Bio-Interventional Uveoscleral Outflow Enhancement with Allograft-Reinforced Cyclodialysis: 12-Month Results

James Lewis MD, Ticiana De Francesco MD, Tsontcho A. Ianchulev MD MPH, Iqbal K Ahmed MD

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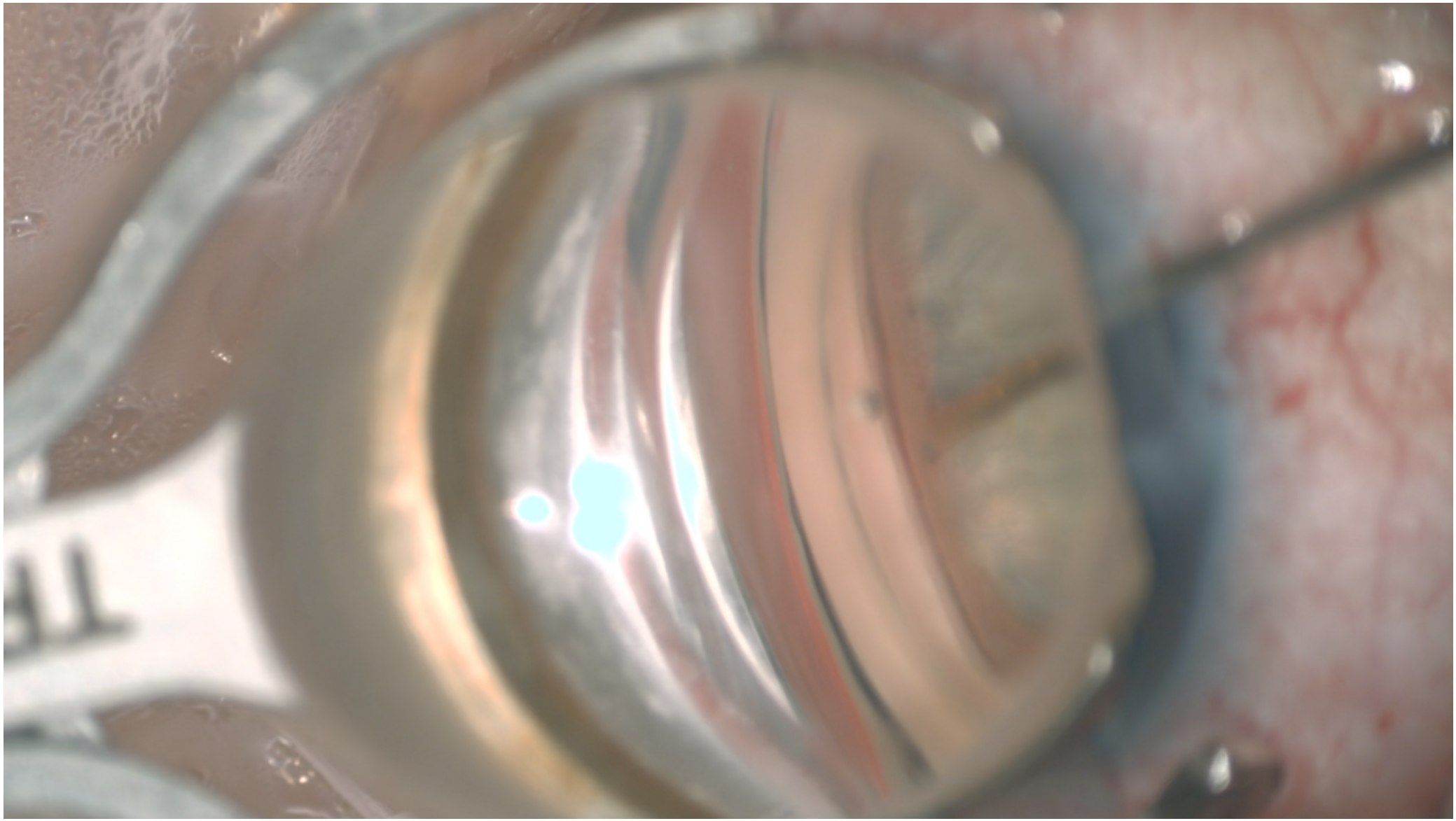
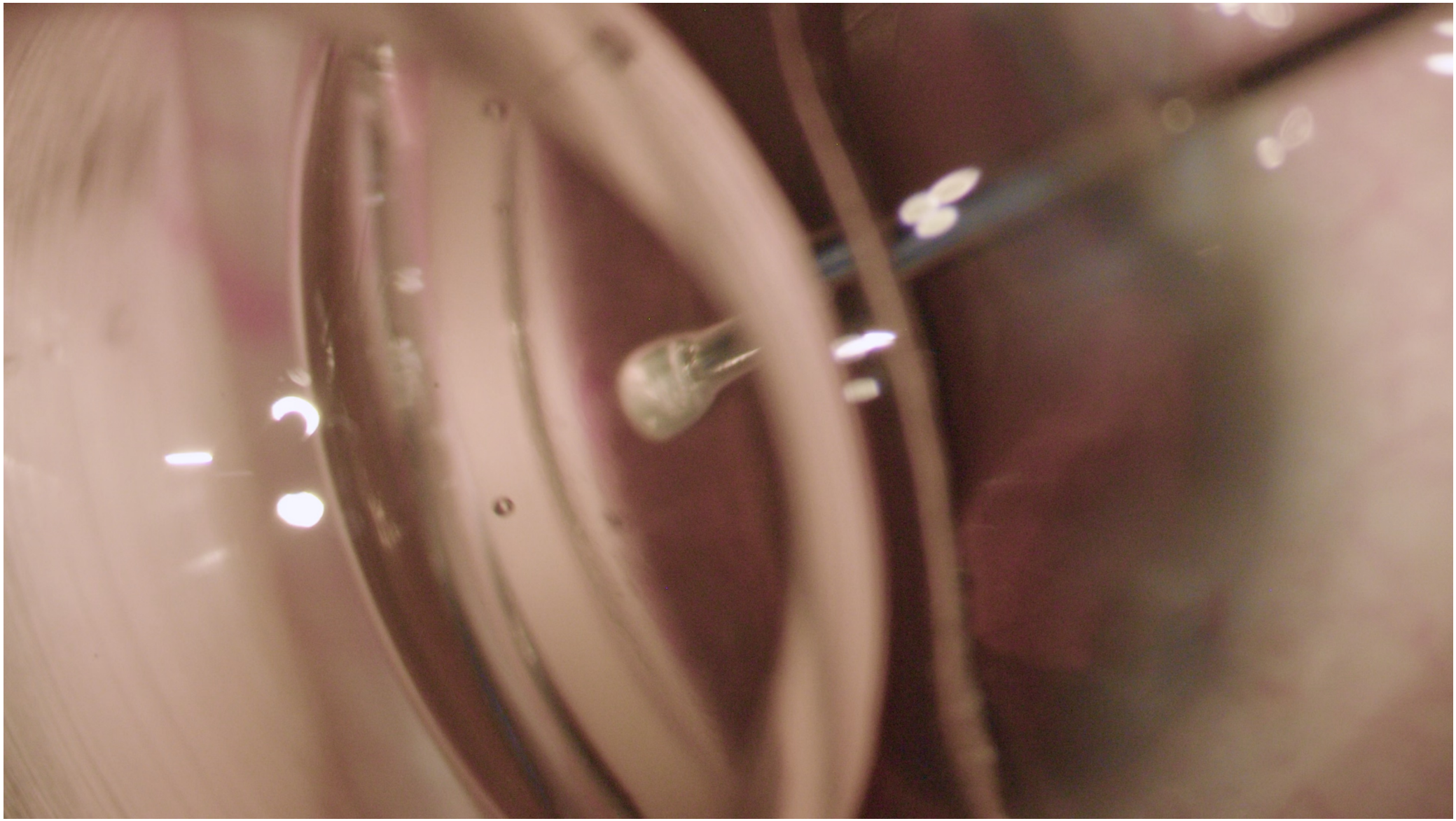
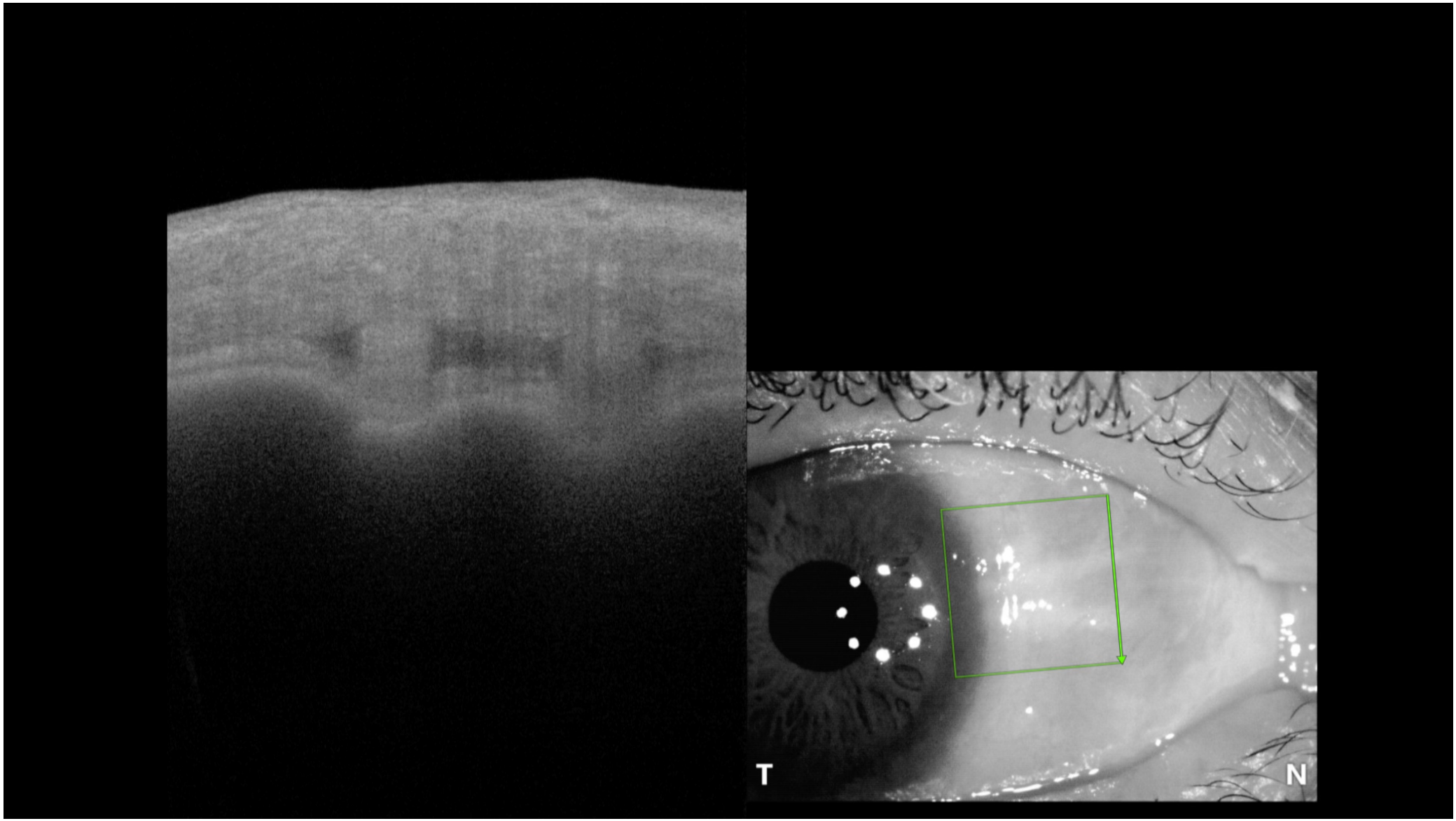
Abstract #108907



