

EARN 2 CE CREDITS—Antibiotics in Eye Care: A Balancing Act, p. 70

# REVIEW<sup>®</sup> OF OPTOMETRY

October 15, 2020

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## TRENDS & CONTROVERSIES: New Directions in Optometry

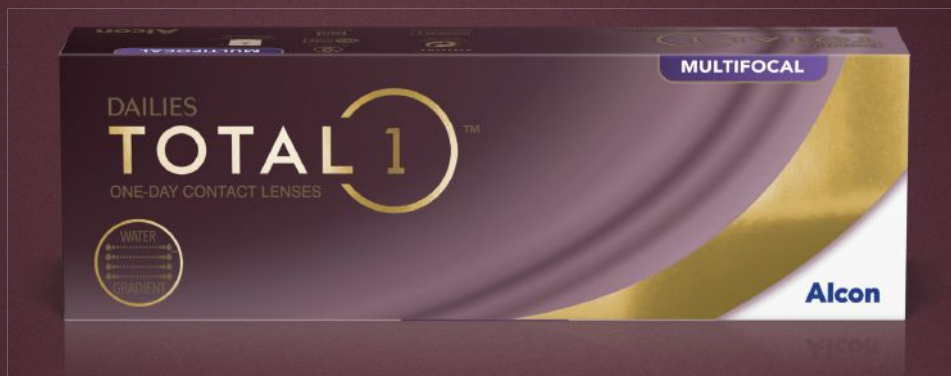


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**References:** **1.** Lemp J, Kern J. Alcon multifocal contact lenses for presbyopia correction. Presented at the Canadian Association of Optometrists Congress; June 28-30, 2017; Ottawa, ON. **2.** Kern J, Kannarr S, Miller J. Clinical Outcomes for Dailies Total1 Multifocal Lens in Symptomatic Patients. Poster presented at the Annual Clinical Conference & Exhibition of the British Contact Lens Association (BCLA); June 9-11, 2017; Liverpool, UK. **3.** Alcon data on file, 2016. **4.** Bauman E, Lemp J, Kern J. Material effect on multifocal contact lens fitting of lenses of the same optical design with the same fitting guide. Poster presented at the British Contact Lens Association (BCLA ) Clinical Conference and Exhibition, June 9-11, 2017. Liverpool, UK. **5.** Merchea M, Evans D, Kannarr S, et al. Assessing a modified fitting approach for improved multifocal contact lens fitting success. Presented at the American Optometric Association Annual Meeting, June 21-25, 2018. Denver, CO.

See product instructions for complete wear, care, and safety information. 

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# REVIEW<sup>®</sup> OF OPTOMETRY

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## TRENDS & CONTROVERSIES: New Directions in Optometry



Find out  
where the profession  
is heading on key  
clinical and operational  
questions.

Myopia: Should We Treat It Like a Disease?  
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How COVID-19 is Reshaping Optometry  
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Telehealth & AI: Eye Care at the Speed of Light  
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Will Subspecialization Help Optometry Evolve?  
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Genetics and Eye Care: DNA Leads the Way  
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*Page 62*



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Clinical significance of these preclinical data has not been established.

## LOTEMAX® SM

(loteprednol etabonate  
ophthalmic gel) 0.38%

**SMALL & MIGHTY**  
SUBMICRON PARTICLES

### \*PROVEN STRENGTH

- 30% of LOTEMAX® SM patients had complete ACC resolution vs vehicle (15%) at Day 8 (N=371,  $P < 0.0001$ )<sup>1,2†</sup>
- 74% of LOTEMAX® SM patients were completely pain-free vs vehicle (49%) at Day 8 (N=371,  $P < 0.0001$ )<sup>1,2‡</sup>

†Pooled analysis of Phase 3 clinical studies. **Study 1:** 29% LOTEMAX® SM (N=171) vs 9% vehicle (N=172). **Study 2:** 31% LOTEMAX® SM (N=200) vs 20% vehicle (N=199);  $P < 0.05$  for all.

‡Pooled analysis of Phase 3 clinical studies. **Study 1:** 73% LOTEMAX® SM (N=171) vs 48% vehicle (N=172). **Study 2:** 76% LOTEMAX® SM (N=200) vs 50% vehicle (N=199);  $P < 0.05$  for all.

## Indication

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

## Important Safety Information

- LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If LOTEMAX® SM is used for 10 days or longer, IOP should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.

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## Important Safety Information (cont.)

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those with diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infections.
- Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
- Contact lenses should not be worn when the eyes are inflamed.
- There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

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

Please see brief summary of Prescribing Information on adjacent page.

References: 1. LOTEMAX SM Prescribing Information. Bausch & Lomb Incorporated. 2. Data on file. Bausch & Lomb Incorporated. 3. Cavet ME, Glogowski S, Lowe ER, Phillips E. Rheological properties, dissolution kinetics, and ocular pharmacokinetics of loteprednol etabonate (submicron) ophthalmic gel 0.38%. *J Ocul Pharmacol Ther.* 2019. doi: 10.1089/jop.2019;35(5):291-300.

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## LOTEMAX® SM

(loteprednol etabonate  
ophthalmic gel) 0.38%



## BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use LOTEMAX<sup>®</sup> SM safely and effectively. See full prescribing information for LOTEMAX<sup>®</sup> SM.

**LOTEMAX<sup>®</sup> SM** (loteprednol etabonate ophthalmic gel) 0.38%  
For topical ophthalmic use  
Initial U.S. Approval: 1998

### INDICATIONS AND USAGE

LOTEMAX<sup>®</sup> SM is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

### DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once to fill tip before instilling drops. Apply one drop of LOTEMAX<sup>®</sup> SM into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

### CONTRAINDICATIONS

LOTEMAX<sup>®</sup> SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, in mycobacterial infection of the eye and fungal diseases of ocular structures.

### WARNINGS AND PRECAUTIONS

**Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.

**Cataracts:** Use of corticosteroids may result in posterior subcapsular cataract formation.

**Delayed Healing:** The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

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

**Viral infections:** Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

**Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

**Contact Lens Wear:** Contact lenses should not be worn when the eyes are inflamed.

### ADVERSE REACTIONS

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. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

### USE IN SPECIAL POPULATIONS

**Pregnancy: Risk Summary:** There are no adequate and well controlled studies with loteprednol etabonate in pregnant women. Loteprednol etabonate produced teratogenicity at clinically relevant doses in the rabbit and rat when administered orally during pregnancy. Loteprednol etabonate

produced malformations when administered orally to pregnant rabbits at doses 4.2 times the recommended human ophthalmic dose (RHOD) and to pregnant rats at doses 106 times the RHOD. In pregnant rats receiving oral doses of loteprednol etabonate during the period equivalent to the last trimester of pregnancy through lactation in humans, survival of offspring was reduced at doses 10.6 times the RHOD. Maternal toxicity was observed in rats at doses 1066 times the RHOD, and a maternal no observed adverse effect level (NOAEL) was established at 106 times the RHOD. The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies. Data: Animal Data. Embryofetal studies were conducted in pregnant rabbits administered loteprednol etabonate by oral gavage on gestation days 6 to 18, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations at 0.1 mg/kg (4.2 times the recommended human ophthalmic dose (RHOD) based on body surface area, assuming 100% absorption). Spina bifida (including meningocele) was observed at 0.1 mg/kg, and exencephaly and craniofacial malformations were observed at 0.4 mg/kg (17 times the RHOD). At 3 mg/kg (128 times the RHOD), loteprednol etabonate was associated with increased incidences of abnormal left common carotid artery, limb flexures, umbilical hernia, scoliosis, and delayed ossification. Abortion and embryofetal lethality (resorption) occurred at 6 mg/kg (256 times the RHOD). A NOAEL for developmental toxicity was not established in this study. The NOAEL for maternal toxicity in rabbits was 3 mg/kg/day. Embryofetal studies were conducted in pregnant rats administered loteprednol etabonate by oral gavage on gestation days 6 to 15, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations, including absent innominate artery at 5 mg/kg (106 times the RHOD); and cleft palate, agnathia, cardiovascular defects, umbilical hernia, decreased fetal body weight and decreased skeletal ossification at 50 mg/kg (1066 times the RHOD). Embryofetal lethality (resorption) was observed at 100 mg/kg (2133 times the RHOD). The NOAEL for developmental toxicity in rats was 0.5 mg/kg (10.6 times the RHOD). Loteprednol etabonate was maternally toxic (reduced body weight gain) at 50 mg/kg/day. The NOAEL for maternal toxicity was 5 mg/kg. A peri/postnatal study was conducted in rats administered loteprednol etabonate by oral gavage from gestation day 15 (start of fetal period) to postnatal day 21 (the end of lactation period). At 0.5 mg/kg (10.6 times the clinical dose), reduced survival was observed in live-born offspring. Doses  $\geq$  5 mg/kg (106 times the RHOD) caused umbilical hernia/incomplete gastrointestinal tract. Doses  $\geq$  50 mg/kg (1066 times the RHOD) produced maternal toxicity (reduced body weight gain, death), decreased number of live-born offspring, decreased birth weight, and delays in postnatal development. A developmental NOAEL was not established in this study. The NOAEL for maternal toxicity was 5 mg/kg.

**Lactation:** There are no data on the presence of loteprednol etabonate in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for LOTEMAX<sup>®</sup> SM and any potential adverse effects on the breastfed infant from LOTEMAX<sup>®</sup> SM.

**Pediatric Use:** Safety and effectiveness of LOTEMAX<sup>®</sup> SM in pediatric patients have not been established.

**Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in the chromosomal aberration test in human lymphocytes, or *in vivo* in the mouse micronucleus assay. Treatment of male and female rats with 25 mg/kg/day of loteprednol etabonate (533 times the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused preimplantation loss and decreased the number of live fetuses/live births. The NOAEL for fertility in rats was 5 mg/kg/day (106 times the RHOD).

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## IN THE NEWS

**New, healthy gas permeable (GP) wearers don't appear to adapt better to lens wear if changes are made to the lens diameter or surface lubricity.**

Researchers found neither coating lenses with Hydra-PEG (Tangible Science) or increasing diameters improved comfort or bulbar redness during the 20-minute adaptation period. Comfort improved and bulbar redness reduced with time. Additionally, corneal staining, ease of insertion and ease of removal did not differ with GP coating or diameter.

Debarun D, Wolffsohn JS. Effect of large diameter and plasma coating on the initial adaptation of gas permeable contact lens fitting for neophytes. *Cont Lens Anterior Eye*. September 8, 2020. [Epub ahead of print].

**Choroidal microvascular dropout may be much higher in patients with primary open-angle glaucoma (POAG) than in those with primary angle-closure or pseudoexfoliation glaucoma in the early stages,** but there appears to be no differences between the groups in advanced stages, a recent study in the *Journal of Glaucoma* suggests. The researchers also noted an association with ischemic injury in the pathogenesis of POAG.

Jo YH, Sung KR, Shin JW. Comparison of peripapillary choroidal microvasculature dropout in primary open-angle, primary angle closure and pseudoexfoliation glaucoma. *J Glaucoma*. September 3, 2020. [Epub ahead of print].

**There is little evidence that adding the 10-2 visual field test after running the 24-2 test provides additional undetected defects in the central visual field.** Given the equivocal results between the two test patterns, "it might be more prudent to **reserve 10-2 testing for following selected patients with a higher risk of progression** in the central visual field," the study authors concluded.

West ME, Sharpe GP, Hutchison DM, et al. Utility of 10-2 visual field testing in glaucoma patients with early 24-2 visual field loss. *Ophthalmology*. September 5, 2020. [Epub ahead of print].

## Glasses: A New Barrier to COVID?

Researchers in China believe they have uncovered evidence that eyeglasses confer a significant protection from infection. **By Oliver Kuhn-Wilken, OD**

In a *JAMA Ophthalmology* article published September 16, researchers note that, despite eyeglasses being commonly worn among the Chinese population, few patients admitted to the hospital for COVID-19 wore glasses.<sup>1</sup> This sparked an investigation that ultimately suggests that habitual spectacle wearers are less likely to be infected with the SARS-CoV-2 virus.<sup>1</sup> Coverage in consumer media soon brought the news, and possible misinterpretations of it, to patients around the world.

The authors studied 276 patients hospitalized with confirmed COVID-19 in Suizhou, China, between January and March 2020. They identified the percentage of myopic patients who were habitual glasses wearers in this hospitalized population, generalizing that myopes are more likely to wear glasses all day long, while presbyopes and hyperopes may set their glasses aside more frequently, especially in social settings.<sup>1</sup>

They found that the rate of glasses-wearing myopes among confirmed COVID-19 patients was extremely low, at 5.8%. The authors compared this to an epidemiological study from 1987 that found the prevalence of myopia in

a different province in China was 31.5%, and noted that in some more recent reports the prevalence in China exceeds 80%. They concluded that wearing eyeglasses more than eight hours a day may be protective against the virus.<sup>1</sup>

This unique study suggests glasses may be a successful barrier to the virus. Despite the promising finding, reality, as always, is more complex. Several experts have pointed out issues with the study, including its small sample size, the poor comparison study, the possibility of other confounding variables (e.g., education, lifestyle, age or some other unknown variable) and that it was conducted before the importance of hand-washing and social distancing was well-known.<sup>2</sup>

*JAMA Ophthalmology* ran an invited commentary on the study by Lisa Maragakis, MD, an infectious disease specialist at Johns Hopkins University School of Medicine. Dr. Maragakis commented that "the observed difference [...] is unlikely to have occurred by chance alone, but it does not indicate a causal relationship between wearing eyeglasses and preventing the disease."<sup>2</sup>

(Continued on p. 6)

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\*Based on clinical studies with AIR OPTIX® for Astigmatism contact lenses.

†Based on a ProVoice Survey of ECPs January 2019 to December 2019.

**References:** **1.** Eiden SB, Davis R, Bergenske P. Prospective study of lotrafilcon B lenses comparing 2 versus 4 weeks of wear for objective and subjective measures of health, comfort, and vision. *Eye Contact Lens.* 2013;39(4):290-294. **2.** Lemp J, Kern J. A comparison of real time and recall comfort assessments. *Optom Vis Sci.* 2016;93:E-abstract 165256. **3.** Based on a 30-day clinical study of 75 habitual lotrafilcon B lens wearers; Alcon data on file, 2017. **4.** Nash WL, Gabriel M, Mowrey-McKee M. A comparison of various silicone hydrogel lenses; lipid and protein deposition as a result of daily wear. *Optom Vis Sci.* 2010;87:E-abstract 105110. **5.** Nash WL, Gabriel MM. Ex vivo analysis of cholesterol deposition for commercially available silicone hydrogel contact lenses using a fluorometric enzymatic assay. *Eye Contact Lens.* 2014;40(5):277-282. **6.** In vitro study over 16 hours to measure wetting substitantivity; Alcon data on file, 2015. **7.** Muya L, Lemp J, Kern JR, Sentell KB, Lane J, Perry SS. Impact of packaging saline wetting agents on wetting substitantivity and lubricity. *Invest Ophthalmol Vis Sci.* 2016;57:E-abstract 1463. **8.** In a randomized, subject-masked clinical study at 11 sites with 83 subjects; significance demonstrated at the 0.05 level; Alcon data on file, 2006. **9.** Alcon data on file, 2019.

**Important information for AIR OPTIX® plus HydraGlyde® for Astigmatism (lotrafilcon B) contact lenses:** For daily wear or extended wear up to 6 nights for near/farsightedness and astigmatism. Risk of serious eye problems (i.e., corneal ulcer) is greater for extended wear. In rare cases, loss of vision may result. Side effects like discomfort, mild burning or stinging may occur.

**Important information for AIR OPTIX® plus HydraGlyde® (lotrafilcon B) contact lenses:** For daily wear or extended wear up to 6 nights for near/farsightedness. Risk of serious eye problems (i.e., corneal ulcer) is greater for extended wear. In rare cases, loss of vision may result. Side effects like discomfort, mild burning or stinging may occur.



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## Corneal Issue Incidence After Ortho-K Low

Overnight orthokeratology (ortho-K) is safe for children with myopia, but a new study helps outline the risk factors for corneal adverse events when they do happen, including younger age, higher myopia and allergic conjunctivitis. The research included a retrospective medical record review of patients who were using ortho-K for myopia correction for more than

one year. The study considered sex, baseline age and related medical histories of 489 eyes of 260 patients between the ages of eight and 15 who had a spherical equivalent refraction of -1.00D to -6.00D.

At the one-year follow-up, 22.7% of eyes had corneal adverse events, including corneal staining and corneal infiltration. Overall, the incidence of significant adverse

events was 6.9%.

The researchers found an association between corneal adverse events and age, as well as spherical equivalent refraction and allergic conjunctivitis. Additionally, high refraction was the key risk factor for significant adverse events.

Hu P, Zhao Y, Chen D, Ni H. The safety of orthokeratology in myopic children and analysis of risk factors. *Cont Lens and Anterior Eye*. September 8, 2020. [Epub ahead of print].

## Glasses' Protection Against COVID Investigated

(Continued from p. 4)

The mechanism by which glasses protect against the virus could include preventing aerosol access to the conjunctiva and decreasing hand-to-eye touching. We know that the SARS-CoV-2 can cause conjunctivitis and that the virus is present on the conjunctiva and in ocular secretions.<sup>3</sup> The presence of the virus in the permeable barrier of the conjunctiva strongly suggests that it can also be transmitted through the mucous membranes of the eye, although researchers believe this is a rare form of transmission.<sup>4</sup>

Since the death of the ophthalmologist Li Wenliang on February 7 in Wuhan, China, after conducting an exam on an asymptomatic but infected glaucoma patient, we have known that eye care providers are at risk.<sup>5</sup> The CDC recommends eye care providers wear a surgical mask and eye protection during all exams.<sup>6</sup>

This recent study is certainly provocative, and the question of the extent of barrier protection afforded by glasses deserves further investigation. For now, we should not let controversy over glasses distract us from what we know

works: universal masking, physical distancing and frequent and vigorous hand-washing.

*Dr. Kuhn-Wilken is a staff optometrist at Pacific & Laser Institute in Tacoma, WA.*

*Note: The content contained in this article is for informational purposes only. The content is not intended to be a substitute for professional advice. Reliance on any information provided in this article is solely at your own risk.*

1. Zeng W, Wang X, Li J, et al. Association of daily wear of

eyeglasses with susceptibility to coronavirus disease 2019 infection. *JAMA Ophthalmology*. September 16, 2020. [Epub ahead of print].

2. Maragakis L. Eye protection and the risk of coronavirus disease 2019: does wearing eye protection mitigate risk in public, non-health care settings? *JAMA Ophthalmology*. September 16, 2020. [Epub ahead of print].

3. Colavita F, Lapa D, Carletti F. SARS-CoV-2 isolation from ocular secretions of a patient with COVID-19 in Italy with prolonged viral RNA detection. *Annals of Internal Medicine*. August 4, 2020. [Epub ahead of print].

4. Inomata T, Kitazawa K, Kuno T, et al. Clinical and prodromal ocular symptoms in coronavirus disease: a systematic review and meta-analysis. *Invest Ophthalmol Vis Sci*. 2020;61(10):29.

5. American Academy of Ophthalmology. In memoriam: Ophthalmologist deaths from COVID-19. [www.aao.org/coronavirus/deaths](http://www.aao.org/coronavirus/deaths). Accessed September 18, 2020.

6. US Centers for Disease Control and Prevention. Interim infection prevention and control recommendations for healthcare personnel during the coronavirus disease 2019 (COVID-19) pandemic. [www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html](http://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html). Updated July 15, 2020. Accessed September 18, 2020.

### Debate Rages On

Early in the COVID-19 pandemic, eye care providers spent a significant amount of time educating patients on the safety of various forms of optical correction. Contact lenses were under fire first as a potential viral vector—a rumor that was quickly quashed by experts. As long as contact lens wearers follow proper care and wear protocols, they should be fine.<sup>1</sup>

In April, researchers from the Centre for Ocular Research & Education (CORE) reported that there was “no scientific evidence that wearing standard prescription spectacles provides protection against COVID-19 or other viral transmissions.”<sup>1</sup> In fact, they speculated that switching from contact lenses to spectacles could actually increase the risk of viral transmission because of increased face-touching and the fact that the SARS-CoV-2 virus can live on hard surfaces, such as spectacle frames, for hours or even days.<sup>1</sup>

Now, months later, this new study suggests the opposite: habitual spectacle wearers are less likely to be infected with the SARS-CoV-2 virus, perhaps because myopes—who are more likely to wear glasses all day—aren't touching their face as often as presbyopes and hyperopes.<sup>2</sup> Perhaps future studies will dive deeper into the associations between COVID-19 infection and optical correction choices.

1. Jones L, Walsh K, Willcox M, et al. The COVID-19 pandemic: important considerations for contact lens practitioners. *Cont Lens Ant Eye*. April 3, 2020. [Epub ahead of print].

2. Zeng W, Wang X, Li J, et al. Association of daily wear of eyeglasses with susceptibility to coronavirus disease 2019 infection. *JAMA Ophthalmol*. September 16, 2020. [Epub ahead of print].

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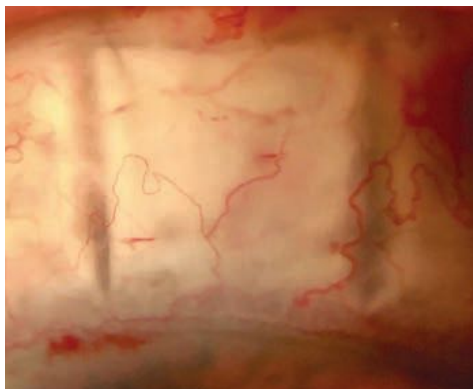
JA013 Rev 6/20

## Deep Sclerectomy Effective for OAG

**D**eep sclerectomy (DS) is an effective, long-lasting surgical procedure for open-angle glaucoma (OAG), a recent study reported.

This retrospective cohort study followed 513 eyes of 409 patients with OAG who underwent deep sclerectomy. A team defined intraocular pressure (IOP) success cutoffs as  $\leq 18$ mm Hg and 20% reduction,  $\leq 15$ mm Hg and 25% reduction and  $\leq 12$ mm Hg and 30% reduction.

The researchers observed a mean IOP decrease from 23.5mm Hg to 13.3mm Hg, 12.8mm Hg and 12.4mm Hg at three, five and seven years, respectively. At the three-year follow-up, success rates were 66.3%, 44.5% and 18.1% for each of the IOP cutoffs, respectively. They were 57.9%, 34.6% and 11.9%, respectively, at



**Long-term deep sclerectomy can lower patients' IOP by as much as 10mm Hg.**

the five-year follow-up and 54.0%, 29.8% and 10.0%, respectively, at the seven-year follow-up.

At each of the cutoffs, the team determined that laser goniotomy, needling and post-op anti-glaucoma medications were associated with increased failure. Intraoperative mitomycin C

(MMC) was associated with reduced failure for IOP  $\leq 15$ mm Hg and  $\leq 12$ mm Hg, while higher preoperative IOP was associated with increased failure for those with an IOP  $\leq 12$ mm Hg.

The investigators found serious complications in 49 eyes, with estimated incidences of 3.5%, 6.0%, 8.3% and 9.3% at one, three, five and seven years, respectively. Pseudoexfoliation or pigmentary glaucoma, poorer preoperative vision, intraoperative macroperforation, avascular blebs, subsequent phacoemulsification and intraoperative bevacizumab, but not MMC, were associated with a higher risk of serious postoperative complications.

Rabiolo A, Leadbetter D, Alaghband P, et al. Primary deep sclerectomy in open-angle glaucoma: long-term outcomes and risk factors for failure. *Ophthalmology*. August 31, 2020. [Epub ahead of print].

Photo: Rick Trevino, OD, Carolyn Malcher, OD, and William Sponser, MD

## ASD Kids Face High Ocular Disorders Risk

**A**utism spectrum disorder (ASD) affects an estimated 1.85% of children in the United States, but despite its increased prevalence, the relationship between ocular disorders and ASD isn't clearly understood. Now, a new study in the *American Journal of Ophthalmology* suggests autistic children are at an increased risk of adverse ocular problems.

The population-based, retrospective cohort study included claims from more than 10 million children from 2007 to 2013. Participants were 18 or younger at the time of the first claim. The researchers looked for a diagnosis of pervasive developmental disorder (PDD) or

autistic disorder and assessed the prevalence of ocular diagnoses, including amblyopia, strabismus, optic neuropathy, nystagmus or retinopathy of prematurity, in a normally developing control group and children with PDD or autistic disorder.

The prevalence of any ophthalmologic diagnosis was 3.5% in the controls, but much higher at 12.5% in children with PDD and at 13.5% in children with autistic disorder.

More research is necessary to further clarify the relationship between ocular disorders and autistic symptoms and severity, the researchers noted in their paper.

“Our study provides epidemio-

logic support for an association between autism and ophthalmologic disorders, including amblyopia, strabismus, nystagmus and optic atrophy,” said researcher Melinda Chang, MD.

“In the meantime, eye care practitioners must be aware of the potential increased risk of visual disorders in children with autism and screen appropriately,” she concluded. “Since these patients have difficulty cooperating with typical vision screening, they may benefit from referral to pediatric ophthalmology specialists.”

Chang MY, Doppee D, Yu F, et al. Prevalence of ophthalmologic diagnoses in children with autism spectrum disorder using the Optum dataset: a population-based study. *Am J Ophthalmology*. September 5, 2020. [Epub ahead of print].



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# OCT-A Shows Impact of Dilation Agents

Understanding the influence mydriatic agents may have on ocular vascular measurements is key to properly interpreting clinical results and comparing study conclusions. A new study found that a combination of topical 2.5% phenylephrine and 0.5% tropicamide in healthy eyes may cause a small, but likely clinically negligible, reduction in vessel density of the optic nerve head as seen on OCT angiography (OCT-A).

The reduction was not likely clinically significant because it was within the previously reported range of measurement variability, the researchers noted.

While no changes in macular vessel densities were detected after dilation, the team of researchers also observed small but significant increases in macular ganglion cell complex thickness in non-high density images.

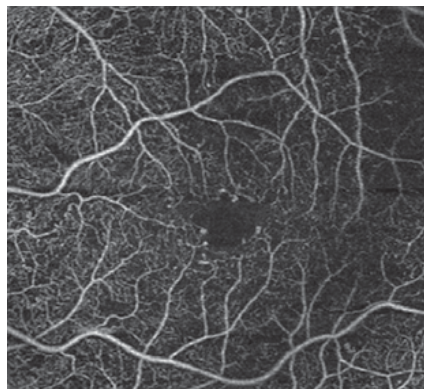


Photo: Steven Fernoci, OD and Jay M. Haynie, OD

**Few studies have investigated the relationship between mydriatic agents and retinal vasculature using OCT-A in non-healthy eyes.**

The study enrolled 26 healthy participants who were about 40 years old. The researchers obtained high density and non-high density OCT-A macula and optic nerve head images at 15-minute intervals before and after dilation.

The investigators observed a

small but statistically significant reduction of 0.6% in non-high density optic nerve head images, from a mean of 45.2% to 44.6%. A similar reduction of 0.8% was observed in the non-high density optic nerve head circumpapillary region, from a mean of 49.3% to 48.5%.

Small but statistically significant post-dilation increases in OCT-derived parafoveal ganglion cell complex thickness of approximately 0.5 $\mu$ m and 0.4 $\mu$ m (an increase of approximately 0.4% of baseline thickness in both cases) were also observed in macula 3x3mm and 6x6mm non-high density images, respectively.

The researchers found no post-dilation decreases in macular vessel density or high density optic nerve head capillary density.

Villatoro G, Bowd C, Proudfoot JA, et al. Impact of pupil dilation on optical coherence tomography angiography retinal microvasculature in healthy eyes. *J Glaucoma*. September 3, 2020. [Epub ahead of print].

# Arkansas ODs Victorious Against Referendum

Optometrists in Arkansas won a huge scope of practice victory with the passage of Act 579 in March 2019. But the battle wasn't over, with the medical lobby, led by Safe Surgery Arkansas, pushing for a veto referendum to put the issue up for a public vote—and hopefully rescind the law. The groups spent the year gathering signatures for the petition but failed to meet the requirements in August of 2019 due to a filing error, a mistake that foretold the movement's ultimate demise.

In September, the Arkansas Supreme Court upheld the ruling that the group opposing the law did not follow proper petition require-

ments, incorrectly validating canvassers' background check status. Of the 64,027 total signatures submitted, 51,911 were deemed invalid by the Court because they were acquired by paid canvassers who did not have a certification stating they had passed a background check—only “acquired” one.<sup>1</sup>

“We are pleased the Court agrees with the Special Master's findings that the group opposing Act 579 did NOT follow petition requirements and the measure does NOT qualify for the ballot,” Vicki Farmer, chairperson for Arkansas for Healthy Eyes, the group leading the cause for optometry, said in a statement. “Patients across Arkan-

sas will now have improved access to quality eye care from the doctor of optometry they know and trust.”

ODs in the state can now forge ahead with the credentialing process to allow optometrists to perform certain procedures, including certain injections, incision and curettage of a chalazion, removal and biopsy of certain low-risk skin lesions and even some laser procedures, such as capsulotomy and trabeculoplasty.

1. Arkansas Judiciary. Arkansas for Healthy Eyes, a ballot question committee; and Vicki Farmer, individually and on behalf of Arkansas for Healthy Eyes v. John Thurston, in his official capacity as secretary of state of the state of Arkansas; Safe Surgery Arkansas, a ballot question committee; and Laurie Barber, M.D., individually and on behalf of Safe Surgery Arkansas, an original action. September 17, 2020. [opinions.arcourts.gov/ark/supremecourt/en/item/485308/index.do](https://opinions.arcourts.gov/ark/supremecourt/en/item/485308/index.do). Accessed September 17, 2020.

# Raising the Bar for Dry Eye Disease Therapy

## Dear Colleagues,

Keratoconjunctivitis sicca (KCS), also known as dry eye disease (DED), is a multifactorial ocular surface disorder characterized by a loss of tear film homeostasis, inflammation, and ocular symptoms such as discomfort and visual disturbance.<sup>1</sup> The central mechanism of KCS is evaporative water loss, leading to hyperosmolar tissue damage. The process directly, or indirectly secondary to increased inflammation, causes a loss of epithelial and goblet cells, and precipitates decreased surface wettability and early tear film breakup.<sup>2</sup> This all serves to exacerbate hyperosmolarity via a “vicious circle.”<sup>2</sup> In particular, chronic inflammation has been identified as a perpetuating factor in DED,<sup>3,4</sup> so controlling ocular surface inflammation has been found to help improve DED treatment outcomes.<sup>5</sup>

While short-term use of topical corticosteroids is reported to be a beneficial treatment for episodic worsening of DED symptoms and signs,<sup>6</sup> long-term use of topical steroids has clinical limitations due to potential side effects such as IOP elevation, infection, and cataract formation.<sup>7</sup> Conversely, the chronic use of cyclosporine A (CsA) to increase tear production has been found to be an effective and safe therapeutic strategy to manage many DED patients.<sup>8,9</sup> Researchers hypothesize that CsA's mechanism of action is related to immunomodulatory activity, which reduces local inflammation,<sup>10</sup> although the exact mechanism of action involved in enhancing tear production is not well understood.<sup>11</sup>

In 2003, the FDA approved a CsA emulsion with 0.5 mg/mL concentration, or 0.05% CsA, after it was found to be effective at treating moderate to severe dry eye disease in clinical trials.<sup>11</sup> However, treatment challenges have plagued the therapy due to cyclosporine's highly lipophilic nature and poor aqueous solubility.<sup>10</sup>

More than a decade later, dry eye therapy has taken another

step forward since the FDA in 2018 approved CEQUA (cyclosporine ophthalmic solution 0.09%), a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca. Not only does CEQUA contain the highest FDA-approved concentration of CsA, it is the first and only approved CsA product incorporating a nanomicellar technology known as NCELL for improved delivery of cyclosporine and increased penetration to ocular tissues.

Nanomicelles, composed of polymers that encapsulate CsA molecules, exhibit a hydrophilic outer layer compatible with the aqueous environment of the tear film to facilitate transport through the tear film onto the ocular surface. In addition, their small size helps them gain entrance into corneal and conjunctival cells.<sup>12,13</sup> Once inside the tear film's aqueous layer,<sup>10,13</sup> the nanomicelles break up to release cyclosporine into the ocular tissues.<sup>10,13</sup> In a single-dose preclinical study, a CsA formulation using NCELL vs. a traditional CsA emulsion enabled nearly three times more of the molecule to penetrate the cornea and 1.6 times more to penetrate the conjunctiva.<sup>12,14,15</sup>

Along with positive findings for CEQUA's efficacy, clinical trials have shown CEQUA to exhibit a good safety and tolerability profile.<sup>15-17</sup> The most common adverse reactions following use of CEQUA have been instillation site pain (22%) and conjunctival hyperemia (6%),<sup>18</sup> with patients rating most ocular adverse events as mild (80%) or moderate (17%).<sup>15</sup>

It is clear that a new era has arrived for CsA, with the powerful combination of a higher concentration offered in conjunction with advanced drug delivery technology. This important clinical development is giving eye care practitioners another tool to help manage the chronic and inflammatory nature of DED for their patients.

**–Scott E. Schachter, OD (Moderator)**



**Scott E. Schachter, OD  
(Moderator)**

Ocular Surface Academy, Founder,  
Pismo Beach, CA



**Josh Johnston, OD, FAAO**

Georgia Eye Partners,  
Atlanta, GA



**Alan G. Kabat, OD, FAAO**

Salus University,  
Elkins Park, PA



**Bridgitte Shen Lee, OD,  
FAAO, FBCLA, FEAOO**

Vision Optique,  
Houston, TX



**1 Dr. Schachter: Can you talk about what signs and symptoms today's keratoconjunctivitis sicca, or dry eye, patients are presenting with at the practice? How has this changed over the years?**

**Dr. Johnston:** The classic signs and symptoms of dry eye are burning and stinging. The other complaints that are more prevalent now with increased patient and doctor awareness are fluctuating vision, decreased vision, pain, eye strain, and fatigue—even computer vision syndrome, these issues that are kind of relevant to dry eye these days. And there are many other masqueraders that can mimic dry eye. Clinical signs such as inflammation, hyperosmolarity, decreased tear breakup time, and corneal and conjunctival staining are vital diagnostic tools used today that have modernized how we evaluate this disease.

**Dr. Kabat:** I've been practicing for more than 30 years, and I've witnessed a substantial maturation in how we approach our patients with dry eye disease. In the past, we very naively waited for patients to tell us that their eyes felt "dry" or "irritated." We were not at all proactive in looking for dry eye, because we had few solutions that could truly help. In fact, dry eye was considered little more than a nuisance by many eye care practitioners.

