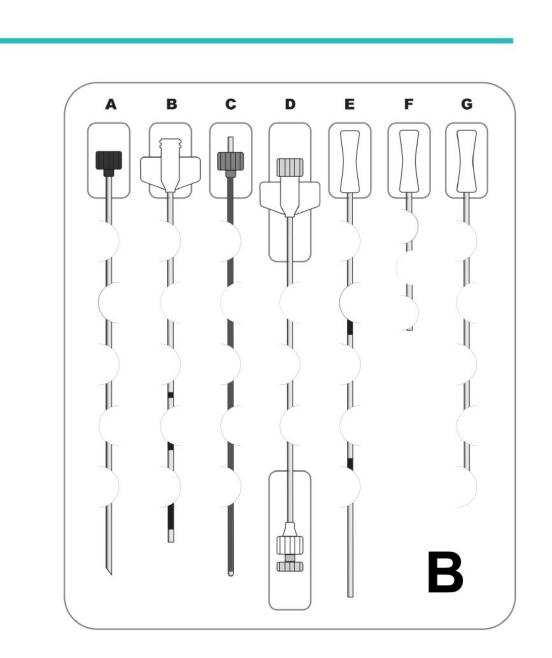
A Self-Anchoring Injectable Helical Wire Rope Structure Electrode Enables Ease of Placement and Clear Imaging

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Introduction

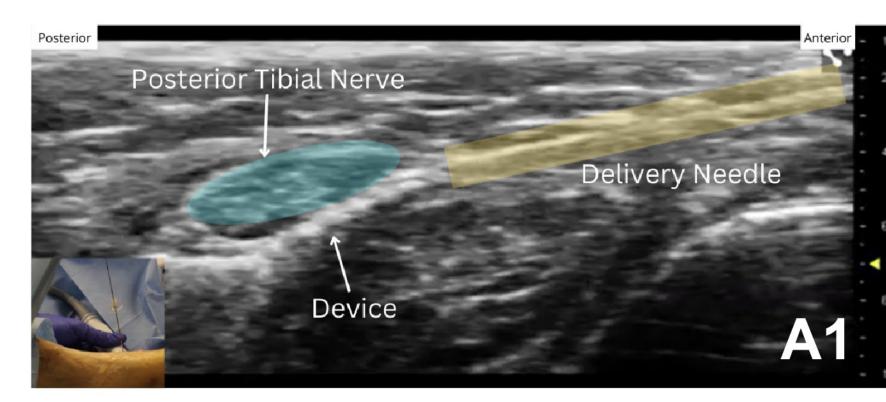
- Neuromodulation solutions often perceived as "last resort" solution due to surgical invasiveness
- Early intervention is associated with improved patient outcomes
- There is a need for a neurostimulator (A) with a simple placement procedure & compatible with common surgical tools/techniques (ultrasound (U/S), MRI)
- Neuronoff has developed a minimally invasive, needle placeable, fully implanted neurostimulator (1A)
- Suitable for clinical imaging (U/S, X-Ray, MRI)
- Self-anchoring
- Consistent placement at variable depths
- 5-component delivery system (B)

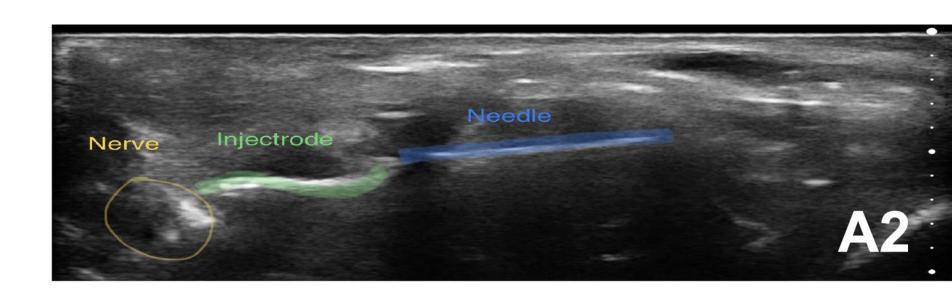




Delivery system: (A) sharp trocar, (B) blunt delivery needle, (C) blunt stimulating trocar, (D) transfer cannula (containing HWSE), (E) delivery pin. Additional pins (F, G) to simplify placement reliability & avoid over-deployment.

