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Can You Spot These Drug-induced Ocular Effects?

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TECHNOLOGY REPORT

Indicated for the treatment of the signs and symptoms of DED

MIEBO is the first and only Rx eye drop for DED that directly targets evaporation[1]

Inhibits tear evaporation[1-3]*

- Forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce evaporation

Rapid and sustained relief[1]†

- Improvement in tCFS and eye dryness as early as Day 15 continued through Day 57 in 2 pivotal studies

Excellent tolerability[1,4-6]‡

- Low rate of burning or stinging on instillation
- Blurred vision and conjunctival redness were reported in 1%-3% of individuals

***The exact mechanism of action for MIEBO in DED is not known.[1]**

†**Study design:** Two 57-day, multicenter, double-masked, saline-controlled studies (GOBI and MOJAVE) were conducted in adults ≥18 years old with a self-reported history of DED in both eyes. Across GOBI and MOJAVE, 614 patients received MIEBO and 603 patients received control with 591 and 575, respectively, assessed on Day 57. **Primary endpoints were change from baseline in tCFS and change from baseline in eye dryness score at Day 57.** Day 15 was the earliest time point at which signs and symptoms were evaluated in the trials. Day 57 was the last.[1,5,6]

‡In 2 pivotal studies of >1200 patients (614 patients received MIEBO), there were no incidences of serious ocular AEs with MIEBO. Most AEs were considered mild. The discontinuation rate for MIEBO was comparable to control (pooled: 0.2% vs 0.5%; GOBI: 0.3% vs 1.0%; MOJAVE: 0% vs 0%). 0.5% (pooled) of patients experienced instillation site pain AEs, such as burning or stinging (GOBI: 1.0%; MOJAVE: 0%). Blurred vision (pooled: 2.1%; GOBI: 3.0%; MOJAVE: 1.3%) and conjunctival redness (pooled: 0.8%; GOBI: 0%; MOJAVE: 1.3%) were reported in 1%-3% of individuals.[1,4-6]

AE, adverse event; DED, dry eye disease; tCFS, total corneal fluorescein staining.

INDICATION

MIEBO™ (perfluorohexyloctane ophthalmic solution) is a semifluorinated alkane indicated for the treatment of the signs and symptoms of dry eye disease.

IMPORTANT SAFETY INFORMATION

- MIEBO should not be administered while wearing contact lenses. Contact lenses should be removed before use and for at least 30 minutes after administration of MIEBO
- Instruct patients to instill one drop of MIEBO into each eye four times daily
- The safety and efficacy in pediatric patients below the age of 18 have not been established
- The most common ocular adverse reaction was blurred vision (1% to 3% of patients reported blurred vision and conjunctival redness)

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

Please see accompanying Brief Summary of full Prescribing Information for MIEBO.

References: 1. MIEBO. Prescribing Information. Bausch & Lomb, Inc; 2023. **2.** Sheppard JD, Nichols KK. Dry eye disease associated with meibomian gland dysfunction: focus on tear film characteristics and the therapeutic landscape. *Ophthalmol Ther*. 2023;12(3):1397-1418. doi:10.1007/s40123-023-00669-1 **3.** Vittitow J, Kissling R, DeCory H, Borchman D. In vitro inhibition of evaporation with perfluorohexyloctane, an eye drop for dry eye disease. *Curr Ther Res Clin Exp.* 2023;98:100704. doi:10.1016/j.curtheres.2023.100704 **4.** Data on file. Bausch & Lomb, Inc; 2023. **5.** Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for dry eye disease associated with meibomian gland dysfunction: results of the randomized phase 3 GOBI study. *Ophthalmology*. 2023;130(5):516-524. doi:10.1016/j.ophtha.2022.12.021 **6.** Sheppard JD, Kurata F, Epitropoulos AT, Krösser S, Vittitow JL; MOJAVE Study Group. NOV03 for signs and symptoms of dry eye disease associated with meibomian gland dysfunction: the randomized phase 3 MOJAVE study. *Am J Ophthalmol*. 2023;252:265-274. doi:10.1016/j.ajo.2023.03.008

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Learn more at MIEBO-ECP.COM

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use MIEBO safely and effectively. See full Prescribing Information for MIEBO.

MIEBO™ (perfluorohexyloctane ophthalmic solution), for topical ophthalmic use

Initial U.S. Approval: 2023

1 INDICATIONS AND USAGE

MIEBO™ (perfluorohexyloctane ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

MIEBO should not be administered while wearing contact lenses. Advise patients that contact lenses should be removed prior to and for at least 30 minutes after administration of MIEBO.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

In patients with DED, 614 patients received at least one dose of MIEBO in two randomized controlled clinical trials across 68 sites in the United States. The most common ocular adverse reaction was blurred vision. Blurred vision and conjunctival redness were reported in 1-3% of individuals.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well controlled studies with MIEBO in pregnant women.

In animal reproduction studies with oral administration of perfluorohexyloctane during the period of organogenesis, no adverse maternal or developmental effects were observed in rats at doses up to 162 times the recommended human ophthalmic dose (RHOD) (*see Data*). Maternal toxicity, miscarriages and reduced fetal weights were observed in rabbits at all doses tested, with the lowest dose as 41 times the RHOD.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies.

Data

Animal Data

An embryofetal study was conducted in pregnant rabbits administered perfluorohexyloctane by oral gavage on gestation days 6 to 19, to target the period of organogenesis.

Perfluorohexyloctane produced maternal toxicity, characterized by reduced body weight gain and food consumption, and miscarriages at all doses tested, with the lowest dose as ≥ 250 mg/kg/day (41 times the RHOD based on body surface area). Reduced fetal weights were also observed at ≥ 250 mg/kg/day but no fetal mortality or malformations. A no observed adverse effect level (NOAEL) for maternal toxicity was not established in rabbits.

An embryofetal study was conducted in pregnant rats administered perfluorohexyloctane by oral gavage on gestation days 6 to 17, to target the period of organogenesis. There was no evidence of embryofetal toxicity or teratogenicity at doses up to 2,000 mg/kg/day (162 times the RHOD).

8.2 Lactation

There are no data on the presence of perfluorohexyloctane in human milk, the effects on the breastfed infant, or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of MIEBO to an infant during lactation; however, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MIEBO.

8.4 Pediatric Use

The safety and effectiveness of MIEBO in pediatric patients below the age of 18 years have not been established.

8.5 Geriatric Use

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

12 CLINICAL PHARMACOLOGY

12.3 Pharmacokinetics

The pharmacokinetics of perfluorohexyloctane following topical ocular administration of MIEBO has not been quantitatively characterized in humans. A single pharmacokinetic (PK) study was conducted that showed low systemic perfluorohexyloctane blood levels after topical ocular administration. Perfluorohexyloctane was not metabolized by human liver microsomes in vitro.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been conducted to evaluate the carcinogenic potential of perfluorohexyloctane.

Perfluorohexyloctane was not mutagenic or clastogenic in a standard battery of genotoxicity tests, including a bacterial mutagenicity assay (Ames assay), an in vitro chromosome aberration assay using human peripheral lymphocytes, and an in vivo bone marrow micronucleus assay in rats.

17 PATIENT COUNSELING INFORMATION

Use with Contact Lenses

Advise patients that contact lenses should be removed prior to and for at least 30 minutes after administration of MIEBO.

Administration Instructions

Advise patients to instill one drop of MIEBO four times daily into each eye as depicted in the Administration Instructions.

Distributed by:

Bausch & Lomb Americas Inc. Bridgewater, NJ 08807 USA

Patented. See https://patents.bausch.com for US patent information.

MBO.0046.USA.23 Issued: 5/2023

Misleading Study Overstates Ophthalmology Access, Undercounts ODs

In an attempt to demonstrate parity between the professions, researchers included only CMS-enrolled providers—excluding one-third of practicing optometrists—and ignored the influence of MD subspecialization and appointment availability.

Two ophthalmologists recently conducted an analysis of geographic access to eye care across the United States, as travel burden of eyecare is commonly cited as a reason for optometric scope expansion. The results purport to show that almost all Americans live within an hour's drive to both an ophthalmologist and optometrist. However, a flawed research design undermines the validity of these claims; in addition to misrepresenting the number of optometrists in practice across the country, the study also neglected various factors aside from drive time that influence access to care.

The most glaring methodological flaw in this research, according to Richard Edlow, OD, known as "The Eyeconomist," is its reliance on data from providers enrolled in the Doctors and Clinicians National File from the Centers for Medicare & Medicaid Services (CMS) and the assumption that this is an accurate accounting of eyecare professionals in the US. In total, the study geocoded locations for 17,417 ophthalmologists (30,770 addresses) and 33,291 optometrists (46,099 addresses).

"While 17,417 ophthalmologists is a pretty accurate estimate (my data tracking indicates 17,312), the number of optometrists in the US is grossly incorrect," comments Dr. Edlow. "There are, in fact, 49,360 practicing optometrists in the country with only 33,291 misleadingly utilized in the study. The authors failed to understand that, as many optometrists are the nation's front line of primary eye care, not all are participating providers with CMS/Medicare." He points out that "this failure missed out on 16,069 practicing optometrists around the country, or roughly one-third of all ODs."

Photo: Getty Images

Among CMS-enrolled providers, there are currently 52.60 ophthalmologists and 100.55 optometrists per million Americans. However, when including those not enrolled with Medicare, the actual number of practicing ODs is much higher.

Keeping this caveat in mind, the present analysis showed that, among CMS-enrolled providers, there are roughly 52.60 ophthalmologists and 100.55 optometrists per million Americans, with variations between states. The researchers claimed in their paper for *Ophthalmology*, "An estimated 74.94%, 90.78% and 97.80% of Americans reside within 15, 30 and 60 minutes of an ophthalmologist, respectively; for optometry, the corresponding proportions are 84.52%, 95.16% and 98.54%." While the figures for one-hour access to MDs and ODs are nearly equivalent (97.8% vs. 98.5%) even with the undercounting of optometrists, those for the shorter commutes surely underrepresent access to optometry, as the study omits one-third of the profession.

The researchers identified 212 counties (6.74%) with >50% of their population living within an hour of a CMS-participating optometrist but not an ophthalmologist, while just eight counties (0.25%) are within an hour of an ophthalmologist but not an optometrist. In 166 counties (5.28%), most residents live beyond 60 minutes of either provider type.

At face value, these results give the impression that geographic eyecare accessibility is a marginal issue pertinent only to select US regions; however, it's important to recognize the many factors this study excluded that affect patients' ability to receive timely care. One, Dr. Edlow points out, is eyecare subspecialization. "This is significant, as initial access to the eyecare system is rarely, if ever, initiated in a subspecialist's office," he says. "By my count, in 2024, utilizing membership in the subspecialty organizations, there are approximately 5,000 subspecialty ophthalmologists, leaving just over 12,200 as general ophthalmologists." Dr. Edlow argues, "The study would have been best served using the number of ophthalmologists at 12,200 and optometrists at 49,300, resulting in a significantly different conclusion."

In other words, access does not equal appropriateness. Proximity to a glaucoma surgeon is of little use to an AMD patient needing anti-VEGF injections or a 10-year-old needing glasses.

The "Eyeconomist" also points out that the study's measurement for access to care—drive time—doesn't speak to the availability of those providers. He suggests "future studies include a significant sampling of next available appointment time by doctor and location."

Finally, Dr. Edlow argues that "the study is looking in the rear-view mirror" by failing to consider the dwindling ophthalmology workforce amidst a growing demand for care. "To truly consider public health issues and access to care, one must be forward-thinking," he states. "The supply of ophthalmologists is increasing, at best, by 0.4% per year while the demand for age-related eye care is increasing by 3.0% per year. Every year moving forward will result in decreased access to ophthalmologists in the US."

If there's one aspect of this research suitable to real-world circumstances, it may be the spotlighting of commonalities between regions where eyecare access still falls short. Two demographic factors associated with reduced access were ethnic homogeneity and socioeconomic status. "[Census] tracts with greater racial and ethnic homogeneity and higher proportions of Medicare-aged and uninsured residents demonstrate higher odds of reduced geographic access (*i.e.*, >60min travel time) to both ophthalmic and optometric care," the researchers wrote. "Moreover, tracts with a greater proportion of college-educated residents exhibit lower odds of reduced access to both eyecare provider types."

In their paper, the study authors posit that their results "are not evidence in favor of optometric scope of practice expansion," a viewpoint that is inherently flawed considering the study's underrepresentation of optometrists and use of drive time as the sole measure of accessibility. They go on assert without evidence that, compared to optometrists, ophthalmologists "may yield improved outcomes" in the surgical management of various eye diseases. However, a study published in July in *Clinical and Experimental Optometry* undercuts this claim, reporting a complication rate of just 0.001% for optometrist-performed laser and minor surgical procedures.

In conclusion, the researchers propose that this data may be used to "direct geographically targeted initiatives such as hospital system-backed mobile health efforts or county-sponsored incentives for practice establishment in underserved areas." One could argue that an entirely new study—which includes an accurate count of ODs and MDs and considers other aspects of accessibility—is necessary to truly assess the state of geographic eyecare access in the US.

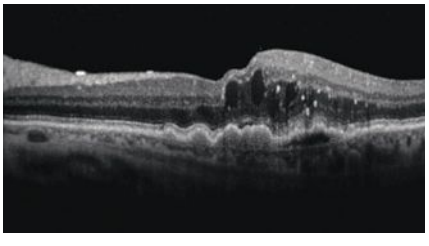
Franco JJ, Pineda R II. Geographic access to eye care in the United States. Ophthalmology. August 5, 2024. [Epub ahead of print].

Some Blood Thinners May Increase Conversion to Wet AMD

The body is an interconnected system and, as clinicians know, side effects from one treatment may wreak havoc in other areas of the body. A recent study in *Ophthalmology* highlighted the delicate balancing act of medication management for the prevention of life-threatening cardiac events and sight-threatening diseases when it reported that warfarin significantly increased the risk of conversion to neovascular AMD.

A newer class of blood thinners called direct oral anticoagulants (DOACs) have proven superior in several studies compared with traditional warfarin and are preferred first-line agents for stroke prevention in certain cases. However, all anticoagulants are associated with bleeding risks, and DOACs' intraocular complications aren't clear yet.

Researchers recently sought to understand the risks in patients with higher bleeding risk such as those with AMD. Their study included patients with non-neovascular AMD initiated on DOACs (n=20,300) or warfarin (n=13,387). The researchers found that at six months and at one year, patients treated with warfarin had a higher risk of developing nAMD vs. those treated with DOACs. They also reported that warfarin-treated patients had an increased risk of requiring anti-VEGF and pars plana vitrectomy.



Communicate with patients' comanaging doctors to adjust needed meds. Four direct oral anticoagulants are approved for atrial fibrillation and venous thromboembolism: apixaban (Eliquis), dabigatran (Pradaxa), edoxaban (Savaysa) and rivaroxaban (Xarelto).

Patients with AMD and atrial fibrillation also had an increased risk of ocular complications and need for anti-VEGF therapy over five years.

Based on the real-world study findings, the researchers wrote that patients with non-neovascular AMD on warfarin are at an increased risk for developing ocular complications such as neovascular disease, macular hemorrhage and vitreous hemorrhage, and are more likely to require anti-VEGF therapy or surgical vitrectomy than patients on DOACs.

They concluded that "switching oral anticoagulation from warfarin to select FDA-approved DOACs in patients with subsequent nAMD or history of nAMD must be considered carefully, given the improved bleeding profile highlighted in the present study."

Alsoudi AF, Koo E, Wai K, et al. Risk of ocular neovascular conversion and systemic bleeding complications in patients with AMD on DOACs or warfarin. Ophthalmology. 2024. [Epub ahead of print].

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GLP-1s May Protect Against Glaucoma in Type 2 Diabetes

Compared to metformin, these agents conferred a significantly lower incidence of POAG, ocular hypertension and need for first-line treatments.

Glucagon-like peptide-1 (GLP-1) receptor agonists are rapidly increasing in use across the US to treat type 2 diabetes and obesity. Preliminary research indicates these drugs may offer a protective benefit against glaucoma development through their neuroprotective and anti-inflammatory effects. "These agents have the potential to reduce oxidative stress and enhance cellular survival pathways, which could lower IOP and safeguard retinal ganglion cells," wrote the authors of a recent study in *Ophthalmology* that compared the effectiveness of GLP-1 receptor agonists with metformin as primary treatments in preventing glaucoma.

Using data from 120 healthcare organizations across 17 countries, researchers compared the risk of primary open-angle glaucoma (POAG), ocular hypertension and the need for primary treatments (eye drops and laser trabeculoplasty) in patients on GLP-1 agonists vs. metformin.

After propensity score matching, both groups (GLP-1s vs. metformin) included 61,998 patients at the one-year follow-up, 27,414 at the two-year follow-up and 14,100 at the three-year follow-up. Patients using GLP-1 receptor agonists showed a significantly lower risk of POAG vs. those treated with metformin, with risk reductions of 41% at one year, 50% at two years and 41% at three years.

GLP-1 agonists also showed similar protective effects for ocular hypertension, with a 56% risk reduction at one year, 57% at two years and 49% at three years. The likelihood of needing first-line glaucoma treatments was also lower among those on GLP-1 agonists, with reductions of 37% at one year, 29% at two years and 25% at three years.

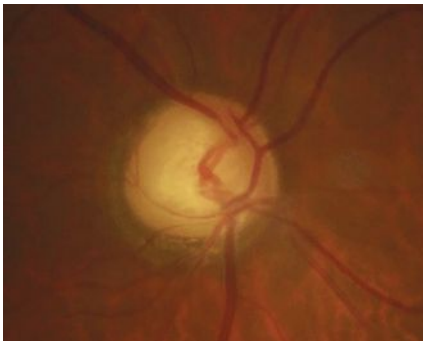


Photo: Justin Cole, OD, and Jarett Mazzarella, OD

In the first three years of therapy, GLP-1 agonists demonstrate a neuroprotective benefit and potential IOP-lowering effects among patients with type 2 diabetes.

"These findings underscore the potential of GLP-1 receptor agonists not only in glycemic control but also in mitigating glaucoma risk," the study authors wrote. "Prior investigations provide compelling insights into the neuroprotective properties of GLP-1 receptor agonists. These agents are shown to reduce inflammation and oxidative stress by downregulating C1q, TNF-α and IL-1α, which are key contributors to neurodegenerative processes in the retina and optic nerve," the authors wrote. Additionally, they "improve neuronal survival and function by activating signaling pathways that enhance cellular resilience and reduce apoptotic cell death." GLP-1 meds also reduce inflammatory responses in the retina by lowering production of proinflammatory cytokines, thus safeguarding retinal ganglion cells from degeneration.

The observed protective effect of GLP-1 agonists against ocular hypertension also demonstrates their proposed IOP-lowering effect. "A recent study showed that GLP-1 receptor agonists, such as semaglutide and liraglutide, were significantly associated with a decrease in IOP, particularly in glaucomatous eyes," the researchers noted. Furthermore, another study "demonstrated a reduced incidence of idiopathic intracranial hypertension in patients treated with GLP-1 receptor agonists," they pointed out.

It's also possible improved diabetes management itself may lower glaucoma risk. This couldn't be evaluated in the present study, but the researchers cited existing literature indicating "poor glycemic control is a significant risk factor for glaucoma development due to the microvascular and neurodegenerative damage from chronic hyperglycemia."

Finally, weight reduction may play a role in the protective effect of GLP-1 agonists against glaucoma, as studies have linked a lower BMI to decreased IOP.

While studies on the ocular effects of these agents are ongoing, the researchers concluded that these insights "highlight the potential ocular benefits of GLP-1 receptor agonists and their expanding role in the clinical management of diabetic patients."

Muayad J, Loya A, Hussain ZS, et al. Comparative effects of GLP-1 receptor agonists and metformin on glaucoma risk in type 2 diabetes patients. Ophthalmology. August 22, 2024. [Epub ahead of print].

IN BRIEF

Study Sheds Light on Post-surgery Positioning for Macular Hole. Following a gas tamponade for macular hole repair, patients are often advised to undergo face-down positioning (FDP) in order to encourage apposition and healing. To investigate if this post-surgery posture is really necessary for successful outcomes, researchers conducted a meta-analysis of five randomized trials (n=379 eyes) that compared FDP to no FDP in adults who had undergone vitrectomy with gas tamponade for idiopathic full-thickness macular hole repair.

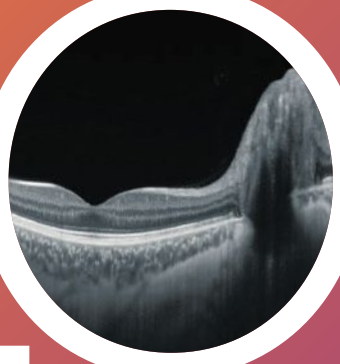
The results demonstrated that **15 patients would need to undergo FDP for three to 10 days for one to have an additional hole closure over no posturing.** The FDP group had a mean improvement in post-op visual acuity (-0.08 logMAR) vs. the no FDP group.

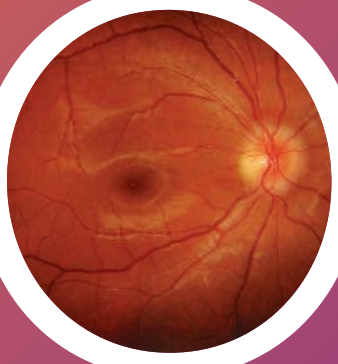
The researchers also noted in their paper that patients with larger holes of minimum linear diameter ≥400µm had more certain benefits from FDP. Each additional day of FDP (plateauing at 13 days) was also associated with improved chances of anatomical success and improvement in vision.

"Considering the generally safe and straightforward nature of this intervention, we recommend considering FDP for full-thickness macular holes larger than 400µm, with a minimum of three days posturing, pending further research," the study authors concluded in their paper.

Raimondi R, Tzoumas N, Toh S, et al. Facedown positioning in macular hole surgery: a systematic review and individual participant data meta-analysis. Ophthalmology. 2024. [Epub ahead of print].

Take a closer LOOK





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Study Finds Long-term Benefits of VT for Convergence Insufficiency Sustained

A recent study of children with convergence insufficiency demonstrated that improvements in the near point of convergence (NPC) and positive fusional vergence (PFV) measurements following office-based vergence/accommodative therapy were maintained one year after treatment completion.

The Convergence Insufficiency Treatment Trial-Attention and Reading Trial (CITT-ART) enrolled 310 children between nine and 14 years old with symptomatic convergence insufficiency. Eligible participants were randomized 2:1 to vergence/accommodative therapy or placebo therapy, respectively. Patients in the vergence/accommodative therapy group underwent a 16-week program of weekly 60-minute sessions of office-based therapy; home reinforcement therapy was also prescribed.

Among enrolled patients, 303 kids completed their 16-week primary outcome visit. Of the 121 patients who returned for their one-year follow-up visit—and had not received any additional treatment since the 16-week primary outcome visit—the data showed no significant change in the mean adjusted NPC at one year. A statistically significant decrease was observed in mean-adjusted PFV. "There were similar percentages of participants classified as 'normal,' 'normal and/or improved' and 'normal and improved' based on NPC and PFV at the one-year visit compared with the 16-week primary outcome visit."

The researchers found that 92% of children who underwent treatment for convergence insufficiency had a normal or improved near point of convergence one year following the completion of office-based vergence/accommodative therapy, according to findings reported in *Ophthalmic and Physiological Optics*. Additionally, 91% of children still had normal and/or improved fusional convergence one-year post-therapy.

"Improvements in NPC and PFV were maintained in children with convergence insufficiency who were randomized to vergence/accommodative therapy in the CITT-ART study, completed both the primary outcome and one-year follow-up visits and reported receiving no additional treatment during the one-year interval," the study authors concluded.

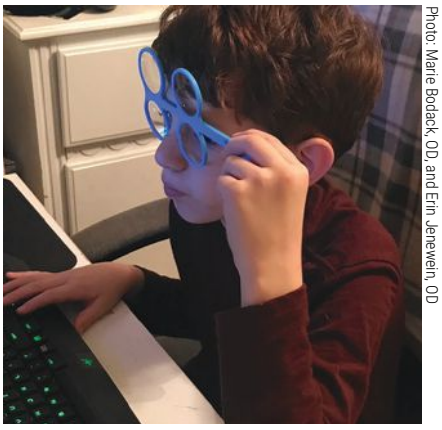

Photo: Marie Bodack, OD, and Erin Jenewein, OD

Children with symptomatic convergence maintained improvements in NPC and PFV one-year after completing 16 weeks of vergence/ accommodative therapy.

Morrison AM, Kulp MT, Cotter SA, et al. One-year follow-up of clinical convergence measures in children enrolled in the Convergence Insufficiency Treatment Trial—Attention and Reading Trial. Ophthalmic Physiol Opt. August 14, 2024. [Epub ahead of print].

Most RVO Patients with Good Initial Vision Maintain It

A recent analysis of patients with retinal vein occlusion (RVO) and initial visual acuity better than 6/12 indicates most individuals sustained good VA. These findings, recently published in the journal *Retina*, also showed that anti-VEGF treatment maintained and improved VA in these patients.

"This study aimed to evaluate functional and anatomical outcomes of intravitreal treatment and observation in patients with cystoid macular edema (CME) due to RVO, who presented with good initial VA," the researchers wrote.

This multicenter, retrospective cohort study included 79 eyes of 79 patients with CME secondary to RVO and initial VA better than 6/12. Study participants were either treated with anti-VEGF therapy or observed.

Data showed that 53% of patients maintained VA at month 12. The study authors reported that VA of 6/6 - 6/7.5 was maintained in 59% and 57% of patients at 12 and 24 months, respectively. At 24 months, a strong correlation was observed between anti-VEGF injections and VA among patients with branch RVO (BRVO) and central RVO (CRVO).

"This study marks the first exploration of patients with vein occlusions and good initial visual acuity better than 6/12, indicating that most patients maintained good VA, and anti-VEGF treatment notably maintained and improved VA," the study authors noted in their paper.

"These findings support our recommendation to closely monitor and consider treatment in patients with macular edema due to RVO and good visual acuity," they concluded.

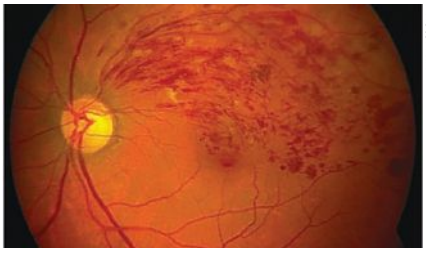

Photo: NIH

In this analysis of patients with CME due to RVO and initial good VA, the majority of participants received intravitreal therapy and maintained good VA over two years.

Gomel N, D'Aloisio R, Wattad A, et al. Good initial visual acuity in patients with macular edema due to retinal vein occlusion- management and outcomes. Retina. August 9, 2024. [Epub ahead of print].

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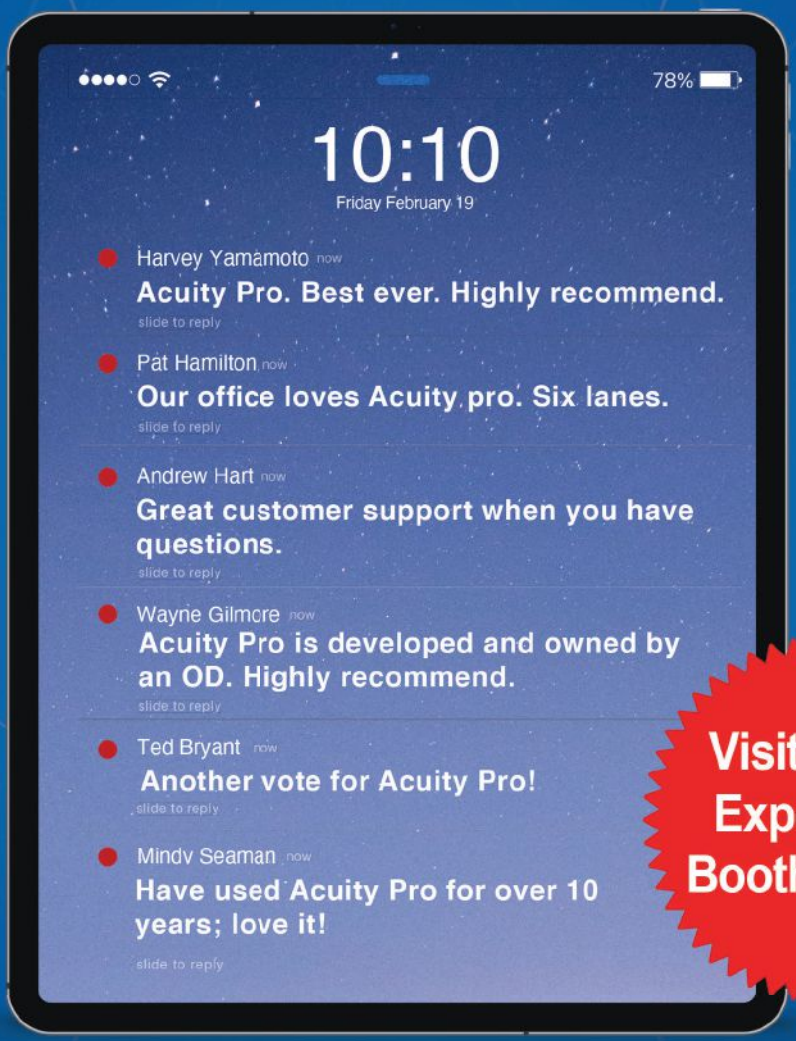

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Different Factors Affect Cataract Likelihood in Men and Women

A team of researchers pulled participants from the UK Biobank database to explore potential sex differences in the relationships between key social, lifestyle and physical health risk factors and incidence of cataracts between men and women. Results were recently published in the journal *Eye*.

The UK Biobank is a prospective cohort study of over 500,000 people aged 40 to 69 living in the UK, who were recruited between 2006 and 2010. Of these, 117,972 individuals had no preexisting eye diseases. Cataract was diagnosed in 4,172 people; per 10,000 person-years, crude incidence rate was 35.1 in women and 29.2 in men. Cataract incidence increased in both men and women with factors of Asian or Black ethnicity, smoking status, obesity, diabetes and myopia. In men, those who consumed alcohol or were unemployed had greater risk when compared to women. Conversely, women who had a high socioeconomic status, elevated blood pressure or metabolic syndrome had greater cataract risk than men.

At baseline, women were found to maintain healthier lifestyle habits and physical conditions. The greater risk of cataract in men with unemployment status was a 47% increased likelihood and 35% elevated risk with current alcohol consumption. Among women, elevated blood pressure resulted in a 63% higher risk of cataract and a 36% higher risk with metabolic syndrome.

The authors also found that employment status reduced cataract risk in men. Socioeconomic status was also a key factor, with high status in men reducing cataract risk but women facing 31% increased risk of developing cataract with high status. Potential reasons for this may be inaccessibility to relative medical services and knowledge. Higher education in both sexes correlated with decreased risk and ethnicity affected cataract risk equally among both sexes.

Lifestyle factors were also studied and can be modifiable contributors in prevention. The difference in risk seen between men and women related to alcohol consumption may be due to alcohol type, drinking frequency and duration as well as presence of antioxidants in alcoholic beverages. Smoking consistently impacted both sexes negatively in terms of risk. In their paper, the authors relay that "our study reveals similarities and differences in the impact of lifestyle on the incidence of cataract in different sexes, and further calls for people to cultivate good lifestyle habits to reduce the risk of cataracts."

Photo: Gleb Sukhovolskiy, OD

Research has associated obesity with greater cataract risk, but the current study revealed a U-shaped relationship between BMI and cataract risk only in women.

Xu Y, Liang A, Zheng X, et al. Sex-specific social, lifestyle, and physical health risk factors in cataracts development. Eye (Lond). July 29, 2024. [Epub ahead of print].

Lower BP Linked to Faster Glaucoma Progression Rate

Although IOP is the most important modifiable characteristic in glaucoma, the condition can still exist in those with "normal" IOPs, suggesting mechanisms not dependent on IOP also affect optic nerve injury. These may include impaired optic nerve perfusion due to impaired blood flow autoregulation which may be exacerbated by systemic arterial hypotension. Consequently, researchers wanted to examine the relationship between systemic arterial blood pressure and the rate of change in standard automated perimetry (SAP) in glaucomatous eyes and suspects. The prospective study in *Ophthalmology* included 124 eyes (91 glaucoma; 33 suspects) of 64 patients at the Bascom Palmer Eye Institute; mean age was 68.4 years.

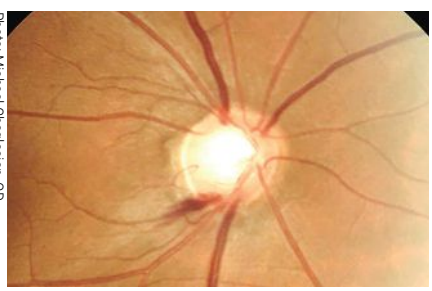

Photo: Michael Chaglasian, OD

Since office-based BP measurement cannot accurately identify the lowest values obtainable using 24-hour BP recording, researchers argue for the latter's use in those at risk of glaucoma progression, particularly those with disc hemorrhage.

On average, eyes had 8.9 SAP exams over 28.3 months of follow-up. Median mean deviation (MD) change rate was 0.14dB/year with 7% presenting moderate to fast progression, defined as MD change ≤-0.50dB/year. Each 10mm Hg lower in 24-hour mean arterial pressure and systolic BP was linked with -0.17dB/year and -0.14dB/year faster rates of mean deviation loss. Mean deviation loss was also associated with lower mean systolic BP.

"We can speculate that glaucomatous eyes with progression at low IOP levels may have a non-IOP dependent mechanism of disease progression and thus would benefit from 24-hour [BP monitoring] to determine if they have vascular risk factors for progression such as low mean arterial pressure or systolic BP," the researchers wrote in their paper.

They go on to say that eyes with optic disc hemorrhage may also benefit from adjunctive 24-hour BP monitoring. "Finally, patients with a history of low systemic BP, or those in whom an office-based BP reading demonstrates low BP, may benefit from such testing given the risk for future fast progression."

Donkor R, Jammal AA, Greenfield DS. Relationship between blood pressure and rates of glaucomatous visual field progression: The Vascular Imaging in Glaucoma Study. Ophthalmology. August 5, 2024. [Epub ahead of print].

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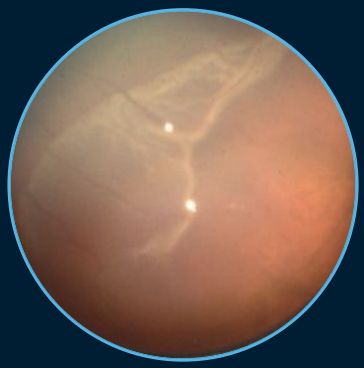

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Check Hyporeflective Band to Differentiate AMD from Aging

Within the RPE basal lamina/Bruch's membrane complex, the ETDRS inner ring was the most sensitive location to detect structural changes in both scenarios with prototype hi-res SD-OCT.

Investigating new imaging and functional biomarkers is critical for evaluating potential therapeutic targets and understanding AMD pathogenesis and progression. The risk for progression is highly concentrated within the 3mm-diameter macula lutea, captured by the grading grid of the Early Treatment of Diabetic Retinopathy Study (ETDRS). Therefore, topographic measurement for understanding AMD pathogenesis and progression now has new importance.

In a recent study, researchers from the Massachusetts Institute of Technology in Cambridge and Tufts University in Boston explored the topographic relationship of the hyporeflective band thickness within the ETDRS grid in normal aging and AMD to determine associations with other imaging or functional biomarkers. They observed ETDRS grid-dependent age-associated differences in the hyporeflective band vi, particularly decreasing band thickness in the inner ring with aging. They noted a statistically significant thickness difference between normal older eyes and early AMD eyes throughout the central 4.2mm diameter, with higher statistical power within the 3mm diameter ETDRS circle.

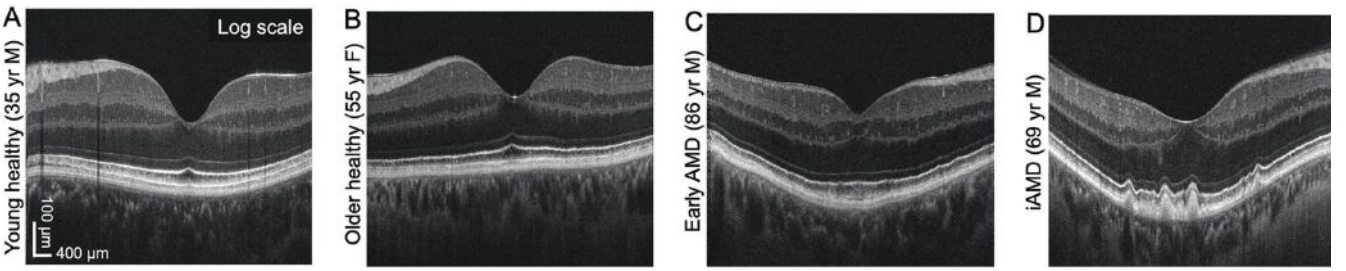
The researchers measured hyporeflective band topography with a high-resolution prototype OCT using isotropic volume raster scanning combined with computational motion correction and volume fusion, as well as a custom-designed neural network. The team analyzed 90 normal eyes from 76 individuals (ages 23 to 90 years) and 53 dry AMD eyes from 47 patients (ages 62 to 91 years). Eyes from subjects with diabetes without clinical retinopathy (31%) were included in the normal group.

The hyporeflective band thickness map (median of 4.3µm and 7.8µm in normal and AMD eyes, respectively) was thicker below and radially symmetric around the fovea. In normal eyes, age-associated differences occurred within 0.7mm to 2.3mm from the foveal center. In AMD eyes, the hyporeflective band was hypothesized to be basal laminar deposits and was thicker within the 3mm ETDRS circle compared with normal eyes. The inner ring was the most sensitive location to detect age vs. AMD-associated changes within the RPE basal lamina/Bruch's membrane complex. AMD eyes with subretinal drusenoid deposits had a thicker hyporeflective band than those without this finding.

"Finer delineation of outer retinal bands will be critical to resolving age-associated changes in RPE cells, photoreceptor outer segments contacting RPE apical processes and deposits between the RPE basal lamina and Bruch's membrane," the researchers wrote in their paper, which was published in *Investigative Ophthalmology & Visual Science*.

"Topographic measurement of the hyporeflective band within the RPE basal lamina-Bruch's membrane complex is candidate for an early structural biomarker that may also be associated with rod vision impairment at 3º to 5º, the earliest functional biomarker in AMD," they suggested.

Won J, Takahashi H, Ploner SB, et al. Topographic measurement of the subretinal pigment epithelium space in normal aging and age-related macular degeneration using high-resolution OCT. Invest Ophthalmol Vis Sci. 2024;65(10):18.



This set of photos from the study shows B-scan visualizations of hyporeflective band vi thickness in normal aging and AMD.

(Images from Won J, et al. Invest Ophthalmol Vis Sci. 2024;65(10):18 used per Creative Commons 4.0 license.)

IN BRIEF

Hormone Therapy in Postmenopausal Women Linked with Later Glaucoma Diagnosis. A recent retrospective study investigated ways in which estrogen may aid in delaying development of open-angle glaucoma. Their goal was to observe the association between hormonal therapy (HT) use and glaucoma diagnosis onset in postmenopausal women. Included were veteran women with OAG from VA records spanning nine years. HT users accounted for 1,926 individuals while 1,026 untreated women served as controls.

Researchers found **a linear relationship between age of glaucoma diagnosis and menopause in women with and without using HT;** however, users typically had a later glaucoma diagnosis. At zero to two years, two to five years and greater than five years of HT use, glaucoma diagnosis was associated with delays of 2.2, 3.7 and 4.5 years, respectively. An interaction between HT duration and age of menopause diagnosis was also seen, with the impact of HT decreasing for later menopause age.

Age at menopause was the largest predictor for age of glaucoma diagnosis, followed by HT use, white descent and antihypertensive medication use. Furthermore, for each additional prescription-year of HT, there was an associated 0.2 year later age of glaucoma diagnosis.

The authors conclude, "Later diagnosis of glaucoma with longer HT durations and the modulating effect of age of menopause suggests that **estrogen supplementation may directly influence the pathophysiological processes involved in glaucoma development and progression."**

Hogan K, Cui X, Giangiacomo A, Feola AJ. Postmenopausal hormone therapy was associated with later age of onset among glaucoma cases. Invest Ophthalmol Vis Sci. 2024;65(10):31.

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Dr. Chaglasian is a paid consultant of Thea Pharma Inc.

INDICATIONS AND USAGE

IYUZEH™ (latanoprost ophthalmic solution) 0.005% is a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to latanoprost or any other ingredients in this product.

WARNINGS AND PRECAUTIONS

IYUZEH may cause changes to pigmented tissues. Most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as IYUZEH is administered. Iris pigmentation is likely to be permanent. Eyelid skin darkening and eyelash changes may be reversible.

IYUZEH may cause gradual change to eyelashes including increased length, thickness, and number of lashes. These changes are usually reversible upon discontinuation of treatment.

IYUZEH should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

IYUZEH should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Reactivation of herpes simplex keratitis has been reported during treatment with latanoprost. IYUZEH should be used with caution in patients with a history of herpetic keratitis.

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

ADVERSE REACTIONS

The most common adverse reactions (5% to 35%) for IYUZEH are: conjunctival hyperemia, eye irritation, eye pruritus, abnormal sensation in eye, foreign body sensation in eyes, vision blurred, and lacrimation increased.

DRUG INTERACTIONS

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

Please see full Prescribing Information at www.iyuzeh.com and Brief Summary on the next page.

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HIGHLIGHTS OF PRESCRIBING INFORMATION

This brief summary does not include all the information needed to use IYUZEH safely and effectively. See full prescribing information for IYUZEH.

Initial U.S. Approval: 2022

----------INDICATIONS AND USAGE----------

IYUZEH is a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

----------CONTRAINDICATIONS----------

Known hypersensitivity to latanoprost or any other ingredients in this product.

----------WARNINGS AND PRECAUTIONS----------

Pigmentation: Topical latanoprost ophthalmic products, including IYUZEH have been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as latanoprost is administered.

The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of latanoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

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

Eyelash Changes: Latanoprost ophthalmic products, including IYUZEH may gradually change eyelashes and vellus hair in the treated eye; these changes include increased length, thickness, pigmentation, the number of lashes or hairs, and misdirected growth of eyelashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: IYUZEH should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation because inflammation may be exacerbated.

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

Herpetic Keratitis: Reactivation of herpes simplex keratitis has been reported during treatment with latanoprost. IYUZEH should be used with caution in patients with a history of herpetic keratitis and should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Contact Lens Use: Contact lenses should be removed prior to the administration of IYUZEH and may be reinserted 15 minutes after administration.

----------ADVERSE REACTIONS----------

The following adverse reactions have been reported with the use of topical latanoprost products and are discussed in greater detail in the prescribing information:

- Iris pigmentation changes
- Eyelid skin darkening
- Eyelash changes (increased length, thickness, pigmentation, and number of lashes)
- Intraocular inflammation (iritis/uveitis)
- Macular edema, including cystoid macular edema

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

In the two clinical trials conducted with IYUZEH (latanoprost ophthalmic solution) 0.005% comparing it to XALATAN the preserved 0.005% latanoprost reference product, the most frequently reported ocular adverse reactions were conjunctival hyperemia and eye irritation (Table 1).

