ESCRS VIENNA 2023
41ST CONGRESS OF THE ESCRS | 8-12 SEPTEMBER 2023

FP16.02

# 24 Month Real-World Study of Intraocular Pressure and Medication Reduction in Ab Interno Microinvasive Glaucoma Surgery Combined with Cataract Surgery Compared with Cataract Surgery Only: An IRIS® Registry Study

Andrew Tatham MD MBA[1], Richard Chapman MS[2], Kristian Garcia MPH[2], Cristina Masseria PhD[3],
John Liu JD[4], Jaime E Dickerson Jr PhD[4,5], Michael Mbagwu MD[2,6]

*[1]Princess Alexandra Eye Pavilion, Edinburgh, UK, [2]Verana Health, San Francisco, CA, USA, [3]AESARA Inc, Chapel Hill, NC, USA, [4]Sight Sciences Inc, Menlo Park, CA, USA, [5]North Texas Eye Research Institute-University of North Texas Health Science Center, Fort Worth, TX, USA,*
*[6]Stanford University School of Medicine, Palo Alto, CA, USA*

# Disclosure for Andrew Tatham

In compliance with COI policy, ESCRS requires the following disclosures to the session audience:

| | |
|---|---|
| **Shareholder** | No relevant conflicts of interest to declare |
| **Grant / Research Support** | AbbVie, iSTAR Medical |
| **Consultant** | AbbVie, Alcon, Thea, Santen, Roche, Sight Sciences, Nova Eye Medical, Viatris, Elios |
| **Employee** | No relevant conflicts of interest to declare |
| **Paid Instructor** | No relevant conflicts of interest to declare |
| **Speaker Bureau** | AbbVie, Alcon, Thea, Santen, Sight Sciences, Nova Eye Medical, Viatris |
| **Other** | No relevant conflicts of interest to declare |

Presentation includes discussion of the following off-label use of a drug or medical device:
**Not applicable – no off-label discussion**

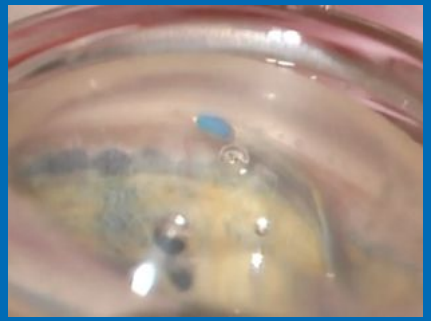
# BACKGROUND

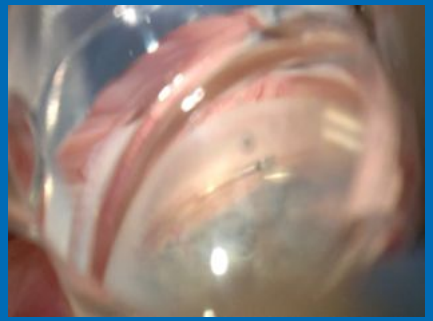
- Eye drops remain the most common first-line glaucoma treatment, but efficacy depends on patient adherence, and they are associated with adverse effects affecting quality of life.[1-3]
- Minimally Invasive Glaucoma Surgery (MIGS) provides an option for earlier surgical intervention in mild and moderate glaucoma, while also potentially delaying or preventing the need for more invasive interventions at later stages.
- The American Academy of Ophthalmology IRIS® (Intelligent Research in Sight) Registry is the largest electronic health record-based comprehensive eye disease and condition registry in the US.[4]

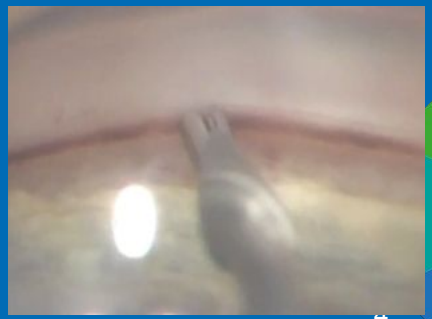
- **Aim: To examine real-world outcomes of FDA approved/cleared ab-interno MIGS devices (OMNI® Surgical System, Hydrus® and iStent Inject®) combined with cataract surgery compared to cataract surgery alone using the IRIS® registry**

