SHILEY EYE INSTITUTE
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Bio-interventional Cyclodialysis in Patients Undergoing Cataract Surgery and Failing IOP Control with Topical Medication Therapy

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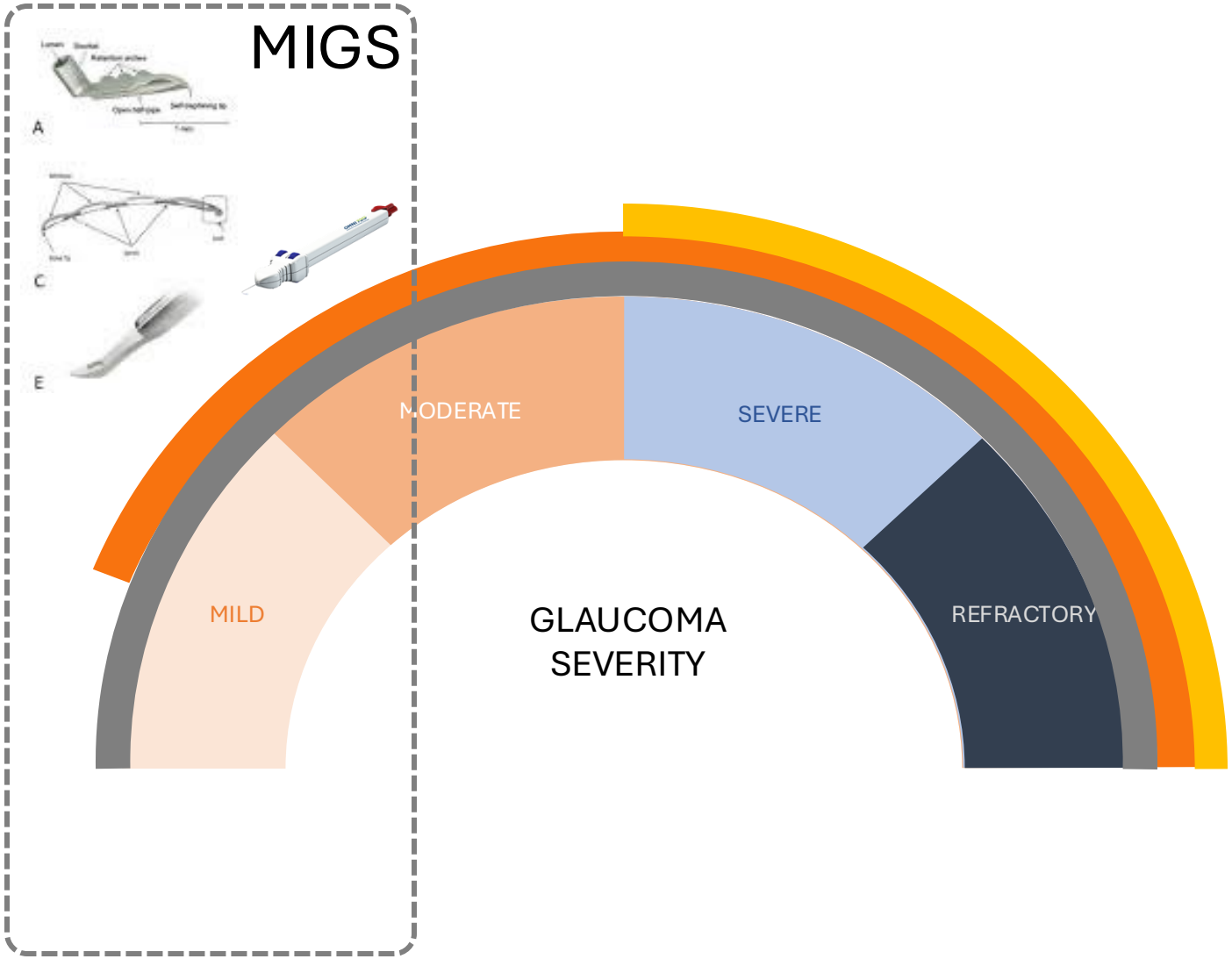
Effective Interventions Needed for Moderate Glaucoma Patients with Medically Uncontrolled IOP

