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AAO 2020 News

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2020
VIRTUAL**

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From the Editor

The Virtues of a Virtual Format

Are you ready for AAO 2020 Virtual? The Academy is ready for you! In past years, the virtual component has been a small but growing part of the Academy's annual meeting. Now, in this pandemic year, the Academy has worked with its longtime technical vendor to take full advantage of the virtual format. It's the annual meeting reimagined.



Start exploring. While I'll miss bumping into old friends in the convention center hallway, I won't miss having to rush from one event to the next. Now that it just takes a couple of clicks to move from one program track to another, I urge you to explore clinical fields beyond your own (see page 26 for some suggestions), as well as the AAOE's practice management sessions devoted to overcoming the challenges of COVID-19. Got 15 minutes until your next event? Pop into the Virtual Expo or the EyePlay Experience. And as for those happenstance hallway encounters, I—and my webcam—will be ready for the virtual lounge.

What a difference a year makes! When we flew out of San Francisco after AAO 2019, who would have thought that our next in-person meeting wouldn't be until AAO 2021 in New Orleans. But you don't have to wait until then to *laissez les bon temps rouler*—after I take my pick of the live sessions, I will see you on Saturday evening at the Virtual Orbital Gala! (Don't forget to sign up at aao.org/gala.)

Ruth D. Williams, MD
Chief Medical Editor, *EyeNet Magazine*

GET YOUR ALL-ACCESS PASS. When you register for AAO 2020 Virtual, you will get access to more than 100 hours of live-streamed sessions from Friday, Nov. 13, through Sunday, Nov. 15. In addition, view all annual meeting content, all eight Subspecialty Day meetings, and more on-demand. Register at aao.org/2020.



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INDICATIONS FOR USE: The Hydrus Microstent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG). **CONTRAINDICATIONS:** The Hydrus Microstent is contraindicated under the following circumstances or conditions: (1) In eyes with angle closure glaucoma; and (2) In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle. **WARNINGS:** Clear media for adequate visualization is required. Conditions such as corneal haze, corneal opacity or other conditions may inhibit gonioscopic view of the intended implant location. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, peripheral anterior synechiae (PAS), angle closure, rubeosis and any other angle abnormalities that could lead to improper placement of the stent and pose a hazard. **PRECAUTIONS:** The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, eyes with significant prior trauma, eyes with abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, eyes with preexisting pseudophakia, eyes with uveitic glaucoma, eyes with pseudoexfoliative or pigmentary glaucoma, eyes with other secondary open angle glaucoma, eyes that have undergone prior incisional glaucoma surgery or cilioabative procedures, eyes that have undergone argon laser trabeculoplasty (ALT), eyes with unmedicated IOP < 22 mm Hg or > 34 mm Hg, eyes with medicated IOP > 31 mm Hg, eyes requiring > 4 ocular hypotensive medications prior to surgery, in the setting of complicated cataract surgery with iatrogenic injury to the anterior or posterior segment, and when implantation is without concomitant cataract surgery with IOL implantation. The safety and effectiveness of use of more than a single Hydrus Microstent has not been established. **ADVERSE EVENTS:** Common post-operative adverse events reported in the randomized pivotal trial included partial or complete device obstruction (7.3%); worsening in visual field MD by > 2.5 dB compared with preoperative (4.3% vs 5.3% for cataract surgery alone); device malposition (1.4%); and BCVA loss of ≥ 2 ETDRS lines ≥ 3 months (1.4% vs 1.6% for cataract surgery alone). For additional adverse event information, please refer to the Instructions for Use. **MRI INFORMATION:** The Hydrus Microstent is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions. **Please see the Instructions for Use for complete product information.**

References:

1. Samuelson TW, Chang DF, Marquis R, et al; HORIZON Investigators. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. *Ophthalmology*. 2019;126:29-37. 2. Vold S, Ahmed II, Craven ER, et al; CyPass Study Group. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. *Ophthalmology*. 2016;123(10):2103-2112. 3. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Glaukos iStent[®] Trabecular Micro-Bypass Stent. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf8/PO80030B.pdf. Published June 25, 2012. 4. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): iStent inject Trabecular Micro-Bypass System. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170043b.pdf. Published June 21, 2018.

*Comparison based on results from individual pivotal trials (of those devices for which pivotal trials are available) and their respective controls and not head to head comparative studies. Other MIGS treatments have not been tested in pivotal trials.

[†]Data on file – Compared to control and includes trabeculectomy and tube shunt.

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You won't want to miss Sunday's Closing Session, featuring a conversation between Mr. Gladwell and Stephen D. McLeod, MD.

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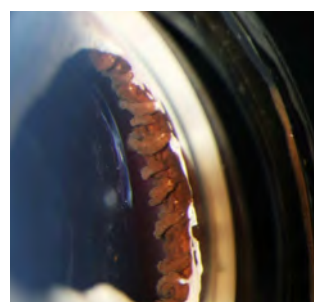
See a demo at the Academy Resource Center.

26-30 What's Hot at Subspecialty Day

The program directors pick their must-see sessions from Friday's live tracks (plus highlights from the on-demand program).

31 Award-Winning Photos

Four winners from the 2019 OPS exhibit.



On the Cover

Excised Iris Melanoma

Jaime Tesmer, CRA, OCT-C
Mayo Clinic
Rochester, Minnesota

NOTICE: This publication was printed in advance of AAO 2020 Virtual. For the most up-to-date information, check the Virtual Meeting Guide at aao.org/2020. American Academy of Ophthalmic Executives[®], *EyeNet[®]*, EyeSmart[®], IRIS[®] Registry, Ophthalmic News and Education Network[®] (ONE[®] Network), the Focus logo, Protecting Sight, Empowering Lives[®], and Preferred Practice Patterns[®], among others, are trademarks of the American Academy of Ophthalmology[®]. All other trademarks are the property of their respective owners. © 2020 American Academy of Ophthalmology.

Who Is Malcolm Gladwell?

Learn More About the Closing Session Speaker

Mark your calendar for Sunday, Nov. 15. You won't want to miss AAO 2020 Virtual's lively conversation between Stephen D. McLeod, MD, editor-in-chief of *Ophthalmology* journal, and Malcolm Gladwell. Mr. Gladwell coauthored a 2018 editorial for the journal titled *The Temin Effect*, about the value of creative endeavors for scientists and clinicians.¹

In case you don't already know, Malcolm Gladwell is an internationally known journalist, bestselling author, podcast host, and cultural observer. He has been included in the *Time* 100 Most Influential People list and has appeared in *Foreign Policy* magazine's list of Top Global Thinkers. His work, which focuses on human psychology and sociology, appears in *The New Yorker*, where he has been a staff writer since 1996. He is also the author of six *New York Times* bestsellers and is the cofounder of Pushkin Industries, an audio content company that produces podcasts.

A journalist. Mr. Gladwell's journalism career began in 1984. After college at the University of Toronto's Trinity College, the English-born Canadian's undergraduate grades precluded him from graduate school and several advertising agencies had rejected his applications. With those doors closed, he moved to Indiana for a position at *The American Spectator*. In 1987, he was hired as a business and science writer at *The Washington Post* and later became the newspaper's New York bureau chief.

A lot had changed by the time he left *The Washington Post* in 1996. In his book, *Outliers: The Story of Success*, which examines a variety of factors that may contribute to a person's success across vocations, Mr. Gladwell described his time at the newspaper: "I was a basket case at the beginning, and I felt like an expert at the end. It took 10 years—ex-

actly that long."

Mr. Gladwell was hired by *The New Yorker* in 1996. By then an expert by his own estimation, he made a splash by taking an unexpected angle on his first piece. The assignment was fashion, and Mr. Gladwell, ignoring the more obvious, high-fashion designers and brands, chose to write about a T-shirt manufacturer, saying "it was much more interesting to write a piece about someone who made a T-shirt for \$8 than it was to write about a dress that costs \$100,000. I mean, you or I could make a dress for \$100,000, but to make a T-shirt for \$8—that's much tougher."

Further exploring fashion and trends, Mr. Gladwell wrote an article called *Coolhunt* for *The New Yorker* in 1996. The piece follows two professional "coolhunters," DeeDee Gordon and Baysie Wightman, as they identify new street fashion trends to use in the design and marketing for their jobs at an advertising agency and Reebok, respectively. Through this story, Mr. Gladwell examines who decides what's cool.

Taking his study of trends one step further, Mr. Gladwell penned another *New Yorker* article called *The Tipping Point* in 1996. This piece focused on the way in which an object or idea becomes a larger phenomenon. This concept, of course, became the basis of Mr. Gladwell's first book.

A bestselling author. Mr. Gladwell published *The Tipping Point: How Little*



CLOSING SESSION. World-renowned writer and cultural observer Malcolm Gladwell will speak with Ophthalmology Editor-in-Chief Dr. McLeod at the AAO 2020 Virtual Closing Session.

Things Can Make a Big Difference in 2000. The book famously tracked the rise in the sales of Hush Puppies shoes in the mid-1990s and New York City's steep drop in its crime rate after 1990. Mr. Gladwell uses both as examples to illustrate the existence of—and significance of—the so-called "tipping point," which Mr. Gladwell himself describes as "that magic moment when an idea, trend, or social behavior crosses a threshold, tips, and spreads like wildfire." In the book, he explains three factors that can determine when and whether the tipping point will occur. First, in the Law of the Few, Mr. Gladwell argues that "the success of any kind of social epidemic is heavily dependent on the involvement of people with a particular and rare set of social gifts." Second, the Stickiness Factor refers to an ineffable quality that will compel the public to pay attention to something. Third, the Power of Context means just that: That the time, place, and environment in which an idea or product is introduced greatly affects how it will be received.

Mr. Gladwell's debut book has achieved its own tipping point. A *New York Times* bestseller, *The Tipping Point* has sold more than five million copies, was Barnes & Noble's fifth bestselling book of the decade, and was voted one of the best books of the decade by Amazon.com customers, *The Guardian*, *The Times*, and The A.V. Club.

After the success of his first book, Mr. Gladwell went on to write five more *New York Times* bestsellers. In his 2005 book, *Blink: The Power of Thinking Without Thinking*, Mr. Gladwell argues that humans have adapted to make unconscious decisions rapidly based on how the mind has interpreted past events. In his 2008 book, the *Outliers: The Story of Success*, Mr. Gladwell examines how a combination of personal ambition and external circumstances can affect any person's potential for success. In his 2009 book, *What the Dog Saw: And Other Adventures*, Mr. Gladwell shares some of his favorite articles from *The New Yorker* since he became a staff writer in 1996. In his 2013 book, *David and Goliath: Underdogs, Misfits, and the Art of Battling Giants*, Mr. Gladwell studies the struggles of underdogs versus favorites. And in his most recent book, published in September 2019, *Talking to Strangers: What We Should Know about the People We Don't Know*, he examines interactions between strangers. Mr. Gladwell said he was inspired to write this book because he was "struck by how many high-profile cases in the news were about the same thing—strangers misunderstanding each other."

A podcast host. Mr. Gladwell is also the cofounder of Pushkin Industries, an audio content company that produces podcasts, such as *Solvable*, *Against the Rules*, and *The Happiness Lab*. He also hosts *Revisionist History*, which "reconsiders things both overlooked and misunderstood," and cohosts *Broken Record*, where he interviews musicians.

A cultural observer. In all his success as writer, author and podcast host, Mr. Gladwell has come to be known as a prominent cultural observer and social commentator. In keeping with that role, he has never been one to shy from conversation surrounding current events including crime, technology, and race. Of the current COVID-19 pandemic, Mr. Gladwell has said: "By the time a vaccine is ready, we will have a much better understanding of who's most vulnerable. And if we give the vaccine to anyone before those people, I will pray for our mortal souls."

A speaker at AAO 2020 Virtual. On Sunday, Nov. 15, Mr. Gladwell joins *Ophthalmology* Editor-in-Chief Dr. McLeod for a live conversation with audience participation at the AAO 2020 Virtual Closing Session.

¹ Epstein D, Gladwell M. *Ophthalmology*. 2018; 125(1):2-3.

Dr. McLeod

Dr. McLeod, who will be speaking with Mr. Gladwell at the AAO 2020 Virtual Closing Session, holds several positions: He is the editor-in-chief of *Ophthalmology*, the Theresa M. and Wayne M. Caygill, MD, Distinguished Professor and Chair of the Department of Ophthalmology at the University of California, San



Francisco, and the Chair of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee of the FDA.

Dr. McLeod is a noted researcher with many peer-reviewed publications and a highly respected clinician, specializing in refractive surgery, cornea, and external disease.

refractive surgery, cornea, and external disease.

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The Jackson Memorial Lecture Improving Amblyopia Outcomes Through Clinical Trials and Practice Measurement

In his distinguished career, Michael X. Repka, MD, MBA, has traveled three distinct but complementary paths: as a clinician, an academic, and an advocate for ophthalmology. Now the David L. Guyton, MD, and Feduniak Family Professor of Ophthalmology as well as professor of pediatrics at Johns Hopkins University School of Medicine in Baltimore, Dr. Repka also serves as the Medical Director for Governmental Affairs of the Academy.

Alongside these professional engagements, Dr. Repka has held leadership roles in several organizations, including the Academy, the American Association for Pediatric Ophthalmology and Strabismus, the International Strabismological Association, and the Association for Research in Vision and Ophthalmology. Among his many awards and honors, Dr. Repka has been chosen to present the 2020 Jackson Memorial Lecture.

Education and Mentorship

While still an undergraduate in college, Dr. Repka said he was first drawn to ophthalmology by “the technology and gadgets.” He set his sights on pediatric ophthalmology during residency at Wills Eye Hospital in Philadelphia—at that time, he knew he wanted to perform surgery but also appreciated the variety offered by pediatrics.

“I liked having office practice as well as some surgical practice,” he said, adding “and I just liked dealing with children and their parents, I suppose, more than dealing with older patients.”

Dr. Repka credits the environment of Wills as being a key element in his training. “Mentorship was freely and generously given by practitioners in all of the disciplines.” In particular, he cited Robert D. Reinecke, MD, and Joseph H. Calhoun, MD, in pediatric ophthalmology, William Tasman, MD, in retina, and Peter Savino, MD, in neuro-ophthalmology as being particularly inspirational. He said, “I could see that they liked what they were doing, and it helped me to envision doing something similar.”

Four Key Influencers

After residency, Dr. Repka completed fellowships in neuro-ophthalmology and pediatric ophthalmology at Wilmer under the guidance of Neil R. Miller, MD, and David L. Guyton, MD.

In addition, Arnall Patz, MD, the pioneer of research in retinopathy of prema-

turity (ROP), spurred Dr. Repka’s lifelong work on that disease. He stayed on at Wilmer, where “there could have been no better place to launch a career.”

“And outside of Wilmer,” said Dr. Repka, “William E. Scott, MD, at the University of Iowa, is a person who provided incomparable support toward my early career development. Although I had no direct training with him, I worked with him on a clinical trial of treatment for acquired esotropia, with the encouragement of Dave Guyton.”

Dr. Repka likened himself in that setting to “a five-year-old going to meetings with the senior men and one woman in the field at the time. But not only did Dr. Scott allow [his presence], he actually fostered my involvement and was certainly instrumental in my early postfellowship career.”

That study, the Prism Adaptation Trial, “helped me learn the field, learn the people, learn study design issues that I had no previous exposure to,” he said. It initiated an interest in clinical trials research, which became an important component in his career.

Dr. Repka called these four prominent ophthalmologists—Drs. Patz, Guyton, Miller, and Scott—“the key change agents in moving me forward in my career.”

Most Important Accomplishment

Since completing his fellowships, Dr. Repka has held academic appointments in ophthalmology at Wilmer and pediatric medicine at Johns Hopkins. Throughout that time, he has served on multiple departmental and university committees, including those in residency education, ethics, clinical practice, and electronic medical records.

Following his earliest clinical trial experience with Dr. Scott, Dr. Repka has been a principal investigator or coinvestigator in many studies, particularly in amblyopia, strabismus, and ROP. When asked what he considers his most important accomplishment, he answered,



SATURDAY HIGHLIGHT. Dr. Repka will deliver the Jackson Memorial Lecture at Saturday’s Opening Session. (There is an Opening Session each day at 7:00 a.m. PST.)

without hesitation, “helping start the Pediatric Eye Disease Investigator Group (PEDIG).” Cofounded in 1997 by Dr. Repka, Roy W. Beck, MD, PhD, and Jonathan M. Holmes, MD, with funding from the National Eye Institute, PEDIG has grown to be a collaborative network of researchers at more than 100 sites that has conducted or initiated more than 20 influential clinical multicenter randomized or observational studies.

Amblyopia Outcomes: Room for Improvement?

Dr. Repka’s Jackson lecture will draw upon PEDIG trial data on amblyopia outcomes going back to 1997 as the “groundwork” and then explore data on 1.7 million amblyopic patients in the IRIS Registry “to ask what amblyopia looks like in the United States in the last half of the second decade of the century,” he said. One striking difference he found was that in the data from the IRIS (Intelligent Research in Sight) Registry, refractive causes alone—as opposed to strabismus alone or in combination with refractive error—were much more common than in the PEDIG data. “I think that is going to change how we think about the condition when we’re seeing that almost 70% of amblyopia cases are from refractive causes alone.”

With regard to amblyopia outcomes, Dr. Repka said that the IRIS Registry

outcome measure showed success in 77% of treated children. “Is that the best we can do?” he asked. “Is there room for improvement? Maybe.” To answer that question, he looked back to data from the first PEDIG trial and found that the success rate was about 83%. Much of that disparity, he said, could be attributed to the differences between a clinical trial setting and real-world clinical practice as reflected in the IRIS Registry.

“In a clinical trial you would have the patients most likely to improve, the parents who were most engaged because they signed up for a clinical trial, study coordinators who help the parents and patients, and even parking vouchers.” In contrast, the IRIS Registry data “are going to include some patients who weren’t cooperative with treatment and some parents who weren’t as committed; they’re interested enough to get care, but they’re not as involved as a clinical trial’s parent population,” he noted. And while these two outcomes—that is, the clinical trial representing our gold standard and the IRIS measure—are good, “both reveal that there is still room for improvement,” he said.

Closing the Gap

“One of the benefits of these outcome measurements is that they can demonstrate gaps in care,” which can be monitored over time, said Dr. Repka. “The data can also be used to show that amblyopia is a very common problem and that there is a benefit to intervention—and that provides a powerful argument to help us advocate for the right kinds of health care at the right time.

“For instance, one disconnect is that a child who has medical coverage for his or her office visits for the diagnosis of amblyopia does not necessarily have coverage for the eyeglasses that are the primary component of the treatment.” And the data can provide additional support for targeted school-based and preschool-based screening programs, Dr. Repka said.

