

Spinal Cord Stimulation for Complex Regional Pain Syndrome I [RSD]: a Retrospective Multicenter Experience from 1995 to 1998 of 101 Patients

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■ ABSTRACT

Objective. To evaluate effectiveness of spinal cord stimulation (SCS) applied to complex regional pain syndrome I (CRPS I). To analyze trends to focus the design of a multicenter prospective study.

Design. Retrospective multicenter series, 3 years.

Outcome measures. We collected visual analog scales for pain and patient satisfaction data on $n = 101$ patients. Patients were divided into two groups: Group I had single-lead quadrupolar systems, Group II had dual-lead octapolar systems.

Results. Mean pain scores decreased in both groups with a significantly greater decrease in Group II ($p < 0.001$). 74.6% of Group II patients preferred multiple programming arrays with 15.5% requiring frequencies $> 250\text{Hz}$; overall satisfaction scores were 70% in Group I and 91% in Group II ($p < 0.05$).

Conclusions. SCS is an effective treatment of pain in CRPS I. Frequencies $> 250\text{Hz}$ were necessary in some patients to maintain or re-establish pain control. Bilateral multielectrode leads appear superior with application of multiple arrays, permitting paresthesia steering with-

out need for surgical revision. A multicenter, prospective design is needed applying dual-lead multichannel systems with high frequency capabilities in the treatment of CRPS I. ■

KEY WORDS: complex regional pain syndrome, high frequency electrical stimulation, neuromodulation, reflex sympathetic dystrophy, spinal cord stimulation.

Electrical neuromodulation, in particular spinal cord stimulation (SCS), has evolved over the last three decades into a practical tool in the armamentarium of the interventional pain physician. Since the first application of SCS in humans (1,2), problems have been encountered that caused many to abandon the application of SCS in the treatment of complex chronic pain. As the technology in systems advanced, clinical work has expanded and has begun to define when and how this modality should be applied in the treatment of complex pain states. It is generally accepted that SCS works well when specific areas of the body are affected and the characteristics of the pain are neuropathic, rather than mechanical or nociceptive. An exception to this general rule is ischemic pain (ie, peripheral vascular

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disease [PVD]) where application of SCS leads to increased peripheral circulation via inhibition of sympathetically maintained vasoconstriction in the affected extremity (3).

Of extreme importance in the clinical application of SCS to complex pain syndromes, was that multiple arrays of electrodes with defined spacing would allow "capture" of pain (ie, the overlap of areas of paresthesia over the region of pain perception) better than a single array of electrodes (4-12). Law showed that a defined area of the spinal cord, the "physiologic midline" which differed from the "anatomic midline," was crucial in the modulation of pain transmission. He also determined that medial dorsal column penetration was improved with bilaterally placed electrode arrays around the physiologic midline, using staggered guarded cathodes (a "guarded cathode" is a selection of three adjacent electrodes with the middle electrode, the cathode ["negative"], having opposite polarity from the surrounding two anodal ["positive"] electrodes) with intercontact spacing of 4 mm and surface contact of 3 mm. The above would enhance the capture of pain in complex dynamic pain syndromes such as failed back surgery syndrome with axial and extremity pain and complex regional pain syndrome (4-6, 12) (See Fig. 1). The concept of dual arrays of elec-

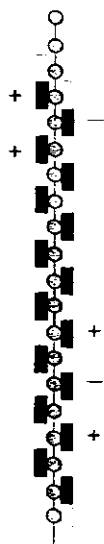


Figure 1. Examples of guarded cathode configurations in longitudinal (bottom) and transverse (top). Note the staggering of the leads across physiologic midline to minimize transverse intra-contact distance. (with permission *Neuromodulation* 1998;1:36)