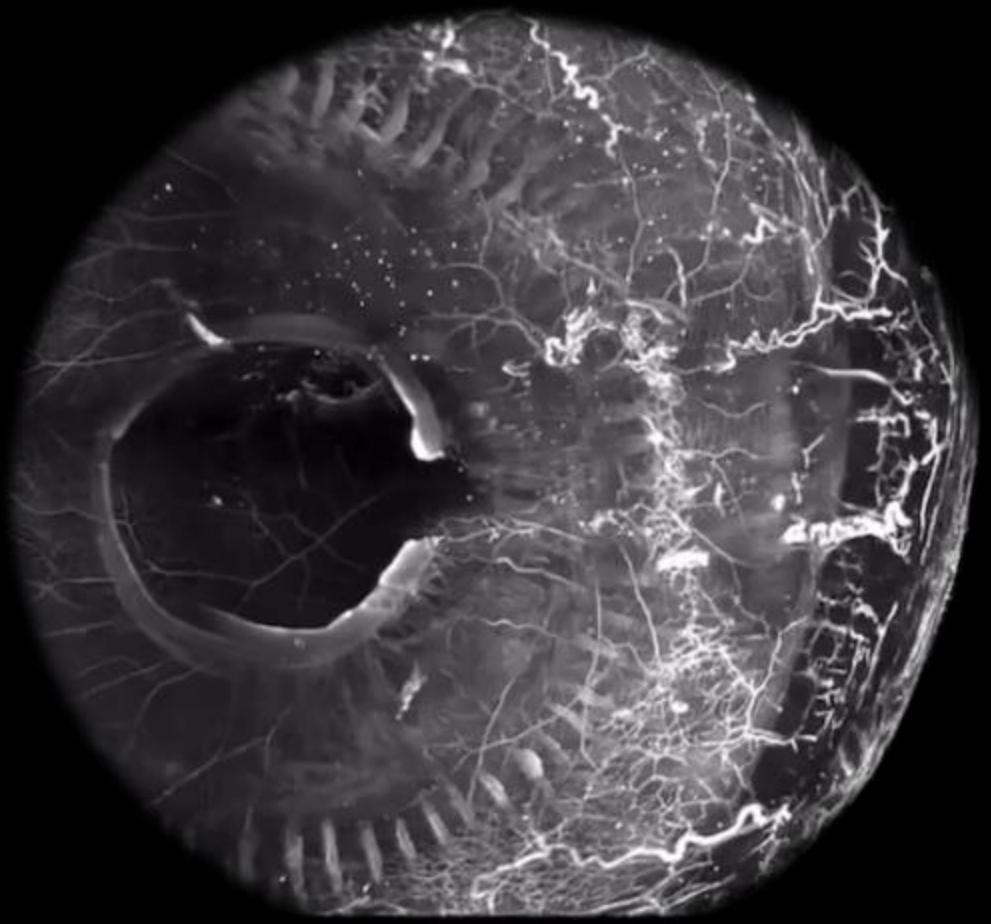
- Medical therapy for IOP reduction is highly effective, however, a subset of patients cannot be adequately controlled using medications alone

- Challenges with polypharmacy
  Multi-medication adherence
  Ocular surface
  Continued progression

- 90% of MIGS used in mild-mod OAG in combination with phaco



Uveoscleral Outflow: A Validated Pathway



- **Uveoscleral outflow is an established therapeutic target**
- **Demonstrated Rx efficacy with pharmacotherapy (PGAs)**
- **Larger aqueous drainage capacity than trabecular pathway**
- **Negative oncotic gradient drives aqueous outflow**

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Surgical Access to the Uveoscleral Outflow Pathway

Cyclodialysis History and Evolving Clinical Paradigm

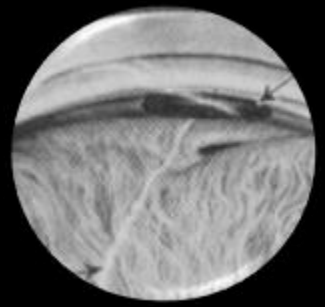
1905
First Cyclodialysis
Heine

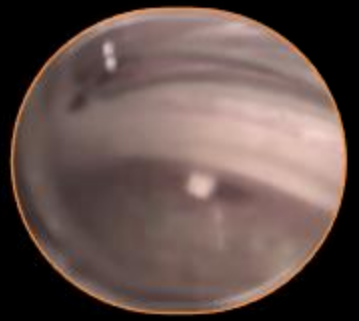
1920-1940+
Most common glaucoma surgery
External approach

