Bio-interventional Uveoscleral Outflow Enhancement

Cyclodialysis And Allograft Bio-Reinforcement

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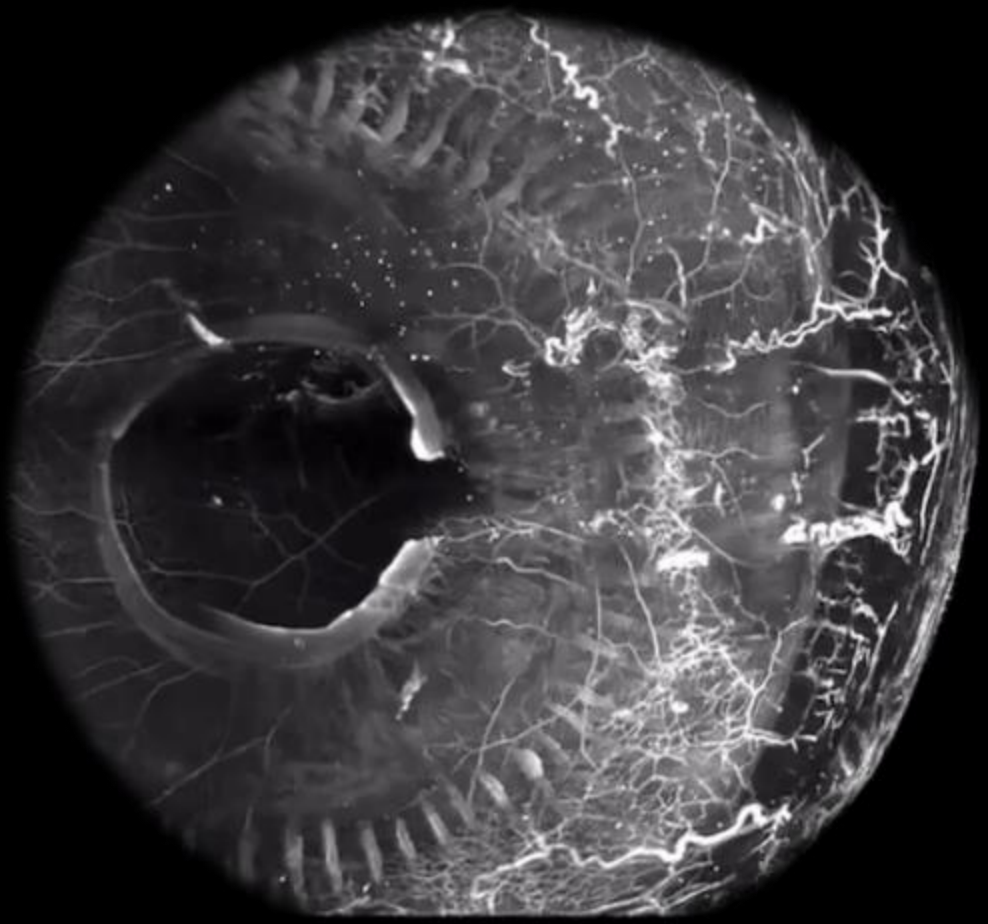
ABSTRACT ID: 30079582

