*European Journal of Pain* (2001) **5**: 299–307
doi:10.1053/eujp.2001.0249, available online at http://www.idealibrary.com on IDEAL®

# Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium

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Spinal cord stimulation is a minimally invasive mode of treatment in the management of certain forms of chronic pain that do not respond to conventional pain therapy. Several authors have reported encouraging findings with this technique. Over a 10-year period in a single centre, 254 patients were subjected to a trial period of spinal cord stimulation with an externalized pulse generator. Two hundred and seventeen of the patients showed satisfactory results justifying permanent implantation of a spinal cord stimulation system. In 1998, an independent physician invited 153 patients (155 pain cases), who still had the system in place and who could be contacted, for an interview. The aim of this study was to evaluate the efficacy of an implanted spinal cord stimulation system in terms of pain relief and quality of life and to assess the accuracy of the patient selection criteria. The results of this study demonstrate a high success rate as evaluated by the patients' own assessments—68% of the patients rated the result of the treatment as excellent to good after an average follow-up of almost 4 years. The resumption of work by 31% of patients who had been working before the onset of pain supports these positive findings. © 2001 European Federation of Chapters of the International Association for the study of Pain

KEYWORDS: spinal cord stimulation, failed back surgery syndrome, neuropathic pain, minimal invasive pain therapy.

## INTRODUCTION

The use of spinal cord stimulation (SCS) for pain control was first described by Shealy *et al.* (1967). In this case study, pain relief was achieved with SCS in a patient who was terminally ill with cancer. This initial positive finding motivated further investigations to optimize SCS and to develop assessment techniques to select those patients who would achieve the maximum benefits from this technique. In a review of 15 years of experience with SCS, Kumar *et al.* (1998) discussed the varied indications for SCS, including 'failed back surgery syndrome', peripheral vascular disease, peripheral neuropathy, multiple sclerosis and reflex sympathetic dystrophy. North *et al.* (1994) reported a randomized study in patients with 'failed back surgery syndrome' in which SCS was a significantly better treatment for pain compared with neurosurgical treatment alternatives. Kumar and Toth (1998) examined the methodologies used in studies of SCS described in the literature (i.e. non-prospective, non-blinding, non-randomized, non-placebo-controlled and short follow-up duration) and suggested that any bias is most likely to be attributable to the non-blinding of the observer and the patient–physician relationship. Kumar and Toth (1998) also highlighted the difficulties of conducting randomized studies.

Kupers *et al.* (1994) found that when SCS is performed by experienced physicians in centres with large volumes of patients, outcomes tend to be better. The Pain Clinic at AZ Maria Middelares, St Niklaas, Belgium, screened 254 patients with chronic pain over a 10-year period for suitability for external SCS treatment for

Paper received 12 December 1999 and accepted in revised form 5 April 2001.
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1090-3801/01/030299 + 09 $35.00/0

a trial period. A total of 217 patients subsequently received permanent implantation. The aim of this study was to evaluate the efficacy of SCS implantation, in terms of pain relief and quality of life, and to assess the accuracy of the patient selection criteria in a single centre with extensive experience of SCS therapy.

## MATERIALS AND METHODS

### Patient selection

Over a period of 10 years in a single centre (the Pain Clinic at AZ Maria Middelares, St Niklaas, Belgium), a total of 254 patients were screened for eligibility for SCS treatment. Screening consisted of a clinical evaluation of the patient's condition, with particular focus on prominent back problems and pain of a potentially neuropathic character. Patients were fully informed regarding the pathology of their disease, the proposed technique and its potential risks and benefits, thus allowing them to provide a verbal informed consent. Based on the experience that SCS is particularly effective for neuropathic pain, patients whose pain appeared to be neuropathic were selected. In 'failed back surgery syndrome' patients, the dominant pain component was that irradiating in the leg rather than the back. However, the irradiating pain had to comply with the clinical signs of neuropathic pain: burning, stinging, electric-like pain with hyper- or hypoesthesia and allodynia. All patients had previously undergone the different therapeutic options available for pain management, including oral pain medication and physiotherapy.

After percutaneous insertion of an electrode, usually a Pisces-Quad® electrode (Medtronic Inc., Minneapolis, MN, USA), trial stimulation was performed via percutaneous extension wires. The electrode implantation was performed under local anaesthesia with the patient in a sitting position. The patient was placed in this position for the following reasons:

- this position is more comfortable for both the patient and the physician;
- it allows better communication with the patient;
- it results in more accurate lead placement than the prone position, which does not correspond to the patient's usual daily situation.

