ReActiv8®

3-Year ReActiv8-B Trial Data Summary

Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients with Chronic Low Back Pain and Multifidus Muscle Dysfunction

Neuromodulation Journal. Sept. 2022. Gilligan et. al.

3-Year Results

- **77%** of participants had ≥50% VAS reduction
- **67%** reported CLBP resolution (VAS ≤ 2.5 cm)
- **63%** had a reduction in ODI of ≥20 points
- **83%** had improvements of ≥50% in VAS and/or ≥20 points in ODI
- **71%*** voluntarily discontinued (49%) or reduced (22%) opioid intake
- **0** Lead migrations

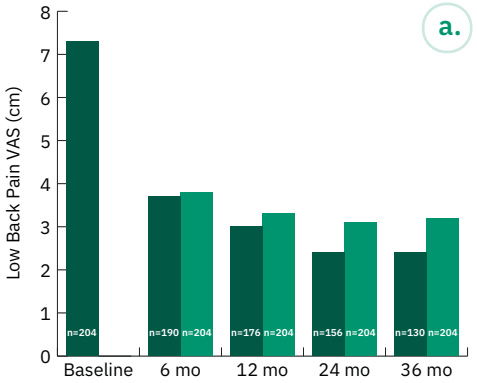
Robust Data Instill Confidence in Conclusions

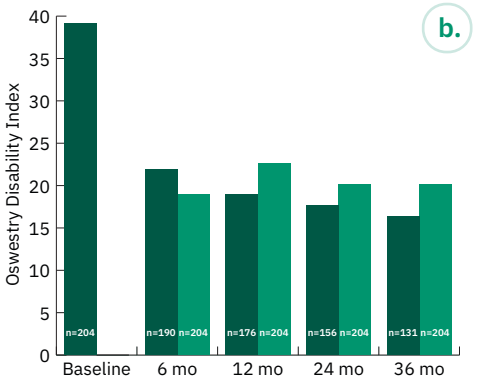
Comparison of completed case analysis (N=133) and the analysis that includes all participants (N=204) using a principled imputation method for missing data, showed a relatively small attenuation of effectiveness measures across all outcome measures.

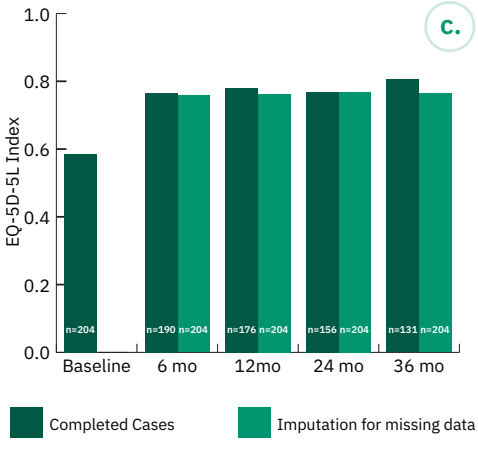
The statistical significance ($p<0.0001$) and clinical relevance of results in both analyses, instill confidence in the robustness of our data and the validity of the conclusions drawn.

Long-Term Treatment Benefits

- ReActiv8® provides an effective, durable, and safe treatment option for carefully selected patients with intractable CLBP and multifidus muscle dysfunction.
- Trajectory and durability of clinical benefits are consistent with restoration of neuromuscular control and muscle rehabilitation.
- Restorative neurostimulation does not appear to be susceptible to loss of efficacy. (i.e., decreasing effectiveness over time)
- The safety profile of the therapy remained favorable compared to available implantable neurostimulators for the treatment of other types of back pain.
- An increasing proportion of participants are eliminating or decreasing opioid consumption.







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.

*Of patients on opioids at baseline (n=36/51)

ReActiv8®

Responder Proportions at Common Clinical Importance Thresholds

d.

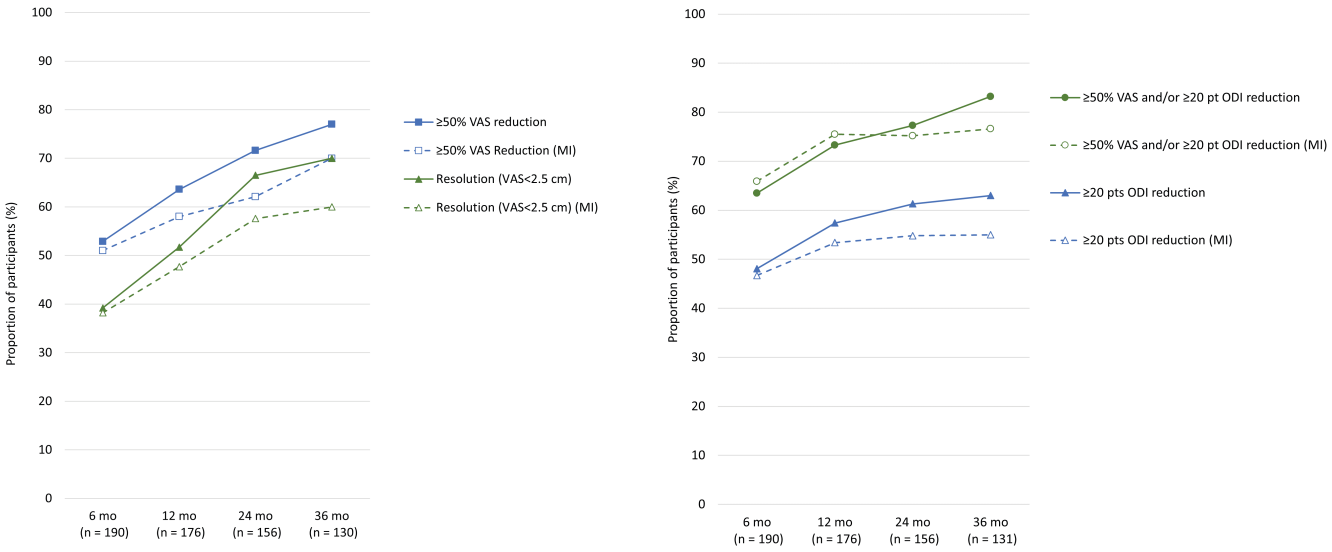


Figure d. ≥50% VAS reduction and residual VAS≤2.5 cm (left), and ≥20-point ODI reduction and composite of ≥50% VAS reduction and/or ≥20-point ODI reduction (right). Solid lines represent completed cases, dashed lines represent results with multiple imputation (MI) for missing data (N=204).

Outcome Measure Comparison by Year

Outcome Measure	1-Year Result	2-Year Result	3-Year Result
VAS Reduction ≥ 50%	64%	72%	77%
ODI Reduction ≥ 20 Points	57%	61%	63%
Resolution of CLBP (VAS < 2.5)	52%	65%	67%
Voluntarily Eliminated or Reduced Opioid Use**	48%	60%	71%

620068 Rev. B

**For patients on opioids at baseline (1-Year = 31/65), (2-Year= 34/57), (3-Year= 36/51)