Disclosures

Iantrek, Inc
CREST Study
Medical Monitor

The uveoscleral outflow revisited



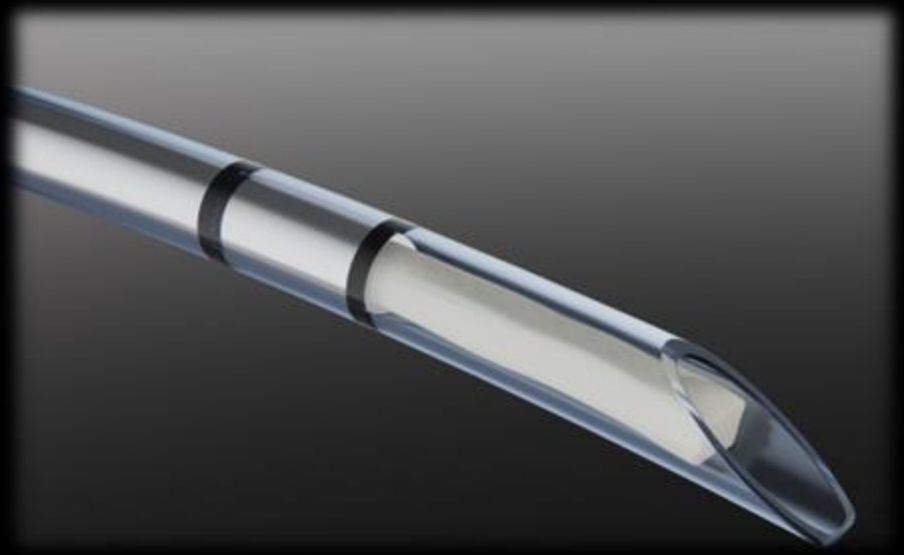
- **Uveoscleral outflow is an important therapeutic target**
- **Larger aqueous drainage capacity than trabecular pathway**
- **Negative oncotic gradient drives outflow**
- **High Rx efficacy with pharmacotherapy (PGAs)**

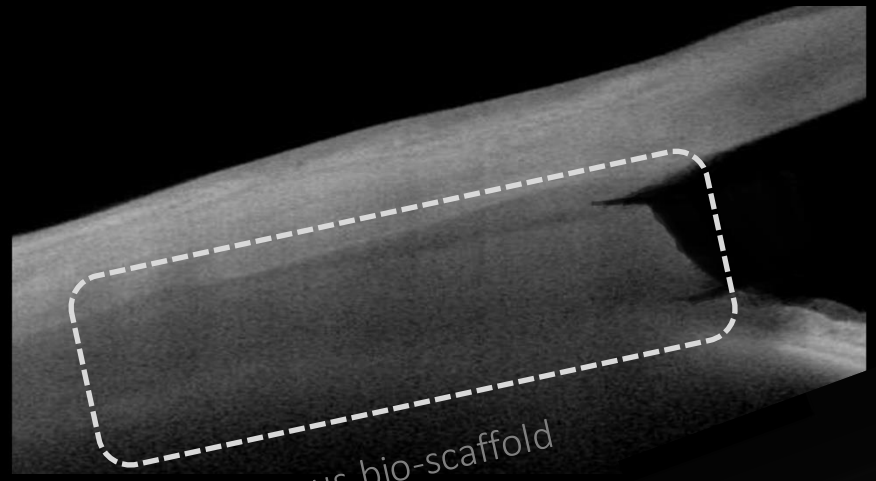
Investigative Ophthalmology & Visual Science June 2021, Vol.62, 3025

Bio-Interventional Cyclodialysis with Allogeneic Biotissue Reinforcement

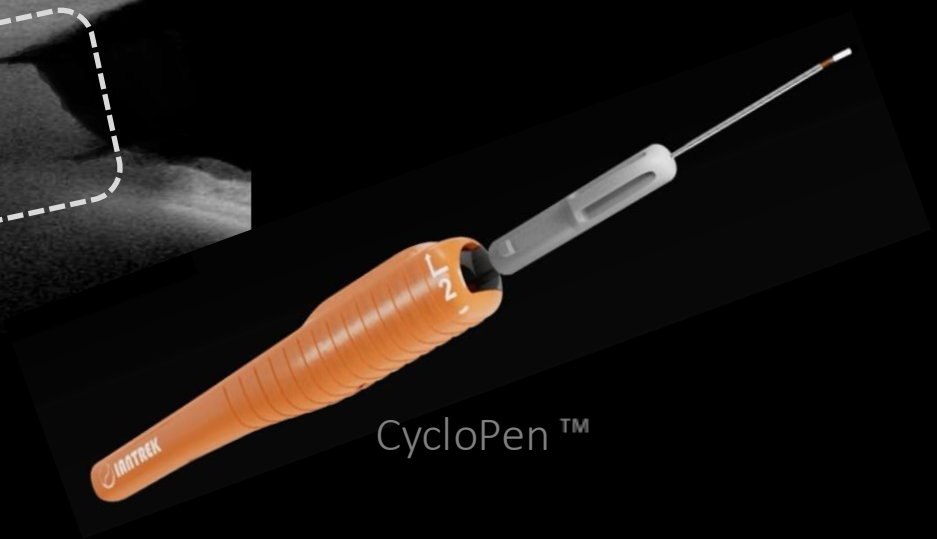
- **Bio-Interventional Cyclodialysis Procedure**
- **Creation of a sectoral ab-interno cyclodialysis**
- **Endoscleral bio-reinforcement with allograft**

