Visual Hallucinations in the Dementia Spectrum, *p. 40* • Urgent Care: Corneal Edema, *p. 98*

REVIEW® of OPTOMETRY

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HOW TO CAPITALIZE ON OPTOMETRIC SCOPE

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HOW TO CAPITALIZE ON OPTOMETRIC SCOPE EXPANSION

This four-part series describes where things stand and the steps you should take to add new services.

This month: incisions and injections, p. 32
June: lasers • July: glaucoma • August: oral meds

Imagine an EYE-OPENING Lift

INDICATION

Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is indicated for the treatment of acquired blepharoptosis in adults.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of acquired ptosis with decreased levator muscle function and/or other neurologic signs.
- Alpha-adrenergic agonists as a class may impact blood pressure. Advise Upneeq patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use Upneeq with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.
- Upneeq may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop.
- Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

ADVERSE REACTIONS

Adverse reactions that occurred in 1-5% of subjects treated with Upneeq were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation, and headache.

DRUG INTERACTIONS

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta blockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.
- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

The only FDA-approved prescription eyedrop proven to lift upper eyelids in adults with acquired blepharoptosis (low-lying lids)[1]

Images are of actual patients. Individual results may vary. Average upper eyelid lift with Upneeq in clinical trials was 1 mm.[2]

UPNEEQ®

(oxymetazoline hydrochloride ophthalmic solution), 0.1%

Now available to sell in your practice!*

Sign up now at https://upneeq.rvlpharma.com/signup

*Some states may not participate.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact RVL Pharmaceuticals at 1-877-482-3788. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see next page for Brief Summary of full Prescribing Information.

References: 1. Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1%. [Prescribing Information]. RVL Pharmaceuticals, Inc; 2021. **2.** Data on file. RVL Pharmaceuticals, Inc.

RVL PHARMACEUTICALS, INC.

Distributed by: RVL Pharmaceuticals, Inc.
Bridgewater, NJ 08807
Customer Service 1-866-600-4799

UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for topical ophthalmic use

BRIEF SUMMARY: The following is a brief summary only; see full Prescribing Information at https://www.upneeq.com/Upneeq-PI.pdf for complete information.

1 INDICATIONS AND USAGE

UPNEEQ is indicated for the treatment of acquired blepharoptosis in adults.

2 DOSAGE AND ADMINISTRATION

Contact lenses should be removed prior to instillation of UPNEEQ and may be reinserted 15 minutes following its administration.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least 15 minutes between applications.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Ptosis as Presenting Sign of Serious Neurologic Disease

Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of ptosis with decreased levator muscle function and/or other neurologic signs.

5.2 Potential Impacts on Cardiovascular Disease

Alpha-adrenergic agonists may impact blood pressure. UPNEEQ should be used with caution in patients with severe or unstable cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

5.3 Potentiation of Vascular Insufficiency

UPNEEQ should be used with caution in patients with cerebral or coronary insufficiency, or Sjögren's syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

5.4 Risk of Angle Closure Glaucoma

UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

5.5 Risk of Contamination

Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

A total of 360 subjects with acquired blepharoptosis were treated with UPNEEQ once daily in each eye for at least 6 weeks in three controlled Phase 3 clinical trials, including 203 subjects treated with UPNEEQ for 6 weeks and 157 subjects treated with UPNEEQ for 12 weeks. Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation, and headache.

7 DRUG INTERACTIONS

7.1 Anti-hypertensives/Cardiac Glycosides

Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives, and/or cardiac glycosides is advised.

Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.

7.2 Monoamine Oxidase Inhibitors

Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on UPNEEQ use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. In animal reproduction studies, there were no adverse developmental effects observed after oral administration of oxymetazoline hydrochloride in pregnant rats and rabbits at systemic exposures up to 7 and 278 times the maximum recommended human ophthalmic dose (MRHOD), respectively, based on dose comparison. [see Data]. The estimated background risks of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Effects on embryo-fetal development were evaluated in rats and rabbits following oral administration of oxymetazoline hydrochloride during the period of organogenesis. Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 0.2 mg/kg/day in pregnant rats during the period of organogenesis (28 times the MRHOD, on a dose comparison basis). Oxymetazoline hydrochloride did not cause adverse effects to the fetus at oral doses up to 1 mg/kg/day in pregnant rabbits during the period of organogenesis (278 times the MRHOD, on a dose comparison basis). Maternal toxicity, including decreased maternal body weight, was produced at the high dose of 1 mg/kg/day in pregnant rabbits and was associated with findings of delayed skeletal ossification.

In a rat prenatal and postnatal development study, oxymetazoline hydrochloride was orally administered to pregnant rats once daily from gestation day 6 through lactation day 20. Maternal toxicity was produced at the high dose of 0.2 mg/kg/day (28 times the MRHOD, on a dose comparison basis) in pregnant rats and was associated with an increase in pup mortality and reduced pup body weights. Delayed sexual maturation was noted at 0.1 mg/kg/day (14 times the MRHOD, on a dose comparison basis). Oxymetazoline hydrochloride did not have any adverse effects on fetal development at a dose of 0.05 mg/kg/day (7 times the MRHOD, on a dose comparison basis).

8.2 Lactation

Risk Summary

No clinical data are available to assess the effects of oxymetazoline on the quantity or rate of breast milk production, or to establish the level of oxymetazoline present in human breast milk post-dose. Oxymetazoline was detected in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for UPNEEQ and any potential adverse effects on the breastfed child from UPNEEQ.

8.4 Pediatric Use

Safety and effectiveness of UPNEEQ have not been established in pediatric patients under 13 years of age.

