An Injectable Electrode Enables Chronic Stimulation of the Porcine Tibial Nerve

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Introduction

- Peripheral nerve stimulation (PNS) is an established treatment for many conditions including chronic neuropathic pain
- However, the invasiveness and complexity of PNS device implantation and removal procedures reduces clinical adoption
- Stimulation via external pulse generators (EPGs) are limited to superficial nerves due to their inability to activate deeper nerve targets without patient discomfort

We present a fully needle injectable helical wire structure electrode (HWSE) which acts as an electrical bridge between a subcutaneous location (the collector) and the posterior tibial nerve (PTN) in a porcine preclinical neurostimulation model.

This electrode was designed to:
1) Be placed and removed through minimally invasive techniques
2) Maintain stimulation efficacy via EPGs in a high mobility area

Device and Stimulation Path

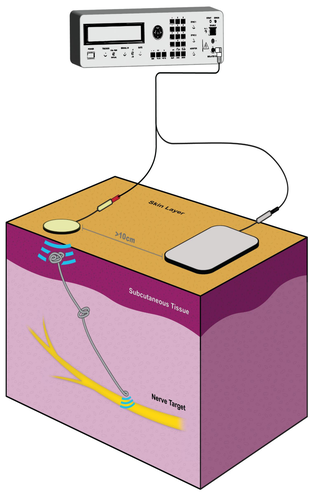

Figure 1A: Full-length HWSE - Device implantation is fully needle based, utilizing a series of sharp and stimulating needle tips to navigate the device towards a nerve target. **1B:** Representation of the electrical path of stimulation through tissue - The electrode serves as a low-resistance path from the skin patch to the deep nerve target. Previous tests have shown that a patch-to-return skin distance of at least 10cm provides the greatest On-Target stimulation with minimal Off-Target effect.

Methods

- Electrodes (PtIr,Polyolefin) and delivery systems were manufactured (Neuronoff, Cleveland OH)
- 3 Yorkshire pigs (36kg, Charles-River, Durham NC) were acclimated per CWRU IACUC-approved protocols and injected with 3 electrodes along each PTN under fluoroscopic guidance (6 total implants/pig)
- Dewclaw thresholds, toe flexion and extension thresholds, superficial "off-target" muscle contractions, and "off-target" EMG were measured pre-implant and at 0, 14, 28, 42, and 56 days post-implant in response to voltage sweeps (A-M Systems 4100, 30Hz cathodic charge-balanced biphasic, 300 μs) applied by skin-patches (Cadwell, Ambu-Neuroline).

Placement and Experimental Setup

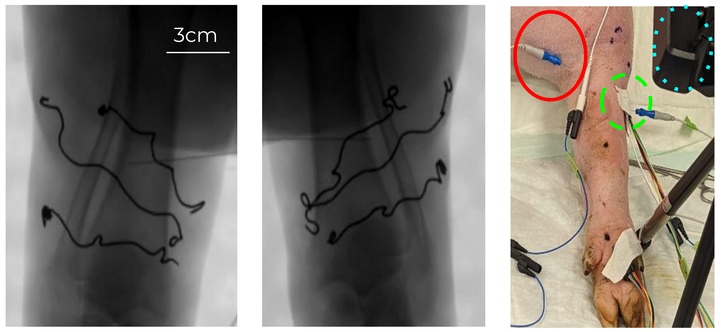

Figure 2A/B: Fluoroscopy of HWSE placement at 3 points along the PTN (left and right, 6 implants total), **2C:** Experimental setup for PTN stimulation, off-target EMG placed in gastrocnemius to quantify off-target muscle activation (red - solid), accelerometer placed on stimulation patch off-target activation (green - dashed), camera used to track dewclaw/toe movement (cyan - dotted)

HSWE Facilitates On-Target Muscle Activation

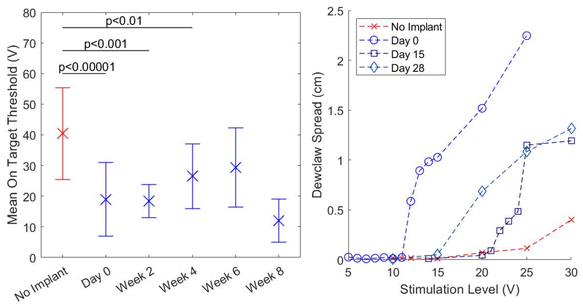

Figure 3A: HWSE implant decreased On-Target thresholds, **3B:** HWSE implant increased On-Target muscle activation (dewclaw spread) at lower levels of stimulation

HWSE Shunts Stimulation from Off-Target Muscles

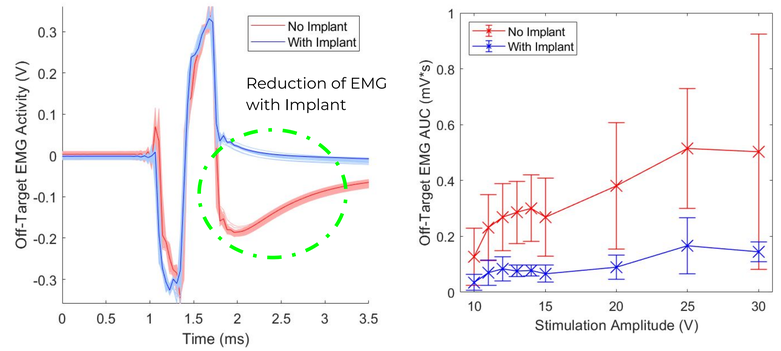

Figure 4A: Off-Target EMG at 15 Volts before (red) and after (blue) device implant, **4B:** Off-target EMG AUC vs voltage-controlled stimulation sweep indicate substantial decrease in Off-Target muscle activation at the same levels of stimulation following device implant

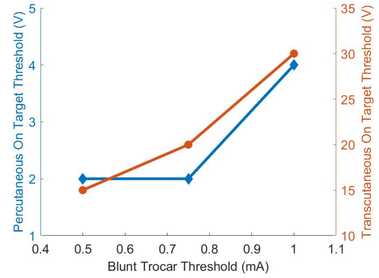

Figure 5: On-Target percutaneous and transcutaneous thresholds vs blunt trocar thresholds verifies implantation method - achieving lower blunt trocar reflects proximity to nerve target and results in lower transcutaneous On-Target thresholds

Conclusions and Future Directions

- HWSEs are transcutaneously efficacious for PTN stimulation, as shown by decreased on-target thresholds and decreased activation of off-target muscle groups following device implant
- HWSE placement, as indicated by blunt needle stimulation threshold, directly affects both percutaneous and transcutaneous thresholds
- Future experiments will refine measurements to achieve more rigorous quantification of separable, specific muscle activations for GLP

Acknowledgement and Disclosures

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