Hardware failures in spinal cord stimulation (SCS) for chronic benign pain of spinal origin

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Summary

Spinal cord stimulation (SCS) has become an established clinical option for treatment of refractory chronic pain not related to cancer. Current hardware and implantation techniques for SCS are already highly developed and continuously improving, however equipment failures over the course of the long-term treatment are still encountered in a relatively high proportion of treated cases. Percutaneous SCS electrodes seem to be particularly prone to dislocation and insulation failures. This review summarizes the experience of the authors with management of hardware failures and their causes in patients treated with SCS for chronic pain of benign origin. The published literature is critically surveyed and discussed.

Keywords: Hardware failure; low back and leg pain; spinal cord stimulation.

Introduction

Spinal cord stimulation (SCS) has been evolving since its clinical introduction in the late 1960-ies to become a routinely used procedure in the clinical treatment of chronic pain conditions of benign spinal origin \cite{4, 5, 8–10, 22, 24}. One of the complex pain syndromes most frequently treated by SCS is chronic back and leg pain (CBLP), often used synonymously with the so-called failed back surgery syndrome (FBSS). CBLP is a permanently disabling condition of multifactorial genesis occurring in 5–10\% of patients with degenerative spinal disease \cite{6, 11, 18}. Typically but not necessarily, CBLP patients have undergone multiple surgeries for disc herniation, lumbar stenosis, or degenerative spinal instability, and have developed adhesive arachnoiditis or epidural and intradural fibrosis resulting in severe radicular or pseudoradicular pain and low back pain \cite{11}. In these patients, SCS is an effective and minimally invasive treatment modality and yields long-term results in 50–70\% of the patients \cite{2, 3, 13, 15–17, 20}. Although SCS hardware and surgical implantation techniques are currently well established and technically highly elaborate, there still are hardware failures caused by physical limitations of the used materials and by variations in the implantation techniques.

This review aims at identifying the most frequent types of hardware failures and their underlying causes in patients with chronic benign pain of spinal origin treated by long-term SCS. The experience of the authors and the pertinent literature are reviewed and compared.

Personal experience with SCS hardware failures

The authors have used SCS for treatment of chronic pain of benign origin since 1992 and have implanted more than 150 patients in total. There have been some dramatic technological improvements in the implantable and non-implantable equipment since the early 1990’s; however an overview of the engineering achievements in SCS is beyond the scope of this article.

Out of the first 100 consecutive cases of the authors, a series of 42 patients with CBLP treated with long-term SCS has been investigated in detail \cite{7}. Twenty-eight of these patients were female (66\%) and 14 male (34\%), with a median age for the whole group of 52 years (range 34–72). The median follow-up period for all patients was 46 months (range 6–74 months). Parameters included in the investigation were: time to failure after implantation of the device, frequency of failures, sites and types of failure, and overall duration of SCS. In all
but 4 patients of this series, percutaneously inserted quadripolar electrodes (PiscesQuad®, Medtronic Inc., Minneapolis, MN) were used. Single electrodes were implanted in 35 cases and dual electrodes in 3 cases. In 4 further patients, minimally invasive partial medial laminectomy was carried out under local anesthesia for placement of flat quadripolar surgical electrodes (Resume®, Medtronic Inc.). Radiofrequency receivers (model 3470, Medtronic Inc.) were implanted in 35 patients and X-trel® external pulse generators were used for stimulation. In the 3 patients with dual electrodes, an implantable dual channel radiofrequency receiver and external pulse generator (Mattrix®, Medtronic Inc.) were used. Patients used their SCS devices for a median time of 8.4 hours daily (range 1–24) over a total of 6,830 stimulation months.

A total of 12 (28.5%) surgical corrections of the hardware were carried out in this group of 42 patients. In 8 cases there was a single corrective procedure, in 2 additional cases two surgical corrections each were necessary: in one patient because of recurrent electrode failure and in the other patient for initial electrode failure and subsequent receiver failure. The most often encountered type of hardware failure was breakage of the electrode with partial or total disruption of insulation leading to short-circuiting and dysfunction (n = 6). In 2 additional cases, the electrode failed but the type of failure remained unknown. Only percutaneous PiscesQuad® electrodes were affected by such failures, while with Resume® electrodes no such failures were encountered. Second in frequency was receiver failure due to insulation leakage (n = 2) and extension cable breakage or disconnection (n = 2).

In order to compare hardware reliability and durability, we calculated the total time of stimulation time to failure (TF), which is the time period from implantation of the complete SCS system to the first surgical revision for a hardware failure. For all hardware failures, median TF was 24 months (range 5–37). For the PiscesQuad® electrodes alone, median TF was 15 months (range 4–29), and for the implanted receivers it was 23.5 months (range 10–37). In comparison, the median total time of SCS usage in our patient population was 57 months (range 6–74). We concluded therefore that hardware failures tend to occur relatively early during the course of long-term SCS treatment, and that this is particularly true for failures of the percutaneous electrodes. There was no correlation between hardware failures and subjective satisfaction of the patients. After surgical revision of the hardware the system was used in the same way and with the same effect as preoperatively [7].

In the last decade radiofrequency receivers and external pulse generators have been completely replaced by fully implantable single electrode pulse generators (IPG) such as Irel-II® and Irel-III® (Medtronic Inc.), or dual electrode IPGs such as Synergy® (Medtronic Inc.). With all these IPGs there is one additional problem – the need for periodic replacement of the IPG because of battery depletion. Stimulation parameters and energy requirements vary between patients and also in each single patient over the course of their long-term treatment, which effectively precludes comparisons of mean battery life of the different IPG types between our patients with fully implantable SCS systems and other cohorts in the literature. On the other hand, electrode types and materials have changed little over the course of the last decade and we were unable to ascertain any significant differences in the type and frequency of electrode failures in patients with radiofrequency receivers versus those with IPGs in our whole series.

Hardware failures of SCS in the literature

Detailed data on SCS hardware failures are relatively rare in the literature. A few studies provide information on hardware failures in the context of data on SCS efficacy and safety. Broggi et al. treated non-malignant chronic pain in 410 patients in a multicenter study and reported 3% technical complications during the 2 years follow-up [3]. Barolat [1] reported only 4 hardware failures in a large series of 509 implanted electrodes, however all of these were surgical electrodes which are sturdier and more resistant than percutaneous electrodes. Bel and Bauer [2] analyzed 18 SCS patients with a mean follow-up time of 24 months and reported electrode breakage in 7 patients (39%). In 5 of these cases, the failure occurred spontaneously and in 2 cases there was an underlying trauma. North et al. published a large series of 298 SCS systems in 249 patients with a mean follow-up time of 7 years. There were 22 electrode failures (fatigue fracture, insulation failure) and 16 additional receiver failures in the whole series [16].

Turner et al. evaluated 39 published studies in a metaanalysis and calculated total hardware complications from the bulk of available data [17]. Across a variable number of evaluable studies, 30% of patients had one or more hardware-related complications (range 0–75%), 24% had electrode insulation failures (range 0–75%), 7% electrode wire failures (range 0–24%), and 2% (range 0–9%) IPG failures [24]. Turner et al. updated their initial review in 2004 to include efficacy and complications