

# Histological evaluation of tissue ingrowth in open-coil percutaneous 60-day peripheral nerve stimulation leads

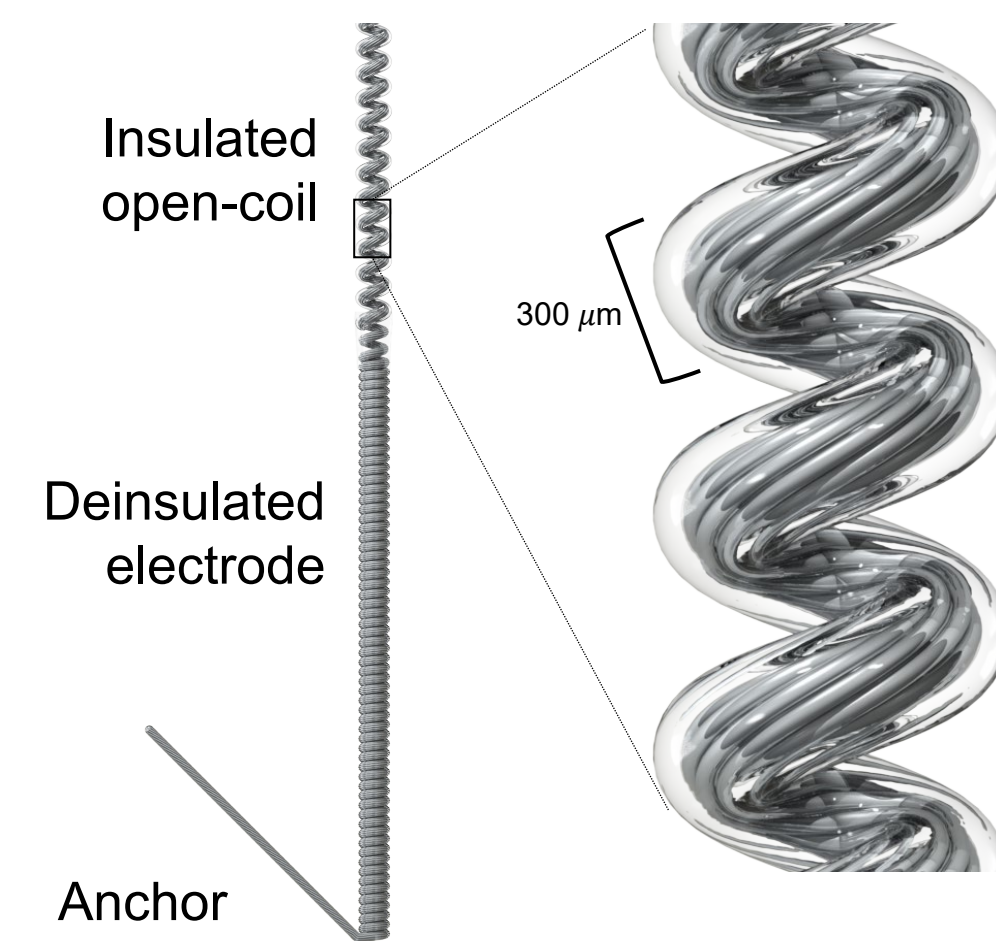
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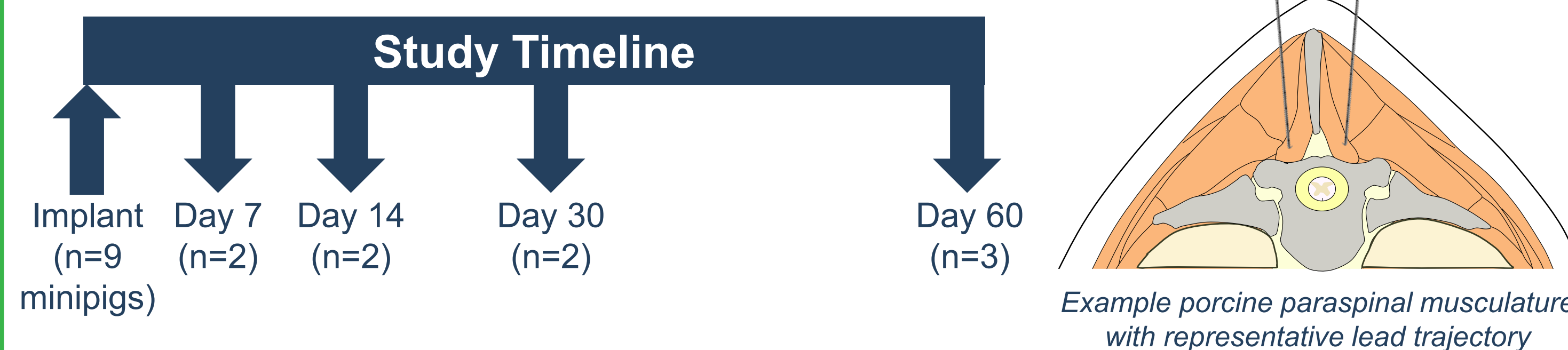
## BACKGROUND