When the paraesthesiae reported by the patient covered all the painful areas, the electrode was fixed in position and connected to an external stimulator. The externalized system remained in place for at least 1 month and the patient stayed at home for a minimum of 2 weeks after implantation. If the pain was reduced by a minimum of 50%, as assessed by the visual analogue scale (VAS) (Carlsson, 1983; Huskisson, 1983), quality of life was significantly improved and the consumption of pain medication was significantly reduced, the patient was considered to be a candidate for permanent implantation of a neurostimulation system. To facilitate this, the electrode, already in place, was connected to the pulse generator via an extension cable. Most of the patients received an Itrel® system (Medtronic Inc.). However, 17 patients with prominent back problems were selected for the dual-stimulation Mattrix® system (Medtronic Inc.) following its market release in 1996 (Van Buyten *et al.*, 1999).

Of the 254 patients subjected to trial stimulations, 217 received a permanent implantation of the SCS system. Two of the patients suffered from two different pain syndromes and therefore had two electrodes each implanted, connected to separate stimulators, resulting in 219 pain cases. In the current study, these 217 patients were followed-up to assess efficacy of the SCS system in terms of pain and quality of life. However, between implantation and follow-up, 22 (10.1%) patients had died and 22 (10.1%) had undergone explantations. Explanations were performed because of lack of effect (10 patients, 4.6%), allergy (two patients, 0.9%), re-operation (one patient, 0.5%), infection (two patients, 0.9%), recovery from pain (two patients, 0.9%) and unknown reasons (five patients, 2.3%).

Of the remaining 173 patients, 20 (9.2%) could not be contacted. Thus, 153 patients (155 pain cases) received a written invitation from an independent physician to a follow-up interview. They also received a questionnaire and an explanation why it was necessary to attend the follow-up interview with the independent physician, who

was not connected to the hospital. A total of 123 (80%) patients (125 pain cases because of the two patients with double implants) attended the pain clinic for the interview with the independent physician.

The most common indication was the neuropathic pain component in 'failed back surgery syndrome' (78.4%) which was also the most frequently reimbursed indication in Belgium until August 1997. Other indications were radiculopathy (5.6%), thoracic outlet syndrome (0.8%), peripheral neuralgia (2.4%), complex regional pain syndrome type I (3.2%), complex regional pain syndrome type II (causalgia) (1.6%), myelopathy (2.4%), spinal stenosis (0.8%), posttraumatic neuropathy (1.6%), whiplash (0.8%), cervical syringomyelia (1.6%) and ischaemic limb pain (0.8%).

The efficacy of SCS was evaluated on the basis of the degree of pain relief, the change in quality of life and changes in pain medication.

## Demographics

In recording patients' histories, attention was focused on the impact of the pain on the patients' occupations and work records at the time of the study, compared with the situations prior to the onset of pain. Previous treatments and any involvement in litigation before the trial stimulation period were noted, as was the number of visits to a doctor for the pain during the period of SCS treatment.

## Pain

The onset and history of the pain were assessed by a modified version of the McGill Pain Questionnaire (Verkes *et al.*, 1989). During the interview, patients were asked to evaluate retrospectively the neuropathic pain component prior to the trial stimulation period by means of a Neuropathic Pain Scale (Galer and Jensen, 1997). Furthermore, patients were asked to indicate, on a drawing of the human body divided into 45 zones, their areas of pain prior to and during the stimulation period as well as where they sensed paraesthesiae after the implantation. This enabled the degree of coverage of the pain distribution to be assessed.

Before and after the implantation, all patients were asked to indicate the pain level (as average, worst or lightest) on the VAS. For patients suffering from back pain, specific questions concerning the components of back pain and irradiating leg pain were asked. Patients were also asked to indicate the percentage of the day that they suffered the following degrees of pain: no pain, mild, uncomfortable, distressing, horrible or excruciating. In order to define the duration of pain, patients could select from the following possibilities for the presence of pain: permanent pain, short pain-free moments, frequent with pain-free periods (one to several hours), pain-free most of the time, periodic spells of pain (occurring once or several times a day and ranging from a few minutes to 1 h), pain only occurring at intervals of several days or weeks, no spontaneous pain but only triggered by external factors, pain during the day but pain-free at night, and completely pain-free.

