PAIN MEDICINE CASE REPORTS

ISSN 2768-5152

Volume 10, Number 3, pp. 289-292

# MICROFRAGMENTED ADIPOSE TISSUE (MFAT) INJECTION FOR REFRACTORY GENERATOR POCKET PAIN (GPP) IN SPINAL CORD STIMULATION (SCS): A CASE REPORT

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**Background:** Generator pocket pain (GPP) may develop in spinal cord stimulation (SCS) patients, with a frequency ranging from 0.9% to 64%. While several treatments have been proposed, the only available options for SCS patients experiencing refractory pain are implantable pulse generator (IPG) relocation or removal.

**Case Report:** We treated a 62-year-old man with late-onset refractory GPP using the autologous microfragmented adipose tissue (MFAT) injection into the IPG pocket. A total of 30 mL of MFAT harvested from abdominal fat was injected. The procedure was well tolerated, with no adverse events. The patient reported a significant reduction in pain intensity immediately after the injection, with his visual analog scale (VAS) score decreasing from 80 to 20/100. At the third-month follow-up, he continued to experience the same level of pain relief.

**Conclusion:** The autologous MFAT injection in refractory GPP patients is a promising salvage option. However, additional cases will be needed to better evaluate the efficacy and long-term outcomes of this treatment.

**Key words:** Generator pocket pain, spinal cord stimulation (SCS), microfragmented adipose tissue

## BACKGROUND

Spinal cord stimulation (SCS) is a widespread neuromodulatory technique for the treatment of chronic refractory painful conditions such as persistent spinal pain syndrome (PSPS), neuropathic pain following radiculopathies, complex regional pain syndromes (CRPS) I and II, and chronic vascular pain (1). To date, the most frequent complications of SCS implantation, with a global rate ranging from 30% to 40%, are lead migration or rupture, battery failure or malfunction, neurological injuries, spinal hematoma, inadvertent dural puncture (IDP) with post-dural puncture headache (PDPH), and spinal infections (2). Other rarely reported complications include wound dehiscence, skin erosions, and testicular pain (2). In some cases, SCS patients report chronic pain localized in the generator pocket (generator pocket pain, GPP). This complication has been reported in the literature, with a frequency ranging from 0.9% to 64%. The variability of the condition reflects the lack of standardization in the definition of GPP. Currently, GPP is defined as "pain localized specifically over the implantable pulse generator (IPG) subcutaneous implant site" (3). In most cases, GPP occurs after a subcutaneous pocket infection, a hematoma, or an IPG malfunction.

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.
Patient consent for publication: Consent obtained directly from patient(s).
This case report adheres to CARE Guidelines and the CARE Checklist has been provided to the journal editor.
Accepted: 2026-01-15, Published: 2026-05-31

Although mechanical mechanisms or neuropathic etiologies have been hypothesized in some instances, the likely cause most often remains unidentified, and the pain is particularly difficult to treat (4). While various pharmacological and non-pharmacological approaches have been attempted, the only options for SCS patients with refractory pain are the relocation or removal of their IPGs (5). We report a case of a patient whose refractory GPP was successfully treated with an injection of autologous microfragmented adipose tissue (MFAT) into the IPG pocket.

## CASE

A 62-year-old man suffering from severe low back pain (LBP) and radiculopathy was referred to our pain therapy center for refractory pain. His medical history included type II diabetes mellitus and a car accident from 10 years ago, which resulted in fractures of the right transverse processes of L3 and L4. Due to herniated discs at the L3-L4 and L4-L5 levels, the patient underwent 3 consecutive spinal surgeries—laminectomy and discectomy—with only partial benefit. Ultimately, he had spinal stabilization surgery but did not experience significant pain relief. Following our initial evaluation, a diagnosis of persistent spinal pain syndrome Type II (PSPS T-II) with bilateral lumbosciatica was made. The patient experienced a significant impact on his daily life, reporting a quality of life (QoL) score of 20% (0-100 scale), a visual analog scale (VAS) score of 90, and an Oswestry Disability Index (ODI) of 42. After several unsuccessful pharmacological treatments and invasive procedures, including epidural steroid injections, epidurolysis, pulsed radiofrequency of the dorsal root ganglia at L4 and L5, and epiduroscopy with direct adesiolysis, the patient underwent a psychological assessment. Subsequently, he received a spinal cord stimulator (SCS) implant, consisting of 2 octopolar catheters at T8 connected to an IPG Wavewriter Alpha™ Spinal Cord Stimulator System (Boston Scientific®), with the device placed in a subcutaneous pocket in the upper part of the right buttock. Two months after the implantation, the patient reported significant improvements: his QoL score increased from 20% to 80%, his VAS score decreased from 90 to 30, and his ODI improved from 42 to 36. He was very satisfied with the results of the SCS, and this improvement was maintained for nearly 5 years. However, in the 4 months before his presentation to the clinic, the patient began experiencing pain in the IPG subcutaneous pocket, especially when sitting or moving. The GPP was suspected to have a mechanical origin. At our evaluation, no signs of infection, hematoma, seroma, swelling, or IPG malfunction were observed. After several unsuccessful attempts with different pain medications, transcutaneous lidocaine patches, and lidocaine injections into the pocket, and to preserve the excellent and persistent efficacy of the SCS, we decided to administer an autologous MFAT injection directly into the IPG pocket. We harvested 60 mL of abdominal fat and processed it using the Lipo-Stem Duo™ System (Biopsybell®). This device, through several steps, allows us to obtain an adequate volume of MFAT for clinical purposes. After obtaining written informed consent by the patient, a total of 30 mL of MFAT was injected, using ultrasound guidance, into the pocket under sterile conditions and local anesthesia. The procedure was well tolerated, with no adverse events. The patient reported a significant reduction in pain intensity immediately after the injection, claiming that his VAS score had decreased from 80 to 20/100. During the third-month follow-up, he continued to experience the same level of pain relief, with no procedure-related complications.