Table 1. Adverse Reactions

	Adverse Reactions [n (%)]	
Symptom/Finding	**IYUZEH (n=378)**	**XALATAN (n=358)**
Conjunctival hyperemia	129 (34)	133 (37)
Eye irritation	72 (19)	112 (31)
Eye pruritus	57 (15)	58 (16)
Abnormal sensation in eyes	51 (14)	52 (15)
Foreign body sensation in eyes	44 (12)	36 (10)
Vision blurred	28 (7)	30 (8)
Lacrimation increased	19 (5)	14 (4)
Photophobia	13 (3)	17 (5)

----------POSTMARKETING EXPERIENCE----------

The following adverse reactions have been identified during post-approval use of topical latanoprost products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ophthalmic latanoprost products, or a combination of these factors, include:

- Nervous System Disorders: Dizziness; headache; toxic epidermal necrolysis
- Eye Disorders: Eyelash and vellus hair changes of the eyelid (increased length, thickness, pigmentation, and number of eyelashes); keratitis; corneal edema and erosions; intraocular inflammation (iritis/uveitis); macular edema, including cystoid macular edema; trichiasis; periorbital and lid changes resulting in deepening of the eyelid sulcus; iris cyst; eyelid skin darkening; localized skin reaction on the eyelids; conjunctivitis; pseudopemphigoid of the ocular conjunctiva.
- Respiratory, Thoracic and Mediastinal Disorders: Asthma and exacerbation of asthma; dyspnea
- Skin and Subcutaneous Tissue Disorders: Pruritis
- Infections and Infestations: Herpes keratitis
- Cardiac Disorders: Angina; palpitations; angina unstable
- General Disorders and Administration Site Conditions: Chest pain

----------DRUG INTERACTIONS----------

The combined use of two or more prostaglandins, or prostaglandin analogs including IYUZEH is not recommended, and administration of these prostaglandin drug products more than once daily may decrease the IOP lowering effect or cause paradoxical IOP elevations.

----------USE IN SPECIFIC POPULATIONS----------

Pregnancy: There are no adequate and well-controlled studies of IYUZEH administration in pregnant women to inform drug-associated risks.

Lactation: It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when IYUZEH is administered to a nursing woman. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for IYUZEH and any potential adverse effects on the breastfed child from IYUZEH.

Pediatric Use: The safety and effectiveness of IYUZEH have not been established in pediatric patients.

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

----------OVERDOSAGE----------

Intravenous infusion of up to 3 mcg/kg of latanoprost in healthy volunteers produced mean plasma concentrations 200 times higher than during clinical treatment with latanoprost ophthalmic solution and no adverse reactions were observed. IV dosages of 5.5 to 10 mcg/kg caused abdominal pain, dizziness, fatigue, hot flushes, nausea, and sweating.

----------HANDLING THE CONTAINER----------

IYUZEH is a sterile solution that does not contain a preservative supplied in a single-dose container. The solution from one individual container is to be used immediately after opening for administration to one or both eyes. Since sterility cannot be maintained after the individual container is opened, the remaining contents should be discarded immediately after administration. Open a new single-dose container every time you use IYUZEH.

Manufactured for: Thea Pharma Inc. Waltham, MA.

U.S. Patent N°. 8,637,054.
Revised: 04/2023

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*Low-dose OTC brimonidine. †Low-dose brimonidine is an α2-AR agonist that primarily constricts the venule. [1]McLaurin E, et. al. *Optom Vis Sci*. 2018;95(3):264-271. ‡In clinical trials, one case of rebound redness was reported. §In Home Use Test, March 2018. n=301.

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BY JACK PERSICO
EDITOR-IN-CHIEF
OUTLOOK

Context is King

Medical statistics get tossed around a lot, but they're only meaningful if you know how they're calculated—and why.

You may have heard the saying—popularized but not coined by Mark Twain—"There are three type of lies: lies, damn lies and statistics." People often bring it up to make the point that citing statistics is an inherently shady business, easily manipulated by bad actors for nefarious purposes. Indeed, that probably was the phrase's original intent. Twain credits it to Benjamin Disraeli, a former UK prime minister, and it does sound like the words of a jaded politician. Interestingly, even though people point to it as an example of Twain's wry cynicism, his own use of the quote was more self-deprecating.

In his autobiography, Twain noted that in his youth he could write 3,000 words a day, but in old age his output had dropped to about half. At first, he was harshly self-critical over this decline but, upon reflection, he realized he had lately been spending only half as much time writing, so in fact his output was consistent throughout his life after all.

"Figures often beguile me, particularly when I have the arranging of them myself," Twain admits in his autobiography before using the Disraeli quote to chastise himself. When he had a full accounting of his productivity, his opinion changed. What he needed was a relative measure rather than an absolute one. In other words, he needed context.

To teach ODs to be more astute consumers of medical statistics—to find that all-important context—this month we're beginning a four-part series on scientific research and how it relates to clinical practice. As optometry is now the dominant provider of primary eye care in America, practitioners need to know the scientific underpinnings of their actions more than previous generations might have. When the work of optometry was predominantly refraction and dispensing, knowing the latest research was less vital day to day. The principles of visual optics haven't changed in centuries, but primary care brings optometry into the ever-changing world of evidence-based medicine—avidly for some, kicking and screaming for others. Either way, its importance will only continue to rise.

Review of Optometry has been devoted to describing clinical insights gleaned from the very latest medical research for years now. Our online news feed provides well over 700 journal article summaries every year. I can say without (much) bragging that there's simply no comparable outlet anywhere else for the latest medical research as it relates to optometry. In addition to summarizing a study's key points, our news stories will now link to the abstracts themselves so that interested ODs can go deeper if they want.

To help, this new series will teach you look at statistics more clearly, starting with the building blocks. The terminology of research is often baffling. If your eyes glaze over at the thought of p-values and ROC curves and hazard ratios and the like, not to worry. On page 74, Andrew Pucker, OD, explains them in clear and simple ways in part one of this series. Future installments will give you the tools to read a study skeptically, evaluate the landmark clinical trials in eye care and understand the inner workings of study design and analysis.

Statistics can be misinterpreted even when there's no bad intent; lack of familiarity combined with reverence for peer-reviewed literature is enough to "beguile," as Twain said. But, when armed with the right tools, you'll be able to learn from others while thinking for yourself. ■

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3. CVI data on file 2021. Decision Analyst online survey of 376 Biofinity prescribing ECPs in USA, Japan, Germany, France and Spain.

BY PAUL M. KARPECKI, OD
CHIEF CLINICAL EDITOR

AI Comes of Age

Decades of promise are finally starting to pay off.

Artificial intelligence is the current buzzword in all walks of life, but few know that it was first coined in 1956! It has taken time for technology to catch up to its promise, but it's improving every day and eye care is one of the major fields that can benefit. The good news is that it can't succeed without our expertise—to interpret, to lead the process and to carry out the decisions. But in combination with ODs, AI has the potential to shape optometry's future.

Areas where I expect AI will help include enhancing diagnostic accuracy, identifying diseases—even those outside of eye care—increasing practice efficiency, providing better treatments and expanding access to remote regions. The recent "Healthcare from the Eye" partnership between Topcon and Microsoft will use AI to identify disease early and create integrated systems to allow for collaborative care.

Current AI Tools

ChatGPT and other chatbots are already changing how we work. While it can write a paper, it can also amass data and science from everywhere on the web into a single document. My cousin even used it to write a love letter to his wife and then, after reviewing the first draft, asked the chatbot to make it less sappy— and it complied. Maybe not the most romantic approach, but the point is that you can modify what's provided, and the need for a human is essential.

Disease diagnosis is another obvious fit. Deep-learning algorithms need large quantities of labeled data to be trained, and eye care has that in abundance.

A 2023 study showed that an AI system had a higher sensitivity for detecting mild DR than either general ophthalmologists or even retina specialists.[1] Another involving more advanced DR also showed improvement over human assessment.[2] This May, we witnessed the FDA approval for an AI-based camera to obtain and analyze DR with 88% sensitivity and 94% specificity.

> **A 2023 study showed that an AI system had a higher sensitivity for detecting mild DR than either general ophthalmologists or even retina specialists.**

A colleague and I worked on an AI-driven OSD algorithm that amazed me in terms of providing insights that may have taken months or years to observe. However, the program would have failed without humans guiding the process.

Emerging Capabilities

Ambient listening and transcription technology—allowing hands-free charting for optometrists—may be one of the most exciting new AI areas. The AI directly captures, structures and summarizes key information in real-time during patient consultations, filtering for relevant details to create concise documentation of each patient's record.

A study conducted at a major ophthalmic center with over 300,000 consultations showed doctors gained two hours per day each, over 96% of text was deemed accurate and the charts were 2.5 times more detailed than the previous manual entry method. The time saved has been used to increase patient visits by up to 30% in some clinics. An optometry-only EHR software (Barti) incorporates this exact technology into its system. To date, not a single optometrist using Barti has returned to their previous set-up.

A technology for advanced AMD called Eyedaptic also uses AI to better serve patients. It already improves reading and functional vision capabilities by over 50% by using augmented reality glasses to move an image off the macula to healthier retinal tissue, but its most recent release taps into generative AI and large-language models to visualize and interpret real-time data. For example, it can read text, describe a room, locate objects and help users with other daily tasks and activities that otherwise may not have been possible due to their vision loss.

A fascinating new spectacle lens called ColorBoost (Hue Lens) is designed using generative AI to enhance color vision. Hue's AI-driven process uses data about ocular biology and lens chemistry to create spectacles designed for various activities, including pickleball and a multitude of special environments. These lenses are used by popular eyewear brands and also used in ballistic-protection eyewear for military and government applications.

While there are many opportunities for AI in optometry, ultimately it's our ability to monitor these advances—through our filter of helping patients, improving practice efficiency and the enjoyment of clinical practice—that will help determine precisely how AI shapes the future of eyecare. ■

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About Dr. Karpecki

Dr. Karpecki is the director of Cornea and External Disease for Kentucky Eye Institute and an associate professor at KYCO. He is the Chief Clinical Editor for Review of Optometry and chair of the New Technologies & Treatments conferences. A fixture in optometric clinical education, he consults for a wide array of ophthalmic clients, including ones discussed in this article. Dr. Karpecki's full disclosure list can be found in the online version of this article at www.reviewofoptometry.com.

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30

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CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS
- **Uveitis:** RYZUMVI is not recommended when active ocular inflammation (e.g., iritis) is present because adhesions (synechiae) may form between the iris and the lens.
- **Potential for Eye Injury or Contamination:** To avoid the potential for eye injury or contamination, care should be taken to avoid touching the vial tip to the eye or to any other surface.
- **Use with Contact Lenses:** Contact lens wearers should be advised to remove their lenses prior to the instillation of RYZUMVI and wait 10 minutes after dosing before reinserting their contact lenses.

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

RYZUMVI was evaluated in 642 subjects in clinical trials across various subject populations. The most common ocular adverse reactions reported in >5% of subjects were instillation site discomfort including pain, stinging, and burning (16%) and conjunctival hyperemia (12%). The only non-ocular adverse reaction reported in >5% of subjects was dysgeusia (6%).

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary: There are no available data with RYZUMVI administration in pregnant women to inform a drug-associated risk. In animal toxicology studies, when phentolamine was administered orally to pregnant mice and rats during the period of organogenesis skeletal immaturity and decreased growth was observed in the offspring at doses at least 24-times the recommended clinical dose. Additionally, a lower rate of implantation was seen in pregnant rats treated with phentolamine administered at least 60-times the recommended clinical dose. No malformations or embryofetal deaths were observed in the offspring of pregnant mice, rats, and rabbits administered phentolamine during the period of organogenesis at doses of at least 24-, 60-, and 20-times, respectively, the recommended clinical dose (see Data). RYZUMVI should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

Data *Animal Data* Oral administration of phentolamine to pregnant rats and mice at doses at least 24-times the recommended clinical dose (based on a body weight per surface area (mg/m^2) comparison with a 60-kg human) resulted in slightly decreased growth and slight skeletal immaturity of the fetuses. Immaturity was manifested by increased incidence of incomplete or unossified calcanei and phalangeal nuclei of the hind limb and of incompletely ossified sternebrae. At oral phentolamine doses at least 60-times the recommended clinical dose (based on a mg/m^2 comparison with a 60-kg human), a slightly lower rate of implantation was found in rats. Phentolamine did not affect embryonic or fetal development in rabbits at oral doses at least 20-times the recommended dose (based on a mg/m^2 comparison with a 60-kg human). No malformations or embryofetal deaths were observed in the rat, mouse or rabbit studies.
Lactation: Risk Summary: There is no information regarding the presence of phentolamine in human milk, the effects on the breastfed infants, or the effects on milk production during lactation to inform risk of phentolamine ophthalmic solution 0.75% to an infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RYZUMVI and any potential adverse effects on the breastfed child from RYZUMVI.
Pediatric Use: The safety and effectiveness of RYZUMVI have been established in pediatric patients aged 3 to 17 years. No overall differences have been observed between pediatric and adult subjects.
Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger adult subjects.

OVERDOSAGE
No deaths due to acute poisoning with phentolamine have been reported. Overdosage with parenterally administered phentolamine is characterized chiefly by cardiovascular disturbances, such as arrhythmias, tachycardia, hypotension, and possibly shock. In addition, the following might occur: excitation, headache, sweating, visual disturbances, nausea, vomiting, diarrhea, or hypoglycemia. There is no specific antidote; treatment consists of appropriate monitoring and supportive care. Substantial decreases in blood pressure or other evidence of shock-like conditions should be treated vigorously and promptly.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY
Carcinogenesis: Carcinogenicity studies with RYZUMVI have not been conducted.
Mutagenesis: Phentolamine was not mutagenic in the in-vitro bacterial reverse mutation (Ames) assay. In the in-vitro chromosomal aberration study in Chinese hamster ovary cells, numerical aberrations were slightly increased after a 4-hour exposure to phentolamine without metabolic activation, and structural aberrations were slightly increased after a 4-hour exposure to phentolamine with metabolic activation only at the highest concentrations tested, but neither numerical nor structural aberrations were increased after a 20-hour exposure without metabolic activation. Phentolamine was not clastogenic in two in-vivo mouse micronucleus assays.
Impairment of Fertility: The effect of phentolamine on female fertility has not been studied. Male rats treated with oral phentolamine for nine weeks (four weeks prior to mating, 3 weeks during the mating period and 2 weeks after mating) were mated with untreated females. At doses up to 648-times human therapeutic exposure levels at the C_{max}, no adverse effects on male fertility parameters or on reproductive parameters in the untreated females mated with the treated males were observed.

Marketed by: Oyster Point Pharma, Inc., a Viatris company

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Presenters

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Professor, Southern California College of Optometry
Residency Coordinator
Primary Care/Geriatric Optometry
Sepulveda VA Ambulatory Care Center
North Hills, CA

Julie Rodman, OD, FAAO
Professor and Chief; Fort Lauderdale (Broward)
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BY MONTGOMERY VICKERS, OD

CHAIRSIDE

The Common Denominator…

Is pain. We all experience it, so you might as well make it worth your suffering.

Humans, even those we call patients, all have a few things in common. Consider this: We all have looked up stupid stuff on our cell phones while at stoplights, which, for some reason, trigger our innate and sudden desire to know where Lebron James was born, for example. You heard me—this is ALL humans—at least in places where stoplights exist.

We all want to be members of big box stores. Five gallons of dill pickles are essential for a household. We all want everyone else to brush their teeth. We all cannot survive without Starbucks. There are so many things we all have in common.

Unfortunately (or fortunately), one of them is pain. Of course, most pain is just our expectation of pain. The question I have been asked the most since graduating from Pennsylvania College of Optometry is as follows: "You're not going to puff me, are you?"

Is the NCT painful? If you think it is, it is.

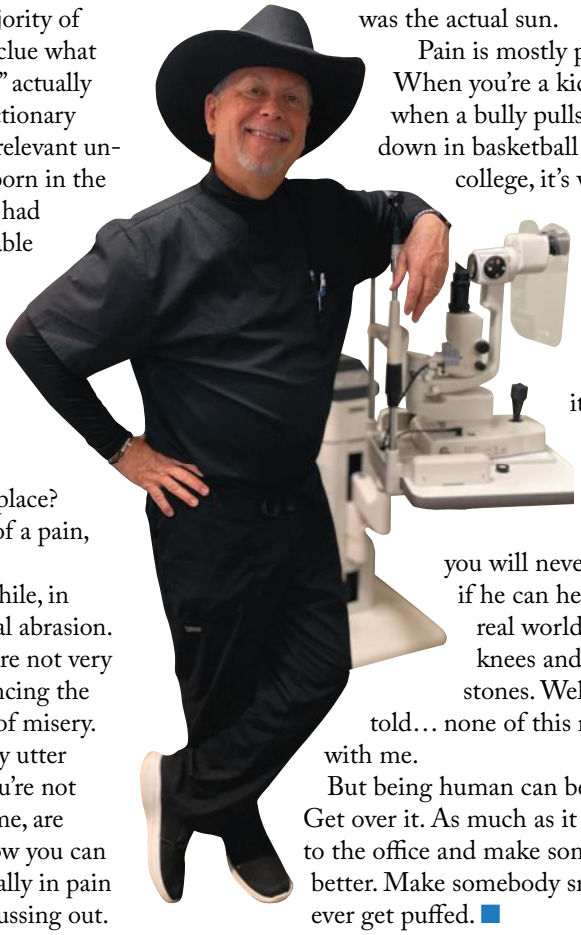
I have been told that I am also a human. Me, I like to alternate between bone-on-bone knee pain (which I blame on 10 years of long-distance jogging, which I was forced to give up to be a dad in '82, because running a couple hours every evening while my wife tried to tame two wild creatures we jokingly labeled our "children" after her full day's work was about to lead to "real" pain) and kidney stones, which gave me the chance to occasionally shriek like James Brown until the ER doc drugged me into submission.

Patients sometimes present in what they perceive as pain:

- "My glasses are killing my ears."
- "These new contact lenses hurt my eyes."
- "You're not going to puff me, are you?"

The vast majority of them have no clue what the word "pain" actually means. The dictionary definition is irrelevant unless you were born in the '50s when you had to literally be able to spell. AI is working on everyone's PhD so we can all be doctors, so why look stuff up in the first place? It's too much of a pain, right?

Once in a while, in comes a corneal abrasion. These people are not very happy experiencing the real sensation of misery. They can barely utter the words, "You're not going to puff me, are you?" That's how you can tell they are really in pain and not just wussing out.



Or, in comes the contact lens wearer who sleeps in his lenses for a couple months in a row but religiously removes them when they cause pain. Why does he do this? Because, he declares, "My glasses are killing my ears," which is strange when you find out he doesn't have glasses and he's a -6.00D myope who is getting married tomorrow to the girl of his dreams who has always slept in her contact lenses and told him he should, too. She should know. She works at a shoe store.

Hey, if it's an ulcer, I do the right thing by prescribing the most expensive pain-relieving pharmaceuticals I can think of and give him 13 drops of atropine so he'll enjoy his honeymoon on what he will later tell his children was the actual sun.

Pain is mostly psychological. When you're a kid, it's painful when a bully pulls your shorts down in basketball practice. In college, it's when a frat brother drives off with your blind date. In optometry school, it's when one of the professors assures you that you will never graduate if he can help it. In the real world, it's your knees and kidney stones. Well, so I am told… none of this rings a bell with me.

But being human can be painful. Get over it. As much as it hurts you, go to the office and make somebody see better. Make somebody smile. Don't ever get puffed. ■

About Dr. Vickers **Dr. Vickers** received his optometry degree from the Pennsylvania College of Optometry in 1979 and was clinical director at Vision Associates in St. Albans, WV, for 36 years. He is now in private practice in Dallas, where he continues to practice full-scope optometry. He has no financial interests to disclose.

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‡To limit blurriness when using contact lenses, remove contacts, apply drops, then insert contacts.

Reference: 1. Thea Data on File.

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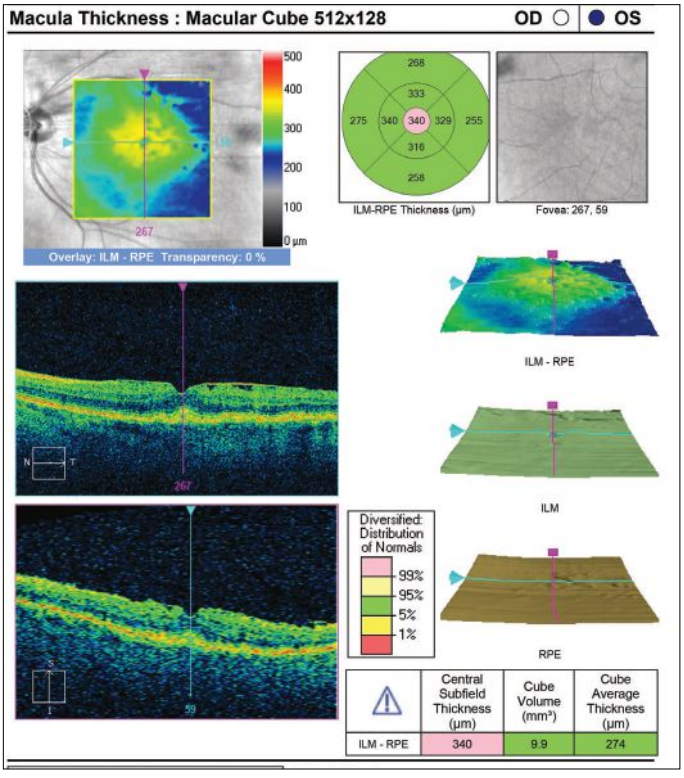
Pucker Up

Gain the confidence to treat patients with epiretinal membranes.

Q I have a patient who underwent successful cataract surgery but is best-corrected 20/30. OCT showed some macular thickening. What is going on?

A "Your patient has an epiretinal membrane (ERM)!" says Julie Rodman, OD, professor and chief of the Eye Care Institute of Nova Southeastern College of Optometry. ERMs are superficial, avascular, contractile sheet-like membranes composed of glial cells, retinal pigment epithelial cells, macrophages, fibrocytes, collagen cells and laminocytes.[1] When in contact with the retina, these cells proliferate and form a membrane over the surface of the retina. These membranes expand and contract, resulting in anatomic changes that include distortion and thickening of the underlying sensory retina. Subsequent visual changes including metamorphopsia and blurry vision may occur.

Various ocular conditions such as anomalous posterior vitreous detachment, cataract surgery, retinal tears, retinal vascular disease and ocular inflammatory disease may result in ERM formation.[2] ERMs may also be idiopathic in nature. Their prevalence varies depending on the etiology and is reported to be in the range of 7% to 11.8%, with age being the most important risk factor.[3,4] ERMs are more common in the elderly population, with an incidence of approximately 2% in individuals over 50 and 20% in individuals over 75.[2] Both sexes appear to be affected equally.



Typical ERM resulting in macular thickening and inner retinal corrugations.

Historically, ERM has been classified based on the degree of retinal traction and distortion. Extended periods of contraction may result in vitreomacular traction or partial- or full-thickness hole formation.[4]

Due to the similarity in appearance between epiretinal membranes and other entities such as exudate, combined hamartoma of the retina and retinal pigment epithelium and other proliferative vitreoretinal diseases, ancillary testing is recommended. OCT is the diagnostic testing modality of choice due to its excellent ability to identify ERM.

On OCT, ERM will appear as a hyperreflective layer superficial to the internal limiting membrane. The band may be irregular or irregular, corrugated or smooth, with or without tooth-like adherent projections Often, the foveal contour will be irregular or distorted due to the contractile forces of the ERM. Cystoid spaces and thickening may occur with significant traction. Outer retinal involvement including distortion of the photoreceptors (IS/OS junction) is correlated with visual acuity.[5] Patients with ERM are more likely to develop inflammation after cataract surgery such as cystoid macular edema, neurosensory detachment and outer retinal involvement.[6] Patients at risk should be treated with a topical NSAID during the entire perioperative period. Other recommended tests include the Amsler grid test and/or Watzke-Allen test. Fluorescein angiography is not routinely ordered; however, it is useful to determine if other retinal problems are causing the ERM.

To Monitor or Treat?

"The majority of ERMs will remain stable and thus can be monitored, not requiring therapy," Dr. Rodman says. "The decision to intervene surgically depends on the severity of the symptoms including impact on daily routine." Vitrectomy with membrane

About Dr. Ajamian **Dr. Ajamian** is board certified by the American Board of Optometry and serves as Center Director of Omni Eye Services of Atlanta. He is vice president of the Georgia State Board of Optometry and general CE chairman of SECO International. He has no financial interests to disclose.

peel is the treatment of choice and is indicated in patients who have a decrease in visual acuity that interferes with lifestyle, metamorphopsia and double vision or difficulty with binocularity.[7,8] Encourage patients to use Amsler grid at home routinely to monitor for changes that may occur over time and to notify their eye physician if symptoms change. Surgical removal of ERM usually results in improvement in both visual acuity and clinical appearance of the retina. Preoperative visual acuity is directly correlated to surgical outcome, where better entering acuity is linked to better overall results.[9] Other factors influencing outcomes include the cause of the ERM (idiopathic have better prognosis than those correlated with other ocular etiologies), the degree of traction and length of time the ERM has been present.

"ERM is in our wheelhouse," Dr. Rodman asserts. "Use ancillary testing as appropriate and be confident in your diagnosis." Reassurance, education and routine monitoring are of the utmost importance. As with cataract patients, only send them to the surgeon when you determine they need or want surgery. ■

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BY BISANT A. LABIB, OD

Doxy: Worth its Moxie

The tetracycline class of antibiotics, doxycycline, is emerging as a versatile drug for ophthalmic use.

When considering the role of oral antibiotics, there are many situations in which an ocular condition would necessitate prescriptive use. Obvious examples include acute bacterial infections of the eyelid, cornea or conjunctiva. But on some occasions, oral antibiotics can be used in noninfectious ocular disease. An example of this is with the often underappreciated and multipurpose drug doxycycline.

Doxycycline

This drug is a member of the tetracycline antibiotics and is widely used in the treatment and management of bacterial infections, including ones that are ocular and systemic. Doxycycline is a metal ion chelator that is effective in killing gram-positive and -negative bacteria as well as preventing bacterial growth. To achieve this, it binds to the 30S ribosomal unit and prevents translation and protein synthesis, which kills the bacteria. It is the most commonly used drug in its class because of its high lipophilicity and ability to cross numerous cell membranes to reach a site of action. Systemically, doxycycline has long been used in the treatment of skin infections and sexually transmitted infections, and in the prophylaxis of Lyme and malaria.[1,2]

In addition to its antibacterial use, doxycycline is used in noninfectious ocular conditions such as acne rosacea, recurrent corneal erosions and keratoconjunctivitis sicca. It does not seem intuitive that an oral antibiotic would be effective in cases such as these, suggesting that the medication possesses additional function in controlling inflammation. In fact, doxycycline is commonly used systemically in rheumatoid arthritis. Understanding the supplementary mechanisms of doxycycline can allow for more effective use in the treatment of many other ocular conditions.[2,3]

Doxycycline is not only an antibacterial agent but an immunomodulator. A secondary effect of this drug is in preventing calcium-dependent microtubular assembly and production of lymphocytes, thereby inhibiting leukocyte migration. It also inhibits nitric acid synthases, which contributes to its anti-inflammatory effect; these functions are the basis of use in conditions such as rheumatoid arthritis. On the ocular surface in particular, doxycycline is shown to inhibit the synthesis and activity of matrix metalloproteinase (MMP), interleukin-1 (IL-1) synthesis, B cell function and collagen synthesis. All these processes, if left uninhibited, promote inflammation and damage to the ocular surface. This is confirmed through studies that have been able to demonstrate the effectiveness of doxycycline use in corneal burns, which are noninfectious etiologies.[3,4]

Ophthalmic Implications

Because of the many properties that doxycycline possesses, there is ongoing research into its treatment benefits. It has been established that in addition to VEGF, MMPs are also elevated in conditions that produce choroidal neovascular membrane (CNV), such as age-related macular degeneration (AMD). In fact, inflammation is a key aspect in the overall underlying pathophysiology of AMD. Animal studies have already demonstrated a significant prevention of CNV formation with oral doxycycline administration by inhibiting endothelial cell migration. In mice with induced CNV, there was a 50% decrease in neovascular choroidal volume with oral doxycycline use compared to placebo.[3,5]

Another ocular condition characterized by angiogenesis, but in the anterior segment, is pterygia. These lesions are much more common and are due to epithelial cell overgrowth and dysregulation of cells over the cornea. MMPs

TABLE 1. SUMMARY OF ORAL DOXYCYCLINE CHARACTERISTICS

Mechanism of Action	Secondary Effects	Current Ocular Uses	Potential Future Uses	Common Adverse Effects
Binds to the 30S ribosomal unit and prevents translation and protein synthesis, killing bacteria and preventing its growth	· Inhibition of leukocyte migration · Inhibition of nitric acid synthesis · Inhibition of MMPs · Inhibition of ILs · Inhibition of collagen synthesis	· Bacterial anterior segment infections · Ocular rosacea · Recurrent corneal erosions · Keratoconjunctivitis sicca	· Pterygium treatment · Choroidal neovascular membranes · Corneal alkali burns	· GI upset · Skin rash · Photosensitivity

About Dr. Labib

Dr. Labib graduated from Pennsylvania College of Optometry, where she now works as an associate dean and professor. She completed her residency in primary care/ocular disease and is a fellow of the American Academy of Optometry and a diplomate in the Comprehensive Eye Care section. She has no financial interests to disclose.

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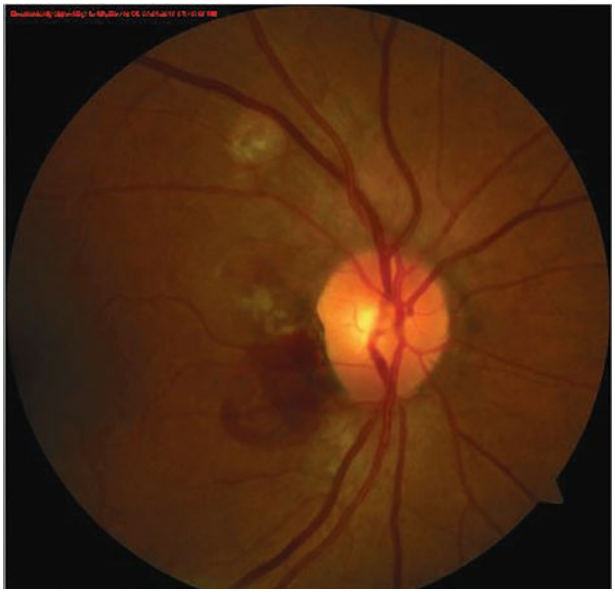

Choroidal neovascular membrane, produced in conditions like AMD, are linked with elevated MMP levels. Doxycycline can inhibit MMP synthesis on the ocular surface.

have been implicated in more advanced lesions, as they have been shown to be present in cells at the pterygium leading edge. Their presence is responsible for the damage that occurs to Bowman's layer, allowing for the local infiltration of abnormal pterygium cells that are made up of fibronectin and pro-inflammatory cytokines. Fibronectin functions in the processes of cellular adhesion and migration, whereas pro-inflammatory mediators such as VEGF and IL are angiogenic. In one study, doxycycline was effective in reducing fibronectin and subsequently pterygium epithelial cell infiltration. Furthermore, neovascularization that occurs in conjunction with pterygium formation was reduced by 30% in the doxycycline-treated group compared to placebo. Many animal models showed regression in these lesions altogether. Similar results were also seen in damage and neovascular formation with corneal alkali burns.[6]

This data suggests that, along with antimicrobial functions, doxycycline also possesses strong anti-angiogenic properties. This could be of significant importance in cases of ocular diseases that result in neovascularization, as there is evidence that it may be effective in both anterior and posterior segment diseases. This is attributed to reports that doxycycline, even at low doses, significantly reduced blood vessel growth and migration by inhibiting levels of tumor necrosis factor-alpha, ILs and MMPs.[3]

Unlike steroids and anti-VEGF agents that are routinely used to treat ocular inflammation and angiogenesis, doxycycline is cost-effective and readily available, easily administered and offers a better safety profile. Common adverse reactions include gastrointestinal symptoms, skin rash, headache or photosensitivity. More serious but rare effects can result in leukopenia, hemolytic anemia, dysuria, shortness of breath, intracranial hypertension and Stevens-Johnson syndrome. More often than not, however, oral doxycycline is easily tolerated.[1]

Doxycycline has long been established for bacterial infections both systemically and on the ocular surface, but little is appreciated in practice regarding its additional effects. More research is needed to solidify its potential use in anterior and posterior neovascular conditions. ■

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2 TORICS
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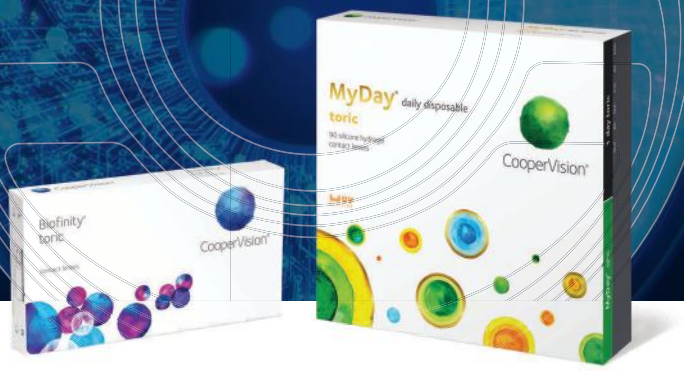
† High oxygen transmissibility promotes clear, white eyes during daily wear.
‡ During daily wear.
§ In the US market. Tylers Quarterly, December 2021 issue.

1. CVI data on file, 2024. US industry reports and internal estimates.
2. CVI data on file, 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs.
3. CVI data on file, 2023. Based on number of US soft contact lens fits, including CooperVision-branded and customer-branded equivalent lenses. US industry reports and internal estimates.
4. CooperVision data on file 2021. Rx coverage database n=101,973 aged 14 to 70 years.

2 TORICS
1 UNMATCHED DESIGN*[1]



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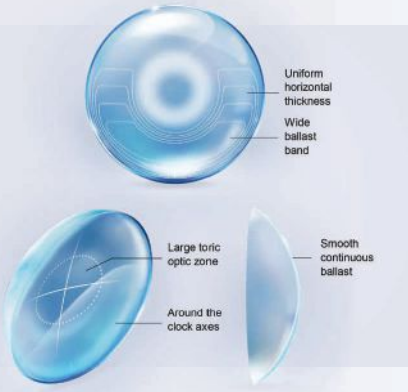

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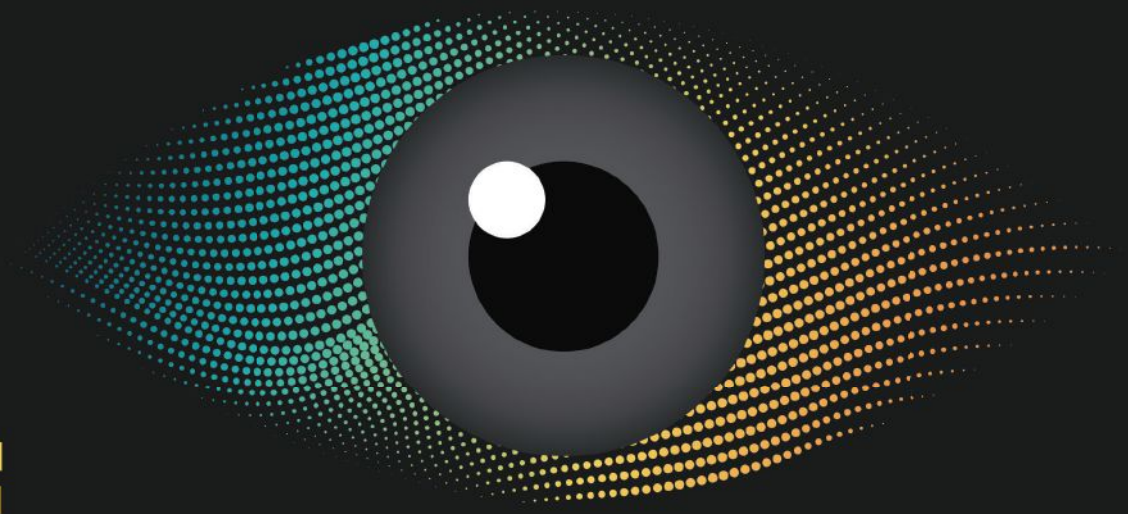
*Unmatched number of patients fit in contact lenses designed with Optimized Toric Lens Geometry in the U.S. (Biofinity toric and MyDay toric). † It is for the ECP to use their professional judgment to determine fitting characteristics on eye with individual patients. ‡ CVI SiHy toric products are compared individually to at least one of the listed products as follows: clariti® 1 day toric vs. Dailies AquaComfort Plus Toric; Biofinity® toric and Avaira Vitality® toric vs. Acuvue Oasys for Astigmatism, Air Optix for Astigmatism, Acuvue Vita for Astigmatism, PureVision Toric, Proclear Toric and Acuvue Advance for Astigmatism. § Combination of 2021 market research based on global volume data and internal estimates. ‖ Significantly higher than toric lens brands from Johnson & Johnson Vision, Alcon and Bausch + Lomb; p<0.05. ¶ Biofinity® toric is a Frequent Replacement lens and MyDay® daily disposable toric is a 1 Day lens. **1.** CVI data on file, 2024. U.S. industry reports and internal estimates. **2.** Sulley A & Greenaway N. Success rates with a toric soft contact lens design. Optom Vis Sci 2020;97(E-abstract):205296. **3.** CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 70% CVI, 45% Alcon, 45% B+L, 55% JJV; p<0.05. **4.** CVI data on file, 2020; review performance 6 soft toric CL studies with CVI toric CLs; n=242. **5.** CVI data on file 2020. Kubic Online Survey of ECPs in US, Germany, Spain, Japan and South Korea. Total weighted sample n = 549. Significantly higher than Johnson & Johnson Vision, Alcon and Bausch + Lomb; p<0.05. **6.** CVI data on file 2022. **7.** CVI data on file, 2019-2021. Based on number of US soft contact lens fits. Includes FRP and 1 day CooperVision branded and customer-branded equivalent lenses. US industry reports and internal estimates. **8.** CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 46% CVI, 11% Alcon, 14% B+L, 25% JJV; p<0.05. **9.** CVI data on file, 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 41% CVI, 10% Alcon, 17% B+L, 22% JJV; p<0.05. **10.** CVI data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 77% CVI, 31% Alcon, 40% B+L, 41% JJV; p<0.05). **11.** CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. CVI 65% vs 4% Alcon, 14% B+L and 14% JJV; p<0.05.



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BY JEROME SHERMAN, OD,
AND SHERRY BASS, OD

YOU BE THE JUDGE

Be Aware of Waxing and Waning Symptoms

Recurrence of complaints in the absence of significant signs can be a red flag.

When symptoms match signs, the diagnosis of ocular conditions is often straightforward. However, when a treatment is discontinued after the condition has improved or resolved and symptoms return, the practitioner must think of other, less common etiologies and look more closely at the patient themselves. This month's case involves a poorly compliant contact lens (CL) patient whose symptoms improved with treatment but continued to recur. The misdiagnosis and erroneous treatment resulted in significant permanent loss of vision in one eye.

Case

A contact lens wearer was vacationing in Hawaii, where she went waterskiing while wearing her lenses. When she returned home, she was examined by her regular eye doctor who had fit her for soft CLs a few years before. A review of her prior records had revealed that she had neglected to return for any follow-up visits for about three years. She also had a history of poor CL hygiene and overwore her contact lenses. Her chief complaint at this visit was that, after returning from Hawaii, she developed an itchy, red eye in her right eye.

Best-corrected visual acuities (BCVAs) through her lenses were 20/25 OD and 20/20 OS. The eye doctor did not record very much on the eye chart, including additional history or examination findings. There was no retinal examination. Despite few findings recorded, the eye doctor diagnosed "conjunctivitis" and prescribed tobramycin/dexamethasone eye drops QID OD. He told the patient to discontinue lens wear until her eye was better and to return in one week.

Follow-up. The patient returned one week later claiming that she felt "better." BCVA was still 20/25 OD and 20/20 OS. The eye doctor noted in the record that the BCVA was not as good as it could be. He told her to continue the medication and return in one week. The patient returned in one week, but there was still no change in the visual acuity. However, the symptoms continued to improve. There was no follow-up visit noted after the first two visits. Three months later, the patient went to a second eye doctor, a cornea specialist, saying that her right eye felt "irritated." The BCVA was 20/25-2 in the right eye. The second eye doctor noted corneal haze and superficial punctate keratitis, the right eye greater than the left eye. The second eye doctor diagnosed "keratitis" and also prescribed tobramycin/dexamethasone eye drops QID OD and artificial tears.

Photo: University of Iowa

Fig. 1. Early AK with central corneal haze and superficial keratitis in another patient.

The patient continued using the prescribed eye drops but subsequently developed intense pain in the right eye with significant loss of vision three weeks later. The patient presented to a third eye doctor, another cornea specialist, at a university medical center complaining of intense pain and loss of vision in her right eye. At this visit, the BCVA in the right eye had dropped to light perception. The eye doctor noted the patient had a peripheral corneal infiltrative ring. The third eye doctor suspected *Acanthamoeba* infection based on the corneal ring, symptoms of intense pain and patient history. A culture subsequently revealed *Acanthamoeba* keratitis (AK). The patient was treated with anti-amoebic medications, but the condition did not improve.

At this late stage, her only option was penetrating keratoplasty (PK). Repeated corneal grafts failed, and additional grafts at that time were not pursued since it was discovered she also had dense *Acanthamoeba* infiltration in her sclera as well. Her final BCVA was 20/800.

Malpractice Allegation and Outcome

The patient sued the first two eye doctors for failure to diagnose AK in a timely manner so she could be treated appropriately. In this case, the two eye doctors were deemed to have culpability, and the case was settled to avoid a more costly jury trial. The case was settled for under $500,000.

About Drs. Sherman and Bass

Dr. Sherman is a Distinguished Teaching Professor at the SUNY State College of Optometry and editor-in-chief of *Retina Revealed* at www.retinarevealed.com. During his 53 years at SUNY, Dr. Sherman has published about 750 various manuscripts. He has also served as an expert witness in 400 malpractice cases, approximately equally split between plaintiff and defendant. Dr. Sherman has received support for *Retina Revealed* from Carl Zeiss Meditec, MacuHealth and Konan. **Dr. Bass** is a Distinguished Teaching Professor at the SUNY College of Optometry and is an attending in the Retina Clinic of the University Eye Center. She has served as an expert witness in a significant number of malpractice cases, the majority in support of the defendant. She serves as a consultant for ProQR Therapeutics.

You Be the Judge

Based upon the information available thus far, what is your opinion?

- Was the first eye doctor culpable for not suspecting *Acanthamoeba* based on the patient's history of poor CL compliance and history of waterskiing?
- Was the same doctor culpable because there were no corneal findings on the record and "conjunctivitis" was diagnosed?
- Since the patient improved while on tobramycin/dexamethasone eye drops, is it the standard of care to assume the drops are working?
- Was the second eye doctor culpable since they also failed to consider AK when corneal haze and punctate keratitis was present?

