

5 -Year - Data of iStent inject in Combination with Phacoemulsification and IOL Implantation

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EYES



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Potential Conflicts of Interest - Disclosure

Affiliation/Financial Relationship

Honoraria for consulting or advisory board activities

Company

Abbott, Alcon, Alimera Sciences, Allergan (an AbbVie company), Alkahest, AMO, Bayer, Carl Zeiss Meditec, Ellex, Fluoron, Geuder, Glaukos, iOptics, LensAR, Kanghong, Medicem, Novartis, Oculentis, Oertli, Revision, Optics, Santen, SightScience, Staar Surgical, Sifi Medtech, Teleon, Thea, Topcon, VISUfarma, Ziemer

Study participant/investigator

Allergan (an AbbVie company), Santen, Alcon, Alimera Sciences, Alkahest, Carl Zeiss Meditec, Kanghong, Hoya, Medicem, Novartis, Thea, Glaukos, Oxurion, Pharma Stulln

Travel stipends

Glaukos, SightScience



iStent inject® Specifications

Central Outlet

80 μm dia.



- 2 preloaded stents
- nonferromagnetic titanium
- heparin-coated

Head

Resides in Schlemm's canal

Side Flow Outlets (4)

50 μm dia.

Thorax

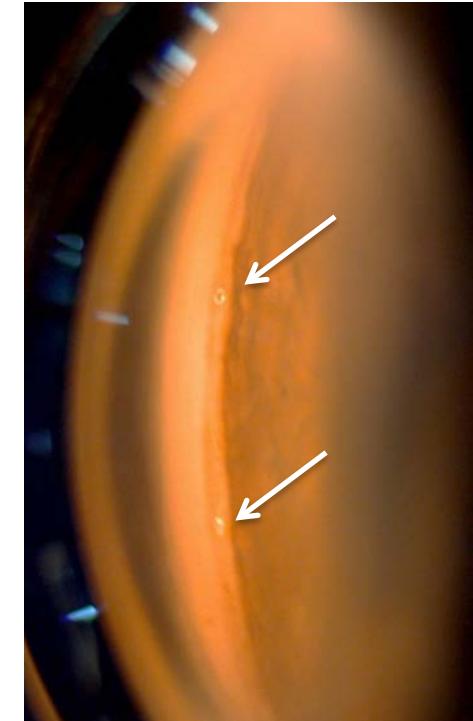
Held by the trabecular meshwork

Flange

Secures placement in the anterior chamber

Central Inlet

80 μm dia.



iStent inject® + Phaco – Patients Population and Preop Interventions

- Retrospective Analysis of 5 years outcome in combined cataract surgery with iStent inject® implantation in patients with open-angle glaucoma

- Phaco + iStent inject Group

- *164 eyes of 103 patients were enrolled*
- Mean Age 75,4 years ($\pm 9,4$)
- Sex: 90 male / 74 female
- POAG n = 135, PXF n = 29
- Baseline medicated IOP 18,5 mmHg
- Baseline Visual field defect - 6,19 dB MD
- Baseline cup / disc ratio 0,59

- Control Group (Phaco alone)

- *90 eyes of 56 patients were enrolled*
- Mean Age 77,95 years
- Sex: 22 male / 34 female
- POAG n = 66, PSXF n = 24
- Baseline medicated IOP 16,7 mmHg
- Baseline Visual field defect - 3,5 dB MD
- Baseline cup / disc ratio 0,6



