“The failed back surgery syndrome”: Definition and therapeutic algorithms – An update

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ABSTRACT

Approximately 30% of patients experience persistent or recurrent low back and/or pain projecting into the legs following technically adequate lumbar or sacral surgery. Such pain conditions are often alluded to as the failed back surgery syndrome (FBSS). FBSS represents a significant clinical and economic concern. The treatment of FBSS presents a challenge to physicians, as conservative therapies and spinal reoperations are often unsuccessful – if not a significant cause (besides fibrosis) of the persistent pain syndrome is found at the post-operative examinations. Neuropathic pain radiating into the leg(s) is often the main component of this persistent and disabling syndrome. In this case, spinal cord stimulation (SCS) has been shown to be a successful therapeutic option. Studies have demonstrated that up to 60% of implanted patients experience 50% or more pain relief following SCS. Moreover, SCS has been shown to improve quality of life and functional status in a significant number of patients. In order to address the challenge of managing both chronic back and leg pain, a multidisciplinary group of physicians experienced in pain management and spinal surgery assembled to discuss and formulate a treatment strategy for FBSS, based on a systematic review of the literature that focused on the role of SCS. The outcome of these discussions however remained unpublished why an update, taking into account also the modern technologies has been performed.

The development of new treatment algorithms should allow, easier, more rational and effective management of this common and clinically – as well as economically – important problem.

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1. Introduction

Each year approximately 5% of the population experience a new episode of low back pain, and over the course of a lifetime 60–85% of people report at least one incident of low back pain (Svensson and Andersson, 1989; Frymoyer and Cats-Baril, 1991; Papageorgiou et al., 1995; Cassidy et al., 1998). Moreover, a third of these patients continue to suffer from a condition that is either chronic or recurs frequently, often accompanied by some degree of functional impairment (Hakelius, 1970; Weber et al., 1993). The large economic impact of this condition on society is illustrated by a report that in the USA more than $24 billion was spent on therapies for low back pain in 1990 (Frymoyer and Cats-Baril, 1991). A European survey on the prevalence, impact on daily life and treatment of chronic pain revealed that almost half of the patients suffering from chronic back pain actually reported back pain (Brevik et al., 2006). A Belgian study on the common treatment and cost of low back pain showed that the direct medical cost consisted predominantly of medical imaging, surgery and the management of the failed back surgery syndrome (FBSS), which constitutes approximately 70% of the global direct medical cost of low back pain (Nielens et al., 2006).

As Onesti states in a review article: “The failed back syndrome (FBSS) is easy to recognize but difficult to define”. (Onesti, 2004). The term FBSS is mainly used to describe patients who have ongoing chronic pain after surgery of the lumbar spine for degenerative disc disease. Some patients who have had prior cervical spine surgery with poor outcome may also be referred to as suffering from FBSS. In general the patients present with persisting spinal (low back or cervical) pain that may or may not radiate into the limb(s).

It deserves, however, to be noted that very similar, almost identical pain syndromes may exist in patients without prior spinal surgery and without a demonstrable spinal lesion, why the designation FBSS for the entire symptom complex actually is a misnomer. However, the wide-spread acceptance and use of the abbreviation FBSS makes it, at present, the most convenient way to address it in a review focusing on back and limb pain, most commonly occurring after previous spine surgery.
The number of spine surgeries performed each year varies according to the source but it is estimated that between 600,000 and 1,100,000 patients undergo spine surgery in the USA each year, with 50% of these operations performed in the lumbosacral area (Segal et al., 1998; Mekhail et al., 2010). Despite proper surgery, approximately 30% of patients fail to improve, as shown by disabling post-operative persistent or recurrent back pain, with or without leg pain (North et al., 1991b; Segal et al., 1998). FBSS represents a significant clinical and economic problem, and the management of these patients is a particular challenge to physicians. Re-operation of FBSS patients is often unsuccessful (Waddell et al., 1979; North et al., 1991a, 2005); instead they require a multidisciplinary approach to address their problem, including the use of spinal cord stimulation (SCS) and other neuromodulation procedures as well as physiotherapy and psychosocial support.

To address these issues and to more clearly define treatment guidelines for FBSS, a multidisciplinary group of physicians experienced in pain management and spinal surgery convened to discuss the treatment of patients suffering back or neck pain following spine surgery. This group consisted of orthopedic surgeons, neurosurgeons and anaesthesiologists experienced in pain management. Several meetings were held at regular intervals throughout 2001 and 2002 where the panel formally reached a consensus that eventually led to the development of a preliminary treatment algorithm, with a particular focus on the potential benefit of minimally invasive therapy such as SCS. The consensus reached back in 2002 was now again challenged against the current knowledge and evidence based medicine guidelines and thereafter updated. In this review, we highlight current treatment options for patients with FBSS, in particular those with radiating neuropathic limb pain but also trying to evaluate the possibilities to treat the midline components, and present an updated examination and treatment decision algorithm, that should facilitate the choice of appropriate therapy for FBSS patients.

