Real-world Safety Analysis of an Intracanalicular Dexamethasone Insert Using the American Academy of Ophthalmology's IRIS® Registry (Intelligent Research in Sight)

Robert T. Chang, MD[1,2], Srilatha Vantipalli, PhD[3], Dina Akasheh, PhD[3], Matthew Cheung, PharmD[3], Aditi Bauskar, PhD[3], Sonya Li[2], Rabia Gurses-Ozden, MD[3], Michael H. Goldstein, MD[3]

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

AAO 2022 | Chicago, IL | September 30 to October 1, 2022

Disclosures

- **Presenter:** Robert T. Chang is a consultant for Verana Health.
- **Co-authors:** Srilatha Vantipalli, Dina Akasheh, Matthew Cheung, Aditi Bauskar and Rabia Gurses-Ozden are employees of Ocular Therapeutix. Sonya Li is an employee of Verana Health. Michael H. Goldstein is a consultant for Ocular Therapeutix.
- **Funding:** This research was supported by Ocular Therapeutix.
- **Acknowledgements:** Editorial assistance was provided by Cecelia Wall of Wall Medical Writing, LLC and funded by Ocular Therapeutix.

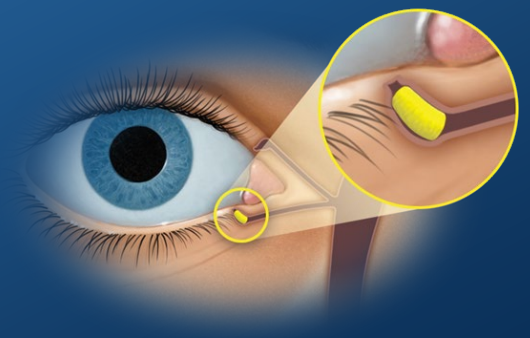
Introduction

Treating Postop Inflammation

- Topical steroids and NSAIDs are often used for perioperative treatment of intraocular inflammation[1]
- Newer approaches deliver corticosteroids via:[2-5]
  - Intracanalicular insert
  - Intraocular depot
  - Intravitreal implant
  - Subconjunctival injection

Intracanalicular Dexamethasone Insert (DEXTENZA)[2]

- Hydrogel insert that delivers 0.4 mg dexamethasone to the ocular surface in a tapered fashion for 30 days
- Antimicrobial preservative-free
- Resorbable; no need for removal
- FDA approved for the treatment postop ocular pain and inflammation in Nov 2018 and Jun 2019, respectively



Objective: To describe real-world safety outcomes of patients who underwent cataract surgery and did or did not receive intracanalicular dexamethasone insert (DEX)

References: 1. Juthani VV, et al. *Cochrane Database Syst Rev*. 2017;7(7):CD010516. **2.** DEXTENZA [prescribing information]. Bedford, MA: Ocular Therapeutix, Inc.; 2021. **3.** Donnenfeld E, et al. *Ophthalmology*. 2018;125(6):799-806. **4.** Li YT, et al. *Int J Ophthalmol*. 2021;14(2):317-322. **5.** Dieleman M, et al. *J Cataract Refract Surg*. 2011;37(9):1589-1597.

Methodology: A Retrospective Analysis of EHR Data using the Academy's IRIS Registry (Intelligent Research in Sight)

IRIS® Registry[a]

Total Unique Patients

73.85 million

Total Patient Visits

440.72 million

Total Ophthalmic Clinicians

15,601

Key Inclusion Criteria

- Underwent cataract surgery[b] from June 1, 2019 to March 31, 2021
- Intracanalicular dexamethasone[c] used within -2 to +7 days of cataract procedure

