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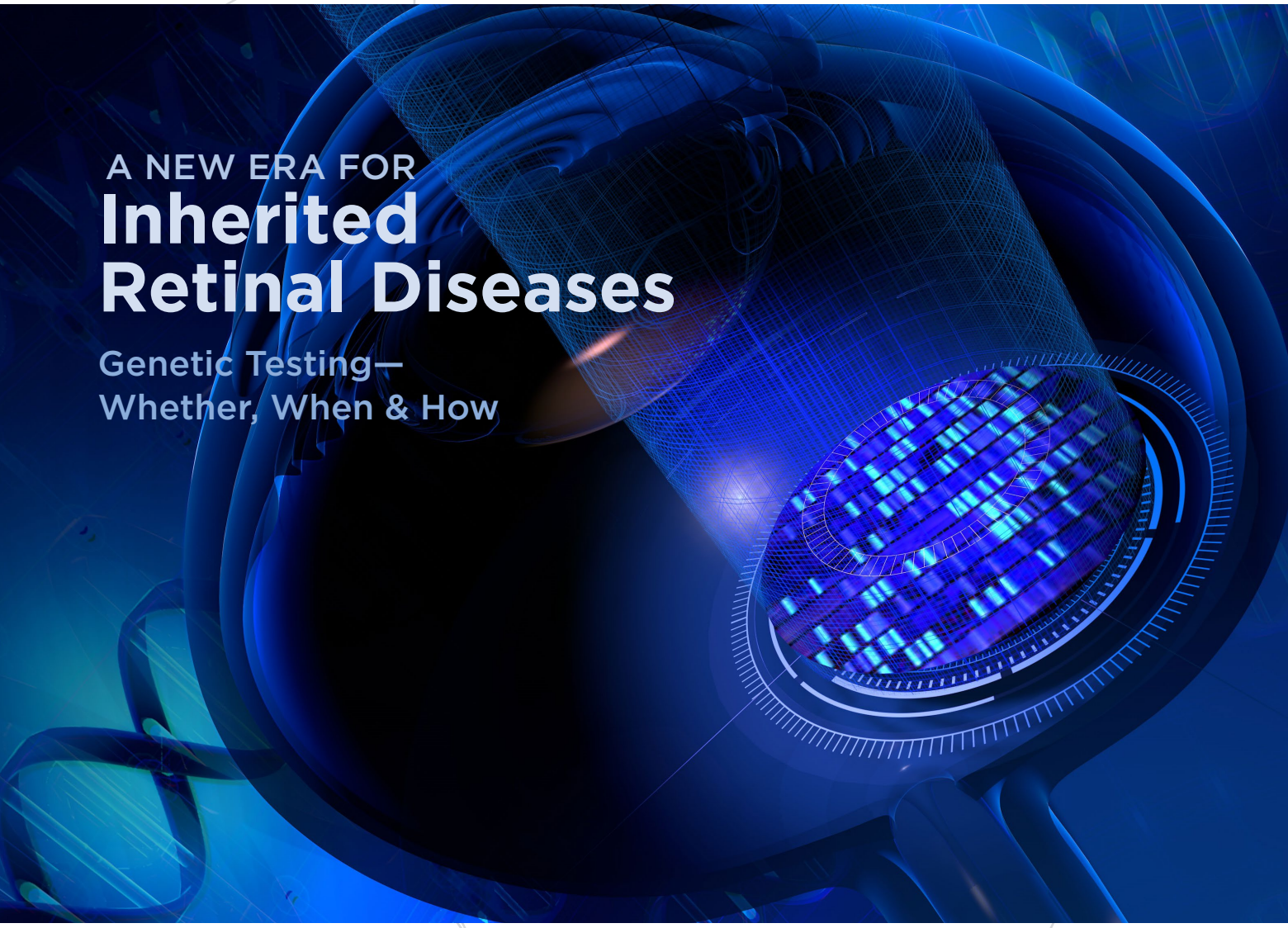

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Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

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Indication

Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information

Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, see accompanying Brief Summary of Safety Information on the adjacent page and Full Prescribing Information on Xiidra-ECP.com.

Shire

xiidra® (lifitegrast ophthalmic solution)5%

Rx Only

BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in 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 practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

Postmarketing Experience
The following adverse reactions have been identified during postapproval use of Xiidra. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg / day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg /kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.
Mutagenesis: Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.
Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

Shire

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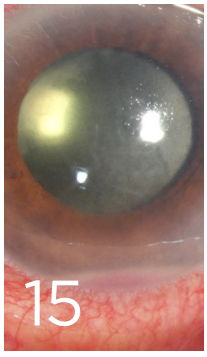

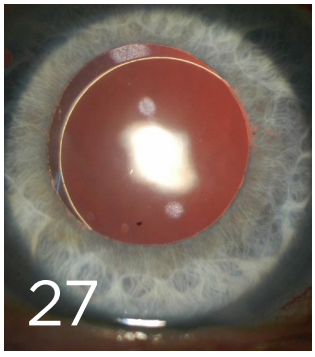

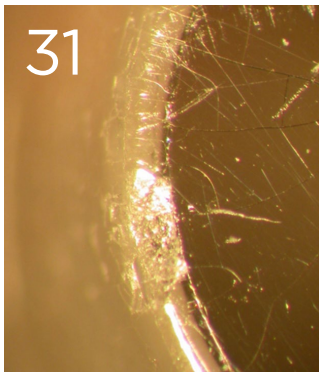

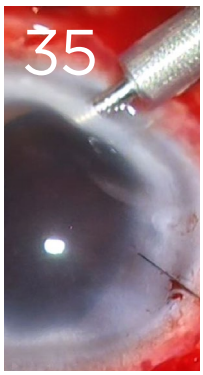

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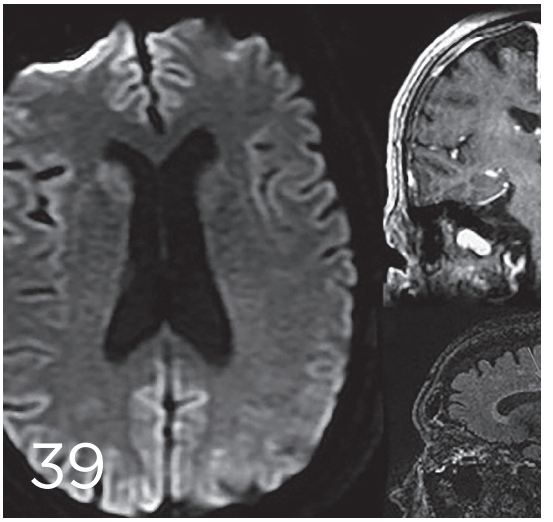

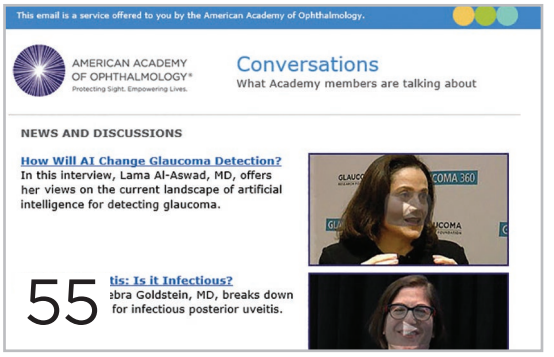

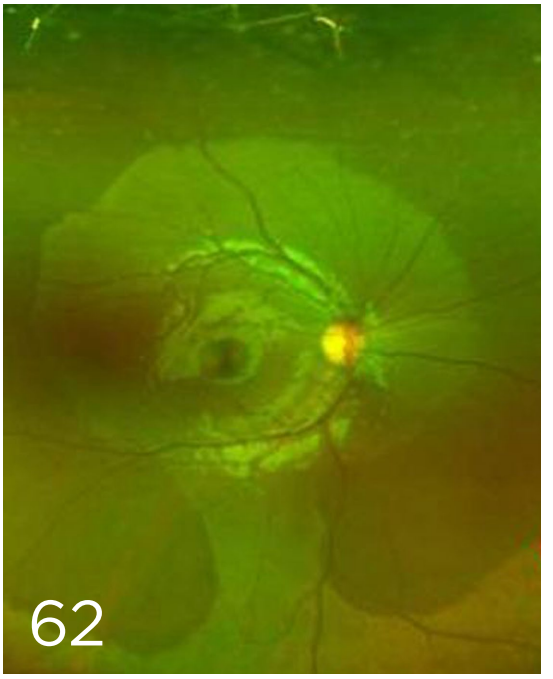

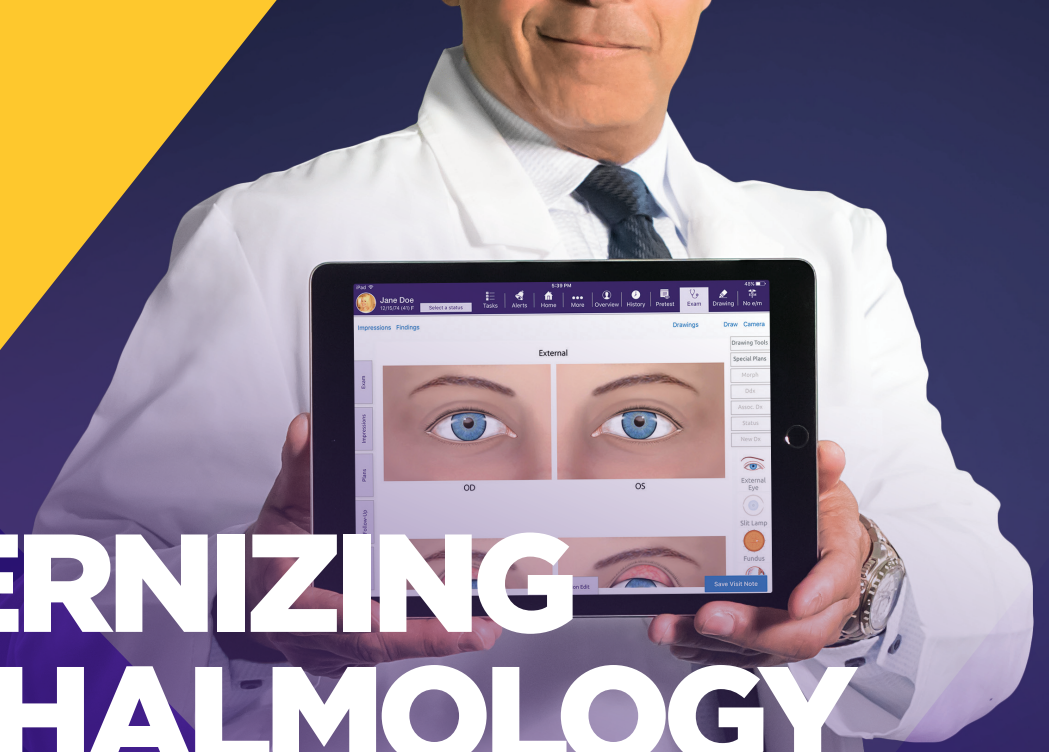

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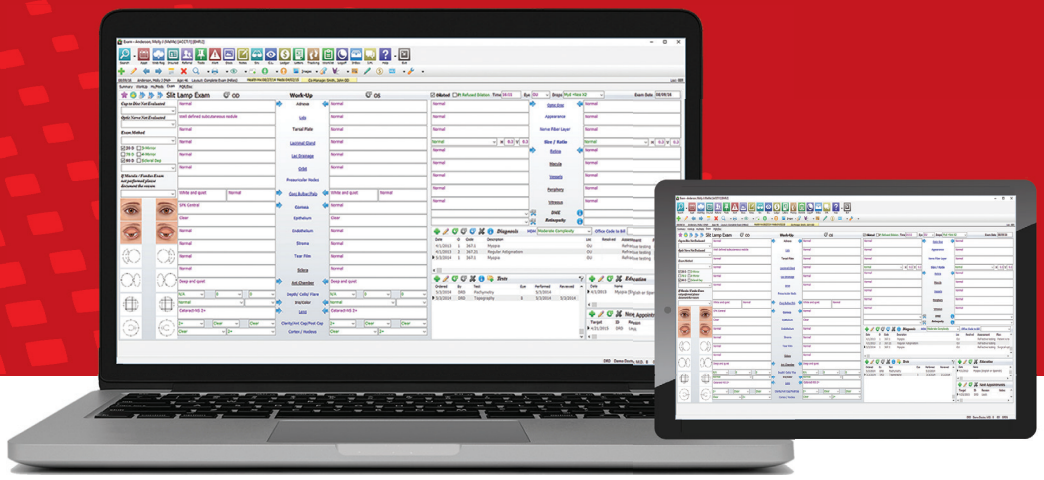

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Letters

Optometrists' Resistance to Telehealth

Telehealth is a means of collection, storage, dissemination, and interpretation of patient health information. In its various forms, telehealth frequently channels a remote patient's critical first engagement with professional health services, providing rapid access, quality of care improvement, and reduced cost. Cost and access are factors that directly influence a patient's ability to travel and seek relief for incipient vision health problems.

Various eye care telehealth systems purport to deliver accurate refractions, excellent health screenings, and efficient contact lens renewals. Telehealth is the stuff that keeps the innovators "burning the midnight oil" to find the next great application of artificial intelligence. Telehealth has the potential to bring innovative technologies to a patient's home, efficiently, and help us find the 30 million Americans with undiagnosed eye disease. It's all of that, and I'm a believer.

Telehealth itself cannot harm. It cannot function without licensed providers making clinical judgments. Unfortunately, optometrists are promulgating Luddite and protectionist statutes to block telehealth in state legislatures.

OD actions. So why does telehealth make optometry so squeamish? I'd like to say it's all about patient safety. However, according to a lobbyist for optometry, it's about "the bread and butter." They have an unfounded fear of reduction in revenue. This has forced lawyers on both sides to clean up the messes left by state legislatures beholden to optometry and its desire to protect the status quo. Ask the Board of Medicine in South Carolina if you don't believe me. It is being sued, along with the Board of Optometry, by the Institute for Justice, for a misguided anti-telehealth bill passed in 2016. Gov. Nikki Haley unsuccessfully tried to veto it. She said, "I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry." Optometrists obtruded on the plenary license of ophthalmologists and walked the physicians in the board of medicine and optometry (and taxpayers) right into a legal battle.

MD actions. It seems obvious that we should not subject our physician "family" to litigation and restrict access to care. But in Kentucky last week, a few ophthalmologists emerged to support optometry's wish to regulate telehealth out of existence. The Kentucky ophthalmology society, following well-vetted Academy talking points, was at the table testifying against HB191 (an anti-telehealth bill) while 5 ophthalmologists supported the optometric position. The Kentucky society members spent numerous hours volunteering, lobbying, and rescheduling patients, all for a position that we felt was good for patients—and we ultimately lost our battle in committee.

What can we do? We must help our dissenters, as well as organized optometry, find the silver lining in telemedicine. Here it is: 30 million undiagnosed patients! I'll state it again: 30 million! Whatever reductions in revenues that eye care professionals experience because of telehealth spectacle prescriptions and contact lens renewals will be more than offset by the detection, via telehealth, of new patients with chronic disease in need of care. This potential for better intervention furthers our professional obligation to the oath that binds us.

I believe that the Academy, medical associations, state ophthalmology societies, Americans for Tax Reform, and the Federal Trade Commission cannot *all* be wrong on this issue. We should not be a party to dismantling some of the most promising patient-access technologies of our lifetime.

For reference, the Academy generated a statement in December 2014 entitled *Innovative Technologies in Diagnosing Eye Diseases.*[1] In it, the Academy "recognizes the potential of information technology, including internet-based screening, refraction, and other diagnostic tests, in increasing access to health care services, enhancing patient involvement in their health care decision making, improving efficiency, and reducing overall health care costs."

William W. Richardson II, MD
Georgetown, Ky.

1 aao.org/clinical-statement/innovative-technologies-in-diagnosing-eye-diseases.

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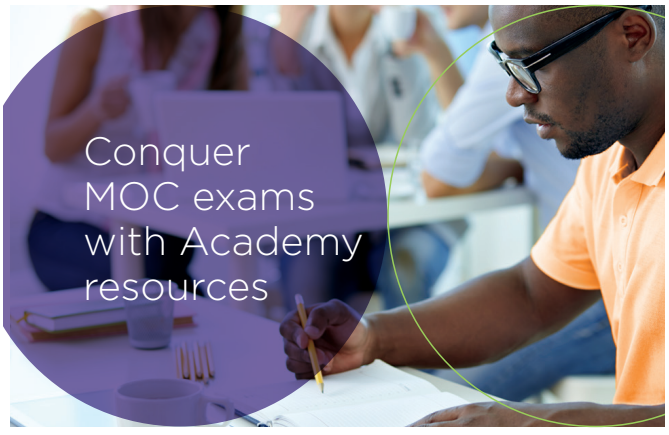

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Opinion

RUTH D. WILLIAMS, MD

The Art of Observation

Stephen Gieser (my husband) is a superb glaucoma specialist. He also knows a lot about 20th-century art. He acquired this expertise as a fourth grader visiting art museums in New York City every Sunday while his father, a retina fellow with Harvey Lincoff, did rounds at New York-Presbyterian Hospital. While it's fun to visit the modern wing of any art museum and talk with Stephen about the paintings, it just might improve my clinical acumen as well, as a study published in January's *Ophthalmology* suggests.[1]

Gurwin et al. randomized medical students into 2 groups: One received art observation training at the Philadelphia Museum of Art during 6 sessions, while the other had no art classes. When taking a written test that assessed ophthalmology clinical observational skills, the group with art observation training scored significantly better than the control group. The students with higher scores attributed their ability to notice clinical details to the art observation training.

The study's findings didn't surprise Alfred Nadel, a vitreoretinal specialist in Manhattan and a serious visual artist. During a visit to his Brooklyn studio, I listened as Alfred described several of his paintings in detail. "If you look at a work of art carefully, you begin to see many things." Alfred believes that observation skills can be taught—and that they make for better clinicians. He emphasized that both clinical skills and astute observations of human behavior (and the interaction between family members) can be developed, via art and in the exam room.

I agree. A quick example: When my husband was a glaucoma fellow at Wilmer, his mentor, Alan Robin, assigned him the task of carefully studying the appearance of filtering blebs and seeing what he could learn about trabeculectomies by taking the time to describe each bleb in detail. That advice was repeated to me, and 3 decades later, I still spend extra seconds to carefully observe a bleb.

To accompany the Gurwin paper, well-known author Malcolm Gladwell and David Epstein wrote an editorial about the value of creative endeavors for scientists and clinicians.[2] They discussed the tension between the specialized education required to be an ophthalmologist (with an expanding knowledge base) and the idea that spending time in an art museum is valuable. Which is more important?

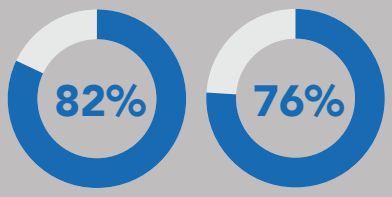
I was particularly intrigued by Epstein and Gladwell's reference to Santiago Ramon y Cajal, the Nobel Prize-winning father of modern neuroscience, whom they quote to support the idea that artistic hobbies are "cross-training" for scientists. I'd just noticed an ink-and-pencil drawing by Cajal, which was reprinted in *The New Yorker* to promote an exhibition of Cajal's works.[3] Cajal combined his scientific and artistic skills to present his understanding of neuroanatomy with stunning aesthetic beauty and scientific clarity that could not be communicated with a photograph.

Teaching medical students about art isn't a new idea. In 2003, Mount Sinai School of Medicine began teaching art appreciation to its third-year medical students, taking them to the Metropolitan Museum of Art. Mount Sinai also joined Yale, Stanford, and Cornell in offering humanities courses during medical school. In response, traditionalists may say that trips to the art museum are superfluous, especially now when students have a larger body of knowledge to learn.

Ruth D. Williams, MD
Chief Medical Editor, EyeNet

However, teaching "softer" skills may become more important. Ophthalmologists can't possibly process the vast amount of data available and will increasingly turn to "point of learning" tools and artificial intelligence. We'll increasingly rely on test results and exquisite images. As digital data interpretation, EHRs, and imaging demand more of our attention, perhaps the role of the physician—more than ever before—is to counsel, interpret, listen, and observe. In fact, cultivating the art of medicine may be what we most need to teach our students.

1 Gurwin J et al. *Ophthalmology.* 2018;125(1):8-14.
2 Epstein D, Gladwell M. *Ophthalmology.* 2018;125(1):2-3.
3 Goings on about town: Art. *The New Yorker.* 2018;93(47):8.



