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47TH ANNUAL CONTACT LENS REPORT

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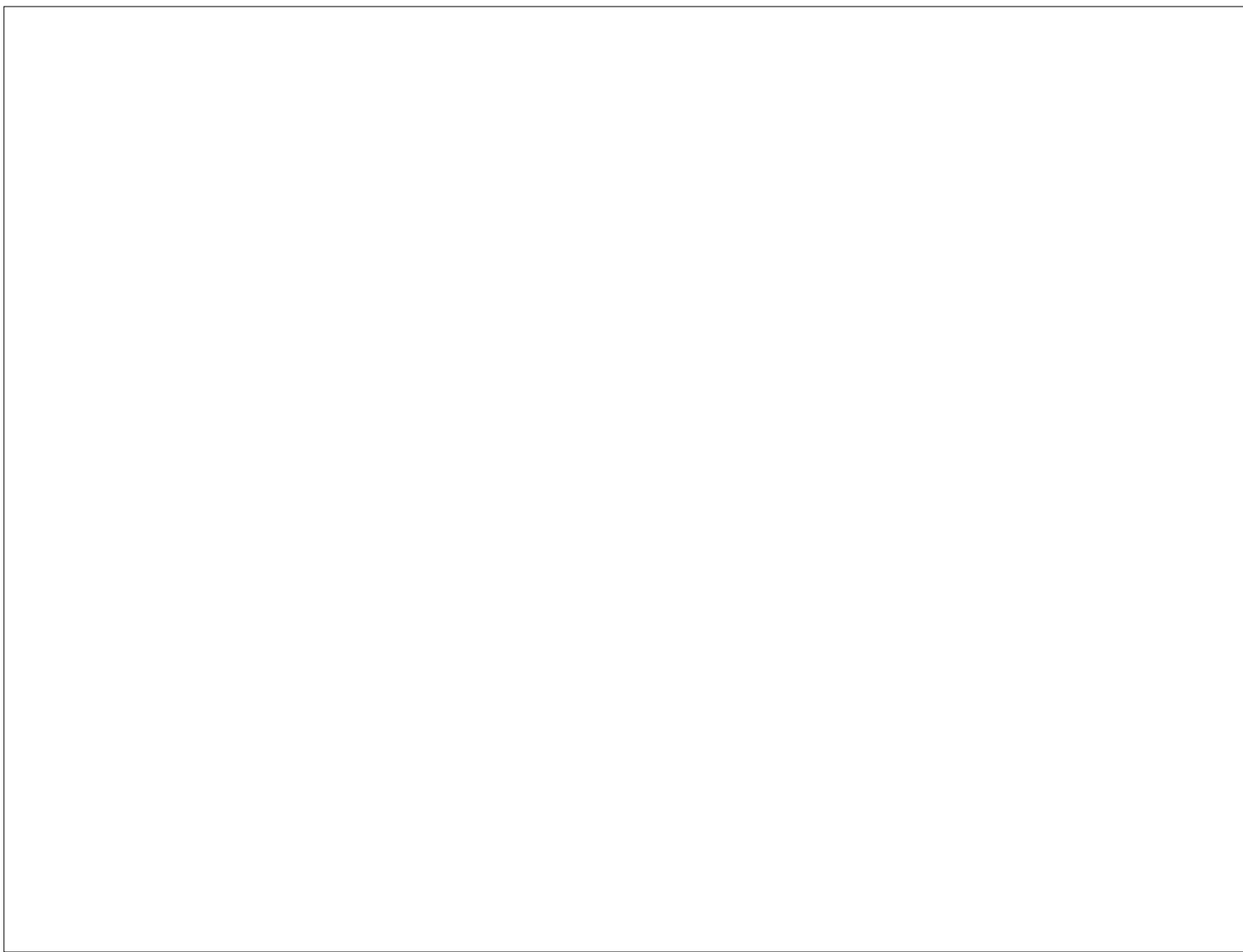
Understanding the **Influence of Water Content** on Contact Lenses



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47TH ANNUAL CONTACT LENS REPORT

Understanding the **Influence of Water Content** on Contact Lenses

A deep dive into how the dual goals of comfort and safety, once at odds, have largely been tackled. ***Page 42.***

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§Share of Requirements, Circana Household Panel, 2022 and 2023 Data.

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MICHAEL HOSTER
(610) 492-1028
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SENIOR MANAGER, STRATEGIC ACCOUNTS
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AOA: Laser Capsulotomies Performed by ODs Improves Wait Times, Satisfaction

Respondents reported that 89% of patients were able to be seen by their optometrist within a week after cataract surgery, while only 9% could see an ophthalmologist that soon.

The safety of optometrists performing certain in-office laser procedures is actively being demonstrated by the 10 states and counting that now authorize this privilege. The direct benefits of an expanded practice scope are also evident, as illustrated by the results of a new survey conducted by the American Optometric Association Research & Information Committee (RIC). The survey found that, in states where ODs can perform capsulotomies after cataract surgery, doctors and their patients reported convenience, shorter wait times and cost savings.

The AOA RIC administered the survey in April to doctors in the following 10 states where ODs can perform capsulotomies (years indicate when such laws were passed): Alaska (2017), Arkansas (2019), Colorado (2022), Indiana (2015), Kentucky (2011), Louisiana (2014), Mississippi (2021), Oklahoma (1998), Virginia (2022) and Wyoming (2021). Of 5,645 invited doctors, 406 responded to the survey.

"More than half of doctors of optometry who responded (56%) reported providing YAG laser capsulotomies in their practices and an overwhelming majority (89%) have the availability to perform the procedures within a week," the AOA reported recently in an article on the society's website. Conversely, respondents reported that only 9% of their patients were able to see an ophthalmologist within a week of cataract surgery.

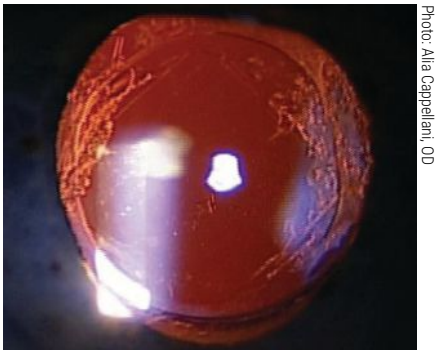

Photo: Alfa Cappellani, OD

Optometrists and their legislative advocates can expect to see these findings used against them in their ongoing scope expansion efforts. Currently, 10 states allow optometrists to perform YAG capsulotomies and other laser procedures.

The following data were also derived from the survey results, according to the AOA article:

- 35% of necessary YAG procedures performed by ODs are done in-office on the same day.
- 97% of responding ODs reported patient satisfaction with the convenience of having YAG performed in an optometrist's office.
- 95% reported satisfaction and value in the continuity of care resulting from YAG being performed by their optometrist.
- 46% reported patient satisfaction with direct cost savings when YAG procedures are performed in their local doctor's office.

The consensus is clear: When optometrists can perform YAG capsulotomies in-office, both ODs and their patients reap the benefits of convenience and efficiency. With an aging population and a growing shortage of ophthalmologists across the United States, allowing more optometrists to provide this necessary procedure to their patients may help reduce the looming burden on the healthcare system.

"The Health Resources and Services Administration predicts a shortage of more than 6,000 ophthalmologists by 2025," the AOA cited in the article from a recent report by its Health Policy Institute (HPI). "The number of doctors of optometry, meanwhile, will remain steady; the optometric workforce is projected to grow 1.4% annually—that's a rate greater than the US population."

These survey results add to the stack of evidence that optometrists are a viable solution to the increasing demand for post-cataract care. "Patients should not have to delay their eyecare procedures or incur unnecessary costs for multiple visits or added travel when doctors of optometry are fully trained to perform these procedures," the HPI report concluded. "Doctors of optometry are in a unique position to fill the gap for YAG surgery (and other ophthalmic procedures), as they are locally accessible to patients in 78% of all US counties and county-equivalents and 82% of counties or county-equivalents where most of the population is rural."

YAG procedures by doctors of optometry, after cataract surgery, better for patients' care and convenience. American Optometric Association. July 13, 2023. www.aoa.org/news/advocacy/state-advocacy/yag-procedures-by-doctors-of-optometry-after-cataract-surgery-better-for-patients-care-and-convenience-aoa-survey-says?sso=y. Accessed July 17, 2023.

Ohio Joins Fight For Optometric Lasers

The proposed bill would permit ODs to perform capsulotomy, trabeculoplasty and LPI, as well as remove certain lesions, give injections and prescribe additional pharmaceutical agents.

Optometrists in Ohio haven't seen an update to their scope of practice in more than 15 years. Hopeful to change this in the next two years, the state introduced SB 129 to the Senate Health Committee on June 28 just before the legislature recessed for the summer. The bill, sponsored by Senator Jerry Cirino, proposes to allow optometrists to perform the following procedures:

- Removal of benign lesions, cysts and skin tags (including incision and curettage of a chalazion or stye and removal and biopsy of skin lesions with low risk of malignancy, such as cysts and skin tags)
- Injections (excluding intravenous or intraocular)
- In-office noninvasive laser procedures (laser capsulotomy, trabeculoplasty and peripheral iridotomy)

The two-year bill also proposes to update pharmaceutical regulations to allow optometrists to treat any eye condition, as well as allow for the use of epinephrine injection in cases of anaphylactic shock. Additionally, it states that authority would be granted to the Vision Professionals Board to establish training and infection control standards.

State Budget Win

At the end of July, Ohio Governor Mike DeWine signed a new state budget into law granting a 15% increase in Medicaid reimbursement for vision and eyecare services. In addition to this, the budget allocates $2.5 million for a children's vision initiative, which will be used toward the creation of a statewide children's vision program aimed at providing comprehensive eye care to kids who do not have an eye doctor. The OOA reports that its charitable foundation, the Ohio Optometric Foundation, will be taking the lead on the development of the statewide vision program.

Photos left to right: Nate Lighthizer, OD, Jackie Burress, OD, Corri Collins, OD

If SB 129 is eventually passed, the scope of optometry in Ohio would finally reflect the profession's current educational and training standards and help increase the efficiency of the eyecare workforce to meet the needs of an aging population.

The Ohio Optometrist Association (OOA), a leading group of advocates for the bill, notes that since the early 2000s when the last scope law was passed in the state, there have been disruptive advances in technology, education and training standards in the profession. Compounding this issue is the nation's aging population and shortage of ophthalmologists, which puts increasing demand on the need for eyecare services for diseases such as glaucoma and macular degeneration.

More and more states are recognizing that optometrists can be part of the solution, with six passing scope expansion legislation in the last five years. There are also several states besides Ohio with one- or two-year scope bills at varying points of the legislative process, including New Jersey, California and Nebraska.

In a recent report, the OOA highlighted several reasons why an update to the state's practice scope is crucial for doctors, patients and the state's healthcare system. The first reason cited is to improve access to care and decrease wait times for patients in need of these essential procedures. Secondly, the association argued that the law will create a more efficient, team-oriented approach to the delivery of care. It noted that allowing ODs to perform these minor procedures (such as capsulotomy after cataract surgery, trabeculoplasty to lower intraocular pressure in glaucoma patients and laser peripheral ididotomy to prevent closed-angle glaucoma) will help reduce the burden placed on ophthalmology practices and allow them to focus more of their time on advanced procedures that fall outside of the skills and training of optometrists. The report further pointed out that the procedures proposed in SB 129 represent a small percentage—around 4%—of the scope of ophthalmology.

The third reason the OOA argues SB 129 is necessary is that it will help Ohio maintain a well-trained eyecare workforce by aligning the state's practice scope with that of surrounding states (including Indiana, Kentucky, West Virginia, Colorado and Virginia). The report also notes that 71% of graduating optometrists say that a state's scope of practice is a factor in determining where to practice, and graduates often cite the inability to practice optometry to the full scope of their training as a primary reason for leaving the state.

The OOA is hopeful that Health Committee hearings will be scheduled for SB 129 following the summer recess. It advises ODs who are interested in supporting the legislation to contact the OOA at info@ooa.org.

First Rx Treatment for Demodex Blepharitis Approved

Despite being one of the more common ocular conditions seen by eyecare professionals, *Demodex* blepharitis has for decades lacked interventions beyond encouraging better lid hygiene to reduce bacterial overgrowth and recommending eyelid cleansers with tea tree oil to help eradicate mites. Now, after much anticipation, the first targeted therapeutic for *Demodex* blepharitis has finally received FDA approval. Called Xdemvy (lotilaner ophthalmic solution 0.25%, Tarsus Pharmaceuticals), the drug is to be used twice daily for six weeks and demonstrates an ability to reduce collarettes in as few as 15 days, the company reports.

The safety and efficacy of the new drug were evaluated through two Phase III trials (Saturn-1 and Saturn-2) in which 833 patients received either Xdemvy or vehicle. Patients on Xdemvy achieved significant improvement by day 43, marked by a reduction of collarettes to no more than two per upper lid. The endpoints of mite eradication (zero per lash) and erythema cure (grade zero) also showed significant gains at day 43 in both trials: in Saturn-1, 81% of treated subjects had a collarette grade of zero or one on day 43 vs. 23% for placebo. In Saturn-2, these percentages were 89% vs. 33%, respectively. By day 15, 68% of patients in Saturn-1 achieved complete mite eradication vs. 18% of those on placebo.

Photo: Tarsus Pharmaceuticals

Tarsus announced the approval of Xdemvy on July 25.

Instillation site stinging and burning was the most common adverse reaction, affecting 10% of patients who received Xdemvy. Less than 2% experienced more severe adverse reactions, which included chalazion/hordeolum and punctate keratitis.

Xdemvy is expected to be available by the end of next month, Tarsus says.

Ophthalmologists Challenge Narrative of Improved Drive Times for OD-performed Laser Procedures

However, the study makes no mention of reduced waiting period when booking appointments with optometrists and other factors relating to the quality, affordability and availability of care.

A leading argument for adding laser procedures to optometrists' scope—including laser peripheral iridotomy (LPI), selective laser trabeculoplasty (SLT) and YAG capsulotomy—is to increase access to care, especially for older individuals with a higher prevalence of eye disease. A team of ophthalmologists and statisticians, but no optometrists, published a study in *JAMA Ophthalmology* that found no association between expanded practice scope and increased access to laser procedures, as measured by reduced drive times to practices offering such services in five states with optometric laser laws: Oklahoma, Kentucky, Louisiana, Arkansas and Missouri.[1] Notably, patient access was solely measured by estimated travel time and 30-minute proximity to an OD or ophthalmologist.

The team reviewed a total of 1,564,307 Medicare Part B claims from 2016 through 2020 for patients who underwent LPI, SLT or YAG capsulotomy by an OD or MD in the five states noted above. The primary outcome measure was the percentage of each state's Medicare population within 30 minutes of an optometrist or ophthalmologist and estimated travel time for patients.

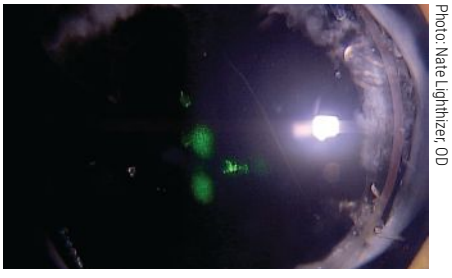

Photo: Nate Lightizer, OD

ODs and legislative advocates can expect to see these findings used against them in their ongoing scope expansion efforts. To date, ten states allow ODs to perform laser procedures such as capsulotomy.

The study authors made the following conclusions from the data:[1]

• ODs performing laser eye surgery cover a geographic area similar to that covered by ophthalmologists.

• Less than 5% of the population in every state but Oklahoma had only ODs (no ophthalmologists) within a 30-minute drive for YAG and SLT.

• Patients had a longer travel time to receive all laser procedures from optometrists than ophthalmologists in Kentucky (for YAG, the difference was 49 minutes vs. 23 minutes, respectively).

• OD-performed YAG also had a longer drive time than ophthalmologist-performed procedures in Oklahoma and Arkansas, but not in Louisiana.

The researchers pointed out that these statistics would change if patients were to see the doctor closest to them. For example, for YAG procedures performed in Kentucky, they noted in their paper that, "Patients who initially chose an ophthalmologist had a median travel time of 23 minutes, which could have been reduced by five to 10 minutes if they selected the closest optometrist (median, 13 minutes) or ophthalmologist (median, 18 minutes)."[1] On the other hand, they added, "patients who chose to see an optometrist traveled significantly more with a median estimated

NOW APPROVED: the first and only FDA-approved treatment for GA secondary to AMD[1]

GA unravels so much
SAVE RETINAL TISSUE BY SLOWING PROGRESSION[1-3]

SYFOVRE achieved continuous reductions in mean lesion growth rate* vs sham pooled from baseline to Month 24[1]

Monthly	Every Other Month (EOM)
OAKS trial (mm^2): (3.11 vs 3.98) **22%**	OAKS trial (mm^2): (3.26 vs 3.98) **18%**
DERBY trial (mm^2): (3.28 vs 4.00) **18%**	DERBY trial (mm^2): (3.31 vs 4.00) **17%**

SE in trials (monthly, EOM, sham pooled): OAKS: 0.15, 0.13, 0.14; DERBY: 0.13, 0.13, 0.17.

*Slope for baseline to Month 24 is an average of slope of baseline to Month 6, Month 6 to Month 12, Month 12 to Month 18, and Month 18 to Month 24.[1]
Based on a mixed effects model for repeated measures assuming a piecewise linear trend in time with knots at Month 6, Month 12, and Month 18.[1]

AMD=age-related macular degeneration; GA=geographic atrophy; SE=standard error.

Learn more about the SYFOVRE clinical data at SyfovreECP.com/efficacy

INDICATION

SYFOVRE™ (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- SYFOVRE is contraindicated in patients with ocular or periocular infections, and in patients with active intraocular inflammation

WARNINGS AND PRECAUTIONS

- **Endophthalmitis and Retinal Detachments**
  - Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
- **Neovascular AMD**
  - In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.
- **Intraocular Inflammation**
  - In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.
- **Increased Intraocular Pressure**
  - Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

Please see Brief Summary of Prescribing Information for SYFOVRE on the adjacent page.

Trial Design: SYFOVRE safety and efficacy were assessed in OAKS (N=637) and DERBY (N=621), multi-center, 24-month, Phase 3, randomized, double-masked trials. Patients with GA (atrophic nonexudative age-related macular degeneration), with or without subfoveal involvement, secondary to AMD were randomly assigned (2:2:1:1) to receive 15 mg/0.1 mL intravitreal SYFOVRE monthly, SYFOVRE EOM, sham monthly, or sham EOM for 24 months. Change from baseline in the total area of GA lesions in the study eye (mm^2) was measured by fundus autofluorescence (FAF).[1,4]

References: 1. SYFOVRE (pegcetacoplan injection) [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; 2023. **2.** Pfau M, von der Emde L, de Sisternes L, et al. Progression of photoreceptor degeneration in geographic atrophy secondary to age-related macular degeneration. *JAMA Ophthalmol*. 2020;138(10):1026-1034. **3.** Bird AC, Phillips RL, Hageman GS. Geographic atrophy: a histopathological assessment. *JAMA Ophthalmol*. 2014;132(3):338-345. **4.** Data on file. Apellis Pharmaceuticals, Inc.

SYFOVRE™ (pegcetacoplan injection) 15 mg / 0.1 mL

Apellis

SYFOVRE ™ (pegcetacoplan injection), for intravitreal use
BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see SYFOVRE full Prescribing Information for details.

INDICATIONS AND USAGE

SYFOVRE is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

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Active Intraocular Inflammation

SYFOVRE is contraindicated in patients with active intraocular inflammation.

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Neovascular AMD

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Intraocular Inflammation

In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves patients may resume treatment with SYFOVRE.

Increased Intraocular Pressure

Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

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.

A total of 839 patients with GA in two Phase 3 studies (OAKS and DERBY) were treated with intravitreal SYFOVRE, 15 mg (0.1 mL of 150 mg/mL solution). Four hundred nineteen (419) of these patients were treated in the affected eye monthly and 420 were treated in the affected eye every other month. Four hundred seventeen (417) patients were assigned to sham.

The most common adverse reactions (≥5%) reported in patients receiving SYFOVRE were ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, and conjunctival hemorrhage.

Table 1: Adverse Reactions in Study Eye Reported in ≥2% of Patients Treated with SYFOVRE Through Month 24 in Studies OAKS and DERBY

Adverse Reactions	PM (N = 419) %	PEOM (N = 420) %	Sham Pooled (N = 417) %
Ocular discomfort*	13	10	11
Neovascular age-related macular degeneration*	12	7	3
Vitreous floaters	10	7	1
Conjunctival hemorrhage	8	8	4
Vitreous detachment	4	6	3
Retinal hemorrhage	4	5	3
Punctate keratitis*	5	3	<1
Posterior capsule opacification	4	4	3
Intraocular inflammation*	4	2	<1
Intraocular pressure increased	2	3	<1

PM: SYFOVRE monthly; PEOM: SYFOVRE every other month

*The following reported terms were combined:

Ocular discomfort included: eye pain, eye irritation, foreign body sensation in eyes, ocular discomfort, abnormal sensation in eye

Neovascular age-related macular degeneration included: exudative age-related macular degeneration, choroidal neovascularization

Punctate keratitis included: punctate keratitis, keratitis

Intraocular inflammation included: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, anterior chamber flare

Endophthalmitis, retinal detachment, hyphema and retinal tears were reported in less than 1% of patients. Optic ischemic neuropathy was reported in 1.7% of patients treated monthly, 0.2% of patients treated every other month and 0.0% of patients assigned to sham. Deaths were reported in 6.7% of patients treated monthly, 3.6% of patients treated every other month and 3.8% of patients assigned to sham. The rates and causes of death were consistent with the elderly study population.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies of SYFOVRE administration in pregnant women to inform a drug-associated risk. The use of SYFOVRE may be considered following an assessment of the risks and benefits.

Systemic exposure of SYFOVRE following ocular administration is low. Subcutaneous administration of pegcetacoplan to pregnant monkeys from the mid gestation period through birth resulted in increased incidences of abortions and stillbirths at systemic exposures 1040-fold higher than that observed in humans at the maximum recommended human ophthalmic dose (MRHOD) of SYFOVRE (based on the area under the curve (AUC) systemically measured levels). No adverse maternal or fetal effects were observed in monkeys at systemic exposures approximately 470-fold higher than that observed in humans at the MRHOD.

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

Lactation

Risk Summary

It is not known whether intravitreal administered pegcetacoplan is secreted in human milk or whether there is potential for absorption and harm to the infant. Animal data suggest that the risk of clinically relevant exposure to the infant following maternal intravitreal treatment is minimal. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, caution should be exercised when SYFOVRE is administered to a nursing woman.

Females and Males of Reproductive Potential

Contraception

Females: It is recommended that women of childbearing potential use effective contraception methods to prevent pregnancy during treatment with intravitreal pegcetacoplan. Advise female patients of reproductive potential to use effective contraception during treatment with SYFOVRE and for 40 days after the last dose. For women planning to become pregnant, the use of SYFOVRE may be considered following an assessment of the risks and benefits.

Pediatric Use

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

Geriatric Use

In clinical studies, approximately 97% (813/839) of patients randomized to treatment with SYFOVRE were ≥ 65 years of age and approximately 72% (607/839) were ≥ 75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies. No dosage regimen adjustment is recommended based on age.

PATIENT COUNSELING INFORMATION

Advise patients that following SYFOVRE administration, patients are at risk of developing neovascular AMD, endophthalmitis, and retinal detachments. If the eye becomes red, sensitive to light, painful, or if a patient develops any change in vision such as flashing lights, blurred vision or metamorphopsia, instruct the patient to seek immediate care from an ophthalmologist.

Patients may experience temporary visual disturbances associated either with the intravitreal injection with SYFOVRE or the eye examination. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Manufactured for:
Apellis Pharmaceuticals, Inc.
100 Fifth Avenue
Waltham, MA 02451

SYF-PI-17Feb2023-1.0

2/23 US-PEGGA-2200163 v2.0

travel time of 49 minutes. Choosing the nearest optometrist or ophthalmologist would have saved nearly 35 minutes of travel time."[1]

The authors did bring attention to some limitations. "The study data are limited to geographical analysis and cannot address whether the quality of care was improved with this expanded access, whether ease or speed of appointments was improved, the impact of physician availability or if costs decreased without compromising quality," they wrote.[1] Additionally, racial, ethnic or cultural factors were not taken into account.

Expanding on these cautionary statements, several ODs authored a commentary on the study, also published in *JAMA Ophthalmology*, highlighting the numerous factors other than geographic location that define patient accessibility.[2] "Distance and drive time are concerns for patients who have limited access to care," they wrote. "However, beyond accessibility, the theory of access framework from Penchansky and Thomas includes affordability, acceptability, availability and adequacy and is now expanded to include awareness and patient-level factors. Understanding how each dimension impacts access is critical to reduce eye health disparities."[2]

The commentary goes on to describe each facet of patient accessibility, beginning with affordability, which focuses on the patient's direct eyecare costs and ability to pay out-of-pocket, as well as transportation costs and lost productivity due to missed work, the authors noted.

Acceptability describes expectations. "Patients may find a service unacceptable due to a poor physician-patient relationship, lack of adequate communication with the eyecare clinician or minimal patient education from the eyecare clinician about eye diagnoses and treatment," the commentary authors explained.[2]

The next measure of patient access is availability, involving supply and demand of patient needs vs. available services. For example, in areas with an older population, there may be more demand for care of eye diseases like glaucoma. Complementing this, the factor of adequacy refers to the capacity of eyecare practices to care for patients and facilitate services.

The final factor, awareness, focuses on the information and communication about available eyecare services. Additional patient-level factors of accessibility include situations that can prevent a person from accessing care (*i.e.*, missed visits due to illness or caregiver difficulties).

The commentary authors argue that "multidimensional approaches are needed to understand where access to eyecare services is lacking," and that "research can grow beyond geographical access."[2] They suggest a follow-up study assess each factor affecting the association between OD- and ophthalmologist-performed laser procedures and patient access. For example, poverty indices could help measure adequacy, and neighborhood-level factors such as fuel cost and median income can help measure affordability, they note.

Overall, while allowing ODs to perform laser procedures wasn't shown to improve patient access based on geographic data alone, it would be beneficial to examine the various dimensions of accessibility in future studies.

1. Shaffer J, Rajesh A, Stewart MW, et al. Evaluating access to laser eye surgery by driving times using Medicare data and geographical mapping. JAMA Ophthalmol. July 20, 2023. [Epub ahead of print].

2. Hicks PM, Asare AO, Woodward MA. Beyond accessibility in exploring access to eye care to achieve vision health equity. JAMA Ophthalmol. July 20, 2023. [Epub ahead of print].

Post-cataract Endophthalmitis Study Identifies Key Risks

Though endophthalmitis is a rare complication, this makes it difficult for surgical centers to calculate their infection rates. Researchers recently turned to the Royal College of Ophthalmologists' National Ophthalmology Database to identify post-cataract endophthalmitis risk factors to inform surgical counseling and strategies to reduce infection risk.

The analysis included more than 1.3 million cataract surgeries performed on 920,286 patients across 76 centers. The team identified 308 cases (0.02%; 55.5% female; median age 76.9) of recorded endophthalmitis (within 42 days of surgery). For the 2,315 immediate sequential bilateral cataract surgery patients, no cases were reported. Overall, endophthalmitis rate ranged from 0.015% to 0.035% between 2010 and 2020.

Posterior capsular rupture (PCR) was the greatest risk factor, since it usually requires additional surgical time, procedures and instrumentation to complete the case, thereby increasing the chances of introducing microorganisms into the eye. Other risk factors included:

- Uveitis/posterior synechiae
- Previous vitrectomy surgery
- Previous anti-VEGF therapy
- Glaucoma
- Corneal pathology
- Diabetes mellitus

The researchers wrote in their *Ophthalmology* paper that "the lowest probability of post-cataract surgery endophthalmitis is 0.015% for a patient without diabetes or prior anti-VEGF therapy with none of the ocular conditions and where PCR is avoided during surgery. This risk increases to 0.108% if PCR occurs." Without PCR but with all other ocular conditions, the risk is 2.645%; with PCR the risk is 16.139%.

Photo: Joseph Sowka, OD

Microbiota on the periocular skin and lid margin are thought to be the main source of contamination during cataract surgery.

The researchers advocate developing national benchmarks of incidence and surveillance networks to monitor cases and respond to potential outbreaks.

Low L, Shah V, Norridge CFE, et al. RCOphth NOD, Report 10: risk factors for post-cataract surgery endophthalmitis. Ophthalmology 2023. [Epub ahead of print].

Fluoroquinolone Offers Some Benefit in Bacterial Infection

A literature review found that therapy reduced time to resolution by 26%. The somewhat small gain should be weighed against cost, adverse effects and worries about antibiotic resistance.

As generous prescribing of broad-spectrum antibiotics can lead to resistance, a group of researchers wanted to specify if their use was warranted in cases of conjunctivitis. Summarizing the key findings from a Cochrane Review for *American Journal of Ophthalmology,* the group analyzed the benefits and safety of antibiotic therapy compared with a placebo in cases of acute bacterial conjunctivitis.

Photo: Alexandra Espejo, OD

Many schools require students with "pink eye" to be prescribed an antibiotic before returning and that alone may argue for the intervention. However, a literature review found only marginal clinical benefit from it.

Included were 21 randomized controlled trials that compared topical antibiotic use with a placebo in a total of 8,805 patients. Most of these trials (71%) examined using fluoroquinolone (FQ) drops; three tested macrolides either alone or with combination steroids and three others compared non-FQ antibiotics.

Intention-to-treat estimates suggested antibiotics may increase clinical recovery by 26% after therapy, increase treatment completion rates and reduce persistent clinical infection after one treatment course vs. placebo. In lab-confirmed cases of bacterial conjunctivitis, antibiotics were associated with 53% higher likelihood of microbiological cure and better treatment adherence vs. placebo.

Non-FQ therapies increased only microbiological, and not clinical, cure efficacy. However, non-FQs were shown likely to increase treatment-associated ocular complications, including eye pain, discomfort and allergic reactions, while FQs did not, but the certainty of evidence for this was low due to potential risk of bias from study design and inconsistent outcome measurement and reporting.

The study authors specify that these findings may be more applicable to acute bacterial conjunctivitis in the older pediatric and adult population than for neonatal bacterial conjunctivitis, since neonatal cases require systemic antibiotics, as well as the common cause being different in the non-neonatal pediatric vs. adult population (*Haemophilus influenzae* vs. *Staphylococcus aureus*, respectively).

The moderate certainty of evidence found in the benefits of topical antibiotic use may be up for debate though, due to self-limited nature and relatively low morbidity of most cases. The authors point out that while a patient pays for a doctor's visit and antibiotic prescription and rarely suffers adverse events, the costs and adverse events are multiplied on a societal level. Even further, topical FQs lead to resistance, which is of concern, since fourth-generation FQs are what's used for vision-threatening bacterial keratitis. Although ocular concentration of topical antibiotics differ from systemic concentrations of antibiotics, tropical resistance may carry over systemically.

Interestingly, intention-to-treat results showed that 55.5% of placebo participants spontaneously resolved clinically by days four to nine, compared with the rate of 68.2% in the antibiotic treatment group. The authors pose that this may argue against the requirement that many schools maintain for a child with conjunctivitis to have been prescribed for conjunctivitis before returning to school.

Although this offers a good general understanding, the authors add that "future research is required to assess the clinical and microbiological efficacy among different antibiotic classes, bacterial species or treatment durations of the same antibiotic in head-to-head trials."

Liu SH, Chen YY, Nurmatov U, van Schayck OCP, Kuo IC. Antibiotics vs. placebo for acute bacterial conjunctivitis: findings from a Cochrane Systematic Review. Cochrane Database Syst Rev. July 21, 2023. [Epub ahead of print].

IN BRIEF

SLT's IOP Reduction Lower Over Time in Patients on Immunosuppressives. SLT is increasingly considered a first-line therapy due its cost effectiveness and potentially superior clinical outcomes compared with drop therapy. But it is contraindicated in certain patients? Researchers at the Mayo Clinic recently hypothesized that, if an immune or inflammatory response is required for IOP reduction following SLT, then the efficacy in immunosuppressed glaucoma patients would be diminished compared with those not on systemic immunosuppressive drugs. They determined that **those in the systemic immunosuppressive therapy group showed equivalent early IOP-lowering after SLT vs. controls, but the treatment response was diminished at one year.**

All patients who underwent SLT at the Mayo Clinic over a five-year period were identified. Patients on systemic immunosuppressive medications at the time of SLT (108 eyes of 72 patients) were compared with controls (1,997 eyes of 1,417 patients) not receiving systemic immunosuppressive medications. The primary endpoints were the percentage IOP reduction at one to two, three to six and 12 months.

There was no significant difference in IOP between groups at the first post-op visit one to two months following SLT (-18.8% vs. -16.0%) or three to six months (-15.2% vs. -18.3%). However, **at 12 months, the IOP reduction in the immunosuppressive group was significantly less vs. controls** (-15.1% vs. -20.3%).

"This study provides much needed efficacy data of SLT in an immunosuppressed population," the researchers wrote in their paper, published in *Journal of Glaucoma*. **"The IOP differences between groups suggests that the immune system does play a role in IOP regulation in patients who underwent SLT,"** they added.

Kaplan TM, Hammer JD, Kohli D, et al. Efficacy of selective laser trabeculoplasty in patients on systemic immunosuppressive therapy. J Glaucoma. June 26, 2023. [Epub ahead of print].