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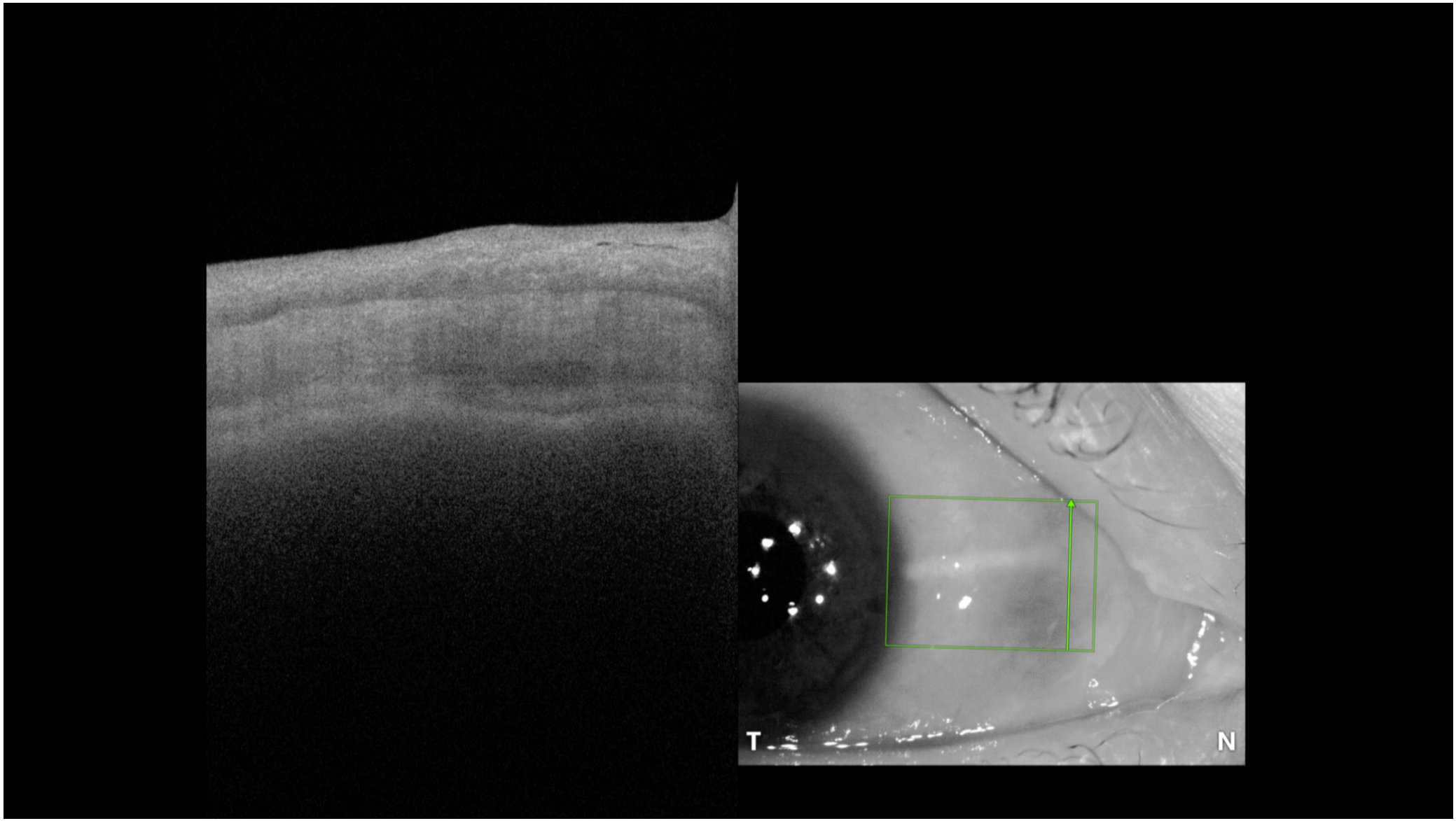
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