

# Spinal Cord Stimulation Explantation and Chronic Pain: A Systematic Review and Technology Recommendations

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**Background:** Chronic pain affects 20.5% of the US population, costing \$296 billion annually in lost productivity. Spinal cord stimulation (SCS) has become a key treatment for refractory neuropathic and nociceptive pain, with increasing usage due to technological advancements. However, the durability of SCS therapy, including explantation rates, remains a concern. Understanding explantation causes is essential for improving patient selection and device effectiveness. This study aims to analyze SCS explantation rates and reasons, as well as evaluate the financial burden of these procedures on the healthcare system.

**Methods:** Three primary screening methods were used: manual search with keywords, MeSH term query, and reference list screening. The search covered PubMed, Cochrane, and Web of Science databases from inception to November 2024, yielding 719 articles. After applying eligibility criteria, 72 articles were identified, and 25 were selected for analysis. Data extraction was done by independent reviewers, with a second reviewer ensuring accuracy. Discrepancies were resolved by the corresponding editor.

**Results:** We reviewed data from 13,026 patients who underwent permanent SCS implantation between 1984 and 2024, across 25 studies. A total of 1882 patients (9.82%) underwent explantation. The most common reason was lack of efficacy and inadequate pain relief (38%), followed by lead failure (15%) and infection (14%). While SCS is generally effective, issues related to device longevity and patient satisfaction persist, with explantation rates due to technical failures and lack of efficacy being concerns.

**Conclusion:** SCS efficacy varies, with explantation rates reaching up to 38%, often due to inadequate pain relief. Most explantations occur within the first year, despite SCS being a safe and effective treatment. High implantation costs (\$35,000 to \$70,000) and revision costs (\$15,000 to \$25,000) raise concerns among payors. The hardware-driven model limits waveform flexibility, highlighting the need for innovation.

**Keywords:** chronic pain, spinal cord stimulation, explantation, implant removal, cost-effectiveness

## Introduction

Chronic pain remains a challenge that affects millions (if not billions) of individuals yearly and has gained increased interest globally to address this debilitating condition.<sup>1</sup> In the United States alone it is estimated that approximately 20.5% of the population (or 50.2 million adults) suffer from chronic pain.<sup>2</sup> For some individuals this translates into activity modification and behavioral changes that result in both avoidance of social events and inability to work. In the US alone, reports estimate that the economic burden for patients with chronic pain costs the US \$296 billion annually in lost productivity.<sup>2</sup> While economic reports may help to demonstrate the severity of the issue on a macro level, they fail to give an accurate perspective of the individual whose quality of life is severely limited due to their chronic suffering. Studies estimate that severe depression is found in up to 85% of chronic pain patients, with approximately 20% demonstrating suicide ideation. In fact, 5% - 14% of these patients eventually attempt suicide, making chronic pain a public health concern as well.<sup>3-6</sup>

In recent decades neuromodulation has emerged as a novel technology that has shown success in the treatment of some chronic pain conditions. Spinal cord stimulation (SCS) has increased in popularity and is now a mainstay for clinicians specializing in treating refractory pain. This technology first debuted in 1967 and was initially based on the gate control theory as outlined by Melzack and Wall but is now thought to be based on activation of the dorsal horn of the dorsal column, changes in the thalamus, and potential impact on wide dynamic range neurons.<sup>7-13</sup> Technological advancements in hardware and software have resulted in significant improvements in neuromodulation and continued technological progress points to a future with better and broader coverage for chronic pain populations. However, this has led to a deeper exploration of device success and failure, as improved technology comes with a price tag that has made some payors more careful about approving device implants.<sup>14-18</sup> The cost of these devices has led some international payors to decline authorization due to speculative reports about lack of efficacy, and overall lack of access to advanced therapies due to the structure of the payor system.

The SCS industry offers several waveforms to treat different pain syndromes although a lack of evidence exists on how practitioners should pair waveforms to the chronic pain patient. The authors believe improved waveform selection may improve outcomes and lead to better SCS innovation. Current literature suggests that SCS explantation is closely tied to decreased efficacy. However, more data is needed to verify this supposition. If found to be true, this information can have important implications for the future of SCS, as it suggests that waveform tolerance should be considered when selecting SCS for our patients. In addition, the recent advancements in closed-loop technology which allows dose measurement of electrical delivery may add additional improvements in explant rates. While in studies, explant for efficacy has been much lower than the numbers discussed here, it will take time to see if these advances lead to long-term improvements.<sup>19,20</sup> To support the body of evidence surrounding SCS durability we conducted a systematic review of SCS explantation rates and their associated causes. By understanding the reasons for SCS explantation across a series of manuscripts, we may gain insight into the long-term efficacy of these devices to improve our ability to enhance patient selection for this important modality.