2. Causes and diagnosis of FBSS

FBSS is defined as persistent or recurrent back and leg pain after technically adequate lumbar spinal surgery where no indication of macroscopic pathology justifying re-operation can be demonstrated (Kumar et al., 1998). It is a complex pain problem with mixed neuropathic and nociceptive (e.g. mechanical, inflammatory) elements, frequently involving the sympathetic nervous system (Wiesenfeld-Hallin et al., 1997). Pain may arise from viscera, blood vessels and nerves, or from muscles or joints of the spine and pelvis (Leveque et al., 2001). There is controversy regarding the impact of fibrosis on post-operative pain. Already Long (1992) described arachnoiditis as a major cause to persistent pain after spinal surgery and after repeated myelograms. In contrast Almeida could not identify a statistical significant correlation between the MRI defined degree of fibrosis and clinical outcome for pain and disability (Almeida et al., 2008). However, Bosscher and Haevner, more recently, found a significant correlation between the degree of epidural fibrosis, identified with epiduroscopy, and the concordant pain (Bosscher and Haevner, 2010).

Irrespective of the cause of FBSS, the type of pain these patients present with consists of fairly similar complaints and findings – pain lasting for more than 6 months that has worsened with time, associated major comorbidities, especially psychological, and heavy utilization of medical services.

One of the most important causes of FBSS is a suboptimal selection of candidates for spine surgery (Fager and Freiberg, 1980; Spengler et al., 1980; Zucherman and Schofferman, 1986; Long et al., 1988). Typically, the course of primary low back pain is benign and in most cases resolves spontaneously. Therefore, early surgical intervention, which may be unnecessary, can lead to further unnecessary complications (Waddell et al., 1979; North et al., 1991a). Poor diagnostic evaluation, resulting in inappropriate surgery, is another major cause of FBSS and the pain may persist after surgery because the original pathology was not resolved (Vaccaro and Silber, 2001), because a new pathology was introduced or because of a worsening of the pre-operative symptoms. Inadequate surgery, resulting in a sequestered disc fragment or spinal stenosis, is another less common cause of FBSS (Fan and Chong, 1995; Ohnmeiss and Rashbaum, 2001). Other causes of FBSS include intra-operative damage to the nerve roots (Ohnmeiss and Rashbaum, 2001) and persistent pain from irreversible nerve injury that may result from the original cause of the pain; for example, either damage to the nerve roots by compression from a herniated disc or exposure to toxic disc contents (containing e.g. TNFα and other irritants resulting in nerve root inflammation (Olmarker et al., 1995)). Failed fusion surgery – although not demonstrable on MRI or X-ray – may also be a cause of persisting back pain (“the micromovement theory”). It is also generally accepted that psychosocial factors or unrealistic expectations may play a significant role in a number of patients (Anderson, 2000). Consequently, following back operations, FBSS patients may suffer from lumbosacral post-operative fibrosis and/or arachnoiditis, root lesion, facet joint pathology, recurrent herniation, foraminal or lateral spinal stenosis and pseudarthrosis after a previous fusion (Long, 2002; Onesti, 2004). The chronic pain and disability of FBSS are often complicated by depression, financial stress, vocational difficulties, strains on personal relationships and loss of productivity and self-esteem (Turner et al., 1995; Thomson and Jacques, 2009). In a recent systematic literature review, not unexpectedly, depression was identified as a major factor reducing efficacy of the SCS therapy (Sparkes et al., 2010).

Since poor diagnostic evaluation, resulting in inappropriate surgery, is one of the major causes of FBSS, diagnostic re-evaluations should be meticulously performed in these patients. Several diagnostic tools are available for this group of patients and the most useful are presented in Table 1 (Borenstein, 1998; Bigos and Müller, 2000; Onesti, 2004). Central to this diagnostic process is the establishment of a patient history, an adequate physical examination, and an evaluation of the different contributions of neuropathic and nociceptive pain. These allow the ascertainment of any ‘red flag’ symptoms that could be indicators of serious problems – most commonly fracture, cancer or cauda equina syndrome – to be excluded. Of course imaging procedures e.g. MRI, CT, as well as plain X-rays are valuable tools in the diagnostic process. In addition, psychological evaluation of the patient is valuable, particularly when making decisions about future invasive therapies, as various psychological factors such as severe untreated depression and anxiety and borderline personality disorder have been associated with poor surgical outcome (Block, 2000; Voorhies et al., 2007).

Chronic low back pain with irradiation into the leg is thus a complex mixed pain syndrome where both neuropathic and nociceptive pain components are represented (Baron and Binder, 2004). Nerve lesions may trigger molecular changes in nociceptive neurons. Inflammatory reactions of the damaged nerve trunk can induce ectopic activation. The resulting hyperactivity can induce secondary changes also in central processing neurons (Baron, 2006; Linderoth and Foreman, 2006).