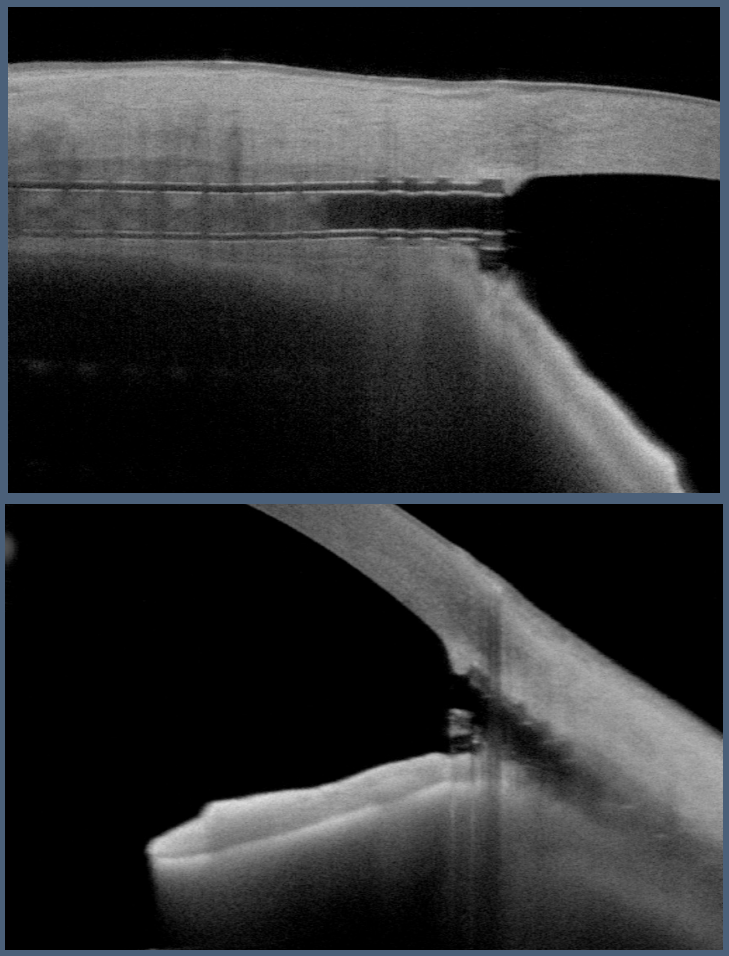
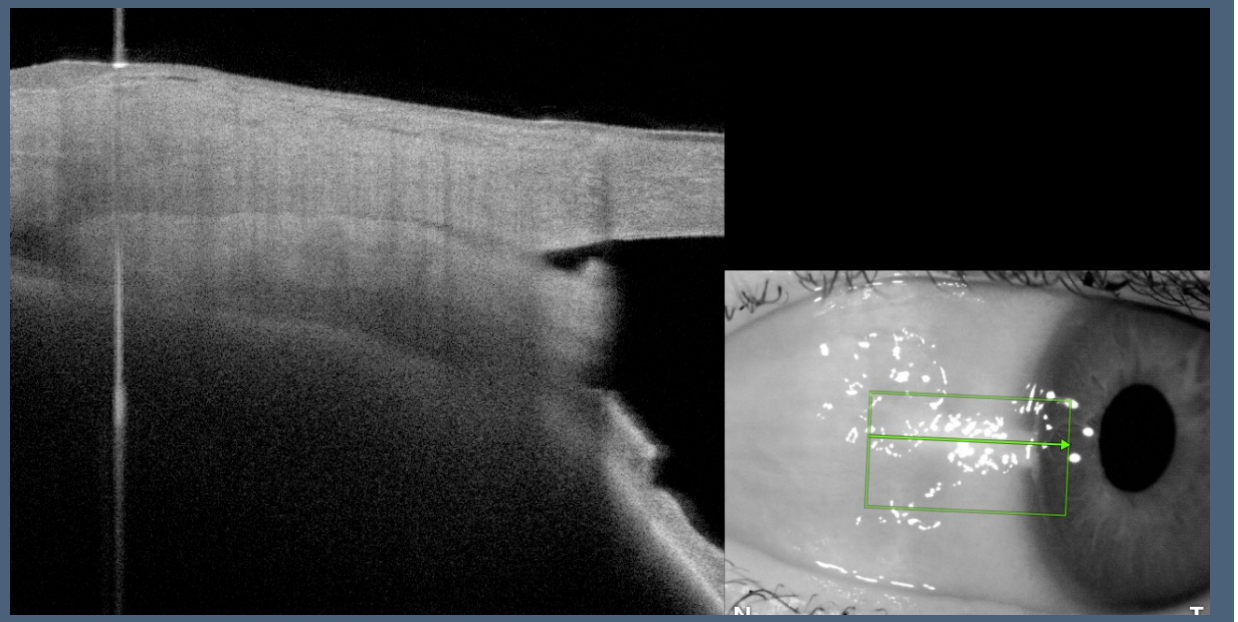
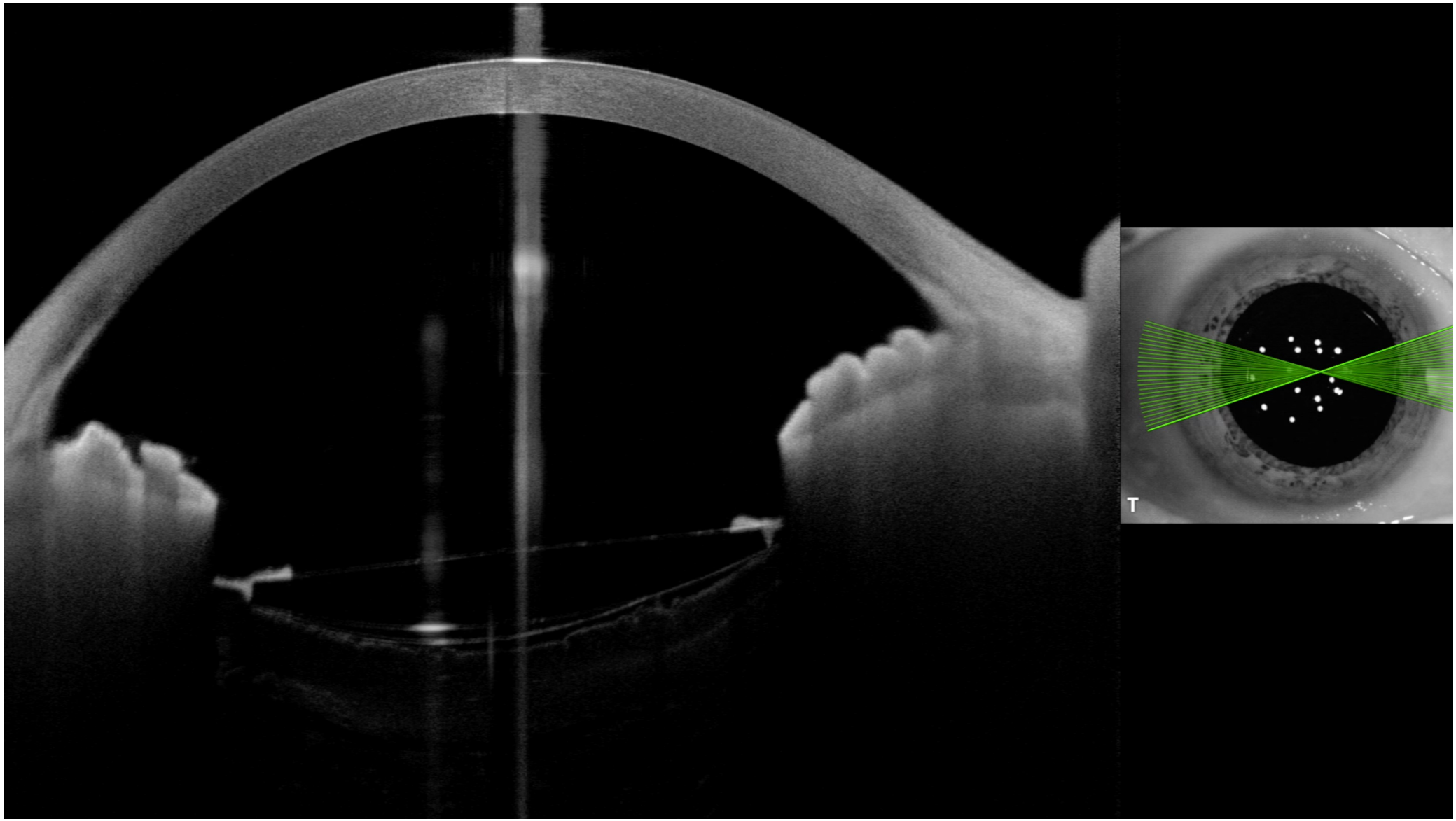
Exogenous Hardware



