Removal Procedure of a Helical Wire Structure Electrode from Benchtop & Chronic Porcine Models

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Introduction

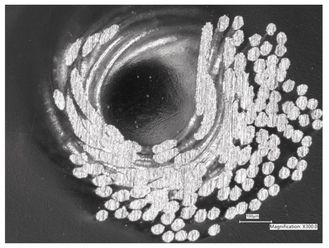
As neuromodulation becomes more common in the treatment of pain, more patients are expected to rely on implanted electronics to receive pain treatment. These devices may need to be removed for a variety of reasons, including loss-of-therapy, yet ease of removability has not kept pace with the increasing volume of implants. The more complicated the removal procedure, the higher chance of treatment delays and patient preference to pursue pharmaceutical therapies. Here we show development of an in-office or ambulatory surgical center (ASC) based removal procedure for a helical wire structure electrode, designed for simplicity and reliable removability.

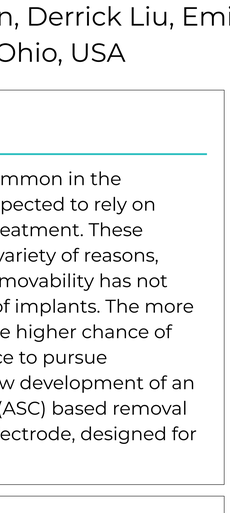
Materials & Methods

Helical wire structure electrodes, also known as Injectrodes (Neuronoff, Inc., OH), were fabricated from platinum-iridium microwires and intermittently coated with polyolefin.
These devices were implanted into Yucatan or Yorkshire farm pigs (Animal Research Core, CWRU, OH) either on the tibial nerve or near the dorsal root ganglion.
These devices were removed under fluoroscopy or ultrasound, using a standard scalpel cut (#10 or #15) and forceps.
Benchtop studies were performed in synthetic Gelatin #0 (Humimic Medical, SC), a mimic of muscle tissue.
Forces were measured with a force transducer (10N or 50N, Nidec Corporation, Japan).

Figure 1 (Right): Microscope image of the HWSE, where the individual platinum-iridium microwires can clearly be seen.

Figure 2 (Below): Cross-section of the HWSE, emphasizing the hollow core of the structure.





Results

Removal of the helical wire structure device can be performed easily and safely because the helical structure elongates when pulled, retracting one coil at a time from the surrounding tissue and distributing the force. Due to the "unzipping" process seen in Figure 3, on the right, the elongation and diameter reduction of the implanted device along its length can be seen in the fluoroscopy in Figure 4, below.

The device visibly narrows at the proximal end, where force is first applied with the hemostat, and transmits distally along the length of the device until the end, which is still located near the nerve, is removed last. This minimizes tissue trauma and keeps the force low, since at a given point in time only a few coils are actively being removed from the tissue.

To confirm that the helical structure is the source of these benefits, benchtop removal comparison of helical and non-helical devices of the same length showed that the helical structure required less force to remove than an equivalent non-helical device (helical 10cm: 1.85 ±0.37N (n=6) non-helical 10cm: 9.57 ±0.78N (n=6)).

The removal process can thus be remarkably simple, consisting of a single scalpel cut (4-5 millimeters across) followed by a locating of the device using standard forceps, as seen in Figure 5. Once the device is found, which is both radiopaque and echogenic, one can simply pull using the forceps until the entire device is externalized.

Figure 3: Illustrated here is the sequential "unzipping" process undergone when a helical wire structure electrode is pulled from tissue, causing coil-by-coil retraction.

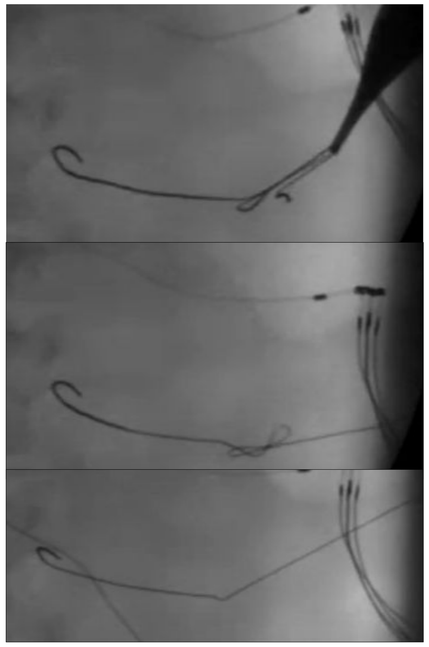


Figure 4: Fluoroscopy images of HWSE removal from a pig from near the dorsal root ganglion (DRG).

