

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

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Toromedes Founder

Advances in MIGS treatment

missing a compelling approach for internal outflow enhancement

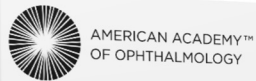
Supra Choroidal Outflow

Controlled Cyclodialysis

- Suprachoroidal space has large absorptive capacity
- Negative pressure gradient

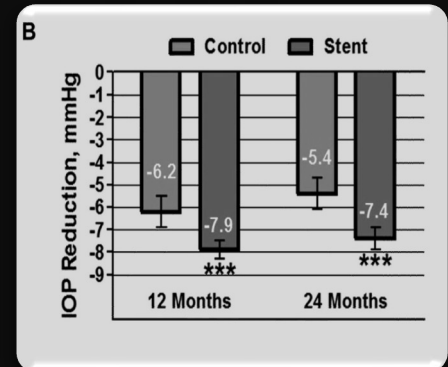
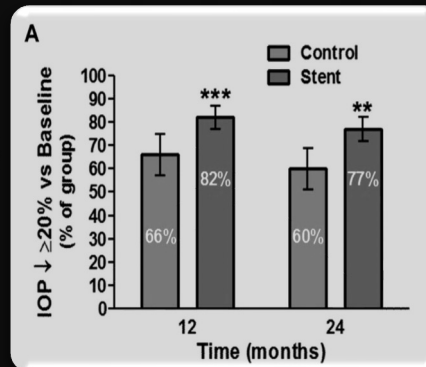
Supraciliary Stenting

already with validated IOP lowering



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

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Robert Stamper, MD,⁶ Mark Packer, MD,⁷ Reay H. Brown, MD,⁸ Tsontcho Ianchulev, MD, MPH,
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 in eyes with open-angle glaucoma (OAG) and visually significant cataract.

DESIGN: Retrospective, 5-year safety extension of a 2-year randomized controlled trial.

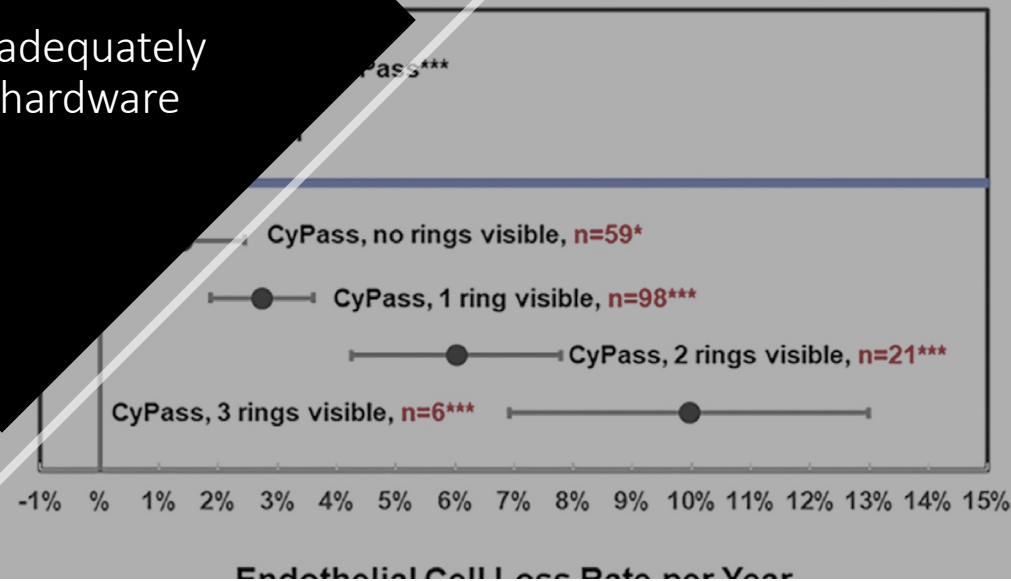
SETTING: Data from the multicenter Study of an Alcon Supraciliary Micro-Stent for Lowering Intraocular Pressure in Eyes Undergoing Cataract Surgery (SALIS) and the subsequent Micro-Stent Implantation Study (MSIS) (n=282) or phacoemulsification (n=282) post hoc. Specular microscopy was used to measure endothelial cell loss (ECL), endothelial cell density (ECD), and endothelial cell loss percentage of area (ECLA).

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/mm². Corneal decompensation can occur when endothelial cell density (ECD) falls below 800 cells/mm².¹

Endothelial loss with
1st generation SC stent

Driven by inadequately
implanted hardware



3 rings

No rings

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

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

Inventor Dr. Ianchulev



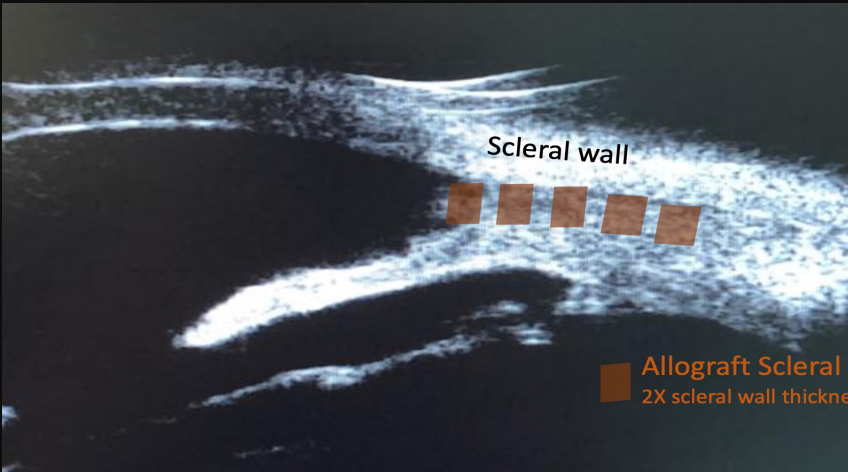
*Scleral allograft tissue implanted contiguous with sclera and to supplement native scleral wall

