

RESET Randomized Controlled Trial: 12-Month Outcomes of 60-Day PNS and Usual Care with Standard Interventional Management in CLBP

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More Clinical Evidence for 60-Day PNS

Background

The **RESET Clinical Trial** (n=222) met its primary endpoint, with a greater proportion of those treated with percutaneous 60-day peripheral nerve stimulation (**Group #1; 60-day PNS**) reporting significant improvements in CLBP compared to usual care with standard interventional management (**Group #2; e.g., ablations, injections, physical therapy**) at 3 months [1].

The present report analyzes outcomes through 12 months post-treatment, evaluating average pain intensity (BPI5), pain interference (BPI9), and back pain-related disability (ODI) in each group.

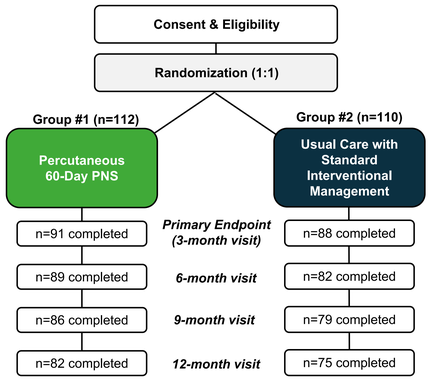
Methods

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*).

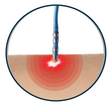
Statistical Methods: Imputation for missing data was conducted using predictive mean matching.









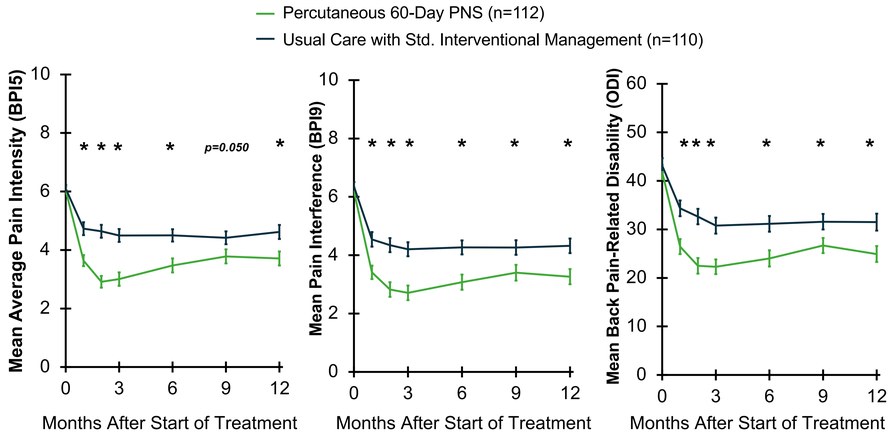


Percutaneous 60-day PNS Treatment:
- Bilateral leads targeting the lumbar medial branches
- 6-12 hrs/day for up to 60 days
- Subjects continued normal activities
- Leads removed after up to 60 days

Usual Care with Standard Interventional Management:
- Most common treatments included radiofrequency ablations, injections, and physical therapy.
- All study participants received follow-up treatments as needed

