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Leveraging real-world data from the American Academy of Ophthalmology's IRIS® Registry to evaluate the use and impact of approved medical devices and software algorithms in support of FDA strategic priorities

Project 1: Expansion of intraocular lens (IOL) to include pediatric population

Flora Lum, MD

AAPOS Presentation

Disclosures

No personal financial interests

Study supported by the US Food and Drug Administration

Study Purpose + Objectives

Purpose

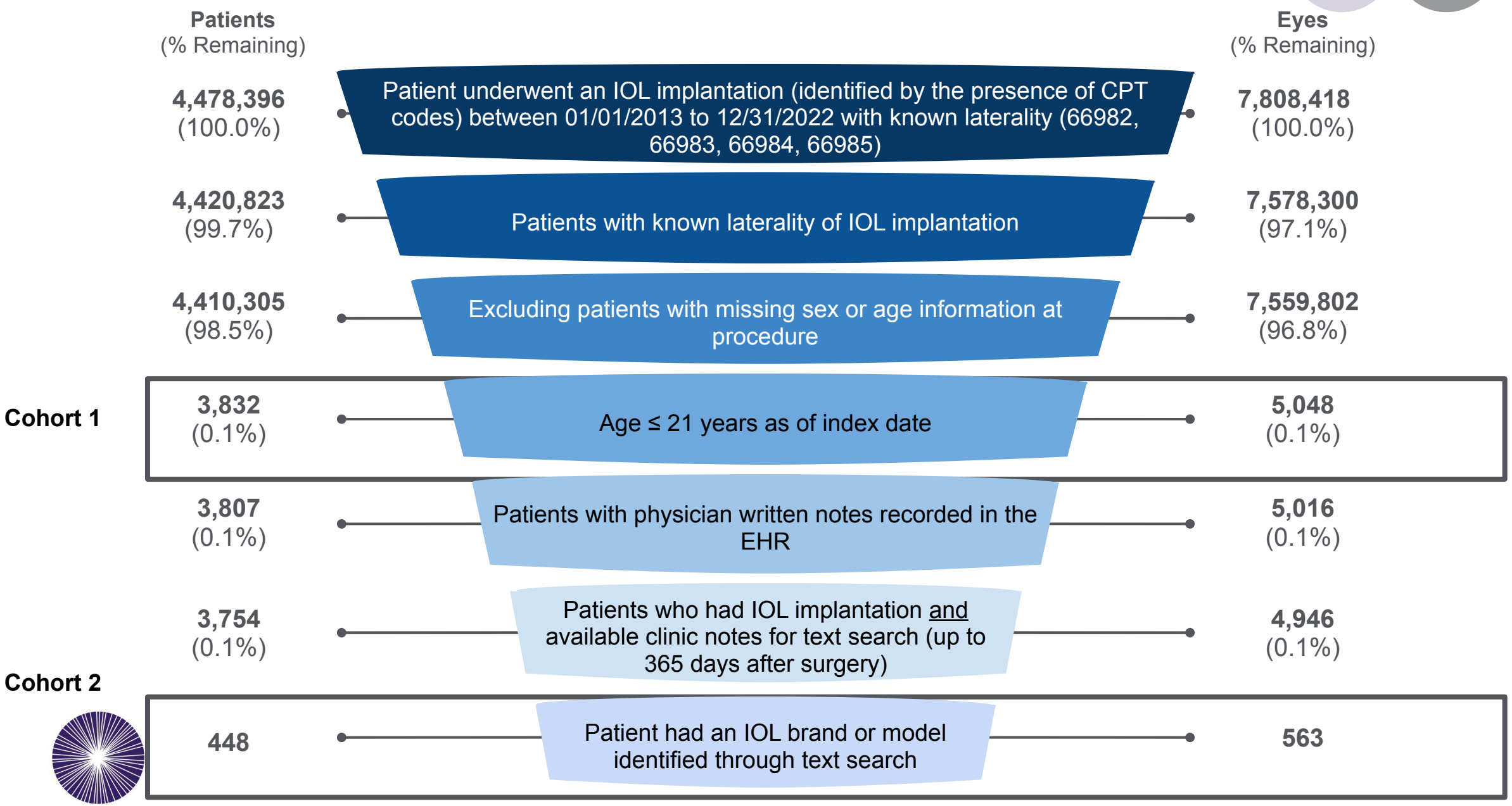
Prevalence of **pediatric cataracts** can range from **1 to 15 per 10,000 children**. To prevent permanent visual impairment, cataracts are generally extracted soon after diagnosis, followed by **implantation of an intraocular lens (IOL).**