Ultimately, using the evidence to identify needs and develop strategies for solving them, he said, “all ties back to the advocacy part of my professional life.”

Looking Ahead

And with regard to advocacy, Dr. Repka envisions continuing to work on behalf of all of ophthalmology in D.C. “From the very beginning,” he said, “I’ve enjoyed bringing our message to congressional and agency leadership and staff.”



STRENGTH IN VISION

LUCENTIS has been extensively studied and
FDA approved in 5 retinal indications.

INDICATIONS

LUCENTIS® (ranibizumab injection) is indicated for the treatment of patients with:

- Neovascular (wet) age-related macular degeneration (wAMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

IMPORTANT SAFETY INFORMATION

- LUCENTIS is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab or any of the excipients in LUCENTIS. Hypersensitivity reactions may manifest as severe intraocular inflammation
- Intravitreal injections, including those with LUCENTIS, have been associated with endophthalmitis, retinal detachment, and iatrogenic traumatic cataract
- Increases in intraocular pressure (IOP) have been noted both pre-injection and post-injection with LUCENTIS
- Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause)
- Fatal events occurred more frequently in patients with DME and DR at baseline treated monthly with LUCENTIS compared with control. Although the rate of fatal events was low and

included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded

- In the LUCENTIS Phase III clinical trials, the most common ocular side effects included conjunctival hemorrhage, eye pain, vitreous floaters, and increased intraocular pressure. The most common non-ocular side effects included nasopharyngitis, anemia, nausea, and cough

Please see Brief Summary of LUCENTIS full Prescribing Information on following page.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Randomized, double-masked clinical trials conducted for the 5 LUCENTIS indications included the following: **wAMD: MARINA, ANCHOR, PIER, HARBOR. DR and DME: RISE, RIDE. mCNV: RADIANCE. RVO: BRAVO, CRUISE.**¹⁻¹⁰

REFERENCES: 1. Rosenfeld PJ, et al; MARINA Study Group. *N Engl J Med.* 2006;355:1419-1431. 2. Brown DM, et al; ANCHOR Study Group. *Ophthalmology.* 2009;116:57-65. 3. Busbee BG, et al; HARBOR Study Group. *Ophthalmology.* 2013;120:1046-1056. 4. Regillo CD, et al; PIER Study Group. *Am J Ophthalmol.* 2008;145:239-248. 5. Brown DM, et al; RISE and RIDE Research Group. *Ophthalmology.* 2013;120:2013-2022. 6. Data on file. Genentech, Inc. South San Francisco, CA. 7. Campochiaro PA, et al; BRAVO Investigators. *Ophthalmology.* 2010;117:1102-1112. 8. Brown DM, et al; CRUISE Investigators. *Ophthalmology.* 2010;117:1124-1133. 9. Nguyen QD, et al; RISE and RIDE Research Group. *Ophthalmology.* 2012;119:789-801. 10. Ho AC, et al; HARBOR Study Group. *Ophthalmology.* 2014;121:2181-2192.



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RANIBIZUMAB INJECTION

Brief summary—please see the LUCENTIS® package insert for full prescribing information.

1 INDICATIONS AND USAGE

LUCENTIS is indicated for the treatment of patients with:

- 1.1 Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- 1.2 Macular Edema Following Retinal Vein Occlusion (RVO)
- 1.3 Diabetic Macular Edema (DME)
- 1.4 Diabetic Retinopathy (DR)
- 1.5 Myopic Choroidal Neovascularization (mCNV)

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

LUCENTIS is contraindicated in patients with ocular or periocular infections.

4.2 Hypersensitivity

LUCENTIS is contraindicated in patients with known hypersensitivity to ranibizumab or any of the excipients in LUCENTIS. Hypersensitivity reactions may manifest as severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments

Intravitreal injections, including those with LUCENTIS, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique should always be used when administering LUCENTIS. In addition, patients should be monitored following the injection to permit early treatment should an infection occur [see Dosage and Administration (2.6, 2.7) in the full prescribing information and Patient Counseling Information (17)].

5.2 Increases in Intraocular Pressure

Increases in intraocular pressure have been noted both pre-injection and post-injection (at 60 minutes) while being treated with LUCENTIS. Monitor intraocular pressure prior to and following intravitreal injection with LUCENTIS and manage appropriately [see Dosage and Administration (2.7 in the full prescribing information)].

5.3 Thromboembolic Events

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

Neovascular (Wet) Age-Related Macular Degeneration

The ATE rate in the three controlled neovascular AMD studies (AMD-1, AMD-2, AMD-3) during the first year was 1.9% (17 of 874) in the combined group of patients treated with 0.3 mg or 0.5 mg LUCENTIS compared with 1.1% (5 of 441) in patients from the control arms [see Clinical Studies (14.1 in the full prescribing information)]. In the second year of Studies AMD-1 and AMD-2, the ATE rate was 2.6% (19 of 721) in the combined group of LUCENTIS-treated patients compared with 2.9% (10 of 344) in patients from the control arms. In Study AMD-4, the ATE rates observed in the 0.5 mg arms during the first and second year were similar to rates observed in Studies AMD-1, AMD-2, and AMD-3.

In a pooled analysis of 2-year controlled studies (AMD-1, AMD-2, and a study of LUCENTIS used adjunctively with verteporfin photodynamic therapy), the stroke rate (including both ischemic and hemorrhagic stroke) was 2.7% (13 of 484) in patients treated with 0.5 mg LUCENTIS compared to 1.1% (5 of 435) in patients in the control arms (odds ratio 2.2 (95% confidence interval (0.8-7.1))).

Macular Edema Following Retinal Vein Occlusion

The ATE rate in the two controlled RVO studies during the first 6 months was 0.8% in both the LUCENTIS and control arms of the studies (4 of 525 in the combined group of patients treated with 0.3 mg or 0.5 mg LUCENTIS and 2 of 260 in the control arms) [see Clinical Studies (14.2 in the full prescribing information)]. The stroke rate was 0.2% (1 of 525) in the combined group of LUCENTIS-treated patients compared to 0.4% (1 of 260) in the control arms.

Diabetic Macular Edema and Diabetic Retinopathy

Safety data are derived from studies D-1 and D-2. All enrolled patients had DME and DR at baseline [see Clinical Studies (14.3, 14.4 in the full prescribing information)].

In a pooled analysis of Studies D-1 and D-2 [see Clinical Studies (14.3 in the full prescribing information)], the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg LUCENTIS, 5.6% (14 of 250) with 0.3 mg LUCENTIS, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg LUCENTIS, 1.2% (3 of 250) with 0.3 mg LUCENTIS, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg LUCENTIS and 10.8% (27 of 250) with 0.3 mg LUCENTIS; the stroke rate was 4.8% (12 of 249) with 0.5 mg LUCENTIS and 2.0% (5 of 250) with 0.3 mg LUCENTIS.

5.4 Fatal Events in Patients with DME and DR at baseline

Diabetic Macular Edema and Diabetic Retinopathy

Safety data are derived from studies D-1 and D-2. All enrolled patients had DME and DR at baseline [see Clinical Studies (14.3, 14.4 in the full prescribing information)].

A pooled analysis of Studies D-1 and D-2 [see Clinical Studies (14.3 in the full prescribing information)], showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg LUCENTIS, in 2.8% (7 of 250) of patients treated with 0.3 mg LUCENTIS, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg LUCENTIS and in 4.4% (11 of 250) of patients treated with 0.3 mg LUCENTIS. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Endophthalmitis and Retinal Detachments [see Warnings and Precautions (5.1)]
- Increases in Intraocular Pressure [see Warnings and Precautions (5.2)]
- Thromboembolic Events [see Warnings and Precautions (5.3)]
- Fatal Events in patients with DME and DR at baseline [see Warnings and Precautions (5.4)]

6.1 Injection Procedure

Serious adverse reactions related to the injection procedure have occurred in < 0.1% of intravitreal injections, including endophthalmitis [see Warnings and Precautions (5.1)], rhegmatogenous retinal detachment, and iatrogenic traumatic cataract.

6.2 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data below reflect exposure to 0.5 mg LUCENTIS in 440 patients with neovascular AMD in Studies AMD-1, AMD-2, and AMD-3; in 259 patients with macular edema following RVO. The data also reflect exposure to 0.3 mg LUCENTIS in 250 patients with DME and DR at baseline [see Clinical Studies (14 in the full prescribing information)].

Safety data observed in Study AMD-4, D-3, and in 224 patients with mCNV were consistent with these results. On average, the rates and types of adverse reactions in patients were not significantly affected by dosing regimen.

Ocular Reactions

Table 1 shows frequently reported ocular adverse reactions in LUCENTIS-treated patients compared with the control group.

Table 1 Ocular Reactions in the DME and DR, AMD, and RVO Studies								
Adverse Reaction	DME and DR 2-year		AMD 2-year		AMD 1-year		RVO 6-month	
	LUCENTIS 0.3 mg	Control	LUCENTIS 0.5 mg	Control	LUCENTIS 0.5 mg	Control	LUCENTIS 0.5 mg	Control
	n=250	n=250	n=379	n=379	n=440	n=441	n=259	n=260
Conjunctival hemorrhage	47%	32%	74%	60%	64%	50%	48%	37%
Eye pain	17%	13%	35%	30%	26%	20%	17%	12%
Vitreous floaters	10%	4%	27%	8%	19%	5%	7%	2%
Intraocular pressure increased	18%	7%	24%	7%	17%	5%	7%	2%
Vitreous detachment	11%	15%	21%	19%	15%	15%	4%	2%
Intraocular inflammation	4%	3%	18%	8%	13%	7%	1%	3%
Cataract	28%	32%	17%	14%	11%	9%	2%	2%
Foreign body sensation in eyes	10%	5%	16%	14%	13%	10%	7%	5%
Eye irritation	8%	5%	15%	15%	13%	12%	7%	6%
Lacrimation increased	5%	4%	14%	12%	8%	8%	2%	3%
Blepharitis	3%	2%	12%	8%	8%	5%	0%	1%
Dry eye	5%	3%	12%	7%	7%	7%	3%	3%
Visual disturbance or vision blurred	8%	4%	18%	15%	13%	10%	5%	3%
Eye pruritus	4%	4%	12%	11%	9%	7%	1%	2%
Ocular hyperemia	9%	9%	11%	8%	7%	4%	5%	3%
Retinal disorder	2%	2%	10%	7%	8%	4%	2%	1%
Maculopathy	5%	7%	9%	9%	6%	6%	11%	7%
Retinal degeneration	1%	0%	8%	6%	5%	3%	1%	0%
Ocular discomfort	2%	1%	7%	4%	5%	2%	2%	2%
Conjunctival hyperemia	1%	2%	7%	6%	5%	4%	0%	0%
Posterior capsule opacification	4%	3%	7%	4%	2%	2%	0%	1%
Injection site hemorrhage	1%	0%	5%	2%	3%	1%	0%	0%

Non-Ocular Reactions

Non-ocular adverse reactions with an incidence of ≥ 5% in patients receiving LUCENTIS for DR, DME, AMD, and/or RVO and which occurred at a ≥ 1% higher frequency in patients treated with LUCENTIS compared to control are shown in Table 2. Though less common, wound healing complications were also observed in some studies.

Table 2 Non-Ocular Reactions in the DME and DR, AMD, and RVO Studies

Adverse Reaction	DME and DR 2-year		AMD 2-year		AMD 1-year		RVO 6-month	
	LUCENTIS 0.3 mg	Control	LUCENTIS 0.5 mg	Control	LUCENTIS 0.5 mg	Control	LUCENTIS 0.5 mg	Control
	n=250	n=250	n=379	n=379	n=440	n=441	n=259	n=260
Nasopharyngitis	12%	6%	16%	13%	8%	9%	5%	4%
Anemia	11%	10%	8%	7%	4%	3%	1%	1%
Nausea	10%	9%	9%	6%	5%	5%	1%	2%
Cough	9%	4%	9%	8%	5%	4%	1%	2%
Constipation	8%	4%	5%	7%	3%	4%	0%	1%
Seasonal allergy	8%	4%	4%	4%	2%	2%	0%	2%
Hypercholesterolemia	7%	5%	5%	5%	3%	2%	1%	1%
Influenza	7%	3%	7%	5%	3%	2%	3%	2%
Renal failure	7%	6%	1%	1%	0%	0%	0%	0%
Upper respiratory tract infection	7%	7%	9%	8%	5%	5%	2%	2%
Gastroesophageal reflux disease	6%	4%	4%	6%	3%	4%	1%	0%
Headache	6%	8%	12%	9%	6%	5%	3%	3%
Edema peripheral	6%	4%	3%	5%	2%	3%	0%	1%
Renal failure chronic	6%	2%	0%	1%	0%	0%	0%	0%
Neuropathy peripheral	5%	3%	1%	1%	1%	0%	0%	0%
Sinusitis	5%	8%	8%	7%	5%	5%	3%	2%
Bronchitis	4%	4%	11%	9%	6%	5%	0%	2%
Atrial fibrillation	3%	3%	5%	4%	2%	2%	1%	0%
Arthralgia	3%	3%	11%	9%	5%	5%	2%	1%
Chronic obstructive pulmonary disease	1%	1%	6%	3%	3%	1%	0%	0%
Wound healing complications	1%	0%	1%	1%	1%	0%	0%	0%

6.3 Immunogenicity

As with all therapeutic proteins, there is the potential for an immune response in patients treated with LUCENTIS. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to LUCENTIS in immunoassays and are highly dependent on the sensitivity and specificity of the assays.

The pre-treatment incidence of immunoreactivity to LUCENTIS was 0%-5% across treatment groups. After monthly dosing with LUCENTIS for 6 to 24 months, antibodies to LUCENTIS were detected in approximately 1%-9% of patients.

The clinical significance of immunoreactivity to LUCENTIS is unclear at this time. Among neovascular AMD patients with the highest levels of immunoreactivity, some were noted to have iritis or vitritis. Intraocular inflammation was not observed in patients with DME and DR at baseline, or RVO patients with the highest levels of immunoreactivity.

6.4 Postmarketing Experience

The following adverse reaction has been identified during post-approval use of LUCENTIS. Because this reaction was reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

- Ocular: Tear of retinal pigment epithelium among patients with neovascular AMD

7 DRUG INTERACTIONS

Drug interaction studies have not been conducted with LUCENTIS.

LUCENTIS intravitreal injection has been used adjunctively with verteporfin photodynamic therapy (PDT). Twelve (12) of 105 (11%) patients with neovascular AMD developed serious intraocular inflammation; in 10 of the 12 patients, this occurred when LUCENTIS was administered 7 days (± 2 days) after verteporfin PDT.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of LUCENTIS administration in pregnant women.

Administration of ranibizumab to pregnant monkeys throughout the period of organogenesis resulted in a low incidence of skeletal abnormalities at intravitreal doses 13-times the predicted human exposure (based on maximal serum trough levels [C_{min}]) after a single eye treatment at the recommended clinical dose. No skeletal abnormalities were observed at serum trough levels equivalent to the predicted human exposure after a single eye treatment at the recommended clinical dose [see Animal Data].

Animal reproduction studies are not always predictive of human response, and it is not known whether ranibizumab can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for ranibizumab [see Clinical Pharmacology (12.1 in the full prescribing information)], treatment with LUCENTIS may pose a risk to human embryofetal development.

LUCENTIS should be given to a pregnant woman only if clearly needed.

Data

Animal Data

An embryo-fetal developmental toxicity study was performed on pregnant cynomolgus monkeys. Pregnant animals received intravitreal injections of ranibizumab every 14 days starting on Day 20 of gestation, until Day 62 at doses of 0, 0.125, and 1 mg/eye. Skeletal abnormalities including incomplete and/or irregular ossification of bones in the skull, vertebral column, and hindlimbs and shortened supernumerary ribs were seen at a low incidence in fetuses from animals treated with 1 mg/eye of ranibizumab. The 1 mg/eye dose resulted in trough serum ranibizumab levels up to 13 times higher than predicted C_{min} levels with single eye treatment in humans. No skeletal abnormalities were seen at the lower dose of 0.125 mg/eye, a dose which resulted in trough exposures equivalent to single eye treatment in humans. No effect on the weight or structure of the placenta, maternal toxicity, or embryotoxicity was observed.

8.2 Lactation

Risk Summary

There are no data available on the presence of ranibizumab in human milk, the effects of ranibizumab on the breastfed infant or the effects of ranibizumab on milk production/excretion.

Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, caution should be exercised when LUCENTIS is administered to a nursing woman.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LUCENTIS and any potential adverse effects on the breastfed child from ranibizumab.

8.3 Females and Males of Reproductive Potential

Infertility

No studies on the effects of ranibizumab on fertility have been conducted and it is not known whether ranibizumab can affect reproduction capacity. Based on the anti-VEGF mechanism of action for ranibizumab, treatment with LUCENTIS may pose a risk to reproductive capacity.

8.4 Pediatric Use

The safety and effectiveness of LUCENTIS in pediatric patients have not been established.

8.5 Geriatric Use

In the clinical studies, approximately 76% (2449 of 3227) of patients randomized to treatment with LUCENTIS were ≥ 65 years of age and approximately 51% (1644 of 3227) were ≥ 75 years of age [see Clinical Studies (14 in the full prescribing information)]. No notable differences in efficacy or safety were seen with increasing age in these studies. Age did not have a significant effect on systemic exposure.

10 OVERDOSAGE

More concentrated doses as high as 2 mg ranibizumab in 0.05 mL have been administered to patients. No additional unexpected adverse reactions were seen.

17 PATIENT COUNSELING INFORMATION

Advise patients that in the days following LUCENTIS administration, patients are at risk of developing endophthalmitis. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist [see Warnings and Precautions (5.1)].

**LUCENTIS®
[ranibizumab injection]**

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA
94080-4990

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The 2020 Presidential Guests Tales of Support, Advice, and Friendship

Each year, the Academy president in office selects three individuals to be guests of honor at the annual meeting. Anne L. Coleman, MD, PhD, 2020 President, chose her guests for the roles each plays in her life as friends and mentors. Here, Dr. Coleman details the specific reasons for each selection. Dr. Coleman will recognize these award recipients at AAO 2020 Virtual.

GUEST OF HONOR

Bradley R. Straatsma, MD, JD

Who is Dr. Straatsma? He was my chairman when I first started as a young faculty member in 1990. We met when I came to the University of California, Los Angeles for a job interview, and he's been extremely supportive of my career ever since.

How have you worked together? He's been a great colleague and advocate of mine; he's nominated me for different positions in the profession, including the American Ophthalmological Society.

What do you admire most about him? I admire his wisdom and broad knowledge, not only about ophthalmology but also other arenas in life.

I've always admired that he's a lifelong learner—always pushing himself to stay engaged and to participate. He even got a law degree after stepping down as chair.

What is the best advice he's ever given you? "All power is elusory."

