A PROSPECTIVE CLINICAL TRIAL TO ASSESS HIGH FREQUENCY SPINAL CORD STIMULATION (HF-SCS) AT 10 KHz IN THE TREATMENT OF CHRONIC INTRACTABLE PAIN FROM PERIPHERAL POLYNEUROPATHY (PPN)

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Introduction

Peripheral neuropathy is caused by damage to or dysfunction of peripheral nerves, resulting in pain, numbness, and/or weakness. Damage may affect small myelinated Aδ and unmyelinated C fibers along with injury to large myelinated fibers. The goal of this study is to assess the safety and effectiveness of periaesthesia-independent, high frequency SCS (HF-SCS) at 10 kHz in the treatment of chronic intractable pain from peripheral polyneuropathy.

Materials & Methods

- Enrolled: 28
- Failed Screening: 2
- Trialed: 26

Diagnoses (n=18)*
- Idiopathic polyneuropathy (n=15)
- Painful diabetic neuropathy (PDN, n=9)
- Medication induced polyneuropathy (n=1)
- Trauma induced polyneuropathy (n=1, surgery)
- Radiation induced polyneuropathy (n=1)
- Hereditary polyneuropathy (n=1)
- Some subjects have multiple diagnoses

Results: Trial Stimulation

Subjects

<table>
<thead>
<tr>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>9 (50.0)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (50.0)</td>
</tr>
</tbody>
</table>

Age (N=18) Years

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>Median</th>
</tr>
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<tbody>
<tr>
<td>62.8</td>
<td>11.3</td>
<td>42.6</td>
<td>79.0</td>
<td>66.4</td>
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</tbody>
</table>

Results: Demographics and Etiology

Sex

<table>
<thead>
<tr>
<th>Race</th>
<th>N</th>
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</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>16</td>
<td>88.9</td>
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<tr>
<td>Black/African-American</td>
<td>2</td>
<td>11.1</td>
</tr>
</tbody>
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Results: Safety

- Procedure related – 4
- 3 AES, 1 SAE (All resolved)
- Non-study related – 13
- 7 AES, 6 SAEs
- No neurological deficits

Results: Global Impression of Change

Conclusions

Results from this multicenter study demonstrate that HF-SCS at 10 kHz provides clinically meaningful and sustained pain relief in subjects with PPN with concomitant improvement in quality of life and pain interference. Subjects also reported improvements in neurological assessments.