

# Back to the future

Next Generation Suprachoroidal Stenting

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## Relevant Disclosures

Iantrek, Inc. Scientific advisor/board member

Implandata Scientific advisor/board member

Abbvie, Aerie Pharma, Allergan, Equinox, Eyenovia, Ioptic,  
Nicox, Topcon Consultant and scientific advisor

Bausch&Lomb, Centervue, Heidelberg Engineering, NEI,  
NIMH, Optovue, Topcon, Zeiss, Zilia Research support

Toromedes Founder

# Advances in MIGS treatment

missing a compelling approach for internal outflow enhancement

## Supra Choroidal Outflow

### Controlled Cyclodialysis

- Suprachoroidal space has large absorptive capacity
- Negative pressure gradient

# Supraciliary Stenting

already with validated IOP lowering

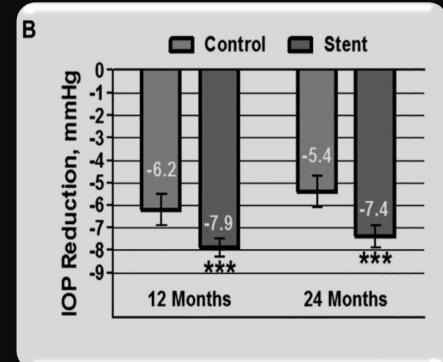
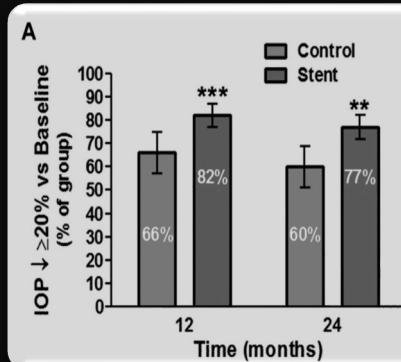


AMERICAN ACADEMY™  
OF OPHTHALMOLOGY

**Two-Year COMPASS Trial Results:  
Supraciliary Microstenting with  
Phacoemulsification in Patients with  
Open-Angle Glaucoma and Cataracts**

Steven Vold, MD,<sup>1</sup> Iqbal Ike K. Ahmed, MD,<sup>2</sup> E. Randy Craven, MD,<sup>3,4</sup> Cynthia Mattox, MD,<sup>5</sup> Robert Stampfer, MD,<sup>6</sup> Mark Packer, MD,<sup>7</sup> Reay H. Brown, MD,<sup>8</sup> Tsontcho Ianchulev, MD, MPH, for the CyPass Study Group\*

for the CyPass Study Group\*



*Ophthalmology* 2016;123:2103-2112

BUT....

## CyPass Micro-Stent

JONATHAN H. LASS, BETH ANN BENETZ, JONATHAN HE, CODY HAMILTON, MARK VON TRESS,  
JAIME DICKERSON, AND STEPHEN LANE

**PURPOSE:** To characterize long-term changes in corneal endothelial cells after phacoemulsification with or without supraciliary Micro-Stent (Alcon) implantation compared with open-angle glaucoma (OAG) and visually normal cataract.

**DESIGN:** A 5-year safety extension of a 2-year randomized trial.

**SETTING:** Sixteen sites from the multicenter Study of an Alcon Supraciliary Micro-Stent Lowering Intraocular Pressure in Eyes Undergoing Cataract Surgery (CyPass).

