Real-World Characteristics of Patients Treated with Intracanalicular Dexamethasone Insert: An IRIS Registry Analysis 2019-2021

Michael Mbagwu, MD[1,2,3]; Srilatha Vantipalli, PhD[4]; Dina Akasheh, PhD[4]; Matthew Cheung, PharmD[4]; Rabia Gurses-Ozden, MD[4]; Sonya Li[3]; Meghan Hatfield[3]; Andrew LaPrise[3]; Michael H. Goldstein, MD[4]

[1]VA Palo Alto, Palo Alto, CA; [2]Stanford University, Palo Alto, CA; [3]Verana Health, San Francisco, CA; [4]Ocular Therapeutix, Bedford, MA

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Disclosures

- **Presenter:** Michael Mbagwu is an employee of Verana Health.
- **Co-authors:** Meghan Hatfield, Andrew LaPrise, and Sonya Li are employees of Verana Health®. Srilatha Vantipalli, Dina Akasheh, Matthew Cheung, and Michael H. Goldstein are employees of Ocular Therapeutix.
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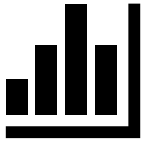
Real-World Evidence Complements Clinical Trial Data

- While randomized, controlled clinical trials serve an important role in demonstrating drug efficacy and safety for regulatory approvals, certain limitations exist:
  - Study population selected from strict inclusion/exclusion criteria
  - Comparator may not reflect clinical practice
  - Can be difficult to assess long-term effects

- Real-world data can provide insights about a drug in routine clinical practice outside the controlled setting of clinical trials:



Efficacy

Which patient subgroup will benefit?

Safety

What safety events have been reported after regulatory approval?

Prescribing Behaviors

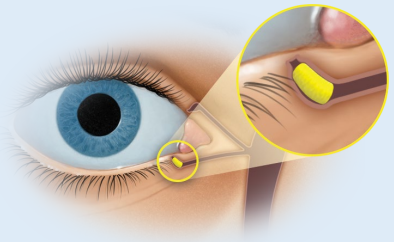
Which patients do HCPs use a certain treatment in?

Patient Health

How do treatments improve outcomes that matter to patients?

Study Objective

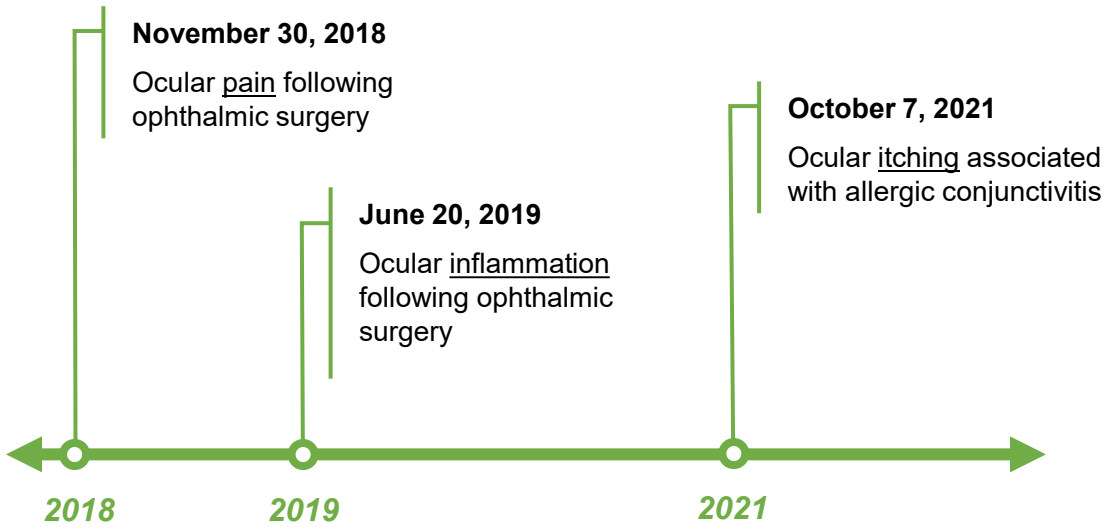
Objective: To characterize patient demographics, clinical comorbidities and type of cataract surgery among real-world patients who underwent cataract surgery and did/did not receive intracanalicular dexamethasone insert



