Technical Note

High-Frequency Spinal Cord Stimulation for the Treatment of Chronic Low Back and Leg Pain: Implantation Technique of Percutaneous Leads and Implantable Pulse Generator

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Abstract: Spinal cord stimulation (SCS) is an evidence-based, reversible but invasive procedure for the treatment of chronic pain syndromes: for example, in patients with failed-back-surgery syndrome or complex regional pain syndrome. A more recent, similar technique uses high-frequency stimulation for SCS and follows a different mechanism of action that does not result in paresthesia. This Technical Note and video present surgical instructions of a “2-way cut-down” technique for a high-frequency SCS trial period and permanent implantation of an implantable pulse generator.

Up to 30% of patients who undergo spinal surgery acquire failed-back-surgery syndrome. Another large percentage of the population suffers from chronic low back pain and leg pain, which are very common conditions (3% to 10%) and are increasing because of demographic changes; thus the health and economic burdens are also increasing. One of several established treatments for chronic low back pain and other pain conditions, including neuropathic pain syndromes, is spinal cord stimulation (SCS). Conventional, tonic SCS with low-frequency stimulation (~40 to 60 Hz) is an evidence-based method for the treatment of failed-back-surgery syndrome and other chronic pain syndromes such as complex regional pain syndrome. The corresponding spinal region of the pain area is stimulated to paresthesia to mask pain perception. In contrast, with high-frequency SCS (10 kHz, known as HF10 therapy), paresthesia is neither observed nor intended, as the stimulation is beneath the neuronal threshold for sensitive perceptions (Tables 1 and 2). Furthermore, randomized controlled trials show the superiority of HF SCS over conventional tonic SCS regarding pain relief.

Surgical Technique

Step 1: Temporary Stimulation for Trial Period

The patient is placed in a prone position and covered with sterile drapes. About 30 minutes before skin incision, a single shot of antibiotics (e.g., cefuroxime) is administered. Correct spinal positioning and the appropriate vertebral level (thoracic vertebra 8 [T8] to T10) for the planned placement of the leads is determined by fluoroscopy.

We aim for the midline of the epidural space at lumbar 1/2 (L1/2) or L2/3. The skin entry point should be 2 pedicles lower, slightly para-midline. The skin is incised, and 2 Tuohy needles are inserted through the ligamentum flavum into the epidural space (Fig 1). The percutaneous lead (Octrode; Nevro) is introduced at a shallow angle of ~30° to prevent contusions to the dura or spinal cord. Once the lead is within the epidural space, it is advanced to the desired vertebral level (T8/9)
in midline by fluoroscopic guidance (Figs 2 and 3). The procedure is repeated for another lead that is recommended to be placed in a more caudal and midline position (T9/10) with respect to the first lead.

A small incision to the lumbar fascia is made. The leads are then fixed to the fascia by anchors and are connected to originator/recipient cables for impedance measurements (Fig 4). If the impedance is within the desired range, the leads are fixed completely by tightening the set screws at the anchor, turning the torque wrench until it clicks. If the impedance is insufficient, the leads have to be repositioned before fixation.

When loose ends of the lead have been wiped clean, lead extensions are connected via an extension adaptor. The loose ends of the lead extension are then inserted into the hollow part of a tunneling tool and guided 10 to 15 cm subcutaneously in a lateral direction to the planned position of the internal pulse generator (IPG) pocket, and the extension lead adaptors are placed. For preventing infections in the planned IPG pocket site, the loose ends of the extension leads are guided ~15 cm cranio-laterally to a temporary exit site that passes the skin surface (Fig 5). For less postoperative wound pain, local anesthetics (e.g., bupivacaine) can be injected along the tunneling route. Once the tunneling tool has exited the skin, the sharp tip is taken off, and the extension leads are gently pulled through the straw, which is then removed. A strain relief loop is prepared for the leads in the wound, and a final check for lead positioning is made by fluoroscopy.

The wounds are closed and covered with sterile wound dressings, and the extension leads are

Table 1. Pearls and Pitfalls for Implantation of an HF-SCS

| Pearls                                      | Pitfalls                                      |
|---------------------------------------------|-----------------------------------------------|
| Objective percutaneous lead positioning     | Risk of infections                            |
| Anatomic positioning without intraoperative paresthesia mapping | Risk of lead migration                        |
| More effective pain reduction than traditional SCS | Necessity of revision surgery if IPG fails (e.g., does not recharge) |
| No paresthesia                             | No data on long-term outcomes >36 mo          |

HF, high-frequency; IPG, implantable pulse generator; SCS, spinal cord stimulation.

Table 2. Indications and Contraindications for Implantation of an SCS Device

| Indications                                      | Contraindications                                      |
|------------------------------------------------|--------------------------------------------------------|
| Failed-back-surgery syndrome, CRPS, peripheral arterial occlusive disease, periphery polyneuropathy | Active disruptive psychological or psychiatric disorder |
| Chronic intractable pain refractory to conservative therapy (minimum 3 mo) | Mechanical spine instability based on flexion/extension x-rays |
| Average pain intensity ≥5 out of 10 on Visual Analog Scale for pain | Previous back surgery (<6 mo), current inoperability (e.g., infection) |
| Oswestry Disability Index 41 to 80 out of 100 | Disorders affecting pain perception |

CRPS, complex regional pain syndrome; SCS, spinal cord stimulation.

Fig 1. Patient in prone position. Anteroposterior view. Two Tuohy needles are inserted for eventual protrusion of the leads. This step can be performed under fluoroscopic guidance. The patient underwent previous spine surgery and was treated with spondylodesis, which can be seen in the lower part of the figure. L1, L2, L3, lumbar 1, 2, and 3.

