



Four Year ReActiv8-A Trial Data Summary

Neuromodulation: Technology at the Neural Interface

Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain

Neuromodulation Journal. July 2021. Mitchell et. al.

Durability Validates Restorative Mechanism

Four-year follow up of the ReActiv8-A study patients. ReActiv8-A is the open label single arm study that led to CE mark approval. The original paper presented 1 year data that showed clinically meaningful effects. This paper shows that these effects are maintained over the long term, as expected from a restorative mechanism.

- **4 year** clinically meaningful and durable data
- **73%** of Completers showed improvement ≥ 2 points on NRS
- **76%** of Completers showed improvement ≥ 10 points on ODI
- **63%** of Completers showed improvement in both NRS and ODI
- **97%** of Completers were very satisfied with treatment

Procedural Evolution

There were originally 53 patients at baseline and 34 at the 4-year follow-up. Initially patients in the ReActiv8-A trial were implanted using a lateral approach. Lead fractures were observed which led to the development of the medial lead trajectory and updated lead designs. These changes have successfully mitigated this risk in later studies and commercial implants.

Long-Term Improvements

In participants with disabling intractable CLBP who receive long-term restorative neurostimulation, treatment satisfaction remains high and improvements in pain, disability, and quality-of-life are clinically meaningful and durable through four years.

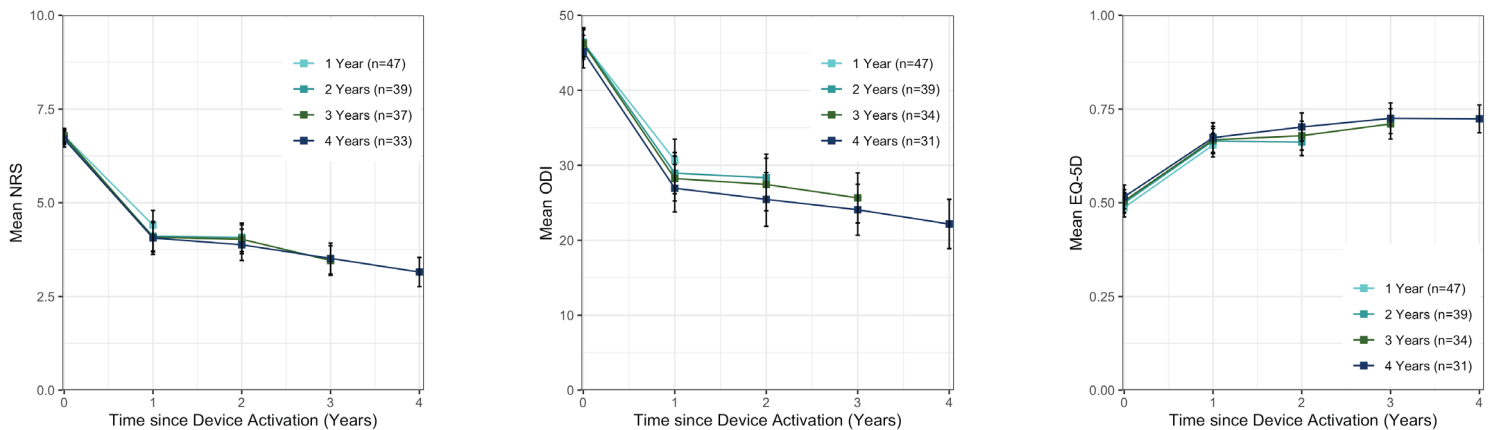


Figure. Mean \pm standard error of the mean (SEM) NRS (left), ODI (center), and EQ-5D (right) in completed cases at one to four years.

For more information on safety, efficacy, and risk, see <https://mainstaymedical.com/safety/> and https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf.