



## **The British Pain Society's**

# Spinal cord stimulation for the management of pain: recommendations for best clinical practice

*A consensus document prepared on behalf of the British Pain Society in consultation with the Society of British Neurological Surgeons*

### **April 2009**

The Chair of the publication working group has considered the review of this publication and as no new evidence is currently available the guidelines still stand. The publication will next be reviewed in late 2013.

Published by  
The British Pain Society  
3rd floor  
Churchill House  
35 Red Lion Square  
London WC1R 4SG

[www.britishpainsociety.org](http://www.britishpainsociety.org)

ISBN: 0-9546703-7-X

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# Introduction

Spinal Cord Stimulation (SCS) is a theoretically principled treatment with a substantial and supportive evidence base that has been used for the treatment of pain since 1967. It is strategically aimed to reduce the unpleasant sensory experience of pain and the consequent functional and behavioural effects that pain may have. For certain painful conditions, SCS has a physiological effect on the pathophysiology, eg, ischaemic conditions. When SCS is used to treat patients with chronic pain, it is important that the treatment is delivered within the context of a full understanding of the impact that pain has upon the patient and of the extent that pain interferes with his or her life and affects psychological well-being and social functions. Treatment with SCS should therefore normally be delivered within facilities that can offer comprehensive assessments and a range of additional physical and psychological pain management options.

These recommendations give guidance to practitioners delivering this treatment, to those who may wish to refer patients for SCS, and to those who care for patients with stimulators in situ, eg, primary care teams. The recommendations also provide a resource for organisations that fund SCS.

These recommendations are accompanied by information for patients to help them and their caregivers understand SCS and to support treatment choices.

## **Methods**

These recommendations have been produced by a consensus group of relevant healthcare professionals and patients' representatives. Opinion outside the consensus group has been incorporated by consultation with representatives of all groups for whom these recommendations have relevance. The recommendations make reference to the current body of evidence relating to SCS.



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The British Pain Society is also grateful to the Neuromodulation Society of UK and Ireland for its expert contribution to and comments during preparation of this document and for its formal endorsement of it.

## **Competing interests**

Members of the group have registered all competing interests as follows:

Karen Simpson has received research funding and honoraria from medical device and pharmaceutical companies for lectures at conferences, to attend advisory boards, to contribute publications, and to attend meetings to support professional development.

Jon Raphael has received research funding and honoraria from medical device and pharmaceutical companies for lectures at conferences and to attend advisory boards.

Cathy Stannard: no competing interests declared.

Rod Taylor is a consultant to Medtronic International. He has received personal payment as an advisor, as a speaker, and as a trial investigator.

Paul Eldridge has received research funding and payment for participation on an advisory board for Medtronic International.

Jon Valentine has received honoraria for lectures on behalf of Boston Scientific.

Beverly Collett: no competing interests declared.

Alf Collins: no competing interests declared.

Diana Dickson: no competing interests declared.

Stephen Morley : no competing interests declared.

Karen Sanderson has received honoraria for lectures and advisory board meetings from medical device companies.

Brian Simpson: no competing interests declared.





# Contents

		Page
1	Executive summary	11
2	Need for recommendations	13
3	Scientific rationale	15
4	Evidence	17
5	SCS: appropriate context for delivery	19
6	Patient selection	21
7	Timing	25
8	Techniques of stimulation	27
9	The procedure	29
10	Special precautions	33
11	Complications of SCS	35
12	Patient information	37
13	Audit	39
Appendix 1:	Spinal Cord Stimulation - Review of literature	41
Appendix 2:	Summary of randomised controlled trials of SCS	49



# 1 Executive summary

- 1.1 Persistent pain is common. Whereas acute pain may only impact by interrupting current activity, episodic and persistent pain is likely to interfere with one or more aspects of a person's life and to affect his or her sense of identity.
- 1.2 There is clinical evidence from randomised controlled trials to support use of SCS in pain from failed back surgical syndrome (FBSS), complex regional pain syndrome (CRPS), neuropathic pain, and ischaemic pain.

The National Institute for Clinical Excellence (NICE) published guidance on SCS for chronic pain of neuropathic or ischaemic origin in 2008 (ref – TA 159) in which it was recommended for severe, prolonged pain responsive to a trial of stimulation in FBSS, CRPS, and neuropathic pain; however, they concluded that there was insufficient evidence of cost effectiveness to recommend its use outside of controlled trials in ischaemic pain. The British Pain Society (BPS) concurs with NICE that further high-quality research on the use of SCS in chronic pain of ischaemic origin is required.

