Intracanalicular scaffold for IOP reduction with cataract surgery in mild to moderate open angle glaucoma

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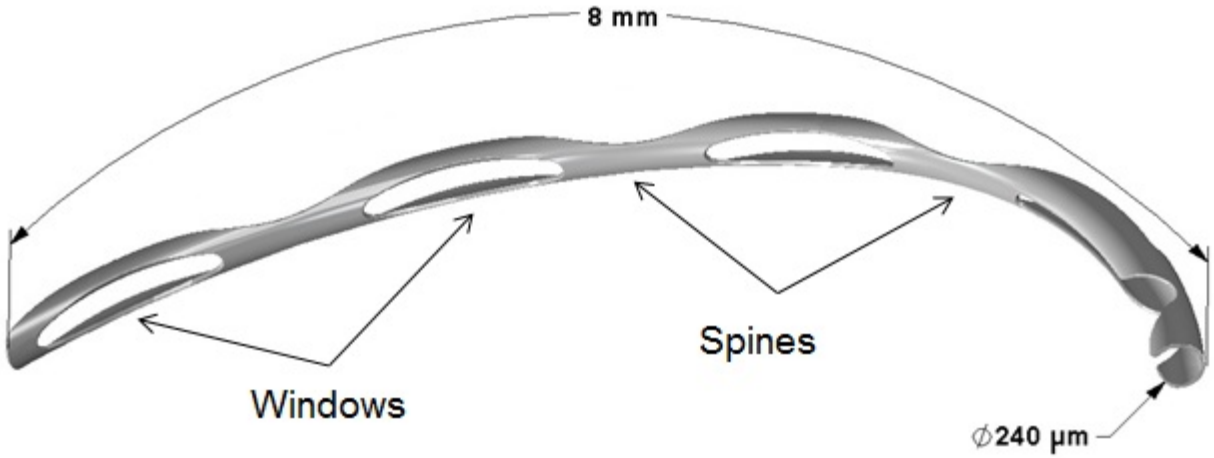
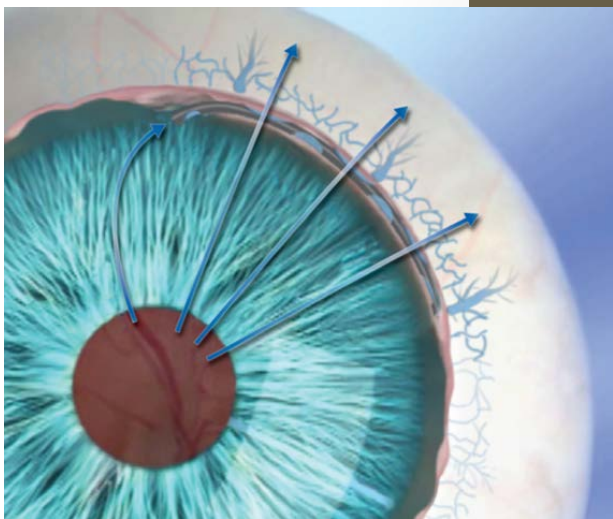
Consultant to Ivantis