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[1]Compared to Biotrue Multi-Purpose Solution.
[2]Based on a laboratory study.
[3]Antioxidant protects hyaluronan against free radicals.
[4]For 12 hours compared to Biotrue Multi-Purpose Solution, based on a laboratory study.
[5]Data on file. Bausch & Lomb Incorporated. Rochester, NY.
[6]Standardized Testing (ISO 14729) against *S. aureus, P. aeruginosa, S. marcescens, C. albicans, F. solani.*

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Does Keratoconus Have a Basis in Systemic Disease?

New research indicates it may be part of a larger pathophysiological issue.

Several diseases involving connective tissue hyperlaxity and collagen disturbances, including Ehlers-Danlos, osteogenesis imperfecta, congenital hip dysplasia and more, have been linked to corneal ectasia, specifically keratoconus. Accordingly, researchers in Israel recently wanted to illustrate just how prevalent a correlation is between keratoconus and various systemic manifestations of tissue hyperlaxity.

Medical records of Israeli adolescents and young adults were reviewed. With a total of 938,411 records included, prevalence rates of ligament injuries, habitual orthopedic deformities and umbilical/inguinal hernia were evaluated in cases with and without keratoconus. With a prevalence of 0.16% in the study sample, keratoconus was significantly more likely to be diagnosed in patients with genu varum/valgus, pes planus, scoliosis and umbilical/inguinal hernias, which remained significant after multivariate analysis. However, joint injuries, including ankle sprains, shoulder dislocation and knee ligament and menisci injuries were found to be not related.

Consequently, the study researchers believe that the link of keratoconus with connective tissue hyperlaxity manifestations of the knees, feet, spine and abdomen may be indicative of "a generalized connective tissue disorder, rather than just a local ocular phenomenon," they explained in their paper for *Contact Lens and Anterior Eye*.

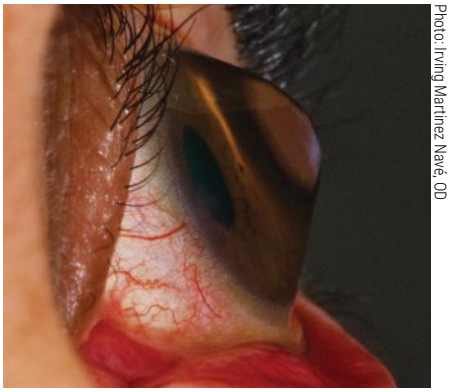

Photo: Irving Martinez Navé, OD

This study's cohort saw association of systemic connective tissue hyper-elasticity manifestation with keratoconus in males, but not females, suggesting a common X-linked underlying pathology may contribute to a generalized tissue hyperlaxity phenotype.

Further validating these findings are the demographic characteristics comparable to previous reports. As well, greater height, weight and BMI were all related to keratoconus, also previously reported in literature. Prevalence was found to be 160 cases per 100,000, also similar to prior research, the team notes in their article.

The authors explain that keratoconus is caused in part by corneal infrastructure deterioration, mainly composed of type I collagen, which also is a main component of tendons and the abdominal wall fascia, relating it to the conditions studied here. However, types III, V and XII collagen have also been linked to keratoconus.

Inguinal hernia was found to persist in 0.8% of people in this study, which follows the overall incidence of 0.8% to 4.4%. Collagen formation abnormalities have been observed in inguinal hernia patients, mainly in types I and III. The researchers posit that the association between keratoconus and hernia in this study, as well as the shared genetic component of a LOX gene mutation on chromosome 5, raise suspicion of common inheritance.

Generalized connective tissue hyperlaxity seems to increase the risk for both keratoconus and orthopedic pathologies like scoliosis, pes planus and genu varum/valgus, as mitral valve prolapse—another systemic connective tissue pathology manifestation—has been reported in joint hypermobility syndrome and keratoconus.

While larger joint injuries encompass a wider variety of injuries to ligaments, menisci, bone and articular space, the lack of association with these pathologies and keratoconus in this study may not reflect real-world situations. Despite this, the researchers note that their findings "suggest the existence of a systemic underlying connective tissue pathology rather than a local one as a cause of keratoconus."

Safir M, Satanovsky A, Hecht I, et al. The association between keratoconus and systemic manifestations of connective tissue hyperlaxity. Cont Lens Anterior Eye. July 19, 2023. [Epub ahead of print].

IN BRIEF

For Horseshoe Tears, Two Tests are Better Than One. In certain telemedicine situations, imaging can make up for the lack of an in-person evaluation but not when it comes to detecting horseshoe tears. According to a paper published recently in *AJO*, which assessed the detection sensitivity of ultra-widefield imaging in isolation (as opposed to the typical combined approach with scleral depression), this approach on its own missed about half of horseshoe tears.

The retrospective analysis (123 patients; 135 horseshoe tears) showed that 51.1% of horseshoe tears were visualized using ultra-widefield images and 48.9% were not. **The researchers reported the following sensitivities for identifying horseshoe tears: 17.1% for the superior quadrant; 32% for the inferior quadrant; 50% for the nasal quadrant; and 85.5% for the temporal quadrant.**

Ultra-widefield imaging performed poorly in the superior and inferior quadrants. The researchers explained in their paper that low sensitivity in the superior quadrant in particular is a cause for concern since missed horseshoe tears in this region are at a greater risk for progression to retinal detachment.

"Considering the urgency of treating horseshoe tears and the potential for significant visual morbidity from retinal detachments, **it's crucial to highlight that ultra-widefield imaging shouldn't be used as a substitute for funduscopic exam in the evaluation of posterior vitreous detachment or symptoms indicative of a horseshoe tear,**" the researchers concluded in their paper. "This cautionary note is essential as **a negative ultra-widefield image can potentially delay diagnosis and management of a critical retinal condition.**"

Lin AC, Kalaw FG, Schönbach EM, et al. The sensitivity of ultra-widefield fundus photography versus scleral depressed examination for detection of retinal horseshoe tears. Am J Ophthalmol. July 17, 2023. [Epub ahead of print].

Strabismus Common in Some Fetal Alcohol Spectrum Disorders

In a new study, only children with facial abnormalities developed the vision condition at a prevalence rate of more than 25%.

Fetuses don't yet have a functioning alcohol elimination system, which is why alcohol exposure during gestation can lead to a host of abnormalities throughout the body. Babies and children who develop health problems from alcohol exposure in utero are described as having fetal alcohol spectrum disorders (FASDs). Evidence suggests the eye is not spared from potential harm; prior research found that alcohol exposure during pregnancy may result in reduced visual acuity, refractive errors, strabismus, anomalies of the anterior segment and malformations of the retina and optic nerve.

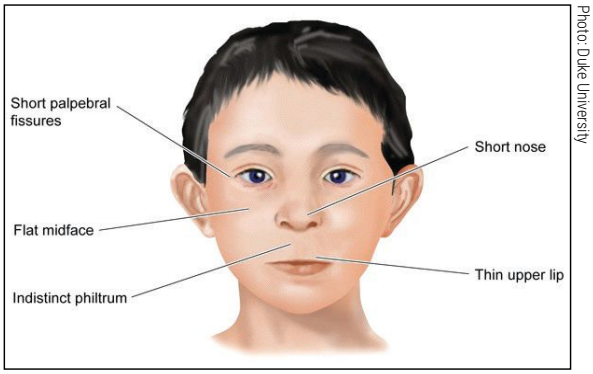

Photo: Duke University

Several small studies have suggested children with FASD may be at an increased risk of various refractive and ocular conditions. A more recent, large study identified strabismus as a potential visual outcome of the disorder, but only in those with partial fetal alcohol syndrome.

Because most previous studies had limited sample sizes, researchers recently conducted a larger study. They were able to identify a significant association between FASD and strabismus, but not between FASD and any other vision outcomes.

The cross-sectional, observational study included a total of 424 five- to seven-year-olds from 30 participating schools. These were the eligible students who remained from an original pool of 4,625 children. Each child underwent a comprehensive assessment including neurobehavioral testing, maternal interviews, dysmorphology exam and teacher reports to assess behavior in school. Ophthalmic data from medical records were also collected and evaluated (including vision screenings completed by a school nurse, ophthalmologist or pediatrician).

Of the 424 participants, 8% were determined to have FASD. The percentage of children with strabismus was significantly greater in the group of children with FASD (5/42, 11.9%) vs. the group without the disorder (6/290, 2.1%). Contrary to prior studies, no association was found between FASD and vision impairment, refractive errors, glasses/contact lens prescription or having one or more ophthalmological abnormalities.

One finding from the present study that is consistent with prior investigations is that all five children with FASD and strabismus had partial fetal alcohol syndrome, translating to a 26.3% strabismus prevalence among children with this form of FASD. Partial fetal alcohol syndrome distinguishes itself from other conditions on the FASD spectrum by referring to children who only have two of the physical aspects of fetal alcohol syndrome.

In contrast, no strabismus cases were detected in the 22 children with another type of FASD known as alcohol-related neurodevelopmental disorder, characterized by the absence of facial abnormalities. In their paper, the researchers note that this "suggests that the effect of prenatal alcohol exposure in order to produce strabismus must be severe enough to result in facial abnormalities of FASD that are seen in partial fetal alcohol syndrome."

The study authors conclude that "since FASD is a potentially preventable condition, it is important to increase public awareness as we deepen our understanding of the consequences of prenatal alcohol exposure. Clinicians examining children with FASD or prenatal alcohol exposure should always screen for eye disease and refer for additional examination when necessary."

Lyubasyuk V, Jones KL, Caesar MA, Chambers C. Vision outcomes in children with fetal alcohol spectrum disorders. Birth Defects Res. July 17, 2023. [Epub ahead of print].

IN BRIEF

Almost 40% of High Myopes Will Develop Fellow-eye MNV. Recently, researchers **investigated the incidence of second-eye involvement after myopic MNV onset and identified clinical risk factors in Europeans.** Their results, published in *Ophthalmology Retina*, demonstrated similar incidence rates to those seen in Asian studies, prompting the authors to **recommend close monitoring and increased awareness, especially in younger patients.**

The researchers retrospectively analyzed 13-year data of 88 patients (mean age 57) with high myopia (mean axial length 30mm, SE -14D) at baseline. **During follow-up, 27% of fellow eyes developed myopic MNV, demonstrating an incidence rate of 4.6 per 100 person years, with cumulative incidences of 8%, 21% and 38% at two, five and 10 years, respectively.** On average, MNV developed in the fellow eye after 48 months. The researchers noted that patients under 40 at initial presentation had a 3.8x higher risk of developing bilateral myopic MNV.

"Current insights are that European and Asian patients show a similar myopic phenotype, with age and axial length as the most important drivers for myopic maculopathy," the researchers reported. "Also, the genetic drivers of refractive error appear to be highly correlated between European and Asian individuals. Taking these parallels together, it is valid to assume that the risk and presentation of myopic MNV for first and second eyes of highly myopic patients is not determined by ethnicity."

They concluded **close monitoring and immediate treatment upon identification of symptoms will "create an optimal starting point for saving sight in high myopes."**

Ravenstijn M, Klaver CCW, Yzer S. Incidence and risk factors of second eye involvement in myopic macular neovascularization. Ophthalmol Retina. July 8, 2023. [Epub ahead of print].

When Selecting a Prescription Dry Eye Treatment

DON'T MAKE HER WAIT.

Not an actual patient.

Indication

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

Important Safety Information

- Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.
- In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.
- To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

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*Xiidra reduced symptoms of eye dryness at 2 weeks (based on Eye Dryness Score compared to vehicle) in 2 out of 4 studies, with improvements observed at 6 and 12 weeks in all 4 studies.[1†]

Important Safety Information (cont)

- Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
- Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Please see Brief Summary of Important Product Information on adjacent page.

†Pivotal trial data
The safety and efficacy of Xiidra were assessed in four 12-week, randomized, multicenter, double-masked, vehicle-controlled studies (N=2133). Patients were dosed twice daily. **Use of artificial tears was not allowed during the studies.** The study end points included assessment of signs (based on Inferior fluorescein Corneal Staining Score [ICSS] on a scale of 0-4) and symptoms (based on patient-reported Eye Dryness Score [EDS] on a visual analogue scale of 0-100).[1]

Effects on symptoms of dry eye disease: A larger reduction in EDS favoring Xiidra was observed in all studies at day 42 and day 84. Xiidra reduced symptoms of eye dryness at 2 weeks (based on EDS) compared to vehicle in 2 out of 4 clinical trials.[1]

Effects on signs of dry eye disease: At day 84, a larger reduction in ICSS favoring Xiidra was observed in 3 of the 4 studies.[1]

References: 1. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. **2.** Data on file. DRF Fingertip Formulary® Novartis Pharmaceuticals Corp; July 2022.

XIIDRA® (lifitegrast ophthalmic solution), for topical ophthalmic use
Initial U.S. Approval: 2016

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

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation *[see Adverse Reactions (6.2)]*.

6 ADVERSE REACTIONS

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

- Hypersensitivity *[see Contraindications (4)]*

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 five clinical trials of DED conducted with lifitegrast ophthalmic solution, 1401 patients received at least one dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had less than or equal to 3 months of treatment exposure. One hundred-seventy patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5%-25% of patients were instillation-site irritation, dysgeusia, and reduced visual acuity.

Other adverse reactions reported in 1%-5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus, and sinusitis.

6.2 Postmarketing Experience

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

Rare serious cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, urticaria, allergic conjunctivitis, dyspnea, angioedema, and allergic dermatitis have been reported. Eye swelling and rash have also been reported *[see Contraindications (4)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Xiidra use in pregnant women to inform any drug-associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from premating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear *[see Clinical Pharmacology (12.3) in the full prescribing information]*.

Data

Animal Data

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

8.2 Lactation

Risk Summary

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low *[see Clinical Pharmacology (12.3) in the full prescribing information]*. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

8.4 Pediatric Use

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

8.5 Geriatric Use

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

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T2020-87

Study Fails to Confirm Efficacy of 0.01% Atropine in US Children

The results are at odds with research conducted in Asia that did find a treatment effect at that concentration. Ethnic differences between subjects may explain it, the authors suggest.

While myopia management is gaining in prominence worldwide, it is still new enough to leave many important questions unanswered. The top interventions—multifocal contact lenses, ortho-K and atropine eye drops—have each demonstrated efficacy, but protocols to guide clinical application are often lacking.

At least since the ATOM1 study in 2006, researchers have sought clarity on how to balance efficacy with side effects when selecting the proper atropine concentration. The intervention has been studied primarily in Asia with generally favorable results, but a new American-based trial in *JAMA Ophthalmology* failed to replicate the slowing of myopia progression seen in East Asian studies.

An OD-MD research group tested atropine 0.01% against placebo for slowing myopia in US children aged five to 12 from 12 community- and institution-based practices. Refractive error ranged from low to moderate bilateral myopia (-1D to -6D). The primary outcome was change in spherical equivalent refractive error (SER), as a mean of both eyes, from baseline to 24 months of treatment. Other outcomes were SE change from baseline to 30 months (no treatment the last six months) and axial length change at both time points.

Of 187 children total (mean age: 10), 67% received atropine and 33% received placebo. Follow-up rates in both groups were above 90% at 24 and 30 months.

The adjusted mean change in SER at the 24-month primary outcome visit was -0.82D in the atropine group and -0.80 in the placebo group. At 30 months—six months after cessation of treatment—adjusted difference in mean SER change from baseline was -0.04D. Adjusted mean changes in axial length from baseline to 24 months was 0.44mm for the atropine group and 0.45mm for placebo, and mean axial elongation from baseline to 30 months was +0.009mm.

Based on the similar numbers between groups, the study authors concluded that "these results do not support the nightly use of low-dose atropine, 0.01%, to slow myopia progression in US children."[1]

They were quick to point out, however, that these results are much different from five clinical trials conducted in East and South Asian populations with similar age and refractive error criteria. In 2012, the ATOM2 trial saw differences in SER myopia progression but not axial elongation over two years, though there was no placebo group. More recently, the 2019 LAMP study saw reduction in myopia progression and axial elongation over one year, but higher atropine concentrations were found more effective than lower ones. Another study saw myopia progression reduction after two years and another after one year, while yet another saw reduction in mean SER progression after one year; all studies used 0.01% atropine.

This contrasts with one two-year clinical trial conducted in Western Australia, which did not find significant myopia progression difference when compared with placebo. That study also had similar age and refractive error eligibility criteria to the present research appearing in *JAMA Ophthalmology*.

Elucidated by the authors and expanded upon by an invited commentary also published by *JAMA Ophthalmology*, one potential reason for this difference is that low-concentration atropine may work better for Asian children than other racial or ethnic populations, particularly Caucasians. Since atropine binds to melanin, the commentary noted that the darker irises typical of Asian subjects may have slower release and longer active drug time, which may increase effectivity. This group also shows faster myopia progression, which means the treatment effect is likely to also be greater. Another possibility, the commentary noted, is that studies longer than one year often don't report additional accrual of treatment effect, so longer trials like the present study may not report significant effect.

Photo: Getty Images

The study found that Asian children experience faster myopic progression, and hence greater responsiveness to 0.01% atropine, than other races.

Finally, the commentators explain age may play a role, since myopia progression slows with age, and studies on Caucasian children have included subjects up to 16 years old, while three of four Asian studies maxed out at age 12.

In light of these possibilities, the study authors believe that "future studies of pharmacologic myopia control in US children should consider increased atropine concentrations, new pharmaceuticals, objective measures of treatment adherence, alternative eye drop delivery systems and schedules as well as evaluating the impact of environmental and genetic factors on myopia control treatment."[1]

The commentary authors add that "stronger concentrations of atropine should be considered for first-line treatment of myopia progression."[2]

1. Repka MX, Weise KK, Chandler DL, et al. Low-dose 0.01 atropine eye drops vs. placebo for myopic control: a randomized clinical trial. JAMA Ophthalmol. July 13, 2023. [Epub ahead of print].

2. Walline JJ, Berntsen DA. Atropine, 0.01%, or myopia control. JAMA Ophthalmol. July 13, 2023. [Epub ahead of print].

FEATURES

REVIEW OF OPTOMETRY • Vol. 160, No. 8 • AUGUST 15, 2023

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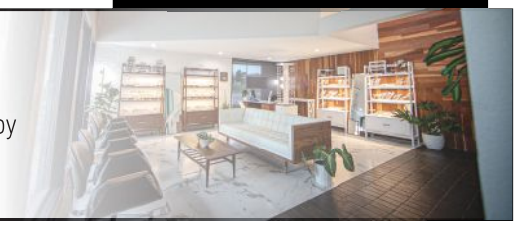

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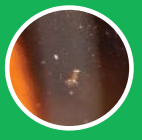

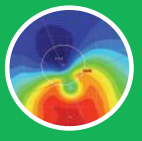

The Paradigm Shift in Keratoconus Treatment

Daniel G. Fuller, OD, FAAO Dipl, FSLS
Memphis, TN

KEY TAKEAWAYS

- Only iLink® cross-linking can slow or halt the progression of keratoconus.
- Referring progressing patients to a cornea specialist prior to vision loss is ideal.
- Slowing or halting keratoconus progression may allow patients to continue to tolerate contact lenses.

Ten years ago, there was little reason to refer a patient with keratoconus to a cornea specialist early in the course of their disease. All we could do was manage patients' vision as long as possible, hoping they didn't progress to needing a corneal transplant.

The approval of iLink® cross-linking marked a major paradigm shift in keratoconus management. Professional societies have adjusted treatment guidelines to reflect the ability of cross-linking treatment to slow or halt progression of the underlying disease. The American Academy of Ophthalmology, for example, now states in its Preferred Practice Pattern (PPP) that referral prior to vision loss is ideal, and that when keratoconus is suspected, more frequent follow-up to look for progression is warranted.[1] Any signs of progression or onset of keratoconus at a young age should lead to a prompt referral.[1]

Optometry is very good at helping patients with keratoconus see better with gas permeable (GP), hybrid, and scleral lenses. But as rewarding as it is to help the vision-impaired, we can have an even greater impact by catching this disease early and referring progressing patients for cross-linking before they lose vision, just as we refer glaucoma patients for treatment as soon as the disease is detected. For patients who are still in their peak earning and learning years, early treatment could mean 50+ years of functional vision.

Cost-effective and FDA approved

A discrete-event simulation model showed that, compared to conventional treatment, iLink cross-linking would reduce the rate of penetrating keratoplasty by 26%, and result in patients spending 28 fewer years in the advanced stages of keratoconus—all while saving money for patients, insurers, and society.[2]

The iLink procedure is an epithelium-off treatment that has undergone the scrutiny of randomized controlled clinical trials as part of the FDA approval process, demonstrating proven efficacy and safety. It is important to refer patients to doctors who use iLink, the only cross-linking procedure approved by the FDA. I believe that good science promotes good patient care and, in the case of iLink, also allows patients to use their insurance.

Vision correction post cross-linking

Slowing or halting keratoconus progression may allow patients to continue to tolerate contact lenses.[3,4] Typically, patients can resume contact lens wear within one to three months of the cross-linking procedure, although I find that corneal remodeling may continue for up to 12 months post-treatment. During this time, lens parameters may need to be adjusted. About one-third of eyes are able to continue in habitual contact lenses after cross-linking, while two-thirds require a new contact lens fit.[5]

With iLink cross-linking and modern specialty contact lenses, we have the best keratoconus management options now that I've ever seen. This represents not just a business opportunity, but the chance to have a life-changing impact on our patients. ▪

Contact Lens Fitting Post Cross-Linking[5]

100% ACCEPTABLE FIT | **65%** IMPROVED SUBJECTIVE COMFORT | **20%** INCREASE IN NEAR-IDEAL FIT

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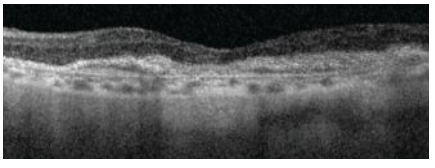

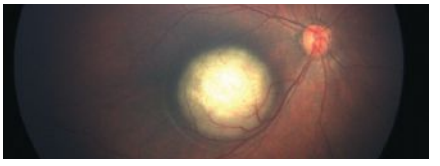

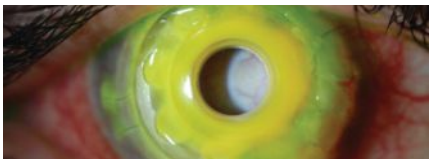

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BY JACK PERSICO
EDITOR-IN-CHIEF
OUTLOOK

No Hollywood Ending

It's worth rooting for cooperation (or at least detente) between the two eyecare professions while still expecting little to none.

The dog days of summer are an odd time to think about the perennial Christmas staple *It's a Wonderful Life*, but that classic movie has been on my mind lately. More than once this year I've wondered what the healthcare system would look like if optometry, like George Bailey, had never existed.

Because, remember, optometry wasn't a sure thing. The profession's history is more erratic and idiosyncratic than most. What came to be called optometry grew out of the disciplines of opticianry and ophthalmology, blending aspects of both but not really sanctioned by either. Optometry owes its existence to many forward-thinking pioneers, most notably Charles Prentice and Andrew Cross, who swam against the tide to create it.

As a result, optometry has been in a defensive posture since its inception. Ophthalmology has been accusing ODs of practicing medicine without a license literally since 1892, when Prentice had the temerity to charge a fee for an eye exam (shocking!) and incurred the wrath of local "oculists," as physicians specializing in the eye were then called. It's no surprise, then, to see the "not a doctor" bills introduced in Florida and elsewhere this year to discredit optometry's standing. The proponents of those bills are spiritual successors to Prentice's detractors from 130 years ago.

Anti-optometry acrimony may ebb and flow but never really dies down. With optometric scope of practice expansion happening on multiple fronts right now, the OD-MD fault lines within the wider world of eye care have been more prominent this year than most.

You can see this all over our news section this month, with stories on a scope expansion bill in Ohio and dueling narratives about optometry's efficacy (touted by the AOA) or lack thereof (naturally, from an ophthalmology analysis) in the delivery of laser procedures.

So, let's ponder: Prentice and Cross (and countless other agents of change over the last century) never went about the business of creating optometry. Fine, we've just reduced the US workforce of eye doctors by two-thirds. The eyecare needs of the 330,000,000 Americans now rest on the shoulders of fewer than 20,000 ophthalmologists. Good luck scheduling grandma's cataract surgery in under six months with ophthalmologists mired in routine care all day! And what of uniquely optometric endeavors like specialty contact lenses, vision therapy, low vision and now myopia management? Kiss those goodbye. How could the overburdened ranks of ophthalmologists fit those in? They would have needed to cultivate a robust team of midlevel eyecare providers to keep their practices from bursting at the seams.

In other words, if optometry had never existed, ophthalmology would have had to invent it just to keep from drowning in routine care. That's why I and so many others greet ophthalmology's many anti-optometry salvos with such indignation.

I'm not so naïve as to expect a Hollywood ending. The entrenched interests in organized medicine won't give up ground—even when it's in their own long-term interests to do so. Instead of holding back the optometry profession, why not offer constructive support—or at least tacit approval by staying out of the fray—so that better OD-MD integration could flourish, to the benefit of literally everyone involved? That's a world that looks a lot more like Bedford Falls than Pottersville. ■

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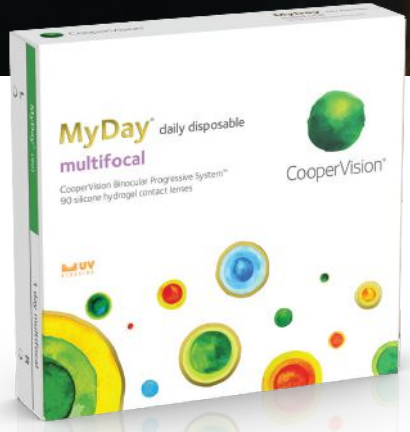
Dr. Micaela Crowley, O.D.
Lexington, MA



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1. CVI data on file as of May 2023 vs. leading manufacturers. **2.** CVI data on file 2020. Prospective, double-masked, bilateral, 1-week dispensing study with MyDay daily disposable multifocal; n=104 habitual MFCL wearers. **3.** CVI data on file 2020. Prospective, double-masked, bilateral, one-week dispensing study UK with MyDay® multifocal; n=104 habitual multifocal contact lens wearers. **4.** CVI data on file 2021. Prospective, subject-masked, randomized, bilateral, two-week dispensing study at 5 US sites with MyDay® multifocal; n=58 habitual multifocal contact lens wearers. **5**. CVI Data on file 2022. Based on global product sales and internal estimates of products using Aquaform® Technology over 12 months in 2022.

BY PAUL M. KARPECKI, OD
CHIEF CLINICAL DITOR

A Big Headache

Contoured prism glasses could solve this ocular-related issue.

It seems hard to believe that the majority of frequent headache sufferers sitting in a neurologist's office could be solved with glasses. A bigger impact is in the area of asthenopia, which may affect more than 125 million people in the United States alone. The average American spends about 13 hours per day on digital devices, with 59% complaining of eyestrain, making this field an attractive opportunity. So, how do we address it?

Prism is the Answer

One day it's likely we'll prescribe prism as an add-on feature for patients suffering from eyestrain (or frequent headaches), just as we might add anti-reflective coatings, blue light blocking or Transitions technology. Who wouldn't want to be more productive on digital devices or significantly reduce frequent headaches? The problem with traditional prism is that the majority of patients require more prism at near distance and previous options only allowed for a uniform prism correction throughout the spectacle lens… until now.

The Connecting Link

Almost two-thirds of patients in the US experience headaches, dry eye or eyestrain, yet less than 10% mention these to their optometrist.[1,2] The link to all of this is the trigeminal nerve, the largest nerve in the brain, responsible for the majority of head, face, jaw, neck and corneal sensations. In a study involving 179 participants with refractory or treatment-resistant chronic headaches, 54% reported their symptoms reduced substantially or basically gone and 81.6% showed a positive response to treatment.[3] Based on this data, we can confidently state that more than 50% of patients with chronic frequent headaches can be resolved with contoured prism glasses.

> **Ocular-related headaches are a relatively new field of understanding, but the effects of treating eye misalignment with contoured prism are significant and life-altering.**

Trigeminal Dysphoria (TD)

This condition involves misalignment of the eyes—in particular exophoria with convergence insufficiency. The compensation required and the proprioception of where the brain thinks the eyes are positioned create conflict and stress on the trigeminal nerve, which is why many patients with traumatic brain injuries also have frequent headaches or other TD symptoms such as headaches, dizziness, dry eye sensation, tired eyes, neck and shoulder pain and photophobia.[1] Pain thresholds vary and range from eye strain or tired eyes to frequent, severe headaches. These patients often "decompensate" their trigeminal nerve by going into a dark, quiet room to remove stimuli until the nerve recovers.

Neurolens

Most clinicians are not measuring phorias because the methods such as Von Graefe to cover testing with prism bars are subjective and time-consuming, with inconsistent endpoints. Enter Neurolens technology, which in under three minutes objectively measures horizontal and vertical phorias, fixation disparity, accommodative convergence response and many other parameters that provide an objective, repeatable, accurate prism correction at both near and far distance.

Contoured Prism is Key

Since 90% of patients have a greater prism requirement when fusing at near, contoured prism increases by 0.75 BI as you move from far to near through the spectacle lens.[4] This prevents prism creep, variability and relieves asthenopia and frequent headaches far more often than standard prism. Even small amounts of contoured prism correction can yield profound symptom relief. Symptoms ranging from headaches, dry eye sensation, neck stiffness and asthenopia are shown to improve by more than 77.8%, with dizziness improving by almost 90%, according to company data.[5] Concerning productivity, patients wearing Neurolenses improved their reading speed by 70%.

Ocular-related headaches are a relatively new field of understanding, but the effects of treating eye misalignment with contoured prism (and/or binocular vision training) are significant and life-altering. I've witnessed this in hundreds of patients and three family members, including one whose frequent migraines went from five to 10 per month down to one to two per year! ■

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About Dr. Karpecki

Dr. Karpecki is the director of Cornea and External Disease for Kentucky Eye Institute, associate professor at KYCO and medical director for the Dry Eye Institutes of Kentucky and Indiana. 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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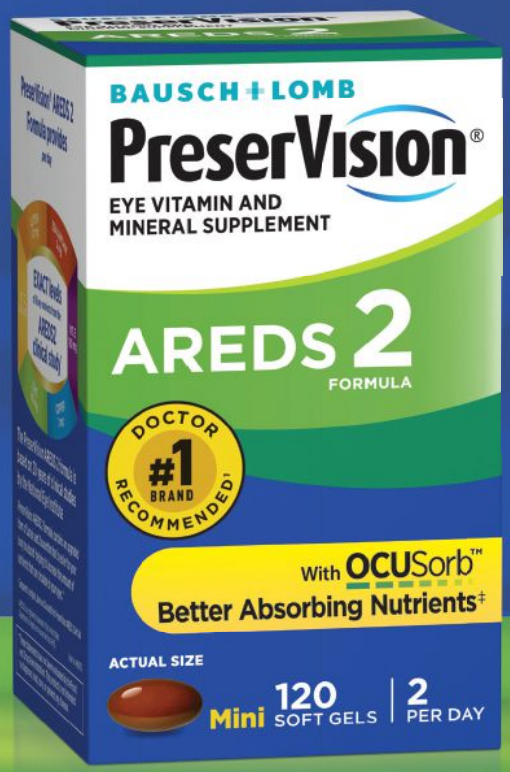

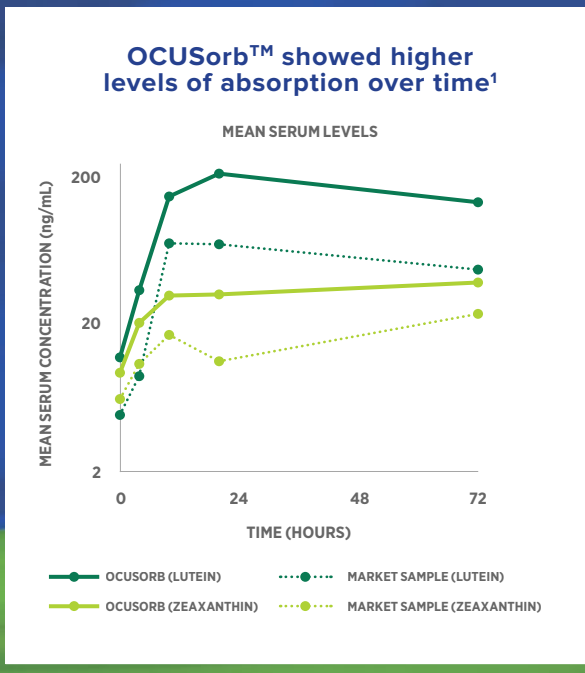

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NEI = National Eye Institute

1. Compared to the market sample. Kotagiri SR, Morde A, Rai D, et al. Ophthalmol Ther. 2022;11(4):1463-1477

‡ Compared to original lutein and zeaxanthin in PreserVision AREDS 2 Soft Gels

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BY MONTGOMERY VICKERS, OD

CHAIRSIDE

Signing Your Life Away

Here are some fun ways to present informed consent to your patients.

So, I'm in the hospital prepping for a little knee clean-out surgery. This was many years ago and all is well now ("assuming all is well" equals "my knee hurts"). The anesthesiologist came in with paperwork to review before he drugged me into submission. I kinda knew the guy, so I decided to mess with him. He said, "Monty, this is the informed consent for anesthesia and surgery. Just initial each page and sign and date the last page."