1950
Cyclodialysis
Ab-interno approach

1960
Supplanted by trabeculectomy

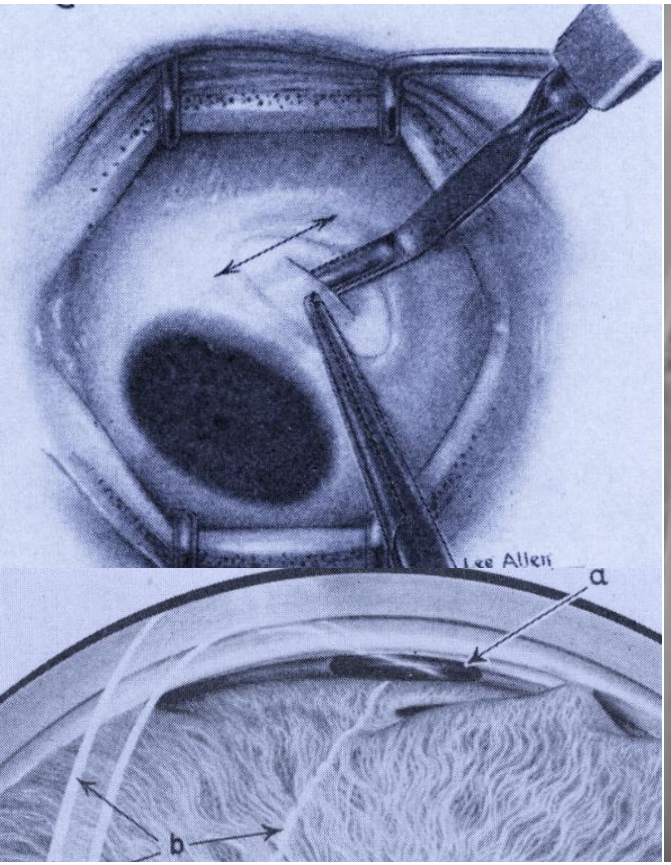
2000+
Interventional ab-interno approach ± reinforcement