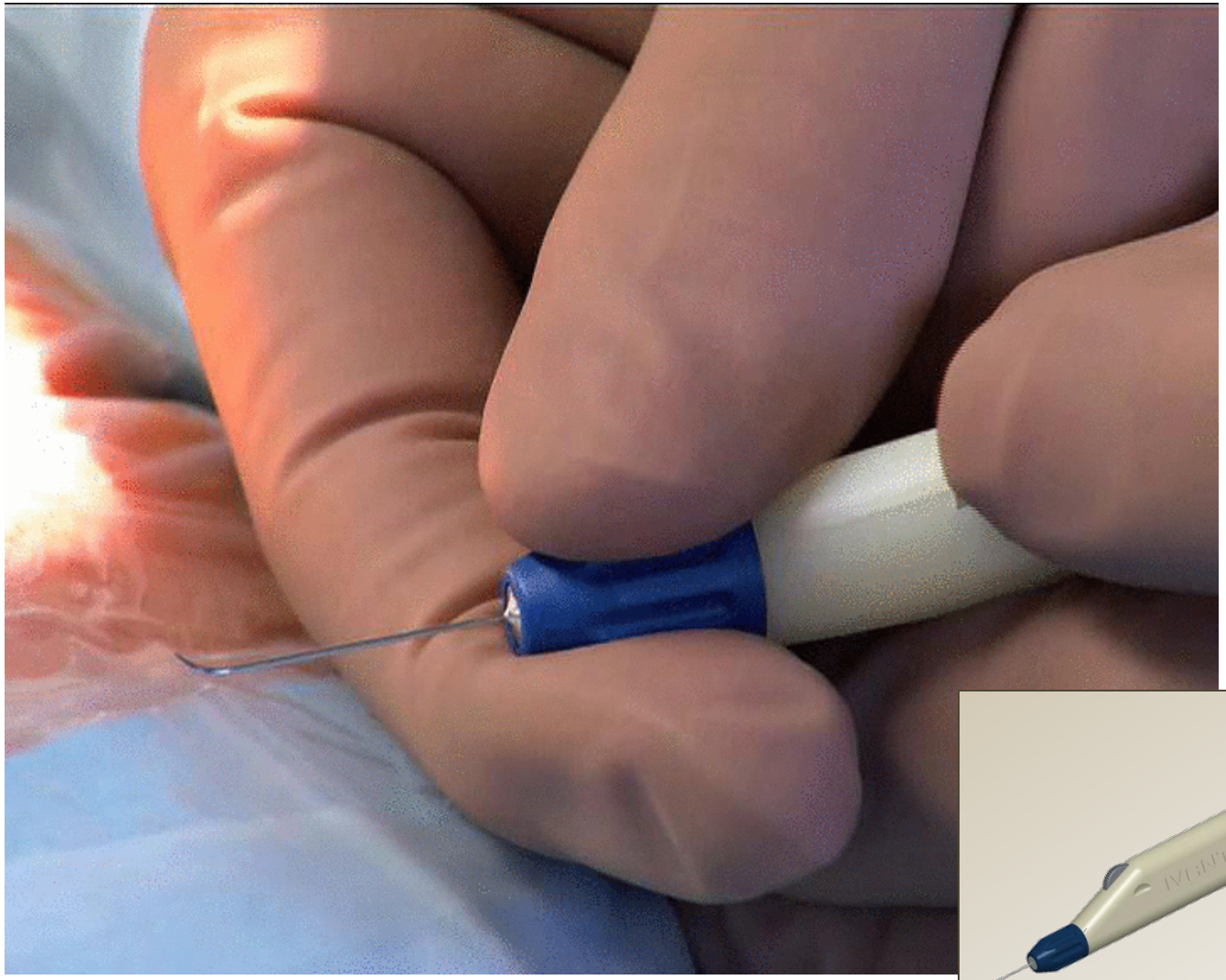
The Hydrus Microstent

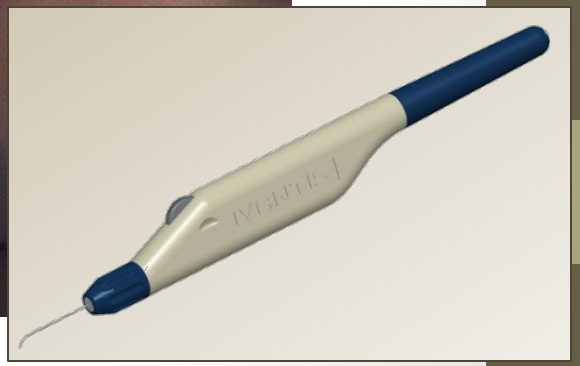


- Micro-invasive glaucoma surgery (MIGS) device
- Flexible, biocompatible intracanalicular “scaffold”
- Scalloped/open design allows aqueous flow
- 3 clock-hour targets multiple collector channels



Delivery System





Purpose

- To assess the IOP lowering ability and side effect profile of the Hydrus microstent when combined with phacoemulsification in patients with mild/moderate glaucoma

Methods

- Consecutive pilot series of patients
- Health Canada approval
- Each patient signs informed consent and permission obtained to import and use devices obtained from Health Canada one-by-one.
- All subjects were treated with Hydrus in combination with cataract surgery
- 6 month data complete for 42 patients

Canadian HYDRUS Series

Demographics	
N	29
Mean Age	72.0±8.9 years
Average MD	-6.93
POAG	59%
PXF	41%
Prior SLT	38%
Mean Screening IOP	22.1
Mean Meds	2.4
Pre-op Medication Wash out	70%

