Transforaminal Electrode Injection on Lumbar Dorsal Root Ganglia in a Porcine Model

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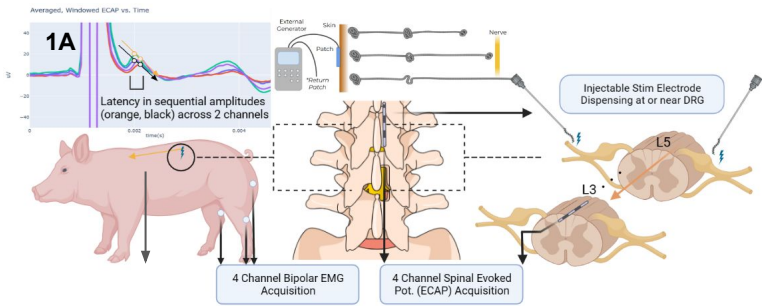
Introduction

- Dorsal Root Ganglion Stimulation (DRGS) is a promising FDA approved treatment for a variety of neuropathic pain conditions, including CRPS.
- However, current DRG systems involve technically challenging placements with complications including lead fracture and migration, limiting widespread clinical adoption.
- More rapid transforaminal approaches commonly used for steroid injections to nerves may be desirable for DRG stimulator implantation, especially for those with non-permitting spinal or epidural anatomy.

We propose a transforaminal approach to DRG stimulation using an fully implanted, injectable helical wire structure electrode (HWSE), as tested acutely in a porcine preclinical neurostimulation model.

Device and Delivery Methods



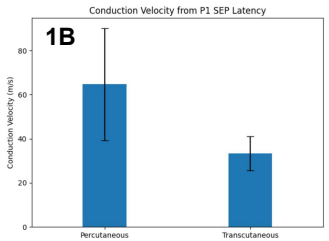


Figure 1A: System for transforaminal injection of HWSE. Percutaneous stimulation done intra-deployment, transcutaneous stim. post-deployment (25Hz, 80µs biphasic). Bipolar Intramuscular EMG & Spinal Evoked Potentials (ECAP) recorded at 25kHz using distal tissue reference in local fat.

Figure 1B: A□ fibers delineated by P1 latency and conduction velocity (35 - 80m/s) measured from adjacent recording contacts.

Porcine DRG Injectable Electrode Placement

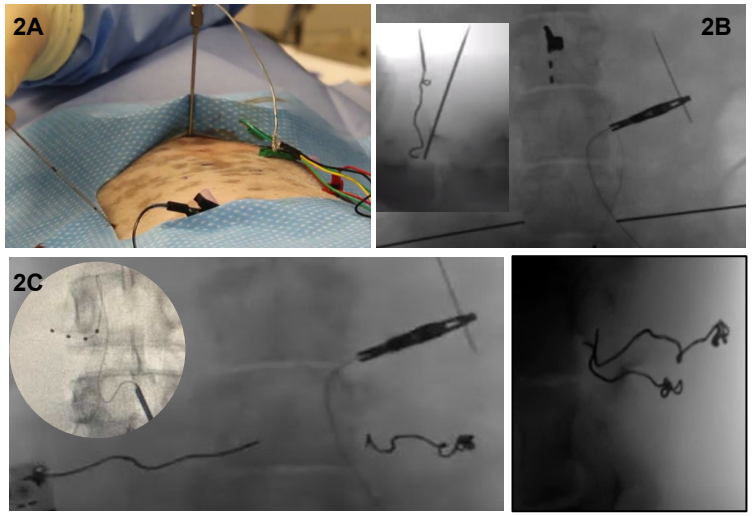


Figure 2A: 4-ch epidural recording lead placed under fluoroscopy, advanced 2 spinal levels rostral to stim. **2B:** Delivery cannulas inserted towards dorsal aspect of L5 foramen (inset) using pedicle for guidance and imaging ensuring careful needle progression prior to HWSE dispensing. **2C**: Electrode post-deployment (AP, lateral). Traditional DRG lead shown (inset) for comparison (Hawash et al, 2021). Time to place HWSE = 3 min.

Percutaneous DRG Stimulation with HWSE

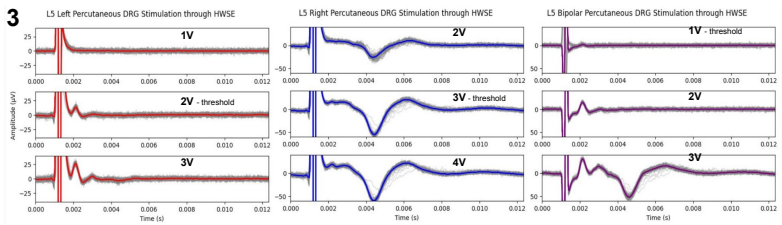


Figure 3: Nearest-DRG (left), post-ganglionic (middle), and bipolar stim. (L5 left to right lead) during deployment produced ECAP components resembling A□ fiber activation. Bipolar stim. achieved A□ activity at lowest threshold (1V).

Transcutaneous DRG Stimulation with HWSE

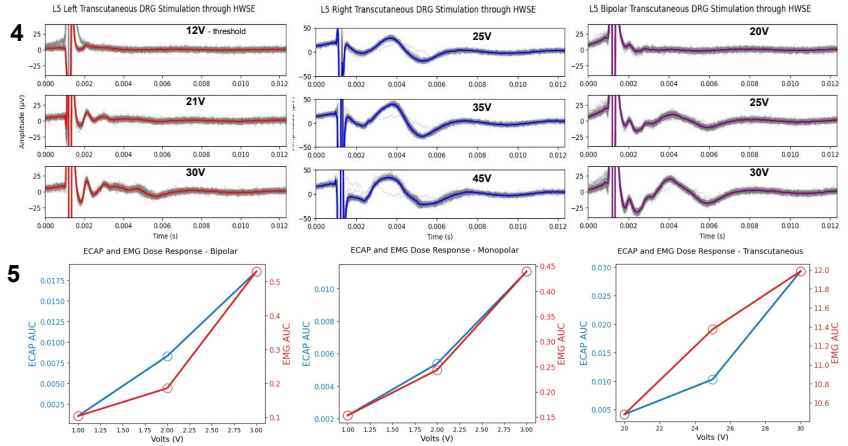


Figure 4: ECAPs for nearest-DRG (left), post-ganglionic (middle), and bipolar stim. (L5 left to right lead) after placement using surface patches (Cadwell 1.25", Ambu-Neuro). A□ ECAP components readily discerned at 6-10x perc. thresholds. Post-ganglionic stim. produces more EMG spillover obscuring SEPs.

Figure 5: Dose response curves of monopolar, bipolar, and transcutaneous stimulation paradigms, with intramuscular EMG recorded in L/R gluteal muscle. Bipolar stimulation produces largest ECAP vs. EMG signal intensity. Recordings during transcutaneous stimulation must account for EMG and high stimulation artifact.

Conclusions and Future Directions

- We demonstrate rapid transforaminal lumbar DRG electrode placement and acute stimulation in a porcine model.
- Both percutaneous and transcutaneous DRG stimulation in monopolar and bipolar configurations resulted in discernable ECAPs in the spinal cord, suggesting DRG capture.
- Future studies will optimize contact placement while addressing chronic electrode stability, performance, and recording limitations

Acknowledgement and References

This project is supported by Neuronoff Inc., NIH 1U18EB029251-01 Grant, and the DARPA EEI program. Opinions, interpretations, conclusions and recommendations are those of the authors and are not necessarily endorsed by the Department of Defense or the National Institutes of Health. The Injectrode has not been cleared or approved for clinical use.