

Factors in Surgical Placement and System Design to Reduce Pocket Awareness and Optimize the User Experience of Spinal Cord Stimulators – A Comprehensive Review

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Abstract: Advancements in spinal cord stimulation (SCS) have enhanced patient outcomes, improved durability, and broadened the range of treatable pain conditions. Technological improvements in battery design have led to smaller implant size, while evolving societal guidelines have played a critical role in optimizing implant safety and quality. This review summarizes recent technological developments in SCS, the impact of such developments on patient satisfaction, and provides an overview of the major systems currently available. We also introduce and explore the emerging concept, “pocket awareness” – referring to a patient’s conscious perception of their implant. Several modifiable factors involving physicians, patients, and manufacturers can influence this awareness, and by extension, patient satisfaction. While pain relief is certainly the primary objective, fostering a comfortable and positive relationship between the patient and their device is essential and merits further clinical attention.

Plain Language Summary: Spinal Cord Stimulation (SCS) is a well-established therapy for chronic pain and has evolved significantly since its inception in the 1960s. Advancements in waveform delivery and battery technology have been significant, yet challenges still exist. One remaining gap in care is device and pocket awareness. The design goal of many devices we use regularly is to be seamless and natural without awareness of their existence. Such device integration becomes part of us. While much attention has been given to waveform optimization and energy delivery, sometimes the patient experience is neglected – ease of recharge, intuitive applications, and battery comfort. The success of SCS not only hinges on its ability to alleviate pain but also on optimizing the patient’s interaction with the device. Factors influencing pocket awareness include device features, surgical techniques, anatomical variations, and patient demographics. This review examines such variables, highlighting how pulse generator size, shape, and placement, along with the patient specific factors can influence outcomes. Recent innovations in battery technology and remote monitoring have advanced the cause, offering more convenience and improved programming; however, further addressing pocket awareness remains a critical area for improvement that involves device manufacturers, physicians, representatives, and patient support teams.

Keywords: spinal cord stimulation, implantable device, pain, spine, patient satisfaction

Introduction

Spinal cord stimulation (SCS) is a treatment that involves modulation of neural pathways responsible for chronic pain perception, altering pain signals traversing the central nervous system.¹ This technology, first utilized in the 1960s has become the standard of care for many suffering pain from persistent spinal pain syndrome type 2 (PSPS-T2), complex regional pain syndrome, non-surgical back pain, diabetic peripheral neuropathy, and other neuropathic pain conditions.

Throughout the years, SCS technology has undergone significant innovation to improve its therapeutic efficacy and to address a broader range of chronic pain conditions. Early systems described in the 1970s and 1980s required the placement of electrodes through a laminectomy within the subdural space and were connected to external generators. Modern SCS systems now utilize fully implantable generators powered by batteries, offering increased convenience and safety.² Additionally, the development of percutaneous techniques for placing electrodes reduces the risk of complications and allows for trial periods before permanent implantation.² SCS systems have experienced advances in waveform technology which have further expanded the potential of this therapy. Emerging research suggests that SCS mechanisms are more complex than the original gate control theory proposed by Melzack and Wall in the 1960s and are believed to selectively activate certain areas of the dorsal horn within the spinal cord.^{2,3} Earlier stimulation therapies were based on tonic waveforms, providing continuous electrical pulses. Newer paresthesia-free devices include burst and high-frequency stimulation have led to more durable outcomes and patient satisfaction. Passive recharge burst waveforms as described by DeRidder may even have a primary action in the medial thalamus based on electroencephalogram (EEG) and functional Magnetic Resonance Imaging (fMRI) studies.⁴ The ability to tailor waveforms and stimulation parameters to individual patients represents a significant shift in the management of chronic pain, highlighting the adaptability and expanding utility of SCS in various clinical scenarios.⁵ In addition, newer systems that measure evoked compound action potentials and respond up to 4 million times per day via closed loop mechanism may have an impact on future product development.⁶

As technology advances, it is important to ensure that the patient experience maintains priority. Certainly, advances in waveforms and battery technology are more widespread, but one important aspect that cannot be overlooked is the patient experience and interaction with technology. This is critical, considering the overall experience may influence the desire to be maintained in therapy with a device. Not only is the interaction with the technology important but so is surgical technique. In this review, we review the available literature and current market products to provide guidance on how to optimize the user experience of spinal cord stimulators for manufacturers and health care providers.

Indications for SCS

Although internal pulse generators can be found in various medical devices, the focus of this review is its use in spinal cord stimulation for chronically painful conditions which are outlined here for context. Common SCS indications include pain of the trunk and limbs due to PSPS-T2, complex regional pain syndrome types I and II, ischemic pain syndromes, diabetic neuropathy, lumbar radiculopathy, persistent spinal pain syndrome type 1 (PSPS-T1), and historically intractable angina pectoris, although rarely treated in contemporary practice. In the United States, PSPS-T2 is the most common indication for SCS. Current evidence supports the use of SCS in treating these conditions in carefully selected patients.^{7–10} Dorsal root ganglion stimulation is similar in process but modulates the dorsal root ganglion and has been shown to be more efficacious in focal neuropathic pain such as complex regional pain syndrome.¹¹ Despite its limited coverage and use in the United States, SCS has shown promise in treatment of peripheral vascular disease and limb salvage, but with the advent of stents, SCS use for intractable angina pectoris is rarely used in present day.^{7,12} A more recent indication for SCS is painful diabetic peripheral neuropathy which has gained more widespread use and is strongly supported by outcome studies.^{8,9} SCS use in treating chronic pelvic and visceral pain is evolving, and studies continue to address the efficacy of these indications. Based on current evidence dorsal root ganglion stimulation may have better utilization.^{10,13–15}

Patient Demographics and SCS Explanation

Despite an estimated 71% trial success rate, some patients who undergo permanent implant require explantation of their device.¹⁶ One study estimated up to 30% of patients received an explant over 15.5 years, with the majority occurring within the first five years for reasons including infection, pocket pain, loss of efficacy, and device failure.¹⁷ Studies show that demographic, health, and pain-related factors may play a role. The relevance of demographic factors, like age and gender, is still evolving, but the most consistent finding is higher explant rates among females.^{18–20} Tobacco, cannabis, and opioid use have been linked to an increased risk of explant, but this has not been reproduced in prospective fashion, so the significance is uncertain.²¹ Patients with psychiatric comorbidities - anxiety, depression, and post-traumatic stress disorder – also tend to have higher rates of explantation.^{21,22} Conversely, those with back pain accompanied by radiculopathy and no prior surgery are less likely to undergo require explant.^{18,23} The interplay between demographic, health, and pain-related factors is complex, and individual patient assessment remains crucial. Future research with larger sample sizes and longer follow up periods may help clarify conflicting findings and provide a better understanding of the patient decision to pursue explantation.

