One-Year Outcomes of Spinal Cord Stimulation of the Dorsal Root Ganglion in the Treatment of Chronic Neuropathic Pain

Liong Liem, MD*; Marc Russo, MD[†]; Frank J.P.M. Huygen, MD, PhD[‡];
Jean-Pierre Van Buyten, MD[§]; Iris Smet, MD[§]; Paul Verrills, MD[¶];
Michael Cousins, MD, PhD**; Charles Brooker, MD[††]; Robert Levy, MD, PhD[‡‡];
Timothy Deer, MD[§§]; Jeffrey Kramer, PhD[¶¶]

Objectives: Spinal cord stimulation of the dorsal root ganglion (DRG-SCS) is a new therapy for treating chronic neuropathic pain. Previous work has demonstrated the effectiveness of DRG-SCS for pain associated with failed back surgery syndrome, complex regional pain syndrome, chronic postsurgical pain, and other etiologies through 6 months of treatment; this report describes the maintenance of pain relief, improvement in mood, and quality of life through 12 months.

Materials and Methods: Subjects with intractable pain in the back and/or lower limbs were implanted with an active neurostimulator device. Up to four percutaneous leads were placed epidurally near DRGs. Subjects were tracked prospectively for 12 months.

Results: Overall, pain was reduced by 56% at 12 months post-implantation, and 60% of subjects reported greater than 50% improvement in their pain. Pain localized to the back, legs, and feet was reduced by 42%, 62%, and 80%, respectively. Measures of quality of life and mood were also improved over the course of the study, and subjects reported high levels of satisfaction. Importantly, excellent pain–paresthesia overlap was reported, remaining stable through 12 months.

Discussion: Despite methodological differences in the literature, DRG-SCS appears to be comparable to traditional SCS in terms of pain relief and associated benefits in mood and quality of life. Its benefits may include the ability to achieve precise pain–paresthesia concordance, including in regions that are typically difficult to target with SCS, and to consistently maintain that coverage over time.

Keywords: Back pain, complex regional pain syndrome, dorsal root ganglion, failed back surgery syndrome , foot pain, leg pain, neuropathic pain, spinal cord stimulation, visual analog scale

Conflict of Interest: Dr. Kramer is an employee of Spinal Modulation, Inc. All the authors with the exception of Prof. Cousins and Dr. Brooker are consultants to Spinal Modulation, Inc.

INTRODUCTION

Relief of intractable neuropathic pain can be achieved via neuromodulation of the sensory tracts in the dorsal column of the spinal cord (1). Thousands of traditional spinal cord stimulation (SCS) devices are implanted every year (2) for failed back surgery syndrome (FBSS) (3), complex regional pain syndrome (CRPS) (4), and other indications. With reports of life-changing improvements in pain, quality of life, and associated variables (5), the value of traditional SCS as an intervention cannot be discounted.

However, traditional SCS is not a panacea. Up to 40% of implanted subjects do not appreciate satisfactory pain relief (6), although strict patient selection criteria may reduce the proportion of treatment failures (7). A particularly vexing limitation with this therapy is its tendency to lose effectiveness over time (8,9), a trend that may affect as many as 50% of implanted patients (10). These problems may be linked to the importance of achieving concordance of paresthesia with the painful areas (11), a necessary condition for

Address correspondence to: Jeffrey Kramer, PhD, 1135 O'Brien Dr., Menlo Park, CA 94025, USA. Email: jeff@spinalmodulation.com

  * Sint Antonius Hospital, Nieuwegein, The Netherlands;
  † Hunter Pain Clinic, Newcastle, NSW, Australia;
  ‡ Erasmus University, Rotterdam, The Netherlands;
  § AZ Nikolas, Sint Niklaas, Belgium;
  ¶ Metro Spinal Clinic, Melbourne, Vic., Australia;
 ** University of Sydney, Sydney, NSW, Australia;
 †† Royal North Shore Hospital, Sydney, NSW, Australia;
 ‡‡ Marcus Neuroscience Institute, Boca Raton Regional Hospital, Boca Raton, FL, USA;
 §§ Center for Pain Relief, Inc., Charleston, WV, USA; and
 ¶¶ Spinal Modulation, Inc., Menlo Park, CA, USA

successful SCS therapy. Reprogramming or surgical repositioning of the leads (in the case of migration) may be attempted but are not always satisfactory.

Converging evidence suggests that the dorsal root ganglion (DRG) is a rich target for treating chronic pain (12,13), including via neuromodulatory interventions (14). Stimulation of the somatotopically organized DRG can result in subdermatomal patterns of paresthesia coverage (15), suggesting that recruitment of specific sensory neuron perikarya may allow more precise "steering" of paresthesias in the body relative to traditional SCS. Given this, DRG-SCS may have some benefits, especially in cases of pain distributions in regions that are typically difficult to treat with traditional SCS (focal distal distributions such as groin and foot). The main difference between DRG-SCS and traditional SCS may be in functional characteristics of the parenchyma activated by the leads. Traditional SCS recruits multiple fibers of passage in the dorsal columns and results in action potentials propagating ortho- and antidromically, potentially recruiting multiple dermatomes and structures outside of the dorsal columns, including primary sensory neurons (16). In contrast, DRG-SCS may directly activate the cell bodies of the very neurons that innervate the painful regions. This distinction may give rise to a different mechanism of action and therefore different interventional profiles for the two electrically active implantable technologies. On the other hand, it should be noted that because some dorsal column fibers arise from cell bodies in the DRG, it is possible that SCS and DRG-SCS share some cellular targets and have mechanistic similarities.