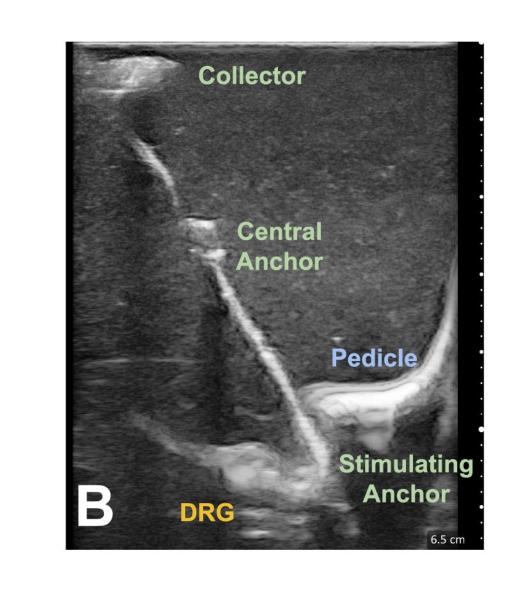
Ultrasound Guided Placement





U/S guided placement onto posterior tibial nerve (PTN) in human (A1) & porcine (A2)

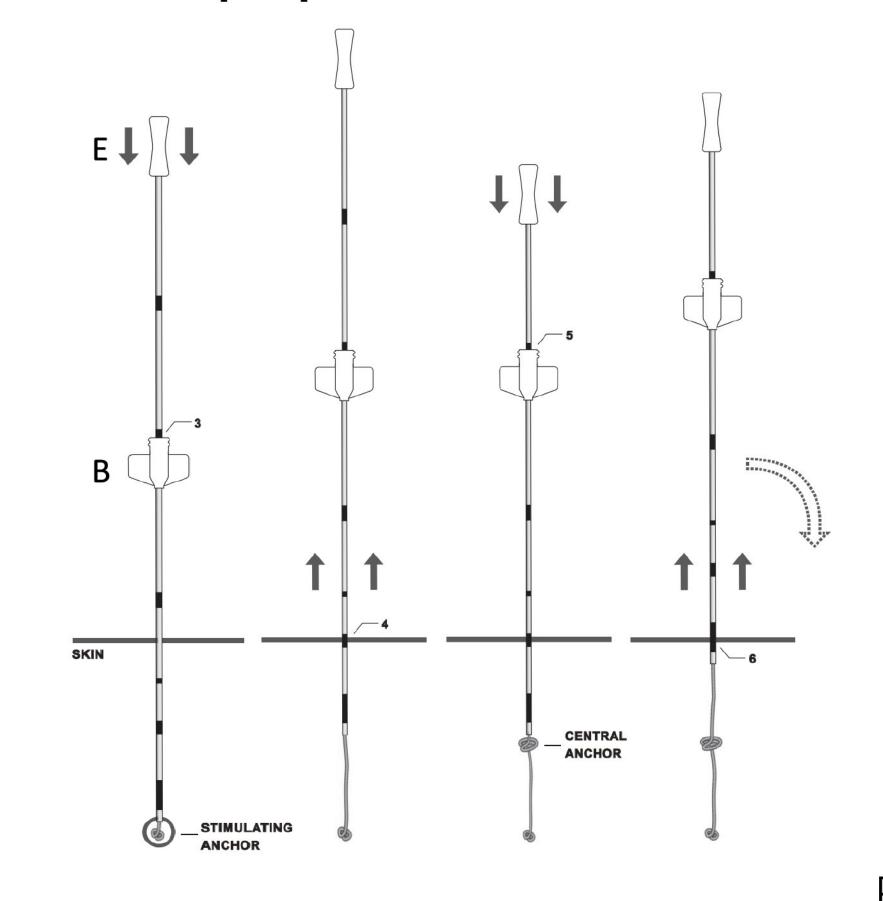
6 clinicians placed device <5 minutes in human cadavers with U/S on first use. Surgical planning & targeting nerves of interest is greatest technical burden.

