

AMERICAN ACADEMY OF OPHTHALMOLOGY®

## Eye Net March 2018

### **Cataract Survey**

8 Tough Cases, 35 Poll Questions, Expert Opinions

**Retinal TIAs** Medical Emergency!

Iridocyclectomy A Step-by-Step Guide

Vitreous Floaters To Treat, or Not to Treat?

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## SIGN & SYMPTOM IMPROVEMENT

The only prescription eye drop FDA-approved to treat both the signs and symptoms of Dry Eye Disease

Xiidra improved patient-reported symptoms of eye dryness and improved signs of inferior corneal staining. So help patients get to know Xiidra.

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Four randomized, double-masked, 12-week trials evaluated the efficacy and safety of Xiidra versus vehicle as assessed by improvement in the signs (measured by Inferior Corneal Staining Score) and/or symptoms (measured by Eye Dryness Score) of Dry Eye Disease (N=2133).

The safety of lifitegrast was evaluated in 5 clinical studies. 1401 patients received at least one dose of lifitegrast (1287 of which received Xiidra). The most common adverse reactions (5-25%) were instillation site irritation, dysgeusia, and reduced visual acuity.

### Indication

Xiidra<sup>®</sup> (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.

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### **BRIEF SUMMARY:**

Consult the Full Prescribing Information for complete product information.

### INDICATIONS AND USAGE

Xiidra<sup>®</sup> (liftegrast 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  $\leq$ 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 liftegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of liftegrast 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 liftegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to liftegrast 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**

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421. For more information, go to www.Xiidra.com or call 1-800-828-2088. Marks designated <sup>®</sup> and <sup>™</sup> are owned by Shire or an affiliated company. ©2018 Shire US Inc. SHIRE and the Shire Logo are trademarks or registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates.

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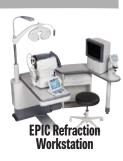


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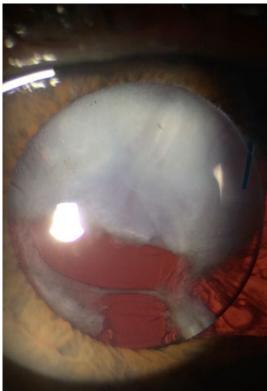


## **SOLUTIONS**

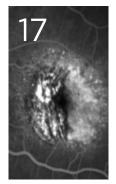
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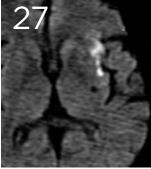
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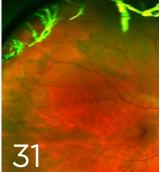




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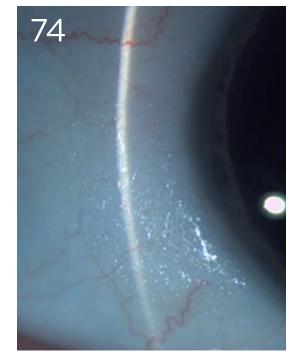
### **MYSTERY IMAGE**

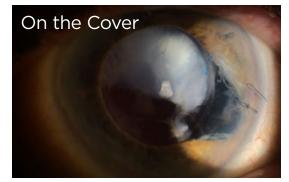
74 Blink What do you see?

### **COVER IMAGE**

David F. Chang, MD









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## It's Time to Get More from Your EHR



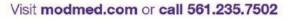
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- CHRISTINE SYKORA, PRACTICE ADMINISTRATOR, ADVANCED EYE CARE SC



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1. Weston K, Nicholson R, Bunce C, Yang YF. An &-yearretrospectivestudy of cataract surgery and postoperative endophthalmitis: injectable intraocular lenses may reduce the incidence of postoperative endophthalmitis. Br J Ophthalmol. 2015;99(10):1377-1380. 2. Goldberg D, Coyle K, Jones M, Lane S, Kim T, Keith M. U.S. multicenter study of time, operational and economic efficiencies associated with using a new preloaded IOL delivery system. Paper presented at: ASCRS-ASOA Symposium and Congress; May 5-9, 2017; Los Angeles, CA. 3-5. Alcon data on file. 6. AcrySof® IQ UltraSert® Pre-loaded Delivery System Directions for Use.

For Important Product Information, please see the next page





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**ATTENTION**: Reference the Directions for Use for Model AU00T0 for a complete listing of indications, warnings and precautions.



### Letters



### Toxic Colleagues: A Step Further

I write in response to Dr. Williams' editorial on toxic colleagues (Opinion, November). I would call the situations she describes "old school," or tribal behavior. Openness to new ideas and others' points of view is crucial to advancing our communal knowledge and understanding. This

instinctive human reaction to the other should improve as we continue to become more diverse in our field in terms of gender and ethnicity. The old boys' club mentality that underlies toxic behavior should become a thing of the past, although vestiges will remain.

Openness has always been an avenue to better collective understanding and intellectual growth. We ophthalmologists now have many media and networks to build our professional knowledge. In the context of broader society, we can look forward to more innovations that will help us share and verify information without much cost or hindrance.

The current movements in general culture toward greater transparency and sharing of insights have created heightened divisions between those who have different views and values. The respect that we have for each other in person is hard to replicate online, where anonymity easily breeds contempt. The social mores that underlie our discourse cannot hold when tested by faceless and divisive media.

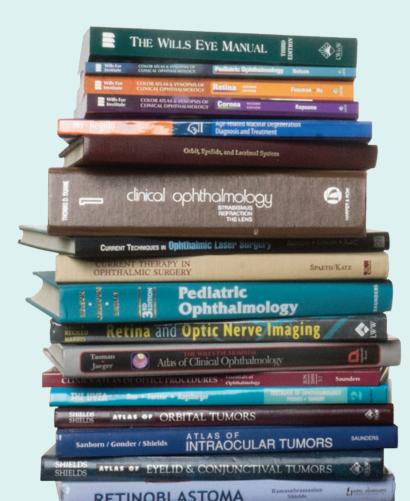
The question remains: How do we hold our institutions and professionals accountable for their behavior? Education is the first step. We need to teach problem-solving skills that involve both colleagues and patients in a respectful manner. Our culture is preoccupied with adversarial conflict and asymmetric profit-taking. This creates an environment in which suggestions are left unsaid by those who wish to avoid creating tension. A more open, quality-oriented environment would value the best outcomes for each patient and provider without innate conflict and competition. Given our human nature, that may be a difficult goal to achieve!

> Christopher F. Wood, MD Arlington Heights, Ill.

**CORRECTION:** In the January News in Review article "Using the Visual System to Treat Multiple Sclerosis" (page 17), *EyeNet* incorrectly identified clemastine fumarate as Claritin. *EyeNet* regrets the error.



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### Opinion

### RUTH D. WILLIAMS, MD

### Blurring the Lines: Are You an Insurance Company?

found the leather-bound 1946 appointment book for our practice. It seems quaint from the vantage of the 21st century. Each entry is handwritten—in cursive—sometimes in blue ink, sometimes in pencil, and the charge to each patient is meticulously recorded. This relic illustrates that ophthalmic practice was simpler when the physician provided care and the patients paid for the service (on the same day). Ophthalmologists concentrated on delivering the best possible medical care and needed only basic accounting and scheduling assistance. Today, not only are scheduling and billing crushingly complex, but we also function as insurance companies.

How so? As financial risk shifts to ophthalmology practices, the lines blur between payer and provider.

The most obvious example is the high deductible, which places the burden of collecting payment for medical services on the ophthalmology practice. In just 5 years, the percentage of employees with a deductible of \$1,000 or more (for single coverage) has increased from 34% to over 50%.<sup>1</sup> On average, the deductible for the popular "Silver Plan" in the insurance marketplace is more than \$3,000. When the ophthalmologist is responsible for collecting payment from the deductible, the practice must devote resources to this extra work, and it risks not getting paid. Furthermore, when a patient needs urgent care or surgery, there are medical-legal and ethical requirements to provide or arrange care even when payment is not assured.

Co-pays are another example. While high co-pays are usually framed as an issue of access, they also pose a financial risk because the ophthalmologist must collect payment. These collections become more difficult when a patient experiences financial hardship from co-pays, especially during episodes that require frequent office visits.

Practices assume risk in more subtle ways, too. After considerable staff time is spent obtaining a preauthorization for a procedure, occasionally an insurance company will retroactively deny payment or even request repayment. The process of rectifying these situations can be so complex and frustrating that a practice might give up or lose track of a particular claim. In fact, the ophthalmology practice must monitor the entire revenue cycle, including eligibility, authorization, predetermination, denial, claims resubmission, eventual payment, and postpayment audits.

And there's more. Practices also assume risk when giving anti-VEGF injections. Expensive medications must be purchased and properly stored, and expiration dates must be monitored. Even with meticulous inventory tracking, one bad claim can have a significant negative impact.

The physician assumes the risk, not the insurance company, the patient, or the pharmaceutical company. Moreover, new and innovative medications and devices are increasingly being offered using the "buy and bill" model, in which the practice purchases the product and bills insurance for reimbursement.

Most significantly, the health care marketplace is further blurring the lines between provider and payer. Large integrated health systems are offering insurance products that only include providers from their own health system. CVS Health announced plans to buy the insurance giant Aetna for \$69 billion. Many CVS pharmacies include retail

clinics that provide health care. Under this model, the health care provider, the pharmacy, and the insurance company are the same.

The roles in health care delivery are exceedingly complex and comingled—and the lines will increasingly blur as providers, health systems, pharmacies, and insurance companies consolidate and integrate. As systems become more complex, responsibility for revenue cycle management and risk analysis may shift to a centralized business office. Interestingly, this just might return ophthalmologists to our real expertise being superb clinicians, counselors, and surgeons.

1 www.kff.org/report-section/ehbs-2017-summary-of-findings/. Accessed Jan. 5, 2018.

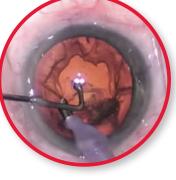
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### **Current Perspective**

DAVID W. PARKE II, MD

### The Eye Care Tipping Point

e may be reaching U.S. health care's tipping point —that critical point in a system when the pace of change accelerates and the impact is unstoppable. The problem with tipping points is that we generally recognize them only in our rearview mirrors—and when we have little opportunity to affect them. In such situations, we have no alternative but to ride the wave of radical change.

We've heard for years that "health care costs are unsustainable," "payment based on value will replace payment based purely on volume," "outcomes matter," and "much of health care will be delivered by teams, not by individuals in silos." Over the past decade, I've been to countless conferences devoted to aspects of this theme. We've all witnessed federal demonstration projects and gradual integration of hospitals and physicians, and we've lived through the incorporation of value-based payment metrics.

So, what is different *now* in this sector—which comprises nearly one-fifth of the nation's gross domestic product particularly when CMS appears to be backing away from bundling payments? The difference is the markets. Consider just these 4 events, which occurred in the past few months:

1. CVS (nearly 10,000 retail pharmacies and 1,100 walk-in clinics with a massive pharmacy benefits manager enterprise) proposes to merge with Aetna (the nation's third largest health plan) in a \$69 billion deal. This potentially aligns drug costs with efficacy and more competitive insurance premiums.

2. Apple entered the health care arena with an application to integrate health records on an iPhone. What's different is that this isn't just Apple. They are using an interoperability standard that involves institutions like Johns Hopkins Medicine and Dignity Health and EHR companies (including Epic, Cerner, and AthenaHealth). We haven't seen that before! Digital integration in global health care has been estimated as an \$8.7 trillion opportunity!

3. Amazon, Berkshire Hathaway, and J.P. Morgan (3 companies without a history of collaborating) announced a joint venture to address the health care costs and outcomes of their collective 1 million employees (in their collective \$1.5 trillion businesses). Their press release refers to "scale and complementary expertise" through establishment of "an independent company." Warren Buffett commented,

"The ballooning costs of health care act as a hungry tapeworm on the American economy." It's worth noting that this announcement (despite little detail) caused health care stocks to plunge.

4. Four of the largest integrated systems (Intermountain Healthcare, Ascension, SSM Health, and Trinity Health, with 450 total hospitals, and consulting with the U.S. Department of Veterans Affairs) are creating a not-for-profit generic drug company to stabilize access to and cost of generic medications in their facilities.

Physicians, other providers, hospitals, drug companies, pharmacy benefit managers, pharmacies, employers, health

care IT companies, and the financial services industry are all swirling around in new alliances for one goal—to implement new approaches to cost, access, and quality. Underlying it all is a sense of desperation—and of opportunity.

Does this all guarantee a seismic shift? No, because it's been famously said, "Nobody knew that health care could be so complicated." This doesn't address the unique issues of safety net hospitals, health care disparities, poverty, obesity, and the myriad factors that relate to substandard health outcomes.

I believe that, as stewards of our

profession's future, the Academy must try to create tools, models, and predictive analyses that will generate opportunities. We have the IRIS Registry to provide data on outcomes and resource use. We are modeling the impact of various cost bundling approaches and alternative payment models on particular subsets of ophthalmologists. We are looking at ways to assess "value" in pricing of drugs and devices. Unless we make these efforts, the only alternative is to keep checking the rearview mirror and passively ride the wave.

David W. Parke II, MD Academy CEO



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## News in Review

COMMENTARY AND PERSPECTIVE

### RETINA

### Novel Protocol for CNV: "Treat-Extend-Stop"

### A VARIATION ON INTRAVITREAL

therapy, in which treatment intervals are first extended to 12 weeks and then injections are stopped altogether, can preserve the visual acuity (VA) of patients with wet age-related macular degeneration (AMD) even if their choroidal neovascularization (CNV) recurs, a study by California retina specialists has found.

Their retrospective analysis of outcomes with this "treat-extend-stop" (TES) protocol showed that 37.3% of 385 eyes treated for CNV met the criteria for cessation of therapy. Of these 143 eyes, 70.6% required no further intervention during a mean of 27 months of follow-up. In those that did have a recurrence, 54.8% recovered after retreatment to 20/40 or better, similar to the mean VA in the group when the injections were stopped.<sup>1</sup> Patients were able to maintain a 2-line gain in vision (10 letters), even after a recurrence.

**Rationale.** "Originally I did this study just out of clinical curiosity. I wanted to know what percentage of patients had a recurrence of the CNV after we stopped therapy," said coauthor Sean D. Adrean, MD, who practices in Fullerton, California. "I was relieved to find out that when patients had a recurrence, overall they did not lose vision." Dr. Adrean said that, based on the literature and on anecdotal reports from colleagues around the country, the most commonly used treat-andextend protocol for intravitreal treatment of CNV lengthens the interval between injections to 10-12 weeks and continues this schedule indefinitely. But his analysis of 8 years of outcomes in his group's practice suggests that many patients with wet AMD could benefit from the TES approach, he said.

"To know that you can actually stop injecting these patients and they can continue to do well, and only about 30% of eyes [experience a recurrence] —well, this means that you can maybe avoid doing unnecessary injections, or at least reduce the number of injections the patient needs," Dr. Adrean said.

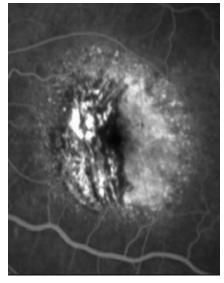
**TES protocol.** The authors described their TES protocol as follows:

• Therapy begins with at least 3 monthly injections of an anti–vascular endothelial growth factor (VEGF) agent, until a "dry" macula is confirmed with spectral-domain optical coherence tomography (SD-OCT).

• If the macula remains free of fluid, the intervals between injections are extended by 1 to 2 weeks between successive visits, until a 12-week time interval is reached.

• If the patient has received at least 7 total injections, and if SD-OCT at 3 successive 12-week visits confirms that CNV has not recurred, the injections are stopped.

• Patients return 1 month later and then successively longer by 2-week intervals until 12 weeks is reached. These



**ACTIVE.** A 30-degree fluorescein angiogram of an 80-year-old patient with wet AMD and active CNV.

patients are then monitored quarterly for signs of recurrence.

**Monitoring a must.** Because the study documented recurrences in a few TES patients as long as 3 years after the cessation of treatment, ongoing monitoring every 3 months is essential, Dr. Adrean said.

"I'm always very frank with them, and I say there's a 30% chance that their CNV could come back. I tell them to come back earlier if they have increased distortion or decreased vision, so we can start treatment again if the CNV has recurred," he said.

—Linda Roach

1 Adrean SD et al. *Ophthalmology Retina*. 2018; 2(3):224-229.

Relevant financial disclosures—Dr. Adrean: Genentech: C,S; Ohr Pharmaceuticals: C,S; Ophthotech: C,S; Regeneron: C,S; SciFluor Life Sciences: C,S.

**MORE ONLINE.** For additional images, see this article at aao. org/eyenet.

### PEDIATRICS Preterm Births Associated With Corneal Aberrations

### RESEARCHERS IN GERMANY REPORT

that extreme prematurity itself—not necessarily the occurrence of retinopathy of prematurity (ROP)—is associated with increased higher-order aberrations of the cornea in former preterm infants.<sup>1</sup> These findings were unexpected, said lead author Achim Fieß, MD, at the University Medical Center in Mainz.

Study design. The prospective cross-sectional study compared the corneal shape of 226 former preterm infants, of a gestational age (GA) of  $\leq$  32 weeks, with 259 randomly selected children who had been born at full term (GA  $\geq$  37 weeks). The researchers evaluated differences in various corneal aberrations in relation to gestational age and ROP occurrence in these children. The various aberrations included astigmatism, coma, spherical aberration, and root-mean square of higher-order aberrations.

The subjects ranged in age from 4 to 10 years, an age group selected because little is known about the association between prematurity and altered corneal shape in early childhood, Dr. Fieß said. "We decided to investigate this age group to provide new insights for corneal aberration development in this decisive time frame of vision development."

Dr. Fieß added that the study was possible only because of modalities, such as Scheimpflug imaging, which allows no-contact examination of the anterior segment. This is ideal for observing children in detail.

**Findings.** In general, total corneal aberrations, both lower- and higherorder, increased as gestational age declined, with effects observed mainly on the anterior surface of the cornea.

Yet because infants on the older end of the preterm spectrum (GA of 29-32 weeks) had corneal aberrations comparable to those children born at full term, the researchers refined the age parameters into *moderate* and *extreme* prematurity. It was extreme prematurity that was associated with increased higher-order and lower-order aberrations of the total cornea.

**Clinical implications.** While corneal aberrations may be one of several factors contributing to increased refractive error and low visual function, particularly in former extreme preterm infants, the visual effects of aberrations are expected to be small compared to myo-

### GLAUCOMA Corneal Hysteresis: New Risk Factor for Glaucoma

### RESEARCHERS WHO PREVIOUSLY REPORTED THAT

corneal hysteresis (CH) was associated with glaucoma progression<sup>1</sup> have found that it should be considered a new risk factor for developing the disease.<sup>2</sup> For every 1 mm Hg reduction in CH, the risk of developing glaucoma increased 21%.

**Study specifics.** CH, a measure of the cornea's viscoelasticity, is the difference (measured in mm Hg) between the pressure at which the cornea bends inward during an air jet applanation and the pressure at which it bends out.

For this prospective observational cohort study, the researchers evaluated 199 glaucoma suspects (287 eyes) who had a history of intraocular pressure (IOP) > 21 mm Hg and/or suspicious appearance of the optic nerve, with normal visual fields (VFs) at baseline. CH measurements were acquired at baseline using the Ocular Response Analyzer (ORA; Reichert Technologies), and the patients were followed an average of 4 years.

**Results.** Glaucoma development, defined as 3 consecutive abnormal standard automated perimetry tests during follow-up, occurred in 19% of eyes.

The study found that lower baseline corneal hysteresis measurements were significantly associated with increased risk of developing glaucomatous VF defects over time, even after adjusting for age, IOP, corneal thickness, and pattern standard deviation.

At baseline, CH was lower in those who developed glaucoma than in those who did not develop glaucoma (CH of 9.5 mm Hg vs. 10.2 mm Hg).

**Predictive power.** The study also found that CH may be a stronger risk factor for glaucoma than central corneal thickness (CCT), said coauthor Felipe A. Medeiros, MD, PhD, at Duke University in Durham, North Carolina. He added that this finding probably is related to the fact that thickness is just 1 component related to corneal biomechanics.

But unlike CCT, which affects estimations of IOP, there appears to be only a weak relationship between CH and IOP. "Corneal hysteresis may actually act more like a surrogate marker for the biomechanical properties of tissues in the back of the eye," Dr. Medeiros said.

What next? Now, along with IOP, age, and CCT, another risk factor has been added to the constellation of those associated with glaucoma. "The challenge," said Dr. Medeiros, "is how to develop new objective risk calculators that merge all these factors." In the meantime, he advised doctors to consider measuring CH in glaucoma suspects. Eyes with a low CH would probably need to be monitored more often or receive early treatment, he said. —*Miriam Karmel* 

1 Medeiros FA et al. *Ophthalmology*. 2013;120(8):1533-1540. 2 Susanna CN et al. *Am J Ophthalmol*. Published online Jan. 2, 2018.

**Relevant financial disclosures**—Dr. Medeiros: NIH: S; Reichert: C,S.

pia or astigmatism, Dr. Fieß said. "Our finding, therefore, is less important for guiding treatment than it is for suggesting a further reason for low visual acuity and refractive error in former preterm children."

**Does the effect persist?** Dr. Fieß is currently investigating the effect of low birth weight on ocular morphology in an adult cohort. This may determine whether corneal aberrations persist into adulthood in former preterm infants.

In the meantime, he said, "Our study highlights that, in particular, gestational age less than 29 weeks affects corneal shape. Extreme early prematurity is one decisive factor affecting corneal aberrations." — *Miriam Karmel* 

1 Fieß A et al. *Invest Ophthalmol Vis Sci.* 2017; 58(14):6374-6378.

Relevant financial disclosures-Dr. Fieß: None.

### TRAUMA

### Compound Can Seal Scleral Injuries —Reversibly

### RESEARCHERS AT THE UNIVERSITY

of Southern California (USC) hope the unique characteristics of their novel copolymer will solve an ophthalmic dilemma posed by combat- and masscasualty-related ocular traumas. That is, scleral perforations sometimes must be left open for hours or even days before they can be repaired.

**Thermoresponsive.** The scientists chose a hydrophilic copolymer that was known to be thermoresponsive.<sup>1</sup> This property makes the material suitable for temporarily closing open-globe wounds without further damaging the tissue, particularly when resources, facilities, or time are limited.

The researchers found that military ophthalmologists and other clinicians were able to rapidly and reversibly occlude scleral perforations in animal eyes with the compound, which is a polymeric combination of N-isopropylacrylamide and butylacrylate—also called poly(NIPAM-co-BA), or N<sub>95</sub>BA<sub>5</sub>.



**TEMPORARY CLOSURE.** (Left) An ocular surgeon attempting to seal a large (~ 2 cm) full-thickness scleral laceration in a cannulated porcine eye using the ocular sealant and its associated customized injector tool designed by the team from USC. (Right) The same eye photographed 5 minutes later, with the sealant fixed in place and capable of maintaining IOP generated by the saline infusion cannula.

"We [have tailored] its thermoresponsive behavior and mechanical strength to create a hydrogel that shape-fills upon injection at a wound site, adapting to irregular margins and sealing traumatic injuries. The thermosensitive behavior allows the sealant ... to be easily removed by the application of cold water," the authors wrote.