This report presents the durability of outcomes in a prospective study to assess the effect of DRG-SCS on pain, quality of life, and mood. It was hypothesized that outcomes, previously reported as positive at 6 months post-implant (17), would continue through 12 months.

MATERIALS AND METHODS

Methods have been described in detail in another recently published report from this research group (17). Briefly, subjects were recruited with full informed consent at European and Australian sites under local ethics committee approval. All subjects were 18 years or older, diagnosed with chronic neuropathic pain (of 60 mm or more on a 100-mm visual analog scale [VAS]) located in the trunk, sacrum, or lower limbs that was intractable to other conventional treatments, and with a stable (30-day) prestudy neurological and medication profile. Subjects with pain involving cervical segments, worsening pain, some corticosteroid or radiofrequency treatments, cancer, clotting disorders, or active implanted devices were excluded.

All subjects used the Spinal Modulation Axium DRG-SCS system, which is a constant-voltage device with up to four quadripolar percutaneous leads. The delivery system consists of a flexible lead with a hollow inner lumen, a curved stylet that is inserted into the lumen to provide rigidity and directionality to the lead during implantation, and a sheath into which the lead, with the stylet in place, is loaded.

With the patient under local anesthesia and lightly sedated, the physician accessed the epidural space using a 14-gauge delivery needle, similar to the standard SCS implantation method. Once the delivery needle was in place, the leads were inserted anterogradely through the needle and steered into the neural foramen near the DRG using fluoroscopic guidance. Because the DRG is located between the medial and the lateral aspects of the lumbar pedicle
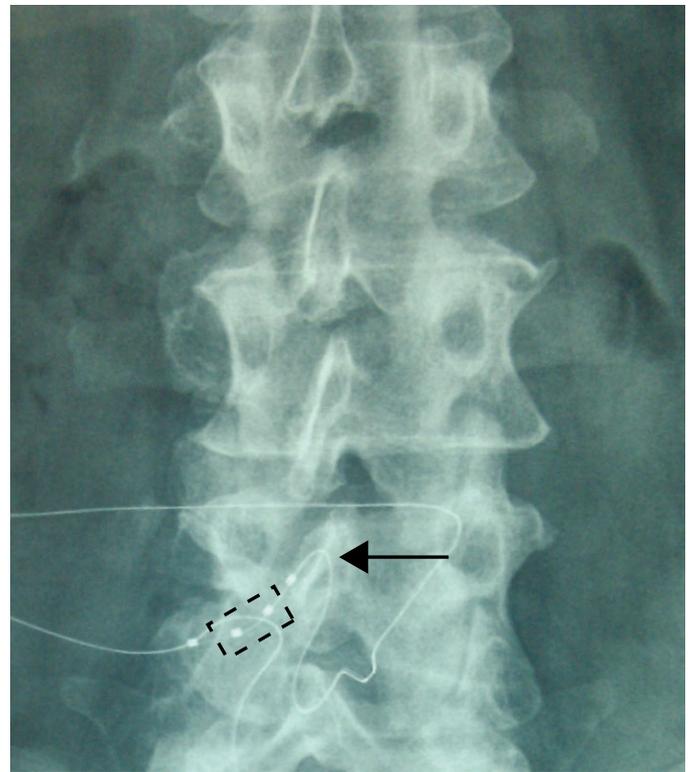
Figure 1. A representative fluoroscopic image obtained during implantation of the DRG-SCS device, illustrating placement of two pedicle-spanning contacts (boxed) and epidural lead slack (arrow).

(18), leads were placed such that a pair of contacts straddled the pedicle. Up to four leads could be deployed at up to four DRGs to capture the painful regions, depending on patient feedback regarding paresthesia coverage obtained in the intraoperative programming phase. Once adequate paresthesia was obtained, the stylet was partially removed and the lead advanced in the epidural space to create slack or a loop intended to prevent lead migration (see Fig. 1). The sheath, needle, and stylet were then completely removed. Permanent leads were anchored to the fascia using tissue anchors, tunneled to the subcutaneous stimulator pocket, typically in the upper buttocks or abdomen, and connected. All incisions were sutured followed by appropriate wound care. Post-implantation programming of the permanent DRG-SCS system was based on individualized subject feedback. At home, subjects used a wireless controller to adjust the stimulation within preset limits.

Subjects completed baseline assessments and then trialed a temporary stimulator (implanted leads attached to an external stimulator) for up to 30 days. Subjects then received a permanent implanted neurostimulator (INS) if at least 50% pain relief was apparent during the trial period, and outcomes were tracked through 12 months. Subjects provided feedback regarding pain, both in general and specific to the back, legs, and feet, using the standard 100-mm VAS (19) and the Brief Pain Inventory (BPI) (20,21); they also answered questionnaires on quality of life (EQ-5D-3L) (22)[1] and mood (Profile of Mood States [POMS]) (23), as well as the McGill Pain Questionnaire (24). Pain and paresthesia distributions were captured on body maps. Subject satisfaction was rated on an

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[1] Australian data (*N* = 10 at baseline and *N* = 7 at 12 months) were not included in the EQ-5D index score calculation, as country-specific value sets are not available.

Table 1. Subject Demographics and Etiology of Pain.		
	All subjects	Subjects with permanent DRG-SCS
Gender, N		
Female	27	17
Male	24	15
Age (years), mean ± SD	54.3 ± 13.3	52.5 ± 12.4
Etiology, N		
Failed back surgery syndrome	16	8
Complex regional pain syndrome	11	8
Chronic postsurgical pain	9	6
Disc-related pain	4	4
Radicular pain	3	2
Lumbar stenosis	2	2
Other	3	2
Postherpetic neuralgia	3	0

11-point Likert scale where 0 = not satisfied and 10 = very satisfied. Subjects' global impression of change (GIC, a 7-point Likert scale) (25) was also captured as a secondary outcome. Adverse events (AEs) were tracked throughout the study.

