

# A 12-channel neuroprosthetic platform for SCI: Applications in the urinary, respiratory and muscle atrophy areas

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The NeuRx<sup>®</sup> Diaphragm Pacing System with Permaloc<sup>®</sup> Electrodes applies functional electrical stimulation (FES) for respiration in quadriplegic spinal cord injury (SCI) patients. The electrode is an intramuscular barb type with a polypropylene anchor, and the electrode evolved from the original Peterson Intramuscular Electrode developed for diaphragmatic pacing in quadriplegic SCI patients at Case Western Reserve University and Cleveland Veterans Administration FES Center [1]. The NeuRx<sup>®</sup> system was commercialized by Synapse Biomedical, Inc. in Oberlin, Ohio and uses four Permaloc<sup>®</sup> electrodes implanted in the diaphragm and a fifth electrode implanted under the skin as a return electrode for monopolar stimulation. All five electrode leads pass through the skin at separate exit sites that are situated close together, and are connected to a small, battery-powered stimulator. Successful respiratory pacing with this system has been reported in over 100 SCI patients with up to ten years of use [2].

A 12-Channel Neuroprosthetic Platform is being developed in a collaborative effort between Synapse Biomedical Inc and our laboratory, Research Service, Hines Veterans Administration Hospital, [3,4]. For this platform, several types of electrodes are under investigation including surface, mapping, intramuscular, and a multi-lead implantable cable with connectors. Several FES applications are also being investigated including respiration, urinary and muscle disuse atrophy with current work focused on optimization of stimulation. Further development of the neuroprosthetic platform is ongoing with a future goal of a small, home-use device.

Optimization of respiratory stimulation is focused on extradiaphragmatic muscles. Positive inspiratory results were obtained in a canine model with surface electrodes applied to the upper thorax (submitted for publication). Large inspiratory volumes were also obtained using three or four sets of bilateral Permaloc<sup>®</sup> electrodes implanted in intercostal spaces ventral to the axilla and stimulated at 50 Hz, and 30 to 50 mA [5-7]. Positive expiratory results were also obtained for abdominal muscles using surface and Permaloc<sup>®</sup> electrodes [5-7]. Further work is needed to study effects of stimulation on muscle fatigue and metabolic responses. In one long term study we identified a problem with securing Permaloc<sup>®</sup> electrodes in extradiaphragmatic muscles [8]. To address this concern we plan to test opening the

polypropylene securing barb and snaking the electrode lead away from the muscle exit site and using multiple sutures. A future goal is to combine extradiaphragmatic muscles with diaphragm stimulation for a more complete respiratory and cough management program. A model of glottal closure for cough has been demonstrated [7].

For urinary applications, we are investigating Permaloc<sup>®</sup> Intramuscular Electrodes for direct bladder wall stimulation and voiding as well as bilateral pudendal nerve stimulation for neuromodulation and bladder inhibition [3,8-11]. Successful clinical methods of Magasi and Simon [12] for direct bladder wall stimulation and Possover *et al.* [13] for pudendal nerve stimulation and neuromodulation are being followed. Management of high urethral resistance during bladder contractions is proposed to be managed with Botulinum toxin injections in the urethra. These injections have already been shown to be useful for SCI individuals using reflex voiding [14]. Thus, outcomes of injections alone should be conducted before stimulation interventions are considered.

For our skeletal muscle disuse atrophy problem, we are following a protocol observed in an SCI individual using the Nashold sacral spinal cord stimulator for urination [15]. Following each stimulation-induced void the stimulator was left on for 15 min causing strong isometric leg contractions. The leg muscles were observed to have great girth and this individual had not experienced pressure ulcers. We conducted isometric leg stimulation tests in a canine model with Permaloc<sup>®</sup> electrodes implanted adjacent to the lumbar vertebra with the induction of strong contractions (unpublished). We plan to optimize this stimulation protocol with the long term goal of preventing pressure ulcers.

The development of the 12-Channel Neuroprosthetic Platform in collaborative with Synapse Biomedical Inc is continuing. The company is interested in working with any research laboratory that can help with the high costs of developing and testing this technology.

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