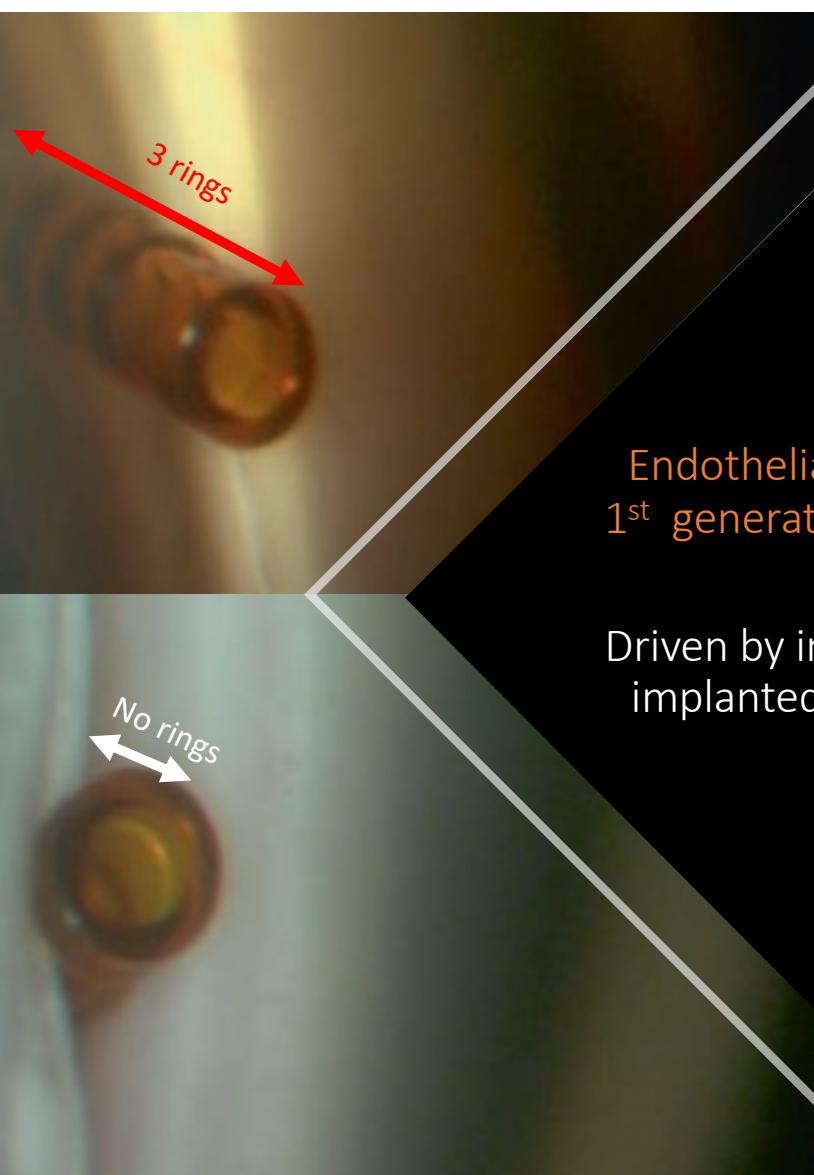
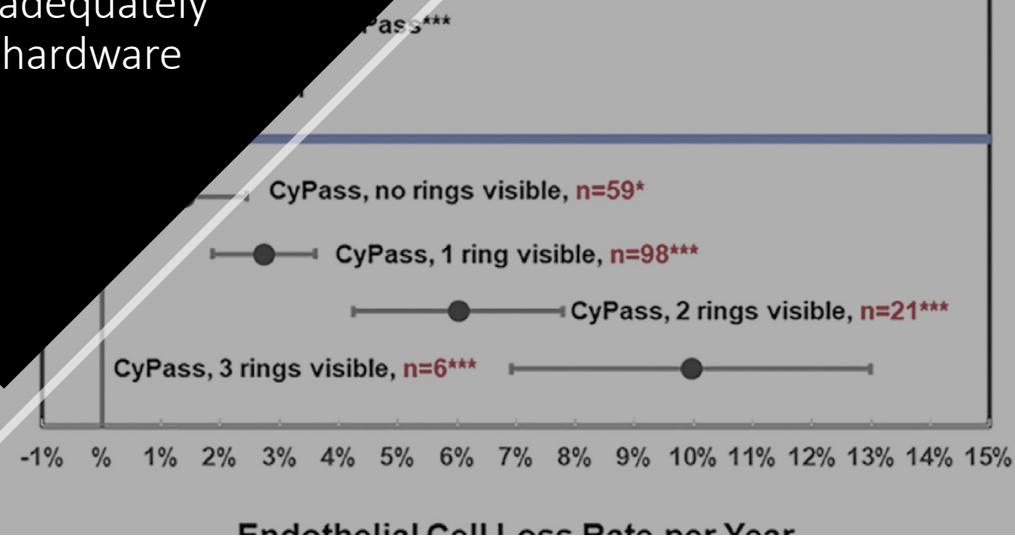
**PATIENTS AND METHODS:** Patients undergoing cataract surgery with CyPass implantation (n = 282) or phacoemulsification only (n = 282) were included. Post hoc, Specular Microscopy was used to measure endothelial cell loss (ECL), defined as the percentage of endothelial cell density compared with the baseline percentage of

**CONCLUSIONS:** In eyes with OAG, ECL after phacoemulsification is acute and stabilizes after 3 months, whereas ECL after phacoemulsification plus Micro-Stent implantation proceeds for at least 5 years. Clinical findings associated with ECL in these eyes were uncommon (3.3% of implanted eyes), suggesting that ECL is generally a subclinical phenomenon. (Am J Ophthalmol 2019;208:211–218. © 2019 Published by Elsevier Inc.)

**T**HE OPTICAL CLARITY OF THE CORNEA IS MAINTAINED BY ITS ENDOTHELIAL CELLS. THE DENSITY OF CORNEAL ENDOTHELIAL CELLS IN A TYPICAL ADULT EYE IS 2,000–3,500 CELLS/MM<sup>2</sup>. CORNEAL DECOMPENSATION CAN OCCUR WHEN ENDOTHELIAL CELL DENSITY (ECD) FALLS BELOW 800 CELLS/MM<sup>2</sup>,

### Endothelial loss with 1<sup>st</sup> generation SC stent

Driven by inadequately implanted hardware



Fundamental question

How can the suprachoroidal outflow be more reliably and safely stented ?

