

# Incidence of Endophthalmitis Following Routine or Complex Cataract Surgery in Practices With and Without Access to Hydrogel Sealant: Retrospective Study Using the IRIS Registry

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# Disclosures

- This study was funded by Ocular Therapeutix
- **MH Goldstein, JL Metzinger, S Vantipalli,** and **N Oliynyk** are employees of Ocular Therapeutix, Inc.
- **H Fevrier** is an employee of Verana Health
- **AA Moshfeghi**
  - Ocular Therapeutix – consultant, personal financial interest
  - Allergan – consultant
  - Allegro – consultant, financial support
  - Genentech – consultant, financial support
  - Graybug – consultant
  - Novartis – consultant, financial support
  - OptiSTENT – personal financial interest
  - Pr3vent – consultant, personal financial interest
  - Placid0 – personal financial interest
  - Regeneron – consultant, financial support

# Endophthalmitis Following Cataract Surgery

**Endophthalmitis after cataract surgery is a rare but vision-threatening event with an incidence of ~0.5 to 2.15 per 1,000 surgeries.<sup>1,2</sup>**

- Necessitates a large sample size to conduct meaningful studies

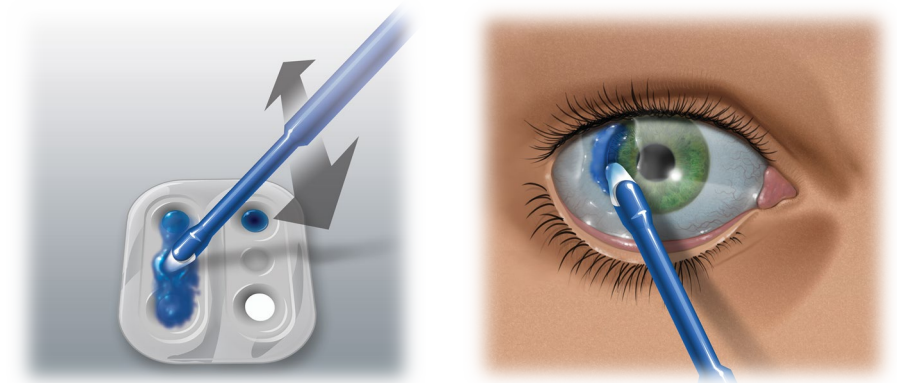
## **American Academy of Ophthalmology IRIS<sup>®</sup> (Intelligent Research In Sight) Registry<sup>3</sup>**

- Clinical registry with aggregated real-world data from nearly 60 million unique patients
- Approximately 16,000 ophthalmology clinicians contribute data to the registry through an electronic health record

**The IRIS Registry is an ideal database to assess rare events like endophthalmitis following cataract surgery**

### **ReSure<sup>®</sup> Sealant**

A hydrogel sealant that creates an in situ temporary, soft surface barrier to prevent wound leakage from clear corneal incisions (up to 3.5mm) after cataract surgery<sup>4</sup>



Rendering of mixing and applying ReSure Sealant

# Study Objective and Design

## Study Design

- Retrospective study
- Data from the IRIS Registry with analyses conducted by Verana Health