## Materials and Methods

In this systematic review, we did not target a specific population, as our primary focus is on evaluating the outcomes of SCS procedures over the past two decades. This comprehensive review encompasses a diverse array of patient populations who have undergone SCS implantation. The principal intervention of interest is the revision, reoperation, hardware removal, and explantation surgeries associated with SCS. The primary outcome of this review is to elucidate the reasons for subsequent revision or explantation surgeries following initial SCS implantation. The secondary outcome is to assess the financial burden of these procedures on the healthcare system. We aim to present findings from both the USA and globally. Studies were included if they focused on removing or revising any component of the SCS system and meeting all inclusion criteria while not meeting any exclusion criteria, detailed in [Table 1](#).

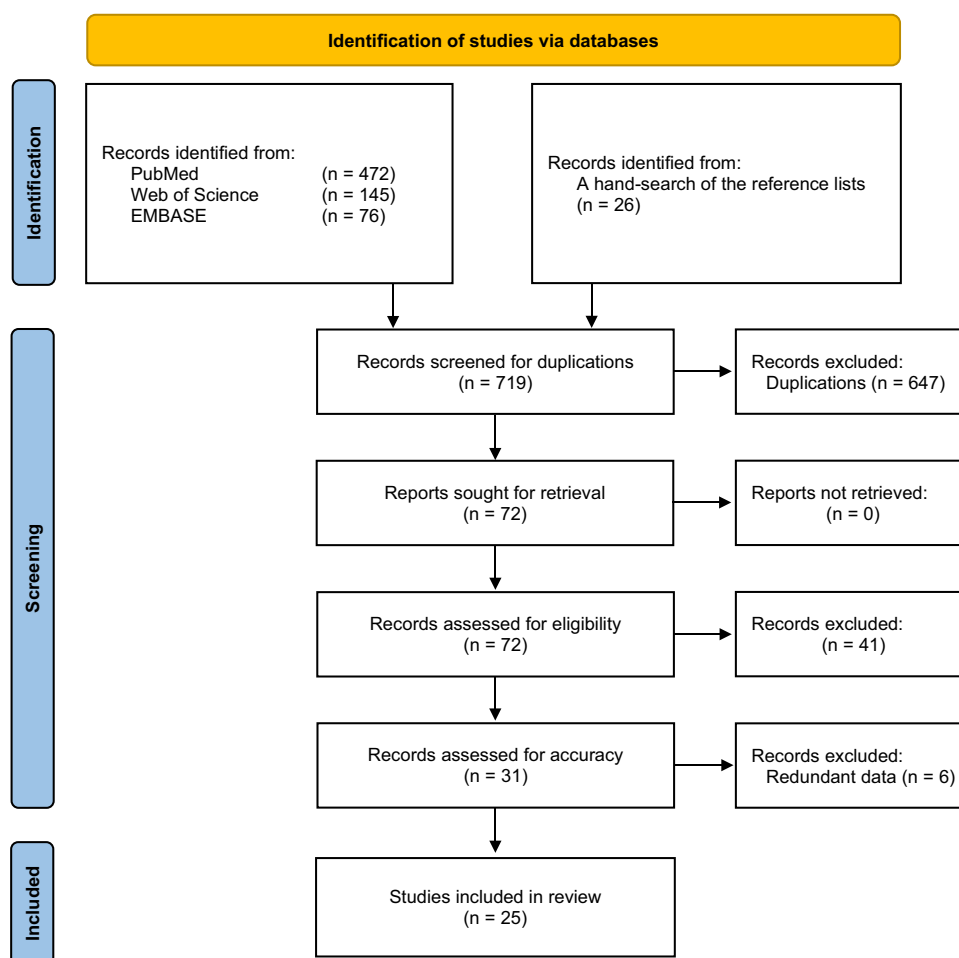
The methodology employed in this systematic review strictly followed the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), ensuring adherence to standards for integrity and reproducibility ([Figure 1](#)).<sup>21</sup>

**Table 1** Inclusion and Exclusion Criteria for Eligibility

Inclusion Criteria (if All the Following are Met)	Exclusion Criteria (if Any of the Following are Met)
Patients of any age who have underwent SCS.	Studies with incomplete or insufficient data for analysis.
Patients who have had any part of the SCS system explanted/revised for any reason.	Studies not reporting explantation rates or reasons following SCS implantation.
Studies reporting on explantation rates and reasons following SCS implantation.	Case reports or case series with fewer than 5 participants.
Studies published in English language.	Studies not available in English language.
Studies with available full-text articles.	Studies without full-text availability.
Studies reporting on explantation procedures and/or outcomes and/or follow-up data.	Studies involving only animals.
	Duplicate publications or redundant data from the same study cohort

## Search Strategy

Three primary screening methods were employed: manual search with keywords, MeSH term query (Medical Subject Headings), and screening of reference lists from relevant articles. The manual search strategy encompassed three databases, PubMed, Cochrane, Web of Science using specific keywords related to spinal cord stimulation, spinal cord stimulator,

**Figure 1** PRISMA flow diagram.

chronic pain, refractory pain, explantation, explant, neuromodulation, failure, and complications, covering literature from inception to November 2024. A comprehensive search strategy was designed utilizing key words for PubMed and this strategy was subsequently adapted for the Cochrane and Web of Science search yielding the following detailed results:

### Keyword Query

#### PubMed Keyword Search: (472)

- Keywords “spinal cord stimulation + chronic pain” yielded 3389 results. Further refinement with “explant” resulted in 88 articles, of which 21 were selected.
- Keywords “spinal cord stimulator + explantation” initially yielded 259 results, refined to 112 articles after adding “neuromodulation”. Following deduplication, 12 articles were selected.
- Keywords “SCS + chronic pain + complication” produced 837 results, refined to 74 with the addition of “failure”. After reviewing and removing duplicates, 6 articles were selected.
- Keywords “spinal cord stimulator + explant” generated 259 results, refined to 28 with “failure”. After review and deduplication, 7 articles were selected.

