Received: April 26, 2012 Revised: October 18, 2012 Accepted: October 25, 2012

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12012

Long-Term Outcomes of Spinal Cord Stimulation With Percutaneously Introduced Paddle Leads in the Treatment of Failed Back Surgery Syndrome and Lumboischialgia

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Objective: The study aims to evaluate the long-term clinical and technical efficacy of recently developed percutaneously introducible plate electrodes for spinal cord stimulation.

Methods: Twenty-one patients diagnosed with failed back surgery syndrome (FBSS) or lumboischialgia were implanted with a small profile plate-type electrode. Patients were followed-up long term and were asked at baseline, after trial, and during each follow-up visit to score their pain on a visual analog scale (VAS) for pain now, worst pain last week, least pain last week, and mean pain last week. Pain location, electrophysiologic parameters, and number of reprogrammings were collected as well. Furthermore, each patient was asked if he/she would redo the procedure post trial and at each of the follow-up visits.

Results: A total of 21 patients were prospectively followed up long term. With a mean follow-up of 40.8 months, a significant mean reduction in patient self-reported pain from baseline to postoperative of 75.79% pain reduction was seen at follow-up 1 and 62.52% at follow-up 2. A significant decrease was obtained for, respectively, pain at the present moment, VAS pain worst last week, VAS pain least last week, and VAS pain mean last week in comparison with baseline VAS scores. All patients indicated that they would redo the procedure.

Conclusion: Percutaneous implantation of small profile paddle leads in patients with FBSS and lumboischialgia produces favorable results over the long term that are at least comparable with surgical implanted paddle leads. The percutaneous approach also allows nonsurgically trained pain physicians to introduce paddle leads. Indices like if patients would redo the procedure may be more appropriate for analyzing long-term outcomes than the arbitrarily taking 50% reduction in VAS scores.

Keywords: FBSS, long term, paddle lead, percutaneous, S-Lamitrode, SCS

Conflict of interest: The authors declare that they have received no editorial or financial support for this study. T. Vancamp is an employee of St. Jude Medical and received or has no financial or other benefits related to this study. D. Logé is a paid consultant of St. Jude Medical. S. Vanneste reports no conflict of interest. D. Rijckaert reports no conflict of interest.

OBJECTIVE

Spinal cord stimulation (SCS) is an implantable, safe, reversible, and efficacious pain treatment option for neuropathic pain syndromes. SCS has furthermore the advantage that screening trials can be performed, evaluating the efficacy of the therapy for that patient, before it is decided to move to a permanent implantation procedure. SCS for neuropathic pain delivers mild electrical stimulation to the spinal cord, more specifically the dorsal columns, with the goal to achieve stimulation-induced paresthesias to overlap the patient's pain topography (1).

SCS has to be considered a symptomatic therapy rather than a curative therapy. It has been shown that SCS has a positive effect on pain suppression, physical activity, quality of life (QOL), activities of daily living, sleep, and reduced pain medication, and is furthermore cost-effective for different chronic medical conditions (2–9).

With regard to leg and back pain relief, QOL, functional capacity, and patient satisfaction, SCS has been shown to have a better success rate when compared with conventional medical management (10) and reoperation (11).

In the early 1970s, the development of percutaneous leads, which could be placed epidural through a Tuohy needle, led to a simplification of the surgical implant technique, obviating the need for laminectomy. This technique allowed implantation procedures to be performed under local anesthesia by nonsurgeons and intraoperative testing of paresthesia coverage over the painful area. One of the drawbacks is that percutaneous placed cylindrical electrodes may be associated with a high rate of migration (12).

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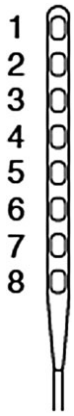

Figure 1. Illustration of the S-Series 8-contact steerable paddle lead, showing contact numbering.

Plate-type electrodes are placed under direct vision, and have a large surface contact area, which improves the stability. In a study by North et al., they found that a plate-type electrode implanted via laminectomy had a broader stimulation pattern and was more energy efficient compared with percutaneously placed cylindrical leads (13). Lower stimulation parameters can be partially explained as the unidirectional electrical field leads to less energy loss. Furthermore, the larger design will occupy more epidural space by which they tend to be closer to the dorsal columns.

Thus, this leaves implanters with two substantially different techniques: a percutaneous introduction approach and the surgical technique to introduce larger sized plate-type electrodes.

Efforts have been made in the search for less invasive approaches to introduce plate-type electrodes and enabling intraoperative testing: the minimally invasive unilateral technique as described by Vangeneugden (14) and the modified technique using a tubular retracting system as described by Beems and van Dongen (15). Still, these techniques require surgically trained implanters.

