

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.^{1,2}

- Necessitates a large sample size to conduct meaningful studies

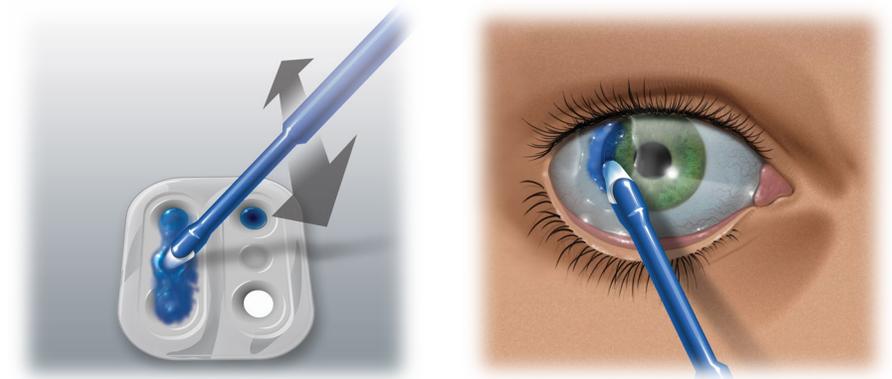
American Academy of Ophthalmology IRIS[®] (Intelligent Research In Sight) Registry³

- 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[®] 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 surgery⁴



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

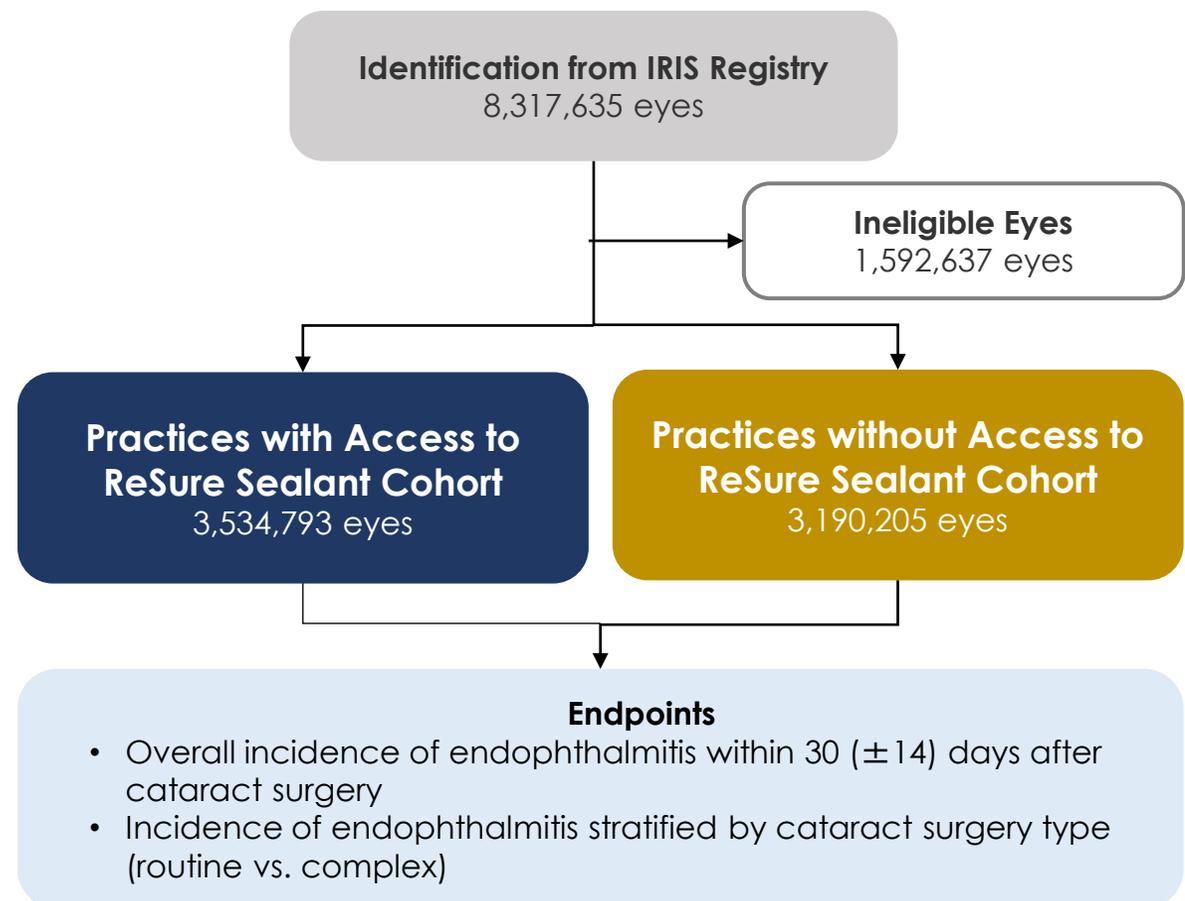
- Extracapsular cataract removal with insertion of intraocular lens prosthesis between January 1, 2016 and December 1, 2019
- Patients ≥ 22 years old and have at least one visit within 30 (± 14) days after surgery
- Practices must have provided data for at least 30 days after each surgery