Intracanalicular Dexamethasone Insert (DEXTENZA)

- Sustained- and tapered- release of 0.4 mg of dexamethasone over 30 days[1]
- Alternative to traditional steroid eye drops
- FDA-approved for the treatment of[1]:
  - Postoperative pain and inflammation following ophthalmic surgery
  - Ocular itching associated with allergic conjunctivitis

FDA Approval Timeline[2]



Reference: 1. DEXTENZA [prescribing information]. Bedford, MA; Ocular Therapeutix, Inc.; 2021. **2.** Drug Approval Package: DEXTENZA. U.S. Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed April 15, 2022.

Study Design: Retrospective Analysis using the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight)

Key Inclusion Criteria

- Underwent cataract surgery[a] from June 1, 2019 (product launch) to March 31, 2021
- Intracanalicular dexamethasone (DEX)[b] used within -2 to +7 days of cataract procedure

Key Exclusion Criteria

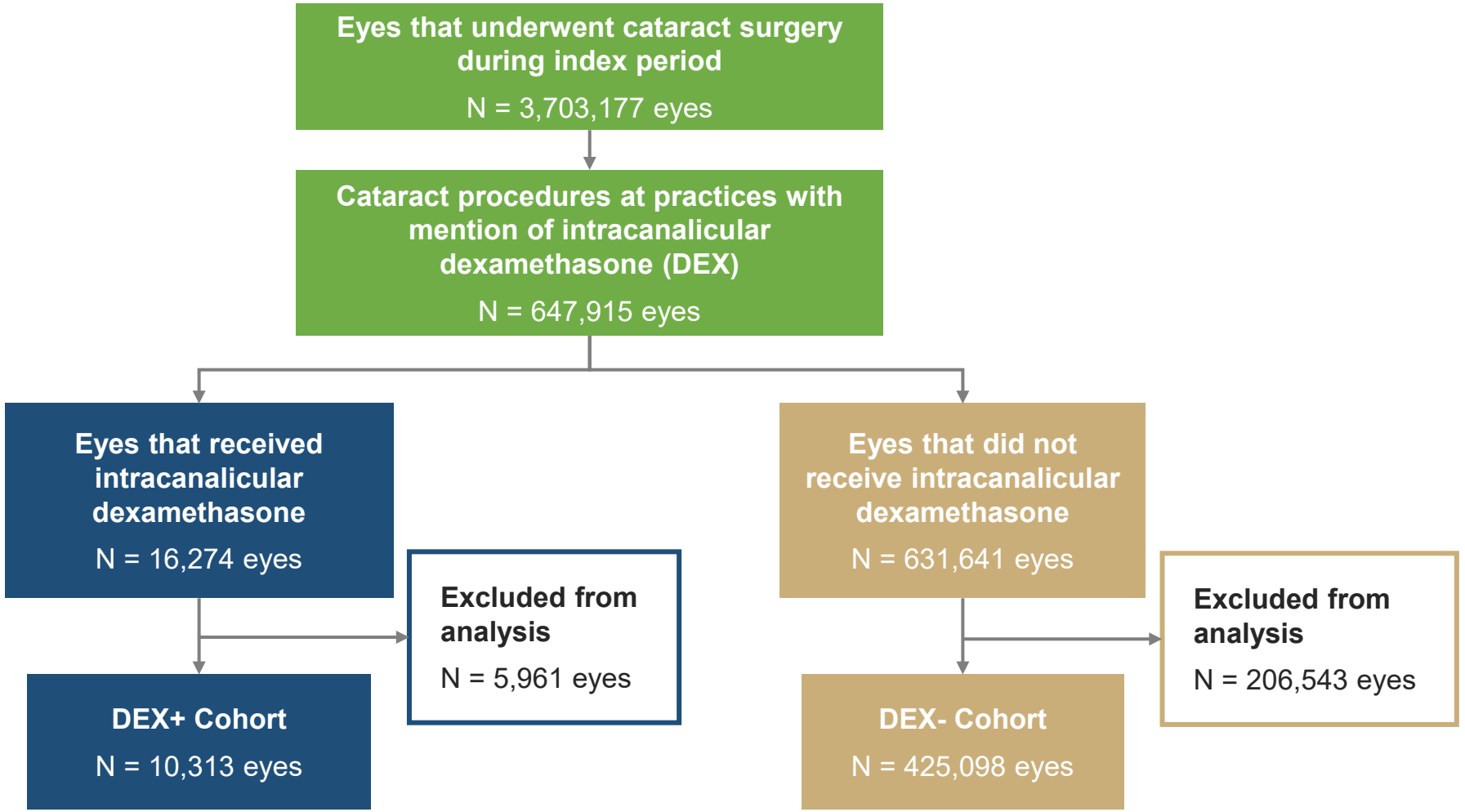
- Missing laterality for cataract surgery
- Missing patient demographic information
- Less than 1-month follow-up after cataract surgery
- Mention of dexamethasone intraocular suspension (DEXYCU®) in the procedure table