trodes led the way for multichannel devices which allow the "steering" of paresthesia (ie, the moving of the active cathode in both longitudinal and transverse directions electronically) without the need for surgical revision. A multichannel device is one that allows for more than one lead to be active simultaneously, thus increasing the area of spinal cord that can be covered (13,14). Barolat, by mapping electrode placement against anatomic location, simplified the difficulty in obtaining capture. His database and the work that culminated from it have substantially increased the accuracy of electrode placement and decreased the amount of time spent during implantation of electrode arrays (15-18). Recently, the work of Struijk and Holsheimer has shown that certain configurations utilizing transverse tripolar arrangements would increase the range between perception threshold and discomfort threshold. These transverse tripolar arrangements allow more accurate targeting of medial dorsal column fibers (responsible for more rostral and caudal dermatomes) over the more lateral dorsal root fibers (responsible for segmental paresthesias) in the cord. Most recently, Holsheimer refined the predicted optimal contact spacing to 1.5 mm contact length having a 2.5-mm center-to-center separation for preferential stimulation of the dorsal columns (19). These concepts, when applied to currently available bilateral lead systems (dual-quadrupolar and dual-octapolar electrode arrays), allows for paresthesia targeting with greater accuracy and flexibility in dynamic complex pain syndromes. (20, 21) Ease of changing paresthesia coverage as neuronal plasticity changes the target (spinal cord area mediating the pain) over time without the need for surgical revision of the electrodes has become possible with the application of dual-lead systems (Fig. 2).

We have applied SCS in the treatment of CRPS I (RSD) and CRPS II (causalgia) for some time with good results. Since the introduction of newer technologies of multichannel devices having interactive computer assisted control and multiple program sequences, our center has applied these systems exclusively in the treatment of CRPS. Our interest in combining data from four centers with similar experience in the application of SCS to CRPS I was to define trends that would focus the design of a multicenter prospective study addressing the application of these newer technologies of SCS in CRPS I.

PainDoc sample programs in either PC-Stim or M-Stim mode

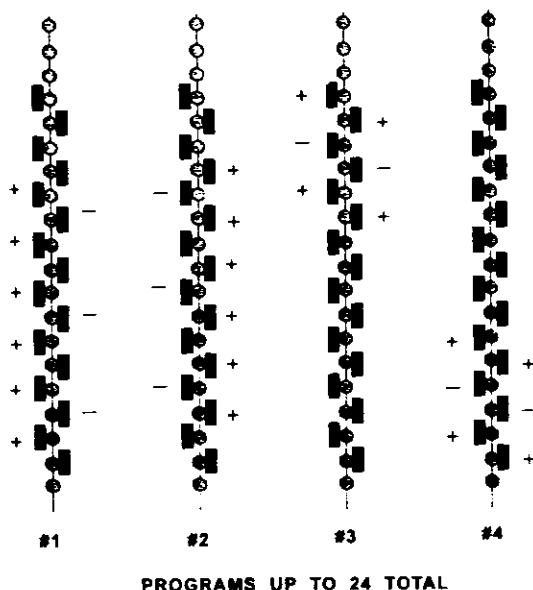


Figure 2. Examples of multiple programmed arrays using a multichannel dual-lead device. Patient's can change paresthesia field by selecting programmed options manually (PC-stim) or programs can cycle automatically (M-stim) through a program sequence. (with permission Neuromodulation 1998;1: 38)

MATERIALS AND METHODS

Data comprising $n = 101$ patients who were trialed and implanted with percutaneous electrode arrays from 1995 to 1998 were pooled from ours and three other centers (from a total of 134 patients implanted for CRPS I). All patients met the criteria for CRPS I as agreed upon in the International Association for the Study of Pain (IASP) consensus statement (22). All patients had undergone psychological screening, including psychological profiling; patients were excluded for significant phobias, personality disorders, high levels of dysfunctional behaviors, or questions of compliance with the modality. Patients were included only after failing more conservative therapies including injection therapies, physical therapy including desensitization, and medical management with various classes of medication (anti-seizure medications, membrane stabilizers, nonsteroidal anti-inflammatories, or systemic adrenergic receptor blocking agents).