Primary Objective

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

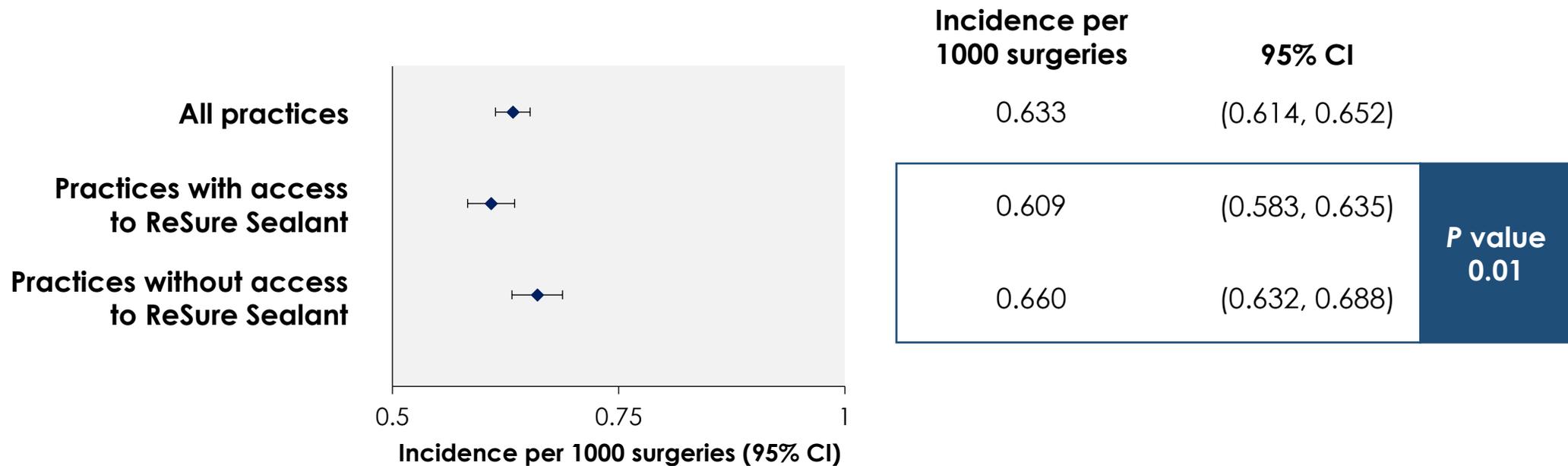
Data Analysis

- 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

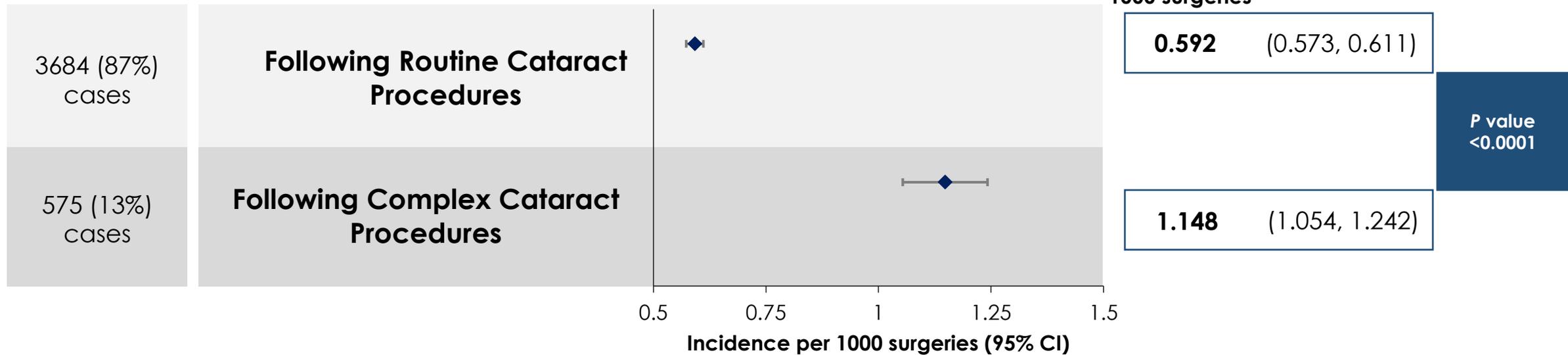


* ±14 day window

Incidence of Endophthalmitis Stratified by Cataract Surgery Type

