

Therapy-Related Explants After Spinal Cord Stimulation: Results of an International Retrospective Chart Review Study

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Objectives: Clinical trials of spinal cord stimulation (SCS) have largely focused on conversion from trial to permanent SCS and the first years after implant. This study evaluates the association of type of SCS and patient characteristics with longer-term therapy-related explants.

Materials and Methods: Implanting centers in three European countries conducted a retrospective chart review of SCS systems implanted from 2010 to 2013. Ethics approval or waiver was obtained, and informed consent was not required. The chart review recorded implants, follow-up visits, and date and reasons for any explants through mid-2016. Results are presented using Cox regression to determine factors associated with explant for inadequate pain relief.

Results: Four implanting centers in three countries evaluated 955 implants, with 8720 visits over 2259 years of follow-up. Median age was 53 years; 558 (58%) were female. Explant rate was 7.9% per year. Over half (94 of 180) of explants were for inadequate pain relief, including 32/462 (6.9%) of implants with conventional nonrechargeable SCS, 37/329 (11.2%) with conventional rechargeable and 22/155 (14.2%) with high-frequency (10 kHz) rechargeable SCS. A higher explant rate was found in univariate regression for conventional rechargeable (HR 1.98, $p = 0.005$) and high-frequency stimulation (HR 1.79, $p = 0.035$) than nonrechargeable SCS. After covariate adjustment, the elevated explant rate persisted for conventional rechargeable SCS (HR 1.95, $p = 0.011$), but was not significant for high-frequency stimulation (HR 1.71, $p = 0.069$).

Conclusions: This international, real-world study found higher explant rates for conventional rechargeable and high-frequency SCS than nonrechargeable systems. The increased rate for conventional rechargeable stimulation persisted after covariate adjustment.

Keywords: Chronic pain, efficacy, explants, spinal cord stimulation, outcomes

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INTRODUCTION

Attempts to provide safe and cost-effective relief of chronic pain have unwittingly contributed to an epidemic of opioid overuse and abuse in the United States, with 2 million abusing or dependent on opioids and 15,000 deaths involving prescription opioids in 2015 (1–3). Limited data from Europe suggest the problem of opioid abuse is less pronounced but still worthy of vigilance (4,5). Long-term opioid usage has little ability to improve function and is associated with work loss, physical dependence, addiction, and excess mortality (6–9). In contrast, accumulating clinical evidence over decades of use has helped to establish spinal cord stimulation (SCS) as a safe, effective, programmable, and reversible therapy for many types of chronic pain (10–14).

The number of technologies for SCS has expanded to include rechargeable systems and paddle leads (15–17). Waveforms such as high-frequency and burst stimulation may deliver pain relief with little or no paresthesia (18–21). Additional emerging therapies include high-density stimulation and direct stimulation of the dorsal root ganglion (DRG), and accumulating evidence can be used to help target therapy precisely to needs of the individual subject (22–24). The increasing number of therapy modalities highlights a need to validate clinical trial results with real-world data. Registries are in development, but the only publications to date on long-term outcomes of SCS are based on single-center experience (25–27).

The implanting centers participating in this European chart review manage hundreds of SCS subjects every year. We undertook a multinational chart review to determine if there are any differences in rate of explant for the different types of SCS systems in use today. The chart review makes it possible to study explants as a function of type of SCS system as well as patient characteristics.

MATERIALS AND METHODS

Study Design

A multinational retrospective chart review study was undertaken, including SCS systems implanted at four centers in three European countries from 2010 to 2013. Participating centers were AZ Nikolaas Hospital, Sint-Niklaas, Belgium; Heinrich-Heine University Hospital, Düsseldorf, Germany; Academic Medical Center, Amsterdam, and

Diakonessenhuis Utrecht in the Netherlands. The period for implant dates was deliberately selected so that each implant could be followed for at least two years, exceeding the length of time of major clinical studies of SCS (10,11,19,20). The chart review was performed in mid-2016, implants at end of 2013 would have approximately two and one half years of follow-up. In accordance with the Declaration of Helsinki, the study protocol was approved by a Medical Ethics Committee or a waiver was obtained, along with a confirmation that individual informed consent was not required for collection and analysis of the deidentified data.

The index event was implantation of any SCS implantable pulse generator (IPG) for the purpose of dorsal column stimulation from January 2010 to December 2013. Exclusions were for implants in subjects less than 18 years old; if the only therapy was Peripheral Nerve Stimulation (PNS), Peripheral Nerve Field Stimulation (PNfS), or Dorsal Root Ganglion (DRG) stimulation; or if precluded by another clinical study. A small number of implants were also excluded due to incomplete digital records. Events reviewed included implants and follow-up visits with date and reason for any explants, revisions, lead additions, deactivations, and documented non-use of SCS up to the point the chart review was conducted in mid-2016.

