Real-World Safety Analysis of an Intracanalicular Dexamethasone Insert Using the IRIS® Registry (Intelligent Research in Sight)

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

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

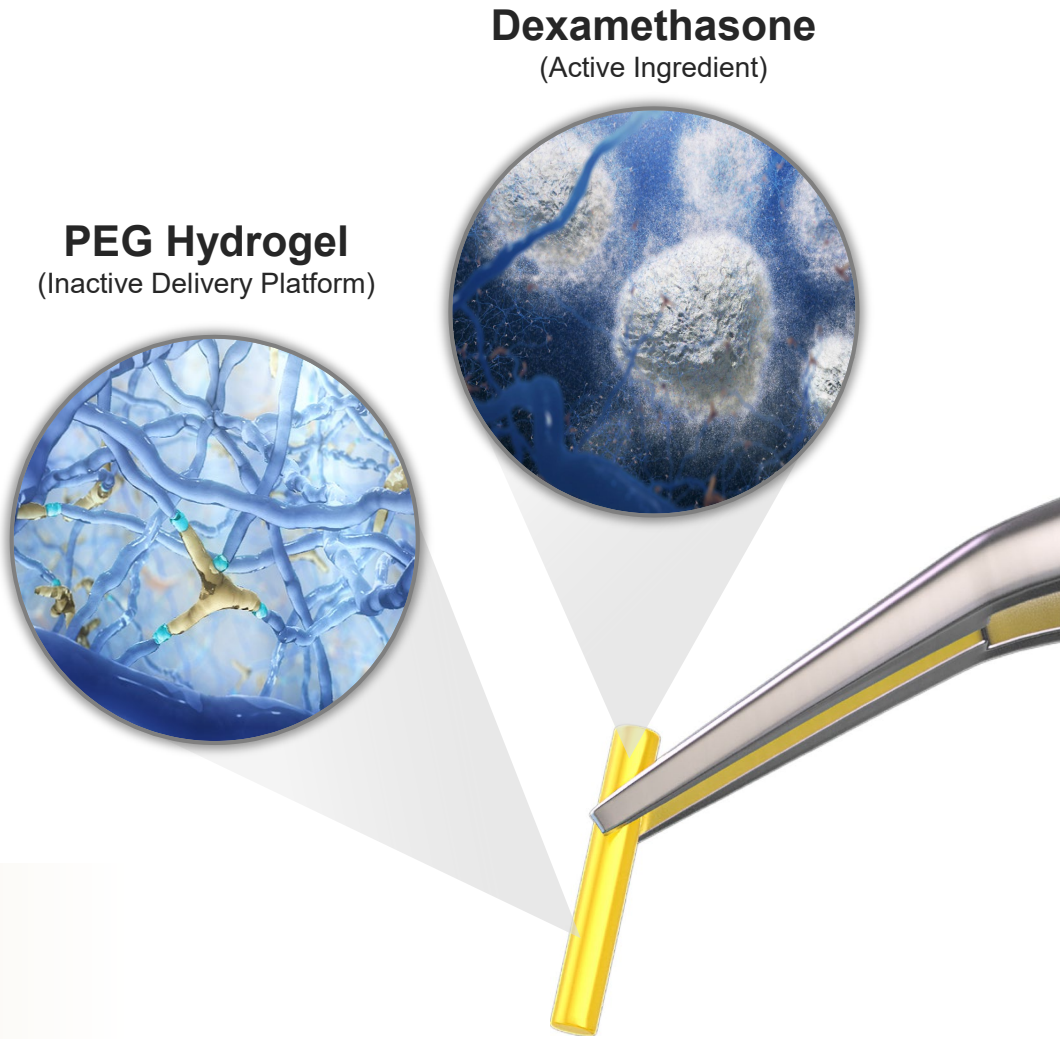
ASCRS ANNUAL MEETING | April 23-26, 2022 | Washington, DC

Disclosures

- **Presenter:** Robert Chang is a consultant for Verana Health.
- **Co-authors:** Srilatha Vantipalli, Dina Akasheh, Matthew Cheung, and Michael H. Goldstein are employees of Ocular Therapeutix. Meghan Hatfield, Andrew LaPrise, Michael Mbagwu, and Sonya Li are employees of Verana Health.
- **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.

Background

- Topical steroids and NSAIDs are often used to prevent and treat postoperative inflammation and pain following ophthalmic surgery[1]
- **Intracanalicular Dexamethasone Insert (DEXTENZA)[2]: Alternative to Topical Steroid Drops**
  - Hydrogel-based insert that releases dexamethasone to the ocular surface in a tapered fashion over 30 days
  - Preservative-free
  - Resorbable; no need for removal
  - FDA-approved for the treatment of:
    - Postop ocular inflammation and pain
    - Ocular itching associated with allergic conjunctivitis



Research Question: What is the safety profile of DEX when used in real-world clinical practice?

References: 1. Juthani VV, et al. *Cochrane Database Syst Rev*. 2017;7(7):CD010516. **2.** DEXTENZA [prescribing information]. Bedford, MA; Ocular Therapeutix, Inc.; 2021.

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

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

Key Inclusion Criteria

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

Key Exclusion Criteria

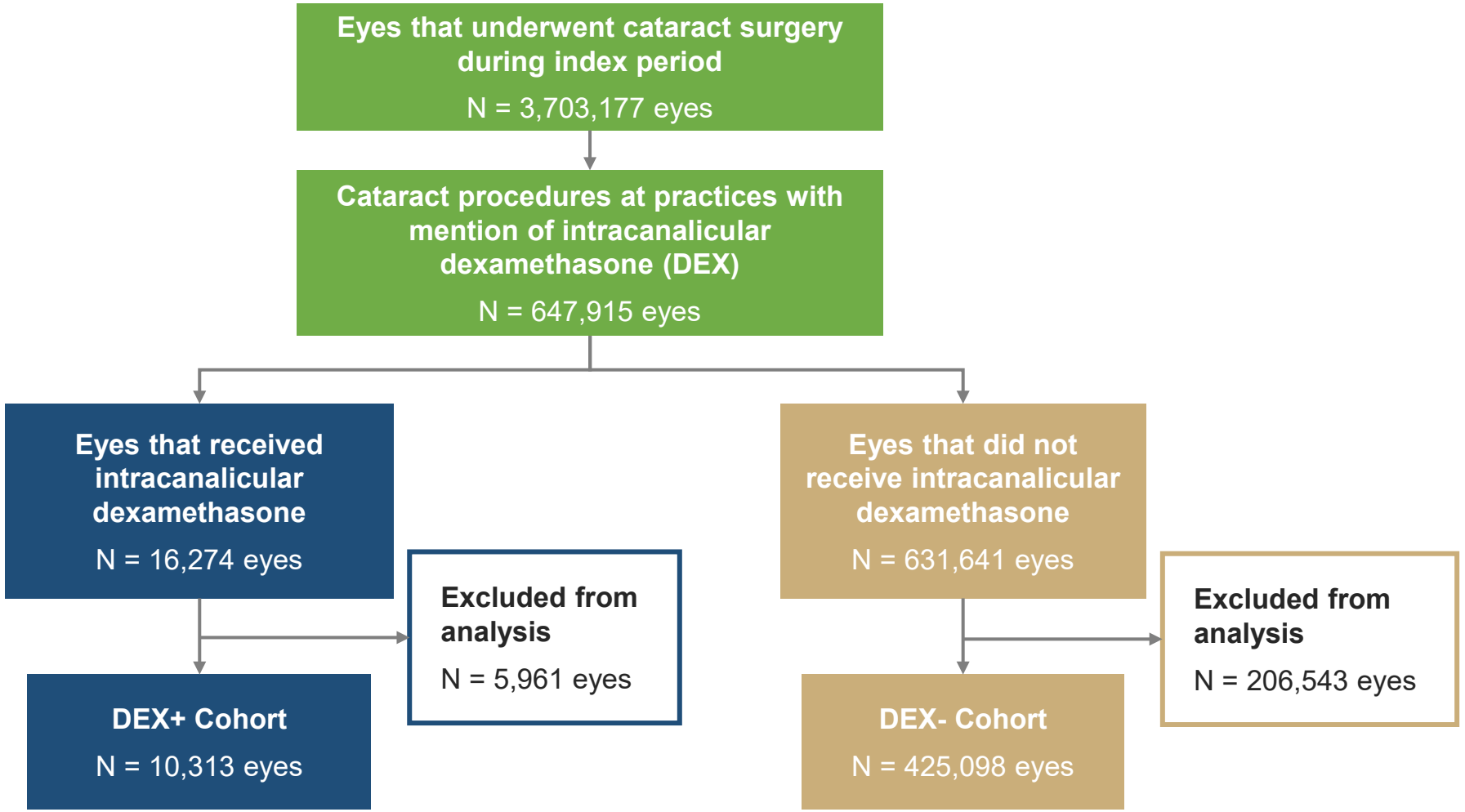
- Missing laterality for cataract surgery
- Missing patient demographic information
- Less than 1-month follow-up after cataract surgery
- Mention of dexamethasone intraocular suspension (DEXYCU®) in the procedure table