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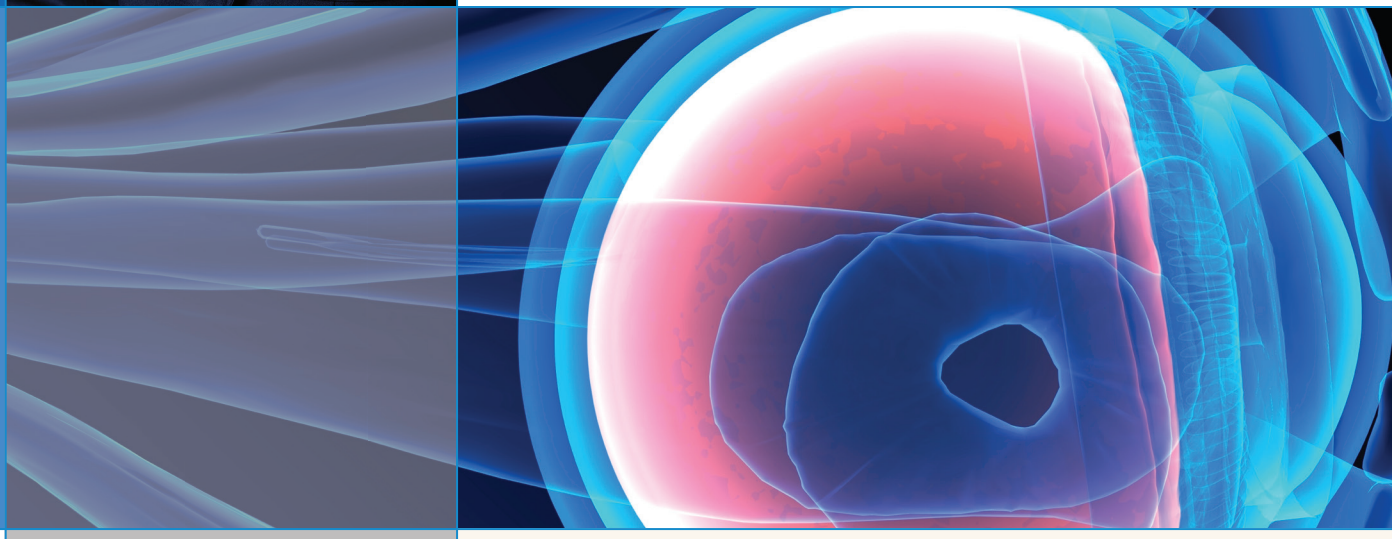

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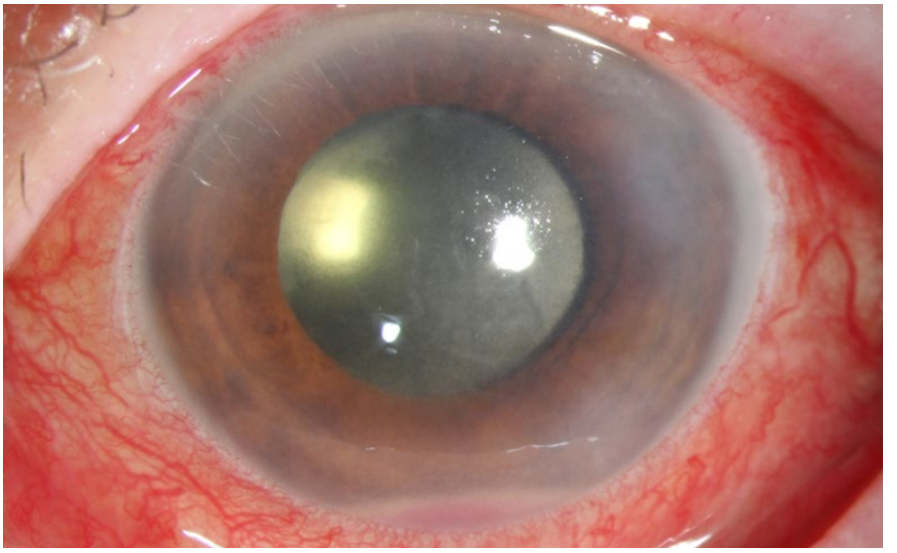


INFLAMMATION. *A case of* S. epidermidis *endophthalmitis.*

Harry W. Flynn Jr., MD

INFECTION

Tracking Antibiotic Resistance and Endophthalmitis

STAPHYLOCOCCUS EPIDERMIDIS, a coagulase-negative, gram-positive coccus, is the most common cause of culture-proven endophthalmitis. Researchers at Bascom Palmer Eye Institute in Miami set out to describe the features and antibiotic resistance profiles of endophthalmitis cases that occurred at their institution from 2006-2016.[1] They then compared the data to findings of a similar case review from the prior decade.[2]

Cataract surgery accounted for nearly half (49%) of the cases caused by methicillin-sensitive and methicillin-resistant *S. epidermidis,* they found. Intravitreal injections were the second most common procedure (22%) linked to the inflammation.[1]

Of the 96 cases of endophthalmitis and culture-positive *S. epidermidis* (96 eyes), 89 (93%) were treated with intravitreal vancomycin and ceftazidime. The remaining 7 (7%) received intravitreal vancomycin and amikacin.

Study specifics. The findings included the following:

- All isolates were sensitive to vancomycin in both decades.
- Resistance to methicillin was present in 53% of eyes, compared to 60% in the previous series.
- Resistance to the fluoroquinolone moxifloxacin has increased to 66% of eyes, compared to 31% in the previous decade.
- Visual acuity was not significantly different between those eyes that were methicillin- or moxifloxacin-sensitive and those that were resistant. At last examination, 33% of all eyes achieved 20/40 or better, and 29% achieved less than 5/200.

The challenge ahead. The vancomycin outcomes are "encouraging," given the drug's effectiveness against all study isolates over time, said coauthor Harry W. Flynn Jr., MD, at Bascom Palmer. Eyes such as those evaluated in the study "are usually responsive to treatment and generally have a favorable visual prognosis," he said.

He cautioned, however, that ophthalmologists cannot presume a rosy prognosis going forward. "In the future, it is reasonable to assume that routine use of intracameral vancomycin prophylactically may contribute to vancomycin resistance."

With regard to methicillin resistance, he noted, "It is reasonable to hypothesize that methicillin sensitivity rates have remained stable given the lack of selective pressure, since methicillin is not a commonly used ophthalmic antibiotic." As for fluoroquinolone resistance, he added, "With increasing use of fluoroquinolones, it is not surprising that resistance to this antibiotic class has increased."

Even so, Dr. Flynn cautioned against connecting any rise in drug resistance to the increased prophylactic use of fluoroquinolones for endophthalmitis. Intracameral antibiotics are not used at Bascom Palmer, and the study "was not designed to determine the cause of increasing *S. epidermidis* resistance to fluoroquinolones," he said. Nonetheless, he noted, "the concept that intracameral fluoroquinolones given at the time of cataract surgery will *prevent* postoperative infection should be challenged." —*Miriam Karmel*

1 Yannuzzi NA et al. *Ophthalmology Retina.* 2018;2(5):396-400.
2 Miller DM et al. *Ophthalmic Surg Lasers Imaging.* 2007;38(16):446-451.

Relevant financial disclosures—Dr. Flynn: None. This study was supported in part by grants from the NIH and Research to Prevent Blindness. No conflicting relationship exists for any author.

CATARACT

How Head, Eye Movements Affect Cataract Surgery

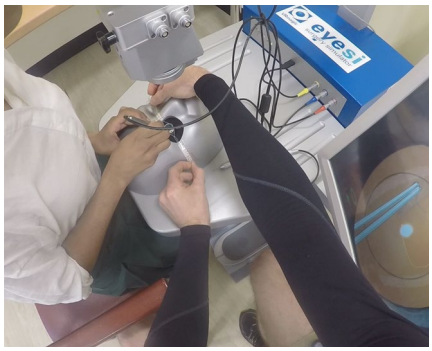
OUTCOMES OF MODERN CATARACT surgery are overwhelmingly excellent. But ophthalmologists are always in search of ways to tweak their protocols to further reduce the incidence of intraoperative complications and subsequent suboptimal results.

A Scottish group set out to investigate a long-posed, but little researched, question: Would limiting head motion during cataract surgery be beneficial to surgical outcomes?

"We realized that without measuring head drift we are unable to quantify how effective head stabilization techniques are and whether they should be used in clinical practice," said coauthor Kerr Brogan, MbCHB, of the Tennent Institute of Ophthalmology at Gartnavel General Hospital, in Glasgow, Scotland. He also noted that "head stabilization is a controversial issue, as some may see taping the head as a form of restraint."

Low- and high-tech tools. In developing the study, the team employed a creative combination of lower-tech tools and a virtual reality device.[1] "The absence of availability of eye tracking technology to accurately measure intraoperative eye movements inspired us to produce our own objective method for measuring head drift during cataract surgery. We also decided to subjectively simulate eye movements on the cataract surgical simulator while trainee ophthalmologists performed the capsulorrhexis exercise," Dr. Brogan said.

Measuring head drift. The first stage of the 2-pronged study was intended to establish baseline measurement of head drift during real-life cataract surgeries (N = 12) by experienced ophthalmologists. In each case, the researchers took a photo of the patient's eye with the speculum in place and rulers alongside it. These images were cropped and edited to only contain the rulers, then superimposed over the original video



TRACKING. *The person at left is performing simulated surgery (through an operating microscope) with the Eyesi simulator. Monitor is at right. The person in long sleeves is holding on to the strings that the authors used to move the "eye" back and forth, to monitor impact on surgical performance.*

Kerr Brogan, MD

RETINA

34-Gauge Needles Reduce Injection Pain

DESPITE THE KNOWN BENEFITS OF INTRAVITREAL anti–vascular endothelial growth factor (VEGF) drugs, the delivery system for these sight-saving medications has a notable downside: injection pain. But a couple of simple changes in needle design might remedy this, Japanese researchers suggest. Their preliminary study in 140 eyes of 110 people found that a thinner, shorter needle caused less discomfort than did a conventional needle.[1]

The researchers embarked on their study after receiving complaints about injection pain with anti-VEGF drugs despite the application of topical anesthetic, said coauthor Kotaro Tsuboi, MD, at Aichi Medical University in Nagakute, Aichi, Japan.

Procedure. Patients were randomized to receive either 0.5 mg of ranibizumab or 2 mg of aflibercept. All eyes were anesthetized with 2% lidocaine and sterilized with 5% povidone iodine eyedrops. Injections were performed with a standard, 30-gauge needle (0.3 × 19 mm; Nipro) and the thinner, more flexible 34-gauge needle (0.18 × 8 mm; Pasny).

Immediately after the injections, patients were asked to rate their pain according to a standard 0-to-10 pain scale. In addition, the 2 ophthalmologists who performed the injections rated puncture resistance, reflux, subconjunctival hemorrhage, and ocular movements for the injections on a 0 (undetectable) to 1 (detectable) scale.

Results. The short 34-gauge needle was associated with a significantly lower pain score than the 30-gauge needle, the researchers found. In addition, the surgeons detected meaningful differences in puncture resistance and reflux. There were zero cases of puncture resistance with the 34-gauge needle, versus 45 with the 30-gauge needle. Reflux occurred once with the 34-gauge needle and 22 times with the larger needle.

Subconjunctival hemorrhage and ocular movements did not differ significantly between the 2 groups.

Making the switch. Dr. Tsuboi said he has switched to using a 34-gauge needle for all intravitreal injections and for other procedures that penetrate the sclera. His institution has done this successfully more than 700 times, with few complications, he said.

Nonetheless, further studies of efficacy and safety are needed, Dr. Tsuboi said. Meanwhile, he suggested that ophthalmologists consider using a short, 34-gauge needle for intravitreal therapy in selected cases, as in patients who have a very low tolerance for pain.

—Linda Roach

1 Sasajima H et al. *Ophthalmology*. Published online Feb. 28, 2018.

Relevant financial disclosures—Dr. Tsuboi: None.

prior to playback. The speculum was used as a fixed point and correlated with the superimposed virtual rulers to measure maximum head drift in each direction throughout the operations.

Measuring eye movements. In the second stage, the researchers attached string to the "eye" of the Eyesi surgery simulator (VRmagic). This enabled them to pull the eye back and forth laterally and medially, in 5-mm increments every 3 seconds, as 6 trainees performed the capsulorrhexis portion of simulated surgeries.

Results. The first phase measured the maximal mean head drift during surgery as 3.1 mm medially (range, 2-7 mm); 2.9 mm laterally (range, 2-4 mm); 2.6 mm superiorly (range, 1-5 mm); and 1.9 mm inferiorly (range, 1-4 mm).

"We found head drift to be greatest medially, with the maximum movement being 7 mm. This caused pooling of fluid at the medial canthus, resulting in a submerged corneal surface and poor view due to light reflections," Dr. Brogan said. "Eleven of our 12 cases ultimately had to have repositioning of the microscope or the patient's head during surgery to compensate for this head drift and to regain an optimal surgical view."

In the study's second phase, the introduction of eye movements caused a statistically significant deterioration in the trainees' performance, as judged by the Eyesi's software on a 100-point scale. Their mean baseline score on the overall task fell from 92.7 ± 4.3 to 76.9 ± 10.3. Their score on "roundness of the capsulorrhexis" fell from 89.4 at baseline to 57.5.

Next step. Dr. Brogan said his group hopes that the study's methods can be replicated by others, to prepare junior cataract surgeons for the challenge of intraoperative eye movement as well as to help determine the value of head stabilization during cataract surgery.

—Linda Roach

1 Brogan K et al. *Eye* (Lond). Published online Feb. 21, 2018.

Relevant financial disclosures—Dr. Brogan: None.

PEDIATRICS

Bone Marrow Transplants: Kids Need Annual Eye Exams

AN INVESTIGATION OF OCULAR complications following allogeneic bone marrow transplantation (BMT) in young children found this population to be at increased risk for cataract development, a risk that increases over time.[1] These children are also at risk for dry eye disease.

"These patients need lifetime yearly eye exams for cataract development," said Mary Ellen Hoehn, MD, at the University of Tennessee Health Science Center in Memphis. What's more, physicians should have a low threshold for detecting and treating dry eye, she said.

The retrospective review included 91 consecutive patients aged 6 years or younger (mean age, 3.2 years) at the time of treatment. Average follow-up was 5.8 years (range, 2 months to 14 years). The most common indications for BMT were acute lymphoblastic leukemia (26 patients) and acute myelogenous leukemia (18 patients).

Complications. Cataract occurred in 72 eyes of 37 patients (41%) over a 14-year period, with the incidence rising over time, from 54.2% at 10 years to 58.4% at 14 years.

Nearly one-fifth of these patients (n = 8) required bilateral cataract surgery. Following intraocular lens implantation, visual acuities ranged from 20/20 to 20/40, with 1 "uncooperative tester" achieving 20/80.

Doctors diagnosed dry eye disease in 13 children (14.3%), none of whom had dry eye prior to BMT. At 14 years, the prevalence was greater than 40%. While the finding did not reach statistical significance, Dr. Hoehn said it might have if the children had been more articulate and more cooperative with Schirmer testing and slit-lamp examinations. Other complications were rare, she added.

Radiotherapy as a risk factor. Every patient in the study who developed cataracts had received total body irradiation (TBI), a form of radiotherapy sometimes used prior to BMT. But not all patients receiving TBI developed cataracts. And dose did not matter: There was no significant difference in TBI dose between those who developed cataract and those who did not.

A new finding. The chemotherapy drug cytarabine has not previously been linked to cataract development. But this study reports a 78.6% incidence for cataract formation over 14 years in those patients who took the drug. In contrast, thiotepa and busulfan were associated with a decreased risk of cataract development.

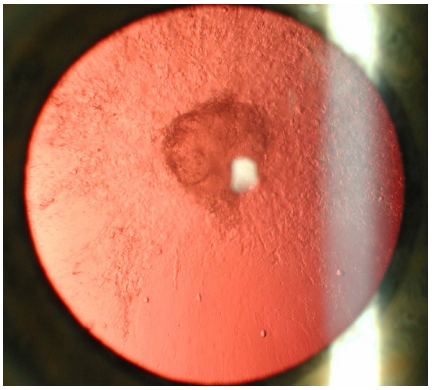
Clinical implications. The study does, however, suggest that "patients need fairly close follow-up during the first year after BMT," Dr. Hoehn said, with at least yearly appointments for life. She added, "They should have urgent dilated eye exams if there is a systemic fungal infection, as these patients may not be able to complain of visual changes. And any suspicion of dry eye should be treated with a trial of lubricating drops."

Despite the complications, Dr. Hoehn said, "I was pleasantly surprised that very few patients lost vision from complications of bone marrow transplantation."

—Miriam Karmel

1 Hoehn ME et al. *J AAPOS*. Published online Jan. 5, 2018.

Relevant financial disclosures—Dr. Hoehn: None.



ELEVATED RISK. *This cataract was observed in a child who underwent a bone marrow transplant.*

Mary Ellen Hoehn, MD

See the financial disclosure key, page 8. **For full disclosures,** including category descriptions, view this News in Review at aao.org/eyenet.

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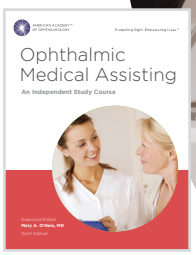

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Journal Highlights

NEW FINDINGS FROM THE PEER-REVIEWED LITERATURE

Ophthalmology

Selected by Stephen D. McLeod, MD

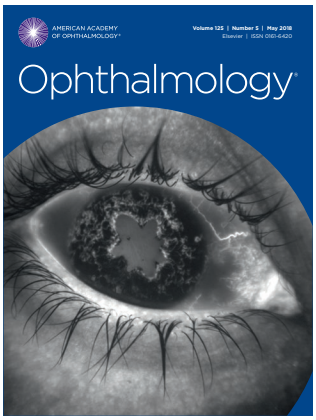
Primary Tube or Trabeculectomy for Glaucoma: 1-Year Outcomes

May 2018

Gedde et al. reviewed 1-year treatment outcomes of the primary tube versus trabeculectomy (PTVT) study and found that trabeculectomy plus mitomycin C (MMC) achieved greater success than did tube-shunt surgery.

This multicenter randomized study included 242 patients (242 eyes) with medically uncontrolled glaucoma and no previous incisional ocular surgery. Patients were enrolled at 1 of 16 centers and were assigned randomly to receive a tube shunt (350-mm^2 Baerveldt glaucoma implant; n = 125) or trabeculectomy and MMC (0.4 mg/mL for 2 minutes; n = 117). Outcome measures were intraocular pressure (IOP), number of glaucoma medications, visual acuity, visual field findings, surgical complications, and treatment failure. Failure was defined as any of the following: IOP > 21 mm Hg or reduced by 20% or less from baseline on 2 consecutive follow-up visits after 3 months, IOP ≤ 5 mm Hg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma, or loss of light-perception vision.

The cumulative probability of failure in the year of follow-up was 17.3% for the tube group and 7.9% for the trabeculectomy group. At 1 year, the mean (± standard deviation [SD]) IOP was 13.8 (4.1) mm Hg for those with a tube shunt and 12.4 (4.4) mm Hg for those with trabeculectomy. The number of glaucoma medications (± SD) at 1 year was 2.1 (1.4) in the tube group and 0.9 (1.4) in the trabeculectomy group.



Postoperative complications occurred in 29% of tube recipients and 41% of trabeculectomy cases. Serious complications resulting in reoperation or a loss of at least 2 Snellen lines occurred in 1 patient (< 1%) in the tube group and 8 (7%) in the trabeculectomy group.

In general, the minimally invasive glaucoma procedures introduced in recent years have been less effective than tubes or trabeculectomy for lowering IOP. The authors stressed that selecting a suitable glaucoma operation involves considering risk/benefit profiles on a case-by-case basis, and they noted that they plan to report 3- and 5-year outcomes of the PTVT study.

Real-World Effect of Anti-VEGF Drugs on IOP

May 2018

In a review of IRIS Registry data, **Atchison et al.** looked at intraocular pressure (IOP) in eyes treated with an anti–vascular endothelial growth factor (anti-VEGF) agent and compared that with IOP levels in untreated fellow eyes. They found that treatment generally resulted in a small but significant decrease in IOP; however, some treated eyes had substantial elevation of IOP.

For their study, the authors identified 23,776 patients who received at least 12 injections of a single anti-VEGF drug (aflibercept, bevacizumab, or ranibizumab) in their right eye. Left eyes were not treated. Diagnoses were neovascular age-related macular degeneration (AMD) only (73%), diabetic macular edema only (12%), vein occlusion with macular edema (11%), and a combination of these conditions (4%). The minimum follow-up period was 1 year.

Primary outcome measures were IOP change from baseline and the proportion of eyes with a clinically significant increase in IOP, defined as a sustained increase of at least 6 mm Hg resulting in IOP > 21 mm Hg. Subgroup analyses were conducted among patients with AMD only and patients who did not have anti-VEGF treatment in the year before study entry.

Mean IOP declined from baseline to ≥ 1 year in all treatment arms, including subsets. Overall, the mean decrease was 0.9 mm Hg for treated eyes and 0.2 mm Hg for untreated eyes. A generalized linear model accounting for confounders showed that, in most groups, the degree of IOP lowering was less with bevacizumab than with aflibercept or ranibizumab.

Clinically significant increases in IOP were sustained in 2.6% of treated eyes and 1.5% of untreated eyes; the rates by treatment were 1.9% for aflibercept, 2.8% for bevacizumab, and 2.8% for ranibizumab. The increases in untreated eyes were significantly lower than in eyes treated with bevacizumab and ranibizumab, but not with aflibercept. The reason for this difference is unclear and requires further investigation. Aflibercept is the only drug in this study with affinity for placental growth factor, which could affect the trabecular meshwork in a manner that is not yet known.

10-Year Review of Liability Claims in Ophthalmology

May 2018

Thompson et al. assessed closed medical professional liability claims against ophthalmologists in the United States and found that 24% of claims resulted in payment. Two-thirds were dropped, withdrawn, or dismissed. Cataract and corneal surgeries were the most common claims-related procedures. The average cost associated with liability claims was lower for ophthalmology than for the average of all health specialties combined.

For their study, the authors obtained 10-year data from the Physician Insurers Association of America data-sharing project. They gathered details of claims in ophthalmology and claims for all health specialties, including physician demographics, prevalence rates, associated costs, resolutions, and various medical factors. They also compared data for the first 5 years (2006-2010) and latter 5 years of the study (2011-2015).

During the full 10-year period, 90,743 liability claims were closed, and 24,670 were paid. Of these, only 2.6% of closed claims and 2.2% of all paid claims were against ophthalmologists. Among the ophthalmology claims with a verdict, 90% favored the ophthalmologist. Cataract and corneal surgeries were the most common and costly surgeries in this dataset, accounting for 50% of ophthalmology claims and for $47,641,376 and $32,570,148 (respectively) in total paid indemnity. The average indemnity was higher for corneal procedures ($304,476) than for vitreoretinal procedures ($270,141) or oculoplastic procedures of the eyelid ($222,471) or the orbit and eyeball ($183,467). The chief medical factors prompting claims against ophthalmologists were improper performance, error in diagnosis, and failure to recognize a complication of treatment.

Between the first and second 5-year periods, the prevalence and cost of claims related to endophthalmitis declined: from 38 (3.3%) of 1,160 (average indemnity, $516,875) to 26 (2.2%) of 1,165 (average indemnity, $247,083). The average indemnity paid and amount spent on legal defense was lower for ophthalmologists than for all health specialists combined (indemnity: $280,227 vs. $335,578; legal: $41,450 vs. $46,391).