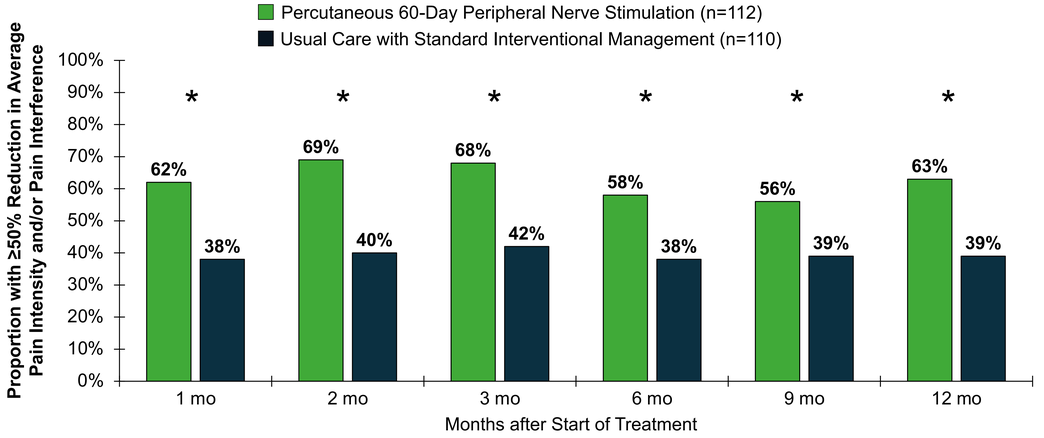
All PNS-related adverse events (AEs) were previously reported [1] and resolved by 3 months. No serious, unanticipated study-related AEs occurred for any participant (most common PNS AE: mild skin irritation or itching at the bandage).

Outcomes through 12 Months



In addition, **significantly greater proportions with 60-day PNS compared to usual care** for CLBP in the following endpoints at 12 months (*p<0.05):
- **Average Pain Intensity** (≥50% reduction in BPI5)
- **Pain Interference** (≥50% reduction in BPI9)
- **Back pain-related Disability** (≥50% reduction in ODI)
- Composite outcome of **average pain and/or pain interference**
- Composite outcome of **average pain and/or disability**

≥50% Reductions in Pain Intensity and/or Pain Interference



A greater proportion of 60-day PNS participants reported ≥50% reductions in average pain intensity (BPI5) and/or pain interference (BPI9) compared to usual care with standard interventional management participants **at all completed timepoints** (*p<0.05).

Healthcare Resource Utilization

CLBP Procedure and Intervention Utilization through 12 Months

	Initial Treatments		Follow-Up Treatments	
	Group #1	***Group #2***	***Group #1***	***Group #2***
Physical Therapy, %	2%	11%	7%	13%
Chiropractic Treatment or Spinal Manipulation, %	1%	4%	2%	8%
Other Conservative Care (e.g., Acupuncture), %	0%	11%	7%	9%
60-Day PNS (G1 Treatment or G2 Crossover†), %	100%	0%	2%	69%†
Ablation (e.g., Lumbar RFA), %	0%	43%	5%	20%
Injection (e.g., ESI, Trigger Point, Facet, SI), %	0%	27%	10%	33%
Permanently Implanted PNS or SCS, %	0%	0%	1%	1%
Lumbar Surgery, %	0%	0%	4%	1%

Utilization shown among participants completing the 12-month follow-up visit for Group #1 (percutaneous 60-day PNS; n=82) and Group #2 (Usual Care with Standard Interventional Management; n=75). †Group #2 participants at their 12-month visit who indicated they wanted to crossover and receive 60-day PNS. Abbreviations: ESI, epidural steroid injection; SI, sacroiliac joint; TENS, transcutaneous electrical nerve stimulation.

Conclusions

- **Percutaneous 60-day PNS demonstrated durable improvements in CLBP at the 12-month follow-up** that were greater than those observed in the usual care with standard interventional management group.
- Consistent with the findings previously reported at 3 months, **60-day PNS participants reported greater improvements in average pain intensity, pain interference, and back pain-related disability at 12 months post-treatment.**
- At 12 months, **a significantly greater proportion of 60-day PNS participants reported ≥50% improvement in average pain intensity and/or pain interference** compared to those in the usual care with standard interventional management group.
- The durability of improvements across multiple outcomes provides **supporting evidence for the use of 60-day PNS of the lumbar medial branches as a treatment option for patients with chronic low back pain.**

References & Acknowledgments

[1] McCormick ZL, et al. Comparison of percutaneous 60-day peripheral nerve stimulation of the lumbar medial branches to usual care with standard interventional management for chronic low back pain-a multicenter pragmatic randomized controlled trial (RESET). Pain Med 2026;27(4):462-473.

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