Safety Outcomes

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

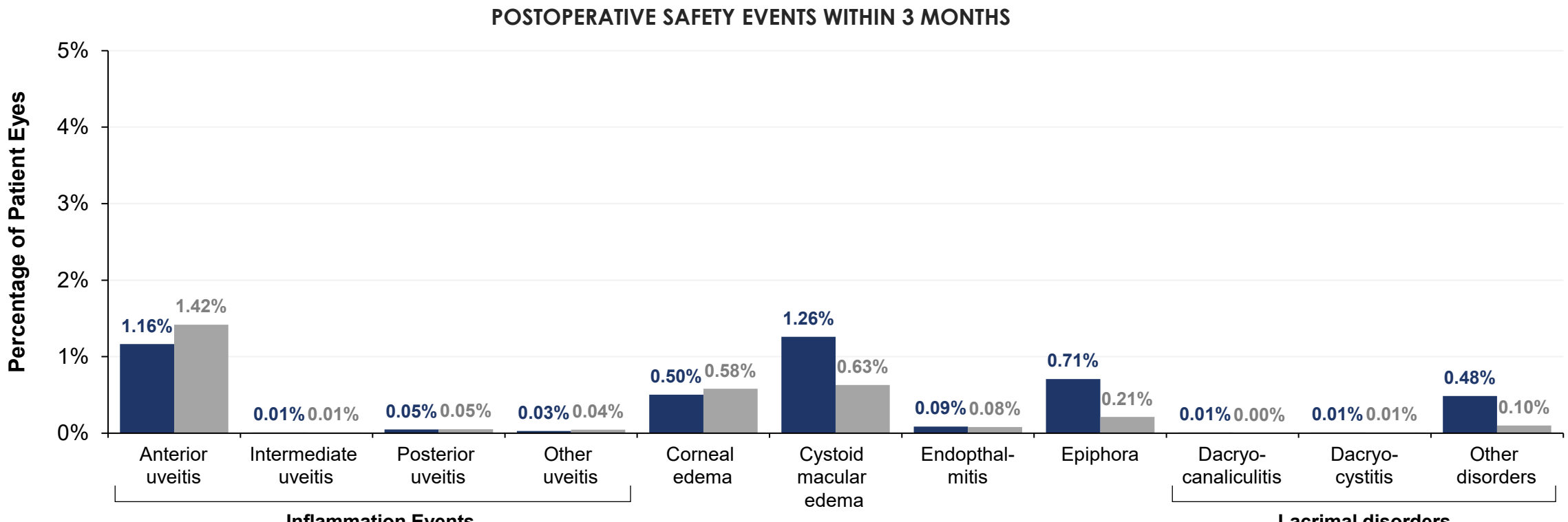
[a] defined as presence of CPT code 66984 or 66982
[b] defined as presence of J-code (J1096), C-code (C9048), CPT code (0356T), NDC number (70382-0204-01, 70382-204-10), or keywords indicated intracanalicular dexamethasone use (eg, “DEXTENZA”, “dexamethasone, lacrimal ophthalmic insert”, “intracanalicular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

