Retrospective Study Comparing the Incidence of Endophthalmitis Following Cataract Surgery in Practices With Access to Hydrogel Sealant

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ASCRS ANNUAL MEETING | JULY 23-27, 2021 | LAS VEGAS, NV

FINANCIAL DISCLOSURES

Leon W. Herndon, MD has financial interests in Ocular Therapeutix, Aerie Pharmaceuticals, Alcon, Allergan, Equinox, Glaukos, Inn Focus, New World Medical, and Sight Sciences.

Helene Fevrier, MPH is an employee of Verana Health

Srilatha Vantipalli, PhD; Jamie L. Metzinger, MPH; and Michael H. Goldstein, MD are employees of Ocular Therapeutix, Inc.

Andrew A. Moshfeghi, MD is a consultant for Ocular Therapeutix, Inc.

This research was funded by Ocular Therapeutix, Inc.

Background

Incidence of Endophthalmitis

Endophthalmitis after cataract surgery is a rare but vision-threatening event with an incidence of ~0.5 to 3 per 1,000 surgeries.[1,2]

- Necessitates a large sample size to conduct meaningful studies

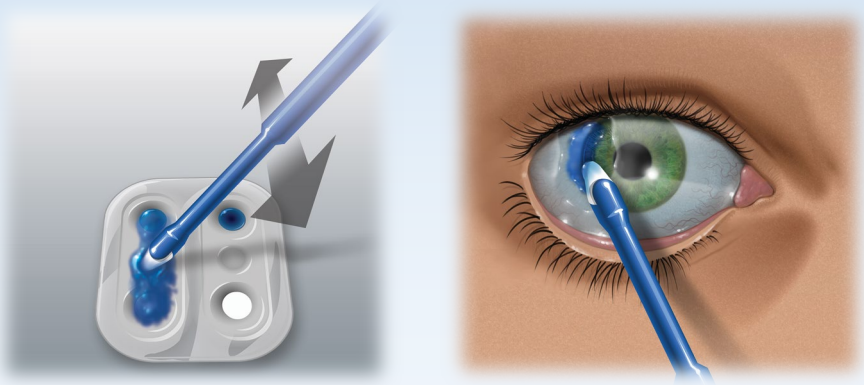
American Academy of Ophthalmology IRIS® (Intelligent Research In Sight) Registry[3]

- Clinical registry with aggregated real-world data from nearly 60 million unique patients
- Approximately 16,000 ophthalmologists and associated ophthalmic 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 3.5 mm) after cataract surgery[4]



Rendering of mixing and applying ReSure Sealant

References: 1. Lundström M, et al. *Ophthalmology*. 2007;114(5):866-70. **2.** West ES, et al. *Ophthalmology*. 2005;112(8):1388-94. **3.** IRIS Registry Data Analysis. American Academy of Ophthalmology. https://www.aao.org/iris-registry/data-analysis/requirements. Accessed April 1, 2021. **4.** ReSure Sealant. Instructions for Use. LCN 80-1004-011 Rev C. Ocular Therapeutix, Inc., Bedford, MA.