8.5 Geriatric Use

Three hundred and fifteen subjects aged 65 years and older received treatment with UPNEEQ (n = 216) or vehicle (n = 99) in clinical trials. No overall differences in safety or effectiveness were observed between subjects 65 years of age and older and younger subjects.

10 OVERDOSAGE

Accidental oral ingestion of topical intended solutions (including ophthalmic solutions and nasal sprays) containing imidazoline derivatives (e.g., oxymetazoline) in children has resulted in serious adverse events requiring hospitalization, including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma. Keep UPNEEQ out of reach of children.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use).

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PM-US-UPN-0203 01/21

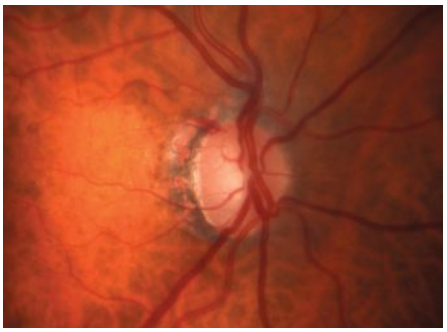
Glaucoma May Get the Stem Cell Treatment

This potentially revolutionizing therapy may offer protection and restoration to the trabecular meshwork.

Current glaucoma therapies are limited to altering the eye's intraocular pressure (IOP), but a recent article proposes another possible therapy pathway: stem cells. Glaucomatous eyes have reduced cellularity in the trabecular meshwork, which has been linked to elevated IOP in mice. The authors wrote that repairing cellularity may improve aqueous outflow, prevent retinal ganglion cell apoptosis and prevent vision loss from elevated IOP. They proposed further investigation into the use of stem cells to not only replace but also proactively protect the trabecular meshwork cells. "That could revolutionize the management of glaucoma," they wrote.

Trabecular meshwork stem cells were first discovered in 1989 in a study that also demonstrated that these resident stem cells can be stimulated to repopulate an area of laser-damaged tissue in human post-mortem eyes. Subsequent studies on human eyes reported that the number of trabecular meshwork stem cells decreases with age and that this decrease is likely associated with diminished cell reproduction capacity. Other *in vivo* mouse model studies found that these stem cells can expand *in vitro* and preferentially integrate *in vivo* into the trabecular meshwork region to become functional after transplantation.

Photo: Michael Chaglasian, OD



Transplantation of stem cells could restore TM function in glaucoma patients.

Native trabecular meshwork cells, adipose-derived and bone marrow-derived mesenchymal stem cells and induced pluripotent stem cells can all be differentiated into trabecular meshwork-like cells and have been successfully integrated into live mouse models to generate IOP homeostasis. So far, studies indicate these cells remain stable for extended periods of time without serious side effects.

The authors noted that a human clinical study should be the next step toward developing this novel treatment. While studying larger animals first would be ideal, they say there isn't a good animal analog of trabecular meshwork changes that occur in humans with angle-closure glaucoma.

Adipose-derived mesenchymal stem cells are the prime candidate for human trials, they argue. One advantage of these cells is that they're autologous, which would decrease the risk of immune rejection. They're also easily obtained through minimally invasive procedures and have a low risk of tumorigenesis.

"Transplantation of human stem cells to restore trabecular meshwork function in glaucomatous eyes is a potentially vision-saving, revolutionary treatment that could impact the lives of millions," the team wrote in their paper on the work.

Coulon SJ, Schuman JS, Du Y, et al. A novel glaucoma approach: stem cell regeneration of the trabecular meshwork. Prog Ret Eye Res. April 6, 2022. [Epub ahead of print].

IN BRIEF

Can UV-Blocking Contacts Mitigate Presbyopia? Ultraviolet radiation (UVR) is recognized as a risk factor for cataracts, pterygia and other eye health concerns, but little is known about its effect on vision. So, researchers recruited 210 pre-presbyopic patients to examine the effects of long-term UVR-blocking contact lenses on multiple factors.

UVR autofluorescence of the conjunctiva was not significantly affected by the UVR-blocking contact lenses. Comparing amplitude of accommodation and the stimulus response curve didn't show a significant difference between participants who wore full UVR-blocking vs. minimal UVR-blocking lenses for the past five years or more. However, the **additional amplitude of those who had worn UVR-blocking lenses was +0.25D** measured objectively at 5D of accommodative demand and +0.7D measured subjectively at the average amplitude of accommodation of around 7.5D of demand."

The amplitude of accommodation measured by push-up or the maximum negative powered lens that distance targets could be resolved through without debilitating blur was lower in the Hong Kong patient cohort. **"As the region with the highest UVR exposure of the cohorts examined in this study, this concurs with the high incidence of presbyopia occurring at younger ages that has been reported in countries with high levels of UVR,"** the authors explained.

Accommodative latency was found to be shorter in those wearing full UVR-blocking contact lenses, suggesting UVR exposure can have an impact on presbyopia. The cohort from Houston had a shorter latency, faster speed and higher step size than several other regions.

In conclusion, **blocking the transmission of UVR seems beneficial in maintaining the eye's ability to focus, suggesting presbyopia may be delayed in long-term UVR-blocking contact lens wearers.** These lenses also provide protection to the critical limbal region.

Wolffsohn JS, Dhallu S, Aujla M, et al. International multi-centre study of potential benefits of ultraviolet radiation protection using contact lenses. Cont Lens Anterior Eye. April 15, 2022. [Epub ahead of print].

