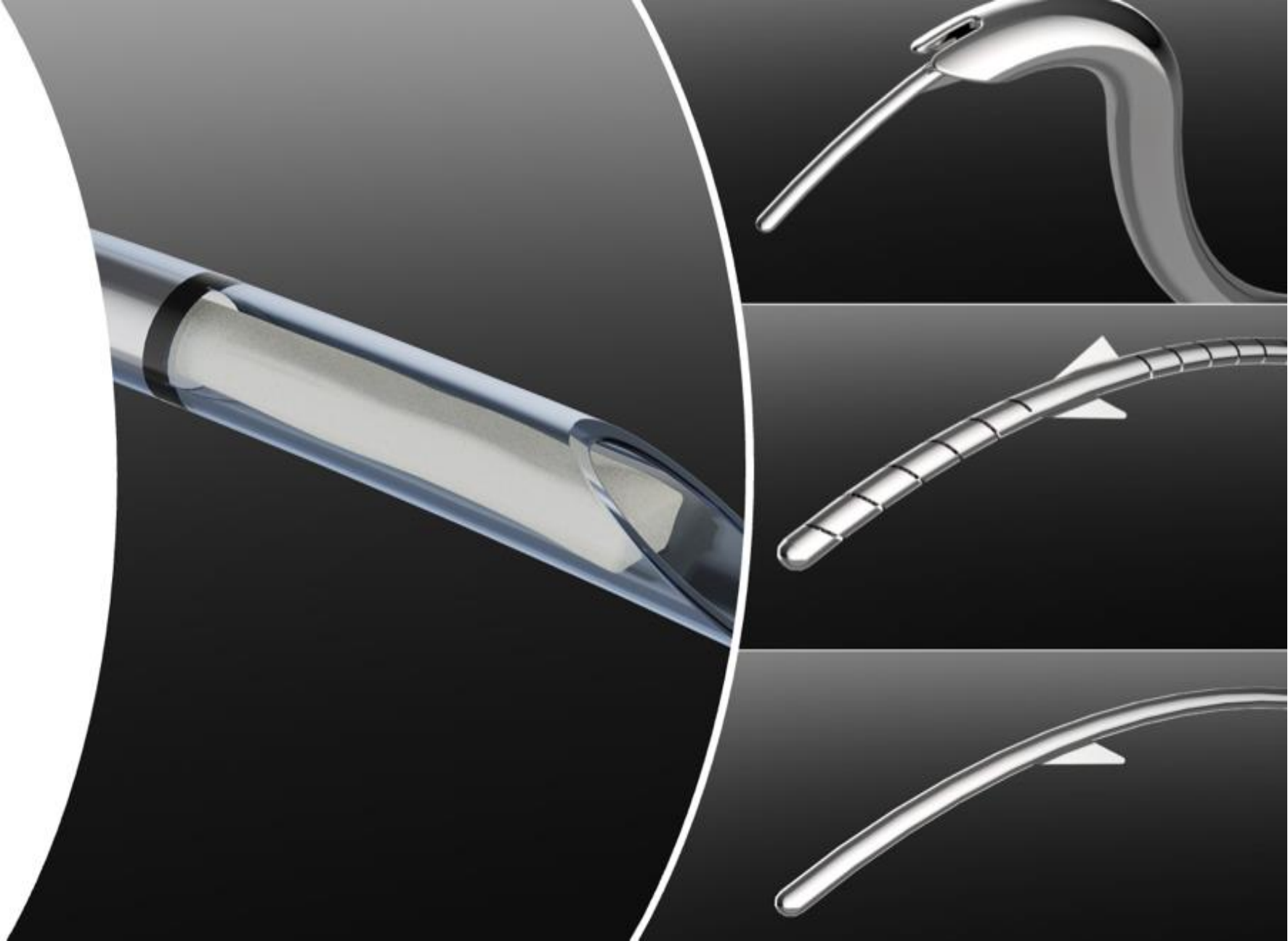


Next
Generation

μ -interventional
Technologies



Celebrating
200
YEARS
1820 - 2020



New York
Eye and Ear
Infirmary of
Mount
Sinai



Sean Ianchulev, MD MPH

Professor
of Ophthalmology
New York Eye and Ear
of Mount Sinai

New York City, New York

Disclosures

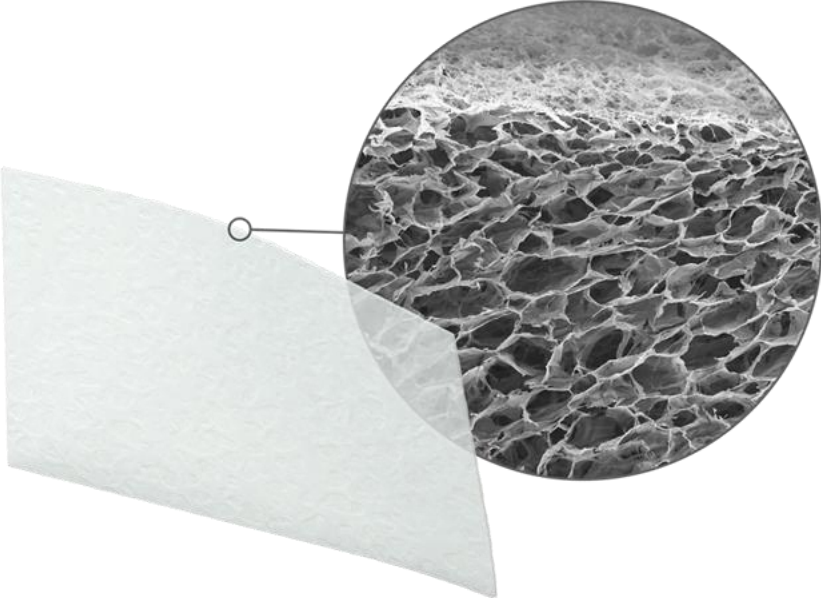
Iantrek, Inc.

Iantech, Inc. [Carl Zeiss Meditec]
Eyenovia, Inc
Preceyes, Inc [Carl Zeiss Meditec]
Aeye Health, inc.
KYS Vision, Inc.
Z-Optic, Inc
Wavetec, Inc. [Alcon]
Transcend Medical [Novartis]
PME Ventures

Scleral Allograft Bio-Tissue

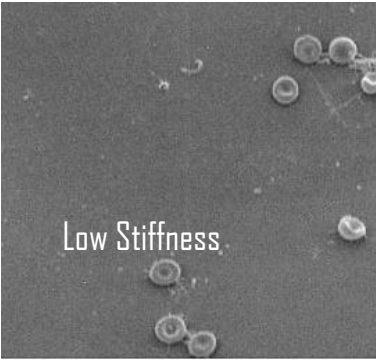