In recent years, efforts have been made to bridge the gap between the percutaneous and surgical technique. Novel percutaneous techniques to implant plate-type electrodes have been developed and described by several authors, allowing nonsurgical- and surgical-trained physicians to minimally invasive position slim designed plate-type electrodes (S-Series™ [Fig. 1], St. Jude Medical Neuromodulation Division, St. Paul, MN, USA). One such technique is the one described by Vonhögen et al. using a 10G needle (16). Caution needs to be taken as the implantation using a large epidural needle may increase the risk for dural puncture and/or spinal cord injury if used by unskilled hands. A safer alternative may be to deliver a paddle lead through the use of the newer developed percutaneous delivery system Epiducer™ (St. Jude Medical Neuromodulation Division) as described by Logé et al. (17).

An uncontrolled, open-label, prospective two-center study was performed to assess the safety of the Epiducer delivery system. In this study, data of 34 patients were collected. The study concluded the safe use of the Epiducer lead delivery system for percutaneous implantation and advancement of the S-Series paddle lead in the epidural canal. The slimline paddle lead was advanced four vertebral levels in most patients (61.8%). Furthermore, patient pain, satisfaction, and QOL were positively impacted throughout the study. They also found that percutaneously implanting this type of paddle lead using the Epiducer lead delivery system provides benefits to the patient without introducing any additional risk (18).

In a multicenter retrospective data collection study, the feasibility and safety of percutaneously introducing and advancing a slimline plate electrode in the epidural canal has been shown in 40 patients. They found that the S-Series lead could be percutaneously implanted and advanced over multiple vertebral segments. No adverse events specifically related to the procedure were found (19).

Vonhögen et al. showed a clinically relevant reduction of 52% in back pain in 17 out of the 20 patients included in this study, after 12 months using this type of electrode. Twelve months postoperatively general patient satisfaction and QOL were statistically better in comparison with preoperative, with improvements of 69% and 75%, respectively. Correlation analyses demonstrated that visual analog scale (VAS) (pre-12 months) for legs and back correlated negatively with VAS pre-12 months satisfaction and pre-12 months QOL, revealing that the more pain reduction in legs and back, the more satisfaction and QOL patients have. Acute pain recordings showed that 40% of the patients experienced no pain postoperative (16).

In a prospective study conducted by de Vos et al., they found that a single hybrid lead placed over the midline was able to capture and alleviate pain in the back and legs. Forty-one patients out of the 45 eligible to a SCS trial were followed for at least 12 months. They furthermore found that pain medication was reduced in 25 patients, and 18 patients could entirely stop their medication (20).

Kinfe et al. found that in their prospective trial, with a median follow-up of one year, there was improved paresthesia coverage in 87% of the 81 patients enrolled. A mean pain reduction of 73% was observed (21).

In this study, we present data on the long-term efficacy of using percutaneously implanted S-Series leads in patients with failed back surgery syndrome (FBSS) and lumboischialgia.

METHODS

Study Design

This single center study was designed to prospectively collect long-term outcomes of patients presenting with FBSS or lumboischialgia who were implanted with a percutaneously implanted S-Series lead. The same implanter performed all implantations and data were collected according to the Belgian reimbursement guidelines. Ethical committee approval was not necessary as according to the Belgian law, data collected as standard practice waive the need for Institutional Review Board approval. Pre- and posttrial data were systematically collected from patients who presented at the clinic between November 2004 and September 2008 and were subsequently implanted with an S-Series lead and had at least one follow-up visit after the trial visit.

Pain scores using a VAS were recorded for pain now, worst last week, lowest last week, and mean last week at baseline, posttrial, and during each follow-up visit. Pain location, number of back surgeries, electrophysiologic parameters, lead tip location, number of reprogramming, and if patients would redo the procedure were also collected.

Follow-up averaged 40.8 months (range: 20.0–73.0) for this patient group. Posttrial visits averaged one month (range: 1.0–2.0), follow-up 1 (FU-1): 14.0 months (range: 3.0–33.0); follow-up 2 (FU-2): 13.9 months (range: 10.0–26.0); and follow-up 3 (FU-3): 15.9 months (range: 11.0–27.0). All visit intervals were counted after the former visit (see Table 1).

Table 1. Follow-Up.

	Follow-up (months)
Average follow-up total [range]	40.8 [20.0–73.0]
Average follow-up PT [range]	1.0 [1.0–2.0]
Average follow-up FU-1 [range]	14.0 [3.0–33.0]
Average follow-up FU-2 [range]	13.9 [10.0–26.0]

PT, Posttrial; FU, follow-up, all measured after the prior visit.

Patients

Twenty-one patients (female: 14 and male: 7) with a mean age of 57 years (range: 33–76) were implanted and followed over a long-term period (see Table 2).