Data Collection

Site personnel with access to patient data entered findings of the chart review, including dates, into an Excel workbook that generated a de-identified version of the data free of any names, dates or other identifying information. A quality check on a subset of implants was performed by an additional person at each site, and compared to ensure accuracy and completeness of the chart review.

Data Analysis

The focus of this analysis is unanticipated explants related to SCS therapy. Unanticipated explants are defined as any removal of an IPG with the subject still alive, except cases of battery depletion or a decision to change to a different IPG with additional waveforms, MRI compatibility, or other lead configurations. Unanticipated explants were further categorized as due to inadequate pain relief, or from infection or wound dehiscence, pocket pain, IPG problem, lead problem, need for MRI, or subject becoming free from pain. Supporting Information Table S1 contains definitions for each of the outcomes.

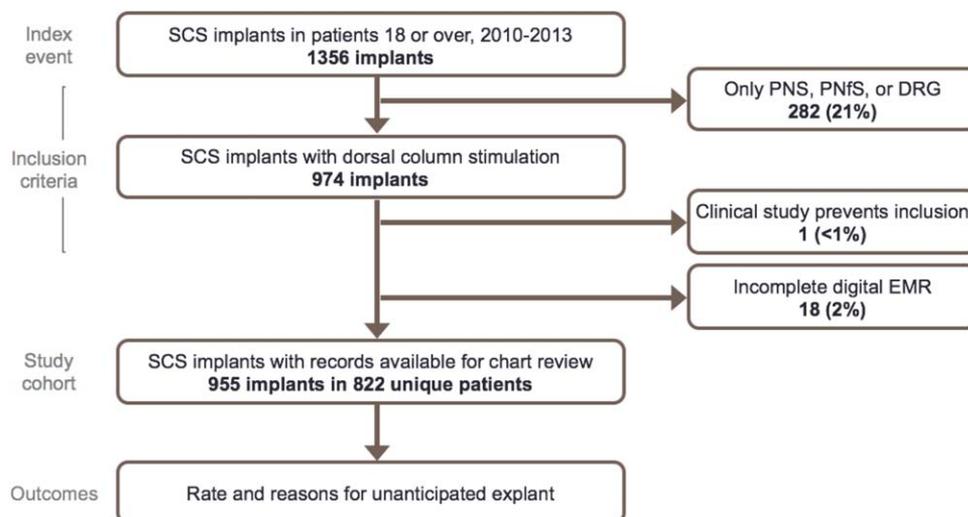


Figure 1. Consort diagram. [Color figure can be viewed at wileyonlinelibrary.com]

Table 1. Demographics and Implant Characteristics. Continuous Variables Are Presented With Median and Quartiles [Q1–Q3]; Categorical Variables as Number and Percentage.

Basic characteristic	All implants (N = 955)
Age in years at implant	53 [45–63] range 18–87
Female	558 (58%)
Male	397 (42%)
Indications for SCS	
Prior spine surgery (FBSS/FNSS)	700 (73%)
CRPS type I or II	60 (6%)
Peripheral neuropathy	130 (14%)
Neuritis/Radiculitis	17 (2%)
Lumbosacral neuropathy with no prior surgery	20 (2%)
Radiculopathies	42 (4%)
Angina pectoris	25 (3%)
Abdominal, pelvic or cancer pain	6 (1%)
Peripheral vascular disease	51 (5%)
Predominant pain location	
Low back and lower extremity	599 (63%)
Low back	66 (7%)
Lower extremity	185 (19%)
Upper extremity	47 (5%)
Thoracic	33 (3%)
Cervical	42 (4%)
Other	23 (2%)
Time from chronic pain diagnosis to implant (years)	3.8 [1.0–8.4]
First (<i>de novo</i>) SCS implant	715 (75%)
Trial performed	568 of 715 (79%)
Days from start of trial to permanent implant	14 [10–31]
One previous SCS pulse generator implant	156 (16%)
More than one previous SCS implant	84 (9%)
Type of SCS system	
Conventional nonrechargeable	462 (48%)
Conventional rechargeable	329 (34%)
High-frequency (10 kHz) rechargeable	155 (16%)
Other or not known	9 (1%)
One percutaneous lead	615 (64%)
Two percutaneous leads	256 (27%)
More than two percutaneous leads	23 (3%)
Paddle lead	61 (6%)
Lead 1 location	
Cervical	82 (9%)
Upper thoracic (T1-T5)	15 (2%)
Mid-thoracic (T6-T9)	622 (67%)
Lower thoracic (T10-T12)	171 (19%)
Lumbar or sacral	31 (3%)

Note: Summary statistics are calculated on each implant. An individual subject may have more than one implant. Additionally, there may be more than one indication per implant.

Statistical Analysis

Deidentified data from all sites were merged and notes from the chart review were used to identify categories for indication, predominant pain location and reasons for explant. Outcomes were classified using the notes from the chart review, and then adjudicated by investigators from each site. Timing of each explant was plotted for visualization and qualitative assessment. Continuous variables are presented using median and quartiles; categorical variables with number and percentage. Crude rate of explant and 95% confidence

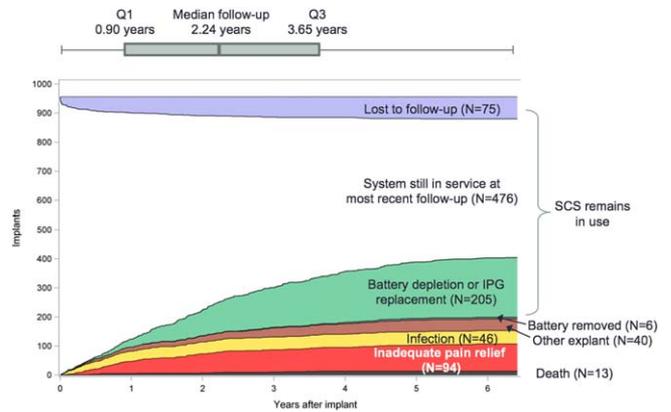


Figure 2. Event timeline. The figure shows a timeline of the 955 SCS systems in the chart review, including unanticipated explants due to inadequate pain relief, unanticipated explants for any other reason, deaths, battery EOL occurrences, upgrades, loss to follow-up, and SCS systems still in use.

interval are expressed as events per year of follow-up. Incidence of explant was evaluated using the Kaplan-Meier estimator and compared among subgroups with log-rank test. Plots of the Kaplan-Meier estimator were limited to the first five years after implant. A Cox proportional-hazards regression model was used to determine factors associated with explant for ineffective therapy. Results of the regression were presented using univariate regression, as well as an adjusted multivariable model with independent variables for type of SCS, age, gender, indication, pain location, time with chronic pain and *de novo* vs. replacement IPG. Age at implant was included as a continuous variable in the regression, but plotted in Kaplan-Meier curves in subgroups of those age 65 or older, corresponding to the U.S. Medicare age group, or less than 65 years old. Lead type and location were not used in the regression because of the potential for multicollinearity. In case of indication and pain location, groups

Table 2. Follow-Ups and Unanticipated IPG Explants.

Number of implants	955
Total follow-ups	8720
Follow-ups per implant	7 [3–12]
Total follow-up duration	2259 years
All unanticipated IPG explants	180 (19% of implants)
Explant rate per year of follow-up [95% confidence interval]	8.0% per year [6.9–9.2%]
Explants for inadequate pain relief	94 (10% of implants)
Rate per year of follow-up [95% confidence interval]	4.2% per year [3.4–5.1%]
Other reasons for unanticipated explant	
Infection or wound dehiscence	46 (5%)
IPG problem	22 (2%)
Lead problem	6 (<1%)
Pain at pocket	4 (<1%)
MRI required	3 (<1%)
Free of pain	3 (<1%)
No specific reason identified	2 (<1%)

*Additional IPGs removed and censored at event but not counted as unanticipated explant: 173 with battery depletion (167 replaced). Thirty-eight IPG replacements to obtain access to additional features, including burst, high-frequency, high-density, MRI conditional system, or additional leads. Thirteen deaths.

Table 3. Explants for Inadequate Pain Relief and Type of SCS System.

Type of SCS	Number of implants	Explants for inadequate pain relief (%)	Total years of follow-up	Explants (% per year) [95% CI]
Conventional nonrechargeable	462	32 (6.9%)	1125.2	2.8% [2.0–4.0%]
Conventional rechargeable	329	37 (11.2%)	671.5	5.5% [4.0–7.6%]
High-frequency (10 kHz) rechargeable	155	22 (14.2%)	439.4	5.0% [3.3–7.6%]

with less than 50 implants were placed in an “other” category. SAS 9.4 (Cary, NC, USA) was used for statistical analysis.

RESULTS

The chart review included four implanting centers in three countries. There were 822 unique subjects with 955 implants performed from January 2010 to December 2013 that satisfied all inclusion and exclusion criteria (Fig. 1). Exclusions were predominantly for neurostimulation systems that did not use dorsal column SCS, with fewer than 2% excluded for any other reason.

Median age at implant was 53 years; 558 (58%) were female. Table 1 contains a summary of basic characteristics at time of implant. There were 462 (48%) implants with conventional nonrechargeable SCS from any manufacturer, 329 (34%) with conventional rechargeable SCS, and 155 (16%) with high-frequency (10 kHz) rechargeable stimulation. There were nine implants (1%) with another waveform or unknown stimulation type that were excluded from the regression analysis.

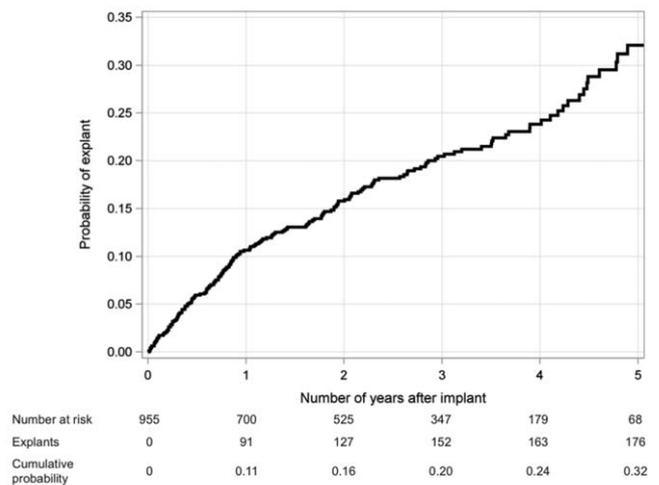
Postimplant management of the 955 implants included 8720 follow-up visits over 2259 years of follow-up. An event timeline, shown in Figure 2, revealed median follow-up for all implants of 2.24 years. There were 180 unanticipated explants (19%). In addition, there were 13 deaths, 173 battery depletions, and 38 IPG upgrades. Of the 173 battery depletions, a replacement IPG was implanted in 167 (97%).

Table 2 details the unanticipated explants by reason for explant. Overall explant rate was 8.0% per year of follow-up [95% confidence interval 6.9–9.2%]. Over half (94 of 180) of explants were for inadequate pain relief. As shown in Table 3, the breakdown of explants for inadequate pain relief was 32/462 (6.9%) with nonrechargeable SCS, 37/329 (11.2%) with conventional rechargeable, and 22/155

(14.2%) with high-frequency SCS. The explant rate for inadequate pain relief was 2.8% per year of follow-up for nonrechargeable SCS, 5.5% for conventional rechargeable SCS, and 5.0% for high-frequency stimulation.

Figure 3 illustrates timing of explants for each case of an unanticipated explant. This qualitative analysis demonstrates that some reasons for explant, such as infection or wound dehiscence, occur most frequently in the first year after implant, while other less common reasons such as the need for MRI could occur at any time. The Kaplan-Meier estimators for all implants in Figure 4 show the incidence of any unanticipated explant, as well as incidence of explant

