Chronic Stability of a Miniaturized Midfield Powered Neurostimulator for Sacral Nerve Stimulation

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Introduction

Overall objective: To demonstrate that midfield technology can chronically power a miniature sacral nerve stimulator to treat urinary and fecal dysfunction.

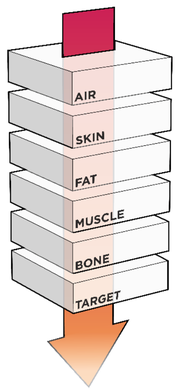
Sacral neuromodulation typically relies upon a conventional battery powered implantable pulse generator connected to a multi electrode lead. Complications such as infection, migration, and pain can occur with this system.

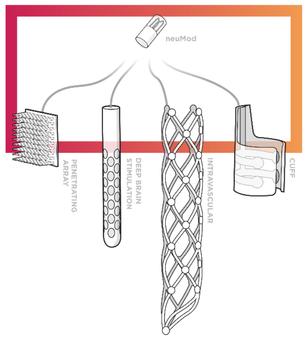
Neuspera Medical has developed a minimally invasive implantable stimulator. We demonstrate that the device can affect bladder volume in sheep. Device migration was evaluated through imaging, functional testing, and histology.

Midfield Powering

Midfield powering uses evanescent and propagating electromagnetic waves to power a deeply implanted medical device.

- The technology transmits radio frequency (RF) energy so it is capable of powering through bone, fat and muscle to deep tissue targets.
- Unlike conventional coil transmitters, a patterned metal plate works in combination with the body to steer energy to an implant.
- Since the energy is spatially focused, multiple implants can be simultaneously powered with very little energy waste or heating.
- The system transmits less power than a cell phone.





Midfield powering is capable of transmitting orders of magnitude more energy to deep implants than conventional inductive or far-field techniques.

- The receiving antenna is only 2mm diameter in the sacral nerve stimulator (SNS).
- Depending on the application, the size of the receiving antenna and the depth of implant can be tailored to meet powering requirements.
- The power harvesting and stimulation circuits are contained within a biocompatible, sterilizable and hermetically sealed enclosure.
- The power harvesting unit can be attached to variety of interfaces to sense or treat deep brain regions, peripheral nerves or ganglia.

Methods

Miniaturized electronics are housed in-line with the distal electrode array to facilitate simple implantation (Figure1). The battery-less stimulator is powered by a novel midfield power transfer technique.

Figure 1: Implanted device

For implantation methods, please see Poster 79.

Note: Prototype enclosures were not hermetically sealed, nor did they have tines.

Two weeks post implantation, awake urodynamics were performed by infusing saline per urethral catheter until spontaneous voiding. Urodynamics were performed with and without stimulation.

- Bladder volume at the onset of urination was recorded.
- The timing between trails was approximately 10 minutes.
- An external powering unit transmitting at the mid-field frequency was placed over the implantation site.
- The stimulation parameters were 2.5Vpp, 210µs pulse-width, and 14Hz. During stimulation trials, stimulation was continuously applied even during voiding.
- A t-test was used to determine if there was a significant difference in mean bladder capacity with and without stimulation.
- Bellows response was also monitored for confirmation of stimulation.

Fluoroscopic images of the sacrum were taken after implantation and after euthanasia (Day 68 and Day 62, respectively) to look for any evidence of migration.

Results

Mechanical stability:

Fluoroscopic images show that the devices did not move significantly from baseline (Figure2A,B). The arrows point to the first electrode positions with reference to the bone. The electrodes have not advanced or withdrawn. These results were representative for both subjects.

The appropriate stimulation response implied the device remained in a functionally relevant position. At post-mortem examination, the stimulator's location was confirmed. Tissue encapsulation likely helped to fix the devices in place.

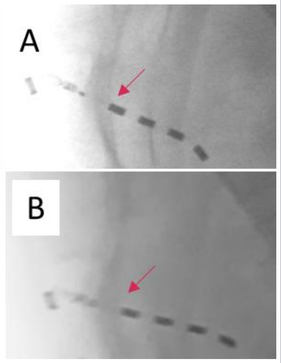


Figure 2: Fluoroscopic images at Day 0 and Day 68. Image is in the sagittal plane with head towards the top.

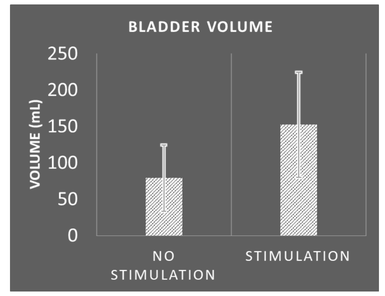


Figure 3: Summarized trial data over 5 experimental days of one subject

Functional response:

The wireless stimulator produced a functional response (significant change in bladder volume, p≤0.05) up to Day 38 (Sheep 1) and Day 25 (Sheep 2). Grouping all wireless stimulation trials against their respective baseline data resulted in a trend, but the difference between the two groups was not significant (P=0.19) (5 days) (Figure 3).

Discussion

This study demonstrated that the implantable stimulators, despite the tine-less prototype design, did not grossly migrate based on fluoroscopic imaging, functional testing and histology examination after approximately 2 months.

Stimulation with the Neuspera device mediated a significant change in bladder capacity within an experiment. Day-to-day variability may be the reason that the two groups were not significantly different when all trials were grouped together. More experimental days would likely reduce variability. Overall, this is a promising therapy for people with urinary incontinence.

Future Work

For future work, please see Poster 79.

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