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DEVELOPMENT OF DORSAL ROOT GANGLION (DRG) MULTICHANNEL STIMULATOR PROTOTYPE FOR USE IN EARLY CLINICAL TRIALS

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ABSTRACT

Spinal Cord Injury (SCI) is characterized by a disruption of the spinal pathways connecting the brain to the rest of the body. This can result in an impairment or complete loss of sensory and/or motor functions, depending on the level and severity of the injury. The most common approach of attempting motor recovery using neuromodulation has been through epidural spinal cord electrical stimulation (eSCS), with or without rehabilitation and robotic assistance[1,2].

Dorsal Root Ganglion (DRG) stimulation is a relatively new neuromodulation treatment, which has already been established as a safe and effective treatment for chronic pain. However, its application for motor recovery after SCI has remained unexplored territory. A recent study by Soloukey et al.[3] showed the first promising results using L4-level DRG-stimulation to evoke strong and reproducible motor responses in the upper leg muscles of patients with motor complete SCI.

The current work presents the development of a prototype stimulator intended for use in early clinical trials for the purpose of further exploring the effects of multi-level DRG-stimulation on motor recovery after SCI. The prototype stimulator is created using commercially available components, focussing primarily on the safety considerations for the use of the prototype in a clinical research environment.

The prototype allows for access to multiple leads in parallel to facilitate faster, sequential stimulation, catering for a maximum of 16 leads at once. The final system is equipped with a microcontroller for the programming of the stimulation parameters, a Bluetooth module for the communication with external components (Graphical User Interface (GUI) on a local PC) and tailored connections to the stimulating DRG-leads. The safety and well-being of the patient is set as a first priority, leading to a tailored design and development of the stimulator accordingly. Parameters like the patient's comfort when connected to the device, the safety of the patient and the medical personnel with regards to powering the device through the mains, and protection from any current or DC voltage leakage, are discussed. The prototype is currently undergoing safety evaluation and the complete system design together with these results will be presented during the conference.

1. V. Giagka et al., "An Implantable Versatile Electrode-Driving ASIC for Chronic Epidural Stimulation in Rats," in *IEEE Trans. Biomed. Circ. Syst.*, vol. 9, no. 3, pp. 387-400, June 2015, doi: 10.1109/TBCAS.2014.2330859.

2. G. E. Ólafsdóttir, et al., "An energy-efficient, inexpensive, spinal cord stimulator with adaptive voltage compliance for freely moving rats," in Proc. 40th Int. Conf. of the IEEE Engin. Med. Biol. (EMBC) 2018, Honolulu, Hawaii, USA, Jul. 2018, pp. 2937 – 40, doi: 10.1109/EMBC.2018.8512904.

3. S. Soloukey et al. 2020. "The Dorsal Root Ganglion as a Novel Neuromodulatory Target to Evoke Strong and Reproducible Motor Responses in Chronic Motor Complete Spinal Cord Injury: A Case Series of Five Patients." in *Neuromodulation*, Jul. 2020; E-pub ahead of print. DOI:10.1111/ner.13235.