

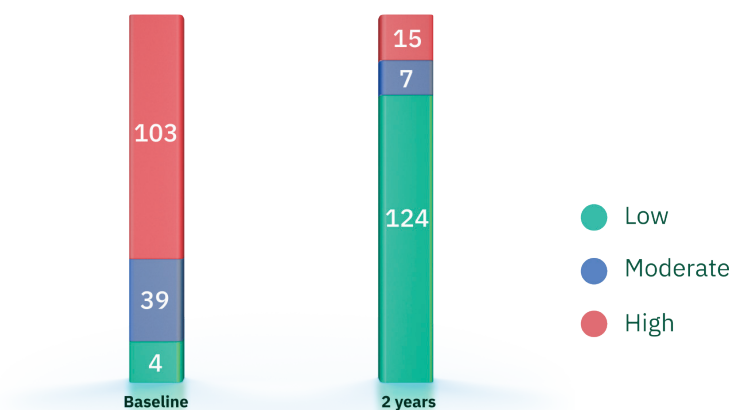


Effect of Restorative Neurostimulation on Major Drivers of Chronic Low Back Pain Economic Impact

Neurosurgery. Article in Press: February 2023. Shaffrey C, Gilligan C.

Key Takeaways

- 71% of patients had High Impact pain at baseline, reducing to 10% at 2 years.
- 85% of patients reported no or low-impact pain at 2 years
- Indirect drivers such as presenteeism and absenteeism were significantly improved at 2 years
- Study suggests significant direct & indirect economic savings by providing ReActiv8 therapy to High Impact pain patients.



Impact Class for Patients (n=146) from Baseline to 2 years

Background

High-impact chronic low back pain (CLBP) correlates with high health care resource utilization. Therapies that can alter impact status may provide beneficial long term economic benefits. The purpose of this study was to **analyze the effect of restorative neurostimulation**, with patients from the ReActiv8-B Study, **on known drivers of direct and indirect long-term health care costs**. This study is a completer analysis of 146 patients at 2 years with work data.

Direct Drivers of Economic Impact

- High Impact Pain** - Pain present on most days for 6 months or more, associated with substantial restriction of participation in work, social, and self-care activities.
- Patient population with very limited therapeutic options other than ongoing palliative treatment.
- Low back pain impact used as an indicator for direct health care resource utilization, as this has been well correlated in the literature and has been adopted by various governments.
- High Impact pain patients tied to continued use of high-cost interventions with estimates of **overall direct healthcare costs of ~\$14,000/yr.**

Direct Driver Results

- Patients overwhelmingly converted from a high impact pain state to a low impact pain state after 2 years.
- Of total patients (n=146), 103 (70.5%) were high impact patients at baseline, reduced to 15 (10.3%) at two years.
- By year two, 85% of patients (n=124) reported low impact pain.
- 2022 Medicare National Average facility payment for ReActiv8 is \$20,913 suggesting the **cost effectiveness is achieved rapidly.**

	Pain Duration / Severity	Restriction in Activities of Daily Living (ADL)			Baseline	2 Years
		Employment Impact	Selfcare Impact	Usual Activities	# of Patients	# of Patients
High Impact	✓	✓ in two or more ADL categories			103	15
Moderate Impact	✓	✓ in one ADL category			39	7
Low Impact	✓	No ADL Impact			4	124
Low Impact	Pain Severity < 4	No ADL Impact				

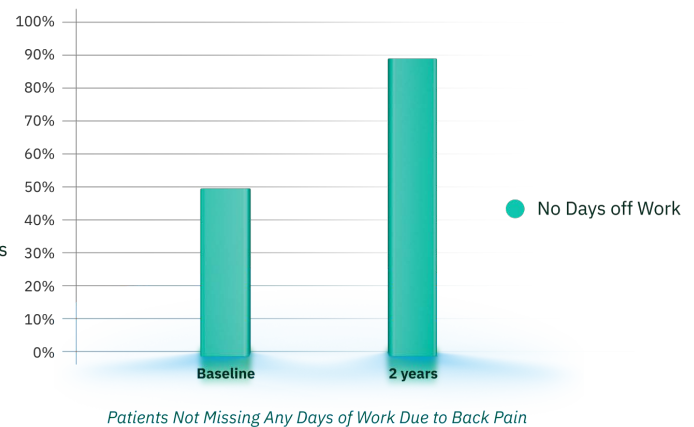
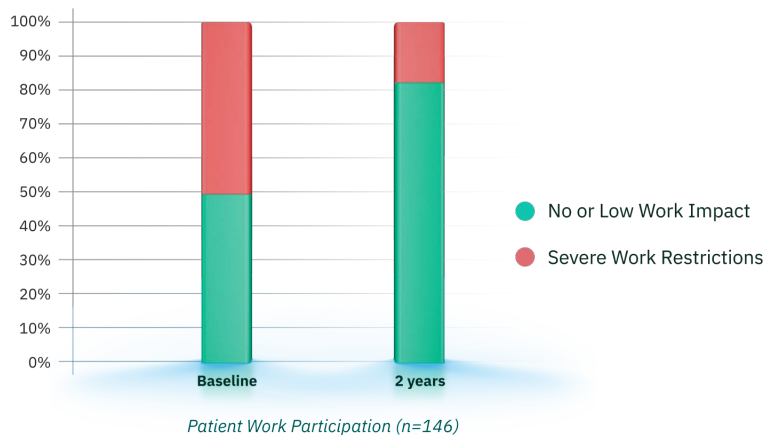
Pain Impact Classification

Indirect Drivers of Economic Impact

- **Presenteeism** - Reduced ability to perform occupational tasks because of back pain.
- **Absenteeism** - Number of days off work because of low back pain.
- Back-pain related productivity costs related to presenteeism were **double** the costs related to absenteeism in a study on American productivity.

Work Impact Improvements

- At baseline, approximately 50% of patients had severe restrictions on **work participation** and less than 50% of patients reported no work problems (left graph).
- After two years, over 80% of patients reported no or only minor impact to their work participation (left graph)
- The number of patients not missing work because of their LBP increased from 50% at baseline to 88% after 2 years (right graph)



Improvements in Work Ability

- Self-assessment of ability to do work collected on a 10-point numerical rating scale (10 being best).
- Proportion of patients rating their work ability as a 9 or 10 was 60% (87/146) at 2 years compared to 14% (21/146) at baseline.
- Results show significant improvements in mean work ability score from baseline to 2 years.



Conclusions

In addition to clinically meaningful improvements in pain and function with long term durability, the overwhelming majority of patients transitioned from a high impact to a no or low-impact CLBP state at 2 years. This is typically associated with significantly lower direct and indirect healthcare utilization levels. The recovery trajectory is consistent with a restorative mechanism of action and suggests that over the long term these health states will be maintained.