- **100% bio-tissue:** hardware-free
- **Endothelial safety by design:** AC-Clear deployment
- **CREST: 400-patient real-world evidence study underway**





Homologous bio-scaffold



CycloPen ™

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Procedure 1

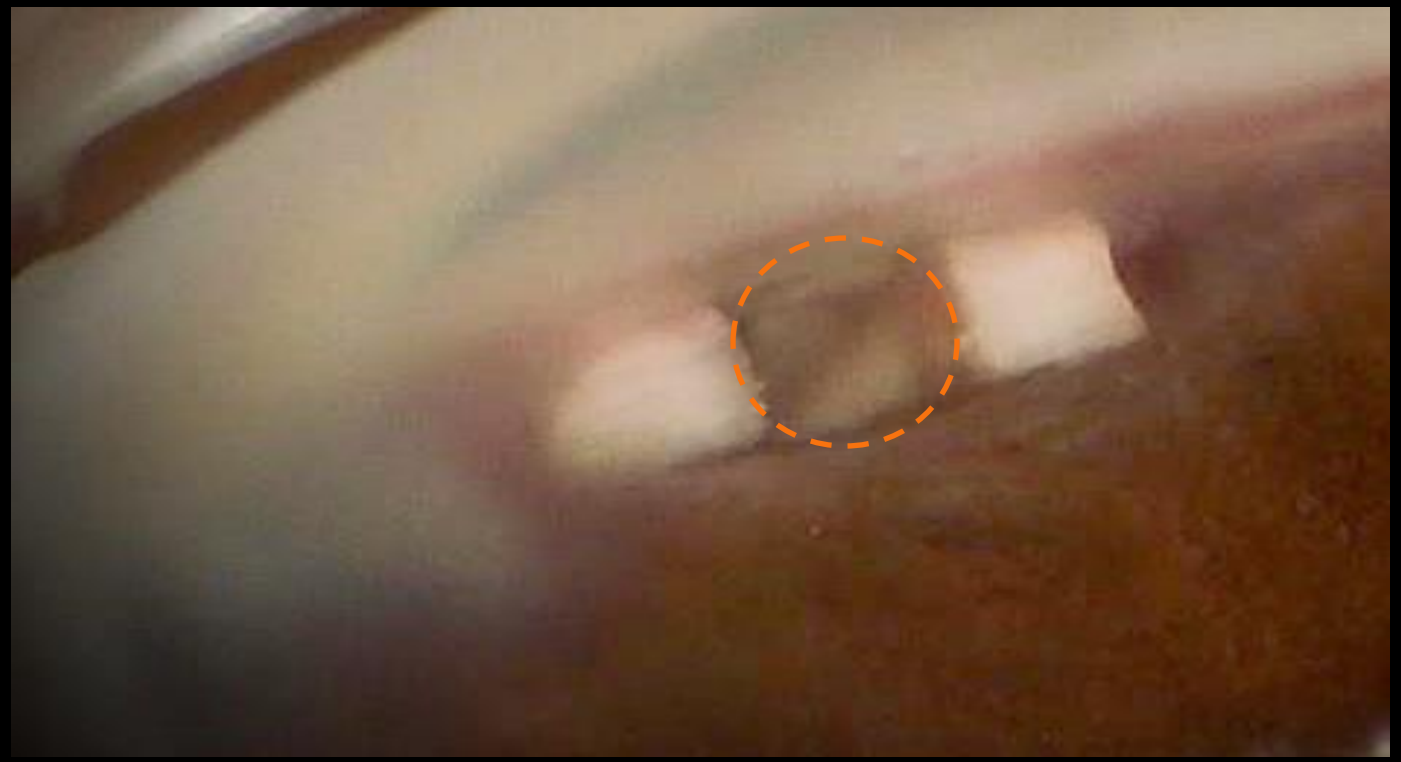
Ab-Interno Cyclodialysis

Allograft Bio-reinforcement
Scaffolded Cyclodialysis for Durable Outflow

Procedure 2

Allograft Endoscleral Reinforcement

Bio-interventional uveoscleral outflow enhancement
Bio-reinforced cyclodialysis with an internal filtration reservoir