Methods

Study Design and Objective

Study Design

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

Key Inclusion Criteria

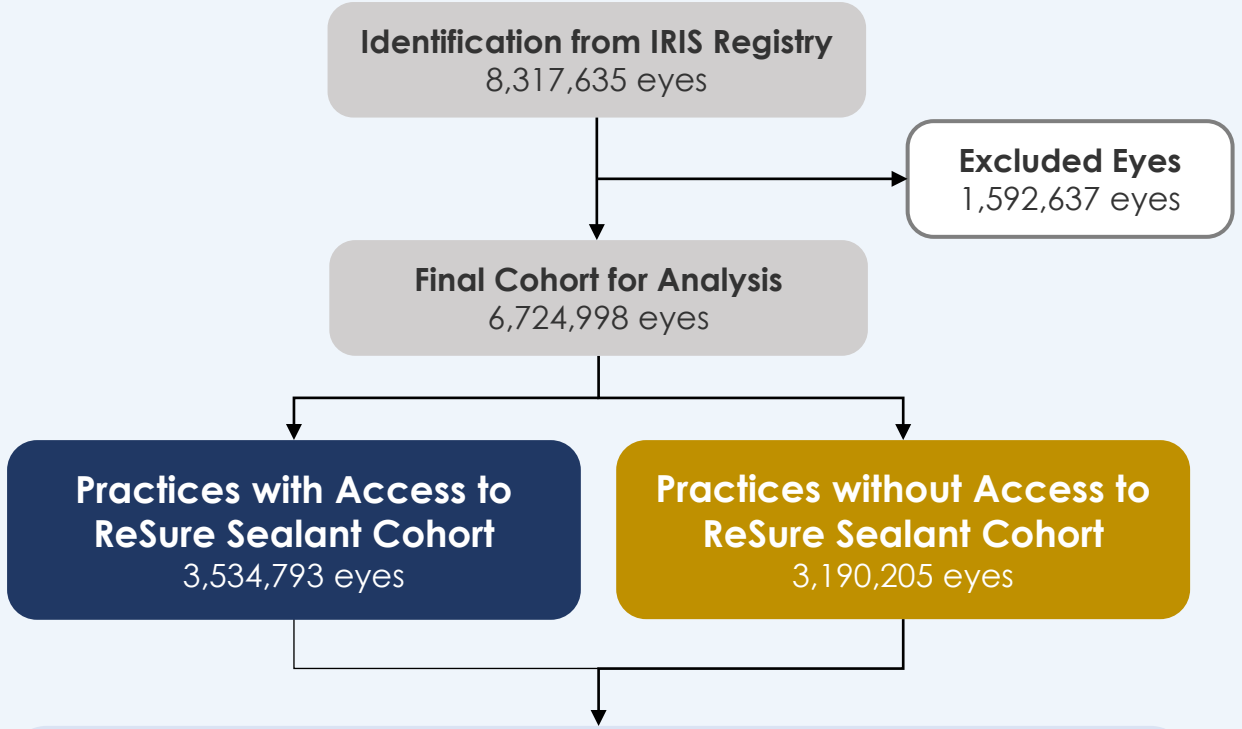
- Extracapsular cataract removal with insertion of intraocular lens prosthesis between January 1, 2016 and December 1, 2019
- Patients ≥22 years old and have ≥1 visits within 30 (±14) days after surgery
- Practices must have provided data for ≥30 days after each surgery

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, the *P* value for statistical significance was $P<0.001$



Results

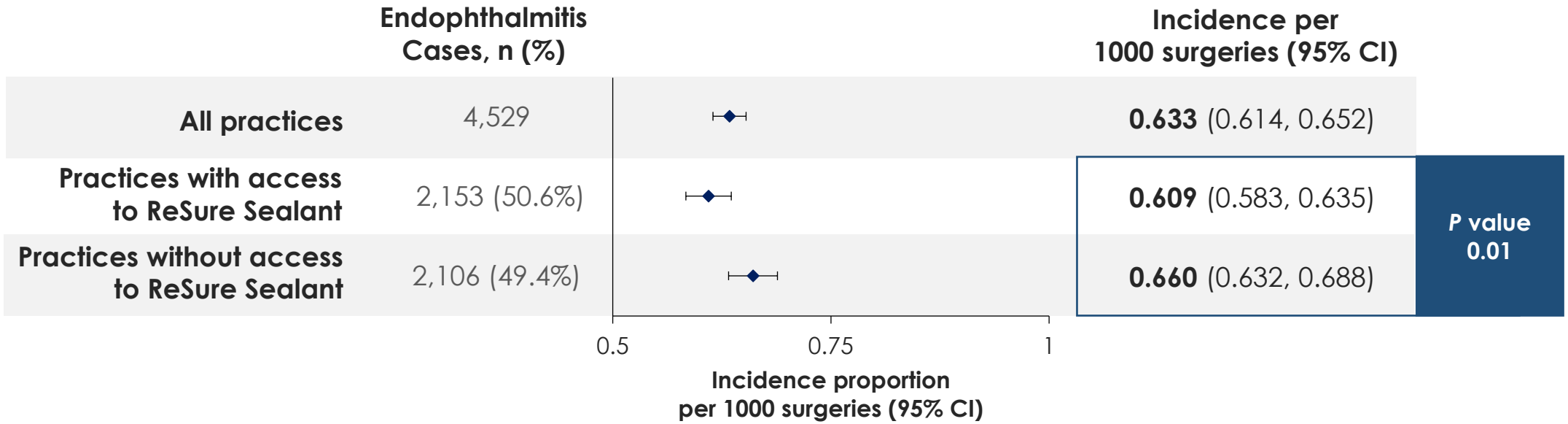
Baseline Demographics

	All patient eyes (N=6,724,998)
Mean age (SD), years	70.91 (8.95)
Sex, n (%)	
Male	2,762,441 (41.1%)
Female	3,962,557 (58.9%)
Race, n (%)	
White	4,927,456 (73.3%)
Black	429,787(6.4%)
Asian	151,199 (2.2%)
Native American/other Pacific	34,833 (0.5%)
Multirace	27,539 (0.4%)
Unknown	1,154,184 (17.2%)
Region, n (%)	
Midwest	1,352,395 (20.1%)
North	837,423 (12.5%)
South	2,484,111 (36.9%)
West	1,155,755 (17.2%)
Unknown	895,314 (13.3%)

