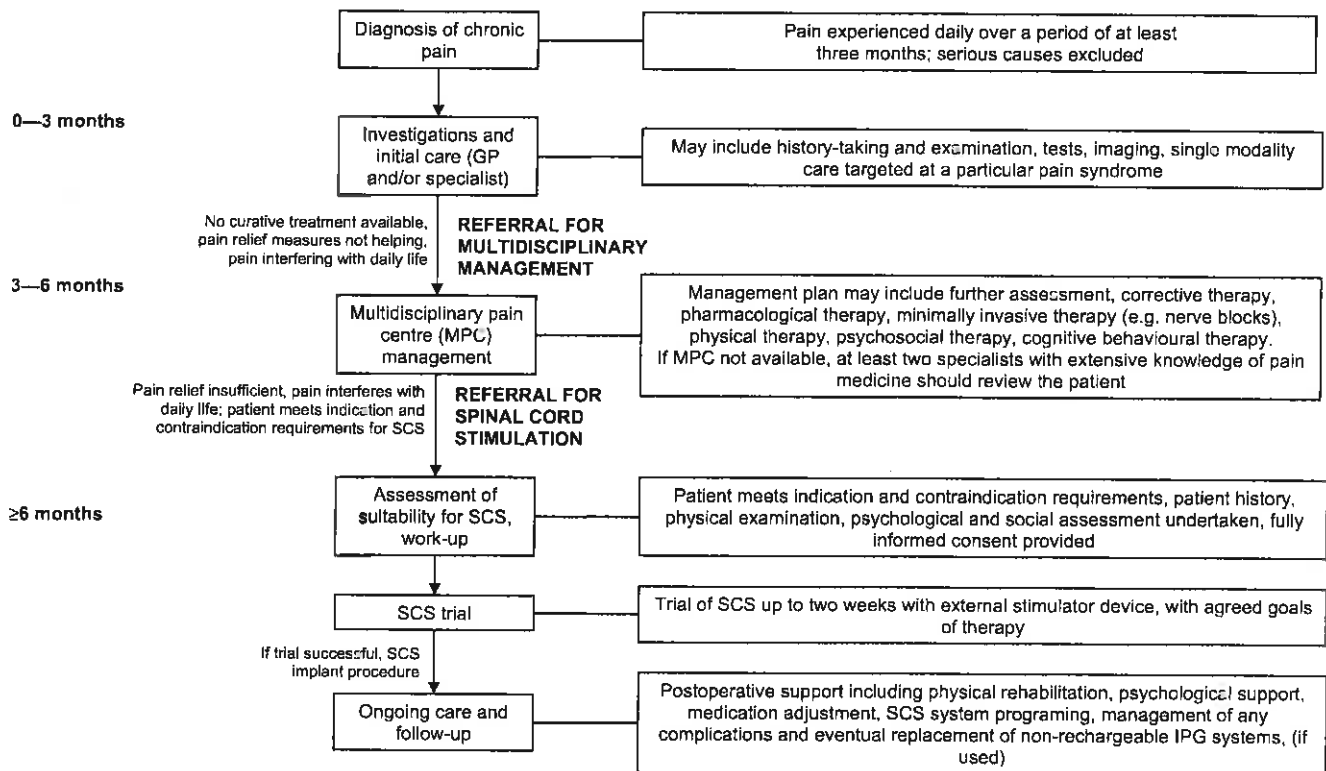


Fig. 1. Algorithm for referral of patients for spinal cord stimulation (SCS). GP = general practitioner, IPG = implanted pulse generator.

anatomically successful lumbar spine surgery, complex regional pain syndrome (CRPS), refractory angina pectoris (RAP) and critical limb ischemia (CLI). Results from these trials are summarized in Table 2. The primary outcome for pain relief is often expressed as the proportion of patients achieving a reduction in pain of at least 50%.

#### 4.1. Failed back surgery syndrome

FBSS is characterized by persistent or recurrent pain, mainly in the lower back and legs, following back surgery. The symptoms range from chronic back pain to radiculopathy, that persists following surgery.<sup>9</sup> FBSS can be diagnosed following an MRI that excludes significant surgical pathology, such as instability (< 5% of patients) or recurrent disc protrusion (7–12% of patients).<sup>21</sup> Between 10% and 40% of patients who have undergone lumbosacral spine surgery to alleviate neuropathic radicular pain instead experience persistent or recurrent pain.<sup>22,23</sup> These patients report diminished health-related quality-of-life and incur high healthcare costs.<sup>23</sup> Conventional medical management including psychological and physical rehabilitation and other non-surgical interventions are often trialled in the first instance and some patients may undergo repeat surgery. However, in selected patients SCS may be an alternative to repeat surgery.<sup>23</sup>