Ab-Interno Supraciliary Implantation of Scleral Allograft
Surgical outcomes in 243 cases

- **STUDY OBJECTIVE**
  Characterization of ocular tolerability and surgical safety of allograft supraciliary reinforcement

- **DESIGN**
  Prospective, observational, multi-site, real-world study (CREST US + OUS)

- **SAMPLE SIZE**
  N243 eyes

- **INTERVENTION**
  Bio-interventional Cyclodialysis

- **STUDY POPULATION**
  Eyes with OAG with or without operable cataract at 10 investigational sites

Demographics

	Group 1 ≤1 Clock h Cyclodialysis	Group 2 >1 Clock h Cyclodialysis	All Eyes
Eyes, N	153	90	243
Eyes evaluable at 30 days (M1), N	148	86	234
Age, Mean ± SD (years)	72.2 ± 8.2	70.9 ± 8.2	71.7 ± 8.2
Female, N (%)	71 (46.4%)	51 (56.7%)	122 (50.2%)
Race/Ethnicity			
White	56 (36.6%)	10 (11.1%)	66 (27.2%)
Black or African American	21 (13.7%)	35 (38.9%)	56 (23.0%)
Hispanic or Latin American	75 (49.0%)	43 (47.8%)	118 (48.6%)
Asian	1 (0.7%)	2 (2.2%)	3 (1.2%)
Baseline BCVA (decimal)	0.46 ± 0.31	0.52 ± 0.27	0.48 ± 0.29
Number of cases combined with phaco, N (%)	134 (87.6%)	58 (64.4%)	192 (79.0%)
B/L IOP lowering medications (Mean ± SD)	1.3 ± 1.0	1.7 ± 1.5	1.5 ± 1.2
B/L medicated IOP (Mean ± SD)	20.4 ± 5.5	18.9 ± 6.2	19.8 ± 5.8

B/L = Baseline, IOP = Intraocular pressure, SD = standard deviation, BCVA = best-corrected visual acuity.

J. Clin. Med. 2024, 13, 4593. https://doi.org/10.3390/jcm13164593

Surgical safety through 30 days post-op
Intraoperative and post-operative

Intraoperative	
Inability to deploy implant, n (%)	1 (0.4%)
Anesthesia reaction (preventing implant deployment), n (%)	1 (0.4%)
Zonular dialysis during phacoemulsification, n (%)	1 (0.4%)
Intraoperative hyphema/reflux, n (%)	2 (0.8%)
Postoperative	
Pneumonia/hospitalization, n (%)	1 (0.4%)
Hypotony, transient, n (%)	1 (0.4%)
IOP elevation (>30 mmHg or +10 mmHg from baseline), n (%)	11 (4.4%)
Post-op hyphema >2 mm present after 1 day post-op, n (%)	5 (2.0%)
Macular edema, cystoid n (%)	4 (1.6%)
Macular folds, anatomic, no maculopathy: no visual sequelae	1 (0.4%)
Iritis transient (unrelated to biotissue implantation), n (%)	1 (0.4%)
Additional laser intervention	2 (0.8%)
YAG laser (synechiae)	1 (0.4%)
Selective laser trabeculoplasty (SLT)	1 (0.4%)
Additional surgical intervention (glaucoma)	3 (1.2%)
Corneal wound burp	1 (0.4%)
Paracentesis	1 (0.4%)
XEN gel stent	1 (0.4%)
Additional surgical intervention (cataract)	
Cortical remnant removal	1 (0.4%)