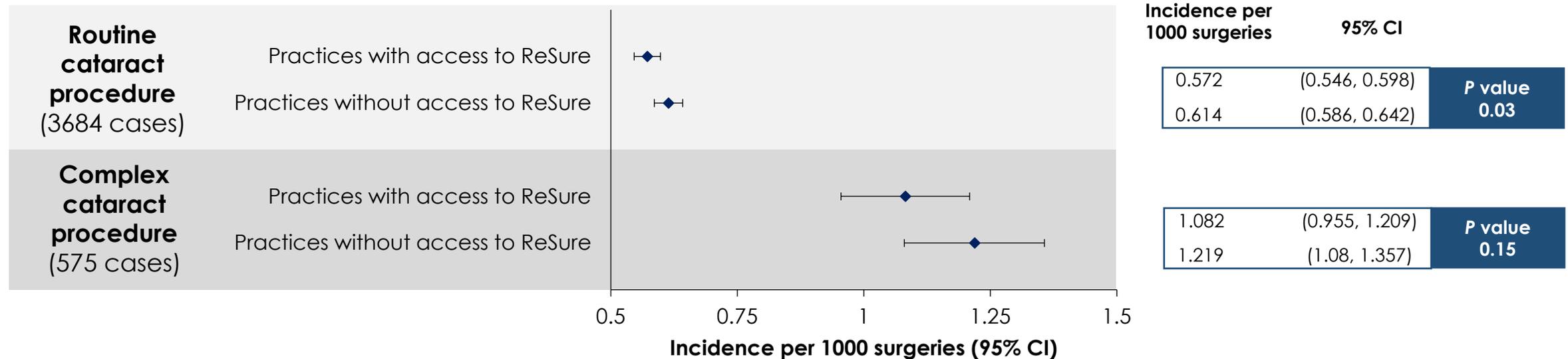
- Overall incidence of endophthalmitis per 1,000 surgeries was **significantly greater following complex cataract procedures when compared to routine procedures (1.148 vs 0.592; P<0.0001)**

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