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JULY 2019

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With a single injection at the end of cataract surgery, anti-inflammatory efficacy begins as early as day 1 and continues through day 30[1]*

- The percentage of patients who received DEXYCU (517 mcg) who had anterior chamber cell clearing on day 8 was 60% (n=94/156) vs 20% (n=16/80) in the placebo group[1]
- The cumulative percentage of subjects receiving rescue medication of ocular steroid or nonsteroidal anti-inflammatory drug (NSAID) at day 30 was significantly lower in the DEXYCU (517 mcg) treatment group (20%; n=31/156) compared to placebo (54%; n=43/80)[1]

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DEXYCU™

(dexamethasone intraocular suspension) 9%

*DEXYCU was studied in a randomized, double-masked, placebo-controlled trial. Patients received either DEXYCU or a vehicle administered by a physician at the end of the surgical procedure. The primary endpoint was the proportion of patients with anterior chamber cell clearing (cell score=0) on postoperative day 8.

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
- 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

Please see brief summary of full Prescribing Information on adjacent page.

References: 1. DEXYCU™ (dexamethasone intraocular suspension) 9% full U.S. Prescribing Information. EyePoint Pharmaceuticals, Inc. December 2018. **2.** Donnenfeld E, Holland E. Dexamethasone intracameral drug-delivery suspension for inflammation associated with cataract surgery: a randomized, placebo-controlled, phase III trial. *Ophthalmology.* 2018;125(6):799-806. **3.** Data on file. EyePoint Pharmaceuticals, Inc.

EyePoint™ PHARMACEUTICALS

480 Pleasant Street, Suite B300, Watertown, MA 02472

01/2019
US-DEX-1900045

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 Warning 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

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References
1. Alcon Data on File (Jul 2016). 2. AcrySof® IQ ReSTOR® +2.5 D Multifocal Toric IOL Directions for Use. 3. Vega F, Alba-Bueno F, Millán MS, Varon C, Gil MA, Buil JA. Halo and through-focus performance of four diffractive multifocal intraocular lenses. *Invest Ophthalmol Vis Sci*. 2015;56(6):3967-3975 (study conducted with corneal model eye with 0.28µ spherical aberration). 4. Wirtitsch MG, Findl O, Menapace R, et al. Effect of haptic design on change in axial lens position after cataract surgery. *J Cataract Refract Surg*. 2004;30(1):45-51 5. Visser N, Bauer NJ, Nuijts RM. Toric intraocular lenses: historical overview, patient selection, IOL calculation, surgical techniques, clinical outcomes, and complications. *J Cataract Refract Surg*. 2013;39(4):624-637. 6. Potvin R, Kramer BA, Hardten DR, Berdahl JP. Toric intraocular lens orientation and residual refractive astigmatism: an analysis. *Clin Ophthalmol*. 2016;10;1829-1836.

AcrySof® IQ ReSTOR® Family of Multifocal IOLs Important Product Information
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AcrySof® IQ ReSTOR® Toric IOL is intended to correct pre-existing astigmatism. The lenses are intended to be placed in the capsular bag. **WARNINGS/PRECAUTIONS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling for each IOL. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery. The ReSTOR® Toric IOL should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. A reduction in contrast sensitivity may occur in low light conditions. Visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. Spectacle independence rates vary; some patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO), when present, may develop earlier into clinically significant PCO with multifocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions. **ATTENTION:** Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

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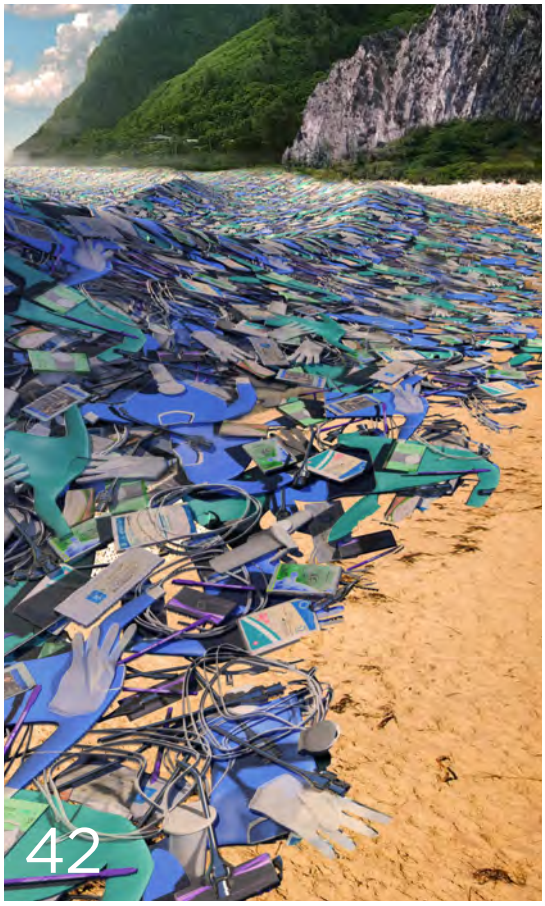

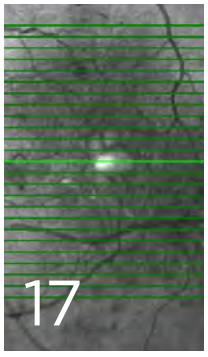

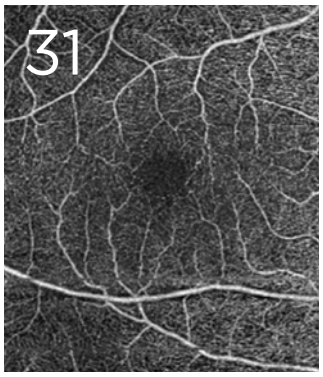

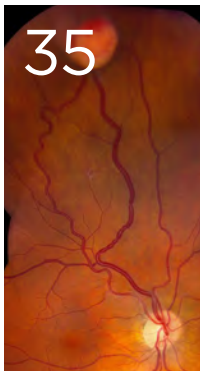

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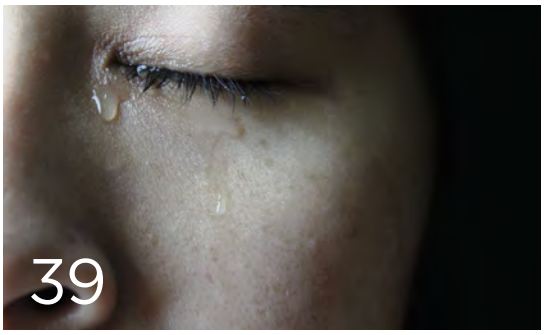

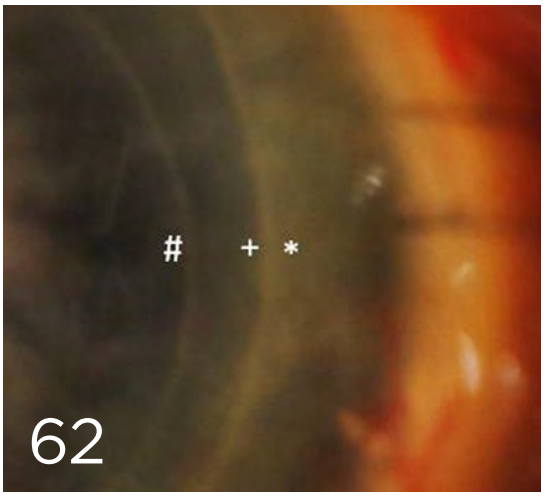

On the cover of the June 2019 *EyeNet*, "New Pupilloplasty Technique for Open-Angle Glaucoma" was incorrect. It should have read "New Pupilloplasty Technique for Angle-Closure Glaucoma." *EyeNet* regrets the error.

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Opinion

RUTH D. WILLIAMS, MD

You Have What It Takes

Three residents approached me after the L.E.A.P. Forward program, an annual leadership forum for ophthalmology residents that is held during the Mid-Year Forum in Washington, D.C. One of them asked, "Have you ever had Imposter Syndrome?"

The question gave me pause, and I've been thinking about it since. When I was a resident and a young ophthalmologist in clinical practice, very few things we experienced were described as a syndrome, and it was even less likely that we would talk about our feelings. It was work, after all. But thankfully, things have changed.

So, what is Imposter Syndrome? First described in 1978, Imposter Syndrome is a psychological pattern in which a person doubts his or her accomplishments and has an internalized fear of being discovered as a fraud.[1] Although it is commonly experienced by high-achieving women and minorities, most people—up to 70%—will experience it at some point in their careers, especially during times of stress, anxiety, or depression.

Kathryn Colby, MD, PhD, gave a talk on Imposter Syndrome at last year's Women in Ophthalmology clinical meeting, so I asked her about it. Kathy is an ophthalmology superstar. Among other accomplishments, she is chair of the Department of Ophthalmology at the University of Chicago and president-elect of the Cornea Society.

Kathy pointed out that moments of self-doubt are ubiquitous among successful people, and she acknowledged that she has dealt with them herself. For instance, last year, Kathy gave an invited talk on ocular surface tumors in children at the 2018 World Ophthalmology Congress. Looking out at the audience, she spotted four experts on the topic, several of whom she was referencing. Her inner voice said, "OMG, how can I be standing up here?" But her well-trained second reaction was to identify the thought as a manifestation of Imposter Syndrome. She chuckled internally and gave a terrific talk.

Her advice for dealing with these episodes: "The most important thing is to recognize these feelings when they arise." Then, she said, the thoughts can be redirected, thus allowing the person to visualize a successful outcome. Kathy pointed out that perfectionism is the enemy of professional development, while a growth mindset is its greatest friend. Acquiring new professional skills requires us to step outside of comfort zones. "One of the most important projects for professional (and personal) growth is coming to terms with one's imperfections and using failures as the fuel for learning and change," Kathy said. She cited the burgeoning body of work that supports the concept of neuroplasticity and suggested that ophthalmologists consciously work on rewriting their inner scripts.

When I think about this process, I remember a night when my husband and I had the kitchen table at Charlie Trotter's, a famous Chicago restaurant. Midway through our remarkable meal of complex and artistically prepared food, the room took on an electric feel when Charlie walked in. When he stopped by our table, I commented that he must be a perfectionist. He responded, "No, I'm an excellentist."

I think this is how to transcend Imposter Syndrome. My ophthalmology colleagues, we are excellentists. Each of us isn't perfect, isn't the only expert, and doesn't have all the answers. But we each have the courage to take on professional challenges, the ability to learn new skills, and the capacity to be leaders.

So, to the residents who asked about Imposter Syndrome: It's normal. It has a name, but it need not have any power. You're excellentists. You have what it takes.

Ruth D. Williams, MD
Chief Medical Editor, EyeNet

1 Clance PR, Imes SA. www.paulineroseclance.com/pdf/ip_high-achieving_women.pdf. Accessed April 30, 2019.

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Current Perspective

DAVID W. PARKE II, MD

How Much Is Not Enough? Part One

As we gear up for the 2020 elections, health care reform is considered the most or one of the most critical issues. In one poll, 88% of respondents said that lowering the cost of health care was "extremely important." And 92% in the same survey said that lowering drug costs was "extremely important." Of note, 53% reported that health care costs affect their household "a lot."

The biggest drivers for lowering costs—based on their percentage of the health care expenditure dollar and/or their rate of rise and/or their vulnerability—appear in most surveys to be drug costs, hospitals, and administrative overhead.

However, physician payment is considered by many economists and policymakers to be a legitimate target as well. Many hold to the aphorism that while physician (and other "provider") fees account for only about 20% of health care costs, they control much of the other 80% by ordering the laboratory tests and imaging, recommending the procedures, and dictating the site of service. (We all know that's not entirely true, but we'll leave it for another column.)

Within the physician community, payment is wielded as a blunt policy axe, approached on a zero-sum basis, shifting reimbursement from specialists to primary care physicians such that over the past decade most primary care physicians have seen Medicare payments increase 15%-20% while many specialty services have decreased by an even greater amount. Although I would argue that primary care has been historically underpaid, the zero-sum approach within aggregate physician payment fails the "fairness" test.

It is true that nearly all other developed countries pay physicians less than in the United States. One study noted that the mean purchasing power equivalent remuneration for both generalists and specialists was significantly higher in the United States. (The same was also true for other health care professionals and is true for many professions.)

At the same time, American physicians can make a very cogent argument that while aggregate compensation has increased in recent decades, it has not done so in real cost-of-living dollars. Data from the Medicare Trustees' Reports and U.S. Bureau of Labor Statistics reveal that between 2001 and 2017 Medicare inpatient hospital updates increased 50%, whereas physicians' increased only 6%. During the same period of time, the Medicare Economic Index (a rough equivalent for practice costs) increased 30%. On an inflation-adjusted basis, physician payments decreased 19% over those 18 years—and more for cost-heavy specialties (like ophthalmology). Surgical procedures have been repeatedly cut to benefit office visits. As an example, between 1992 and 2019, the work value for cataract surgery (CPT 66984) has decreased 18%—while the work value for a Level 4 established patient office visit (CPT 99214) has increased 61%.

In fact, an oft-quoted study targeted this disparity when it concluded that reduction of health care spending "should be primarily focused on addressing growth in hospital rather than physician prices."

David W. Parke II, MD
Academy CEO

Most of us know that our practices have economically weathered this situation by increasing patient volumes, finding business efficiencies, and developing other revenue sources. Ophthalmologists generally make comfortable incomes. But many recognize that the MACRA payment schedule calls for 0% fee updates between 2020 and 2025—even as physician practice costs will continue to escalate.

At what point does this become unsustainable? Are we there already? And what will happen when it does? Does patient access to unique ophthalmic services worsen? Does it stress professional behavior? Does it impact the very existence of small practices? Tragically, the patient will also pay the price.

In my next column I'll address where this may lead us, what you can do, and how the Academy and other organizations can potentially impact the course of future events.

SOURCES:
Blendon RJ et al. *N Engl J Med.* 2019:DOI:10.1056/NEJM p1905710.
Cooper Z et al. *Health Affairs.* 2019;38:184-189.
Papanicolas I et al. *JAMA.* 2018;319:1024-1039.

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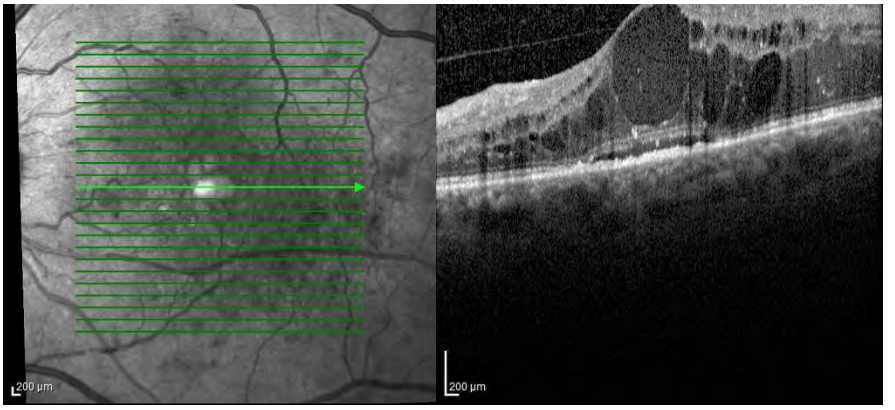
News in Review

COMMENTARY AND PERSPECTIVE



WATCHFUL WAITING? *This patient's DME (shown here at initial presentation) was treated with an anti-VEGF injection. Observation without treatment may be appropriate for selected eyes, results of Protocol V indicate.*

COMPREHENSIVE

Careful Observation Preserves VA in Certain DME Eyes

UNLESS VISION BEGINS DETERIORATING, observation without treatment appears to be a safe and effective management strategy in patients with center-involved diabetic macular edema (CI-DME) and good baseline visual acuity (VA), a landmark study by the Diabetic Retinopathy Clinical Research network has concluded.[1]

Protocol V. The prospective, randomized clinical trial, called Protocol V, compared visual outcomes in 702 eyes with CI-DME that were managed initially with aflibercept (Eylea), laser photocoagulation, or observation. All study subjects began the trial with VA of at least 20/25, and aflibercept treatment was initiated in the observation eyes (and in the laser-treated group) if vision worsened during follow-up.

After two years, there was no significant difference in final mean VA among the three groups, the researchers reported. The percentage of eyes with at least a 5-letter VA decrease compared to baseline was 16% (33/205), 17% (36/212), and 19% (39/208) in the aflibercept, laser, and observation groups, respectively.

Furthermore, two-thirds of the observation eyes and three-quarters of the laser-treated eyes never required any intravitreal injections during the two-year period, said Carl W. Baker, MD, the research network's Protocol V chair.

Support for watchful waiting. The evidence that a large subset of DME patients can be managed successfully with watchful waiting is important, because approximately 40% of DME eyes presenting to ophthalmologists have vision of 20/25 or better, said Dr. Baker, a vitreoretinal specialist who practices in Paducah, Kentucky.

"Vitreoretinal specialists see a lot of DME patients like these, but until this point we haven't really known the best way to treat them," he said. "Our study demonstrated that with these patients you could wait until vision drops and, with careful observation, you end up with the same chance for good results after two years."

Areas of concern. In clinical practice, following the study's findings could pose issues of compliance, Dr. Baker said, because patients under observation must unfailingly return for frequent examinations every eight to 16 weeks. "We don't know how the issues of compliance might affect outcomes in these three different groups," he noted.

Concerns also have been raised that the Protocol V findings could negatively impact decisions about reimbursement for intravitreal injections, Dr. Baker said. "It's important for us to sit down with clinicians inside and outside our research network and discuss the implications of these results" as they relate to working with third-party payers, he said. "We certainly would not want this to limit the availability of treatment options for our patients."

Dr. Baker said the results support a more personalized approach to interventions for DME. "This is another point we are going to make with the payers: that these strategies were shown to be successful but that we used the individual patient's progress or loss of vision to determine whether they were going to get the injectable medicine. Each individual DME patient had different needs that had to be met," he said.

Next steps. The Protocol V researchers, who practice at 91 sites in the United States and Canada, plan to conduct further analyses of study data to try to better define factors affecting DME progression. They also will look for biomarkers that might be used to identify patients most at risk, Dr. Baker said. —*Linda Roach*

1 Baker CW et al., for the DRCR Retina Network. *JAMA*. Published online April 29, 2019.
Relevant financial disclosures—Dr. Baker: Alcon: S; Genentech: S; Novartis: S; Regeneron: S.

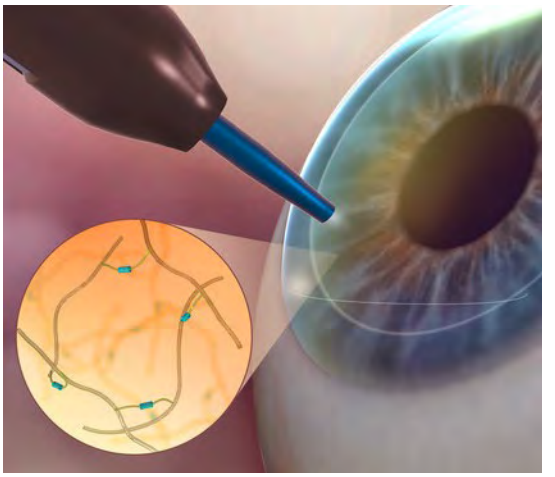
EXTRA **MORE ONLINE.** For more on Protocol V, listen at aao.org/audio/episode-168-drcr-net-protocol-v-study-results-real. The two-part episode covers study design, results, and real-world implications.