He handed me a pen. I did note that the pen was "stolen" from the Charleston Marriott hotel. Hmm, wonder if he just went to a seminar on how to drug a fellow before knee surgery?

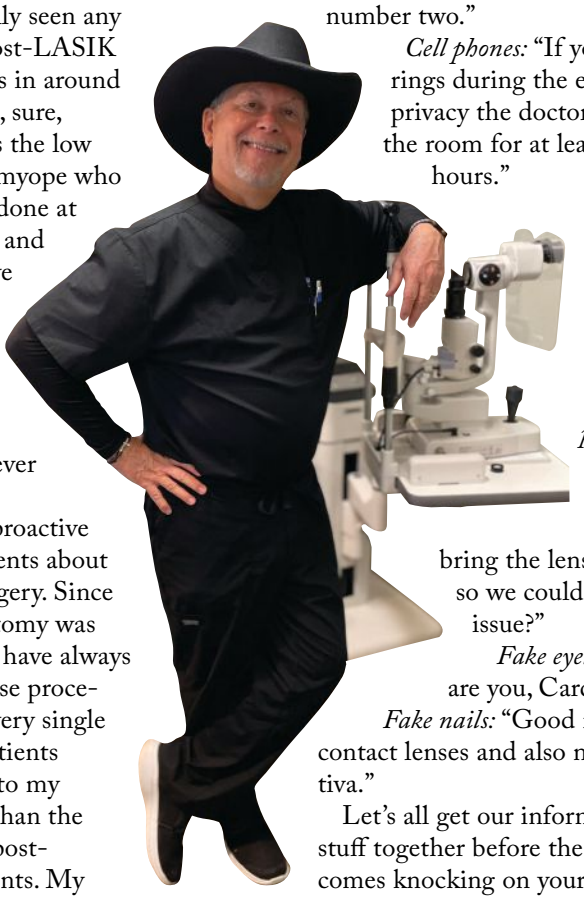
I started reading… every single word. That's probably never happened to him and he looked a little (by which I mean, a lot) annoyed. This all came to a head when I asked, "What's this line about there's a 1:10,000 chance I may die?"

The anesthesiologist reacted just like any caring physician would. He declared emphatically, "JUST SIGN IT, MAN!" Fearing that he would photograph me with my pants down for his fake Facebook account, I did just that.

The informed consent is an important tool in the toolbox. It is designed to inform the patient about the medical procedure they are about to undergo and probably—mostly—to protect the doctor against that one in 10,000 "Wow! Didn't see that coming… OK, bring in the next patient" moment.

Optometry is not that great with the presentation of informed consent. If we were, nobody in their right mind would let their kid get contact lenses and dilation would disappear from our universe in total favor of widefield imaging, right?

Now, the government (you know, the folks who always do the right thing) is forcing LASIK providers to make the refractive surgery informed consent more accurately reflect the risks of this cosmetic procedure. I haven't actually seen any significant post-LASIK complications in around 20 years. Oh, sure, there's always the low to moderate myope who gets LASIK done at the age of 43 and now they have to wear glasses all day when they never used to. Best $4,000 they ever spent?



I am very proactive with my patients about refractive surgery. Since radial keratotomy was introduced, I have always discussed these procedures with every single one of my patients who come into my office, other than the 90-year-old post-cataract patients. My favorite line? "The only time LASIK stops the normal aging process is if it kills you." To my knowledge, no one has ever died from LASIK. If they did, I would write a paper and get famous.

Of course, as mentioned above, maybe the anesthesia could kill you. That would suck.

Let's all shore up our use of the informed consent, doctors. Here are some ideas:

Visual fields: "During the test, you may feel the urge to run screaming from the room."

Gonioscopy: "If you jump backwards during the test, there will be a small surcharge for enucleation."

Refraction: "Don't blame the doctor if you chose number one instead of number two."

Cell phones: "If your cell phone rings during the exam, for your privacy the doctor will leave the room for at least one to two hours."

Crying child: "Melatonin is in the lollipop we will give your kid."

Contact lens problems: "Then why didn't you actually bring the lenses to this visit so we could figure out the issue?"

Fake eyelashes: "Who are you, Cardi B?"

Fake nails: "Good news. No lost contact lenses and also no conjunctiva."

Let's all get our informed consent stuff together before the government comes knocking on your door. ■

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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*Prescription market data, Dec. 2022 – S01K without cyclosporine.

†In a chronic dry eye patient usage study, participants from a variety of socioeconomic backgrounds answered questions about iVIZIA. There were 203 chronic dry eye patients, ranging from ages 28-80, who used their current eye drops before switching to iVIZIA for 30 days.[1]

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

Reference: 1. Data on file.

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Lighten the Load

A new drug could reduce the burdens of anti-VEGF injections.

Q Many of my patients with AMD need monthly injections. I just heard about the new drug Vabysmo (faricimab-svoa, Genentech) that extends this to every four months. What can I tell my patients?

A In the last nearly two decades intravitreal injections of anti-VEGF have become standard in treatment of neovascular (or wet) AMD, diabetic retinopathy, diabetic macular edema and retinal vein occlusion. Agents such as Lucentis (ranibizumab, Genentech) and Eylea (aflibercept, Regeneron) have shown safety and efficacy in clinical trials, and as a result, have received FDA approval for several years. Avastin (bevacizumab, Genentech) is a good inexpensive alternative and has been used frequently as a non-FDA approved agent.

"Although these remedies are effective in addressing a variety of conditions, there are pitfalls associated with the drug's duration as well as mechanism of action," says Mohammad Rafieetary, OD, of Charles Retina Institute in Germantown, TN. "The short durability of these agents results in the need for frequent injections, often once per month in many cases."

The need for repeated injections can cause several burdens and barriers, which include injection anxiety and fatigue, access to care and transportation and cost, especially to the uninsured. These factors lead to poor compliance and adherence with the treatment regimen and, subsequently, poor outcomes. Another issue is partial effectiveness. The biologic processes such as angiogenesis and vascular permeability are not just VEGF driven. There are other biological systems and chemicals, including different growth factors such as angiopoietins and platelet-derived growth factor, that can lower the effectivity of the drug. These issues have prompted a surge in research and development of alternative therapies, such as novel molecules, dosing variations and different routes of administration.

Two for One Deal

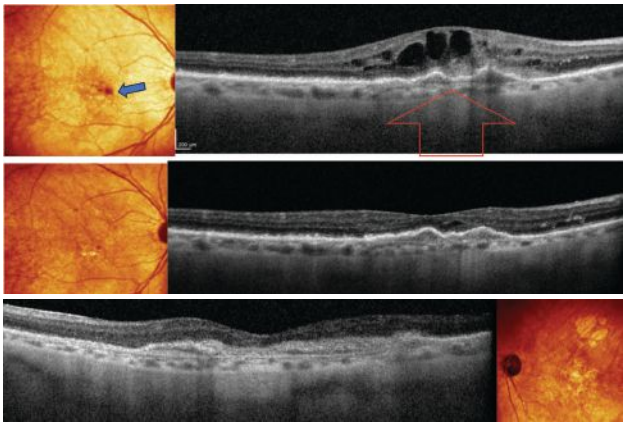
Vabysmo (faricimab, Genentech) is a biphasic agent, meaning that it has two distinct components each with a different mechanism of action. This drug targets VEGF-A and the Tie-2/angiopoietin pathway. The STAIRWAY and AVENUE studies were Phase II clinical trials that showed its efficacy for treatment of wet AMD. The BOULEVARD trial showed its superiority to monthly injections of Lucentis for DME.

Because of that, the FDA has approved the following regimens: four loading doses of 6mg (0.05mL) every four weeks (q28 days), followed by OCT and visual acuity evaluation at eight and 12 weeks, followed by a 6mg dose given in one of the following three regimens: (1) weeks 28 and 44; (2) weeks 24, 36 and 48; or (3) weeks 20, 28, 36 and 44.

"Although additional benefit was not noted in the every four week group as compared with every eight week dosing, some patients may require monthly treatment based on disease activity," Dr. Rafieetary noted.

According to him, this extended treatment strategy may improve treatment adherence by reducing the burden of frequent visits. Based on these studies and benefits, many retina specialists are switching their patients from traditional anti-VEGF to this new generation biphasic therapy when clinically appropriate and when insurance coverage is available.

"The development of novel agents and increased availability of pharmaceutical agents such as Vabysmo will improve compliance and the quality of life of patients with chronic retinal conditions such as wet AMD and DME," Dr. Rafieetary concludes. "Know what your retinal surgeon is doing so that you can properly advise patients. Some retinal specialists may not adopt this new modality as quickly as others." ■



OD fundus exam shows small subretinal hemorrhage (blue arrow) and OCT (top) is remarkable for choroidal neovascularization (CNV), as shown with red arrow. OS has a large disciform scar (bottom image). Patient received an intravitreal injection of Vabysmo. At one month follow-up, regression of CNV was noted (middle image) and VA has improved to 20/30. At this time, patient receives her second injection, with her next appointment set for three months.

1. Nicolò M, Ferro Desideri L, Vagge A, Traverso CE. Faricimab: an investigational agent targeting the Tie-2/angiopoietin pathway and VEGF-A for the treatment of retinal diseases. Expert Opin Investig Drugs. 2021;30(3):193-200.

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.

Simplify Grading and Risk Assessment in Diabetic Retinopathy

Paul Chous, MA, OD, FAAO
Chous Eyecare Associates

Ansel Johnson, OD
Vision Salon Eye Care Associates

Julie Rodman, OD, MSc, FAAO
The Eyecare Institute – Broward

What can be done to make it easier for optometrists to grade diabetic retinopathy (DR) and assess risk?

Dr. Johnson: A Diabetic Retinopathy Taskforce was formed last year, and we are currently finalizing a consensus document that will spell this out. The approach includes five pillars. In short, optometrists need to 1) detect, 2) grade, 3) assess risk, 4) manage and 5) support.
Dr. Chous: As members of that task force, I think I speak for the three of us when I say that, even from our very first meeting, we knew that grading and risk assessment are pain points in optometry. It tends to be highly subjective, can take a lot of time and skill, and therefore needed to be a central focus of our initiative.

With regard to grading, can you give us a preview of where the taskforce landed?

Dr. Chous: We all unanimously agreed that we need to grade diabetic retinopathy at the time of diagnosis and at each subsequent visit. Furthermore, we should chart structural retinal damage and quantify retinal cell function.
Dr. Rodman: Most of us already conduct grading at some level and note it in the chart. But the quantification of retinal cell function is where we see the most significant opportunity loss. Although both structure and function are useful, functional changes generally appear well before structural ones. In studies comparing the ability of ERG and structural imaging to evaluate sight-threatening DR, ERG outperformed traditional imaging at predicting which patients would likely need subsequent medical intervention.[1,2]
Dr. Johnson: Importantly, visual acuity alone is not sufficient to assess function.

What tools do you use to grade DR?

Dr. Johnson: An objective test, such as ERG, is needed. In my practice, we use the RET*eval*® device. This handheld technology is fast, reliable and easy to perform. It also generates an extremely user-friendly report that's excellent for charting purposes.
Dr. Rodman: I rely on the RET*eval* device as well. It streamlines care and gives me peace of mind. It's easy enough for my technicians to use, coding is straightforward, and the reimbursement is fair.

Moving on to risk assessment, can you give us a preview of where the taskforce landed on this as well?

Dr. Chous: This can be challenging because you want to know where the patient stands in that moment, but generating an answer about risk at a single moment in time isn't easy because different tests can tell different stories. You have to put the puzzle together to create a portrait of risk.
Dr. Johnson: This is probably the most important reason to look at both structural and objective functional measures because the two may not align and, if one of them raises alarm, we need to keep digging. Having baseline functional and structural assessments can be tremendously valuable.

What test do you use to get a baseline and to monitor for risk over time?

Dr. Chous: Dilated retinal exams are important, preferably with fundus photography and red-free filtration to detect subtle structural abnormalities, and OCT/OCTA imaging is helpful for future comparison. In terms of the functional risk assessment, initial ffERG is recommended for patients with any DR at baseline to establish a comparator if future DR worsening is detected subsequently.
Dr. Rodman: With an objective ERG test, functional signs of loss can predict progression.[1,2] Specifically, a RET*eval* DR Score of 23.4 or higher indicates an 11-fold risk of requiring medical intervention within 3 years.[2]
Dr. Johnson: This score also can guide the follow-up schedule or referral decision. (See *Monitoring and Referral Guidelines.*)

[1]Al-Otaibi H, Al-Otaibi MD, Khandekar R, et al. Transl Vis Sci Technol. 2017;6(3):3. doi:10.1167/tvst.6.3.3

[2]Brigell MG, Chiang B, Maa AY, Davis CQ. Transl Vis Sci Technol. 2020;9(9):40. doi:10.1167/tvst.9.9.40

Monitoring and Referral Guidelines

- Patients with any DR who demonstrate a RET*eval* score >23.5 should be referred to a retina specialist, particularly if NPDR severity is moderate or worse
- Patients with RET*eval* score >23.5 with what appears, clinically, to be mild NPDR, should be monitored closely or considered for referral to a retinal specialist to confirm appropriate staging of DR severity
- Patients with a RET*eval* score >26 should be referred to a retina specialist
- Patients with a RET*eval* score <23.5 with mild or moderate NPDR should have repeat examination, including repeat measure of ffERG and RET*eval* score
- Patients with mild or worse NPDR with RET*eval* score >21 should be considered for repeat ffERG/clinical exam within 6-12 months to assess for worsening severity of structural or functional abnormalities

BY JEROME SHERMAN, OD, AND SHERRY BASS, OD

YOU BE THE JUDGE

Avoid Inattention to Anisometropia

A normal DFE in an infant may not rule out a retinal disorder that can result in blindness or even death.

The American Optometric Association–sponsored InfantSee Program has been quite successful and resulted in an increase in the number of infants between six and 12 months old evaluated by optometrists. These free exams have uncovered myriad disorders including strabismus, high refractive errors, amblyopia and occasionally pathologies, such as cataracts, congenital toxoplasmosis and optic nerve hypoplasia.

It is crucial to recognize that changes in refractive error over the first few years of life may indicate a serious pathology such as an orbital or retinal tumor.

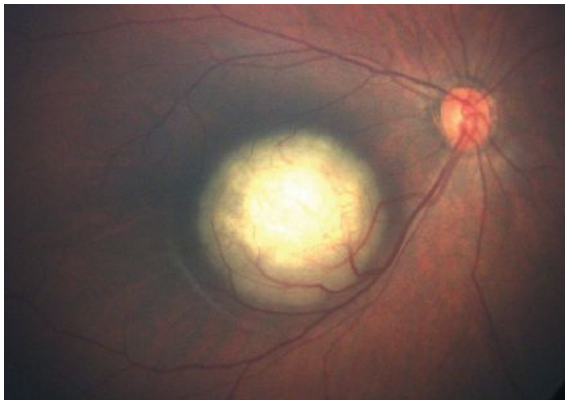


Photo: Julia Canestraro, OD

Right eye from a different patient with a retinoblastoma within the arcades and impinging on the fovea. Since the lesion includes the fovea, the axial length will decrease and the refractive error will become more hyperopic. Like the case in question, there was no retinoblastoma in the fellow eye and hence, the anisometropia will increase.

Case

Amanda was first examined by eye care practitioner (Dr. J) at seven months of age for an InfantSee exam. Her mom reported nothing unusual but heard about the free exam and thought it would be a good idea to have her youngest examined. The evaluation was rather routine, and all findings, including a dilated fundus exam (DFE) with binocular indirect ophthalmoscopy, were assessed as within normal limits. The measured refractive error was +1.50D OD and + 1.00D OS. The mom was reassured that all was okay and that glasses for the minor refractive error were not necessary now.

As recommended, the mom made an appointment a few months later before Amanda's first birthday. Again, no symptoms were reported and the exam, including a DFE, was noted as normal. The optic disc, macula, vessels and mid and far peripheral retina were judged by Dr. J as normal. The refractive error on this exam was + 3.50D OD and +1.50D OS. Both exams were performed under the same cycloplegic conditions. The mom was reassured and correction of the refractive error was discussed but not highly recommended. The OD scheduled a follow-up appointment in one year. The mom did not keep the appointment, perhaps because she recognized this exam would not be a "freebie."

About 18 months later, mom noticed what she thought was an occasional white spot in her daughter's right pupil. More recently, the dad took iPhone pictures of all four kids together and noticed that only Amanda appeared to have slightly different colored pupils. On a routine scheduled exam two weeks later, the mom mentioned it to her daughter's pediatrician. The pediatrician attempted to do an external and internal eye exam on this now fidgety, nearly three-year-old but with minimal success. He strongly recommended an exam by a new pediatric ophthalmologist in town who was very good with kids and quite thorough.

About a month before her third birthday, Amanda was examined by the pediatric ophthalmologist who was highly recommended by her pediatrician. This young and highly trained physician immediately noted the hint of a white pupil in the right eye in several positions of gaze. The DFE revealed a white mass in the macula of the right eye extending to the temporal retina. B-scan ultrasound confirmed a mass retinal lesion OD, which matched the observations made with the DFE. The fellow left eye was judged to be normal with both DFE and B-scan ultrasonography.

The pediatric ophthalmologist and several subsequent ophthalmic oncologists all agreed with the diagnosis of retinoblastoma in the right eye only.

You Be the Judge

- Should the optometrist who performed the two InfantSee exams have

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 52 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.

realized that the change in refractive error may have been a sentinel sign of an underlying problem?

- Are increases in hyperopia as common in infants as increases in myopia?
- Should the optometrist have known that anisometropia followed by a further increase in anisometropia in infants are both quite unusual and an indication of a potential problem?
- Would a like practitioner under like circumstances have provided the same level of care as this optometrist?
- Since the OD did not charge a fee for the two exams, do you agree that he cannot be held culpable of malpractice?

Comments and Our Opinion

There are two refractive error clues that often go unrecognized by many clinicians but may suggest a possible retinal, choroidal or orbital mass. The first is increasing hyperopia in the first several years of life, which contradicts the anticipated decrease in hyperopia expected in most normal infants.[1] Increases in myopia, in contrast, are somewhat more common. Even a small retinoblastoma in the macula will decrease the axial length and hence increase hyperopia. It has been reported that a 1mm change in axial length can alter the refractive error by 2.50D to 3.00D.[2] The vast majority of ODs rarely measure axial length in infants, but most of us do perform retinoscopy on almost every exam.

In a recent study of more than 12,000 newborns, researchers concluded that "anisometropia is present in a very limited number of cases, reported as 0.01%."[3] Knowledge of this study may prove to be vital in select cases to prevent blindness and perhaps death.

Anisometropia in an infant followed by a further increase in anisometropia six months later would be most applicable to unilateral or bilateral (but asymmetric) retinoblastoma. An orbital tumor compressing the posterior pole of the globe can also result in anisometropia.

In this case, the hyperopia increased by 2.00D OD and 0.50D OS and the anisometropia increased from 0.50D to 2.00D.

Would a like practitioner under like circumstances recognize these changes as a red flag? Unsure, I (JS) very recently decided to ask my new associate, Diana Geraghty, OD, (who graduated from SUNY Optometry in June 2023, as the #1 in her class of nearly 100) about these findings. Dr. G thought for a moment, and then this humble superstar responded that, with a normal DFE, she would have attributed these refractive error findings to her less-than-perfect retinoscopy. Of course, we will never know in this case whether the retinoblastoma OD was or was not visible with a routine DFE with binocular indirect ophthalmoscopy.

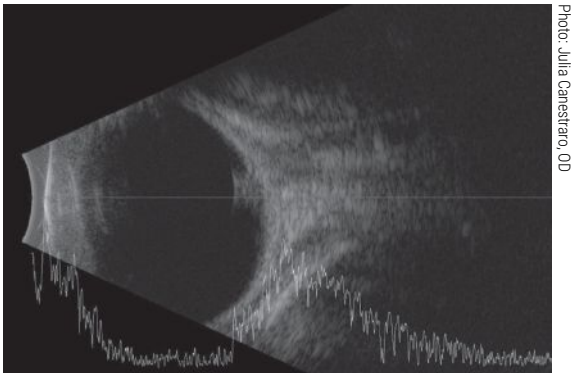


Photo: Julia Canestraro, OD

The B-scan reveals a mass in the posterior pole and close to the optic nerve head.

In many cases of alleged malpractice, most reasonable clinicians and experts can agree when the care rendered clearly deviated from the acceptable standard. In this unfortunate case, it is far more difficult to conclude culpability, or lack thereof.

Most legal and health experts will argue that it matters little or none at all if the exam was performed as a "freebie." Once a doctor enters into a patient/doctor relationship, the doctor has the responsibility to provide care at the existing standard, regardless of the fee. However, if such a case goes to trial, a jury member may take that into account and have sympathy for the doctor. In a minority of states, a unanimous verdict is required for civil cases, such as malpractice allegations.

Follow-up

Amanda was taken by her parents from specialist to specialist in surrounding states. The final decision was to enucleate the right eye. The left eye remains tumor free. Amanda can wear her prosthetic eye successfully but on rare occasions it dislodges at school, and she is then quite embarrassed.

Not surprisingly, a lawsuit was filed based upon the premise that a diagnosis two or so years earlier could have resulted in successful treatment without sacrificing the eye. Numerous experts gave depositions via Zoom with contradictory opinions. Prior to a jury trial, the case was settled for an amount alleged to be shy of a million dollars. We wish Amanda, her family and the optometrist the best.

Note: A review of the world's literature reveals that David Abramson, MD, chief of Ophthalmic Oncology Service at Memorial Sloan Kettering Cancer Center, is perhaps the world's most experienced specialist in treating retinoblastoma. He is credited with developing several procedures that have spared many infants from enucleation. More recently, this procedure has been modified to be used for bilateral retinoblastoma. ■

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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.

BY MARC B. TAUB, OD, MS, EdD, AND PAMELA H. SCHNELL, OD

Visuoscopy Review

The dusting off of rarely used techniques can prove more useful than initially meets the eye.

As students—regardless of which optometry school we attended—we all went through similar educational programs. Our earliest semesters involved hours of didactic work, including both classroom and laboratory activities. In the optometric theory and methods sequence at most schools, all of the basic testing procedures are taught in just a few semesters, with refinements to our skills coming as we entered clinical rotations. As we learned so much in such a relatively short time frame, it makes sense that some lesser-used techniques may have been forgotten and are no longer used in our day-to-day practice.

One such procedure is visuoscopy, a quick way to determine whether or not a patient is fixating appropriately with their fovea. The technique can be an invaluable method for evaluating odd or confusing decreases in visual acuity (VA) and, as such, is one that bears reviewing.

Brushing Up

While we often think of visuoscopy as a technique reserved exclusively for doctors who practice vision therapy, it can be useful for any practitioner who wants to assess a patient's fixation quickly.

In order to perform visuoscopy, you only need a working direct ophthalmoscope that has a graduated, built-in reticule target; most ophthalmoscopes do. Different brands have different targets, but all are useful for the technique as long as you know how many prism diopters are represented by each of the gradations in your particular instrument. This information can be found online or in the manual that came with your ophthalmoscope—if you still have it! *Figure 1* shows the visuoscopy targets from several commercially available directs.

Visuoscopy can be used to evaluate not only the steadiness (or lack thereof) of a patient's fixation, but it can also help you to determine whether there is either a microesotropia (defined as an esotropia of between one and 10 prism diopters that has an accompanying foveal suppression) or a small central scotoma present.[1-3] Both of these clinical presentations are easy to miss with standard testing procedures, since the small angles in microesotropia are often cosmetically unnoticed and peripheral fusion is usually good. As a result, we can often be left with unexplained decreases in VA.

The procedure itself is simple, but it may require a bit of practice if you don't routinely perform direct on patients. Not to worry, muscle memory comes back quickly. I (PS) spend the vast majority of my clinic time at Southern College of Optometry in pediatrics and vision therapy, so I have the opportunity to practice the technique on a regular basis—and I'm also one of the strabismus and amblyopia lab instructors at SCO. I know that this makes me biased, but I believe that everyone can learn or refresh this skill with relative ease.

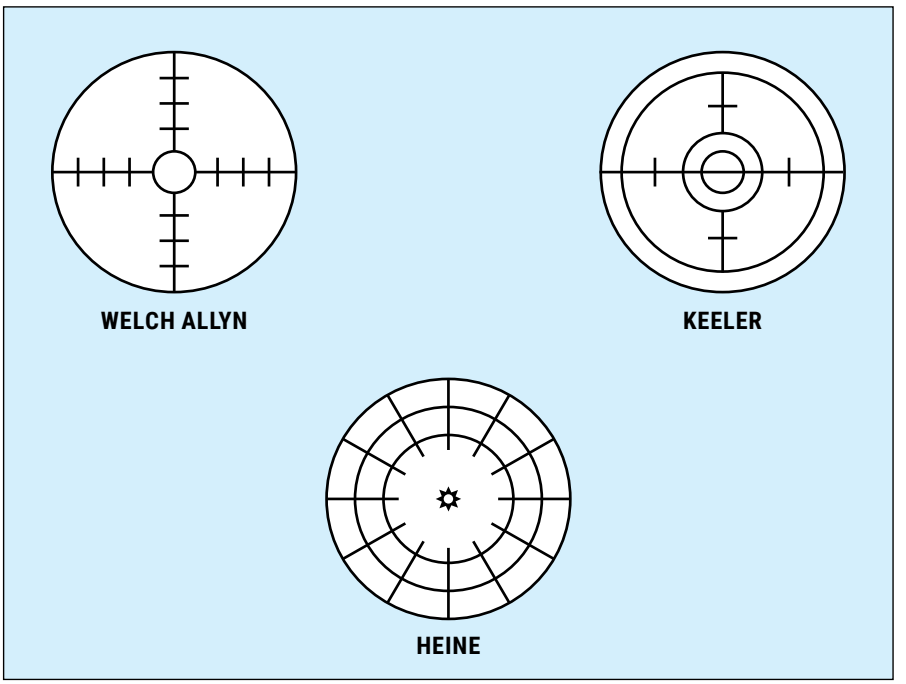

Fig. 1. Visuoscopy targets from several commercially available direct ophthalmoscopes.

About Drs. Taub and Schnell

Dr. Taub is a professor, chief of the Vision Therapy and Rehabilitation service and co-supervisor of the Vision Therapy and Pediatrics residency at Southern College of Optometry (SCO) in Memphis. He specializes in vision therapy, pediatrics and brain injury. **Dr. Schnell** is an associate professor at SCO and teaches courses on ocular motility and vision therapy. She works in the pediatric and vision therapy clinics and is co-supervisor of the Vision Therapy and Pediatrics residency. Her clinical interests include infant and toddler eye care, vision therapy, visual development and the treatment and management of special populations. They have no financial interests to disclose.

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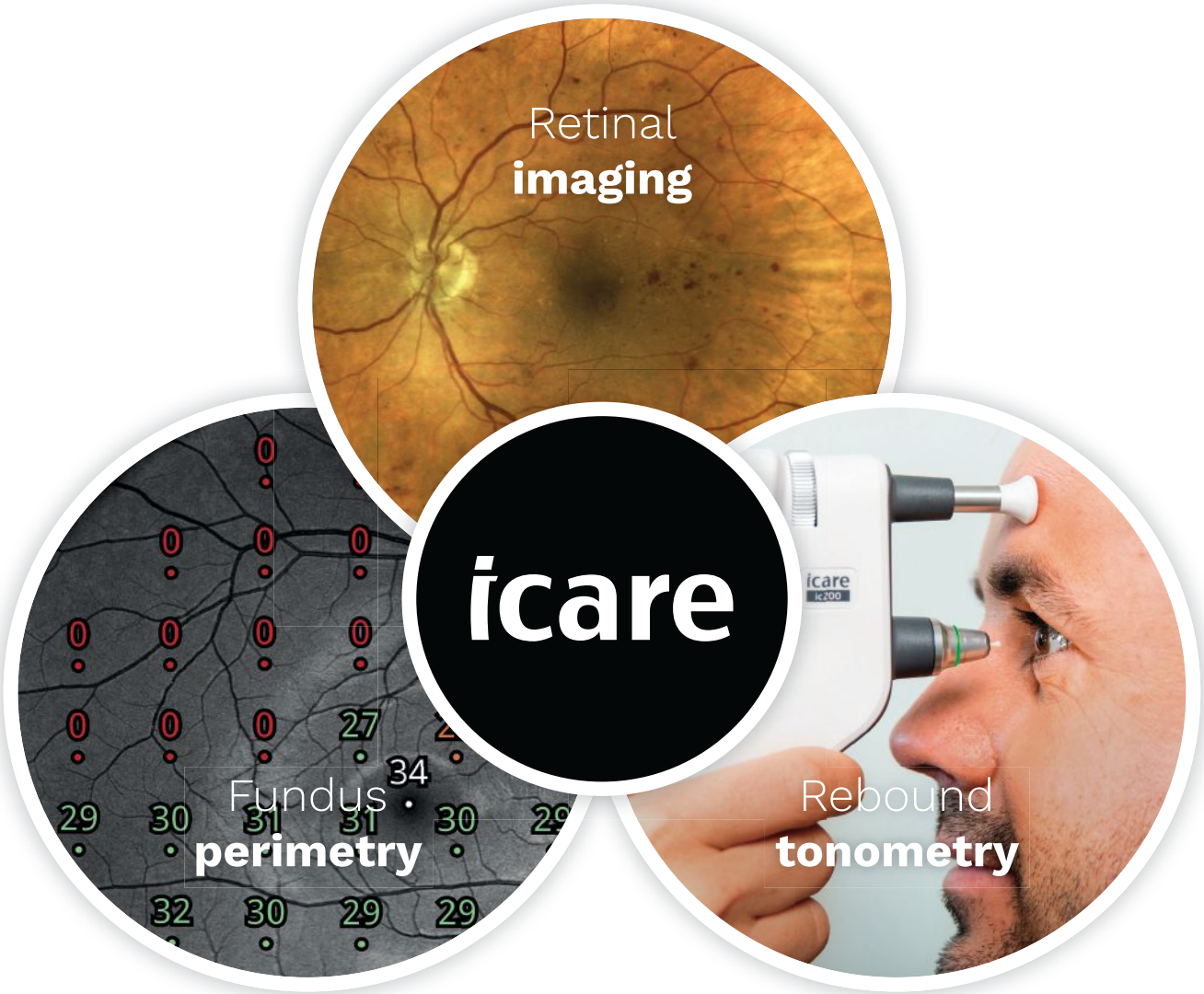

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An Answer to Digital Eye Strain

Eye care professionals can leverage **CooperVision® MyDay Energys® and Biofinity Energys®** contact lenses to address eye tiredness and dryness associated with digital eye strain—and as a tool for building their practice.

Americans spend a significant amount of time throughout the day on digital screens[1]—we are all on, all the time. Patients of all ages rely on digital devices to stay connected, productive, educated and entertained, and sometimes all at once. In fact, nearly 67% of adults reported using two or more digital devices simultaneously.[2]

THE ISSUE: DIGITAL EYE STRAIN

The hours spent fixated on screens can take a toll on the eyes. Digital eye strain is the ocular discomfort—including dryness and tiredness—that is felt after two or more hours on digital devices.[3] And today's patients are seeking solutions.

THE OPPORTUNITY: HELP PATIENTS ADDRESS THE SYMPTOMS

As a trusted resource for patients, eye care professionals have a unique opportunity to educate about digital eye strain and help them address some symptoms of digital eye strain.[6‡]

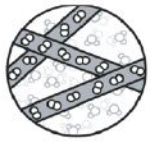
Nearly **4 out of 5** contact lens wearers are interested in knowing more about reducing eye strain/tiredness associated with digital devices[4]

Fewer than **1 of 4** adults said that their eye care professional had ever talked to them about digital device use and its effect on the eyes[5]

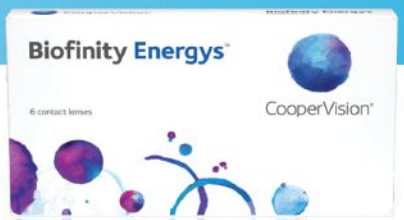
THE ANSWER: MYDAY ENERGYS® AND BIOFINITY ENERGYS®

MyDay Energys® and Biofinity Energys® combine an innovative aspheric design and material technology to help eye tiredness and dryness associated with digital eye strain.

DigitalBoost™ single vision aspheric design delivers a +0.3D boost of power that may help ease strain on eye muscles so the wearer can shift focus from on screen to off screen with less effort.[7†]



Aquaform® Technology hydrates contact lenses to twice their weight in water for natural wettability[8] and incredible comfort, which can help eyes feel less dry, even during times of reduced blinking.



8 out of 10 patients agree that **MyDay Energys®** and **Biofinity Energys®** lenses help reduce eye tiredness associated with digital eye strain.[9,10]

Contact lens wearers reported **reduced eye tiredness and dryness** after wearing **MyDay Energys®** compared to their habitual contact lenses.*[11]

Patients experiencing eye tiredness and dryness had **high overall satisfaction** when wearing **Biofinity Energys®** with their level of digital eye strain.[12]

THE FUTURE: PRACTICE GROWTH

With this innovative contact lens technology now available in both the monthly and 1-day modalities, eye care practices can meet the vision correction needs of more patients experiencing digital eye strain.