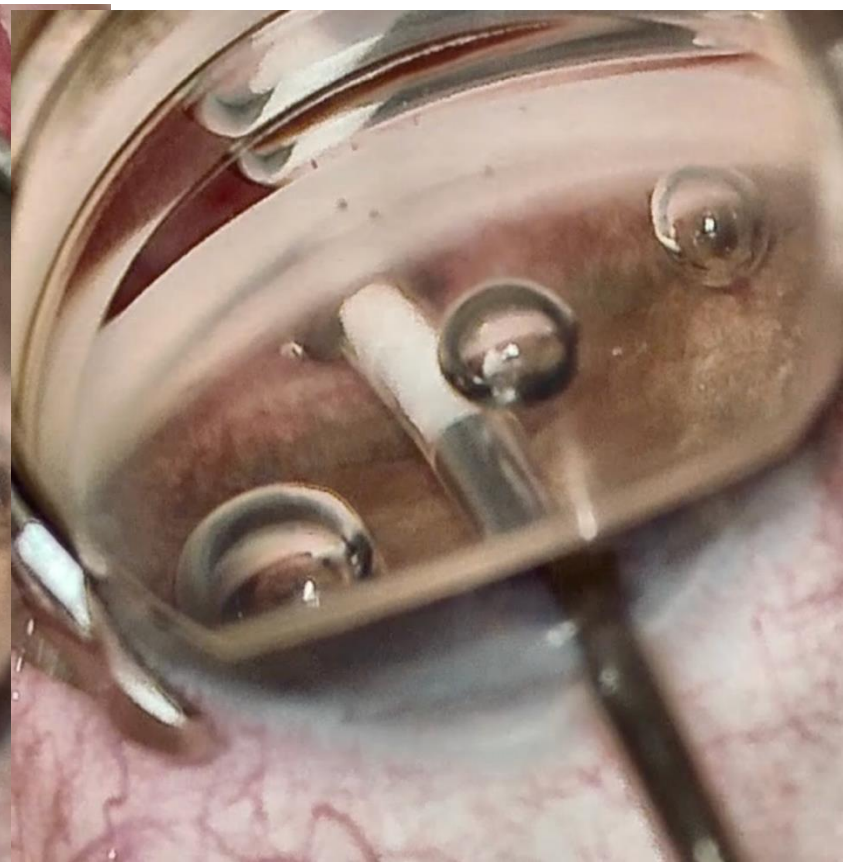




Cyclodialysis Evolution of Surgical Technique

Ab-externo >> Ab-Interno >> μ-interventional >> Reinforced





Material Matters!
Bio-tissue reinforcement of cyclodialysis
a novel bio-interventional approach for uveoscleral enhancement

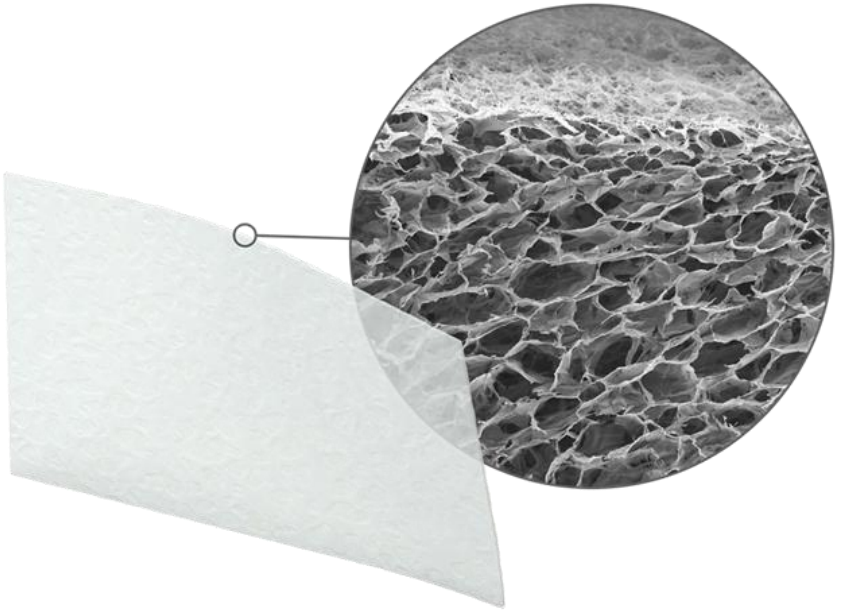
Inventor
Dr. Ianchulev

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

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

Goniometric Controlled Depth Implantation
Transparent goniometric tip to preempt anteriorized deployment

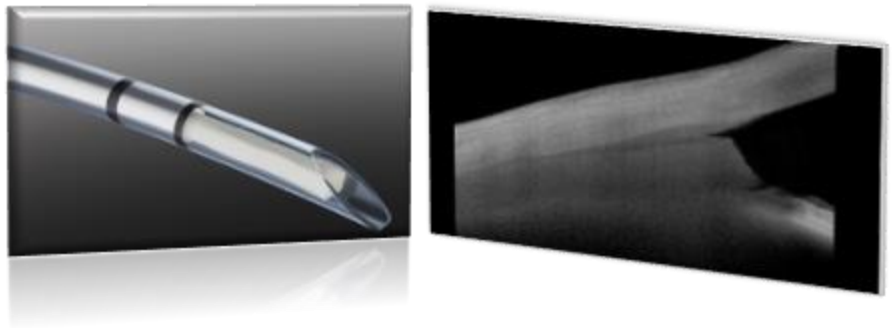
No Rebound Movement
Enhanced post-deployment fixation - tissue expansion in cleft



Blakney AK, Swartzlander MD, Bryant SJ. The effects of substrate stiffness on the in vitro activation of macrophages and in vivo host response to poly(ethylene glycol)-based hydrogels. J Biomed Mater Res A. 2012 Jun;100(6):1375-86. doi: 10.1002/jbm.a.34104. Epub 2012 Mar 7. PMID: 22407522; PMCID: PMC3339197.