—Summaries by Lynda Seminara

Ophthalmology Retina

Selected by Andrew P. Schachat, MD

Ziv-Aflibercept for Diabetic Macular Edema

May 2018

Ziv-aflibercept, a recombinant fusion protein, has a mechanism that is similar in action to that of aflibercept—and is available at a lower cost than the proprietary anti–vascular endothelial growth factor (VEGF) drug. **Bonyadi et al.** set out to evaluate 2 doses of ziv-aflibercept and compare them with intravitreal bevacizumab for the treatment of center-involving diabetic macular edema (DME). They found that patients who received ziv-aflibercept improved more than those who received bevacizumab, with the caveat that the greatest improvement was noted in those eyes that had the worst visual acuity (VA) at baseline.

For this 1-year double-blind study, the researchers randomly assigned 123 eyes with center-involving DME to 1 of 3 arms: 1) 2.5 mg of intravitreal ziv-aflibercept (n = 42); 2) 1.25 mg of intravitreal ziv-aflibercept (n = 42); and 3) 1.25 mg of intravitreal bevacizumab (n = 39). Initially, all patients were treated every 4 weeks for 3 loading injections. After that, patients in the bevacizumab cohort were treated every 4 weeks, while those in the 2 ziv-aflibercept cohorts were treated every 8 weeks. The main outcome measure was change in best-corrected VA (BCVA) at 1 year.

At final follow-up, BCVA was superior in the ziv-aflibercept patients to that of those who received bevacizumab, with mean improvements of 16 and 18 ETDRS letters found for ziv-aflibercept 2.5 mg and 1.25 mg, respectively, versus 14 letters for bevacizumab. This effect was pronounced in those patients who had worse levels of vision at baseline (defined as ≤ 20/50)—improvements of 24, 25, and 14 letters were found for the 2.5-mg ziv-aflibercept, 1.25-mg ziv-aflibercept, and bevacizumab groups, respectively.

With regard to central macular thickness (CMT), the final measurement was less than 250 µm in 64.7% of those who received 2.5 mg of ziv-aflibercept, 53.3% of the 1.25-mg ziv-aflibercept cohort, and 40% of those who received bevacizumab.

All told, those who received 2.5 mg of ziv-aflibercept were given an average of 6.71 injections, versus 6.67 injections in the 1.25-mg ziv-aflibercept arm and 11.56 in the bevacizumab arm. No cases of major ocular or systemic complications were noted.

—Summary by Jean Shaw

American Journal of Ophthalmology

Selected by Richard K. Parrish II, MD

POAG Progression and Diabetes

May 2018

Risk factors for glaucoma progression have not been clearly defined, and there is long-standing debate on the role of type 2 diabetes mellitus (DM) in primary open-angle glaucoma (POAG). Elevated intraocular pressure and impaired vascular supply to the optic nerve head have both been implicated in the pathophysiology of POAG—and as type 2 DM has been thought to involve both pathogenic processes, it may be a risk factor for POAG.

With this in mind, **Hou et al.** compared rates of visual field (VF) loss

and retinal nerve fiber layer (RNFL) thinning for patients with POAG and found no difference in VF progression between patients without type 2 DM and those who had type 2 DM with undetectable diabetic retinopathy. They also found that treated DM was linked to significantly slower loss of RNFL thickness.

This study included 197 eyes. The POAG/DM group consisted of 55 eyes (32 patients) and the POAG-only group included 142 eyes (111 age-matched patients). Participants had been enrolled in the Diagnostic Innovations in Glaucoma Study; those with type 2 DM were identified by self-reporting a history of DM and use of medication for diabetes. Univariate and multivariable mixed-effects models were applied to compare rates of VF loss and RNFL loss between the study groups. Median follow-up time was 5.7 years.

Results showed that the mean rate of global RNFL loss was 2-fold slower in the POAG/DM group (–0.40 vs. –0.83 µm per year; p = .01). The POAG/DM group also had slower rates of VF mean deviation and pattern standard deviation loss, but the between-group differences were not significant.

The global and sectoral RNFL thinning rates for metformin users and nonusers in the POAG/DM group were compared to determine whether metformin could have a protective effect, but no significant difference was observed. Not surprisingly, most subjects in the POAG/DM group (84.4%) were taking metformin (solo or combined), so the subanalysis is limited by the small sample of nonusers.

If glaucoma is diabetes of the brain, which has been proposed by some investigators, insulin and other diabetes medications might be remedies for glaucoma. Research is needed to address this topic and assess whether such treatments could protect against glaucomatous damage.

Culture Results May Guide Treatment of Severe Fungal Keratitis

May 2018

In a secondary analysis of data from the Mycotic Ulcer Treatment Trial–II (MUTT–II), **Ray et al.** aimed to identify patients with fungal keratitis who are at risk of poor outcomes and thus may benefit from aggressive treatment and additional monitoring. They found that patients with positive (vs. negative) cultures on day 6 had a 2-fold greater risk for corneal perforation or the need for therapeutic penetrating keratoplasty (PK).

For this secondary analysis, the researchers included patients with smear-positive filamentous fungal ulcer and visual acuity (VA) of 20/400 or worse at presentation, at which time medical therapy was started. Using backward stepwise regression with covariates for baseline traits, the authors compared clinical outcomes between patients who had positive cultures and those who had negative cultures on day 6. The primary outcome measure was the rate of corneal perforation and/or need for therapeutic PK. Secondary outcomes included 3-month best spectacle-corrected VA (BSCVA), size of infiltrate/scar at 3 months, and rate of re-epithelialization.

The analyses showed that, even after controlling for baseline ulcer characteristics, patients with positive cultures on day 6 had twice the hazard of experiencing corneal perforation or needing therapeutic penetrating keratoplasty (p = .002) than patients with negative cultures. Moreover, culture positivity correlated with poorer BSCVA at 3 months (average of 0.26 logMAR lines worse than for patients with negative cultures; p = .001). However, a positive culture on day 6 was not predictive of infiltrate/scar size or the time to re-epithelialization.

Hence, 6-day culture results may be a valuable tool for making treatment decisions for patients with severe fungal keratitis. Findings of repeat cultures may be useful for risk stratification and for identifying patients at high risk of poor outcomes. Culture positivity is an objective indicator of response to medical therapy. The authors stated that this research, coupled with their earlier findings for less severe ulcers, represents the advent of a new standard of care for fungal keratitis.

—Summaries by Lynda Seminara

JAMA Ophthalmology

Selected by Neil M. Bressler, MD, and Deputy Editors

Anti-VEGF for Macular Edema: Monthly or Treat-and-Extend?

April 2018

In a randomized clinical trial, the Study of Comparative Treatments for Retinal Vein Occlusion 2 (SCORE2) established that, in the first 6 months of treatment, bevacizumab, on average, does not result in inferior visual acuity (VA) outcomes when compared to aflibercept for managing macular edema from central retinal or hemiretinal vein occlusion.

In a subsequent analysis of SCORE2 data among the participants who exhibited a good response to 6 months of monthly injections, **Scott et al.** compared monthly and treat-and-extend (TAE) regimens of aflibercept or bevacizumab. They found that TAE was associated with fewer injections and no meaningful differences in VA between the treatment schedules. Nonetheless, they advised that—because of the wide confidence intervals on VA differences between these 2 retreatment regimens—caution is warranted before concluding that the 2 treatment schedules are associated with similar vision outcomes.

For this analysis, participants with a protocol-defined good response to monthly injections in the first 6 months of SCORE2 continued on aflibercept or bevacizumab after random assignment to a monthly or TAE schedule. The primary outcome was difference in best-corrected VA letter score (VALS) from month 6 to month 12.

At month 12 in the aflibercept arm, the mean VALS was 72.7 (approximately 20/40) in the monthly group (n = 79) and 71.6 (approximately 20/40) in the TAE group (n = 80), with a mean improvement of 0.8 letters in the monthly group and a mean decline of 1.2 letters in the TAE group. The between-group difference in VALS change was 1.88 letters (97.5% confidence interval [CI], –1.07 to 4.83). At month 12 in the bevacizumab arm, mean VALS was 75.2 (approximately 20/32) in the monthly group (n = 67) and 74.0 (approximate-

ly 20/32) in the TAE group (n = 67), with mean decreases of 1.6 and 0.4 letters, respectively. The between-group difference in VALS change was 1.98 letters (97.5% CI, –1.08 to 5.03 letters). In both treatment arms, more injections were administered in the monthly group than the TAE group (aflibercept: 5.8 vs. 3.8 injections, respectively; bevacizumab: 5.8 vs. 4.5 injections, respectively). *(Also see related commentary by Jennifer K. Sun, MD, MPH, in the same issue.)*

Unmet Psychosocial Needs of Adults With Uveal Melanoma

April 2018

Williamson et al. researched the type and frequency of medical, psychosocial, and sociodemographic factors associated with unmet needs of patients with uveal melanoma. In their study, nearly all patients had at least 1 unmet need in the week following diagnosis. Although the severity of these unmet needs subsequently declined, they did not vanish altogether, as most patients reported having the same concerns several months later. Psychosocial support represented the greatest domain of unmet needs.

The study included 107 patients (mean age, 59 years) with uveal melanoma diagnosed by an ophthalmologist. Patients used the Cancer Needs Questionnaire to report their unmet needs 1 week after diagnosis and 3 months later. Eighty-six patients completed the questionnaire at 1 week, and 82 patients completed it 3 months later.

One week after diagnosis, 99% of patients noted at least 1 unmet need. Three months later, 86% reported at least 1 unmet need. The most common concerns pertained to health information and psychosocial support. Although the number of unmet needs declined during the 3-month period, the severity of sociodemographic and medical factors remained similar. Prediagnosis factors found to correlate with lower severity of unmet needs 1 week after diagnosis were greater instrumental social support and lower neuroticism.

Although large social networks are often thought to lead to more robust emotional health, the opposite proved true in this study, as having a smaller social network correlated with lower severity of unmet needs at the 3-month assessment and a decline in needs during the 3-month period. Patients with large interactive social networks may be overwhelmed by the magnitude of available information, and smaller social networks may offer support that is better suited to the patient's unique needs, the authors suggested.

Findings of this study suggest that needs assessments may promote early identification of patients in greatest need of supportive care. The authors encouraged testing of interventions that target health information and psychological factors, particularly neuroticism. Ensuring social support, such as transportation to medical appointments, also may be helpful. *(Also see related commentary by Zélia M. Corrêa, MD, PhD, in the same issue.)*

Race and Glaucoma Progression

April 2018

In a multicenter longitudinal study of visual field changes in Europeans and Africans with glaucoma, **Gracitelli et al.** found that African descent is linked to larger variability in standard automated perimetry results and greater time to detect disease progression.

Participants were enrolled from the Diagnostic Innovations in Glaucoma Study and the African Descent and Glaucoma Evaluation Study; 173 patients (236 eyes) were of European descent and 171 (235 eyes) were of African descent. Mean baseline age was similar for the study groups, as was gender distribution. Differences in test-retest variability were investigated, and the simulated time to detect glaucoma progression was estimated. For each eye, standard automated perimetry mean deviation values were regressed over time, and the standard deviation (SD) of residuals was used as a measure of variability. Distributions of residuals were used in computer simulations to reconstruct real-world standard automated perimetry mean deviation trajectories under different assumptions for change rates and testing schedules. The mean follow-up period was 7.5 years.

The mean (SD) of residuals was found to be larger for eyes in the African group: 1.45 (0.83) dB versus 1.12 (0.48) dB in the European group (mean difference, 0.33 dB). As glaucoma progressed, those of African descent were more likely to have a greater increase in visual field variability. Disease progression was detected earlier in the European group, as demonstrated by simulation analyses. For a scenario with baseline mean deviation of –10 dB and a change rate of –0.5 dB/year, progression detection was delayed by 3.1 years in the African group (assuming 80% power and annual testing).

This research adds to previous studies of the high prevalence of glaucoma-related visual impairment among people of African descent. The high variability in visual field test-retest results can prolong detection of progression. To avert this, the authors suggested increasing the frequency of testing, which may yield better estimates of change indices over time; using complementary methods to assess progression; and combining structural and functional testing. *(Also see related commentary by Eve J. Higginbotham, SM, MD, in the same issue.)*

—Summaries by Lynda Seminara

OTHER JOURNALS

Selected by Deepak P. Edward, MD

Clear Lens Extraction for PACG in EAGLE

British Journal of Ophthalmology
Published online February 16, 2018

Refractive outcomes for eyes with primary angle-closure glaucoma (PACG) that undergo lens extraction can be unpredictable because of anatomic features such as shallow anterior chamber depth, short axial length, and a thickened lens positioned anteriorly. In the EAGLE study (Effectiveness in Angle-closure Glaucoma of Lens Extraction), patients with PAC/PACG who were treated with clear lens extraction (CLE) had better quality of life and control of intraocular pressure than

their counterparts who received laser peripheral iridotomy (PI).

In a subsequent report, **Day et al.** described the surgical details, visual outcomes, and postoperative refractive errors of EAGLE participants who received CLE. They concluded that CLE is appropriate for some patients with PAC or PACG, but they emphasized the importance of individualized treatment, as CLE may result in suboptimal refractive outcomes in some eyes.

In the original study, eligible patients were assigned randomly to receive CLE or PI. The CLE group underwent phacoemulsification and implantation of a monofocal intraocular lens (IOL) within 60 days of randomization. Synechiolysis was permitted in accordance with local practice.

In this subsequent review, the authors reported postoperative corrected distance visual acuity (CDVA) at 36 months for the CLE group (n = 208). Collected data included the IOL formula and predicted refraction. Laser biometry was used to estimate axial length and IOL power.

Mean baseline CDVA was 77.9 letters (± standard deviation [SD], 12.4) and did not change significantly by month 36 (mean CDVA, 79.9; SD, 10.9). Spherical equivalents were +1.7 D (SD, 2.3) preoperatively and +0.08 D (SD, 0.95) at 36 months.

Overall, by 3 years postoperatively, 59% of eyes were within ± 0.5 D of their predicted refraction, and 85% eyes were within ± 1.0 D of that goal. Axial length < 22 mm correlated with outcomes that varied by > 1 D from predictions.

Although the mean CDVA of patients who underwent clear lens extraction for PACG appeared stable in the ensuing 3 years, and refractive error improved, the predictability of refractive outcomes was less than optimal, the authors said.

—Summary by Lynda Seminara

AI, Transfer Learning, and Retinal Disease

Cell
2018;172(5):1122-1131

Artificial intelligence (AI) systems typically employ a highly specialized deep learning machine and a dataset of millions of images. **Kermany et al.** evaluated a new deep learning framework that uses transfer learning, thus allowing these systems to use a smaller dataset of images. They found that their system effectively classified spectral-domain optical coherence tomography (SD-OCT) images of age-related macular degeneration and diabetic macular edema (DME), matching the proficiency of human experts.

For the study, a dataset of 108,312 SD-OCT images from 4,686 patients was used to train the deep learning framework. The model was then tested with a validation dataset of 1,000 images from 633 patients, with the images evenly drawn from image subsets of choroidal neovascularization (CNV), DME, drusen, and no disease.

The AI system categorized the OCT images as "urgent referrals" (those with CNV or DME); "routine referrals" (those with drusen); and "observation" (those with no disease), achieving an accuracy rate of 96.6%, with a sensitivity of 97.8% and specificity of 97.4%. An independent test set of images was used to compare the network's referral decisions with those made by 6 experienced ophthalmologists; the network's performance was comparable to that of the human experts.

The researchers also performed occlusion testing to identify the areas of greatest importance used by their AI system in assigning a diagnosis. They noted that the greatest benefit of occlusion testing is that it sheds light on how neural networks "think," thus making the process more transparent and bolstering confidence in the results. In this study, the occlusion tests confirmed that the AI system made its decisions using accurate distinguishing features.

In a novel twist, the researchers also used their system to evaluate chest x-ray images for the purposes of diagnosing pediatric pneumonia. They found that the system successfully differentiated between viral and bacterial pneumonia, with an accuracy of 92.8%. This demonstrates that the system can be applied to a wide range of medical imaging techniques across multiple medical specialties, they said.

—Summary by Jean Shaw

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Endophthalmitis** may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.
- **Permanent decline in visual acuity** may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.
- **Retinal abnormalities** may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.
- **Increased intraocular pressure** may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.
- **Expansion of intraocular air bubbles** Instruct patients to avoid air travel, travel to high elevations or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.
- **Cataract** Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

Adverse Reactions

- In clinical studies, ocular adverse reactions occurred in 66% of study participants (57% of injected eyes), and may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.

A New Vision

for your patients with an inherited retinal disease (IRD)

LUXTURNA (voretigene neparvovec-rzyl) is a one-time gene therapy that improves functional vision in individuals with an IRD who have confirmed biallelic *RPE65* gene mutations and viable retinal cells.[1]

With LUXTURNA, patients experienced a clinically meaningful improvement in the ability to navigate at lower light levels.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

- The most common adverse reactions (incidence ≥ 5% of study participants) were conjunctival hyperemia (22%), cataract (20%), increased intraocular pressure (15%), retinal tear (10%), dellen (thinning of the corneal stroma) (7%), macular hole (7%), subretinal deposits (7%), eye inflammation (5%), eye irritation (5%), eye pain (5%), and maculopathy (wrinkling on the surface of the macula) (5%).

Immunogenicity
Immune reactions and extra-ocular exposure to LUXTURNA in clinical studies were mild. No clinically significant cytotoxic T-cell response to either AAV2 or RPE65 has been observed. In clinical studies, the interval between the subretinal injections into the two eyes ranged from 7 to 14 days and 1.7 to 4.6 years. Study participants received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye, which may have decreased the potential immune reaction to either AAV2 or RPE65.

Pediatric Use
Treatment with LUXTURNA is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during the cell proliferation. The safety and efficacy of LUXTURNA have been established in pediatric patients. There were no significant differences in safety between the different age subgroups.

Please see a brief summary of the US Full Prescribing Information on the following pages.

Reference: 1. LUXTURNA [package insert]. Philadelphia, PA: Spark Therapeutics, Inc; 2017.

P-RPE65-US-360005 April 2018

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Brief Summary of US Full Prescribing Information for LUXTURNA (voretigene neparvovec-rzyl)

1 INDICATIONS AND USAGE

LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physicians.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis

Endophthalmitis may occur following any intraocular surgical procedure or injection. Proper aseptic injection technique should be used when administering LUXTURNA. Following the injection, patients should be monitored to permit early treatment of any infection. Advise patients to report any signs or symptoms of infection or inflammation without delay.

5.2 Permanent decline in visual acuity

Permanent decline in visual acuity may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.

5.3 Retinal abnormalities

Retinal abnormalities may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. LUXTURNA must not be administered in the immediate vicinity of the fovea. *[See Dosage and Administration (2.3) in full prescribing information]*

Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.

5.4 Increased intraocular pressure

Increased intraocular pressure may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.

5.5 Expansion of intraocular air bubbles

Instruct patients to avoid air travel, travel to high elevations, or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.

5.6 Cataract

Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

6 ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) were conjunctival hyperemia, cataract, increased intraocular pressure, retinal tear, dellen (thinning of the corneal stroma), macular hole, subretinal deposits, eye inflammation, eye irritation, eye pain, and maculopathy (wrinkling on the surface of the macula).

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 the clinical trials of other products and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to LUXTURNA in two clinical trials consisting of 41 subjects (81 eyes) with confirmed biallelic *RPE65* mutation-associated retinal dystrophy. Forty of the 41 subjects received sequential subretinal injections of LUXTURNA to each eye. One subject received LUXTURNA in only one eye. Seventy-two of the 81 eyes were exposed to the recommended dose of LUXTURNA at 1.5×10^{11} vg; 9 eyes were exposed to lower doses of LUXTURNA. Study 1 (n=12) was an open-label, dose-exploration safety study. Study 2 (n=29) was an open-label, randomized, controlled study for both efficacy and safety *[see Clinical Studies (14) in full prescribing information]*. The average age of the 41 subjects was 17 years, ranging from 4 to 44 years. Of the 41 subjects, 25 (61%) were pediatric subjects under 18 years of age, and 23 (56%) were females.

Twenty-seven (27/41, 66%) subjects had ocular adverse reactions that involved 46 injected eyes (46/81, 57%). Adverse reactions among all subjects in Studies 1 and 2 are described in Table 1. Adverse reactions may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.

Table 1. Ocular Adverse Reactions Following Treatment with LUXTURNA (N=41)

Adverse Reactions	Subjects n=41	Treated Eyes n=81
Any ocular adverse reaction	27 (66%)	46 (57%)
Conjunctival hyperemia	9 (22%)	9 (11%)
Cataract	8 (20%)	15 (19%)
Increased intraocular pressure	6 (15%)	8 (10%)
Retinal tear	4 (10%)	4 (5%)
Dellen (thinning of the corneal stroma)	3 (7%)	3 (4%)
Macular hole	3 (7%)	3 (4%)
Subretinal deposits*	3 (7%)	3 (4%)
Eye inflammation	2 (5%)	4 (5%)
Eye irritation	2 (5%)	2 (2%)
Eye pain	2 (5%)	2 (2%)
Maculopathy (wrinkling on the surface of the macula)	2 (5%)	3 (4%)
Foveal thinning and loss of foveal function	1 (2%)	2 (2%)
Endophthalmitis	1 (2%)	1 (1%)
Foveal dehiscence (separation of the retinal layers in the center of the macula)	1 (2%)	1 (1%)
Retinal hemorrhage	1 (2%)	1 (1%)

*Transient appearance of asymptomatic subretinal precipitates inferior to the retinal injection site 1-6 days after injection.

Immunogenicity

At all doses of LUXTURNA evaluated in Studies 1 and 2, immune reactions and extra-ocular exposure were mild. In Study 1 (n=12), the interval between the subretinal injections into the two eyes ranged from 1.7 to 4.6 years. In Study 2, the interval between the subretinal injections into the two eyes ranged from 7 to 14 days. No subject had a clinically significant cytotoxic T-cell response to either AAV2 or RPE65.

