# **Original Article**

# Dorsal paddle leads implant for spinal cord stimulation through laminotomy with midline structures preservation

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### Abstract

**Background:** Pain relief obtained with spinal cord stimulation (SCS) in failed back surgery syndrome (FBSS) has been shown to be more effective with paddle leads than with percutaneous catheters. A laminectomy is generally required to implant the paddles, but the surgical approach may lead to iatrogenic spinal instability in flexion. In contrast, clinical and experimental data showed that a laminotomy performed through flavectomy and minimal resection of inferior and superior lamina with preservation of the midline ligamentous structures allowed to prevent iatrogenic instability. Aim of the study was to assess degree of instability and pain level in patients operated for SCS through laminectomy or laminotomy with midline structures integrity. The surgical technique is described and our preliminary results are discussed.

Methods: Nineteen patients with FBSS underwent SCS, 12 through laminectomy and 7 through uni- or bilateral interlaminotomy with supraspinous ligament preservation. Postoperative local pain was evaluated at 15, 30, and 60 days. Static and dynamic X-rays were performed after 2 months.

Results: The techniques allowed implanting the paddle leads in all cases. No intraoperative complications occurred. Local pain was higher and recovery time was longer in patients with laminectomy. We did not observe radiological signs of postoperative iatrogenic vertebral instability. Nevertheless, two patients who underwent laminectomy showed persistence of local pain after 2 months probably due to pathologic compensatory stability provided by the paraspinal musculature.

Conclusions: The laminotomy is a minimally invasive approach that ensures rapid recovery after surgery, spinal functional integrity, and complete reversibility. Further studies are needed to confirm our preliminary results.

Key Words: Failed back surgery syndrome, laminotomy, paddle lead, spinal cord stimulation minimally invasive technique



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# INTRODUCTION

Spinal cord stimulation (SCS) is an effective therapy in chronic intractable pain of failed back surgery syndrome (FBSS) with pain relief rates between 50% and 75% in long-term follow-up.<sup>[1,4,28]</sup> Insulated arrays implanted via laminectomy demonstrated performance advantages, in comparison with percutaneous electrodes.<sup>[22]</sup> As a matter of fact, several authors reported better coverage of pain<sup>[13]</sup> and clinical outcome<sup>[3,12,18,29]</sup> with fewer adverse effects.<sup>[18]</sup> A systematic review of the English language literature from 1996 to 2008 evaluating the effectiveness of SCS in relieving chronic pain in FBSS indicated the evidence to be level II-1 or II-2.<sup>[9]</sup>

The paddle lead is usually implanted through a bilateral flavectomy and partial laminectomy with midline ligamentous structures resection. In contrast, a bilateral laminotomy with midline structures preservation<sup>[2,24,25]</sup> may ensure the spinal stability<sup>[30]</sup> and this is confirmed by biomechanical experimental tests carried out on animal models.<sup>[6,7,26,27]</sup>

In our Neurosurgical Division SCS for FBSS was performed in 19 patients through a uni- or bilateral laminotomy or a partial laminectomy. Aim of the study was to assess if a minimally invasive approach may allow reducing spinal instability and local pain after surgery.

We presented our preliminary findings and discussed advantages and limitations of this microinvasive technique. The clinical efficacy of SCS in terms of pain relief is not debated.

# **MATERIALS AND METHODS**

Between July 2009 and December 2011, 19 patients with FBSS underwent SCS. Uni- or bilateral interlaminotomy with supraspinous ligament preservation was used in seven patients. A standard approach, through a partial laminectomy<sup>[13]</sup> was performed in 12 cases [Table 1].

| Table  | 1:  | Summa  | ary of | patients | undergoing | interlaminotomy |
|--------|-----|--------|--------|----------|------------|-----------------|
| or lan | nin | ectomy |        |          |            |                 |

| Patient's data                                | Interlaminotomy   | Laminectomy       |
|---|-------------------|-------------------|
| Number of patients (pz)                       | 7 (4 M, 3 F)      | 12 (5 M, 7 F)     |
| Age   | Mean 60,7 (49-74) | Mean 65,6 (52-78) |
| Previous instrumented<br>vertebral fusion     | 5 pz              | 9 pz              |
| Previous percutaneous<br>SCS-lead dislocation | 1 pz              | 2 pz              |
| Pain localization                             |                   |                   |
| Lumbar and lower limbs<br>bilaterally         | 4                 | 8                 |
| Lumbar and lower limb<br>monolaterally        | 1                 | 2                 |
| Lower limbs bilaterally                       | 2                 | 2                 |
| Epidural trial: Mean trial length             | 17 days           | 17 days           |

The technical features of paddle leads and implantable pulse generator (IPG) are summarized in Table 2.

