***In Situ* Biocompatibility of Thin-Film Polyimide Neural Electrodes in a Peripheral Nerve Interface Setting**

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Background: Optimization of the biomaterials comprising neural electrodes minimizes scarring at the biotic-abiotic interface. In this study, we investigate the *in situ* biocompatibility of a flexible, 32-channel, low-profile electrode with thermoset polyimide as the substrate. Our hypotheses are polyimide neural electrodes (1) do not alter underlying muscle viability and (2) cause minimal scarring at the muscle-electrode interface.

Methods: In fifteen rats, the epimysium of the left extensor digitorum longus (EDL) muscle was implanted with either electrode alone (electrode, *n*=5), silk suture alone (suture, *n*=5), or electrode with silk suture (electrode+suture, *n*=5). Each group including the right EDL muscle (control, *n*=15) was encircled with a single layer of decellular small intestinal submucosa (SIS). After 30 days, needle electromyography (EMG) and nerve conduction studies were performed, and muscles were harvested for histology.

Results: All electrodes remained intact and none migrated from the implantation site. Needle EMG indicated no muscle injury or denervation as evidenced by lack of sustained fibrillations in all groups. Stimulation threshold was significantly increased for all experimental groups compared to control, but no differences between experimental groups. No differences were found for signal amplitude, area, latency, or conduction velocity. A significant increase in wet muscle mass was also noted in all experimental groups compared to control. Representative histology is demonstrated in Figs. 1 and 2.

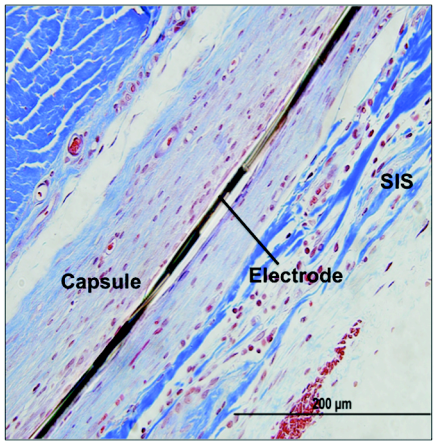

Figure 1. Trichrome staining of muscle-electrode interface demonstrating 25 µm capsule of compact, parallel-oriented collagen fibers around the electrode (40x).

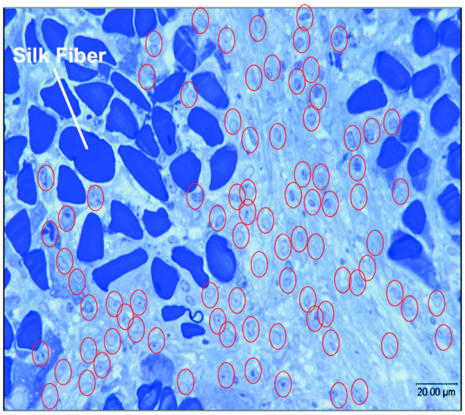

Figure 2. Strong foreign body reaction in the suture group characterized by the infiltration of immunoreactive cells (red circles, 400x).

Conclusions: Polyimide neural electrodes induce a thin capsule (~25 μm) with only slight untoward effects on underlying muscle viability and minimal scarring at the muscle-electrode interface. The inflammatory response produced by silk suture may function as an expedited failure model for peripheral nerve interfaces.

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