Abstract

STIMFIX™: Innovative Percutaneous Spinal Cord Stimulation Trial Anchoring Technology demonstrates significantly less lead migration compared to various other anchoring techniques: An Interim Analysis of a prospective, single-arm, open label, Multicenter study.

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Objective: Spinal cord stimulation (SCS) is a well-established treatment option for chronic pain conditions. One of the most common complications during the trial period is lead migration which can compromise its therapeutic efficacy. Although attaining zero-lead migration is challenging, providers take every measure to minimize the lead migration, with the anchoring technique being the most crucial. To date, three conventional lead anchoring techniques include Suture, Tape, and Manufacturer Anchor. This interim Analysis has compared the lead migration observed with innovative non-invasive STIMFIX™ anchoring technology to the migration observed with the three conventional anchoring methods.

Methods: This Interim Analysis has compared the outcomes of two prospective data sets.

Group 1: Twenty-eight individuals of age 27 or older who are scheduled for a 7-day percutaneous SCS trial are enrolled in the study. Individuals are assigned to one of three lead anchoring groups: nine with manufacturer anchor, ten with adhesive tape alone, and nine with a simple suture technique. Fluoroscopy was used to determine the position of the lead, and images were taken on the following time points, Day1, 3, and 7 prior to the lead removal. A standardized fluoroscopy measurement protocol was used to measure the lead migration.

Group II: STIMFIX™ Twenty individuals were prospectively enrolled under STIMFIX™ lead anchoring placement. A total of 40 leads were anchored with STIMFIX™. Fluoroscopy images were obtained at the following time points: On day 1, after the procedure and STIMFIX™ placement, an image was taken in lateral decubitus position, which is taken as a baseline and compared to the image taken before the lead removal on the seventh day (D7) of post-trial follow-up. Lead migration is assessed by standardized fluoroscopy measurement protocol.

Results: Interim Analysis has found that the average migration of STIMFIX™ is 19.59 millimeters, compared to 21.1 millimeters for sutures, 29.4 millimeters for tape, and 33.5 millimeters for manufacturer anchors. A one-way ANOVA analysis within group 1 has demonstrated no significant difference between the three commonly used anchoring techniques ($p=0.404$), Group 1 and Group 2 raw data were presented for comparison. In addition, no major adverse events were reported within Group II (NCT05651646).

Conclusion: During the post-trial period, percutaneous trail lead migrates, with inferior migration occurring most frequently. Lead anchoring techniques play a major role in reducing lead migration. Compared to suture, tape, and manufacturer anchors, a novel, non-invasive STIMFIX™ lead anchoring technique has demonstrated promising results with minimal lead migration and the added benefit of improving providers' efficiency.