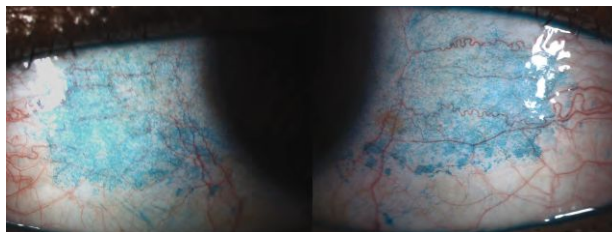
Today, we recognize that many of the early clues to ocular surface disease are subtle and vague. Sometimes, the patient reports little more than blurry vision, or glare, or difficulty with prolonged visual tasking such as reading, driving, or viewing a computer screen. We recognize that these visual changes are, in many cases, the first indications of tear film instability.

And as tear instability becomes more chronic, hyperosmo-

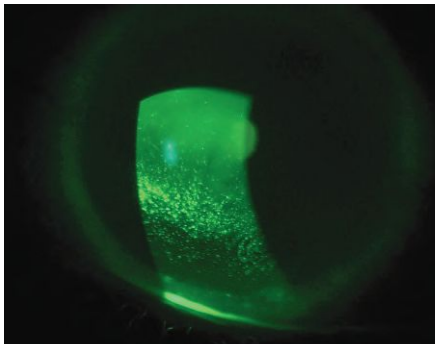


**Dry Eye Disease Presentation.** Dry eye disease often presents with vague symptoms and red, irritated-looking eyes. Careful examination with vital dyes will reveal ocular surface damage. *Photos: Alan G. Kabat, OD, FAAO*

larity and inflammation become manifest. It is at this point that we then begin to hear complaints about discomfort, such as burning, stinging, and foreign body sensation. In my clinic, I like to quantify patients' complaints by using a validated symptom questionnaire, such as the Ocular Surface Disease Index (OSDI). This tool may have little predictive value as to the severity of dry eye signs, but it does help to establish the degree to which the patient's activities of daily living are adversely impacted by the disease.



**Vital Dye Staining.** Lissamine green shows devitalized areas of the conjunctiva (and cornea) that lack adequate mucin protection. This photo shows significant staining of the right and left temporal bulbar conjunctivae.



**Coarse Staining.** Disease progression leads to corneal epithelial breakdown, as demonstrated by coarse staining with sodium fluorescein. Patients like this are usually prime candidates for anti-inflammatory therapy.

In terms of dry eye signs, we have always relied on slit lamp examination using vital dye staining of the cornea and conjunctiva, as well as tear film break up time to establish a diagnosis.

We may have even used some very time-consuming and uncomfortable methods such as the Schirmer test in order to estimate tear volume and production. Fortunately, today, much of the diagnostic testing can be performed with semi-automated technology to determine tear meniscus height, noninvasive tear break up time, and even lipid layer thickness. Moreover, point-of-care testing can give us an indication as to whether the inflammatory cascade has been initiated, in terms of hyperosmolarity or the presence of matrix metalloproteinase-9 in the tear film. These advances in dry eye evaluation allow us to diagnose and intervene sooner than in the past, averting more serious presentations and complications.

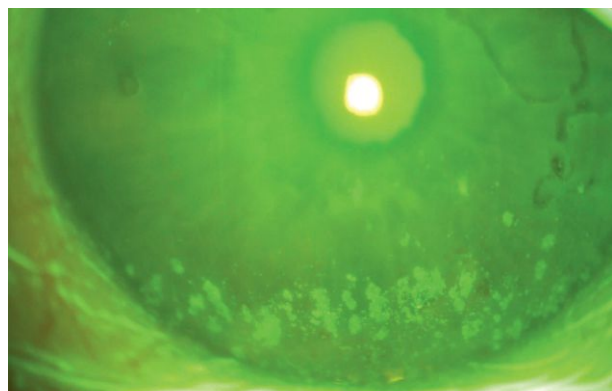
**Dr. Shen Lee:** My private practice provides both comprehensive primary eye care and medical services, which include dry eye disease, specialty contact lenses, and myopia management. We screen for dry eye symptoms during the case history and the preliminary testing. In addition, we inquire about our patients' digital device usage and habits, and any digital eye strain symptoms that include dry eyes.

During the slit lamp exam after the Goldmann tonometry, I can usually see the clinical signs of blepharitis, *Demodex* manifestations, conjunctiva follicular or papillary response, cornea staining, and tear film quality. The findings are discussed with patients, especially if they match the presenting symptoms. Patients who show significant clinical signs or have reported symptoms are invited to return for a separate comprehensive ocular surface disease (OSD) exam.

In 2016, we started taking meibomian gland images of

every patient age 18 and older, and every symptomatic patient younger than age 18. Our discovery of the high prevalence of meibomian gland dysfunction (MGD) among the healthy patient population (young and old) has changed how we practice. In addition, a discussion of dry eye symptoms is now included with every patient's comprehensive annual eye exam.

**Dr. Schachter:** We can stereotype the typical dry eye sufferer as a post-menopausal woman, but we are now seeing dry eye disease in all demographics. Younger patients are on ADD/ADHD and allergy medications as well as oral contraceptives, which may dry out their eyes. This is at the same time digital device use is at an all-time high. We give all patients a validated questionnaire to elicit symptoms, and are finding that screen time is up, and symptoms are as well.



**Inferior Corneal Staining.** Inferior corneal staining with fluorescein seen with Wratten #12 filter. This 70-year old female patient had a diagnosis of keratoconjunctivitis sicca. Photo: Scott E. Schachter, OD

## 2 Dr. Schachter: How has your dry eye management approach changed over recent years, and what have been your greatest challenges in developing a successful treatment regimen?

**Dr. Johnston:** Initially in my career—I graduated in 2004—I ignored dry eye. I thought it was boring, it was unimportant. I would hand patients many different kinds of artificial tears and say, 'Come back in a year and see me.' In 2009-2010, I adopted the model of staining every patient, looking for signs and symptoms, talking to patients about their symptoms, and looking closely for this disease state. At that point, I really became aggressive about diagnosing and treating inflammation. Inflammation, we now know, is the root cause of aqueous deficient dry eye, and we can use things like corticosteroids short-term. But those have side effects, and they're off-label. So we need something to address inflammation long-term that's safe and that helps the body produce more natural tears. That was sort of step 1. Step 2, we know there's more information out there about meibomian gland dysfunction and obstruction. Dry eye is multifactorial; it's not easy, it's complex. There's a lot going on, and you need to examine the biofilm of the lids, assess

for issues such as lagophthalmos, micro-lagophthalmos, and conjunctivochalasis while also evaluating staining, meibomian gland function for the quantity and quality of the meibum—looking for things like inflammation, hyperosmolarity, and decreased tear breakup time. All of these different factors are relevant. So now that I'm doing this at a high level, I've learned that dry eye diagnosis and treatment can be very esoteric. It's gone from basic treatments using an assortment of tears, to targeting inflammation, to evaluating and managing the entire lacrimal functional unit with a wide variety of therapy options available today.

**Dr. Kabat:** Until the late 1990s, drug therapy for dry eye was unheard of. We had artificial tears, which accounted for as much as 80% of our therapeutic management, and the remainder of patients became candidates for punctal occlusion. Dr. Steven Pflugfelder and other pioneers showed us that anti-inflammatory medications could provide significant relief for those suffering from dry eye,<sup>19</sup> but many of us hesitated because the approach involved off-label use of a corticosteroid—a drug class that we had been taught was to only be used in extreme cases and with the utmost caution. When topical cyclosporine was introduced in 2003, we were initially elated to finally have a medication that was specifically indicated for treating keratoconjunctivitis sicca. However, we quickly found that a good percentage of patients failed to respond to this new formulation in the manner that we had hoped. Moreover, it was very difficult to predict which patients would succeed and which would ultimately fail or discontinue therapy because of intolerability, cost issues, or simply frustration.

My biggest challenge in developing an effective treatment regimen for dry eye is two-fold. First, it has taken many years to realize that not all dry eye is alike in its composition or manifestations, and, hence, there is no single therapy that works for every patient. A good dry eye doctor understands that, to be successful, one must first identify the most significant contributory element of the ocular surface disease and manage it aggressively through whatever means are most appropriate. Second, when inflammation is present, we can no longer afford to use agents that take up to six months to begin yielding improvement. If my experience has taught me anything, it's that patients are not very patient! The symptomatic individuals who I see today want and expect relief, or at least some indication of recovery, in a matter of days or perhaps weeks. If I'm lucky, they may give me one or two months.

**Dr. Shen Lee:** My dry eye management approach has changed from taking care of symptomatic patients to also addressing concerning clinical signs demonstrated by patients before they become problematic. The improvement in diagnostic technology (meibomian gland imaging and osmolarity testing), two new prescription eye drops, and noninvasive treatment options (meibomian gland expression, microblepharoexfoliation, intense pulsed light) have made major improvements in how we take care of dry eye patients.

The greatest challenge is the general lack of public understanding about dry eye disease. The majority of patients have not heard of meibomian gland dysfunction, and they do not understand why their health insurance will not cover all of the effective treatments.

**Dr. Schachter:** Years ago, I felt like many of my colleagues do—that treating dry eye disease just wasn't important enough. Once I recognized the impact of dry eye on my patients' vision, I embraced the expert recommendations of the TFOS Dry Eye Workshop of 2007 and introduced a process into practice for managing the disease. That took some fine-tuning, but it didn't take long before it was part of every eye exam.

### 3 **Dr. Schachter: How did the initial approval of cyclosporine A (CsA) in 2003 change the dry eye treatment landscape, from your perspective?**

**Dr. Johnston:** I think it was huge. It was the first FDA-approved drug to treat dry eye due to ocular inflammation. By treating and addressing inflammation—the root cause of aqueous deficient type—we were able to decrease inflammation and help the body produce more natural tears. With that FDA approval, we saw more understanding among our colleagues—ophthalmologists and optometrists alike—about this disease state and treating inflammation. We also saw an uptick in consumer awareness about dry eye through direct-to-consumer marketing leading to increased education and exposure, increased prescriptions, and basically a landmark drug that brought this drug category to where it is today.

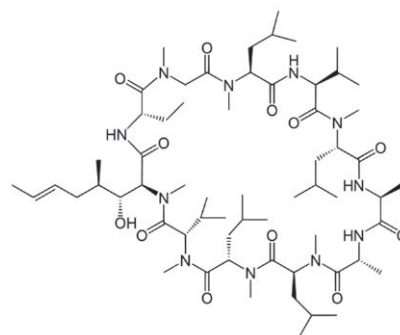
**Dr. Kabat:** After the release of CsA 0.05% in 2003, even doctors who had previously taken little interest in managing dry eye became prescribers overnight because there were virtually no safety issues with the medication and the message was very clear: Dry eye is inflammatory, and CsA is a potent immunomodulatory agent. Unfortunately, as with so many newly introduced therapies, the product simply did not live up to the hype. Many patients were unwilling to continue using a therapy that afforded them little tangible benefit over the course of the first three months, and so they either discontinued therapy independently or complained to the doctor such that he or she would move on to another therapy—usually punctal plugs.

**Dr. Shen Lee:** It was very exciting to finally have a prescription eye drop to treat dry eye disease. Patients were happy to have a pharmaceutical option in addition to over-the-counter tear supplements.

**Dr. Schachter:** The introduction of Cyclosporin A finally gave us an option other than artificial tears. When I started following the TFOS DEWS treatment algorithm and prescribing CsA, patients started getting meaningful symptomatic relief, and objective signs also improved.

### 4 **Dr. Schachter: Can you talk about treatment obstacles with the earlier formulations of CsA in your patients? How did this impact your ability to manage patients?**

**Dr. Johnston:** We know cyclosporine is a great molecule; it's efficacious, it's been around for 17 years now to treat ocular inflammation, commercially approved. I didn't see a lot of obstacles with CsA, but in some cases, all three FDA-approved treatments might take a while for patients to get a symptomatic breakthrough. We know CsA works, even pretty quickly in some patients, but it's all about symptoms. So, if patients aren't getting that symptomatic breakthrough and feeling better, that's one obstacle. With this disease state in general, patients—especially those with more severe cases—can feel like the response to treatment can be slow.



**Cyclosporine Molecule.** Cyclosporin was isolated in 1971 from the fungus *Tolypocladium inflatum* and came into medical use in 1983.<sup>20</sup> It is on the World Health Organization's List of Essential Medicines as one of the safest and most effective medicines needed in a health system.<sup>21</sup>

**Dr. Kabat:** Between the side effects—most notably the stinging on instillation—and the lengthy delay in achieving any substantial clinical improvement in signs or symptoms, a lot of patients simply quit using their drops. I'm sure many blamed their doctors and moved on to other practices. It was very humbling and very, very frustrating.

**Dr. Shen Lee:** During the early 2000s, we did not have sophisticated diagnostic tests or the ability to analyze and view meibomian glands. For patients with more severe corneal staining and very low tear quality, we used prescription steroid drops on a tapered schedule in conjunction with the first-generation 0.05% CsA drops. It was very important to teach patients to stay on CsA even if they did not notice more immediate symptom relief, and to stay on the prescribed course even after feeling better.

**Dr. Schachter:** Some of my patients struggled with CsA over the years because of how long it took them to experience symptomatic improvement. Many discontinued use or identified themselves as CsA failures. However, they didn't take the medication long enough to really know what their outcome could have been. Historically, CsA required thorough patient



education to set up appropriate and realistic expectations.

## 5 Dr. Schachter: How did the 2018 approval of CEQUA with a higher concentration, and NCELL technology to improve cyclosporine delivery and increase penetration to ocular tissues impact your management of dry eye patients?

**Dr. Johnston:** Doctors love innovation, patients love innovation. So it's nice to see new formulations and FDA approval of advancing therapeutics. The thought here with the higher concentration and the nanomicelles is you get increased uptake into the ocular tissues, which then leads to higher bioavailability with potentially increased speed of the mechanism of action addressing inflammation. With a higher concentration of cyclosporine, as well as the nanomicelles technology, or NCELL technology, the data is compelling showing an increased uptake of this into the ocular tissues, whether that be the corneal tissue or the conjunctival tissue in one study. If we can deliver a medication at a higher dose, at a higher concentration, increasing the active drug with greater bioavailability, ultimately we have a therapeutic that might work quicker in some patients.

**Dr. Kabat:** Fortunately, several companies continued to work on topical dry eye formulations to provide an alternative to CsA 0.05%. We saw the first of these formulations launch in 2016, and it really renewed my faith in the dry eye cause. Here were patients who were just barely getting by with artificial tears and/or CsA 0.05%, and within a month of starting this new medication, they were

In a single-dose preclinical study, a CsA formulation using NCELL vs. a traditional CsA emulsion enabled...



Up to **3X** higher absorption across ocular tissues.<sup>12,14,15</sup>

experiencing unparalleled relief. Similarly, when CEQUA gained approval and was finally made available to us in 2019, we witnessed that same type of watershed moment. In patients returning for three- or four-week follow-up visits, we were already seeing substantial improvements in ocular staining and visual function. I absolutely believe that the higher concentration of CsA in CEQUA, combined with NCELL technology to help ensure greater bioavailability in the target tissues is the reason for this success.

**Dr. Shen Lee:** The faster onset of conjunctiva and corneal staining improvement or clearing has helped patients feel better sooner and has increased patient compliance with staying on the treatment course.

**Dr. Schachter:** CEQUA caused me to look at CsA through a new lens. The improved penetration and higher concentration of CsA provided my patients with another effective tool in treating dry eye disease. The more options, the better for both patient and provider.

## NCELL™ TECHNOLOGY ENHANCES OCULAR DELIVERY OF CYCLOSPORINE<sup>12,15</sup>



### HYDROPHOBIC CORE

Prevents the encapsulated cyclosporine, which has poor aqueous solubility, from being released until after penetration through the aqueous layer of the tear film<sup>10,12,13,22</sup>

### HYDROPHILIC SHELL

Allows for transport through the tear film onto the ocular surface<sup>10,12,13,22</sup>

CEQUA is the first and only FDA-approved treatment to combine cyclosporine with NCELL technology for improved delivery of cyclosporine and increased penetration to ocular tissues.<sup>12,15,17</sup> NCELL uses nanomicelles composed of polymers—a blend of polymers including polyoxyethylene hydrogenated castor oil 40, or HCO-40, and Octoxynol-40, or Oc-40—that encapsulate cyclosporine molecules.<sup>12,13</sup>

The units of polymers self-assemble into a nanoscale aggregate via a thermodynamic process. Once assembled, the polymers work together as a unit, or nanomicelle, with a hydrophilic outer layer and hydrophobic core. The hydrophilic outer layer, which is compatible with the aqueous environment of the tear film, allows for transport through the tear film onto the ocular surface. At the same time, the hydrophobic core prevents the encapsulated cyclosporine from being released until after the nanomicelle penetrates the aqueous layer of the tear film.

The small size of the nanomicelles, which measure an average of 22 nanometers or approximately one three-thousandth the width of a human hair, helps facilitate the entry of cyclosporine into corneal and conjunctival cells. The nanomicelles penetrate the aqueous layer of the tear film and release the active cyclosporine molecules for penetration into ocular tissues.

Once released, cyclosporine starts working to reduce inflammation, helping improve the ocular surface and increase tear production.

## 6 **Dr. Schachter: What differences did you notice in patients treated with this newer formulation of CsA vs. earlier formulations?**

**Dr. Johnston:** It's still pretty early, but, anecdotally, we've seen some patients respond faster on this new formulation. Dry eye is a tough disease state; there's no magic bullet or cure. A lot of the patients I see are more advanced, older in age, and have a lot going on as far as risk factors. So dry eye is particularly challenging in the patient population that I serve. But I think patients are excited about new options—whether that be a different formulation or new technology like the NCELL technology. And the thought here, and we see this echoed in the clinical data, is that this new formulation has the potential to work faster.

**Dr. Kabat:** More than anything else, I noticed patient acceptance. When I ask, "How are you doing with these drops?" a lot fewer patients tell me, "I'm not sure." More often I hear things along the lines of "I like them!" and "I'm seeing better" and even "I don't have to use my artificial tears as often anymore." It's very encouraging, and it makes my next move just that much easier.

**Dr. Shen Lee:** I have seen complete central cornea staining clearing in some of my long-term dry eye patients. The clinical data shows that 65% of patients on 0.09% CsA achieved complete central cornea clearing on day 84.<sup>16</sup>

**Dr. Schachter:** CEQUA, with an increased concentration of CsA and novel vehicle, provides the symptomatic improvement patients are seeking. At the six-week follow up, many identify a decrease in symptoms and improved comfort.

## 7 **Dr. Schachter: Following the use of CEQUA, the most common adverse reactions, which were reportedly primarily mild (80%) or moderate (17%), were instillation site pain (22%) and conjunctival hyperemia (6%). What has your experience been with adverse events in patients?**

**Dr. Johnston:** My experience using CEQUA has been great. The tolerability is wonderful. When we look at therapeutics, we want drugs that are effective and efficacious, and we want them to be well-tolerated by patients, with low AEs, and obviously commercially available and easy to get, from an access and affordability standpoint. So this is a medica-

tion that I am never concerned about with tolerability. We see some patients who complain about burning or stinging, or instillation site pain sometimes, but it's very mild. Most patients have no pain with use. So it's never been a barrier to me to prescribe this. I think most of my patients are doing pretty well with it.

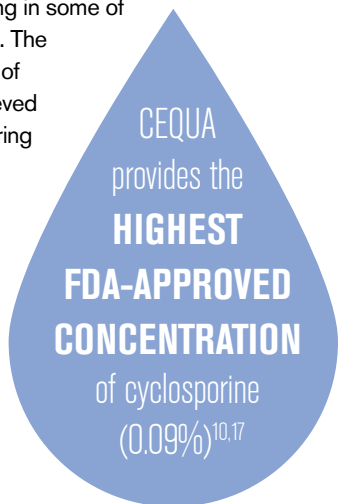
**Dr. Kabat:** I may be the odd-man-out here, but I like to try all the new topical formulations that hit the market whenever feasible, just so that I can relate to patients' complaints. When I first put CEQUA in my eye, I had no adverse reaction whatsoever—no stinging, no blurring of my vision, no unusual taste after five or ten minutes. Truly, there were no adverse effects whatsoever. Now, I will admit that some of my patients (and my colleagues) have reported some stinging with continued use, but on the whole, it is typically mild and quite tolerable. As a long-time practitioner, I understand that many excellent drugs can cause irritation upon instillation. Most of our glaucoma drugs induce temporary stinging and redness of the eyes, but we ask our patients to persevere because in the end, the treatment is necessary and the adverse events are fleeting. Our approach should be no different with dry eye therapies like CEQUA.

**Dr. Shen Lee:** The instillation site burning sensation is more common in patients with worse clinical presentations, especially those patients with high superficial punctate keratitis (SPK) staining scores. I use the following two methods to educate patients and to help alleviate instillation discomfort symptoms:

1. I put sample CEQUA drops in the patient's eyes after the dry eye exam to both assess the patient's sensitivity and educate the patient that the "burning" sensation is normal. I tell patients that the burning sensation reduces with each week's use, and I make sure they understand to wait 15 to 20 minutes before they put on their contact lens.
2. For patients who have a high SPK staining score and who experience instillation burning sensation, I ask them to use a preservative-free tear first thing in the morning, wait 10 minutes, and then put in CEQUA.

It is important to educate patients about potential symptoms and to help them figure out a morning/evening routine with their eyecare and skin care products. We email every dry eye patient a very detailed step-by-step plan for using their drops (OTC and Rx), lid/lash hygiene products, and other dry eye at-home care products.

**Dr. Schachter:** In my clinical experience, the adverse events experienced have been mild. As always, when prescribing a new medication, it's important to let patients know what side effects they may experience. We do this by instilling a drop in one eye the same day we prescribe it. Typically, when patients know what side effects they may encounter, it helps them maintain compliance if those effects are mild.



## 8 Dr. Schachter: In what clinical cases/scenarios, do you feel CEQUA performs best for your patients?

**Dr. Johnston:** I think CEQUA works best when you catch dry eye patients early. For example, if you have a 35- or 40-year-old patient suffering from dry eye, these patients respond much quicker than say an 85-year-old female with Sjogren's and rheumatoid arthritis, who has had multiple ocular surgeries. If you start to stack on increased age and other risk factors, it just takes much longer to get an effective decrease in clinical signs as well as improvement in symptoms. So I think CEQUA works well when you catch dry eye early on in your patients—before they're further down that severity pathway.

**Dr. Kabat:** Based upon the clinical studies and personal experience, I believe CEQUA is currently the best initial choice for those patients who have documented inflammatory dry eye disease with symptoms that are exceeded by clinical signs, particularly epithelial disruption of the cornea and/or conjunctiva as demonstrated by fluorescein and lissamine green, respectively. I also feel it is a good option for patients who had had some success with CsA 0.05%, but who now find that they need to use it more frequently, for example three to four times a day, to obtain the same relief that they previously had with BID dosing. And while it may seem counterintuitive, I have even had a few successful cases where patients have been switched to CEQUA after experiencing unacceptable side effects or a poor response to lifitegrast 5%. Despite being completely different drug classes and having different mechanisms of action, both ultimately address inflammation at the level of the ocular surface, and, hence, one may be able to "fill the void" where the other cannot.

**Dr. Shen Lee:** Unfortunately, in the US, the patient's health insurance coverage dictates what prescription eye drops can be used. That said, we know that CEQUA has a broad and effective coverage for patients who are diagnosed with dry eye disease.

### OFFICE TIPS FOR PATIENT SUCCESS WITH CEQUA.



**Dr. Shen Lee:** It is important to train a designated team member to learn the prior authorization (PA) process and to help patients obtain insurance coverage for CEQUA to increase prescription fill rates. In addition, a detailed treatment plan helps patients improve their understanding of and compliance with the doctor's recommendations

**Dr. Schachter:** Many of my patients have tried other medications without success. Those failures may have been due to adverse events or lack of efficacy for those particular individuals. They are often concerned that there are no options for them and are excited to try CEQUA.

## 9 Dr. Schachter: What do you say to critics of older CsA formulations who complain about a lack of efficacy or effect in their patients, with respect to a newer offering that includes a higher concentration and improved drug delivery platform?

**Dr. Johnston:** When we look at the older formulation, it's a billion-dollar-a-year drug,<sup>23</sup> so that's pretty robust validation that it's working. However, we get some doctors and patients who say that the drug does not work as well as they want. But again, it's all about symptoms. So, we have to talk to our doctors and patients and ask them how they are using the medication. I often hear, "Oh, I used it for two weeks." Well, two weeks is not enough. This is a chronic disease state. It's progressive. You need therapeutics to be onboard sometimes for a lifetime. The patient may not respond in two or even four weeks, depending on how severe they are. Now, it's nice to have new therapeutics that are available with higher concentrations and different delivery technology with the hope of increasing delivery to the ocular tissue to speed things up and give these patients a better chance at improving signs and symptoms of dry eye.

**Dr. Kabat:** My biggest criticism of 0.05% CsA emulsion has always been that it cannot afford patients the improvement they desire within the time frame that they are willing to invest in therapy. If we're being honest, we now live in a world that expects, and even demands, immediate gratification. Those colleagues who fail to recognize the distinctive qualities of CEQUA are clearly not aware of the benefits that enhanced drug delivery systems bring to the game. CEQUA with NCELL technology is just the latest in a long line of well-established ophthalmic drugs being repurposed using new delivery models in order to achieve greater efficacy, tolerability, and safety. Before the year is over, I predict that we will see several more new products in the United States that employ existing medications in unique ways to achieve substantially improved outcomes for dry eye patients.

**Dr. Shen Lee:** So much technology improvement has happened over the last 15 years. Eye care professionals need to learn the "3 Cs of CEQUA" and prescribe this new formulation to their dry eye patients. They are:

#### 1. Concentration:

The CsA concentration increased from 0.05% to 0.09%.

#### 2. Composition: CEQUA

is encapsulated inside a high-tech nanomicelles polymer.

### CYCLOSPORINE HELPS RESTORE TEAR PRODUCTION<sup>17</sup>

Although the exact mechanism of action of cyclosporine is not known, cyclosporine has helped restore tear production in patients with ocular inflammation due to dry eye by acting as a partial immunomodulator. Since poor aqueous solubility has limited cyclosporine's ocular tissue penetration, CEQUA's nanomicelles are designed to enhance the ocular tissue penetration.<sup>10,12,13</sup>



- **Nano** means the size of each molecule is 22nm, which is 1/3000th the width of a single human hair.
- **Micelles** have a hydrophilic exterior that facilitates transport through the aqueous tear, and a hydrophobic core that keeps the CsA molecule stable until it reaches the ocular surface.

### 3. Cornea Clearing

- Decrease in cornea staining can be achieved in **1 month** after using CEQUA.
- Complete central cornea clearing can be achieved in **65% of patients after 3 months** on CEQUA.

**Dr. Schachter:** When I educate my patients about CEQUA, I highlight the differences between prior formulations and lean on CEQUA's own data to support my discussions. Many of my patients have done their homework and want to have a greater understanding of what I'm prescribing and why it will benefit them.

## PHARMACOKINETICS OF CYCLOSPORINE DELIVERED WITH NCELL<sup>14</sup>

Here is a snapshot of the study, published in the Sept. 9, 2019, online edition of the *Journal of Ocular Pharmacology and Therapeutics* evaluating the preclinical pharmacokinetics of cyclosporine delivered with NCELL technology and the resulting positive findings for the new delivery model:

Researchers evaluated the ocular distribution, tolerability, and systemic exposure of cyclosporine (CsA) in New Zealand white rabbits following topical administration of OTX-101, a novel, clear aqueous nanomicellar solution developed for the treatment of dry eye disease (DED).

The study design included single- and repeat-dose phases. In the single-dose phase, rabbits received a single instillation of OTX-101 0.05% or CsA ophthalmic emulsion 0.05% (Restasis®, Allergan) as a comparator. In the repeat-dosing phase, OTX-101 (0.01%, 0.05%, or 0.1% CsA) or comparator was instilled 4 times per day for 7 days. Samples collected included whole blood, tears, and ocular tissues/fluids (aqueous humor, choroid-retina, conjunctiva, cornea, superior eyelid, third eyelid, iris/ciliary body, lacrimal gland, lens, sclera, and vitreous humor). CsA concentrations were analyzed using liquid chromatography-tandem mass spectrometry.

Analysis included samples from 112 rabbits. The highest concentration of CsA following a single OTX-101 0.05% instillation occurred in the third eyelid (C<sub>max</sub>=1,200 ng/g). Concentrations of CsA in the cornea and superior bulbar conjunctiva increased in a dose-related manner following repeated administration of OTX-101 formulations; C<sub>max</sub> [T<sub>max</sub> (h)] for cornea was 1,543 ng/g (6.50), 5,410 ng/g (7.0), and 8,123 ng/g (6.50), for 0.01%, 0.05%, and 0.1% CsA concentrations, respectively; for superior bulbar conjunctiva was 726 ng/g (6.50), 1,468 ng/g (6.50), and 2,080 ng/g (6.25), respectively.

Researchers concluded that OTX-101 topical ophthalmic instillation resulted in extensive distribution of CsA in ocular tissues, particularly in target tissues for DED (cornea and conjunctiva), while systemic exposure was negligible.

**10** **Dr. Schachter: Do you have any case examples you could share about how CEQUA has helped specific DED patients in your practice increase their tear production and better manage their disease?**

**Dr. Johnston:** Most patients have a combination of aqueous

deficient as well as evaporative dry eye, so what are you going to do for that? Some of these treatments are out of pocket, and the patient might still be dry. So we need to prescribe a therapeutic that will decrease inflammation and help the body to produce more natural tears to help improve symptoms. Hundreds of our patients have used therapeutics like CEQUA and noticed an improvement in symptoms. Ultimately, the drug is increasing tear production and decreasing inflammation. It's been fun to have another option out there, and a lot of our patients, if we correctly diagnose them and catch them early, will do well on this therapy.

**Dr. Kabat:** Unfortunately, COVID-19 really interfered with our ability to follow-up and gain feedback from the numerous patients we initiated on CEQUA in the early part of this year. Only a dozen or so of my patients who were seen and started on CEQUA were able to return for multiple follow-ups. But of those, I recall that the improvement in corneal staining was the most remarkable aspect of their change. I had few, if any, tolerability issues, and while access is always a bit challenging with newly approved drugs, we found ways to get the drug to more than 90% of the patients who needed it and wanted it. I cannot recall more than one or two patients who have found the adverse effects to be intolerable. I think the most encouraging thing was watching patients who were simply ready to give up using their CsA 0.05% because it "wasn't doing any good," come "back from the brink" within three to four weeks on CEQUA BID. That's a very rewarding feeling for any health care provider. ♦

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I was only seeing light flashes early on, but light

**FLASHES**

when you've not seen anything for  
so many years—it was wonderful

—Keith H, retinal prosthesis recipient

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## SITA Faster Lags in Reliability, Study Says

The Swedish Interactive Threshold Algorithm (SITA) Faster test may save considerable time in obtaining visual field (VF) measurements in patients with manifest or suspect glaucoma, but a research team from India suggests this method still needs further amendments before it's accurate enough to replace SITA Fast (SF) or SITA Standard (SS).

SS and SF 24-2 tests use gaze tracking, blind spot check and false-negative catch trials, whereas SITA Faster 24-2 tests are run with gaze tracking engaged but without blind spot check and false-negative catch trials.

The study compared the three methods' test time, mean deviation (MD), pattern standard deviation (PSD), VF index, foveal threshold, number of points depressed on a

PSD probability plot, individual threshold test points, glaucoma hemifield test (GHT) and grade of field defect.

In 70 eyes of 70 patients, the researchers found SITA Faster test times were about 36.1% shorter than SF and 60.7% shorter than SS. However, additional findings question the new tool's accuracy:

- MD values were lower with SITA Faster compared with SF and SS.
- Mean PSD and VF index showed no significant differences between the algorithms.
- Mean foveal threshold was higher for SITA Faster compared with SF and SS.
- The number of points depressed at  $p < 0.5\%$  was less in SITA Faster than in both SF and SS.

- Bland-Altman plots showed considerable variability between the algorithms.

SITA Faster provides benefits in test time and shows similar VF indexes compared with SF and SS; however, detection of early cases with SITA Faster is questionable, and a few modifications are needed to improve its accuracy, the researchers said.

As a side note, the researchers found SF and SS gave almost similar results.

However, "the algorithms cannot be used interchangeably for the same patient on different test sessions," the researchers noted in their paper.

Patyel S, Thulasidas M. Comparison of 24-2 faster, fast, and standard programs of Swedish interactive threshold algorithm of Humphrey field analyzer for perimetry in patients with manifest and suspect glaucoma. *J Glaucoma*. September 3, 2020. [Epub ahead of print].

## Avoid Tonometry With High Tear Volume

Although many questions about COVID-19 remain, there is evidence to suggest the virus spreads through direct contact and aerosolized droplets from an infected person—bringing tonometry best practices into question. Many are moving to non-contact options to avoid direct contact with patients—but even that could pose a risk, a new study suggests. Researchers are now recommending clinicians avoid non-contact tonometry (NCT) in patients with high tear volume, whether natural or due to eye drops, as the diagnostic procedure could spread droplets to the device and the operator.

This experimental study evaluated eight healthy participants. A

team performed NCT on one eye of each of the eight participants in three scenarios: normal setting, one drop of lubricant and two drops of lubricant. They used high-speed shadowgraphy, frontal lighting and fluorescein analysis to detect any possible droplets or aerosols.

In a natural setting, the investigators found no droplet or aerosol production. However, they reported minimal splatter and droplet ejection with one drop of lubricant prior to NCT. With two drops of lubricant, they added that there was a significant amount of fluid ejection that broke up into multiple droplets. They noted that some of these droplets traversed back to the tonometer. They measured droplets ranging from

100µm to 500µm in diameter.

The researchers stress the need for further studies that assess the best methods of protecting the operator and disinfecting the device, suggesting the use of a protective shield on the operator's face and ensuring proper ventilation with airflow to minimize contact with any potential droplets. ■

*Note: The content contained in this article is for informational purposes only. The content is not intended to be a substitute for professional advice. Reliance on any information provided in this article is solely at your own risk.*

Shetty R, Balakrishnan N, Shroff S, et al. Quantitative high-speed assessment of droplet and aerosol from an eye after impact with an air-puff amid COVID-19 scenario. *J Glaucoma*. September 17, 2020. [Epub ahead of print].