The centralization of the pain mechanisms may be one cause for failure of various peripheral treatment trials.

3. FBSS primarily associated with leg pain

Pain radiating to the leg may be caused by pressure on or damage to the nerve root – or may be referred to the leg as a result of a
suspected. Patients pain recurs slowly within weeks/months after surgery, lodged intervertebral implant. However, in the majority of patients, pain also encompasses a worsening of pre-operative symptoms. This may be caused either by pre-operative root lesions, in the area of the sensory abnormality, or by previous structural abnormalities (including some degree of fibrosis; see above) are often observed despite the patient’s persistent severe pain. If no gross structural abnormalities are found the persistent pain may be neuropathic in nature, caused by the prolongation of the original condition, and/or by the additional effects of surgery (Vaccaro and Silber, 2001; Onesti, 2004). Neuropathic pain is often associated with sensory abnormalities and is normally, at least during the initial period of time, located in the area of the sensory abnormality, but may eventually disperse because of dynamic changes in central mechanisms (Linderoth, 2000).

It is important to clearly distinguish between the symptoms of leg pain present pre- and post-operatively. Pre-operative persistent symptoms may be caused either by pre-operative root lesions, resulting in dorsal horn dysfunction, or by previous incomplete surgery. In contrast, post-operative pain may be due to post-operative fibrosis with pressure and tearing of the roots on intra-operative damage to the nerve. Post-operative complaints also encompass a worsening of pre-operative symptoms. It should be noted, however, that many patients with significant leg problems often visit the doctor for their “back problems”, and their major pain component may not become evident until after a thorough examination and interview.

4. FBSS primarily associated with back pain

FBSS patients presenting with lower back pain as the only or dominant complaint are difficult to treat (Ohnmeiss and Rashbaum, 2001). In such patients, symptoms may arise from one or several sources. These include recurrent disc herniation, degeneration of zygapophyseal joints, symptomatic pseudarthrosis, fibrosis/arachnoiditis, failure to address symptomatic pathology at the initial surgery (wrong spinal level or failure to remove all pathology), scarring, nerve root injury, sacroiliac joint problems, spinal stenosis and spondylitis (North et al., 1997; Onesti, 2004). Traditionally, results of further surgical intervention in this population are less good than for patients with predominant complaints of lower extremity pain (Ohnmeiss and Rashbaum, 2001). It should be noted, however, that many patients with significant leg problems often visit the doctor for their “back problems”, and their major pain component may not become evident until after a thorough examination and interview.

5. Treatment options

5.1. Conservative treatment

Treatment guidelines recommend the use of conservative treatment as first line option for patients suffering low back pain with or without accompanying leg pain. There is however little evidence of the added value of physiotherapy and recommendations for most pharmacologic treatments which are based on general trials including patients with chronic pain or patients with typical neurological pain syndromes such as diabetic polyneuropathy and/or
post herpetic neuralgia and often restricted to 6 months follow-up. Recently published treatment guidelines for neuropathic pain suggest oral amitriptyline, gabapentin or pregabalin as first line treatment (NICE, 2010). An evidence based practice guideline suggests the use of conservative treatment for both acute and chronic lumbar radicular pain. When an insufficient result is achieved the use of epidural corticosteroid administration could be tried – but should be restricted to the (sub)acute form of the syndrome. For the chronic form of the disease (pulsed) radiofrequency treatment adjacent to the dorsal root ganglion may be considered (Van Boxem et al., 2010). For those patients suffering from therapy-refractory symptoms after the initial therapeutic efforts, trials with spinal cord stimulation are strongly recommended (Van Boxem et al., 2010) (Fig. 1).

5.2. Type of surgical intervention

New surgery is rarely indicated for FBSS, as repeated lumbosacral operations are successful in only 20–30% of patients (North et al., 1991a; Fritsch et al., 1996). Re-operation should therefore only be considered for FBSS patients whose pain can be attributed to a clearly demonstrable and surgically remediable lesion. However, the persistent root or nerve lesion may still perpetuate the pain following technically adequate surgery. Repeat surgery for peripheral fibrosis rarely results in persistent pain relief (Ohnmeiss and Rashbaum, 2001). Importantly, over the last decade, it has been clearly demonstrated in several studies that neurostimulation is an effective treatment option for FBSS patients who have had anatomically adequate surgery, but still experience pain (North et al., 1991a,b, 2005).

5.3. Spinal cord stimulation (SCS)

SCS is currently indicated for FBSS patients with predominant leg pain whose conservative treatments have failed, and who have no obvious indication for re-operation. The goal of SCS in patients with back and leg pain is to obtain at least 80% (ideally 100%) coverage of the painful areas with paraesthesias, and to maintain at least a 50% reduction in pain with a significant improvement in quality of life at a 1–2 year follow-up.