Our Opinion

Acanthamoeba is a free-living protozoa commonly found in soil and water. AK is considered a very rare corneal infection, with an estimated prevalence of one to nine cases per 100,000.[1] However, in many developed countries, that number is increasing due to increasing CL wear—a main risk factor, especially with soft lens wear. About 93% of all cases of AK are reported in lens wearers, and infection is usually unilateral.[1] Risk factors include poor lens hygiene, overnight wear, wearing lenses during swimming and showering, reuse of disposable contact lenses and the use and efficacy of lens cleaning solutions. The organism exists in an active trophozoite form and an inactive cystic form. The organism is much more difficult to treat when it is present for a long time and exists in cystic form. Topical polyhexamethylene biguanide, an antimicrobial and antiviral medication, and chlorhexidine are effective treatments against the organism but only if initiated early on. The prognosis for visual recovery is excellent, with BCVA as good as 20/25 with early treatment.[1]

AK, unfortunately, is difficult to diagnose early on. In this case, the patient presented with symptoms of an itchy, red eye and eye irritation. The first eye doctor did not note any significant findings and diagnosed conjunctivitis. When the patient went to the second eye doctor, she only complained of eye irritation. The corneal haze and punctate keratitis that was seen at that visit could have been a sign of an early AK infection, but just "keratitis" was diagnosed likely based on the lack of symptoms and rarity of AK (*Figure 1*).

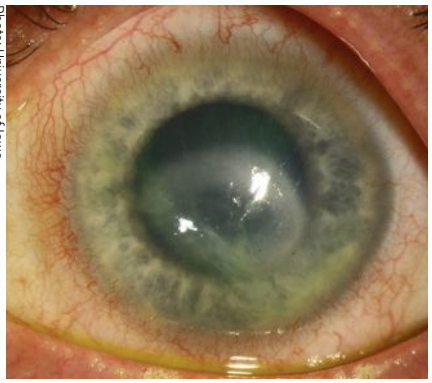

Photo: University of Iowa

Fig. 2. Advanced AK with a ring infiltrate and central stromal haze in another patient.

Symptoms of advanced AK include photophobia and pain disproportionate to the corneal findings, symptoms the patient did not report. The patient's symptoms waxed and waned with periodic improvement, since the eye doctors she saw prescribed antibiotic/steroid eye drops and the patient continued to use them as it improved her symptoms.

Steroids can promote the transition of cysts to active trophozoites, hence the steroid eye drops only made the condition worse. Also, the patient did not follow-up for a few months after her second visit with the first eye doctor, presumably because the symptoms resolved with use of the steroid eye drops. The patient had a history of poor follow-up compliance with her CLs, missing check-ups for years and likely reusing her disposable lenses. She also had a history of waterskiing while wearing her lenses. Hence, one of us (SB) opined that, since the first eye doctor did not record any findings but only a diagnosis of conjunctivitis, it is difficult to say what was seen during the examination, possibly just a red eye. The second eye doctor noted corneal haze and punctate keratitis; again, it is difficult to prove the patient had AK since she only complained of eye irritation. Therefore, it is questionable whether the two practitioners are culpable since the standard of care would likely not be to suspect AK based on the symptoms, the findings and the rarity of AK, as well as the fact that the patient appeared to be improving.

By the time she was diagnosed, the only treatment was a corneal graft, but unfortunately, multiple grafts failed. The prognosis was poor, and future treatment was not advised because additional testing revealed the *Acanthamoeba* had spread into her scleral tissue. This is an unfortunate series of events, but the two eye doctors had no reason to suspect AK. Once the patient developed intense pain and a ring infiltrate, AK became more suspect, but by then it was too late for treatment to be effective.

Takeaways

When should an *Acanthamoeba* infection be suspected? Unfortunately, once the peripheral corneal ring is seen (*Figure 2*) and the patient is photophobic and in intense pain, treatment may be too late and a PK may be the only option. However, if a patient initially "feels better" while on an antibiotic/steroid combination but then symptoms return and keep returning once the medications have been discontinued and there is a history of being in the water while wearing contact lenses in a patient as well as a history of poor compliance with lens wear and follow-up, there may be red flags to consider an early AK infection. It might be prudent in these cases to consider getting or referring for a culture even if it turns out not to be AK. ■

1. Varacalli G, Di Zazzo A, Mori T, et al. Challenges in *Acanthamoeba* keratitis: a review. J Clin Med. 2021;10(5):942.

NOTE: This article is one of a series based on actual lawsuits in which the author served as an expert witness or rendered an expert opinion. These cases are factual, but some details have been altered to preserve confidentiality. The article represents the authors' opinion of acceptable standards of care and do not give legal or medical advice. Laws, standards and the outcome of cases can vary from place to place. Others' opinions may differ; we welcome yours.

ONLINE REFRACTION AND TELEHEALTH: FRIEND OR FOE?

These options can expand access and patient convenience but must be matched with protocols and public awareness campaigns that preserve the value of a comprehensive exam.

BY BRIAN CHOU, OD, AND JERRY LEGERTON, OD, MS, MBA
SAN DIEGO

Optometry continues to transform, driven by scope expansion and technological advances. While increased scope is consciously chosen by the profession's advocates as a goal and pursued with intent, technological change is a mixed bag that includes some elements we actively embrace and others that are beyond our control or, indeed, wishes. New telehealth technologies employed by online retailers, including those accessible on a smartphone, enable consumers to self-administer Rx fulfillment and renewal, diminishing the traditional role of ODs while skirting statutes and regulations intended to protect the public. At the same time, more eye doctors are wondering if these same technologies can better serve their patients.

Below, we explore the impact of these developments, offering our own opinions on many contentious issues; other optometrists will have different perspectives. Refraction and vision correction are central to optometry and there's justifiable reluctance to relinquish them, especially to lesser modalities where patient care might suffer. Our hope is to stimulate discussion and a reckoning, both individually and collectively, with ongoing changes that will continue whether we want them to or not.

Online Vision Service Currently is Rx Duplication

Unlike dentistry, where *hands-on procedures* are a mainstay, optometry possesses a greater proportion of *hands-off services,* which positions optometry for greater (but not limitless) opportunities to adopt telehealth services and self-administered measurements. An obvious constraint with remote digital services is the need for the patient to be seated alongside the measurement device.

The appeal of smartphone-based service is that most of the population already owns a smartphone, whereas measurement with specialized larger instruments requires their co-location with the patient. Smartphone adapters such as Netra (EyeNetra) and Insight (EyeQue), where mobile service is enabled, may bridge the gap, or these adapters may be delivered to the patient for self-administration. Once the clinical data (refraction and imaging) is collected, it is reviewable by a doctor at a different location and time.

The constraint to online retailers is their need for a valid prescription to sell product. Hence, they desire to generate their own eyeglass and contact lens prescriptions, even if these are duplications of expired Rxs. Most of today's "online eye exams" embraced by these retailers are built around duplicating prior prescriptions. A remote doctor signs a duplicating script if the patient demonstrates reasonable self-administered visual acuity (VA) and attests that they are not at high risk for eye disease and they are not experiencing unusual symptoms. These online questionnaires are supposed to prevent users with significant risk factors or eye disease from renewing prescriptions, but they can be easily gamed: the user merely clicks the back-button to answer the same question differently to pass validation.[1] These questionnaires to elicit self-reported vision problems are already suspect, as even the same questions presented in a different order can yield a different prevalence of vision problems.[2]

About the authors

Dr. Chou practices in San Diego at ReVision Optometry, a referral-based clinic for keratoconus and scleral lenses. He has consulted for two start-ups innovating in the field of refraction technology with remote capabilities. **Dr. Legerton** is a Life Member of the American Optometric Association and is honored with the Outstanding Achievement Award; he is an Emeritus Fellow of the American Academy of Optometry and recipient of the Founders Award. He is an inventor on more than 200 US and international patent cases. His contributions to optometry span seven decades, including 26 years in private independent practice in San Diego.

Fig. 1. A range of telehealth options exists currently. Some providers employ specialized equipment in a standalone location to allow direct examination of the patient while the OD is remote.

The looming prospect is for self-administered *de novo* smartphone-based refraction. Meanwhile, *de novo* remote refraction today is performed with technologies like 20/20Now (20/20 Vision Center) and DigitalOptometrics (*Figure 1*), where specialized equipment is placed inside a standalone location so that eyeglass prescriptions are generated without a doctor physically present.

Consumers Mistake VA and Refraction

In the same manner that the lay public confuses optometrists, ophthalmologists and opticians, consumer confusion abounds between VA and refraction; the public does not appear to understand that these two measurements are different and that whether taken separately or together, they do not constitute a complete eye exam. They are, of course, separate components of an eye exam used by a doctor in clinical decision-making. Online retailers, however, are doing vision screenings and labeling them as "exams," further confounding the definition with consumers. Perhaps one solution would be a regulatory requirement for a service to qualify as an "eye exam" in the same manner that "organic" is a legal term and a "Realtor" is a special designation obtained by some real estate agents.

Online prescription services today concentrate on self-administered VA, with the apparent unintended effect of mistakenly leading consumers to believe that VA is a substitute for refraction. It is possible that some even believe that VA testing *is* a comprehensive eye examination. This may explain fallacious patient comments like, "I'm 20/20 so nothing is wrong." The mistaken narrative that prescription services are "eye examinations" diminishes the consumer's perceived value of an actual comprehensive eye and vision exam conducted in an office. The burden of educating the public and correcting misunderstandings is imposed on our profession and our industry partners. Doing so is no easy task, given a plethora of noisy messages competing for each consumer's limited attention and their inherent desire for a simplified experience enabled by digital alternatives to traditional in-person services.

When is Refraction a Prescription?

Experienced optometrists do not always prescribe their subjective refraction for eyeglasses. Instead, they may modify the prescription to attenuate the patient's adjustment by decreasing the magnitude of oblique cylinder or skewing the prescription closer to their habitual correction. Other factors including binocular status, accommodative reserve, eye dominance, level of anisometropia, vocational and lifestyle demands, historical correction and personality can collectively influence the doctor's prescription. In effect, two patients with identical refractions may need different eyeglass prescriptions.

As an example, the primary eyeglass prescription for a presbyopic software engineer may be a near-variable focus lens design, whereas the priority for an airline pilot may be single vision distance glasses or even double D bifocal lenses. It is understandable how a patient with difficulty adapting to new glasses who makes a comment like, "My doctor gave me the wrong prescription and it made my stigmatism worse," may find it appealing to take a do-it-yourself approach. Contrary to the consumer notion that there is only one correct prescription, there is a range of acceptable prescriptions and the practitioner's judgement is valuable in guiding the patient to a desirable outcome.

If self-administered refraction becomes more of a reality, should refraction alone drive eyeglass fulfillment? If so, the dystopian optometric future is one with no need for an eye doctor to create a prescription or validate and modify a refraction outcome. In theory, artificial intelligence could be trained to understand how doctors modify eyeglass prescriptions to facilitate patient satisfaction.

Until such methods prove themselves equal to human intellect and empathy, it would seem prudent that doctors still maintain prescriptive authority to modify their refraction. It is an ideal time for our profession to guard against the negative consequences of this potential future, especially as the segregation of refraction from a comprehensive eye exam would surely diminish patient care. Meanwhile, the current hybrid model of an off-site doctor remotely operating the phoropter with assistance from ancillary staff, while less than ideal, still allows for a clinician to make judgements in modifying the refraction outcome for the resulting prescription.

It is noteworthy that most of today's electronic medical records by default populate the refraction outcome into the fields for the eyeglass prescription. Practitioners still reserve the authority to modify the prescription for eyeglasses according to their judgement. Unfortunately, most consumers are unaware that the refraction outcome is not necessarily what is prescribed. Without this awareness, there is an inherent tendency for consumers to undervalue the role of clinical judgement in eyeglass prescribing.

Some eyecare professionals feel that autorefraction is not sufficient enough to prescribe glasses. We interpret this to mean that their final eyeglass prescription frequently and noticeably deviates from autorefraction. Historically, one definition of a subjective refraction was the most plus (or least minus) spherical value with full cylinder and respective axis to yield the best VA. However, for non-presbyopes, the prescription frequently has less plus or more minus spherical power than the refraction.

Over 30 years ago, one study discussed the repeatability of measurement of the ocular components. Of note, the limits of agreement for 95% confidence of two non-cycloplegic subjective refractions of the same eyes was found to be ±0.63D.[3] This means that to have 95% confidence that the difference between two refractions is real, the difference must be at least 0.63D. One conclusion from this is that subjective manifest refractions appear to lack the precision that our colleagues assign to their subjective refraction results.[3] Subsequent clinical investigations of the agreement limits of autorefractors find values that are significantly smaller.[4-6] The suggestion is that autorefraction is more repeatable than subjective refraction performed by clinicians. Nonetheless, the authors hold that an autorefraction is one component that drives determination of the eyeglass prescription and is not necessarily the same as the eyeglass prescription.

Self-refraction, Today and Tomorrow

The trajectory of technological advances suggests we could see a viable self-refraction soon. Most optometrists may bristle at this notion, since refraction is the historical foundation and economic driver of our profession. While refraction can, in certain instances, be a component of systemic or ocular disease detection, is that enough reason to make self-refraction available only under the supervision of a licensed professional? Some ODs will surely say yes, while others will demur.

Self-refraction is arguably already crudely available. Consumers can select over-the-counter readers intended for presbyopia at retail outlets or online; a consumer with pre-presbyopic hyperopia can do the same. Minus-powered glasses are ubiquitously available on online retailers like Amazon, allowing consumers to select and purchase them without an eyeglass prescription. Consumers can even purchase their own trial lens set online (*Figure 2*) or lens bars and refract themselves, though this would be an unlikely scenario. The US patent application 2014/0176909 by Spivey and Dreher (*Figure 3*) illustrates an Alvarez plate self-refractor where two adaptive optical components slide against each other to produce a continuum of sphere, cylinder and axis lens powers.[7] Alvarez plates were also the basis of adjustable-focus eyewear.[8] Adjustable-focus Alvarez plate eyewear are available through various online retailers like Amazon along with one company in the UK named Eyejusters.

Is the greater public good better served by keeping refraction and eyeglass prescribing controlled only by eye doctors? A fundamental question is whether self-selection of lens power significantly risks injury or harm to consumers. So far, there is scant data supporting this concept from countries where prescriptions are not needed for eyewear purchase. Perhaps the more pressing issue is helping consumers understand the value of a comprehensive examination vs. believing that VA and refraction are all that is needed for their vision care. Far too many laypeople believe the only reason to see an eyecare professional is to get an eyeglass Rx.

Will Glasses and Contact Lenses Go Over the Counter?

Should eyewear orders continue to require a prescription in the US? In many other countries, purchasing eyeglasses and contact lenses does not require a prescription, which prompts the question of whether the US should follow suit. After all, consumers are allowed to measure or select their own anatomic dimensions for hats, clothing, shoes, rings and other personal items. They can measure their own blood sugar, blood pressure, pulse, temperature and other vital signs; they can administer their own pregnancy tests and COVID tests and they inject their own insulin. As of October 17, 2022, most consumers can purchase over-the-counter hearing aids.[9] People are free to pierce and tattoo their own bodies and YouTube videos abound on how to fix a dislocated shoulder yourself. It is natural for consumers to wonder why a prescription is needed to order spectacle eyewear. It is incumbent upon our profession to give them a compelling answer.

Fig. 2. Trial lens sets available for online purchase without a professional license.


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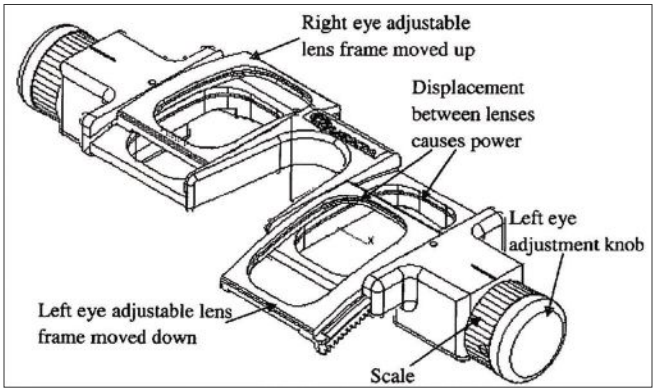

Fig. 3. Alvarez plate self-refraction device (Spivey and Dreher).

Most eye doctors, including us, believe patients are still best served by spectacles and contact lenses requiring a prescription; this is because the modification of the refraction based on their unique lifestyle visual demands and their binocular vision factors optimizes visual performance and aspects of their quality of life. There is also value in refractive data signifying potential eye disease. For example, fluctuating refractive error could indicate systemic blood sugar anomalies; a unilateral myopic shift in one eye can signify a developing nuclear cataract; a soft refraction endpoint with high oblique cylinder may indicate elevated higher-order aberrations and keratoconus. The refractive state of the patient is just one way we are alerted to their ocular and systemic health; direct examination yields countless more opportunities that would be lost in a move to online fulfillment.

Nevertheless, remote and "do-it-yourself" eye care can expand access to vision correction and eyewear. These newer methods of service also reveal different levels of eye care: some consumers are content with "good enough" and prioritize minimal spending for their eyewear, while others who want greater accuracy, precision and an elevated overall experience will seek out a licensed eyecare practitioner. Increasing emphasis on ocular disease in the optometric curriculum may unintentionally trivialize the importance of refraction and the art and science of prescribing eyewear. The expanding scope of optometry may be associated with a concomitantly lower interest in refraction and optical fulfillment. Some ODs are indeed less interested in eyewear prescribing and increasingly resigned to the growth of retail fulfillment and efficacy of online vision testing. We believe the fate of refractive prescriptive authority in the US depends on the attitudes and practice patterns of optometrists, as it will influence how far online retailers get toward selling glasses and contacts without prescriptions. Can we thread the needle of allowing online refraction and Rx fulfillment without degrading or marginalizing the comprehensive eye exam? Time will tell.

Telehealth and Optometry

Optometry is well-positioned for telehealth with ever-improving technology for digital image and data gathering by ancillary personnel and by patient self-administration. The highest calling of a licensed optometrist is not data collection and making measurements but rather diagnosis, treatment and consultation. We believe the systematic approach to case history and data collection, including refraction, biomicroscopy and retinal imaging, enables the remote practitioner to diagnose, treat and consult. Technology in development for tele-optometry may support eyecare delivery that surpasses the ability of current office-based systems, at least in terms of access and convenience, such as with the capability to allow for data-driven diagnosis and to provide the practitioner flexibility to remotely care for patients.

Still, one can't help but feel that telehealth diminishes important parts of the patient care encounter. Body language, eye contact and vocal tone—all facilitators of empathy and connection—just don't land the same way through a computer screen. Tele-optometry protocols should be developed with such trade-offs in mind and include efforts to preserve the doctor-patient relationship, such as an annual in-person visit with telehealth offered as a supplementary role throughout the year.

Cost containment is a major influence in health care. Expenditures continue to increase disproportionate to growth of the US GDP.[10,11] Cost-cutting comes with the objective of not compromising the quality or efficacy of care. Increased doctor productivity and reduced costs are major factors in profitability. The key question regarding telehealth is whether it maintains efficacy while achieving greater efficiency and productivity.

Trends often fall into "supply-push" or "demand-pull" forces. The demand-pull forces include a shortage of optometrists in some markets along with a concomitant expansion of eyecare outlets by some aggregate eyecare providers. This reality is particularly apparent in the UK and Europe, where stores without an eye doctor are called "dark stores." The corporations owning these dark stores are eager to employ technology for remote care, as the growth in new stores opening outpaces the number of eyecare professionals seeking employment there. In this case, the demand for eyecare professionals cannot be met. At the same

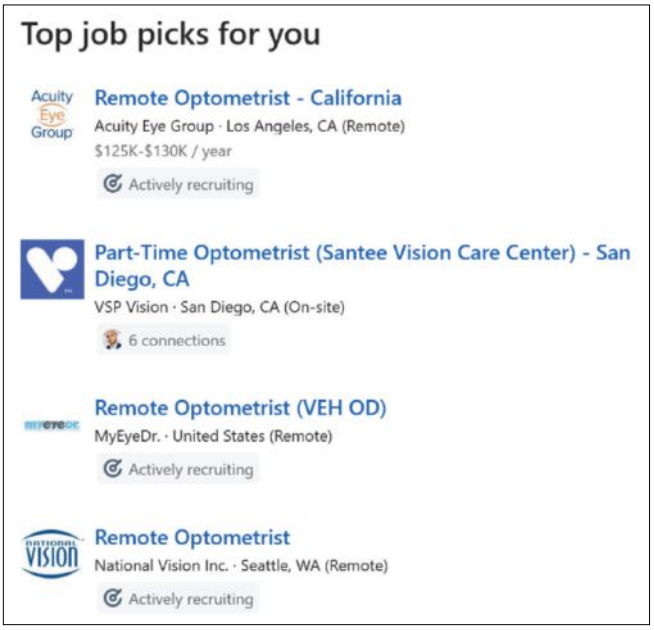

Fig. 4. LinkedIn remote employment opportunities for ODs.

time, there is a supply-push force manifest in the strategy of opening new outlets and providing eyewear at lower price points to reach new markets.

The growth of private equity–backed practice groups and other large aggregate vision care delivery entities in the US is already driving telehealth adoption in eye care (*Figure 4*). These entities must grow to complete their ultimate exit goals or shareholder value, respectively. We forecast that private equity–owned groups have reached or will reach a point where they no longer need to purchase practices. As they build their individual brands, they may open new practices instead of purchasing existing ones. The cost to open and market a practice may be less than purchasing a practice that generates similar revenue.

The missing element is the eyecare practitioner. Private equity–backed eyecare networks lose more than a few former-owner optometrists when their retainer period ends. If the number is significant, it portends a relative shortage of corporate ODs. The financial incentives for private equity networks appear to be manifest in the reduction in practitioner chair time per patient to increase patient volume, while concurrently reducing staffing costs. Remote telehealth models may help meet these objectives.

Dark stores and the desire for increased productivity appear to support instrument companies like Topcon, Zeiss, Eyoto and others that are developing telehealth technology and instrument suites (*Figure 5*).[12-15] These instrument companies may be responding to a more global demand rather than perceived eyecare provider demand. At least one national retailer adopted using remote eye doctors to perform eye exams systematically.[16] However, this remote approach was heavily criticized by the American Optometric Association (AOA) before the COVID lockdown.[17] The retailer still appears to operate using this model.

Consumer-driven Online Care: Smartphone Today, Smartglasses and Headsets Tomorrow

In 2011, the first broadly downloaded smartphone app related to vision, EyeXam for iPhone, hit a million consumer downloads.[18] This demonstrated high consumer demand for self-administered health measurements. There is now a plethora of other self-administered vision apps for visual acuity, color vision, visual skills, pupillometry, dark adaptation, retinal imaging and anterior eye imaging. All these apps can increase the public's awareness of eye and vision issues while allowing eye doctors to access clinical data remotely. These apps do not even provide self-refraction to generate *de novo* eyeglass prescriptions.

It is hard to project if virtual reality headsets like Meta Quest 3 and Apple Vision Pro will become as common in everyday use as smartphones. If so, they could become the newly distributed platform to administer remote eye care.[19,20] As an example, many of the new automated perimeters use headsets as the measurement platform, foreshadowing smartglasses and headsets to mediate more aspects of future remote eye care.[21] Extended reality headsets are already delivering objective and subjective assessment measurements that include and extend beyond VA, including perimetry. Headsets also employ software for visual rehabilitation and vision therapy; for example, Luminopia

Photo: Eyoto

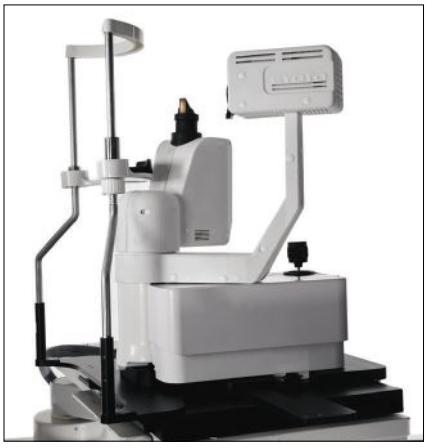

Fig. 5. Commercially available, remotely operated slit lamp.

(Luminopia) and Vivid Vision (Vivid Vision). Extended reality technology with machine learning software is forecast to assist practitioners in telehealth monitoring and patients in automated adjustment of settings to assist their visual rehabilitation and visual performance.[22]

Which Direction Shall Optometry Take?

The direction of the optometric profession will depend on our coordinated efforts. It takes decision-makers of our profession to coordinate direction—that would include representatives in the AOA and Association of Schools and Colleges of Optometry along with state associations and local optometric societies—and the effort can also be through grassroots-level online groups like ODs on Facebook and ODWire. In the absence of coordination, online retail corporate entities may drive the market.

Eyeglass and contact lens prescription renewal by online companies is silently eroding patient visits to traditional optometric practices. To stem the loss of patients, more optometrists are extending patient prescriptions for corrective lenses, but this is a slippery slope. It may give consumers what they want, but not what they need. While prescription extension was common by optometrists during the COVID lockdown, its continued use by ODs may be more to reduce the loss of patients to online prescription renewal rather than doing what is best for their well-being.

Individual ODs may not have much influence on the overall trend of telehealth except in collective marketing efforts with colleagues and in optimizing their practice patterns. Meanwhile, the dominant third-party vision plan is exploring tele-optometry in response to some employers expressing interest in a remote care option.[23] Under the supervision of eyecare professionals, remote technology can help provide improved access and convenience to patients. This would keep doctors making decisions for their patients rather than corporate executives.

It is an uphill climb to educate at large scale, getting the public to understand that VA and refraction are merely two components of a comprehensive exam and to understand the value of a comprehensive exam in disease detection and preventive care. Likewise, it is not simple to convey that a practitioner's judgement is valuable to determine their eyeglass prescription, as the refraction is not always what is prescribed. Surely, online algorithms will continue to improve. Even so, there is no substitute presently for a clinician's empathy nor their consultative skill to encourage the patient toward a favorable treatment path.

Consumer trendlines show the impetus for adoption of telehealth in eye care will continue.[24] Among practitioners, the motivations and capabilities are more mixed. One *JAMA Ophthalmology* study found that telehealth in ophthalmology peaked during COVID and has returned to baseline.[25] Because the specialized equipment of eyecare requires patients to physically go to an office, there may be a natural limit to how successful telehealth in eyecare can become. Nevertheless, even with these constraints in mind we still anticipate growth in tele-optometry. Just like how autorefraction and laser vision correction were once perceived as threats to the optometric profession, history suggests that optometrists will harness these new technologies to provide better and more efficient patient care. ■

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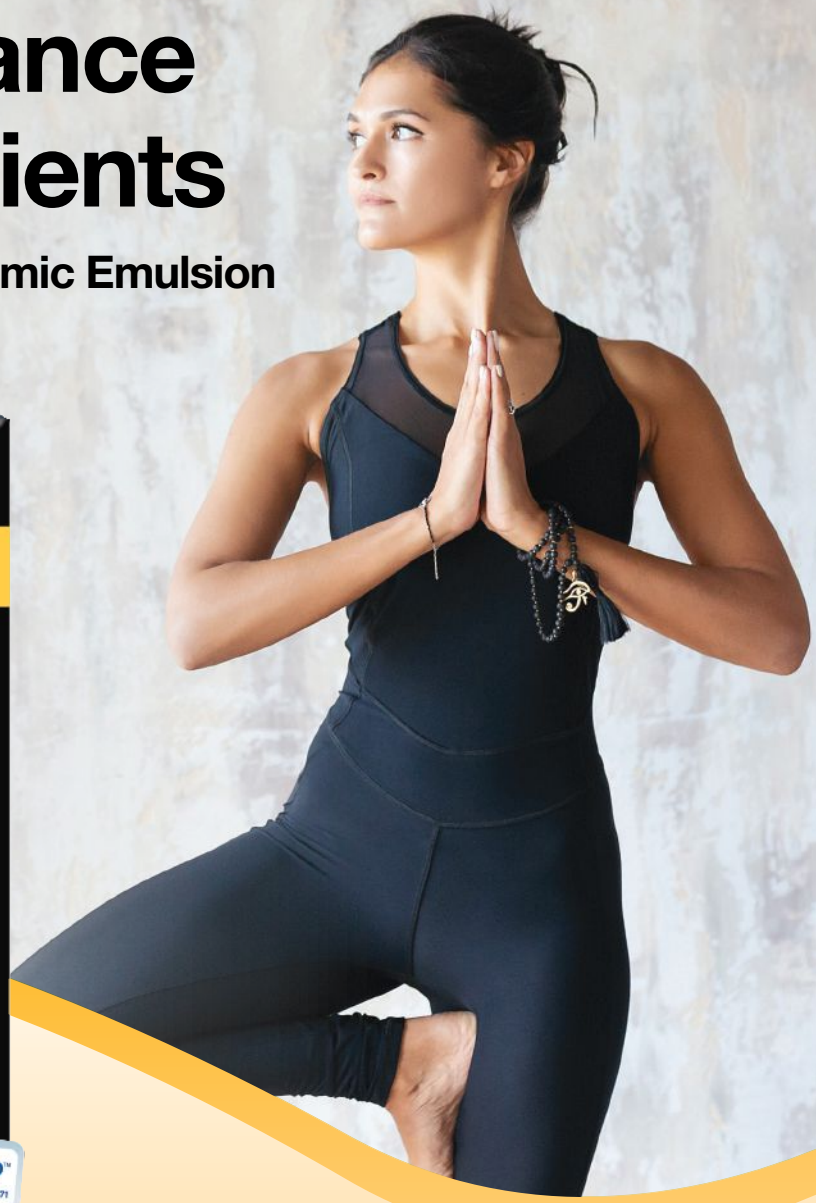

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READER SURVEY: WHAT'S ON YOUR TECH SHOPPING LIST?

Find out what matters most to optometrists when adding tools and techniques to their practices.

BY JACK PERSICO
EDITOR-IN-CHIEF

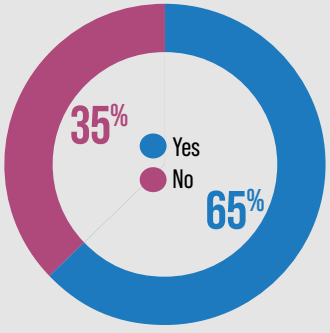
Fall is when most ODs turn their attention to goal-setting for the coming year. What do you want to shoot for in 2025—adding new skills and procedures? Boosting office productivity? Patient retention? A healthier bottom line? More breathing room in the daily schedule? Those are usually among the top options, and there's any number of ways to pursue them without spending a penny, of course, but they are all key motivators that guide purchasing decisions for a practice.

To stay competitive and continually provide the best care, optometrists must make informed decisions when investing in new equipment. We recently conducted a survey of ODs on their priorities and considerations when purchasing new technology. This article delves into the key findings, providing insights for optometrists looking to make strategic investments. In all, 155 optometrists took the time to share their real-world stories and experiences with us.

Taking the Plunge

A significant majority of optometrists have invested in new medical technology in the past two years, according to our survey. Specifically, 64.5% of respondents confirmed that they had made such investments (*Figure 1*). This finding underscores the importance of staying current with technological advancements to enhance practice capabilities and patient care.

FIG. 1. HAVE YOU INVESTED IN ANY NEW MEDICAL TECHNOLOGY FOR YOUR PRACTICE IN THE PAST TWO YEARS?



"Being ahead of technology is what patients expect from their doctors these days," noted Jaya Pathapati of Amarillo, TX, in her survey response. She recently bought several new devices primarily involving retinal disease diagnosis.

The survey asked optometrists to rate the importance of various factors when purchasing new technology on a scale of 1 to 5 (*Figure 2*). The top priority was improving patient care outcomes, with a weighted average score of 4.62. "If the new technology doesn't improve patient care, you are buying it for the wrong reason," an OD from Idaho wrote.

This was followed by creating a positive impression on patients (4.37), ease of use (4.28) and increasing practice value (4.18). Other important factors included training and technical support from manufacturers (4.18), good warranty and service plans (4.15), improving efficiency and office flow (4.13) and increasing revenue (4.13).

"ODs cannot survive on what we get from vision plans, so the sooner we invest in peripheral equipment, the better off we will be," wrote Troy Ogden, OD, from Sparks, NV.

The reputation of the manufacturer didn't make much impact as a whole, ranking second to last among the options with a weighted average of 3.91. However, it's notable that some of the most emotionally charged comments in the responses came from ODs venting about lousy service, purchase terms or behavior by certain vendors.

One survey respondent who bought a headset perimeter last year lamented that "the tech they sent for us to train was a newbie (week one at his job), he couldn't answer the most basic questions" and said they returned that device within a week. "If one can't provide a good staff to

train us, I don't see the value in that device. I need good support from the manufacturers. There are plenty of devices in the market—what sets you apart?"

Another reader concurred: "We look for the company rep to be experienced not only with this product but within the industry itself," a Wisconsin OD wrote. "They should know what they're selling and what they're talking about."

Coming in last in importance when buying, with a weighted average of 3.72, was the availability of a CPT code linked to use of the device, a plaudit that often gets trumpeted by manufacturers as a selling point.

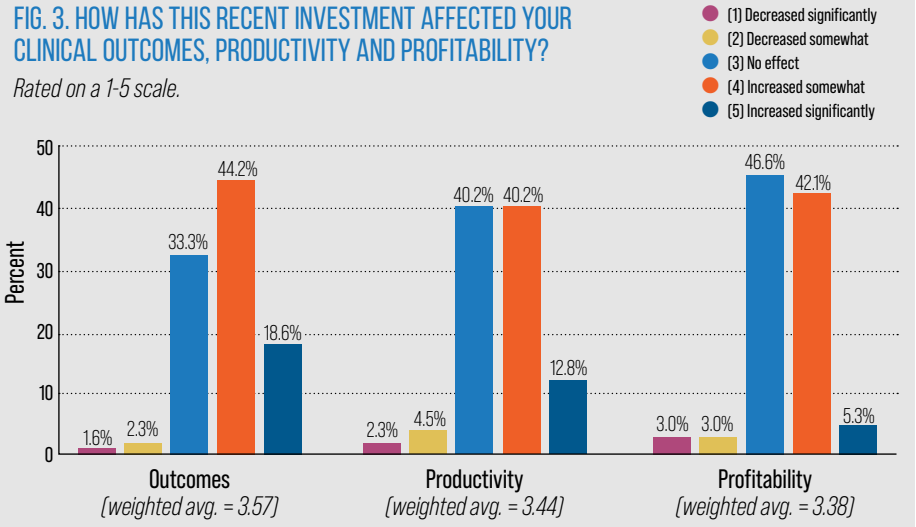
Reaping the Rewards

Optometrists who invested in new technology reported notable improvements in various practice metrics. When asked about the impact on profitability, productivity and clinical outcomes (again using a 1-5 scale), the responses were generally positive (*Figure 3*).

For clinical outcomes, 44.2% of respondents reported at some increase and 18.6% called it a significant gain. Combined, that's a healthy 62.8% of readers who felt their recent purchase delivered on their patient care goals in at least some ways.

FIG. 3. HOW HAS THIS RECENT INVESTMENT AFFECTED YOUR CLINICAL OUTCOMES, PRODUCTIVITY AND PROFITABILITY?

Rated on a 1-5 scale.



Productivity gains from new tech saw a similar trend, with 40.2% reporting at least some improvement and 12.8% noting a significant one—for a "top two boxes" score of 53% reporting productivity enhancements.

Profitability, however, didn't quite make it past the 50-yard line. While 42.1% of respondents experienced some increase in the bottom line, only 5.3% felt their investment's ROI was significant last time around. That's 47.4% overall reporting a positive financial position after their recent purchase. Good, then, that patient care outcomes rank higher in priority anyway.

"Our OCT works great and we love it, but in reviewing reimbursements for OCT we have come to realize that capital equipment is now just a break-even proposition," one reader commented. "Low reimbursements, and by the time the equipment is paid for, you will likely need a new machine."

While every medical practice in every discipline needs to periodically upgrade its equipment, a rapidly evolving one like optometry always has an array of new clinical responsibilities to pursue, whether it's adding specialty contact lens fitting, going deep on dry eye or getting more gung-ho about retinal

FIG. 2. RATE THE IMPORTANCE OF EACH WHEN BUYING NEW TECHNOLOGY. *On 1-5 scale (1 = least impact, 5 = most impact)*

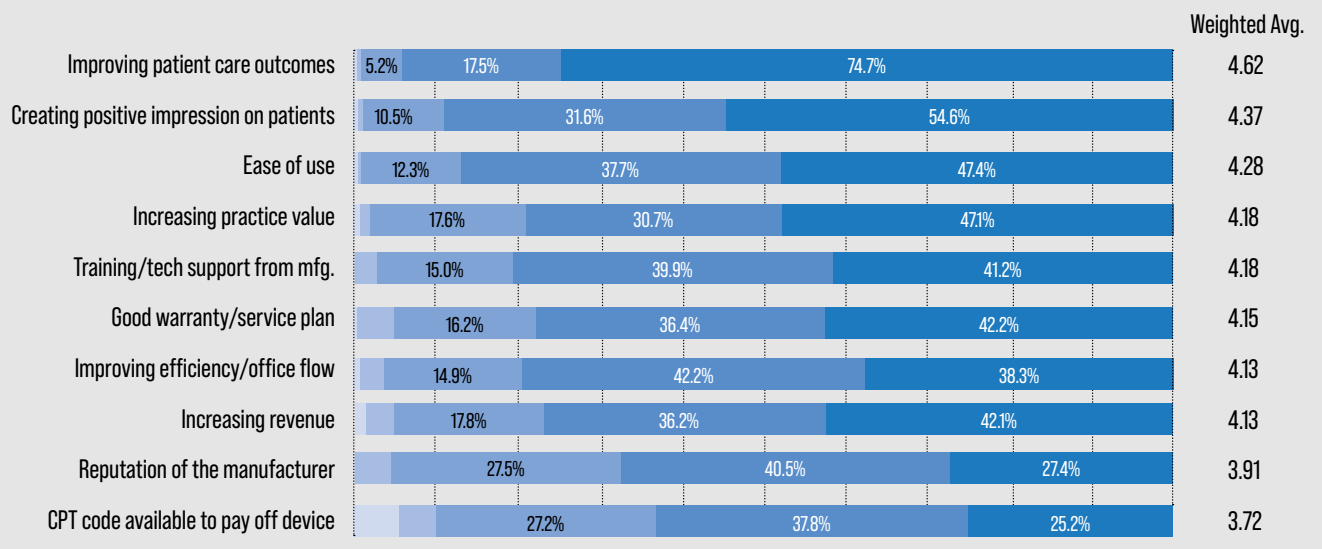
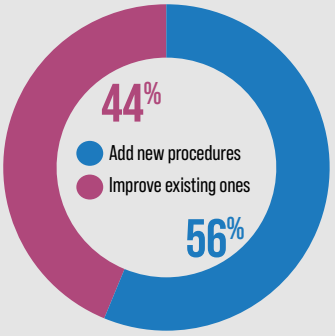


FIG. 4. FOR YOUR NEXT MAJOR EQUIPMENT PURCHASE, WHAT IS YOUR PRIMARY CLINICAL GOAL?



comanagement. So, it's no surprise that more than half (56.2%) of respondents said they aimed to add new procedures or services to their practice when considering their next major equipment purchase (*Figure 4*).

Choosing Wisely

A sizable portion of the survey explored the types of equipment ODs already have, plan to buy and just can't justify at the moment. You can browse the results in *Figures 5, 6 and 7*, and see how closely these match up with your own.

The top five tools respondents already have are exactly what you'd expect: slit lamp, Goldmann tonometer, autoref/keratometer, diagnostic lenses and a phoropter—the table stakes for practicing optometry. Things get more interesting after that as trends start to emerge.

Just about three-quarters of ODs in the survey say they have an OCT (74.2%), a respectable gain of 6.9% from two years ago, when we last ran this survey. "The addition of OCT-A opened new clinical capabilities to diagnose and monitor patients," one OD commented.

EHR systems equipped with practice management capabilities, at 79.9% this year, jumped 15% from 2022's figure of 64.7%. Of course, this year's survey pool was different than that of 2022, making direct comparisons difficult. Still, as each of these surveys constitutes a snapshot of the profession at a given time, it's interesting to note differences between them even if they lack statistical rigor.

One area of care where we feel confident calling out a trend is the adoption of head-mounted visual field testers. In 2022, just 8.5% of respondents had one

FIG. 5. WHICH OF THESE TOOLS DO YOU ALREADY HAVE?

Slit lamp	96.8%
Tonometer, Goldmann	92.2%
Autorefractor/keratometer	93.4%
Diagnostic lenses	91.5%
Phoropter, manual	90.7%
EHR with practice management features	79.9%
Tonometer, non-Goldmann	74.2%
Pachymeter	70.1%
Perimeter, conventional	62.8%
Corneal topographer	58.9%
OCT, no angiography	59.4%
Fundus camera, conventional	55.2%
Fundus camera, ultra-widefield	54.1%
Gas permeable/scleral lens fitting sets	50.7%
Phoropter, digital	48.7%
Slit lamp camera attachment	38.9%
Fundus autofluorescence	38.4%
Perimeter, headset	20.6%
B-scan ultrasound	18.4%
Thermal pulsation device for MG expression	17.8%
OCT, with angiography	14.8%
Lid microexfoliation device	14.7%
Wavefront aberrometer	14.1%
Tear osmolarity tester	13.3%
Optical biometer	13.0%
Dark adaptometry	9.8%
ERG	9.8%
Intense pulsed light	9.0%
Scleral topographer	8.3%
Radiofrequency device	8.3%
Low-level light therapy	6.3%

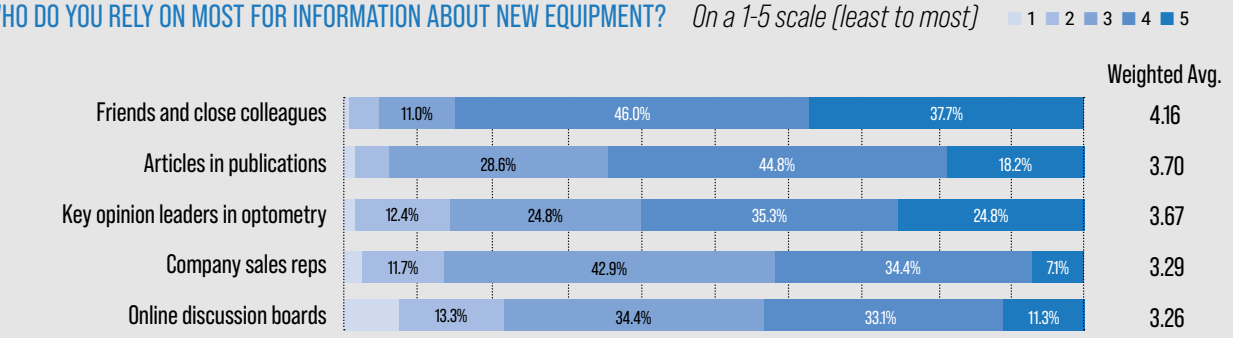
FIG. 6. WHICH ARE YOU CONSIDERING BUYING IN THE NEAR FUTURE?

Slit lamp camera attachment	27.8%
Perimeter, headset	27.4%
Fundus camera, ultra-widefield	22.3%
Intense pulsed light	22.2%
OCT, with angiography	19.0%
Thermal pulsation device for MG expression	18.4%
Tear osmolarity tester	18.2%
Low-level light therapy	16.2%
Lid microexfoliation device	15.4%
Tonometer, non-Goldmann	13.9%
Corneal topographer	13.7%
Phoropter, digital	13.5%
Optical biometer	12.2%
OCT, no angiography	11.9%
Radiofrequency device	11.8%
Fundus autofluorescence	11.0%
Fundus camera, conventional	9.7%
Pachymeter	9.5%
Scleral topographer	9.0%
Dark adaptometry	7.7%
ERG	7.7%
B-scan ultrasound	7.1%
EHR with practice management features	6.7%
Gas permeable/scleral lens fitting sets	6.1%
Wavefront aberrometer	5.6%
Perimeter, conventional	5.4%
Slit lamp	3.9%
Autorefractor/keratometer	2.0%
Diagnostic lenses	2.0%
Phoropter, manual	1.4%
Tonometer, Goldmann	1.3%

FIG. 7. WHICH WOULD YOU LOVE TO HAVE BUT JUST CAN'T JUSTIFY RIGHT NOW?

