Design and Fabrication of Novel Flexible and Elastomeric Device for Bladder Neuromodulation

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OBJECTIVE

This project aims to design a flexible and elastomeric electrode made of polydimethylsiloxane (PDMS) and platinized graphene that improves the effectiveness of neuromodulation of the bladder, potentially providing a new treatment alternative for urinary incontinence (Underactive Bladder).

BACKGROUND

- Urinary incontinence (UI) is a prevalent condition among women affecting between 20 – 50% of adult women[1]. Aging, muscle weakness, degenerative diseases, and nerve damage are the primary causes of the condition.
- Currently, there are several UI treatment options, including medications, physical therapy, and surgery. Neuromodulation is beginning to be looked at to treat many ailments, including UI, as current methods have been shown to have their implications and varied outcomes [2].
- Neuromodulation involves the use of electrical stimulation, in this case, to modify the behavior of the bladder, and it has become a widely applied treatment to restore functions in damaged nerve regions throughout the body.
- Current electrodes used for the electrical stimulation of the bladder are unable to withstand the forces exerted by the bladder's filling and contraction, which can limit their effectiveness.

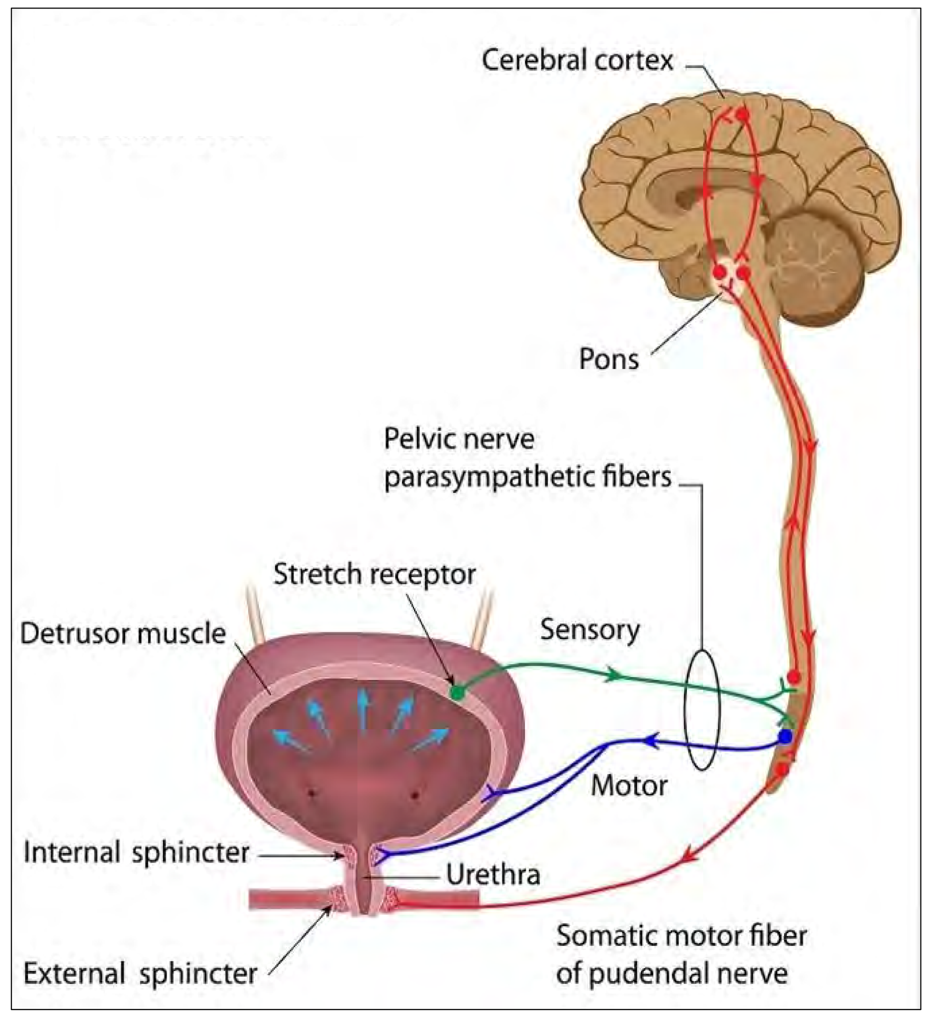

Figure 1. *Mechanism of Underactive Detrusor [3]*

METHODS & MATERIALS

- The electrode went under a design stage aimed at being able to anchor itself onto the bladder and withstand the forces for chronic implantation.