Homologous Bio-ware

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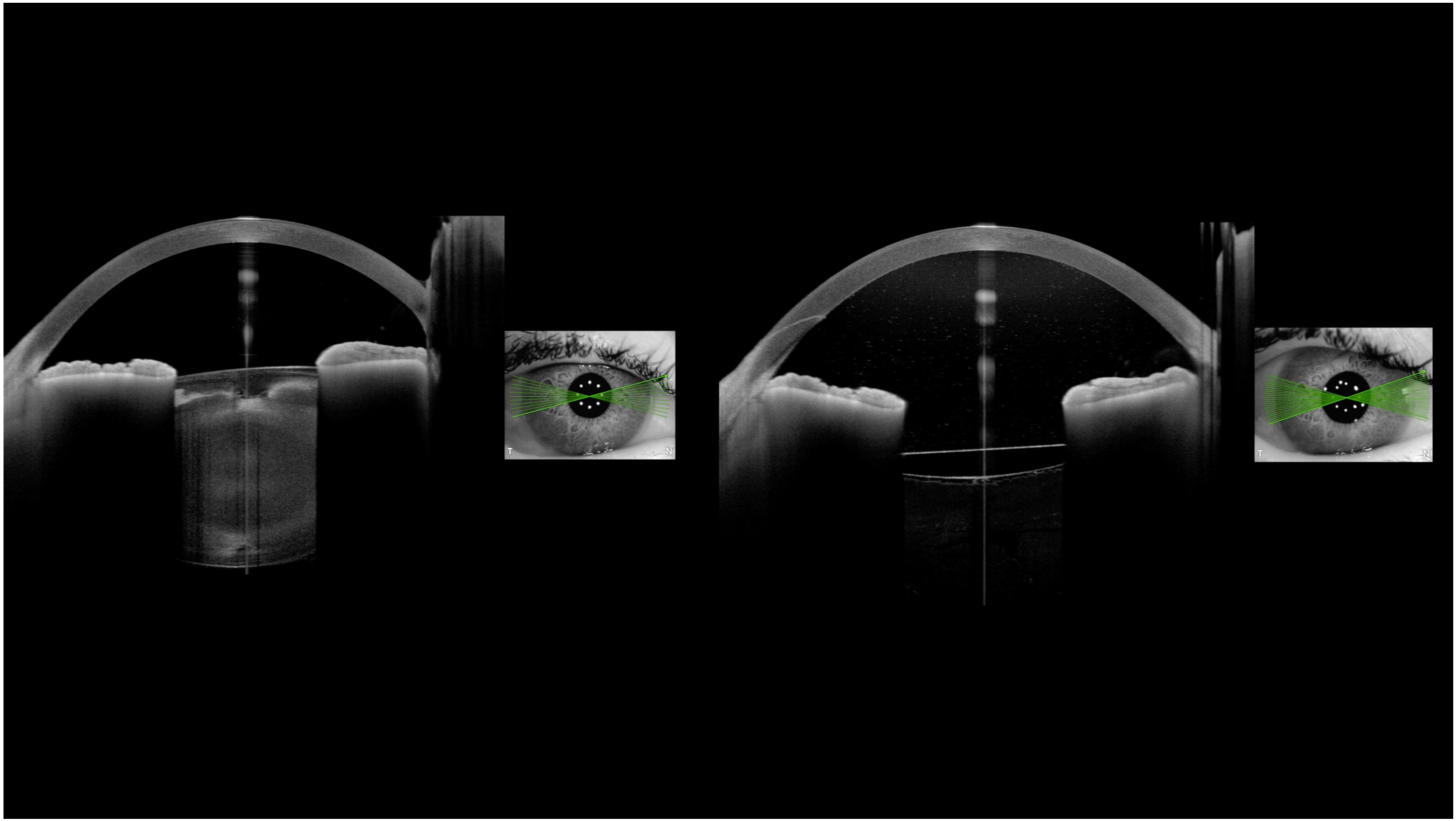
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CREST Study

