Percutaneous Peripheral Nerve Stimulation for Chronic Pain in Amputees: 12-Month Follow-Up of a Multicenter, Randomized, Placebo-Controlled Trial

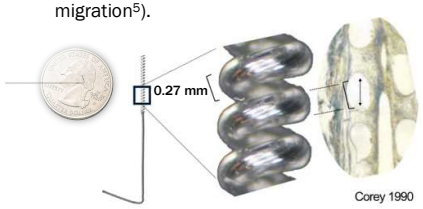
Gilmore CA, MD,[1] Ilfeld BM, MD, MS,[2] Rosenow JM, MD,[3] Li S, MD,[4] Desai MJ, MD, MPH,[5] Hunter CW, MD,[6] Nader A, MD,[3] Mak J, MD,[4] Rauck RL, MD,[1] Cohen SP, MD,[7] Crosby ND, PhD,[8] Boggs JW, PhD[8]
[1]Center for Clinical Research, Winston-Salem, NC; [2]University of California San Diego, San Diego, CA; [3]Northwestern University, Chicago, IL; [4]Premier Pain Centers, Shrewsbury, NJ; [5]International Spine, Pain, and Performance Center, Washington, D.C.; [6]Ainsworth Institute of Pain Management, New York, NY; [7]Walter Reed National Military Medical Center, Bethesda, MD; [8]SPR Therapeutics, Cleveland, OH

INTRODUCTION

- Peripheral nerve stimulation (PNS) has historically been used to treat a wide range of chronic pain states but has generally required a short trial (4-7 days) followed by implantation of a permanent system for sustained relief.[1]
- A recent study found that a 60-day PNS treatment provided significant relief of post-amputation pain.[2,3] This work presents long-term secondary outcomes from the study up to 12 months from the start of the 60-day treatment.

MINIMALLY INVASIVE, PERCUTANEOUS PNS:

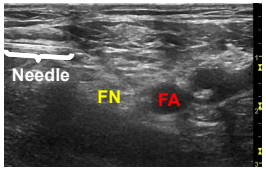
- Wearable stimulator and percutaneous fine-wire (<0.3 mm), coiled lead (designed to anchor in tissue) could mitigate infection risk[4] and other limitations of conventional neuromodulation (e.g., invasiveness, lead migration[5]).



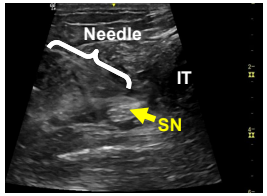
MATERIALS & METHODS

Participants: 28 traumatic lower extremity amputees with baseline residual (RLP) and/or phantom limb pain (PLP) ≥ 4 provided written consent and enrolled. Participants were randomized 1:1.
Lead Implantation: Percutaneous PNS leads remotely targeted the sciatic and/or femoral nerves proximal to the regions of RLP and PLP under ultrasound guidance.

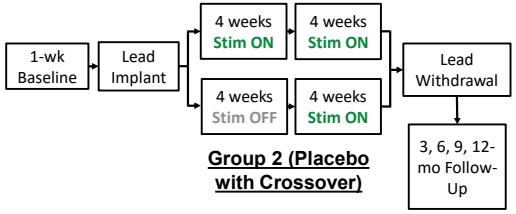
Femoral



Sciatic



Group 1 (60-day PNS Treatment)



Group 2 (Placebo with Crossover)

Long-Term Follow-up (secondary endpoints):

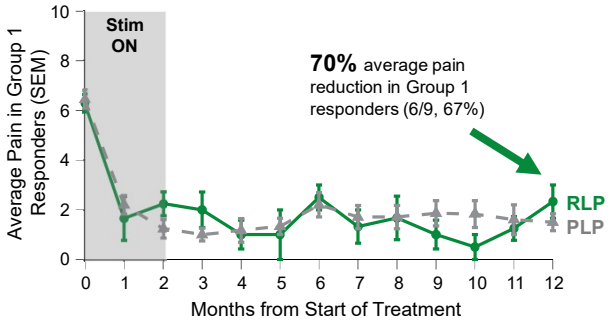
- Average residual and phantom limb pain (BPI-5)
- Average interference of RLP and PLP (BPI-9)
- Beck Depression Inventory II (BDI-II)

All statistical analyses conducted by an independent biostatistician.