Multidisciplinary assessment of patients and careful psychological screening pre-operatively are of major importance for successful SCS treatment. For example, in a Belgian study, SCS treatment was successful in 64% of patients who had a favorable psychological profile compared with 18% of patients with psychological disturbances (Kupers et al., 1994). When FBSS patients are selected as candidates for SCS they should always undergo a test stimulation period of at least 2 weeks to assess their suitability for stimulation therapy.

5.3.1. Mechanism of action

SCS has been used to relieve chronic pain for more than 30 years; however, the mechanism of action has yet to be fully elucidated. Clinical results support the gate-control theory of pain as ‘the basic concept’, which states that selective recruitment and stimulation of the low-threshold, large-diameter nerve fiber collaterals in the dorsal columns of the spinal cord inhibits central transmission of noxious input (Melzack and Wall, 1965).

Although the exact mechanisms of action for SCS are not yet completely mapped, during the last two decades more solid evidence for the underlying physiological mechanisms has emerged. Experimental evidences from the laboratory paired with clinical observations clearly demonstrate that SCS applied to different sites of the neuro-axis exerts fundamentally different effects on various target organs or parts of the body. A cascade release of neuro-active substances is probably induced or modulated by SCS both in the dorsal horn and in other sites, e.g. in the brain stem (Stillier et al., 1996) and multiple, as yet unknown, mechanisms thereby activated (Linderoth and Meyerson, 2002; Meyerson and Linderoth, 2003; Linderoth, 2006; Linderoth et al., 2009). In short multiple inhibitory systems are activated by the SCS both segmentally (GABAergic, cholinergic) and suprasegmentally (serotonergic and noradrenergic) leading to a concerted action on hyperactive cells in the dorsal horns perpetuating the neuropathic pain components. It goes beyond the scope of the present review to dwell in this issue but the interested reader is recommended to consult e.g. Linderoth et al. (2009), Linderoth (2009), Linderoth and Foreman (2006), Meyerson and Linderoth (2005).

The electrical stimulation at the level of the spinal cord generates paraesthesia in the corresponding dermatome. Thanks to the multipolar, multichannel and multiprogram techniques the stimulation can now be optimally adapted to each patient’s specific needs.

5.3.2. Methodological considerations

5.3.2.1. Topography of paraesthesias generated by SCS. A computer model of SCS at levels T 8–T 9 generated by Holsheimer and Wesselink (1997) has been used to calculate the dorsal column areas recruited in stimulation by various electrode configurations used in clinical practice. The thickness of the cerebrospinal fluid (CSF) layer at the T 8–T 9 level varies between 1 and 5 mm. The model predicts that stimulation through greater distances of CSF...
results primarily in dorsal root stimulation, and therefore does not produce satisfactory paraesthesia coverage of either the back or the lower limbs. By contrast, stimulation through CSF layers of 1–2 mm may recruit sufficient dorsal columns to produce paraesthesias in the low back and legs and thus relieve pain. In addition, Barolat et al. (1993) have presented a helpful database of sensory responses to electrical stimulation of the dorsal neural structures at various spine levels in patients undergoing epidural SCS.

5.3.2.2. Dual-lead stimulation. Single-lead SCS may be inadequate to produce paraesthesia coverage and corresponding pain relief in the lower back, as well as the leg. Therefore, dual-lead stimulation, multi-programmable systems (presently using up to 16 electrode poles), may enable better coverage and improve long-term treatment outcomes. Two leads and/or several different programs run simultaneously may be used to steer paraesthesias, to correct for differences between the anatomical and physiological midline and to obtain better paraesthesia coverage.

5.4. Implant procedures

The majority of electrode leads implanted have, during the last decades, been, and still are, percutaneous, cable-like multipolar. Implantation is usually performed with the patients in the prone position assisted by frontal fluoroscopy. Usually some antibiotic protection is used. The procedure is performed under local anaesthesia. The level of epidural puncture is determined by the desired position for the active electrodes and the length of the lead but it is usually situated in the interlaminar interspace in between T 12 and L2 (Fig. 2). The approach is usually lateral-oblique, a technique which is mandatory for the thoracic spine (Figs. 2 and 3) using loss-of-resistance with air or saline. Fluoroscopy is used to guide the steering of the lead and intra-operative test stimulation is used to finally place the lead on the target region where paraesthesia should cover the entire painful region (or at least 80%). In some cases a sitting position is preferable because it may enable a more...
stable electrode position and may be more comfortable for patients who are unable to maintain the prone position for the length of the procedure.

