ReActiv8®

UK Post-Market Clinical Trial Data Summary

Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort

Pain and Therapy. December 2021. Thomson et. al.

- **57%** of patients experienced a substantial improvement of ≥ 50% reduction in NRS pain score
- **51%** of patients experienced a substantial improvement of ≥ 15-point reduction in ODI score
- **Excellent** safety profile compared to similarly implanted devices

Post Market Study with Consistent Results

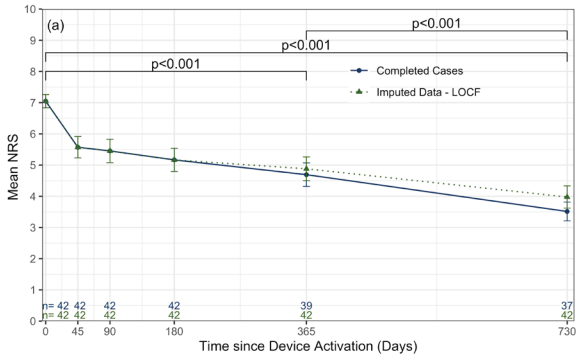
Two-year follow of patients in the Post Market Clinical Follow-up study conducted in the UK. Inclusion criteria consisted of only the device indications and patient inclusion was not supervised or controlled by Mainstay Medical.

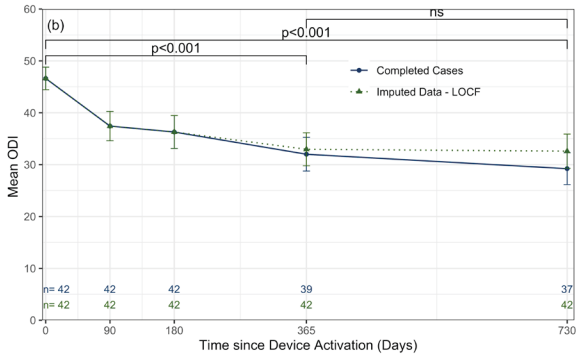
Patients with chronic mechanical low back pain benefit significantly from the episodic contraction that result from stimulation of the medial branch of the L2 dorsal ramus. Improvements in pain, disability, and health-related quality of life accrue with treatment and are durable at the 2-year follow-up.

This is consistent with the findings from the ReActiv8-B trial.

Real World Evidence of Long-Term Effectiveness

This real-world sample of patients shows that restorative neurostimulation can provide substantial and durable benefit to a cohort of patients that have traditionally had few reliable treatment options. These findings support the continued use of ReActiv8 therapy in well-selected patients.





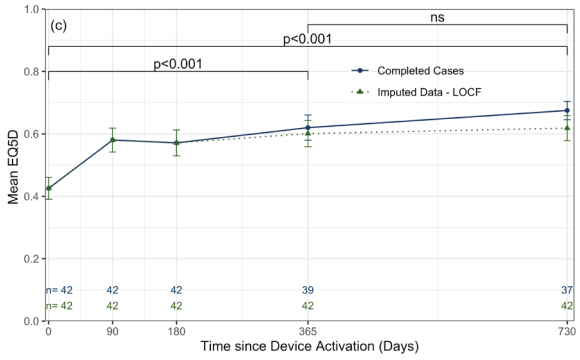


Fig. Mean ± SEM patient-reported outcomes. (a) NRS, (b) ODI, (c) EQ-5D-5L showing statistically significant improvements over baseline at all time points (repeated measures ANOVA with Bonferroni adjustment for multiplicity). Missing data were imputed using last observation carried forward.

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

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