a Cumulative probability of unanticipated explants



b Cumulative probability of explant for inadequate pain relief

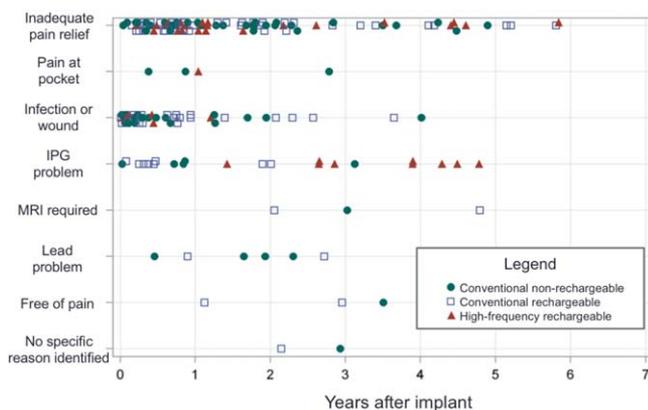
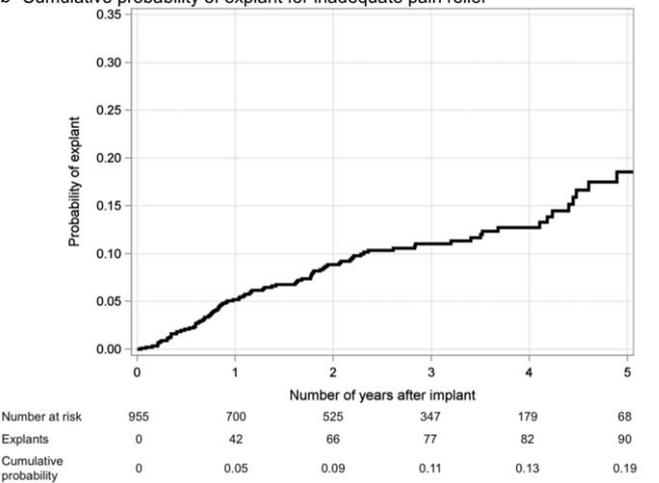
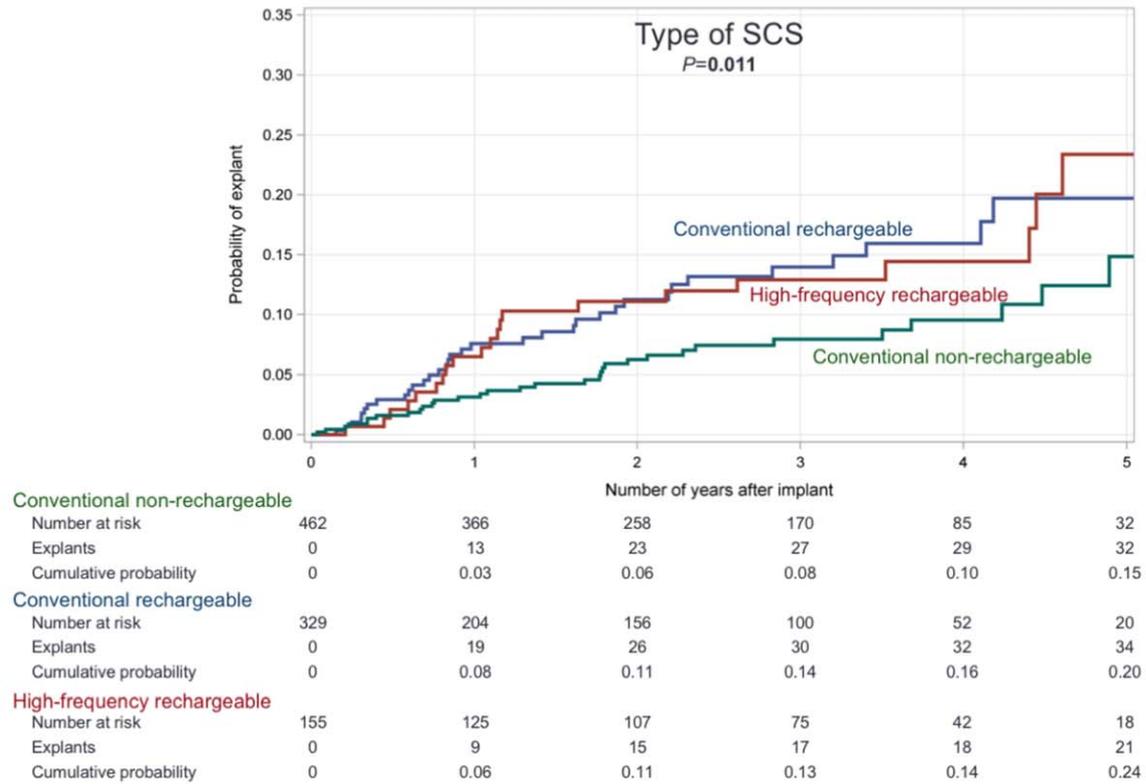


Figure 3. Timing of explants. Each marker indicates an unanticipated explant. As shown in the legend, the color and shape of the marker indicate the type of SCS system.

Figure 4. Cumulative probability of explant using the Kaplan-Meier estimator. Panel a shows estimated probability of unanticipated explant for any reason, while panel b is probability of explant for inadequate pain relief.