Plate electrodes (“surgical leads”) are considered to be less likely to dislocate and are preferred as first implants by some surgeons. The majority, however, uses plate implants when a cable lead has been dislocated several times or when scar tissue from previous spine surgery prevents the passing of a cable lead to the target area. Plate implants can be performed under local or full anaesthesia but also in spinal anaesthesia which actually still enables intra-operative test stimulation with just a little higher amplitude (Lind et al., 2003; Kumar et al., 2009). With the latest version of the surgical leads, double or triple columns of electrode poles enhance the possibility to steer the paraesthesiae electrically (Fig. 6). Fig. 5 demonstrates some useful electrode pole configurations for stimulation preferably of the back (a) or the leg(s) (b) using cable leads.

There are many different electrode designs and configurations available on the market. Fig. 6 displays a variety of cable leads, plate electrodes and pulse generators. The latest generations of pulse generators are multi-programmable and some are rechargeable. Multi program possibilities are also desired when complex programming with several channels/programs/stimulation settings are used to cover a wide-spread or otherwise difficult painful area. In addition rechargeable technology is preferable when the current need is high as it may be in individual patients. Rechargeable batteries last for at least 9 years.

There is a general trend to use more and more complex pole configurations, often supplied by dual channel pulse generators, but there is little evidence supporting that the technically more advanced types of SCS systems are more effective than a simple quadripolar, transcutaneously implantable electrode lead in experienced hands (Papageorgiou et al., 1995; Turner et al., 1995). A single octopolar lead inserted paramedially and crossing the midline at e.g. the T 10–T 11 may (Fig. 7), for the experienced implanter, be an equally satisfying option providing the possibility to stimulate one or both legs as well as the low back/buttocks (Mironer et al., 2008).

For more detailed descriptions of the designs, procedures and recommended clinical indications for the different kind of electrodes, the reader is referred to the extensive manuals supplied by the manufacturers and to reviews and book chapters on the SCS technique (e.g. Linderoth and Meyerson, 2009; Kumar et al., 2007a).

6. Efficacy of SCS in FBSS

6.1. Leg pain more dominant than the low back pain

Overall, the clinical benefits of SCS have been obtained predominantly with neuropathic pain of a peripheral or nerve root origin (North et al., 1994; Cybels et al., 1998; Meyerson and Linderoth, 2000), and FBSS is the most frequent indication for SCS treatment (North, 1991; Van Buyten et al., 2001). Initial studies of SCS used single leads and demonstrated approximately 50–60% improvements (North et al., 1991b, 1993; Turner et al., 1995). Results appear to be consistently better than those of repeated back surgery (North et al., 1994, 2005).

Taylor et al. (2005) performed a systematic review of publications, from 1995 to 2002 on SCS applied for “chronic back and leg pain”. Seventy-two case series were identified and subjected to a meta-analysis. These studies comprised 3427 implanted patients and 62% of them had experienced >50% pain relief; relative to the total number subjected to trial stimulation 48% reported this benefit. Furthermore, it should be noted that 70% of the implanted patients expressed satisfaction with the treatment, and there were also significant improvements of health-related quality of life (HRQL). The maximal follow-up time was 10 years. The review includes also one RCT (North et al., 1994, 2005) where patients with radicular pain after lumbosacral spine surgery were randomized to SCS or repeat spinal surgery. North et al. demonstrated that of 51 patients randomly assigned to receive either SCS or re-operation,
after 6-months of follow-up 67% of patients who had been re-operated crossed over to receive SCS, whereas only 17% of the SCS treated patients crossed over to surgery, \( p = 0.018 \) (North et al., 1994).

The late follow-up assessment was performed by “a third-party interviewer”. A total of 45 patients were available for a mean follow-up of about 3 years and it appeared that SCS was more successful (nine out of 19 patients) than re-operation (3 out of 26 patients) \( p < 0.01 \). Patients initially randomized to SCS were significantly less likely to cross-over than those randomized to re-operation.

Kumar and colleagues further demonstrated that in 235 patients who had undergone previous surgical procedures, the shorter the duration of time to implantation, the greater the rate of success. In their study, the success rate of SCS dropped from a maximum of 93% for those with less than a 3-year delay, to just 9% for those with a greater than 12-year pre-operatively waiting period, \( p < 0.001 \) (Kumar et al., 1998).

In a prospective randomized controlled trial (the PROCESS study), patients with neuropathic pain secondary to FBSS were assigned to conventional medical management (CMM) or SCS. All patients were followed for 2 years but cross-over was allowed after 6 months. Fifty percent pain reduction was achieved in 48% of SCS patients compared to (9%) of patients in CMM group \( p < 0.001 \). Before the evaluation at 1 year five SCS patients crossed to CMM, and 32 CMM patients crossed to SCS (Kumar et al., 2007b). Assessment of the treatment outcome 2 years after randomization illustrates that selected failed back surgery syndrome patients reported sustained pain relief (>50% relief significantly more often than the CMM patients), clinically important improvements in functional capacity and health-related quality of life, and satisfaction with treatment (Kumar et al., 2008). Further analysis of this material confirms the positive effects of SCS but at 24 months it also highlights that still 36–40% of patients suffer from ongoing marked disability and chronic pain problems (Eldabe et al., 2010).