Key Exclusion Criteria

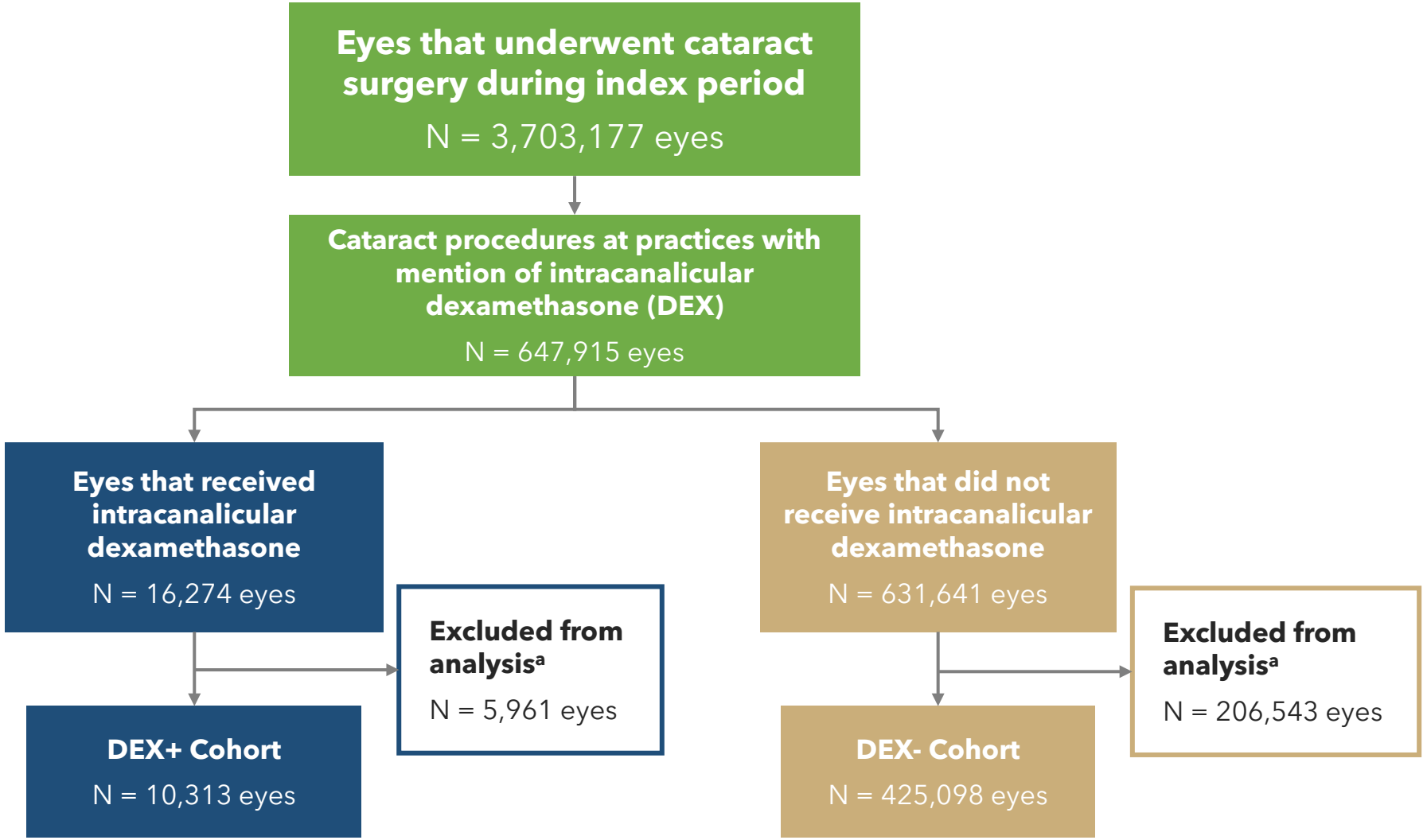
- Missing laterality for cataract surgery
- Missing patient demographic information
- Less than 1-month follow-up after cataract surgery
- Mention of dexamethasone intraocular suspension (DEXYCU®) in the procedure table

Safety Outcomes

- Incidence of inflammation events, corneal edema, CME, endophthalmitis, epiphora and lacrimal disorders[d]
- Intraocular pressure elevations and changes from baseline