Fun fact. Dr. Straatsma played a part in establishing the National Eye Institute in 1968. He participated by convincing organizations representing the blind to support the NEI concept. Initially, they were hesitant to be involved. However, with encouragement from Dr. Straatsma, they became strong supporters of the NEI during critical congressional hearings.

GUEST OF HONOR

Bartly J. Mondino, MD

Who is Dr. Mondino? Dr. Mondino was my second chair. Before that he was vice chair, and I met him because he was one of the advisors to the junior faculty. He has always given great advice, not just in my academic career but also in regard to my personal life, especially when I was a new mother, and then, later, as a mother of a teenager and

a college kid. You cannot find a better listener!

How have you two worked together? When I became vice chair of academic affairs, I had the opportunity to meet with him weekly to discuss the faculty and our direction. He's been a fantastic mentor and has spent a lot of time working with me on professional development. He also helped me learn how to handle situations—being able to look at them and figure out the best way to approach them, given the circumstances, the people involved, and the desired outcomes.

What do you admire most about him? He's always making sure things flow, everything is taken care of, everybody is succeeding. His ego isn't in the game, and that makes him extremely successful because he's not worrying about taking credit. I appreciate that he is the kind of person who shares everything he knows—he doesn't hold back his knowledge, which is immense.



Dr. Straatsma

What's the best advice he's given you? There's a quote from the movie "Jerry Maguire" that he likes to use. It's "Help me help you."

Fun facts. He's got a great garden, a dog named Kyla, and a little cat named Kitty that he adopted when it showed up in his garage. He also has two very talented daughters; one is a primary care doctor in Palm Springs and the other oversees community outreach at the Stein Eye Institute.

GUEST OF HONOR

M. Roy Wilson, MD

Who is Dr. Wilson? I also met Dr. Wilson when I interviewed at UCLA. I met all three of my guests on the same day, how about that?



Dr. Mondino

During the interview, I learned that he had gotten a master's in epidemiology. That was one of the reasons why I took the job at UCLA. Because he had been able to do it while he was on faculty, I felt it was an environment where I could also pursue further education. He was very supportive of me getting my master's and



THE PRESIDENT'S GUESTS. Dr. Coleman will honor her three guests during Friday's Opening Session. Why did she select Drs. Straatsma, Mondino, and Wilson? Find out below.

doctorate degrees. He was on my doctorate committee, he was a colleague in the glaucoma division, and he's been one of my lifelong friends.



Dr. Wilson

He left UCLA back in 1998, and since then he's held academic positions around the country. His career has just been stellar, as he's become more and more responsible for other health care providers and education. Now he's president of Wayne State in Detroit and has turned that university around. He's really an amazing

person to have had the opportunity to be friends with.

What do you admire most about Dr. Wilson? He's got drive and he's brilliant, and I admire that. He's also one of those wildly successful men who doesn't forget his friends.

He and I have been friends since 1990. We haven't even been in the same city for the past 20 years, yet we've maintained a friendship. That takes work and energy and effort that a lot of highly driven and ambitious people would never put into a friendship. He's also very wise and supportive.

How do you keep in touch with one another? When we see each other at meetings, we make a point to get together, not just for fine dining but just to hang out. His wife, Jacqueline, and he usually invite me along to go

for walks and just spend time together.

Fun facts. He loves cycling and pelotons. Not Peloton the exercise bike but cycling around in big groups. He's a great cyclist. He's also a wine aficionado. One time we went to Sonoma and did this huge wine tasting and five-course meal that was phenomenal. So, he's a really fun person to do extreme fine dining with!

THE ACADEMY LOOKS FORWARD TO MORE FEMALE LEADERSHIP

Dr. Coleman, who began her term as Academy president in January, is a glaucoma specialist and an educator with a deep commitment to expanding access to quality eye care.

Dr. Coleman is the fourth female president in the Academy's 124-year history. Susan H. Day, MD, was the first in 2005; Ruth D. Williams, MD, was the second in 2012; and Cynthia A. Bradford, MD, was the third in 2017. The Academy looks forward to more female leadership with the president-elect, Tamara R. Fountain, MD, who will become the Academy's first Black woman president in 2021.

The president is the chair of the Academy Board of Trustees and presides at all annual and special Academy meetings. She acts as a representative of the Academy to the medical community at large and federal, state, and local governmental and private agencies and organizations. In her year of service, she works with the Academy CEO to ensure that Academy policies and programs are formulated and executed. She may create special committees and appoint interim Academy representatives to civic, professional, and governmental organizations as may be required to execute the business and affairs of the Academy. She may attend meetings of all committees of the Academy and the Council, other than the Academy's Nominating Committee; and shall have all other duties and responsibilities prescribed by these Bylaws, the Procedural Rules, and the Operational Procedures and that the Board of Trustees may determine.

Passing of the gavel. Attend Sunday's Opening Session to see Dr. Coleman introduce her successor.



Dr. Fountain

Back to the Future: Responses to Global Pandemics

This year's museum display compares and contrasts COVID-19 and trachoma. Visit the Truhlsen-Marmor Museum of the Eye booth at the Resource Center and see why COVID-19 may not be so novel after all.

The year 2020 is now indelibly linked to the COVID-19 global pandemic. As the SARS-CoV-2 virus first hit, many news outlets compared it to other pandemics, particularly the influenza outbreaks of 1918 and 2009 (H1N1). Those retrospective articles were instructive to frame the public's understanding of the seriousness of the pandemic. The news reports also helped convince populations to shelter in place and "flatten the curve."

For its exhibit at AAO 2020 Virtual, the Truhlsen-Marmor Museum of the Eye decided to look at the world's response to COVID-19 and compare it to an ophthalmic pandemic in hopes that ophthalmologists might discover interesting insights.

COVID-19 Versus Trachoma

The disease chosen for comparison is trachoma. Trachoma can be thought of as a slow pandemic. It has been documented for thousands of years and has been labeled a pandemic at several points in its history. Now it is hyperendemic in 37 countries, and it is responsible for the blindness or visual impairment of 1.9 million people worldwide.

Immediately, it could be argued that COVID-19 and trachoma have very little in common. One is caused by a virus, the other is a bacterial infection. One attacks the lungs, the other primarily eyes. Most notably, one has an alarming mortality rate, while the other has none. These differences are incredibly important to the etiology and treatment of these diseases. Yet, the world's reaction to trachoma and COVID-19 are strikingly similar given how different they are.

Travel Bans

Patients with trachoma and those with COVID-19 have been subject to travel bans. During the COVID-19 pandemic, governments worldwide closed their borders. One of the earliest travel bans was instituted by the United States, and by March 13, 2020, the United States had

barred foreign nationals from China, Iran, and several European nations. Then on March 21, 2020, the borders with Mexico and Canada were closed. There are historical precedents for such measures.

Inception of travel bans. Between 1851 and 1938, a total of 14 international meetings were held to help countries coordinate their protocols on how to handle diseases arriving at a nation's ports and standardizing methods of quarantine and hygiene. At the time, the focus was primarily on cholera and its effects on people and commerce. In response to the prevalence of global epidemic disease, the United States passed the Immigration Act of 1891, which specifically barred immigration by those "suffering loathsome or contagious diseases." To safeguard the border, the law also created federal immigration stations, the most famous of which was established in 1892 on Ellis Island.

Trachoma travel ban. In 1897, trachoma was the first disease the U.S. government classified as "loathsome or contagious." By 1905, all immigrants were to be examined by the new Public Health Service (PHS) for signs of the disease. Medical officers of the PHS used hooks and fingers to look at the underside of the eyelids. Public hospitals set up trachoma wards for those who could pay for medical treatment or appeared to have less severe cases. Immigrants who were too ill to recover and become self-sufficient citizens were barred entry to the United States, causing headaches for their home countries and the steamship companies that brought them. Seeing the success of U.S. immigration policy, other countries soon followed suit, including Canada, England, and Germany.

New Infrastructure

As fear of the SARS-CoV-2 virus spread, many countries and local communities worried that hospitals would not have enough beds, ventilators, and personal protective equipment for doctors and nurses. In the United States, the Army



TESTIMONIAL. The human tragedy of trachoma in the United States.

Corps of Engineers established more than 30 field hospitals to alleviate the pressure. These were housed in convention centers and temporary structures. The field hospitals had over 10,000 beds. Through May 2020, the stay-at-home orders issued by a majority of U.S. states meant that the virus remained relatively contained and approximately 8,000 of those beds were never used.

Similar infrastructure, but of a more permanent kind, occurred during the 1803 outbreak of trachoma in Europe. At the time, many countries established eye hospitals in part to separate the trachoma patients from others. The London Dispensary for Curing Diseases of the Eye and Ear was opened in 1805 as part of this movement. It ultimately became Moorfields Eye Hospital.

Lessons Learned

As ophthalmologists worldwide reflect on the crisis during 2020, it is worthwhile to remember that the future of a post-COVID-19 world may well mirror our past experiences of pandemics. Comparing two very different diseases like COVID-19 and trachoma has its limits, but it is very likely that the SARS-CoV-2 virus will become hyperendemic in countries with poorer populations and limited access to health care, just like trachoma.

Let us hope that the current focus on COVID-19 helps to bring the world's attention to all the diseases that could use the same proactive global fight.



Museum Display at the Resource Center

The Truhlsen-Marmor Museum of the Eye has a significant collection related to trachoma, from published accounts of outbreaks in the 1800s to 20th century public awareness campaigns. In 2015, the museum came into possession of a rare set of teaching slides prepared by the National Trachoma Service documenting the struggle to contain the disease in the United States. It also has the oral history and papers of Phillips Thygeson, MD, a pioneer in the search for a cause and cure of trachoma.

See for yourself. Delving into this trachoma collection, the Truhlsen-Marmor Museum of the Eye has developed a new display for AAO 2020 Virtual.

At aao.org/2020, sign in to the AAO 2020 Virtual Platform; next, click the link for the Resource Center; and then visit the museum booth, where you will find a link to the exhibit.

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Best of Show at AAO: 5 Must-See Videos

Out of the 46 scientific videos viewable during AAO 2020 Virtual, these five were selected as Best of Show. They cover cataract; cornea, external disease; glaucoma; oculoplastics, orbit; and refractive surgery.

The 2020 Best of Show winners have provided descriptions, below, of what you can learn from watching their videos. All of this year's videos are accessible through the virtual meeting platform.

CATARACT

New Pupil Expander Used for Capsular Bag Support (V04)

In this video, we evaluated the use of the Xpand (Diamatrix), a nitinol pupil expander with a 6.7-mm internal aperture created from a laser-welded wire for a technique called iridocapsular capture.

A cadaver eye study, as well as use of the device in surgical cases with weak zonules, showed the stability of the capsular bag zonular complex during all of the steps of the phacoemulsification procedure, and up to IOL implantation. In pseudophakic eyes, stability was also maintained during viscodissection of the capsulorrhexis edge and irrigation/aspiration of Soemmering ring material, as well as mobilization of the haptics of the IOL out of the equatorial region. Owing to its design and material characteristics, use of this new pupil expander to perform iridocapsular capture is a promising technique in cases with zonular instability. *Senior author: Alan S. Crandall, MD.*

CORNEA, EXTERNAL DISEASE

Bowman Layer Transplantation: Bridging the Gap in the Management of Keratoconus (V06)

What can be done with keratoconus cases that showed progression on follow-up, were not eligible for corneal cross-linking, and were too early to be candidates for deep anterior lamellar keratoplasty? In our study, three such cases underwent the Bowman layer transplant procedure after informed consent was obtained from patients.

After the donor cornea was mounted on a Barron artificial anterior chamber, first the epithelium was debrided and the stroma was delineated from the Bowman membrane by injecting air. The Bowman layer was then identified by staining with trypan blue. A 360-degree scoring was done with a bent 26-gauge needle to delineate the Bowman membrane. Using

a crescent blade and fine-toothed forceps, the Bowman membrane was gently separated from the underlying stroma.

Corneoscleral tunnel incision was done superiorly/temporally, and the same tunnel was extended throughout the cornea from limbus to limbus at the midstromal level with the help of regular crescent blades and lamellar dissectors. The harvested Bowman layer was then inserted into the stromal pocket with the help of a lens glide, and any folds in the layer were ironed out with a spatula. All three cases showed considerable visual improvement and stabilization of astigmatism in the early post-op period. *Senior author: Madhu Uddaraju, MS.*

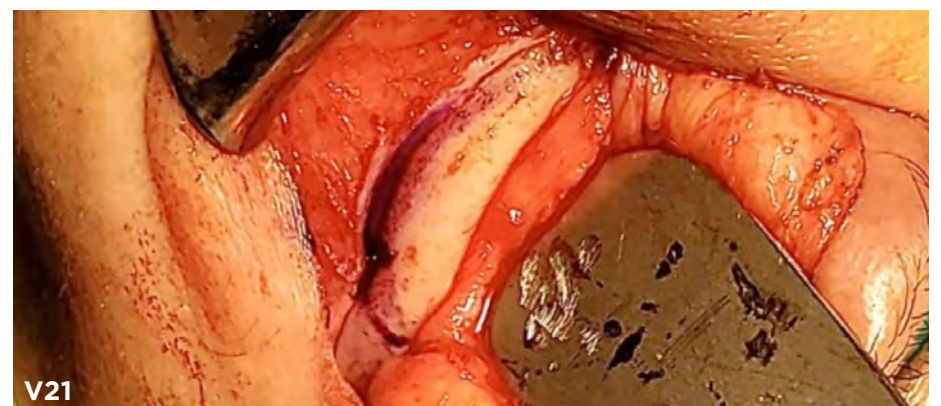
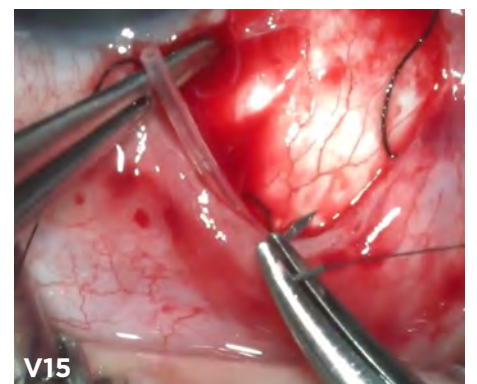
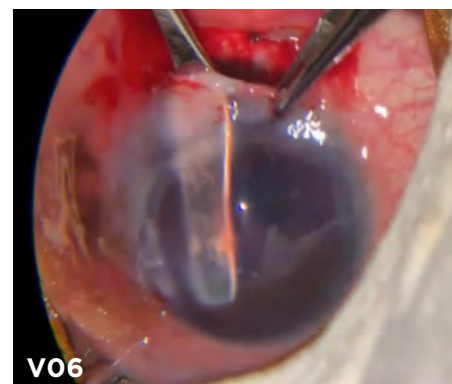
GLAUCOMA

Procedures Held During My First Year Glaucoma Fellowship (V15)

The glaucoma subspecialty is increasingly diverse in terms of surgical procedures. In recent years, many minimally invasive glaucoma surgery (MIGS) devices and procedures have been developed, which reduce the rate of complications and require less postoperative care compared to traditional glaucoma surgeries. However, all glaucoma surgery involves a certain learning curve. Hospital Asociación para Evitar la Ceguera en México (APEC) in Mexico City has a two-year glaucoma fellowship. During the first year, different types of low- to medium-risk surgery are performed, so that in the second year more complex surgeries can be undertaken. This video shows the most commonly used techniques, as well as intraoperative complications that may occur. *Senior Author: Kristell Mariana Hernandez, MD.*

OCULOPLASTICS, ORBIT TONES (V21)

In this video, we demonstrate the TONES (transorbital neuroendoscopic surgery) approach facilitated with the chopstick technique for a sphenoidal ridge meningioma. A 63-year-old woman presented with right eye prominence and visual loss over three months. On exam she had 20/200 vision, signs of optic neuropathy, a -2 deficit in extraocular movement in all directions, and a 3-mm proptosis. The traditional approach is through a craniotomy. For this case, a TONES approach



with real-time navigation was used to remove the hyperostotic lateral orbital bone and intracranial meningioma. *Senior author: Stacey L. Lam, MBCHB.*

REFRACTIVE SURGERY

OVD-Free Posterior Chamber Phakic ICL Implantation (V25)

The use of an ophthalmic viscoelastic device (OVD) during implantable collamer lens (ICL) implantation has been

essential to maintaining the stability of the anterior chamber. However, there are also some disadvantages of OVD use. An OVD can cause postoperative elevation of intraocular pressure when it is not completely removed, and it can increase overall operation time because extra time is needed to insert and remove the injected OVD. Herein, we introduce ICL implantation without the use of OVD. *Senior author: Young-Taek Chung, MD.*

Explore the Academy's New Products Don't Miss Out on the 10% Discount

During AAO 2020 Virtual, visit the Resource Center to explore scores of products developed by the Academy and its practice management arm, the American Academy of Ophthalmic Executives (AAOE).

Don't miss out on this year's discount. Visit the Resource Center during AAO 2020 Virtual to learn what Academy and AAOE services are available and to find out how you can get a 10% discount (see box) on most Academy and AAOE products.

See what's new, as well as the tried and true. This article focuses on what's new since AAO 2019, but you shouldn't overlook the Academy's and AAOE's full range of products, which include many niche products.

Where to find the Resource Center. When you sign in to the AAO 2020 Virtual platform, there will be a link that takes you to the Resource Center.

When will staff be on hand? Academy and AAOE staff will be available to answer your questions from Friday, Nov. 13, through Sunday, Nov. 15, 7:00 a.m. to 4:00 p.m. PST.

New in Clinical Education

What's new in the 2020-2021 Basic and Clinical Science Course (BCSC). Each year, the 13-volume BCSC is reviewed by more than 100 ophthalmologists to ensure that its information is as concise and current as possible. Each volume features videos, tables, self-assessment questions (with answers), photos and illustrations, and opportunities for earning AMA PRA Category 1 Credit.

While all 13 volumes have been updated, three of them have undergone major revisions:

- Section 04: Ophthalmic Pathology and Intraocular Tumors
- Section 10: Glaucoma
- Section 11: Lens and Cataract

While you are visiting the Resource Center. Over the years, the Academy has developed a rich repository of educational resources. In addition to learning about this year's new products, you can ask Academy staff about the AAO Ophthalmic Education App; the new AAO e-books app, which allows you to search

across all the Academy's clinical education e-book titles; the BCSC Self-Assessment Program, which now features more than 3,000 high-yield questions (see

"Self-Assessment Tools," page 23); *Basic Principles of Ophthalmic Surgery* and *Basic Techniques of Ophthalmic Surgery*; the *Dictionary of Eye Terminology*, Sev-

enth Edition, which uses plain-language definitions and full-color illustrations to make ophthalmic terminology accessible to everybody in your office; and more.