Surgical-related pain was evaluated after 15, 30, and 60 days through the numeric rating scale (NRS-11).<sup>[10]</sup> Dynamic X-rays were used to assess spinal stability.

### Surgical technique

The paddle leads were placed in all cases at D8-D9 level. The laminectomy was performed using a standard approach.<sup>[13]</sup> Uni- or bilateral interlaminotomy was achieved as described below:

The unilateral approach was preferred in case of 4 + 4-poles plates, whereas the bilateral was used for 5 + 6 + 5-poles devices.

In both cases we used the following protocol: (a) general anesthesia; (b) prone position; (c) antibiotic prophylaxis; (d) D9-D10 interlaminotomy for 4 + 4-poles electrodes and D10-D11 interlaminotomy for 5 + 6 + 5-poles plates positioning; and (e) 3 weeks of trial stimulation.

### Unilateral approach [Figure 1]

We performed the unilateral approach in two cases.

(a) unilateral paraspinal muscles dissection; (b) interlaminotomy: Flavectomy and minimal resection of both inferior lamina of D9 (or D10) and superior lamina of D10 (or D11) [Figure 1a and b] slightly extended controlaterally under the midline ligamentous structures [Figure 1a]; c) a space to introduce the lead blank is obtained [Figure 1c] completely preserving the supraspinous ligament [Figure 1a and b]; (d) paddle lead insertion [Figure 1d] in median position [Figure 2a] with unilateral release of the two extension cables that are later fixed to muscular fascia; and (e) trial pulse generator standard connection.



Figure I: (a-b) Monolateral interlaminotomy with dura mater exposed (white arrow). Supraspinous ligament structures are preserved (white star). Controlateral extension of the exposure under the midline ligamentous structures (blue star), (c) Lead blank insertion through the interlaminotomy, (d) Lead paddle insertion through the interlaminotomy

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*Bilateral approach [Figure 3]* The bilateral approach was used in five cases.

(a) bilateral paraspinal muscles dissection; (b) symmetrical bilateral interlaminotomy: Bilateral flavectomy and minimal bilateral lamina resection performed as in the monolateral approach; (c) a space to introduce the lead blank and the lead paddle is obtained completely preserving the supraspinous ligament [Figure 3]; (d) median paddle lead positioning [Figure 4] with bilateral release of extension cables [Figures 3 and 5]; (e) the cables are fixed to the supraspinous ligament; and (f) trial pulse generator standard connection.

### **Pain evaluation**

Surgical-related pain was divided in four levels according NRS-1:<sup>[10]</sup> no pain (rating 0), mild (1-3), moderate (4-6), severe pain (7-10). Follow-up for all patients lasted up to 60 days.

### **Radiological assessment**

In all cases we performed a radiological control through static and dynamic X-rays at discharge and after 2 months [Figure 2a and b].

#### RESULTS

#### Interlaminotomy

In all cases the paddle leads (3 Hinged 4 + 4 and 4 Specify 5 + 6 + 5) were implanted through uni- or bilateral interlaminotomy with complete preservation of the supraspinous ligament. In one case a unilateral approach was converted to a bilateral to achieve a median position of the electrode. We did not have any intraoperative problem during surgery technique related.

All patients stood up on the same day of surgery and were discharged within 48-72 hours without neurological



Figure 2: (a) A-P view of postoperative X-ray show a 4 + 4 surgical lead placement at T8-T9, (b) The L-L view of the dynamic X-ray in flexed position does not show any sign of vertebral instability

deficits or wound problems. The postoperative X-rays showed the correct position of the plates.

After the epidural trial, we removed 1 Hinged 4 + 4 because ineffective and 1 Specify 5 + 6 + 5 because of an infection. The other five patients underwent the IPG implant (two, Synergy Versitrel – three, Prime Advanced).

After 2 months no patient complained of local pain where the interlaminotomy was performed. The radiological assessment showed that no paddle displacement occurred and no signs of segmental instability were observed [Figure 3b].

#### Laminectomy

The paddle leads were implanted with midline ligamentous structures resection. No surgical complications were reported. Ten patients were discharged within 72 hours, but 2 patients remained hospitalized 10 days for severe pain at surgical site. X-rays showed that all plates were correctly positioned. Two Hinged and 1 Specify were removed after the epidural trial because it was ineffective. Therefore, IPG implant was performed in nine patients (four, Synergy Versitrel – five, Prime Advanced).

Six patients showed moderate and severe local pain 15 days after surgery. Mild and moderate pain was still present in six cases after 30 days. Only two patients presented mild local pain after 2 months. No paddle displacement occurred and no radiological signs of instability were reported.

