

EMERGING EVIDENCE FOR THE APPLICATION OF RESTORATIVE NEUROSTIMULATION IN AN AGING POPULATION

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Introduction

- Low back pain prevalence in the ageing population is similar to working aged people despite their underrepresentation in the literature.¹
- Data on a Medicare population shows that eligible patients are still major consumers of LBP interventions.^{2,3}
- In 2016, CMS reported over 2.4 million facet joint related procedures including approximately 1 million primary procedures.
- **The high proportion of repeat interventions (~60%) underscores the need for more effective and durable interventions in this population.**
- Restorative neurostimulation (ReActiv8, Mainstay Medical, Dublin Ireland) is an approach for patients with mechanical LBP that has been refractory to conservative management.
- The efficacy of restorative neurostimulation has been demonstrated in a prospective, randomised, controlled trial with 3 year published follow-up⁴⁻⁶ and several multi centre cohort studies with 2⁷ and 4 year⁸ published data, showing a consistent durable effect.

Design

- Data from three prospective studies were aggregated.

Clinical Study	n	Study Locations
ReActiv8-B ⁴⁻⁶	204	US, UK, Europe, Australia
ReActiv8-C	87	Germany
ReActiv8-PMCF	42	UK

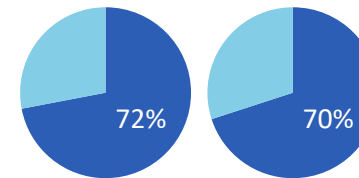
- Two cohorts identified to examine the effect of age at 2 years follow-up:
 - OP: Older patient ≥ 60 years old
 - YP: Young patient < 35 years old
- Patients were assessed as proportion of patients per group at each time point:
 - Change in disability (ODI: ≥10 point minimal clinically important change (MCIC))
 - ≥20 point clinically substantial improvement
 - Health related quality of life (HRQoL EQ-5D) was compared to baseline
- Differences in proportions were assessed using Chi-squared and continuous variables by repeated measures ANOVA.

Results and discussion

Both groups improved statistically and clinically over their baseline condition in ODI and EQ-5D.

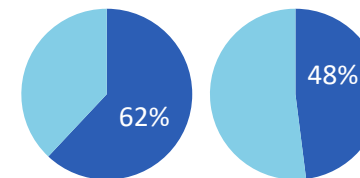
ODI Completer Analysis (patients with 2 years of continuous data)

Younger Population (n=28)



≥10 Point ≥20 Point

Older Population (n=33)



≥10 Point ≥20 Point

- This aggregate analysis of three independent studies provides insight into the performance of restorative neurostimulation in a population over 60.
- These patients derived significant and clinically meaningful benefit in disability and HRQoL similar to younger patients.

References and disclosures

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