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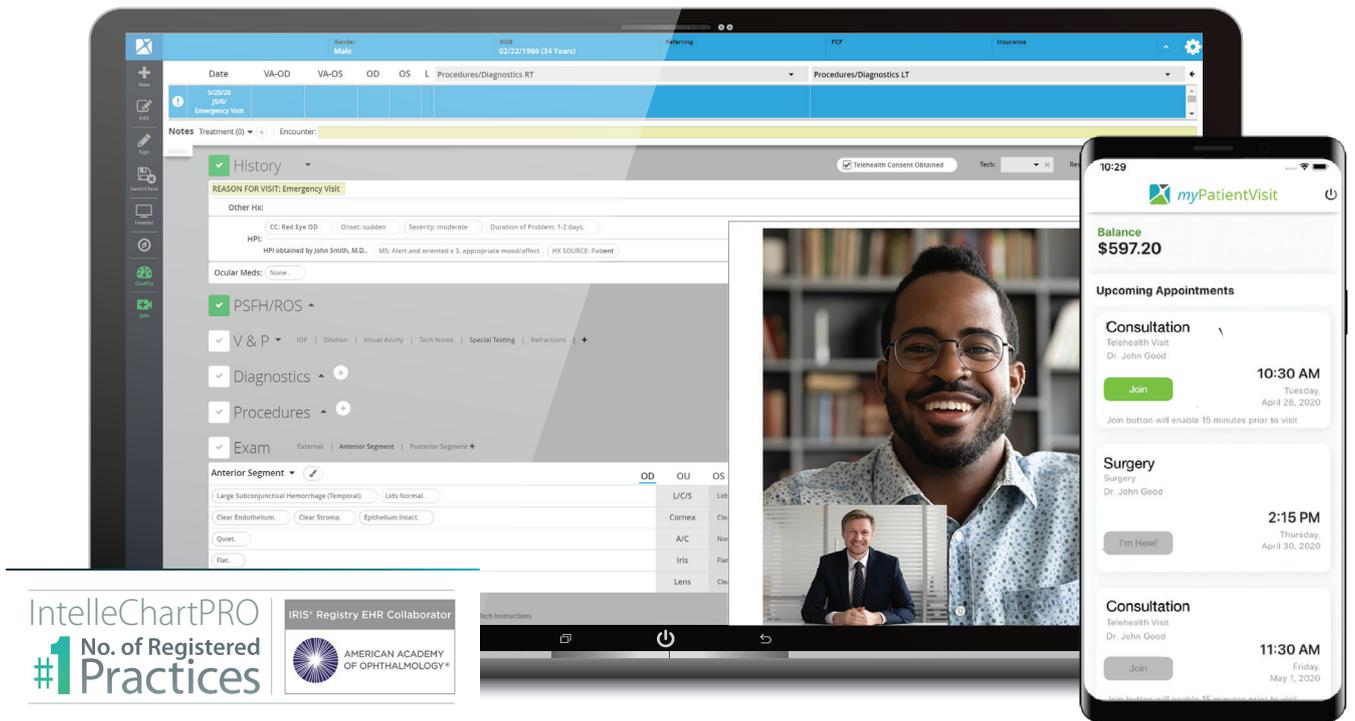
Cornea Donor Tissue
How Old Is Too Old?

OPINION
Rubber Bullets and Responsibilities



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**DEXYCU (dexamethasone intraocular suspension) 9%,
for intraocular administration
Initial U.S. Approval: 1958**

BRIEF SUMMARY: Please see package insert for full prescribing information.

1 INDICATIONS AND USAGE

DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Increase in Intraocular Pressure

Prolonged use of corticosteroids including DEXYCU may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma.

5.2 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids.

5.3 Exacerbation of Infection

The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection.

5.4 Cataract Progression

The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Increase in Intraocular Pressure [see *Warnings and Precautions (5.1)*]
- Delayed Healing [see *Warnings and Precautions (5.2)*]
- Infection Exacerbation [see *Warnings and Precautions (5.3)*]
- Cataract Progression [see *Warnings and Precautions (5.4)*]

6.1 Clinical Trials Experience

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

The following adverse events rates are derived from three clinical trials in which 339 patients received the 517 microgram dose of DEXYCU. The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis. Other ocular adverse reactions occurring in 1-5% of subjects included, corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, blurred vision, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia, and vitreous detachment.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of DEXYCU (dexamethasone intraocular suspension) in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice and malformations of abdominal wall/intestines and kidneys in rabbits at doses 7 and 5 times higher than the injected recommended human ophthalmic dose (RHOD) of DEXYCU (517 micrograms dexamethasone), respectively [see *Data in the full prescribing information*].

In the US general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. There is no information regarding the presence of injected DEXYCU in human milk, the effects on breastfed infants, or the effects on milk production to inform risk of DEXYCU to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for DEXYCU and any potential adverse effects on the breastfed child from DEXYCU.

8.4 Pediatric Use

Safety and effectiveness of DEXYCU in pediatric patients have not been established.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between older and younger patients.

Manufactured for: EyePoint Pharmaceuticals US, Inc. Watertown, MA 02472



DEXYCU[®]
(dexamethasone intraocular
suspension) 9%

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and your patients**

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visit DEXYCU.com or call 1-833-EYEPOINT (1-833-393-7646).**

INDICATION AND USAGE

DEXYCU[®] (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Increase in Intraocular Pressure

- Prolonged use of corticosteroids, including DEXYCU, may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision
- Steroids should be used with caution in the presence of glaucoma

Delayed Healing

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

Exacerbation of Infection

- The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures

WARNINGS AND PRECAUTIONS (cont'd)

Exacerbation of Infection (cont'd)

- Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections
- Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection

Cataract Progression

- The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts

ADVERSE REACTIONS

- The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis

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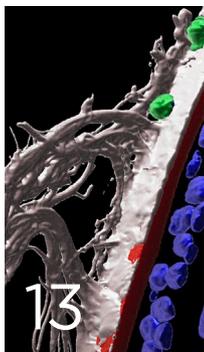
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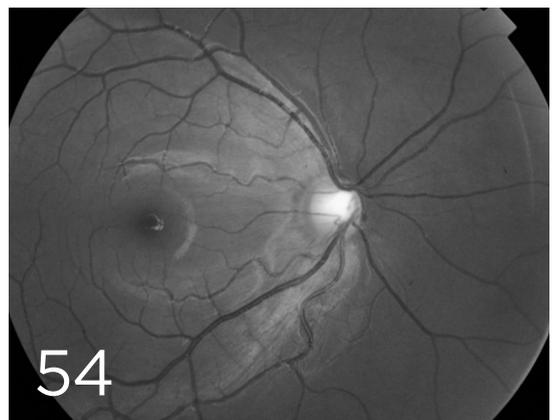
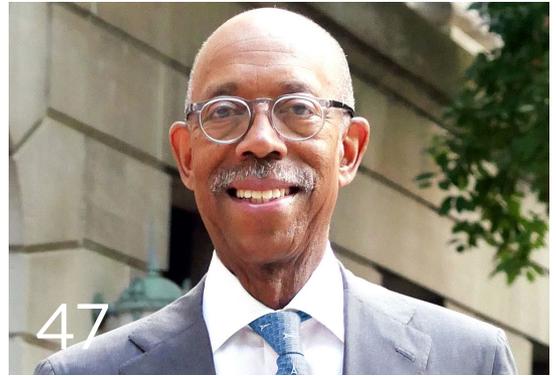
MYSTERY IMAGE

54 Blink

What do you see?

COVER PHOTOGRAPH

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Letters

Ophthalmic Disease and Dating Apps

We live in a society where virtual socialization is the new norm. These interactions include finding romantic partners using online dating applications, which typically require profile pictures and strongly emphasize appearance.



Control



Corneal edema



Strabismus

Now consider patients with ophthalmic diseases, such as strabismus or various corneal pathologies, who experience psychosocial distress due to the physical effect of their conditions and, as a result, on how others perceive them.

We conducted a study in which we created a series of profiles on Tinder, a widely used dating application. These profiles differed only by the pictures, which were altered using Photoshop software to create three groups: a control group, a group in which the subjects showed physical symptoms of corneal edema, and a group that showed physical symptoms of strabismus. Our study showed that the strabismus group had a statistically significant lower match rate compared with the normal profile ($p < 0.05$) while the corneal edema group did not ($p = 0.35$). These results indicate the potential negative effect that ocular pathologies have on psychosocial functioning and health. Quantifying the societal effects of these diseases enables a greater appreciation of the condition and proper evaluation of treatment effectiveness.

Guidelines for treatment of disfiguring ocular diseases are based on visual potential and ability to restore binocular vision. Cosmetic reconstruction is rarely an indication, especially if restoration of visual function is limited. Treatments to benefit psychosocial functioning and quality of life should be factored in when determining surgical management.

Brice I. Hwang, MD
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The 19th Annual Downeast Ophthalmology Symposium

OCTOBER 2-4, 2020 Virtual Meeting



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RUTH D. WILLIAMS, MD

Rubber Bullets and Responsibilities

On Friday, May 29, Linda Tirado, a photojournalist covering the Minneapolis protests that followed the death of George Floyd, was shot in the left eye with a rubber bullet. True to her calling as a journalist, she tweeted about her experience on her way to the OR. Ophthalmologists and news outlets reported dozens of similar devastating ocular injuries from the rubber bullets that police use for crowd control.

The right to protest is embedded in the political culture of many countries. Indeed, the First Amendment of the U.S. Constitution reads, “Congress shall make no law . . . abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.” Peaceful public protest is a hallmark of a vibrant democracy. However, as some large protests have led to violence and riots, police and security forces have used a variety of crowd-control weapons that are meant to cause pain without causing death.

Rubber bullets, a type of kinetic impact projectile (KIP), come in a variety of styles. Some are single projectiles; others are fired as a group of pellets. While KIPs may be nonlethal, they can cause harm, including significant harm to the eye.

Ocular injuries from rubber bullets aren’t new. Last fall, with the backdrop of unrest over economic issues, protesters packed the streets in Santiago, Chile. Several hundred people suffered severe ocular injury from rubber bullets—and the image of a bandaged eye became a rallying symbol.¹ Even though Chile’s president defended the use of force to maintain order, in response to the outcry, the police chief suspended their use except in circumstances of extreme danger.²

Law enforcement in the United States needs similar guidelines. After performing emergency surgery on two young men who sustained penetrating ocular injuries from KIPs—one was peacefully protesting, while the other was merely walking a half block to his car—Prem Subramanian wrote the Denver mayor. He explained the balance between the need for order and the need for restraint: “I am a former U.S. Army officer with 21 years of service. I believe in the rule of law, and I also believe in the concept of a proportional response. Police should not unleash violence, lethal or not, upon individuals who may be protesting peacefully or even violating laws such

as curfews. Arrest, detention, fines—these are all appropriate penalties for legal violations. Blindness from exercise of police force from a distance is not.” I would add that police need crowd-control measures when riots or looting develop, but that these measures must not permanently maim.

The Academy condemns the use of KIPs, publicly stating that “Following numerous serious injuries . . . the American Academy of Ophthalmology calls on domestic law enforcement officials to end the use of rubber bullets to control or disperse protesters. The Academy asks physicians, public health officials and the public to condemn this practice.”³ Our approach to these issues isn’t through a political lens; rather, it reflects our commitment to saving vision.

What can an individual ophthalmologist do? Many have participated in the Academy social media campaign #NoRubberBullets #NotOneMoreEye. A letter from a treating surgeon, like Prem’s, to the local police chief or mayor is impactful. Another option: Consider writing a Letter to the Editor in the local newspaper.

As for Linda Tirado, after her surgery, she tweeted, “No worries, I’ve been back at work for five hours now. My job is to witness and they only got my left eye.” Just as Ms. Tirado is deeply committed to her work—even after being partially blinded—we ophthalmologists are committed to our work of saving vision. And right now, in addition to treating ocular injuries, that work includes public action.



Ruth D. Williams, MD
Chief Medical Editor, EyeNet

1 www.nytimes.com/2019/11/19/world/americas/chile-protests-eye-injuries.html.

2 www.cnnchile.com/pais/mario-rozas-suspende-uso-balines-antidisturbios_20191119/.

3 aao.org/newsroom/news-releases/detail/statement-on-rubber-bullets-crowd-dispersion. Accessed June 17, 2020.

Current Perspective

DAVID W. PARKE II, MD

Humility

Like most medical students, I was convinced that I would choose for a career whichever specialty I was currently assigned. When I was on ob-gyn, I was sure that was my calling. The same was true for cardiology, vascular surgery, pediatrics, and (ultimately) ophthalmology. I also loved infectious diseases—really loved infectious diseases. But when I told my attending this, he said (and I paraphrase) “I wouldn’t go into it now. There are no new diseases, and the antimicrobials we’ve got work well. There are just no real clinical challenges left.”

So much for that.

Since that time, we’ve had Legionnaires disease, HIV-related diseases, H5N1, SARS, MERS, Ebola, prion diseases, flesh-eating bacteria, MRSA and other emerging patterns of drug resistance, resurgences of measles and polio, West Nile virus, Lyme disease, bacterial causes for presumed chronic inflammatory conditions, and many other infectious disease challenges.

And now, in an era of gene therapy, stem cell research, monoclonal antibody technology, siRNA molecules, CRISPR technology, personalized medicine, and big data, our shortcomings have been spotlighted by a tiny virus.

SARS-CoV-2 is not as lethal as SARS-CoV-1, nor is it as contagious as measles. Its onset is generally not as rapid as Ebola or as indolent as prion diseases. Yet the combination of transmissibility, lethality, incubation period, and lack of a specific vaccine or treatment has killed over one-half million people, dooms thousands more each day, and brought global commerce to a virtual halt.

As our tragic experience with the virus matures, we are coming to appreciate some of the more insidious legacies of the disease—medical, economic, and cultural. Many of the survivors have permanent myocardial damage and deficits from thrombotic strokes. Some of our world’s most vulnerable citizens have to choose between, on the one hand, sheltering and hunger and, on the other, working and an increased risk of death. Entire sectors of the economy are at risk of collapse—along with the jobs they provide. And the psychological stresses, the personal isolation, and fraying of the general social fabric has led to increases in certain crimes, violence, abuse of children and spouses, and of suicide.

Some communities made the mistake of thinking “it won’t happen here because we are different/smarter/better.” The virus has shown it really doesn’t care. Put enough people in enough proximity, introduce the virus, and it will spread—sooner or later. And it can kill regardless of age, state of fitness, or access to care.

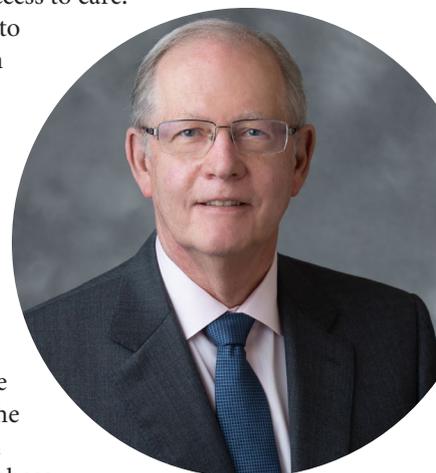
In retrospect, it humbles us to think that a handful of random nucleic acid resequencings in an animal-derived virus in the interior of China could bring down a sophisticated global medical, economic, and social juggernaut.

BUT . . .

We must also believe in ourselves and marvel at the amazing initiatives to defeat the virus. In less than six months the scientific community has taken vaccine development through phase 2 trials—something that typically takes over five years! In order to achieve the necessary scalability to vaccinate a planet, companies are investing billions of dollars now to prepare hundreds of millions of doses even before phase 3 testing is completed. If their drugs are proven safe and effective, we will then already have a large (but still inadequate) supply on hand.

Some of the underlying economic and social damage will take longer to repair. The first step involves personal and community ownership of issues that render us vulnerable—be they economic problems like manufacturing capacity and supply chain redesign or social issues of justice and poverty.

Our public health arrogance must be a thing of the past. We should presume that future global microbial challenges are inevitable and prepare to defend against them. As physicians and healers with a responsibility for individual and community health, this is both a scientific and a moral imperative. We don’t want to go through this again!



David W. Parke II, MD
Academy CEO



We are
Here for you

To our colleagues...

We understand the COVID-19 pandemic has severely impacted you both emotionally and financially.

Like you, OMIC's Board of practicing ophthalmologists has been forced to cease or severely limit practice during the COVID-19 pandemic.

We are recovering but the effects on all of us will be felt for some time. Ultimately, we know that the resiliency of the ophthalmic community will help us pull through these challenging times.

Here is how we are helping.

COVID-19 PREMIUM RELIEF

OMIC was one of the first carriers to announce financial assistance for policyholders. On April 10, 2020, our Board approved a COVID-19 premium credit, which was effective for all insureds active on May 1, 2020 and has been applied to policies. Insureds do not need to do anything to qualify; premiums will be automatically adjusted.

COVID-19 PAGE

- ➔ COVID-19 Sample Patient Consent Documents
- ➔ Risk Management Resources and Recommendations
- ➔ OMIC News and Coverage Information

[OMIC.com/COVID-19-PAGE](https://www.omic.com/COVID-19-PAGE)

COVID-19 RISK MANAGEMENT

OMIC created a COVID-19 page in March 2020; visit [OMIC.com](https://www.omic.com) to learn more. Policyholders requiring assistance should call OMIC's confidential Risk Management Hotline for COVID-19 questions and assistance at (800) 562-6642 and Press 4 or email riskmanagement@omic.com.



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News in Review

COMMENTARY AND PERSPECTIVE

IMMUNOLOGY

Immune Privilege in the Lens? Think Again

CONTRARY TO LONG-STANDING ophthalmic dogma, immune privilege in the crystalline lens does not exist, scientists investigating the intraocular response to eye injury have discovered. Instead, the lens and associated structures should be regarded as immune-quiescent.¹

“While the lens is avascular, it’s not an immune-privileged tissue, and this is a huge sea change in the way we think about things. Everyone, including myself, just presumed that because this tissue was avascular there would be no source of immune cells” to protect the lens, said senior author A. Sue Menko, PhD, at Thomas Jefferson University in Philadelphia.

A surveillance response to corneal injury? In their experiments in mice, Dr. Menko and her colleagues found that the ciliary zonules, which contain a reservoir of two likely immune-mediator molecules, MAGP1 and TSP-1, react to corneal injury by recruiting leukocytes to the lens. Scanning electron microscope images showed that the immune cells travel along the zonular fibers, but they can also migrate onto the capsule and sometimes into the lens itself.