a Type of SCS



b Other characteristics known at time of implant

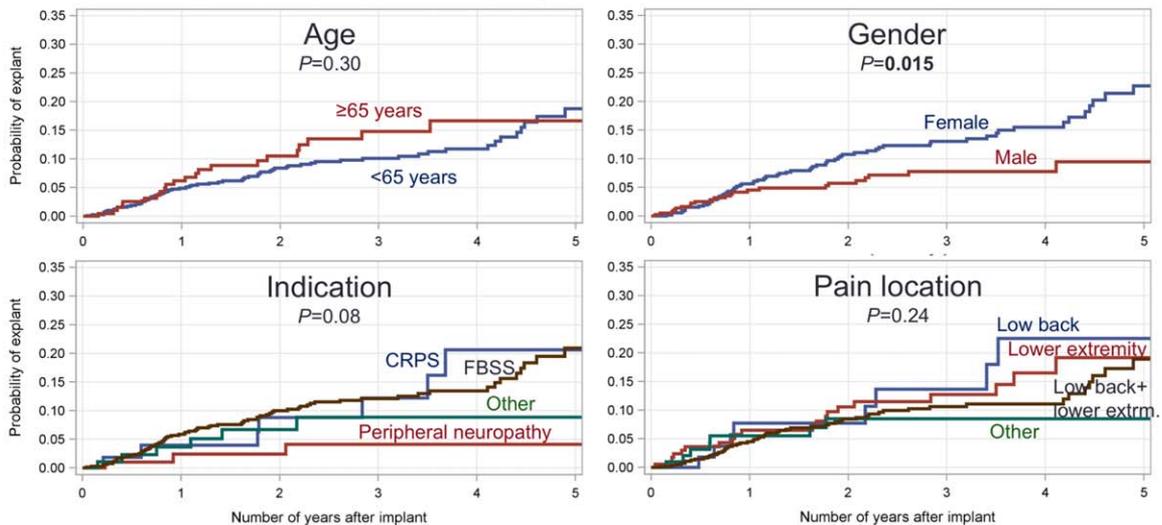


Figure 5. Explants by subgroup. Kaplan-Meier curves show probability of explant for inadequate pain relief as a function of type of SCS (panel a), age, gender, SCS indication, and predominant pain location (panel b).

for inadequate pain relief. Figure 5 compares Kaplan-Meier estimates of the incidence of explant for inadequate pain relief in different subgroups. Type of SCS (panel a) was a significant predictor of explant ($p = 0.011$). Explants for inadequate pain relief were also more common in women than men ($p = 0.015$). There was no significant association between age in subgroups above or below 65 years old, indication or predominant pain location and incidence of explant.

The results of Cox proportional-hazards regression are shown in Figure 6. In the univariate regression shown on the left side, conventional rechargeable, high-frequency rechargeable stimulation, and female gender were associated with greater risk of explant. Among the different indications for SCS, peripheral neuropathy was least associated with risk of explant. Significant differences persisting in the multivariable regression were for conventional rechargeable (HR 1.95, $p = 0.011$), female gender (HR 1.87, $p = 0.011$), and peripheral

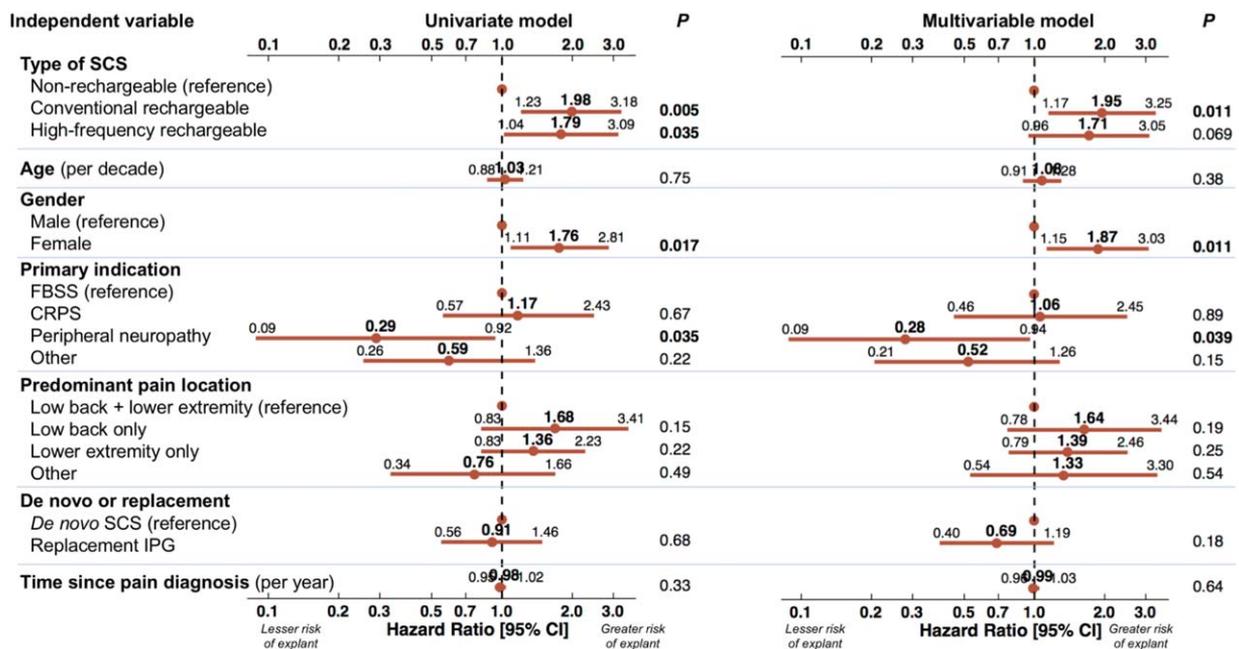


Figure 6. Factors associated with explant for inadequate pain relief. Univariate Cox proportional-hazards regression (left) shows relationship of each individual variable with explants for inadequate pain relief. Multivariable Cox regression (right) includes all variables in a single model. Each point is the Hazard Ratio; lines indicate 95% confidence interval. Significant associations have p value shown in bold.