## ZERVIAE™ (cetirizine ophthalmic solution) 0.24%

### Brief Summary

#### INDICATIONS AND USAGE

ZERVIAE (cetirizine ophthalmic solution) 0.24% is a histamine-1 (H1) receptor antagonist indicated for treatment of ocular itching associated with allergic conjunctivitis.

#### DOSAGE AND ADMINISTRATION

**Recommended Dosing:** Instill one drop of ZERVIAE in each affected eye twice daily (approximately 8 hours apart). The single-use containers are to be used immediately after opening and can be used to dose both eyes. Discard the single-use container and any remaining contents after administration. The single-use containers should be stored in the original foil pouch until ready to use.

#### CONTRAINDICATIONS

None.

#### WARNINGS AND PRECAUTIONS

**Contamination of Tip and Solution:** As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle or tip of the single-use container to avoid injury to the eye and to prevent contaminating the tip and solution. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using in each eye.

**Contact Lens Wear:** Patients should be advised not to wear a contact lens if their eye is red.

ZERVIAE should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of ZERVIAE. The preservative in ZERVIAE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 10 minutes following administration of ZERVIAE.

#### ADVERSE REACTIONS

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial 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 7 clinical trials, patients with allergic conjunctivitis or those at risk of developing allergic conjunctivitis received one drop of either cetirizine (N=511) or vehicle (N=329) in one or both eyes. The most commonly reported adverse reactions occurred in approximately 1%–7% of patients treated with either ZERVIAE or vehicle. These reactions were ocular hyperemia, instillation site pain, and visual acuity reduced.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

###### *Risk Summary*

There were no adequate or well-controlled studies with ZERVIAE in pregnant women. Cetirizine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

###### *Data*

##### Animal Data

Cetirizine was not teratogenic in mice, rats, or rabbits at oral doses up to 96, 225, and 135 mg/kg, respectively (approximately 1300, 4930, and 7400 times the maximum recommended human ophthalmic dose (MRHOD), on a mg/m<sup>2</sup> basis).

##### Lactation

###### *Risk Summary*

Cetirizine has been reported to be excreted in human breast milk following oral administration. Multiple doses of oral dose cetirizine (10 mg tablets once daily for 10 days) resulted in systemic levels (Mean C<sub>max</sub> = 311 ng/mL) that were 100 times higher than the observed human exposure (Mean C<sub>max</sub> = 3.1 ng/mL) following twice daily administration of cetirizine ophthalmic solution 0.24% to both eyes for 1 week. Comparable bioavailability has been found between the tablet and syrup dosage forms. However, it is not known whether the systemic absorption resulting from topical ocular administration of ZERVIAE could produce detectable quantities in human breast milk.

There is no adequate information regarding the effects of cetirizine on breastfed infants, or the effects on milk production to inform risk of ZERVIAE to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZERVIAE and any potential adverse effects on the breastfed child from ZERVIAE.

**Pediatric Use:** The safety and effectiveness of ZERVIAE has been established in pediatric patients two years of age and older. Use of ZERVIAE in these pediatric patients is supported by evidence from adequate and well-controlled studies of ZERVIAE in pediatric and adult patients.

**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

#### NONCLINICAL TOXICOLOGY

##### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

###### *Carcinogenicity*

In a 2-year carcinogenicity study in rats, orally administered cetirizine was not carcinogenic at dietary doses up to 20 mg/kg (approximately 550 times the MRHOD, on a mg/m<sup>2</sup> basis). In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign liver tumors in males at a dietary dose of 16 mg/kg (approximately 220 times the MRHOD, on a mg/m<sup>2</sup> basis). No increase in the incidence of liver tumors was observed in mice at a dietary dose of 4 mg/kg (approximately 55 times the MRHOD, on a mg/m<sup>2</sup> basis). The clinical significance of these findings during long-term use of cetirizine is not known.

###### *Mutagenesis*

Cetirizine was not mutagenic in the Ames test or in an *in vivo* micronucleus test in rats. Cetirizine was not clastogenic in the human lymphocyte assay or the mouse lymphoma assay.

###### *Impairment of Fertility*

In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64 mg/kg (approximately 875 times the MRHOD, on a mg/m<sup>2</sup> basis).

#### PATIENT COUNSELING INFORMATION

**Risk of Contamination:** Advise patients not to touch dropper tip to eyelids or surrounding areas, as this may contaminate the dropper tip and ophthalmic solution. Advise patients to keep the bottle closed when not in use. Advise patients to discard single-use containers after each use.

**Concomitant Use of Contact Lenses:** Advise patients not to wear contact lenses if their eyes are red. Advise patients that ZERVIAE should not be used to treat contact lens-related irritation. Advise patients to remove contact lenses prior to instillation of ZERVIAE. The preservative in ZERVIAE solution, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 10 minutes following administration of ZERVIAE.

**Administration:** Advise patients that the solution from one single-use container is to be used immediately after opening. Advise patients that the single-use container can be used to dose both eyes. Discard the single-use container and remaining contents immediately after administration.

##### **Storage of Single-use Containers:**

Instruct patients to store single-use containers in the original foil pouch until ready to use.

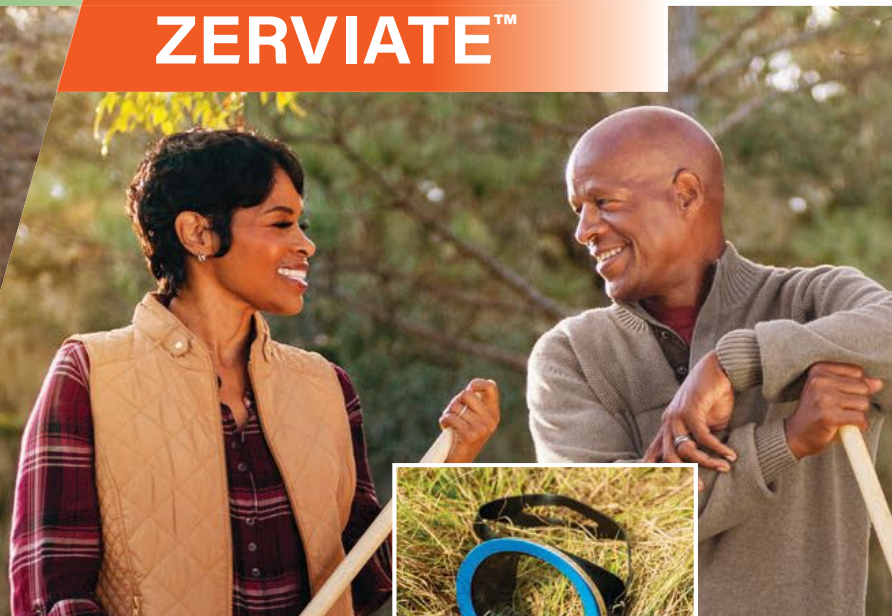
##### **Rx Only**

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ZERVIAE delivers the proven power of cetirizine—  
a leading oral allergy medication—now targeted  
to the eyes.<sup>1,2,a</sup>

- Rapid reduction in ocular itch in 3 minutes that lasts for 8 hours
- Designed for comfortable delivery with Hydrella™, a glycerin and HPMC formulation
- Available in single-use containers for convenience



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STUDY DESIGN: The pivotal trials for ZERVIAE included two Phase 3, double-masked, randomized, vehicle-controlled, parallel-group studies involving 201 patients. Study 2 required more severe allergic conjunctivitis symptoms. Patients were screened for an allergen response using the conjunctival allergen challenge (CAC) model and randomized to receive either ZERVIAE or vehicle. Primary efficacy endpoints were ocular itching and conjunctival redness 15 minutes and 8 hours post treatment instillation.<sup>3</sup>

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#### DOSAGE AND ADMINISTRATION

Instill one drop in each affected eye twice daily (approximately 8 hours apart).

#### IMPORTANT SAFETY INFORMATION

##### WARNINGS AND PRECAUTIONS

**Contamination of Tip and Solution:** As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle or tip of the single-use container in order to avoid injury to the eye and to prevent contaminating the tip and solution. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using in each eye.

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HPMC=hydroxypropyl methylcellulose.

<sup>a</sup>Based on a U.S. News report on data from the 2019 Pharmacy Times Survey of Pharmacists' OTC Recommendations.

**References:** **1.** ZERVIAE [package insert]. Fort Worth, Texas: Eyeavance Pharmaceuticals LLC; 2020. **2.** *U.S. News & World Report*. Antihistamines for allergies. <https://health.usnews.com/health-products/top-rec-antihistamines-oral-8>. Accessed October 7, 2019. **3.** Meier EJ, Torkildsen GL, Gomes PJ, et al. Phase III trials examining the efficacy of cetirizine ophthalmic solution 0.24% compared to vehicle for the treatment of allergic conjunctivitis in the conjunctival allergen challenge model. *Clin Ophthalmol*. 2018;12:2617-2628. **4.** Malhotra RP, Meier E, Torkildsen G, et al. Safety of cetirizine ophthalmic solution 0.24% for the treatment of allergic conjunctivitis in adult and pediatric subjects. *Clin Ophthalmol*. 2019;13:403-413.



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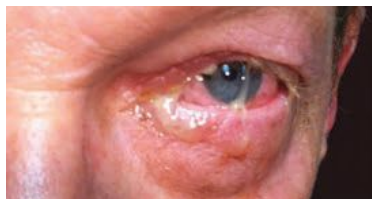
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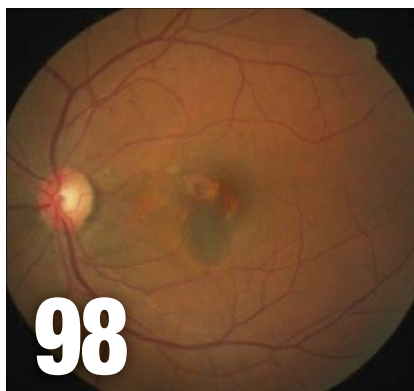
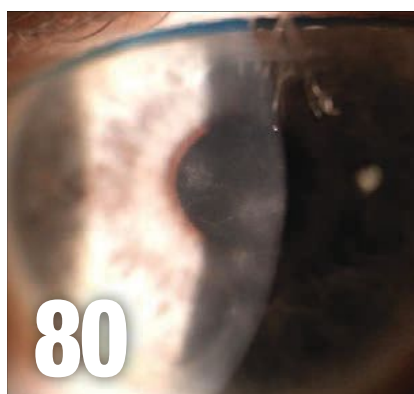
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**Outlook**

By Jack Persico, Editor-in-Chief



**Winds of Change**

Numerous trends in optometry are reaching an inflection point. Will they disrupt, or just distract?

In Ernest Hemingway’s *The Sun Also Rises*, a character asks someone, “How did you go bankrupt?” The other replies, “Two ways: gradually, then suddenly.” The passage is famous for its terse articulation of how it feels to realize a behavior that had been slowly working its way through one’s life has become inescapably dominant, seemingly overnight.

A lot of 2020 has felt that way, in both good and bad ways. Leaving aside hot-button issues of cultural and political import, much of day-to-day life is getting a major overhaul. Working from home, once a rare indulgence, became a necessity for white-collar employees, and many companies will keep generous flex time policies even when there’s no longer a health-related imperative. Online education, previously not much more than a punchline, is shakily beginning to get its sea legs. Shopping online went from steady growth to behemoth, with enormous consequences for retailers—and ODs. Those who rely on product revenue are clearly feeling the pinch.

This month’s issue unpacks numerous trends in optometry that have a transformative element—things like myopia control, telemedicine, artificial intelligence (AI), online product sales, private equity, subspecialization within optometry, genetic markers of eye disease and a new concept in E/M coding. Some are farther along than others in their impact on the profession right now, but all pose significant questions for optometrists: “Will this change how I practice? Should it?”

It’s likely that at least a few of these trends will. Artificial intelligence, for instance, is clearly on a trajectory that will shake up the traditional model of eye care delivery. In our personal lives, we already rely on the predictive algorithms in our computing devices that anticipate our needs by tracking how we shop, read news, watch TV and find dating partners. Medical imaging and diagnostic assessment is ripe for the same. If anything is going to follow the “slowly, then all at once” timeline, it’s medical AI.

So-called clinical genetics, in which doctors make medical decisions based on genetic data, has a checkered history in eye care. The controversy over AMD screening and AREDS vitamin formulations from a few years ago left many with the impression that genetics isn’t ready for prime time—then, the approval of Luxturna for inherited retinal dystrophies suddenly validated the role of gene therapy.

Optometric subspecialization has been discussed for decades but always faced obstacles at the institutional level over credentialing requirements and implementation challenges. It may never be wholly embraced—ODs perform 85% of primary eye care services, so generalists will always be essential—but those doctors who want to carve out a niche will find a formal path available to them.

If it all seems a bit too much to take in, just pick and choose. You don’t need to be an expert in everything. Just make sure you don’t get blind-sided by anything. ■



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# The Post COVID-19 Game Plan

Here's why some practices are closing their doors while others are thriving.

By Paul M. Karpecki, OD, Chief Clinical Editor

There's no playbook for the pandemic but these three considerations will help: (1) protect your practice from both a health and liability perspective; (2) adapt with hybrid strategies for medical eye care; and (3) focus on patient-pay procedures.

## Protect Your Practice

You have to keep you, your staff and your patients healthy—and protect the practice from a liability perspective. Even when we have a vaccine, the protocols now in place will continue for some time:

- Use gloves, masks and proper PPE, and make sure patients are all wearing masks.
- Wear scrubs you can remove at the end of the day and take a hot shower before settling in at home.
- Check temperatures before patients enter the office, have them complete a COVID-19 symptom questionnaire and ensure proper social distancing between patients.
- Assume every patient could be a carrier and try to limit time within 24 inches of the patient to about a minute; discussions can take place from at least two feet away.<sup>1</sup>

Not only do these steps protect everyone, they also show that you care about the patient's health.

Richard Hom, OD, Gregory Moore, OD, and, now, Fadi Al Akkrass, MD, a top infectious disease expert, have weekly webinars that provide updates on everything from the vaccine pipeline to patient flow ([www.homandmoore.com](http://www.homandmoore.com)). In one

episode, they interviewed an attorney who noted that patients cannot sue a practice for getting COVID-19 *unless* they can prove negligence. Currently, every positive test requires that patients provide a list of places they have visited days before symptoms began or testing was positive. If a certain optometrist's office crops up often, the health department may intervene and consider the practice negligent. In addition, new laws allow insurance companies to forego paying if the doctor is found negligent.

To help ODs avoid accusations of negligence, Drs. Hom and Moore provide a regularly updated workbook with standard operating procedures for COVID-19 patient care, checklists and the latest research behind those recommendations.

## Adapting Medical Eye Care

Although most practices, like mine, are seeing fewer patients per day, we are making up for it in efficiency and more hybrid examination options. For example, if, during the exam, I determine a patient requires dilation (and it's not a high-risk situation, such as a retinal detachment), we reschedule them for a follow-up visit. In cases of glaucoma, the patient may come in only for OCT or visual fields and then go over the results and next steps via telemedicine. Our one-month moderate-to-severe dry eye follow-ups, provided the patients are not using topical corticosteroids, are conducted via telemedicine as well.

## Patient-pay Options

Many practices have survived COVID-19 by focusing on patient-pay procedures. While most patients with vision plans delayed their yearly eye exams, patients with medical ocular conditions did not. In fact, many who missed exams during the shutdown are more willing to have in-office procedures, including thermal pulsation, Blephex and intense pulsed light/low-level light therapy (LLLT). Our LLLT procedure volume is up over 400%—perhaps because mask-wearing patients are developing far more hordeola and chalazia. Other patient-pay options like NeuroLens (eyeBrain Medical) have also increased for us substantially. Patients may be saving more money, using their stimulus checks or are more aware of ocular symptoms while at home on digital devices.

It's not too late to implement these changes or enhance what you are doing. The private equity-owned Keplr Vision, with more than 350 medically focused optometry practices, is a great example. They are seeing their highest revenue per practice to date. Going medical, offering patient-pay procedures, embracing technology, taking precautions and lowering liability risk are keys to your COVID-19 game plan. ■

*Note: Dr. Karpecki consults for companies with products and services relevant to this topic.*

1. Lai X, Wang M, Qin C, et al. Coronavirus Disease 2019 (COVID-2019) Infection Among Health Care Workers and Implications for Prevention Measures in a Tertiary Hospital in Wuhan, China. *JAMA* May 21, 2020. [Epub ahead of print].

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# Musings Behind the Mask

My PPE is getting to my head, causing more reflection than usual. These notes might just spark something in you, too. **By Montgomery Vickers, OD**

I have let a lot of things slide lately, with the global pandemic and all. But it's time to shape up. These are just a few things I should be doing—and you, too.

I should probably trim my beard, but nobody ever sees it. I haven't seen a chin in two months. When I walked into the exam room the other day, a patient had pulled her mask down, and I saw her whole face. It was a beautiful sight.

I should also start writing in my “daily” journal again. By daily I mean every other month. Regardless, all I write is stuff about sitting on my back porch, not finding sanitizing wipes at the store and whether it is legal in Texas to open a liquor store/gun range—both essential businesses here.

I should get back to my morning yoga routine; the one where I squat down and reach as far as I can into the refrigerator for that can of soda I have for breakfast with my gluten-free cinnamon roll.

I should quit telling patients my life story. They may not actually care about Dr. Bodie, in 1979, sternly instructing me to make certain patient charts are detailed and accurate, even though his charts barely had the patient's name spelled right and smelled like nicotine since he smoked during the exams.

I should accept the fact that I won't attend a live CE meeting before the end of 2020. I have to get over it, get on Zoom and get my hours. The problem is I don't get the satisfaction of watching my col-

leagues fall asleep next to me after the 40th slide of drusen. Oh, and I miss the free continental breakfast buffet and, I admit, I kind of miss that nerd up front who asks the lecturers those stupid questions.

I should be grateful that people are showing up for their exams. In my offices, even no-shows are way down. Maybe they just want to prove they can go get their eyes checked and there's nothing the government can do about it. Maybe they are so ready to get out of their basements and hang out with other humans that they are willing to hang out with optometrists. Whatever. Welcome you poor lost souls!

I should thank my lucky stars my family tolerated me during lockdown and not be hurt that they are thrilled I'm no longer hanging around the house looking for stuff to fix or, especially, wisdom to share. They are survivors. But some families actually did not tolerate each other during lockdown and there may be some shakeups in my records; I'll have to be careful how I broach the subject of, “How come Bill hasn't come in lately?”

I should be kind to my reps. I doubt their superiors

truly give a big hoot that they are not hitting their planned sales goals because of the pandemic. At least say hello and thank them for the cookies they bring in... you know, the cookies you take home before the staff sees them.

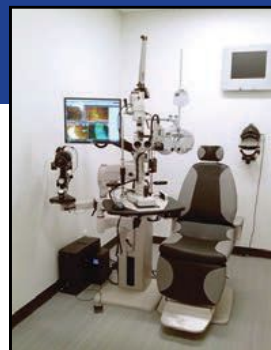
I should think of the one or two things I did during shutdown that I really enjoyed. I loved playing my guitars for the first time since I moved to Texas five years ago. For you, it can be something as simple as binge watching *Cheers* or dusting off the ol' hula hoop.

I should be grateful I'm helping people see for a living. I'm not up on a roof with a nail gun when it is 107 degrees outside, shoveling French fries into cardboard cups or intubating a helpless soul in the ICU—but I am grateful someone is. I'm helping people with the gift of vision. For that, I am grateful. ■



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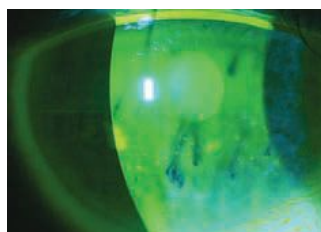
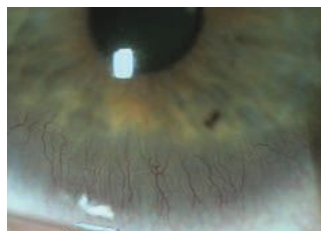
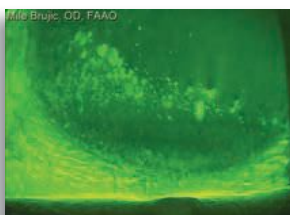
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# Red Herring

A potential misdiagnosis might bump the proper treatment for EKC off track.

Edited by Paul C. Ajamian, OD

**Q** A 25-year-old presents with bilateral red eyes. He has a past history of chlamydia. Could the two be related?

**A** “When a patient presents with a red eye, you should keep sexually transmitted infections (STIs) in the back of your mind, but not necessarily at the top of your differential list,” Julie A. Tyler, OD, associate professor at the Southern California College of Optometry at Marshall B. Ketchum University, says. It is important to thoroughly review the patient’s systemic and social history along with the ocular complaints.

The hallmark of a gonorrhea-related conjunctivitis is hyperacute discharge and is less likely to be missed. Chlamydia, on the other hand, is often overlooked by presenting with characteristics of both viral and bacterial infections. “Ask the patient if they or their partner(s) have experienced any rashes, lesions or painful urination,” she says. “Also, check for a follicular response of the palpebral conjunctiva.”

You may find it awkward to ask patients about STIs, but do it anyway. If they feel uncomfortable discussing their sexual history or getting tested, seek out their primary care physician. If they are looking for anonymity, think about suggesting a community medical clinic.

Whatever you suspect, always rule out a viral etiology by making



**Fig. 1.** This 25-year-old patient presented with swollen lids and preauricular nodes.

it standard protocol to check for preauricular nodes (PAN) on all red eye patients. If nodes are swollen and the patient has a red eye, suspect epidemic keratoconjunctivitis (EKC). Swollen lids can be a hallmark as well (*Figure 1*).

## Check It Early

With EKC, early identification is important to try and prevent spread to the other eye or to other people. “Some practitioners recommend diluted Betadine (povidone-iodine 5%) lavage,” Dr. Tyler says. This can be quite irritating to the ocular surface and can create additional issues, so this treatment is not universally embraced.

Another option Dr. Tyler recommends is off-label use of Zirgan (ganciclovir 0.15%, Bausch + Lomb) ophthalmic gel to decrease the chance of developing corneal infiltrates.

Other supportive measures include topical steroids, especially if infiltrates or pseudomembranes are present, and lots of lubricants, along with cold compresses and isolation to prevent spread.

## What’s the Difference?

Chlamydia is the most common STI in the United States and is the result of an intracellular obligate organism that presents with properties of bacteria and virus in the eye. *Chlamydia trachomatis* is the most common pathogen, but others include *Chlamydia psittaci* and *Chlamydia pneumoniae*.

According to Dr. Tyler, there are many ways to assess for chlamydial infection that are more sensitive and specific than in the past—such as urine testing and even at-home tests. The preferred testing to identify chlamydia is nucleic acid amplification testing (NAAT), which is recommended because of its greater sensitivity. Ideally, direct tissue specimens, which may include conjunctival sampling, are preferred over urinalysis.

A variety of enzyme-linked immunosorbent assay tests are also available for chlamydial detection, such as MicroTrak (Syva Company), Chlamydiazyme (Abbott Laboratories), EIA (Pharmacia) and SureCell Chlamydia Test Kit (Kodak).

“Treatment of choice is a 1g, one-time dose of azithromycin, but doxycycline 100mg BID for one day and then 100mg daily for 21 days is also an alternative,” Dr. Tyler said. To be safe, the patient was referred to a local clinic where he tested negative for chlamydia. EKC, the original working diagnosis, was confirmed, and the patient was treated accordingly. ■





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# A Patient on Thin Ice

We had to help an athlete break a bad habit so that he could return to his sport.

By **Marc B. Taub, OD, MS, and Paul Harris, OD**

**B**rian's fourth concussion had put him out of professional hockey for about a year, and he wondered if his NHL career might be over. Looking for help, he reached out to Sue Durham, OD, who was an officer of the Neuro-Optometric Rehabilitation Association at the time. Dr. Durham prescribed Brian glasses with low plus and a small amount of cylinder. The lenses helped him begin his recovery, but he was ultimately referred to us with the goal of getting back on the ice.

## The Problem

When Brian presented, he reported improvement with his glasses—but not without a few hitches. While they allowed him to drive, play with his children and start exercising again, if his heart rate passed 100 beats per minute he had to lie down on the couch to rest. Watching television and looking at a computer screen caused similar types of visual overload.

Brian moved in a very guarded way, keeping his head locked with his torso and rarely moving his eyes away from primary gaze. To look from one thing to another, he turned his entire body, or he just didn't look at all.

Brian saw clearly, at least 20/15 OD, OS and OU with and without glasses. We proceeded with chair testing with the glasses. Stereo, color, near point of convergence and other tests in the standard bat-



**After a few rounds of vision therapy, Brian was able to return to the ice.**

tery were all normal. The refractive elements of the exam confirmed that the glasses did indeed offer maximum visual acuity and comfort. However, the analytical data, including the base-in and base-out ranges at distance and near, told a different story.

Brian's base-out breaks were greatly reduced at both distance and near. At distance, the base-out break was three instead of 19; at near, it was six instead of 21. Though base-out prism ranges measure convergence in response to a prismatic challenge, they could also indicate a general stressor, which Brian gave into when challenged. These are not the kind of numbers we typically see with elite athletes who switch into higher

gears when the going gets tough. But they did match his complaints of fogginess and fatigue. He had not been on the ice since his fourth concussion because he found it too overwhelming and overstimulating.

## The Solution

It is common for people to alter their daily routine to get back to a successful life after suffering an injury. Brian had done this by avoiding the things that caused him to suffer the symptoms secondary to his traumatic brain injury. But we were over a year out from the injury and surely his brain had recovered, so why was he still having all these symptoms? The answer was in his guarded, unnatural movements.

Most people have smooth, accurate eye movements, unencumbered by having to carry out those movements by moving the whole body. The body acts as a platform to allow the visual system its freedom of movement to collect the space-time data it needs to direct the athlete to achieve a certain level of performance. When the eyes are held steady in the head and the head is held steady on the body so that ocular movements are made with the whole body, all precision is lost and we are forced to overcompensate. This excess effort leads to overstimulation and overload, causing the brain to react and preserve overall health. Thus, the symptoms Brian suffered were protective and telling him to minimize these actions.

The first thing I (Dr. Harris) realized was that we couldn't do anything more with glasses. What Brian needed was vision therapy. The main goal of his therapy was to reestablish normal movement patterns. A key activity was the Marsden ball held inches from his face that he had to track in two different ways—what we call the Greenwald Eye Movements. The first involved him moving his eyes without moving his head. We started out with him lying on the ground with the ball just clearing



**The Marsden ball was one of the most important parts of Brian's vision therapy.**

his nose while moving from side-to-side. Next, he had to track it by moving his head without moving his eyes. Once he mastered this lying down, we then moved from a seat with a back to a seat without a back to standing on both feet to standing on one foot. It took several sessions to work through these patterns.

Since Brian's commute was about 75 minutes each way to our practice, we scheduled 90-minute sessions. I was surprised when, at the end of the second session, he asked if he could begin cardio work. His team physician and athletic trainer deferred to me, and

I told him to go for it. At the beginning of the third session, he stated he could now get his heart rate up to well over 120 without experiencing any adverse symptoms. After the fourth session, he began practicing on the ice once more. He progressed so quickly that, by the end of the sixth session, he was cleared to play again by the head physician of the NHL Players' Association.

Brian returned just in time for his team to make a run at the playoffs. We watched on TV as he successfully cleared loose pucks from the goalmouth and made beautiful vertical passes up the ice to hit the tape of a teammate skating at full speed

who was then able to make a play on the offensive end. It was clear that our hard work had paid off.

Early on after Brian's fourth concussion, he learned to move in a more guarded way to avoid triggering symptoms of the traumatic brain injury he had sustained, but this caused other symptoms instead. Vision therapy helped restore Brian's natural movements by recalibrating his vestibular system. Once he started moving more fluidly and naturally again, his system was able to process visual input much more efficiently without overloading and overwhelming him. ■



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## INDICATIONS AND USAGE

CEQUA™ (cyclosporine ophthalmic solution) 0.09% is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**Potential for Eye Injury and Contamination:** To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces.





**Use with Contact Lenses:** CEQUA should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of CEQUA ophthalmic solution.

#### **ADVERSE REACTIONS**

The most common adverse reactions reported in greater than 5% of patients were pain on instillation of drops (22%) and conjunctival hyperemia (6%). Other adverse reactions reported in 1% to 5% of patients were blepharitis, eye irritation, headache, and urinary tract infection.

**Please see brief summary of Full Prescribing Information on the adjacent page.**

**References:** 1. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2018. 2. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. 3. US Patent 9,937,225 B2. 4. Tauber J, Schechter BA, Bacharach J, et al. A Phase II/III, randomized, double-masked, vehicle-controlled, dose-ranging study of the safety and efficacy of OTX-101 in the treatment of dry eye disease. *Clin Ophthalmol.* 2018;12:1921-1929.

**Brief Summary of Prescribing Information for CEQUA™ (cyclosporine ophthalmic solution) 0.09%, for topical ophthalmic use**

**CEQUA™ (cyclosporine ophthalmic solution) 0.09%  
See package insert for Full Prescribing Information.**

**INDICATIONS AND USAGE**

CEQUA ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

**CONTRAINDICATIONS**

None.

**WARNINGS AND PRECAUTIONS**

**Potential for Eye Injury and Contamination**

To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces.

**Use with Contact Lenses**

CEQUA should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of CEQUA ophthalmic solution.

**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.

In clinical trials, 769 patients received at least 1 dose of cyclosporine ophthalmic solution. The majority of the treated patients were female (83%).

The most common adverse reactions reported in greater than 5% of patients were pain on instillation of drops (22%) and conjunctival hyperemia (6%). Other adverse reactions reported in 1% to 5% of patients were blepharitis, eye irritation, headache, and urinary tract infection.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Risk Summary

There are no adequate and well-controlled studies of CEQUA administration in pregnant women to inform a drug-associated risk. Oral administration of cyclosporine to pregnant rats or rabbits did not produce teratogenicity at clinically relevant doses.

Data

*Animal Data*

Oral administration of cyclosporine oral solution (USP) to pregnant rats or rabbits was teratogenic at maternally toxic doses of 30 mg/kg/day in rats and 100 mg/kg/day in rabbits, as indicated by increased pre- and postnatal mortality, reduced fetal weight, and skeletal retardations. These doses (normalized to body weight) were approximately 3200 and 21,000 times higher than the maximum recommended human ophthalmic dose (MRHOD) of 1.5 mcg/kg/day, respectively. No adverse embryofetal effects were observed in rats or rabbits receiving cyclosporine during organogenesis at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively (approximately 1800 and 6400 times higher than the MRHOD, respectively).

An oral dose of 45 mg/kg/day cyclosporine (approximately 4800 times higher than MRHOD) administered to rats from Day 15 of pregnancy until Day 21 postpartum produced maternal toxicity and an increase in postnatal mortality in offspring. No adverse effects in dams or offspring were observed at oral doses up to 15 mg/kg/day (approximately 1600 times greater than the MRHOD).

**Lactation**

Risk Summary

Cyclosporine blood concentrations are low following topical ocular administration of CEQUA. There is no information regarding the presence of cyclosporine in human milk following topical administration or on the effects of CEQUA on breastfed infants and milk production. Administration of oral cyclosporine to rats during lactation did not produce adverse effects in offspring at clinically relevant doses. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CEQUA and any potential adverse effects on the breastfed child from cyclosporine.

**Pediatric Use**

The safety and efficacy of CEQUA ophthalmic solution have not been established in pediatric patients below the age of 18.

**Geriatric Use**

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

**PATIENT COUNSELING INFORMATION**

**Handling the Vial**

Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the solution. Advise patients also not to touch the vial tip to their eye to avoid the potential for injury to the eye.

**Use with Contact Lenses**

CEQUA should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that if contact lenses are worn, they should be removed prior to the administration of the solution. Lenses may be reinserted 15 minutes following administration of CEQUA ophthalmic solution.

**Administration**

Advise patients that the solution from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

**Rx Only**

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# A Tipping Point for Telehealth

Temporary changes have made this platform useful, but that might not be the case moving forward. **By John Rumpakis, OD, MBA, Clinical Coding Editor**

This issue of *Review*, focused on trends and controversies, is one of my favorites because it affords me the opportunity to address timely issues within the profession. One of the most significant headline items in health care this year has been COVID-19 and the rapid growth of telehealth it has caused. Now, seven months into the pandemic with most practices offering telehealth services in one way or another, is a good time to examine its impact.

Telehealth, available since 2017, refers to a distinct level of services that have traditionally been performed via a virtual face-to-face interaction, with audio and/or video connections, between the patient and physician.

Prior to the COVID-19 Public Health Emergency (PHE), both the popularity and use of telehealth was minimal due to several constraints. The service platform came with significant restrictive rules on its use, as well as low reimbursements. Perhaps the most significant for us, it's not conducive to a hands-on, close-quarters profession such as optometry. It is difficult to see a staining pattern or examine the retina via telehealth. I'm not saying that it can't be done, but it's difficult to say the least.

## Emergency Action

In response to the PHE in March, the CMS relaxed the rules that surround how and where a clinician can provide telehealth services:

- Medicare can pay for office, hospital and other visits furnished

via telehealth across the country, including the patient's place of residence. In essence, this allows telehealth services to be provided without the previous geographic or location-based restrictions.

- The Office of Inspector General is allowing health care providers to reduce or waive cost-sharing for telehealth visits paid by federal health care programs. Of course, patients must be notified that a claim will be submitted to the payer.

- The requirement to store communication and ensure HIPAA compliance for all patient communications is not being enforced during the PHE, which allows for telehealth services to be provided using "everyday communications technologies" such as FaceTime or Zoom.

- Services can now be provided to both *new* and *established* patients.

- Telephone services are now reimbursed.

- Place of service rules were modified to all POS 11 (office) to be used for telehealth services rather than the POS 2 (telehealth) indicator.

- CMS added the eye visit codes to the list of covered exams during the COVID-19 PHE. Documentation requirements, however, remain the same: 92002 and 92012 are achievable via virtual face-to-face interaction; place of service is 11 and append modifier -95.

*Note that this expansion of coverage may be unique to CMS.*

These relaxed rules were given a 90-day extension on July 25, 2020. So, they will be in place until the end of this month, at least.

## Shaky Future

Once this PHE has subsided, I suspect some of these relaxations will stay in place and others will revert to their prior status. For example, the prior requirement that a patient must live in a physician shortage area and must travel to a properly qualified facility to initiate a telehealth service will likely never be reinstated. I believe that the patient will be able to live anywhere and will be able to initiate the telehealth service from anywhere, including their home.

