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Percutaneously Implanted Plate Electrodes in Failed Back Surgery Syndrome (FBSS)

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Objective: To evaluate the clinical efficacy of pain suppression in back area and lower extremities by recently developed plate electrodes for spinal cord stimulation through percutaneous access.

Methods: A retrospective analysis is performed: 20 consecutive patients with both lower extremity pain and low back pain, with low back counting for at least 30% of the overall pain were implanted with a small profile plate type lead, S-Series (SJM), via percutaneous approach. Patients were asked to rate their back and leg pain as well as their overall satisfaction and data on quality of life (QOL) on a (0–10 point) visual analog scale (VAS) before and after implantation. Medication use, functional pain (pain when bending forward, moving), and patient satisfaction scores also were collected.

Results: A significant reduction of 55% and 45.7% in, respectively, VAS legs and VAS back pain was found. One year postoperatively the reduction was still present, respectively, 43% and 27% for the legs and the back. In 17 patients (85%) a clinically relevant reduction (defined as reduction of 2 points or 30% in VAS) in back pain was seen, with a mean decrease of 4.3 points (2.0–10.0) or 52% (22–100). Only three patients had no reduction in back pain, although they had reduction of their pain in the lower extremities. A significant and clinically relevant improvement of 66% and 70% was seen, respectively, for general satisfaction and QOL, respectively. One year postoperatively this improvement was still present, respectively, 69% and 75% for the satisfaction and QOL. Importantly functional pain also decreased by 51%. No infections occurred. Mean duration of post-op wound pain was 13.5 hours.

Conclusion: Percutaneous implantation of the S-Series plate electrodes using a 10 gauge epidural needle combines the advantages of a minimal invasive technique with the possibility to cover the back area supplementing leg coverage in 85% of the failed back surgery syndrome patients.

Keywords: EON, FBSS, low back pain, percutaneous, plate electrode, SCS, S-Lamitrode

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OBJECTIVE

Based on Melzack and Wall's gate theory model for pain (1), spinal cord stimulation (SCS) has been developed (2) to treat a variety of disorders characterized by chronic intractable benign pain (3). These pain syndromes include failed back surgery syndrome (FBSS), spinal cord injury, complex regional pain syndrome type I and type II, phantom limb pain, ischemic limb pain, peripheral vascular disease, peripheral neuropathy, postherpetic/intercostal neuralgia, bone and joint pain syndromes, arachnoiditis, brachial plexus injury, angina pectoris, and interstitial cystitis (4). 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 (3,5). Furthermore, SCS has been shown to be cost-effective for different indications (3,5–8).

Compared with conventional medical management, SCS was shown to have better effects on leg and back pain relief, QOL, and functional capacity as well as greater patient satisfaction in a group of FBSS patients with predominant leg pain of neuropathic radicular origin (9). Randomized controlled studies also demonstrate that SCS is more successful than re-operation for pain suppression, and patients initially randomized to SCS were significantly less likely to cross over than were those randomized to re-operation (10).

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Although SCS has been predominantly used for treating the intractable chronic neuropathic pain component of the extremities, several studies also have reported an improvement of the back pain component (2,11,12), even though the axial low back pain has been shown to be more difficult to suppress.

Several studies have shown the benefit of surgically implanted plate type electrodes with regards to stability (migration), lower output parameters, less lead breakages, and sustained long-term coverage (3,4,5,11,13). A drawback is the more invasive character of this technique, which has led to the development of techniques allowing implantation of plate type electrodes through less invasive techniques (14,15).

The authors present a new percutaneous technique, placing a small dimension plate type lead (Lamitrode S-Series St. Jude Medical—Neuromodulation Division, Plano, TX, USA) through a 10 gauge epidural needle (O.m.t. GmbH, Lübeck, Germany), hereby combining the minimal invasiveness of percutaneous implantation with the possible advantages of back area coverage, an advantage reserved for surgical type leads.

METHODS

Methods and Materials

This study was designed retrospectively to collect efficacy and safety data from patients with uni- or bilateral lower extremity pain and back pain, with back pain being at least 30% of their total pain (pre-op backVAS score was at least 30% of the sum of the pre-op back and legVAS scores) implanted with a small dimension plate type electrode (S-Series) through a percutaneous approach with a 10 gauge epidural needle. All implantations were performed in the St. Maartenskliniek, Nijmegen, The Netherlands, by L.H. Vonhögen, R. Dirksen, and P. Bakker.

