Prospective Study

Patient Experience with Open-Loop Spinal Cord Stimulation Devices Across Manufacturers and Waveforms: Results of a Double-Blind Survey

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Background: Spinal cord stimulation (SCS) is an established, efficacious therapy for chronic neuropathic pain. SCS therapy has the unique challenge of variability in the amount of applied stimulation that reaches the cord as it moves within the spinal canal during the patient's activities of daily living (ADLs). This variability is experienced by the patient as transient instances of overly strong (i.e., overstimulation) or overly weak (i.e., understimulation) therapy when the person changes their posture. While patients report a high degree of satisfaction with the pain reduction and quality-of-life improvement from this therapy, they make manual adjustments to the programmed settings, including turning the amplitude up, down or off, to avoid these events.

Objective: This study was undertaken to understand patients' experiences with the current generation of open-loop (OL) SCS devices and what innovations would be meaningful to those patients.

Study Design: The study was a prospective, double-blind survey of a representative sample of SCS patients.

Setting: The study was executed by a third-party vendor as a 20-minute electronic survey.

Methods: Patients were recruited from the database of another market research vendor and screened via email or phone. Eligibility was determined based on screening questions, including location of implant, manufacturer, time since implant, and location of pain. Consent was obtained prior to participation, and patients were compensated for their time. The questions were tested prior to being administered to the patients in a separate cohort for ease of understanding and adequacy of choices.

Results: One hundred patients representative of the SCS population provided responses to this survey; the patients were implanted with devices manufactured by Medtronic (33%), Nevro (28%), Boston Scientific (24%), and Abbott (15%). Over 80% of patients were being treated for low-back pain with or without leg pain.

Regardless of whether the patient was programmed to receive sub- or supra-perception therapy, 58% reported experiencing overstimulation, and 46% reported understimulation as they engaged in ADLs. Most of the patients (85%) reported avoiding one or more ADLs, and 70% reported increasing or decreasing the level of therapy proactively to avoid those side effects, resulting in a significant burden of device management. Over 80% of patients expressed being satisfied or very satisfied with the pain relief provided by the devices and technology.

Limitations: This study has the inherent limitations of a direct-to-patient survey design, including subjective interpretation of the questions without a complete understanding of the relative merits of different waveforms or devices (e.g., MRI conditionality).

Conclusion: Patients report a high degree of satisfaction with SCS therapy for chronic pain regardless of the years since their implants. The data from this survey suggest opportunities for

further innovation, especially attempts to minimize the side effects of therapy, reduce the burden of device management, and offer a more automatic and seamless experience. Novel closed-loop SCS systems have been demonstrated to be effective in reducing therapy side effects and ensuring consistent dosing as patients engage in ADLs. More evidence from long-term follow-up on patients implanted with closed-loop SCS systems is necessary to understand the overall benefits for SCS patients

Key words: fixed-amplitude SCS, Double Blind Survey, Activity Avoidance, Burden of Therapy Adjustment, Loss of SCS Therapy Efficacy, MRI access

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Spinal cord stimulation (SCS) is an established treatment for chronic neuropathic pain, demonstrating efficacy, safety, and cost-effectiveness. The dynamic movement of the spinal cord within the spinal canal during daily activities poses a unique challenge, causing variability in the energy that reaches the spinal cord. Studies indicate up to a 30% difference in perception thresholds between supine and upright positions, leading to a varying dose of therapy (1-6).

Movement of the spinal cord results in varying amounts of stimulation. Depending on the lead-to-cord distance, patients may experience the results as overstimulation or as inadequate pain relief due to understimulation; these events typically occur during certain activities of daily living (ADLs) (e.g., household chores, exercise, etc.). This reality of dynamic changes in stimulation may not be emphasized by practitioners during the pre-procedure phase of the SCS treatment continuum. The varying stimulation amounts may come as a surprise to patients during the trial period or even after permanent implantation of the device. Patients accept inconsistent stimulation as part of the therapy and may not mention the issue after the system is implanted.

Patients may manage these events by making proactive or reactive adjustments with their patient programmer (7) or opt to lower the therapy intensity altogether to avoid sudden uncomfortable stimulation. These manual adjustments may lead to a significant burden of therapy management. Older-generation SCS devices that relied on conventional SCS therapy (e.g., use of paresthesia for pain relief) showed a decline in patient controller use over time (8). More recently, a randomized controlled trial showed that patients who used conventional open-loop (OL) therapy were below their prescribed therapy level by a median of 49.3% [interquartile range: 22.7 – 74.1] of the time (9). In contrast, the patients who used closed-loop (CL) SCS maintained consistent dosing, within a "therapy window," 94.9% of the time, resulting in higher pain reduction rates (9).