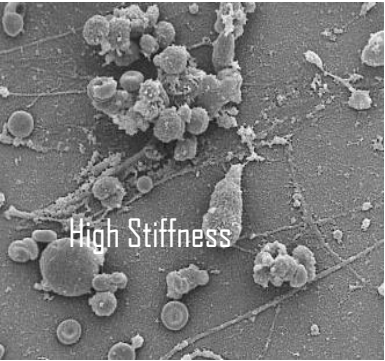
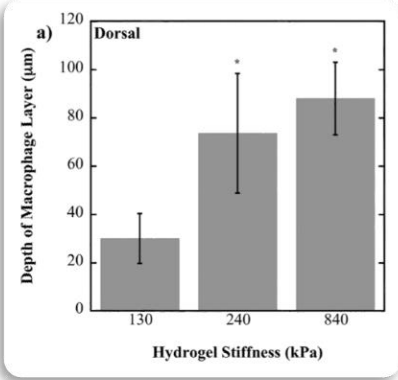
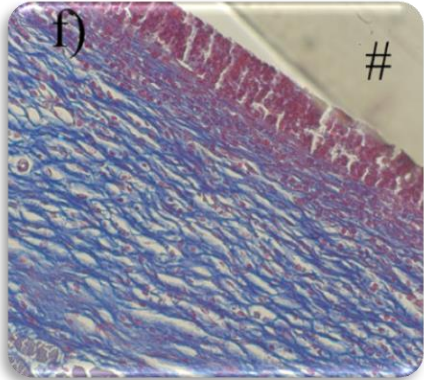
Hardware-free bio-stenting and reinforcement

- **Bio-Conforming Implant Material**
Soft, bio-tissue acellular matrix for structural reinforcement
- **No Hardware**
Bio-conforming soft tissue; no plastic, metal or rigid foreign body
- **Highly permeable and porous**
Hydrophilic porous matrix



Flexible Material

Bio-mechanical match to surrounding tissues



Highly Permeable Material

Molecule		Cornea	Sclera	Fold Incr.
Benzamide	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

Bio-Tissue μ -interventional Clinical Applications

Supraciliary bio--stenting

Reinforcement and maintenance of
supraciliary cleft



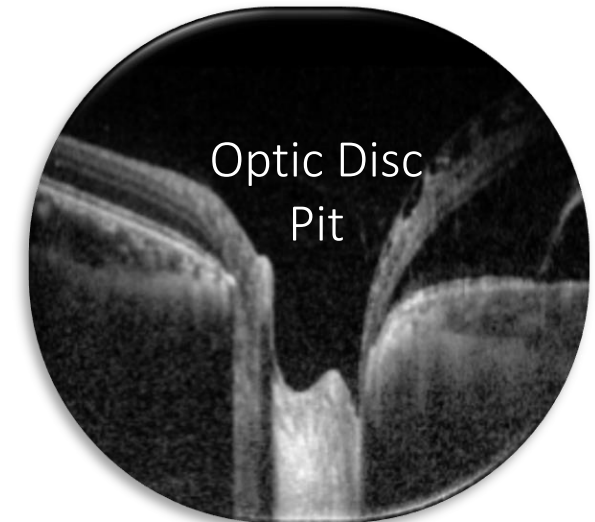
Ab-Interno Trab/bleb rescue

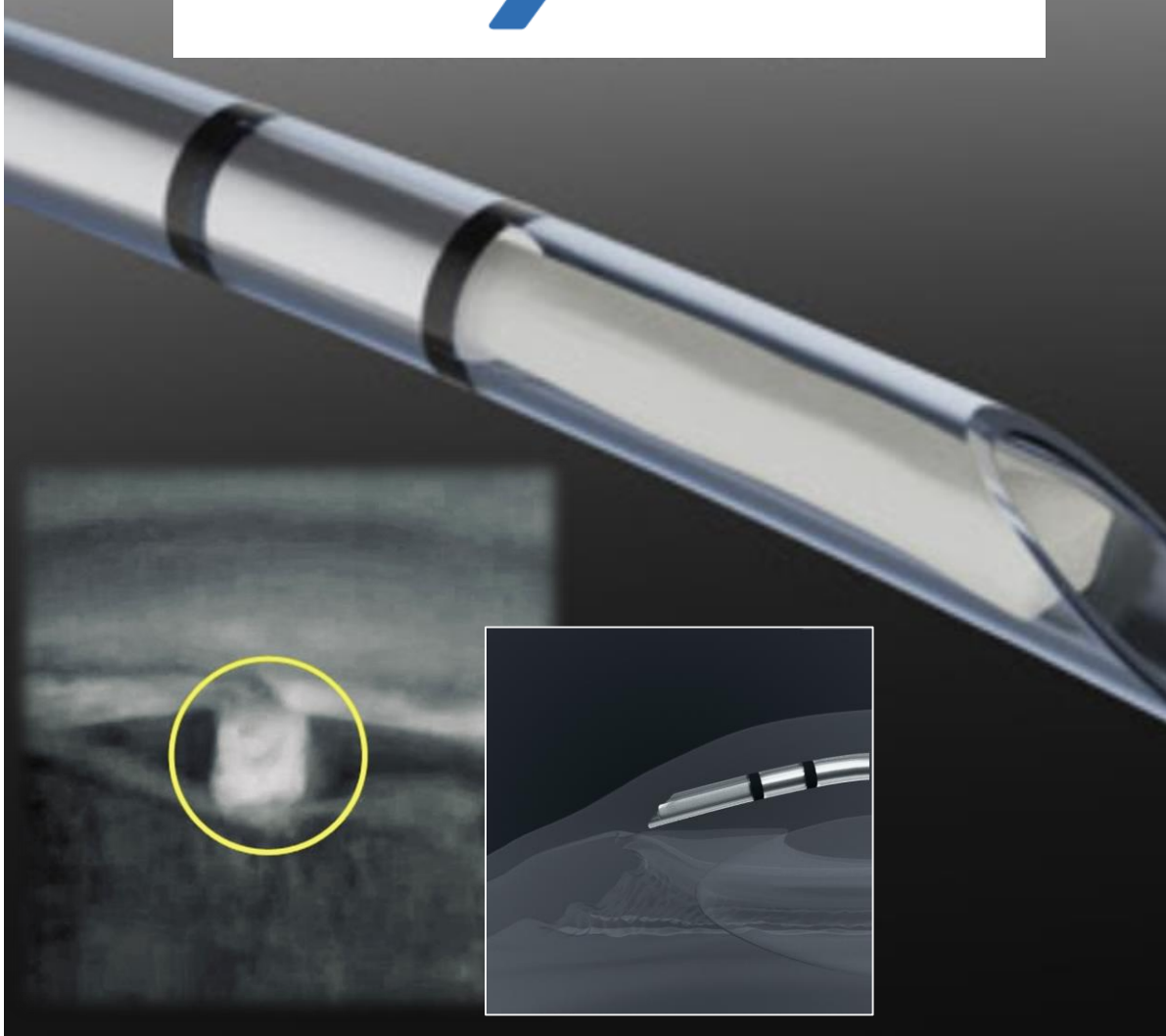
Reformation of sclerostomy



Optic disc pit maculopathy

Occlusion of aberrant CSF serous ingress





OPEN ACCESS

Biotissue stent for supraciliary outflow in open-angle glaucoma patients: surgical procedure and first clinical results of an aqueous drainage biostent

Tsontcho Ianchulev¹,² Robert N Weinreb,² Gautam Kamthan,³ Ernesto Calvo,⁴ Ravinder Pamnani,⁵ Iqbal K Ahmed⁶

¹Ophthalmology, New York Eye and Ear Infirmary of Mount Sinai, New York City, New York, USA
²UCSD, La Jolla, California, USA
³New York Eye and Ear Infirmary of Mount Sinai, New York City, New York, USA
⁴Clinica de Ojos Orillac-Calvo, Panama City, Panama
⁵Stanford University, Stanford, California, USA
⁶Ophthalmology and Vision Sciences, University of Toronto, Mississauga, Ontario, Canada

Correspondence to
 Dr Tsontcho Ianchulev,
 Ophthalmology, New York Eye and Ear Infirmary of Mount Sinai, New York City, NY 10003, USA; tianchul@yahoo.com

Received 16 September 2022
 Accepted 16 December 2022

ABSTRACT

Background/aims To report a first-in-human trial in open-angle glaucoma (OAG) subjects treated with a new microinterventional biostent-reinforced cyclodialysis technique to enhance supraciliary aqueous drainage.

Methods Subjects (N=10; 74.1±7.9 years old) with OAG and cataracts underwent combined phacoemulsification cataract surgery with implantation of a permanent endoscleral supraciliary biostent to reinforce a controlled cyclodialysis cleft. The biostent comprised decellularised scleral allograft tissue microtrephined into a polymer tubular implant intraoperative/postoperative safety, intraocular pressure (IOP) and glaucoma medications were tracked through 12 months postimplantation.

Results Baseline medicated IOP averaged 24.2±6.9 mm Hg with subjects using 1.3±0.8 IOP-lowering medications. Successful biostent implantation was achieved in all individuals without significant complications. Immediate IOP lowering was sustained through 1 year. Twelve-month mean IOP was reduced 40% from baseline to 14.6±3.2 mm Hg (p=0.004; paired two-tailed t-test), and 80% of patients achieved >20% IOP reduction. Biostenting reduced glaucoma medication use 62%, from a baseline mean of 1.3 required medications to 0.5 medications (p=0.037) at postoperative 12 months. The biotissue implant was well tolerated and demonstrated good endothelial safety with only 11% endothelial cell loss at 12 months after combined phaco-biostenting surgery, similar to that expected after phacoemulsification alone. Mean BCVA increased from baseline 20/130 Snellen to 20/36 at postoperative 12 months (p=0.001).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Open-angle glaucoma is often recalcitrant to medication therapy alone and requires surgical intervention to lower intraocular pressure (IOP). Minimally invasive glaucoma surgical approaches such as biostenting promise safe and effective long-term IOP reduction by facilitating outflow of aqueous humour.

WHAT THIS STUDY ADDS

⇒ Minimally invasive supraciliary scleral allograft biostent insertion during phacoemulsification cataract surgery safely lowered IOP by >20% through 1 year in 8/10 patients with open-angle glaucoma and reduced the average number of glaucoma medications needed by 62%.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Biostenting with an allograft implant may be a safe and effective approach for reducing IOP for long-term treatment of open-angle glaucoma.

or for those who cannot tolerate or afford topical medications in the form of eye-drops, conventional glaucoma surgery such as trabeculectomy and glaucoma drainage shunts have been used. However, such approaches are invasive, characterised by a variable healing response, and are often associated with significant ocular complications.^{6–11}

Minimally invasive



Biotissue stent for supraciliary outflow in open-angle glaucoma patients: surgical procedure and first clinical results of an aqueous drainage biostent

Tsontcho Ianchulev^{1,2}, Robert N Weinreb², Gautam Kamthan³, Ernesto Calvo⁴, Ravinder Pamnani⁵, Iqbal K Ahmed⁶

ABSTRACT

Background/aims To report a first-in-human trial in open-angle glaucoma (OAG) subjects treated with a new microinterventional biostent-reinforced cyclodialysis technique to enhance supraciliary aqueous drainage.

Methods Subjects (N=10; 74.1±7.9 years old)

WHAT IS ALREADY KNOWN ON

⇒ Open-angle glaucoma is often treated with medication therapy alone as an intervention to lower intraocular pressure (IOP). Minimally invasive

¹Ophthalmology, New York Eye and Ear Infirmary of Mount Sinai, New York City, New York, USA
²UCSD, La Jolla, California, USA
³New York Eye and Ear Infirmary of Mount Sinai, New York City, New York, USA