#### Table 2: SCS technology (Medtronic, Inc-Minneapolis-USA)

| Paddle lead   | IPG               |
|---------------|-------------------|
| Hinged 4+4    | Synergy versitrel |
| Specify 5+6+5 | Prime advanced    |



Figure 3: Bilateral interlaminotomy performed at T10-T11 for a 5 + 6 + 5 surgical lead insertion. The supraspinous ligament is intact (white star). The two cables of the lead paddle (white arrows) coming out from the spinal canal on both sides are fixed to the spinous process (blue arrow)

## DISCUSSION

Literature showed that the paddle leads<sup>[21]</sup> are more effective than the percutaneous catheters in FBSS treatment in terms of pain relief<sup>[3,5,12,17,18,22,29]</sup> and cost-effectiveness.<sup>[16]</sup> Nevertheless, the standard surgical technique used to place the plates may lead to segment instability.<sup>[6,7,14]</sup>

In an animal experimental model by Tai et al., a hydraulic testing machine was used to generate a 8400 N-mm increasing force in flexion and extension. The intervertebral displacement was measured after lumbar decompression obtained through bilateral laminotomy with suprapinous ligament preservation and through bilateral laminectomy with supraspinous ligament resection and was compared with an intact group. Authors showed that the lumbar spine group with a destroyed supraspinous ligament is more likely to develop instability, whereas no significant differences were found between the other two groups.<sup>[27]</sup> The posterior elements play a role even in the stability of the thoracic spine. As a matter of fact, an experimental biomechanical study showed an increased range of motion due to posterior elements impairment, though costovertebral joints and rib cage are important stabilizers.<sup>[19]</sup>

Various studies showed that total laminectomy, both in lumbar and in thoracic spine, increases segmental instability.<sup>[6,7,14,31]</sup> Moreover, postlaminectomy cervical deformity is a challenging condition that often requires surgical correction.<sup>[8]</sup> Therefore, several modifications of the standard laminectomy were proposed in the attempt to preserve the spinal integrity.<sup>[23,30]</sup>

Bilateral laminotomy with resection of ligamentum flavum and superior and inferior laminar margins<sup>[2,24,25]</sup> has been shown to maintain the spinal stability by

preserving the midline structures (spinous process, supraspinous ligament).<sup>[30]</sup> In contrast, resection of the spinous process and interspinous-supraspinous ligaments causes a iatrogenic damage to the paraspinal musculature that provides pathologic compensatory stability.<sup>[11,15]</sup>

Moreover, recent experimental data<sup>[6,7,26,27]</sup> confirm that vertebral instability after spinal surgery is rare in laminotomy with preservation of midline ligamentous structures. The ideal procedure would require minimal resection of bony structure and maintenance of integrity of posterior supporting ligaments.<sup>[11,15,20,23,30]</sup>

In our experience, in case of FBSS, paddle leads for SCS were placed through standard laminectomy or interlaminotomy, which allowed to preserve the midline structures.<sup>[30]</sup> No differences were observed in technical difficulties, surgical times, and risks between the two approaches. In contrast, local pain was higher in patients with laminectomy and recovery after surgery was faster in patients with interlaminotomy [Figure 6]. Therefore, the minimally invasive approach allowed to improve the surgical-related pain and to reduce the hospitalization time.

Radiological signs of spinal instability were not observed. Nevertheless, two patients with laminectomy showed local pain after 2 months. The pathologic compensatory stability provided by the paraspinal musculature might be related to the persistence of pain. However, a long-term radiological and clinical follow-up is required to confirm this hypothesis.

Paddles placed through unilateral interlaminotomy tend to arrange itself in oblique cranial-lateral direction. Therefore, several attempts may be required to achieve the right position and it could be necessary to switch to a bilateral approach. Thus, we suggest the unilateral approach for small multi-column paddles (8-poles).



Figure 4: L-L and A-P view of postoperative CT scan show the 5+6+5 surgical lead placement at T8-T9 in the same case described in Figure 3. The lead is correctly aligned with the median line



Figure 5: 3-D postoperative CT scan of the same case described in Figure 3. The two cables of the lead paddle coming out from the spinal canal on both sides of the spinous process are shown



Figure 6: Surgical-related pain after 15, 30, and 60 days in patients operated through interlaminotomy (a) and laminectomy (b)

### CONCLUSIONS

We consider the interlaminotomy with preservation of spinous process and supraspinous ligament for paddle leads placement a minimally invasive technique that provides a complete spinal functional integrity and reversibility. It allows achieving similar results compared with the traditional procedure with less local pain, rapid recovery after surgery, and without the risk of segmental instability.

The bilateral approach may be used in case of large paddles (16-poles), whereas the unilateral techniques should be preferred for small plate leads.

We speculate that it should be performed in all cases of paddle lead insertion for SCS, especially in the cervical spine where postlaminectomy instability is often observed.

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