Transforaminal Electrode Injections Near the 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 chronic regional pain syndrome (CRPS).
- However, current DRG systems involve technically challenging, time-consuming placements which face complications including lead fracture and migration. These complications limit the widespread clinical adoption of DRGS.
- More rapid transforaminal approaches used for steroid nerve injections may be desirable for DRGS implantation, especially for patients with non-permitting spinal or epidural anatomy.

We propose a transforaminal approach to near-DRG, and alternatively, on-DRG stimulation using a fully implanted, injectable, helical wire structure electrode (HWSE), as tested sub-chronically over 2 weeks in a porcine preclinical neurostimulation model.

Materials & Methods

1A

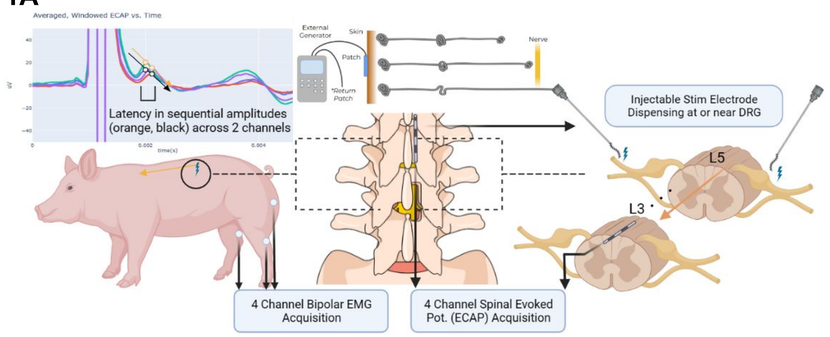
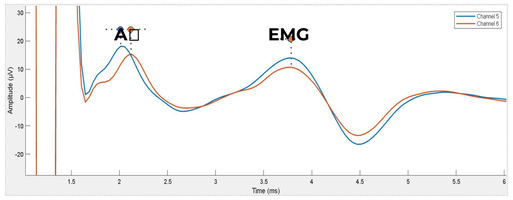


Figure 1A: System diagram for lateral to medial injection of HWSE. Percutaneous stimulation done intra-deployment, transcutaneous stim. is done post-deployment (25Hz, 80µs biphasic). Bipolar Intramuscular EMG & Spinal Evoked Potentials (SEP / ECAP) recorded at 25kHz with a distal reference in placed local fatty tissue.

1B



1C

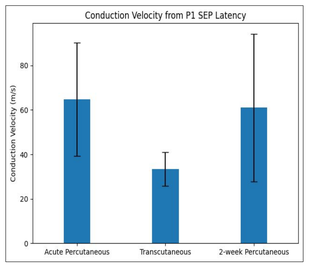


Figure 1B: Aβ fiber activation deduced by P1 latency (0.081ms - the delay between peaks of adjacent epidural recording channels). EMG contamination present with no propagation delay (0.000 ms). **1C:** Aβ conduction velocity (35 - 80 m/s) measured from peak to peak latency between adjacent recording contacts in the acute percutaneous, transcutaneous, and 2-week post-implant percutaneous settings. Transcutaneous CV is likely contaminated by stimulation artifact and EMG bleedthrough.

Results

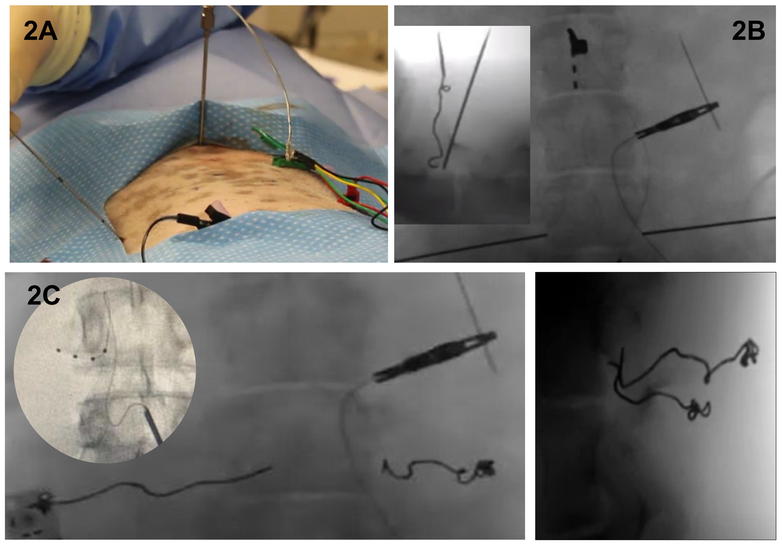


Figure 2A: 4-ch epidural recording lead placed and advanced 2 spinal levels cranial to stim lead. **2B:** Delivery cannulas inserted towards dorsal aspect of L5 foramen (inset) using pedicle for guidance and imaging ensuring careful needle progression prior to HWSE dispensing. **2C**: Electrode post-deployment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