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

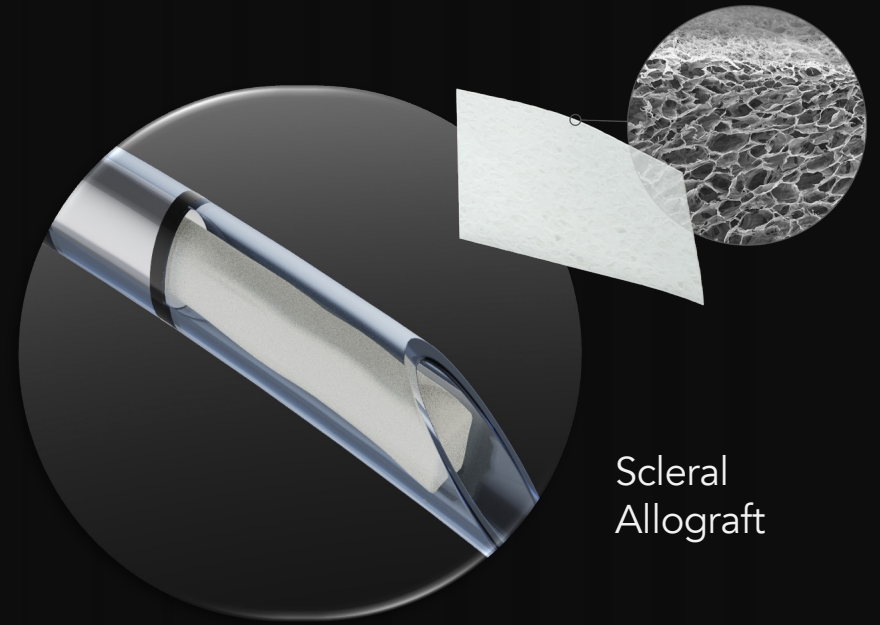
Soft, scleral wall compliant bio-tissue; no vertical rigid tip

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

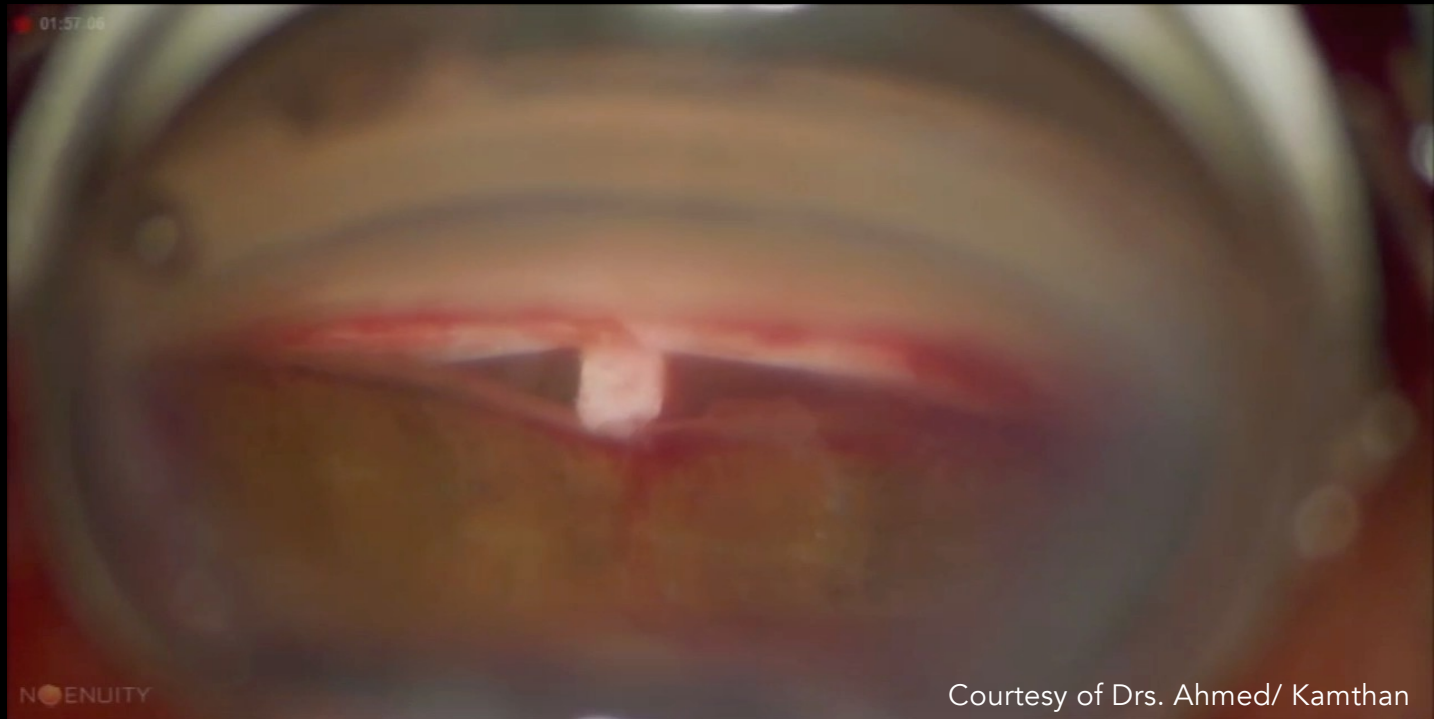
Manual μ TREPHINATION

2

Step 2

Bio-Stent Implantation

Cyclodialysis Cannula



Courtesy of Drs. Ahmed/ Kamthan