Hair Loss Drug Ups Risk of MGD, Ocular Surface Issues

In an effort to characterize dry eye disease (DED) in patients taking finasteride, a potent targeted anti-androgenic medication, researchers recently found an association between usage of the drug and meibomian gland dysfunction (MGD), in addition to conjunctival and corneal abnormalities. They noted that androgen-sensitive meibomian glands may be altered by anti-androgen medications, especially finasteride, given its unique potency and targeted effects compared with other anti-androgenics. The team presented their findings earlier this month at the 2022 ARVO conference in Denver.

The extended case series had a mean follow-up period of 55 months. It included a retrospective chart review of 116 DED patients on finasteride seen in the Scheie Eye Institute Dry Eye Clinic at the University of Pennsylvania from 2005 through 2021 (average age: 67.9, 95% male, 86% Caucasian). Patient demographics, diagnosis, prior treatment, questionnaire data and DED clinical exam outcomes were extracted. The researchers performed statistical analysis to assess clinical characteristics and Ocular Surface Disease Index (OSDI) scores among patients on varying doses of finasteride (23 patients were taking 1mg or 2.5mg, and 93 were taking 5mg).

Photo: Getty Images

Meibomian glands are adversely affected by anti-androgenic medications, study finds.

When comparing exam findings during the initial and follow-up exams, the latter visit saw a significantly greater percentage of patients present with MGD (62.9% vs. 85.3%), conjunctival abnormalities (21.1% vs. 41.9%) and corneal abnormalities (26.3% vs. 40.5%). Mean OSDI score was 24.4 and slightly higher in patients taking 5mg of finasteride, though this was not statistically significant. Low-dose finasteride use was associated with a greater frequency of cyclosporine use at the first (26.1% vs 6.5%) and last exams (25% vs. 3.4%). Otherwise, treatment modalities were no different between the low- and high-dose groups.

"To our knowledge, this represents the largest demographic study over 15 years of DED patients on finasteride," the study authors concluded. "This study reinforces the importance of considering the long-term effects of finasteride use on DED as part of the systemic sequelae of androgen depletion and provides anticipatory guidance for patients and ophthalmologists."

Original abstract content ©Association for Research in Vision and Ophthalmology 2022.

Nguyen B, Meer E, Gupta A, et al. The effect of finasteride on dry eye disease. ARVO 2022 annual meeting.

Study Highlights Unique Impact of Hormones on KCN

The multiple factors that can contribute to the onset and progression of keratoconus, including environment, genetics and hormonal imbalances, have been well established. However, questions remain regarding the pathobiology of the condition. In a recent study, researchers sought to establish the relationship between sex hormones and their receptors and the disease process of keratoconus. They presented their findings during the 2022 ARVO conference in Denver.

To determine the interaction between major androgens/estrogens and sex hormone receptors in healthy and keratoconus corneal stromal cells, the study authors used a 3D *in vitro* self-assembled extracellular matrix model. The *in vivo* analysis measured androgen/estrogen ELISA expression before and after corneal crosslinking (CXL) among patients with keratoconus.

The authors observed significant changes between healthy corneas and those with keratoconus, as well as between males and females in the tested sex hormone receptors. Estrone and estriol stimulation among healthy women revealed significant up-regulation of the androgen receptor, progesterone receptor and estrogen receptor beta compared with men. The data also showed higher expression of estrogen receptor alpha and estrogen receptor beta in women vs. males with keratoconus.

Following CXL, DHEA sulfate levels were found to be lower while estrone and estriol levels were higher. These *in vivo* findings indicate this treatment affects the corneal tissue and modulates hormonal levels in the bloodstream, according to the researchers.

"Our data suggests that the human cornea is a sex-dependent and a hormone-responsive tissue. We posit that keratoconus is a systemic disease, at least initially, and is heavily dependent on systemic and local hormone alterations," the study authors concluded.

Original abstract content ©Association for Research in Vision and Ophthalmology 2022.

Karamichos D, Escandon P, Nicholas S, et al. The surprising impact of hormones on keratoconus. ARVO 2022 annual meeting.

Disulfiram Could Improve Sight in RP

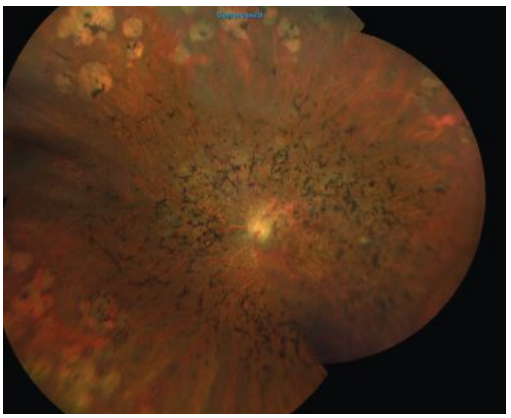
Inhibiting retinoic acid synthesis with this medication, a deterrent of alcohol abuse, improves behavioral image detection in vision-impaired mice.

Rod and cone photoreceptors degenerate in retinitis pigmentosa. Downstream neurons survive and undergo physiological changes, including accelerated spontaneous firing of retinal ganglion cells (RGCs). Retinoic acid is the molecular trigger of RGC hyperactivity, but whether this interferes with visual perception is unknown. Researchers recently found that retinoic acid-induced retinal hyperactivity was a major contributor to vision impairment in mice. They believe that inhibiting retinoic acid could lead to a new therapeutic strategy for mitigating vision loss that may be applicable across a wide range of photoreceptor degenerative disorders, regardless of the underlying etiology.