Modern SCS therapies with newer waveforms aim to reduce the problem of overstimulation by using lower amplitudes below the perception threshold (10-13). Despite these advancements, overstimulation remains a concern across all SCS therapies. Sensations resulting from high amplitudes in patients using 10 kHz programming have been reported as "tightness" and "pressure" (14). Like patients using low-frequency SCS, patients using these newer waveforms and higher frequencies may experience uncomfortable sensations, causing them to lower therapy amplitudes to a chronic "underdosed" state. Underdosing, which is more difficult to detect than overstimulation, can manifest as inadequate pain relief and reduced therapy efficacy, prompting some patients to request device explants.

The survey was undertaken to evaluate the role of closed-loop SCS as a potential solution to some of the challenges associated with current generation devices that are known in clinical practice. Among these challenges are the need for frequent reprogramming, activity avoidance or other adaptive behaviors, incidences of under- and/or overstimulation, and manual adjustment to therapy settings; notably, van Buyten et al (8) have previously described these problems with providing paresthesia-based therapy through conventional SCS. Some of these events may not be reported with fidelity due to their frequency and/or the patients' choice to adopt strategies to work around them. For that reason, the present study was intentionally designed as a direct-to-patient survey to capture the scope and burden of those issues. Here, we summarize patients' experiences in a survey of a representative sample of chronic pain patients implanted with OL SCS devices within the last 10 years.

Methods

Study Design and Objectives

The study was a prospective, double-blind survey

of a representative sample of SCS patients to better understand and highlight the day-to-day experiences of patients implanted with SCS devices and identify opportunities for technological improvements. The survey was developed by a third-party vendor (StrataMark LLC) in partnership with the sponsor (Medtronic plc). It was reviewed by subject matter experts familiar with medical market research (e.g., programmers, statisticians, etc.) by the vendor and M3, Inc. that programmed the survey, to ensure the effectiveness and completability of the survey. The survey was pre-tested in blinded, one-on-one telephone and screen sharing interviews with potential participants who met the screening criteria to check the clarity of the questions, the adequacy of the choices of responses, and appropriateness of the language for the audience; duration of the survey was short enough to minimize dropouts and completeness of answer sets. The programmed survey was further tested to ensure the instrument was robust enough to be completed in a variety of ways (i.e., different combinations of responses) and could capture complete data. The categories of questions included in the survey are described further in Table 1.

Setting

The survey was administered between June and July 2023 as a 20-minute, multiple-choice, Web-based questionnaire. A direct-to-patient approach was adopted to understand the patients' day-to-day experience with their SCS devices and any limitations they may experience with their ADLs due to the therapy or device. The survey was administered by the vendor to patients who had been screened by M3, Inc (see Patient Recruitment section below). As a result, the survey was blinded to the patients' characteristics and specific device implant details, ensuring unbiased data collection. Additionally, patients were blinded to the study sponsor to further minimize potential response bias.

Patient Recruitment

Patients were recruited by the vendor from the database of M3, Inc., a US-based market research agency, which maintains "ISO20252 – Market, opinion and social research, including insights and data analytics: Vocabulary and service requirements" and "ISO 27001 – Information security, cybersecurity and privacy protection — Information security management systems — Requirements" certifications and is in compliance with all other applicable market research standards (e.g., the Informed Consent and Sunshine Acts in the US). M3 identified potential participants and evaluated their eligibility using the screening questions listed below, via email or telephone. Patients consented to participate in the research and were compensated for their time according to fair market value. Eligibility criteria included year of birth (1933 or later), geography (for sample distribution), diagnosis indicated for SCS, location of pain, current SCS status, year and location of implant (to screen out fraud), manufacturer (for sample distribution), confirmation that the patient had an SCS device based on images and device description, type of pain treated (to make sure that the patient was indicated for SCS per labeling), and recharge frequency (for sample distribution).