ONCE-DAILY
rocklatan®
(netarsudil and latanoprost
ophthalmic solution) 0.02%/0.005%

Superior efficacy.
Optimal simplicity.^{1,2}

Once-daily Rocklatan® significantly lowers IOP in patients with open-angle glaucoma or ocular hypertension—superior to latanoprost and netarsudil at every measured timepoint in phase 3 clinical trials.^{1,2}

The first and only once-daily fixed-dose combination of prostaglandin + ROCK inhibitor



Nearly 60% of Rocklatan® patients achieved a target pressure of 16 mmHg or less²



The majority of ocular adverse events were mild and tolerable, with minimal systemic adverse events^{1,3}



Once-daily dosing relieves treatment burden and may improve adherence and treatment outcomes^{1,4}

IOP: intraocular pressure; ROCK: rho kinase



Visit Rocklatan.com to learn more about this innovative drop for elevated IOP

IMPORTANT SAFETY INFORMATION

Contraindications
None.

Warnings and Precautions

- Pigmentation changes
- Eyelash changes
- Intraocular inflammation
- Macular edema
- Herpetic keratitis
- Bacterial keratitis
- Contact lens wear

Adverse reactions

Rocklatan®: The most common ocular adverse reaction is conjunctival hyperemia (59%). Five percent of patients discontinued therapy due to conjunctival hyperemia. Other common ocular adverse reactions were: instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%). Eye pruritus, visual acuity reduced, increased lacrimation, instillation site discomfort, and blurred vision were reported in 5-8% of patients.

Netarsudil 0.02%: Instillation site erythema, corneal staining, increased lacrimation and erythema of eyelid.

Latanoprost 0.005%: Foreign body sensation, punctate keratitis, burning and stinging, itching, increased pigmentation of the iris, excessive tearing, eyelid discomfort, dry eye, eye pain, eyelid margin crusting, erythema of the eyelid, upper respiratory tract infection/nasopharyngitis/influenza, photophobia, eyelid edema, myalgia/arthralgia/back pain, and rash/allergic reaction.



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Please see brief summary on the adjacent page.

For full Prescribing Information, please visit Rocklatan.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

INDICATIONS AND USAGE

Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening. If one dose is missed, treatment should continue with the next dose in the evening. The dosage of Rocklatan® should not exceed once daily. Rocklatan® may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

References:

1. Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% Prescribing Information, Aerie Pharmaceuticals, Inc., Irvine, Calif. 2019.
2. Asrani S, McKee H, Scott B, et al. Pooled phase 3 efficacy analysis of a once-daily fixed-dose combination of netarsudil 0.02% and latanoprost 0.005% in ocular hypertension and open-angle glaucoma. Presented at the 13th Biennial Meeting of the European Glaucoma Society, March 2018.
3. Data on file. Aerie Pharmaceuticals, LLC.
4. Prum B Jr, Rosenberg L, Gedde S, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern guidelines. *Ophthalmology*. 2016;123(1):P41-P111.

US-ROC-P-0003

10% Discount

Visit the Academy Resource Center to get discount codes for Academy and AAOE products. Once you have the codes, you can—for a limited time—save 10% on most purchases at aao.org/store. (The codes are valid from Nov. 13 through Nov. 29; no minimum purchase is required.)

New for Patient Education

What’s new in the Print-on-Demand Handout Subscription. This 12-month subscription provides access to the most comprehensive library of patient education handouts in ophthalmology. It features 164 topics in both English and Spanish, including four brand-new handouts:

- *Corneal Cross-Linking*
- *Myopia Control in Children*
- *Lattice Degeneration*
- *Coronavirus and Your Eyes*

These handouts are easy to customize with your practice information. You can then print them in your office as-needed in unlimited quantities (color or black and white).

While you are visiting the Resource Center. As well as asking about the new handouts, you can explore the Academy’s other popular patient education resources, including dozens of English- and Spanish-language brochures and a collection of video animations, for use on your website or patient portal, depicting eye anatomy, common eye

conditions, and treatment options.

COVID and your patients: Digital patient education tools, such as the video collections (see page 19), are more valuable than ever. As direct patient interaction is more limited during the pandemic, enhance your reach by showing treatment-specific informed consent videos on your website or patient portal. Use the Academy’s subspecialty-specific video collections to reinforce your diagnosis and treatment messaging when patients are best able to focus—at home, with family, or any time it’s convenient for them. Documenting use of these OMIC-approved videos helps to mitigate malpractice risk.

New in Practice Management

Conquering New E/M Documentation Guidelines for Ophthalmology. Starting Jan. 1, 2021, Medicare is streamlining the requirements for using the office-based Evaluation and Management (E/M) codes. To help your practice understand what needs to be performed and documented under the new policies, Academy and AAOE experts have developed Conquering New E/M Documentation Guidelines, an online tutorial with accompanying workbook that includes step-by-step instructions, clinical examples, and worksheets. By passing the exam section of the tutorial, you can earn an electronic certificate of completion.

Get your practice ready for 2021. Each year, there are changes to reimbursement codes and regulations, and each year the AAOE updates its arsenal of coding references:

- *2021 Coding Coach: Complete Ophthalmic Coding Reference*
- *2021 CPT: Complete Pocket Ophthalmic Reference*
- *2021 Retina Coding: Complete Reference Guide*
- *2021 ICD-10-CM for Ophthalmology: The Complete Reference*
- *2021 Fundamentals of Ophthalmic Coding*
- *2021 CPT Professional Edition*
- *2021 HCPCS Level II Professional Edition*
- *2021 Coding Assistant: Cataract and Anterior Segment*
- *2021 Coding Assistant: Cornea*
- *2021 Coding Assistant: Glaucoma*
- *2021 Coding Assistant: Oculofacial*
- *2021 Coding Assistant: Pediatrics/Strabismus*
- *2021 Coding Assistant for Subspecialties*

While you are visiting the Resource Center. In addition to the aforementioned new and revised coding products, ask AAOE staff about their ophthalmology-specific practice management primers and references. These include *The Lean Practice: A Step-by-Step Guide to Running an Efficient and Profitable Ophthalmic Practice*; *The Profitable Retina Practice* series; *The Dispensing Ophthalmologist* e-book; and much more.

Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% Rx Only

BRIEF SUMMARY

Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening.

If one dose is missed, treatment should continue with the next dose in the evening. The dosage of Rocklatan® should not exceed once daily. Rocklatan® may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Pigmentation

Rocklatan® contains latanoprost which has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as latanoprost is administered.

The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Beyond 5 years the effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with Rocklatan® can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes

Rocklatan® contains latanoprost which may gradually change eyelashes and vellus hair in the treated eye; these changes include increased length, thickness, pigmentation, the number of lashes or hairs, and misdirected growth of eyelashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation

Rocklatan® contains latanoprost which should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation because it may exacerbate inflammation...

Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with latanoprost. Rocklatan® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Herpetic Keratitis

Reactivation of Herpes Simplex keratitis has been reported during treatment with latanoprost. Rocklatan® should be used with caution in patients with a history of herpetic keratitis. Rocklatan® should be avoided in cases of active herpes simplex keratitis because it may exacerbate inflammation.

Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Use with Contact Lenses

Contact lenses should be removed prior to the administration of Rocklatan® and may be reinserted 15 minutes after administration.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Rocklatan®

The most common ocular adverse reaction observed in controlled clinical studies with Rocklatan® was conjunctival hyperemia which was reported in 59% of patients. Five percent of patients discontinued therapy due to conjunctival hyperemia. Other common ocular adverse reactions reported were: instillation site pain (20%), corneal verticillata (15%), and conjunctival hemorrhage (11%). Eye pruritus, visual acuity reduced, increased lacrimation, instillation site discomfort, and blurred vision were reported in 5-8% of patients.

Other adverse reactions that have been reported with the individual components and not listed above include:

Netarsudil 0.02%

Instillation site erythema, corneal staining, increased lacrimation and erythema of eyelid.

Latanoprost 0.005%

Foreign body sensation, punctate keratitis, burning and stinging, itching, increased pigmentation of the iris, excessive tearing, eyelid discomfort, dry eye, eye pain, eyelid margin crusting, erythema of the eyelid, upper respiratory tract infection/nasopharyngitis/influenza, photophobia, eyelid edema, myalgia/arthralgia/back pain, and rash/allergic reactions.

DRUG INTERACTIONS

Although specific drug interaction studies have not been conducted with Rocklatan®, in vitro studies have shown that precipitation occurs when eye drops containing thimerosal are mixed with latanoprost ophthalmic solution 0.005%. If such drugs are used, they should be administered at least five (5) minutes apart.

The combined use of two or more prostaglandins or prostaglandin analogs including latanoprost ophthalmic solution 0.005% is not recommended. It has been shown that administration of these prostaglandin drug products more than once daily may decrease the IOP lowering effect or cause paradoxical elevations in IOP.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on netarsudil ophthalmic solution use in pregnant women to inform any drug associated risk; however, systemic exposure to netarsudil from ocular administration is low. Intravenous administration of netarsudil to pregnant rats and rabbits during organogenesis did not produce adverse embryofetal effects at clinically relevant systemic exposures.

Animal Data

Netarsudil administered daily by intravenous injection to rats during organogenesis caused abortions and embryofetal lethality at doses ≥0.3 mg/kg/day (126-fold the plasma exposure at the RHOD, based on C_{max}). The no-observed-adverse-effect-level (NOAEL) for embryofetal development toxicity was 0.1 mg/kg/day (40-fold the plasma exposure at the RHOD, based on C_{max}).

Netarsudil administered daily by intravenous injection to rabbits during organogenesis caused embryofetal lethality and decreased fetal weight at 5 mg/kg/day (1480-fold the plasma exposure at the RHOD, based on C_{max}). Malformations were observed at ≥3 mg/kg/day (1330-fold the plasma exposure at the RHOD, based on C_{max}), including thoracogastroschisis, umbilical hernia and absent intermediate lung lobe. The NOAEL for embryofetal development toxicity was 0.5 mg/kg/day (214-fold the plasma exposure at the RHOD, based on C_{max}).

For latanoprost, in 4 of 16 pregnant rabbits, no viable fetuses were present at a dose that was approximately 80 times higher than the RHOD. Latanoprost did not produce embryofetal lethality in rabbits at a dose approximately 15 times higher than the RHOD.

Lactation

There are no data on the presence of netarsudil or latanoprost in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to netarsudil following topical ocular administration is low, and it is not known whether measurable levels of netarsudil would be present in maternal milk following topical ocular administration. It is also not known whether latanoprost or its metabolites are excreted in milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Rocklatan® and any potential adverse effects on the breastfed child from netarsudil and latanoprost.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of netarsudil. Netarsudil was not mutagenic in the Ames test, in the mouse lymphoma test, or in the *in vivo* rat micronucleus test. Studies to evaluate the effects of netarsudil on male or female fertility in animals have not been performed.

Latanoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 170 mcg/kg/day (approximately 2800 times the recommended maximum human dose) for up to 20 and 24 months, respectively. Latanoprost was not mutagenic in bacteria, in mouse lymphoma, or in mouse micronucleus tests. Chromosome aberrations were observed in vitro with human lymphocytes. Additional *in vitro* and *in vivo* studies on unscheduled DNA synthesis in rats were negative. Latanoprost has not been found to have any effect on male or female fertility in animal studies.

For additional information, refer to the full prescribing information at www.Rocklatan.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.



Manufactured for: Aerie Pharmaceuticals, Inc., Irvine, CA 92614, U.S.A.

Rocklatan® is a registered trademark of Aerie Pharmaceuticals, Inc.
U.S. Patent Nos.: 8,450,344; 8,394,826; 9,096,569; 9,415,043; 9,931,336; 9,993,470

NGENUITY[®]
DIGITALLY ASSISTED SURGERY

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TRANSFORM YOUR EXPERIENCE.

Contact your Alcon representative to schedule a personalized demo of the latest **NGENUITY[®] 3D Visualization System** advancements featuring **CENTURION[®] Vision System** and **ORA SYSTEM[®]** with **VerifEye[®]+ Technology** integration.

IMPORTANT PRODUCT INFORMATION

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Indication: The NGENUITY[®] 3D Visualization System consists of a 3D stereoscopic, high-definition digital video camera and workstation to provide magnified stereoscopic images of objects during micro-surgery. It acts as an adjunct to the surgical microscope during surgery displaying real-time images or images from recordings.

Warnings: The system is not suitable for use in the presence of flammable anesthetics mixture with air or oxygen. There are no known contraindications for use of this device.

Precautions: Do not touch any system component and the patient at the same time during a procedure to prevent electric shock. When operating in 3D, to ensure optimal image quality, use only approved passive-polarized glasses. Use of polarized prescription glasses will cause the 3D effect to be distorted. In case of emergency, keep the microscope oculars and mounting accessories in the cart top drawer. If there are any concerns regarding the continued safe use of the NGENUITY[®] 3D Visualization System, consider returning to using the microscope oculars.

Attention: Refer to the user manual for a complete list of appropriate uses, warnings and precautions.

Alcon

Safety Data

YOU CAN TRUST¹

Confidence in Demonstrated Safety Data Across 4 FDA-Approved Indications¹



WET AMD, DME, DR, and MEfRVO¹

Visit HCP.EYLEA.US to see safety and efficacy results

anti-VEGF = anti-vascular endothelial growth factor; AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema; DR = Diabetic Retinopathy; MEfRVO = Macular Edema following Retinal Vein Occlusion.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

- EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019.
2. Data on file. Regeneron Pharmaceuticals, Inc.

Please see Brief Summary of Prescribing Information on the following page.



**Anti-VEGF
Treatment Backed
by Extensive
Clinical and
Real-World
Experience¹**

8 YEARS
of extensive
clinical experience
and the integrity
of data from large,
well-controlled
trials¹

**9 An Estimated
MILLION
DOSES**
administered to
≈790,000 eyes
since launch
(and counting)²

**8 PHASE 3
CLINICAL
TRIALS**
including more
than 3000
EYLEA-treated
patients across
all approved
indications¹

WARNINGS AND PRECAUTIONS (cont'd)

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON



BRIEF SUMMARY—Please see the EYLEA full Prescribing Information available on HCP.EYLEA.US for additional product information.

1 INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of:

Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR).

4 CONTRAINDICATIONS

4.1 Ocular or Periorcular Infections

EYLEA is contraindicated in patients with ocular or periorcular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [see Adverse Reactions (6.1)]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [see Patient Counseling Information (17)].

5.2 Increase in Intraocular Pressure.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [see Adverse Reactions (6.1)]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

5.3 Thromboembolic Events.

There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [see Contraindications (4.3)]
- Endophthalmitis and retinal detachments [see Warnings and Precautions (5.1)]
- Increase in intraocular pressure [see Warnings and Precautions (5.2)]
- Thromboembolic events [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.

A total of 2980 patients treated with EYLEA constituted the safety population in eight phase 3 studies. Among those, 2379 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEW1 and VIEW2) for 24 months (with active control in year 1).

Safety data observed in the EYLEA group in a 52-week, double-masked, Phase 2 study were consistent with these results.

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 96	
	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)	EYLEA (N=1824)	Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%	27%	30%
Eye pain	9%	9%	10%	10%
Cataract	7%	7%	13%	10%
Vitreous detachment	6%	6%	8%	8%
Vitreous floaters	6%	7%	8%	10%
Intraocular pressure increased	5%	7%	7%	11%
Ocular hyperemia	4%	8%	5%	10%
Corneal epithelium defect	4%	5%	5%	6%
Detachment of the retinal pigment epithelium	3%	3%	5%	5%
Injection site pain	3%	3%	3%	4%
Foreign body sensation in eyes	3%	4%	4%	4%
Lacrimation increased	3%	1%	4%	2%
Vision blurred	2%	2%	4%	3%
Intraocular inflammation	2%	3%	3%	4%
Retinal pigment epithelium tear	2%	1%	2%	2%
Injection site hemorrhage	1%	2%	2%	2%
Eyelid edema	1%	2%	2%	3%
Corneal edema	1%	1%	1%	1%
Retinal detachment	<1%	<1%	1%	1%

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal tear, and endophthalmitis.

Macular Edema Following Retinal Vein Occlusion (RVO). The data described below reflect 6 months exposure to EYLEA with a monthly 2 mg dose in 218 patients following CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following BRVO in one clinical study (VIBRANT).

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

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Issue Date: 08/2019
Initial U.S. Approval: 2011

Based on the August 2019 EYLEA® (aflibercept) Injection full Prescribing Information.

EYL19.07.0306

Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

Adverse Reactions	CRVO		BRVO	
	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival hemorrhage	12%	11%	20%	4%
Intraocular pressure increased	8%	6%	2%	0%
Corneal epithelium defect	5%	4%	2%	0%
Vitreous floaters	5%	1%	1%	0%
Ocular hyperemia	5%	3%	2%	2%
Foreign body sensation in eyes	3%	5%	3%	0%
Vitreous detachment	3%	4%	2%	0%
Lacrimation increased	3%	4%	3%	0%
Injection site pain	3%	1%	1%	0%
Vision blurred	1%	<1%	1%	1%
Intraocular inflammation	1%	1%	0%	0%
Cataract	<1%	1%	5%	0%
Eyelid edema	<1%	1%	1%	0%

Less common adverse reactions reported in <1% of the patients treated with EYLEA in the CRVO studies were corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR). The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 100	
	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium defect	5%	3%	7%	5%
Intraocular pressure increased	5%	3%	9%	5%
Ocular hyperemia	5%	6%	5%	6%
Vitreous detachment	3%	3%	8%	6%
Foreign body sensation in eyes	3%	3%	3%	3%
Lacrimation increased	3%	2%	4%	2%
Vision blurred	2%	2%	3%	4%
Intraocular inflammation	2%	<1%	3%	1%
Injection site pain	2%	<1%	2%	<1%
Eyelid edema	<1%	1%	2%	1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.

Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

6.2 Immunogenicity.

As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS.

8.1 Pregnancy

Risk Summary

Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [see Animal Data].

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg.

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocoele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternbrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

8.2 Lactation

Risk Summary

There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 3 months after the last intravitreal injection of EYLEA.

Infertility

There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment.

8.4 Pediatric Use.

The safety and effectiveness of EYLEA in pediatric patients have not been established.

8.5 Geriatric Use.

In the clinical studies, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

17 PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [see Warnings and Precautions (5.1)].

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [see Adverse Reactions (6)]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Online Patient Portals: 3 Keys to Better Patient Engagement

A patient portal can boost patient engagement while improving practice efficiency and productivity. Here are three key ways to engage patients with your portal.

Throughout the COVID-19 pandemic, the patient portal has been an important tool for providing education remotely. Beyond giving patients access to data from their electronic health records (EHRs), portals can allow you to provide an extra level of information when your time is at a premium.