The BPS accepts that there is not high-quality randomised controlled trial evidence to support the use of SCS in chronic pain of ischaemic origin. Nonetheless, the BPS believes that the available evidence (from controlled trials, observational studies, and clinical experience) supports the use of SCS when individuals are carefully assessed by multidisciplinary teams of healthcare professionals experienced in using the technology.

- 1.3 Not all patients are suitable for SCS.
- 1.4 At the time of writing, SCS is not available to all patients who may benefit; however, recent NICE guidance may alter this.
- 1.5 A multidisciplinary pain management team is the most appropriate context in which to provide SCS.
- 1.6 Members of the team must include clinicians competent to deal with the complications of SCS.

- 1.7 SCS may be delivered in parallel with other therapies and should be used as part of an overall rehabilitation strategy.
- 1.8 Techniques of SCS vary. Clinical teams must have and maintain the competencies needed to offer the most appropriate technique according to an individual patient's needs.
- 1.9 Clinicians performing this intervention should insert a sufficient number of SCS systems to maintain competence (see 5.8).
- 1.10 SCS must be performed in an operating theatre environment suitable for implant work with appropriate anaesthesia and post-anaesthesia care facilities. Patients must have comprehensive access to advice if they experience problems with the stimulating system.
- 1.11 The commonest organism to infect SCS systems is *Staphylococcus aureus*. Patients scheduled for SCS should be screened for methicillin-resistant *Staphylococcus aureus* less than four weeks before the procedure to allow rational choice of antibiotic prophylaxis at the time of surgery.
- 1.12 SCS is a long-term treatment for a chronic condition, and appropriate infrastructure for ongoing surveillance and support must be in place.
- 1.13 Implanting centres should audit their SCS activity and provide patients with information on outcomes and complications.
- 1.14 Compatibility of SCS with magnetic resonance imaging (MRI) is problematic. Whilst there have now been small series of cases reported without problems, there remain concerns, and other imaging modalities should be used if at all possible. If MRI is required, the advice of a radiologist should be sought and, depending on imaging site and sequencing, imaging may be possible; however, at present, the majority of radiologists would not advise use of MRI with an SCS in situ. Therefore, if MRI is needed, it may be necessary to remove the SCS system.
- 1.15 Professional communication between implanting centres should be encouraged.

## 2 Need for recommendations

- 2.1 Persisting pain occurs in up to one-half of the adult population at some time in their lives. One in ten of these adults with persisting pain would describe themselves as being severely disabled by pain. Most patients with chronic pain can be managed in primary care, but some patients need specialised multidisciplinary assessment and management.
- 2.2 Patients who are referred to a pain service have frequently seen a number of other secondary care specialists and have usually been extensively investigated.
- 2.3 Multidisciplinary pain services should offer a range of evidence-based interventions to patients with persisting pain. It is rarely possible to provide complete pain relief. Patients should also be offered advice on self-management and coping strategies, in tandem with any interventions.
- 2.4 Persisting pain is difficult to treat, and some patients will continue to experience intrusive and distressing symptoms following a variety of interventions.
- 2.5 SCS may be helpful in carefully selected patients. Some patients will not be helped by SCS.
- 2.6 At the time of writing, SCS is not available to all patients who may benefit; however, recent NICE guidance may alter this.
- 2.7 Some indications for SCS are well-established (eg, FBSS, CRPS, neuropathic pain, refractory angina [RAP], peripheral vascular disease), and others are emerging (eg, visceral pain, interstitial cystitis). As knowledge and expertise develop, the techniques change and may be refined. Whilst there is a need to allow development, there is also a requirement for consistency in approach so that meaningful data can be collected.
- 2.8 The recommendations will:

Guide **healthcare professionals** regarding

- whom to refer
- whom not to refer
- what to tell patients
- how to look after patients in the community who have had SCS implanted
- how to deal with complications after SCS implantation that may occur in primary care

Promote **best clinical practice** for clinical teams involved in providing SCS to

- select patients appropriately
- prepare patients for the therapy
- deliver SCS safely with minimal morbidity
- optimise outcomes
- provide appropriate continuing care

Allow **patients** to make an informed decision.

Inform **commissioners** of healthcare services.

Facilitate data collection, audit, and research.

Create an environment in which advances in SCS are encouraged and supported.