"Being in the heart of the Silicon Valley, we are known in the community for offering the best and the latest technology. Our patients expect us to bring that to them," said Nikki Iravani, OD, of EyeXam in Santa Clara, Calif. "We have always liked Biofinity Energys® in our practice because of the lens design and its benefits for digital device users. Now, having that available in a 1-day with MyDay Energys®—this was the missing piece that I can now offer to a wider spectrum of patients. These lenses are great additions to my toolbox."

Nikki Iravani, OD

"We see patients come in every day asking for a solution [to digital eye strain], and CooperVision has given it to us," said Torrey Carlson, OD, of Dr. Carlson & Associates in Johnson City, Tenn. "Put these lenses on some eyes. They are a huge practice builder."

Torrey Carlson, OD

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LEARN MORE

† Based on a statistically significant difference of the mean change in Accommodative Microfluctuations and when compared to a lens without DigitalBoost™/Digital Zone Optics® after reading on an iPhone 5 for 20 minutes held at a distance of 25 cm. Study conducted with Biofinity Energys and sphere. ‡ Experience symptoms of digital eye strain 3.0/5 vs overall comfort after 1 week daily wear with MyDay Energys® 3.4/5 (statistically significant $p<0.05$). Scored on a scale from 1-5 with 1=always, 5=never. Common symptoms of digital eye strain include eye tiredness and dryness. * Experience symptoms of digital eye strain 3.0/5 vs overall comfort after 1 week daily wear with MyDay Energys® 3.4/5 (statistically significant $p<0.05$).

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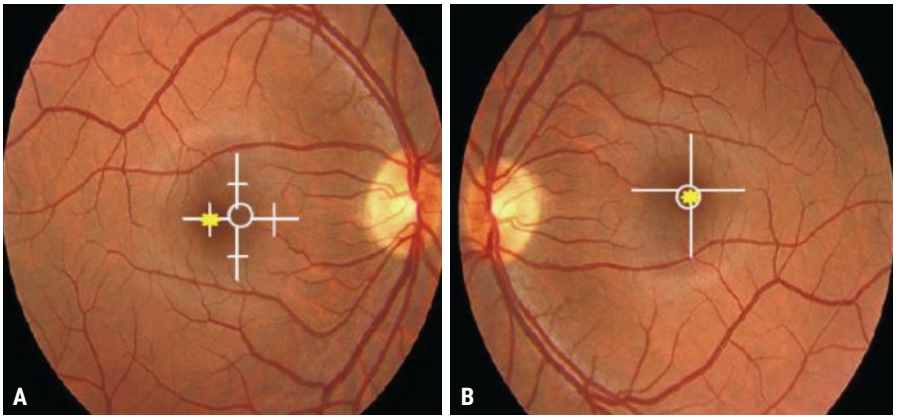

Fig. 2. (A) Approximately one prism diopter nasal EF in the right eye; (B) Central fixation (no EF) in the left eye.

My particular visuoscopy procedure is as follows:

1. Have the patient seated comfortably in the exam chair (or standing, as needed for some children) and occlude the eye not being observed/tested.

2. Show the patient your visuoscopy target, either on the wall or on your hand, so that they know what they'll be asked to look for.

3. Focus your view on the patient's optic nerve just as you would for standard direct ophthalmoscopy.

4. Once in focus, move over to the patient's fovea and ask them to fixate the center of your target as steadily as they can. For some targets, the center is a small circle; in others, there is a star for the patient to locate.

5. Assess the various attributes of the patient's fixation and document accordingly.

When we perform visuoscopy, we assess several aspects of the patient's fixation ability. First and foremost, of course, we need to determine whether the macula is healthy. If there is noticeable pathology present, appropriate follow-up testing should be run. Once we see that the macula and fovea are healthy, we can ask ourselves the other important questions;

• ***Is the patient fixating centrally?*** Do they actually use their fovea for fixation, or are they fixating with an eccentric point?

• ***If the patient is not fixating centrally but is instead exhibiting eccentric fixation (EF), what is the magnitude?*** How far off of the fovea is their eccentric point, and in what direction does it lie? The magnitude of EF is determined by assessing where on the target the patient's foveal light reflex appears, relative to the center of your particular visuoscopy target.

The question I pose to my students to help them make this determination is, "What part of the retina is the patient using to fixate instead of their fovea?" This helps them to be able to document superior/inferior, nasal/temporal correctly. *Figure 2* shows examples of EF and how they are documented.

• ***Is the patient's fixation steady or unsteady?*** This question is pertinent regardless of whether fixation is central or eccentric. Even when foveal fixation is seen, unsteadiness can cause a mild drop in acuity. (Of course, the steadier a patient's fixation is, if they happen to show EF the harder it can be to remediate with vision therapy, but that's another column!)

If you determine that your patient is showing EF, you can predict their best-corrected VA (BCVA) using this formula:

Expected VA = 20/(EF in prism diopters + 1) x 20

For a patient who is showing two prism diopters of EF, this would equal an estimated BCVA of 20/(2 + 1) x 20, or 20/60. Granted, this is an estimate, but it will give you a place to start to determine whether the patient's drop in VA makes sense.

Case

To illustrate how useful visuoscopy can be, I'll share an example from a recent clinic day. In the summer semester, third-year interns at SCO are taking their Amblyopia & Strabismus course, as well as beginning clinical care. Once we cover visuoscopy in the lab portion, I generally have my interns practice the technique in-clinic when they dilate patients, since it's much easier to learn through a dilated pupil. As fate would have it, a patient presented who had a BCVA of 20/15 OD but only 20/30-2 OS. Chair skills were all normal. Retinoscopy and refraction were similar, around +0.50 DS in each eye. Anterior segment evaluation showed mild allergic conjunctivitis OU (we do live in Memphis, after all) but was otherwise unremarkable.

No obvious cause could be found for the mild decrease in VA OS, so we dilated the patient and planned a post-DFE retinoscopy to see whether there was additional refractive error in the left eye that might account for the asymmetry. All posterior segment findings appeared negative, but we still didn't have an explanation for the decrease OS. Call me proud—before I could suggest it, my intern asked, "What about trying visuoscopy?" Sure enough, we saw an unsteady EF of about 0.5PD temporal to the fovea, which lined up perfectly with our expected VA from the formula. Not only was the patient spared additional testing, we were able to send them for a vision therapy evaluation to determine whether their condition could be improved. The student in question, of course, got an A for the day!

Visuoscopy may not be a technique you'll need often, but it can be invaluable when there's an unexplained drop in VA. Quick and simple to perform, it not only can provide an explanation but can help guide your management in the best way possible for the patient. Pull out your direct and give it a try! ■

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BOOST YOUR FIRST-FIT SUCCESS RATES

Here's how to prevent and address common reasons for dropout in new contact lens wearers.

BY THOMAS STOKKERMANS, OD, MS, PhD,[1] AND DEREK LOUIE, MSc, OD[2]
[1] CLEVELAND, OH, [2] PORTLAND, OR

A successful initial contact lens fitting is not the experience of many patients. In fact, a recent study that evaluated the incidence of contact lens discontinuation and associated factors in neophyte wearers found that nearly half of patients who stopped wearing their newly fitted lenses did so within the first two months.[1] The most common reasons reported by participants included poor vision (42%), handling problems (15%) and discomfort (14%). Importantly, most patients in this study (71%) were not offered any alternative lens or management strategy, which also contributes to early lens dropout.[1]

What can we do as clinicians to reduce neophyte dropout? There is a host of factors to consider when selecting the most appropriate contact lens for a patient including vision goals and expectations, type and severity of refractive error, ocular surface health, age and lifestyle, to name a few. In this article, we discuss how to get ahead of the common causes of early lens discontinuation and stack the odds in your favor even for your more challenging patients.

1. Vision Concerns

Let's begin by discussing the primary reason why patients discontinue contact lens wear: quality of vision.[2] There are numerous circumstances that could cause a patient to be unsatisfied with the vision provided by their new lenses, including unmet (or undiscussed) vision goals and expectations, misleading in-clinic vs. real-world visual experience and fitting challenges specific to certain types of refractive errors.

Below, we discuss the potential culprits of poor vision to look out for in various types of contact lens wearers.

Goals and Expectations

One of the most important responsibilities that influences first-fit success is the need to ensure reasonable expectations of vision performance are set before selecting a contact lens. It is essential to ask the patient about their visual goals, a discussion that will invariably include the patient's type of work, hobbies and recreational activities that may influence the successful use of contact lenses.

Besides obtaining sharp vision at all distances, visual goals may include the reduction of glare, UV protection, reduction of spectacle-related distortion and cosmesis and avoidance of fogging of spectacle lenses (as became an important concern following the mask mandates that began during the COVID-19 pandemic).[3] In addition, a discussion on the steps involved in the fitting process may help patients understand what to expect.[4]

Once a contact lens is selected, a brief review of the level of vision the patient should anticipate may help set realistic expectations. It's also helpful to communicate to patients that they should schedule a follow-up or call the clinic if expectations aren't being met for an opportunity to troubleshoot or try an alternative lens.

About the authors

Dr. Stokkermans is an associate professor at the Case Western Reserve School of Medicine, director of optometric services at University Hospitals Cleveland Medical Center and an adjunct faculty member of five optometry schools in the US. He is a fellow of the American Academy of Optometry, the chief editor of Advanced Medical Care at www.statpearls.com and a medical writer and reviewer at www.allaboutvision.com. He has participated in over 30 contact lens trials. He discloses financial relationships with Biotissue and Tarsus. **Dr. Louie** is a professor of ophthalmology at the Casey Eye Institute at Oregon Health & Science University, where he is the director of the Medical Contact Lens Service, Optometric Services and the Medical Contact Lens Fellowship Program. He is also a fellow of the AAO.

In-clinic vs. Real-world

The in-clinic visual experience with diagnostic lenses should mimic actual wear as much as possible. Researchers studying patient acceptance of multifocal vs. monovision contact lenses emphasized this when it became clear from the study that patients' in-clinic experience was better with monovision contact lenses, but their real-world experience was better with multifocal contact lenses.[5] Be aware that conditions (such as lighting, working distance and availability of expert advice) in the clinic are usually skewed to provide a good experience, but that testing the lenses in the "real world" may change the patient's experience of the trial lenses.[5]

Astigmatism

Neophyte contact lens wearers with astigmatism are significantly more likely to discontinue wearing their new toric contact lenses compared with those requiring spherical correction.[6,7] However, patients with low amounts of astigmatism (1D and lower) should be offered the benefit of a toric contact lens, as objective, subjective, high-contrast and low-contrast visual acuity have all been shown to be superior to correction with spherical lenses in these cases.[8,9] It has also been shown that driving performance—a task that demands good distance correction—is better when low amounts of astigmatism are corrected with contact lenses.[10] Thinking that high-modulus lenses or aspheric lenses will mask small amounts of astigmatism was shown to be a myth and should not be used as an alternative to correcting low amounts of astigmatism.[11]

What about higher amounts of astigmatism? It's important to have trial lenses on the eye and determine rotation after the lenses have settled. The higher the astigmatic correction, the more rotation of the lenses will degrade visual acuity with every 10° of rotation of a 1.75D astigmatic lens causing an additional 0.75D of residual astigmatism.[12] LARS adjustment of the axis of the new trial lens can be a solution. This only applies if the lens is truly stable on the eye, and changing to another lens with a different toric stabilization design may be a better option (*Figure 1*).

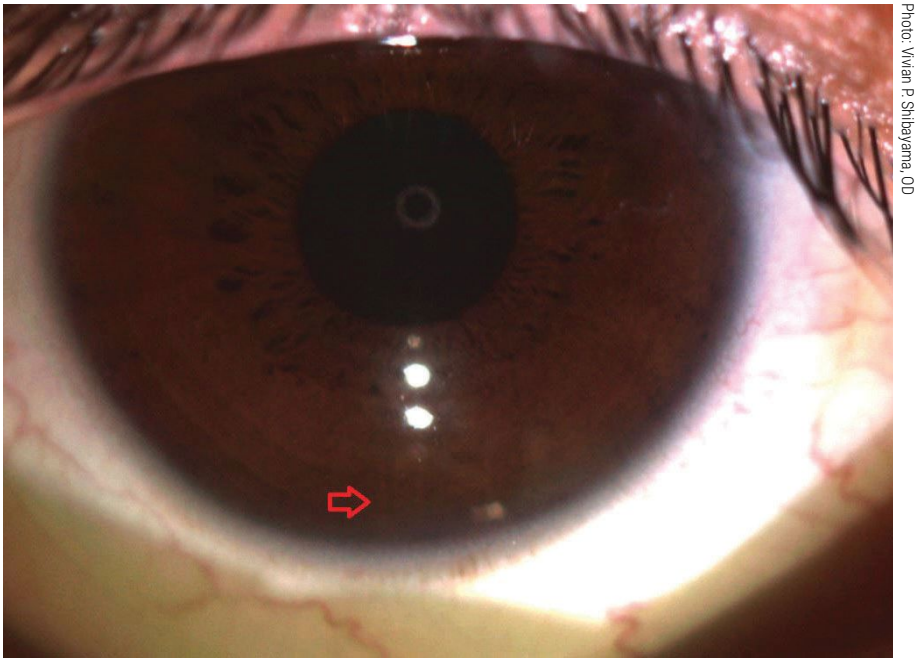


Photo: Vivian P. Shibayama, OD

Fig. 1. Determining the appropriate cylinder axis is essential to ensure the best quality of vision. Pictured here is a soft toric lens aligned at six o'clock.

Presbyopia

Providing a comprehensive approach to lens fitting for presbyopia can be an invaluable practice builder. An approach tailored to the needs of the patient is most successful, which starts by recognizing the multiple options available that include multifocal, monovision and distance-vision contact lenses with reading glasses (*Figure 2*). The OD needs to keep in mind that neophyte dropout is highest for multifocal contact lens wearers when compared with toric and spherical lens wearers.[1]

All these options should be considered and discussed briefly; however, one option should be presented to the patient as the top choice based on the individual's characteristics and vision goals and needs. The following factors should be taken into account when choosing the most ideal lens for each patient:[13]

- Range of vision
- Binocular balance between eyes
- Dependence on reading glasses
- Clarity of vision
- Available range of contact lens parameters
- Impact of cost

Also consider and remind patients that an adaptation period of up to 15 days may be required to acclimate to multifocal lenses.[14] When one option is deemed less than optimal by the patient, adjustments can be made as shown in the "presbyopia triangle" in *Figure 2*.

Other tips to increase the chance of success are to keep patients mildly undercorrected in both eyes—as long as distance acuity stays 20/20—or to prescribe a spectacle option to enhance distance acuity that can be worn over undercorrected, multifocal or monovision contact lenses. Patients should understand the impact the distance of their reading material has on acuity, as well as the trade-off between distance vision clarity and the increasing presbyopic add power.[15]

Those patients who regularly experience mild near blur or strain in single vision contact lenses may benefit from the introduction of a low multifocal add so that future incremental changes

can be made more easily as presbyopia progresses.

Practitioner preference has certainly changed in the past decade with fitting multifocal lenses becoming increasingly popular (80% in 2021 vs. 63% in 2020) and a drop-off in monovision fits (14% in 2021 vs. 28% in 2020) and spectacles combined with contact lenses (6% in 2021 vs. 9% in 2020).[16]

Evaluating presbyopic patients for first-time success with contact lenses is what makes the practice of prescribing these lenses both art and science.

Other Refractive Errors

There are generally good options available in our trial lens sets when the spherical power is between -12D and +8D, cyl power is below 2.75D and the bifocal add is no more than 2.50D. When the refractive error surpasses these cutoffs or if oblique astigmatism is present, an empirical diagnostic lens order may be necessary. In these cases, patients should be made aware that the optimal on-eye experience will be delayed and an overrefraction and slit-lamp exam at the initial evaluation may necessitate another lens order.

To avoid vertex adjustment errors when a spherical trial lens order is based on the refraction, place the closest available power contact lens on the eye and perform a careful sphero-cylindrical overrefraction. If the overrefraction is under 4D, a vertex adjustment is not necessary. Otherwise, measure the vertex distance of the overrefraction, making sure that each meridian is individually vertex-adjusted to ensure greatest accuracy. Similarly, for cylindrical powers that must be empirically ordered, the closest cylinder power with the same axis as the one that will be ordered should be placed on the eye to assess fit and rotation. This overrefraction can avoid additional orders and time by maximizing the likelihood that the new trial lens is the correct prescription. If the lens is unstable on initial evaluation with the lower power, then a different toric lens design or manufacture should be considered.[17]

Enough Options?

Many patients—particularly those with little or no knowledge or experience with contact lenses—won't know which options are available unless we educate or, better yet, show them. This is why it's crucial to have a wide and comprehensive stock of diagnostic contact lenses on-hand in your practice. Allowing patients to try multiple types of lenses in-clinic will provide them with more options to choose from to help find the one best suited for their unique needs and desired level of vision.

Introducing both an entry level and a premium lens option or even a "good, better, best" approach and dispensing trial lenses can greatly help patients gauge their level of satisfaction for

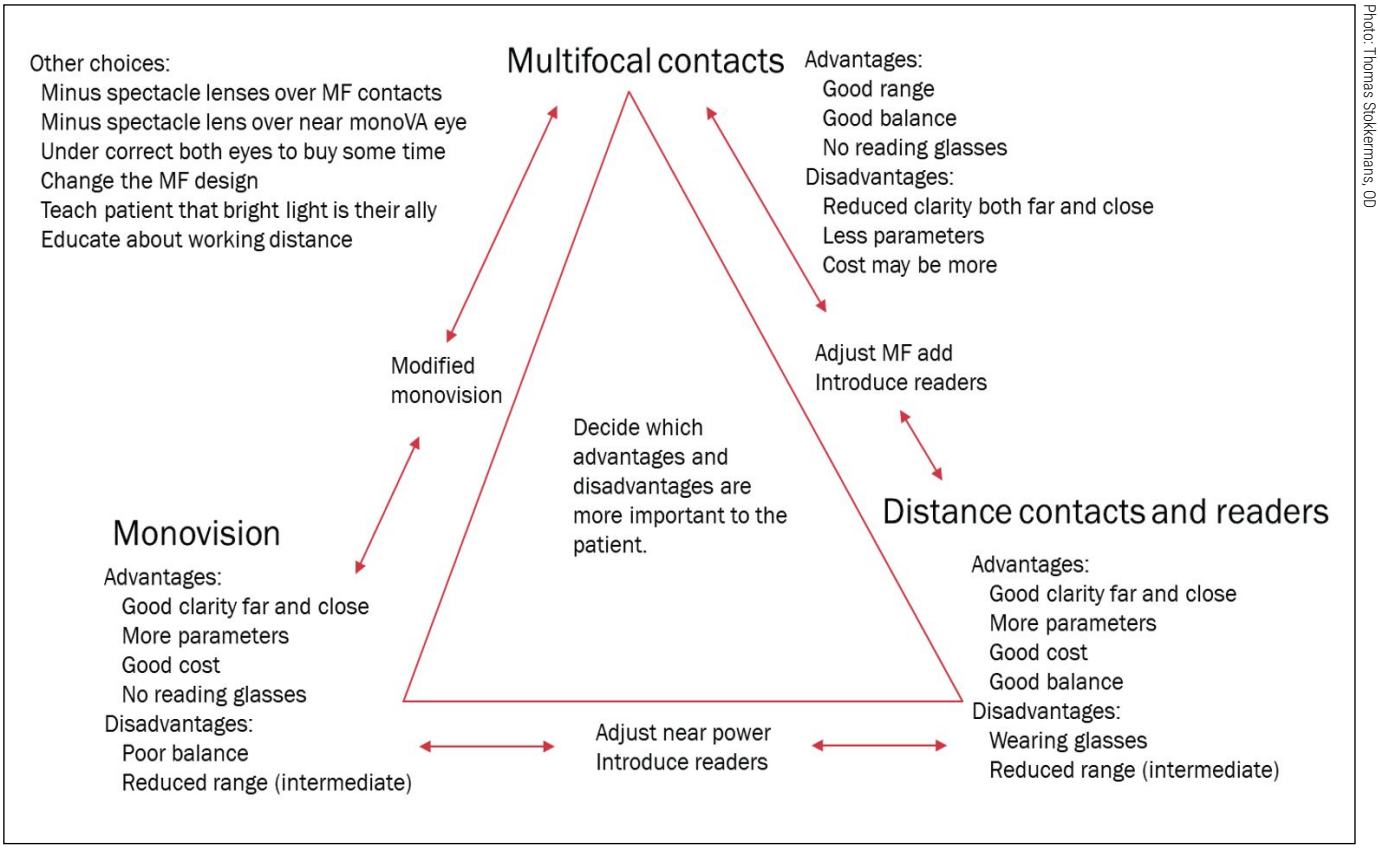
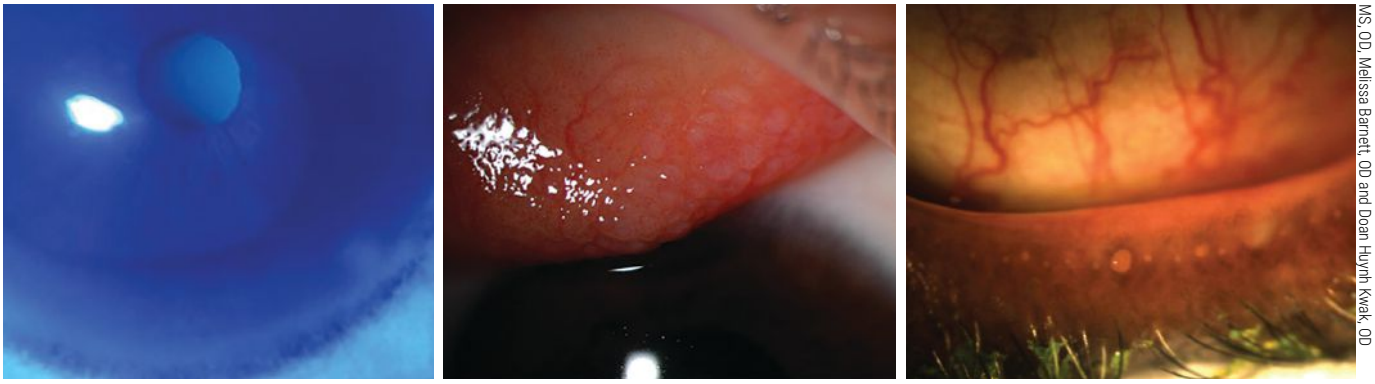


Photo: Thomas Stokkermans, OD

Fig. 2. Dr. Stokkermans created this "presbyopia triangle," which he uses to teach his optometry students about the different options available for presbyopes interested in contact lenses. (Note: "MF" refers to "multifocal).



Photos left to right: Elyse L. Chaglasian, OD, Tammy Than, MS, OD, Melissa Barnett, OD and Doan Huynh Kwak, OD

Fig. 3. Different ocular conditions affecting the ability to wear contact lenses will have to be treated prior to the intial fitting and will require a specific fitting approach (left to right: keratoconus with Fleisher ring, giant papillary conjunctivitis and meibomian gland dysfunction).

each. The same holds true for providing different presbyopia options (*e.g.*, a low multifocal add in both eyes along with a high multifocal add as a second option for the nondominant eye).[18]

Careful consideration should be given to the potential downsides of this approach, as it may devalue the contact lens practitioner's perceived expertise. Additionally, self-selected choices may cause confusion for those with no prior contact lens experience, or the patient may lose track of which lens they are wearing.

2. Handling Problems

An inability or unwillingness to properly handle contact lenses contributes to nearly one in six cases of lens dropout within the first two months.[1] A practical way to prevent or reduce this issue is by increasing in-clinic patient education. A successful application and removal (A&R) training class to ensure patients are comfortable with handling their lenses is essential to avoid rejection at the initial fit or subsequent contact lens dropout.

In older adult first-time wearers, decreased dexterity and sensitivity may be associated with an inability to adequately apply and remove lenses. Even following A&R training, patients may not be ideal candidates for full-time contact lens wear if they are unable to handle them safely and properly. Comorbid ocular disease may also influence success and increase discomfort upon insertion and removal. Careful management of underlying risk factors should be discussed upfront to ensure future expectations of contact lens wear and upkeep will be met.[19]

> **To avoid vertex adjustment errors when a spherical trial lens order is based on the refraction, place the closest available power contact lens on the eye and perform a careful sphero-cylindrical overrefraction.**

While young children may need more training and practice to comfortably insert and remove their lenses, one study found that patients as young as eight are able to successfully handle soft contact lenses with only 5% requiring an additional training class and only 2% unable to wear the lenses due to inability of handling.[20]

A&R training on the day of the fit allows you to make immediate changes in lens parameters to account for the patient's ability to handle the lenses. For example, noticing during training that a patient quickly rips a lens may prompt a switch to a material with a different lens modulus. A patient who cannot remove a lens because it feels too slippery may benefit from one with lower lubricity and modulus or a different edge design.[21] This is another reason why ensuring you have a wide assortment of diagnostic contact lenses in your practice is essential for first-fit success.

Follow-up visits will allow for adjustment of the trial lenses and to address concerns that may have arisen during the trial wear period. These visits have been on the decline due to practitioner perception that newer-generation lenses are safer with less complications, as well as the temporary reduction in access to eye care throughout the COVID-19 pandemic.[22]

The fact that 71% of patients who dropped out of contact lens wear were never offered an alternative lens—according to the study cited in this article's introduction—drives home the need for clinicians to make a greater effort to find solutions to the problems leading to patient dissatisfaction.[1]

3. Discomfort

The third leading cause of neophyte dropout in contact lens wearers is ocular discomfort. It's a two-way street: contact lenses can impact the ocular surface, and the ocular surface can impact the success of first-fit contact lenses.[23] Both the type of lens prescribed and the presence of diagnosed or undiagnosed ocular disease can affect the initial and long-term comfort of contact lenses. A thorough evaluation and history can uncover ocular and general health conditions that will need to be addressed to achieve initial-fit success. Depending on the condition's severity and the patient's desire to wear contact lenses, the ocular and systemic conditions may need to be managed prior to introducing the first contact lens.

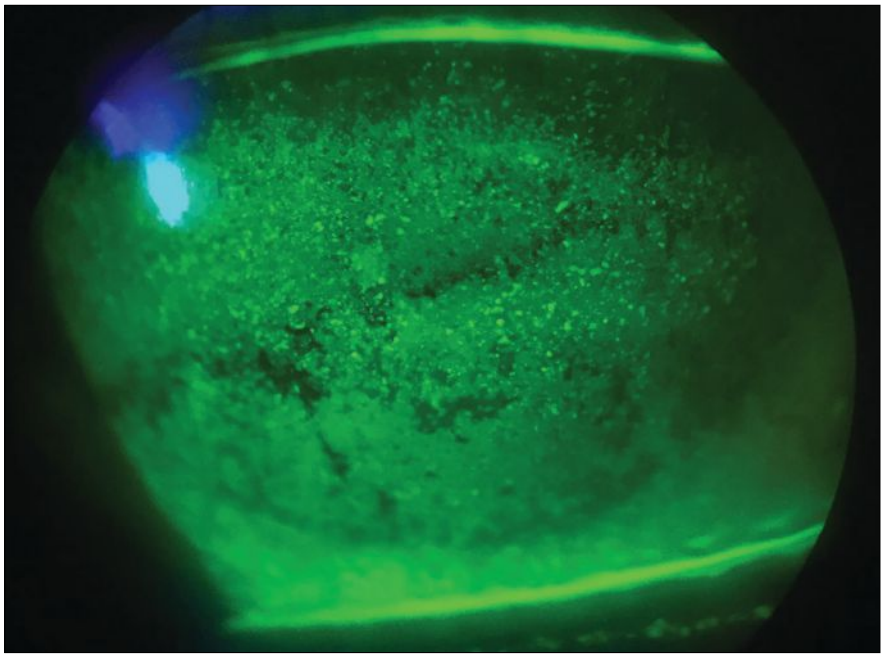


Photo: Alexandra Wiechmann, OD

Fig. 4. Patients with signs and/or symptoms of dry eye may need to be evaluated and treated prior to contact lens selection and fitting.

Type of Lens

In 2021, 43% of all contact lens wearers were prescribed daily disposables in the United States, a percentage that has been creeping up especially in recent years.[24] Subjective comfort is generally better for daily disposable lenses compared with reusable ones.[25] However, other attributes of daily disposable lenses such as parameters, diameter and material need to be considered when deciding to fit a daily disposable lens to provide the best comfort.

Lens material can affect comfort of wear, though the evidence is not definitive due to confounding factors. In 2022, the majority (58%) of all fits were with silicone hydrogel (SiHy) lenses, which have been reported to improve comfort and extend the number of hours the lenses can comfortably be worn.[26,27] However, a meta-analysis of multiple studies revealed that SiHy lenses do not necessarily provide superior comfort, but rather, similar to daily disposable lenses, other parameters all play an important role, such as lens design and material, replacement regimen and the type of lens cleaner.[28]

Dry Eye and Blepharitis

While the treatment and management of dry eye and blepharitis is beyond the scope of this article, these conditions that affect the ocular surface should be carefully evaluated and treated before or concurrently when prescribing any contact lens (*Figure 4*). A decreased tear break-up time and increased tear evaporation have been associated with dry eye symptoms during contact lens wear.[29]

Many studies suggest that patients with existing dry eye disease and blepharitis achieve the best comfort when fit with daily disposable contact lenses as long as the dry eye management is implemented concurrently.[30]

Allergies and Giant Papillary Conjunctivitis

The best way to avoid causing allergic conjunctivitis and giant papillary conjunctivitis (GPC) with newly fit contact lenses is for the practitioner to take a good medical history. An evaluation of ocular redness, conjunctival chemosis and the presence of papillae—including GPC—is central. While many practitioners do not routinely evert the eyelid, it is indicated in those patients with an allergic/atopic profile. The lower tarsal conjunctiva should be routinely evaluated for signs of allergies.

Patients with multiple allergies and those with atopic disease are best candidates for daily disposable lenses that are low in modulus and have consistent high lubricity. Some SiHy lenses—especially early generation ones that were not designed for a daily disposable modality—have a high modulus. These lenses may cause "localized" GPC with large papillae in the central upper tarsal conjunctiva.[31] SiHy lenses may also attract lipid deposits that reduce lubricity.[32]

While lens cleaning with a peroxide-based solution is a hypoallergenic option, patients need to follow the instructions carefully. This cleaning system is not conducive to intermittent use of contact lenses. However, it does provide longer, more comfortable wear time for patients wearing SiHy lenses.[33]

Treatment with allergy medications is certainly an option, but try to avoid systemic antihistamines whenever possible, as these may exacerbate dry eye symptoms. Most allergy drops are taken once or twice daily, and it's important to remind patients that these should be administered without the contact lenses in the eyes.

Takeaways

To maximize the success of the neophyte contact lens wearer, a special emphasis must be placed on factors affecting visual performance, comfort and lens handling.[34] With the many advanced technologies and extensive selection of contact lenses practitioners have in their armamentarium, there are many ways to improve the experience of new contact lens patients.

Besides technology, we should not underestimate that in the end, our most effective tools are our abilities to set realistic expectations, educate the patient on the fitting process, provide opportunities for the patient to explain what needs to be improved and include them in the process of deciding which options are available. ■

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UNDERSTANDING THE INFLUENCE OF WATER CONTENT ON SOFT LENSES

A deep dive into how the dual goals of comfort and safety, once at odds, have largely been tackled.

BY LANGIS MICHAUD, OD
MONTRÉAL

On a recent commute home, I listened with a distracted ear to a science podcast, and my interest grew as the columnist asked a simple question: What would we be without water? My thoughts then spiraled into the concrete world of my professional life. Extrapolating the question to eye care, I pondered: What would contact lenses be without water?

We all remember learning in optometry school that the first lenses were made of glass with no water content, then eventually of rigid polymer with a water content of no more than 1%.[1] The physiological limitations of these materials and the difficulty of wearing them due to discomfort limited their use. In 1961, Otto Wichterle succeeded in developing a softer, more comfortable hydrophilic material, as well as a reliable centrifugal manufacturing process.[2] As a chemist working on an artificial mandible, he had realized that material had optical properties and that the presence of water in a polymer provides a degree of flexibility and comfort, while promoting the passage of oxygen and other gases through its matrix, improving ocular physiological response to lens wear.

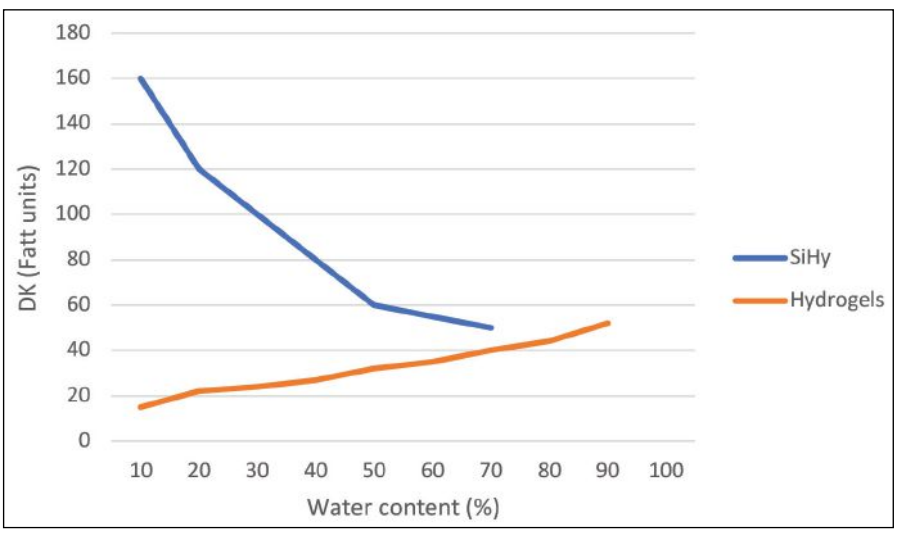

Fig. 1. Graph of DK values (oxygen permeability) of silicone hydrogel and hydrogel lenses vs. their water content.

