

A Late Complication Related to Percutaneous Implantable Leads for Spinal Cord Stimulation: Myelopathy due to Fibrous Scar Tissue

Takuma MAEDA,¹ Takashi AGARI,¹ Takashi KOMORI,² and Keisuke TAKAI¹

¹Department of Neurosurgery, Tokyo Metropolitan Neurological Hospital, Tokyo, Japan

²Laboratory Medicine and Pathology, Tokyo Metropolitan Neurological Hospital, Tokyo, Japan

Abstract

A 59-year-old woman, after surgery for cubital tunnel syndrome, developed complex regional pain syndrome in her right upper limb. Spinal cord stimulation (SCS) electrodes were placed at the C2-C5 level. A conventional low-frequency tonic stimulation was carried out, which attenuated pain. However, 4 years later, left-sided motor weakness and tolerance to SCS therapy occurred. Magnetic resonance imaging revealed epidural granulation tissue around the electrodes that severely compressed the cervical cord. We surgically removed the granuloma, which attenuated motor weakness. A histological examination showed that an allergic reaction to platinum or the insulator appeared responsible for fibrosis.

Keywords: spinal cord stimulation, complications, neurosurgical procedures

Introduction

Since its introduction in 1967, spinal cord stimulation (SCS) has been an efficient and safe method for the treatment of chronic pain.¹⁾ Randomized controlled trials presented its efficacy for neuropathic conditions, including failed back surgery syndrome and complex regional pain syndrome (CRPS).²⁾ Previous studies reported that the complications of SCS were numerous, with an incidence of 30%-40%.^{2,3)} However, most complications were related to the hardware utilized, including electrode displacement and migration. Biological and surgical complications, such as infection, cerebrospinal fluid leakage, pain, and epidural hematoma, have rarely been reported.⁴⁾ To the best of our knowledge, there have been very few reports of myelopathy due to epidural fibrous scar tissue associated with SCS in the past few decades.⁵⁻¹⁵⁾ In this report, we present a case of progressive severe cervical cord compression that occurred 4 years after the surgical placement of SCS electrodes in the cervical epidural space.

Case Report

Clinical history

A 59-year-old woman presented with CRPS of the right forearm and hand several weeks after surgery for cubital tunnel syndrome in the right elbow. In her right upper limb, she developed right-sided allodynia, temperature asymmetry, and motor weakness. In 2013, at another hospital, two cylindrical epidural electrodes (Octad, Medtronic Japan, Tokyo, Japan) were percutaneously placed at the C2-C5 level, which attenuated pain after a several-day stimulation trial. The implantable pulse generator (RestoreSensor, Medtronic Japan, Tokyo, Japan) was then implanted. Her symptoms were successfully controlled, and pain intensity on the numeric rating scale (NRS) ranged between 3 and 7. She underwent electrode replacement (Vectris, Medtronic Japan, Tokyo, Japan) to switch to a new spinal cord stimulator (RestoreSensor SureScan MRI model, Medtronic Japan, Tokyo, Japan) that is compatible with magnetic resonance imaging (MRI) in 2016. She had no complications during the perioperative period of reoperation, and analgesic effects were achieved with the new device. Stimulation parameters were a frequency of 15 Hz with pulse duration and an intensity of 2.0 mA, respectively. A

Received May 15, 2024; Accepted July 16, 2024

Copyright © 2024 The Japan Neurosurgical Society

This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives International License.