Scleral topographer	82.6%
Dark adaptometry	83.2%
ERG	82.5%
Wavefront aberrometer	80.3%
Radiofrequency device	79.9%
Low-level light therapy	78.9%
Optical biometer	74.8%
B-scan ultrasound	74.5%
Lid microexfoliation device	69.9%
Intense pulsed light	69.4%
Tear osmolarity tester	69.2%
OCT, with angiography	66.9%
Thermal pulsation device for MG expression	65.1%
Perimeter, headset	52.8%
Fundus autofluorescence	50.7%
Gas permeable/scleral lens fitting sets	43.9%
Phoropter, digital	37.8%
Fundus camera, conventional	35.9%
Slit lamp camera attachment	35.4%
Perimeter, conventional	34.5%
OCT, no angiography	29.4%
Corneal topographer	27.4%
Fundus camera, ultra-widefield	23.7%
Pachymeter	20.4%
EHR with practice management features	14.1%
Tonometer, non-Goldmann	11.9%
Phoropter, manual	7.9%
Diagnostic lenses	6.6%
Tonometer, Goldmann	6.5%
Autorefractor/keratometer	4.6%
Slit lamp	1.3%

FIG. 8. WHO DO YOU RELY ON MOST FOR INFORMATION ABOUT NEW EQUIPMENT? *On a 1-5 scale (least to most)*



of these new devices, but they also said it was their second most anticipated purchase. Fast-forward to 2024 and 20.6% of this year's survey group tells us they've got one, a 12.1% gain, and the product category is again among the top three desired purchases for the future, with 27.4% of readers considering one.

Headset perimetry "has been great for staying up to date on latest technologies and provides a 'wow' factor that patients love," wrote one OD from Connecticut.

Another encouraging sign in adoption trends is greater uptake of pachymetry, from 57.8% in 2022 to 70.1% this year. With positive movement for that category plus headset perimetry and OCT, optometrists look to be getting more serious about glaucoma management.

Dry eye care—the most crowded category of devices for sure, with purpose-specific products comprising six out of our 31 options—is difficult to characterize. Five of the top 10 wish list items in the 2024 survey are dry eye devices—but five of the top 11 that ODs can't justify right now are, too.

"There's a lot of new dry eye tools that I think would add value to the practice and there certainly is a need for it," wrote Madison Rhoton, OD, of Auburn, ME. "However, we have a lot of tools at our disposal currently and I'd like to become optimally efficient at using those before adding more to the mix."

Still, dry eye tech demand clearly has some strong indicators in our survey data. When going product by product through the "have it" and "want it" questions, the two product categories with the biggest positive difference (want > have) are both dry eye therapies: intense pulsed light (+13.2%) and low-level light (+9.9%).

Signing on the Dotted Line

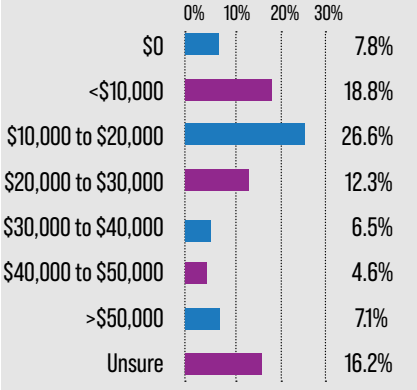
When researching a new purchase, ODs rely on various sources for input on the wisdom of the prospect. Friends and close colleagues were rated as the most important, with a weighted average score of 4.16 on a 1-5 scale (*Figure 8*). This was followed by articles in publications (3.70) and the advice of key opinion leaders in optometry (3.67); company sales representatives (3.29) and online discussion boards (3.26) didn't fare as well.

"I depend a lot on experiences from people I know," wrote Mary Hoang, OD, of Tustin, CA. "You can always tell by how they respond to your inquiry to know if the product is good or not. I trust them more than a sales rep or online."

Asked about their budget for new instruments and equipment in the next year, 45.4% intend to keep the investment below $20,000 (*Figure 9*).

"Get multiple quotes," advised one reader. "You get a feel for the company and decide who you want to give your business."

FIG. 9. HOW MUCH DO YOU PLAN TO SPEND ON NEW INSTRUMENTS AND EQUIPMENT IN THE NEXT YEAR?



Said a reader from Boston, "I like it least when pricing is a mystery and I have to spend valuable time with 30-minute phone calls just to hear a demo/the price of the device. Ranges should be advertised, at a minimum."

Sales reps focus heavily on ROI; while that's important, "they need to have realistic numbers and understand our perspective on expectations like life span," wrote Mark Burke, OD, of Plainfield, IL. "I had a vendor recently tell me how a camera would pay for itself and I looked right back at him and said the wellness images I take now are $39/patient with 96% conversion—will medical images alone pay the $1,250/month if I'm bringing four patients back for retinal evaluations per month?"

Looking Ahead

Buying a new device opens up new possibilities, and that's exciting, but there are more than a few bumps along the way. "Patients like new stuff, but it's not always an upgrade on previous equipment in terms of ease of use," wrote Annette Morgan, BOptom, of Wellington, New Zealand. "And we can't always compare data from old to new machines, argh!"

With a significant portion of ODs planning investments in the coming year, staying informed through trusted sources is crucial for making strategic decisions. "Generally, enhancing flow and patient benefit takes top priority, with a close second as profitability and equipment filling a need," Dr. Rhoton summed up.

By understanding these trends and priorities, ODs can make informed decisions that align with their clinical goals and practice needs, ultimately enhancing patient care and practice success. ■

DEVICES YOU MIGHT NOT HAVE: ARE THEY A GOOD FIT?

Experts weigh in on how advanced tools can help with specific clinical responsibilities, providing you clarity on whether their benefits will serve your specific needs.

BY CATLIN NALLEY
CONTRIBUTING EDITOR

Most primary care optometrists are well-equipped to serve any patient who walks in the door with the standard battery of tools and technology that make up the core pieces of an exam suite, but technological advancements are continuously creating new options to improve your existing clinical procedures or even add entirely new ones for those doctors looking to level up. From sophisticated imaging systems to cutting-edge diagnostic tools, a range of optometric devices have emerged that can enhance patient care and improve clinical outcomes.

This article will explore a diverse selection of optometric devices that are newer to the scene or mostly associated with different types of specialty care that may help you advance your skills in a particular sphere of care you want to develop. We'll delve into their potential benefits and whether they might be a good fit for your specific needs. No single OD would conceivably want or need all of these, but as more doctors gravitate toward a particular niche or subspecialization to concentrate on, it's worth looking at advanced tools.

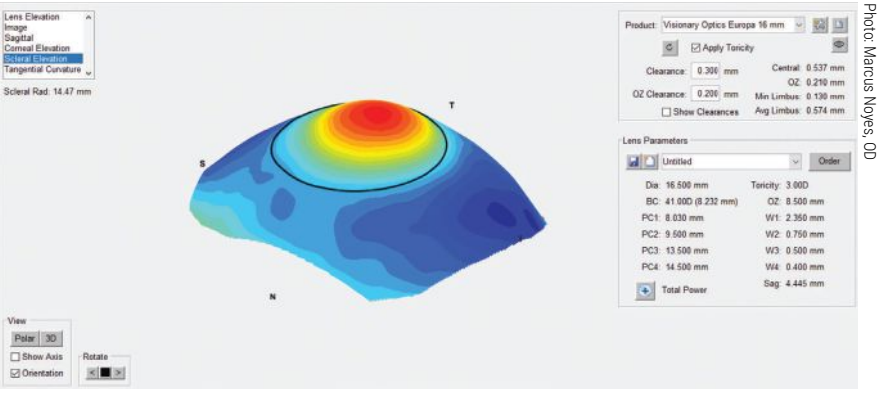
By asking experts about the latest innovations and assessment of their practicality, we aim to provide insights on what these devices can offer for ODs who are currently kicking the tires on a new purchase.

Scleral Topography/Profilometry

One big success story in recent years has been resurgence of scleral contact lenses. Fitting sets do a nice job, but a scleral topographer allows doctors to assess exact curvature and surface characteristics—a crucial component of fitting sclerals with precision. Scleral topography, or scleral profilometry, helps design lenses that conform optimally to the eye's unique surface, ensuring better lens alignment, stability and comfort.

"The promise of profilometry is reduced chair time to complete the specialty lens fitting. More information can be gathered regarding the ocular surface shape before any lens is manufactured," notes Lindsay Sicks, OD, of the Illinois College of Optometry. "Highly customized geometry can be manufactured based on the scans obtained, so these devices can be very useful in patients who have failed with standard scleral lenses or who want a more streamlined fitting process."

John Gelles, OD, who specializes in keratoconus and contact lenses at The Cornea and Laser Eye Institute of Teaneck, NJ, considers this device indispensable for his clinical practice. "Scleral profilometry can significantly improve your ability to fit complex



The sMap 3D scleral elevation map after image-stitching.

Photo: Marcus Noyes, OD

eyes and helps you understand scleral shape on a higher level. The data allows you to predetermine the lens design that will work best for your patient," he says, while also noting that using scleral profilometry does come with a learning curve.

There can be the misconception that the device will give you perfect lenses on one try and need no modifications, bypassing practitioner skill. However, that is not the case. "Rather," Dr. Gelles explains, "think of these devices as giving you a better start point."

While a scleral topographer can produce better-fitting lenses, you need good scans to do so, he explains. "Familiarizing yourself with the device and learning how to capture and identify good data is crucial for success," he adds. When using scleral topography in clinical practice, it is important that ODs take into account that they may not be able to take images on the same day as the comprehensive exam, according to Dr. Sicks. "We typically recommend the patient be out of their habitual lenses for 48 hours before scans for best results. Thus, the patient often returns for an additional visit for scans."

When determining if this device is the right fit, ODs must consider the unique needs and dynamics of their clinical practice. "While I believe that every patient should have the best fitting experience and care possible, this device may not make dollars and sense for every optometrist," acknowledges Dr. Gelles. "That being said, scleral profilometry is a valuable addition and, if it is an option, I would encourage ODs to consider investing in this device for the benefit of their patients and practice."

LLLT, IPL and Thermal Pulsation

Dry eye is an area of optometric care that's teeming with new technology options that can improve outcomes. Tried-and-true medical therapies will always be a mainstay, but there are now several device categories that offer in-office procedures to accelerate symptomatic improvement.

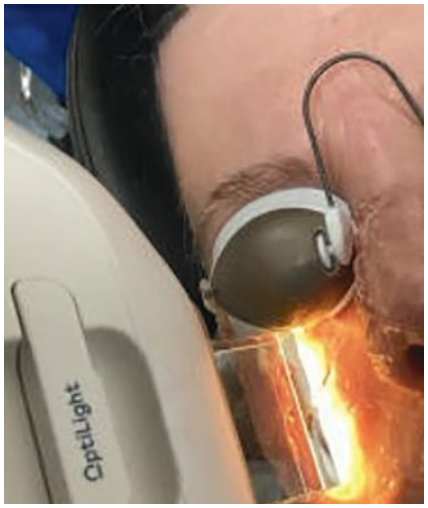


Photo: Harriette Canellos, OD

Intense pulsed-light therapy.

There is a strong case, according to Paul Karpecki, OD, medical director of the Dry Eye Institutes of Kentucky and Indiana, for the use of low-level light therapy (LLLT), a photobiomodulation intervention, in the management of ocular surface disease. It can work as a standalone treatment or in conjunction with intense pulsed-light therapy (IPL).

"LLLT can come in various forms—ranging from blue, which has antimicrobial properties and can be used for blepharitis, including *Demodex*—to yellow for postsurgical edema to red for meibomian gland dysfunction (MGD), hordeola and chalazion," explains Dr. Karpecki. Red LLLT is by far most commonly used.

In Dr. Karpecki's experience, combining LLLT with IPL further enhances the effects of each when treating conditions such as MGD, evaporative dry eye or ocular rosacea. In the case of hordeola or chalazia, red LLLT alone is all that is needed, he notes. "In fact, I have only had to surgically remove two hordeola and inject two in the last two years since incorporating red LLLT alone for this condition."

For Harriette Canellos, OD, associate clinical professor at SUNY College of Optometry, IPL is her go-to treatment for ocular rosacea. While she acknowledges that the initial cost of the device may be a factor, her clinic has found success with IPL. "The number of patients interested in the procedure will likely be greater than one might expect—especially when you educate them that IPL can also help treat fine lines and wrinkles."

Thermal pulsation, which combines heat and gentle pulsating pressure, is primarily used to treat MGD. In addition to using the device to treat patients with MGD, Dr. Canellos also has many patients who report a reduction in their recurrent chalazia after LipiFlow (Johnson & Johnson). "It does not require much chair time," she notes. "Once you place the applicators on, the procedure is automatic for 12 minutes and the doctor does not need to be present during that time."

Dr. Canellos and her colleagues perform meibography on every patient. "We are able to show our patients the damage to their meibomian glands. Once they see these images, they start to understand the importance of taking care of their eyelid health and the value of thermal pulsation," she says. The overwhelming majority of dry eye patients have MGD and Dr. Canellos believes that having a thermal pulsation device available as a treatment option is essential.

Each of these devices offers benefits for optometric practice. "IPL and LipiFlow work differently and, in my opinion, it is not a choice between having one or the other in practice," she advises. "Many patients benefit from both treatments and a combination often gives the best results."

In Dr. Canellos' practice, a significant amount of time during initial consult is dedicated to discussing the patient's diagnosis and all treatment options that pertain to the individual. "I do not promote one particular

Photo: Harriette Canellos, OD

LipiFlow treatment.

treatment but I recommend the ones I think will work best for each individual patient," she notes. "It is important to me that my patients trust my care and treatment recommendations. I never want to give them the impression I am pushing a particular procedure for my financial gain."

Tear Osmolarity

Dry eye is so familiar to optometrists that many can diagnose it literally with their eyes closed—just by talking to the patient about their symptoms and lifestyle. A simple slit lamp exam can then confirm it. However, some clinicians swear by the benefits of sophisticated measurements of tear film properties for both diagnostic purposes and long-term monitoring of treatment response.

Osmolarity testing is a measure of the level of solutes in a fluid, one that Dr. Karpecki considers an essential tool for any practice that treats ocular surface disease and wants to perform at the highest level. A reading above 308mOsm/L indicates dry eye disease and poor-quality tears. A difference of more than 6mOsm/L between eyes suggests tear instability, and the higher of the two eyes is the measurement to determine dry eye, he explains.

"The value of osmolarity testing lies in the area of efficiency. Not only does a reading only take about 12 to 15 seconds, but the efficiency in clinic is observed in making an accurate diagnosis of dry eye, determining a differential diagnosis and for patient education," says Dr. Karpecki. "In my experience, it is the most reliable and accurate test I have."

Toward the end of treatment, patients with longstanding dry eye often experience symptom relief, so showing continuous improvement in osmolarity allows them to know the treatment is helping and they are on track. Furthermore, patients are used to knowing their numbers, like when their blood pressure is checked or when glaucoma patients receive intraocular pressure measurements, according to Dr. Karpecki, and this is a similar scenario.

Photo: Harriette Canellos, OD

InflammaDry positive results for matrix metalloproteinase-9, an inflammatory marker elevated in tears of dry eye patients.

"If I don't have access to osmolarity testing in my clinic, it's difficult to know the diagnosis, difficult to teach patients or track progression and the clinic day is often running hours behind as we try to use less efficient tests to figure out the disease and if treatment is working," Dr. Karpecki explains.

Dr. Canellos also considers this a key component of clinical practice. "We use TearLab (Trukera/Bausch + Lomb) as well as InflammaDry (Quidel) as part of our full dry eye work-up. TearLab evaluates tear osmolarity of each eye and InflammaDry tests for matrix metalloproteinase-9, which is an inflammatory marker elevated in tears of patients with dry eye," she explains. Both are easy use, low-cost and billable to insurance, with the two also helping determine appropriate treatment strategies.

Wavefront Aberrometry

Another advanced diagnostic device that provide detailed information about optics of the eye to enhance specialty lens fitting, wavefront aberrometers also have use outside of the contact lens clinic, explains Dr. Gelles. They can aid in the understanding of patient visual complaints and can raise suspicion of disease affecting the optics of the eye and the need for further testing, according to Dr. Gelles. "By replacing an autorefractor with a wavefront aberrometer, much further insight is gained and can help a practitioner emphasize with a patient," he offers.

By mapping aberrations with high precision, wavefront aberrometry enables optometrists to understand the visual quality of patients. With specific aberrometers, this data can be used to tailor the optics of scleral lenses to an individual's unique visual needs. These wavefront-guided scleral lenses can provide significant improvements for those with complaints of poor visual quality in standard scleral lens optics.

The ability to customize lenses based on wavefront data helps improve visual clarity, reduce visual distortions and enhance overall visual performance, ultimately contributing to a more personalized and effective approach to vision correction, according to Dr. Gelles, who has found that the vast majority of patients prefer wavefront-guided lenses.

"Patients want these optics," he emphasizes. "They definitely offer an improved level of visual acuity, which provides patients with better functionality and overall quality of life. He says many patients are able to achieve an 'age-matched normal' level of vision quality with wavefront guided lenses. He notes that there is a strong case for the use of wavefront aberrometry in optometric practice, urging optometrists to consider if this is a device that would benefit their patients.

Dark Adaptometry

This tool has been shown to be a sensitive test for detecting early functional changes among patients with age-related macular degeneration (AMD). Studies have demonstrated that

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impaired dark adaptation (DA) often precedes visible structural changes, making it a potentially valuable tool for early diagnosis and intervention.

While a number of diagnostic tests for AMD exist, optometrists who concentrate on retinal disease can stay ahead of this condition by identifying AMD risk during routine examinations and using dark adaptation, which can identify the earliest functional biomarker of AMD, explains Amanda Legge, OD, practicing at the Wyomissing Optometric Center based in the Reading, PA area.[1]

"Most of the time with especially early AMD, there is not a definitive line that's crossed when someone is diagnosed" with conventional methods, Dr. Legge says. However, she argues, "having any drusen with delayed dark adaptation = AMD." She explains that the test is 90% specific, sensitive and accurate in differentiating small or pinpoint drusen from normal age-related changes vs. early AMD. It also helps identify patients with subretinal drusenoid deposits (SDDs). "These studies reveal that the presence of reticular pseudodrusen (RPD) is associated with an additional two- to sixfold increased risk of progression to neovascular AMD or central GA, with the risk even higher for RPD located outside the macula."

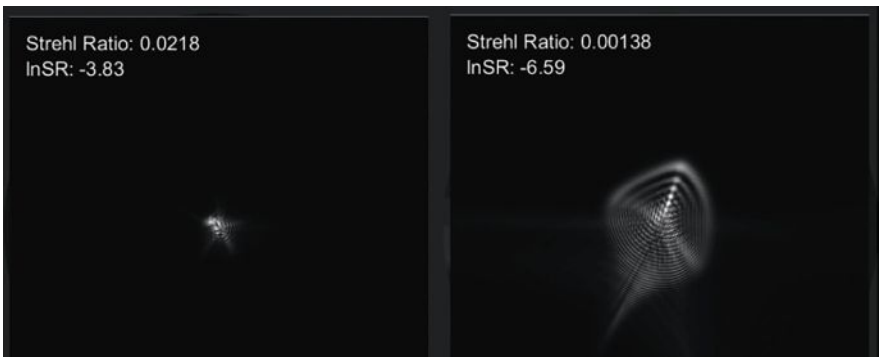


Photo: John D. Gelles, OD, and Travis M. Pfeifer, OD

A point spread function, shown here, can be calculated using wavefront aberrometry, which simulates how a patient would see a perfect white point on a black background; the left and right images depict two different patients. On the left is a normal cornea and on the right is an individual with keratoconus.

SDDs appear in eyes that are clinically unremarkable, Dr. Legge explains, but their dark adaptation is deeply impaired even early on. "These are maculae that look clinically benign but have a dark adaptation of >20 minutes. When you know what and where to look on OCT to diagnose SDDs, this deep delay in DA usually signifies overall advanced AMD that matches the clinical picture OR the presence of SDDs even in a mild clinical appearance."

Getting out in front of these disease processes can make a meaningful impact on the long-term course. "These patients can convert to choroidal neovascular membrane but were never told they even had AMD previously because of the mild clinical appearance," she notes.

The AdaptDx (LumiThera Diagnostics) headset device measures a patient's rod intercept (RI) time. This measurement is the number of minutes it takes for the eye to adapt from bright light to darkness. An RI time of less than 6.5 minutes suggests normal dark adaptation, indicating healthy photoreceptor function, while anything higher is a sign of impaired function, which is typically associated with AMD in patients over 50 years old.[2]

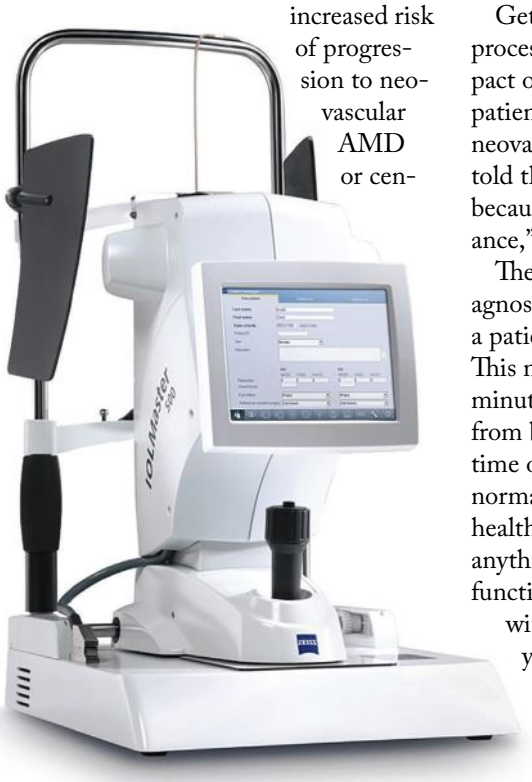
Dark adaptation serial testing over time also provides a functional measure of the patient's AMD, Dr. Legge explains. "Those progressing quicker functionally (more delayed in DA with each test) are monitored more closely in office regardless of clinical appearance. It is a way to individualize treatment of AMD because every person is very different in AMD risk and management."

Dark adaptometry has the potential to enhance retinal care in optometric practice. "It's easily reimbursable and we have very few (if any) denials for testing for drusen, AMD or acquired night blindness," says Dr. Legge. It's also convenient for the practice, as the test can be conducted in any room. However, it does take time—up to 20 minutes to complete both eyes, she says, adding that most do not take that long.

As with any technology, implementation requires careful consideration to determine whether it is the right fit for the needs of a specific clinical practice. If you don't see a lot of elderly patients and emphasize AMD in your practice, it may not be a good fit.

Optical Biometry

After scleral lenses, the other rising star in optometric care lately is myopia management. An optical biometer is key for those interested in adding this



Optical biometry is an essential tool for any practice offering myopia management. Buying a used older model from a cataract surgeon can be an afffordable option.

service, notes Dr. Sicks. The main goal with myopia management is to reduce axial elongation rate. "The only direct way to measure that rate is via optical biometry (a reduction in refractive progression does not always correlate with a reduction in axial length progression)," she says.

She adds that "it helps you monitor the success of your intervention," while noting that, in her practice, she prefers to obtain biometry at baseline and then every six months thereafter.

Most instruments marketed for myopia management are non-contact, interferometry-based devices, which are more accurate (resolution to 0.03D) than older A-scan applanation ultrasound devices (resolution to 0.30D), according to Dr. Sicks. "Thus, I would recommend the interferometry-based devices to manage myopia; a non-contact instrument is preferable for pediatric patients as well. Some instruments also have additional risk factor analysis reports available."

For Langis Michaud, OD, a professor of the School of Optometry at the L'École d'optométrie de Université de Montréal, biometry is the most important tool he employs in his clinic for the care of myopic children. "From the beginning, axial length—not refraction—along with growth charts, allows me to determine the risk of high myopia in adulthood," he explains. "The higher the risk, the more aggressive my control management will be," he explains.

Dr. Michaud provides the example that an eight-year-old myopic child with -1.00D (cyclo ref) and an axial length of 23mm would not be treated the same as if 24.5mm was observed at baseline. "During follow-ups, axial length is the only parameter on which I base my assessment of the patient's progression, especially for those fitted with orthokeratology lenses."

While many might say that biometry is nice to have, but not a necessary tool for myopia management, Dr. Michaud considers it mandatory and standard of care: "Compare it to glaucoma. Can you consider managing that condition based solely on Goldmann intraocular pressure? The obvious answer is no." To properly manage glaucoma, a practitioner needs optic nerve scans, visual fields, gonioscopy, etc. to make a proper assessment, he explains. Managing myopia without axial length measurements taken at baseline and follow-ups is risky, as is treating glaucoma based on intraocular pressure alone, Dr. Michaud comments. You can do it, but you can also miss the mark that way.

Investing in new equipment can often come with a hefty price tag. "Some of my colleagues argue that they cannot afford a biometer for their practice. Fortunately, there are many affordable options available today," notes Dr. Michaud. "And we need to learn how to charge for our services. If you charge every time you use your biometer, it becomes a profit center, not an expense. More importantly, you will bring your practice up to the standard that our young patients and their parents/caregivers expect," he adds.

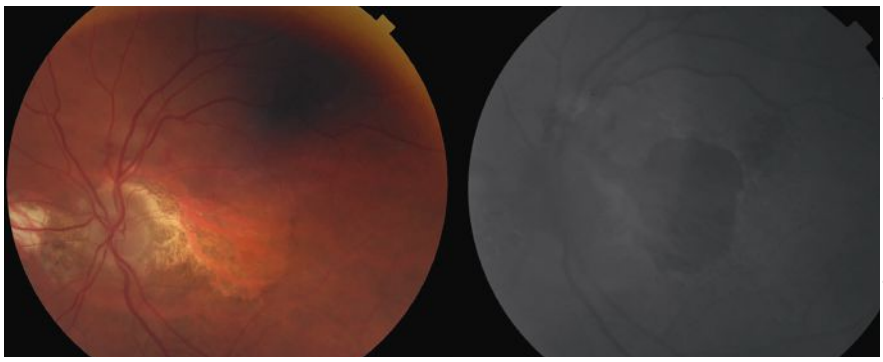


Photo: Steve Njeru, OD, MS, and Daniel Grangaard, OD

The left photo depicts advanced AMD with extensive, central GA. At right is an FAF photo showing extensive amounts of central hypofluorescence due to retinal pigment epithelium loss and a small area of hypofluorescence superior to the optic nerve caused by increased metabolic activity from the neovascular membrane.

Fundus Autofluorescence (FAF)

This type of retinal imaging is a useful tool for conditions that affect the outer retina— particularly the retinal pigment epithelium—and it is often incorporated into current imaging devices, such as OCT and fundus photography systems, Jessica Haynes, OD, of the Charles Retina Institute in Germantown, TN explains.

FAF can support the detection of geographic atrophy (GA) in AMD as well as monitoring progression of the disease. It can also help identify and diagnosis less common conditions, such as retinal diseases, macular telangiectasia type 2 and pattern dystrophies, among others, Dr. Haynes elaborates.

"Many imaging devices used by optometrists are already equipped with FAF capability or are modifiable to have FAF technology," notes Mo Rafieetary, OD, another practicing physician at the Charles Retina Institute. When purchasing a new camera or OCT, optometrists may want to ask if it comes with FAF.

Presently, FAF is billed the same as fundus photography (92250) and does not have its own CPT code, explains Dr. Haynes. "This does limit its reimbursement, as FAF is often best interpreted alongside information from other retinal imaging that may not be billable on the same day, such as OCT and fundus photography."

When deciding if FAF is a good fit for their clinical practice, ODs should take into consideration various factors, recommends Dr. Haynes. How many patients with retina disease are seen in your practice—particularly those with AMD or others that would benefit from FAF? Would having FAF allow you to better manage these patients or keep them in your practice longer?

"With new treatment options available to slow down the progression of GA secondary to AMD, it is critical to identify these patients and provide them with appropriate education and

referral, when necessary," advises Dr. Haynes. "FAF is a helpful tool in making this possible."

Dr. Rafieetary adds that FAF also holds prognostic value. For instance, a hyper-AF border of a GA lesion suggests its progressive nature, he notes. "Once the eyecare provider becomes familiar with this imaging technique, they can explore its strengths and weaknesses, then the technique when indicated, can be used as another tool for better patient care."

Electroretinogram (ERG) Testing

This type of device can give early and objective indicators in diagnosis and management of ocular diseases affecting the retina, particularly diabetic retinopathy (DR), retinitis pigmentosa and AMD.

"I think of ERG as analogous to an electrocardiogram of the retina," notes Paul Chous, OD, who has a private practice specializing in diabetes eye care in Tacoma, WA. "It essentially measures the electrical current generated by various retinal cell subtypes—photoreceptors, bipolar cells, ganglion cells—to varying intensities of a flickering light stimulus."

Discussing clinical applications ERG, Dr. Chous says, "We all know that 100% contrast visual acuity is affected late in many retinal disorders, including DR. Full-field ERG allows clinicians to assess the function of the entire retina and then compare that function with structural examination findings such as those from dilated funduscopy, retinal photography, fluorescein angiography and both conventional OCT and OCT angiography."

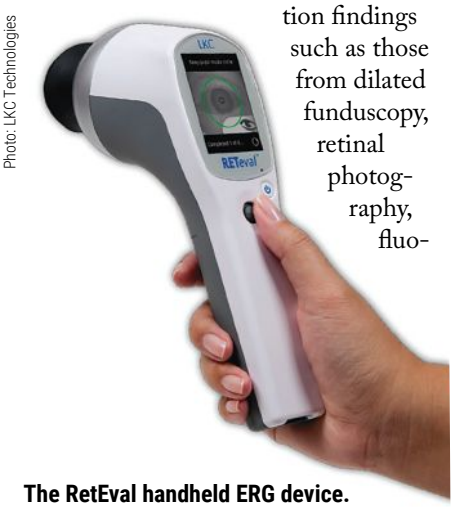


Photo: LKC Technologies

The RetEval handheld ERG device.

What is interesting is that some patients have relatively mild DR based on clinical exam but poor retinal function using full-field ERG, Dr. Chous observes, who notes that this structure-function discrepancy can help optometrists reassess clinical findings and even reconsider referral to retina specialty.

"In fact, abnormal full-field ERG results, in combination with diminished pupillary responses to the same stimulus, have been shown to predict which DR patients are most likely to require a retinal intervention (laser or intravitreal injection) over the next three years," he explains. "Just like in glaucoma, we are trying to look for structure-function agreement or disagreement and more actively monitor and/or intervene in patients with DR."

When integrating this technology into clinical practice, Dr. Chous recommends that ODs consider the number of patients they examine with diabetes and DR, the relatively easy use of full-field ERG technology in daily practice (about five minutes from start to finish), the objective nature of ERG vs. other subjective functional tests commonly performed (visual acuity and perimetry) and return on investment. Shortcomings can include ERG's relative lack of reference database guidance compared to technologies like OCT and uncertainty on indications for use in various clinical scenarios.

"The most important question, in my view, is whether this technology benefits patients and, in my diabetes-centric practice, it certainly does," he says. "My experience with ERG has been positive, and it's been interesting to see some patients' retinal function significantly improve with better metabolic control, anti-VEGF therapy or nutraceutical intervention."

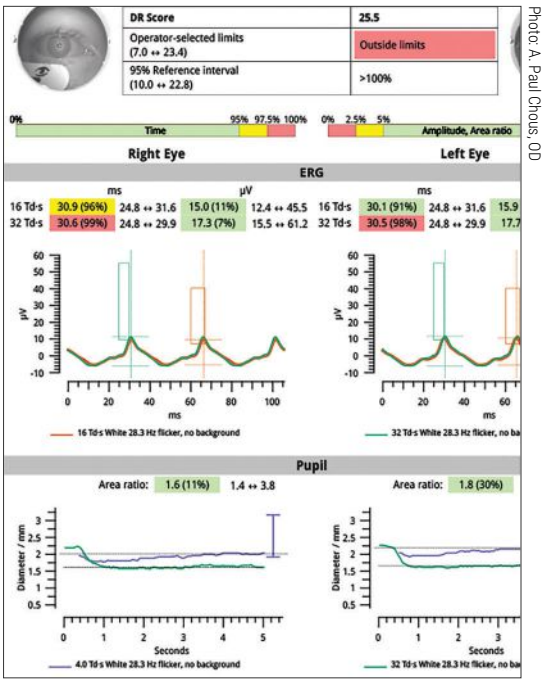


Photo: A. Paul Chous, OD

Full-field ERG wave form showing delayed signal (longer implicit time) and reduced amplitude. Diminished pupillary response differential between brighter and dimmer full-field ERG stimulus.

Head-Mounted VF Testers

A more patient-friendly approach to perimetry, "virtual reality" visual field instruments represent a significant advancement in the convenience and patient-friendliness of such tests.

Humphrey visual field testing remains the gold standard, and while visual field instruments over the years have gotten somewhat smaller, there can still be space constraints, notes James Fanelli, OD, founder and director of Cape Fear Eye Institute in Wilmington, NC. He also notes that there can be challenges for certain patients, especially elderly individuals who cannot lean forward into these devices comfortably for the duration of the visual field tests.

After extensive consideration, Dr. Fanelli integrated a headset perimeter into his practice. "These instruments have transformed visual field testing in our office," he says. "We no longer have the space constraints of a dedicated room for visual field testing. These portable, head-mounted devices can be used while a patient is waiting to be seen or during pre-testing. They can be moved

Photo: Olleyes

Olleyes virtual reality visual field tester.

around to different locations in the office, and, in fact, we have not used the 'box' perimeter in over a year and a half."

While discussing concerns regarding reproducibility and reliability, Dr. Fanelli has found the virtual reality visual field tester he uses (VisuAll, Olleyes) is comparable to traditional devices. The one downside is that Humphrey information is not transferable, he notes. "However, you can compare two pages side by side (when you complete the first test) and pick up where you left off. You just don't have the trend analysis converting from one to the other," he cautions.

Since incorporating these devices, Dr. Fanelli has received a positive response from his patients. "When I asked them why they preferred these devices, they pointed to their improved comfort and ease of use. It was an incredibly positive reaction from patients, much more so than I was expecting to hear."

Unlike traditional perimeters, this type of device can test both eyes simultaneously, at once saving time and enhancing the patient experience, says Dr. Fanelli. Another benefit he outlines is the tracking capabilities available on these testers. "Fixation losses are always a problem with any type of visual field test, but what is nice about this device is if the patient does move their eye just before the stimulus is presented, the visual field unit will move the stimulus according to where their eye is, so fixation losses go down significantly and accuracy goes up," he explains.

With a heavy glaucoma and neuro-optometric based practice, Dr. Fanelli and his partners are typically running these units all day. If an optometrist is in the market for a new visual field device, he highly recommends they consider the option of a virtual reality visual field tester, which allows ODs to perform comprehensive visual field testing with greater efficiency, accuracy and flexibility, elevating the overall quality of eye care.

Takeaways

Just as the many interviewees for this article focus on or specialize in certain areas of optometry, the devices they use and outline here also are geared toward certain specific uses. Not every optometrist will need every technology listed here, but certainly one may apply to your practice's demands. ■

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PROSPECTS FOR REMOTE MONITORING IN EYE CARE

Clinicians can improve the quality of services provided to patients from underserved populations and extend the surveillance of disease status beyond their clinics.

BY AMANDA LEGGE, OD, AND CAROLYN MAJCHER, OD
WYOMISSING, PA; TAHLEQUAH, OK

Healthcare is not experienced equitably by all populations. Rural communities in particular face barriers to care that urban and suburban populations do not. These barriers are multifaceted and include geographic, technological and economic factors. Any approach to mitigation must itself be multifaceted, since addressing only one will not overcome the effects of the other dynamics at play that limit access to care.

Technological innovations have led to a boom in digital health, a network of systems that allows patients to interact with their provider via digital interfaces. Importantly, digital health tools are adjunctive technologies, not ones to be used in lieu of seeing a clinician in office. That is, they allow practices to extend and deepen patient relationships but do not replace providers.

In eye care, services such as autonomous diabetic retinopathy severity grading, home tonometry for patients with glaucoma and home monitoring for age-related macular degeneration (AMD) progression empower providers to keep patients in rural areas or those with other access limitations within their orbit of care. These services also help providers in regions that straddle the rural-suburban divide to keep patients at risk of loss to follow-up on the right side of the care spectrum.

We, the authors, have direct experience in treating such populations. One of us (CM) practices in Tahlequah, OK, where the patient base is largely Native American. These individuals face barriers to care linked to their rural status, among other factors such as historic marginalization. The other (AL) practices in Wyomissing, PA, a small suburban metro nestled between suburban population centers to its south, east and west, and the more rural Appalachian Mountains to its north.

Given our experience with rural populations who face barriers to care, we hope to update our optometric colleagues about the latest data surrounding rural health disparities and explore how digital health tools could better serve our patients and improve our practices.

The State of Play in Rural Health Care

One of the most obvious challenges to accessing care for rural inhabitants is the distance from the patient's home to the clinic. A review of cardiovascular clinical trial sites, which typically enroll in larger population centers, found that only 5% of sites were in rural areas.[1] The median distance between a clinical trial site and the patient's home was 5.8km; this distance was 4.5km for urban patients and 24.2km for rural patients. It stands to reason that when patients cannot dedicate the time and financial costs of longer travel, they lose access to care (whether from conventional clinical visits or clinical

About the authors

Dr. Legge practices at the Wyomissing Optometric Center in Wyomissing, PA. She serves as a member of the Allied Health Professional Staff at Penn State Health St. Joseph Medical Center (inpatient consults and emergency department eye care). She is a consultant and speaker for LKC Technologies, and has previously held these roles for MacuLogix, MacuHealth, Notal Vision and Astellas Pharma. **Dr. Majcher** is a professor and the director of residency programs at the Northeastern State University Oklahoma College of Optometry, as well as a fellow of the American Academy of Optometry and the Optometric Retina Society. She received her doctorate in optometry from the Pennsylvania College of Optometry at Salus University and completed an ocular disease residency at the Eye Institute of the Pennsylvania College of Optometry. She is a paid speaker and consultant for Regeneron, Carl Zeiss Meditec, Apellis and Astellas. She is also a paid consultant for Topcon, Notal Vision, Lenz Therapeutics and Tarsus and has received non-financial support from Roche.

trial enrollment). Distance to the clinic may be a uniquely intense barrier to care for patients with vision-related issues, as they often require a caregiver to be available to drive them to their appointment, which means that two people (rather than just the patient) need to be available for an appointment.

In eye care, the differences in access to care have led to higher rates of blindness in rural areas compared with non-rural areas.[2] A 2023 retrospective analysis of the IRIS Registry from the American Academy of Ophthalmology found that blindness rates were positively associated with patients in rural settings. Blindness rates were also positively associated with having public or no insurance, underscoring the link between low income and worse outcomes.

Rates of ophthalmic care are worse among Native American and Alaska Native populations. A recent retrospective, cross-sectional study of peer-reviewed literature from the past 25 years found that retinopathy, cataract, vision impairment and blindness were higher among these populations than other American population cohorts.[3] Although rates of macular degeneration and glaucoma were similar among all patient populations, treatment rates were lower among Native populations, which led to poorer outcomes in those groups.

Zooming out to focus on healthcare disparities in general for rural populations can help us grasp the dynamics at play. One study that focused on American providers' perspectives on the barriers to care concluded that costs, insurance-related issues, geographic dispersion and provider shortage/burnout were some of the chief issues facing rural populations.[4] These providers suggested that greater use of telehealth services and establishment of mobile clinics for specialty care could be key to improving access to health in rural communities.

Still, implementation of, say, a fleet of mobile clinics would require expensive and time-consuming projects that local specialists may be ill-equipped to initiate or uninterested in undertaking. Home-based telehealth tools—with little to no capital overhead, physical clinical footprint or changes to practice workflow—could give patients access to care that they otherwise may have found too difficult to acquire.

The Rise of Remote Monitoring

Outside of eye care, researchers have examined the utility of remote monitoring to detect atrial fibrillation via an Apple Watch.[5] Approximately 419,000 patients with no self-reported history of atrial fibrillation wore an Apple Watch for a median 117 days. Patients were notified if irregular pulse was detected, at which point an electrocardiography (ECG) patch was mailed to them with instructions to wear it for seven days. Among all patients, 0.52% received notifications of irregular pulse, and among those who returned the ECG patch for analysis, approximately 35% of patients were confirmed to have atrial fibrillation. Interestingly, no site visits were required in this study, as all testing and communications were performed at home. This illustrates the power of remote monitoring to effectively trigger further scrutiny of a patient.

There are benefits to embracing innovative technology in eye care. Using

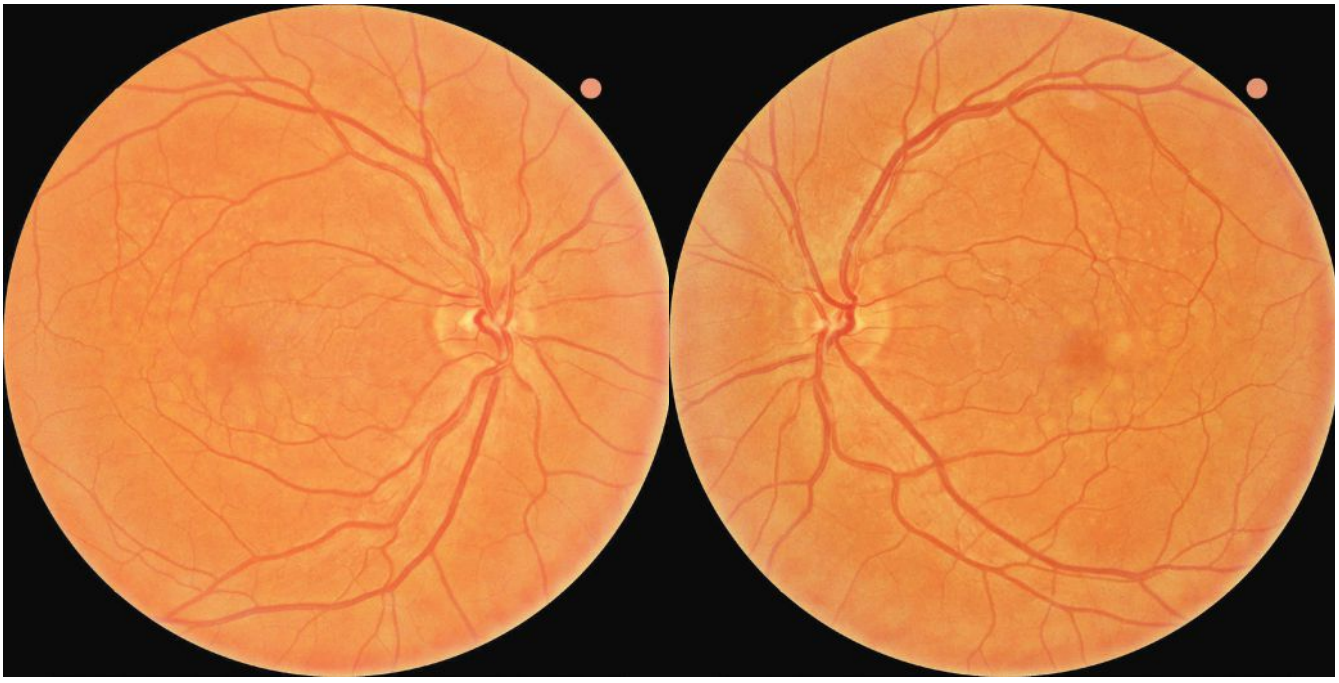


Fig. 1. Baseline fundus photography revealed large soft drusen bilaterally consistent with intermediate stage AMD. The patient was referred to the ForeseeHome AMD Monitoring Program and instructed to follow up in six months.