- Multicenter, interventional, safety and effectiveness clinical study with 24-month prospective follow-up. Real-world evidence study
- One of the largest prospective cohorts in surgical glaucoma (400+ cases of bio-interventional glaucoma cases enrolled at 10+ investigational sites)
- Primary and secondary OAG patients consented and enrolled across a broad disease spectrum – mild, moderate, advanced, refractory. With and without phaco-cataract surgery.
- Pre-specified outcomes and analysis plan
- Active study monitoring to facilitate good clinical practices

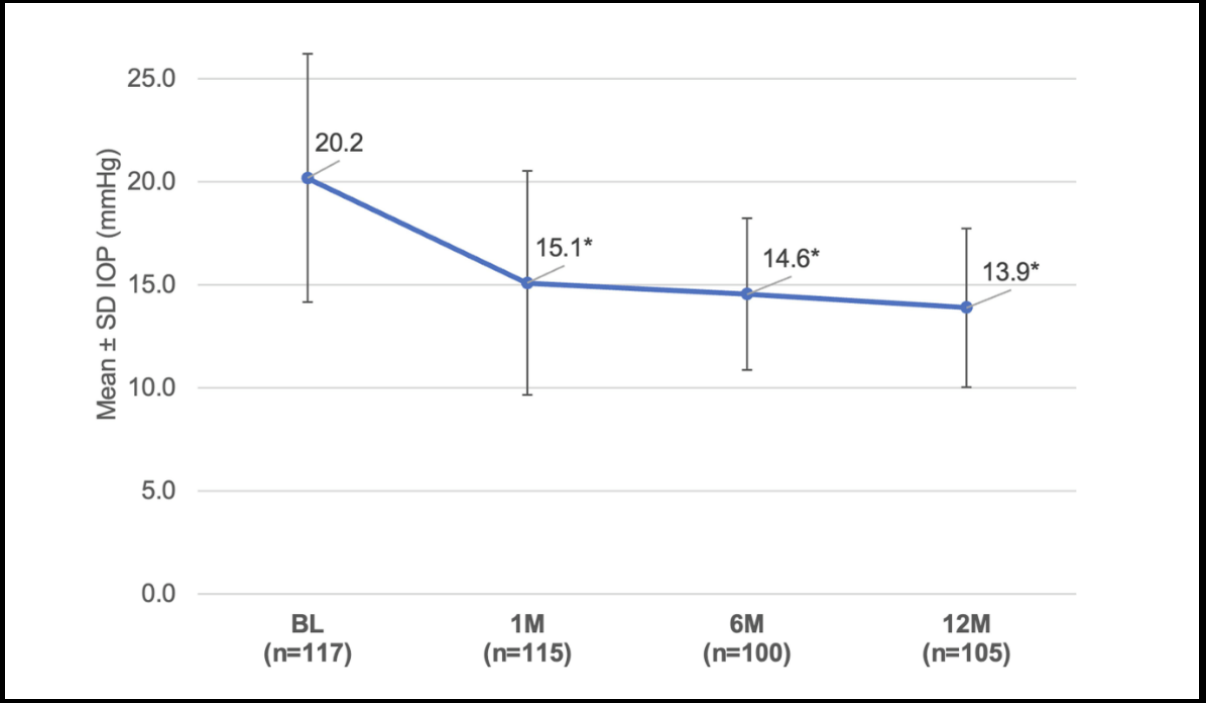
12M Cohort Baseline Demographics

Bio-interventional Cyclodialysis With Phaco

Sample size, eyes, N	117
Patients, N	89
Age, mean ± SD, years	70.4 ± 8.7
Ethnicity White, non-Hispanic, n (%) White, Hispanic, n (%) Black, n (%)	 32 (27.3%) 50 (42.7%) 35 (29.9%)
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

12M Efficacy Cohort

Bio-interventional Cyclodialysis With Phaco



- Subjects undergoing combination cataract surgery with bio-reinforced cyclodialysis
- Mean medicated intraocular pressure (IOP) below baseline at all timepoints ($p<0.001$)