While IOLs are currently used in the pediatric population, the procedure is often performed in an "off-label" manner because IOLs are **not explicitly FDA approved** at this time for this patient population. **Complications** following **intraocular lens (IOL) implantation** can include posterior capsular opacification (PCO), glaucoma, ocular hypertension, amblyopia, among others.

Primary Objective

The purpose of the study is to understand the **safety and outcomes of IOL use in pediatric patients with cataracts** using the IRIS® Registry.

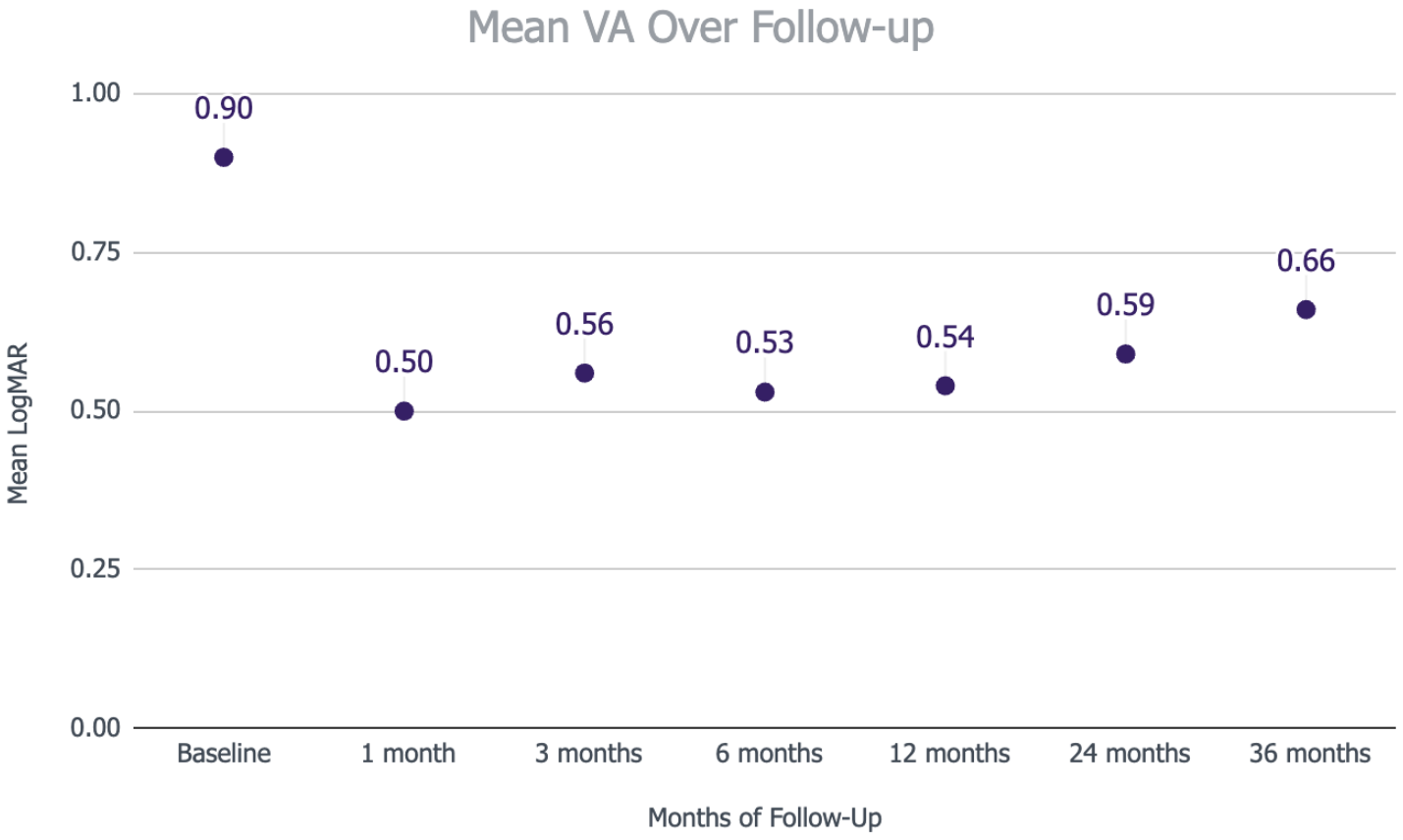
Attrition - Cohort 1 and Cohort 2



Majority of patients in Cohort 1 and Cohort 2 are ≥ 10 years of age

	Cohort 1: CPT only		Cohort 2: CPT + IOL brand/model	
	Patients	**Eyes**	**Patients**	**Eyes**
Overall Total patients, % of total	**3,832 (100%)**	**5,048 (100%)**	**448 (100%)**	**563 (100%)**
Age (years)				
0-<2	175 (4.57%)	228 (4.52%)	6 (1.34%)	7 (1.24%)
2-<7	643 (16.78%)	849 (16.82%)	37 (8.26%)	47 (8.35%)
7- <10	354 (9.24%)	443 (8.78%)	25 (5.58%)	29 (5.15%)
≥10	2,660 (69.42%)	3,528 (69.89%)	380 (84.82%)	480 (85.26%)