Patients were divided into two groups based upon

the type of system with which they had been trialed and implanted. Group I ($n = 30$) was comprised of patients who had quadrapolar transcutaneous radiofrequency coupled external power (RF) or internal pulse generators (IPG) (Pisces Quad with Xtrel or Itrel system, Medtronic, Inc., Minneapolis, MN). Group II ($n = 71$) was comprised of patients who had dual octapolar RF systems. (dual-Octrode system, Advanced Neuromodulation Systems [ANS], Plano, TX) All centers utilized lead positioning based on information of Tulgar and Barolat (7, 10, 15-18), with cervical placement at C2-C6 and thoracic placement at T10-T11 for upper extremity and lower extremity pain, respectively. In the dual lead (Group II) patients, bilateral paresthesia coverage was assessed, with leads on either side of the physiologic midline as determined by intraoperative electrical mapping. In the single lead (Group I) patients, the lead was placed over the physiologic midline as determined by intraoperative electrical mapping. All patients had stimulation assessed in the operating room with activation of the lead(s) insuring paresthesia capture of the areas of reported pain. Because patients in Group II utilized computer-assisted pain mapping/programming (PainDOC Software, ANS), data regarding the percentage of paresthesia overlap, specific array configurations by individual program, and type of mode (individually activated or patient controlled [PC-stim] vs. automatically sequentially activated programs or multistim [M-stim]) were available. (see Fig. 2) However, these data were only used in this retrospective review to determine the percentage of patients utilizing more than one array, reported as a percentage of the group. Visual analog scale (VAS) was available for initial (pretrial/implantation) scoring (i VAS) and current (date of last visit) scoring (f VAS). The date of last visit was compared to initial implantation date to determine the months of stimulation for each patient. Group I had a mean follow up of 18.7 months ($SD \pm 4.9$, range 11-33 months). Group II had a mean follow up of 23.5 months ($SD \pm 8.7$, range 8-44 months). Complications such as infection, dehiscence, surgical revision secondary to loss of paresthesia, surgical revision secondary to trauma, erosion of skin over hardware, and epidural hematoma were tabulated by group. No consistent information was supplied as to duration of symptoms prior to stimulation from the four centers, therefore this was not tabulated.

Statistical Analysis

Data fields were entered by grouping type into a database which was then statistically analyzed (Stat-View, SAS, Cary, NC). Mean values for each type of field were calculated and are reported with their corresponding standard deviations (SD). VAS data was parametric, therefore an ANOVA test rather than Wilcoxon analysis was applied; a two-tailed *p*-value ($p < 0.0001$) pairing *iVAS* vs. *fVAS*, was considered significant. Satisfaction scores were determined based on a yes/no question format, and therefore are reported as observed frequencies for each group.

RESULTS

Demographics

Table 1 shows the demographic breakdown of each group. There were 23 females (77.7%) and 7 males

Table 1. Patient Demographics

	Group I (N = 30)	Group II (N = 71)
Female	23 (77.7%)	40 (56.3%)
Male	7 (22.3%)	31 (43.7%)
Mean Age \pm SD	43.7 \pm 12.5 ^a	42.9 \pm 11.5 ^a
Age (Range)	26-80	23-77
Cervical Lead(s)	20 (66.7%)	29 (40.8%)
Thoracic Lead(s)	9 (30%)	29 (40.8%)
Cervical/Thoracic Lead(s)	1 (3.5%)	5 (7.1%)

^a SE, 2.278

^b SE, 1.363

Table 2. Outcome Variables

		Group I (N = 30)	Group II (N = 71)
Baseline	(Mean)	7.97 \pm 0.93 ^a	8.17 \pm 1.18 ^c
VAS (<i>iVAS</i>) $p < 0.0001$	(Range)	(6-10)	(5-10)
Current	(Mean)	4.27 \pm 0.94	2.17 \pm 1.18
VAS (<i>fVAS</i>) $p < 0.0001$	(Range)	(3-8)	(0-7)
% Recaptured with			11/71
Frequency > 250 Hz with no change or		N/A	15.5%
increase in pulse width ^a			
% using multiple arrays			53/71
as multiple programs		N/A	(74.6%)
% surgical revisions 2 ^a to loss		5/30	3/71
of paresthesia	($p < 0.05$)	(16.7%)	(4.2%)
% overall satisfaction	($p < 0.05$)	70%	91%