One of the largest randomized clinical trials of SCS, conducted in 100 patients with FBSS, demonstrated that 48% of patients who received SCS achieved a 50% reduction in pain at 6 months, compared with 9% who received conventional medical management ( $p < 0.001$ ).<sup>24</sup> This study also demonstrated improved quality-of-life and functional capacity as well as greater treatment satisfaction for patients. North and colleagues also demonstrated SCS was more effective than reoperation ( $p < 0.01$ ) as a treatment for persistent radicular pain after lumbosacral spinal surgery and negated the need for reoperation ( $p = 0.02$ ).<sup>25</sup> A recent systematic review of the evidence for SCS in FBSS, which included two randomized clin-

Table 1

Multidisciplinary pain clinic and pain management service requirements<sup>13</sup> by the Australian Pain Society

- Designated space and adequate support staff
- Maintain patient records to allow assessment of individual patient outcomes and evaluate overall program effectiveness
- Round-table discussions of individual patients and the services provided
- Staff should include a suitably qualified director/coordinator, together with additional physician and non-physician healthcare providers who are appropriately qualified and able to assess and treat the medical, physical, psychosocial and vocational aspects of a wide variety of patients with painful conditions
  - Physicians may include neurosurgeons, medical specialists, psychiatrists, anesthetists
  - Other healthcare professionals may include registered nurses, occupational therapists, physiotherapists, psychologists, social workers, vocational counsellors

ical trials and nine observational studies, concluded that 60% of selected patients could expect at least a 50% reduction in chronic pain on a long-term basis (level II-1 or II-2 evidence).<sup>26</sup>

#### 4.2. Complex regional pain syndrome

Another historical indication for SCS is CRPS. CRPS is pain in a regional distribution, described as excruciating (aching, prickling or shooting) and often of unclear pathology.<sup>27</sup> CRPS may be divided into types: CRPS type I (reflex sympathetic dystrophy) and CRPS type II (causalgia). Both present with continuing pain, allodynia or hyperalgesia and evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of the pain.<sup>27</sup> CRPS type I often follows an initial event or period of immobilization and CRPS type II follows an identifiable nerve injury.<sup>27</sup> Treatment combines rehabilitation (functional restoration), pain management and psychological therapy.<sup>27</sup>

**Table 2**  
Evidence for spinal cord stimulation (SCS) in different indications from randomized clinical trials. Table adapted from the British Pain Society guidelines<sup>1</sup>

Indication	Evidence	No. patients
Failed back surgery syndrome	Randomized clinical trials comparing SCS with control (medical therapy or repeat surgery) have demonstrated: <ul style="list-style-type: none"> <li>• improved pain relief</li> <li>• reduction in medication use</li> <li>• improved quality-of-life</li> <li>• patient satisfaction</li> </ul>	(n = 50) <sup>25</sup> (n = 42) <sup>53</sup> (n = 100) <sup>54</sup>
Complex regional pain syndrome	A randomized clinical trial comparing SCS plus physical therapy with physical therapy alone demonstrated: <ul style="list-style-type: none"> <li>• improved pain relief</li> <li>• improved quality-of-life</li> </ul>	(n = 52) <sup>28,29</sup>
Critical limb ischemia	Some, but not all, randomized clinical trials comparing SCS with medical care demonstrated: <ul style="list-style-type: none"> <li>• improved pain relief</li> <li>• reduction in amputation</li> <li>• reduction in medication use</li> <li>• clinical improvement</li> </ul>	(n = 38) <sup>39</sup> (n = 86) <sup>40</sup> (n = 51) <sup>41</sup> (n = 37) <sup>42</sup> (n = 120) <sup>43</sup> (n = 112) <sup>55</sup>
Refractory angina pectoris	Some, but not all, randomized clinical trials comparing SCS on with SCS off or no SCS demonstrated: <ul style="list-style-type: none"> <li>• improved exercise capacity</li> <li>• improved quality-of-life</li> <li>• reduction in anti-anginal drugs</li> <li>• reduction in anginal attacks</li> <li>• improved CCS angina class<sup>*</sup></li> </ul>	(n = 22) <sup>56</sup> (n = 25) <sup>57</sup> (n = 10) <sup>58</sup> (n = 12) <sup>35</sup> (n = 68) <sup>59,*</sup> (n = 11) <sup>60</sup>

\* SCS versus percutaneous laser myocardial reperfusion. CCS = Canadian Cardiovascular Society.

SCS has been used in patients refractory to minimally invasive pain management techniques.<sup>27</sup> A randomized study carried out in patients with CRPS demonstrated pain relief and an improvement in health-related quality-of-life with SCS plus physical therapy compared with physical therapy alone up to 2 years.<sup>28-30</sup> Thirty-six patients with CRPS in the upper or lower limbs for at least 6 months were randomized to receive either SCS plus physical therapy or physical therapy alone and their progress followed for up to 5 years. Pain intensity was assessed on a visual analog scale from 0 cm to 10 cm, with SCS patients reporting a mean reduction of 2.4 cm compared with an increase of 0.2 cm in patients on physical therapy at 6 months ( $p < 0.001$ ).<sup>28</sup> At 2 years, the intent-to-treat population showed reduction in pain intensity ( $p < 0.001$ ), global perceived effect ( $p = 0.001$ ) and improved health-related quality-of-life compared with physical therapy alone.<sup>29</sup> At the 3-year and 5-year follow-up of patients enrolled in this trial it was concluded that, despite diminishing pain-relieving effectiveness over time, most patients were satisfied with their treatment.<sup>30,31</sup> A recent analysis of 36 patients with CRPS examined prognostic factors that predict successful outcome with SCS. Patient age, duration and localization of the disease, intensity of the pain, and the presence of mechanical hypoesthesia did not predict SCS success, but the presence of brush-evoked allodynia predicted a poor outcome in this small trial.<sup>32</sup> Another study of SCS in 32 patients with CRPS demonstrated that catastrophizing thoughts did not predict SCS outcome.<sup>33</sup> In all of these studies the patient numbers are relatively low, thus the authors suggest the efficacy for SCS in CRPS is inconclusive and should be a relative indication for SCS based on potential effectiveness.