Pre- and post-op data, being part of the standard follow-up at the implanting center, were systematically collected from patients scheduled for SCS treatment for the above mentioned pathology between February 2008 and November 2008. Scores for pain in the legs and the back, QOL, functional pain (pain when bending forward, moving), and general satisfaction were collected, using a 0–10 visual analog scale (VAS). Complications and pain medication use also were recorded.

Patients were comfortably positioned in prone position on a fluoroscopic table. The thoracolumbar skin area was prepped and draped in a sterile fashion. Local anesthetic Lidocaine HCL 1%—Adrenaline 1:100,000 was injected at the needle entry and deeper layers up to the yellow ligament.

Under fluoroscopic guidance an epidural needle (10 gauge) was inserted in the epidural canal using a paramedian approach. The skin introduction site was at the middle of L3 paramedian. The angle between skin and needle was always less than 30 degrees (Fig. 1) for a smooth introduction of the lead without resistance in the epidural space. The epidural space was entered under the lamina of L1 or T12 (Fig. 2).

Entry was verified using the loss-of-resistance technique and confirmed through latero-lateral fluoroscopic image.

A guide wire was used to confirm entrance in the dorsal part of the epidural space (Fig. 3).

The Lamitrode S8 (St. Jude Medical—Neuromodulation Division, Plano, TX, USA) was introduced in the epidural canal through the needle and advanced, under fluoroscopic guidance (Fig. 4), to the anticipated level of stimulation in a cephalad direction. The electrodes were targeted toward the anatomic midline. The Lamitrode S-Series has a build-in radiopaque marker, allowing the implanter to verify easily if the contacts are facing the neural target. The tip of the lead was positioned according to intraoperative feedback from the patient to cover leg pain as well as back pain. The position varied with the tip between the upper endplate of vertebral body T6 and the lower endplate of T10 (Fig. 5). Once at the desired location, the physiologic midline was determined and the area of paresthesia was verified through intraoperative test stimulation using a Rapid Programmer® (St. Jude Medical—Neuromodulation Division, Plano, TX, USA). If unilateral or unsatisfactory coverage was seen, the lead was repositioned until a satisfactory result was achieved. Lead integrity was tested via sub-threshold automated impedance measurement with the Rapid Programmer.

A Long Anchor (St. Jude Medical—Neuromodulation Division, Plano, TX, USA) was used to secure the Lamitrode S8 to the fascia of the paravertebral musculature.

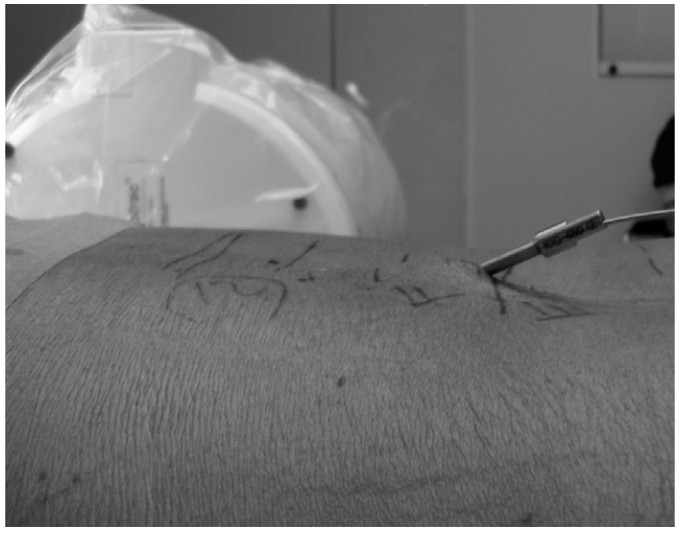

Figure 1. Angle of the 10 gauge Tuohy epidural needle.