Improvement was seen at all timepoints compared to baseline VA

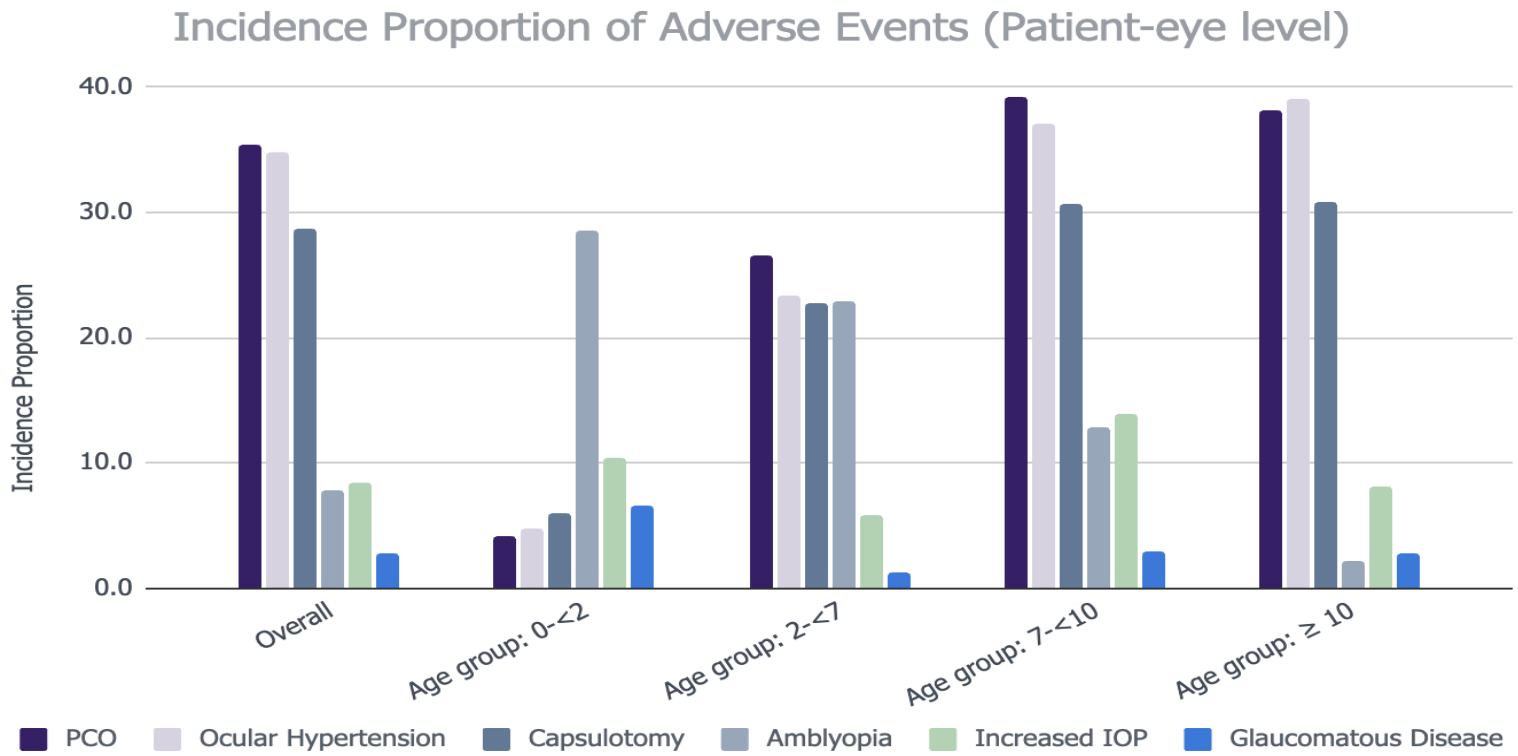


* Baseline VA was defined as an VA reading within 6 months prior to the IOL implantation. If more than one VA record per day per eye per patient was recorded, the best VA reading (lowest LogMAR record) closest to the date of the IOL implantation was selected.

Note: This table includes only patients with a recorded baseline VA measurement (4,119 patient eyes among 3,149 patients in Cohort 1).