CycloPen™ System For Supraciliary Intervention

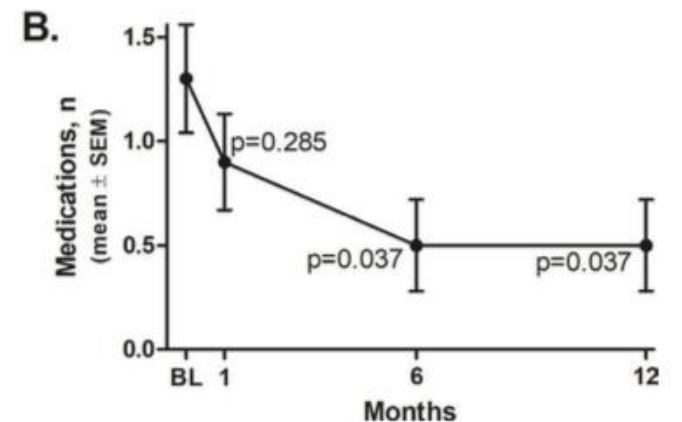
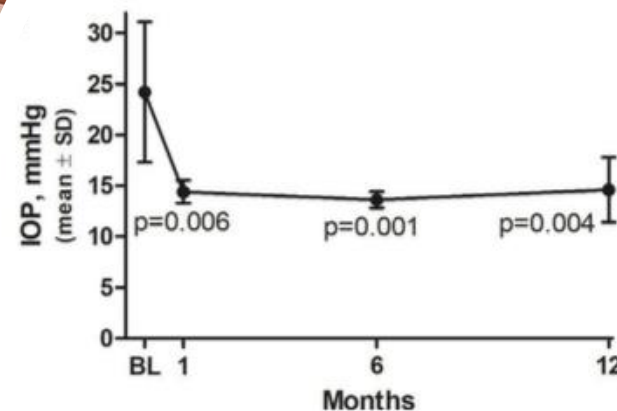


Figure 3 Intraocular pressure (IOP) and glaucoma medication use through 12 months after biostenting eyes with open-angle glaucoma.