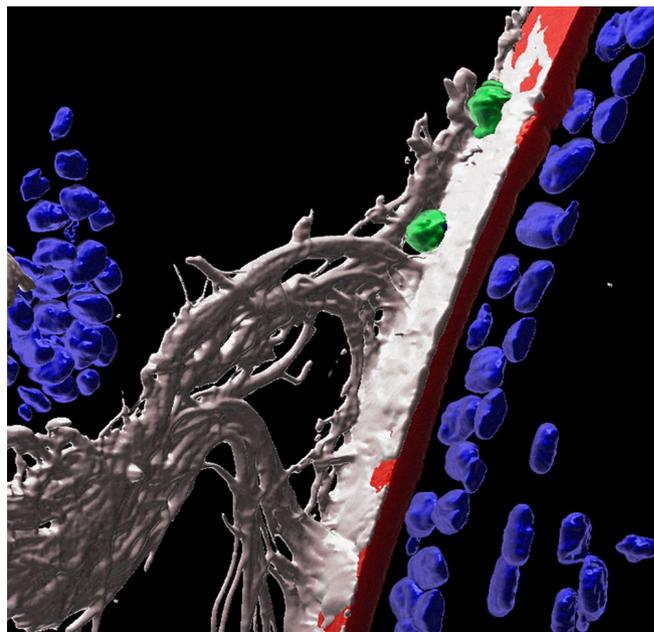
“We imagine what we’re describing is a protective response to the lens, as the cornea is getting repaired. It’s not

an overabundance of immune cells. It looks like a surveillance response,” Dr. Menko said.

Robustness of immune response.

Patient-specific cofactors, such as genetics and concurrent ocular inflammation, appear to influence the robustness of the immune response and its potential to be pathologic, she said.

However, research has shown that some of the recruited immune cells acquire a myofibroblast phenotype and begin producing a fibrotic collagen matrix. Fibrosis triggered by these cells might explain the genesis not only of posterior capsular opacification after cataract surgery but also of anterior subcapsular cataracts associated with corneal wounds, Dr. Menko said. She and coauthor Mary Ann Stepp, PhD, at George Washington University in Washington, D.C., along with Rachel R. Caspi, PhD, of the NEI, are investigating this possibility by studying the movement of autoimmune cells into the lens and resulting cataract formation in patients with inflammatory conditions such as uveitis. They hope to publish their results within the next year, she said.



RESPONSE. At day 1 following corneal wounding, 3D surface structure imaging shows immune cells (CD45+, green) migrating within ciliary fibrils (MAGP1+, white) that extend along the surface of the matrix capsule that surrounds the lens (perlecan+, red). The ciliary zonules (white) are also evident, as are the nuclei (blue).

Obvious in hindsight? The researchers’ paradigm-shifting conclusion that the lens does not have immune privilege might seem surprising at first—but it may appear less startling in retrospect, Dr. Menko said. “In science, sometimes we believe things because they’re dogma, but if you think about it you realize that those things don’t make sense,” she said.

“We began looking for signs of an immune response to the lens because it just seemed against all logic that you’d have a tissue that is so crucial throughout a lifetime, but which evolved in such a way that the body would not try to protect or repair it.” —Linda Roach

1 DeDreu J et al. *FASEB J*. Published online May 25, 2020.

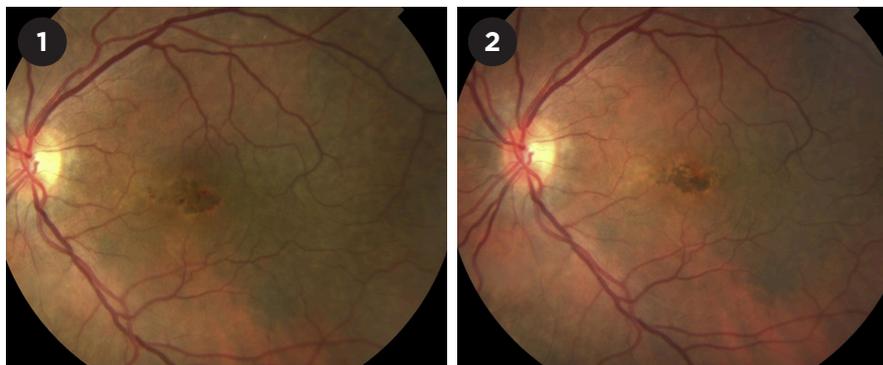
Relevant financial disclosures—Dr. Menko: None.

Beware Burn Risk With Dual-Mode Laser Systems

DESPITE WARNINGS, INJURIES WITH dual-mode laser capsulotomy/selective laser trabeculoplasty (SLT) laser systems continue to occur. A team of retina subspecialists recently presented a case of a 65-year-old woman whose left macula was scarred when capsulotomy was attempted using the system's SLT mode.¹

This is not the first publication to warn of the potential for serious injury when dual-mode capsulotomy/SLT systems are operated in the wrong mode.² However, published reports of misuse have been scarce. Moreover, gag rules imposed in malpractice settlements prohibit publication of cases, including two other current cases known to the authors.¹

Lack of awareness. “Many clinicians are unaware of and often surprised to



INJURY. (1) Baseline fundus photograph shows foveal retinal pigment epithelium (RPE) mottling from multiple laser lesions. (2) Three months later, traumatic RPE hyperplasia is more prominent, while surrounding hemorrhages have resolved.

learn of this serious recurrent injury,” said coauthor Martin A. Mainster, PhD, MD, at the University of Kansas School of Medicine in Kansas City. “The SLT mode of a capsulotomy-SLT laser system can cause devastating, permanent foveal damage when it’s used erroneously in an attempted capsulotomy.”

Current case report. Dr. Mainster and his colleagues described the case of a woman who underwent cataract surgery—and then, a year later, required

capsulotomy for each eye. Although the treatment of her right eye was successful, the capsulotomy of her left eye failed, and she reported severe vision loss in that eye one week later.

She was referred to the authors, and imaging revealed permanent macular and extramacular photothermal and photomechanical damage. The best-corrected visual acuity (BCVA) in her left eye declined from 20/30 to 20/400. Within three months, the BCVA in that

ONCOLOGY

How to Monitor Adult Retinoblastoma Survivors

IMPROVEMENTS IN THE TREATMENT AND CARE OF retinoblastoma (RB) have resulted in a growing population of adult survivors of the disease. But how should they be managed, particularly given their increased risk of developing additional cancers in adulthood?

An international interdisciplinary panel was convened to review the science and generate recommendations for long-term follow-up for adult survivors of heritable RB, which is associated with mutations in the *RB1* gene. “After abstract and full-text review of 139 papers, we chose 37 papers for detailed data abstraction to quantify risk and evidence regarding surveillance,” said coauthor Emily S. Tonorezos, MD, MPH, at Memorial Sloan-Kettering and Weill Cornell Medical College in New York City.

Risk of subsequent cancers. Adult RB survivors are at risk of developing additional neoplasms, particularly bone and soft tissue sarcomas, melanoma, and uterine leiomyosarcoma.

In addition, the panel noted, those with a history of radiotherapy are at increased risk of brain and central nervous system tumors.

Recommendations for surveillance. The panel, which included ocular oncologists, issued the following recommendations for follow-up:

Strong. An annual skin examination, especially among those with dysplastic nevi, is strongly recommended.

Moderate. The panel issued a moderate recommendation in favor of the following: 1) an annual history and physical exam with attention to bony structures; and 2) prompt evaluation of signs and symptoms that involve the head and neck, such as persistent sinusitis, pain, or skeletal tenderness.

Avoid. The panel advised against the following: 1) routine surveillance for uterine leiomyosarcoma; 2) an annual thyroid ultrasound to screen for thyroid cancer; and 3) additional surveillance (beyond what is recommended based on local guidelines) for bone, brain, breast, colorectal, hematologic, or lung cancers, “where risk is uncertain or benefit cannot be anticipated.”

Uncertain. The panel also noted that “Consideration should be given in favor of surveillance modalities that do not include ionizing radiation, although evidence for or against this recommendation in heritable RB survivors is lacking.”

—Arthur Stone

1 Tonorezos ES et al. *Ophthalmology*. Published online May 15, 2020.

Relevant financial disclosures—Dr. Tonorezos: None.

eye was count fingers at 4 feet, and she was informed of her poor visual prognosis. The diagnosis: laser maculopathy. “SLT mode laser pulses passing through a patient’s pupil reach and destroy retinal tissue,” Dr. Mainster said.

How these accidents occur. These incidents occur when the laser system is inadvertently turned on in its SLT mode or left on after an SLT procedure for others to use, Dr. Mainster said. He explained, “A clinician performing a capsulotomy might confuse the SLT mode’s single-spot capsular reflection with the in-focus fusion of the capsulotomy mode’s multiple-spot-aiming interface.”

How to prevent further incidents. To prevent similar iatrogenic injuries, the authors recommend taking the following steps:

- Have clinicians—not technicians—select the laser delivery mode.
- Double-check the laser mode before treating.
- Enhance engineering controls, such as different-colored backgrounds for each laser mode on a touch screen.
- Require entry of a personal identification number by clinicians—not technicians—to acknowledge a warning before the SLT mode can be used.
- Affix a conspicuous note to every machine warning users never to attempt capsulotomy when the device is in SLT mode.

Ounce of prevention. Administrative and engineering controls could have prevented the woman’s injury, but such controls were either absent or ignored, the authors wrote.

With regard to treatment, Dr. Mainster said that treatments such as anti-inflammatory and neuroprotective drugs are usually ineffective for severe macular injuries. As he noted, “The best way to treat a laser injury is to prevent it.”
—Miriam Karmel

1 Ledesma-Gil G et al. *Ophthalmology*. Published online May 17, 2020.

2 Liyanage SE et al. *Br J Ophthalmol*. 2014;98(1):141-142.

Relevant financial disclosures—Dr. Mainster: Ocular Instruments: C.

RETINA

Topical Tx for Macular Holes?

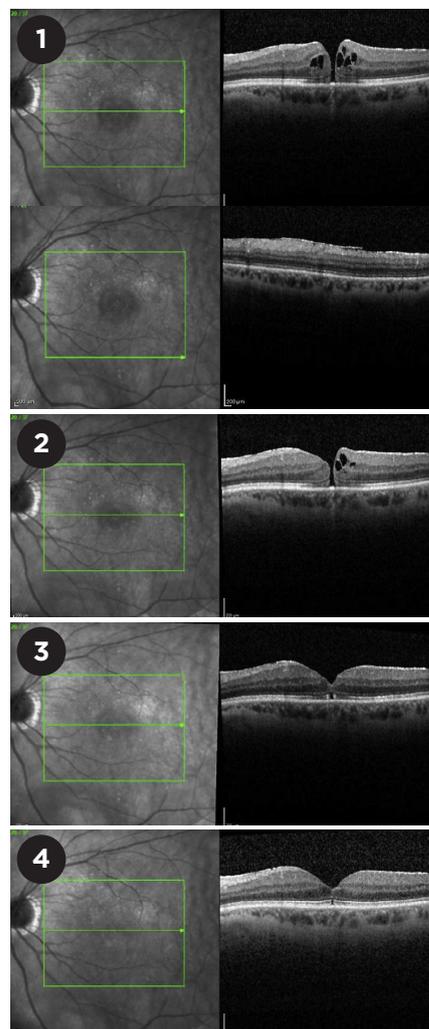
TOPICAL THERAPY MAY BE ABLE TO close small secondary macular holes and potentially eliminate the need for surgery.¹

Study specifics. This retrospective analysis involved nine cases of topically treated, secondary full-thickness macular holes (FTMH). Eight of the eyes (89%) had successful hole closure and resolution of their associated cystoid macular edema. The hole in the ninth eye, in a patient with topically treated bilateral holes, did not close after six weeks of topical therapy, and the patient was then lost to follow-up.

All patients received corticosteroid drops (difluprednate ophthalmic emulsion 0.05%). Six eyes also received a topical carbonic anhydrase inhibitor (dorzolamide 2% or brinzolamide 1%), and two eyes received a nonsteroidal anti-inflammatory drug (bromfenac 0.07%). The average initial hole diameter was 79.6 μm (range, 44 to 132 μm), and the average time until closure was six weeks (range, two to 19 weeks).

A paradigm shift? “The standard of care for primary macular holes caused by vitreomacular traction is vitreoretinal surgery,” said coauthor John Niffenegger, MD, at Retina Associates of Sarasota, Florida. “In cases of small holes (<250 μm) that are secondary to something other than vitreomacular traction, patients often would like to avoid surgery, and interest in addressing their problem with topical therapy has been increasing.”

The outcomes of this study support a role for comprehensive ophthalmologists to consider medical therapy for patients who have small, secondary macular holes, Dr. Niffenegger said. “With spectral-domain optical coherence tomography fairly available now, it’s easier for a comprehensive ophthalmologist to determine the hole’s size and etiology,” he said. “So, in the absence of vitreoretinal traction, it would be reasonable for them to consider a



OCT SEQUENCE. (1) Cystoid macular edema, high retinal surface reflectivity from epiretinal membrane, and a FTMH. The patient was started on difluprednate three times daily. (2) At four weeks, the hole is closed, and the drops are reduced to twice daily. (3) At 22 weeks, the hole remains closed, the outer retinal break is decreased, and treatment is discontinued. (4) At 81 weeks, the hole remains closed without drops.

trial of topical therapy as they refer the patient for vitreoretinal consultation or await scheduling for macular hole surgery. You might be able to spare these patients the expense and possible complications of surgery.”
—Linda Roach

1 Niffenegger JH et al. *Ophthalmol Retina*. Published online Jan 28, 2020.

Relevant financial disclosures—Dr. Niffenegger: None.

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

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Journal Highlights

NEW FINDINGS FROM THE PEER-REVIEWED LITERATURE

Ophthalmology

Selected by Stephen D. McLeod, MD

Comparison of Repair Strategies for Moderately Complex RRD

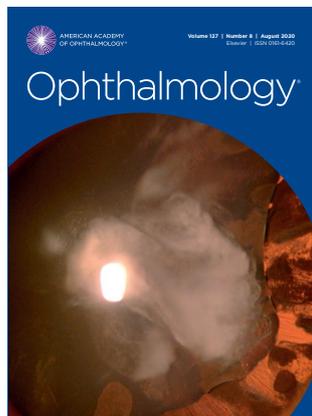
August 2020

Which surgical strategy is best for repairing moderately complex rhegmatogenous retinal detachments (RRDs)? Ryan et al. compared the visual and anatomic outcomes for patients with moderately complex RRD who were treated by scleral buckle (SB), pars plana vitrectomy (PPV), or the combination of PPV and SB. All three methods delivered good clinical outcomes. SB was superior to PPV in anatomic and visual outcomes, and the best anatomic results were achieved with the combination procedure.

For this retrospective study, data were derived from the phakic patient subset of the Primary Retinal Detachment Outcomes Study, gathered in 2015 from five large health care centers with strong expertise in all three retinal attachment procedures. The primary outcome was single-surgery anatomic success (SSAS), defined as attainment of retinal attachment without need for a follow-up procedure within 90 days. Another outcome of interest was final visual acuity (VA) following each procedure.

The final analysis set included 715 phakic patients. Among them, SSAS

was achieved in 155 of 169 (91.7%) SB cases, 207 of 249 (83.1%) PPV cases, and 271 of 297 (91.2%) PPV/SB cases. SB and PPV/SB were superior to PPV for achieving SSAS ($p = .0041$). SB produced better final VA outcomes ($p = .0089$) than did PPV or PPV/SB, even in patients whose cataract grade was 3+ or higher. SB also showed superior visual outcomes in macula-on and macula-split cases.



The authors affirmed the limitations of their study, including lack of randomization, imbalance of baseline traits among treatment groups, and non-standardization of VA measurements. Future studies are needed to control for

confounding variables, said the authors. Regardless, their data show the continued value of SB in the treatment of moderately complex phakic RRD and, as a result, the need for this technique to be an essential component of fellowship training.

Cataract Outcomes: FLACS Versus Phacoemulsification

August 2020

Day et al. set out to prospectively compare the effectiveness and safety of femtosecond laser-assisted cataract surgery (FLACS) with that of phacoemul-

sification. They found that the newer procedure, which remains costly, was similar to phacoemulsification in terms of vision outcomes, safety, and patient-reported quality of life.

This study included 785 patients and randomization by surgery type, surgeon, and facility (one of three participating hospitals). Only ophthalmologists who had performed at least 10 FLACS surgeries and were certified by the device manufacturers were allowed to participate. Standard phaco surgeries, as well as post-op care for both approaches, were conducted according to the practice standard of each hospital. The primary outcome was uncorrected distance visual acuity (UDVA) three months after surgery. Secondary outcomes included complications, the quantity of corneal endothelial cell loss, and the presence of unintended refractive errors. In addition, participants in both study arms completed post-op self-assessment questionnaires (at six weeks and three months)—one for quality of life, the other for vision health.

FLACS was performed on 392 patients, while 393 had standard phacoemulsification. Three months after surgery, the mean UDVA difference between treatments was -0.01 logMAR. Refractive outcomes were within 0.5 D of target values for 71% of each group and within 1.0 D in 93% of FLACS and 92% of phaco cases. Two posterior capsule tears occurred in the phaco arm and none in the FLACS arm. There were no significant between-group differences in any secondary outcome.

According to the authors, their sample size (determined by power analysis) was sufficient to distinguish major differences in vision between the two types of surgery. They concluded that FLACS is as good as standard phaco at three months in regard to vision, patient-centered outcomes, and safety. They acknowledged that larger randomized trials and meta-analyses are needed to analyze differences in complication rates and assess longer-term outcomes, including cost-effectiveness.

Changes in GCC Thickness and Microvasculature in POAG

August 2020

Research has shown that ocular blood flow impairment and decreased perfusion lead to neuronal damage, causing thinning of the circumpapillary retinal nerve fiber layer and ganglion cell complex (GCC). Moreover, reduced ocular perfusion has been detected in glaucomatous eyes. In a prospective longitudinal study, **Hou et al.** used optical coherence tomography angiography (OCTA) to detect and compare structural thinning and microvascular density changes over time in healthy, preperimetric, and glaucomatous eyes. Decreases in GCC and macular vessel density were detected in all groups. In eyes with primary open-angle glaucoma (POAG), the decline in macular vessel density occurred more quickly than the GCC thinning.

The authors recruited participants from the Diagnostic Innovations in Glaucoma Study, and categorized the eyes as healthy (no evidence of glaucomatous damage), preperimetric (suspicious signs of glaucoma, no repeatable measured visual field damage), or POAG (repeated verifiable visual field damage). POAG severity was graded at study start and reflected the extent of visual field damage. All patients had full ophthalmologic exams at baseline and six-month intervals, for a mean of at least two years. Using predefined protocols, OCTA and spectral-domain OCT scans were performed to measure GCC thinning and macular vascular density. Poor quality images were excluded.

The final analysis included 139

eyes (23 healthy, 36 preperimetric, 80 POAG). Throughout follow-up, all groups exhibited significant ($p < .05$) GCC thinning and decreased macular vascular density. The decrease in vascular density was greatest in POAG eyes, and the rate of decrease outpaced that of GCC thinning in these eyes. The rate of macular vascular density decline correlated strongly with glaucoma severity at baseline. Relative rates of GCC thinning and macular vascular density decline coincided with the range of glaucoma severity; quick rates of vascular density loss were common in severe disease. Intraocular pressure (IOP) during follow-up significantly influenced the rate of GCC thinning in all groups (higher IOP = faster thinning) but did not seem related to vessel density decline. These results are consistent with others showing no strong link between IOP and vascular density decline.