The team used a pharmacological approach to block retinoic acid signaling and discriminate the effects of decreased signal from increased noise. Indirect evidence strongly suggests retinoic acid-induced retinal hyperactivity contributes to human vision impairment. Direct evidence, however, is difficult to obtain because methods for detecting hyperactivity are invasive and therefore inappropriate for humans.

The researchers' previous studies had shown that retinoic acid-induced hyperactivity is maladaptive, presenting background noise that obscures signals that are already attenuated by the loss of photoreceptors. Their current study found that this hyperactivity specifically impairs not only simple light detection but also higher-order visual capabilities, such as reliable detection of specific visual scenes.

Photo: Mark Dunbar, OD



Retinoic acid inhibitors could be able to treat patients with retinitis pigmentosa.

To assess whether disulfiram can inhibit degeneration-dependent activation of the retinoic pathway, the researchers injected the eyes of rd10 mice with the RAR reporter virus early in degeneration. They continuously provided them with ad libitum regular food or food containing disulfiram (2mg/kg) for 20 to 30 days and imaged their retinas later in degeneration.

They found that inhibiting retinoic acid does not affect events in the outer retina, leaving events in the inner retina as the primary mechanism of retinoic acid-induced hyperactivity. The study's results on vision-impaired mice revealed that disulfiram improves behavioral contrast sensitivity, sharpens cortical neuron representations of spatial orientation and increases the fidelity of responses to naturalistic scenes, all consistent with improved visual perception.

"Whether disulfiram will improve vision in humans remains to be seen, but the barriers to answering this question seem relatively low," the researchers wrote in their paper. "If disulfiram shows efficacy, then it could be administered orally, but local ocular delivery involving a new drug formulation might ultimately be more appropriate for avoiding the undesired systemic consequences associated with alcohol consumption."

"Vision restoration therapies are aimed, at least for now, at the small fraction of patients with end-stage photoreceptor degeneration, but treatments targeting the retinoic acid pathway may be relevant to the much larger patient population with low vision," they concluded.

Telias M, Sit KK, Frozenfar D, et al. Retinoic acid inhibitors mitigate vision loss in a mouse model of retinal degeneration. Sci Adv. March 18, 2022. [Epub ahead of print].

IN BRIEF

Laser Scleral Microporation as Emerging Treatment for Presbyopia. Two surgeons presented data last month at the ASCRS 2022 conference in Washington, DC on an interesting new way to treat presbyopia by "uncrosslinking" scleral fibers to create a more pliable structure that can be more responsive to contraction of the ciliary muscle. Called **laser scleral microporation (LSM), the procedure uses an erbium YAG laser to create tiny pores within the sclera,** which is treated in four quadrants (superotemporal, inferotemporal, superonasal and inferonasal). The resultant loosening of the sclera can re-establish some accommodative effect lost due to aging, explained Robert Ang, MD, and Mitchell Jackson, MD.

The treatment was able to reduce average add power needed to achieve reading acuity from 2.03D to 1.43D. Uncorrected near visual acuity improved from 20/63 to 20/32.

As the effect is sparing of the visual axis, it does not compromise distance vision and it can be combined with other presbyopia interventions, both doctors noted. The procedure is in early development and numerous improvements are being pursued, the presenters explained, including **faster treatment times and eye tracking/registration to allow retreatment.**

Ang M. Early pilot study results of laser scleral microporation in presbyopic eyes. ASCRS 2022 Washington, DC.

Jackson M. Comparison of laser scleral microporation to current therapeutics in presbyopia. ASCRS 2022 Washington, DC.

Alabama Scope Bill Fails to Pass the House

The legislation would've allowed the state's ODs to perform various in-office procedures. Advocates vow to retrench and try again. Meanwhile, Nebraska eyes a 2023 push of its own.

It's been 27 years since Alabama has expanded the state's optometric scope of practice—and things will stay that way for now after the defeat of a recent bill. Optometrists in 21 states are currently allowed to do more than those who practice in Alabama, including perform various types of ocular surgeries, lesion removal and administer injections. Eager to update the law to match the current education and training of optometrists, which has greatly evolved since the state's last scope bill passed in 1995, the Alabama Optometric Association (ALOA), along with the State Government Relations Committee and the American Optometric Association, has been working for five years to try and pass a bill that better reflects the capabilities of today's ODs.

In March, SB 120 passed the Senate with a vote of 17 to 12. The bill would allow optometrists with the proper training to perform several advanced procedures: YAG capsulotomy, laser peripheral iridotomy, selective laser trabeculoplasty (SLT), removal of chalazia or other skin lesions around the eyelid, corneal crosslinking and injections near the eye or within the most superficial layers. For residents of the 31 counties in Alabama where optometrists are the only eyecare providers, the bill would make these services more accessible and reduce the need for patients to travel to receive potentially vision-saving treatment.

Unfortunately, after moving forward to a public hearing before the House Health Committee, the bill did not pass. "The session ended, and we didn't get a vote in the House because we ran out of time, which ultimately is because of the power of our opposition," explains Caleb Gardner, OD, president of the ALOA. "There was opposition from medicine, ophthalmology and the medical association of the state of Alabama, who all fought really hard against this bill."

Dr. Gardner says that although ODs and scope expansion advocates in the state have been making an increasing level of effort to advocate for SB 120, the momentum must continue to build to push for change before the bill is again put before the Senate.