Voilà, the soft contact lens era began and it became a mainstream hit.

Because current-generation contact lenses are so advanced and relatively foolproof, we practitioners may have lost some awareness of their inner workings and how that affects clinical performance—so, let's revisit the materials science fundamentals that make these products tick!

Contact Lens Material

A polymer is a large macromolecule composed of several series of repeating molecules called monomers. Every monomer has a covalent bond between each connecting unit.[3] The polymer is composed of both hydrophilic and hydrophobic groups. The hydration of this polymer occurs as a result of the

About the author

Dr. Michaud is is the former dean of the School of Optometry at the L'École d'optométrie de Université de Montréal. He is a diplomate of the American Academy of Optometry and a fellow of the British Contact Lens Association, the Scleral Lens Education Society, the European Academy of Optometry and the International Academy of Orthokeratology and Myopia Management. He was awarded the Donald R. Korb for excellence in research by the AOA in 2023. He has received honoraria from Bausch + Lomb, CooperVision, Johnson and Johnson and Alcon.

physicochemical equilibrium established between the water molecules and these two groups.[4] More specifically, the water molecule can either be bound to a hydrophilic group, which retains it, or be trapped in a space formed within the polymer matrix. The physical properties of the material developed are governed by the state of the water molecules trapped or bound inside.[5]

Contact lenses often have tight bonds, meaning there is a direct hydrogen bond between the water and the polar groups of the matrix. Water molecules can also be attached with looser bonds, especially when the water molecules remain trapped in the small spaces in the matrix.

The rate of hydration, or the ability of a polymer to absorb water, depends on a number of factors: the nature of the hydrophilic groups, the density of crosslinks in the matrix, the rate of water saturation, the storage (or wear) environment of the polymer and the ambient temperature.[4] Contrary to what one might intuitively think, the rate of absorption does not correlate with the matrix's ability to generate tight bonds to water molecules. The rate of contact lens material hydration should be known by its ratio of tight bonds to free molecules, although this information is not provided by manufacturers. This ratio will increase in favor of tightly bound molecules in the presence of a larger network of crosslinks (as in the case of the HEMA polymer), since there are fewer spaces in which molecules can move freely.[6]

The presence of salts and electrolytes in a lens matrix, such as when it comes in contact with tears, increases the attachment sites of tight bonds and reduces the number of free water molecules in the matrix. Conversely, due to the limited number of tight bonds the matrix can form, as the water content of the polymer increases, the ratio decreases. However, maintaining a minimum number of free water molecules is essential because it is through these molecules—not the tightly bound ones—that the exchange of gases, including oxygen, can take place.[7]

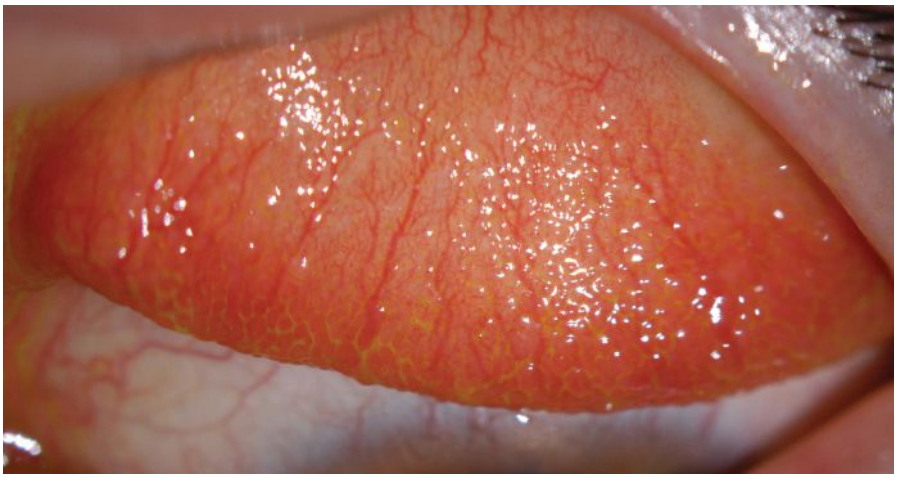

Fig. 2. Inflamed superior conjunctiva with papillary reaction (GPC).

Once applied to the eye, the lens is subject to body temperature, tear exchange, blinking forces and the environmental conditions affecting the tear film, such as osmolarity, pH and other properties. These factors cause the hydration level of the lens to vary throughout the day.

Free water molecules evaporate first, followed by molecules that are more tightly bound to the matrix. Therefore, it becomes clear that materials with a low level of bound molecules, and therefore more free molecules in the matrix, will tend to dehydrate more quickly.[8]

It's important to understand that it's not the percentage of water per se but the nature of the bond between the water molecules and the matrix that determines the rate of water loss from the polymer. For example, a lens with 40% water content may dehydrate faster than a lens with 75% water content, especially if the former has a higher proportion of free water molecules. In the end, a dehydrated lens will be more uncomfortable and will perform less well optically than a fully hydrated lens.

HEMA vs. Silicone Hydrogel

All of the above applies primarily to HEMA (hydroxyethyl methacrylate) soft lenses manufactured and prescribed primarily between 1970 and 1990. HEMA is a polymer whose water content could vary from 30% to 80%, depending on what was desired.

A higher water content HEMA lens brings more oxygen to the eye and allows for better elimination of carbon dioxide produced by the normal metabolism of corneal cells. In the absence of adequate exchange, hypoxia or hypercapnia can occur, resulting in corneal acidosis, characterized in particular by a reduced cellular metabolism and rate of mitosis, loss of corneal transparency and the appearance of neovascularization from the limbus.[9] The accumulation of microcysts in the cornea reflects a chronic lack of gas exchange over several weeks.[10]

HEMA lenses with a higher water content, however, are more difficult to handle and more prone to breakage. Lenses with higher water content were therefore reserved for extended wear. Based on very short-term trials, manufacturers advocated an escalation to longer and longer wearing periods without lens removal, ranging from a few days to several months. The negative consequences for ocular health are now well known and this practice has been hopefully abandoned.[11] In response to these problems, a whole new generation of polymers has been developed, namely silicone hydrogels.

Silicone is highly permeable to oxygen and is an important addition to contact lens materials. This is particularly true of rigid gas permeable contact lenses, where the addition of silicone to other monomers such as fluorine or acrylate (as well as urea moieties)

generates a biocompatible polymer that is rigid and tough, but gas permeable.[3] Unfortunately, silicone alone is inherently hydrophobic and lipophilic: it repels water and attracts lipids. These two elements are not really compatible with contact lens wear in the ocular environment of an adult. However, because of the different composition of an aphakic infant's tear film, this type of lens can be fitted to compensate for the absence of the crystalline lens in these children.[12] For any other clinical applications, it was therefore necessary to find a way to treat silicone in a way that would minimize its negative aspects while maintaining its advantage in terms of gas permeability.

Kyoichi Tanaka was the first to successfully combine the TRIS monomer (its chemical name is a mouthful: tris[trimethylsiloxy] silylpropylmethacrylate) used in rigid gas permeable lenses with a hydrogel. Thus, silicone hydrogels (SiHy) lenses were born.[13] A TRIS-like structure combined with polar groups made it hydrophilic.[13] Another strategy created siloxy macromers containing hydrophilic polyethylene oxide (PEGS) with siloxane units. The result, at least for the first generation of silicone hydrogel lenses, was biphasic matrices with one hydrophilic and one hydrophobic phase, much like superimposed layers. The phase separation results in opacity, which was not optically suitable. The first generation of SiHy materials overcame the opacity issue by decreasing the size of the phase separation, making it smaller than the wavelength of light to ensure material clarity. Though extremely oxygen permeable, these early SiHy lenses remained relatively hydrophobic and required surface treatment, primarily using gas plasma techniques.

The introduction of silicone disrupted the established relationship between water content and oxygenation that had previously existed with hydrogels. First-generation SiHy has a very low water content, mostly because of the limited hydrophilic phases, with extreme oxygen transmissibility explodes compared to HEMA lenses (*Figure 1*).

Over the years, the FDA had to develop a new lens class (Group V) for SiHy materials to add to the four already present:

Group I – low-water (<50%), non-ionic
Group II – high-water (>50%), non-ionic
Group III – low-water, ionic
Group IV – high-water, ionic

SiHy Growing Pains

Early generations of SiHy lenses (lotrafilcon A, balafilcon A, asmofilcon A) with high oxygen transmissibility were associated with a much higher modulus (and hence stiffness) than HEMA lenses, resulting in greater wearer irritation, particularly in the superior cornea or upper palpebral conjunctiva (*Figure 2*).[14] This high modulus, coupled with spherical posterior curvature, also created new, previously unknown debris under the lens: mucin balls, which are harmless but do temporarily indent the cornea (*Figure 3*).[15] Another new phenomenon was the accumulation of lipids (*Figure 4*) rather than proteins on the surface of the lens due to the attraction of silicone, as care products were not formulated accordingly.[16]

All of these new issues prompted manufacturers to go back to the drawing board to improve SiHy materials with the goal of making them more like HEMA hydrogels, particularly in terms of modulus and resistance to deposits. This was all the more necessary as it became increasingly clear that the new materials, in addition to improving hypoxia and hypercapnia rates, did not reduce the incidence of microbial keratitis in extended wear, while also increasing adverse events such as sterile corneal infiltrates in extended wear.[17]

The second generation of SiHy lenses (galafilcon A, senofilcon A) is characterized by the incorporation of a long chain of high molecular weight polyvinylpyrollidone (PVP) into the lens matrix. PVP attracts and retains water within the lens, removing the need for lens surface treatment, thereby eliminating ocular irritation and reducing lens friction on the ocular surface and conjunctiva. The presence of PVP and a greater amount of water molecules help to reduce the lens modulus (from roughly 1.3 MPa on average down to about 0.6 MPa on average). All of these modifications have had an immediate effect in improving patient comfort and reducing the mechanical problems caused by the first-generation lenses.[18]

It wasn't until the third generation of SiHy lenses (comfilcon A, enfilcon A, fanfilcon A), around 2013, that the Dk and water content paradigm was broken once again. This new technology allows lenses to be made from a long siloxane macromer chain with one end modi-

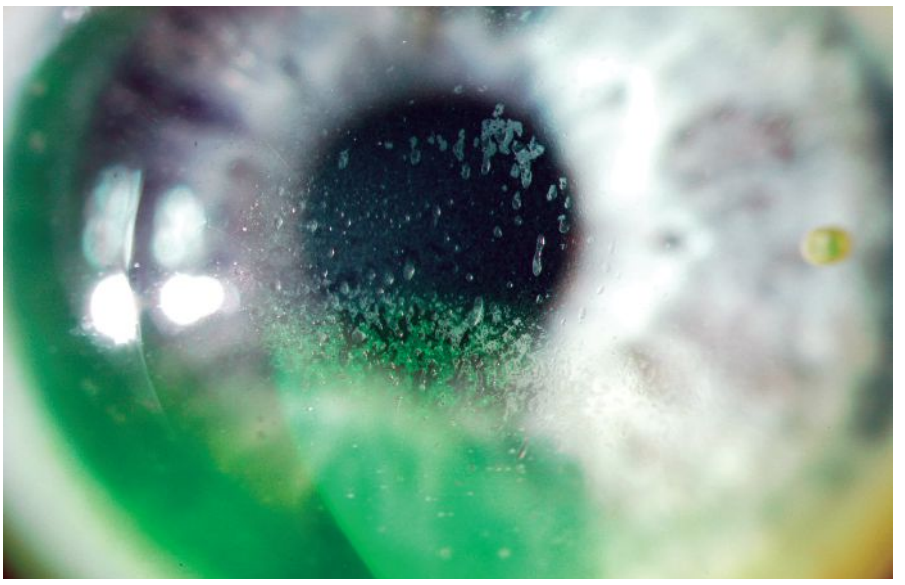

Fig. 3. Mucin balls trapped under the lens.

TABLE 1. MODERN CONTACT LENS MATERIALS AND THEIR WETTING STRATEGIES

Material	DK/t (Fatt units)	Water content (%)	Modulus (MPa)	Wetting strategy
Balafilcon A	99	36	1.1	Plasma oxidation
Lotrafilcon A	140	24	1.4	Plasma treatment
Lotrafilcon B	110	33	1.2	Plasma + HydraGlyde surface coating
Asmofilcon A	161	40	0.9	Nanogloss surface coating
Galyfilcon A	60	47	0.4	Internal wetting agent (PVP)
Senofilcon A	103	38	0.73	
Filicon II	86	56	0.5	Siloxane modified – becomes naturally wettable
Comfilcon A	128	48	0.75	
Fanfilcon A	110	55	0.6	
Enfilcon A	100	46	0.5	Siloxane modified + integrated PEG
Nesofilcon A	42	78	0.46	Internal wetting agent
Senofilcon C	147	41	0.77	Internal wetting agent (lipid integration)
Samfilcon A	163	46	0.7	Double polymerisation including PVP within the matrix
Kalifilcon A	134	55	0.5	PVP in the matrix + addition of Poloxamine 1107 and Poloxamer 181
Delefilcon A	156	33 to 80	0.7	Water gradient technology
Lehfilcon A	154	55 to 100	0.6	

fied to be hydrophilic.[19] The silicone matrix becomes then naturally wettable on surface. There is no need to add a hydrophilic macromer to the silicone chains. However, it is still possible to inject other elements that promote water retention (*e.g.*, polyethylene glycol) or, together with tear exchange, create a new, more hydrophilic environment around the lens.

In an effort to bridge the gap between SiHy and hydrogels, a new class of material, called a hypergel, has been introduced (nesofilcon A). The principle here is to develop a material that mimics the physiology of the cornea in order to optimize the biocompatibility of the lens with the ocular environment.[20] The water content of the lens is thus similar to that of the cornea at 78%, close to the maximum values of hydrogel lenses, but delivering a higher gas permeability. The polymerization of the lens surface attempts to generate a barrier, thus preventing evaporation of the higher water content of the lens. Although highly hydrated, the matrix is designed to maintain a certain modulus to facilitate lens insertion and removal.

A fourth-generation material (samfilcon A) has contributed to a significant evolution in technology by introducing dual polymerization to the lens manufacturing process. While the silicone matrix body is formed after an initial polymerization, a second phase of this type not only binds but also incorporates PVP, which has the ability to attract six times its molecular weight in water, directly into the matrix. Retention time is improved, as is the surface quality of the lens.

So, it's no longer the percentage of water in the contact lens that matters but rather the method used to maintain the most consistent hydration throughout the hours of wear. Even more recently, this technology has benefited from the injection of electrolytes, surfactants and emollients, which, when released by tear exchange and blinking, help maintain tear film homeostasis (kalafilcon A).

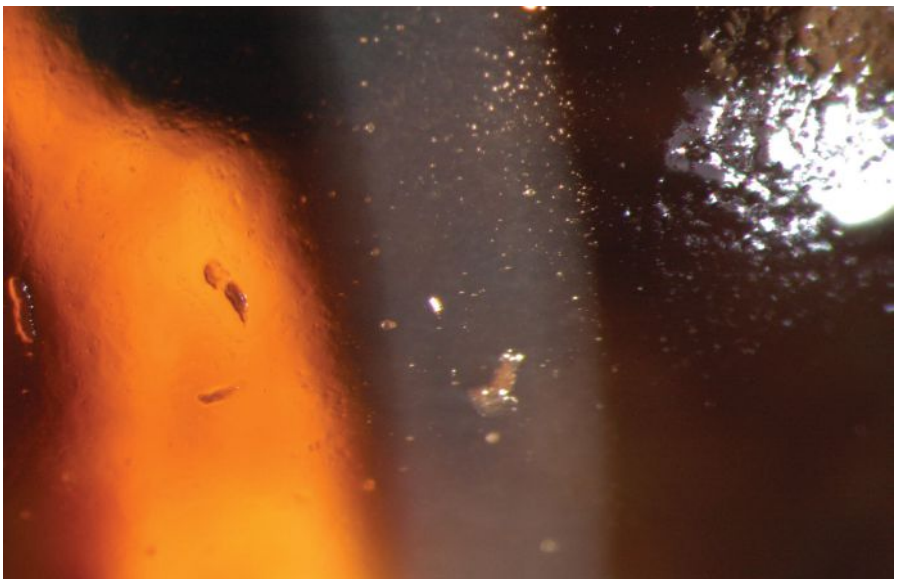

Fig. 4. Close-up of lipids and proteins adsorbed on a SiHy lens surface.

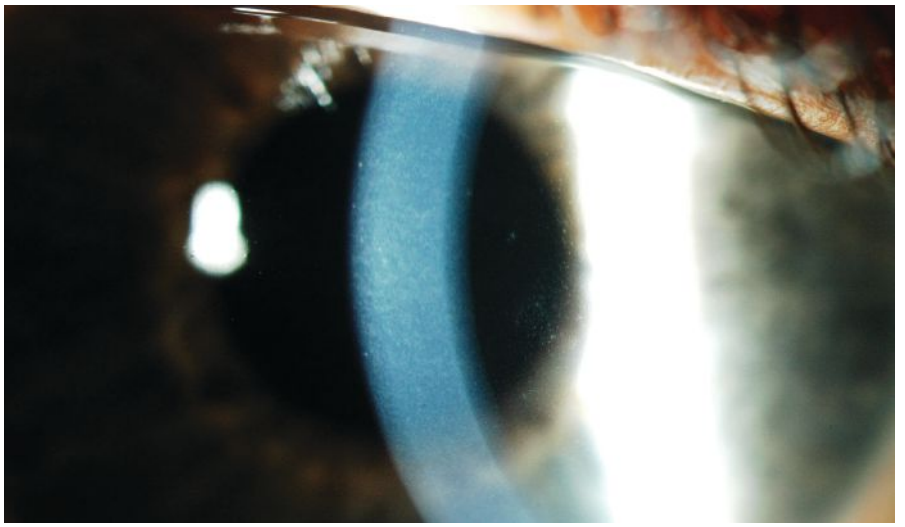

Fig. 5. Corneal edema and microcysts following extended wear with low Dk lenses.

Significant Breakthrough

Water gradient technology represents not only a new generation of lenses but also a completely new way of thinking about the relationship between the lens, the tear film and the ocular environment. With such new material, the paradigm is again broken, since there is no compromise in the relationship between oxygen and surface water, which is unique. A water gradient lens is able to achieve high oxygen permeability while maintaining a low water content at the core.[21] Even better, modulus is not compromised and the lens is acting like one of hydrogel.

The core of the lens is a low water content SiHy material (33% or 55% delefilcon A or lehfilcon A). It increases toward the surface, up to 80%. At the surface, however, there is essentially no silicone at all and the content of water is almost 100%, favoring a high compatibility with the tear film. Instead, a hydrophilic gel has been designed to mimic corneal water content. The material coefficient of friction is reduced, lowering the potential adverse effects on ocular health. In the case of lehfilcon A, this surface is also designed to mimic the corneal surface architecture, which may help to resist protein and lipid deposition, considering that this lens is worn on a monthly disposable modality.

See Table 1 for a summary of lens parameters and wetting strategies.

Clinical Impact: What Makes a Difference?

It's worth remembering that the original purpose of hydrating rigid lens materials was twofold: to improve patient comfort and to maintain normal ocular health, particularly by promoting gas exchange.

When looking at HEMA lenses, it's clear that the water content of the product has a major impact on both factors. Practitioners made their choices based on the patient's needs and, most importantly, ocular parameters. If a patient requires a highly convex lens to correct aphakia, or a highly concave lens with thick edges, they would be fitted with the most permeable lens, which means a HEMA lens with the highest water content.

The fragility of such lenses meant that practitioners had to strike a delicate balance between the need to handle the lenses daily at the risk of tearing the lens or resorting to extended wear, which could reduce the positive impact on patients' ocular health (*Figure 5*). The fit will be loose as well to allow tear exchange, which brings another source of oxygen and nutrients to the cornea. At a time when HEMA lenses were being prescribed, it's clear that water content was a key factor in the fitting decision.

The addition of silicone to the lens matrix removes the oxygenation factor from the equation. If we look at the lenses currently prescribed (*Table 1*), especially the latest generation, they all far exceed the permeability requirements for daily wear and even extended wear according to the criteria of Harvitt and Bonnano (DW = 32 Fatt units; EW = 120 Fatt units).[22]

SiHy lenses are available in a variety of wearing modalities, including single-use lenses, which excludes extended wear by definition. Single-use lenses also improve comfort, which improves the patient experience.[23] This modality limits the amount of accumulated deposits or biofilm and avoids chronic exposure to chemical solutions used to disinfect and store the lenses. The preservatives and buffers in this type of solution can increase patient sensitivity and may generate negative reactions (*Figure 6*).[24] What's more, a recent study showed that lenses worn for 300 hours or more (*i.e.*, monthly disposable or conventional lenses) release plastic microparticles that can penetrate conjunctival cells and alter their metabolism.[25] This also increases the inflammatory response to lens wear. This is not the case when patients are fitted into a single-use lens modality.

While the wearing modality can influence patient comfort, there are many other factors at play, keeping in mind that contact lens discomfort is multifactorial in nature.[26] The water content of the lens may play a role here, especially if we consider the modulus of the lens.

Looking at the history of SiHy lens development over the past 30 years, it is clear that the composition of SiHy lenses in use today is very different from those first introduced in the early '90s. The early designs broke the paradigm of water content vs. oxygen permeability. Technological advances of the modification of the silicone chains themselves and the use of different types of silicone have allowed for greater attraction and retention of water molecules in the lens matrix. Thus, without significantly altering oxygen transmissibility, these new structures have tended to adopt the modulus of hydrogel lenses (*i.e.*, greater flexibility for improved comfort

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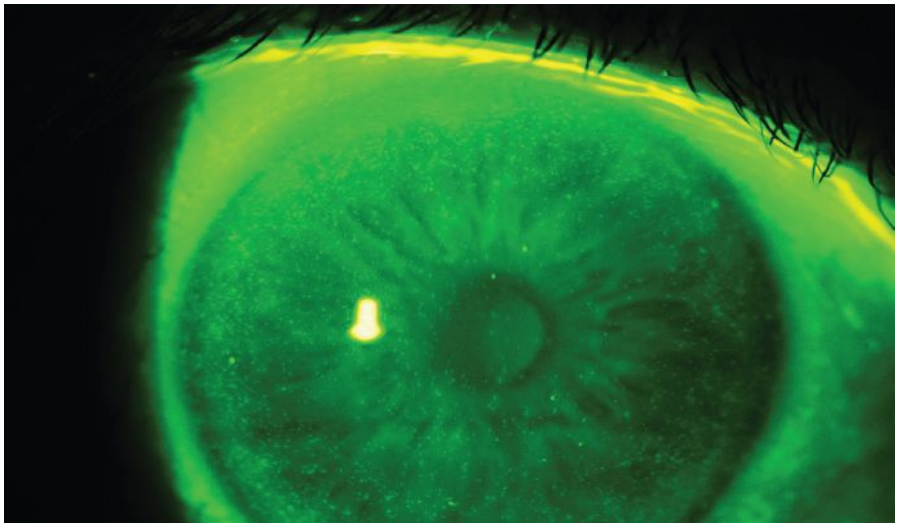

Fig. 6. Epithelial cells hyperfluorescence related to preservative agents reaction.

while maintaining a degree of rigidity necessary for easy lens handling). Consequently, today's practitioners should be guided more by lens modulus than water content, understanding that, under the new paradigm, both are not so correlated.

Another lesson to be learned from the first years of exposure to silicone hydrogels is the importance of the mechanical aspect of their presence on ocular tissues. The first generations of lenses were characterized by a much different tribological behavior (*i.e.*, the friction, lubrication and wear forces of two surfaces in contact) than hydrogels, notably due to the surface treatments required by the combination of silicone and hydrophilic phases. As mentioned, this mechanical stress led to episodes of giant papillary conjunctivitis, inflammation of the tarsus and conjunctiva, and even keratitis.

The latest generations of lenses offer a very different picture, and the coefficient of friction of SiHy lenses is now improved, notably if the lenses are single-use (vs. frequently replaced) and when PVP is kept in the matrix.[27] In this respect, the development of water gradient technology opens up a whole new perspective, further reducing the mechanical impact of contact lens wear on the eye. Even in single-use lens modality, materials offering this technology stand out from the rest.[28]

Takeaways

Following in Otto Wichterle's footsteps to improve the comfort and physiological effects of contact lenses, practitioners have all the tools at their disposal to achieve these goals. Specifying the latest generation of silicone hydrogel lenses ensures safe gas exchange, while the use of lower modulus and parameters that reduce the troublesome lens/eye surface interactions associated with contact lens wear, particularly by limiting the coefficient of friction, is becoming a must. Disposable lenses that eliminate the need for solutions, and in particular those that are able to maintain a high PVP level throughout the wear period or are based on water gradient technology, seem to be the best answer we can offer to wearers looking for comfortable all-day lenses. The water content of these lenses then becomes a contributing factor, but not the only criterion to consider. ■

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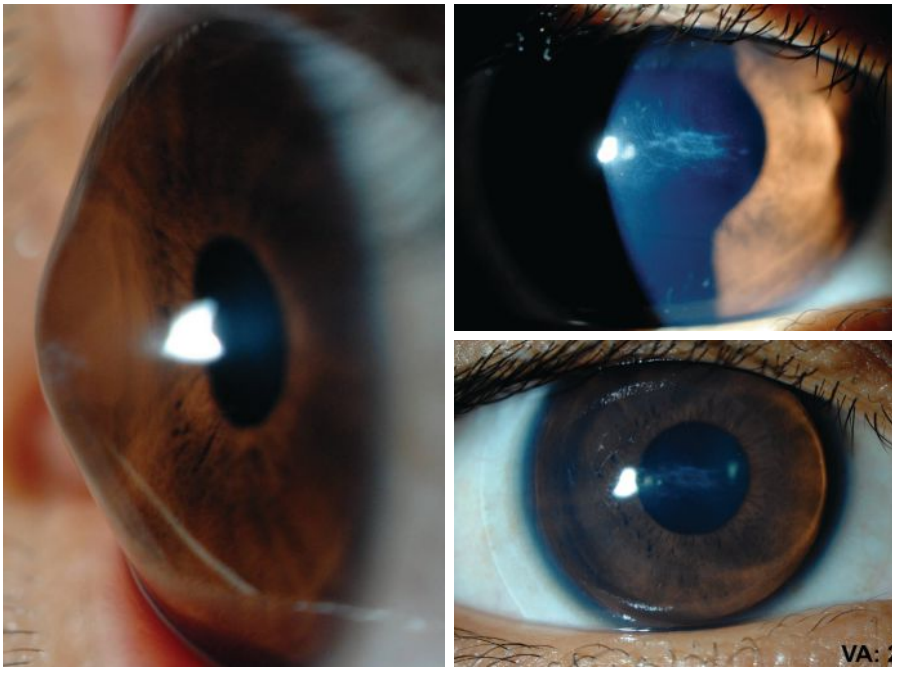
CUSTOM SOFT LENSES FOR IRREGULAR ASTIGMATISM

Know when to consider this option for your patient's corneas.

BY MATTHEW LAMPA, OD
FOREST GROVE, OR

The standard approach to contact lens correction of irregular astigmatism today and for the foreseeable future is to prescribe a non-flexing rigid gas permeable (GP) lens design, whether that be a corneal contact lens, scleral lens, hybrid lens or piggyback system. However, these lens designs do not work in all cases, either due to poor physical fit or comfort or various other reasons. Perhaps, the patient or practitioner is not satisfied with their performance, finds the lenses inconvenient, their size intimidating or application and removal challenging. Custom soft contact lens designs can serve as a viable alternative for these cases. Learn how and when to prioritize these lenses as an option when fitting patients.



Figs. 1 and 2. A custom soft lens may allow for a stable fit and significant improvement in patient comfort for an individual who has failed with other options.

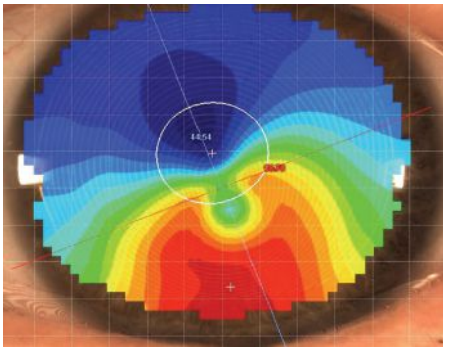
Anticipate Keratoconus

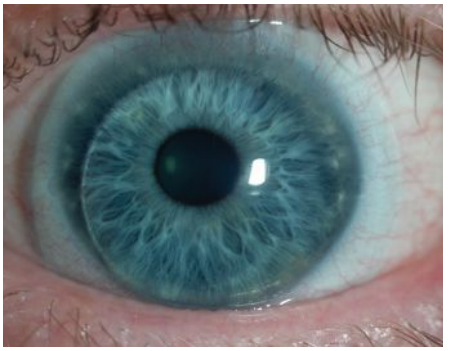
The potential sources of irregular astigmatism are injury, surgery and disease. Of course, one of the more common corneal conditions that can lead to irregular astigmatism is keratoconus. Early in the condition, patients are often frustrated with spectacle lenses and standard mass-market soft lenses that do not provide adequate visual acuity. However, these patients are often fairly functional and not overly motivated to try traditional specialty lenses such as corneal GP and scleral lenses. This can be a great time to consider custom soft lenses to provide improvement in visual acuity since these lenses often center well, provide limited movement and offer stable visual acuity and adequate comfort.

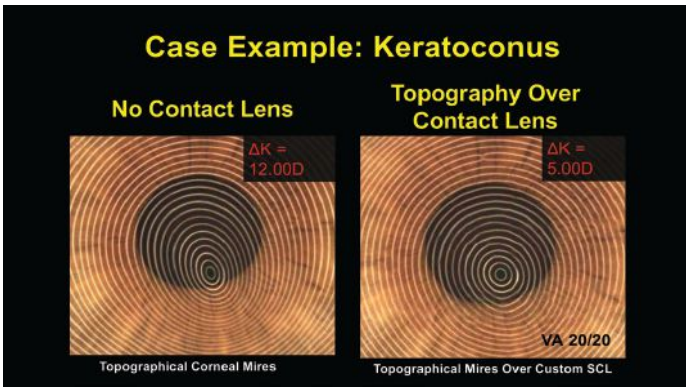
If keratoconus progresses, it leads to higher and higher amounts of corneal irregularity. As the cornea is further

About the author

Dr. Lampa is a professor at the Pacific University College of Optometry. He is a fellow of the American Academy of Optometry. He is a consultant/advisor to SpecialEyes and has received honoraria or travel expenses from Art Optical, ABB Optical, Contamac and Medmont.







Figs. 3 and 4. Note the thickened custom soft lens that has decreased the corneal distortion in this patient with irregular corneal toricity over the visual axis.

disrupted by this irregularity increasing, a corneal scar may result and limit best-corrected visual acuity regardless of the contact lens design chosen. In these more advanced stages, the central corneal curvature may steepen to the point that designing a corneal rigid contact lens may be too challenging and the forgiveness of fit that a soft lens provides may be warranted.

In the case of severe keratoconus, a custom soft lens may provide the same level of vision as a corneal GP or scleral lens has, as the patient's vision is more limited by the corneal scar than the irregularity. This may allow for a stable fit and significant improvement in comfort (*Figures 1 and 2*). Another benefit to providing a custom soft lens to a patient with severe keratoconus who has failed in other lens modalities is that this option may help that person avoid or delay corneal transplantation.

What has been covered here so far related to keratoconus are options and rationale for the patient with mild and severe forms of keratoconus as it relates to custom soft lenses and the decision-making around them. Patients in the moderate category may still benefit from these lenses as evidenced by a case discussed here where the patient presented with keratoconus with 12.00D of irregular corneal toricity over their visual axis. After a thickened custom soft lens was placed on the eye, the corneal distortion was dramatically decreased along with the amount of astigmatism from 12.00D to 5.00D, and the contact lens provided the patient 20/20 visual acuity (*Figures 3 and 4*).

The Right Choice

Custom soft lenses are able to be used in patients who have irregular astigmatism due to the increased central thickness of the lens. As the contact lens thickness is increased over the area of the optic zone, it begins to approach the non-flexing nature of GP lens material. However, this does not eliminate the irregular astigmatism like a GP material does. Instead, it converts irregular astigmatism to be more regular in nature, and the necessary toric lens power can be placed on the front surface of the contact lens to optimize the patient's vision (*Figures 5 to 7*).

The effect of masking the irregular astigmatism begins around 0.2mm, and if there needs to be more irregular astigmatism–correcting ability, the lens can be additionally thickened from 0.2mm to 0.3mm and then from 0.3mm to 0.4mm and so on. To understand how much irregular astigmatism correction the custom soft lens is providing, perform keratometry (either manually or via corneal topography) over the top of the contact lens and analyze the mires reflecting back. If significant amounts of irregularity are present, increasing the central thickness may be warranted.