**Material properties.** Coauthor John J. Whalen, PhD, at USC's Roski Eye Institute in Los Angeles, said that  $N_{95}BA_5$  has the following properties:

• It exists as a viscous, translucent hydrophilic fluid at below 14 degrees Celsius (C). They designed a special double-walled (jacketed) syringe, capable of cooling the hydrogel on demand to below 10 degrees C for 10 minutes.

• It transitions to a more hydrophobic, opaque, sticky soft-solid state when body heat raises the temperature above 30 degrees C. This closes the wound and alleviates hypotony. (The solidification process takes approximately 5 minutes.)

• It returns to the liquid state when rehydrated with cold (< 10 degrees C) water, at which time the fluid can be aspirated away.

Early results. During in vivo testing in animals, the eyes showed some early signs of inflammation, which disappeared by 24 hours, the authors reported. There was no evidence of neurotoxicity, no retinal tissue degradation, and no significant chronic inflammatory response to sustained exposure (30 days).

**Potential applications.** Delayed treatment for open-globe injuries has added importance today because of traumatic eye injuries from explosions in war zones and in mass-casualty events, such as the Boston Marathon bombing. In the former scenario, scleral perforations are left open while patients are airlifted to a hospital, sometimes thousands of miles away. In the latter, care for more critically injured patients might take precedence over open-globe injuries, Dr. Whalen said.

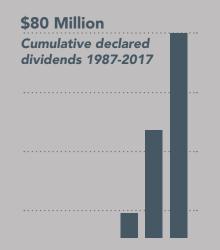
Dr. Whalen, who is a bioengineering materials specialist on the USC research team that conducted research supporting the Argus II retinal implant (Second Sight), said the group originally investigated hydrogel polymers to reversibly adhere the Argus II to the retina. But serendipity pointed them to open-globe injuries instead.

"We couldn't quite get this compound to work with the Argus. But when we saw that the Army was looking for temporary treatments for ocular trauma, we wondered if our adhesive could do the trick—and, from the first bench-top experiment, we had success," Dr. Whalen said. —*Linda Roach* 

1 Bayat N et al. *Sci Transl Med.* 2017;9(419). doi: 10.1126/scitranslmed.aan.3879. **Relevant financial disclosures**—Dr. Whalen: None.

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## Journal Highlights

### Ophthalmology

Selected by Stephen D. McLeod, MD

### Foveal Development in Preterm Infants Treated for ROP March 2018

Vogel et al. studied foveal development and cystoid macular changes (CMCs) in preterm infants, including the potential effects of treatment with intravitreal bevacizumab or laser photocoagulation. They found that outer retinal thickening at the foveal center occurs faster with bevacizumab—and that laser treatment produces earlier extrusion of inner retinal layers and delayed development of the ellipsoid zone at the foveal center.

This observational case series included 131 preterm infants who underwent screening for retinopathy of prematurity (ROP). Of these, 108 did not receive treatment, 9 had intravitreal bevacizumab only, 10 had laser only, and 4 received both treatments.

Handheld optical coherence tomography was performed longitudinally for all participants. Thickness of the inner and outer retinal layers was measured at the foveal center and the nasal and temporal foveal rims. Treated and untreated eyes were compared, with adjustments made for confounding variables. Correction for distortions and measurement errors caused by offaxis scans was accomplished by rescaling images to their native anatomic aspect ratio (this is important because off-axis scans are more common when nonsedated infants are imaged). The main outcome measures were 1) weekly changes in thickness of the inner and outer retinal layers and 2) the presence of inner retinal layers, the ellipsoid zone, and CMCs.

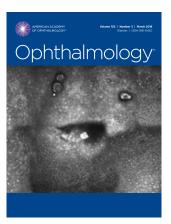
Results showed that foveal center thickness increased 3.1 µm per week

in untreated eyes and 7.2  $\mu$ m per week in bevacizumab-treated eyes (p = .038). Laser-treated eyes were less likely than untreated eyes to have all inner retinal layers present at the foveal center (odds ratio, 0.04; p = .001) and to have an ellipsoid zone at the foveal center (odds ratio, 0.07; p = .024). CMCs were observed in 53% of patients and 22% of imaging sessions.

A strength of this study is the large sample size, resulting in data for 744 imaging sessions. Long-term follow-up and additional studies are needed to determine the anatomic and functional significance of the findings. Such knowledge may help guide treatment decisions for infants with ROP.

### Prescribing Patterns and the Cost of Brand Medications March 2018

Prescription drugs are the fastestgrowing sector of health care spending. Newman-Casey et al. conducted research to quantify the costs of



ophthalmic medications prescribed by eye care providers, compare prescribing patterns between these and other providers, and estimate savings from negotiating prices and substituting generic/therapeutic alternatives for brand medications. They found that, among all providers, eye care specialists prescribe the highest proportion of brand name drugs by volume.

The study used data from the 2013 Medicare Part D prescriber public use file and summary file (released in 2015) to calculate medication costs by specialty and drug. Potential savings from substituting generic or therapeutic options for brand drugs were calculated. Potential savings were estimated using drug prices negotiated by the U.S. Veterans Health Administration.

Eye care providers (ophthalmologists and optometrists) accounted for \$2.4 billion of the \$103 billion total Medicare Part D costs for prescription drugs and produced the highest percentage of claims for brand medications among all specialties. Medications accounted for a significantly higher proportion of monthly supplies by volume as well as by total cost for eye care providers relative to other providers (38% vs. 23% by volume; 79% vs. 56% by total cost).

As for medication type, glaucoma drugs accounted for the largest proportion of costs generated by eye care providers (\$1.2 billion; 54% of total cost; 72% of total volume), followed by



drugs for dry eye syndrome. Restasis, which currently has no generic alternative, was responsible for nearly 99% (\$371 million) of drug expenditures in the dry eye category (17% of total cost; 4% of total volume). The Medicare Part D average payment for a monthly supply of Restasis was \$293, higher than the amount for any other drug.

If generics could be substituted for brand drugs, savings of approximately 7% (\$148 million) would be realized. The combination of generic and therapeutic substitutions would yield savings of 42% (\$882 million). If Medicare could attain Veterans Health Administration rates for medications, the resulting savings would be 53% (\$1.09 billion).

Efforts to reduce drug expenditures associated with eye care professionals should focus on greater use of generic and therapeutic options. Policy changes enabling Medicare to negotiate lower prices for prescription drugs could yield substantial savings for the program.

### New Visual Disturbances by Site of Laser Peripheral Iridotomy March 2018

In a multicenter study, **Srinivasan et al.** aimed to determine whether the site of laser peripheral iridotomy (LPI) has any bearing on the emergence of postoperative visual symptoms. They found that the incidence of new visual dysphotopsias is similar for the superior and nasal/temporal locations.

For this prospective randomized, single-masked trial, the authors included 559 South Indian adults who were primary angle-closure suspects (PACS) or had a diagnosis of primary angle closure (PAC) or primary angle-closure glaucoma (PACG) in both eyes. Participants were assigned randomly to receive bilateral superior LPI (n = 285) or bilateral nasal/temporal LPI (n = 274)and were matched for age, gender, and PACS/PAC/PACG distribution. The main outcome measure was occurrence of new-onset dysphotopsia symptoms. Visual disturbances were assessed preoperatively and 2 weeks post-LPI, utilizing a survey based on the 7-symptom dysphotopsia questionnaire used by Spaeth et al. in 2005.

Laser energy settings were similar for both LPI groups, but superior LPI involved more shots and greater total energy. There were no significant between-group differences in postoperative anterior chamber reaction or LPI area. The proportion of patients with at least 1 symptom before LPI was similar (superior, 15.8%; nasal/ temporal, 13.9%), as was the incidence of each symptom.

After LPI, 8.9% of the study population reported 1 or more new symptoms; the most common were linear dysphotopsias (2.7%), glare (4.3%), and blurring (4.3%). Patients who underwent superior LPI did not report more new-onset dysphotopsia symptoms than those who had nasal/ temporal LPI (8.4% vs. 9.5%), and the incidence of any new individual symptom was comparable. None of the following influenced the odds of new dysphotopsia symptoms postoperatively: location of LPI, size of LPI area, or quantity of laser energy.

Although dysphotopsia symptoms emerged after LPI in a large portion of the study population, the overall frequency of dysphotopsias did not increase. LPI site selection should be based on individual factors, such as location of the optimal crypt in patients with a thick iris.

-Summaries by Lynda Seminara

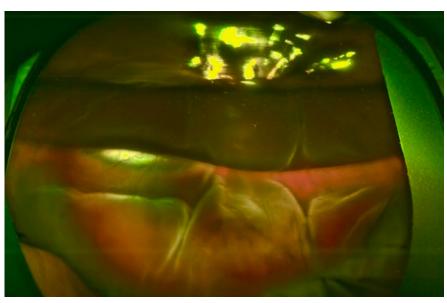
### **Ophthalmology Retina**

Selected by Andrew P. Schachat, MD

### Subretinal Air and tPA for Submacular Hemorrhage: First U.S. Results March 2018

At present, there is no consensus on the optimal management of submacular hemorrhage (SMH), which is a rare but potentially devastating complication of choroidal neovascularization. Sharma and Kumar et al. set out to determine whether massive SMHs can be managed with subretinal injections of tPA (tissue plasminogen activator) and air. They found that the combination was successful, resulting in consistent displacement of SMH out of the fovea as well as improved visual acuity (VA) and retinal thickness.

This retrospective interventional case series included 24 patients with SMH from 5 sites in the United States. The patients' mean age was 79.1 years (range, 62-92 years). The underlying cause of SMH was polypoidal choroidal vasculopathy (n = 4) and age-related macular degeneration (n = 20). In addition, 13 (54%) of the patients were on anticoagulation therapy for stroke prevention (n = 9), stroke history (n = 3), or atrial fibrillation (n = 1). Main outcome measures included



**DISPLACED HEMORRHAGE.** This wide-field image taken on postop day 1 shows an inferiorly displaced SMH, with partial gas fill in the vitreous cavity to prevent the subretinal air from migrating superiorly.

frequency and extent of SMH displacement and postoperative VA, retinal thickness, and complications.

Based on image review, SMH was considered subretinal in 5 patients, sub-RPE (retinal pigment epithelium) in 2, and both subretinal and sub-RPE in 17. Hemorrhage size was small (does not reach arcades) in 6 patients, large (extending to the arcades) in 2, extensive (extending past the arcades) in 9, and massive (extending to 2 quadrants and/ or past the equator) in 7. With regard to retinal thickness, the hemorrhages were < 500  $\mu$ m in 7 patients and > 500  $\mu$ m in 17.

All patients underwent pars plana vitrectomy (with induction of a posterior vitreous detachment, if necessary), followed by subretinal injection of tPA and filtered air. Most (n = 23) of the patients also received bevacizumab as part of the surgery or treatment. They were then followed for an average of 12.5 months (range, 3-28 months).

At 3 months postoperatively, there was complete displacement of SMH in all eyes. Although 13 eyes experienced no complications, 5 had a recurrent subretinal SMH that was successfully displaced with the same treatment. The remaining 6 eyes had a nonclearing vitreous hemorrhage (n = 3), retinal detachments (n = 2), or macular hole (n = 1). Mean retinal thickness improved from 463.7  $\mu$ m preoperatively to 311.3  $\mu$ m postoperatively, and VA improved in 23 eyes and remained stable in 1. —Summary by Jean Shaw

### American Journal of Ophthalmology

Selected by Richard K. Parrish II, MD

### Choroidal Thickness Changes in Patients With Glaucoma February 2018

The peripapillary choroid is of interest to researchers because its branches lend vital support to the prelaminar region of the optic nerve head, a primary site of glaucomatous optic neuropathy. Although the link between glaucoma and the choroid has been studied using optical coherence tomography, findings have been inconsistent. **Mundae et al.**  performed spectral-domain optical coherence tomography (SD-OCT) in patients with glaucoma and healthy controls to compare rates of peripapillary choroidal thinning. Their results showed no significant difference between the study groups.

The authors' research included participants of the multicenter African Descent and Glaucoma Evaluation Study and the Diagnostic Innovations in Glaucoma Study. The testing protocols of those studies were identical.

The healthy group (68 patients) contributed 132 eyes, and the glaucoma group (115 patients) consisted of 165 eyes. At baseline, the global mean peripapillary choroidal thickness (PCT) was significantly greater for healthy controls: 155.7  $\pm$  64.8  $\mu m$  vs. 141.7  $\pm$ 66.3 μm for patients with glaucoma (p < .001). However, when age was factored into the model, the difference was not significant (p = .38). Every eye was imaged by SD-OCT on at least 3 days. The San Diego Automated Layer Segmentation Algorithm was used to automatically segment and measure PCT from circle scans centered on the optic nerve head. Mixed-effects models were applied to calculate the rate of PCT thinning. The median follow-up time was 2.6 years.

In both study groups, PCT decreased significantly over time:  $-2.18 \mu m$  per year in controls and  $-1.88 \mu m$  per year in patients with glaucoma. Similarly, both groups had significant decreases in PCT percentage over time: -3.32% for controls and -2.85% for patients with glaucoma. However, the mean rate of PCT change over time was similar for the study groups, as was the change in PCT percentage.

Despite the observed similarities, the authors emphasized that longer follow-up is needed to determine with certainty whether monitoring the rate of PCT change has a role in glaucoma management.

### Do Experts Agree on the Diagnoses Assigned to Uveitis Cases? February 2018

Jabs et al. conducted an interobserver study to ascertain the level of expert

agreement on diagnoses assigned to cases of uveitis. They found that independent assessment yielded only moderate agreement, which improved greatly after conference calls with colleagues.

For their study, 5 committees (each with 9 uveitis experts) reviewed a total of 5,766 cases from a preliminary database representing 25 uveitic diseases. Initially, the experts voted online, independently, on whether each case coincided with its assigned diagnosis. The agreement statistic ( $\kappa$ ) was calculated for 36 pairwise comparisons per disease, and the mean κ was calculated for each disease. After independent voting, committees held consensus conference calls to discuss the cases that lacked supermajority agreement, defined as > 75%. Nominal group techniques were applied to attempt to reach the targeted level of agreement.

The mean k achieved from independent voting was 0.39, denoting moderate agreement. Disease-specific variation ranged from 0.23 (for toxoplasmic retinitis) to 0.79 (for cytomegalovirus anterior uveitis). After the conference calls, supermajority agreement was attained for approximately 99% of cases, with disease-specific variations ranging from 96% to 100%. The remaining cases (approximately 1%) were permanently "tabled." Ultimately, 71% of the cases evaluated were accepted into the final database and 28% were rejected. Acceptance rates ranged from 42% for herpes simplex anterior uveitis to 92% for serpiginous-like tuberculous choroiditis. Throughout the study, perfect agreement ( $\kappa = 1.00$ ) was achieved by only 1 pair of experts. For several diseases, the agreement of at least 1 pair of experts was essentially "chance alone."

Although diagnostic agreement was only moderate early in the study, it was improved by collaborative discussion. Only during the conference calls did many essential disease-specific acceptance/rejection criteria begin to emerge. The obstacles to consensus that arose in this study indicate the need for clear, validated, widely accepted classification criteria for uveitic conditions. With better criteria, the data derived from case series, cohort studies, and

multicenter trials should become more homogeneous and thus more useful for establishing accurate diagnoses.

-Summaries by Lynda Seminara

### JAMA Ophthalmology

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

### **Risk of Intraocular Bleeding** With Novel Antithrombotics February 2018

Novel oral anticoagulation and antiplatelet therapies have become popular in the treatment of thromboembolic disease, but their ocular safety profiles are uncertain. Uyhazi et al. compared the risk of intraocular hemorrhage between novel and traditional antithrombotic agents and found that bleeding rates were no worse with the newer medications.

For their retrospective study, the authors utilized a large national insurance claims database to generate 2 parallel analyses. First, incident use of dabigatran etexilate or rivaroxaban was compared with incident use of warfarin sodium. For the second analysis, new use of prasugrel hydrochloride was compared with new use of clopidogrel bisulfate. Patients with previous intraocular hemorrhage or a prescription for the comparator drug were excluded from the study. The main outcome measure was the incidence of intraocular hemorrhage within 90 days and 365 days. Multivariate regression models were applied to compare hazard ratios for developing intraocular hemorrhage.

Data were compared for 146,137 patients who took warfarin (mean age, 69.8 years) and 64,291 patients who took dabigatran or rivaroxaban (mean age, 67.6 years) The hazard ratio for hemorrhage development was lower with dabigatran or rivaroxaban versus warfarin at 365 days (0.75) but not at 90 days (0.73). Data for the 103,796 patients taking clopidogrel (mean age, 68.0 years) and the 8,386 patients taking prasugrel (mean age, 61.0 years) did not show a greater risk of intraocular hemorrhage with prasugrel at either 90 or 365 days.

The authors emphasized that the

growing use of novel antithrombotics for coronary conditions requires greater understanding of ocular safety profiles. Their findings suggest that the risk of intraocular hemorrhage is lower with dabigatran etexilate and rivaroxaban than with warfarin and is similar for prasugrel hydrochloride and clopidogrel bisulfate. Additional studies are needed to fully characterize the ocular safety profiles of the new antithrombotic agents. (Also see related commentary by Daniel Caldeira, MD, *PhD*, *in the same issue.*)

### **Ophthalmologists' Adoption and** Perceptions of EHRs February 2018

Lim et al. looked at rates of electronic health record (EHR) use among ophthalmologists and gathered EHR-related financial and clinical opinions from these specialists. They found that, although EHR adoption has increased in recent years, ophthalmologists continue to express concerns about the systems.

For their study, the authors used a population-based, cross-sectional, random sample of 2,000 ophthalmologists. The sample was obtained from the Academy's 2015 active membership database (U.S. members), and the research was conducted in 2015 and 2016. A survey was emailed to each ophthalmologist to inquire about adoption of the EHR, perceptions of financial and clinical productivity related to EHRs, and involvement in Medicare/ Medicaid programs that offer incentives for EHR use.

Among the 348 ophthalmologists who responded, 72.1% were currently using an EHR system. This rate is substantially higher than in a 2011 survey (47% adoption rate) and is similar to that for primary care physicians (79% adoption rate). Most respondents believe that EHR use contributed to declines in productivity and net revenue and to higher practice-related costs. Of the respondents who attested to stage 1 of the EHR meaningful use incentive program, 83% planned to attest to stage 2.

Most respondents are of the opinion that EHR use has not affected the ability to capture charges for office visits,

procedures, and tests. One-fourth of the surveyed specialists believe the EHR system has improved their ability to provide quality care, but 35% suspect that paper records are more conducive to delivering quality care. Most respondents noted that patients' attitudes toward the EHR are either positive or neutral. Subanalyses of data by the number of years in practice showed no statistically significant differences between junior and senior ophthalmologists.

These results suggest that the EHR system needs modification to optimize its value for ophthalmologists. Ideally, the utility of the record itself should be improved, and the government's requirements for using it meaningfully should be clarified and incorporated. (Also see related commentary by Jennifer S. Weizer, MD, Joshua R. Ehrlich, MD, MPH, and Paul P. Lee, MD, JD, in the *same issue.*)

### **Binocular Video Game for** Unilateral Amblyopia February 2018

Binocular treatment of amblyopia by contrast-rebalanced stimuli has shown promise in laboratory studies and is being investigated in real-world settings. Gao et al. compared a binocular video game with a placebo version. They found that the binocular game was not superior for improving visual function.

The multicenter, double-masked, randomized clinical trial included 115 participants aged 7 to 55 years (mean, 21.5 years). All had unilateral amblyopia caused by anisometropia, strabismus, or both; the visual acuity of the amblyopic eye was 0.30 to 1.00 logMAR (Snellen equivalent, 20/40 to 20/200). Eighty-nine participants (77.4%) had previously undergone occlusion or penalization therapy. Patients were classified by age group and were assigned randomly to play the active-treatment (binocular) video game or the placebo game.

The Falling Blocks game was used in both study arms and was played at home on an iPod Touch. The activetreatment game split visual elements between the eyes, with a dichoptic contrast offset, whereas the placebo game presented identical images to both eyes. Patients were instructed to play the game for 1 hour a day for 6 weeks. The main outcome measure was change in visual acuity of the amblyopic eye from baseline through week 6. Secondary outcomes included compliance, stereoacuity, and interocular suppression.

The mean (SD) visual acuity of the amblyopic eye improved 0.06 (0.12) logMAR (3 letters) from baseline in the active-treatment group and 0.07 (0.10) logMAR (3.5 letters) in the placebo group. Compliance with at least 25% of prescribed play was achieved by 64% of the active-treatment group and by 83% of the placebo group. By 6 weeks, fellow-eye contrast > 0.9 was attained in 36 active-arm participants (64%). There were 3 reports of asthenopia (2 in the active-treatment group), which was transient, and no reports of diplopia. There were no significant differences between groups for any primary or secondary outcomes.

Various requisites presumably should be satisfied before binocular video games are ready for clinical use. These include robust effectiveness data from randomized trials; sophisticated methods to monitor compliance; and development of more engaging games, aimed at improving compliance and effectiveness. (*Also see related commentary by Jonathan M. Holmes, BM, BCh, in the same issue.*)

—Summaries by Lynda Seminara

### **OTHER JOURNALS**

Selected by Deepak P. Edward, MD

### Visual Structure and Function of Athletes in Collision Sports

Journal of Neuro-Ophthalmology Published online Sept. 6, 2017

Vision-based measures are known markers for Alzheimer disease, multiple sclerosis, and Parkinson disease, and they may aid in understanding associations between repetitive head trauma and neurodegenerative sequelae. In a comparison study of athletes in collision sports and matched controls, **Leong et al.** noted substantial retinal axonal and neuronal loss in the athletes, along with reduced visual function and quality of life (QOL). Patterns were similar to those of the above-mentioned neurologic diseases.

In their cross-sectional study, the authors compared 46 professional athletes (active or retired) with 104 age/ race-matched healthy controls who had not participated in collision sports. All study participants received spectraldomain optical coherence tomography (SD-OCT) to measure thickness of the peripapillary retinal nerve fiber layer (RNFL) and the macular ganglion cell complex. High-contrast visual acuity (100% level) and low-contrast letter acuity (1.25% and 2.5% levels) were determined, and the King-Devick test of rapid number naming was administered. Vision-specific measures of QOL also were assessed.

On average, the RNFL of athletes (14 boxers, 29 football players, and 3 ice hockey players) was 4.8  $\mu$ m thinner than that of controls. RNFL thinning was highest for boxers (10.8  $\mu$ m vs. controls). Binocular and monocular low-contrast letter acuity at 2.5% contrast, as well as vision-specific QOL, differed significantly between athletes and controls. Performance time for rapid number naming was similar for the study groups.

Trauma-related vision changes that are detectable in vivo represent a unique opportunity to study related mechanisms of neurodegeneration. In future research, the authors plan to assess fluid biomarkers and apply imaging and cognitive measures of evaluation. Longitudinal examination will help determine whether structural and functional deficiencies signal neurodegeneration. Such knowledge will be important for establishing outcome measures in trials of drugs that target neuroprotection.

### Galcanezumab for Episodic Migraine

JAMA Neurology Published online Dec. 18, 2017

Current medications for migraine have variable efficacy, low adherence, and considerable adverse events (AEs). Recent studies have shown that calcitonin gene-related peptide is involved in migraine pathophysiology, which has prompted interest in monoclonal antibodies such as galcanezumab as preventive therapy. In a phase 2b trial, **Skljarevski et al.** compared various monthly doses of galcanezumab with placebo and found that the 120-mg dose of the drug was well tolerated and reduced migraine frequency.

The trial was conducted in 2014 and 2015 by 37 physicians in the United States. It consisted of 4 periods: screening/washout, prospective baseline (to determine migraine headache days [MHDs]), double-blind treatment, and post-treatment. The primary endpoint was superiority to placebo, evidenced by reduction in MHDs, from baseline to 9 or 12 weeks. Short-term migraine treatments—excluding opioids and barbiturates—were permitted during the trial.

The 410 enrollees (83% female) had onset of episodic migraine before 50 years of age and were experiencing 4 to 14 MHDs per month. Participants were assigned randomly (2:1:1:1:1) to receive monthly subcutaneous injection of placebo or galcanezumab (5, 50, 120, or 300 mg) for 3 months.

Period 3 of the trial was completed by 375 patients (galcanezumab, n = 249; placebo, n = 126). By month 3 of treatment, the 120-mg dose of galcanezumab had significantly reduced MHDs (-4.8 MHDs; -5.4 to -4.2 MHDs) versus placebo (-3.7 MHDs; -4.1 to -3.2 MHDs). From baseline to month 3, both the 120- and 300-mg doses of galcanezumab were more effective than placebo in reducing the overall number of MHDs. The frequency of treatmentemergent AEs was comparable for active-treatment groups. The most common AEs were upper respiratory tract infection, pain at the injection site, nasopharyngitis, nausea, and dysmenorrhea.

The authors cautioned that the small sample size precludes definitive conclusions about the safety of galcanezumab. However, they encouraged phase 3 investigation of varying doses of the drug to further assess its safety and efficacy for episodic migraine.

—Summaries by Lynda Seminara



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### COMPREHENSIVE

### Retinal TIAs: A Medical Emergency

any ophthalmologists consider retinal TIA (transient ischemic attack), or amaurosis fugax, to be a relatively benign condition that carries a low risk of stroke. But transient monocular vision loss (TMVL) of vascular origin has the same mechanisms and causes as cerebral ischemia —and, unfortunately, the same systemic implications.

Moreover, new evidence is challenging the old teaching that retinal TIAs have a better prognosis than hemispheric/ cerebral TIAs, highlighting the need to treat the conditions with equal urgency.<sup>1,2</sup>

In other words, retinal TIAs need to be taken as seriously as cerebral TIAs are, as they carry a high risk of stroke and cardiac events—and their occurrence calls for immediate evaluation and, when required, urgent referral.

### What Is a TIA?

Previously, the definition of TIA was entirely time-based: That is, patients with spontaneous acute visual loss or neurologic deficits were considered to have a TIA if the deficit lasted under 24 hours.

Today, however, the definition of TIA is tissue-based and includes the absence of ischemia on funduscopic examination and on brain magnetic resonance imaging (MRI) performed with diffusion-weighted imaging (DWI), which indicates that DWI-MRI needs to be performed. According to the stroke association, a TIA plus a positive DWI-MRI is a stroke (Fig. 1).

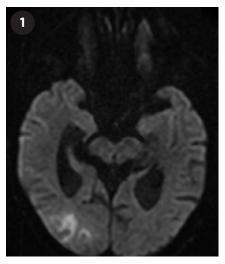
### Why Worry?

Data published over the past decade in the neurology and emergency medicine literature have demonstrated the need for a prompt stroke workup in all patients with acute cerebral and ocular ischemia. Unfortunately, many ophthalmologists are unaware of how urgent the disposition should be, said Jonathan D. Trobe, MD, at the University of Michigan in Ann Arbor.

Warning sign. Dr. Trobe urged ophthalmologists to recognize that a retinal TIA is a warning sign of possible impending stroke, especially in patients older than 50 years or those who have other conventional risk factors for stroke, such as high blood pressure, smoking, elevated blood lipids, ischemic heart disease, obesity, and family history of premature ischemic heart disease, hypertension, or stroke.

**Poor prognosis.** Not only is there a clear connection between retinal TIA and stroke, but recent research also demonstrates that retinal arterial ischemia (both transient and fixed) carries almost the same overall poor vascular prognosis as cerebral ischemia.

**Don't delay.** To date, the average time from onset of TIA to treatment



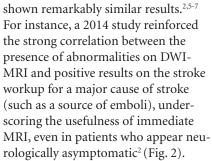
**NOT BENIGN.** According to the American Stroke Association, a retinal TIA plus positive findings on DWI-MRI equals a stroke.

has tended to be much longer for retinal TIAs than for cerebral TIAs (48.5 vs. 15.2 days in a 1995 study).<sup>3</sup> Likewise, a 2012 Canadian study showed that carotid stenosis surgery is often delayed by 1-2 months when the symptom is a retinal TIA.<sup>4</sup>

Beware asymptomatic strokes. In a 2012 study, approximately 1 of every 4 patients with acute retinal ischemia had acute brain infarctions on DWI.<sup>1</sup> In other words, there was evidence of an asymptomatic stroke. "Although this study was published in a major neurology journal, it has remained largely unnoticed by eye care providers," said Valérie Biousse, MD, at Emory University School of Medicine in Atlanta.

More recent studies in both the stroke and ophthalmic literature have

Prem S. Subramanian, MD, PhD



The big picture. "Increased awareness of the dangers of retinal TIAs should change the practice of eye care providers," said Dr. Biousse. "I am not saying that ophthalmologists should send every patient with TMVL for an MRI. I am saying that they need to take the time to identify the small subgroup of TMVL cases that appear to be vascular and refer those to a stroke center immediately."

"It may seem like a big leap, but the most recent evidence demonstrates that up to 25%-30% of MRIs on people who have had retinal TIAs will show the same acute changes in the brain on DWI sequences that we see in patients who have had hemispheric TIAs with transient weakness or loss of speech," said Prem S. Subramanian, MD, PhD, at the University of Colorado School of Medicine in Aurora.

He added, "This is the same percentage as hemispheric TIA patients, and we send those patients for an immediate stroke workup without question; it's standard treatment. We need to do the same for retinal TIAs."

### Is It a Vascular Event?

When you see patients with TMVL, the greatest challenge will be to identify the small subgroup of patients with TMVL of vascular origin. Because the vision loss is transient, by the time the ophthalmologist sees the patient, most of the time the patient is fine and the eye exam is normal.

Listen to the patient. "The only way to know [whether your patient is at elevated risk] is to spend a lot of time with the patient and to do a very thorough eye exam," said Dr. Biousse. "Nowadays, ophthalmologists don't have the time. That's why having a systematic approach to this symptom is so important."

Assess symptoms. Transient vascular

events tend to last a few minutes but not more than 60-90 minutes (if an event lasted longer, it would likely leave some permanent damage). They tend to be painless and come on within seconds. The vision goes "black" or "gray" or "dim." Some patients describe a "curtain over the eye" effect where the vision loss seems to close in from one direction.

"If there are positive symptoms like sparks and flashes and colors, that's rarely a vascular occlusive event," said Dr. Subramanian. Vascular TMVL has more negative symptoms. "If the dimness restores over the course of a minute or so, as what we presume is a little clot dissolving and the blood flow returning, that's suggestive of vascular origin," Dr. Subramanian said.

So, if a patient says, "My vision gets blurry sometimes and then it gets better," the patient doesn't have a retinal TIA. On the other hand, if he says, "I was fine, then had trouble seeing, then completely lost vision in 1 eye but it returned a minute or 2 later," this should raise your suspicion that a vascular process is involved. systemic symptoms of GCA (e.g., headache, jaw claudication, scalp tenderness, weight loss), then you can rule out GCA." If the lab results are abnormal, you should investigate further and potentially treat the patient with steroids until you have a definite diagnosis.

### **Refer to a Stroke Center**

If you've ruled out ocular causes or TMVL, the question remains: Do you obtain a workup for retinal TIA, and how do you do that?

At this point, follow the guidelines, Dr. Biousse stressed. "The guidelines from the heart and stroke associations are very clear. If you're an ophthalmologist, do not get any workup. You've done the differential diagnosis and ruled out GCA; you're done. This patient must go to a stroke neurologist promptly." She urged ophthalmologists to send the patient immediately to the closest emergency department (ED) affiliated with a stroke center (see next page).

The main difficulty when one sees a patient with a retinal or cerebral TIA is to identify which patients are at very

Ophthalmologists need to recognize that our thinking about stroke risk has changed. In a classic episode of amaurosis fugax, we have taught ophthalmologists to think about GCA, but they need to think about stroke as well. The patient is at significant risk for stroke, and the ophthalmologist can potentially save him or her from a devastating neurological event. —Dr. Subramanian

Assess risk factors. Take an inventory of the patient's vascular risk factors, as outlined by Dr. Trobe (see "Warning sign," previous page). If your patient is a 70-year-old with diabetes and hypertension, you'll probably fall on the side of assuming it's vascular until proven otherwise. You should also examine the patient for any vascular signs, perhaps a residual clot in the retina, though most often there is nothing.

Rule out GCA. The most important thing at this point is to make sure that any patient over age 50 does not have giant cell arteritis (GCA). "Get 3 quick blood tests: erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and complete blood count (CBC)," said Dr. Biousse. "If they are normal and the patient has a normal eye exam and no high risk of stroke or cardiovascular death. After any TIA, the risk of stroke is estimated at 10%-15% at about 3 months, explained Dr. Biousse. More than half of those patients who are going to have a stroke will have it within 48-72 hours of the TIA. "It makes no sense to wait a week for an MRI, because if the patient is still alive and has not had a stroke by then, there is a very good chance the patient will be fine," said Dr. Biousse.

On the other hand, if the patient happens to be one who is at very high risk of stroke, you will have missed the opportunity to prevent it. "This is why we tell ophthalmologists to send the patient to a stroke center where the entire workup is done within 24 hours," Dr. Biousse said.

### Set Up a Referral Pathway

Seek a stroke center. The experts urge ophthalmologists to take the time today to identify the closest stroke center to their practice. (For more information, see the Internet Stroke Center locator at www.strokecenter.org/trials/centers.)

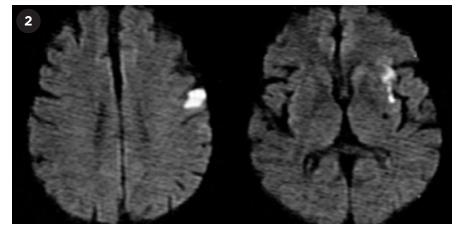
A stroke center is an urgent care facility in which there is 24/7 availability of neuroimaging and any ancillary testing necessary for a stroke patient and access to a stroke neurologist. "An enormous number of EDs in the United States have been certified as stroke centers," said Dr Biousse. "Even in remote areas, it is completely worth it to tell the patient to drive 80 miles to a stroke center instead of going to the closest ED 25 miles away. The extra hour of transportation will save a lot of money and energy [in the end] by helping providers reach a definitive diagnosis, whereas a local workup by physicians who are not experts in stroke neurology will only delay appropriate management."

**Establish contact.** "I recommend calling the stroke neurologist at the center and introducing yourself to establish a collaboration," said Dr. Biousse. "Tell the stroke neurologist that you are a local ophthalmologist and that occasionally you will see a patient with a retinal TIA (or central or branch retinal artery occlusion) and that you will tell the patient to come to his or her ED immediately for a stroke workup. Ask the stroke specialist to confirm that he or she will take care of your patient."

Dr. Biousse added, "Sometimes ophthalmologists will say that they can't send their patients to the ED because the ED does not want them, but it's because they are sending the patients to the wrong ED. Send them to one affiliated with a stroke center. A stroke neurologist will know that you are following current guidelines."

How to handle urgent referrals. If you see a retinal TIA patient within 1-2 days of the TMVL episode, the patient should be sent to the ED immediately, Dr. Biousse said.

When this happens, have a staff member call the ED triage nurse or the preestablished contact person to



**ASYMPTOMATIC.** Area of asymptomatic acute cerebral ischemia (in white) seen on DWI-MRI obtained 24 hours after an episode of TMVL in the left eye. The patient had no neurologic symptoms and was found to have left internal carotid artery dissection on a magnetic resonance angiogram.

say that you're sending over a patient who has had a "stroke in the eye" for an immediate workup and treatment by stroke neurology. Dr. Subramanian recommended sending the patient with a brief note, along the lines of "This patient had TMVL that I suspect is from ischemia. Patient has the following risk factors. Please evaluate for stroke risk." The stroke specialist will know you are not overreacting, Dr. Subramanian reiterated.

What if a week has passed? Ophthalmologists often see patients 1 week or more after the retinal TIA episode, and it can be more difficult to know what to do in these instances.

If the patient has had recurrent episodes of TMVL or has major cardiovascular risk factors (such as a recent mvocardial infarction or known arrhythmia), Dr. Biousse still sends the patient to the ED. In other situations, she just calls the stroke neurologist she works with (or the one on call) and asks him or her what is best and most efficient. "The answer will vary greatly depending on where you work, who is on call, what day of the week it is, and what time it is," said Dr. Biousse. "As long as the stroke neurologist agrees to see the patient within a day or 2 and helps coordinate the necessary tests, I am fine waiting."

Even so, Dr. Biousse always starts the patient on an antiplatelet agent and warns the patient about stroke symptoms and signs. She gives the patient the address of the closest stroke center and tells him or her to go to the affiliated ED immediately if another episode of TMVL occurs or any neurologic symptoms are noted. Dr. Subramanian manages his patients in a similar manner.

What the patient can expect. When patients arrive at the ED saying they've had a "stroke in the eye," they are immediately put in a bed, often in the ED. They can expect to receive cardiac monitoring right away, along with blood tests, an EKG, and a consultation with a stroke neurologist. Within the next 23 hours, they will have brain and vascular imaging.

Depending on the evaluation, the patient may then undergo echocardiography to look for a cardiac source of emboli and, at the same time, the aortic arch will be evaluated. If one of the tests is abnormal, the patient will immediately be admitted to a stroke unit and treated appropriately.

If all the tests come back negative, the stroke neurologist will make recommendations for medical treatment/ secondary prevention of stroke, and the patient will be discharged with a scheduled follow-up with the neurologist. "The patient is safe, everything is done quickly, and the ophthalmologist doesn't have to worry about getting any of those tests," said Dr. Biousse.

Even though this approach might sound aggressive, the reality is that it is not, Dr. Biousse insisted. "It is the current recommended practice so that you



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can prevent a devastating neurological and/or cardiovascular event, without wasting your own time trying to evaluate something you are not trained to evaluate." This advice is reflected in the Academy's Retinal and Ophthalmic Artery Occlusions Preferred Practice Pattern (aao.org/preferred-practicepattern/retinal-ophthalmic-arteryocclusions-ppp-2016).

A note on incidence. Dr. Biousse sees about 1-2 patients a week with TMVL. Of those, she sends maybe 1 a month to the ED. Dr. Subramanian estimated that a busy comprehensive practice may see 1 retinal TIA every 1-2 weeks.

Thus, there is no need to worry that you will overwhelm the local ED, Dr. Subramanian said. Instead, the experts advised, just focus on the quality of the initial clinical evaluation and slow down during this phase so that you can confidently rule out ocular causes.

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Dr. Subramanian is professor of ophthalmology, neurology, and neurosurgery; vice chair for academic affairs in ophthalmology; and chief of the Neuro-ophthalmology Division at the University of Colorado School of Medicine in Aurora. Relevant financial disclosures: None.

Dr. Trobe is professor of ophthalmology and visual sciences, neurology, and neurosurgery, and co-director of the Kellogg Eye Center for International Ophthalmology at the University of Michigan in Ann Arbor. Relevant financial disclosures: None.

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### RETINA/VITREOUS

### To Treat—or Not to Treat—Vitreous Floaters

Pick virtually any ophthalmologist's practice and you'll find patients who complain of vitreous floaters. When, if ever, should these patients receive treatment? Like most of his colleagues, Chirag P. Shah, MD, MPH, with Ophthalmic Consultants of Boston, prefers observation in 99.9% of these cases. "However," he said, "I do think that paradigm is slowly changing."

A combination of more sophisticated patient selection and enhanced technology and techniques may be diminishing some concerns about the risks of surgery for vitreous floaters. And although a recent study<sup>1</sup> conducted by Dr. Shah also suggested that YAG vitreolysis may offer benefits for troublesome floaters, it also raises questions about its efficacy and safety, as well as the necessity for multiple costly sessions.

Three vitreoretinal surgeons offer their perspectives on whether, and how, to treat vitreous floaters.

### **Troublesome Vitreous Floaters**

Vitreous floaters may occur following a retinal tear, retinopexy, scleral buckling, or vitreous hemorrhage associated with a tear, said Gaurav K. Shah, MD, with The Retina Institute in St. Louis, Missouri. But most patients who experience vitreous floaters fall into 2 groups: those with a posterior vitreous detachment (PVD) or myopic vitreopathy.

**PVD and myopic vitreopathy.** People in their 50s, 60s, or 70s may develop



**BEFORE AND AFTER.** Laser treatment for a Weiss ring floater.

a PVD and have more significant floaters, said Dr. Chirag Shah. "Most of the time, patients can cope with them because the brain neuroadapts. But a certain percentage of patients continue to be bothered by the floaters." People in their 20s and 30s may also develop opacities in their vitreous as a result of myopia, said Jerry Sebag, MD, at VMR Institute for Vitreous Macula Retina in Huntington Beach, California.

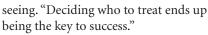
Impact of light. "Because the impact is greater in bright light, individuals with floaters—often younger people typically complain about the inability to work long hours on computers," said Dr. Sebag. In addition, snow reflections, bright skies, and looking at the ocean may be bothersome. "I've had patients tell me they've stopped camping, fishing, or skiing because they no longer find these activities pleasurable. Some even tell me they can't wait to go to sleep at night."

Why worse for some? Why some people are more afflicted than others is not fully understood, said Dr. Sebag. It may be connected to more than 1 factor, he said, such as biochemistry and the effects of aging, genetics, hormones, and the ability to neuroadapt. "For example, some have a denser posterior vitreous cortex, and these people won't be able to adapt well to their floaters."

What is clear, he said, is that many of these patients feel ignored by the medical profession. "What they are complaining about may not fit neatly into our diagnostic boxes, but that doesn't mean they don't have a problem."

#### **Evaluating Vitreous Floaters**

Fewer than 5% of Dr. Chirag Shah's patients complain of floaters. Given that not all floaters are created equally, he said, it's important to demonstrate a correlation between what the patient is experiencing and what the physician is



**Basic exams.** Why do physicians underestimate serious symptoms of vitreous floaters? "One reason is that we usually check patients' visual acuity and visual fields," said Dr. Chirag Shah, "but we don't check contrast sensitivity, which can be degraded by significant floaters." Also, floaters may move into the patient's central vision, affecting their ability to read or drive, but doctors rarely check reading speed.

Dr. Sebag was the first to discover that patients with significant vitreous floaters are bothered with decreased contrast sensitivity function.<sup>2-4</sup> He coined the diagnostic term "visiondegrading vitreopathy" to help distinguish debilitating floaters from those that are relatively benign. "Screening with vitreous-specific questionnaires, structural assessments with ultrasound, and contrast sensitivity functional (CSF) assessments give me the ability to diagnose vision-degrading vitreopathy and make me more comfortable about offering treatment," he said.

**Floaters questionnaire.** Dr. Sebag and colleagues devised a screening tool called the Vitreous Floaters Functional Questionnaire (VFFQ) to help evaluate the impact of floaters on patients' quality of life. "We've shown a statistically significant correlation between the VFFQ and the National Eye Institute's (NEI's) Visual Function Questionnaire, a gold standard for assessing vision in more general terms," he said. In addition, there is a high correlation among the results of the VFFQ and CSF and the density of the vitreous body as assessed by ultrasound.

**Contrast sensitivity function.** A CSF assessment provides a functional evaluation of the impact of vitreous (as well as cornea or lens) opacification on vision, by measuring the ability to distinguish shades of gray, said Dr. Sebag. One of his studies found that patients with bothersome floaters had a 67% reduction in CSF compared with age-matched controls.<sup>2</sup>

"These days, I never operate on someone with normal CSF," said Dr. Sebag. More than 140 patients with abnormal CSF on whom he has performed vitrectomy attained normal CSF within 1 week of surgery.<sup>2-4</sup> Dr. Sebag has followed these patients for an average of nearly 3 years; during this time, their CSF has remained normal.

**Quantitative ultrasound (QUS).** Dr. Sebag also advocates the use of quantitative ultrasound, which gives an index of the structure of the vitreous body. "The quantitative ultrasound measurements we perform clearly show that the greater the density of the vitreous, the more patients are bothered by their floaters," he said. He added that QUS is also a useful way to show patients what's going on inside their eyes and to assess the effectiveness of vitrectomy.

Wide-angle color photography. In his clinical study, Dr. Chirag Shah used wide-angle color photography to visualize floaters. "Oftentimes, patients would look at their color photographs and say, 'That's the bug-like floater that keeps going in and out of my vision," he said. "If a patient had significant symptoms but the photograph was crystal clear except for a few normal vitreous wisps, that patient may not be easy to satisfy."

**OCT.** To assess floaters, Dr. Gaurav Shah takes optical coherence tomography (OCT) infrared video scans. "This allows us to see what the patients are seeing," he said. "If I do a video scan and don't see much, the patient's symptoms are not from the eye, and I won't treat them with vitrectomy. If patients truly have something, it is a very dramatic demonstration of their symptoms."

### Vitrectomy for Troublesome Floaters

"Vitrectomy is valuable for some patients with floaters, but I tend to reserve it only for those with the most debilitating floaters because of the potential side-effect profile," said Dr. Chirag Shah. Vitrectomy is invasive, agreed Dr. Gaurav Shah. "But it has evolved and been vindicated by improvements in technology and technique. My patients have been ecstatic with the results, although it's first critical to determine that they are truly symptomatic and have been given a chance to neuroadapt or to allow the floaters to resolve."

Exclusion criteria. Dr. Sebag uses the

VFFQ, CSF, and QUS to select the best candidates for vitrectomy. "I don't take surgery lightly," he said, explaining that he's performed only about 200 surgical floater cases in over 8 years. "I rarely meet someone and say, 'Let's operate."" In fact, he said the average time between the first onset of symptoms and surgery is more than 30 months.

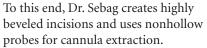
Dr. Gaurav Shah uses slightly different criteria for excluding patients. "I exclude patients who are phakic, who have 360 degrees of lattice or a lot of peripheral retinal problems, or who have expectations that are way beyond what the surgery can provide." To help assess expectations, he asks his patients, "If you are driving on a road and the entire windshield is clear except for one little spot, does that bother you?" If the answer is "yes," he is more concerned about the ability to please the patient with surgery.