The authors suggest that OCTA may be useful to monitor glaucoma progression and identify factors other than IOP that may contribute to glaucoma. OCTA measurement of macular vessel density may be especially helpful to monitor progression of advanced disease. Further research with larger samples is warranted. (*Also see related commentary by Ji Eun Lee, MD, in the same issue.*)

—Summaries by Lynda Seminara

Ophthalmology Glaucoma

Selected by Henry D. Jampel, MD, MHS

Deep Learning Can Predict Glaucoma Before Its Onset

July/August 2020

Deep learning (DL) has shown promise for automated assessment of glaucoma from fundus photographs after disease onset. **Thakur et al.** tackled a more challenging question: Does the integration of DL models into portable fundus cameras help identify glaucoma before its onset? They found that these models consistently predicted the disease several years before clinical manifestations were apparent.

This prospective longitudinal study

included 66,721 fundus photographs of 1,636 participants (3,272 eyes) of the prospective multicenter Ocular Hypertension Treatment Study (OHTS). At baseline, patients had a normal-appearing optic disc and normal visual field. Ocular measurements and fundus photographs were collected annually for 16 years during the OHTS and were examined by two independent readers. Any observed abnormalities prompted retesting and confirmation by an endpoint committee.

Using these photographs, the authors generated datasets to develop three DL models. The first classified the images as glaucomatous or nonglaucomatous according to gradient-weighted class activation maps. The other two models were trained via transfer learning to predict glaucoma in two time periods before disease onset. The models were validated using 85% of the fundus photographs and were retested on the remaining 15%. Primary outcome measures were accuracy and area under the receiver-operating characteristic curve (AUC).

At study end, the AUC of the DL model for diagnosing glaucoma was 0.95. The AUC for predicting glaucoma development one to three years prior to onset was 0.88; that for predicting it four to seven years beforehand was 0.77.

These findings suggest that DL models are sensitive enough to identify pre-clinical signs of glaucoma from baseline fundus photographs, thus offering a simple, inexpensive, portable screening method to complement routine assessments. The authors cautioned that the models were less accurate for eyes without apparent glaucomatous optic neuropathy.

—Summary by Lynda Seminara

Ophthalmology Retina

Selected by Andrew P. Schachat, MD

SD-OCT Assessment of the Vitreomacular Interface in Adults

August 2020

Quinn et al. evaluated the ability of spectral-domain optical coherence tomography (SD-OCT) to assess the prevalence of vitreomacular interface

(VMI) features and risk factors in a representative sample of adults from Northern Ireland. In addition to observing a link between VMI interactions and age, they found a greater reduction in vitreous separation in the horizontal than in the vertical meridians, which differs from findings in other ethnic groups.

Geographically stratified participants aged 40 years and older were enrolled in the authors' multidisciplinary cross-sectional Northern Ireland Cohort for the Longitudinal Study of Ageing. For the study, which was conducted from December 2013 to April 2018, patients underwent multimodal testing, including SD-OCT for vitreomacular traction (VMT), macular hole (MH), and epiretinal membrane (ERM). All were graded according to International Vitreomacular Traction Study Group definitions. A subset of participants was evaluated further to estimate the prevalence, size, and location of vitreomacular adhesion (VMA).

Descriptive analysis and risk factors were determined for each VMI feature, and results were standardized to the 2011 Northern Ireland census population. The primary outcomes were cohort profile, standardized prevalence, and risk factor associations for each VMI feature, all weighted by age and gender.

In all, 3,351 participants (mean age, 62 years) had gradable SD-OCT images for at least one eye. VMT was found in 30 eyes, MH in 23 eyes, and ERM in 503 eyes. The subgroup analysis showed a weighted VMA prevalence of 22.6%, with VMA area ranging from 0.25 to 42.7 mm² (mean, 12.53 mm²). In multivariate analyses, older age was linked to higher odds of VMT, MH, and ERM; larger VMA area correlated with younger age and normal blood pressure. ERM and MH also were associated with worse myopia and elevated lipid and triglyceride levels.

These findings indicate that VMI interactions throughout life are age dependent. The authors recommend further longitudinal study of VMI changes to track and understand their evolution.

—Summary by Lynda Seminara

American Journal of Ophthalmology

Selected by Richard K. Parrish II, MD

Simple Scleral IOL Fixation Without Glue or Sutures

August 2020

Although ideal placement for an IOL is within the capsular bag, this may not be possible in difficult cataract cases. Scleral-fixated IOLs (SFIOLs) are an alternative in such situations, and their risk of corneal endothelial damage, adhesions, and glaucoma are lower than for anterior chamber or iris-claw lenses. **Boral and Agarwal** assessed the effectiveness of a modified SFIOL in cataract surgery. The SFIOL significantly improved patients' vision and did not require any complicated instruments or scleral-fixation tools.

This retrospective study included 81 eyes (73 patients) with post-op follow-up of at least six months. The procedures were performed by a single surgeon during a four-year period and involved the following steps:

- Two diagonally opposed paralimbal curved self-sealing pockets were created 3 mm from the limbus. During surgery, patients underwent sutureless vitrectomy and sclerotomy.
- An acrylic multipiece foldable IOL was used for scleral fixation. The external haptics were placed inside a linear scleral tunnel that was created under the superficial scleral flap of the scleral pockets.
- Forceps were used to place the haptics in this tunnel, and the IOL was positioned properly. The haptics stayed in place without suture or glue because the scleral fibers held them in the linear scleral tunnel. Cautery was used to replace the conjunctival flap.
- All patients received topical steroids postoperatively. Haptic positioning and optic tilt were assessed by optical coherence tomography of the anterior segment and ultrasound biomicroscopy.

This simplified SFIOL approach significantly improved best-corrected visual acuity from pre-op values, without any major complications. (Two cases of haptic slippage into the vitreous cavity occurred; these were fixed

in a new scleral tunnel.) Moreover, the lenses maintained stability and optimal placement. These findings echo those of previous SFIOL investigations, and the authors encourage multicenter prospective studies to evaluate long-term outcomes.

Tube Shunts and Long-Term VF Outcomes

August 2020

Until recently, glaucoma drainage devices were reserved for patients with refractory glaucoma and poor vision. Now, however, these devices are popular for reducing intraocular pressure (IOP), even in patients with good vision. Previous studies of tube shunts focused on outcomes such as visual acuity, IOP, and overall surgical success. In a retrospective case series, **Liu et al.** looked at the visual field (VF) changes associated with these types of implants, with emphasis on global and regional VFs. During three years of follow-up, they noted that surgery and shunt implantation appeared to stabilize IOP and VF progression.

Study participants had been fitted with one of three tube shunts (Ahmed, Baerveldt, or Molteno) during a five-year period. All patients had visual acuity that was correctable to 20/20 and evidence of worsening glaucoma or IOP that would likely start contributing to further visual damage. VF testing was performed before surgery. Shunt placement was followed by a post-op regimen of antibiotic and prednisolone eye drops.

Data were collected for 95 patients (106 eyes) and included demographics, comorbidities, and results of glaucoma exams before surgery and annually thereafter for three years. Collaborative Initial Glaucoma Treatment Study (CIGTS) scores were applied to assess changes in VFs following the surgery. Regression analysis was used to determine risk factors that may affect VF changes after implantation.

Data analysis showed that shunt implantation led to decreases in IOP; the mean value dropped from 23.1 mm Hg to 12.7 mm Hg. The number of glaucoma medications needed by pa-

tients three years post-op also declined markedly. Global VF metrics (including mean deviation, pattern deviation, and CIGTS pattern deviation probability) remained stable, whereas global CIGTS total deviation probability increased mildly. The greatest risk factors for CIGTS changes were older age and higher number of pre-op glaucoma medications.

The authors suggest that the shunts offer safe and effective IOP control but may not be as good as traditional trabeculectomy. In their study, the Ahmed device was used more often than the others, so further work is needed to compare outcomes for the various implants.

—Summaries by Lynda Seminara

JAMA Ophthalmology

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

Impact of Dementia and Visual Impairment on Daily Functioning

July 2020

Patel et al. looked at a national sample of senior citizens and found that those with dementia plus visual impairment (VI) had greater limitations in self-care, mobility, and other daily activities than would be expected for either condition alone.

For this research, the authors gathered data from the National Health and Aging Trends Study, an annual sampling of U.S. adults 65 years and older. Participants of the 2015 survey who had complete data on outcomes, associated factors, and covariates were included. Main outcome measures were independent associations and interactions of dementia and self-reported VI status on three functional activity scales: self-care, mobility, and household activities. Marginal predicted proportions were calculated, and findings were adjusted for sociodemographic and medical factors.

The final analysis included 7,124 participants, 8.6% of whom reported VI. Probable dementia was present in 6.3% and possible dementia in 8.3%. Self-reported VI was associated with expected score decreases of 14.7% for

mobility, 9.5% for self-care, and 15.2% for household activities. For probable dementia, the expected declines were 27.8%, 22.9%, and 34.7%, respectively. Individuals with both VI and probable dementia had the greatest limitations, with score decreases of 50.1% in mobility, 42.4% in self-care, and 52.4% in household activity. This suggests that co-occurring VI and dementia yield poorer functional ability than either of these disabilities alone.

The severe limitations of concurrent VI and dementia show the need for strategies to address this burden. Such efforts should maximize vision, preserve or enhance cognition, and promote functional independence. (Also see related commentary by David S. Friedman, MD, PhD, and Pradeep Y. Ramulu, MD, PhD, in the same issue.)

Does IOP Variability Help Predict POAG?

July 2020

Whether and how the long-term variability of intraocular pressure (IOP) may contribute to the occurrence of primary open-angle glaucoma (POAG) is not well understood. In a post hoc secondary analysis of two randomized trials, Gordon et al. examined this issue. They found that, for people with untreated ocular hypertension, taking into account the variable long-term IOP data did not seem to improve the ability to predict POAG.

For this study, the researchers used data from the Ocular Hypertension Treatment Study (OHTS) and the European Glaucoma Prevention Study (EGPS). The model used in these two studies to predict POAG development included baseline values for age, IOP, central corneal thickness, vertical cup-disc ratio, and pattern standard deviation (SD). In this analysis, the authors tested whether predictions could be improved by replacing baseline IOP data with mean follow-up IOP, SD of IOP, maximum IOP, range of IOP, or coefficient of variation IOP. They used the C statistic to compare the predictive accuracy of multivariable landmark Cox proportional hazards regression models for the development of POAG.

The OHTS data consisted of 97 POAG end points from 709 of 819 participants (58.7% women, 25% African American, 69.1% white). Mean age was 55.7 years, and the median follow-up period was 6.9 years. EGPS data included 44 POAG end points from 397 of 500 participants in the placebo group (50.1% women, 100% white). The mean age was 57.8 years, and the median follow-up time was 4.9 years. The C statistic for the original prediction model was 0.741.

When the other IOP values were substituted for baseline IOP in the OHTS prediction model, the C statistic was 0.784 for mean follow-up IOP, 0.781 for maximum IOP, 0.745 for SD of IOP, 0.741 for range of IOP, and 0.729 for coefficient of variation IOP. EGPS findings were similar. No measure of IOP variability, when added to the complete prediction model, increased the C statistic by more than 0.007 in either cohort.

These findings suggest that factoring in long-term IOP variability does not strengthen POAG prediction models. Even so, given that IOP is the only known modifiable risk factor for glaucoma, understanding how its dynamic variation is linked to the onset and progression of POAG could play a crucial role in management, the authors said.

Need to Check for Uncorrected Refractive Errors

July 2020

Guo et al. measured the degree of visual acuity (VA) improvement attained in adults with previously uncorrected refractive error who also had glaucoma or retinal disease. Nearly 28% of patients in their study (mean VA, 20/100) had improvement of at least 2 lines, and more than half improved by 1 or more lines. Overall, African Americans and middle-aged working adults experienced the greatest visual benefits.

This study was a retrospective review of patients who were new to low vision rehabilitation (defined as no visit to address VA in the preceding three years) and were receiving care for glaucoma or a retina-related condition. Uncorrected refractive error was defined as

absent, inaccurate, or outdated correction of refractive error. Habitual VA of the 2,923 patients ranged from 20/40 to counting fingers. Patients younger than 20 years of age were excluded from the analysis, as were those with habitual VA of 20/40 or better or counting fingers or worse.

The mean habitual VA of included patients (n = 1,773) was 20/100. Refraction showed improvement of at least 2 lines in 27.8% and at least 1 line in 57.7%. Improvement of 2 or more lines was more common in the older subset (40-64 vs. 20-39 years; odds ratio [OR], 1.57), in African American than in white patients (OR, 1.41), and with moderate versus mild visual impairment (OR, 1.36). Patients with corneal disease had greater refractive benefit than those with other conditions, despite having poorer habitual VA. Improvement of 6 or more lines occurred in 1.2%, and VA of at least 20/40 was attained for a third of the study group.

These findings show that uncorrected refractive error is prevalent among patients with ocular disease. The authors encourage routine refractive checks to maximize social, psychological, and occupational functioning. Moreover, optimally corrected VA can reduce the need for magnification and enhance quality of life. Understanding how patients become connected to low vision care would help in designing outreach programs that improve delivery of refractive care, the authors said. They also suggested that future work include assessing the effects of refractive correction on patient-centered outcomes in those with ocular disease.

—Summaries by Lynda Seminara

Other Journals

Selected by Prem S. Subramanian, MD, PhD

Real-World Assessment of BRVO Treatment

British Journal of Ophthalmology

Published online June 12, 2020

Evidence from clinical trials suggests that anti-VEGF drugs are more effective than dexamethasone implants for the treatment of macular edema

secondary to branch retinal vein occlusion (BRVO). However, it can be difficult to translate clinical trial results to daily practice. Therefore, Gale et al. set out to evaluate this conclusion in a real-world setting with data from a large and diverse population, and they included macular laser outcomes for additional comparison. They found that visual acuity (VA) improved more with anti-VEGF treatment than with the other strategies. In addition, although anti-VEGF injections conferred a higher treatment burden, some of the impact of that burden decreased over time.

For this study, the researchers used data collected at 27 U.K. National Health Service centers between February 2002 and September 2017 from patients who received treatment for BRVO. Of an initial dataset of 19,141 eyes, 5,251 met the inclusion criteria of being treatment-naïve at the start of therapy and having both baseline and follow-up VA measurements. The mean age of the study population was 72.1 years, and 52.6% were female. Outcomes of interest were changes in VA and mean number of treatments over a 36-month period.

Mean baseline VA was 57.1 ETDRS letters in those treated with anti-VEGF injections (n = 3,939), 53.1 in those who received the dexamethasone implant (n = 676), and 62.3 for those treated with laser (n = 636). Following treatment, VA changed as follows:

- At 12 months, mean VA was 66.72 letters in the anti-VEGF group, 57.6 in the dexamethasone group, and 63.2 in the laser group.
- At 18 months, mean VA was 66.6, 56.1, and 60.8 letters, respectively.
- Only the anti-VEGF group had adequate 36-month data; mean VA in this group at that point was 68 letters.

With regard to treatment burden, the anti-VEGF group received a mean of 5.1 treatments during the first 12 months, while the dexamethasone and laser groups received 1.5 and 1.2, respectively. During the first 18 months, the mean number of treatments were 5.9, 1.7, and 1.2, respectively. Again, 36-month data were available for only those in the anti-VEGF group, who received a mean of 6.9 treatments

during this time period. The authors suggest that, despite the treatment burden, visual outcomes were better with anti-VEGF therapy.

Medication Burden After Combined CyPass/Cataract Surgery

Journal of Glaucoma

Published online May 26, 2020

Law et al. set out to assess how well combined cataract surgery and implantation of the CyPass Micro-Stent controlled intraocular pressure (IOP). They found that the combined surgery reduced the glaucoma medication burden at one year by 28% to 42%, depending on different target IOP levels.

For this retrospective study, the authors reviewed all cases of combined surgery performed at two U.S. eye institutes between February 2017 and July 2018. The primary outcome was qualified success with IOP targets as follows: 1) final IOP of ≤ 18 mm Hg and reduction of 20%; 2) final IOP of ≤ 15 mm Hg and reduction of 25%; and 3) final IOP of ≤ 12 mm Hg and reduction of 30%. Secondary outcomes included post-op IOP and number of medications, complications, additional glaucoma surgery, and postoperative refractive error.

All told, 141 eyes (107 patients) were included in the analysis. Mean pre-op IOP was 15.4 ± 3.4 mm Hg on an average of 2.2 ± 1.1 medications. At 12 months postoperatively, IOP was 13.8 ± 4.2 mm Hg, and medication use was 1.3 ± 1.3 . Cumulative success rates based on the three IOP targets were 42%, 33%, and 28%.

Fifteen eyes experienced a post-op IOP spike (defined as a postoperative IOP of ≥ 30 mm Hg or an increase of more than 10 mm Hg over preoperative IOP). Additionally, 13 eyes experienced 17 complications, and additional glaucoma surgery was performed in three eyes of two patients. Factors associated with failure included lower pre-op IOP, greater number of pre-op medications, and the occurrence of a post-op IOP spike. Further study is needed to determine the amount of long-term IOP control gained by combined surgeries.

—Summaries by Jean Shaw

Safety Data

**YOU CAN
TRUST¹**

**Confidence in
Demonstrated
Safety Data Across
4 FDA-Approved
Indications¹**



**WET AMD,
DME, DR,
and MEfRVO¹**

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

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

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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



EYLEA[®]

(aflibercept) Injection
For Intravitreal Injection

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

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

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

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

WARNINGS AND PRECAUTIONS (cont'd)

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

ADVERSE REACTIONS

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

INDICATIONS

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

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON



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

1 INDICATIONS AND USAGE

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

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

4 CONTRAINDICATIONS

4.1 Ocular or Periorcular Infections

EYLEA is contraindicated in patients with ocular or periorcular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

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

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [see *Adverse Reactions (6.I)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [see *Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [see *Adverse Reactions (6.I)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

5.3 Thromboembolic Events.

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

6 ADVERSE REACTIONS

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

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

6.1 Clinical Trials Experience.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage. Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

6.2 Immunogenicity.

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

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

8 USE IN SPECIFIC POPULATIONS.

8.1 Pregnancy

Risk Summary

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

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

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

Data

Animal Data

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

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

8.2 Lactation

Risk Summary

There is no information regarding the presence of afibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

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

Infertility

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

8.4 Pediatric Use.

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

8.5 Geriatric Use.

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

17 PATIENT COUNSELING INFORMATION

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

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

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
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Issue Date: 08/2019
Initial U.S. Approval: 2011

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

EYL19.07.0306

Cornea Tissue: How Old Is Too Old?

If you perform endothelial keratoplasty, are you comfortable accepting cornea tissue that's 10 or 11 days old? Although the FDA has approved hypothermic storage of donor cornea tissue for up to 14 days, most U.S. surgeons are offered tissue that is three to seven days old because of the typical surplus of cornea tissue in this country.

