

Experiences From the Patient Perspective on Spinal Cord Stimulation for Failed Back Surgery Syndrome: A Qualitatively Driven Mixed Method Analysis

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ABSTRACT

Introduction: When neither pharmacological therapies nor alternative interventions provide sufficient pain relief, spinal cord stimulation (SCS) can be used to treat Failed Back Surgery Syndrome (FBSS). Although it seems reasonable that quality of life (QoL)- and psychosocial-related factors contribute to the outcome of SCS since pain is a multidimensional experience, few qualitative studies have explored the expectations of SCS and experiences on SCS to treat FBSS from the patient perspective.

Objectives: The aim of this study was to qualitatively and quantitatively map the FBSS patients' experiences with SCS and the effects of SCS on low back pain caused by FBSS.

Materials and Methods: A qualitative study with in-depth semi-structured interviews, assisted by the Brief Pain Inventory (BPI)-questionnaire.

Results: Seven themes regarding patients' experiences, subdivided into 15 categories, were identified, including an understudied theme within this field of research, Spiritual Well-Being. "Acceptance" and "coping" emerged as pre-eminent motifs throughout these themes. Moreover, the realization of patients' expectations were variable throughout the presented themes. According to the BPI Questionnaire, four out of 13 patients (31%) had significant pain relief ($\geq 50\%$). Seven out of 13 (54%) reported a $\geq 50\%$ increase regarding enjoyment of life.

Conclusion: Multiple QoL- and psychosocial-related themes are related to SCS-outcomes. In order to improve SCS-outcomes for both short- and long-term, these themes should be implemented as a multidimensional approach, both prior to implantation as during follow-up.

Keywords: Experiences, failed back surgery syndrome, psychosocial-factors, quality of life factors, spinal cord stimulation

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INTRODUCTION

Failed Back Surgery Syndrome (FBSS) is considered one of the iatrogenic etiologies of chronic low back pain (1) and is defined as persistent lumbar pain despite surgical intervention or radicular pain in the same topographical distribution emerging after spinal surgery (2). When neither pharmacological therapies nor alternative interventions provide sufficient pain relief, spinal cord stimulation (SCS) can be applied to treat FBSS (3,4).

Chronic pain is strongly related to physical and emotional suffering, social problems, limitations in daily functioning, and absence from work through illness (5). According to the Global Burden of Disease 2010 study, low back pain ranks highest in terms of years lived with disabilities and sixth in terms of disability-adjusted life years (6). Hence, patients suffering from FBSS are restrained in multiple ways.

It seems reasonable that quality of life- (QoL) and psychosocial-related factors contribute to the concluding outcome of SCS since pain is a multidimensional experience (7). Several qualitative studies have explored the effects of SCS and the expectations regarding SCS from the patient perspective (8–10), as well as the identification of outcome goals (11). The selection of such goals is believed to enhance patients' motivation and engagement to achieve their selected outcome parameters (12). In addition, a systematic review by Werbrout et al. disclosed that successful therapies often incorporated goal setting and action planning (13). Moreover, outcome goals should not be predefined by healthcare providers, nor restricted to disease or treatment-related outcomes, but should be discussed and negotiated with each patient, according to his/her own life priorities (14). To elaborate on SCS experiences from the patient perspective, only one qualitative study assessed these as a treatment for FBSS (15). This study by Ryan et al. identified a list of crucial informational needs, which can be utilized to enhance patient information provision prior to SCS. Since patient preparation plays an essential role in aligning a patient's expectations and individual outcome goals, it could indirectly influence SCS-outcomes (16–18). However, it still not further elucidates the role of QoL-associated factors regarding SCS. First, a delicate understanding of experiences from the patient perspective is needed. Therefore, the aim of this study was to qualitatively and quantitatively map the FBSS patients' experiences with SCS and the effects of SCS on low back pain caused by FBSS.

MATERIALS AND METHODS

Design

We performed a qualitative study with face-to-face, in-depth, semi-structured interviews, enriched with quantitative data extracted from the Brief Pain Inventory (BPI)-questionnaire.

Participants and SCS Procedure at Our University Medical Center

The same 13 FBSS patients who were interviewed before SCS surgery (8) participated again between 25 and 35 months after surgery. The studied cohort was recruited by use of purposive sampling in order to recruit patients of both genders with a range of age and daily activities. The inclusion criteria were: 1) adults who suffer from chronic pain; and 2) who were on the waiting list for SCS to treat FBSS. Patients were excluded if: 1) their cognition was impaired; 2) (relative) contraindications emerged from the

pre-SCS psychological screening (i.e., the "yellow and/or red flags"); or 3) had no full comprehension of the Dutch Language. For the current study, patients were contacted by one of the researchers (D.H.) in order to inform them about this follow-up study. If patients were willing to participate again, they were asked to provide written informed consent. Ethical approval was granted by the ethical research committee of the region Arnhem-Nijmegen (file number 2018-4770).

The SCS procedure is started with the percutaneous implant of an electrode in the epidural space using local anesthesia and procedural sedation after perioperative antibiotic prophylaxis. The patient is awake during the test phase of this procedure and can help the operator navigate by the experienced sensory stimulation. When the most optimal position is found, the electrode is surgically fixed at the fascial layer and connected with externalized extension cables for the two weeks trial period using an external pulse generator. During this phase, it is tested whether pain relief is adequate (at least 50% pain relief as measured by pain intensity scores). If the trial period is considered successful, the pulse generator connected to the electrode is internalized in a second session. If not, the SCS system is removed during this second session.

Data Collection

Face-to-face, semi-structured interviews were conducted by one of the researchers (R.W.), either in the hospital or at the patient's home. It was made clear to the patients that the researchers played no role in their medical treatment. The setting was informal, where patients were both encouraged to speak openly and express their thoughts and feelings. The interviews were audio-recorded and transcribed verbatim.

Additionally, patients were asked to fill out the Dutch version of the BPI prior to the interview (19). This questionnaire consisted of eight numerical rating scales (NRS) linked to various domains (i.e., pain intensity, and severity of limitations in terms of daily activities; mood; walking; work and chores; social engagement; sleep and enjoyment of life). Furthermore, on four consecutive days preceding the follow-up, contact (i.e., one month and one year) patients were instructed to rate their pain intensity in a digital pain diary by use of the NRS, three times a day. The digital nature of this diary enabled us to check if the moment in time at which the pain intensity score was filled in, matched the corresponding prearranged date and time. Hence, it provided a way to monitor potential recall bias.

Data Analysis

The first three transcripts were independently analyzed by two researchers (R.W. and D.H.). The six steps proposed by Braun and Clarke were followed for each transcript (20). These six steps comprised: 1) data familiarization (transcribing data and [re-]reading these transcripts); 2) generation of initial codes (coding the entire data set in a systematic way and collecting relevant data for each code); 3) searching for themes (combining codes into categories and themes and gathering relevant data for each category and theme); 4) reviewing categories and themes (reviewing the categories and themes in relation to the extracted codes and entire data set); 5) defining and naming categories and themes (refining categories and themes and defining the overall narrative), and 6) producing the final report (selecting patient quotes and writing the paper). Subsequently, the two codebooks were screened side by side, to ensure no standalone codes were being left out and to

Table 1. Characteristics of Implanted Patients.