Fig 2. Patient in prone position. Fluoroscopic placement control of percutaneous leads in anteroposterior projection. The arrow indicates the first placed lead.
connected to the external pulse generator (EPG). After using the lead location tool in the appropriate software, it is necessary to connect the proximal lead, which is blue, to lead port 1 of the EPG. Parameters for stimulation such as the pulse amplitude can then be changed and adjusted by the software (Fig 4).

Step 2: Permanent Stimulation via IPG Implantation
During the trial period of 7 to 14 days, pain relief is monitored and evaluated. If there is significant pain reduction (>50%), the permanent implantation of an IPG is scheduled. The extracorporeal part of the extension leads is cut off under sterile conditions. A subcutaneous part of the extension leads remains until IPG implantation. Before surgery, the pocket site should be marked with the patient in a sitting position. A subcutaneous pocket (gluteal or abdominal region) is prepared, and its size is checked with a dummy the size of the IPG (Fig 6). The extension lead adaptors are disconnected, and the IPG is connected to the epidural leads. Again, the proximal leg (blue) is connected to the lower port of the IPG. Finally, the IPG is inserted, and the wound is closed and covered with sterile wound dressings (Fig 7). Recharging (and if necessary, reprogramming) of the IPG is done via transcutaneous transduction (Video 1, Table 3).

Discussion
Recent advancements in the field of neuromodulation have yielded significant improvements in treatment outcomes and have expanded the application of SCS treatment to a wider range of chronic pain patients. As different studies have found, high-frequency (HF) SCS is a superior alternative to conventional, low-frequency SCS.6,7
HF SCS yields several advantages such as a different mechanism of action that does not require paresthesia...
to mask pain. There seems to be modulation of the dorsal horn and the wide-dynamic-range neurons. Furthermore, there is evidence that the pain-reducing effect of HF SCS is vast and of long endurance. In addition, this technique may serve as a treatment option for pain-refractory patients who experience long-duration medical management and previous spinal surgery. There is some evidence that HF SCS may be more cost-effective than other treatment procedures (conventional SCS or pain medication) for the same indications when comparing cost and quality-adjusted life years. Furthermore, HF SCS reduces opioid usage in most cases. SCS patients report greater improvements to pain, quality of life, and activity levels and have a higher return-to-work rate than those receiving conservative treatment.

The HF SCS procedure described here is surgically undemanding, and the placement of the leads, which is crucial for the success of the operation, can be controlled objectively by fluoroscopy. Furthermore, it can be performed under general anesthesia. In contrast, conventional SCS requires waking the patient during the intervention to subjectively map the pain area and success of paresthesia.

Table 3. Principle Treatment Algorithm for Implantation of an HF-SCS Device

| Step | Description |
|------|-------------|
| 1.   | Patient positioning and sterile draping |
| 2.   | Determination of vertebral level |
| 3.   | Skin incision |
| 4.   | NaCl injection for proof of loss of resistance |
| 5.   | Insertion of Tuohy needle into epidural space |
| 6.   | Insertion of first percutaneous lead |
| 7.   | Insertion of second percutaneous lead |
| 8.   | Lead position control by fluoroscopy |
| 9.   | Impedance measurement |
| 10.  | Lead fixation by anchoring |
| 11.  | Subcutaneous tunneling of lead extensions |
| 12.  | Connection to EPG |
| 13.  | Evaluation of pain reduction during trial period |
| 14.  | Preparation of subcutaneous pocket |
| 15.  | Impedance measurement |
| 16.  | Subcutaneous implantation of IPG |

HF, high-frequency; EPG, external pulse generator; IPG, implantable pulse generator; SCS, spinal cord stimulation.
Conclusions
The treatment of chronic low back and leg pain by HF SCS is a safe and effective procedure. The technique may be of increasing relevance, as studies investigating long-term results are ongoing, and the first results are very promising.

References
1. Tronnier V, Baron R, Birklein F, et al. Epidural spinal cord stimulation for therapy of chronic pain. Summary of the S3 guidelines. Schmerz 2011;25:484-492 [in German].
2. Freburger JK, Holmes GM, Agans RP, et al. The rising prevalence of chronic low back pain. Arch Intern Med 2009;169:251-258.
3. Juniper M, Le TK, Mladsi D. The epidemiology, economic burden, and pharmacological treatment of chronic low back pain in France, Germany, Italy, Spain and the UK: A literature-based review. Expert Opin Pharmacother 2009;10:2581-2592.
4. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. Pain Pract 2011;11:148-153.
5. Chakravarthy K, Richter H, Christo PJ, Williams K, Guan Y. Spinal cord stimulation for treating chronic pain: Reviewing preclinical and clinical data on paresthesia-free high-frequency therapy. Neuromodulation 2018;21:10-18.
6. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: The SENZA-RCT randomized controlled trial. Anesthesiology 2015;123:851-860.
7. Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. Neurosurgery 2016;79:667-677.
8. Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. Pain Med 2014;15:347-354.
9. Al-Kaisy A, Palmisani S, Smith T, Harris S, Pang D. The use of 10-kilohertz spinal cord stimulation in a cohort of patients with chronic neuropathic limb pain refractory to medical management. Neuromodulation 2015;18:18-23.
10. Annemans L, Van Buyten JP, Smith T, Al-Kaisy A. Cost effectiveness of a novel 10 kHz high-frequency spinal cord stimulation system in patients with failed back surgery syndrome (FBSS). J Long Term Eff Med Implants 2014;24:173-183.
11. DiBenedetto DJ, Wawrzyniak KM, Schatman ME, Kulich RJ, Finkelman M. 10 kHz spinal cord stimulation: A retrospective analysis of real-world data from a community-based, interdisciplinary pain facility. J Pain Res 2018;11:2929-2941.
12. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: A 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery 2008;63:762-770.