Characterization and Quality Control of Electrospun Medical Devices

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www.nanofibersolutions.com
Why Nanofibers?

• Mimics extracellular matrix (ECM)
• Variety of polymer sources: synthetic or natural
• Broad application from tissue engineering to drug discovery

Articular Cartilage ECM from sheep femur
Electrospun polycaprolactone (PCL) nanofiber
Why Aligned?

- Aligned white matter in the corpus callosum
- Aligned myocardium
- Aligned polymer nanofibers
Product Roadmap

Institutional Research → Drug Discovery → Diagnostics → Regenerative Medicine → Tissue Engineering
Synthetic Regenerative Medicine Pipeline

- Synthetic blood vessel
- Synthetic intestine
- Synthetic cartilage
- Synthetic chronic wound repair
First in Man Nanofiber Trachea Transplant
Multi-Layered Nanofiber Implants

- (left) PGA microfiber can’t produce a clean/discrete lumen

- (bottom) nanofibers produce discrete layers to hold cells into proper spatial orientations
Fibers, Fibers, and Even More Fibers

• Nanofibers
• Microfibers
• Core/shell fibers
• Porous fibers
• Composite fibers
• Aligned fibers

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Anisotropic Mechanical Properties

Longitudinal UTS: 2.8 ± 0.3 MPa
%Elongation: 30 ± 2

Transverse UTS: 0.39 ± 0.01 MPa
%Elongation: 188 ± 6

Rotational Speed and Mechanical Properties

Water Permeability = Cellular Infiltration?

- No cellular infiltration
- Breaking pressure: 2.6 ± 0.4 psi
- Darcy permeability: $1.3 \times 10^{-13}$ m$^2$

- Complete cellular infiltration
- Breaking pressure: 1.2 ± 0.3 psi
- Darcy permeability: $2.0 \times 10^{-13}$ m$^2$
Summary

• Nanofiber scaffolds can be complex, multi-layered implants
• Combination of fiber diameters, porosity, resorbable/non-resorbable, etc.
• Nanofiber implants are being used clinically (need standards!)

Thank You!