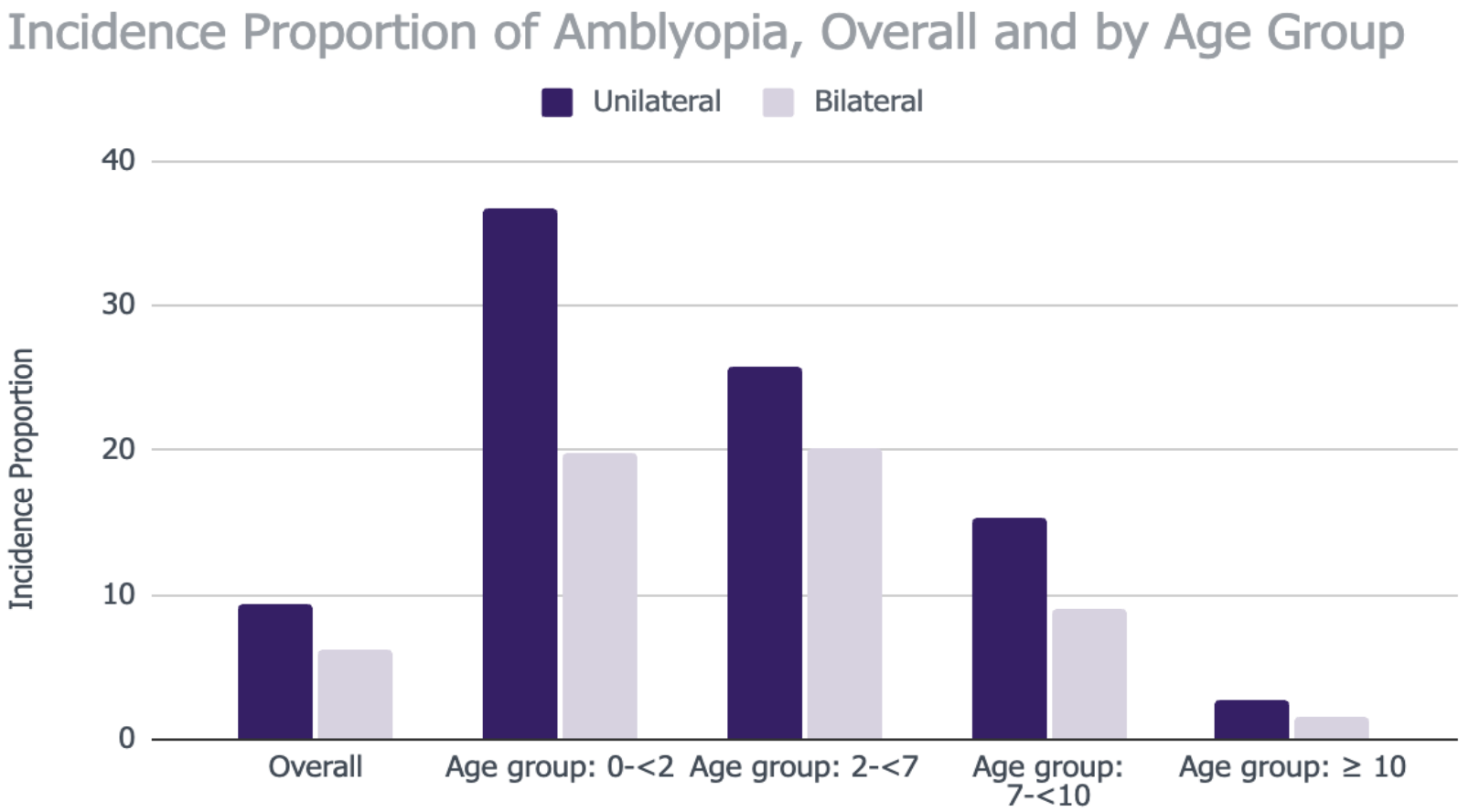
Note: Different patient eyes may contribute to each time point. Patient eyes are not required to contribute to consecutive time points.

PCO was the most common AE overall at the patient-eye level



Note: Denominator is 3,832 for all AEs with the exception of PCO, increased IOP, and capsulotomy, which had denominators of 3,528, 2,844, and 3,528, respectively.
Note: The following secondary interventions, intraocular lens Exchange, removal of intraocular lens, and lens reposition, were allowed to be counted more than once.
Note: Pre-operative baseline IOP was defined as an IOP reading within 6 months prior to the IOL implantation. If more than one IOP record per day, per eye, per patient recorded, the average IOP was taken if there were 2 IOP readings, and the median was taken if there were >2 IOP readings. The IOP reading closest to the date of the IOL implantation was reported.