Study Population



Incidence of Post-Operative Events

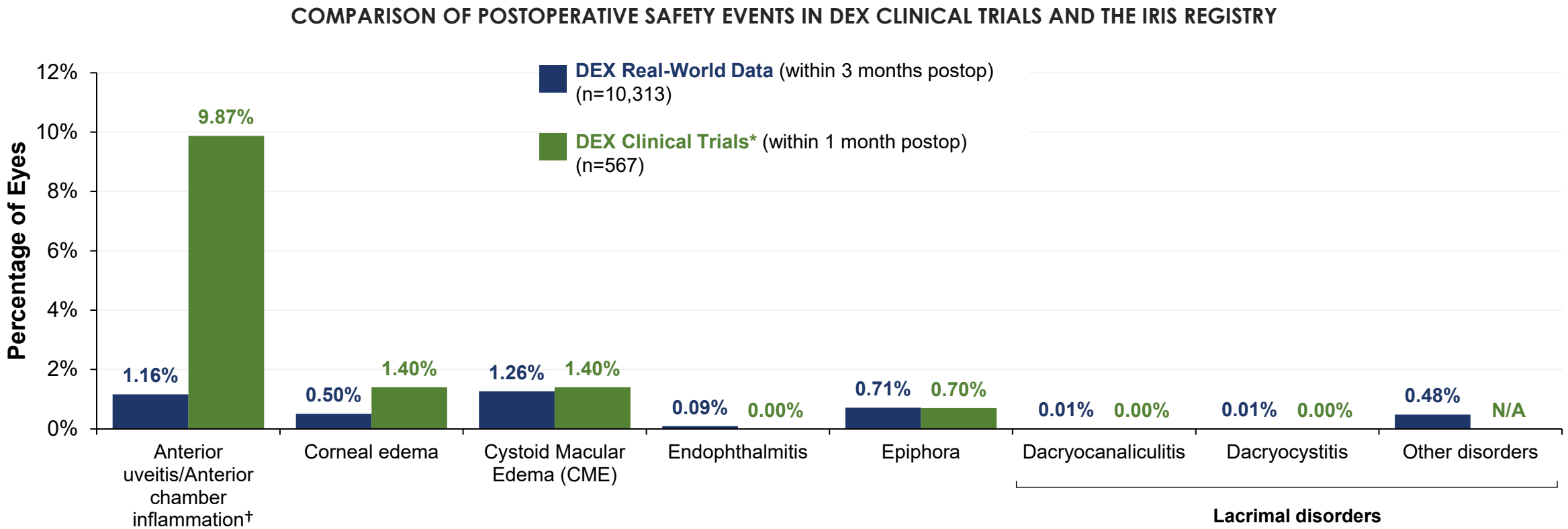
The overall incidence of inflammation events post-op was low and comparable between the DEX+ and DEX- cohorts



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

Post-Operative Safety Events in Real World vs Clinical Trials

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



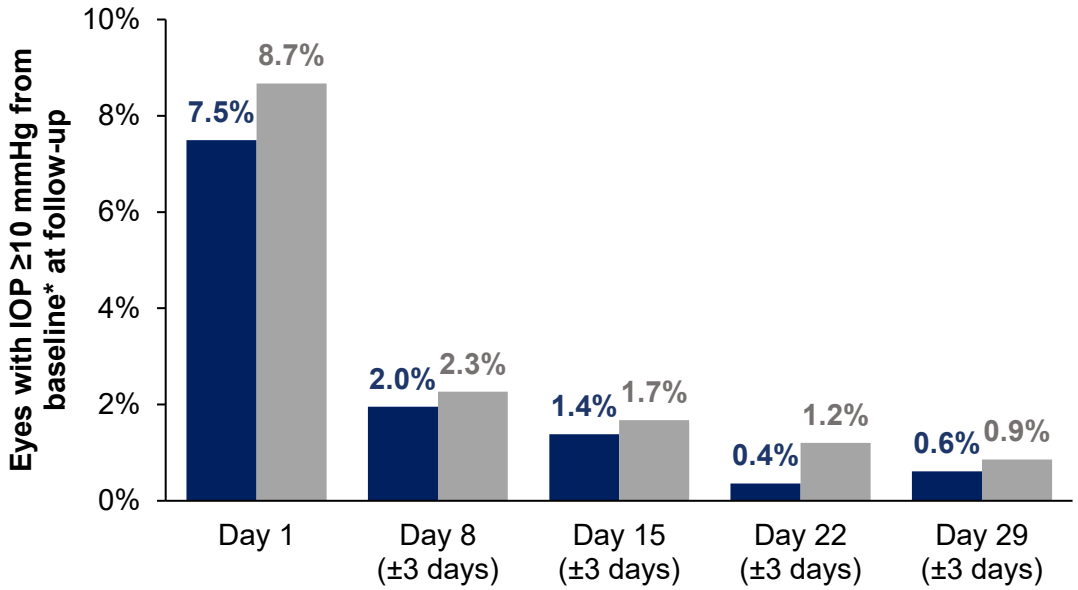
* Incidences of safety events from DEX Clinical Trials were pooled from one Phase 2 (NCT01666210) and three Phase 3 (NCT02034019, NCT02089113, and NCT02736175) clinical trials in cataract surgery subjects

