ReActiv8®

Two-Year ReActiv8-B Trial Data Summary

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 Journal. Dec 2021. Gilligan et. al.

- **72%** of participants had ≥50% pain relief
- **67%** reported CLBP resolution (VAS ≤ 2.5 cm)
- **62%** had a reduction in ODI of ≥20 points
- **77%** had substantial improvements of ≥50% in VAS and/or ≥20 points in ODI
- **57%** had substantial improvements in both VAS and ODI

Transparent and Robust Data

The completed-case (N=156) and intention-to-treat analyses (N=204) demonstrated clinically substantial and statistically significant improvements across all outcome measures and follow-up intervals.

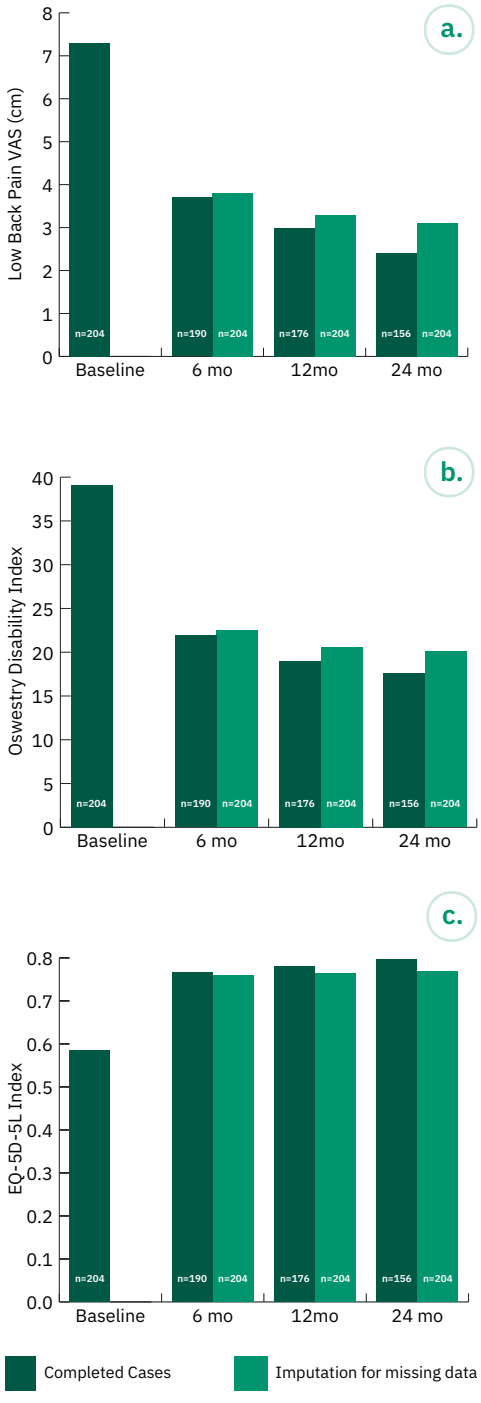
The small difference between both methods instills confidence in the robustness of the data and the validity of the conclusions drawn.

Clinically Meaningful Conclusions

Two-year results show durable, statistically significant, and clinically substantial benefits in patients with severe, disabling CLBP and multifidus muscle dysfunction who were refractory to conservative care, including physical therapy and medications.

Patients reported improvements in pain and disability that increased the longer they were treated. This recovery trajectory is consistent with restoration of neuromuscular control of lumbar spine stability.

The ReActiv8-B Trial demonstrated a strong safety profile for ReActiv8 (particularly compared to spinal cord stimulator devices). Among 204 randomized patients, 8 serious adverse events (SAEs) related to the device/procedure were reported (4 percent overall) at the 120-day mark. There were no unanticipated SAEs related to the device/procedure, and no instances of lead migration. (Among all adverse events, 53 percent occurred within the first 30 days; 83 percent of all related adverse events were resolved.) See mainstaymedical.com/safety.



Mean ratings over time for a. low back pain VAS, b. Oswestry disability index, and c. EQ-5D-5L index. All changes from baseline are significant (p < 0.0001). Error bars represent the standard error of the mean.

620070 Rev. A