All patients met the inclusion criteria according to the Belgian reimbursement guidelines. Exclusion criteria were absent and all patients had a psychologic screening, prior to implantation and after the trial period.

A bylaw mandatory minimum of 28 days trial was performed for all patients before final implantation could take place.

Mean preoperative VAS pain score (mean VAS pain last week) was 7.3 (range: 5.5–9.5). Twelve patients (57.1%) were diagnosed with FBSS and nine (42.9%) with lumboischialgia (see Table 3).

Pain was respectively located as follows: 10 (47.6%) patients presented with pain in the back and both legs, seven (33.3%) in the back and left leg, three (14.3%) patients in the back and right leg, and one (4.8%) patient in the buttock and right leg (see Table 2).

An average number of 0.8 (range: 0–3) back surgeries were performed in this patient group. Twelve (57.1%) patients underwent previous back surgery and nine (42.9%) were implanted without prior surgery (see Fig. 2). We looked at the number of prior surgeries and found that eight patients (38.1%) had one surgery, three patients (14.3%) had two surgeries, and one patient (4.8%) had three surgeries.

Implantation Methods

Patients were comfortably positioned on the operating table as usual for dorsal SCS procedures. Anesthesia monitoring was used in a standard fashion for local interventions. Fluoroscopy using a C-arm was used to identify the desired entry level and to monitor the progression of the different stages of the procedure. Disinfection, aseptic draping of the surgical field, and local anesthetics (xylocaine 2% with adrenaline 1 : 200.000) were applied.

All patients were implanted with an 8-contact S-Series lead using a percutaneous technique as described by Vönhogen et al. (16) before the availability of the Epiducer introductory system after which we started using this novel percutaneous implant technique as described by Logé et al. (17).

Once the electrode was entered in the epidural canal, the lead was advanced to the anticipated level of stimulation in a cephalad direction under constant fluoroscopy. Verification of the electrodes facing the spinal cord was done looking at the built-in radiopaque marker.

Once at the anticipated location, the area of paresthesia was verified through intraoperative test stimulation using a Rapid Programmer® (St. Jude Medical Neuromodulation Division). If unsatisfactory coverage was noted, the lead was repositioned until a satisfactory result was achieved. The position varied with the tip between T5 and T10. Lead integrity was tested via subthreshold automated impedance measurement with the Rapid Programmer.

A silastic long anchor (St. Jude Medical Neuromodulation Division) was used to secure the Lamitrode S8 to the fascia of the paravertebral musculature.

The lead was then connected to a 60-cm extension and tunneled subcutaneously to the opposite site of where the implantable pulse generator (IPG) would be located in the second stage. Again, the integrity of the system was measured. A strain relief loop was applied and the connection was buried in a subcutaneous pocket lateral of the spinous process, after which the wound was closed in a multilayer fashion. Postoperatively, patients were instructed on the use of their Multiprogram Trial Stimulator (MTS®, St. Jude Medical Neuromodulation Division).

A trial of minimum 28 days, as mandated by the Belgian reimbursement guidelines, was performed, and a second-stage procedure was only performed after a successful trial. The externalized extension was disconnected from the lead and removed in a sterile way. After this, either the lead was directly connected to the IPG or through the use of an extension. The IPG, GenesisXP, or EON C (St. Jude Medical Neuromodulation Division) was placed in a subcutaneous pocket at the buttock (*N*: 19; 90%) or the abdomen (*N*: 2; 10%).

Postoperative patients were instructed on the use of their programmer.

Statistical Analysis

Calculations were performed using SPSS software package (IBM SPSS Statistics, IBM Co., Armonk, NY, USA). Preoperative, postoperative, and follow-up scores were compared using a repeated measures analysis of variance (ANOVA). We conducted this analysis comparing baseline with postoperative, FU-1, and FU-2. This analysis was also conducted including FU-3. However, for this latter analysis, only 14 patients were included as there were only 14 patients that already had a third follow-up. In addition, we conducted a repeated measures ANOVA with the previously described within-subjects variables (preoperative, postoperative, and follow-up scores) and the diagnosis (failed back surgeries vs. chronic lumbioschialgia) as between-subjects variable. A similar analysis was conducted with a between-subjects variable the amount of surgeries the patient had before implantation.

RESULTS

A significant mean reduction in patient self-reported pain from baseline to postoperative of 75.79% was seen; 62.52% pain reduction was seen at FU-1; and 62.52% at FU-2. The obtained significant effect can be seen in Table 3. If we also include F-U3 ($N = 14$), a significant effect for the mean VAS scores ($F = 53.93$, $p < 0.001$) was also observed, with a 47.33% reduction in mean VAS score.