#### 4.3. Refractory angina pectoris

Angina pectoris is ischemic chest pain, occurring in patients with coronary heart disease in at least one epicardial artery. RAP is a chronic condition where frequent attacks occur, despite optimal drug

therapy or surgery in those patients not suitable for coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI).<sup>34</sup> These patients often experience frequent hospitalization and limited physical activity in addition to inadequate symptom relief.<sup>34</sup> Thoracic SCS is an option for patients with severe disabling angina that is refractory to conventional forms of treatment.<sup>35</sup>

In Europe, there is clinical support for SCS in RAP, with the European Society of Cardiology considering SCS as a first-line additional treatment in patients with chronic RAP.<sup>34</sup> However, SCS in RAP has not been widely accepted by cardiologists elsewhere in the world. However, there have been few randomized trials with strong clinical evidence. The majority of trials are limited to small subsets and therefore extrapolation of their efficacy is limited. In the smaller trials of RAP (Table 2), the primary outcome is usually exercise capacity or frequency of angina attacks. Results differ between trials, but a recent meta-analysis of seven small, randomized controlled trials (pooled,  $n = 270$ ) determined SCS to be an effective and safe treatment option with similar effectiveness to alternative treatments including CABG and percutaneous myocardial laser revascularization (PMR).<sup>36</sup> Compared to no (or inactive) SCS, there was evidence of some improvement in all outcomes including ischemic burden, decreased use of anti-anginal drugs and a significant improvement in pooled exercise capacity ( $p = 0.03$ ) and health-related quality-of-life ( $p = 0.001$ ).<sup>36</sup> Recently, a larger trial in Europe ( $n = 235$ ) demonstrated the effectiveness of SCS in reducing angina attacks from  $> 7$  to 3-7 attacks per week at 12 months post implant ( $p < 0.0001$ ).<sup>37</sup> While the current literature demonstrates an association with SCS and good outcomes for patients with RAP, larger randomized trials will be required to provide conclusive evidence of the efficacy of SCS for this condition.

#### 4.4. Peripheral ischemic limb pain

CLI is a manifestation of peripheral arterial disease, where patients experience chronic ischemic rest pain or ischemic skin lesions, with symptoms persisting beyond 2 weeks.<sup>38</sup> They often require surgery to improve peripheral circulation, relieve pain and salvage the limb.<sup>38</sup> For inoperable patients, the remaining options are analgesic and vasodilator pharmacotherapy and wound care, culminating in amputation.

Another alternative for patients with inoperable ischemic limb pain may be SCS. Randomized studies conducted in patients with CLI usually report mortality as the primary outcome. Secondary endpoints that improved with SCS compared with best medical care in a few randomized trials include pain relief, analgesic use and ulcer healing.<sup>39-43</sup> As with RAP, the literature on SCS in CLI has been limited and inconclusive. Therefore, the Working Group is reserved about this indication.

### 5. Benefits associated with spinal cord stimulation

SCS is a costly intervention, with expenses including consultation and surgery time, equipment and follow-up. However, for FBSS and other chronic pain conditions treated with SCS, less follow-up care is generally required than treatment with conventional medical management.<sup>44</sup> This can reduce the burden on health resources over time.<sup>44</sup> A recent report by Simpson and colleagues presented cost-benefit profiles for SCS in different indications, calculated using a wide range of mathematical modeling techniques.<sup>45</sup> They concluded that SCS was cost effective compared with alternative pain management techniques for indications where there was good evidence of benefit, such as FBSS and CRPS. Similarly, the multidisciplinary body National Institute of Health and Clinical Evidence has recently reported SCS with rechargeable devices is a cost-effective alternative to conventional medical

management.<sup>23</sup> Additional evidence of comparative efficacy from randomized clinical trials is needed before the cost effectiveness for other indications can be determined.<sup>2,45</sup>

Other beneficial outcomes of SCS include the improvement in overall quality-of-life. For instance, the provision of analgesia on demand at any time makes patients feel more in control and less restricted in their daily activities, including return to work.<sup>3</sup> This can lead to improved morale, treatment satisfaction and improvement in depressive symptoms.<sup>3</sup> Studies have also demonstrated that SCS can reduce the requirement for additional pain medications, thereby avoiding the side effects of, and reliance on, pharmacotherapy.<sup>3</sup> Finally, SCS is a reversible procedure that does not alter neural pathology.<sup>20</sup>