## Key Inclusion Criteria

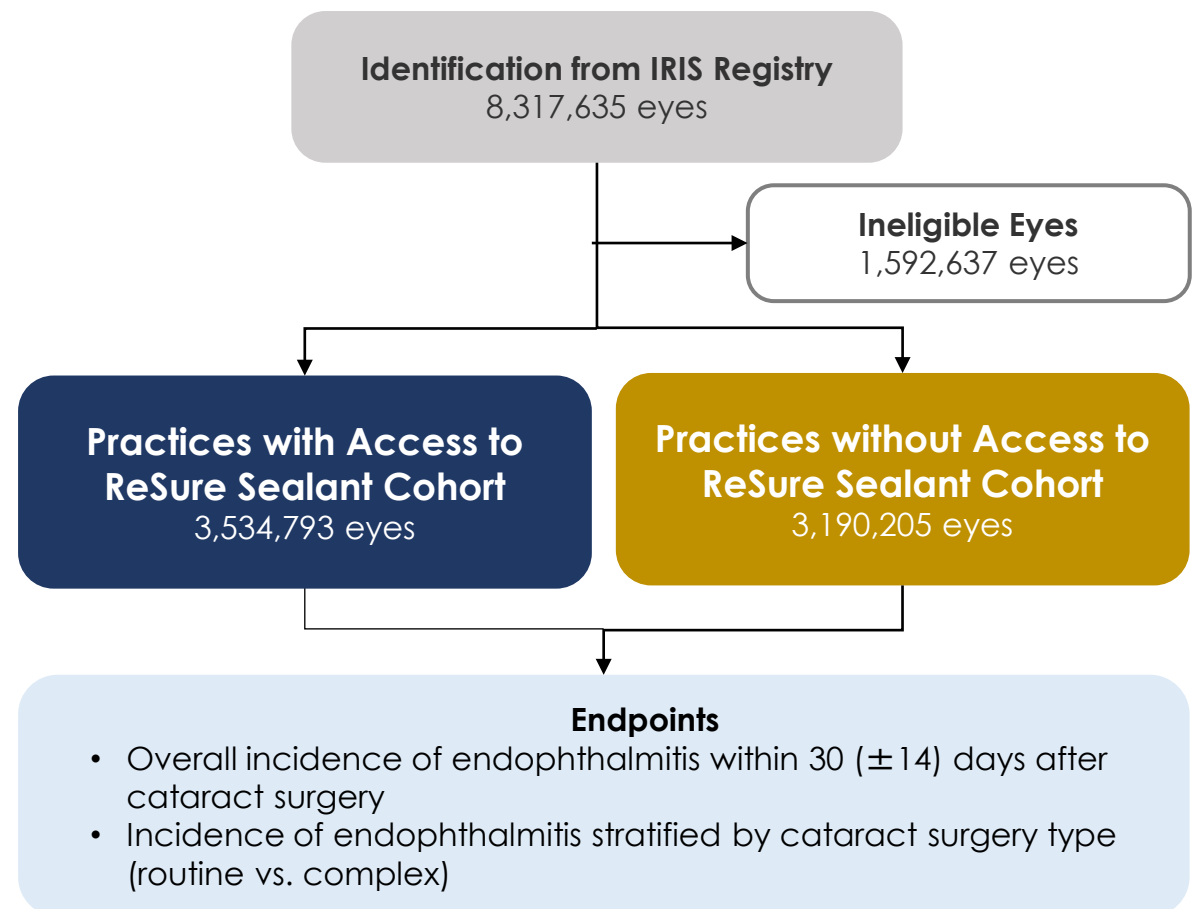
- Extracapsular cataract removal with insertion of intraocular lens prosthesis between January 1, 2016 and December 1, 2019
- Patients  $\geq 22$  years old and have at least one visit within 30 ( $\pm 14$ ) days after surgery
- Practices must have provided data for at least 30 days after each surgery

## Primary Objective

- To compare the incidence of endophthalmitis within 30 days of any cataract surgery between sites with and without access to ReSure Sealant

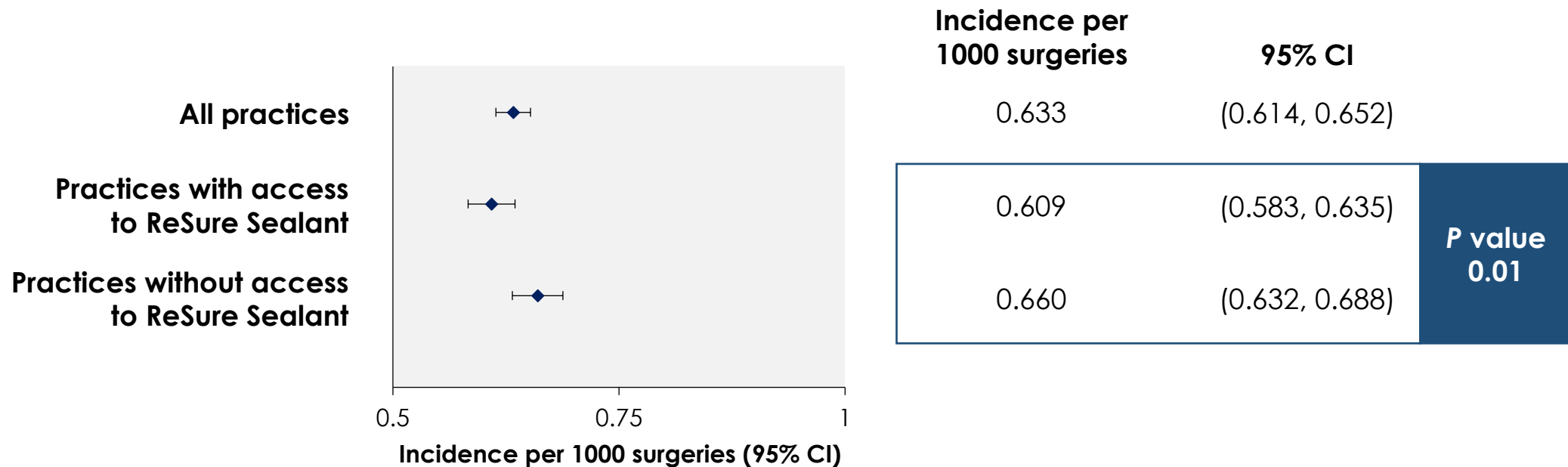
## Data Analysis

- Given the large sample size, P value for statistical significance was  $P < 0.001$



# Overall Incidence of Endophthalmitis

- A total of 4,259 cases of endophthalmitis with prespecified laterality were identified within 30 days after cataract surgery\*
- **Incidence of endophthalmitis post-cataract surgery was 0.633** per 1,000 cataract surgeries in 2016-2019
- **No clinically meaningful difference** (i.e., doubling) in incidence rate of endophthalmitis was found between eyes treated at practices with and without access to ReSure Sealant