Study Outcomes

- Patient baseline demographics
- Clinical ocular comorbidities (up to 6 months preceding date of cataract surgery)
- Type of cataract surgery

[a] defined as presence of CPT code 66984 or 66982
[b] defined as presence of J-code (J1096), C-code (C9048), CPT code (0356T), NDC number (70382-0204-01, 70382-204-10) or keywords which indicated intracanalicular dexamethasone use in the procedural table
[c] identified by the presence of new ICD-10 codes

Study Population



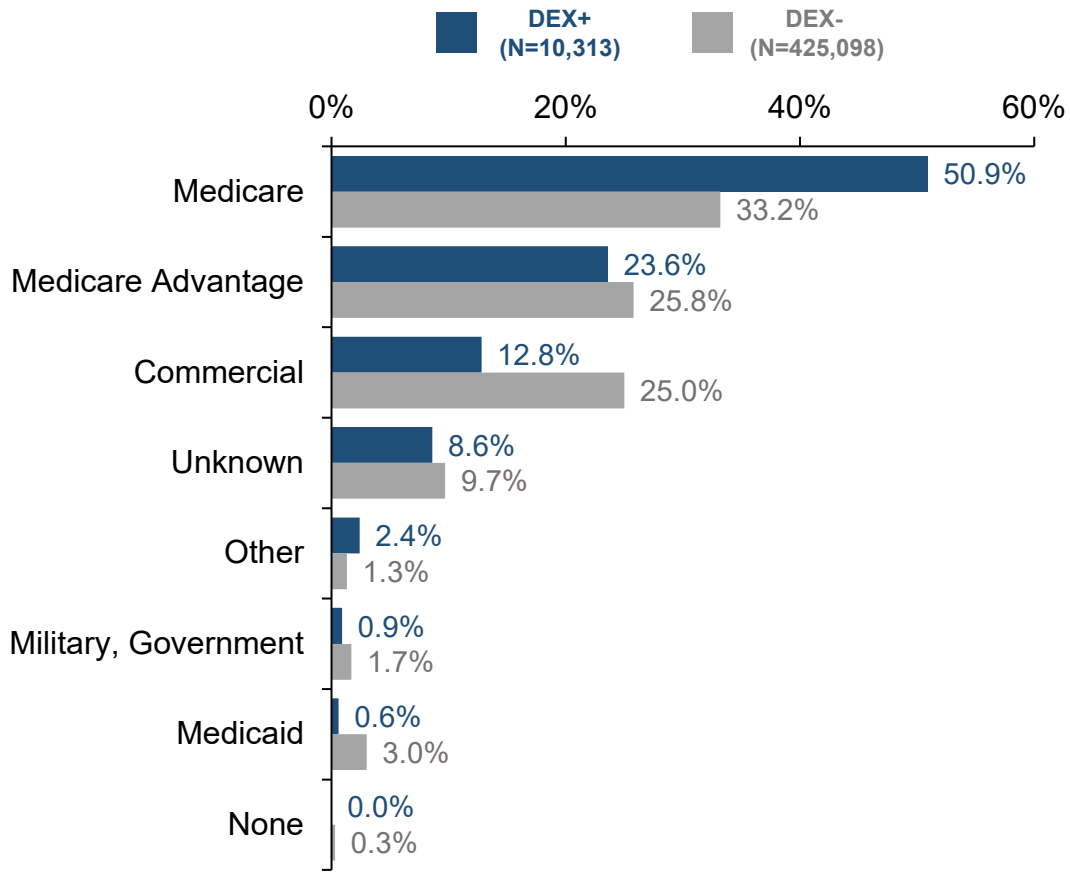
Patient Demographics

DEX+ patients were mean 73.4 years, 59.4% female and 74.6% Medicare beneficiaries

