



Four-Year Durability of Restorative Neurostimulation Effectiveness in Patients with Chronic Low Back Pain and Impaired Neuromuscular Control of Lumbar Spine Stability

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Background

- **Mechanical chronic low back pain** (CLBP) can result from impaired multifidus neuromuscular control
- **Restorative neurostimulation** facilitates overriding multifidus neuromuscular inhibition
- Restorative **neurostimulation sham-controlled pivotal trial 4-year data** shows long-term durability

Methods

- **Clinicaltrials.gov ID = NCT02577354**^{1,2}
- **Inclusion criteria:**
 - visual analog scale (VAS) ≥ 6 cm
 - Oswestry Disability Index (ODI) ≥ 21 points despite optimal medical management (OMM)
 - Prone Instability Test =positive for impaired motor control
 - No indicated surgery

¹Gilligan, et al. *Pain*. (2021); ²Gilligan et al. *Neuromodulation*. (2021)

Baseline Demographics

- IRB consented participants implanted with restorative neurostimulation system (*ReActiv8®*, *Mainstay Medical, Inc., Ireland*)
- N=204, mean age ($\pm$ SD) = 47($\pm$ 9) years
- Mean VAS = 7.3 $\pm$ 0.7 cm
- Mean ODI = 39 $\pm$ 10
- EQ-5D-5L = 0.585 $\pm$ 0.174 points
- 97 $\pm$ 8% pain-filled days in previous year
- 37% on opioids
- 52% failed interventional pain therapies

4-year follow-up data analysis demonstrated **restorative neurostimulation** delivered significant:

- **pain and disability reductions**
- **increased quality of life**

Patients with **refractory mechanical chronic low back pain (CLBP)**

- **reduced opioid consumption**
- **“definitely satisfied”**
- **Requested explant due to successful resolution of CLBP**

One of the few neuromodulation trials with outcomes beyond 2 years

Results

- 4-Year Data: N=115 with complete data

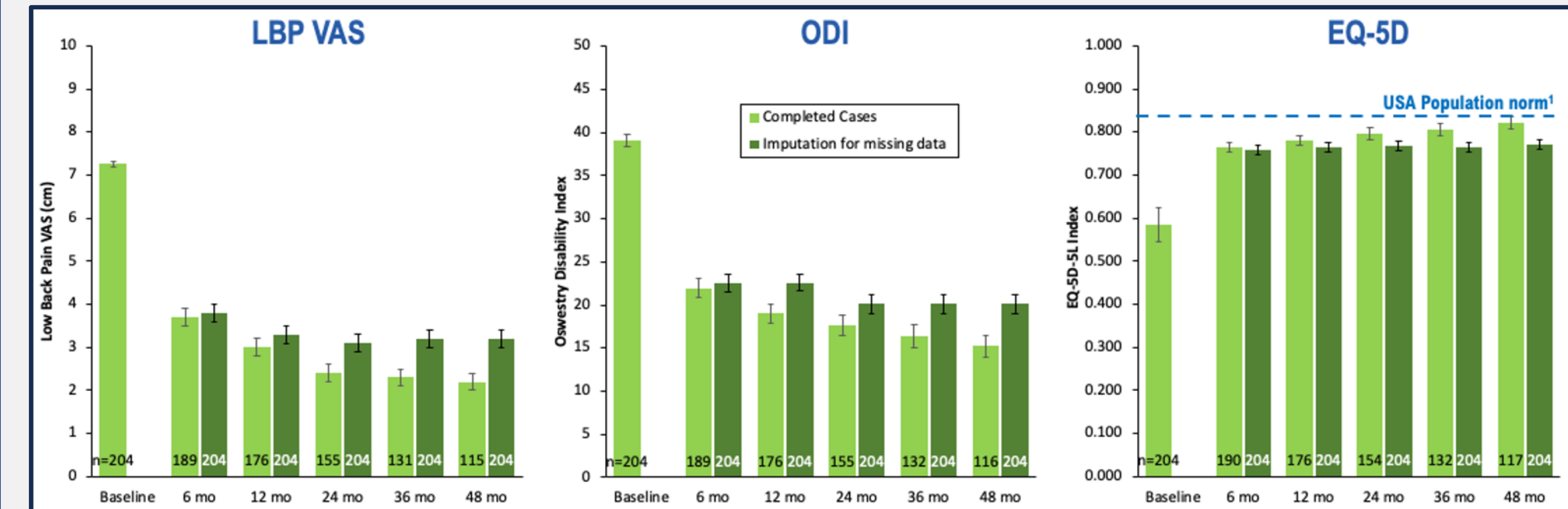


Figure 1. Restorative neurostimulation 4-year primary outcomes. Visual analog scale (VAS) reduced by 5.1 $\pm$ 2.3 cm, Oswestry Disability Index (ODI) by 23 $\pm$ 14.4 and EQ-5D-5L increased by 0.235 $\pm$ 0.206 (p<0.0001 for all outcome measures)

- 73% of participants had a $\geq 50\%$ VAS improve
- 64% reported low back pain resolution (VAS ≤ 2.5 cm)
- 63% had a ≥ 20 -point ODI improve
- Composite VAS and ODI scores: 79% had improvement of $\geq 50\%$ in VAS cm and/or ≥ 20 ODI points
- 76% using opioids at baseline showed reduced or discontinued consumption
- No lead migrations
- Explants due to inadequate relief = 26/204 (13%)
- Explants due to CLBP resolution = 12/204 (6%)

Discussion

- Restorative neurostimulation demonstrates effectiveness, durability, and safety after 4 years
- Imputed data accounted for attrition
- Effective minimally-invasive, reversible treatment for impaired multifidus neuromuscular control and refractory mechanical CLBP