**Risks of vitrectomy.** "With vitrectomy, you are creating 3 holes in the eye," said Dr. Chirag Shah, "which carries a small risk of infection." Vitrectomy also accelerates cataract formation, because of increased oxygen concentration in the vitreous cavity following removal of the vitreous. "But for me, retinal detachment is the most concerning risk, with published reports as high as 10.9%," he said.

Presenting vitrectomy findings from 151 eyes at the 2016 Academy annual meeting, Dr. Sebag reported no cases of endophthalmitis or hypotony; 1 case each of glaucoma, cystoid macular edema, and retinal break; 2 cases of retinal detachments that were surgically corrected; and 6 cases of vitreous hemorrhage, which all cleared spontaneously.

**Reducing risks.** Dr. Gaurav Shah has found that being discerning in choosing patients has resulted in fewer complications. Operating on 5 to 10 floaters patients last year, he has had no patients experience retinal tears or detachments. The key, he said, is 27-gauge topical vitrectomy, which minimizes complications with blocks and intraoperative issues. Dr. Sebag also credits the development of sutureless, smallgauge vitrectomy in reducing risks, as well as a couple of other techniques.

Reduce risk of endophthalmitis.



Leave a little vitreous. "I have modified my approach by leaving a few millimeters of vitreous behind the lens. The antioxidants in the vitreous gel help mitigate cataract formation," Dr. Sebag said. He and his colleagues compared the incidence of cataract using this modified approach with extensive vitrectomy, which is used at the University of Amsterdam. At 24 months, the incidence of cataract was 35% with the modified approach and 87% with the extensive approach. The time until cataract formation was also 5 months longer with a limited vitrectomy.<sup>5</sup>

Two philosophies on surgical PVD. Younger patients have vitreous floaters because of collagen cross-linking in the vitreous body, not because of PVD, said Dr. Sebag. To reduce the risk of tears in these patients, he recommends simply removing the central vitreous and not separating the posterior vitreous from the retina. By contrast, Dr. Gaurav Shah said that he always creates a complete PVD because he's concerned that contracture of the residual cortical vitreous may cause problems in the future. That has not been the case in Dr. Sebag's experience of 200 cases, where only 1% experienced retinal detachment.

### YAG Laser Vitreolysis for Troublesome Floaters

Before conducting the first randomized clinical trial of YAG vitreolysis for symptomatic Weiss ring floaters, Dr. Chirag Shah wondered whether lasers could provide a niche between performing vitrectomy and doing nothing. "I was very skeptical going into the study, and I'm not currently performing this procedure," he said, "but the study has shown me that YAG vitreolysis may have some value."

Laser study results. In the trial, 54% of the laser group reported symptom improvement after 1 treatment. In addition, no differences in adverse events were identified between the laser and sham groups.<sup>1</sup> "We need to do larger studies of longer duration to determine the best candidates and the number of treatments needed, as well as [the treat-

ment's] true risks and benefits," said Dr. Chirag Shah.

Although more than half of the patients in Dr. Chirag Shah's study reported significant or complete resolution of their vitreous floaters, only about one-third of patients in an earlier study by Delaney et al. reported similar results.<sup>6</sup> "We used a higher laser power in our study, which may account for the differences in response," said Dr. Chirag Shah. "At a lower power, you're doing more fractionating, but when you turn the power up, you form plasma and can see the tissue vaporize into gas bubbles."

Dr. Sebag, however, disputes this assertion, saying that YAG laser does not vaporize tissue. "YAG lasers are photodisruptors," he said. "They take something large and break it into smaller pieces."

Anomalous? In Dr. Chirag Shah's trial, 8 patients self-reported zero improvement out of a scale of 100 despite color photography showing significant or complete objective improvement. "Some patients recognized that the floater was virtually gone, but a little speck that was mobile, possibly more than previously, annoyed them to the same degree as their large floater did," he said.

**Exclusion criteria.** In Dr. Chirag Shah's study, the following patients were excluded: those with Snellen best-corrected visual acuity worse than 20/50 in the nonstudy eye; history of retinal tear, retinal detachment, uveitis, diabetic retinopathy, macular edema, retinal vein occlusion, or aphakia in the study eye; and history of glaucoma or high intraocular pressure.

**Risks and costs of laser.** "To my knowledge, just a handful of doctors are doing YAG vitreolysis, and with variable results," said Dr. Chirag Shah. With no dedicated insurance code, the procedure is done off-label, he said. In his study, Dr. Chirag Shah only did 1 treatment session because he could not treat patients with 2 sham lasers without unmasking them. "In the real world, patients may require 2 or more laser sessions to vaporize the majority of their floaters."

With YAG vitreolysis, there is a risk of glaucoma, retinal tear, retinal detach-

ment, cataract if you hit the lens, and retinal damage if you hit the retina, said Dr. Chirag Shah. To minimize risks of lens or retinal damage, he recommends ensuring a safe distance between the focal point of the laser and the retina and crystalline lens. In the study, he required the Weiss ring floater to be 5 mm posterior to the posterior capsule of the crystalline lens and 3 mm anterior of the retina, as measured by B-scan ultrasonography.

Dr. Gaurav Shah has not personally used laser for floaters but is concerned that it may be a time-consuming procedure, and he noted, "Although laser appeared quite safe in this recent laser study, it may have potential drawbacks."

He added, "It's important to remember that the vast majority of patients don't require intervention. However, there are those who are truly symptomatic and might require a procedure and, even more importantly, [who may benefit from] a conversation that acknowledges their pathology."

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**Dr. Gaurav Shah** is a retina specialist and codirector of the retina fellowship at The Retina Institute in St. Louis, Mo. *Relevant financial disclosures: None.* 

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# OPHTHALMIC PEARLS

# Iridocyclectomy: Surgical Technique

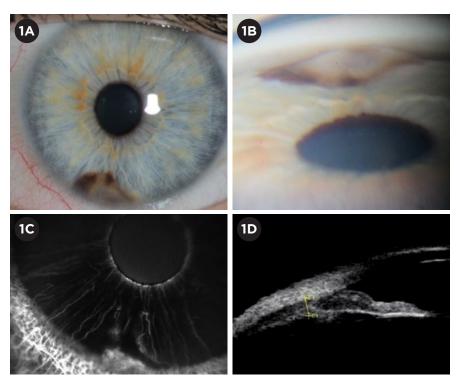
ris tumors and their simulating conditions are amenable to excisional biopsy<sup>1,2</sup> depending upon the size, location, and suspected clinical diagnosis.<sup>3-6</sup> Where indicated, surgical excision for localized iris melanoma has the advantage of providing diagnosis, prognosis, and treatment with a single surgical procedure.<sup>7</sup> The surgical excision can be limited to the iris (iridectomy) or ciliary body (cyclectomy), or it may involve a combination of both tissues (iridocyclectomy).

### **Surgical Steps**

The surgical technique of iridocyclectomy can be considered as a sequence of steps, including those below. (For an accompanying video, go to aao. org/clinical-video/iridocyclectomytechnique-tumor-excision.)

**1. Conjunctival flap.** The conjunctival flap extends at least 1 clock hour beyond the limits of the proposed outer scleral flap. In general, a fornix-based conjunctival flap is preferred over a limbus-based approach, as it offers a better view of the inner scleral/corneal incisions. A conjunctival flap may not be required if the incision to access the anterior chamber is at the limbus, such as during iridectomy.<sup>1-3, 8-10</sup>

**2. Outer scleral flap.** The size and location of the outer scleral flap is determined by the size and location of the tumor as confirmed by preoperative



**BEFORE THE PROCEDURE.** A 37-year-old Caucasian woman had an iris lesion since age 16, and her optometrist noted that it had enlarged. Visual acuity was 20/20 in both eyes with normal intraocular pressures bilaterally. Slit-lamp examination of the left eye disclosed mild corectopia and a pigmented iris lesion inferiorly measuring 4 mm x 3 mm x 2 mm (1A). On gonioscopy, the central aspect of the lesion had an amelanotic nodular component (1B). Anterior segment fluorescein angiogram revealed hyperfluorescence consistent with intrinsic vascularity (1C). Ultrasound biomicroscopy showed absence of ciliary body extension (1D).

ultrasound biomicroscopy and intraoperative transillumination. The flap is about 2 mm beyond the lateral and peripheral tumor margins. As an example, for a 4-mm-wide tumor, the ideal outer scleral flap will be 8 mm wide. The outer scleral flap is outlined on the sclera with a fine-tipped marking pen after the sclera is dried and bleeders are cauterized.

The depth is about 80%-90% of scleral thickness (1 mm near the limbus). The desired depth of incision can

BY **ARUN D. SINGH, MD, JORGE J. ECHEGARAY, MD,** AND **JAQUELINE DAVANZO, BSN.** EDITED BY SHARON FEKRAT, MD, AND INGRID U. SCOTT, MD, MPH.

be achieved by using a diamond blade. Once the plane of dissection of desired depth is created, the flap is reflected with a crescent blade. Optimal flap thickness is critical because a thin flap poses problems in achieving watertight wound closure while a thick flap will expose underlying uvea or tumor with resultant bleeding.

**3.** Inner scleral/corneal incision. The limits of the inner scleral flap should be constructed 1 mm smaller than the outer scleral flap (and 1 mm beyond the lateral and peripheral tumor margins). This 1-mm strip of overlap facilitates watertight wound closure.

The initial incision into the inner scleral flap is made with an upward cut using a microincision blade. The incision is then extended using fine scissors, which exposes the underlying ciliary body. The radial margins are extended up to the limbus and then circumferentially along the limbus by entering the anterior chamber with left and right cutting corneal scissors for about 2 mm beyond the visible tumor margin.

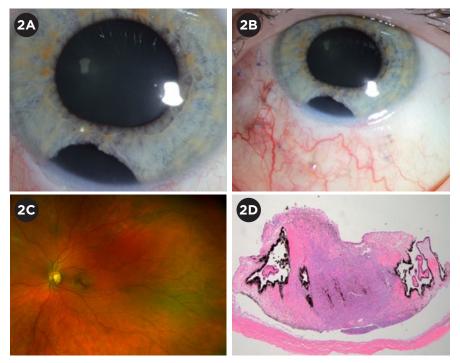
The inner scleral incision also is extended along the limbus, thereby freeing the inner scleral flap from the cornea. The anterior chamber can be stabilized with the use of viscoelastic at any stage during the procedure.

**4. Uveal incisions.** Once the inner scleral incisions are made as described above, the underlying ciliary body becomes visible. Cautery is applied to the ciliary body before it is incised.

The uveal incision is initiated from the iris by creating a small iridotomy 1 mm beyond the iris margin of the tumor with the possibility of sparing iris sphincter muscle. The iridotomy is converted to a peripheral iridectomy by extending the iridotomy toward the limbus incising a triangular portion of the peripheral iris and staying 1 mm beyond the visible tumor margin.

If the tumor is close to the pupillary margin or involves the pupil, then the incision is initiated from the pupil, creating a sector iridectomy.

The cornea is lifted gently by the assistant to provide adequate exposure, thereby avoiding contact with the corneal endothelium and the lens.



**AFTER THE PROCEDURE.** Our clinical impression was of an iris melanoma. After an explanation of the risks and benefits of the procedure, the patient agreed to proceed with our recommendation of iridocyclectomy. Two weeks postoperatively, the cornea was clear without hyphema (2A). The surgical site was well healed (2B). The posterior segment was normal without hemorrhage or retinal detachment (2C). Histopathology confirmed the presence of iris melanoma, of a mixed spindle cell and epithelioid type. Mitotic activity was inconspicuous. The tumor cells were MelanA and HMB45 positive (not shown). Central bluish-colored tumor with thin scleral flap along the base was flanked by normal ciliary processes on either side (2D). (Hematoxylin and Eosin, 40 x.)

The iris incisions are extended into the ciliary body corresponding to the limits of the inner scleral flap. Bleeding during this part of the surgery can be controlled by careful application of cautery or topical application of epinephrine (1 in 100,000), phenylephrine (2.5%), or thrombin (5,000 IU/mL).

Any uveal bulge or vitreous upthrust can be relieved by releasing any inadvertent pressure on the globe or by aspirating 0.1 mL of the vitreous through the pars plana (4 mm behind the limbus, using a 25-gauge short needle attached to a tuberculin syringe).

**5. Pupilloplasty.** In cases of large peripheral iridectomy or sector iridectomy (smaller than 1 clock hour), pupilloplasty is attempted with a 10-0 nylon suture using the modified Siepser technique.<sup>11</sup>

**6. Wound closure**. Meticulous watertight closure is achieved with 8-0 and 10-0 nylon sutures. Overlapping edges between the outer and inner scleral incisions facilitate good closure. At the end of the procedure, the anterior chamber should be of normal depth. Small residual hyphema can be left in the anterior chamber as it tends to absorb spontaneously without secondary complications.

### Discussion

The first reported case of iridocyclectomy is attributed to Zirm (1911)<sup>12</sup> and the early experience of iridocyclectomy from 1911-1970 has been reviewed elsewhere by Vail.<sup>13</sup> The technique reported herein has evolved over the years based upon the work of Stallard<sup>14</sup> and others.

The optimal outcome following iridocyclectomy requires careful selection of cases, familiarity with surgical steps, awareness of potential complications, and appropriate postoperative management. The surgical technique can be modified to perform iridectomy or cyclectomy alone, although iridocyclectomy is performed most often. Repair of a large corneoscleral incision has the potential for wound leak, hypotony, hyphema or hemorrhage, cataract, corneal edema, and astigmatism with visual recovery requiring up to 6 weeks or longer,<sup>10,15</sup> reminiscent of recovery after extracapsular cataract surgery.<sup>16</sup>

As uveal melanoma may extend into the overlying sclera,<sup>17</sup> creation of a partial-thickness scleral flap allows removal of melanoma cells that may be present in the inner sclera. This technique also obviates the need for a full wall resection, which requires use of graft material for closure.<sup>18</sup> In addition, a partial-thickness scleral flap allows watertight closure of the wound, minimizing the risk of hypotony. Excessive resection of ciliary body (more than half) is not recommended, as it may lead to chronic hypotony.<sup>19,20</sup>

The long-term functional results after iridocyclectomy are good, and complications and recurrences are rare.<sup>20-22</sup> Intraoperative hemorrhage is the most frequent complication, which can be minimized, although not completely avoided, with the use of hypotensive anesthesia, cautery, and diathermy of the uvea. Topical thrombin (5,000 IU/mL) is easy to apply and effective.

Potential for incomplete excision, lack of definite assessment of tumor margins,<sup>22</sup> and concerns for delayed recurrence<sup>20</sup> are important considerations before recommending iridocyclectomy. Such concerns are particularly valid for larger, posteriorly located tumors (choroidectomy).<sup>23</sup> Adjuvant use of radiation is associated with a lower risk of recurrence.<sup>23</sup>

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**MORE ONLINE.** To view the authors' acknowledgments of their colleagues, find this article online at aao.org/eyenet. For a video of the various steps of this procedure, from making the conjunctival and scleral flaps to closing the wound, visit aao. org/clinical-video/iridocyclectomy-technique-tumor-excision.



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- 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.
- 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 full US Prescribing Information for LUXTURNA on the following pages

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

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Brief Summary of Prescribing Information—Please see the LUXTURNA™ package insert for US full Prescribing Information

### **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 x 10<sup>11</sup> 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.

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

<u>Risk Summary</u>: 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

<u>Risk Summary</u>: 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* mutationassociated 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.

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



### 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.

<u>Permanent decline in visual acuity</u>: 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.

<u>Retinal abnormalities</u>: 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.

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

<u>Shedding of LUXTURNA</u>: 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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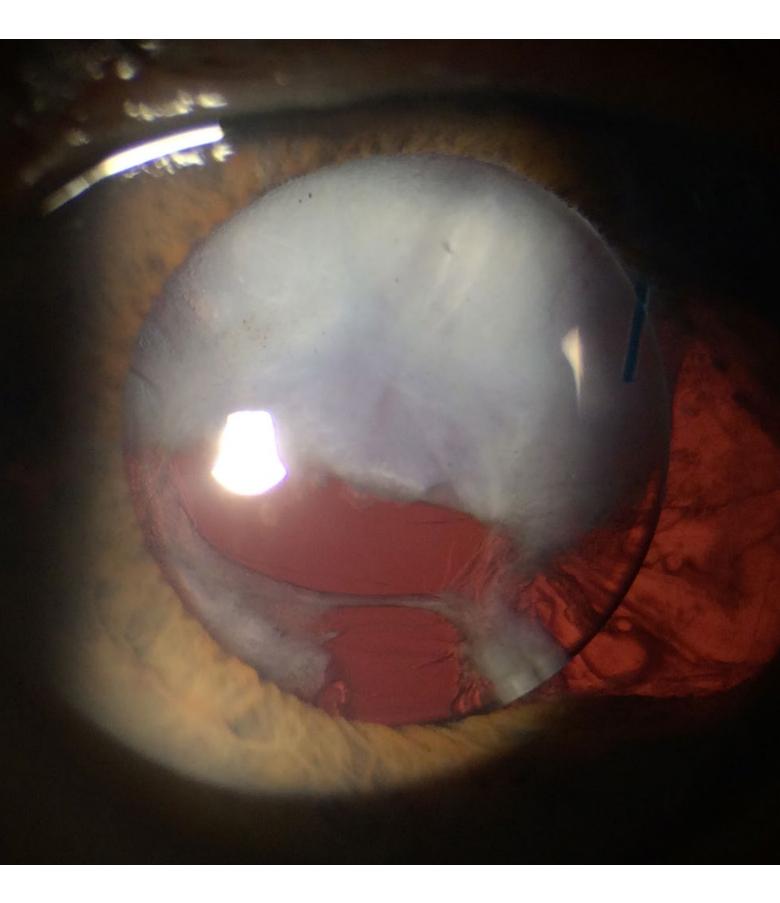
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# Cataract Complications

Eight difficult cases that require complex management decisions.

HIS PAST NOVEMBER, THE 16TH ANNUAL SPOTLIGHT ON CATARACT SURGERY Symposium at AAO 2017 was entitled "Clinical Decision-Making With Cataract Complications: You Make the Call." Cochaired by Mitchell P. Weikert, MD, and myself, this 4-hour symposium was organized around 8 video cases that presented a range of cataract surgical challenges and complications.

The 8 cases were selected from my own practice. As I presented the videos, I would pause at selected points to note a complication or introduce the need to make a management decision. The attendees were then asked to make clinical decisions using their electronic audience response keypads. This was followed by several rapid-fire didactic presentations by invited experts on topics of relevance to the case. Next, a rotating panel of 2 discussants (who had never viewed the case) was asked to make a management recommendation before the video of the outcome was shown. Following additional audience polling about preferences and practices, the 2 panelists would provide their own opinions and pearls.

In all, nearly 40 presenters and panelists spoke about a wide variety of topics, including managing a postvitrectomy cataract, posterior capsular rupture in a multifocal or toric IOL patient, traumatic cataracts, ultrabrunescent cataracts, small pupils, crowded anterior segments, unhappy multifocal IOL patients, iris prolapse, traumatic iris defects, and retained cortex. Alan S. Crandall, MD, concluded the symposium by delivering the 13th annual Academy Charles D. Kelman Lecture, "Phaco at 50: The Collision of Cataract and Glaucoma (Plus)."

This *EyeNet* article reports the results of the 35 audience response questions, accompanied by written commentary from the symposium speakers and panelists. The polled respondents included both the onsite audience and those viewing online. Because of the anonymous nature of this polling method, the audience opinions were candid, and they were discussed in real time during the symposium by our panelists. The entire symposium with videos and PowerPoint was viewed live online by a virtual audience; it also was captured for online archiving and can purchased as part of AAO Meetings on Demand (aao. org/store).

Cataract Monday continues to comprise a daylong, continuous series of cataract symposia. The afternoon featured the ASCRS cosponsored symposium, "Refractive Cataract Surgery Today: Maximizing Your Outcomes."

—David F. Chang, MD Cataract Spotlight Program Cochairman

FROM CASE 8. This case involved retained cortex and a large stromal iris defect (left).



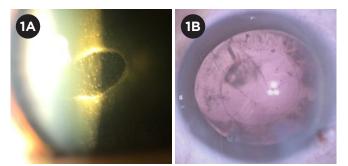
# **Case 1: Postvitrectomy Cataract**

This 58-year-old patient underwent a 3-port vitrectomy and epiretinal membrane peeling 8 weeks before she presented with a rapidly advancing cataract (Fig. 1A).

# **Q1.1** How would you approach this cataract with a suspected posterior capsular (PC) defect?

Perform hydrodelineation and partial	
hydrodissection	12.7%
Perform hydrodelineation and partial	
viscodissection	11.8%
Hydrodelineate only	52.9%
Skip all "hydro steps"	16.7%
Refer this patient	5.9%

Steve Safran The slit-lamp image of this postvitrectomy cataract appears to show a PC defect in the inferonasal quadrant of the lens. The position of this defect and its shape, given the history of a prior pars plana vitrectomy (PPV), suggests that it occurred during placement of a trocar at 8 o'clock, which most likely was used for infusion during the membrane peeling procedure. It also appears that the edges of this defect have rolled or thickened somewhat, which suggests that some fibrosis has occurred during the 8-week postoperative period. The posterior surface of the lens itself appears fairly continuous and transparent in this area, so it appears that there is no herniation and minimal damage/disruption of the lens itself other than the formation of the secondary cataract. The audience response to the question posed about the hydro steps would indicate an awareness of the risk for extending this capsular defect and possibly blowing lens material through the defect with aggressive hydrodissection. Any aggressive increase in capsular pressure created during hydrodissection or even with aggressive hydrodelineation here can raise the pressure within the capsular bag-and in a vitrectomized eye, that could cause lens material to herniate through the defect and move posteriorly very quickly. In such a situation, I would do very gentle hydrodelineation to create some separation between the nucleus and epinucleus. I would then perform a horizontal chop at an angle perpendicular to the capsular defect while supporting the lens from behind with the chopper in the second hand, to minimize risk of extending the defect. Generally, these postvitrectomy cataracts will have a fairly dense central nugget with a softer outer shell, and it should not require much pressure with hydrodelineation to create separation with minimal infusion pressure. If the nucleus was too dense to gently hydrodelineate and it resisted the fluid wave, I'd abandon hydro steps altogether and move straight to horizontal chop (as described above) and then do a second chop and remove that first quadrant with a combination of vacuum and pulling/tumbling with the chopper. I would use a lower bottle height/infusion pressure during phaco and reduced vacuum settings as well. After I removed the first quadrant, I'd gently try to rotate the lens. If it remained resistant, I'd chop off another piece and then try to gently displace the remaining nucleus more centrally, if needed, to loosen it up a bit and facilitate rotation. After



**CASE 1.** (1A) The preoperative slit-lamp photo of this posterior subcapsular cataract shows a PC abnormality. (1B) Following phaco and I/A, there is a PC defect with an intact capsulorrhexis.

the first quadrant is removed, dispersive viscoelastic could be safely injected gently under the lens to help loosen and support the nucleus with little or no risk of raising pressure within the capsular bag.