## 6. Complications associated with spinal cord stimulation

As with any interventional procedure, there are complications associated with SCS. A review in 2004 by Turner and colleagues found on average 34% of patients who received a stimulator experienced complications.<sup>9,46</sup> Major complications such as neurological injury may occur as a result of direct trauma, requiring explantation of the device. Direct trauma may occur from the placement of the Tuohy needle, advancement of the introducer wire or SCS lead. This can be minimized by having the patient awake and responsive during the insertion. Bleeding can also occur from trauma to epidural vessels and result in an epidural hematoma, requiring urgent surgical treatment. Similarly, neurological injury may occur as a result of an epidural abscess, mostly requiring explantation of the device.<sup>47</sup> Reported neurological damage relating to epidural electrode placement is a rare but serious complication requiring prompt attention from an experienced SCS team. Minor complications can be more common (Table 3). Their incidence varies among different centers and with different models of SCS devices. The most common complications are electrode migration (11%), lead fracture (6%), infection (5%), hardware malfunction (2.5%), discomfort over the generator implant site (2.5%), rotation of the generator (2.5%) and insulation damage (1%).<sup>47</sup>

Most commonly, electrode migration occurs within the first few days after implantation and is more common in the cervical than in the lumbar region.<sup>9,47</sup> Percutaneous leads have higher rates of migration than surgical leads. Electrode displacement (most commonly axial) manifests as a loss of stimulation and thus of pain control.<sup>47</sup> If stimulation cannot be recaptured, lead revision may be required.

Infection with *Staphylococcus* species is the most commonly reported organism in (48%) patients with SCS implants.<sup>47</sup> The most common site of infection is the generator pocket (54%).<sup>47</sup> In the event of infection, appropriate antibiotic therapy may be initially trialled, but should this fail, the device needs to be removed and replaced later. Superficial infections have been treated successfully with antibiotics alone. Prevention of infection commences with intravenous administration of antibiotics prior to implantation, preparation of the site with a bactericidal agent such as chlorhexidine or povidone iodine, and in the operating theatre, attention to aseptic operating technique.<sup>47</sup>

Dural puncture is reported as very rare (0–0.3%), but may occur during the placement of the SCS leads, depending on the experience of the operator.<sup>47</sup> This may affect lead conductivity and may make assessment of lead placement difficult.<sup>47</sup> The procedure can be rescheduled in a few weeks in patients following resolution of the problem.<sup>47</sup>

## 7. Indications, contraindications and other considerations for spinal cord stimulation

The authors suggest SCS may be considered for the management of certain types of neuropathic or ischemic pain in selected

**Table 3**

Complications and special considerations associated with spinal cord stimulation (SCS). Table adapted from the British Pain Society guidelines<sup>1</sup>

<b>Complications</b>	
<i>Immediate complications include:</i>	
Superficial infection e.g. <i>Staphylococcus aureus</i>	Removal of the implant may be required if antibiotic therapy does not resolve the infection within a short period
Epidural hemorrhage	Rare, but serious complication, requiring prompt exploration and evacuation to avoid neurological sequelae
Epidural abscess	Rare complication within the epidural space
<i>Delayed complications include:</i>	
Lead migration	Lead migration may occur at any time. This causes paraesthesia in areas not associated with pain, and leads to lack of pain relief. Patients should not undertake activities that require excessive twisting or stretching
Lead fracture, system malfunction	Current leads are more resilient than those used in the past
Delayed cerebrospinal fluid leak, meningitis	These are rare complications
<b>Special considerations</b>	
Battery life	SCS systems with non-rechargeable batteries will need to be replaced at some stage. Patients need to be aware that repeat surgery will be required
Security systems	Airport and other security systems may be activated by a stimulator. Patients should carry relevant documentation about the device in case it is required
Diathermy	Short wave diathermy, microwave diathermy and therapeutic ultrasound diathermy are hazardous for patients with an SCS implant. If possible, unipolar diathermy should be avoided
Cardiac pacemaker	Electrical activity from an SCS device may be misinterpreted by a cardiac pacemaker, leading to potentially dangerous pacemaker malfunction. A cardiac pacemaker is a relative contraindication for SCS, but if considered necessary, bipolar rather than unipolar pacemaker sensing should be employed
MRI	The magnetic field may produce SCS lead movement, resulting in loss of effect or neuronal damage, or heating of the implant components, leading to discomfort, tissue damage or software malfunction. The presence of the SCS implant may cause MRI image corruption. The need for MRI studies should be discussed with an experienced neuroradiologist who has full details of the make, model and serial number of the implant and alternative imaging techniques considered. If necessary, the SCS implant may need to be removed to allow MRI

patients, after initial care has failed and pain has persisted for a prolonged period (e.g. more than 6 months).<sup>48,49</sup> Some indications such as FBSS, CRPS and RAP are now more established, whereas others are emerging as knowledge and techniques advance. Indications for SCS, categorized by the authors according to good, intermediate and not indicated, depending on the likelihood of response, are listed in Table 4.