[a] as of April 1, 2022
[b] defined as presence of CPT code 66984 or 66982
[c] defined as presence of J-code (J1096), C-code (C9048), CPT code (0356T), NDC number (70382-0204-01, 70382-204-10), or keywords indicated intracanalicular dexamethasone use (eg, "DEXTENZA", "dexamethasone, lacrimal ophthalmic insert", "intracanalicular dexamethasone", "lacrimal dexamethasone insert") in the procedural table
[d] identified by the presence of new ICD-10 codes

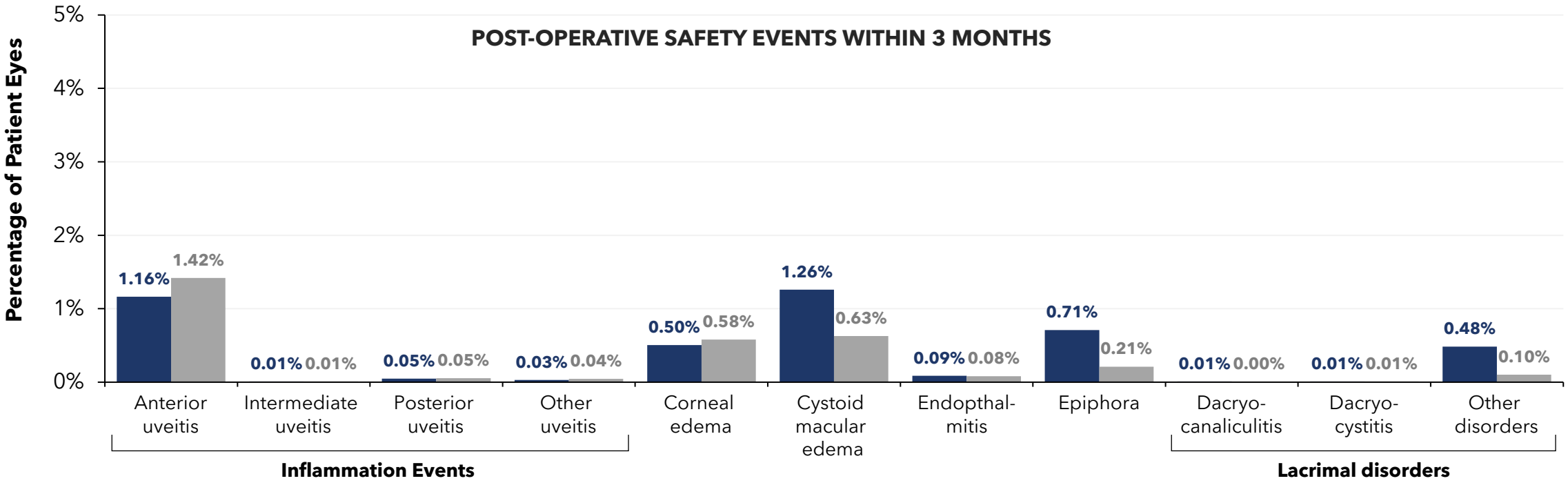
Study Population



[a] based on exclusion criteria: 1) Missing laterality for cataract surgery 2) Missing patient demographic information 3) Less than 1-month follow-up after cataract surgery 4) Mention of dexamethasone intraocular suspension (DEXYCU®) in the procedure table