Amblyopia is the most common AE among 0-<2



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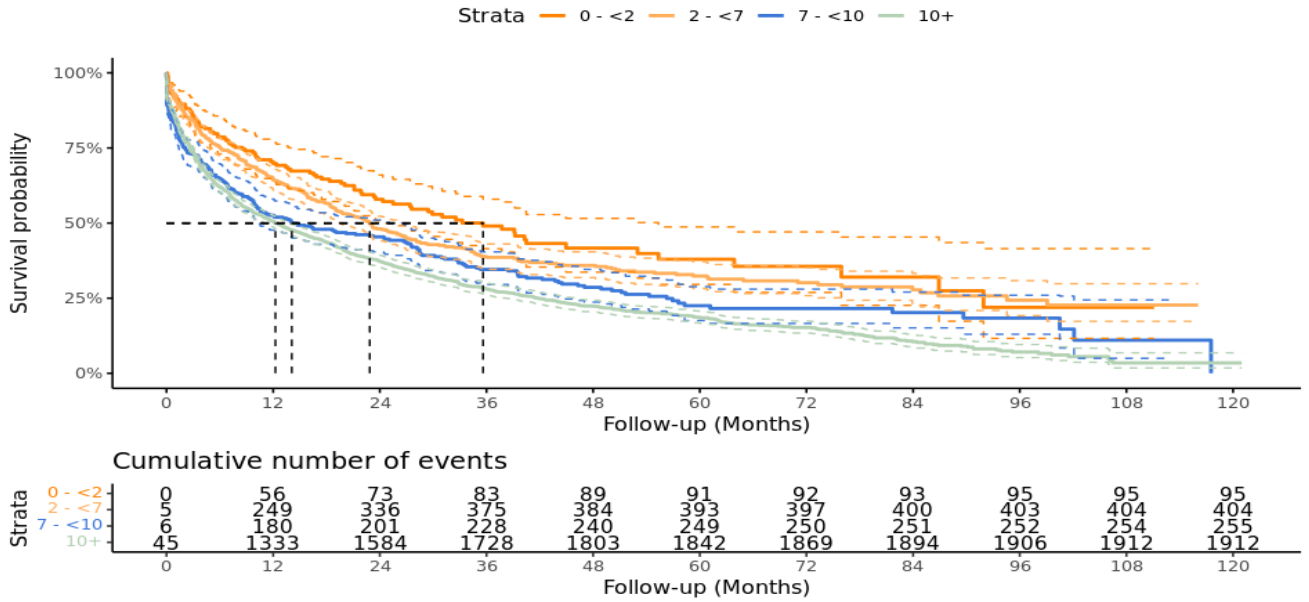
Median time to first AE is 15 months for Cohort 1

Time to First Adverse Event Cohort 1: CPT only																	
Overall				**Age Group: 0-<2**				**Age Group: 2-<7**				**Age Group: 7-<10**				**Age Group: ≥10**			
N Events	**Median (months)**	**Lower 95% CI**	**Upper 95% CI**	**N Events**	**Median (months)**	**Lower 95% CI**	**Upper 95% CI**	**N Events**	**Median (months)**	**Lower 95% CI**	**Upper 95% CI**	**N Events**	**Median (months)**	**Lower 95% CI**	**Upper 95% CI**	**N Events**	**Median (months)**	**Lower 95% CI**	**Upper 95% CI**
2,666	**15.38**	13.77	16.66	95	**35.64**	24.36	55.40	404	**22.88**	19.59	26.60	255	**14.10**	10.26	25.08	1,912	**12.26**	10.98	13.81