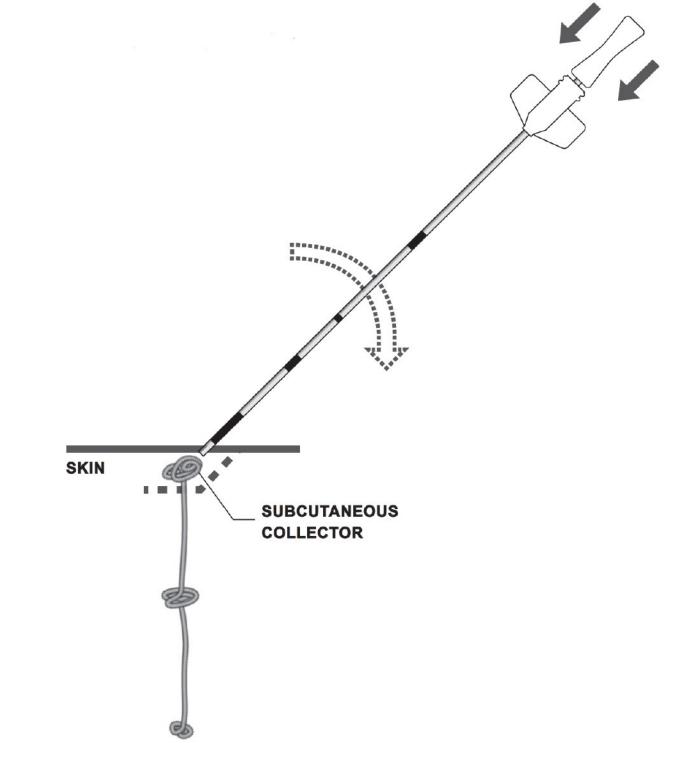


Acoustic shadow evident in anchor regions (B) on DRG benchtop model (including bone model)

Placement Procedure

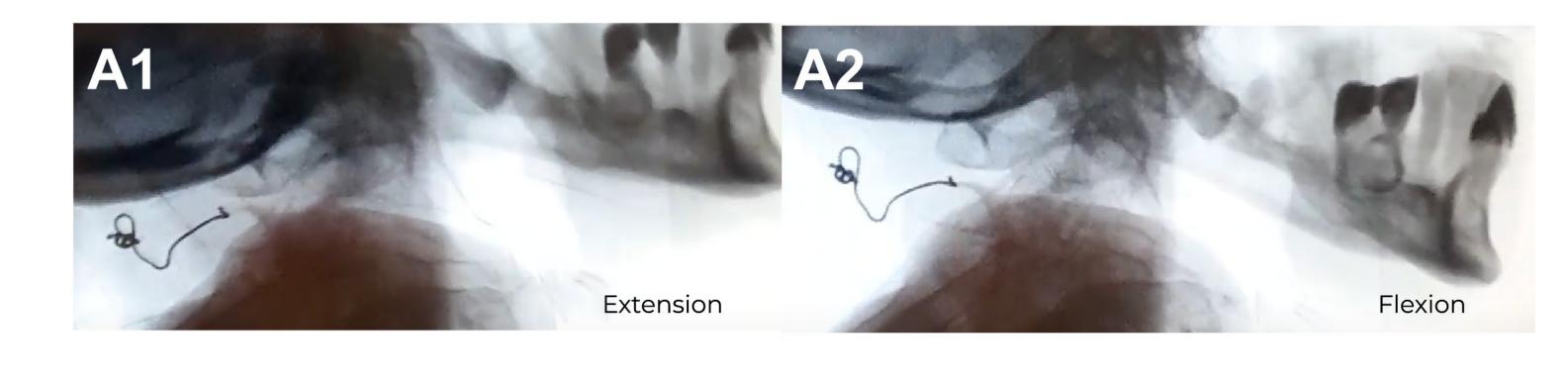
- Helical wire structure electrodes (HWSE, Injectrodes)) (gold or platinum-iridium, polyolefin) & delivery systems (18g)
- Devices placed in benchtop gelatin models, preclinical animal models & human cadavers on peripheral nerves





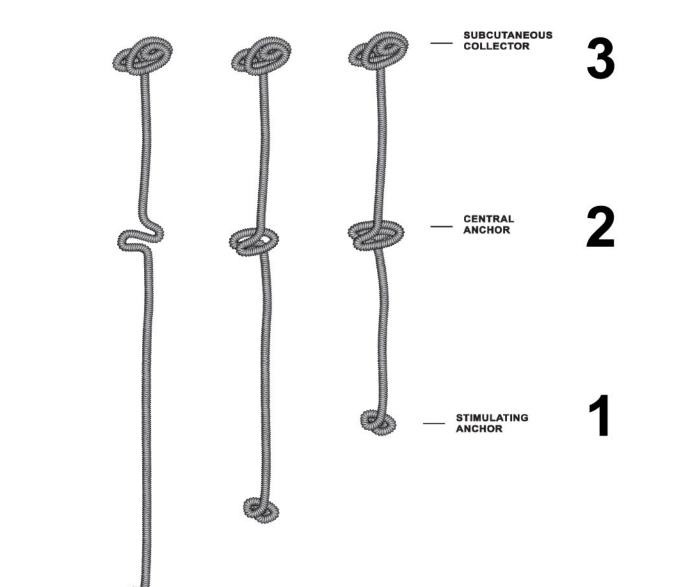
Placement procedure via 18g needle.

