



Review article

Peripheral subcutaneous field stimulation for the treatment of spinal cord injury at-level pain: case report, literature review, and 5-year follow-up

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ABSTRACT

Spinal cord injury (SCI) frequently engenders chronic pain which may be classified as occurring above, at, or below the level of injury. Since patients with SCI may have a complex combination of nociceptive and neuropathic pain, pharmacological interventions often fail. Peripheral subcutaneous field stimulation (PSFS) is a novel neuromodulation surgery for pain in which subcutaneous electrodes designed for spinal cord stimulation are placed subcutaneously in a region of pain. We report the case of a 26-year-old man who was an unrestrained driver in a motor vehicle accident and suffered a complete ASIA A spinal cord injury with paraplegia due to a T4 three-column burst fracture. He underwent successful surgical fixation of the fracture (7/27/12) and developed severe at-level SCI-associated pain which failed all conservative measures. After a successful trial, two octrode leads (Abbott Medical, Plano, TX, USA) were placed for PSFS under general anesthesia and were connected to a right flank rechargeable pulse generator (11/6/13). At 60 months postoperative, the patient continues to use the peripheral field stimulation system on a daily basis and reports near complete relief of his at-level spinal cord injury pain. He noted instantaneous relief of his pain once ideal stimulation programming was achieved and has tolerated complete cessation of all narcotic use. His current programming settings are: Frequency of 50 Hz (Hz), Pulse Width of 350 μ s (μ sec), Amplitude of 0.00 milliamps (mA), Comf of 7.70 mA, and Perc of 4.50 mA. Chronic pain is a challenging and expensive sequela to manage in SCI patients and newer therapies are needed. Our case suggests that SCI at-level pain may respond durably to PSFS and provides the longest published follow-up on a case of PSFS. Peripheral subcutaneous field stimulation remains an investigational treatment for chronic pain syndrome and larger, long-term follow up studies are needed for the FDA and payers to approve this modality.

1. Introduction

Spinal cord injury (SCI) is a debilitating condition affecting an estimated three million people worldwide, with approximately 180,000 new cases each year (Lee et al., 2014). The devastating impacts of SCI include medical, functional, and socioeconomic sequela which play a lifelong role in the care of these patients. In addition to the resulting physical limitations, mechanical, toxic, or ischemic lesions of the white matter tracts of the spinal cord in SCI may be either temporary or permanent, and associated with severe motor, sensory and autonomic dysfunction (Assinck et al., 2017). A recent meta-analysis across 17 studies and involving 2529 SCI patients found that chronic pain was common among secondary complaints to SCI; 53% of all SCI patients reported neuropathic pain was distressing and debilitating, leading to worsened quality of life, depression, and poor sleep quality (Burke et al., 2017). In the same

meta-analysis, it was reported that post-SCI neuropathic pain most frequently presents at or below vertebral-level injury (Burke et al., 2017; Bryce et al., 2012), which is rated by patients as the most 'severe pain' of all pain experienced in the post-injury state (Siddall et al., 2003).

In addition to the personal, patient-level burden caused by debilitating post-SCI neuropathic pain, larger costs to the health care system loom (Burke et al., 2017). A well-controlled study of 3524 commercially insured SCI patients with neuropathic pain matched to 3524 SCI patients without neuropathic pain in similar insurance schemes were retrospectively reviewed 12 months after neuropathic pain onset for resources used, cost incurred, and hospitalization (Margolis et al., 2014). When compared to individuals without post-SCI neuropathic pain, those patients with post-SCI neuropathic pain visited physicians and emergency departments more often and required procedures and prescriptions for

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neuropathic pain that exceeded their matched counterparts by \$17,369 per annum per patient (Margolis et al., 2014).

Post-SCI neuropathic pain is treated with conventional pharmacotherapeutic pain management techniques, often with limited success in meaningful pain reductions that stabilize or improve quality of life (Siddall et al., 2006; Cardenas et al., 2013; Burke et al., 2017). In other neuropathic pain conditions, such as failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS), spinal cord stimulation (SCS) is supported by high-quality class 1 evidence for chronic pain of the back and lower limbs (Barolat, 1999; Aló et al., 2002; Turner et al., 2004; North et al., 2005a; North et al., 2005b), and indicated for peripheral vascular disease and severe angina pectoris in Europe (Amann et al., 2003; Ubink and Vermeulen, 2006). Neuromodulation therapy with SCS has been used to achieve pain reduction outcomes superior to conventional pharmacotherapeutic pain management (Kumar et al., 2007), which has been shown durable in some patients up to 8 years after implantation and device activation (Barolat et al., 1998).

