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.[1] Another large percentage of the population suffers from chronic low back pain and leg pain, which are very common conditions (3% to 10%)[2] and are increasing because of demographic changes; thus the health and economic burdens are also increasing.[3] 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.[4] 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[5] (Tables 1 and 2). Furthermore, randomized controlled trials show the superiority of HF SCS over conventional tonic SCS regarding pain relief.[6]

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)

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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.

in midline by fluoroscopic guidance (Figs 2 and3). 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

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.

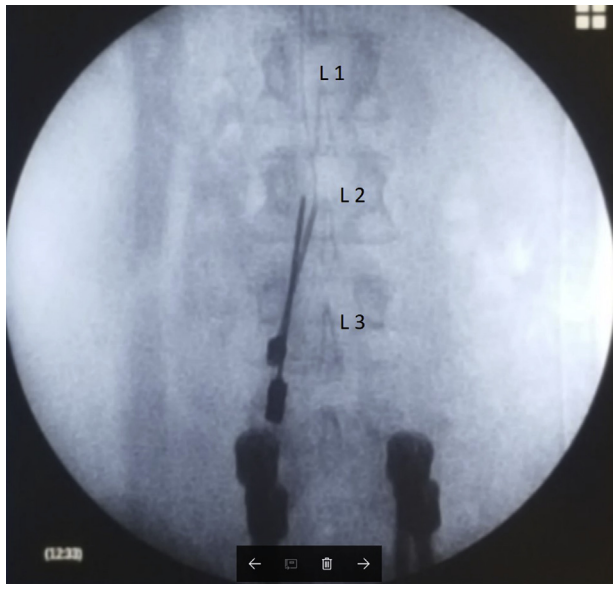

Fig 1. Patient in prone position. Anteroposterior view. Two Tuohy needles are inserted for eventual protrusion of the leads. This step can be performed under fluoroscopic guidance. The patient underwent previous spine surgery and was treated with spondylodesis, which can be seen in the lower part of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

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

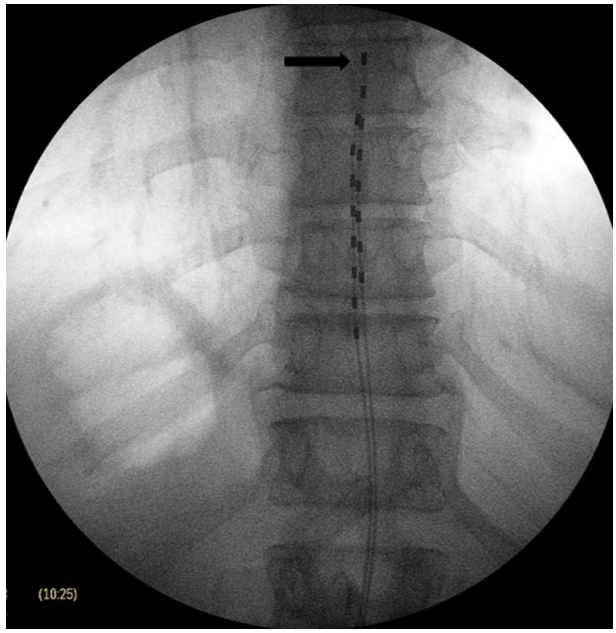

Fig 2. Patient in prone position. Fluoroscopic placement control of percutaneous leads in anteroposterior projection. The arrow indicates the first placed lead.

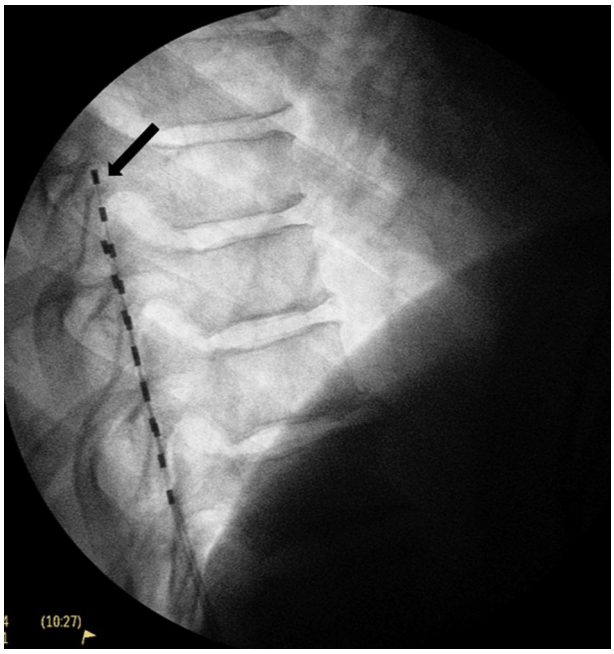

Fig 3. Patient in prone position. Lateral view. Fluoroscopic placement control of percutaneous leads in lateral projection. The arrow indicates the first placed lead.