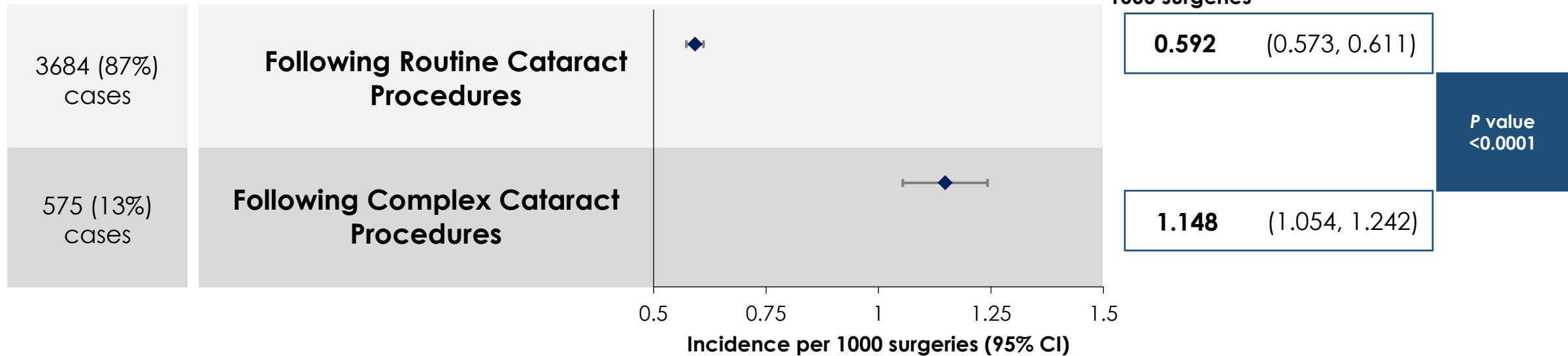


\* ±14 day window

# Incidence of Endophthalmitis Stratified by Cataract Surgery Type

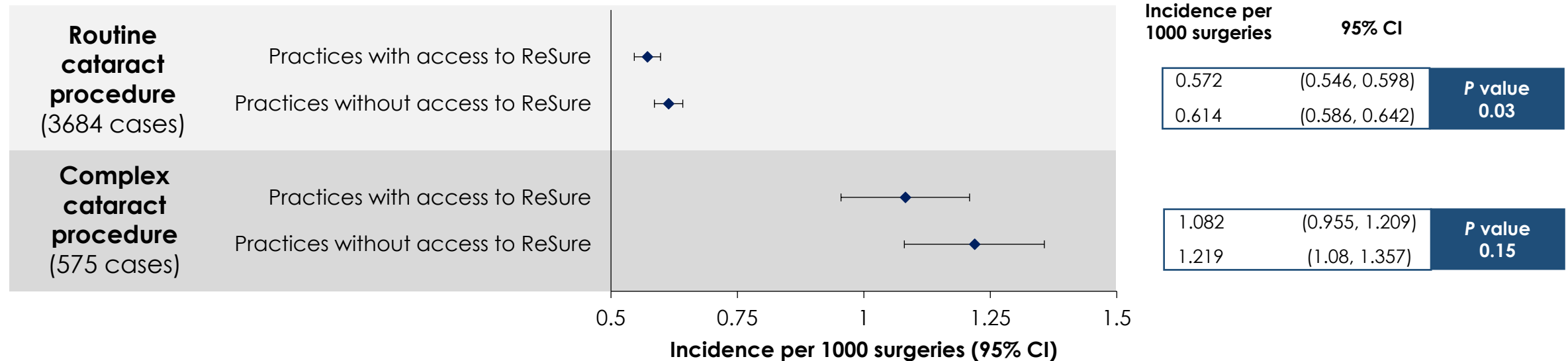
- Overall incidence of endophthalmitis per 1,000 surgeries was **significantly greater following complex cataract procedures when compared to routine procedures (1.148 vs 0.592; P<0.0001)**

Of 4259 endophthalmitis cases identified



# Incidence of Endophthalmitis Stratified by Cataract Surgery Type for Cohorts with & without Access to ReSure

- There was **no clinically meaningful difference** in endophthalmitis incidence between the cohort with ReSure Sealant access and cohort without ReSure Sealant access for routine or complex cataract surgeries



# Conclusions

- To our knowledge, this is one of the **largest reported recent review** of endophthalmitis cases following cataract surgery
- Overall post-cataract surgery endophthalmitis rate in 2016 to 2019 was **low (0.633 per 1,000 cataract surgeries)**
- Patients undergoing **complex cataract surgery had a higher incidence of endophthalmitis** (routine: 0.592 vs complex: 1.148 per 1000 cataract surgeries;  $P < 0.0001$ )
- **No clinically meaningful difference** in incidence rate of endophthalmitis between eyes treated at practices with and without access to ReSure Sealant