Aló and Holsheimer (2002) distinguish the management of chronic pain using SCS from other so-called “peripheral” forms of electrical stimulation that do not directly target white matter tracts of the central nervous system by applying the terms ‘intraspinal stimulation’ (IS) and ‘extraspinal stimulation’ (ES), to each of the different stimulation modalities, respectively. Where IS targets specific nerves and neural tissue in the spinal cord, the percutaneous ES modality targets extraspinal nerves – wherever the neuropathic pain region is thought to be (Aló & Holsheimer, 2002; Abejón and Krames, 2009).

Ghonomie and colleagues (1999) published the first randomized crossover study of stimulation (acute) of the subcutaneous tissues in the back for low back pain, calling the technique “percutaneous electrical nerve stimulation” (PENS). Various iterations on this name have been used in studies of chronic subcutaneous peripheral stimulation with permanent device implantation for pain relief from the early 2000s, including “peripheral subcutaneous electrostimulation/neurostimulation” (Stinson et al., 2001; Reverberi et al., 2009), “subcutaneous peripheral nerve stimulation” (SQ PNS) (Kruttsch et al., 2008; Tamimi et al., 2008, 2009; Ordia and Vaisman, 2009; Burgher et al., 2012), “subcutaneous targeted neuromodulation” (STN) (Goroszeniuk et al., 2006; Theodosiadis et al., 2008, 2010), and “subcutaneous targeted stimulation” (STS) (Sator-Katzenschlager et al., 2010).

More recently, the terms “peripheral nerve field stimulation” (PNFS) (Paicius et al., 2006; Paicius et al., 2007; Verrills et al., 2011; Reverberi et al., 2013; McRoberts et al., 2013; Deogaonkar and Slavin, 2014; D'Ammando et al., 2016) and “peripheral subcutaneous field stimulation” (PSFS) (Lipov et al., 2009; McRoberts and Roche, 2010; Yakovlev and Resch, 2010; Navarro and Vercimak, 2012; Goroszeniuk et al., 2012), the suggested standardized nomenclature of Abejón and Krames (2009), have been used to denote the procedure whereby electrode(s) are inserted percutaneously into the peripheral (non-spinal) subcutaneous space near regions of chronic pain to elicit paresthesias to mask chronic neuropathic pain. Although similar in surgical procedure and naming convention, “peripheral nerve stimulation” (PNS), another studies form of ES for chronic pain management, and PSFS differ in that the former (PNS) aims to induce paresthesia along a single nerve and its innervated regions, while PSFS aims to spread a paresthesia “field” across any number of neuropathic fibers in a region of chronic pain, not an identified neural structure, via an electric field generated around the electrode's activated subcutaneous bipoles (Abejón and Krames, 2009). Although the mechanisms of PSFS have not been completely elucidated, there is evidence that electrical stimulation of large A- β fibers modulates the flow of afferent pain information from A- δ and smaller C fibers (Ellrich and Lamp, 2005), which may lead to local membrane depolarization and release of anti-inflammatory molecules (O'Neill et al., 2004). Clinicians have reported successful pain reduction using both high- (50–150 Hz) and low-frequency (1–10 Hz) PSFS, suggesting mechanisms of action that differ from transcutaneous nerve stimulation (Abejón and Krames, 2009).