Data Collection and Analysis

The goal was to gather 100 complete data sets that had been programmatically screened by M3, Inc. to ensure that the survey was not completed by bots or other fraudulent agents before being provided to the vendor. Screening criteria included too short of a response time, an overly short duration of implant,

Table 1. *Domains sampled in patient surveys. The questions focused on the patient experience, including overall satisfaction, pain control, frequency of adjustments, company representative support, and interest in further innovation.*

Category	Variables
Screening/eligibility	Diagnosis, presence of SCS device, manufacturer, device location, current age, years with device, rechargeable/ or non-rechargeable device
Device selection and satisfaction	Patient role in selection, satisfaction with pain control and other aspects of the device
Daily experience with the device	Incidence of transient instances of discomfort due to the stimulation and/or periods of inadequate pain control during certain activities or postures
Device management	Frequency of contact with reps and HCPs as well as triggers for contacting others about the device
Patient handheld device (remote) use	Frequency of using the remote, triggers for turning device up or down and on or off, and effectiveness of actions taken with the remote
MRI experience	Need for MRI, ability to obtain MRI
Interest in further innovation	Interest in a range of innovations impacting the patient-device interface

flat responses – e.g., selecting the same response to all questions (such as agreeing or disagreeing with every query), and inappropriate responses to open text fields. Furthermore, the survey had additional built-in checks based on the responses to the aforementioned eligibility questions to ensure the patient was in fact implanted with an SCS device for the treatment of chronic pain. Responses are summarized as percentages and number of patients; respondents were able to select multiple responses to certain questions, and this is indicated when applicable. The vendor performed the survey data analysis and was further validated by 2 independent sponsor reviewers.

Results

Demographics and Baseline Characteristics

The survey included 100 patients with a mix of OL SCS devices for the treatment of chronic pain (> 90% had back/leg pain) residing in the United States. Sixty-eight percent of the survey participants had been implanted with their devices 2-10 years ago. The average age of the patients was 48.2 (SD 11.0), and 82% were between 31 and 60 years of age. The proportion of SCS patients who chose their devices from a list of options was approximately equal to those whose devices were selected by clinicians (43% vs. 44%); 12 patients reported, "I asked my doctor for a specific stimulator, and my doctor gave me that stimulator" (12%). Patients were implanted with devices manufactured by Medtronic (33%), Nevro (28%), Boston Scientific (24%), and Abbott (15%).

Since the survey was completed by the patients (without their pain physicians), the determination of waveform type, sub- or supra-perception, was made based on their responses to the question (14.1) "How often do you feel buzzing or tingling from your stimulator?" Nineteen (19%) patients responded "always/almost always" to this question. They were categorized as experiencing "paresthesia-based" programming (also known as supra-perception therapy), and the rest were sorted into the sub-perception group. Other baseline characteristics are summarized in Fig. 1.

Patient Experiences During ADLs

Questions 7 and 8 were intended to ask whether the SCS device provided adequate pain relief or had changed over time and if the patients experienced any discomfort during their ADLs. Regardless of the waveform type they experienced, over 50% of the respondents reported unwanted shocking/jolting/tingling (i.e., overstimulation) and/or inadequate pain relief (i.e., understimulation) during certain activities or body positions (Fig. 2).

To gain a further understanding of the impact of these transient instances of over- or understimulation, questions 9-12 probed how the patients managed therapy (e.g., making proactive/reactive device adjustments and avoiding certain movements [Fig. 3]) and what limitations these events imposed on their ADLs (Fig. 4). Patients adjusted therapy up/down/off (58%) and avoided one or more ADLs/postures (85%), and/or 45% assumed rescue positions (e.g., lying down) when they experienced a pain flare.

Burden of Proactive or Reactive Management of Device

In addition to the reactive management of the device when the transient over- or under-stimulation events occurred, 7 out of 10 patients reported proactively turning their stimulators up/down, and half of the respondents made adjustments from a "few times a week to 5+ times per day." A third of the patients reported visiting their clinics 3 or more times in the last year for reprogramming, and over 60% reached out frequently (weekly to every few months) to their representatives for reprogramming or other technical support. The reasons for needing support are summarized in Fig. 5. Most patients (85%) responded that they "would be somewhat or very interested in a solution that [was] self-adjusting to automatically give strong pain control when needed while avoiding shocks/jolts."