## Other pain medication

Patients were asked to indicate any pain medication, doses and administration route they had used prior to the trial stimulation period and at the time of the interview. They also reported the frequency of intake of pain medication as: none, less than once a week, several times a week, once or twice a day, three to four times a day, or five times or more a day. To evaluate the efficacy of the pain medication, patients were asked to select whether the pain had: ceased completely, ceased almost completely, diminished markedly, diminished moderately, diminished slightly, remained as was, or worsened.

## Quality of life

Assessment of quality of life was based on the following aspects using the visual analogue scores (VAS): daily activities, social activities, dependency on other persons, sport recreation and leisure time, and ability to relax.

### Sleep disturbance

The influence of pain on sleep was evaluated by questions determining whether pain prevented patients from sleeping or whether patients woke up because of pain.

### Global patient assessment

Patients were asked to rate the general outcome resulting from the SCS as follows: excellent, very good, good, moderate, weak, no improvement, or worse.

### Complications

Complications and side effects of the SCS treatment were classified as either technical or medical (this information was obtained directly from the patient).

### Statistics

The treatment effect was defined as the difference between the mean changes before and after treatment. The precision and statistical significance was indicated by a 95% confidence interval and statistical analysis was performed using the Wilcoxon signed-rank test.

## RESULTS

### Demographics

Of the 153 patients (155 pain cases) who received a written invitation from the independent physician, 123 (80%) patients (125 pain cases) completed the questionnaires and attended the clinic for a follow-up interview. All the 17 patients who had been selected for a dual-stimulation system because of their prominent back problems participated in this study. Because of insufficient back pain relief or disease progression generating mainly back pain, 13 of the patients received supplementary treatment with intrathecal drug administration via the implant passage.

The typical patient receiving SCS was a semi-skilled male who had performed heavy labour before the pain started. The onset of pain was associated with: degenerative disease (55.2%, $n=69$), trauma (26.4%, $n=33$), surgery (16.8%, $n=21$) and other reasons (including lithotripsy and poliomyelitis) (1.6%, $n=2$).

Previous treatments for pain included: massage (118/125), bed rest (114/125), nerve block (111/125), back surgery (103/125), physiotherapy (94/125), heat therapy (91/125), ultrasound (83/125), transcutaneous electrical nerve stimulation (72/125), manual therapy (62/125), stretching (59/125), acupuncture (45/125) homeopathy (29/125), psychotherapy (27/125) and hypnosis (1/125). The median time that elapsed between the onset of the pain and SCS was 6 years (range 5 months–36 years). The median patient age was 48 years (range 30–86 years) and the median follow-up period after implantation was 3.4 years (range 3 months–10 years).

### Occupation

Before the onset of pain, 84.4% of the patients were employed. No information was collected concerning work activities at the time of implantation. At follow-up, 26.4% of the patients were employed. When retired individuals and women not pursuing a career were excluded, it was calculated that 31% of the active population continued to work.

### Frequency of visits to the doctor

The median consultation rate was twice a year (range 0–365 times a year).

### Electrodes and stimulation systems

Most of the single electrodes were implanted at the levels D10–D11. For the dual stimulation, the majority of both electrodes were implanted at

level D9 with the objective of stimulating the back. In these patients, this implantation level resulted in excellent coverage of the painful areas. Of all the 17 patients with a dual-stimulation system in place, 35% reported more than 90% coverage of the painful areas. Of the 125 pain cases (123 patients), 105 (84%) had a coverage of the painful area greater than 41%, while 31% of the total patient population experienced a coverage greater than 90%.

The power supply systems used were Itrel® 3 ($n=84$; 67.2%), Mattrix® ($n=18$; 14.4%), Itrel® II ($n=13$; 10.4%), X-trel® ($n=9$; 7.2%) and EMA ($n=1$; 0.8%) (Medtronic Inc.).

## Pain

The degree of neuropathic pain prior to the trial stimulation period as measured by the Neuropathic Pain Scale (Galer and Jensen, 1997) at follow-up is illustrated in Figure 1. The high scores on this scale indicate that the pain experienced prior to trial stimulation was essentially neuropathic.

The percentage of the day that patients reported defined degrees of pain showed that there were statistically significant improvements following SCS for distressing and horrible pain but not excruciating pain (Table 1).