The baseline mean scores of pain at present moment, VAS pain worst last week, VAS pain least last week, and VAS pain mean last week can be found in Table 3.

A significant decrease was obtained for, respectively, pain at the present moment, VAS pain worst last week, VAS pain least last week, and VAS pain mean last week, indicating that over time a significant decrease in pain was perceived in comparison with baseline VAS scores (see Table 3).

A comparison between patients that had chronic lumboischialgia or failed back surgery between the pain scores obtained postoperative, FU-1, FU-2, and FU-3 revealed no significant effect.

In addition, an analysis was conducted to verify if the amount of surgeries before implantation had an influence on the outcome at

Table 2. Patient Demographics, History of Back Surgeries, Average Mean VAS Scores at Baseline and Pain Location.

		Overall	Female	Male
Patients	*N* (%)	21	14 (66.7)	7 (33.3)
Age	Average (±SD)	57 (±11.4)	56,9 (±12.6)	57,1 (±9.4)
	[range]	[33–78]	[33–75]	[50–76]
Diagnosis	CL (%)	9 (42.9)	7 (50.0)	2 (28.6)
	FBSS (%)	12 (57.1)	7 (50.0)	5 (71.4)
Average prior surgeries	CL	0	0	0
	FBSS [range]	1.4 [1–3]	1.4 [1–3]	1.4 [1–2]
Average VAS baseline	CL [range]	7.4 [6.2–9.1]	7.3 [6.3–8.7]	7.7 [6.2–9.1]
	FBSS [range]	7.2 [5.5–9.5]	7.0 [5.5–8.5]	7.4 [6.3–9.5]
Pain location	Back and both legs (%)	10 (47.5)	7 (50.0)	3 (42.9)
	Back and left leg (%)	7 (33.3)	3 (21.4)	4 (57.1)
	Back and right leg (%)	3 (14.3)	3 (21.4)	0 (0.0)
	Buttock and right leg (%)	1 (4.8)	1 (7.1)	0 (0.0)

CL, chronic lumboischialgia; FBSS, failed back surgery syndrome; VAS, visual analog scale.

Table 3. Mean VAS Scores for Pain Now, Worst Last Week, Lowest Last Week, Mean Last Week, and % Suppression Compared With Baseline.

VAS	Baseline	Postoperative	Follow-up 1	Follow-up 2	*F*
Pain now	6.57	1.37	3.00	3.29	37.06
Pain highest	8.99	3.66	5.17	6.28	50.07
Pain lowest	4.76	0.60	1.47	2.20	22.74
Pain mean	7.31	1.77	2.74	3.74	113.76

All comparisons were significant at $p < 0.001$.
VAS, visual analog scale.

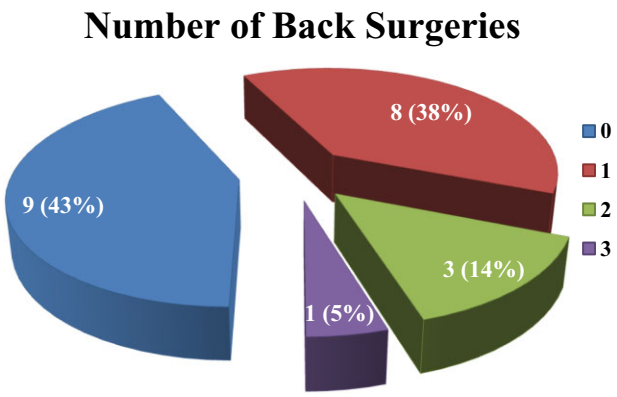

Figure 2. Number of back surgeries before implantation.

baseline, as well as the follow-up. The analysis revealed no significant results, however, indicating that the amount of surgeries before implantation had no influence on the outcome.

The mean electrophysiologic parameters found were frequency: 38.4 Hz (range: 20–70 Hz); pulse width: 356.5 µsec (range: 104–494 µsec); perception amplitude: 5.3 mA (range: 0.9–16.0); comfort amplitude: 6.9 mA (range: 1.9–17.2 mA); and maximum tolerable amplitude: 8.0 mA (range: 2.8–17.4) (see Table 4). We furthermore collected the number of activated electrodes: 3.3 (range: 2–7). The mean number of anodes used was 2.0 (range: 1–5). Those that were activated as cathodes: 1.3 (range: 1–2). In total, 23 stimulation sets were used in 21 programs. In two patients, two stimulation sets were used, and in 19 patients a single stimulation set covered the patients' entire pain area. Twelve ($N = 23$, 52.2%) bipolar combinations were used, of which six were narrow bipoles (+ –) and six were other bipolar configurations. A longitudinal guarded electrode array was programmed 11 times (47.8%), of which seven were simple guarded configurations (+ – +), and four were guarded combinations with multiple anodes and/or cathodes.

