



Second-Generation Trabecular Micro-Bypass in Eyes Failing Prior Surgical and/or Medical Glaucoma Therapy

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Disclosures

- ▶ Fritz Hengerer: Glaukos Corp 1,3 (unrelated to study/publication)
- ▶ Gerd U. Auffarth: Acufocus 3; Alcon 1,2,3,4;
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- ▶ Ina Conrad-Hengerer: No disclosures
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Introduction

- ▶ Glaucoma filtering surgery has numerous associated concerns including¹:
 - ▶ Bleb failure
 - ▶ Hypotony
 - ▶ Tear film disturbances
 - ▶ Postoperative infections
- ▶ There is an ongoing need for micro-invasive options to reduce IOP in both cataract and non-cataract patients, including those who have failed prior surgical or medical treatment for their glaucoma.
- ▶ IOP-lowering has been demonstrated with trabecular micro-bypass implant technology with favorable safety, including in three prior publications by this surgeon.^{2,3,4,5,6,7}

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3. Samuelson TW, et al. *Ophthalmology* 2019;126(1): 29-37.

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Introduction

- ▶ In Germany, 2nd-generation trabecular micro-bypass (iStent inject) can be implanted with cataract surgery or as a standalone procedure.
- ▶ Germany was one of the first countries to have commercial availability of the iStent inject trabecular microbypass device, so German datasets are some of the longest-running to-date.

Purpose

- ▶ The current study evaluated both combined and standalone efficacy and safety outcomes at **7 years** in a single longitudinal cohort, stratified by whether eyes had undergone prior glaucoma surgery (No-Surg and Prior-Surg groups, respectively).

Methods

- ▶ Prospective, non-randomized, unmasked study
- ▶ 125 consecutive iStent inject cases of a single surgeon at a large German academic hospital in Heidelberg
- ▶ Outcomes for Overall Cohort, and Subgroups (No Prior Surgery and Prior Surgery) assessed through **7 years**:
 - ▶ IOP
 - ▶ Number of ocular hypotensive medications
 - ▶ Visual fields
 - ▶ Adverse events
 - ▶ Secondary surgeries