Patient	Sex/age (years)	Duration of pain prior to implantation (years)	Time of follow-up interview (months)	Occupational status (baseline)	Occupational status (current)	Additional treatments (baseline)	Additional treatments (current)	Pain reduction due to all treatments (%; baseline)*	Pain reduction due to all treatments (%; current)*
1	F/47	15	35	Unable to work	Unable to work	Analgesics	Analgesics (less)	70	40
2	M/70	13	33	Retired	Retired	None	None	0	40
4	M/72	16	27	Retired	Retired	None	None	0	70
5	M/66	10	32	Retired	Retired	Analgesics	Analgesics (less)	20	80
6	M/48	4	26	Unable to work	Working	Analgesics	None	30	60
8	M/60	9	29	Unable to work	Working	Analgesics	None	60	100
9	F/39	4	33	Unable to work	Unable to work	Analgesics	Analgesics (less)	30	40
10	M/48	20	30	Unable to work	Unable to work	Analgesics	Analgesics (less)	40	70
11	F/66	12	25	Unable to work	Unable to work	Analgesics	None	0	0
12	M/54	3	25	Unable to work	Unable to work	Analgesics + TENS	None	70	70
13	M/50	3	34	Unable to work	Unable to work [†]	None	None	0	50

*Retrieved by the Dutch BPI Questionnaire.

[†]Patient "13" returned to work, but only for the first year postimplantation. TENS, transcutaneous electrical nerve stimulation.

enhance the dependability of the data. If R.W. and D.H. did not reach consensus, the research team was consulted to discuss the emerged codes and themes in-depth until consensus was reached. Additionally, the preoperative qualitative data also were included in the analyses, in order to integrate the patients' expectations and experiences. However, since also different themes emerged in the postoperative interviews, it was not feasible to correlate all of the currently presented themes to corresponding preoperative qualitative data. The coding process was performed using Atlas.ti software (Atlas.ti 8 for Windows, v. 8.3.16, released 2018; ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). Data were represented as a median with range (minimum–maximum), since they were not normally distributed. Differences between pre- and postsurgery data of the BPI were analyzed with the Related-Samples Wilcoxon Signed Rank Test by use of SPSS software (IBM SPSS Statistics for Windows, v. 25.0, released 2017; IBM Corp., Armonk, NY, USA). Statistical tests were two-sided and had a significance level of $p < 0.05$.

RESULTS

All 13 patients were included in this study in order to complete follow-up. The point of saturation of data was reached after ten interviews, since the next three interviews did not provide new insights. Characteristics of the included thirteen FBSS patients are provided in Tables 1 and 2. Nine patients were male (69%). The interviews lasted between 32 and 67 min. The median age was 54 years (range 39–79). Seven patients did not have a job, four were retired, and two were employed. Eleven patients had an SCS device implanted permanently, whereas two did not proceed to permanent implantation. One of the two (No. 07) patients' pain relief was not sufficient to consider full implantation, and the other patient (No. 03) suffered from postimplantation infection during the trial phase. Technical specifications and complications for each patient are shown in Tables 3 and 4. Baseline (i.e., preoperative) and expectation BPI-scores (i.e., estimated SCS-outcomes by patients prior to initiating the SCS procedure) retrieved during the study of Henssen et al. were combined with the pain diary scores preceding the follow-up contacts and the outcome BPI-scores of this study (Tables 5 and 6).⁸

Themes

Fifteen categories emerged from the qualitative data. Out of these categories, we identified seven themes: 1) Physical Well-Being; 2) Material Well-Being; 3) Spiritual Well-Being; 4) Social Well-Being; 5) Emotional Well-Being; 6) Development and Activity; and 7) SCS Therapy (Fig. 1). Moreover, "acceptance" and "coping" emerged as pre-eminent motifs throughout these seven themes. These data were substantiated with quantitative data derived from the BPI. Additionally, both qualitative and quantitative data from the pre-SCS period were used to enrich findings.

Physical Well-Being

Pain Reduction and Coping Strategies. Ten out of 11 implanted patients reported reduced pain intensities at the time of the follow-up interview, though, all 11 were satisfied with the outcome of SCS. At the preoperative interview, all participants expected a decrease in pain intensity. Quantitatively, median reported baseline pain intensity score was 8.0 (6.0–9.0) and median expected post-SCS pain intensity score was 5.0 (1.0–10.0). This expected score was equal to the outcome pain intensity scores

Table 2. Characteristics of Non-implanted Patients.

Patient	Sex/age (years)	Duration of pain prior to implantation (years)	Time of follow-up interview (months)	Occupational status (baseline)	Occupational status (current)	Additional treatments (baseline)	Additional treatments (current)	Pain reduction due to all treatments (%; baseline)*	Pain reduction due to all treatments (%; current)*
3	F/54	3	34	Unable to work	Unable to work	Analgescics + TENS	Analgescics (less)	50	20
7	M/79	4	34	Unable to work	Retired	None	None	0	0

*Retrieved by the Dutch BPI Questionnaire. TENS, transcutaneous electrical nerve stimulation.

(median 5.0; range 1.0–10.0). This decrease in pain intensity also was found to be statistically significant ($p = 0.003$). The mean pain intensity scores over time for each patient are shown in Figure 2. In the qualitative interviews, various explanations arose to explain the individual discrepancies between the expected and actual post-SCS pain intensity score. One of these was that patients experienced improved range of motion which provoked pain, and thus slightly increased pain intensity. In one of the interviewed nonimplanted patients, no change in pain intensity scores was noted, whereas the other nonimplanted patient also showed decreased pain score over time (Fig. 2). This patient in particular expressed that her ability to cope with pain improved over the years and consequently the pain intensity decreased. Distraction (e.g., work) and changing positions were the two primary pain coping strategies reported.

Laying supine was experienced as the least painful position by five patients. Two patients (No. 02 and 11) had the urge to change their stance every few minutes. Two patients specifically marked the typical tingling sensation of SCS as preferable to pain, whereas another patient criticized this sensation.

No. 11—*“Although the tingling sensation is different from my pain, it definitely is as strange and undesirable. So, that’s why I turn my device off from time to time.”*

Medication. In line with the preoperative expectations, all participants disclosed to have managed to either reduce or wean off their pain medication intake. No quantitative data were available for this outcome. Additionally, the medication induced side-effects, a reduced level of awareness and energy in particular, indeed seemed to be the primary motivators. As a result, patients experienced enhanced levels of awareness and energy.

No. 02—*“It would probably have been better to down half a litre of booze, since ‘me’ was not me anyway and maybe it would have given more pain relief too.”*

Most patients marked the withdrawal period as intense and challenging, whereby social support and guidance was considered of high importance. However, they all stated that the reduced intake of analgesics felt as an accomplishment on its own and that they experienced an increased level of awareness.

