



Restorative Neurostimulation for Chronic Low Back Pain – A disease modifying pain medicine therapy

Meredith Langhorst, MD --OrthoIndy, Fishers, IN, USA

Introduction

- **Chronic low back pain (CLBP)** encompasses experiences from a considerable portion of the population
- Many patients with CLBP find inadequate symptom relief from prevailing conservative management strategies
- **Restorative neurostimulation** is a disease-modifying intervention aimed at treating CLBP symptoms arising from impaired multifidus function
- **Aim:** Evaluate and present aggregate analysis from a significant volume of clinical published data across multiple clinical studies

Methods

- Data was analyzed from consented patients who underwent restorative neurostimulation implantation (ReActiv8, Mainstay Medical, Ireland) in 3 major studies:
- ReActiv8-B study (US, UK, Europe, Australia)
- ReActiv8-C study (Germany)
- ReActiv8-PMCF (UK)
- A cohort of 261 patients with complete records were identified out of 333 total in all studies
- Patient-reported outcomes were analyzed pre-operatively, and at 6-, 12-, and 24-months post-op:
- Numeric rating scale (NRS) or Visual Analog Scale (VAS) – recorded as response
- Oswestry Disability Index (ODI)
- EuroQol 5-Dimension 5-Level (EQ-5D-5L)

Combined Demographics

- N=261;
- Females=51%;
- Age_{mean}=49.1±0.7yrs;
- BMI_{mean}=28.4±0.3kg/m²

Current evidence demonstrates continued durability and efficacy with restorative neurostimulation

Patients with mechanical chronic low back pain continue to benefit in pain reduction, improved function, and quality of life over time with the implant

