

Retrospective, Multicenter Study Evaluating Safety and Efficacy at 3 Months of a Novel Partial Facetectomy and Medial Branch Nerve Avulsion for the Treatment of Symptomatic Lumbar Spondylosis: The TRAK Study

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INTRODUCTION

Lumbar spondylosis is a recognized cause of axial low back pain, with prevalence estimates of 15-45%. Radiofrequency ablation (RFA) of the medial branch nerves is commonly performed but has a recognized variability in duration of effect and efficacy. Surgical techniques have been utilized with limited access.

OBJECTIVES

To present initial clinical data evaluating the safety and preliminary effectiveness of TRAK, a novel fluoroscopy-guided device designed to facilitate partial facetectomy and nerve avulsion in patients with symptomatic lumbar spondylosis.

METHODS

Study Design: Retrospective, multicenter, IRB-exempt
Study Period: June 2025 to February 2026
Population: Patients who underwent novel fluoroscopic-guided partial facetectomy and nerve avulsion for symptomatic lumbar spondylosis.
Primary Outcome: Numerical Rating Scale (NRS) pain score at baseline and 3-month follow-up.
Safety Endpoint: Serious adverse events (SAEs) defined as: bleeding, infection, or nerve injury at time of surgery and within 90 days post-procedure.

RESULTS

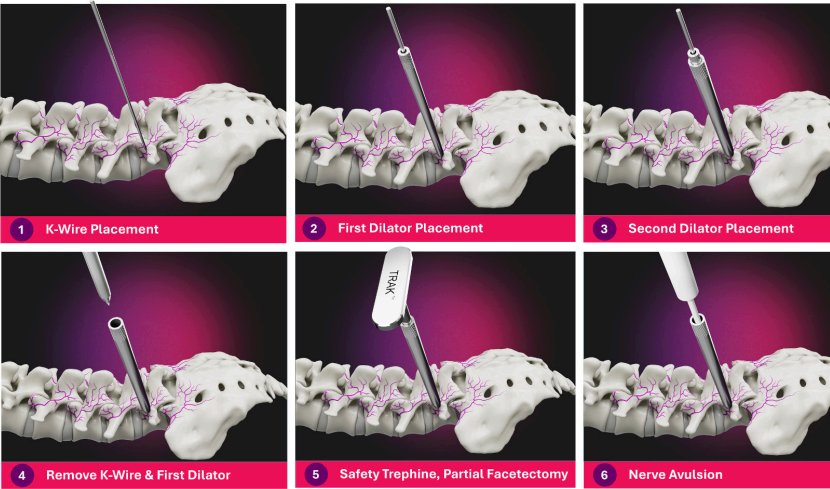
Among 56 patients evaluated at 3-month follow-up, the following outcomes were observed:

	n = 56
Gender	
Male	24 (40%)
Female	32 (60%)
Age (years) mean (min, max)	66 (31, 97)
	n = 56
Baseline NRS (mean)	7
3 months NRS (mean)	4
Percent reduction from baseline	50%
MCID (average)	1.67
	n = 56
Bleeding (> 50 mL blood loss)	0 / 56
Infection (within 90 days)	0 / 56
Nerve injury (within 90 days)	0 / 56

No procedure-related serious adverse events were recorded within 90 days. One patient experienced transient increased back pain that resolved within 7 days. At 3 months, mean NRS improved 50% from baseline, with an average MCID of 1.67; 25% of patients achieved 70% or greater relief.

TRAK PROCEDURE

TRAK enables a controlled partial facetectomy and targeted medial branch nerve avulsion through a minimally invasive, fluoroscopy-guided approach, performed in an outpatient setting.



CONCLUSION

- This investigation is the first to demonstrate the safety of a novel, minimally invasive partial facetectomy and nerve avulsion for symptomatic lumbar spondylosis.
- No procedure-related serious adverse events occurred within 90 days.
- At 3 months, the cohort demonstrated 50% mean NRS improvement, with 25% of patients achieving ≥70% pain relief.
- Longer-term prospective studies are warranted to further assess durability of the treatment effect.

REFERENCES

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