12M Efficacy Cohort

Bio-interventional Cyclodialysis With Phaco

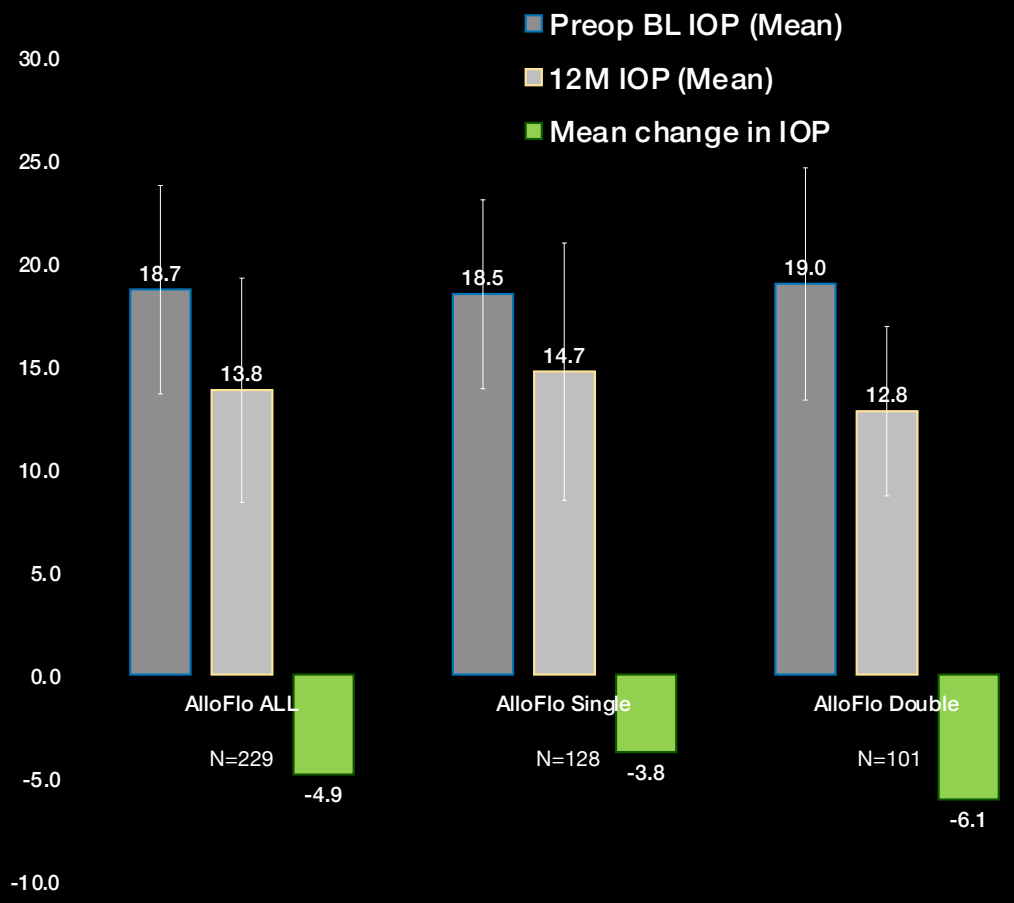
Additional Outcomes

- 84% achieved > 20% reduction in medicated IOP
- 27.1 % mean paired reduction in IOP (all eyes)
- Eyes with IOP ≥ 21 mmHg achieved 39.7% reduction in medicated IOP
- IOP lowering medications dropped from 1.4 to 0.8 at 12 M
- One Ahmed Valve; One Xen

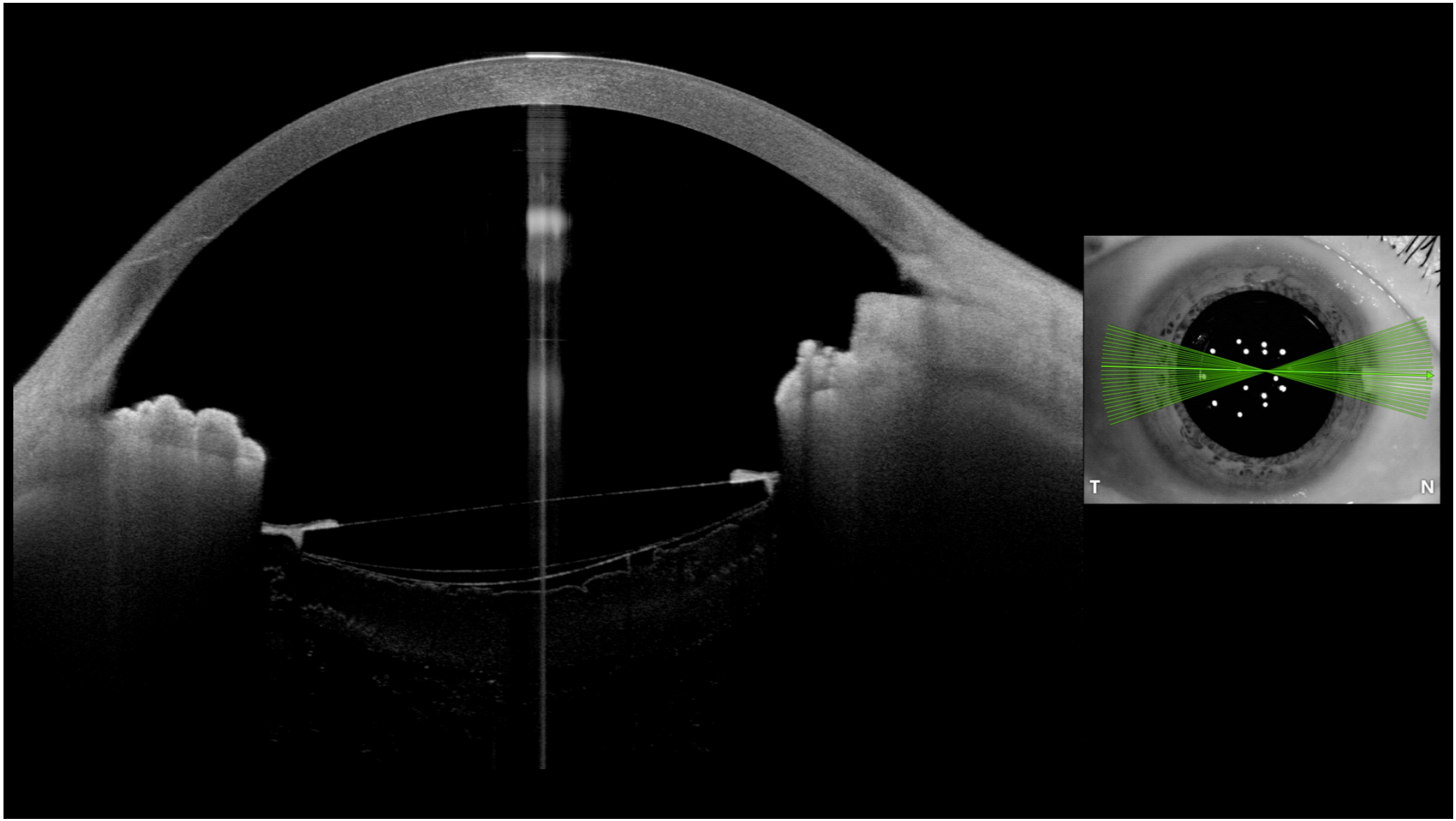
Safety outcome	Events, n (%)
>2 lines drop in BCVA, n (%)	0 (0%)
Persistent inflammation (>1M), n (%)	0 (0%)
Severe inflammation (grade 4+), n (%)	0 (0%)
Biotissue migration, n (%)	0 (0%)
Biotissue-corneal touch, n (%)	0 (0%)
Persistent corneal edema (>1M), n (%)	0 (0%)
Transient post-op IOP elevation, n (%)	9 (7.7%)
Transient hyphema greater than 2 mm present after 1 day postoperatively	3 (2.6%)
Transient hypotony, no visual sequelae	1 (0.8%)
Transient macular edema (phaco surgery-related)	4 (3.4%)
Zonular dehiscence during phaco	1 (0.8%)
Endothelial cell loss (ECD subgroup, n=54, mean ECL)	6%

