IANTREK

# NEXT GENERATION
## Glaucoma μ-Interventions

AECOS MEETING 2022

Dr. Toby Tyson

TWO MIGS TECHNOLOGIES
one company

# IANTREK: Leap Forward

## Into the future of MIGS

- Company founded by Dr. Tsontcho Ianchulev
- Two µ-interventional technologies for glaucoma surgery
- Address both trabecular and suprachoroidal outflow
- Meaningful improvement on well-established MIGS clinical paradigm
- Strong reimbursement and economics

# IANTREK Leadership

## Board

**Dr. Ianchulev**
Chairman of the Board, Founder
Professor NYEE | CEO, Eyenovia

**Jeffry Weinhuff**
Board Member
Partner
Visionary Ventures

**Dr. Bloch**
Board Member
Partner
Canaan Ventures

**Dr. Weinreb**
Board Member
Chairman and Director
Shiley Eye Institute

**Andrew Corley**
Board Member
Co-Founder of
Flying-L Partners

**Jim Mazzo**
Board Member
Former Global
President Zeiss

**Dr. Tyson**
Board Observer
Visionary ventures

**Serial Entrepreneur**
$1Bn+ in exit valuations
Wavetec Inc., Transcend Inc.,
Iantech Inc., Eyenovia, Inc.
Kurobe Inc.

**Inventor | Innovator | Developer**
Intraoperative Aberrometry
CyPass MIGS Microstent
Lucentis | miLOOP (Iantech)
Eyenovia Microtherapeutics

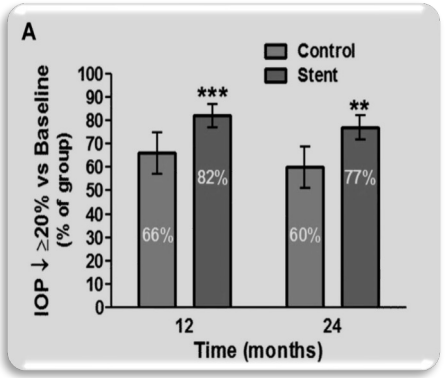
# Supraciliary Stenting: Clinically Validated IOP-Lowering Approach

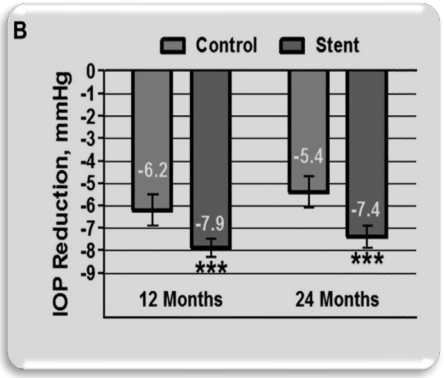
1st generation cyclodialysis cleft maintainers/stents show best-in-class MIGS profile


AMERICAN ACADEMY™ OF OPHTHALMOLOGY

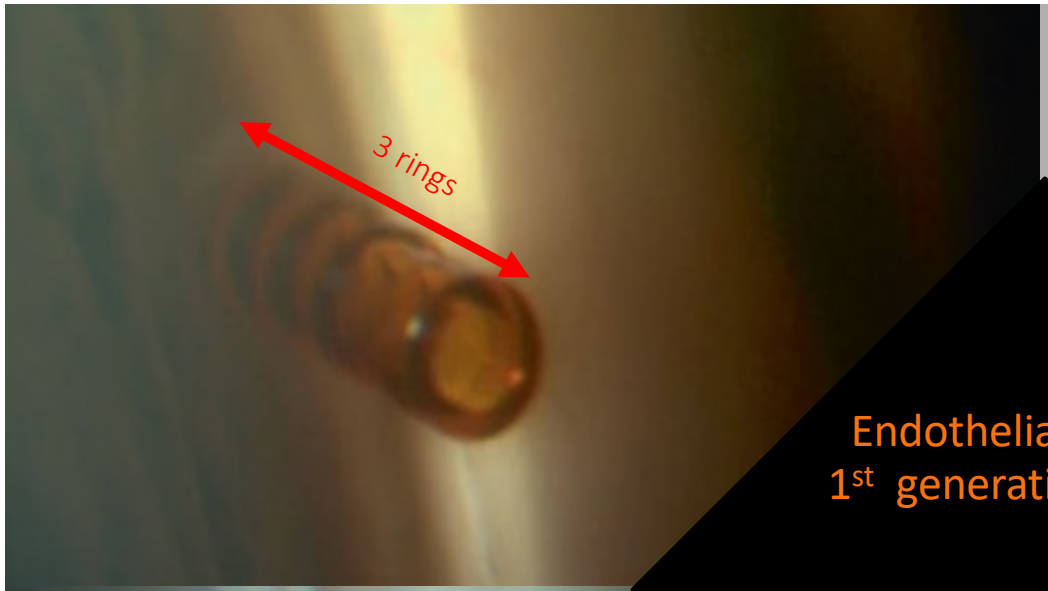
**Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts**