Clinical experience has shown that the maximum irregular astigmatism–correcting ability is reached at a center thickness of 0.5mm, as the soft lens does not seem to be able to mask additional amounts of irregularity beyond 0.5mm. The industry standard central thickness of a soft lens designed for irregular astigmatism is 0.4mm. Of note, this increased thickness is just in the area over the central optic zone and does not extend over the carrier/haptic portion of the contact lens (*Figure 8*).

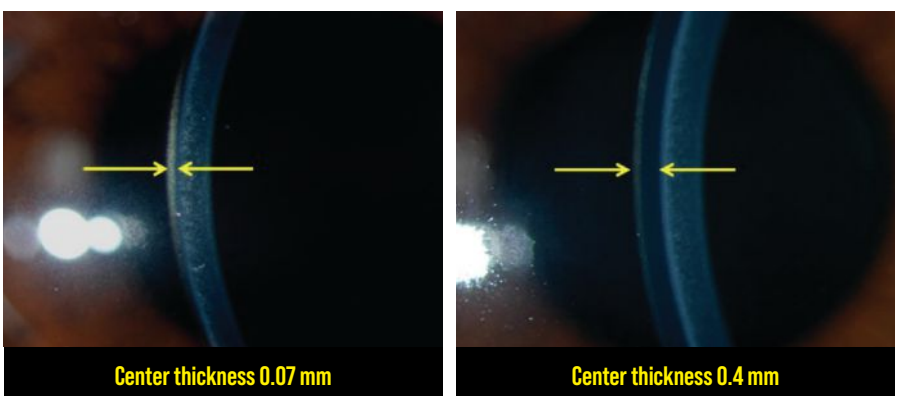


Fig. 5. Custom soft lenses can be used in patients who have irregular astigmatism due to the increased central thickness of the lens.

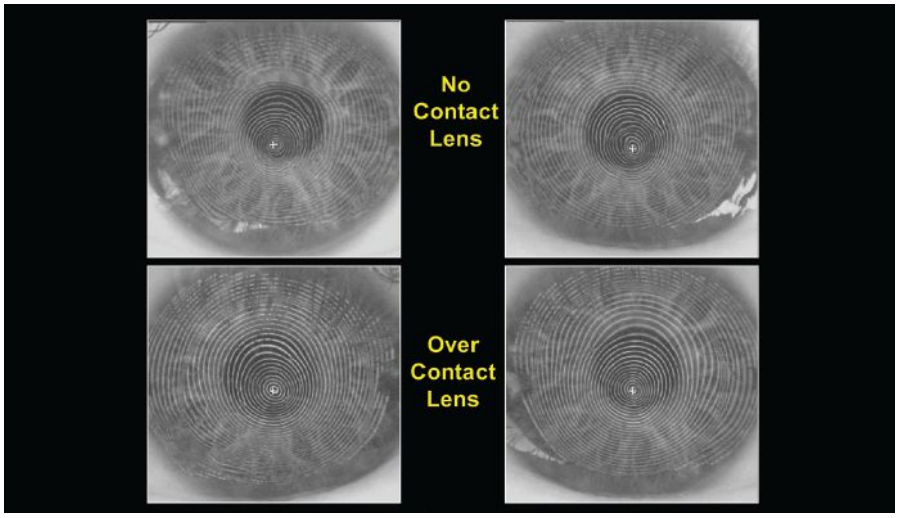


Fig. 6. Videokeratoscopy helps demonstrate how custom soft lenses can be used for irregular astigmatism.

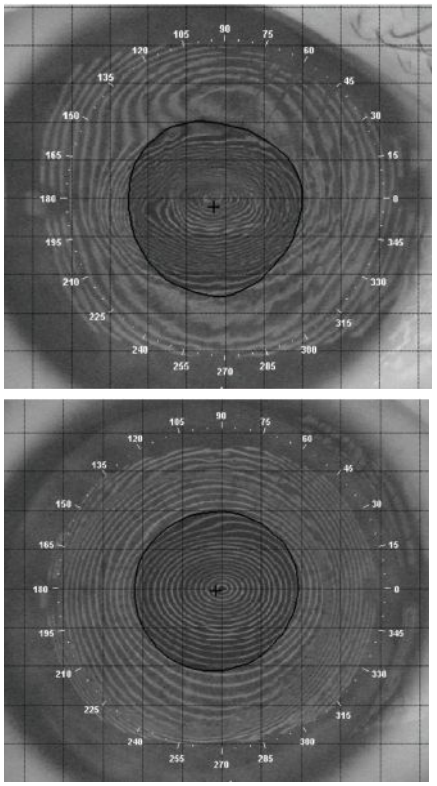


Fig. 7. The thickened contact lens, as seen with topography, converts irregular astigmatism to be more regular in nature, and the necessary toric lens power can be placed on the front surface of the contact lens to optimize the patient's vision.

Lens Design in Keratoconus

Custom soft lenses for keratoconus early in the condition may be designed with similar or nearly identical base curves and diameters to those used in standard soft lenses; however, as the disease progresses and the cornea steepens, an alternate lens design may be needed. These custom soft lenses specific for keratoconus are designed with a two-part construction: one part with the central base curvature and the second part being the fitting curve that is sometimes referred to as the peripheral haptic or supportive portion of the contact lens (*Figure 9*).

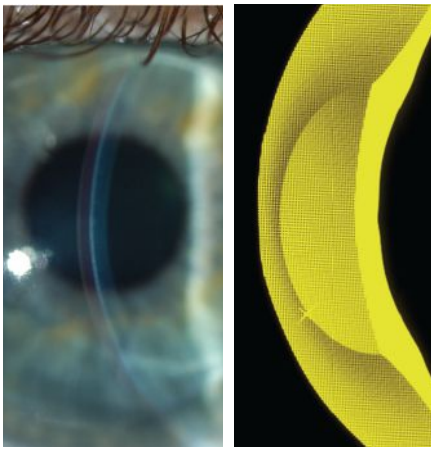


Fig. 8. The maximum irregular astigmatism correcting ability is reached at a center thickness of 0.5mm, which is over the central optic zone and does not extend over the carrier/haptic portion of the lens.

The central base curve is determined by first assessing the patients central keratometry (K) values, determining an average K by adding the flat and steep K together and dividing that by two. Then, convert the mean K number from diopters to millimeters and add a fit factor of 1.0mm to arrive at the initial recommended base curve value.

Example: Step 1—Central Ks 55.00D @ 084 / 61.50D @174. Step 2—Mean K (55.00 + 61.50 = 116.5) ÷ 2 = 58.25 D. Step 2 Convert diopters to millimeters radius of curvature = 5.79mm. Step 3—Add fit factor of 1.0mm: 5.8mm + 1.0mm = 6.8mm.

Initial recommended central base curve to be ordered: 6.8mm. The fitting curve is ordered with a more traditional soft lens curve value, e.g., 8.3mm or 8.6mm. As these lenses are often ordered with toric powers, the recommended overall diameters ordered are between 14.0mm to 14.5mm.

Other Possible Hurdles

Another corneal ectasia similar to keratoconus is pellucid marginal degeneration. With this condition, the ectasia is often near the inferior limbus. This results in the inferior cornea migrating forward, creating a significant elevation to that region as well as high amounts of against-the-rule astigmatism within the central cornea. The significant corneal elevation inferiorly creates a challenging environment for a corneal GP to be supported by the cornea itself due to the amount of asymmetry present.

Thankfully, though the amount of against-the-rule astigmatism present in the central cornea is high, it is often fairly regular over the pupil and visual axis as demonstrated by the axial display of the corneal topographer (*Figure 10*). This sets up a scenario where custom soft lenses may be employed to correct the high amount of astigmatism, mask some of the irregularity with an increase in central lens thickness and provide enough steepness and depth to cover the ectasia.

Other sources of irregular astigmatism are corneal injury and surgery. The amount of irregularity these events can cause varies widely. If the injury or surgery is unilateral and results in irregularity that is not able to be successfully managed with standard spectacles and

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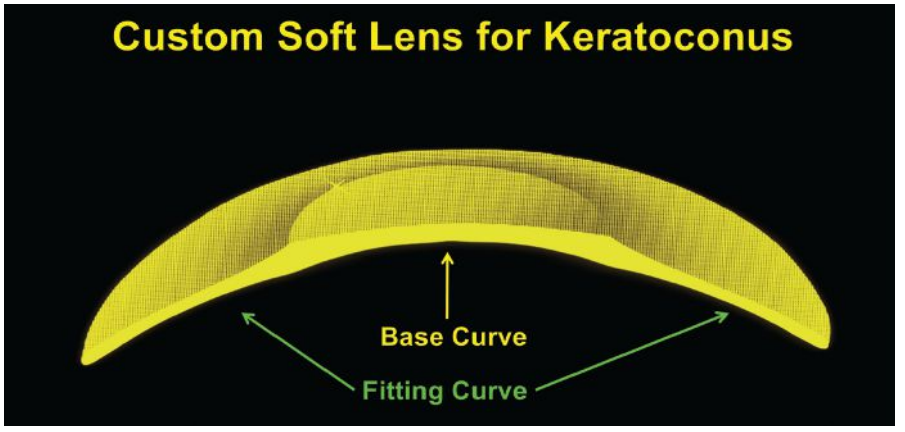
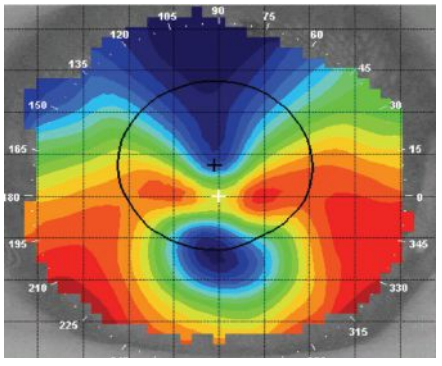


Fig. 9. The central base curve and the fitting curve make up the design of a custom soft lens for keratoconus.



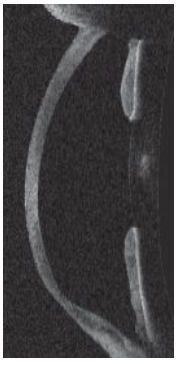


Fig. 10. A corneal topographer helps demonstrate that, though the amount of against the rule astigmatism present in the central cornea is high in a patient with pellucid marginal degeneration, it is often regular over the pupil and visual axis.

soft contact lenses, a custom soft lens may be an excellent choice as the other contact lens options such as corneal GP lenses, scleral lens, hybrids and piggyback systems may not be tolerated by the patient in one eye alone. A custom soft contact lens may offer the patient the comfort and stability they need to adapt to wearing a contact lens unilaterally.

If the patient has undergone previous myopic refractive surgery, the central cornea is relatively flatter and lower in height than the surrounding steeper midperipheral cornea. This oblate shape is just the opposite of the normal prolate profile of the human cornea. The standard off-the-shelf soft lens mimics the normal cornea by having a prolate shape. If these lenses are used in the post-myopic refractive surgery cornea, the lens will often vault in the center and provide variable vision with each blink. Custom soft lenses, however, can be ordered with reverse geometry to better align the post-myopic refractive surgery cornea and not provide the excessive central clearance standard that off-the-shelf lenses do and provide clearer and more consistent vision instead. These lenses have a similar two-part construction to their back surface like lenses for keratoconus; however, instead of being designed steeply in the center, the lens is significantly flatter centrally than peripherally.

The central base curve is designed by first identifying the flat K, then converting from diopters to millimeters radius of curvature and then adding an additional fit factor of 0.4mm to arrive at the initial recommended base curve radius.

Example: Step 1—central flat K 37.25D. Step 2—convert diopters to millimeters radius of curvature = 9.05mm. Step 3—add fit factor of 0.4mm: 9.05mm + 0.4mm = 9.4mm base curve.

The surrounding fitting curve is selected of some normal value (example: 8.3mm or 8.6mm), as this portion of the ocular surface is not altered by the history of refractive surgery.

Lens Care and Handling

Due to the custom nature of soft lenses for irregular astigmatism, the recommended replacement schedule is often quarterly and open-eye daily wear only. As these lenses need to last longer than their traditional off-the-shelf counterparts, care and handling and recommended lens care products are of critical importance.

The impact of nightly rubbing and rinsing with the recommended lens care product can aid in the process of keeping the lens free of significant deposition. Either multipurpose or peroxide systems can be used with these customs soft lenses. When a patient asks what the ideal lens care products are to use with a specific custom soft lens, the consultation department at the manufacturer can provide its recommendations around the specific soft lens material and design.

Additionally, an isopropyl alcohol solution may be needed to clean the lenses with its additional deposit-removing property in order to optimize lens comfort longer into the wearing cycle. If an isopropyl alcohol solution is recommended, the patient will additionally need to ensure that they have thoroughly rinsed the lens with saline to remove all the isopropyl alcohol before storing the lens in solution for overnight disinfection.

Takeaways

Patients who have a history of irregular astigmatism are often visually frustrated and even debilitated with spectacle lenses and standard soft lenses and will require some specialty lens management. There are many wonderful products in the marketplace to optimize lens fit and visual potential. Custom soft lenses are a wonderful example of a product capable of providing a stable lens-to-ocular surface fit profile with good centration, limited movement to optimize comfort and a central optical profile capable of exceptional vision. For the patient with irregular astigmatism, these lenses provide the patient and practitioner another significant and reliable tool to optimize fit, vision and comfort. ■

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2023 DESIGN CONTEST:

PLEASING TO THE EYE

Our winners succeed both aesthetically and functionally. Prepare to be inspired by their clean lines and calming vibe.

Review's biennial Office Design Contest is not only an opportunity for optometrists to showcase their spaces, but to share their inspiration and, in some cases, their personality. At the same time, the goal is to enhance the overall patient experience. The ODs behind each of this year's winning practices did exactly that—adding the latest technology, having better functionality to accommodate all types of patients (as well as their staff) and integrating bold and unique features to help patients feel more at ease.

We look forward to conducting this contest every other year and we know you do, too, based on the feedback, responses and general excitement we can feel, even through e-mail. This year, we received the most entries out of all the years we've held this contest—37 practices! Our judges were blown away with the imagination and creativity behind each space, and they know a thing or two, considering they were winners previously. The photo collage to the right includes just a few of this year's entries, but you can view all of them in the online version of this article at www.reviewofoptometry.com. We urge you to check it out, as it might inspire you to reimagine your own office space.

From modern and contemporary to comfortable and inviting, this year's winners have the 'wow' factor and will transport you to a peaceful place. They include a zen-like Japanese-inspired garden, a relaxing spa area for dry eye treatments and a unique contact lens bar.

Peruse the collage, pick your faves, then turn the page for a celebration of this year's winners!

MEET THE JUDGES

In 2021, these practices excelled with their own office renovations. This year, they provided expert feedback to pick the cream of the crop in the 2023 cycle.

Garrett Wada, OD
Wada Optometry
Anaheim, CA
2021 Winner

Brad Bodkin, OD
The Vision Center at Seaside Farms
Mount Pleasant, SC
2021 1st Runner-up


goodr
LIFE VISION

WINNER

IDEAL EYECARE, NORMAN, OK

ANNA HUGHES, OD

Sit back and relax in this inviting and peaceful setting.

Let's be honest—most people either aren't exactly relaxed or excited to go to any kind of doctor's office. So, when Anna Hughes, OD, started envisioning her optometry space back in 2021, converting it from a dental practice (and doing quite a bit of the demolition herself), she wanted to change that mindset and have patients be completely at ease as they step into her office. She did that and more, creating a calm, zen-like space, just how judge Brad Bodkin, OD, described it.

"This is a very inviting, comfortable space—almost zen-like with that entryway," he says.

Adds Dr. Hughes, "I wanted my new office space to inspire patients and my staff to see beauty and feel relaxed when coming to this building."

Before even stepping in the front door, a fun set of teal glasses hangs outside the building—a welcoming sign, pun intended—greeting patients as they park. Because of its easy visibility from a distance, Dr. Hughes says it's brought in new

patients who frequently tell her they live down the street. "Using the hanging pair of glasses outside is a nice touch to help passersby know exactly what is going on inside," Dr. Bodkin adds.

Once inside, you are greeted with an open and spacious area with tall ceilings and wood shiplap. The pretest and exam rooms are full of color and one of them is fitted specifically to easily convert into a wheelchair exam lane.

"Before we would have to move a heavy exam chair. Also, I now have a truly ADA bathroom and front desk to that allows easy visibility and access for my wheel chair bound patients to check out," Dr. Hughes says.

The biggest part of this space that makes it feel the most peaceful is a zen rock garden, a project inspired by Dr. Hughes' sister, who moved to Japan.

"When I started learning more about the culture and different gardens in Japan, especially the zen gardens, it intrigued me since I like to garden," Dr. Hughes explains. "I thought, what a perfect place to have something so peaceful. I look out and gives me a sense of well-being and I'm trying to create that space for my patients, too. The waiting room isn't the most fun place to be; you can get anxious or get bored, and this garden is visibly interesting to look at and gives you an overall sense of calmness."

1st RUNNER-UP

EYEXAM OPTOMETRY, NEWPORT BEACH, CA

NIKKI IRAVANI, OD

"When you walk into a space that has marble floors and double chandeliers, you'd think you were in a beautiful mansion, but this lavish, modern space is what greets every patient at eyeXam Optometry of Southern California.

"This is a very modern and sleek design," says judge Dr. Brad Boykin. "I love that they keep the theme with the 45-degree lines throughout the design."

"The captivating graphics display a great attention to detail, while the wonderful lighting design adds a touch of ambiance and elegance," Dr. Wada says.

In addition to being aesthetically pleasing, Dr. Iravani created this space with the intention of having it flow nicely for patients and staff, alike. This includes a substantial-sized pretesting room in the heart of the office that has double doors on both sides.

A unique part of this space is the eyeSpa, a dedicated room for dry eye treatment to perform OptiLight IPL and LipiFlow in a spa-like ambiance.

"Patients can relax with dimmed lighting, relaxing music and lay comfortably in a spa bed and an aesthetically pleasing room," Dr. Iravani says. "Each patient gets a warm blanket and pillow, as well as a hydrating hand mask during their session."

One thing the judges couldn't get enough of is the contact lens bar, which has a long counter with built-in sinks, mirrors and iPads with training videos that allow patients and staff to work together for quality training.

"I can't praise it enough—it's a very cool way to do that," Dr. Bodkin says.

"I particularly appreciate the long dispensing bench seating, which not only provides functionality but also contributes to the overall aesthetic appeal," Dr. Wada says. "The overall execution of the design is truly commendable and has left a lasting impression on me."

"We created this space with the intention of impressing everyone in our community and industry," Dr. Iravani says. "Patients really appreciate what a nice office we have, how clean and modern it is, and that we have the latest equipment."

2nd RUNNER-UP

ARENA EYE CARE
SACRAMENTO, CA

KRISTER L. HOLMBERG, OD

Clean and contemporary were the words used to describe our second runner-up, Arena Eye Care. "The contemporary design truly stands out, creating a sense of modernity and sophistication," judge Garrett Wada, OD, says. "The open area concept adds a refreshing touch, while the sleek and stylish elements enhance the overall aesthetic appeal."

It's quite a difference from the cramped feel Dr. Krister Holmberg described his office before undergoing a complete renovation.

"The office has a much more contemporary/modern aesthetic now, but we did our best to make it not feel sterile," Dr. Holmberg says. "We totally redesigned the optical area so the aesthetic is much more modern and consumer friendly. We also emphasized the quality of the lighting throughout the building. Patients love how easy it is to see the frames in the displays."

"I must commend the wonderful design of the front desk area, which adds a touch of professionalism and elegance,"

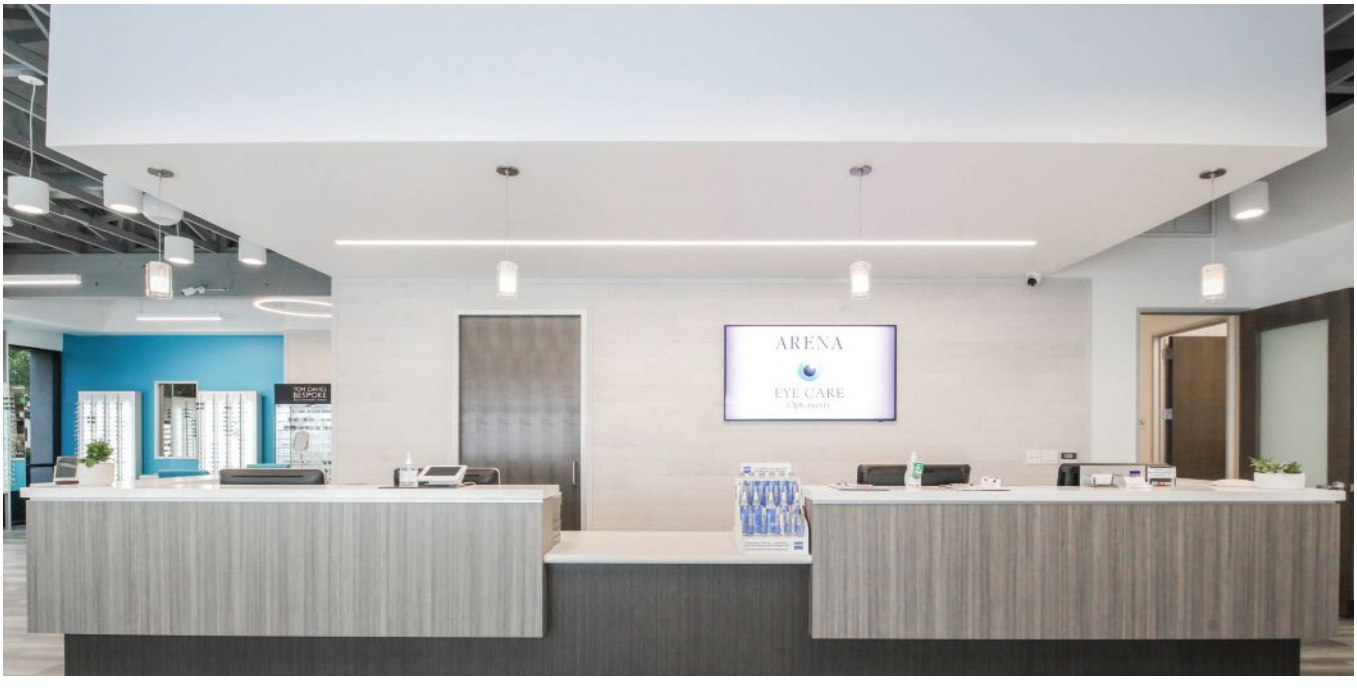
adds Dr. Wada. "Additionally, the frame display styling adds a unique and captivating element to the overall design."

This new office has a larger optical area, reception area, two private offices, two pretest rooms, two diagnostic rooms, a large easily accessible diagnostic contact lens closet, six exam lanes and a new in-office lab that's three times as big as previously, Dr. Holmberg notes.

"Not only are we not on top of each other any more, but we have lots of room for growth," he says.

Dr. Holmberg added a fourth exam room along with two additional exam rooms that will be equipped as the practice grows. Upgrading equipment was also essential, which included a new visual field machine and an intense pulsed light device. They are also in the process of upgrading their OCT to the latest model.

"All of this allows us to work more efficiently, it adds to the modern feel of the practice and ultimately allows us to practice at a higher level," Dr. Holmberg says. "Also, patients are much more excited about their experience, so we are getting a lot more first-hand referrals."



HONORABLE MENTIONS

These three offices also stood out by crafting unique expressions shaped by their personalities and practice setting.

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Leah Ramos, OD

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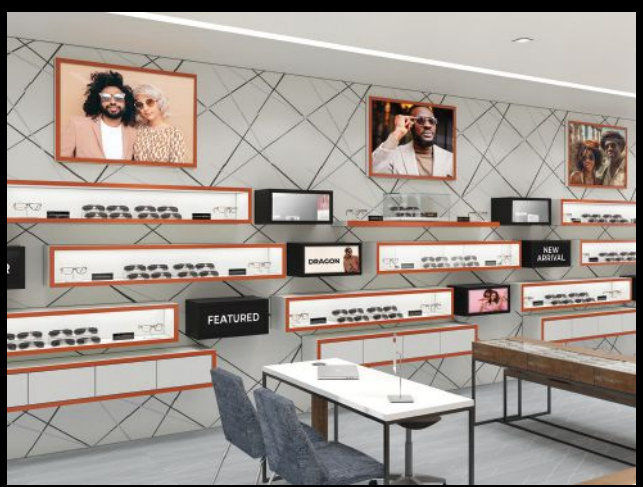

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WHAT TO DO WHEN THE PATIENT SAYS THEY HAVE "OCULAR MIGRAINE"

This misleading phrase can further obscure an already tricky diagnosis. Here's how to connect the symptoms to the source.

BY LEONARD MESSNER, OD,[1] LUCAS ROCKNE, OD,[1] MELISSA TURNER, OD,[2] AND JACKIE BURRESS, OD[2]

[1] CHICAGO, [2] MUSKOGEE, OK

A Google search of the term "ocular migraine" yields north of four million results, an impressive level of popularity for a term that is not a true diagnosis and has in fact fallen out of favor with headache specialists. Ocular migraine is a common misnomer often used synonymously to describe *migraine aura with headache*, *migraine aura without headache*, *retinal migraine* or *ophthalmoplegic migraine*. Each of these diagnoses has distinguishing characteristics outlined by the International Headache Society (IHS) in the latest International Classification of Headache Disorders, third edition (ICHD-3). Rather than using the term ocular migraine diagnostically, it is helpful to think of ocular migraine as an umbrella term encompassing those various entities.

Accurate diagnosis is important, as use of these terms interchangeably, under the guise of ocular migraine, may lead to inappropriate workup and management. Note that ocular migraines are a diagnosis of exclusion. It is important to rule out substantial ocular pathology and/or systemic causes of the visual disturbances to ensure no further testing or referral is needed for your patient.

How are Migraines Classified?

The ICHD-3 provides the classification system of migraine headaches and identifies what features a migraine must demonstrate to fit within a certain category. Management and care of these patients depends on a clear understanding of these classifications.

Migraine aura with headache. Formerly known as classic migraine, this form accounts for approximately one-third of all cases.[1] It is defined by brief, recurrent attacks of visual, sensory or other central nervous system symptoms (*i.e.*, auras) that are bilateral in nature and develop gradually, with subsequent headache and associated migraine symptoms.

Visual aura symptoms (VAS) are overwhelmingly the most common of these auras, with one study demonstrating such phenomena occurring in 98% of those with migraine aura. Less common types of auras include somatosensory disturbances, dysphasia

About the authors

Dr. Messner is Vice President for Strategy & Institutional Advancement at the Illinois College of Optometry. He also holds the rank of professor of optometry at ICO. He is the immediate past Chair of the Neuro-ophthalmic Disorders Special Interest Group of the American Academy of Optometry. **Dr. Rockne** is a clinical ocular disease/primary care resident at the Illinois College of Optometry. His professional interests include emergency eye care, neuro-ophthalmic disease and medical retina. **Dr. Turner** is a staff optometrist and residency and externship coordinator at the Jack C. Montgomery VA Medical Center in Muskogee, OK. She is a fellow of the American Academy of Optometry and serves as adjunct faculty for several colleges of optometry. **Dr. Burress** is also a staff optometrist at the Jack C. Montgomery VAMC. She is a fellow of the American Academy of Optometry and currently serves as an executive member of the Oklahoma Association of Optometric Physicians Congress Committee. Dr. Burress also serves the ACOE as a chairperson for residency accreditation visits. None of the four authors have any financial interests to disclose.

Photos: George Banyas, OD

Migraine aura often includes a scintillating, or fortification, scotoma. Often, the central scotoma is bordered by a crescent of shimmering zigzags.

and motor and brainstem abnormalities. It is critical to note that the visual aura symptoms experienced in migraine aura are homonymous (occupy the left or right visual field) and binocular. Their binocular nature is a key distinguishing feature for a diagnosis of migraine with aura compared to the unilateral visual symptoms of retinal migraine.

Hemiplegic migraine, a rare subtype, includes familial and sporadic forms and is characterized by motor weakness accompanying the migraine with aura.[2]

Migraine aura without headache. Previously known as acephalgic migraine, this presentation fulfills the criteria of migraine aura with headache but lacks a concomitant or succeeding headache. It is essentially a periodic neurological phenomenon occurring in isolation. As in migraine aura with headache, VAS are binocular, and its diagnosis requires comprehensive neurologic investigation to rule out thromboembolic disease of the eye or brain.

Migraine without aura. Migraines are considered to be a neurological disorder with debilitating headaches, which should be accompanied by either or both nausea and/or vomiting or light sensitivity and noise sensitivity. These severe headaches can affect each person in many different ways. Photophobia or light sensitivity may occur simultaneously to the migraine headache, but photophobia is not considered to be an aura. Additionally, 54% of migraine sufferers note blurred vision accompanying the migraine headaches.[3]

Retinal migraine. These are episodes of transient vision loss in only one eye that are followed by a headache/migraine.[4,5]

Retinal migraine is a diagnosis of exclusion and although the incidence is difficult to ascertain, a review done by Hill et al. showed retinal migraine (as defined in the IHS classification) to be exceedingly rare, suggesting most diagnosed cases would be more properly classified as presumed retinal

What to Do When the Patient Says They Have "Ocular Migraine"

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

Release Date: August 15, 2023

Expiration Date: August 15, 2026

Estimated Time to Complete Activity: two hours

Target Audience: This activity is intended for optometrists engaged in optic nerve disorder management.

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

- Recognize the pathophysiology and presentation of "ocular migraines."
- Evaluate and appropriately classify migraines.
- Educate patients on potential migraine triggers.
- Manage this condition and determine when referral is needed.

Faculty: Leonard Messner, OD, Lucas Rockne, OD, Melissa Turner, OD, Jackie Burress, OD

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All About Aura

Migraine auras are considered to be transient visual, sensory or speech disturbances. Visual disturbances are the most likely form of disturbance, present in with 98% to 99% of migraine auras.[25] Visual aura symptoms are typically bilateral, fully reversible and have a variety of presentations. Some of the most commonly described visual disturbances include flashes of light or photopsia, scintillating scotomas, blurred or "foggy" vision, jagged or wavy lines, bright spots or blind spots.[25]

The classic scintillating scotoma is typically a blurred scotoma of vision encircled by sparkling lights or jagged shimmering lines like heat waves over hot pavement.[30] Of the wide variety of symptoms of visual auras, the symptoms can also often be categorized as positive or negative. Positive symptoms add to the visual space such as photopsia symptoms or jagged lines. Negative symptoms subtract from the visual space such as blurred or blind spots.[4] Optic nerve abnormalities typically produce negative scotomas and need to be ruled out when patients experience those types of visual disturbances.

Migraines may also present with a brainstem aura. This is an aura accompanied by at least two brainstem symptoms and no motor or retina symptoms. The brainstem symptoms include dysarthria, vertigo, tinnitus, hyperacusis, diplopia, ataxia and decreased consciousness.[2]

vasospasm.[6] The latest ICHD-3 criteria classifies retinal migraine as repeated attacks of monocular visual disturbance involving positive and/or negative visual phenomena associated with typical migraine headache. As in migraine with aura, symptoms spread gradually over minutes and are fully reversible.[6-9]

The vision loss can range from various types of scotomas (black, white or even shaded) to blurred vision to complete loss of vision in the affected eye.[4] The most stereotypical pattern of a retinal migraine involves "patchy" areas of fading vision over the course of one minute. Then, the vision becomes further reduced one to five minutes into the event. Finally, the vision returns in the opposite pattern to which it faded.[10] While this may be the typical case, episodes may last up to 60 minutes, and there have been documented cases lasting several hours.[4,5] While these negative symptoms are the most common in retinal migraine, positive symptoms including flashing lights and scintillating scotomas can occur.[4]

Of note, the appellation "ophthalmoplegic migraine" is now known as recurrent, painful ophthalmoplegic neuropathy (RPON). It has since been removed from migraine types and is now classified as a neuronitis. RPON is characterized by episodes of ipsilateral headache followed by paresis of one or more cranial nerves and is strongly associated with youthful age. Cranial nerve III is most commonly involved, followed by VI and IV, respectively.

Oculomotor palsy may occur with or without pupillary involvement. The cranial neuropathy may occur coincident with or up to 14 days after onset of headache. Ophthalmoplegia may persist for weeks to months and is typically self-limiting. In the acute phase, there is often an enhancing lesion of the involved cranial nerve on MRI.[11]

Presentation and Pathogenesis

The visual symptoms of these diagnoses are often what prompts patients to seek care from an eyecare provider. Although not experienced by every migraineur, migraine aura has four phases that include the following:

1. Prodrome. This phase, occurring in up to 77% of those who suffer from migraines by one account, occurs days to hours before a migraine attack.[12] Fatigue, incessant yawning, food cravings and muscle stiffness are common prodromal symptoms. Activation of the hypothalamus is thought to have an intimate role in the prodromal phase of migraine.[13,14]

2. Aura. VAS accompanying migraine are classically described as scintillating scotomas, and sometimes referred to as fortification spectra. They present as convex-shaped visual phenomena with zigzag edges that gradually "march" from fixation, often enlarging and leaving a scotoma in their path. Photopsia (flickering/flashing lights) is the most common visual complaint.[15] Other visual auras include dots, foggy vision, tunnel vision and hemianopic field defects. The visual auras last anywhere from five to 60 minutes with eventual complete recovery.

As previously mentioned, VAS are binocular and homonymous in migraine aura (with or without headache). It is important to note that patients will often report monocular symptoms due to the common perception that the left half of the visual world is coming from the left eye and the right half of the visual field is coming from the right eye. Other non-visual auras (somatosensory, dysphasic, motor and brainstem auras) are less common than visual symptoms.