Fundamental question

How can the suprachoroidal outflow be more reliably  
and safely stented ?

..... without the implantable hardware?

# Bio-stenting

USING SCLERAL Allograft tissue

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- ✓ WELL-ESTABLISHED
- ✓ DECADES LONG USE IN GLAUCOMA SX
- ✓ HOMOLOGOUS\*
- ✓ READILY AVAILABLE FROM EYE BANKS

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Inventor Dr. Ianchulev

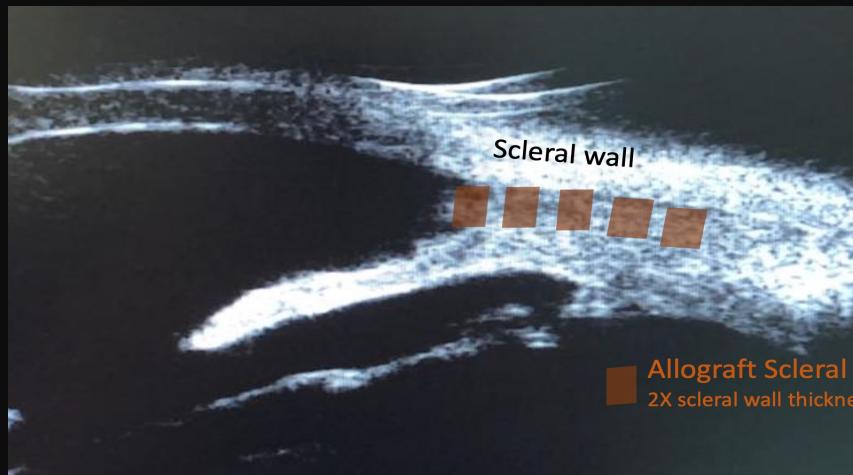


\*Scleral allograft tissue implanted contiguous with sclera and to supplement native scleral wall

# SCLERAL ALLOGRAFT FOR BIO-STENTING

Highly permeable bio-tissue

Homologous to native sclera



Hydrophilic, with high permeability index

	Cornea Permeability (cm/s)	Sclera Permeability (cm/s)
BENZOLAMIDE	1.4 E-7	2.0E-5
INULIN	5.5 E-7	9.0 E-6
PROPRANOLOL	3.1 E-6	5.8 E-5
SUCROSE	4.4 E-6	2.2 E-5

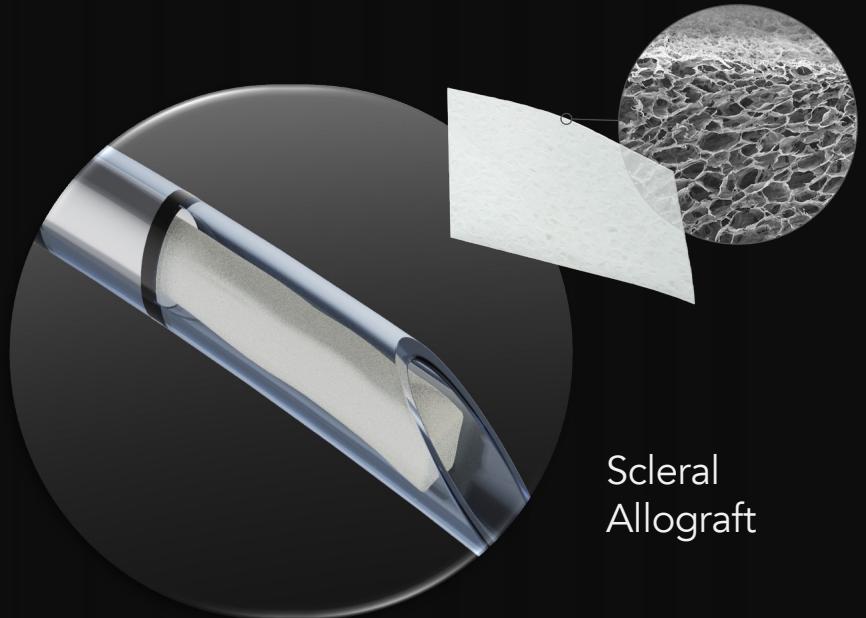
Weinreb RN. *Trans Am Ophthalmol Soc*. 2001.

*Journal of Pharmaceutical Science Dec 1998,*

# Bio-Stenting

## Designed for endothelial Safety

- 1. Conforming Implant Material**  
Soft, scleral wall compliant bio-tissue; no vertical rigid tip
- 2. No Hardware**  
no plastic, metal or rigid foreign body
- 3. No Rebound Movement**  
Enhanced post-deployment fixation - compressed tissue re-expands



Scleral  
Allograft

# AlloPass Supraciliary Bio-stent Implantation

Gonio-based implantation

1

Step 1  
Tissue preparation  
Manual  $\mu$ TREPHINATION

2

Step 2  
Bio-Stent Implantation  
Cyclodialysis Cannula