Incidence of Post-operative Events

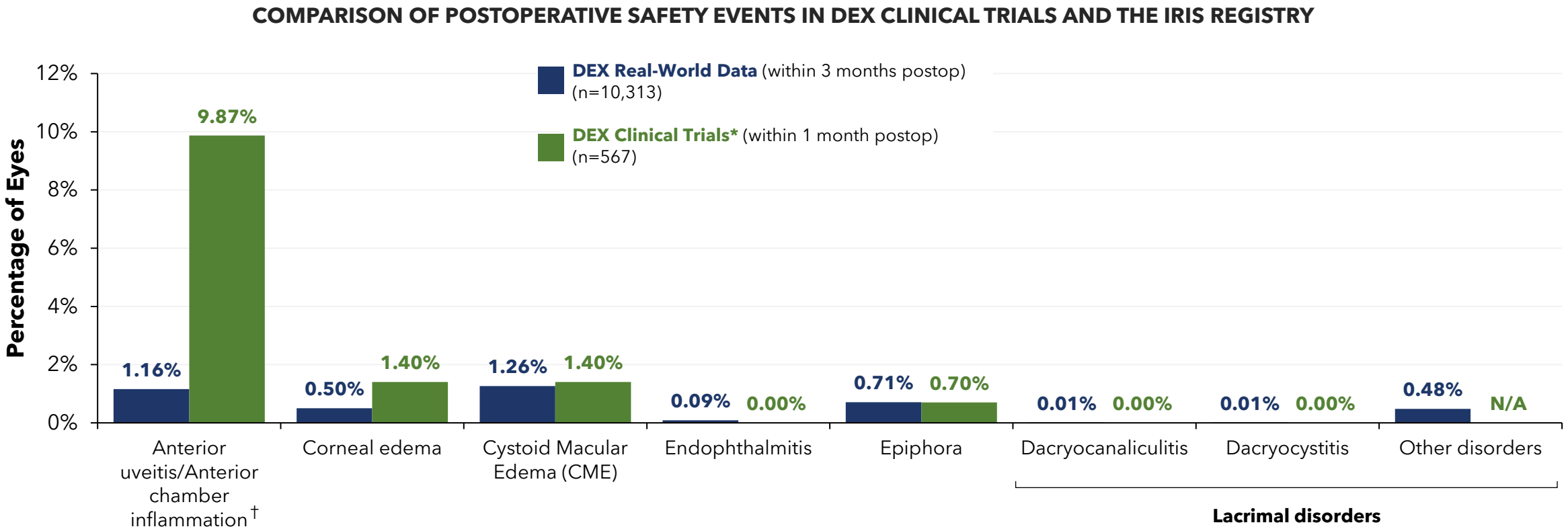
The overall incidence of inflammation events post-op was low and comparable between the DEX+ and DEX- cohorts



	Anterior uveitis	Intermediate uveitis	Posterior uveitis	Other uveitis	Corneal edema	Cystoid macular edema	Endopthal-mitis	Epiphora	Dacryo-canaliculitis	Dacryo-cystitis	Other disorders
DEX+, n (N=10,313)	120	1	5	3	52	130	9	73	1	1	50
DEX-, n (N=425,098)	6,028	38	223	189	2,467	2,673	338	899	16	31	432

Real-world Post-operative Safety Events vs. Clinical Trials

Anterior uveitis and corneal edema were documented less frequently in the real world than observed in clinical trials