Dose-response with Additive Bio-reinforcement

Dual Spacer Provides Incremental Efficacy



- Single bio-reinforcement has robust and sustained efficacy response (~4 mmHg mean IOP lowering)
- Dual bio-reinforcement has additive effect with similar safety (~6 mmHg mean IOP lowering)
- Similar ~ 45% reduction in medication burden from baseline through 12 months.
- No serious procedure related adverse events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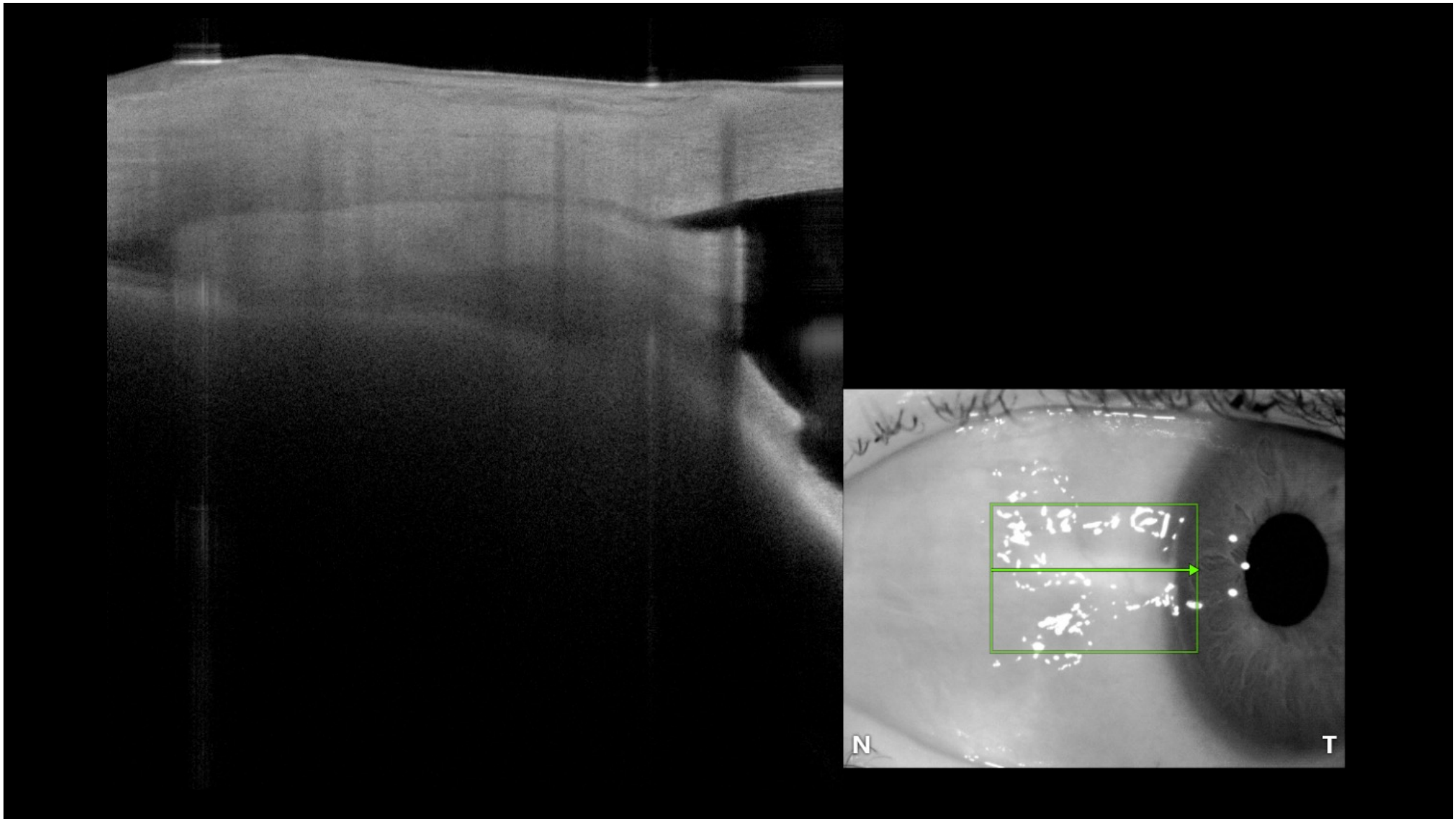
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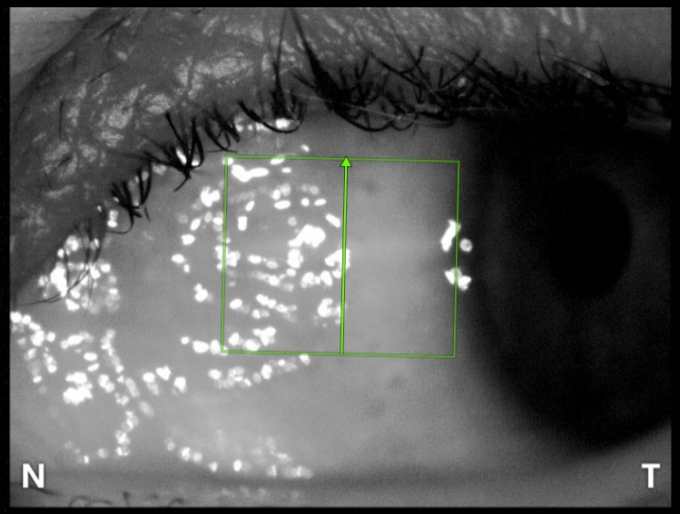
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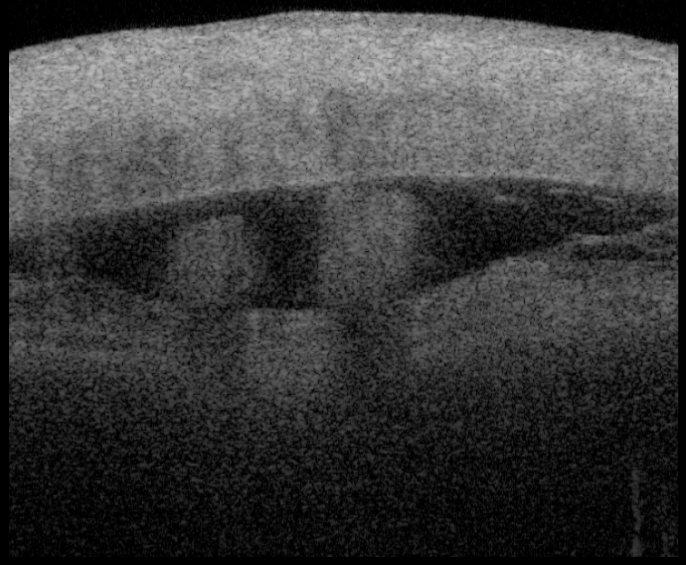

