

Percutaneous Implantation and Stimulation Versatility of Thin-Film Paddles – Cadaveric and in vivo Sheep Study

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Introduction

- In Spinal Cord Stimulation (SCS) therapy, paddle and percutaneous leads are two types of electrodes used to manage chronic pain. They are chosen based on the patient's specific needs and the physician's assessment. Paddles offer superior stability and broader stimulation coverage, making them ideal for complex pain cases. However, they require more invasive surgical implantation. Percutaneous leads, while minimally invasive, are more prone to migration and are less energy efficient than paddles.
- Recent advances in implantable thin-film technology have promoted the development of thin-film paddle leads in the SCS field. Due to their thin profile and design versatility, they offer the opportunity of combining broad stimulation coverage and minimally invasive implantation.

Objectives

- To design and develop a novel SCS lead with the full functionality of a paddle while maintaining the benefits of existing percutaneous implantation technique.
 - Test the percutaneous implantation of thin-film paddle leads in human cadavers using custom-made implantation tools.
 - Test the stimulation capabilities of the paddle in a large animal model (sheep)

Methods

Human cadavers:

- All experiments were conducted under an ethics committee approved protocol.
- Fresh cadavers (adult male and female, n=3), without spinal surgeries were utilized to develop and validate the implantation tools.
- Paddles 7 mm wide, 40 mm long, 75 μ m thick were percutaneously implanted using custom made tools compatible with a 14G Tuohy needle.

Animals:

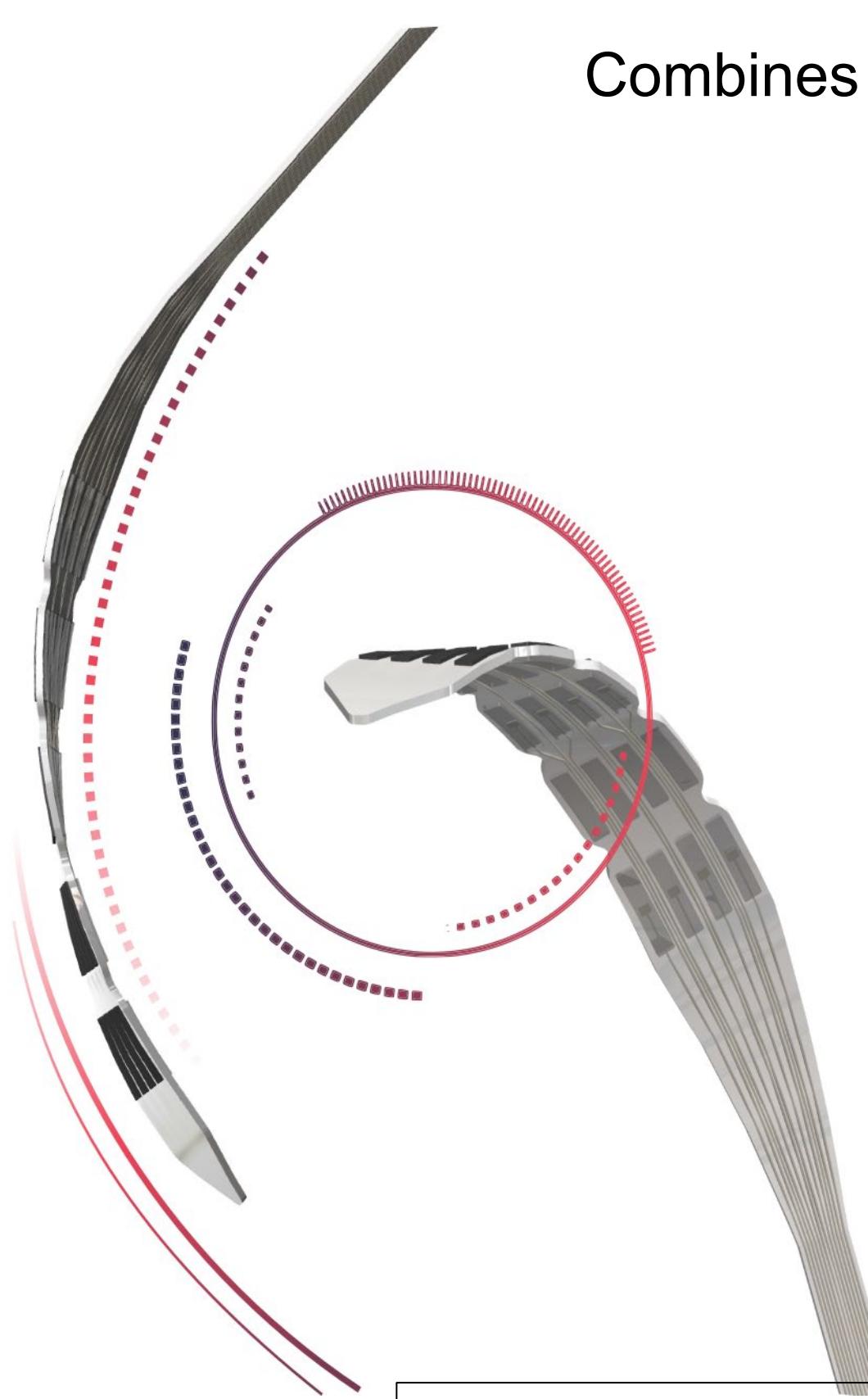
- All experiments were conducted under an approved IACUC protocol.
- Sheep (n=3; ~75 kg) were used to demonstrate stimulation capabilities of paddles and assess tissue reaction to the implant in sub chronic stage.
- Lead was positioned at L1-L2 level via a laminotomy at L3.