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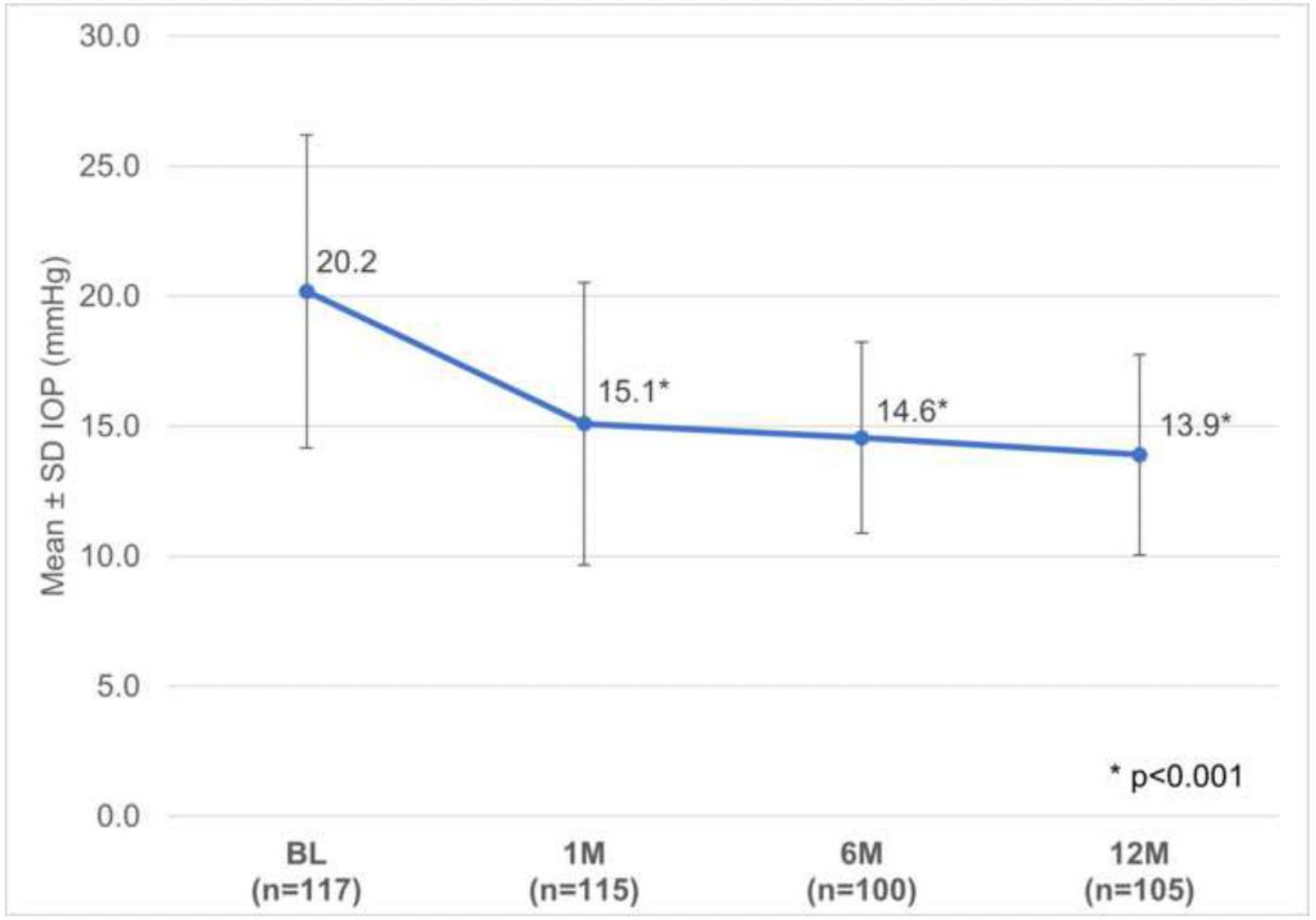
12M Effectiveness Cohort