Subjects received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye. The corticosteroids may have decreased the potential immune reaction to either vector capsid (adeno-associated virus serotype 2 [AAV2] vector) or transgene product (retinal pigment epithelial 65 kDa protein [RPE65]).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary: Adequate and well-controlled studies with LUXTURNA have not been conducted in pregnant women. Animal reproductive studies have not been conducted with LUXTURNA. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

Risk Summary: There is no information regarding the presence of LUXTURNA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LUXTURNA and any potential adverse effects on the breastfed infant from LUXTURNA.

8.3 Females and Males of Reproductive Potential

No nonclinical or clinical studies were performed to evaluate the effect of LUXTURNA on fertility.

8.4 Pediatric Use

Treatment with LUXTURNA is not recommended for patients younger than 12 months of age because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during cell proliferation.

The safety and efficacy of LUXTURNA have been established in pediatric patients. Use of LUXTURNA is supported by Study 1 and Study 2 *[see Clinical Studies (14) in full prescribing information]* that included 25 pediatric patients with biallelic *RPE65* mutation-associated retinal dystrophy in the following age groups: 21 children (age 4 years to less than 12 years) and 4 adolescents (age 12 years to less than 17 years). There were no significant differences in safety between the different age subgroups.

8.5 Geriatric Use

The safety and effectiveness of LUXTURNA have not been established in geriatric patients. Clinical studies of LUXTURNA for this indication did not include patients age 65 years and over.

17 PATIENT COUNSELING INFORMATION

Advise patients and/or their caregivers of the following risks:

Endophthalmitis and other eye infections: Serious infection can occur inside of the eye and may lead to blindness. In such cases, there is an urgent need for management without delay. Advise patients to call their healthcare provider if they experience new floaters, eye pain, or any change in vision.

Permanent decline in visual acuity: Permanent decline in visual acuity may occur following subretinal injection of LUXTURNA. Advise patients to contact their healthcare provider if they experience any change in vision.

Retinal abnormalities: Treatment with LUXTURNA may cause some defects in the retina such as a small tear or a hole in the area or vicinity of the injection. Treatment may cause thinning of the central retina or bleeding in the retina. Advise patients to follow up with their healthcare provider on a regular basis and report any symptoms, such as decreased vision, blurred vision, flashes of light, or floaters in their vision without delay.

Increased intraocular pressure: Treatment with LUXTURNA may cause transient or persistent increase in intraocular pressure. If untreated, such increases in intraocular pressure may cause blindness. Advise patients to follow up with their healthcare provider to detect and treat any increase in intraocular pressure.

Expansion of intraocular air bubbles: Advise patients to avoid air travel, travel to high elevations, or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. A change in altitude while the air bubble is still present may cause irreversible damage.

Cataract: Advise patients that following treatment with LUXTURNA, they may develop a new cataract, or any existing cataract may get worse.

Shedding of LUXTURNA: Transient and low-level shedding of LUXTURNA may occur in patient tears. Advise patients and/or their caregivers on proper handling of waste material generated from dressing, tears, and nasal secretion, which may include storage of waste material in sealed bags prior to disposal. These handling precautions should be followed for up to 7 days following LUXTURNA administration.

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Philadelphia, PA 19104
US License #2056

Intrascleral Haptic Fixation as an Alternative to Sutures

When lack of capsular and zonular support prevents placement of an intraocular lens (IOL) in the posterior chamber, some surgeons turn to sutureless intrascleral fixation of a 3-piece, posterior chamber IOL (PCIOL) as the solution.

Small Incision

Many ophthalmic surgeons who perform sutureless intrascleral fixation (also known as extracapsular fixation) say that this method of stabilizing IOLs, which uses a small-incision approach, represents an improvement over large-incision scleral suturing.

Indications. Intrascleral fixation is indicated in patients who have undergone traumatic injury or who have posterior capsular rupture, pseudoexfoliation, or other factors that have damaged the posterior capsule or weakened the zonules. These patients may have subluxations, crystalline lens fragments (or a dislocated IOL) in the vitreous, or visual problems from decentration, and they sometimes need a secondary implant.

Improvement. Before the development of intrascleral fixation methods, surgeons typically stabilized IOLs in problem eyes by suturing them to the sclera or the iris with polypropylene[1] or, more recently, Gore-Tex (an off-label use), said George H.H. Beiko, BM, BCH, FRCSC, who practices in St. Catharines, Ontario, Canada. But iris- and scleral-sutured IOLs are not ideal, because of associated complications such as cystoid macular edema, postoperative inflammation, induced astigmatism, and late suture breakage, Dr. Beiko said.

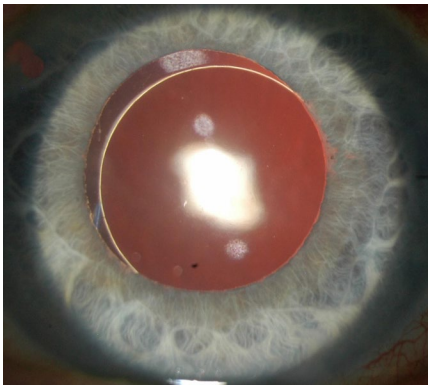
Two Techniques

Surgeons considering intrascleral fixation have 2 methods to consider.

Glue. Building on earlier work by Gabor B. Sharioth, MD, PhD, Amar Agarwal, MD, first published the glued IOL technique in 2008.[2] For this technique, the surgeon uses forceps to place the lens haptics inside scleral tunnels, which are located underneath scleral flaps. The flaps are then repositioned over the haptics, and fibrin glue is applied to keep the flaps secure during the eye's early healing.

Yamane. This newer intrascleral fixation method was developed by Shin Yamane, MD, and colleagues,[3,4] and it is also known as the double-needle flanged haptic technique.

Using a pair of bent thin-walled, wide-bore 30-gauge needles, and with the IOL already in situ, the surgeon inserts the needles through the sclera 2 mm posterior to the limbus and feeds the PCIOL haptics into the lumen of the needles. The needles and sheathed haptics are then drawn out of the scleral tunnels, which simultaneously fixates the 2 haptics in those tunnels. The surgeon cauterizes the protruding end of each haptic, fashioning flanges that prevent the haptics from slipping back into the eye through the tunnels and dislocating internally.



DAY 1 POSTOP. *Sclerally fixated PCIOL using double-needle flanged haptic (Yamane) technique (dilated).*

Choosing One Over the Other

Both methods are "wonderful techniques, because you can stay [with the] small incision, and this can potentially lead to faster visual recovery and possibly better refractive outcomes," said Nicole R. Fram, MD, who practices in Los Angeles. That said, surgeons differ as to which technique they prefer to use (see also "Pros and Cons").

Preference for glue. "I prefer the glued fixation method," Dr. Beiko said. "I've been doing it for 7 or 8 years, and I use it about a dozen times a year. Dr. Agarwal's technique is generally thought to be the first-line method for intrascleral fixation."

Dr. Beiko said that after trying the Yamane technique in a few eyes and listening to presentations about it at

BY LINDA ROACH, CONTRIBUTING WRITER, INTERVIEWING **GEORGE H.H. BEIKO, BM, BCH, FRCSC, NICOLE R. FRAM, MD,** AND **SADEER B. HANNUSH, MD.**

Sadeer B. Hannush, MD

international meetings, he concluded that the technique has problems that make it unsuitable for him to use.

"What they found in Japan, in a prospective study, was more IOL tilt with the Yamane than with the glued technique," Dr. Beiko said. Specifically, the study found that IOLs fixated with the Yamane method were tilted, on average, 13.2 degrees, compared to 4.8 degrees with the glued IOLs.[5]

"The other thing I've never been quite happy with is just blindly leaving the first haptic that's been placed within the needle floating in the back of the eye while I'm fixating on the other haptic," Dr. Beiko said. "I'm worried that this loose haptic, which is hidden behind the iris, might be touching the retina. It's a perfect place to create a break in the retina if you touch it."

Using both. Sadeer B. Hannush, MD, at Wills Eye Hospital in Philadelphia, said he began using the glue-assisted fixation technique 5 years ago, after Dr. Agarwal's group reported that their IOLs had remained stable for several years after implantation. "In 2013, it became my preferred fixation method in eyes with inadequate capsular support, and it remains the gold standard in sutureless intrascleral haptic fixation," Dr. Hannush said.

Dr. Hannush started exploring the Yamane technique in late 2016, after stumbling on an early paper describing the procedure. Today, he uses both approaches. He cautioned that the eye should remain pressurized at all times either with a chamber maintainer or with perfusion through a sclerotomy.

"I believe both techniques are here to stay, each offering advantages in certain settings and in the hands of the particular surgeon," he said. "The glued IOL technique is very effective, and it may be a little bit easier to perform for surgeons who don't do a lot of intrascleral fixation."

Cautious about both. Dr. Fram said she has primarily been using scleral suture fixation and some glued IOL techniques over the past 10 years. In the last year, she said she has been evaluating the Yamane technique, because she views it as a clever small-incision technique with much promise. Another intriguing characteristic of the Yamane technique is that there is less hypotony associated with it in the early postoperative period, in comparison to larger-incision scleral suture fixation or even the glued IOL, she said.

But Dr. Fram is quick to point out that both intrascleral fixation methods are 2-point fixation and require symmetrical scleral tunneling and sclerotomy entries. Better standardization of these steps may improve outcomes, she said. "My experience with both the glued IOL and the Yamane technique is that critical steps of tunneling in the sclera and sclerotomy entry can be challenging in terms of reproducibility and standardization. Because this is 2-point fixation, IOL tilt is an issue."

Out of the approximately 42 Yamane procedures Dr. Fram has performed, 4 IOLs had significant tilt, and 2 of them required refixation. "Interestingly, I had a patient who was 20/20 uncorrected—and as he healed over a 2-week period he developed 2.5 D of astigmatism," she said. While corneal topography and wavefront analysis (OPD-Scan; Marco) revealed little corneal astigmatism, internal astigmatism > 2 D was detected. Ultrasound biomicroscopy confirmed the IOL was tilted, she said.

"So although there can be very rapid visual recovery, which makes for a wonderful procedure that you want to try, you have to be prepared and know how

Pros and Cons

Dr. Hannush provided a concise overview of the 2 methods.

Glue: advantages.

- It compartmentalizes the eye nicely into anterior and posterior segments.
- It allows the use of foldable IOLs and thus a small corneal incision.
- All maneuvers are performed under direct visualization.
- The desired length of the haptic may be embedded in a scleral tunnel. This may be adjusted to optimize IOL centration and minimize rotation.
- It has a decade-long track record.

Glue: limitations.

- It requires familiarity with transscleral work, transferring the haptic from 1 forceps to the next (termed the "handshake technique" by Dr. Agarwal), as well as help from a third hand at certain points in surgery.
- It requires takedown of the conjunctiva and the creation of scleral flaps.
- It requires familiarity with the use of fibrin sealant.
- It requires familiarity with anterior vitrectomy techniques, ideally through the pars plana.

Yamane: advantages.

- The technique is conceptually simple.
- The need for conjunctival takedown and scleral flaps is obviated.
- It allows implantation of a foldable IOL through a small incision.
- It is currently the fastest method of sutureless PCIOL intrascleral haptic fixation.
- Eyes tend to be very quiet postoperatively with rapid visual rehabilitation.

Yamane: limitations.

- Despite its conceptual simplicity, it is surgically challenging even for a surgeon who is experienced in methods of scleral fixation.
- It requires familiarity with anterior vitrectomy techniques, ideally through the pars plana.
- As with the glued technique, and possibly more importantly, haptic placement is critical (180 degrees apart and 2 mm posterior to the limbus).
- The surgeon's view is obstructed during the intrascleral passes.
- To decrease the chance of optic rotation, it is important to achieve at least a 2-mm tunnel during the intrascleral pass that is circumlinear with the limbus.
- Limited international experience.

to refixate the IOL in the event that you get significant tilt," she said. In addition, it is imperative that the surgeon examine the patient every 6 months for potential extrusion of the haptics subconjunctivally through potentially thin-walled scleral tunnels.

Surgical Tips and Pearls

Two essentials. In order to do these procedures, "a surgeon should feel comfortable with a thorough triamcinolone-assisted anterior vitrectomy prior to the fixation portion of the procedure," Dr. Fram said. "This is a must-have [technique] in your skill set, or else you shouldn't be attaching anything to the wall of the eye."

It also is essential to use an anterior chamber maintainer during these procedures, Dr. Beiko noted.

IOL selection. Dr. Beiko implants a 3-piece silicone IOL (LI61SE, Bausch + Lomb) for his glued intrascleral fixation cases. "But I think that virtually any 3-piece IOL can be used," he said, with 1 exception: IOLs with PMMA haptics, because these are very friable.

Dr. Hannush said that specific IOL selection is crucial in Yamane cases, because conventional PMMA haptics are prone to kinking, breaking, or even disinserting from the optic during the potentially significant manipulation that the method involves. He recommends the EC-3 PAL lens (originally available from Aaren Scientific, now renamed Lucia 602 and available from Carl Zeiss), because its haptics are made from polyvinylidene fluoride, which is very resilient.

Special equipment. With the glued technique, conventional intraocular forceps should not be used, because they might damage the haptics, Dr. Beiko said. The 23-gauge forceps he uses to externalize and manipulate the haptics have blunt ends; some surgeons use forceps with ridges on the ends, he said.

The Yamane technique requires a special type of 30-gauge needle with thin walls and a wide lumen, Dr. Hannush said. (The TSK Ultra Thin Wall Needle is manufactured in Japan and distributed by Delasco.)

Geometry matters. The surgeon performing a Yamane fixation lacks tools to assure that the intrascleral tunnels are precisely equal in length (with 20-degree angulation and 5-degree tilt) and that sclerotomy entry occurs in the right places, 180 degrees apart, Dr. Fram said. "These are hard things to standardize," and this might help explain the IOL tilt problem in Yamane eyes, she said.

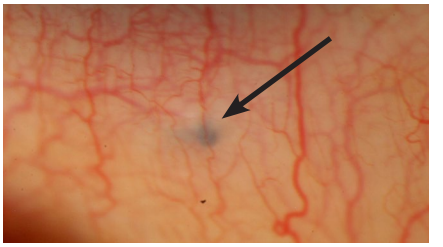
Visualization. "With the glued IOL technique, you are able to directly visualize everything, at every step," Dr. Fram said. In contrast, "with the Yamane [technique], you are marking, and then you're going through the conjunctiva, through Tenon's, and through the sclera—and you're doing it blind."

Consequently, although the Yamane technique does not call for taking down the conjunctiva, sometimes it will be helpful to do a small peritomy, about 2 clock hours, for better visualization of the sclera, she said.

Shorten the haptics. In Yamane eyes, Dr. Hannush said he has learned from experience to clip off the haptic tips before making the flanges. "Sometimes the lens will rotate in the eye if I keep them long." Instead, he recommended, "After the IOL is centered, an asymmetric amount of haptic is clipped off, as is deemed necessary by the surgeon, thus allowing continued good centration of the lens when the 2 haptics are tucked back into the sclera."

Glue or sutures? Some surgeons modify Dr. Agarwal's original technique by holding the scleral flap in place with a suture instead of fibrin glue, but Dr. Beiko recommends using the glue. "The main advantage of the glue is that it decreases the postoperative inflammation. It's not so much for stabilization of the haptic. The eyes seem to be much quieter when you don't use sutures."

Avoiding haptic loss. After externalizing the leading haptic during a glued procedure, the surgeon must begin externalizing the second haptic. To keep the first haptic from moving, Dr. Beiko said he devised a simple solution: He takes a tiny silicone ring (a "tire") from an iris hook and threads the ring onto the haptic. "I've found this makes the fixation procedure easier for me, because it stops the haptic from slipping back into the eye."



POSTOP. *Flanged haptic end seen in the inferior subconjunctival space 2 mm from the limbus. (Arrow = haptic end.)*

Final note. "With either technique, it may be a good idea to place 1 or 2 peripheral iridectomies to prevent reverse pupillary block," Dr. Hannush said.

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See the disclosure key, page 8.

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How to Disinfect and Calibrate Your Goldmann Applanation Tonometer

Does your practice use alcohol or hydrogen peroxide to disinfect its Goldmann applanation tonometers? If so, you may risk exposing patients to infection. According to a 2017 Academy *Ophthalmic Technology Assessment (OTA)*, the 3 most commonly used disinfectants are alcohols, hydrogen peroxide, and sodium hypochlorite (bleach); only the last was found to be effective disinfection against adenovirus and herpes simplex virus (HSV), the viruses commonly associated with nosocomial outbreaks in eye care.[1]

Teresa C. Chen, MD, of Harvard Medical School, who coauthored the *OTA*, suspects that many physicians are not yet using bleach on prisms. "The common misconception is that alcohol wipes—which are easier—are adequate," she said.

And good tonometer care does not stop with disinfection. Calibration is important for getting accurate and consistent monitoring of intraocular pressure (IOP), yet calibration protocols are often neglected.[2]

Learning a few best practices for tonometer maintenance can help ensure safe and effective IOP monitoring in your practice, the experts say.

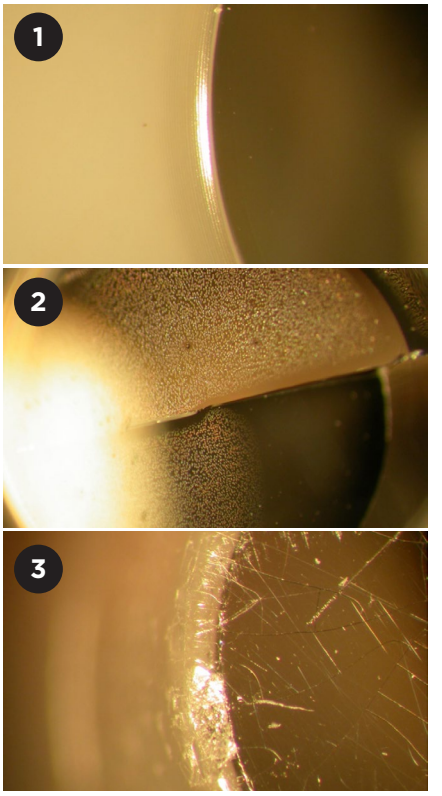
Disinfecting Reusable Prisms

Because the GAT prism contacts the corneal surface, reusable prisms that are inadequately disinfected between patients can be a source of disease transmission. In fact, tonometer tips have been implicated in clusters of epidemic keratoconjunctivitis.[3]

The *OTA* panel evaluated 10 laboratory studies on disinfection of tonometer prisms and concluded that soaking in 10% bleach for 5 minutes afforded the most effective disinfection.[1] This finding is consistent with the 2008 Centers for Disease Control and Prevention (CDC) *Guideline for Disinfection and Sterilization in Healthcare Facilities*[4] and with recommendations of tonometer manufacturers.

Microbes of concern. Anna K. Junk, MD, lead author of the *OTA* and an ophthalmologist at the Bascom Palmer Eye Institute and the Miami Veterans Affairs Healthcare System, stated that most iatrogenic infections in ophthalmic settings can be traced to adenovirus 8, adenovirus 19, or HSV 1. The studies reviewed by the *OTA* panel address contamination of the tonometer tip with adenovirus 8 and 19, enterovirus 70, HSV-1 and -2, human immunodeficiency virus (HIV) 1, hepatitis C virus (HCV), and prions.

Bleach eliminates a broad spectrum of microorganisms by rapidly oxidizing cell membranes and denaturing proteins, without leaving a toxic residue. The *OTA* found that a bleach soak is the only method that consistently inactivates adenovirus and HSV—though it may be more troublesome to use than alcohol or hydrogen peroxide.



SLIT-LAMP MICROGRAPHS. *(1) An undamaged tonometer prism and (2, 3) tonometer prisms that have been damaged over time. Cracks formed in the prism can cause corneal abrasions and may harbor microorganisms or residual disinfectant.*

Although no case of Creutzfeldt-Jakob disease has been linked to GAT, prions are extremely resistant to disinfection, and the incubation period between exposure and observable illness can be several decades. Practitioners should consider using dispos-

BY JENNIFER S. GRIFFIN, MS, CONTRIBUTING WRITER, INTERVIEWING **ANNA K. JUNK, MD, TERESA C. CHEN, MD,** AND **NIKHIL S. CHOUDHARI, DNB.**

able tip covers or single-use prisms if evaluating a patient with suspected or confirmed prion disease, according to the *OTA*. However, the risk of prion disease transmission is thought to be extremely low, said Dr. Junk, emphasizing that when you are disinfecting the tonometer prism, "the concerns should be adenovirus and HSV."

Adenovirus is a causative agent of acute follicular conjunctivitis and epidemic keratoconjunctivitis. And the adenovirus particle is extremely hardy: Desiccated virus can remain viable on surfaces for well over a month, and disinfection with 70% isopropyl alcohol or 3% hydrogen peroxide does not reliably destroy infectivity.[1]

Safe, aseptic applanation. "The perfect disinfectant would kill viruses commonly involved in infectious outbreaks but would not damage the tonometer tip," said Dr. Chen. "There isn't a perfect disinfectant," she continued, "but diluted bleach inactivates the most commonly involved viruses, and proper disinfection technique can minimize damage to tonometer tips." The duration of the soak is important. A soak for less than 5 minutes may not inactivate contaminating microbes, and a longer soak is more likely to damage the tonometer tip.

Checking for damage. The *OTA* panel determined that all disinfectants "have been identified as causing tonometer prism damage and may result in patient injury."[1,5] According to Dr. Junk, over multiple disinfection cycles, the disinfectant may dissolve the glue holding the hollow tip together, causing cracks to form along the rim. These cracks can irritate the cornea and may harbor microorganisms, and the cracked hollow tip can retain disinfectant that could leak out during subsequent applanation. Dr. Junk advised inspecting reusable tips for integrity "under the slit-lamp microscope, every time before use."

When to discard. Haag-Streit, a manufacturer of tonometer tips, recommends that any reusable tip be discarded 2 years after the first use.[6] Dr. Junk noted that all prisms also have "an expiration date after which the tip should be discarded, regardless of the duration of use. Monitoring these dates can be very challenging logistically, especially in a teaching institution."