Components of a SCS System

SCS systems consist of several components: the implantable pulse generator, leads, and external controller. The generator is the power center of the device. It not only generates waveforms but also interacts with external devices to change programming, alter modes, or upgrade software. The leads transmit the signal created by the implantable pulse generator (IPG) and lie adjacent to the target tissue. The external controller provides a patient interface to the SCS, and several platforms now offer remote programming where the patient can have a virtual visit in a different physical location than the representative programmer.

Implantable Pulse Generator (IPG)

An IPG is an electrical power source that delivers current to neural tissue through lead electrodes. IPGs may be either rechargeable or non-rechargeable (primary cell). Initially, IPGs were powered by non-rechargeable lithium cells that required frequent replacement. Current primary cell batteries have longer lifespans, but this can vary based on each system's energy consumption. To avoid frequent surgical replacement, IPGs with rechargeable batteries were developed. Unfortunately, over time the IPG's ability to recharge can become less efficient and may even require daily recharging in some cases. Early evidence suggested that patients with rechargeable, high-frequency IPGs were more likely to undergo explantation in a retrospective analysis.^{24–26} Recharge burden was identified as an important variable due to greater energy usage for high frequency stimulation. Battery technology has continued to improve since these studies were published, and the recharge burden has lessened for some devices. There is now a trend towards smaller rechargeable IPGs over larger non-rechargeable primary cell IPGs, but ultimately this depends on patient preference. As such, it is important to outline the pros and cons with patients when discussing different devices. [Table 1](#) highlights the various SCS IPGs on the market and their unique features. [Figure 1](#) depicts images of each IPG when permission to do so was granted.

IPG Magnetic Resonance Imaging (MRI) Compatibility

Early SCS IPG models were not MRI conditionally approved and created dilemmas when patients required imaging for spine or other medical conditions, even requiring explant in some cases. Recent technological innovation has allowed for MRI conditionally approved systems for most brands, although they have different specifications. Some systems are MRI compatible under certain conditions and others are MRI conditionally approved regardless of system integrity. A common cause of incompatibility is high impedance commonly caused by lead fracture, lead scarring, or contact issues in the generator. If impedances are out of an approved range, MRIs for some systems are not possible. Studies have reported a range of 10–12% of SCS explants due to inability to undergo MRI.^{27,28} Barriers to standard care due to an implantable device can lead dissatisfaction and negative awareness of the device that leads to explantation. There is ongoing work with the FDA by several manufacturers to demonstrate safety despite the presence of lead fractures, and approval may be available after submission of this manuscript. [Table 1](#) references different MRI compatibility across the market at time of writing.

Table 1 Various SCS IPGs on the Market, Including Rechargeable and Non-Rechargeable with Features Highlighted

	Abbott	Boston Scientific	Medtronic		Nevro	Saluda
Rechargeable	Eterna	WaveWriter Alpha	Intellis	Inceptiv	HFXiQ, Omnia	Evoke
Battery technology	Lithium ion cell	Lithium ion cell	Lithium titanate		Lithium ion cell	Lithium ion cell
Volume	13.6 cc	21.6 cc	13.77 cc	13.77 cc	26 cc	33 cc
Thickness	8.9 mm	10.7 mm	6 mm	6 mm	11.5 mm	12 mm
Expected Lifetime	10 year	12 years	9 years	15 years	10 year	10 year
*Time to full recharge	1 hour/month or 3 hour if 5x per year	1 hour	1 hour		30 min-1 hr	Not listed
*Estimated charge frequency from company based on set parameters	5x per year	1x per week - 1x per month	Not listed	Not listed	1x per month	Not listed
MRI Conditionality	Full Body MRI Conditional 1.5T	Full Body MRI Conditional 1.5T	1.5 and 3T full body		Full Body MRI Conditional 1.5T, 3T Head/Extremity	Full Body MRI Conditional 1.5T, 3T Head/Extremity
Recommended depth from skin	0.5–2.5 cm	0.5–2.0 cm	< 3 cm	< 3 cm	< 2 cm	5mm - 20mm
Closed Loop Capable	No	No	No	Yes	No	Yes
Non-Rechargeable (Primary Cell)	Proclaim	WaveWriter Alpha Prime	Vanta			
Battery technology	Carbon monofluoride/silver vanadium oxide cell	Lithium ion cell	Lithium ion cell			
Volume	30.4 cc	36.6cc				
Thickness	13.4 mm	10.7 mm	11.4 mm			
MRI Conditionality	Full Body MRI Conditional 1.5T	Full Body MRI Conditional 1.5T	1.5 and 3T full body			
Recommended depth from skin	< 4cm	<2.5 cm	< 4 cm			
Closed Loop Capable	No	No	No			
Expected Lifetime based on manufacturer established Nominal program settings	10 years (5 year warranty)	5.1 years	5.5–7.5 years			

Notes: * Time to full recharge and Frequency of charging are estimates based on nominal use at beginning of therapy. As a system ages or stimulation amplitude increases these numbers can change.

Rechargeable



Non-rechargeable



Figure 1 Various Internal Pulse Generators (IPG) on the market. Image provided courtesy of Boston Scientific. ©2025 Boston Scientific Corporation or its affiliates. All rights reserved. Images reproduced with permission from Medtronic. Images reproduced with permission from Abbott. Image reproduced with permission from Nevro. An image for Saluda was omitted as no permission was granted.

SCS Leads

SCS leads may be cylindrical or paddle shaped. Cylindrical leads are placed percutaneously via needle epidural access, and SCS trials are performed with this technique. Permanent implantation may either be performed with percutaneous approach using cylindrical leads, or via laminectomy for paddle lead placement. **Figure 2** shows SCS lead options. Paddle implantation is associated with slightly higher initial postoperative complications, but significantly lower long-term reoperation rates, likely due to reduced risk of migration compared to percutaneous leads. Percutaneous leads offer

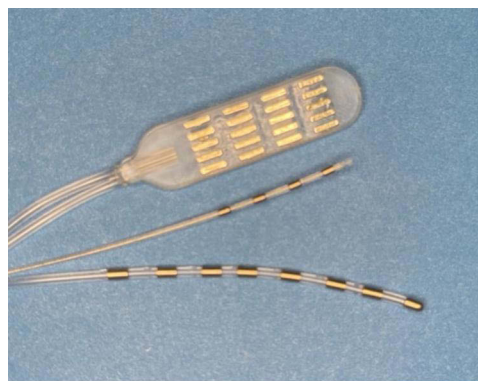


Figure 2 Various SCS lead types including paddle (top), dorsal root ganglion (middle) and dorsal column (bottom). (Personal photo).

reduced initial complication risk and less invasiveness, while long-term healthcare costs are similar between paddle and percutaneous leads.²⁹ There does appear to be an initial increase in postoperative pain with paddle placement, as it is a more invasive surgical procedure, but there is no evidence to suggest that this pain persists in the long term.^{29,30} A minimally invasive approach to paddle placement involving interlaminar flavectomy using tubular retractors appears to reduce immediate postoperative pain, which could be advantageous in improving patient experience in the long term.³¹

Patient Controller

Patients may access their SCS through handheld controllers or phone applications connected via Bluetooth. The controller allows users to toggle the device on/off, switch between preset programs, adjust individual parameters such as amplitude, and place the system in temporary modes to minimize interactions with external environments - airport security, electrocautery, radiofrequency, and MRI. Some systems allow for an application to be placed on their personal phone, reducing the need for an additional device. Interfacing with such applications can be a barrier for technologically illiterate or elderly patients and should be considered prior to moving forward. Simplifying the technical interface on these devices may make navigating easier for those patients that are less technologically savvy.