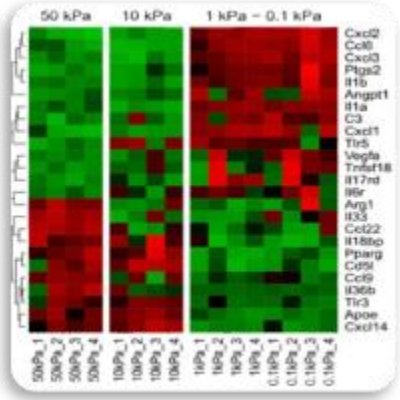
Material Matters!

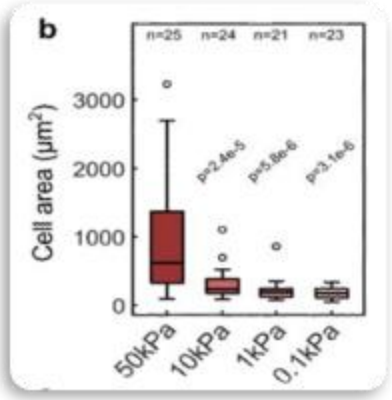
100% Biologic, hardware-free, allogeneic reinforcement of cyclodialysis



Homologous Allograft
Minimal foreign body reaction
Designed for corneal safety

Porous
For aqueous conductivity





Foreign body response: Reduced Macrophage activation with more homologous implant material biomechanics

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

	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

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Front. Bioeng. Biotechnol. 9:622524. doi: 10.3389/fbioe.2021.622524

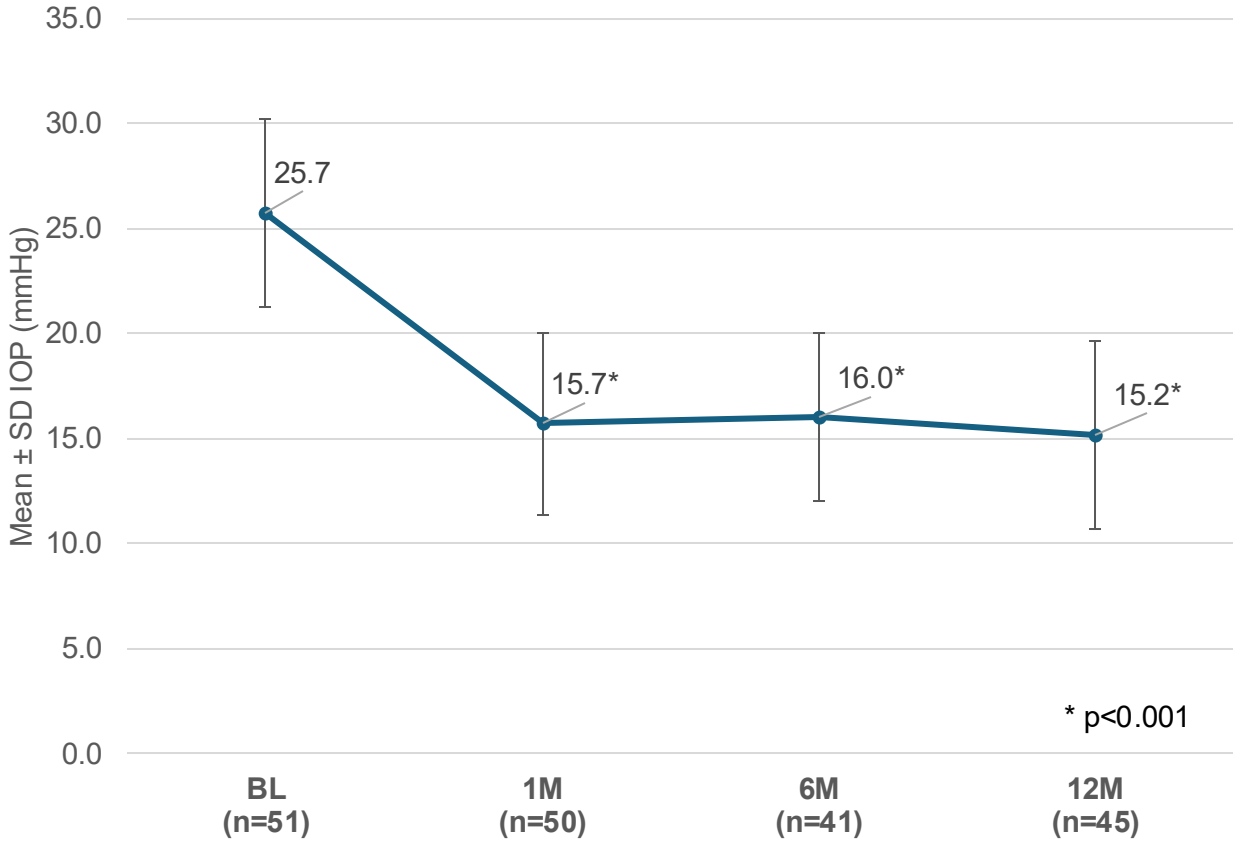
Micro-interventional Cyclodialysis with Scleral Reinforcement