Reusable Versus Disposable

As an alternative to reusable prisms, practitioners can applanate with disposable prisms (e.g., Tonosafe, Haag-Streit; Tonomate, Keeler). The choice of tip may be based on personal preference, results of cost-benefit analyses, or concerns about disease transmission. In general, researchers have observed a "gradual but definite shift to the use of disposable prisms worldwide."[7]

Dr. Chen said that many physicians continue to utilize reusable tips for 2 reasons: 1) single-use tips can be cost-prohibitive [Tonosafe and Tonomate are more than $1/prism], and 2) "some physicians are uncertain whether the disposable tips have the same accuracy as the reusable tips."

Cost comparison. In a cost-benefit analysis of reusable versus disposable prisms conducted nationally in the United Kingdom, Jasani et al.[7] noted substantial savings (£2 million annually) with reusable GAT prisms. (However, the authors did not account for the added costs and time associated with disinfecting tonometer tips.) Tsai et al.[8] found that Tonosafe prisms were approximately 8-fold more costly than reusable prisms.

At Veterans' Affairs Medical Centers nationally, Dr. Junk explained that implementation of CDC guidelines[4] involved either transitioning to disposable tips or submitting used reusable tips to a central sterilization unit. "We were looking at purchasing roughly 1,000 reusable tips to make sure we would not run out given a 2-day turnaround for sterilization. We chose disposable tips." She also noted that disposable tips are a mainstay among glaucoma faculty at Bascom Palmer.

Accuracy differences? In a study of 326 patients at general and specialty eye care clinics, IOP measurements of Tonosafe disposable prisms and GAT with reusable prisms were found to correlate closely, and repeated measurement variability was similar for the 2 modalities.[9] In a prospective study of 100 patients with glaucoma, Tsai et al.[8] demonstrated good correlation in IOP results between Tonosafe and reusable GAT prisms.

Safety differences? Sterile, single-use tips have the obvious safety benefit of minimizing disease transmission between patients due to insufficient disinfection. Nonetheless, caution should be exercised even when applanating with a disposable prism. In an assessment of Tonosafe prism use at the Sussex Eye Hospital (United Kingdom), 16 of 35 questionnaire respondents admitted to touching the applanating face of the disposable prism prior to use, and *Staphylococcus epidermidis* and *S. aureus* were cultured from briefly touched prisms.[10] This occurred despite respondents indicating that the reusable prisms were easier to handle and were unlikely to be touched on the applanating face during preparation.[10]

Handheld Tonometry Devices

Handheld tonometers include the Tono-Pen XL and Tono-Pen Avia (Reichert) and iCare devices. Cross-contamination and transmission of infectious disease are less of a concern because these tonometers are supplied with single-use tip covers (Ocu-Film, Reichert) or with disposable probe tips (iCare). The iCare does not require calibration.[1] And the Tono-Pen Avia requires no regular calibration.[2] Dr. Choudhari noted that calibration checks with the Tono-Pen XL are only needed before the first use of the day and when indicated by the instrument display. A common source of inaccurate readings is debris in the handheld tonometer tip.

1 http://icare-usa.com.

2 www.reichert.com/products.

Calibrating the Tonometer

In GAT, calibration error (CE) typically is assessed at 0, 20, and 60 mm Hg, but widely accepted guidelines on CE check frequency are lacking, said Nikhil S. Choudhari, DNB, at the VST Glaucoma Centre of L.V. Prasad Eye Institute in Hyderabad, India.

Acceptable level of error. Dr. Choudhari and colleagues assessed 132 GATs at their institution and found only 4% compliance with manufacturer-recommended CE tolerance for GAT at 20 mm Hg, even though their bioengineering department performs annual servicing and recalibration on the devices.[11] However, Dr. Choudhari noted that manufacturer limits are stringent in a clinical sense and may actually represent an industrial (ISO) convention. The levels of acceptable CE set by the World Glaucoma Association (WGA) and the Asia Pacific Glaucoma Society (APGS) are more likely to be achievable in clinical practice. The WGA recommendation is within ± 1 mm Hg at all testing levels, and the APGS guideline is within ± 2 mm Hg at 0 mm Hg, ± 3 mm Hg at 20 mm Hg, and ± 4 mm Hg at 60 mm Hg.[11]

"I am of the opinion that the acceptable level of CE should depend on the severity of glaucoma," said Dr. Choudhari. "A wider range of CE might be acceptable in early to moderate glaucoma, but error in the measurement of IOP should be minimal in advanced disease." His practice generally applies a CE tolerance limit of ± 2 mm Hg.

Calibration frequency. In a study of 100 ophthalmology residents, 85 acknowledged that they never check the GAT for CE, and only 7 stated that they perform CE checks at the start of each clinical session.[2] Dr. Choudhari emphasized the importance of checking the GAT frequently for CE. He and others have found that as many as "20% of tonometers between 1 and 10 years of age and as many as 50% of tonometers more than 10 years of age can develop CE in a month."[12] Dr. Choudhari recommended that new tonometers be checked biannually in the first year. Tonometers more than 1 year old should be checked monthly.[12]

Dr. Choudhari and others have proposed a "screening approach" in which CE is determined frequently, but only at 0 mm Hg.[13] This is the testing level at which CE check weight bars are not involved. The screen can be performed quickly and easily on a weekly or even daily basis and had a good negative likelihood ratio of 0.11 when the less stringent APGS guideline was applied.[13] Dr. Choudhari asserted that this simplified approach "should not be used as a substitute for the monthly checks of CE with the weight bars, especially in the context of advanced glaucoma."

"Wipe the tonometer tip clean. Soak in 10% bleach for 5 minutes. Rinse with water, and let dry. Check for cracks every time before use with 16 × magnification on slit lamp." —Dr. Junk

Sources of error. GAT calibration can be affected by dust accumulation or fluctuations in humidity or temperature. Dr. Choudhari also noted, "The GAT is a balancing instrument, and any tilt in the surface on which the tonometer is mounted can cause errors in measurement of IOP." In addition, operator-related factors can increase the likelihood of CE, Dr. Choudhari explained. "For example, an inadvertent backward push on the tonometer tip during cleaning may cause wear to the spring mechanism."

Correcting the problem. Dr. Choudhari said that there are 2 ways to address CE in GAT. "If an instrument is found to have an unacceptable CE, the ophthalmologist should send the instrument to the manufacturer for repair." Alternatively, he and others have described a technique by which a bioengineer can address CE in-house. (View the video that accompanies this article at aao.org/eyenet.)

Best Practices

Dr. Junk gave the takeaway message for disinfection of the reusable prism after every patient: "Wipe the tonometer tip clean. Soak in 10% bleach for 5 minutes. Rinse with water, and let dry. Check for cracks every time before use with 16 × magnification on slit lamp."

Based on the current evidence, doing so—coupled with frequent calibration of the GAT—can improve patient safety and precision of IOP measurements at the slit lamp.

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Dr. Junk is associate professor of clinical ophthalmology at Bascom Palmer Eye Institute and Miami Veterans Affairs Medical Center, both in Miami. *Financial disclosures: None.*

EXTRA **MORE ONLINE.** To view an 8-minute video showing how to address calibration error, look for this Clinical Update at aao.org/eyenet.

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Management of Suprachoroidal Hemorrhage

Suprachoroidal hemorrhage (SCH) is a rare but potentially devastating complication of intraocular surgery. It is defined as the accumulation of blood within the potential space between the choroid and sclera, with the source of the blood being the long or short posterior ciliary artery.[1]

SCH occurs less commonly in association with modern techniques of cataract surgery than with glaucoma, vitreoretinal, and penetrating keratoplasty (PK) procedures. The extent of SCH ranges from localized, self-limiting hemorrhages to expulsion of intraocular contents. It is important to recognize this complication early and to manage it expediently.

Risk Factors

Factors that increase the risk for SCH include the following:

Systemic

- Advanced age
- Cardiovascular conditions, including hypertension and peripheral vascular disease
- Medications, including anticoagulation and antiplatelet agents and cardiovascular drugs

Ocular

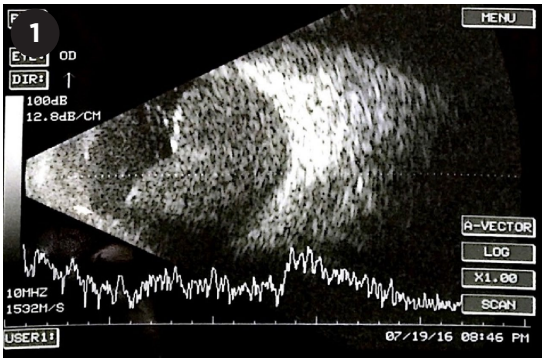
- High myopia
- Aphakia
- Glaucoma
- Elevated preoperative intraocular pressure (IOP)
- Previous intraocular surgery such as PK or vitrectomy

Intraoperative

- Retrobulbar anesthesia
- Failure to administer ocular compression to reduce IOP before and after retrobulbar anesthesia
- General anesthesia ("bucking" on tube)
- Posterior capsular rupture with vitreous loss
- Elective extracapsular cataract extraction (ECCE)
- Conversion from phacoemulsification to ECCE
- Longer duration of intraocular surgery

Postoperative

- Hypotony
- Valsalva maneuvers, including coughing and straining



RETINAL APPOSITION. *B-scan showing "kissing choroidals," a term that describes suprachoroidal hemorrhage with retinal apposition. The scan shows low to medium internal reflectivity, as it was made before the clots liquefied.*

Cataract Surgery

The incidence of SCH during cataract surgery has decreased with the evolution of newer techniques. These include the use of topical anesthesia instead of retrobulbar block and the adoption of smaller-incision surgery and self-sealing clear corneal incisions instead of ECCE, with its larger surgical wounds.

The estimated incidence of SCH during cataract surgery reported in the past 25 years is approximately 0.03% to 0.1%,[2-4] compared with earlier reports of up to 0.8%[1] with older techniques. The majority (up to 50%) of cataract surgery–related SCH occurs during phacoemulsification or nuclear expression or after removal of the nucleus.[4,5]

Signs. Intraoperative signs of SCH include the following:

- Anterior chamber shallowing
- Loss of the red reflex
- Increased IOP, with firming of the eye
- Wrinkling and bulging of the posterior capsule
- Extrusion of intraocular contents: spontaneous nuclear expression, iris prolapse, and vitreous prolapse

Glaucoma Surgery

The incidence of intraoperative SCH during incisional glaucoma surgery has been reported to be about 0.15%.[6] However, glaucoma surgery–related SCH is more likely to occur postoperatively, with an incidence ranging from 1.6% to 6.1%,[7,8] than intraoperatively.

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Laurence Lim, MBBS, MMed(Ophth), FRCOphth

The later onset is likely due to the possible occurrence of hypotony after glaucoma filtration surgery and postoperative inflammation.

Signs and symptoms. SCH in the postoperative period may include the following signs and symptoms:

- Severe eye pain
- Headache, nausea, and vomiting
- Decreased visual acuity
- Anterior chamber shallowing
- Loss of the red reflex
- Elevated IOP
- Prolapse of vitreous into the anterior chamber
- Choroidal elevation

Vitreoretinal Surgery

The incidence of intraoperative SCH during vitreoretinal surgery has been reported to range from 0.17%[9] to 1.9%.[10] Risk factors include rhegmatogenous retinal detachment, scleral buckle placement, and the presence of retained lens fragments.

In a 5-year retrospective study by Reibaldi and colleagues, SCH was reported to occur in 0.8% of patients during the postoperative period; and extensive intraoperative photocoagulation was identified as a risk factor.[11]

Penetrating Keratoplasty

Intraoperative SCH during PK can be attributed to the use of an open-sky technique, which leads to a longer period of intraocular hypotony. The reported incidence ranges from 0.09% to 1.08%.[12,13]

Preventive Measures

Preoperative steps to reduce the risk of SCH include controlling IOP and—in cooperation with the patient's other physicians—withholding anticoagulants or antiplatelet agents and managing comorbidities such as hypertension. Also, nonurgent intraocular surgery may be delayed in a patient who has a cough until it resolves.

If peribulbar or retrobulbar anesthesia is used, orbital compression helps to lower the IOP before starting the intraocular surgical procedure.

Postoperative hypotony should be avoided, especially with glaucoma filtration surgeries.

Intraoperative Management

Wound closure. Early detection of SCH is the first step in management. Prompt suture closure of surgical incisions is important to tamponade the bleeding vessels and prevent extrusion of intraocular contents. Prolapsed vitreous or nonviable iris tissue may need to be surgically excised to allow wound closure.

Deepening of the anterior chamber. The anterior chamber can be deepened by injecting either a viscoelastic agent or air into the anterior chamber after repositing any expulsed intraocular contents.

Surgical drainage. The creation of a posterior draining sclerotomy is controversial. Paradoxically, the elevated IOP resulting from SCH may have a tamponading effect against further bleeding, and this effect may be lost when the hemorrhage is drained.

Postoperative Management

Medical management. High IOP is managed with antiglaucoma medications. Topical or oral steroids may be used to control inflammation and promote clot liquefaction. Secondary pain can be managed with topical cycloplegics and oral analgesia.

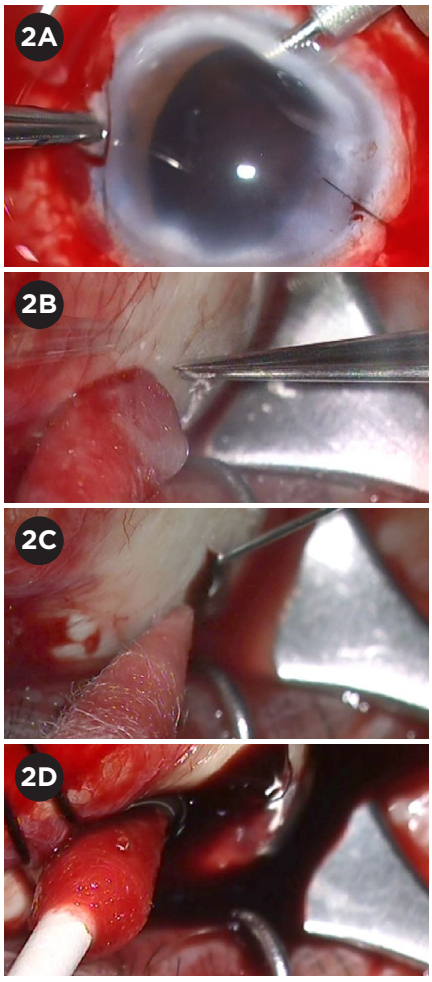
Secondary surgical drainage. Limited, nonappositional SCHs may not require surgical intervention. Rather, they may be observed, as spontaneous resolution may occur over a period of weeks to months.

Indications for surgical drainage include retinal apposition ("kissing choroidals," Fig. 1), uncontrolled IOP, flat anterior chamber, and rhegmatogenous retinal detachment. There is no consensus on the best timing for drainage. In most cases, drainage is performed when B-scan ultrasonography shows signs of clot liquefaction (usually in 7-14 days).

Surgical Techniques

The following techniques may be employed for secondary surgical drainage of SCH (Figs. 2A-2D).

Posterior draining sclerotomy. A 1- to 2-mm posterior draining sclerotomy is made 3 to 4 mm from the limbus in a radial fashion in the quadrant that contains the largest collection of blood (i.e., the highest point of SCH). Care is taken to place it anterior to the vortex veins. Clots that have not fully liquefied can also be evacuated from the sclerotomy with a cyclodialysis spatula.



DRAINAGE SURGERY. *(2A) Anterior chamber maintainer is used to avoid hypotony. (2B) Creation of a posterior sclerotomy. (2C) A needle is used to facilitate drainage of blood from the suprachoroidal space. (2D) Gentle pressure with a cotton-tipped applicator can help to express the blood.*

Increasing or maintaining IOP during drainage. IOP can be maintained by means of a limbal infusion, an anterior chamber maintainer, or a long pars plana infusion if the infusion tip can be visualized in the vitreous cavity (which may be difficult in eyes with apposed SCH). IOP is increased in a controlled fashion to allow for the extrusion of suprachoroidal blood through the sclerotomy.

Pars plana vitrectomy and clot removal. Vitrectomy is not commonly

Laurence Lim, MBBS, MMed(Ophth), FRCOphth

performed for the sole reason of draining the SCH, but it may be used if there is also associated rhegmatogenous retinal detachment or other conditions warranting intraocular surgery. Vitreous incarcerated in the wound can be excised externally.

Injection of heavy liquids. When necessary in selected cases, perfluorocarbon liquid (PFCL) can help to force blood from the suprachoroidal space out through the sclerotomy, allowing more complete removal of the blood. Subsequently, gas or oil may be exchanged for the PFCL to provide an internal tamponade to possibly reduce rebleeding into the suprachoroidal space.

Conclusion

SCH is a vision-threatening complication, and the guarded prognosis should be discussed with the patient and family. Prompt recognition and appropriate management may limit its consequences and provide a reasonable visual outcome for many patients.

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An Unusual Case of Left-Sided Vision Loss

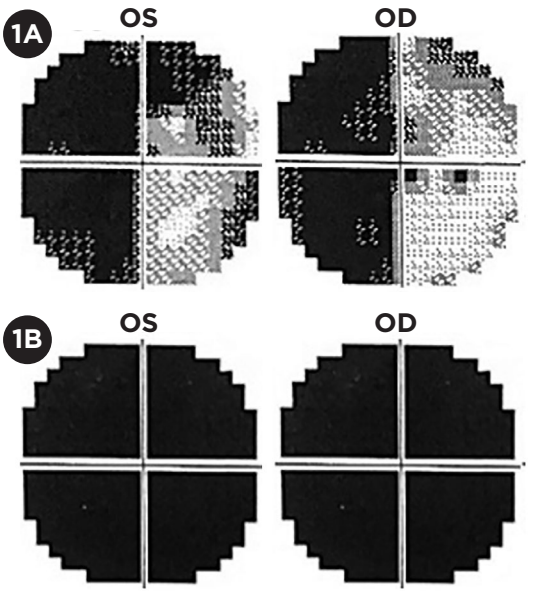
Janet Jenkins* was a witty and active 73-year-old woman, who regularly participated in sewing and enjoyed keeping up with friends and family. She first presented to her optometrist with the chief complaint of a 1-week history of a new green tint to her vision. She had a past medical history of well-controlled type 2 diabetes mellitus and essential hypertension.

Her optometrist informed her that her ocular examination was within normal limits, and her symptoms were likely due to an acute cerebrovascular accident (CVA). Mrs. Jenkins was instructed to follow up with her primary care physician, who ordered noncontrast computed tomography (CT) of the head. The results showed no acute intracranial abnormality, and she was referred to ophthalmology for further evaluation.

We Get a Look

One week later, Mrs. Jenkins presented to the general ophthalmology clinic complaining of new-onset difficulty with writing and worsening vision. Her best-corrected visual acuity at distance was 20/20 in both eyes. Intraocular pressure (IOP) as well as pupil size and reactions were within normal limits. Likewise, the anterior and posterior segment examinations were both within normal limits. However, confrontation visual fields demonstrated a possible left homonymous hemianopia. A subsequent 30-2 Humphrey visual field test confirmed a complete left homonymous hemianopia with an additional peripheral nasal defect in the left eye and a superotemporal defect in the right eye (Fig. 1A).

At that time, the differential diagnosis included acute CVA, atypical brain mass, inflammatory disorders, cerebral vasculitis, and autoimmune encephalopathy. An outpatient magnetic resonance image (MRI) of the brain without contrast, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) levels were ordered. All of the imaging studies and blood work were unremarkable.



FIELD LOSSES. *Humphrey visual field tests from the patient's 2 encounters. (1A) Visual fields from the first visit show a complete left homonymous hemianopia with additional superior nasal quadrant defects in the left eye (OS) and a superotemporal defect in the right eye (OD). (1B) Retesting 19 days later shows complete bilateral loss of vision.*

Follow-up Visit

Mrs. Jenkins returned 19 days later for a follow-up visit. Her husband stated that her personality had changed rapidly since the last appointment, and she had become increasingly confused.

During examination, her speech was dysarthric and dysphonic, with transient perseveration, irregular rhythm, and frequent pauses. She demonstrated dysarthric posturing of her upper extremities (see this article online for a video). Additionally, she exhibited significant startle myoclonus.

At that time, her visual acuity had decreased to light perception in both eyes. IOP, pupil size and reactions, and the anterior and posterior segment examinations remained within normal limits. A repeat 30-2 Humphrey visual field test showed complete bilateral vision loss (Fig. 1B). However, this study's reliability was questionable, given the patient's substantial decrease

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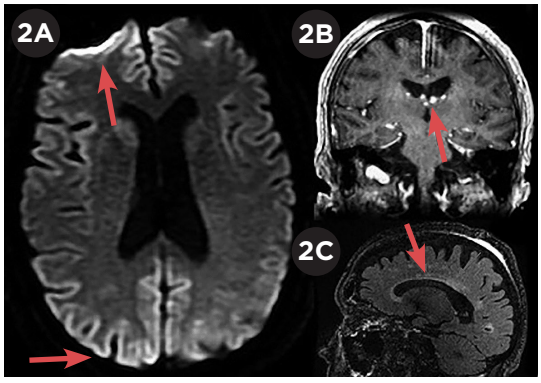
in visual acuity and mental status changes.

Further evaluation in the ED. Mrs. Jenkins was sent directly to the emergency department for further evaluation. A CT scan of the brain without contrast was unremarkable and stable from her previous study. Lumbar puncture was performed, which showed a normal opening pressure, cell count, protein level, glucose level, and white blood cell count. Cerebrospinal fluid (CSF) was sent for Gram stain, culture, and assessment of numerous infectious and immunological markers, all of which were unrevealing.



FLAIR FINDINGS. *MR images (FLAIR sequence) of Mrs. Jenkins, taken approximately 4 weeks after symptom onset. (2A) Image shows cortical hyperintensities, most prominent in the bilateral frontal lobes and the right occipital cortices. (2B) Enhancing ependymal nodular structures of unclear significance around the lateral ventricles. (2C) Scattered areas of white matter hyperintensity, most notable in the periventricular region.*

A comprehensive metabolic panel, blood culture, urine culture, complete blood count, ESR, CRP, urinalysis, thyroid-stimulating hormone with reflex thyroxine (T4), coagulation studies, and an arterial blood gas test were obtained. The findings were all unremarkable.