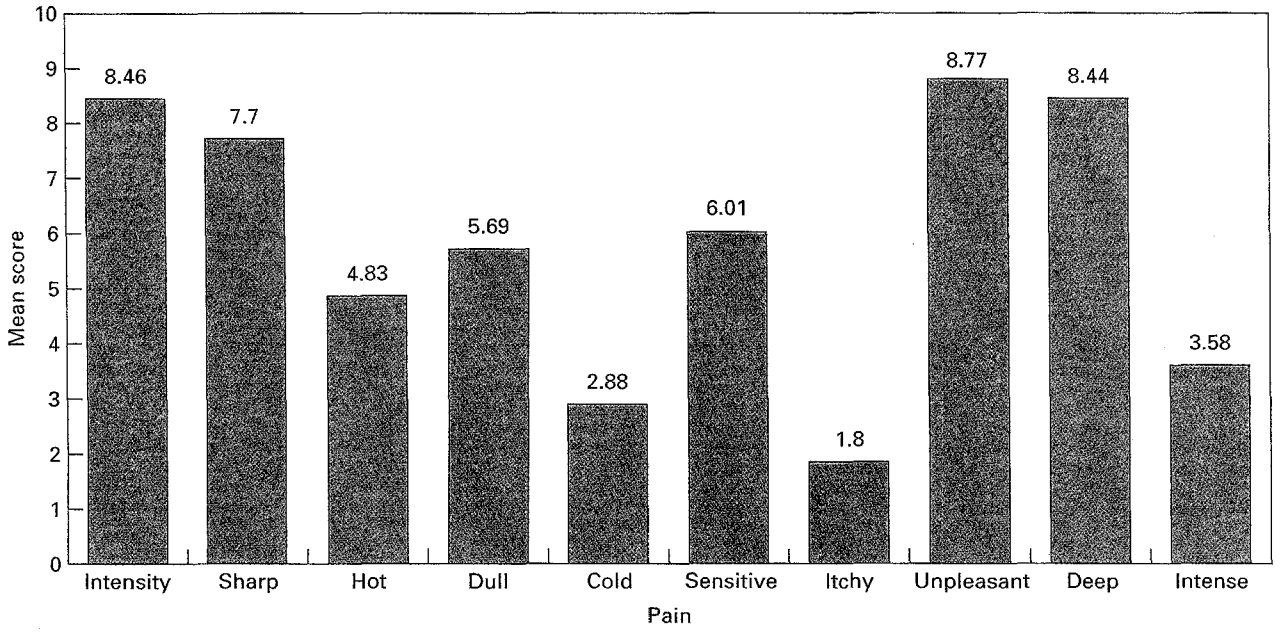


FIG. 1. Mean scores obtained using the Neuropathic Pain Scale (Galer and Jensen, 1997) at follow-up, prior to the trial stimulation period ($n=125$).

TABLE 1. Percentage of the day patients reported defined degrees of pain ($n=124$) before and after SCS.

| Degree of pain | Before SCS (%) | After SCS (%) | Difference | $p$ value |
|---|---|---|---|---|
| No pain | 0.2 | 10.5 | +10.3 | $<0.01$ |
| Mild | 2.3 | 28.2 | +25.4 | $<0.01$ |
| Uncomfortable | 9.8 | 30.0 | +20.2 | $<0.01$ |
| Distressing | 33.6 | 21.0 | −12.6 | $<0.01$ |
| Horrible | 53.8 | 10.3 | −43.5 | $<0.01$ |
| Excruciating | 0.3 | 0.00 | −0.3 | $=0.09$[a] |

[a]Not statistically significant; results from one patient were not attained.

TABLE 2. VAS scores for each pain description before and after SCS.

| Pain description | VAS score | | Improvement (%) | $p$ value |
|---|---|---|---|---|
| | before | after | | |
| Patients without back pain (but with complex regional pain syndrome or peripheral neuropathic pain) ($n=25$) | | | | |
| Average pain | 7.6 | 4.5 | 40.6 | $<0.01$ |
| Worst pain | 8.5 | 7.4 | 12.3 | $=0.016$ |
| Lightest pain | 5.8 | 2.4 | 58.4 | $<0.01$ |
| Patients with back pain – component of pain in the back ($n=100$) | | | | |
| Average pain | 6.8 | 3.9 | 43.1 | $<0.01$ |
| Worst pain | 8.4 | 6.1 | 27.5 | $<0.01$ |
| Lightest pain | 4.7 | 2.2 | 53.0 | $<0.01$ |
| Patients with back pain – component of pain in the leg ($n=100$) | | | | |
| Average pain | 7.0 | 3.0 | 57.4 | $<0.01$ |
| Worst pain | 8.3 | 5.3 | 36.6 | $<0.01$ |
| Lightest pain | 5.2 | 1.8 | 64.5 | $<0.01$ |