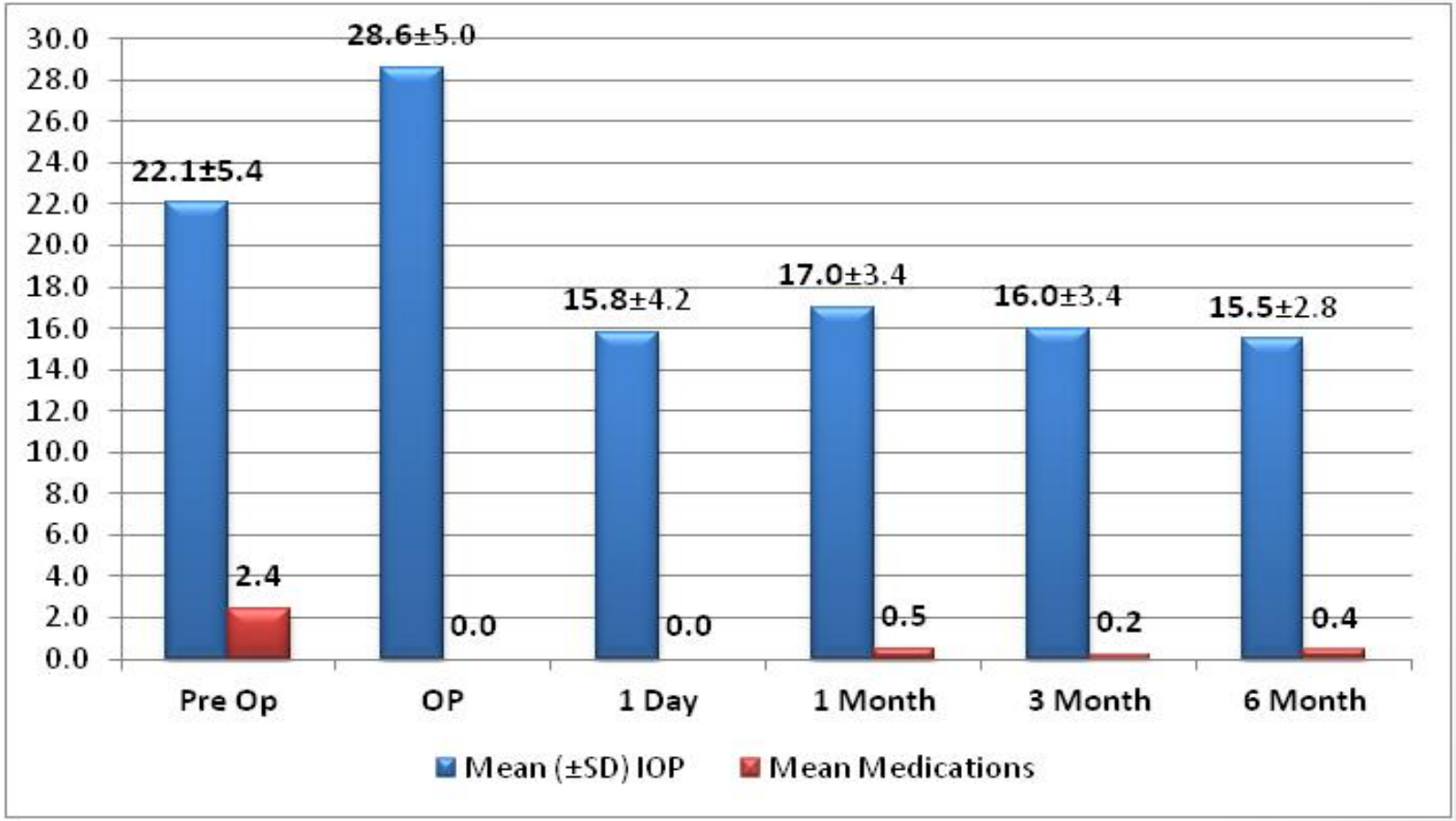
All patients with mild to moderate glaucoma severity based on Hodapp Anderson Parrish criteria