"I think optometry just really woke up in Alabama toward the end of February when we decided that if we're going to get this done, it was going to take our own boots on the ground; we can't just farm this out to third parties like lobbyists, although they are an important part and we thank them for the work that they do," says Dr. Gardner. "But, optometrists in Alabama have to get out, shake hands, make donations, work in campaigns and build relationships with their legislators if we're ever going to get this done."

Dr. Gardner says he is optimistic about the future of the bill, especially since several US states have recently been successful passing similar laws.

"Even though we lost this year, which did feel like a punch in the gut after all the work we put into it, we learned some lessons the hard way, and now we're in a place where we're communicating with each other and are really working hard and focused on getting this done," he says. "We'd love to get it done next year, but we know that it could be a long battle. After this recent loss, I think there's a lot of optometrists in Alabama who are in this fight for the long haul, which is great."

The ALOA created a task force earlier this year for scope expansion that will continue to discuss and potentially make amendments to the bill before it's reintroduced to the Senate in 2023.

"Optometry in Alabama is now awake," says Dr. Gardner. "We know that this is what's best for access to care for our patients, and we are committed to seeing this through whether it takes one year or 10. We'll keep learning lessons and coming back. We'll lean on our friends who have done it to gain wisdom from them as we try to go forward and make next year better than this year was."

Photo: Carol M. Highsmith/Library of Congress

The ALOA plans to resubmit the bill next year.

Despite this recent setback for AL, other states are continuing to push their own legislative battles forward. The Nebraska Optometric Association (NOA) introduced an initial request to the Department of Health and Human Services that would allow ODs in the state to perform SLT to treat glaucoma. The state formed a technical review committee to oversee the request, which held its first hearing on April 7th and plans to hold a second on June 7th. Presentations were heard from both the NOA and the opposition, and both answered questions from the committee. Janet Seehoff, executive director of the NOA, says they anticipate having the bill ready to introduce in January 2023.

"We really hope that this goes favorably for our members and so that Nebraskans can receive SLT treatment for glaucoma," says Mrs. Seehoff. "There's definitely a need for it, and this will be a great opportunity to enhance the scope of practice. It's all about access to care and services, and this future bill would help a lot."

#01 OF SERIES

KERATOCONUS and CROSS-LINKING

Optometry's Role in the Patient Journey

Gloria Chiu, OD, FAAO, FSLS
Associate Professor
of Clinical Ophthalmology
USC Roski Eye Institute,
USC Keck School of Medicine
Los Angeles

KEY TAKEAWAYS

- Cross-linking with the only FDA-approved iLink™ System can stop or slow progressive keratoconus.
- Early diagnosis and treatment are essential to preserve as much vision as possible.
- Optometrists are uniquely positioned to change lives and protect vision by identifying at-risk patients in the mild stages of the disease.

Keratoconus (KC) is a degenerative condition with onset in early adolescence. It is characterized by gradual thinning of the corneal stroma, causing a cone-shaped protrusion and worsening vision. As doctors of optometry, our top priority with these patients should be to manage their disease—and only secondarily to correct their vision.

A referral for corneal collagen cross-linking, which has been shown to halt progression in 92%-100% of cases[1], may be able to preserve vision. As with any surgical procedure, there is the potential for complications and cross-linking may not be right for everyone. After treatment, patients will still need regular optometric care. Follow-up care is similar to that required for PRK. However, there is no global period, so each follow-up visit is charged as a regular exam.

Without cross-linking treatment, progressive KC typically continues to worsen until around age 40 (and sometimes longer), with 10%-20% of cases requiring a penetrating keratoplasty (PKP).[2] When patients reach the advanced stages of keratoconus, it becomes a debilitating disease that affects every aspect of their lives. Worsening KC severity is associated with significant declines in reading, mobility, and emotional well-being quality of life (QoL) scores.[3] The impact on QoL can be even greater than that of retinal diseases and can be felt even when one eye still has good vision[4] so it is important that patients get help as early as possible.

In the U.S., when cross-linking is performed with the iLink™ platform (Glaukos), the only FDA-approved cross-linking system, it is generally covered by insurance for 96% of those with commercial insurance. In a recent simulation model, treatment with iLink™ was found to be highly cost effective, resulting in a 26% reduction in PKPs and patients spending 28 fewer years in the advanced stages of KC.[5] Young patients who can be treated early while their vision is still good have the most to gain.

That's where optometrists' role becomes so critical. Our awareness of early progressive KC signs and risk factors can be nothing short of life changing for that young myope in our chair. There is no need to wait until a patient has lost vision or has slit lamp signs (e.g., thinning or striae) to refer for a more in-depth KC evaluation. It is standard of care to intervene with cross-linking upon detection of progression.[6]

Advanced tomography/topography provides the most sensitive and accurate diagnostic information. However, there are a number of signs and symptoms that should heighten suspicion of KC and prompt further testing, either in the practice or by referral. These include myopic shift, rapidly changing astigmatism, vision that won't correct to 20/20 (with no other known reason), distorted mires on manual keratometry, and scissoring or an irregular retinoscopy reflex. Patients with a history of eye rubbing, connective tissue disease, Down syndrome, or a family history of KC are also at higher risk.

By promptly referring these patients for further testing and, if warranted, iLink™ cross-linking treatment, optometrists are uniquely positioned to protect and preserve patients' vision over their entire lifetime. ■

With Cross-Linking[5]

26% fewer PKPs | **28** fewer years in late-stage KC

REFERENCES:
1. Koller T et al. J Cataract Refract Surg 2009;35:1358. **2.** Davidson AE et al. Eye (Lond) 2014;28:189. **3.** Tan JCK, et al. Cornea 2019;38:600. **4.** Kandel H, et al. Clin Exp Ophthalmol 2022;Epub ahead of print. **5.** Lindstrom RL et al. J Med Econ 2021;24:410. **6.** American Academy of Ophthalmology Preferred Practice Pattern, Corneal Ectasia, 2018

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Current Vision Test for Licensure Penalizes Older Drivers

A recent study found acuity to be an inadequate predictor of motor vehicle collision that may be taking more people than necessary off the road.