However, the future of that surplus is uncertain. The U.S. population is aging, and there is a concomitant increase in demand for cornea tissue, noted Jonathan H. Lass, MD, at Case Western Reserve University School of Medicine and the University Hospitals Eye Institute in Cleveland, Ohio. In addition, the donor pool is at greater risk from emerging infections—and the current opioid epidemic means eye banks need more time to screen donors.

Extending storage time gives eye banks greater flexibility to evaluate and distribute donor corneas, significantly expanding supply. But U.S. surgeons have become so accustomed to the current practice of shorter-term storage that “many are reluctant to go beyond seven days should the need arise,” said Dr. Lass, who also served as chair of the Cornea Preservation Time Study (CPTS).

Evidence From the CPTS

For evidence-based guidance on storage times, cornea surgeons can turn to the CPTS for assurance.



COMPARISON. These images are from the same patient. (1) Right eye, two months after DMEK (Descemet membrane endothelial keratoplasty). Best-corrected visual acuity (BCVA) was 20/20; the edges of the graft are not visible on direct diffuse illumination. (2) Left eye, eight months after DSAEK. BCVA was 20/25; the nasal graft edge is visible (red arrows).

Question of preservation time. The NEI-sponsored CPTS was the first to study whether endothelial keratoplasty using donor corneas preserved for eight to 14 days could be as successful as surgery with donor corneas that had been preserved for up to seven days.

The CPTS enrolled 1,330 study eyes that underwent Descemet stripping automated endothelial keratoplasty (DSAEK) for corneal conditions associated with endothelial dysfunction and moderate risk for graft failure (Fuchs dystrophy or pseudophakic/aphakic corneal edema [PACE]).¹

The objective of the CPTS was to provide scientific evidence regarding best practices for preservation time and usage. The noninferiority design rigorously demonstrated that donor corneas can be preserved for up to 11 days and still have a greater than 90% probability

of graft success at three years.¹ Data on endothelial cell loss at three years mirrored these findings.²

“A big question in eye banking has been the optimal timing for using tissue,” said Jennifer Y. Li, MD, at the University of California, Davis. “The CPTS gives us an evidence-based approach to deal with misperceptions about the ideal ‘freshness’ of donor corneas and should increase our eye banks’ ability to place tissue,” said Dr. Li, who also holds an advisory position with the Eye Bank Association of America (EBAA).

Of note, the three-year success rates were still high in the 12- to 14-day preservation time group (89.3%, versus 94.1% in the one- to 11-day group).¹ When logistics dictate, surgeons should be encouraged to accept corneas stored 12 to 14 days, Dr. Lass said. “The minimal reduction in survival translates to a clinically acceptable level.”

Impact on surgeons’ attitudes. “As with any scientific discovery, disseminating the findings of the CPTS and

BY GABRIELLE WEINER, CONTRIBUTING WRITER, INTERVIEWING ANTHONY J. ALDAVE, MD, JONATHAN H. LASS, MD, AND JENNIFER Y. LI, MD.

influencing practice patterns will take some time,” said Anthony J. Aldave, MD, at the Stein Eye Institute in Los Angeles. “The effort to influence or change surgeon criteria for donor tissue begins at the cornea fellowship level because it is easier to shape practice patterns as opposed to changing them.”

The CPTS appears to have had an impact on the preservation time that surgeons say they are willing to accept.³ However, in practice, it hasn’t been fully tested, given the domestic supply. “Now, as eye banks ramp up in the shadow of COVID-19, we might see more corneas offered that will be over seven days old at the time of surgery. That will show if surgeons are truly comfortable accepting tissue with longer storage times,” Dr. Aldave said.

Predicting Graft Success

The CPTS was also designed to study the effect of factors other than preservation time on DSAEK outcomes. It

prospectively tracked over 50 factors that might impact graft success or failure and endothelial cell loss three years after surgery.⁴

Risk: diabetic donors. The most remarkable finding, according to Dr. Lass, was that diabetes in the donor correlated with lower graft success and greater endothelial cell loss at three years, as well as more graft dislocations overall, particularly among patients who experienced primary or early graft failures.^{1,2,4} “Prior to the CPTS, there were conflicting studies on whether diabetes in the donor could affect transplant success and cell loss,” said Dr. Lass.

Going forward, researchers need to define and study disease severity in donors (e.g., from prediabetes to diabetic nephropathy, neuropathy, and peripheral vascular disease). “Given that this country has an epidemic of diabetes,” Dr. Lass said, “we need to establish” whether tissue from particular subsets of diabetic donors can be used.

Risk: recipients with PACE. Failure was more likely in PACE recipients than in recipients with Fuchs dystrophy, with a significant difference in late failures, but not in primary/early failures.⁴ This may be due to the PACE group having a lower peripheral endothelial cell reserve than the Fuchs group, said Dr. Lass, who noted that further study is needed.

Risk: operative complications. By far the strongest predictor of failure was operative complications. These included an inverted graft, unplanned vitreous loss, posterior capsule rupture, and significant hyphema. They also comprised difficulty with unfolding and positioning tissue with/without use of a positioning hook, a difficult air fill and retention in positioning, and/or reinsertion of the donor tissue after extrusion.⁴ “The most important thing to focus on for your patients is minimizing iatrogenic donor tissue damage by any means possible,” said Dr. Aldave.

Not a risk: donor age. Aligning with prior findings from the Cornea Donor Study on penetrating keratoplasty (PK), CPTS found no evidence to suggest that advanced donor age is correlated with DSAEK survival.⁵

Not a risk: additional factors. In addition, no evidence suggests that preoperative donor endothelial cell density or donor DSAEK diameter is associated with graft survival, according to Dr. Aldave.

Dr. Aldave further noted that outcomes were not affected by donor gender, race/ethnicity, or cause of death. In addition, they were not affected by death to preservation time, time from dissection to surgery, gender mismatch, or type of injector used.

Unclear: lenticule thickness. In the CPTS report on graft dislocations, much of the data mirrored the reports on graft success and endothelial cell loss.³ Operative complications and diabetes in the donor were two of three predictors of failure. But the third factor—one that Dr. Aldave called a mystery—involved lenticule thickness. That is, a donor cornea with thicker *precut* thickness, despite the *postcut* lenticule thickness (ranging in eyes from 14% under 100 μm to 31% over 150 μm),

COVID-19 Update: Impact on Eye Banks

During the first wave of the COVID-19 pandemic, 90% of eye bank business in the United States was suspended. At that time, eye banks were struggling to retain their skilled work force, Dr. Lass said. “It was unprecedented and extremely difficult.”

Tracking supply and demand. Surgical supply and demand were in sync during the early phase of the pandemic, Dr. Aldave said. “Even though many donors were being ruled out because of possible COVID, it was no major issue because demand was so low” at that time, he said.

However, demand had begun to recover by mid-June, according to data presented at the EBAA’s annual meeting:¹

- At the end of March, domestic surgeries using donor tissue were at 6% of normal levels; by mid-June, this had increased to 70%.
- Internationally, surgical volumes increased from 4% of normal levels to 35% during the same time frame.
- Similarly, the use of donor tissue in teaching and research settings was at 5% of normal levels at the end of March and had risen to 39% by mid-June.

Looking ahead. As we continue to move forward, “demand will exceed the normal level because of the need to clear the backlog of cases,” Dr. Aldave said. “We have to be ready for this by safely increasing the recovery and distribution of donor tissue.”

“Our goal is that donor tissue criteria will be stringent enough to maintain the safety of our supply while balancing the needs of surgeons here in the United States,” Dr. Li said. “Eye banks have been very conservative about making sure cornea tissue is safe. We are carefully monitoring the situation, making [real-time] adjustments based on data or the lack thereof.”

1 Drury D. Eye donation and transplantation update: Current snapshot and future outlook. Presented at: EBAA Annual Meeting; June 18, 2020; Dallas.

was more likely to be associated with complications.⁶

“Much focus has been placed on lenticule thickness and graft dislocation, but why, if the eye bank is able to prepare lenticules of a given thickness from donors of variable thicknesses using different microkeratome heads and preparation techniques, should the original thickness matter?” Dr. Aldave asked.

Additional nuances regarding graft rejection. The only statistically significant factor associated with graft rejection was recipient age. Older DSAEK recipients had a lower rejection risk than younger recipients (defined as those younger than age 50), Dr. Lass said.

Factors identified by two major PK studies (the Cornea Donor Study and the U.K. Registry Study) as being associated with a higher risk of rejection—gender, gender mismatch, prior use of glaucoma medications, and a history of glaucoma surgery—were not found to be significant with DSAEK.^{5,7}

Practical Advice

When discussing the freshness and safety of donor tissue, Dr. Li emphasized that EBAA-accredited eye banks require donor tissue to meet a rigorous standard of quality and safety. In her personal practice, she has never questioned or sent back a donor cornea to her eye bank. “Accreditation is not just a rubber stamp. Standards are updated on a regular basis, including amidst the COVID-19 pandemic. As long as a surgeon works with an accredited eye bank, freshness and safety of donor tissue are not factors he or she should need to think about.”

Thus, she and Drs. Aldave and Lass said, surgeons should worry less about donor tissue quality and more about minimizing operative complications. They offered the following suggestions:

Patient age. Surgeons should carefully monitor patients younger than age 50 because of their higher risk for rejection, Dr. Lass said.

Other considerations. In addition, it is prudent to be cautious with patients who have had prior glaucoma surgery, Dr. Li said. (Only 31 eyes in the CPTS had a history of glaucoma surgery, and

eyes with previous tube shunts were not included. Though not statistically significant, eyes with prior glaucoma surgery had a lower graft success rate.³ As noted above, in PK studies, prior glaucoma surgery was associated with a higher risk of rejection.⁷)

Dr. Aldave added, “For eyes at highest risk for donor detachment, rejection and/or failure, such as hypotonous eyes or those with prior glaucoma surgery, maybe it would be justified to request tissue from a nondiabetic donor whose corneas are of normal thickness. I’ll probably get a lot of flak for suggesting that, but these are the only factors within the surgeon’s control besides operative skills.”

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5 Mannis MJ et al., for the Writing Committee for the Cornea Donor Study Research Group. *Ophthalmology.* 2013;120(12):2419-2427.

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Dr. Aldave is professor of ophthalmology, Walton Li Chair in Cornea and Uveitis, chief of the Cornea and Uveitis Division, and director of the Cornea and Refractive Surgery Fellowship at The Jules Stein Eye Institute in Los Angeles. He is also chair of the Policy Position and Review Committee for the EBAA in Washington, D.C. *Relevant financial disclosures: None.*

Dr. Lass is Charles I. Thomas Professor and Vice Chair for Academic Affairs in the Department of Ophthalmology and Visual Sciences at Case Western Reserve University in Cleveland, Ohio. He is also a member of the Center for Anterior Segment Diseases and Surgery at the University Hospitals (UH) Eye Institute, medical director of the UH Cornea Image Analysis Reading Center, and medical director of Eversight Ohio. *Relevant financial disclosures: NEI: S.*

Dr. Li is professor of ophthalmology and chief of Cornea and External Disease at the University of California, Davis. She is also chair of the Medical Advisory Board for the EBAA in Washington, D.C. *Relevant financial disclosures: None.*

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

Antifungal Supplementation? Not Yet

An increasing incidence of fungal infection following endothelial keratoplasty has stimulated discussion in eye bank meetings about whether to pursue antifungal supplementation of donor storage media. “Though fungal infection is still uncommon, the incidence is trending upward, and it is devastating for patients when it occurs,” Dr. Li said.

At this point, there is some support for the hypothesis that antifungal supplementation with a number of different antifungal agents does reduce the growth of fungi, usually *Candida*, in storage media, Dr. Aldave said. However, study findings on the safety and efficacy of antifungal supplementation are inconsistent, he noted. Problems include variations in study designs, *Candida* species tested, choice of antifungal agents and concentrations, and duration of exposure of the cornea to the antifungal agent.

Although the CPTS showed that you can use cornea tissue that is 12-14 days old, “can an antifungal agent be in a solution for that long without damaging the tissue?” Dr. Aldave asked. (In the CPTS, two cases of fungal infections occurred among the 1,330 study eyes, but there was no statistically significant difference in terms of infections between the two preservation times. In addition, with regard to rim cultures, no difference emerged between the two preservation times.)

Going forward, researchers are working on finding the optimal way to confer maximum protection with minimal toxicity.

1 Mian SI et al. *Cornea.* 2018;37(9):1102-1109.



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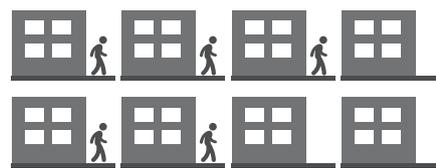
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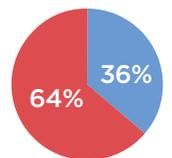
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MD Roundtable: The Enduring Role of Traditional Glaucoma Surgery, Part 2

In the second installment of this two-part article about traditional glaucoma surgery, Ruth D. Williams, MD, of the Wheaton Eye Clinic, continues the conversation with Anne L. Coleman, MD, PhD, of University of California, Los Angeles (UCLA), and Dale K. Heuer, MD, past president of the American Glaucoma Society. They talk about complications to watch for in trabeculectomy (and MIGS), tubes, how important it can be to learn techniques from colleagues, and future directions for filtering surgery.

Long-Term Complications

Dr. Williams: *One of the advantages of trabeculectomy is that it's not very expensive. From a population health perspective, compared to many of our MIGS options, filters are more cost-effective. Dr. Coleman, as an expert in public health, how does this factor into your decision-making?*

Dr. Coleman: Yes, it is less expensive right now. However, I don't know if I would go out and do trabeculectomies in certain environments; the opportunity for consistent, good hygiene needs to be available as does access to eye care. This is something to be aware of: The way specialists are able to practice at state-of-the-art centers may be very different from how a general ophthalmologist practices in a remote area.

I really do worry about the long-term risk of endophthalmitis, so I think

that it will be beneficial if we develop newer procedures that are less invasive than trabeculectomies or even some of today's MIGS that create blebs.

Dr. Heuer: I'd like to follow up on that last thought about MIGS. One of my mentors, Paul Palmberg, talked about "the curse of long-term follow-up," and we're already starting to see some longer-term problems with MIGS. For example, there are a couple of case reports of gel microstent devices that have eroded through the conjunctiva, and with that comes the risk of endophthalmitis. So, it's like everything in glaucoma: There's an initial enthusiasm and then reality starts to set in. Over time we'll have a better sense of where these procedures fit.

All of our patients who are undergoing any procedure that has a subconjunctival filtration approach need to be aware of the symptoms of bleb infection. One of my other mentors, Richard Parrish, taught me the mnemonic "RSVP," for Redness, Sensitivity to light, Vision change, and Pain. I added another P for Pus, so it's RSVP squared. Patients really get that, and I put it in the visit summary notes for everyone who's had a trabeculectomy.

Dr. Coleman: And we need to keep



TUBE SURGERY. *In contrast with trabeculectomy, aqueous shunt surgery is slightly on the rise.*

reminding our patients. We may have told them at one point; however, they may forget. So repeating that message is very important.

Tubes Versus Trabs

Dr. Williams: *If we look at the Medicare database, the number of tubes being done is increasing slightly over time. Why are the number of trabeculectomies decreasing, but the number of tubes has been stable or increasing over time?*

Dr. Heuer: I think, in part, that MIGS has displaced more patients who might have been classic trabeculectomy candidates than classic aqueous shunt patients. Also, because of the outcomes of the Tube Versus Trabeculectomy (TVT) study and the Primary Tube Versus Trabeculectomy (PTVT) study, we may be a little more inclined to do a tube in some patients in whom we otherwise might have done a trabeculectomy.

Dr. Williams: Let's talk more about

ROUNDTABLE HOSTED BY RUTH D. WILLIAMS, MD, WITH ANNE L. COLEMAN, MD, PHD, AND DALE K. HEUER, MD.

how the TVT and PTVT studies affected your choice of procedures.

Dr. Heuer: I should disclose that I am a cochair of both of those studies. But even with the findings, I think there's still a bias toward trabeculectomy. Although the five-year results from TVT and three-year data from the PTVT suggest that tubes do much better than we historically thought (based on the fact that we were initially using them in very high-risk situations), I have to admit that I would probably still have a trabeculectomy. Glaucoma is a very

"Patients need to be aware of the symptoms of bleb infection. . . . RSVP, for Redness, Sensitivity to light, Vision change, and Pain . . . and P for Pus, so it's RSVP squared."

long-term issue, and if the trabeculectomy fails, moving on to a tube is a logical sequence. However, if I have an aqueous shunt first and that doesn't work, in most patients it will probably be technically more difficult to perform trabeculectomy. We've learned a lot of things, ever since the TVT/PTVT studies were designed, that make trabeculectomy a little safer than it was in those studies.

Dr. Coleman: I think that's true. At a meeting, I saw a video by one of the surgeons in the TVT study, and the trabeculectomy was done very differently from the way some of the faculty do it at UCLA. The different ways that people are trained to do their trabeculectomies could have influenced the results in that study because the trabeculectomies weren't really standardized.

Dr. Heuer: Well, I'm not sure you can standardize it completely, but having said that, you're right.

Dr. Coleman: But you could standardize the size of the scleral flap. You could potentially standardize the size of the sclerostomy and the conjunctival closure.

Dr. Williams: Although you could standardize techniques for a study, one of the things that makes great surgeons is that we figure out what works in our hands—and what you figured out might be different from what I figured out. You really want a surgeon to do

what works best for him or her. And we're such individualists, and very particular about our techniques, that even if you standardize a procedure, the best outcome might be achieved when the surgeon has developed as his or her own expertise.

Dr. Heuer: This reminds me of a phrase that I think was coined by Doug Rhee: "artisanal surgery." And if it was ever true of anything, it's trabeculectomy!

Dr. Coleman: I agree. I think one reason that procedures like drainage devices and MIGS are so popular is because they are more standardized procedures that can be done by an eye surgeon.

It is harder to standardize an "artisanal" technique like trabeculectomy.

Dr. Heuer: Trabeculectomy techniques have also evolved. If you look back to when we started the TVT study, many people were still doing a lot of limbus-based flaps. There are occasions where I still prefer a limbus-based flap—for example, if someone has a gossamer-thin conjunctiva—but I think most of us have switched to fornix-based flaps with some modifications. Perhaps even the way the mitomycin was applied in the study may not reflect the current approach; many of us have migrated to using injection rather than sponges. Furthermore, the concentration of mitomycin tends to be individualized based on our assessment of each patient's scarring risk-profile, such that lower concentrations are used in many patients than the 0.4 mg/mL concentration that was applied with sponges in the TVT study.

Learning From Colleagues

Dr. Williams: One of the great advantages of having colleagues and watching them do surgery or seeing their post-ops is that we bring training from different programs and learn how to do things differently. I've found it very enriching to learn different techniques and the varied approaches from the glaucoma specialists in my practice.

Dr. Heuer: Something has been lost since the dark ages when I came out of training. At that time, an ophthalmologist going into practice would often serve as an assistant, whether it was for cataract surgery or another procedure, so there was cross-fertilization. Now that we're in the era of ambulatory surgery centers and no assistants, we've lost some of that. So, as Dr. Williams suggests, you should avail yourself of that opportunity whenever you can.