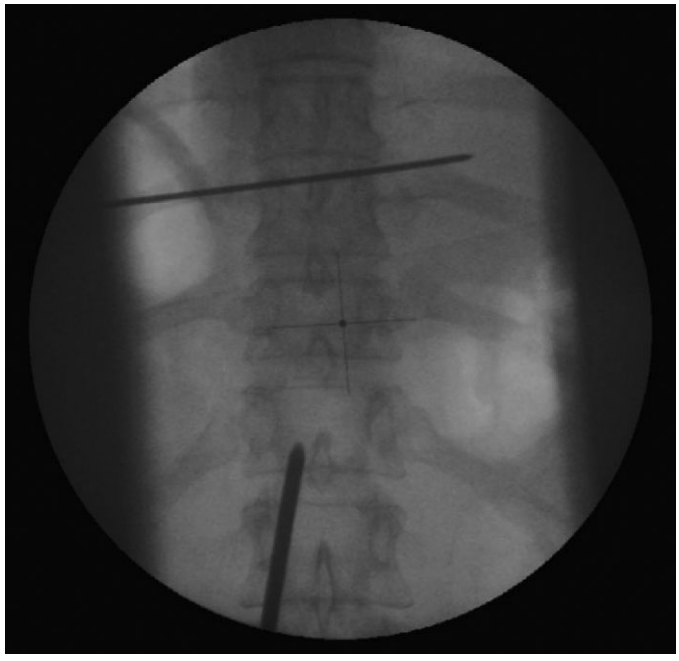

Figure 2. Needle tip position left paramedian at the moment of loss of resistance.

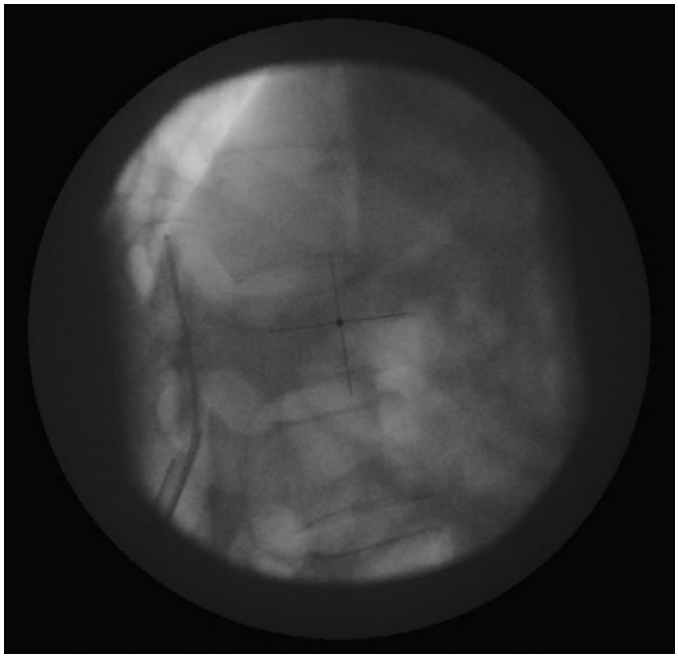

Figure 3. Position of the tip of the needle in lateral fluoroscopy view. Guide wire confirming correct position in dorsal part of the epidural space.

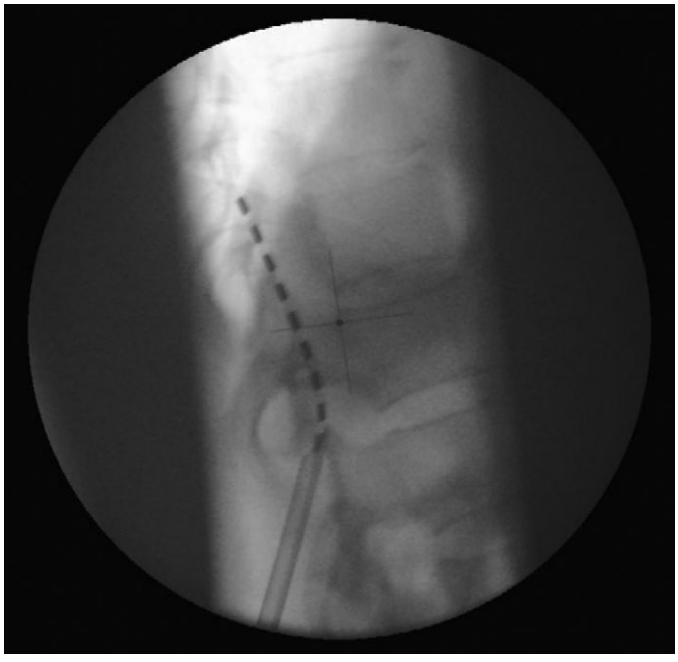

Figure 4. Epidural electrode in epidural space, lateral view.