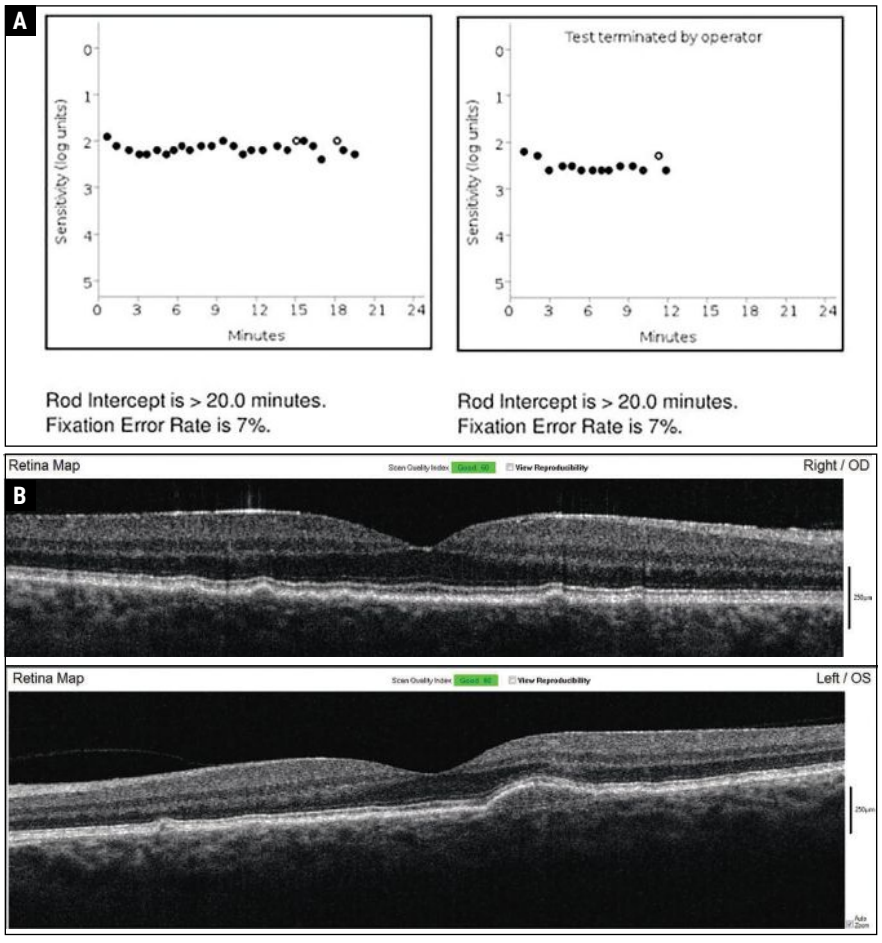


Fig. 2. Baseline dark adaptation (A) and OCT imaging (B) were established in-office upon initiation of home monitoring for wet exudative AMD conversion.

AI-driven technology in eye care for rural patient populations has been effective at increasing examination rates. A study published in 2024 assessed the completion rate of diabetic eye exams among pediatric patients with type 1 or type 2 diabetes in rural settings.[6] Patients were randomly assigned to an intervention arm (wherein an autonomous AI diabetic eye exam was used at the point of care in an academic pediatric diabetes center; n=81) or a control arm (wherein the patient received scripted eyecare provider referral and education; n=83). At six months, the researchers found that 100% of patients in the intervention arm had completed a diabetic eye exam compared with 22% of controls. Furthermore, of those in the interventional arm whose results indicated that follow-up was needed (25 of 81 patients), 64% completed a follow-up appointment with an eyecare provider. This was significantly higher than the 22% of patients in the control arm who followed up with an eyecare provider.

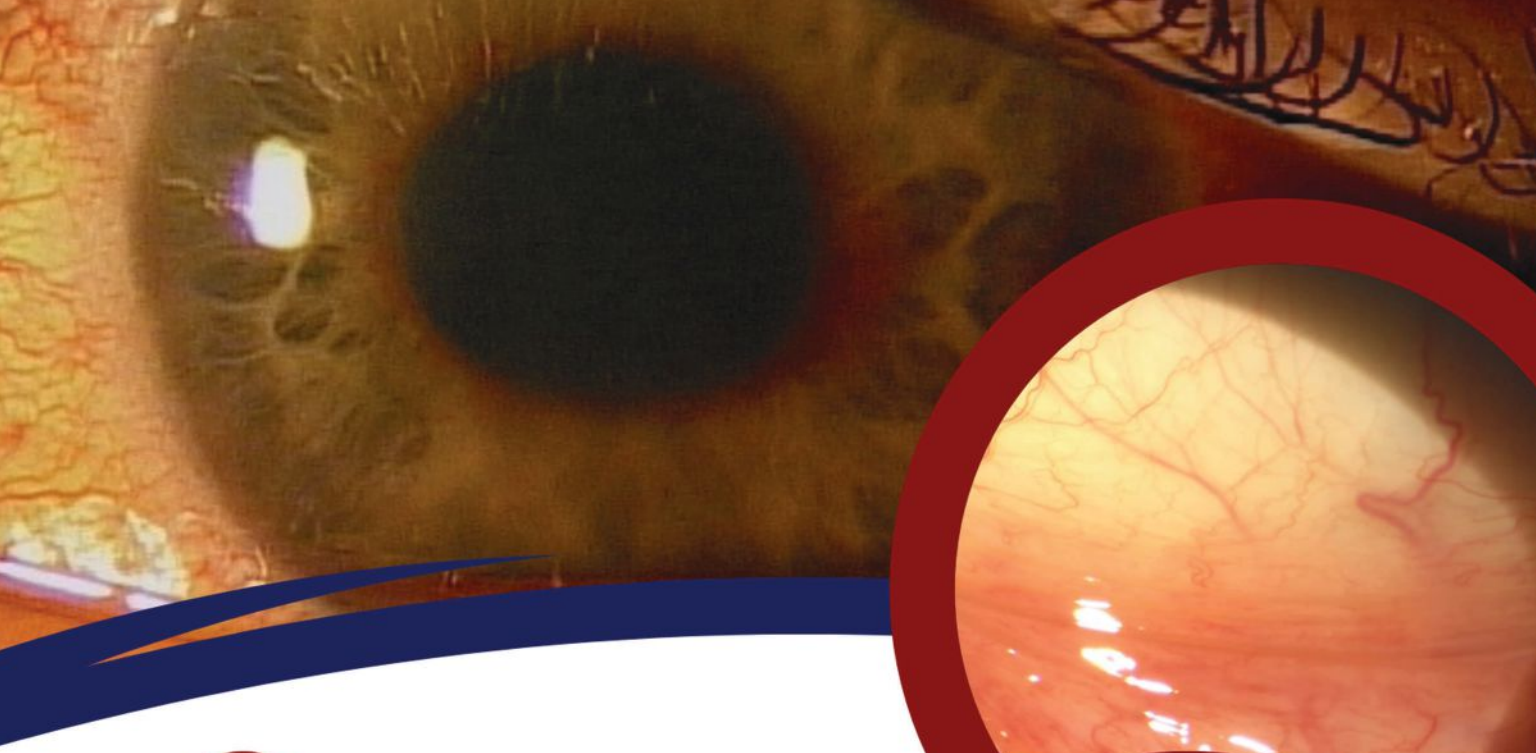
At-home Monitoring in Glaucoma

Three of the modalities often used in the care of glaucoma patients are potentially conducive to remote data capture. If these modalities—nonmydriatic fundus photography, visual field testing and tonometry—were to become more widely used in-home or in remote settings, providers dedicated to glaucoma care in primary or specialty settings may be able to harvest accurate data more frequently, thereby better informing treatment strategies.

The iCare Home and iCare Home2 (iCare) are home-based tonometers that track diurnal intraocular pressure (IOP). They provide longitudinal data that supplement those captured in the clinic. A pivotal study assessing the iCare Home's efficacy showed that it detected therapy-related changes in IOP, and further research has found it useful in monitoring peri-interventional patterns.[7,8] Agreement between the home tonometers and the office-based Goldmann tonometry has been shown to be within 5mm Hg in 91% of cases, with a mean difference of 0.33mm Hg, suggesting that the two devices may be similar enough to render differences negligible for some patients.[9] Perhaps most importantly, patients like it: 89% of those who have used the iCare Home said they would recommend it to other patients with glaucoma.[10]

Optometrists can purchase the iCare Home or the iCare Home2 and charge patients for at-home use. Alternatively, they can write a prescription for the device, permitting the patient to either purchase or rent the device from a third party. Doctors receive patient results either through a web portal (if they have loaned out the device) or via a report sent from the third party (if the patient has received a prescription and has rented or purchased the device for themselves). Long-term glaucoma patients in the care of optometrists seeking to increase the frequency of IOP monitoring may be well-suited for these devices. In particular, home tonometry may provide valuable insight for patients with glaucomatous progression despite seemingly well-controlled IOP measures in office.

Use of smartphone-based non-mydriatic fundus photography to measure cup-to-disc ratio of the optic nerve head has been shown effective in assessing at-risk patients. A 2021 study assessing the ability of PanOptic iExaminer (Welch Allyn), an apparatus that attaches to an iPhone camera, concluded that use of a such a device was an effective, low-cost means of screening patients for glaucoma risk. Of the 206 patients enrolled in the study, 16% had characteristics suggestive of glaucoma; these patients were referred for subspecialist evaluation, 94% of whom met the criteria for potential glaucoma.[11]



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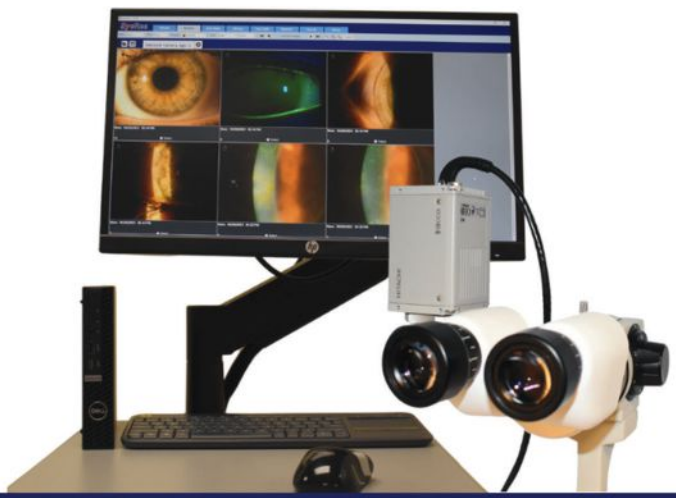

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The study in question took place in Samoa, which, per the study authors, is "an underserved setting with one full-time ophthalmologist in the entire country"—precisely the type of rural setting that we feel could maximally benefit from remote data capture.[11]

The VisuAll Virtual Reality Platform (VRP; Olleyes) is a headset device that can be used in remote (*i.e.*, home) settings to perform visual field testing. A 2024 study assessing the feasibility, accuracy and repeatability of home-based visual field testing enrolled 15 participants, nine of whom completed the study; the six patients who did not complete the study had difficulty acquiring home-based tonometry data, which was a requirement for study completion.

During a session in which patients were trained to use the VRP, patients sat for a Humphrey Field Analyzer (HFA) visual field test, and the results of VRP testing were compared to HFA assessments.[12]

The results were encouraging. After three consecutive days of home testing, the researchers observed significant correlation between the average mean deviation values of VRP and HFA testing and found that the time to capture VRP data was significantly shorter compared to HFA. Five of the six Garway-Heath sectors on the visual field were significantly correlated between VRP and HFA.

Providers need deeper datasets to understand if home-based visual field data capture is reliable, but this early feasibility study reflects positively on the concept of home-based visual field data capture. Patients with glaucoma living in remote settings may benefit from this technology if, for instance, their provider instructs them to visit the clinic less frequently than in the days when clinic-based assessments were key to patient care.

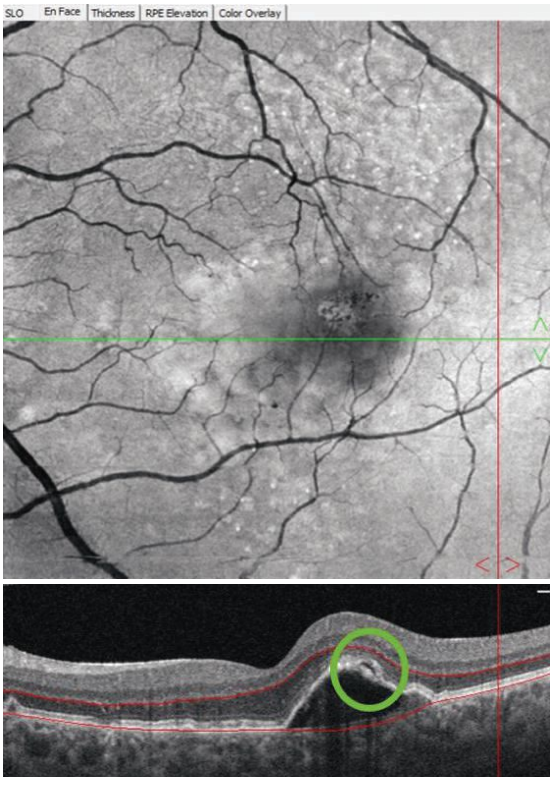

Fig. 3. Following a device alert three years into home monitoring, the patient returned to the optometry clinic for examination. A pigment epithelial detachment with overlying subretinal fluid (green circle) was observed on OCT imaging and anti-VEGF therapy was initiated upon retinal consultation.

Digital Remote Monitoring and Quality of Care

Options that can help detect the progression from intermediate AMD to advanced wet AMD include mobile applications and a dedicated device. Apps that we have heard mentioned by our colleagues, but we have not used, include myVision Track and Macustat. Mobile applications are easy for patients to access via their smart devices or computers and represent an important development in the digital remote monitoring landscape. Still, although reports have appeared in the literature assessing these technologies, they have not been validated in randomized controlled trials.[13-15]

One such technology that both uses AI and has been proven effective in a randomized controlled trial is the ForeseeHome (Notal Vision).[16] This technology marries two approaches outlined above: a dedicated home-based device (outlined in the Apple Watch study) that is driven by AI (as seen in the pediatric diabetic eye disease study), giving patients the chance to embrace a remote monitoring solution with an AI foundation.

First, a primer on ForeseeHome, which is used to assist the physician in detecting conversion from intermediate to advanced wet AMD. Per the Beckman Classification, patients are subtyped into having early, intermediate or advanced AMD; patients with advanced disease are subtyped into wet AMD or geographic atrophy (GA), which are not mutually exclusive.[17] Treatments for both wet AMD and GA are approved for use; still, close monitoring for intermediate AMD patients is advised, as early detection of conversion to advanced AMD can lead to early intervention which is associated with improved anatomic and visual outcomes.

Providers prescribe ForeseeHome, which measures hyperacuity, to patients with intermediate AMD to help in the early detection of wet AMD; hyperacuity is impacted earlier in AMD than conventional acuity. Patients set up the device in their homes and perform regular testing between routine eye examination visits. Data is collected by a monitoring center operated by the manufacturer. If the software detects an aberration that may signal conversion from intermediate to advanced AMD, the prescribing provider's office is notified so that they can reach out to the patient to schedule an exam. If the device has not been used for an extended period, the patient is contacted and reminded by the monitoring center to use the device; any troubleshooting that the patient needs occurs at this time.

In the pivotal HOME study, researchers concluded the device was effective at detecting choroidal neovascularization (CNV) and increased "the likelihood of better visual acuity results after intravitreal anti-VEGF therapy."[18]

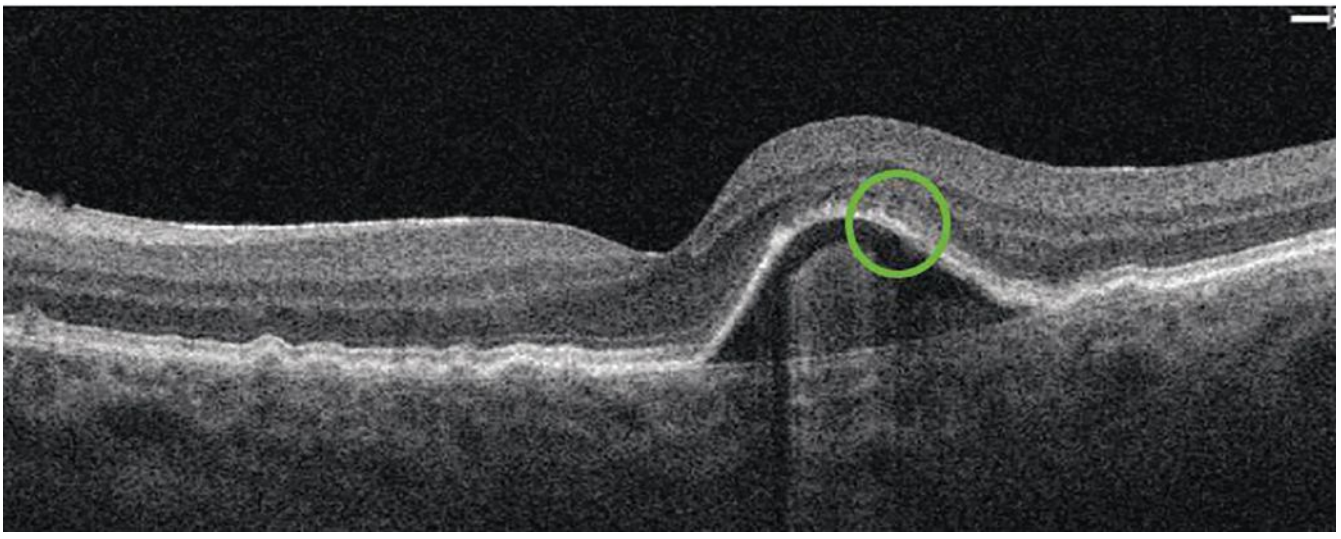

Fig. 4. The subretinal fluid (previously in the green circle) observed during the first post-alert examination resolved after the initiation of anti-VEGF therapy.

Real-world studies have shown that use of ForeseeHome led to early detection of wet AMD conversion, and that median visual acuity at baseline, conversion and final follow-up for eyes that converted during the study's monitoring period were 20/30, 20/39 and 20/32, respectively.[19]

For rural populations, remote monitoring of conversion to wet AMD could be particularly beneficial. Patients will still be expected to present for in-office eye exams but will also be kept in the practice's orbit via remote monitoring. Rural patients (as well as older patients who have difficulty making it into the clinic) may find that remote monitoring engenders a sense of closeness to their provider and deepens their relationship to care. After all, testing several times per week keeps ocular health top of mind for the patient, and knowing that your provider's office will contact you if the device triggers an alert ensures that your provider won't let you slip through the cracks. These benefits mitigate the challenges rural patients face and "reduce the distance" between the patient's home and a specialist's clinic.

False Positives and Potential Challenges

Patients and providers may be understandably worried that use of remote devices may trigger an alert of possible conversion to wet AMD that is, upon in-person clinical assessment, not observed. Such a visit could be a waste of time and money; however, false positives (FPs) still hold value. A subanalysis of the ALOFT study found that eyes that had triggered an FP on the ForeseeHome were at higher risk for conversion to wet AMD than eyes that hadn't.[20] One study speculated that FPs could be due to the non-observable changes to retinal tissue that affect the functional hyperacuity test score measured by the device.[20]

In this sense, at-home remote monitoring still informs patients and providers even in the event of an FP. If such an event were triggered, a provider may direct the patient to come in more frequently such that any clinically observable conversions to wet AMD could be detected via examination.

This is not to say, of course, that home-based monitoring is not without its limits. Two fundamental facts may be at loggerheads: reliable digital connectivity is fundamental to capturing data with a device such as the ForeseeHome, and patients in rural settings may struggle to access a high-quality connection. Patients with limited tech literacy may find remote monitoring platforms intimidating or, even if they find themselves using such a platform, too difficult to troubleshoot even with the direct-to-patient assistance offered by the Notal Vision Monitoring Center. Even though the program is covered by Medicare, some patients may nevertheless be turned off by the idea of service that could be (however erroneously the conception) associated with a recurring fee.

Real-World Case

A 55-year-old Caucasian man presented to the Wyomissing Optometric Center for baseline retinal exam with uncorrected acuity of 20/20 in each eye. Ophthalmoscopy revealed large soft drusen, and the patient was diagnosed with intermediate stage nonexudative AMD bilaterally (*Figure 1*). Baseline baseline dark adaptation and OCT were obtained in-office (*Figure 2*).

AREDS2 supplementation was recommended, and the patient was referred to the ForeseeHome AMD Monitoring Program and began home surveillance. He was asked to return to clinic in six months.

Almost three years later, a ForeseeHome alert OS was generated, and the patient was brought in to the office for examination that same day. OCT showed a pigment epithelial detachment with overlying subretinal fluid OS suspicious for new-onset advanced wet AMD (*Figure 3*).

Uncorrected VA of 20/20 OS was measured at this visit and the patient was referred to a retina specialist for further evaluation and treatment. Intravenous fluorescein angiography performed by the retina specialist revealed late leakage OS, and anti-VEGF therapy was initiated. At the six-week post-injection follow-up, excellent uncorrected visual acuity of 20/20 OS was maintained, which may be, in part, due to early detection of wet AMD before symptoms developed.

Future of Home-Based Care in Retina and Glaucoma

The prospects for remote monitoring in eye care will likely include use of home-based OCT imaging for monitoring retinal tissue. One such device, the Scanly Home OCT (Notal Vision), was recently granted FDA de novo marketing authorization. It will allow treating physicians to garner never-before-seen disease insights of wet AMD activity by capturing and collating data in the time between office visits.

The latest data on home OCT imaging show that patients are comfortable and competent at acquiring usable OCT images.[21] The quality of home OCT scans is comparable to those obtained by in-office OCT. Pivotal trials specifically compared visualization of key biomarkers for wet AMD in home OCT and in-office OCT, demonstrating an equivalence between the two.[22] Similar results were found in DRCR Retina Network's clinical study, Protocol AK, where investigators found strong agreement in presence of fluid between home OCT and in-office OCT.[23] When optometric physicians familiarize patients with remote monitoring protocols and technology before the patient converts to wet AMD, in addition to better long-term visual outcomes from early detection, patients may be more likely to embrace the home OCT monitoring during treatment.[19]

Patients in rural settings who face difficulties with follow-up adherence to retina specialists' appointments may be particularly drawn to Scanly Home OCT, as it could lessen the frequency with which they need to visit a retinal clinic for care. Reduced treatment burden for wet AMD could aid in reducing the disparities between rural and non-urban populations, as well as the disparities between low-income and wealthier patients.

Takeaways

Optometric physicians play a unique social role for communities that have faced barriers to health care access. Embracing remote monitoring may play a role in closing the disparity gap in these areas. It falls on us primary eyecare providers to make sure that the right patients are prescribed, trained on and educated on these technologies that could eventually be available for them to take advantage of. Timely delivery of care may depend on it. ■

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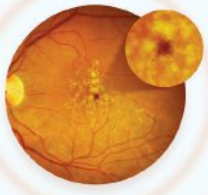

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FDA Indications for Use
ForeseeHome is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with AMD.
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GEOGRAPHIC ATROPHY: LOOKING BEYOND VA

A discussion on the many other markers of visual function and quality in these patients, as well as the options available to help them see better.

BY KAITLYN SAPOZNIK, OD, PhD, AND EMILY R. HABLE, OD
HOUSTON; INDIANAPOLIS

Geographic atrophy (GA) is the most advanced form of dry age-related macular degeneration (AMD) and can occur concomitantly with choroidal neovascular membrane (CNVM) or wet AMD. Patients with GA present with highly variable visual complaints that range from a minor impact on vision to severe visual impairment that significantly affects activities of daily living and quality of life. Not all patients with GA have decreased visual acuity, but many still suffer from deficits in visual function not often assessed with routine eye exams, including reduced contrast sensitivity, central visual field loss, reduced reading speeds and alterations in dark adaptation.[1]

Visual symptoms are often related to the degree of photoreceptor loss lesion number, size and locality, with respect to the fovea. Several clinical tests of retinal structure and function are available to help optometrists monitor disease progression and provide the necessary tools to improve these patients' visual experiences.

Pathophysiology of GA

In AMD, the complex of photoreceptors, retinal pigment epithelium (RPE), Bruch's membrane and choriocapillaris is disrupted. Large, soft drusen develop often as a precursor to GA and are an accumulation of sub-RPE waste product.[2] In some patients, they continue to accumulate or coalesce and eventually may collapse, resulting in well-demarcated GA lesion(s) where photoreceptor loss, RPE atrophy and choriocapillaris thinning occur.[2,3] Particular to GA, the RPE is inhibited, leading to photoreceptor dysfunction and death and, consequently, a thinned choriocapillaris in corresponding areas.[4]

Numerous factors may contribute to the development of AMD, including genetics, environmental stressors, oxidative stress and inflammation.

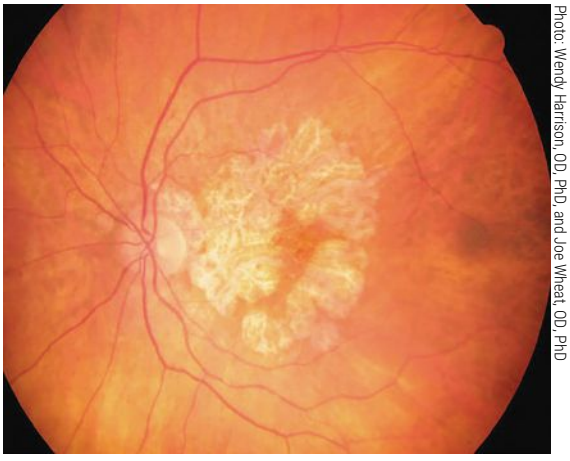

Photo: Wendy Harrison, OD, PhD, and Joe Wheat, OD, PhD

Fig. 1. GA not only impacts patients' ability to perform daily living activities, but also their quality of life.

Systemic diseases such as dyslipidemia and hypertension are associated with an increased risk of AMD, as is smoking.[5] Concerning GA development, the complement pathway is dysregulated and many gene polymorphisms related to the complement pathway have been implicated in individuals with GA.[5]

Clinical Assessment

Retinal imaging modalities in combination with a dilated fundus exam

About the authors

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are invaluable to clinically assess GA. Optical coherence tomography (OCT) and blue fundus autofluorescence (FAF) imaging provide keys to the integrity of the outer retinal layers that are affected. OCT provides cross-sectional images of the retinal layers, allowing for assessment of the presence, absence and integrity of these layers, as well as the evaluation of biomarkers associated with GA. A recent meta-analysis identified six OCT biomarkers with a greater predictive value for late AMD than large drusen: external limiting membrane, ellipsoid zone and interdigitation zone abnormalities as well as concurrent large drusen, reticular pseudodrusen, hyporeflective drusen cores and intraretinal hyperreflective foci (IHRF).[6] The latter two findings had the highest predictive value; similarly, other studies have associated IHRF with GA.[6,7] IHRF may represent migrating RPE cells, activated microglia or dissagregated photoreceptors that occur with GA.[7]

En face OCT is also useful when monitoring patients with GA, providing clinicians a more comprehensive view of the entire macular region or posterior pole to assess the number and size of GA lesions. Many OCT systems have built-in or manual tools to view the full GA lesions and quantify their area over time.

FAF is another great clinical tool that allows us to assess RPE activity by the fluorophore A2E, which is present in lipofuscin. This lipid-based pigment is generally upregulated when there is an increase in RPE activity, and patterns of FAF may signal active RPE stress. In GA lesions, the RPE has atrophied, so no signal is generated and the lesions appear black. However, different phenotypic patterns can be observed at the borders of GA lesions. Banded and diffuse FAF patterns at the border of GA lesions are associated with increased growth of lesion size.[8]

Instruments such as the Spectralis OCT (Heidelberg Engineering) can capture both FAF and OCT images. The size of GA lesions identified on FAF corresponds to complete degeneration of the outer retinal layers on OCT.[9] As our knowledge of OCT biomarkers and how to use them in clinical practice evolves, so must our understanding of how these may be related to visual function metrics that could be impaired in GA patients.

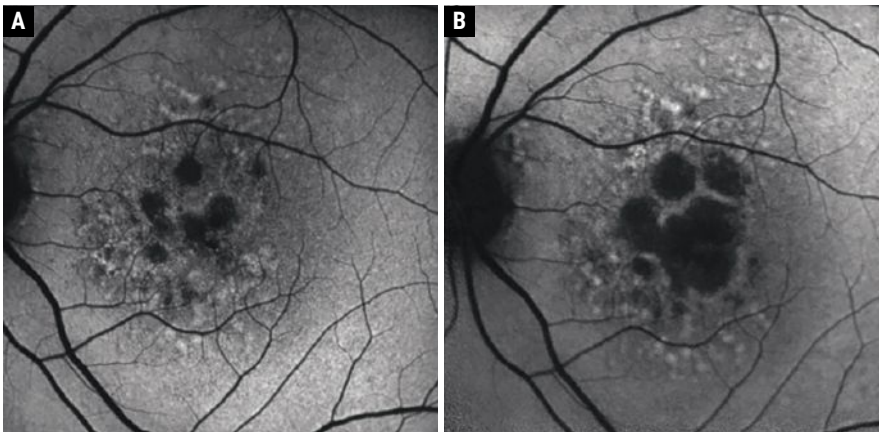

Fig. 2. Example of GA progression over two years with FAF. At baseline, the patient had numerous small atrophic lesions (A). After two years, there was significant enlargement of the GA lesions encroaching the fovea (B); however, visual acuity was maintained at 20/25. Despite good visual acuity, this patient has substantial photoreceptor loss and suffers from other deficits of visual function that should trigger a referral to a vision rehab specialist.

The visual function of patients with GA often depends on the number and area of GA lesions and their proximity to the fovea or foveal involvement. When monitoring GA patients, pay special attention to markers of progression on retinal imaging. This may include increases in area or number of lesions combined with photoreceptor loss detected with OCT. These findings should then be considered alongside each patient's unique visual demands and needs. For example, *Figure 2* shows the progression of a lesion over two years, but the visual acuity remained at 20/25 due to some sparing of the central fovea. However, this patient has several large GA lesions that encompass a substantial area of the macula.

Intravitreal injections that inhibit the complement pathway have been approved for GA, providing some hope for patients in slowing disease progression. However, there is still substantial debate in the retina community regarding the effectiveness of these medications. While the size of the lesion may benefit from treatment, the benefit to visual function for the patient is unclear.[10] Additionally, these medications do not restore the areas of GA lost. Therefore, even when patients are treated or slowly progressing, they often require vision rehabilitation. When tasks of daily living or quality of life are impacted in patients with GA, additional functional assessments of vision are warranted even when visual acuity is maintained.

When monitoring GA patients, take the time to inquire about the visual demands of each patient to determine additional tests of visual function, like contrast sensitivity or reading speed. The results of these tests can provide the necessary tools and education needed to maintain or improve their quality of life by helping patients meet their visual demands. Findings from the examination and clinical imaging can help guide discussions with the patients about their visual deficits that may be masked by good visual acuity.

Assessing Visual Function

Functional day-to-day tasks are significantly impacted from vision impairment due to AMD, as evidenced by a review of 1,111 studies on humanistic burden using the National Eye Institute's Visual Function Questionnaire.[11] Specifically, patients with GA have lower composite and subscale scores for near and distance activities, color vision, dependency, driving, social

functioning and mental health.[11] Although visual acuity is often our first piece of testing, it rarely provides a full picture of the level of impairment and retinal function. To better understand the level of impairment due to GA in each patient, a handful of tests can be performed, including reading speed, contrast sensitivity, Amsler grid and microperimetry, among others.

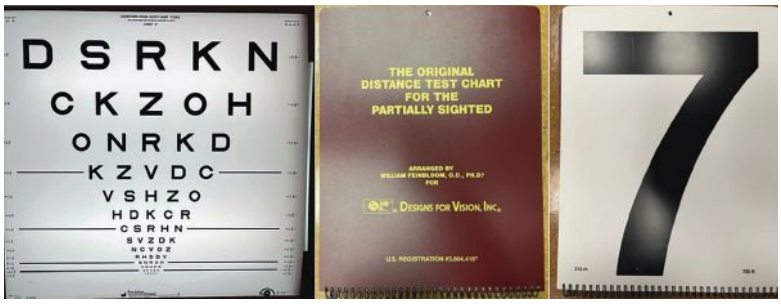

Fig. 3. The ETDRS chart (left) and Feinbloom Low Vision chart (middle/right) are useful for assessing vision in GA patients who are unable to read the largest optotypes from the standard 4m viewing distance.

In patients with GA, the Early Treatment Diabetic Retinopathy Study (ETDRS) chart or Feinbloom Low Vision chart allows for a more accurate assessment of vision than the traditional Snellen chart because of their smaller jumps in optotype size (*Figure 3*). When a low vision chart is unavailable, electronic visual acuity charts will work better than standard projector charts due to higher contrast. Depending on the extent of foveal involvement, patients can often continue to read isolated individual letters and maintain normal best-corrected visual acuity (BCVA) despite having significant symptoms. Lesion size alone does not necessarily allow for predictive visual acuity values, however, as GA progresses from nonsubfoveal to subfoveal involvement, central vision suffers. This progression takes on average 1.4 to 2.5 years.[7]

> **When tasks of daily living or quality of life are impacted in patients with GA, additional functional assessments of vision are warranted even if visual acuity is maintained.**

A meticulous refraction gives the best possible starting place for magnification. In a retrospective study of 739 patients referred to a low vision clinic for the first time, refraction improved visual acuity by two lines or more in 11% of the patients.[12] Phoropters' eye openings limit field of view and can cause contrast reduction.[13] Trial frame refraction (TF) is the best technique to obtain a BCVA for a patient with reduced visual acuity from GA. TF allows for larger jumps in lens testing compared to the single 0.25D jumps seen on phoropter refraction, as the just-noticeable difference threshold will likely be different in GA patients. TF refraction also allows for different head postures due to neck and back issues and eccentric viewing, using nonfoveated areas of the retina due to scarring or atrophy at the fovea. Trial frame use allows patients to sample the new glasses prescription in more "real-world scenarios" that mimic their daily visual tasks and demands, such as at a computer, on their phone or walking around the clinic.[13]

Reading speed demonstrates a patient's functional ability to read longer phrases of words or sentences rather than spotting single-target letters. This measure is quantified by the number of words correctly identified in a prescribed amount of time. As GA progresses, reading speed declines.[14] Patients with GA with a BCVA of 20/50 or better read significantly slower than the average intermediate AMD patient.[1] Over just two years, patients with GA in a prospective natural history study were found to decrease in reading speed from 110 words per minute (wpm) at baseline to just 51 wpm.[1] Over the same two-year period, reading speed decreased from 130 wpm at baseline to 117 wpm in patients with drusen alone.[1] Patients with lesions of GA larger than 10mm^2 have a median reading speed of 71.1 wpm compared to the smaller lesion size of less than 10mm^2 reading at a median of 150.0 wpm.[15]

An Amsler grid can help determine central visual field impairment and potential areas of distortion or blind spots. Ease of use is beneficial, as patients can use the chart to self-monitor their vision. Amsler grid has 67% sensitivity and 99% specificity in exudative macular degeneration. With nonexudative macular degeneration, the specificity (71%) and sensitivity (63%) are much closer, indicating that it is far less specific.[16] Due to the higher sensitivity, this test is more beneficial for a new area of CNV in exudative macular degeneration. This is likely because the onset of new CNVM is acute, whereas changes due to GA may be so gradual that a patient may not notice the metamorphopsia or blind spots occurring due to adaptation.

Low-luminance visual acuity (LLVA) is a measure of visual function in low light and is performed similarly to BCVA but with a neutral density filter covering one eye to attenuate light exposure.[17] The low-luminance deficit (LLD) is then calculated as the difference between a patient's BCVA and LLVA. In addition to assessing vision in reduced illumination, LLD has potential as a robust study endpoint as it may predict lesion enlargement in GA and resultant vision loss.[17] This is intuitive, as the LLVA is testing cone function in dim illumination and we know that cone function in a dark-adapted state is reduced in AMD.[18] Therefore, we are likely assessing the dysfunctional cones adjacent to the GA lesions in addition to the cones we know are lost within the lesions. It is, however, important to recognize that the LLD may improve as GA progresses when foveal cones are lost and

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1. CVI data on file, 2024. US industry reports and internal estimates.
2. CVI data on file, 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs.
3. CVI data on file, 2023. Based on number of US soft contact lens fits, including CooperVision-branded and customer-branded equivalent lenses. US industry reports and internal estimates.
4. CooperVision data on file 2021. Rx coverage database n=101,973 aged 14 to 70 years.

spared peripheral cones are used for eccentric fixation.[18]

Similar to LLVA, contrast sensitivity is an indirect measure of cone function and is measured with charts like the Pelli-Robson or Mars contrast sensitivity tests. Contrast sensitivity measures the ability to detect targets of equal size as they decrease in contrast. Compared to BCVA, LLVA and reading speed, there is a strong correlation between contrast sensitivity and retinal function as well as total area of macular GA defined by hypoautofluorescence in the central 1mm on FAF.[19]

Microperimetry also measures central retinal sensitivity and allows a more precise way to map areas of functional and nonfunctional retina in the macula when compared to reading charts. The test is performed similarly to most automated visual field tests by varying light intensity to stimulate the macula. Like all other visual field tests, results depend on a patient's subjective ability to respond to a stimulus. Patients with central vision loss often use eccentric viewing to use their peripheral retina that is yet to be affected. This can influence most peripheral visual field tests, as the fixation tracker senses poor fixation and results in lower reliability.

Fortunately, with microperimeters, GA patients can still use eccentric viewing, as an infrared camera monitors the patients' fixation point to track more accurately and map out the visual field on the fundus. This fundus map can help isolate a patient's preferred retinal locus and allow them to use eccentric viewing to the best of their ability. Microperimetry performed in patients with GA reveals that retinal sensitivity reduction is more global in the fundus and not confined only to the GA and adjacent regions.[17]

Impacts on Quality of Life

This important measure can be greatly reduced in a short time in geographic atrophy patients, especially when their ability to do everyday tasks is impacted. Many patients with GA express difficulty with daily tasks such as cooking, reading and driving, as well as with hobbies like painting and crochet. Patients also complain of difficulty with facial recognition, especially once central vision is impacted, which may be isolating and cause them to avoid social situations that may bring attention to their deficit. Studies have shown this becomes a more pressing challenge in the later stages of AMD, with one finding that GA patients could identify fewer faces on average than those with early and intermediate AMD.[20]

It is also common for patients with GA to give up driving, which markedly impacts independence.[21] A study in the UK of 1,901 patients with GA found 66.7% of those with bilateral GA who were previously eligible to drive dropped below the eligibility level (better eye visual acuity>20/40) at a mean rate of 1.6 years.[22] In that same cohort, 89% of the patients who were not initially blind (n=1,693) became legally blind over a median period of 6.2 years.[22] The ability to drive is not taken for granted by GA patients, as most with active driver's licenses in one study reported mainly traveling with a partner or friend. Additionally, the main reason for giving up driving was eyesight.[23]

When you need to ask for help to do most things, dependence can lead to clinical depression. Patients with GA are at high risk of developing clinical depression due to a lack of independence stemming from vision loss. Interestingly, patients with blindness in one eye due to AMD are more affected by depression than those with loss in both.[24] It is suggested that the fear of losing vision in the unaffected eye increases the rate of depression.[24] Patients with AMD have an elevated emotional stress level similar to patients with disabling chronic illness (*i.e.*, arthritis, acquired immunodeficiency syndrome, chronic obstructive pulmonary disease and bone marrow transplant).[24]

Furthermore, GA patients experiencing high levels of depression, fear, anxiety and social isolation are more likely to fall.[25] In one cohort study, patients with a code of atrophic AMD (n=26,942) had an increased risk of hip fracture of 11% over four years compared to those without an AMD code (n=1,012,748).[26] As many of us are aware, a hip fracture increases mortality in the year following the incident. Not only does GA increase difficulty with daily living activities, but it can also have a profound impact on mental health and potentially lead to increased mortality.

Fig. 4. Three low vision aids include Optivisor (Donegan Optical Company) with light for intermediate tasks (top), spectacle-mounted telescope for distance enhancement (middle) and Optelec illuminated handheld magnifier for spot reading (bottom).

As mentioned above, new therapeutic interventions are now approved for GA. As it is unclear how substantial the benefit to visual function is for patients, there is a looming concern that the addition of frequent office visits necessary for treatment may further burden patients with GA and negatively impact their quality of life.[10]

Low Vision Rehabilitation

By helping GA patients use the vision they *do* have to the best of their ability, low vision rehabilitation may reduce some of the visual difficulties these individuals face. This may include magnification tools, adaptive technology, increased lighting or contrast, tints and filters or education on alternative ways to perform everyday tasks.

Magnification increases the size of the target to subtend a larger area of the retina than the area impacted by the GA. Even though the image may still not be clear, this allows the patient to distinguish the target more easily. This can allow a patient to improve character recognition and reading ability.[27] The downsides are that as magnification increases, the field of view decreases, and if using optical magnification, the working distance reduces proportionally. Therefore, a "stronger is better" mantra does not work. Low vision providers choose a magnification power just large enough to pick out the targeted size while maintaining as much field of view as possible.

Depending on a patient's vision level, target size, target distance, dexterity and financial budget, they choose a device that best works for their situation. This can include handheld, stand or spectacle-mounted for near tasks. Telescopes can be either handheld or spectacle-mounted for distance tasks and, in some cases, even driving, depending on one's state and legal requirements (*Figure 4* shows several examples of low vision aids).[28,29]

When optical magnification does not suit a patient's needs, electronic magnification can often fill in the gap. Electronic magnification allows for closer imaging and a greater field of view than optical magnification. This tool often also includes increased contrast settings to help offset the decreased contrast sensitivity many patients with GA have.[30] Increased contrast can be used in other settings, as well, such as bright-colored tape on the edges of stairs, differing contrast with light-colored foods on dark plates and vice versa or much brighter lighting in home or work settings. When light becomes too glaring (such as outdoors on a bright sunny day), absorptive filters and tints can help block bothersome wavelengths of light and increase overall contrast levels.[13] When a patient's ability to use magnification becomes too laborious, text-to-speech and adaptive technology options are quite useful. Audiobooks, text-to-speech on tablets, computers, phones and other electronic tools allow patients to dial back their vision demands.[30]

When limited time and resources restrict time with a patient's care, referral to low vision rehabilitation can help give a patient back some independence, activities of daily living and improved mental health.[13]

Takeaways

Each patient with GA is unique, as are their visual function deficits. A team of eyecare providers is needed to monitor disease progression, potentially treat GA and maximize patients' vision with education and tools. Additionally, healthcare providers from occupational and physical therapy or psychology services may be warranted for those with mobility and mental health issues due to their vision loss. In the context of GA, coordination of care is critical. ■

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Data: *Animal Data*: Pregnant rats and rabbits received varenicline succinate during organogenesis at oral doses up to 15 and 30 mg/kg/day, respectively. While no fetal structural abnormalities occurred in either species, maternal toxicity, characterized by reduced body weight gain, and reduced fetal weights occurred in rabbits at the highest dose (4864 times the MRHD on a mg/m^2 basis).