Dr. Coleman: In my experience, my colleague Joseph Caprioli and I trained at different places. When he came to UCLA 20 years ago, we were very different in terms of how we operated, but over the years, and with the cross-fertilization of the fellows, we now operate more similarly, according to the fellows.

Looking to the Future

Dr. Williams: In closing, can you imagine a time when either trabs or tubes are no longer performed or no longer necessary?

Dr. Coleman: I can. I think people are going to work on a cure. I think that's really what the public expects, what patients want, and really what I want.

Dr. Heuer: We've been putting a hole in the eye wall for over 150 years, and so I hope that time does come. Still, I think there will be niche diagnostic categories where something akin to trabeculectomy or perhaps aqueous shunts will be necessary. But maybe a hundred years from now, doctors will look back and say, "My goodness, how in the world could they bring themselves to do that to the eyes?"



Dr. Coleman is president of the American Academy of Ophthalmology and a glaucoma specialist at UCLA, Stein Eye Institute.

Financial disclosures: None.



Dr. Heuer is past president of the American Glaucoma Society. Financial disclosures: National Eye Institute: S; Santen: S.



Dr. Williams is a glaucoma specialist at Wheaton Eye Clinic, Wheaton, Ill., and the chief medical editor of *EyeNet Magazine*.

Financial disclosures: None.

See the disclosure key, page 8.

Open Globe Injury: Assessment and Preoperative Management

Open globe injuries are a significant cause of permanent visual impairment and ocular morbidity worldwide. Prompt assessment of the type and extent of the injury is critical to ensure timely management.

Etiology and Terminology

Open globe injury (OGI) is defined as a full-thickness wound of the eyewall, due to either a laceration or an occult rupture.¹ Classically, a ruptured globe occurs when a considerable amount of blunt force is applied to the eye. This force causes a rapid elevation of intraocular pressure (IOP) that leads to frank rupture of the eyewall by means of an inside-out mechanism.

Lacerating injuries are full-thickness disruptions of the eyewall that are caused by external trauma, usually by a sharp object (Fig. 1). These injuries are further subdivided into penetrating, perforating, and intraocular foreign body (IOFB) trauma (Fig. 2).¹ Penetrating trauma has an entry point into the globe but no clearly defined exit wound, whereas perforating ocular injuries have both entrance and exit wounds through the eyewall.

Zones. The anatomic region, or zone, of an OGI is an important prognostic factor for visual potential.

Zone I trauma involves the cornea and limbus.

Zone II extends posteriorly from the limbus up to 5 mm posterior to the

limbus; these injuries usually involve deeper structures of the anterior segment, including the lens and zonules.

Zone III trauma extends more than 5 mm posterior to the limbus, involving the posterior segment (e.g., the retina, optic nerve, and choroid).²

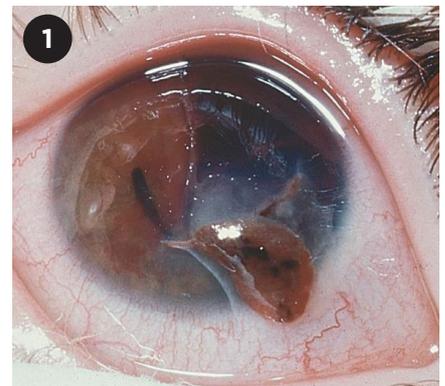
Epidemiology

The worldwide incidence of OGI has been estimated at 3.5 injuries per 100,000 persons, with more than 203,000 cases occurring each year.² Men and boys make up approximately 80% of patients with OGI, with those aged 10 to 30 years being at greatest risk.³ Young men are more likely to sustain perforating or penetrating injuries, particularly during occupational activities.

Evaluation

Presentation. When a patient presents with ocular trauma, the clinician should first evaluate for life-threatening injuries. If necessary, the patient should be triaged and sent to the nearest trauma center and/or stabilized. Potentially lifesaving procedures and surgery take priority over ocular assessment and treatment. When the patient is stable, an ocular evaluation can proceed to determine the magnitude of the ocular injury and its subsequent management.

History. It is critical to determine when the injury occurred, as repair should ideally be conducted within 24 hours of the trauma. Details of



OPEN GLOBE INJURY. Full-thickness corneal laceration, with iris prolapse through the wound.

the circumstances are important. For example, the involvement of a sharp object, high-impact blunt trauma, or high-velocity projectiles should raise the suspicion of an OGI. Where the injury took place is also pertinent because contamination of the wound with soil or organic matter is more likely in rural or agricultural settings.

The initial symptoms following the trauma should be noted, as well as any significant changes such as increasing pain or worsening vision, which could indicate the development of endophthalmitis. A thorough review of the patient's past ocular and surgical history is important in evaluating the visual potential; moreover, prior surgical sites may be predisposed to rupture. If surgery is contemplated, it is necessary to determine when the patient last consumed food or liquids.

External exam. Care should be taken to minimize manipulation of the globe whenever an OGI is suspected. Inspec-

BY DANIEL WANG, MD, AND AVNISH DEOBHAKTA, MD. EDITED BY BENNIE H. JENG, MD.

tion starts with an external assessment of the head, face, eyelids, and periocular regions to note any ecchymosis, edema, or superficial lacerations that may be present. Facial asymmetry or bony discontinuities are suggestive of concurrent facial fractures.

If protruding foreign bodies are seen, they should not be removed until the patient is in the controlled conditions of the OR. Additionally, any eyedrops administered should come from a new, sterile bottle.

Visual acuity and pupils. Measurement of visual acuity is necessary to establish a baseline for future visits and to prognosticate visual outcomes.

Pupillary examination may reveal subtle clues about the extent of injury. A dilated pupil may indicate traumatic mydriasis, iris sphincter damage, or possible third nerve palsy. A peaked pupil is often considered pathognomonic for OGI. A relative afferent pupillary defect is suggestive of severe optic nerve damage or retinal injury.

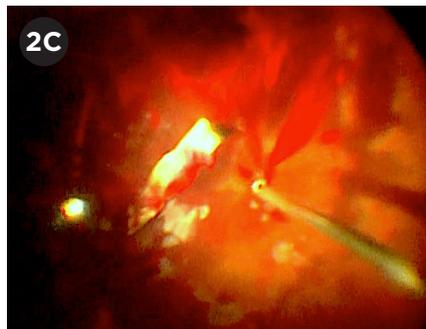
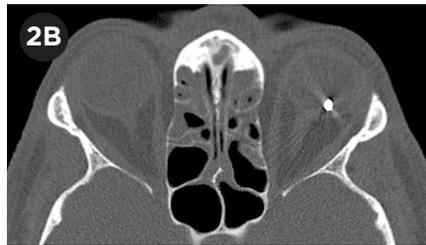
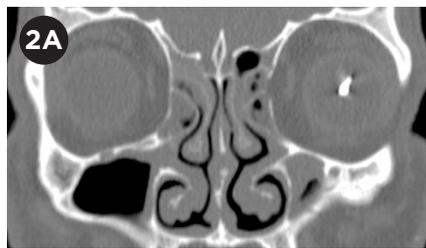
IOP. Measurement of IOP should be delayed until an OGI is ruled out to avoid further damage and extrusion of intraocular contents. In general, hypotony is highly suggestive of OGI; however, a normal IOP does not eliminate the possibility of OGI.

Slit-lamp studies. The slit-lamp exam should include a detailed inspection of the conjunctiva and sclera. Subconjunctival hemorrhage and chemosis may hide underlying scleral lacerations. Eyelid eversion may be performed carefully, and the fornices swept gently for retained foreign material.

All layers of the cornea should be thoroughly inspected for superficial abrasions, edema, and lacerations. A Seidel test is required to evaluate the thickness of identified lacerations. The anterior chamber should be assessed for uniform depth, the presence of cells, flare, hyphema, and vitreous.

The iris should be examined for tears or breaks by both direct and retroillumination. Lens position and clarity and the integrity of the lens capsule and zonular fibers should be evaluated.

Finally, the posterior segment should be examined for the presence of hemorrhage, retinal or choroidal detach-



INTRAOCCULAR FOREIGN BODY. (2A) Coronal and (2B) axial CT images show an IOFB in the patient's left eye. (2C) Removal of the same metallic IOFB.

ment, and possible IOFBs.

Diagnostic imaging. In cases where ocular examination is limited, ancillary imaging studies are recommended to aid in the structural evaluation of the eye and to rule out the presence of a foreign body.

Computed tomography (CT). Non-contrast orbital CT is the recommended imaging modality for ocular trauma and should be employed for most patients with a suspected OGI. Globe contour, abnormality of the lens, vitreous hemorrhage, retinal detachment, orbital and facial fractures, and obvious orbital volume loss can all be assessed with this modality. CT scans have a reported sensitivity between 56% and 68% in diagnosing patients with an open globe.⁴ Most important, CT is particularly useful if a metallic IOFB is suspected, in which case magnetic resonance imaging is contraindicated.

Although plain film x-ray may be used to screen for the presence of a metallic IOFB, it lacks CT's ability to

identify radiolucent material and soft tissue. Thus, it is not the optimal imaging modality for OGI.

Ultrasonography. B-scan ultrasonography may be useful in providing information about the posterior segment, particularly when the fundoscopic examination is limited by hazy media resulting from significant hemorrhage or corneal edema. In some cases, the presence and location of an IOFB may be identified. Care should be taken to avoid pressure on the globe from the probe; however, in many cases, this modality is not recommended prior to globe repair.

Preoperative Management

In anticipation of possible surgery, patients should be kept on NPO status (no food or liquids by mouth). The eye should be covered with a protective shield at all times to prevent further injury. In general, topical ointments should be avoided, although topical nonpreserved antibiotics may be used if there is a delay in getting the patient to the OR. Treatment may be given for nausea (ondansetron 0.15 mg/kg per dose, up to 12 mg IV) and severe pain (morphine, 0.1 mg/kg per dose, up to 10 mg), ideally with IV medications.

Antibiotics. Endophthalmitis is a potentially devastating complication after OGI. The rate of endophthalmitis following OGI has been reported to be higher in patients with IOFBs.⁵ Antibiotic prophylaxis to prevent development of posttraumatic endophthalmitis has become common practice. Although standardized guidelines for antibiotic selection and route have not been established, there is strong evidence to support the use of 48 hours of IV therapy.⁶ Gram-positive cocci, gram-positive and gram-negative bacilli, and fungi are the most common organisms isolated in culture-positive cases of endophthalmitis after trauma.⁷

Broad-spectrum antibiotics are needed to provide coverage for both gram-positive and gram-negative bacteria. IV vancomycin (15 mg/kg; maximum dose, 1.5 g) and a third-generation cephalosporin such as ceftazidime (50 mg/kg; maximum dose, 2.0 g) may be given. Unless there are high-risk

features such as intraocular organic foreign material, prophylactic antifungal coverage is not routinely given.

The use of intravitreal antibiotics is controversial in the absence of endophthalmitis, unless there is delayed primary closure or presence of an organic IOFB.⁸

Tetanus prophylaxis. Although rare, cases of posttraumatic endophthalmitis caused by *Clostridium tetani* have been reported in the literature. Tetanus prophylaxis may be considered after perforating or penetrating globe injury, particularly when the patient's immunization status is unknown or not up to date. In addition, tetanus immune globulin may be administered on an individual case-by-case basis.

Prognosis

The mechanism and extent of initial injury and findings at presentation are important predictors of final outcome. To establish an objective, standardized system for assessment of ocular injuries and prognosis, Kuhn and colleagues developed the Ocular Trauma Score (OTS) from an analysis of 2,500 eye injuries.⁹ The OTS can be easily calculated following the initial examination or surgery and can assist in clinical decision-making and patient discussion. The OTS is a point system based on factors that have strong prognostic significance. These include initial visual acuity as well as the presence of globe rupture, perforating injury, IOFB, endophthalmitis, retinal detachment, or relative afferent pupillary defect.⁹ Zone III and ruptured globe injuries carry a statistically significant poor prognosis.¹⁰

Surgical Considerations

As a general principle, primary globe repair should be completed within 24 hours of injury and evaluation. Either a staged or comprehensive surgical approach may be taken.

In a staged surgical strategy, the primary surgery addresses proper wound closure, management of any prolapsed tissue, and removal of blood and foreign material in the anterior chamber to permit an adequate view for subsequent ocular procedures. Secondary surgeries (such as vitrectomy) are planned and performed later, often in collaboration

with colleagues.

In a comprehensive surgical approach, all injuries are managed during initial wound repair and closure. Depending on the zone of trauma, this approach may require the ability to manage both the anterior and posterior segments.

There are advantages and disadvantages to both staged and comprehensive approaches. In addition, controversy persists on the ideal timing of the secondary intervention when a staged approach is elected.

Postoperative Follow-up

After surgical repair, the patient should be directed to wear a protective shield at all times, including while sleeping, and be given careful instructions to refrain from rubbing or touching the eye. In addition, the patient should not engage in heavy lifting, exercise, or swimming for at least six weeks.

The use of safety goggles should be strongly encouraged, particularly for patients in occupations that elevate their risk of ocular injury. Further, the patient may require a multidisciplinary team including social work and psychiatry to provide support following definitive repair.

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Dr. Wang is a third-year ophthalmology resident, and **Dr. Deobhakta** is clinical assistant professor of ophthalmology; both are at the New York Eye and Ear Infirmary, in New York City. *Financial disclosures: None.*

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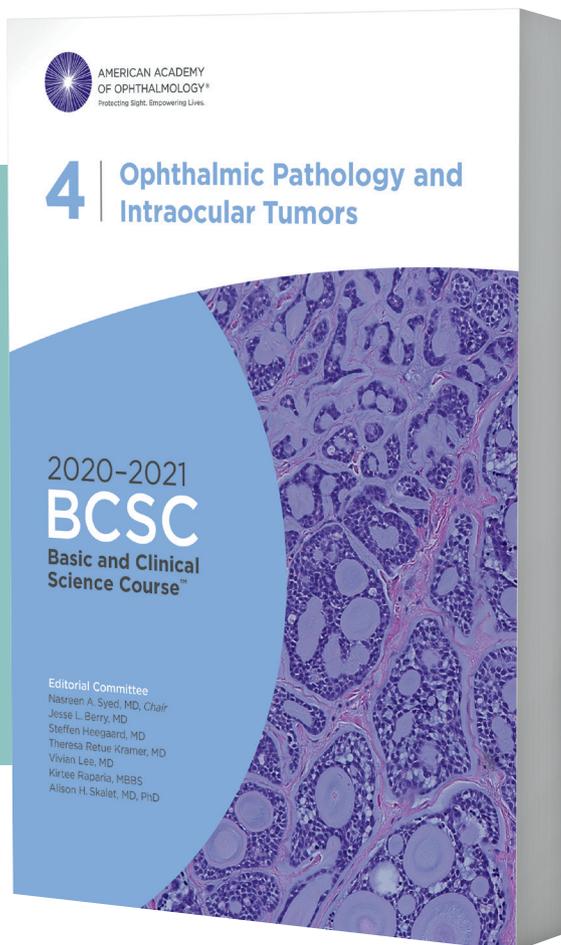
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The Case of the Droopy Eyelid and Frozen Globe

Poindexter Peterson,* an 84-year-old man, had been diagnosed with herpes zoster ophthalmicus (HZO). He had a vesicular rash over his left eye and the left side of his face, and he was prescribed a one-week course of oral antiviral medication. His rash and swelling almost completely resolved, but the pain persisted. One month after the initial diagnosis, no longer able to bear the intractable pain around his left eye, and unsure why his left eyelid was still droopy, Mr. Peterson went to the emergency department.

The Presentation

Medical history. Mr. Peterson had an extensive past medical history, including hypertension, chronic obstructive pulmonary disease, myasthenia gravis (which was in remission), obstructive sleep apnea, and multiple skin cancers.

Medications. He was taking albuterol, meclizine, metoprolol, and enalapril.

Ophthalmic history. His ophthalmic history included open-angle glaucoma treated with latanoprost and cataract extraction with implantation of a posterior chamber IOL in both eyes.

The Exam

Vision exam. On initial examination, Mr. Peterson's visual acuity (VA) was 20/20 in his right eye and 20/60 in his left. Intraocular pressure (IOP) was 21 mm Hg in the right eye and 34 mm Hg



EOM TEST. He showed decreased ductions in all directions of gaze upon presentation in the left eye (1A), with improvement on follow-up exam (1B).

in the left. Pupils were reactive without relative afferent pupillary defect (rAPD). Color vision, tested with Ishihara plates, was intact in both eyes.

Extraocular movement. Extraocular movements (EOM) demonstrated significant limitation of ductions in all directions of gaze in the left eye (Fig. 1A). The remainder of the cranial nerve examination was unremarkable.

External exam. We noted complete

ptosis, 2 mm of proptosis, and moderate injection in the left eye.

At the slit lamp. Slit-lamp biomicroscopy of the left eye revealed punctate epithelial keratopathy without dendritiform lesions, moderate central corneal stromal haze, and a deep and quiet anterior chamber.

Funduscopy exam. We noted a moderately enlarged cup-to-disc ratio, but the exam was otherwise normal.

First thoughts. The EOM limitations demonstrated involvement of multiple cranial nerves, bringing to mind two possible lesion locations: the orbital apex and the cavernous sinus.

BY MATTHEW M. ROLAIN, BS, MATTHEW G.J. TRESE, DO, MA, DAVID M. ROONEY, MD, ANANT KRISHNAN, MD, LORI STEC, MD, AND ROBERT J. GRANADIER, MD. EDITED BY INGRID U. SCOTT, MD, MPH.

Because of the absence of an rAPD, we localized the lesion to the cavernous sinus and obtained emergent neuroimaging to confirm our suspicion. In addition to a mass lesion, our differential included Tolosa-Hunt syndrome, a painful ophthalmoplegia secondary to granulomatous inflammation of the cavernous sinus. However, given the association between HZO and cavernous sinus/superior orbital fissure syndrome,¹

and the fact that the patient's pain was consistent with postherpetic neuralgia in the distribution of the ophthalmic division of the trigeminal nerve (V1), we believed his current presentation was most likely related to HZO.

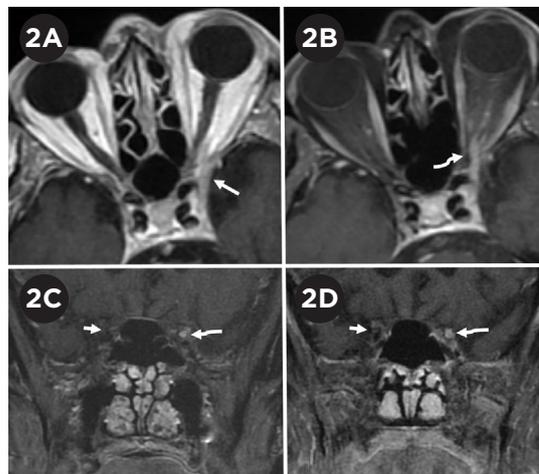
Testing and Final Diagnosis

Magnetic resonance imaging (MRI) of the head and orbits with and without gadolinium demonstrated asymmetric thickening and enhancement of the left cavernous sinus, superior orbital fissure, and oculomotor nerve as it tracked from the cavernous sinus to the orbital apex. In addition, there was concern for an early septic thrombophlebitis (Figs. 2A and 2B). The patient was diagnosed with cavernous sinus syndrome secondary to chronic HZO. Mr. Peterson was admitted and received intravenous acyclovir and methylprednisolone. After five days of therapy, he was transitioned to oral valacyclovir and prednisone. Betaxolol was also initiated for IOP control in his left eye.