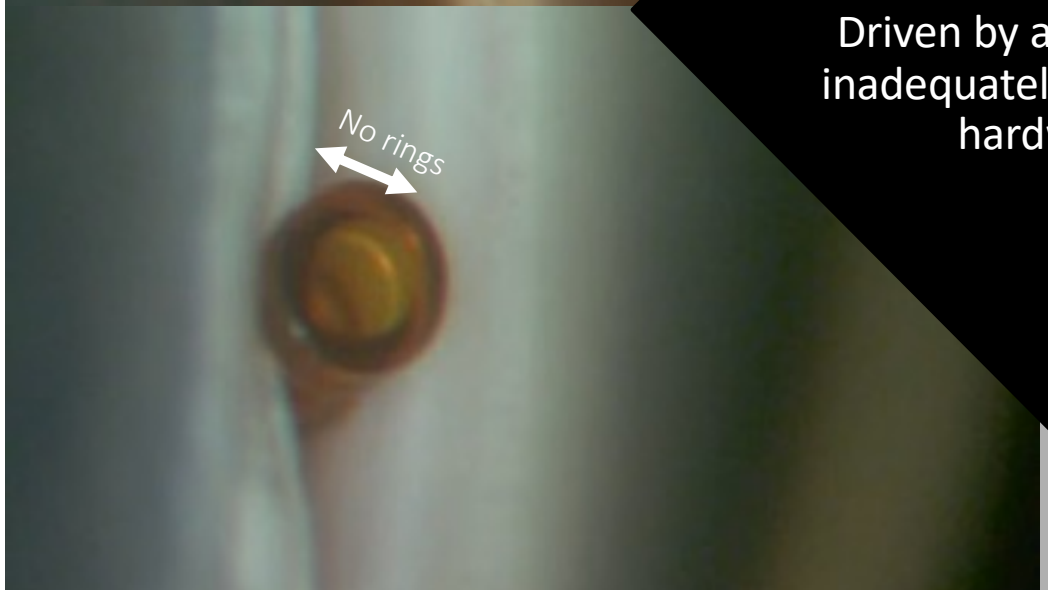
*Steven Vold, MD,[1] Iqbal Ike K. Ahmed, MD,[2] E. Randy Craven, MD,[3,4] Cynthia Mattox, MD,[5] Robert Stamper, MD,[6] Mark Packer, MD,[7] Reay H. Brown, MD,[8] Tsontcho Ianchulev, MD, MPH, for the CyPass Study Group**




- 2-year data from COMPASS CyPass pivotal FDA Randomized Controlled Study
- 2-year data from MiniJect Randomized Controlled Study
- Existing clinical supraciliary stenting experience in more than 10,000 patients




