Flexible Nanofiber-Based Materials for Material Property-Matched Neural Interfacing

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Statement of Purpose: The inability to properly match the material properties of neural interfacing devices to native tissues has limited the implementation of newly developed technologies. To address the 5-6 order of magnitude discrepancy in elastic modulus that currently exists with available products and materials, Luna is working with collaborators at UT-Dallas and IUPUI to develop a unique nanofiber-based interface system. These interfaces utilize the unique material properties of electrospun nanofiber mats (e.g., bending stiffness scales cubically with diameter) to achieve the material properties required for surgical implantation and sustained bidirectional communication with peripheral nerves without compromising electronic functionality. This material technology is being proposed for use with the transverse intrafascicular multichannel electrode (TIME) system, but will also be applicable to other neural interface technologies in the future.

Materials and Methods: Polymer nanofiber mats were created using standard needle-free (Elmarco Nanospider® NSLab[3]) electrospinning techniques (Figure 1), embedding a flexible conductive-polymer layer between electrospun insulating nanofiber mats. Micropatterning techniques were developed for the insulating and conductive layers by adapting standard lithography processes, and placement protocols were developed *ex vivo* using excised porcine sciatic nerve tissue. Luna characterized the material resistivity, electrolytic impedance, and electrical encapsulation with four-point probe and electrochemical impedance spectroscopy (EIS) and cyclic voltammetry (CV). Tensile properties were quantified with an Instron 5943 system (5 mm/min deformation rate) and compared to relevant neural tissue. Rat Schwann cells (S42) were cultured in direct contact with prototype samples, and the lactate dehydrogenase (LDH) and (4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assays were used to assess cytocompatibility. A reactive accelerated aging system has been developed to provide simulated *in vivo* durability data, and acute and chronic rat hindlimb implantation models are in ongoing to confirm functionality and efficacy *in vivo*.

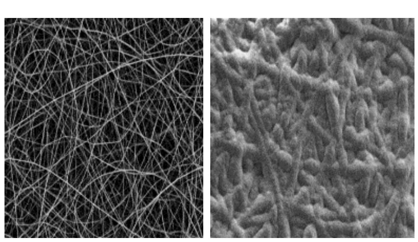

Figure 1. Polymer substrate before (left) and after (right) insulator application.

Results: Preliminary prototypes of a soft, nanofiber-based material system for neural interfacing have been designed and fabricated. These prototypes have been developed using an optimized insulating chemistry combined with several initial conductive components. Lithographic patterning of the nanofiber and conductive components was demonstrated (Figure 2) to create first generation prototype devices. These prototypes demonstrate significantly improved material tensile and electrical properties, including confirmed insulating-layer encapsulation with inherent conductivities of 100 S/cm and capacitance values up to 100 mF/cm^2. Luna reduced the elastic modulus of the device to 2600 MPa (as compared to 160,000 MPa for current electrodes) and demonstrated >10% elongation at failure. Preliminary prototypes containing a 400 nm gold conductive layer have been fabricated for preliminary *in vivo* functional assessment. Extended prototype immersion in 37 °C PBS (6 months) suggests prolonged stability of the conductive-polymer layer, and these samples have been demonstrated cytocompatible with rat Schwann cells.

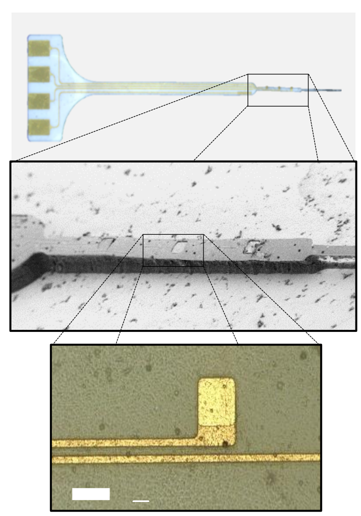

Figure 2. Prototype devices developed using a gold conductive layer patterned onto nanofiber-based substrate.

Conclusions: Luna has successfully demonstrated the feasibility of a nanofiber-based material for neural interfacing applications. This approach provides better mechanical match to native tissue, while maintaining the electronic and biologic properties required for bidirectional communication with the peripheral nervous system. *In vivo* studies are being completed to investigate the functionality of these prototypes.

This work was supported by DARPA (Contract # D17PC00125). The views, opinions, and findings contained are those of the author(s) and should not be construed as official DARPA position, policy, or decision unless designated by other documentation.