

Observations from the RESET RCT: A Post-Hoc Per Protocol Analysis of Clinical Outcomes with Percutaneous 60-Day Medial Branch PNS in Chronic Low Back Pain

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BACKGROUND



The RESET Clinical Trial[1] is an RCT comparing percutaneous 60-day peripheral nerve stimulation (PNS)[2] to usual care with standard interventional management (e.g., ablations, injections, physical therapy)[3,4] for chronic low back pain (CLBP).

Primary Endpoint results for the Full Analysis Set were recently published in 2025[1].

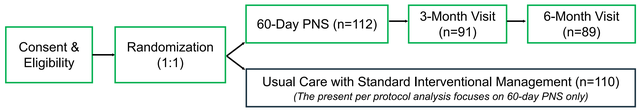
This post-hoc analysis aimed to characterize the relationships between baseline variables, treatment delivery, and 60-day PNS outcomes.

- Additional goals included exploring how outcomes vary among patients with facetogenic or discovertebral pain features.

RESET Low Back Pain

RCT DESIGN AND METHODS

Patients with moderate to severe CLBP confined to the lumbar region without radiation to the extremities were included (*key exclusion: RFA within ≤6 months, radicular leg pain, BMI >40, prior lumbar surgery*).

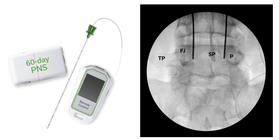


Participant demographic and clinical characteristics (Full Analysis Set; n=112)	
Age (years), mean ± SD	55 ± 14
CLBP duration (years), mean ± SD	14 ± 13
Female, % (n)	53% (59)
Baseline scores	
Average pain Intensity, BPI5, mean ± SD	6.0 ± 1.2
Pain interference, BPI9, mean ± SD	6.2 ± 1.4
Oswestry Disability Index, ODI, mean ± SD	42 ± 16
Per Protocol utilization (among n=93 participants who completed treatment)	
Completed treatment as prescribed, % (n)	72% (67)

PERCUTANEOUS 60-DAY PNS

Bilateral percutaneous 60-day PNS targeting the lumbar medial branches (SPRINT® PNS System, SPR).

- 12 Hz, 0-30mA, 10-200µs
- Leads removed after up to 60 days



OUTCOMES AT 3 MONTHS

PER PROTOCOL 60-DAY PNS TREATMENT DELIVERY

✓ Bilateral stimulation usage of 6-12 hours per day for 56-60 days

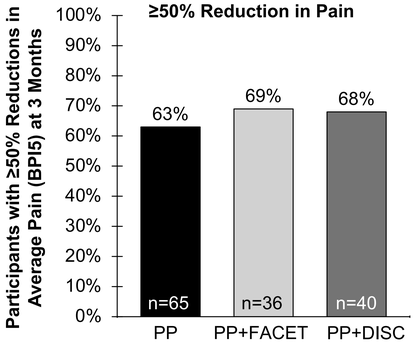
✓ Stimulation sensations overlapping >50% of the painful area (assessed at lead implant, 1-month visit, and end of treatment)

Univariate logistic regressions (alpha=0.05) evaluated associations between variables (baseline and treatment characteristics) and responder rate (defined as a ≥50% reduction in average pain at 3 months post start of treatment).

Odds Ratios (ORs) for Assessed Clinical Variables	Full Analysis Set (n=112)		Per Protocol Set (n=65)	
	OR [95% CI]	p-value	OR [95% CI]	p-value
Per protocol device utilization				
completed treatment as prescribed	3.04 [1.16, 7.93]	0.023	n/a	n/a
Participant demographics				
Age (years)	1.00 [0.97, 1.03]	0.934	1.01 [0.97, 1.05]	0.716
Back pain duration (years)	1.00 [0.97, 1.04]	0.865	1.00 [0.95, 1.04]	0.818
Gender (female)	1.33 [0.57, 3.11]	0.503	0.77 [0.27, 2.15]	0.614
Baseline scores				
Average pain Intensity, BPI5	1.09 [0.77, 1.54]	0.620	1.08 [0.71, 1.64]	0.712
Pain interference, BPI9	1.09 [0.80, 1.48]	0.586	0.87 [0.61, 1.25]	0.456
Oswestry Disability Index, ODI	1.01 [0.98, 1.04]	0.589	1.01 [0.97, 1.06]	0.495
Diagnostics				
≥80% relief from single MBB	2.34 [0.97, 5.66]	0.058	2.21 [0.77, 6.32]	0.139

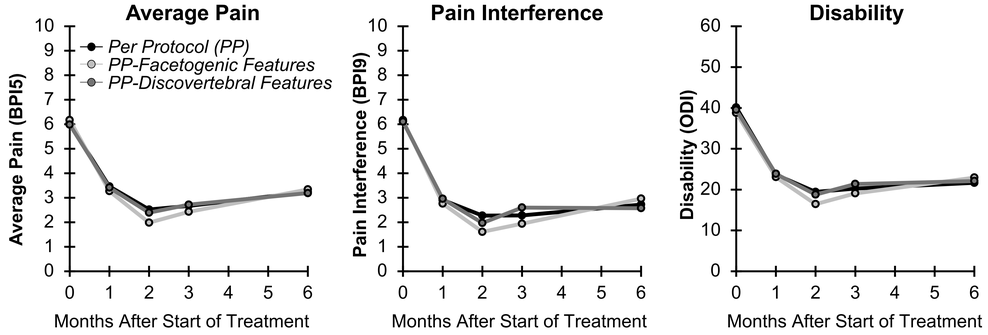
- **Per protocol treatment delivery was associated with achieving meaningful pain relief**, as those participants had **3.04 times higher odds of achieving ≥50% reduction in average pain** (n=65; p=0.023).
- Baseline characteristics, diagnostic imaging, and response to a MBB did not have a significant association with treatment response.

Responder rates are shown for cohorts with **facetogenic features** (PP+FACET; determined via clinical exam or ≥80% relief from a medial branch block) and **discovertebral features** (PP+DISC; determined via clinical exam or moderate to severe findings on medical imaging) **within the Per Protocol Set** (PP).



DURABILITY OF RELIEF THROUGH 6 MONTHS

Reductions in pain extended to improvements in pain interference and disability, with sustained benefits for the Per Protocol (n=65), facetogenic (n=36), and discovertebral (n=40) cohorts.



Safety: *No serious, unanticipated study-related adverse events (AEs) occurred for any participant. The most common AEs related to percutaneous 60-day PNS were mild skin irritation or itching at the bandage.*

CONCLUSIONS

- In this study, **per protocol treatment delivery of 60-day PNS was significantly associated with achieving meaningful pain relief** (3.04 times higher odds of achieving ≥50% pain reduction at 3 months).
- Baseline characteristics, diagnostic imaging, and response to a medial branch block were not significantly associated with 60-day PNS outcomes.
- Exploratory cohort analyses **demonstrated effectiveness among patients with facetogenic or discovertebral pain features**, with improvements sustained through 6 months (follow-up ongoing).
- These findings suggest that 60-day PNS treatment delivery is an important determinant of outcomes, **underscoring the role of proper lead implantation, patient education, and treatment adherence**.

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Disclosures: Li, Gilmore, Jameson, Desai, Deer, and Cohen are consultants for SPR. Deer, Desai, Clark, McGee, and Boggs hold stock or stock options in SPR. Clark, McGee, and Boggs are employees of SPR.

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McCormick et al. 2025[1]
Findings from the Full Analysis Set