Remote Monitoring

A newer feature of SCS device management is remote monitoring, similar to technology that exists in cardiac monitoring. Patients with adequate internet connection can have their device accessed, interrogated, and reprogrammed remotely by a representative without having to be physically present in the office. These virtual visits allow providers to efficiently respond to patient needs and monitor for continued efficacy. This addresses a common pitfall – lack of close follow up. In this situation a patient may have felt the device was no longer efficacious but only needed reprogramming to return to their therapeutic window. This technology is expected to become more commonplace among patients and clinics, but changes to postoperative protocols and scheduling flow must be adopted. Reducing barriers to optimal stimulator programming and taking a proactive stance would logically improve the user experience and patient satisfaction.

Anatomic and Surgical Factors Affecting IPG Site Discomfort

SCS is safe and well established in treating chronic pain, but there are possible complications. Some are rare complications such as infection, spinal hematoma or spinal abscess. Others are less urgent but can compromise patient outcomes, such as lead fracture, lead migration, or IPG site pain – often termed *pocket pain*. The incidence of SCS related pocket pain is well described in literature, but reported rates are widely variable ranging from less than 1% to 60%. The presentation of pocket pain can also be variable. A recent literature review compiled over 50 studies with varying levels of evidence from Level I to IV. This was comprised of several retrospective reviews, but only a few included large sample sizes.^{32–34} Bao et al evaluated 785 patients with 43 (5.5%) reporting pocket pain. The average time described from initial surgery was 7.5 months with significantly more female than male.³⁵ All patients ultimately required revision or explant. Another review by Cameron et al included 2,753 patients, 24 (0.9%) of which reported device-related discomfort.³⁶

Three notable randomized controlled trials reported an incidence of pocket pain between 4% and 11.9%. In the studies reviewed, several interventions were offered, including repositioning the IPG to a different anatomical location, utilizing a smaller or differently shaped generator, and providing pharmacological management to alleviate pain. In many of these cases surgical revision of the IPG pocket was necessary to address the discomfort. Additionally, patients were counseled on the potential for long-term management strategies to cope with persistent pocket pain.³⁷

Body Mass Index (BMI)

Clinical studies have shown that obese patients experience a 2% reduction in efficacy for every unit increase of BMI and a 20% improved response rate to pain relief in normal or underweight patients compared to morbidly obese individuals.³⁸ Lead migration appears to be more likely in the subacute postoperative period in obese patients, placing emphasis on anchoring techniques in this patient population.³⁹ Studies have also found a higher incidence of superficial wound

dehiscence and infection in obese patients.^{40,41} Despite these risks, SCS can be safely performed in this patient population. Obesity can also make surgical technique more challenging due to large skin folds with excess tissue affecting the position of an IPG in different planes. An IPG that is skin parallel when implanted prone may be angled or protrude against the skin in the seated position. Surgeons must also be aware of tissue depth requirements for each device manufacturer as excess adipose tissue can make proper generator placement challenging with regards to depth. No direct correlation has been identified between and increased incidence of pocket pain and BMI, but evidence specific to this question is limited.³² The opposite situation can also present a problem, wherein a patient implanted loses a significant amount of weight. This can affect the original generator placement and may require revision. Direct evidence of the risk of migration, lead stability, or need for revision in patients that have lost weight is absent at the time of writing.

Demographics

Previous studies have demonstrated gender disparities in the rates of pocket-mediated pain in patients undergoing spinal cord stimulation implantation.^{42,43} Females reported a higher incidence of IPG site pain attributable to psychosocial and biological factors.⁴⁴ Biological factors include hormone variation in pain levels during the menstrual cycle in females and the testosterone mediated activation of the descending inhibitory pathway in males.⁴⁵ Psychosocial factors include higher rates of depression among females, which may account for decreased efficacy. Authors have suggested that a lack of female experts in the field may result in less female-specific needs research.⁴⁵ In addition, social pressures and prejudiced may cause males to report understated pain levels.^{46–48} Although previous research has demonstrated females have a higher risk of pain and explant, no significant correlation has been found between race or ethnicity in these patients other than small case studies.^{35,49,50}

IPG Location

Clinical studies have shown that implant location may affect the propensity to develop pocket pain.⁵¹ A survey study included patients undergoing device implantation for movement disorders, chronic pain disorders, and psychiatric conditions. The anterior chest site was commonly chosen for movement disorder neuromodulation and abdominal, flank, and gluteal locations dominated for chronic pain indications.⁵¹ Results demonstrated significantly more pocket pain at the gluteal implant site in patients with psychiatric disorders, but when the general population was evaluated, no significant differences were found. This indicates that there may be a significant psychiatric component to implant site pain.

Sex dimorphisms should also be considered for IPG location, as men tend to have larger flank circumferences than females. Women also tend to have greater tissue distribution in the hips and thighs and lower flank circumference. Suboptimal device placement in the flank would thus be more noticeable in females.⁵² Clinical studies have shown significantly more females compared to males experiencing pocket pain with a tendency towards IPG placement in the buttocks.⁵³ Ideally future studies would identify particular locations that may cause an increased incidence of pocket related pain. But current evidence suggests the question is much more complicated, that the propensity for IPG site-mediated pain can be affected by sex dimorphisms, implant indication, and psychiatric conditions, not one single factor. These influences should be accounted for when offering and planning SCS, with particular attention paid to IPG placement and incorporation of patient input. Some surgeons advocate for a temporary device worn externally prior to implantation so the patient can play a more active role in choosing an IPG site location. Additionally, one must account for the need for longer leads at some locations, particularly for cervical lead placement.

Patient Satisfaction

SCS is backed by years of clinical evidence supporting use in improving pain outcomes for certain conditions.^{7–10} Overall patient satisfaction is arguably a different measure than pain improvement on Visual Analog Scale (VAS) scale or functional improvement on Oswestry Disability Index (ODI). Patient satisfaction can vary and may be linked to factors other than pain relief. Salekiet al evaluated such factors and found an expected correlation between magnitude of pain relief and satisfaction. In patients receiving >50% pain relief, 81% reported satisfaction, and less so (38–41%) for patients receiving <50% relief.⁵⁴ Findings also demonstrated significant changes in sleep, fatigue, and quality of life,

which may contribute to improved psychological response to pain. Although other studies have previously identified the negative impact of psychological factors, BMI, and gender on SCS success, they have yet to look at pocket pain specifically.^{38,44,55–57} Measures of overall patient satisfaction, while closely correlated to pain relief, may encompass a variety of factors including ease of device interaction, remote interface, and charging convenience where applicable.