Differential diagnosis. Given the clinical course and extensive negative workup at that time, the updated differential diagnosis included conversion disorder, rapidly progressive dementia, immune-mediated encephalopathy, prion disease, and leptomeningeal carcinomatosis.

Hospital Stay

Mrs. Jenkins was initially admitted to the psychiatry ward but was transferred to the ICU when an electroencephalogram (EEG) revealed epileptiform discharges arising from the right temporal lobe. Numerous blood, CSF, and imaging studies were performed, none of which revealed a definitive diagnosis. Infectious, immunologic, and neoplastic processes were excluded.

Repeat MRIs with and without contrast, taken 7 days after admission, showed subtle heterogeneity of cortical diffusion on diffusion-weighted imaging (DWI) and fluid-attenuated inversion recovery (FLAIR), most prominent in the bilateral occipital and right frontal cortices (Fig. 2). A repeat EEG, performed the same day, showed independent bilateral left frontal and right frontal 1-Hz periodic lateralized epileptiform discharges with diphasic and triphasic morphology. Neurologically, her mental status continued to decline rapidly.

Making the Diagnosis

A repeat CSF analysis tested positive for 14-3-3 and neuron-specific enolase (NSE) protein. These CSF findings, along with the MRI and EEG results, rapidly progressive neurological decline, and prominent startle myoclonus, supported the diagnosis of Creutzfeldt-Jakob disease (CJD). Mrs. Jenkins continued to decline rapidly and passed away 53 days after symptom onset.

Discussion

CJD refers to a group of human transmissible spongiform encephalopathies (also known as prion diseases) that present as rapidly progressive neurodegenerative disorders. The presentation, and course of CJD are highly variable, but the disease is universally fatal.[1]

Pathophysiology. The pathophysiology of CJD is not fully understood, but it is related to deposition of misfolded prion proteins in the brain. Natural prion protein (PrP^{c}) is normally found in the synaptic cleft and becomes pathological only when mutated to its stereoisomer (PrP^{Sc}). The PrP^{Sc} protein is resistant to degeneration by proteases, resulting in accumulation and subsequent degradation of neuronal tissue. Additionally, PrP^{Sc} induces native prion protein mutation, creating a feedback loop that is self-sustaining and impossible to control (Fig. 3, online).[2-4]

Visual effects. The visual manifestations of CJD are highly variable. They include decreased visual acuity, visual hallucinations, homonymous visual field defects, cortical blindness, micropsia, macropsia, palinopsia, dyschromatopsia, metamorphopsia, and chromatopsia.[2-4]

A homonymous visual field defect, as in this case, is a common initial presentation of CJD and often leads to a misdiagnosis of an acute CVA. Other common misdiagnoses include primary optic disorders or neurodegenerative disorders such as Alzheimer disease or Lewy body dementia.[2,3]

Diagnostic considerations. CJD can be definitively diagnosed only by means of brain biopsy with standard neuropathologic techniques. "Probable CJD" can be diagnosed if the patient has rapidly progressive dementia and at least 2 of the following features: myoclonus, visual or cerebellar signs, pyramidal/extrapyramidal signs, and akinetic mutism. In addition, diagnosis requires a positive result on at least 1 of the following studies: atypical EEG (periodic sharp wave complexes) during an illness of any duration; a positive 14-3-3 CSF assay in patients with a disease duration of less than 2 years; or MRI high signal abnormalities in the caudate nucleus and/or putamen on DWI or FLAIR.[1]

The patient's husband declined a postmortem brain biopsy; however, her laboratory studies and clinical course met the criteria for "probable CJD."

Role of protein assay. The diagnostic utility of the CSF 14-3-3 protein assay is controversial, although it has acceptably high sensitivity and specificity within appropriate clinical contexts. A systematic review by Muayquil et al. reported a sensitivity of 92% and a specificity of 80% in diagnosing CJD.[5]

The utility of the 14-3-3 assay is limited by the pretest probability of CJD,

as assessed by patient demographics, clinical course, and results of ancillary testing. Thus, the practitioner's determination of pretest probability is essential, as the assay will be useful only in patients with a pretest probability of CJD between 20% and 90%.[5]

CJD subtypes. The mechanism of acquiring the PrP^{Sc} mutation can be sporadic, iatrogenic, or familial, with the most common subtype being sporadic.[1] Interestingly, iatrogenic CJD has been reported in association with both corneal transplants and tonometry.[6] CJD has also been linked to exposure to human brain products, dural grafts, dural electrode implants, and human growth hormone injections.[1] Our patient had no history of any such events related to her condition, making sporadic CJD most likely.

Variants. Sporadic CJD can be further divided into 2 subtypes: the Heidenhain and Oppenheimer-Brownell variants.[3] The former accounts for only approximately 3.7% to 4.9% of confirmed cases of sporadic CJD.[2]

The Heidenhain variant is associated with isolated visual symptoms at disease onset and rapid deterioration.[2-4] The mean length of time between initial symptoms and death for this variant is 5.7 months, compared to approximately 7.5 months among all patients with definitive sporadic CJD.[4] Mrs. Jenkins' precipitous decline and death 53 days after onset suggest that she had the rare Heidenhain variant.

Key Points for Clinicians

Keep CJD in mind. As ophthalmologists, we must keep CJD in the differential diagnosis for various ocular complaints when the initial workup does not reveal a more common etiology.

Recognize the risk of iatrogenic transmission. Moreover, although extremely uncommon, the iatrogenic spread of sporadic CJD via ophthalmic surgeries and examination techniques has been recorded in the literature. Specifically, while definitively confirmed in only a handful of cases, corneal allograft transplantations and tonometry have been linked to CJD cases.[6,7]

Additionally, there is a theoretical risk of iatrogenic spread of prion proteins during intraocular surgeries. In 2003, Head et al. demonstrated that PrP^{Sc} is found in similar concentrations to brain tissue in the neural retina, optic nerve, and retinal pigment epithelium in variant and sporadic CJD cases. Several cases have been reported of misdiagnosed sporadic CJD in patients who underwent ophthalmic surgery shortly after clinical onset. The subsequent use of reusable surgical instruments presented serious potential risk of the spread PrP^{Sc} to future patients. Importantly, standard sterilization technique does not adequately eliminate prion proteins from surgical instruments.[6,7]

The points discussed above highlight the importance—for all practicing ophthalmologists—of knowledge about this rare but devastating disease.

*The patient's name is fictitious.

1 Centers for Disease Control and Prevention. Creutzfeldt-Jacob Disease, Classic (CJD). www.cdc.gov/prions/cjd. Accessed March 6, 2018.

2 Baiardi S et al. *J Alzheimers Dis.* 2015;50(2):465-476.

3 Cornelius JR et al. *J Neuroimaging.* 2009;19(3):283-287.

4 Wong A et al. *J Clin Neurosci.* 2015;22(10):1688-1689.

5 Muayqil T et al. *Neurology.* 2012;79(14):1499-1506.

6 Hamaguchi T et al. *Neuropathology.* 2009;29(5):625-631.

7 Head MW et al. *Invest Ophthalmol Vis Sci.* 2003;44(1):342-346.

Mr. Holicki and **Mr. Sims** are third-year medical students at Michigan State University College of Osteopathic Medicine in East Lansing. **Dr. Gelinas** and **Dr. Sherman** are PGY1 residents who will begin ophthalmology residency at Ascension St. John Macomb-Oakland Hospital in Detroit in July 2018. **Dr. Holicki** is a general ophthalmologist at Holicki Eye Center in Coldwater, Michigan. **Dr. Kaufman** is the founding chair of the Department of Neurology at Sparrow Hospital and a professor and chair of the Department of Ophthalmology and Neurology at Michigan State University in East Lansing, Michigan. *Financial disclosures: None.*

EXTRA **MORE ONLINE.** See this article at aao.org/eyenet for a video of the patient and online Figure 3.

Inherited Retinal Disease
REDEFINING PATIENT CARE

The first gene therapy approved for a small subset of IRD patients puts the profession on the cusp of a new era in genetics. Peek inside an IRD clinic to learn whether, when, and how to do genetic testing.

By Annie Stuart, Contributing Writer

AT THE END OF 2017, THE U.S. FOOD and Drug Administration (FDA) approved Luxturna (voretigene neparvovec-rzyl), the first gene therapy for an inherited retinal disease (IRD). "Patients with Leber congenital amaurosis due to mutations in the *RPE65* gene now have hope that their progressive blindness can be arrested," said Alan E. Kimura, MD, MPH, at Colorado Retina Associates in Denver.

This step is remarkable, he said, not only for establishing the scientific principles of successful gene therapy, but also for attracting greater financial capital to develop subsequent marketable gene therapies for IRDs. But that's not all. It reveals what can be accomplished when previously fragmented silos of human activity integrate to achieve an aspirational goal, said Dr. Kimura. "And it likely heralds the dawn of a new role for ophthalmologists, working collaboratively to deliver care to people with inherited retinal diseases in our communities."

Common patient experience. To date, however, the experience of a patient with a rare disease such as an IRD has often been punishing, said Dr. Kimura. "They may end up seeing multiple doctors, receiving several misdiagnoses, and spending a lot of their own money for testing." But worse, he said, is getting to an ophthalmologist who lacks knowledge about IRDs and doesn't know where to refer the patient for a proper diagnostic evaluation. "Too many patients report, 'The doctor said I am going to go blind and walked out the exam room door.'"

Benign neglect? Misdiagnosis or mismanagement of these patients isn't intentional; instead, it's largely due to a lack of awareness in the ophthalmic community, said Christine N. Kay, MD, at Vitreoretinal Associates in Gainesville, Florida. "The field has grown so much in the last 10 years that doctors might not have the most up-to-date information to share with their patients."

Find the specialists. For MDs who don't know what to do for these patients, it's important to reach out to specialists who can pick the right tests, interpret the results, and answer patient questions, said Josie Kagey, a certified genetic counselor who worked with Dr. Kimura's practice until recently. "Patients need to be guided to physicians and genetic counselors experienced in treating IRDs."

First Step: Specialized IRD Testing

"I was born with nanophthalmos," said 20-year-old Seth Bynum, who was referred to Dr. Kimura's practice, Colorado Retina Associates, in the spring of 2017. "I've lived my whole life going to eye clinics, and I grew up accepting that," he said. "The best I've ever seen was close to 20/20 with

Alfred T. Kamajian

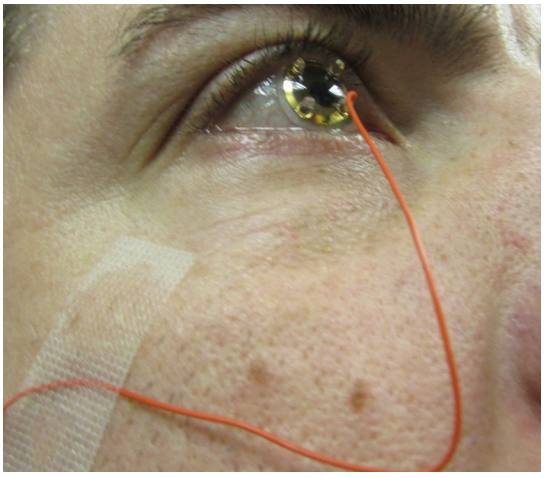
really strong corrective lenses. But recently, I was diagnosed with retinitis pigmentosa (RP) and am now at about 20/80."

First contact. Patients like Mr. Bynum first make contact with Colorado Retina Associates' ocular genetics coordinator, Andy Humes, who runs the eye lab, conducts specialized IRD testing, and helps facilitate genetic testing by sending out test kits and receiving results.

Because of the variety and rarity of IRDs, there's nothing "typical" about these patients. Diagnosis can be elusive. Some have subtle conditions previously masquerading as cobblestone degeneration or early macular degeneration, for example, so a diagnosis of IRD can come as quite a surprise, said Mr. Humes. "Before patients come in, I may spend 30 minutes to 3 hours talking with them on the phone, explaining some of the implications of testing." For example, test results will not legally affect employment.

Specialized IRD testing. Dr. Kimura emphasizes the importance of first confirming a phenotype to home in on the type of genetic testing needed. "Although it is expensive and used infrequently in most practices, specialized diagnostic equipment, including electroretinograms (ERGs) and full-field perimetry, is integral to establishing a good clinical diagnosis," he said. "For this reason, patients are often referred into regional testing centers across the country."

The Foundation Fighting Blindness (FFB) just designated Colorado Retina Associates as one of more than a dozen IRD testing sites across the country. FFB, as well as other offices or members of the community, refer about 50 new IRD patients annually to Colorado Retina Associates, which has seen IRD patients from 7 different states, said Mr. Humes.



ERG. *Electroretinography is one of the many specialized tests conducted at Colorado Retina Associates for patients with inherited retinal diseases.*

Patients are scheduled for time-consuming specialized tests a couple of weeks in advance of seeing Dr. Kimura for an exam. "Visual fields are important because retinal dystrophies present so differently," said Mr. Humes. "Monitoring whole retina function, ERGs provide a signal of the eye much like an EKG provides a signal of the heart." As it involves dilation, electrodes, gold-plated contact lenses, and bright lights, an ERG is no picnic for the patients, he added.

Other testing. "You can also use imaging and other tests, such as OCT (optical coherence tomography) and visual acuity, to give you clues that the cones are more involved," said John W. Kitchens, MD, at Retina Associates of Kentucky in Lexington. "As far as a rod-mediated process, autofluorescence and peripheral visual fields will help." Imaging is also incredibly helpful for patients and their families who may never have previously seen what their inherited retinal process looks like, he said.

Scheduling New Patients

The pace and rhythm of an IRD clinic is much different from that of a high-throughput clinic of established macular degeneration and diabetic patients.

The new IRD patients who are typically referred to Dr. Kitchens' practice often have a preexisting diagnosis of a hereditary cone or rod disorder. "That gives us the opportunity to schedule them at a time when I'll have more time to talk with them upfront. Last patient in the morning or last patient in the afternoon are good places for these patients, who may take 3 to 4 times as long as a patient with diabetic retinopathy or a macular hole, for example."

It can be challenging to break unexpected news to patients, who need different information and levels of support at different ages, said Mr. Humes. To allow undivided time for discussions like these, Dr. Kimura schedules his IRD patients into half-day clinics devoted exclusively to the needs of IRD patients.

Medical and family history. Dr. Kimura takes a medical history and performs a standard clinical eye exam. Then, said Ms. Kagey, "I would have my conversation with the patients. I start with a targeted family history, asking about siblings, children, and other family members." This information, she said, lets you "get a picture of where this patient is on his or her journey."

Building rapport along the way, Ms. Kagey begins to assess which patients need more education or support to grapple with a serious diagnosis. "There are so many places where these patients can fall out of the system—where they can get lost

Colorado Retina Associates

or misdirected—and so I think a key piece of a genetic counselor's work is being that safety net," she said.

Taking a thorough family history also helps better direct genetic testing and develop your differential, said Ms. Kagey. She cited the example of a patient who years earlier had pursued about $800 in testing for X-linked RP. "We drew his family tree and found male-to-male transmission of RP, which made it impossible for his RP to be X-linked. Helping him choose the right testing could have saved him a lot of money."

Genetic Testing—More Important Than Before

"In the past, we couldn't do much for patients with IRDs, so knowing a patient's genetic defect was more academic," said Dr. Kitchens. "Now we're entering an era where, although it's still limited, we're starting to have options that will undoubtedly grow in the future."

When Dr. Kimura first saw Mr. Bynum, he suspected that he had a rare form of RP due to his nanophthalmos, so he recommended genetic testing to confirm. "Within 4 months, Mr. Bynum had

What Gene Therapy May Mean for the Future

The FDA approval of Luxturna gives hope to patients with IRDs, said Dr. Kitchens. "If this is successful for a devastating condition such as *RPE65*-mediated blindness, then less severe conditions may respond even better."

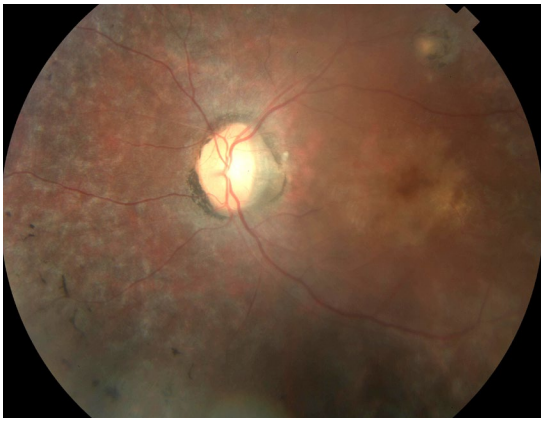
The data on Luxturna. Colleagues who participated in the Luxturna trials call this a game changer, said Dr. Kitchens. "Patients have a 200% to 300% improvement in their field of vision. This isn't just a marginal benefit—it's functionally relevant and life changing for patients."

Dr. Kay is personally calling all her patients with *RPE65* Leber congenital amaurosis (LCA) who don't have significant vision loss and advising them to get treated—and not wait for other trials. "Having delved into the 3-year follow-up data on Luxturna, I am convinced of both its safety and efficacy," she said.

Excitement mixed with realism. At the same time, Dr. Kay clarifies with other patients that only one FDA-approved gene therapy is currently available and that their likelihood of having this form of LCA is very low. The prevalence of *RPE65* mutation-associated retinal dystrophy is thought to be approximately 1/200,000.

Finding trials. When there's a strong suspicion of a genetic disease or a confirmed genetic diagnosis, Dr. Kitchens typically checks Clinicaltrials.gov to see whether any appropriate drug or gene therapy trials are available and then refers the patient for an evaluation. It's important to help patients discern which trials are not legitimate, added Ms. Kagey, especially those that require fees to participate. Dr. Kimura and staff have also found the FFB website and events to be a great source of information about trials.

Not a one-stop shop. Gene therapy is not an easy fix for all IRD problems, said Dr. Kay. "For example, with a prevalence of 1 in 4,000, RP is the most common type of inherited retinal dystrophy, but it is caused by hundreds of genes, so developing replacement-based gene therapies for all genetic forms of RP would be challenging. There's less we can offer these patients right now from a gene therapy standpoint."



LCA. *Luxturna, the new gene therapy for IRD patients with mutations in both copies of the* RPE65 *gene, holds hope for future IRD treatments.*

Other areas of research. However, optogenetics is an example of a therapeutic field that may someday be able to address multiple retinal conditions, even where significant visual loss has already occurred, said Dr. Kay. This form of treatment uses light and gene therapy but is not dependent upon a specific genotype, as it doesn't replace a missing or mutant gene. Optogenetics involves reprogramming healthy inner retinal cells to function like photoreceptors.

And, although human clinical trials are still in very early phases, the field of stem cell therapy holds some promise for the future, she said.

David Burley, CRA, Colorado Retina Associates

a molecular diagnosis and family genetic counseling," said Mr. Humes, "something that could have taken upward of 5 years and thousands of dollars in the past."

Who should be tested? After the initial testing and exam, it's important to equip patients with enough information to decide whether to do genetic testing. To prepare for prospective clinical trials and treatment, and to inform patients and subsequent generations about their risk of passing on the disease, Dr. Kimura strongly recommends genetic testing for most—if not all—of his IRD patients.

Dr. Kay does not think testing is mandatory for every patient with an IRD but recommends it for most patients. "I would say it absolutely is necessary for pediatric patients with a diagnosis of an IRD and anybody with an X-linked or autosomal dominant disease because of the importance of genetic counseling within families. It is also absolutely mandatory to perform genetic testing if the diagnosis is Leber congenital amaurosis or early onset retinitis pigmentosa, given the recent FDA approval of Luxturna for *RPE65*-associated retinal degeneration."

In addition, Dr. Kay recommends testing for anyone who may be a candidate for a current gene or drug clinical trial, such as patients suspected of having choroideremia, Stargardt disease, X-linked RP, X-linked retinoschisis, Usher syndrome, or achromatopsia.

The kids are all right? When a parent is diagnosed with an IRD, often their first question is, "Are my kids affected?" What follows is a discussion about whether to test seemingly unaffected minors, said Ms. Kagey. "Are they at a point in their lives where they have the capacity to process this information? Or should we wait until later? The general guideline is not to test unaffected minors." However, she said, a 16-year-old might

IRD Resources for Doctors and Patients

For doctors and patients who want to learn more, a wealth of information exists.

Education for clinicians. For each of the past several years, Dr. Kay has taught a course with several international and domestic faculty at the annual meetings of the Academy and the American Society of Retina Specialists. The instruction course provides information about IRDs, genetic testing, and gene therapy updates. In addition, Dr. Kay wrote a comprehensive overview titled "Logistics of Genetic Testing: An Overview for Retina Specialists" discussing the how-tos of genetic testing in a clinical setting.[1]

Genetic testing services. Commercial labs that offer comprehensive retina dystrophy panels, said Dr. Kay, include Baylor Genetics, Blueprint Genetics, GeneDx, Molecular Vision Lab, and PreventionGenetics. In addition, some universities and nonprofit labs, such as the Carver Nonprofit Genetic Testing Laboratory at the University of Iowa, offer testing.

Genetic counseling services. The website of the National Society of Genetic Counselors has a tool for finding genetic counselors in your area, said Ms. Kagey. "And online resources that provide telephone genetic counseling, such as InformedDNA, are good options for those who don't have local access to genetic counselors."

Registries. In addition to My Retina Tracker, the National Institute of Health's Genetic Testing Registry is a central location for providers to voluntarily submit information about genetic tests.

Other websites. A variety of websites, including the following, provide more insights about IRDs:

- NEI's **eyeGene** (The National Ophthalmic Disease Genotyping and Phenotyping Network) facilitates research into the causes and mechanisms of rare IRDs and works to accelerate development of treatments.
- **Foundation Fighting Blindness** was founded by families of loved ones with IRDs; today, it is the leading private funder of retinal disease research. To date, its support has helped researchers identify more than 250 genes linked to retinal disease and has helped launch 20 clinical trials.
- The **National Organization for Rare Disorders** is a patient advocacy organization dedicated to individuals with rare diseases and the organizations that serve them.
- **Online Mendelian Inheritance in Man** is an online catalog of human genes and genetic disorders, including IRDs with syndromic conditions.

Low vision resources. The Academy offers resources for physicians working with low vision patients at aao.org/low-vision-and-vision-rehab.