PSFS may prove particularly useful in targeting regions of pain where conventional SCS use has been shown to be ineffective or limited, including the face, thorax, cervico-dorsal and lumbar areas, and other sacral, abdominal, and inguinal regions (Reverberi et al., 2009). This perceived advantage of peripheral lead placement in PSFS has led to a recent surge in successful reports of its use in treatment of chronic pain of the back (Table 1) (Burgher et al., 2012; D'Ammando et al., 2016; Goroszeniuk et al., 2006; Kloimstein et al., 2014; Kruttsch et al., 2008; McRoberts et al., 2013; Mitchell et al., 2016; Ordia and Vaisman, 2009; Paicius et al., 2007; Reverberi et al., 2009; Reverberi et al., 2013; Sator-Katzenschlager et al., 2010; Verrills et al., 2009; Verrills et al., 2011; Yakovlev et al., 2011), face (Yakovlev and Resch, 2010), knee/joints (McRoberts and Roche, 2010), abdomen (Paicius et al., 2006), pelvis (Tamimi et al., 2008), shoulder (Theodosiadis et al., 2008; Tamimi et al., 2009), and in cases of refractory angina (Goroszeniuk et al., 2012), post-thoracotomy pain (Tamimi et al., 2009; Theodosiadis et al., 2010; D'Ammando et al., 2016), and post-operative inguinal pain (Stinson et al., 2001).

Neuromodulation therapy for the treatment of post-spinal cord injury neuropathic pain has been proposed in the literature but rarely reported on (Epstein and Palmieri, 2012). The authors identified only one case of PSFS for post-SCI intractable pain in the literature (Navarro and Vercimak, 2012). Navarro and Vercimak (2012) utilize a combination therapy of SCS and PSFS in 40 patients with varying etiologies of chronic back pain, most of whom are failed back surgery syndrome (FBSS) patients (n = 26), and one post-SCI neuropathic pain patient. The aim of Navarro and Vercimak's 2012 study is to resolve an implantation procedure and programming paradigm for combination SCS and PSFS therapy. The authors do not report individual outcomes, although they do report $\geq 50\%$ mean reductions in pain measured on the visual analog scale (VAS) from pre-operative baseline to six months in 7/23 (30%) subjects with data (Navarro and Vercimak, 2012). Combination therapy technique and optimization has been the focus of several case reports and cohort studies in recent years (Bernstein et al., 2008; Falco et al., 2009; Mironer et al., 2011; Reverberi et al., 2013; Hamm-Faber et al., 2012), particularly as a salvage therapy for SCS non-responders.

In this case report, we present a long-term, 60-month follow-up of a patient with traumatic spinal cord injury and post-SCI at-level pain who failed conventional pharmacological pain management case before implantation of a chronic PSFS system. This is the first report of PSFS for treatment of post-SCI at-level pain published in the literature. The 60-month follow-up in this case matches or exceeds the follow-up duration reported in all other PSFS studies for intractable back pain identified in the literature. Informed by these findings, a prospective study may be planned to critically assess the utility of PSFS for post-SCI neuropathic pain in a more rigorous investigation.

2. Methods

2.1. Case report

A 26 year old male was brought into our emergency room after being involved in a roll-over motor vehicle accident in July of 2012. The patient was an unrestrained driver, found ejected from the vehicle, unresponsive. He was intubated prior to his arrival, and a chest tube was placed for a large hemothorax in the setting of multiple bilateral rib fractures. After being hemodynamically stabilized, he underwent a thorough trauma evaluation which revealed a three column burst fracture at the level of T4 with radiographic evidence of an epidural hematoma resulting in a complete, ASIA A spinal cord injury.

He was taken to the operating room on July 27, 2012 for T3-4 decompressive laminectomies and posterior instrumented fusion from T2-T6. Following the procedure, he developed severe, debilitating neuropathic pain located in the center of his back, corresponding to his level of injury. After failing all conservative measures, he was introduced to neuromodulation through our pain management colleagues and

Table 1. Previous studies of peripheral subcutaneous field stimulation (PSFS) for intractable back pain.