^a Mean 455 Hz \pm 104.5

^b SE, 0.140

^c SE, 0.171

(22.3%) in Group I and 40 females (56.3%) and 31 males (43.7%) in Group II. Mean age in each group was 43.7 \pm 12.5 (range 26-80) in Group I and 42.9 \pm 11.5 (range 23-77) in Group II. Cervical placement (for upper extremity CRPS I) comprised 66.7% in Group I and 40.8% in Group II, with thoracic placement (for lower extremity CRPS I) comprising 30% in Group I and 52.1% in Group II. In Group I, one patient (3.5%) had upper and lower extremity pain and was implanted with a single lead in the cervical area and a single lead in the thoracic area. In Group II, five patients (7.1%) had both upper and lower extremity pain and were implanted with dual octapolar leads in both cervical and thoracic regions. Stratification of patients with only one extremity involvement vs. bilateral extremity involvement was not made.

Outcome Variables

There was a significant reduction in follow up post-implantation VAS (*fVAS*) when compared to preimplantation VAS (*iVAS*) in each group, as indicated by a paired *t*-test ($p < 0.0001$) (Tables 2 and 3). *iVAS* in Group I of 7.97 (\pm 0.93) decreased to 4.26 (\pm 0.94) [*fVAS*] while in Group II, *iVAS* of 8.17 (\pm 1.18) decreased to 2.17 (\pm 1.18) [*fVAS*]. In Group II, 74.6% preferred using multiple arrays (either as PC-stim or M-stim). In Group I, *fVAS* scores were reduced, but not to the degree seen when compared *fVAS* in Group II. Analysis of variance for improvement in pain score showed a significant improve-

Table 3. ANOVA Analysis for Pain Improvement (see Fig. 3)

Improvement in Pain Score (Δ VAS) = (iVAS-fVAS)							
	DF	Σ squares	Mean Square	F-Value	P-Value	Lambda	Power
Type Lead	1	111.238	111.238	56.081	<0.0001	56.081	1.000
Residual	99	196.370	1.984	**	**	**	**
	Count	Mean	Standard Deviation	Standard Error			
Dual-Octapolar	71	6.000	1.595	0.189			
Quadrapolar	30	3.703	0.796	0.145			

ment (F -value 56.081, $p < 0.0001$) with dual octrode leads vs. a single quadrapolar lead to (see Fig. 3), with mean pain improvement (Δ VAS) in Group I being 3.70 ± 0.79 , while in Group II Δ VAS was 6.00 ± 1.59 ($p < 0.0001$). In Group I, five patients were subsequently revised secondary to loss of paresthesia coverage that failed to respond to electrical programming changes, representing 16.7% of the group. In Group II, 15.5% lost pain control with paresthesia coverage; all of these patients recovered pain control when frequency was increased above

250Hz (mean 455 Hz \pm 104.5) without changing or increasing pulse width settings or electrode configurations. None of the patients in Group II spontaneously lost paresthesia coverage that was not regained with programming. In Group I, 9 patients reported dissatisfaction with their system (4 of whom had their system removed) representing 30% of the sampled population ($p < 0.05$). In Group II, 6 patients reported dissatisfaction with their system (two patients eventually had the system removed due to lack of pain control) representing 8.5% of the sample ($p < 0.05$).

Complication Rates

Table 4 shows complications. Spontaneous lead migration occurred in 4 patients in Group I, with no spontaneous migrations reported in Group II. Five patients in Group II were involved in motor vehicle collisions, either as a passenger or driver, that caused movement of the implanted leads and required surgical revision to replace the electrodes in optimal position (noninvasive electrical reprogramming failed to re-establish paresthesia coverage which had been present before the motor vehicle accident. As electrical re-programming failed to establish paresthesia coverage, and plain film X-rays were distinctly different than X-rays of final lead placement [postoperatively], traumatic dislocation of the leads was determined to be the cause of inadequate paresthesia coverage.) One patient had a postoperative infection at the receiver site in Group II. In Group I, one epidural hematoma, one skin erosion over an IPG, and two wound dehiscences were reported.