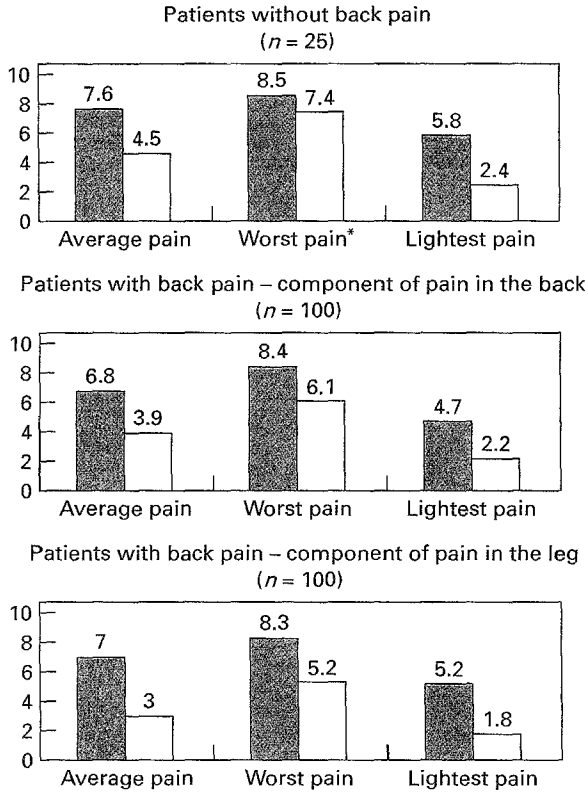


FIG. 2. VAS for each pain description before and after SCS ($p<0.01$). $p=0.016$. ▨ before; □ after.

The VAS score improved significantly for all ratings of average, worst or lightest pain (Table 2 and Fig. 2). The VAS score for the component of pain in the leg, rated by patients who suffered from back pain and leg pain, showed a higher improvement than the VAS score for patients with complex regional pain syndrome or peripheral neuropathic pain.

## Pain medication

Before the trial stimulation period, 53 patients needed 3–4 intakes a day of oral pain medication, 51 patients used medication more than four times a day while only four patients did not use any pain medication. After SCS, only 11 patients needed more than four intakes a day of oral pain medication, while 32 used medication only 1–2 times a day and another 19 took pain medication only a few times a week. The median shift was from 3–4 intakes per day before SCS to 1–2 per day after SCS, which corresponded to an improvement of more than 50%.

The effect of the medication also improved: before SCS, medication resulted in a small reduction in pain intensity but this increased to a fair reduction after SCS. The same trend could be seen in the consumption of opioids and NSAIDs. Not only did the number of patients taking medication decrease (opioids from 83 to 54; NSAIDs from 76 to 54) but so did the total number of medications being taken (opioids from 143 to 64; NSAIDs from 148 to 65).

## Quality of life

Patients' ratings on the VAS from 0 to 10 for quality of life parameters prior to the trial stimulation

period and at the time of the interview yielded the following improvements: 26.6% in daily activities, 30% in social activities, 43.8% in increased independence, 26.9% in leisure time and 42% in ability to relax. All these activities improved significantly ($p < 0.01$; $n = 125$).

### Sleep disturbance

Difficulties in sleeping and waking during the night due to pain diminished markedly. The duration of sleep was statistically significantly increased—from 4.5 h per night before SCS to 6.2 h after SCS ($p < 0.01$; $n = 120$).

### Global patient assessment

Overall, 68% of the interviewed patients rated the result of SCS as excellent to good. Some patients marked two possibilities when rating their evaluation. For the calculations, the median value of those ratings was taken.

### Time scale and VAS

In an attempt to confirm more objectively the high success rate, as noted by the patients' global assessments, the results obtained from two of the evaluation tools were combined: the percentage of the day patients experienced a defined degree of pain and the VAS scores. The mean VAS score for the worst pain was plotted on the Y-axis of a graph and the percentage of the day patients reported they had horrible or excruciating pain was plotted on the X-axis. A similar correlation was made for the VAS score for average pain with the percentage of the day patients reported they had uncomfortable or distressing pain, and for the lightest pain with mild or no pain. The area under the curve before and after SCS was calculated, and the improvement could be defined by the percentage of an average day a patient felt a lesser degree of pain. The leg pain of patients without back pain improved by 50%. The patients with back pain had 54% less back pain and 64% less leg pain on an average day.