# METHODS

- Retrospective analysis from the IRIS® Registry
- Patients with an ICD-10 diagnosis of glaucoma treated with Phaco-OMNI®, Phaco-Hydrus®, Phaco-iStent inject® or Phaco alone between 1st July 2016 and 31st December 2020 with a minimum follow up time of 6 months
- Surgical procedures identified using CPT codes coupled with clinic note text processing. Glaucoma medication regimens were ascertained using linked commercial claims data (Komodo Health, Inc) during the study period (1st July 2016 to 30th June 2022)
- **Primary outcomes**: Change in IOP and number of IOP-lowering medication classes at 6, 12, 18, and 24-months
- Analysis stratified by baseline IOP: > 18mmHg (Group 1) and ≤ 18mmHg (Group 2)
- **Primary analysis:** two-sample t-tests and two-proportion z-tests (with Bonferroni correction)







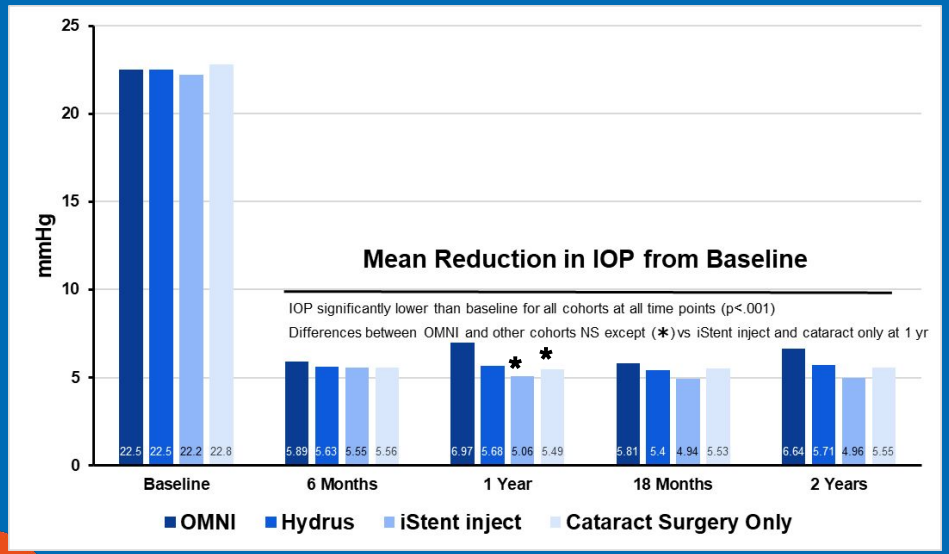
# RESULTS

- **109,745 eyes of 77,391 patients**
- Baseline characteristics generally comparable, including baseline IOP
- Phaco-OMNI and Phaco-Hydrus groups had slightly more medication use at baseline
- Phaco-OMNI group had a higher proportion of Black/African American patients

| | OMNI | Hydrus | iStent Inject | Phaco |
|---|---|---|---|---|
| **N (patients/eyes)** | 428/541 | 1,435/1,901 | 4,769/6,558 | 70,759/100,745 |
| **Age (mean, SD)** | 72.1 (8.7) | 72.1 (8.3) | 72.4 (8.1) | 71.9 (9.7) |
| **Sex (%)** | | | | |
| **Female** | 52.1 | 54.0 | 56.7 | 55.7 |
| **Male** | 47.9 | 46.0 | 43.3 | 44.3 |
| **Race (%)** | | | | |
| **Asian** | 2.1 | 2.1 | 1.9 | 3.0 |
| **Black/African American** | 23.4 | 15.7 | 11.5 | 13.9 |
| **Native American** | 0.5 | 0.3 | 0.4 | 0.4 |
| **White** | 53.3 | 66.4 | 71.3 | 66.2 |
| **Other** | 1.2 | 0.9 | 1.0 | 1.5 |
| **Not Reported** | 19.6 | 14.6 | 13.9 | 15.0 |
| **POAG (%)** | | | | |
| | 90.4 | 99.3 | 98.2 | 79.6 |
| **Baseline IOP (mmHg)** | | | | |
| | 16.5 (4.9) | 16.7 (5.0) | 16.4 (4.5) | 17.0 (5.2) |
| **Baseline Medications** | | | | |
| | 1.99 | 1.82 | 1.60 | 1.61 |
| **Glaucoma Severity (%)** | | | | |
| **Mild** | 29.2 | 42.1 | 51.7 | 30.1 |
| **Moderate** | 36.2 | 42.3 | 37.6 | 21.5 |
| **Severe** | 24.2 | 9.6 | 6.1 | 9.5 |