Comparison of Stimulation Parameters

Because of differences in the number of electrodes, number of leads, electrode contact separation, and

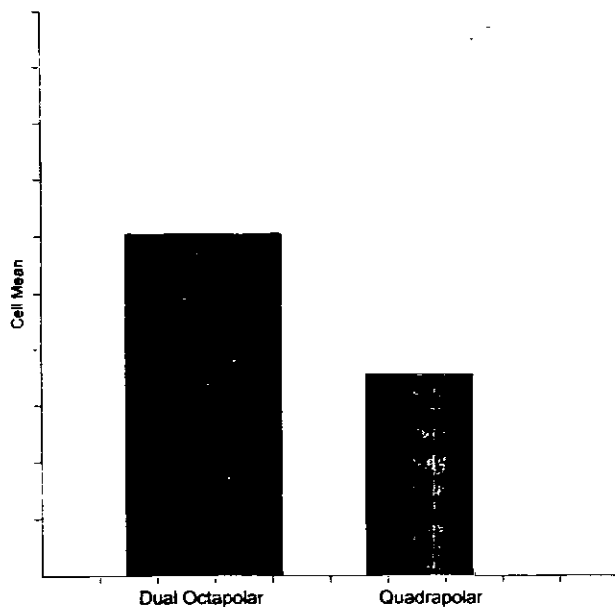


Figure 3. Analysis of Variance for Improvement in Pain Score. (Improvement in Pain Score Δ VAS = iVAS - fVAS)
Bar Plot for Pain Improvement/Effect by Type of Lead. VAS data was parametric, therefore an ANOVA analysis was used to test the CHANGE in pain reports. Results were significant at $p < 0.0001$, showing dual-octapolar was clearly superior in this retrospective study.

Table 4. Complication and Explantation Rates

	Group I (N = 30)	Group II (N = 71)
Lead Migration (spontaneous)	4/30(13.3%)	None
Lead Migration (traumatic)	None	5/71(7%)
Post Operative Infections (receiver/IPG)	None	1/71(1.4%)
Epidural Hematoma	1/30(3.3%)	None
Erosion of receiver/IPG	1/30(3.3%)	None
Dehiscence	2/30(6.7%)	None
System removed 2° to poor or no pain coverage after multiple attempts at reprogramming	4/30(13.3%)	2/71(2.8%)

frequency parameters, comparison between the two groups was not made with the exception of *vVAS* and *fVAS* (Table 5).

DISCUSSION

We retrospectively reviewed data from four centers looking at SCS as applied to CRPS I (RSD), looking for trends that would allow us to better design a multicenter prospective study addressing the use of SCS in CRPS I. Patients who met criteria by history and physical examination recommended by the IASP were selected from our combined database.

In collecting these data, we felt a distinction should be made between patients implanted with quadrapolar systems versus those implanted with dual-octapolar systems. We made this distinction as we do not believe that a dual-lead multichannel system offering multiple stimulation modes and frequency capabilities exceeding 250 Hz should be compared with single lead systems that do not offer this capability. We are unaware of any study that has looked at data from dual-lead, multichannel, multi-programmable systems and compared this to the data from single lead systems. As previous data that has been published on the use of SCS in CRPS I

relied on quadrapolar technology, it was important to look at the trends that emerged from this comparison.

vVAS were significantly decreased in the group using the dual-octapolar system with reductions in overall VAS approaching 70%. The reduction in pain in those using a dual-octapolar system compared with data published by Aló in his prospective study of 80 patients (20). Of the dual-octapolar group, 74.8% used multiple arrays to maximize paresthesia coverage. *fVAS* in the group using quadrapolar systems compared with data previously published, with pain relief approaching 50% ($p < 0.0001$) (23-27). 86.3% of quadrapolar systems and 97.2% of dual-octapolar systems continued to be utilized, although overall satisfaction with stimulation was 91% in the dual-octapolar group and only 70% in the quadrapolar group ($p < 0.05$). We thus conclude that SCS is effective in the management of chronic pain associated with CRPS I. From our retrospective analysis, use of dual-octapolar systems with multiple-array programming capabilities appears to increase the paresthesia coverage and thus, further reduce pain.