However, I don't see the use of common platforms such as Zoom or FaceTime continuing, and the return to the specific use of a HIPAA-protected portal is inevitable. Additionally, the ability to waive copays and deductibles most likely won't continue, as carriers will resume passing that cost on to the consumer of care.

How and when things go back to normal is yet to be seen, but we can now all speak from experience when it comes to telehealth and can better evaluate its place in our practice going forward. So, friend or foe? ■

*Send your coding questions to [rocodingconnection@gmail.com](mailto:rocodingconnection@gmail.com).*

1. US Department of Health and Human Services. Renewal of determination that a public health emergency exists. [www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx](https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx). July 23, 2020. Accessed September 3, 2020.



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# Myopia: Should We Treat It Like a Disease?

The research is mounting, but whether the projections hold true in clinical practice is still up for debate. **By Julie Poteet, OD**

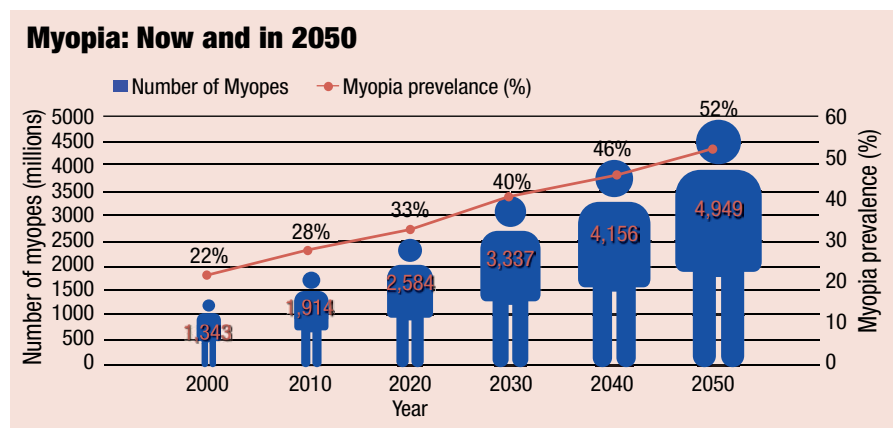
**T**he rising rates of myopia worldwide leave little up for debate—the condition is already considered a public health concern by the World Health Organization (WHO).<sup>1</sup> But what to do about it is less clear. Most agree mitigating the spread of high myopia is a must, but what about low myopia? Will a lifetime correction of just -2.00D or -3.00D really make a difference in the long run for the patient's ocular health and quality of life? A close look at the numbers and the host of possible long-term effects suggests the answer is yes.

## By the Numbers

In 2015, the WHO, along with the Brien Holden Vision Institute, gathered top myopia researchers from around the world for a global scientific summit on myopia. The researchers noted that in 2010, myopia and high myopia were estimated to affect 28% and 3.0% of the world's population, respectively. Current models project that by 2050, myopia and high myopia will reach epidemic proportions affecting 52% and 10% of the world's population, respectively (Figure 1).<sup>1</sup>

Based on these projections, the WHO identified the increase in myopia as the number one health threat facing vision worldwide, in part because of its association with myopic macular degeneration and other conditions such as cataracts and glaucoma.<sup>1-3</sup>

Rates of high myopia are on the rise as well (Figure 2).<sup>1</sup> Although the definition of high myopia varies in the literature from -5.00D to a threshold as high as -8.00D—making analysis challenging—the WHO consensus recommends clinicians and researchers define



**Fig. 1.** The WHO estimates 52% of the world's population will be myopic by 2050, up from just 22% in 2000. Adapted from: *The Report of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia.*<sup>1</sup>

it as -5.00D of myopia or worse.<sup>1</sup> Children are being diagnosed at a much younger age now than in the past, and younger age at onset has been linked to faster progression and increased myopic severity.<sup>4,5</sup>

A study published in September 2020 also found that the age of onset significantly impacts the risk of high myopia in adulthood.<sup>6</sup> Onset at age seven or eight led to a more than 50% risk of high myopia, and the risk drops with each year free of myopia. Patients with myopia onset at nine had a 30% risk, onset at age 10 had a 20% risk and onset at the age of 12 or older only had a 5% risk for progression to high myopia.<sup>6</sup>

Current research suggests myopia rates vary by population as well. Among late teenagers and young adults in Korea, Taiwan and China, for example, the prevalence is now between 84% and 97%.<sup>7</sup>

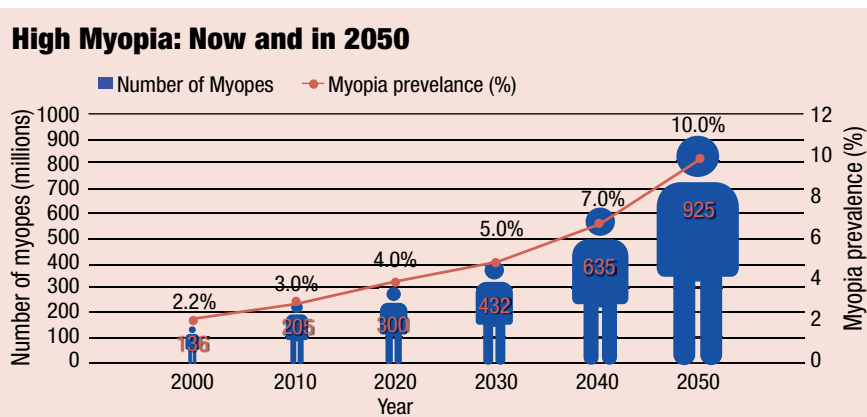
In the United States, one study found that the prevalence of myopia between -2.00D and -7.90D nearly doubled from 11.4% between 1971 and 1972 to 22.4% between 1999 and 2004.<sup>8</sup> The same study found that the prevalence of high myopia, defined as more than -8.00D, increased eightfold, 0.2% to 1.6%, during the same period.<sup>7,8</sup>

### An Environmental Issue

Although myopia develops as a complex interaction between environmental and genetic factors, environmental changes are believed to be the primary drivers behind the current myopia epidemic.<sup>9</sup> Emmetropization, a visually guided process, depends on environmental exposures as a child. Myopia progression is due to elongation of the axial length, which is primarily due to the elongation of the vitreous chamber of the eye. Optical blur produced by a lag of accommodation or the eye's response to accommodation may be what drives excessive growth.<sup>10,11</sup>

However, the visual processes at play with myopia development remain unclear, and research has yet to solidify a strong correlation with near work and the onset or progression of myopia.<sup>12</sup>

In fact, a recent study suggests the lag of accommodation develops concomitantly with, not prior to, myopia.<sup>13</sup> The same researchers propose the involvement of the ON and OFF pathways in reading and myopia. While the natural environment is largely balanced



**Fig. 2. By 2050, high myopia is projected to reach 10% of the world's population. Adapted from: The Report of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia.<sup>1</sup>**

between ON and OFF signaling, the team found reading dark text on a light background overstimulates the OFF channels and leads to reduced choroidal thickness within an hour. The opposite is true with light text on a dark background, which overstimulates the ON channels and increases choroidal thickness in one hour.<sup>13</sup>

Risk factors for myopia development include age, family history, race (Asian>Caucasian>Black), cycloplegic refraction at six years of age (<+0.75D increases risk of myopia later in life), near work and less time outdoors.<sup>9,14</sup> A new study now suggests other environmental factors may increase the risk of myopia, such as the use of LED lighting when doing homework, dim light while performing near tasks, fewer sleeping hours, a consistent reading distance less than 25cm and living in an urban setting.<sup>14</sup>

Smartphone use was recently implicated as a possible risk factor, as school-aged children with myopia appear to use about twice as much data as their normal vision counterparts.<sup>15</sup> Another study suggests less than three hours a week of physical activity and more than six hours a day of screen time can approximately double the risk of a teen developing or worsening myopia.<sup>16</sup>

Still, a literature review and meta-analysis published January 2020 found no significant association between screen time and myopia.<sup>17</sup> The researchers speculate that reduced time outdoors, not increased screen time, might be more to blame for the myopia risk.<sup>17</sup> The authors noted that myopia prevalence increased primarily with increasing education in urban Asia a few decades ago, not recently alongside increasing screen time. Yet another team found viewing electronic displays didn't cause study subjects any more hyperopic defocus than the defocus caused by other stimuli.<sup>18</sup>





## Visual Impact

Worsening myopia comes with a number of drawbacks, all of which are proportional to the degree of myopia present, highlighting the importance of myopia control, even for low myopes.

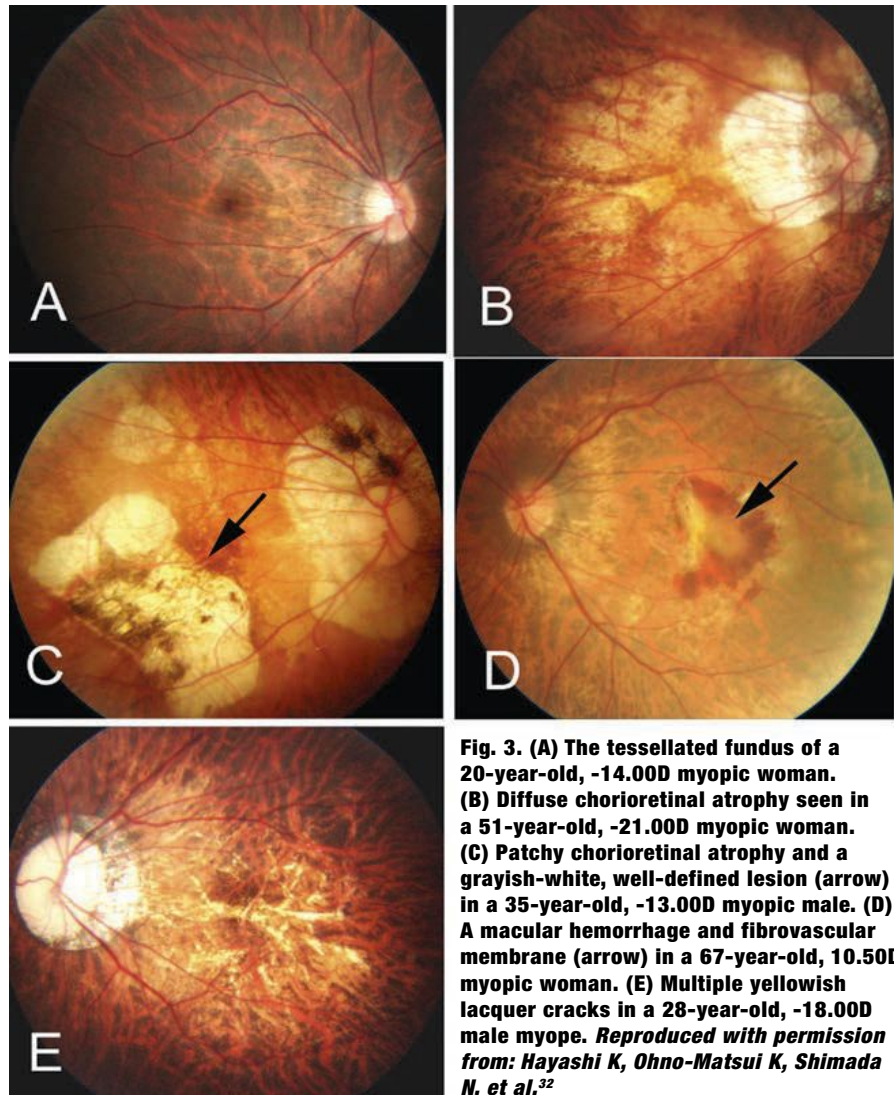
**Cost.** The disease is associated with high financial costs to an individual, with one study finding a lifetime cost of as much as \$17,020 for those who have myopia for 80 years.<sup>19</sup> The mean cost per individual was approximately \$709 per person per year and, not surprisingly, costs increased the earlier patients began wearing glasses. The Singaporean study noted the costs were driven by spectacles, contact lenses and optometry services, culminating in a total cost of approximately \$755 million per year in Singapore.<sup>19</sup>

**Impaired vision.** Even if myopic patients are correctable to 20/20, their vision impairment can restrict their vocational options and provide them with poorer quality of life.

One study found patients with pathologic myopia experienced reduced quality of life and functional status in daily living compared with controls as a result of handicap, disability and lack of support.<sup>20</sup> Even patients using vision correction experienced lower quality of life, the study found, and the average decrease in quality of life was -7.1% for LASIK patients, -13.0% for those using orthokeratology, -15.8% for spectacle wearers and -17.3% for soft contact lens wearers.<sup>20</sup>

**Vision-threatening conditions.** These are typically the result of excessive axial elongation, which leads to degenerative retinal and choroidal changes.<sup>1,21</sup> Globally, high myopia is ranked second behind cataracts as the leading cause of correctable visual impairment, with 10% of all myopes having 6.00D of refractive error or worse.<sup>21</sup> Myopic degeneration is the leading cause of blindness in Japan and the second leading cause of vision impairment in China and Denmark.<sup>22</sup>

Myopic maculopathy is the most significant myopia-related cause of irreversible vision loss.<sup>1</sup> Research suggests as many as 10% of pathologic myopia patients will



**Fig. 3.** (A) The tessellated fundus of a 20-year-old, -14.00D myopic woman. (B) Diffuse chorioretinal atrophy seen in a 51-year-old, -21.00D myopic woman. (C) Patchy chorioretinal atrophy and a grayish-white, well-defined lesion (arrow) in a 35-year-old, -13.00D myopic male. (D) A macular hemorrhage and fibrovascular membrane (arrow) in a 67-year-old, 10.50D myopic woman. (E) Multiple yellowish lacquer cracks in a 28-year-old, -18.00D male myope. *Reproduced with permission from: Hayashi K, Ohno-Matsui K, Shimada N, et al.*<sup>32</sup>

develop this complication, of whom 30% will have a bilateral presentation.<sup>23</sup>

It is characterized by stretched blood vessels, peripapillary atrophy, posterior staphyloma, lacquer cracks in Bruch's membrane, geographic atrophy of the retinal pigment epithelium and choroid, subretinal hemorrhages and choroidal neovascularization (*Figure 3*).<sup>23,24</sup>

One meta-analysis estimates that 10 million people globally had myopic maculopathy in 2015, of whom 3.3 million were blind.<sup>24,25</sup> The researchers estimate that by 2050, visual impairment will grow to 55.7 million (one in 175), 18.5 million of whom will be blind.<sup>24,25</sup>

The risk of myopic maculopathy and its impact on public health are not limited to high myopes.<sup>24</sup> Significant disease associations exist even at low levels of myopia.<sup>3,24</sup> For example, patients with less than -5.00D

## Are axial length measurements part of your myopia management program?

of myopia contributed to 43% of the cases of myopic maculopathy in the Australian Blue Mountains Eye Study.<sup>24,26</sup> There is no evidence of a safe threshold level of myopia for any of the known ocular diseases linked to myopia, including myopic maculopathy.<sup>3</sup>

A recent meta-analysis evaluated all observational studies performed between 1988 and 2019 related to myopia and found the condition is a risk factor for retinal detachments, primary open-angle glaucoma (POAG) and early and posterior subcapsular cataracts.<sup>27</sup>

The team found a prevalence of myopic macular degeneration of only 0.1% to 7% in patients with low myopia, but in as many as 65% of high myopes.<sup>27</sup> While only a handful of studies investigate retinal detachment based on refractive error, the pooled analysis suggests an increased odds ratio of 3.45 for patients with any level of myopia, but as high as 12.62 for high myopes.<sup>27</sup> The risk of cataract and POAG increased for all patients with myopia as well, and for high myopes in particular. Overall, the researchers found myopic patients had:<sup>27</sup>

- 100-fold higher risk of myopic macular degeneration
- Three-fold higher risk of retinal detachment
- Three-fold higher risk of posterior subcapsular cataract
- 1.59-times the risk of POAG

Based on this analysis, one in three high myopes is at risk of bilateral low vision with age.<sup>27</sup>

### Why Control Matters

In a recent review, researchers used data from five population-based studies of the prevalence of myopic maculopathy to show that a 1.00D myopic increase was associated with a 67% increased prevalence of myopic maculopathy. The researchers further suggest that slowing myopia by 1.00D—regardless of baseline myopia—should reduce the risk of myopic maculopathy by 40%.<sup>24</sup>

According to myopia experts at the WHO Myopia World Summit, reducing the rate of myopia progression by 50% could reduce the prevalence of high myopia by up to 90%.<sup>1</sup> And with a projected global prevalence rate of high myopia of 10.0% (925 million people) by 2050, the potential benefits are significant.<sup>1</sup>

Another study suggests that if a child could be kept from progressing from -1.00D to -3.00D, the risk of myopic maculopathy would decrease four- to five-fold, retinal detachment by three-fold and posterior subcapsular cataract by 1.5-fold.<sup>28</sup>

A study published in April 2020 analyzed 4,257 retinal detachment patients and 39,181 controls from the UK Biobank cohort. The researchers found that for each 6.00D increase in myopia, retinal detachment increased



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7.2-fold. The study authors concluded that their results add weight to existing evidence suggesting that myopia control efforts may help prevent retinal detachments.<sup>29</sup>

Maintaining a patient at -1.50D instead of progressing to -5.00D or -6.00D is not only a matter of reducing the risk of axial elongation; it also significantly affects quality of life.

Consider the patient who never progresses beyond -1.50D of myopia and can still drive without glasses or contacts. Keeping a patient functional without glasses is important, and a -1.50D myope is typically better able to navigate their surroundings than a -5.00D or -6.00D myope. Consider these scenarios: a patient loses their glasses during a car accident, or a hiker loses their glasses and has to navigate without them. Every diopter matters not only in visual acuity but also in their ability to function at different lighting levels.

Researchers recently looked at the relationship between myopia severity and macular retinal thickness as it pertains to visual performance and found that visual acuity worsened progressively with dimmer lighting and higher myopia.<sup>30</sup> The authors concluded that visual performance under photopic, mesopic and simulated night vision (with goggles) lighting conditions is influenced by both refractive error and retinal thickness.<sup>30</sup> Thus, because visual acuity worsens progressively with dimmer lighting, going from -8.00D to -9.00D may not seem like a large jump as far as visual acuity, but the quality of vision will differ significantly based on lighting.<sup>30</sup>

Research on myopia is growing quickly, now showing that if Caucasian children diagnosed with myopia progress, on average, by -0.50D per year, then a six-year-old with -1.00D of myopia could be a -6.00D to -7.00D myope by the time they graduate from high school.<sup>9,31</sup> Asian children progress even more rapidly, at an average of -0.87D per year.<sup>32</sup> Of note: estimated progression rates are dependent on baseline age with decreasing progression rates as age increases.<sup>31</sup> Intervening at age six could mean the difference between a final prescription of -2.00D to -3.00D compared with -6.00D or -7.00D, or even more depending on the child. One study shows reducing progression by 33% will keep 73% of



**Fig. 4. The Brien Holden Institute's free myopia calculator can help clinicians better understand the effects of myopia control strategies.**

myopic children below -5.00D—a threshold linked with an increased risk of choroidal neovascularization, retinal detachment, glaucoma and cataract.<sup>33</sup>

Available options to control the rate of myopia progression include low-dose atropine, multifocal soft contact lenses, orthokeratology and, in some countries, bifocal or multifocal eyeglasses. The Brien Holden Vision Institute provides a free

myopia calculator that can help clinicians estimate the annual progression of myopia, showing the approximate refractive error that will result with and without myopia management (*Figure 4*). Clinicians can choose the management method, and based on probability and predicted efficacy of treatment, the calculator provides the predicted amount of myopia with and without treatment. This is calculated using the patient's age, refractive error at presentation and ethnicity.

### A Group Effort

Convincing a patient and their parents of the need to intervene now to prevent future risk takes strong conviction on the practitioner's part. If clinicians do not advocate for the prevention of myopic progression, it will be almost impossible to prevent future vision loss from the increasing rates of myopia. Optometrists must take an interest, or patients will not.

Key points for patient education:

- Myopia rates are increasing at epidemic proportions, which is environmentally related.
- Every small increase in myopia is associated with a greater risk of permanent vision loss.
- By being proactive, rather than reactive, we have the opportunity to reduce myopia progression, which can improve quality of life and protect against disease risk.
- Slowing myopia by 1.00D should reduce the risk of myopic maculopathy by 40%.<sup>24</sup>

With more than half of the world's population projected to be myopic by 2050, it is imperative that we heed the warning by the WHO and other proponents of myopia control—and treat myopia as a disease. This could make a significant difference in the lives of those



with myopia, particularly those at higher risk of progression, including those of Asian descent, those with a higher refractive error at a young age and those who have myopic parents. ■

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# How COVID-19 is Reshaping Optometry

With all the changes wrought by the pandemic, optometrists must be nimble and willing to adapt—or else find themselves outmaneuvered. **By Brian Chou, OD**

**C**COVID-19 is not an extinction event for optometry, but that does not diminish its stressful and humbling effects. The post-COVID-19 landscape is bound to change many facets of eye care, including consumer behavior, business strategy and practice operation. What follows is a view into each of these windows of what may lie ahead.

## Online Product Sales Get Turbo-Charged

A lot of practices reopened following the COVID-19 shutdown to find accumulated prescription verification faxes from online contact lens retailers. During the closures earlier this year, more consumers purchased goods online, including eyeglasses and contact lenses.

During the height of the COVID-19 shutdown, 1-800-CONTACTS reported a 100% year-over-year increase in new and returning customers.<sup>1</sup> Concurrently, the company's ExpressExam app saw a 200% increase in use, while its Rx Reader app saw a 700% increase in monthly active users.<sup>1</sup>

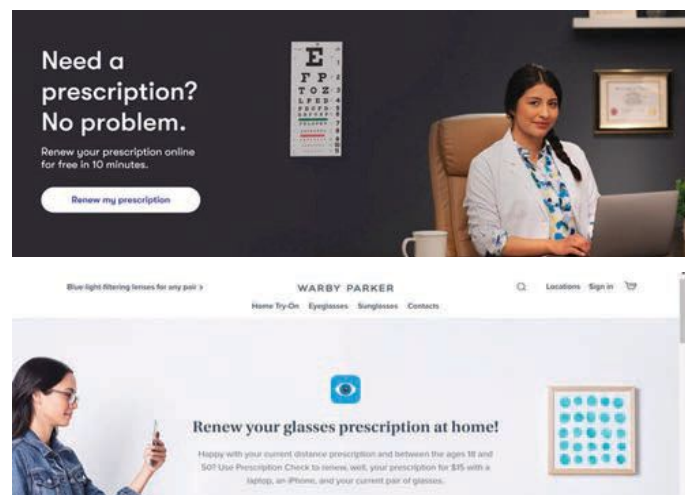
Along the same lines, other major online eye care retailers in

addition to 1-800-CONTACTS, such as Warby Parker and GlassesUSA, stepped up promotion of their prescription renewal services (*Figure 1*). Their ability to duplicate old prescriptions allows them to bypass a doctor-generated prescription, the major constraint to selling their products.

GlassesUSA and 1-800-CONTACTS have apps that offer smartphone lensometry for single vision lenses with a spherical power between -6.00D and +3.00D and cylinder up to -2.50D (*Figure 2*). Using this service, shoppers can buy glasses without a valid prescription. While GlassesUSA's Prescription Scanner app's terms of use state that it should only be used if the user is free of eye disease and 18 to 45 years old

and the prescription is valid and newer than 24 months, this is not enforced.

Online prescription renewal appeals to consumers who want to obtain glasses or contact lenses without undergoing a comprehensive eye examination whether due to perceived inconvenience, cost or risk of contracting illness. Optometrists can expect these technologies to improve in simplicity, speed and accuracy, growing the online vision correction market.



**Fig. 1. Online eye care retailers, such as 1-800-CONTACTS (top) and Warby Parker (bottom), benefited from remote glasses prescription renewal services during the COVID-19 shutdown.**



**Fig. 2. GlassesUSA offers a scanner app to help customers renew their prescription.**

Simon Seshadri, senior vice president of global marketing at CooperVision, describes how the field experienced an increase in online activity with COVID-19. “When they ran out of lenses, consumers went looking for other options. The online sellers were highly active during that time in gaining new clientele.”

For the practices set up for online sales, Mr. Seshadri said that their contact lens sales provided some of their only revenue in the absence of eyeglass sales. CooperVision worked with offices to direct-ship contact lenses to patients. One of the biggest changes the company noted was a decrease in annual supply sales of disposable contact lenses with more consumers purchasing smaller quantities of lenses, likely due to economic anxiety, adds Mr. Seshadri.

At the height of COVID-19 closures, Aaron See, senior vice president of manufacturer partnerships at ABB Optical Group, said the company experienced the says dramatic drop in ophthalmic and specialty contact lens sales, with a more modest decline in disposable soft contact lens sales. As practices reopened, these sales began to rebound, and by June 2020, ophthalmic and specialty contact

lens sales had already reached pre-COVID-19 levels, noted Mr. See.

According to Mr. See, ABB Optical’s patient-facing website helped propel almost a 300% increase in online ordering through independent eye care practitioners during the closures. Direct delivery to patients still operates at around 50% growth, Mr. See reports, suggesting a more lasting change. Contact lens subscriptions have also increased, added Mr. See.

Sarah Salvador, strategic operations manager at SportRx, a prescription sports sunglasses e-retailer, observed an increase in new online eyewear shoppers with the pandemic. “The influx mostly came from those who could not connect with their existing doctor’s office, as well as those avoiding face-to-face interactions.”

Ms. Salvador says more patients are realizing that online eyewear purchase is a viable option, and the company’s numbers reflect this.

The shift to online prescription renewals

and eyewear and contact lens purchases seems natural under the circumstances, which explains the increasing popularity of this channel.

### **In-office Adaptations**

Practicing optometry is more demanding now. From an operational standpoint, most practices are asking pre-appointment screening questions to affirm that patients do not have symptoms of COVID-19 and have not been around anyone who is being tested or has tested positive for the virus.<sup>2</sup> They are also taking forehead temperatures upon arrival (*Figure 3*).<sup>2</sup> Most practices have fewer available appointment slots, with 26.8 patients seen per day before COVID-19 and 21.6 patients seen per day as offices reopened, a 19.4% reduction in volume.<sup>2</sup> Almost all practices have placed more emphasis on hygiene and protective equipment (*Figures 4 and 5*).<sup>2</sup> About one-third of practices have had difficulty getting former employees to return to work.<sup>2</sup>

For all these reasons, optometrists who practice in-office have felt like they are at a disadvantage when compared with their online counterparts. “There is an unfair playing field because independent optometrists have to buy protec-



**Fig. 3. Before their appointment, patients have their forehead temperature taken.**





**Fig. 4.** Shields between staff and patients serve as protective barriers.

tive equipment and disinfecting supplies, see fewer patients and continue managing the costs of maintaining a physical location, while online retailers avoid many of these costs because they don't physically interact with the patient," notes Albert Chang, OD, co-owner of Family EyeCare Center in Campbell, CA.

With additional operational costs and reduced appointment availability, patients who no-show, cancel or reschedule at the last minute are even costlier. Some practices now require patients to make a deposit to book an appointment. Others are preferentially recalling their most profitable patients and dropping low-paying vision plans to maximize profitability.

Mr. Seshadri emphasizes the importance of bringing in revenue from services as well as products. "The other sales channels cannot compete in the professional services realm, so build a wall of defense around your practice with your service offerings because that cannot be as easily commoditized."

Jim Thimons, OD, medical director and founding partner of Ophthalmic Consultants of Connecticut, explains that vertical expansion of services is another needed adjunct to day-to-day dis-

ease management for increased profitability. Employing fee-for-service technology, such as the burgeoning field of in-office eyelid treatments for meibomian gland expression, is a great way to accomplish both goals simultaneously, he said. With these systems, "you can augment your medical care services to an existing patient base and create new fee-for-service revenue while improving the overall quality of care for your patients."

There is an economic advantage to providing higher-revenue products and specialized services while also limiting face-to-face interaction when possible and promoting convenience. This includes medical services, low vision, vision therapy, specialty contact lenses and myopia management.

"When you rely on the sale of goods that are common and undifferentiated, it is difficult to be unique," Dr. Thimons says. "On the other hand, expanding the breadth of care across the ocular disease space is a great way to increase patient services and at the same time develop additional recurrent sources of revenue that are not reliant on optical good sales."

### Telemedicine Services

In an interesting twist, despite

optometric proponents denouncing remote eye care in years previous due to threats of online refraction, the profession has seemingly had a change in heart.

"COVID-19 has made it apparent that optometry needs to acknowledge that online eye care is here to stay and that telemedicine has become an accepted technology and will maintain a presence going forward," notes Dr. Thimons.

*Telemedicine* refers to a diverse range of health technologies used at a distance. In the past, telemedicine was attractive because it improved access to care in rural areas. Today, the motivation is physical distancing to reduce contagion.

One of the simplest, but not necessarily obvious, forms of telemedicine is the phone. Most doctors have unknowingly offered telemedicine by conducting consults this way. However, we tend to pay more attention to video chat and flashier technologies. Mr. See believes that platforms such as Eyecare Live and others maintain the doctor-patient relationship, provide patients with increased access to varied methods of care, augment a doctor's presence, help triage patients and reduce the number of in-office visits during a time in which patients may hesitate to visit a doctor's office.

# Five Reasons to Partner with Private Equity: One OD's Perspective

By Russell Beach, OD

Private equity–led consolidation of eye care practices is leading to significant growth in value for owners and an accelerated timing of ownership transitions. Many ODs—myself included—are now realizing that their peak earning years may offer the best potential to realize maximum valuations. The move could also come with professional and personal benefits worth considering. Here are five reasons to consider private equity in your future:

## 1. Value

Practice owners must consider the long-term value, not just the immediate liquidity event. Three factors are important:

*Valuations are at historic highs.* Private equity has driven some practice valuations—a multiple of earnings before interest, tax, depreciation and amortization—beyond what practices could have ever realized on their previous trajectories. Even during the COVID-19 pandemic, many groups are giving valuations based on pre-COVID earnings and holding a small portion of the closing proceeds as an “earnout,” which will be realized once a practice hits a revenue target equal to their pre-COVID earnings. This is great for practices that paused services or are running at half capacity—as long as the practice does, in fact, bounce back.

*Practices are more attractive during a healthy growth phase.* Peak earning years are when a practice has several years of impressive revenue growth with a strong potential for future growth. Many consolidators are willing to pay a higher multiple for that type of practice than one with flat or declining revenue. If a practice owner waits until the practice's growth slope flattens, the opportunity for a peak valuation multiple has passed.

*Equity growth is key.* Some groups allow selling optometrists to convert a portion of their proceeds into equity shares in the consolidator. Optometrists who can take an equity position early in the life cycle of a consolidator could have a high potential return on investment if the practice succeeds. Of course, practice owners who remain invested after consolidation retain some risk in doing so; if the practice struggles, so does the investment.

## 2. Risk Reduction

Many financial advisors tell clients to reduce their risk for losses as they age because high levels of risk in the second half of life could negate the financial achievements of the first half. The same could be said for a practice owner, and the COVID-19 pandemic has made this painfully clear for some.

Depending on the fine print of the deal, fully transitioning ownership could reduce the risk to an OD's personal wealth. The later years of a career are secured by employment with a larger entity, and the practice owner has additional resources to invest elsewhere, such as for family and retirement planning.

However, practice owners have to be careful that the partnership does not include conditions that increase risk. For example, practice owners could still be liable if personal guarantees, such as real estate and vendor accounts, remain in their name.

## 3. Work-Life Balance

Creating a carefully constructed ownership transition to relieve managerial responsibilities can significantly improve a practice owner's work-life balance. Often, a practice's peak earning years coincide with growing family or personal responsibilities. For me, my five- and eight-year old boys had myriad sports and social activities that often conflicted with my practice responsibilities.

Of course, not all consolidating groups are created equal and optometrists interested in selling must do their research. Some may require partner ODs maintain operational involvement, for example. The goal is to partner with a group that fosters a work climate that aligns with the aspirations of the selling optometrist.

## 4. Refocus on Patient Care Skills

The successful practice owner often balances a full schedule of patients with practice management and family responsibilities—leaving little time for professional growth. Given that peak earning years are often 10 to 20 years after optometry school, clinical care standards and technological advances demand that optometrists keep pace. If not, patient care could fall behind advanced standards.

Partnering with private equity can allow someone else to assume administrative duties and provide the OD time to keep up with continuing education and learn about new equipment or procedures.

## 5. Develop Outside Interests

As much as I have loved building and nurturing my practice, I also cherish providing free eye care to the most underserved members of my community. Every year, I provide pro bono exams and glasses to homeless individuals. Most of that is at the office, but once a year we do a pop-up clinic at a local homeless shelter. Last year, I purchased my own exam lane of equipment for a local shelter so I can better care for homeless individuals. My partnership with a private equity firm has given me more time and energy to invest in this passion.

Partnering with private equity-backed groups may not be the best decision for every optometrist. However, these practice ownership transitions and partnerships can allow for significant financial, professional and personal value. Rather than an exit strategy, the greatest opportunity may exist in peak earning years.

*Dr. Beach is a co-owner of Coastal Vision in Virginia. His practice partnered with Keplr Vision in August 2020. He can be contacted at [drbeach@coastalvisionva.com](mailto:drbeach@coastalvisionva.com).*



While these technologies enable doctors to diagnose and treat low-stakes conditions, such as allergic conjunctivitis, hordeola and blepharitis, our initial collective experience is tempered by the reality that telemedicine is more adjunctive than substitutive. Accordingly, in May 2020, 90% of optometrists indicated plans to integrate telemedicine into their practice on a regular basis, but by July 2020, that number had dropped to about 60%.<sup>2</sup>

Dr. Thimons's was one of the many practices that offered telemedicine during the shutdown. He says patients accepted and readily adapted to this avenue, which could introduce a shift in the field and impact the direction optometry moves in. For nearly two months, he handled up to 20 telemedicine consults per day. As practitioners returned to their offices and patients began leaving their homes, however, he went from all of his appointments being remote to only 10% to 15%.

Dr. Thimons says that while telemedicine has a place within optometry, its ongoing role will depend on several factors. "The big issue in its success is whether the reimbursement of virtual care will continue to

compare with office revenues from direct patient encounters."

This is not the only implication with telemedicine. It could inadvertently open the door for direct-to-consumer remote online refraction technologies, some of which skirt the best interests of patients just to sell product. Telemedicine could also silo patient health information between different information systems, potentially creating a data entry burden, especially if these systems do not talk to one another.