The number of reprogramming sessions was documented as well, with an average of 3.1 reprogrammings (range: 0–15) necessary to sustain paresthesia in the required area over the course of all visits. A median of 3.0 was found for the reprogramming sessions.

All patients indicated they would redo the procedure posttrial and during all follow-ups using a descriptive scale: Definitely Yes, Yes, Maybe, Probably Not, Definitely Not (see Fig. 3).

There were 90.5% of patients ($N = 19$) who used pain medication before the implantation and 9.5% ($N = 2$) used no medication prior to the trial. Of the 19 patients who took medication, five patients (26.3%) could stop their medication entirely, nine patients (47.4%) showed a reduced intake, and one (5.3%) patient had an unchanged intake of medication. Four patients (21.1%) had an increased intake of medication (see Fig. 4).

The majority of the leads ($N = 8$, 40%) were implanted with the tip at T7, one (5%) at T5, five (25%) at T8, four (20%) at T9, and two (10%) at T10.

In this study we found one lead migration (4.8%), one lead breakage (4.8%), three extension breakages (14.3%), and one IPG communication loss (4.8%). Loss of effectiveness was encountered after an average time of 2.5 years in three patients (14.3%), without an identifiable cause or apparent lead migration. A single event (4.8%) of IPG communication loss was uneventful and resolved by a replacement. No infection, dural puncture, epidural bleeding, sensory or motor deficit was observed in this patient group (see Table 5).

Table 4. Parameter Settings for Each Patient.

Patient	Freq (Hz)	Pulse width (μsec)	Perception amplitude (mA)	Comfort amplitude (mA)	Maximum tolerable amplitude (mA)	Electrode configuration
1	30	390	6.0		7.4	1 + 2–3-4 +
2	30	338	9.1	13.7	16.5	3 + 4–7 + 8-
3	30	390	4.0	4.5	5.0	1 + 7–8-
4	30	104	4.5	6.5	8.5	4 + 5 + 6–7-
5	30	455	2.0	2.1	3.5	5 + 7–8 +
6	30	300	0.9		3.0	4 + 5-
7	30	337	8.9	10.9	12.9	1 + 2–3-
8						
Stim Set 1	70	377	2.8	3.6	4.4	4 + 5 + 6 + 7 + 8-
Stim Set 2	70	442	5.0	5.5	6.0	1 + 2–3-4 + 5 + 6 + 7 +
9	38	325	16.0	17.2	18.4	2 + 3 + 4–5-6 +
10	50	312	3.3	4.2	5.1	2 + 3 + 4–5 +
11	50	299	1.6	1.9	2.8	4–5 +
12	50	416	4.0	4.8	5.6	1 + 2–3 +
13	46	412	2.6	6.3	10.0	2 + 3-
14						
Stim Set 1	30	494	5.2	7.0	8.8	7 + 8-
Stim Set 2	30	494	3.7	4.7	5.7	4 + 5–6 +
15	40	182	2.0	2.6	3.2	2–3 +
16	40	390	3.5	4.1	4.7	2 + 4–6 +
17	30	300	12.0	13.5	15.0	5 + 6–7 +
18	30	312	8.4	9.9	11.4	1 + 2 + 3-
19	20	403	7.4	11.8	14.5	5 + 6–7 +
20	50	377	4.1	4.3	5.1	3–5 +
21	30	350	5.0	5.9	6.8	3 + 4 + 5–6 + 7 +

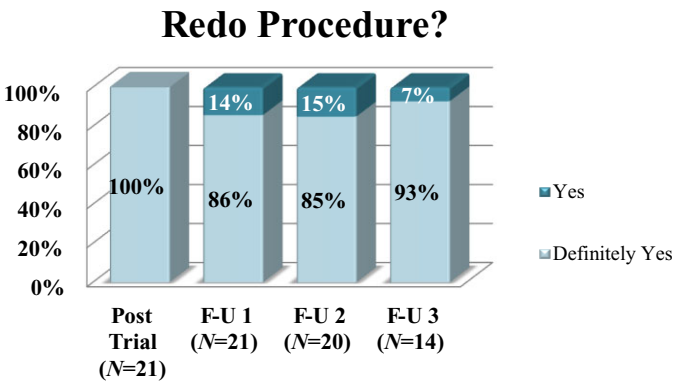

Figure 3. Percentage of patients that would redo the implantation posttrial, follow-up 1 (F-U1), follow-up 2 (F-U2), and follow-up 3 (F-U3). Between brackets, the number of patients who did the respective follow-up visits is represented.