Baseline Demographic Characteristics

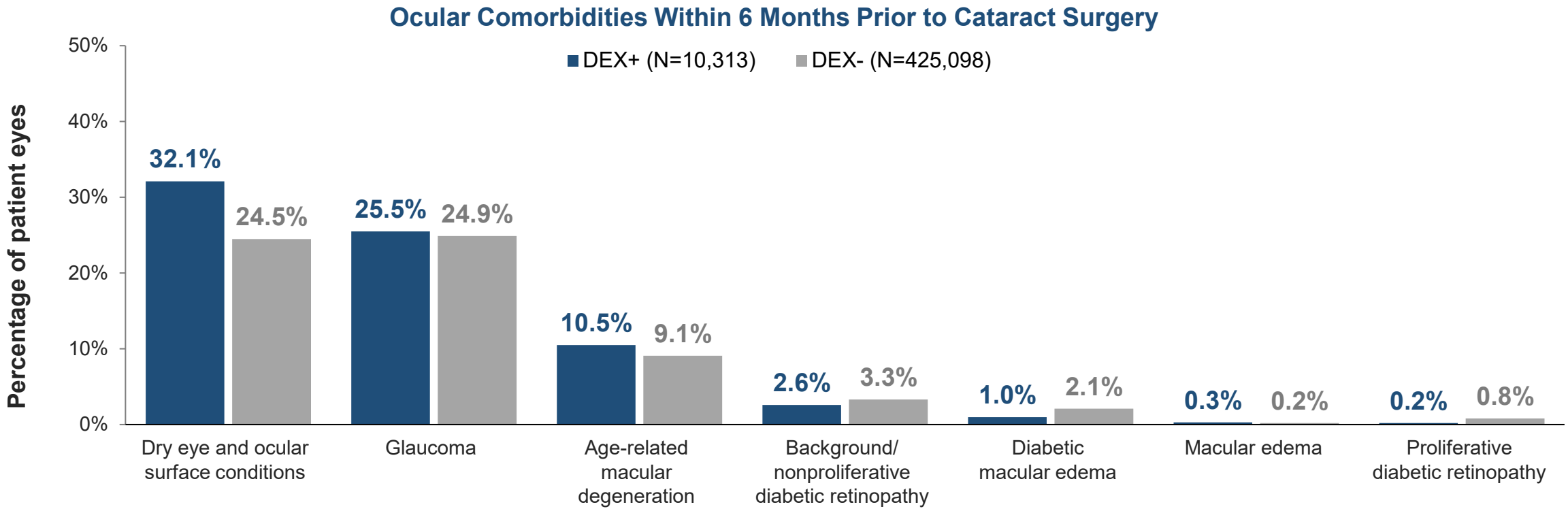
	DEX+ (N=10,313)	DEX- (N=425,098)
Mean age, years (SD)	73.44 (6.83)	70.54 (9.09)
Sex, n (%)		
Female	6,128 (59.4%)	250,237 (58.9%)
Male	4,185 (40.6%)	174,861 (41.1%)
Race, n (%)		
White/Caucasian	7,807 (75.7%)	274,451 (64.6%)
Black/African American	534 (5.2%)	34,901 (8.2%)
Asian	113 (1.1%)	8,160 (1.9%)
Other	79 (0.8%)	7,844 (1.8%)
Unknown	1,780 (17.3%)	99,742 (23.5%)
Ethnicity, n (%)		
Not Hispanic or Latino	6,364 (61.7%)	238,040 (56.0%)
Hispanic or Latino	212 (2.1%)	23,684 (5.6%)
Unknown	3,737 (36.2%)	163,374 (38.4%)