Self-Anchoring





flexion/extension in humans (A, B) & rodents (C), with no migration or pistoning



Flexible helical structure & placement technique (linear or curvilinear) leads to tissue ingrowth & 3 self-anchoring points without sutures

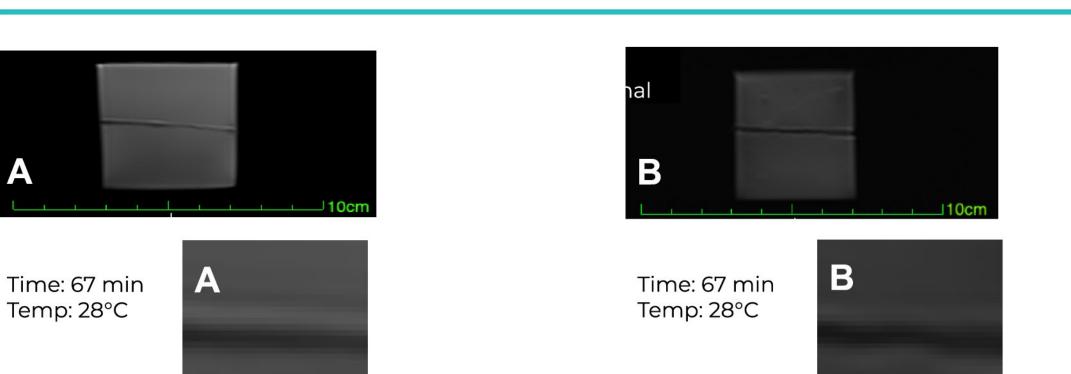
- 1: Stimulating Anchor
- 2: Central Anchor
- 3: Subcutaneous Anchor

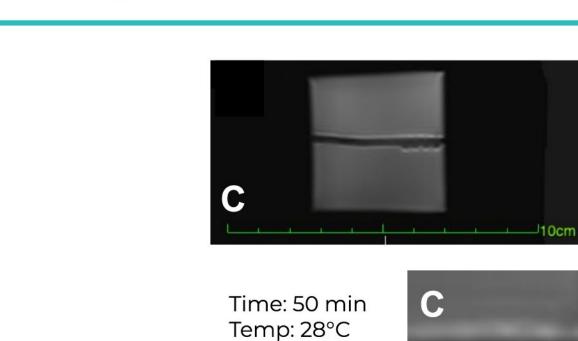
[1] Neuronoff, Inc., Cleveland, OH

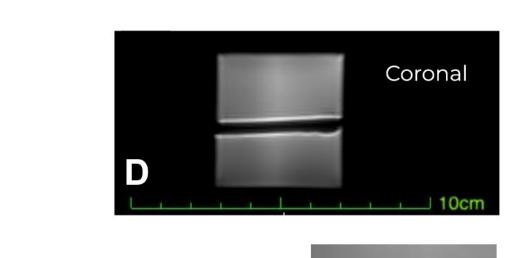
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- and Public Health, Madison, WI
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Magnetic Resonance Imaging