No. 12—*“It was really hard to stop, but I’m so happy that I managed to since a completely different person emerged [...] And that person was me from before.”*

Sleep. Ten out of 11 implanted patients reported enhanced quality of sleep due to better sleep continuity, while only four of them explicitly expressed such expectations during the preoperative interview. They experienced being less tired during the day as a result. This was in agreement with the quantitative data, as the median baseline BPI-sleep score of 7.0 (0.0–10.0) decreased to a median outcome score of 5.0 (0.0–10.0) ($p = 0.056$). Despite this decrease, before surgery patients expected that sleep quality would improve even more as the median expectation score was 3.0 (0.0–5.0). This indicates that the expectations were not fulfilled, though still experienced as satisfactory.

Table 3. Technical Specifications and Complications of Implanted Patients.

Patient	System	Stimulation	Paresthesias	Rechargeable device	Complications
1	Nevro	High-Frequency	None	Yes	None
2	Medtronic	Tonic	None	No	None
4	Medtronic	Tonic	None	No	None
5	Medtronic	High-Density	None	No	None
6	Medtronic	Tonic	None	No	None
8	Nevro	High-Frequency	None	Yes	None
9	Medtronic	High-Density	None	Yes	None
10	Medtronic	Tonic	None	No	None
11	Abbott	Burst and Tonic	None	No	None
12	Medtronic	Tonic	None	No	None
13	Abbott	Burst	None	Yes	None

Table 4. Technical Specifications and Complications of Non-implanted Patients.

Patient	System	Stimulation	Paresthesias	Rechargeable device	Complications
3	Nevro	High-Frequency	None	N/A	Infection
7	Medtronic	Tonic	None	N/A	Insufficient pain relief

No. 02—*"I still wake up from time to time due to my pain levels, but definitely fewer times a night. At the moment I'm content with my quality of sleep, which also enhances my energy level during the day."*

However, two participants reported a decrease in sleeping hours after one year. They believed that the SCS system was not functioning properly anymore, since they simultaneously experienced increased pain intensity scores. This also was observed in the corresponding pain intensity scores. Six patients explicitly mentioned the need for lowering the voltage when lying in bed as a supine position provokes the stimulation.

Activity and Mobility. With regard to walking, the baseline, expectation, and outcome scores showed a median of 8.0 (6.0–9.0), 3.0 (0.0–8.0), and 5.5 (1.0–9.0), respectively. Although expectations were not fulfilled, patients experienced a statistically significant improvement with regard to activity and mobility ($p = 0.009$ for walking; $p = 0.004$ for daily activities). Qualitatively, expectations varied from undertaking hobbies with less restraints to increased mobility either by foot or by bike. In line with these expectations, the experiences also were quite disparate, which indicated that alterations within this domain might be difficult to predict. Most patients experienced increased physical activity and mobility, either by foot or by bike, which coincided with their expectations. Since walking improved for most patients, they also tried other sports and ways of getting around. One patient improved from barely mobile to walking without a cane at home, after switching his device to high-density mode. Additionally, he managed to go cycling again with a hand bike. One patient even started skiing and race cycling again.

No. 06—*"I managed to go race cycling again [...] Oh and skiing as well, no problem at all! Those were two hobbies that I never expected to be able to pick up again."*

Another patient, who also picked up race cycling, was able to do so because of a physiotherapist was helping him out training his lower back and abdominal muscles 2–3 times a week. In contrast, one patient was disappointed about still not being able to engage in a sport consistently due to the unpredictability of her pain. Another patient mentioned being able to go to the gym every day after he had altered his exercise sets.

No. 12—*"Before it was the other way around, a low frequency of exercises with heavy weights and now I do way more exercises with very little weights. And that's okay, since I still enjoy it and manage to withdraw energy from it."*

All patients mentioned that they were somewhat limited in moving, especially in stretching and rotational movements. Following this, one patient regretted the fact that she was not allowed to do yoga. Another participant considered the absence of the tingling sensation as a sign of a system malfunction.

No. 04—*"If I bend over, it stops stimulating. I don't feel it anymore. But as soon as I stretch my back, it starts to vibrate, and it resumes to suppress my pain."*

Another patient specifically addressed constraints while travelling, due to the shaky and bumpy nature of most roads and railways. Increased pain intensities as a result discouraged him from going outside. Improved pain intensities due to (physical) activities were often neglected since these activities contributed to enhanced enjoyment of life. Hence, being active is preferable to remain idle according to the participants.

No. 10—*"Most of the time it's a consideration between the costs and benefits, like do I take the upcoming pain for*

Table 5. Implanted Patients: Baseline, Expectation, and Outcome BPI-Scores (NRS-Scores) Concerning Various Domains.

Patient	Sex/age	Pain intensity		Daily activities		Mood		Walking		Work and chores		Social engagement		Sleep		Enjoyment of life									
		b	e	b	e	b	e	b	e	b	e	b	e	b	e	b	e								
1	F/47	8	3	6	8	3	5	7	1	3	7	2	5	9	2	6	8	1	4	3	0	4	7	2	3
2	M/70	7	5	4	7	5	4	7	4	3	6	8	2	8	4	5	0	1	7	5	3	7	3	3	3
4	M/72	7	2	3	6	3	3	3.5	1	2.5	6	1	3.5	5	2	4	2	1	3	0	0	1	5.5	0	3
5	M/66	8	4	6	10	5	3	6	2	1	9	4	N/A	10	4	7	8	2	3	10	4	1	5	2	3
6	M/48	8	3	4	8	3	2	6	0.5	0	8	3	2	8	3	3	4	1	0	9	1	5	5	0.5	0
8	M/60	8	3	1	8	3	2	4	2	0	8	3	1	9	3	5	3	1	0	7	3	0	3	2	0
9	F/39	7	4	5	9	5	9	4	4	3	9	5	7	9	6	9	4	4	1	5	4	5	4	4	2
10	M/48	9	0	3	8	0	5	9	0	5	7	0	2	9	0	7	8	0	1	7	0	5	9	0	2
11	F/66	6	3	7	7	3	7	7	1	0	6	2	7	7	2	7	2	1	6	6	0	7	4	2	2
12	M/54	8	5	5	8	5	5	7	4	6	8	6	6	8	5	5	5	5	4	5	5	4	6	3	4
13	M/50	7	3	5	7	4	7	8	2	7	8	3	7	9	3	9	8	3	5	5	3	5	5	2	7

Baseline and expectation scores were retrieved at the same moment, prior to receiving a trial SCS system. The outcome scores were retrieved prior to the follow-up interview (Tables1 and 2). Patient "5" had no outcome for walking since he became wheelchair dependent.

b, baseline; BPI, Brief Pain Inventory; e, expectation; NRS, Numeric Rating Scale; o, outcome.

Table 6. Non-implanted Patients: Baseline, Expectation, and Outcome BPI-Scores (NRS-Scores) Concerning Various Domains.

Patient	Sex/age	Pain intensity		Daily activities		Mood		Walking		Work and chores		Social engagement		Sleep		Enjoyment of life									
		b	e	b	e	b	e	b	e	b	e	b	e	b	e	b	e								
3	F/54	8.5	3	6	9	4	8	7	2	7	9	3	8	9	3	8	5	3	5	8	3	7	8	2	5
7	M/79	9	4	10	9	2	9	10	0	9	9	0	9	9	2	9	9	1	8.5	10	0	10	9	0	7

Baseline and expectation scores were retrieved at the same moment, prior to receiving a trial SCS system. The outcome scores were retrieved prior to the follow-up interview (Tables1 and 2).

b, baseline; BPI, Brief Pain Inventory; e, expectation; NRS, Numeric Rating Scale; o, outcome.