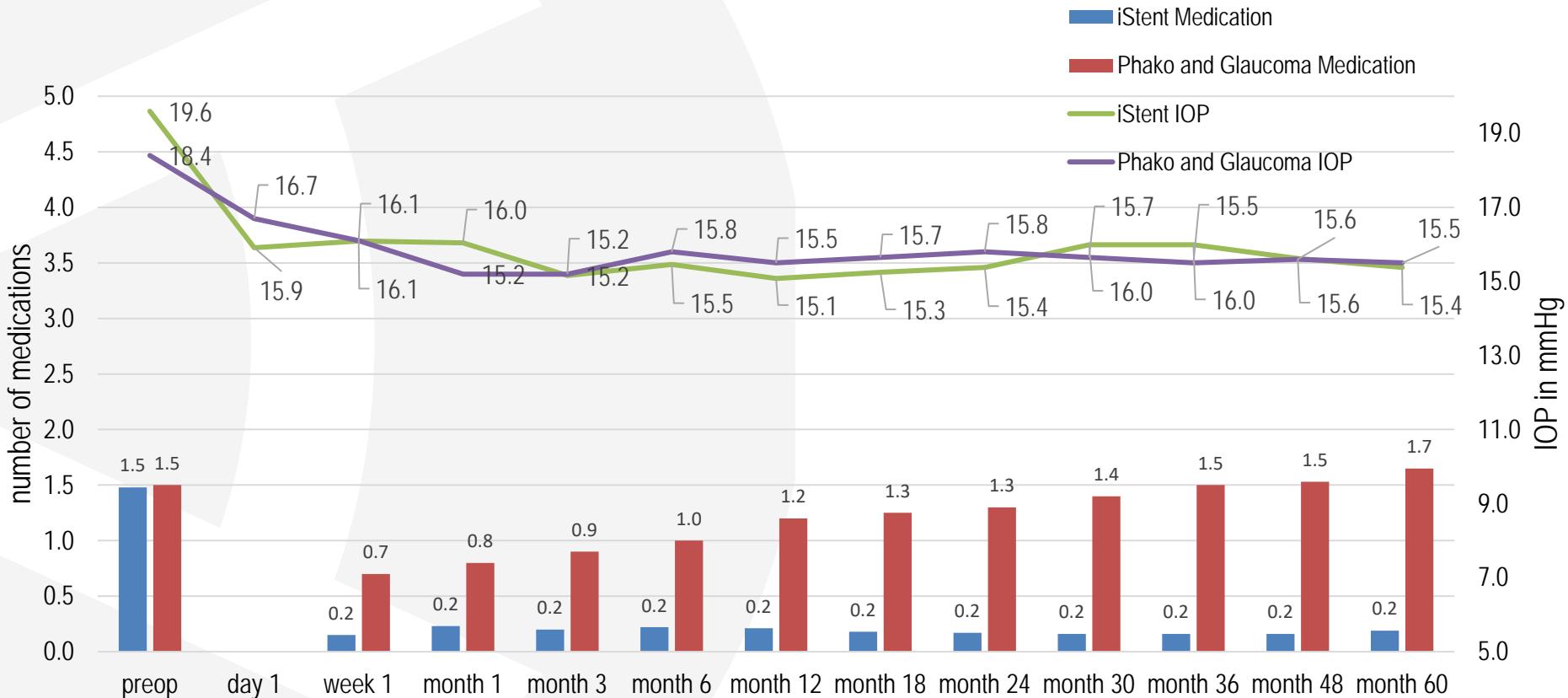
iStent *inject*[®] + Cataract Surgery - Preoperative Interventions

Intervention	n (%)
SLT	29 (17,7%)
XEN - gelstent	1 (0,6%)
canaloplasty	3 (1,8%)
trabeculectomy	2 (1,2%)
iridotomy	2 (1,2%)

* all cases of previous surgery were performed more than 3 month before iStent intervention



iStent inject® + Phaco versus Phaco stand alone - IOP lowering and medication reduction



iStent inject® + Cataract Surgery – Detailed Results

Mean intraocular pressure (mmHg) and mean number of glaucoma medications with 60 month follow up

n = 61	Preop	Month 1	Month 6	Month 12	Month 24	Month 36	Month 48	Month 60
Mean IOP in mmHg								
Mean (SD)	20,4 (4,29)	16,0 (3,46)	15,7 (2,19)	14,9 (2,47)	16,0 (2,39)	16,0 (2,3)	15,7 (2,26)	15,4 (1,82)
Range	14 - 34	6 - 24	12 - 23	7 - 23	12 - 23	13 - 29	10 - 21	10 - 18
Mean No. of Medication								
Mean (SD)	1,4 (0,77)	0,26 (0,63)	0,43 (0,74)	0,36 (0,62)	0,21 (0,52)	0,24 (0,53)	0,19 (0,51)	0,19 (0,51)
Range	0 - 4	0 - 2	0 - 2	0 - 2	0 - 2	0 - 2	0 - 2	0 - 2

* Data were excluded from eyes that underwent second glaucoma surgery postoperative