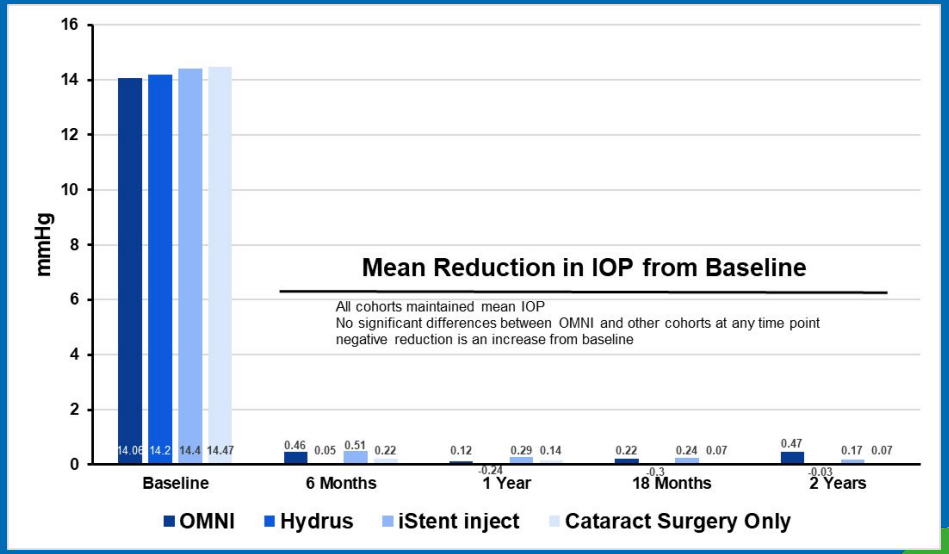
# RESULTS: IOP REDUCTION

## Group 1: Baseline IOP >18 mmHg




**Treatment goal**
**IOP reduction**

## Group 2: Baseline IOP ≤18 mmHg

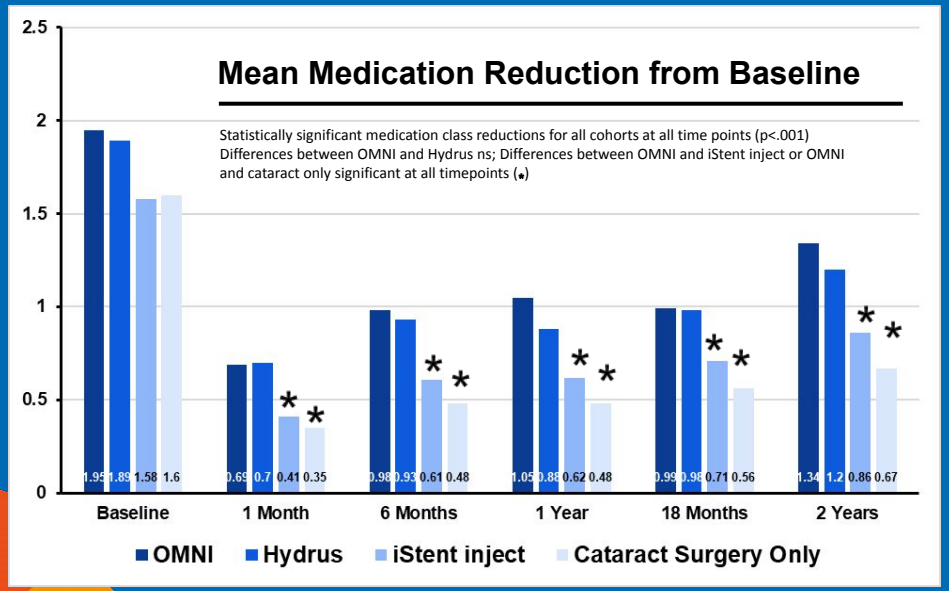



**Treatment goal**
**Maintain IOP**
**Reduce medication burden**

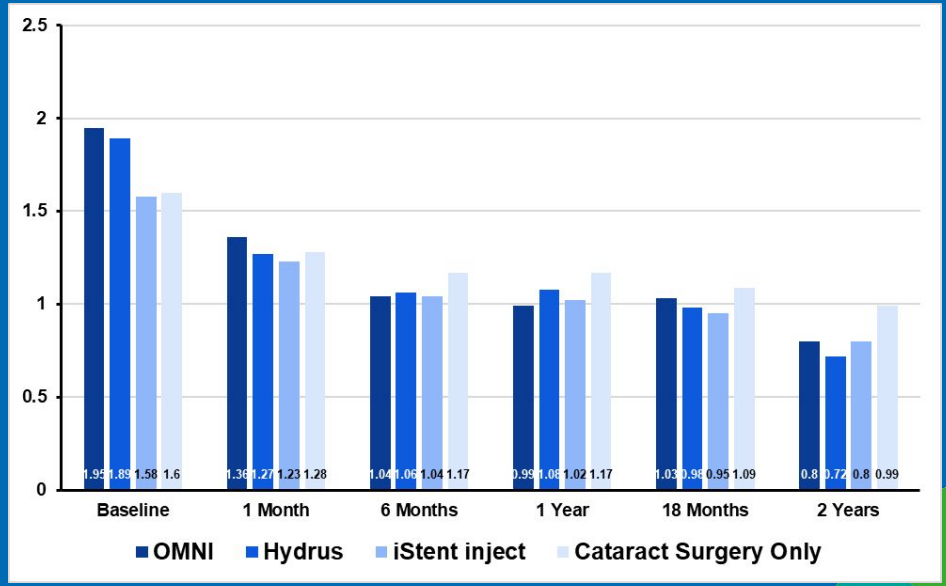
# RESULTS: MEDICATION REDUCTION

## Group 1: Baseline IOP >18 mmHg

### Change from Baseline



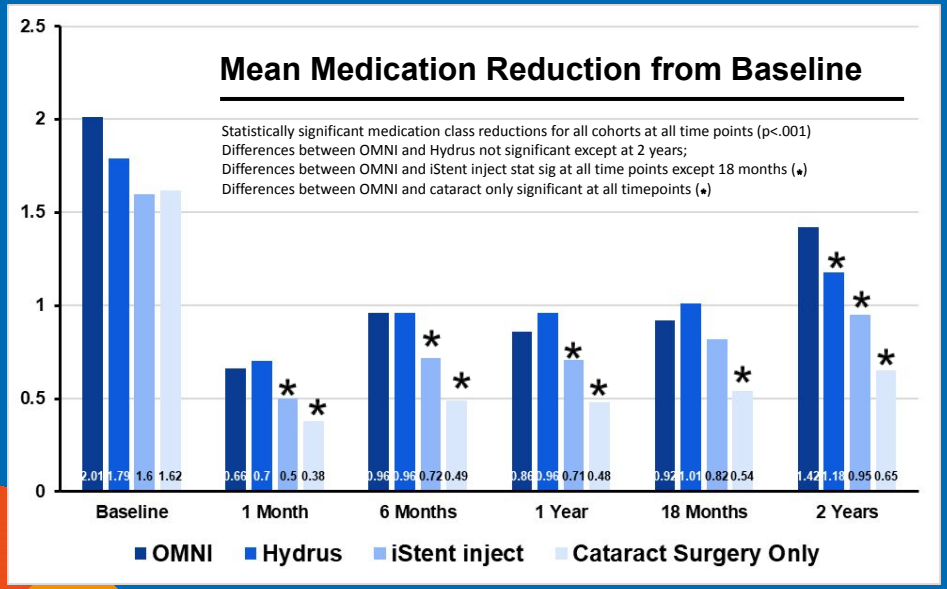

### Mean number of medication classes at each visit



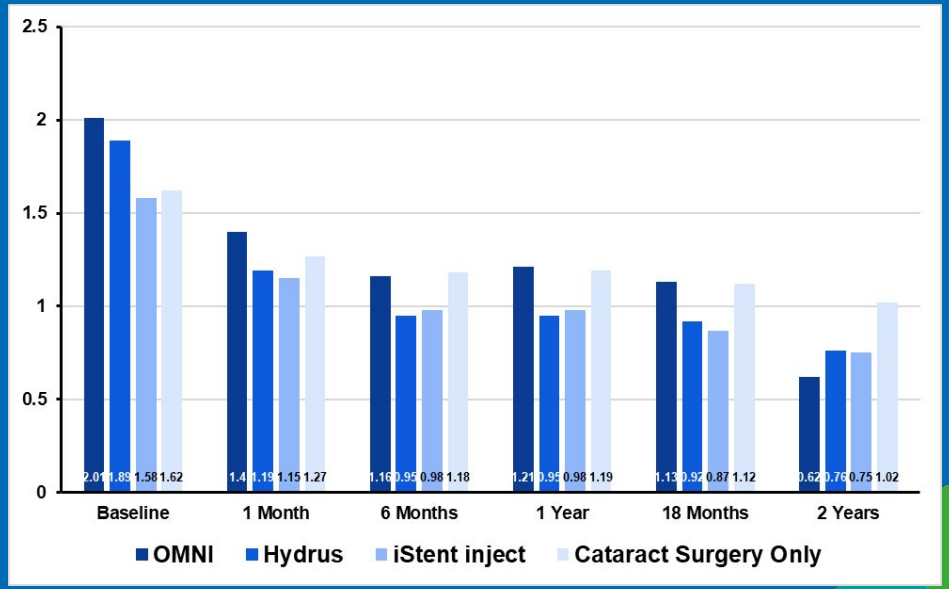
# RESULTS: MEDICATION REDUCTION

## Group 2: Baseline IOP ≤18 mmHg

### Change from Baseline




### Mean