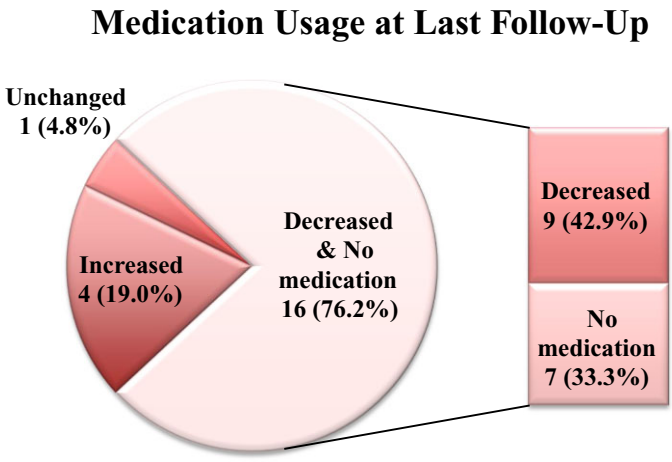

Figure 4. Medication usage at last follow-up of all 21 patients.

DISCUSSION

The SCS with a percutaneous implanted paddle lead has been shown to be feasible and safe in trained hands.

This study's aim was to investigate the sustainability of SCS in patients implanted with a percutaneous implanted paddle lead.

The results confirm the possibility of sustaining stimulation in the pain areas over a mean of 3.3 years, in patients with neuropathic leg and back pain. Similar results have already been published in three other studies with 12 months follow-up (16,20,21).

In the study by Vonhögen et al., a correlation analysis revealed that VAS scores for legs and back correlated negatively with baseline satisfaction and QOL, showing that better pain reduction results in improved satisfaction and QOL outcomes. They found improvements of 69% and 75% in satisfaction and QOL after one year compared with baseline (16). In the studies of de Vos et al. and Logé et al., 90% and 88.3% of the patients, respectively, rated their QOL to be improved or greatly improved (18,20). There were 85.3% of the patients in the study by Logé et al. who mentioned satisfaction or were very satisfied with the treatment outcome after implantation (18).

In this study, we found that all patients indicated that they would redo the procedure. We do have to point out that in this study, only patients who received a permanent implant were followed up and this may therefore somewhat bias this result. On the other hand, this

Table 5. Adverse Events Overview With Corrections Toward Events Per Year.

	N	%	Average time to event (years)	Corrected events/year	%/year
Migration	1	4.8	2.2	0.5	2.2
Lead breakage	1	4.8	3.4	0.3	1.4
Extension breakage	3	14.3	3.8	0.8	3.8
Loss of effectiveness	3	14.3	2.5	1.2	5.6

Table 6. Comparisons of Electrophysiological Parameters and Tip Location With Other Percutaneously Introduced Lamitrode Studies.

	Vonhögen et al. (16)	de Vos et al. (20)	Kinfe et al. (21)	Logé et al. (18)	This study
Electrophysiological parameters					
Frequency (Hz)	36.0 (30–60)	Not given	Not given (30–100)	33.1 (Not given)	38.4 (20–70)
Pulse width (μsec)	420.1 (287–500)	Not given	Not given (50–450)	403.0 (Not given)	356.5 (104–494)
Perception amplitude (mA)	3.4 (1.0–9.0)	Not given	Not given	Not given	5.3 (0.9–16.0)
Comfort amplitude (mA)	4.5 (1.9–10.5)	Not given	Not given (1.1–9.7)	3.6 (Not given)	6.9 (1.9–17.2)
Maximum tolerable amplitude (mA)	6.7 (2.9–12.0)	Not given	Not given	Not given	8.0 (2.8–17.4)
Anatomical location of the tip of the S-Series lead					
Tip location	T8 (T6-T10)	T8 (T7-T9)	T7 (C4-T11)	Not given	T7 (T5-T10)

confirms that the stimulation sustainability adds to the treatment satisfaction in these patients, even long term.

Vonhögen et al. found a mean reduction of 43% and 27% for the legs and back, respectively. All reductions' statistical significance improved compared with baseline at one year. In 85% of the patients, they found a clinical significant reduction of the back pain component with a mean decrease of 4.3 points or 52% (16). In another study where similar leads were used, they found a decrease of VAS of 50% or more in 71% of the patients for the legs and in 51% of the patients for back pain at one year postoperatively (20).

Logé et al. recently published an average patient-reported pain relief of 78.8% posttrial and Kinfe et al. found an overall median pain reduction of 73% at one year (18,21). In this study, we found statistically significant pain reduction for pain at present moment, VAS pain worst last week, VAS pain least last week, and VAS pain mean last week, at different time points: posttrial, F-U1, F-U2, and even F-U3. We excluded to time the FU-3 data as not all patients had done the third follow-up visit. We found reductions of 75.79%, 62.52%, and again 62.52% for posttrial, F-U1, and F-U2, respectively. In this study, we did not differentiate between back and leg pain, as the primary endpoint was stimulation sustainability. The significant reductions in pain, together with the sustained results at F-U1 and F-U2, show that long-term electrically induced paresthesia and pain suppression can be achieved using these leads, both for back and leg pain.

