Abstract: 3548

Scientific Abstracts > Chronic Pain

3-Year Durability of Symptom Relief with Restorative Neurostimulation for Chronic Mechanical Low Back Pain

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Introduction

Mechanical chronic low back pain (CLBP) can be caused by impaired neuromuscular control and degeneration of the multifidus muscles, the most important stabilizers of the lumbar spine.
An implantable Restorative Neurostimulation system bilaterally stimulates the medial branches of the L2 dorsal rami to override underlying multifidus inhibition to facilitate motor control restoration.[1]
The ReActiv8-B randomized sham-controlled pivotal trial provided evidence of safety, effectiveness, and durability of this therapy (clinicaltrials.gov/show/NCT02577354).[2,3] Here we report the three-year durability results.

Materials and Methods

Eligible patients had activity limiting mechanical CLBP (VAS ≥6cm; Oswestry Disability Index (ODI) ≥21 points) despite medical management, which included at least pain medications and physical therapy. They had evidence of impaired multifidus motor control (positive prone instability test) and no indication for spine surgery. All participants were implanted with a restorative neurostimulation system (ReActiv8® by Mainstay Medical) and during the long-term follow-up phase self-administered up to 60-minutes of stimulation per day and were followed up at 1, 2 and 3 years. The study was performed under an investigational device exemption (IDE), the investigational plan was approved by the institutional review boards (IRB) and informed consents were obtained from all participants.

Results/Case Report

At baseline (N=204), participants were 47±9 years of age, had history of backpain for 14±11 years, had an average low back pain VAS of 7.3±0.7 cm, ODI of 39±10, EQ-5D of 0.585±0.174 points and had pain on 97±8% of days in the year prior to enrollment.
Three-year ReActiv8-B data are available for 133 participants. Average LBP-VAS improved by 4.9±0.2 cm (mean± SE) or 67%, ODI by 22.7±1.3 points (59%) and EQ-5D by 0.220±0.017 ($P<0.0001$ for all outcome measures); 77% of participants had a ≥50% LBP-VAS improvement; 67% reported LBP-Resolution (LBP-VAS≤2.5 cm); 63% had a ≥20-point ODI improvement and 86% of participants were

“definitely satisfied” with the treatment. Pain intensity and disability are interdependent symptoms and treatment success is determined by composite improvements in ODI and LBP-VAS: 83% had a substantial improvement of ≥50% in LBP-VAS and/or ≥20points in ODI, and 56% had these improvements in both LBP-VAS and ODI. Of participants using opioids at baseline, 71% had voluntarily discontinued (49%) or decreased (22%) consumption. The overall safety profile is favorable compared to other neurostimulation systems and no lead migrations were observed.

Figure 1 compares the complete-case analyses (N=133) and the analysis including all participants (N=204) using a principled imputation strategy based on reason for missingness.

Discussion

The 3-year results of the pivotal trial show that restorative neurostimulation is an effective, durable, and safe treatment option for patients with intractable CLBP and multifidus muscle dysfunction, who have no indications for spine surgery, and are refractory to conservative care including physical therapy and medications. Consistent with mechanism of restoration of neuromuscular control and muscle rehabilitation, participants demonstrated improvements in pain, disability and healthcare related quality of life that increased with treatment duration.
The relatively small attenuation of effectiveness measures across all outcome measures between the completed-case and imputed (N=204) analyses, and the statistical significance and clinical relevance of results in both, instills confidence in the robustness of our data and the validity of the conclusions drawn.

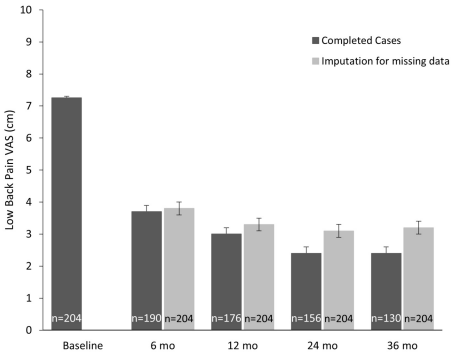
References

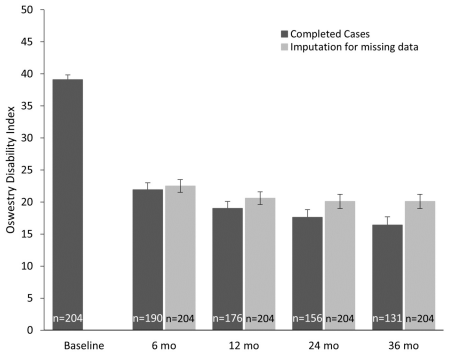
[1] Russo M, Deckers K, Eldabe S, Kiesel K, Gilligan C, Vieceli J, Crosby P. Muscle Control and Non-specific Chronic Low Back Pain. Neuromodulation. 2018 Jan;21(1):1-9. doi: 10.1111/ner.12738.
[2] Gilligan C, Volschenk W, Russo M, Green M, Gilmore C, Mehta V, Deckers K, De Smedt K, Latif U, Georgius P, Gentile J, Mitchell B, Langhorst M, Huygen F, Baranidharan G, Patel V, Mironer E, Ross E, Carayannopoulos A, Hayek S, Gulve A, Van Buyten JP, Tohmeh A, Fischgrund J, Lad S, Ahadian F, Deer T, Klemme W, Rauck R, Rathmell J, Levy R, Heemels JP, Eldabe S; ReActiv8-B investigators. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. 2021 Oct 1;162(10):2486-2498. doi: 10.1097/j.pain.0000000000002258.
[3] Gilligan C, Volschenk W, Russo M, Green M, Gilmore C, Mehta V, Deckers K, De Smedt K, Latif U, Georgius P, Gentile J, Mitchell B, Langhorst M, Huygen F, Baranidharan G, Patel V, Mironer E, Ross E, Carayannopoulos A, Hayek S, Gulve A, Van Buyten JP, Tohmeh A, Fischgrund J, Lad S, Ahadian F, Deer T, Klemme W, Rauck R, Rathmell J, Maislin G, Heemels JP, Eldabe S; ReActiv8-B Investigators. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. Neuromodulation. 2021 Dec 18:S1094-7159(21)06386-8. doi: 10.1016/j.neurom.2021.10.011. Epub ahead of print.

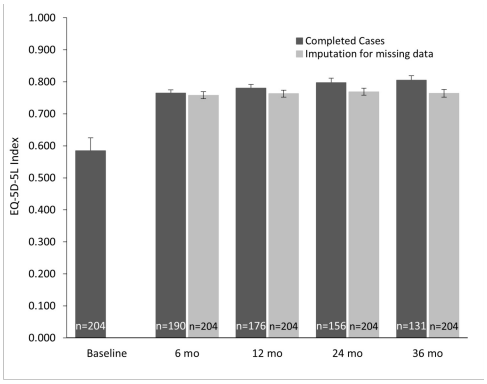
Disclosures

Yes

Tables / Images


Low Back Pain VAS (cm)
Completed Cases
Imputation for missing data
n=204
n=190 n=204
n=176 n=204
n=156 n=204
n=130 n=204
Baseline
6 mo
12 mo
24 mo
36 mo


Oswestry Disability Index
Completed Cases
Imputation for missing data
n=204
n=190 n=204
n=176 n=204
n=156 n=204
n=131 n=204
Baseline
6 mo
12 mo
24 mo
36 mo


EQ-5D-5L Index
Completed Cases
Imputation for missing data
n=204
n=190 n=204
n=176 n=204
n=156 n=204
n=131 n=204
Baseline
6 mo
12 mo
24 mo
36 mo