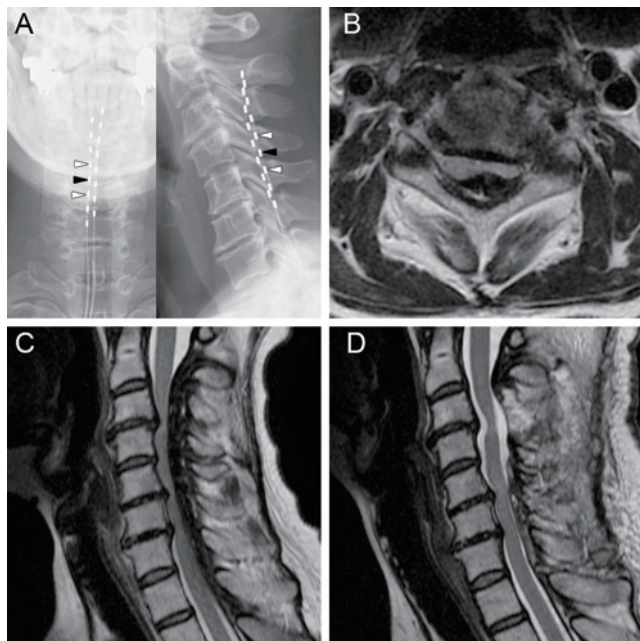


Fig. 1

A. Plain radiographic films showing SCS electrodes at the C2 level. The right-sided fifth contact is a cathode (black arrowhead), and the fourth and sixth are anode (white arrowheads). **B and C.** Preoperative axial and sagittal T2-weighted MRI showing severe spinal compression due to epidural fibrosis around electrodes. **D.** Postoperative sagittal image showing the resolution of spinal cord compression after the removal of scar tissue and electrodes.

follow-up MRI was not performed because stimulation conditions remained unchanged. In 2019, pain intensity gradually increased without mechanical issues with SCS or other symptoms. Despite the current intensity of SCS, which increased to the maximum level of 10.3 mA to maintain analgesic effects, her pain was tolerant to SCS, and she reported 8-10 on NRS.

In 2020, four years after electrode replacement, the patient developed progressive left motor weakness, neck and occipital head pain, and paresthesia in the forearms, wrists, and hands. MRI presented extensive compression of the cervical cord by an epidural mass (Fig. 1). She was transferred to our hospital for surgery to remove the mass and device.

Examination

She had allergies to pollen and chicken meat. Blood sample tests such as IgG, IgE, and IgG4 were within normal range. Systemic or local skin allergic reaction to the SCS device was not observed.

Surgery

The patient underwent cervical laminectomy from the C3 to C7 levels. Thick scar tissue was observed around the

electrodes, which compressed the spinal cord. Scar tissue was completely removed from the dura mater.

Histopathological findings

A histopathological examination showed an acute episode of inflammation with neutrophils and eosinophils around the electrodes, surrounded by chronic inflammation with plasma cells (Fig. 2). The electrodes were also encapsulated by reactive collagen. An immunostaining method using sections revealed fibrosis with IgG and IgG4 plasma cells (IgG > IgG4) (Fig. 3). CD3+ and CD20+ T cells were also detected. No evidence of infection, major hemorrhage, or malignancy was found. No marked differences were noted in these histopathological findings between the cathode, anode, and nonactive contacts. Furthermore, these histopathological findings were uniformly observed over the entire lesion segment.

Postoperative course

After surgery, motor weakness and paresthesia on the left side of the body improved without complications. Postoperative spinal MRI showed complete mass removal (Fig. 1).

Discussion

In this report, we present a case of cervical spinal cord compression owing to scar tissue after percutaneous SCS placement. SCS is a safe and effective treatment for chronic pain syndromes, including intractable neuropathic pain. Complications related to SCS were minor,⁴⁾ and the rate of serious complications was low.¹⁶⁾

Thirteen cases of spinal cord compression caused by scar tissue around the electrodes, including the present case, have been reported in the past two decades (Table 1).⁵⁻¹⁵⁾ Interestingly, not only invasive surgical placement of large paddle electrodes ($n = 8$) but also minimally invasive percutaneous placement of small rod electrodes ($n = 4$) led to thick epidural mass development. An epidural electrode may have inherent risks because the epidural mass may not have been related to the open surgical procedure.

As hypothesized by previous studies, foreign body reaction may be a type of chronic inflammatory response to the presence of epidural electrodes.^{11,15)} Allergic reactions to electrodes have been reported and result in local dermatitis and, in rare cases, systemic dermatitis.¹⁷⁾ Our histological results were consistent with previous studies, in which histological specimens of epidural masses included scar tissue, fibrosis, and a foreign body giant cell reaction.¹⁵⁾ In the present case, an acute episode of inflammation with neutrophils and eosinophils around the electrodes was also evident, although cutaneous manifestations were not observed. Based on these findings, allergic reactions to platinum, iridium alloy, polyurethane resin, or epoxy resin, which are the constituent materials of epidural electrodes

