S-Series™ Leads Case Study #1

Spinal Cord Stimulation for FBSS With an S-Series Perc-Paddle Lead

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Introduction and Patient History

In July 2008, a female patient presented with lumbalgia after two low back surgeries and complained of radiation pain in the groin, left leg, and foot. The patient was referred to the department of pain therapy by an orthopedic surgeon, and no paresis, paresthesia, or allodynia was found. The patient was subsequently diagnosed with failed back surgery syndrome (FBSS) with lumboischialgia, describing her pain as deep and stinging and rating her pain at 8/10 on the Visual Analogue Scale (VAS).

Gender	Female
Age at time of implantation	58
Height	1,68 m
Weight	89 kg

Table 1. Demographic data

Prior to the symptoms recurring, the patient had two weeks of pain improvement from infiltrations of the S1 nerve root. This procedure was repeated twice before the decision was made to implant her with a spinal cord stimulation (SCS) trial system. Other previous treatments included epidural injections, facet joint injections, and medication. A psychiatric evaluation revealed no mood anomalies, psychotic elements, or toxicomanic behavior, and the EEG showed a normal trace. The clinical psychological evaluation (McGill Parr Pain Questionnaire [MPQ], Pain Disability Index [PDI], Pain Catastrophizing Scale [PCS], Oswestry Low Back Pain Questionnaire, four-dimensional complaints questionnaire, Tampa scale for kinesiofobia, BECK depression scale, Utrecht Coping List [UCL], Minnesota Multiphasic Personality Inventory [MMPI]) was obtained and showed the patient to be a suitable candidate for spinal cord stimulation.

In October 2008, the patient was implanted with a 30-cm S-Series S-8 perc-paddle lead (St. Jude Medical Neuromodulation Division, Plano, TX) via percutaneous approach. A skin incision was made with an 11-blade scalpel at the L2-L3 level, after which a Touhy needle was inserted using a paramedian approach and a flat angle (<30°) to enter the epidural canal at T12/L1. The Epiducer™ lead delivery system (St. Jude Medical Neuromodulation Division, Plano, TX) was used to allow for minimally invasive placement of the perc-paddle lead. The lead was passed into the epidural canal and steered cephalad to the desired target level, with the tip of the lead at T8 and slightly to the left of the physiologic midline (Figure 1).

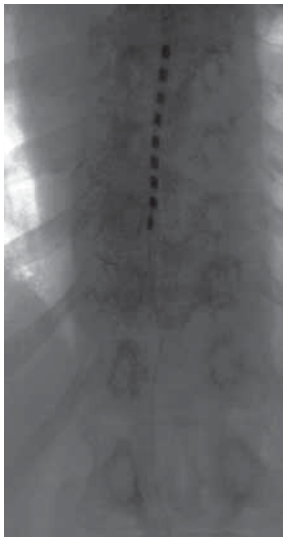

Figure 1. Final position of the lead with tip at T8

Intraoperative stimulation, with the Rapid Programmer™ system (St. Jude Medical Neuromodulation Division, Plano, TX), was used to confirm adequate paresthesia overlap in the patient's painful area. The patient reported paresthesia throughout the entire painful area, covering the left leg, foot, and groin as well as the left lower back area. The patient was then discharged and trialed for 28 days as required by Belgian reimbursement guidelines.

Outcome research has demonstrated that patients with FBSS benefit significantly from spinal cord stimulation.[1] The use of S-Series perc-paddle leads for percutaneous implantation and advancement in the epidural space has been found to be efficacious and safe.[2] In this case report, FBSS with lumboischialgia is treated with the perc-paddle lead.

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Results

At follow-up after the trial (Table 2), average pain intensity decreased to 1/10 on the Visual Analogue Scale (VAS). The stimulation also resulted in a positive effect on the patient's functionality and quality of life (QoL), as measured by her rating of a number of functional activities (Tables 4 and 5) and her rating of QoL on a scale from 0–10. She also rated the stimulation as having a positive effect on her ability to perform daily activities, social activities, dependency on others, ability to perform hobbies and sports, and rest required as a result of pain (Tables 6 and 7). The stimulation was rated excellent in its ability to help with her pain problem, and she also indicated that she would definitely redo the procedure (Tables 8 and 9). In addition, compared to baseline, the patient's quality of sleep and problems falling asleep and waking up during the night due to pain improved during the trial period (Table 7).

After the successful trial, the lead was connected via a 60-cm extension to a Genesis*XP*™ primary cell implantable pulse generator (St. Jude Medical Neuromodulation Division, Plano, TX) and implanted in a subcutaneous abdominal pocket. Parameters programmed were as follows: electrode polarity: 4+ 5- 6-; frequency: 30 Hz; pulse width: 450 µs; perception amplitude: 2,5 mA; comfort amplitude: 4,0 mA; Maximum Tolerable amplitude: 6,5 mA.