Follow-Up

Two months later, Mr. Peterson returned for a follow-up visit. VA was stable at 20/25 in his right eye and 20/60 in his left. IOP was 19 mm Hg bilaterally on ocular hypotensive therapy. Ptosis and duction deficits had significantly improved, but minimal limitations of supraduction and mild ptosis of the left eye remained (Fig. 1B). The patient was orthophoric in primary gaze and reported no diplopia.

Despite significant improvement in the ophthalmic exam, Mr. Peterson



IMAGING. Axial postcontrast T1-weighted image (2A) reveals asymmetrically thickened left cavernous sinus (arrow). Fat-saturated image (2B) also demonstrates a thickened and enhancing left third nerve (curved arrow) extending from orbit into cavernous sinus. Coronal fat-saturated T1 postcontrast image (2C) displays the difference between the abnormally thickened and enhancing left third nerve (curved arrow) from the right side (short arrow) where the normal nerve is difficult to even identify. Follow-up image (2D) after two months of intensive steroid and antiviral treatment reveals persistent thickened and enhancing left third nerve (curved arrow) with mild improvement in the thickened left cavernous sinus.

mentioned that he was feeling slightly off. He stated that he was confused and reported gait instability that had persisted for several hours. Confrontation visual fields revealed a new right homonymous hemianopsia.

Urgent neuroimaging identified an occlusion of the left posterior cerebral artery with associated acute/subacute ischemia of the left occipital and temporal lobes. Despite dramatic clinical improvement of the patient's initial symptoms of ptosis and ophthalmoplegia, repeat MRI showed only slight improvement in the left cavernous sinus thickening and continued abnormal enhancement of the left oculomotor nerve (Figs. 2C and 2D).

Discussion

There are approximately 1 million cases of herpes zoster each year in the United States, of which HZO accounts for 10%-20%.² HZO occurs when reactivation of varicella zoster virus (VZV) involves the V1 distribution. Ophthalmic complications of HZO can involve any of the ocular tissues, the orbit, and—in rare instances—the central nervous system (CNS).² Resolution of the acute phase of HZO does not translate into remission, as evidenced by a significant number of patients who suffer a chronic/recurrent disease course. Involvement of the orbital apex, cavernous sinus, and/or CNS is rare but can result in significant morbidity—and even mortality—if not addressed promptly. Neuroimaging is an important diagnostic tool, and its utility is optimized by localization as directed by comprehensive ophthalmic

examination. This case serves as a reminder that the constellation of ptosis and multiple cranial neuropathies without rAPD localizes the lesion to the cavernous sinus/superior orbital fissure.

The pathophysiologic mechanism underlying HZO-associated cranial neuropathies is unknown. Histologic studies that have attempted to elucidate an underlying etiology have focused on either direct infection of the cranial nerves or inflammatory changes resulting in vascular and neurologic compromise.³ While there is no agreed-upon consensus on treatment, dual therapy with antivirals and steroids, which aim to treat the reactivated virus and mitigate the inflammatory damage, is the mainstay of therapeutic intervention.

Finally, our patient—with multiple known risk factors (i.e., age, hypertension, and obstructive sleep apnea) for cerebrovascular accident (CVA)—developed a posterior circulation stroke shortly after VZV reactivation. In a recent meta-analysis, HZO was associated with an increased risk of stroke within three months to one year of HZO reactivation.⁴ The mechanism that underlies this association is unknown. One possible explanation for the relationship between HZO and CVA was proposed by Grose and Adams.⁵ Upon viral reactivation within the dorsal root ganglia of the trigeminal nerves, there is anterograde transmission of the

virus within the nerves. These nerves terminate within the adventitia of nearby cerebral vasculature, specifically the internal carotid artery and Circle of Willis. Grose and Adams postulate that viral replication may extend to this vasculature, resulting in an occlusive inflammatory vasculitis. Support for this theory in large part stems from the giant cell arteritis literature, where VZV has similarly been implicated as a contributing factor for occlusive vasculitic disease.⁶

Take-Home Points

This case underscores the importance of complete ophthalmologic evaluation in cases of HZO, as our patient's cavernous sinus/superior orbital fissure syndrome went undiagnosed for weeks because ptosis masked the recognition of ophthalmoplegia and diplopia.

Further research into the pathophysiologic mechanisms underlying HZO involving the cavernous sinus/superior orbital fissure should allow for optimized treatment protocols. And because VZV is associated with significant morbidity, this case should remind us of our role in advising patients to discuss the potential benefits of shingles vaccination with their primary care physician.

*Patient name is fictitious.

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Mr. Rolain is a medical student at Wayne State University School of Medicine in Detroit. Dr. Rooney is a glaucoma fellow at the University of Pittsburgh Medical Center. Dr. Krishnan is a radiologist at Beaumont Hospital in Royal Oak, Mich. Dr. Trese is an ophthalmology resident, Dr. Stec is a comprehensive ophthalmologist, and Dr. Granadier is a neuro-ophthalmologist; all three are at Beaumont Eye Institute in Royal Oak, Mich. *Financial disclosures: None.*



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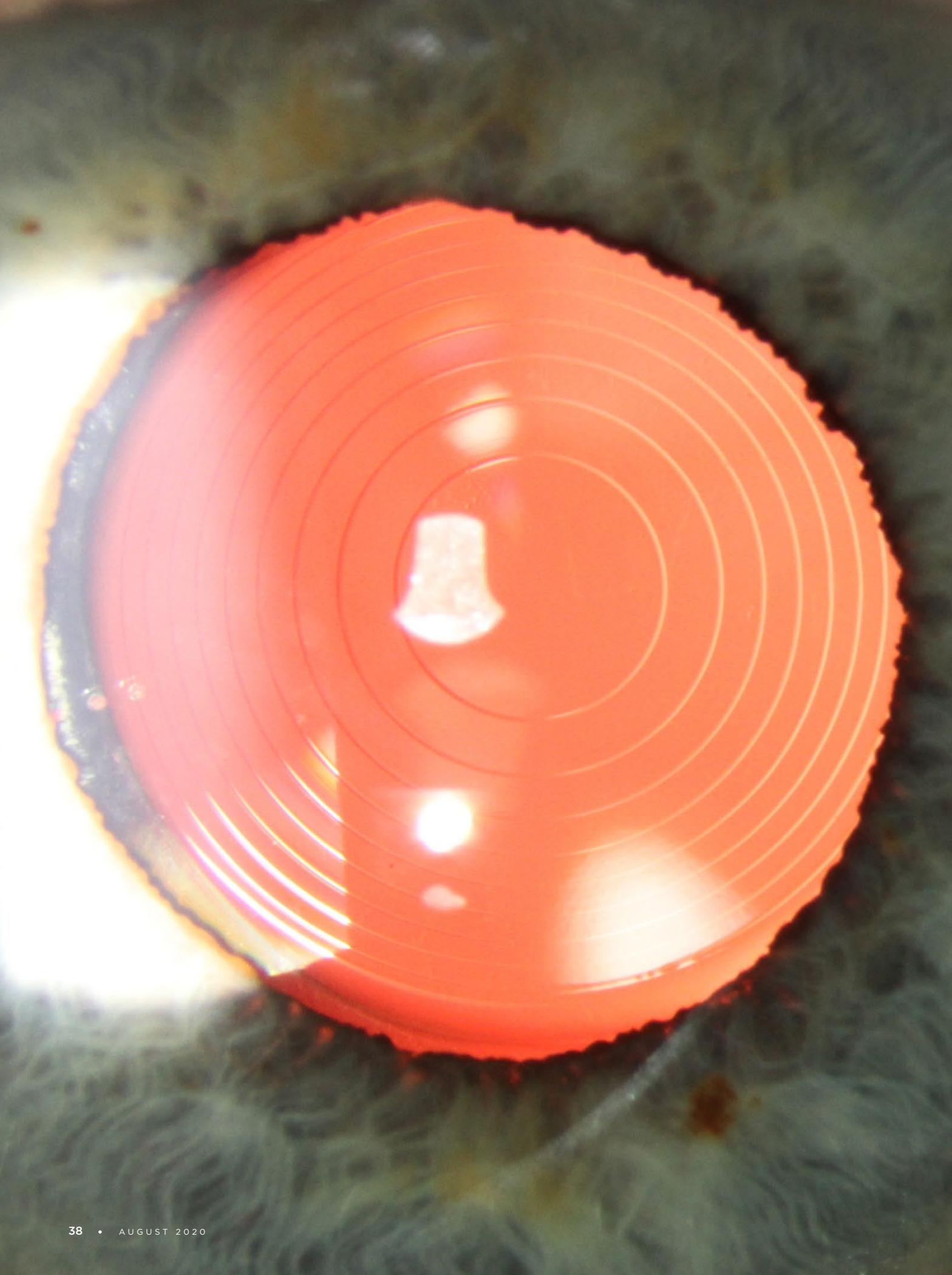
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Climbing the Stepladder to Manage Astigmatism

Now more than ever, patients expect to be free of glasses and contact lenses following cataract surgery. As a result, ophthalmologists must pay close attention to the management of preexisting corneal astigmatism.

A stepwise approach can help.

By Mike Mott, Contributing Writer

Armed with the latest IOLs and power formulas, cataract surgeons have largely solved the problem of minimizing postoperative spherical error, with close to 80% of patients being within 0.5 D of target.¹ But what are the best ways to also manage or reduce preoperative corneal astigmatism at the same time? A comprehensive plan is essential for both your patients and your practice.

“Over the last decade, we’ve experienced an explosion of technology in terms of IOLs and femtosecond lasers that has allowed us to concentrate on astigmatism,” said Kendall E. Donaldson, MD, MS, at the Bascom Palmer Eye Institute in Plantation, Florida. “It’s an important evolution in cataract surgery. No longer are we just fixing a cataract and putting a patient in a pair of glasses.” She explained that the secondary goal in cataract surgery involves targeting and treating astigmatism, with a goal of increasing spectacle independence.

Establishing Initial Expectations

To begin with, it’s critical to manage patient expectations. In particular, the notion of astigmatism “correction” is a popular misnomer, said Kevin M. Miller, MD, at the University of California, Los Angeles. “Treating astigmatism during cataract surgery isn’t like putting a muffler on a car. It’s not going to bring the noise level down to a perfect zero—that almost never happens.” As a result, he said, he uses the term “astigmatism management” to express reality.

“I always tell my patients that our goal is not to eliminate the astigmatism but just minimize it to a point that it’s under a threshold of affecting vision significantly,” said Sumit Garg, MD, at the University of California, Irvine. You also have to discuss the inherent unpredictability when it comes to managing astigmatism, he noted. “Following surgery there’s always the small chance that the patient will need something else done, such as [surgical correction of] an IOL rotation or some kind of additional procedure to help achieve the refractive goal.”

***INCISIONS OR TORIC IOLS?** Surgeon preference drives this decision, especially for particular levels of astigmatism.*

The Stepladder Approach

Several options for managing astigmatism can be used alone or in combination. These include incision placement on the steep axis of the cornea, single or paired peripheral corneal-relaxing incisions (PCRIs), and implantation of toric IOLs.² And different surgeons will opt for a particular technique given the amount and type of astigmatism as well as the patient's age.

"There's a lot to sort out," said Dr. Miller. That's why he teaches his residents a systematic stepwise approach. "It's important to take a few steps back and look at the big picture. How can I develop a plan of attack for handling astigmatism for any patient who walks in my door?"

Categorize your patients. Dr. Miller's approach is simple and straightforward. After measuring the magnitude of astigmatism by corneal topography, and in some instances corneal tomography, he places patients into one of four categories: astigmatism of less than 1 D, 1 D up to 1.5 D, 1.5 D up to 4 D, and more than 4 D.

"Each 'bucket' necessitates a certain approach or combination of approaches," said Dr. Miller. "It's similar to treating glaucoma. You climb the ladder as you need to."

Measure early and often. This tier-based approach is a nice way to organize your surgical options, said Uday Devgan, MD, FACS, but it only works if the astigmatism in question is regular and symmetric. "This is an important factor," said Dr.

Devgan, in private practice in Los Angeles and Beverly Hills. "The only way we can really treat astigmatism effectively is if we have regularity. So measure, measure, measure prior to categorizing your astigmatic patients. Be diligent when you look at the ocular surface, make sure all of your measurements agree,

look at your topography and tomography with an eye on symmetry and regularity. Only then can we move forward with effective treatment."

Nuances of Treatment

Surgical preference will vary from ophthalmologist to ophthalmologist. However, there is a general consensus on which techniques work

well for managing different levels of astigmatism.

Treating astigmatism of <1 D. For most eyes, said Dr. Miller, placement of the phacoemulsification incision on the steep corneal axis is sufficient to manage small amounts of astigmatism, and it takes care of 80% of his patients. "If the patient is steep at axis 48, I'll move the incision over to 48 degrees and operate there," he said. "It's of course important to have in mind your surgically induced astigmatism here. Personally, I use 0.4 D as my own value—but it might be 0.1 D for some surgeons or 0.7 D for others. If you move your incision on the steep axis, you're going to knock the astigmatism in that axis down by whatever your surgically induced value is. So, if a patient starts off with, say, 0.7 D at 48 degrees, I move my incision to 48 degrees, and I'm getting, on average, 0.4 D of effect. I've just knocked their astigmatism down to 0.3 D."

Treating 1 D to 1.5 D. For this range, Dr. Miller prefers PCRIs for both ease and cost. "Some surgeons might not feel comfortable performing relaxing incisions because of their unpredictability and will prefer to switch to a toric IOLs."

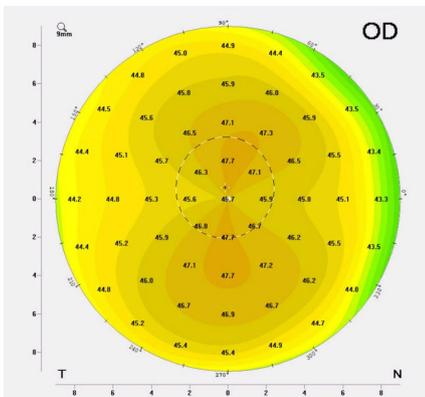
But as Dr. Miller pointed out, unlike relaxing incisions, toric lenses can sometimes rotate and can add a significant out-of-pocket cost. "Relaxing incisions are therefore my go-to in this group of patients," he said. "I'll make the relaxing incisions on the steep axis. So if it's at 48 degrees, I'll make my two incisions at 48 degrees and then make the phaco incision through the most convenient relaxing incision. If we perform the cataract surgery in that fashion, I can get up to 1.5 D of astigmatism treatment very readily and with very good predictability."

Beyond 1.5 D, Dr. Miller notes, the downsides associated with PCRIs can start to outweigh the potential benefits, particularly when toric IOLs can be used.

Treating 1.5 D to 4 D. Because of the technological advances associated with the latest generation of toric IOLs, they are the preference of many cataract surgeons when preoperative astigmatism is anywhere above 1.5 D. But many surgeons extend their use to anything above 1 D.

"For 1 D all the way up to 4 D, a toric IOL is the best choice for me," said Dr. Devgan. "Yes, there is potential for misalignment or post-op rotation, but these IOLs are very accurate, very effective, and very predictable."

Dr. Donaldson agreed. "There is a question of whether relaxing incisions regress over the first six months, so the toric lens is my preference for any astigmatism over 1 D—and definitely anything over 1.25 D—especially considering the level of quality, stability, and accuracy that the new gener-



WITH-THE-RULE. An example of vertically steep corneal astigmatism.

ation of lenses provides.” The distinction between with-the-rule and against-the-rule astigmatism is important here as well, she added. “Because a small amount of with-the-rule astigmatism can result in better vision for some patients, I tend to be more aggressive when treating the against-the-rule variety and will start using a toric lens at a slightly lower level of astigmatism in those instances.”

And with regard to misalignment or post-op rotation experienced with these IOLs, “digital alignment improves the former, and surgical repositioning can rectify the latter,” said David

F. Chang, MD, in private practice in Los Altos, California. “I’d therefore recommend a toric IOL when it is most important to have a spherical refractive outcome. This would include any patient receiving a presbyopia-correcting IOL, those who are most determined to avoid spectacles, and monofocal IOL patients with higher amounts of astigmatism.”

Treating 4 D and beyond. A combined procedure is likely necessary if your patient is in this range. But first look carefully at the topography. Does this patient have truly regular and symmetric astigmatism—or is irregularity or asymmetry

Helping Patients Decide

In general, the treatment of preexisting astigmatism during cataract surgery is not covered by Medicare, and so any management of the condition will result in the patient paying out of pocket.

And that presents a quandary: How best to explain the benefits of astigmatism management to patients? “There is no refractive benefit to having astigmatism, so correcting it should be advantageous for any patient who doesn’t wear glasses full time,” Dr. Chang said. “Our challenge is explaining this to patients so that they can decide whether the value is worth the extra cost.”

Keep it simple. “It starts with a mindset of not leaving opportunity on the table,” said Dr. Garg. “Not just from the financial perspective of your practice, but also—and more importantly—from a patient’s perspective. You can really make a big difference in people’s lives if you’re treating even low amounts of astigmatism. So we try to put it in terms that the patient can relate to, such as, ‘Yes, the cataract surgery will be covered by insurance, but the astigmatism correction will be your responsibility, much like hearing aids, dentures, or glasses.’”

When Dr. Donaldson outlines astigmatism management to her patients, she focuses on outcomes. “There’s a tendency for ophthalmologists to present too many options to patients at once, which can make the decision-making process very complex,” she said. “So we have to do our best to simplify how we explain new things to our patients.” Thus, instead of leaning on terms such as “corneal-relaxing incisions” and “toric lens,” she focuses on what patients would like to achieve in practical terms, “because they can relate more to the ability to see distance and near more clearly.”

And Dr. Chang shows patients their color topography map and compares it to a spherical cornea map. “I then explain that whenever they are not wearing spectacles, what they are able to see naturally—for instance, at distance—will be better if we cancel out the astigmatism blur. I might also explain that the less astigmatism they have, the better non-prescription sunglasses and readers will work.”

Don’t presume. Ultimately, however, a patient may decide that he or she is comfortable forgoing any additional pro-

cedure above and beyond the removal of the cataract.

“My initial patient questionnaire is rather simple,” said Dr. Devgan. For example, he asks, “Will you be interested in correcting your vision so that you can see some ranges far or near without glasses? Or do you prefer to wear glasses full time?” The answers can be surprising, he said. “Believe it or not, quite a few of my patients don’t want me to bother with their astigmatism. They want to go back to the same glasses. That’s just how they like to be seen and how they like to see the world.”