## 3 Scientific rationale

- 3.1 The use of stimulation techniques in modern pain medicine dates from the publication of the gate theory of Melzack and Wall in 1965, which described how stimulation of neural pathways carrying innocuous (non-painful) information could influence the onward transmission of noxious information in the nervous system.
- 3.2 Although the introduction of SCS was inspired by the gate theory, its mechanism of action involves more than a direct inhibition of pain transmission in the dorsal horn of the spinal cord. If this were the principal mode of action, then SCS would control nociceptive pain, and this is not generally the case. Pain modulation by SCS also involves supra spinal activity via the posterior columns of the spinal cord, probably recruiting endogenous inhibitory pathways. Our understanding of the neurotransmitter systems involved, eg, gamma-aminobutyric acid (GABA) and adenosine, is increasing steadily. There is also a pronounced autonomic effect; the mechanisms of this are not fully understood.
- 3.3 The preservation of topographically appropriate posterior column function seems to be necessary for SCS to be effective, but there is debate regarding which elements are necessary and to what degree.





## 4 Evidence

- 4.1 Randomised controlled trials (RCTs) of SCS have been undertaken for failed back surgery syndrome (FBSS), complex regional pain syndrome Type 1 (CRPS 1), refractory angina pectoris (RAP), and chronic critical limb ischaemia (CLI). A summary of these RCTs and their findings is listed in Appendix 2. There are systematic reviews of SCS that, in addition to RCT evidence, have included case series and observational comparisons, particularly for FBSS and CRPS (see Appendix 2).
- RCTs demonstrate that SCS is more effective for radicular (limb) pain following spinal surgery than either reoperation or management by nonsurgical therapy.
  - SCS produces analgesia in patients with CLI. There is RCT evidence that SCS may be limb-salvaging in a subgroup of patients with CLI whose transcutaneous oxygen concentrations are in the midrange.
  - There is RCT evidence that SCS offers similar outcomes to coronary artery bypass grafting (CABG) and percutaneous myocardial laser revascularisation (PMR) for patients with RAP. There is some preliminary evidence about SCS for syndrome X; more detailed work is needed.
- 4.2 NICE published guidance on SCS for chronic pain of neuropathic or ischaemic origin in 2008 (ref – TA 159). With provisos regarding the severity and duration of pain and a trial of stimulation after multidisciplinary assessment, SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin. This recommendation was based on RCT data and robust cost-effectiveness analyses for trials in FBSS and CRPS. The recommendation was extended to include all causes of chronic pain of neuropathic origin on the advice of nominated specialists. SCS is not, however, recommended for chronic pain of ischaemic origin except in the context of research as part of a clinical trial.
- 4.3 NICE felt unable to recommend SCS for chronic pain of ischaemic origin for a combination of two reasons: lack of high-quality RCT data and insufficient data to support robust economic modelling. Consideration was given to functional outcomes as well as improvements in pain.

- 4.4 In the case of CLI, NICE acknowledged that non randomised evidence suggests there may be functional benefit for certain subgroups of people. The evidence for improvement in health related quality of life was not robust, and it was not possible to perform a cost-effectiveness analysis.
- 4.5 With regard to RAP, NICE assessed that the available data did not allow accurate identification of the population to be treated, or the available comparator treatments. The committee accepted that SCS was as effective as comparator treatments in the included studies. Again, no cost-effectiveness analysis was possible.
- 4.6 The BPS concurs with NICE that further high-quality research on the use of SCS in chronic pain of ischaemic origin is required.
- 4.7 The BPS accepts that there is not high-quality RCT evidence to support the use of SCS in chronic pain of ischaemic origin. Nonetheless, the BPS believes that the available evidence (from controlled trials, observational studies and clinical experience) supports the use of SCS when individuals are carefully assessed by multidisciplinary teams of healthcare professionals experienced in using the technology.