3. Headache. This will manifest as a unilateral, pulsatile pain often localizing to the frontotemporal aspect of the head and ocular area, although it can be distributed anteriorly or posteriorly in regions of the head and upper neck. Movement (*e.g.*, standing up or walking up stairs) exacerbates head pain. Accompanying symptoms such

Epidemiology of Migraines

Migraines are one of the most common type of headaches. In fact, 12% to 15% of people experience migraines.[12] Migraines occur more often in women than men, affecting approximately 17% to 18% of women and only 6% of men.[3,12] These numbers illustrate that migraines are even more prevalent than asthma and diabetes mellitus put together.[3]

According to the ICHD-3, migraine headaches without aura are the most common type of migraine, accounting for 80% of migraine occurrences.[2,27] Migraines with typical aura and with headache account for 8% to 10% of migraines.[25,27] It is also likely that there is a genetic component to migraines. It has been reported that 70% to 90% of people who suffer from migraine attacks have a family history of migraines.[17]

as nausea, vomiting, photophobia and phonophobia will be present as the headache progresses.

4. Postdrome. Succeeding symptoms of migraine attacks include weakness, fatigue, irritability and difficulty concentrating.

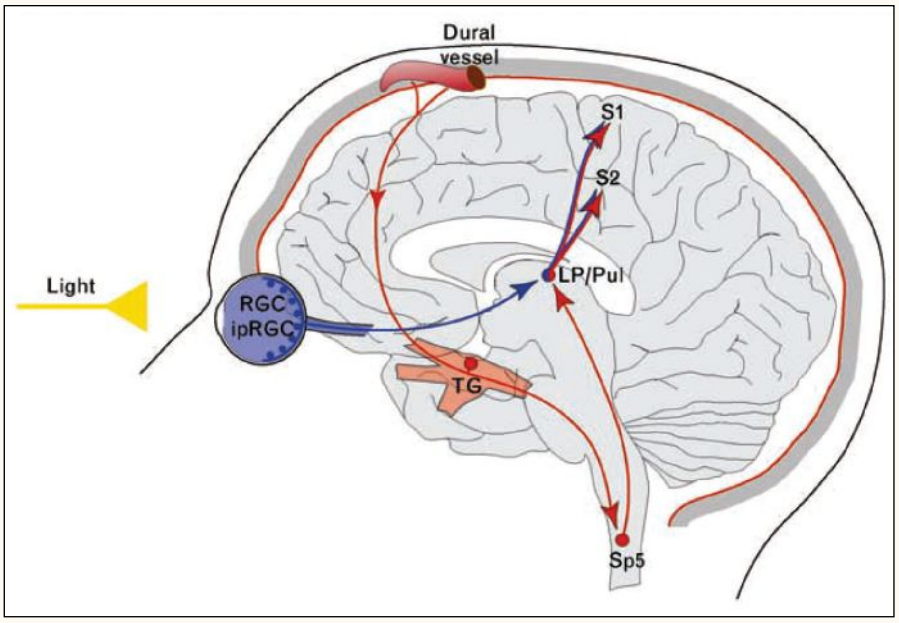
Pathophysiology

The complete mechanism by which migraines arise is still not entirely understood. It was previously thought that migraine aura (with or without headache) was facilitated by changes in brain vasculature. The now outdated vascular theory of migraine suggested aura was a result of vasoconstriction and migraine headache a result of subsequent vasodilation.[16] However, it is now known that vasodilation does not usually occur during migraine attacks, and vasoconstriction occurs in the late stage of migrainosus pain.[12,17] Portions of the vascular theory may still hold true, but the pathophysiology is now thought to be related to activation and release of chemical mediators that lead to a cascade of neural and vascular events.[12,17]

There are many nociceptive structures found in the head, including the skin and associated superficial blood vessels, dura, venous sinuses, arteries and the sensory fibers of the 5th, 9th and 10th cranial nerves.[17]

Cortical spreading depression (CSD). Aura of migraine (specifically visual aura) is a cortical process resulting in binocular symptoms. CSD is recognized as a key neuropathogenic mechanism in the visual aura of migraine. It originates in the visual cortex as a slow-moving wave of depolarization of neurons and glial cells, which then propagates throughout the cortex at a rate of 2mm to 3mm per minute.[12,17] The wave of hyperexcitability is thought to elicit positive visual symptoms (scintillations, phosphenes). It is also believed to trigger the trigeminovascular system and the resultant migraine pain due to changes in the meningeal vessels.[12,17]

Following the wave of hyperexcitability, areas of depressed electrical activity are thought to be responsible for the accompanying visual scotoma.[15,18]



Proposed mechanism for exacerbation of migraine headache by light through convergence of the photic signals from the retina and nociceptive signals from the meninges on the same thalamic neurons that project to the somatosensory cortices. Red depicts the trigeminovascular pathway. Blue depicts the visual pathway from the retina to the posterior thalamus.

ipRGCs: intrinsically photosensitive retinal ganglion cells; LP: lateral posterior nucleus; Pul: pulvinar; RGCs: retinal ganglion cells; S1: primary somatosensory cortex; S2: secondary somatosensory cortex; Sp5: spinal trigeminal nucleus; TG: trigeminal ganglion.

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Trigeminovascular system (TVS). This is thought to play a role in pain and other associated symptoms of migraine. The TVS consists of small-caliber sensory neurons that originate in the trigeminal ganglion and upper cervical roots with terminals in the pial and dural blood vessels. The afferent neurons of this system aid in relaying nociceptive input from neural vessels and dura mater to the central nervous system component of the TVS. From there, release of vasoactive neuropeptides such as calcitonin gene-related peptide (CGRP), neurokinin A and substance P influence responses in the brainstem and cervical spinal cord components of the TVS with further signaling to the thalamus and cortex.

Ultimately, this cascade of events leads to neurogenic inflammation, results in migraine pain and contributes to other associated symptoms (photophobia, phonophobia, nausea and vomiting).[12,17-19] In addition, the anatomical network of the TVS helps explain the anterior and posterior distribution of migraine pain in regions of the head and upper neck.

Retinal migraine. The pathophysiology of retinal migraine is not fully understood. Some suggest the condition is due to reversible retinal vasospasm. Recorded observations of arterial vasospasm episodes of retinal migraine support this theory.[20-23] Others believe retinal spreading depression, similar to CSD, may contribute to the underlying cause.[24] It is important to note that a true retinal migraine is extraordinarily rare and that individuals must satisfy all components of the IHS criteria described earlier in this paper (*Tables 1–3*).

Complications of Migraines

ICHD-3 lists four potential complications for migraines: *status migrainosus*, *persistent aura without infarction*, *migrainous infarction* and *migraine aura–triggered seizures*. Status migrainosus is a migraine that

TABLE 1. DIAGNOSTIC CRITERIA: MIGRAINE WITH AURA

A. At least two attacks fulfilling criteria B and C
B. One or more of the following fully reversible aura symptoms:
   1. visual
   2. sensory
   3. speech and/or language
   4. motor
   5. brainstem
   6. retinal
C. At least three of the following six characteristics:
   1. at least one aura symptom spreads gradually over ≥5 minutes
   2. two or more aura symptoms occur in succession
   3. each individual aura symptom lasts five to 60 minutes[1]
   4. at least one aura symptom is unilateral[7]
   5. at least one aura symptom is positive[8]
   6. the aura is accompanied, or followed within 60 minutes, by headache
D. Not better accounted for by another ICHD-3 diagnosis[7]

TABLE 2. DIAGNOSTIC CRITERIA: MIGRAINE WITHOUT AURA

A. At least five attacks fulfilling criteria B-D
B. Headache attacks lasting four to 72 hours untreated or unsuccessfully untreated
C. Headache has at least two of the following:
   1. unilateral location
   2. pulsating quality
   3. moderate or severe pain intensity
   4. aggravation by or causing avoidance of routine physical activity
D. During headache at least one of the following:
   1. nausea and/or vomiting
   2. photophobia and phonophobia
E. Not better accounted for by another ICHD-3 diagnosis

lasts longer than 72 hours without resolution and is debilitating.[2] Persistent aura without infarction is when the symptoms of the aura continue for one week or longer without resolution and without infarction indicated on neuroimaging. This is uncommon, but when it does occur it is typically bilateral and homonymous, and the symptoms may continue for months or years. A migrainous infarction is a migraine with aura symptoms lasting longer than an hour and an ischemic infarction shown on neuroimaging. Migraine aura-triggered seizures are seizures activated due to an aura.[2]

An individual who suffers from migraines with aura is at risk for certain other health issues, including an increased risk of an ischemic cerebrovascular event and atrial fibrillation.[25] Patent foramen ovale is also more common in individuals who suffer from migraine with aura.

Since ischemic events are also a differential diagnosis for migraines with aura, it is important to remember some key differences between the two. Auras tend to occur progressively with worsening of symptoms, whereas ischemic events (whether a transient ischemic attack or stroke) occur suddenly. Auras also tend to have more positive photopic visual disturbances whereas ischemic events usually involve more of a dimming or loss of vision. Migraines are more likely to be associated with symptoms such as nausea, vomiting, photophobia and phonophobia.[12]

Retinal migraines may have ocular complications. They are typically vascular complications and may cause permanent loss of vision. Because of the pathophysiology of retinal migraines, blood flow may be impaired, leading to complications such as retinal artery occlusions, retinal vein occlusions or retinal hemorrhages.[4]

Associations and Potential Triggers

Patients susceptible to migraines of all forms, including acephalgic or retinal types, can be helped with proper education regarding migraine triggers and how to deal with those issues. Lifestyle changes or removing/avoiding possible triggers for migraines may help keep migraines away for some patients.

Stress, hypertension, hypoglycemia, menstruation, oral contraceptives, heat exhaustion and physical exertion may be potential triggers, as well as weather changes, higher altitude and dehydration.[4,12] Some patients may be sensitive to certain foods, notably chocolate, aged cheeses, cured meats, wine and nuts.

Encouraging patients to pursue lifestyle changes, including drinking plenty of water, getting outdoors for fresh air, decreasing stress, a regular exercise routine, smoking cessation and avoiding alcohol (specifically red wine), may all aid in preventative therapy.[17]

Clinical Workup

Any complaint of visual disturbances requires a comprehensive ocular examination. Case history is an important component of the examination, including a description of the visual disturbance from the patient's perspective and follow-up with additional questions. Is it

constant or transient? How long does it last? Is it monocular or binocular? Does a headache accompany or follow the visual disturbance?

Determining the laterality of visual symptoms in a patient presenting with visual aura is a critical first step in establishing an accurate diagnosis. If visual symptoms are binocular, migraine aura (with or without headache) becomes a viable differential diagnosis. However, particularly in patients who are older than 40 years old with complaints of an aura or visual disturbance without headache, other diagnoses must be ruled out such as transient ischemic attack (TIA), seizure and ocular pathology.[17] This can become particularly challenging in patients with established vascular risk factors and/or diagnosed epilepsy. More youthful patients who have a positive past history of a migraine headache may not need any additional testing.[17]

Careful inquiry about the timing, duration, accompanying symptoms and history of similar episodes can assist in proper diagnosis. For example, an elderly male with ongoing visual symptoms, an abnormal neurologic exam and no prior history of similar visual episodes is suspicious for a TIA or giant cell arteritis rather than of migraine aura and should be worked up accordingly. It is sometimes difficult to differentiate the photopsia or migraine aura from that of vitreoretinal traction. A helpful technique is to instruct individuals with presumed visual aura of migraine to digitally manipulate the globe during subsequent events. If the visual phenomenon appears stable, it is in the brain. If it moves when the eye is moved, it is most likely in the eye.[15]

If visual complaints are monocular, etiologies resulting in transient monocular vision loss (TMVL) must be ruled out before diagnosing retinal migraine (see *Table 4* for common etiologies of TMVL). These may include, among other things, amaurosis fugax, transient ischemic attacks, increased intracranial pressure, orbital apex mass, optic neuritis, carotid artery occlusive disease or arteritic/non-arteritic anterior ischemic optic neuropathy.[9,26]

A thorough physical examination along with appropriate in-office testing (visual field, OCT, OCT angiography, fundus photography) should be performed as indicated. On rare occasions, retinal vasospasm can be observed on funduscopic examination.

Assuming a normal ophthalmic examination, further workup is dictated by patient age, vascular risk factors and accompanying symptoms. Patients over 50 with vascular risk factors and new onset or worsening symptoms warrant an expedited workup encompassing immediate serology for inflammatory markers (ESR and CRP) and carotid imaging to rule out GCA and carotid occlusive disease, respectively. A baseline electrocardiogram, MRI of the brain and CTA or MRA of the head and neck should follow if serology and carotid imaging are normal. Patients over 50 without vascular risk factors and progressing or new onset symptoms can be worked up within 24 to 72 hours.

Workup can be bypassed in younger patients with long-standing symptoms, no vascular risk factors, a normal ophthalmologic exam and symptoms indicative of migraine. Young patients with symptoms that deviate from that of classic migraine, are new in onset and/or are worsening warrant further workup for hypercoagulopathies along with brain MRI. Once all underlying etiologies have been excluded, only then can a diagnosis of retinal migraine be made. If persistent deficits remain (*e.g.*, visual field defects, RAPD), the patient no longer fulfills ICHD-3 criteria for retinal migraine and other thromboembolic etiologies must be ruled out.[9,24,26]

Management Approach

Treatment for migraines accompanied by headache starts with attempting to eliminate potential triggers for attacks.[27] When this is not enough to keep migraines at bay, medication may be indicated. Medication may be either abortive (taken when the headache starts) or prophylactic. Patients who suffer from recurrent or chronic migraine occurrences warrant prophylactic treatment.[27]

For mild to moderate migraines, many people are able to relieve the headache pain with an over-the-counter pain reliever such as acetaminophen or a non-steroidal anti-inflammatory drug (NSAID). This is typically the first line of treatment. If over-the-counter pain relievers are not enough to mitigate the migraines, consider a consult with a neurologist or internist for treatment with medications.

TABLE 3. DIAGNOSTIC CRITERIA: RETINAL MIGRAINE

A. Attacks fulfilling criteria for migraine with aura (listed in Table 1) *and* criterion B below

B. Aura characterized by both of the following:

1. fully reversible, monocular, positive and/or negative visual phenomena (*e.g.*, scintillations, scotomata or blindness) confirmed during an attack by either or both of the following:
   - clinical visual field examination
   - the patient's drawing of a monocular field defect (made after clear instruction)
2. at least two of the following:
   - spreading gradually over ≥5 minutes
   - symptoms last five to 60 minutes
   - accompanied, or followed within 60 minutes, by headache

C. Not better accounted for by another ICHD-3 diagnosis and other causes of amaurosis fugax have been excluded[7]

TABLE 4. COMMON ETIOLOGIES OF TRANSIENT MONOCULAR VISION LOSS

Disease Category	Examples
Vascular	· Carotid artery disease (amaurosis fugax) · Giant cell arteritis · Central retinal artery occlusion
Ocular	· Dry eyes · Epithelial basement membrane dystrophy · Intermittent angle closure
Optic nerve	· Acquired or congenital optic nerve head disease (*e.g.*, papilledema, optic disc drusen) · Optic nerve compression · Uhthoff's phenomenon secondary to demyelinating disease

Although numerous drug classes exist in the abortive management of migraine, triptans are the most common, especially in patients who do not respond to or tolerate simple analgesics or NSAIDs. Triptans are selective 5-hydroxytriptamine serotonin receptor agonists that, among other things, help prevent vasoactive neuropeptide release and block transmission of pain signals. They are well-tolerated by most migraineurs but should be used with caution among those with an established history of hypertension.[28] For these patients, calcitonin gene-related peptide blockers (gepants) and serotonin 5-HT 1F agonists (ditans) have a better safety profile.[29]

Migraine prophylaxis is indicated for individuals who experience four or more headaches per month or eight or more headache days per month. First-line agents for prevention include divalproex, topiramate and beta blockers. The side effects of these agents are problematic for many individuals. CGRP inhibitors are gaining popularity as prevention agents, given their favorable safety profile and minimal side effects.

Antiemetic medications can be taken during a migraine event if needed for nausea or vomiting. Stroke is an increased risk in patients who have migraines, even more so if the patient is a smoker, so smoking cessation should be strongly encouraged.[10]

Conclusion

In summary, the visual symptoms of migraine are a frequent cause of patient visits to the optometrist or ophthalmologist. Migraine aura accompanied by headache in a youthful patient is a straightforward diagnosis that does not require further investigation. Migraine aura without headache is a diagnosis of exclusion requiring a comprehensive investigation for thromboembolic disease. Finally, retinal migraine is exceedingly rare and must meet all IHS criteria stated in this paper. If these criteria are not fully satisfied, such patients must be promptly worked-up for thromboembolic disease associated with transient monocular vision loss.

As eyecare providers, we are uniquely equipped to help diagnose visual auras by ruling out any other ocular pathologies from being the cause of a subjective visual disturbance. Once a diagnosis of ocular migraine is made, patient reassurance and referral to a primary care provider can help improve our patient's quality of life. ■

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1. All of the following fall under the category of ocular migraine EXCEPT?
a. Migraine aura with headache.
b. Migraine aura without headache.
c. Retinal migraine.
d. Cluster headache.

2. Which version of the International Classification of Headache Disorders (ICHD) is currently used for the diagnostic criteria of migraine?
a. One.
b. Two.
c. Three.
d. Four.

3. What is the minimum number of attacks required to satisfy the ICHD criteria for migraine aura?
a. One.
b. Two.
c. Three.
d. Four.

4. What is the most common presentation of migraine aura?
a. Visual.
b. Motor.
c. Sensory.
d. Brainstem.

5. What type of migraine is characterized by brief, recurrent attacks of visual, sensory or other central nervous system symptoms (auras) that are binocular in nature and develop gradually with subsequent headache and associated migraine symptoms?
a. Migraine aura with headache.
b. Migraine aura without headache.
c. Retinal migraine.
d. Ophthalmoplegic migraine.

6. What type of migraine is characterized by periodic neurologic disturbance in the absence of headache?
a. Migraine aura with headache.
b. Migraine aura without headache.
c. Retinal migraine.
d. Ophthalmoplegic migraine.

7. What type of migraine is characterized by repeated attacks of monocular visual disturbance involving positive and/or negative visual phenomena associated with typical migraine headache?
a. Migraine aura with headache.
b. Migraine aura without headache.
c. Retinal migraine.
d. Ophthalmoplegic migraine.

8. Which of the following is TRUE of the visual aura associated with retinal migraine?
a. It is commonly associated with a persistent visual deficit.
b. It is completely reversible.
c. It may be the cause of a retinal artery occlusion.
d. It is never associated with a headache.

9. What is the time range for a typical migraine aura?
a. 30 to 60 seconds.
b. 5 to 60 minutes.
c. 100 to 120 minutes.
d. 120 minutes to 24 hours.

10. Which of the following cranial nerves is most associated with recurrent painful ophthalmoplegic neuropathy (RPON)?
a. III.
b. IV.
c. V.
d. VI.

11. All of the following are commonly associated with migraine prodrome EXCEPT?
a. Yawning.
b. Food cravings.
c. Muscle stiffness.
d. Hyperactivity.

12. All of the following are associated with the visual aura of migraine EXCEPT?
a. Are frequently described as a scintillating scotoma.
b. Are hemianopic.
c. Are associated with complete loss of vision.
d. Are associated with a "march" from central fixation into the peripheral visual field.

13. All of the following are common characteristics of migraine headache EXCEPT?
a. Are often frontotemporal in nature.
b. Frequently present with a sensation of scalp tightness.
c. Are often associated with photophobia.
d. Are exacerbated by body movement.

14. Which migraine phase is associated with weakness, fatigue, irritability and difficulty concentrating?
a. Prodrome.
b. Aura.
c. Postdrome.
d. None of the above.

15. The neurologic disturbance that originates in the visual cortex as a slow-moving wave of depolarization of neurons and glial cells which then propagates throughout the cortex is called which of the following?
a. Cortical spreading of depression.
b. Amaurosis fugax.
c. Reversible ischemic neurologic deficit.
d. Epileptic seizure.

16. The pain of migraine headache is strongly linked to which of the following?
a. Cerebral edema.
b. Activation of the trigeminovascular system.
c. Activation of the pre-frontal cortex.
d. Vasoconstriction of cerebral blood vessels.

17. Which of the following neuropeptides is responsible for the pain of migraine headache?
a. Myelin oligodendrocyte glycoprotein.
b. Aquaporin-4 IgG.
c. Calcitonin gene-related peptide.
d. C-reactive protein.

18. The majority of cases thought to be retinal migraine are most likely which of the following?
a. Presumed retinal vasospasm.
b. Thromboembolic disease associated with underlying cardiac disease.
c. Thromboembolic disease associated with underlying carotid artery disease.
d. Giant cell arteritis.

19. A patient presents to you complaining of intermittent, transient photopsia. The patient physically manipulates the globe during a subsequent episode and reports that the photopsia remains stationary. What is the most likely anatomical location of the pathology?
a. In the eye.
b. In the brain.
c. Either eye or brain.
d. Cannot determine.

20. Which of the following anti-migraine agents should be used with caution in individuals with hypertension?
a. Gepants.
b. Ditans.
c. Triptans.
d. Aspirin.

Examination Answer Sheet

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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. Recognize the pathophysiology and presentation of "ocular migraines." ① ② ③ ④ ⑤
22. Evaluate and appropriately classify migraines. ① ② ③ ④ ⑤
23. Educate patients on potential migraine triggers. ① ② ③ ④ ⑤
24. Manage this condition and determine when referral is needed. 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: _____

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Rate the quality of the material provided:

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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
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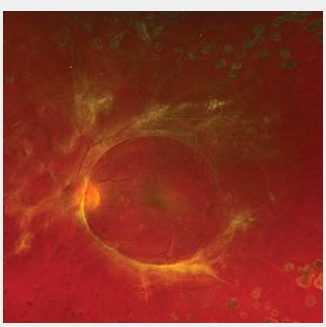

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REVIEW Education GROUP

Be a Pro at Boston KPro

Post-op management of this prosthesis can be boiled down to just two main components.

Q I have my first Boston KPro prosthesis patient (following severe stem cell deficiency) coming in next month for her first follow-up. There doesn't seem to be much published on proper follow-up care of these patients. Any suggestions on what works best to minimize infection? Also, how to best estimate IOP, since conventional measures are not possible?

A The Boston Keratoprosthesis (KPro) is a polymethylmethacrylate (PMMA) two- or three-piece prosthesis constructed similarly to a rivet through a traditional cornea (called the carrier cornea), explains cornea specialist Brandon Ayres, MD, of Philadelphia's Wills Eye Hospital. The PMMA front plate of the prosthesis has a stalk that looks like a mushroom. The stalk is placed through a 3mm hole punched in the center of a traditional donor cornea, leaving the cap on the epithelial side. A titanium back plate is then snapped in place on the endothelial side of the carrier cornea, locking the prosthesis in place. Several small holes are drilled in the posterior plate to allow aqueous access to the cornea, which prevents melting of the carrier cornea (*Figure 1*).

"After surgery, most KPro patients wear a bandage contact lens to help prevent discomfort from the prosthesis and to help with tear distribution," Dr. Ayres elaborates. "The KPro is a wonderful option for patients with multigraft failure and other conditions where a traditional corneal transplant has a very low chance of success," he explains. For example, cases of chemical injury and stem cell deficiency are prime candidates. The challenge of the KPro, however, is preventing infection and glaucoma progression.

Management

In the case presented, the KPro is being placed due to limbal stem cell deficiency (LSCD). KPro is a good option for LSCD patients, preventing the need for autologous or cadaveric stem cell transplants. In cases such as this one, the surgery is the easy part; the challenge is following the patient for glaucomatous changes and infection prevention.

Many times, patients with stem cell deficiency also have a history of glaucoma. If a patient is already on glaucoma medications, a tube shunt may have already been placed or can be placed at the time of KPro surgery, which can make it much easier to regulate intraocular pressure, Dr. Ayres elucidates. In the event a tube was not placed, topical drops are still effective.

"The PMMA front plate makes it very difficult to accurately check the IOP of an eye with a prosthetic cornea," explains Dr. Ayres. "As such, finger

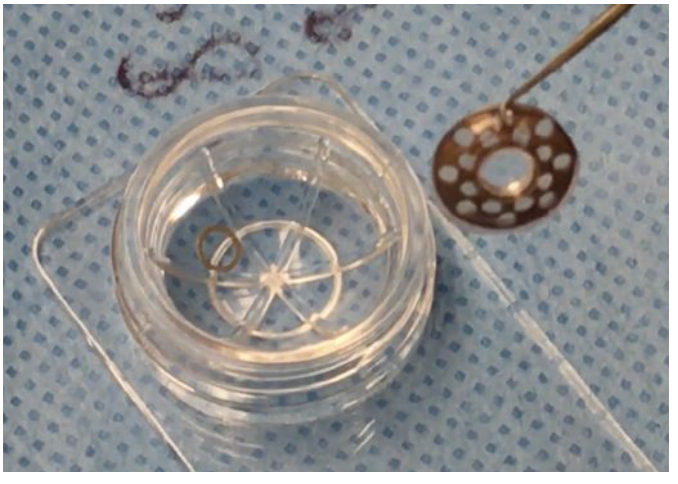


Fig. 1. An intraoperative image of the Boston Keratoprosthesis. The PMMA front plate is held in place by a titanium back ring that "sandwiches" a human donor carrier cornea in place. The prosthesis will be sutured in place from carrier cornea to recipient cornea using 10-0 nylon suture.

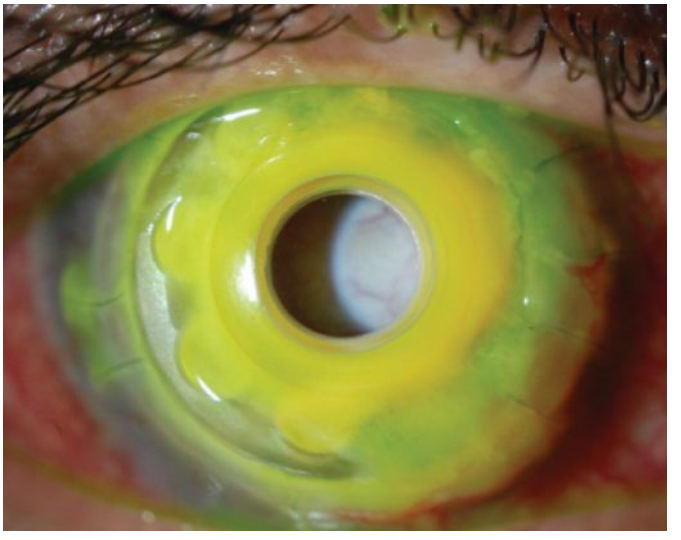


Fig. 2. A KPro with melting carrier cornea and fungal infiltrate around the stalk of the prosthesis. Note, this is an older version of the KPro with a PMMA back plate.

About Dr. Shovlin **Dr. Shovlin**, a senior optometrist at Northeastern Eye Institute in Scranton, PA, is a fellow and past president of the American Academy of Optometry. He consults for Kala, Aerie, AbbVie, Novartis, Hubble and Bausch + Lomb and is on the medical advisory panel for Lentechs.

tension pressure should be checked on all patients every three to four months. Luckily, the KPro is clear from post-op day one, so the optic nerve can be directly visualized."

Estimation of the cup-to-disc ratio should be documented every visit; a visual field and OCT should be performed every six months, Dr. Ayres counsels. It is also common to manage these patients in conjunction with a glaucoma specialist.

Preventing infection is critical in the KPro patient, and there are several acceptable medical regimens. Many patients are started on topical fluoroquinolone therapy four to six times daily after surgery and then tapered to once daily within the first two weeks post-op. The fluoroquinolone eye drop should be continued daily for life; very often, a drop of vancomycin (with concentration between 14mg/ml and 25mg/ml) is also used daily for life. An accepted alternative to this combination is to use polymyxin B/trimethoprim instead.

"In patients with severe stem ocular surface disease, as is often the case with LSCD, fungal overgrowth and infection (*Figure 2*) in the carrier cornea is a problem," warns Dr. Ayres. To prevent this, amphotericin B (compounded) or natamycin (commercially available) can be pulsed twice daily during the first week of every third month. "In my own patients with LSCD, pulsing the antifungal has made a tremendous difference in the rate of fungal keratitis," adds Dr. Ayres.

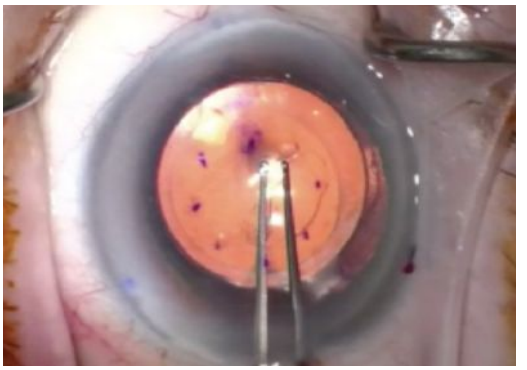
Lastly, the bandage lens needs to be managed in the KPro patient; almost any lens works. "We have patients who use daily, extended wear, hybrid and scleral contact lenses," says Dr. Ayres. The lens will need to be changed according to its replacement schedule and how it looks during follow-up exams. "It is common to see deposits on the contact lens, indicating the need for change, but the lens is vital in preventing melting of the carrier cornea," Dr. Ayres urges. "Best of luck with your patient—the KPro patient can be quite challenging!" ■

Get to Know DSO

This new procedure may eliminate the need for a corneal transplant.

BY RANJANI PANDA, OD
NORFOLK, VA

For some time, Descemet's membrane endothelial keratoplasty (DMEK) has been the preferred procedure for treating Fuchs' endothelial disease. However, Descemet stripping only (DSO)—also known as descemetorhexis without endothelial keratoplasty—may eliminate the need for DMEKs in patients with centrally isolated Fuchs' corneal dystrophy.



Descemet stripping only allows a person's own endothelial cells to redistribute, skipping the need for a cornea transplant.

Strip Away

This procedure is indicated in eyes with guttate within 5mm of the central cornea with a clear peripheral cornea and endothelial cell count of >1,000 cells/mm^2 seen on specular or confocal microscopy. Contraindications for DSO include presence of Descemet's membrane folds, any stromal pathology (*e.g.*, bullae. stromal haze,) presence of other corneal pathology, history of herpes keratitis and endothelial cell count below 1,000 cells/mm^2.[1] It is imperative that the peripheral cornea is clear and that guttate is isolated centrally in patients prior to DSO. Patients should also not have any stromal disease or history of keratitis.

DSO can be performed in both phakic and pseudophakic eyes and is relatively quick, performed in approximately five to six minutes under local anesthesia; it does not require injection of air or gas into the anterior chamber.[2]

Surgeons may choose to dilate the pupil beforehand to obtain a better red reflex and therefore better visualization of Descemet's. Using viscoelastic, a central circular descemetorhexis of approximately 4mm to 5mm is performed using a Sinskey or Fogla Descemet's membrane stripping hook. It is important that Descemet's is carefully peeled and not scraped, as scraping can cause a larger descemetorhexis, as well as involvement of the stroma.

During the healing process, peripheral endothelial cells from the healthy cornea migrate toward the central area of the descemetorhexis and regenerate the central posterior cornea.

Postoperative treatment should include topical steroids, antibiotics and hypertonic sodium chloride. It has also been shown that rho-kinase inhibitors can increase endothelial cell proliferation, suggesting that its post-op use can decrease corneal edema and increase corneal clarity.[3,4]

For a video of the procedure, read this article online at www.reviewofoptometry.com.

Advantages and Complications

A great advantage of DSO is the elimination of donor tissue implanted in the eye. This alone prevents some of the postoperative complications involved in DMEKs such as graft rejection, potential IOP spikes from gas in the anterior chamber that's used to initially hold the graft in place and the risk for secondary procedures such as a refloat. DSO also eliminates the need to perform a prior peripheral iridotomy and supine positioning following surgery. However, like any procedure, DSO also has potential complications, including decentration of the descemetorhexis that can impede visual acuity or cause posterior stromal opacity, irregular corneal astigmatism, persistent corneal edema and Descemet's membrane detachment.

Although there is a longer healing period compared to DMEK, DSO has shown similar visual outcomes with fewer adverse events.[1,5] ■

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ABOUT THE AUTHOR

Dr. Panda completed her residency in ocular disease and ocular/refractive surgery management at Virginia Eye Consultants in Norfolk, VA, where she currently works as a provider. She has no financial disclosures.

About Drs. Cunningham and Whitley **Dr. Cunningham** is the director of optometry at Dell Laser Consultants in Austin, TX. He has no financial interests to disclose. **Dr. Whitley** is the director of professional relations and residency program supervisor at Virginia Eye Consultants in Norfolk, VA. He is a consultant for Alcon.

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To our readers: **Thank you for your loyalty, time and trust. We'll keep working hard to earn your support.**

BY RAMI ABOUMOURAD, OD

RETINA QUIZ

Separation Anxiety

Retinal detachment can be a complication of this condition.

A 74-year-old Hispanic male presented with acute onset new red spots, "web-like" floaters and blurred vision in his left eye for five days. Past medical history included hypertension, hyperlipidemia and atrial fibrillation that were controlled with metoprolol, dofetilide, apixaban, telmisartan, atorvastatin and spironolactone. His ocular, social and family histories were unremarkable, and he denied history of trauma.

