Analysis of a Patient-Selected Programs from a New Spinal Cord Stimulation System

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Abstract

Advanced Bionics has developed a first-generation rechargeable, current-controlled implantable pulse generator (IPG) for spinal cord stimulation (SCS). The clinician programmer of the IPG, called the Bionic Navigator\(^{TM}\), employs current-steering algorithms to enable the patient to participate in programming the stimulator for maximal paresthesia pain overlap. To investigate the clinical application of this new programming system, we performed a multi-center clinical study on 18 patients, undergoing trial of SCS for various chronic pain etiologies. The study showed that, when patients are involved in the programming of their stimulators, they choose stimulation programs that are relatively complex: 1.8 ± 0.8 channels/program and complex current distributions (mean: 1.8 ± 0.9 cathodes, 2.6 ± 1.1 anodes per current distribution).

1 Introduction

Spinal cord stimulation (SCS) has been employed in the treatment of chronic, intractable neuropathic pain for over 30 years [1]. Technical advancements in SCS systems have improved the long-term efficacy of the therapy: these include an increase in the number of stimulating contacts on a lead and more flexibility in the programmability of the devices [2].

With these advances, however, comes the challenge of programming the systems to an optimal set of stimulation parameters (contact combination, amplitude, PW, rate, etc) for each patient. In SCS, overlap of the painful area with paresthesia has been identified as a critical factor for a successful outcome [2]. Paresthesia location is determined by activation of specific fiber populations within the spinal cord; to a first approximation, optimal location of the stimulation field involves identifying the anode-cathode combination which recruits the desired fiber population. With SCS systems incorporating 16 stimulating contacts, individually programmable as anode, cathode, or ‘off’, there are 43 million possible anode-cathode combinations.

Even a motivated clinician using a well-defined programming algorithm, the programming session may be suboptimal since the patient’s involvement is likely to be limited. The numerical challenge of possible contact combinations and the general complexity of the programming equipment reduces the role of the patient to providing only verbal feedback.

A new stimulation system has been designed which addresses these issues. This system employs a continuous adjustment of the contact current distribution for paresthesia steering in fitting SCS patients. The system has been made simple enough so that patients can directly change the stimulation current distribution, select ‘good’ contact combinations, and specify the creation of complete stimulator programs. In essence, the patient’s can “program themselves.” This paper discusses the stimulator programs that were generated in a clinical study of the new system.

1.1 Stimulator Programmability

The new system’s implantable pulse generator (IPG) is a current-controlled stimulator which supports up to two 8-contact leads. Additionally, the case may be programmed to be a passive anode. The IPG also includes independent channel assignments, which may be programmed to different frequency and pulse widths.
Each channel may independently configure each of the contacts as either an anode, a cathode, or off. The percentage of the stimulation current assigned to each cathode (and to each anode) is also programmable, which allows a very high degree of control over the stimulating electric field and the resulting stimulation. Additionally, this architecture allows for gradual change in the percent stimulation current on each contact. The system takes advantage of this unique architecture to allow the patient to electrically “steer” the current along the leads in real-time (see Figure 1).

![Current Steering as performed by Bionic Navigator™](image)

**Figure 1**: Current Steering as performed by Bionic Navigator™

### 1.2 Clinician’s Programmer
The programmer of the IPG, called the Bionic Navigator™, is a software program that runs on a tablet PC. The Bionic Navigator™ allows clinicians to program all stimulation parameters on each channel, including the current distribution to the contacts (as % cathodic current, % anodic current, or off). Additionally, the Bionic Navigator™ programmer software allows the patient, working with the clinician, to program the device in a more graphical manner rather than by directly altering numerical values.

Using a current-steering technique called ‘Navigation,’ the current distribution is adjusted while the stimulation amplitude is maintained at a comfortable usage threshold, so that the patient always feels paresthesia. To adjust the stimulation field, the patient uses a hand-held controller to shift paresthesia locations on their body. Navigation enables the patient to self-direct the stimulation field for optimal paresthesia-pain overlap.

### 2 Methods

#### 2.1 Clinical
Patients were brought into the physician’s office during their trial period and disconnected from their portable trial stimulator. Their implanted, percutaneous lead(s) were then connected to the Bionic Navigator™ programming system.

Patients were instructed that goal of programming was to optimize paresthesia-pain overlap. They were educated on the use of the fitting system: using the Patient Controller, they could adjust stimulation amplitude, Navigation, or both. Patients were told that they should adjust level of stimulation so that they always feel paresthesia while Navigating.

