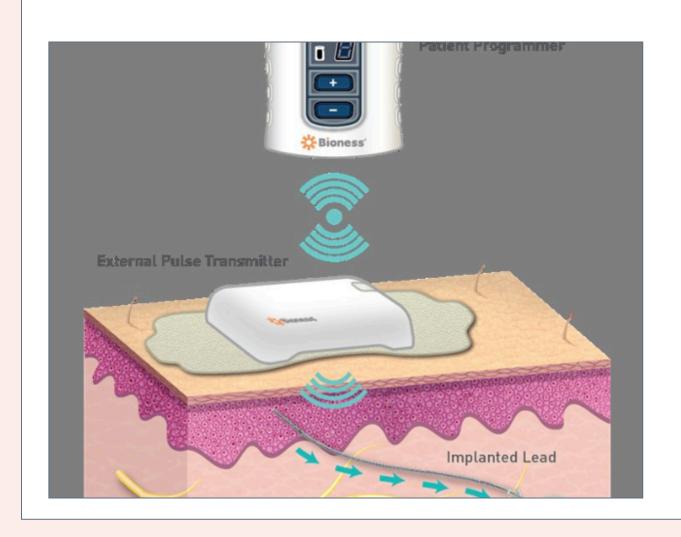
# A Comparison of the use of PNS to SCS and DRG for Lower Extremity Pain

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## Introduction

Chronic neuropathic pain of the lower extremity (LE) can be challenging to treat. Beyond physical therapy, nerve blocks, and medication management, spinal cord stimulation has been frequently utilized with inconsistent results, particularly when targeting the sole of the foot. Dorsal root ganglion (DRG) stimulation was introduced in 2016 as a viable alternative to target leg pain; however, the procedure involves complex neuraxial intervention. Advances in peripheral nerve stimulation (PNS) addresses the challenges in treating chronic LE pain conditions inadequately treated with SCS and DRG stimulation. The Bioness StimRouter PNS System is indicated for chronic pain of peripheral nerve origin in the upper extremity, trunk, and LE. The system allows placement of a compact, flexible percutaneous lead on the target peripheral nerve guided by ultrasound, fluoroscopy or surface anatomy. The procedure is generally performed in 30-minutes or less. No existing literature could be found comparing PNS to other forms of neuromodulation in treatment of chronic LE pain.