Standard data management procedures were employed, and data analysis was completed using SPSS v. 20 (IBM, Armonk, NY, USA). Except where noted, data are presented as means ±SEM, with hypothesis testing employing two-tailed paired t-tests with $p < 0.05$. Data from baseline through 6 months' follow-up time point have been published previously (17) and are presented here to provide context regarding the durability of outcomes.

RESULTS

The DRG-SCS device was trialed in 51 subjects. Prior to this, some subjects had unsuccessfully used pulsed radiofrequency denervation ($N = 12$), SCS ($N = 9$), peripheral nerve stimulation ($N = 3$), and transcutaneous electrical nerve stimulation ($N = 3$). Subjects' demographics and pain etiologies were representative of chronic neuropathic pain populations (26) (see Table 1). At the end of the trial period, 76.5% of subjects ($N = 39$) had good outcomes, with average pain relief of 74.2% (±16.5), in contrast to the nonresponders, who reported an average pain relief of 5.0% (±8.7). Permanent INS devices were placed in 32 subjects; diagnoses were CRPS ($N = 8$), FBSS including radicular pain ($N = 16$), peripheral nerve damage ($N = 1$), pain after vascular stenting ($N = 1$), and postsurgical neuropathic pain ($N = 6$).[2] A total of 67 leads were implanted, with most subjects receiving two each.

Between baseline and the 12-month follow-up, overall pain improved by 56.3% (±8.4), decreasing from 77.6 mm (± 2.1; $N = 32$) at baseline to 33.6 mm (± 6.3; $N = 25$; $p < 0.005$) at 12 months. Back pain improved by 41.9% (±14.0), decreasing from 74.5 mm (± 5.3; $N = 10$) to 39.7 (± 9.6; $N = 9$; $p < 0.05$). Leg pain improved by 62.4% (± 10.8), decreasing from 74.6 mm (± 3.3; $N = 25$) to 28.7 (±7.2; $N = 20$; $p < 0.005$). Foot pain improved by 79.5% (±12.4), decreasing from 81.4 mm (± 2.5; $N = 13$) to 22.0 (± 10.7; $N = 10$; $p < 0.05$). The
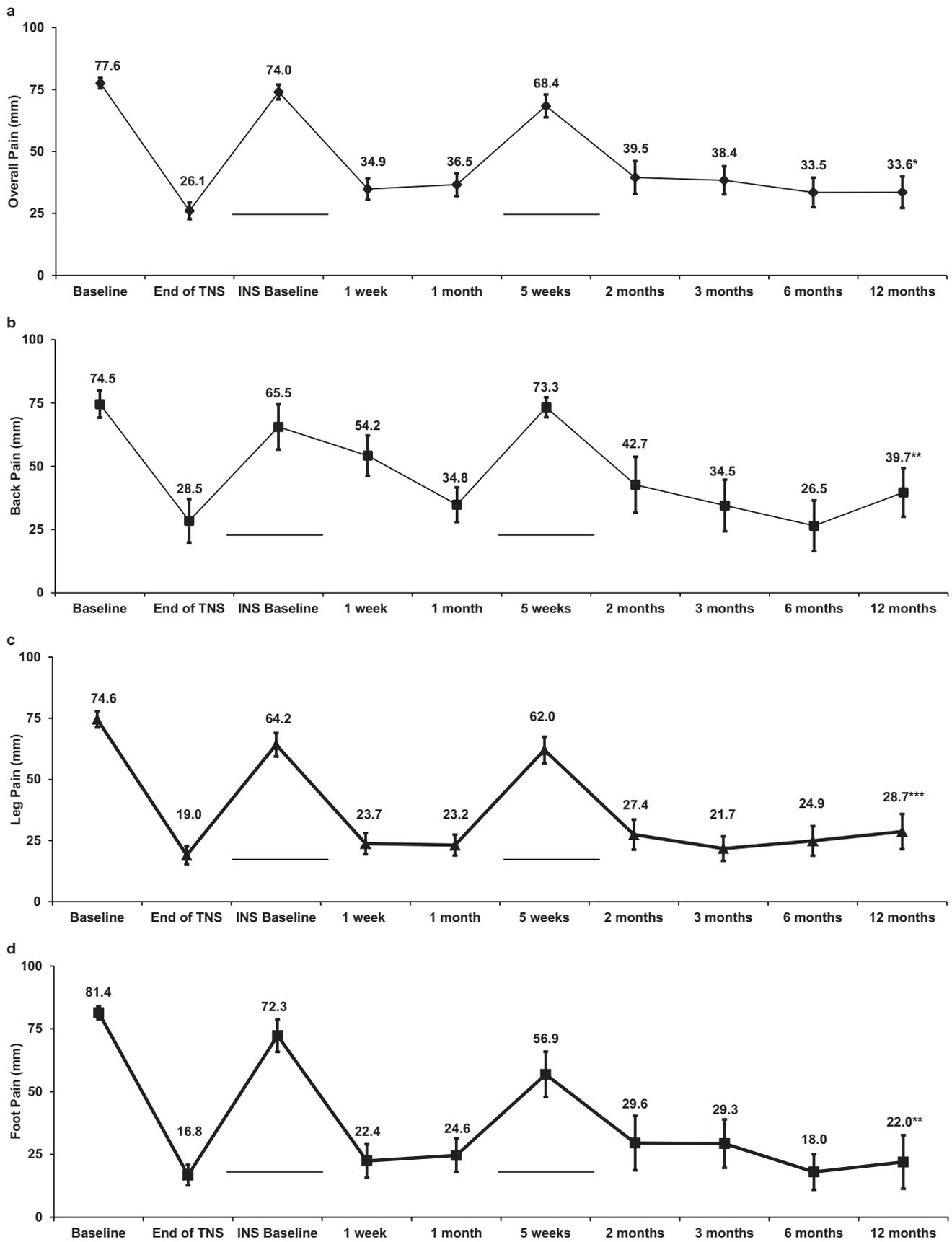
proportion of subjects achieving at least 50% improvement of their overall pain was 60.0%; 37.5%, 68.4%, and 87.5%, respectively, reported at least 50% improvement in their back, leg, and foot pain; see Figure 2. As assessed by the BPI, pain severity and interference of pain with activities were also significantly and sustainedly reduced through 12 months of the DRG-SCS intervention (6.9 ± 0.2, $N = 32$; 3.2 ± 0.6, $N = 25$; 6.5 ± 0.4, $N = 32$; and 3.3 ± 0.5, $N = 25$, respectively; $p < 0.001$ for all); see Figure 3.

