Ab Interno Minimally Invasive Glaucoma Surgery Effectiveness in Black Patients: IRIS® Registry Study

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Purpose

Rationale: Glaucoma is a leading cause of irreversible blindness among Black patients in the U.S. While minimally invasive glaucoma surgeries (MIGS) have transformed surgical options, the impact of race on MIGS outcomes remains insufficiently understood

Objective: To compare clinical outcomes following ab interno MIGS procedures having an US Food and Drug Administration cleared or approved indication for intraocular pressure (IOP) reduction in primary open-angle glaucoma (POAG) combined with cataract surgery versus cataract surgery alone in Black patients with glaucoma

Methods

Background/Eligibility:

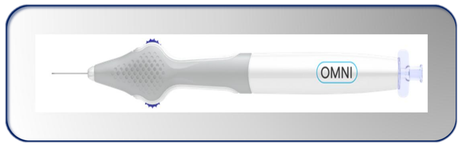
- Observational, retrospective study in Black patients treated with either, Hydrus, iStent Inject, or OMNI Surgical System in combination with cataract surgery or cataract surgery alone
- Deidentified data derived from the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight) linked with Komodo Health claims between 7/01/2016 and 12/31/2020
- Eyes that received cataract surgery, were diagnosed with glaucoma in the same eye that received cataract surgery, had documented IOP within 6 months prior to and including the index date, and ≥1 pharmacy claim for an IOP-lowering medication pre/post index date.
- Outcome measures for all 4 cohorts at baseline and at months 6, 12, 18, 24, and 36 included:
  - Glaucoma severity
  - IOP and change in IOP
  - Medication utilization
- Subgroup analysis was performed based on baseline IOP (≤18 mmHg versus >18 mmHg)

Table 1. Demographic information for each study cohort. All subjects were Black/African American

Parameter	OMNI (N=108)	Hydrus (N=238)	iStent Inject (N=634)	Cataract Surgery (N=17,300)
Age (yrs), mean (SD)	70.9 (9.8)	70.1 (8.6)	70.2 (7.9)	71.0 (8.8)
Sex, n (%)				
Male	52 (57.1)	113 (59.8)	300 (61.1)	7499 (62.2)
Female	39 (42.9)	76 (40.2)	191 (38.9)	4558 (37.8)
Glaucoma type, n (%)*				
Primary open-angle	108 (100)	235 (98.7)	631 (99.5)	17004 (98.3)
Secondary open-angle	1 (0.9)	3 (1.3)	7 (1.1)	200 (1.2)
Glaucoma severity, n (%)				
Mild	23 (21.3)	74 (31.1)	298 (47.0)	5423 (31.3)
Moderate	44 (40.7)	128 (53.8)	274 (43.2)	6087 (35.2)
Severe	38 (35.2)	32 (13.4)	49 (7.7)	4091 (23.6)
Unknown	3 (2.8)	4 (1.7)	13 (2.1)	1699 (9.8)
Index cataract procedure, n (%)				
Routine (CPT 66984)	101 (93.5)	226 (95.0)	591 (93.2)	15384 (88.9)
Complex (CPT 66982)	7 (6.5)	12 (5.0)	43 (6.8)	1916 (11.1)
Baseline IOP (mmHg), mean (SD)	15.6 (4.1)	17.2 (6.1)	16.3 (4.6)	16.9 (5.3)
Baseline Medications, mean (SD)	1.95 (0.95)	1.89 (0.94)	1.62 (0.84)	1.79 (0.92)

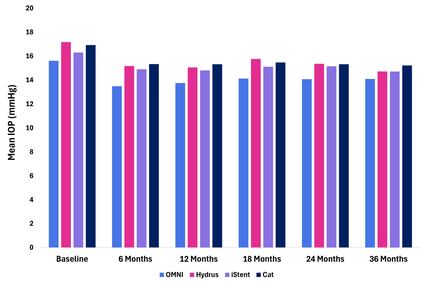
*All included eyes had a diagnosis of primary or open–angle. In some cases, eyes had multiple other glaucoma diagnoses in their medical history.