It's required by law that all drivers in the United States undergo vision screening prior to obtaining their license. However, researchers of a recent study argue that using this measurement of visual function to determine whether an individual is allowed to drive may cause more harm than good, especially for the senior population. The study found that while the number of motor vehicle collisions experienced by those with impaired visual acuity exceeded that of the general population, the effect was not significant enough to outweigh the negative impacts of involuntary driving cessation, including those on mental health and mobility.

The population-based sample consisted of 2,000 licensed drivers 70 and older residing in Alabama. During the baseline visit, the following measurements were performed on all participants: visual acuity, contrast and visual field sensitivity, the Useful Field of View test and the Motor-Free Visual Perception test. The cohort was then followed for up to four years for involvement in police-reported motor vehicle collisions. After the study period, the researchers determined the screening performance of each visual function in regard to motor vehicle collision occurrence by calculating values for area under the curve (AUC), sensitivity and specificity; in addition, they estimated rate ratios for the association between each visual function measure and motor vehicle collision.

Photo: Wonderlane on Unsplash

Fewer than 10% of adults aged 70 or older in this study who had a motor vehicle collision during the follow-up period had impaired visual acuity or contrast sensitivity.

Throughout the four-year follow-up period, 359 motor vehicle collisions occurred, and 16% of the cohort was involved in at least one collision. The researchers found that "less than 10% of the study participants had impaired visual acuity or contrast sensitivity, as defined by clinical cutpoints, and the prevalence of Useful Field of View impairment was slightly greater than 10%." They also determined that none of the measurements of visual function exhibited adequate values for sensitivity or specificity, and AUC values were only about 0.5.

"For all visual function measures except visual acuity, there were statistically significant positive rate ratios for the association between vision impairment and future motor vehicle collision occurrence, though the magnitude of the associations were weak," the researchers noted. "When considering all of the measures collectively as a test battery, the results similarly demonstrated inadequate sensitivity and specificity for being a general population screener."

The researchers concluded, "The results of the current study indicate that such screening will unduly penalize older drivers who, while at increased risk for motor vehicle collision, are not likely to experience one." They suggest alternative approaches to improving driver safety, particularly for seniors, include driver evaluation and training programs, transportation alternatives and targeted screening initiatives."

McGwin Jr. G, Owsley C. Vision screening for motor vehicle collision involvement among older drivers. Ophthalmology. April 25, 2022. [Epub ahead of print].

IN BRIEF

Study Confirms Validity of At-home Vision Tests. Though ODs have little good to say about online refraction tests from corporate entities that actively undermine the value of in-person care, the notion of moving some aspects of vision testing to the home is gaining traction in the COVID era.

A randomized comparative study investigated the validity of at-home tests for visual acuity (VA) measurement. A total of 218 participants with acuity of 20/200 or better were prospectively randomized to self-administer two of three at-home tests (printed chart, mobile phone app and website) within three days prior to their standard-of-care clinic visit. They then compared results of the at-home and in-office VA tests, and participants completed a survey to assess usability of the tests.

Mean in-office VA was 0.11logMAR (Snellen equivalent 20/25) with no significant difference between the tests. The researchers also observed a mean difference (logMAR) between the at-home and in-office tests of -0.07 for the printed chart, -0.12 for the mobile app and -0.13 for the website test.

The three at-home VA tests were comparable within one line to in-office VA measurements, the study authors reported. **The printed chart had the smallest mean difference and greatest correlation when compared with in-office acuity;** however, no significant difference was noted among the three at-home tests.

While participants found the tests easy to use and showed interest in future at-home testing, overall feedback indicated that **they didn't want in-office acuity testing replaced by at-home methods due to accuracy concerns.**

Bellsmith KN, Gale MJ, Yang S, et al. Validation of home visual acuity tests for telehealth in the COVID-19 era. JAMA Ophthalmol. March 31, 2022 [Epub ahead of print].

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Seasonal Allergic Conjunctivitis Can Trigger MG Changes

This study cohort often had multiple signs of tear film instability and higher rates of gland distortion and dropout.

Of all cases of allergic conjunctivitis, 90% are of the seasonal subtype. Because the meibomian gland plays such an important role in keeping the tear film stable and preventing harm to the ocular surface, researchers recently conducted a study to determine how this structure is affected in patients with seasonal allergic conjunctivitis. They found that compared with controls, those with seasonal allergic conjunctivitis had more significant morphological and cytological changes in the meibomian gland.

The study observed 89 eyes from 89 patients diagnosed with seasonal allergic conjunctivitis along with 112 healthy volunteers. The OSDI questionnaire was used to evaluate symptoms, and the following tests were performed on each patient: tear evaporation rate from the ocular surface, slit lamp exam, tear film breakup time, Schirmer test, vital staining, meibography and meibum expression grading.

Scores on the OSDI questionnaire were higher in the seasonal allergic conjunctivitis group than in the control group. According to the responses, 92.1% of patients had tear film instability compared with 29% of controls. Nearly every parameter of meibomian gland function and ocular surface health measured during the clinical exam was worse in patients than in controls, including tear evaporation rate from the ocular surface, breakup time, vital staining, meibomian gland expression, meibomian gland distortion rate and meibomian gland dropout grade. When the research team used laser scanning confocal microscopy to examine participants' meibomian glands, the findings also confirmed that seasonal allergic conjunctivitis patients had significantly worse average parameters compared with healthy controls.

