



Safety and Adverse Events of Percutaneous Peripheral Nerve Stimulation at a Major Academic Medical Center

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INTRODUCTION

Percutaneous peripheral nerve stimulation (PNS) represents an evolving treatment modality for chronic back or peripheral nerve pain, potentially offering an alternative to traditional therapies. Historically, nerve stimulation involved a brief (~7-day) trial followed by the implantation of a permanent device, with issues such as cost, permanence, and inconsistent outcomes limiting its use only as a last-resort option. Although early studies have suggested that PNS is both effective and safe, further investigation into its safety profile and adverse events is necessary as its use becomes more widespread.

METHODS

Following institutional review board approval, we conducted a retrospective review of 90-day outcomes for peripheral nerve stimulator implants performed at our institution from 2021 to 2024 for axial, low back pain or implants into the multifidus muscles. Data were collected and analyzed from 219 instances of percutaneous nerve stimulation.



RESULTS

Among the 219 procedures, 24 cases (10.9%) involved early elective lead removal, and 21 cases (9.5%) experienced accidental lead pullout. Additionally, 15 instances of lead breakage were identified (6.8%), with 11 detected at the 60-day lead pull and 4 identified as the cause of device dysfunction before lead removal. Other adverse events included skin reactions (n=16, 7.3%), insertion site pain (n=9, 4.1%), and insertion site infections (n=3, 1.4%).



Figure 1
Visual Representation of Peripheral Nerve Stimulation Device, including introducer needle, and lead.

Complication	Total (n=219)	Percentage
Early Elective Lead Removal	24	10.9%
Accidental Lead Pullout	21	9.5%
Lead Breakage	15	6.8%
During Device Removal	11	5%
Prior To Device Removal	4	1.8%
Skin Reactions	16	7.3%
Insertion Site Pain	9	4.1%
Insertion Site Infection	3	1.4%

DISCUSSION

Our review reveals a notable incidence of early elective lead removal, accidental lead pullout, and lead breakage, alongside previously documented adverse events. These findings indicate that over 20% of patients did not complete the intended 60-day stimulation period. Lead breakage underscores potential complications, including the risk of permanent device remnants. This study provides a deeper understanding of the adverse events associated with this emerging treatment modality.

CONCLUSIONS

- While percutaneous peripheral nerve stimulation has demonstrated efficacy, our findings highlight a relatively higher rate of early complications, including lead removal, accidental lead pullout, and lead breakage.
- These issues suggest that further optimization and monitoring are needed to enhance the safety and effectiveness of PNS.

REFERENCES

- Gilmore CA, Desai MJ, Hopkins TJ, Li S, DePalma MJ, Deer TR, Grace W, Burgher AH, Sayal PK, Amirdelfan K, Cohen SP, McGee MJ, Boggs JW. Treatment of chronic axial back pain with 60-day percutaneous medial branch PNS: Primary end point results from a prospective, multicenter study. *Pain Pract*. 2021 Nov;21(8):877-889. doi: 10.1111/papr.13055. Epub 2021 Jul 27. PMID: 34216103; PMCID: PMC9290596.
- Steven Cohen, Christopher Gilmore, Leonardo Kapural, Steven Hanling, Anthony Plunkett, Meredith McGee, Joseph Boggs, Percutaneous Peripheral Nerve Stimulation for Pain Reduction and Improvements in Functional Outcomes in Chronic Low Back Pain, *Military Medicine*, Volume 184, Issue Supplement_1, March-April 2019, Pages 537-541, <https://doi.org/10.1093/milmed/usy310>
- Gilmore CA, Kapural L, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation for Chronic Low Back Pain: Prospective Case Series With 1 Year of Sustained Relief Following Short-Term Implant. *Pain Pract*. 2020 Mar;20(3):310-320. doi: 10.1111/papr.12856. Epub 2019 Dec 2. PMID: 31693791; PMCID: PMC7079182.
- Timothy R Deer, Christopher A Gilmore, Mehul J Desai, Sean Li, Michael J DePalma, Thomas J Hopkins, Abram H Burgher, David A Spinner, Steven P Cohen, Meredith J McGee, Joseph W Boggs, Percutaneous Peripheral Nerve Stimulation of the Medial Branch Nerves for the Treatment of Chronic Axial Back Pain in Patients After Radiofrequency Ablation, *Pain Medicine*, Volume 22, Issue 3, March 2021, Pages 548-560, <https://doi.org/10.1093/pm/pnaa432>