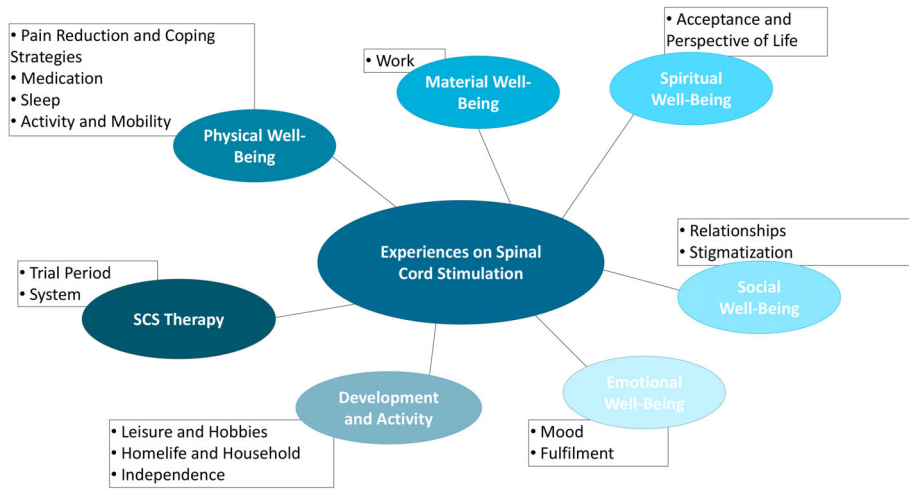


Figure 1. Qualitatively explored experiences on SCS grouped in themes according to patients suffering from FBSS. The emerged themes are shown in the outer seven circles. Accessory categories are presented in boxes, pinned to each corresponding theme. FBSS, failed back surgery syndrome; SCS, spinal cord stimulation. [Color figure can be viewed at wileyonlinelibrary.com]

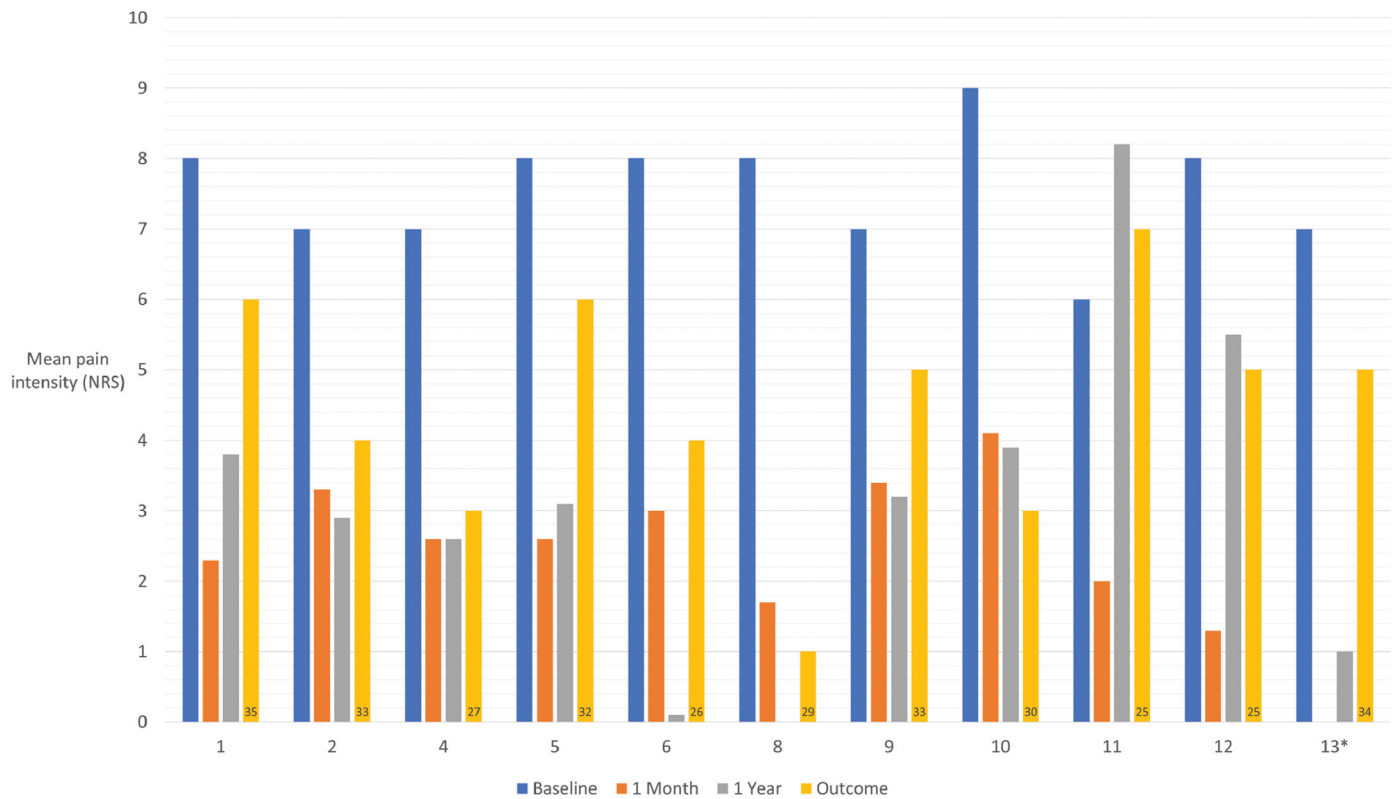


Figure 2. Mean reported pain intensities over time of implanted patients (NRS-scores). “Baseline” and “Outcome” scores were derived from the BPI as a single moment measurement. The numbers shown at the bottom of the yellow “Outcome” bars represent the follow-up contacts in time (months). The “Baseline” score was derived as a single moment measurement. Though, on four consecutive days preceding the follow-up contact (i.e., one month and one year) patients were instructed to rate their pain intensity in a digital pain diary by use of the NRS, three times a day. A mean pain intensity score was derived as a result. Since the digital diary enabled us to monitor the moment in time at which the pain intensity score was filled in, we found out that all pain intensity scores were filled in at appropriate moments in time (i.e., ±60 min of the prearranged date and time). However, patient “13” failed to do so at one month follow-up. NRS, Numeric Rating Scale. [Color figure can be viewed at wileyonlinelibrary.com]

granted as long as I can join my friends and family to a concert, or will I bail? I mostly go with the manner since that's what makes me happy."