Publication	Study design	Intervention terminology	N (back pain pts)	Pain type/ known etiology	Follow-up duration	Pain outcome(s)	Notes
Goroszeniuk et al. (2006)	Retrospective review	STN	2	Costovertebral angle tenderness (CVAT); post-lobectomy pain	Pt 1: 3 years Pt 2: 26 months	Pt 1: Baseline VAS 9/10 reduced 95% Pt 2: Baseline VAS 10/10 reduced 100%	Both pts stopped analgesics; 1–2 h of stim (<10 Hz and <3 mA) per day provided 12–24 h relief
Paicius et al. (2007)	Retrospective review	PNFS	6	5/6 failed back surgery syndrome (FBSS); 1 chronic back pain of unknown etiology, but previous SCS failure	Reported range of follow-ups: 0–12 months	6/6 patients reported significant reductions in pain on VAS, and reductions in analgesics	Most used parameters: 30–102 Hz, 250–500 μ s
Krutsch et al. (2008)	Retrospective review	PNS	1	FBSS	1 year	Baseline VAS 7/10 reduced to 1/10, stopped analgesics	
Ordia and Vaisman (2009)	Retrospective review	SQ PNS	1	FBSS, epidural fibrosis, with previous SCS failure, and previous PSFS percutaneous lead failure	1 year	Reported pain relief of 95% from baseline (with paddle lead)	Pt failed SCS, failed PSFS with percutaneous leads at L4/S1 after 3 mo of stim (increasing to 3 V). Replaced with 1 paddle lead at L5 for 1 yr at amplitude 0.5 V
Reverberi et al. (2009)	Retrospective review	PSNS	2	Unknown paravertebral pain; lumbosacral spondyloarthrosis (stenosis) with previous SCS failure	1 year	Pt 1: Baseline VAS 10/10 reduced to 4/10 Pt 2: Baseline VAS 10/10 reduced to 2/10	Stimulation parameters: 2–2.5 V, 20 Hz, 300 msec
Verrills et al. (2009)	Retrospective review	PNS	13	11 FBSS; 2 chronic low back pain (CLBP)	6.5 \pm 3.39 months	Baseline avg. VAS 7.42 \pm 1.16 Follow-up: 3.92 \pm 1.72	7/13 pts reported decrease in analgesics
Sator-Katzenschlager et al. (2010)	Multicenter retrospective review	STS	70	37 FBSS; 29 CLBP; 4 thoracic back pain	3 months	FBSS baseline NRS avg: 8.0 \pm 1.4 Follow-up avg: 3.3 \pm 2.1 CLBP baseline NRS avg: 8.3 \pm 0.9 Follow-up avg: 4.2 \pm 2.2 Thoracic pain baseline NRS avg: 8.8 \pm 1.5	18% pts reduced analgesic consumption, and additional 12% pts stopped analgesic use. Reduction in analgesics most pronounced in FBSS patients. Most used parameters: 50–100 Hz, 210–450 μ s, 0.5–2.9 V

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Table 1 (continued)

Publication	Study design	Intervention terminology	N (back pain pts)	Pain type/ known etiology	Follow-up duration	Pain outcome(s)	Notes
Verrills et al. (2011)	Prospective, observational study	PNFS	52	44 lumbosacral pain of various etiologies; 8 thoracic back pain of various etiologies	8.1 ± 4.7 months	Follow-up avg: 2.5 ± 0.6 Baseline NRS avg.: 7.4 ± 1.7 Follow-up: 3.2 ± 2.3	69% pts had relief >50%; 72% pts reduced analgesics
Yakovlev et al. (2011)	Retrospective review	PNFS	18	Post-laminectomy syndrome (PLS)	1 year	Baseline VAS avg: 7.44 ± 1.04 Follow-up avg: 1.67 ± 0.60	5 pts reduced analgesics; 11 pts stop analgesics; Parameters: 1.8–3.2 V, 250–450 µs, 40–50 Hz
Burgher et al. (2012)	Retrospective review	SQ PNS	6	FBSS	4.5 months (range 2–9 mo)	Avg. percent pain relief from baseline at follow-up: 45% (range 20–80%)	Only 1 pt reduced analgesic intake at follow-up; parameter: 0–6.4 V, 210–450 µs
McRoberts et al. (2013)	Prospective, multicenter randomized controlled study	PNFS	23	Axial pain (cervical, dorsal, lumbosacral)	1 year	Baseline VAS avg: 7.8 ± 1.1 Follow-up: 2.5 ± 2.4 16/23 (69%) of pts responded (>50% pain relief) at 1 yr	80% responded (>50% pain relief) to active stim during randomized, crossover trial (4–8 day periods for each condition); 10 pts reduced analgesics
Kloimstein et al. (2014)	Prospective, multicenter observational study	PNFS	40	Lumbosacral pain of various etiologies	6 months	Baseline VAS 7.6 ± 1.52 1 mo: 3.85 ± 2.24 (n = 40) 6 mo: 4.36 ± 2.31 (n = 28) 44% avg. pain reduction at 6 mos.	65 pts received combination SCS + PSFS therapy with statistically equivalent VAS score reductions (results not shown here)
Mitchell et al. (2016)	Prospective case series	PNFS	20	Thoracic pain of various etiologies	1 year	Baseline NRS avg.: 7.75 ± 1.4 Follow-up: 2.25 ± 2.14 (n = 17) Avg. pain relief 72.41% ± 21.69% (range 55.6%–100%)	10 pts reduced analgesic; 3 pts explanted before follow-up (1 pain at IPG site, 1 recurrent lead infection, 1 non-responder)
D'Ammando et al. (2016)	Retrospective review	PNFS	6	FBSS	60 months	Baseline VAS avg: 9.66 Follow-up: 4.66	Significant reduction in analgesics after PSFS; greatest responder rate in lumbosacral pain FBSS; Parameters: 210–310 µs, 20–30 Hz, 3.2 mA