NeuroOne's Perc-Paddle Lead

Designed to Enhanced Therapy, Simplified Implantation

Combines paddle lead benefits with ease of use of percutaneous leads

- True percutaneous approach via standard 14-gauge needle.
- Low-profile design (75 μ m thick) for compatibility with complex anatomies.
- Precise, targeted stimulation at lower current levels.

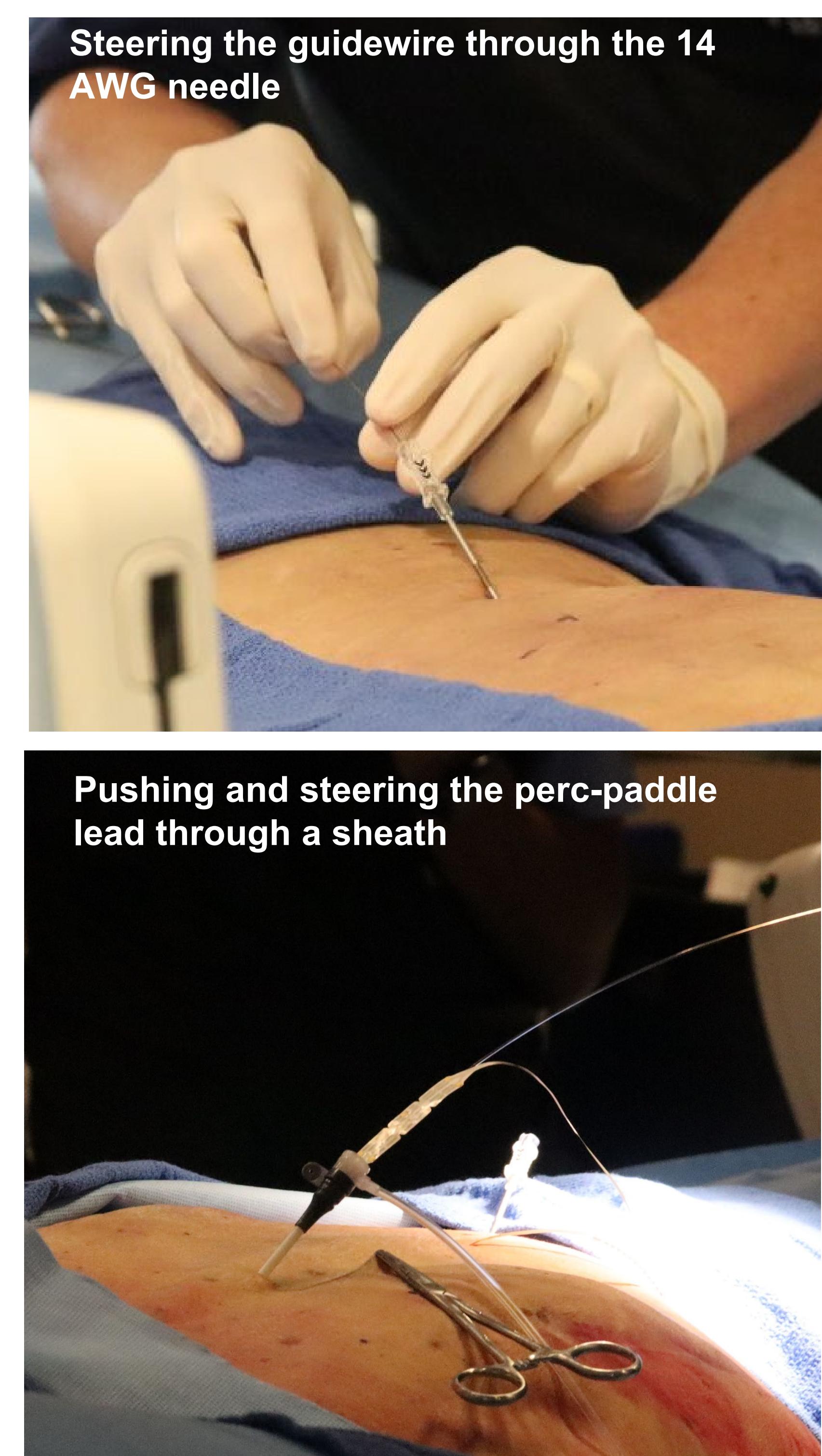