#### Web of Science Keyword Search: (145)

- Keywords “spinal cord stimulation + chronic pain” yielded 3101 results, refined to 73 with “explant”, and 1 publication was selected.
- Keywords “spinal cord stimulator + explant” initially yielded 32 results. After review and deduplication, 3 articles were selected.
- Keywords “SCS + chronic pain + complication” produced 400 results, refined to 40 with “failure”. After review and deduplication, 3 articles were selected.

#### Cochrane Keyword Search: (76)

- Keywords “spinal cord stimulator + explant” generated 56 results, none of which met the inclusion criteria following the deduplication (12 included from PubMed search).
- Keywords “spinal cord stimulation” yielded 20 results, none of which were selected following the deduplication (6 included from PubMed search).

Following the manual search, a MeSH term query was devised for PubMed with five query concepts and their various combinations as shown in [Appendix 1](#), utilizing the same keywords outlined below:

### MeSH Query

Query Concept 1: “Chronic Pain” OR “refractory Pain” OR “intractable pain”

Query Concept 2: “Spinal Cord Stimulation” OR “spinal cord stimulator” OR “dorsal column stimulation” OR “electric stimulation therapy”

Query Concept 3: “Neuromodulation” OR “Transcutaneous Electric Nerve Stimulation”

Query Concept 4: “Explantation” OR “Explant” OR “Device Removal”

Query Concept 5: “Equipment failure” OR failure OR complication OR migration OR infection

Additionally, reference lists of prominent systematic and literature reviews were manually searched to identify potential articles for inclusion. Eight out of 26 articles included following the deduplication.

### Study Selection

Following these three primary search methods, a total of 72 articles were identified: 53 articles from the manual keyword search, 11 articles from the MeSH term query, and 8 articles from the reference list screening of other relevant publications.

Initial screening of articles retrieved from the search strategy involved the assessment of titles and abstracts by 11 independent reviewers (UY, TN, JL, DL, RM, JD, DC, SY, AV, EC, SW), with approximately 6 articles assigned to each reviewer for the mention of spinal cord stimulation explantation. Subsequently, a thorough examination of full manuscripts was conducted for articles meeting the eligibility criteria (Table 1). Articles with unclear reasons for explanation or uncertain eligibility criteria were referred to the corresponding editor for further evaluation and resolution. Some studies included multiple articles reporting results from the same patient cohort at different follow-up periods. In such cases, only the publication with the longest follow-up period and most comprehensive data was selected for inclusion.

After this rigorous screening and evaluation process, a total of 31 articles were determined to meet the criteria for inclusion in our study. Six out of 31 articles were excluded for redundant data after accuracy review.

## Data Extraction

Following the screening and eligibility processes, 25 articles were selected for further analysis (Table 2).<sup>22–46</sup> Data extraction was carried out by 13 independent reviewers (BC, MC, NO, CF, SP, AP, UY, TN, DL, EC, JD, DC, SY), with a second reviewer ensuring accuracy. Discrepancies in decisions were referred to the corresponding editor for resolution.

The information extracted from the selected articles included author, year of publication, authors' institution, title of the article, type of study, number of study participants, participant demographics, study location, characteristics of the study (including study design, timeline, follow-up time, and cohort size), reason for explantation, number of replacements with the same vendor and different vendor, and key results. The reasons for explantation were detailed as follows: Lack of efficacy/loss of stimulation, Infection, lead high impedances, lead failure/migration, pain at IPG (Implantable Pulse Generator) site, IPG failure/migration, IPG charging problem, resolution of pain, repeat spine surgery, MRI requirement, and other reasons.

In some publications, the sum of explantations or revisions reported exceeded the number of individual patients due to multiple reoperations observed in certain patients. Furthermore, some studies detailed reasons for explantation where the total count of reasons surpassed the number of explantation procedures observed, with a note indicating multiple adverse events contributing to a single explantation.

## Results

This review summarizes the findings from twenty-five key studies examining failure rates, and complications associated with SCS procedures. These studies collectively cover data from 1984 to 2023 and involve single-center and multicenter approaches across the USA, Canada, and Europe.

### Study Characteristics

- **Study Types and Locations:** The studies include retrospective single-center and multicenter analyses and a prospective clinical trial. Sixteen studies were conducted in the USA, with two studies extending globally, and other involving centers in Canada, France, UK, Germany, Belgium, and the Netherlands (Table 3).
- **Patient Population:** The total number of patients who underwent SCS procedures across the studies ranges from 18 to 2737, with a mean age between 43–67.8 (Table 2).