### Private Equity Acquisitions

Recent years have seen a flurry of interest in eye care practice acquisition from the investment community. Ophthalmology practices, and their enviable cash flows, were the first target; then, investors saw the value of optometry as the gatekeepers of eye care. But, as it has with so much else, the pandemic tamped down private equity activity.

David Sheffer, chief growth officer at MyEyeDr., reports that in April and May 2020, the company's network largely shut down and refocused on establishing safety protocols, obtaining personal protective equipment and redoing scheduling templates. The company re-opened

in waves of about 100 practices and is now fully operational.

"Our acquisitions were paused from March onward," Mr. Sheffer says. Acquisitions were also paused, even for those with letters of intent, "but we are still honoring the purchase prices with demonstrated business recovery." The company planned to start closing acquisitions at the end of the summer and intends to acquire more than 100 practices before the end of 2020.

Mr. Sheffer names two key implications for consolidation due to COVID-19. "First, there will be a significant flight by buyers to quality practices. MyEyeDr. was always picky with the type of practice, quality of doctor and financials, but now we are even pickier. Second, our practices need to get creative because we cannot see as many patients per day. To increase capacity, options can include adding evening or weekend availability." He adds that this period of uncertainty demonstrates that none of us are in complete control, which may give some doctors more reason to sell to reduce their business risk.

James Wachter, OD, chief professional officer and co-chairman of Eyecare Partners, says the company is still moving forward with acquisitions and offering valuations similar to the company's pre-COVID-19 offers. He notes that, in some cases, letters of intent may provide the company some protection for practices that do not fully recover.

"COVID-19 may not go away any time soon, so there may be some retraction of aggressive acquisitions across the board," Dr. Wachter says. "The deal structures and evaluations may change, but the consolidation players will be here for the long-term."

Claude Labeuw, chief growth officer of Keplr Vision Services,



**Fig. 5.** Extra hygiene measures are taken to prevent the spread of illness.



says that the company has regained operational footing and resumed acquisitions with valuations based on pre-COVID-19 numbers for practices able to return to their historical level of business. “More than ever, we are focusing on acquiring quality, well-run practices that have recovered quickly from closure,” he says. “We seek practices with the right culture, mindset and infrastructure.”

### A Brighter Road Ahead

This new era has raised more questions than it has answered. Still, there are a few things we can all be doing.

“In moving from emergency to recovery, success depends on how we reframe business,” Mr. Seshadri says. “Post-COVID-19 does not need to

be worse, but it can be different.”

COVID-19 highlighted the vulnerability of the optical element of the profession, according to Dr. Thimons. “During the shutdown, the interface to patients was driven by online medical care and embraced by clinicians throughout the country. As a profession, I believe that the natural evolution of optometry is to become the ‘internal medicine’ of eye care, interfacing with the larger medical community in a more substantive way.”

Charissa Lee, OD, head of North America professional affairs at Johnson & Johnson Vision Care, says, “COVID-19 has forced all of us to evaluate our priorities and compelled us to look at different ways of operating. The silver lin-

ing may be that it has propelled us to form new ideas and search for unique solutions that will continue to best serve our patients and the optometric industry.”

From the hardship of COVID-19 comes new opportunities. Even if vaccines with durable immunity are forthcoming, the reality is that this virus may be with us for decades to come. Plan accordingly, keeping these new opportunities in mind. ■

*Dr. Chou practices in San Diego at ReVision Optometry, a referral-based keratoconus and scleral lens clinic.*

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# Eye Care at the Speed of Light

Telehealth and AI rely on digital tools when human interaction is hard to come by. Here's how these trends have been accelerated by the shutdown and other catalysts.

By Khadija Shahid, OD, and Mark E. Wilkinson, OD

**T**echnology has brought a steady stream of improvements to optometry in recent years, mostly in the form of improved diagnostic devices, but the bedrock principles of clinical care haven't really changed. We still examine patients directly and make our assessments by synthesizing all relevant data in a mental calculus that draws upon our expertise, intellect and instincts. Two emerging tech trends—artificial intelligence (AI) and telehealth—hold the potential to revolutionize that. In fact, one already has.

The social distancing policies put in place this spring amid the COVID-19 pandemic included recommendations by the Centers for Disease Control and Prevention (CDC) to temporarily suspend all medical services other than urgent or emergent care.<sup>1</sup> Suddenly, optometrists and their patients were isolated from each other. Telehealth solutions



**Social distancing policies have affected safety protocols, motivating some doctors and patients to turn to telehealth.**

quickly emerged—in a sporadic, improvised way—to bridge the gap.

The CDC's nationwide recommendation to postpone routine eye care is no longer in effect, but our continued need to maintain social distancing has introduced a challenge to the existing model of eye care. How can we protect our patients, our staff and ourselves as providers and still provide a high level of care without risking the spread of infection? Advances in telemedicine and telehealth, including the use of AI,

may offer solutions.

This article reviews how some optometrists have used telehealth to evaluate patients as well as the options available to practitioners to provide remote ocular and visual health assessment, and how AI-enabled devices can shoulder some of the work of eye health assessment when doctors are inaccessible.

## Virtual Visits

Aspects of optometry can pair well with telemedicine. We have become increasingly reliant on imaging technology, such as optical coherence tomography (OCT) and advanced retinal imaging, to provide diagnostic capabilities above and beyond conventional slit lamp and binocular indirect ophthalmoscopy exam. Current telehealth imaging is significantly below the quality of our in-office professional tools, but it affords us an opportunity to observe the patient's ocular anatomy in a

limited way. Though it can't replace the in-person doctor-patient relationship, telehealth is helping primary and specialty care providers find new ways to offer optometric services at home and expand the reach of care for those who may not currently be using ophthalmic services.

Current CDC recommendations advocate the use of telemedicine in place of live clinic visits, and it appears this recommendation has been well-received. Before COVID-19, less than 25% of patients were aware of telemedicine as a form of healthcare available to them. Since the pandemic, leading telehealth platforms report increases of 257% to 700% in virtual patient visits.<sup>2</sup> Many have participated in virtual visits through video conferencing platforms during the stay-at-home quarantine period, allowing patients to access their practitioner from home, either to address new concerns or continue follow-up care. While a good number of individual practices are using platforms that are HIPAA compliant, such as [doxy.me](#) and Eyecare Live, the requirement to store communication and ensure HIPAA compliance for all patient communications is not being enforced currently, allowing doctors to even use FaceTime or Zoom to contact patients.

Larger entities in eye care have been able to bring their institutional muscle to the problem. The New England College of Optometry partnered with EyeCare Live to establish a telehealth program that allowed NECO docs to conduct urgent evaluations, vision therapy, low vision rehabilitation and other essential consultations.<sup>3</sup> The MyEyeDr network of practices is also working on a telehealth pilot with

EyeCare Live to integrate telehealth options for patients as a routine part of its services.<sup>4</sup> And the Veterans Affairs Administration leaned into its long-established Technology-based Eye Care Service program even more this year to perform remote screenings and exams.

The current upswing in telehealth use was borne of necessity during the pandemic but some aspects may remain even after clinical care return to more conventional modes. Telehealth expands the reach of our practices and connects us with patients who cannot physically make it to the office. The added convenience allows these patients to get eye care when they need it and enhances compliance.

For example, removing barriers of scheduling time off from work, finding transportation and/or commuting to the doctor's office and time spent in crowded waiting rooms, will encourage more people to support and manage their ocular health.<sup>5</sup> Many practitioners have found that their telehealth visits were faster compared with in-office visits and believe, as patients become more familiar with telehealth, efficiency will continue to improve.<sup>5</sup>

### Remote Eye Exams

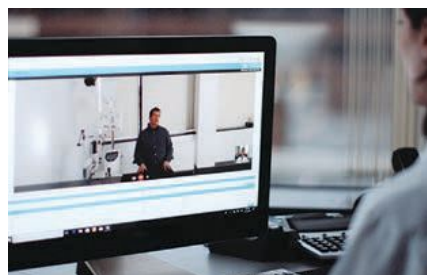
A number of companies have developed or are developing diagnostic testing systems using virtual reality headsets and smart device applications for ophthalmic assessments

that include visual acuity testing, refraction determination and central visual field testing.

DigitalOptometrics has developed optical software for comprehensive eye exams via telemedicine that allows the optometrist at a remote location to evaluate patients at another location via live video conference.<sup>6</sup> The OD can remotely operate exam equipment to perform subjective refractive findings among other tests. A comprehensive exam is reported to take less than 30 minutes on average. During the pandemic, large national retail optical providers and independent practices requested installations of the remote eye exam system at their closed locations during government-required closures.<sup>7</sup>

The ESG 1200 Eye Screening Globe by GlobeChek is a kiosk equipped with diagnostic instruments capable of distance and near visual acuity, wavefront autorefraction, intraocular pressure corrected for corneal thickness, high-resolution external photography, corneal topography, anterior segment OCT, cataract grading, fundus photography and macular and optic nerve OCT. The entire no-touch/no-dilation scan is reported to take about eight minutes.<sup>8</sup>

GlobeChek is selling and leasing its unit to customers who intend to put them in hospitals, retail chain stores, even malls, airports and other public locations where they will be operated by on-site technicians.<sup>9</sup>



**During the stay-at-home order, some optometrists have used remote refraction software from DigitalOptometrics and used Eyecare Live to video conference with patients.**





**As offices continue to open in limited capacities, many optometrists wonder whether they will continue to rely on telehealth in their day-to-day. The optometric mainstay refraction remains difficult to replicate online, though advances continue.**

Currently, the GlobeChek devices are only located in eye care providers' offices, but the company is also working on a mobile solution that uses a trailer as an office so that patients won't need to enter a doctor's building.<sup>7</sup>

A similar refraction device that connects to a smart phone is the EyeQue VisionCheck.<sup>10,11</sup> A few of the concerns with this type of at-home testing involve the accuracy of results, the lack of clinical validation, and the inability to provide an assessment of the ocular health of the eye. In April, in response to COVID-19, EyeQue offered its Personal Vision Tracker vision test free to US residents and waived annual membership fees for refraction testing in an effort to help those suddenly unable to see their optometrist check their vision.<sup>7</sup>

And an optometry-led service called Telasight launched in May at the height of the shutdown. The main intent of the service is to ease more optometrists into medical eye care by providing a safety net of experts to reach out to, but the same capabilities can be applied in the telehealth sphere as well. The company says it gives optometrists the ability to conduct a professional consult with another doctor remotely and securely, including the

sharing of clinical data and images such as visual fields and OCTs.

### Quality Control

While many optometrists vocalize approval and support for telehealth, there are also detractors who are equally doubtful the impact of telehealth will hold past the pandemic. Though patients with emergency red eyes, dry eye, contact lens follow-ups and other anterior segment conditions seem amenable to such methods, those with corneal foreign bodies, retinal detachment, angle closure and infectious keratitis, for example, are among the many conditions that require in-office consultation and expertise.<sup>12</sup> Techniques such as viewing the fundus, or anterior segment ocular structures with staining, also requires additional equipment and skilled, in-person evaluation.

As offices continue to open in limited capacities, some optometrists doubt that they'll continue to rely on telehealth in their day-to-day. They resolve to prioritize in-person visits with patients that will increase slowly but surely and anticipate the time-consuming schedule.<sup>5</sup>

On the other hand, many optometrists suggest that using virtual follow-up and visits could assist with the overwhelming number

of patients that desire eye care.

One practice noted that telehealth allowed them to resolve space issues to have multiple doctors working at the same time, as some practitioners field telehealth appointments from their home while their colleagues physically see patients in office.<sup>5</sup> Any patient encounters that can be done remotely opens a slot for in-person care that can't be handled efficiently otherwise.<sup>12</sup> Some ODs envision a hybrid model moving forward, where they can conduct in-person testing and then call to discuss the results and any care and management moving forward.

Telehealth is here to stay, but its value in the core strength of optometry—refractive assessment—has some ways to go. Many optometrists formed their opinions of remote refraction a few years ago when the now-defunct Opternative service put vision screening in the hands of patients. The confluence of low quality refractive data and an existential threat to the refractive component of practices made remote refraction a non-starter for most ODs. But its proponents will continue to iterate on such services and will look to integrate them with optical shops. Optometry's disinterest won't deter advancement—ignore it at your own peril.

Ultimately, it is up to each optometrist to determine which elements from the expansive field of telemedicine will augment their traditional practices to help provide and expand quality patient care, especially for those with unique situations.

### AI Gets Smarter...

The incorporation of artificial or augmented intelligence has further enhanced telemedicine capabilities, even outgrowing the provider altogether. More recently, autonomous AI systems can be trained to make clinical decisions without human oversight. AI software is developed using vast amounts of data to teach systems to diagnose conditions. In ophthalmology, autonomous AI has been studied in fundus photography, OCT and visual fields for automated detection of age-related macular degeneration (AMD), and diabetic retinopathy among other ophthalmic diseases.

**AMD.** One such system, DeepMind, developed by Google and the Moorfields Eye Hospital in London, demonstrated the ability to detect and classify OCT pathologies including choroidal neovascularization, macular edema, drusen, geographic atrophy, epiretinal membrane, vitreomacular traction, full- and partial-thickness macular holes, and central serous chorioretinopathy.<sup>13</sup>

In a recent study of patients diagnosed with wet AMD in one eye, the DeepMind system was able to predict progression to the second eye within a clinically actionable, six-month time window.<sup>14</sup> By combining models based on three-dimensional OCT images and corresponding automatic tissue maps, the system predicted conversion and achieved a per-volumetric-scan sensitivity of

80% at 55% specificity, and 34% sensitivity at 90% specificity.<sup>14</sup>

**Diabetic retinopathy.** Screening for DR has proven to be a simple and cost-effective way to detect disease that adapts easily to telemedicine and AI, either as a first pass to reduce burden on human expert graders or as a replacement for human expert graders for even more cost-effective means.

In April 2018, the FDA approved the first autonomous software (IDx-DR) for point-of-care diagnosis of DR without physician or human interpretation. IDx has since become part of the American Diabetes Association standard of diabetes care recommendations.<sup>15,16</sup>

A recent study found the IDx-DR was a reliable screening tool when used to diagnose diabetic retinopathy in the primary care office that could reduce barriers to screening and improve gaps in diabetes treatment.<sup>16</sup> The sensitivity of detecting “more than mild” DR was 87% and specificity was 91%.<sup>17,18</sup> The camera used in the system was easy to learn, and staff were taught to reliably obtain images without direct physician supervision. Examination with the IDx-DR system was not invasive and did not require dilation.<sup>17</sup>

A second device, EyeArt (Eyenuk), has recently been cleared by the FDA to automatically detect

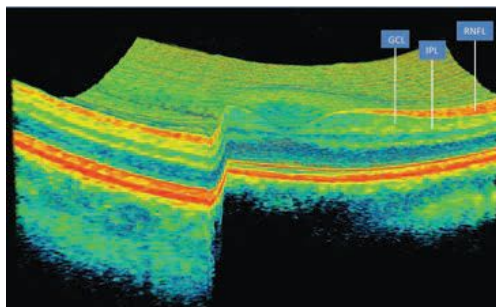
“more than mild” DR and vision-threatening DR in eyes of adults diagnosed with diabetes.<sup>19</sup> Similar to the IDx, novice operators can be trained to obtain medical grade retinal images. EyeArt provided disease detection results for 97% of eyes, and a vast majority of participant eyes (90%) received disease detection results without needing dilation.<sup>19</sup>

“Eyenuk is on a mission to screen every eye in the world to ensure timely diagnosis of life- and vision-threatening diseases,” said its founder and CEO, Kaushal Solanki, PhD, in a press release announcing its partnership with Devlyn Optical, a chain that operates in the US and Mexico, to put devices in their stores.<sup>20</sup>

### ...But More Troublesome

While these diagnostic telemedicine and AI systems hold great promise, they are not without challenge and concern. Most development has been occurring in private industry, so there is limited research, scrutiny and transparency that would be needed for incorporation into the medical industry. Rigorous validation is needed to ensure safety and limit any unexpected problems during real world implementation.<sup>15</sup>

There are also ethical and legal concerns. Autonomous AI is a very new concept, there are no generated rules to follow for ethical human-computer interaction. Liability is a concern, as, legally, the creators of the autonomous AI assumes liability for harm caused by the diagnostic output of the device, but who owns the patient data generated and who defines appropriate use of patient data? Most state medical boards do not consider an autonomous AI output to have the same medicolegal status as physician.



**The DeepMind system can convert a raw OCT scan into a 3D-tissue map to aid treatment decisions.**



**In practices using the IDX-DR system, staff were taught to reliably obtain images without direct physician supervision.**

And finally, the successful clinical implementation of AI requires provider trust that the system improves patient outcomes, works equally well on the vast majority of patients and doesn't threaten physicians. The IDX-DR system has been met with professional concern, where some ophthalmologists disagree, resent or even fear autonomous AI for the diabetic eye exam for disease.<sup>21</sup>

In an effort to protect the many forms of AI in healthcare, the American Medical Association adopted the term "augmented intelligence" to portray AI as broad, with autonomous AI as just one subtype. Many other forms of AI exist that rely on human physician interpretation.<sup>22</sup>

Advanced technology like AI can help improve access to care with increased accuracy and decreased cost. Deployed in retail or health settings outside the eye care's office, it can identify more patients that need our expertise in-office. Though AI can be trained to be consistently detail-oriented and resistant to fatigue, it will not replace the eye care provider. Our human ability to use higher levels of metacognition and intuition allows us to recognize

and manage out of the box abnormalities, something that is yet transferable to an algorithm.

Whether or not there's another shutdown that forces change in our practice, optometrists should be prepared for the future of expanded eye care. Many have now seen the value and the opportunity of technology to care for patients remotely. We need not worry that we are going to be replaced by telehealth or AI—clinical decision-making has always been and will continue to be required for optimal patient care. Advances in both of these spheres will increase accessibility to healthcare, increase awareness of ocular disease and identify more patients whose outcomes can be improved by the unique skill set that optometrists can provide. ■

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# Will Subspecialization Help Optometry Evolve?

After years of discussion, it just may happen. Some think it's long overdue—others say it's unnecessary. Here's a preview. **By Cheryl G. Murphy, Contributing Editor**

**T**he story of optometry is that of a profession constantly evolving to meet the needs of the day. The refracting opticians who founded optometry more than a century ago would scarcely recognize it now—or, rather, would likely mistake it for ophthalmology. Though refractive services are still integral to optometry, medical eye care has occupied an ever-increasing share of our training and day-to-day practice.

But one notable difference between our profession and that of our MD colleagues is the approach to subspecialization. Ophthalmology has long recognized that many segments of the population need doctors to build expertise in a subset of the wider field of care by relinquishing other responsibilities. Surgical procedures essentially demand it. The ophthalmologists who perform trabeculectomies shouldn't also do ILM peels, and vice-versa.



**Clinicians with an expertise in binocular vision disorders may soon have a path for validation as subspecialists.**

Optometry has a far less concrete approach to subspecialty practice. Anyone can call themselves a specialist of one kind or another—doing so is common among contact lens pros, for instance—but our institutions mostly leave validation of such claims to the honor system

or a “proof is in the pudding” *post hoc* assessment of the outcome by patients. But that may be changing in the near future.

## Reaching Higher

Generalists in optometry will always play a vital role, screening patients for a multitude of diseases—both ocular and systemic—and triaging their care while also serving the day-to-day refractive needs of the community. But for optometry to thrive, many practitioners must adapt to the many changes taking place in the field of medicine. Some say that one way ODs can reach higher is through a residency or by becoming an American Academy of Optometry (AAO) diplomate. However, these two programs traditionally do not have a mutually agreed upon, uniform set of standards. Some leaders in optometry have been looking to change that and are working to establish a shared, universal under-

standing of subspecialties in the field of optometry.

The profession itself is already considered a primary care specialty in the broader healthcare system, so when we refer to different areas of interest or expertise within optometry, we should use the term “subspecialty,” according to David Heath, OD, president of SUNY College of Optometry. Dr. Heath has served as president of the Association of Schools and Colleges of Optometry (ASCO) twice. He’s also the co-chair of the Task Force on Subspecialization (TFSS), an initiative set up by ASCO and the AAO.

The TFSS was officially formed in 2018, although the AAO and ASCO joined forces with others to start its preliminary development in 2014 and 2015. At its outset in 2018, the TFSS set three goals:

1. Establish a set of guidelines that define parameters for determining what is a subspecialty and a process by which the two organizations could formally recognize subspecialties in optometry.
2. Facilitate the development and use of a designation called Advanced Competencies, which define the required knowledge and skills that represent a given subspecialty and what an optometrist should possess to be validated in that subspecialty.
3. Establish more uniform nomenclature between what the ASCO uses as titles within residencies and what the AAO uses for credentialing diplomates in certain areas of fellowship.

According to Dr. Heath, while the TFSS has made progress toward those three goals, only the redesign of residency title guidelines has been fully realized, where increased

development and use of Advanced Competencies is ongoing. He touts the significance of this milestone, noting that it will allow optometrists to know when an area actually qualifies for recognition as a subspecialty.

An interim report published by the TFSS in April 2020 states, “Through these three goals, ASCO and the AAO hope to establish the foundation and the conditions within which optometric subspecialties may evolve and be [accepted] in a considered and intentional manner against a recognized set of criteria and quality standards.” The TFSS is working on its final report.

### Why Make It Official?

The move toward subspecialization in optometry is nothing new, Dr. Heath says, noting that exploration of the need “has arisen on a regular basis since the late 1960s.”

While high-level thinking on the prospect of subspecialization has flourished—in the form of committees, commissions, publications, presentations and recommendations—not much has trickled down to the level of clinical practice just yet. “In spite of past initiatives to proactively manage the development of post-graduate specialization within the profession, these efforts have failed,” says Dr. Heath.

Instead, what has transpired is the creation of special interest groups, sections and committees among various institutions. However, Dr. Heath points out that “the nomenclature for areas of interest



Photo: Alexis Malkin, OD

**Experts speculate that low vision will be the first subspecialty formally recognized in optometry.**

used by these groups is varied, and few have clearly defined criteria.”

The defining of specialties and the evolution of subspecialties seems to occur in nearly all areas of medicine. While the American Board of Medical Subspecialties (ABMS) recognizes general ophthalmology as a specialty in medicine, it does not recognize any subspecialties in ophthalmology. However, subspecialties in ophthalmology are recognized by the Association of University Professors in Ophthalmology, and they have a well-developed program with requirements linked to fellowship education, laying the groundwork for perhaps someday making subspecialties in ophthalmology accepted by the ABMS as well.

The TFSS April 2020 report states, “The example of ophthalmology’s subspecialties is effectively a credential-based system that stands in contrast to the board certification-based process of ABMS. It is possible that at some point in time, those subspecialties could move toward developing the appropriate structure and [board certification] process to apply for ABMS recognition.”





Photos: Jackie Burruss, OD



**The dearth of MDs may push ODs to pursue subspecialty training in some lid and laser procedures, according to Dr. Damari.**

However, the question on many optometrists' minds once they hear about the push for subspecialty recognition and validation in optometry remains, "Do we really need this?"

Kristin Protosow, OD, part-owner of Eye Vision Associates, a multispecialty practice in Nesconset, NY, and past president of her county's optometric society for five years, says she's not sure. Her practice employs optometrists who focus on low vision, specialty contact lens fitting, myopia control and dry eye, as well as serving those who need primary care and ocular disease management. All five of the doctors who work there have completed residencies and are AAO

fellows. When she asked them if they would consider going for subspecialty validation, should it someday be an option, she said her colleagues were torn.

"I think that we would do it if we had to, but not advocate for it," says Dr. Protosow. "We feel like it would go unnoticed by patients, and we are already known for our specialties, so I'm not sure what the point would be."

The motivation could be stronger for new doctors pursuing residency. "It might be easy because it will already set up for them to be validated with a subspecialty upon completion of their residency," Dr. Protosow suggests.

Dr. Protosow is right in that the

stage is being set to make it easy for residents to also become validated in certain subspecialties in the future, now that the TFSS has succeeded in achieving one of its goals: increasing the use of common nomenclature and the development of commonly understood advanced competencies.

Would it be beneficial for optometrists who are already well established in their career and their area of specialty, like Joseph Shovlin, OD, to go for subspecialty validation? Anyone can see that he has the credentials of an expert in the area of cornea and specialty contact lenses—he's an AAO diplomate in the Cornea, Contact Lenses and Refractive Technologies Section. He also chaired the American Optometric Association's (AOA) Cornea and Contact Lens Section, was a consultant and voting member of the FDA's Ophthalmic Devices panel and has lectured on related topics for more than 30 years. He was even there when soft contact lenses first started being produced in the United States. "I had the pleasure of working very early in

### Academy Sections and SIGs Help ODs Delve Deep

Future optometry students will have the option to pursue formalized subspecialties as part of their educational curricula. But less formal ways to develop a niche area of expertise are already available to existing practitioners, most notably through the Sections and Special Interest Groups (SIGs) within the American Academy of Optometry (AAO).

The Academy has eight Sections that each act as a vehicle for optometrists with interest in subspecialty areas to meet around particular topics, according to the AAO:

- anterior segment
- binocular vision, perception and pediatric optometry
- comprehensive eye care
- cornea, contact lenses and refractive technologies
- glaucoma
- low vision
- optometric education
- public health and environmental vision

SIGs, by contrast, are for members who have a special interest in areas that are too narrow to warrant a complete diplomate program. These groups provide a forum for clinicians interested in academic medical centers, research, neuro-ophthalmic disorders, nutrition, disease prevention, wellness, retina, vision in aging and vision science.

Sections and SIGs produce symposia for the Academy's annual meeting and serve as the Academy's resource in these particular topics. "The American Academy of Optometry's Sections and SIGs give our members a home within the Academy where they can connect, share knowledge and collaborate on a particular topic that interests them," says President Barbara Caffery, OD, PhD.

Members make use of these tailored resources and networking opportunities with like-minded ODs to advance their skills and capabilities. In so doing, they start on the path to a subspecialization, or at least concentration, in the areas of care they're most passionate about.

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my career with Bob Morrison in Harrisburg, PA. He held the patents along with his attorneys for the first soft lens from the Czech Academy of Science under Otto Wichterle,” Dr. Shovlin notes.

Dr. Shovlin says he definitely would go for subspecialty validation himself when it becomes available, but his advice to others is simple. “Regardless of attaining specialization status someday or not, it goes without saying that doing the very best you can do for each and every patient is paramount to success.” He defines success as “personal satisfaction in what we do daily in helping others and being rewarded fairly” for it.

He also adds, “Keep in mind, nothing really beats ‘word of mouth’ recommendations from satisfied patients.”

Although only some optometrists may see the advantages of optometry obtaining subspecialty validation, Dr. Heath says there are not only advantages for the individual OD but also for the public as well. Dr. Heath reasons that subspecialization will help encourage more intra-optometry referrals. It may be one way for other ODs to identify true experts in certain areas and allow us to place patients who have needs we think we cannot handle into the trusted hands of another optometrist, he says.

Also, Dr. Heath says, it would help the public better understand who could best address their specific problems. Optometrists with subspecialty training will have demonstrated competency, and those skills will be more consistent between those who consider themselves subspecialists. He says that when one OD does a residency in one program, they may not have had the same experiences or exposures as another OD doing the same type of residency in a different program, so we cannot be sure their knowledge base and level of expertise is equivalent.

The development of common Advanced Competencies for subspecialties will be one step toward ensuring that each subspecialist has been subjected to a similar post-graduate experience and has demonstrated a mastery of common knowledge and skills.

David A. Damari, OD, is the dean of Michigan College of Optometry and, like Dr. Heath, is all for subspecialization in optometry. Dr. Damari is not only a member on the TFSS but also past president of the College of Optometrists in Vision Development, an organization that administers an extensive credentialing process to certify advanced competence in the care of binocular vision, accommodative, eye movement and visual perceptual disorders.

Dr. Damari agrees with Dr. Heath that subspecialization may lead to more OD-to-OD referrals. “Our profession needs to better serve patients who have non-surgical vision and ocular health needs that go beyond the scope of what we can teach in a four-year program.” In fact, as access to some eye surgeries becomes constrained by overwhelming pressure on ophthalmologists’ schedules, “I

### The AOA on Securing Optometry’s Future

Although not part of the subspecialization task force spearheaded by the AAO and ASCO, the AOA also advocates for the evolution of the profession, particularly in scope of practice expansion. When asked about the current state of optometry and its future, AOA President William T. Reynolds, OD, provided the following summary of the AOA’s position and priorities:

*“Just as technology has progressed, health care has been rapidly evolving during the past several decades. Knowing that optometry needs to adapt and anticipate the future, the AOA, along with the dedicated Board of Trustees and volunteers, has focused on key long-term strategies to help pave the way for the future and position doctors of optometry as frontline providers of essential care. To accomplish this, we’ve made ensuring full recognition of our physician role and advancing our scope of practice immediate priorities.*

*As a profession, optometry delivers 85% of the primary eye health care in America, with doctors of optometry practicing in counties that make up 99% of the US population. And when routine care was halted during the pandemic, about 80% of doctors of optometry, surveyed by AOA’s Health Policy Institute, indicated they provided urgent/emergent care, reducing the burden on hospital emergency departments. And 25% of the medical care AOA members delivered during COVID was surgical.*

*Building on this accessibility, a report by Avalon Health Economics detailed that Americans would save at least \$4.6 billion annually if states modernized their optometric scope of practice acts to a level commensurate with optometry’s advanced education and training. That level of accessibility and economic savings is why the AOA and state affiliates contend that optometry is well-positioned, highly educated and qualified to provide the breadth of expanded eye health and vision care services that doctors have delivered for years in progressive states, including Louisiana, Oklahoma, Kentucky and Alaska. However, restrictive state laws based on outdated and tired misrepresentations of optometry’s education and capabilities have created barriers to maintain a status quo.*

*AOA and affiliates are working tirelessly across the country to modernize state scope of practice statutes to allow doctors of optometry to practice to the top of their license and utilize their full skillset, including fully recognizing new and advanced procedures that reflect contemporary optometry practice.”*



could easily see some optometrists earning subspecialty certification in some lid or laser procedures.”

He recounts an anecdote about Anthony Adams, OD, PhD, former dean of UC Berkeley School of Optometry. “Dr. Adams once said to me that our profession wasn’t truly mature until we began referring to each other for these types of specialty services,” says Dr. Damari. “I firmly believe that one of the reasons many optometrists do not recognize the benefits of vision therapy for strabismus, or even non-strabismic disorders, is that they are not confident that if they refer that patient to another OD, the patient will be receiving truly effective, advanced care. A certification process would help provide that assurance.”

Subspecialization will help to get the public the best care possible, says Dr. Damari. When patients have conditions such as strabismus and other binocular vision disorders, “it truly has a significant impact on their quality of life, and can even change the course of their career or academic progress. For them not to receive services to manage those disorders has a negative impact on their future earning ability, on the economy and their employer.”

If referred by their primary optometrist, says Dr. Damari, “that OD would look like a hero for detecting the condition and recognizing that it needed to be treated. And the patient would know that their primary OD was referring them to a subspecialist in that one specific area who knows how to get the best outcome for the patient, and then the patient can return to the primary optometrist for their other vision care needs.” Additionally, “as technology develops and our entire US economy moves even



Photo: Marc B. Taulb, OD, MS, and Paul Harris, OD

**Vision therapy is another subspecialty that could benefit significantly from a formalized certification process. Optometrists could refer patients with more confidence, Dr. Damari speculates.**

farther away from working with the hands to working with our vision, we need, more than ever, to service people’s complex visual conditions and needs, such as myopia, visual efficiency disorders and visual spatial perception disorders. We are the only profession that is well-trained to provide these services.”

### The Road Ahead

Dr. Heath says that for optometrists entering the residency program beginning July 2021, “new residency title guidelines will be used, and these do anticipate the development of subspecialties in optometry.” He does say, however, that it will take a number of years for more formal development of subspecialties to happen, and he predicts low vision will be the first official subspecialty to be formally recognized, given its set of well-developed Advanced Competencies.

The contentious question, as always, surrounds the issue of validation. Who sets the criteria and performs the assessments? There are many stakeholders in optometry who could lay claim to that role.

Some optometrists will also likely worry that the entire enterprise could come off as Board Certification 2.0—another bitter internecine fight. Proponents of subspecialization will need to roll out the discourse in a way that encourages participation without alienating those who choose to refrain.

Even though the Task Force hasn’t fully accomplished all three of its goals, it hopes the work already done provides the foundation for and momentum toward a more formal structure that will facilitate the emergence of subspecialties in optometry. Ultimately, it would like other associations and organizations within optometry to get involved and unite toward the same goal of defining subspecialties and developing validation. Dr. Heath says he would like to see a national summit on optometric subspecialties take place, but notes such a summit is unlikely until after the COVID-19 pandemic recedes. ■

*Dr. Murphy practices at Sachem Eye Care in Lake Ronkonkoma, NY, where she provides comprehensive eye exams and contact lens fittings of all types.*



# Genetics in Eye Care: DNA Leads the Way

Knowledge of disease processes is flourishing, but questions remain regarding clinical application. **By Catlin Nalley, Contributing Writer**

**M**ost optometrists approach patient care from a clinical perspective, and rightly so. Direct examination of the eye is straightforward, painless and fruitful. However, breakthroughs in genetics and molecular biology have opened new avenues that begin at the most elemental level: our own DNA. The work of connecting these intrinsic factors to the reality of the patient in the chair is fraught with challenges—scientific, logistical, financial—but holds enormous potential, too. In fact, the first FDA-approved gene therapy was for a retinal degenerative disease. This has sparked significant interest in the role gene therapy plays in eye care, and where it's headed in the future.

The nascent field of clinical genetics “will offer optometrists more avenues for diagnosis and treat-



Photo: NEI

**The right eye of a 72-year-old white woman who has intermediate AMD with evidence of large drusen, drusenoid pigment epithelial detachment and hyperpigmentary changes. Based on the patient's fundus photographs, we know the risk of developing late AMD, either neovascular and geographic atrophy, is as high as 50% in five years.**

ment,” speculates Albert Morier, OD, MA, an associate clinical professor of ophthalmology at Albany Medical College. “As our

understanding of ocular conditions and their molecular biology grows, we will be able to treat people more effectively. It will help us identify at-risk patients and determine the monitoring and treatment they need based on their genetic pattern.”

While such enthusiasm is warranted, optometrists must also consider the practical questions and ethical implications raised by these genetic discoveries. Some advance our understanding but are years away from clinical value or raise the spectre of patients living in fear of an “inevitable” disease that may never manifest. But there are a few clear success stories that make the effort worthwhile.

What follows is a look at how genetics is informing, and in some cases advancing, the practice of eye care in four key spheres.