CORNEA

Novel Bioadhesive Gel for Corneal Repair

A TEAM OF RESEARCHERS HAS described a simple treatment for the repair of corneal wounds that involves nothing more than a tube of adhesive and visible light.[1] In animal models, GelCore (for "gel for corneal regeneration"), a transparent bioadhesive gel that is still in development, sealed the eyeball and filled structural defects in the cornea for long periods of time without sutures, grafts, or bandage contact lenses.

"GelCore provides an alternative to current standard treatment options," said Nasim Annabi, PhD, at the University of California, Los Angeles. "It is designed to be applied easily, without the need for an operating theater, surgical skills, or even surgery rooms." She singled out its potential on battlefields, where ocular injuries account for over 10% of injuries sustained by soldiers in combat.



NO SUTURES. *The biopolymer solution is injected into the corneal defect and exposed to visible light, forming the hydrogel.*

Gelatin plus light. GelCore is a naturally derived biopolymer with characteristics similar to the native cornea. It is made from chemically modified

CATARACT

Preoperative Astigmatism Planning: High-Tech Isn't Necessarily Better

A STUDY EVALUATING OUTCOMES AFTER ASTIGMATISM correction found that an image-guided system and intraoperative aberrometer, when used together, yielded outcomes that were not significantly better than the surgeon's standard of care.[1]

The findings, however, are dependent on the surgeon's use of "modern and advanced formulas with accurate preoperative measurements and detailed attention to all aspects of the preoperative evaluation," said Kerry D. Solomon, MD, a cataract specialist in Mount Pleasant, South Carolina.

Study design. This prospective case series involved patients who were having uncomplicated bilateral cataract extraction or refractive lens exchange with IOL implantation and astigmatism correction. Dr. Solomon performed all of the surgeries.

The patients served as their own controls, and their eyes were randomly assigned to two groups: 1) Group A eyes received Dr. Solomon's standard of care. He used Lenstar LS 900 (Haag-Streit) keratotomy and calculator/nomogram to determine toric power and orientation of astigmatic incisions. 2) For eyes in Group B, Dr. Solomon used the Verion image-guided system (Alcon) to preoperatively determine the placement of the toric IOL or incision. He also used the Optiwave Refractive Analysis system with VerifEye+ (Alcon) for intraoperative aberrometry calculations.

Results. All told, 38 eyes received toric IOLs, and 40 eyes received manual limbal-relaxing incisions. No significant differences in outcomes between the two groups were noted. Other results were as follows:

- On average, toric IOLs resulted in approximately 0.25 D less cylinder than corneal astigmatic incisions. This was consistent with a large meta-analysis reporting lower residual astigmatism with toric IOLs than with relaxing limbal incisions.[2]
- At three months, the IOL in four eyes (11%; two in each group) was more than 10 degrees of absolute orientation from the intended orientation. No eye with a toric IOL had a secondary surgical intervention to reorient the IOL.
- The reduction in residual astigmatism did not improve other clinical outcomes, such as uncorrected and corrected distance visual acuity.

What if? Might the results differ in the hands of other surgeons? "We don't know for sure if—or how—having a different or less experienced surgeon would have affected the results," Dr. Solomon said. "But we believe that using older formulas and not following our standard procedures could affect the results."

—Miriam Karmel

1 Solomon KD et al. *J Cataract Refract Surg.* 2019;45(5):569-575.
2 Kessel L et al. *Ophthalmology*. 2016;123(2):275-286.
Relevant financial disclosures—Dr. Solomon: Alcon: C,S.

Masoud Moosavi Basri

porcine gelatin mixed with light-activated compounds. After application to the wound and brief exposure to a visible light cross-linking system, GelCore solidifies and firmly adheres to the corneal tissue, sealing the defect without sutures. To overcome biosafety concerns, the light intensity used in the cross-linking system is well below the maximum exposure limit, the researchers said.

Early results. Tests in rabbit eyes indicated that GelCore effectively sealed corneal defects and also promoted re-epithelization. In tests of wound closure strength, shear resistance, and burst pressure, GelCore performed significantly better than existing adhesives, which lack both high adhesion to wet corneal tissue and long-term retention.

"The glues in current use are associated with low biocompatibility, low adhesion, and poor transparency, and they are undesirably rough and difficult to handle," said Dr. Annabi. "Our biomaterial has shown prolonged retention even when filling in large corneal tissue defects. And it could regenerate the damaged corneal tissue."

Potential uses. GelCore is designed mainly for corneal deep scars, but the researchers are working on different formulations for uses ranging from large lacerations and corneal scars to infection and inflammation.

Dr. Annabi noted that its physical and chemical properties can be fine-tuned for use not only in the cornea but also elsewhere in the body, including the lungs, skin, and heart. Moreover, she said, the gel can be used as a platform for delivering antimicrobial agents or drugs to a targeted site to foster wound healing and prevent infection.

Years to market. Since testing in human patients has not yet begun, it could take five to six years to reach the market, Dr. Annabi said.

—Miriam Karmel

1 Sani ES et al. *Sci. Adv.* Published online March 20, 2019.

Relevant financial disclosures—Dr. Annabi: NIH: S; UCLA: S; U.S. Department of Defense: S.

RETINA

Simple Fixes Improve Retinal Detachment Outcomes

Two simple changes in office routines can significantly reduce the incidence of keratopathy after complex retinal detachment (RD) surgery with pars plana vitrectomy and silicone oil tamponade, a study at the University of California, San Francisco (UCSF) has found.[1]

The changes involved:

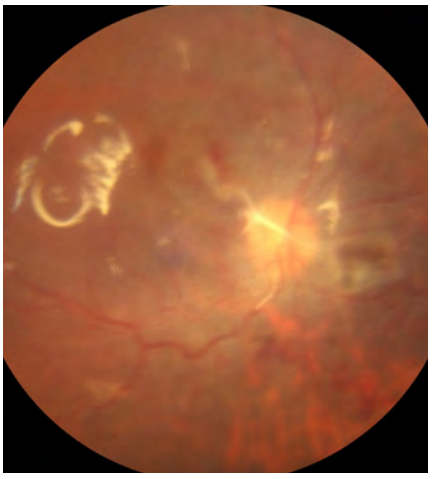
- keeping a registry of patients who received silicone oil, and
- calling to remind them to return for follow-up appointments.

After UCSF vitreoretinal surgeons adopted these procedures, the proportion of patients with complex RD who developed keratopathy fell from 33.3% to 12.8%. "We were surprised that it was so simple to achieve such a difference," said coauthor Jay M. Stewart, MD, at UCSF and Zuckerberg San Francisco General Hospital.

Instigation. Dr. Stewart said the vitreoretinal division in the hospital's ophthalmology department implemented this registry and reminder system in 2014, after physicians and staff noticed that patients were experiencing complications in the months after complex RD surgery.

These adverse outcomes appeared to be related to a lack of follow-up and the duration of the silicone oil in their eyes, Dr. Stewart said. "We encountered complications that could have been avoided if the oil had been removed sooner."

Improved outcomes. After early indications that the reminders were working, the practice did a retrospective records review to compare outcomes in 48 eyes treated before the system was in place (control group), and 39 eyes treated afterward. The review showed statistically significant reductions not only in keratopathy cases but also in two other key areas:



TAMPONADE. *Silicone oil was used in this patient with an RD (note retinal surface reflex). A lengthy period of tamponade has been shown to be the greatest risk factor for silicone oil emulsification, which can lead to keratopathy, glaucoma, and cataracts.*

- The number of patients lost to follow-up was 23 (47.9%) in the control group, versus six (15.4%) in the treatment group ($p = 0.0015$).
- The mean duration before silicone oil removal was 79.6 ± 91.7 weeks (mean ± standard deviation) in the control group and 36.3 ± 31.5 weeks in the treatment group ($p = 0.015$).

With regard to other outcomes, intraocular pressure measurements did not vary significantly between the two groups. Finally, cataract formation was not analyzed as an outcome measure in this study.

Standard practice. Dr. Stewart said the registry and reminder system is now standard practice in the hospital's clinic. "If patients don't show up, then they start getting chased down by the staff" until they do return, he said. "Establishing a line of communication directly between the clinic and the patient gets it back on their radar. It reinforces to them that we consider the appointment to be important—and that there's value in keeping it." *—Linda Roach*

1 Ma D et al. *Ophthalmol Retina.* 2019;3(7):543-547.

Relevant financial disclosures—Dr. Stewart: None.

See the financial disclosure key, page 10. **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

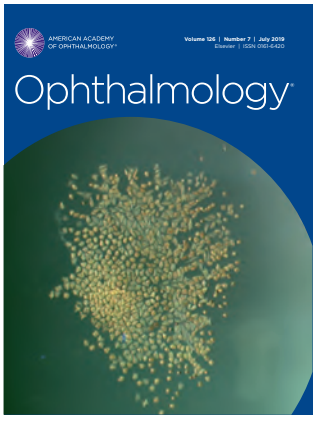
Physical Activity Slows VF Loss in Patients With Glaucoma

July 2019

Growing evidence suggests that physical activity may protect against visual field (VF) damage. **Lee et al.** looked at the relationship between glaucoma-related VF loss and various levels of physical activity. They found that greater physical activity correlated with slower loss of vision.

This longitudinal observation study included 141 adults (mean age, 65 years) with confirmed or suspected glaucoma. Participants wore an accelerometer for one week to determine steps per day and the time spent being active. To measure the rates of VF loss, the authors analyzed all available VF data. The main outcome measure was the pointwise change in VF sensitivity associated with the various measures of physical activity.

Among the study group, eye mean deviation (MD) at the time of assessment was -6.6 dB, and the average number of steps per day was 5,613 ± 3,158. The unadjusted average rate of VF loss, measured by pointwise VF sensitivity, was 0.36 dB per year. Multivariable models showed slower VF loss for patients who took more steps (+0.007 dB/year/1,000 daily steps; $p < .001$), who had a higher level of moderate-to-vigorous activity (+0.003 dB/year/10 more minutes of moderate-to-vigorous activity per day; $p < .001$), and who engaged in more nonsedentary activity (+0.007 dB/year/30 more minutes of nonsedentary time per day; $p = .005$). Factors linked to quicker VF loss included older age, nonwhite race, history of glaucoma surgery or cataract surgery, and moderate VF damage at baseline. Similar relationships between baseline accelerometer-measured physical activity and rates of VF loss were noted for extended time periods (i.e., within one, three, and five years of the activity assessment).



This study showed that taking an extra 5,000 steps per day (2.6 hours of nonsedentary physical activity) decreased the average rate of VF loss by about 10%. Further research is needed to confirm this association. If proven true, it would mean that physical activity is a novel modifiable risk factor for preventing glaucoma-related ocular damage.

EHR Use and Incentives Among Ophthalmologists: 2011-2016

July 2019

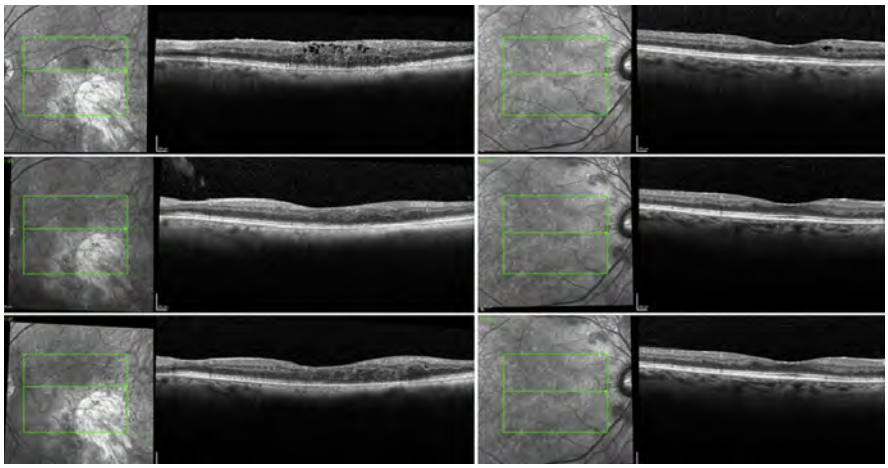
Boland et al. studied ophthalmologists' rate of meaningful use of electronic health records (EHR) in the Medicare Incentive Program, as well as the compensation received. The authors compared these data with those of four other Medicare-billing specialties and found that ophthalmology had better results than optometry and dermatology but was outperformed by otolaryngology and urology. In addition, ophthalmologists were more likely to stay in the program after their first year of attestation than were all eligible providers from four other selected specialties.

The study included providers who participated in the Medicare EHR Incentive Program during program years 2011 through 2016. Publicly available sources were consulted to determine attestation and payment data, which were gathered for ophthalmology, optometry, dermatology, otolaryngology, and urology. Attestation data for each year and stage of the program were used to determine the number of participating professionals. Also calculated was the proportion of attestations for each EHR vendor. Outcomes of interest were the number of attesting ophthalmologists (by year and stage of the program), the number of attestations per EHR vendor, and the amount of incentive payments. Data were compared for the various specialties.

The authors found that, in the peak year of participation for each specialty, 51.6% of ophthalmologists attested to meaningful use of EHR systems (2016),

versus 37.1% of optometrists (2013), 50.2% of dermatologists (2016), 54.5% of otolaryngologists (2013), and 64.4% of urologists (2016). During the six-year period, the average incentive payments were $17,942 for ophthalmologists, $11,105 for optometrists, $16,617 for dermatologists, $20,203 for otolaryngologists, and $23,821 for urologists. The EHR systems used most often by ophthalmologists were Epic and NextGen.

Even though ophthalmology fared relatively well in meaningful EHR use, many ophthalmologists have not participated in the incentive program or stopped participating; 2015 data indicated that 25% were not engaged in the program. Top reasons for nonparticipation by ophthalmologists were high costs and complex reporting.



COMPARISON. *A patient in the treat-and-extend arm (left) and the fixed-schedule arm (right), during the initial visit (top), the fifth visit (center), and the final visit (bottom). Adapted from* Ophthalmology Retina.

Systemic Safety Profile of Anti-VEGF Therapy for DME

July 2019

Although intravitreal anti-VEGF therapy is the standard of care for diabetic macular edema (DME), the systemic safety of this treatment has not been established. **Maloney et al.** used a large claims database to ascertain the risk of serious systemic events among patients with DME who received intravitreal injections of anti-VEGF drugs. Their analysis showed that, compared with patients treated by corticosteroids or macular laser, those who received intravitreal injections did not have a higher risk of cerebrovascular disease, myocardial infarction, or major bleeding.

For this retrospective cohort study, the researchers included adults treated with intravitreal anti-VEGF therapy from 2006 to 2015. Patients were identified from a large U.S. insurance database. Eligible participants had private insurance or were members of a Medicare Advantage plan; all had medical coverage for at least one year before starting DME treatment. Using the same database, the authors also identified patients who were treated with macular laser or intravitreal corticosteroids; these patients served as controls.

Main outcome measures were associations between the treatments and predefined systemic outcomes, using Cox proportional hazards regression, and they included the risk of cerebrovascular disease, myocardial infarction (MI), major bleeding, and all-cause hospitalization occurring within six months of initial DME treatment.

For the comparison between anti-VEGF and macular laser therapy, inverse propensity score weighting was used to account for treatment selection bias. Because relatively few patients received corticosteroids, the comparison with anti-VEGF treatment required 2:1 propensity score matching for demographics, study year, and baseline comorbidities. Results were expressed as hazard ratios (HRs) and 95% confidence intervals (CIs).

Altogether, 23,348 patients met the inclusion criteria. Of these, 13,365 were initially treated with macular laser, 9,219 with anti-VEGF therapy, and 764 with intravitreal corticosteroids. The analysis showed no link between anti-VEGF therapy and elevated risk of cerebrovascular disease (HR, 0.96; CI, 0.65-1.41; p = .83), major bleeding (HR, 1.23; CI, 0.76-1.99; p = .41), or MI (HR, 1.03; CI, 0.73-1.44; p = .88), as compared to macular laser treatment. Rates of primary systemic serious event were similar for anti-VEGF and corticosteroid treatment (all p > .05). The risk of all-cause hospital admission after treatment was higher with anti-VEGF therapy than with macular laser (HR, 1.17; CI, 1.05-1.30; p = .01). This finding may warrant further study.

—Summaries by Lynda Seminara

Ophthalmology Retina

Selected by Andrew P. Schachat, MD

Aflibercept Effective for Radiation Maculopathy

July 2019

Murray et al. set out to evaluate whether intravitreal aflibercept could help maintain vision in patients who received radiation for uveal melanoma. They found that the anti-VEGF treatment appears to limit vision loss associated with radiation maculopathy.

For this prospective study, the researchers enrolled 40 patients with uveal melanoma and documented tumor control. All patients had visually compromising radiation maculopathy, which was documented by spectral-domain optical coherence tomography (SD-OCT) and confirmed by a decline in best-corrected visual acuity (BCVA).

The patients were randomly assigned to receive injections of aflibercept 2.0 mg/0.05 mL either on a fixed six-week schedule or under a treat-and-extend protocol. For those in the treat-and-extend arm, improvement in maculopathy, as seen on SD-OCT, allowed for a one-week increase in the follow-up interval; conversely, a worsening in maculopathy mandated a one-week decrease. Main outcome measures were

BCVA and SD-OCT measurements of central retinal thickness.

Thirty-nine of the 40 patients completed the study with 60 weeks of follow-up. Mean BCVA at baseline was 20/63; this was maintained at 20/62 at the study's conclusion. Mean SD-OCT central retinal thickness was 423 µm at baseline; this improved to 294 µm at 60 weeks.

Visual acuity improved by 3 or more lines in five patients, decreased by 3 or more lines in six patients, and held stable in the remainder. One patient experienced a single episode of an inflammatory response after receiving an intravitreal injection. No other adverse side effects were noted.

With regard to the two treatment approaches, the authors noted that they initially hoped that the treat-and-extend arm would allow for fewer intravitreal injections during the course of the study. However, this did not prove to be the case, as virtually all patients required treatment every six weeks.

—Summary by Jean Shaw

American Journal of Ophthalmology

Selected by Richard K. Parrish II, MD

Use of Confocal Microscopy to Diagnose Corneal Graft Rejection

July 2019

Chirapapaisan et al. investigated whether laser in vivo confocal microscopy can help support the diagnosis of corneal graft rejection. They found that it could, as immune cell density was significantly higher in rejected grafts than in those that were not rejected.

For this prospective case-control study, the researchers enrolled 38 patients who had undergone penetrating keratoplasty (15 with graft rejection; 23 without) and nine age-matched healthy controls. Full-thickness confocal microscopy scans were performed in the central cornea of all eyes with grafts and in one eye of each of the nine control subjects. In addition, multiple scans were taken of the epithelial, sub-basal, stromal, and endothelial layers, and five representative images of each layer were selected for analysis of immune cell density by a masked observer. The main outcome was the immune cell density in the corneal layers and its associations with any clinical signs and symptoms of graft rejection.

Significant differences in immune cell densities were found among normal control patients, nonrejected grafts, and rejected grafts: Total immune cell density was 48.60 ± 10.67 cells/mm^2 in controls, 187.70 ± 22.80 cells/mm^2 in nonrejected grafts, and 285.32 ± 53.23 cells/mm^2 in rejected grafts. When immune cell densities were compared layer by layer, higher densities were seen only in the sub-basal and endothelial layers of the rejected grafts than in the nonrejected ones.

With regard to clinical signs and symptoms of graft rejection, all of the 15 patients who had experienced graft rejection experienced decreased vision, 10 had ocular irritation, nine complained of light sensitivity, and seven reported ocular pain. Those with pain, ocular irritation, and light sensitivity were more likely to have increased immune cell density in the sub-basal layer, and those with pain were also more likely to have a higher density in the epithelial layer.