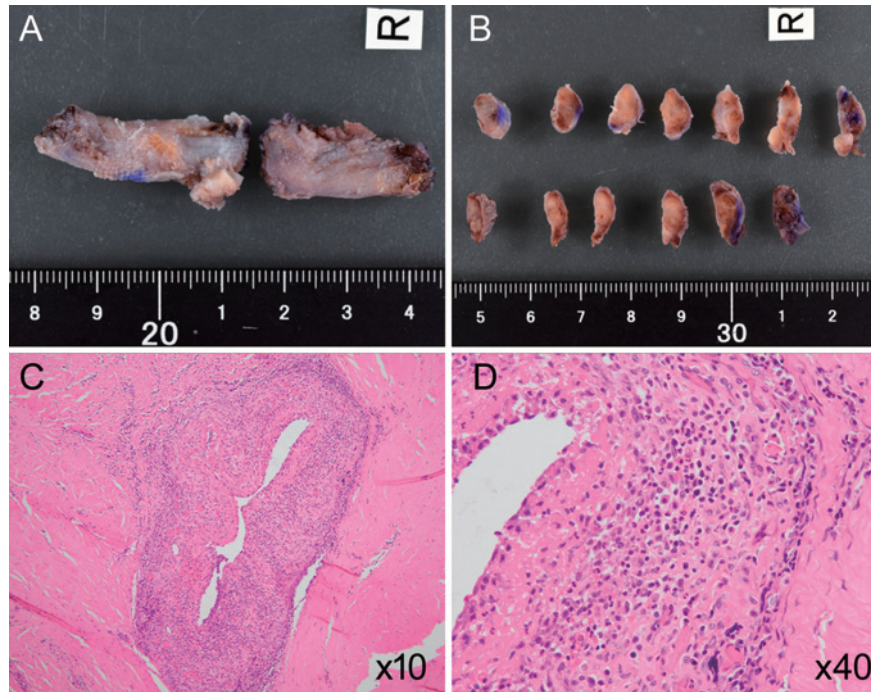


Fig. 2

A and B. Overall and cross-sectional photographs showing the scar tissue removed.

C and D. Histopathological images showing acute inflammation with neutrophils and eosinophils, surrounded by chronic inflammation with plasma cells. Hematoxylin and eosin stain: (C) $\times 10$; (D) $\times 40$.

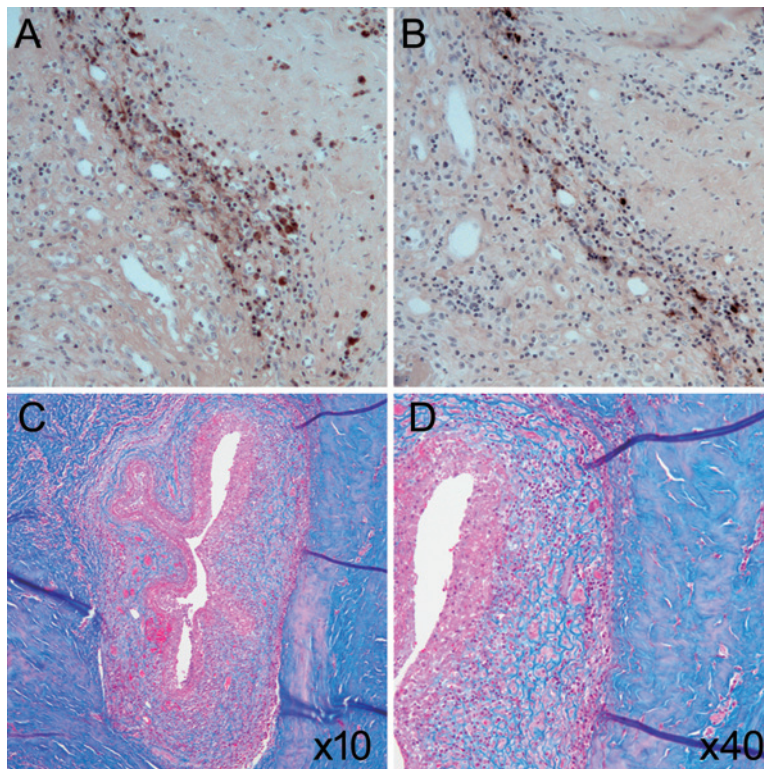


Fig. 3

A and B. Immunohistochemistry for IgG and IgG4 is positive in the tissue mass (IgG > IgG4).

C and D. Histopathological images showing the deposition of blue collagen around the electrodes. Masson's trichrome stain: (C) $\times 10$; (D) $\times 40$.