If necessary, a 30-cm lead extension was connected to the electrode and passed subcutaneously with a tunneling tool to the pocket site. Impedance measurement was used to verify the lead extension and entire system's integrity.

Patients were sedated with low dose propofol and remifentanil (conscious sedation), both ultra short-acting anesthetics, during the introduction of the 10 gauge Tuohy needle until the lamina was reached, as confirmed in lateral fluoroscopy. At that moment the sedation was stopped and the entrance in the epidural space was verified by the loss of resistance technique.

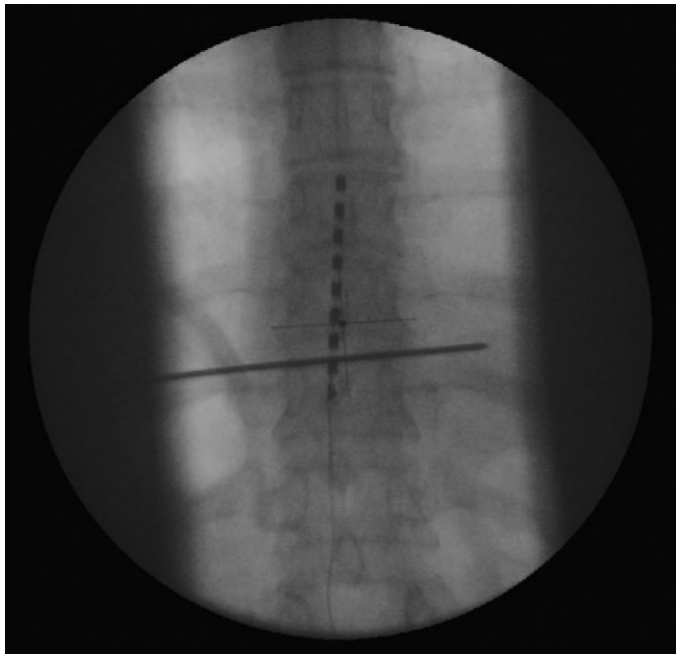

Figure 5. Electrode in final position.

Intraoperative trialing started at the moment that the patient was able to respond adequately.

After a successful intraoperative trial, patients were implanted using a one-step procedure with an EON® rechargeable pulse generator (rIPG) (St. Jude Medical—Neuromodulation Division, Plano, TX, USA).

Postoperatively parameters were installed and patients were instructed on the use of their EON Patient Programmer and Mobile Charging device (St. Jude Medical—Neuromodulation Division, Plano, TX, USA). Pain scores for the legs and back, functional pain, QOL, and patient satisfaction were measured using a 10-point VAS with "0" very bad or very severe and "10" very good or no pain. In addition, postoperative pain management, complications, and ease of use also were assessed

Calculations were performed using SPSS software package (version 16, IBM SPSS, Somers, NY, USA). Preoperative, postoperative, and postoperative after one year scores were compared using a paired *F*-test. A Bonferroni correction was applied for multiple comparisons. In addition, the Pearson correlations were calculated between the comparison VAS preoperative minus postoperative for legs and back and VAS preoperative minus postoperative for satisfaction and QOL, respectively. A similar analysis was conducted after one year of stimulation (see Table 1).

Patients

Twenty patients (female: 11 and male: 9) with a mean age of 52.15 years (range: 33–81) were implanted (see Table 2).

All patients met the inclusion criteria according to the Dutch national quality system for neuromodulation (surgery is not indicated, no adequate response to pain medication, nor other minimal invasive techniques). Exclusion criteria were absent (addiction, blood coagulation disorders, severe psychologic problems, etc.).

Mean pre-op VAS pain scores were 8 (5–10) and 8.1 (3–10) for legs and back, respectively. All patients had back pain on top of the pain

on their lower extremities, back pain being at least 30% of their overall pain.

All but two patients took analgesics.