Higher frequencies of stimulation were found to be essential in re-establishing pain control in 15.5% of the patients using dual-octapolar systems. Of the

Table 5. Comparison of Stimulation Parameters

Variable	Unit	Single-Lead Quatrapolar RF	Quatrapolar IPG	Dual-Lead Octapolar RF
Frequency	Hertz	5-240	2.1-130	10-1500
Amplitude	Volts	0-12	0-10.5	0-12
Pulse Width	μ sec	50-500	60-450	50-500
Electrode Length	mm	3	3	3
Electrode spacing	mm	6	6	4

71 patients in this group, 11 lost pain control in the presence of paresthesia coverage over the area of described pain. With use of frequencies greater than 250 Hz (with no change or an increase in pulse width), all had return of pain control. This percentage is similar to neuropathic patients reported in a recent study where 16.3% (7 of 43) of patients experienced paresthesia without pain relief (28). We could not analyze the effect of high frequency in the quadrapolar system group, as this capability is not present. With the exception of the dual-octapolar system, we are not aware of any commercially available system that allows for frequency > 250 Hz without affecting pulse width parameters and none that offer this capability with greater than eight electrode contacts. Our ability to re-establish pain control in this subgroup prevented those patients from being labeled as "nonresponders" to SCS. Aló and Rossi have reported the effectiveness of increased frequencies in case reports of CRPS patients, but to our knowledge no mechanism has been proposed to explain this (29,30). We are not aware of any studies that have specifically addressed high frequency stimulation in CRPS I (prospectively or retrospectively), although high frequency stimulation has been anecdotally reported as useful by others as far back as 1975 (31-33).

In patients with CRPS I treated with SCS, changing paresthesia requirements over time has been a problem (20,23,26,28). This phenomena has resulted in need for surgical revisions to re-establish paresthesia coverage when single-lead systems are used. With the use of dual-lead systems, in particular dual-octapolar systems which can span greater than two spinal levels, the ability to steer paresthesia coverage (ie, repositioning of the electric field by changing the active cathode in both longitudinal and transverse planes) allows the changing of paresthesia without the need for physical electrode repositioning (see Fig. 2). This "programming" capability does not diminish the need for vigilance in exacting electrode placement during initial implantation, but rather allows a greater degree of coverage within the implanted system, thus expanding the system's "value" in complex states such as CRPS that require programming alterations over time. This was apparent in our retrospective data as surgical revision due to lost paresthesia was 16.7% in patients with single lead quadrapolar systems versus 4.2% in the dual-lead octapolar group.

The literature shows that multichannel devices with bilateral leads having 3 mm contacts separated by 4 mm interspaces in staggered fashion around the physiologic midline optimize capture of dorsal column fibers and are essential for optimal coverage in complex pain states (4-6,13,14). The dual-octapolar system adds multiple program capability (20,21), clearly preferred by our patients with CRPS, expands the frequency range (10-1500 Hz), thus allowing for high frequency stimulation in the subset of patients who require this for pain control, and covers a larger area of spinal cord which expands dermatomal coverage. The ability to measure the percentage overlap of paresthesia covering a painful area for each electrical configuration (cathodal array) is useful in optimizing programming to elicit positive outcomes in these patients. Aló's prospective study and its follow up (21,22) support the benefit of this system.

CONCLUSIONS

Our retrospective data show a significantly greater reduction of pain, reduction in surgical revisions to maintain paresthesia coverage, and distinct advantage with high frequency capabilities in the dual-octapolar system when compared with a single-lead quadrapolar system in treatment of CRPS I. The use of a dual-lead system may offer benefit in patients with CRPS I, as the topography of paresthesia coverage can vary with time, provided the system has capabilities for frequency generation greater than 250 Hz (without decreasing pulse width potential). Because these conclusions are solely based on our pooled and retrospective data, we understand that a multicenter, prospective study applying dual-lead technology (dual-quadrapolar and dual-octapolar) in the treatment of CRPS I is needed.

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