CLBP: chronic low back pain; FBSS: failed back surgery syndrome; NRS: numerical rating scale; PNFS: peripheral nerve field stimulation; PNS: peripheral nerve stimulation; PSFS: peripheral subcutaneous field stimulation; SQ PNS: subcutaneous peripheral nerve stimulation; STN: subcutaneous targeted neurostimulation; STS: subcutaneous targeted stimulation; VAS: visual analog scale.

underwent a PSFS trial in September of 2013. His symptoms were characterized using a Visual Analogue Scale (VAS) for pain with a pretrial score of 10/10. His daily opioid use averaged 45 mg morphine equivalent daily dose (MEDD).

At the conclusion of the trial, our patient reported a significant improvement of his neuropathic pain and subsequently underwent permanent implantation of two octrode leads (Abbott Medical, Plano, TX, USA) connected to a right flank rechargeable pulse generator on November 6, 2013.

2.2. Literature review

The authors performed a review of the literature by searching PubMed and Embase databases for primary research articles with the search terms: “spinal cord injury” or “chronic pain” or “back pain” and combinations of the following phrases “peripheral nerve stimulation”, “peripheral subcutaneous nerve stimulation”, “peripheral nerve field stimulation”, “subcutaneous targeted stimulation”, “subcutaneous targeted neurostimulation”, or “stimulation”. Out of a total of 37 identified articles referencing SCI or chronic pain treated with PSFS, 14 articles fulfilled our inclusion criteria of treating chronic back pain with PSFS (Table 1). Articles using combination therapy of SCS and PSFS were excluded, as were articles where PSFS was used to treat other regions of pain excluding the back.

3. Results

3.1. Case report

Following the implantation of the PSFS, our patient reported instantaneous relief of his pretrial pain with a VAS score of 1/10. Ideal stimulation programming was achieved after approximately 6 separate adjustments. At his most recent follow up, over 5 years post-implantation, he continues to report 100% reduction in his pain and complete cessation of all opioid use. His current programming settings are: Frequency of 50 Hz (Hz), Pulse Width of 350 μ s (μ sec), Amplitude of 0.00 miliamps (mA), Comf of 7.70 mA, and Perc of 4.50 mA.

3.2. Literature review

We identified 14 published studies where PSFS was investigated for the treatment of chronic back pain in a total of 260 patients (Table 1). The first published reports of PSFS for intractable back pain were small retrospective reviews of patient records and case series (Goroszeniuk et al., 2006; Paicius et al., 2007; Krutsch et al., 2008; Ordia and Vaisman, 2009; Reverberi et al., 2009; Verrills et al., 2009). In these first six studies, a total of 25 patients underwent permanent implantation of PSFS systems. The leading pain etiology for these patients was failed back surgery syndrome (FBSS) (n = 18), followed by chronic low back pain (CLBP) (n = 3), costovertebral angle tenderness (CVAT) (n = 1), post-lobectomy pain (n = 1), paravertebral pain of unknown origin (n = 1), and severe lumbo-sacral spondylo-arthritis (n = 1) (Table 1). Patients were followed for a minimum of 1 year – with the exception of Verrills et al. (2009) – and all reported significant reductions in VAS ratings after PSFS compared to baseline for each patient, with some patients achieving 100% pain relief at 1 year (Table 1).