Follow Up Accountability

	1 Day	1 Month	3 Months	6 Months
N	29	27	27	26
Missed Visit	0	2	1	2
Lost to follow up	0	0	1	1

Results

Cataract + HYDRUS in Mild to Moderate Glaucoma



Medication Use
Pre Op to 6 Months

	Pre Op	6 Months
3 meds	59%	0
2 meds	24%	10%
1 med	10%	20%
Medication Free	7%	70%

Adverse Events

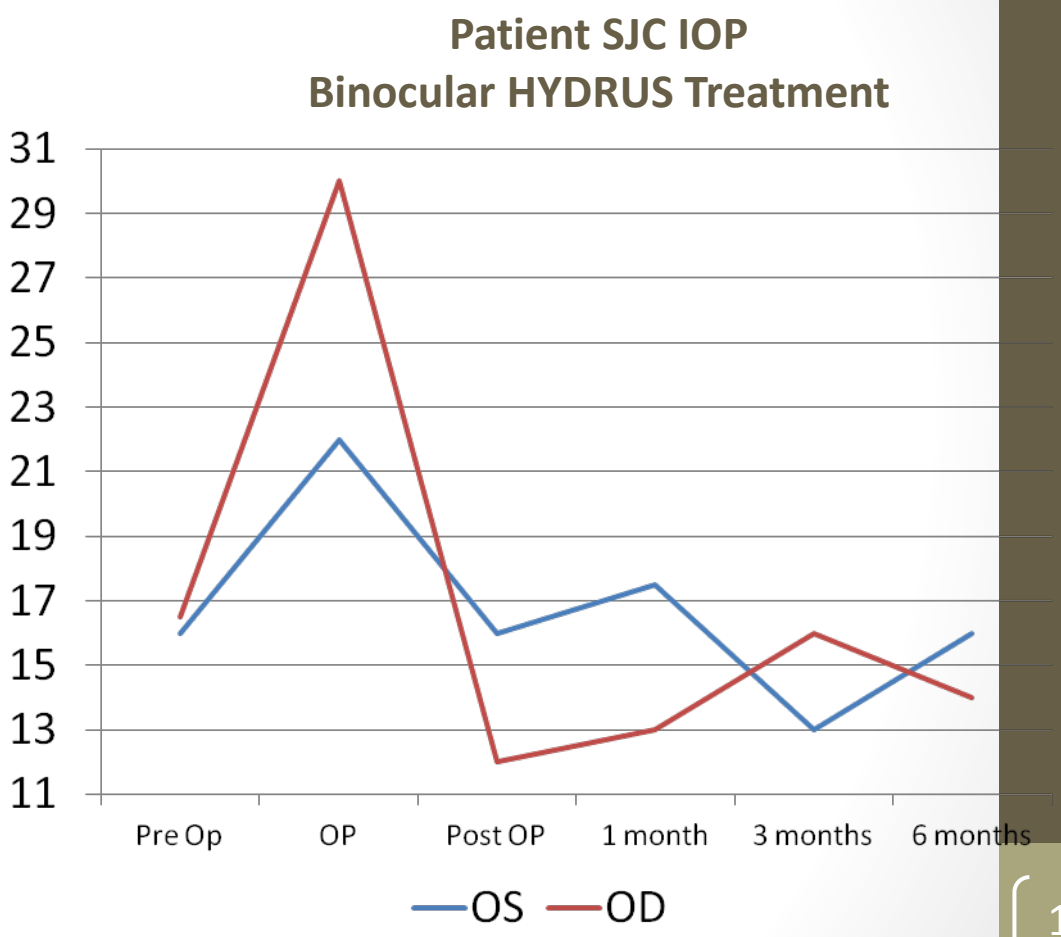
Post Operative Adverse Events	N
Hypotony, endophthalmitis	0
Transient corneal edema	1
Transient hyphema	3
Subconjunctival hemorrhage	1
IOP spike (>10 mmHg above baseline)	1

Case Study

- Patient H07-SJC
- Pre operative OS IOP 16.0 mm Hg on 3 medications, MD = -11.7
- Washed out to 22 mm
- Successful implant with eye deep and quiet by 30 days
- Pressure stable at 13-16 mmHg on no medications between 1 to 6 months follow up

Binocular Implant Case Study

- Same patient: mild glaucoma OD, baseline IOP 16.5 mmHg on 3 medications
- Washed out 30 mmHg
- Combination cataract+Hydrus
- Both eyes controlled 13-16 mm Hg in both eyes at with no medications



Conclusions

- Reliable surgery with no significant safety issues in the early follow up stages
- Mild/Moderate population reaching mean IOP in the 15 mmHg range with >70% of patients medication free
- This procedure offers a potential alternative for medical therapy to control IOP after cataract surgery in mild to moderate glaucoma patients