Portals can increase family involvement in a patient's care. "Our patients are happy to have education sent to them in their portals," said Raj K. Maturi, MD, a retina specialist in Indianapolis. "They especially appreciate sharing patient education videos with family. They return to the office with very specific questions, and that tells me they are watching and absorbing the educational messaging. It saves time when I talk with them because we can focus on their questions."

The value of patient engagement. By extending the relationship between doctors and patients beyond the exam lane, portals are designed to improve patient engagement. Patients who are engaged in their care maintain stronger attachments to their medical practices. That, in turn, leads to greater patient satisfaction and an improved experience.

1 Make Portal Promotion an Everyday Routine

Make a concerted effort to help patients become accustomed to the portal. They are more likely to use it when doctors and office staff *repeatedly* demonstrate how to use it and discuss what it can do for them.

Motivate staff to promote the portal. Promoting the portal should be a routine part of staff procedures. Throughout the patient visit, multiple staff can reinforce this effort: the receptionist, medical assistants, nurses, and physicians. To help keep staff members motivated in this endeavor, track increases in portal usage (e.g., the number of patient online messages collected) and the impact on practice productivity (e.g., estimates of time saved during an office visit because patients already entered information via the portal). Set targets for portal use, and when you reach those milestones make

sure you share the news (and the credit) with staff.

Physicians need to promote the portal. Keep in mind that your personal recommendation as a doctor has a strong impact on portal use. If you tell patients that registering for the portal is important, they are more likely to register.

Get patients using the portal while still in your office. To reinforce learning, if feasible, ask patients to do a simple portal task such as updating their insurance information or medication information while at the practice.

Don't let patients leave your office without portal instructions. Include instructions for the portal on the visit summary page you provide the patient.

2 Instruct Patients When and How Often to Use the Portal

Be specific in explaining to patients exactly when and why they should use the portal. For example, if you have sent an educational handout or video to the portal, remind your patients as they leave the office, "information about today's visit is in your portal. Be sure to look at it and share this information with your family, if you like. It will help you understand your condition/treatment."

Consider using social media to remind them of the portal, and regularly send valuable content to the portal (see below) to keep it fresh and top of mind.

3 Make Sure the Portal Is Worth Your Patients' Time

If you consistently provide your patients with the information they want and need via the portal, they will return to it.

Beyond the critical health care data, offer educational materials. In addition to lab results, physician notes, and their health histories, be sure to include appropriate patient education material. This enables patients to learn about specific conditions and treatment options at home, so they are not inundated with information during the office visit, and they can share the information with their families—a vital way to improve patient understanding and compliance.

Share Short Videos Via Your Portal

Make face-to-face discussions with your patients more efficient and productive using Academy patient education videos. When offered on your patient portal or practice website, high-quality Academy videos can be viewed by patients outside of the office, saving valuable time and improving clinic flow.

Five subspecialties, 71 videos.

Choose from five collections:

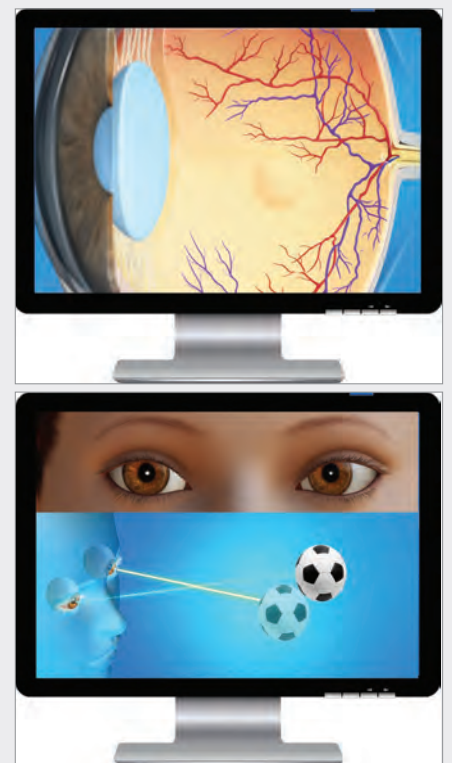
- Cataract and Refractive Surgery (22 videos)
- Retina (23 videos)
- Glaucoma (10 videos)
- Oculoplastics (7 videos)
- Pediatric (9 videos)

What you (and your patients) will get.

Each of these subspecialty collections:

- includes multiple videos (all 5 minutes or shorter),
- outlines the most common treatments,
- supports the informed consent process,
- is advertising-free,
- can be posted to any platform, and
- includes English- and Spanish-language versions.

These videos are yours to own



(no subscription required).

See for yourself. Visit aao.org/patient-videos to view samples from each collection. If you have questions about patient education products, visit the Resource Center (see box) and use the chat feature.

Help patients communicate their concerns. Consider including a feature that allows patients to record questions and concerns, such as symptoms to remember to report, questions to ask the doctor, or other information to share at their next appointment. If they can send a secure email, that creates another reason to use the portal.

Provide links to online tools and resources. For the patient with diabetic retinopathy, for instance, include links to online diabetes management information.

Engage Your Patients Outside the Office for Better Outcomes

As an extension of the doctor-patient interaction, a portal allows patients to become more actively involved in their health care. With that involvement, evidence shows that patients experience better outcomes.

Although EHRs and patient portals are not perfect, making the effort to directly engage patients in using your portal can pay dividends.

Dr. Maturi is a retina specialist at the Midwest Eye Institute, which has clinics in central Indiana. *Relevant financial disclosures: None.*

The Resource Center

Got questions? After signing in to AAO Virtual 2020, click the link to the Resource Center. Staff will be available from Friday, Nov. 13, to Sunday, Nov. 15, 7:00 a.m. to 4:00 p.m. PST.

Don't miss out on the 10% discount. While at the Resource Center, you can get discount codes that—for a limited time—will save you 10% on most purchases at aao.org/store.

Ophthalmology + Twitter = A Successful Pair

Only a few years ago, *Ophthalmology* had a minimal presence on social media. Now it commands attention across the Twittersverse. What happened?

Stephen D. McLeod, MD, editor-in-chief of *Ophthalmology*, wanted to grow the social media presence of the journal in order to get more young ophthalmologists (YOs) excited about its peer-reviewed studies. So, in 2018, he invited several members of the Academy YO Committee to help. The social media editors represent various subspecialties and were selected for their well-established presence on Twitter and other social media outlets; each has 1,000 to 2,700 followers. Dr. McLeod hoped that these editors would grow the journal's social media following as well as engage their colleagues in discussion about the

articles. So far in 2020, the editors have cumulatively posted an average of 60 tweets each month, resulting in average total monthly impressions exceeding 154,000. This is up dramatically from 2018, when monthly impressions averaged 63,000 for a total of 54 tweets.

How it's done. Each week, articles in press from *Ophthalmology*, *Ophthalmology Retina*, and *Ophthalmology Glaucoma* are posted to @AAOjournal on Twitter. Each social media editor is assigned journal articles to tweet about in their personal accounts, and these are retweeted on the *Ophthalmology* Twitter account.

Pictured here are five successful tweets from the last two years. Success can be defined by the number of impressions (i.e., the number of times that it shows up in a user's timeline or search results, which reflects the popularity of the tweet). In addition, it can be defined by engagement (i.e., how many times the tweet was shared, how many commented on the tweet, and how many times a branded hashtag was tweeted). What makes a tweet successful? Senior social media editor Lorraine M. Provencher, MD explained that a well-crafted tweet should cover the salient points of a study but should also pique curiosity, drawing the social media user back to the original work.

Be sure to follow the *Ophthalmology* journal year-round at @AAOjournal and by following each of the editors on their personal accounts. And watch for their live tweets during the AAO 2020 Virtual. The social media editors are:

Lorraine Provencher, MD, is a glaucoma specialist at the Cincinnati Eye Institute. Her Twitter handle is @DrLorraineEyeMD.

Andrew R. Carey, MD, is a neuro-ophthalmologist at the Wilmer Eye Institute in Baltimore, @DrewCareyMD.

Matt Feng, MD, is a cornea, cataract, and anterior segment surgeon in private practice in Indianapolis, @iDrFeng.

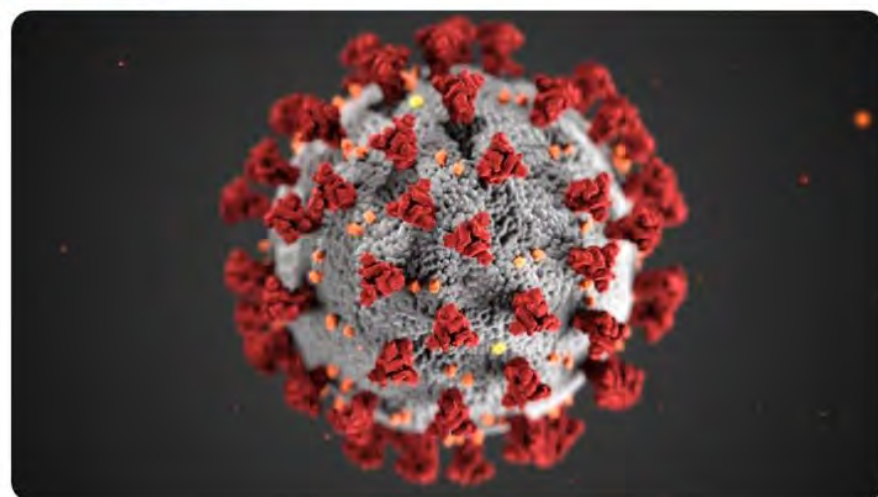
Rajesh C. Rao, MD, is a retina specialist at the University of Michigan, Ann Arbor, @SurgeonRetina.

Edmund Tsui, MD, is a uveitis specialist at the Stein Eye Institute in Los Angeles, @EdmundTsuiMD.

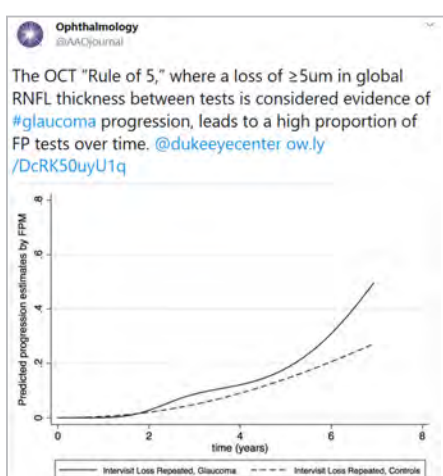
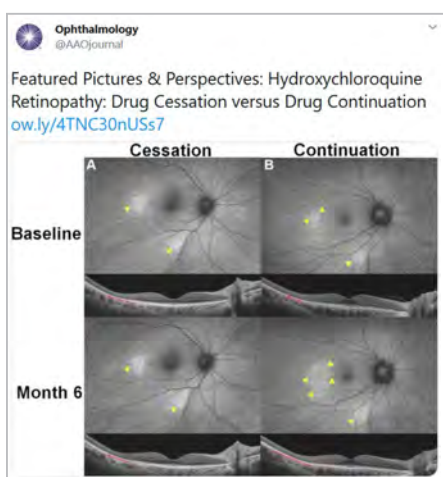
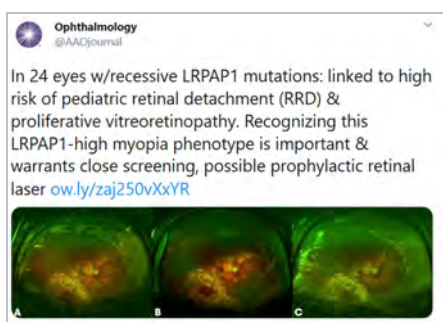
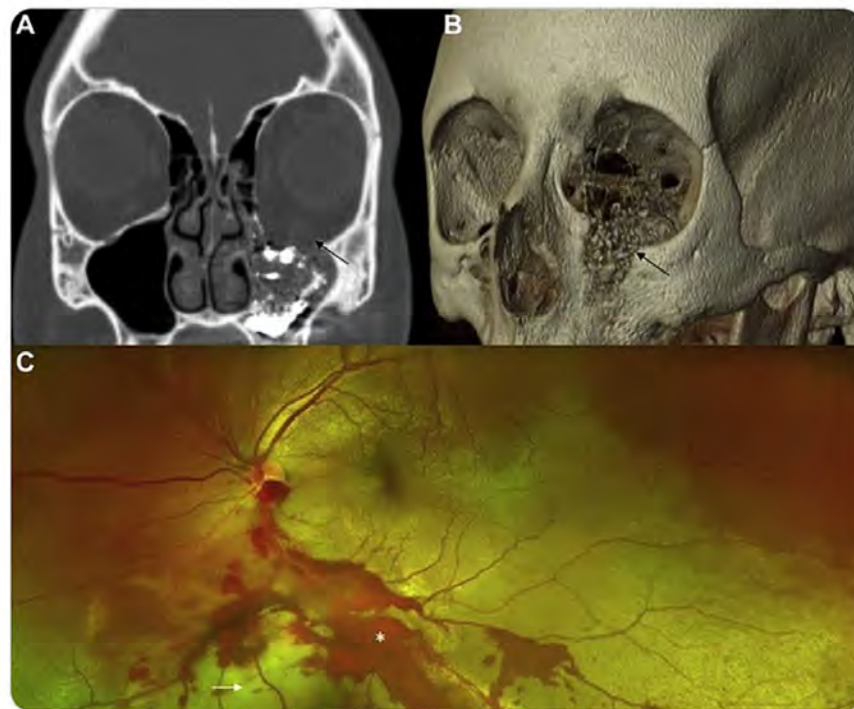
During the AAO 2020 virtual meeting, follow the Academy on Twitter at @aao_ophth and use the hashtag #aao2020.



NEW #COVID-19 study from Singapore suggests the risk of #ocular transmission is low, with no evidence of viral shedding detected in tears through the course of the disease. #ophthalmology #coronavirus #COVID19 @AmerMedicalAssn @CDCgov @NIH aaojournal.org /article/S0161-...



Devastating and potentially blinding - the ophthalmic impact of a rubber bullet. #ophthalmology #NotOneMoreEye #NoRubberBullets #RubberBullets #protests2020 From: @EmoryEyeCenter aaojournal.org /article/S0161-...



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5 Principles and Tips for Effective Self-Education

Physician learning and maintenance of knowledge is critical to expertly managing patients. After all, it doesn't inspire confidence in your patients if you must consult "Dr. Google" to recall facts you learned in residency.

Many self-assessment tools are available to help with professional learning and review. Below Kevin E. Lai, MD, shares principles and tips for using these tools.

1 Don't Memorize

One common study strategy I used during my residency was to read and re-read the *Basic and Clinical Science Course (BCSC)* books. While the BCSC is a fantastic high-yield ophthalmic knowledge reference, memorization of the text can lead to a false sense of knowledge, or "false fluency." I discovered this firsthand when I encountered multiple questions on the OKAP during my first year of residency that weren't verbatim from the BCSC. I struggled with those questions because my knowledge was based more on the *phrasing* of the text rather than truly understanding the underlying *concept*.

Tip #1. Avoid false fluency. Self-assessment questions and answers can also be easily memorized. Bolstered by false fluency, you may be tempted to skip or gloss over a question that was previously answered correctly. It is important to make the effort to consciously process every question. One way to do this is by covering up the answer choices and forcing yourself to generate the answer without seeing any choices. Other ways to combat a false sense of mastery include quizzing yourself as you read, making a detailed outline, or writing out the key points in your own words.

2 Learning Requires Effort

Mental shortcuts, mnemonic devices, and "high yield" reviews are intended to shorten the time and mental energy required to recall complex topics. But to initially learn those concepts and to retain full conceptual understanding requires continued work in order to successfully acquire and retain knowledge over the long term. Learning "the hard way" stays with you longer. For example, even years later, it is much easier for me to recall the differences between meibomian glands and Zeis glands because I

had to look them up.

Tip #2. Reflect when reviewing.

Whether you're still in training or in clinical practice, take time at close of business to reflect and learn about the patients seen that day. If you're working on practice questions, read each answer choice and ask yourself: Why are the other choices wrong? What are the reasons why I chose the right answer?

Avoid the temptation to move ahead to the next question before understanding your rationale.

3 Space Out Your Review

Another common study strategy is to review a concept over and over in rapid succession, or "cramming." In the book, *Make It Stick: The Science of Successful Learning*,¹ the authors recommend learning by "spaced repetition." They assert that long-term retention and comprehension suffers with the cramming technique. Instead, returning to the same material after a period of time forces your brain to recall information that may be difficult to retrieve. The

effort that comes from retrieving that information helps your brain "load" that concept into your working memory. Multiple repetitions spaced over time helps your brain flag that concept for rapid retrieval.

Tip #3. Use flashcards. Flashcards are one of the prototypical applications of spaced review. Because the information presented on each flashcard is naturally cycled through the deck, it forces your brain to move away from the topic and return to it later for effortful retrieval. This study technique can be augmented by reviewing difficult questions more frequently and reviewing easier topics less frequently: As you flip through a



FIGURE 1: FEEDBACK. Timely feedback helps to focus attention on key concepts and to build a framework for understanding. The BCSC Self-Assessment displays scores in easily scannable bar graph format.

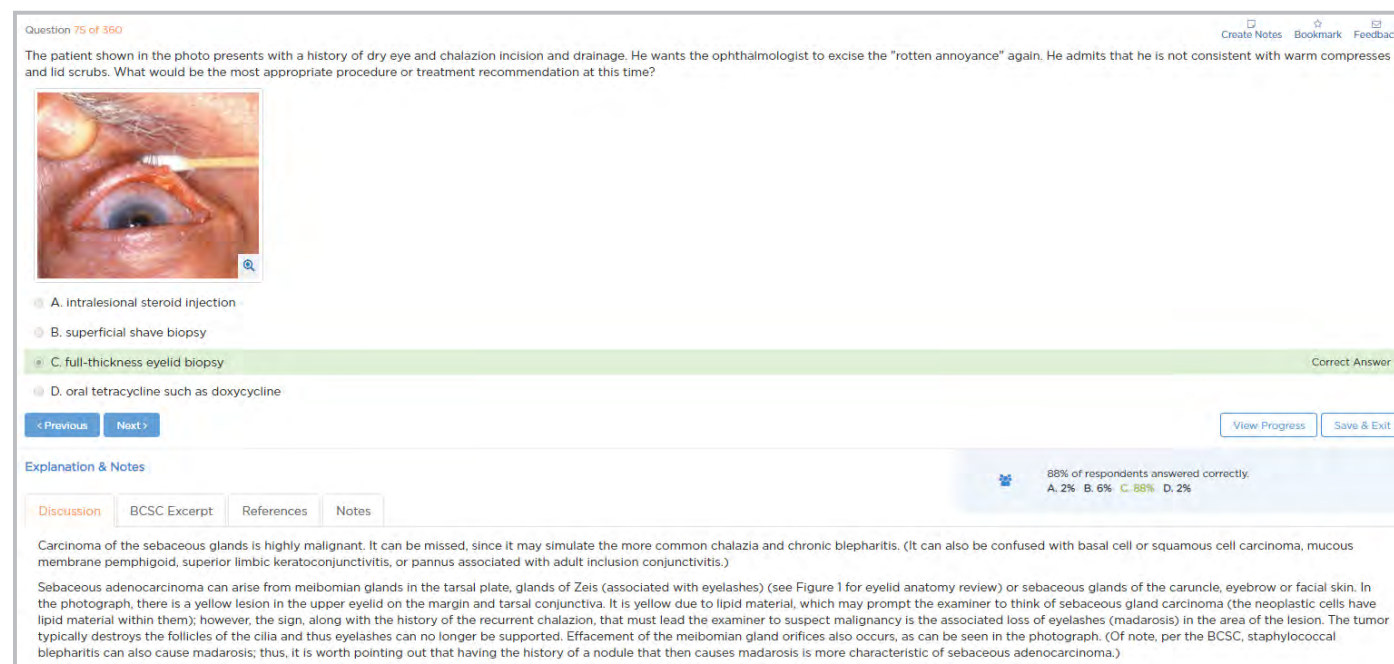


FIGURE 2: READ EXPLANATIONS. The BCSC Self-Assessment and other study tools provide discussion of both correct and incorrect answers. These explanations can help check your rationale.

