

# Real World Registry Data Shows Significant and Sustained Long-Term Pain Relief in Patients Receiving Peripheral Nerve Stimulation with a Micro-IPG Device

**Authors:** Hatheway J<sup>1</sup>, Ratino Ti<sup>2</sup>, Swain R<sup>3</sup>, Ratino Th<sup>2</sup>, Latif U<sup>4</sup>, Arulkumar S<sup>5</sup>, Ruais J<sup>6</sup>, Hartley L<sup>6</sup>, and Desai M<sup>7</sup>

**Affiliations:** 1 Northwest Pain Care, Spokane, WA; 2 Ratino Interventional Pain Management, Fort Worth, TX; 3 Hurricane Pain Management, Springfield, OH; 4 Kansas University Medical Center, Kansas City, KS; 5 SSM Health Neurosciences; 6 Nalu Medical, Inc., Carlsbad, CA; 7 International Spine Pain and Performance Center, Washington, DC.

## Introduction

Peripheral Nerve Stimulation (PNS) is an established modality for the treatment of chronic peripheral neuralgia/neuropathy.<sup>1</sup> Recent data from the COMFORT RCT showed significant and sustained long-term improvements.<sup>2</sup>

Real-world evidence can help confirm outcomes outside of the research environment and provide insights into common clinical practice. This work represents the largest, long-term real-world study of PNS with sustained outcomes beyond 12-months.

## Methods

Anonymized patient records from a national IRB approved database were reviewed for patients implanted with Nalu micro-IPG for PNS (Nalu, Medical, Inc.) between 4/19/22 and 5/2/2024. Data included patient responses to standardized surveys on pain score (0-10 scale) and Patient Global Impression of Change (PGIC).

Patients included in this evaluation

- Baseline pain score  $\geq 4/10$
- completed the surveys prior to implant
- Completed at least one survey 6 to 9-month intervals post implant
- A responder was defined as those achieving  $\geq 50\%$  pain reduction and/or improvement in PGIC

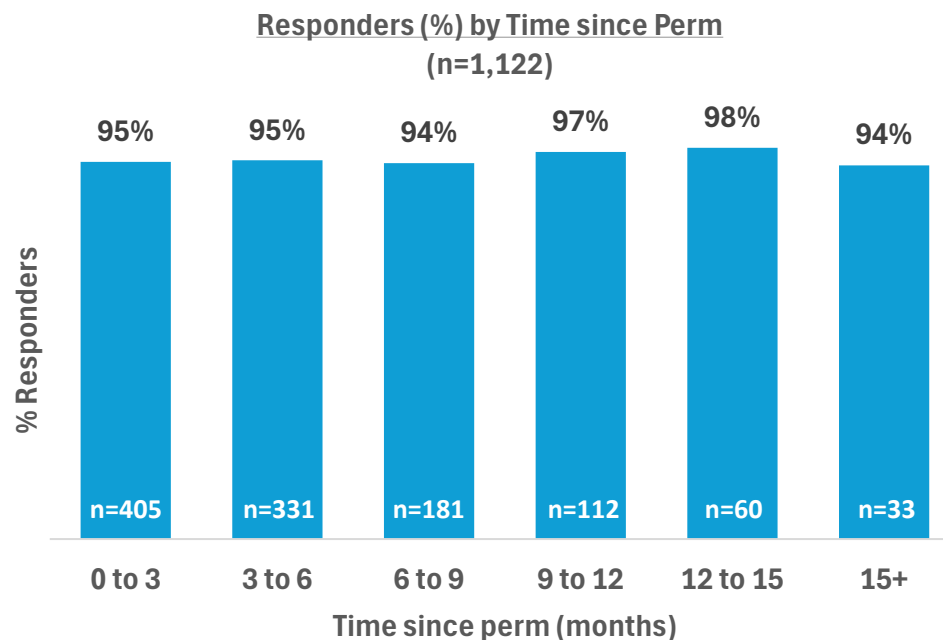
## References

1. Slavin KV (ed): Peripheral Nerve Stimulation. Prog Neurol Surg. Basel, Karger, 2011, vol 24, pp 1–15 <https://doi.org/10.1159/000323002>

2. Hatheway J, et al A Report on Interim Long-term Pain Outcomes from the COMFORT Peripheral Nerve Stimulation Randomized Control Trial, presented at the 2024 World Congress of the International Neuromodulation Society

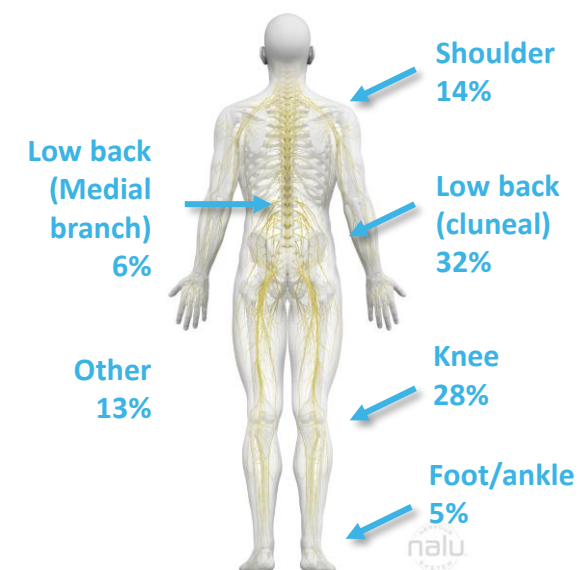
## Results & Discussion

- 1,122 patients met the inclusion criteria.
- 93 patients provided data 12+ months.



- 95% (1069/1122) of all patients in this cohort were responders.
- 71% average pain relief for responders ( $\geq 50\%$  pain relief)

## Major Areas Treated



- 40+ nerve targets and/or combinations were treated
- The response was consistent across all anatomic targets

## Conclusions

These real-world PNS results confirm the data seen in the COMFORT RCT and demonstrate durability of effectiveness beyond one-year. These data add to and slightly outperform previously reported RWD. Additional data will be reported as it becomes available.