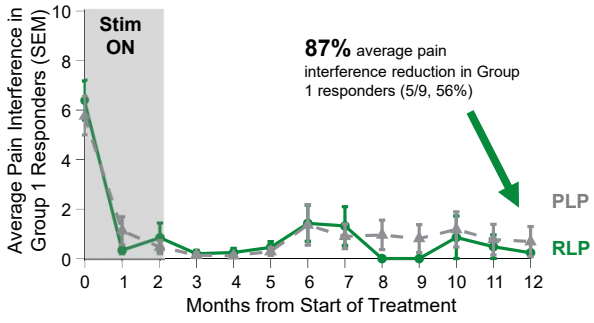
FN = femoral nerve; FA = femoral artery; SN = sciatic nerve; IT = ischial tuberosity

RESULTS

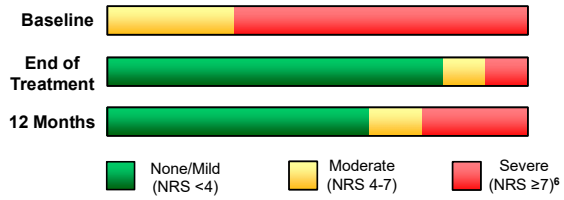
Average Pain

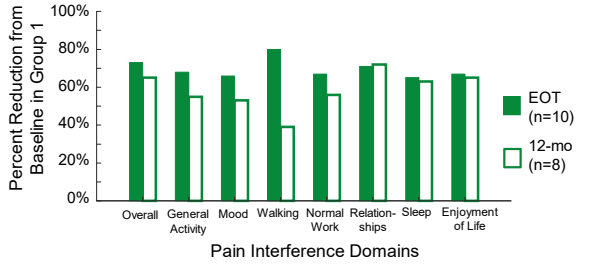


Average Pain Interference



Severity of Worst Region of Pain (RLP or PLP):





10/12 (83%) participants in Group 1 were reduced one or more severity categories including 9 (75%) to Mild or No Pain. 5/14 (36%) in Group 2 were reduced by one category but none (0%) were reduced below Moderate Pain at the end of the placebo period.

Depression: Average reductions in BDI-II score in Group 1 (32% at EOT, 16% at 12 months) were clinically significant and statistically greater than Group 2 at the end of the placebo period (8% increase, p<0.035).

Safety: No serious or unanticipated adverse device effects were reported

DISCUSSION

- Percutaneous PNS delivered for up to 60 days may provide significant and enduring pain relief through one year, enabling subsequent improvements in function and quality of life.
- Potential mechanism includes activation of large diameter sensory fibers that generates non-painful input focally from the region of pain to reverse maladaptive expansion of cortical nociceptive representations.
- A 60-day PNS treatment may preclude the need for a permanent implant in some patients.

REFERENCES

1. Corriveau et al., Neurosurg Clin, 2019
2. Gilmore et al., Reg Anesth Pain Med, 2019
3. Cohen et al., Mil Med, 2019
4. Ilfeld et al. Pain Practice, 2017.
5. McJunkin et al., Reducing Risks and Complications of Interventional Pain Procedures, 2012.
6. Jensen et al., Pain, 2001

Funding: DoD (CDMRP/PRORP W81XWH-12-2-0132) and SPR Therapeutics.

CG, JR, MD, RR have consulted for SPR Therapeutics. The institutions of CG, BI, SL, MD, JM, RR have received funding from SPR Therapeutics for other clinical studies. NC and JB are have options in and are employees of SPR Therapeutics.