Quality of life ratings were better at the 12-month follow-up than at baseline. Subjects' EQ-5D VAS scores increased from 47.0 (±3.8; $N = 32$) at baseline to 68.4 (±4.7; $N = 25$; $p < 0.005$), an improvement of 64.0% (±18.8). Similarly, the EQ-5D index score increased from 0.298 (±0.238; $N = 22$) at baseline to 0.698 (±0.267; $N = 18$; $p < 0.001$), an improvement of 134.2% (±12.2). For all five EQ-5D subscales, the proportion of clients reporting "no problems" was larger at 12 months than at baseline. In most domains the change appeared to be because a substantial proportion of subjects with "some problems" at baseline rated themselves as having "no problems" at 12 months. For the pain–discomfort subscale, 72% of subjects reported "a lot of problems" at baseline, but only 16% of subjects remained in this category at 12 months; see Figure 4.

Subjects rated their mood as improved between baseline and 12 months; there was a statistically significant improvement in four out of six domains of the POMS, and the total mood disturbance score decreased from 27.5 (±3.5; $N = 32$) at baseline to 9.4 (±3.9; $N = 25$; $p < 0.05$); see Figure 5. Subjects were largely satisfied with DRG-SCS: for the item "pain relief provided by stimulation," the mean score was 7.52 (±0.57), with 10 of 25 subjects (40.0%) rating their satisfaction as 8 or higher. For the items "therapy in general" and "likelihood of undergoing the therapy again," the mean scores were 8.92 (±0.20) and 8.88 (±0.39), respectively. According to GIC scores, 23 of 25 subjects (92.0%) rated their pain as "a little better," "better," or "much better" at 12 months as compared with before the device was implanted. Lastly, although it was not quantified for statistical comparison, considerable precision and durability of the pain–paresthesia overlap was noted; see Figure 6.

Subjects also completed the 78-item McGill Pain Questionnaire, which is divided into four classes (sensory, affective, evaluative, and miscellaneous) and 20 subclasses. A weighted pain rating index (PRI) score was calculated based on the choice of descriptor words and their weighted rank value in each subclass. Extent of pain relief can also be correlated based on the number of words chosen (NWC) to describe the pain. Significant decreases in both weighted PRI and NWC were observed at 12 months ($N = 21$) compared with the baseline ($p < 0.0001$, $N = 32$; Fig. 7).

There were 86 safety events reported across 29 subjects; approximately half were judged by the investigators to be related to the device (see Table 2). The most common AEs were temporary motor stimulation (12 events; 14.6%), cerebrospinal fluid leak with associated headache (7 events; 8.5%), and infection (7 events; 8.5%). Four lead revisions were completed due to high impedance (2 subjects, procedures at 2 months and 9 months post-implant), possible lead migration (2 months), and lead fracture (6 months). One implantable pulse generator revision was performed. Seven subjects had their devices explanted and were withdrawn from the study; three of these subjects had infections, two subjects did not comply with study procedures, and two subjects (one with postappendectomy pain and another with neuropathic compartment syndrome) reported lack of efficacy. Two of the explants took place after 2 months, four explants took place after the 3-month follow-up, and one explant took place after 6 months.

[2] Note that the previous report (17) listed nine subjects with CRPS and five with chronic postsurgical pain (CPSP). An error in acronym transposition led to one subject's etiology of pain being mislabeled in the previous report; this has been corrected here.