In addition, all patients with rejected grafts had one or more typical clinical signs of rejection, with specific signs associated with increased density in particular corneal layers. Patients with anterior chamber cells and the Khodadoust line were more likely to have elevated immune cell density in every corneal layer.

The results suggest that confocal microscopy may be useful as an adjunct tool for diagnosing corneal graft rejection during the early stages of immunologic reaction, particularly in questionable or subtle cases, the authors said.

Timolol and Aqueous Humor Outflow in Healthy Eyes

June 2019

Kazemi et al. assessed the effect of timolol on outflow facility in healthy human eyes. They found that the drug reduces outflow facility—and that this effect is greater in eyes with higher outflow facility at baseline.

For this prospective study, the researchers evaluated 113 participants who were 40 to 81 years old. At baseline, intraocular pressure (IOP) was measured in both eyes of each participant in both a sitting and supine position. Outflow facility was measured while participants were in a supine position. The participants were instructed to instill timolol 0.5%, one drop every 12 hours in both eyes, for one week. At that point, IOP and outflow facility measurements were repeated.

The mean IOP at baseline was 15.1 ± 3.0 mm Hg; this decreased to 12.4 ± 2.4 mm Hg after one week of timolol. Mean outflow facility at baseline was 0.23 ± 0.08 µL/min per mm Hg; this decreased to 0.18 ± 0.08 µL/min per mm Hg after the treatment week. In addition, higher baseline outflow facility was associated with greater decrease in outflow facility after timolol treatment.

This reduction in outflow facility may partially negate the overall IOP-lowering effect of timolol, the authors noted. Although the precise mechanism behind this phenomenon remains to be determined, one possible explanation may involve the blockade of beta-receptors in the trabecular outflow pathway. Alternatively, compensatory physiologic changes may be involved.

—Summaries by Jean Shaw

JAMA Ophthalmology

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

Impact of Vision Loss on Hospitalization Costs

June 2019

Patients with vision loss who are hospitalized for common illnesses may not be identified as needing special attention for their vision deficits. **Morse et al.** compared health care utilization for older adults with and without vision loss who were hospitalized for similar conditions. They found that those with severe visual impairment had longer hospital stays, higher readmission rates, and greater costs during and after hospitalization.

For this study, the authors looked at claims data from Medicare and the Clinformatics Data Mart. Individuals with vision loss were matched (1:1) to those with no visual impairment based on age, years since initial hospitalization, and other demographics. All patients were members of Medicare or a commercial health plan, and all had been hospitalized for a common illness such as congestive heart failure, major joint replacement, or pneumonia. Vision loss was categorized as either partial or severe. ICD-9-CM billing codes (369.xx) were used to classify those patients with severe vision loss (≥1 record of codes 369.0x to 369.4x), partial vision loss (≥1 record of 369.6x to 369.9x and no SVL code), or no vision loss (no record of any 369.xx code).

Main outcomes were lengths of stay, readmission rates, and hospital costs (during hospitalization and within 90 days after discharge). Multivariable logistic and linear-regression models were used to identify factors associated with these outcomes in each study arm. Data were analyzed for 2015 to 2018.

There were 6,165 Medicare beneficiaries with no vision loss (mean age, 82.0 years), 3,401 with partial vision loss (mean age, 80.4 years), and 2,764 with severe vision loss (mean age, 83.9). In the Clinformatics database, the number of patients in those categories were 5,929 individuals (mean age, 73.7 years), 3,515 (mean age, 71.8), and 2,414 (mean age, 76.6), respectively.

Hospital stays were longer, readmission rates were higher, and hospitalization costs (through 90 days following discharge) were greater for Medicare members with severe vision loss versus those with no visual impairment (mean stay, 6.48 vs. 5.26 days; mean readmission rate, 23.1% vs. 18.7%; mean costs, $64,711 vs. $61,060).

In addition, those with severe vision loss stayed 4% longer in the hospital (estimated ratio, 1.04; $p = .02$), had 22% higher readmission rates (odds ratio, 1.22; $p = .007$), and incurred 12% higher costs (estimated cost ratio, 1.12; $p < .001$). Results were similar for patients with commercial health plans.

In extrapolating their findings to nationwide hospitalization, the authors estimated that the additional cost of caring for patients with vision loss exceeds $500 million annually. In addition, they noted that addressing the vision deficits of hospitalized patients could result in substantial cost savings and better health outcomes. *(Also see related commentary by David W. Parke II, MD, and Anne L. Coleman, MD, PhD, in the same issue.)*

Advantages of the DUCK Scoring System for Determining Keratoconus Progression

June 2019

Defining keratoconus progression is crucial for treatment decisions, but consensus is lacking as to which parameters are best suited for this purpose. **Wisse et al.** compared two methods for determining keratoconus progression and found that the Dutch Crosslinking for Keratoconus (DUCK) score was superior to conventional methodology (e.g., change in maximum keratometry).

The comparative prospective study was conducted at two academic treatment centers (one for discovery and the other for validation). The discovery and validation cohorts were comparable with respect to demographics and maximum keratometry. Eligible patients had keratoconus and were referred from January 2010 through June 2014. The study goal was to assess whether the DUCK scoring system could identify patients who require corneal cross-linking (CXL).

The DUCK system includes five parameters that are assessed routinely: age, visual acuity, refraction error, keratometry, and the patient's subjective experience. Each item is scored on a three-point scale (0-2). For instance, patient-reported quality of vision is scored as 0 (no complaints), 1 (complaints mildly affecting quality of life), or 2 (complaints severely affecting quality of life). The overall DUCK score range is 0 to 10 points, with 10 indicating the highest rate of disease progression. In addition, a score ≥6 indicates the need for CXL.

The authors compared DUCK scoring with the conventional criterion of 1.0-D increase in maximum keratometry during the preceding 12 months and conducted sensitivity analyses. Main outcomes were the overall rate of treatment reduction and the rate of duly withheld treatment.

Among the 504 eyes (388 patients) that qualified for analysis, the DUCK score proved superior to maximum keratometry for recognizing progressive keratoconus. The overall treatment rate was reduced by 23% without increasing the risk of disease progression. The DUCK score also was more sensitive in identifying eyes for which treatment was correctly withheld.

Improving patient selection for CXL would avoid unnecessary treatment risks for patients who don't require this procedure, the authors said.

Accuracy of the WebMD Symptom Checker for Ophthalmic Diagnoses

June 2019

As the accessibility of internet-based resources continues to grow, more patients are conducting self-guided research of symptoms, making it important to determine the accuracy of online symptom checkers. In a cross-sectional study using validated ophthalmic clinical vignettes, **Shen et al.** looked at the accuracy of the popular WebMD symptom checker. They found that the primary diagnosis generated by the symptom checker was correct for only 26% of the clinical scenarios. Moreover, the correct diagnosis was not on the list of possibilities for nearly half of the vignettes.

This cross-sectional descriptive study involved generating 42 validated clinical vignettes of ophthalmic symptoms and distilling them to their core presenting signs. The "cases" were entered into the WebMD symptom checker by two people who were masked to the diagnoses (one of whom was medically trained).

Output from the symptom checker was documented, including triage urgency and the list of diagnoses ranked from most to least likely. The main outcome was diagnostic accuracy of the symptom checker.

The mean number of symptoms entered for each case was 3.6 (range, 1-8). The median number of generated diagnoses per case was 26.8 (range, 1-99). The checker's primary diagnosis was correct for only 11 (26%) of the 42 vignettes. The correct diagnosis was among the top three entries in 16 (38%) of cases. However, for 18 cases (43%), the correct diagnosis was not on the list.

The triage urgency for the top-listed diagnosis was appropriate in seven (39%) of 18 emergency cases and in 21 (88%) of 24 nonurgent cases. Inter-user variability for the correct diagnosis being among the top three was at least moderate.

The clinical vignettes generally were devoid of comorbid and distractor symptoms, which may indicate that the checker's accuracy was overestimated. However, the vignettes devised for this study resemble those used for training physicians in pattern recognition.

The authors emphasized that although the WebMD symptom checker may pinpoint an ophthalmic diagnosis, its overall accuracy is low. As a result, patients should exercise caution when using such online resources and should understand that symptom-checker output "is not a substitute for professional medical advice, diagnosis, or treatment," as stated on the main page of the WebMD tool.

After this study was completed, the WebMD interface and output scheme were revised. *(Also see related commentary by Rahul N. Khurana, MD, in the same issue.)*

—Summaries by Lynda Seminara

Other Journals

Selected by Deepak P. Edward, MD

Vision Screening of Disadvantaged Children

Journal of AAPOS
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Barugel et al. compared the specificity and sensitivity of the Spot Vision Screener, a handheld automatic photoscreener, with gold standard cycloplegic measurements in a population of underprivileged children and teenagers with limited access to medical care. They found that although the handheld screener detected most refractive errors, it fell short in accurately identifying cases of hyperopia.

For this study, 41 children 4 years and older with poor access to medical care were recruited by social workers and referred to a single hospital in Paris for refractive error screening during a full-day dedicated session. The children had a mean age of 126 months (range, 48-246 months).

The same orthoptist performed noncycloplegic refraction measurements using the Spot Vision Screener in all patients. In the absence of contraindications, cycloplegic autorefraction using the Retinomax K-Plus 3 autorefractometer (Righton) was performed and independently evaluated by an ophthalmologist. Slit-lamp and fundus examinations were performed in all cases. Glasses were prescribed as necessary.

The sensitivity of the Spot Vision Screener to detect myopia was high (>80%), at 84.61%. However, its sensitivity for the detection of hyperopia, astigmatism, and anisometropia was lower (<80%), at 27.27%, 78.57%, and 66.67%, respectively. The specificity for hyperopia, myopia, astigmatism, and anisometropia was high, at 100%, 98.55%, 89.71%, and 94.29%, respectively. The referral rate was 39.02%.

The Spot Vision Screener's low sensitivity with regard to hyperopia seems to remain a limitation of the device, the researchers said, and they recommended cycloplegic refraction be considered in public health initiatives. Even with this limitation, they noted that the study offered a real-world example of a dedicated day of screening in disadvantaged children.

Retinal Emergencies: Ultrasonography in the ER

JAMA Network Open
2019;2(4):e192162

Lahham et al. set out to determine whether ocular point-of-care ultrasonography (POCUS) could be effectively used to screen ER patients for retinal detachment, vitreous hemorrhage, and vitreous detachment. They found that emergency medicine practitioners can use POCUS to accurately detect these three conditions, thus allowing ER staff to confer needed information to the ophthalmologist.

This prospective study was conducted at four ERs in Southern California (two academic and two county hospital locations). All four sites support an emergency medicine residency, ophthalmology residency, and emergency ultrasonography fellowship.

The researchers enrolled 225 patients age 18 years and older who presented to the ER with symptoms suggestive of retinal detachment (RD), vitreous hemorrhage (VH), or vitreous detachment (VD).

Chief concerns included blurry vision, flashers and floaters, and vision loss. Patients who had ocular trauma or a suspected globe rupture were excluded from the study.

A total of 75 ER personnel (20 emergency medicine attendings, 50 emergency medicine residents, and five supervised physician assistants) evaluated the patients with POCUS. This was performed before the patients' ophthalmic consultations, and the ophthalmologists who examined the patients were masked as to the POCUS results.

All told, as diagnosed by an ophthalmologist, 47 of the patients (20.8%) had an RD, 54 (24%) had a VH, and 34 (15.1%) had a VD. The ER staff correctly identified RDs in 46 of the 47 patients, for a sensitivity of 96.9%. With regard to VH, they identified 46 of the 54 cases, for a sensitivity of 81.9%. Finally, the ER practitioners identified 19 of the 34 cases of VDs, for a sensitivity of 42.5%. Specificity results were as follows: 88.1% for RD, 82.3% for VH, and 96% for VD.

These results suggest that POCUS may be an effective adjunct technology in the ER, helping ER staff detect ophthalmic emergencies and provide needed information to ophthalmologists. In particular, the researchers noted, POCUS may be of particular benefit to ERs in areas where around-the-clock ophthalmologic consultation is not available.

—Summaries by Jean Shaw

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Current Questions in Dry Eye Therapy

Managing dry eye disease (DED) can be a challenge, and treatment is an inexact science, even in light of the well-vetted DEWS II treatment recommendations. In addition, consider how rapidly the field of dry eye is evolving—the surprising DREAM study results came out last year, and new therapeutics are hitting the market at a brisk pace. As ophthalmologists question how to integrate new developments, drugs, and devices into practice, some insights from dry eye experts may be helpful.

Why Is DREAM Important?

In May 2018, much-anticipated study results from the Dry Eye Assessment and Management (DREAM) Study Research group showed that there was no benefit of omega-3 over placebo in treating either signs or symptoms of DED.[1] "I was blown out of the water to see that the results were not even a little bit positive for omega-3, since prior studies did show some benefit," said Giacomina Massaro-Giordano, MD, at the University of Pennsylvania in Philadelphia—one of the dry eye specialists involved in the study.

What sets the DREAM study apart. DREAM was the largest study of omega-3 supplementation for DED worldwide and used the highest dose of omega-3, said Penny A. Asbell, MD, FACS, at the University of Tennessee Health Science Center in Memphis. The study tested 3,000 mg fish-derived omega-3 fatty acid in triglyceride form versus a placebo of 1,000 mg refined olive oil. It included typical DED patients from practices across the United States; all had signs and symptoms of moderate to severe disease and were allowed to use concurrent DED therapies. By contrast, other studies have been small and/or very specific in terms of population, such as studies done in India, where diet is significantly different.[1]

Heterogenous group. Although Dr. Massaro-Giordano described DREAM as well designed, she pointed out how difficult it is to see a significant treatment effect in a disease as heterogeneously defined as DED. Dr. Asbell, the principal author of the DREAM study, noted that the study included a heterogeneous group of patients, varying in terms of Ocular Surface Disease Index (OSDI) scores, conjunctival and corneal staining scores, tear break-up times, and Schirmer test results, etc. However, the researchers found no beneficial effect of omega-3 supplementation in the many subgroups based on degree of symptoms, severity of signs, level of omega-3 in the blood at baseline, and presence of specific diseases associated with DED.

Olive oil effect. Dr. Massaro-Giordano noted another possibility: It's not that omega-3 didn't have a positive effect but that the control—olive oil—may also have had a beneficial effect. After all, the study showed that 54% of control patients and 61% in the study group had a 10-point or greater improvement in OSDI outcomes.[1] However, Dr. Asbell noted that DREAM researchers carefully examined the possibility of a beneficial effect of their olive oil placebo, but they found an effect implausible. The dose of olive oil was approximately 1 teaspoon a day, and it was refined, lacking the polyphenols in extra virgin olive oil that are believed to provide beneficial effects in other conditions.[1] "The severity of nearly all signs in both treatment groups was essentially unchanged from baseline levels over the year of the study," said Dr. Asbell. The only large change was in symptoms, and it was identical in both groups, consistent with the placebo

TREATMENT. *Dr. Shen uses IPL to treat a patient with MGD.*

Joanne F. Shen, MD

BY GABRIELLE WEINER, MS, CONTRIBUTING WRITER, INTERVIEWING **PENNY A. ASBELL, MD, FACS, GIACOMINA MASSARO-GIORDANO, MD, JOANNE F. SHEN, MD,** AND **SONAL S. TULI, MD, MED.**

effects seen in other DED trials.

Dr. Massaro-Giordano said, "We don't know if olive oil has a positive effect, as there may be a substance in it that we can't measure. Yes, it's only 1 teaspoon a day, but it's still something." She added, "It's possible we didn't see a better effect because the 'purification' process of the omega-3 may be different from what has been studied previously."

What to tell patients. "A lot of patients have heard the hype about omega-3 and gravitate toward it because they like the idea of using something natural," said Sonal S. Tuli, MD, MEd, at the University of Florida in Gainesville. She tells patients about the lack of randomized controlled trials to support the effectiveness of omega-3 and the strong placebo effect observed in many dry eye studies. Still, she said that she sees little harm in patients trying omega-3 supplements. Moreover, several studies demonstrate positive effects of omega-3 fatty acids on other organs (e.g., the heart, lungs, and skin), which could benefit the patient even if there is no effect on their dry eyes. So, if a patient asks for advice on which omega-3 to try, she tells them to buy the triglyceride formulation (1 g/day).

In the past, Dr. Massaro-Giordano advised patients to take fish oil. "Not anymore. Now I explain all the studies, including the most recent DREAM results." Some patients ask, "Could olive oil have a benefit?" To them, she says, "If you want to, try the olive oil. If you can afford a good purified fish oil, high in EPA and DHA, go for it."

"Omega-3 appears to be safe," said Dr. Asbell, "but, for any treatments, look for quality evidence, such as randomized controlled trials, before you believe in their ability to 'cure.'"

What Do Users of LipiFlow and IPL Have to Say?

LipiFlow Thermal Pulsation System (Johnson & Johnson Vision) and intense pulsed light (IPL) represent two instruments for expressing meibomian glands that are clogged with waxy deposits in patients with meibomian gland dysfunction (MGD). While some clinicians believe that warm compresses and lid scrubs are just as effective as the more expensive systems, said Dr. Massaro-Giordano, "That's not quite correct. There is a head-to-head study[2] showing that LipiFlow is more effective than warm compresses, but success rates depend heavily on choosing the correct candidates. It works best for posterior blepharitis patients whose meibomian glands aren't scarred down."

LipiFlow for mild to moderate MGD. LipiFlow, FDA approved in 2011, consists of an inner shield that slides beneath the lids and over the globe, emitting heat out toward the lids to liquify the meibum. An air bladder sits on the eyelid and massages the lid to open the glands and express the liquified meibum. The design of the device protects the cornea and the globe from the heat and pressure created by the system. The treatment takes about 15 minutes.

The Mayo Clinic in Arizona acquired LipiFlow in 2012, said Joanne F. Shen, MD, who practices there. "When I first started in 2012, I followed the manufacturer's protocol, but 50% of my dry eye patients were returning dissatisfied, saying that the treatment didn't work and requesting their money back. I spent a lot of time doing service recovery. My patients who could afford it were averaging 75-80 years old and had MGD for 40-plus years. Since then, Level I evidence has been published showing that LipiFlow is effective in patients with a mean age of 50-66."[3-6]

More affordable. Now the wholesale prices of the actuators (the inner heating shield) have dropped, enabling many centers to offer LipiFlow at more affordable prices, said Dr. Shen. Its advantages are that it treats both the upper and lower lids and is extremely well tolerated, she said. "I have patients who definitely improve symptomatically and clinically on exam with LipiFlow, but the benefits require retreatment every three to 12 months, and it doesn't work on everyone."

Dr. Shen pointed out that the associated diagnostic module, LipiView II Ocular Surface Interferometer, is able to detect partial blinks, and this helps her identify good candidates who are likely to respond. Specifically, she said, "Simply expressing the meibomian glands may not lead to improvement if a patient isn't blinking fully, especially in Arizona's dry climate."

IPL for severe MGD. For more severe DED, Dr. Shen may turn to IPL, which is used by dermatologists to treat rosacea, acne, and sun damage. IPL followed by meibomian gland expression for treatment of dry eye in ocular rosacea patients was discovered and popularized by Rolando Toyos, MD, an ophthalmologist based in Memphis, Tennessee.[7] The mechanism of action has not been proven but its efficacy has been hypothesized to be due to powerful bursts of light at specific wavelengths to alter blood vessels near the surface of the skin to alleviate inflammation, minimize bacteria on the skin and eyes, and possibly reduce oxidative stress, all of which may have a beneficial effect on MGD.[8] Typically, it is only used when the patient has run out of options, said Dr. Shen.