Payer Type



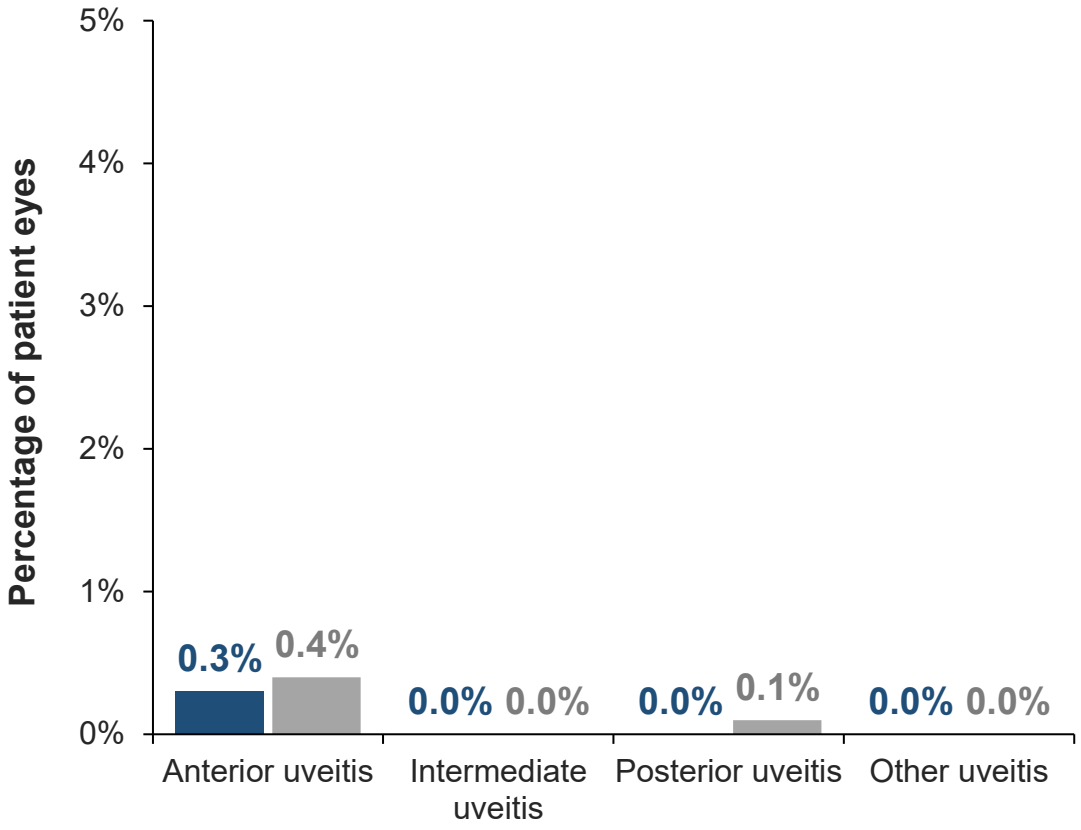
Preoperative Characteristics: Ocular Comorbidities

- DEX was used more frequently in patients with dry eye/ocular surface conditions vs. the non-DEX cohort
- Use of DEX was observed in patients with glaucoma