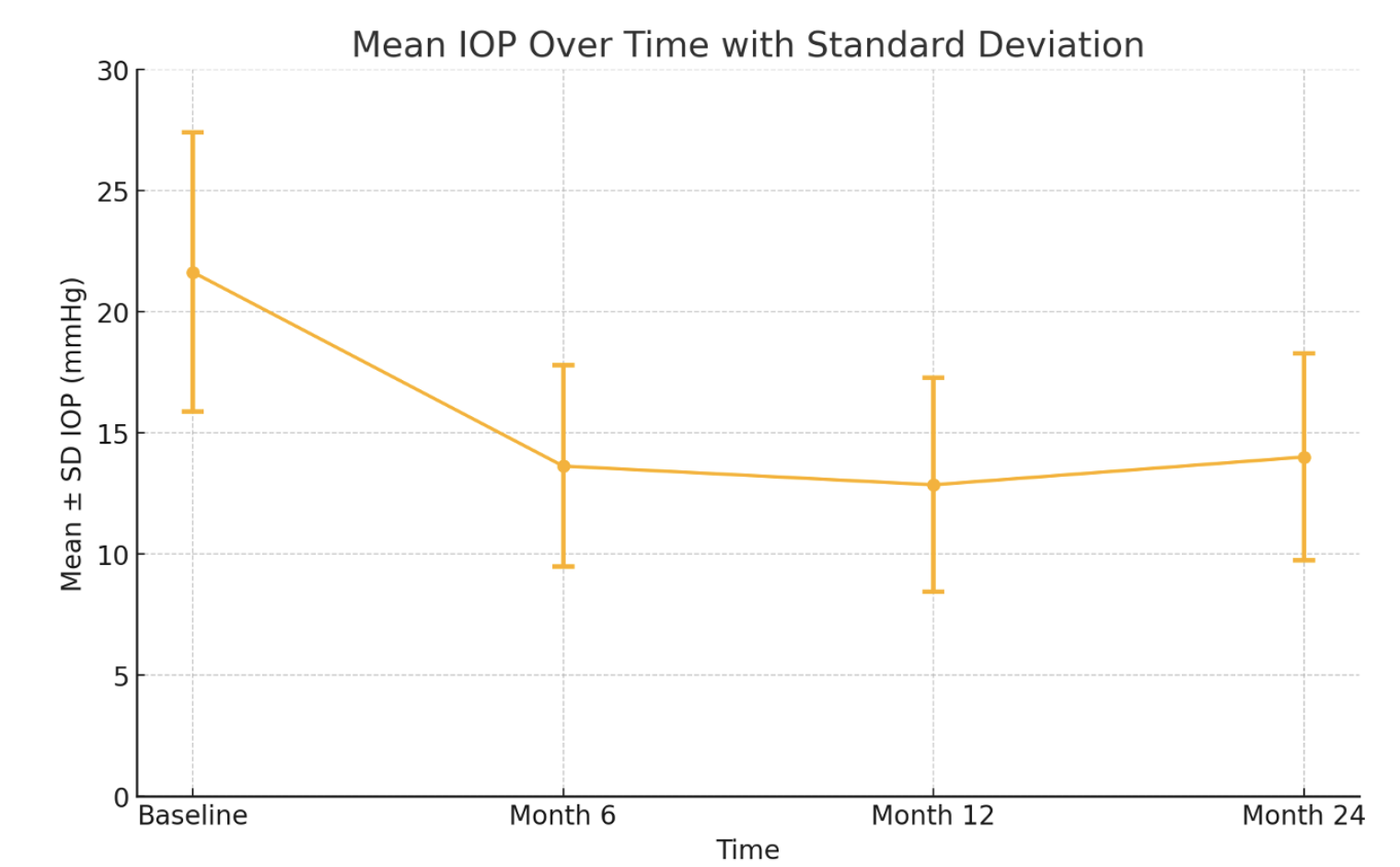
117 evaluable eyes with 12-month data



Sample size, eyes, N	117
Patients, N	89
Age, mean ± SD, years	70.4 ± 8.7
Ethnicity: Hispanic, n (%)	50 (42.7%)
Gender: female, n (%)	63 (53.8%)
Eyes undergoing concomitant phaco-emulsification cataract surgery	108 (96.4%)
Baseline BCVA, medicated, mean decimal value (95% CI)	0.48 (0.42-0.54)
Baseline IOP, mmHg, mean ± SD	20.2 ± 6.0
Number of IOP-lowering drugs, mean ± SD	1.4 ± 1.3

	BL (n=117)	6M (n=100)	12M (n=105)
IOP, mean ± SD	20.2 ± 6.0	14.6 ± 3.7	13.9 ± 3.9
Meds, Mean ± SD	1.4 ± 1.3	0.9 ± 1.1	0.8 ± 0.9