RESULTS

A mean reduction in patient self-reported pain from pre-op to post-op of 55% and 46% was seen, respectively, for the legs and the back. After one year there is still a mean reduction of, respectively, 43% and 27% for the legs and the back. Analysis further revealed that postoperative and postoperative after one year did not significantly differ for the legs. However, for the back we found a significant increase of 19% after one year postoperative in comparison with postoperative. Yet, there is still a significant difference in comparison with preoperative (see Table 3).

In 17 patients (85%) a clinically significant reduction (defined as reduction of 2 points or 30% in VAS (16)) in back pain was seen, with a mean decrease of 4.3 points (2–10) or 52% (22–100). In 10 (50%) patients, a reduction of ≥50% in back pain was seen. Only three patients perceived only a reduction in leg pain, without any reduction in back pain. One year postoperatively one patient had an increase in VAS legs and VAS back. For this patient the battery was turned off.

General patient satisfaction and QOL postoperatively was statically significantly better in comparison with preoperatively (see Table 3), indicating an improvement of 66% and 70%, respectively, which is considered clinically very relevant (17). One year postoperatively patients were still very satisfied with an improvement of 69% in comparison with preoperatively, and a QOL improvement of 75% in comparison with preoperatively. This latter finding was statistically better than the early postoperative improvement.

Table 1. Pearson Correlations Between VAS Pre–postoperative (One Year) for Back and Legs and VAS Pre–postoperative (One Year) Satisfaction and Pre–postoperative (One Year) QOL.

	VAS satisfaction	QOL
VAS pre–postoperative back	–0.64**	–0.35
VAS pre–postoperative legs	–0.52*	–0.44†
After one year		
VAS pre-1 year back	–0.69**	–0.65**
VAS pre-1 year legs	–0.53*	–0.59*

†$p < 0.10$, *$p < 0.05$, **$p < 0.01$.
QOL, quality of life; VAS, visual analogue scale.

Table 2. Patient Demographics, History of Back Surgeries, IPG Site Implantation, and Extension Use.

No.	Sex	Age	Number of back surgeries	IPG location		Extension	
				Buttock	Abdomen	30 cm	None
1	F	44	0	×		×	
2	F	49	0		×	×	
3	M	50	2	×			×
4	M	51	0		×	×	
5	F	58	1		×	×	
6	F	50	0		×	×	
7	F	56	4		×	×	
8	F	81	3		×	×	
9	M	63	3		×	×	
10	M	62	3		×	×	
11	F	33	1		×	×	
12	M	51	4		×	×	
13	M	56	5		×	×	
14	F	36	1		×	×	
15	F	57	0		×	×	
16	M	50	0		×	×	
17	F	59	0		×	×	
18	M	43	1		×	×	
19	F	40	3	×			×
20	M	54	1		×	×	

F, female; IPG, implantable pulse generator; M, male.

Table 3. Means, Ranges, *F*-scores Between Preoperative and Postoperative Scores for VAS Legs, VAS Back, SCS.

	Preoperative	Postoperative	One year postoperative	*F*-score
VAS legs	8.0 (5–10)	3.6 (0–8)	4.6 (1.5–8)	30.58
VAS back	8.1 (3–10)	4.4 (0–9)	5.9 (0–9)	18.26
Satisfaction	2.3 (1–5)	6.8 (2.5–10)	7.5 (1.5–9.5)	39.71
QOL	2.1 (1–5)	6.89 (5–8)	8.4 (1.5–9.5)	90.32

All comparisons were significant at $p < 0.001$.
QOL, quality of life; VAS, visual analogue scale.

Table 4. Parameter Settings for Each Patient.

No.	Electrophysiologic parameters					
	Perception amplitude (mA)	Comfort amplitude (mA)	Maximally tolerated amplitude (mA)	Pulse width (μsec)	Frequency (Hz)	Polarities
1	1.5	3.0	4.5	500	50	3+ 4– 5–
2	1.7	3.1	4.5	400	30	3+ 4– 5+
3	4.0	5.0	6.0	425	30	1+ 2– 3– 4+
4	1.5	2.2	3.0	500	30	3+ 4– 5– 6+
5	3.5	4.2	5.0	500	40	3+ 4– 5+
6	2.0	3.7	5.4	400	50	3+ 4– 5– 6+
7	6.5	7.5	8.5	400	30	3+ 4– 5+
8	2.6	4.0	5.4	300	60	1+ 8–
9	4.0	5.0	6.0	300	30	3+ 4– 5+
10	4.5	5.9	7.3	300	30	3+ 4– 5+
11	2.5	4.2	5.7	450	30	2+ 3– 4– 5+
12	2.8	3.8	4.8	500	30	3+ 4– 5+
13	1.0	1.9	2.9	450	50	3+ 4– 5– 6+
14	3.5	4.6	5.7	500	30	1+ 2– 3– 4+
15	3.5	5.0	6.5	500	30	3+ 4– 5– 6+
16	9.0	10.5	12.0	470	40	3+ 4– 5– 6+
17	3.4	4.2	5.0	420	30	3+ 4– 5+
18	3.5	4.5	5.5	400	30	3+ 4– 5+
19	3.0	4.0	5.0	400	30	2+ 3– 4+
20	3.7	4.6	5.5	287	40	2+ 3– 4– 5+