Figure 2. DRG-SCS significantly reduced pain through 12 months post-implant: overall a, back b, leg c, and foot d. Solid lines represent follow-up time points with stimulation turned off (*$p < 0.005$, **$p < 0.05$, and ***$p < 0.0005$). TNS, trial neurostimulator; INS, implanted neurostimulator.
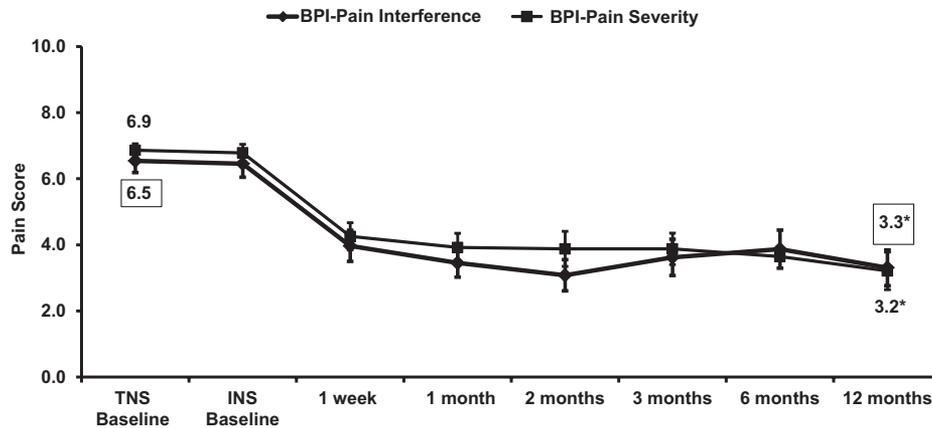
Figure 3. Pain severity and interference with activity as measured by the Brief Pain Inventory (BPI) was significantly and durably reduced through 12 months of treatment with DRG-SCS. TNS, trial neurostimulator; INS, implanted neurostimulator.
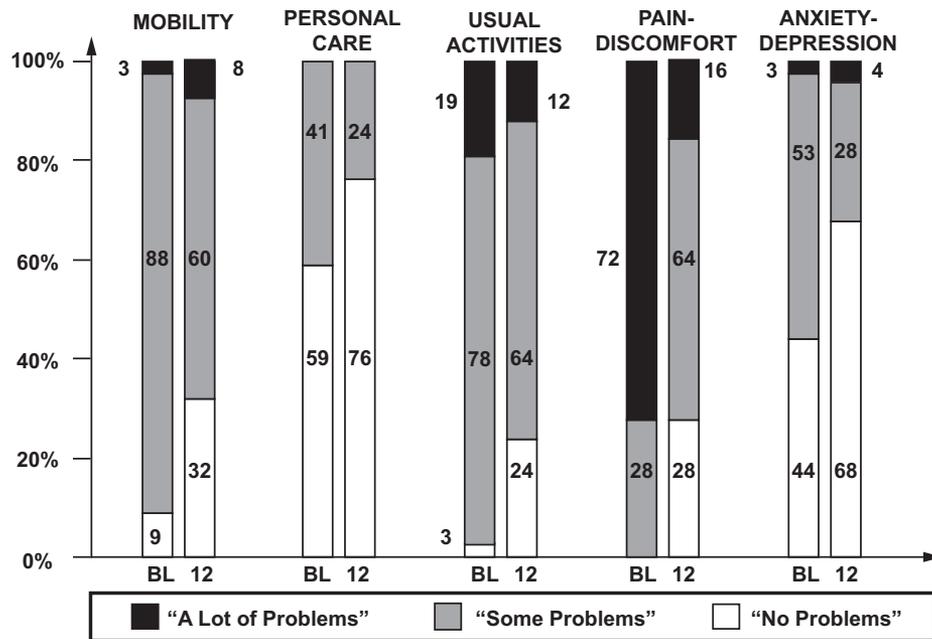

Figure 4. The proportion of people reporting problems across EQ-5D subscales declined from baseline (BL) to 12 months, particularly for the pain–discomfort domain.

DISCUSSION

Initial responder rates in SCS are approximately 80% (27). One-year pain relief outcomes for prospective SCS studies have been reported at 40–50% for radicular pain (28–30), although smaller samples have reported larger-magnitude pain relief of up to 70% in the leg (31) and 80% in the back (32). Studies have also reported improvements in secondary outcomes such as function, mood, and quality of life (28,29,33). The results presented in this report are comparable to these benchmarks. Reduction in SCS-related pain relief over time has been documented in systematic reviews (8,34). In that context, the 1-year maintenance of robust pain relief with DRG-SCS (56.3% relief of overall pain, with 60% of subjects attaining at least 50% pain relief) is promising indeed, though this must be tempered with the acknowledgment that the observational design of this relatively small study may inflate its effect (35). Recent findings with DRG-SCS for lower-limb CRPS, however, agree that pain relief of more than 50% is sustainable through at least 12 months (14). A randomized controlled trial comparing outcomes of traditional SCS against DRG-SCS is needed to definitively evaluate these interventions.