Other Considerations

Chronic pain patients may have other comorbidities, including cancer, cardiovascular or metabolic diseases, and even progressive spinal pathologies. Questions 29 and 30 explored the need for magnetic resonance imaging (MRI) and whether the patient was able to get the required imaging or was denied it due to the presence of the SCS device. The number of patients who responded yes to the question "Has a physician told you that you needed to get an MRI in the time since you received your stimulator?" was similar to the number who responded no (49% vs. 51%). Of the 49% who needed an MRI, 18% (9/49) were unable to get the scan due to the presence of the stimulator.

Satisfaction with SCS Therapy

However, despite those transient periods of

discomfort or inadequate pain relief, 83% of patients (n = 93 more than one year since implant) were "very/somewhat satisfied" with their SCS devices (range by manufacturer: 74-90 %), and 87% reported sustained pain relief ("about the same/little better/much better") in response to the question "How is your pain relief now compared to the relief our stimulator provided the first year after you received your stimulator?" The responses to this question were consistent with the satisfaction with overall (84%), short-term (over the course of a day: 85%), and long-term (months/years: 77%) pain control provided by their device (questions 2.3-2.5).

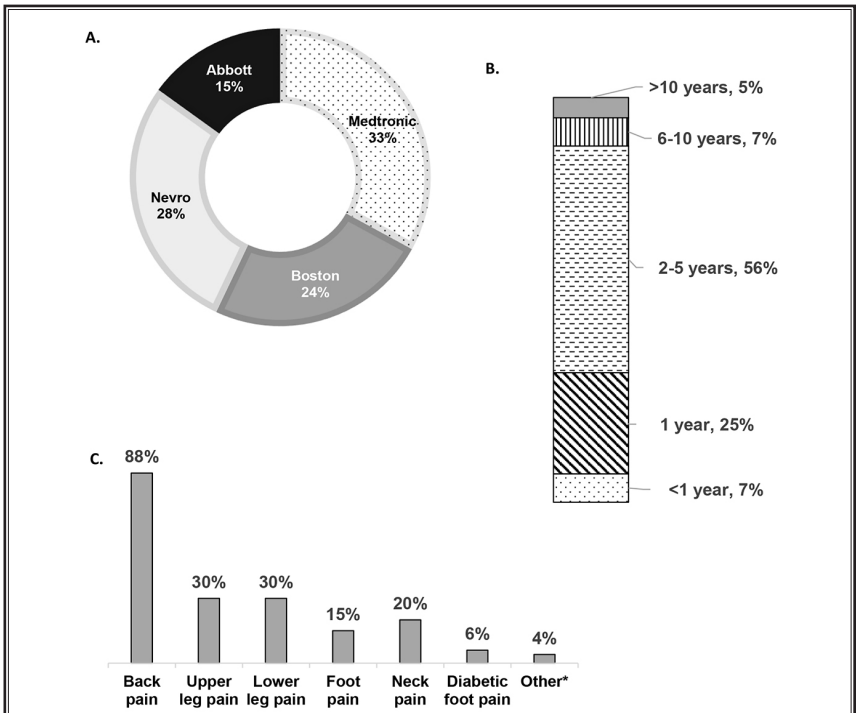

Fig. 1. *Baseline characteristics of survey responders. A) Most of the SCS device manufacturers were represented in the sampled data. B) Years since SCS device implant. C) Majority of the patients were being treated with SCS for chronic back and/or leg pain.*
*Other includes one instance each of neuropathy, other foot pain, stomach pain, and pelvic pain. Subjects were able to choose more than one location of pain.

Discussion

Several new waveforms across manufacturers have all demonstrated significant and sustained reductions in pain, health-related quality-of-life benefits, and cost-effectiveness (9,10,15-21). The outcomes of this survey suggest that while patients are satisfied with the overall pain relief SCS provides, there are opportunities to improve the day-to-day experience further. Half of the respondents expressed making frequent adjustments to the device, and a third of the patients visited their clinics 3 or more times a year for reprogramming. Over 80% of patients expressed interest in devices that would be self-adjusting while providing adequate pain control and avoiding very strong stimulation.