In a pre- and postnatal development study, pregnant rats received up to 15 mg/kg/day of oral varenicline succinate from organogenesis through lactation. Maternal toxicity, characterized by a decrease in body weight gain, was observed at 15 mg/kg/day (1216 times the MRHD on a mg/m^2 basis). Decreased fertility and increased auditory startle response occurred in offspring at the highest maternal dose of 15 mg/kg/day.

Lactation: Risk summary: There are no data on the presence of varenicline in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies varenicline was present in milk of lactating rats. However, due to species-specific differences in lactation physiology, animal data may not reliably predict drug levels in human milk.

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BY ANDREW PUCKER, OD, PhD
MILLEDGEVILLE, GA

A profession cannot advance without scientific study and, because of this, we need to be able to easily read and understand new developments within our field. We also need to be able to critically evaluate these advances to determine if they are worthy of incorporating into practice. Medical research and medical practice are very different realms, however, each with its own priorities, strategies and customs. While the typical clinician is exposed to research concepts during their training and throughout their career, some of the terms and concepts used in scientific papers may seem like a distant memory; thus, the purpose of this article is to provide clinicians with a quick reference that describes key clinical research terms and concepts so that they can more easily digest the vast body of medical knowledge.

This article is part 1 of a four-part series *Review of Optometry* is publishing on the role of medical research in guiding our clinical decisions. This month, we will share straightforward definitions of the workhorse terms used in medical studies. Part 2 will build on this foundation to teach critical analysis of research findings. Part 3 will canvass experts for their opinions on the lasting value of the landmark clinical trials in eye care. Part 4 will delve into the workings of one specific research group so that we can see how tomorrow's insights are being worked on today. The overarching goal is to equip busy optometrists with the capacity to read, understand and apply medical research in their practices.

Study Designs

A first step toward deciphering a clinical study is to understand its design, as this choice both empowers and

Not all studies merit equal consideration by clinicians, nor are they necessarily intended to by their authors. Bear in mind the hierarchy shown here.

About the author

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constrains the researchers in various ways. Most studies can be broadly considered to be either *observational* or *experimental*. In the former category, the researchers do not control the data that's collected in any way other than by making a choice to study a group with certain characteristics—myopes under age 10 or non-smokers over age 60, for instance. Examples of observational studies include *cohort study*, *case-control study* and *cross-sectional study*. By contrast, studies that use an experimental design set inclusion and exclusion criteria and aim to measure a specific exposure (*e.g.*, a medical therapy or risk factor) and the researchers set one or more *primary outcomes* and *secondary outcomes* that would define success or failure.

Below are the most common types of study designs, ordered from least complex/lowest level of evidence to most complex/highest level of evidence.

Case Study: A report on an individual patient.[1] Case reports are only descriptive of that patient's condition.[2] With regards to advancing clinical research, a case report is often the beginning of a scientific understanding of a clinical question, typically by documenting a novel presentation or treatment effect.

Case Series: This is a report on more than one subject and thus has a bit more substance than a single case study, but still lacks the rigor that a formal trial demonstrates. This type of work might involve a chart review to evaluate all potential subjects with an uncommon condition.

Cross-Sectional Study: A study that evaluates all comers within the population of interest at a single timepoint over a finite amount of time.[1,2] No causal relationships can be determined from this type of study.[2]

Case-Control Study: A type of study that compares subjects with a specific condition (*e.g.*, dry eye) to subjects who do not have a condition (*e.g.*, asymptomatic subjects) to determine between-group differences to better understand a condition.[1,2] With this type of study, one can only calculate the odds of an association between factors.

A Journal Club 'Starter Pack'

There are dozens of journals devoted to advancing the scientific underpinnings of our profession. While not meant to be a comprehensive list, the titles here are worth keeping tabs on.

General-purpose journals covering a broad swath of eye care:

Niche journals concentrating on a particular specialty:

Recent years have seen the rise of online-only open-access journals, where researchers can share their results more quickly than through the established veterans. The online version of this article will include links to each of the above and many digital journals as well.

Cohort (Longitudinal) Study: A study that enrolls a group of subjects and follows them over an extended period to determine if they develop an outcome and how it may change over time.[1,2] This type of study allows one to prove temporal relationships and allow for determination of risk.

Randomized Controlled Trial (RCT): A study that assigns subjects to treatment groups by chance.[1,2] Subjects are then compared at the end to determine if there are between-group differences. The randomization is intended to wash out any differences unrelated to the mechanism being evaluated to help avoid confounding factors, such as having the subjects of the treatment group being older than the controls, which might bias the results.

Review Manuscript: A summary of the literature on a specific topic. A review manuscript can serve as a good reference on a topic while also helping the field determine knowledge gaps and future directions for scientific study.

Systematic Review Manuscript: This is a special type of review that first evaluates any publication that might be remotely related to the topic of study. After selecting articles that meet the entry criteria, the authors then collect the predefined clinical data relevant to the topic. When enough data is available, a meta-analysis (mathematical evaluation) can be conducted to determine the current state of the field.

Systemic reviews are typically limited to completed RCTs. A systemic review is often considered the highest level of data, and this effort has been pioneered by the Cochrane Library (www.cochranelibrary.com). Cochrane reviews are typically considered the highest level of systematic reviews, given that they have exceptionally high quality standards.

FDA Trial Phases

The FDA classifies drug trials based upon four different categories. Some are classified as a combination (*e.g.*, Phase I/II) if they contain components of both. The following describes each of the four phases individually:[1,3,4]

Phase I: This type of trial is aimed at understanding initial safety and drug concentration. These trials tend to be

unmasked and have a small number of subjects, who may be healthy or have the indication (disease) of interest. Phase I vision trials tend to have included subjects undergo a short duration of treatment (*e.g.*, one month), and the data obtained are typically used for subsequent trial planning and for fundraising. About 75% of Phase I trials are successful.[5]

Phase II: These tend to be larger than Phase I trials and they enroll subjects with the indication of interest to understand initial drug safety and efficacy. A Phase II trial may not be adequately powered; however, they yield important data for sample size planning for future trials. Phase II trials likewise are important for selecting primary outcomes for pivotal trials (*e.g.*, what outcomes are mostly likely to improve with the investigational drug) and logistical planning. About 50% of Phase II trials are successful.[5]

Phase III: The make-or-break moment for a new drug. Phase III trials tend to have hundreds to even thousands of subjects with the indication of interest. These trials are adequately powered to demonstrate safety and efficacy to the FDA. While not always the case, more than one Phase III trial is typically needed before a drug is approved by the FDA. The duration of these trials varies by indication, but some may be a year or longer. About 60% of Phase III trials are successful.[5]

Phase IV: A product only makes it to market about 20% of the time.[5] Once a drug is approved, the FDA may require additional study via a Phase IV trial to gain more safety information. The sponsors may also initiate studies without FDA mandate for marketing purposes. Phase IV trials tend to be large, and they may run for an extended duration (*e.g.*, >1 year) depending upon the indication.

Glossary of Terms

The next step in being a critical reviewer of the literature is understanding the terms commonly used to describe clinical parameters and the statistical analysis used in the scientific community. While this glossary is not a complete list, it does cover the commonly encountered research terms.

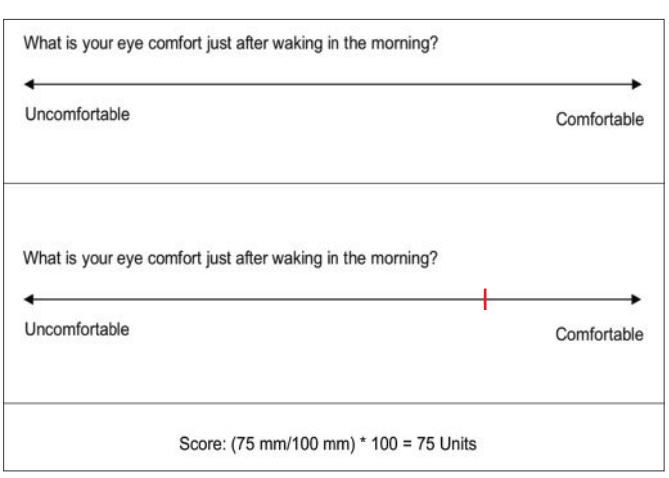
Alpha (α): Also known as the *level of significance* or *margin of error*.[1] A typical alpha value for a vision trial is 0.05, which means that there is a 5% or one in 20 chance that a study will find a significant association by chance alone; said another way, there is only a 5% chance the study will erroneously show a significant result. The confidence level is defined as 1-α or, in this case, 95%.

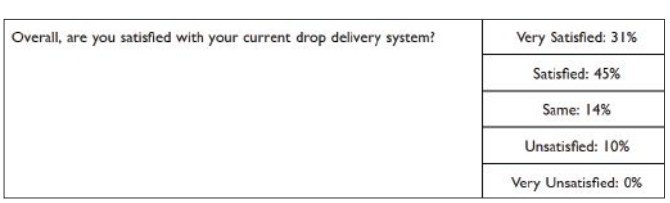
The closely related concept of *confidence interval* describes the minimum and maximum thresholds within which you would expect to find the mean value of the sample. The level of significance is sometimes adjusted downward (closer to zero) to adjust for multiple comparisons (several statistical tests) because increased testing increases the chance of erroneous findings. If the *p-value* (probability value) is lower than the alpha value, the finding can be said to have statistical significance.

Categorical Data: A variable that only has a finite number of response options, which may not have even intervals between the potential choices.[1] A good example of this in vision research is a questionnaire that asks subjects to indicate if they *strongly agree*, *agree*, *have no preference*, *disagree* or *strongly disagree* with a question. With this sort of question, the difference between each level is subjective (varies by subject's interpretation). One person may judge *strongly agree* to be closer to *agree* than *agree* is to *no preference*, yet these sorts of data are typically reported as percentages even if the relative weights differ for a given subject or between subjects.

Clinically Meaningful Difference: A distinction between groups or circumstances that is large enough for the clinician to be able to detect it in the clinical setting. If we take refractive error as an example, the typical phoropter has 0.25D steps in sphere power. If a study finds a significant difference of 0.12D, this would not be a clinically meaningful difference (no discernible effect on care), given that it is too small to measure on the phoropter.

Continuous Data: A variable that could in theory have limitless potential values. It may be helpful to think of continuous variables as a line of numbers.[1] A common continuous variable is a visual analog scale (VAS), which typically has a range of scores anywhere between 0 and 100 units, and a subject can rate their condition by placing a vertical line anywhere along the horizontal VAS line.





Here are examples of continuous and categorical data. In a visual analog scale (left), a subject conveys their subjective assessment by drawing a line along a continuum of possible values. By contrast, a Likert scale (above) forces a choice among specific responses. Note that Likert scales are often converted to percentages or weighted averages based on the assumption that the intervals between the options are uniform—which may not be the case for every subject.

From Pucker AD, et al. Quality of life in digital device users who are treated with systane hydration PF. Clin Optom 2023. Mar 7;15:45-54. Reproduced per Creative Commons 4.0 license.

Cronbach's alpha: This evaluates how each questionnaire item is correlated with all the other items in the instrument.[6,7] An acceptable Cronbach's alpha is typically considered to be >0.70 (lower values suggest not measuring a single trait/multidimensionality) and <0.90 (greater values suggest items are redundant).[6,7]

Effect Size: The size of the between-group difference used in a sample size calculation.[1] When discussing clinical studies, this is typically considered the clinically meaningful difference.

Frequency: How often something occurs in a sample of subjects. This term should be used unless a representative sample is evaluated; in that case, the terms *incidence* or *prevalence* can be applied.

Generalizability: How applicable the study results are to the population of interest.[1] When designing a study, one should try to make it as inclusive as possible to help ensure generalizability (*inclusion criteria*), yet certain groups of subjects are typically excluded (*exclusion criteria*) because they could confound the study results.

Incidence: The rate by which new cases of a condition occur over a specific time, which in clinical research is typically within the past year.[1] If the term *incidence* is used, the sample must be representative (people included in the study should mirror the population of interest). If not, the term *frequency* should be used.

Intention-to-Treat (ITT): An analysis approach used in randomized trials wherein subjects are analyzed based on the group they were originally assigned to at the time of randomization even if they got a treatment different than intended, were shown to be nonadherent to the study protocol or otherwise deviated from instructions. [1] In this way, ITT reflects real-world circumstances and reduces the risk of overestimating the statistical significance of the findings.

Interquartile Range: A value that reflects the central 50% of a dataset, calculated by adding the 2nd and 3rd quartiles but excluding the 1st and 4th.[8] Interquartile range is typically reported with medians and is sometimes a better representation of data that has the potential to be skewed by outliers (*e.g.*, billionaires skew the average net worth of a population).

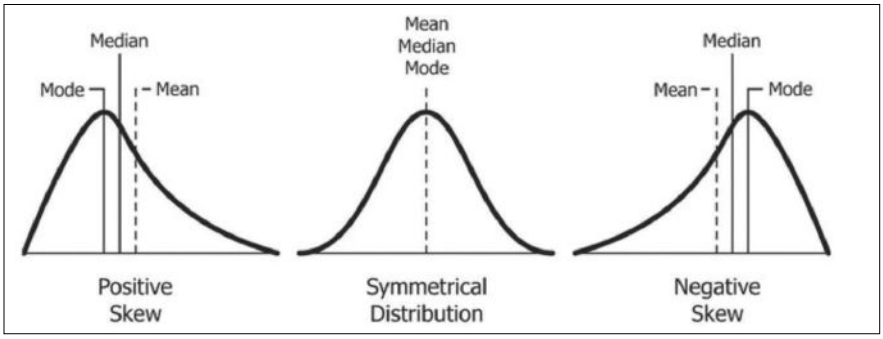


Photo: Diva Jain/Wikimedia Commons

The mean, median and mode values are identical when study data are symmetrically distributed along a classic bell curve.

Intra/Inter-class Correlation Coefficient: These describe the repeatability of a continuous variable on a scale of 0 to 1.[7] A value of >0.70 is recommended to discriminate between groups and one of >0.90 is recommended to discriminate between individual participants within a group.[7]

Intra-Subject and Test-Test Repeatability: These describe how similarly one subject or measurement provides the same test score on two different occasions under the same circumstances.[9]

Investigator-Developed Questionnaire: An instrument created by subject matter experts to gather general data about a topic. These questionnaires are not typically psychometrically validated, which is not of great concern because they are usually used to gather valuable patient-reported outcomes that can help guide clinical practice or patient education. These instruments are not suitable for diagnosing a condition or tracking disease progression.

Likert Scale: A type of questionnaire with qualitative response options, typically reported as percentages.[1] An example of a Likert scale is when a subject is asked if they *strongly agree*, *agree*, *have no preference*, *disagree* or *strongly disagree* with a question.

Mean: The average of a set of numbers.[8] Like median, it is a measure of central tendency. It should be used when the data *are* normally distributed.

Median: The middle number of a set.[8] It is a measure of central tendency and it is less affected by outliers; thus, it should be used when the data *are not* normally distributed.

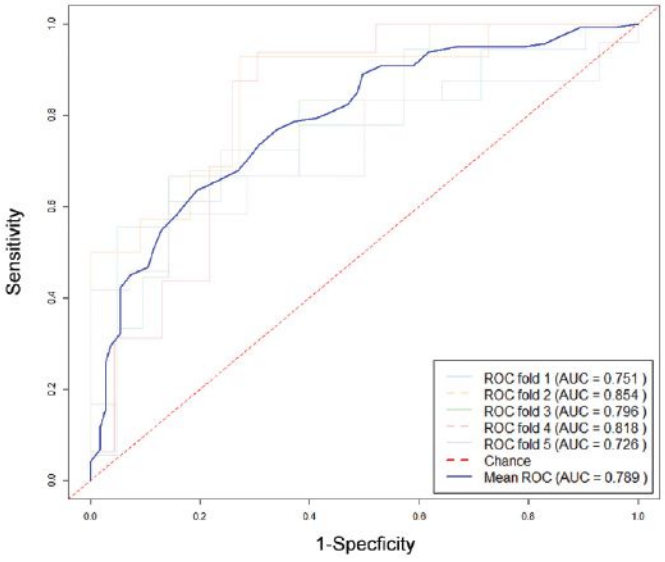
Normal Distribution: A pattern in which continuous data follow a bell-shaped curve where the likelihood of a value occurring decreases as it moves away from the center number.

Paired Comparison: In clinical research, this is when a comparison is made within the same subject.[8] Performing comparisons within the same subjects typically results in decreased variability and the need for fewer subjects in a study compared to comparisons between subjects.

Person-Separation Index: This evaluates measurement precision—the ability to discriminate between subjects with different amounts of a trait. A value >2.0 is considered to be acceptable.[6,7,10]

Prevalence: The proportion of people within a defined population who have a specific condition.[1] For the term *prevalence* to be appropriate, the sample being used must be representative (*i.e.*, people included in the study should mirror the population of interest). If the population is not fully represented, the term *frequency* should be used.

Principal Components Analysis: In a Rasch analysis, this is a statistical approach for determining if the questionnaire is unidimensional (measuring a single trait). A value >2.0 suggests multidimensionality (measuring more than one trait), which is not ideal for a questionnaire aimed at quantifying a specific trait (*e.g.*, dry eye symptoms).[10]



ROC curves are a staple of medical research. This one appeared in a recent issue of *IOVS*, in a study exploring the relationship between visual field defects and high myopia. Do such defects occur by chance in these patients? No, says this analysis. The diagonal red line in an ROC curve represents pure chance. Anything above it shows an association. The area under the curve (AUC) value quantifies the strength of the association, with 1.00 being perfect and 0.50 being purely random.

From Li C, et al. Long-term prediction and risk factors for incident visual field defect in nonpathologic high myopia. Invest Ophthalmol Vis Sci. 2024;65(10):43. Reproduced per Creative Commons 4.0 license.

Rasch Analysis: A statistical approach for testing the psychometric properties (ability to measure a trait) of a questionnaire with categorical items.[6,7]

Receiver Operating Characteristic (ROC) Curve: This is a statistical approach used for balancing the sensitivity and specificity of a measure to determine a cut-point between normal and abnormal subjects.[11] An *area under the curve* (AUC) value obtained from this approach of 0.50 has no ability to differentiate between having a condition and not, while a value of 1.00 indicates a perfect ability to differentiate between them.[11]

Sample Size: The number of subjects needed in a study to correctly determine if a significant difference in a comparison can be determined.[1] When sample size calculations are performed, they typically yield the number of subjects needed per group. The sample size for a study is typically only calculated for the primary outcome or for key outcomes.

Sensitivity: How likely one can detect a condition in an individual using a test (in percentage).[12]

Specificity: How likely one can rule out a condition in an individual using a test (in percentage).[12]

Standard Deviation: A measure of variability from the mean value for a continuous variable.[1] Higher numbers indicate a greater spread of the data and hence more randomness to the association being studied.

Statistical Power: The probability of finding a non-random correlation in the data and thus rejecting the null hypothesis (*i.e.*, a presumption of no effect) if the effect size in the population is equal to or greater than the study's prespecified effect size.[1] If, for example, a study uses a power of 80%, which is common in medical science, this means it would correctly reject the null hypothesis 80% of the time. When discussing power, the term beta (β) is sometimes mentioned.[1] Beta is the probability of failing to reject the null hypothesis when it is false. Power is calculated by subtracting beta from 100 (*e.g.*, 100-20=80% power).

Statistically Significant Difference: This formal term can be said to be present when there is a mathematical relationship between variables.[8] The phrase can sometimes be misconstrued to suggest the more colloquial use of the word *significant*. However, as a matter of statistics, all it means is that the *p-value* of the results is less than the *alpha* (also called the *level of significance*). This relationship may or may not be a clinically meaningful difference.

Unpaired Comparison: In clinical research, this is typically when a comparison is made between two different subjects.[8] Comparing different subjects typically results in increased variability compared to comparisons within a subject.

Validated Questionnaire: An instrument that has undergone psychometric testing (*e.g.*, Rasch analysis) to ensure that it is evaluating the desired trait.[6]

Sample Sizes

The concept of sample size is worth dwelling on for a moment. While there are multiple ways to determine a sample size, which are based upon the type of data being evaluated and the desired study outcomes, the most common method used in vision studies involves calculating paired or unpaired superiority sample sizes for continuous data to determine the number of subjects who should be enrolled to demonstrate if there is no association found. This is an important distinction because once an

TABLE 1. HOW PARAMETERS AFFECT SAMPLE SIZE

	Paired Design (n)	Unpaired Design (n)
Standard Deviation		
3 units	7	10
5 units	15	26
7 units	27	50
Effect Size (Clinically Meaningful Difference)		
3 units	24	45
4 units	15	26
5 units	10	17
Statistical Power		
70%	7	21
80%	8	26
90%	9	34

An alpha of 0.05 was used for all calculations and 5 units, 4 units and 80% were used for standard deviation, effect size and power, respectively, when a parameter was not being analyzed.

Commonly Confused Terms

• ***Adverse event (AE) vs. serious adverse event (SAE) vs. side effect:*** FDA trials typically define an *AE* as any untoward medical occurrence in a clinical trial subject that is temporally associated with the use of study intervention. An AE does not need to be related to the study treatment to be considered one. An AE reaches the level of *SAE* when it meets specific criteria such as death or elevated mortality risk. The *severity* of an event is graded (mild, moderate, severe) based upon how big of an impact the event has on daily activities. The term *side effect* is more broad than AE or SAE and, strictly speaking, does not always connotate a negative consequence. When Allergan received reports of eyelash growth as a side effect of Lumigan use, it spun that off into its own indication for the cosmetic product Latisse.

• ***Vehicle-controlled vs. placebo-controlled vs. comparator-controlled studies:*** A *vehicle* is a control treatment that is the same as the active treatment, just without the active drug present. A *placebo* is a general, inert substance that is not thought to have any treatment effect (*e.g.*, saline drops). A *comparator* control is an active treatment, which is typically the standard of care. Comparator controls are typically used when it is determined that it is unethical to withhold treatment from a subject.

• ***Parallel assignment vs. crossover study:*** A *parallel group* study is when a subject is assigned a treatment and they stay on that same treatment until the end of the trial, while a *crossover study* is when a subject enters a study on one treatment and switches to another at a defined point in the trial. A crossover study design allows investigators to see how an individual subject will respond to more than one treatment (less subject variability), yet crossover studies are not typically used because it is challenging to determine if the first treatment has a spillover effect into the next study phase (*e.g.*, delayed appearance of an adverse event).

• ***Primary outcomes vs. secondary outcomes:*** The *primary outcome* is the main question of the trial (*e.g.*, will drug X treat sign Y). The primary outcome is key to trial planning (*e.g.*, sample size, study duration). *Secondary outcomes* are other key signs or symptoms evaluated in a trial. Exploratory outcomes are also sometimes included to help gather information for future trials or marketing purposes. While rare, a drug can get approved by the FDA even if a trial fails to meet its primary outcome if the results of a secondary outcome are compelling enough to affect clinical practice.[14] The FDA may likewise approve a drug if a trial fails to meet its primary outcome if there is compelling data from a companion trial.

• ***Confidence interval (CI) vs. standard deviation (SD):*** These both describe the spread of data. A *CI* is a measure of variability for non-parametric data (non-normally distributed data) while *SD* is a measure of variability for parametric data (normally distributed data).

• ***Odds ratio (OR) vs. relative risk (RR) vs. hazard ratio (HR):*** All of these describe the chance of seeing a disease in those exposed to a risk factor. They differ in that an *odds ratio* describes associations between an intervention and risk while *relative risk* describes how an intervention changes risk.[1,5] Similarly to RR, a *hazard ratio* also describes how an intervention changes the rate of an event happening but it is a measure of rate of change within two groups, whereas relative risk is a calculation of risk in a single population.[15] HR deals with rates over time, providing insights into the timing of events, while OR and RR both describe cumulative risk over the duration of the study.[5] OR is typically used in case-control studies, RR in cohort studies and randomized controlled trials, and HR in survival analysis and time-to-event studies.

outcome reaches statistical significance, the significance typically only gets stronger with more subjects, assuming that the analysis was done with a sample size in the parametric statistics range (roughly a normal distribution of values with >20 subjects).

Table 1 demonstrates by example how sample size can vary wildly by the factors included in the calculation. The example specifically uses Standard Patient Evaluation of Eye Dryness Questionnaire data (score range=0-28 units), a common dry eye symptoms questionnaire, which has a published clinically meaningful difference of 4 units.[10,13]

This example highlights that smaller sample sizes are calculated with smaller standard deviations, larger effect sizes, less power and paired designs, yet the more power you include in the calculation, the more likely your results will represent the true result.

Conclusion

As clinicians, it is imperative that we regularly review new research as it becomes available so that we can bring the best and newest treatments to our patients. To that end, we not only need to read the most recent research but fully understand and critically evaluate it to determine if new developments merit incorporation into our practice. While the above information is not a comprehensive lexicon of clinical research, it does provide you with the tools to help you become a more critical reviewer. ■

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CAN YOU SPOT THESE DRUG-INDUCED OCULAR SIDE EFFECTS?

Consider these four cases involving toxic optic neuropathy and maculopathy to learn more about the potential mishaps of systemic meds.

BY SWETA DAS, OD
NEW YORK CITY

Optometrists play a critical role in not only managing vision but also safeguarding overall eye health. With the increasing prevalence of systemic medications that can affect the eyes, being able to identify drug-induced ocular side effects is more important than ever. From dry eyes to vision-threatening conditions, a wide range of medications can cause adverse effects that may be subtle yet significant.

Our goal is not only to accurately diagnose structural changes occurring in our patients' eyes but also to manage the condition appropriately to mitigate functional visual deterioration. This article will discuss the typical features of toxic optic neuropathy (gradual bilateral symmetric painless decrease in vision, cecocentral or central visual field loss, and decrease in color vision) and highlight a case of toxic optic neuropathy secondary to oral ciprofloxacin use.[1]

Toxic optic neuropathy selectively affects the papillomacular bundle, but, rarely, maculopathies, like hydroxychloroquine-related retinal toxicity, may cause changes in the macula region nasal to the fovea and mimic the structural changes seen in toxic optic neuropathy.[2,3] This discussion will highlight hydroxychloroquine (HCQ)-related retinal toxicity that mimics neurogenic etiologies.[3] An antibiotic drug minocycline is known to cause discoloration of tissue (skin, conjunctiva and sclera), but this article will discuss pigmentary and structural changes in retinal pigmentary epithelial (RPE) cells secondary to oral minocycline use.[4] Additionally, it will touch upon a case of serous retinal detachment from immune dysregulation after the use of immune checkpoint inhibitors for treatment of metastatic cancer.[5]

Equipped with the knowledge to recognize potential issues early, optometrists can provide the best care for their patients, supporting their health and well-being as a whole.

Toxic Optic Neuropathy

Some of the ocular side effects of oral ciprofloxacin—an antibacterial drug

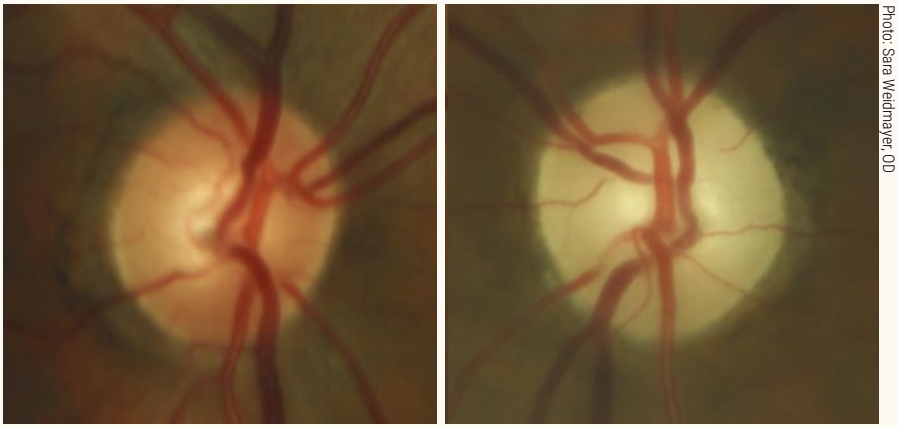

Photo: Sara Weidmayer, OD

Late-stage, severe optic atrophy in a patient on chronic amiodarone therapy, an antiarrhythmic drug.

About the authors

Dr. Das currently serves as a clinical assistant professor at SUNY College of Optometry committed to providing premier care to patients and remaining at the forefront of advancements in eyecare technology. She completed a primary care residency at the Northeastern State University Oklahoma College of Optometry in 2022 and is a fellow of the American Academy of Optometry.

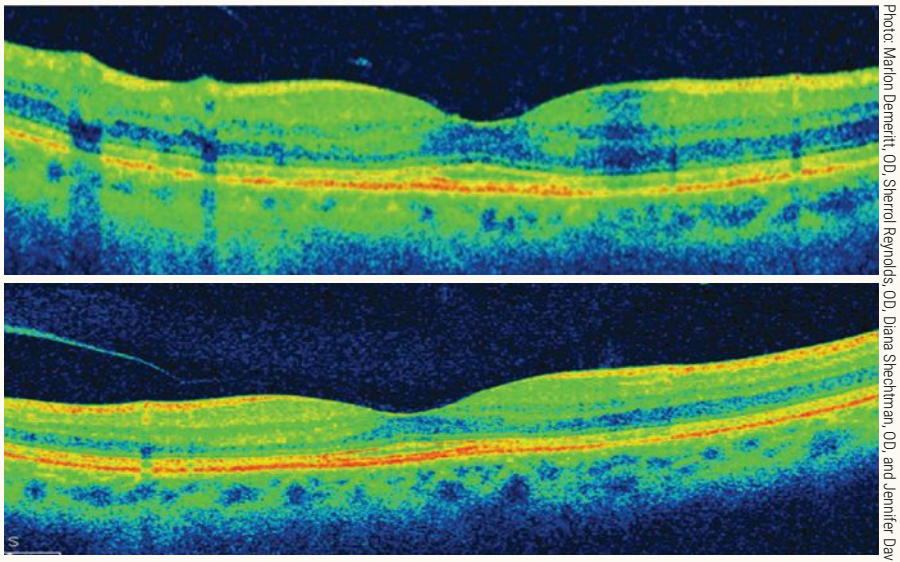

Photo: Marlon Demeritt, OD, Sherrol Reynolds, OD, Diana Shechtman, OD, and Jennifer Davidson, OD

OCT demonstrating localized parafoveal thinning in a patient with early HCQ toxicity.

that belongs to a class of drugs called fluoroquinolones—are eyelid irritation and retinal detachment. Oral use of moxifloxacin is associated with iris transillumination defects and retinal detachment, and fluoroquinolones in general are also associated with exacerbation of myasthenia gravis. One of the lesser-known side effects of oral ciprofloxacin use, as discussed below, is optic neuropathy.

One study reported a case of a 55-year-old male who experienced bilateral progressive loss of vision and color vision along with central scotoma over a two-month period from toxic optic neuropathy.[1] He reported difficulty recognizing faces and reading.

Case history. His ocular history was unremarkable and medical history was remarkable for chronic osteomyelitis managed with oral ciprofloxacin 1,500mg per day and opioid analgesics for the last six years. The patient also reported intermittent use of cephalexin for recurrent urinary tract infection. His social history included variable use of alcohol intake, but the patient denied intake of alcohol in the last four months.

Pertinent findings. The patient's corrected visual acuity was reduced bilaterally to 6/60 [20/200] in each eye. His visual acuity recorded 12 months prior was 6/6 [20/20] in each eye. Color vision measured with Ishihara color plates (IHP) was 3/15 in each eye. His pupils were equally round and reactive to light without a relative afferent pupillary defect. The optic nerves did not show any indication of edema or pallor. A 24-2 Humphrey visual field (HVF) test showed bilateral central scotoma.

Additional tests. Computed tomography and gadolinium-enhanced magnetic resonance imaging (MRI) of the brain and orbits did not reveal

Can You Spot these Drug-induced Ocular Side Effects?

Jointly provided by Postgraduate Institute for Medicine (PIM) and Review Education Group

Release Date: September 15, 2024

Expiration Date: September 15, 2027

Estimated Time to Complete Activity: two hours

Target Audience: This activity is intended for optometrists interested in recognizing and treating toxic optic neuropathy.

Educational Objectives: After completing this activity, participants should be better able to:

- Evaluate and identify various ocular side effects associated with systemic agents.
- Recognize toxic optic neuropathy and the potential for structural changes after drug use.
- Effectively use diagnostic tests to identify changes in the retina and optic nerve due to systemic medications.
- Determine appropriate management strategies for drug-induced ocular side effects.

Faculty: Sweta Das, OD

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a compressive lesion and the result was unremarkable. Laboratory tests to evaluate for inflammatory, infectious, vascular and hereditary causes were unremarkable. Of note were elevated gamma glutamyl transferase levels and macrocytic anemia, which raised suspicion of alcohol abuse but his normal levels of vitamin B12, folate and thiamine did not support the diagnosis of alcohol abuse.

Diagnosis and management. This patient was diagnosed with ciprofloxacin-induced toxic optic neuropathy and was switched to oral cephalexin 500mg four times a day for the management of chronic osteomyelitis. He was asked to discontinue the use of oral ciprofloxacin 1,500mg per day.

Prognosis. At the three-month follow-up exam after cessation of oral ciprofloxacin, visual acuity improved to 6/30 [20/100] in each eye. There was further improvement in visual acuity at a 36-month follow-up exam to 6/6 [20/20] in the right eye and 6/12 [20/40] in the left eye. Visual field showed improvement in both eyes with only a shallow central scotoma seen in the left eye's field. Even though the patient's visual acuity and field improved after cessation of oral ciprofloxacin, color vision remained affected at 3/15 with IHP with each eye, and the patient developed bilateral sectoral optic disc pallor and optic nerve atrophy.

Discussion. As clinicians, it is important to determine the speed at which our patient experiences a decrease in vision or loss of vision. When a patient presents with sudden onset vision loss without subsequent progression, it is likely that the culprit is an ischemic insult such as an arterial occlusion. Patients with ischemic optic neuropathy may complain of sudden onset of vision loss with subsequent progression in loss of vision over days to weeks. Loss of vision that occurs gradually over days to weeks indicates an inflammatory, infectious or demyelinating cause, whereas gradual decrease in vision progressing over months to years is suspicious for a compressive lesion, nutritional/toxic optic neuropathy or glaucomatous optic neuropathy, but it is crucial that we keep atypical maculopathies in the differential. The pathognomonic feature of toxic/nutritional optic neuropathy is gradual progressive bilateral symmetric painless loss of vision, loss of color vision and symmetric central or cecocentral loss of visual field. Improvement in visual function but often not in structural change (retinal nerve fiber layer/ganglion cell-inner plexiform layer thinning and optic nerve pallor) after discontinuation of the offending agent is also a common characteristic of toxic optic neuropathy.[2] *Table 1* lists agents that are known to induce toxic optic neuropathy.[6]

Long-standing use of oral ciprofloxacin can lead to toxic optic neuropathy; therefore, it is prudent to monitor patients, who are on long-term oral ciprofloxacin, yearly with a comprehensive dilated eye exam, color vision, fundus photos and visual field tests. Discontinuation of oral ciprofloxacin on a timely basis can lead to resolution of central scotoma and near normalization of visual field slowly over months but does not reverse development of optic disc pallor and structural changes (retinal nerve fiber layer and ganglion cell-inner plexiform layer thinning).

TABLE 1. TOXIC OPTIC NEUROPATHY-INDUCING AGENTS[1]

Agents/Medications	Use
Methanol	Toxic alcohol
Ethylene Glycol	Antifreeze agent
Lead, Mercury, Thallium	Toxic agents
Tobacco (Cigars)	Toxic agent (questionable evidence)
Ethambutol	Antibacterial drug
Isoniazid	Antibacterial drug
Linezolid	Antibacterial drug
Amiodarone	Management of arrhythmia
Digitalis	Management of congestive heart failure
Disulfiram	Management of alcoholism
Ciprofloxacin	Antibacterial
Chloramphenicol	Antibacterial
Streptomycin	Antibacterial
Sulphonamides	Antibacterial
Didanosine	HIV medication
Methotrexate	Chemotherapy and immunosuppressant
Antineoplastic Drugs (Cisplatin, Vincristine)	Chemotherapy
Interferon α and Anti-Tumor Necrosis Factor Agents (Etanercept, Infliximab, Adalimumab)	Disease modifying therapy

Is this Retinopathy or Neuro-Ophthalmic Disease?

HCQ is a chloroquine derivative that is used in the management of rheumatologic and dermatologic conditions and is less likely to cause retinal toxicity than chloroquine. Even though the incidence rate of HCQ-related retinopathy is low, there are well-documented cases of retinopathy in patients on HCQ, not exceeding the maximum recommended daily dose of 5mg/kg real body weight/day

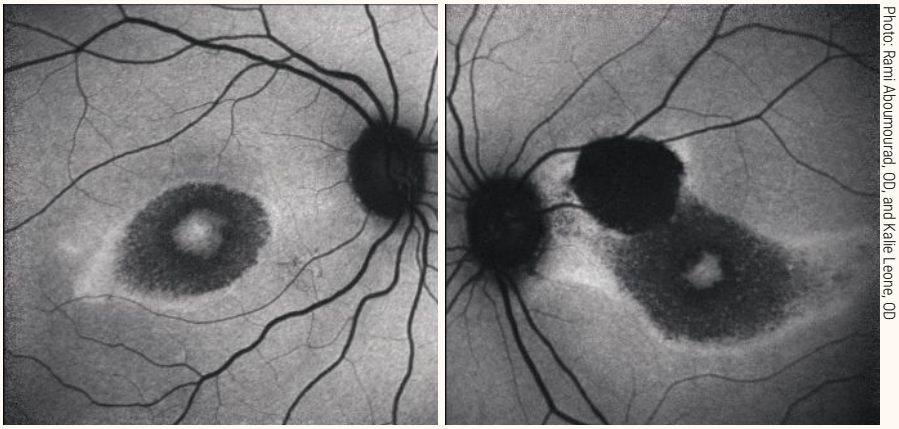


Photo: Rami Abdumourad, OD, and Kalie Leone, OD

Perifoveal hypoautofluorescence in both eyes and a dense hypoautofluorescent lesion in the superonasal macula consistent with the chorioretinal scar observed on fundus exam.

and in the absence of associated risk factors for developing drug-induced toxicity.[3,7,8]

Risk factors known to increase the risk for HCQ-related retinal toxicity include cumulative total dose of HCQ greater than 1,000g, greater than five years of HCQ intake, presence of kidney disease, concomitant use of tamoxifen and presence of retinal disease, such as age-related macular degeneration (AMD). HCQ is known to bind to melanin in RPE. Rare but irreversible manifestations of HCQ-related retinal toxicity includes damaged photoreceptors and underlying RPE parafoveally, which we know as the classic bullseye maculopathy. If drug-related retinal toxicity is not diagnosed early on and the patient continues the use of HCQ, retinal pigmentary changes may progress to peripheral retinal degeneration that appear similar in presentation as retinitis pigmentosa. There are case reports of early-onset pericentral and peripheral retinopathy, but HCQ-related retinopathy may even be localized nasal to the fovea in a peripapillary pattern.

Case report of an atypical manifestation of HCQ-related retinopathy. One study shared a series of case reports highlighting atypical manifestations of HCQ associated retinopathy.[3] A 54-year-old Korean female from the case series reported intake of HCQ for approximately six years for Sjögren's syndrome, whose 30-2 HVF result was remarkable for bitemporal central sparing hemianopsia. Given the bitemporal nature of the visual field defect, a brain MRI was performed without remarkable findings. Her ultrawide fundus autofluorescence (FAF) showed bilateral peripapillary and pericentral (involving superior and inferior vascular arcade region) hypoautofluorescence. Macular OCT scan showed loss of ellipsoid, interdigitation zone and damage to the RPE and pigment migration pericentrally (along vascular arcade).

Diagnosis and management. The center-sparing bitemporal hemianopsia corresponding with bilateral nasally localized retinopathy was recognized as HCQ-associated retinal toxicity in this case series.[3] Acute macular neuroretinopathy is a rare condition, but it may also present as bilateral disruption of the ellipsoid zone, nasal to the fovea, on macular OCT, and therefore it is worth keeping in the differentials.[6]

Discussion. HCQ-associated retinopathy may be localized nasally and may lead to bitemporal hemianopsia. This case report highlighted the importance of expanding our differential diagnosis for bitemporal hemianopsia from chiasmal disorders to medication induced retinal toxicity.[3] The abnormal hypoautofluorescence seen nasally in both eyes, in addition to the corresponding outer retinal layer disruption seen on macular-OCT in the setting of normal brain MRI, confirms the diagnosis of HCQ-associated retinal toxicity.

The researchers also reported a case of retinal toxicity in a 44-year-old female after being on unknown daily dose of HCQ for as early as six months without any of the risk factors like kidney disease, concomitant use of tamoxifen, presence of retinal disease, cumulative total dose of HCQ greater than 1,000g or duration of HCQ intake for longer than five years.[3] They also highlighted a case of HCQ-related retinopathy that started out in the peripheral retina in both eyes as opposed to parafoveal or pericentral regions, which are the most commonly affected. Yet another interesting case reported was HCQ retinopathy noted in one eye of a patient, while the contralateral eye remained unaffected.

Even though parafoveal and pericentral outer retinal layer disruption is considered pathognomonic features of HCQ-associated retinopathy, we must be cognizant of peripapillary, peripheral, asymmetric or early-onset outer retinal changes secondary to HCQ-related retinal toxicity. This also means that patients who are on HCQ may benefit from screening every six to 12 months with not only a careful macular evaluation but also a thorough evaluation of the peripheral retina. Macular OCT, HVF 10-2 and/or fundus photos are commonly administered for patients on HCQ as part of their retinal evaluation. Ultra-widefield (UWF) FAF and color photos along with HVF 24-2 or HVF 30-2 may be beneficial, so we do not miss peripheral or pericentral retinal changes from HCQ-related toxicity.[3] As primary eyecare providers, it is crucial that we are aware of the atypical presentation of HCQ-associated retinal toxicity in order to prevent this iatrogenic cause of progressive and irreversible vision loss.

Pigmentary and Structural Change in RPE

Discoloration of tissue (skin, nail, teeth), sclera and conjunctiva is a widely known side effect of a synthetic tetracycline antibiotic, known as minocycline hydrochloride.[9,10] Pigmentary and structural change of RPE cells is a lesser-known adverse effect of oral

minocycline.[10] Minocycline agent is commonly used to treat rosacea, acne vulgaris, bullous pemphigoid and rheumatoid arthritis on a long-term basis.[10]

Case reports. One study reported a case of a patient in their early 70s on prolonged use of oral minocycline (100mg twice a day for over 30 years) for acne vulgaris, who presented with blue-gray discoloration of sclera and bluish-gray conjunctival inclusions in inferior palpebral conjunctiva.[4] His visual acuity was 20/20 in the right eye and 20/30 in the left eye secondary to nuclear sclerosis, more significant in the left eye. There were also dark gray pigment changes noted in the macula region of both eyes. On spectral-do OCT scan of the macula, these dark pigment deposits appeared as sub-RPE hyper-reflective material, which did not show abnormal hyper- or hypofluorescence on fluorescein angiography. The patient had no visual complaints and reported no metamorphopsia.