6.2. Low back pain component more dominant than leg pain

The use of SCS in the treatment of axial lower back pain as the only or main complaint (>50% of the pain) is still being explored, with some promising results. In two studies of patients with chronic intractable pain in the low back, some of whom were treated using dual leads, 69% reported fair to excellent relief of back pain after 1 year (Barolat et al., 2001) and 60% of patients considered themselves improved (Ohnmeiss and Rashbaum, 2001). However, techniques are still being developed to adequately manage this patient population and to improve therapeutic success rates.

During the last decade, dual-lead stimulation systems have become available, providing the potential to manage conditions with prominent low back pain or multiple pain foci. Furthermore, the advent of multi-programmable systems has even more added to the benefits of SCS. Ohnmeiss and Rashbaum have shown that of 41 patients with predominant axial low back pain, 90% of those initially treated with a single-lead system later required a second lead (Ohnmeiss and Rashbaum, 2001). The addition of a second lead re-
Table 2
Summary of results from studies of spinal cord stimulation in patients with failed back surgery syndrome.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Patient status</th>
<th>No. of patients</th>
<th>Duration of follow-up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>De la Porte and Siegfried (1983)</td>
<td>Low back pain, with or without spread into the lower extremities, after surgeries</td>
<td>94</td>
<td>4 years (mean 35.8 months)</td>
<td>60% subjective improvement of pain</td>
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<td>40% reduction in medication usage</td>
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<td>26% increase in working capacity</td>
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<td>North et al. (1991b)</td>
<td>FBSS (averaging 3.1 previous operations)</td>
<td>53</td>
<td>Up to 5 years</td>
<td>Successful outcome (at least 50% sustained relief of pain and patient satisfaction with the result) was recorded in 53% of patients at 2.2 years and 47% of patients at 5 years</td>
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<td>10 of the 40 patients who were disabled returned to work</td>
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<td>54% of patients reported that SCS was more effective than previous operations</td>
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<td></td>
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<td>Most patients reported improvements in their abilities to perform almost all activities; loss of function was rare</td>
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<td>48% reduced or eliminated analgesic intake</td>
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<td>North et al. (1993)</td>
<td>FBSS</td>
<td>205 (153 with FBSS)</td>
<td>7.1 ± 4.5 years</td>
<td>52% reported at least 50% continued pain relief</td>
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<td>The majority reported improvements in activities of daily living and a reduction in analgesic use</td>
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<td>Burchiel et al. (1996)</td>
<td>Chronic back or unilateral and bilateral extremity pain</td>
<td>219 enrolled, 182 implanted</td>
<td>1 year (70 patients)</td>
<td>SCS successfully managed pain in 55% of patients</td>
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<td>Significant improvement in pain and quality of life measures was found at 1 year follow-up using the Visual Analog Scale, the McGill Pain Questionnaire, the Oswestry Disability Questionnaire, the Sickness Impact Profile and the Back Depression Inventory</td>
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<td>Complications were minimal; those requiring surgical intervention were reported by 17% (12 of 70) of patients</td>
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<td>Ohnmeiss et al. (1996)</td>
<td>Intractable leg pain</td>
<td>40</td>
<td>2 years</td>
<td>Statistically significant improvement in isometric lower extremity function was demonstrated at 6 weeks</td>
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<td>In the more painful leg, the performance increased from 457.8 ft-lb-sec to 629.8 ft-lb-sec, p &lt; 0.01</td>
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<td>Statistically significant decreases in pain, assessed by changes in visual analogue scale scores, were noted in the legs, when walking, and in overall lifestyle</td>
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<td>At least 66% of patients who were receiving SCS at baseline were taking reduced amounts or no narcotics 2 years later</td>
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<td>Kumar and Toth (1998)</td>
<td>Postlaminectomy pain</td>
<td>165</td>
<td>8.8 ± 4.5 years</td>
<td>48% experienced 50% or greater long-term pain relief</td>
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<td>All patients who were employed reported significant increases in their level of work</td>
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<td>13% of patients who were not working at baseline reported entry into gainful employment</td>
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<td>Kumar et al. (1998)</td>
<td>FBSS (sub-group of a larger group)</td>
<td>101 implanted</td>
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<td>50% of patients reported 50% or greater long-term pain relief</td>
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<td>Successful patients reported improvements in daily living as well as a decrease in analgesic use</td>
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<td>There was a 93% success rate in a subgroup with a delay between the last surgery and SCS implant of 3 years or less</td>
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<td>The success rate dropped to just 9% for patients with a greater than 12-year waiting period</td>
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<tr>
<td>Van Buyten et al. (1999)</td>
<td>Neuropathic pain</td>
<td>125 (98 with FBSS)</td>
<td>Up to 4 years</td>
<td>68% rated SCS as excellent to good</td>
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<td>31% of patients returned to work</td>
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<td>50% reduction in medication usage</td>
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<td>The VAS pain score improved significantly following SCS for all ratings of ‘average’ (uncomfortable, distressing), ‘worst’ (horrible, excruciating) and ‘lightest’ pain (mild or no pain)</td>
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<td>Barolat et al. (2001)</td>
<td>Chronic, intractable lower back pain</td>
<td>44*</td>
<td>6 months (21 patients)</td>
<td>91.6% and 82.7% of patients reported fair to excellent leg and back pain relief, respectively, at 6 months</td>
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<td></td>
<td>All patients reported more than 50% of their pain in their low back, pre-operatively</td>
<td></td>
<td></td>
<td>88.2% and 68.8% of patients reported fair to excellent leg and back pain relief, respectively, at 12 months</td>
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<td>All patients had pain in both their backs and legs</td>
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<td>Most patients showed a decrease in their 10-point VAS scores compared to baseline</td>
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<td>Significant improvement in function and quality of life was found at both the six-month and 1 year follow-ups using the Oswestry and SIP, respectively</td>
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<td>The majority of patients reported that the procedure was worthwhile (93% at 6 months, 88% at 1 year)</td>
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sulted in 60% of patients considering themselves improved from their pre-operative condition. The authors concluded that these technological advancements have broadened the potential indications for this mode of therapy.