## DISCUSSION

GPP is actually defined as "pain localized specifically over the IPG implant site." Although the condition has been labeled as "pocket neuritis" due to its presumed neuropathic pathophysiology, the broader term GPP is now preferred to reflect all possible etiologies that may contribute to it condition (Table 1).

Risk factors for GPP are summarized in Table 2. Regarding treatment, after excluding major pocket or IPG complications that would require immediate intervention, the management of GPP involves a stepwise approach ranging from conservative to surgical measures. Conservative strategies include local approaches (ice or heat applications, topical lidocaine creams, lidocaine or capsaicin patches), systemic analgesic drugs (nonsteroidal anti-inflammatory drugs [NSAIDs] and/or acetaminophen, opioids, gabapentinoids), or physical measures (massage). Injections of local anesthetics and/or steroids into the pocket site are recommended if medical management fails to produce results after 2 to 4 weeks (5). Although conservative measures are a valuable initial approach, they are often insufficient for some refractory cases of GPP, which may indicate a structural or IPG-related cause rather than purely inflammatory or neuropathic etiology. For these patients, surgical intervention becomes necessary. Revision surgery

may involve repositioning the IPG within the same site or, more often, to a contralateral site. In some cases, IPG replacement may also be considered. For totally refractory patients, removal of the IPG and, consequently, of the entire SCS system remains, unfortunately, the only therapeutic option (3). To avoid this scenario, advanced therapeutic options should be explored, such as injecting autologous MFAT directly into the IPG pocket. The rationale for giving autologous MFAT to these patients is based primarily on the widespread use of this type of tissue in plastic surgery and regenerative medicine. First, the well-known properties of MFAT in soft tissue augmentation, as demonstrated in various plastic and aesthetic procedures, support its potential application (7). In this context, injecting MFAT into a painful pocket could help increase the distance between the IPG and surrounding tissues, reducing contact and mechanical rubbing. Additionally, MFAT injections are used widely to attempt the regeneration of different tissues, particularly in symptomatic osteoarthritis and other musculoskeletal diseases, due to its content of adipose-derived mesenchymal stem cells and their regeneration proprieties (8,9). These properties have been demonstrated also in soft and fibrous tissue regeneration, leading to several ongoing clinical applications (10). This regenerative capacity could result in the formation of a tissue layer that acts as a protective sheath around the IPG (11). Finally, MFAT may be considered in GPP management by taking advantage of their immunomodulatory and anti-inflammatory properties in cases of chronic local inflammation (12). To date, a thorough review of the available literature shows no reports on the use of MFAT for GPP, and our case report represents the first documented experience in this context.

Table 1. Possible etiologies of GPP.

| Possible Etiologies of GPP (6) | | |
|---|---|---|
| **Pocket-Related Complications** | **IPG-Related Complications** | **Others** |
| Infections | Mechanical tissular conflicts | Neuritis/nerve lesions |
| Hematoma | IGP intolerance/ rejection | Idiopathic |
| Pocket scars | IPG failure/warming | |
| Seroma | IPG and/or lead migration | |

IPG: implantable pulse generator, GPP: generator pocket pain.

Table 2: Risk factors for GPP.

| Risk Factors for GPP (4) | Comments |
|---|---|
| Female gender | 76.7% of GPP patients are female ($P$ = 0.015). |
| Legal litigation | 65.1% of patients who have ongoing litigations also have GPP vs. 24.9% without GPP. |
| Basal neuropathic pain scores | The highest basal neuropathic pain scores are in GPP patients. |
| Smoking cigarettes | 70% of GPP patients have an active cigarette-smoking habit. |
| Anxiety/depression | 35-37% of GPP patients have anxiety/ depression. |
| Abdominal pocket site | 28% of GPP occurs in an abdominal site vs 19% in a gluteal site. |
| Rechargeable IPG | 93% of GPP occurs in patients with rechargeable IPGs. |

IPG: implantable pulse generator, GPP: generator pocket pain.

## CONCLUSION

GPP is a relevant complication in some SCS patients and may be particularly difficult to treat, leading sometimes to the removal of SCS devices. In our opinion, the autologous MFAT injection in the painful pocket is a promising salvage treatment when other therapies have failed. However, additional cases will need to better evaluate efficacy and long-term outcomes of this treatment for GPP.

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