It should be noted, however, that the statistics above were generated by studies across a number of methodologies; those studies employing conservative intent-to-treat designs may minimize the positive outcomes experienced by some individuals. In contrast, this study utilized a simple prospective cohort design in which subjects were treated in accordance with standard clinical practice. Although only two subjects (6.3% of the sample) were withdrawn from the study due to lack of effectiveness of the device, the exclusion of treatment failures from analysis could potentially accentuate positive outcomes. Regardless, high levels of subject satisfaction and favorable impressions of change support the effectiveness of DRG-
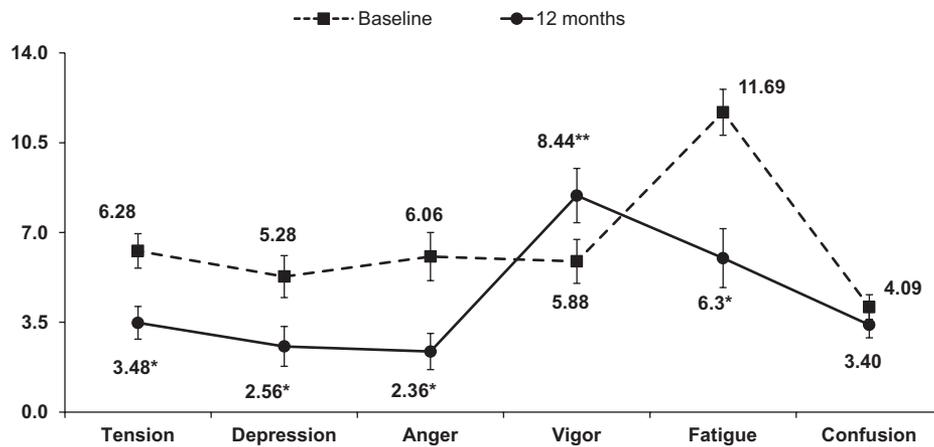
Figure 5. Mood ratings improved significantly in four out of six domains on the Profile of Mood States; the total mood disturbance score was also significantly lower after 12 months of DRG-SCS than at baseline. Notice the reversal in vigor and fatigue patterns at 12 months compared with baseline. *$p < 0.05$, **$p = 0.06$.
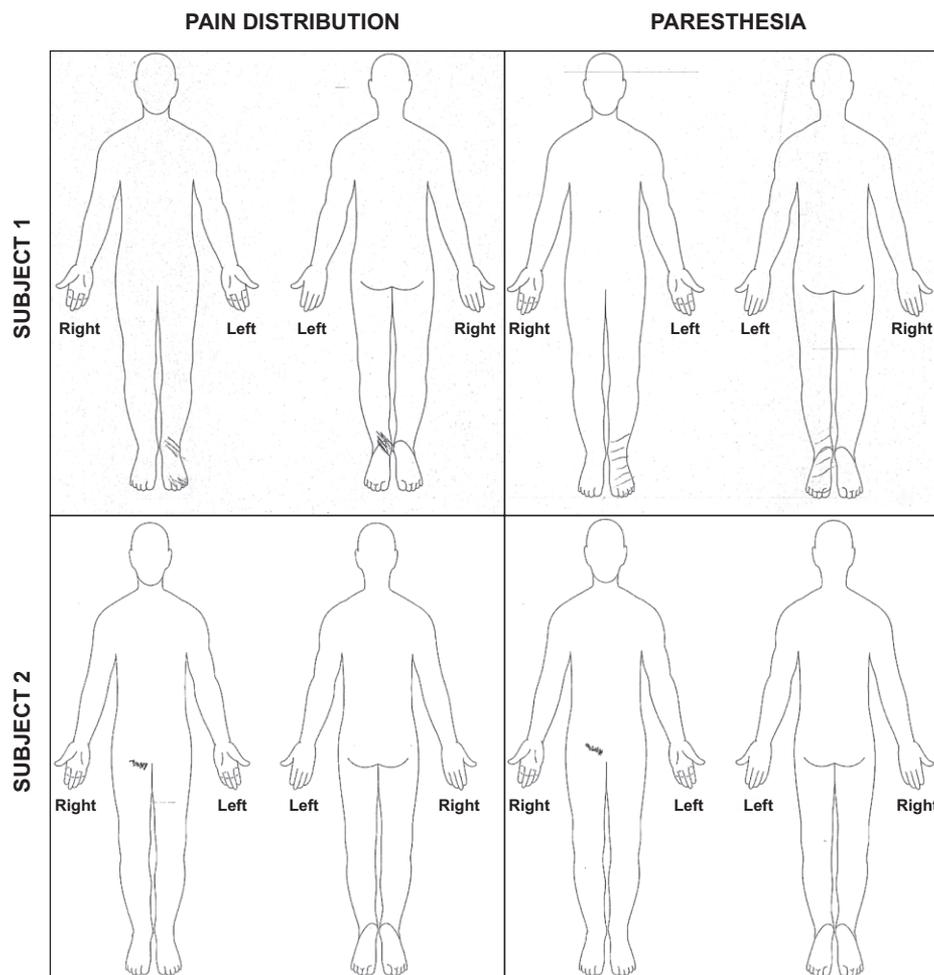
Figure 6. Paresthesia distributions precisely and discretely covered painful areas with very little extraneous coverage at 12 months post-implant, as illustrated in two representative subjects. Mapping was completed while subjects were standing.