## Retina

Genetics are at play in a number of retinal diseases, with both glowing successes and ongoing controversies:

**Age-related macular degeneration (AMD).** This complex disease is associated with multiple environmental and genetic risk factors. As researchers identify more genetic variants linked to AMD, the interest in developing genetic testing continues to grow.

Researchers have already developed gene-based AMD risk prediction models that account for disease status, genetic risk and lifestyle factors.<sup>1</sup> In addition, two genetic tests for AMD risk assessment are now commercially available, ArcticDx and a recently launched option from Visible Genomics, a Chicago-based genetic testing company.<sup>2,3</sup>

However, the value of these genetic assessments remains controversial. Some argue that genetic tests overstate the risk of AMD and can lead to avoidable anxiety and unnecessary treatment.

The American Academy of Ophthalmology recommends clinicians avoid routine genetic testing for complex disorders such as AMD, at least until prospective clinical trials show specific benefits regarding surveillance or treatment.<sup>4</sup>

“While it can be beneficial to identify high-risk patients to ensure they are monitored appropriately, what are the medical ethics of telling someone at an early age that they have this gene?” explains Dr. Morier. “We have to consider these implications as well.”

The key is knowing how to use the information genetic testing provides, according to Emily Chew, MD, of the National Eye Institute/National Institutes of Health. “Without discernment, patients can be given a sentence that may not be appropriate,” Dr. Chew explains.

“For some patients, genetic findings can cause anxiety needlessly. For others, it may provide a false sense of security. It is really important that patients understand that it’s just a number. It’s a finding that can be difficult to interpret, and routine eye exams remain vital.”

In addition, the debate rages on about whether genotyping should be standard care for AMD patients taking antioxidants and zinc. Research suggests that zinc in the Age-Related Eye Disease Studies (AREDS) formula actually increases progression risk in some individuals with specific genetic variants in CFH and ARMS2/HTRA. Three statistical teams from separate academic centers examined the data from AREDS, as well as the findings that support genetic testing, and determined that the data does not currently support genotyping for AMD and additional research is required.<sup>5</sup> According to Dr. Morier, a community-based study shows that, among patients with neovascular AMD, those in the previously identified genetic zinc-risk group were three times more likely to have taken AREDS supplements than those in other genetic groups.<sup>6</sup>

“Genetic testing is important for research, but not for management at this point,” says Dr. Chew, who ran both the AREDS1 and AREDS2 studies. “I would love to be able to use genetic testing to personalize treatment, but we just don’t have the treatment or the genetic data to suggest that the patients respond differently because of genetic interactions.”

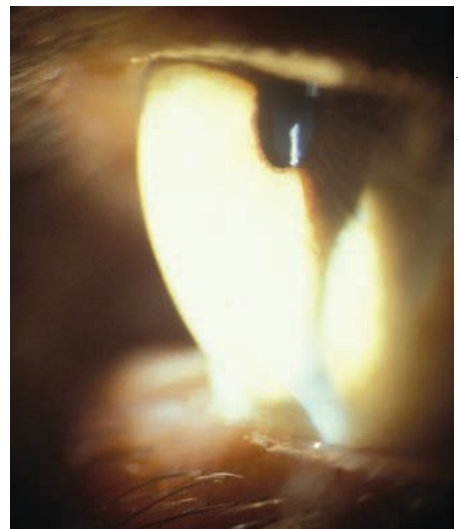
**Retinitis pigmentosa (RP).** Patients with this condition have very few therapeutic options due to, in part, the genetic complexities of the condition, which is linked to about 70 known genes and 3,000 genetic mutations.<sup>7</sup> Additionally,

other retinal degenerative diseases, including Leber’s congenital amaurosis, are genetically associated with RP. Gene therapy could offer new hope to this patient population.

One of the recent genetic breakthroughs in retinal diseases was the 2017 FDA approval of Luxturna (voretigene neparvovec, Spark Therapeutics), the first directly administered gene therapy approved in the United States. It is approved for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy.<sup>8</sup>

While an important step forward in genetics and eye care, voretigene is a limited therapy. It is only beneficial for the 1,000 to 2,000 patients in the United States with the recessive *RPE65* mutation.<sup>8</sup> Far more patients with other hereditary retinal degenerative diseases are still waiting for a viable gene therapy.

Additionally, this particular therapy calls attention to an ongoing challenge associated with personalized medicine: cost. At \$425,000 per eye, it comes with a hefty price tag.<sup>7</sup> Even though it’s a significant cost up-front, one study found voretigene neparvovec was cost effective



**Cornea steepening in a patient with keratoconus.**

Photo: Joseph Showlin, MD



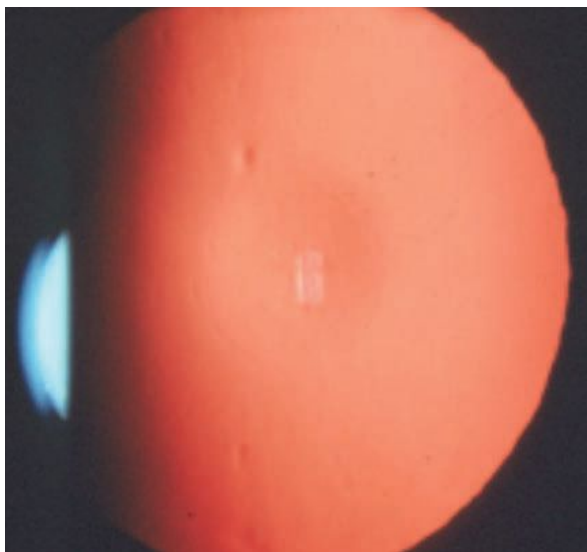


over a lifetime, associated with lower total costs (\$2.2 million vs. \$2.8 million) and higher quality-adjusted life-year (18.1 vs. 8.6) compared with standard of care.<sup>9</sup>

**Other conditions.** Choroideremia (CHM), an x-linked recessive chorioretinal dystrophy that affects approximately one in 50,000 to 100,000 individuals, currently has no approved treatment options. More than 100 variations in the *CHM* gene have been discovered, paving the way for potential gene therapies.<sup>10,11</sup> A number of studies exploring gene therapies in these patients are underway, including the first Phase III trial for the treatment of choroideremia.<sup>12</sup>

The development of gene therapies for Stargardt's disease, another rare retinal condition with a genetic inheritance pattern, has proven challenging because adeno-associated viruses (AAVs), the engineered pathogens used for gene therapies, are ineffective with the *ABCA4* gene. To overcome this, a gene therapy in development uses dual-vector AAV technology. Researchers are also exploring another delivery method that uses chemically modified lipids.<sup>13</sup> In animal models, they found that Stargardt's did not return for up to eight months after treatment.<sup>13</sup>

"If you suspect your patient may have one of these conditions, genetic testing can confirm your suspicions, but it is important you make it clear that there is no treatment available at this time," says Mohammad Rafieetary, OD, a consultative optometrist at a large retina practice in Germantown, TN. "In the future, however, having this genetic information could help them gain access to clinical trials and new therapies."



**Distorted retinoscopic reflex in a patient with keratoconus.**

### Cornea

Degenerations and dystrophies of the cornea require diligent screening, particularly to identify surgery contraindications such as keratoconus and transforming growth factor beta-induced (TGFB-I) dystrophies. Advancements in genetic screening can help clinicians recognize at-risk patients before they undergo refractive surgery, possibly saving patients from progression and exacerbation of their condition.

A growing understanding of the genetics behind keratoconus can help clinicians identify these patients before the condition becomes vision threatening. One study identified five genetic loci associated with corneal hysteresis and corneal resistance factor, which are linked to keratoconus.<sup>14</sup> Another trial showed that the heritability of posterior corneal curvature was slightly higher compared with anterior corneal curvature.<sup>15</sup> When examining corneal topographic measures, researchers reported that the index of surface variance, central keratoconus index and index of vertical asymmetry had the highest levels of heritability.

Photo: Joseph Shovlin, OD

Testing for some corneal conditions is now possible with the AvaGen (Avellino) that examines more than 1,000 variants across 75 genes for keratoconus and over 70 mutations of the *TGFBI* gene for corneal dystrophies.<sup>16</sup>

"Identifying genetic predisposition can help monitor or even avoid disease progression, and that is key," notes Joseph Shovlin, OD, of Scranton, PA. "For example, in keratoconus, you can make a diagnosis earlier and educate the patient as to what their options are, including crosslinking, which could—if

used early enough—slow the progression of the disease."

Unlike other conditions that don't have viable treatment options, Dr. Shovlin recommends genetic testing for corneal diseases.

**Fabry's disease.** There are a number of ocular manifestations of this condition, including cornea verticillata, distinctive lenticular opacities and vascular tortuosity of the conjunctiva and retina.<sup>17</sup> Although identifying this disease can be challenging because several systemic drugs can cause the same presentation, early detection is key to reduce morbidity and mortality. Gene therapy is currently under investigation for this patient population.

MARVEL1, the first trial of an AAV-based gene therapy for Fabry's disease, is currently studying the safety of FLT190. It is also looking at whether this treatment approach leads to continuous production of high alpha-GAL A levels.<sup>18</sup> Interim data from another study supports the potential firstline use of the gene therapy AVR-RD-01.

The first patient treated with this therapy continued to show

increased leukocyte and plasma AGA enzyme activity 22 months following treatment.<sup>19</sup> While the other three patients in the study have a shorter follow-up, they are showing increased enzyme activity as well.

**Other conditions.** Fuchs' corneal dystrophy, strongly associated with *TCF4*, is also of interest to geneticists.<sup>20</sup> Researchers performed a genome-wide association study (GWAS) on 1,404 Fuchs' cases and 2,564 controls.<sup>21</sup> This was followed by a replication and meta-analysis, for a total of 2,075 cases and 3,342 controls. They identified three novel loci meeting genome-wide significance. Additionally, the researchers reported an overwhelming effect of the established *TCF4* locus.

Researchers also linked the susceptibility and severity of microbial keratitis in contact lens wearers to genetic variants in different cytokine genes and *DEFB1*.<sup>22</sup> Genetic susceptibility testing could one day play a role in addressing this condition and help ODs take preventive measures.

By using genome sequencing, researchers discovered the root cause of posterior polymorphous corneal dystrophy (PPCD), a rare autosomal-dominant corneal dystrophy. The investigators uncovered the variation to the DNA, which is located on *GRHL2* gene, that causes dysfunction in the endothelial barrier and PPCD.<sup>23</sup> This lays the groundwork for future study and potential therapies.

## Glaucoma

This condition can be divided into two groups: early-onset forms—e.g., juvenile open-angle glaucoma (JOAG), congenital glaucoma, anterior segment development syndromes—and adult-onset types such as primary open-angle glaucoma (POAG), angle-closure glaucoma and exfoliative glaucoma.<sup>24</sup>

Early-onset glaucomas, while rare, can have large biological effects and often involve multiple generations. Mutations in *MYOC*, the first gene to be implicated in glaucoma, are linked to familial JOAG.<sup>24</sup> These patients often develop a severe form of glaucoma with a high intraocular pressure (IOP) that's difficult to manage with current therapies.<sup>25</sup> While intervention is key, many patients are asymptomatic and may not seek treatment until their disease has progressed. Therefore, identifying genes associated with JOAG and other early-onset glaucomas opens the door to genetic testing, which allows for early detection.

Adult-onset glaucoma can have a complex inheritance and is often associated with multiple genetic or environmental risk factors.<sup>24</sup> Unlike early-onset disease, researchers do not have the same access to multiple generations, which makes it more challenging to explore genetic variants in this patient population. As a result, GWAS has become an important avenue to discovery. In 2017, 16 genomic regions were associated with POAG at a genome-wide level of significance. With rapid breakthroughs, the total number of identified POAG loci has increased to 74.<sup>26</sup>

The NEIGHBORHOOD Consortium—supported by the National Eye Institute—was founded in 2012 to gain a better understanding of the genomic architecture of glaucoma. Since then, researchers have collected data on more than 5,000 POAG cases and have conducted a number of genetic analyses. A meta-

analysis of GWAS findings identified *FOXC1*, *ATXN2* and *TXNRD2* as susceptibility loci for POAG and potential therapeutic targets.<sup>27</sup>

Recent studies have proven the heritability of primary angle-closure glaucoma, and analyses confirm the presence of eight loci significantly associated with a risk of the disease.<sup>28</sup> Current literature suggests a significant portion of normal-tension glaucoma (NTG) patients have a family history of glaucoma.<sup>29</sup> There are a number of candidate genes for NTG, but further study is needed.<sup>29</sup>

Despite the growing body of literature, the immediate clinical implications remain unclear. Currently, genetic testing is only recommended when it will impact treatment or surveillance.<sup>30</sup> For glaucoma, this typically applies to early-onset disease, such as JOAG, where patients could derive significant benefit. The applicability of widespread testing for other forms of glaucoma has not yet been established.

“While significant progress has been made, we're still in the discovery phase,” notes Andrew Rixon,

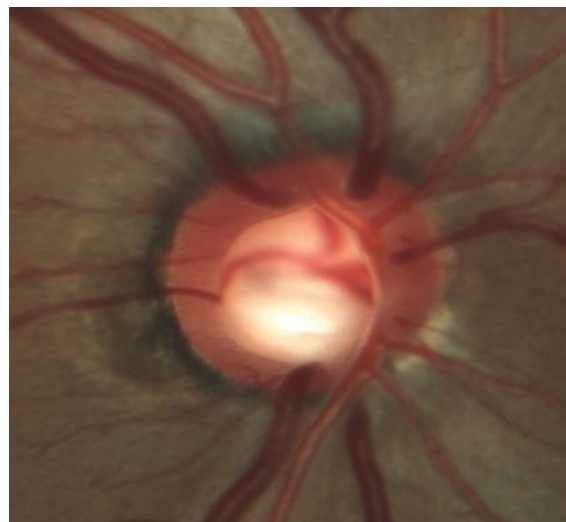


Photo: Andrew Rixon, OD

**Rim erosion and lamellar remodeling in a patient with POAG. The total number of identified POAG loci has increased to 74 in the past few years, enhancing our understanding of the genetic aspects of this condition.**



OD, an attending optometrist at the Memphis VA. “As we gain a better understanding of glaucoma and are able to predict these conditions earlier, we will be able to intervene sooner, offering patients a better quality of life with, hopefully, less disease burden and better outcomes.”

Until then, Dr. Rixon urges practicing clinicians to stay current on the latest research and discoveries. “As healthcare providers, we need to be aware of the research and its potential impact on our field and practice,” he says. “There’s enough information out there that our patients are going to come to us with questions and we have to be prepared to have those discussions.”

### Vision Disorders

The genetic study of vision disorders such as myopia and achromatopsia has become a priority for many researchers in recent years.

**Myopia.** Researchers have uncovered up to 50 loci and genes by early linkage and candidate gene studies; however, these findings remain largely unverified by replication studies.<sup>31</sup> A recent study of 3,300 children concluded that the *ZC3H11B* and *BICC1* genes are risk factors for moderate and high myopia, and five genes—*ZC3H11B*, *KCNQ5*, *SNTB1* and *GJD2*—increase a child’s risk of excessive axial length.<sup>32</sup>

The Consortium for Refractive Error and Myopia examined the

genes of more than 250,000 individuals and found 139 independent susceptibility loci by single variant analysis and 22 additional loci through post-GWAS.<sup>33</sup> While these findings provide a new understanding of myopia and its mechanisms, this analysis documents just 8% of the phenotypic variance, highlighting the need for additional exploration.<sup>31</sup>

“While hundreds of variants have been identified, it only explains a small percentage of the variability in refractive error,” notes Donald O. Mutti, OD, PhD, a professor at the Ohio State University College of Optometry. “Our understanding of the disease is growing, but these discoveries don’t describe as much of the trait as we would like. And so, today, the best way to predict myopia is to measure a child’s refractive error regularly.”

Even environmental factors associated with myopia, such as an individual’s level of education, are entangled with genetics. Myopia prevalence doubles among individuals who pursue higher education compared with those who do not, and research shows individuals with a high genetic load as well as university-level education had a significantly greater risk of myopia compared with those who only had one of these two factors.<sup>31,34</sup> A GWAS for educational attainment identified 74 genome-wide significant loci associated with number of years of schooling completed.<sup>35</sup>

“The big question is, how much of myopia is genetic and how much is environmental?” notes Dr. Mutti. “This has prompted interest in the genes related to educational attainment and their connection to myopia. Is it about doing more near work, spending less time outdoors or inheriting some cognitive skill that makes for better success in school? Or is it some combination

### Gene Therapies in the Pipeline

As discoveries continue, more gene therapies will become a reality. Luxturna (voretigene neparovec, Spark Therapeutics) was granted FDA approval in 2017 for patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy.<sup>8</sup> Here is a rundown of where some other promising treatments stand:

#### AMD

- Administered via intravitreal injection, AAV2-sFLT01 (Sanofi/Genzyme) uses the AAV2 vector.<sup>40</sup> Phase I/II studies support the safety of this treatment.
- RGX-314 (RegenxBio) for wet AMD recently completed Phase I/IIa trials and demonstrated safety as well as a reduction in the need for other anti-VEGF treatments. Researchers are preparing to initiate Phase IIb trials.<sup>40</sup>
- The ongoing OPTIC trial for ADVM-022 (Adverum Biotechnologies) is a Phase I study examining the therapy’s safety and tolerability.<sup>41</sup> Preliminary data is promising, and the drug demonstrates a good safety profile.<sup>40</sup>

#### Stargardt’s Disease

- A dual *ABCA4*-AAV vector is currently in development. The functional *ABCA4* genes were successfully and safely delivered in preclinical models.<sup>42,43</sup>
- Researchers have developed a non-viral gene therapy. Preclinical data shows that ECO/pRHO-*ABCA4* nanoparticles induced a substantial response.<sup>13</sup>

#### Achromatopsia

- AAV-CNGA3, an investigational gene therapy, received orphan drug designation by the FDA in 2018.<sup>38</sup>
- AAV8.CNGA3 has led to improved visual outcomes among adult patients in an open-label, exploratory nonrandomized controlled trial.<sup>39</sup>

#### Fabry’s Disease

- FLT190 uses AAV8 to deliver a healthy copy of the *GLA* gene in an effort to induce the production of normal alpha-GAL A. A Phase I/II study is currently underway.<sup>18</sup>
- AVR-RD-01, an ex vivo lentiviral gene therapy, is under investigation in a Phase II study, and interim data are promising.<sup>19</sup>



or interaction between heredity and environment?”

“Untangling this association between genes for educational attainment and myopia is where, in my opinion, genetics is heading,” Dr. Mutti adds.

According to Dr. Mutti, any possible genes related to educational attainment may help researchers better identify at-risk children who would particularly benefit from more time outdoors.

**Achromatopsia.** Six gene variants are associated with this condition, explaining greater than 90% of cases.<sup>36,37</sup> The most prevalent are *CNGA3* and *CNGB3*.<sup>37</sup>

While no treatments currently exist for achromatopsia, a number of gene therapy trials are underway, including one for AAV-CNGA3. The therapy, designed to restore cone function, is delivered to the cone receptors at the back of the eye via subretinal injection. In 2018, AAV-CNGA3 was granted orphan drug designation by the FDA.<sup>38</sup>

Recent findings from an open-label, nonrandomized controlled trial suggest that another gene therapy, AAV8.CNGB3, improved visual outcomes in nine patients with *CNGB3*-linked achromatopsia. The study found no significant safety issues.<sup>39</sup> The study authors noted that future studies must explore this approach at an earlier age to determine if this will “lead to greater functional benefit because of higher cortical plasticity.”

## A Look to the Future

While some ocular conditions are already witnessing the impact of genetic advancement, the exact timeframe for broad applications in optometric practice remains to be seen. As breakthroughs continue, it is crucial for optometrists to educate themselves on the latest research

and engage in meaningful discussions around the potential impact—both positive and negative—these advances can have on their patients.

“Genetics-guided therapy is in our future and, as a field, we have to embrace this technology,” notes Dr. Rafieetary. “We have to stay on top of these subjects so, as they become more accessible and commonplace, we didn’t miss the boat. To optometrists I would say, stay tuned, study as much as you can and use common sense, evidenced-based medicine and standard of care when using any therapies or technologies.” ■

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# A Simpler Way to Code Office Encounters

A major update coming in January will finally make things much easier.

By John Rumpakis, OD, MBA

**M**ajor changes to the outpatient and office evaluation and management (E/M) codes are slated to go into effect on January 1, 2021.<sup>1</sup> These changes have been long awaited and will certainly reduce the administrative burden on the average practice by making coding your office encounters much easier and straightforward. The changes, made by the American Medical Association CPT Editorial Panel and others, are in response to the Centers for Medicare & Medicaid's (CMS) request to collapse the E/M codes and reduce the burden of medical record keeping on the physician.

## A Look at the Past

The history of determining appropriate reimbursement levels for professional medical services is entrenched in mystery and confusion. For optometry, it began with the profession's inclusion in the Federal Medicare program on April 1, 1987, which formally classified optometrists as physicians—an important milestone for medical

reimbursement protocols in optometry.

The Medicare physician fee schedule is founded on the resource-based relative value system (RBRVS), which stemmed from the Harvard/American Medical Association's (AMA) RBRVS developed in the late 1980s. The first RBRVS was a Harvard research study initiated by the government because of double-digit annual increases in the cost of medical care in the United States and a perceived opinion that physician fees based on the reasonable/usual/customary methodology were not consistent or equitable. To address this inequity, physician work values and practice expenses for key AMA CPT codes were determined by a survey and validated by physician consensus panels known as the Clinical Practice Expert Panels.

Based on this early RBRVS, the Health Care Finance Administration implemented the new RBRVS for Medicare physician reimbursement in 1992 for all CPT codes, using a crosswalk methodology to fill the

gaps where surveyed data was not yet available.

Today's RBRVS is based on a series of relative value units (RVUs) associated with each CPT code. The three major elements of Medicare's current system include:

### *The relative value scale (RVS).*

This is a list of physician services ranked according to value. The total RVU, in turn, consists of three relative values: physician-work, practice expense and malpractice risk. Values for new and revised procedures in the CPT are included in the updated RVS each year. The malpractice risks are directly assigned by the CMS based on a survey of estimated risk levels by specialty.

### *The geographic adjustments.*

The RVS components are factored by a corresponding adjustment for the locality, as geographic adjustments to Medicare payment amounts were introduced in 1995. Three geographic practice cost indices (GPCIs, pronounced "gypsies") were developed by private researchers, including the Urban Institute, with funding from the CMS.

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**The conversion factor.** Reimbursements are determined for each and every CPT code with a mathematical formula. The formula incorporates all six of the above variables and then uses a conversion factor determined by Congress in the budget-balancing process (Figure 1). This factor is also published each year in the *Federal Register*.

### Changes on the Way

Starting January 1, 2021, performing a history and/or exam will still be medically appropriate for reporting all levels of an E/M service but will no longer play a significant role in the E/M code selection. Instead, providers will select the code based only on the level of medical decision making or total time. These other major changes—for the better—will also make workflow easier to code:

- Deletion of CPT code 99201: Due to low use of the level 1 code for office/other outpatient visit for the evaluation and management of a new patient, this code will be deleted in 2021.
- Although they are necessary factors when reporting an E/M visit, the history and exam elements will no longer be key in the office/outpatient E/M code selection.
- The definition of time associated with E/M levels 99202–99215 is changing from “typical face-to-face time” to “total time spent on the day of the encounter”—a critical distinction. Providers will no longer need to establish how much time was devoted to counseling and coordinating on the day of the encounter. The time values associated with each of the revised office/outpatient E/M codes will reflect the total time spent.

• There are changes to the wording of the medical decision-making elements:

1. “Number of diagnoses or

management options” is changing to “number and complexity of problems addressed.”

2. “Amount and/or complexity of data to be reviewed” is becoming “amount and/or complexity of data to be reviewed and analyzed.”
3. “Risk of complications and/or morbidity or mortality” is changing to “risk of complications and/or morbidity or mortality of patient management.”

Practitioners will have a choice on factors to use to determine the E/M code for the encounter: time or medical decision making. That being said, time has a new definition as well, before being applied to the clinical circumstance:<sup>1</sup>

“When time is used to select the appropriate level for E/M services codes, time is defined by the service descriptors. The E/M services for which these guidelines apply require a face-to-face encounter with the physician or other qualified health care professional. For office or other outpatient services, if the physician’s or other qualified health care professional’s time is spent in the supervision of clinical staff who perform the face-to-face services of the encounter, use 99211.”

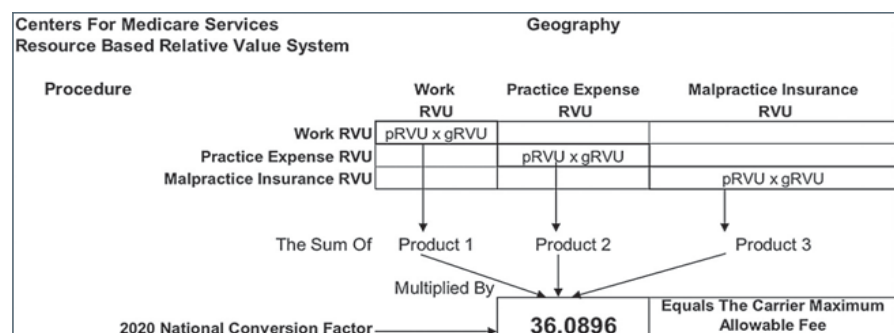
For coding purposes, time for office or other outpatient services (99202-99205, 99212-99215) is the total time on the date of the encoun-

ter, including both the face-to-face and non-face-to-face time personally spent by the physician and/or other qualified health care professional(s). This also encompasses the time spent in activities that require the physician or other qualified health care professional but does not include time in activities normally performed by clinical staff.

The physician’s or other qualified health care professional’s time includes the following activities, when performed:

- Preparing to see the patient (e.g., review of tests).
- Obtaining and/or reviewing separately obtained history.
- Performing a medically appropriate examination and/or evaluation.
- Counseling and educating the patient/family/caregiver.
- Ordering medications, tests or procedures.
- Referring and communicating with other health care professionals (when not separately reported).
- Documenting clinical information in the health record.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver.
- Care coordination (not separately reported).

These changes in how the practitioner’s total time is recorded will be



**Fig. 1. This is the mathematical formula that determines Medicare reimbursement.**

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helpful in achieving specific levels of coding for an individual encounter.

The new E/M code definitions clearly demonstrate the elimination of the history and exam requirements while emphasizing the time and/or medical decision-making elements by using the wording “medically appropriate history and/or examination.”

Here are the new definitions:<sup>1</sup>

**New Patient** (99201 has been deleted; to report, use 99202)

- **99202:** Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or exam and straightforward medical decision making. When using time for code selection, 15 to 29 minutes of total time is spent on the date of the encounter.

- **99203:** Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or exam and low level of medical decision making. When using time for code selection, 30 to 44 minutes of total time is spent on the date of the encounter.

- **99204:** Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or exam and moderate level of medical decision making. When using time for code selection, 45 to 59 minutes of total time is spent on the date of the encounter.

- **99205:** Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or exam and high level of medical decision making. When using time for code selection, 60 to 74 minutes of total time is spent on the date of the encounter.

**Established Patient**

- **99211:** This code may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal.

- **99212:** Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or exam and straightforward medical decision making. When using time for code selection, 10 to 19 minutes of total time is spent on the date of the encounter.

- **99213:** Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or exam and low level of medical decision making. When using time for code selection, 20 to 29 minutes of total time is spent on the date of the encounter.

- **99214:** Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or exam and moderate level of medical decision making. When using time for code selection, 30 to 39 minutes of total time is spent on the date of the encounter.

- **99215:** Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or exam and high level of medical decision making. When using time for code selection, 40 to 54 minutes of total time is spent on the date of the encounter.

Clinicians must ensure their electronic health record (EHR) has the ability to record total time spent while working in a patient’s record, so it will be easy to tally the total

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<b>Table 1. AMA Office Visit CPT Coding</b>				
CPT Code	Level Of Medical Decision Making	Number and Complexity Of Problems Addressed	Amount/Complexity of Data Reviewed and Analyzed	Risk of Complications and Morbidity
99211	NA	NA	NA	NA
99202/99212	Straightforward	<b>Minimal</b> • One self-limited or minor problem	Minimal or none	Minimal risk of morbidity from additional diagnostic testing or treatment
99203/99213	Low	<b>Low</b> One of the following: • Two or more self-limited or minor problems • One stable chronic illness • One acute, uncomplicated illness or injury	<b>Limited</b> Must meet the requirements of at least one of the two categories: <i>Category 1</i> (any combination of two from the following): • Review of prior external note(s) from each unique source* • Review of the result(s) of each unique test* • Ordering each unique test* <i>Category 2:</i> Assessment requiring an independent historian(s) (For the categories of independent interpretation of tests and discussion of management or test interpretation, see moderate or high)	Low risk of morbidity from additional diagnostic testing or treatment
99204/99214	Moderate	<b>Moderate</b> One of the following: • One or more chronic illnesses with exacerbation, progression, or side effects of treatment • Two or more stable chronic illnesses • One undiagnosed new problem with uncertain prognosis • One acute illness with systemic symptoms • One acute complicated injury	<b>Moderate</b> Must meet the requirements of at least one of three categories: <i>Category 1</i> (any combination of three from the following): • Review of prior external note(s) from each unique source* • Review of the result(s) of each unique test* • Ordering of each unique test* • Assessment requiring an independent historian(s) <i>Category 2:</i> Independent interpretation of a test performed by another physician/ other qualified health care professional (not separately reported) <i>Category 3:</i> Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported)	Moderate risk of morbidity from additional diagnostic testing or treatment  Examples: • Prescription drug management • Decision regarding minor surgery with identified patient/ procedure risk factors • Decision regarding elective major surgery without identified patient/procedure risk factors • Diagnosis or treatment significantly limited by social determinants of health
99205/99215	High	<b>High</b> One of the following: • One or more chronic illnesses with severe exacerbation, progression or side effects of treatment • One acute or chronic illness or injury that poses a threat to life or bodily function	<b>Extensive</b> Must meet the requirements of at least two of three categories: <i>Category 1</i> (any combination of three from the following): • Review of prior external note(s) from each unique source* • Review of the result(s) of each unique test* • Ordering of each unique test* • Assessment requiring an independent historian(s) <i>Category 2:</i> Independent interpretation of a test performed by another physician/ other qualified health care professional (not separately reported). <i>Category 3:</i> Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported)	High risk of morbidity from additional diagnostic testing or treatment  Examples: • Drug therapy requiring intensive monitoring for toxicity. • Decision regarding elective major surgery with identified patient/procedure risk factors. • Decision regarding emergency major surgery. • Decision regarding hospitalization. • Decision not to resuscitate or to de-escalate care because of poor prognosis.

\*Each unique test, order, or document contributes to the combination of two or the combination of three in Category 1 above.



time, in minutes, spent on preparation, review, examination and so on.

### Medical Decision Making

Whether in the office or for other outpatient services, this code set is defined by three elements (Table 1):<sup>1</sup>

1. *The number and complexity of problem(s) that are addressed during the encounter.*

2. *The amount and/or complexity of data involved.* This includes medical records, tests and other information that must be obtained, ordered, reviewed and analyzed. It also encompasses information obtained from multiple sources or interprofessional communications not separately reported, as well as the interpretation of tests not separately reported. Ordering a test is included in the category of test result(s) and the review of the test result is part of the encounter, not a subsequent encounter. Data is divided into three categories: (1) tests, documents, orders or independent historian(s), where each unique test, order or document is counted to meet a threshold number; (2) independent interpretation of tests; and (3) discussion of management or test interpretation with external physician or other qualified health-care professional or appropriate source.

3. *The risk of complications, morbidity and mortality of patient management decisions made at the visit, as it relates to the patient's problem(s), diagnostic procedure(s) and treatment(s).* This includes the possible management options selected and those considered, but not selected, after shared medical decision making with the patient and/or family. For example, a decision about hospitalization includes consideration of alternative levels of care. Examples may include a psychiatric patient with sufficient sup-

port in the outpatient setting or the decision to not hospitalize a patient with advanced dementia with an acute condition that warrants inpatient care, but for whom the goal is palliative treatment.

The new E/M coding system provides practitioners with both flexibility and choice due to the reduced administrative burden of documenting specific levels of history and examination to reach a particular code level.

It is important to prepare your practice for these changes by ensuring that your EHR system allows for appropriate documentation of time and that you are tallying it correctly if you use time for the code determinant. If using medical decision making, spend the time between now and January to become familiar with the new requirements for documentation. They are not all that different from the previous methodologies, but they are just different enough that they warrant your attention.

Change is coming and, for once, it just might make things easier. ■

*The information in this article is not intended as a substitute for AMA guidelines. For coding purposes, see the AMA's original document at [www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf](http://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf).<sup>1</sup>*

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1. American Medical Association. CPT evaluation and management (E/M) office or other outpatient (99202-99215) and prolonged services (99354, 99355, 99356, 99357) code and guideline changes. [www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf](http://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf).

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# ANTIBIOTICS IN EYE CARE: A BALANCING ACT

Here's what you need to consider when weighing the benefits vs. the risks in the era of resistance. **By Tracy Offerdahl, PharmD, BSc, and Greg Caldwell, OD**

**A**lthough antibacterial drugs have been a boon for treating ocular infections, the downside—resistance—always looms in the shadows. Optometric physicians must educate themselves to become cautious and judicious prescribers of these agents.

Antibiotics have long been the cornerstone of treatment to stop infections caused by bacteria, and with many different types of agents, practitioners have a number of choices. The agents categorized

as “narrow” tend to treat only one or two bacterial strains, while “broad” agents treat a few to many bacterial strains. We are fortunate to have a category of antibiotics categorized as “multi-drug resistant,” which should be reserved for infections for which we have no typical choices available.

In general, clinicians should use an agent with a spectrum of activity that is wide enough to eliminate the bacteria without being so broad that it destroys the normal flora of the gut biome or sets bacterial resis-

tance in motion. This balancing act requires the clinician to constantly monitor bacterial susceptibilities, resistance patterns, new drug interactions, contraindications and adverse effects.

Another practical consideration includes ensuring that the antibacterial agent is able to reach the site of infection in the eye and surrounding ocular tissues. This is particularly important for the optometrist who often must choose between topical and oral agents when treating bacterial ocular infections.

**Release Date:** October 15, 2020

**Expiration Date:** October 15, 2023

**Estimated Time to Complete Activity:** 2 hours

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

**Educational Objectives:** After completing this activity, the participant should be better able to:

- Describe the balance necessary to improve the patient's condition without building antibiotic resistance.
- Appropriately prescribe antibiotics for conditions that warrant them.
- Decide which antibiotic strategy is best for common conditions.
- Discuss contraindications and possible side effects of antibiotics.