	VAS Before	VAS After
Current pain (at visit)	2,9	0,0
Worst pain in the last week	10,0	5,9
Lowest pain in the last week	1,9	0,0
Mean pain in the last week	5,1	1,0

Table 2. Pre- and postoperative pain scores

	Before	After
Extremely intense	30%	
Intense		
Strong	30%	
Mild	40%	5%
Light		
No pain		95%

Table 3. Description of the pain variation a day before and after implantation

	Without problems	Small problems	Some problems	A lot of problems	Impossible
Lift heavy weights (+10 kg)					X
Sitting down 30 min		X			
Walk 500 m					X
In and out of bed without help		X			
Dress without help		X			
Take 10 steps on stairs					X
Shower/bathe without help			X		

Table 4. Activity questionnaire according to Belgian Reimbursement requirements at baseline

	Without problems	Small problems	Some problems	A lot of problems	Impossible
Lift heavy weights (+10 kg)			X		
Sitting down 30 min	X				
Walk 500 m	X				
In and out of bed without help	X				
Dress without help	X				
Take 10 steps on stairs	X				
Shower/bathe without help	X				

Table 5. Activity questionnaire according to Belgian Reimbursement requirements after implantation

	Before	After
Daily activities (cleaning, cooking, shopping, etc.)	6,3	1,3
Social activities (going out, meet with friends, etc.)	4,6	1,7
Dependency of other people	4,6	0,1
Hobbies, sports, leisure	9,3	5,7
Rest due to the pain (bed/couch)	3,6	0,1

Table 6. Influence of the pain on daily activities and rest in the week, measured before and after implantation. 0 = Pain does not inhibit the activity at all; 10 = Pain totally prevents doing the activity. 0 = No rest necessary due to the pain; 10 = Rest the whole day.

	Before	After
Quality of sleep	Very good Good **Mild** Bad Very bad	Very good **Good** Mild Bad Very bad
Problems falling asleep	Never Some nights Most nights **Every night**	Never **Some nights** Most nights Every night
Waking up due to the pain	Never Some nights **Most nights** Every night	**Never** Some nights Most nights Every night

Table 7. Answers to questions on sleeping patterns

Did the therapy help with your pain problem?

X			
	Excellent		Little
	Very good		Not at all
	Good		Increased the problem
	Mild		

Table 8. Answer to the question "Did the therapy help with your pain problem?"

Would you redo the procedure?

X	
	Definitely yes
	Yes
	Maybe
	No
	Definitely not

Table 9. Answer to the question "Would you redo the procedure?"

Conclusion

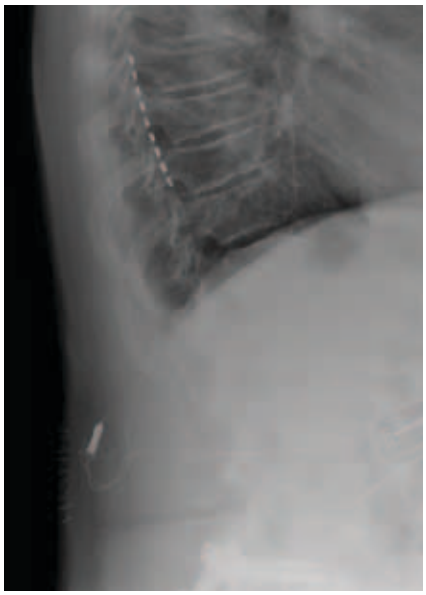

Figure 2. Lateral view on the lead to confirm posterior epidural lead placement. The trial cable connection can also be seen on the lower left of the picture.

This case report describes a successful outcome using a novel approach to implant S-series perc-paddle leads in a patient diagnosed with FBSS and lumboischialgia. Following implant, the patient had three control visits at which no reprogramming was necessary and paresthesia was reported in the entire painful area, including the low back. In August 2009 (10-month follow-up), the patient's VAS score remained 1/10. Tramadol was entirely stopped and paracetamol was only used as needed. Our result, as reported in this case report, has been encouraging.

One key to this successful outcome was performing intraoperative testing of the lead placement while the patient was awake (Figure 2). The case suggests that a perc-paddle lead implanted with a novel percutaneous implant technique is safe and efficacious for failed back surgery syndrome, as has been reported previously.[3]

All data, including VAS, pain characteristics, medication intake, functional activities, and QoL parameters were collected using the Belgian Pain Society evaluation form. This form was developed by the Belgian Pain Society in 1997 and is ruled necessary by the Belgian government for reimbursement of all patients with chronic pain treated with implantable devices. According to Belgian law, an application for Institutional Review Board (IRB) was not required (at the initiation of this case report) for studies that concern regular medical practice and follow-up, and thus no application for IRB approval was made.

Our result, as reported in this case report, has been encouraging. One key to this successful outcome was performing intraoperative testing of the lead placement while the patient was awake. The case suggests that a perc-paddle lead implanted with a novel percutaneous implant technique is safe and efficacious for failed back surgery syndrome as has been reported previously.

— D. Loge, MD[3]

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1. Mekhail NA et al. Clinical applications of neurostimulation: forty years later. *Pain Practice*. 2010; 10(2): 103-122.
2. Logé D, De Coster O, Washburn S. A retrospective data collection study to evaluate the feasibility and safety of percutaneous introduction of a narrow paddle lead into the epidural space. Poster presented at: WIP Congress; March 2009; New York, NY.
3. Logé D, De Coster O. A prospective evaluation to assess the safety of using a newly developed delivery system for percutaneous introduction of SCS paddle leads into the epidural space. Poster presented at: Annual meeting of the North American Neuromodulation Society; Dec 3-6, 2009; Las Vegas, NV.

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