Role of Psychiatric Conditions on Pocket Pain

A thorough review of the literature suggests that there is a paucity of information on the psychological implications of pain caused by IPGs. However, this absence of literature does not suggest that pocket-pain related emotional sequelae are not real and distressing. Regarding etiology, a small 2021 study appears to have been the first to look at psychological factors as predictive of pocket pain - with findings suggesting that anxiety and depression were non-predictive.³⁵

Although studies and systematic reviews have noted pocket pain as a frequent complication, none have examined the relationship between pocket pain and psychological phenomena. A 2017 article was dedicated solely to the phenomenon of pocket pain in neuromodulation.⁵¹ The authors covered important issues, including prevalence, etiology, demographics, coverage in the literature, and medical management of patients experiencing pocket pain, yet they chose not to address potential psychological sequelae.

Given this lack of empirical support, we warn against “common sense extrapolation”, and the resulting assumption that pocket pain is related to depression and/or anxiety. Of greatest concern, however, is the possibility that severe pocket pain has an adverse impact on quality of life. The study of such a potential association would not be particularly onerous, although would likely require a prospective approach to better understanding the broad impact of pocket pain. However, irrespective of the high incidence of post-IPG implantation pain well described in the empirical literature, researchers have curiously neglected what would potentially be a useful topic of investigation.

IPG Features and Potential Role in Pocket Pain

IPGs come in both rechargeable and non-rechargeable versions, each with distinct characteristics that may affect pocket awareness and patient experience. However, this awareness may vary based on patient preferences and priorities. Reviewing the features of each is important before proceeding with implantation.

Rechargeable

Rechargeable SCS devices must be recharged at varying intervals, depending on the device model and patient specific energy usage. Traditionally most devices required recharging every few days to weeks, although new technology has lengthened this interval to months in some cases. Experience with newer rechargeable batteries is limited and data on long-term use is still sparse.⁵¹ Rechargeable devices are generally designed to last 9 years or more, depending on the manufacturer, but their longevity depends more on usage patterns. Manufacturers estimate lifespans and provide warranties for IPGs if energy usage remains within a prescribed window.³⁵ Early versions of rechargeable IPGs devices struggled to recover after an extended period of full depletion, but newer models have improved this issue.^{58,59} Table 1 lists the estimates for charge frequency and duration of charge from complete depletion, as provided by the manufacturer. These estimates are difficult as there is individual variance in energy usage based on unique programming options. Despite this, gathering estimates with nominal use from each manufacturer for the purpose of this manuscript was very difficult and, in some cases, impossible. We as authors and physicians call for greater transparency going forward to better inform patients of the expectations with rechargeable systems even if this is based on average energy requirements with the understanding that individual experiences may vary.

Recharging an IPG requires placement of an external charging unit over the IPG and repletes the battery via inductive coupling. Recharging capabilities, initially seen as a significant clinical advantage, have not always met patients' expectations. For some, the necessity of regular recharging has become a burden rather than a convenience.⁶⁰ While convenient, recharging can be uncomfortable, especially if the charging device causes pressure over the pocket or generates heat.⁵⁹ In rare cases, the recharging process must be broken into multiple sequences to avoid excessive heating and discomfort.⁵² The need for precise alignment during charging increases patient interaction with the device, giving

rise to greater pocket awareness. Because of the need for precise alignment, proper surgical placement is important and is addressed in a later section.

Conversely, an advantage of rechargeable IPGs is smaller size due to reduced capacity needs. Smaller IPGs tend to be less noticeable, easier to conceal under the skin, and allow for smaller incisions. Recent innovation in the battery sector has translated to charging improvements. The estimated frequency of recharge for current IPGs is noted in [Table 1](#). Some manufacturers have not reported and did not respond to query as noted. As with other non SCS batteries, recharging capabilities can change over time, particularly with lithium-ion cell batteries. With age and many recharge sessions, lithium-ion cell batteries may experience decreased capacity and increased internal resistance by means of energy and power loss. This can translate to longer charging times and shorter duration on a full charge. Some manufacturers utilize a lithium-titanate cell in attempts to reduce this effect.⁶¹

One area that is not well understood is the pattern of recharging. Lithium-ion batteries are known to have greater lifespan if maintained within the range of 20–80% charge and demand higher energy with greater battery stress to charge from 90 to 100% than at lower capacities.⁶² Some patients may charge only when the battery is fully depleted, and others may charge a short amount every day. This interval may change over the life of the battery based on charging patterns and other factors. It is yet to be determined what the optimal schedule is, but future research should help elucidate this to optimize patient experience and battery function. Ideally a specific charging pattern should be prescribed. It should also be noted that complex recharging protocols may be too difficult for elderly patients or the technologically challenged.

Non-Rechargeable (Primary Cell)

Non-rechargeable IPG device lifespan can range on average from three to seven years, depending on patient energy usage.³⁸ IPG capacity depletion ends pain therapy and requires surgical replacement. Replacing the IPG involves surgically accessing the pocket and risks worsening pain and discomfort. Despite eliminating the need for recharging, the larger size of non-rechargeable IPGs can increase risk of pocket discomfort, particularly in patients with a lower BMI.⁵⁶ Studies have shown that larger pulse generators may shift within the pocket, contributing to greater pain and a higher likelihood of revision surgeries.⁶³ Despite expected differences in battery lifespan, a real-world retrospective study of 106,462 Medicare beneficiaries found similar clinical longevity for primary cell and rechargeable batteries.⁶⁴ Moreover, the pocket location itself plays a significant role in patient experience with non-rechargeable devices.⁵² Proper surgical planning and consideration of pocket location are crucial to minimizing discomfort with both rechargeable and non-rechargeable devices.⁵⁵

While rechargeable devices offer a smaller form factor, frequent recharging can increase the patient's device interaction, contributing to pocket awareness. On the other hand, non-rechargeable devices eliminate the need for recharging but may cause greater pocket pain due to their larger size and the need for surgical replacement. Careful consideration of these factors, along with patient specific attributes such as BMI and tissue density are essential in selecting the appropriate device and minimizing the risk of pocket pain and awareness. The authors of the Medicare study concluded that patient factors other than device lifespan should be considered when choosing an implantable device given their similar clinical longevity.⁶⁴

Size

Currently available SCS IPGs vary significantly in volume, size, and shape. These factors may be relevant in influencing the propensity for developing pocket pain. The design and functionality of these devices have evolved, with focus on optimizing therapeutic outcomes and patient satisfaction, while minimizing invasiveness and complications. Smaller IPGs are associated with reduced rates of pocket pain and higher patient comfort and satisfaction than larger IPGs.⁵¹ Even smaller micro-IPGs have been found to reduce complications and improve usability.⁶⁵ The implications of device size extend beyond patient comfort and surgical ease, as IPG size influences system capacity, lifespan, and recharge burden, particularly for high energy waveforms. [Table 1](#) shows the various sizes of available IPGs on the market.