Hz, Hertz; mA, milliampere; μsec, microsecond.

Ninety percent of all patients ($N = 18$) used pain medication before the implantation. Of these 18 patients, two patients (11%) could stop their medication entirely, nine patients (50%) showed a reduced intake (M = 45%, range: 10–80%), and seven (39%) did not reduce their medication intake after the operation.

Acute postoperative pain also was recorded, showing that eight patients (40%) had no pain, ten (50%) patients had postoperative pain that lasted for three hours to four days, and two patients (10%) reported wound pain lasting two weeks in one patient and two months in the other.

Correlation analyses further revealed that VAS (pre–postoperative) legs and back correlated negatively with VAS pre–postoperative satisfaction, indicating a higher level of satisfaction postoperative goes together with less leg and back pain postoperative. In addition a marginal significant effect was revealed between VAS left (pre–postoperative) for legs and pre–postoperative QOL indicating that the QOL improves is related to a decrease in leg pain. After one year correlation analyses demonstrated that VAS (pre–one year) legs and back correlated negatively with VAS pre–one year satisfaction and pre–one year QOL, revealing that the more pain reduction in legs and back the more satisfaction and QOL patients have.

Mean parameters were: frequency 36 Hz (range: 30–60 Hz), pulse width 420.1 μsec (range: 287–500 μsec), perception amplitude 3.4 mA (range: 1.0–9.0 mA), comfort amplitude 4.5 mA (range: 1.9–10.5 mA), and maximum tolerable stimulation 5.7 mA (range: 2.9–12.0 mA). In 18 patients a guarded electrode combination was used (see Table 4).

The majority of leads were implanted with the tip at T8 (11/20) or above (6/20). Only four were implanted at a lower thoracic vertebral level.

One dural puncture occurred, but resolved uneventfully: The lead was implanted and bed rest was prescribed for a few days. No infections, epidural bleedings, neurologic, or other medical adverse events were observed during this study. No migrations have been reported to date.

In one case an implantable pulse generator had to be replaced during the intraoperative procedure because of a defect set-screw in the header. In another case an extension was replaced because of breakage after implantation. This problem was resolved without complications.

DISCUSSION

The results on coverage of back pain supplementing those of extremity pain obtained with the percutaneously implanted plate electrode demonstrate a pain suppression rate, similar to what is being achieved by surgically implanted series, i.e., >50% back pain suppression or more in 50% of patients (9,10).

Spinal cord stimulation results in better pain control than both conventional medical management (9) and re-operation (10). Its success is, however, dampened by the common need for reintervention due to lead displacement or hardware problems, like lead breakage. Displacement of percutaneous leads occurs more frequently than in plate electrodes (3,5–8,13). In addition, lead breakages tend to occur more commonly (6,8) in wire leads as well. For these reasons, long-term effectiveness tends to be better for surgical placed plate electrodes than for wire leads (3,5,6,8). As no displacements or breakages were encountered in this study the percutaneous plate electrode seems to behave more like a plate electrode than a percutaneous electrode with regards to robustness.

The major disadvantage of plate electrodes over wire shaped electrodes is the surgical approach, usually requiring general anesthesia, muscle retraction, and partial or complete lamina removal, leading to decreased early postoperative comfort and more scar tissue (14,15).

The authors therefore used an innovative technique using implantation of a plate type electrode through a percutaneous way, combining the minimal invasiveness of this procedure together with the advantages of plate electrodes (back area coverage, reduced displacement, and reduced lead breakage).