The removal procedure is time efficient, taking approximately 5-10 minutes including imaging, and can potentially be performed in an outpatient clinic without the need for an Operating Room environment. The procedure uses clinically-familiar, unspecialized tools, and could increase patient access through ease and reliability.

In addition, the device itself was built with safety in mind. The platinum-iridium Injectrode has an average tensile breaking force of 32.90±2.09N (n=26). The force it takes to remove the device from a previously-implanted pig, measured by a system pictured in Figure 5, averages 3.63 ±1.70N (n=33) over the span of 8 weeks. This peak removal force, the highest force a device will experience while being taken out of the body, is much less than the force it takes to break the device, leading to a very large safety factor of 9.06.

Over time, the force it takes to remove one of these devices does increase, as seen in Figure 6. However, the graph aligns with the current understanding of inflammation and wound remodeling, and aligns with longer term data from rodents.

Implanted devices must be able to be removed quickly, safely, and completely, and the ability to do so with this procedure renders the helical wire structure electrode a prudent option.

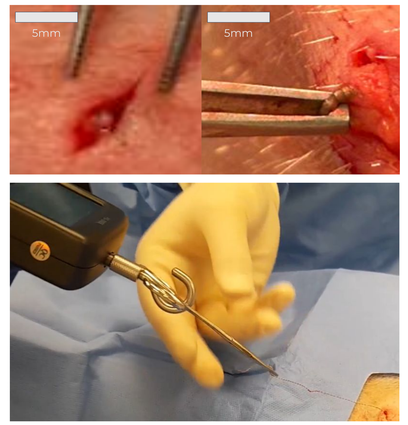


Figure 5: Procedure for removal of the device and capturing force data during removal. Hemostats were clamped onto the device, which had been extracted by a scalpel and forceps, and hooked onto a force transducer.

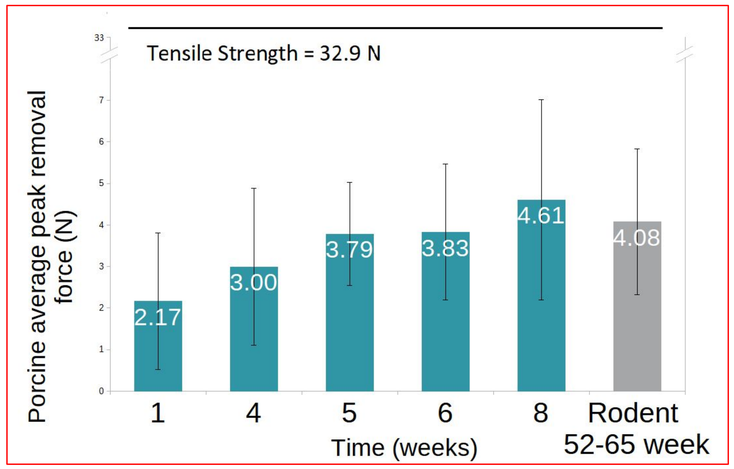


Figure 6: Average peak removal force data at different time-points over 8 weeks from pigs (blue bars) with standard deviations. Tensile strength of device provided as reference for relative safety factor. Rodent forces gathered under the same procedure are additionally shown for much longer time-points (grey bar).

Conclusions and Future Directions

Implantable electrodes should be easily removable in a clinic or office setting in order to facilitate an ever increasing patient population. Relative to the helical wire structure electrode's tensile strength, removal force remained low and consistent over time. As such we show that using clinically familiar techniques the device can easily be completely removed in a chronic model.

Acknowledgements and Disclosures

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