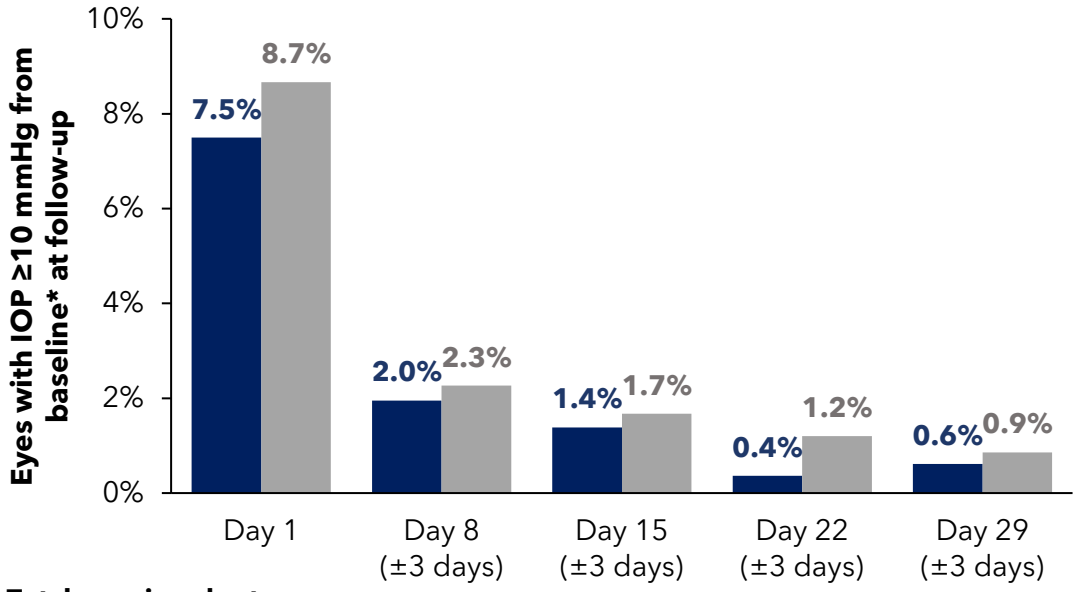


* Incidences of safety events from DEX Clinical Trials were pooled from one Phase 2 (NCT01666210) and three Phase 3 (NCT02034019, NCT02089113, and NCT02736175) clinical trials in cataract surgery subjects
† Anterior chamber inflammation reported in DEX clinical trials included iritis and iridocyclitis

Intraocular Pressure: Patients *without* Prior History of Glaucoma

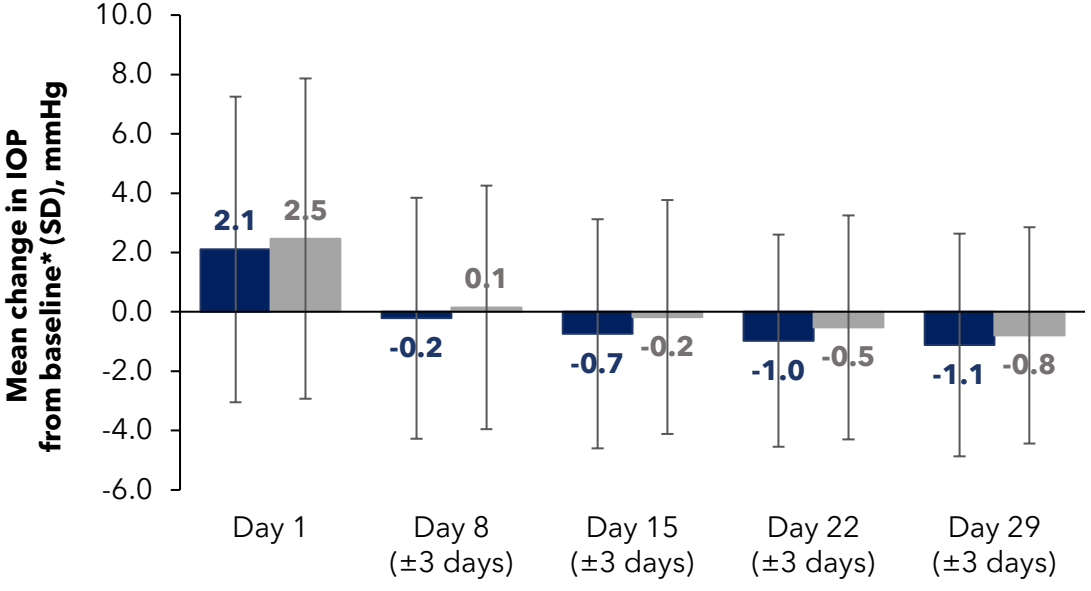
In patients without glaucoma, rates of IOP elevation ≥10 mmHg were comparable between the DEX+ & DEX- cohort and more frequent on post-op day 1

PERCENTAGE OF EYES WITH IOP ≥10 MMHG FROM BASELINE AT FOLLOW-UP



Total eyes in cohort	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX+	4,696	3,331	1,881	1,386	1,307
DEX-	170,661	118,264	67,566	51,960	52,260