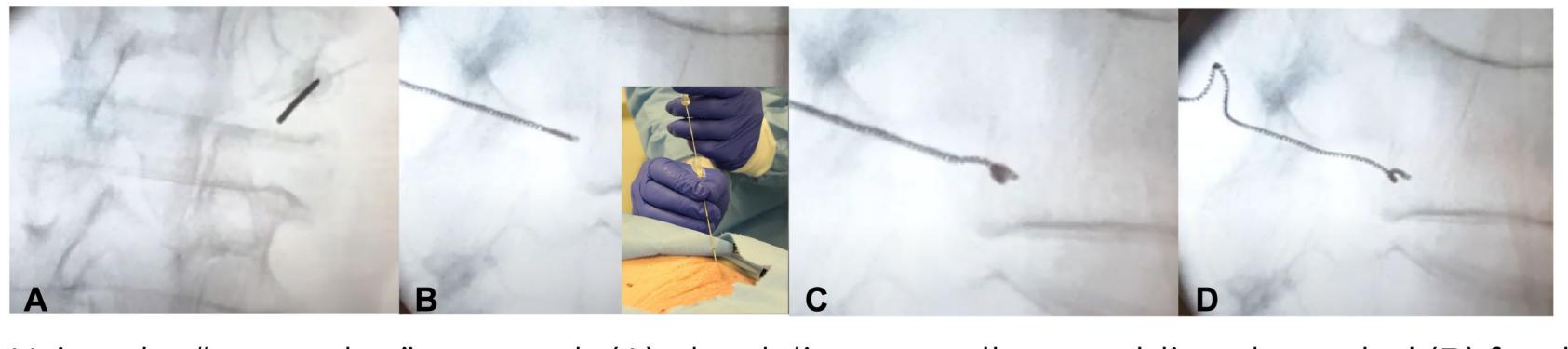


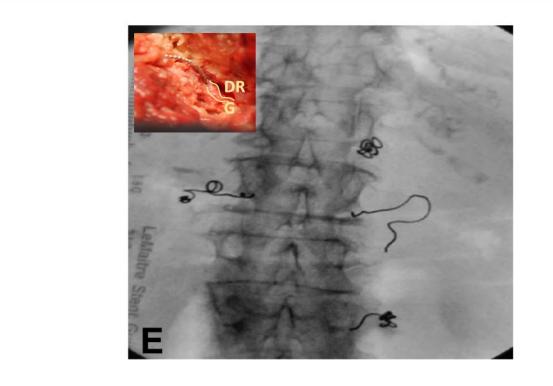




- HWSE (A) uncoated & (B) coated regions displayed little to no artifact (agar gel, 3T)
- Standard clinical lead with (C) four or (D) eight contacts exhibit mild (C) to significant (D) artifact at shorter imaging times compared to device (A, B)
- Negligible temperature increases in all leads

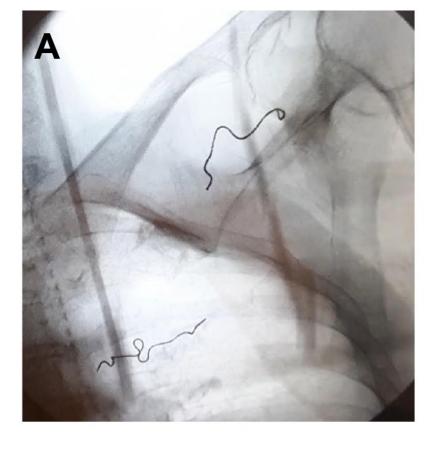
Dorsal Root Ganglion Placement

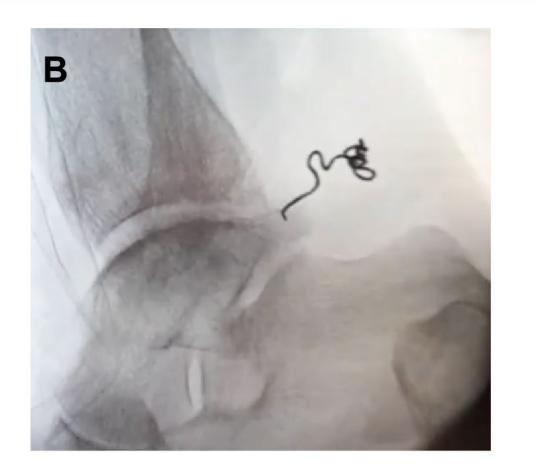


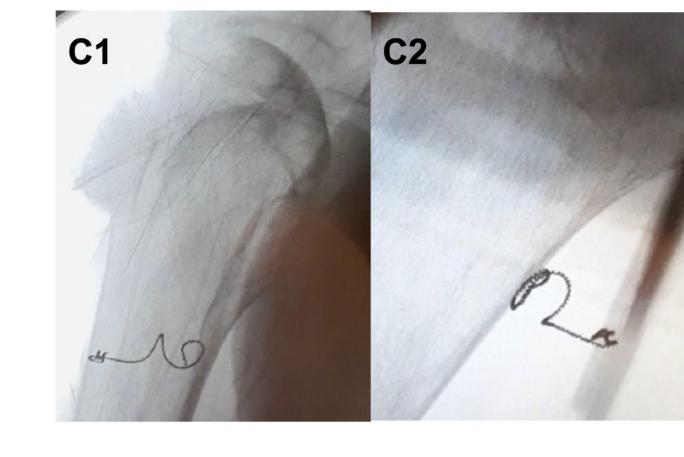


Using the "scotty dog" approach (A), the delivery needle was obliquely angled (B) for device placement (C). Stimulating & central anchors (D) were repeatedly placed with this method (E) & confirmed with open cut-downs.

Peripheral Nerve Placement







Devices were successfully placed <5 min along suprascapular (A), posterior tibial (B), & genicular (C) nerves.

Conclusions & Future Directions

- Device placement onto various nerve targets uses clinically familiar procedures (steroid/epidural/block injections) and imaging modalities (U/S, Fluoroscopy)
- Self-anchoring upon placement may mitigate migration
- Minimal MRI artifact supports future compatibility investigation
- Preclinical and clinical trials to further demonstrate device anchoring & stimulation efficacy

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