Results

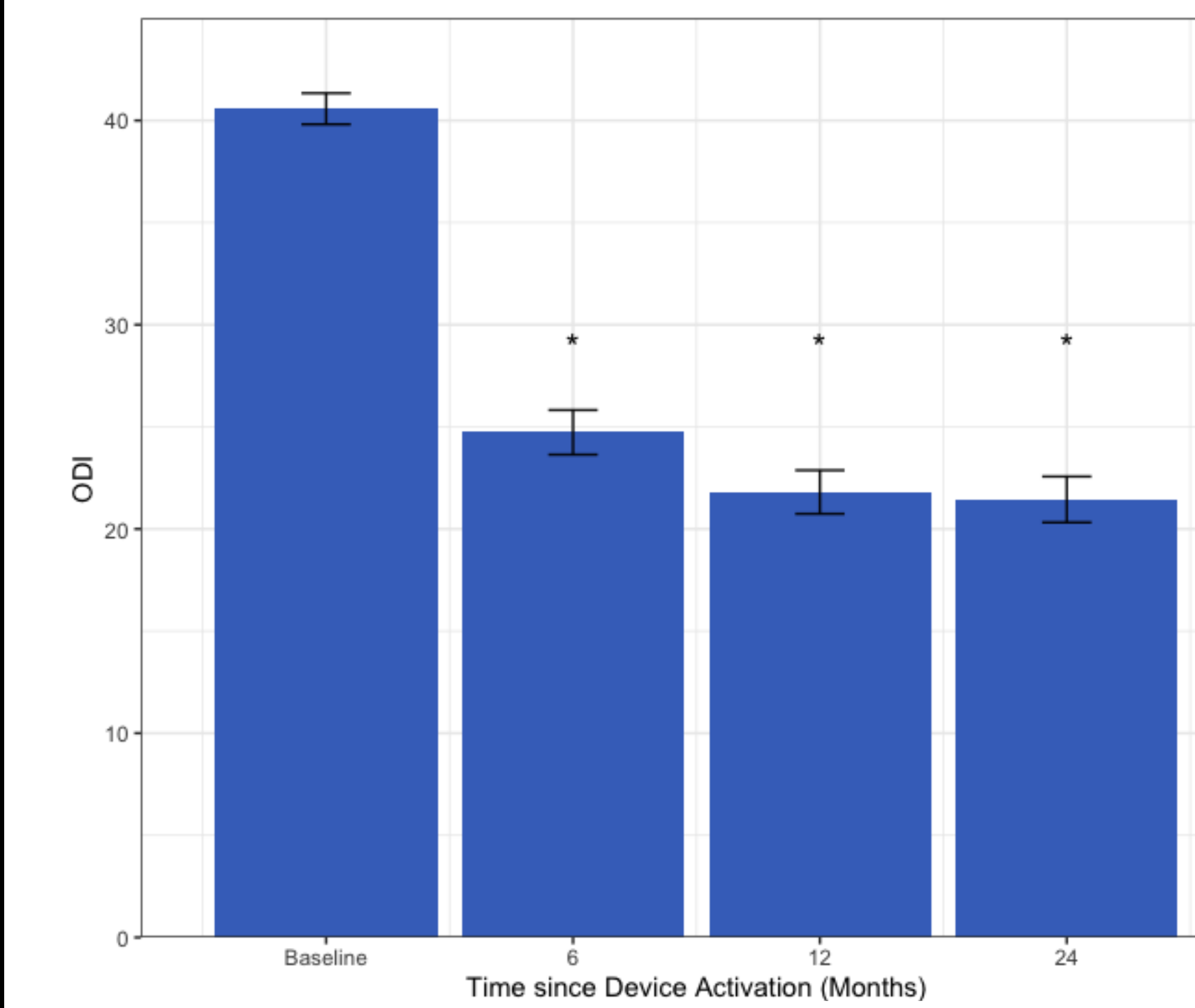


Figure 1: Mean Change in ODI

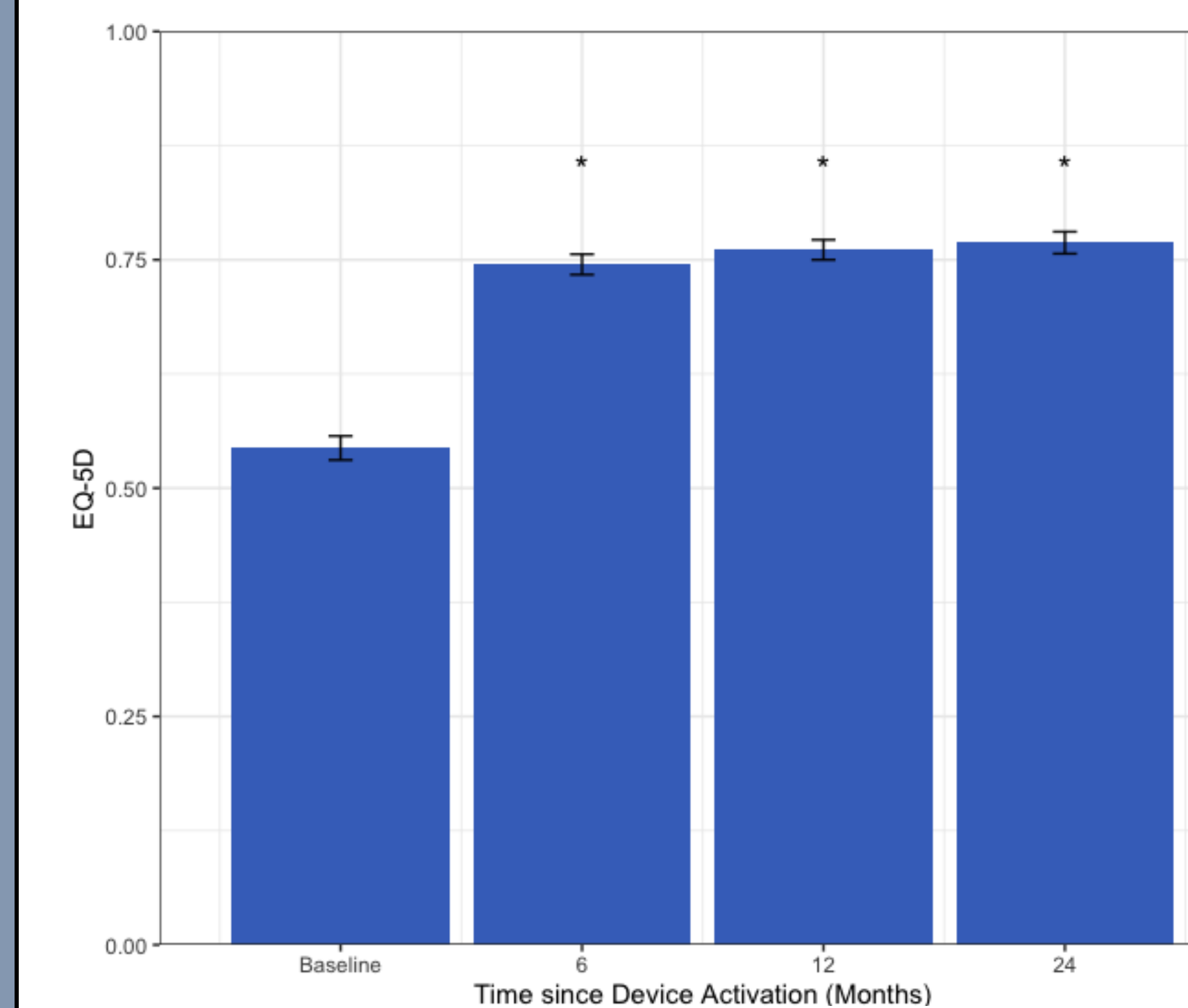


Figure 2: Mean Change in EQ-5D

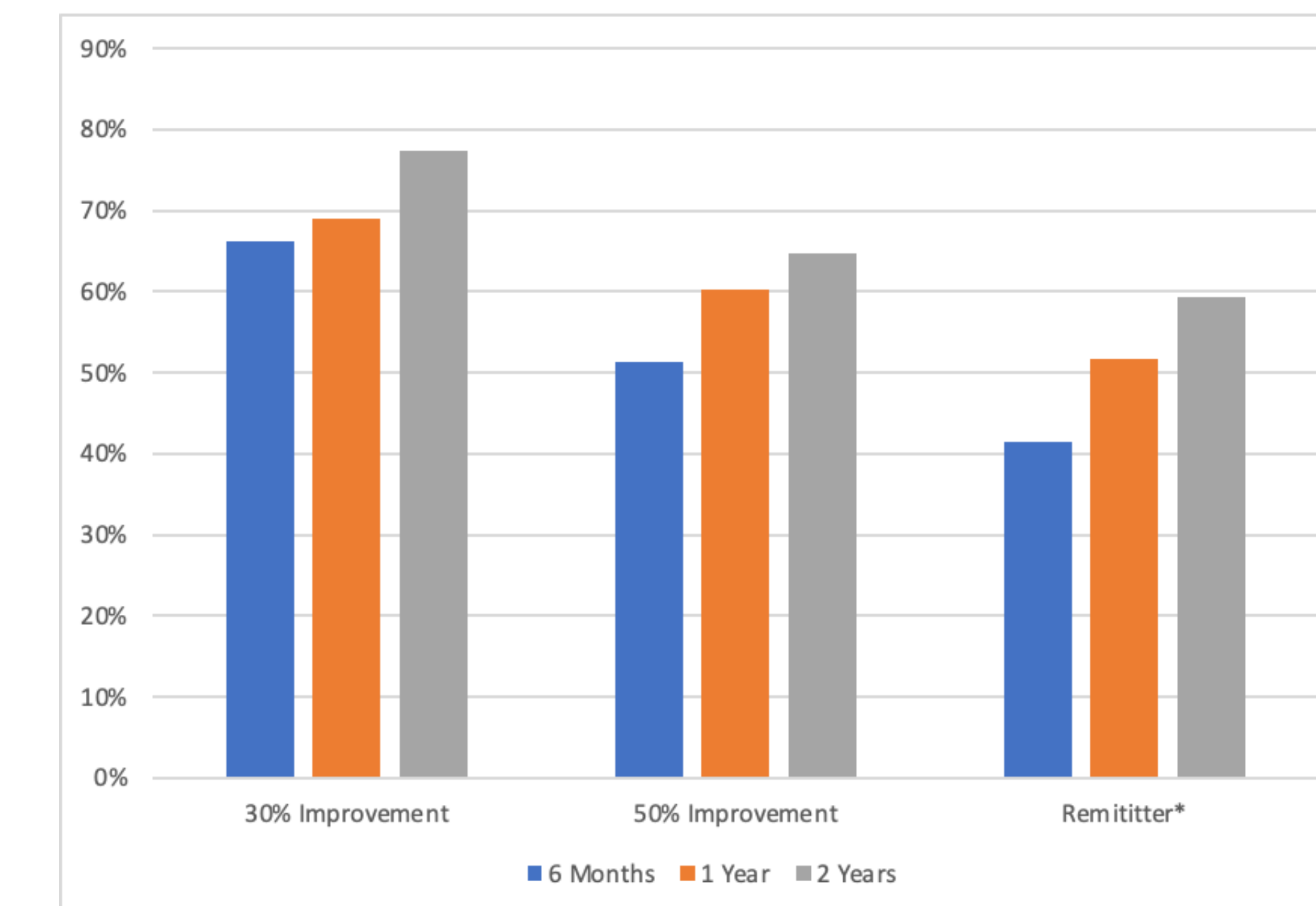


Figure 3: VAS/NRS Responder rates

At two years of follow-up:

- ODI improved from 41 to 21
- 60% had <15-point reduction in ODI
- EQ-5D improved from 0.544 to 0.769
- 65% reported < 50% reduction in pain
- 60% were classified as remitters(*≤2.5 on VAS or ≤3 on NRS)

Conclusion

Evidence across multiple clinical studies shows consistent efficacy and durability in mechanical CLBP patients with multifidus dysfunction.