neuropathy (HR 0.28, $p = 0.039$). For high-frequency stimulation, the HR was 1.71 and p value 0.069 after covariate adjustment.

DISCUSSION

This multinational chart review study of 955 SCS implants, performed from 2010 to 2013 and followed until mid-2016, found that the rate of unanticipated explants was 8.0% per year of follow-up in a cohort of subjects known to suffer from complex chronic pain. The most frequent reason, inadequate pain relief, occurred in 4.2% of implants per year of follow-up. The survival curve showed a total rate of explant for inadequate pain relief of 19% at five years after implant. Stated another way, pain relief was achieved up to five years after implant in 81% of implants. Furthermore, the vast majority of subjects who used SCS until battery depletion (167 of 173, 97%) chose to continue on with a replacement SCS system.

A higher explant rate was found for devices with conventional rechargeable SCS compared to conventional nonrechargeable SCS, both in unadjusted regression and after adjusting for covariates. There was also an elevated risk of explant for high-frequency rechargeable SCS in the unadjusted regression, but the difference did not reach significance after covariate adjustment.

Possible reasons for higher explant rate for rechargeable SCS systems are varied and may include patient compliance, as well as physiology and technical aspects of the SCS system design. Habituation may be a possible physiological reason inadequate pain relief, but it is not possible from the available data to determine if there were any differences in habituation. Also, compliance may be reduced as a result of the burden of recharging. Manufacturers of SCS systems should be encouraged to develop technologies for rapid recharging, wireless communication, and hardware design with smaller batteries and ergonomic shape. Updateable software may also help to reduce risk of explantation.

The rate of explant for inadequate pain relief was also higher in females than males. The covariates collected in this retrospective chart review did not clarify the difference, which persisted in the multivariable model. There may be additional covariates that might help to clarify this finding, such as prescription medications, prior treatments, pain scores, and work and disability status. However, the reasons may also involve complex physiological and psychosocial factors, expectations, and individual variations in perception of pain.

Comparison With Prior Work

In a single-center chart review of 234 subjects who received permanent SCS implants, Hayek et al. reported an explant rate of 23.9% (56 of 234) over a mean follow-up of 44.5 months.⁽²⁶⁾ The most common reason was loss of therapeutic effect, which was followed by infection. These findings are largely concordant with results of this multinational chart review. Also notable in the present multicenter chart review was the observation that explants for MRI were relatively infrequent (amounting to <1% of implants), even though the implant period was before availability of MRI-conditional SCS systems. While there have been few reports on long-term outcomes of SCS, it is hoped that this systematic investigation of outcomes will encourage further exploration of the longer-term rate and reasons for explants. There is a particular need for such analysis given the proliferation of technologies available in SCS. Likewise, there is a need for further exploration of the appropriate clinical response when challenges occur with the therapy. Strategies such as lead addition and new stimulation waveforms have the potential to avoid some explants.

The recently published SENZA-RCT⁽¹⁹⁾ and ongoing SUNBURST studies demonstrate promise of new waveforms. The former study found that 84.5% of patients with high-frequency (10 kHz) stimulation were responders for back pain and 83.1% for leg pain, while the responder rate was 43.8% for back pain and 55.5% for leg pain with conventional stimulation.⁽¹⁹⁾ Recent work with burst stimulation found that a 62.5% responder rate was achieved with burst SCS in

the fraction of patients who did not respond to tonic SCS (28). The findings of the present chart review study, particularly with regard to high-frequency stimulation, demonstrate the need for further real-world experiences to complement the findings of carefully conducted clinical trials.