SCS therapy manufacturers first addressed the overstimulation issue by providing patients with patient programmers. The programmer allows the patient to make their own programming adjustments, offering a way to address the variability in stimulation

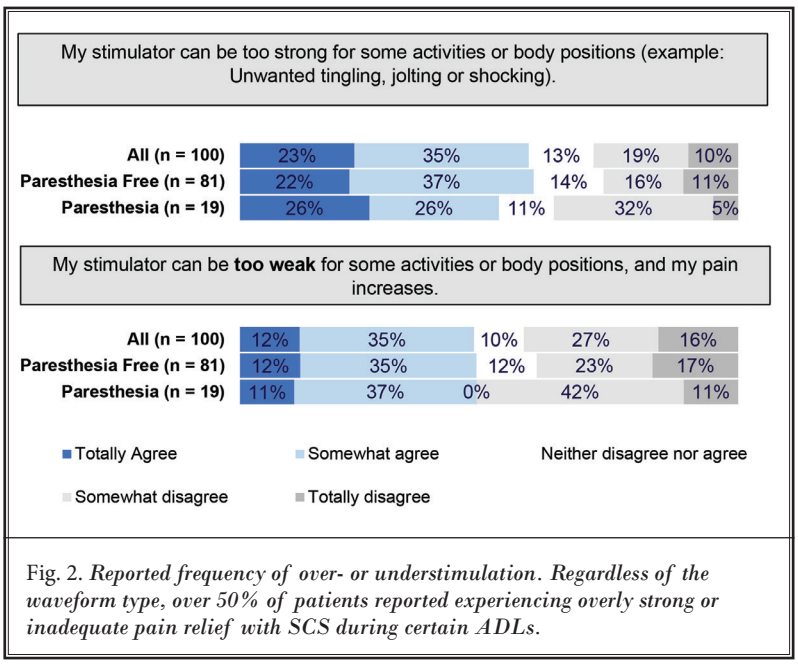

Fig. 2. *Reported frequency of over- or understimulation. Regardless of the waveform type, over 50% of patients reported experiencing overly strong or inadequate pain relief with SCS during certain ADLs.*

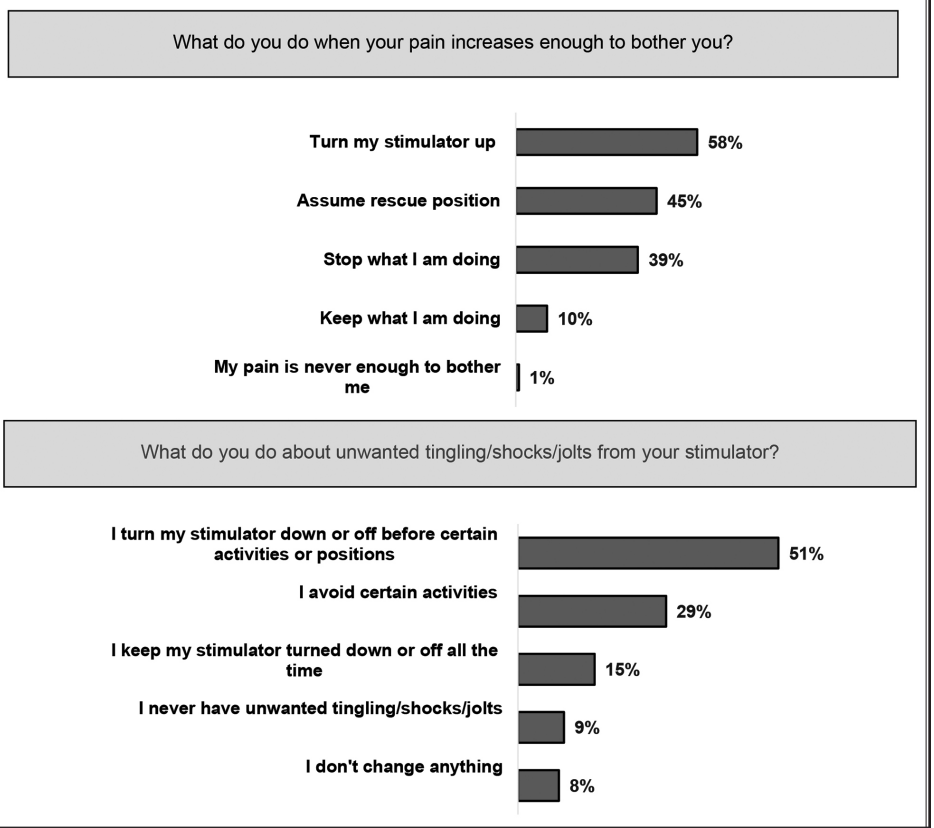

Fig. 3. *Patient-reported strategies for managing increases in pain (top) and unwanted stimulation (bottom). Changing the stimulation intensity and modifying activities were the most employed strategies in both situations. Patients were able to choose more than one option.*