Avoid overselling. Whatever the patient chooses, you don’t want to come off as being too pushy.

“Some patients get upset because they perceive their surgeon as more of a salesperson than a physician,” said Dr. Donaldson. “So, there’s a little finesse that goes into this process. We have to be very careful in the way we present our technology, and we have to be aware of our patients’ perception of that technology. The goal is creating understanding through a partnership with the patient, avoiding misperceptions, and establishing accurate expectations.”

present? That could be a sign of keratoconus or forme fruste keratoconus, pellucid marginal degeneration, or another condition. “Patients who have irregular corneas or keratoconus may not be suitable for toric IOLs or even incisional approaches,” said Dr. Devgan. “We may even choose to leave them with their existing astigmatism because they can be happy going back to their rigid contacts, which certainly provide excellent vision for them. These are rare instances though.”

If the patient is truly regular and symmetric, the best approach is a high-powered toric lens followed by laser refractive surgery, Dr. Devgan said. “I’ll increase the spherical IOL power to leave the patient a little myopic so that I can clean up the remaining diopters of astigmatism with an excimer laser, for example, photorefractive keratectomy or LASIK. The first shot is going to put the patient on the green, and with the second shot a few months later, we’ll sink the putt. We just can’t get a hole in one under these circumstances.”

A note on challenging eyes. “Since last fall, we’ve been using the Light Adjustable Lens (RxSight) for our most challenging astigmatism patients,” such as post-LASIK or post-RK eyes,

Dr. Chang said. “With the ability to do multiple sequential light adjustments postoperatively, this technology can correct up to 4.5 D of astigmatism.”

Hitting That Sweet Spot

Another variable to consider is the post-op refractive target. Should you aim for zero astigmatism from the outset—or aim higher and let the patient drift down to zero over time?

Accounting for potential drift. “Early on in my career, my target was zero, but that’s no longer the case,” said Dr. Miller. “My sweet spot now is to leave the patient a little bit vertically steep, around 0.3 D at 90 degrees, because we know that people go from vertically steep to horizontally steep as they age. So if they end up zero dead-on postoperatively, they’re going to have great vision right away, but then years later they’re going to be back in glasses. But if we leave them a little vertically steep, they’ll eventually drift down to zero.”

Considering patient age. The post-op target also depends on the patient’s age. “Someone who is on the older side most likely won’t experience significant astigmatic shift in the next several years,” said Dr. Garg. For patients who are approaching age 70, he said, “a tiny bit of shift will occur—but if someone is younger, you could see a much more pronounced shift. It’s not always linear over time, but that’s the general principle: The older the patient is, the less the potential shift.”

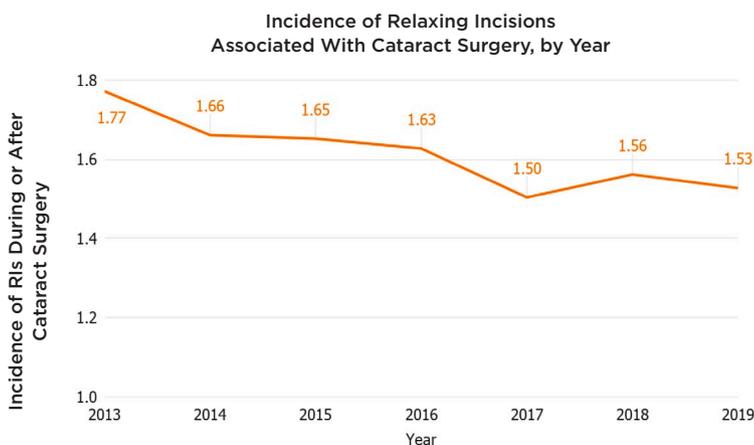
Thus, Dr. Garg said, if he has a 75-year-old patient with a posterior subcapsular cataract, “my target is pretty close to zero.” In contrast, in a 55-year-old patient, “I aim for a little with-the-rule astigmatism so it can drift down with time.”

Considering patients’ preferences. Whatever approach you take to manage astigmatism, be sure to give your patient a voice in the matter, Dr. Miller said. “What kind of outcome does the patient prefer? Do they prefer to wear glasses in certain situations and environments? Are they comfortable with multiple procedures to reduce their astigmatism? You need to make them a partner in the process and tailor your treatment to their desires because, ultimately, this is an investment in the rest of the person’s life.”

IRIS Registry Snapshot: Use of Relaxing Incisions

Verana Health analyzed data from the Academy’s IRIS Registry (Intelligent Research in Sight) to determine how the use of PCRI—formerly known as limbal-relaxing incisions—in patients undergoing cataract surgery has changed in the last several years. Registry data from 2013 to 2019 showed that the real-world incidence of relaxing incisions has decreased since 2013, possibly due to a rise in toric IOL use.

Note: The Academy has partnered with Verana Health to curate and analyze IRIS Registry data.



SOURCE: Verana Health

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MEET THE EXPERTS



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Relevant financial disclosures: CataractCoach.com: O.

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+ Lomb: C; Carl Zeiss: C; Johnson & Johnson Vision: C.

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New E/M Rules for Office Visits, Part 1: The Medically Relevant Patient History

If you have been using the office-based evaluation and management (E/M) codes, you'll know that the history component involves an onerous series of steps—but not for much longer!

Almost gone are the days of obtaining and documenting a review of 10 or more body systems *plus* a past medical history, family history, and social history *plus* a chief complaint *plus* a minimum of four elements to the history of the present illness.

Big changes coming. Beginning Jan. 1, 2021, Medicare is streamlining the requirements for patient history when using office-based E/M codes 99202-99215. The history will need to be *medically appropriate*, which means that you need to document only information that will be medically relevant for the physician. What's relevant? This will vary depending on the nature of the patient encounter.

This month and next month, Savvy Coder provides some typical examples seen daily in ophthalmic practices.

Get ready with technician training. While this change to the documentation requirements is great news, technicians will need some help. In addition to giving them the AAOE's new resources (see "Train Your Staff"), ophthalmologists should walk their technicians through the types of information that are needed for a medically relevant history.

Who can obtain and document the history? Any part of the chief complaint or history that is recorded in the medical record by ancillary staff or the beneficiary (patient) does not need to be documented again by the billing practitioner. Instead, that person may review the information, update or supplement it as needed, and indicate in the record that he or she has done so.

Cataract Example

When patients are referred for cataract surgery, John T. McCallister, MD, asks that his technicians capture these details of their blurred vision.

- Laterality: Is the blurriness in the right eye, left eye, or both?
- Onset: Gradual or sudden?
- Duration: When did the blurred vision start?
- Effect on daily life: What activities are affected? Specifically ask about driving, working, reading, using a computer or device, watching television, and doing crafts or other activities.
- Glare or halos: Is the patient bothered by glare or halos? If so, during daytime and/or nighttime? In the rain? In certain indoor lighting conditions?
- Surgical history: Any history of refractive surgery? If so, what type of refractive surgery, when, how many times, and can we get past records?
- Injury: Any history of trauma or other injury?

Train Your Staff

Conquering New E/M Documentation Guidelines for Ophthalmology is now available. It combines a narrated online tutorial with an accompanying workbook. Review the step-by-step instructions, clinical examples, and worksheets, and then pass the exam section to earn an electronic certificate of completion.

To buy this coding product, visit aao.org/codingproducts.

- Eye disorders: Any concurrent eye disorders (e.g., blepharitis, diabetic retinopathy, dry eye syndrome, epiretinal membrane, epithelial basement membrane dystrophy, glaucoma, lattice degeneration, macular dystrophy, pseudoexfoliation syndrome, retinal tear or detachment, uveitis, etc.)?
- Medications: Taking, or have previously taken, any prostate or bladder medications? Any blood thinners?
- Family history: Any family members with eye issues?
- Allergies: Any medication allergies? Latex allergies?
- Anesthesia: Any adverse reactions to anesthesia?
- Noncovered services: What has the patient heard regarding premium IOLs and femtosecond lasers?

Dr. McCallister is a comprehensive ophthalmologist at Northern Virginia Ophthalmology Associates, which has offices near Alexandria and D.C.

BY SUE VICCHRILLI, COT, OCS, OCSR, ACADEMY DIRECTOR OF CODING AND REIMBURSEMENT, WITH DAVID B. GLASSER, MD, ROBERT S. GOLD, MD, FAAP, EMILY P. JONES, MD, AND JOHN T. MCCALLISTER, MD.

Cornea Example

There are many potential indications for a corneal transplant, such as scarring, endothelial failure, dystrophy, infection, and trauma. That said, David B. Glasser, MD, considers the following as medically relevant:

- Chief complaint: What is the primary problem for which you seek consultation and possible surgery? What are the vision problems? Describe any pain or discomfort.
- Laterality: Right eye, left eye, or both? If both, which is worse?
- Duration: When did it start/how long has it been going on?
- Cause: Do you think anything in particular caused it?
- Onset: Did it come on suddenly or gradually?
- Stability: Is it getting better or worse or has it been stable? If stable, for how long has it been stable?
- Associations: Does anything in particular make the symptoms better or worse?
- Effect on daily life: What activities does it affect? Driving, reading, any specifics?
- Surgical history: Any past eye surgery? What was the surgery and when did it take place?
- Medications: Any systemic or topical medications?

Dr. Glasser is the Academy Secretary for Federal Affairs.

Glaucoma Example

Under the new rules, Emily P. Jones, MD, will be asking her technicians to document the following elements for a typical glaucoma patient:

- Surgical history: Any history of prior eye surgeries?
- Family history: Is there a strong family history of glaucoma with glaucoma surgeries or vision loss at an early age?
- Medical history: Examples of pertinent histories include:
 - A stroke resulting in homonymous visual field defects.
 - A history of poorly controlled diabetes with renal disease, limb amputations, hospitalizations.
 - A distant history of trauma to one eye.

What About MIPS Reporting?

Are you participating in the Merit-Based Incentive Payment System (MIPS) this year? Depending on which quality measures you select, your technicians may need to add extra questions to their history-taking checklist. For example, this would currently be the case if you selected any of the following:

- Measure 110: Preventive Care and Screening: Influenza Immunization
- Measure 111: Pneumonia Vaccination Status for Older Adults
- Measure 130: Documentation of Current Medications in the Medical Record
- Measure 226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- Measure 238: Use of High-Risk Medications in the Elderly
- Measure 402: Tobacco Use and Help With Quitting Among Adolescents

Many of these quality measures are likely to still be available for reporting during the 2021 MIPS performance year. For detailed descriptions of them, visit aao.org/medicare/quality.

- Medications: Examples of pertinent details include:
 - Any glaucoma medications that a patient took in the past but did not tolerate or did not respond to?
 - A history of asthma with use of inhalers that would make the patient a poor candidate for beta-blocker drops?
 - Long-term use of oral or inhaled steroids?
 - A history of exudative macular degeneration with intravitreal Avastin injections (which can lead to very elevated eye pressure).

Dr. Jones is a glaucoma specialist at the Devers Eye Center in Portland, Oregon.

Pediatric Example

Suppose a patient is referred by his pediatrician to your practice for strabismus?

Robert S. Gold, MD, FAAP, would want to make sure that the following information is documented in the patient's record:

- Direction of misalignment: In, out, up, or down?
- Duration: Days, months, or years?
- Constant or intermittent strabismus?
- Double vision?
- Is it better or worse at certain times of day?
- Family history of strabismus/amblyopia?
- Eye history: Used glasses, patching, and/or undergone surgery?

- Pertinent information from past history, medical history, neurologic history, and genetic history (syndromes).

And what if you're examining an adult strabismus patient? In that case, Dr. Gold would want the technician to also document any history of diabetes, hypertension, vascular problems, trauma, neurologic issues, and medications.

Dr. Gold is a pediatric ophthalmologist at Eye Physicians of Central Florida, with offices in the Orlando metropolitan area.

The Eye Visit Codes

What about the history component for Eye visit codes 92002–92014? Whether the patient is new or established, and whether the exam is limited or comprehensive, the history documentation requirements for Eye visit codes will be the same in 2021 as they were in 2020.

Increased E/M Payments

Payments for office-based E/M codes—but not for Eye visit codes—are slated for a “significant” increase on Jan. 1, 2021. The Centers for Medicare & Medicaid Services (CMS) will announce the size of those increases in November, when it publishes the 2021 Medicare Physician Fee Schedule. Unfortunately, unless Congress intervenes to amend CMS' budget-neutrality mandate, these increases in E/M payments could result in cuts to other codes (see page 49).

Telemedicine During COVID-19: Managing Medical Malpractice Risk

When an active physician-patient relationship has been established,¹ telemedicine can help you meet your legal duty of care during the COVID-19 pandemic. As always, management of patient expectations is critical in mitigating liability risk. It is also helpful to keep in mind the following tips.

Follow up with patients requiring care. When following up with patients, check to see if their conditions are progressing and determine if a telemedicine visit is appropriate or an in-person exam is necessary. For cases in which you aren't able to render timely and appropriate care, you will need to direct patients to where they can obtain such care. You should also advise the patient of the medical consequences if recommended care is not obtained promptly. (Note: Some states have passed legislation that may protect you from liability due to delays in surgery during this pandemic. Also confirm that your medical malpractice insurance company will cover such suits.)

Telemedicine visits should be fully integrated into your existing documentation system. Documentation of the telemedicine service not only will be helpful for billing and reimbursement but also will ensure a complete account of care, which would be critically important in the defense of a medical malpractice claim.

Document that the patient consented to telemedicine. Obtain consent and

remind patients that communicating via telemedicine is not the same as a face-to-face exam. If you can't get the patient to sign a consent form, verbal consent should be obtained and documented in the medical record—for example, "Patient initiated a request for care and consented to care by phone." If there is a fee for the telemedicine visit, be sure to notify the patient.

Meet state requirements. The Center for Connected Health Policy has posted information on telehealth-related laws (www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies#). Also check with your state regulator to see if it has introduced any temporary waivers or other regulatory changes during the current pandemic.

Meet ADA requirements. Be sure that your telemedicine protocols include specific accommodations for patients with special needs. The Americans with Disabilities Act (ADA) requires practices to communicate effectively with people who have vision, hearing, or speech disabilities (www.ada.gov/effective-comm.htm).

Do not use a public-facing platform for telemedicine. The best way to ensure privacy when providing telemedicine services is to adhere to HIPAA's rules on Protected Health Information (PHI). However, at the outbreak of the COVID-19 pandemic, many practices weren't set up to provide HIPAA-compliant telemedicine services. Recogniz-

ing this, the Department of Health and Human Services Office for Civil Rights is exercising its enforcement discretion during the national public health emergency: If physicians are providing telehealth services in good faith, the agency will not impose penalties on them for using an electronic platform that doesn't comply with HIPAA's regulatory requirements as long as the platform is not public facing.² For example, this exception allows you to use FaceTime, Facebook Messenger video chat, Google Hangouts video, Skype, and text, even though those platforms are not HIPAA compliant. However, you are not permitted to use Facebook Live, Twitch, and TikTok because these are public-facing platforms that allow others to view an exchange.

Telemedicine Resources

Risk management. The Ophthalmic Mutual Insurance Company (OMIC) offers free resources online (www.omic.com). These include consent forms for the telemedicine visit (www.omic.com/telemedicine-consent-form) and for elective services during the pandemic (www.omic.com/covid-19-consent).

Practice management. For more information on the practice management aspects of telemedicine, visit aao.org/practice-management/telehealth.

1 www.omic.com/when-is-a-physician-patient-relationship-established/. Accessed June 30 2020.

2 www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html. Accessed June 30, 2020.

Academy Notebook

NEWS • TIPS • RESOURCES

WHAT'S HAPPENING

Ophthalmologist to Be Next President of the UC System

On July 7, The University of California Board of Regents named Academy member Michael V. Drake, MD, as its 21st president. Dr. Drake will oversee the entire University of California (UC) system.

Since earning his medical degree as well as completing his ophthalmology residency at the University of California, San Francisco (UCSF), Dr. Drake has served the UC system in several positions. He spent 20 years on the faculty of UCSF's School of Medicine, where he was the Steven P. Shearing Professor of Ophthalmology. He later served as the UC vice president of Health Affairs and the chancellor of the University of California, Irvine. Now, after six years as president of Ohio State University, Dr. Drake will return to the UC system for his new appointment on Aug. 14.

Academy Members Run for Congress

Earning 47.7% of the vote, Academy member and Iowa State Senator **Mariannette J. Miller-Meeks, MD**, won the June 2 Republican primary for Iowa's open 2nd District seat in the House of Representatives. She will be on the ballot in the general election Nov. 3.



UNIVERSITY OF CALIFORNIA PRESIDENT. *This month, Dr. Drake takes the helm at the UC system, which consists of 10 campuses and more than 280,000 students.*

She's not the only Academy member seeking a congressional seat in 2020. Academy Board Trustee-at-Large and Air Force veteran **William S. Clifford, MD**, is running for Kansas' open 1st District seat, and the primary election will be held Aug. 4. Dr. Clifford, who has been a Finney County commissioner since 2014, is one of four Republican candidates vying for the "Big First" spot, which has come to be known as a valuable stepping-stone for politicians seeking higher offices. Both of Kansas' current senators, Jerry Moran and Pat Roberts, previously represented the 1st district, as did former Senate Majority Leader and 1996 Republican presidential nominee Bob Dole. The House seat is open because incumbent Rep. Roger Marshall has made a bid to fill retiring Sen. Roberts' seat. If Dr. Clifford wins the Aug. 4 primary, he will be on the Nov. 3 general election ballot.

To find out more about the two candidates, visit millermeeks2020.com and cliffordforcongress.com.

FOR THE RECORD

Board Nominees

In accordance with Academy bylaws, notice is hereby given of the following nominations for elected board positions on the 2021 board. These nominations were made by the Academy Board of Trustees in June. If elected, the following individuals will begin their terms on Jan. 1, 2021.

President-Elect

Robert E. Wiggins Jr., MD, MHA

Senior Secretary for Advocacy

George A. Williams, MD

Trustees-at-Large

Anna Luisa

Di Lorenzo, MD

Aaron P. Weingeist, MD

Board appointments. During the June Board of Trustees meeting, the following individual was appointed to the 2021 Board of Trustees and will begin her term on Jan. 1, 2021.

International Trustee-at-Large

Alison Blake, MPH, MBBCh
Dublin, Ireland

Nomination procedures for the Academy Board. Elections to fill the four open elected positions on the 2021 Board of Trustees will take place by ballot after the November Annual Business Meeting. To nominate a candidate by petition, submit a written petition to



Dr. Wiggins



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the Academy's CEO no later than Sept. 16. The petition must be signed by at least 50 voting Academy members and fellows.

To suggest a nominee for the 2022 board, watch for the call for nominations that will be published in the January *EyeNet*.

To read the rules in full, visit aao.org/about/governance/bylaws/article5.