Shape

How we interact with objects often depends more on shape than we may appreciate. The more an object's form resembles the natural world, the more likely we are to seek interaction. A common design theme used by technological companies incorporates rounded, smoother edges in objects with which we interact closely (ie – smartphones, watches) and reserves straighter lines and edges for objects that we view at a distance (ie - desktop computer, television). Even these more squared objects have rounded edges, and have been referred to as “squircles”, shown in [Figure 3](#).

The smooth, rounded edges draw us in to fidget with the device, a closer resemblance to the natural world. No current data has examined patient satisfaction specific to IPG shape, but more rounded edges approaching circular are expected to be favorable. Obviously, a patient cannot interact with an IPG as if it were a smartphone, but rounded edges can reduce erosion risk, stress on surrounding tissues, and are less likely to pinch the tissues when contacted. Various shapes of current IPGs on the market are shown in [Table 1](#). Future IPGs might increasingly adopt a more circular design as they aim to build upon this design strategy.

Surgical Factors for Pocket Creation

Pocket pain can arise due to various factors, including patient body habitus, IPG characteristics, and surgical technique.³⁵ The creation of the IPG pocket during SCS device implantation is a critical step to minimize postoperative pain and long-term discomfort at the IPG site, enhance SCS functionality and patient outcomes, and improve overall satisfaction. Studies suggest that the revision rates for SCS due to intractable IPG site pain range from 1% to 19%.⁵¹ On average, pocket pain develops 7.5 months post-surgery, with revision surgery occurring approximately 4.5 months after pain onset.³⁵ As mentioned previously, sex-based and anthropometric differences are key factors in the preoperative planning and potential development of pocket pain.^{35,53}

The location of IPG implantation correlates with the incidence of site-specific pain. The lowest rates of IPG related pain have been observed in the posterior chest wall (13%) and the highest in the abdomen (28%). Flank implants, both small rechargeable and non-rechargeable IPGs exhibited similarly low rates of pocket pain.⁵²

Current literature underscores the importance of carefully selecting the IPG pocket location to minimize the risk of revision and pocket pain while optimizing patient comfort. Biomechanical and computer modeling studies have previously suggested the abdomen as the most appropriate site for thoracic SCS, and midaxillary placement for cervical SCS to reduce the mechanical forces on the system that contribute to lead fracture,⁶⁶ but this is in conflict with the pocket pain reported to be associated with these implant sites. Implanters must therefore take each patient into account when deciding on an implant location to optimize patient comfort and system preservation.

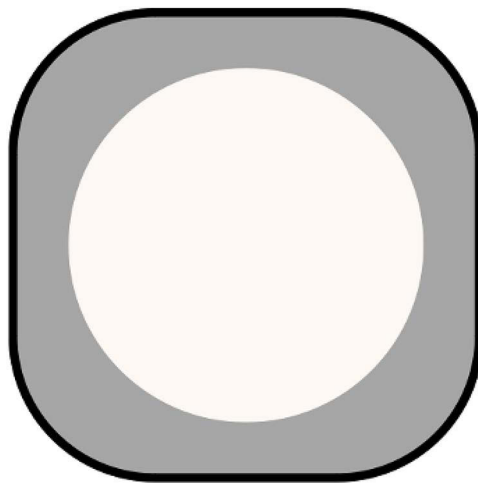


Figure 3 A “squircle”, is demonstrated as the outer edge of the object, compared to the circular shape in the center. (Personally created).

The optimal IPG site thus remains controversial and should be individualized based on patient-specific factors, surgical technique, and device type. Chest wall placement risks damaging the supraclavicular nerves (anterior pectoral placement) or the anterior cutaneous branches of the upper thoracic nerves (posterior chest wall). Conversely, the subcutaneous fat density in the abdominal and posterior flank regions may offer an advantage for IPG placement, although the complex vascular and nerve structures in the anterior abdominal wall, including branches of the subcostal, thoracoabdominal, and iliohypogastric nerves can increase the likelihood of pocket pain.⁵² Flank placement may be preferred due to reduced lead extension length, decreased risk of IPG migration with proper anchoring, and improved patient comfort. An example of flank placement and proximity to the lead incision is shown in [Figure 4](#). Although buttock placement is commonly performed, it has been associated with a higher incidence of pocket pain and revision surgery, due to the proximity to the posterior superior iliac spine and cluneal nerves as demonstrated in [Figure 5](#).⁵² Moreover, IPG placement in the buttock has been linked to higher revision rates compared to flank placement.⁵⁸ Several common IPG implant sites for thoracic SCS are shown in [Figure 6](#).

Shared decision making is important when deciding on an IPG implant site, informed by a detailed discussion of the risks and benefits of each option. The patient's preference should be documented during the preoperative visit, and the selected location should be marked on the skin with a surgical pen preoperatively in various positions. For gluteal placement, the patient should wear pants during the preoperative marking, and a model of the IPG should be positioned over the skin while the patient is both seated and standing to ensure that the device will not interfere with normal activities such as sitting or lying down. Similarly, for midaxillary placement, women should wear a bra during the preoperative marking process. A suggested strategy is to apply an IPG model to the patient's body a few days before surgery to confirm the chosen site and reduce the likelihood of revision due to suboptimal placement.

Pocket Depth, Size, and Orientation

In addition to location, other surgical factors such as pocket size, depth, and tunneling techniques also contribute to IPG site pain. The pocket should be created with precision to closely match the dimensions of the IPG, minimizing dead space and reducing the risk of migration or rotation. Pockets that are too tight may cause compression of the device against surrounding tissues and potentially cause ischemia, while overly large pockets can lead to excessive mobility. Large pockets with excess dead space may allow the IPG to flip or turn inside the pocket. The torsional strain placed on the leads can cause coiling followed by migration or fracture, requiring revision surgery. Furthermore, constant friction can increase the incidence of pocket pain. Patients with less subcutaneous tissue may be at higher risk for battery flipping or device movement, as there is less tissue to stabilize the device. Furthermore, the composition of the soft tissue (eg,



Figure 4 SCS leads placed near midline, anchored to thoracolumbar fascia and tunneled to the left flank for generator implantation. (personal photo).