24M Effectiveness Cohort
31 evaluable eyes with 24-month data

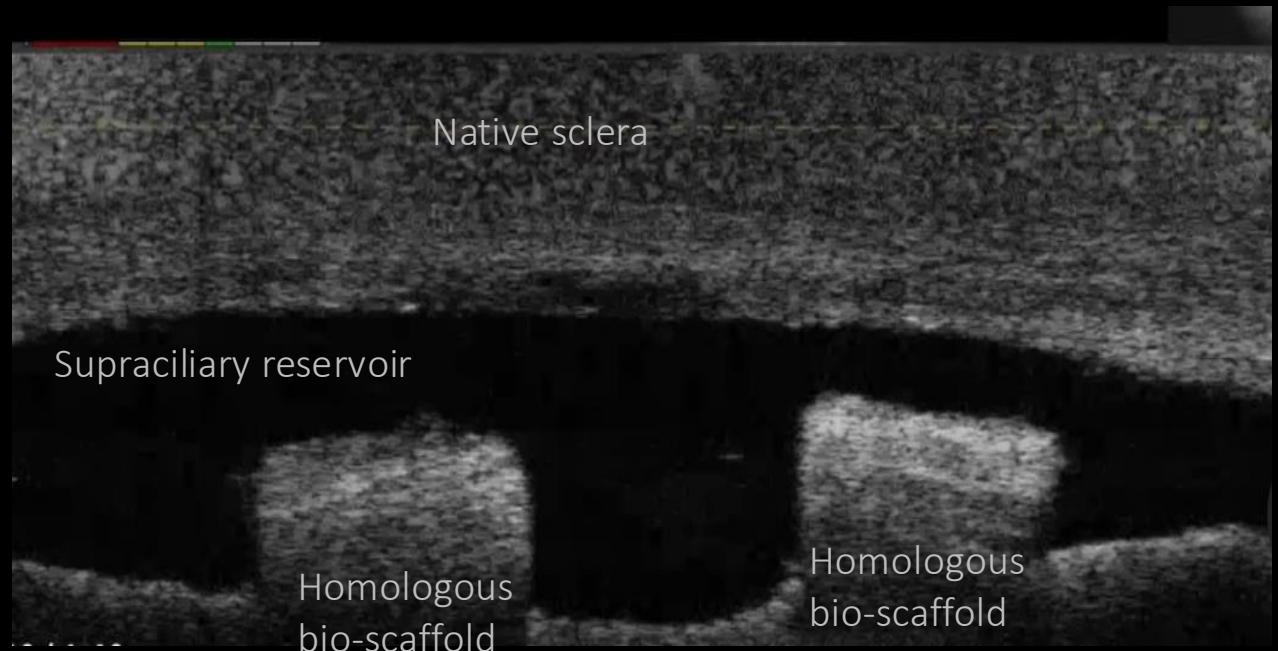


Efficacy Outcomes

	Baseline	6M	12M	24M
Mean Medicated IOP, mmHg ±SD	21.9 ± 4.92	13.76 ± 3.45	12.61 ± 2.62	13.84 ± 2.42
IOP-lowering medications, n, mean ± SD	1.42 ± 1.3	0.68 ± 0.65	0.52 ± 0.51	0.55 ± 0.52

Anterion OCT imaging of the cyclodialysis
After bio-scaffolded reinforcement

- **Easy imageability with anterior OCT**
- **Imaging consistent with hardware-free biotissue design: homologous OCT reflectivity**
- **Supraciliary filtration reservoir maintained with bio-scaffolding**
- **Non-resorbable scleral acellular bio-matrix visible and permanent through 24 months**



Conclusion

- Scleral allograft can be successfully used for ab-interno, endoscleral reinforcement in addition to conventional ab-externo application on the episcleral surface
- Allograft tissue demonstrates inert, biocompatible and bio-conforming material implant properties
- Allograft material is homologous on OCT imaging when implanted at the endoscleral surface
- Allograft material shows durable structural stability with no post-operative migration
- Strong biologic effect of bio-reinforced interventional cyclodialysis with sustained IOP lowering