Patient selection. "If a patient has rosacea and their main concern is eye redness, I recommend IPL," Dr. Shen said. For these cases, she said that IPL and meibomian gland expression can be more helpful than LipiFlow. Controlled prospective studies from Asia have shown a significant advantage of IPL in improvement of symptoms and meibum quality.[9-12] Dr. Massaro-Giordano added that she finds IPL helpful for any patient with severe lid disease whose glands are still active. She reports a success rate for IPL that can range from 40%-60% in the right patients.

Considerations. Because IPL can be painful, Dr. Shen will often try LipiFlow first, especially if a patient has a high sensitivity to pain. Dr. Massaro-Giordano uses lower IPL settings for patients with MGD (instead of the setting used for acne and rosacea in the dermatologist's office). Her patients haven't found it to be all that painful, she said.

Theoretically, said Dr. Shen, "after you have their glands open and the patients feel a little better, you should be able to transition to LipiFlow." So far, though, she has not been able to wean her successful IPL patients to LipiFlow. "Many patients are fearful that a change in treatment plan might derail their

improvement," she said.

Although Dr. Massaro-Giordano uses IPL before LipiFlow successfully, she noted that you can't use IPL in patients with heavily pigmented skin. Dark skin absorbs the light from IPL and the skin can heat up, leading to inflammation or hyperpigmentation, she said. Thus, she recommends LipiFlow for these patients.

Alternatives. Dr. Shen said, "I do a series of four to test whether the patient will respond. If treatment is unsuccessful, we focus instead on protective mechanisms to sequester the firing of the corneal nerves with goggles or scleral lenses, cocooning the ocular surface from the environment." If a patient can't afford LipiFlow or IPL, warm compresses and eyelid scrubs are still helpful, Dr. Massaro-Giordano noted.

"We don't know exactly why IPL works," said Dr. Shen. "Yes, there may be a psychological component, but I have definitely seen patients' conjunctival redness get better along with some other signs and symptoms." Dr. Massaro-Giordano added that although preliminary studies of IPL show positive results, more research is needed.

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See disclosure key, page 10.

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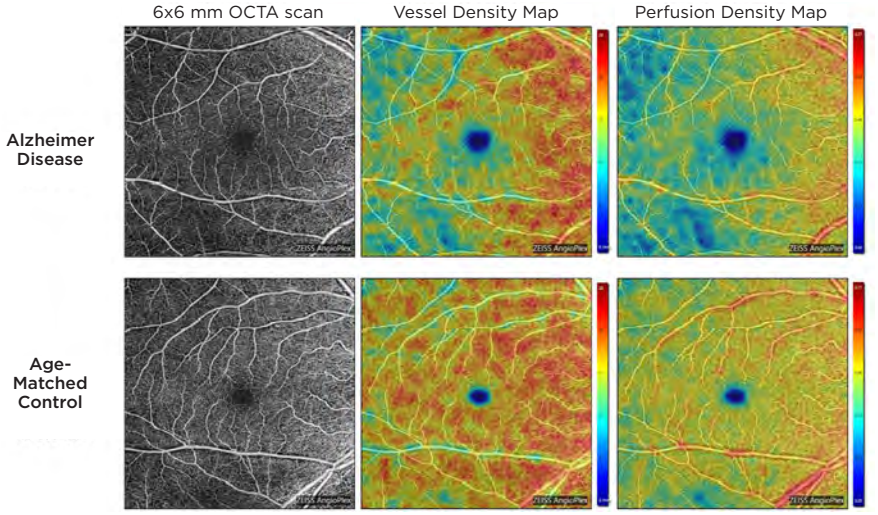
Alzheimer Disease Update: Clues From the Retina

Modern ophthalmic imaging techniques are uncovering multiple lines of evidence that structural and functional changes in the retinal microvasculature could be the surrogate biomarkers needed for physicians to detect Alzheimer disease (AD) noninvasively at its earliest—and, potentially, most treatable—stages.

Although the specific reasons for correlations between retinal signs and the characteristic neurodegeneration in AD remain murky, ophthalmic researchers express confidence that the many investigations being conducted by large collaborative groups around the world will lead to clinically useful discoveries.

Crucially, these groups are assembling vast libraries of retinal images acquired with specialized techniques, such as optical coherence tomography angiography (OCTA). They also plan to develop artificial intelligence (AI) algorithms to find patterns in the images that the human eye can't detect.



COMPARISON. *OCTA images of the superficial capillary plexus of the right eye from a patient with AD (top row) and an age-matched control (bottom row). Corresponding quantitative color maps of vessel density (middle column) and perfusion density (right column) with their respective color scales on the right show decreased vessel density and perfusion density in the subject with AD compared to the control.*

A Window to the Brain

"There is evidence of correlations between the health of the eye and [that] of the brain because the two are directly connected. And the retina exists as an extension of the central nervous system, offering a window to study brain changes—particularly the blood vessel changes and the levels of neurodegenerative damage in the brain," said Carol Y. Cheung, PhD, at the Chinese University of Hong Kong.

Alison G. Abraham, MHS, MS, PhD, at Johns Hopkins University in Baltimore, agreed. "It's not hard to believe that there would be a link between what's happening in the retina and in the brain, because the eye is an offshoot embryologically of the brain. So the fact that we see parallels should not be surprising." She added, "The eye shares a lot of common features with the brain—the microvasculature is regulated in a similar way, and both are patterned similarly."

Tracking changes. "At this point, a good number of imaging studies are showing that there are differences that we can see in the eye that are related to Alzheimer. Those seem to be both microvascular and neuronal," Dr. Abraham said. For instance, she pointed out, "Studies have found differences in one part or another of the nerve fiber layer in patients with already-diagnosed AD, or they found differences in various aspects of the perfusion of the microvasculature. That has established the relationship."

However, distinctive retinal differ-

BY LINDA ROACH, CONTRIBUTING WRITER, INTERVIEWING **ALISON G. ABRAHAM, MHS, MS, PHD; CAROL Y. CHEUNG, PHD; SHARON FEKRAT, MD; DILRAJ S. GREWAL, MD;** AND **TIEN Y. WONG, MD, PHD.**

ences that inform our understanding of preclinical disease processes have yet to be found, Dr. Abraham noted. "The big question we're trying to answer is: Can we identify some period during the long-term progression of cognitive disease, when we might be able to see things in the eye that would allow us to intervene effectively?"

Potential benefits for drug trials. This knowledge might hasten the development of therapies for AD, because biomarkers for early-stage dementia, called mild cognitive impairment (MCI), would enable drug companies to determine the impact of potential new therapies over time in people with preclinical disease, before profound and irreversible brain damage has occurred.

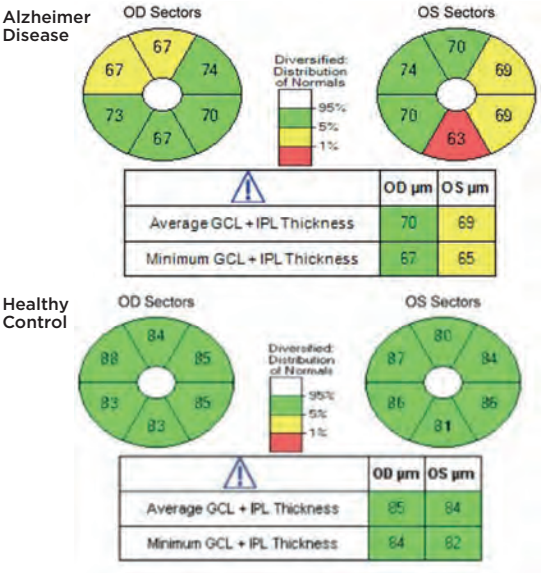
"Hundreds of clinical trials looking at novel therapeutics for Alzheimer have been unsuccessful," said Sharon Fekrat, MD, at Duke University in Durham, North Carolina. Earlier this year, for instance, Biogen and Roche halted AD trials because of lack of efficacy. "We don't really know why this happened, but one potential reason could be that the individuals entered into these studies had advanced disease, too advanced for the medication being studied to show benefit," Dr. Fekrat said.

Potential Biomarkers

Dr. Fekrat and Dilraj S. Grewal, MD, also at Duke, recently reported on OCT and OCTA findings in the superficial capillary plexus in eyes of patients with MCI and AD. They found reduced macular vessel density, perfusion density, and ganglion cell-inner plexiform layer thickness in eyes with AD, compared with MCI and normal controls.[1]

Other possible retinal biomarkers for early Alzheimer that are under exploration include the following:

- Ultra-widefield, nonmydriatic scanning laser ophthalmoscopy to acquire images showing the presence and status in the retinal periphery of hard drusen, which may be associated with early AD.[2]
- Near-infrared fluorescence ocular imaging and other tests to look for beta-amyloid protein in the retinas of eyes with preclinical AD.[3]



COMPARISON. *Ganglion cell inner plexiform layer thinning in a patient with AD (top), compared with a cognitively normal subject (bottom).*

- Structural OCT scanning to quantify volumetric alterations in certain areas of the retina.[4]
- Differences in microcapillary tortuosity and in "retinal fractal dimensions" (vascular branching complexity).[5]
- The influence of comorbidities such as diabetes, hypertension, and glaucoma on retinal signs associated with AD.
- The status of capillaries deeper inside the retina, in the deep capillary plexus and the whole capillary plexus, compared to the smaller microvessels in the superficial plexus. (Dr. Fekrat's group is investigating this angle.)

Image Repositories

Large numbers of retinal images are necessary to provide the raw data needed to analyze imaging data using AI techniques, said Tien Y. Wong, MD, PhD, at the National University of Singapore. "We need better international collaborative framework to share images and validate algorithms."

Dr. Wong led the multidisciplinary, multinational team that reported the validation of a deep learning algorithm capable of automatically detecting referable diabetic retinopathy—a project that required nearly 500,000 fundus photographs.[6]

Sample datasets needed. "Our recent success in AI/deep learning on diabetic retinopathy is being transferred to other systemic diseases, including dementia," Dr. Wong said. "However, we remain limited by good quality and large sample datasets on AD."

To address this deficit, the Duke research group is collecting multimodal retinal images in eyes of persons with a variety of neurodegenerative diseases and placing them into an open-access repository of deidentified images that they and researchers elsewhere can analyze. In addition to angiograms from controls and AD/MCI patients, the repository recently began adding images from patients with other neurodegenerative diseases, including Parkinson disease, amyotrophic lateral sclerosis, and Huntington disease, Dr. Grewal said.

"We would want to collect images from all over the world into a central registry that all researchers can access," Dr. Grewal said. "We imaged 500 patients in the last 10 months; we're moving quickly. We are looking to get images from several thousand or more patients, at least."

Similarly, Dr. Abraham and her colleagues at Johns Hopkins are gathering OCTA and structural OCT scans from about 1,200 people with normal cognitive ability for a longitudinal four-year study that will monitor subjects' retinal microvasculatures and cognitive abilities. This study is known as EyeDOC (for "Eye Determinants of Cognition"), Dr. Abraham said.

Call for Collaboration

The image repositories will facilitate multidisciplinary and multi-institutional collaborations in the hunt for retinal signposts of AD, Dr. Fekrat said. "It's very early, and I think the more people involved in this, the better. To have an impact in our lifetimes we need collaboration. We can't be in our silos to try to figure this out."

Her group at Duke includes ophthalmologists, a neurologist, radiologists, and computer engineers with AI

Carol Y. Cheung, PhD

expertise. The Duke team is collaborating with international teams who employ ultra-widefield scanning laser ophthalmoscopy to image peripheral hard drusen and other fundus vascular biomarkers.[2] And in Singapore, Dr. Wong has coauthored papers about retinal diseases and cognition with scientists from around the world.

Will multimodalities be key? Ultimately, it is unlikely that any single test of retinal structure or function will be enough to screen patients for early AD and/or track its progress in individuals, Dr. Cheung said. "I think we will want to be looking at the whole retina using different modalities, a whole suite of biomarkers."

Dr. Grewal agreed. "We will likely need multimodal retinal and optic nerve images to optimize the accuracy of an MCI or AD diagnosis. You will want to capture as much information as you can to improve the sensitivity and specificity of the biomarker suite, which may allow us to stratify the various stages of disease and monitor response to new treatments in the context of clinical trials."

Furthermore, even if one high-tech metric, such as OCTA, proved to be the best single method for detecting microcirculatory signs of early AD, "whether it really can be used [outside of a clinical study] is not clear," Dr. Abraham said. "These are people in their 70s, 80s, and even 90s, and we're asking them to sit very still and fixate on a blue light. This can be difficult for them. What if the people that we have the hardest times imaging are the ones that have the highest risk?"

Reality Check

"Right now, none of this is ready for prime time," Dr. Fekrat cautioned. "No one can go to their ophthalmologist and say, 'Please look at my retina and tell me if I am going to get AD.'"

However, she said, "when the details have been sorted through in the coming years, we may potentially be able to use this multimodal imaging approach to diagnose Alzheimer during the 20-year, relatively asymptomatic period of neuropathogenesis, for earlier clinical trial intervention."

Dr. Fekrat added, "Ultimately, we would hope to gather enough information to convert these multimodal tests into more easily understood numbers, like physicians do now with the lipid panel blood test." In such a scenario, she said, "If the quantitative number on one test were higher than X, and this other number were less than Y, and so on, then your risk of Alzheimer would be a certain percentage. But we're a long way from that."

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Dr. Wong is professor and medical director of the Singapore National Eye Center, chairman of the Singapore Eye Research Institute, and vice dean of the Duke-NUS Medical School, all at the National University of Singapore. *Relevant financial disclosures: EyRiS: O; plano: O.*

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Ocular Findings in von Hippel–Lindau Disease

Von Hippel–Lindau (VHL) disease is a tumor syndrome that affects the central nervous system (CNS), retina, and visceral organs. Inherited in an autosomal dominant manner, it arises from germline mutations in the *VHL* gene.[1] The syndrome is rare, with an incidence of approximately 1 in 40,000 people; an estimated 7,000 people with VHL disease live in the United States.[2]

In the early 1900s, Eugen von Hippel, a German ophthalmologist, described retinal hemangioblastomas that were passed down through several generations. In 1926, Arvid Lindau, a Swedish pathologist, recognized the association between retinal lesions and cerebellar hemangioblastomas in addition to findings in other organs, as part of a familial syndrome. In subsequent years, clinical diagnostic criteria for VHL disease were established (See "Clinical Criteria" page 37), and the *VHL* tumor suppressor gene on the short arm of chromosome 3 was identified.[3]

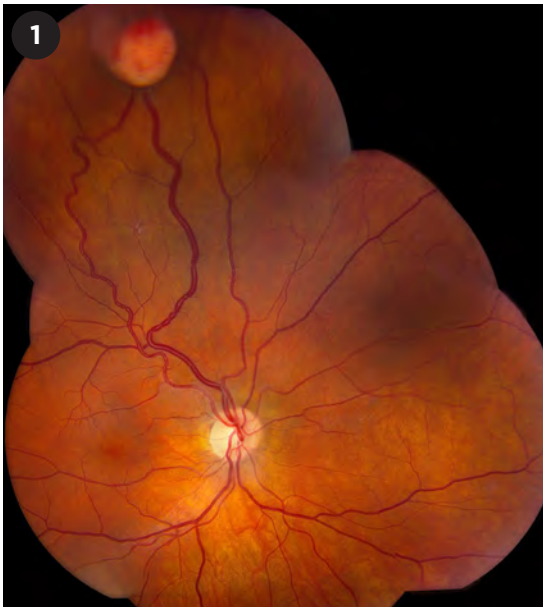
Although multiple benign or malignant tumors and cysts may develop in the tissues of the CNS and in visceral organs including the kidney, adrenal gland, pancreas, epididymis, and broad ligament, the ophthalmic manifestations of the syndrome are both characteristic and diagnostic of VHL disease.[4] Retinal hemangioblastoma is a common, early manifestation of VHL disease.[2] Thus, ophthalmologists are instrumental in the diagnosis and care of affected patients.

Pathophysiology

Carriers of a *VHL* germline mutation are especially at risk for developing VHL disease. The *VHL* gene is a tumor suppressor gene and, consistent with Knudson's two-hit hypothesis, requires mutation of both copies of the *VHL* gene for tumors to develop. When a germline mutation is present, a second "hit" in the other *VHL* gene allele at the somatic level transforms the cell into a tumor cell. Also, VHL disease can occur in the absence of a germline mutation. In this case, both *VHL* gene alleles would have to be affected by independent hits at the somatic level. Patients who have *VHL* germline mutations tend to develop tumors multicentrically and bilaterally in the CNS and viscera, and the disease manifests at a younger age than patients without a *VHL* germline mutation.[5]

Mechanism. In healthy people, the VHL protein helps to target specific transcription factors for degradation. These hypoxia-inducible factors (HIFs) are produced in the presence of low tissue oxygen tension, upregulating proteins that enable a cell to survive in a hypoxic state. These proteins include erythropoietin (EPO), platelet-derived growth factor, and vascular endothelial growth factor (VEGF).

A mutation in the *VHL* gene leads to disruption of VHL protein function, which results in unregulated levels of HIFs and, subsequently, increased levels of downstream gene products. Elevated levels of VEGF and EPO stimulate cell growth and angiogenesis, which contribute to tumor formation.[4]



VIEW OF A TUMOR. *Fundus photograph of a VHL patient with retinal hemangioblastoma.*

Signs and Symptoms

Retinal hemangioblastomas. Typically, this is the earliest lesion identified in VHL patients, often presenting in the first three decades of life. Although

BY **PAULINE M. DMITRIEV, BS,** AND **MIGUEL MATERIN, MD.** EDITED BY INGRID U. SCOTT, MD, MPH, AND BENNIE H. JENG, MD.

most patients with this finding are asymptomatic and detected by surveillance ophthalmoscopy or fluorescein angiography (FA), some may present with vision loss.[6,7]

CNS hemangioblastomas. These also occur earlier in life and most commonly develop in the spinal cord and cerebellum. Presenting symptoms vary depending on tumor location and may include pain, headaches, paresthesia, and limb weakness due to the tumor's compressive effects.

Renal cysts and renal cell carcinoma. These normally develop in middle age and may manifest as flank pain, hematuria, and a palpable abdominal mass.

Pheochromocytoma. This may present with hypertension and other signs of catecholamine excess.

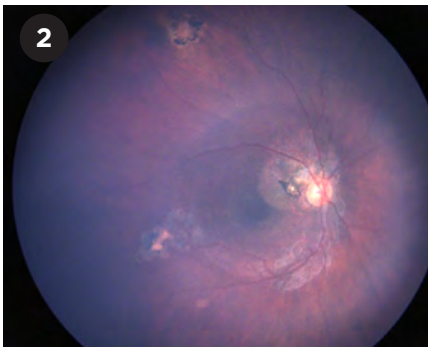
Other VHL-associated lesions. Patients may develop pancreatic tumors and endolymphatic sac tumors of the inner ear. Due to the autosomal dominant inheritance pattern of VHL disease, tumors in patients with a family history of the syndrome are often identified via routine surveillance at an early age before they become symptomatic.[7]

Ophthalmic Manifestations

The principal ophthalmic finding in VHL disease is retinal hemangioblastoma. Its prevalence is between 45% and 65%.[8] The probability of developing retinal hemangioblastoma increases with age, with the median age of onset being 21 years.