## 5 SCS: appropriate context for delivery

- 5.1 Pain interferes with physical function and is often associated with psychological problems. All patients being considered for SCS must be assessed with regard to physical, psychological, and social functioning.
- 5.2 An important approach to the treatment of pain is to attempt to modulate the unpleasant sensory experience by reducing the intensity, duration, and frequency with which pain is felt. Medication, nerve blocks, physical therapies, and SCS are all strategies used to achieve this outcome.
- 5.3 Psychological interventions – mainly cognitive-behavioural therapy – are largely focused at mitigating the interference in function that persistent pain induces. Such treatments may be offered in conjunction with SCS.
- 5.4 Qualitative psychological testing does not predict outcome, but assessment by a psychologist is desirable to assess the patient's beliefs, expectations, and understanding of the treatment in relation to the condition. It is also an important opportunity to discuss pain management strategies, including activity pacing, both before and after the procedure.
- 5.5 A multidisciplinary pain management team is the most appropriate context in which to provide SCS. Such a team should be able to deliver a range of therapies for pain.
- 5.6 The team will usually comprise several professionals. Members may include a consultant in pain medicine and one or more consultants from other relevant specialties, eg, neurosurgery, spinal surgery, cardiology, or vascular surgery. Other members of the team might include psychologists, physiotherapists, and nurse specialists in pain management. The team must have access to a spinal surgeon or neurosurgeon competent to deal with the complications of SCS.
- 5.7 Clinicians performing the SCS interventions must understand the multidisciplinary management of pain. They must have and maintain relevant surgical competence in insertion of the SCS system and management of complications such as infection. This will usually be a consultant in pain medicine, neurosurgeon, or spinal surgeon.

- 5.8 The competence of the implanter and the activity and competence of the team must be maintained. An average caseload of 10 electrode system insertions per year (averaged over 3 years) may satisfy this requirement. It is recognised that there are circumstances when less frequent insertion of implants may be compatible with competence; for example, an experienced implanter working regularly in the context of an active multi disciplinary pain team. Where a new service is being established there, should be evidence of progression toward an annual caseload that will maintain competence, or there should be the opportunity to regularly work within other units that have a high level of activity. It is important to maintain networks of clinicians involved in neuromodulation therapy.
- 5.9 SCS is a long-term therapy. Teams must have appropriate arrangements for ongoing care of patients including availability for investigation and management of potentially serious problems such as neurological deficit, bleeding, or infection. Practitioners must make appropriate arrangements for cover during their absence and for ongoing care of their patients. SCS is a significant commitment for patients and their healthcare team, and it is not usually appropriate for a single consultant to manage this therapy without the support of colleagues.

## 6 Patient selection

- 6.1 Patients must have an up-to-date assessment in relation to the indication for SCS.
- 6.2 History and physical examination should be detailed, and include, in relevant cases, an assessment of posterior column function.
- 6.3 The indications for SCS are summarised in Table 1.

Good indications for SCS (likely to respond)	Neuropathic pain in leg or arm following lumbar or cervical spine surgery (FBSS/FNSS)
	Complex regional pain syndrome (CRPS)
	Neuropathic pain secondary to peripheral nerve damage
	Pain associated with peripheral vascular disease
	Refractory angina pectoris (RAP)
	Brachial plexopathy: traumatic (partial, not avulsion), post-irradiation
Intermediate indications for SCS (may respond)	Amputation pain (stump pain responds better than phantom pain)
	Axial pain following spinal surgery
	Intercostal neuralgia, such as post-thoracotomy or post-herpetic neuralgia
	Pain associated with spinal cord damage
	(other peripheral neuropathic pain syndromes, such as those following trauma may respond)
Poor indications for SCS (rarely respond)	Central pain of non-spinal cord origin
	Spinal cord injury with clinically complete loss of posterior column function
	Perineal or anorectal pain
Unresponsive to SCS	Complete spinal cord transection
	Non-ischaeamic nociceptive pain
	Nerve root avulsion

- 6.4 The use of SCS for other conditions such as pelvic and visceral pain has been described. Its use in this and other emerging indications should be carefully audited.
- 6.5 Contraindications to the use of SCS are summarised in Table 2.

**Table 2 Medical contraindications to the use of SCS**

Uncontrolled bleeding disorder. Ongoing anticoagulant therapy is a relative contraindication.
Systemic or local sepsis
Presence of a demand pacemaker or implanted defibrillator (relative contraindication)
Immune suppression (relative contraindication)

- 6.6 There are specific considerations regarding surgical insertion of plate electrodes. These are summarised in Table 3.