Endothelial loss with 1st generation SC stent

Driven by anteriorized inadequately implanted hardware

# CyPass Micro-Stent

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

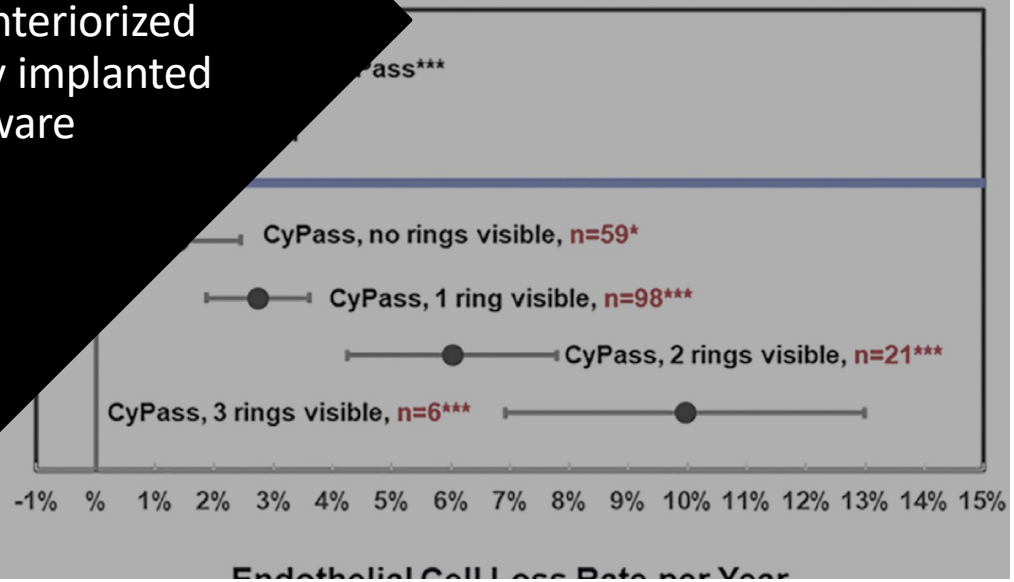
URPOSE: To characterize long-term changes in al endothelial cells after phacoemulsification with ut supraciliary Micro-Stent (Alcon) implantation h open-angle glaucoma (OAG) and visually aract.

-year safety extension of a 2-year ran- l.

from the multicenter Study of an owering Intraocular Pressure dergoing Cataract Surgery nt Micro-Stent implanta- 282) or phacoemulsi- l post hoc. Specular l cell loss (ECL), elial cell den- centage 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.)

THE 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$^2$. Corneal decompensation can occur when endothelial cell density (ECD) falls below 800 cells/mm$^2$,[1]



Fundamental question

# How can we stent the suprachoroidal outflow ….

…..without the implantable hardware?

# Bio-stenting

USING SCLERAL BIO-TISSUE

- ✓WELL-ESTABLISHED
- ✓DECADES LONG USE IN GLAUCOMA SX
- ✓HOMOLOGOUS
- ✓POROUS AND HYDROPHILIC
- ✓READILY AVAILABLE FROM EYE BANKS

Inventor Dr. Ianchulev

# Supraciliary Bio-stenting ...without the hardware

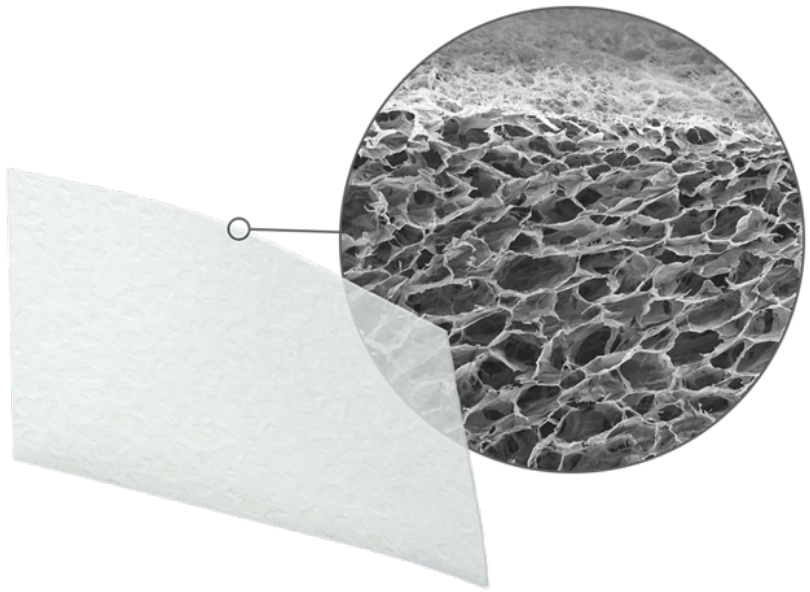
## Advanced smart bio-tissue MIGS intervention and instrumentation

1. **Conforming Implant Material**
   Soft, scleral wall compliant bio-tissue; no vertical rigid tip

2. **No Hardware**
   Bio-conforming soft tissue; no plastic, metal or rigid foreign body