Retinal hemangioblastomas usually develop as solitary tumors, but up to 50% of patients have multiple and bilateral lesions.[1] These circumscribed, rounded, vascular tumors appear orange-red in color and are supplied by enlarged, tortuous feeder vessels. Most commonly, hemangioblastomas are found in the temporal peripheral retina but may also be present in the juxtapapillary region in up to 15% of patients.[4]

Although small lesions may remain stable for years, most hemangiomas tend to increase in size over time, leading to retinal changes. Blindness or significant visual loss from ocular VHL occurs in less than 10% of patients. This is often caused by secondary tumor effects including intraretinal and subretinal exudation,[9] with exudation usually localized to the area surrounding the tumor.[2] In later stages, the tumors may cause massive exudation and retinal detachment (RD), macular edema, uveitis, cataracts, and glaucoma.[9]



POST TREATMENT. *(2) Appearance of multiple retinal hemangioblastomas on funduscopy after treatment with laser photocoagulation.*

Diagnosis

Appearance on imaging. Retinal hemangioblastomas may be diagnosed with indirect ophthalmoscopy, fundus photography, and FA. Specifically, fluorescein hyperfluorescence in the dilated feeder arteriole is seen in the arterial phase. The tumor then displays homogeneous capillary filling, followed by increased fluorescence of a prominent draining vein in the venous phase. FA is particularly helpful in identifying juxtapapillary retinal hemangioblastomas and in detecting occult lesions. Indocyanine green angiography is used to help differentiate choroidal lesions, and ultrasonography is used to assess tumor thickness. Patients undergo magnetic resonance imaging and/or computed axial tomography to detect concurrent CNS and visceral tumors.[9]

DDx. The differential diagnosis for retinal hemangioblastoma includes other ocular conditions in which vascular tumors may be found (e.g., Coat's disease, retinal cavernous hemangioma, racemose hemangioma, and vasoproliferative tumors of the retina).

Genetic testing. The ability to test for *VHL* gene mutations has allowed researchers to study possible associations between mutational genotype and ocular phenotype. After the diagnosis of VHL disease has been confirmed, genotypic analysis may be used to assess the likelihood of particular disease manifestations, including probable organ involvement, age of onset, and type and severity of characteristic features. For example, a recent study found that deletion of the *VHL* germline gene leads to less severe eye disease compared with missense or truncating mutations in the gene. This finding suggests that abnormal VHL protein function may be more pathogenic in retinal tissue than complete absence of the protein.[4]

Treatment

Management of patients with VHL disease often requires a multidisciplinary approach given the complexities associated with multiple tumors in various organs. Treatment of the ocular manifestations of VHL disease can be particularly challenging because of the possibility of bilateral, multiple tumors and new tumor formation. Current treatment modalities include laser photocoagulation, cryotherapy, plaque radiotherapy, and vitreoretinal surgery.[1]

Photocoagulation. In eyes with clear media, laser photocoagulation is indicated for treatment of small tumors located in the peripheral retina. In general, the feeder artery is occluded first, and, if necessary, the tumor's surface can also be treated. This treatment modality has a response rate of 91% to 100%, and complications, including RD or retinal/vitreal hemorrhages, are uncommon.[10]

Cryotherapy. Cryotherapy is preferred for lesions found in the periphery of the retina with subretinal fluid.[11] A double freeze-thaw technique is used under indirect ophthalmoscopy. This method is particularly successful in treating larger hemangioblastomas.[12]

Radiation. Plaque radiotherapy may be useful in treating ocular VHL disease in cases that respond poorly to conventional laser or cryotherapy.[12]

Surgery. Vitreoretinal surgery is reserved for patients who have complications secondary to their eye disease. For example, vitreous hemorrhage may occur in the presence of large tumors, or tractional RD may result from con-

traction of the fibrovascular tissue that often accompanies retinal hemangioblastomas. These complications may be treated with vitrectomy.[12]

Possible role for antiangiogenics? The discovery that upregulation of downstream genes, such as *VEGF*, may play a role in tumor development has prompted the study of antiangiogenic drugs as a therapeutic option for ocular VHL disease.[4] Although antiangiogenic therapy has often been used for extraocular manifestations of VHL disease, there have been conflicting reports on its usefulness in treating retinal hemangioblastomas. Several case reports have found that although anti-VEGF therapy did not reduce tumor size, it did decrease exudation, which led to a subsequent improvement in visual acuity and visual field. Prospective trials are needed to further evaluate the efficacy of this approach.[4]

Other considerations. Ocular tumor location has been found to play a role in treatment success. Peripheral tumors may be treated successfully with laser photocoagulation, photodynamic therapy, cryotherapy, and plaque radiotherapy. Generally, small peripheral tumors respond best to photocoagulation while larger peripheral lesions are better managed, initially, with cryotherapy.[13]

Clinical Criteria

If family history is:	Feature
Positive	One retinal or CNS hemangioblastoma *or* Pheochromocytoma *or* Renal cell carcinoma
Negative	Two or more retinal or CNS hemangioblastomas *or* One retinal or CNS hemangioblastoma plus a visceral tumor*

*Visceral lesions include renal cysts, renal carcinoma, pheochromocytoma, pancreatic cysts, islet cell tumors, epididymal cystadenoma, and endolymphatic sac tumor.

SOURCE: Binderup M et al. *Eur J Hum Genet.* 2017;25(3):301-307.

However, juxtapapillary tumors are more difficult to treat. Treatment of tumors near the optic nerve and major retinal vessels involve higher risk of visual loss. Because tumor progression in this location may lead to adverse visual effects, treatment considerations must be based the patient's visual symptoms and tumor progression.

Summary

Retinal hemangioblastoma is a common, early sign of VHL disease. The typical fundus findings, appearance on FA, and other diagnostic tools allow ophthalmologists to play a key role in diagnosing the disease as well as managing the ocular manifestations. Although treatments such as laser photocoagulation and cryotherapy may help mitigate visual loss, further development of therapies targeting the pathophysiology of the syndrome is promising for patients living with VHL disease.

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The Case of the Double-Edged Protector

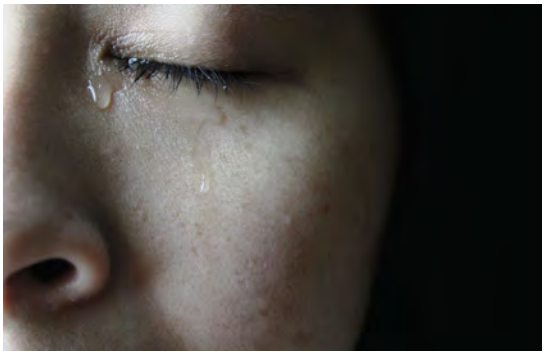
This article is part of an occasional series of patient safety cases, written by the American Board of Ophthalmology (ABO) and appearing in Morning Rounds.

Angela Lee* was tired of dabbing away her tears and looked forward to the dacryocystorhinostomy (DCR) that she hoped would allow her to put away the tissue box that was always by her side. Although she had more bleeding than usual, the procedure was otherwise uncomplicated. Her eye was covered with a pressure dressing, and after routine observation in the surgery center, she was discharged home in the care of her husband.

The surgeon called Mrs. Lee on the evening of her procedure, but no one answered the phone. Because of the intraoperative epistaxis, the patient had been instructed to arrange an office appointment within 48 hours after surgery, so the surgeon was not highly concerned. However, no appointment was scheduled.

The ophthalmologist next heard about Mrs. Lee four days after surgery, when her husband called the office to report that his wife couldn't see out of the eye and was experiencing mild discomfort. He described what he saw when he parted his wife's eyelids: "Everything looks white." This information was relayed to the surgeon, who asked the staff to arrange an office visit the following day. At the beginning of that exam, the technician who was screening Mrs. Lee quickly discovered that the metallic corneal protector used during surgery was still in place within the palpebral fissure.

When the protector was removed, Mrs. Lee's visual acuity, which had been 20/20-1, was now decreased to counting fingers at 2 feet. The cornea was edematous, and keratometry showed 8 D of central corneal flattening. The surgeon immediately apologized and took full responsibility for the retained corneal protector. She referred Mrs. Lee to a cornea specialist and offered to pay the cost of the cornea specialty care. Over the next several months, Mrs. Lee's cornea gradually regained a more normal shape, and her final visual acuity was 20/25.



DCR. *A dacryocystorhinostomy led to important lessons for one practice.*

Safety Event Investigation/ Root Cause Analysis

An adverse event or near miss should automatically prompt a formal investigation to determine the root cause of the incident, followed by intervention and changes in processes to reduce the risk for repeated events. Larger health care facilities have reporting systems and designated safety specialists to coordinate such an investigation. However, these resources were not available at either the surgery center or in the practice of Mrs. Lee's ophthalmologist.

A review of this case shows that several factors might have contributed to the retained corneal protector and subsequent corneal injury:

- There was no "counting" process during the DCR to ensure that the corneal protector had been removed from the patient's eye at the end of the procedure.
- The surgeon might have been distracted while managing the increased epistaxis during the DCR.
- The surgeon did not examine the eye at the completion of surgery.
- Someone other than the surgeon might have placed the eye patch at the end of the case, being unaware the protector had been used.
- There was no office protocol to ensure that the patient was examined shortly after surgery, as requested by the physician.
- Cultural and language barriers

BY **TAMARA FOUNTAIN, MD,** AND **PHILP L. CUSTER, MD.** EDITED BY **JANE BAILEY, MD.**

might have inhibited the patient or family from contacting the ophthalmologist sooner after surgery. (See "Health Literacy" section, below.)

- The surgeon did not recognize the significance of the problem when the husband called four days after surgery.

Root cause. The root cause for this adverse event was determined to be inadequate intraoperative protocols to ensure that corneal protectors are always removed at the completion of a procedure. Inadequate office processes for appropriate scheduling of postoperative appointments and handling of phone calls contributed to patient harm by prolonging the duration of the corneal injury.

Discussion of Patient Safety Principles

Failure to remove the corneal protector is considered a preventable medical error. The unintended retention of foreign objects (URFOs)—also called retained surgical items (RSIs)—is a well-recognized medical error in other surgical specialties. There are many reports of sponges, needles, and whole instruments or broken parts inadvertently left in surgical fields. Most of these cases result in additional care and/or prolonged hospital stays for the patients; some are fatal. Lawsuits are common. Typical root causes for these mistakes include 1) inadequate policies or inconsistent adherence to those policies and 2) poor staff education or team communication.[1] Certain types of cases carry an increased risk of URFOs, including emergency procedures, operations involving multiple surgical teams, and situations in which the surgical plan changes unexpectedly.

It would be wise for all ophthalmology surgery centers to institute a counting policy for protectors and other temporary external or internal devices used during ophthalmic procedures.

Operating room protocols are used to ensure that any item at risk for being inadvertently retained is counted both when introduced to the case and at the end of the procedure. Counts are also advised whenever there is a change in the scrub nurse. Any inconsistency in these counts must be rectified prior to the completion of surgery.

Eye surgery safety procedures. The true incidence of URFOs in ophthalmology is unknown. Although failure to remove a corneal-scleral protector might seem like a rare occurrence, the authors are aware of similar events having occurred at other institutions. It would be wise for all ophthalmology surgery centers to institute a counting policy for protectors and other temporary external or internal devices used during ophthalmic procedures. Examining the status of the globe at the completion of surgery should be part of every operation.

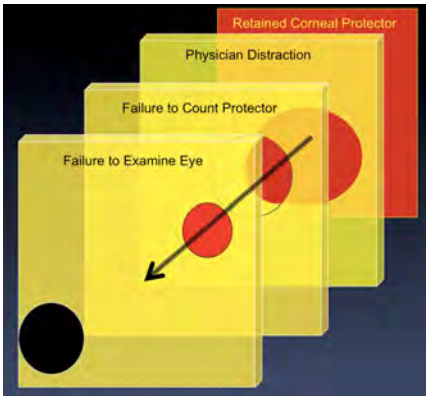
Communication. Poor communication between providers, staff, patients, and families is a common cause of medical adverse events. Each medical office should have protocols to ensure that appointments are scheduled, documented, and communicated to the patient. Postoperative patients who miss appointments should be contacted in a timely fashion to reschedule or verify their status.

Additional office protocols must be implemented to manage phone calls from patients who are having unexpected symptoms. When Mrs. Lee's husband called to report her discomfort and decreased vision, the "white appearance" was attributed to Bell's phenomenon, and neither staff nor physician recognized the significance of the postoperative visual change.

Health literacy. Poor health literacy can make it difficult for patients both to communicate symptoms and to understand instructions, contributing to poor health care. Mrs. Lee and her husband might not have completely understood their postoperative instructions, as English was not their primary language. In addition, cultural factors might have contributed to their delay in reporting visual loss after surgery. It is important to identify those patients who have educational or language barriers that may hinder their ability to understand and follow instructions or to communicate with providers.[2]

Culture of medical facility. All members of the health care team must be mindful of the potential for medical errors. Adverse medical events can occur in a variety of health care settings, including physician offices and freestanding surgery centers. Reliable and standardized processes of care, as well as communication and teamwork, can decrease the risk of dangerous mistakes. Continual education, vigilance,

Swiss Cheese



"Swiss cheese" is a metaphor proposed by James Reason[1] to explain medical mishaps. Considering that redundant checks are put in place to prevent mistakes, it follows that medical errors often involve mistakes at multiple levels, often by different providers. Hazards are supposed to be prevented by a series of barriers; however, each barrier has weaknesses, or "holes." If by chance the holes align as they constantly open, close, and shift, the patient can be harmed. Mr. Reason writes, "When an adverse event happens, the important issue is not who blundered, but how and why the defenses failed." In the case of Mrs. Lee, the physician might have been distracted, there was no protocol to count the protector, and the eye was not checked at the completion of the case.

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and process improvement are needed to identify and reduce the risk of errors.

Investigation. Each entity should have a designated person to coordinate patient safety activities. In a small office, this person may be an office manager or lead technician who wears multiple hats, including compliance and safety. Adverse events, near misses, and at-risk behavior should be reported and investigated. Once the underlying root causes are identified, changes in protocol can then be instituted. Open, nonpunitive communication is essential to create an atmosphere that fosters a team approach to reducing medical error and improving patient care.

*Patient name is fictitious.

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Dr. Fountain is professor of ophthalmology at Rush University Medical Center in Chicago, emeritus director of oculoplastic and reconstructive surgery; and board chair emeritus of OMIC. **Dr. Custer** is professor of ophthalmology at Washington University School of Medicine, St. Louis, Mo., and emeritus director of the ABO. **Dr. Bailey** is clinical assistant professor of ophthalmology and visual sciences at the University of Iowa, Iowa City, and director of the ABO.
Relevant financial disclosures: None.
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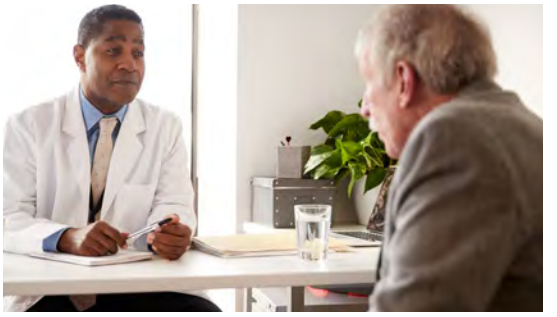
A Risk Management Perspective



HONESTY. *For clear errors, a forthright account from the surgeon can help mitigate risk.*

Dealing with unanticipated outcomes is one of the most difficult aspects of medical practice, especially if an error contributed to the result. Ophthalmologists have been sued for failure to remove shields, trocars, clips, scleral plugs, and Weck-Cel sponges. Leaving an object in the eye is considered a preventable error, as are operating on the wrong eye and implanting the wrong IOL. Sometimes, as in this case study, it is clear that an error occurred. At other times, it is necessary to review the care before determining the cause of the unexpected outcome. When you ascertain that an error has been made, you need to respond. The following discussion explores disclosure and payment for subsequent care.

Honest acknowledgment. Although ophthalmologists are understandably wary of admitting liability, risk managers advise them to handle clear errors differently from other types of adverse events. It is best to admit the error and apologize to the patient, as the ophthalmologist in this case study did. Communicating in a sympathetic and nondefensive way with the patient or patient's family about the error may help dispel much of the anger, confusion, and distrust. It is when patients believe that they are not being told the whole story, or are not being given the opportunity to ask the physician questions and vent feelings, that they may seek the advice of an attorney and pursue a medical malpractice claim. An honest approach can prevent allegations of fraudulent concealment, for which attorneys may seek punitive damages.

Payment considerations. Acknowledge that the patient is likely to require care that would not have been needed without the error, and discuss who will pay for this care. Not surprisingly, patients do not feel it is fair to incur additional charges after an error. The surgeon in the case study offered to pay for the corneal care when she referred the patient to a cornea specialist. Taking such a step may not prevent a lawsuit, but it does show the patient that you care.

Note that you may choose to waive or refund your own fees, but you do not have the authority to waive those of other providers who were involved in the care, such as the nurses at an ambulatory surgery center or the anesthesiologist. Contact your professional liability carrier if you want to pay for care provided by another physician. Your carrier can advise you on whether fee refunds or payments need to be reported to your state board of medicine or the National Practitioner Data Bank. Discuss whether you want to pay for the care yourself or would like any payments to be made on your behalf by the carrier. Arrange to pay other physicians directly, rather than the patient. Clarify the extent of the care that you will pay for. Many patients have chronic eye conditions that require ongoing care, and they may believe they will not have to pay for it.

For detailed guidance on disclosure, preserving evidence, documentation, analyzing the error, and healing the health care team, see www.omic.com/unanticipated-outcomes-steps-for-responding.

—Written by Anne M. Menke, RN, PhD, OMIC Patient Safety Manager
Reviewed by Denise Chamblee, MD, Chair of OMIC's Risk Management Committee

The Greening of Ophthalmology

Excessive environmental waste has become part and parcel of the practice of ophthalmology. Here's a look at how you can help reverse the trend.

By Michael Mott, Contributing Writer

THE MODERN PRACTICE OF OPHthalmology excels at myriad remarkable treatments and outcomes. It also excels at producing appalling amounts of discarded packaging and other garbage.

Is it possible to take the profession in a greener direction—to follow the dictum "First, do no harm" not only for patients but also for the environment?

A growing number of ophthalmologists argue that it's time to tackle this challenge. "As ophthalmologists, the impact we have on our environment is becoming clearer and more significant than ever before," said Alan L. Robin, MD, at the University of Michigan in Ann Arbor and Johns Hopkins University in Baltimore. But as Dr. Robin noted, "changing our habits is not a matter of fundamentally changing what we do—patient care is always our first priority. Practicing green medicine is about acknowledging the waste we produce, reducing our impact wherever possible, and spreading the word."

A Rising Tide of Waste

"There is no doubt that modern ophthalmic practice creates an unbelievable amount of waste on a daily basis," said Rengaraj Venkatesh, MD, at the Aravind Eye Hospital in Pondicherry, India. "Think about the disposables involved in a typical cataract surgery in the United States: Single-use eyedrops. Single-use phaco tips, tubing, sleeves, and other accessories. Single-use gowns and sheets. Single-use surgical markers. And don't forget the cartons, the boxes, the plastic wrapping, and the paper inserts that come with IOLs and other packaging. Now multiply that by the millions. The generation of ophthalmic waste is unprecedented."

What's behind this avalanche of waste? Key factors include regulatory policy, economic factors, and a general frame of mind.

A wasteful mindset. "In many high-income countries, ophthalmology's waste largely stems from a single-use disposable mindset that filters down to almost everything we do," said Jeff H. Pettey, MD, at the University of Utah in Salt Lake City. "We're not aware of the volume we throw away or where it ends up, nor are we conscious of the life cycles of our medical products—everything from how they are produced to how they are discarded. The lack of awareness drives our waste problem."