Material Well-Being
Work. Median baseline, expectation, and outcome scores regarding work and chores were 9.0 (5.0–10.0), 3.0 (0.0–8.0), and

7.0 (3.0–9.0), respectively. Although statistically significant changes were observed ($p = 0.007$) and these results indicate a slight improvement, this domain still remained most incapacitated as reviewed by the median scores. During the presurgery interview, five patients shared that they expected to return to work at least part-time, while no patients were employed prior to SCS. However, only three patients initially managed to return to work and, one of them became unemployed again when pain relief dropped. The other two patients were still employed at the time of the follow-up interview. However, they mentioned that some adjustments had to be made (e.g., less physical load), as expected prior to SCS. Being financially restrained due to unemployment was disclosed twice.

No. 10—*"I consider myself lucky with my spouse having a well-earning job, but if that hadn't been the case, we would definitely have been in trouble financially wise."*

Spiritual Well-Being

Acceptance and Perspective of Life. Median enjoyment of life scores were found to be 5.5 (3.0–9.0), 3.0 (0.0–8.0), and 3.0 (0.0–7.0) for the baseline, expectation, and outcome phase, respectively. Moreover, the domain enjoyment of life was found to be least incapacitated and improved significantly after SCS ($p = 0.003$). According to the presurgery interviews, eight patients believed that SCS helped them in accepting their situation and enabled them to deal with the constraints coming with FBSS.

No. 12—*"I Don't think that neurostimulation resets you, that it makes you as new, that's nonsense! Just accept who you are. And of course, it comes with constraints, certain things you cannot do yourself, but then just find someone else who can do it for you."*

One patient particularly addressed the ability of extracting enjoyment and satisfaction from different matters than before.

No. 10—*"Although it took a year to accept I cannot work and that I'm the one responsible for the household, but eventually I managed to accept it and then you will see the usefulness of life again."*

Additionally, three patients reported an altered life perspective and believed that it aids in enhancing their enjoyment of life. According to them, it helps to look on the bright side of life.

No. 09—*"I'm not allowing my mental state anymore to make me hide in a corner somewhere. Instead, I learned to extract my life energy from different things than before."*

Social Well-Being

Regarding social engagement, the baseline, expectation, and outcome scores showed a median of 5.0 (0.0–9.0), 1.0 (0.0–5.0), and 3.0 (0.0–8.5), respectively ($p = 0.059$). These median scores indicated that the improvement was smaller than expected. This coincided with the qualitative data, as the number of relationships and friends together with stigmatizing behaviors from

others were the main reasons mentioned for restraints still being experienced.

Relationships. Preoperatively, all participants expected an increase of friends and relationships after SCS due to being able to be more socially active. Nonetheless, four patients still experienced a decline in their number of friends and social contacts. According to them, practical issues related to the SCS system (e.g., charging the battery) and experiencing increased pain levels during social activities is what hindered them in social participation. Two participants explicitly mentioned that "being home alone" has a negative impact on one's social and mental state.

No. 08—*"There is a saying 'once you are sick, you are forgotten' [...] and that is exactly what I have experienced."*

No. 12—*"Social interaction is of high importance for each individual, but being home alone is the same as being isolated, and thus missing out on those interactions [...] And obviously, this has some influences on my mind and mental state."*

Stigmatization. An inappropriate understanding of chronic pain by others, either due to incomprehension or unfamiliarity, was reported by 11 patients. Because of this, two patients refused to talk about their pain to others. One of them believed that talking about her pain was interpreted by others as attention-seeking behavior. Moreover, patients reported feelings of chronic pain being a disadvantage in nowadays society, that is, less healthcare options and fewer opportunities to pursue life goals.

No. 09—*"Government, society and municipalities who don't take me seriously frustrate me heavily, a waste of energy I would say. One's appearance is the only thing that matters to them, but I just don't want to fake myself and that shouldn't be needed either. The fact I'm already thinking about this [disguising who you really are] is humiliating."*

Another reason mentioned for "feeling misunderstood" was the fact that chronic pain is not something you recognize at first sight. In contrast to the expectations, one participant experienced an increase in his family's ignorance concerning chronic pain after the implantation.

No. 11—*"If the word 'cancer' is written down somewhere in your patient files, then all of a sudden doors open, but until now with chronic pain? They remain closed."*

No. 02—*"Even my brothers and sisters were convinced that it was over and done after the implantation. 'But now that you've got that thing [SCS], just turn it up.' was said once. I replied: 'It's not a radio where you can fix the volume or frequency easily by turning a simplistic button.' No, others don't know what they are talking about and it's nearly impossible to explain it [chronic pain] to them."*

Emotional Well-Being

Mood. Although all patients disclosed that FBSS influenced their state of mind negatively, only two expected SCS to improve

their mood. However, they were unable to specify in what manner these expectations would occur. Nevertheless, the baseline, expectation, and outcome scores concerning mood showed a median of 7.0 (3.5–10.0), 2.0 (0.0–4.0), and 3.0 (0.0–9.0), respectively. These median scores indicated a remarkable improvement, and also were found to be statistically significant ($p = 0.002$). While the quantitative scores reflect notable changes in the domain of emotional well-being, information from the follow-up interviews mainly showed patients struggling with anxiousness and uncertainty, as well as feelings of disappointment. Patients disclosed that several occasions led to an anxious or uncertain state of mind. Two participants mentioned being anxious about not being able to tell whether the battery of the device was nearly empty. Moreover, a sudden system failure crossed their minds from time to time, especially when being abroad. Because of this, they labeled the follow-up contacts as desirable as this provided certainty.

No. 04—*“At a certain moment in time either the battery will be empty, or the device is not working at its fullest anymore, but when has that moment come and how can I differentiate between these causes? Lastly, we went abroad for nine weeks, so I held my fingers crossed. What should I have done when it had happened in that period?”*

Receiving a second (spare) remote control aided two patients in reducing their anxious feelings. One patient told to be more cautious when it comes to walking on a slippery or bumpy surface since he is afraid to fall. One patient became concerned when his device turned off.

No. 12—*“I had surgery the other day, so I had to turn my device off. The rapid phase of the pain returning definitely caught me off guard. I was convinced my brain would be dazed by now after all the time of stimulation, but to no avail. That’s something I can’t get out of my head, what if the device will fail all of a sudden?”*

Another patient referred to the first weeks postimplantation when it came to being anxious.

No. 06—*“Especially in the beginning, when you are afraid of moving unexpectedly because of the possible dislocation of the lead, you are constantly checking if the device is still doing his job. Also at that time, you’re not used to the tingling sensations, making it even harder to judge.”*

Feelings of disappointment were particularly experienced during days with less pain relief and at moments where patients had to withdraw themselves from social engagements due to their pain intensity.

Fulfillment. Eleven patients disclosed an improved mental and emotional state of mind as a positive contributor to their outcome, mostly as a result of reductions in analgesic intake and decreased pain levels. The latter coincides with the preoperative disclosures as patients expected that only a slight decrease of pain levels could enhance enjoyment of life.

No. 02—*“Before, I couldn’t do anything about the pain, but now with the stimulator, I’m a bit more in control since I can adjust the settings whenever I feel like to.”*

Despite minor constraints coming along with SCS, ten patients would choose to undergo the procedure again.

No. 06—*“A rating in terms of quality of life at the moment would be a 9 out of 10. Of course, no 10, since it can’t be perfect and SCS comes with minor constraints. They should’ve placed this device many years earlier.”*

One of the nonimplanted patients (No. 03; failed at trial level due to postimplantation infection) was still unsure whether she wanted to receive a device. Three patients specifically mentioned that they would recommend SCS to others.