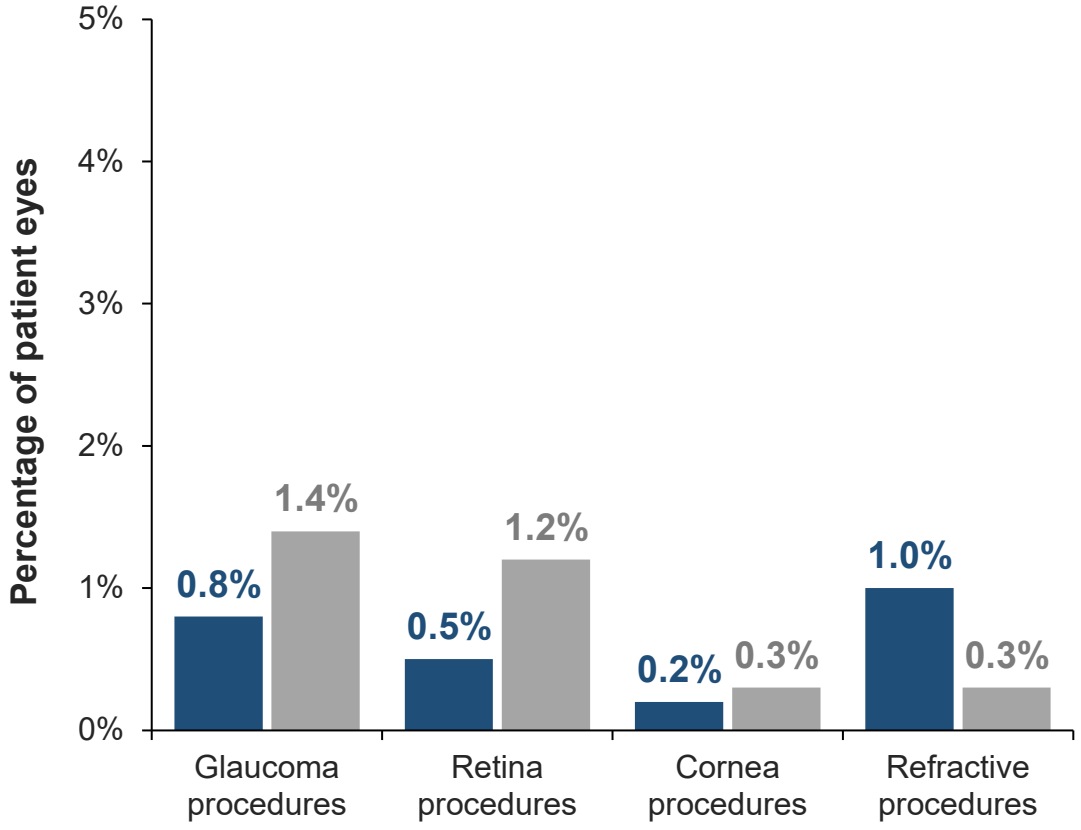
Preoperative Characteristics: Prior History of Inflammation Events and Ocular Procedures

History of Inflammation Events in the Prior 6 Months



	Anterior uveitis	Intermediate uveitis	Posterior uveitis	Other uveitis
DEX+, n (N=10,313)	28	0	3	3
DEX-, n (N=425,098)	1,776	38	241	194

Ocular Procedures in the Prior 6 Months

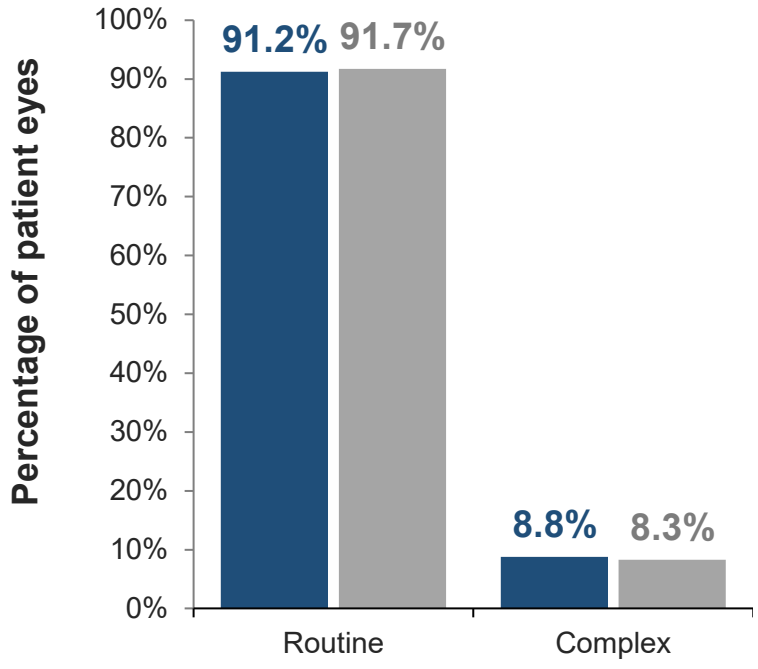


	Glaucoma procedures	Retina procedures	Cornea procedures	Refractive procedures
DEX+, n (N=10,313)	85	48	24	99
DEX-, n (N=425,098)	5,965	5,152	1,161	1,206