## Key Findings

### Explantation Rates

Explantation rate was as low as 1.8% in Bendel et al study (2017)<sup>42</sup> and as high as 38% in Langford's study (2021)<sup>34</sup> (Table 2).

Hagedorn et al (2021)<sup>23</sup> reported an explantation rate for 10 kHz-SCS devices of approximately 10%, primarily due to inadequate pain relief and surgical complications. Similarly, Rauk et al (2023),<sup>24</sup> reported a 7.6% explantation rate primarily due to inadequate pain relief. In Patel's 2019 study<sup>14</sup> the main reasons for SCS removal were lack of efficacy and loss of stimulation. Van Buyten et al (2017)<sup>25</sup> observed a 19% rate of therapy-related explants (8% per year), mostly related to inadequate pain relief. Of 577 SCS implants in Rosenow's study (2006),<sup>26</sup> 7.9% were removed and 35.6% were revised. Chapman in 2022<sup>30</sup> studied 249 patients and 2% of them underwent explantation secondary to inadequate pain

**Table 2** Studies Included in the Review

Study	Study Design	Study Period	Study Location	Nu. of Perm. Imp. Procedures	Nu. of Exp. Procedures	Mean age	Index to Exp. Median Time (IQR)
Patel et al <sup>22</sup> (2019)	Retrospective - Single Center	2005–2013	USA	N/A	129	51	20 months (7.5–45.5)
Hagedorn et al <sup>23</sup> (2021)	Retrospective - Multicenter	2016–2019	USA	744	76 (10%)	67.9	N/A
Rauck et al <sup>24</sup> (2023)	Prospective (PCT) - Multicenter	2013–2021	Global	1289	98 (7%)	57.6	N/A
Van Buyten et al <sup>25</sup> (2017)	Retrospective - Multicenter	2010–2013	Europe*	955	180(18.8%)	53	N/A
Rosenow et al <sup>26</sup> (2006)	Retrospective - Single Center	1998–2002	USA	289	42 (14.5%)	43	N/A
Mekhail et al <sup>27</sup> (2011)	Retrospective - Single Center	2000–2005	USA	527	32 (6.1%)	46	N/A
Wolter et al <sup>28</sup> (2012)	Retrospective - Single Center	2001–2011	Germany	18	2 (11.1%)	54.4	N/A
Hunter et al <sup>29</sup> (2020)	Retrospective - Multicenter	Unspecified	USA	N/A	127	60	54 months
Chapman et al <sup>30</sup> (2022)	Retrospective - Multicenter	2016–2020	USA	249	10 (4%)	55	13 months (3–23)
Hines et al <sup>31</sup> (2022)	Retrospective - Single Center	2016–2020	USA	31	8 (25.8%)	N/A	9.3 months
Moeschler et al <sup>32</sup> (2015)	Retrospective - Case series	2001–2011	USA	199	33 (16.5%)	N/A	12 months (5–25)
Dupre et al <sup>33</sup> (2018)	Retrospective - Single Center	1997–2014	USA	595	165 (27.7%)	55	22 months (0–197)
Langford et al <sup>34</sup> (2021)	Retrospective - Single Center	2003–2018	USA	31	12 (38%)	52	40 months (1–140)
Kleiber et al <sup>35</sup> (2016)	Retrospective - Single Center	2002–2014	France	212	15 (7.1%)	51	11 months (0–122)
Stauss et al <sup>36</sup> (2019)	Retrospective - Database global	2014–2018	Global	1290	48 (3.7%)	N/A	N/A
Papadopoulos et al <sup>37</sup> (2023)	Retrospective - Single Center	2010–2020	USA	1014	51 (5%)	53	N/A
Nissen et al <sup>38</sup> (2019)	Retrospective - Single Center	1996–2014	Finland	175	45 (25.7%)	48	N/A
Hayek et al <sup>39</sup> (2015)	Retrospective - Multicenter	2007–2013	USA	234	56 (23.9%)	53.6	N/A
Pope et al <sup>40</sup> (2017)	Retrospective - Multicenter	2011–2016	USA	N/A	346	58	N/A
Kumar et al <sup>41</sup> (2006)	Retrospective - Single Center	1984–2006	Canada	328	10 (3%)	54	N/A
Bendel et al <sup>42</sup> (2017)	Retrospective - Multicenter	2007–2014	USA	2737	52 (1.8%)	N/A	N/A
Maldonado-Naranjo et al <sup>43</sup> (2018)	Retrospective - Single Center	2009–2016	USA	382	68 (17.8%)	51.9	N/A
Thomson et al <sup>44</sup> (2017)	Retrospective - Single Center	2008–2015	UK	298	20 (6.7%)	58	N/A
Simopoulos et al <sup>45</sup> (2019)	Retrospective - Single Center	2002–2015	USA	252	75 (29.7%)	48.7	N/A
Al-Kaisy et al <sup>46</sup> (2020)	Retrospective - Single Center	2008–2019	UK	1177	182 (15.4%)	48.6	N/A

