

# APPLICATION OF RESTORATIVE NEUROSTIMULATION FOR CHRONIC MECHANICAL LOW BACK PAIN IN AN OLDER POPULATION WITH 2 YEAR FOLLOW-UP

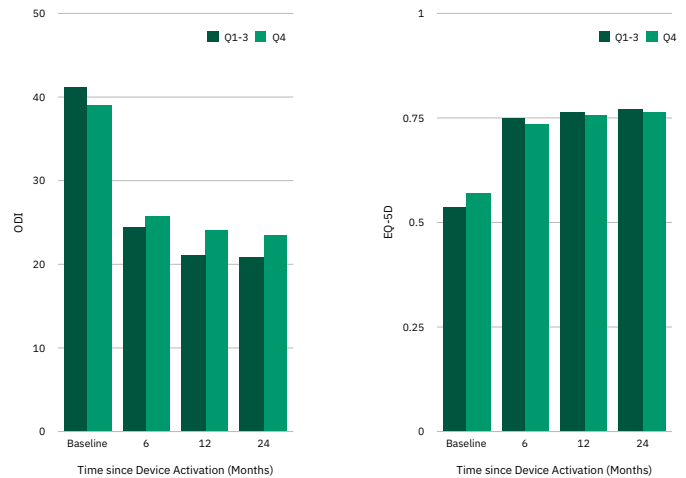
Regional Anesthesia & Pain Medicine. Accepted for Publication: January 2024. Ardeshiri A., Amann M., Thomson S., Gilligan C.



### Key Takeaways

- Data from 261 patients completing 2 year follow up from 3 clinical studies (ReActiv8-B, ReActiv8-C, and PMCF)
- Combination of RCT data and Real World Evidence
- Four equal sized cohorts analyzed based on age range (n=65)
- Statistically significant improvements in disability (ODI) and quality of life (EQ-5D-5L) were seen at all assessment time points compared to baseline.**
- Consistent improvements in pain (VAS/NRS) at all time points compared to baseline.
- Patients derived significant and clinically meaningful benefit in disability, health related quality of life, and pain, irrespective of age.**

### Younger and Older Cohort Comparison - Function & Quality of Life



Two-year complete analysis of ages 22-56 (Q1-Q3) and 56-82 (Q4) showing ODI (left) and EQ-5D-5L (right). Statistically significant improvements over baseline at all time points in all quartiles ( $p < 0.01$ ). There were no statistically significant differences between quartiles at any time point.

### Cohort Composition by Study

Group/Age Range	B Study	C Study	PMCF
Q1 (n=66)/22-43 yr.	45	11	10
Q2 (n=65)/43-49 yr.	45	9	11
Q3 (n=65)/49-56 yr.	37	20	8
Q4 (n=65)/56-82 yr.	28	29	8
<b>Total</b>	<b>155</b>	<b>69</b>	<b>37</b>

### Responder Rate - Back Pain (VAS/NRS)

		30% Δ Pain	50% Δ Pain	Remitter*
Q1-Q3 (n=196)	6 Months	67%	52%	40%
	12 Months	70%	61%	53%
	24 Months	78%	66%	61%
Q4 (n=65)	6 Months	63%	49%	45%
	12 Months	65%	57%	48%
	24 Months	75%	62%	55%

\*Remitter defined as NRS  $\leq 3$  (ReActiv8-C & PMCF) or VAS  $\leq 2.5$  (ReActiv8-B)

### Consistent Long-term Outcomes Irrespective of Age

When Restorative Neurostimulation is applied to older patients with mechanical chronic low back pain and multifidus dysfunction, the likelihood of meaningful improvement is consistent with younger ages and published outcomes.

ReActiv8 is an implantable neurostimulation device designed to restore muscle control of the lumbar spine for improved low back pain management, and indicated for managing intractable chronic low back pain associated with multifidus muscle dysfunction for adults who (i) have failed pain medications & physical therapy and (ii) are not candidates for spine surgery. ReActiv8 (Rx-only) is implanted by certified physicians in an outpatient setting. For important safety information, visit [mainstaymedical.com/safety](http://mainstaymedical.com/safety).

### Response by EQ-5D Dimension in 2 Year Completers Across Cohorts

*	Q1-Q3		Q4	
	Baseline	24 mos.	Baseline	24 mos.
Mobility	15%	4%	26%	8%
Self Care	4%	1%	2%	2%
Activities	32%	8%	22%	8%
Pain	48%	8%	42%	9%
Anxiety	5%	3%	3%	3%

\*Proportion of patients reporting a score of 4 or 5 for severe problems in that domain