

ReActiv8®

RESTORE Clinical Summary

Restorative Neurostimulation Therapy Compared to Optimal Medical Management: A Randomized Evaluation (RESTORE) Clinical Trial for the Treatment of Chronic Mechanical Low Back Pain due to Multifidus Dysfunction

Pain and Therapy. Accepted for Publication: January 2025. Frank Schwab, MD et al.



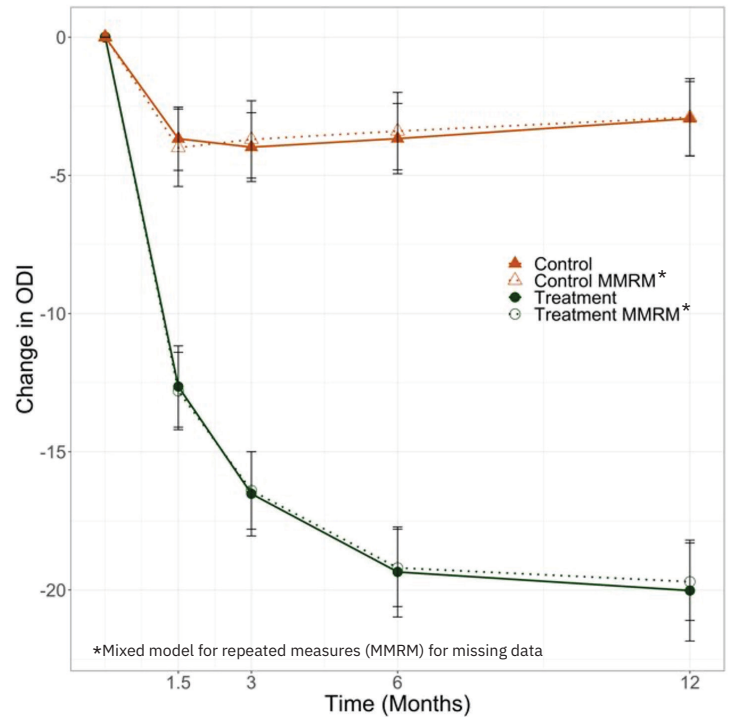
PRIMARY ENDPOINT:

Mean change in **Oswestry Disability Index (ODI)** score between the treatment and control arms at the 1-year follow-up visit:



-19.7 ± 1.4 vs. **-2.9 ± 1.4**
ReActiv8 group vs. **OMM group**

Treatment Control



Study Design

- Comparing the effectiveness of ReActiv8 vs. Optimal Medical Management (OMM) for the treatment of mechanical chronic low back pain (CLBP)
- Prospective, randomized, controlled multi-center study
- **203** patients randomized 1:1 to **ReActiv8** or **OMM**; 25 sites; average age **47** years, and an average **11-year** history of CLBP, were included in the analysis
- All patients will be followed out to 2 years

Key Takeaways

- ReActiv8 is **superior** to OMM for the treatment of mechanical chronic low back pain associated with multifidus muscle dysfunction
- **Clinically and statistically significant improvements** in:
 - Disability (Oswestry Disability Index)
 - Low back pain (NRS)
 - Health-related Quality of Life (EQ-5D)
- ReActiv8 patient improvements accumulate over time, consistent with the restorative mechanism of action
- The majority of patients treated with OMM derived no benefit or had worsening disability, pain and health related quality of life at 1-year
- ReActiv8 should be considered earlier in the care continuum for mechanical CLBP

CLINICAL AND STATISTICAL IMPROVEMENTS OVER OMM ALONE AT 1-YEAR

Endpoint	ReActiv8 Mean ± SE	OMM Mean ± SE	Difference Mean ± SE
ODI	-19.7 ± 1.4	-2.9 ± 1.4	16.8 ± 1.9
NRS	-3.6 ± 0.2	-0.6 ± 0.2	3.0 ± 0.3
EQ-5D	0.155 ± 0.012	0.008 ± 0.012	0.147 ± 0.018