**Target Audience:** This activity is intended for optometrists engaged in the care of patients with corneal dystrophies.

**Accreditation Statement:** In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and Review Education Group. Postgraduate Institute for Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education, the Accreditation Council for



Pharmacy Education, and the American Nurses Credentialing Center, to provide continuing education for the healthcare team. Postgraduate Institute for Medicine is accredited by COPE to provide continuing education to optometrists.

**Faculty/Editorial Board:** Tracy Offerdahl, PharmD, BSc, Pennsylvania College of Optometry, and Greg Caldwell, OD, Optometric Education Consultants.

**Credit Statement:** This course is COPE approved for 2 hours of CE credit. Course ID is **69695-PH**. Check with your local state licensing board to see if this counts toward your CE requirement for relicensure.

**Disclosure Statements:**

*Dr. Offerdahl* has nothing to disclose.

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**Managers and Editorial Staff:** The PIM planners and managers have nothing to disclose. The Review Education Group planners, managers and editorial staff have nothing to disclose.

## Oral vs. Topical

Some ocular infections should be treated with an oral antibacterial agent as standard of care, including hordeolum, preseptal cellulitis and dacryocystitis. Oral antibacterial agents provide high systemic levels, which results in better penetration of the agent into the lacrimal apparatus and surrounding tissues.<sup>1-3</sup>

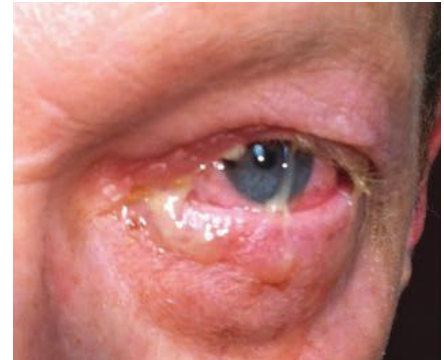
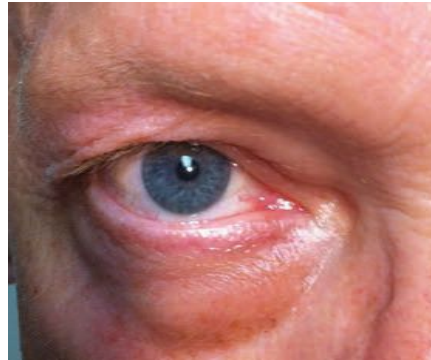
On the other hand, bacterial infections of the cornea and conjunctiva are adequately treated with a topical agent. Topical application produces higher local concentrations, fewer systemic adverse events, lower risk of resistance and little to no effect on the gut microbiome. Additionally, if it is a non-purulent presentation, a viral pathogen is likely, and an antibacterial agent is not warranted. This simple prescribing strategy is proven to decrease the spread of resistant organisms.<sup>3-5</sup>

The most common infectious organisms associated with ocular infections are gram-positive isolates, including *Staphylococcus aureus*, *Staphylococcal epidermidis* and *Streptococcus pneumoniae*. Gram-negative organisms may also be present and include *Haemophilus influenzae* and, less likely, *Pseudomonas aeruginosa* (Table 1).<sup>3,6-8</sup>

## Patient Considerations

Many patient-specific issues affect the clinician's medication choices:

**Pregnancy/lactation.** An important consideration for any prescribing practitioner is the safety of a systemic agent in patients who are pregnant or nursing. In 2015, the Food and Drug Administration (FDA) discontinued the use of the historic pregnancy and lactation letter



**This patient's examination reveals acute bacterial conjunctivitis. Despite the severity of this infection, the location is limited to the conjunctiva, so using a topical antibiotic is an acceptable treatment choice. Appropriate topical choices include Polytrim, a fluoroquinolone (ciprofloxacin, ofloxacin) or tobramycin.<sup>1-4</sup>**

categories A, B, C, D and X (where A is considered the safest and X is absolutely contraindicated) for all prescription drugs. The main reason for this change is because the historic letter categories are often considered confusing and overly simplistic.<sup>9</sup>

The new Pregnancy and Lactation Labeling Rule (PLLR), which went into effect on June 30, 2015, provides important information not only for pregnancy and lactation, but also adds a category that evaluates whether or not a prescription drug has any potential reproductive risk in males and females of reproductive age. While many

prescription drugs currently have both a letter and PLLR designation, this is temporary, as the FDA has implemented a plan to completely eliminate the letter categories over the next few years.<sup>9</sup>

**Allergies.** Medical practitioners in every discipline know that penicillin allergies often emerge when obtaining a patient's history. However, these allergies aren't always black and white, and it is sometimes difficult to interpret a patient's description of their penicillin allergy. The current medical literature is murky on what constitutes a true allergy, and any concrete interpretation of risk and

cross reactivity is hard to find. A valuable piece of information comes from the patient's description of their allergy, so practitioners must always investigate the specific nature of the allergic reaction. It is estimated that 90% of patients who claim to be allergic to a penicillin are not actually allergic.<sup>3,10-15</sup>

A provider should always approach an allergy with caution and watch for any signs of a Type 1 hypersensitivity reaction. Symptoms of concern include a "wheal-and-flare" rash, swelling

**Table 1. Likely Organisms Responsible For Ocular Infections<sup>3,35-38,41</sup>**

Conjunctivitis	<i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Streptococcus pneumoniae</i> <i>Haemophilus influenzae</i>
Dacryocystitis	<i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Streptococcus pneumoniae</i> <i>Pseudomonas aeruginosa</i>
Hordeolum	<i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i>
Preseptal cellulitis	<i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Streptococcus pneumoniae</i> <i>Haemophilus influenzae</i>

**Table 2. Dosing Regimens for Community-Acquired MRSA<sup>31-34,42</sup>**

Medication(s)	Dose
Sulfamethoxazole + trimethoprim	800mg/160mg; one tablet BID for 10 days
Clindamycin	300mg to 600mg TID for 10 days
Doxycycline	100mg BID for 10 days

of the face, throat or mouth or any respiratory problems such as wheezing or shortness of breath. Patients with any of these issues should avoid drugs in the penicillin class.<sup>14,15</sup>

When evaluating the potential of a cross allergy with the cephalosporins, medications that possess the most similar side chains increase the likelihood of a cross-reaction. For example, cephalexin, a first-generation cephalosporin, is more likely to cross-react with a patient who has a penicillin allergy compared with a drug lacking the side chain (e.g., cefuroxime axetil, which is a second-generation cephalosporin). Clinical experience and some studies support this model, so if a patient does describe what appears to be a potentially dangerous allergic reaction to a penicillin, then it seems to be a safer choice to use a cephalosporin in the second or third generation groups.<sup>3,12-16</sup>

**Methicillin-resistant Staphylococcus aureus (MRSA).** We see this organism frequently in both the community and hospitals. While sulfamethoxazole + trimethoprim, clindamycin and doxycycline may not be an optometrist's typical go-to drugs when treating hordeolum, preseptal cellulitis and dacryocystitis, they are important to consider when managing community-acquired (as opposed to hospital-acquired) MRSA infections.

Vancomycin, a super gram-positive antibiotic, is considered the standard for MRSA infections; however, it is reserved for inpatient use because it must be administered intravenously.

When a patient fails traditional therapy that covers *Staphylococcus aureus*, or when a patient is known to be colonized with MRSA, it is a good time to consider a potential MRSA infection. Additionally, young patients, those who

are incarcerated and athletes are increasingly more likely to have a MRSA infection, as are health care workers, patients who are in assisted living homes or patients with a recent hospitalization. Anyone with a history of previous MRSA infection is also at an increased risk since the bacteria can live under our fingernails and in our nasal cavities for years (Table 2).<sup>17-19</sup>

### Antibacterial Resistance

Resistant organisms continue to appear at a rate faster than science and research are able to produce new antibiotics to fight them. The World Health Organization's Global Action Plan on Antimicrobial Resistance plan emphasizes the importance of education, surveillance and research to combat growing bacterial resistance.<sup>20</sup>

The main mechanism for bacterial resistance is through genetic mutations and a well-known list of factors that contribute to it, including overprescribing of antimicrobials, agricultural use and prescribing inappropriate or incorrect dosing regimens. Optometric-specific issues of resistance are perpetuated by empirical use of antibacterials,



**This patient presented with a typical acute bacterial conjunctivitis. Empirically treating for a bacteria rather than a virus would be the optimal choice due to the purulent exudate. A topical antibiotic would be an acceptable treatment option. Appropriate topical choices include polymyxin B + trimethoprim, a fluoroquinolone (ciprofloxacin, ofloxacin) or tobramycin.<sup>1-4</sup> If this patient has a penicillin or sulfa allergy, all of these agents would still be appropriate. If the patient is pregnant or breastfeeding, all of these agents would still be appropriate due to little/no systemic absorption.**





**This patient's examination reveals a hordeolum and preseptal cellulitis. Because the hordeolum is like an abscess and the preseptal cellulitis involves the skin/skin structures, an oral antibiotic is appropriate. Fever or other systemic signs/symptoms of infections may warrant hospitalization with intravenous antibiotics. Appropriate systemic agents include Augmentin, Keflex, azithromycin or Bactrim. When none of these agents can be used due to allergy, a fluoroquinolone (levofloxacin, moxifloxacin) may be considered. If there is concern regarding the potential for MRSA, systemic options include Bactrim, doxycycline or clindamycin.<sup>1-4,32-34,42</sup>**

**If this patient has a severe, life-threatening penicillin allergy (Type 1 hypersensitivity), Augmentin would be contraindicated and Keflex should also be avoided.<sup>6-9,11-16</sup> If they have a mild reaction to penicillin (mild, non-descript rash), Keflex may still be considered a safe choice.<sup>6-9,11-16</sup> Bactrim is contraindicated in patients with a sulfa allergy.<sup>32-34</sup> Augmentin, Keflex and azithromycin are safe for pregnant or breastfeeding patients while Bactrim and fluoroquinolones are contraindicated.<sup>32-40</sup>**

short-course or inadequate dosing of antibacterials and repeated use of the same antibacterial agent in a patient.<sup>5,19-24</sup>

Augmentin (amoxicillin + clavulanate, GlaxoSmithKline) is a beta-lactam plus beta-lactamase inhibitor combination that is designed to treat one type of resistance in some bacterial isolates. The addition of clavulanate, a beta-lactamase enzyme inhibitor, helps to provide increased protection for the amoxicillin against hydrolysis when it is exposed to infections caused by organisms that produce beta-lactamase. These include *Haemophilus influenzae* and *Moraxella catarrhalis*.<sup>3,5,10,25</sup>

### Antibiotic Review

Antibacterials are categorized into four classifications: beta-lactams, protein-synthesis inhibitors, fluoroquinolones and sulfonamides.

The beta-lactams, which include penicillins, combined penicillin/

beta-lactamase inhibitors and cephalosporins, are the preferred drug for most ocular conditions due to high efficacy and low toxicity. The mechanism of action is bacterial cell wall synthesis inhibitors.

Protein-synthesis inhibitors—macrolides, tetracyclines, clindamycin and aminoglycosides—bind to either 30S or 50S ribosomal unit on bacteria. Among the macrolides, azithromycin is the drug of choice for most atypical infections.

The mechanisms of action for fluoroquinolones, include bacterial DNA gyrase and topoisomerase inhibitors. Fluoroquinolones have coverage of *Pseudomonas*.

Sulfonamides, which inhibit sequential steps in folate synthesis, are a good medication choice for skin/soft tissue infections due to MRSA coverage.

It is important to note that no anti-infective provides ideal coverage for all pathogens for all infected sites. Here's a look at the most com-

mon antibiotics used in eye care.

**Augmentin.**<sup>3,10-12</sup> This agent includes a beta-lactam (amoxicillin) combined with a beta-lactamase inhibitor (clavulanate). The addition of the beta-lactamase enzyme inhibitor clavulanate provides increased protection for amoxicillin against *Haemophilus influenzae* and *Moraxella catarrhalis*, as well as some anaerobes.<sup>10-12</sup> In pus-producing infections, the clavulanate is essential to protecting the beta-lactam ring.

Augmentin is one of our first choices if a systemic agent is needed in an ocular infection since it covers all of the most likely causative organisms. It is safe across all age ranges (beginning at 12 weeks of age) and is generally considered safe for use during pregnancy and lactation (historic category B). This medication is typically well tolerated, with the most common side effects being stomach upset and diarrhea. Taking the medication with food

**Table 3. Oral Antibiotic Dosing**<sup>11,26,27,32,33,35,39-41</sup>

Medication(s)	Dose
Amoxicillin + clavulanate	500mg/125mg BID to TID for 10 days 875mg/125mg TID for 10 days*
Cephalexin	500mg BID for 10 days
Azithromycin	Two tablets (500mg total) on day one, then 250mg once a day on days two through five
Sulfamethoxazole + trimethoprim	Double strength = 800mg sulfamethoxazole and 160mg trimethoprim/tablet One tablet every 12 hours for seven to 10 days
Levofloxacin	500mg daily for 10 days
Moxifloxacin	400mg daily for 10 days
Ciprofloxacin	500mg to 750mg BID for 10 days**

\*Higher doses of amoxicillin provide better coverage for potential *Streptococcus pneumoniae* bacteria. This organism is more likely to cause infection in adults with an ocular infection.

\*\*Choose only if *Pseudomonas aeruginosa* is suspected or documented.

often helps to mitigate these issues. Clinicians should always evaluate a patient's allergy history prior to use.

**Keflex (cephalexin, Advancis Pharmaceutical).**<sup>10-16,26</sup> This agent is a beta-lactam, first-generation cephalosporin. It is not generally destroyed by beta-lactamase producing organisms. The spectrum of activity against common bacterial organisms is similar to amoxicillin, such as methicillin-sensitive *Staphylococcus aureus* (MSSA), as well as some gram negatives including *Haemophilus influenzae* and *Moraxella catarrhalis*.

*mophilus influenzae* and *Moraxella catarrhalis*.

It is considered safe for individuals eight weeks of age or older as well as for those who are pregnant or breastfeeding (historic category B). Keflex, which is generally well tolerated, is the drug of choice for blowout orbital fractures at a higher dose of 500mg four times a day.

Clinicians should make sure to evaluate patients' allergy history prior to prescribing this agent, specifically any allergies that have

occurred with a penicillin or other beta-lactam agents. The incidence of allergic cross-reaction between a penicillin and a first-generation cephalosporin ranges from 1% to 10%, with most data and expert opinions leaning on the low end of the estimate.

**Azithromycin.**<sup>27,28</sup> This agent is a macrolide antibiotic with a decent spectrum of bacterial coverage. It has slightly better coverage for *Haemophilus influenzae* when compared with Augmentin, and its atypical bacterial coverage is better than its gram-positive coverage. Additionally, azithromycin is usually the drug of choice for chlamydial conjunctivitis.<sup>29,30</sup> This is another reasonable choice when a systemic agent is needed because it covers all of the likely causative organisms. It's also a good option for some patients with a presumptive or documented true penicillin allergy.

Systemic azithromycin has a dynamic pharmacokinetic profile. Once it is in the bloodstream, it has a very wide distribution into most tissues and compartments, with the exception of the brain and cerebral spinal fluid. Once distributed, azithromycin tissue concentrations are much higher than they are in simultaneous serum concentrations. Wide distribution coupled with liver and biliary elimination results in an elimination half-life of 40 to 68 hours. This means that when a patient takes the last dose of azithromycin on day five, azithromycin continues to provide high enough tissue concentrations to treat an infection for an additional 1.5 to 2.8 days. In serious infections, however, treatment failure is sometimes an issue.<sup>27,28</sup>

Safe across all age ranges, this drug can generally be used safely in patients who are pregnant or lactating (historic category B). It is typically well tolerated but can



**This patient has a periorbital skin infection with bacterial purulence. Since the infection involves the skin/skin structures surrounding the eye, an oral antibiotic agent would increase treatment success. Appropriate systemic agents include Augmentin, Keflex, azithromycin or Bactrim. When these agents are contraindicated due to an allergy, a fluoroquinolone (levofloxacin, moxifloxacin) may be considered. If there is concern regarding the potential for MRSA, systemic options include Bactrim, doxycycline or clindamycin.**<sup>1-4,32-34,42</sup>

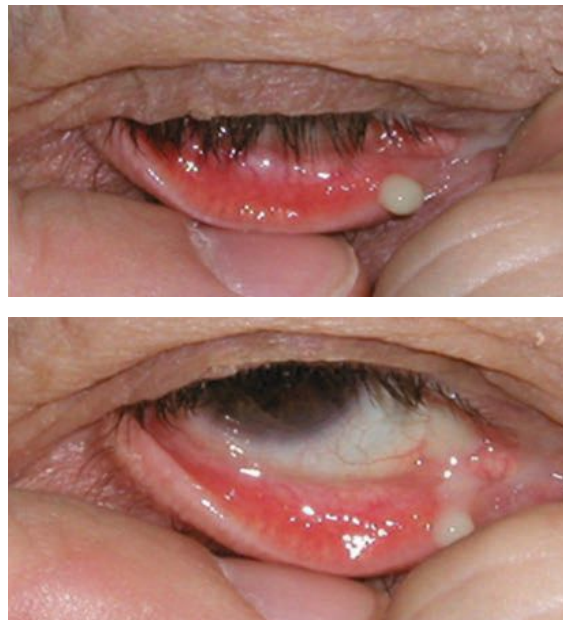
cause stomach upset and diarrhea. Post-marketing surveillance has indicated that azithromycin may cause heart issues, such as prolongation of QT interval and torsades de pointes, which can be fatal. Patients on other drugs that may prolong the QT interval (antipsychotics, antifungals, hydroxychloroquine, etc.) or those with a known arrhythmia are at higher risk.<sup>27,28</sup>

**Bactrim (sulfamethoxazole + trimethoprim, Roche).**<sup>31-34</sup> This agent is the sulfa antibiotic that some patients may be allergic to. Unlike a penicillin allergy, the sulfa allergic patient should generally be assumed to have significant morbidity and potential mortality associated with exposure to this medication. Additionally, this drug has a decent spectrum of bacterial coverage for *Staphylococcus spp.* (including community-acquired MRSA), *Streptococcus spp.* and *Haemophilus influenzae*.

While safe across all ages (beginning at four weeks of age), it should be avoided in patients with a sulfa allergy. Risk of use in pregnant patients cannot be ruled out, as it may cause hyperbilirubinemia in later pregnancy (historic category C). While usually well tolerated, serious allergic reactions may occur, including rash, anaphylaxis, Stevens-Johnson syndrome and toxic epidermal necrolysis.<sup>32</sup> Some clinical pearls to remember include:

- Bactrim DS (double strength) is more often prescribed for ocular infections compared with single strength.
- Sulfamethoxazole and trimethoprim are synergistic when used together, and this increases the bacterial spectrum and the efficacy.
- Sulfamethoxazole monotherapy was once widely used as a single agent; however, the development of bacterial resistance has rendered it nearly obsolete. This is seen in a number of treatment failures from some physician groups using topical 10% sulfamethoxazole.

**Fluoroquinolones.**<sup>31,33,35-40</sup> The most widely used agents in this class include moxifloxacin, levofloxacin and ciprofloxacin. The last of these has better (and broad) gram-negative coverage, including *Haemophilus influenzae* and *Pseudomonas aeruginosa* but gram-positive coverage is more limited due to resistance. Levofloxacin and moxifloxacin have fair to good



**A clinical examination reveals acute dacryocystitis. Due to the location of this infection, an oral antibiotic agent is the best option. Appropriate systemic choices include Augmentin, Keflex, azithromycin or Bactrim. In the case of an allergy, a fluoroquinolone (levofloxacin, moxifloxacin) may be considered. When MRSA is a concern, systemic options include Bactrim, doxycycline, or clindamycin.**<sup>1-4,32-34,42</sup>

gram-positive coverage, including *Staphylococcus spp.* and *Streptococcus spp.*

Topical fluoroquinolones are safely used in pregnancy, breastfeeding and in infants and children older than age one. However, oral fluoroquinolones should only be used in patients 18 years or older and are contraindicated in those who are pregnant or breastfeeding due to

**Table 4. Topical Antibiotic Dosing**<sup>1-4,23-47</sup>

Medication(s)	Dose
Polymyxin B + trimethoprim solution	One drop in the affected eye(s) every three hours (maximum of six drops per day) for seven to 10 days.
Ofloxacin solution	One to two drops in affected eye(s) every two to four hours for the first 2 days, then one to two drops QID for an additional five days.
Ciprofloxacin solution	One to two drops into the affected eye(s) every two hours while awake for two days, then one to two drops every four hours while awake for the next five days.
Moxifloxacin solution	One drop in affected eye(s) two to three times a day for seven days.
Tobramycin	<i>Mild/moderate infection:</i> One to two drops in the affected eye(s) every four hours for seven to 10 days. <i>Severe infection:</i> Two drops in the affected eye(s) hourly until improvement, then one to two drops every four hours for seven to 10 days.



the risk of arthropathy and cartilage damage (historic category C).

Adverse effects may be severe, and these medications have a black box warning from the FDA. Research shows fluoroquinolones are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy and central nervous system effects.<sup>35-40</sup>

Discontinue therapy immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions. Because fluoroquinolones have been associated with serious adverse reactions, reserve fluoroquinolones for use in patients who have no alternative.<sup>35-40</sup>

**Miscellaneous topical antimicrobials.** Commonly used topical antibiotics include Polytrim (polymyxin B + trimethoprim, Allergan), fluoroquinolones such as ofloxacin, ciprofloxacin or Vigamox (moxifloxacin, Novartis), and tobramycin. While this does not represent a complete list of available agents, it does highlight reasonable choices for the topical treatment of acute bacterial conjunctivitis, since they are applied directly to the infected organ.<sup>1-4</sup> These agents are typically considered safe for patients who are pregnant or breastfeeding. In general, adverse effects are minimal and may include eye redness, eye irritation and allergy.

As medical professionals, it is always important to evaluate patients from both a macroscopic and microscopic perspective before making any drug therapy choices. This is more challenging every year as more prescription and over-the-counter medications are approved and marketed to patients in many therapeutic categories. Resistant

bacteria add another dynamic to patient care.

Our call-to-arms as antibiotic custodians is to choose an antimicrobial agent only when the chances of a bacterial infection are likely. When we do empirically treat a bacterial infection of the eye, choose an agent that is broad enough to treat the most likely organisms with a treatment duration that will mitigate the infection.

Keeping all of these things in mind will help to ensure that the patient is cured and that few to no resistant bacteria have been let loose in the world. Both of these are important factors for a successful treatment plan. ■

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## OSC QUIZ

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Please check with your state licensing board to see if this approval counts toward your CE requirement for relicensure.

1. Which of these ocular infections can generally be treated with a topical antibiotic?
  - a. Hordeolum.
  - b. Preseptal cellulitis.
  - c. Conjunctivitis.
  - d. Dacryocystitis.
2. In general, which organism is least likely to cause an ocular infection?
  - a. *Pseudomonas aeruginosa*.
  - b. *Streptococcus pneumoniae*.
  - c. *Staphylococcus aureus*.
  - d. *Haemophilus influenzae*.
3. Which historic category means a drug is absolutely contraindicated during pregnancy?
  - a. Category A.
  - b. Category B.
  - c. Category D.
  - d. Category X.
4. In general, \_\_\_\_\_% of patients who state "penicillin allergy" are not actually allergic.
  - a. 10.
  - b. 25.
  - c. 60.
  - d. 90.
5. A patient with a Type 1 hypersensitivity to amoxicillin should generally avoid:
  - a. Fluoroquinolones.
  - b. Macrolides.
  - c. Cephalosporins.
  - d. Aminoglycosides.
6. Which scenario is least likely to produce resistance in a bacterial organism?
  - a. Inappropriate use of an antibiotic.
  - b. Patients finishing their prescribed course of antibiotics.
  - c. Short-course use of antibiotics.
  - d. Repeated use of the same antibiotic.
7. Which of these is formulated specifically to treat an organism that produces an enzyme that breaks down an antibiotic?
  - a. Amoxicillin + clavulanate.
  - b. Azithromycin.
  - c. Sulfamethoxazole + trimethoprim.
  - d. Ciprofloxacin.
8. All of these agents can treat a community-acquired MRSA infection of the eye, except:
  - a. Doxycycline.
  - b. Cephalexin.
  - c. Sulfamethoxazole + trimethoprim.
  - d. Clindamycin.
9. Amoxicillin + clavulanate is generally safe in patients from \_\_\_\_\_.
  - a. Two to 65 years old.
  - b. Two years and older.
  - c. 12 to 65 years old.
  - d. 12 weeks and older.
10. Cephalexin is historic pregnancy category \_\_\_\_\_.
  - a. A.
  - b. B.
  - c. C.
  - d. D.
11. Which antibiotic may cause arthropathy of the joints and/or tendon damage?
  - a. Penicillins.
  - b. Cephalosporins.
  - c. Macrolides.
  - d. Fluoroquinolones.
12. Which of these is most likely to cause Stevens-Johnson syndrome or toxic epidermal necrolysis as a rare effect?
  - a. Sulfamethoxazole + trimethoprim.
  - b. Ciprofloxacin.
  - c. Erythromycin.
  - d. Amoxicillin.
13. Which of these is the drug of choice for those with a true beta-lactam allergy?
  - a. Amoxicillin.
  - b. Cephalexin.
  - c. Azithromycin.
  - d. Sulfamethoxazole + trimethoprim.
14. Which agent has a wide distribution into most tissues and can be given for five days due to its long half-life?
  - a. Amoxicillin.
  - b. Cephalexin.
  - c. Azithromycin.
  - d. Ciprofloxacin.
15. Which antibiotic is contraindicated in a patient with a sulfa allergy?
  - a. Sulfamethoxazole + trimethoprim.
  - b. Ciprofloxacin.
  - c. Erythromycin.
  - d. Amoxicillin.
16. Which of these fluoroquinolone antibiotics has the best gram-negative coverage?
  - a. Levofloxacin.
  - b. Moxifloxacin.
  - c. Ciprofloxacin.
  - d. They all have the same coverage.
17. Which of these should not be used in people < 18 years of age?
  - a. Penicillins.
  - b. Cephalosporins.
  - c. Macrolides.
  - d. Fluoroquinolones.
18. Which antibiotic is generally the drug of choice for orbital blowout fractures?
  - a. Amoxicillin.
  - b. Cephalexin.
  - c. Azithromycin.
  - d. Ciprofloxacin.
19. Which agent is generally not used in pregnancy or breastfeeding due to the potential for hyperbilirubinemia?
  - a. Amoxicillin.
  - b. Cephalexin.
  - c. Azithromycin.
  - d. Sulfamethoxazole + trimethoprim.
20. In general, which of these is not likely to cause conjunctivitis?
  - a. *Staphylococcus aureus*.
  - b. *Staphylococcus epidermidis*.
  - c. *Haemophilus influenzae*.
  - d. *Klebsiella pneumoniae*.

# Examination Answer Sheet

## Antibiotics in Eye Care: A Balancing Act

Valid for credit through October 15, 2023

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**Answers to CE exam:**

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

**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. Describe the balance necessary to improve the patient's condition without building antibiotic resistance. (1) (2) (3) (4) (5)
22. Appropriately prescribe antibiotics for conditions that warrant them. (1) (2) (3) (4) (5)
23. Decide which antibiotic strategy is best for common conditions. (1) (2) (3) (4) (5)
24. Discuss contraindications and possible side effects of antibiotics. (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)

- (A) I do plan to implement changes in my practice based on the information presented.
- (B) My current practice has been reinforced by the information presented.
- (C) 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)

- (a) Apply latest guidelines (b) Change in pharmaceutical therapy (c) Choice of treatment/management approach
- (d) Change in current practice for referral (e) Change in non-pharmaceutical therapy (f) Change in differential diagnosis (g) Change in diagnostic testing (h) Other, please specify: \_\_\_\_\_

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

- (a) Very confident (b) Somewhat confident (c) Unsure (d) Not confident

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

Signature \_\_\_\_\_ Date \_\_\_\_\_

Lesson 120337

RO-OSC-1020

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

- (a) Formulary restrictions
- (b) Time constraints
- (c) System constraints
- (d) Insurance/financial issues
- (e) Lack of interprofessional team support
- (f) Treatment related adverse events
- (g) Patient adherence/compliance
- (h) Other, please specify: \_\_\_\_\_

30. Additional comments on this course:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Rate the quality of the material provided:  
1=Strongly disagree, 2=Somewhat disagree, 3=Neutral, 4=Somewhat agree, 5=Strongly agree

31. The content was evidence-based. (1) (2) (3) (4) (5)
32. The content was balanced and free of bias. (1) (2) (3) (4) (5)
33. The presentation was clear and effective. (1) (2) (3) (4) (5)



REVIEW OF OPTOMETRY

# The OD's TOP CHOICE

Ranked #1 Eye Care  
Publication In  
**FIVE**  
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Average Page Exposures



Websites Visited within  
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Source: Kantar Media Eyecare 2020 Study

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- Solo Practitioners
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- Perform Refractions (51+ per week)
- Contact Lens Prescribers
- Years in Practice (1-15 and 15+)
- Among Key Opinion Leaders

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We'll keep working hard to earn  
your support.**



# The Value of Vaccination

Shingrix is the recommended vaccine for shingles, especially for patients taking a prophylactic antiviral. **Edited by Joseph P. Shovlin, OD**

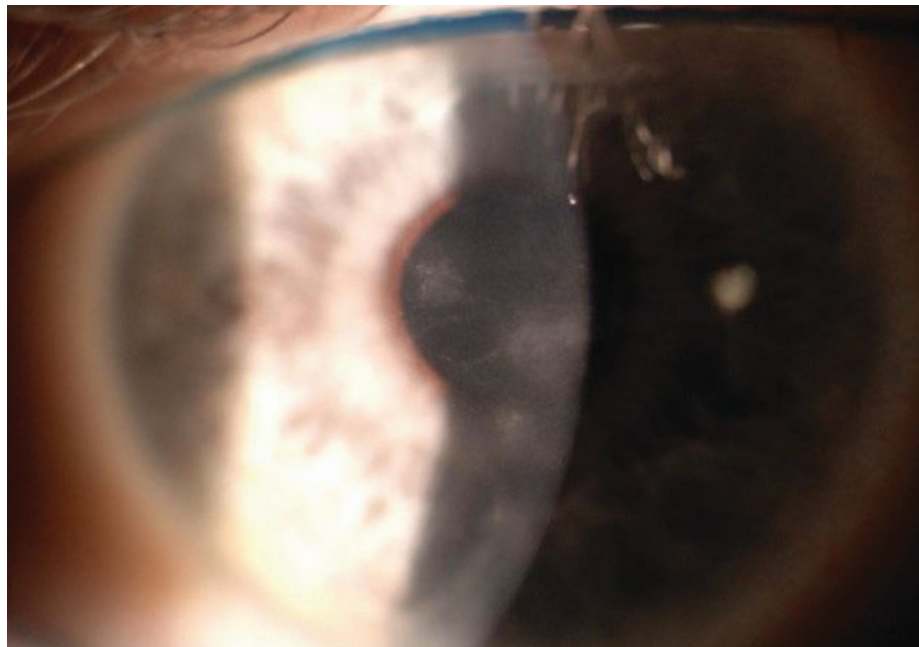
**Q** I have a 60-year-old patient who gets herpes simplex almost twice a year. Since taking prophylactic Valtrex (valacyclovir, GlaxoSmithKline), she has not had any new outbreaks. She now wants to get Shingrix (glycoprotein E, GlaxoSmithKline). What is recommended here?

**A** Shingrix, a shingles vaccine, was FDA-approved in 2017 for immunocompetent individuals who are at least 50 years old. It is a recombinant, adjuvant subunit vaccine that does not contain live virus. “Because it does not contain live virus, it will likely not be significantly affected by antiviral therapy,” according to Stephanie Klemencic, OD, of Cincinnati Vision Partners and the Cincinnati Eye Institute. “This allows our patients to continue their antiviral medications, such as Valtrex, while receiving this two-dose vaccine.”

## First-line Treatment

On the other hand, Zostavax (live-attenuated vaccine, Merck), the first shingles vaccine, contains live virus. Patients must cease antiviral medication use at least one to two days prior to vaccination with Zostavax and not resume use until at least two weeks later.

As of July 1, 2020, Zostavax is no longer sold in the United States. Some pharmacies and clinics may still have the vaccine in stock and use it until the supply



**Persistent opacities from past herpes simplex events are present in this eye.**

expires on November 18, 2020.

Shingrix is at the forefront of shingles vaccination, as it is almost two times more effective than Zostavax, at around 97%.<sup>1</sup> This is one of the main reasons the Advisory Committee on Immunization Practices recommends Shingrix as the preferred vaccine for reducing the incidence of herpes zoster.<sup>1</sup>

Vaccination with Shingrix should be every clinician’s first line of defense against herpes zoster ophthalmicus, Dr. Klemencic suggests. She recommends encouraging vaccination for patients who are potential candidates to prevent shingles and its complications, including post-herpetic neuralgia,

even if they already received the Zostavax vaccine.

Both herpes simplex and herpes zoster can be visually devastating ocular diseases, says Dr. Klemencic. Fortunately, patients have effective options that they can pair with a vaccine, she notes, one of them being antiviral therapy. Long-term suppressive doses of antiviral therapy can reduce the recurrence of herpes simplex virus by 50%, especially in those with recurrent episodes of stromal keratitis.<sup>2</sup> ■

1. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. *Morb Mortal Wkly Rep.* 2018;67(3):103-8.

2. Wilhelmus KR, Beck RW, Moke PS, et al. Acyclovir for the prevention of recurrent herpes simplex virus eye disease. *N Engl J Med.* 1998;339:300-6.

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# The Space Between

A unique OCT pattern will reveal what is affecting our elderly patient.

By Eric Dillinger, OD, and Mark Dunbar, OD

An 80-year-old Caucasian female presented with new floaters in her left eye, which started about a month ago. She reported her right eye sees well. Her past ocular history was significant for cataract surgery in both eyes more than 10 years ago. Her last eye exam was two years earlier. Her medical history was significant for hypertension and high cholesterol.

On examination, her best-corrected visual acuity was 20/30 OD and 20/400 OS. Confrontation visual fields were full-to-careful finger counting. The anterior segment was remarkable for posterior chamber lens implants in both eyes.

Dilated fundus exam showed clear media. She had moderate-size cups with good rim coloration and perfusion. The macula of both eyes were significant for changes (*Figure 1*). An SD-OCT is available for review of the right eye (*Figure 2*).