SCS as a therapy for chronic pain. A relatively high overall incidence of AEs was noted in this study as compared with that reported in SCS reviews (9,36,37). This is likely due to two factors. First, all AEs occurring during the study were reported, regardless of their relationship to the device, procedure, or study, in order to provide transparency to clinical outcomes. Second, the two most frequently occurring AEs in this study, temporary motor stimulation and cerebrospinal fluid leak with associated headache, were consequences of the implant procedure and/or intraoperative programming. As clinical experience with this novel device and implant location have
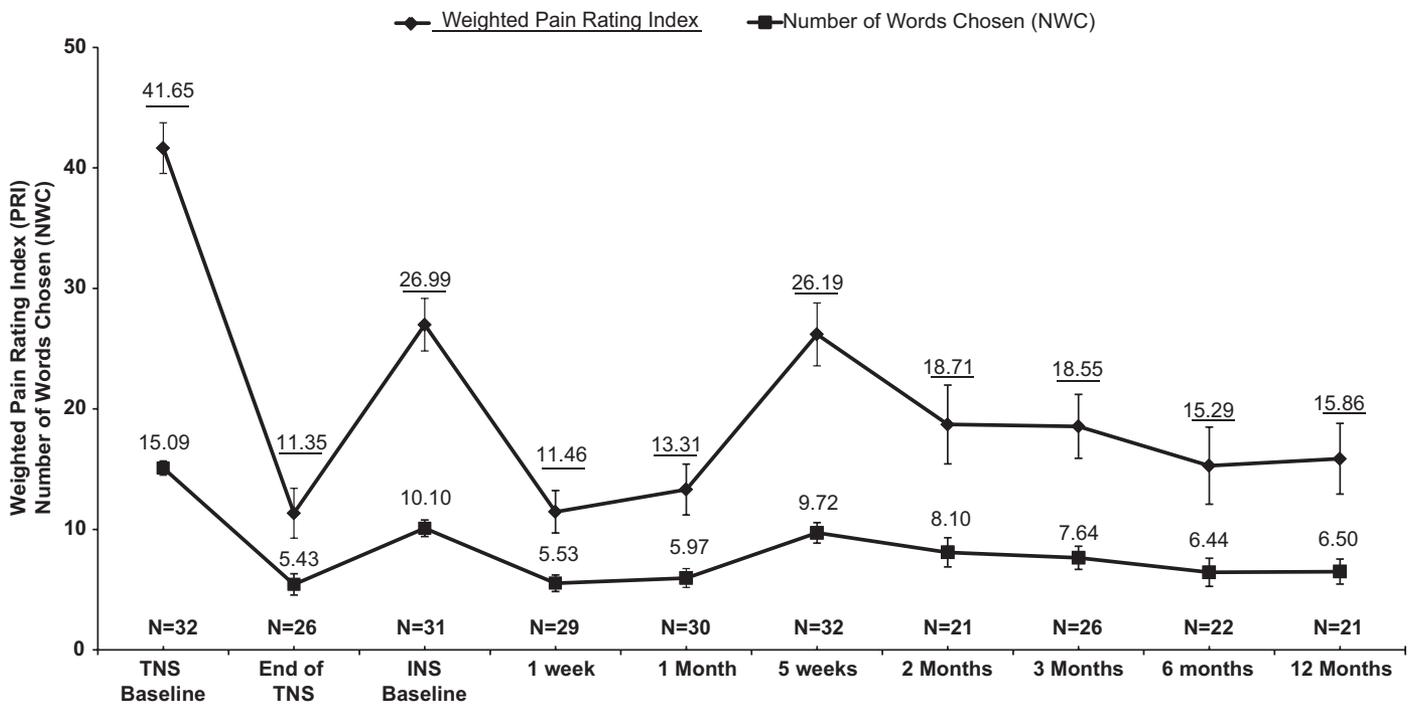
Figure 7. Compared with the baseline McGill Pain Questionnaire scores, weighted pain rating index (PRI) scores (underscored data values) and number of words chosen (NWC) decreased significantly at 12 months ($p < 0.0001$). Note the increase in weighted PRI and NWC when the stimulation was turned off at INS baseline and at 5 weeks. TNS, trial neurostimulator; INS, implanted neurostimulator.

Table 2. Numbers and Device-Relatedness of Adverse Events.			
Treatment phase		Type of event	
	Serious adverse event	Adverse event	All
Trial DRG-SCS ($N = 51$), N	3	21	24
Permanent DRG-SCS ($N = 32$), N	6	56	62
Total, N	9	77	86
Events possibly, probably, or definitely related to device, N (%)	3 (37.5%)*	40 (51.9%)	43 (50.0%)
*Device-relatedness information was not available for one event.			

increased during the course of this and other clinical trials, implant techniques have been optimized. New refinements such as the implementation of acute needle incision angles for epidural access and avoidance of ventral lead placement are likely to minimize the occurrence of such events in future cases. Rates of biologic complications in this study, such as infection, were more comparable to published rates.

A beneficial feature of DRG-SCS is its precise coverage of discrete regions and of areas that cannot easily be recruited in traditional SCS (14,38). Importantly, paresthesia coverage can remain stable through 12 months (39). In follow-up postmarket studies, stability of paresthesia and pain relief has been demonstrated over 15 months (38). Combined with the lack of positional effects (that is, differences in paresthesia intensity when standing vs. lying down) (39), DRG-SCS may provide some solutions for common complaints with SCS therapy. This may be due to the recruitment of the distally extending sensory neurons, which may have different neurophysiological properties than the complex nociceptive and nonnociceptive sensory processing mechanisms of SCS (40).

CONCLUSIONS

Improvements in ratings of pain, mood, and quality of life with DRG-SCS have been demonstrated through 12 months of therapy. Additionally, good agreement in pain–paresthesia overlap and high levels of user satisfaction were noted. Although further study into long-term outcomes with DRG-SCS is needed, particularly to differentiate it from SCS and (potentially) peripheral nerve stimulation, the present study suggests that this intervention may hold some clear benefits.

Authorship Statements

Drs. Levy and Deer designed the study and assisted in data interpretation. The rest of the authors conducted the study, recruited subjects, collected data, and reviewed the manuscript. Drs. Liem and Van Buyten also analyzed the data. All authors approved the final manuscript. The manuscript was drafted with