**Table 3 Surgical insertion of electrodes: Special considerations**

General contraindications to surgery should apply such as coagulopathy or sepsis.
Surgical electrode systems are larger than percutaneous systems; special note must be taken of the possibility of spinal canal stenosis if the electrodes are to be inserted beneath intact/residual laminae, to avoid the risk of cord compression. Pre-operative MRI of the target area of the spine should be considered (if not already performed).
Extensive laminectomy (particularly in the cervical spine) has potential morbidity. The appropriateness of further laminectomy to insert electrodes must be considered carefully when patients have previously undergone extensive laminectomy in or adjacent to the target area.
Open insertion of an electrode permits fixation of the electrode to the dura; if this option is taken, then sutures should pass through only the outer layer of dura to avoid the development of a cerebrospinal fluid (CSF) hygroma.
Approximately 5% of people undergoing thoracic laminectomy may experience postoperative thoracic backache persisting for weeks or months. Patients should be warned of this possibility.

- 6.7 Many patients, such as those with pain following spinal surgery, will present a mixed neuropathic/nociceptive picture. Patients should be told that SCS will probably only help part of their pain. Teams offering SCS must be able to deliver appropriate additional therapies including pain management programmes.
- 6.8 Physical and psychological co-morbidity does not preclude treatment with SCS. Patients with concurrent physical or mental illness should be assessed in close conjunction with relevant clinical teams. Cognitive impairment, communication problems, or learning difficulty resulting in failure to understand the therapy is not a reason to exclude patients from SCS, but these patients must have a cognisant caregiver and adequate social support.

- 6.9 The management of children being considered for SCS should be in conjunction with a specialised multidisciplinary children's pain management team.





## 7 Timing

- 7.1 SCS may be delivered in conjunction with other therapies such as medication and psychologically based therapies. If there is significant psychological distress identified at assessment, such patients may benefit from individual psychological therapy (eg, CBT) before proceeding to SCS. For those patients who may also benefit from a pain management programme, it is preferable to provide that treatment before SCS.
- 7.2 SCS should be considered early in the patient's management when simple first-line therapies have failed. SCS should not necessarily be considered a treatment of last resort.
- 7.3 For patients with RAP, the European Society of Cardiology recommends that:
- an interventional cardiologist with experience in managing patients with refractory angina should review the patient.
  - there should be documented evidence of reversible myocardial ischaemia.
  - SCS should be considered only if the patient continues to suffer from disabling angina pectoris despite cognitive behavioural intervention and the use of transcutaneous electrical nerve stimulation (TENS)



## 8 Techniques of stimulation

- 8.1 Stimulation of the spinal cord is by an implanted electrode powered by an implanted pulse generator (IPG). Electrodes may be inserted percutaneously via an epidural needle or surgically implanted via laminotomy. Electrodes may be bipolar or multipolar, and multiple electrodes may be used. Pulse generation is achieved by a fully implantable battery-powered device (similar to a cardiac pacemaker). Rechargeable battery systems may be preferred for some patients such as those with high current use, including those with multiple electrodes.
- 8.2 Clinical teams must have the requisite skills to offer the most appropriate technique according to an individual patient's needs.
- 8.3 Electrodes must be placed to elicit paraesthesia that cover the region of reported pain.
- 8.4 It is recommended that percutaneous electrodes be placed under a local anaesthetic with minimal sedation. This optimises electrode placement and reduces the risk of inadvertent neural trauma.
- 8.5 Surgical electrodes require open surgery (laminotomy or partial laminectomy) for placement. This is usually carried out under a general anaesthetic. Such electrodes are less likely to be dislodged.
- 8.6 It is common practice to connect electrodes temporarily to an external stimulating device before proceeding to insertion of an IPG. This allows the patient to undergo a period of trial stimulation during which time pain relief, improvement in function, and reduction in medication may be assessed. If the outcome of the trial is favourable, then the patient may wish to proceed to IPG insertion.
- 8.7 The same team should carry out trial stimulation and definitive implantation.
- 8.8 Although a period of trial stimulation has considerable intuitive appeal, the predictive value of a period of trial stimulation is uncertain, and it is well-accepted practice to insert electrodes without trial stimulation.

- 8.9 Following IPG insertion, the patient may switch the device on and off with a hand-held programmer and may vary voltage and frequency within physician-determined limits.
- 8.10 IPG battery life is variable, but is usually between 2 and 8 years depending on the pattern of use and the output required. Rechargeable batteries are now available with increased longevity.
- 8.11 Centres offering SCS to patients must ensure that their service is appropriately funded to support ongoing system maintenance, including the inevitable need for IPG replacement in those who do not have a rechargeable system in situ and the possible need for lead or system revision.