The herd mentality plays a large role as well, Dr. Venkatesh added. "When I travel and meet other ophthalmologists to discuss the merits of the Aravind system [which has implemented measures to reduce waste], I get the sense that many physicians don't want to antagonize the status quo or question what they've become accustomed to. Perhaps they've been taught that the cleaning and sterilization of reusable instruments is simply not efficient. Perhaps it's simply a fear of 'What if? What if something were to happen to my patient?'"

Safety constraints. Maintaining patient and consumer safety is the cornerstone of the U.S. regulatory system. For instance, the Federal Food, Drug, and Cosmetic Act requires that all drugs and devices labeled for single use be used as such,

Peter Bollinger

even if a surgeon believes they can be safely reused. But the notion that single-use instruments and devices are safer for patients is not always supported by actual evidence, said David F. Chang, MD, in private practice in Los Altos, California. "We should challenge industry to provide us with safe, reusable options that minimize waste as well as cost."

Instructions for use. For example, consider the common international practice of reusing phacoemulsification tips. In the United States, surveyors that accredit or license ambulatory surgical centers (ASCs) do not allow for any deviation from the manufacturer's instructions for use (IFU). Some manufacturers specify a single use, while others label for multiple uses, even though these are virtually the same titanium tips. Dr. Chang and his colleagues tested both reusable and single-use phaco tips in the lab on porcine nuclei with multiple simulated uses. They found no structural differences between the two types of tips—nor any changes that would pose a safety risk to patients.[1]

WASTE NOT. *What can be recycled or reused? How can ophthalmic practices and surgery centers rethink sterilization and disposal practices?*

"IFUs are often worded in order to limit liability and may be overly cautious by addressing a worst-case scenario," Dr. Chang said. "But surgeons should be allowed to use their judgment and discretion in certain situations—much as we are allowed to practice medicine off label. There is no way that emulsifying a soft cataract could damage a single-use tip. On the other hand, I might damage a multiuse tip against a chopper on its first case. As long as accreditation and licensing require strict adherence to these IFUs, it falls on industry to provide for rational reuse and [to allow for] surgeon discretion."

Controlling infections. One of the strongest arguments in support of single-use devices is infection control. But endophthalmitis rate studies by Dr. Chang and clinicians at the Aravind hospitals raise the possibility that many of the costly, but unquestioned, infection control regulations for ORs in the United States could be unnecessary.[2]

"Approximately 60% of Aravind's surgical volume is performed in charity patients, which necessitates maximizing surgical efficiency and eliminating wasteful, unnecessary practices," Dr. Chang pointed out. "So Aravind routinely reuses gowns, gloves, irrigation/aspiration tubing, phaco tips, cannulae, irrigating solution, and medications. What's remarkable is that their endophthalmitis rate was 0.01% in their last 335,000 consecutive phaco cases using routine intracameral moxifloxacin." (See "Pushing the Boundaries of Green Surgery," page 47.)

The profits of waste. Unfortunately, however, there's money to be made in waste, Dr. Robin noted. "The waste of medication in the United States is almost criminal. Look at the example of anesthesia in a single cataract surgery," he said. "During a single procedure, a nurse anesthetist will use 1 to 5 mL of a 20-mL bottle of propofol. Where does the rest go? At best, a hazardous materials container. At worst, [into] the garbage can and into our drinking water."

The same wasteful patterns are also evident outside of surgery, said Dr. Robin, especially with regard to eyedrops. Microdrops could reduce pharmaceutical waste and provide cost savings to patients, he pointed out.

This is not a new concern: In 1992, Dr. Robin was the principal investigator of a research team that was tasked by a leading pharmaceutical manufacturer to assess a smaller drop for one of its glaucoma drugs. The company became aware that many patients were complaining of stinging and burning due to drop overflow. So the team recruited 29 patients to test a microdrop (an amount almost half the size of the standard 30-mL drop). The microdrop was just as effective at reducing IOP as the larger drop—and all of the patients preferred its use.[3]

A similar study in 2006 funded by another pharmaceutical company came to the same conclusion.[4] But the manufacturers never took the products to market. Now, however, technology—in addition to heightened awareness and environmental advocacy—may be spurring change (see "A Green Mainstream," page 48).

Aravind Eye Hospital

Call to Action

"We're limited in the United States as to how we can practice green medicine," said Dr. Pettey. "But if we maintain our focus on quality patient care and safety, we can find ample avenues and simple opportunities in our daily lives to decrease our footprint. The little things can really add up."

Some steps to consider:

Cultivate a green culture. Whether you're in private practice, academia, or anything in between, it begins with the habits and customs of your organization. "Establishing a green way of thinking is paramount," said Dr. Pettey. "Putting a recycling can in the break room is a start, but sustainability is about trying to create a top-to-bottom approach where everyone is focused on minimizing environmental impact as a team. Mindfulness is the secret sauce that can bring about larger change."

Communicate to your staff why reducing waste is important and encourage ideas from every level. Once you've created that green mindset, each person can take ownership of their role with a common goal, said Dr. Pettey. "If you're in the OR, everyone involved can reflect on that culture when making decisions. 'Do we need to open up that surgical pack for this specific procedure? Or is it just part of our routine? Is it something that we can reuse safely? Can it be recycled? How?'"

NO SEDATION. *The majority of Aravind surgeries are conducted with topical anesthesia. A side benefit: less environmental waste.*

These new habits will need constant attention, nurturing, and revisiting, he added. "It's a lot like a garden. It really requires you to be deliberate and intentional—otherwise things will die on the vine and go by the wayside."

This intentional approach is key to the success of the Aravind system, said Dr. Venkatesh. New personnel hear the same story—the "Bedsheet Story"—upon walking in the door of an Aravind hospital their first day. "When your bedsheet becomes frayed and tattered after years of use,

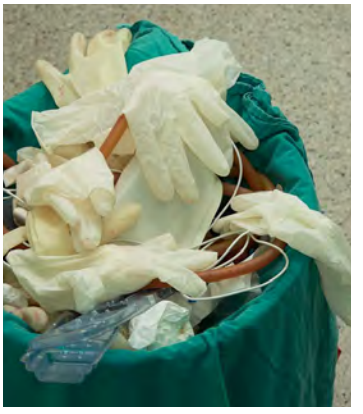
Reducing Surgery's Carbon Footprint

Destruction of the environment is one of the most significant challenges of our century—and the medical industry plays no small role in this global issue.

Evidence indicates that the surgical systems in most developed countries produce a carbon footprint that is not environmentally sustainable.[1] For instance, one recent study confirmed that the U.S. health care sector is responsible for 10% of the country's total greenhouse gas emissions, 10% of its smog formation, and 9% of its ozone depletion.[2]

How does ophthalmology contribute to harming the environment? Consider this: Cataract surgery is the most commonly performed surgical procedure in the United States and one of the most common surgeries performed worldwide. According to researchers in the United Kingdom, the carbon footprint of a single phacoemulsification procedure is equivalent to the energy consumed by the average U.K. person during any given week. Or in other words, performing the surgery is the equivalent of driving an automobile over 400 miles.[3,4]

Eye ASCs and ORs can take a number of steps to reduce their environmental emissions, starting with the basic mantra of "reduce, reuse, and recycle" and extending toward rethinking the supply chain and adopting green building practices. For more information, see Healthcare Without



Harm (https://noharm.org) and Practice GreenHealth (https://practicegreenhealth.org).

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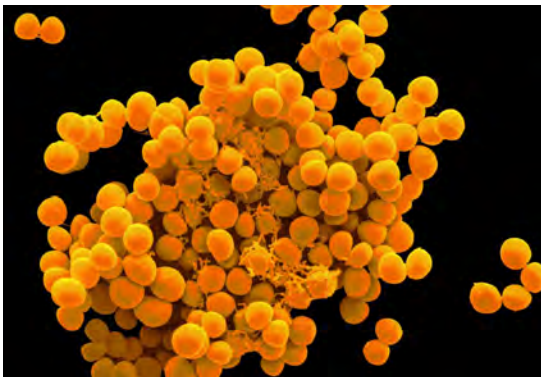
Aravind Eye Hospital; Teeradej/Shutterstock



CONCERN. Staphylococcus epidermis *(shown here) is a leading culprit in endophthalmitis. But are U.S. infection control regulations overly restrictive?*

you don't just throw it in the trash," he said. "You cut out the damage and make a pillow cover out of it. When the pillow cover becomes frayed and tattered after years of use, you don't just throw it in the trash then either. You cut out the damage and make a dust cloth. Only then, when you have gotten every use possible out of your original bedsheet, is it disposable."

Reduce, reuse, recycle, repeat. Reuse underscores everything that happens at Aravind, said Dr. Venkatesh. "We don't throw anything away. For example, when the teeth of our surgical forceps become blunted from overuse, we remove the teeth and make cotton swab tweezers."

For those working with U.S. regulations, the challenge then becomes, how can you get the most out of your materials?

Switch to reusable if possible. "Entire single-use instrument sets are thrown away at the end of procedures," said Dr. Pettey. "Consider multiuse alternatives. And if you don't know of any, ask your colleagues what they are doing or reach out to manufacturer reps in your network for advice."

If the surgical situation does dictate single-use supplies, minimize as many nonessentials as possible in your prepackaged surgical packs. "Get with the other ophthalmologists in your group and evaluate your standardized equipment list," said Dr. Robin. "Ask yourselves, 'How often do we use item A? Is it a majority of surgical cases or just on an as-needed basis? Is it necessary to bring it to the table and dispose of it unused every time?'"

Expand recycling efforts. "We should of course recycle everything [we possibly can]," said Dr. Robin. "And in my experience around the country, it's not being done nearly as much as it could be. I've seen entire bags of garbage thrown into the trash before a surgery even begins." But most of the waste materials that come out of a surgical center's back end aren't meant for the landfill; they're recyclable. Examples include paper products, plastics, glassware, and other items that don't come into contact with a patient, including toner cartridges, fluorescent lights, steel, aluminum, and several different types of batteries.

Rethink anesthesia. Dr. Robin's wife recently underwent cataract surgery at Aravind Eye Hospital. She received no systemic anesthesia, no IV equipment or anesthesiologist was in the room, and she was entirely comfortable during the process. The experience helped Dr. Robin rethink the role of general anesthesiologists in eye care. "Can we reduce unnecessary sedation? It's already happening around the world for cataracts, and most high-volume surgeons in the United States can perform without it," he said. "By eliminating the presence of an anesthesiologist whenever possible, we can simplify our procedures and produce less waste—fewer unused drugs discarded, less discarded tubing in our landfills, and fewer disposables of every kind. It's another small step we can take."

Rethink sterilization. Last year, the Ophthalmic Instrument Cleaning and Sterilization Task Force—which is cochaired by Dr. Chang and comprised of representatives from the Academy, the American Society of Cataract and Refractive Surgery, and the Outpatient Ophthalmic Surgery Society—published updated specialty-specific guidelines for anterior segment surgery.[5] "The guidelines include evidence-based support of short-cycle sterilization for sequential same-day cataract surgery," said Dr. Chang.

Approved containment devices can be used without wrapping if allowed by the sterilizer IFU. "This also reduces the waste, energy burden, and expense associated with instrument processing and sterilization," Dr. Chang noted.

Reduce patient travel. Being green isn't only limited to what's going on in your office or surgical center, Dr. Venkatesh noted. "A significant portion of our carbon footprint involves the extensive travel of patients. And that's largely ignored by physicians. A patient will drive hundreds of miles, sometimes three or four times a week, to receive the care they need—one for an evaluation, another for a procedure, another for a follow-up, and so on."

There isn't always a simple solution to such a complex problem, Dr. Venkatesh said, but ophthalmologists should at least be cognizant of how much they are asking patients to travel. "Can we develop networks with other clinicians who are closer to patients in order to help alleviate travel time? Can we use telemedicine to help reduce the amount of pre- and postoperative visits? Can we use artificial intelligence to change the nature of the typical in-office medical encounter?"

Science Source

Pushing the Boundaries of Green Surgery

The Aravind Eye Care System is challenging conventions about the delivery of health care and showing the world that cutting waste and maintaining high quality can go hand in hand.

Founded over 40 years ago as an 11-bed clinic in a small town in southern India, the network has grown to eight tertiary eye care hospitals and more than 70 primary and secondary eye care centers. Each year, Aravind teams see almost 4 million patients and perform nearly half a million ophthalmic surgeries and procedures—a large majority of which are cataract related.[1]

How do they do it? They employ a lean approach that focuses on eliminating as much waste as possible and streamlining the patient encounter. "We began with a mission to eradicate needless blindness," said Dr. Venkatesh. "To meet that kind of surgical volume, we constantly focus on putting good systems in place."

For example, no appointment system exists at Aravind. Anyone can walk in and receive treatment immediately. "We have open registration from 7:30 a.m. until 5 p.m. Monday through Saturday," said Dr. Venkatesh. "If somebody is medically cleared for a cataract surgery today, we schedule them for the procedure tomorrow."

Roughly 1,500 surgeries are performed each day throughout the Aravind network. "Our doctors operate on two tables," Dr. Venkatesh said. "With the assistance of mid-level ophthalmic personnel, a cataract surgeon will operate on the first patient while the second is being prepped. When the first is complete, the surgeon simply rolls the phaco machine over to the second table, sterilizes with an antiseptic, and proceeds, all while another patient is prepped for the first table. It's an assembly-line system that maximizes what ophthalmologists do best—surgery."

INNOVATION. *The two-bed surgical system (top) is a key component of the lean approach in place at Aravind. Surgical instruments (bottom) undergo daily sterilization and reuse.*

It's also a system designed for efficiency. Ten surgeons can comfortably perform 300 cataract surgeries before lunch. And nothing is casually discarded. Instruments, syringes, and phaco tools are washed, sterilized, and reused the same day. Surgical gloves are discarded after 10 cases, while plastic table drapes are disposed of once daily. Caps, gowns, and masks are laundered at the end of the operating day. Pharmaceuticals are used until either the bottle is empty or the day has ended. The Aravind team has even created their own wetlands to treat wastewater. (For a video overview of the Aravind system's multifaceted approach, go to aao.org/annual-meeting-video/environmentally-sustainable-high-volume-eye-care-m.)

The reduction in waste is astounding. Aravind generates 250 grams of waste per phacoemulsification—roughly 5% of the waste generated by the same procedure in the United States.[2] Moreover, an average trabeculectomy with phacoemulsification performed at Aravind produces half the waste of the same procedure performed in the United States—with similar surgical outcomes and complication rates.[3]

1 Namburar S et al. *Am J Ophthalmol Case Rep.* 2018;12:87-90.
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Aravind Eye Hospital

Join Forces

Helping reverse wasteful trends in ophthalmology requires individual effort, but the support of organized medicine is critical for overcoming the larger legal-political challenges. How can you get involved?

Collect data. Clinical research is a critical first step, said Dr. Robin. "We need to show the powers that be as much medical waste data as possible. We need good data on cataract surgeries, glaucoma surgeries, high-volume surgeries of all sorts. Without it, we're powerless."

Cross-specialty collaboration is needed as well, he said. "We need ophthalmologists from all walks of life to come together with infectious disease specialists and epidemiologists to empirically evaluate the efficacy of today's regulations that govern medical waste. The more data [that's available], the more convincing our argument."

Advocate. Will you take up the mantle and be the messenger? "If I were to give one piece of advice for overcoming the regulatory burdens affecting our environment, it would be to get involved in advocacy efforts," said Dr. Pettey. He pointed out that national medical associations, such as the Academy, provide participants with "the loudest voice and the most robust resources for affecting large-scale change when it comes to regulatory burdens that aren't based in valid or sound evidence."

And the power of advocacy is real. Most recently, the Illinois State Medical Society heard the voices of ophthalmologists speaking out against the unnecessary disposal of medications. As a result, the society passed a resolution calling for certain patients in ER, OR, and ASC settings to be able to receive stock supplies of glaucoma drops and other antibiotic and anti-inflammatory medications upon discharge. The next step will involve working with the state department that oversees all Illinois pharmacies to achieve a regulatory change.

A Green Mainstream

It will take time to turn the minds of many, but as Dr. Pettey noted, there's a sense of inevitability when it comes to sustainable health care. "As a member of the Academy's Young Ophthalmologist Committee, I'm witnessing a refreshing [level of] awareness and concern among young physicians. As they become the leaders of tomorrow, I predict green medicine will become a core value for all of ophthalmology."

And in a positive note of change on the biopharmaceutical front, one company, Eyenovia, recently received patents for an innovative drug delivery system that uses piezo-print technology to apply microdroplets of medication to the eye in less than 80 milliseconds, much like an inkjet applies a pixel-sharp amount of ink to paper.[6]

This type of disruptive technology is only going to become more common, said Dr. Robin. And when it does, physicians will really start to take notice of how practicing green ophthalmology and reducing waste is good for patients, the planet, and the bottom line. "As ophthalmologists, we want our patients and our profession to do well. But we have to ask ourselves, 'If we could do better with less, why are we doing worse with more?'"

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6 Pasquale LR et al. *Clin Ophthalmol.* 2018;12:2451-2457.

Meet the Experts

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Jeff H. Pettey, MD Associate professor of ophthalmology, vice chair of education, and medical director of global outreach at the University of Utah's Moran Eye Center in Salt Lake City. *Relevant financial disclosures: None.*

Alan L. Robin, MD Professor of ophthalmology at the University of Michigan in Ann Arbor, associate professor of ophthalmology at the Wilmer Eye Institute in Baltimore, and associate professor of international health at the Johns Hopkins Bloomberg School of Public Health in Baltimore. *Relevant financial disclosures: None.*

Rengaraj Venkatesh, MD Chief medical officer of the Aravind Eye Hospital in Pondicherry, India. *Relevant financial disclosures: None.*

See disclosure key, page 10. **For full disclosures,** view this article at aao.org/eyenet.

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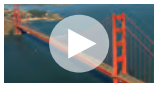

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Coding for Eye Injuries, Part 2: A Bad Day at Work

Despite ophthalmology's best efforts to educate the public about eye safety, you won't have to wait long for the next ocular injury. Get prepared with *EyeNet*'s two-part series on coding for eye injuries featuring a list of CPT codes that only commercial payers use (see Part 1, June), three case studies (one in Part 1, one below, and one online), and web extras (see "More Online").

Case #2: A Bad Day at Work

During his first day on the job at a home improvement store, 18-year-old Blake* cut the metal band around layers of stacked wood. The metal band sprang toward his face, lacerating it from cheek to forehead, including his left eye. Blake's manager drove him to the closest hospital ER. The ER physician closed the skin laceration, packed the left eye with antibiotic ointment, and applied a pressure patch to that eye. Blake was told to see an ophthalmologist "first thing in the morning for severe corneal abrasion."

The next morning, when staff arrived at the practice, Blake and his mother were already at the office door. Blake, who is an established patient at the practice, was in terrible pain and felt nauseated.

Staff action. The technician took Blake to the exam room and, per HIPAA requirements, she asked him if his mother could join them. The technician obtained the name of Blake's employer and manager and gave that information to the front-office staff so they could call for an injury report, as this was a workers' compensation claim. The front-office staff notified scheduled patients that there was an emergency and, if they were unable to wait, offered to reschedule their appointments.

Exam and history. Blake's uncorrected visual acuity (VA) in the right eye was 20/25. In order to obtain the VA of the left eye, she needed to remove the patch. But when she did so, she saw that the eye looked "flat," which made her wonder why a pressure patch had been applied (it was unknown whether the ER doctor had requested an ophthalmology consult). She reclined Blake's chair, instructed him not to touch his face, and immediately got a physician. Seven exam elements were performed, but—because of the trauma—the physician was unable to obtain the other five elements. In such circumstances, credit is still given for those elements (but only if they were considered medically necessary). A mental assessment was performed as the 13th element of the exam. An exam that includes that 13th element is considered comprehensive. The technician had obtained a comprehensive history from Blake. The level of medical decision-making reached the high-complexity threshold.