**Notes:** \*Germany, Belgium, Netherlands.

**Abbreviations:** Nu, Number; Exp, Explantation; Imp, Implantation; Perm, Permanent.

**Table 3** Study Summary

Variables	Values
Number of Included Studies	25
Study Design	
Prospective	1 (4%)
Retrospective	24 (96%)
Study Location	
USA	16 (64%)
Canada	1 (4%)
Europe	6 (24%)
Mixed/Worldwide	2 (8%)
Study Interval	1984–2023
Sample Size	
Patients who got permanent implant	13026 (based on 22 studies)*
Patient who underwent explantation	1882 (based on 25 studies)
Explant Rate	9.82% (1280/13,026)**

**Notes:** \*Permanent implantation number was not given in 3 studies. \*\*Based on publications reporting both permanent implantations and explantations.

relief. In Hines' study in 2021<sup>31</sup> with 31 patients, 26% had explantation surgery. Among 199 implants in Moeschler's study (2015),<sup>32</sup> 33 devices were explanted, representing a 17% explantation rate.

### Removal Reasons and Complications

The literature reports various reasons for the removal of spinal cord stimulators, with the most common being lack of efficacy and inadequate pain relief. Other frequently cited reasons include infection, lead migration or failure, pain at the IPG site, and IPG failure or migration, as detailed in Table 4. While most studies did not extensively discuss post-operative complications, some did report infection rates and general complications. For instance, Patel et al (2019)<sup>22</sup> noted that 129 patients required reoperation due to various complications, with 15 experiencing postoperative complications. Kleiber et al<sup>35</sup> documented postoperative complications in 74 out of 212 patients (34.9%). Additionally, Maldonado-Naranjo et al<sup>43</sup> reported postoperative adverse events in 8 out of 382 patients (2.1%).

### Revised or Re-Implanted SCS

Some studies discussed the explantation of SCS systems but also detailed their associated revision procedures. In particular, revisions were highlighted due to battery failure or charging issues, which led to IPG changes, and IPG relocations prompted by site pain or discomfort. Moreover, revisions involving electrode replacements due to hardware (lead, wire, IPG) failures were nearly as prevalent as explantations and, in some publications, even more common. In the study by Mekhail et al<sup>27</sup> 50 cases required revision due to connection failures, compared to 32 cases of explantation. Similarly, Wolter et al<sup>28</sup> documented that two patients required an IPG change due to battery discharge (after 4 and 9 years, respectively), and one patient needed an IPG relocation. Furthermore, Papadopoulos et al<sup>37</sup> reported six cases of SCS replacement due to malfunctioning, along with 31 cases of SCS replacement or repositioning due to inadequate pain coverage. Eight studies discussing revision surgeries have explicitly reported the number of permanent implant and revision procedures. Based on these studies, a total of 1784 patients with permanent implants underwent 591 (33.1%) revision surgeries (Table 5).



**Table 4** Reasons for SCS Explanation

Study	LoE / LoS	Infection	Lead: High Impedance	Lead Failure/ Migration	Insulating Damage	Lead Breakage	Pain at IPG Site	IPG Failure/ Migration	IPG Charge Problem	Pain Free	Repeat Spine Surgery	MRI Need	Other
Patel <sup>22</sup>	104	18	0	18	0	0	0	0	0	0	0	0	2
Hagedorn <sup>23</sup>	39	16	0	0	0	0	8	0	0	4	5	0	4
Rauck <sup>24</sup>	32	30	69	65	0	0	12	16	14	0	0	0	17
Van Buyten <sup>25</sup>	94	46	0	6	0	0	4	22	0	3	0	3	2
Rosenow <sup>26</sup>	59	18	0	50	0	39	0	0	0	0	0	0	0
Mekhail <sup>27</sup>	50	32	0	119	0	33	86	0	0	0	0	0	0
Wolter <sup>28</sup>	0	0	0	5	0	5	4	0	2	1	0	0	1
Hunter <sup>29</sup>	127	0	0	0	0	0	0	0	0	0	0	0	0
Chapman <sup>30</sup>	6	1	0	2	0	0	0	0	0	1	0	0	0
Hines <sup>31</sup>	5	2	7	2	0	0	3	0	0	0	0	0	0
Moeschler <sup>32</sup>	5	3	0	6	0	0	5	1	0	5	1	4	7
Dupre <sup>33</sup>	121	15	0	0	0	0	36	0	0	7	0	16	28
Langford <sup>34</sup>	2	2	0	1	0	0	1	0	1	3	0	0	2
Kleiber <sup>35</sup>	8	8	0	3	0	8	0	0	2	0	2	0	0
Stauss <sup>36</sup>	15	22	0	0	0	0	0	0	0	0	0	0	11
Papadopoulos <sup>37</sup>	31	30	0	31	0	7	19	0	0	0	0	0	6
Nissen <sup>38</sup>	34	7	0	3	0	0	4	0	3	3	0	0	0
Hayek <sup>39</sup>	23	10	6	20	0	9	0	28	0	0	1	4	2
Pope <sup>40</sup>	152	0	0	16	0	0	0	0	0	21	0	67	70
Kumar <sup>41</sup>	0	14	20	88	9	24	5	3	0	0	0	0	6
Bendel <sup>42</sup>	0	67	0	0	0	0	0	0	0	0	0	0	0
Maldonado <sup>43</sup>	49	9	0	0	0	0	0	0	0	0	0	6	4
Thomson <sup>44</sup>	6	7	0	0	0	0	0	1	0	2	0	0	0
Simopoulos <sup>45</sup>	21	20	0	1	0	0	5	0	1	4	0	2	21
Al-Kaisy <sup>46</sup>	119	31	0	0	0	0	5	0	0	7	0	17	3
<b>TOTAL (n) (%)</b>	<b>1102 (38.3%)</b>	<b>408 (14.2%)</b>	<b>102 (3.5%)</b>	<b>436 (15.2%)</b>	<b>9 (0.3%)</b>	<b>125 (4.3%)</b>	<b>197 (6.9%)</b>	<b>71 (2.5%)</b>	<b>23 (0.8%)</b>	<b>61 (2.1%)</b>	<b>9 (0.3%)</b>	<b>119 (4.1%)</b>	<b>186 (6.5%)</b>