Promising results have also been observed in other studies. In a trial of 21 patients with FBSS, after nearly 40 months of follow-up patients’ pain scores substantially decreased and 76% of patients indicated satisfaction with their treatment (Van Buyten et al., 1999). In another trial, which included 23 patients with complex back and leg pain, and a history of back surgery, patients’ visual analog scores (VAS) improved by an average of 58% and 45% for back and leg pain, respectively (Milbouw and Van Buyten, 2000).

6.3. Systematic review and meta-analysis of the effectiveness of SCS in FBSS

The benefits of SCS in FBSS and other indications (non-operative peripheral vascular disease, myocardial ischaemia, complex regional pain syndromes) have been previously reviewed (North et al., 1991b; North, 1993; Kupers et al., 1994; Turner et al., 1995) and some key studies are summarized in Table 2 (de la Porte and Siegfried, 1983; North et al., 1991b, 1993, 2005; Burchiel et al., 1996; Ohnmeiss et al., 1996; Kumar and Toth, 1998; Kumar et al., 1998, 2007b, 2008; Van Buyten et al., 1999; Barolat et al., 2001; Leveque et al., 2001; Ohnmeiss and Rashbaum, 2001).

In addition, a systematic review and meta-analysis of the clinical effectiveness of SCS for FBSS patients that expands on a previous systematic review of the clinical effectiveness of SCS for FBSS patients (Turner et al., 1995) has been conducted by Taylor and colleagues (Taylor et al., 2005).
rechargeable IPGs should be considered when IPG longevity is likely to be short (Taylor et al., 2010).

7. Selective treatment algorithms for FBSS

Several algorithms for the treatment of FBSS that focuses largely on diagnosis and possible orthopedic and neurosurgical interventions have been published; however, the place of SCS in these algorithms has remained unclear e.g. (Anderson, 2000). Consequently, a working group was established to reach a consensus and develop a novel treatment algorithm to address the management of predominantly neuropathic pain in patients with FBSS, highlighting the role of neurostimulation. These algorithms were based on both a series of discussions held during 2001 and 2002 with a multidisciplinary team of treating physicians and a systematic review of the literature (Jadad et al., 1998), and recently expanded to encompass also the most recent advances in neuromodulation treatment.

Once conservative treatments including physiotherapy and appropriate doses of analgesics such as selected antidepressants and anticonvulsants have failed, the first step in the algorithm is to establish whether the major component of the pain is in the low back or in the leg, and to identify the cause of the persisting pain (Fig. 8). For predominantly leg pain, if pain persisting after surgery is mainly neuropathic in nature and no structural cause is evident, an SCS trial is recommended. A trial period of at least 2 weeks on an outpatient basis using daily VAS ratings and ‘pain diaries’ is advised. Trial stimulation is normally carried out with percutaneous leads with extensions and an external stimulator (or by laminotomy lead with percutaneous extension in the same manner). Trial stimulation assists in avoiding initial false positive results, reducing the risk of a placebo effect and giving sufficient time for patients to evaluate their pain relief and changes in quality of life in their home environment. The SCS algorithm allows for the addition of a second lead (Figs. 8 and 9) during or after a prolonged trial period (i.e. approximately 3 weeks) if insufficient paraesthesia coverage occurs with one lead. If the trial is successful (more than 80% paraesthesia coverage and at least 50% reduction in pain), the patient should undergo permanent implantation of the appropriate SCS equipment (Fig. 8). If insufficient pain relief is achieved during the trial this is normally an indication that the pain is nociceptive. These patients should receive a thorough medication trial and optimal non-surgical care. However, if this does not relieve the pain or if side-effects of oral medication occur, intrathecal drug administration should be considered. Clinical studies have shown that intrathecal drug administration provides good to excellent long-term pain relief with enhanced performance of activities of daily living (Winkelmuller and Winkelmuller, 1996; Follet, 2000). Due to the substantially lower doses required, intrathecal drug administration provides effective pain relief with fewer side-effects than systemic routes of administration (Follet, 2000). The technique, outcomes and side-effects of intrathecal drug administration have been extensively described elsewhere (Naumann et al., 1999; Follet, 2000; Henderson, 2000; Slavin et al., 2000).