Intraoperative Characteristics: Cataract Surgery Type

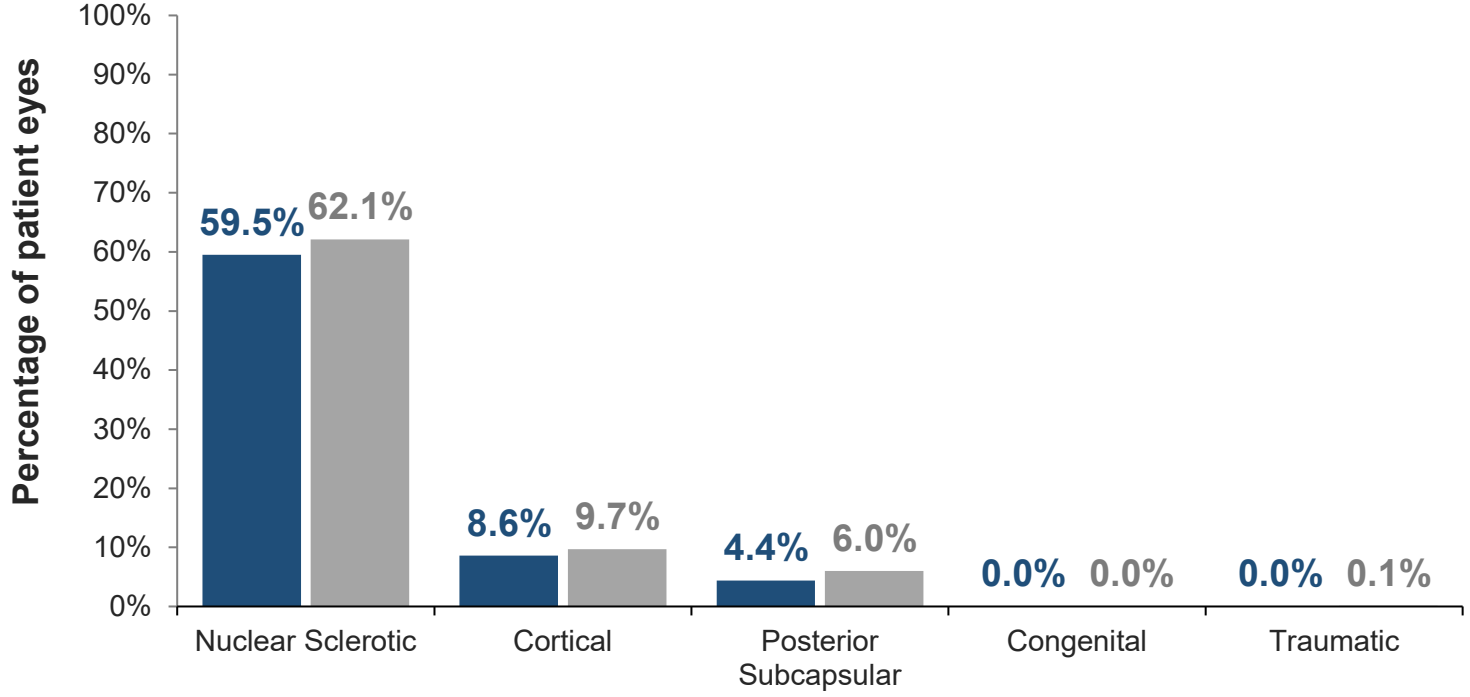
Intracanalicular dexamethasone use was comparable for cataract etiology and surgery type