Finally, there are suggested indications for SCS that have little reported evidence of success and are unlikely to work and therefore the use of SCS in these areas is not supported by the authors (Table 4). They include pain associated with spinal cord injury, central pain of non-spinal cord origin, avulsive brachial plexopathy and axial lumbar spinal pain pre-surgery and post-surgery.

Contraindications to SCS include general contraindications to surgery; uncontrolled bleeding disorder (including ongoing

**Table 4**  
Indications for spinal cord stimulation (SCS). Working Group consensus adapted from the British Pain Society guidelines<sup>1</sup>

Good indications for SCS (likely to respond)	Intermediate indications for SCS (may respond)	Not indicated for SCS (rarely respond)
<ul style="list-style-type: none"> <li>Failed back surgery syndrome</li> <li>Refractory angina pectoris</li> <li>Neuropathic pain secondary to peripheral nerve lesion</li> <li>Radicular pain following cervical spine surgery</li> </ul>	<ul style="list-style-type: none"> <li>Pain associated with peripheral vascular disease</li> <li>Intercostal neuralgia, such as post-thoracotomy</li> <li>Other peripheral neuropathic pain syndromes, such as those following trauma, may respond</li> <li>Complex regional pain syndrome</li> </ul>	<ul style="list-style-type: none"> <li>Avulsive brachial plexopathy</li> <li>Nociceptive axial pain following surgery*</li> <li>Central pain of non-spinal cord origin</li> <li>Pain in spinal cord injury</li> <li>Postherpetic neuralgia</li> <li>Phantom pain/post amputation</li> </ul>

\* Except when part of failed back surgery syndrome.

**Table 5**  
Criteria for identifying patients suitable for consideration of spinal cord stimulation (SCS)

- Neurogenic pain pathology is the basis of pain complaint
- Clear diagnosis of neuropathic pain is evident, although accompanying nociceptive pain may be present (e.g. FBSS with neuropathic pain in limb(s), CRPS)
- Patient has a suboptimal response to comprehensive conservative therapy (that is, failed trials of physical and functional therapies, polypharmacy including anticonvulsants, antidepressants and other drugs [such as opioids] due to lack of efficacy or serious side effects)
- No significant unmanaged psychological issues present
- Further corrective surgical intervention not indicated
- No serious drug or chemical substance dependence or abuse
- No surgical contraindication to implantation
- Successful trial screening for duration of up to 2 weeks. Too short a trial may mislead success and too long adds potential complications
- Patient understands and is willing to participate in the therapy
- Implantation centre and hospital staff are educated, familiar and willing to participate as a team
- Spinal neural pathway to painful site distally must be preserved to experience pleasant paraesthesia with SCS

CRPS: complex regional pain syndrome; FBSS: failed back surgery syndrome.

anticoagulant therapy, which is a relative contraindication) and systemic or local sepsis.<sup>1,3</sup>

Cognitive impairment will also preclude SCS if the patient is unable to understand the therapy, unless adequate support from carer and social services is available. The authors extend the list of contraindications to include patients with unresolved psychological disorders such as active psychosis, major untreated mood disorder and somatization disorder. In addition, active or untreated abuse of alcohol, drugs or medication (e.g. opioids) are contraindications for SCS and would require other appropriate management before consideration, as determined in pre-screening by the multidisciplinary management team.<sup>48,50,51</sup> In one study, over 80% of patients treated with SCS required counseling and cognitive behavioral therapy prior to implant.<sup>50</sup>

Relative contraindications that would delay, defer or modify a screening trial for SCS include immune suppression and the presence of a cardiac pacemaker or implanted defibrillator (as the pulse generator may compromise function of these devices).<sup>1</sup> Factors such as active litigation may also temporarily preclude SCS, as unresolved issues of secondary gain or litigation could influence the perception and reporting of pain.<sup>48</sup> In addition, as described by North and colleagues, pregnancy, inconsistency among the pain description, history and physical examination, abnormal or inconsistent pain ratings or occupational risk are relative contraindications for SCS.<sup>3</sup>

Other important considerations prior to patient selection for SCS include the need for MRI. The magnetic field may produce lead migration, or heating of the components. MRI studies should be scheduled prior to electrode insertion if they are required for co-

**Table 6**  
Example of a psychological test battery used for assessing the psychological profile of patients prior to spinal cord stimulation (SCS). Table adapted from Sundaraj et al. (2005)<sup>50</sup>

Beck depression inventory
Depression Anxiety Stress Scales (DASS)
McGill pain questionnaire
Strait trait anxiety inventory
Pain coping strategies questionnaire
Pain locus of control scale
Pain self-efficacy questionnaire
Short Form 36 medical outcomes questionnaire
Personality assessment inventory

morbid conditions. MRI studies post implant would be contraindicated.