Diagnosis and management. Bilateral darker macular pigmentation noted on ophthalmoscopic examination did not resemble the appearance of drusen, and the nodular hyperreflective sub-RPE deposits noted on the macular OCT bilaterally were diagnosed as minocycline-induced pigmentary and structural change in RPE. Even though the patient did not complain of visual distortion, cessation of minocycline was recommended due to subfoveal pigmentary and structural change noted in RPE of both eyes. It was also suggested that the patient be followed closely with eye exam to further assess for ocular and visual changes in the future. A dilated fundus examination supplemented with fundus photographs, macular OCT and central 10-2 visual field test is usually sufficient in careful monitoring of patients with minocycline-induced retinal pigmentary and structural changes. Macula appears normal (hypoautofluorescent) on fundus autofluorescence indicating low lipofuscin content but rather melanin-associated RPE changes instead.[11]

Discussion. Minocycline is a yellow lipophilic substance that turns black upon oxidation. It is known to bind various proteins in the body like ferritin, hemosiderin and melanin.[3] This oxidized drug complex with various proteins in the body is the cause for discoloration of the skin, teeth, bone, sclera and conjunctiva. Studies suggest that subfoveal RPE cells have the highest concentration of melanin and is believed to be the cause for pigmentary and structural change of RPE in the macula region. Even though cessation of minocycline leads to resolution of discoloration noted elsewhere in the body without functional alteration of the organ in question, discontinuation of minocycline use and its long-term effect on pigmentary and structural change of RPE is not well established yet.

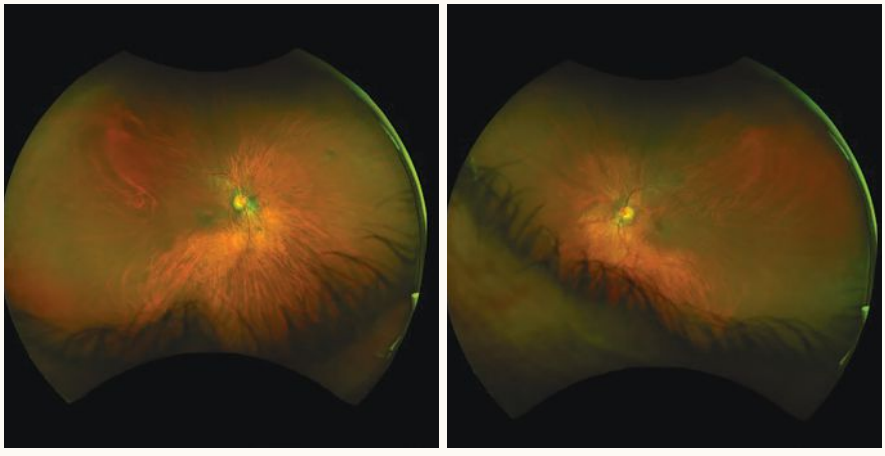


Photo: Luanne Chubb, OD

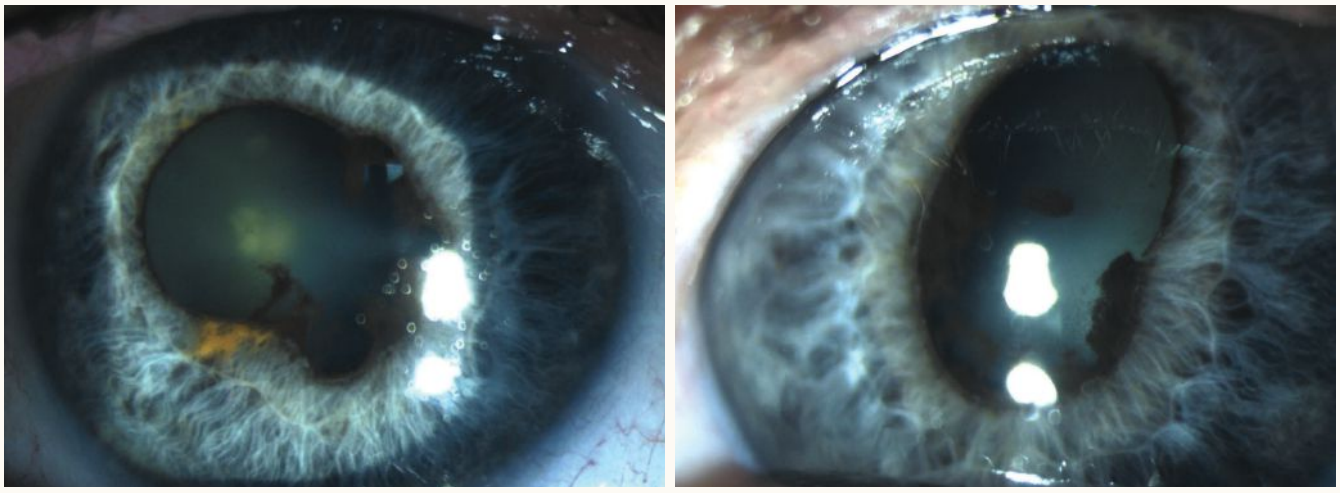
Five years after this patient stopped taking HCQ, these fundus images highlight some of the damage it left behind. Note the incomplete bullseye maculopathy at left.

Long-term use of oral minocycline can not only cause blue-gray discoloration of skin, teeth, sclera and palpebral conjunctiva but also of the macula, specifically the subfoveal RPE cells. This nodular deposit appears as sub-RPE hyperreflective material in the fovea region and can resemble drusen (commonly seen in nonexudative macular degeneration) on OCT scan of the macula. However, ophthalmoscopic exam shows minocycline-induced dark pigmentary change in the macula instead of drusen. Therefore, it may be beneficial for optometrists to keep minocycline-induced RPE change as one of our differentials when macular OCT suggest drusenoid sub-RPE deposit without corresponding appearance of drusen in the macula ophthalmoscopically.

Structural Change of Photoreceptor Outer Segment and Choroid

Immune checkpoint inhibitors are used for managing advanced cancer, including malignant melanoma, renal carcinoma and Hodgkin lymphoma. The mechanism of action includes preventing cancer cells from growth by stimulating T-cell activation. Immune checkpoint inhibitors are associated with autoimmune-mediated complications; ocular complications reported include dry eye, Vogt-Koyanagi-Harada disease and uveitis. Below is a case reported involving multiple bilateral serous retinal detachments, thickening of photoreceptor outer segments and choroid after treatment with nivolumab (immune checkpoint inhibitor) for stage 4 malignant nasal melanoma.[5]

Case report. A 73-year-old Japanese man was seen for an eye exam due to complaints of bilateral metamorphopsia, which developed two months after he was started on the immune checkpoint inhibitor nivolumab for treatment of stage 4 nasal malignant melanoma. On examination, his best-corrected visual acuity was noted as 20/20 in the right eye and 20/16 in the left eye. Intraocular pressure was 10mm Hg in both eyes. There were no cells



Findings due to chronic anterior uveitis associated with a cancer immunotherapy drug.

or flare noted in anterior chamber or vitreous, which could indicate Vogt-Koyanagi-Harada disease. Fundus examination showed bilateral macular vitelliform lesions with associated serous retinal detachments. Of note was diffuse thickening of the photoreceptor outer segments and choroid. Fluorescein angiography and indocyanine green angiography did not reveal pooling or leakage, which could indicate metastatic choroidal melanoma.

Diagnosis and management. Bilateral multifocal serous retinal detachment in the setting of diffuse thickening of photoreceptor outer segments and choroid, without indication of ocular inflammation, was diagnosed as iatrogenic impairment of RPE from treatment with nivolumab. The patient maintained a visual acuity of 20/20 in both eyes during his last eye examination visit, which was two months before his systemic condition deteriorated and the patient passed away. The authors noted that in the hypothetical scenario of decreased vision, they would have consulted the patient's oncologist to discuss altering his systemic medication and starting treatment with topical dexamethasone at the same time.

Discussion. It is believed that immune checkpoint inhibitors, like nivolumab, may promote T-cell directed impairment of RPE cells, which affects RPE cells' pumping and phagocytosis function, leading to serous retinal detachment and diffuse thickening of photoreceptor outer segments. Immunomodulators, used for management of various rheumatologic disorders and cancer, may cause serous retinal detachment secondary to immune dysregulation. A thorough history, entrance testing, slit lamp exam and a dilated fundus examination supplemented with fundus photographs, macular OCT and visual field test is usually sufficient in careful monitoring of patients to diagnose immune dysregulation related ocular changes. In the event that structural and/or functional changes are noted, communicating this urgently with the patient's oncologist, rheumatologist and family doctor is essential so the risk versus benefit of altering medication can be thoroughly investigated.

Takeaways

Systemic drugs are commonly associated with various ocular side effects. For example, there are agents known to cause toxic optic neuropathy, which selectively affects the papillomacular bundle and therefore presents as bilateral symmetric painless decrease in vision and color vision along with central or cecocentral visual field defect.[2] In addition to toxic optic neuropathy, systemic drugs may cause maculopathies, and in some cases, like the atypical HCQ-related retinal toxicity case discussed above, may lead to changes in the macula region nasal to the fovea and mimic the structural changes seen in toxic optic neuropathy or chiasmal disorders.[3] Therefore, as eyecare physicians, we must keep drug-induced ocular side effects, such as maculopathy and optic neuropathy, in our differential in the event of visual, functional and/or structural changes noted in our patients' eyes. ■

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OPTOMETRIC STUDY CENTER QUIZ

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1. Which of the following oral medications can cause retinal detachment?
a. Fluoroquinolones.
b. Sumatriptan.
c. Canthaxanthine.
d. Pyridostigmine.

2. What are the characteristic signs of toxic optic neuropathy?
a. Gradual, progressive, bilateral (may be asymmetric) and painless vision loss.
b. Dyschromatopsia.
c. Central or cecocentral visual field defect.
d. All of the above.

3. Which of the following meds is known to exacerbate symptoms of myasthenia gravis?
a. Fluoroquinolones.
b. Metformin.
c. Latanoprost.
d. Rosiglitazone.

4. Which of the following medications can cause iris transillumination defect?
a. Fluoroquinolones.
b. Amlodipine.
c. Betaxolol.
d. Metformin.

5. Which of the following agents/medication can cause toxic optic neuropathy?
a. Amiodarone.
b. Ciprofloxacin.
c. Digitalis.
d. All of the above.

6. Which of the following agents are considered toxic?
a. Methanol.
b. Lead.
c. Mercury.
d. All of the above.

7. Minocycline can cause pigmentary change in which of the following structures?
a. Sclera.
b. Conjunctiva.
c. Retina.
d. All of the above.

8. Which of the following medications is a tetracycline derivative?
a. Azithromycin.
b. Cephalosporin.
c. Minocycline.
d. Gentamycin.

9. Which of the following conditions can be managed with oral minocycline?
a. Acne vulgaris.
b. Rosacea.
c. Bullous pemphigoid.
d. All of the above.

10. What is the underlying mechanism responsible for discoloration noted as a side-effect of oral minocycline use?
a. Xanthophyll pigment is responsible for discoloration.
b. Lipophilic minocycline turns black upon oxidation, penetrates tissue and binds to various protein; the oxidized drug-protein complex is the cause of discoloration.
c. Chlorophyl pigment is the cause of discoloration.
d. Drug's interaction with ascorbic acid causes discoloration.

11. How does minocycline cause pigmentary and structural change in RPE?
a. It binds to ion transport channels.
b. It binds to melanin in RPE cells.
c. It does not interact with RPE cells.
d. It accumulates on photoreceptors.

12. Which of the following medications is not used in management of rheumatologic conditions?
a. Minocycline.
b. Hydroxychloroquine.
c. Chloroquine derivatives.
d. Didanosine.

13. What are the risk factors associated with HCQ-induced retinal toxicity?
a. Exceeding the maximum recommended daily dose.
b. Cumulative total dose greater than 1,000g.
c. Duration of HCQ use longer than five years.
d. All of the above.

14. HCQ is used for management of which of the following conditions?
a. Hypertension.
b. Rheumatologic disorder.
c. Myopia.
d. Type 2 diabetic mellitus.

15. What are some additional risk factors that can increase the probability of HCQ-induced retinal toxicity?
a. Concomitant use of tamoxifen.
b. Preexisting kidney disease.
c. Presence of retinal condition, like AMD.
d. All of the above.

16. What is the mechanism underlying the HCQ-induced retinal toxicity?
a. It can bind to melanin in RPE cells and causes damage to the RPE-photoreceptor layer.
b. It binds to external limiting membrane and cause damage to nerve fiber layer.
c. It causes thinning of the choroid.
d. It can never lead to retinal toxicity.

17. What are some of the most common patterns seen during ophthalmoscopic exam or on macular OCT in HCQ-associated retinal toxicity?
a. Bull's eye maculopathy.
b. Parafoveal outer retinal layer disruption.
c. Pericentral outer retinal layer disruption.
d. All of the above.

18. What are some atypical manifestations of HCQ-induced retinal toxicity?
a. Pigmentary change noted in the peripheral region of retina.
b. Asymmetric retinal pigmentary change.
c. Peripapillary retinopathy.
d. All of the above.

19. What of the following tests may not be beneficial to perform as part of HCQ-related retinal screening?
a. Ultra-widefield color and autofluorescence photos.
b. Long line OCT scans.
c. Vergence facility.
d. Visual field test.

20. Which of the following ocular tissue can immune checkpoint inhibitors impair?
a. RPE cells.
b. It can stain tear film.
c. It does not have any effect on ocular tissue.
d. Tenon's layer.

Examination Answer Sheet

Can You Spot these Drug-induced Ocular Side Effects?

Valid for credit through September 15, 2027

Online: This exam can be taken online at revieweducationgroup.com. Upon passing the exam, you can view your results immediately and download a real-time CE certificate. You can also view your test history at any time from the website.

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Answers to CE exam:

1.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
2.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
3.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
5.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
14.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
16.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
17.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

Post-activity evaluation questions:

Rate how well the activity supported your achievement of these learning objectives. *1=Poor, 2=Fair, 3=Neutral, 4=Good, 5=Excellent*

21. Evaluate and identify various ocular side effects associated with systemic agents. ① ② ③ ④ ⑤

22. Recognize toxic optic neuropathy and the potential for structural changes after drug use. ① ② ③ ④ ⑤

23. Effectively use diagnostic tests to identify changes in the retina and optic nerve due to systemic medications. ① ② ③ ④ ⑤

24. Determine appropriate management strategies for drug-induced ocular side effects. ① ② ③ ④ ⑤

25. Based upon your participation in this activity, do you intend to change your practice behavior? (Choose only one of the following options.)

Ⓐ I do plan to implement changes in my practice based on the information presented.

Ⓑ My current practice has been reinforced by the information presented.

Ⓒ I need more information before I will change my practice.

26. Thinking about how your participation in this activity will influence your patient care, how many of your patients are likely to benefit? (please use a number): ☐

27. If you plan to change your practice behavior, what type of changes do you plan to implement? (Check all that apply.)

Ⓐ Apply latest guidelines
Ⓑ Change in diagnostic methods
Ⓒ Choice of management approach
Ⓓ Change in current practice for referral
Ⓔ Change in vision correction offerings
Ⓕ Change in differential diagnosis
Ⓖ More active monitoring and counseling
Ⓗ Other, please specify: _____

28. How confident are you that you will be able to make your intended changes?

Ⓐ Very confident Ⓑ Somewhat confident Ⓒ Unsure Ⓓ Not confident

29. Which of the following do you anticipate will be the primary barrier to implementing these changes?

Ⓐ Formulary restrictions
Ⓑ Time constraints
Ⓒ System constraints
Ⓓ Insurance/financial issues
Ⓔ Lack of interprofessional team support
Ⓕ Treatment related adverse events
Ⓖ Patient adherence/compliance
Ⓗ Other, please specify: _____

30. Additional comments on this course: _____

Please retain a copy for your records. Please print clearly.

First Name
Last Name
E-Mail
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Business Name
Address
City State
ZIP
Telephone # - -
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Rate the quality of the material provided:

1=Strongly disagree, 2=Somewhat disagree, 3=Neutral, 4=Somewhat agree, 5=Strongly agree

31. The content was evidence-based. ① ② ③ ④ ⑤

32. The content was balanced and free of bias. ① ② ③ ④ ⑤

33. The presentation was clear and effective. ① ② ③ ④ ⑤

By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

Signature Date Lesson 125352 RO-OSC-0924

BY JESSICA STEEN, OD

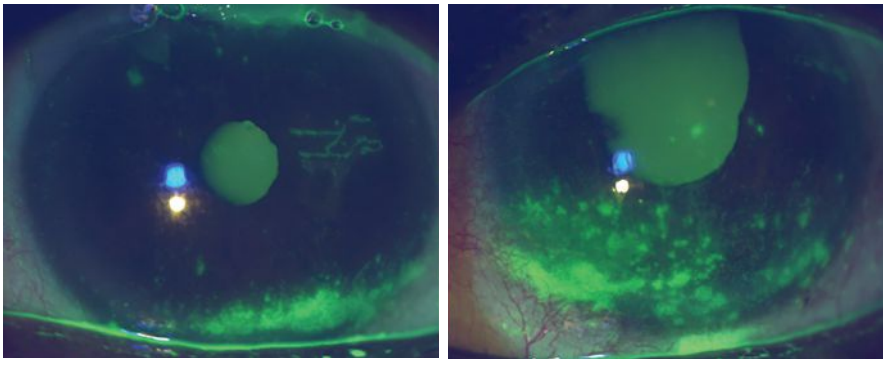
All Roads Lead to Dry Eye

Glaucoma patients are even more likely to develop this condition.

A 61-year-old woman presented for follow-up of primary open-angle glaucoma (POAG) with an ongoing report of feeling grittiness and tearing in both eyes. She has a history of bilateral trabeculectomy with mitomycin C with clinical failure in the left eye. She takes Vyzulta (latanoprostene bunod 0.024%, Bausch + Lomb), Rhopressa (netarsudil 0.02%, Alcon) and dorzolamide-timolol in the left eye only with on-label dosing and reported excellent adherence. Additional procedures for the left eye were not planned by the operating physician leading to release from care. Systemically, she has seropositive rheumatoid arthritis, for which she takes 200mg of hydroxychloroquine BID (for the past four years) in addition to weekly etanercept (Enbrel, Amgen) subcutaneous injection. Best-corrected visual acuity was 20/25 OD and OS.

Her SPEED score was 21/28, and she was using nonpreserved tear substitutes two to four times daily in addition to a moist heat mask and eyelid hygiene products. She had significant conjunctival injection, coalesced inferior staining bilaterally, reduced tear meniscus and inspissated meibomian glands which were poorly expressible. Intraocular pressure (IOP) was 5mm Hg in the right eye with a formed anterior chamber and 11mm Hg in the left eye with central corneal thicknesses of 479µm OD and 467µm OS. She had advanced glaucomatous optic neuropathy bilaterally and corresponding constricted visual fields. There was no evidence of early ellipsoid zone loss on SD-OCT.

When managing multiple chronic ocular conditions, dry eye disease often takes a secondary or tertiary seat, despite having a significant impact on quality of life and a important impact on adherence to IOP-lowering therapy.[1,2] For someone in such a case, treatment considerations are nuanced and may require multiple strategies, including prescription medications and in-office procedures.



Right and left anterior segment photographs demonstrating corneal epithelial staining, reduced tear meniscus and conjunctival injection.

The Basis for Treatment

In dry eye disease, the positive feedback loop that precipitates inflammation and ocular surface damage has formed the basis of therapeutic strategies that disrupt the cycle by targeting evaporation, inflammation or tear production to restore tear film homeostasis.[1,3] Risk factors for the development and exacerbation of the condition require attention to systemic diagnoses, systemic medications, concomitant ocular conditions and their treatment strategies, history of ocular surgery, in addition to environmental and lifestyle features.[1,4-6]

Glaucoma and Dry Eye

Individuals with glaucoma are more likely to develop dry eye disease than the general population, with risk factors driven by glaucoma severity, duration of treatment, benzalkonium chloride (BAK)-containing therapies, history of filtration surgery and number of therapies.[6-9] These topical IOP-lowering agents may be the low-hanging fruit for symptoms and signs related to dry eye and are often contributory. Removal or reduction of BAK-containing medications may not be possible, nor will removal alone cure the underlying multifactorial disease state.

The LiGHT study provided long-term evidence that SLT is a safe and effective therapy for newly diagnosed patients with POAG or ocular hypertension.[10] Interestingly, an American health claims-based report determined that approximately 44% of individuals diagnosed with OAG require a modification to their initial treatment within the first four years of therapy, with nearly 30% of those patients requiring a second modification in the same time period.[11] Incidence of filtration surgery increases with time following diagnosis, from 3.1% at five years to 5.4% at 10 years.[12]

About Dr. Steen

Dr. Steen is an associate professor at Nova Southeastern University College of Optometry, where she serves as director of the Glaucoma Service, coordinator of the Primary Care with Emphasis in Ocular Disease Residency and teaches courses in glaucoma and ocular pharmacology. Her financial disclosures include Bausch + Lomb, Santen, Ocuphire, Carl Zeiss Meditec, Oyster Point Pharma, Ocuterra, Peripherex, Clearside Biomedical, Allergan, Iveric Bio, Alcon and Thea Pharma.

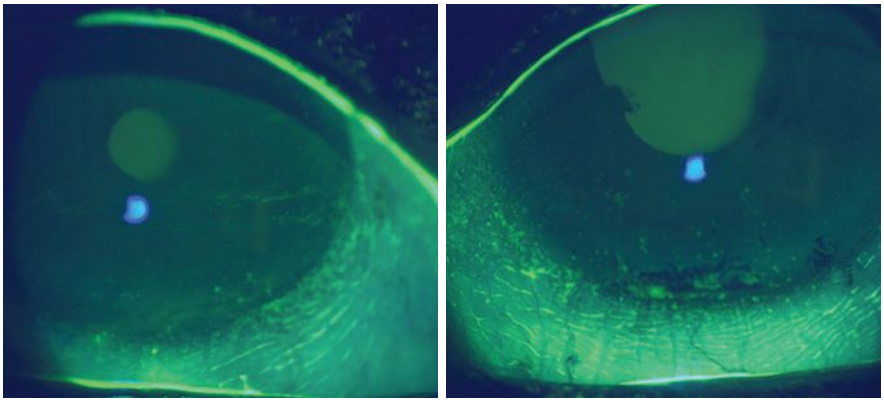
Cumulative risk of blindness in one eye increases with time to 13.5% at 20 years following diagnosis. Managing patients through their lifetime often requires multiple escalations in therapy.[13,14]

Trabeculectomy with antimetabolite use has been demonstrated to increase risk of symptomatic dry eye.[15] Conjunctival irregularities due to the presence of a filtration bleb alter tear film distribution and stability and reduce tear break-up time.[9] Antimetabolites such as mitomycin C (MMC) and 5-fluorouracil (5-FU), when used intra- and postoperatively, have led to increased surgical success; however, they may lead to meibomian gland loss and limbal stem cell deficiency.[9] Increased inflammation and hyperosmolarity can stimulate remodeling of the bleb wall, which may drive fibrosis and reduce functionality.[9]

Systemic medications and systemic inflammatory conditions that impact the lacrimal functional unit can result in an unstable tear film and lead to ocular surface damage, so be sure to identify those in the medical history.[4-6] Also, note systemic inflammatory conditions, including autoimmune thyroid disease, rheumatoid arthritis and Sjögren's syndrome, as well as neurological conditions, including trigeminal neuralgia, Parkinson's disease and chronic viral infections.[1] In particular, rheumatoid arthritis has been associated with hyperosmolarity, a central etiology of dry eye disease.[3,16]

Individualized Treatment

Current prescription options have provided the ability for a truly individualized approach that allows for direct targeting of underlying mechanisms, including evaporation, inflammation and tear production, either alone or in combination. Despite the patient's significant IOP-lowering medication and BAK load and taking note of the unilateral use and bilateral but asymmetric clinical presentation, her topical regimen did not seem to be a central factor in her dry eye disease. Still, caution was taken to ensure she was not overtreated. She reported a history of steroid response and was highly reluctant to a short course of topical steroids. Her travel schedule also limited her ability to return for evaluation within an appropriate time course, leading to deferral of a topical steroid despite its role in reducing ocular surface inflammation. She had felt that she was at her maximum threshold for topical medication instillation use, despite her candidacy for a topical ophthalmic immunomodulating agent or topical agent to reduce tear film evaporation.



Eight weeks following initiation of prescription medication therapy with continued use of artificial tears, eyelid hygiene and moist heat mask use.

Considering the patient's preferences, she was prescribed Tyrvaya (varenicline nasal spray 0.03mg, Viatris), in addition to current nonpreserved tear substitutes, eyelid hygiene and a moist heat mask. The expected efficacy and tolerability profile of the nasal spray were discussed, including the expected adverse effect of sneezing following instillation, and the patient demonstrated correct placement of the bottle tip in the examination room.

Eight weeks later, she returned for follow-up and reported significant improvement in symptoms and improvement in vision. Her SPEED score improved to 10/28, and while mild epithelial staining was present, it and the conjunctival injection significantly improved bilaterally. An update was provided to her rheumatologist regarding ongoing therapy with a query of investigation into Sjögren's syndrome.

Despite the patient's success with her current prescription therapy, she still displays corneal staining and has moderate symptoms of dry eye disease. She represents an ideal candidate for in-office heat- or light-based treatment related to her meibomian gland dysfunction, with the understanding of likelihood of flares and necessity of ongoing adjustments to dry eye treatment, along with continued treatment, POAG monitoring and evaluation of risk for developing hydroxychloroquine toxicity. ■

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Hidden in Good Sight

Unilateral mild blur leads to diagnosis of primary clinoid meningioma.

BY SAMUEL CALVERT, OD
BOWLING GREEN, KY

A 43-year-old woman presented to the ophthalmic emergency department with complaints of intermittent blurred vision and colorful spots in her left eye for the past five weeks, accompanied by gradually improving generalized headaches. The patient reported no eye pain or double vision. She had been diagnosed with ocular migraine two weeks prior; otherwise, her medical history was unremarkable.

On examination, her vision pinholed to 20/20 OD and 20/20-2 OS. Her intraocular pressures were 13mm Hg OD and 11mm Hg OS. There was no relative afferent pupillary defect (APD) in either eye. Extraocular motilities were full without pain, confrontation visual fields were intact and there was no proptosis. The anterior and posterior segments were unremarkable without evidence of glaucomatous cupping or optic disc edema.

Given an unrevealing exam thus far, the patient was asked to describe her visual symptoms in greater detail. She then reported a stationary hazy, horizontal dark line extending through the center of her vision with details of images below the line appearing darker and less clear. Given this information, further testing was completed. She identified 11/11 color plates in the right eye and 9/11 in the left, noted an estimated 40% red cap desaturation in the left eye vs. the right and had an inferior visual field defect on formal perimetry testing. Optical coherence tomography corroborated the visual field results.

Differentials

The first differential that often comes to mind for patients with an altitudinal visual field defect is non-arteritic anterior ischemic optic neuropathy (NAION). This condition typically presents with decreased vision, dyschromatopsia, an APD, optic disc edema with splinter hemorrhages and a visual field defect. The unaffected fellow eye will often exhibit a small optic disc with a small cup-to-disc ratio. NAION is presumed to result from insufficient blood flow to the retrolaminar portion of the optic nerve, which is supplied by the short posterior ciliary arteries. Common confounding variables include diabetes, hypertension and certain medications. This diagnosis is typically made when characteristic clinical signs are present and other conditions have been excluded. In atypical cases, ordering infectious or inflammatory labs and/or neuroimaging may be prudent. In elderly populations, it is recommended to complete a comprehensive review of systems and consider ordering laboratory testing such as a complete blood count, erythrocyte sedimentation rate and C-reactive protein to stratify risk of giant cell arteritis.[1]

Our patient showed no signs of current or previous optic disc edema or pallor, making NAION less likely. In our patient's age group (40s), a new onset inferior altitudinal visual field defect could also be associated with retrobulbar optic neuritis. Typically, optic neuritis occurs in young to middle-aged patients

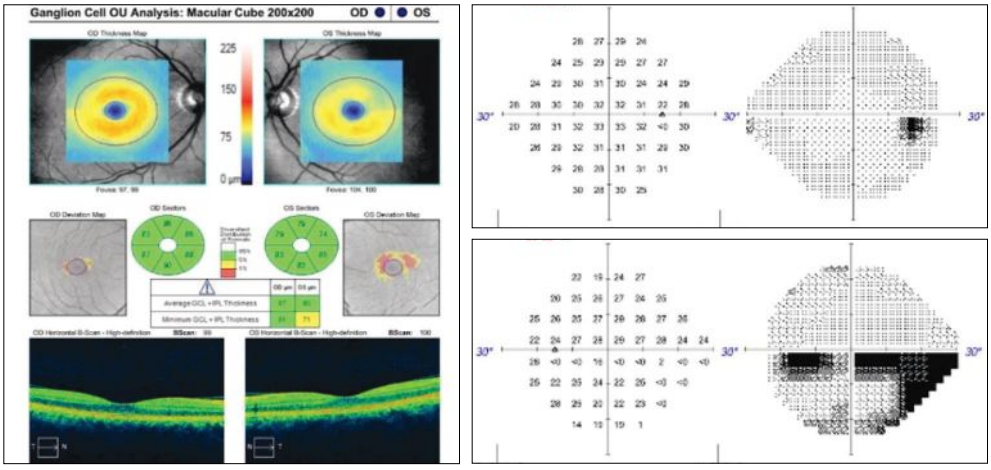

Fig 1. OCT ganglion cell analysis of the left eye indicated superior temporal thinning. The 24-2 visual field of the right eye was largely unremarkable but the left eye demonstrated an incomplete inferior altitudinal defect.

About Dr. Bozung

Dr. Bozung practices at Bascom Palmer where she primarily sees patients in the hospital's 24/7 ophthalmic emergency department. She also serves as the optometry residency program coordinator. Dr. Bozung is a fellow of the American Academy of Optometry and a member of the Florida and American Optometric Associations. She is a founding board member of Young OD Connect and serves on the editorial board for *Review of Optometry*. She has no financial interests to disclose.

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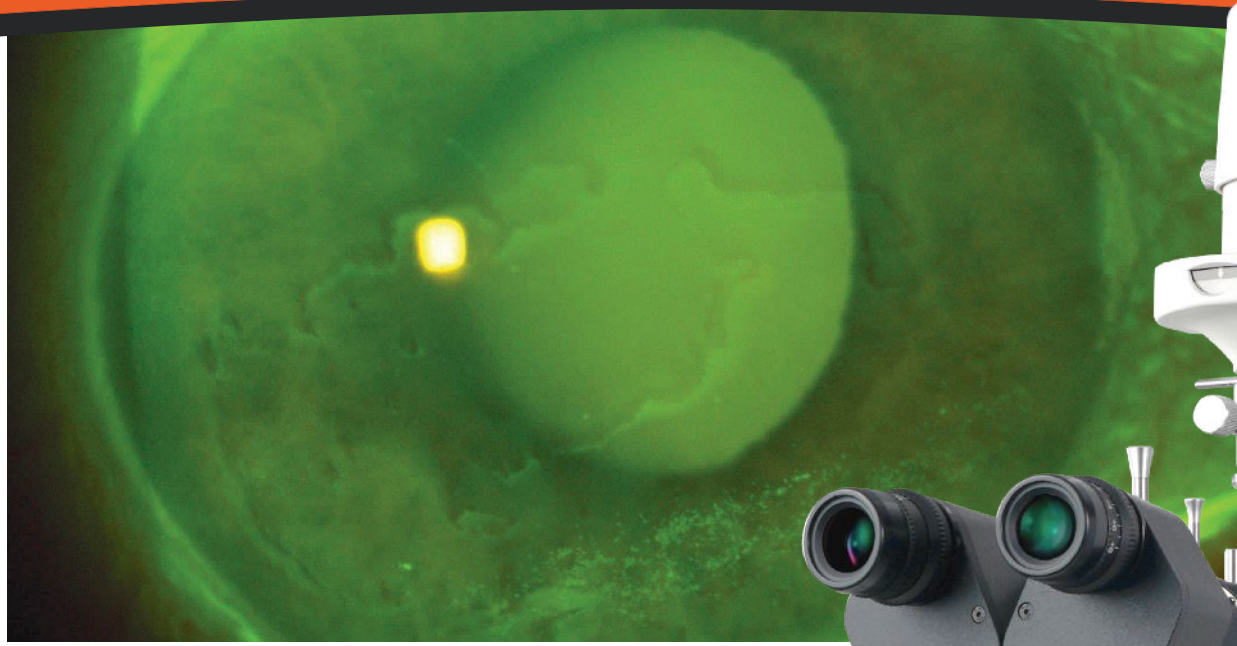

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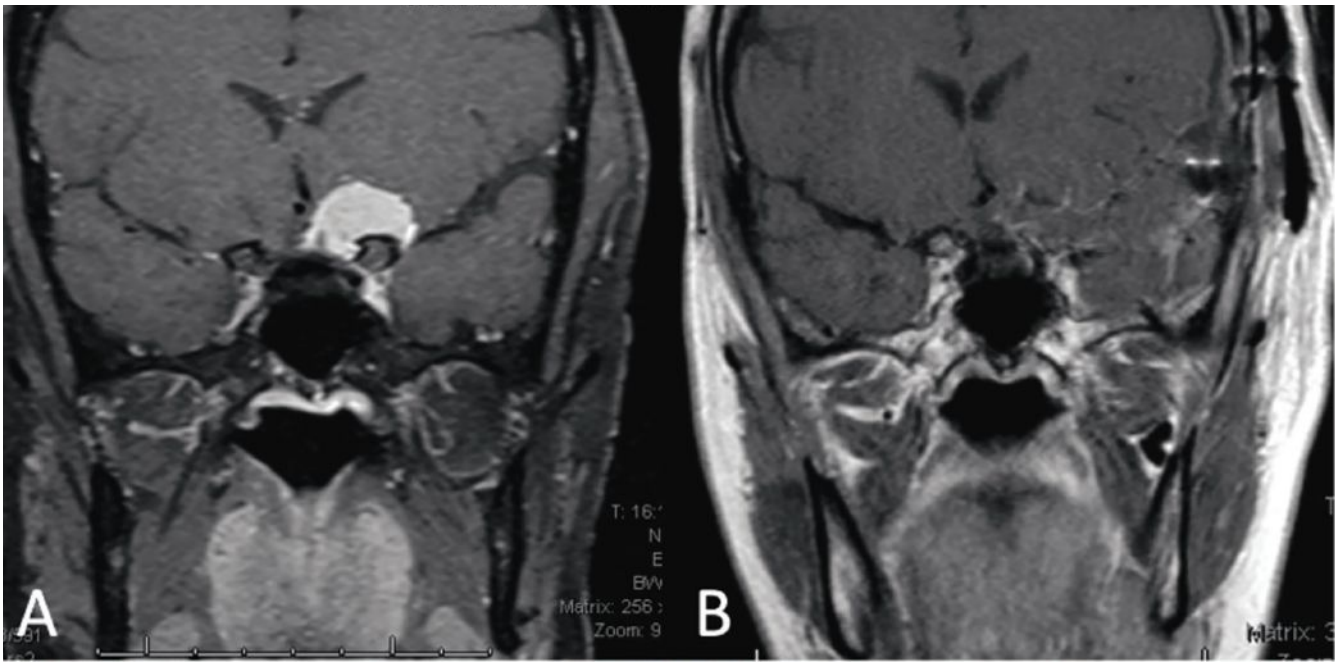

Fig 2. (A) Coronal MRI depicts an approximately 2cm paraclinoid meningioma exerting its mass effect on the left half of the optic chiasm and the prechiasmic optic nerve. (B) Coronal MRI taken two weeks post-craniotomy and resection of the meningioma.

with decreased vision, pain associated with eye movement, a relative APD, dyschromatopsia and a visual field defect.[2] Although the most prevalent visual field defect seen in optic neuritis is diffuse depression with central or cecocentral scotomas, there have been documented cases of optic neuritis initially presenting with altitudinal defects; interestingly, this includes some that were secondary to neuromyelitis optica.[2] When suspecting optic neuritis, an MRI of the brain and orbits with gadolinium contrast is warranted.

When a patient presents with visual field defects but no identifiable ocular cause, compressive lesions must be ruled out. These lesions may be secondary to numerous etiologies, and they are associated with various signs and symptoms. Compression of fibers along the visual pathway can occur due to direct pressure from a mass lesion or indirect compression caused by inflammation or hemorrhage as a consequence of the lesion. Depending on the lesion's location, the patient can experience several non-specific symptoms such as headache, a relative APD, peripheral neuropathies and difficulty performing daily tasks.[3] With a unilateral inferior visual field defect, our patient raises suspicion for a lesion along the superior optic nerve between the globe and the optic chiasm. Common lesions to compress the intraorbital and intracranial optic nerve include, but are not limited to, cavernous hemangiomas, meningiomas and optic nerve gliomas. A prompt MRI with gadolinium contrast is critical to rule out these types of lesions, particularly with acute symptoms.

> **[Meningiomas] often manifest with symptoms such as headaches, neurological deficits and seizures with insidious onset due to their slow-growing nature.**

Further Imaging

Given our patient's clinical vignette, neuroimaging was indicated to assess for optic neuritis or a compressive lesion. MRI of the brain and orbits with and without contrast revealed a ~2cm round mass arising from the left anterior clinoid process and extending medially over the tuberculum sella, exerting its mass effect on the left half of the optic chiasm and prechiasmatic segment of the left optic nerve. The lesion was reported to be consistent with a paraclinoid meningioma.

Given evidence of optic nerve compression, the patient was seen emergently by neurosurgery. The following day, she underwent a left pterional craniotomy and resection of the tumor without complication. Pathology confirmed the mass to be a grade I meningioma based on WHO guidelines. At the patient's two-week follow-up, she reported improvement of vision in her left eye with residual headaches but no other symptoms. She had resumed normal daily activities.

The Culprit

Meningiomas are the most common primary intraorbital tumor. While usually classified as benign, these tumors can still lead to serious consequences due to their effect on other structures of the brain. They often manifest with symptoms such as headaches, neurological deficits and seizures with insidious onset due to their slow-growing nature.[4]

Clinoid meningioma arises from the dural tissue surrounding the anterior clinoid process. It has been reported

that about 60% of clinoid meningiomas induce visual symptoms by encroaching on areas such as the optic canal due to their close proximity. These tumors can disrupt vision through these three mechanisms: direct compression of the optic nerve, small-vessel compromise leading to ischemia, and demyelination.[5]

The gold standard for management of these lesions is total resection, aiming to decompress the optic nerve, relieve ischemia and prevent recurrences. Although complete resection is not always feasible, new microsurgical techniques have increased total resection rates to just under 90%, up from the previous rate of 55%. Despite a low recurrence rate, recurrent or residual lesions tend to be more aggressive and are managed with Gamma Knife radiosurgery due to higher risk associated with repeat resection.[5]

Clinical Pearls

This case emphasizes several important points. First, it may be helpful to differentiate between positive and negative visual phenomena when patients report "seeing spots." A positive visual phenomenon (seeing lights or images) will typically result from disruption of visual input such as migraine auras, retinal traction causing flashes or, in some cases, even hallucinations. Negative visual phenomena (seeing dark areas), on the other hand, are more commonly caused by lesions or ischemic insult along the visual pathway inhibiting visual signals to the brain.[6] In such cases, an in-office visual field test is essential, as it can help localize a suspected lesion.

This case also illustrates the difficulty some patients may face in describing certain visual phenomena and the importance of having them describe their symptoms in detail. Even a prominent inferior altitudinal defect might be perceived by the patient as their vision "being off" until proper testing and history are completed. As primary eyecare providers, our exam chair may be the initial setting where these symptoms come to light. Requesting additional details and thorough testing of pupils, color perception and visual fields can play a vital role in saving a patient's vision—or possibly even their life. ■

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ABOUT THE AUTHOR

Dr. Calvert earned his Doctor of Optometry degree from The Ohio State University College of Optometry and completed a residency in ocular disease at Bascom Palmer Eye Institute in Miami, FL. He recently launched his private practice career in Bowling Green, KY.

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BY JAMES L. FANELLI, OD

Pituitary Problems

A tumor of this brain structure made identifying glaucomatous damage more complicated.

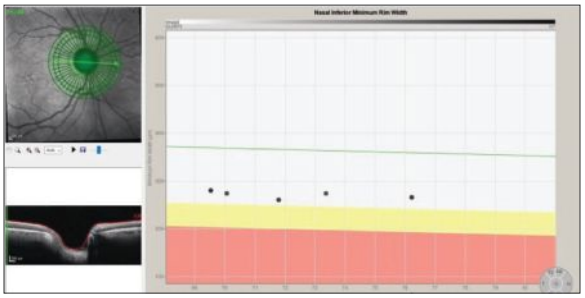

Fig. 1. The progression analysis of the right neuroretinal rim demonstrates no significant deterioration.

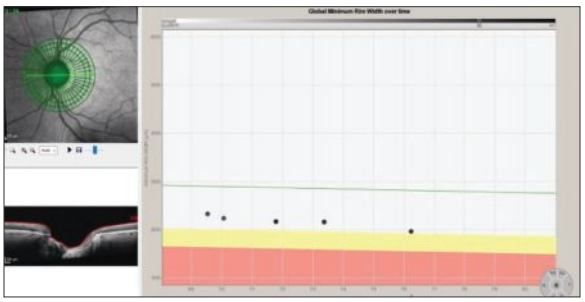

Fig. 2. A slight decrease in the neuroretinal rim thickness in the left eye, especially with the most recent scan.

In this second of two columns focused on identifying structural changes related to progressive disease, there is a neuro-ophthalmic twist.

Case

This 74-year-old Caucasian man was last seen by me in May 2024 as a follow-up to his normal tension glaucoma with a couple of interesting twists in his health since we first met in 2017. Back then, he initially presented to me as a new patient carrying a diagnosis of normal tension glaucoma. At this first visit, he was taking latanoprost h.s. OU and had been so for approximately three years.

At that visit, visual acuities were 20/25- OU through hyperopic astigmatic correction. Pupils were ERRLA with no afferent pupillary defect. Pachymetry readings were 574µm OD and 581µm OS. Applanation tensions were 18mm Hg and 16mm Hg OD and OS, respectively. The anterior segments were essentially normal OU, and the patient was pseudophakic with clear centered intraocular lenses OU with clear posterior capsules. Gonioscopy at that visit demonstrated grade 4 open angles with moderate trabecular pigmentation OU.

The cup-to-disc ratio as seen through dilated pupils was judged to be 0.7x0.7 OD and 0.65x0.65 OS with slightly large optic discs. The retinal vascular picture as well as the macular evaluations were normal, given his age with no peripheral retinal problems noted.

Since the patient was establishing care with me, I did not make any changes to his medication regimen, as none were needed and he was scheduled for regular follow-ups. Subsequent visits demonstrated stable OCT scans and stable visual field studies with minimal defects OU on 24-2 strategy.

Figures 1 and *2* show the progression analyses of the right and left Bruch's membrane opening-minimum rim width (BMO-MRW) indices over the past seven years, respectively. Note there was no change whatsoever in the right eye (*Figure 1*) and only a slight, gradual decline in the left eye (*Figure 2*). During this time interval, he did present with a disc hemorrhage in the right eye, but there was clearly no evidence of neuroretinal rim loss in the right eye following resolution of the disc hemorrhage.