CHANGE FROM BASELINE IOP IN PATIENTS WITHOUT HISTORY OF GLAUCOMA

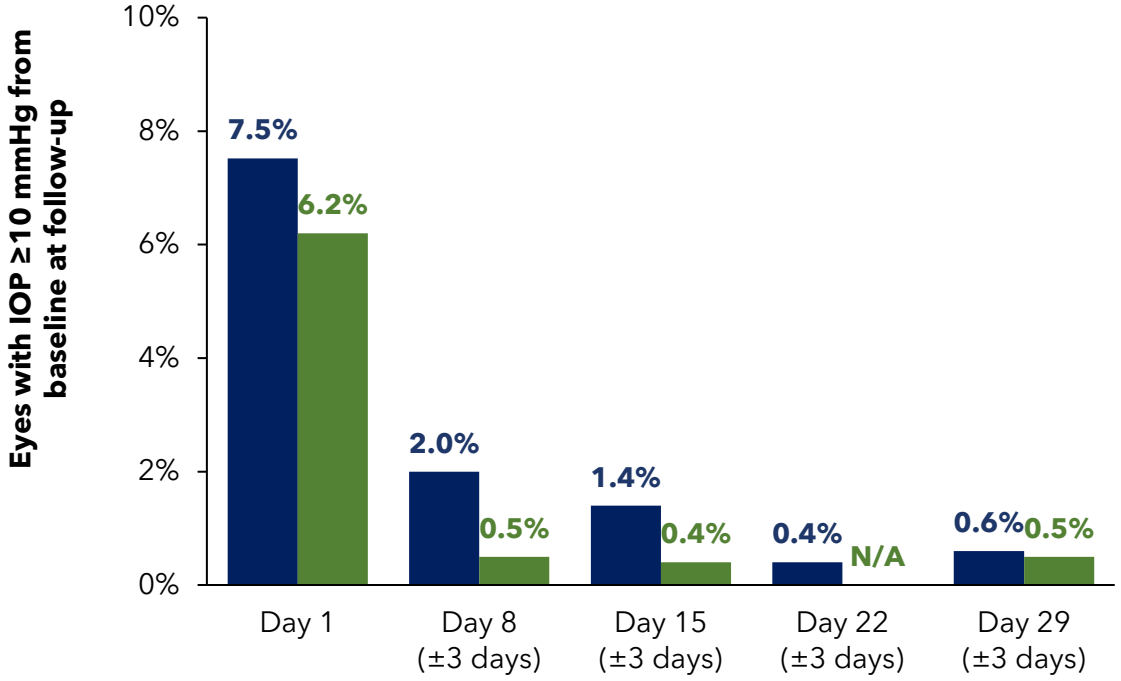


	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX+	4,696	3,331	1,881	1,386	1,307
DEX-	170,661	118,264	67,566	51,960	52,260

*Baseline IOP calculated as the average of the two most recent IOP assessments up to 6 months pre-index. If only one pre-index assessment is available, that IOP measurement is the baseline IOP.