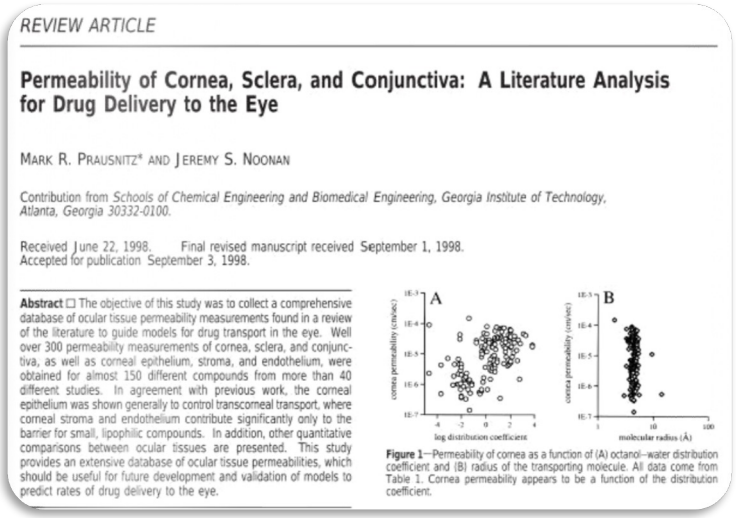
3. **Goniometric Controlled Depth Implantation**
   Transparent goniometric tip to preempt anteriorized deployment

4. **No Rebound Movement**
   Enhanced post-deployment fixation - tissue expansion in cleft



# Allostent Supraciliary Material

## Scleral bio-tissue up to 10x more permeable than cornea



REVIEW ARTICLE

**Permeability of Cornea, Sclera, and Conjunctiva: A Literature Analysis for Drug Delivery to the Eye**

MARK R. PRAUSNITZ* AND JEREMY S. NOONAN

Contribution from *Schools of Chemical Engineering and Biomedical Engineering, Georgia Institute of Technology, Atlanta, Georgia 30332-0100.*

Received June 22, 1998. Final revised manuscript received September 1, 1998. Accepted for publication September 3, 1998.

**Abstract** ☐ The objective of this study was to collect a comprehensive database of ocular tissue permeability measurements found in a review of the literature to guide models for drug transport in the eye. Well over 300 permeability measurements of cornea, sclera, and conjunctiva, as well as corneal epithelium, stroma, and endothelium, were obtained for almost 150 different compounds from more than 40 different studies. In agreement with previous work, the corneal epithelium was shown generally to control transcorneal transport, where corneal stroma and endothelium contribute significantly only to the barrier for small, lipophilic compounds. In addition, other quantitative comparisons between ocular tissues are presented. This study provides an extensive database of ocular tissue permeabilities, which should be useful for future development and validation of models to predict rates of drug delivery to the eye.



**Figure 1**—Permeability of cornea as a function of (A) octanol–water distribution coefficient and (B) radius of the transporting molecule. All data come from Table 1. Cornea permeability appears to be a function of the distribution coefficient.



| Molecule | Model | Cornea Permeability (cm/s) | Sclera Permeability (cm/s) | Fold Increase |
|---|---|---|---|---|
| Benzolamide | Human | 1.4 E-6 | 1.5 E-5 | 10.7 |
| Inulin | Rabbit | 5.5 E-7 | 2.5 E-6 | 4.5 |
| Propranolol | Rabbit | 3.1 E-5 | 5.8 E-5 | 1.9 |
| Sucrose | Rabbit | 4.3 E-6 | 4.2 E-5 | 9.8 |

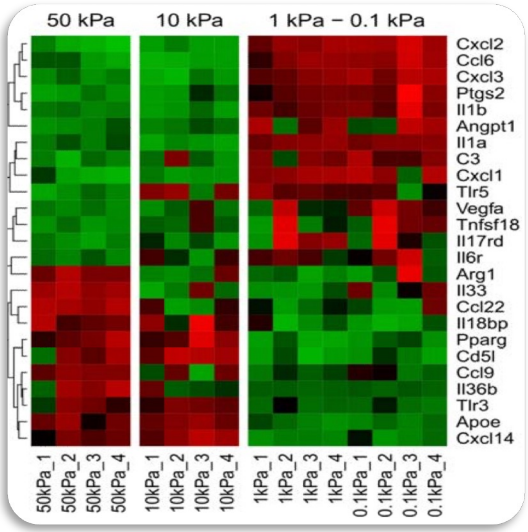
Journal of Pharmaceutical Science Dec 1998, Vol 87 No 12