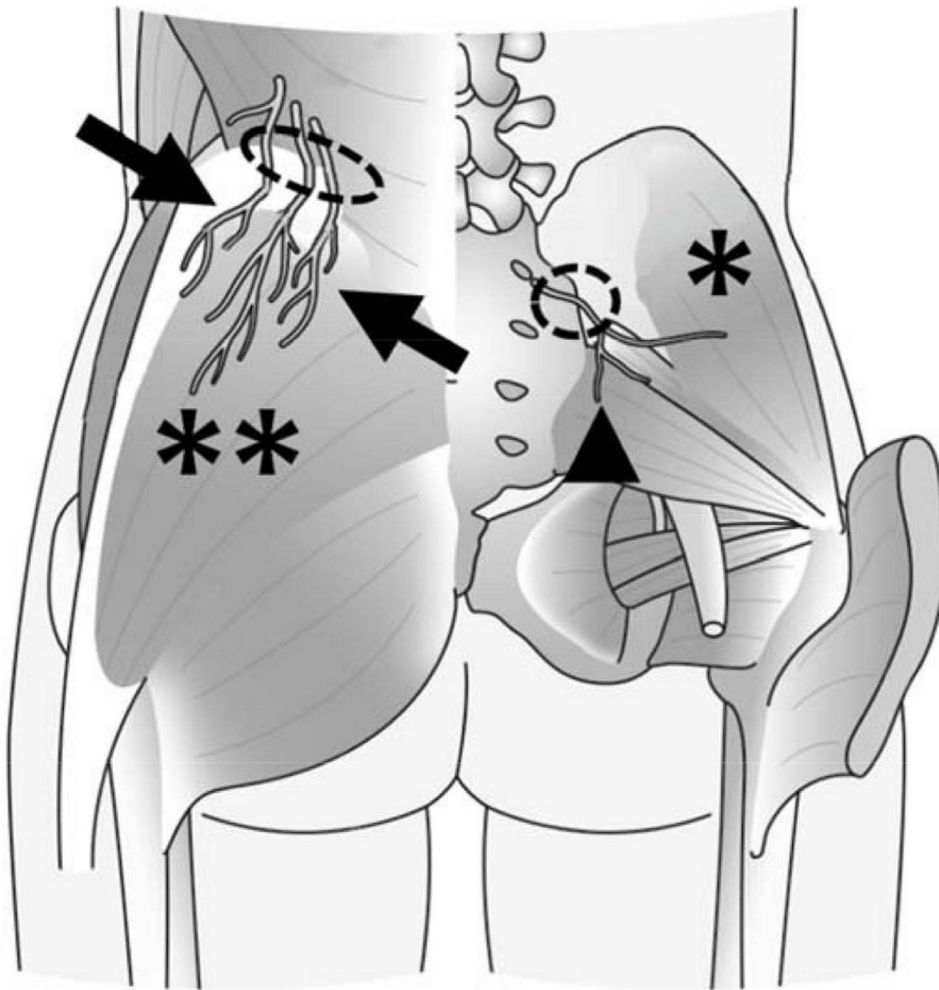


Figure 5 Anatomic depiction of superior (arrows) and middle (arrowhead) cluneal nerves. Note the superior cluneal nerve location relative to the iliac crest (dotted circles), which may be affected with gluteal generator placement. Gluteus medius muscle (*) and gluteus maximus muscles are represented (**)⁶⁷ (Creative Commons Permissions).

muscle versus fat) can also affect device stability. This can be exacerbated by excessive body movement causing the device to flip or angle within the pocket. Using an IPG template during surgery helps ensure proper pocket sizing.⁶⁸

The depth of the pocket and whether the IPG is placed subcutaneous or subfascial are important considerations. All devices communicate wirelessly and require specific depths to reduce interference. Subfascial placement, while sometimes recommended, may interfere with recharging or communication capabilities.⁶⁸ The recommended implant depth for individual rechargeable and non-rechargeable IPGs are listed in [Table 1](#). If the pocket is too shallow, the recharging process becomes paradoxically inefficient, leading to longer recharging sessions. Conversely, a pocket that is too deep can reduce the recharging coil's energy transfer.^{14,51,60} Implanters should reference the recommended implant depth per manufacturer specification to allow for proper device communication.

The orientation of the incision relative to the IPG may affect IPG aesthetics and position. If the incision is the superior or inferior most portion of the IPG it is more likely that the IPG could angle within the pocket and potentially create pressure points. To avoid this an incision that crosses the center of the IPG is ideal as in [Figure 7](#). When creating the pocket blunt dissection is performed just above and below the incision at the appropriate size to accommodate the chosen IPG.

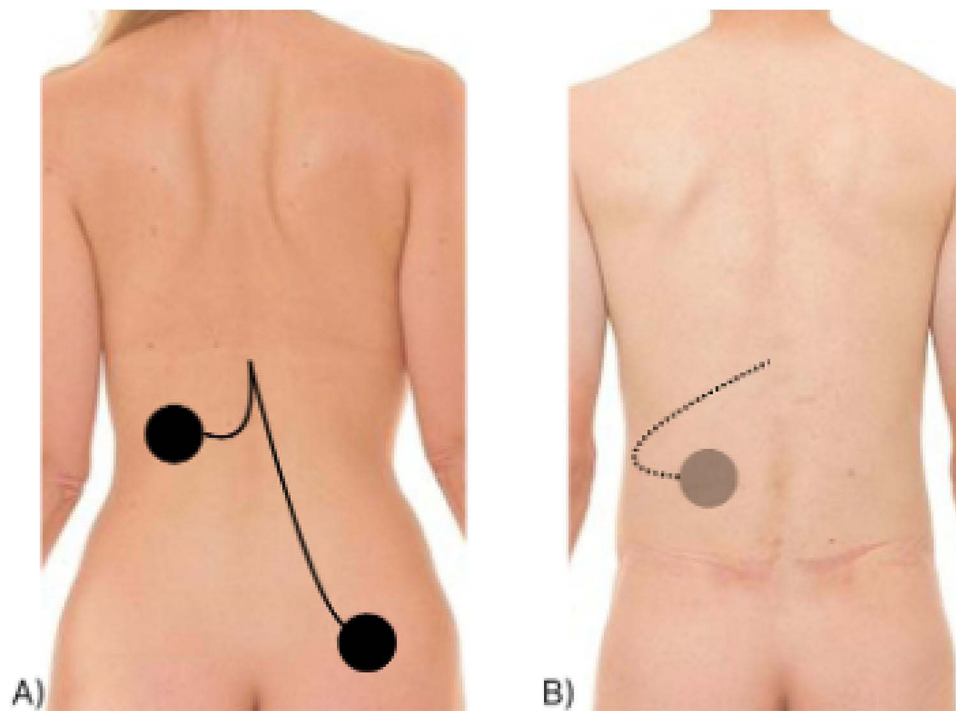


Figure 6 Possible locations for generator placement after thoracic SCS placement (**A**) paraspinal and gluteal, (**B**) abdominal (Adapted from Stockholm photos –109) Taken at City Studios in Stockholm (www.stockholmsfotografen.se), September 29, 2011, with assistance from KYO (The organisation of life models) in Stockholm. Wikimedia Commons. [https://commons.wikimedia.org/wiki/File:Posterior_view_of_human_female_and_male_backs_\(cropped\).jpg](https://commons.wikimedia.org/wiki/File:Posterior_view_of_human_female_and_male_backs_(cropped).jpg).