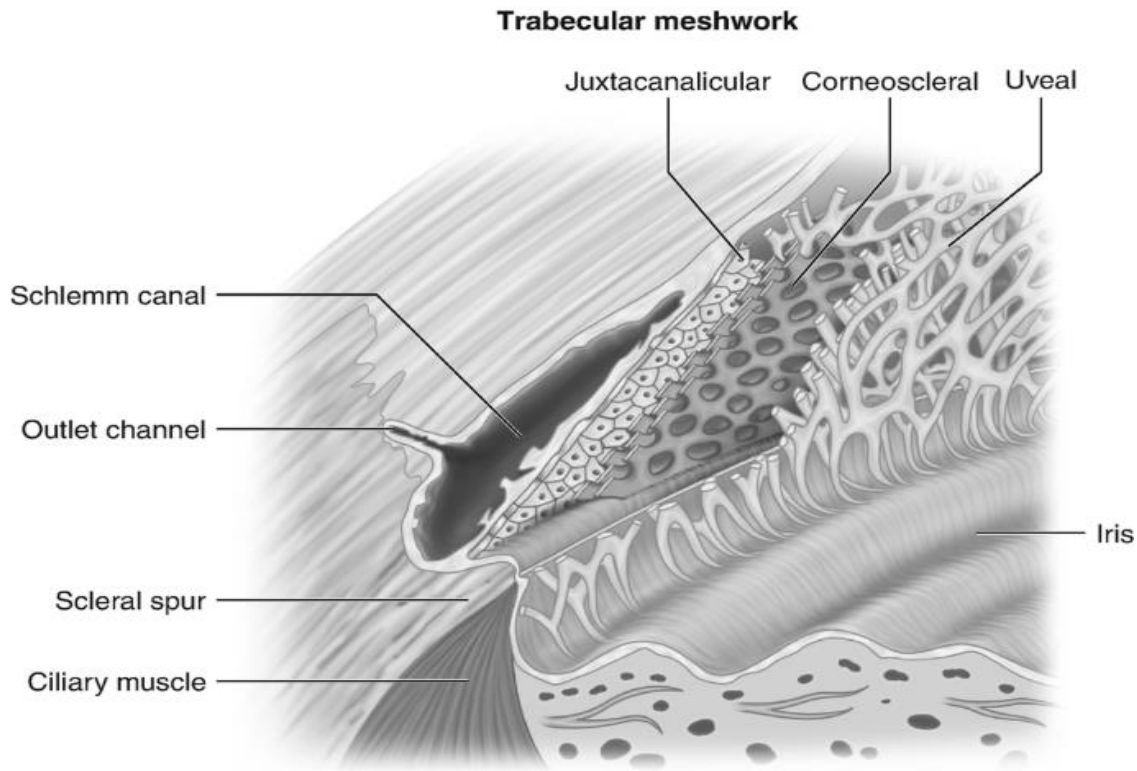


T-Rex

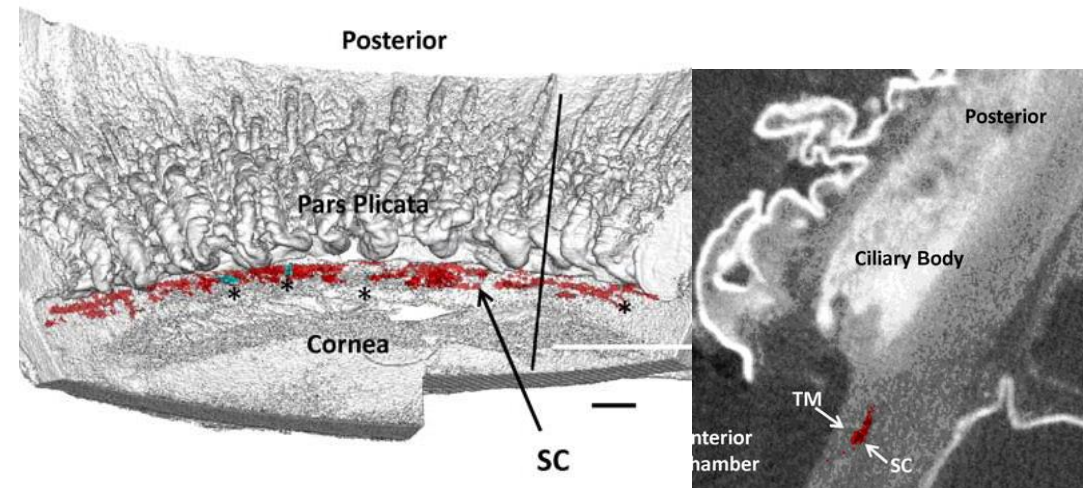
NEXT GEN Canalotomy

Conventional/Trabecular Outflow Pathway

- 100% of trabecular interventions address the **proximal portion** (e.g. goniotomy)
- Yet, 30-50% of outflow resistance is in the **distal portion**



3D Micro Computed Tomography Scanning



Invest Ophthalmol Vis Sci. 2014;55:5834-5841. DOI:10.1167/iov.14-14128

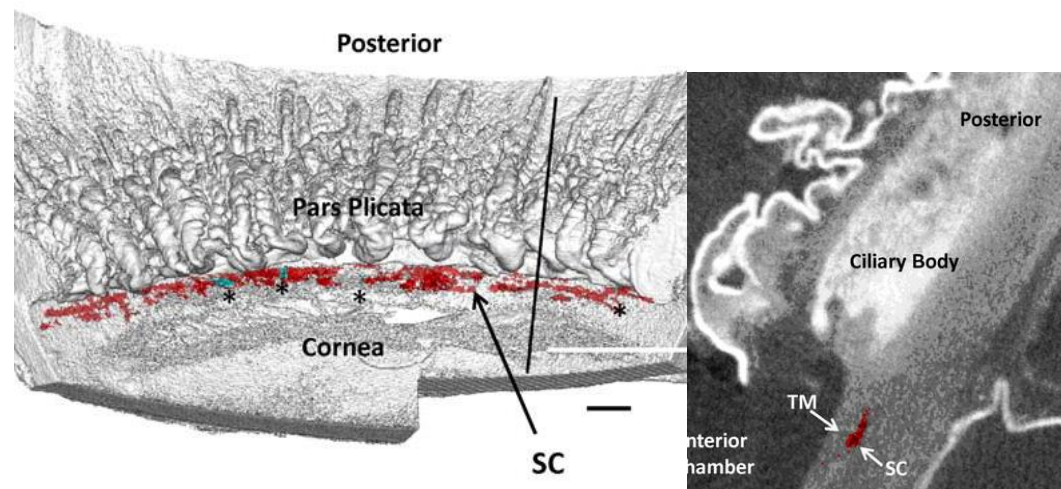


Conventional/Trabecular Outflow Pathway

- 100% of trabecular interventions address the **proximal portion** (e.g. goniotomy)
- Yet, 30-50% of outflow resistance is in the **distal portion**