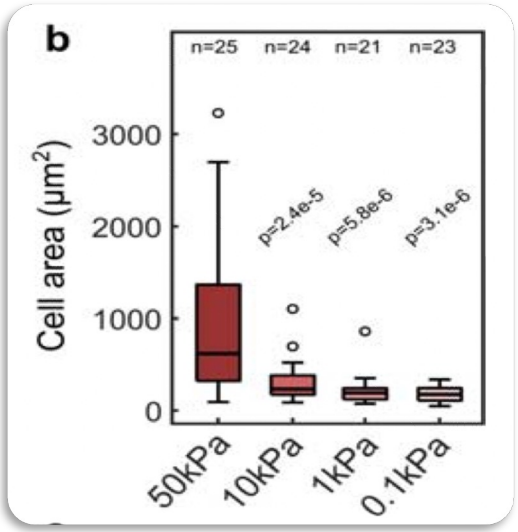
# Implant fibrosis and stiffness mismatch to surrounding tissue

## Homologous bio-tissue designed for minimal foreign body response and fibrosis

### High Stiffness Mismatch

triggers macrophage expression/fibrosis




| Scleral Allograft | Tensile Strength MPa 1-2 [1] | SC Implant vs Tissue Mismatch 0 |
|---|---|---|
| Titanium | 240 [3] | 239 |
| Polyimide | 80 [2] | 70 |

BioRxiv 829648; doi: https://doi.org/10.1101/829648 / Front. Bioeng. Biotechnol. 9:622524. doi: 10.3389/fbioe.2021.622524

# AlloPass Supraciliary Bio-stent Implantation

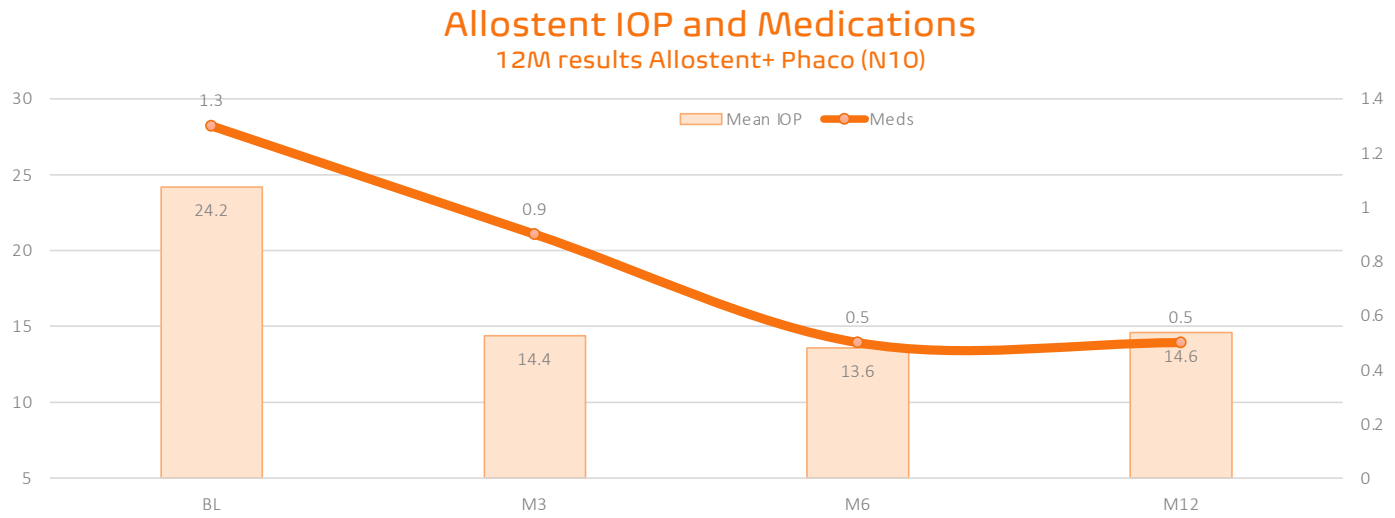
## Gonio-based and gonio-free implantation

# Allostent Initial Clinical Experience

## 12M results

- Initial 12-month results demonstrate robust IOP lowering effect (40%)
- Efficacy is consistent with the CyPass clinical results
- Bio-tissue  material showed good ocular tolerability with no emergent side effects

| | AEs |
|---|---|
| Hypotony | 0 |
| Hyphema | 0 |
| Corneal edema | 0 |
| Persistent iritis | 0 |
| IOP spike >30mm Hg | 0 |



# Supraciliary Bio-stenting ...without the hardware

## Next generation SC stenting

1st generation suprachoroidal stents with synthetic plastic or metal hardware

CYPASS

iSUPRA

MINIJECT

Allostent uses biocompatible acellular scleral matrix

ALLOSTENT

# Thank you