Finally, implantation of a SCS device is also contraindicated if a short-term trial of stimulation using an external pulse generator fails to achieve goals of therapy agreed with the patient, such as pain relief, improvement in function and/or reduction in medication use.

## 8. Recommendations for patient selection for spinal cord stimulation

SCS is a very expensive, labor intensive and invasive procedure with complications and long-term issues that require specialists with specific skills and judgment and (often) lifetime management of the patient. As such, some of the greatest barriers to the technology in Australia remain their cost in both the public and private system and the rigid algorithms for qualification under current Worker's Compensation guidelines. For the health system, following a comprehensive, multidisciplinary patient selection process may reduce costs by selecting only the most appropriate patients for implantation. This process would also help to clarify unresolved issues of secondary gain, a limitation for Worker's Compensation cases. It is important that the procedure is applied with a complete understanding of the impact of pain and the impact of the procedure on the patient's life, particularly in the long term. Table 5 highlights which patients may be suitable for consideration for SCS implantation. Patients will require ongoing management, therefore before proceeding, patients for SCS should ideally be selected and assessed by a multidisciplinary team, or if a multidisciplinary team is not available, there should be consultation between at least two specialists with extensive knowledge of pain medicine. An algorithm for the use of SCS in the management of chronic pain is given in Fig. 1.

Age, gender and laterality of pain do not appear to influence SCS success rates, and thus, should not influence the decision to refer patients.<sup>48</sup>

The authors strongly recommend the establishment of a national register to assist the implementation of this integrated, multidisciplinary SCS patient management.

Successful SCS requires careful patient selection, work-up and management, even for patients with good indications. An experienced multidisciplinary pain management team who can deliver a range of pain therapies and provide long-term follow-up after implantation is an important requirement for the provision of SCS. The SCS team should implant and manage sufficient patients to maintain competence.

All patients being considered for SCS should undergo appropriate multidisciplinary assessment of physical, psychological and social functioning on referral for SCS. This may include interview(s) with the patient and their family/carer and psychological testing (an example of a psychological test battery is given in Table 6). Ideally, assessment should be carried out within a multidisciplinary pain centre and include a psychiatrist in the assessment process (Fig. 1).<sup>1,48,52</sup>

The goals of SCS therapy should be discussed with the patient, and may include reduction (not elimination) of pain, improvement of quality-of-life (including improved physical and social functioning), return to work and reduction of medication requirements, such as opioids.

Patient expectations regarding the outcome of SCS should be managed appropriately. Not all patients will benefit from SCS; even in well-selected patients, many may not experience significant benefit. Like most interventions and therapies for chronic pain, SCS will not eliminate pain entirely, and will only help relieve the neuropathic component of mixed pain syndromes.

The SCS implant team should seek and document fully informed consent from referred patients. Patients should be counselled about what outcomes to expect, the procedure itself, follow-up requirements, potential complications (including the local complication rate in the unit where the procedure will be carried out) and ongoing special considerations (Table 3).

## 9. Trial and permanent implantation

One of the benefits of SCS is the ability to test patients before implanting the pulse generator.<sup>18</sup> All patients should undergo a screening trial for up to 2 weeks in an outpatient setting, during which SCS is delivered using an external stimulator device temporarily connected to the implanted leads (Fig. 1). During the trial period, patients keep a pain diary assessing pain relief and other goals. A successful screening trial results in a patient-reported pain relief of at least 50% with appropriate physical activity. Stable or reduced analgesic consumption, improved daily activity function, and sleep, which contribute to improved patient satisfaction, should also be considered. The screening trial provides important information that will influence the choice of lead and stimulator to be implanted, the optimum stimulator configuration and identification of permanent electrode segmental "sweet spot" position.<sup>1,48,50</sup> An unsuccessful screening trial is a contraindication to SCS implantation. In considering the optimal trial duration, the team should consider the relative risk of infection and complications that would theoretically increase with trial duration. The SCS manufacturing company representative is an important team member in the trial process, programming the device during the trial and for long-term follow-up.

## 10. Ongoing patient care and monitoring

After insertion, the stimulator device is adjusted by the treating physician to identify optimal settings (maximal pain/paraesthesia overlap and minimal power requirements). Regular follow-up vis-

its are required in the first year following implant to adjust stimulation parameters, medication and other aspects of the patient's rehabilitation program. Thereafter, annual visits should be scheduled to assess the need for modification of pain management and to monitor the IPG battery life (for non-rechargeable devices). The SCS team should be available at all times in case of problems or complications. If patients move beyond a reasonable travelling distance from the implanting centre, systems must be in place to transfer their care appropriately to other suitable services.

SCS is a long-term therapy, and appropriate infrastructure that allows ongoing follow-up and management should be in place. This may include physical rehabilitation, psychological support (including cognitive behavioral therapy-based pain management psychotherapy), medication adjustment, device reprogramming and future replacement of the IPG (Fig. 1).

## 11. Conclusions

Over the last 40 years, SCS has shown positive outcomes for patients across some indications. As our understanding, technology and techniques advance, it is likely SCS will grow in popularity as an alternative therapy across more indications. In the future, the true place of SCS in the context of multidisciplinary pain management is likely to become clearer in terms clinical and cost effectiveness.