Figure 2. *The mold for the electrode was then designed on AutoCAD based on the ellipsoid-shape bladder of rodent models (19mm x 10 mm).*

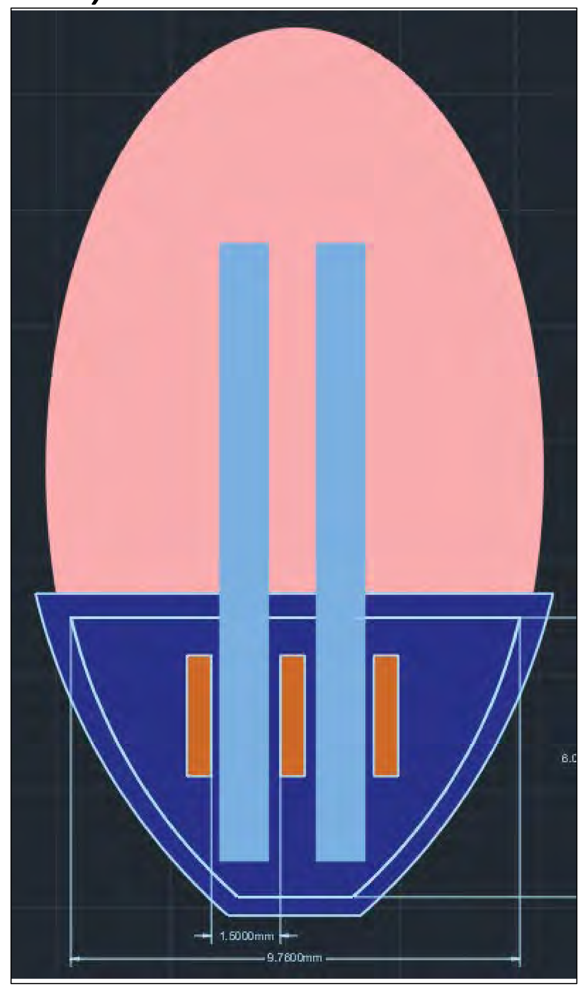

Figure 3. *The mold design was sliced using IdeaMaker software and 3D printed in 1.75mm ABS plastic using an FDM printer at ultra-high quality ABS setting with a layer height: 0.0500mm, infill density: 15%, shells: 2, infill speed: 60 mm/s*

- The PDMS was fabricated using a ratio of 9:1 silicone elastomer base to curing agent which was then placed in a desiccator to remove trapped air bubbles.
- Adhesive was put on the mold to ensure contacts for the electrodes were exposed, then the PDMS was casted and left to be cured at room temperature for 48 hours.
- After curing and some post-processing, the device will be ready for testing.

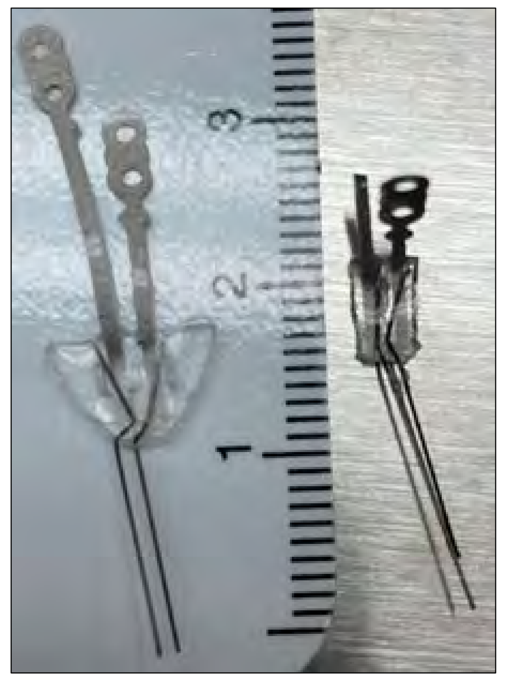

Figure 4. *Final devices after curing and removal from mold before and after trimming. Trimmed device is 5mmx3mm and bottom nitinol wires will be cut to length during surgery.*

- Testing will include electrical testing using a Gamry Instruments Reference 600+ to perform electrochemical impedance spectroscopy(EIS) and cyclic voltammetry (CV). Additionally, the device will be tested in vivo to characterize its capability in stimulating the bladder.