# **Q1.2** After removing the nucleus, there is a very adherent epinucleus. What would you do next?

Angle and aim the phaco tip more	
posteriorly	.0.7%
Rotate or claw the epinucleus out of	
the bag with the chopper	.3.7%
Pause to hydrodissect the epinucleus free	4.4%

Pause to viscodissect the epinucleus free ........... 58.8%

Bob Cionni This patient has an open posterior capsule following vitrectomy. Any forces that expand the capsular bag will likely open the tear further and risk loss of the epinucleus into the vitreous cavity. This potential risk is accentuated by the lack of vitreous, which would otherwise lend support to any lenticular debris.1 As hydrodissection will expand the bag, extend the tear, and potentially flush the epinucleus posteriorly, I would avoid it. The audience seems to agree, as only a small percentage chose this option. Instead, gentle, limited viscodissection with a dispersive ophthalmic viscoelastic device (OVD) would be my preferred approach to loosen the epinucleus, followed by its removal with either the I/A or the phaco tip. Most of the audience agreed with this approach. Although a high percentage favored switching to the I/A tip, if the epinucleus is dense, using the phaco tip after viscodissection may be a better choice in order to lessen the likelihood of losing your grasp of the epinucleus and perhaps flushing it posteriorly through the posterior capsule tear. 1 Osher R et al. VJCRS. 2009;2.

# **Q1.3** Now that the epinucleus is loosened, how will you remove it?

Phaco tip (using low vacuum)	33.6%
Coaxial I/A tip	23.4%
Biaxial I/A tip	25.0%
"Dry" aspiration with OVD	10.2%
Vitrectomy cutter tip	7.8%

**Tal Raviv** I agree with the audience: There are many valid approaches here. Once the epinucleus is loosened, we must proceed with the presumption of an existing capsular defect. To have the most control, I would switch to the coaxial I/A and work in a slow methodical way beginning farthest away from the compromised area and moving outside in. Care must be taken to maintain the chamber and prevent capsular trampolining that may extend a tear. A biaxial approach would work equally well, if that is the surgeon's preferred I/A technique or if the area of concern was subincisional. If the very last piece was adherent to the capsule, I would use a dispersive OVD to dissect it—and, if needed, I would perform a dry aspiration.

# **Q1.4** How would you proceed to remove the remaining epinucleus after a large PC rent is discovered?

-	
	Continue I/A9.2%
	First perform an anterior vitrectomy
	(via limbus); then I/A29.0%
	First perform an anterior vitrectomy
	(via pars plana); then I/A15.3%
	Viscolevitate the epinucleus (via limbus);
	then I/A44.3%
	Viscolevitate the epinucleus (pars plana
	posterior assisted levitation, or PAL);
	then I/A2.3%

**Dennis Han** As a retina surgeon, my role has been to support the anterior segment surgeon in cases in which vitreous involvement is highly likely during cataract surgery. However, in this case, if the epinucleus is successfully separated and there is no vitreous presentation through the PC defect, it is reasonable to proceed with removal of lens material with phaco or I/A, whichever can be done most efficiently. I would keep the instrument port occluded with lens material to minimize flow, as—even in a previously vitrectomized eye —some vitreous may remain immediately behind the lens. Thus, viscolevitation of the epinucleus makes sense. If vitreous is encountered, phaco or I/A should be temporarily suspended, and an anterior vitrectomy should be performed. For this, I favor a limbal approach over a pars plana approach to eliminate the risk of pars plana sclerotomy site complications.

# **Q1.5** This patient hates glasses. Preoperatively, she requested a presbyopia-correcting IOL. What would you do now, considering the PC defect (Fig. 1B)?

Single piece extended-depth-of-focus	
(EDOF) IOL in bag9.8	%
3-piece multifocal IOL in sulcus with continuous	
curvilinear capsulorrhexis (CCC) capture37.9	%
Single-piece monofocal IOL only (in bag)7.8	%
3-piece monofocal IOL only (in sulcus) 43.1	%
Other	%

**Bonnie Henderson** IOL choice in a case with an unexpected capsular tear can pose a challenge. In this patient, there is an opening in the posterior capsule that does not originate

as an extension of the anterior capsulorrhexis. Instead, the anterior capsule is intact and, more importantly, the opening is centered. Because of these factors, the audience choice of IOL type is not surprising-37.9% still chose to implant a multifocal IOL in the sulcus with optic capture even with a compromised posterior capsule. If the anterior capsulorrhexis were not intact, this percentage would have been much lower. The most common choice (43.1%) was to implant a 3-piece monofocal IOL in the sulcus. This is a safe option to prevent further damage to the posterior capsule. However, this option does not deliver the spectacle independence that the patient desires. Given the patient's previous history of a PPV and membrane peel, the patient may decide to forego the benefits of a multifocal or EDOF IOL if [she is] worried about the loss of contrast sensitivity associated with these lenses. So, a monofocal IOL remains a good conservative choice. As for the audience, 7.8% of attendees chose a singlepiece monofocal IOL. This points to the advances made in IOL delivery systems. Today, single-piece monofocal IOLs can be delivered gently in a controlled fashion, which allows surgeons to use them even in a setting of a PC tear. Nearly the same percentage of the respondents (9.8%) chose to implant a single-piece EDOF IOL in the capsular bag. However, of all the choices, this would be the trickiest because of the need for perfect centration. With a PC tear, vitreous could prolapse anteriorly during the implantation or during the viscoelastic removal, destabilizing the capsule and IOL. Although an EDOF IOL in the bag could be successful, a reverse optic capture (ROC) may improve the chances of long-term centration.

# **Case 2: Posterior Capsular Defect**

This 68-year-old patient is ecstatic with her 20/20 and J1 uncorrected vision following a diffractive multifocal IOL (AcrySof ReStor 3.0, Alcon) in her first eye. She is expecting to receive the same IOL model in her second eye, but a large nasal PC defect is noted after nuclear removal.

# **Q2.1** How would you remove the cortex in the presence of the PC defect?

Coaxial cortical I/A	10.5%
Biaxial cortical I/A	19.6%
"Dry" cortical aspiration with OVD	39.2%
Cortical I/A with vitrectomy cutter tip	10.5%
Perform vitrectomy first prior to cortical I/A	20.3%

**Boris Malyugin** Most of the responders (39.2%) would use the dry cortical aspiration in the presence of the PC defect. That would be my personal preference, too. The main advantage of that technique is that it helps in avoiding hydration of the vitreous and preventing displacement of the vitreous strands into the anterior chamber. One important prerequisite for the dry aspiration technique is the absence of vitreous prolapse through the capsular defect into the anterior chamber. If that is the case, vitrectomy should be performed first (this option was chosen by 20.3%), followed by resid-



ual cortex aspiration by the same vitrectomy probe or the aspiration handpiece. Dispersive OVD (Viscoat, Alcon) is very helpful to accomplish dry aspiration because it is not as easily evacuated from the eye compared with the cohesive OVD (sodium hyaluronate 1%). The surgeon can either use the cannula directly attached to the syringe with balanced salt solution (BSS) or the aspiration handpiece from the bimanual I/A set. And, of course, it is necessary to be vigilant not to aspirate the vitreous, which sometimes can be confused with the strands of cortex.

# **Q2.2** What backup IOLs do you have for a single-piece multifocal IOL?

I don't have any backup on hand	.16.4%
I have 1-piece multifocal backup IOLs only	.10.3%
I have both 1-piece and 3-piece multifocal	
backup IOLs	35.8%
I don't implant multifocal IOLs	.37.6%

Nick Mamalis This is a difficult situation, in which a patient had uncomplicated surgery in her first eye with a diffractive multifocal IOL and an excellent result. In the second eye, the patient had a large nasal PC defect found after nuclear removal, which can create potential problems with the possible use of a multifocal IOL in the second eye. An open posterior capsule may preclude the use of a capsule-fixated multifocal IOL or certainly make the use of such a lens more problematic. It is very important in this setting that the surgeon has a backup IOL in case he or she is unable to use the initially selected multifocal IOL. What is interesting about the polling of the audience members regarding backup IOLs is that 37.6% of the audience stated that they don't implant multifocal IOLs in the first place. In terms of the other answers, the most commonly chosen answer was that surgeons have both 1-piece and 3-piece multifocal backup IOLs on hand for this situation (35.8%). A 3-piece multifocal IOL would be an excellent choice for a patient who has a PC tear, which would preclude placement of a lens within the capsular bag. The haptics of the lens could be placed in the ciliary sulcus and the optic captured behind the intact anterior capsule, which would allow good fixation of the implant and excellent centration. The problem is that some manufacturers no longer have a 3-piece multifocal IOL available. In addition, there is the added expense of having a second consignment of 3-piece multifocal lenses available. The surgeon may get around this problem by ordering a backup 3-piece multifocal lens for cases in which a single-piece multifocal lens implant is planned. For those audience members (10.3%) who have 1-piece multifocal backup IOLs only, it is very important to be aware that a 1-piece hydrophobic acrylic IOL is not designed for placement within the ciliary sulcus. Because these lenses are designed with a relatively thick, square-edged haptic, there is the possibility of problems with pigment dispersion and subsequent glaucoma if they are placed in the sulcus. Furthermore, there is significant chance of uveitis-glaucoma-hyphema (UGH) syndrome with these lenses, if they are implanted in the ciliary sulcus. If a 1-piece



**CASE 2.** Following phaco and I/A, there is a large nasal PC defect with an intact capsulorrhexis.

multifocal is the only backup available, the surgeon may consider the possibility of placing the haptics of the lens in the capsular bag with placement of the optic in front of the anterior capsule in a so-called ROC. This would allow the intact anterior capsule to help fixate the IOL and prevent any possible dislocation or decentration and avoid the problems of the 1-piece haptics within the ciliary sulcus. It is interesting that having a 3-piece monofocal IOL available as a

backup in this setting was not asked of the audience participants. This IOL is a reasonable choice for a backup lens in the setting of a PC tear in which the multifocal lens cannot be placed into the capsular bag. It is very important that careful preoperative counseling of the patient is done to let the patient know ahead of time that if surgical complications occur, it may not be possible to implant a multifocal IOL and that a monofocal lens may have to be used.

# **Q2.3** Lacking a backup 3-piece multifocal IOL with this large PC tear, what would you implant?

3-piece monofocal in sulcus (target plano)
3-piece monofocal in sulcus (target -1.00)25.2%
Implant 1-piece multifocal IOL despite PC tear 18.9%
Leave aphakic—order 3-piece multifocal IOL
and reoperate
Leave aphakic—refer0.8%

Jason Jones More than 60% of the audience chose a monofocal IOL in the sulcus with the majority electing plano as the target and the remainder choosing a mild near target of -1.00. This is a conservative option and can be enhanced with optic capture through an intact anterior capsulorrhexis. The remaining audience essentially split between attempting implantation of a single-piece multifocal IOL despite the PC tear and leaving the eye aphakic and reoperating with a 3-piece multifocal IOL at a later date. Although a single-piece lens can sometimes be implanted despite a PC tear, depending on the size and location of the tear (which is fairly large in this case), the flexible nature of the single-piece design makes this choice tenuous. And ordering a 3-piece lens for a later reoperation exposes the patient to additional risk of another surgery as well as inviting concerns and doubts from the patient and family. Only a few respondents chose to leave the eye aphakic and refer, which is an undesirable option. In my practice, if presented with a similar situation of a second eye surgery having a PC tear, I would elect to implant the singlepiece multifocal IOL using ROC. This places the haptics behind the anterior capsule and prolapses the optic anteriorly through the intact capsulorrhexis. I have used this technique

in the rare situation in which I want to use a single-piece lens in the setting of a PC tear. Over many years of follow-up (my longest follow-up is 10 years at this time), I have found this technique to be well tolerated in terms of safety and well suited to refractive outcome. For those surgeons who are uncomfortable with ROC and without a 3-piece multifocal IOL on hand, I would recommend using a monofocal in the sulcus with optic capture. I would target either plano or slight myopia depending on surgeon preference; if this proves unacceptable, then a second operation could be performed with a 3-piece multifocal IOL using optic capture.

# **Q2.4** What would you implant if this were, instead, the first eye surgery?

3-piece monofocal in sulcus (target plano)73.2%
3-piece monofocal in sulcus (target -1.00)
Implant 1-piece multifocal IOL despite PC tear4.6%
Leave aphakic—order 3-piece multifocal IOL
and reoperate0.7%
Leave aphakic—refer0.0%

**Bill Wiley** Because of the PC rent, the most conservative approach would be in line with the majority of the audience. A 3-piece monofocal IOL placed in the sulcus targeted for plano is a very reasonable choice if this were the patient's first eye. If a monofocal plano target was achieved in the first eye, there would be multiple options for the patient to choose from for the second eve. Distance monofocal (to match the first IOL), near monofocal (to achieve a monovision outcome), or a multifocal could be considered in the second eye, depending on the patient's motivation. With that said, a 1-piece multifocal could be considered even in situations of a PC rent. Assuming there is a well-centered and -sized capsulorrhexis, the lens can be placed in the bag with optic capture in the anterior rhexis. For this to be considered, the rhexis must be well centered and smaller than the size of the optic. This is achievable with a manual rhexis; however, this may be made easier when an automated rhexis is performed with a femtosecond laser or a device like the Zepto (Mynosys). Lens-in-the-bag with anterior optic capture may slightly alter the effective lens position and theoretically will result in a slightly myopic outcome, which may be more pronounced in higher dioptic powers. An IOL power adjustment may be reasonable depending on the initial IOL power and original predicted refractive target.

# **Q2.5** What would you tell the patient immediately postop?

Don't mention any complication, unless a pro	oblem
later arises	10.4%
Discuss unexpected "difficulty" but offer	
no specifics—"everything's fine"	28.8%
Discuss the PC tear, but not the lack of 3-pie	се
multifocal IOL backup	24.0%
Discuss PC tear and lack of 3-piece multifoca	al
IOL backup	36.8%

**Rich Tipperman** In this patient (who experienced a PC rupture and subsequently had a 1-piece multifocal IOL placed with ROC), it is interesting that 90% of the audience is evenly split-almost in thirds-as to what to tell the patient. Discussing complications with patients is always difficult, but I believe that transparency is the best approach. As such, the first choice would not be a reasonable approach, and it is interesting that only 10% of the audience favored this answer. The second choice is a "bare minimum" explanation, wherein the patient at least knows that something was not routine at the time of surgery. One could argue that a voluminous discussion of potential complications would not empower the patient in any way and likely would just create more stress and fear. Even when everything goes well surgically, some cataract operations are easier while others are more difficult, and patients can intuitively understand this concept. I have always been surprised when I see a patient for a second opinion and the patient is having obvious problems, but the surgeon has told the person that everything is fine or normal. The patient realizes that his or her postoperative course is not "normal" or "routine"-and as a result, the surgeon's attempt to provide reassurance by saying "everything is fine" undermines the physician-patient relationship. At the very least, telling patients that their surgery was difficult but you expect them to heal well helps maintain a therapeutic relationship. The final 2 choices are actually somewhat similar, depending on the surgeon's perspective and experience. By this, I mean that many surgeons would prefer to place a 1-piece IOL with ROC rather than a 3-piece IOL in the sulcus with posterior optic capture. As such, the direction of the discussion may vary depending on the surgeon's clinical judgment. Nonetheless, complete transparency is always a good choice when speaking with patients who experience unexpected or unplanned surgical experiences.

# Case 3: Toric IOL

This 96-year-old patient is more than 3 years out from a T5 toric IOL in his right eye with minimal residual cylinder. He is scheduled for surgery in the left eye with a T6 toric IOL (preop +0.50 +3.00 × 180). However, as the I/A tip is withdrawn, there is a temporal PC tear with vitreous strands to the clear-corneal incision.

# **Q3.1** Through what port will you perform the anterior vitrectomy?

Clear-corneal incision + coaxial infusion	5.9%
Clear-corneal incision + split limbal infusion27	7.7%
New limbal incision + split limbal infusion	.3%
Pars plana + limbal infusion cannula	3.2%
Pars plana + pars plana infusion cannula5	5.8%

**Steve Charles** The audience response is concerning and indicates the need for further education on anterior vitrectomy. Surgeons who teach anterior vitrectomy agree that infusion and the vitreous cutter should be separate—that is, coaxial infusion should never be utilized. In addition, there

is consensus that the vitreous cutter should not be inserted through the clear-corneal incision. A limbal side port should always be used for infusion. Optimally the vitreous cutter should be used through the pars plana. Surgeons who are not trained in pars plana incision utilization or are uncomfortable with this approach should use a second side port for the vitreous cutter.

### Q3.2 What IOL will you implant with the PC tear?

Toric 1-piece acrylic IOL in bag1	3.1%
Toric 1-piece acrylic IOL in bag with ROC40	0.6%
Nontoric 1-piece acrylic IOL in bag	7.5%
Nontoric 3-piece IOL in sulcus	5.9%
Enlarge temporal (axis 180) incision to implant	
an anterior chamber or a posterior chamber	
PMMA IOL (sulcus)	1.9%

**Marie-José Tassignon** Given the situation pictured in Fig. 3, there is still a chance this patient can be implanted with the planned toric IOL. Based on the scores of the audience, half of them agreed with this statement. However, the conditions for implanting a toric IOL must be met prior to deciding on implantation (e.g., a stable capsule and no vitreous prolapse into the anterior chamber). Half of the audience predicted further possible complications and chose a safer option (not implanting a toric IOL). If the preoperative examination demonstrated the right eye (already operated eye) being



dominant and there is suppression of the left eye, the surgeon might be more comfortable implanting a nontoric IOL. However, binocularity would benefit from toric IOL implantation in all other ortho-

**CASE 3.** Following I/A, there is a temporal PC defect with vitreous strands to the clear-corneal incision.

ptic conditions. What is the risk-benefit analysis of implanting a toric IOL in this eye? The pros are: 1) a good anterior capsulorrhexis that is well centered in the pupillary area; 2) the capsular bag is totally emptied of any lens material; and 3) the iris and anterior chamber are quiet. In contrast, the cons are: 1) a PC tear; 2) vitreous prolapse with vitreous strand in the pupillary area; and 3) positive pressure from the vitreous side. The first and mandatory condition prior to deciding in favor of toric IOL implantation is to release the posterior pressure by performing a partial vitrectomy. This can be done from an anterior or posterior approach. The anterior approach is more demanding regarding the bimanual pressurization of the eye. The surgeon should start with a low bottle level and low aspiration values and the vitrector opening facing the retina. This approach would have my preference in this case, as the PC tear is round and relatively small. I do not favor a pars plana approach because this

may cause scleritis, destruction of the zonular vitreous, and vitreoretinal traction at the level of the vitreous base. Because of the vitreous prolapse through the wound, it is known that the anterior hyaloid is ruptured. All vitreous must thus be removed. Kenacort (triamcinolone acetonide) can be used, but since it is an off-label use, the surgeon will need patient consent. On the assumption that all vitreous has been removed, the PC tear will not bulge anteriorly any more as shown in Fig. 3 but will have its rim moved posteriorly and its opening eventually will become a little smaller (but certainly not larger). In my hands, the first choice of IOL would be a toric bag-in-the-lens, which needs a posterior capsulorrhexis of the same size as the anterior. Once the partial vitrectomy has been completed, this is still possible to do by supporting the backside of the posterior capsule with viscoelastic material in order to fully separate the anterior hyaloid from the posterior capsule. This lens would ensure a stable and well-centered position.

### Q3.3 Would you do ROC of a 1-piece acrylic IOL?

I have tried it with good results
I have tried it but am not happy with
the results4.9%
I haven't tried it and am not interested10.8%
I haven't tried it but am interested in trying 58.4%

Rich Hoffman ROC is an important technique to be aware of, especially given the increasing utilization of single-piece lenses. Single-piece IOLs that are placed in the ciliary sulcus without fixation have been reported to cause pigment dispersion, glaucoma, and recurrent hyphemas and vitreous hemorrhages.1 Most of these complications are due to the sharp-edged haptics rubbing up against the posterior surface of the iris. Although capturing the optic of these sulcus lenses posteriorly through an intact anterior capsulorrhexis will prevent movement of the IOL, the haptics will still be flexed forward into an undesirable position with regard to iris chafing. Jones et al.<sup>2</sup> published a nice article demonstrating that placing a single-piece IOL in the capsular bag and prolapsing the optic anteriorly through the intact anterior capsulorrhexis (e.g., ROC) resulted in well-centered IOLs with no visionthreatening complications. In the vast majority of cases, iris pigment dispersion will be avoided with this orientation. If a single-piece or 3-piece IOL is placed in the capsular bag and subsequently subluxes at the time of surgery or postoperatively, ROC is an excellent maneuver for rescuing these lenses and recentering them. There will usually be a small myopic shift due to the new effective lens position being slightly more anterior than what was calculated; however, this small shift is usually quite acceptable. ROC can also be quite useful when a toric lens has been placed or needs to be placed in an eye with a compromised posterior capsule. If a toric lens will not remain oriented along the desired axis, or if subsequent subluxation is a strong possibility due to a significantly compromised capsule, ROC will allow the lens to be centered and accurately oriented along the steep meridian, with little to no chance of rotation following the maneuver. This would be

especially useful in patients who have had their first eye successfully treated with a high-powered toric IOL and require a similarly high-powered toric IOL in their second eye, which now has a compromised posterior capsule. Interestingly, over 84% of respondents have tried ROC with good results or are interested in trying it. I believe the 10% of respondents who are not interested in trying this maneuver may one day change their minds when faced with a subluxed single-piece IOL inside of a compromised capsular bag. Tearing a capsule while implanting these lenses is rare but can happen.

Chang DF et al. J Cataract Refract Surg. 2009;35(8):1445-1458.
Jones JJ et al. Ophthalmic Surg Lasers Imaging. 2012;43(6):480-488.

2 Jones J) et al. Opninumic Surg Lasers Imaging. 2012;45(6):480-488.

# **Q3.4** The toric IOL was placed within the capsular bag and was centered at 180 axis at the conclusion of surgery. What would you do for a symptomatic 15-degree toric IOL misalignment presenting at postop week 3?

Leave it alone and correct with spectacles	.50.3%
Reposition the toric IOL in the bag	9.7%
Reposition the toric IOL and perform ROC	. 32.0%
Exchange the toric IOL for a 3-piece,	
nontoric IOL in sulcus	2.9%
Refer the patient	5.1%

**Doug Koch** I am surprised by this response. Patients choose and pay extra for a toric IOL to reduce dependence on glasses, so most will be unhappy if glasses are required to see well at the targeted distance (far or near). The question indicates that the patient is symptomatic, so I recommend offering the option of surgical correction to the patient. If it is a lowpower toric, then the residual astigmatism will be around 1 diopter. I typically treat this with corneal-relaxing incisions, which are highly effective, can be done in the office, and are quick and minimally invasive for the patient. For residual astigmatism over 1.25 D, I usually recommend IOL rotation if the spherical power is accurate and either PRK/LASIK or an IOL exchange if a spherical error of at least 0.5 D exists.

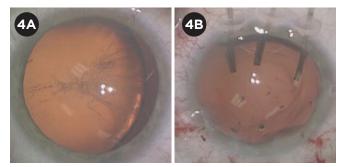
# **Case 4: Traumatic Cataract**

This 62-year-old patient is referred for a traumatic cataract. Although there is no phacodonesis or vitreous prolapse, there is a shallow anterior chamber, moderate nuclear sclerosis, and a significant traumatic mydriasis.