- Open-coil leads used to deliver 60-day percutaneous peripheral nerve stimulation (PNS) are designed to encourage tissue integration.<sup>1-3</sup>
- Healthy tissue ingrowth is intended to reduce “pistoning” at the skin to inhibit the ingress of contaminants and thereby reduce infection risk.<sup>1,4</sup>
- The present study evaluated open-coil percutaneous PNS leads in a porcine model over the course of a 60-day implant period to assess the timeline and extent of tissue ingrowth.



## METHODS

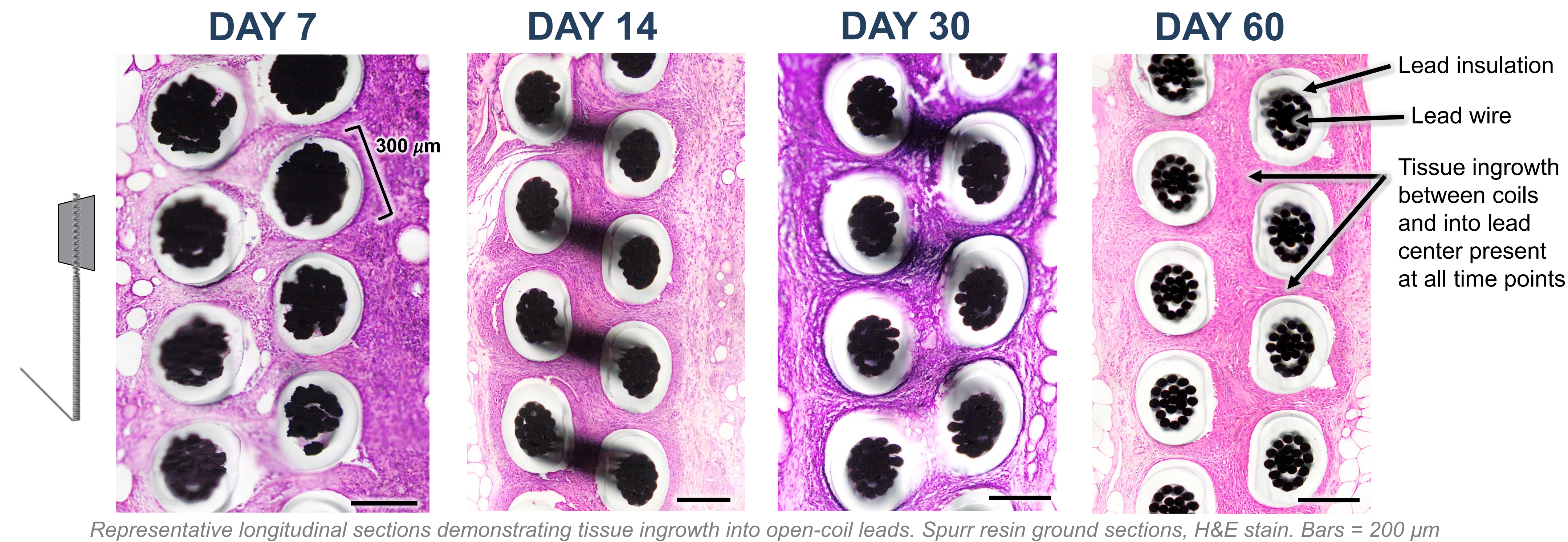
- IACUC-approved study in Yucatan minipigs (n=9). Up to 16 leads per minipig were implanted bilaterally in the dorsal paraspinal musculature for up to 60 days:



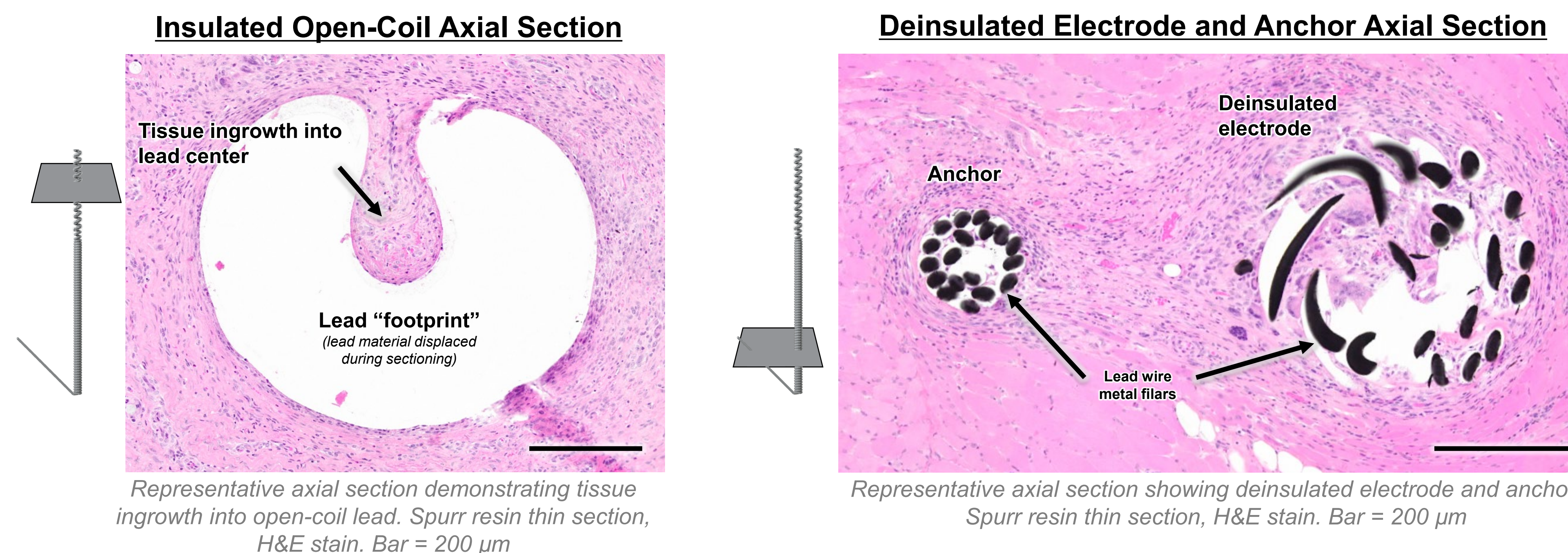
- For minipigs sacrificed at each timepoint, a subset of leads were withdrawn to measure force required for removal while another subset of leads were removed with the surrounding tissue *en bloc* and fixed in 10% formalin.
- During sample collection, additional leads were implanted and immediately removed for histology or withdrawal force as negative controls (i.e., representing no tissue ingrowth).
- Gross and microscopic histological features including tissue fibrosis and ingrowth were evaluated qualitatively and quantitatively scored by an independent certified pathologist

## RESULTS & DISCUSSION

**Healthy tissue ingrowth into and around the open-coil 60-day PNS lead was evident by Day 7 and consistent through Day 60.**