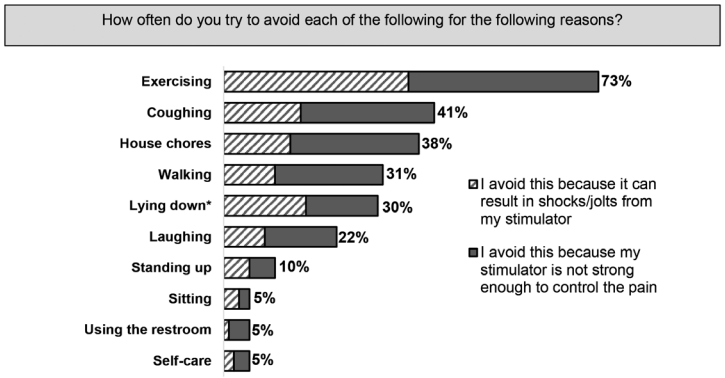

Fig. 4. *Classification of activities avoided secondary to over- or understimulation. Eighty-five percent of patients reported avoiding one or more ADLs due to fear of being shocked/jolted or experiencing a significant increase in pain. Self-care includes activities such shaving, hygiene, showering, etc.*
*Activities other than sleeping that require lying down. Patients were able to choose more than one activity.

sensation during postural changes and other ADLs. Unfortunately, this solution places the burden of therapy management on the patient and can require frequent use of the programmer for stimulation adjustments. To avoid making constant therapy adjustments to avoid overstimulation, patients may settle for suboptimal stimulation amplitudes that prevent or lessen the occurrence of overstimulation events. This pattern is reflected in the survey response, in which half of the patients reported making frequent adjustments (a few times a week to 5+ times per day) to their therapy settings with their remote controls. Worse, patients may decide to keep the device turned down/off and thereby be unable to benefit from SCS therapy, which was seen in 15% of the respondents to the survey.

The first technology to address the issue of stimulation inconsistency was posture-responsive stimulation. The feature of AdaptiveStim™ technology (Medtronic, Inc.) used an accelerometer embedded in the neurostimulator to detect patient position (upright, reclining, lying left, lying right, supine, prone). Posture-responsive stimulation was an effective solution for gross changes in body position, providing 86.5% of patients with better pain relief and/or greater convenience (22). A major limitation of this approach was that it was ineffective for cord movements not associated with a change in position (laughing, coughing, stretching) or different movements in a similar body position (sitting, standing, riding a bicycle).

An elegant CL solution to the issue of inconsistent therapy has been to leverage the evoked compound action potential (ECAP). ECAPs are generated in the dorsal columns of the spinal cord in response to SCS therapy. Capturing ECAP readings from stimulated nerves in the spinal cord allows for real-time stimulation adjustments, thereby improving the consistency of therapy dosing. An ECAP-based approach has the advantage of being more sensitive to subtle movements, such as laughing and coughing (23), and has a faster response time than an accelerometer-based approach (24). This approach has also been demonstrated to improve the patient's experience with SCS therapy (22). Durable outcomes out to 36-month follow-up were demonstrated with conventional low-rate stimulation when using an ECAP-based CL algorithm (25). A potential limitation of both the position-adaptive and ECAP-based CL technology is the inability to respond directly to pain severity since no real-time biomarker indicating true pain perception exists. However, simply by providing a more consistent therapy delivery during dynamic cord movement, patients with both CL approaches reported better pain relief (22,26).