Results – Baseline Characteristics

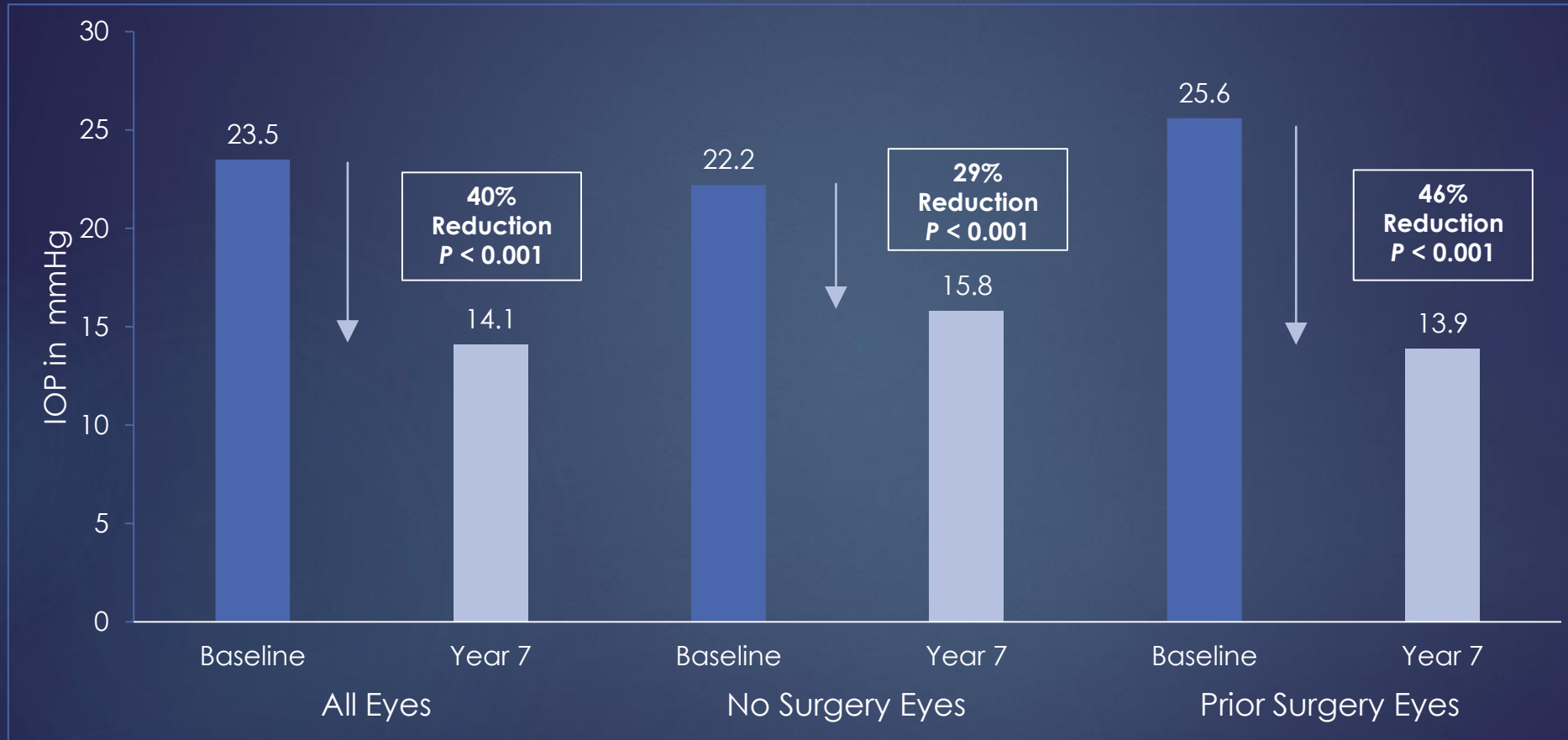
Baseline (Preop)		
Eyes N (%)	All	125 (100%)
	No Surgery	77 (62%)
	Prior Surgery	48 (38%)
Prior surgeries completed (66 total)	Cyclophotocoagulation	27
	Trabeculectomy	18
	Laser trabeculoplasty	7
	Surgical iridectomy	6
	Single 1 st -gen iStent	3
	XEN gel stent	2
	Laser iridotomy	2
	Goniotomy	1
Mean Preop IOP mmHg	All eyes	23.5 ± 6.2
Preop # of Meds ± SD	All eyes	2.68 ± 1.02

- A substantial proportion of eyes (38%) had undergone prior surgery.
- The overall cohort had a significant preoperative medication burden.