### Complications

Most of the complications were of a technical nature: breaking the electrode ($n = 8$), breaking the extension cable ($n = 8$), breaking the temporary wires ($n = 12$), dislocation of the electrode ($n = 13$), bad connection of the battery or receiver ($n = 5$) or a bad connection of the electrode ($n = 7$). In seven cases, there were problems with the external stimulator. Seventeen patients experienced pain at the electrode–extension connection while seven had a changed perception of the paraestheseiae and 13 had a changed distribution of tingling. Leakage of cerebrospinal fluid was reported in nine cases. Infection occurred in 17 patients over the entire follow-up period, leading to an explanation of the system in two patients. However, these two patients were subsequently re-implanted with the system.

### Litigation *vs* no litigation

Seventeen patients declared their involvement in a litigation case. The results of the VAS assessment from patients in the population who had an ongoing litigation case at the time of implantation were compared with those of the total study population. This analysis indicated that the results obtained in the litigation group were comparable to those in the total study population.

## DISCUSSION

This study reports the findings of an evaluation by an independent third party of the efficacy of SCS in the management of pain intractable to other therapies. The study is retrospective, and the information is based on patients' memories. For this reason, questionnaires were completed in conjunction with an interview with an independent third party. The study population consisted of patients who are normally considered for SCS. The selection criteria published in August 1997 by the Belgian government for granting reimbursement for SCS are concordant with the criteria used in this study. This method of screening has

also been endorsed by a European consensus document (Gybels *et al.*, 1998). The results confirm the efficacy of SCS for a well-selected patient population. Sixty-eight percent of patients assessed the outcome of SCS as excellent to good at long-term follow-up. This success rate is among one of the highest reported for SCS (North *et al.*, 1993). One possible explanation for this is provided by Kupers *et al.* (1994), who found that centres with larger volumes of patients and experienced physicians tended to produce better outcomes. The physicians at the Pain Clinic at AZ Maria Middelares, St Niklaas, Belgium, had extensive experience of SCS treatment and saw a relatively large volume of patients over the 10-year period of the current study.

All of the tools used to evaluate improvements in pain and quality of life support the finding of the global patient assessment. The improvement measured by the correlation between the VAS scores and the percentage of the day a patient was experiencing a defined degree of pain confirms the success rate reported by the global patient assessment. This finding is typical for chronic pain because the patient feels relieved when he/she has a lesser degree of pain during a prolonged period of the day. These results also confirm the findings from the quality of life questionnaire. The results in patients suffering back pain irradiating in the leg demonstrate a larger pain relief of the leg-pain component compared with the back-pain component. This could be expected since the leg pain generally represents neuropathic pain and the lower back is more difficult to cover with paraesthesiae using one electrode. This also explains why 13 of the patients needed an intrathecal drug delivering system on top of their neurostimulation system.

In contrary to the rather disappointing results reported by Kupers *et al.* (1994) on work resumption after SCS, the results from this study found that 31% of the active population were employed at the time of the interview. Work resumption often requires a career change to less labour-intensive work, which is difficult for unskilled or semi-skilled persons. However, the Belgian Social Security system provides a reasonable revenue to individuals incapable of work due to a physical disability.

The results obtained from the patients involved in a litigation case are encouraging and confirm the report of Kumar *et al.* (1998), which included a group of patients involved in a Workman's Compensation Board claim who had similar success rates to the rest of the population (Nelson *et al.*, 1996; Burchiel *et al.*, 1995)

The rate of complications noted in the current study is relatively low. The reports on pain at the site of the connection between the electrode and the extension can be explained by the size of the connection, which is sometimes felt by lean patients.

The rate of infections can be partly explained by the fact that prior to a change in the law in August 1997, some patients were maintained on an externalized system for several months while awaiting reimbursement. Nowadays, Belgian law requires a minimum of 4 weeks' screening. However, the infections were superficial and did not spread into the spinal canal.

This study demonstrates that SCS is a valuable treatment modality for the management of patients with certain types of chronic pain and confirms the accuracy of the selection criteria used. A relatively long period of trial stimulation presumably excludes some of the placebo responders. The trial stimulation periods were 4 weeks in this study, while other authors have reported trial periods of only 1 week or less (Rainov *et al.*, 1966).

## ACKNOWLEDGEMENTS

The authors wish to thank: Dr Kathleen Parmentier, specializing in insurance medicine, for interviewing the patients; Kathleen Castelein (Medtronic Belgium) for the data input and statistical analysis; and Medtronic Belgium for logistic support.

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