number of medication classes at each visit



# CONCLUSION

- Patients treated with Phaco-MIGS showed greater medication reduction at 24-months compared to those treated with cataract surgery alone.
- Patients with high baseline IOP treated with Phaco-MIGS also experienced greater IOP reduction at 24-months compared to patients treated with cataract surgery alone.
- Those treated with Phaco-OMNI needed fewer glaucoma medications at 24-months compared to other cohorts (Phaco-Hydrus, Phaco-istent inject, Phaco alone).
- Results are consistent with multiple published studies of individual MIGS and suggest better outcomes for those treated with Phaco-MIGS compared to Phaco alone.
- This real-world evidence study provides longer term evidence of the durable effectiveness of three FDA approved/cleared MIGS devices though there were differences between devices.

# REFERENCES


1. Gedde SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern®. Ophthalmology. 2021;128:P71-P150.
2. Inoue K, Shiokawa M, Higa R, et al. Adverse periocular reactions to five types of prostaglandin analogs. Eye (Lond) 2012;26:1465-1472.
3. Inoue K. Managing adverse effects of glaucoma medications. Clin Ophthalmol 2014;8:903-913.
4. American Academy of Ophthalmology IRIS Registry. https://www.aao.org/iris-registry Available at: Accessed Feb 27 2023.