Q4.1	Do you	generally	operate	on	traumatic	cataracts
No		r all of the				17.8%

Yes, unless there is a zonular dialysis7.2%
Yes, unless there is phacodonesis (would
operate on option 2)10.6%
Yes, unless the lens is subluxated (would
operate on options 2 and 3) 15.6%
I would operate on all of the above48.9%

**Brad Shingleton** It is a tribute to the skill and confidence of ophthalmologists worldwide and the technology available to all of us that nearly half of the respondents would tackle this



**CASE 4.** (4A) A traumatic cataract with nasal zonular dialysis and severe traumatic mydriasis. (4B) The capsular bag is preserved with the aid of capsule retractors.

challenging cataract. Challenge is the appropriate word, and an appreciation of this challenge is reflected in the response of the more than 50% of respondents for whom referral may be considered. Caution is indicated regardless of one's choice to refer or operate because zonular and pupillary management issues can frequently complicate traumatic cataract surgery. All surgeons addressing these cases must have a plan to deal with zonular dialysis, vitreous presentation, IOL fixation in absence of capsule support, and visually significant mydriasis. I deal with traumatic cataracts on a regular basis and spend extra time preoperatively anticipating special needs that may arise related to scheduling, length of operation, anesthesia issues, surgical approach, equipment and materials (capsule support elements, microforceps, sutures, and capsule dyes), and IOL choices. We also arrange to have posterior segment backup immediately available so that all intraoperative eventualities can be taken care of in a single trip to the operating room (OR).

# **Q4.2** What is your next step after the capsulotomy step reveals severe 360-degree zonulopathy?

Hydrodissect and proceed with phaco4.8%	<b>5</b>
Insert a capsular tension ring (CTR) prior	
to phaco	>
Insert iris retractors around CCC prior	
to phaco19.8%	>
Insert capsule retractors prior to phaco	>
Insert capsule tension segment prior	
to phaco4.8%	>

**Kevin M. Miller** The audience members were somewhat divided on how they would proceed at this point. The most common response was to insert capsule retractors prior to phaco. I agree that this is the way to go. I favor placing capsule retractors in the areas of zonular laxity or dehiscence to stabilize the bag and serve as artificial zonules. Hydrodissection might be done before their placement if the zonules were able to tolerate it. The surgeon should place as many capsule retractors are necessary to provide 360-degree stability. (Note: Capsule retractors are different from iris retractors. Iris retractors are single stranded and much more likely to cut through the capsulorrhexis than capsule retractors.) Once the cataract and most of the cortex have been removed by a



gentle phaco technique, a CTR can be implanted to expand the equatorial diameter of the capsule bag and redistribute forces from weaker zonules to stronger zonules. Premature placement of a CTR risks trapping cortex, thus making its removal more difficult. It's important when implanting a CTR to not let it get caught inside the loop of a capsule retractor. Newer generation retractors have a smaller loop that prevents this from happening.

# Q4.3 Now that the capsular bag has been preserved, how will you fixate the IOL?

•	
Bag fixation without a CTR	4.3%
Bag fixation following CTR insertion	
Bag fixation following sutured CTR or	
capsular tension segment (CTS)	35.3%
Place a 3-piece IOL in sulcus	
Scleral IOL fixation	5.8%
Other	1.4%

Yuri McKee For focal zonulopathy of 3 clock hours or less, a CTR is appropriate for stabilization of an intact capsule. For 3 to 6 clock hours, the placement of a suture-supported Ahmed segment (FCI Ophthalmics) results in a more stable capsule and IOL. More significant loss of zonules will require the use of multiple Ahmed segments or a Cionni CTR (FCI Ophthalmics) with suture support. For this case, I believe the majority of audience responses are appropriate. It is, however, important to keep in mind that suture-supported IOLs and capsules can have a limited life span of 10-15 years in many cases due to degradation of nylon sutures. The off-label use of Gore-Tex (ePTFE) sutures solves this problem, but the surgical technique for using this ePTFE material is slightly more complicated than for nylon or polypropylene material. While many options exist for fixation of an IOL in the setting of poor zonular support, few are as simple, relatively speaking, as intrascleral haptic fixation (ISHF). This technique is useful in many situations, ranging from 4 to 6 clock hours of zonular dehiscence up to complete loss of the capsular bag. The advantage of ISHF over suture-based techniques includes lack of pseudophacodonesis and a simpler surgical approach through small limbal incisions. The glued IOL technique was popularized by Amar Agarwal and based on Gabor Scharioth's scleral tunnel technique. Yamane devised an ISHF technique that simplified the surgery and eliminated the use of fibrin glue. Known as the "double-needle technique," this version of ISHF relies on the use of a thinwalled 30-gauge needle (TSK) to create the scleral tunnels via a transconjunctival approach. The haptics of the IOL are threaded into the needle lumen and externalized via the scleral tunnels. The haptic tips are gently melted by the proximity of a heat-loop cautery, which creates a terminal rivet. These riveted haptic tips are buried into the scleral tunnels beneath the conjunctiva. The result is a stable, well-centered posterior chamber IOL in the absence of capsular support accomplished in the least-invasive fashion possible. As with all ISHF approaches, the Yamane technique requires the haptic exit sites to be exactly 180 degrees apart and the scleral tunnels to be exactly the same length. Care should be taken when applying heat to the haptic terminals. The polymer melts quickly, shortening the haptic. Once the rivet forms, no additional heat application is useful. Not more than 0.5 mm of haptic should be lost in the melting process. An important aspect of any ISHF technique is the placement of an intraocular infusion line. These eyes are prone to intraoperative hypotony due to the absence of an intact hyaloid face. As with any new technique, it is strongly recommended that the delicate skills are perfected in the wet lab and learned under the tutelage of a surgeon who is experienced with these maneuvers.

# **Q4.4** What is your strategy for the severe traumatic mydriasis?

Defer and return to the OR for later repair	
if needed	24.8%
Defer and refer patient if repair is needed	10.7%
Use continuous suture for cerclage	
pupilloplasty	30.6%
Use interrupted sutures for cerclage	
pupilloplasty	31.4%
Implant an artificial iris device	2.5%

**Mike Snyder** The approach to managing a severe traumatic mydriasis generated a wide variation of responses from the audience. About a third of respondents preferred to defer iris management (either by themselves or others) to a second surgical intervention on an as-needed basis. Given the very large pupil of the eye presented, halos and possible shadow images due to exposure of the edge of the lens optic are nearly inevitable. Sometimes these symptoms can actually be worse than they were preoperatively, as the natural lens fills the entire pupillary space. Those who chose to defer because of concerns of breaking the capsule with the sharp needle tip while performing a cerclage have a legitimate concern; repairing the iris in a subsequent surgery makes this less of a risk, as the capsules will have fused together by that time (though the risks of a second surgery should be considered as well). Those who would defer based on optimism of an absence of photic symptoms following surgery are likely to be disappointed. Given the lightly colored nature of the iris and, likely, a light choroid as well, there is a particularly high likelihood of photic symptoms. Of the nearly two-thirds (62%) of surgeons who preferred a cerclage repair of the mydriatic pupil, there was a nearly even split between continuous circumferential cerclage (30.6%) and multiple interrupted sutures (31.4%). Continuous circumferential suture, as initially taught by Ogawa,<sup>1</sup> is technically more demanding and more time consuming than interrupted sutures, but it yields a cosmetically superior result, especially in the lightly colored iris. An equally effective functional result can be achieved with either approach. In lightly colored irides, it can be difficult to ascertain before cerclage whether the iris pigment epithelium (IPE) remains intact. Some patients can achieve anatomically successful relief of the mydriasis with suture repair, but if the IPE is damaged, light-related symptoms can persist. Furthermore, it may be possible to

"cheese-wire" a suture repair, sometimes multiple times (see Fig. 4C online). The fewest number of attendee respondents chose an artificial iris device (2.5%). This rather low number likely represents the current lack of an FDA-approved iris prosthetic device in the United States. At this time, only those surgeons in the investigational device exemption study have access to the custom-matched, flexible artificial iris. This study is drawing to a close, and we are hopeful that approval will permit wider surgeon access to this option. International surgeons have broad access to a variety of iris prosthetic devices, which offer varying degrees of cosmetic improvement. When placed at the time of cataract surgery, as in this case, an artificial iris may be more expeditious and more facile than a cerclage suture, and it nearly assures photic reduction. 1 Ogawa GS. *Ophthalmic Surgery and Lasers*. 1998;29(12):1001-1009.

# **Case 5: Ultrabrunescent Cataract**

This 66-year-old has a 20/20 pseudophakic right eye and is interested in surgery in her left eye despite long-standing poor vision. She has a black lens as well as open-angle glaucoma, and her intraocular pressure (IOP) is 22 mm Hg on 2 topical meds. A MIGS (microinvasive glaucoma surgery) device is planned.

# **Q5.1** How would you approach this 5+ ultrabrunescent cataract?

Manual phaco	38.3%
Femtosecond laser-assisted phaco	
Manual extracapsular cataract extraction	
(ECCE, large incision)	
Manual ECCE (small incision)	15.4%
I would refer the patient	

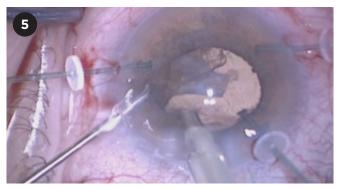
Soon-Phaik Chee There are 2 main problems to deal with in this patient: 1) a brunescent cataract, and 2) glaucoma that is not well controlled. Preoperative endothelial cell count and assessment of the optic nerve are important for counseling the patient regarding the risks and benefits of cataract surgery. I would also perform an ultrasound biomicroscopy to assess the state of the zonules, as these may be deficient and/ or at risk during surgery with the anticipated surgical manipulations. A dense cataract such as this is likely to hinder clinical examination of the optic nerve, but the history and examination for a relative afferent pupillary defect may be helpful in determining whether there is significant preexisting glaucomatous optic neuropathy that may preclude the use of a femtosecond laser. In view of the possible need for further glaucoma surgery following MIGS, cataract surgery sparing the conjunctiva is preferred. Cataract removal by phacoemulsification is thus preferred to ECCE. However, in a black lens, dealing with the leathery posterior nuclear plate can be especially challenging. In addition, there may be areas of capsular fibrosis that are difficult to tear through. I would therefore use the femtosecond laser in this case to perform the capsulotomy and nuclear fragmentation, using the maximum energy. One may prefer a slightly larger capsulotomy in an ultrabrunescent cataract, but I generally keep to a 5.0-mm capsulotomy. I would select a grid pattern that softens and segments the nucleus into multiple small pieces, keeping the posterior offset at 500  $\mu$ m and maximizing the extent of radial fragmentation. In such a challenging case, I prefer to use manual incisions. It is important to top up the dispersive viscoelastic frequently during surgery and to keep the phaco tip away from the endothelium, stepping down the phaco parameters as the nuclear fragments are consumed. The MIGS device can then be implanted.

# **Q5.2** Following capsulorrhexis and hydrodissection, the nucleus won't rotate. How would you proceed?

Initiate some sculpting and then try

rotating again
Attempt to use 2 instruments to rotate
Insert capsule retractors and then rotate
Sculpt and crack the nucleus without
employing rotation
Phaco chop without employing rotation7.5%

Abhay Vasavada Ultradense brunescent cataracts are often difficult to rotate. One of the major challenges is that the bulky nucleus may not allow the passage of a fluid wave across the capsular bag. Furthermore, it is not uncommon to have dense corticocapsular adhesions in such cataracts. These make the large nucleus adhere to the capsular bag equator and resist rotation. My strategy in such cases is to inject small amounts of fluid in multiple quadrants. I do not aim for a complete fluid wave, for fear of inducing a capsular blowout (there is minimal space available with such a large nucleus, and the capsule can often be less elastic). If the nucleus does not rotate, I prefer to create a division in the nucleus. I find that the chop technique is more efficient for dividing dense nuclei. Horizontal, vertical, or modified versions of the stop-andchop technique may be used, depending on the surgeon's ergonomic comfort. However, many times, these leathery nuclei do not divide completely in a single chop, and I find the multilevel chop technique very useful. In this technique, an initial partial thickness crack is created without aiming for a complete division. Then, the phaco tip is occluded in the lens substance at a deeper plane, and the original crack is



**CASE 5.** With a large nuclear fragment behind the iris, the phaco tip aspirates the posterior capsule due to postocclusion surge, creating a capsular defect.



extended both centrally and in a deeper vertical plane. Creating a division opens up the subcapsular space and allows the fluid to create a cleavage between the lens and capsular bag. Many times, this is sufficient to make the nucleus mobile. However, if the nucleus doesn't rotate even after a division is created, I then perform gentle, multiquadrant hydrodissection, injecting small amounts of fluid in multiple places. The key is to understand that hydrodissection can be repeated as many times as required to make the nucleus mobile. Proceed further only once the lens is freely mobile; otherwise you might be inviting trouble. Also, as surgeons we need to understand that focal, gentle hydrodissection can be performed at any stage of surgery, even during sculpting, chopping, or fragment removal. Looking at the audience responses, about 40% of the surgeons feel that some form of nucleus division should be carried out without attempting further rotation. However, nearly 37% of the participants feel that sculpting should be performed and then rotation attempted. I differ in this point, as I feel that sculpting alone will not help make rotation easier. Either additional hydrodissection or nucleus division would be preferable.

# **Q5.3** The posterior capsule tears with the last nuclear quadrant still present. What would you do next?

Enlarge the incision and manually extract
the remaining quadrant6.1%
Resume phaco after injecting a barrier of
OVD over the capsular defect
Resume phaco after inserting a scaffold
beneath the nuclear quadrant
Resume phaco after performing an anterior
vitrectomy11.7%
Resume phaco after performing an anterior
vitrectomy and inserting a scaffold

Amar Agarwal If one has a PC rupture with retained lens fragments, one of the best ways to manage it is to perform an IOL scaffold. The audience has voted for the same; if we combine the third and fifth answers, we see that support for the IOL scaffold comes to nearly 44%. The basic principle of the scaffold technique is as follows: When a PC rupture is present with the nuclear fragment still in the eye, just lift the nucleus and bring it anteriorly above the iris with the PAL technique. Then do a little bit of vitrectomy if needed, and inject a 3-piece IOL above the iris but under the nucleus. The haptics of the IOL can be placed as follows: 1) both above the iris, 2) 1 haptic above the iris and the other kept out of the incision, or 3) both above the rhexis, if it is seen clearly. In any event, we have thus created our own posterior capsule with the IOL, which acts as a temporary platform (e.g., a scaffold) and prevents the nuclear fragments from falling. Next, use the phaco handpiece to emulsify the fragment. At this stage, one can use gas forced infusion so that the corneal endothelium is away from the phaco handpiece, as the anterior chamber will become deep. Once the nucleus is removed, apply iris hooks. This will help us better visualize and clear up the cortex with the vitrectomy probe. If the rhexis

is present, just dial the IOL above the rhexis; if there is no capsular support, one can do a glued IOL by transferring the haptics from above the iris to behind the iris using the hand-shake technique. Thus we have done 3 techniques—PAL, IOL scaffold, and glued IOL—which form the triumvirate technique. Finally remove the iris hooks and close the case. A couple of final points: Remember to do the entire surgery by fixing a trocar anterior chamber maintainer so that fluid is in the eye, which maintains the eye. Also, hypersonic vitrectomy has just been brought out by Bausch + Lomb. One can do vitrectomy and nuclear emulsification with the same 23-gauge hypersonic vitrectomy probe.

# **Q5.4** With this PC tear, through what port will you perform the anterior vitrectomy?

Clear-corneal incision + coaxial infusion	5.0%
Clear-corneal incision + split limbal infusion	23.3%
New limbal incision + split limbal infusion	35.2%
Pars plana + limbal infusion cannula	30.8%
Pars plana + pars plana infusion cannula	5.7%

**Carl Regillo** There is no wrong way to proceed as long as you adhere to the basic principles of a good, safe anterior vitrectomy by moving slowly with the vitreous cutter and avoiding blind maneuvers so that traction on the vitreous base and the risk of iatrogenic peripheral retinal tears are minimized. A small amount of triamcinolone to "dust" the vitreous gel is a useful intraoperative tool; it ensures a complete anterior vitrectomy and the lack of any vitreous adherence to anterior structures at the end of the case. Stretching the pupil with whatever technique you are comfortable is also important if the pupil becomes small during this stage of surgery. This helps make sure that there is a complete anterior cleanup with removal of all lens material, including the cortex. It also facilitates assessment of the remaining capsule in order to properly determine the best lens implant and position. Going back to the specific question of which port to use for the anterior vitrectomy, my recommendation for the cataract surgeon is either "clear-corneal incision + split limbal infusion" or, if comfortable with the pars plana approach, "pars plana + limbal infusion cannula." The use of coaxial infusion is best avoided, and pars plana infusion is not necessary for a limited anterior vitrectomy.

**Thomas Samuelson** While I believe that surgeons should employ the procedures and techniques most in line with their experience, comfort level, and skill set, I firmly believe that all surgeons should commit themselves to upgrading their skills as better surgical methods evolve. Accordingly, I encourage the 5% of surgeons in this audience who currently use coaxial infusion/vitrectomy to update their anterior vitrectomy technique. It is counterintuitive to have the irrigation cannula and the vitrector on the same sleeve. While coaxial I/A works well for cortical cleanup in the setting of cataract surgery, coaxial vitrectomy is suboptimal. Unlike cortex—which is fixed to the capsule and finite—vitreous is free floating, and the goal is to remove only the amount that might become incarcerated in wounds or within anterior segment structures. Coaxial vitrectomy is inefficient and results in removal of more vitreous than is necessary, because the infusion hydrates and mobilizes additional vitreous. A better technique is to create a closed system, which generally requires a new, smaller incision than the original cataract wound and an infusion port separate from the vitrectomy port. I have not found it necessary to move the infusion port to the pars plana for each case. Rather, I believe a tight limbal infusion site, separate from the vitrectomy site, is perfectly adequate. However, I believe that a vitrectomy via a pars plana sclerotomy is the most efficient and physiological method to remove the vitreous, removing the vitreous from a posterior vantage point rather than pulling vitreous anteriorly. That said, I believe that a limbal vitrectomy via a closed system, with a separate infusion site, is perfectly reasonable, and it might be preferred in some instances. Finally, triamcinolone is often very helpful to identify and stain any occult vitreous strands that may remain in the anterior segment.

# **Q5.5** Following PC rupture and an anterior vitrectomy, would you still implant a MIGS device?

Yes—I would use an iStent (Glaukos)	19.5%
Yes—I would use the CyPass (Alcon)	2.4%
Yes—I would use another MIGS procedure	3.3%
No, I don't perform MIGS	53.7%
I perform MIGS, but wouldn't in this case	
due to the PC rupture	21.1%

**Reay Brown** Just over half of the respondents don't perform MIGS at all. But this means that almost half do-a remarkably rapid adoption rate for a technically sophisticated procedure that has only been available for 5 years. Of the respondents who do perform MIGS, almost half would not follow through with a planned MIGS procedure in this case. The decision to perform MIGS in the context of a complication depends on many factors-the severity of the glaucoma, surgeon familiarity [with the procedure], the expectation for visual recovery, the extent of the complication, and whether proceeding with the implant is even technically possible. In most complications—including a capsule rupture—it should still be possible to safely and successfully implant the MIGS device. In a PC rupture, once the lens optic is captured and the vitreous removed, the angle should be widely open for placement of the iStent or a goniotomy with the Kahook Dual Blade (New World Medical) or Trab360 (Sight Sciences). Of the respondents who would implant a MIGS device in this case, most would favor an iStent. This would be the safest MIGS option and would be my choice here. One possible concern about a CyPass suprachoroidal stent after a PC rupture with vitreous loss is the risk of anterior chamber shallowing postoperatively. In this particular case, the history of limited vision can be used to argue both for going ahead with the implant and for aborting the surgery. In this case, if I wasn't too worn out from battling the dense lens and PC rupture—and I had good visibility—I would still implant an iStent. But at the same time, I would have a low threshold for skipping the MIGS device altogether.

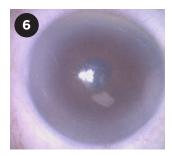
# **Case 6:** Small Pupil and Shallow Anterior Chamber

This 85-year-old patient's pseudophakic right eye was always her best eye, but it has now declined to counting fingers due to geographic age-related macular degeneration (AMD). She desires surgery in her left eye, which has hand motions vision, a black lens, a fixed small pupil with 360 degrees of posterior synechiae, and an extremely shallow anterior chamber. The axial length is 21.34 mm.

Q6.1 How would you manage the patient's small pupil?		
Viscodilate it (e.g., Healon5)	5.0%	
Manual pupil stretching	6.4%	
Partial sphincterotomies followed by		
manual pupil stretching	2.8%	
Pupil expansion ring (e.g., Malyugin)	46.8%	
Iris retractors	37.6%	
Other method	1.4%	

**Kendall Donaldson** The optimal management in this case should include a variety of tools and techniques to facilitate the removal of this cataract while hastening visual recovery for a patient who is visually compromised in both eyes. A small eye (axial length of 21.34 mm) limits the working space for removal of such a dense lens. In conjunction with a small pupil, the dense lens and potentially compromised zonules

in an older patient can be a recipe for disaster if not approached in a careful fashion utilizing all available tools. I would start by attempting to instill some capsular dye for visualization. I would then follow this with viscodilation and lysis of the synechiae in preparation for placement of a Malyugin ring (MST). Once the ring is in place, the case instantly becomes more manageable. Of the respondents, 46.8%



**CASE 6.** Mature black cataract with a fixed small pupil and an extremely shallow anterior chamber.

chose placement of a Malyugin ring. Placement of iris hooks or other stretching techniques could certainly be effectively used, depending on the surgeon's familiarity with those techniques. If necessary, the OVD could then be irrigated and the capsule re-stained for improved visualization. A nuclear disassembly technique such as chopping could be used to limit the energy dissipated during lens fragmentation while also reducing stress on potentially compromised zonules. Alternatively, if a femtosecond laser is housed in the OR, it could be used under sterile conditions to prefragment the lens in preparation for manual evacuation. In such cases, it is wise to allow extra time and to be prepared with all potential tools before the case begins. As with any challenging case, this leads to a better experience for the surgical team and improves outcomes for our patients.