Notice of the Annual Business Meeting

Notice is hereby given that the Annual Business Meeting of the American Academy of Ophthalmology will be held during the AAO 2020 virtual meeting.

For more information, visit aao.org/2020.

TAKE NOTICE

Get Credit for MIPS and MOC

If you have an electronic health record (EHR) system and have integrated it with the IRIS Registry, you can use data from your IRIS Registry dashboard to design and implement an improvement project that can earn you credit for both Maintenance of Certification (MOC) and the Merit-Based Incentive Payment System (MIPS). For the 2020 MIPS performance year, this project would count as a medium-weighted improvement activity.

Submit your plan to the ABO no later than Aug. 31. Using the IRIS Registry dashboard, select one or two quality measures in which to improve your performance. Then, set goals for those measures and submit your plan for achieving those goals to the American Board of Ophthalmology (ABO).

If the ABO approves your plan, implement it for 90-120 days. Use the IRIS Registry dashboard to track your progress and fine-tune your processes as needed. Once the project is complete, review its effectiveness and send a summary to the ABO.

Learn more at aao.org/iris-registry/maintenance-of-certification and <https://abop.org/IRIS>.

Follow the Truhlsen-Marmor Museum of the Eye

Get to know the Truhlsen-Marmor

Museum of the Eye on Instagram and Twitter (@museumoftheeye) and facebook.com/museumoftheeye. Learn about upcoming exhibits at aao.org/museum-of-the-eye.

Submit a Mystery Image to Be Featured in *EyeNet*

Got an image that is perplexing or intriguing? Send your mystery ophthalmic image and its 150- to 200-word case description to the *EyeNet* editors for consideration in the Blink section (see page 54).

To get started, head to aao.org/volunteering and select "Submit a Mystery Image and Case Report" under "Write."

Submit Your Research to *Ophthalmology Glaucoma*

The Academy and the American Glaucoma Society have collaborated in producing *Ophthalmology Glaucoma* to expand publishing opportunities for this booming subspecialty.

Submit your research today at editorialmanager.com/ogla.

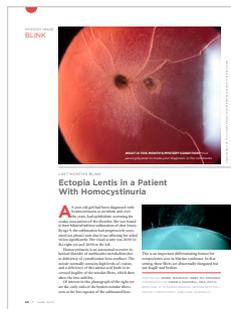
OMIC Tip: Managing Equipment-Related Risk

Ophthalmologists regularly use equipment and medical devices (EMDs) while caring for their patients. Sometimes, things go wrong. In these cases, injured patients may allege that an EMD malfunctioned or was used improperly. They may sue the ophthalmologist, the surgery center, and the manufacturer of the EMD.

Using select closed claims, an issue of the *OMIC Digest* illustrates the initial steps that the ophthalmologist, staff, and surgery center should take to manage these EMD events.

Visit omic.com/digest-vol-29-no-2-2019 to read the issue.

OMIC offers professional liability insurance exclusively to Academy members, their employees, and their practices.



New ABN Form

CMS has updated its Advance Beneficiary Notice of Noncoverage (ABN) form. What's changed? The form's expiration date now reads "06/30/23," but it is otherwise the same.

Until Aug. 30, you can use either the old ABN form or the new one. As of Aug. 31, you can only use the new form.

Download the form at cms.gov/Medicare/Medicare-General-Information/BNI/ABN.

ACADEMY RESOURCES

Reopen Your Practice With Help From Academy Experts

In this new age of telemedicine, with hybrid exams and shifting E/M documentation requirements, the Academy's Ophthalmic Advisors Group is your first line of defense for avoiding claim denials, remaining HIPAA compliant, and safeguarding your practice's revenue. Consultations are now available with Academy senior coding and practice management experts via video conference.

Learn more at aao.org/consultation-services.

New Academy eBook App Is Now Available

The Academy released an upgraded app for reading its eBooks, from the *Basic and Clinical Science Course* to the *Dictionary of Eye Terminology*.

The platform is designed to enhance your learning experience, and it improves upon the previous version. For example, the new app's search function now works across all Academy eBook titles.

Apple or Android device users need only download the free AAO eBooks app from the Apple Store or Google Play. If you access your eBooks via the Academy website, no updates are required to use the new functions.

Users who have logged into the app since March 30, 2019, will have their notes, bookmarks, and highlights automatically migrated to the new app. Other users can contact Customer Service for assistance in migrating their preferences to the new platform.

For help with the new app, contact Customer Service at customer_service@aao.org.

Reboot Your Health Routine During COVID-19

As ophthalmologists have started to tackle a backlog of eye surgery, their increased workload is putting them at a higher risk of musculoskeletal disorders (MSDs). This is compounded by the added anxiety of practicing during a pandemic, with physical and mental stressors potentially having a pernicious synergy. And while a workout or a yoga session can help to alleviate tension and avert MSDs, the COVID-19 crisis has forced people to look beyond their local fitness studio.

Home fitness tips from the physical wellness professionals. When gyms and yoga studios closed, athletes and professional dancers started fine-tuning their own home-wellness routines. Not only has this helped them to stay in shape, but, just as importantly, it is also helping them to cope with the anxiety of living through a pandemic.

For their perspective on physical and mental wellness, and to get their tips on home-based fitness routines, visit aao.org/wellness.

MEMBERS AT LARGE

Illinois Society Hosts First Virtual Town Hall

On June 10, **Sohail J. Hasan, MD, PhD**, president of the Illinois Society of Eye Physicians and Surgeons (ISEPS), hosted the first ever ISEPS International Virtual Town Hall for ophthalmologists across Illinois, its neighboring states, and beyond.

Featured speakers included **Ngozi O. Ezike, MD**, director of the Illinois Department of Public Health, who provided a public health perspective and spoke to the challenges of COVID-19. **Nguyen Xuan Tam**, director of the Community Development Fund in Quang Tri Province, Vietnam, and friend of ISEPS, discussed how eye care in Vietnam is adapting to the challenge of COVID-19. **Academy President-Elect Tamara R. Fountain, MD**, covered the national outlook for restoring the prac-

tice of ophthalmology in the United States.

Then Dr. Hasan presented results from the ISEPS membership survey about how Illinois practices are faring in the COVID-19 era. Dr. Hasan also provided updates on ongoing projects aimed at reopening practices in the state. In addition, he reported the accomplishments of the ISEPS outreach program for communicating with key Illinois state legislators during the pandemic.

Anna Luisa Di Lorenzo, MD, who is a regional member of the Academy's Secretariat for State Affairs covering the states of Illinois, Michigan, Ohio, and Wisconsin, summed up her ISEPS International Virtual Town



VIRTUAL TOWN HALL. The Illinois Society of Eye Physicians and Surgeons (ISEPS) held its first ever Virtual Town Hall. Host and ISEPS President Dr. Hasan welcomed ophthalmologists from across Illinois, its neighboring states, and an international guest from Vietnam to talk about COVID-19 and more.

Hall experience by noting, "I was lucky to be on the call, and it was a great webinar full of excellent and essential information."

D.C. REPORT

Battling Cuts to Surgical Codes

An Academy priority is to battle policy changes that would—if implemented as planned—result in an estimated 7% reduction in reimbursement for ophthalmology.

E/M payments and Medicare's unjust zero-sum game. Starting in January, evaluation and management (E/M) services will receive a welcome boost in payment. However, the Centers for Medicare & Medicaid Services (CMS) is obliged to administer the Medicare Physician Fee Schedule in a budget-neutral manner. This means that unless Congress intervenes, payments for other services will take a hit, resulting in drastic reductions in reimbursement for many specialties, with surgery-based specialties hit particularly hard.

Amid COVID-19, a broad base of opposition to the cuts. This summer, medical organizations opposed to the reimbursement reductions came together to form a 53-society coalition, including societies that represent nonsurgical specialties such as radiology and dermatology. The coalition has warned Congress that many practices have been rocked by the current public health emergency, and reimbursement cuts would undermine their prospects for recovery. This makes it more urgent than ever for legislators to release CMS from its budget-neutrality mandate.

Signs of progress. In the House of Representatives, a bipartisan group of legislators introduced a bill that would avert the cuts. But because this bill includes other provisions that might hamper its progress, the Academy and its allies have been working with legislators to develop a simpler bill that would command more widespread support.

Stay up to date. For the latest advocacy news, check your email each Thursday evening for *Washington Report Express*.

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— Dr. Arsham Sheybani



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GET READY FOR THE VIRTUAL MEETING • PART 4 OF 6

NEW FORMAT

AAO 2020: Now Virtual

In light of epidemiological projections, government regulations, and public health mandates to prevent the spread of disease—including social distancing, limited crowd sizes, and face coverings—the Academy was forced to cancel its in-person annual meeting this year.

The Academy will present a virtual-only event to engage and connect members and to deliver the critical scientific and clinical information that you expect from the most important ophthalmology meeting of the year.

Programming is available for your entire team, including practice managers. Don't miss this opportunity to deepen your skills, discover clinical advancements, review the latest products, interact with colleagues, and ask presenters your questions. You can also view recorded sessions at your convenience.

As the meeting approaches, check for virtual meeting updates at aao.org/2020.

Registration and Hotel

Registration. Be sure to take part in the Academy's first-ever fully virtual meeting. Registration will open on Wednesday, Aug. 12.

Automatic cancellation of in-person

registration. If you registered for the in-person meeting in Las Vegas, the Academy will automatically cancel your registration and send you an email confirmation. If you paid ticket or registration fees, they will be refunded in full. The cancellation and refund process will be completed by Friday, Aug. 7.

Hotel. If you booked a hotel room in Las Vegas through the Academy's official housing service, Expovision, your reservation was automatically canceled. If you made a hotel reservation on your own, you will need to cancel directly with the hotel.

For further information, check aao.org/2020.

Revised Total CME Credits

The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. As the virtual program was developed, the number of CME credits for AAO 2020 and Subspecialty Day were revised. View the latest information at aao.org/annual-meeting/cme.

SUBSPECIALTY DAY

The Lineup

Subspecialty Day meetings include the following:

- Cornea Subspecialty Day 2020
- Glaucoma Subspecialty Day 2020
- Ocular Oncology/Pathology Subspecialty Day 2020
- Oculofacial Plastic Surgery Subspecialty Day 2020



HOW TO NAVIGATE THE NEW NORMAL.

Want authoritative, ophthalmic-specific advice for your practice? Make time for a panel discussion, *From Recovery to Resilience: Creating a Thriving Practice Post-COVID-19*, at the AAOE General Session. Panelists include Ruth D. Williams, MD (above), as well as other Academy leaders and practice management experts. Organized by the American Academy of Ophthalmic Executives (AAOE), this session will be open to all AAO 2020 virtual meeting registrants.

- Pediatric Ophthalmology Subspecialty Day 2020
 - Refractive Surgery Subspecialty Day 2020
 - Retina Subspecialty Day 2020
 - Uveitis Subspecialty Day 2020
- Check for updates** at aao.org/2020.

Subspecialty Day Previews: What's Hot

This month, program directors from two of the Subspecialty Day meetings preview some of this year's planned highlights. Keep an eye on aao.org/2020 for the most current content.

Cornea 2020: Seeing Clearly Into the Future

Program Directors: Sanjay V. Patel, MD,



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*FRCOphth, Sophie X. Deng, MD, PhD,
and Vishal Jhanji, MD, FRCOphth.*

The 2020 Cornea Subspecialty Day will encompass a wide range of topics of interest to a broad audience, including cornea specialists and comprehensive ophthalmologists. The program will incorporate evidence-based information for the medical and surgical management of corneal and ocular surface diseases delivered by leaders in the field. Panel discussions will be complemented by case presentations and audience participation.

Keratoconus and Fuchs dystrophy once were common indications for penetrating keratoplasty, but with evolving techniques and new treatment options, the management of these conditions has changed dramatically. Sessions dedicated to corneal ectasias and Fuchs dystrophy will review current best practices as well as peer into future treatment options.

The hot topics of ocular surface inflammation and infection will feature medical and surgical approaches to common and complex diseases. From dry eye to corneoscleral melting and from new antimicrobials to infection after keratoprosthesis placement, experts will share tips for diagnosis and management. And as we remember 2020 as the year in which we directly experienced the impact of a pandemic, we will take an opportunity to discuss what we have learned so far about SARS-CoV-2.

Cornea Subspecialty Day would not be complete without reviewing the latest updates on keratoplasty and ocular surface surgery. Experienced surgeons will discuss a range of surgical techniques for corneal and conjunctival diseases, including indications, outcomes, and complications, which will have direct relevance to comprehensive ophthalmologists as well as cornea specialists.

Cornea Subspecialty Day is organized in conjunction with the Cornea Society.

**Uveitis 2020: Beating the Odds—
How to Make Sure You Get a Full
House When You're Dealt Uveitis**

*Program Directors: Hatice N. Sen, MD,
and Nisha Acharya, MD.*

The 2020 Uveitis Subspecialty Day

will address current challenges in the diagnosis and management of uveitis. Its format will be a hybrid between the familiar topic-driven presentations and the case-based approach.

With a theme of “Beating the Odds—How to Make Sure You Get a Full House When Dealt Uveitis,” the initial section on fundamentals—the “Uveitis 101”—is intended to provide general ophthalmologists and retina specialists, who are frequently the first to encounter uveitis patients, with a structured and logical approach to the diagnosis and treatment of intraocular inflammation, both local and systemic. Particular emphasis will be placed on generating the differential diagnosis, ordering appropriate laboratory and ancillary testing, and formulating an effective treatment plan. A new highlight of this section will be a lecture on pediatric uveitis.

With this foundation, the program will then center on case-based presentations that will illustrate and amplify the principles established in Uveitis 101. Organized according to the anatomic location of inflammation, cases with increasing degrees of complexity, from the very basic to the truly baffling, will be presented to a panel of experts for discussion. These cases will run the gamut of the major infectious and noninfectious uveitic entities, both sight-threatening and benign, from the common and obvious to the rare masquerader. This case-based approach, enriched with multimodal imaging, is intended to simulate real-life clinical decision making.

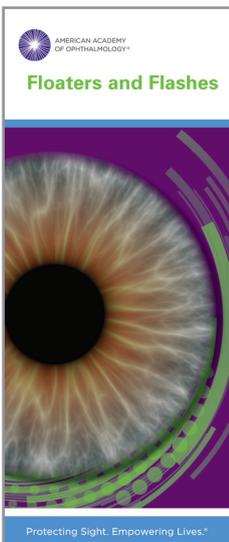
The surgical management of the complications of uveitis requires special attention and will be addressed separately. Fundamentals in the approach to patients with uveitic cataract and glaucoma will be discussed first, followed by the application of vitreoretinal surgical techniques for both diagnostic and therapeutic purposes. The final section of the program will give the audience a glimpse into the exciting and rapidly evolving future of the field of uveitis.

Uveitis Subspecialty Day is organized in conjunction with the American Uveitis Society.



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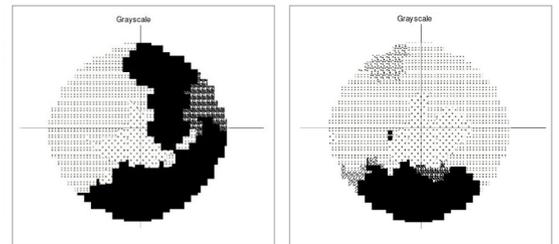
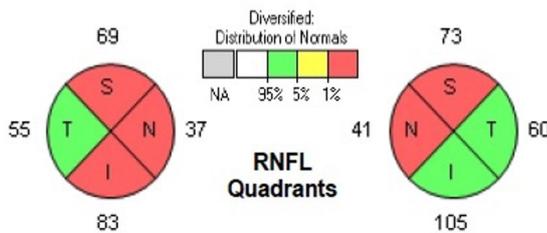
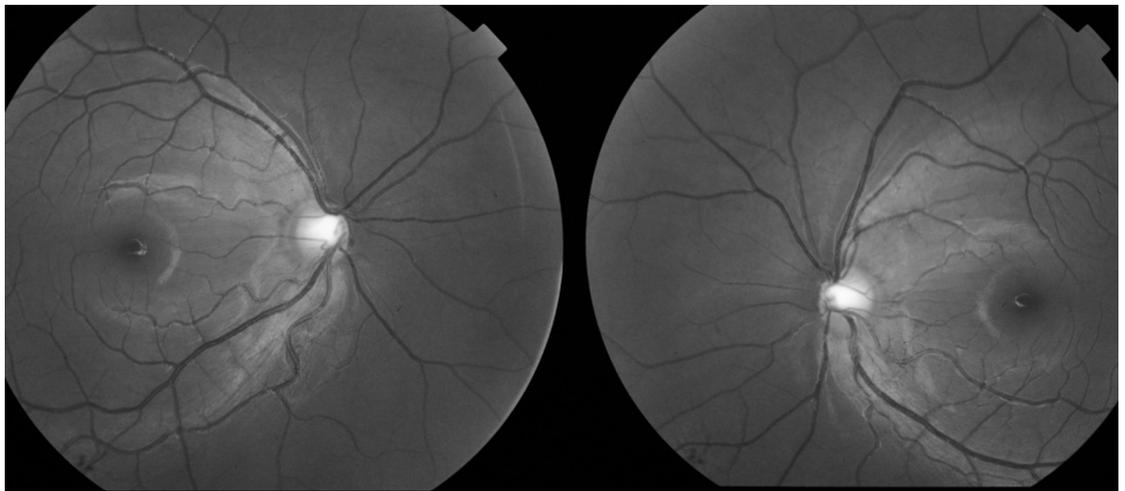
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MYSTERY IMAGE
BLINK



WHAT IS THIS MONTH'S MYSTERY CONDITION?

Visit aao.org/eyenet to make your diagnosis in the comments.

Anamika Dwivedi, MS, Shyam Shah Medical College, Rewa, Madhya Pradesh, India.

LAST MONTH'S BLINK

Asymmetric Papilledema With Vitreous Hemorrhage Caused by Cryptococcal Meningitis

A 48-year-old man with AIDS (CD4 lymphocyte count, 27 cells/mm³) presented with headache and fever. Lumbar puncture revealed an opening pressure of 35 cmH₂O and positive cryptococcal antigen in the cerebrospinal fluid. The patient reported mild blurring of vision in the right eye. Visual acuity was 20/40 in the right eye and 20/20 in the left, with no afferent pupillary defect. The right eye (Fig. 1) showed marked disc edema, intraretinal hemorrhage, preretinal hemorrhage, vitreous hemorrhage, macular edema, and hard exudates. The left eye (Fig. 2) had mild sectoral disc edema and a few flame-shaped hemorrhages. There was no evidence of infectious retinitis or endophthalmitis.



The patient was treated with IV amphotericin and fluconazole. On repeat lumbar puncture, the opening pressure was normal (13 cmH₂O). The disc edema and hemorrhage resolved, and the patient's visual acuity returned to 20/20 in both eyes.

WRITTEN BY TAHIRA SCHOLLE, MD, BAYLOR COLLEGE OF MEDICINE, HOUSTON. PHOTO BY DENISE SWARTZ THOMPSON, PARKLAND HOSPITAL, DALLAS.



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