Figure 1. OMNI Surgical System



Results

Figure 2. Mean IOP Across all Time Points in full population



P≤0.014 in all cohorts and at each time point except for month 36 (*P* = 0.131) in the OMNI cohort

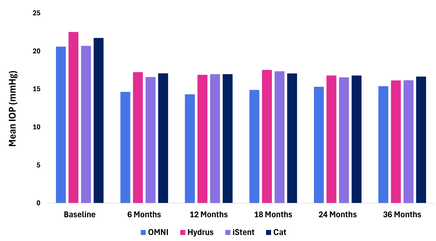
Table 2. Mean Change in medication use in full population

	OMNI				Hydrus				iStent Inject				Cataract Surgery			
Time Point	N	Mean (SD)	Mean Change from Baseline (SD)	*P*-value*	N	Mean (SD)	Mean Change from Baseline (SD)	*P*-value*	N	Mean (SD)	Mean Change from Baseline (SD)	*P*-value*	N	Mean (SD)	Mean Change from Baseline (SD)	*P*-value*
Baseline	91	1.95 (0.95)	--	--	189	1.89 (0.94)	--	--	491	1.62 (0.84)	--	--	12057	1.79 (0.92)	--	--
6 months	66	1.44 (1.33)	-0.64 (1.38)	<0.0001	155	1.1 (1.13)	-0.87 (1.18)	<0.0001	355	1.12 (1.04)	-0.58 (0.98)	<0.0001	9516	1.42 (1.16)	-0.43 (1.10)	<0.0001
12 months	60	1.38 (1.38)	-0.63 (1.37)	0.001	144	1 (1.06)	-0.94 (1.19)	<0.0001	351	1.12 (1.04)	-0.56 (1.06)	<0.0001	9167	1.42 (1.18)	-0.43 (1.15)	<0.0001
18 months	58	1.41 (1.36)	-0.6 (1.36)	0.001	139	1.01 (1.05)	-0.94 (1.09)	<0.0001	336	1.04 (1.04)	-0.65 (1.05)	<0.0001	8691	1.32 (1.18)	-0.53 (1.18)	<0.0001
24 months	61	1.16 (1.25)	-0.9 (1.43)	<0.0001	134	0.93 (1.06)	-1.01 (1.20)	<0.0001	330	0.97 (1.05)	-0.72 (1.07)	<0.0001	8294	1.24 (1.16)	-0.61 (1.21)	<0.0001
36 months	33	0.33 (0.69)	-1.82 (1.33)	<0.0001	99	0.65 (1.13)	-1.35 (1.20)	<0.0001	270	0.69 (0.97)	-0.99 (1.13)	<0.0001	6947	1.02 (1.12)	-0.83 (1.23)	<0.0001

*P-Value for mean number of IOP-lowering medications classes reflects 1 sample t-test within given cohort, comparing follow-up period value vs. baseline value

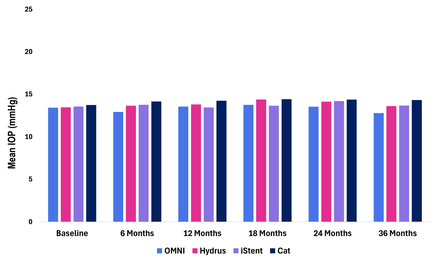
Figure 3. Mean IOP for Patients with A) baseline > 18mmHg and B) baseline ≤18 mmHg

A)



P≤0.002 in all cohorts and at each time point except for month 36 (*P* = 0.192) in the OMNI cohort

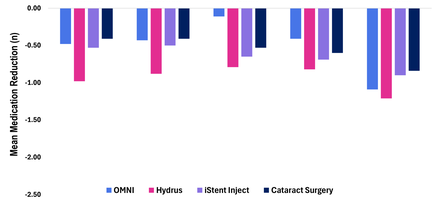
B)



No significant reductions in IOP in any cohort; IOP in the cataract surgery cohort significantly increased vs. baseline at all time points (*P<0.0001*)

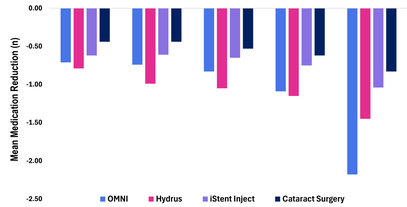
Figure 4. Mean Medication Reduction for Patients with A) baseline > 18mmHg and B) baseline ≤18 mmHg

A).



P≤0.014 in all cohorts and at each time point except for M6, 12,18, and 24 in the OMNI cohort

B).



P≤0.002 in all cohorts and at each time

CONCLUSION

MIGS in combination with cataract surgery resulted in clinically significant reductions in IOP and IOP-lowering medications up to 36 months in Black patients. Surgeons should consider offering MIGS at the time of cataract surgery to this population.