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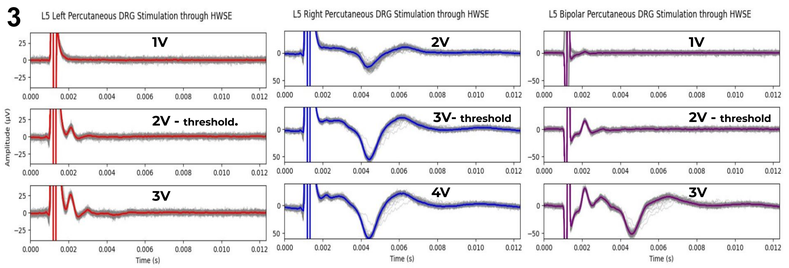

Figure 3: Nearest-DRG (left), post-ganglionic (middle), and bipolar stim. (L5 left to right lead) produces ECAP resembling Aβ fiber activation during deployment. Bipolar percutaneous stim. directly after deployment achieved Aβ activity at the lowest threshold (1V).

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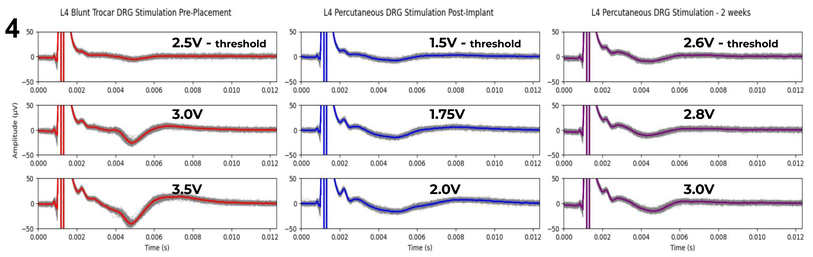

Figure 4: Blunt-Trocar Pre-Placement (left), acute percutaneous post-ganglionic (middle), and subchronic percutaneous stim after 2 weeks of implantation (right) produced Aβ ECAP components. ECAP Threshold after 2 weeks increased by 1.1V.

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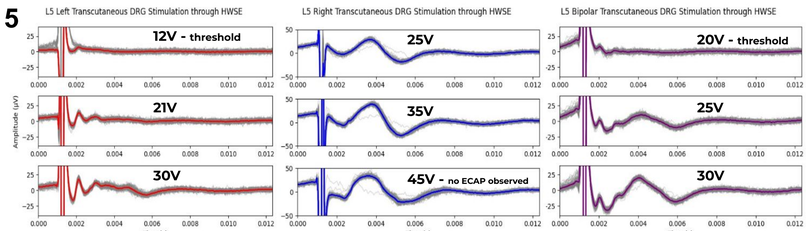

Figure 5: ECAPs for nearest-DRG (left), post-ganglionic (middle), and bipolar stim. using surface patches (Cadwell 1.25'', Ambu-Neuro) after placement . DRG-proximal ECAP components discernable at 6 to 10 times the percutaneous thresholds after placement. Post-ganglionic transcutaneous stim. produces EMG spillover, fully obscuring SEPs.

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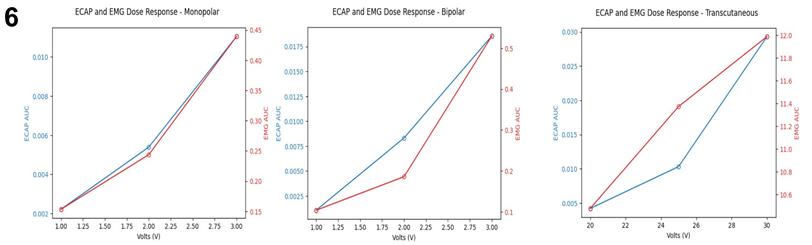

Figure 6: Dose response curves of monopolar, bipolar, and transcutaneous stim. paradigms, with intramuscular EMG recorded in L/R gluteal muscle. Bipolar stim. produces largest ECAP vs. EMG signal intensity. Recordings during transcutaneous stim. must account for EMG and high artifact presence.

Conclusions and Future Directions

- We demonstrate rapid transforaminal lumbar DRG electrode placement and stimulation in a porcine model.
- Percutaneous DRG stimulation in monopolar and bipolar configurations resulted in discernable ECAPs in the spinal cord, suggesting DRG capture up to 2 weeks after placement thus far.
- Future studies will optimize contact placement while addressing chronic electrode stability, transcutaneous stimulation performance, and recording limitations over longer placement durations.

Acknowledgements and Disclosures

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