Development and Activity

Leisure and Hobbies. While ten patients before surgery shared that they expected improvements, only eight of them mentioned that day trips became feasible again and that moments of leisure were experienced as more enjoyable. Patients reported that participating in these moments of leisure impacted pain intensity scores and the corresponding BPI scores. This also was observed when investigating the daily activity scores. The median baseline- and expectation scores of daily activity were found to be 8.0 (6.0–10.0) and 3.0 (0.0–5.0) points, respectively. The outcome phase scores were found to be higher (5.0; range 2.0–9.0) than expected, although still was statistically significant ($p = 0.004$). Additionally, in the preoperative setting, eight participants expressed their hopes to participate more actively in their hobbies. However, only two patients managed to achieve this. These findings suggested that these expectations were not realistic. Being able to go on holiday again was reported twice. Two patients reported that they still could not enjoy from engaging in moments of leisure.

No. 09—*“I have to plan my days on beforehand like I have to prioritize carefully and I always need to have a plan B up my sleeve in case I wake up and know it’s not going to happen that day.”*

Homelife and Household. Median BPI scores with regard to work and chores were found to be 9.0 (5.0–10.0), 3.0 (0.0–8.0), and 7.0 (3.0–9.0) at the baseline, expectation, and outcome phase, respectively. When comparing baseline with outcome scores, a significant change was notable ($p = 0.007$). Qualitatively, patients’ improvements regarding chores and household were disparate between participants, ranging from no constraints at all to being unable to stand for longer than 5 min at the kitchen counter. Overall, postoperative improvements were reported by nine patients, whereas only four patients expected an improvement preoperatively. However, four of these nine patients also mentioned that adjustments had to be made in order to make them feasible. Such adjustments included taking time off when needed, spreading tasks throughout the day or executing tasks at a slower pace. Besides, more burdensome chores were left to others. One patient managed to do chores for the first-year postimplantation but failed to do so due to an increase in pain. Two patients were still fully incapacitated.

No. 13—*“My days are nothing at the moment. I barely move around the house, and I don’t go outside.”*

Independence. Four patients reported that SCS enabled them to drive their car again, which increased their sense of independence. Baseline qualitative data showed that this was an expected outcome of SCS. Another patient became able to rise from his seat independently and to move around the house, which enhanced his self-independency. Uncertainty of the near future in terms of self-reliance and independence was the reason for one participant to move in with his daughter and son-in-law, in a so-called “caregiver home.” This theme could not be evaluated quantitatively by use of the BPI scores.

No. 09—*“It’s such a joy to be able to drive a car myself early in the morning just like everyone else [...] That feeling of being autonomous and of independence, that’s definitely a moment where I consider myself as a blessed individual!”*

SCS Therapy

System. Unfamiliarity with SCS as a treatment option by other healthcare providers, mostly general practitioners, was reported seven times. An infection (No. 03) was the only complication reported. One patient reported the implantation of the lead as extremely painful. Seven patients underwent implantable pulse generator (IPG) implantation subcutaneously in the left inferior abdominal region while in four patients the left gluteal region was selected. Although two implantation sites were observed in the presented cohort, all participants reported that the position of the IPG was acceptable. Nevertheless, all patients were aware of the IPG physically. The following drawbacks were mentioned: 1) Difficulties when wearing clothes, especially jeans and belts ($n = 4$); 2) The IPG compressing the adjacent lower ribs when bending over ($n = 2$); 3) Problems with performing physical exercises ($n = 2$); and 4) Difficulties with connecting the charger at the left gluteal region ($n = 1$). Although none of the patients would have wanted the implant in another body region, two participants reported being dissatisfied with their body image as a result of the visibility of the implanted IPG. One of them is uncomfortable by wearing swimwear. Although patients with a rechargeable device stated that they needed to specifically take “the moment of charging the battery” into consideration concerning their daily schedule (everyone to two days, dependent of the battery usage), they all integrated this easily into their daily lives. Sitting with a stretched back against a hard surface was experienced as uncomfortable by another patient.

Trial Period. Three patients required additional care to cleanse their wound. The experiences concerning the external wire were mixed. Three patients reported limitations while washing, whereas one patient mentioned not wanting to go outside. Another patient slept uncomfortably.

No. 06—*“The question is where to put the thing [device] because if you turn in bed, that thing [device] comes along with you.”*

Overall, patients stated that the trial period was bearable as long as they experienced pain relief as a result of SCS. The

Table 7. Related-Samples Wilcoxon Signed Rank Test: Correlations of BPI-Scores (NRS-Scores) Between Baseline and Outcome.

Corresponding BPI-domain	Baseline vs. outcome
Pain intensity	0.003
Daily activities	0.004
Mood	0.002
Walking	0.009
Work and chores	0.007
Social engagement	0.059
Sleep	0.056
Enjoyment of life	0.003

Statistically significant differences are shown in bold.
BPI, Brief Pain Inventory; NRS, Numeric Rating Scale.

temporary aspect of the trial period was the second most reported motivator.

The Dutch Brief Pain Inventory Questionnaire

The median outcome pain intensity score was 5.0 (1.0–10.0). Mean pain reduction per patient, whereby all individual treatments were taken into account, appeared to be 49% (Tables 1 and 2). Four out of thirteen (31%) patients responded positively to SCS, that is, reporting a level of pain relief $\geq 50\%$. However, seven out of 13 (54%) reported a $\geq 50\%$ increase regarding enjoyment of life. Eight out of 11 implanted patients reported increasing pain intensity (Fig. 2). Statistically significant improvements between baseline and outcome were found in terms of mood ($p = 0.002$), enjoyment of life ($p = 0.003$), pain intensity ($p = 0.003$), daily activities ($p = 0.004$), work and chores ($p = 0.007$), and walking ($p = 0.009$) (Table 7).

DISCUSSION

By exploring the experiences on SCS for patients suffering from FBSS, we found seven patient-reported themes: 1) Spinal Cord Stimulation; 2) Physical Well-Being; 3) Material Well-Being; 4) Spiritual Well-Being; 5) Social Well-Being; 6) Emotional Well-Being, and 7) Development and Activity. These themes almost entirely reflect the QoL-themes defined by Felce and Perry (Fig. 1) (21). However, the presented results proposed the addition of another theme; Spiritual Well-Being. Moreover, “acceptance” and “coping” emerged as pre-eminent motifs throughout the seven reported themes. Unawareness and incomprehension of chronic pain by others were mentioned as major constraints, which might have led to stigmatizing behaviors according to our participants.

According to the BPI Questionnaire, four out of 13 patients (31%) had significant pain relief. A large study ($n = 3025$) by Taylor and colleagues showed a larger responder ratio of 58% for patients suffering from chronic back and leg pain (i.e., $\geq 50\%$ pain relief) (22). The smaller rate presented within our study could be explained by the small sample size. Although the responder ratio was relatively small in the presented cohort, seven out of 13 (54%) patients reported a $\geq 50\%$ increase regarding enjoyment of life. Furthermore, both quantitative (i.e., 8/11 implanted patients) as qualitative results from the present study showed diminishing pain-relieving effects of SCS during follow-up.