An analysis of the number of prior surgeries revealed no relationship with the pain reduction outcome in this study.

We did not find any statistical significance between patients with FBSS or lumboischialgia at each follow-up, indicating that both indications can benefit well of SCS when indicated.

The mean electrophysiologic parameters did not differ significantly from what was found in other studies (see also Table 6) where a similar type of electrode was used. In contrast to the studies of Vonhögen et al. and de Vos et al., we found that guarded combinations were not used more than bipolar configurations. These contradictory findings in the studies indicate the interindividual differences between patients and the need to have control over the different electrophysiologic parameters to shape an optimal electrical field in order to achieve optimal paresthesia coverage for patients with chronic neuropathic pain syndromes.

We found an average tip location at T7, which is slightly higher than the studies of Vonhögen et al. and de Vos et al., but similar to the findings of Kinfe et al. (Table 6).

In this series, we have found one migration (4.8%), in a cranial direction. After repositioning the lead, paresthesia covered the full pain area in both legs and the low back again. The event occurred after 2.2 years and when recalculated into events per year to make it comparable with the other S-Series studies, we found an average incidence rate of 0.5 per year (2.2%/year). One lead breakage was seen so far, which happened after a trauma (fall). This happened after 3.4 years. Three extension breakages were seen (Table 7), of which one happened after a trauma (same patient as with the lead breakage). The average time of the extension breakage incidents was 3.8 years, resulting in 0.8 events per year (see also Table 5).

In an evaluation of lead migration in four clinical research studies as published by Monroe et al. in 2008, they found an incidence rate of paddle lead migration of 3.0% (2 out of 67 implants) and 6.4% (15 of the 233 implants) for percutaneous leads, totaling the migration rate at 5.7% (17 out of 300) at one year follow-up (22). A literature review performed by Cameron revealed an incidence rate of 13.5% (23). With an incidence rate of 4.8% (one event), our data (2.2% when corrected for yearly incidence rate) show a lower migration rate compared with the literature. Vonhögen et al. found no migra-

Table 7. Adverse Events: Percutaneously Implanted S-Series Studies Comparison.

	Vonhögen et al. (16)	de Vos et al. (20)	Kinfe et al. (21)	Logé et al. (18)	This study	Total	%	Action
N	20	41	81	34	21	177	—	—
Dural puncture	1	0	0	0	0	1	0.6	Bed rest
Infection	0	1	0	3	0	4	2.3	Explant & reimplanted
Epidural bleeding	0	0	0	0	0	0	0	N/A
Neurological or motor deficit	0	0	0	0	0	0	0	N/A
Migration	0	1	2	2	1	6	3.4	Repositioning, percutaneous lead added
Loss of effectiveness	0	4	0	0	3	7	4.0	Not mentioned
Lead breakage	0	0	0	0	1	1	0.6	Replaced
Extension breakage	1	0	0	0	3	4	2.3	Replaced

Table 8. Lead Migration Comparison of Reported S-Series Studies With Literature.

Author	Year	Lead migration rate (%)	Comments
Lead migration rates in literature			
Monroe et al. (22)	2008	5.7	Data of four prospective, multicenter, Institutional Review Board-approved clinical research studies
Cameron (23)	2004	13.5	Literature review
Percutaneously implanted S-Series leads			
Vonhögen et al (16)	2011	0.0	Retrospective data collection
de Vos et al. (20)	2012	2.4	Prospective study
Kinfe et al. (21)	2012	2.5	Prospective study
Logé et al. (18)	2012	5.9	Prospective study
Logé et al. (this study)	2012	4.8	Prospective study
Averages per implant procedure type			
Literature: percutaneous and surgical	N/A	9.6	See higher
Percutaneously implanted paddle	N/A	3.4	See higher

tions with one-year follow-up and a comparable number of patients included in their study (16). Kinfe et al. found a 2.5% migration rate in 81 patients, with a median follow-up of one year (21). It is recommended to follow up over longer terms and with more data points, but there seems to be an increasing trend that the percutaneously implanted paddle leads behave more like surgical-implanted larger paddle leads over the longer term (see also Table 8). In contrast to these findings, the study of Logé et al. showed an incidence of 5.9% or two patients, which is around double of the earlier mentioned study of de Vos et al. (20). An explanation for this can be the initial experience with this new technique, plus the fact that the number of patients was limited, which then quickly increases the percentage. Furthermore, we have to highlight here that this study had only a follow-up of 28 days (trial period).

