

St. Jude Medical Dorsal Root Ganglion (DRG) Stimulator Procedure and The Rowe S1/S2 Lead Placement Technique

Allow for a Lead Placement at the S1/S2 Level Utilizing a Transforaminal Approach with Epidural Lead Strain Relief S-Curves to Anchor.

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Introduction

CRPS Type I & CRPS Type II lower extremity pain (i.e., foot, knee, hip, groin) associated with focal chronic intractable pain affects hundreds of thousands of patients every year in the United States alone.

Research has shown that DRG stimulation is clinically superior to conventional tonic SCS in treating lower extremity pain (i.e., foot, knee, hip, groin) associated with focal chronic intractable pain, due to CRPS I and CRPS II.

The stimulation of the DRG allows for the ability to precisely stimulate specific regions of the dermatome that is otherwise difficult to individually target with broadly applied traditional SCS therefore DRG stimulation provides a therapy option for patients with focal chronic intractable pain, due to CRPS, who were not optimal candidates for conventional tonic SCS.

The Rowe S1/S2 Lead Placement Technique is used for the transforaminal placement of S1/S2 Dorsal Root Ganglion (DRG) leads utilizing a specific sequence of steps to allow for the accurate deployment of the S1/S2 lead adjacent to the S1/S2 DRG on the right or left followed by the steps necessary to place Epidural strain relief S-Curves to anchor.

Case Description

In this case St. Jude Medical Axium™ Neurostimulator System –the only FDA-approved system specifically designed to stimulate the dorsal root ganglion (DRG) was used to treat CRPS II in a patient who had suffered a minor right ankle sprain/strain injury which lead to the development of CRPS II. This patient was a 30 year old female with an initial minor right ankle sprain/strain injury diagnosed as tarsal tunnel syndrome. Related to this diagnosis she underwent a tarsal tunnel release which further added to the description of severe burning/stabbing pain with severe allodynia and dysesthesias . After the diagnosis of CRPS was made she had progressively worsening pain over the next 2 years dramatically impacting her quality of life and adversely impacting her ability to perform Activities of Daily Living.

Note that the following is a description of the Rowe S1/S2 Lead Placement Technique for the treatment of CRPS Type I & CRPS Type II and lower extremity pain associated with focal chronic intractable pain. The specific steps included below and methods described here may be employed by the Physician/Surgeon for cases which include S1 dermatome symptomatology.

Surgical Method

S1 Foramial Identification and Introducer Needle Placement

1. The patient is placed on the OR x-ray table in the prone position.
2. Fluoroscopic imaging of the patient's lumbosacral spine is obtained in an AP view appropriately angled to best visualize the S1 foramen.
3. The patient is then prepped and draped utilizing a standard surgical prep and drape technique.
4. With S1 DRG lead placement utilizing a transforaminal approach on the right, the 5 o'clock position on the bony perimeter of the right S1 foramen is identified fluoroscopically. With S1 DRG lead placement utilizing a transforaminal approach on the left, the 7 o'clock position on the bony perimeter of the left S1 foramen as identified fluoroscopically.
5. The skin and subcutaneous tissue overlying the right and/or left S1 foramen is anesthetized utilizing 1-2 cc of 1% lidocaine.
6. The straight introducer needle supplied within the DRG kit supplied by St. Jude medical is then used to penetrate the skin perpendicular to the skin with the bevel of the needle facing in a caudal direction and is then advanced through the subcutaneous tissues to contact the bony edge of the right S1 foramen at the 5 o'clock position to determine accurately S1 foraminal depth. If the foramen to be accessed is the left S1 foramen a straight introducer needle would be utilized to penetrate the skin perpendicular to the skin with the bevel of the needle facing in a caudal direction and would be advanced through the subcutaneous tissues to contact the bony edge of the left S1 foramen at the 7 o'clock position to determine accurately the S1 foraminal depth.
7. With the bevel of the needle maintained in a caudal direction the needle is stepped off the bone edge from the 5 o'clock position of the right S1 foramen and the hub end of the introducer needle is angled 10-15° cranially and 10-15° to the right when accessing the right S1 foramen. When accessing the left S1 foramen the hub and of the introducer needle is angled 10-15° cranially and 10-15° to the left after stepping off the bone edge from the 7 o'clock position.
8. Prior to advancing the needle into the S1 foramen on the right or left the bevel of the needle requires repositioning angled medially by 45° turned clockwise when accessing the right S1 foramen and turned counterclockwise when accessing the left S1 foramen.
9. The straight introducer needle is then advanced through the S1 foramen on the right or left approximately 1 cm to 1.5 cm.