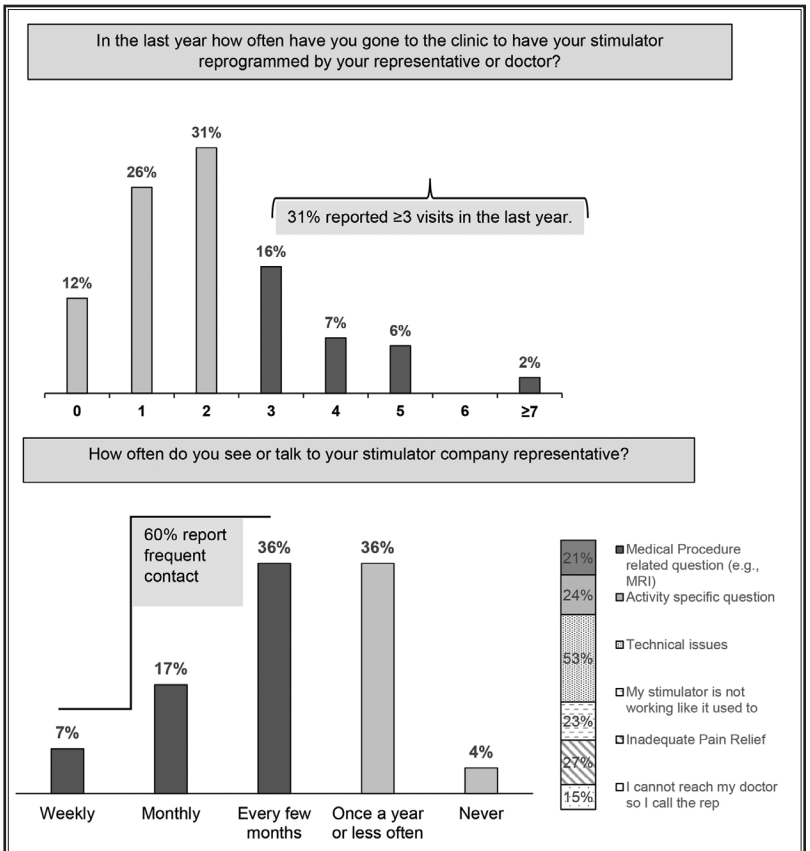

Fig. 5. *Frequency of device reprogramming (above) and company representative contact (below). A majority of patients (60%) reported frequent contact with a company representative, and technical issues with the device were the most common reason for assistance. Patients were able to select more than one reason for reaching out for support. "Technical issues" encompasses respondents' selection of one of the following 3 choices: "I lost or dropped the remote," "[m]y remote locked up/stopped working," "[r]echarge is taking too long/not working."*

SCS therapy has been shown to improve quality of life significantly, and patients often report high satisfaction with the therapy (9,10,15-21). However, patients in this survey, who used SCS therapy from multiple manufacturers, reported fear and avoidance behavior related to ADL to prevent uncomfortable stimulation events. Over 80% of the respondents reported avoiding one or more ADLs. Although SCS therapy has been shown to provide sustained improvement in function and a decrease in disability (9,10,15-21), patients may be hesitant to engage in exercise or change from their preferred exercise to avoid unwanted stimulation. In the survey, 73% of respondents avoided exercising due to concerns related to the appropriate stimulation level, and 31% avoided walking. Social interaction may be impacted, as demonstrated by the 22% of patients who avoided laughing and the 41% who avoided coughing. A total of 38% of respondents avoided household chores. A solution to this issue could improve aspects of patients' quality of life beyond pain control across all types of SCS therapy.

Implementing a solution to this patient need cannot ignore other aspects of the patients' lives. For example, disease progression and the appearance of new health care conditions (e.g., joint pain or injury) or disease states (e.g., cancer) will require diagnostic imaging tools for care and management decisions. MRI is a recommended diagnostic tool for many conditions and is essential to the diagnosis and appropriate treatment of these conditions. Desai et al (27) have reported that over 82 to 84% of patients with chronic low back pain

indicated for SCS will require one or more MRI scans within 5 years of implant; approximately 89% to 98% of SCS patients are expected to need at least one MRI within 10 years of implant. When limited to non-spine MRIs, approximately 59% to 74% of SCS-implanted patients are expected to need at least one scan within 10 years of implant.

No SCS system is considered MRI safe or "compatible;" many SCS systems have been tested for specific scan conditions and are therefore are classified as MRI conditional. MR conditionality is influenced both by the testing performed on the system and by features of the SCS system itself. For example, certain leads have been manufactured with a shield that shunts the radiofrequency (RF) current and heat along the length of the lead (28). This feature prevents heat from accumulating at the tip of the lead or at any fracture point within the lead. For systems that can safely scan leads with out-of-range (OOR) impedances (e.g., impedance-independent MR conditional systems), impedance checks prior to an MRI scan are not required. In contrast, impedance-dependent MR conditional systems require all contacts to be within an acceptable impedance range before an MRI scan. While this condition appears to be simple to meet, a single-center retrospective analysis reported that 18.5% of patients with impedance-dependent MR conditional systems had at least one OOR impedance at an average follow-up time of 2.25 years post-implant. The rate of impedance-driven lead failure increased by 35.4% per year, peaking at 43% of patients with at least one OOR impedance at 5 years post-implant. Since high impedances may indicate lead fractures, SCS systems that do not have mitigation for localized heating no longer meet the MRI scanning conditions. Patients may need to forgo critical diagnostic MRIs (29), opt for other imaging modalities that may not offer the same diagnostic abilities as an MRI, or undergo an explant procedure to remove the system before having MRI scans, accounting for about 9%-12% of all explants (30).

