Investigating a Closed Loop Neural Control System to Optimize Sacral Neuromodulation

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Background and Hypothesis:

Approximately 16% of the American population suffers from overactive bladder, with 25-40% of patients reporting unsatisfactory results following first line treatments. Sacral neuromodulation is a well-established, minimally invasive treatment option for several forms of bladder and bowel dysfunction that are non-responsive to first line pharmacologic or behavioral therapies. While more broadly applicable stimulus parameters are being investigated, the precise set of nerve fibers whose activity regulates optimal bladder function(s) is not known, leading to high levels of treatment variability between patients and within patients over time. We hypothesize that treatment efficacy and durability could be rapidly improved by continuously tuning the electrical stimulus waveform and pattern of stimulation to recruit the nerve fiber populations that mediate micturition.

Experimental Approach:

We aim to access the sacral (S2-4) nerves and implant a set of recording and stimulating bipolar cuff electrodes (FNC-400-V-R-C-2C-30, Micro-Leads, Somerville, MA, USA) to measure the evoked CAP of the sacral nerves at various combinations of pulse amplitude and duration. Simultaneously, we will measure changes in bladder pressure using a pressure transducer attached to a bladder catheter and amplifier. By measuring how the bladder responds to all applied nerve stimulation parameters we will be able use an Autonomous Neural Control algorithm to identify the compound nerve action potential response that produces the most robust changes in pressure.

Results:

We developed a surgical protocol, currently pending PACUC approval, that allows us to decode and encode specific CAP signatures that represent the firing activity of distinct subsets of nerve fibers, each differing in diameter, degree of myelination, activation threshold, conduction speed, and presumably function.

Conclusion and Potential Impact:

This study aims to act as proof of concept for a system that selects stimulation parameters based on fibers required to produce a desired response rather than patient tolerance to stimulation parameters, ultimately improving efficacy of sacral neuromodulation therapy.