S-Series™ Leads Case Study #4

An S-Series Paddle Lead for the Pain Management of Bilateral Leg and Back Pain

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Introduction and Patient History

A 25-year-old healthy female sustained an injury to her back in 2005 when she fell off a horse that then stepped on her lower back. Since the time of the injury, the patient has complained of lumbar back pain and leg pain consistent with lumbar radiculopathy.

MRI of the lumbar spine revealed a herniated nucleus pulposis at L5-S1. In 2006, the patient underwent lumbar surgical decompression at L5-S1. Postoperatively, she experienced an exacerbation of the radicular pain in the right leg with both sensory and motor derangement. EMG showed denervation in all muscle groups innervated by the right S1 nerve root.

The patient was not considered a good candidate for additional spine surgery, and she was referred to the department of pain therapy at St. Maartens Hospital.

The patient was diagnosed with a persistent right S1 radiculopathy with complaint of pain from the area of the right sacroiliac joint (SIJ) radiating into the distal right lower extremity. Treatment included selective nerve root injections on the right at L5 and S1, pulsed radiofrequency ablation of the L5 dorsal nerve root ganglion, intra-articular SIJ injection, and intralaminar epidural steroid injections at L5-S1. The patient failed to respond to this interventional management.

The patient obtained a second opinion from the orthopedic surgery department at St. Maartens Hospital. Clinical findings continued to show decreased sensation in the right leg as well as motor weakness in the distal right lower leg and foot. MRI showed degenerative disc disease with disc bulging at L5-S1 and evidence of postoperative fibrosis at the right S1 nerve root. The patient was not considered to be a candidate for additional corrective spine surgery.

Additional non-interventional treatment also included: transcutaneous electrical nerve stimulation (TENS) and medication management consisting of paracetamol (acetaminophen), NSAIDs, tramadol, pregabaline, amytriptiline, and oral opioids.

As a result of the patient's persistent pain complaints and failure to respond to conservative and interventional management, evaluation for a trial of spinal cord stimulation (neuromodulation) was pursued.

During the evaluation, symptoms consistent with failed back surgery syndrome (FBSS) were elicited, including an evolving pain pattern extending to both legs (right > left) and the low back. The back pain was reported as 40% of the patient's total pain, and the leg pain was reported as 60%.

A Visual Analogue Scale (VAS) was used to measure the patient's pain on a scale of 1–10, with 10 being excruciating pain.

VAS scores were reported as 7–8 for the back and 6–10 for the legs. (Table 1). In both the back and bilateral legs, there were areas of hypoesthesia and hyperesthesia. The pain was described as "continuous," "electric," and "shooting."

	VAS Legs	VAS Back
Baseline	6–10	7–8
Post-implant	3–4	3–4

Table 1. Pre- and postoperative pain scores

The Douleur Neuropathique 4 Questions (DN4) and the painDETECT questionnaires revealed a high possibility of neuropathic pain in the legs and back.

The patient's history and physical examination revealed no contraindications for neuromodulation. Because the patient fulfilled the inclusion criteria and no exclusion criteria were met, a trial/implantation procedure was indicated according to the Dutch national protocol for neuromodulation.

Because the hospital had experience with the S-Series (Lamitrode™ S-8) paddle lead, also known as a perc-paddle lead (St. Jude Medical Neuromodulation Division, Plano, TX), for managing back and leg pain (success rate for back pain was >50% and for leg pain was >80%), it was decided to implant this lead type.

Materials and Methods

In January 2010, the patient underwent a trial/implant procedure of the electrode and the implantable pulse generator. This was performed in the prone position. The presence of a mild kyphoscoliosis at the thoracolumbar junction made steering the electrode to the target level of T7 and radiographic midline placement in the dorsal epidural space slightly more difficult.

Intraoperative trial stimulation was performed with the use of a Rapid Programmer™ system (St. Jude Medical Neuromodulation Division, Plano, TX). The stimulation pattern revealed that the anatomical and physiological midlines were not overlapping. The paresthesia coverage was only felt in the left leg and not in the back or the right leg. The Lamitrode S-8 lead was then retracted and steered to the upper endplate of T7. To facilitate the placement, a guide wire was used and placed in the midline before the perc-paddle lead was inserted. The perc-paddle lead was then guided along the right side of the guide wire to the target location in the physiologic midline. The guide wire was then removed without movement of the lead.

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Results

Paresthesia covered both legs and the low back. On the right, paresthesia extended to the lower endplate of the T12 vertebral body. On the left, paresthesia extended to the middle of the T11 vertebral body.

Figure 1. Paresthesia coverage of the low back area.

Because the intraoperative stimulation confirmed the entire pain area was covered with paresthesia, the decision was made to proceed to the permanent implantation. An Eon Mini™ implantable pulse generator (IPG) (St. Jude Medical Neuromodulation Division, Plano, TX) was connected directly to the lead and implanted in the left buttock.

Parameters were programmed as follows in Table 2:

Electrode polarity	3+ 4- 5- 6+
Pulse width (µs)	500
Frequency (Hz)	30
Perception amplitude (mA)	7,6
Comfort amplitude (mA)	8,2
Maximum tolerable amplitude (mA)	8,8

Table 2. Stimulation parameter settings

Six weeks after the implantation, the patient reported VAS scores of 3–4 for both legs and the back (Table 2). Pain medication was not reduced by recommendation of the pain management physician.

Conclusion

This case report describes a 25-year-old female patient suffering from debilitating pain in the legs and back after trauma and subsequent surgery. Despite surgery, conventional medical management, and minimally invasive pain treatment, she failed to achieve a satisfactory outcome.

Six weeks after the implantation, the patient experienced a pain reduction of more than 50% in both the legs and the back.

This outcome aligns with the experience we have had at St. Maartens Hospital with the use of the Lamitrode S-8 paddle leads (S-Series leads). It is our experience that in the immediate postoperative period, back and leg pain may vary, necessitating periodic reprogramming to maintain optimal paresthetic coverage and pain control.

Expectations are that the patient will be tapered off of pain medication and that she will be able to increase her physical activity level with an improved quality of life.

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