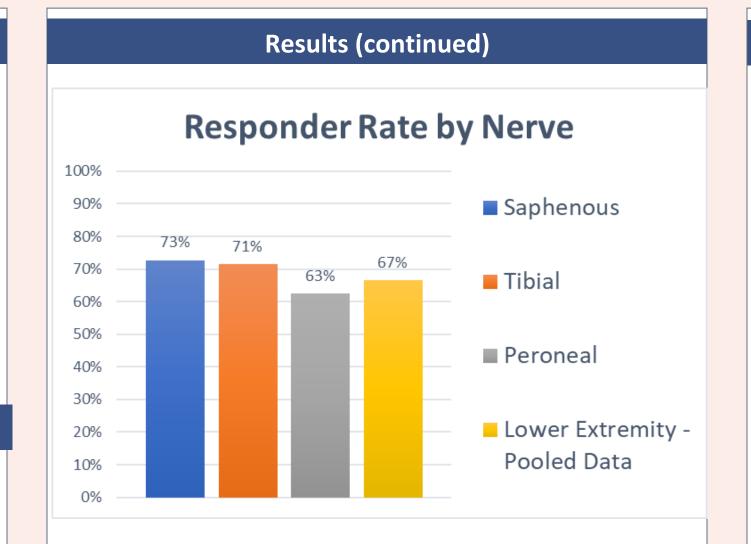


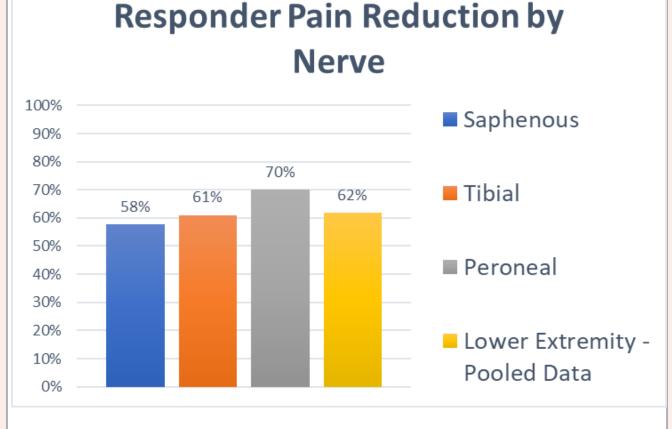
#### **Methods**

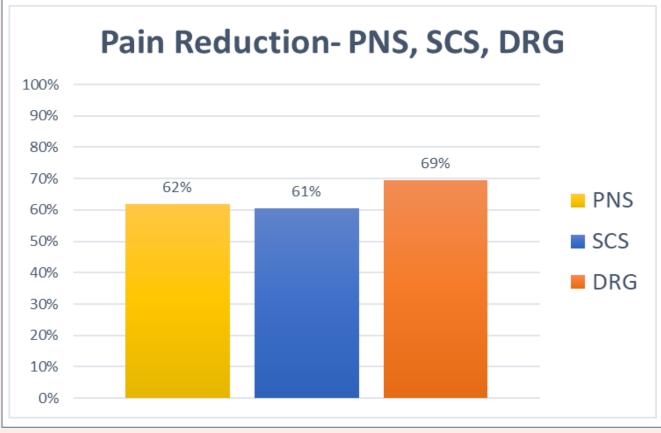
A 27-patient case series is presented to study PNS efficacy (responder rate & pain reduction), safety (adverse events) and efficiency (procedure time) for chronic pain of the LE with no exclusion for participation. 63% of the patients surveyed were female and 37% were male.

## Results

There was an average responder rate of 67% for lower extremity pain using pooled data for the saphenous, peroneal, and tibial nerves. The average pain reduction in responders was 62%, with an average implant duration of 0.9 years. Saphenous nerve stimulation exhibited the highest responder rate (73%), where 58% of patients suffered from persistent postsurgical pain s/p TKA. 94% of patients who were taking prescription opioids prior to their PNS implant reported opioid sparing effects post-implant. 47% of patients who were taking prescription opioid pain medication prior to implant reported at least a 50% reduction in their opioid use. Average procedure time across all implant locations was 32 minutes. Of note, in a larger multicenter, RCT by Deer et al\* there were no reported serious adverse events, infections, or lead migration. Of the 27 patient respondents, 96% would recommend permanent PNS to other patients with chronic pain.







Discussion					
Event description	Nerve root incidence rate*	Published SCS incidence rates	SCS incidence rate	DRG incidence rate	PNS incidence rate
CSF leaks	12%	0.3%-7%	0.30%	0.54%	N/A
Infection	12%	2.5%-14%	1.12%	1.08%	0%
Persistent pain at					
the implant site	N/A	0.9%-12%	0.56%	0.18%	0%

Table 1: Comparison between events reported in current analysis and published rates with SCS and DRG stimulation.

Table 1 compares the available neuromodulation treatment modalities for lower extremity chronic pain taking into consideration procedure length, invasiveness, adverse events, responder rate, and pain reduction. PNS is a safe and viable tool that may be integrated into treatment algorithms for chronic lower extremity pain of peripheral nerve origin.

# Conclusion

Permanent PNS systems like the StimRouter represent a minimally invasive neuromodulation modality that continues to show promise. Taken together, integration of PNS into existing algorithms for the treatment of chronic neuropathic pain of the lower extremity should be considered.

#### References

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# **Authorship Statement**

Einar Ottestad MD, Ofer Wellisch MD, and David Spinner DO are consultants of Bioness Inc. Andy Veldkamp is an employee of Bioness Inc.





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