## Acknowledgements

This work was supported by an unrestricted educational grant from Medtronic Australasia Pty Ltd. The manuscript was developed by the Australasian Neurostimulation Working Group. Medtronic Australasia Pty Ltd. had no input into or knowledge of the contents of the manuscript prior to publication.

## References

1. British Pain Society. *Spinal cord stimulation for the management of pain: recommendations or best clinical practice*; April 2009. <www.britishpainsociety.org>.
2. National Institute for Health and Clinical Excellence. *Spinal cord stimulation for chronic pain of neuropathic or ischemic origin*; October 2008. <www.nice.org.uk>.
3. North R, Shipley J, Prager J, et al. Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. *Pain Med* 2007;**8**:S200–75.
4. Meyerson BA, Linderth B. Mode of action of spinal cord stimulation in neuropathic pain. *J Pain Symptom Manage* 2006;**31**:S6–12.
5. Melzack R, Wall PD. Pain mechanisms: a new theory. *Science* 1965;**150**:971–9.
6. Shealy CN, Tasslitz N, Mortimer JT, et al. Electrical inhibition of pain: experimental evaluation. *Anesth Analg* 1967;**46**:299–305.
7. Linderth B, Gazelius B, Franck J, et al. Dorsal column stimulation induces release of serotonin and substance P in the cat dorsal horn. *Neurosurgery* 1992;**31**:289–97.
8. Stiller CO, Cui JG, O'Connor WT, et al. Release of gamma-aminobutyric acid in the dorsal horn and suppression of tactile allodynia by spinal cord stimulation in mononeuropathic rats. *Neurosurgery* 1996;**39**:367–75.
9. Jeon Y, Huh BK. Spinal cord stimulation for chronic pain. *Ann Acad Med Singapore* 2009;**38**:998–1003.
10. Access Economics. *The high price of pain: the economic impact of persistent pain in Australia*; November 2007. <www.access-economics.com.au>.
11. Goucke CR. The management of persistent pain. *Med J Aust* 2003;**178**:444–7.
12. Nicolaidis S. Neurosurgical treatments of intractable pain. *Metabolism* 2010;**59**:S27–31.
13. Australian Pain Society Position Statement. *Evidence-based recommendations for the pharmacological management of neuropathic pain*; June 2008. p. 1–6.
14. O'Connor AB, Dworkin RH. Treatment of neuropathic pain: an overview of recent guidelines. *Am J Med* 2009;**122**:S22–32.
15. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. *Mayo Clin Proc* 2010;**85**:S3–14.
16. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology* 2010;**112**:810–33.
17. Nicholas MK. When to refer to a pain clinic. *Best Pract Res Clin Rheumatol* 2004;**18**:613–29.

