Clinical Highlights

Anchoring DRG-S Leads Reduces Rate of Lead Migration and Fracture — A Multicenter Pooled Data Analysis¹


OVERVIEW

Dorsal root ganglion (DRG) stimulation is clinically proven to provide superior* and sustainable pain relief and quality of life improvement for patients with CRPS I or causalgia due to traumatic or surgical nerve injury (CRPS II).² While the DRG therapy pivotal randomized controlled trial demonstrated comparable DRG migration rates to spinal cord stimulation (SCS),² recent studies found higher than expected DRG lead migration and fracture incidences.¹ Continued study of the technology has led to data-backed best practices and procedural techniques. The goal of this study was to investigate one such technique: the influence of lead anchoring on migrations and fractures through a retrospective review of individuals implanted with DRG stimulation systems (Abbott’s Axium™ and Proclaim™ DRG Neurostimulation Systems).

STUDY SUMMARY

The study was a retrospective, multicenter pooled data analysis. The data was collected from 249 patients equating to 756 DRG-S leads implanted from 2016 to 2020 from four centers in the United States. Lead migration and fracture rates were compared between anchored and unanchored leads in the entire study cohort. Anchoring techniques included use of Abbott’s proprietary silastic anchor or suture tie fixation. Lead migrations and fractures were confirmed either radiologically or with the clinician programmer to identify lead shift or structural compromise.

KEY RESULTS

- Anchoring DRG-S leads results in significantly lower rates of lead migration.
- Unanchored leads were 6x more likely to migrate than anchored leads.
- Of the two different anchoring techniques studied, Abbott’s proprietary silastic anchor resulted in a lower migration rate per lead compared to suture tie fixation leads [silastic anchor: 0.6%; suture tie: 2.5%].
- Unanchored leads were 1.6x more likely to fracture than anchored leads.

Figure 1:

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<table>
<thead>
<tr>
<th>Anchored Leads (N = 565)</th>
<th>Anchored with Abbott’s proprietary Silastic Anchor (N = 324)</th>
<th>Anchored with Suture Tie (N = 241)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migration Rate</td>
<td>0.6%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Fracture Rate</td>
<td>2.2%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Unanchored Leads (N = 191)

<table>
<thead>
<tr>
<th>Fracture Rate</th>
<th>Migration Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1%</td>
<td>8.4%</td>
</tr>
</tbody>
</table>

N = 249 Patients
756 ImPLanted DRG-S Leads

Survival distribution out to a minimum of ~50 months
CONCLUSIONS

- Less than 1% of leads anchored with Abbott’s proprietary silastic anchor experienced migration.
- Strain relief loops alone may not always be sufficient in securing DRG-S leads, and anchoring should be the surgical standard.
- Anchoring leads does not increase fracture rates; absolute fracture percentages unadjusted for observation time were higher in the unanchored cohort.

Figure 2: Tunneled epidural catheter technique, a superficial stab incision at the skin and no lead anchoring. Note transection of superficial fascial plane, which can potentially contribute to lead fracture.

Figure 2a

Figure 2b

Abbott-approved labeling recommends anchoring of all Proclaim™ DRG leads. Failure to comply with the anchoring technique may result in lead migration and/or motor activation or painful stimulation.

*When compared to traditional tonic SCS based on outcomes from the ACCURATE investigational device exemption study.


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One St. Jude Medical Dr., St. Paul, MN 55117 USA
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Brief Summary: Prior to using Abbott devices, please review the Clinician’s Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: U.S.: Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

**Indicates a trademark of the Abbott group of companies.

Adverse Effects:

- Unanchored leads, often placed through small incisions with a shallow lead tunneling angle, may increase the likelihood of entrapment of the lead in the superficial fascial plane (Figure 2), hence increasing the risk of fracture.
- The larger incision required to achieve adequate depth for anchoring may reduce the risk of lead entrapment in the superficial fascia and thus reduce the risk of lead fracture (Figure 3).

Figure 3: Implant technique demonstrating anchoring of a lead deep into the membranous plane, with subsequent passing of the tunneling device deep into the membranous layer to avoid entrapment within the fascial plane.

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Warnings/Precautions:

- Patients who are unable to operate the system, are poor surgical risks, have failed to receive effective pain relief during trial stimulation, or are poor candidates for another modality of therapy.
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Contraindications: U.S.: Patients who are unable to operate the system, who are poor surgical risks, are poor candidates for another modality of therapy.

International: Management of chronic intractable pain.

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Indications for Use: International: Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.

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Figure 2

Figure 3

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