# 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 Verena Health
- AA Moshfeghi
  - Ocular Therapeutix consultant, personal financial interest
  - Allergan consultant
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# Endophthalmitis Following Cataract Surgery

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

 Necessitates a large sample size to conduct meaningful studies

### IRIS® (Intelligent Research In Sight) Registry<sup>3</sup>

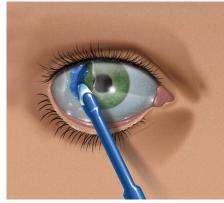
- Clinical registry with aggregated real-world data from nearly 60 million unique patients
- Approximately 16,000 ophthalmology clinicians contribute data to the registry through an electronic health record

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

#### ReSure® 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**

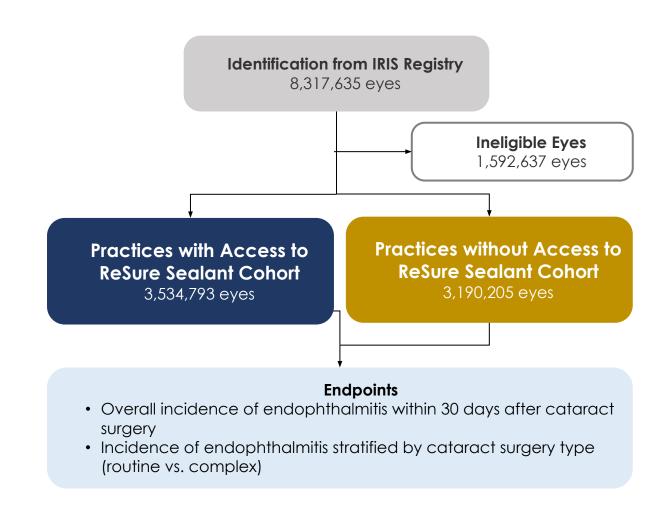
- Retrospective study
- Data from the IRIS Registry with analyses conducted by Verana Health

#### **Key Inclusion Criteria**

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

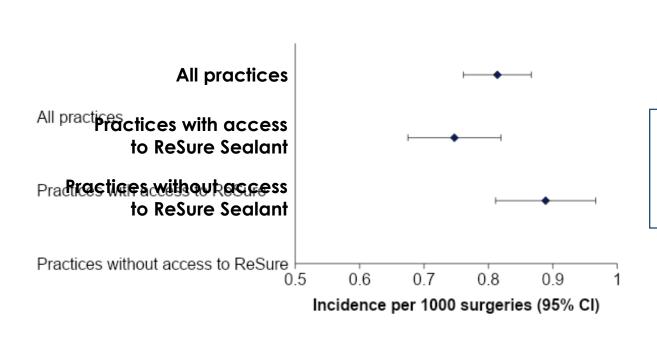
#### **Primary Objective**

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



# Overall Incidence of Endophthalmitis

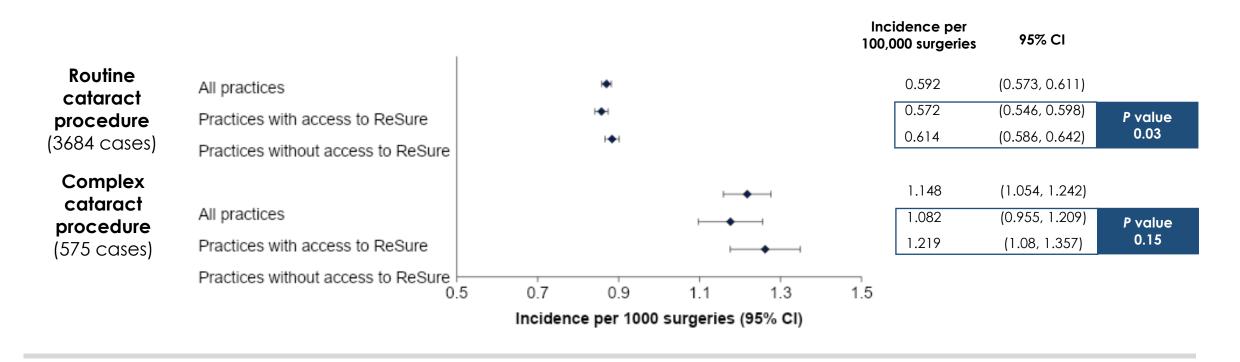
- A total of 4,259 cases of endophthalmitis with prespecified laterality were identified within 30 days after cataract surgery
- No clinically significant difference (i.e., doubling) in incidence rate of endophthalmitis was found between eyes treated at practices with and without access to ReSure Sealant



Incidence per 100,000 surgeries	95% CI	
0.633	(0.614, 0.652)	
0.609	(0.583, 0.635)	P value
0.660	(0.632, 0.688)	0.01

# Incidence of Endophthalmitis Stratified by Cataract Surgery Type

- The overall incidence of endophthalmitis among complex cataract procedures (3684 total cases; 87% cases) was higher than routine procedures (575 total cases; 13% cases)
- There was no clinically significant difference in endophthalmitis incidence between the cohort with ReSure Sealant access and cohort without ReSure Sealant access



## Conclusions

- To our knowledge, this is 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
- Practices with access to ReSure Sealant had a significantly lower rate of endophthalmitis than sites without access to ReSure Sealant and the difference was not clinically meaningful