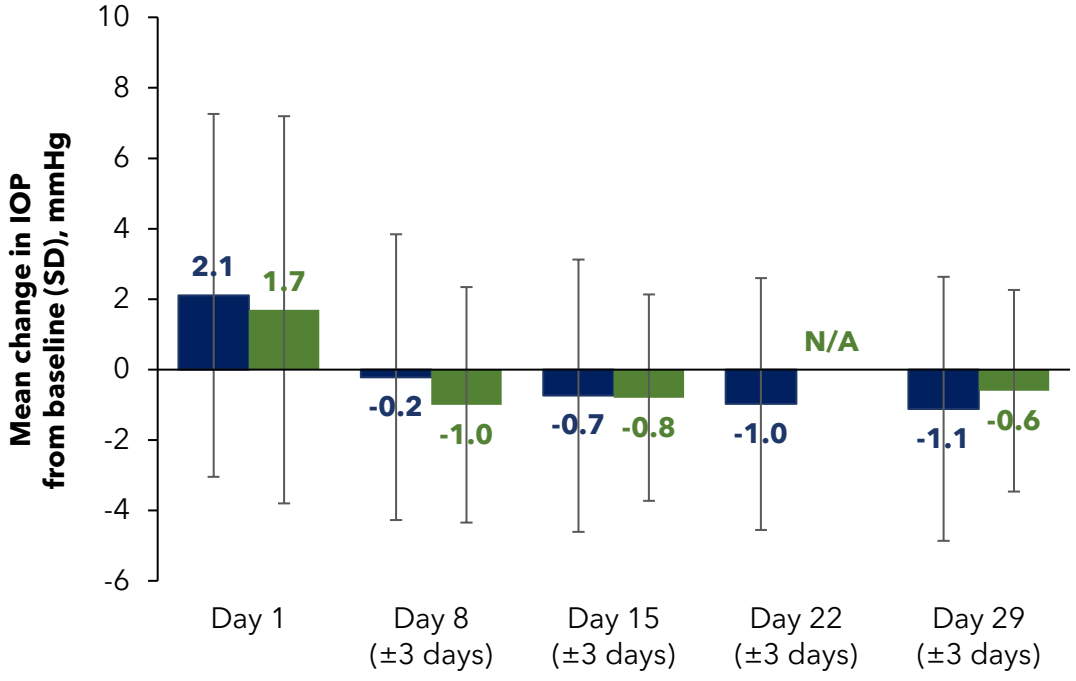
Intraocular Pressure: Real-world vs. Clinical Trial Data in Patients without Glaucoma

PERCENTAGE OF EYES WITH IOP ≥10 MMHG FROM BASELINE AT FOLLOW-UP



Total eyes in cohort	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX Real-World*	4,696	3,331	1,881	1,386	1,307
DEX Clinical Trials†	567	565	565	N/A	562

CHANGE FROM BASELINE IOP IN PATIENTS WITHOUT HISTORY OF GLAUCOMA

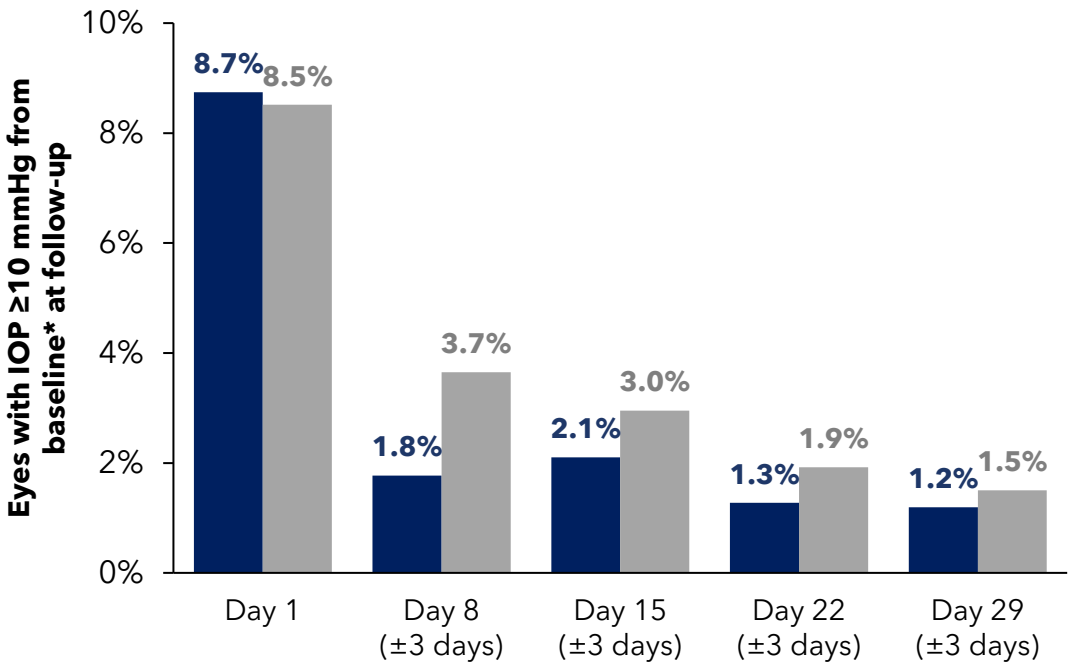


	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
	4,696	3,331	1,881	1,386	1,307
	567	565	565	N/A	562