REFERENCES

1. Jung JH, Ignatius MI, Schulz CF, Ornelas CO. Advances in spinal cord stimulation for treatment of chronic pain. *Curr Phys Med Rehabil Rep* 2013;1:120–124.
2. Meyerson BA, Linderoth B. Mode of action of spinal cord stimulation in neuropathic pain. *J Pain Symptom Manage* 2006;31:S6–S12.
3. Lee N, Vasudevan S. Spinal cord stimulation use in patients with failed back surgery syndrome. *Pain Manage* 2012;2:135–140.
4. Kumar K, Rizvi S, Bishop S. Spinal cord stimulation is effective in management of complex regional pain syndrome I: fact or fiction. *Neurosurgery* 2011;69:566–580.
5. Epstein LJ, Palmieri M. Managing chronic pain with spinal cord stimulation. *Mt Sinai J Med* 2012;79:123–132.
6. Frey ME, Manchikanti L, Benyamin RM, Schultz DM, Smith HS, Cohen SP. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. *Pain Physician* 2009;12:379–397.
7. Atkinson L, Sundaraj SR, Brooker C et al. Recommendations for patient selection in spinal cord stimulation. *J Clin Neurosci* 2011;18:1295–1302.
8. Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004;108:137–147.
9. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg* 2004;100:254–267.
10. Sears NC, Machado AG, Nagel SJ et al. Long-term outcomes of spinal cord stimulation with paddle leads in the treatment of complex regional pain syndrome and failed back surgery syndrome. *Neuromodulation* 2011;14:213–218.
11. North RB, Ewend MG, Lawton MT, Piantadosi S. Spinal cord stimulation for chronic, intractable pain: superiority of "multi-channel" devices. *Pain* 1991;44:119–130.
12. Sapunar D, Kostic S, Banozic A, Puljak L. Dorsal root ganglion—a potential new therapeutic target for neuropathic pain. *J Pain Res* 2012;5:31–38.
13. Pope JE, Deer TR, Kramer J. A systematic review: current and future directions of dorsal root ganglion therapeutics to treat chronic pain. *Pain Med* 2013;14:1477–1496.
14. Van Buyten J-P, Smet I, Liem L, Russo M, Huygen F. Stimulation of dorsal root ganglia for the management of complex regional pain syndrome: a prospective case series. *Pain Pract* 2014. Epub ahead of print.
15. Deer TR, Grigsby E, Weiner RL, Wilcosky B, Kramer JM. A prospective study of dorsal root ganglion stimulation for the relief of chronic pain. *Neuromodulation* 2013;16:67–72.
16. Smits H, van Kleef M, Holsheimer J, Joosten EA. Experimental spinal cord stimulation and neuropathic pain: mechanism of action, technical aspects, and effectiveness. *Pain Pract* 2013;13:154–168.
17. Liem L, Russo M, Huygen FJ et al. A multicenter, prospective trial to assess the safety and performance of the Spinal Modulation dorsal root ganglia neurostimulator system in the treatment of chronic pain. *Neuromodulation* 2013;16:471–482.
18. Hasegawa T, Yoshihiro M, Ryo W, An HS. Morphometric analysis of the lumbosacral nerve roots and dorsal root ganglia by magnetic resonance imaging. *Spine* 1996;21:1005–1009.
19. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. *Pain* 1983;17:45–56.
20. Atkinson TM, Mendoza TR, Sit L et al. The Brief Pain Inventory and its "pain at its worst in the last 24 hours" item: clinical trial considerations. *Pain Med* 2010;11:337–346.
21. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. *J Pain* 2004;5:133–137.
22. EuroQol Group. EuroQol—A new facility for the measurement of health-related quality of life. *Health Policy (New York)* 1990;16:199–208.
23. Curran SL, Andrykowski MA, Studts JL. Short form of the Profile of Mood States (POMS-SF): psychometric information. *Psychol Assess* 1995;7:80–83.
24. Melzack R, Katz J, Jeans ME. The role of compensation in chronic pain: analysis using a new method of scoring the McGill Pain Questionnaire. *Pain* 1985;23:101–112.
25. Guy W. *Early Clinical Drug Evaluation Unit (ECDEU) assessment manual for psychopharmacology. Revised.* Bethesda, MD: National Institute of Mental Health, 1976.
26. Bouhassira D, Lanteri-Minet M, Attal N, Laurent B. Prevalence of chronic pain with neuropathic characteristics in the general population. *Pain* 2008;136:380–387.
27. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006;58:481–496.
28. Burchiel KJ, Anderson VC, Brown FD et al. Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. *Spine* 1996;21:2786–2794.
29. Kemler MA, De Vet HC, Barendse GA, Van Den Wildenberg FA, Van Kleef M. Effect of spinal cord stimulation for chronic complex regional pain syndrome type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg* 2008;108:292–298.
30. Kumar K, Taylor RS, Jacques L et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179–188.
31. Oakley JC, Krames ES, Prager JP et al. A new spinal cord stimulation system effectively relieves chronic, intractable pain: a multicenter prospective clinical study. *Neuromodulation* 2007;10:262–278.
32. Rigoard P, Delmotte A, D'Houtaud S et al. Back pain: a real target for spinal cord stimulation? *Neurosurgery* 2012;70:574–585.
33. Eldabe S, Kumar K, Buchser E, Taylor RS. An analysis of the components of pain, function, and health-related quality of life in patients with failed back surgery syndrome treated with spinal cord stimulation or conventional medical management. *Neuromodulation* 2010;13:201–209.
34. Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess* 2009;13:1–154.
35. Taylor RS, Taylor RJ, Van Buyten J-P, Buchser E, North R, Bayliss S. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. *J Pain Symptom Manage* 2004;27:370–378.
36. Kumar K, Wilson JR, Taylor RS, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. *J Neurosurg Spine* 2006;5:191–203.
37. Kumar K, Buchser E, Linderoth B, Meglio M, Van Buyten J-P. Avoiding complications from spinal cord stimulation: practical recommendations from an international panel of experts. *Neuromodulation* 2007;10:24–33.
38. Schu S, Gulve A, Eldabe S et al. Spinal cord stimulation (SCS) of the dorsal root ganglion (DRG) for groin pain—a retrospective review. *Pain Pract* 2014; available as E-pub.
39. Kramer J, Liem L, Russo M, Huygen F, Smet I, Van Buyten J-P. Lack of body positional effects on paresthesias when stimulating the dorsal root ganglion (DRG) in the treatment of chronic pain. *Neuromodulation* 2014; available as E-pub.
40. de Andrade DC, Bendib B, Hattou M, Keravel Y, Nguyen J-P, Lefaucheur J-P. Neurophysiological assessment of spinal cord stimulation in failed back surgery syndrome. *Pain* 2010;150:485–491.