## Take the Retina Quiz

- How would you characterize the macula in the left eye?
  - Preretinal hemorrhage
  - Subhyaloid hemorrhage
  - Subretinal hemorrhage
  - Sub-RPE hemorrhage
- What is the cause of the hemorrhage in the left eye?
  - Valsalva maneuver
  - Polypoidal choroidal vasculopathy
  - Retinal arterial microaneurysm
  - Choroidal neovascularization (CNV)

3. How would you describe the OCT findings in the right eye?

- Normal
- Shallow elevation of the RPE and Bruch's membrane
- Double-layer sign
- RPE detachment

4. What is the correct diagnosis for the right eye?

- Early-stage age-related macular degeneration (AMD)
- Intermediate-stage dry AMD
- AMD with geographic atrophy
- Wet AMD with CNV

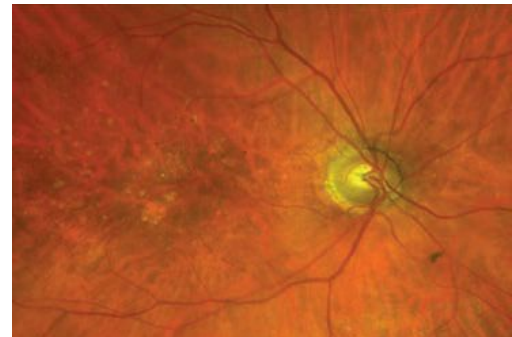
5. How should our patient be managed?

- Close observation
- Observe the right eye, anti-VEGF injection in the left eye
- Observe the right eye, surgical vitrectomy for the left eye
- Anti-VEGF injection in both eyes

For answers, see page 98.

## Discussion

It is obvious from the fundus photos that our patient has macular degeneration. The patient fits the demographic perfectly, and her clinical finds are also consistent with macular degeneration. In the right eye, there are scattered drusen in the macula and posterior pole. There is also a focal area of geographic atrophy that can be seen inferotemporal from the fovea. The clinical question



**Fig. 1. In these photos of the right (top) and left (bottom) eyes, where is the blood located?**

that needs to be determined—is this still dry AMD, or has she converted to the wet form of AMD?

To determine the stage of AMD, try and quantify the extent and size of the drusen. From the Beckman classification of AMD, early-stage AMD is defined as medium-sized drusen measuring between 63 $\mu$ m and less than 125 $\mu$ m with no pigmentary abnormalities. In intermediate-stage AMD, there needs to be at least one large drusen larger than 125 $\mu$ m and/or pigmentary abnormalities.<sup>1</sup>

The size of the drusen in our patient is at least 125 $\mu$ m, which, for comparison, is the size of the central



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Professional Strategies  
Healthy Eyes Advantage



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retinal veins. There are also pigmented abnormalities present, making this intermediate-stage AMD at minimum.

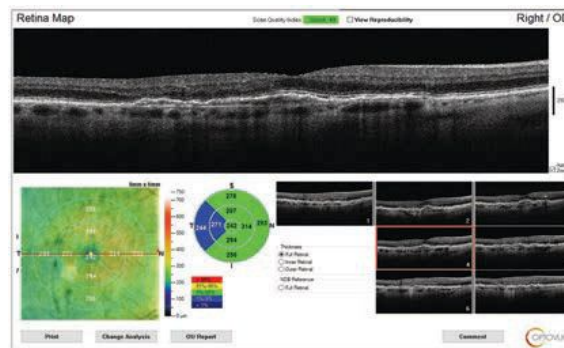
The macula looked flat, and there was no exudate or subretinal hemorrhage present, so, based on the clinical exam, she wouldn't have a CNV. However, the OCT tells a different story. On the OCT, we can see a shallow elevation of the RPE, and, below that, another reflective band that corresponds to Bruch's membrane. That OCT pattern has been referred to as a "double-layer sign (DLS)" and is very specific for CNV. With the DLS, the CNV resides in the space between the RPE and Bruch's membrane.<sup>2</sup> Unfortunately, based on this finding, our patient has probably converted to wet AMD.

The left eye is very striking, with the massive hemorrhage involving the macula. The blood is below the RPE and has caused a hemorrhagic detachment of the RPE due to a choroidal neovascular membrane. Unfortunately, we were not able to capture a quality OCT image.

## Management

The treatment for wet AMD has evolved considerably over the past 15 years. Intravitreal injections of anti-VEGF medication have revolutionized AMD management. These medications include ranibizumab, aflibercept and bevacizumab; all three show great efficacy in treating CNV. Treatment choices are based on physician preferences as well as economic considerations, with bevacizumab being the least expensive.

The majority of clinical trials have shown monthly injections to be slightly more favorable than PRN injections when it comes to visual outcomes. The main advantage of PRN injections is reduced treat-



**Fig. 2. What can you see in this SD-OCT of the right eye through the macula?**

ment frequency over the first year: approximately six to seven injections compared with 10 to 11 injections for monthly dosing.<sup>3</sup>

Treat and extend (T&E) is also a protocol many retinal specialists use around the world. They treat patients monthly for three months and every visit thereafter. If there is no sign of exudation, the treatment intervals are gradually extended for one to two weeks. When there are signs of recurrence, the intervals are shortened.

The ultimate goal is to maintain an exudation-free macula with minimal number of injections and fewer office visits. This might reduce the cost, but will it translate into comparable visual outcomes?

## Injection Scheduling

The TREX study compared monthly injections to T&E dosing and showed fewer injections (25.5 in the monthly group compared with 18.6 in the T&E groups) with similar visual acuity outcomes, though the monthly injection group trended toward better vision.<sup>4</sup>

Unfortunately, visual outcomes tend to worsen when patients receive less frequent injections. In the SEVEN-UP study, patients, at seven years, on average lost 8.6 letters from baseline.<sup>5</sup> Those receiving either fewer than five injections or

none lost on average 8.7 letters and 10.8 letters from baseline, respectively. Patients receiving more than 11 injections gained 3.9 letters from baseline.<sup>5</sup>

More recently, a 10-year study compared T&E vs. PRN dosing outcomes from Australia-New Zealand (ANZ) and Switzerland.<sup>6</sup> The investigators showed that the ANZ group's vision decreased by 0.9 letters from baseline at

10 years with a T&E regimen that resulted in a median of 5.3 injections/year compared with the Swiss patients, whose vision decreased by a mean of 14.9 letters on a PRN regimen with a median of 4.2 injections per year.

The study concluded that continuous treatment and more injections achieved better visual outcomes. Other studies show similar outcomes with the central message being that, on average, more injections translates into better vision.<sup>6</sup>

Our patient received intravitreal injections in both eyes. In the left eye, she received three monthly injections before discontinuing due to a guarded prognosis. Her vision is stable at 20/200. The right eye had monthly injections of bevacizumab (extended out to six weeks) for a total of 16 injections. Her vision has been stable at 20/30. ■

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4. Wykoff CC, Ou WC, Brown DM, et al. Randomized trial of treat-and-extend versus monthly dosing for neovascular age-related macular degeneration: two-year results of the TREX-AMD study. *Ophthalmol Retina*. 2017;1(4):314-21.

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# RETINAUPDATE2020

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# Equilibrium in the Eye

Immediate medical intervention can stabilize the acute angle-closure patient for LPI.

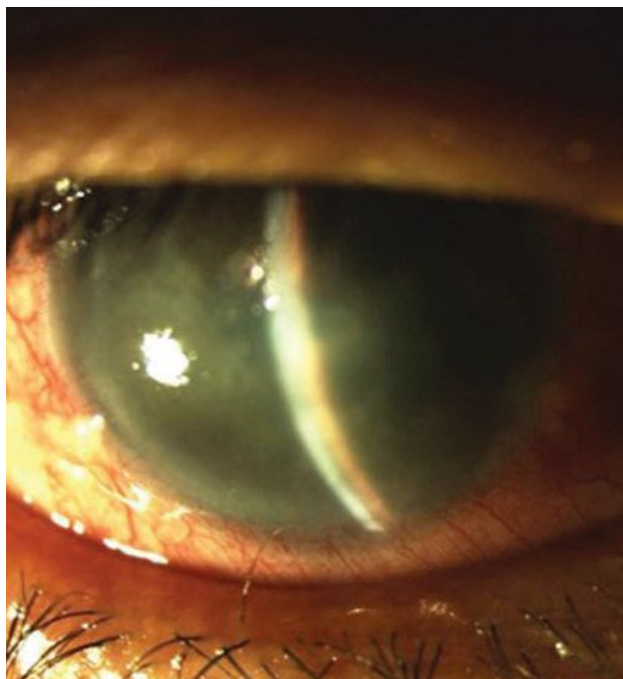
By Joseph W. Sowka, OD

**A**n 85-year-old woman was brought in by her family for a red right eye. The patient didn't express herself well verbally because of her age and because she spoke little English, but her family believed that she was having pain as well. When directly asked, she contradicted herself saying that it was painful and then later saying it wasn't.

The examination was a bit challenging due to some aging infirmities and generally poor cooperation (likely indicating that she was in pain), but her biomicroscopic examination revealed some rather significant corneal edema and a very shallow anterior chamber, which did not allow for a cell and flare assessment.

Her intraocular pressures (IOP) were 44mm Hg OD and 18mm Hg OS. Gonioscopy was challenging due to her cooperation and corneal edema, but the fleeting views of her right angle showed no structures. The assessment was a bit smoother in her left eye, and only anterior trabecular meshwork could be seen for about half of her angle.

Her current spectacles indicated that she was a +4.50D hyperope in each eye. Considering her refractive error, pronounced symptoms,



**Corneal edema in acute angle-closure attack.**

elevated IOP, shallow chamber and apparent lack of any angle structures on gonioscopy, she was diagnosed with an acute primary angle-closure attack in the right eye.

## Discussion

One of the most challenging and visually morbid conditions is primary angle-closure glaucoma (PACG), which can present either acutely or chronically. When acute, the symptomatic nature of the patient requires prompt and accurate intervention. When chronic, it can be overlooked and confused with primary open-angle glaucoma (POAG).

Patients with primary acute angle-closure glaucoma (PAACG) manifest the signs and symptoms of ocular and facial pain, unilateral blurred vision, photopsia in the form of colored haloes around lights and, occasionally, nausea and vomiting. Visual acuity may be reduced significantly in the involved eye, often to 20/80 or worse.<sup>1</sup>

PAACG is frequently unilateral, but may be bilateral and, as a rule, should always be considered to have bilateral potential, though the timing of the fellow eye involvement may be different.<sup>2</sup>

Applanation tonometry reveals IOP often in the range of 30mm Hg to 60mm Hg, occasionally higher in some cases.<sup>3</sup> Gonioscopy, which may prove difficult because of microcystic corneal edema, reveals no visible angle structures without indentation.

There is a high resistance to forward movement of aqueous through the iris-lens channel due to apposition between the posterior iris and anterior lens capsule, known as relative pupil block. This apposition is most pronounced when the pupil is in the mid-dilated state. In this situation, there is an increased pressure differential between the anterior and posterior chambers, creating a marked bowing forward (convexity) of the iris,



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termed iris bombé. Angle closure occurs when the peripheral iris physically opposes the trabecular meshwork and impedes aqueous outflow.

In primary pupil block, the tight apposition of the posterior iris to the anterior lens surface in the mid-dilated state must be broken, you must lower the IOP so that the iris can function normally and move from this mid-dilated, pupil-blocking state. Do this quickly, as structural damage to the nerve fiber layer and trabecular meshwork and functional damage to the visual field can occur quickly.<sup>4</sup>

## Management

Primary medication depends upon the pressure at presentation. As most miotics are ineffective at pressures over 40mm Hg due to iris ischemia, initially use aqueous suppressants such as topical beta-blockers, alpha-2 adrenergic agonists and carbonic anhydrase inhibitors.<sup>5,6</sup> These medications are typically dosed twice at 30-minute intervals as long as no medical contraindications exist. Prostaglandin analogs will not cause harm, but the medications' effects may be too slow to be effective in acute situations.<sup>7</sup> Also employ an oral carbonic anhydrase inhibitor (two 250mg acetazolamide tablets).

No reliable information exists regarding the efficacy of the topical rho-kinase inhibitor Rhopressa (netarsudil 0.02%, Aerie Pharmaceuticals). Rho-kinase inhibitors act mainly to enhance trabecular meshwork outflow, and this structure is physically impeded in PAACG, so this medication should have little or no effect.

Once the IOP is below 40mm Hg, use topical pilocarpine 1% or 2% to miosis and reopen the

angle. Avoid higher concentrations of pilocarpine, as they can lead to uveal congestion and worsen the condition. A hyperosmotic agent, such as three to five ounces of oral glycerin over ice, may also assist in lowering the IOP and breaking the attack.

It is safe to discontinue acute medical intervention when the IOP falls below 30mm Hg and the angle structures are again visible with gonioscopy. Maintain patients on topical medications as well as oral acetazolamide 500 mg QD-BID until surgical therapy can be obtained.

## Surgical Options

Standard treatment for PAACG is laser peripheral iridotomy (LPI) and should be performed as soon as safely possible.<sup>6,8</sup> LPI will allow the aqueous fluid pressure to equilibrate between the posterior and anterior chamber, permitting the iris to relax backward with dissipation of iris bombé, allowing aqueous access to trabecular drainage again.

Perform LPI subsequently on any fellow eyes that are potentially occludable. Incisional ocular surgery in the form of trabeculectomy, lens extraction, cyclodestructive procedures, glaucoma implant and goniosynechiolysis remain as options for cases unresponsive to medical and laser therapies.<sup>9</sup>

Trabeculectomy and goniosynechiolysis are often combined with cataract extraction. Kahook dual blade-assisted goniosynechiolysis and excisional goniotomy at the time of phacoemulsification safely provide significant reductions in both IOP and IOP-lowering medication burden in eyes with angle-closure glaucoma, while simultaneously improving visual acuity.<sup>10</sup>

After assessing the patient and determining she had no medical contraindications to any glaucoma medications, she was given two drops of Combigan (topical dorzolamide timolol/brimonidine, Allergan), separated by 30 minutes. She was also given two tablets of acetazolamide 250mg PO at the commencement of breaking her attack. A topical carbonic anhydrase inhibitor, Azopt (brinzolamide 1%, Novartis), was also instilled twice over a 30-minute period. After an hour, IOP in the involved eye dropped to 28mm Hg and she appeared to be more comfortable and in less distress.

She was discharged with the topical fixed-combination agent and acetazolamide 500mg sustained release, both to be used twice daily. At follow-up the next day, she was much more comfortable with near complete resolution of her corneal edema and an IOP of 19mm Hg. Subsequent examination was easier to perform and confirmed the diagnosis of an acute angle-closure attack. She was kept on the medications and scheduled for LPI. ■

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“ I didn't realize  
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were little dots that twinkled ”

—Misty L, *RPE65* gene therapy recipient

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# Evading the Hallmark of Glaucoma

Patients lost to follow-up aren't always a train wreck when they finally re-emerge.

By James L. Fanelli, OD

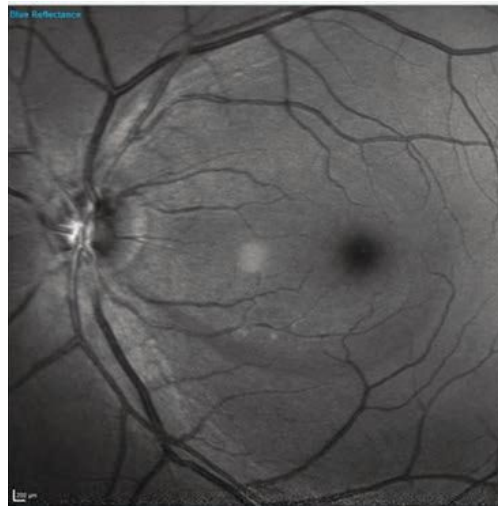
There's no avoiding the glaucoma patients and suspects who, for whatever reason, do not comply with follow-up care and visits. When they do eventually return to the office, most of the time their condition has worsened and your work has is much harder. Oddly enough, for one of my recent patients, the opposite was true.

## The Case

In 2016, a 66-year-old Caucasian male presented as a new patient. It had been about eight years since he had last seen an eye specialist. He reported gradually decreasing vision in both eyes that involved both distance and near. His medications included lisinopril, hydrochlorothiazide, Lipitor (atorvastatin calcium, Pfizer), famotidine, metformin, Cialis (tadalafil, Eli Lilly) and 81mg acetylsalicylic acid, and he reported no allergies to medications.

The patient's entering visual acuities were 20/40 OD and 20/30- OS, and his best-corrected visual acuities through hyperopic astigmatic and presbyopic correction were 20/20- OD and 20/25+ OS. His pupils were equal, round and reactive to light and accommodation, with no afferent pupillary defect, and his extraocular muscles were full in all positions of gaze.

Slit lamp examination of the anterior segment was essentially unremarkable. The patient's appla-



**Fig. 1. Note the inferior wedge defect clearly visible in the patient's left eye.**

nation tensions were 18mm Hg OD and 19mm Hg OS.

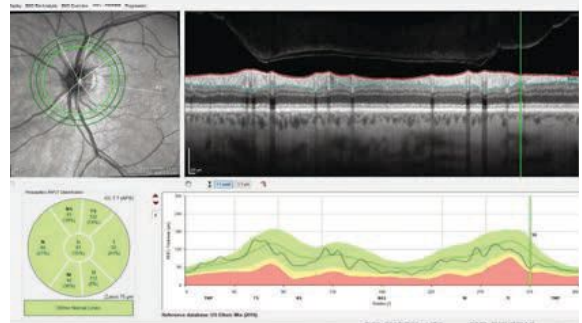
Through dilated pupils, the patient's crystalline lenses were characterized by early nuclear sclerosis bilaterally and cortical spokes in the anterior cortex outside of the visual axis. His optic nerves were characterized by cup-to-disc ratios of 0.3/0.3 OD and OS. The neuroretinal rims were plush and well-perfused.

The patient's retinal vascular examination revealed mild arteriolar-sclerotic retinopathy and venular dilation consistent with well-controlled type two diabetes. His last HbA1c was 6.2, which

was obtained about four months prior. There was no evidence of neovascularization or diabetic macular edema in either eye. Both maculae had age-consistent retinal pigment epithelium granulation. Bilateral posterior vitreous detachment was present, and the peripheral retinal evaluation was normal OU.

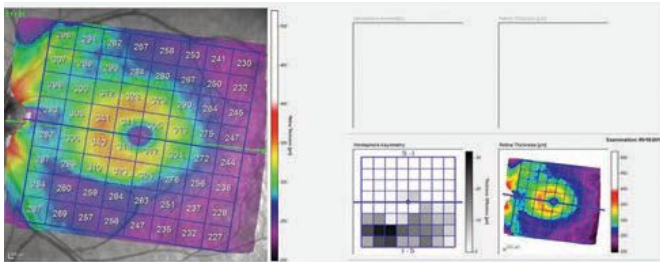
Of interest in the patient's left eye was a clearly visible retinal nerve fiber layer (RNFL) wedge defect originating inferiorly just temporal to the foveal avascular zone and extending to the optic nerve (Figure 1). The wedge defect was consistent with those often seen in glaucoma. But similar wedge defects are also seen in focal anterior retinal vascular problems, such as severe arteriolar stenosis. A closer look at the vasculature in this area did not raise any red flags to indicate that this wedge defect was of vascular origin.

Given the lack of a suggested vascular etiology, the question turned



**Fig. 2. The patient's inferotemporally thinned RNFL in the area of the wedge defect measured 56µm.**





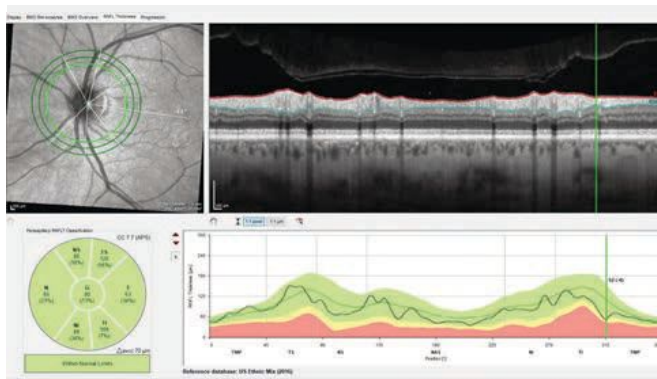
**Fig. 3. Total retinal thickness in the left macula shows asymmetry between the superior and inferior hemispheres, with the inferior hemisphere thinner in the area of the wedge defect.**

into whether the wedge defect was associated with early-onset glaucoma, as the optic nerve was normal in appearance and the neuroretinal rim did not appear to be compromised. Accordingly, I asked the patient to return for further evaluation.

The patient presented about three weeks later, at which point his intraocular pressures were essentially the same. His pachymetry readings were 566 $\mu$ m OD and 549 $\mu$ m OS. Periopic RNFL scans of the left eye demonstrated a depression in the area of the wedge defect OS (Figure 2). The macular scan also showed hemispheric asymmetry in the area of the wedge defect (Figure 3). The Bruch's membrane opening minimum rim width (BMO-MRW) scan had a normal appearance, indicating that the wedge defect did not extend into the neuroretinal rim. The clini-

cal appearance as seen *in vivo* confirmed this finding. There was not enough firm evidence at this time that the patient did, in fact, have glaucoma, but he did need close monitoring. I scheduled a threshold field test for a month out, but he was a no-show. He was lost to follow-up until this past August, at which point he returned with complaints of gradually decreasing vision OU. I anticipated that his cataracts had progressed (they had) and was worried that he had developed frank glaucoma in the interim.

Surprisingly, repeat imaging of the periopic RNFL, the macula and the BMO-MRW did not indicate any significant changes over the four-year period (Figures 4 and 5). Funduscopically, the wedge defect was still present but did not appear to have enlarged. This certainly made my life easier, as no change meant no conversion to glaucoma. This was not what I was expecting and was a rare surprise. I asked the patient to return in a year. Will he show up this time? I'll let you know in a year.



**Fig. 4. Note the difference of only 4 $\mu$ m in the wedge defect and overall stability in this follow-up scan of the periopic RNFL.**

cal appearance as seen *in vivo* confirmed this finding.

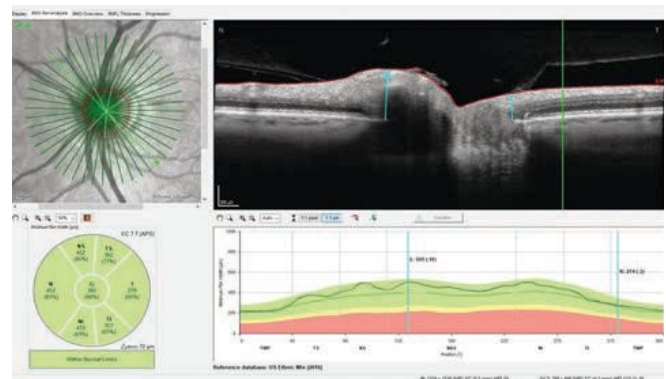
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## Discussion

One of the hallmark structural signs of glaucoma is change that worsens over time. With the advances in OCT technology that we've experienced over the past several years, determining this change is now much easier, improving the quality of glaucoma care for our patients.

It's incumbent that we as clinicians obtain quality baseline measurements of areas susceptible to glaucomatous damage so that we have a point of comparison. It's necessary to obtain baseline scans in all three areas where glaucomatous damage can occur, namely the neuroretinal rim, circumpapillary RNFL and macula. In reality, while damage can be seen in any or all of these areas, we really don't know exactly where the damage initially presents and progresses from. It may be that damage occurs initially in different locations depending on patient-specific characteristics.

While there are many pieces to the glaucoma puzzle, structurally there are only two scenarios: stability or progression. Glaucoma does not get better; loss of the neuroretinal rim tissue of ganglion cells does not reverse and regenerate. Taking advantage of the technology we have at our disposal is our best chance of pinpointing which situation we're dealing with. ■



**Fig. 5. The neuroretinal rim remained stable compared with baseline despite the four years the patient was lost to follow-up.**

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# Up Your ERM Referral Game

Innovations in instrumentation have made epiretinal membrane surgery a more viable option for many patients. **By Derek N. Cunningham, OD, and Walter O. Whitley, OD, MBA**

**E**piretinal membranes (ERMs) are caused by defects in the surface layer of the retina. Glial cells are released, migrating through and developing a membranous sheet on the retinal surface. They may look like a piece of cellophane, a wrinkle or puckered folds on the retina.

ERMs are one of the most common reasons to refer a patient for a retinal consultation. Historically, most optometrists waited until a patient's best-corrected visual acuities were life-limiting before sending them for a surgical consultation. This delay was due to the risks associated with surgical intervention and the limitations of visual recovery.

The threshold for recommending surgery, however, has changed dramatically over the last few decades. More precise instruments coupled with better imaging systems have effectively lowered the risks that come with surgery. These advancements have also led to much better re-establishment of macular architecture in even the mildest cases of ERM. It's not uncommon any more to refer a patient for membrane peel surgery who has a best-corrected visual acuity around 20/20 but suffers from metamorphopsia.



**New techniques limit the risks associated with surgical intervention for ERMs.**

## Surgical Intervention

Many great innovations are now available to assist retinal surgeons in removing ERMs, such as the 25-gauge Finesse Sharkskin ILM Forceps (Alcon). With smaller instruments and faster cutting speeds, surgeons can use less force when separating retinal layers and attempt to peel membranes that would otherwise be considered too risky.

Surgeons now use fine forceps to tease away strong adhesion areas and a green dye for better visualization of the internal limiting membrane. Partway through the procedure, surgeons can change the color channel for better visualization of the dye that stains the internal limiting membrane. The macula appears paler once both the internal limiting membrane and ERM are removed.

With this technique, surgeons can remove both of these layers in one step as opposed to two, which was typical of the procedure up until this point, and

ensure complete removal of the membrane with the best chance of re-establishing normal foveal architecture.

Due to the advancements in instrumentation, postoperative sutures are no longer required for ERM surgery. This allows for a much more comfortable and smoother post-op experience. Although the surgery is usually performed in a hospital or surgical center, it is an outpatient procedure.

While the patient can lead a relatively normal life starting the following day, post-op restrictions include Valsalva-type straining and swimming for two weeks. Medications include topical antibiotics and anti-inflammatories for several weeks.

Complication risks are small, with about one in 100 patients developing retinal detachment and one in 2,000 developing infection post-surgery.<sup>1</sup> Those who still have their natural lens have an increased risk of cataract progression.<sup>1</sup>

Any amount of macular structural integrity loss that causes visual consequences should warrant a conversation about the potential risks and benefits of surgical intervention. Even the subtlest levels of visual distortion can often be improved with minimal risk to the patient thanks to new advances in the field. ■



For a video of this procedure, visit [www.reviewofoptometry.com](http://www.reviewofoptometry.com) or scan the QR code.

1. American Society of Retina Specialists. Epiretinal membranes. [www.asrs.org/patients/retinal-diseases/19/epiretinal-membranes](http://www.asrs.org/patients/retinal-diseases/19/epiretinal-membranes). Accessed September 3, 2020.

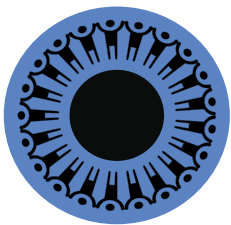
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## Diagnostic Testing

### VR Headset for Visual Field Testing

A new heads-up virtual reality display called VisuAll allows practices to perform threshold perimetry in about three minutes and screenings in 90 seconds, says manufacturer Olleyes. The device analyzes retinal sensitivity in patients with glaucoma and other visual disorders and enables examination of multiple patients at a time in a number of settings, increasing office productivity, according to Olleyes.

VisuAll includes commonly used perimetry protocols (10-2, 24-2, 30-2) as well as some specific to pediatric testing. However, the company says its platform is more than just a portable perimeter; rather, it's a multi-test system that includes acuity testing, color vision and more to come.

Visit [olleyes.com](http://olleyes.com).



### New Genetic Test for AMD

Optometrists who want to include genetic testing in their AMD work-ups have a new option to consider. Start-up company Visible Genomics has launched a test that helps clarify a patient's likelihood of developing AMD, according to a press release. The saliva-based test captures the patient's genetic status, which is then combined with ocular findings and demographic and lifestyle characteristics in the Visible Genomics risk assessment. The results, the company says, could shed light on an AMD patient's progression risk and the lifetime risk of those with affected family members.

Visit <https://visiblegenomics.io/about-amd>

## Dry Eye/Allergy

### Dry Eye Mask You Can See Through

Warm compresses are a mainstay of dry eye therapy, but clinicians may notice patients struggling to carve out the time to use a traditional eye mask. A new start-up company, TearRestore, is debuting a system designed to overcome this compliance issue. The reusable heat



packs target the meibomian glands without covering the eyes, leaving the user free to continue with their daily routine, according to the company. The heat pack clicks into a head-mounted mask for a hands-free experience.

Patients can purchase the TearRestore mask with two reusable heat packs or the TearRestore bundle, which includes the mask, three heat packs and a reactivation kettle.

Visit [www.tearrestore.com](http://www.tearrestore.com).

### Allergy Drop Goes Preservative-free

The ocular allergy mainstay Alaway (ketotifen fumarate 0.035%) from Bausch + Lomb will come in a preservative-free option next spring, according to a press release from the company. The new formulation was recently approved by the FDA.

B+L says this will be the first preservative-free over-the-counter antihistamine on the market, and it relieves ocular itching due to pollen, ragweed, grass, animal hair and dander. The press release states that the drug works within minutes and can provide up to 12 hours of relief with one dose.

Visit [www.bauschhealth.com](http://www.bauschhealth.com).



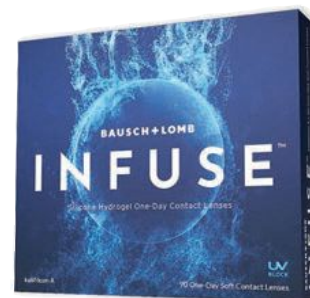
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Infuse is available in powers of -12D to +6D, with half-diopter steps in the -12D to -6D range and quarter-diopter steps thereafter. The material, kalifilcon A, has a Dk/t of 134 and a 55% water content.

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# Decreased Vision Indecision

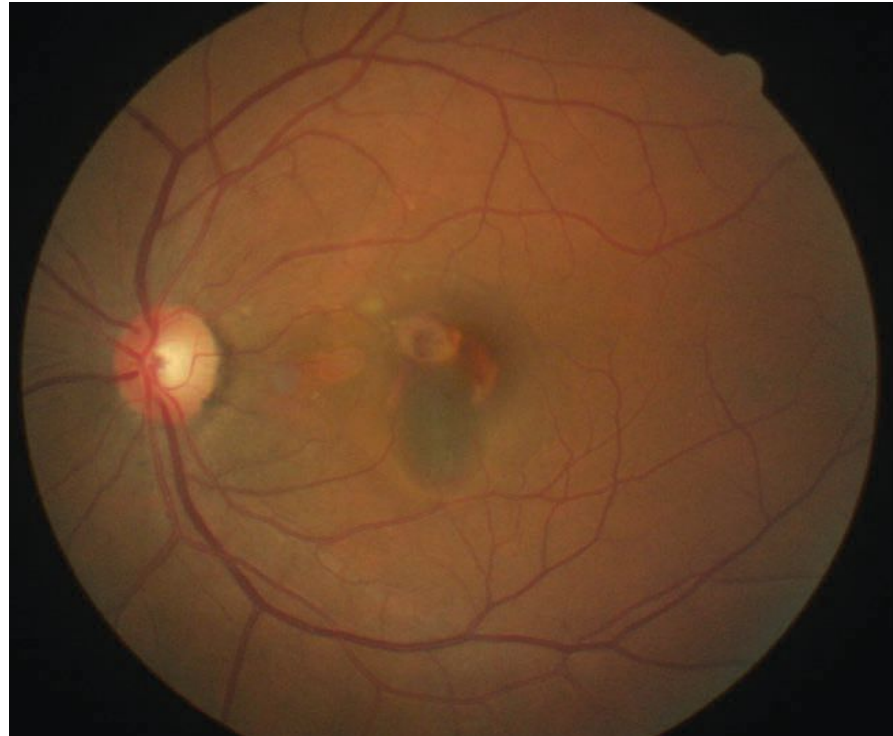
Macular involvement and a swift decline in acuity prompt many questions about the condition's causes and potential interventions. **By Andrew S. Gurwood, OD**

## History

A 67-year-old African female presented with a chief complaint of sudden-onset blurred vision OS. Her history was positive for mild cataracts; otherwise, she had excellent ocular health. Her systemic history was positive for hypertension, for which she was adequately controlled with medication.

## Diagnostic Data

Her best-corrected entering visual acuities were 20/20 OD and 20/400 OS at distance and near. Her external examination was normal with the exception of the facial confrontation field, which revealed a large relative central scotoma. There was no evidence of afferent pupillary defect. The biomicroscopic examination of the anterior segment was normal with mild, grade II lenticular opacities OU. Goldmann applanation tonometry measured 15mm Hg OU. The pertinent posterior pole pathology OS is demonstrated in the photograph.



**What's causing the presentation shown here? What is the best course of action?**

## Your Diagnosis

Does the case presented here require any additional tests, history or information? What

would be your diagnosis? What is the patient's likely prognosis? To find out, please visit [www.reviewofoptometry.com](http://www.reviewofoptometry.com). ■

### Next Month in the Mag

Coming in November, *Review of Optometry* will present an overview of pertinent topics in ocular surface health. Articles in this series will include:

- Red Eye Remedies: New Ideas for an Old Problem
- Evaluating and Protecting the Meibomian Glands

- Answering the "Why?" in Dry Eye
- Artificial Tears: Yes, Differences *Do* Matter
- Accounting for Lid Wiper Epitheliopathy

*Also included in November:*

- How CNS Diseases Affect the Eye—and the Optometrist

**Retina Quiz Answers** (from page 82)—Q1: d, Q2: d, Q3: c, Q4: d, Q5: d

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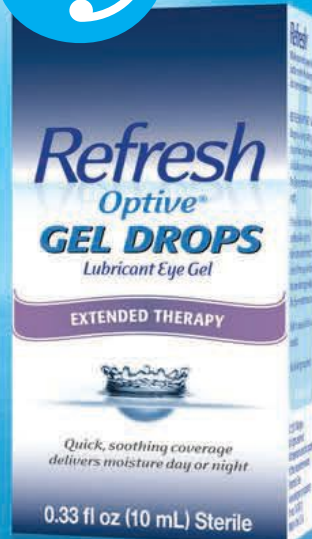




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