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OPTIMAL MEDICAL MANAGEMENT

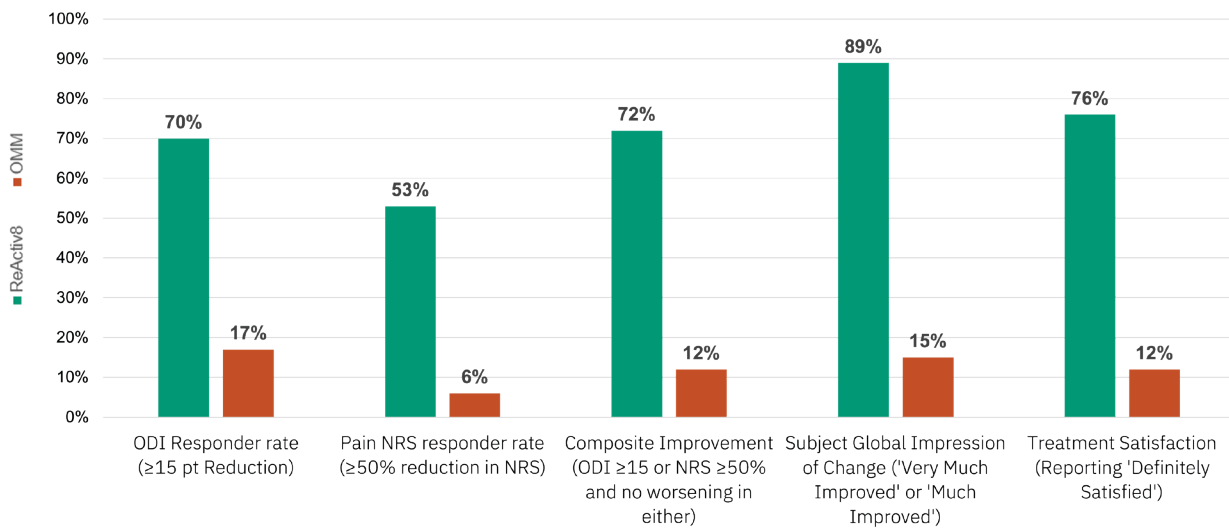
The OMM plan for the control group was individualized to each patient's specific needs and was established between the treating physician and the patient. This was documented in a standardized format prior to randomization and only considered the use of non-investigational interventions, including pharmacologic agents, physical or psychosocial therapies (e.g., physiotherapy, spinal manipulation, exercise programs, and cognitive behavioral therapy) and various spinal interventions.

Percentage of patients that had at least one of the following interventions, prior to study enrollment



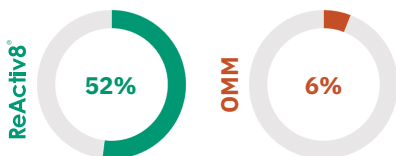
Epidural Injection	58%
Medial Branch Block	32%
Facet Joint Injection	21%
Radiofrequency Ablation	20%

KEY OUTCOMES



RESOLUTION OF PAIN

Pain resolution, defined as **NRS of ≤3** at 1-year, was observed in **52%** of patients in the ReActiv8 group and **6%** of those in the OMM group

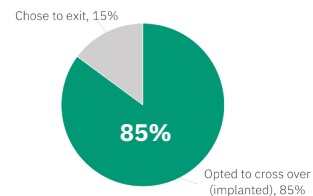


SAFETY

- No lead migrations
- Profile of related adverse events was similar to previously reported studies

CROSS-OVER

High cross-over rate: **85%** of OMM control group subjects elected to cross-over and receive the ReActiv8 implant



Established Therapy for Mechanical CLBP with Consistent Durable Outcomes

- **ReActiv8** is the most thoroughly researched neuromodulation therapy for mechanical CLBP globally
- **ReActiv8** is **superior** to Optimal Medical Management for the treatment of mechanical chronic low back pain associated with multifidus muscle dysfunction
- **ONLY** restorative therapy for patients suffering from non-surgical, mechanical CLBP evidenced by multifidus dysfunction
- **ReActiv8** is an early interventional treatment option that can significantly impact the clinical and economic burden of mechanical CLBP by reducing the need for repeated palliative treatments



The ReActiv8 System is an implantable neurostimulation system that employs a rehabilitative therapy designed to restore muscle control of the lumbar spine for improved low back pain management. ReActiv8 is a prescription device implanted by certified physicians in an outpatient setting. For important safety and product information, see www.mainstaymedical.com/safety.