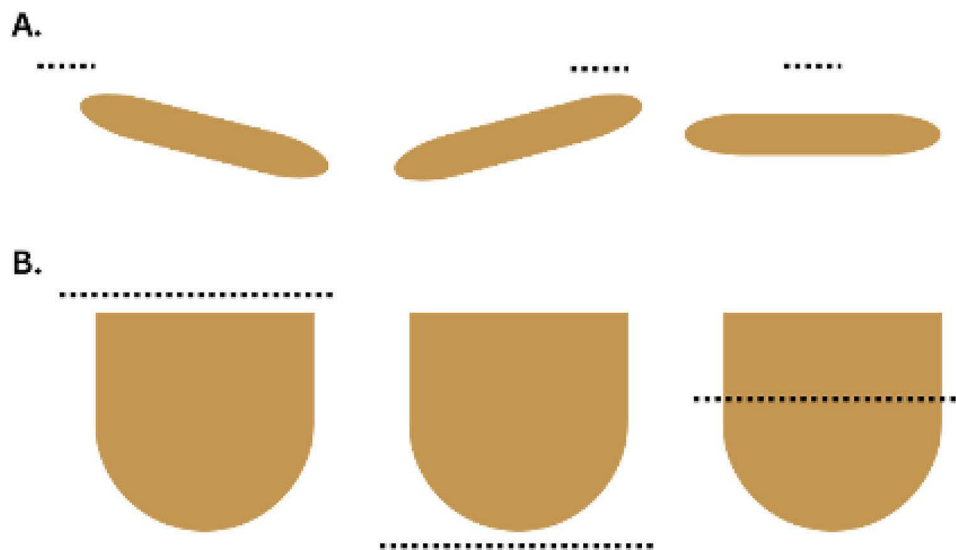


Figure 7 (**A**) Lateral and (**B**) Coronal view of IPG (brown) orientation relative to incision (dotted line) and potential for IPG angulation or flipping relative to the incision. (Personally created).

Surgical Dissection

Surgical dissection techniques include blunt, sharp, and electro-surgical dissection. Blunt dissection is the separation of tissues along natural tissue planes utilizing non-cutting edges. Blunt dissection is less likely to damage to surrounding structures but may lead to tissue edema and seroma formation if excess force is used.⁶⁹ Sharp dissection uses a cutting edge, is necessary for skin incision, and may be utilized in deep tissues at the surgeon's discretion. However, excessive use can cause damage to surrounding structures, particularly peripheral nerves. Electro-surgical dissection with monopolar

electrocautery is often utilized for cutting and hemostasis, resulting in decreased blood loss and operative times when compared to traditional cold sharp dissection.⁷⁰ While electrocautery has also been shown to decrease postoperative pain and tissue damage, excessive electrocautery use may lead to seroma formation and poor wound closure. Postoperative wound complications can lead to heightened awareness of pocket pain. Additionally, it is important to ensure that the dissection is performed within the same tissue plane, so that the IPG remains parallel to the skin surface, as angulation of the IPG may place unnecessary pressure on the skin and underlying tissues increasing the risk of pocket discomfort.

Wound Closure

There are various described methods for wound closure. Wound closure can be completed in one or multiple layers, utilizing any combination of sutures, staples, and/or topical skin adhesive. The Neurostimulation Appropriateness Consensus Committee (NACC) recommends utilization of a multi-layer closure to reduce tissue tension and thus the risk of circulatory compromise and wound dehiscence.⁷¹ This technique also minimizes dead space which decreases the risk of hematoma, seroma, and IPG movement. A multilayer closure involves closure of tissue planes in a sequential order. Typically, absorbable braided sutures, such as Vicryl (Polyglactin 910, Ethicon Inc., New Jersey, USA), in running interrupted fashion are used to approximate the deep tissue layers due to their high tensile strength. Sutures should be placed in an inverted fashion as to bury the knot to reduce the risk of stitch abscess and inflammatory reaction.⁷² For skin closure, non-absorbable sutures (silk, nylon) can be placed in a transdermal fashion (simple interrupted, running, vertical mattress, etc) or an absorbable running subcuticular suture such as Monocryl (copolymer glycolide and caprolactone, Ethicon Inc., New Jersey, USA) can be utilized. A running subcuticular suture is preferred to transdermal sutures for cosmesis.^{73,74} The risk of wound dehiscence with running subcuticular closure can be mitigated by applying a topical skin adhesive. If staples are used for closing the superficial layer, it is imperative to use proper technique of eversion for approximating the skin edges, allowing for proper wound healing and cosmesis. Staples offer the advantage of speed when compared to sutures and topical skin adhesive^{75,76} however, there is evidence to suggest that there is less acute postoperative pain and increased cosmetic satisfaction when using sutures compared to staples.⁷⁷ Topical skin adhesive such as Dermabond (Ethicon Inc., New Jersey, USA), can be used as an alternative to or in conjunction with suture or staples for the skin. Studies suggest that topical skin adhesive decreases postoperative pain, decreases risk of surgical site infection, and provides better cosmesis when compared to sutures and staples.^{76,78,79} Despite this evidence, a retrospective review compared postoperative pain levels after SCS implant closed with running suture and staples and found no difference in pain scores between the two cohorts at postoperative days 1 and 10.⁸⁰

Wound dressings provide protection of the wound from injury and contamination and should adequately cover the entire wound closure. A multi-center retrospective review of 2,737 SCS implants and revisions found a statistically significant reduction in surgical site infection (SSI) rates with the application of a sterile occlusive dressing in the operating room. Although the data in SCS patients supports the use of a sterile occlusive dressing, it should be noted that a Cochrane systematic review was unable to determine with any certainty whether covering a surgical wound with a wound dressing decreases the rate of SSI or if a particular wound dressing (transparent film, silver-containing, hydrocolloid) was more effective at reducing SSI or reducing pain.⁸¹ Despite the findings of the systematic review, the Neurostimulation Appropriateness Consensus Committee (NACC) continue to recommend the use of a sterile occlusive dressing for 24 to 48 hours for surgical wounds healing under primary intention to reduce the risk of SSI.⁷¹

When implanting SCS systems, patient safety and positive outcomes are priority, however we argue that reduced pocket pain and awareness is as important as relief of preoperative pain. Meticulous planning and operative skill during surgical placement can reduce risk of infection, tissue trauma, and postoperative pain, as has been described. Minimizing postoperative pocket pain reduces patient focus on the newly implanted IPG and is expected to reduce pocket awareness in the long term, although this has not yet been formally evaluated.