† Anterior chamber inflammation reported in DEX clinical trials included iritis and iridocyclitis

Intraocular Pressure: No Prior History of Glaucoma

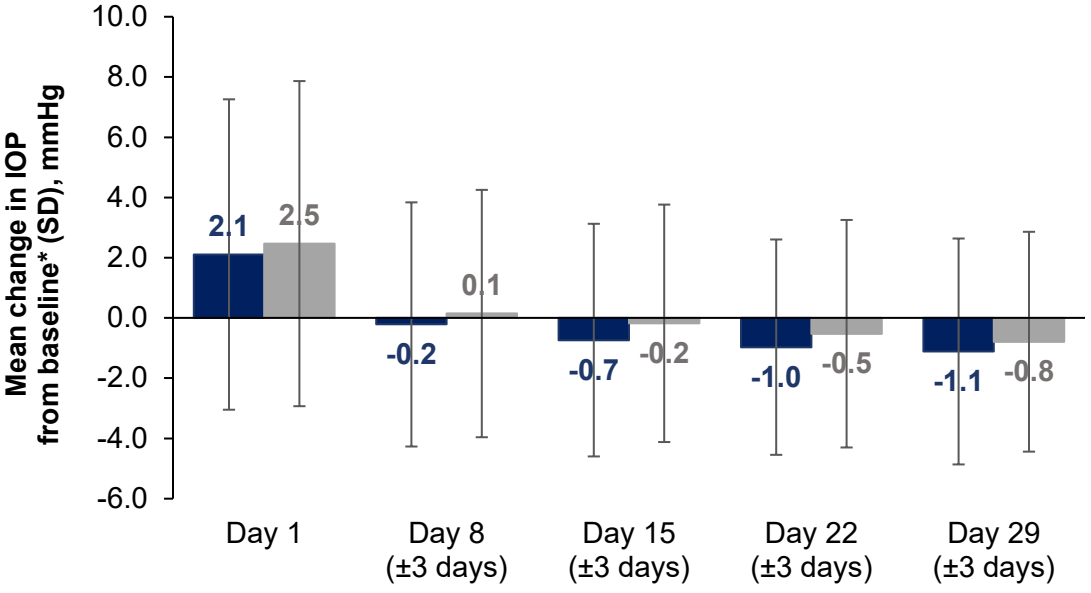
In patients without glaucoma, rates of IOP elevation ≥10 mmHg were comparable between the DEX+ & DEX- cohort and more frequent on post-op day 1