# **Q6.2** How would you approach this 5+ black cataract with an extremely shallow anterior chamber?

•	
Phaco with extra OVD and mannitol	51.3%
Phaco following a vitreous tap	9.0%
Femtosecond laser assisted phaco	3.2%
Manual ECCE (large incision)	21.8%
Manual ECCE (small incision)	5.8%
I would refer the patient	9.0%

Samuel Masket It is interesting to note the bimodal distribution of responses; roughly 50% of the audience would attempt "routine" phaco with the aid of intravenous mannitol, whereas nearly 25% would prefer a "standard" manual ECCE approach. And, perhaps most interesting, nearly 10% would refer rather than accept the risks of surgery. Only a small number would consider a femtosecond laser (FLACS) approach. However, given the small fixed pupil, FLACS becomes impossible unless the laser is available in a sterile OR setting, allowing the pupil to be managed prior to the laser treatment. The concern regarding ECCE is the risk of suprachoroidal hemorrhage. The need for anticoagulation and the presence of chronic obstructive pulmonary disease, hypertension, and a short thick neck are among those factors that must be taken into account when considering largeincision cataract surgery in the elderly individual with a short axial length, as in the case at hand. Alternatively, phaco for this patient brings risks for cornea and iris damage and an increased likelihood for PC rupture. A key factor for me in deciding which mode to select is the cornea, and the endothelial cell status would tip me in one direction or the other. That said, given the cutting ability of some of our newer phaco needles, I would opt for phaco with mannitol pretreatment, unless the endothelium was significantly compromised. If a cohesive OVD created adequate space for pupil synechiolysis, placement of a Malyugin ring, and comfort for capsulorrhexis, I would proceed with caution in a stop-and-



**KELMAN LECTURE.** Alan S. Crandall, MD, was the 2017 Charles D. Kelman lecturer. He is shown here with Drs. Chang (left) and Weikert (right).

chop fashion, adding dispersive OVD as needed for corneal protection. If space was inadequate for those maneuvers, I would remove a small amount of vitreous via the pars plana via a single port 23-gauge trocar for the vitrector while OVD was added to the chamber; the sclerotomy is closed temporarily during cataract removal should it be necessary to remove additional vitreous. Finally, cases of this nature are often accompanied by zonulopathy, and capsule support devices should be used as necessary.

# **Q6.3** The surgeon elected to perform a manual smallincision ECCE. What IOL would you implant with this technique?

A foldable acrylic IOL	
A foldable silicone IOL	6.1%
A PMMA IOL	
I don't do manual ECCE	6.1%
Another IOL	

**Susan MacDonald** Small-incision ECCE surgery is an excellent, safe technique for a mature black cataract. When considering lens choice for these cases, it is important to consider the size of the capsulorrhexis. The surgeon may choose to make the capsulorrhexis larger than 5.5 mm in order to assist in delivery of the lens into the anterior chamber; if so, it is important to choose a large lens that will stay in the capsular bag, and my choice would be a PMMA lens.

# **Q6.4** Describe your level of experience with manual large-incision ECCE.

•	
Very experienced40.7%	5
Some experience, and I am comfortable	
performing19.1%	5
Some experience, but I am not that	
comfortable performing11.6%	5
Very limited (or no) experience	5
I am also comfortable with sutureless, manual	
small-incision cataract surgery (SICS)	5

Aravind Haripriya It's good to know that a majority of the surgeons are comfortable with the manual large-incision ECCE technique. However, there is room for many surgeons to also learn the SICS technique, which will be a valuable addition to the cataract surgeon's armamentarium. The biggest advantage of the SICS technique over ECCE is that the surgery is a closed chamber technique. In this patientwhere the axial length is short and anterior chamber is extremely shallow—doing a SICS reduces the chances of an explosive hemorrhage while enabling a good clinical outcome and early visual rehabilitation. My personal preference in this situation is a SICS technique. I would initially create a large sclerocorneal tunnel and stretch the pupil using 2 Kuglen hooks, so that the pupil can accommodate the large nucleus. In addition, numerous minisphincterotomies are very useful to enlarge the pupil further. It is good to plan for a 6.5-mm capsulorrhexis so that the nucleus can be prolapsed through it into the anterior chamber. Following gentle

hydrodissection, 1 pole of the nucleus is prolapsed out into the anterior chamber using a Sinskey hook. The prolapsed pole is supported from below using a cyclodialysis spatula in the nondominant hand. Using this spatula as a fulcrum, the rest of the nucleus is wheeled out of the capsular bag into the anterior chamber. The nucleus is then extracted from the eye using an irrigating vectis after coating the endothelium with viscoelastic. Following cortex aspiration with a Simcoe cannula (Accutome), a PMMA IOL is placed in the bag.

# **Case 7: Unhappy Multifocal IOL Patient**

This 67-year-old is unhappy with a right Tecnis +4 add multifocal IOL (Johnson & Johnson) implanted 30 months ago due to halos, glare, and "waxy, washed-out" vision. An Nd:YAG capsulotomy did not improve the symptoms, nor have they improved with time. The right eye is 20/30+ with a -0.50 + 0.50 × 65 refraction and a well-centered multifocal IOL with an overlapping capsulorrhexis.

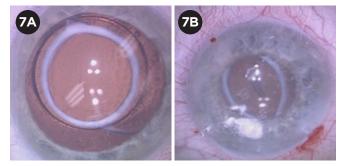
### Q7.1 What would you recommend?

Discourage IOL exchange and allow more	
time for neuroadaptation	21.0%
Implant a multifocal IOL in the left eye	5.0%
Implant an EDOF IOL in the left eye	2.0%
Implant a monofocal IOL in the left eye; then	
decide on the right eye based on her	
experience	36.0%
Perform IOL exchange with a monofocal IOL	.17.0%
Refer for IOL exchange with a monofocal IOL	19.0%

Steven Dell This IOL needs to be removed and replaced with a monofocal. In the largest published meta-analysis of multifocal implantation, my colleagues and I found that although these lenses were well tolerated, and photic phenomena were typically outweighed by the improved near function, a small cohort of patients remained unhappy until they underwent an exchange.1 Our data also indicated that residual refractive error was perhaps the most important source of postop dissatisfaction. This patient's refractive error is too small to account for the complaints. In our study, unwanted photic phenomena tended to improve with time, but after 30 months, it is unreasonable to expect further improvement. The presence of an open capsule highlights a critical decision point in the management of unhappy multifocal patients. IOL exchange is much simpler with an intact capsule, but sometimes the patient's complaints can mimic those found with posterior capsular opacification (PCO). The key is to determine whether there was an interval of time postoperatively when the vision was acceptable, followed by deterioration. That would argue for PCO as the culprit. A little over one-third of the audience suggested exchange for a monofocal, but interestingly, about the same number suggested that the other eye should first receive a monofocal, followed by reevaluation. While there is some logic to that conservative approach, I think the multifocal needs to be replaced.

1 Rosen E et al. J Cataract Refract Surg. 2016;42(2):310-328.

David F. Chang, MD



**CASE 7.** (7A) Well-centered Tecnis multifocal IOL with overlapping capsulorrhexis. There is a large central YAG posterior capsulotomy. (7B) Following IOL exchange without a vitrectomy and CCC optic capture, there is a strand of vitreous (triamcinolone stained) incarcerated in the paracentesis.

# **Q7.2** After the multifocal IOL is explanted, the posterior capsule is open but there is no obvious vitreous prolapse. Prior to implanting the replacement 3-piece IOL in the sulcus, what would you do?

Perform anterior vitrectomy via a limbal	
incision	3.9%
Perform anterior vitrectomy via a pars plana	
incision	1.6%
Inject triamcinolone and then decide	69.0%
Implant the 3-piece IOL in the sulcus without	
any vitrectomy	5.4%
The fourth option, but with capsulorrhexis	
optic capture	20.2%

Kerry Solomon Explanting a multifocal IOL should be part of every refractive cataract surgeon's armamentarium. Several years ago, multifocal IOLs were most commonly explanted because of issues with quality of vision. Fortunately, the quality of vision experienced with today's multifocal and EDOF IOLs is dramatically improved for both distance and near vision. As a result, the most common reasons currently given for explanting multifocal or EDOF lenses are the need for a power adjustment or the presence of night vision symptoms. In the setting of an open capsule with no vitreous present, placing a 3-piece IOL in the sulcus with optic capture (as 20% of the respondents suggested) makes sense after a multifocal IOL is explanted. Having the optic inside the capsular bag will improve the consistency of the IOL calculation for the new lens, because of the optic resting in the capsule (more accurate ELP, or effective lens position). Additionally, optic capture serves as an excellent way to tamponade the open posterior capsule, preventing short- and long-term vitreous prolapse by restoring the 2 chambers of the eye (essentially separating the posterior and anterior segments, as the intact posterior capsule once did). In turn, this may decrease the likelihood of vitreous or retinal traction. macular edema, retinal detachment, or other complications. Most (69%) of the respondents suggested using triamcinolone first to confirm the presence or absence of vitreous. This is a great step to ensure that no vitreous is present. In the presence of vitreous, a vitrectomy should be performed, and



then the same plan of sulcus fixation with optic capture can be followed.

# **Q7.3** Following sulcus IOL implantation and optic capture, triamcinolone staining reveals a vitreous strand incarcerated in the side port incision (Fig. 7). What now?

Thomas Kohnen The presence of vitreous strands in the wound after posterior chamber sulcus implantation and optic capture (as seen in this case with triamcinolone staining) indicates that vitreous prolapse has occurred. After PC rupture, a posterior chamber IOL can still be implanted into the capsular bag, if the rent is small and relatively centraland if the anterior capsular (AC) margins are well defined. If possible, the PC tear should be converted to a posterior CCC. If the rent exceeds 4-5 mm in length or there is extensive zonular loss, the capsular bag is not adequate for IOL support. In such cases, the ciliary sulcus is opened with an OVD, and the iris is retracted in all quadrants so that the status of the peripheral capsule and zonules can be assessed. The IOL is inserted with its haptics oriented away from the area of the rent and positioned in areas of intact zonules and capsule. Another alternative, if the AC rim is intact, is sulcus placement of the IOL, with capture of the optic through the capsulorrhexis or laser capsulotomy. To allow this maneuver to take place, the AC opening must be intact when the cataract or refractive lens procedure is started. Optic capture of the IOL optic enables a more secure fixation of the sulcus-placed IOL (e.g., for toric IOLs). If vitreous is present in the anterior segment before IOL implantation (again, this is best demonstrated with triamcinolone staining), vitrectomy should be performed first, with the necessary caution taken to prevent extension of the rent. Depending on the type of capsular tear, vitrectomy is performed through either the limbal incision



case to (from left) Drs. Weikert, Cionni, and Han.

or the pars plana. The former approach is used when the tear is located near the incision, as this permits vitrectomy with minimal risk of enlargement of the tear. A pars plana approach is preferred when the tear is remote from the incision and therefore less accessible anteriorly. In either case, irrigation is provided with an infusion cannula in the paracentesis opening or via a 23-gauge trocar inserted through the pars plana. If a vitreous strand is incarcerated in the side port incision following IOL implantation, this can cause pupil ovalization; more importantly, it can lead to chronic inflammation of the eye. Therefore, the link between the anterior and posterior segments should be disconnected. In my experience, 2 procedures have been very successful: 1) The vitreous strand to the side port can be cut with a YAG laser after maximal miosis has been achieved pharmacologically. If the laser can cut the strand, vitreous from the area close to the implant will revert behind the lens. This approach avoids a second intraocular procedure. 2) If this procedure is not successful, a limbal anterior vitrectomy allows complete and easy removal of the vitreous strand. Just sweeping the vitreous may not be successful, and snipping with microscissors may leave some vitreous in the wound; therefore, if a sterile intervention is performed, limbal anterior vitrectomy would be the preferred technique. A pars plana approach is usually not necessary for a simple vitreous strand. In summary, regardless of the preferred approach, a vitreous strand to the side port incision should be disconnected or removed to avoid long-term complications.

# Q7.4 If a cataract patient hates glasses and is a good candidate for a presbyopia-correcting IOL, I most commonly recommend:

Standard diffractive multifocal IOL (+3)	18.5%
Low-add diffractive multifocal IOL (+2.5)	24.6%
Diffractive EDOF IOL	26.2%
Monofocal monovision	20.8%
Other refractive IOL	0.8%
Refer	9.2%

Eric Donnenfeld Most of the audience has voted for one of the following 4 ways to manage a patient who is a good candidate for a presbyopia-correcting IOL and does not want to wear glasses: a standard diffractive multifocal IOL, a low-add diffractive multifocal IOL, a diffractive EDOF IOL, and monofocal monovision. In my opinion, all 4 choices are correct. When we have this many viable options it overwhelmingly means one thing: No choice is perfect, and each has advantages and disadvantages. The lenses with the least glare and halo (EDOF and low add) have the fewest side effects and provide good intermediate vision, but they often do not provide complete spectacle independence at near. The high-add multifocal IOLs have more spectacle independence but more glare and halo, while monovision results in a loss of stereopsis and depth perception. The correct answer for an individual patient is found in his or her willingness to accept glare and halo and lack of stereopsis in pursuit of spectacle independence.

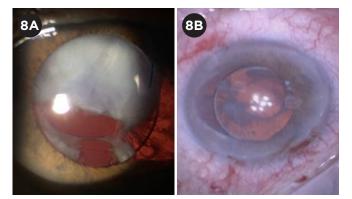
# Case 8: Iris Prolapse

This 71-year-old patient had complications from cataract surgery that was done 6 weeks prior. She has chronic narrow angles despite a YAG iridotomy and a small pupil, iris prolapse, posterior pressure, and an AC tear that extended into the posterior capsule. The prolapsed iris that could not be reposited was excised; cortex was left behind due to the posterior pressure. Her vision is now 20/200.

# **Q8.1** If iris prolapse occurs in association with increased posterior pressure, what would you generally do to remove the remaining cortex?

Perform cortical I/A via a separate new incision18.1%
Reduce the posterior pressure with a pars plana
vitreous tap65.0%
Stop surgery and resume after waiting for
an hour8.8%
Excise the prolapsed iris and abort the surgery5.0%
Abort surgery, and leave any prolapsed
iris alone2.5%

**Bob Osher** The first maneuver should be to reposit the iris by lowering the IOP. Often the eye can be overfilled with OVD, which can be aspirated. Rather than push the iris back through the incision, which never works very well, a second stab incision can be made through which a dull instrument can be used to sweep the iris back through the main incision. I prefer an OVD cannula because a retentive OVD like Healon5 (AMO) can then be injected onto the iris, displacing it posteriorly. I would also hydrate the incision to retard recurrent prolapse. Once the iris is safely reposited, the surgeon must manage the increased IOP. External causes like speculum pressure against the globe or retrobulbar hemorrhage should be excluded. The patient should be asked if he or she is uncomfortable (e.g., has to urinate), as any Valsalva can raise the IOP. The most likely cause is an intraocular etiology like BSS passing through the zonules and hydrating the vitreous gel. I keep a special lens (Osher Fundus Lens, Ocular Instruments) on my back table, which allows me to quickly view the fundus through the microscope to exclude a choroidal hemorrhage or effusion. In my experience, a pars plana vitreous tap is rarely necessary. I would prefer to inflate the capsular bag with a cohesive OVD and then remove the cortex by a dry aspiration technique. I will use a curved cannula (Crestpoint and Bausch + Lomb) on a 3-cc syringe to aspirate subincisional cortex and then a straight 27-gauge cannula for the remainder of the cortex. Alternatively, I can use a bimanual technique or a coaxial I/A technique, entering the OVD without infusion. Once inside the incision, the infusion is initiated and the cortex can be safely engaged at the most anterior proximal location, then removed with slow-motion parameters. Before withdrawing the I/A tip, the infusion should be reduced or even stopped to prevent iris prolapse. The knowledgeable management of iris prolapse can result in an excellent functional and cosmetic surgical result.

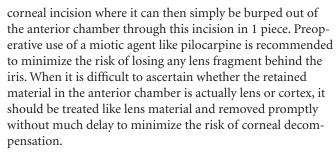


**CASE 8.** (8A) Slit-lamp image showing retained cortex behind the IOL and a large stromal iris defect temporally. (8B) Following removal of cortex and centration of the IOL, the temporal iris defect persists.

# **Q8.2** What would you do in this eye with retained cortex and a PC tear 6 weeks following complicated cataract surgery with posterior pressure and iris prolapse (Fig. 8)?

Continue medical treatment for longer0.7%	
Attempt to YAG a central optical opening	
in the layer of cortex9.7%	
Surgically remove the cortex67.4%	
Refer to an anterior segment surgeon8.3%	
Refer to a posterior segment surgeon	

**Terry Kim** In this patient with retained cortex 6 weeks following complicated cataract surgery, the majority of the audience voted to surgically remove the cortex from behind the IOL. The other responses are reasonable considering the potential complexity in pursuing this approach. For this specific case, I was asked to lecture on the related topic of retained lens fragments in the *anterior* chamber after cataract surgery. In this scenario, the response of surgically removing the retained lens fragment is highly recommended. In our retrospective series on this topic,<sup>1</sup> we found that all of the patients who were initially managed medically (usually with topical corticosteroids) failed therapy and eventually underwent surgical removal of the lens fragment. The primary reasons for removal included worsening/persistent corneal edema (63%) and worsening/persistent anterior chamber inflammation (37%). Our study also revealed that the patients' visual acuity improved after lens fragment removal and that delayed diagnosis (and delayed removal) increased the risk of prolonged and/or permanent corneal edema, with some cases requiring corneal transplantation. Management strategies for the surgical removal of a lens fragment from the anterior chamber include using an I/A handpiece to aspirate this fragment, which may require a second instrument to "crush" the fragment into the aspiration port. However, one of the problems associated with this approach includes the possibility of further fragmentation of the lens fragments into smaller pieces that can be flushed by irrigation behind the iris or somewhere in the anterior chamber where it may be difficult to visualize. Hence, an alternative approach involves using a cohesive OVD to direct the entire lens fragment to the main



1 Zavodni Z et al. Am J Ophthalmol. 2015;160(6):1171-1175.

### Q8.3 How would you address the temporal iris defect?

Leave it alone for now and try miotics or	
colored soft contact lens	4.8%
Leave it alone for now—operate later if	
symptomatic	16.1%
Leave it alone for now—refer later if	
symptomatic	
Perform suture repair	68.8%
Implant an artificial iris device	0.0%

Brandon Ayers In this scenario, we have a surgical complication that includes a large temporal iris defect. Most attendees indicated they would attempt primary suture repair of the iris defect during the surgery. In many cases this is possible by reapproximating the 2 ends of the iris defect with a 10-0 polypropylene suture and then tying with an intraocular knot (such as a Siepser knot). This technique can be very helpful, especially with smaller iris defects, where the 2 ends can easily be approximated with minimal stress placed on the iris root. The source of iris damage is often intraoperative iris prolapse from intraoperative floppy iris syndrome (IFIS), and often can be repaired at the time of surgery. Caution should be taken in cases of intraoperative iris damage when the anterior segment is unstable due to posterior pressure or violation of the posterior capsule. In this situation the IOL or anterior chamber may not be stable, and attempting iris repair may jeopardize the success of the surgery. Secondary repair is a better option. Time gives the eye the ability to heal, reduces inflammation, and allows the capsule to fibrose, holding the IOL more securely. Miotics or prosthetic iris contact lenses can be tried to see if glare is reduced. If nonsurgical techniques work well, repair may not be needed. In some cases, the iris damage can be severe enough that primary repair is not possible. In cases where repair is not an option, prosthetic contact lenses may be the best choice. Currently, no FDA-approved devices are available for iris replacement in the United States. Multiple iris prosthesis FDA trials are ongoing; the hope is that a device will be approved in the near future.

# **Q8.4** If operating on this patient's 2nd eye, I would . . .

Employ iris retractors early on	. 12.8%
Employ a pupil expansion ring early on	25.5%
Perform a pars plana vitreous tap	20.2%
Use mannitol or other strategy	. 37.2%
Refer the patient elsewhere	4.3%

sonable, and the use of a combination of them makes sense to me. I would approach a patient with a shallow anterior chamber, poorly dilating pupil, and dense cataract who had a complex course in the first eye-with intraoperative iris prolapse, positive posterior pressure, a capsular tear, and retained cortex-with several strategies. First, I would utilize a peribulbar block of combined lidocaine and Marcaine (bupivacaine hydrochloride and epinephrine) followed by digital and balloon compression to soften the eye. I no longer use intravenous mannitol, but it is a reasonable option as recommended by many in the audience. I would be prepared with a Malyugin ring or similar pupil expansion device as well as iris and capsule retractors. Following preparation of the primary incisions, I would inject nonpreserved lidocaine with epinephrine diluted 5:1. I usually prefer 4-5 iris retractors over a pupil expansion device, which requires 4-5 small paracenteses. I would also use Omidria (Omeros) in the BSS infusion bottle. A high viscosity cohesive viscoelastic such as Healon GV or Healon5 can also be helpful in creating an adequate anterior chamber and initiating viscomydriasis. If the anterior chamber was difficult to form, I would not hesitate to perform a limited vitreous aspiration using a vitrector through the pars plana. No infusion is required, and I turn the cutting port posteriorly to avoid any chance of opening the posterior capsule. This always results in a deep anterior chamber. I rarely use a femtosecond laser these days, but I have found that the Mynosys (Zepto) device creates an excellent round and strong anterior capsulotomy. If it is available, I would employ it in a case such as this patient. I also like the MiLoop (Iantech), which would be useful in cutting this dense nucleus into 4-6 pieces following hydrodissection. I would inject some dispersive viscoelastic to subluxate the nuclear pieces anteriorly and further protect the posterior capsule prior to phacoemulsification. A phacoemulsification machine with forced infusion would enhance anterior chamber stability. Cortical cleanup should be routine, but I would be prepared to do biaxial I/A. A standard 1-piece aspheric hydrophobic acrylic IOL would be implanted in the capsular bag. I would have a 3-piece IOL available, and if a PC tear occurred, my plan would include sulcus placement of the haptics and posterior optic capture in the 5.2-mm Zepto capsulorrhexis. With Healon GV and Healon5, I am very compulsive about removing viscoelastic to reduce the risk of an IOP spike. I would utilize intracameral carbachol and also inject a combination of intracameral moxifloxacin/ dexamethasone/ketorolac (Imprimis). I would have ReSure wound sealant (Ocular Therapeutix) available if hydration did not result in watertight wounds. If possible, this patient might benefit from a same-day postoperative visit with an IOP pressure check. My postoperative regimen in this complex case would include a topical steroid and a nonsteroidal anti-inflammatory drug (NSAID), preferably in a combination drop to enhance compliance.

**Dick Lindstrom** The audience recommendations are all rea-

**MORE ONLINE.** For additional images relevant to Case 4, view this article online at aao.org/eyenet.

# **Financial Disclosures**

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

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WARNINGS/PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling for each IOL. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

The ReSTOR Toric IOL should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation.

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# The Code-a-Palooza Challenge, Part 2: Cataract, Cornea, and Retina

his month, you are back in the hot seat, tackling 4 more questions from November's Code-a-Palooza, a game show–style event that takes place at the Academy's annual meeting. It pits 2 teams against each other *and* against the audience.

# **Tackle These Questions**

**Q4—corneal triple procedure.** When a cornea surgeon performs a triple procedure—involving penetrating keratoplasty (PK) with extracapsular cataract extraction and intraocular lens (IOL) implantation—what CPT codes should you submit?

**A.** 65755 *PK pseudophakic* and 66984 *Cataract surgery.* 

**B.** 65750 *PK aphakic* and 66984 *Cataract surgery.* 

**C.** 65756 *Endothelial keratoplasty* and 66984 *Cataract surgery.* 

**D.** 65730 *PK phakic* and 66984 *Cataract surgery*.

**Q5—fundus photography of diabetic retinopathy.** A primary care group in your area has a fundus camera. They take fundus pictures of patients with diabetic retinopathy, and your ophthalmology office interprets the results. What code should the ophthalmologist submit?