S1 Transforaminal Sheath and Lead Placement

10. The DRG introducer sheath with the large curve is then loaded with the DRG lead with approximately 1 mm of the lead tip exposed beyond the blunt edge of the introducer sheath. The DRG introducer sheath hub should be snugly locked around the DRG lead to maintain proper positioning of the lead within the introducer sheath displaying 1 mm of the lead tip exposed to be on the blunt edge of the introducer sheath.

11. The stylette is now removed from the introducer needle positioned appropriately within the S1 foramen ensuring the depth and positioning of the needle is maintained throughout the stylette removal process. The DRG introducer sheath containing the DRG lead appropriately locked into position is then advanced through the introducer needle ensuring that the introducer sheath injection port is pointing caudal and inferior while maintaining the introducer needles position and depth during the process of advancing to sheath through the introducer needle.

12. When the introducer sheath reaches a depth where the first white band on the introducer sheath enters the hub of the introducer needle the lead should be exiting the introducer needle into the S1 foramen.

13. The sheath containing the DRG lead with the injection port in a downward direction should be advanced into the S1 foramen while fluoroscopically imaging the advancing lead live and in a lateral view. The sheath and DRG lead should be advanced through the S1 foramen until one DRG contact is positioned ventral to the sacrum when imaged laterally.

14. The DRG lead sheath hub is then loosened to allow the sheath to be back off the lead until the radio opaque marker at the distal end of the sheath is contained within the introducer needle well maintaining the depth of the DRG lead with one contact ventral to the sacrum visualized with live fluoroscopy during the sheath retraction process.

15. Once the sheath radio opaque marker is within the introducer needle to protect the sheath from shearing testing of the DRG lead position can begin utilizing the expertise of the St. Jude medical DRG stimulator representative to facilitate programming and optimization of programming for adequate testing of lead position.

S1 Introducer Needle Depth Positioning and Verification

16. After verifying appropriate lead depth and position through intraoperative testing with the St. Jude Medical DRG specialist facilitating this testing the introducer sheath and introducer needle are withdrawn as a single unit under live fluoroscopy to lie just inside the inner foraminal edge at the upper edge of the epidural space.

S1 Anchoring S-curve Placement

17. As a unit the sheath contained within the introducer needle and the introducer needle itself are rotated 180° to position the bevel and injection port cranial in an upward facing position.

18. Using the mechanical advantage of the large curved sheath, the lead and sheath are advanced through the epidural space to form the upper part of the epidural anchoring S-curve. Once an S-curve of adequate size, not advanced beyond the S1 and plate, is formed the lead is maintained in position while retracting the sheath off the lead to allow the radio opaque marker to lie protected within the introducer needle.

19. Once the sheath radio opaque marker is within the introducer needle to protect the sheath from shearing the introducer sheath and introducer needle are rotated 180° as a unit to allow the bevel of the introducer needle and injection port of the large curved sheath to lie in a downward facing position.

20. Using the mechanical advantage of the large curved sheath, the lead and sheath are advanced through the epidural space to form the lower part of the epidural anchoring S-curve. Once an S-curve of adequate size is formed the lead is maintained in position while retracting the sheath off the lead to allow the radial opaque marker to lie protected within the introducer needle.

21. Once appropriate lead depth is verified in the lateral and AP view the sheath can be retracted off the lead well maintaining lead position. After full removal of the DRG lead introducer sheath the introducer needle is removed off the lead well ensuring maintenance of lead positioning.

22. The steps utilized to place needles and leads at the S1 level on the right and left can be used to place leads through a transforaminal approach at the S2 level on the right or left.

Outcome and Conclusion

St. Jude Medical DRG stimulator System, when utilized with appropriate steps taken to ensure sheath protection within the needle during needle manipulation and bevel repositioning, allowed for transforaminal S1 DRG lead placement with anchoring S-curves to be placed safely within the epidural space consistently and reproducibly. Stabilization of the DRG leads by bony anatomy and S-curve anchoring of DRG leads allowed for consistent S1 dermatome coverage during intraoperative testing and postoperatively during the DRG stimulator trial. Follow-up assessment utilizing AP and lateral x-ray imaging obtained following DRG stimulator trials and 7-10 days post permanent implantation of DRG leads utilizing the above steps to place S-curve anchors at the S1 level determined that leads remained in position with no change in lead depth or configuration and that there was no change in S-curve anchor size or configuration.