## 9 The procedure

### 9.1 Preoperative assessment and preparation

- 9.1.1 Preoperative preparation should be carried out before admission for the procedure.
- 9.1.2 Patients must be investigated appropriately for fitness to undergo surgery and anaesthesia or sedation.
- 9.1.3 The commonest organism to infect SCS systems is *Staphylococcus aureus*. Patients should be screened for the presence of methicillin-resistant *Staphylococcus aureus* (MRSA) before implantation of SCS. Swabs should be taken from the nose, groin, and perineum not more than 1 month before the proposed implantation date; this may be done by the patient's primary care team. Patients who are carriers of MRSA should undergo eradication therapy with antimicrobials as dictated by local infection control guidance.
- 9.1.4 The proposed position of the IPG should be agreed preoperatively between the patient and operator.
- 9.1.5 There is little published evidence regarding the use of antibiotic prophylaxis for SCS. However, infection of an SCS system is a significant problem and, the consequences of infection justify the use of antibiotic prophylaxis. Antibiotics should be given as a single intravenous dose 30 minutes before the procedure.

### 9.2 The theatre environment

- 9.2.1 Standard operating and post-anaesthesia care facilities must be available.
- 9.2.2 The operating theatre must be suitable for implant work.
- 9.2.3 X-ray screening is needed for percutaneous lead placement.

9.2.4 A practitioner skilled in programming and trialling of SCS must be present for the percutaneous procedures. This individual must be familiar with the indication for which SCS is being used, and they should have experience working with patients who have persistent pain.

### 9.3 Post-anaesthesia care and ward management

9.3.1 Programming of the SCS should not usually begin until the patient is fully conscious. It may be preferable that this happens when the patient has returned to the ward, and the acute postoperative pain has settled.

9.3.2 Ward staff should be familiar with the aims and procedure of SCS, the condition that it is used to manage, and the potential complications that may arise.

9.3.3 The postoperative observation regimen should take account of potential complications such as spinal cord compression, neurological injury, bleeding, and infection.

9.3.4 Ward staff should be able to seek advice from a member of the implant team at any time.

### 9.4 Discharge and ongoing care

9.4.1 Adequate arrangements for surveillance and follow-up by the implant team must be made; the patient should be able to contact an appropriate and experienced professional if problems occur.

9.4.2 The primary care team must be given timely and appropriate advice in writing about all patients who are sent home under their care after SCS implant.

9.4.3 The patient will need continuing postoperative support from the implant team regarding appropriately paced physical rehabilitation, psychological support, medication adjustment, and reprogramming of the SCS system.

- 9.4.4 In the event of complications related to the SCS or other pathology, there should be established relationships with other relevant disciplines such as spinal surgery and neurosurgery, microbiology, and neuroradiology.
- 9.4.5 SCS is a long-term treatment for a chronic condition. Patients with non-rechargeable systems will need IPG replacement at some stage. Mechanisms should be in place to predict when this is likely to occur, so that with planning, SCS function can be restored promptly.
- 9.4.6 If patients move beyond a reasonable travelling distance from the implanting centre, systems must be in place to transfer their care appropriately to other services.





## 10 Special precautions

- 10.1 Unipolar diathermy should be avoided where possible in patients with SCS in situ. If its use is unavoidable, the reference plate should be positioned so that the SCS components are outside the electrical field of the diathermy.
- 10.2 The interaction of MRI and SCS is complex. The magnetic field may produce lead movement with loss of effect or neural damage, or heating of the implant components resulting in discomfort, tissue damage, or software malfunction. In addition, the location of the leads in relation to the site of imaging interest may cause image corruption. Patients with SCS in situ needing investigation with MRI may pose specific problems that should be discussed with an experienced neurologist who will require details of the SCS manufacturer, the type of SCS, the serial number, and date of manufacture. If there is any doubt about the compatibility, then alternative imaging (such as computed tomography [CT] scan or myelography) should be performed. On occasion, the SCS must be removed to allow MRI.
- 10.3 The presence of a cardiac pacemaker is a relative contraindication to SCS. Most contemporary pacemakers are operated in the demand mode; they monitor intrinsic cardiac activity, and they may be inhibited by spontaneous extra cardiac electrical activity. Extraneous electrical activity from SCS devices may be sensed and misinterpreted as appropriate cardiac activity. The pacemaker may then either respond by inhibition of pacing or by reverting to an asynchronous pacing mode. Inhibition of pacing can be potentially dangerous for the patient; asynchronous pacing is less serious, but still compromises pacemaker function. In such circumstances, it has been suggested that bipolar pacemaker sensing should be employed, as it is inherently less sensitive to extraneous signals than the unipolar pacing mode.
- 10.4 Patients should be advised that airport (and other) security systems may be activated by the presence of a stimulator. Patients should carry information relating to their SCS in situations where this may be relevant.
- 10.5 Patients must inform their medical caregivers that they have SCS in place.