Figure 6.3.2: Time to First Adverse Event by Age Group



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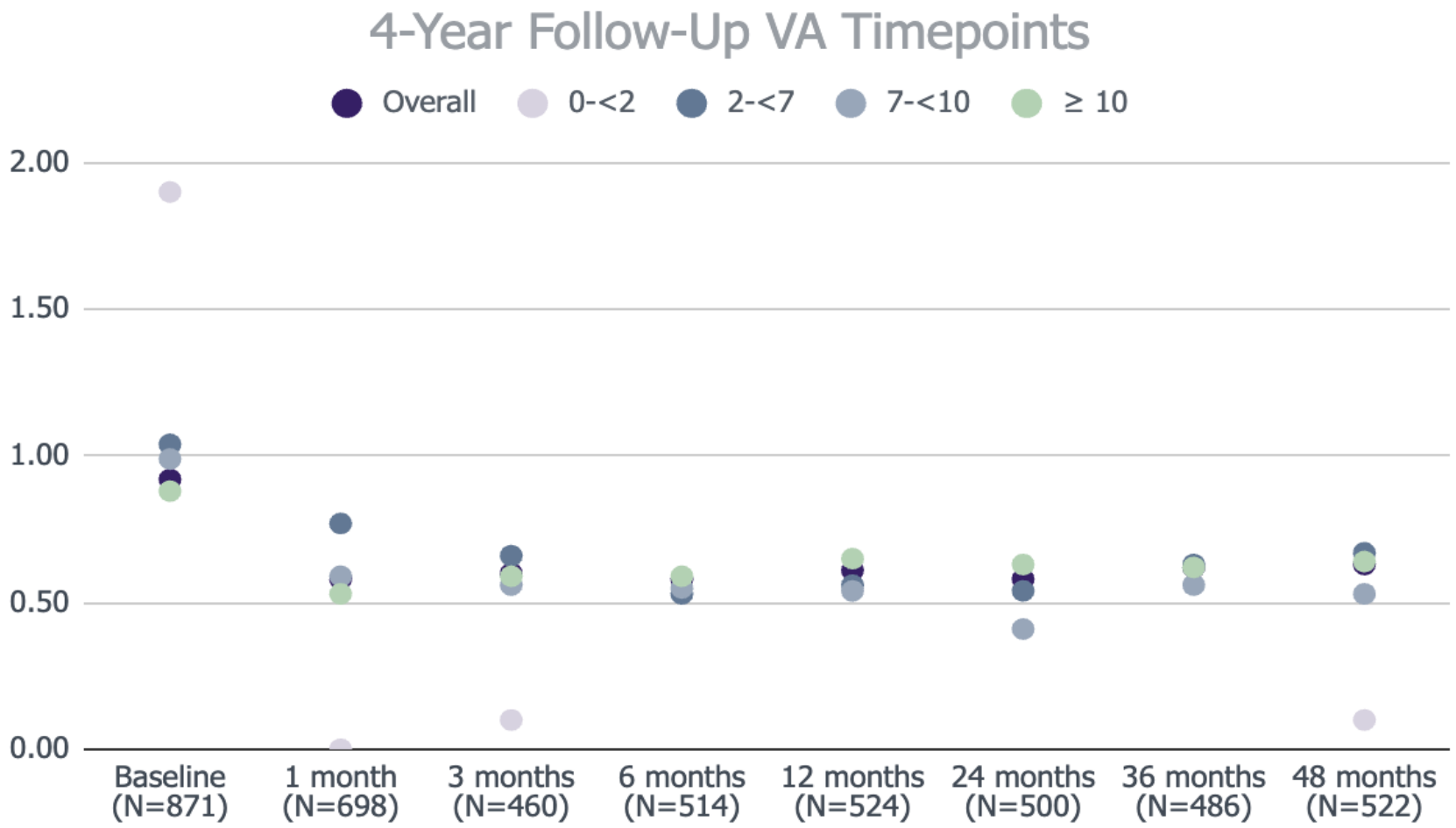
VA Improvement seen across age groups