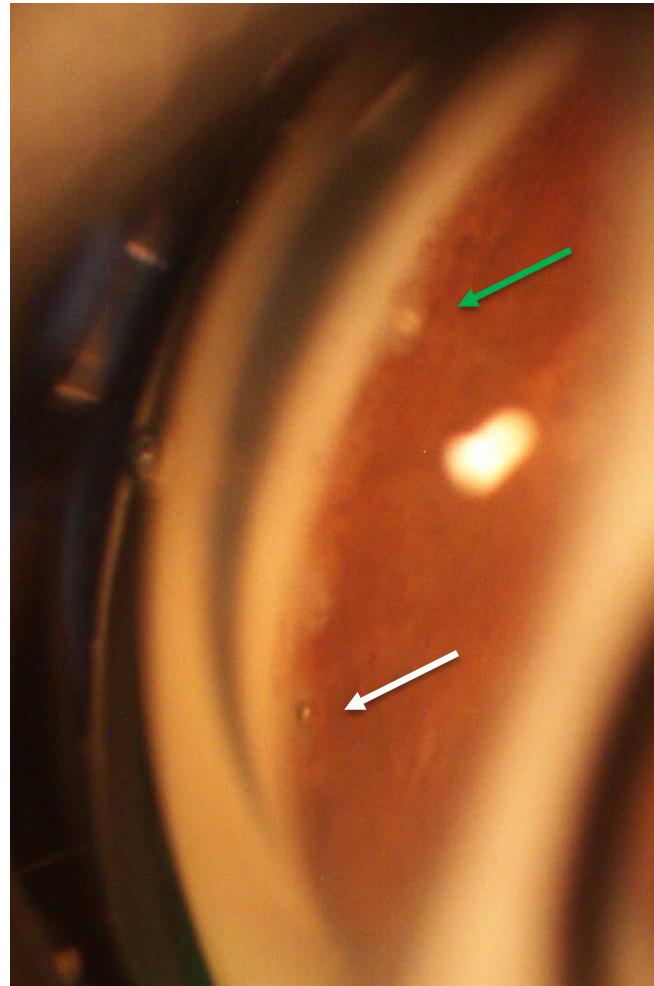


iStent inject® + Cataract Surgery - Complications

	n (%)
hyphaema	11 (6,7%)
hypotony < 10 mmHg*	2 (1,2%)
iris incarceration	2 (1,2%)
stent occlusion*	7 (4,3%)

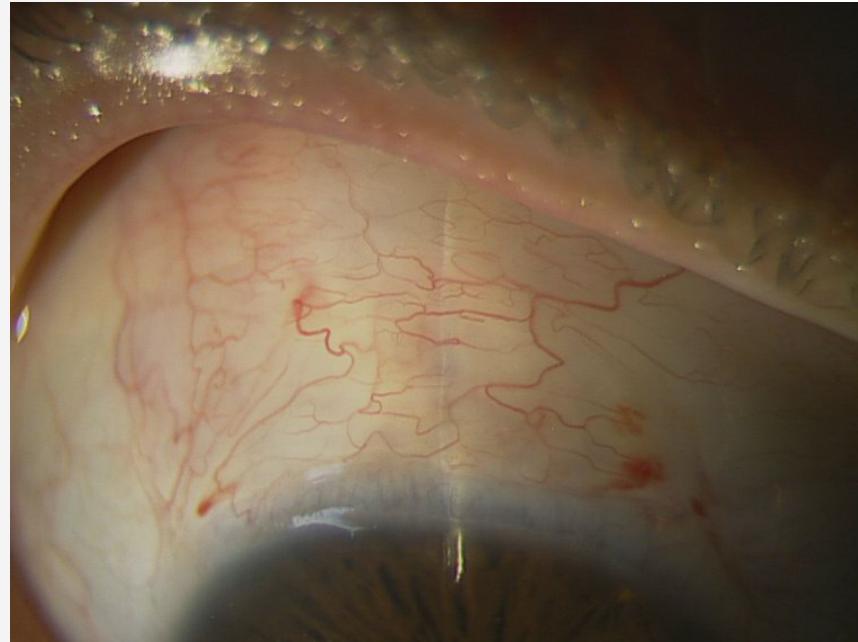
* persistent hypotony over more than 1 month

* Stent occlusion was caused by to deep implantation and was observed later than 3 month after surgery



iStent *inject*[®] + Phaco – Postoperative Interventions

- In all 164 cases over 5 year only in 7 (4.3%) of the cases a second glaucoma intervention was needed:
 - 1 SLT
 - 1 CPC
 - 2 Preserflo Microshunt
 - 3 XEN - Gelstent



iStent *inject*[®] + Phaco – Conclusions

- significant IOP – lowering effect and medication reduction
- long lasting effect
- high safety profile
 - only minor and rare complications due to glaucoma procedure
 - hypotony, hyphaema
- excellent in combination with cataract surgery
 - minimal additional settings and instruments needed
 - short learning curve
- *Fullfills patients and surgeon expectations:*
 - *quality of life, adherence, less ocular surface disease*
 - *predictability, ease of use, easy to adapt*