- 10.6 Short wave diathermy, microwave diathermy, and therapeutic ultrasound diathermy are hazardous in patients with SCS.
- 10.7 Antibiotic prophylaxis is not recommended for patients with SCS systems in situ undergoing incidental procedures that may generate bacteraemia.

# 11 Complications of SCS

- 11.1 SCS has been used in many thousands of patients worldwide; some clinical centres have reported follow-up of more than 10 years. Major complications of SCS are rare. Minor complications with SCS are common. Most problems are technical ; the most common complication is lead migration.

These complications should be discussed during the consent process; this must be documented. Patients should be told about the local complication rates in the unit where the procedure is to be carried out.

- 11.2 Neurological damage relating to epidural electrode placement is a rare complication and may occur with both percutaneous and surgical electrodes. Damage may occur directly or from epidural haematoma or infection. These latter complications are reversible if diagnosed and treated promptly, emphasising the importance of postoperative neurological observations by experienced staff. Vigilance and access to early imaging are essential (see 10.2).
- 11.4 Dural puncture may occur during percutaneous insertion of electrodes. This happens most frequently with the Tuohy needle, but may occur with the guide wire or the stimulating electrode. It is often best to abandon the procedure if this happens, and attempt it at a later date as it is often difficult to test stimulation in these circumstances.
- 11.5 Infection of implanted neurostimulators is a serious problem and must never be ignored; usually, the infection will not resolve unless the whole SCS system is explanted. Infection of the entire system is rare but can result in epidural abscess with potentially disastrous neurological consequences. Explantation in this circumstance is required.
- 11.6 Patients should be aware that not only will surgery be necessary to replace a depleted IPG but that it may also be necessary to revise the electrodes or connections.

- 11.7 Electrode migration (see 11.1) may occur immediately following the procedure, at any time during the trial period (if used), or following IPG insertion. Cervical electrodes are more likely to be dislodged than those in the thoracic region. Migration is less likely with surgical electrodes. Recent improvements in anchor designs have been shown in controlled experiments to reduce migration in vitro.
- 11.8 Other potential problems include ingress of fluid into the connectors or electrode, lead breakage, and disconnection.

## 12 Patient information

(also see the Patient Information leaflet)

- 12.1 The risks and limitations of SCS should be discussed with patients, and they should be given written information in a form that they can understand.
- 12.2 Patients must be aware of the evidence for efficacy of SCS for the indication in their case.
- 12.3 Patients should be given information relating to complications and outcomes specific to the unit where the therapy is taking place.
- 12.4 Detailed information regarding the procedure of SCS insertion including the operating theatre environment is necessary.
- 12.5 Patients should understand that SCS provides benefit only as part of a multidimensional approach to symptom management.
- 12.6 Patients should understand the need for ongoing care following SCS, including the likelihood of needing further surgery.
- 12.7 Patients must be given adequate time to consider the benefits and burdens of the technique before consenting to treatment.
- 12.8 Patient support groups are a valuable information resource for patients considering SCS.
- 12.9 When their SCS is switched on, patients should not drive, climb, or operate dangerous machinery/equipment, and they must take care with their choice of activity, in case an unexpected surge from the SCS causes distraction or a motor effect.



## 13 Audit

- 13.1 There is currently no national database of patients treated with SCS.
- 13.2 Local audit of implanted patients is recommended.
- 13.3 Formal professional communication between implanting centres is strongly recommended.





# Appendix 1

## Spinal Cord Stimulation - Review of literature

### Search method

Randomised controlled trials and systematic reviews were identified from searches of MEDLINE (PubMed) and Cochrane Library based on a search of 5th January 2004 and updated in September 2008.

### Results

#### 1. Randomised controlled trials

##### FBSS

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## CRPS

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### **Cost effectiveness of SCS [all indications]**

ScHaRR assessment report for NICE.