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

Fig 4. User's interface of the programming software for adjustment, configuration, and impedance measurement of the external or implantable pulse generator.

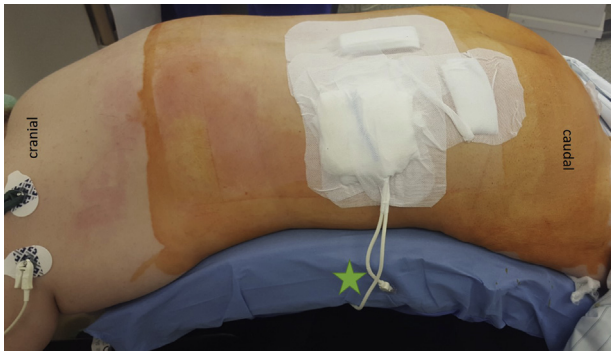

Fig 5. Externalization of leads and final wound dressing for temporary implantation (~10 days). The left side of the picture is cranial and the right side caudal. The green * indicates the extension leads.

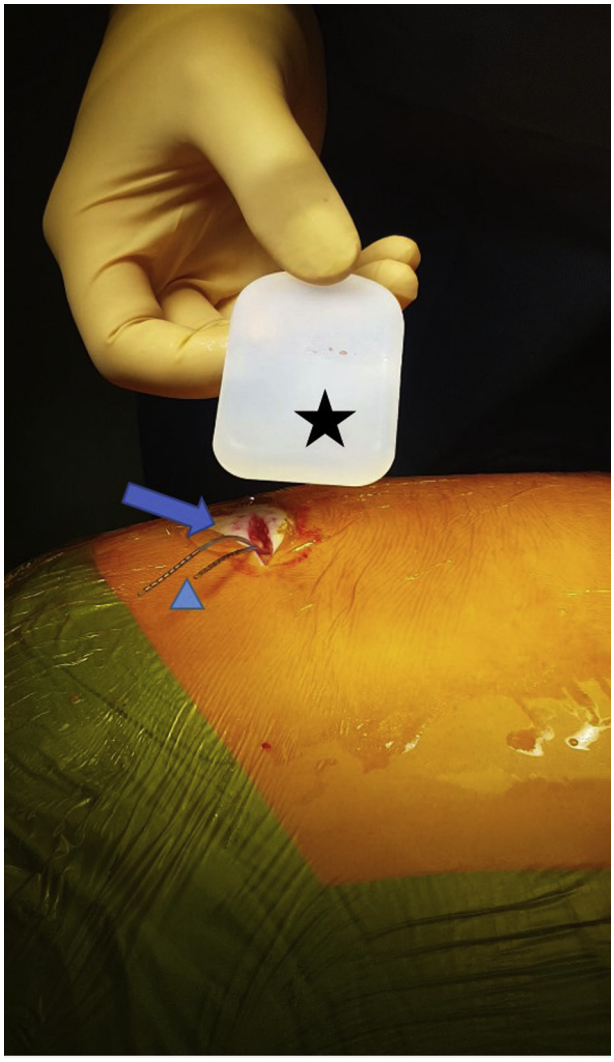

Fig 6. An implantable pulse generator (IPG) dummy (black *) is used for evaluation whether the planned subcutaneous pocket (blue arrow) is large enough for the placement of lead extensions (blue triangle) and IPG.

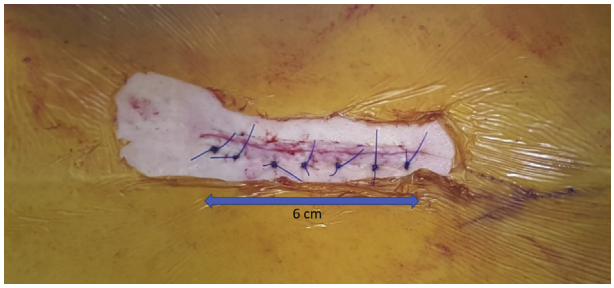

Fig 7. Final wound closure after definitive implantable pulse generator implantation.

to mask pain. There seems to be modulation of the dorsal horn and the wide-dynamic-range neurons.[5] Furthermore, there is evidence that the pain-reducing effect of HF SCS is vast and of long endurance.[8] In addition, this technique may serve as a treatment option for pain-refractory patients who experience long-duration medical management and previous spinal surgery.[9] 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.[10] Furthermore, HF SCS reduces opioid usage in most cases.[11] 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.[12]

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

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.

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