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Percutaneous Implantation Method



Novel Implantation Method - Preliminary Data

- Can be completed in under 5 minutes
- Utilizes familiar tools and techniques
- Enables precise targeting of pain areas
- Minimizes risks of surgical complications

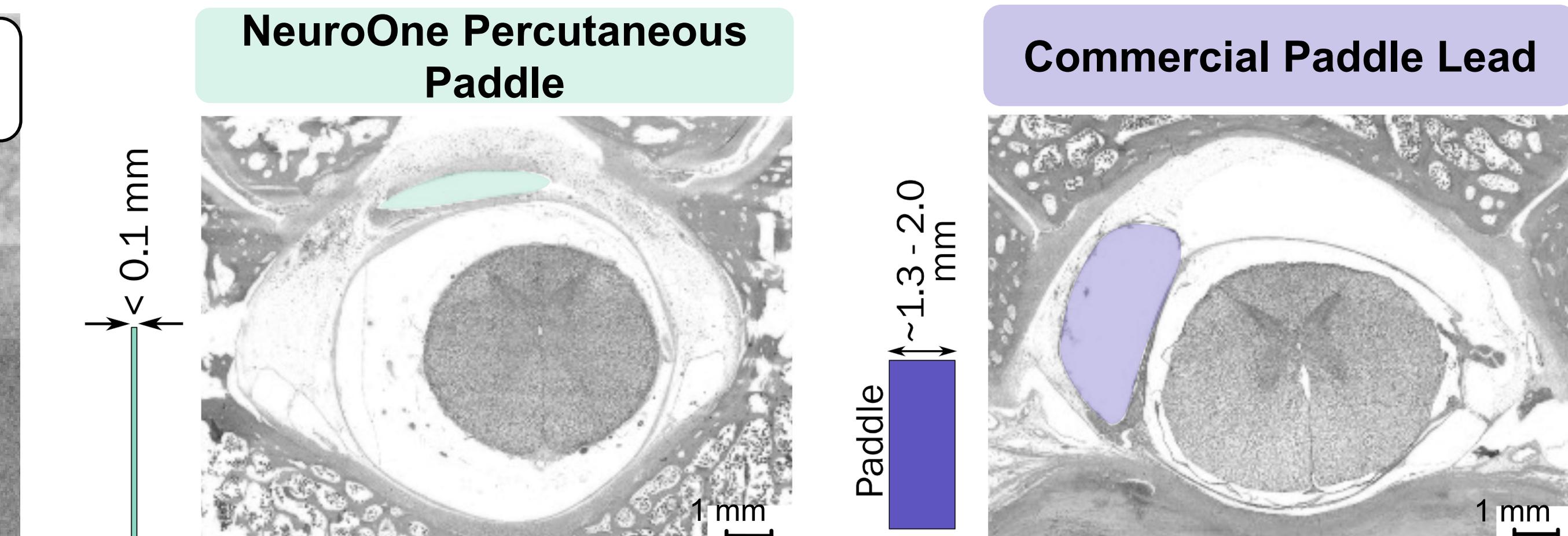
Summary and Conclusions

Perc-Paddle competitive advantages:

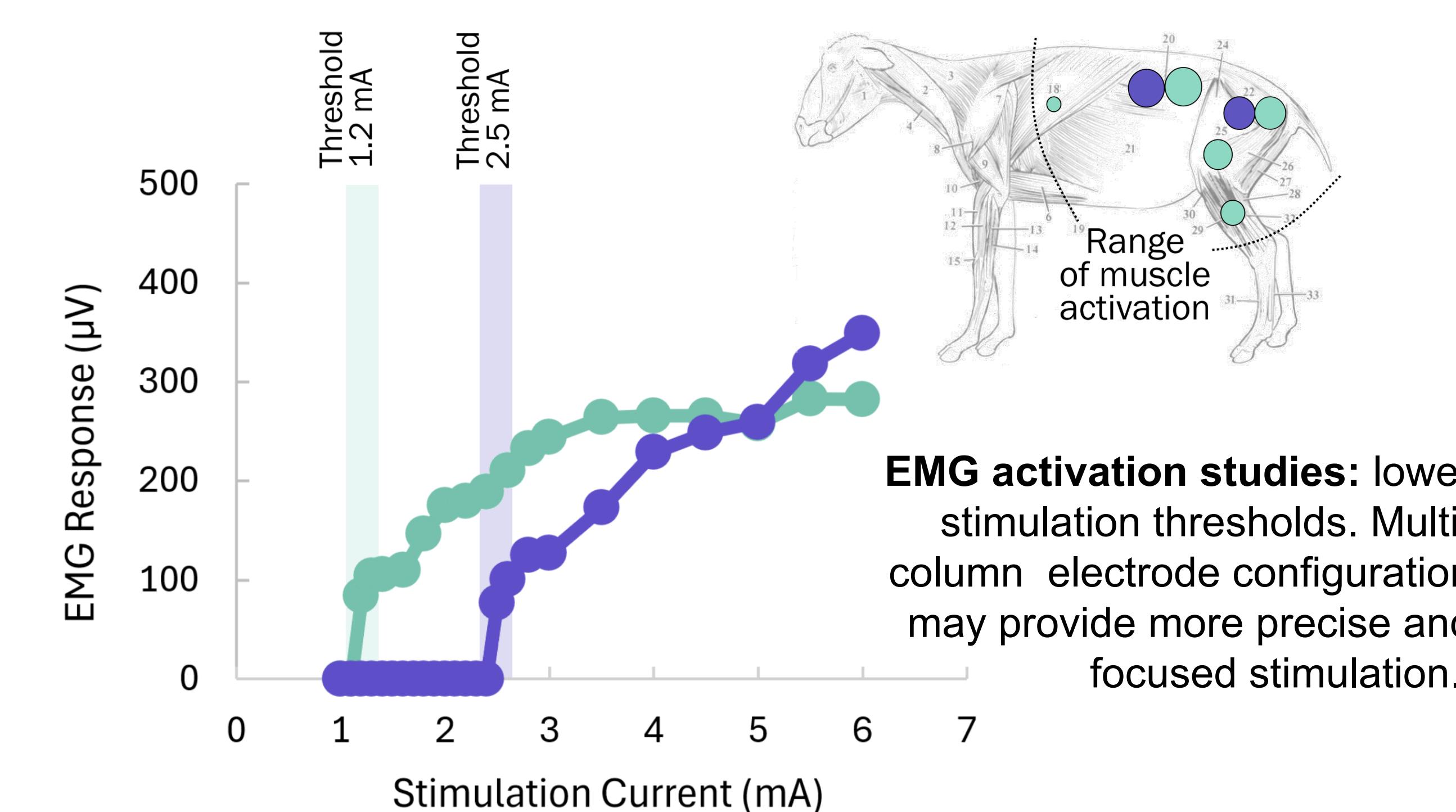
- Percutaneous implantation - no surgical intervention.
- Precise and targeted stimulation - allows the use of stimulation patterns that leverage electric field steering and shielding of dorsal structures.
- Low profile - occupies 1/20 of the volume of a standard paddle, being suitable for difficult anatomies.

The availability of a percutaneous paddle lead has the potential to improve both safety and efficacy of spinal cord stimulation for chronic pain relief.

