

ISENS – PROGRESS AND PROSPECT OF A FULLY IMPLANTED SYSTEM FOR SENSORIMOTOR INTEGRATION

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ABSTRACT

Since May 2012, peripheral nerve cuff electrodes have been providing direct sensory feedback to individuals with upper extremity limb loss and in lower extremity limb loss since May 2016. In April of 2016 and February 2017, we added new subjects with eight bi-polar myoelectric (EMG) channels for recording muscle activity for simultaneous, arbitrary multi-degree-of-freedom control in the upper extremity. There are a total of 48 nerve or EMG channels implanted on the peripheral nerves and in the muscles, but are routed to external stimulation and recording hardware via percutaneous leads. The sensory restoration system has provided stable feedback over multiple discrete points of the phantom hand since its implant; has eliminated phantom pain in subjects; can provide multiple qualities of sensation; and can provide the same capabilities of intensity discrimination as an intact hand. The implanted EMG electrodes have provided stable, isolated, high signal-to-noise recordings since implant and can provide naturalistic 3 degree-of-freedom control without retaining for over six months.

These results encouraged the development, starting in May 2015, of a clinically-viable, fully-implanted, wireless system to eliminate the percutaneous leads. The implanted somatosensory electrical neurostimulation and sensing (iSens) will drive 64 stimulation channels for restoration of sensory feedback and record from 32 channels, configured into 16 bipolar EMG recording electrodes, for device control. The system will connect to an external device via a high-reliability, low-power Bluetooth wireless link. The system consists of a central battery and communications module (INC); four "smart leads" that are each connected to the INC via a four conductor lead and then connects to 32 stimulation or recording leads. The sensing smart lead can simultaneously record from 8 bipolar EMG channels with 10-bit resolution at 1000 Hz sampling rate. The stimulation smart lead can simultaneously stimulate twelve channels asynchronously at up to 100 Hz on each channel with patterned intensity stimulation paradigms. The final system will place 32 channels on the median nerve and 16 on each the radial and ulnar nerves. External transmission will be to a Bluetooth dongle connected to personal mobile device or lab laptop computer via USB that serves as the user interface and the main algorithm processor. The Full device engineering and component verification will be completed by end of

2017; full system verification, animal testing, and IDE submission by 8/18; and anticipated approval for clinical study initiation in early 2019.