Limitations

The results described here reflect the limitations inherent to data collected via direct-to-patient surveys. Every effort was made to capture the patient experience without bias by administering the survey in a double-blind fashion. The inclusion of patients from various types of facilities, from private clinics to large hospital systems, was intended to represent differences in standard-or-care practices. Most pain patients had comorbidities, including pain resulting from the increased activity made possible by the SCS therapy (e.g., nociceptive/mechanical pain), which could have also influenced the responses. Not all patients can differentiate between neuropathic pain and mechanical pain. Over time, preexisting comorbidities, including spinal conditions, may worsen, adding confounding pain. Since the study included patients who had received their implants from one to 10 years ago, the significant advancements made both in therapy waveforms and MRI conditionality might not have been entirely represented in the cohort included in this study.

Conclusions

The newer generation of SCS devices and waveforms has significantly improved efficacy in reducing pain and enhancing patients' quality of life. Several large, randomized controlled studies have provided high-quality evidence to support these claims for SCS therapy and have demonstrated the durability of these outcomes. The data presented here highlight the need for devices that integrate seamlessly with the patients' lives. New SCS technologies should alleviate patient burden by managing the therapy dose as patients go about their daily activities, reducing the need to return to the clinic for reprogramming visits and eliminating the tradeoff between pain relief and access to critical diagnostic imaging. CL SCS devices provide real-time adjustments to stimulation based on patients' dynamic movements throughout the day, potentially improving therapeutic effectiveness and comfort.

Data Availability Statement

The dataset analyzed in the current study is available from the corresponding author upon reasonable request for scientific research purposes only.

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Author Contributions

SP, MD, SL, MM, VO, DP, HV, KR, LA, LJ, AF, and AG contributed to the critical review and edits to the manuscript and presentation of data. KR managed the

survey and recruitment of the participants, collated the data, and performed the analysis and initial interpretation of the data. LA and AF were involved in the validation of the data. LA, LJ, and AF participated in the interpretation and presentation of the data. LJ and AF drafted the first version of the manuscript.

Conflicts of Interest

Dr. Pritzlaff declares consulting for Bioness, SPR Therapeutics, Nalu Medical, Medtronic; royalties from Oxford University Press and Wolters Kluwer; research grants from Medtronic, Nevro Corp, Abbott and Biotronik.

Dr. Desai declares consulting for Medtronic, Abbott, Nalu Medical and SPR Therapeutics; stock options from Virdio Health, SynerFuse and SPR Therapeutics.

Dr. Li declares stock options from Nalu and NeuroOne; consulting with Avanos, Abbott, Biotronik, Nalu, NeuroOne, Nevro, PainTeq, Saluda, SPR Therapeutics, and Vertos; and research support to institution from Avanos, Averitas Pharma, Biotronik, Ethos Laboratories, Nalu, Neuralace, PainTeq, Saluda and SPR Therapeutics.

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Dr. Orhurhu is consulting for Medtronic.

Dr. Provenzano has consulted for Avanos, Boston Scientific, Medtronic, Nevro, and SI Bone. Pain Diagnostics and Interventional Care has received research support from Avanos, Medtronic and Boston Scientific.

Dr. Vucetic declares consulting fees from SPR Therapeutics, Boston Scientific, Saluda, Vertos.

Dr. Gulve declares honoraria from Medtronic, Boston Scientific, Saluda Medical, Mainstay Medical, Nevro, Grunentahl, Pfizer and Abbott; declares consulting fees from Medtronic, Boston Scientific, Mainstay Medical and Saluda Medical; research funding from Medtronic, Boston Scientific, Mainstay Medical and Saluda Medical.

Kate Robertson is the proprietor of Strata Mark LLC and collaborated with Medtronic on the development of the survey questionnaire and execution of the study.

Louis Archilla, Lisa Johanek and Abi Franke are Medtronic employees.

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