Anchoring the Generator

Anchoring the generator by placing a nonabsorbable stitch reduces the risk of the IPG moving or flipping within the pocket. The ability of the IPG to move significantly increases risk of pocket awareness and discomfort. The IPG is typically anchored at the level of the Scarpa's fascia in the abdomen or the thoracolumbar paraspinous fascia posteriorly

but may vary based on the patient's body mass index.⁸² A combination of sharp and blunt dissection is often used to delineate an anchor plane and subsequently anchored the IPG.^{82,83} Depth may vary based on individual body habitus and battery requirements, but the optimal plane for the pulse generator to reduce the risk of erosion and allow for successful telemetry is approximately 0.5 to 2 cm when anatomically possible and always considering the manufacturer recommendations (Table 1).⁸⁴ If the IPG is not anchored to fascia appropriately or if sutures absorb over time, movement risk increases.⁸⁵ Therefore, it is recommended to use 2–0 non-absorbable sutures when anchoring is performed.^{85,86}

Strain Relief Loops

Strain relief loops in the pocket not only absorb the pushing and pulling forces exerted on the lead wires during use but also increase their bend radius. An increase in the bend radius increases the force required to cause lead displacement. It is well appreciated that implanting SCS leads in the IPG pocket without strain relief loops may reduce the functional survival time of the leads.⁸⁵ The use of multiple strain relief loops might provide an additional buffer against potential effects of longitudinal forces, minimizing the potential for lead migration.⁸⁶ A bend radius that is too small, however, may increase the risk of lead compromise due to lack of strain relief. Tissue encapsulation around the loops is expected to prevent such an occurrence. It is also important to consider that knot tightness and possible tissue ingrowth may restrict the free movement of the loop during a patient's range of motion.⁶⁶

External Pocket Factors

IPG rotation within the pocket can be caused by a condition called Twiddler's syndrome.⁶⁶ There are two recognized forms of this phenomenon: spontaneous and external. In the spontaneous form, the IPG moves without external manipulation by the patient.⁶⁶ Factors that predispose a patient to spontaneous syndrome include subcutaneous pouches that are too large, become filled with fluid such as seromas, or IPGs that are not anchored.^{66,87} In these circumstances, even normal patient activity can cause twiddling. External Twiddler's syndrome is caused by digital manipulation of the IPG by the patient, usually soon after implantation before the device has had adequate time to scar.⁸⁷ Either form can lead to complications, including IPG flipping, lead fracture, lead migration due to winding, and pocket pain. IPGs must be implanted with the label facing the skin for external programmers to be able to communicate and IPGs to charge. If the IPG flips, communication with external devices may be rendered nonfunctional, the known exceptions being Abbott (Texas, USA) Eterna and Medtronic (Minnesota, USA) Intellis/Vanta/Inceptiv which allows communication in both IPG directions. The lead wires can also twist around each other, placing a tremendous amount of strain on the leads potentially leading to lead migration. Fractures of the leads as they enter the IPG ports can result in localized paresthesia's, loss of efficacy, and current drain from an open circuit with rapid depletion of the IPG.⁷³

It is important to take care when creating subcutaneous pockets, anchoring the IPG to the wall of the pouch with a nonabsorbable suture, and counseling patients to avoid manipulation. Subfascial pouches have much less potential space than subcutaneous pouches, and the incidence of IPG movement and seroma formation seems to have been reduced significantly.⁷³ Creating an IPG pocket in a single plane, in a low strain area, and utilizing the above surgical techniques to reduce pocket pain should reduce pocket awareness and result in enhanced patient outcomes.

Pocket Awareness

Providers who implant and manage SCS devices often focus on the obvious goals of improving chronic pain. As growing evidence has supported the use of SCS for a variety of indications, we should now begin to focus more closely on the user experience. First and foremost, improvement of preoperative pain is the objective, but patients interact with their device physically, emotionally, and electronically. As we have demonstrated in this manuscript, a variety of factors affect this experience.

Here we introduce a new term - *pocket awareness*. Success should be defined as the patient having a seamless interaction with the device and passively unaware of its existence. Pocket pain obviously increases pocket awareness, and we have reviewed the engineering and surgical factors that increase the risk of pain, but the technical interface for changing programs, mechanism of recharging, MRI compatibility, and other factors greatly influence a patient's satisfaction with their device.

Consumers have grown accustomed to interacting with technology as an extension of themselves. The more seamless and natural this interaction, the greater device attraction, be it conscious or not. Achieving this goal begins with the engineers who design and manufacturers who produce. We have made the case for choosing appropriate candidates and devoting proper attention to surgical implantation. Thorough preoperative education helps patients maximize device function, and long-term care should include regular follow up after implantation to ensure the device is meeting therapeutic goals.

Management of an Existing Painful Generator Pocket

Though there are currently no guidelines for addressing pocket pain, management can range from conservative to explanting the entire SCS system.³² Obviously, explanting a functioning system is the least desirable route. After infection and other acute issues have been ruled out, initial management may include topical analgesics, neuropathic medications, and physical therapy accounting for patient comorbidities.^{35,37,51} Topical analgesics such as lidocaine, capsaicin patches, or EMLA (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) cream can be utilized.^{88–91} Oral medications may include duloxetine, gabapentin, and pregabalin for pocket neuralgia symptoms, but may be fraught with side effects.^{42,51,88,92,93}

If conservative management has been trialed and pain persists, surgical revision should be considered.³² The pocket may be revised to create a single level plane for IPG positioning if there is undue skin pressure from a mispositioned battery. If appropriate, the IPG should be repositioned to avoid skin folds or pressure points. The IPG may also be relocated deep to the current location so long as depth is still compatible with manufacturer recommendations. Finally, the IPG can be moved to an alternate site, possibly the contralateral side. If replacement is necessary, a smaller IPG may cause less discomfort.³² Alternatively, a non-rechargeable IPG would allow the pocket to be created deeper, however manufacturers may still require a minimum depth to communicate with an external device for programming changes. If pain continues despite revision or replacement, explant may then be required after a thorough discussion with the patient.

Above all, managing patient expectations may reduce the risk of pocket pain and decrease awareness of the implanted device.³⁷ Furthermore, cognitive behavioral therapy is an option to reduce the awareness or angst associated with the implanted device, as has been demonstrated in other conditions.⁹⁴ Though these treatments are suggested options for pocket pain, future research is necessary to evaluate the efficacy and safety.

Conclusion

Arguably the best strategy for managing pocket discomfort is prevention. Several patient and device specific strategies have been discussed here, and inferences can be made regarding application to individual practice. A comprehensive conversation with the patient should include rechargeable versus non-rechargeable batteries, implant location, lead type, and potential demographic and psychosocial factors that increase the risk of pocket pain. A detailed operative plan with implementation of proper surgical skills is necessary for positive outcomes. Future studies, and perhaps guidelines, should provide clarity and specific recommendations for providers and manufacturers to reduce the risk of pocket pain and even awareness to optimize device interaction for success and longevity of neurostimulation. Additionally, components of the system such as remote monitoring and technical interface are important considerations manufacturers should pursue to improve the patient experience with their device. A common barrier to spinal cord stimulation is patient resistance to an implantable device. Manufacturers should and are pursuing device development to minimize this patient burden, which would be expected to increase patient interest in the therapy in the future. As an established therapy for various chronic painful conditions future advancements may be therapy related, however we hope this manuscript highlights the important factors that contribute to a positive or negative patient experience based on device features, patient factors, and surgical implementation.

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