

WV Overcoats for Silicone: Long-Lasting, Broad Spectrum, Biocompatible Protection Against CAUTIs

WynnVision LLC

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NIDDK

National Institute of Diabetes and Digestive and Kidney Diseases



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Outline

- Background: Imaging *Escherichia coli* cell disruption
- Challenge: translation of solution to a silicone catheter surface
- Progress: evidence for antimicrobial effectiveness with biocompatibility
- A pathway to FDA 510k clearance

The Company

WynnVision

- Founded in 2016 by Kenneth J. Wynne
Commonwealth Professor
Chemical and Life Science Engineering
Virginia Commonwealth University
- Based on 20 years experience with antimicrobial technologies
- **Mission:** to generate ground breaking technologies for preventing infections from medical devices

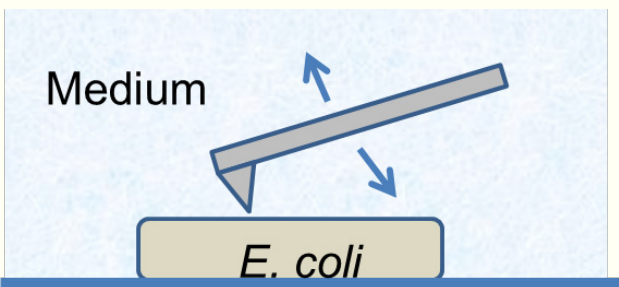
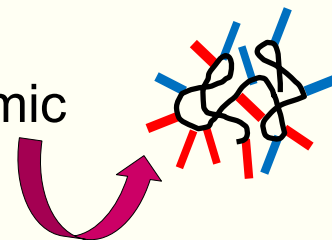


Virginia Bio+Tech Research Park
800 East Leigh Street, Suite 57
Richmond, VA 23219-1551



Conceptual basis

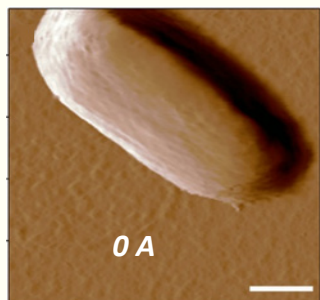
- Learned about Nature's **Antimicrobial Peptides** "AMPs"
- Create a water soluble chain molecule that is an AMP-mimic
- Atomic Force Microscopy to image biocidal action



- AFM images of *E. coli* in (PBS)
- *E. coli* cell wall disruption
- Cell dies
- Osmotic pressure inside cell
- Cell disruption like a pin in a balloon

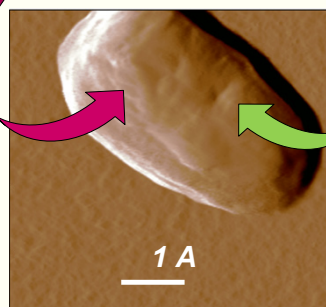
Nano-bulge

Nano-pit

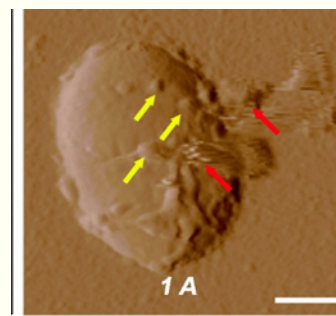


time = 0

500 nm



time = 1 h



time = > 1 h

How to translate from water soluble antimicrobial to antimicrobial surface?

