Simple, Minimally Invasive Removal of an Injectable Electrode From Hydrogel and Chronic Preclinical Models

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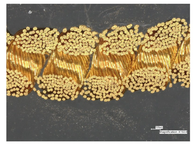
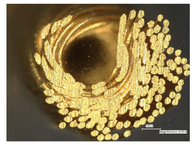
Introduction

- Removal of neuromodulation devices can be a risky and involved procedure, involving surgery and potential nerve damage.
- Implanted devices should be able to be removed without issues.
- **There is a need for a neurostimulator with a simple, minimally invasive removal procedure minus the risk of device breakage.**
- We have developed a fully implanted neurostimulator that can be removed with little to no impact to the patient.
- Helical wire structure electrodes (HWSE, Injectrodes) (gold or platinum-iridium, polyolefin) & delivery systems (18g) developed & manufactured by Neuronoff, Inc. (Cleveland, OH)
- **Devices placed in benchtop gelatin models & preclinical rodent models**

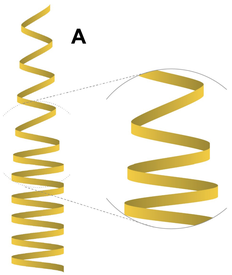


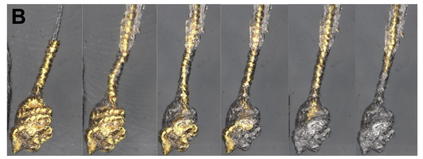


Electrode made of 100 strands of metal wire, twisted and then wrapped around an inner core. Cross-sections can be seen here demonstrating the helical structure..

Helical Unzipping

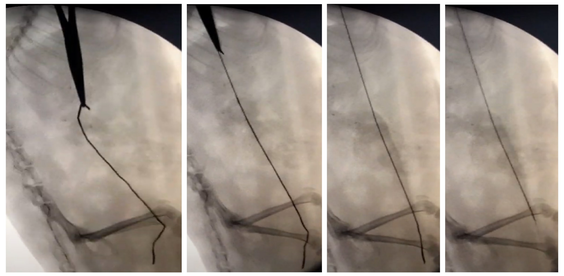
- When vertical force is applied to the wrapped helical injectrode, each individual wrap stretches upwards, tightening its diameter, before transferring the force to the next wrap.
  - In Figure A below, the decreasing diameter can be seen clearly in the cutout image.
- **This results in a staggered overcoming of friction and therefore an easier removal.**
- In addition, since the device is pulled inwards instead of just laterally, it can be removed through its own footprint, minimizing the impact on tissue encapsulation, as demonstrated in gel in Figure B.





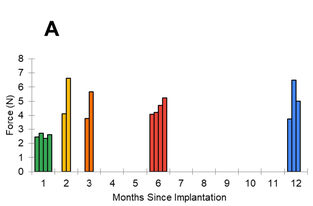
Benefits of Coiled Structure

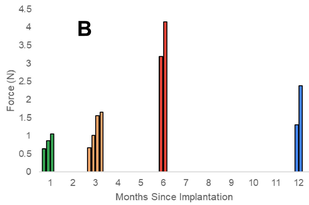
- The helical structure decreases the force needed to explant the device once implanted, as the equivalent of removing along an inclined plane.
- Peak removal force of an HWSE is lower than that of the peak force required to remove a congruent non-coiled electrode (1.4 N +/- 0.4N average for coiled vs 5.1N +/- 2.95N N average for uncoiled).
- **Force transmits down the device laterally as coils lengthen, as seen under fluoroscopy.**



Removal over Time

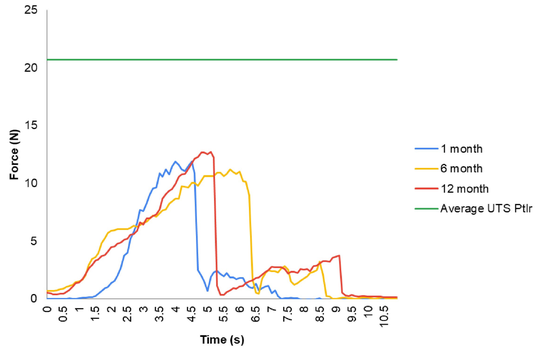
- When it comes to long-term implantation and removal, the force it takes to remove the HWSE after 12 months is comparable to the force to remove at one month, as seen below.
  - Figure A contains chronic data from rodents implanted with platinum-iridium devices
  - Figure B describes the equivalent study done with gold-based devices
- **Even over different electrode materials, the overall structure does not change and thus the dynamics of the system over time remain consistent.**
- Remodeling of tissue, wound healing may account for pattern over time.





Inherent Strength of Design

- Since the device is easy to remove, even after long periods of implantation, it compares very favorably to its own tensile strength.
- **Is there a significant risk of the device breaking upon removal? No.**
- Even when taking into account the force it takes to detach the tissue encapsulation, shown below as the large initial peaks, the strength of the device remains greater than any force put upon it in the removal process.
- **Actual removal force of the device averages 4.2N, a full 5 times less force than the 20.7N it takes to cut the device.**
- This holds fast over timepoints ranging from one month to twelve months.



Functional Safety During Removal

- Both acute and chronic implant removal studies have been performed in rodents so far, and to this date every rodent has recovered full ambulation after anesthesia.
- **No functional nerve damage from removal has occurred, even when devices were placed directly on the sciatic nerve and confirmed via stimulation.**

Conclusions & Future Directions

- The helical wire structure electrode can be removed from the body after long-term implantation with low risk and even lower impact to the body.
- A safety factor of 5 is inherently built into the structure of the device.
- Preclinical and clinical trials will be performed to further demonstrate ease and safety of removal

Acknowledgements

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