18. Raphael JH, Mutagi H, Kapur S. Spinal cord stimulation and its anaesthetic implications. *Contn Ed Anaesth Crit Care Pain* 2009;9:78–81.
19. Meyerson BA, Linderoth B. Mechanisms of spinal cord stimulation in neuropathic pain. *Neurol Res* 2000;22:285–92.
20. Kunnumpurath S, Srinivasagopalan R, Vadivelu N. Spinal cord stimulation: principles of past, present and future practice: a review. *J Clin Monit Comput* 2009;23:333–9.
21. Schofferman J, Reynolds J, Herzog R, et al. Failed back surgery: etiology and diagnostic evaluation. *Spine* 2003;400–3.
22. North RB, Kidd DH, Zahurak M, et al. Spinal cord stimulation for chronic, intractable pain: experience over two decades. *Neurosurgery* 1993;32:384–95.
23. Taylor RS, Ryan J, O'Donnell R, et al. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain* 2010;26:463–9.
24. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179–88.
25. North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery* 2005;56:98–106.
26. Frey ME, Manchikanti L, Benyamin RM, et al. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. *Pain Physician* 2009;12:379–97.
27. Stanton-Hicks M. Complex regional pain syndrome: manifestations and the role of neurostimulation in its management. *J Pain Symptom Manage* 2006;31:S20–4.
28. Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 2000;343:618–24.
29. Kemler MA, de Vet HC, Barendse GA, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Ann Neurol* 2004;55:13–8.
30. Kemler MA, de Vet HC, Barendse GA, et al. Spinal cord stimulation for chronic reflex sympathetic dystrophy—five-year follow-up. *N Engl J Med* 2006;354:2394–6.
31. Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg* 2008;108:292–8.
32. van Eijs F, Smits H, Geurts JW, et al. Brush-evoked allodynia predicts outcome of spinal cord stimulation in complex regional pain syndrome type 1. *Eur J Pain* 2010;14:164–9.
33. Lame IE, Peters ML, Patijn J, et al. Can the outcome of spinal cord stimulation in chronic complex regional pain syndrome type I patients be predicted by catastrophizing thoughts? *Anesth Analg* 2009;109:592–9.
34. Borjesson M, Andrell P, Lundberg D, et al. Spinal cord stimulation in severe angina pectoris—a systematic review based on the Swedish Council on Technology assessment in health care report on long-standing pain. *Pain* 2008;140:501–8.
35. Eddicks S, Maier-Hauff K, Schenk M, et al. Thoracic spinal cord stimulation improves functional status and relieves symptoms in patients with refractory angina pectoris: the first placebo-controlled randomised study. *Heart* 2007;93:585–90.
36. Taylor RS, De Vries J, Buchser E, et al. Spinal cord stimulation in the treatment of refractory angina: systematic review and meta-analysis of randomised controlled trials. *BMC Cardiovasc Disord* 2009;9:13.
37. Andrell P, Yu W, Gersbach P, et al. Long-term effects of spinal cord stimulation on angina symptoms and quality of life in patients with refractory angina pectoris—results from the European Angina Registry Link Study (EARL). *Heart* 2010;96:1132–6.
38. Ubbink DT, Vermeulen H. Spinal cord stimulation for critical leg ischemia: a review of effectiveness and optimal patient selection. *J Pain Symptom Manage* 2006;31:S30–5.
39. Suy R, Cybels J, Van Damme H, et al. Spinal cord stimulation for ischemic rest pain. The Belgian randomized study. In: Horsh S, Claeys L, editors. *Spinal cord stimulation*. Darmstadt: Steinkopff Verlag; 1994. p. 197–202.
40. Claeys LG, Horsch S. Transcutaneous oxygen pressure as predictive parameter for ulcer healing in endstage vascular patients treated with spinal cord stimulation. *Int Angiol* 1996;15:344–9.
41. Jivegard LE, Augustinsson LE, Holm J, et al. Effects of spinal cord stimulation (SCS) in patients with inoperable severe lower limb ischaemia: a prospective randomised controlled study. *Eur J Vasc Endovasc Surg* 1995;9:421–5.
42. Spincemaille GH, Klomp HM, Steyerberg EW, et al. Technical data and complications of spinal cord stimulation: data from a randomized trial on critical limb ischemia. *Stereotact Funct Neurosurg* 2000;74:63–72.
43. Klomp HM, Spincemaille GH, Steyerberg EW, et al. Spinal-cord stimulation in critical limb ischaemia: a randomised trial. ESES Study Group. *Lancet* 1999;353:1040–4.
44. Mekhail NA, Cheng J, Narouze S, et al. Clinical applications of neurostimulation: forty years later. *Pain Pract* 2010;10:103–12.
45. Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess* 2009;13:iii. ix–x. 1–154.
46. Turner JA, Loeser JD, Deyo RA, et al. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004;108:137–47.
47. Woods DM, Hayek SM, Bedder M. Complications of neurostimulation. *Tech Reg Anesth Pain Manage* 2007;11:178–82.
48. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58:481–96.
49. Simpson BA. The role of neurostimulation: the neurosurgical perspective. *J Pain Symptom Manage* 2006;31:S3–5.
50. Sundaraj SR, Johnstone C, Noore F, et al. Spinal cord stimulation: a seven-year audit. *J Clin Neurosci* 2005;12:264–70.
51. Olson KA, Bedder MD, Anderson VC. Psychological variables associated with outcome in spinal cord stimulation trials. *Clin J Pain* 1995;17:155–61.
52. Kim SH, Tasker RR, Oh MY. Spinal cord stimulation for nonspecific limb pain versus neuropathic pain and spontaneous versus evoked pain. *Neurosurgery* 2001;48:1056–64.
53. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery* 2008;63:762–70.
54. Manca A, Kumar K, Taylor RS, et al. Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *Eur J Pain* 2008;12:1047–58.
55. Amann W, Berg P, Gersbach P, et al. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). *Eur J Vasc Endovasc Surg* 2003;26:280–6.
56. de Jongste MJ, Hautvast RW, Hillege HL, et al. Efficacy of spinal cord stimulation as adjuvant therapy for intractable angina pectoris: a prospective, randomized clinical study. Working Group on Neurocardiology. *J Am Coll Cardiol* 1994;23:1592–7.
57. Hautvast RW, DeJongste MJ, Staal MJ, et al. Spinal cord stimulation in chronic intractable angina pectoris: a randomized, controlled efficacy study. *Am Heart J* 1998;136:1114–20.
58. Lanza GA, Sestito A, Sgueglia GA, et al. Effect of spinal cord stimulation on spontaneous and stress-induced angina and 'ischemia-like' ST-segment depression in patients with cardiac syndrome X. *Eur Heart J* 2005;26:983–9.
59. McNab D, Khan SN, Sharples LD, et al. An open label, single-centre, randomized trial of spinal cord stimulation vs. percutaneous myocardial laser revascularization in patients with refractory angina pectoris: the SPiRiT trial. *Eur Heart J* 2006;27:1048–53.
60. Chua R, Keogh A. Spinal cord stimulation significantly improves refractory angina pectoris—a local experience spinal cord stimulation in refractory angina. *Heart Lung Circ* 2005;14:3–7.