CPT codes. The practice submitted CPT code 99215–57 for the exam, with modifier –57 indicating that this office visit was used to determine the need for surgery. The practice can also bill CPT code 99058 *Emergency disrupting office hours* (99058 is from a family of codes that can't be used for Medicare or Medicaid, as discussed in Part 1 of this series).

Diagnoses. ICD-10 codes: S05.22XA *Ocular laceration with prolapse or loss of intraocular tissue, left eye, initial encounter* and W22.8XXA *Striking against or struck by other objects, initial encounter.*

Post-op. During the postoperative period, Blake was fitted for a bandage contact lens. The practice billed for this using CPT code 92071 *Fitting of bandage lens* and HCPCS code V2599 *Supply of bandage lens.*

After the eye had healed, Blake was referred to a cornea specialist, as a corneal transplant would eventually be needed. In order to bill a workers' compensation claim for the transplant, that specialist would need a corneal transplant diagnosis plus S05.32XS *Corneal laceration without prolapse or loss of intraocular tissue, left eye*, indicating sequela.

* Patient name is fictitious.

EXTRA **MORE ONLINE.** For case study #3, tips on ICD-10 codes for eye injuries, and a practice checklist, see this article at aao.org/eyenet. Part 1, which discusses CPT codes 99050-99060, is available at aao.org/eyenet/archive.

BY **ANTHONY P. JOHNSON, MD,** AAOE BOARD MEMBER, AND **SUE VICCHRILLI, COT, OCS, OCSR,** ACADEMY DIRECTOR OF CODING AND REIMBURSEMENT.

Stress? Back Pain? Try Yoga Sequences That Are Tailored for Ophthalmology

Each day, ophthalmologists accumulate tension and stress as they lean toward the slit lamp, perform precision surgeries, and deal with patients' complex concerns.

Your job is putting you at risk for musculoskeletal strains that can limit—or even end—your career. Studies have repeatedly underscored just how widespread musculoskeletal disorders are among ophthalmologists. For example:

- Vitreoretinal surgeons spend up to 75% of their time in moderate flexion during indirect procedures; this puts them at risk of spinal pain due to frequent ergonomically unacceptable posture.[1]
- When the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) distributed a survey via its listserv, 73% of the 130 respondents reported discomfort due to operating, and 9% had stopped operating due to pain or neck injury.[2]

Yoga can help you to prolong your career. Camille V. Palma, MD, and Justin L. Gottlieb, MD, have found that yoga can reduce and relieve tension and stress. The two retina specialists practice yoga and breathing exercises regularly, both in the office and outside work. Dr. Palma is in private practice in the Chicago area and Dr. Gottlieb is a professor in the Department of Ophthalmology and Visual Sciences at the University of Wisconsin, Madison.

Yoga for Ophthalmologists

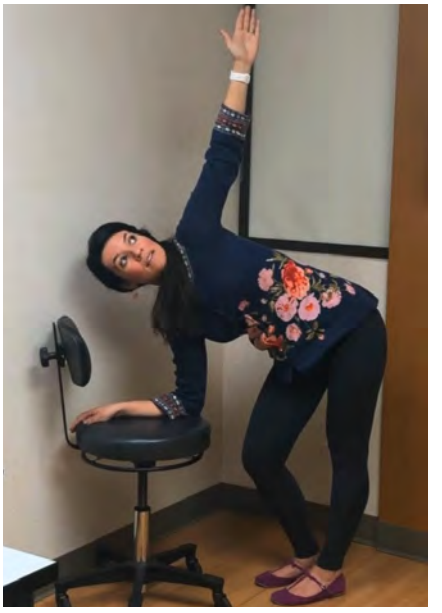
Yoga simultaneously builds flexibility, strength, and balance. Add breathing exercises to reduce stress.

Yoga in practice. Dr. Palma is also a certified yoga instructor (http://yogaeyedoc.com), and she has developed yoga sequences tailored to ophthalmologists' specific physical challenges and work schedules. Doing just one or two postures at a time can boost your physical energy, she said. "You can release muscle tension and clear your mind to prepare for your next patient."

Benefits of some key yoga sequences. Dr. Palma's selection of yoga sequences includes the following:

- **Modified sun salutation** decompresses the lower back and hamstrings; mobilizes and strengthens the spine.
- **Forward fold with spinal twist,** using chair or desk, mobilizes the spine; opens and releases tension in the shoulders and upper back.
- **Side bends to right and left** mobilize the spine; lengthen and strengthen the obliques; and stretch the psoas.
- **Hand and wrist exercises** increase the strength and mobility of the wrists and fingers; helps to prevent arthritis and carpal tunnel syndrome.

Watch online. Dr. Palma demonstrates these sequences and others, including a warm-up sequence, during a short video (see "More Online") that provides a safe and simple way to explore yoga. The sequences can be performed in the exam room in regular work clothes in 1- to 2-minute increments, as needed, during your workday. Or you can do the entire 12-minute session when you arrive at the office or during break time.



Camille V. Palma, MD

STANDING SPINAL TWIST. *Start by placing your right forearm or, if you are a beginner, right hand on a chair. Bend your right knee and keep your left leg straight. Keep your left hip above your left heel. Lengthen through your spine and stretch the left arm up toward the ceiling. Hold for two breaths, then bring your arm down. Repeat using the other side of your body.*

Yoga and Mid-Career Renewal

While it is never too early in your career to incorporate yoga into your working day, Dr. Palma observes that

BY MARY WADE, CONTRIBUTING WRITER, INTERVIEWING **JUSTIN L. GOTTLIEB, MD,** AND **CAMILLE V. PALMA, MD.**

mid-career ophthalmologists may be the most likely to need and benefit from the practice.

Losing that spring in your step? When he turned 50, Dr. Gottlieb took up yoga at his health club. "Basically, I was looking for a way to feel better," he said. "I'd played men's soccer for years but was increasingly sore and worn out after games. I wanted exercise that offered fitness and energy. My wife suggested yoga."

How Dr. Gottlieb got started. Walking into his first Yoga for Athletes class was a bit intimidating, but the teacher and fellow students were welcoming, not judgmental, he said. The teacher set an accepting, realistic tone. As Dr. Gottlieb's core conditioning and energy level increased, he felt stronger and more comfortable at work and in daily life.

Using yoga to unwind. Now, five years later, he goes to class after work several times a week. "I go to the same three classes weekly, and so also enjoy the benefits of a practice community," Dr. Gottlieb said. "By the end of an early evening class, my workday stress is gone."

How Dr. Gottlieb uses yoga at work. Dr. Gottlieb asked his teacher to recommend practices to use at work. She recommended standing (or seated) forward bending, with long, slow inhales and exhales. Dr. Gottlieb added that the breathing aspect is key to releasing tension. He uses this practice often between surgeries and after seeing especially complex patients.

Start Now

"I'd encourage ophthalmologists at any career stage to explore yoga and related mind-body exercises," said Dr. Gottlieb. "If you can, start during your fellowship or residency. Make it a part of your life."

How to find a good studio and teacher. Dr. Gottlieb offered two key recommendations for ophthalmologists who want to explore yoga:

- Find a teacher who offers variations appropriate for beginners and encourages you to make the practice your own.
- Look for a class geared to people with a range of abilities, rather than to 20-something dancer-types.

Dr. Palma added these suggestions:

- Ask your friends and colleagues for recommendations. Online reviews may also be useful.
- Check for free or discounted classes for new students. Most studios offer this option.
- If you dislike your first class, don't get discouraged. Try a different studio or teacher next time.
- Let the teacher know if you're a beginner, and always note any musculoskeletal issues you're having.
- Good teachers give verbal cues for proper alignment in the postures and offer variations for different ability levels.

Find the yoga style that works for you. There are several styles of yoga, ranging from more athletic forms, such as Vinyasa, to forms with a slower, gentler pace, such as Hatha and Yin. Dr. Gottlieb now prefers "flow-style" hot yoga, in which students move rhythmically from one posture to the next in a heated studio. This style stimulates your cardiovascular response and increases flexibility by warming your muscles, he said.

Incorporating yoga into your working day. To build a yoga habit, Dr. Palma recommends picking a regular practice time and sticking with it for at least 30 consecutive workdays. "Continuing for 90 days is even more potent for experiencing the benefits." And in the OR, commit to doing at least one posture between each case, she added.

Never push yourself beyond your physical capabilities. Yoga is about honoring your body. If you find yourself in a class that's too advanced, or if you feel pain in any posture, remember that it is always OK to stop and rest. (Child's pose, also known as Balasana, can be calming and restful, for example.) Starting small and building gradually are key. Be kind and patient with yourself as you discover what works for you, and acknowledge and celebrate each step along the way.

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Dr. Palma is a retina specialist in private practice in the Chicago area. *Financial disclosures: None.* **Dr. Gottlieb** is a professor in the Department of Ophthalmology and Visual Sciences at the University of Wisconsin–Madison. *Financial disclosures: None.*

Posture, Ergonomics, and Aerobic Exercise

Take time at the slit lamp and operating scope to set yourself up properly. Each time you sit down, intentionally check and adjust your posture. Eventually your body will automatically find a neutral spinal alignment. Yoga practice can help you to develop better body awareness.

Stand when you work, as often as possible. Many clinics have adjustable screens and keyboards, so you can stand to use the computer. Inexpensive standing desks can be purchased online. Move more, sit less.

Complement yoga with aerobic exercise. Yoga and other mind-body practices can be balanced with some form of aerobic exercise. Thirty minutes of brisk walking (at a pace that raises your heart rate) several times a week is possible for almost everyone.

For more tips, see aao.org/member-services/individual-wellness.

MORE ONLINE. See this article at aao.org/eyenet to view Dr. Palma's video, in which she demonstrates several yoga sequences that can be performed in the office in regular work clothes. This provides a safe and simple way to explore yoga. For more wellness suggestions, including additional yoga and ergonomics tips, visit aao.org/wellness.

Read "Glaucoma and Exercise" (Clinical Update, March) for advice on yoga poses that glaucoma patients might need to modify or skip altogether (aao.org/eyenet/archives).

Academy Notebook

NEWS • TIPS • RESOURCES

WHAT'S HAPPENING

Grayson W. Armstrong, MD, MPH, Joins AMA Board

On June 8, the American Medical Association (AMA) elected Grayson W. Armstrong, MD, MPH, a resident in ophthalmology at Massachusetts Eye and Ear/Harvard Medical School, to its Board of Trustees Resident and Fellow seat.

"I am honored to be chosen by my colleagues to represent them on the Board of Trustees," said Dr. Armstrong. "The resident and fellow perspective will be vital as health care evolves and medical education shifts to develop young physicians poised to promote the health of the nation."

Dr. Armstrong was an AMA delegate in medical school. He has served as a board member on AMPAC, the AMA's political action committee, and he also serves on the executive committee of the Massachusetts Society of Eye Physicians and Surgeons.

After medical school, Dr. Armstrong pursued a Master of Public Health and went on to advise Jordanian governmental and other organizations regarding the Syrian refugee crisis. He also founded a teleophthalmic medical device company to bring eye exams to patients in remote areas globally.

"Grayson is the first ophthalmologist in a long time to serve on the AMA Board—and the first Academy Member in Training! He is knowledgeable about the issues and the role of the AMA, and he will articulately and passionately reflect the interests of our profession and our patients. We could not be better served," said David W. Parke II, MD.

FOR THE RECORD

Annual Business Meeting

Notice is hereby given that the Annual Business Meeting of the American Academy of Ophthalmology will be held Sunday, Oct. 13, in West 3002 at the Moscone Convention Center in San Francisco, California, from 8:30-10:30 a.m.

Board Nominees

In accordance with Academy bylaws, notice is hereby given of the nominations for elected board positions on the 2020 board. The nominees are listed at aao.org/about/governance/elections.

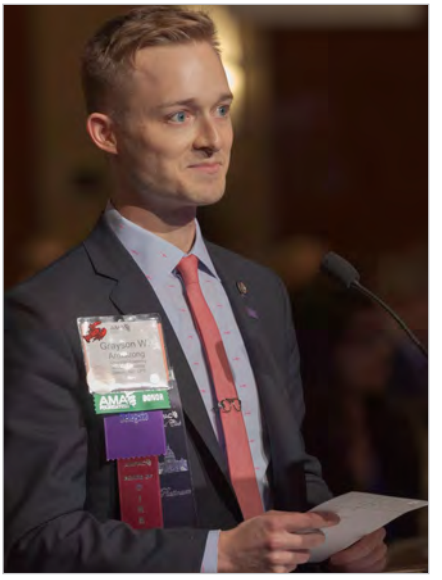
These nominations were made by the Academy Board of Trustees in June. If elected, the individuals will begin their terms on Jan. 1, 2020.

Elections to fill the seven open positions on the 2020 Board of Trustees will take place by ballot after the Oct. 13 Annual Business Meeting.

Additional nominations. To nominate a candidate by petition, submit a written petition to the Academy's CEO no later than Aug. 14. The petition must be signed by at least 50 voting Academy members and fellows.

To suggest a nominee for the 2021 board, watch for the call for nominations that will be published in January's *EyeNet Magazine*.

Read the rules in full at aao.org/about/governance/bylaws/article5.



JOINING THE BOARD. *Dr. Armstrong, newly elected to the AMA Board of Trustees, makes his acceptance speech on June 8 during the AMA Annual House of Delegates 2019 Meeting.*

TAKE NOTICE

Meet the Aug. 1 Deadline for IRIS Registry–EHR Integration

Stressed about the Merit-Based Incentive Payment System (MIPS)? The least onerous way to report quality measures is to integrate your electronic health record (EHR) system with the IRIS Registry. You may do so this year if:

- you registered for IRIS Registry–EHR integration by June 1, 2019, or
- you had previously registered for the IRIS Registry web portal and then notified the IRIS Registry vendor (FIGmd) by June 1, 2019, that you wanted to migrate to IRIS Registry–EHR integration.

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In addition, you need to complete the integration process by Aug. 1, 2019. Meeting this deadline requires that you are actively involved in the process and respond promptly to emails from FIGmd.

The IRIS Registry is your one-stop shop for MIPS reporting. You also can use the IRIS Registry to manually attest to promoting interoperability (PI) measures and improvement activities, and—if you aren't able to report quality via IRIS Registry–EHR integration—manually enter data for quality measures.

Free for members. Why pay fees to your EHR vendor for MIPS reporting and consulting? IRIS Registry is a free benefit for U.S. Academy members.

Learn more at aao.org/iris-registry.

Donate to the Truhlsen-Marmor Museum of the Eye

The generous Academy community has raised three-quarters of the funds needed to launch the Truhlsen-Marmor Museum of the Eye in 2020. Ground has broken on the new space at Academy headquarters, and interactive exhibits are in production. Donate toward the Foundation's $12 million goal at aao.org/museumcampaign.

Advice From OMIC: Responding to Reviews on Social Media

Not all reviews on social media and physician rating sites will be positive. For handling critics online, the Ophthalmic Mutual Insurance Company (OMIC) recommends the following:

- Maintain confidentiality when responding in order to comply with HIPAA. Do not acknowledge that the reviewer is a patient.
- Conduct an internal review of the person's care.
- Determine if the comments violate the website's policies. If they do, ask to have them removed.
- Respond politely to the effect of: "We appreciate the feedback. We take patient satisfaction seriously. In order to protect patients' privacy, we prefer to handle situations like this offline. Please contact our office."
- Reach out to the reviewer privately.
- Develop a written social media policy for your practice so there is a consistent process for responding.

Read more best practices at www.omic.com/social-media-liability.

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

Submit Your Phase 3 Trial Results to *Ophthalmology*

Ophthalmology has established an expedited review and publication pathway for phase 3 clinical trials. Upon acceptance, with author agreement, the manuscript will be posted online within seven days.

Ophthalmology has a 7.47 Impact Factor and a print circulation of 27,000 subscribers. Contact the journal early with plans for submission.

Submit your manuscript by visiting https://www.evise.com/profile/#/OPHTHA/login.

D.C. REPORT

FTC Revises Contact Lens Rules Proposal

The Federal Trade Commission (FTC) has proposed changing the long-standing Contact Lens Rule governing prescriptions and sales. In a departure from the 2015 iteration, the FTC is outlining new pathways for prescribers to confirm prescriptions' release. The pathways are designed to better reflect today's market.

Under the new proposal, confirmation occurs when the patient:

- acknowledges receipt of the contact lens prescription by signing a separate confirmation statement;
- signs a prescriber-retained copy of the prescription that contains a statement confirming they received it;
- signs a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming they received the prescription; or
- is provided with a digital copy of the prescription, and the prescriber retains evidence that it was sent and received or made accessible, downloadable, and printable.

A prescriber would have to keep evidence that it satisfied the Confirmation of Prescription Release requirement for at least three years. The proposal also includes a new exemption for prescribers who do not have a financial interest in lens sales operations. For example, ophthalmologists who do not sell contact lenses would not be subject to these requirements.

Several of the FTC's other proposed changes would place a greater onus on contact lens sellers. These include new parameters for automated telephone verification requests. The FTC is also proposing a 40-hour period for prescribers to issue secondary copies of contact lens prescriptions to patients.

ACADEMY RESOURCES

Find the Right Forms

AAOE has compiled a variety of ophthalmic medical practice documents shared by AAOE members. Accessible through the Practice Forms Library, this collection includes sample forms, policies, checklists, and procedures that can be used for business/financial operations, patient information, examinations, HIPAA, human resources, job descriptions, and practice protocols. All forms are de-identified and can be modified to suit your practice.

The Practice Forms Library is an AAOE member benefit. AAOE will feature new additions in its weekly e-newsletter. For access, visit aao.org/practice-management/practice-forms-library. To contribute, send an email to aaoe@aao.org.

Destination AAO 2019

GET READY FOR SAN FRANCISCO • PART 3 OF 6

REGISTRATION CHANGES. *This year, all AAO 2019 badges must be picked up on-site. Registration counters will be located in all three Moscone Center buildings.*

BEAT THE CLOCK

Register Before Aug. 7 and Save

Register today for AAO 2019, Subspecialty Day meetings, and coding sessions. Aug. 7 is the early registration fee deadline. Registration fees for specific registration categories and ticket fees increase starting Aug. 8.

Find registration information, including pricing, at aao.org/registration.

Reserve Your Hotel Room

Hotel reservations opened June 12 for Academy and AAOE members and June 26 for nonmembers. Group reservations for international attendees are also available.

See map, page 58, or view an interactive map at aao.org/hotels.

Fraud alert! Several companies pretending to be associated with the Academy and AAO 2019 may appear in web searches or may have contacted you via email. These companies claim that they can book hotel rooms and/or register you for the Academy's annual meeting, but they are unaffiliated with the Academy. Make sure that you book only through the Academy's website, which links to AAO 2019's official hotel reservation provider, Expovision.

If you are ever in doubt, email meetings@aao.org or call 415-561-8500.

You can also contact Expovision directly at aaohotels@expovision.com.

PROGRAM

ASORN Joins AAO 2019

As medicine moves toward team-based care, the Academy has invited the American Society of Ophthalmic Registered Nurses (ASORN) to join AAO 2019. Review the ASORN two-day program, taking place on Friday, Oct. 11, and Saturday, Oct. 12, in the Program Search at aao.org/programsearch. Access to ASORN sessions is included with AAO 2019 registration.

Access Program Search

Program Search is an online tool to find course information and abstracts. Look up information by day, topic of event/course, special interest, or presenter. A login is not required to browse the AAO 2019 program.