1 Kay C. *Retinal Physician.* 2017; 14:55-58.

benefit from testing, for example, because it might help direct career choices.

Advise and consent. As part of the consent process, it's important to infuse realism into the discussion and inform patients that not every test finds every mutation, said Ms. Kagey. "There are 20,000 genes in the human body, and we are only testing some of them. We don't always find an answer."

On the other hand, testing can spring surprises on everyone involved. "Years ago, we tested one gene at a time," said Ms. Kagey. "Now, with the advent of next-generation sequencing, we can sequence multiple genes on a chip and may uncover a gene we hadn't suspected—possibly one associated with a genetic syndrome." This means that, out of the blue, a patient could not only be grappling with an IRD diagnosis, but also be asked to undergo a scan to check for kidney involvement, she explained.

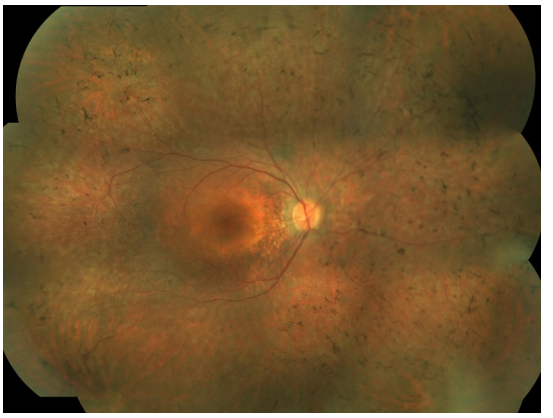
A tale of 2 sisters. Sometimes, however, the ability to do genetic testing can have strikingly positive consequences. Dr. Kitchens recounts meeting a 40-year-old patient with RP, who also had severe hearing loss but thought it was due to a viral infection she'd acquired as a child. While taking a family history, Dr. Kitchens learned that another sister was also blind and deaf. Genetic testing subsequently confirmed that both sisters had Usher syndrome. "Even though we couldn't do anything for the RP part of the syndrome," he said, "the sisters could get cochlear implants and hear again."

How to pay for genetic testing. First, you can help patients investigate whether there's a way to get genetic testing for free. The FFB is supporting genetic testing and counseling for ophthalmic practices that are members of the My Retina Tracker registry. "I am now able to offer these patients free, very accurate, grant-funded genetic testing typically with a 6-week turnaround," said Dr. Kay.

Today, a genetic panel of 180 to 250 genes costs somewhere between $1,500 and $2,500, said Ms. Kagey, but insurance coverage is "all over the map." Sometimes that cost is eaten up by huge deductibles, for example, or there's a 20% copay. "That's why finding a lab that works with the patient's insurance is so important," she said. "If necessary, you can follow up with a second lab that conducts testing utilizing a different methodology."

Who Counsels Patients?

"At Retina Associates of Kentucky, we do some of the rudimentary pretest counseling, draw the blood or collect saliva samples, and send samples out for testing," said Dr. Kitchens.



CAUSATION. *A classic case of retinitis pigmentosa caused by a mutation in the* PRPF31 *gene.*

In-house certified genetic counselor. With more than 250 genes implicated in inherited retinal dystrophies, the genetic landscape is vast, said Ms. Kagey. "When you run that many genes, you are going to get background noise. A certified genetic counselor helps patients sort through the ambiguity of genetic testing—explaining which genetic changes mean something and which may be disease-causing but are something we've never seen before."

Posttest counseling also helps patients navigate the emotional landscape of a molecular diagnosis, said Ms. Kagey. For example, parent studies can confirm the cause of the IRD, but results are often accompanied by guilt. "We help parents process these emotions," she said. "Having a space for families to voice these emotions is critical for adapting to a new diagnosis."

Physician input. Dr. Kay spends many evenings calling patients from home to counsel them about their genetic results. She describes the genetic components, the demographics of the disease, the prognosis, and whether a relevant clinical trial is available—offering to help patients navigate their options. "I tell my patients that they will also get ocular genetic testing through InformedDNA, which is an ocular genetic testing telecounseling service."

Local resources. Dr. Kitchens prefers having someone local do the genetic counseling. "We typically use the University of Kentucky, where they have a geneticist and genetic counselors on staff," he said.

In Denver, however, getting appointments with local genetic counselors is not as expeditious or easy for patients to access as online resources, said Mr. Humes. Now that Ms. Kagey is no longer working with Colorado Retina Associates, Dr. Kimura prefers making use of the services provided by InformedDNA.

Carissa Hurdstrom, CRA, Colorado Retina Associates

Patient Care in the Absence of Tx

Genetic testing isn't the end of the road. But without a treatment to offer, doctors tend to pull away from patients, said Dr. Kimura. Yet, there is much that physicians can do to help, he said.

Low vision resources. Of course, low vision resources are an important part of the continuum of care. Mr. Bynum's vision has changed for the worse recently, said Mr. Humes, so he's at a point in his life where these services can be of great use. (The Academy offers low vision resources at aao.org/low-vision-and-vision-rehab.)

Social services. Dr. Kimura has also integrated social services into the traditional clinical model of care, and he said that patients seem to find it very valuable, although not currently reimbursable. "These services can help patients manage a range of challenges, from school to driving, employment, family, and concerns about risks to the next generation."

Local services. Helping patients find local resources where they can connect with others like them is also invaluable, said Mr. Humes. "These patients often form a close-knit community, taking advantage of social events and peer-to-peer counseling." Mr. Humes recently referred a longtime IRD patient to a newly diagnosed patient, who found the connection quite helpful. Likewise, Mr. Bynum was inspired after he met another person born with RP who was able to navigate working in an office.

One of Dr. Kimura's patients is exploring an entrepreneurial idea to create a rideshare service similar to Lyft and Uber but specifically tailored for the blind. Mr. Bynum expressed excitement about the prospects of a service like this because he voluntarily stopped driving due to the risks. But it's taken a toll. "Transportation and freedom are big things to learn to let go of," he said, adding that he also lost his job (which involved climbing telephone poles) due to hazards related to his vision loss.

Data registries. Registries are another helpful aspect of care. Hosted by the FFB, My Retina Tracker empowers patients who have their genetic information, said Ms. Kagey.

Online data registries like My Retina Tracker are a platform for patients to voluntarily and securely share their genetic information, making it easier for qualified researchers to find patients with a given IRD and known molecular diagnosis, said Dr. Kimura. "From this enriched pool of patients with an accurate diagnosis of a specific molecular defect, scientists and clinicians can work together to drive toward the next gene therapy," said Dr. Kimura.

Mr. Bynum said that being on My Retina Tracker has taken a weight off his shoulders. "You'll always have the feeling that if a clinical trial starts up, you'll be considered for participation because you're right where all the doctors are looking."

MEET THE EXPERTS

SETH BYNUM Patient at Colorado Retina Associates in Denver. *Relevant financial disclosures: None.*

ANDY HUMES Ocular genetics coordinator at Colorado Retina Associates in Denver. *Relevant financial disclosures: None.*

JOSIE KAGEY Certified genetic counselor formerly with Colorado Retina Associates in Denver. *Relevant financial disclosures: None.*

CHRISTINE N. KAY, MD Vitreoretinal specialist at Vitreoretinal Associates in Gainesville, Fla. *Relevant financial disclosures: Spark Therapeutics: C; AGTC: S; Foundation Fighting Blindness: S.*

JOHN W. KITCHENS, MD Vitreoretinal specialist at Retina Associates of Kentucky in Lexington. *Relevant financial disclosures: None.*

ALAN E. KIMURA, MD, MPH Vitreoretinal specialist at Colorado Retina Associates and clinical associate professor of ophthalmology at the University of Colorado Health Sciences Center, both in Denver. *Relevant financial disclosures: None.*

See financial disclosure key, page 8. **For full disclosures,** view this article at aao.org/eyenet.

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How to Code for Glaucoma Procedures in the Anterior Chamber Angle

What does gonioscopy-assisted transluminal trabeculotomy (GATT) using a suture or iTrack microcatheter (Ellex) have in common with procedures that use the Kahook Dual Blade (New World Medical), Trab360 (Sight Sciences), or Trabectome (NeoMedix)? Per the Academy Health Policy Committee, these ab interno trabeculotomy (also known as goniotomy) techniques can be billed using CPT code 65820.

CPT Code 65820: Goniotomy

Code description. Trabecular meshwork is incised and/or excised with a blade or other tool for at least several clock hours to create an opening of Schlemm's canal into the anterior chamber. The approach is internal via a corneal incision into the anterior chamber.

Rationale. These new tools and approaches enhance our ability to perform canal-based procedures by allowing better egress of aqueous out of the eye through the physiologic outflow system of collector channels, thereby lowering intraocular pressure (IOP).

Coding clues. Keep in mind the following:

- Goniotomy should not be coded in addition to other angle surgeries or canal implants.
- Goniotomy treats congenital glaucoma and adult open-angle glaucomas.
- If using an ophthalmic endoscope, you can bill 66990 as well as 65820.
- Payment is per eye.
- For Medicare Part B patients, when surgery is performed bilaterally, submit a 1-line item with modifier –50 (bilateral procedure) appended to the surgical code, per the Medically Unlikely Edits (MUEs) that became effective on April 1, 2013. Place a "1" in the unit field and double the charge.
- This procedure does not qualify for coverage for team surgery, cosurgery, or an assistant-at-surgery.

Reimbursement rates. The national averages are as follows:

Surgeon allowable: $768.59

Ambulatory surgery center (ASC) allowable: $1,772.23

Hospital outpatient allowable: $3,610

It is a major surgery. This means that it has a 90-day global period under Medicare Part B, though that might not be the case for commercial and Medicaid plans.

CCI Bundling

The Correct Coding Initiative (CCI) lists pairs of codes—known as bundled codes or CCI edits—that should not be billed separately when services are performed by the same physician on the same eye on the same day.

Some pairs can be unbundled; others are mutually exclusive. Under certain circumstances, some of those CCI edits can be paid separately if you indicate to the payer (by appending a modifier code) that those circumstances apply. This process is known as unbundling.

Dozens of codes are bundled with 65820, but some can be unbundled. The main ones to watch for are 65800, 65810, 65815, 66020, 66030, 67250, and 67500. For a longer list, see this article online.

Bundled with 65820, and can never be billed separately. 99149, 99150, 99155, 99156, 99157, 99446, 99447, 99448, 99449, 99495, and 99496.

65820 is bundled with the following codes but can be unbundled.

65850 *Trabeculectomy ab externo*

65855 *Trabeculoplasty by laser surgery*

66711 *Ciliary body destruction; cyclophotocoagulation, endoscopic*

Coding for ABiC and Visco360

ABiC and Visco360 are used in ab interno procedures. They viscodilate Schlemm's canal for at least several clock hours, without creating a goniotomy.

Use CPT code 66174 *Transluminal dilation of aqueous outflow canal; without retention of device or stent.*

This should not be coded in addition to any other angle procedure or canal implant.

BY **CYNTHIA MATTOX, MD,** ASSOCIATE PROFESSOR OF OPHTHALMOLOGY, TUFTS UNIVERSITY SCHOOL OF MEDICINE, AND **SUE VICCHRILLI, COT, OCS, OCSR,** ACADEMY DIRECTOR OF CODING AND REIMBURSEMENT.

EXTRA **MORE ONLINE.** For more listings and a case scenario, see this article at aao.org/eyenet.

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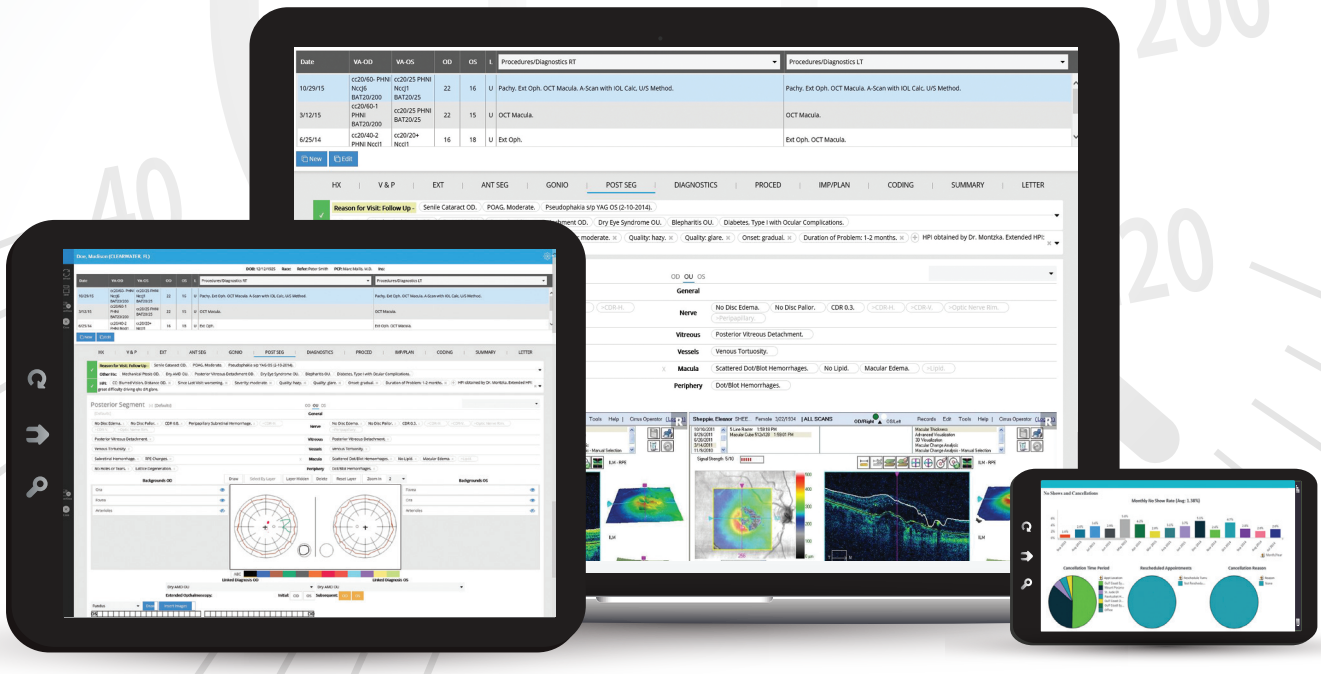

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EHRs: Improve Data Accuracy to Avoid Compliance Pitfalls

Whether you are working with electronic health records (EHRs) or paper charts, accurate data entry is essential for good patient care. In addition, the integrity of these data is mandatory for meeting federal compliance requirements. Although electronic records can substantially improve documentation accuracy compared with paper charts, it is also easy to inadvertently create errors that may then be repeated throughout a patient's record.

Here are some common mistakes that can lead to erroneous entries in an EHR system—and what you can do to avoid them and improve compliance and data integrity.

Avoid EHR Pitfalls

Fine-tune preference lists. Drop-down menus of commonly prescribed medications or frequently used diagnoses help facilitate completion of the record. Although these preference lists can expedite a patient encounter, they can also pose problems. Mistakes may occur if you choose quickly from the list without verifying your entry.

For example, said Michele Lim, MD, at the University of California, Davis, Eye Center, "We frequently order the antibiotic eyedrop ofloxacin, which is a medication that is also routinely prescribed for ear infections. The way our drop-down list was created, ofloxacin eardrops come first, which increases the likelihood of selecting the incorrect medication."

To avoid confusion, she recommends that you logically organize your system's preference lists and drop-down menus, putting the most commonly used medications at the top of the list and excluding unnecessary items.

Use care when copying data. The ability to copy patient data forward from a previous encounter to the current exam can save time. David Silverstone, MD, at the Yale School of Medicine, said, "It is a handy tool because when you copy something forward and then modify it, 1) you do not have to re-create the entire description, and 2) you are reminded of everything you previously observed." Although this makes it less likely that you'll overlook something important, he noted that this feature should be used with caution.

Modify templates as needed. Similar concerns were expressed by AAOE EHR committee chair Joy Woodke, COE, OCS, at Oregon Eye Consultants, in Eugene. It can be so effortless to navigate an EHR's built-in templates that there may be a tendency to copy information without thoroughly reviewing it and verifying the accuracy. As a result, potential medical issues may be missed.

"One way to avoid this pitfall is to design the templates in a way that prompts users to verify information before it can be saved," she said. For example, rather than simply being copied forward, the prior information could be displayed, but the user would be required to enter it or check off boxes to confirm it. She suggested modifying templates to include an extra step to help ensure that the data being documented for the encounter are current.

Don't let the template tell the whole story. EHRs offer various ways to import information within templates. A typical example is a brief boilerplate paragraph summarizing topics commonly discussed with patients. Some are more detailed than others (e.g., consent for cataract surgery), and they may contain elements that were not actually performed during a specific encounter.

"When we first embarked on EHR use, we all thought that documentation would be so much better and faster because we can import these templates," said Dr. Lim. But now she advises clinicians that "typing out one free-text sentence of what actually occurred, and was discussed with a patient, is worth an entire paragraph of a beautifully written template that includes information that did not really happen." She emphasized the importance of careful editing when using templates that include prewritten text.

Document what was done. Leaving out key details of an encounter results in an incomplete record. Nonetheless, said Dr. Silverstone, "It is easy to inadvertently omit a vital piece of information when conducting an exam because you are often multitasking." When you later look back at the record, you know

BY LESLIE BURLING-PHILLIPS, INTERVIEWING **MICHELE LIM, MD, DAVID SILVERSTONE, MD,** AND **JOY WOODKE, COE, OCS.**

that a particular task was performed because it is an integral part of your regular routine, he said. But if it was not actually documented in the record, you cannot prove it. Such an omission "can potentially pose a multitude of problems with patient care, billing, meeting compliance requirements, and possible litigation," he said.

Dr. Silverstone related a recent experience: "I was scheduled to operate on a woman who had just been seen by her internist for a thorough preoperative physical." According to the patient, the internist had listened to her heart and lungs. "However, this information was not documented in her record, so it had to be repeated prior to surgery."

Ms. Woodke said, "Whether you are conducting an exam, responding to a patient's phone call, or consulting with another physician, all the pertinent information should be recorded during a patient encounter and reviewed before the record is signed by the physician." She warned that if something doesn't appear in the chart, the auditors will presume that it hasn't been done.

But beware of overdocumentation. On the other hand, EHRs are so efficient and thorough that it may be tempting to populate every single field within your template. Before doing so, said Ms. Woodke, ask yourself, "Is it medically necessary today, in this exam, to document all of these fields?" She added, "Embrace the functionality, but always provide checks and balances. Most importantly, always keep in mind what is medically necessary. If these elements are met, we should feel comfortable that we are not over- or undercoding and that our documentation is accurate."

Be Proactive

Conduct regular internal audits and train your staff. Every practice, no matter the size, should have a compliance protocol in place and should also conduct periodic internal audits to identify errors within its records. Ms. Woodke recommended performing quarterly audits, which are followed by staff education and training.

"There are reports that you can run to identify missing data. These quality control measures should be constantly monitored so you can quickly detect any anomalies. Any time you see a change in documentation, it should be an immediate cue for a review." She also suggested regularly reviewing—weekly or monthly—chart documentation procedures and compliance requirements with staff.

"Practices should also provide education and training to end users when specific problems arise or when new services are offered, or for unique cases that are not frequently documented. Consistently accurate documentation all boils down to good training and education for every person who touches the system," she said.

Maintain a compliance folder. Everyone makes mistakes. It is important to note, however, that a mistake is much different from intentional fraud. Ms. Woodke said, "We want to ensure that anyone auditing our charts can quickly differentiate the two.

"One way to do that is to implement clinical protocols that document how our chart records should and should not be recorded. Education and training should also be recorded so that when an error is identified, you can instantly prove how and when training occurred." All of this goes into a compliance folder that provides your practice with another layer of protection, she said. "The more that we document our policies, procedures, and education, the more we are protected."

Best Practices for Data Integrity in EHRs[1]

- Learn your EHR system.
- Establish rules and policies for entering data into a medical record.
- Ensure that the EHR has an auditing function to monitor who enters and modifies data.
- Document what you do and only what you do. The note should reflect your thought processes.
- Use shortcuts carefully. Review and edit final notes.
- Never copy from one patient's chart to another.
- Avoid including data that are irrelevant to the current exam, especially notes created during previous encounters with the patient.
- At the end of an exam, review the data, sign the note, and lock the note so changes cannot be made by others.

1 Silverstone DE et al. Electronic Health Records: Compliance and Medicolegal Issues. Presented at: AAO 2017; Nov. 12, 2017; Las Vegas.

Dr. Lim is professor of ophthalmology, vice chair, and medical director at University of California, Davis Eye Center. **Dr. Silverstone** is a clinical professor of ophthalmology at Yale Medical School, in New Haven, Conn. **Ms. Woodke** is the administrator at Oregon Eye Consultants in Eugene. *Financial disclosures: None.*

Academy Notebook

NEWS • TIPS • RESOURCES

PASSAGES

Dr. Hutchinson, Founding Chairman of EyeCare America, Passes Away

B. Thomas Hutchinson, MD, founding Chairman of EyeCare America, passed away on April 10. He was 84.

Dr. Hutchinson is best known for his role in establishing EyeCare America (ECA), a public service program of the Academy's Foundation that provides eye care through a pool of nearly 6,000 volunteers. ECA is the largest medical public service program in America and has helped more than 1.8 million people.

Dr. Hutchinson was heavily involved in ophthalmic organizations. For the Academy, he served as President in 1993, Chair of the Foundation's Advisory Board, and Senior Secretary of Ophthalmic Practice. Other positions included Associate Clinical Professor at Harvard, founding partner of Ophthalmic Consultants of Boston, Chair of the American Board of Ophthalmology, Director of the Ophthalmic Mutual Insurance Company, President of the New England Ophthalmological Society, President of the Chandler Grant Glaucoma Society, and many others.

Dr. Hutchinson received numerous awards, including the Academy's Senior Honor Award, and he was a Guest of Honor at the Academy's 100th annual meeting. Other honors include Man of the Year in 1998 from the New England Ophthalmological Society, a Man of Vision award from Prevent Blindness America-Massachusetts in 2001, and the Howe Medal from the Buffalo Ophthalmology Society.