- Basic AMP-like **solution** antimicrobials
- Fundamental knowledge about bacterial cell wall disruption

National Science Foundation, DMR

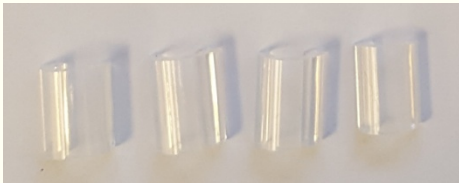


- Create a **surface** that disrupts bacterial cell walls **on contact**
- Solid state surface science
- Leap toward commercialization
- NIH NIDDK



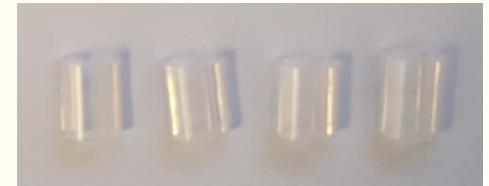
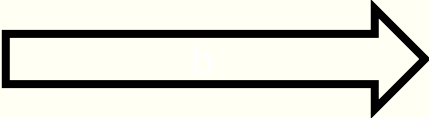
Implementation:

- A process for low cost overcoats on off-the-shelf silicone catheter segments
- “Simple is Good” for ready scaleup / manufacturing



Segments of a commercial, catheter with FDA clearance

Proprietary WV
overcoat technology



WV overcoated catheter

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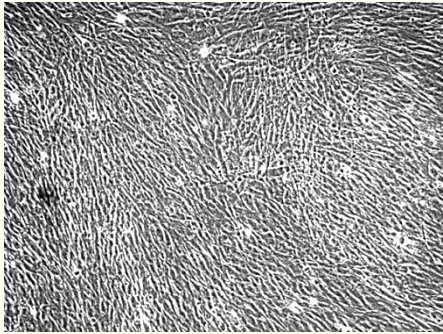
Most frequent pathogens associated with HAI CAUTIs cited by a CDC panel

Time, 24 hr		Gram stain	Strain	% HAI CAUTIs
ASTM E2149 % kill	Kill			
99.999%	log 5	G(-)	<i>Escherichia coli</i>	21.4
99.999%	log 5	N/A	<i>Candida albicans (spp)</i>	21.0
		G(+)	<i>Enterococcus spp</i>	14.9
99.96%	log 3.4	G(-)	<i>Pseudomonas aeruginosa</i>	10.0
		G(-)	<i>Klebsiella pneumoniae</i>	7.7
99.999% <i>Klebsiella aerogenes</i>	Log 5	G(-)	<i>Enterobacter spp</i>	4.1
99.999% <i>S. epidermidis</i> methicillin resistant	Log 5	G(+)	Coagulase negative staphylococci (CoNS)	2.5
		G(+)	<i>Staphylococcus aureus</i>	2.2
		G(-)	<i>Acinetobacter baumannii</i>	1.2
		G(-)	<i>Klebsiella oxytoca</i>	0.9

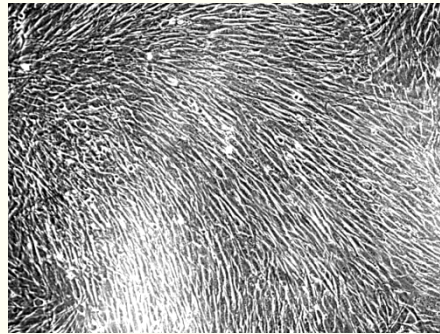
Hidron, et al. *Infection Control and Hospital Epidemiology*, Nov. 2008, Vol. 29, No. 11

ISO 10993-5 test for toxicity of any leachate to human cells

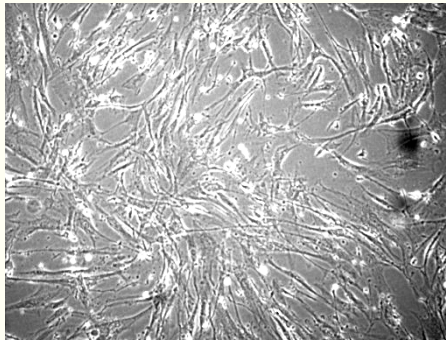
- Human Dermal Fibroblast (HDF)
- Photomicrographs of HDFs after 48 h growth in medium extracts



Untreated silicone tube



WV-overcoated silicone tube



Latex

- Cell viability was 0% for latex

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 - *In vivo* tests: NAMSA
 - Biologics Consulting: seeking 510k



Acknowledgement



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