Results

Overall Incidence of Endophthalmitis

- **The incidence of endophthalmitis post-cataract surgery was 0.633 per 1,000 cataract surgeries** between 2016 and 2019 (4,259 cases of endophthalmitis identified within 30 days of cataract surgery*)
- Incidence of endophthalmitis between eyes treated at practices with access to ReSure Sealant was lower than practices without access to ReSure Sealant (0.609 vs 0.660; *P*=0.01). This difference was **not clinically meaningful or statistically significant.**



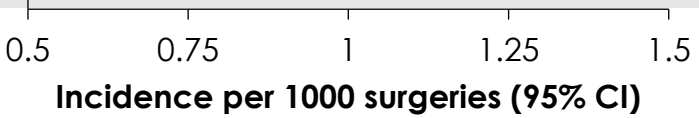
*±14-day window

Results

Incidence of Cataract Surgery Stratified by Cataract Surgery Type

The overall incidence of endophthalmitis was **significantly greater following complex cataract procedures compared to routine procedures** (1.148 vs 0.592; *P*<0.0001)

	Endophthalmitis Cases, n (%)	Incidence per 1000 surgeries (95% CI)	*P* value
Routine Cataract Procedures	3684 (87%)	**0.592** (0.573, 0.611)	**<0.0001**
Complex Cataract Procedures	575 (13%)	**1.148** (1.054, 1.242)	

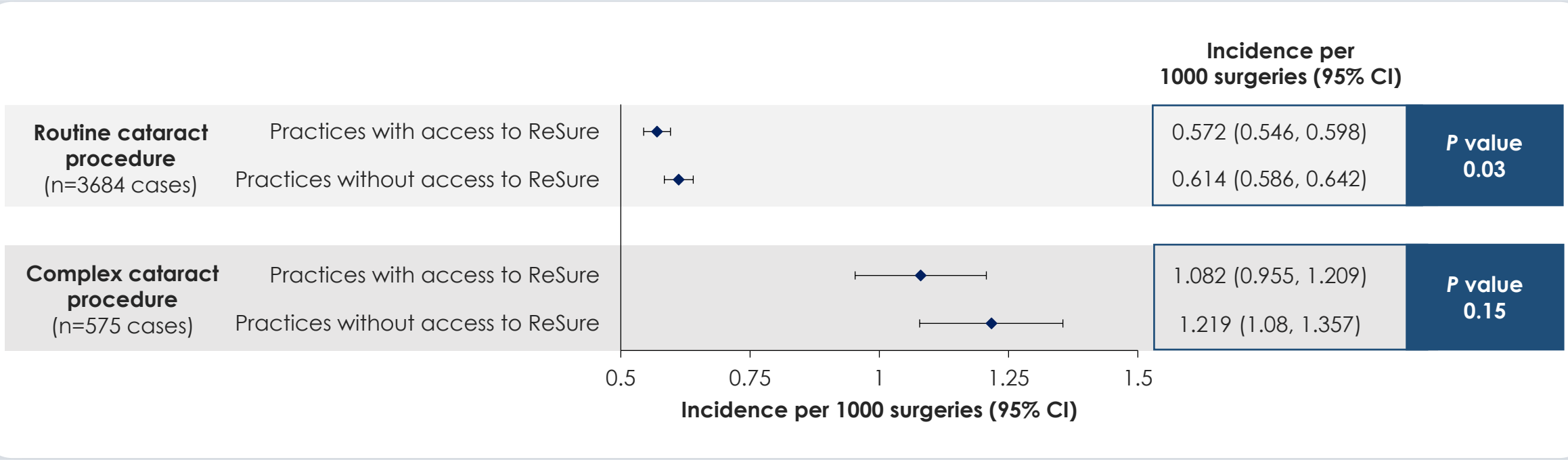


CI, confidence interval

Results

Incidence of Endophthalmitis Stratified by Cataract Surgery Type for Cohorts With/Without Access to ReSure Sealant

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



Conclusions

These data represent **one of the largest recent analyses** of acute postoperative endophthalmitis following cataract surgery

Overall post-cataract surgery endophthalmitis rate in 2016 to 2019 was low at **0.633 per 1,000 cataract surgeries** (95% CI: 0.614, 0.652)

Patients undergoing **complex cataract surgery had a statistically significant higher incidence of endophthalmitis** compared to routine cataract surgery (1.148 vs. 0.592 per 1000 cataract surgeries, respectively; $P<0.0001$)

Incidence of endophthalmitis between eyes treated at practices with access to ReSure Sealant was lower than practices without access to ReSure Sealant (0.609 vs 0.660; $P=0.01$). This difference was **not clinically meaningful or statistically significant.**