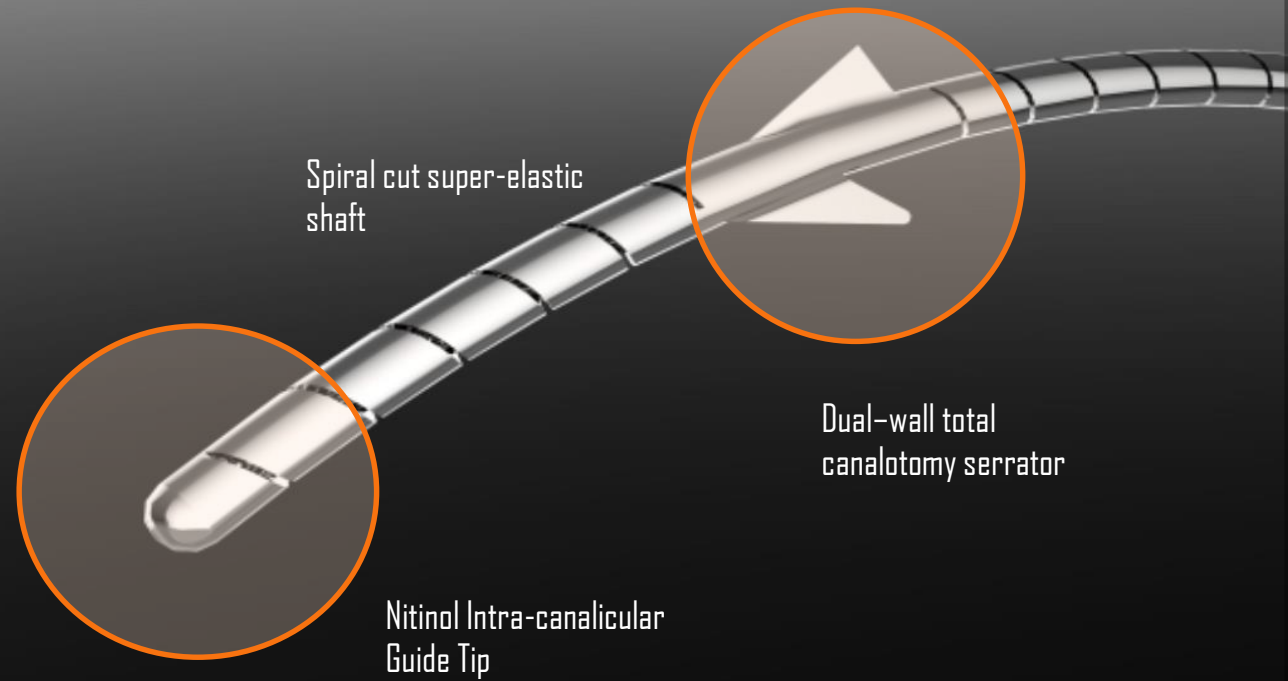
24%
of Collector Channels
Totally Occluded in POAG

3D Micro Computed Tomography Scanning



Invest Ophthalmol Vis Sci. 2014;55:5834-5841. DOI:10.1167/iov.14-14128





T-Rex DUO

DUAL WALL CANALOTOMY

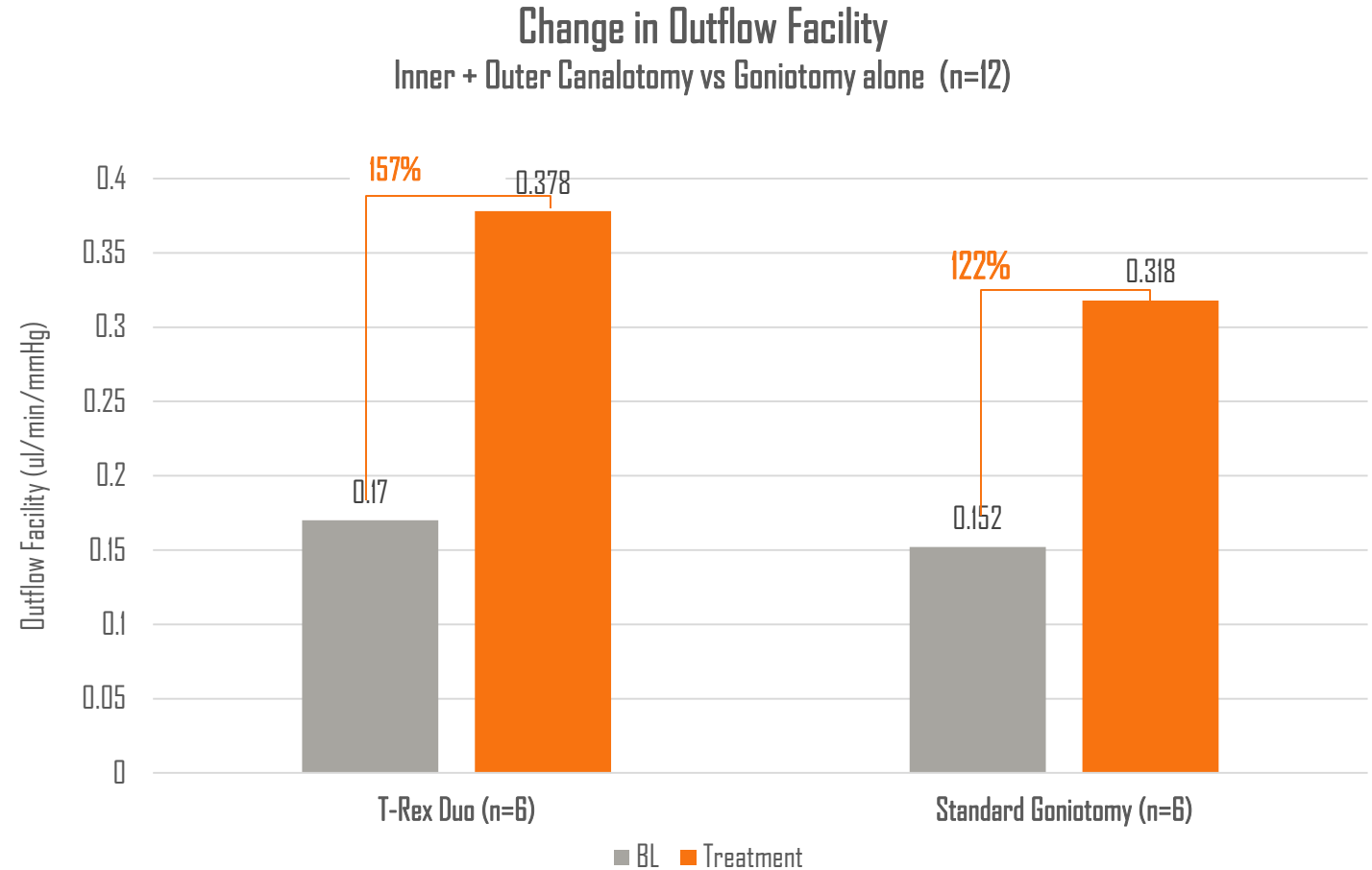
- Dual-wall intervention: Trabecularhexis-goniotomy + outer wall canaloplasty
- 180° or 360° continuous, single-pass guided total canalotomy
- Micro-serrated inner and outer outer-wall modulation and modification