LIMITATIONS

Several additional limitations of this retrospective chart review should be considered. Data in the medical charts were not recorded systematically in a standardized manner across all centers. The charts only provide general reasons for explant; a prospectively designed study would be necessary to assess the specific factors that lead to loss of efficacy in some implants. The results of this chart review study draw on data from four experienced, high-volume centers, and may be different from long-term outcomes at other sites. However, the centers draw on a patient population from three different countries, have slightly different implant indications due to national reimbursement policies, and make use of a variety of SCS devices and technologies from various manufacturers. The implant period selected for this chart review from 2010 to 2013 allowed for a comparison of several technologies, but are not recent enough to make a comparison with newer technologies such as burst and high-density stimulation. As the chart review did not collect information on pain scores, medications, SCS usage patterns, and patient satisfaction, we are not able to draw further conclusions on the exact causes of inadequate pain relief. There were 75 implants (8%) lost to follow-up, in whom it was unable to determine if SCS continued in use or if an explant may have occurred elsewhere. Finally, a competing risk analysis was not performed. Competing risks that could have affected the rate of explants for inadequate pain relief included death (1% of the study cohort), explant for another reason, battery depletion, and device upgrade. It would not be possible to use battery depletion as a competing risk, since it disproportionately affects the nonrechargeable SCS systems in the first few years after implant. However, the replacement rate of 97% indicates that it was not a widespread practice to discontinue SCS upon battery depletion.

CONCLUSION

This multinational European real-world outcomes study found a higher rate of explants for inadequate pain relief for conventional rechargeable and high frequency rechargeable SCS than for nonrechargeable systems. The increased rate for conventional rechargeable stimulation persisted after covariate adjustment. Prospective investigation is warranted to understand the precise reasons for loss of efficacy over time.

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Authorship Statement

Prof. Vesper, Drs. Van Buyten, Wille, and Smet, Ms. Wensing, Mrs. Breeel, and Mr. Karst designed the study. Drs. Van Buyten, Wille, Smet, and Vesper, Ms. Wensing, Mrs. Breeel, and Mr. Karst contributed to data analysis and interpretation and participated in writing and reviewing the manuscript. Ms. Devos and Mrs. Pöggel-Krämer contributed to the data collection and analysis. All authors approved the final version of the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the supporting information tab for this article.

COMMENTS

This multicentre, multinational, chart review is a laudable addition to the clinical literature on spinal cord stimulation. It represents a cumulative total of 2259 years of follow-up for 995 implants. More importantly, it focuses on why implanted devices are removed and for what reason. The authors report an explant rate of 8% per year, half of which are due to inadequate pain relief. Female gender and implantation with a conventional rechargeable device were associated with a higher rate of explantation. This knowledge has significant implications for patients giving informed consent and benchmarking of clinical outcomes for clinicians and institutions.

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Spinal cord stimulation is an established treatment for certain types of chronic pain. This international retrospective chart review analyzes associations between patient demographics and type of SCS with explantation. The authors evaluated patients that had long-term follow-up data, which allows changes in the explant rate to be examined over several years. Associations found in this review may be helpful in lowering explant rates for future SCS procedures.

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This multi-national chart review study of 955 SCS implants is focusing on the type of SCS and the overall explant rate with a follow-up period of 3 to 6 years. Interestingly, it has been shown that the newer systems (conventional rechargeable and high frequency rechargeable SCS) have an elevated risk of explant compared to the conventional non-rechargeable SCS (11.2% and 14.2% vs. 6.9%, respectively). It was stated by the authors that the possible reasons for the higher explant rate are patient compliance, as well as physiology and technical aspects of the SCS system design.

But in my experience, factors contributing to a poor therapy outcome are suboptimal lead placement, insufficient or no intraoperative testing, insufficient paresthesia coverage to the area of pain, multifocal pain syndromes or just a loss of pain-relieving effect of the SCS in the long run.

Unfortunately, in this study the precise reason for explant remains unclear. It would be of interest to obtain information about the frequency of reprogramming sessions to compare explanted and still running SCS systems. Also, the kind of indication and patient selection for SCS should be addressed. The new multichannel and rechargeable SCS systems are capable of producing high frequency, high density, whisper or burst stimulation patterns. These new stimulation patterns have been invented to improve stimulation outcome and also to expand the indication for SCS. This is especially true for patients having predominant back pain. As we know, there are several influencing factors causing back pain. Usually, the physician is obliged to take a careful physical, psychological and radiological examination of the patient to determine the best treatment. As is generally known, undifferentiated surgical approaches do not have a promising and long lasting effect on chronic back pain. Therefore, a more sophisticated approach to “low-back” patients is mandatory. SCS might be one option for treating back pain in selected patients, but SCS is not the universal solution for all back pain patients.

Furthermore, a comparison of the data of each of the four implanting centers would be helpful to get characteristic results of each single center.

This multi-national chart review study is a further contribution to analyze failure of SCS, but for receiving “real-world-data” a more sophisticated and detailed approach is needed.

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Comments not included in the Early View version of this paper.