A close examination of *Figure 2* shows a gap in OCT scans prior to the most recent scan in May 2024—he was last seen by me, prior to the most recent visit, in December 2022. There was a two-fold reason for this interval: the first had to do with COVID shutdowns, with many people not seeking care during that time. The other, however, was a more

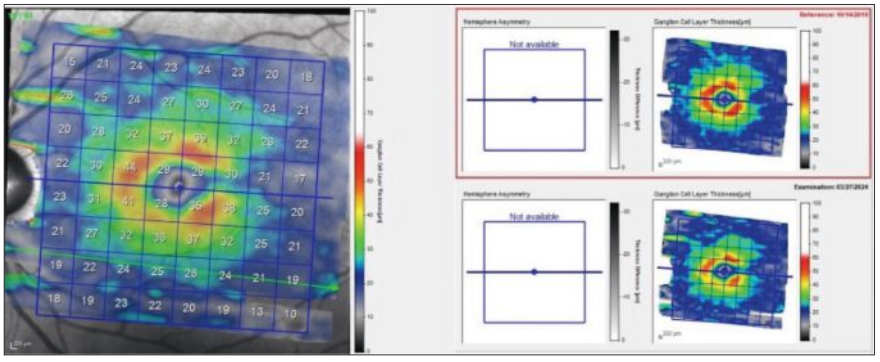

Fig. 3. The change in retinal ganglion cell thickness from baseline to most recent scan. Note loss of retinal GCL thickness over this time period.

About Dr. Fanelli **Dr. Fanelli** is the founder and director of the Cape Fear Eye Institute in Wilmington, NC. He is chairman of the EyeSki Optometric Conference and the CE in Italy/Europe Conference. He is an adjunct faculty member of PCO, Western U. and UAB School of Optometry. He is on advisory boards for Heidelberg Engineering and Glaukos.

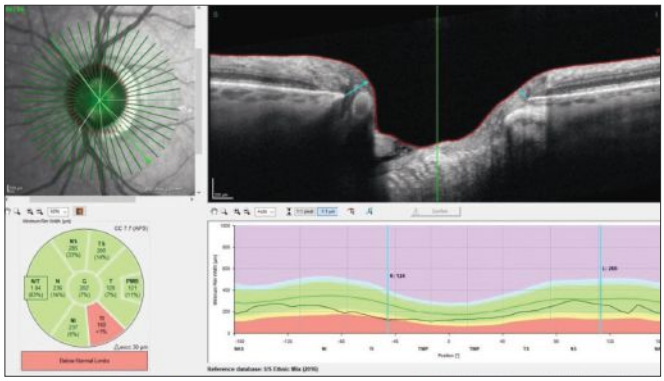

Fig. 4. The baseline neuro OCT of the left eye shows a rather normal BMO-MRW, except for the inferotemporal sector, which is consistent with the glaucomatous defect seen at the initial visit.

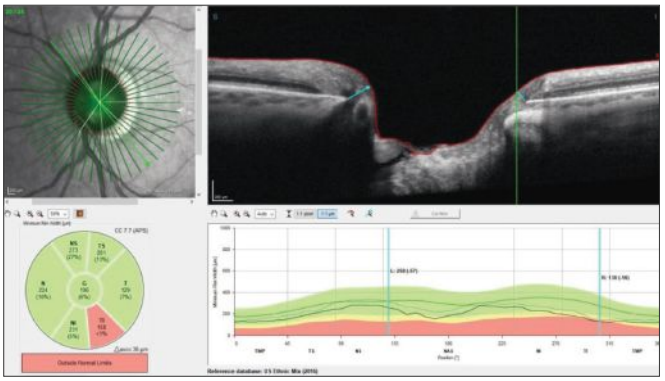

Fig. 5. The changes to the BMO-MRW readings in the left eye from baseline until the most recent visit. Notice the global reduction in neuroretinal rim thickness.

ominous issue with persistent headaches of several months' duration in the early part of 2022. Ultimately, the patient was evaluated with MR imaging that revealed a pituitary adenoma skewed more anatomically to the left side, which also invaded the cavernous sinus on that side. Review of his medical records demonstrated no efferent cranial neuropathy or evidence of cavernous sinus syndrome, and the patient underwent uneventful neurosurgery to remove as much of the adenoma as was possible.

Ultimately he returned to my care, at the request of the neurosurgeon, in May 2024. At this visit, repeat OCT scans were obtained. As you can see in *Figure 3*, there is a decline in the retinal ganglion cell layer (GCL) thickness at the most recent visit compared with the baseline scan in 2019. This is consistent with glaucoma, though the question remains as to whether the anteriorly displaced pituitary adenoma which also invaded the left cavernous sinus may have played a role in the GCL thinning, as well as the last BMO-MRW scan OS showing neuroretinal rim thinning.

In any event, a neuro profile scan was also obtained in addition to the standard glaucoma scans performed at the last visit. The purpose of this scan was to help dissect out any changes in the neuroretinal rim that may occur in the future that are not related to glaucoma but rather consistent with the pituitary adenoma causing axonal damage. Of course, interval MR imaging is part and parcel to his continued care.

Note the neuro profile OCT scan of the left eye (*Figure 4*). In particular, pay attention to the segmentation of the papillomacular bundle separate from the global temporal rim sector. This segmentation is very sensitive to showing axonal damage not related to glaucoma, though in advanced glaucoma, this too, can ultimately be affected.

Figure 5 shows the BMO-MRW scan of the left eye from baseline in 2019 through the most recent visit occurring in 2024. Note the global reduction in neuroretinal rim thickness throughout all sectors of the optic nerve except for the temporal sector. Most of this change occurred during the time interval when he was absent from ophthalmic oversight.

Discussion

Could the changes seen in *Figure 5* be related to his glaucoma potentially not being adequately treated during the hiatus from care? This is certainly a possibility. Could the changes seen in *Figure 4* conversely be related to the pituitary adenoma? That, too, is possible, and I suspect that may partially be involved, but this is purely speculation on my part at this time. It is important to note that during this same time frame, there was absolutely no change to the right neuroretinal rim.

In moving forward with management of this patient, he will be scheduled for OCT imaging. When going for imaging, he will receive the following scans: peripoptic retinal nerve fiber layer scans, GCL scans, BMO-MRW glaucoma scans and additionally, the neuro profile scans. Note in *Figure 6* the symmetry and precision of the standard BMO-MRW scan on the left and the neuro scan on the right. The resolution and image registration of the Spectralis software should make dissecting out future glaucomatous vs. non-glaucomatous change easier to see, ultimately lending to better patient care. ■

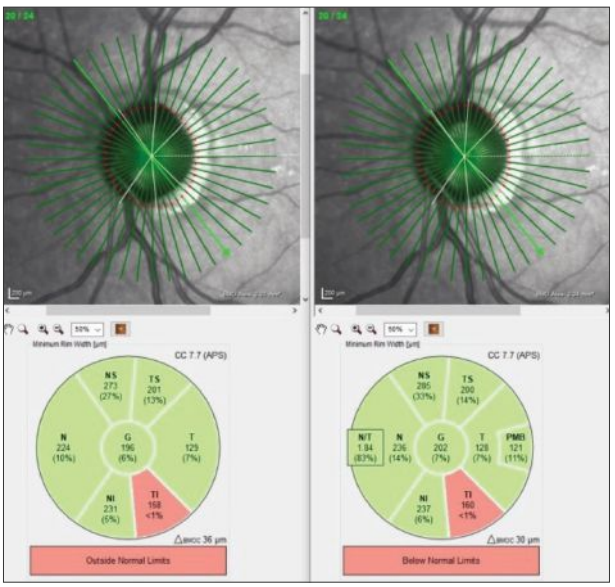

Fig. 6. The BMO-MRW scans using glaucoma software on the left and the neuro on the right. Note the Garway-Heath sectors are almost identical between the differing scans.

Atypical YAG Laser Capsulotomy Cases

Learn how this procedure can be used in complex scenarios.

BY PAUL M. BARNEY, OD
ANCHORAGE, AK

YAG laser capsulotomy is becoming a bigger part of optometric care as more states advance optometric scope of practice. Studies have shown, when doctors of optometry provide these procedures, they are delivering safe and effective outcomes, as well as increasing access to this valued care.[1] Most cases involve a single vision intraocular lens (IOL) well-positioned within the capsular bag. This article addresses cases that involve specialty IOLs, malpositioned IOLs and atypical capsular fibrosis and contraction.

Prep

Careful evaluation of the IOL type and its position, the integrity of the lens capsule and the degree of capsular opacification is necessary before making the decision to perform a capsulotomy. These findings may influence the techniques used to perform the capsulotomy, and a meticulous evaluation prior to the capsulotomy will help ensure optimal results are achieved.

With some specialty IOLs, subtle capsular opacification will often create visual symptoms and YAG laser capsulotomy may need to be considered sooner than with single vision IOLs. Diffractive multifocal and some extended depth-of-focus (EDOF) IOLs create more reflections than single vision IOLs. These reflections may be seen by the patient as dysphotopsia but are also seen by the physician during YAG laser capsulotomy. The additional reflections can make it more difficult to visualize the posterior capsule, requiring extra caution when performing the capsulotomy to prevent IOL pits. Yellow-tinted IOLs and those that have excessive lens glistenings can also create similar difficulty in lens capsule visualization.

Procedural Technique

Placing the first laser shots in the peripheral capsule superiorly is a prudent approach. If lens pits do occur, the pits will be peripheral to the line of sight. Lens pits from the laser rarely cause visual problems, but a practitioner should try to avoid lens pits near the line of sight. The use of a laser capsulotomy lens will also help stabilize the eye and lids, give better capsule visualization, and allow higher illumination use without patient photophobia and blepharospasm interfering with performing the capsulotomy. Once a few successful shots have been placed and a capsular opening is created, the capsule becomes easier to visualize despite IOL reflections, tints and glistenings.

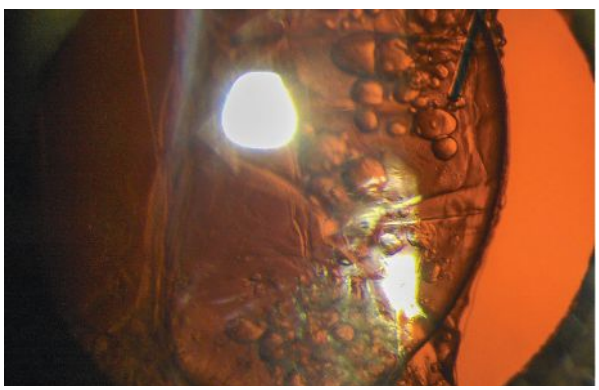

Fig. 1. The IOL was successfully placed within the capsular bag in a patient who had "loose zonules."

IOL position also may play a role in capsulotomy technique and should be carefully evaluated prior to YAG laser capsulotomy. Ideally, the IOL optic and haptics are placed in the capsular bag at the time of cataract surgery. With IOL placement in the capsular bag, significant displacement of the IOL is not common. Mild IOL displacement that has the optic and haptics clearly in the capsular bag should not be of concern when performing a YAG laser capsulotomy.

If the IOL is significantly decentered, careful evaluation should determine the cause of the displacement. If a capsular break or radial capsular tear occurred at the time of surgery, it may be difficult for the surgeon to place the haptics in the capsular bag, and the IOL may be fixated in the ciliary sulcus. Sulcus-fixated IOLs are less stable than IOLs fixated within the capsular bag and have a greater incidence of dislocating. Dislocation of sulcus-fixated IOLs is usually very gradual, but the energy released and capsular disruption that occurs with a YAG laser capsulotomy can cause a rapid dislocation of the IOL.

Sulcus-fixated IOLs are not a contraindication for YAG laser capsulotomy, but, because sulcus-fixated IOLs are less stable, IOL dislocation is more

About Dr. Lighthizer

Dr. Lighthizer is the dean and director of continuing education and chief of specialty care clinics at the NSU Oklahoma College of Optometry. He is a founding member and immediate past president of the Intrepid Eye Society. Dr. Lighthizer's full disclosure list can be found in the online version of this article at www.reviewofoptometry.com.

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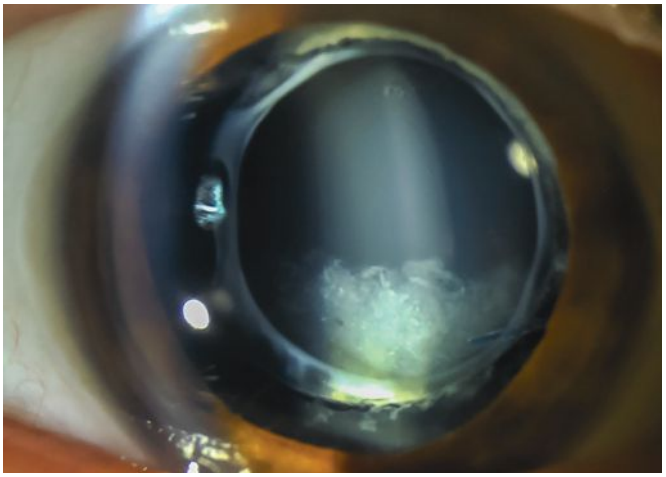

Fig. 2. Opaque, turbid fluid between the IOL and the posterior capsule is present in late capsular bag distention syndrome.

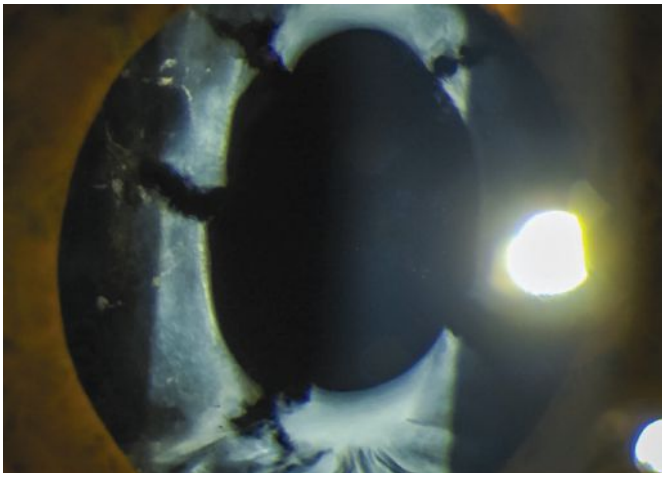

Fig. 3. Radial slits in the anterior capsule will stop the contraction from progressing and widen the diameter of the capsular opening.

common. Higher laser energy levels used during capsulotomy increase the risk for IOL dislocation.

IOL decentration can also occur when the IOL is fixated within the capsular bag and there is zonular compromise causing a dislocation of the IOL-capsular complex. With significant zonular compromise, pseudophacodonesis may also be present. Depending on the degree of decentration and pseudophacodonesis, YAG laser capsulotomy may be contraindicated until the IOL and capsule can be surgically stabilized.

The patient shown in *Figure 1* had "loose zonules" noted by the surgeon at the time of surgery, but the IOL was successfully placed within the capsular bag. During follow-up for the cataract surgery, the IOL was found to be well-centered and stable. The patient presented two years later with posterior capsular opacification (PCO), a decentered IOL, zonular dehiscence and pseudophacodonesis.

Due to the degree of decentration and pseudophacodonesis, YAG laser capsulotomy was delayed until the IOL and capsule could be surgically stabilized. The IOL was surgically repositioned, and the haptics were fixated to the sclera. After the patient had recovered from the IOL repositioning, a YAG laser capsulotomy was safely and successfully performed.

Other Considerations

Capsular distention and anterior capsular contraction (phimosis) are conditions that also require special consideration when laser capsulotomy is necessary. Capsular bag distention syndrome occurs when there is accumulation of fluid between the IOL and posterior capsule. This can occur early after cataract surgery, within days or weeks, or can occur late, months to years after cataract surgery.

Early capsular bag distention syndrome is associated with incomplete removal of viscoelastic material during cataract surgery. It frequently results in an anterior displacement of the IOL with a myopic refractive shift, shallowing of the anterior chamber, and elevation of the IOP. Treatment of early capsular bag distention syndrome includes surgical removal of the viscoelastic material vs. YAG laser capsulotomy. Surgical removal of the viscoelastic is usually the preferred treatment if there has been a significant anterior displacement of the IOL, since it will also allow for repositioning. If there is no IOL displacement, YAG laser capsulotomy will allow release of the accumulated fluid and alleviate the distention.

Late capsular bag distention syndrome occurs when lens epithelial cells produce collagen and extracellular material, which accumulates as an opaque, turbid fluid between the IOL and the posterior capsule (*Figure 2*). The turbidity of the accumulated fluid causes light scatter, producing symptoms of glare and decreased vision. It's not uncommon for the posterior capsule to be relatively clear despite symptoms consistent with PCO. Treatment of late capsular bag distention syndrome is YAG laser capsulotomy.

Opening the posterior capsule in late capsular bag distention syndrome releases the turbid fluid into the vitreous where it will be absorbed. Since the fluid is opaque, it can make visualization of the posterior capsule difficult while performing YAG laser capsulotomy. Making the initial capsular opening in the inferior capsule will allow gravity to pull the fluid into the inferior vitreous allowing for better visualization of the posterior capsule. It may also be necessary to wait a minute or two after the initial opening is made, to allow the fluid to drain into the inferior vitreous. Once released, the fluid can sometimes cause mild inflammation and an increase in IOP, consequently it is prudent to place patients with capsular distention syndrome on 1% prednisolone acetate QID for one to two weeks following YAG laser capsulotomy.

Phimosis occurs when there is fibrosis of the anterior capsule and contraction of the capsulorhexis. Although phimosis usually occurs slowly,

it can occur rapidly, within weeks of cataract surgery, especially in cases with excessive postoperative inflammation. Treatment for phimosis is YAG laser anterior capsulotomy and should ideally be performed before the contraction encroaches into the line of sight.

The treatment strategy is to make radial slits in the anterior capsule to break the contraction and widen the diameter of the capsulorhexis. If the fibrosis has not encroached into the line of sight, completely amputating the anterior capsule will not be necessary. Amputating pieces of the anterior capsule will result in those pieces dropping into the anterior chamber angle, whereas simply making radial slits in the anterior capsule will not leave capsular remnants in the anterior chamber angle.

Many physicians use a posterior offset when doing a YAG laser posterior capsulotomy. A posterior offset when doing an anterior capsulotomy will result in laser pits in the IOL. If you prefer to use a laser offset when doing a capsulotomy, it is important to change to an anterior offset before performing an anterior capsulotomy.

The anterior capsule is anatomically thicker than the posterior capsule and frequently requires more laser energy to break through the capsule. My typical starting laser settings for a YAG laser anterior capsulotomy are a 100µm to 200µm anterior offset and 2.5mJ to 3.0mJ. I place four to six radial slits in the anterior capsule, which will stop the contraction from progressing and will widen the diameter of the anterior capsular opening (*Figure 3*).

These simple strategies on atypical capsulotomy cases will make the procedure easier and will ensure better outcomes. ■

1. Lighthizer N, Johnson S, Holthaus J, et al. Nd:YAG laser capsulotomy: efficacy and outcomes performed by optometrists. Optom Vis Sci. 2023;100(10):665-9.

ABOUT THE AUTHOR

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BY RAMI ABOUMOURAD, OD

RETINA QUIZ

A Bloody Mess

This clinical diagnosis is based on characteristic fundus features.

A 92-year-old Hispanic male presented to our institute for acute vision loss and new floaters for one week in the left eye (OS). Past ocular history included cataract surgery OS in 2008 and strabismic amblyopia in the right eye (OD) since childhood. Medical history included benign prostatic hyperplasia, hypercholesterolemia and hypothyroidism, all of which were controlled medically.

Entering visual acuity (VA) was counting fingers OD and 20/150 OS with pinhole improvement to 20/100. Intraocular pressures were 16mm Hg OD and 14mm Hg OS. His extraocular motilities were full and his pupils were equally round and reactive without a relative afferent pupillary defect. Slit lamp exam revealed a cataract OD and well-positioned intraocular lens OS with posterior capsular opacification. Fundus imaging is available for review.

Take the Retina Quiz

1. Optical coherence tomography (OCT) of the left eye shows that the hemorrhage is located in what space?

a. Vitreous cavity.
b. Sub-internal limiting membrane.
c. Subretinal.
d. Subretinal pigment epithelium.

2. What is the most likely diagnosis?

a. Choroidal melanoma.
b. Peripheral exudative hemorrhagic chorioretinopathy.
c. Polypoidal choroidal vasculopathy.
d. Ruptured retinal arterial microaneurysm.

3. *Which of the following is FALSE regarding this patient's disease?*

a. It is often asymptomatic.
b. Lesions often present between the posterior pole and equator.
c. It is often bilateral.
d. The mean age of patients is about 80 years.

4. Which of the following is TRUE regarding management of this disease?

a. Intravitreal anti-VEGF injections are used when lesions are progressive and threaten the macula.
b. Observation is elected when lesions involve the periphery and patients are asymptomatic.
c. Vitrectomy is a reasonable option for non-clearing vitreous hemorrhages.
d. All of the above are true.

5. What is the general prognosis for this disease?

a. Prognosis is excellent, as all cases resolve without permanent visual deficits.
b. Prognosis is overall good, as many cases spontaneously regress in absence of treatment.
c. Prognosis is fair, as most cases will progress but respond to treatment.
d. Prognosis is guarded, as most cases progress despite treatment.

Diagnosis

Fundus examination disclosed a vitreous hemorrhage (VH) OD and bilateral peripheral hemorrhagic lesions with extensive subretinal hemorrhage OS>OD involving

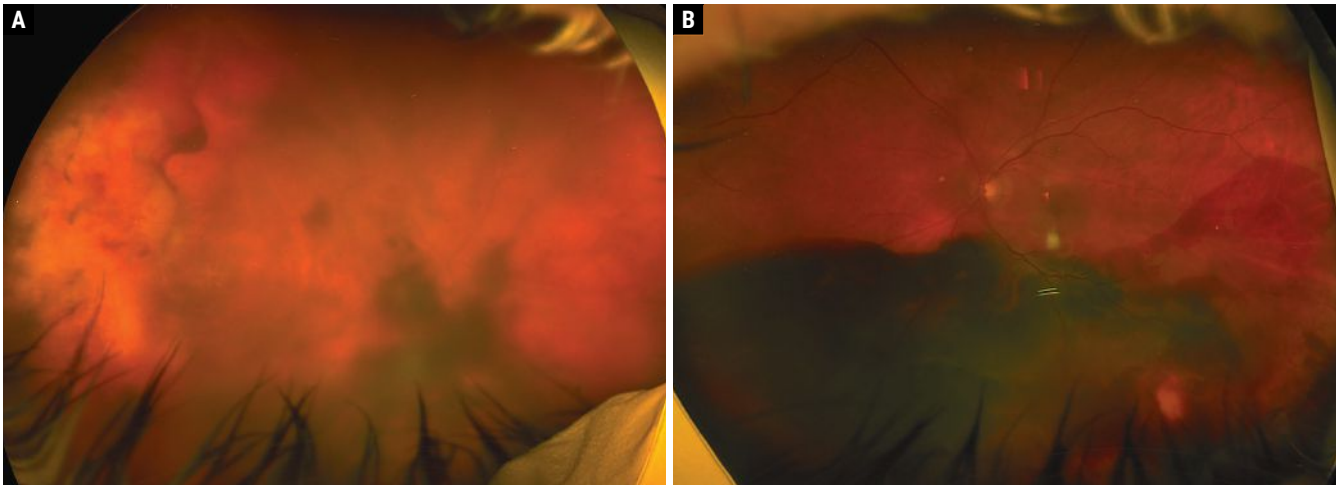

Fig. 1. Optos widefield fundus photos of the right eye (A) and left eye (B).

About the author

Dr. Aboumourad currently practices at Bascom Palmer Eye Institute in Miami. He has no financial disclosures.

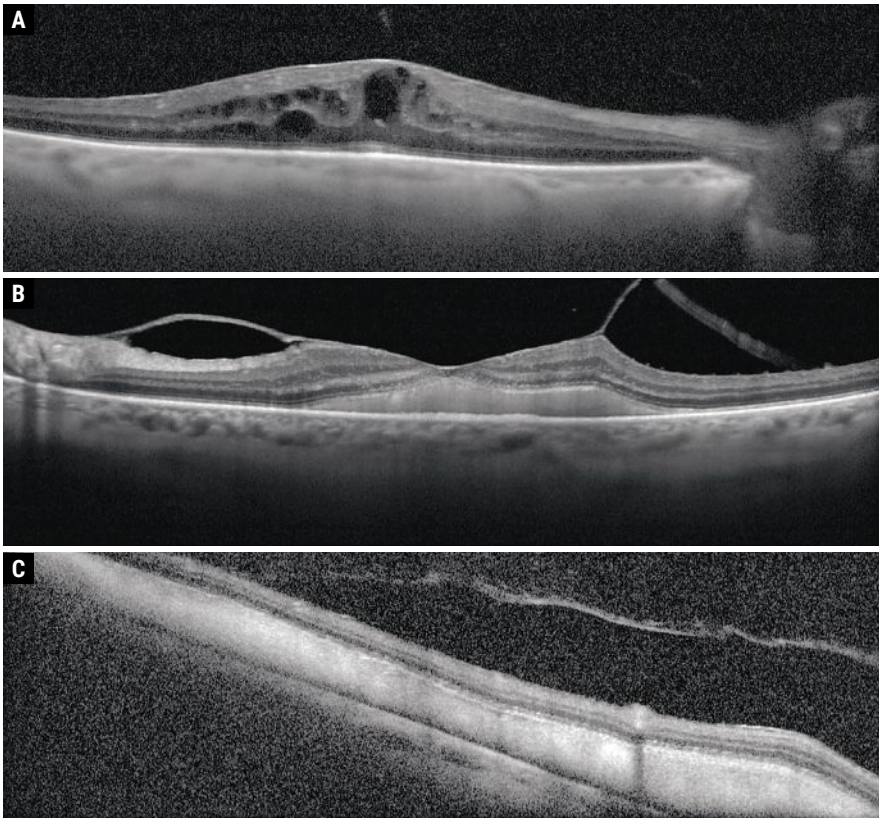

Fig. 2. Macular OCT of OD (A) and OS (B), as well as eccentric OCT over inferior macula OS (C).

the macula OU (*Figure 1A and B*). Macular OCT showed an epiretinal membrane with intraretinal fluid OD (*Figure 2A*) and vitreomacular traction with heterogeneous subretinal hyperreflective material involving the fovea extending inferiorly throughout the macula OS (*Figure 2B and C*). B-scan ultrasonography was obtained to rule out underlying choroidal etiology and further demonstrated the extent of subretinal hemorrhage OU. A diagnosis of peripheral exudative hemorrhagic chorioretinopathy was made, and the patient received intravitreal bevacizumab OU given foveal involvement.

Discussion

Peripheral exudative hemorrhagic chorioretinopathy (PEHCR) is a rare, bilateral, peripheral exudative-hemorrhagic retinal degeneration that typically occurs between the equatorial fundus and ora serrata.[1,2] Up to 100% of patients are reported to be Caucasian and 67% to 69% female, with a mean age at presentation of 77 to 80 years old (range 57 to 97).[1–4] Interestingly, only about half of patients are symptomatic and only 20% have a reduction in VA; there is likely underrepresentation of the disease entity due to initial extrafoveal involvement during the acute phase.[1,4,5]

Symptoms are often due to extension of the peripheral hemorrhage into/toward the macula and/or breakthrough hemorrhage into the vitreous cavity.[2,3] The PEHCR lesion is found in the temporal fundus in 77% of eyes, spans one to two quadrants in 92% of eyes and is located between the equator and ora serrata in 89% of eyes.[4] More specifically, lesions are most frequently present inferotemporally (56%), followed by superotemporally (40%), superonasally (24%) and inferonasally (20%).[3]

PEHCR can be categorized as hemorrhagic (63%), exudative (6%) or exudative-hemorrhagic (31%).[3] Isolated exudation appears as yellow-white material, and the combined exudative-hemorrhagic form has a more reddish orange-brown coloration as the lipid mixes with the blood.[3] Subretinal hemorrhage may appear heterogeneously bright red to dark red (sometimes almost black, depending on thickness of blood accumulation) with poorly demarcated edges.[3] In contrast, subretinal pigment epithelial (RPE) hemorrhages tend to appear more uniformly dark red-to-brown/gray/black with larger dome-shaped elevations and more well-demarcated margins.[3,5] One study has reported VH was present in 7% of affected eyes.[4]

PEHCR is a clinical diagnosis based on characteristic fundus features. Fluorescein angiography (FA) is of little diagnostic utility in this disease due to blockage from overlying subretinal and sub-RPE hemorrhage as well as secondary RPE hyperplasia.[1,5] However, indocyanine green angiography (ICGA) may have more use locating the neovascular lesion, which is often near the border of hemorrhage.[1] PEHCR is thought to be on the spectrum of age-related macular degeneration (AMD) and polypoidal choroidal vasculopathy (PCV); in particular, the exudative lesion in PEHCR resembles polyps seen in PCV on ICGA.[2,5]

When vitreous hemorrhage is present, B-scan ultrasonography can demarcate the area of involvement and better characterize the lesion.[3-5] Importantly, B-scan features of PECHR include a retraction cleft, as well as greater internal reflectivity, greater echogenicity and heterogeneity, and absence of mushroom configuration as compared with uveal melanoma.[4]

The differential diagnosis includes choroidal nevus, choroidal hemangioma, choroidal/ciliochoroidal melanoma, choroidal/ciliochoroidal detachment, PCV, retinal arterial microaneurysm and retinal detachment. Of note, uveal melanoma is the most significant differential diagnosis and the most frequent presumptive diagnosis that these patients are referred to a specialist with; furthermore, PEHCR is the second-most common pseudomelanoma following choroidal

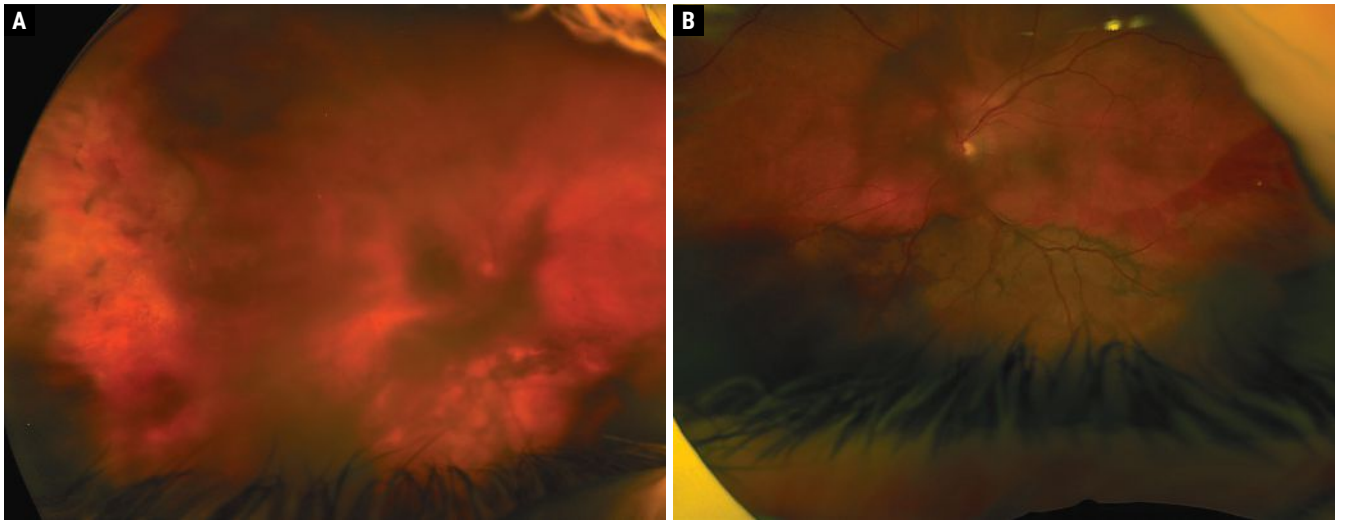

Fig. 3. One-month follow-up Optos fundus photos of the right eye (A) and left eye (B).

nevus.[1,2,4] It is critical to distinguish between PEHCR and uveal melanoma, as a timely and accurate diagnosis can avoid unnecessary radiotherapy and/or enucleation.

Management and Prognosis

To date, there are no randomized trials investigating appropriate management of these patients. Prognosis is generally good when sparing the macula, as one study demonstrated in a retrospective series of 90 cases that 89% improved or remained stable with observation alone, and only 11% worsened.[4,6,7] Therefore, observation is a reasonable management option, though patients should be followed closely, as progressive hemorrhage and/or exudation may threaten both peripheral and central vision.[4,7] When it is macula-involving, intravitreal anti-VEGF injections are the mainstay of modern treatment for this disease; however, visual recovery may be limited based on extent and duration of hemorrhage or exudation.[2,4,7] Pars plana vitrectomy may be considered in patients with non-clearing VH.[4]

Our patient received intravitreal bevacizumab OU. At one-month follow-up, he demonstrated reduction in intraretinal fluid OD and subretinal hemorrhage OS with stable VA OU (*Figures 3 and 4*). He was recommended a second intravitreal bevacizumab injection OU at follow-up but declined due lack of subjective improvement experienced from the prior injection. The patient was recommended to maintain close observation but was ultimately lost to follow-up. ■

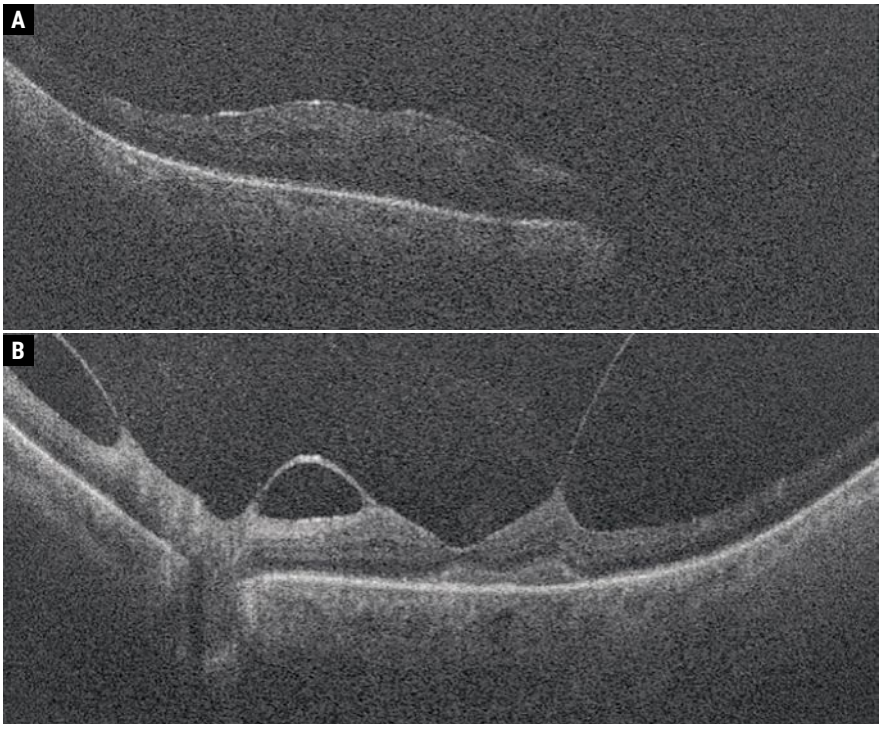

Fig. 4. Macular OCT scans of the right eye (A) and left eye (B).

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▶ DIAGNOSTIC EQUIPMENT

New Fundus Camera Automates Retinal Screenings

To help streamline retinal exams, the VX 610 non-mydriatic fundus camera from Visionix is equipped with automatic functions for alignment, focus and capture to enhance imaging accuracy and consistency, according to the company.

The camera uses technology referred to by Visionix as "cross-polarized light," which developers say enables high-quality imaging clarity without the need for pupil dilation. It offers a 45˚ field of view and a 90˚ mosaic function. The company website explains that, using AI, the system is trained to auto-detect early signs of 13 common retinal pathologies. Visionix notes that it correctly flags a positive result 93% of the time and negative results at a rate of 90.6%.

The VX 610 device employs a touch-screen interface and occupies a compact space, making it easy to integrate into various practice settings, says Visionix.

First At-home OCT Device Approved for Wet AMD

Patients with neovascular AMD are often subject to frequent office visits so that eyecare providers can monitor anatomical changes and signs of disease progression on OCT. The recent FDA approval of the first at-home OCT, Scanly from Notal Vision, lets doctors analyze scans remotely between scheduled visits while possibly also cutting back on patient travel time.

The company explains in a press release that the device captures spectral-domain OCT images in a 10˚x10˚ area centered on the point of fixation. Once scans are complete, AI software is used to segment and estimate the volume of hyporeflective spaces. All images are stored in the cloud for later analysis. There, physicians can review data and set eye-specific notification criteria (including a volume threshold for total retinal hyporeflective spaces).

Two pivotal trials involving more than 500 patients (mean age: 77) assessed the accuracy and user-friendliness of the home OCT device. Notal Vision reports that 97% of the total 5,426 scans performed by patients in the study eye were successful. The company further noted an adherence rate of 5.9 scans/week; on average, patients took 48 seconds to self-image.

To have a Scanly Home OCT shipped to a patient's home, they must first enroll in a company-run monitoring program.

Oculus VR Headset Now Offers Dual VF Testing

Earlier this year, Oculus introduced its Easyfield virtual reality (VR) headset for assessing patients' visual field (VF), color vision and stereopsis. The device uses standard automated perimetry (SAP) for VF testing; now, an optional update also gives it the capability to perform frequency doubling perimetry (FDP). Compared to SAP, FDP—which uses a series of flickering white and black bands—has been shown to evaluate the extent and pattern of VF loss with high precision and specificity. Particularly in glaucoma or ocular hypertensive patients, FDP may detect functional damage sooner.

"Practitioners can configure the Easyfield VR with one testing strategy, then upgrade to a dual configuration combining FDP and SAP as their needs or methods evolve," a press release explained. The headset can be used in a fully lit room, with no internet connection required.

▶ CONTACT LENSES

New Multifocal Accommodates More Presbyopes

If you're a fan of Coopervision's MyDay Multifocal, with its three distinct approaches for different levels of presbyopia, but wish you could have that in the more affordably priced Clariti line, you'll be pleased to hear that the company recently announced a new lens combining the best of both platforms. Called "Clariti 1-day Multifocal 3 Add," the lens's hallmark feature is its three add power designs: low (+0.75D to +1.25D), medium (+1.50D to +1.75D) and high (+2.00D to +2.50D), with a wider distance component in the low add lens, a sizable transition zone in the medium add and a spherical center-near correction in the high add lens. Clariti 1-day Multifocal 3 Add will replace the existing Clariti 1-day Multifocal, which only offered two add power options. Both lenses will remain in the lineup for a period of time, a spokesperson says.

The newer lens will also be offered in more sphere powers (-12.00D to +8.00D) than the older design, and the lens edge profile has been upgraded for improved stability and ease of fit, a press release explains. ■

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BY ANDREW S. GURWOOD, OD

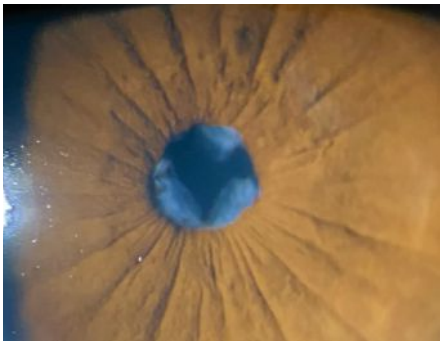
DIAGNOSTIC QUIZ

Film at 11

Slit lamp exam shows evidence of a potential media opacity. What could it be?

A 57-year-old African-American gentleman presented to the office for a routine diabetic eye exam. He had no complaints; his general practitioner asked him to obtain a funduscopic examination because he had systemic diabetes and hypertension. His systemic history was remarkable for well-controlled hypertension and type 2 diabetes. He denied allergies of any kind.

His best-corrected entering visual acuities were 20/30 OU at distance and near. His external exam was normal and there was no afferent pupil defect. The pertinent anterior segment finding discovered during the biomicroscopic exam is demonstrated in the photograph. Goldmann applanation tonometry measured 15mm Hg OU. The dilated fundus findings were normal peripherally and centrally with normal nerves and maculae.



A wispy membrane can be seen through the pupil on biomicroscopy.

Additional studies included inspection of the pupillary margin to ensure there was neither posterior synechiae (PS) nor iris neovascularization, detailed exam of the corneal endothelium for keratic precipitates or Krukenberg's spindles, gonioscopy to look for peripheral anterior iris synechiae (PAS) or angle dysgenesis, inspection of the iris stroma to ensure there was no evidence of inflammatory cells (Busacca nodules, Koeppe nodules) and photodocumentation.

What would be your diagnosis based on the findings presented? What's the likely prognosis? To find out, read the online version of this article at www.reviewofoptometry.com.

About Dr. Gurwood

Dr. Gurwood is a professor of clinical sciences at The Eye Institute of the Pennsylvania College of Optometry at Salus University. He is a co-chief of Primary Care Suite 3. He is attending medical staff in the department of ophthalmology at Albert Einstein Medical Center, Philadelphia. He has no financial interests to disclose.

Retina Quiz Answers—Q1: c, Q2: b, Q3: b, Q4: d, Q5: b

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HEAT

- Bruder® Microwave Activated Moist Heat Eye Compresses
- Eyedration™ Air Activated Moist Heat Eye Compress
- Eyeleve® Contact Lens Compress
- Samureye® Game Enhancing Mask

HYDRATION

- The Dry Eye Drink™ by Bruder®.

Available in AM and PM formulations and three flavors.

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- **AllerFocus™** In-office Allergy Testing
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xdemvy®
(lotilaner ophthalmic solution) 0.25%

This is not the actual product. It is a depiction of the product for dramatic purposes.

1 YEAR ANNIVERSARY

XDEMVY.
Easy on eyelids. Tough on mites.

Real XDEMVY results

Abby, real patient with *Demodex* blepharitis (DB). Results after 6 full weeks of treatment. Results may vary.

Learn more at XDEMVYHCP.com

44% and 55% of patients taking XDEMVY in SATURN-1 (N=209) and SATURN-2 (N=193), respectively, achieved a significant improvement in their eyelids (reduction of collarettes to no more than 2 collarettes per upper lid) at Day 43 vs 7% (N=204) and 12% (N=200) of patients taking vehicle ($P<0.01$ in each trial).*

INDICATIONS AND USAGE

XDEMVY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of *Demodex* blepharitis.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS

Risk of Contamination: Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with Contact Lenses: XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS: The most common adverse reaction with XDEMVY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

Please see next page for a Brief Summary of the full Prescribing Information.

*The safety and efficacy of XDEMVY for the treatment of DB were evaluated in a total of 833 patients (415 of whom received XDEMVY) in two 6-week, randomized, multicenter, double-masked, vehicle-controlled studies (SATURN-1 and SATURN-2). Patients were randomized to either XDEMVY or vehicle at a 1:1 ratio, dosed twice daily in each eye for 6 weeks. All patients enrolled were diagnosed with DB. The primary efficacy endpoint was defined as the proportion of patients with collarette reduction to no more than 2 collarettes per upper eyelid at Day 43.

Reference: XDEMVY [prescribing information]. Tarsus Pharmaceuticals, Inc; 2023.

tarsus