DR. HUTCHINSON. *Visit the Museum of Vision's Oral Histories to listen to or read a conversation between Dr. Hutchinson and Richard P. Mills, MD, MPH. Go to aao.org/oral-histories and click "Hutchinson, B. Thomas, MD."*

Dr. Hutchinson was a visiting professor at multiple universities and medical centers in the United States and internationally. For more than 30 years, he maintained an active role in the teaching of medical students, residents, and fellows in ophthalmology.

"Tom always placed his patients first, was deeply concerned about ethical issues and public service, and retained a passion for his chosen profession of ophthalmology," said **David. W. Parke II, MD,** Academy CEO. "We will all miss him."

The Academy has established the B. Thomas Hutchinson, MD Fund in support of ECA and public service programs of the American Academy of Ophthalmology in his memory. To make a memorial tribute gift, please visit aao.org/foundation/donate and select "The Hutchinson Fund."

TAKE NOTICE

MIPS via the IRIS Registry: June 1 Deadline to Sign Up for EHR-Based Reporting

The IRIS Registry can streamline your reporting for the Merit-Based Incentive Payment System (MIPS) as long as you meet the deadlines.

Report quality measures using automated data extraction. The least burdensome way to report MIPS quality measures is to integrate your electronic health record (EHR) system with the IRIS Registry.

June 1 deadline for getting started with IRIS Registry/EHR integration. If you haven't yet integrated your EHR system with the IRIS Registry, you must sign up by June 1 and complete the integration process by Aug. 1.

The IRIS Registry is a 1-stop shop for MIPS reporting. You also can use the IRIS Registry web portal to manually attest to advancing care information (ACI) measures and improvement activities, and—if you aren't able to report quality via IRIS Registry/EHR integration—manually enter data for quality measures. If you are new to the IRIS Registry, you will need to sign up for manual reporting by Oct. 31.

For more information on using the

Academy's IRIS Registry for MIPS, go to aao.org/iris-registry/medicare-reporting.

Ask the Ethicist: Cell Phone Use and Professionalism

Q: *An on-call ophthalmologist used a personal cell phone to document a patient's facial wound involving the medial canthus after a motor vehicle accident. Seeking advice for closing this complicated wound, the ophthalmologist sent patient photos, including close-ups of the lacrimal area, to an oculofacial colleague for a second opinion. Later that evening, his daughter was playing with the phone and uploaded these "super gross" photos to Facebook to share with her friends. Without a doubt, allowing his daughter access to these photos on his phone was a mistake, but is the request for a colleague's opinion in the manner noted problematic?*

A: Depending on how much of the patient's face was revealed in the photographs and whether any other identifying information was available to the recipients, both instances could be considered a breach of confidentiality. Even if you do not include the patient's name, any information that allows others in the community to identify the patient is too much. Examples include sex, age, dates, location, time frame, unique identifying numbers, and sometimes even the diagnosis. It could be considered an unauthorized disclosure, or breach, of personal health information (PHI).

It is common for health care providers to communicate with patients and colleagues using mobile devices or to access/relay PHI to others using mobile devices. The unauthorized disclosure of PHI is a big risk when using such devices because they are portable, unlikely to be password-protected or encrypted, and likely to connect with Wi-Fi (further risking interception), and they can be easily lost or stolen.

Physicians should approach social media, email, and text messages in the same way they approach conversations in hospital elevators: Don't discuss confidential patient information in a public setting, whether physical or virtual. When using social media, those who post information should safeguard confidential health information consistent with the law.

For more information, visit aao.org/ethics-detail/advisory-opinion-social-media-professionalism.

D.C. REPORT

Telemedicine Information Statement

The Academy Board of Trustees approved a new information statement on telemedicine, formalizing a groundbreaking assessment of the technology landscape and how ophthalmologists are using it to provide quality patient care. The statement eschews formal recommendations from the Academy's health policy committee; instead, it outlines where technology's influence in eye care is growing. In some cases, it settles long-standing arguments about the effectiveness of teleophthalmology for the diagnosis of some ailments. This is especially true with regard to retinopathy of prematurity and diabetic retinopathy. This statement will be used as a baseline for future recommendations and to identify areas of opportunity for our profession.

Telemedicine is emerging in various sectors. For example, numerous states consider online refraction to be a means for expanding patient access to care. In addition, the Academy is a vocal supporter of the successful Technology-Based Eye Care Services program launched by the U.S. Department of Veterans Affairs. The program involves technicians in primary care clinics who gather data following an eye screening protocol. It has expanded access to screenings, especially in rural areas, for cataract, glaucoma, and other diseases.

To read the statement, visit aao.org/clinical-statement/telemedicine-ophthalmology-information-statement.

MEMBERS AT LARGE

Dr. Huang Receives 2018 Jose Rizal International Medal

On Feb. 8 at the Asia-Pacific Academy of Ophthalmology's (APAO) 31st Congress in Hong Kong, the APAO awarded **Suber S. Huang, MD, MBA,** the Jose Rizal International Medal. This medal commemorates Dr. Jose Rizal, a hero of the Philippines. It recognizes exceptional contributions to ophthalmology in the Asia-Pacific region.

Dr. Maa Receives 2018 Wolcott Award

On March 27, **April Maa, MD,** received the Wolcott Award from the U.S. Department of Veterans Affairs. The Wolcott Award program is named after Mark Wolcott, MD, who dedicated more than 40 years of his life to serving and improving the quality of health care for the Veterans Health Administration's (VHA) veteran population. It recognizes outstanding VHA health care practitioners who are deserving of special recognition for their contributions in enhancing clinical care.

Dr. Stein Receives 2018 Pisart Award

On March 14, Lighthouse Guild announced **Joshua D. Stein, MD, MS,** as the recipient of its 2018 Pisart Award. The Pisart Award recognizes an early career clinician or scientist whose contributions have the potential for substantial influence in the understanding of vision loss, treatment of eye disease, or the rehabilitation of people with vision loss. Dr. Stein will receive a $32,000 prize at Lighthouse Guild's annual Alfred W. Bressler Vision Science Symposium in the fall.

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MEGHA AGRAWAL, MD
GARLAND, TEXAS

The Academy's **EyeCare America**® program helps medically underserved older Americans receive the care they need to see the world and flourish. It's one of the most successful public service programs in American medicine, having helped nearly 2 million people nationwide. As a volunteer, you can make a meaningful difference in the lives of these patients, with a minimal time commitment and without leaving your office.

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Please note that attendance at these events listed in this brochure is limited to healthcare professionals that are attending the ASCRS Annual Meeting. No hotel accommodations, ground transportation or travel will be covered for this meeting. No continuing education credits will be available. As part of Alcon's commitment to complying with relevant legal & industry requirements, food, beverage and other transfers of value will be tracked and reported in accordance with Physician Open Payments reporting, commonly referred to as the Sunshine Act. Additionally, we regret that we may not be able to provide meals for healthcare professionals employed by the government and/or licensed in the state of Vermont. If you have questions, please speak with an Alcon representative.

Destination AAO 2018

GET READY FOR CHICAGO • PART 1 OF 6

WELCOME

Five Days in Chicago

Engage with colleagues from around the world, learn new skills, and hear about the latest and most innovative treatments at AAO 2018, the Academy's 122nd meeting.

When to be there. AAO 2018 is held Oct. 27-30 and is preceded by Subspecialty Day Oct. 26-27.

How to prepare. Over the coming months, *EyeNet*'s Destination AAO 2018 will guide you through deadlines, preview the scientific program, and highlight must-attend events.

INTERVIEW WITH DR. PALMON

An Insider's Perspective

Florentino E. Palmon, MD, Chairman of the Annual Meeting Special Projects Committee, discusses this year's program and what he's looking forward to in Chicago.

Q: *When you took on this job, what did you most want to change about the annual meeting?*

A: I am honored to help organize this meeting. It is important that the annual meeting offers a variety of learning modalities to accommodate individual learning styles. Although the most popular sessions are continually updated and offer a lively format to discuss and learn from clinical and surgical challenges, we must modernize our teaching approach. Gone are the days when everyone must sit in a dark room and stare at a projector screen. Modern technology that facilitates interactive learning should be used to transform and energize the meeting. Clinical cases and management options with instant participant feedback can help to solidify that information in our minds.

Dr. Palmon's recommendations.

Last year's Diagnose This! live session, which created teams of participants to solve each clinical dilemma, was both invigorating and informative. Small group discussions to examine specific questions and formulate solutions should be incorporated into more sessions.

I hope that someday we will use advanced technology to enhance the learning experience. Imagine practicing a surgical case in virtual reality, experiencing a complication, and then finding the solution so that surgeons can leave the meeting feeling more confident about managing complicated cases.

Q: *What are some new things we will see at this year's meeting?*

A: There are 2 exciting spotlight sessions this year. The first, Common Approaches to Ophthalmic Urgencies, should appeal to most ophthalmologists. We've all had a late afternoon consult from a colleague who sends a patient with sudden loss of vision. Our experts will help guide participants through a systematic approach to diagnosing and treating these difficult patients. It will be a multidisciplinary approach, with patient problems drawn from all subspecialties, which will be especially helpful for the comprehensive ophthalmologist.

Our second spotlight will focus on the art of bedside manner: How to Handle the Unhappy Patient. Again, this will cross multiple subspecialties. We are all human and, despite our best efforts, cannot please every single patient. Some patients have had a successful surgery yet are not happy with their outcome. Others may have had complex problems that had been anticipated. Still others had unanticipated problems during treatment or surgery. This session addresses how we can convey what has happened to help the patient understand and cope with the situation and to protect ourselves from any legal consequences.

Q: *What are some of the most exciting course topics being planned?*

A: The best session to attend will be Hot Topics 2018. Experts in each subspecialty will present their work on the latest, most innovative, most talked-about research and surgical

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techniques for 2018. We wait as late in the year as possible to choose the cutting-edge topics.

Also, the Great Debates are always entertaining and informative. The most controversial questions facing 2 subspecialties are presented. Then, an expert on each side of the argument will attempt to convince the audience why he or she is correct. This year we will be debating topics specific to retina and cornea. The boxing gloves will be off, and hopefully nobody will be hit with a low blow.

Q: *What is the No. 1 extracurricular activity you are looking forward to in Chicago?*

A: It has to be the world-class museums. The annual meeting has been in Chicago many times in the 27 years that I have been attending the meeting, so I've been fortunate to visit most of them either with my wife and kids or in conjunction with an evening educational event. The kids love visiting the Shedd Aquarium, seeing the dinosaurs at the Field Museum, exploring the Museum of Science and Industry, and going to the Adler Planetarium. My wife and I love visiting the Art Institute of Chicago to gaze at the Impressionist and post-Impressionist work and the large American art collection. For those with more modern tastes, there is the Museum of Contemporary Art. Other options include the Chicago History Museum, the National Museum of Mexican Art, The DuSable Museum of African American History, and the Peggy Notebaert Nature Museum. If you're looking for a little nighttime entertainment, check out one of the blues or jazz clubs. And of course, don't forget to stop by Giordano's or Gino's East for some of the best Chicago-style deep-dish pizza, where 1 slice has enough calories for a single meal—but who eats only 1 slice?

BEAT THE CLOCK

June 13: Registration, Hotels, and Program Information

Starting June 13, Academy, AAOE and PAAO members—and starting June 27, nonmembers—can register for AAO 2018 and Subspecialty Day, make hotel reservations, and peruse the online program.

AAO 2018 registration. With annual meeting registration, you have access to hundreds of symposia, paper sessions, posters, videos, and interactive learning opportunities. The Academy also offers more than 350 instruction courses that you can access with the Academy Plus course pass. Find more information about Academy Plus at aao.org/annual-meeting/registration/academy-plus-course-pass. Note that Skills Transfer labs are ticketed events that must be purchased separately. Visit aao.org/registration for more registration information, including fees.

Hotels. Visit aao.org/hotels for reservations, information on group reservations, an interactive map, and information on hotel amenities and availability.

Program. The AAO 2018 Program Search will be launched as part of online meeting registration. Look up information by day, topic, type of event/course, special interest, or presenter. You do not need to log in to view program information, but login is required to register, build your personal calendar and purchase the Academy Plus course pass or tickets.

PROGRAM

Subspecialty Day 2018

Subspecialty Day features prominent ophthalmologists presenting the latest in diagnosis, treatment, and procedures. When you register for a 1-day meeting, you can float among the Subspecialty Day meetings taking place that day. Registrants for the 2-day retina meeting may attend any Subspecialty Day presentation on Friday or Saturday. The programs are:

AAO 2018
ART + SCIENCE
SUBSPECIALTY DAY

- Refractive Surgery 2018: Better Together—Lens- and Cornea-Based Surgery—Friday, Oct. 26 (1 day).
- Retina 2018: The Art + Science of Retina + Vitreous—Friday, Oct. 26, and Saturday, Oct. 27 (2 days).
- Cornea 2018: What's Tried, True, and New—Saturday, Oct. 27 (1 day).
- Glaucoma 2018: A New Renaissance—Saturday, Oct. 27 (1 day).
- Ocular Oncology and Pathology 2018: Hot Topics in Ocular Pathology and Oncology—An Update—Saturday, Oct. 27 (1 day).
- Oculofacial Plastic Surgery 2018: Oculoplastics Real World: Real Cases, Real Lessons, True Learning—Saturday, Oct. 27 (1 day).
- Pediatric Ophthalmology 2018: Winds of Change in the Windy City—Saturday, Oct. 27 (1 day).
- Uveitis 2018: Uveal Blues in Chicago—Saturday, Oct. 27 (1 day).

EVENTS

Schedule Time for *EyeNet* Corporate Lunches

Be sure to leave room in your schedule for *EyeNet*'s free corporate educational lunches on Saturday, Oct. 27, Sunday, Oct. 28, and Monday, Oct. 29, located onsite at McCormick Place. Check-in and lunch pickup is at 12:15 p.m., and the program is 12:30-1:30 p.m. These non-CME events are developed independently by industry—they are not affiliated with the official programs of AAO 2018 or Subspecialty Day. By attending these presentations, you may be subject to reporting under the Physician Payment Sunshine Act.

For more information and program updates, check aao.org/eyenet/corporate-events.

Orbital Gala: Tickets on Sale

Celebrate a legacy of serving patients at AAO 2018's Orbital Gala on Sunday, Oct. 28, at the Chicago Cultural Center. The renowned center is home to Louis Comfort Tiffany's historic glass dome, where our 1960s-themed bash will take place. Expect a night of exquisite dining, live entertainment, and a silent auction. U.S. Academy members, regardless of whether they plan to attend the gala, can bid online for fine wine, festive trips, and other notable items. All Orbital Gala proceeds support the Academy's programs.

To purchase tickets, register to bid, and preview items, visit aao.org/foundation.

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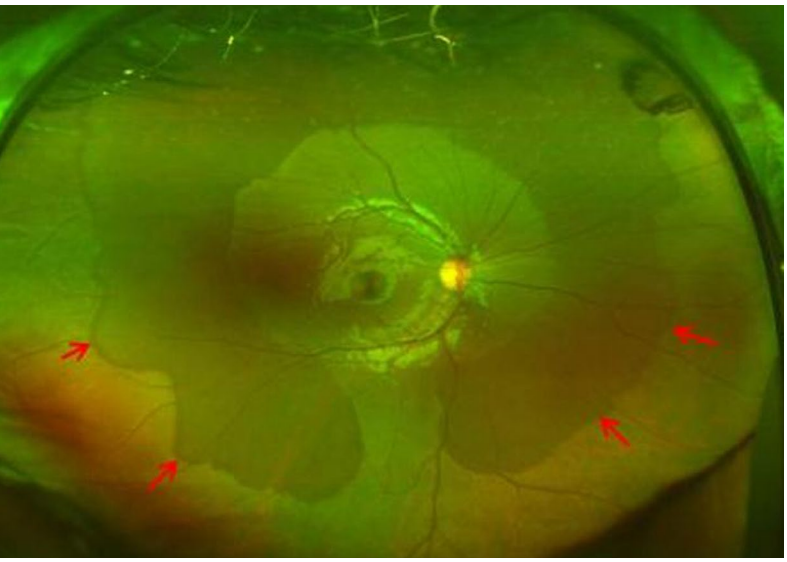
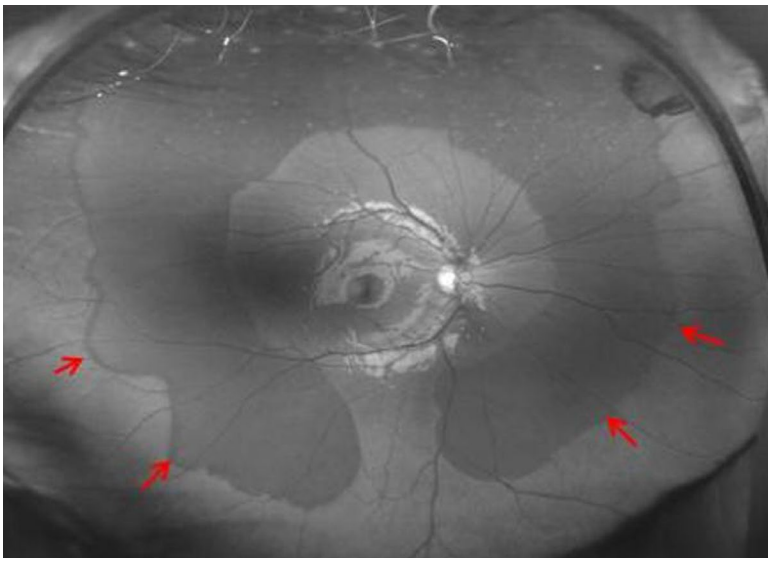
MYSTERY IMAGE

BLINK





Arun Kapil, Advanced Eye Centre, Post Graduate Institute of Medical Education and Research, Chandigarh, India.

WHAT IS THIS MONTH'S MYSTERY CONDITION? *Visit aao.org/eyenet to make your diagnosis in the comments area and get the answer to last month's mystery.*

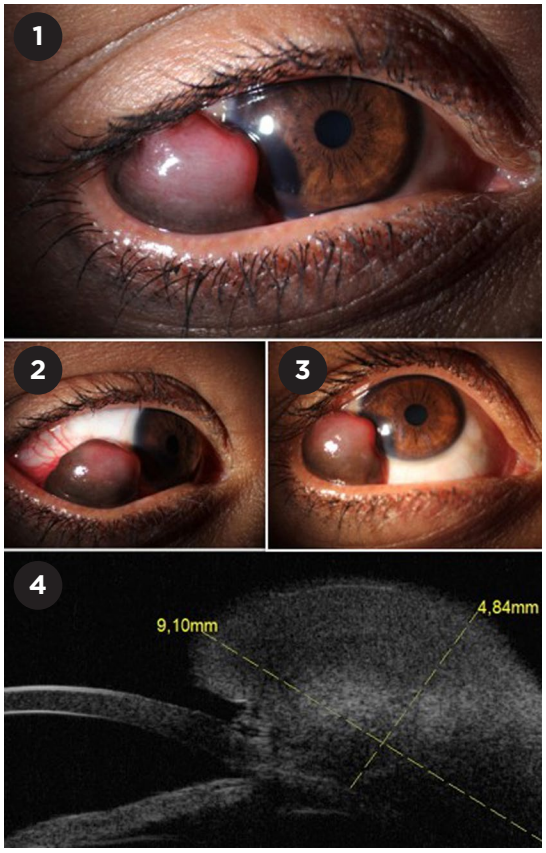
LAST MONTH'S BLINK

Giant Conjunctival Melanoma

A 24-year-old woman presented with a rapidly growing, painless, pigmented lesion of the conjunctiva (Fig. 1). Physical examination showed a mobile, dark brown lesion in the temporal conjunctiva near the corneal limbus (Figs. 2-3) that compromised palpebral closure. Ultrasound biomicroscopy was performed to obtain approximate measurements of the lesion and to determine its exact location for diagnostic and management considerations (Fig. 4). Diagnosis of giant conjunctival melanoma was made via excisional biopsy, and the patient was referred to the ocular oncology service.

The differential diagnosis of this perilimbal lesion includes a large nevus and melanoma of the ciliary body with extraocular extension.

WRITTEN BY **CARLOS E. CHACON, MD,** AND **ALEXANDER RABINOVICH, MD.** PHOTO BY **SERGIO ALFONSO GARCES URIBE, MD**. ALL ARE AT MARACAIBO UNIVERSITY HOSPITAL, ZULIA, VENEZUELA.



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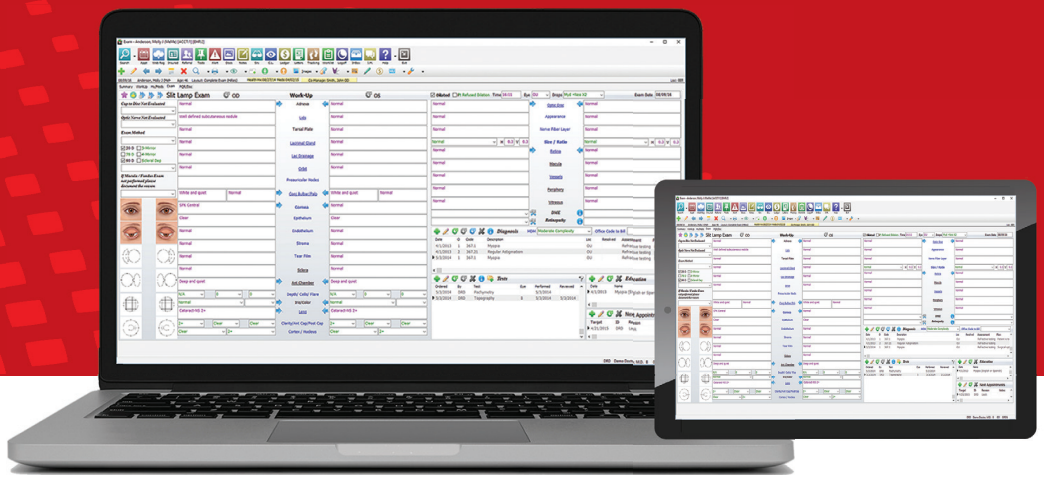

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