Cataract Surgery Type



	Routine	Complex
DEX+, n (N=10,313)	9,410	903
DEX-, n (N=425,098)	389,632	35,466

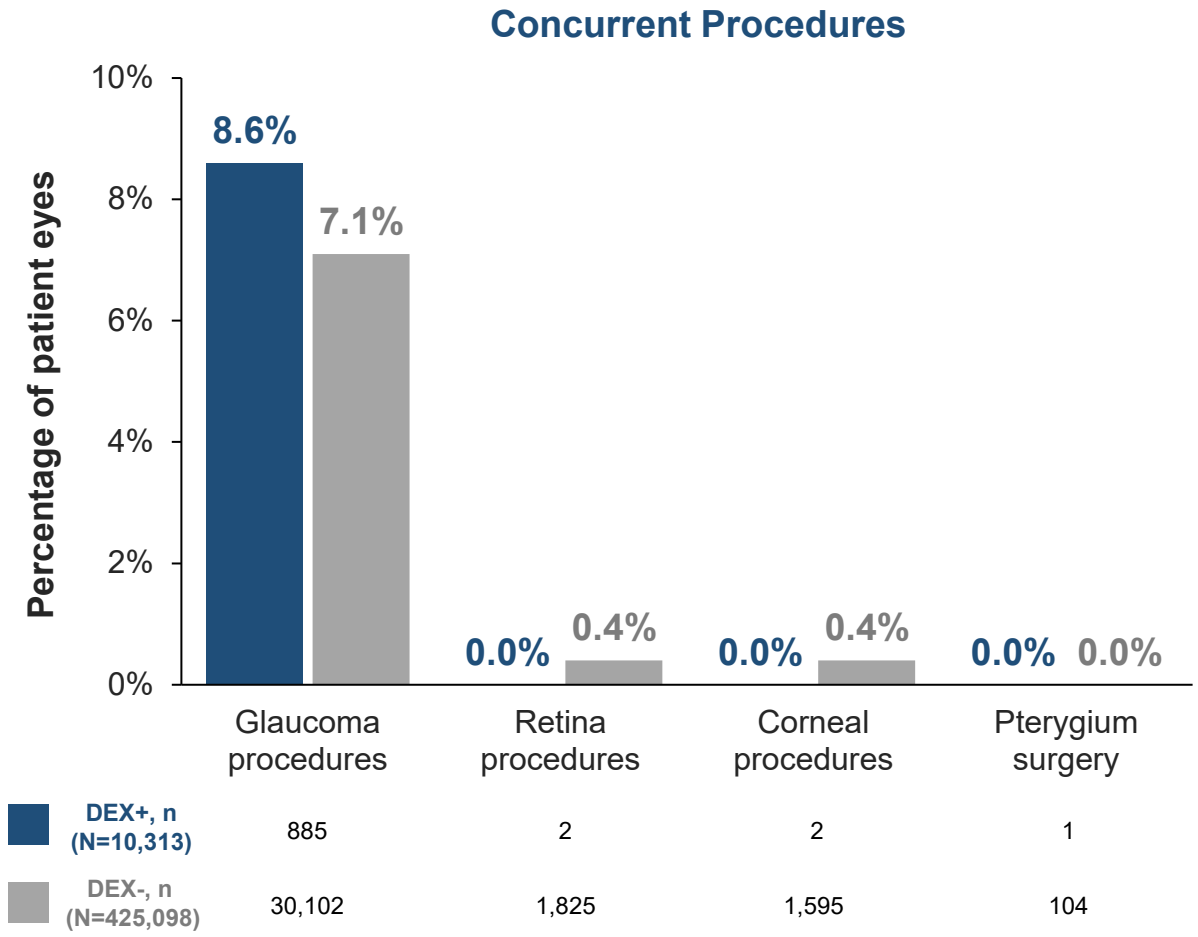
Cataract Type



	Nuclear Sclerotic	Cortical	Posterior Subcapsular	Congenital	Traumatic
DEX+, n (N=10,313)	6,138	885	450	5	3
DEX-, n (N=425,098)	263,865	41,438	25,676	161	462

Intraoperative Characteristics: Concurrent Procedures

8.6% of intracanalicular dexamethasone patients underwent concurrent glaucoma surgery on the same day as cataract surgery



Conclusions

- Current study is **the largest analysis** performed on patients treated with intracanalicular dexamethasone insert (**N=10,313 eyes**)
- Results identified demographics and pertinent clinical characteristics of **cataract surgery patients treated with intracanalicular dexamethasone from 2019 to 2021** that can help inform practice patterns
- Real-world data showed **more frequent use in patients with ocular surface diseases** suggesting a potential prescriber preference in patients with dry eye or ocular surface diseases
- Use of the sustained-release steroid insert was observed in **patients with glaucoma** or who underwent **combined cataract and glaucoma surgery**