A retrospective review by Verrills and colleagues (2009) reported results in 13 patients at a 6.5-month average follow-up timepoint, where group mean VAS pain ratings improved from 7.42 ± 1.16 at baseline to 3.92 ± 1.72 at last follow-up. In addition to improvements in significant improvements in pain ratings, 7 of 13 patients significantly reduced oral opioid consumption at last follow-up (Verrills et al., 2009).

Sator-Katzenschlager and colleagues (2010) published the first multicenter review of PSFS in 111 patients with focal, non-cancer pain, with 70 individuals classified as chronic back pain patients (FBSS: n = 37, CLBP: n = 29; thoracic back pain: n = 4). After three months of stimulation, PSFS significantly reduced pain intensity measured on the 11-point numerical rating scale (NRS) by $\geq 50\%$ in all 111 patients. Patients diagnosed with FBSS saw their NRS scores reduce from 8.0 ± 1.4 at pre-implant baseline to 3.3 ± 2.1 at 3-month follow-up. Chronic low back pain patients saw similar mean improvements in NRS scores (8.3 ± 0.9 to 4.2 ± 2.2), and the smaller thoracic pain cohort reported the greatest improvement from baseline (8.8 ± 1.5 to 2.5 ± 0.6) over the same follow-up period.

Verrills and colleagues (2011) published a larger, prospective, observational study of PSFS for a range of different pain conditions in 100 patients, 40 of whom with occipital/facial pain, 44 with lumbosacral pain, 8 with thoracic pain, 5 with groin/pelvic pain, and 3 with abdominal pain. Of the 100 chronic pain patients who underwent implantation of PSFS systems, 69% reported relief $>50\%$ at an average follow-up of $8.1 (\pm 4.7)$ months (Verrills et al., 2011). Mean NRS scores were improved 4.2 ± 2.5 points at following PSFS, and 72% of patients were able to reduce their opioid consumption.

Two retrospective reviews in 24 patients with post-laminectomy syndrome (PLS) (n = 18) and FBSS (n = 6) reported similarly significant reductions in pain rating scores at 1 year, and 4.5-month (range 2–9 months) follow-up, respectively (Yakovlev et al., 2011; Burgher et al., 2012). While 88.9% (16/18) of PLS patients were able to reduce (n = 5) or stop (n = 11) oral opioid consumption at 1 year, only 1 (16.7%) patient in the FBSS cohort successfully reduced their opioid intake after an unspecified period of time.

Reviews from the Yakovlev and Burgher groups were followed by two larger prospective observational studies of 60 total patients with lumbosacral pain (n = 40) or thoracic pain (n = 20) (Kloimstein et al., 2014; Mitchell et al., 2016). After 6 months of PSFS, patients with lumbosacral pain reported a mean reduction in pain scores of 44% [baseline VAS 7.6 ± 1.52 (n = 40) to follow-up VAS 4.36 ± 2.31 (n = 28)] (Kloimstein et al., 2014). At 1-year follow-up, patients receiving PSFS for thoracic pain reported mean reduction in pain scores of 72% [baseline NRS 7.75 ± 1.4 to follow-up 2.25 ± 2.14 (n = 17)], with 10 (50%) patients able to reduce analgesic consumption (Mitchell et al., 2016).

McRoberts and colleagues (2013) published the only randomized controlled study of PSFS. This multicenter study was designed to gather safe and efficacy data for PSFS in management of chronic back pain in 44 patient reporting predominantly axial pain (cervical, dorsal, lumbosacral pain), 30 of whom went on to participate in Phase 1 of the study (McRoberts et al., 2013). In phase I, patients were randomized to one of four stimulation groups – minimal, sub-threshold, low frequency, and standard stimulation – for a period of 4–8 days, after which they would crossover to a subsequent stimulation paradigm, randomly and in a blinded fashion. Significant improvements in pain reduction between the four groups were seen in relation to increasing stimulation intensity (increased frequency and pulse-width) (McRoberts et al., 2013). Twenty-four (80%) patients responded to therapy ($>50\%$ reduction in pain score during any of the three active stimulation periods) and were enrolled in Phase II of the study, an open-label stimulation phase. After 1-year follow-up during Phase II, 16 (69%) patients were still classified responders, and mean VAS decreased from 7.8 ± 1.1 at baseline to 2.5 ± 2.4 at last follow-up (McRoberts et al., 2013).