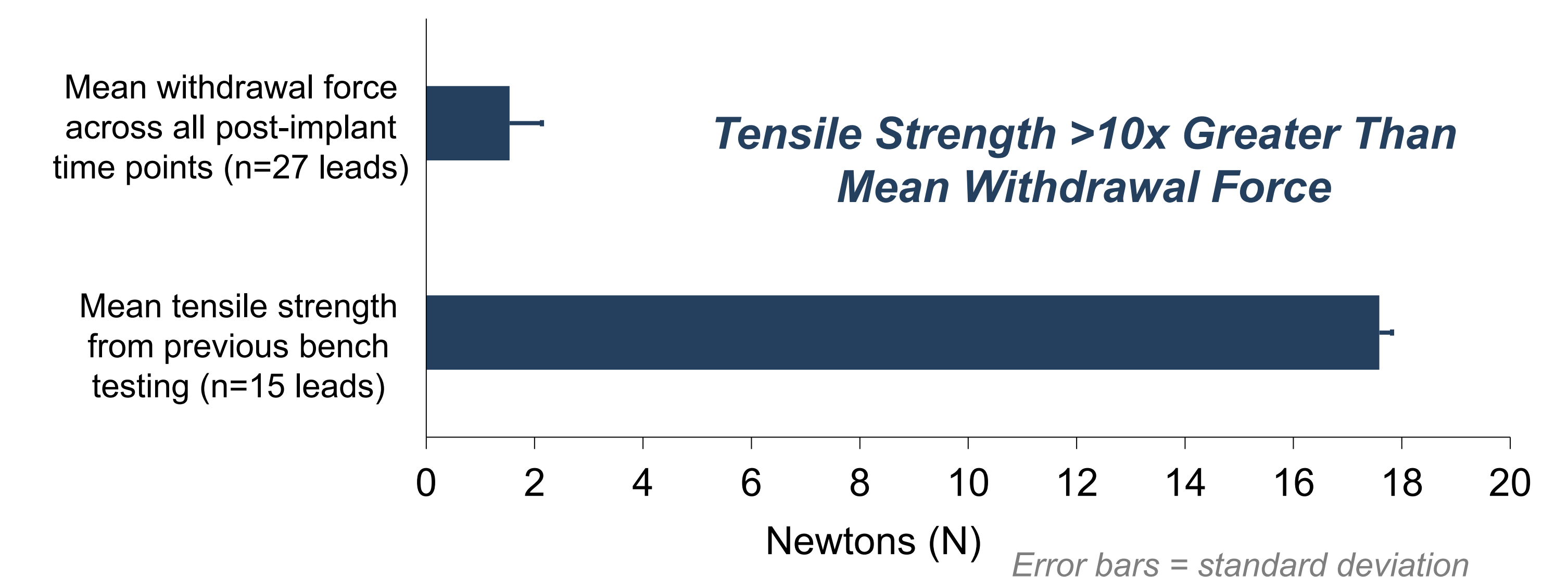
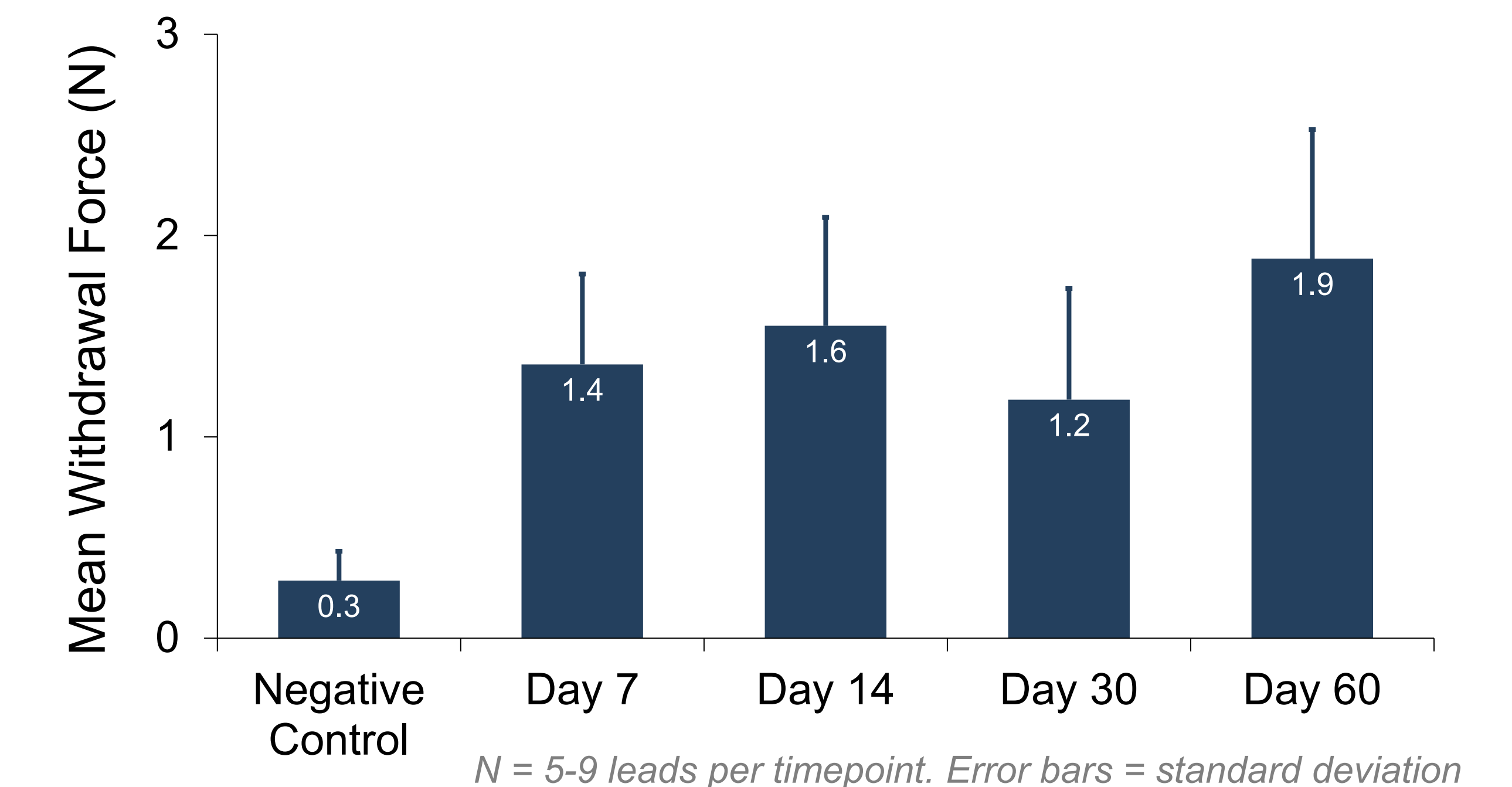
Representative longitudinal sections demonstrating tissue ingrowth into open-coil leads. Spurr resin ground sections, H&E stain. Bars = 200 µm