Table 1 Summary of previous case reports of epidural mass lesions around electrodes

Author, years [ref]	Age, sex	SCS indication	Electrode type	SCS procedure	Location	Tolerance	Latency	Histopathology	Outcome
Dam-Hieu et al., 2010 [14]	66, F	Arm pain after BPAI	Paddle (Resume, Medtronic)	Surgical	C4-C5	Yes	16 years	Fibrosis, chronic inflammation	Full recovery
Dam-Hieu et al., 2010 [14]	58, M	CRPS	Paddle (Symix, Medtronic)	Surgical	C4-C5	Yes	5 years	Scar tissue*	Full recovery
Lennarson et al., 2010 [11]	56, F	CRPS, FBSS	Paddle (Resume II, Medtronic)	Surgical	C3-C5	Yes	3 years	Fibrosis, foreign body giant cell	Incomplete recovery
Wada et al., 2010 [12]	42, M	Arm pain after BPAI	Rod (N/A, Medtronic)	Percutaneous	C3-C4	No	5 years	Fibrosis	Full recovery
Cicuendez et al., 2012 [13]	66, M	FBSS	Paddle (Specify, Medtronic)	Surgical	Th7-Th8	Yes	2 years	Fibrosis, chronic inflammation	Full recovery
Wloch et al., 2013 [6]	69, M	Arm pain after cervical discectomy	Paddle (Resume II, Medtronic)	Surgical	C2-C4	Yes	17 years	Fibrosis	No further progression
Fransen, 2015 [8]	N/A, M	Leg pain after L4-L5 PLIF	Paddle (Specify, Medtronic)	Surgical	Th8	Yes	5 years	Fibrosis*	Full recovery
Scranton et al., 2015 [15]	41, F	Neck pain	Rod (Octrode, St. Jude Medical)	Percutaneous	C2-C5	Yes	9 months	Fibrosis, foreign body giant cell	Incomplete recovery
Benfield et al., 2016 [9]	61, M	FBSS	Paddle (Specify, Medtronic)	Surgical	Th7-Th9	No	10 years	Soft tissue, acute/chronic inflammation	Incomplete recovery
Al Tamimi et al., 2017 [10]	48, F	Arm and leg pain due to MS	Rod (Cover-Edge, Boston Scientific)	Percutaneous	C3-C7	Yes	N/A	Fibrosis, granulomatous tissue, chronic inflammation	Incomplete recovery
Guzzi et al., 2019 [5]	59, F	CRPS	Paddle (Resume II, Medtronic)	Surgical	C3-C5	Yes	7 years	Fibrosclerosis	Incomplete recovery
Pallotta ML et al., 2022 [7]	58, F	FBSS	N/A	N/A	Th9	Yes	8 years	Scar tissue*	Full recovery
Present case	59, F	CRPS	Rod (Vectris, Medtronic)	Percutaneous	C2-C5	Yes	4 years	Fibrosis, acute/chronic inflammation	Full recovery

BPAI, brachial plexus avulsion injury; CRPS, complex regional pain syndrome; FBSS, failed back surgery syndrome; MS, multiple sclerosis; N/A, not available; PLIF, posterolateral interbody fusion. *Intraoperative findings.

may be responsible for fibrosis.

Other studies reported that a pre-existing spinal instability with the addition of a stimulator may result in the development of repetitive local trauma and progressive scarring.¹⁵⁾ However, in 13 previously reported cases, electrodes were positioned not only at the mobile cervical level (n = 9) but also at the nonmobile thoracic level (n = 4). The epidural mass may not have been related to the mobility of the cervical spine.

In the present case, strong electric fields (a maximum level of 10.3 mA) may have contributed to the development of fibrous scar tissue because the intensity of the stimulation progressively increased as the effects of SCS decreased. In previous basic studies, fibrous cells preferentially moved toward the cathode in the electric field.^{18,19)} In our case, however, no significant differences were observed in the histopathological findings of fibrosis over the entire lesion segment, and fibroblasts were not aligned to the electric field between active and nonactive contacts.

Previously reported cases presented with myelopathy with a median duration of 5 years (range 9 months to 17 years) after implantation (Table 1). The tolerance phenomenon preceded the detection of fibrous lesions in 10 out of 12 cases. Tolerance and habituation are the most important factors contributing to long-term SCS failure,²⁰⁾ and abnormal "tolerance" may indicate the presence of an abnormal mass, such as epidural fibrosis, as in the present case.

Conclusions

Spinal compression secondary to fibrous scar tissue around epidural electrodes must be considered a possible cause of myelopathy in long-term follow-up patients after SCS. Follow-up CT or MRI are required in cases of SCS when tolerance to SCS takes place during long-term treatment.

Acknowledgments

Portions of this work were presented in abstract form at the 36th Annual Meeting of the Neurospinal Society of Japan, held in Kyoto, Japan, on June 3, 2021. No funding was received for this research.