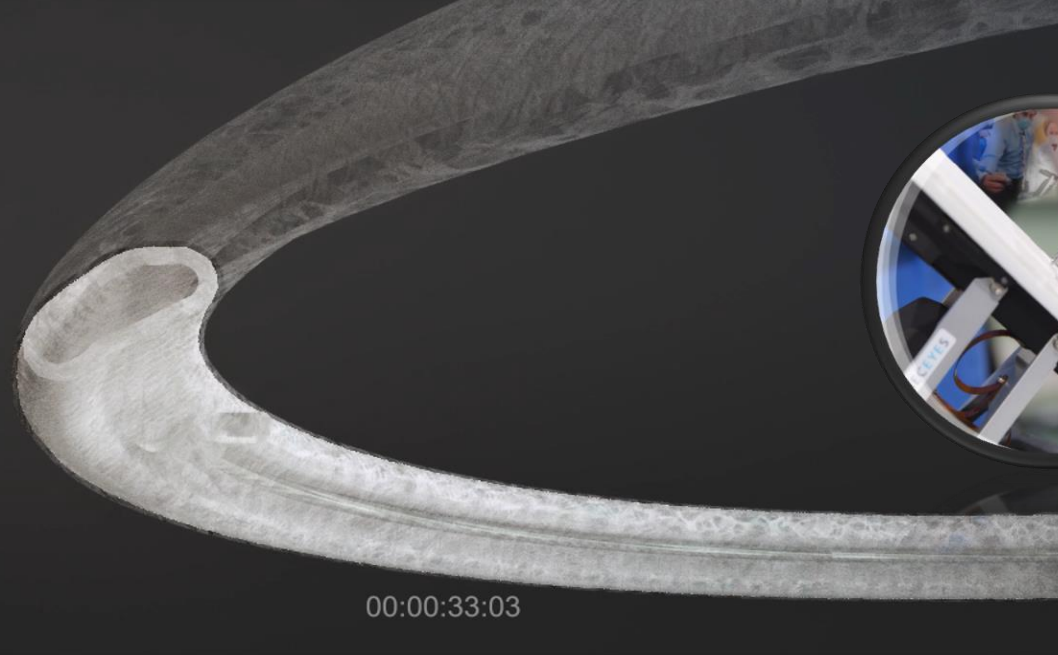
Inner + Outer Wall Canalotomy Increases Aqueous Outflow Facility Over Goniotomy Alone

Dr. Carol Toris, et al



- T-Rex Duo goniotomy with outer wall canalotomy resulted in an additional 35%-point improvement in aqueous outflow facility
- Aqueous outflow facility was measured in paired eyes before and after intervention





μ -robotic gonio intervention

- Nitinol memory-shaped super-elastic filament
- Designed for inner and outer wall intervention
- Adapted for manual and robot-assisted surgery

Thank you

Celebrating
200
YEARS
1820 - 2020



New York
Eye and Ear
Infirmary of
Mount
Sinai

