## A Review of Clinical Evidence for Percutaneous Peripheral Nerve Stimulation Demonstrating Sustained Relief of Chronic Pain in a Majority of Subjects

Gulati A, MD¹, Desai MJ, MD², Rosenow JM, MD³, Cohen SP, MD⁴, Nathan D. Crosby, PhD⁵, Joseph W. Boggs, PhD⁵

¹Memorial Sloan Kettering Cancer Center, New York, NY; ²International Spine Pain Performance Center, Washington, D.C.; ³Northwestern University, Chicago, IL; ⁴Walter Reed National Military Medicine Center, Bethesda, MD; ⁵SPR Therapeutics, Cleveland, OH, USA

#### **BACKGROUND**

- Peripheral nerve stimulation (PNS) can be an effective tool for the treatment of chronic pain, and recent years have seen the advancement of various PNS features and techniques intended to overcome many of the limitations of conventional PNS.
- •Recent studies across multiple pain indications support that PNS treatments for up to 60 days with temporary percutaneous leads can produce significant and sustained relief without permanent implantation.
- This pragmatic review discusses the clinical evidence for sustained relief of pain following temporary percutaneous PNS treatment.

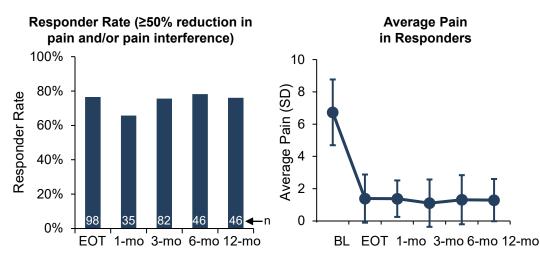
# STATES OF THE STATE OF THE STAT

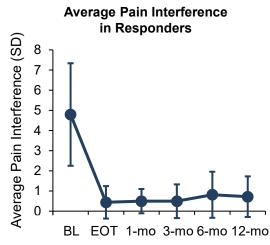
#### **METHODS**

- PubMed, Google Scholar, and Web of Science were searched through February 2020 for clinical studies demonstrating the use of percutaneous PNS for chronic pain with leads that were removed at the end of treatment (EOT).
- Search terms included "peripheral nerve stimulation", "percutaneous", and/or "chronic pain". Publications were excluded that used permanently implanted systems, transcutaneous or subcutaneous field stimulation targeting cutaneous fibers rather than a peripheral nerve, or in-office needle-based stimulation methods such as peripheral electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT).
- Per subject data were compiled, as available, for each study to enable aggregate analyses of responder rates (defined as those that had ≥ 50% relief) and average reductions in pain and pain interference in responders at baseline (BL), end of treatment (EOT), and at 1-mo, 3-mo, 6-mo, and 12-mo follow-up.

### RESULTS

- •16 publications representing 12 studies were identified, including 3 randomized controlled trials (RCTs), 6 prospective case series, and 3 case reports. 1-16
- •Although there were differences in approach, stimulation targets, and PNS devices, all identified studies delivered percutaneous PNS for up to 60 days for the treatment of chronic pain without a permanently implanted device. Pain indications included chronic shoulder pain, low back pain, and post-amputation pain.





- •The aggregate responder rate (≥50% pain relief and/or ≥50% improvement in pain interference) based on available per-subject data was 77% (75/98), with an average of 81% reduction in pain intensity and 90% reduction in pain interference among responders.
- •A majority of subjects reported sustained relief during long-term follow-up. Three studies (including two RCTs) reported outcomes at one year of follow-up, with a 76% responder rate (35/46).

#### **CONCLUSIONS**

- •Studies using percutaneous PNS for up to 60 days for chronic pain have reported substantial and sustained reductions in pain with follow-up periods up to 12 months and consequent improvements in quality of life.
- •A growing body of recent literature supports that percutaneous PNS for up to 60 days may provide significant and enduring pain relief.

#### REFERENCES

1. Yu et al., 2001; 2. Chae et al., 2001; 3. Yu et al., 2004; 4. Chae et al., 2005; 5. Renzenbrink et al., 2004; 6. Rauck et al., 2012; 7. Rauck et al., 2014; 8. Wilson et al., 2011; 9. Chae et al., 2013; 10. Wilson et al., 2014a; 11. Wilson et al., 2014b; 12. Kapural et al., 2018; 13. Gilmore et al., 2018; 14. Gilmore et al., 2019a; 15. Gilmore et al., 2019b; 16. Gilmore et al., 2020

AG, MD, JR, and SC are consultants and meeting participants/lecturers with SPR Therapeutics. NC and JB are employees of SPR Therapeutics.