BY KEVIN E. LAI, MD, ACADEMY RESIDENT SELF-ASSESSMENT COMMITTEE MEMBER.

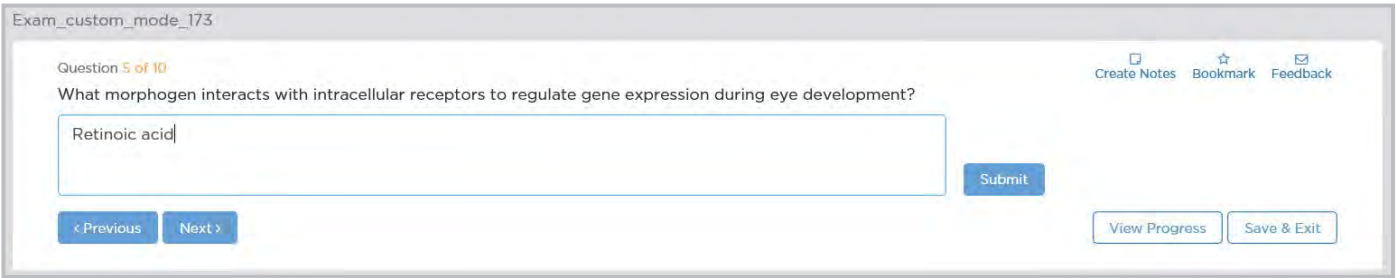


FIGURE 3: CHALLENGE MODE. The BCSC Self-Assessment Program gives you the option of turning on Challenge Mode, which forces you to come up with the correct answers rather than relying on multiple choice.

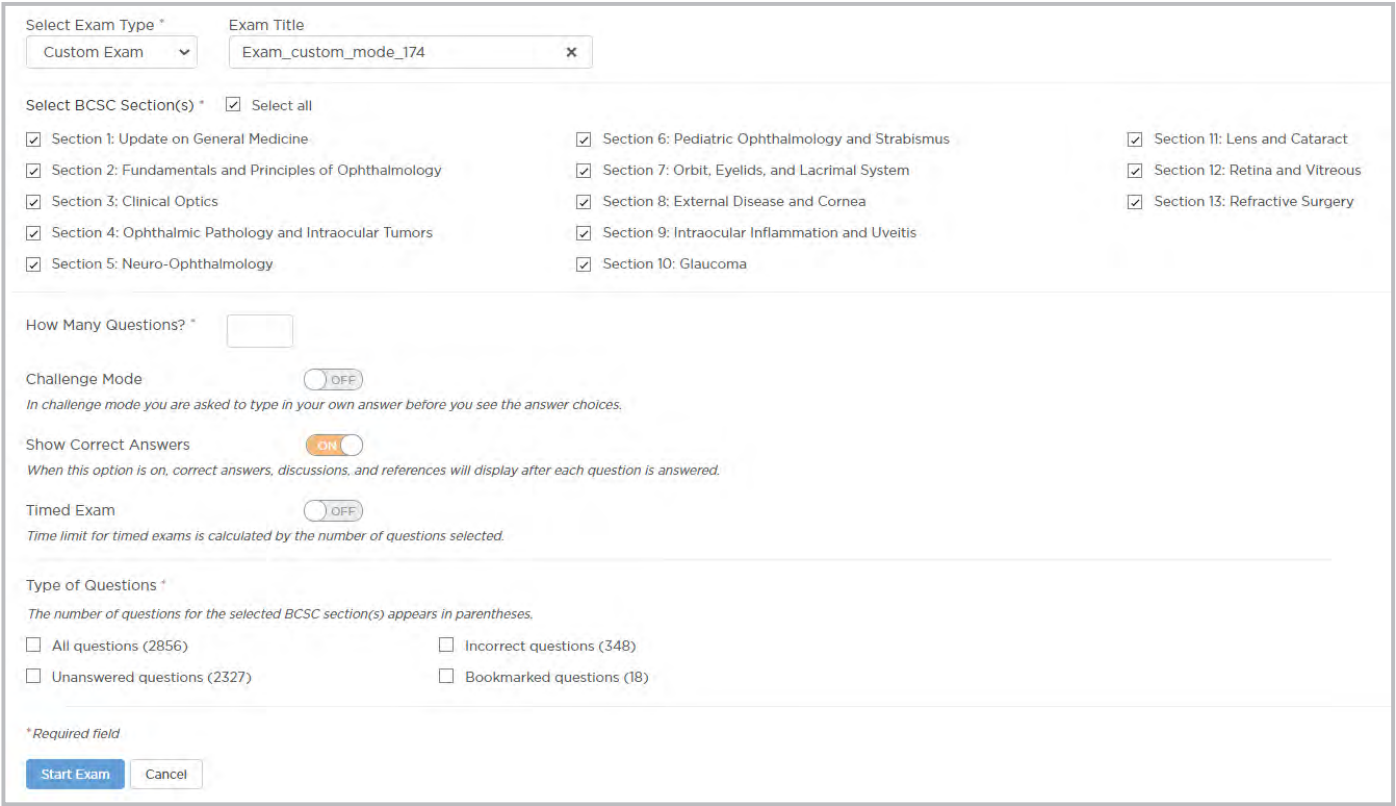


FIGURE 4: SPACE OUT YOUR REVIEW. Myriad options for customizing exams allow you to space out review and challenge yourself in other ways.

stack of flashcards, place the concepts you struggle with toward the front of the stack to review again sooner and the concepts you are most familiar with toward the end of the stack to review again later.

4 Mix It Up

Studying several different subjects helps solidify topics better than focusing solely on one topic at a time. One of the landmark studies in cognitive learning is the California Polytechnic State University research on contextual interference in skilled baseball players.² Researchers found that players who practiced batting by hitting a random sequence of pitches improved their skills more than players who focused on mastering one type of pitch before moving onto a new type of pitch.

Tip #4. Randomize study topics. Based on the results of that study, cognitive scientists propose that studying multiple different topics in one session may be more effective than trying to master one topic at a time. For example, reading about different diseases in a few BCSC volumes during a study session may lead to better long-term retention than trying to read through a single chapter in one BCSC volume. Likewise, practice questions may be more effective if worked in

a random fashion, rather than choosing one subject at a time.

5 Get Timely Feedback

Feedback, both positive and negative, is helpful in the learning process (Fig. 1). For example, I had many conversations with attendings as I was learning cataract surgery. After each case, we discussed every step so that I intentionally reflected on what was effortless and what was challenging. That feedback allowed me to refine my techniques so that my skills improved with each case. Feedback focuses attention on key concepts and helps to build frameworks for understanding what we are learning.

Tip #5. Read discussions. Reading through the explanations provided after self-assessment practice questions helped me learn both what I was “doing right” and where my rationale was lacking (Fig. 2). *Make It Stick* states that immediate feedback is not always as helpful as mildly delayed feedback, but that any feedback is better than none at all. So, it may be advisable to work through a set of practice questions and then go back to review the correct answers and rationale, rather than taking it question by question. However, the latter is more effective than not reviewing the answers and rationales at all.

Self-Assessment Tools

In addition to the highly detailed BCSC texts, the Academy has multiple resources available on its website (aao.org/education-browse) for self-assessment, such as Diagnose This challenges (available weekly), self-assessment questions, disease reviews, and clinical webinars.

BCSC Self-Assessment. You can also purchase a subscription to the BCSC Self-Assessment Program, which contains over 3,000 practice questions and is constantly being edited and expanded by the Academy Resident Self-Assessment Committee. The Self-Assessment Program incorporates the strategies listed above to help you learn more effectively.

• **Avoiding false fluency.** The “Challenge Mode” allows you to answer questions in a free-form, short answer style (Fig. 3). This mode prevents you from using multiple-choice test-taking strategies and forces you to assess whether you truly understand the material.

• **Facilitating effortful learning.** Every question has a detailed explanation for correct and incorrect answers. Page references to the corresponding section in the BCSC are provided, and a short excerpt from the relevant BCSC text is also provided. When using the BCSC Self-Assessment Program for learning, you

may find it helpful to intentionally slow the pace of questions, read each explanation carefully, and look up the relevant passages to reinforce knowledge or to correct deficiencies.

• **Spacing out your review.** When working through practice questions, be sure to return to questions you answer correctly in addition to the questions you answer incorrectly. In the BCSC Self-Assessment Program, there are several options when creating a new practice exam (Fig. 4). It may be beneficial to review only the incorrectly answered and bookmarked questions once a week while reviewing all questions (allowing for correctly answered questions to cycle through again) monthly.

• **Randomizing the questions.** The BCSC Self-Assessment Program allows you to create quizzes on specific topics (organized by BCSC volumes). In some cases, this approach may be beneficial. However, there is also significant value in quizzing on all topics at random, which forces your brain to retain information from all subjects in working memory.

• **Getting timely feedback.** The BCSC Self-Assessment Program gives feedback in two ways. It allows you to read the answer choices immediately after answering a question, or you may answer all the questions in a quiz before reviewing the correct answers and explanations. For shorter quizzes (five to 10 questions), having immediate feedback may work well. For longer quizzes (>10 questions), waiting to review answers affords the opportunity to read over each question again, effectively forcing you to avoid memorizing the question phrasing (tip #1), to reflect on the rationale for your answer (tip #2), and to space out your review (tip #3).

1 Brown PC et al. *Make It Stick: The Science of Successful Learning*. Belknap Harvard. 2018.

2 Hall et al. *Perceptual and Motor Skills* 1994;78(3): 835-841.

Dr. Lai is assistant professor of clinical ophthalmology, Indiana University School of Medicine in Indianapolis, and founder of OphthalmologyReview.org, which is dedicated to self-studying ophthalmology for OKAP, board exams, and maintaining ophthalmic knowledge. *Financial disclosures:* OphthalmologyReview.org: O.

O = Equity owner.

Coming Soon

To register for upcoming webinars that feature self-assessment CME, visit aao.org/clinical-webinars. These include:

- Core Knowledge in Neuro Ophthalmology (Jan. 14)
- Diagnose This Live! (Jan. 21)
- Core Knowledge in Pediatric Ophthalmology/Strabismus (Jan. 28)

New MIPS Reporting Dashboard for IRIS Registry Participants

Check out how you can ease the burden of the MIPS program and look for data-driven insights on your practice patterns, see how you'll be able to use the new MIPS reporting dashboard to track your scores on MIPS quality measures, and learn about the IRIS Registry's new MIPS reporting partner during AAO 2020 Virtual.

In April, the Academy announced that it had chosen Verana Health to serve as the end-to-end data and technology partner for the IRIS Registry. The goal is to provide an enhanced physician experience and enable exceptional data quality for Merit-Based Incentive Payment System (MIPS) reporting and for practice insights.

Practices that are participating in the IRIS Registry via an eligible electronic health record (EHR) system will need to integrate with Verana Data Link, Verana's EHR integration technology (see "Converting to the Verana platform," next column).

New future MIPS reporting partner. Practices that integrate their EHR system with Verana Data Link will have future access to a new dashboard to oversee their MIPS quality scores. This dashboard was developed in partnership with the Academy.

No near-term changes for MIPS reporting. There will be no impact on practices' 2020 MIPS reporting. The current service provider, FIGmd, will continue to support practices until the transition to Verana is complete.

Subspecialty-specific MIPS quality measures. Practices that report quality measures via the IRIS Registry will continue to have access to CMS-approved quality measures that were developed by the Academy.

- Three examples:
- IRIS41: Improved Visual Acuity After Epiretinal Membrane Treatment Within 120 Days
 - IRIS44: Visual Field Progression in Glaucoma
 - IRIS59: Regaining Vision After Cataract Surgery

Such measures enable ophthalmologists to focus on quality improvement activities in their own subspecialty.

Reliability. For MIPS quality category scores, Verana has developed scoring algorithms that are maintained by the company's in-house team of quality reporting experts who have implemented a logic infrastructure in strict accordance

with CMS specifications. In addition, clinicians and informatics experts provided guidance to make sure that quality measure scores are consistent with clinical expectations. Indeed, earlier this year, to ensure that the integrated data are complete and reflective of providers' activities and documentation practices, Verana engaged with practices that were already using Verana Data Link to receive feedback on data mappings.

Converting to the Verana platform. If you are already using EHR-IRIS Registry integration to gather data for MIPS quality measures, your 2020 MIPS reporting will continue to be facilitated by the IRIS Registry's initial vendor, FIGmd.

To prepare for MIPS reporting, Verana Health has already started contacting practices about switching to the IRIS Registry's new MIPS reporting platform. Important: Make sure your practice's IRIS Registry point person knows to watch for an email from Verana's Practice Experience team—they will contact your practice once they start converting practices that are on your EHR system.

When your practice receives its onboarding email from Verana, please respond promptly. (For more information, visit www.veranahealth.com/aaopartnership-expansion-faqs/.)

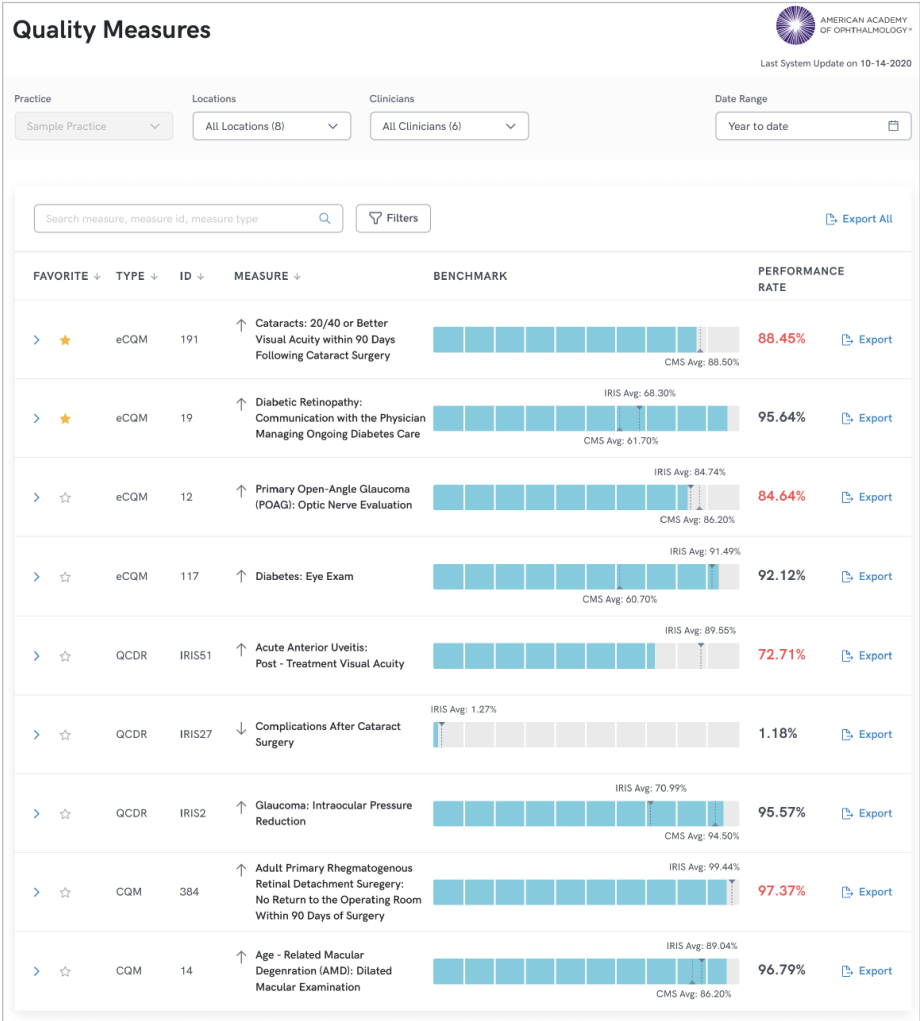
Learn more about Verana Data Link. Bring your questions to the Verana Health exhibit and the Academy Resource Center at AAO 2020 Virtual:

At aao.org/2020, you can sign in to the AAO 2020 Virtual platform, where you can click links to the Virtual Expo (where you'll find the Verana booth) and to the Resource Center (for the IRIS Registry booth).

You also can email queries about the new MIPS quality reporting dashboard and the Verana Data Link to irisdata.link@veranahealth.com.

Visit aao.org. For more information on the IRIS Registry and MIPS reporting, visit aao.org/iris-registry and aao.org/medicare, respectively.

Note: This PDF differs from the mailed article to reflect potential changes in the dashboard timeline.



COMING SOON. Practices that have integrated their EHR system via the Verana Data Link will have access to a new quality measure dashboard in 2021.

IRIS Registry Findings

By integrating your EHR system with the IRIS Registry, your anonymized patient data is helping researchers to advance eye care. Recently published studies include the following:

- Rao P et al. Reoperation rates of patients undergoing primary noncomplex retinal detachment surgery in a cohort of the IRIS Registry. *Am J Ophthalmol*. Published online Sept. 5, 2020.
- Repka MX. Amblyopia outcomes through clinical trials and practice measurement: Room for improvement: The LXXVII Edward Jackson Memorial Lecture. *Am J Ophthalmol*. Published online Aug. 6, 2020.
- Rubino SM et al. Return to the operating room after vitrectomy for vitreous opacities: IRIS Registry analysis. *Ophthalmology Retina*. Published online July 17, 2020.
- Glasser DB et al. Intravitreal anti-vascular endothelial growth factor cost savings achievable with increased bevacizumab reimbursement and use. *Ophthalmology*. Published online June 13, 2020.
- Mahr MA et al. Return to the operating room for removal of retained lens fragments after cataract surgery: IRIS Registry (Intelligent Research in Sight) analysis. *Ophthalmology*. 2020;127(5):698-699.
- Cantell RA et al. Treatment patterns for diabetic macular edema: An IRIS Registry analysis. *Ophthalmology*. 2020;127(3):427-429.
- Pershing S et al. Endophthalmitis after cataract surgery in the United States: A report from the Intelligent Research in Sight Registry, 2013-2017. *Ophthalmology*. 2020;127(2):151-158.