**Notes:** The total number of reported reasons was observed to exceed the number of explantation procedures. This was attributed in the articles to instances where a single explantation surgery for a patient was driven by multiple reasons. The rates of reasons were calculated based on the total number of reported reasons.

**Abbreviations:** IPG, Implantable Pulse Generator; LoE, Lack of Efficacy; LoS, Loss of Stimulation.



**Table 5** Studies Reporting Revision Surgeries

Study	Nu. of Perm. Implantation	Nu. of Total Reoperation	Nu. of Revision	Nu. of Explantation	Outcomes/Details
Rosenow et al <sup>26</sup>	289	246 (85.1%)	204 (70.6%)	42 (14.5%)	Out of 289 patients, 204 underwent revision surgery, and 42 required implant removal. Overall, 133 patients (46%) needed at least one revision of their spinal cord stimulation (SCS) system
Mekhail et al <sup>27</sup>	527	234 (44.4%)	202 (38.3%)	32 (6.1%)	Among the patients who underwent revision, lead migration was observed in 119 cases (22.6%). Additionally, lead connection failure occurred in 50 cases (9.5%), and lead break was reported in 33 cases (6%)
Wolter et al <sup>28</sup>	18	16 (88.9%)	14 (77.8%)	2 (11.1%)	For revision surgeries, 2 patients required an IPG change due to battery discharge (after 4 and 9 years) and one patient required IPG relocation due to pain at the pocket site. Other revisions included IPG revision and lead revision due to electrode breakage/dislocation.
Hines et al <sup>31</sup>	31	18 (58.1%)	10 (32.3%)	8 (25.8%)	Revisions were performed in 7 cases due to electrode breakage, in 2 cases due to hardware migration, and in 1 case due to IPG site irritation
Kleiber et al <sup>35</sup>	212	31 (14.6%)	16 (7.6%)	15 (7.1%)	Revisions included 8 lead replacements due to lead breakage, 2 drainage procedures with IPG relocation due to pulse generator site infection, 3 lead relocations due to misplacement, and 2 IPG relocations because the devices were deeply.
Papadopoulos et al <sup>37</sup>	1014	175 (17.2%)	N/A	51 (5%)	Reoperations related to spinal cord stimulators included SCS replacement/repositioning in 31 cases due to inadequate pain coverage caused by lead migration/misplacement and SCS replacement in 6 cases due to malfunctioning SCS, and SCS removal was conducted for 32 patients due to LoE.
Nissen et al <sup>38</sup>	175	N/A	70 (40%)	45 (25.7%)	A total of 70 revisions and 45 explantations were performed in 64 patients. However, the sum of these values does not accurately represent the total number of reoperations
Hayek et al <sup>39</sup>	234	112 (47.9%)	56 (23.9%)	56 (23.9%)	Most revisions were attributed to IPG site discomfort or migration, accounting for 12% of cases. Indications for revision included IPG discomfort/migration (18 cases), lead migration (18 cases), LoE (9 cases), lead fracture/malfunction (7 cases), IPG malfunction (2 cases), and wound dehiscence or seroma formation (2 cases).
Kumar et al <sup>41</sup>	328	164 (50%)	N/A	10 (3%)	A total of 40 leads were repositioned and 48 replaced due to electrode displacement. Additionally, 24 leads were replaced for breakage, 20 for high impedances, and 4 for electrical leaks. Nine leads were replaced due to insulating damage, and 8 IPGs were repositioned for discomfort.
Thomson et al <sup>44</sup>	298	39 (13.1%)	19 (6.4%)	20 (6.7%)	In this study, there were 13 lead revisions, 6 IPG pocket revisions, and a total of 20 explantations performed.

**Abbreviations:** IPG, Implantable Pulse Generator; LoE, Lack of Efficacy; SCS, Spinal Cord Stimulator; Nu, Number; Perm, Permanent.