The early results of this cohort confirm the possibility to cover the back area in 85% of the patients without major intraoperative adverse events. This seems better than other studies, and whereas no definite explanations can be given, it can be related to the high position (Th8) of the electrodes in comparison with other studies, where the electrode is usually located at Th9–10 for obtaining low back coverage (18). This should be further explored. Paddle electrodes seem to yield better pain control than wire electrodes for back pain (12), another factor that could contribute to this relatively high coverage rate.

The major problem inherent to all SCS studies is the lack of placebo controls. As the patient perceives paresthesias on stimulation activation, placebo controls cannot be performed for tonic SCS. The development of newer stimulation designs, such as burst stimulation that do not generate paresthesia (19), should permit to eliminate this methodological problem.

CONCLUSION

The percutaneous implantation of plate electrodes combines the non-invasiveness of percutaneous technique with equally good results as described in the literature for plate electrodes. This new technique could therefore benefit pain patients' physicians with or without surgical experience.

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Authorship Statements

L.H. Vonhögen, R. Dirksen, and P. Bakker conducted the study. I. Mestrom and T. van de Looij did the data collection. L.H. Vonhögen, T. Vancamp, and D. De Ridder prepared the manuscript draft. S. Vanneste and M. Plazier did the data analysis with additional input of W. Pollet. All authors approved the final manuscript.

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COMMENTS

I would like to commend the authors on exploring the idea of inserting a mini-paddle electrode via a percutaneous Touhy introducer. Even though paddle electrodes work so well and are likely robust over time, I have always felt disturbed at how much muscle and tissue must be dissected during its insertion, and shifting this paradigm over time represents an important step.

The authors provide some data to suggest that there is some benefit for SCS for back pain. They arbitrarily define a VAS reduction by 2 points or 30% as clinically significant. However, they also noted that the efficacy in sustaining pain relief in the low back did not maintain over time. This is a very important question that needs to be specifically studied in the setting of the newer three or five column electrode systems that are currently available. I suspect that we are maintaining stimulation in the mid and low back, but it is not obvious if this is associated with significant improvements in pain and/or function.

The authors also have practiced meticulous technique as I would have thought that there would have been issues to the electrodes potentially flipping, or even migrating over time. It would be nice to see a two and five year follow up on the latter potential complication over time. Finally, it appears again, that in many patients, a single midline electrode is capable of capturing the back and perhaps this plate electrode through a less invasive approach offers another good option.

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We have long debated the relative benefits and weaknesses of percutaneously implanted coaxial leads versus surgically implanted paddle type leads for spinal cord stimulation. Percutaneous leads are less traumatic to implant and are easy to navigate within the epidural space. On the other hand, they provide circumferential stimulation including that of the intended spinal cord as well as extraneous, potentially pain inducing targets such as the dorsal and lateral ligamentous and periosteal structures. In addition, they are less efficient, require greater power to generate a comparable degree of stimulation and produce different electrical fields than those produced by paddle type leads. Surgically implanted paddle leads provide unidirectional stimulation and are much more efficient due in part to their much larger area of electrode contact with the dura. These leads, however, require open surgical trauma to implant and are relatively unmaneuverable within the epidural space. Vonhogen and colleagues provide their experience with a much needed synthesis of these two approaches: a percutaneously delivered paddle lead. Their retrospective results suggest that this is a less traumatic and possibly equally effective technique for spinal cord stimulation when compared to traditional paddle type leads.

While I believe that this is a valuable and important study, I do believe that we should look upon the conclusions with some caution. The implantation of a paddle lead through a large Tuohy needle by unskilled hands raises the potential for significant dural puncture and/or spinal cord injury. This suggests the need for a safer alternative delivery system; such systems are currently available in Europe. One hopes that such devices will become available soon in the United States. Furthermore, before comparative conclusions can be made, we need head to head prospective randomized trials to determine relative efficacy and complication rates. Particular attention should be paid to the potential complications of implantation and the longevity of the effect to determine whether larger surgically implanted paddle leads provide better long term efficacy when compared to the smaller percutaneously implanted paddle leads or whether these percutaneously implanted smaller paddle leads are safer than larger surgically implanted leads.

Nonetheless, I laud the authors on their successful experience thus far and look forward to future studies in this area.

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