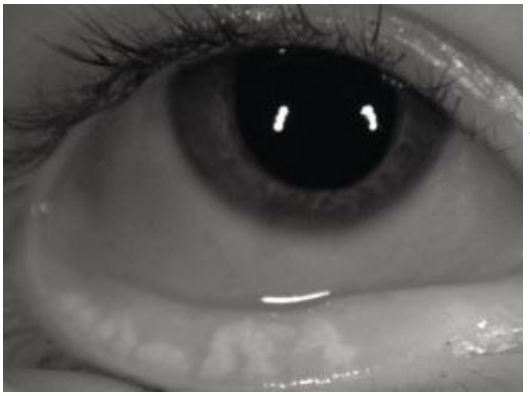

Photo: Kambiz Sllani, OD

Nearly two-thirds of seasonal allergic conjunctivitis patients in this study had meibomian gland dropout compared with roughly a quarter of controls.

"Our results showed that 60.7% of the seasonal allergic conjunctivitis patients had meibomian gland dropout compared with 26.8% among the normal controls," the researchers wrote in their study. "These results suggest that the symptom of xerophthalmia (instability of the tear film) among seasonal allergic conjunctivitis patients might be due to the changed tear film lipid layer, and this is possibly related to meibomian gland distortion, meibomian gland dropout and changed meibomian gland orifices."

This study, along with previous ones, has demonstrated that a large portion of seasonal allergic conjunctivitis patients exhibit meibomian gland alterations. However, the underlying mechanisms of these changes are not yet known. "Some hypotheses have been proposed, like meibomian gland infiltration by lymphocytes and meibomian gland ductal epithelial hyperkeratinization and, more recently, the inflammatory damages to the cornea and conjunctiva," the researchers noted. Further research may help to better understand why this patient subset is more prone to these morphological changes.

Liu L, Yang J, Ji W, Wang C. Assessment of meibomian gland impairment among seasonal allergic conjunctivitis patients. Med Sci Monit. April 5, 2022. [Epub ahead of print].

IN BRIEF

Pay More Attention to Photophobia, Study Argues. Photophobia is associated with a number of different ocular and neurological conditions. However, **the most common causes of abnormal sensitivity to light are still not well-understood.** To better equip primary eyecare providers, researchers recently initiated a retrospective chart review involving 147 patient records.

The following data was collected: demographics, presenting symptoms, medical history, examination findings, assessment and plan. Photophobia was the chief complaint for 90.5% of patients. The researchers found that 10 men and three women linked their symptoms to a recent injury. Seven men and one woman attributed their photophobia to a workplace injury. The mean age of presentation was 37 years, with the most frequent cause of photophobia being migraine headache (53.7%). Other causes were dry eye syndrome (36.1%), ocular trauma (8.2%), progressive supranuclear palsy (6.8%) and traumatic brain injury (4.1%).

The researchers observed that **a significant number of patients left the clinic without a documented cause for their photophobia (25.9%)**. This included 11.7% of adults and 69.4% of children. These findings indicate, according to the study authors, that **eyecare providers—particularly those who care for children—may not understand the most common causes of photophobia**. As a result, they may not know what history questions to ask and what examination techniques to use.

"Photophobia affects patients of all ages, and many patients are left without a specific diagnosis, indicating a significant knowledge gap among ophthalmologists and optometrists evaluating these patients," the study authors wrote. They are currently studying vision-related quality of life impact and developing a curriculum to help clinicians diagnose and treat photophobia in adults and children.

"We hope that a better understanding of the most common causes of photophobia, the pathophysiology of photophobia and the impact of photophobia on vision-related quality of life will help us better address the knowledge gap identified in this study," the study authors concluded.

Buchanan TM, Digre KB, Warner JEA, et al. The unmet challenge of diagnosing and treating photophobia. J Neuroophthalmol. March 25, 2022. [Epub ahead of print].

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Dr. Gupta and Dr. Schweitzer are paid consultants for Alcon.

Artificial tears are a cornerstone of eye care. With nearly 60% of eye care professionals expressing a preference for preservative-free formulations,[1] it's important to have options that are Effective, Ergonomic, Economical, and Environmental—the 4 Es of eye drop success! SYSTANE® COMPLETE Multi-Dose Preservative Free (MDPF) is a preservative-free formulation featuring the same lipid nanoparticle technology as SYSTANE® COMPLETE,[2-4] but in a convenient multi-dose bottle that avoids the need for wasteful single-use packaging.

Preservative-free lubricant drop formulations play an important clinical role, particularly pre- or post-eye surgery, in those who instill drops several times a day, or in those who should avoid preserved eyedrops for another reason. However, preservative-free options can be limited by the patient's underlying type of dry eye. Furthermore, preservative-free formulations are often packaged as single-use vials, which can generate a lot of plastic waste and may be cumbersome for some patients to use. There is a need for an advanced preservative-free lubricant eyedrop appropriate for many different underlying forms of dry eye, but packaged in an easy-to-use multidose bottle.