### Duration Between SCS Implantation and Explantation

Only 8 out of 25 studies provided the average duration until the explantation procedure, with the reported duration varying from 9.3 months to 54 months (Table 2). Some studies additionally noted explantation rates by year, with the majority of procedures occurring in the first and second years following initial implantation. Hagedorn et al (2021)<sup>23</sup> reported on the timing and rates of explantation, finding that most explants (40/76; 52.6%) occurred during the first year after implantation. By the second year, the rate of explants decreased to 23.7% (18/76), and this further declined to 15.8% (12/76) in the third year and 7.9% (6/76) in the fourth year.

## Device and Vendor Replacement

The vast majority of patients who underwent replacement surgery were replaced with the same vendor SCS system. Notably, replacements with different vendors were minimal, suggesting brand loyalty or limited alternatives.

However, Hunter et al (2020)<sup>29</sup> investigated SCS waveform rotation in reversing lack of efficacy. In one cohort, patients underwent surgical revision of their existing SCS platforms to enable the transmission of the D-Burst waveform, either by modifying the IPG with adaptors or by replacing both the IPG and leads. Another cohort required only reprogramming to initiate the transmission of D-Burst (D-Burst On). He demonstrated that waveform modification salvaged SCS as therapy for the patients in his study.

## Safety

The prospective study by Rauck et al (2023)<sup>24</sup> demonstrated the long-term safety of SCS systems, with adverse events primarily related to technical failures rather than biological reactions. Other studies echoed these findings, emphasizing that while technical failures are prevalent, serious adverse events are relatively rare.<sup>22–46</sup>

Overall, these studies indicate that while SCS is generally effective, there are significant challenges related to device longevity and patient satisfaction primarily due to diminished efficacy of the original SCS waveform. Explantation rates due to lack of efficacy are the most common reason for explantation. Device related challenges are relatively uncommon but remain an important reason for device failure.

## Discussion

Spinal cord stimulation is a widely used technology to treat recalcitrant chronic pain which has demonstrated efficacy in some of the most challenging clinical scenarios. There is robust evidence supporting its use in the management of several different pain disorders. However, the long-term efficacy of the procedure has been recently debated. The issue to consider is whether the cost of the device is worthwhile considering the overall success of therapy and potential reduction in health care utilization. The cost of an SCS implant can range between \$35,000-\$70,000 and repeat surgeries to regain efficacy can cost another \$15-25K per patient. Therefore, the viability of the SCS industry may rest on the ability to achieve long-term outcomes. Here, the authors reviewed the literature and confirmed habituation as the main reason for SCS failure in order to spur pain neuromodulation innovation and revitalize the industry.

In this systematic review examining the post-operative outcomes of SCS, explantation rates varied between 1.8 to 38% among various studies. Inadequate pain relief was consistently highlighted as the primary cause in nearly every study reviewed. Many patients underwent removal of their device within the first one to two years with a reported range of 9 to 54 months to explant. More than half of explants occurred within the first year. Explantation rates declined each consecutive year afterward, suggesting that patient selection or physician performance may also play a role. Despite the rate of reoperation, SCS is a safe procedure. The most common cause of SCS revision surgeries other than lack of efficacy included device migration, pain at the IPG site, and system replacement. However, these revision surgeries may suggest SCS efficacy because the patient would have had the device removed otherwise. Infection and hardware rejection were uncommon.

The current industry model is heavily hardware dependent, permitting the use of waveforms only compatible with the implanted devices, limiting patient treatment options. Waveform innovation directed toward spinal cord gray matter neurons and synaptic molecules may improve durability and outcomes. Therefore, continued investment into waveform development by independent and corporate partners is needed. Most SCS companies will attempt to reprogram patients, offering different energy options, sometimes blending their proprietary waveforms, to salvage patient satisfaction. Currently, most device companies can only offer a limited number of therapeutic options due to the restrictions of the hardware and software, as well as regulatory hurdles. Responders to SCS therapy are identified during the trial phase when they are waveform-naïve but may later develop tolerance to the trialed therapy. Currently, most physicians do not have the option of selecting different waveforms from different vendors during the trial, so they do not know if they are choosing the optimal waveform for their patient. A typical SCS trial duration is 3–10 days for most practitioners in the United States and may not offer enough time for a patient to appreciate the efficacy of the trialed system. There is growing evidence that different waveforms may be preferred for specific pain conditions. In our review Hunter et al<sup>29</sup>

implanted a burst waveform delivery system for patients who failed ultra-high frequency and did demonstrate improvement in pain, suggesting that waveform modification can improve symptoms. Waveform switching/cycling has also been documented as superior over singular therapy by other authors.<sup>47–49</sup> We submit that more research is needed to evaluate the effect of multiple and combined waveform therapy to determine if it improves outcomes and decreases revision surgery. Therefore, there is utility in creating practice guidelines which direct waveform selection based on individualized patient criteria such as medical history, anatomy, physiology, psychology, and activity level. A future innovation may be the use of artificial intelligence toward this endeavor.