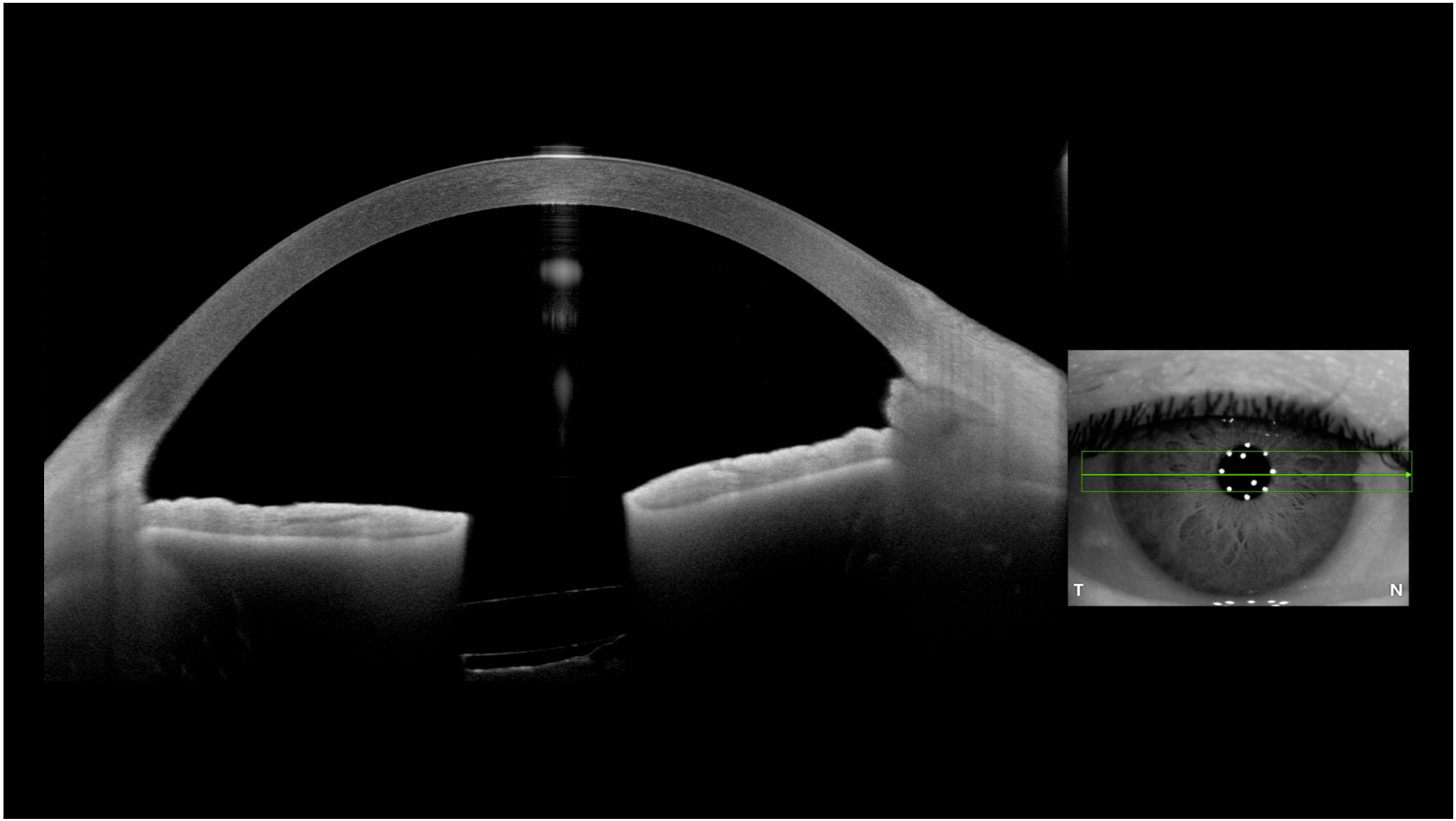
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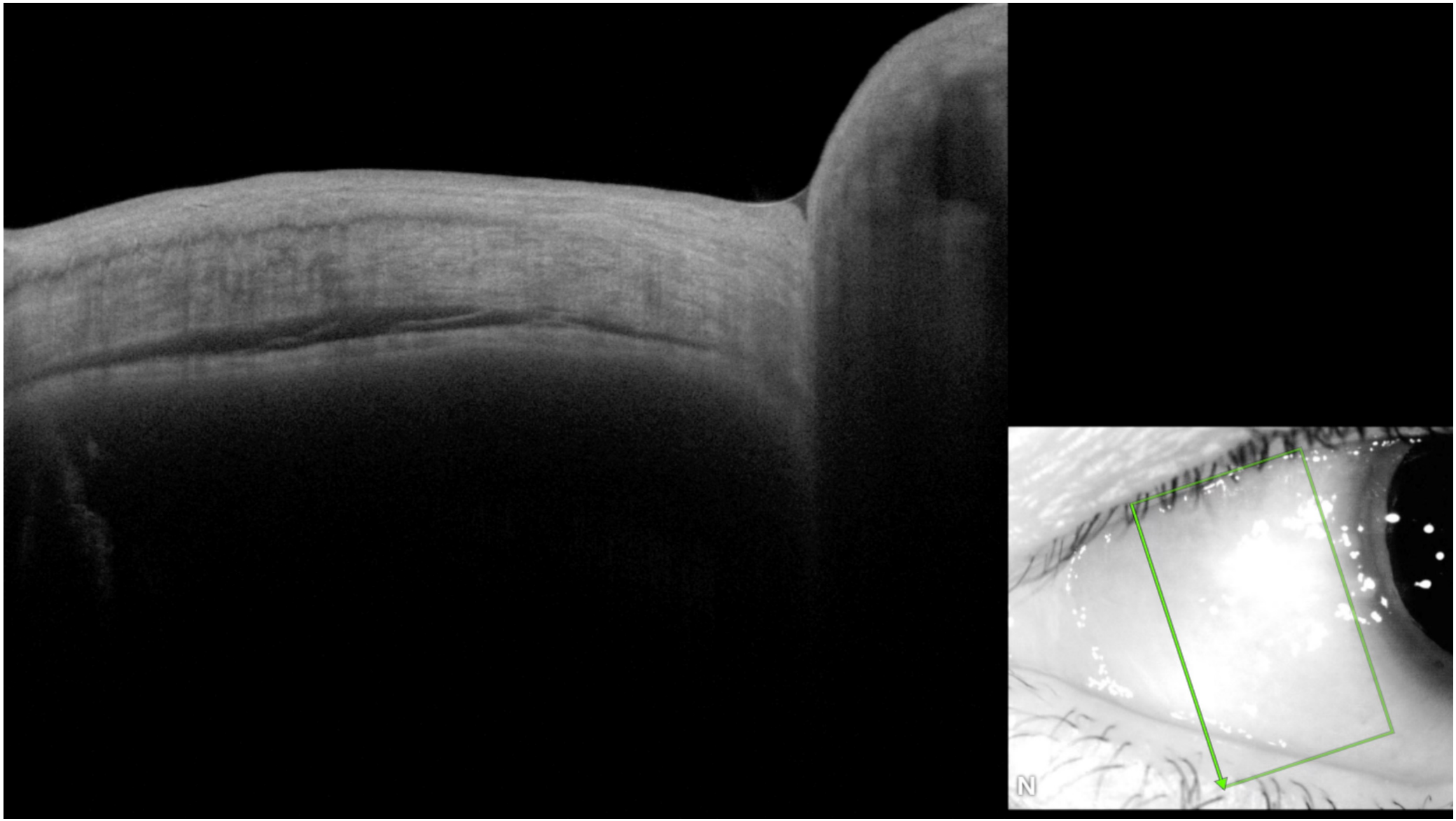
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Conclusion

Bio-interventional enhancement of uveoscleral outflow demonstrated to achieve safe and sustained IOP lowering when combined with cataract surgery.