Clinical Highlights

A non-industry sponsored study

Anchoring DRG-S Leads Reduces Rate of Lead Migration and Fracture — A Multicenter Pooled Data Analysis[1]

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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).

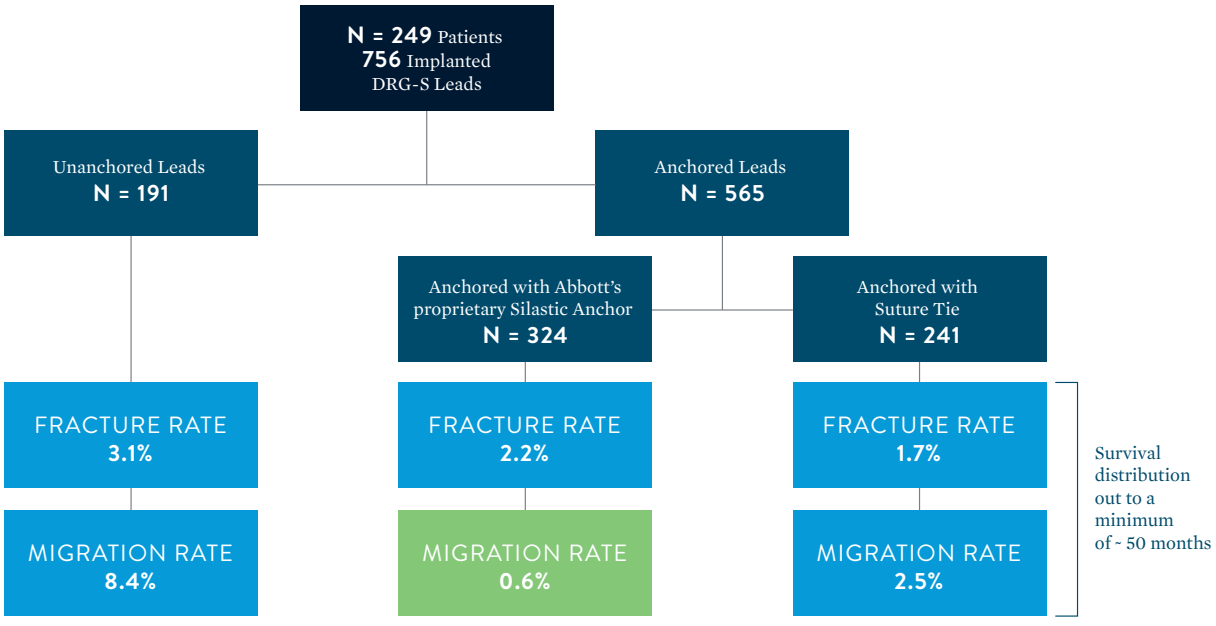
STUDY SUMMARY

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 fixated leads [silastic anchor: 0.6%; suture tie: 2.5%].
- Unanchored leads were 1.6x more likely to fracture than anchored leads.

Figure 1:



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.
- 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.[3]
- 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**).[3]

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

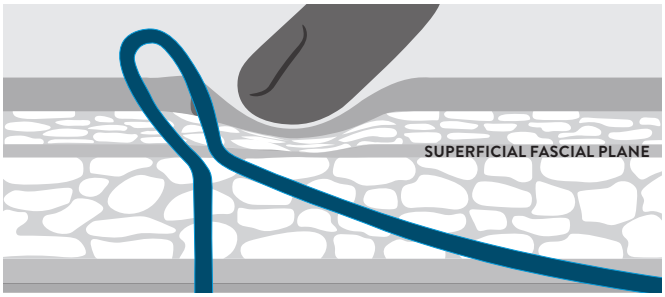


Figure 2b

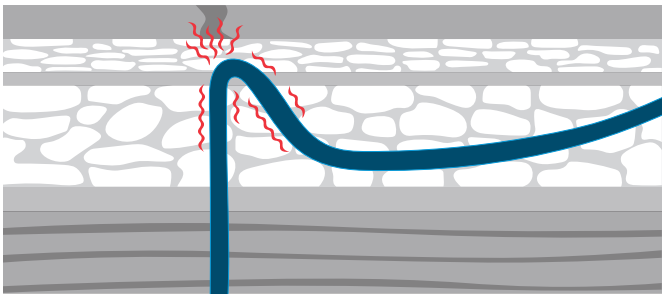
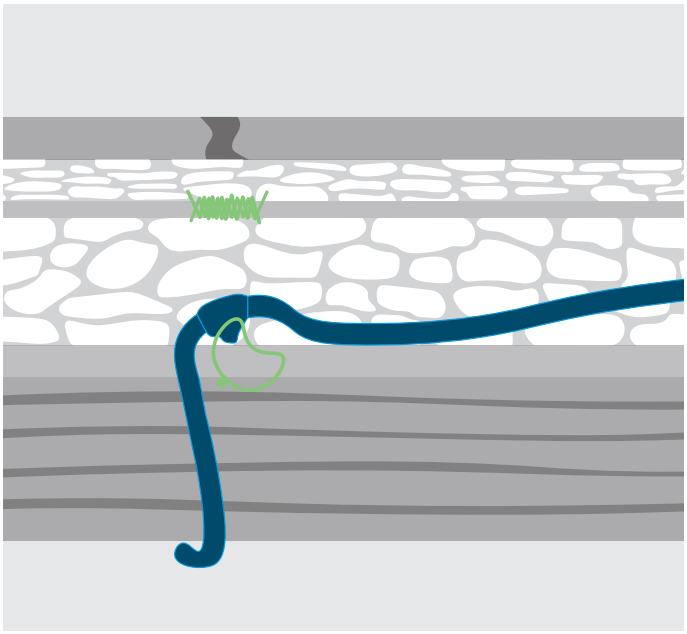


Figure 3: Implant technique demonstrating anchoring of a lead deep into the membranous plane, with subsequent passing of the tunneling device deep into the membranous layer to avoid entrapment within the fascial plane.



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.

1. Chapman KB, Mogilner AY, Yang A, et al. Lead Migration and Fracture Rate in Dorsal Root Ganglion Stimulation Using Anchoring and Non-Anchoring Techniques: A Multicenter Pooled Data Analysis. *Pain Practice*. Published online June 18, 2021.
2. Deer T, Levy R, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017;158(4):669-681.
3. Chapman KB, Patel KV, van Helmond N, Chang Chien GC. Dorsal Root Ganglion Stimulation Lead Fracture Within the Superficial Fascial Layers in 4 Cases. *A&A Practice*. September 2020;14(11):e01307.

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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.

**Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively. CRPS II (causalgia) is defined as a painful condition arising from damage to a nerve. Nerve damage may result from traumatic or surgical nerve injury. Changes secondary to neuropathic pain seen in CRPS I (RSD) may be present, but are not a diagnostic requirement for CRPS II (causalgia).

International: Management of chronic intractable pain.

Contraindications: U.S.: Patients who are unable to operate the system, who are poor surgical risks. Patients who have failed to receive effective pain relief during trial stimulation. **International:** Patients who are unable to operate the system, are poor surgical risks, are pregnant, or under the age of 18.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive and flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pediatric use, pregnancy, and case damage.

Adverse Effects: Unpleasant sensations, undesirable changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, tissue damage or nerve damage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain where needle was inserted or at the electrode site or at IPG site, seroma at implant site, headache, allergic or rejection response, battery failure and/or leakage. Clinician's Manual must be reviewed for detailed disclosure.

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