Patients were free to try as many contact current distributions as they desired from a pre-defined set. Finally, patients were told that when they found ‘good’ contact current distributions (those distributions that provided the best paresthesia coverage of painful areas), they should save them for later program creation. Program creation consisted of patients self-assembling up to 4 of these ‘best’ contact current distributions into the final program.

#### 2.2 Data Acquisition & Analysis
Basic patient demographics were obtained from case report forms, implanted lead information was obtained from operative records and fluoroscopic images, and all stimulation adjustments were recorded in time-stamped log file on the Bionic Navigator™ programmer.

To assess how patients used the system to program their stimulators, we evaluated the following variables from the resulting patient-selected stimulator programs:

- Number of active anodes and cathodes used in current distribution per channel
- Number of channels per program

A retrospective analysis of the log file for each patient was performed using spreadsheets and custom analysis macros (Microsoft Excel 5.0, Redmond, WA).

### 3 Results
We defined a complex current distribution as having more than one cathode and two anodes. (e.g. ‘+-+’). We found that 72% of all patients (40% with single leads; 85% with dual leads) chose complex combinations for at least one of their ‘good’ current distributions.
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Table 1: Patient Demographics

<table>
<thead>
<tr>
<th>Primary Pathology</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBSS (Low Back/Leg Pain)</td>
<td>9</td>
</tr>
<tr>
<td>RSD/CRPS</td>
<td>3</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>3</td>
</tr>
<tr>
<td>Neuroma</td>
<td>1</td>
</tr>
<tr>
<td>Post-Viral Neuralgia</td>
<td>1</td>
</tr>
<tr>
<td>Sub-Occipital Neuralgia</td>
<td>1</td>
</tr>
</tbody>
</table>

### 3.1 Analysis of Current Distributions

<table>
<thead>
<tr>
<th>Patients with:</th>
<th># of Cathodes</th>
<th># of Anodes</th>
<th>Total # of Active Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-Lead</td>
<td>1.3 ± 0.5</td>
<td>1.9 ± 0.3</td>
<td>3.0 ± 0.7</td>
</tr>
<tr>
<td>(N=5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dual-Lead</td>
<td>2.1 ± 1.0</td>
<td>3.1 ± 1.3</td>
<td>5.2 ± 2.0</td>
</tr>
<tr>
<td>(N=13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (N=18)</td>
<td>1.8 ± 0.9</td>
<td>2.6 ± 1.1</td>
<td>4.4 ± 1.8</td>
</tr>
</tbody>
</table>

### 3.2 Analysis of Multi-Channel Programs

![Figure 2: Number of Channels per Program Selected by Patients, by Number of Implanted Leads](image)

The mean number of channels per program for all patients was 1.8 ± 0.8. We found that 55% of all patients chose multi-channel programs. Additionally, in patients that chose multi-channel programs, the current distributions for different channels were different in 80% of patients (e.g. Pt. 14’s multi-channel program for a single quadripolar lead has three very different current distributions; see Table 3).

<table>
<thead>
<tr>
<th>Channel</th>
<th>E1</th>
<th>E2</th>
<th>E3</th>
<th>E4</th>
<th>mA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-100</td>
<td>0</td>
<td>+100</td>
<td>0</td>
<td>1.9</td>
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<tr>
<td>2</td>
<td>0</td>
<td>+70</td>
<td>-100</td>
<td>+30</td>
<td>8.3</td>
</tr>
<tr>
<td>3</td>
<td>+11</td>
<td>-89</td>
<td>-11</td>
<td>+89</td>
<td>5.7</td>
</tr>
</tbody>
</table>

Table 3: Stimulation Program Selected by Patient 14

We also observed that a majority (5/9) of patients with dual-parallel, epidural leads chose only single-channel programs.

### 4 Discussion and Conclusions

We found that patients typically selected complex current distributions and assembled multi-channel programs using the Bionic Navigator™. One interesting observation was that 4/5 patients with a single lead created multi-channel programs – this is unusual, since patients with a single lead usually receive only single channel stimulators [3]. In the dual-parallel lead patients who chose only single-channel programs, all of their current distributions were complex and had current distributed to both leads. This suggests that it may be important to achieve some superposition of stimulation fields as suggested by modeling results [4].

### References


### Acknowledgements

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