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### **Further reading**

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## Appendix 2

### Summary of randomised controlled trials of SCS

N\*: Number of patients randomised; \*\*: Latest follow-up reported with group randomisation maintained; ++Mean follow-up

#### Results:

- + Statistically significant ( $P \leq 0.05$ ) improvements in outcome in SCS group compared to comparator at follow-up;
- statistically significant ( $P \leq 0.05$ ) decrement in outcome in SCS group compared to comparator group at follow-up;
- = no statistically significant ( $P > 0.05$ ) difference in outcome between SCS group compared to comparator group at follow-up.

Failed back surgery syndrome						
First author Trial name (year)	Country	N*	Comparisons	Follow-up**	Outcomes	Results
North (2005)	USA	50	SCS vs reoperation	2.8 years ++	Pain relief Analgesic use	+ +
Kumar PROCESS (2008)	Europe/Canada	100	SCS + medical therapy vs medical therapy alone	6 months/2 years	Pain relief Analgesic use Quality of life Satisfaction Work status Complications	+ +/ = + = +

### Complex regional pain syndrome

First author Trial name (year)	Country	N*	Comparisons	Follow-up**	Outcomes	Results
Kemler (2000 & 2004)	Netherlands	52	SCS + physical therapy vs physical therapy alone	2/5 years	Pain score Functional capacity Quality of life Complications	+ = +/ -

### Peripheral neuropathy

First author Trial name (year)	Country	N*	Comparisons	Follow-up**	Outcomes	Results
Testaye (1996)	United Kingdom	20	SCS on vs SCS off	3 months	Pain score Exercise capacity Neurophysiological indices Metabolic control Complications	+ +/ = = -

<b>Critical limb ischaemia</b>						
<b>First author Trial name (year)</b>	<b>Country</b>	<b>N*</b>	<b>Comparisons</b>	<b>Follow-up**</b>	<b>Outcomes</b>	<b>Results</b>
Suy (1994)	Belgium	38	SCS vs conservative therapy	20 months++	Amputation Fontaine stage Ulcer healing Complications	= + + =
Claeys (1996)	Germany	86	SCS + PGE1 vs conservative treatment + PGE1	1 year	Amputation ABPI Fontaine Stage Ulcer healing TcPO2 Complications	= + + + + =
Jivegard (1995)	Sweden	51	SCS + oral analgesics vs oral analgesics	18 months	Amputation Pain relief ABPI Complications	+ +/ = =
Spincemaille (2000)	Netherlands	37	SCS + best medical vs best medical	2 years	Amputation Pain relief	= +
Klomp ESES (1999)	Netherlands	120	SCS + conventional medical vs conventional medical alone	2 years ++	Pain score TCPO2 Quality of life Amputation Mortality Analgesic use Complications	= - = = = + =
Amann EPOS (2003)	Europe (multicentre)	112	SCS + best medical care vs best medical care alone	18 months	Amputation Complications	+ -

<b>Refractory angina pectoris</b>						
<b>First author Trial name (year)</b>	<b>Country</b>	<b>N*</b>	<b>Comparisons</b>	<b>Follow-up**</b>	<b>Outcomes</b>	<b>Results</b>
Mannheimer ESBY (1998)	Sweden	104	SCS vs Coronary artery bypass grafting	6 months/4.8 years	Antianginal drug intake Anginal attacks Exercise capacity Quality of life Mortality/morbidity	= = - = +/-
DeJongste (1994)	Netherlands	22	SCS vs no SCS	8 weeks	Exercise capacity Quality of life Anginal attacks Anginal medication 24 ECG Ejection fraction	+ + + + = =
hautvast (1998)	Netherlands	25	SCS on vs SCS off	6 weeks	Antianginal drugs Anginal attacks 24 ECG Exercise capacity Quality of life	+ + = = =
Jessurum (1999)	Netherlands	12	SCS on vs SCS off	4 weeks	Antianginal drugs Ischaemic burden Exercise capacity	= = =
Depede (2001)	Italy	19	SCS vs no SCS	48 hours	Ischaemic burden	=
Lanza (2005)	Italy	10	SCS on vs SCS off	2 weeks	Exercise capacity Antianginal drugs Anginal attacks Quality of life	+ + + +
Eddicks (2007)	Germany	12	SCS on vs SCS off	4 weeks	Exercise capacity Antianginal drugs Anginal attacks Quality of Life CCS class	+ + + +/- -
McNab SPiRiT (2006)	United Kingdom	68	SCS vs percutaneous laser myocardial reperfusion	12 months	Exercise capacity CCS class Quality of Life	= +/ =









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