RESULTS

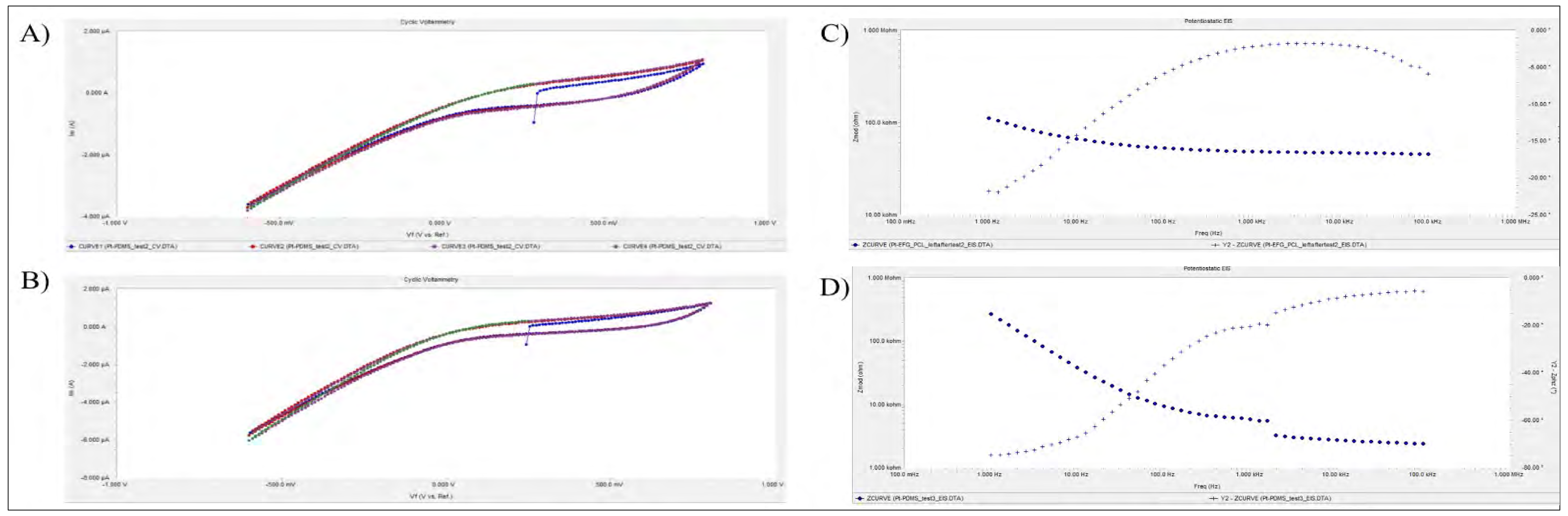

Figure 5. *Results of the Cyclic Voltammetry Test (CV) and Potentiostatic EIS Test for electrodes shows no significant change in electrode characteristics after encapsulation: A) CV test results before encapsulation B) CV test results after encapsulation (C) EIS test results before encapsulation (D) CV test results after encapsulation.*

- **CV** - voltage was applied in a sawtooth from -0.8 to 0.8 [V] with similar output voltages indicating capable voltages for bladder stimulation before and after encapsulation.
- **EIS-** Frequency and Impedance values:
  - Before Encapsulation - x=1.266 kHz, y=3.6kohms After Encapsulation - x=1.266 kHz, y=276.7kohms

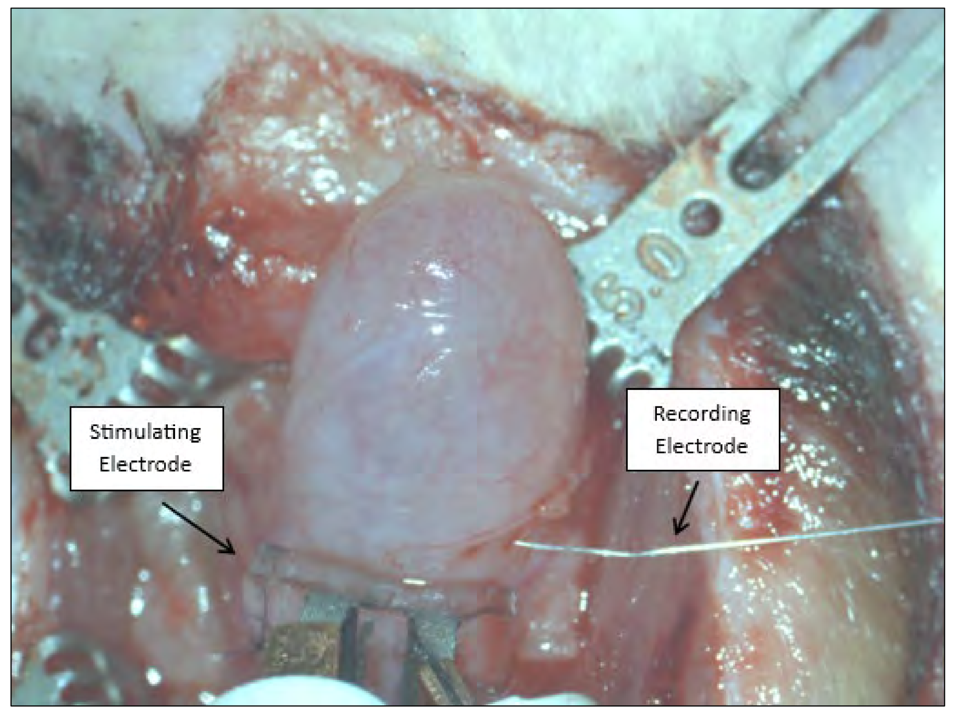

Figure 6. *In vivo implantation of our stimulating electrode in a rodent model while EMG data was being recorded through a needle electrode and oscilloscope. (Video of bladder contractions will be included during the BME Day presentation)*

CONCLUSIONS

An elastomeric electrode using PDMS and platinized graphene was successfully design and fabricated. The fabrication process included the use of an FDM printer while still being able to achieve desired electrical characteristics and induce bladder contractions in vivo. There are many more opportunities for future development in our device like wireless power supply, using higher printing resolution, or testing other forms of anchoring.

Nonetheless, this novel electrode could have a profound impact on the quality of life for those suffering from various forms of UI as it holds great potential for a chronic method of treatment through neuromodulation.

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