Spiritual Well-Being, Coping, and Acceptance

Adding the theme of Spiritual Well-Being complies with a recently proposed redefinition of “health” by Huber and colleagues (23) and is understudied within this research field. This redefinition of “health,” as not being the mere absence of disease or infirmity (WHO, 1946) (24), leads to a more dynamic formulation based on the resilience to cope and maintain one’s equilibrium, integrity, and sense of well-being. The two components of Spiritual Well-Being which arose from the interviews (i.e., coping and acceptance) are, however, well-known topics within the field of neuromodulation.

In the present study, SCS-outcomes seemed to be positively influenced by practicing active coping strategies, including acceptance, and a reduction of analgesics intake, leading to an altered state of mind. The participants felt being more in control concerning their daily lives than before. Our findings suggest that addressing acceptance and coping strategies of patients suffering from FBSS are of great importance in the patients’ experiences concerning SCS. This is in agreement with the study of Sparkes et al. (9). They identified four subthemes of influence regarding coping with pain: 1) helplessness, controlled by pain; 2) frustration and anger; 3) responsibility for pain relief; and 4) acceptance of pain. Another review article addressed preoperative psychosocial factors that could play a role in causing FBSS, with “poor coping strategies” being one of them (25). Moreover, negative outcome expectancies are known to provoke passive pain coping strategies (26).

The understanding of psychosocial characteristics (e.g., acceptance and coping strategies) in chronic pain patients, FBSS patients in particular, remains elusive since many QoL- and psychosocial-related factors have not been fully uncovered (27). Even though several psychosocial factors have been proposed as possible influencers on SCS-outcomes, the impact of these factors is not consistent across studies (28). For instance, the European Federation of Pain (EFIC) Chapters listed depression and anxiety disorders as a few exclusion criteria for SCS (29), while some studies reported that depression and anxiety may improve following SCS. One could, therefore, argue that these two symptoms should be addressed carefully before considering them as exclusion criteria (30–32). Subsequently, Beltrutti and colleagues claimed that a reciprocal relationship exists between chronic pain and depression and anxiety, which makes it difficult to determine whether the anxiety and/or depression preceded the chronic pain or vice versa (32). Following this, since psychosocial factors could persist after spinal surgery and thus are possibly of influence on SCS-outcomes, we also should consider addressing presurgical psychosocial factors associated with a negative outcome of spinal neurosurgery. Overall, both the degree of impact as moment of action of such psychosocial factors remain unclear.

The presented themes suggest that multiple QoL- and psychosocial-related factors are of influence on the concluding outcome of SCS. We hypothesize that those factors act on SCS-outcomes in a complementary way. The understanding of such a complex interlinked network, however, remains rather elusive. Supplementary qualitative studies, followed by a grounded theory approach, could aid in understanding the role of these factors on the outcome of SCS.

Another field of interest to influence this could be cognitive behavioral therapy (CBT), which is believed to aid both in reducing negative attributions as increasing active coping strategies (9,33). Moreover, it also may help in enhancing acceptance of pain, which is described as neglecting avoidance and control behaviors and thus continuing with an individual’s life and pursuing personal

goals (34). Since negative psychosocial influencers may arise over time, CBT also should be considered during follow-up (9). Hence, CBT could possibly enhance both post-SCS-outcomes as further reduction of pain intensities when already being treated with SCS.

Stigmatization of Chronic Pain Patients

Feelings of stigmatization were widely mentioned across the presented cohort of patients. One patient even experienced enhanced levels of incomprehension by family members post-implantation. To our knowledge, perceived stigma in patients suffering from FBSS has not been reported before. Stigmatization is defined as devaluing and discrediting responses of others towards individuals who possess a particular characteristic that deviates from societal norms (35). Although the association between stigmatization and the well-being of chronic pain patients is not well understood, preliminary evidence shows that the discrediting responses of others are related to poorer physical and psychological well-being (36). Chronic pain patients reported that stigmatizing responses from others challenge the preservation of their self-esteem and dignity (37). Additionally, qualitative evidence shows that chronic pain patients do not feel believed by relatives (38) and friends (39). Furthermore, two qualitative studies suggest that absence of a clear diagnosis makes the pain patients question the nature and reality of their symptoms and, question the credibility of their pain as a result (38,39). Another environment prone to stigmatization is work, where patients experienced hostility from colleagues (38,40). An interesting finding as FBSS patients are mostly willing to return to work (8). Additionally, as this study suggests, patients feel disbelieved by doctors (37,41), which could be partially declared by studies disclosing that healthcare providers attribute lower levels of pain to patients lacking a clear basis in tissue pathology (42–44). Moreover, healthcare providers are less inclined to help and feel less empathy when it comes to pain patients (42,45,46).

Although stigmatization within the field of chronic pain patients has been identified, the role and impact remain elusive. Future research should focus on understanding the mechanisms and impact of perceived and public stigma regarding chronic pain patients (47), for FBSS patients in particular. Furthermore, social contacts (e.g., family members and colleagues) of FBSS patients should be addressed during information provision.

Decrease of SCS Effectiveness Over Time

According to our results, addressing the patient’s coping mechanisms, beliefs about pain and pain acceptance, may assist in improving SCS-outcomes and also may allow the patient to retain control over their pain intensities. Because of this, one patient (No. 03) still reported an increased overall QoL, in the absence of receiving permanent implantation. Furthermore, eight implanted patients disclosed increasing intensities of pain during follow-up (Fig. 2). One patient (No. 13) in particular, who experienced a decreased quality of sleep, activity and mobility from one year postimplantation onward and even had to quit his hobby once again.

Although Kumar and his colleagues stated that pain relief as a result of SCS is sustainable in the long-term, their study also showed that pain intensities relief slowly dropped over time (48). Nissen and colleagues also reported that 34 out of 175 permanently implanted patients had their device removed eventually, due to insufficient pain relief (49). Hence, despite positive long-term outcomes shown in multiple SCS-related studies, the question of why

the number of nonresponders increases over time remains unresolved. The existing theories are mainly focused on technical issues of the SCS procedure, such as fewer spinal operations and lead positioning (49). Conversely, no strong correlations between predictor variables and treatment outcomes have been found thus far (22,50,51). Another mechanism possibly contributing to the decrease of SCS effectiveness and the increase of explantation rates over time is habituation. Habituation is believed to occur in 20–40% of the patients and refers to the phenomenon that the initial effectiveness declines due to a central nervous system tolerance (52). It is believed to cause inadequate pain relief over time (53). A few studies showed that switching from standard SCS to the novel subthreshold stimulation protocol may salvage habituation for some patients (54–56). Although it seems reasonable that psychosocial factors also play a role in long-term SCS-outcomes since pain is a multidimensional experience (7), no studies managed to report consistent psychological predictors of long-term SCS-outcomes (57). Nevertheless, Kumar et al. showed significant improvements regarding QoL in seven out of eight domains of the 36-Item Short-Form Health Survey when comparing SCS to conventional medical management (CMM) to treat FBSS at six months follow-up (58). Comparison of two randomized controlled trials (RCTs) relating to treating neuropathic pain showed a 1A+ level of evidence (effectiveness demonstrated in various RCTs of good quality. The benefits clearly outweigh risks and burdens) in terms of QoL, favoring SCS to CMM (59).