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

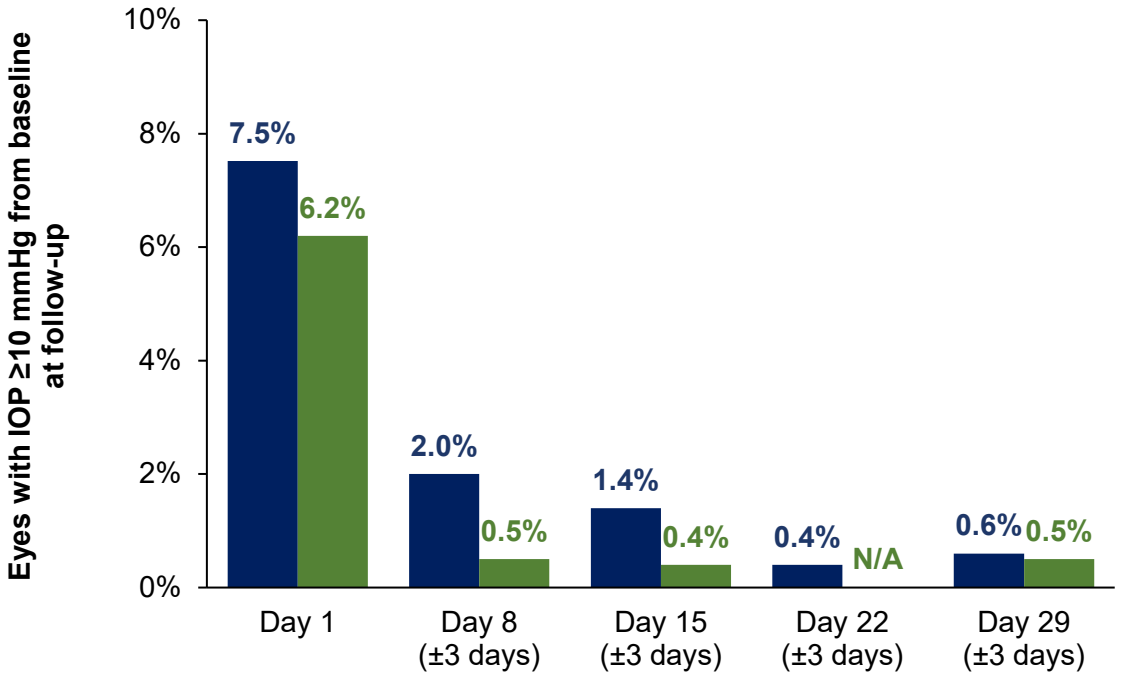


	Day 1	Day 8 (±3 days)	Day 15 (±3 days)	Day 22 (±3 days)	Day 29 (±3 days)
DEX+	4,696	3,331	1,881	1,386	1,307
DEX-	170,661	118,264	67,566	51,960	52,260

*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. IOP outcomes were consistent between patients with or without glaucoma: rates of IOP elevation ≥10 mmHg in eyes with glaucoma were comparable between both cohorts and more frequent on postop day 1 (data not presented)

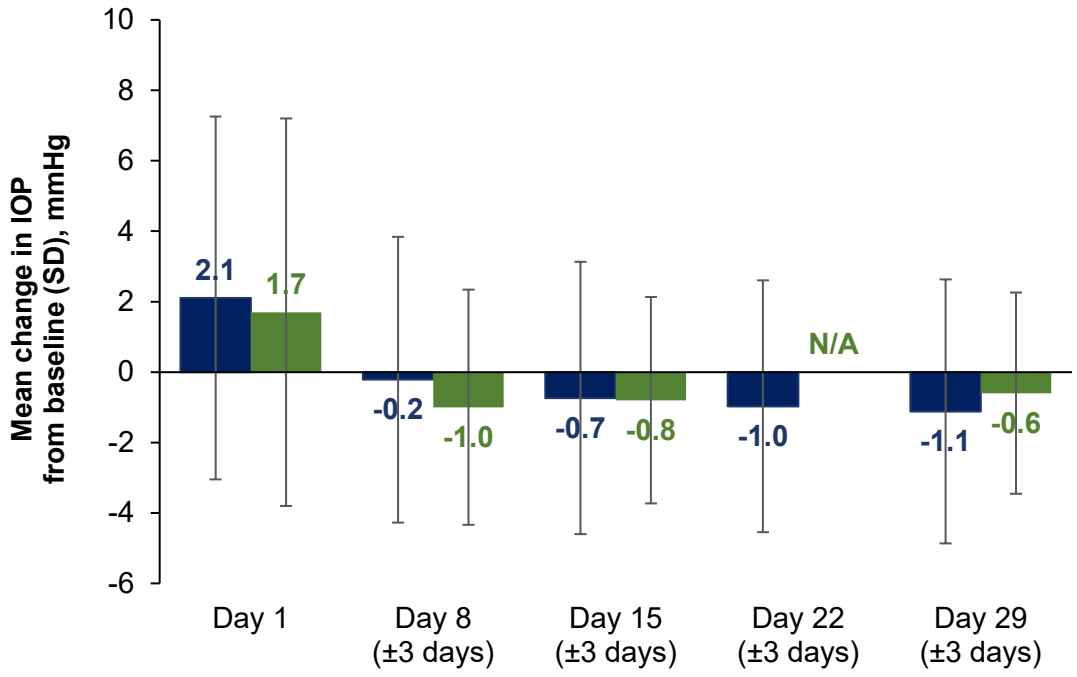
IOP: Real-World vs Clinical Trial Data in Patients without Glaucoma

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)
DEX Real-World	4,696	3,331	1,881	1,386	1,307
DEX Clinical Trials	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

Real World DEXTENZA Safety Conclusions

- Current study is the largest analysis performed on patients treated with intracanalicular dexamethasone insert (N=10,313 eyes)
- **Incidences of inflammatory events, corneal edema, CME, endophthalmitis, epiphora, lacrimal disorders 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 glaucoma
- Real-world data of treatment with DEX in cataract surgery patients can help inform post-market safety