**A.** 92250–26 Fundus photography with interpretation and report.

**B.** 92227 Remote imaging for detection of retinal disease (e.g., retinopathy in a patient with diabetes) under physician

supervision, with analysis and report under physician supervision, unilateral or bilateral.

**C.** 92228 Remote imaging for monitoring and management of active retinal disease (e.g., diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral.

**Q6—a limbal-relaxing incision.** A patient had cataract surgery 3 years ago and now needs a limbal-relaxing incision for the correction of surgically induced astigmatism. Which of the follow statements is correct?

**A.** You should submit unlisted CPT code 66999; the patient is responsible for payment.

**B.** You should obtain an Advance Beneficiary Notice of Noncoverage (ABN) from the Medicare Part B patient.

**C.** Most insurances do not specify the specific diopter of astigmatism induced by surgery.

**D.** Correction, if necessary, is part of the global surgical package.

**Q7–Optos.** The physician used Optos, rather than dilating the pupil, to examine an established patient's posterior segment. Should you bill for a comprehensive exam with an E&M code or Eye visit code?

**A.** Choose either.

- B. E&M code.
- **c.** Eye visit code.

**D.** Neither. This was not a comprehensive exam.

### How Many Did You Get?

**4—corneal triple procedure.** Answer: D. 65730 *PK phakic* and 66984 *Cataract surgery.* 

More to the story. List PK first, as it has the higher allowable. Payment, per the guidelines on multiple procedures, will be 100% of the allowable for the PK and 50% for the cataract surgery. There is a 90-day global period.

**5—fundus photography of diabetic retinopathy.** Answer: C. 92228 *Remote imaging for monitoring and management of active retinal disease* 

**More to the story.** It is inappropriate to submit 92250–26 when there is a CPT code for this telemedicine service. However, not all payers have assigned an allowable, and the patient may be responsible for payment.

**6—a limbal-relaxing incision.** Answer: C. Most insurances do not specify the specific diopter of astigmatism that must be induced by the initial surgery in order for the correction to be covered.

More to the story. The appropriate CPT code is 65772 *Corneal relaxing incision for correction of surgically induced astigmatism*. The code reflects the scenario that trauma or previous surgery resulted in surgically induced astigmatism. (For correction of natural astigmatism at the time of cataract surgery, use either the unlisted code 66999 or an internal tracking code that you've developed.)

**7–Optos.** Answer: D. Optos is not a substitute for a dilated posterior segment exam. As an analogy, a chest x-ray does not take the place of examining the heart and lungs.

BY **SUE VICCHRILLI, COT, OCS,** DIRECTOR OF CODING AND REIMBURSEMENT, AND **JENNY EDGAR, CPC, CPCO, OCS,** ACADEMY CODING SPECIALIST.

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# CODING & REIMBURSEMENT PRACTICE PERFECT

# MIPS: The IRIS Registry Makes Quality Reporting Relevant to Your Subspecialty

ay-for-performance is becoming an increasingly important factor in physician reimbursement. The quality performance category of the Merit-Based Incentive Payment System (MIPS) evolved out of the Physician Quality Reporting System (PQRS). In turn, PQRS started in 2007 as the Physician Quality Reporting Initiative (PQRI).

Since PQRI launched, 2 perennial complaints about this evolving program have been that the reporting requirements are too burdensome, and ophthalmologists—especially subspecialists—were being asked to report quality measures that weren't sufficiently relevant to clinical care. The Academy's IRIS Registry helps members to surmount these problems.

# How the Academy Can Help With Quality Reporting

**Reducing your reporting burden.** Compared with other reporting mechanisms, the Academy's IRIS Registry (aao.org/iris-registry) involves less labor and, thanks to its dashboard, less uncertainty about your MIPS performance. It offers 2 options for reporting quality measures: 1) IRIS Registry/EHR integration, which involves integrating your electronic health record system with the IRIS Registry or 2) manually entering MIPS quality data into the IRIS Registry web portal (no EHR system required). Note: Advancing care

# What Are QCDR Measures?

Qualified Clinical Data Registry (QCDR) measures augment the standard MIPS quality measures that are published by CMS.

The standard MIPS quality measures published in the CMS regulations were mostly drawn from PQRS measures. You can report some of these measures by claims, some by manual entry via the IRIS Registry web portal, and some via your EHR vendor or IRIS Registry/EHR integration. Of the 13 ophthalmology-specific measures, only 6 qualify for EHR-based reporting.

**QCDR measures are developed by medical specialties and subspecialties.** CMS recognized that its legacy quality measures don't meet the needs of all physicians, and it encouraged specialty societies to develop their own measures that can only be reported via QCDRs, such as the IRIS Registry.

information measures and improvement activities are reported manually via the portal.

**Providing QCDR measures for subspecialists.** The IRIS Registry has been designated a Qualified Clinical Data Registry (QCDR). This gives the Academy latitude to develop quality measures for MIPS that capture the genuine value of medical and surgical eye care. Since launching the IRIS Registry in 2014, the Academy, working in conjunction with subspecialty societies and teams of subspecialty physicians, has developed 32 quality measures.

The QCDR measures may become even more important because the Centers for Medicare & Medicaid Services (CMS) is considering implementing stricter criteria for determining which quality measures will be included in the program in future years. These include a preference for 1) patient outcome measures over process measures and 2) measures that can address a "gap in care" or that do not have high performance rates across all physicians who report those measures. If CMS reassesses existing MIPS measures based on these criteria, it could remove some of the legacy PQRS quality measures that had been carried over into MIPS. However, the IRIS Registry QCDR measures—most of which are outcome measures—would ensure that you still have enough quality measures to report.

**Fine-tuning the QCDR measures.** The Academy can modify its QCDR measures on an annual basis if changes are needed to make them more technically feasible for EHR extraction or to update them for changes in clinical practice or technology.

**Boosting performance with benchmarking.** Regardless of whether you are participating in MIPS, you can use

BY **REBECCA HANCOCK,** DIRECTOR, IRIS REGISTRY, AND **FLORA LUM, MD,** VICE PRESIDENT OF THE ACADEMY QUALITY AND DATA SCIENCE DIVISION.



the IRIS Registry dashboard to track your performance against that of your peers. By comparing your performance against the norm, you can identify areas that need improvement. The dashboard is available to practices that integrate their EHR system with the IRIS Registry, and it monitors those measures that have been successfully data mapped.

# How to Use the IRIS Registry

Who can report QCDR measures? In order to report the Academy's QCDR measures, you must be signed up for the IRIS Registry.

Most QCDR measures can be reported via the web portal. If you choose to report MIPS manually via the IRIS Registry web portal, you can report any of the IRIS Registry QCDR measures except for measure IRIS16.

NEW—you *may* be able to report 16 QCDR measures via IRIS Registry/EHR integration. If you integrated your EHR system with the IRIS Registry, you'll recall that you went through a mapping process that enabled the transmission of your data for the various measures. This year, you can attempt that mapping process for 16 QCDR measures (see table). If successful, you'll have the

option of reporting those measures. Furthermore, these measures will be valuable for your practice's internal quality improvement efforts.

Use the IRIS Registry's QCDR measures to score high-priority bonus points. Reporting an outcome measure or an appropriate use measure can contribute 2 bonus points or 1 bonus point, respectively, toward your quality score. This bonus is capped at 6 or 7 points, depending on the size of your practice. Note: You don't get bonus points for the first high-priority measure that you report. This is because you are required to report on at least 1 outcome measure (or, if no outcome measure is available, you must report an alternative high-priority measure).

A caveat about benchmarking. When you report a MIPS quality measure, your score will depend on how well you perform compared with the benchmark for that measure. CMS hasn't vet set benchmarks for the IRIS Registry QCDR measures. It will do so retroactively for those 2018 measures that receive sufficient physician data. In this case, you may be able to score up to 10 points depending on how you fare against that benchmark. However, if

insufficient data are reported for a measure, CMS won't be able to establish a benchmark, and your score for that measure will be capped at 3 points.

Measures that aren't available for MIPS reporting. The Academy developed 3 additional measures that aren't available for 2018 MIPS reporting: •

Avoidance of Preoperative Medical Testing for Cataract Surgery

Chronic Anterior Uveitis: Post-Treatment Grade 0 Anterior Chamber Cells

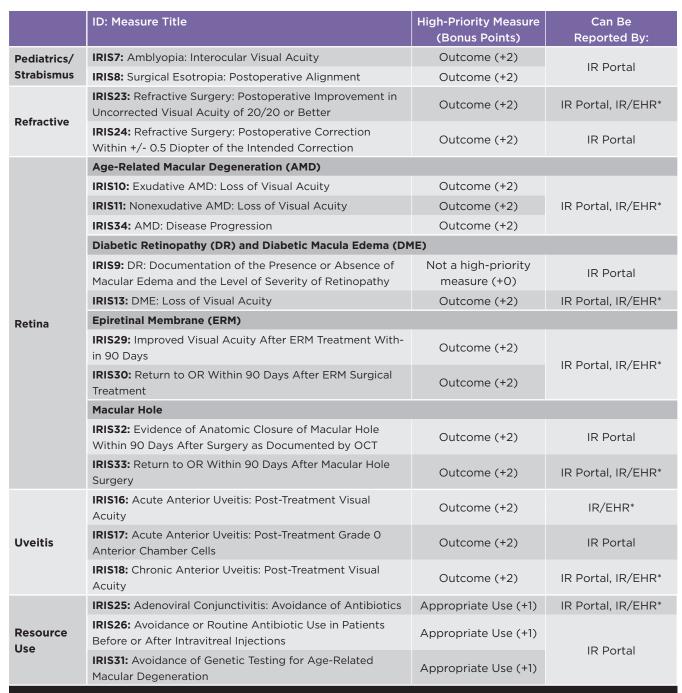
Removal of Macular Epiretinal • Membrane

CMS may accept these as QCDR measures for MIPS in future years.

If you haven't signed up for the IRIS Registry, do so today. The IRIS Registry team is currently processing 2017 MIPS data. Later this spring, it will start processing new applications. To get in the queue, sign up now at aao. org/iris-registry. To learn more about the application process, visit aao.org/ iris-registry/application-process.

MORE ONLINE. Learn more at EXTRA aao.org/eyenet; download this chart and click on the measure titles for detailed information on each measure.

30 QCDR Measures for 2018 MIPS Reporting					
	ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported By IRIS Registry (IR):		
Cataract	IRIS27: Adverse Events After Cataract Surgery	Outcome (+2)	IR Portal, IR/EHR*		
Cataract	IRIS28: Regaining Vision After Cataract Surgery	Outcome (+2)			
Cornea	<b>IRIS1:</b> Endothelial Keratoplasty: Postoperative Improve- ment in Best-Corrected Visual Acuity to 20/40 or Greater	Outcome (+2)	IR Portal, IR/EHR*		
	IRIS2: Intraocular Pressure (IOP) Reduction	Outcome (+2)	IR Portal, IR/EHR*		
Glaucoma	IRIS3: Visual Field Progression	Outcome (+2)	IR Portal		
	<b>IRIS4:</b> Intraocular Pressure Reduction Following Laser Trabeculoplasty	Outcome (+2)	IR Portal, IR/EHR*		
	<b>IRIS20:</b> Idiopathic Intracranial Hypertension: No Worsening or Improvement of Mean Deviation	Outcome (+2)			
Neuro-Oph- thalmology	<b>IRIS21:</b> Ocular Myasthenia Gravis: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2)	IR Portal		
	<b>IRIS22:</b> Giant Cell Arteritis: Absence of Fellow Eye Involvement After Corticosteroid Treatment	Outcome (+2)			
Oculo-	<b>IRIS5:</b> Surgery for Acquired Involutional Ptosis: Patients With an Improvement of Marginal Reflex Distance	Outcome (+2)	IR Portal		
plastics	<b>IRIS6:</b> Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2)	IK Polta		



\* You may be able to report this measure via IRIS Registry/EHR integration but only if the IRIS Registry is able to extract the relevant data from your EHR. An initial data mapping process will determine whether this is feasible.

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# Academy Notebook

# <image>

**CREATING CHANGE ON THE HILL.** Young ophthalmologists take a stand at Congressional Advocacy Day, during last year's Mid-Year Forum.

registration fee for the Mid-Year Forum increases from \$225 to \$325 on March 7; however, Congressional Advocacy Day's day of lobbying (April 19) is free to all members. Register by April 3.

For registration information and the event schedule, visit aao.org/myf.

# TAKE NOTICE

# A Request From *EyeNet*'s Editors

This month, some of you will be asked to take part in a readership survey conducted by Kantar Media. If you are a fan of *EyeNet* and the work we do, please participate to help keep our scores high. Being ranked among the most widely and thoroughly read ophthalmic publications enables us to secure funding for projects that help you in the clinical realm as well as your practice, like the *MIPS Manual*—the most popular supplement we've ever created. We appreciate your support! Your Academy's Year in Review

Each year, Academy leadership and more than 1,000 physician volunteers provide you

with the best member experience. Find out what the Academy achieved in the last year on all fronts, including advocacy, education, public service, and more. The 2017 Year in Review highlights some of the Academy's achievements:

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• launched the David E.I. Pyott Glaucoma Education Center on the ONE Network

• promoted our profession to the public through impactful patient stories

• fought for ophthalmology's best interests in state and federal affairs

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# WHAT'S HAPPENING

# Advocate for Ophthalmology's Future at Mid-Year Forum 2018

At the Mid-Year Forum, the ophthalmology community comes together to shape its future and drive change.

Attend the panel discussions. Key topics will include "Drugs in 2018: Access, Pricing, and Payment" and "The Changing Role of the Veterans Health Administration." You'll also hear panel discussions on the scientific advancements and practice insights of the IRIS Registry; private equity and equity transfers; how to handle information overload; the future of artificial intelligence in ophthalmology; and more.

Visit Capitol Hill to educate legislators and their staff on health care issues. During Congressional Advocacy Day, join your colleagues and Academy leaders in directly advocating for your profession and patients. On the evening of April 18, you'll be briefed over dinner. On April 19, from 8:00 a.m. to 3:00 p.m., attend Academy-facilitated meetings with your members of Congress and their staff to advocate for your patients and the profession of ophthalmology.

The Mid-Year Forum 2018 will be held April 18-21 at the Renaissance Downtown in Washington, D.C. The



AMERICAN ACADEMY OF OPHTHALMOLOGY®



specialists globally. The journal prioritizes papers that teach clinicians how to make better diagnoses, select preferred treatments, and follow best practice patterns with the goal of delivering optimal outcomes for patients.

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# ACADEMY STORE

# Access AAO 2017 Practice Management Program

More than 30 hours of practice management courses from the 2017 AAOE Program in New Orleans are available on demand. Order this package to view your favorite practice management presentations again or see what you missed.

**To order,** visit store.aao.org/aao-2017-meetings-on-demand.html.

# Register for March 28 Benchmarking Webinar

Benchmarking provides practices with a distinct competitive advantage. In this 60-minute webinar, you'll review case studies and learn how comparative insights about financial performance and practice efficiency can significantly increase profitability. An introduction to the Academy's AcadeMetrics benchmarking tool—free for Academy and AAOE members—will be covered.

To order, visit store.aao.org/practicemanagement.html and choose Webinar under media type.

# **MEETING MATTERS**

# Registration and Hotels: Mark Your Calendar

Starting June 13, Academy and AAOE members can register and make hotel reservations for Subspecialty Day (Oct. 26-27) and AAO 2018 (Oct. 27-30), which will be held in Chicago. On June 27, nonmembers can register and reserve hotel rooms.

# AAO 2018 Abstract Deadlines: Papers/Posters and Videos

To present at AAO 2018, you must submit abstracts online. The abstract submitter for papers/posters and videos opens March 8 and closes April 10.

# D.C. REPORT Delay for Multistate Modifier -25 Cut

Since October, the Academy has fought Anthem BlueCross and Blue-Shield's 12-state cut to reimbursements for office visits associated with modifier -25. In response to this advocacy, Anthem said it would delay the cut's implementation from Jan. 1 to March 1. It also said it would decrease the cut to these reimbursements from 50% to 25%. The policy will affect the following states: California, Colorado, Connecticut, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, and Wisconsin.

Modifier -25 applies to office visits bundled with same-day treatment, including intravitreal injection. To ensure adequate reimbursements, physicians might be compelled not to provide 2 services on the same day, instead having patients return to the office for a separate visit for treatment. The Academy is partnering with the affected ophthalmic state societies to halt this cut.

The Academy has specific guidance on the use of modifier -25. Even when an established patient exam is medically necessary, if you perform it solely to confirm the need for the minor surgical procedure, you cannot separately bill the exam. Medicare Part B does not require you to append new patient exams with modifier -25 when you perform a minor surgical procedure the same day.

For abstract guidelines for videos and paper/posters, visit aao.org/presentercentral. To submit an abstract, visit aao.org/abstracts.

# **International Attendees**

Foreign travelers coming to the United States to attend conferences need visitor visas, unless they qualify for entry under the Visa Waiver Program. There are several steps to apply for a visa, so get started early. To help you obtain travel documents, the Academy has an online letter generator to create a letter of invitation to attend AAO 2018. Enter your information into the form and print out the personalized letter.

For the letter generator and other helpful information, visit aao.org/visa.

# PEOPLE

# Passages

Benjamin F. Boyd, MD, FACS, ophthalmic surgeon and professor, passed away on February 5. He was 93.

Dr. Boyd was past president and executive director of the Pan-American Association of Ophthalmology (PAAO), where he made significant inroads in organizing and promoting ophthalmic education throughout the Western hemisphere and fostered the development of international relations between ophthalmologists. In recognition of his contributions to education and the restoration of sight, PAAO created the Benjamin F. Boyd Humanitarian Award and Gold Medal in 1987. The award is presented every 2 years to an individual who participates in charitable activities, indigent care, community service, and humanitarian activities through a public service program.

Dr. Boyd was past president of the Academia Ophthalmologica Internationalis, president of the Panamanian Academy of Medicine and Surgery of the Republic of Panama, founder and president of the Panamanian Society of Ophthalmology, founder of the Boyd Ophthalmology Center, and a founder of the School of Medicine of the University of Panama, where he was the first professor of ophthalmology and then dean of the faculty of medicine. He was also the founder, author, and editor-in-chief of *Highlights of* Ophthalmology, a bimonthly journal published in English and Spanish.





# **Register Today**

Register for Mid-Year Forum 2018 and let our collective voice be heard.

The registration fee is \$225 (\$325 after March 6). There is no fee for Congressional Advocacy Day. Academy members in training receive complimentary registration to all events.

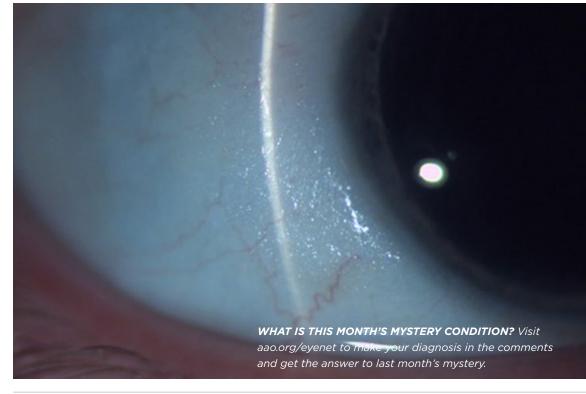
# aao.org/myf

# Help Make a Positive Impact on Ophthalmology's Future

Mid-Year Forum is one of the Academy's most significant yearly meetings, bringing the ophthalmology community together to drive change and shape our profession's future.

- Meet with federal lawmakers during Congressional Advocacy Day.
- Directly advocate for your profession and patients.
- Learn about changes that impact how you practice.
- Develop key strategies for successfully implementing new programs into your patient-care approach.
- Hear from expert panels on the future of our profession.
- Play a key role in driving the highest quality of care for your patients.

# MYSTERY IMAGE

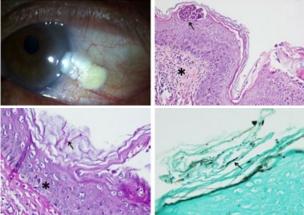


# LAST MONTH'S BLINK

# Ocular Surface Squamous Neoplasia With Superficial Fungal Colonization

n 85-year-old man presented with a leukoplakic conjunctival mass in the temporal aspect of the left eye that had been there for 10 months. The mass was encroaching onto the cornea. No significant inflammation or dilated feeder vessels were present. Clinical diagnosis of leukoplakic ocular surface squamous neoplasia (OSSN) was made.<sup>1</sup> The mass was surgically excised along with 4 mm of healthy conjunctiva, with cryotherapy at the margins.<sup>2</sup> Histopathology of the mass showed microabscess formation in the conjunctival epithelium with moderate lymphonuclear infiltration and a few foci of moderate dysplasia.3 Scattered fungal profiles were seen in the superficial layers of the mass on H & E, and Grocott's methenamine silver stains confirmed the diagnosis of conjunctival mycosis<sup>4,5</sup> along with carcinoma in situ. This is the first report of leokoplakic OSSN with fungal colonization, an extremely rare co-occurrence.

1 Krachmer JH et al. *Cornea: Fundamentals, Diagnosis and Management.* St. Louis, Mo.: Mosby Elsevier; 2005.



2 Reidy JJ et al. *Basic and Clinical Science Course, 2011-2012.* San Francisco: American Academy of Ophthalmology; 2011.
3 McKelvie PA et al. *Br J Ophthalmol.* 2002;86(2):168-173.
4 Sehgal SC et al. *Mycopathologia.* 1981;73(1):17-19.
5 Ando N, Takatori K. *Am J Ophthalmol.* 1982;94(1):67-74.

WRITTEN BY **ANCHAL THAKUR, MBBS,** ADVANCED EYE CENTRE, POST GRADUATE INSTITUTE OF MED-ICAL EDUCATION AND RESEARCH, CHANDIGARH, INDIA.



# Create a Lasting Legacy

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Empower our profession by making a planned gift today to support Academy programs.

To learn more, visit **aao.org/planmylegacy**.

"The Academy provides the education and professional support necessary to achieve the highest quality of patient care nationally and globally. Working with professional colleagues in support of the Academy's mission continues to be a highlight of my professional career. My wife and I are pleased to be able to make a planned gift to help secure the future of our profession."

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MD



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**INDICATIONS FOR USE:** The TRULIGN® toric posterior chamber intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision. **WARNINGS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient. Rotation of toric lenses away from their intended axis can reduce their effectiveness, and misalignment can increase postoperative refractive cylinder. The TRULIGN® Toric IOL should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye. Unlike most other IOLs, the TRULIGN® Toric IOL optic has hinges connecting it to the haptic; please see adverse events section below for more information. **PRECAUTIONS:** The safety and effectiveness of the TRULIGN® Toric intraocular lenses have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Long-term stability in the human eye has not been established; therefore postoperative monitoring after implant should be performed on a regular basis. Lens rotation less than 5° may not warrant reorientation. Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the TRULIGN® Toric IOL directions for use. **ADVERSE EVENTS:** The incidence of adverse event experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control

1. TRULIGN Toric IOL Directions for Use. 2. Data on file, Bausch & Lomb Incorporated. Study 650. 3. AcrySof IQ Toric Directions for Use. 4. Tecnis Toric Directions for Use.

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