To summarize, previous studies concerning long-term predictor variables remained inconclusive, and the reason behind increasing pain intensities in certain patients is still uncovered. Few quantitative studies point in the direction of QoL-related outcomes measures. However, these QoL factors were explored through questionnaires. In addition to this article, long-term in-depth interview studies of patient-reported experiences will be of great value, since interviews allow the gathering of rich, more salient data, which might help understand the diminishing efficacy in the long term.

Strengths and Limitations

The majority (9/13) of the participants were interviewed in a nonhospital setting, which may have contributed to a more comfortable atmosphere, enhancing the quality of the data concerning their personal experiences and opinions. This is the first qualitative study to present an integration of patients' expectations, experiences, and beliefs concerning SCS among patients suffering from FBSS at a mid-term follow-up (2–3 years). Furthermore, both a large variety of bio-psycho-social as important existential aspects were addressed. Studying these topics showed to be very important in describing the changes that really seem to matter in an invasive treatment with SCS. An important limitation is that the presented findings cannot be easily transferred to another population since the study sample consisted of only Dutch-speaking individuals living in the Eastern part of the Netherlands. Subsequently, disparities between thoughts and experiences may rely on the healthcare system and the corresponding healthcare providers, the inhabitants and the culture of the corresponding country. In addition, patient experiences also are defined by specific patient characteristics and personal character traits. This has been suggested by Goudman et al. in goal identification by FBSS patients, though this is topic of a broader debate in other diseases as well (60,61). As only a limited number of patients was included in the present study, analysis to elucidate discrepancies between expectations and experiences of different patients with different personalities was not feasible. Since

not all medication verification reports were completely filled in for each patient within the retrospective data, we were unable to quantify the alterations in medication intake for the presented cohort. Last, our statistical analysis should be interpreted carefully due to the small number of included patients.

CONCLUSIONS

In general, as seemed reasonable from the previous literature, multiple QoL- and psychosocial-related themes also are related to patients' experiences and the subsequently reported SCS-outcomes, whereby "acceptance" and "coping" emerged as pre-eminent motifs. The presented themes also included an understudied theme, Spiritual Well-Being. The disparate discrepancies between patients' expectations and experiences suggested that SCS-outcomes are difficult to predict from the patient perspective. Moreover, imbalances within these themes in a certain patient may alter SCS outcomes and could emerge both prior to or after implantation. Therefore, all themes should not only be taken into consideration when establishing a treatment plan prior to implantation but also during follow-up. First, however, supplementary qualitative studies are needed to both understand the impact of QoL- and psychosocial-related factors on SCS-outcomes at both short and long term as to elucidate possible factors responsible for the decrease of SCS effectiveness over time. Last, the role and impact of perceived and public stigma concerning chronic pain patients lack evidence, for FBSS patients in particular.

Authorship Statement

Richard L. Witkam, Dylan J.H.A. Henssen, and Yvonne Engels designed and conducted the study, including patient recruitment and data collection. The data analysis was performed by all authors throughout multiple interdisciplinary sessions. Richard L. Witkam prepared the manuscript with indispensable intellectual input from all coauthors. All authors approved the final manuscript. The authors have no acknowledgements, financial aid, or statistical support to declare.

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COMMENTS

This is an incredibly important article. It embraces the concept of moving beyond the visual analog scale (VAS) to look at the lived experience of the patient. This article explores what is important to these particular patients (13 Dutch patients from an academic implanting center) and arranges their thoughts on well-being into

multiple domains, with acceptance and coping prominent across these domains.

Firstly, we need to acknowledge that it is high time we see these articles appear in the literature. Indeed it is perhaps remiss of the entire field that they appear in 2020 and not 2000 or 2005. The historical obsession with VAS of course explains this.

Secondly, it should be obvious to all that when a patient is presented with their "end therapy" (regardless of what it is) and it reduces their disease burden, doesn't eliminate it, then acceptance and coping will always feature for the patient as they adapt their life around their now reduced symptoms and lifestyle restrictions. This paper clearly confirms that. That, of course, mandates that we should be assisting those patients who struggle with their acceptance and coping to reduce their distress, hence the need to integrate cognitive-behavioral techniques with SCS for a subpopulation.

Thirdly, it tells us that well-being and VAS reduction are not tightly linked and certainly not linear. What then are the techniques that can be used to increase well-being for these patients? Opioid reduction? Broad based access to cognitive-behavioral techniques? Low dose cannabinoids? Patient empowerment groups? We need to start researching these questions and derive adjuvant techniques for SCS that boost well-being where VAS reduction ends up in the mild to moderate range. This is an absent field of endeavor at this point.

This is our first step on this journey. I do not think these 13 patients can speak for the world or probably even the Netherlands, although they likely can speak for the type of patients referred to this implanting center. It has been suggested in the literature that to achieve thematic saturation one may need 24 (1) or even 50 (2) subject samples. An excellent recent paper (3) outlines an objective way one should determine this and I recommend it to those interested in pursuing this line of research. Thus, from here I believe we should move forward with a multicenter, multicultural, multi-geographical sampling of patients exactly along the lines the authors have conducted. I would go so far as to say that this would make a worthy INS endeavor. Commendations to the authors and may well-being take its place alongside VAS in our research lexicon.

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1. Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? Hennink MM, Kaiser BN, Marconi VC. *Qual Health Res* 2017 Mar;27(4):591-608

2. Point of data saturation was assessed using resampling methods in a survey with open-ended questions. Tran V-T, Porcher R, Falissard et al. *J Clin Epidemiol* 2016 Dec;80:88-96

3. A simple method to assess and report thematic saturation in qualitative research. Guest G, Namey E, Chen M. *PLOS ONE* 2020 May 5:1-17

This is a very interesting, well written manuscript that begins to unravel/tackle the question of how we assess response to pain therapies. The authors noting of the theme of spiritual well-being in the qualitative patient responses is new in this field. Stigmatization for patients is also a topic that readers and implanters may not have considered. The following are comments/questions that should not detract from the publication of this manuscript:

1. I think this should be presented as a qualitative and quantitative assessment by the authors as both modalities were employed.

2. In the results (page 8) please could Figure 1 be available near this entry and/or could the categories be listed beside the themes e.g. Physical well-being (medication, sleep, activity and mobility). I found myself scrolling up and down to try to link the themes and the categories.

3. The suggestion of CBT post-SCS implantation is interesting. Did patients attend a pre-SCS implant pain management program with CBT?

4. Did the authors feel that any of the qualitative themes correlated with the Dutch BPI in this group? I suspect the number was too small to answer this question.

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This manuscript provides a fascinating collection of patients with Spinal Cord Stimulation for treatment of failed back surgery syndrome. The patient narratives and themes that are developed from their interviews, particularly spiritual well-being and stigmatization are important findings for the spinal cord stimulation patient population.

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