* Baseline IOP calculated as the average of the two most recent IOP assessments up to 6 months pre-index. If only one pre-index assessment is available, that IOP measurement is the baseline IOP.
† Clinical trials of DEX excluded subjects with a history of glaucoma or ocular hypertension

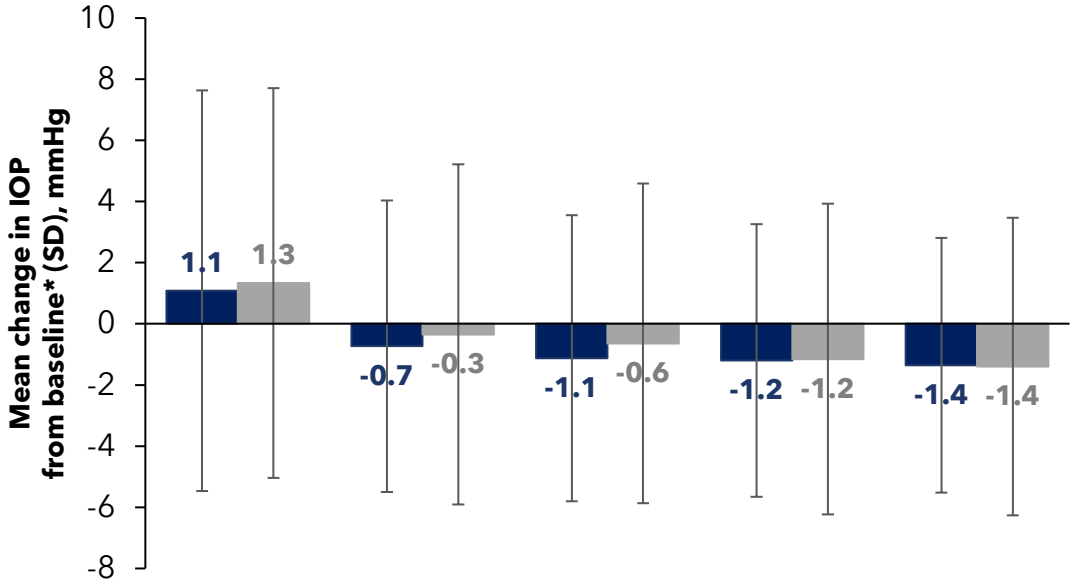
Intraocular Pressure: Patients *with* Prior History of Glaucoma

PERCENTAGE OF EYES WITH IOP ≥10 MMHG FROM BASELINE AT FOLLOW-UP



Total eyes in cohort	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX+	1,578	1,129	713	548	503
DEX-	64,498	46,449	27,620	21,931	21,996

CHANGE FROM BASELINE IOP IN PATIENTS WITH HISTORY OF GLAUCOMA



	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX+	1,578	1,129	713	548	503
DEX-	64,498	46,449	27,620	21,931	21,996

*Baseline IOP calculated as the average of the two most recent IOP assessments up to 6 months pre-index. If only one pre-index assessment is available, that IOP measurement is the baseline IOP.

Conclusions

- Current study is the largest analysis performed on patients treated with intracanalicular dexamethasone insert (N=10,313 eyes)
- **Incidence of inflammatory events, corneal edema, CME, endophthalmitis, epiphora, lacrimal disorders including dacryocanaliculitis and dacryocystitis in DEX patients were low**
- Real world data shows anterior uveitis and corneal edema were less frequently documented compared to clinical trials
- Percentage of patients with **IOP elevations ≥10 mmHg was comparable in DEX+ and DEX- eyes** with or without preexisting glaucoma
- Real-world data of treatment with DEX in cataract surgery patients can help inform post-market safety profile