The durability of automated closed-loop and surround inhibition paradigms are on the horizon. However, they were not evaluated as part of this systematic analysis because they are newer generation products with limited long-term evidence. Preliminary data suggests that they may not be subject to habituation to the same degree as older generation products.<sup>19,50</sup> Current closed-loop technology modulates tonic waveforms via Evoked Compound Action Potentials (ECAPs) to deliver consistent stimulation to the axons of the dorsal columns; however, an innovation in this space may be to create constant delivery to the other cell lines in the spinal cord such as wide dynamic neurons and oligodendrocytes which are thought to produce clinical effect as well.<sup>51,52</sup>

Comorbid depression, anxiety, sleep deprivation, post-traumatic stress, and sleeping disorders are known to have a limited response to SCS and can skew durability data. The authors submit that better physician education around chronic pain psychology is required to target these patients for implant appropriateness. Though psychiatric evaluations are the standard of care for selecting patients for SCS trial appropriateness, they have not demonstrated to change SCS explantation rates. Patel et al reported association between early SCS explantation and the presence of depression and anxiety, emphasizing the impact of psychological factors on SCS outcomes. A potential innovation to temper fluctuating maladaptive mood and behavioral challenges in patients with SCS may be to integrate bidirectional wearable devices such as a watch or phone which monitor physiology as a function of mood and subsequently execute a command to calm a patient who is having a pain or emotional crisis. Additionally, SCS devices may be configured to work with other neuromodulation devices, such as hypoglossal, vagal stimulators, or deep brain stimulation to modify sleep or mood. Seamless integration of SCS neuromodulation with other devices known to affect behavior may also improve SCS patient satisfaction.

Several articles included in this study mentioned post-operative complications, but did not specifically share details surrounding these complications.<sup>22,24,35,39,43</sup> It will remain important that future SCS studies include more widespread post-operative outcomes as this awareness will spur innovation from understanding.

Despite the challenges reported in this paper the superiority of neuromodulation as salvage therapy over other treatments in chronic pain patients has not been widely criticized. Millions of patients worldwide are benefactors of this treatment modality; however, the durability is debated and is highlighted by our review. Unfortunately, there is growing literature focusing on SCS limitations primarily due to the rate of explanation and revision. Insurance carriers have used this information to deny or reduce payment, and there is concern amongst SCS implanters in the community that this may lead to the demise of the field.<sup>53–55</sup>

The authors submit that for there to be an enlightenment of SCS a revised industry thought model may be needed to propel innovation. Continued dedication to waveform design, closed-loop sub perception innovation, improved physician education for SCS patient selection, guidelines for pairing technology with pathology, and integration of neuromodulation devices to limit catastrophizing may be ways to improve the patient experience. The ideas here represent ideas for future investigation but require an abundance of research to actualize their conception.

Limitations to this study are present. Firstly, the initial screening involved a review of journals and abstracts from independent reviewers. Opinion and bias are inevitably inherent, but these were minimized by consistently referring to the eligibility criteria outlined in Table 1. Secondly, some patients underwent multiple reoperations and revisions following the initial SCS implantation. This makes the analysis of post-operative complications, such as infection rates, more complex.

All in all, the discussion regarding spinal cord stimulator removals and revisions is multifaceted. Although there remains work to be done in perfecting this treatment modality, our team is hopeful that changes made to spinal cord stimulators will offer improved pain relief to millions of patients globally.

## Conclusion

SCS is an effective treatment for a range of chronic pain conditions, but the therapy requires better durability data to withstand criticism from payers if we hope to preserve this treatment for future generations. The recent expansion of SCS therapy waveforms provides patients with several options for pain relief, but the industry still lacks the ability to deliver all available energy formats to every patient with an SCS device, limiting the potential for maximizing outcomes. Our results suggest that tolerance is the most common reason for SCS explantation, which aligns with the conclusions of other reports. However, the industry has yet to develop a solution to this problem. One potential solution may be a shift toward an application-based software commercial model. The integration of artificial intelligence and physiological monitoring could also lead to more patient-specific energy delivery, maximizing patient benefit.

## Abbreviations

SCS, Spinal Cord Stimulation; IPG, Implantable Pulse Generator; LoE, Lack of Efficacy; LoS, Loss of Stimulation; ECAPs, Evoked Compound Action Potentials.

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Disclosure

Dr. Wahezi receives research funding from Boston Scientific, Abbott, and Vertos. He is also a consultant for Boston Scientific. He reports patents 11,964,153, 12,138,454 and 12,138,455 issued. Dr. Deer is a consultant for Abbott, SpineThera, Biotronik, Saluda, and Boston Scientific (relevant). He also consults with SPR, Nervonik, Painteq, Cornorloc, Spinal Simplicity and Aurora. He reports a pending patent for Abbott. Dr. Pritzlaff is a consultant for SPR Therapeutics, Nalu Medical, Bioventus, royalties from Wolters Kluwer and receives educational grants from Medtronic, Abbott, Biotronik, and Nevro. Dr. Schatman is a senior medical advisor for Apurano Pharma. Dr. Hunter is a consultant for Abbott, Saluda, Biotronik, and Mainstay. All other authors declare that they have no known competing interests or personal relationships that could have appeared to influence the work reported in this paper.

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