Minimally Invasive Interfascicular Nerve Stimulation System for Pain Management

Dustin Tyler, PhD, Jenifer Sweet, MD

Department of Biomedical Engineering, Case Western Reserve University

Need

Chronic pain is a complex, poorly understood disease. Al- though several treatments exist for its management, one in five adults still suffer from unmanaged chronic pain in the US. Chronic neuropathic pain specifically affects nearly 10 million Americans. The continuum of pain management includes pharmaceuticals, physical therapy, injections, surgical intervention, and neuromodulation. Spinal cord stimulation (SCS) is currently the most common neuromodulation intervention. Patients report extensive side effects pharmaceutical treatment with and drug Surgical SCS resistance over time. and interventions are invasive and very expensive.

Many patients are on multiple treatments simultaneously to manage their pain. Even with all these available treatments, 50% of patients report less than 50% pain reduction. Unmanaged chronic neuropathic pain has multiple co-morbidities including but not limited to increased cardiovascular risk. cognitive decline. sleep disorders, and early mortality.

Solution

Our MiiNS technology consists of an interfascicular a lead, and percutaneous, electrode, а microdermal connector. The electrode consists of eight tines inserted with minimal trauma in the connective tissue (epineurium) that loose surrounds the nerve bundles (fascicles), but does not disturb these nerve bundles. The eight tines result in eight electrical interface points (contacts) dispersed across the nerve, between the fascicles. The electrode placement and its multiple contacts creates an intimate interface with the nerve to stimulate neural tissue with higher efficiency, specificity, and efficacy than existing technology. This multi-contact design also allows us to modulate stimulation amplitude and duration in advanced patterns for maximal pain relief.

Device



A "needle" canula is advanced under ultrasound visualization to the nerve. The MiiNS is advanced out of the canula, inserting the tines into the nerve. It is important to note that the tines will not penetrate through the perineurium and into the nerve bundles, but reside between the bundles, minimizing the risk of nerve damage.

Solution (con't)

The patient has control of a pre-programmed menu of stim- ulation paradigms that she can choose from for optimum pain relief. Current PNS devices place the electrode farther from the nerve and are hence not able to closely target fibers within the nerves that they stimulate, result- ing in diffuse sensation with little physician or patient control. In addition, current neurostimulation devices also create paresthesia when the nerve is stimulated.

Opportunity

We seek commercialization partners with commitment to and a leadership position in global health issues. Opportunities for collaboration may take a variety of forms, including: license of IP; participation directly or in conjunction with a private equity investor in a startup to develop and commercialize the technology; sponsored research.

Intellectual Property

Provisional patent applications were filed in June 2020.

Contact: Wayne Hawthorne, Senior Licensing Manager, CWRU Technology Transfer Office wayne.hawthorne@case.edu or (216) 368-6104