To learn more about the use of IRIS Registry data for research, visit aao.org/iris-registry/research.

DURYSTA™

(bimatoprost implant) 10 mcg
For intracameral administration



EXTENDED IOP CONTROL

Discover the DURYSTA™ difference:

- A first-in-class, biodegradable, intracameral implant¹
- 24/7 drug release for several months^{1,2}
- Delivers drug within the eye to target tissues^{1,3}

SEVERAL MONTHS OF IOP REDUCTION WITH 1 IMPLANT¹

► **LEARN MORE AT [DURYSTAHCP.COM](https://durystahcp.com)**

IOP=intraocular pressure.
Not an actual patient.

INDICATIONS AND USAGE

DURYSTA™ (bimatoprost implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

IMPORTANT SAFETY INFORMATION

Contraindications

DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]); absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; hypersensitivity to bimatoprost or to any other components of the product.

Warnings and Precautions

The presence of DURYSTA™ implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of DURYSTA™ should be limited to a single implant per eye without retreatment. Caution should be used when prescribing DURYSTA™ in patients with limited corneal endothelial cell reserve.

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including DURYSTA™ intracameral implant. DURYSTA™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Prostaglandin analogs, including DURYSTA™, have been reported to cause intraocular inflammation. DURYSTA™ should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Ophthalmic bimatoprost, including DURYSTA™ intracameral implant, has been reported to cause changes to pigmented tissues, such as increased pigmentation of the iris. Pigmentation of the iris is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. While treatment with DURYSTA™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering DURYSTA™, and patients should be monitored following the administration.

Adverse Reactions

In controlled studies, the most common ocular adverse reaction reported by 27% of patients was conjunctival hyperemia. Other common adverse reactions reported in 5%-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, and headache.

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. DURYSTA™ [Prescribing Information]. Irvine, CA: Allergan, Inc.; 2020. 2. Data on file, Allergan, 2020. 3. Standring S. Orbit and accessory visual apparatus. In: *Gray's Anatomy: The Anatomical Basis of Clinical Practice*. 41st ed. Philadelphia, PA: Elsevier Limited; 2016: 666-708.

Program Directors Share Insights on Subspecialty Day From Cornea to Uveitis

To provide an inside look at Subspecialty Day, *EyeNet* contacted the program directors from each meeting and asked the following questions: 1) Which presentation will have

broad appeal across subspecialties? 2) Which presentation might cause subspecialists to reconsider an area of their clinical practice? 3) Which presentation addresses particularly novel or exciting

developments within the field? Here are their answers to the first two questions; for the third, check your email on Thursday, Nov. 12 for AAO 2020 Daily.

How to sit in on this year's Subspe-

cialty Day. First, you'll need to register for AAO 2020 Virtual at aao.org/2020. After making your payment, you will receive an All-Access Pass, which provides access to more than 100 hours of live-streaming, interactive sessions and all on-demand content from the eight Subspecialty Day meetings, the annual meeting, the AAOE Practice Management Program, and the AAO 2020 Virtual Expo. After the meeting is over, the pass will give you access to recorded sessions.

Search the program online. Many of the events highlighted below will be presented live on Friday, Nov. 13, but some are part of the on-demand program. To check the time of a specific live event, see the Subspecialty Day schedule in the Virtual Meeting Guide, accessible at aao.org/2020.

Browse the subspecialties. This year's virtual format makes it more convenient than ever to explore disciplines other than your own. Often, pearls from one subspecialty can be applied to a completely different arena in surprising and useful ways. Live Subspecialty Day presentations take place on Friday, Nov. 13, with half-day sessions for most meetings, and a full day for the Retina Subspecialty Day.

Friday, Nov. 13, 7:40-11:30 a.m. PST.

In the morning, take your pick of five live Subspecialty Day meetings:

- Glaucoma Subspecialty Day 2020: Winning Bets: Strategies in Glaucoma Care
- Pediatric Ophthalmology Subspecialty Day 2020: The Only Game in Town
- Refractive Surgery Subspecialty Day 2020: Celebrating 2020
- Retina Subspecialty Day 2020: Vision for the Future
- Uveitis Subspecialty Day 2020: Beating the Odds—How to Make Sure You Get a Full House When You're Dealt Uveitis

Friday, Nov. 13, 12:30-4:20 p.m. PST.

The Retina Subspecialty Day meeting continues into the afternoon, and you can explore three additional meetings.

- Cornea Subspecialty Day 2020: Seeing Clearly Into the Future
- Ocular Oncology and Pathology Subspecialty Day 2020: Collaboration Now More Than Ever
- Oculofacial Plastic Surgery Subspecialty Day 2020: Back to the Basics With Tips and Tricks
- Retina Subspecialty Day 2020: Vision for the Future

More presentations. Additional presentations will be available on demand.

Note: All summaries were written in advance of Subspecialty Day. For the latest information, check the Virtual Meeting Guide, at aao.org/2020 or in the virtual meeting platform.

DURYSTA™
(bimatoprost implant) 10 mcg
for intracameral administration

Brief Summary—Please see the DURYSTA™ package insert for full Prescribing Information

INDICATIONS AND USAGE

DURYSTA™ is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

CONTRAINDICATIONS

DURYSTA™ is contraindicated in patients with active or suspected ocular or periocular infections; corneal endothelial cell dystrophy; prior corneal transplantation, or endothelial cell transplants; absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; or hypersensitivity to bimatoprost or any other components of the product.

WARNINGS AND PRECAUTIONS

Corneal Adverse Reactions: The presence of **DURYSTA™** implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of **DURYSTA™** should be limited to a single implant per eye without retreatment. Caution should be used when prescribing **DURYSTA™** in patients with limited corneal endothelial cell reserve.

Iridocorneal Angle: Following administration with **DURYSTA™**, the intracameral implant is intended to settle within the inferior angle. **DURYSTA™** should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including **DURYSTA™** intracameral implant. **DURYSTA™** should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Intraocular Inflammation: Prostaglandin analogs, including **DURYSTA™**, have been reported to cause intraocular inflammation. **DURYSTA™** should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Pigmentation: Ophthalmic bimatoprost, including **DURYSTA™** intracameral implant, has been reported to cause changes to pigmented tissues, such as increased pigmentation of the iris. Pigmentation of the iris is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. While treatment with **DURYSTA™** can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Endophthalmitis: Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering **DURYSTA™**, and patients should be monitored following the administration.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common ocular adverse reaction observed in two randomized, active-controlled clinical trials with **DURYSTA™** in patients with OAG or OHT was conjunctival hyperemia, which was reported in 27% of patients. Other common ocular adverse reactions reported in 5-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, and iritis. Ocular adverse reactions occurring in 1-5% of patients were anterior chamber cell, lacrimation increased, corneal edema, aqueous humor

leakage, iris adhesions, ocular discomfort, corneal touch, iris hyperpigmentation, anterior chamber flare, anterior chamber inflammation, and macular edema. The following additional adverse drug reactions occurred in less than 1% of patients: hyphema, iridocyclitis, uveitis, corneal opacity, product administered at inappropriate site, corneal decompensation, cystoid macular edema, and drug hypersensitivity.

The most common nonocular adverse reaction was headache, which was observed in 5% of patients.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no adequate and well-controlled studies of **DURYSTA™** administration in pregnant women to inform a drug associated risk. Oral administration of bimatoprost to pregnant rats and mice throughout organogenesis did not produce adverse maternal or fetal effects at clinically relevant exposures. Oral administration of bimatoprost to rats from the start of organogenesis to the end of lactation did not produce adverse maternal, fetal or neonatal effects at clinically relevant exposures.

In embryo/fetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost which achieved at least 1770 times the maximum human bimatoprost exposure following a single administration of **DURYSTA™** (based on plasma C_{max} levels; blood-to-plasma partition ratio of 0.858).

In a pre/postnatal development study, oral administration of bimatoprost to pregnant rats from gestation day 7 through lactation resulted in reduced gestation length, increased late resorptions, fetal deaths, and postnatal pup mortality, and reduced pup body weight at 0.3 mg/kg/day (estimated 470-times the human systemic exposure to bimatoprost from **DURYSTA™**, based plasma C_{max} and a blood-to plasma partition ratio of 0.858). No adverse effects were observed in rat offspring at 0.1 mg/kg/day (estimated 350-times the human systemic exposure to bimatoprost from **DURYSTA™**, based on plasma C_{max}).

Lactation: There is no information regarding the presence of bimatoprost in human milk, the effects on the breastfed infants, or the effects on milk production. In animal studies, topical bimatoprost has been shown to be excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when **DURYSTA™** is administered to a nursing woman.

The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for **DURYSTA™** and any potential adverse effects on the breastfed child from **DURYSTA™**.

Pediatric Use: Safety and effectiveness of **DURYSTA™** in pediatric patients have not been established.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses up to 2 mg/kg/day and 1 mg/kg/day respectively for 104 weeks (approximately 3100 and 1700 times, respectively, the maximum human exposure [based on plasma C_{max} levels; blood-to-plasma partition ratio of 0.858]).

Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the *in vivo* mouse micronucleus tests.

Bimatoprost did not impair fertility in male or female rats up to doses of 0.6 mg/kg/day (1770-times the maximum human exposure, based on plasma C_{max} levels; blood-to-plasma partition ratio of 0.858).

PATIENT COUNSELING INFORMATION

Treatment-related Effects: Advise patients about the potential risk for complications including, but not limited to, the development of corneal adverse events, intraocular inflammation or endophthalmitis.

Potential for Pigmentation: Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent.

When to Seek Physician Advice: Advise patients that if the eye becomes red, sensitive to light, painful, or develops a change in vision, they should seek immediate care from an ophthalmologist.

Rx only



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Of Interest Across Subspecialties

CORNEA

How Imaging Helps Me Assess Fuchs Dystrophy in Clinical Practice, presented by Keith H. Baratz, MD

The decision to proceed with cataract surgery alone versus in combination with keratoplasty in the setting of Fuchs endothelial corneal dystrophy (FECD) often poses a challenge for comprehensive ophthalmologists, especially when corneal edema is not detected by slit-lamp examination. Cutoff measurements for corneal thickness have been suggested, but these are unreliable, as are measurements of endothelial cell density.

A more reliable method of predicting the prognosis of FECD is through interpretation of posterior elevation and pachymetry map patterns derived from Scheimpflug tomography. The method is simple, repeatable, easy to implement in clinical practice, and independent of corneal thickness. Keith H. Baratz, MD, will review the rationale and recommendations for using Scheimpflug imaging in the assessment of FECD.

*Sanjay V. Patel, MD, FRCOphth
Cornea program director*

GLAUCOMA

Papers to Increase the Odds in Your Practice: Journal Club, moderated by Teresa C. Chen, MD, and Annette L. Giangiacomo, MD

What should you know about the ever-expanding options in glaucoma surgery? This has been a banner year for peer-reviewed articles spanning the range of glaucoma surgical procedures and devices. Our glaucoma journal club will give the lowdown on the traditional tube versus trabeculectomy debate, how the Xen gel stent compares to trabeculectomy, and the latest information on the newest filtration stent, the SIBS microshunt. Plus, the latest data on the Hydrus and iStent devices and follow-up on the Cypass shunt will make this a journal club not to be missed!

*Eydie Miller-Ellis, MD, and
Brian A. Francis, MD
Glaucoma program directors*

OCULAR ONCOLOGY/ PATHOLOGY

The Diagnosis, Management, and Prognosis of Vitreoretinal Lymphoma, presented by Jose S. Pulido, MD

Jose S. Pulido, MD, will discuss the diagnosis, prognosis, and management of vitreoretinal lymphoma.

This disease presents both diagnostic and management challenges. For example, there is often a significant delay between the onset of a patient's symptoms and diagnosis of vitreoretinal lymphoma; and in many patients, multiple surgeries and biopsies are performed before a

definitive diagnosis is made.

After that, management and treatment can be complex. Managing vitreoretinal lymphoma requires a coordinated, collaborative approach that includes retina specialists, ocular oncologists, ocular pathologists, cytopathologists, hematopathologists, and the medical oncology team. Dr. Pulido will discuss surgical planning, key steps in obtaining and transporting specimens, various types of

pathology testing, and treatment.

The session will be relevant to comprehensive ophthalmologists as well as to subspecialists in areas outside of oncology and pathology, as these practitioners are often involved at each of these important steps.

*Paul J. Bryar, MD, and
Dan S. Gombos, MD
Ocular Oncology and Pathology
program directors*

OCULOFACIAL PLASTIC SURGERY

A Wrinkle in the Plan: Aesthetics, moderated by Hee J. Kim, MD

Join us for the aesthetic oculofacial session! Experts will offer insights and best practices with neuromodulators and cosmetic eyelid surgery. Talks will offer keys to avoiding complications as well as optimizing cosmetic surgery outcomes.

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From forming a solid and symmetric eyelid crease to avoiding lagophthalmos, this session will boost the skills of cosmetic oculofacial surgeons of all levels.

*Jeremiah Tao, MD, FACS, and
Catherine J. Hwang, MD
Oculofacial Plastic Surgery
program directors*

PEDIATRIC OPHTHALMOLOGY

Anterior Segment Innovators and

Influencers. Find this session in the on-demand program.

Medical and surgical management of corneal disorders has evolved rapidly during recent years, but adoption of these advances in pediatric ophthalmology has been slower. If you see children in your practice, this session will be of interest because it reviews the state of the art in management of ante-

rior segment disease in children.

Pediatric ophthalmologists and cornea specialists with expertise in the management of children will discuss key topics in anterior segment management. The session will include talks on pediatric corneal cross-linking; management of neurotrophic cornea in children; pediatric refractive surgery; aniridia or limbal stem cell deficiency and transplantation; and amniotic membrane grafting for

ocular surface disorders in children.

*Michael F. Chiang, MD, and
Gena Heidary, MD, PhD
Pediatric Ophthalmology program
directors*

RETINA

The 2020 Debates, moderated by Colin A. McCannel, MD, and Tara A. McCannel, MD

This year's debate session will include five debates. Topics include how best to manage submacular hemorrhage, first-line treatment for disabling vitreous floaters, anti-VEGF for management of retinopathy of prematurity, management of subretinal fluid in neovascular age-related macular degeneration (nAMD), and preferred dosing treatment for nAMD. The debate on the management of floaters would be of interest to broad areas of ophthalmology since it is a common problem in our aging population. In addition, there remains significant controversy as to whether subretinal fluid in nAMD needs to be completely eliminated or not and which is the best dosing interval for treating nAMD. Hearing both sides of these arguments should be highly beneficial to all ophthalmologists. This session will be especially engaging because the audience around the world will be able to vote during the session. We will select the argument that most successfully changed the opinions of the audience.

*Judy E. Kim, MD, and
Mark W. Johnson, MD
Retina program directors*

UVEITIS

Uveitis 101. Find this session in the on-demand program.

The 2020 Uveitis Subspecialty Day takes a combined approach, encompassing both fundamental principles and their application to cases. The initial section on fundamentals, Uveitis 101, is intended to provide the nonuveitis specialist with a structured and logical approach to intraocular inflammatory disease with particular emphasis on the generation of a differential diagnosis, selection of appropriate testing, and formulation of a treatment plan. Highlights of this section will include presentations on epidemiology and diagnostic approaches to uveitis, as well as practical treatment paradigms for both local and systemic therapy.

*H. Nida Sen, MD, MHSc, and
Nisha Acharya, MD
Uveitis program directors*

Clinical Practices to Reconsider

CORNEA

Ectasia: Rounding the Bend, moderated by Vishal Jhanji, MD

The management strategies for keratoconus have undergone a paradigm shift in the last five years. Corneal cross-linking is

The burden of GA goes well beyond the Snellen chart

IN ONE STUDY*

63%

of patients with GA reported difficulty reading for everyday tasks or leisure¹

38%

reported feeling helpless or embarrassed at their need for assistance¹

*Outcomes reported from a survey of 8 patients; no visual acuity data were collected. In an additional study surveying 16 GA patients, 100% reported difficulty with reading, and 43.8% reported feeling frustrated or irritated at performing simple tasks.²

Apellis

is developing a targeted
investigational C3 therapy in GA

VISIT [APELLIS.COM](https://www.apellis.com)

1. Singh RP, Patel SS, Nielsen JS, Schmier JK, Rajput Y. Patient-, caregiver-, and eye care professional-reported burden of geographic atrophy secondary to age-related macular degeneration. *Am J Ophthalmol Clin Trials*. 2019;2(1):1-6 2. Sivaprasad S. Living with Geographic Atrophy. *Ophthalmology and Therapy*. 2019.

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now the first-line treatment for progressive keratoconus. Compared to corneal transplantation, cross-linking in combination with highly specialized contact lenses has helped to save both sight and health care costs. New imaging platforms are available for monitoring disease progression, and nontomographic diagnostic modalities aim to detect prestructural changes in the cornea, which might allow timely decision-making. Lamellar corneal transplantation has also increased in popularity compared to penetrating keratoplasty. During this session, experts in the field will discuss the latest insights into the evaluation and management of corneal ectasias.

*Sanjay V. Patel, MD, FRCOphth, and
Vishal Jhanji, MD
Cornea program directors*

GLAUCOMA

Glaucoma and Retina: Making the Most of the Hand You're Dealt, moderated by Leon W. Herndon Jr, MD, and Christine L. Larsen, MD

A special session this year will address the challenge of managing glaucoma in the retina patient. IOP elevations can result from retinal vascular disease or be related to a retina intervention, for example multiple anti-VEGF injections or vitrectomy. Management may depend on the approach, whether from the perspective of the glaucoma specialist or the retina specialist. An additional consideration: Presence of retinal disease also makes it difficult to assess glaucoma progression. This session presents the unique opportunity to discuss this topic from the point of view of both specialties.

*Eydie Miller-Ellis, MD, and
Brian A. Francis, MD
Glaucoma program directors*

OCULAR ONCOLOGY/ PATHOLOGY

There Is No Increased Risk of Systemic Metastasis Associated With the Use of Intra-Arterial Chemotherapy for Retinoblastoma. Pro, presented by Jasmine H. Francis, MD, and **Con**, presented by Matthew W. Wilson, MD

The Ocular Oncology and Pathology Subspecialty Day will begin with a discussion and pro/con debate about the role of intra-arterial chemotherapy (IAC) in treating patients with retinoblastoma. Jasmine H. Francis, MD, and Matthew W. Wilson, MD, will discuss the clinical role of IAC, including indications, contraindications, efficacy, and adverse effects. The presentation will go into detail on the question of whether IAC is associated with an increased risk of systemic metastasis. This session provides an up-to-date, evidence-based examination of the benefits and pitfalls of this emerging treatment.