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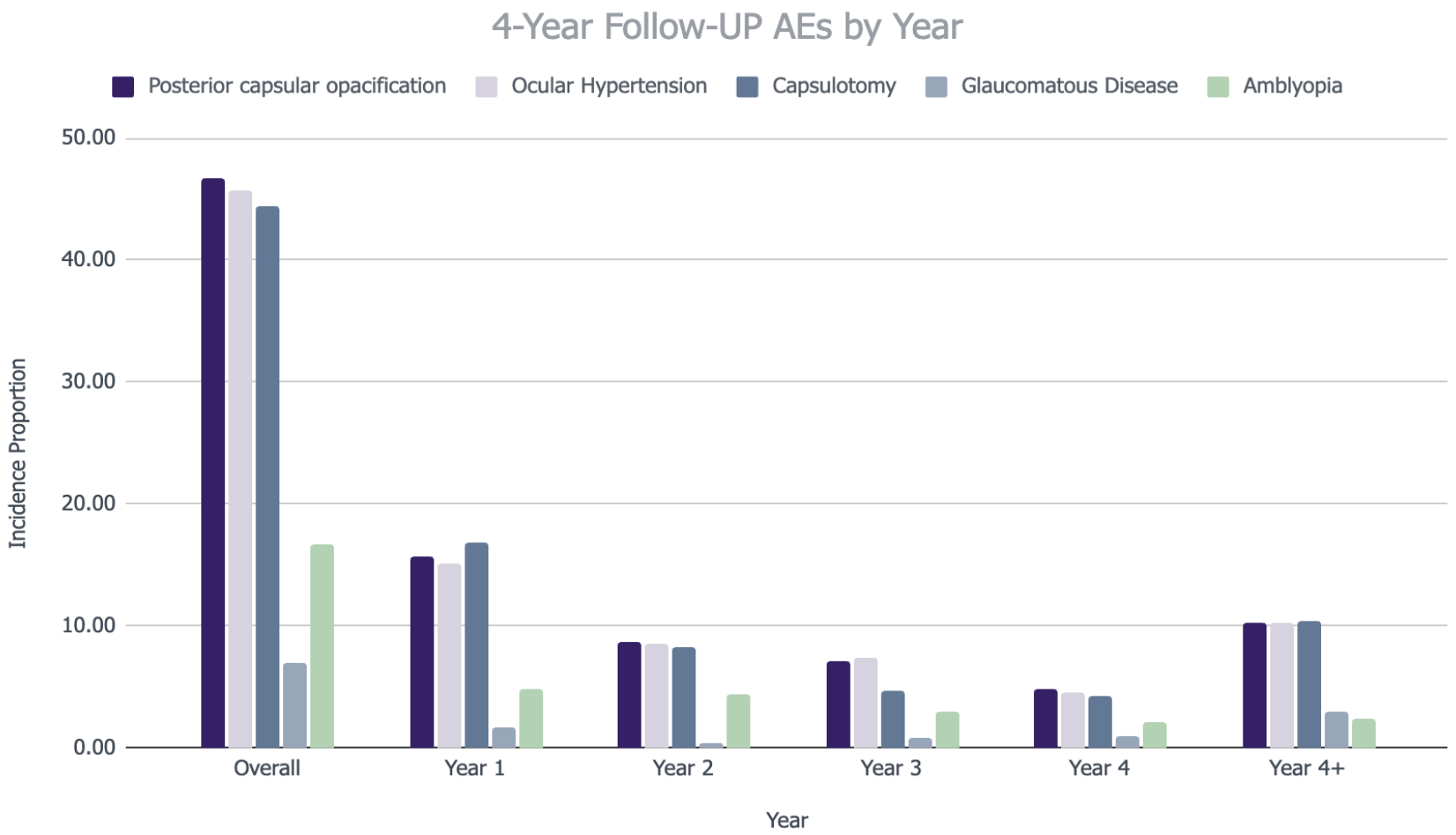
AEs observed for patients who underwent an IOL implantation



Limitations

- Structured data (i.e., ICD/CPT codes) were used to identify relevant AEs
- Potential selection bias as IRIS Registry captures a lower proportion of academic medical centers and will not capture private practices that do not use EHRs
- Small cohort of patients with IOL model and/or brand numbers identified
- UDIs were not able to be captured in the study

Summary

- 5,048 surgeries among 3,832 patients that were ≤21 years old
- VA improvement at all timepoints; mean VA at one year was 20/70
- PCO was the most frequent overall adverse event
- Amblyopia most frequent in the 0-<2; OHT most frequent in ≥10
- Similar rates of AEs and VA improvement compared to literature

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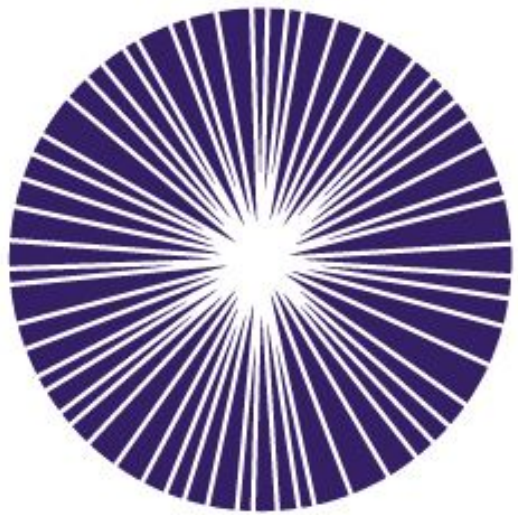

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