Informed Consent

In this report, the patient provided verbal informed consent.

Conflicts of Interest Disclosure

None

References

- 1) Shealy CN, Mortimer JT, Reswick JB: Electrical inhibition of pain by stimulation of the dorsal columns: preliminary clinical report. *Anesth Analg* 46: 489-491, 1967
- 2) Kumar K, Taylor RS, Jacques L, et al.: Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 132: 179-188, 2007
- 3) Kemler MA, Barendse GA, van Kleef M, et al.: Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 343: 618-624, 2000
- 4) Turner JA, Loeser JD, Bell KG: Spinal cord stimulation for chronic low back pain: a systematic literature synthesis. *Neurosurgery* 37: 1088-1095; discussion 1095, 1995
- 5) Guzzi G, Volpentesta G, Chirchiglia D, Della Torre A, Lavano F, Lavano A: Cervical spinal cord compression from delayed epidural scar tissue formation around plate lead for SCS. *J Neurosurg Sci* 63: 337-343, 2019
- 6) Wloch A, Capelle HH, Saryyeva A, Krauss JK: Cervical myelopathy due to an epidural cervical mass after chronic cervical spinal cord stimulation. *Stereotact Funct Neurosurg* 91: 265-269, 2013
- 7) Pallotta ML, Lovi A, Luca A, Babbi L, Brayda-Bruno M: Spinal cord stimulator medullary compression-a very rare SCS complication and surgical treatment. *Spinal Cord Ser Cases* 8: 84, 2022
- 8) Fransen P: Reversible late thoracic myelopathy and neurostimulation tolerance caused by fibrous scar tissue formation around the spinal cord stimulation electrode. *Neuromodulation* 18: 759-761, 2015
- 9) Benfield J, Maknojia A, Epstein F: Progressive paraplegia from spinal cord stimulator lead fibrotic encapsulation: A case report. *Am J Phys Med Rehabil* 95: e30-e33, 2016
- 10) Al Tamimi M, Aoun SG, Gluf W: Spinal cord compression secondary to epidural fibrosis associated with percutaneously placed spinal cord stimulation electrodes: case report and review of the literature. *World Neurosurg* 104: 1051.e1-1051.e5, 2017
- 11) Lennarson PJ, Guillen FT: Spinal cord compression from a foreign body reaction to spinal cord stimulation: a previously unreported complication. *Spine* 35: E1516-E1519, 2010
- 12) Wada E, Kawai H: Late onset cervical myelopathy secondary to fibrous scar tissue formation around the spinal cord stimulation electrode. *Spinal Cord* 48: 646-648, 2010
- 13) Cicuendez M, Munarriz PM, Castaño-Leon AM, Paredes I: Dorsal myelopathy secondary to epidural fibrous scar tissue around a spinal cord stimulation electrode. *J Neurosurg Spine* 17: 598-601, 2012
- 14) Dam-Hieu P, Magro E, Seizeur R, Simon A, Quinio B: Cervical cord compression due to delayed scarring around epidural electrodes used in spinal cord stimulation. *J Neurosurg Spine* 12: 409-412, 2010
- 15) Scranton RA, Skaribas IM, Simpson RK: Spinal stimulator peri-electrode masses: case report. *J Neurosurg Spine* 22: 70-74, 2015
- 16) Cameron T: Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg* 100: 254-267, 2004
- 17) Delaplace M, Maitre F, Dufour T, et al.: [Two cases of cutaneous erythema following spinal cord stimulation]. *Ann Dermatol Venerol* 137: 297-300, 2010
- 18) Liu J, Guo X, Ren X, et al.: A novel FPCL model producing directional contraction through induction of fibroblast alignment by biphasic pulse direct current electric field. *Exp Cell Res* 371: 426-434, 2018

- 19) Huang YJ, Samorajski J, Kreimer R, Searson PC: The influence of electric field and confinement on cell motility. *PLOS ONE* 8: e59447, 2013
- 20) Fishman MA, Antony A, Esposito M, Deer T, Levy R: The evolution of neuromodulation in the treatment of chronic pain: forward-looking perspectives. *Pain Med* 20: S58-S68, 2019

Corresponding author: Keisuke Takai, MD, PhD

Department of Neurosurgery, Tokyo Metropolitan Neurological Hospital, 2-6-1 Musashidai, Fuchu, Tokyo 183-0042, Japan.

e-mail: takai-nsu@umin.ac.jp