Ready to build a schedule, or select favorite sessions? Log in on the search page to add items to your calendar. Later, when you log into the Mobile Meeting Guide, your calendar will transfer automatically so you can easily view your schedule in San Francisco.

Visit aao.org/programsearch.

New: Get Meetings on Demand When You Register

New this year, Subspecialty Day meeting attendees will receive complimentary access to Meetings on Demand (MOD) video recordings of presentations from all seven Subspecialty Day meetings. Additionally, purchase of an Academy Plus course pass includes access to the MOD presentations from AAO 2019 and the AAOE Program.

See a list of planned AAO 2019 MOD content at aao.org/annual-meeting/aao-on-demand.

Attendee Badges Are More Sustainable

To make AAO 2019 more environmentally friendly, the Academy will no longer mail badges ahead of the meeting and will discontinue use of plastic

Continued on page 60.

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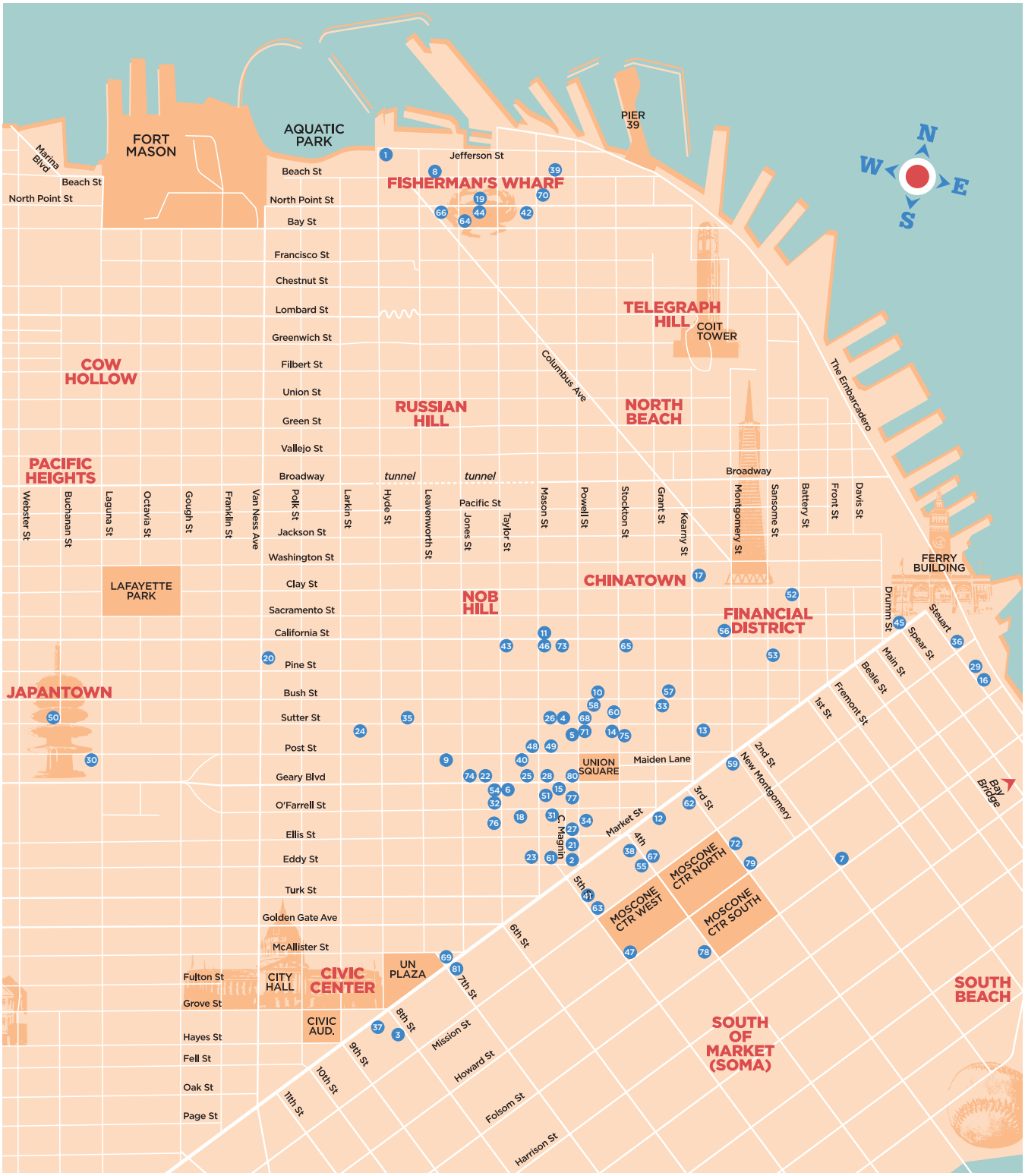
OFFICIAL AAO 2019 HOTELS

Reserve a hotel room for AAO 2019 today. Visit aao.org/hotel for reservations, an interactive map, and information on hotel amenities and availability.

Beware of scams. Fraudulent companies pretending to be associated with the Academy and AAO 2019 may appear in web searches or contact you via email. Only book hotel rooms and registration through the Academy's website and official housing provider, Expovision. If you are ever in doubt, email meetings@aao.org or call 1-415-561-8500 to confirm.



1. Argonaut Hotel
2. Axiom
3. BEI San Francisco
4. Cartwright Hotel Union Square
5. Chancellor Hotel on Union Square
6. Clift Royal Sonesta San Francisco
7. Courtyard San Francisco Downtown
8. Courtyard San Francisco Fisherman's Wharf
9. Courtyard San Francisco Union Square
10. Executive Hotel Vintage Court
11. Fairmont San Francisco
12. Four Seasons Hotel San Francisco
13. Galleria Park Hotel
14. Grand Hyatt San Francisco
15. Handlery Union Square Hotel
16. Harbor Court Hotel
17. Hilton San Francisco Financial District
18. Hilton San Francisco Union Square
19. Holiday Inn Express Fisherman's Wharf
20. Holiday Inn Golden Gateway
21. Hotel Abri
22. Hotel Adagio, Autograph Collection
23. Hotel Bijou
24. Hotel Carlton
25. Hotel Diva
26. Hotel Emblem
27. Hotel Fusion
28. Hotel G
29. Hotel Griffon, a Greystone Hotel
30. Hotel Kabuki
31. Hotel Nikko San Francisco
32. Hotel Spero
33. Hotel Triton
34. Hotel Union Square
35. Hotel Vertigo
36. Hotel Vitale
37. Hotel Whitcomb
38. Hotel Zelos
39. Hotel Zephyr
40. Hotel Zeppelin
41. Hotel Zetta
42. Hotel Zoe
43. Huntington Hotel
44. Hyatt Centric Fisherman's Wharf
45. Hyatt Regency San Francisco
46. InterContinental Mark Hopkins San Francisco
47. InterContinental San Francisco
48. JW Marriott San Francisco
49. Kensington Park Hotel
50. Kimpton Buchanan
51. King George Hotel
52. Le Meridien San Francisco
53. Loews Regency San Francisco
54. Marker San Francisco
55. Mosser Hotel
56. Omni San Francisco
57. Orchard Garden Hotel
58. Orchard Hotel
59. Palace Hotel
60. Palihotel
61. Parc 55 Hotel San Francisco, A Hilton Hotel
62. Park Central San Francisco
63. Pickwick Hotel
64. Pier 2620 Hotel Fisherman's Wharf
65. Ritz-Carlton San Francisco
66. San Francisco Marriott Fisherman's Wharf
67. San Francisco Marriott Marquis
68. San Francisco Marriott Union Square
69. San Francisco Proper Hotel
70. Sheraton Fisherman's Wharf
71. Sir Francis Drake, A Kimpton Hotel
72. St. Regis Hotel
73. Stanford Court Hotel
74. Staypineapple San Francisco
75. Taj Campton Place
76. Tilden Hotel San Francisco
77. Villa Florence San Francisco
78. Virgin Hotels San Francisco
79. W San Francisco
80. Westin St. Francis
81. YOTEL San Francisco (capsule-type rooms)

badge holders. Instead, attendees must pick up their badges onsite.

EVENTS

Your Evening on the Red Carpet Supports Academy Programs

Join the Academy at the Palace Hotel in San Francisco for a glamorous, Hollywood-themed evening on the red carpet. At the Foundation's 16th annual fundraiser, you'll support the Academy's mission to protect sight and empower lives while dining and dancing in the footsteps of presidents and royalty.

See fun moments from last year's Orbital Gala at aao.org/foundation/orbital-photo-recap. **Purchase tickets** at aao.org/foundation.

SUBSPECIALTY DAY

Subspecialty Day Previews: What's Hot

This month, program directors from two Subspecialty Day meetings preview some of this year's highlights. View the schedules at aao.org/programsearch.

OCULOFACIAL PLASTIC SURGERY 2019: A Decade to Remember 2010-2019

Program directors: *Richard C. Allen, MD, PhD, and Jeremiah P. Tao, MD.*
When: *Saturday, Oct. 12 (8:00 a.m.-5:27 p.m.)*

Major changes in the treatment of eyelid, lacrimal, and orbital disease have occurred over the last decade. At this year's Oculofacial Plastic Surgery Subspecialty Day, presenters will limit their discussions to literature from the last 10 years to give the attendees the most up-to-date information.

Cosmetic oculoplastic surgery has undergone significant developments with the skyrocketing use of dermal fillers, botulinum toxin, and skin resurfacing. One session will spotlight how to develop a cosmetic practice building off advances from the last decade.

Innovations in pediatric oculoplastic surgery include the treatment of lacrimal disease and congenital ptosis. Bill R. Katowitz, MD, and Angela M. Dolmetsch, MD, will discuss how endoscopic approaches are now commonplace in the treatment of pediatric lacrimal disease. And Augusto Cruz, MD, will describe his experience with treatment of congenital ptosis using the frontalis flap, which has been gaining popularity. The last decade has also seen major shifts in the treatment of orbital vascular malformations, which will be discussed by Daniel B. Rootman, MD, MSc.

Some of the greatest advances in oculofacial plastic surgery have been in the medical treatment of inflammatory and neoplastic disease. Molecularly targeted agents may very well make surgical treatment of some diseases obsolete. Small molecule inhibitors and monoclonal antibodies now play a major role in the treatment of orbital inflammatory disease (including thyroid eye disease) and eyelid and orbital malignancies. An all-star cast will discuss the use of these newer agents.

This year's meeting will be valuable to both the comprehensive ophthalmologist and the oculofacial plastic surgeon. The program will also have more time for case presentations and discussion related to each session.

The Oculofacial Plastic Surgery meeting is organized in conjunction with the American Society of Ophthalmic Plastic and Reconstructive Surgery.

GLAUCOMA 2019: Crossing the Golden Gate to Exceptional Glaucoma Care

Program directors: *JoAnn A. Giaconi, MD, and Eydie G. Miller-Ellis, MD.*
When: *Saturday, Oct. 10 (8:00 a.m.-5:11 p.m.)*

Based on previous attendee feedback, this year's Glaucoma Subspecialty Day program will feature more open discussions and free-form debates. The program planning committee has been tasked with creating symposia that utilize audience response systems in creative ways, and speakers have been instructed to incorporate cases into their presentations. We are building in opportunities for attendees to directly question our expert panels and for presenters to query attendees about the cases they will be presenting. We hope that Subspecialty Day 2019 will be a very interactive one that keeps everyone engaged throughout the day.

Some highlights to look forward to: presentation of Ocular Hypertension Treatment Study III outcome results by Richard K. Parrish II, MD; results of an IRIS Registry study on racial and demographic differences in the use of minimally invasive glaucoma surgery by Mildred M.G. Olivier, MD; and a session entitled "Evidence and Implications of an IOP-Controlling Aqueous Outflow Pump" by the American Glaucoma Society Subspecialty Day Lecturer, Murray A. Johnstone, MD.

The Glaucoma meeting is organized in conjunction with the American Glaucoma Society.

Participate in the AAO 2019 Meeting Ambassador Program

The Meeting Ambassador Program is designed to provide mentors to international members attending the annual meeting for the first time.

Volunteer. If you are an annual meeting veteran, consider volunteering to be paired with an international ophthalmologist. By acting as a liaison for your partner, you will be helping to make the annual meeting more approachable and, in doing so, fostering inclusion and international connections within the Academy. Sign up to be an ambassador at aao.org/member-services/volunteer/connect/serve-as-meeting-ambassador.

Get an Ambassador. If you are an international member who has never attended an annual meeting with the Academy, it can be overwhelming. With more than 350 instruction courses and dozens of Skills Transfer labs, symposia, and special events to navigate, it helps to have an experienced colleague to provide advice and support. Register for an ambassador at https://www.surveygizmo.com/s3/4815974/AAO2019BuddyRequestForm.

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David F. Chang, MD

CLINICAL PROFESSOR
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

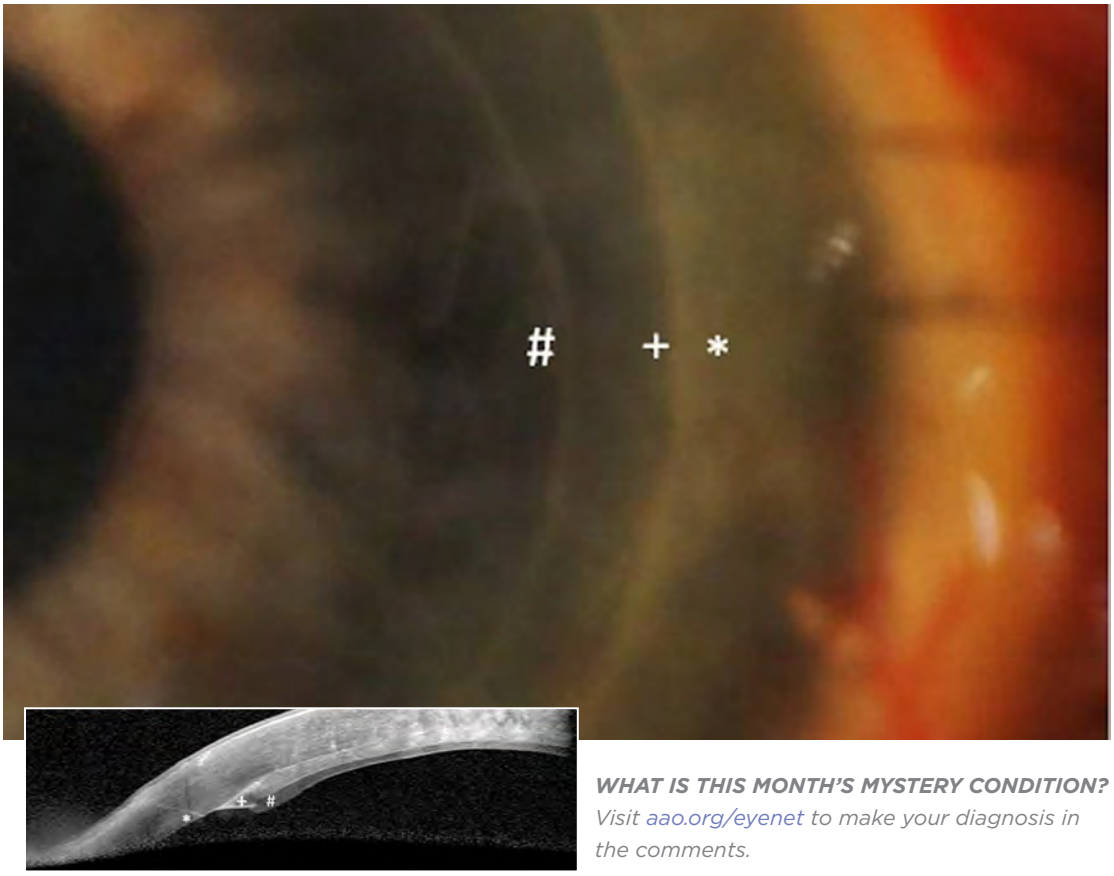
"None appreciate the perils of ophthalmic surgery better than us. Our consequential responsibility is to advocate for patient safety, so that only those with proper training — ophthalmologists — are allowed to operate on this precious, fragile organ. That's why every ophthalmologist should join me in contributing to the Surgical Scope Fund."

Be a Champion for Patient Safety by Supporting the Surgical Scope Fund
When high surgical standards are threatened nationwide, the Academy's Surgical Scope Fund can deliver resources, expertise and winning strategies for protecting patient safety and preserving surgery by surgeons.

Read more of Dr. Chang's thoughts and make your confidential Surgical Scope Fund contribution at aao.org/ssf.

MYSTERY IMAGE

BLINK

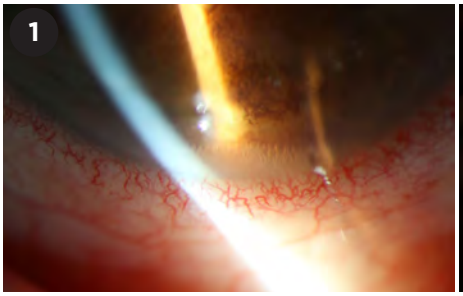


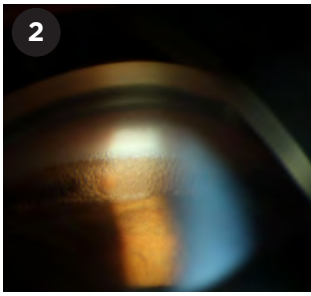
Rony R. Sayegh, MD, University Hospitals Eye Institute, Cleveland, Ohio.

WHAT IS THIS MONTH'S MYSTERY CONDITION?
Visit aao.org/eyenet to make your diagnosis in the comments.

LAST MONTH'S BLINK

Tiny Bubbles: Perfluorocarbon





A 53-year-old man presented with an IOP of 29 mm Hg in his right eye eight months after repair of a rhegmatogenous retinal detachment in the same eye. Residual perfluorocarbon (PFC) bubbles with a characteristic "fish egg" appearance were observed in the inferior angle on slit-lamp exam (Fig. 1) and gonioscopy (Fig. 2). On dilated fundus exam, the patient was noted to have developed asymmetric cupping, with a cup-to-disc ratio of 0.6 in the right eye and 0.4 in the left eye. Optical coherence tomography showed mild thinning of the nasal retinal nerve fiber layer in the right eye only. After a discussion with the patient, we removed the PFC bubbles through a paracentesis without complication. His IOP improved to 14 mm Hg after he began dorzolamide-timolol drops twice daily in the right eye.

Retained PFC in the anterior chamber is a rare but serious cause of elevated IOP after retinal surgery. PFC bubbles not only physically obstruct aqueous outflow through the trabecular meshwork but may also cause toxic damage to the delicate structures of the angle. If PFC collects in the anterior chamber, sustained IOP elevation and glaucomatous optic nerve damage may result.

WRITTEN BY **ATALIE C. THOMPSON, MD, MPH,** AND **SHARON FEKRAT, MD,** DUKE UNIVERSITY MEDICAL CENTER, DURHAM, N.C. PHOTOS BY **JOSEPH HALABIS, OD,** DURHAM DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, DURHAM, N.C.

DO YOU HAVE *ENOUGH* LIFE INSURANCE?

If you passed away unexpectedly, would your family be able to continue on financially? Or would they face drastic changes to their lifestyle—at the worst possible time? The American Academy of Ophthalmology Group Insurance Program can help with:

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Act now to help ensure that your family has the financial security they need—when they need it the most. Visit AAOinsure.com or call 1-888-424-2308 to learn more!*

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INDICATIONS: Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag. **WARNINGS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient. **PRECAUTIONS:** Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 43°C (110°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the enVista IOL Directions for Use. **ADVERSE EVENTS:** As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon transient or persistent glaucoma, and secondary surgical intervention. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. **ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications and important safety information.

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