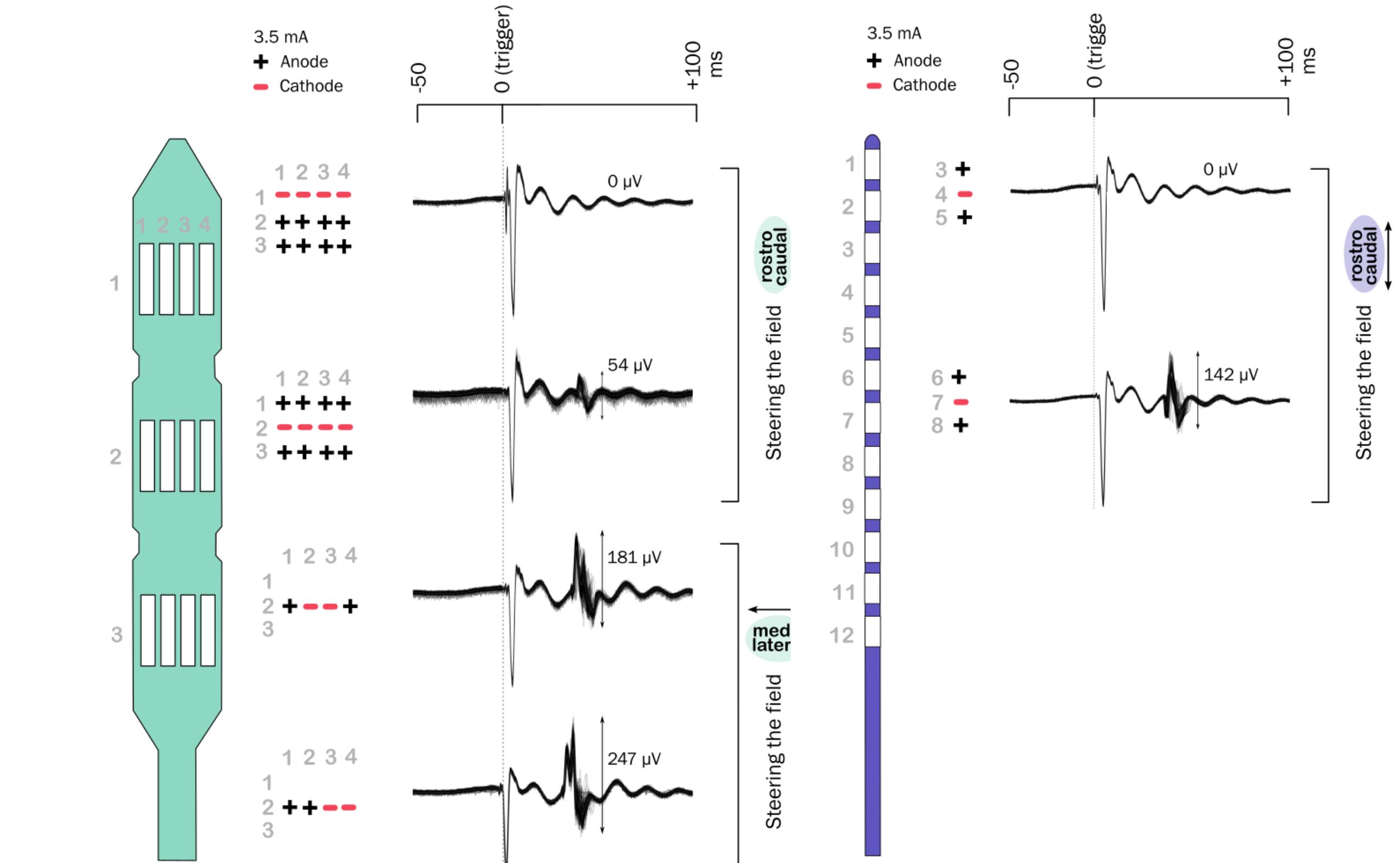
Pre-Clinical Studies in Sheep



Ideal for challenging anatomical spaces - preliminary studies in sheep (28-day implants): NeuroOne Perc-Paddle leads occupy a fraction of the volume compared to standard paddles, maintaining the integrity of surrounding tissues.



EMG activation studies: lower stimulation thresholds. Multi-column electrode configuration may provide more precise and focused stimulation.



- Traditional percutaneous leads are restricted in anode-cathode configurations, limiting electric field steering to the rostrocaudal direction.
- NeuroOne's Perc-Paddle Lead is designed to and able to steer the electric field in both rostrocaudal and mediolateral directions, enhancing selectivity and potentially increasing efficacy.
- NeuroOne's Perc-Paddle Lead is designed to be compatible with transversal bipolar stimulation, which should effectively shield lateral structures from unwanted stimulation, limiting side effects.