Acuity was 20/40 OD and 20/150 OS. Extraocular motilities were full, confrontation fields were full and there was no relative afferent pupillary defect. IOP was 15mm Hg OD and 11mm Hg OS. Anterior segment exam revealed 3+ nuclear sclerotic cataracts OU.

Take the Retina Quiz

1. Which of the following is true of the inferotemporal lesion in the right eye?

a. It is a choroidal effusion.
b. It is a choroidal hemangioma.
c. It is a retinal detachment.
d. It is a retinoschisis.

2. How would you interpret the B-scan of the left eye?

a. There is a full-thickness macular hole.
b. There is a retinal detachment.
c. There is an epiretinal membrane.
d. There is an inner retinal hole.

3. What is the appropriate management for the left eye?

a. Close observation.
b. Intravitreal anti-VEGF injection.
c. Laser retinopexy.
d. Pars plana vitrectomy.

4. Which of the following is a potential complication of this patient's condition?

a. Glaucoma.
b. Irregular astigmatism.
c. Macular degeneration.
d. Retinal detachment.

5. Which of these is true regarding prognosis?

a. There is a high risk of progression to retinal detachment in the right eye.
b. There is a high risk of progression to retinal detachment in the left eye.
c. There is a low risk of progression to retinal detachment in the left eye.
d. Risk of retinal detachment is the same for inner retinal breaks as well as combined inner and outer retinal breaks.

For answers to the quiz, see page 90.

Diagnosis

Fundus exam revealed a posterior vitreous detachment (PVD), macular scar and inferotemporal retinoschisis OD, and a vitreous hemorrhage and superotemporal retinoschisis OS (*Figures 1 and 2*). B-scan ultrasound confirmed the retinoschisis OU and identified a focal inner-retinal hole within the retinoschisis cavity OS that was otherwise challenging to locate on clinical exam due to presence of a vitreous hemorrhage (*Figures 3 and 4*).

Retinoschisis was diagnosed OU, and the vitreous hemorrhage OS was presumed secondary to a hemorrhagic PVD that created vitreoretinal traction and

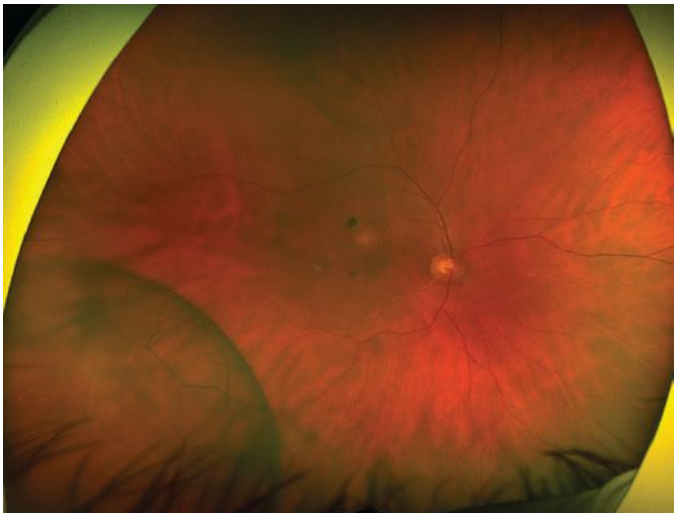

Fig. 1. Optos widefield fundus photography of the right eye.

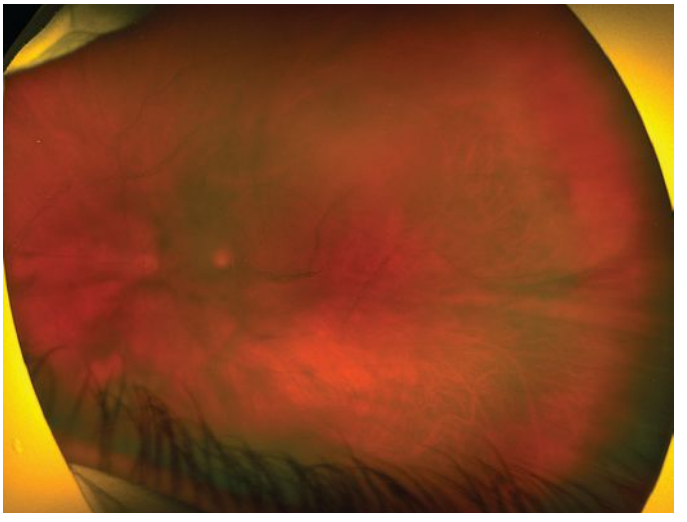

Fig. 2. Optos widefield fundus photography of the left eye.

About Dr. Aboumourad **Dr. Aboumourad** currently practices at Bascom Palmer Eye Institute in Miami. He has no financial disclosures.

ultimately an inner-retinal hole within the superotemporal schisis pocket. Close observation was elected with serial dilated fundus exams and B-scans to rule out new retinal breaks, expansion of the schisis cavity or progression to combined retinoschisis and retinal detachment.

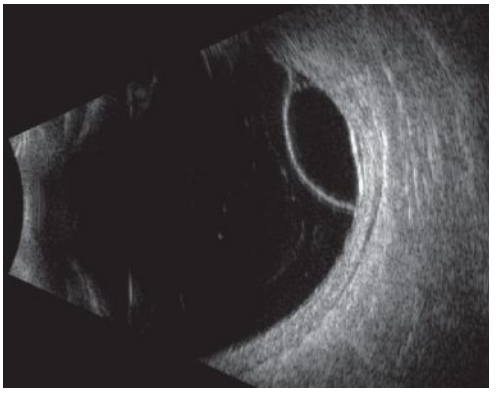

Fig. 3. Longitudinal B-scan of the right globe along the 7:30 meridian.

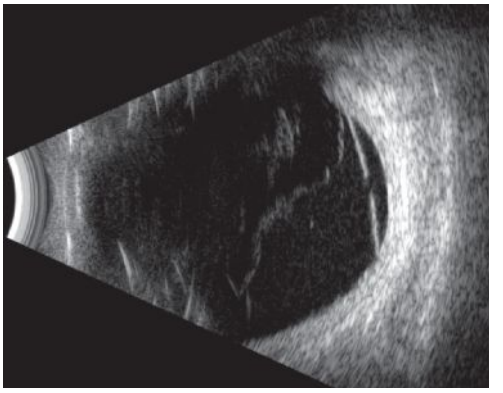

Fig. 4. Longitudinal B-scan of the left globe along the 1:30 meridian.

Discussion

Retinoschisis is defined as a splitting of the retina most commonly at the level of the outer plexiform layer; it can also occur at the level of the nerve fiber layer.[1-3] Juvenile (X-linked) retinoschisis is inherited and the most common cause of juvenile macular degeneration in males, as it presents with a foveal schisis.[4,5] Peripheral, degenerative (also known as acquired, senile) retinoschisis is typically found in middle-aged individuals with an incidence of 1% to 3.7% of adult patients and up to 7% of patients over the age of 40.[5,6] It is most frequently bilateral (40% to 82% of patients) with a predilection for the inferotemporal quadrant (72%), and can expand posterior to the equator in up to 42% of patients.[1,2,5,6] There is no sex predilection, and there is a trend towards hyperopic refractive error.[2,6]

This condition is typically seen as a round/ovoid, transparent, immobile, flat (typical) or dome-shaped (reticular), smooth bullous elevation involving the inferotemporal quadrant.[1,2,6,7] The thin inner walls of a schisis cavity often contain retinal vessels that take on an attenuated or sheathed appearance.[5] Nearly all retinoschises are anteriorly continuous with or begin just posterior to the ora serrata, and are delineated by cystoid degeneration at their posterior margins.[5,6]

It is crucial to differentiate retinoschisis from other conditions, including retinal detachment, combined retinoschisis-detachment, choroidal effusion and choroidal malignancy (*e.g.*, melanoma). Unlike retinoschisis, retinal detachments are more opaque, mobile, have a corrugated/wrinkled surface and tend to produce a relative, rather than absolute, scotoma.[1,5,6]

Prognosis and Treatment

Retinoschisis is asymptomatic and often remains stable in the absence of intervention.[8] Observation is indicated to monitor for progressive enlargement of the schisis, development of inner and/or outer wall breaks and evolution to combined retinoschisis-detachment.[8] Schisis cavities may enlarge laterally (6%), vertically (5%) and posteriorly (3%) toward the macula, but in a series of 218 eyes, none progressed to macular involvement over an average of nine years.[7,8]

Inner retinal breaks are less common than outer retinal breaks and are seen in up to 4% and 17% to 23% of retinoschisis, respectively.[9] Outer retinal breaks create a direct communication with the schisis cavity and the subretinal space that can lead to retinal detachments; those associated with outer wall breaks tend to be localized, asymptomatic and nonprogressive, therefore infrequently requiring intervention.[8,9]

Progressive and symptomatic retinal detachments in the setting of retinoschisis are most common in patients with retinal breaks in the inner and outer schisis walls, allowing a direct communication between the vitreous cavity, schisis cavity and subretinal space, though there are cases of progressive retinal detachments related to large outer retinal breaks.[8,9] Progressive combined retinoschisis-detachments necessitate prompt intervention to stabilize or repair the retinal detachment, depending on the extent.[8,9]

Prognosis is favorable as many retinoschisis patients retain baseline visual acuity. Treatment is seldom necessary for isolated retinoschisis irrespective of the presence or absence of retinal breaks.[8] However, swift intervention is needed when progressive combined retinoschisis-detachments occur.[8] Retinoschisis with localized detachment should be monitored closely for progression; intervention should be at the discretion of a retinal specialist.[8] It is worth noting that retinoschisis cavities may occasionally undergo spontaneous collapse and regression.[3,8]

Our patient was observed with serial dilated fundus and scleral depressed exams every two weeks until the vitreous hemorrhage cleared, at which point appointments were extended. He ultimately underwent cataract surgery in both eyes after three months of stability following the resolution of vitreous hemorrhage and achieved final acuity of 20/20 OD and OS. ■

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BY JAMES L. FANELLI, OD

Old-School Schooling

Sometimes, patients need a dose of a firm yet understanding conversation to lead them to proper management.

A 65-year-old Caucasian female presented to the clinic as a new patient this past June with complaints of decreased vision in her right eye and that it has been blurry for the better part of a year. Her last eye examination was three years prior and her glasses, as she explained, were never 'just right.'

Case

Medical history included systemic medications of hydralazine, carvedolol, nifedipine, bupropion, citalopram and Lumify (brimonidine tartrate, Bausch + Lomb) PRN. She reported no allergies to medications, and she had undergone LASIK surgery OU several years ago, apparently when it was first approved in the USA.

When questioned about the visual complaints, she intimated that her right eye was just not seeing well and that her last pair of glasses didn't seem to help too much. Entering visual acuities were 20/30- OD and 20/25+ OS. Best-corrected acuities were 20/30 OD and 20/20- OS through hyperopic astigmatic correction OU. Pupils were ERRLA and there was an equivocal afferent pupillary defect OD. Extraocular movements were full in all positions of gaze.

A slit lamp exam of the anterior segments was remarkable for clear corneal flaps with pristine interfaces OU; there were no flap edge abnormalities nor epithelial ingrowth in either cornea. Angles were open OU by Van Herick estimation. Applanation tensions were 17mm Hg OD and 13mm Hg OS.

Fig. 1. The patient's right eye in 2009. Note the thinning of the inferotemporal neuroretinal rim, calling into question the likelihood of glaucoma.

Central corneal thickness readings were 504µm OD and 532µm OS.

The patient was dilated in the usual fashion with phenylephrine and tropicamide. Through dilated pupils, her crystalline lenses were characterized by incipient nuclear sclerosis OU. Close examination of her optic nerves demonstrated a cup-to-disc ratio of 0.75x0.95 OD and 0.6x0.65 OS. The neuroretinal rim in the right eye was eroded from six to 11 o'clock; there were no disc hemorrhages noted at this visit. Her retinal vasculature was characterized by grade 2 arteriolar sclerosis OU consistent with her cardiovascular picture. The macular evaluations were essentially unremarkable with fine RPE granulation, and the peripheral retinal evaluations were also unremarkable OU.

Given the findings, a diagnosis of advanced glaucoma was made OD and probable early glaucoma OS. Also, given her complaints of decreased vision in the right eye, along with the extent of neuroretinal rim damage OD, I would imagine a visual field defect most likely involving fixation was present, accounting in part to the decreased subjective vision OD. Accordingly, the patient was scheduled for a complete glaucoma evaluation.

When discussing these findings with her, I asked if any of her previous doctors had mentioned the possibility of glaucoma with her. She said that they didn't; furthermore, she stated that when she saw me years ago, neither did I. I was surprised by this comment, as she was registered as a new patient. Upon hearing this, my tech began looking for her previous records in our EMR; sure enough, she was seen by me in 2009.

In looking back at that visit, she had a cup-to-disc ratio of 0.5x0.7 OD and 0.5x0.55 OS with a thin, questionably eroded inferior temporal neuroretinal rim. The chart notes from that visit specifically listed glaucoma suspect OU as a diagnosis, and the patient was scheduled for a follow-up to evaluate the situation. The patient never returned to the office—until 2023.

Discussion

We've all seen patients on both sides of this equation. They either present as new patients with clinical findings of a long-standing condition and deny any other provider mentioned this, or they dismiss your plan of action at visitation and do not return for further care; this patient fell into both categories. How do you handle these situations?

Let's take a look at the first scenario, in which the patient presents with advanced glaucoma—which we know has been there for a substantial amount of time. Perhaps it did develop in the

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.

interim between your visit with the patient and their previous visit by another provider, which in this case was three years earlier. In either case, we are dealing with the present situation, namely, uncontrolled normal tension glaucoma, although here, the thin post-LASIK corneas are resulting in artificially low IOP readings. As such, the situation needs to be brought under control. They need intervention of some kind, either medical or surgical.

The crux of managing glaucoma is multifactorial, but it certainly involves mitigating the risk factors for progressive optic nerve damage. But, equally important is the 'buy in' of the patient to your plan of action. Without it, any management plan will have a hard time succeeding, usually due to noncompliance. Of course, patient education is important, but so is a frank discussion of the potential negative effects on vision that may occur if the plan is not followed precisely and stringently.

A trusting doctor-patient relationship is not developed overnight, nor in one visit in many cases. However, that first visit is important to begin to build that sound relationship. Communication, compassion, understanding and, of course, sound clinical care are all important aspects to fostering that relationship. Unfortunately, the simple truth is that sometimes, whether the patient doesn't understand the importance of what you're saying, or they simply don't want to hear it or don't believe it, they just don't follow through with your clinical advice, despite your best efforts. An old axiom comes to mind: a patient needs to assume a certain amount of responsibility for their own care. That holds true whether we are talking about glaucoma or diabetes, for example, or any other condition.

The second scenario is the patient who dismisses your plan of action and seeks care elsewhere. Perhaps the severity of the situation was discussed previously (as in this instance) and, for whatever reason, the patient forgot, actively ignored the advice or didn't understand what was being said. Or, maybe even more unfortunately, a previous provider did not identify the disease process in the intervening period. In any case, it is now even more important to clear up any misunderstanding the patient may have. Firm, but clear explanations are in order here.

Fig. 2. This is an HRT 3 tomogram of the right optic nerve taken in 2009. Note the significant thinning and notching of the neuroretinal rim at the seven o'clock position. Moorsfield's classification of this optic nerve at that time demonstrated a high likelihood of this sector being affected by disease rather than a statistical anomaly.

This then prompts the question: if they were told about this situation previously and dismissed it, why would they now act differently? In fact, I am the same provider who mentioned to the patient 14 years prior that they may have glaucoma, yet they dismissed me then—why would they not dismiss the idea now? They may, in reality, do just that, but now I have a distinct advantage. She is presenting with noticeably decreased vision in one eye, which is bothersome to her. Importantly, it is not because I said the vision was decreased but because she had noticed her vision is decreased, thus precipitating the current visit with me. Patients may deny my thought process, but they probably won't deny their *own* thought process—she knew her vision has worsened.

> **I asked if any of her previous doctors had mentioned the possibility of glaucoma with her. She said that they didn't; furthermore, she stated that when she saw me years ago, neither did I.**

This becomes our profession's opportunity to be firm yet gentle with the patient. This is my second chance at the 'first visit' with me, in a sense. I told her at exam completion that she had glaucoma and that was playing a role in why her vision was decreased. To help foster compliance, I did mention to her that I had noticed this at our previous visit, but that she chose not to follow through with recommendations then and it is now time to start adhering to a management plan. Was this an 'I told you so'? Not really, as in my opinion it was a way to break any lines of miscommunication or misunderstanding about the severity of her situation. Mentioning this was simply a tool to hopefully get her attention, so that I could then begin to get the situation under control.

As it turned out, we were not able to obtain structural images of her optic nerves at this particular visit due to time constraints. Unlike 14 years ago, however, the patient is scheduled for visual field and OCT imaging in a week. Her images from 2009 are presented here for completeness. Though technology has changed over the past 14 years, the imaging in 2009 was indicative of a problem. Let's see if my second 'first visit' with the patient results in compliance. ■

BY JESSICA STEEN, OD

There and MAC Again

Optometrists need a roadmap when dealing with the potential spectrum of conditions these bacteria can cause.

An incomplete medical and therapeutic history and the need to untangle often complex, vague past events to ensure the correct diagnosis can pose challenges to clinical care. In one particular case, a 59-year-old man was referred for evaluation of suspicion of glaucoma based on optic disc appearance. He reported taking three medications for *Mycobacterium avium* complex (MAC). While he wasn't sure of the names of the medications, he did share that two drugs were oral tablets and the third was inhaled via a nebulizer. His vision was 20/20 in each eye, he had a subtle afferent pupillary defect in the right eye, intraocular pressure of 9mm Hg OD and OS, and superotemporal pallor of the right optic disc more than the left without notching of either neuroretinal rim. Deciphering his medical and treatment history through communication with managing providers led to the determination that he was taking rifampicin, isoniazid and inhaled liposome amikacin.

Background

Considered a mainstream illness in respiratory medicine, MAC pulmonary disease is a condition caused by non-tuberculosis mycobacteria.[1,2,3] Unlike tuberculosis, the MAC group of pathogens are not contagious, but their increasing prevalence in the population and potential for serious ocular adverse events related to treatment mean that clinicians should be familiar with the condition and its management.[4] *Mycobacterium avium*, and the 11 other species of gram-positive, aerobic bacteria that are responsible for MAC pulmonary disease are generally not pathogenic and are naturally found in water and soil sources around the world.[2,3] In susceptible immunocompetent individuals, which primarily include those with underlying pulmonary disease and those with past smoking history and bronchiectasis, widening and scarring of the airways result in the inability to clear mucus and MAC-causing bacteria after inhalation or ingestion resulting in infection that leads to symptoms of fatigue, shortness of breath and chronic cough.[3]

While diagnosis of MAC is made by clinical, radiologic and microbiologic evaluation, treatment is not always necessary in immunocompetent individuals.[1,3] Careful evaluation of pathogenicity and individualized evaluation of risks and benefits of therapy may lead to the decision to monitor without antibiotic treatment. Even with aggressive long-term, multidrug therapy, clearance of the infection is not always possible, as a recent meta-analysis described the resolution rate of MAC in 3,800 individuals to be only 68.1%.[5]

Despite the lack of risk of contagious spread of MAC, when treatment is indicated, patients will generally be managed by an infectious disease specialist. Long-term antibiotic therapy for 18 or more months may be needed, with current guidelines recommending continued treatment for 12 months following conversion to negative culture.[1] Standard therapy for MAC is a three-antibiotic regimen incorporating a macrolide (usually azithromycin), ethambutol and a rifampicin-based drug.[1] The array of antibiotics used in MAC treatment are associated with known adverse systemic and ocular events that clinicians must be familiar with in order for prompt recognition and communication with the managing physician in order to minimize vision or life-threatening effects.

Incorporating ethambutol into the MAC treatment regimen, generally at a dosage of 15mg/kg/day, is primarily

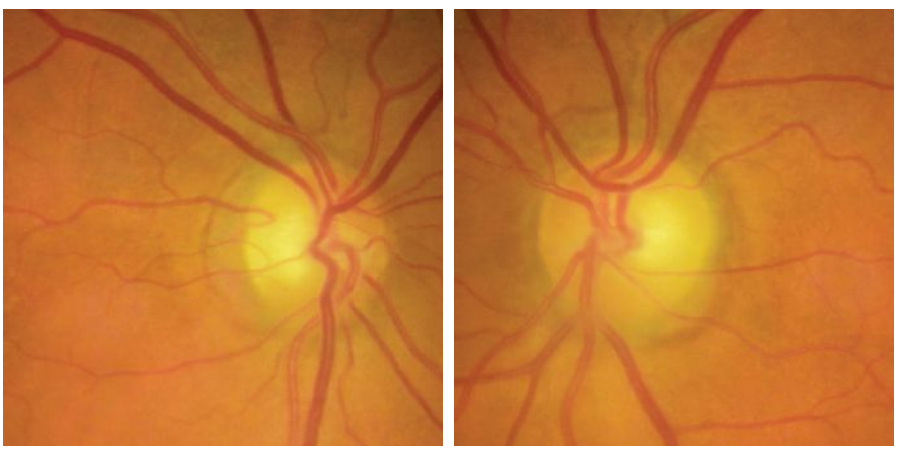

Fig. 1. Optic disc photos demonstrating subtle superotemporal optic disc pallor of both eyes.

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 and Carl Zeiss Meditec.

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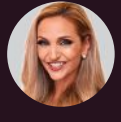

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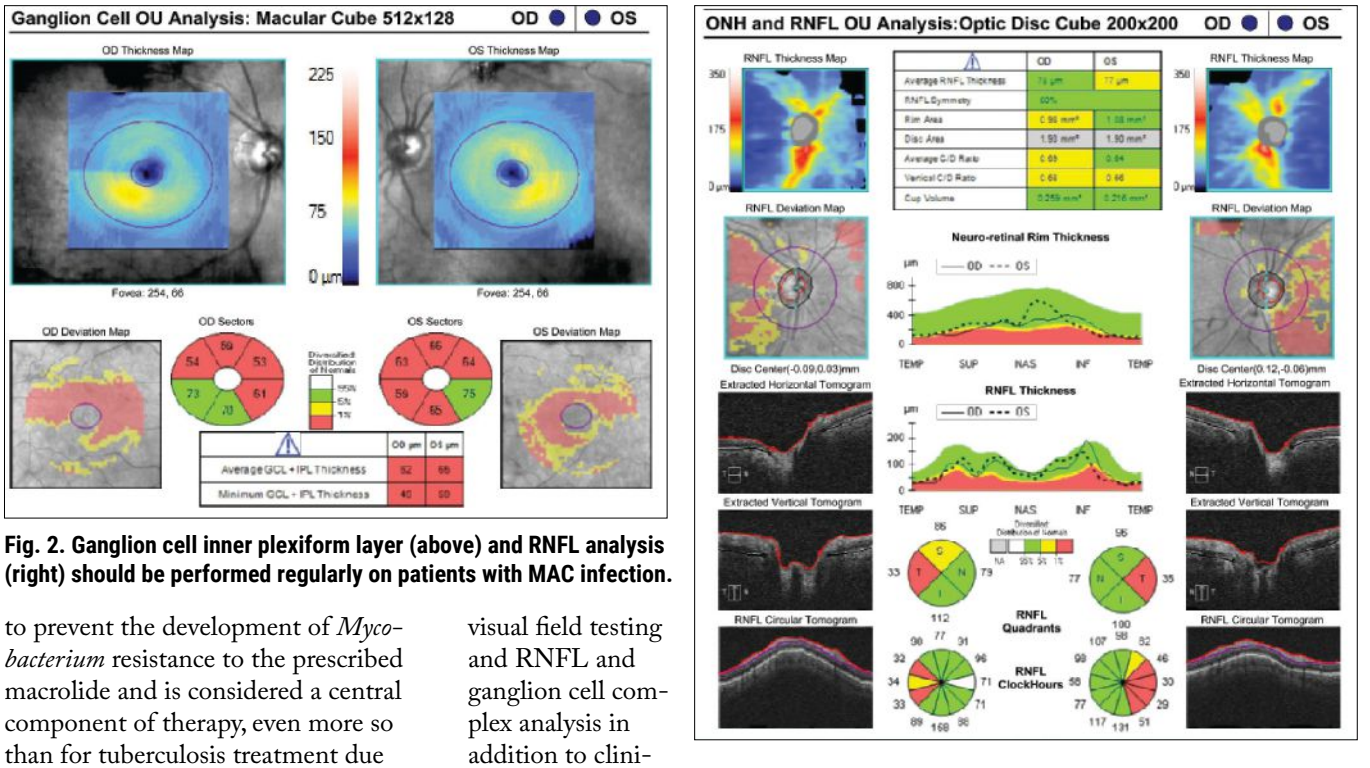

Fig. 2. Ganglion cell inner plexiform layer (above) and RNFL analysis (right) should be performed regularly on patients with MAC infection.

to prevent the development of *Mycobacterium* resistance to the prescribed macrolide and is considered a central component of therapy, even more so than for tuberculosis treatment due to the extended period of antibiotic therapy required.[1,6,7] Patients have up to a 6% risk of ethambutol-associated optic neuropathy in MAC lung disease treatment regardless of the dosage, despite the risk generally being described as dose-related.[8] While time to onset of ethambutol-associated optic neuropathy varies, a recent analysis identified that most patients experienced symptomatic change between 181 and 300 days after initiation of therapy.[9]

Monitor Treatment

Careful, frequent, ophthalmic evaluation that incorporates automated visual fields and retinal nerve fiber layer (RNFL) and ganglion cell analysis in individuals taking ethambutol have been recommended due to the risk of progressive, often irreversible vision loss and the goal of early diagnosis and intervention. For patients taking an ethambutol dosage greater than 15mg/kg/day, for those treated for longer than two months, and for those with renal insufficiency, monthly evaluation with visual symptom screening, visual acuity assessment and color vision evaluation have been recommended.[10,11] Incorporation of automated visual field testing and RNFL and ganglion cell complex analysis in addition to clinical examination are advised for detection of asymptomatic, preclinical optic neuropathy. A recent prospective study of individuals taking ethambutol for tuberculosis for a period of six months identified that 46% of eyes demonstrated subclinical, asymptomatic change from baseline attributable to ethambutol toxicity detected by RNFL and ganglion-cell inner plexiform layer loss.[12] Other agents that may be used in the treatment of MAC also have known ocular effects. Isoniazid, while a less common cause of optic neuropathy than ethambutol, has been reported to cause optic neuritis, and rifampin may cause the discoloration of tears, sweat, and saliva.[13,14]

Unlike tuberculosis, MAC is not a reportable disease, which means that epidemiological data are uncommon. However, we do know that in North America, MAC prevalence is on the rise, primarily in older individuals, with a recent Canadian study identifying a 2.5-fold increase in the number of individuals diagnosed with MAC between 2010 and 2020.[4] Proposed reasons for increased prevalence related to increased environmental exposure, the long duration of treatment and the rise of biologic agents resulting in low-grade immunosuppression.[3,15]

While standard therapy in MAC pulmonary disease relies on agents developed more than 30 years ago, advancements in MAC are continuing to be developed to meet the needs of patients and managing physicians. For individuals with MAC refractory to treatment after six months of standard therapy, the addition of the FDA-approved inhaled amikacin liposome suspension, Arikayce (Insmed), is recommended.[1] While systemically administered aminoglycosides carry the risk of ototoxicity and nephrotoxicity, the risk of systemic exposure been proposed to be reduced with localized drug delivery to the lungs. In an open-label extension trial investigating the safety and efficacy of amikacin liposome suspension through an additional 12 months of treatment, 7.8% of participants experienced hearing loss and 6.7% experienced tinnitus with an additional 33.3% of treated individuals demonstrating culture conversion through 12 months.[16]

Patient Follow-up

Considering the patient's clinical appearance of subtle optic atrophy in the

absence of glaucomatous optic neuropathy, targeted questioning about MAC treatment history revealed the patient had been diagnosed with MAC in 2019, and after initial treatment of ethambutol, it was discontinued after approximately 22 months due to concern of ocular toxicity, with documentation of the absence of progressive optic neuropathy since the drug's discontinuation. After nearly four years of continued antibiotic therapy for MAC, the patient continues to require ongoing multidrug treatment without conversion to negative culture. His current treatment regimen, while not including ethambutol, still requires careful clinical evaluation, periodic OCT of the RNFL and ganglion cell inner plexiform layer, as well as automated visual fields, due to known risk of ocular adverse effects and continued communication with his managing providers.

MAC pulmonary disease represents a heavy ailment and treatment burden on patients and their caregivers due to chronic morbidity and burden of long-term therapy with significant risk of toxicity, often without disease resolution. Recognizing the adverse ocular effects of systemic medications begins with an accurate and complete history, which often requires a great deal of legwork, as well as an up-to-date medical knowledge of the underlying disease process and potential ocular complications. ■

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Contact Lenses

Practice For Sale

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Contact Lenses

BY ANDREW S. GURWOOD, OD

DIAGNOSTIC QUIZ

Stowaway

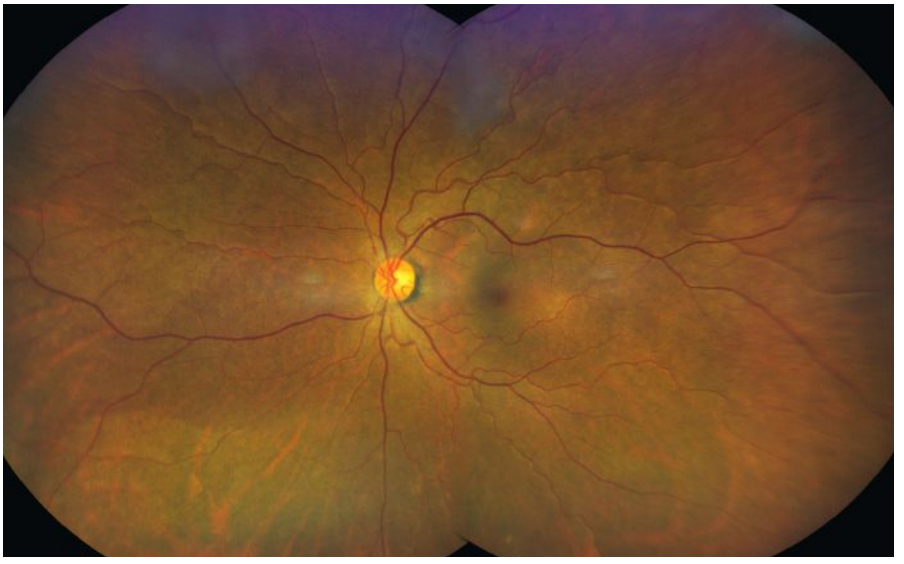
A routine exam uncovers findings that suggest a long-standing condition is present, unbeknownst to the patient.

A 71-year-old Hispanic female presented for a comprehensive eye exam. She had an ocular history of cataracts and dry eye, managed with over-the-counter artificial tears. Her medical history was significant for hyperlipidemia controlled with atorvastatin and osteoarthritis controlled with periodic steroid injections. She reported no history of trauma or allergies.

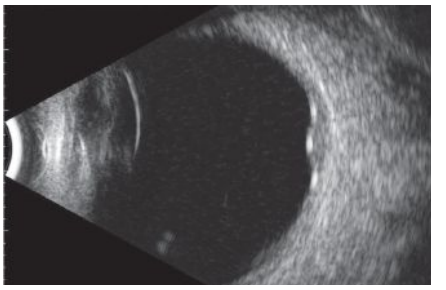
Clinical Findings

The patient's best-corrected visual acuities were 20/20 in the right eye and 20/30 in the left with a mild hyperopic prescription. There was no improvement with the pinhole OS.

Her external testing was unremarkable and there was no afferent pupillary defect. Refraction uncovered hyperopia OU with no changes to the acuities. Biomicroscopy demonstrated normal anterior segment tissues, mild nuclear cataracts and normal intraocular pressures measuring 12mm Hg OD and 13mm Hg OS using Goldmann applanation. Her optic nerves were normal and healthy OU.



Here's what the patient's posterior segment exam looked like. See anything unusual?



Does this ultrasonography scan confirm any suspicions raised by the findings shown in the fundus photo?

The pertinent posterior segment findings in the left eye are demonstrated in the photograph. B-scan ultrasound of the same eye is also available for review. An OCT scan was also performed, which showed atypical subretinal findings.

Your Diagnosis

What would be your diagnosis in this case based on the findings presented? What's the likely prognosis? Which interventions, if any, would you recommend? To find out, read the online version of this article at www.reviewofoptometry.com. ■

Dr. Gurwood thanks Dr. Nick Karbach for contributing this case.

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 (from page 80)—Q1: d, Q2: d, Q3: a, Q4: d, Q5: c

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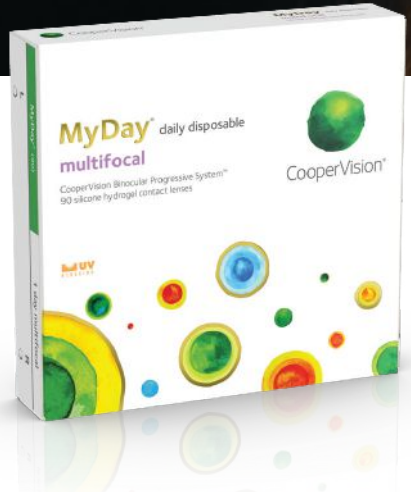

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