SD = Standard Deviation

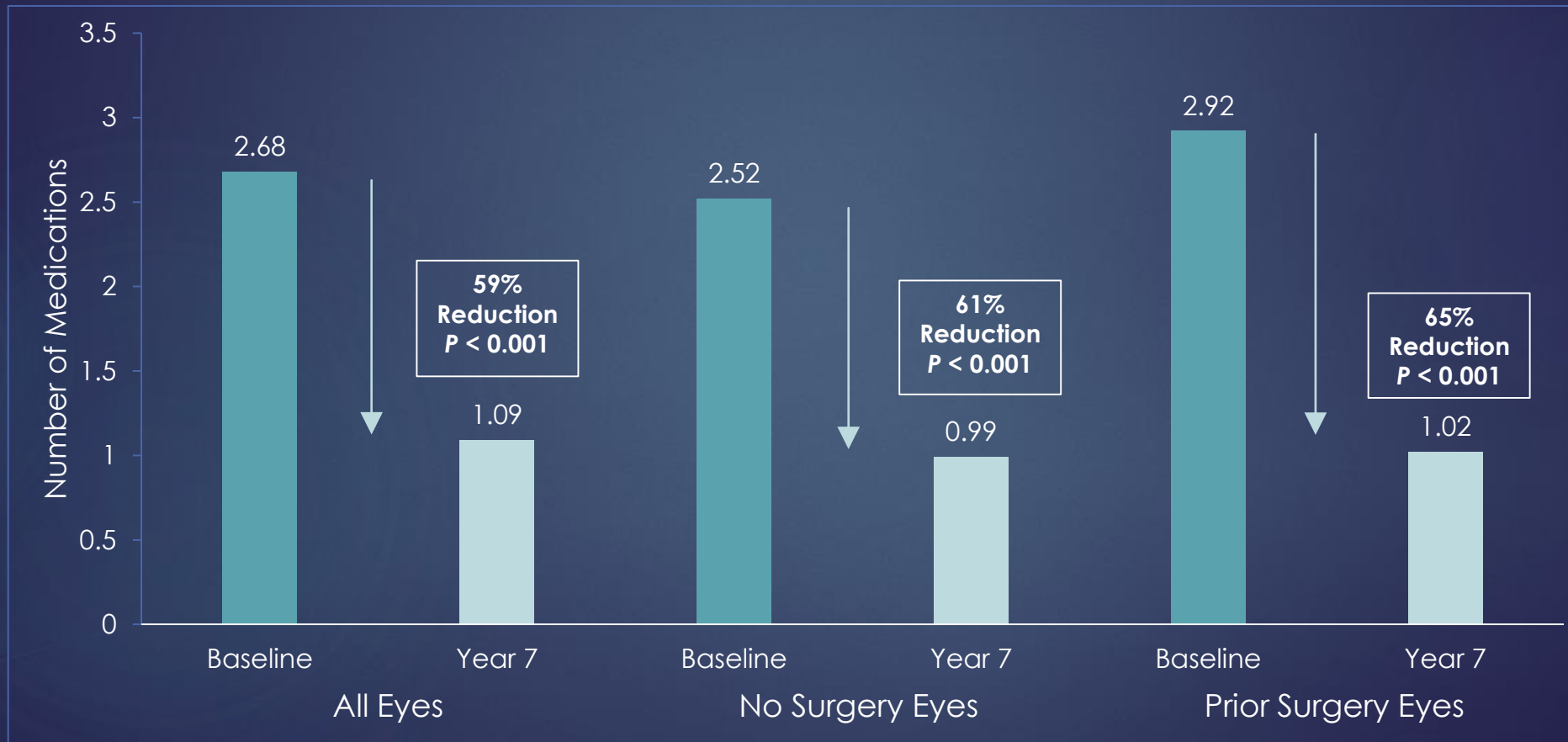
Some eyes had undergone more than 1 prior surgery.

IOP Reductions at Year 7



All eyes maintained or reduced IOP at Year 7 vs baseline.

Reductions in Ocular Hypotensive Medication Burden at Year 7



All eyes maintained or reduced medication burden at Year 7 vs baseline.

Safety

- ▶ All eyes were successfully implanted with 2 iStent inject stents.
- ▶ 7 eyes underwent a secondary glaucoma procedure (Cyclophotocoagulation or Xen).
- ▶ **No eyes required filtering surgery over 7 years.**
- **Preservation of visual fields:** Only 4.84% of eyes experienced clinically significant visual field loss over 7 years of follow-up
 - Favorable compared to the 8.4% rate reported in the closest comparator MIGS study, a 5-year assessment of Hydrus.¹

Conclusions

- ▶ iStent inject implantation with/without cataract surgery yielded significant and sustained 7-year IOP and medication reductions in eyes regardless of whether they had undergone prior glaucoma surgery.
- ▶ Mean IOP decreased by 29-46%, while the mean number of medications decreased 59-65%.
- ▶ The safety profile was favorable:
 - ▶ no filtration surgeries required over the 7-year follow-up
 - ▶ preservation of visual fields



Thank You!

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