Study Design and Baseline Characteristics

- CREST is a multicenter, interventional, safety and effectiveness, real world clinical study (n=410)
- Medically uncontrolled cohort of glaucoma patients with a confirmed diagnosis of open-angle glaucoma, operable cataract, baseline IOP ≥ 21 mmHg. Prospectively followed for 24 months
- Interventions: interventional ab-interno cyclodialysis with subsequent bio-tissue scleral reinforcement with or without phaco surgery
- Analysis: Ocular safety, concomitant procedures, IOP and medication usage over 12 months

Baseline Characteristics **Sample size, eyes, N**	 **51**
Patients	38
Age, mean ± SD, years	71.4 ± 10.5
Gender: female, %	44.7%
Pseudophakic	68%
Baseline BCVA, mean +SD	0.40 ± 0.32
Baseline IOP, mmHg, mean ± SD	25.7 ± 4.4
Number of IOP-lowering drugs, mean ± SD	1.2 ± 1.3

Efficacy Outcomes



	BL (n=51)	1M (n=50)	6M (n=41)	12M (n=45)
IOP, mean	25.7	15.7	16.0	15.2
IOP, SD	4.4	4.4	4.0	4.5

	BL (n=51)	1M (n=50)	6M (n=41)	12M (n=45)
Mean IOP Meds	1.2	0.9	0.9	0.7
+SD	1.3	1.2	0.9	0.9

Safety Events

	N=51
BCVA, decimal, mean ± SD	0.73 ± 0.23
IOP increase (10 mmHg or >30mmHg), n (%)	4 (7.8)
IOP increase (>30mmHg), n (%)	4 (7.8)
>2 lines drop in BCVA, n (%)	0 (0)
Significant intraoperative complications (bleeding, tissue damage)	0 (0)
Persistent inflammation (>1M), n (%)	0 (0)
Severe inflammation (grade 4+), n (%)	0 (0)
Persistent hyphema (>1M), n (%)	1[1] (1.9)
Severe post-operative hyphema (>3 mm), n (%)	0 (0)
Persistent corneal edema (>1M), n (%)	0 (0)
Bio-tissue migration, n (%)	0 (0)
Cystoid macular edema	2[2] (3.9)
IOP <6 mm on more than 2 visits, without maculopathy	0 (0)
Hypotony with Maculopathy	0 (0)
Post-operative Laser Enhancement	2[3] (3.9)
Secondary Glaucoma Intervention	4[3] (7.8)

1. Fully resolved
2. With phaco surgery and diabetic retinopathy. No hypotony
3. 1 case of aqueous humor release (wound bupring) at the 1-week postop visit, 1 case of Ahmed tube, 1 Case of Xen implant, and 1 case of CPC/Goniotomy

Conclusion

- Bio-interventional enhancement of uveoscleral outflow is achieved through ab-interno cyclodialysis and homologous allograft scleral reinforcement
- Allograft tissue demonstrates inert, biocompatible, and bio-conforming material properties
- Allograft bioscaffold shows durable structural stability with no post-operative migration.
- Bio-interventional cyclodialysis surgery demonstrates robust IOP lowering effect in the setting of cataract surgery in medically uncontrolled OAG patients