

Understanding Real-World Patient Characterization and Safety Outcomes of DEXTENZA

Ocular Therapeutix engaged with Verana Health to understand real-world patient demographics, clinical characteristics and safety profile of their corticosteroid ophthalmic insert.

Ocular Therapeutix wanted to better understand the real-world usage and safety profile of their Intracanalicular Dexamethasone Insert (DEXTENZA) using the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight). The life sciences company wanted to compare postoperative safety events in the real world versus their clinical trials, as well as to understand patient preoperative demographics. These included patient ocular comorbidities, history of ocular inflammation, and ocular procedures. The company was also interested in learning which other surgeries DEXTENZA was being used for when in combination with cataract surgery (i.e. MIGS).

Effort by Verana Health:

Verana Health helped identify a cohort of de-identified patients for analysis who underwent cataract surgery at practices who use DEXTENZA and are in the IRIS Registry.

DEXTENZA is an alternative to traditional steroid eye drops and is FDA approved for:

- Postoperative pain and inflammation following ocular surgery
- Ocular itching associated with allergic conjunctivitis

The Verana Health and Ocular Therapeutix teams collaborated to identify criteria for this study protocol. The study population included those who underwent cataract surgery from the time of the DEXTENZA launch in June 2019 through March 2021, and was then filtered to only include patients treated in practices that use DEXTENZA.

Some of this study period was prior to the approval of DEXTENZA's unique J code, so the teams generated a list of keywords or phrases in the electronic health record (EHR) notes that would inform the use of their product. Using natural language processing, Verana Health was able to curate the data from the unstructured notes to identify these patients at scale. Once the study cohort was defined, several key clinical characteristics and outcomes were evaluated in both the patients who received DEXTENZA and those who did not.

Study Population

3.7M+ Eyes
underwent cataract
surgery during index
period

10,313 Eyes
in final study cohort
received DEXTENZA

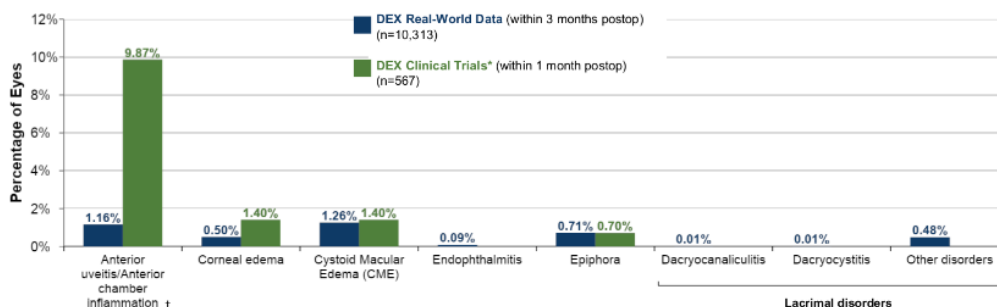
Results:

This study is the largest analysis performed on patients treated with DEXTENZA. The learnings help inform practice patterns and postmarketing safety studies.

Safety: The study found that the incidence of post-operative inflammatory events in DEXTENZA patients were low. Specifically, anterior uveitis and corneal edema were documented less frequently in the real world than observed in clinical trials.

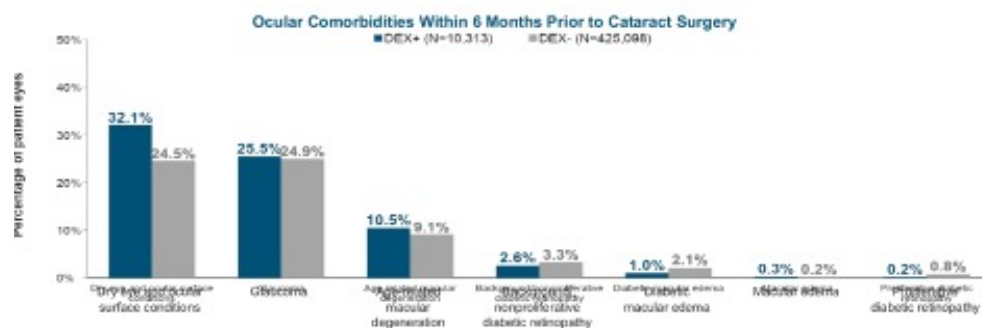


COMPARISON OF POSTOPERATIVE SAFETY EVENTS IN DEX CLINICAL TRIALS AND THE IRIS REGISTRY



* 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

Demographics & Clinical Characteristics: Patients who received DEXTENZA in this study were an average of 73.4 years old, 59.4% female, and 74.6% Medicare beneficiaries. Real-world data showed more frequent use of DEXTENZA in patients with ocular surface diseases, which suggests a potential prescriber preference in patients with those conditions.



“This data has been invaluable in providing additional information about the safety of Dextenza post-marketing.”

Srilatha Vantipalli

Sr. Director, Internal Medical Affairs
Ocular Therapeutix

Understanding baseline patient demographics, clinical characteristics, surgery type, and the safety profile of this therapy helped Ocular Therapeutix better understand how DEXTENZA was being used in the real-world. This can help inform how the company works with clinicians and inform their postmarketing safety and commercialization strategies.

This study was refreshed to extend the study period from March 2021 to November 2022. This extended time period resulted in an additional 43,300 patients and 118 practices, compared to the previous report. The clinical findings were generally consistent with the initial report and the study further characterized DEXTENZA's use in a variety of other procedures and in combination with an intraoperative medication.

About Verana Health

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