Representative axial section demonstrating tissue ingrowth into open-coil lead. Spurr resin thin section, H&E stain. Bar = 200 µm

Representative axial section showing deinsulated electrode and anchor. Spurr resin thin section, H&E stain. Bar = 200 µm

**Mean force required for lead withdrawal was consistently increased from negative controls and remained well below the mean tensile strength of the leads established in previous benchtop testing.**



- Histological and withdrawal force data demonstrated significant tissue ingrowth into percutaneous open-coil leads beginning by Day 7 that was observed consistently through Day 60.**
- These findings support previous work suggesting tissue ingrowth may reduce pistoning to contribute to lower infection risk relative to conventional non-coiled leads, enabling extended treatment for patients who may benefit from up to 60 days of stimulation.**

1. Ilfeld, et al. (2017). Pain Pract 17(6): 753-762. 2. Boggs, et al. (2018). Peripheral Nerve Stimulation for Pain Suppression. Neuromodulation. 2:729-740; 3. Cohen, et al. (2019). Mil Med 184(7-8): e267-e274; 4. Gabriel and Ilfeld (2021). Expert Review of Medical Devices 18(2): 145-150; 5. Strand, et al. (2021). "Mechanism of Action of Peripheral Nerve Stimulation." Curr Pain Headache Rep 25(7): 47.

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