When we compare the incidence rate of lead breakages with this type of paddle lead as reported to date with other lead studies (see also Table 9), we can conclude that the percutaneously introduced paddle lead seems to behave as a surgically introduced paddle lead. The averages even show a trend to outperform the surgically implanted leads, although we need to nuance this, as the average follow-up of the surgically introduced paddle lead studies is more than twice as long as those for the S-Series paddles to date and there is also a lot of variability seen in outcomes by the different authors.

We acknowledge that this study discusses only a limited number of patients included and we therefore plan to follow up on more patients to see if the results are also sustained in larger patient groups implanted with this type of electrode. Furthermore, this study was designed as a single center study and we did not randomize with patients treated, for example, with only conventional medical treatment.

Placebo-controlled studies are to date impossible with tonic stimulation, but may in the future eliminate this methodologic problem when new stimulation designs such as burst stimulation become widely available. This novel stimulation design may furthermore advance the clinical outcomes in patients with chronic pain conditions as earlier reported by De Ridder et al. (33). For example, the patients with loss of effectiveness might perhaps benefit from another stimulation design in the future to regain their benefits of SCS.

Further research is warranted to compare and/or confirm these findings.

CONCLUSION

Percutaneous implantation of small profile paddle leads in patients with FBSS and lumboischialgia produces favorable results over the long term that are at least comparable with surgically implanted paddle leads, thus combining some favorable aspects of percutaneous as well as paddle leads.

The percutaneous approach also allows nonsurgically trained pain physicians to introduce paddle leads.

Indices like patients' willingness to redo the procedure, QOL, or patient satisfaction may be more appropriate for analyzing

Table 9. Lead Breakage Comparison of Reported S-Series Studies With Literature.

Author	Year	*N*	Follow-up (years)	Lead failure rate (%)	Cause of lead failure
Lead breakage rates in literature					
Racz et al. (24)	1989	26	3.60	23.0	Lead fracture
Bell and Bauer (25)	1991	24	2.00	38.8	Lead fracture
North et al (26)	1991	50	5.00	5.0	Lead breakage /fatigue fracture
Kumar et al (27)	1991	121	3.30	3.3	Lead fracture
North et al (28)	1993	302	7.10	7.0	Lead breakage /insulation failure
Anderson (29)	1997	60	2.00	3.0	Lead fracture
Heidecke et al (30)	2000	42	6.10	19.0	Lead breakage /insulation failure
Kumar et al (31)	2006	410	8.13	5.9	Lead breakage /fatigue fracture
Akmal and Eljamel (32)	2008	107	14.00	14.9	Lead breakage /fatigue fracture
Percutaneously implanted S-Series leads					
Vonhögen et al (16)	2011	20	1.00	0.0	N/A
de Vos et al. (20)	2012	41	1.00	0.0	N/A
Kinfe et al. (21)	2012	81	1.00	0.0	N/A
Logé et al. (18)	2012	34	30 days	0.0	N/A
Logé et al. (this study)	2012	21	6.10	4.8	Lead breakage (trauma)
Averages per implant procedure type					
Literature percutaneous and surgical	N/A	126.9	5.7	13.3	See higher
Percutaneously implanted paddle	N/A	27.3	2.0	1.0	See higher

outcome results, especially long term, than arbitrarily takings 50% reduction in VAS scores, as has been postulated earlier.

The authors believe that the increased focus on product development, professional training and educational activities, best practice sharing, together with an expanded experience, led to improved outcomes for patients in need of a neuromodulation device.

Acknowledgment

The authors would like to thank Mr. Frank De Meutter from St. Jude Medical Belgium—Neuromodulation Division, for his logistical and technical support during this study.

Authorship Statements

Drs. Logé and Vancamp were responsible for the inception and design of the study. Dr. Logé performed all the implantations and collected the data. Drs. Vancamp and Vanneste performed the statistical analysis and data interpretation. Drs. Vancamp and Logé drafted the manuscript with intellectual input from Drs. Vanneste and Rijckaert. All authors approved the final manuscript.

How to Cite this Article

Logé D., Vanneste S., Vancamp T., Rijckaert D. 2013. Long-Term Outcomes of Spinal Cord Stimulation With Percutaneously Introduced Paddle Leads in the Treatment of FBSS and Lumboischialgia
Neuromodulation 2013; 16: 537–545

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COMMENTS

Hybrid leads may provide outcome benefits over the traditional paddle lead or cylindrical percutaneous leads. This work highlights some of the potential advantages of the percutaneous paddle over an extended follow-up period, heralding another novel strategy for neuromodulation.

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This article represents a follow up on the European experience with the Epiducer. This provides a good review of the improvement in pain control and lead stability

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Comments not included in the Early View version of this paper.