*Paul J. Bryar, MD, and
Dan S. Gombos, MD*

*Ocular Oncology and Pathology
program directors*

OCULOFACIAL PLASTIC SURGERY

No Implant, No Problem, moderated by Vinay K Aakalu, MD, MPH

Several eyelid and orbital conditions are treated with implants or nonautologous grafts. But is hardware or antigenic tissue always the best option? Off-the-shelf implants or grafts avoid a second surgical site but add cost and have other possible drawbacks, including extrusion, infection, and rejection.

Autologous options should not be forgotten; in many instances, a flap or graft may be an ideal choice. Experts will familiarize attendees with various classic or novel autologous tissue transfer techniques. They will describe best practices and their pearls for these procedures. In particular, speakers will explore frontalis flaps for congenital ptosis repair in lieu of alloplastic slings, tarsoconjunctival suspension flaps for paralytic lagophthalmos instead of gold weight implants, hard palate grafts in the place of spacer implants, and dermis fat grafts rather than sphere devices. Whether or not these grafts and flaps are already in your repertoire, these presentations should provide insights.

*Jeremiah Tao, MD, FACS, and
Catherine J. Hwang, MD
Oculofacial Plastic Surgery
program directors*

PEDIATRIC OPHTHALMOLOGY

Section IV: Tell Me What to Say in Common Systemic Scenarios. Find this session in the on-demand program.

Pediatric ophthalmologists and comprehensive ophthalmologists who see children often find themselves handling questions from parents on common systemic scenarios. In some cases, these are scenarios about which current clinical understanding and research are rapidly evolving. Questions that parents may ask include, for example, What is the impact of traumatic brain injury and concussion on visual function? Does my child have cortical visual impairment, and is there anything I can do to improve vision? What is the interplay between dyslexia and vision? Do screen time and blue light adversely affect my child's vision and body?

Faculty of the Pediatric Ophthalmology Subspecialty Day program will share their expertise and insight on these scenarios through a careful consideration and discussion of the latest clinical and scientific data.

After completing this session, practicing ophthalmologists will be better informed on the relationship between visual function and these common scenarios and better prepared to counsel patients and their families.

*Michael F. Chiang, MD, and
Gena Heidary, MD, PhD
Pediatric Ophthalmology
program directors*

REFRACTIVE SURGERY

Presbyopia Treatment in 2020: My Personal Experience and the European View. Find this presentation in the on-demand program.

Ongoing developments in the surgical correction of presbyopia present new challenges. There are now numerous options, but none has yet emerged as the gold standard. Among the methods are laser procedures, specialized IOLs, different versions of monovision, and small-aperture optics—the latter option probably has a brighter future when used in a lens rather than in a corneal inlay. The “European view” in this presentation is particularly valuable, as the presenter, Thomas Kohnen, MD, PhD, also has extensive insight into the “American view,” gained through his endeavors at Baylor College of Medicine.

*George O. Waring IV, MD, and
H. Burkhard Dick, MD, PhD, FEBOS-CR
Refractive Surgery program directors*

RETINA

Business of Retina Session and Panel Discussion. Find this session in the on-demand program.

The year 2021 will bring about coding and reimbursement changes that you will want to know about! Hear about them in the Business of Retina session on demand. Furthermore, the COVID-19 pandemic has affected all of us around the world in a profound and unprec-

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ARVO's Translational Vision Science & Technology (TVST) journal is now accepting manuscripts from all phases of translational research — from pre-clinical, through clinical to outcomes in populations.

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edented way. Our practices were temporarily limited to caring only for urgent and emergent patients. Unlike most subspecialties, retina specialists had relatively large numbers of patients requiring essential treatment, such as intravitreal injections and urgent retina surgeries, throughout the pandemic. The practices then slowly returned to a “new normal,” but how different practice settings and regions adapted to this pandemic varied. John W. Kitchens, MD, who produced a virtual program series that addressed many pandemic issues affecting retina practices, leads an expert panel of private and academic retina specialists in a robust discussion of how we can continue to provide the best care to our patients now and beyond 2020.

*Judy E. Kim, MD, and
Mark W. Johnson, MD
Retina program directors*

UVEITIS

Case Presentation: Pediatric Uveitis/Surgery—A Nod to Tough Uveitis: Cataract Is in the Cards, presented by Anjum F. Koreishi, MD

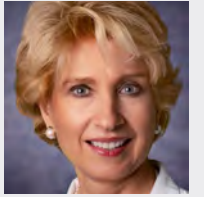
Building on the fundamental principles presented in Uveitis 101, the majority of the program will center on case-based presentations that illustrate and amplify

Honorary Lectures at Subspecialty Day

This year’s Retina and Pediatric Ophthalmology Subspecialty Days will each feature a live honorary lecture. Below, the speakers provide a sneak peek of their talks. Take a look, and plan to attend! Check the Virtual Meeting Guide (VMG) schedule for presentation times. Find a link to the VMG at aao.org/2020.

Charles L. Schepens, MD, Lecture: *Retina in the Pandemic*, presented by Julia Haller, MD.

“As 2020, The Year of the Eye, morphed under our gaze into the Year of SARS-CoV-2, ophthalmology became the specialty most impacted by the seismic upheavals of the pandemic. All subspecialties, including retina, reeled under the impact. This year’s first-ever virtual Schepens Lecture will delve into COVID-19 and its mark on our specialty—the ways we confronted its assault, some of the outcomes of that confrontation, and its long-term reverberations.”



The Leonard Apt Lecture: *Surgical Management of Infantile Nystagmus*, presented by Sean P. Donahue, MD, PhD.

“The differential diagnosis and management of children (and adults) with infantile nystagmus syndrome (INS) can be perplexing. All patients with infantile nystagmus must have the integrity of their afferent visual system confirmed, either through direct examination, neuroimaging, or genetic testing. INS must be distinguished from fusion maldevelopment syndrome and compressive lesions of the anterior afferent visual pathways (spasmus nutans syndrome). Surgical management seeks to eliminate abnormal head positioning (AHP) to achieve a null position and to reduce any coexisting strabismus by employing techniques of strabismus surgery. Augmenting Kestenbaum’s original 5-6-7-8 formula is effective in reducing AHP for up to 10 years or more. Modifications of these numbers should be used when strabismus coexists. Surgery on the cyclovertical muscles can reduce or eliminate vertical (chin up or chin down) or torsional head positions.”



those concepts. The cases will be organized according to the anatomic location of inflammation: anterior, intermediate, posterior, and panuveitis. This year’s program covers pediatric uveitis in both the fundamentals section and the surgical section. During the Surgery in Uveitis—Pearls session, Anjum F. Koreishi, MD, will present a pediatric uveitis surgery case.

In each category, a progression from basic to more complex cases will be presented to provide educational value for both the comprehensive ophthalmologist and the uveitis specialist. This case-based learning system is intended to be engaging and interactive and to simulate real-life clinical decision-making. The surgical management of uveitis complications

will be addressed through both instructional talks and case-based presentations.

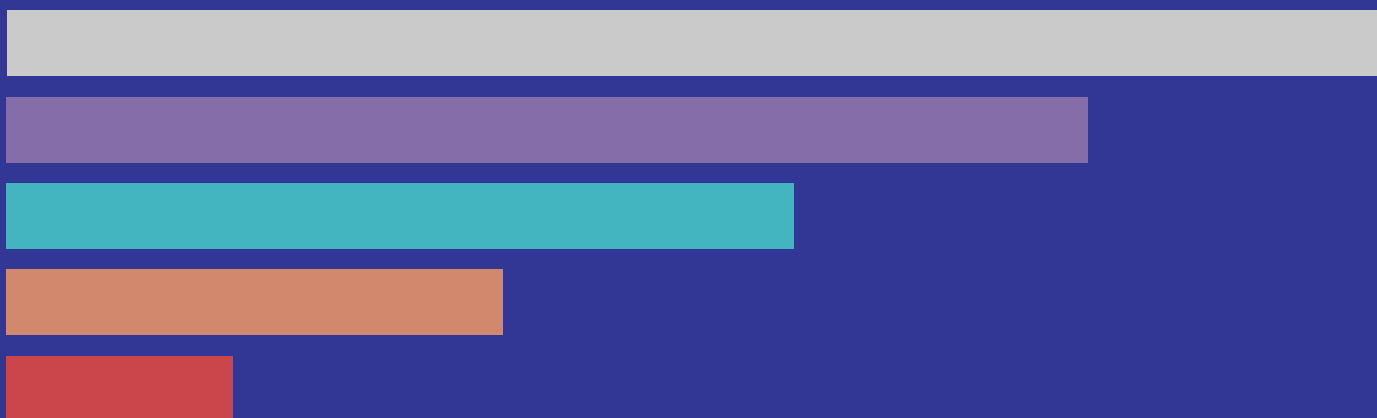
*H. Nida Sen, MD, MHSc, and
Nisha Acharya, MD
Uveitis program directors*

WATCH YOUR INBOX. Read more Subspecialty Day previews in the Thursday, Nov. 12, AAO 2020 Daily e-newsletter.



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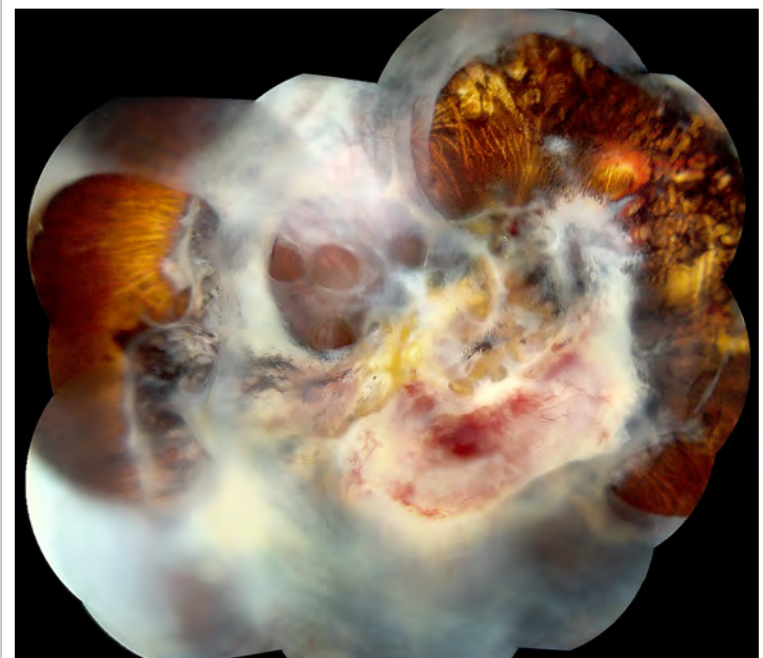
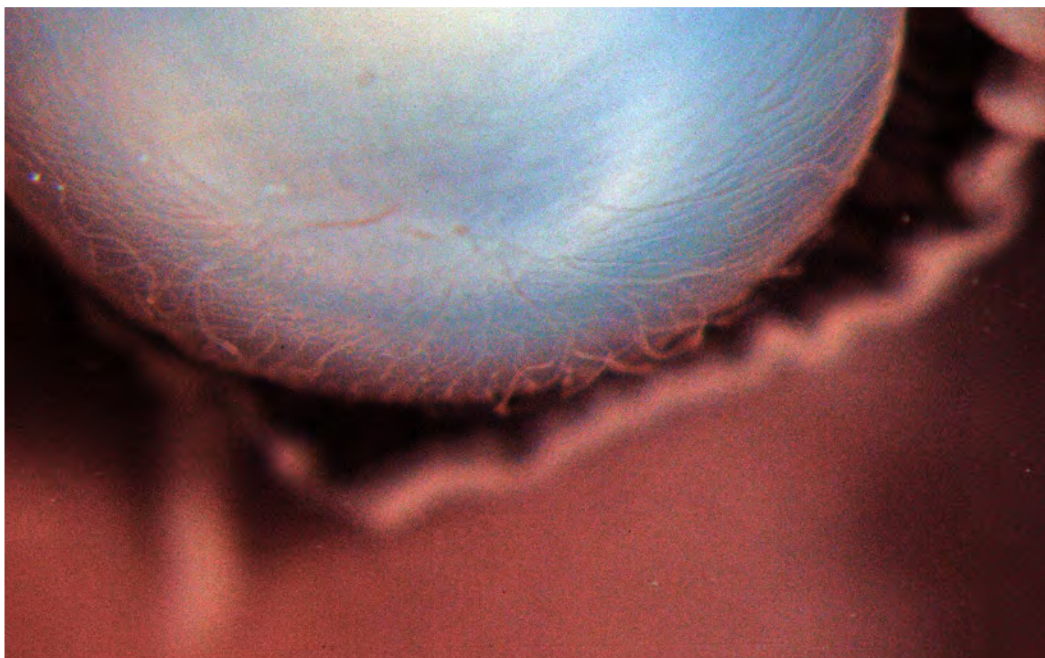
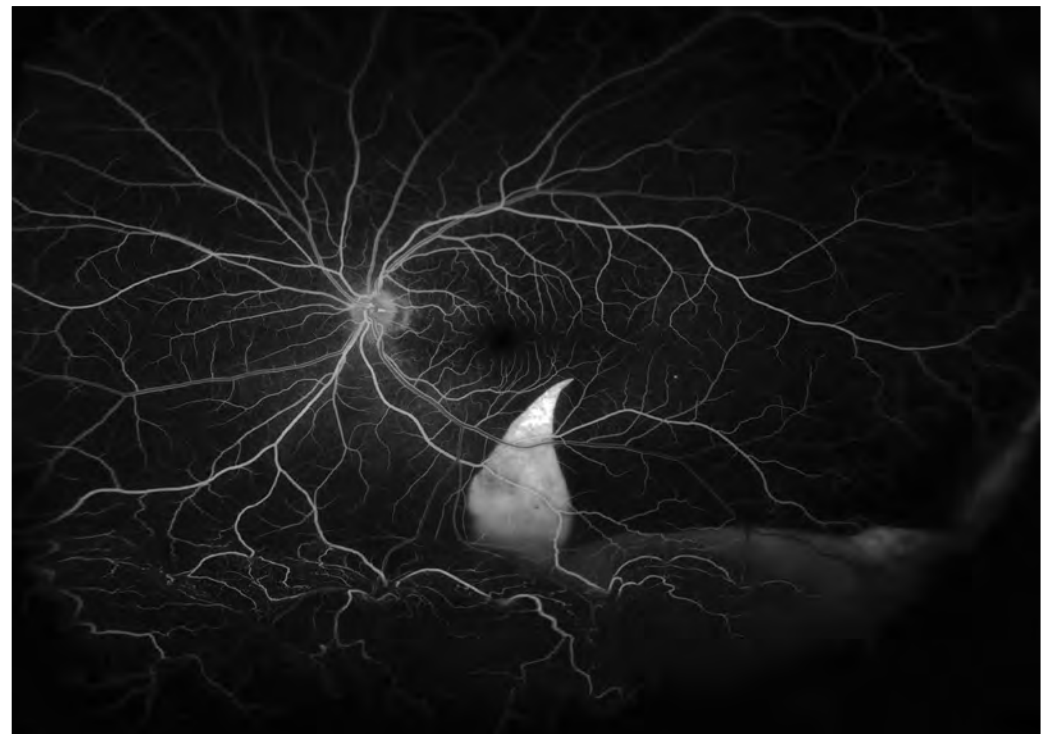
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Winning Photography Goes Virtual

The photos shown here were selected from among the winners at the 2019 Ophthalmic Photographers' Society (OPS) Scientific Exhibit during AAO 2019 in San Francisco.

This fall OPS kicked off its virtual program with a "live" Scientific Paper Session, Saturday, Oct. 17. Three weeks later, it concluded when Steve Charles, MD, presented the 15th annual J. Donald M. Gass Memorial Lecture: Full Thickness Macular Patch Graft and Other Applications of Medium Term PFO. Winners of the 2020 OPS photo contest will also be showcased on the website.

View the 2020 winners and learn about OPS at www.opsweb.org.



2019 OPS Exhibit Winners

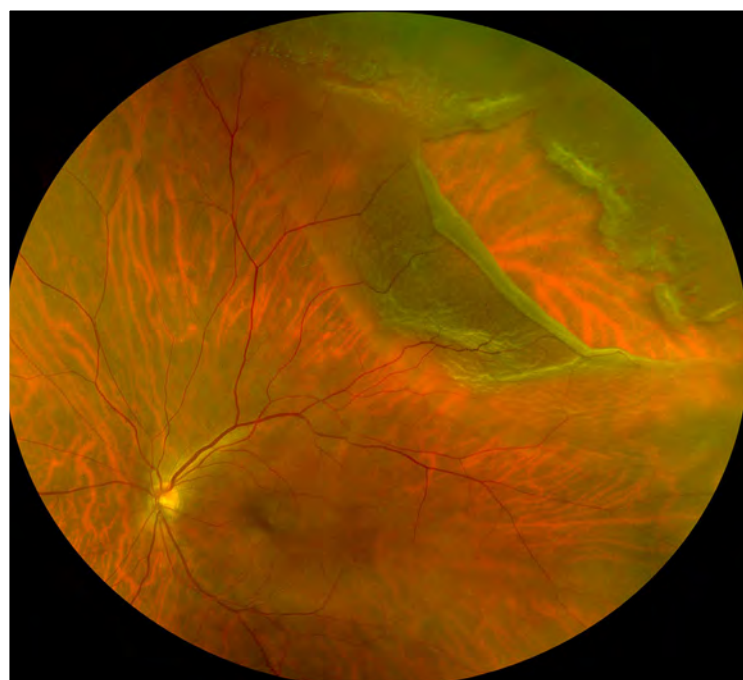
From top to bottom, and left to right.

Fluorescein Angiography, Second Place. *RPE Detachment, Retinal Tear.* Antoinette Venckus, CRA. University of Iowa Department of Ophthalmology & Visual Sciences, Iowa City.

Gross Specimen, Third Place. *Tunica Vasculosa Lentis-Infant Eye.* Ralph Eagle Jr., MD. Wills Eye Hospital, Philadelphia.

Composite Image, Third Place. *Severe Tractional Retinal Detachment.* Jody Troyer, CRA, OCT-A. University of Iowa, Iowa City.

Ultra-Widefield Imaging, First Place. *Retinal Detachment With Giant Tear.* Becky Weeks, CRA, COA, OCT-C. John Moran Eye Center, Salt Lake City.



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