Only one identified study reports follow-up data on PSFS over three years, a recent retrospective review of 6 FBSS patients by D'Ammando and colleagues (2016). In this study, patients were followed 60-months after implantation, with significant reductions in VAS reported at long-term follow-up (4.66) compared to pre-operative baseline (9.66).

The authors note pain scores were most improved in a subset of patients with a lumbosacral component of FBSS pain.

4. Discussion

Peripheral subcutaneous field stimulation (PSFS) has become an increasingly popular therapeutic option in difficult-to-treat cases of focal, intractable pain in recent years (McRoberts et al., 2013; Deer et al., 2015). PSFS requires stimulation of neuropathic cutaneous afferent fibers in a region of chronic pain, as opposed to identified nerves and anatomical central nervous system structures in PNS and SCS, respectively, meaning placement is based solely on location of maximal pain (the so-called “epicenter of pain”) (Deer et al., 2015; Goroszeniuk et al., 2006). Accurate subcutaneous placement of low-frequency stimulation electrodes over an epicenter of pain has been shown to significantly reduce pain felt in the entire region (O’Keeffe et al., 2006). As a result, lead placement accuracy and insertion depth play pivotal roles in ensuring successful nociceptive pathway targeting and significant patient outcomes (Abejón et al., 2011; Goroszeniuk and Pang, 2014). The flexibility in region-specific placement, rather than anatomically-informed placement, may allow patients who suffer from axial back pain, for example, where conventional SCS is less effective, to experience pain relief with PSFS alone (McRoberts et al., 2013). The additive ability of PSFS – to create combination therapy for poor responders to SCS – yields an additional benefit to the procedure as a salvage therapy in the most treatment-refractory cases of pain (Bernstein et al., 2008; Lipov, 2011).

4.1. Limitations

Lack of prospective, observational, randomized controlled studies in the literature is certainly concerning, as is the noticeable lack of basic research on PSFS mechanisms of action in treating chronic pain. It is possible that case series amplify the treatment affect and mitigate complication rates.

4.2. Adverse events

Adverse events in PSFS have been reported in the literature in 9%–24% of patients (Slavin et al., 2018), with the most commonly reported hardware-related events being lead migration and dislocation (13%), lead fracture and/or equipment failure (2%–5%), and the most commonly reported procedure events being infection (1%–6%) and lead erosion (5%) (Sator-Katzensclager et al., 2010; Verrills et al., 2011; Kloimstein et al., 2014; Slavin et al., 2018).

5. Conclusion

Spinal cord injury (SCI) is a devastating diagnosis which carries significant physiologic, psychologic, and economic burden for those who are affected. Healthcare for these individuals requires a holistic approach in order to maximize the potential for recovery. Research efforts have historically been focused on physical rehabilitation and neurologic outcomes with ongoing advancements in neuroprotective and regenerative therapies (Wilson and Fehlings, 2012). Continued progress in these technologies is paramount, yet, recent literature has shifted focus toward efforts to improve patient-reported, subjective outcomes.

Functional procedures have the potential to impact multiple SCI-injury related sequelae including pain, autonomic dysregulation, and bladder function. Modulation of the nervous system via electrical stimulation has provided promising alternatives to the current standard approaches utilized in chronic pain management. Our case supports the use of PSFS in the treatment of at-level SCI-injury related pain and provides long-term follow up as evidence to suggest its durability and future therapeutic potential.

Declarations

Author contribution statement

All authors listed have significantly contributed to the investigation, development and writing of this article.

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Competing interest statement

The authors declare the following conflict of interests: Nestor D. Tomycz; served as a consultant for St. Jude Medical/Abbott Laboratories (Chicago, Illinois, USA) and has received research funding and compensation for consulting and/or other services other than consulting as a part of relevant financial activities outside the submitted work. All other authors have no conflicts to disclose.

Additional information

No additional information is available for this paper.

IRB approval statement

This study was IRB-approved and carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). Informed consent was obtained from the patient prior to intervention.

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