If the cause of the predominant leg pain persisting after surgery can be identified as structural, for example recurrent herniation, re-operation should be considered (Fig. 8). If leg or back pain per-

Fig. 8. General therapy algorithm for FBSS. Flow diagram illustrating the different levels of choices of therapeutic interventions depending on the outcomes of previous trials and on findings at examinations.
sists after this re-operation, the patient may be entered into an SCS trial as above. If insufficient pain relief is achieved during this SCS trial, the patient may still be treated with systemic medication and optimal non-surgical care. Intrathecal drug administration may be used if the back pain persists or if side-effects to oral medication occur.

With predominant low back pain (Figs. 8 and 10), if pain relief after a fusion operation is unsuccessful and no structural cause can be demonstrated, the patient is recommended to enter an SCS trial, most likely with dual leads. However, if pain persists during the SCS trial, optimal non-surgical care should be continued. If the cause of the predominantly low back pain persisting after sur-

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**Fig. 9.** Algorithm for SCS therapy in predominant extremity pain conditions. Flow diagram illustrating the decision making in the selection of therapies for a case with predominantly leg pain.

**Fig. 10.** Algorithm for SCS therapy in predominant low back pain conditions. Flow diagram illustrating the decision making in the selection of therapies for a case where low back pain is the predominant complaint.

8. Safety of SCS

The effects, side-effects and complications have been reviewed in two articles. (Cameron, 2004; Kumar et al., 2007a) Up till now no major neurological complications have been reported after correct positioning of the electrode(s) and battery. Complications can be divided into electrode or lead problems (27%), infections (7%), generator problems (10%), extension cable problems (10%) or other issues (e.g. CSF leaks) (7%). The last figure may seem high but it deserves to be pointed out that spinal puncture following spine surgery with the subsequent fibrosis increases the risk for a dural puncture when the needle entrance is close to the operated region. Otherwise the incidence of such punctures is extremely low (Taylor et al., 2005).

9. Conclusions

The complex pathophysiology of chronic back and leg pain after spine surgery represents a great therapeutic challenge. Nevertheless, good therapeutic outcomes can be achieved in many patients. Careful history taking and physical and psychological examination are crucial for accurate patient selection for appropriate therapy. If pain persists or recurs after technically and anatomically adequate surgical intervention (i.e. FBSS), there are few indications for repeated surgery. Treatment guidelines usually recommend the use of conservative therapy consisting of physiotherapy and pharmacological treatment.

Based on the available evidence for efficacy and safety of SCS it is reasonable to recommend a trial with SCS prior to envisioning reoperation (Fig. 8). Studies on the efficacy of the novel neurotropic drugs mainly performed in patients suffering diabetic polyneuropathy or post herpetic neuralgia justified the recommendation of these drugs as first line treatment for neuropathic pain. Extrapolating these recommendations to the management of chronic low back and leg pain, mostly after spine surgery (FBSS) may be questionable because of the complexity of the condition and the need for long-term treatment, which makes side-effects particularly burdensome. When patients have insufficient pain control or suffer side-effects of the pharmacological treatment a trial stimulation should be considered prior to placing patients on chronic opioid treatment. The simultaneous use of pharmacotherapy and SCS may be necessary to treat the entire syndrome that consists of a neuropathic and a nociceptive pain component. In severe cases additive intrathecal drug administration (baclofen or clonidine) has been demonstrated to enhance the effect of SCS (Lind et al., 2008; Schechtmann et al., 2010).

The development of neurostimulation is continuously progressing partly due to the advances in electronics, programming and miniaturization. The size of the generators and the possibility to recharge the battery so that a 9 years use is guaranteed represent a major advantage. An MRI compatible technique is currently under development which means that SCS will be possible also for patients who might need further investigation of their spinal problem. Additionally the imminent release of “intelligent systems” (e.g. Medtronic Sensor®) where the generator automatically adapts the program according to the patients’ position will facilitate the appropriate use of SCS. We foresee an enlarged interest in neurostimulation since the few side-effects compare beneficially with those of long-term pharmacotherapy and also because recent studies amplify the positive cost-benefit of neurostimulation as regarded in the long-term perspective.

Conflict of interest statement

None.

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