SYSTANE® COMPLETE MDPF is an exciting and welcome addition to our armamentarium of artificial tears, since it is appropriate for all major types of dry eye, and can also be instilled before and after contact lens wear†—making it the "go to" artificial tear. Just 1 drop of SYSTANE® COMPLETE improves symptoms immediately, and for up to 8 hours.[5‡] Another SYSTANE-family preservative-free drop, SYSTANE® HYDRATION MDPF, is available for aqueous deficient forms of dry eye in patients who need frequent hydration—and is particularly useful following ocular surgery to relieve dry eye symptoms. These preservative-free products employ multidose bottles to prevent backflow and contamination, thereby avoiding the need for wasteful single-use packaging.

SYSTANE® COMPLETE MDPF and SYSTANE® HYDRATION MDPF are built on the backbone of HP-Guar, which forms a polymer meshwork gel that helps retain active lubricants on the ocular surface and helps support hydration[6] and protection against desiccation.[6,7] In addition, SYSTANE® COMPLETE MDPF adds nano-sized lipid droplets, which provide better delivery and spread of the formulation* to help fortify the lipid layer of the tear film,[2-4] while SYSTANE® HYDRATION MDPF includes a second polymer, sodium hyaluronate—a naturally occurring hydrophilic moisture magnet[8] with viscoelastic properties[4,8]—which helps the active lubricants provide longer-lasting hydration.[5,7,9§]

With so many lubricant eyedrops available, it is essential to make recommendations to help patients purchase a product with the right formulation to address their dry eye needs. Recommend the SYSTANE® family of preservative-free drops with HP-Guar technology—SYSTANE® COMPLETE MDPF or SYSTANE® HYDRATION MDPF—when your patients need preservative-free dry eye relief.

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*SYSTANE® COMPLETE vs. SYSTANE® BALANCE; SYSTANE® HYDRATION vs. SYSTANE® ULTRA Lubricant Eye Drops.
†Not a rewetting drop.
‡Based on 0–10 visual analog scale, where 0 = "no symptoms at all" and 10 = "worst imaginable symptoms"; study examined SYSTANE® COMPLETE preserved formulation.
§vs. SYSTANE® ULTRA Lubricant Eye Drops; based on in vitro outcomes using SYSTANE® HYDRATION preserved formulation.

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US-SYX-PRA-2100001

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Tetracyclines May Up Pseudotumor Cerebri Risk

Pseudotumor cerebri (PTC) is a neurological disorder that typically manifests with ocular signs and symptoms such as increased intracranial pressure with normal brain parenchyma, absence of hydrocephalus, mass lesion and underlying infection or malignancy. Researchers recently compared the incidence of PTC among tetracycline users and the incidence of idiopathic intracranial hypertension (IIH) among the general population and found the former to be higher (63.9 vs. <1 per 100,000 person-years).

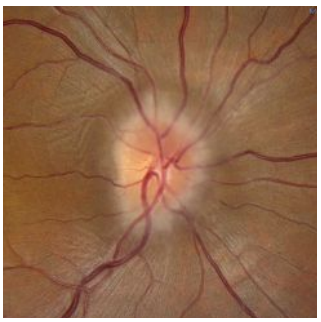

Photo: Mark Dunbar, OD

One in 20 patients prescribed a tetracycline antibiotic were diagnosed with tetracycline-induced PTC.

Among a total of 960 patients between the ages of 12 and 50 who were prescribed a tetracycline antibiotic, 4.7% were diagnosed with tetracycline-induced PTC. Researchers included patients who developed signs and symptoms of PTC within 30 days of starting the drug and whose signs and symptoms improved with its cessation.

"Our data are consistent with the hypothesis that tetracyclines may predispose patients to the development of PTC," the authors wrote in their paper. "The data presented here demonstrate an association, but not being a clinical trial, do not confirm a cause and effect."

Almost all tetracycline-induced PTC patients were women, possibly indicating that tetracycline antibiotics could be more likely to cause this type of PTC in patients with a gender-associated susceptibility. Although most of the affected patients were prescribed minocycline, it wasn't possible for the team to determine whether this antibiotic is more likely to induce tetracycline-induced PTC compared with other antibiotics in this class.

The reason for the association between this class of antibiotics and PTC remains poorly understood, as does the pathophysiology of IIH.

Regardless of the disease's underlying pathogenesis and the contribution by tetracycline antibiotics, the researchers believe that their data suggests that these medications put patients at increased risk for PTC development. They recommend that "physicians who prescribe these antibiotics consider educating their patients about this adverse reaction.Patients who are taking these antibiotics and have symptoms of increased intracranial pressure should be counseled to contact the prescribing physician for further advice."

Passi SF, Butcher R, Orme DR, et al. Increased incidence of pseudotumor cerebri syndrome among users of tetracycline antibiotics. J Neuroophthalmol. March 25, 2022. [Epub ahead of print].

Erectile Dysfunction Drugs Can Cause Ocular Adverse Effects

Several case reports and small epidemiologic studies have quantified the risk of ocular adverse events associated with the use of phosphodiesterase type five inhibitors (PDE5Is). However, results have been conflicting, and epidemiologic data on the risk of serous retinal detachment (SRD) and retinal vascular occlusion (RVO) is not available.

This cohort study included data from 213,033 men who received PDE5Is at any time over a 15-year period. All four major drugs in this category—sildenafil, tadalafil, vardenafil and avanafil—were included. The case-control analysis included 278 cases of SRD, 628 of RVO and 240 of ION, as well as 4,584 controls (mean age=64.6).

Cohort members were followed up until the first diagnosis of SRD, RVO or ischemic optic neuropathy (ION) or termination of insurance coverage. For each case, four controls were matched by age and time of study entry. Risk for regular users of PDE5Is was compared with that of nonusers.

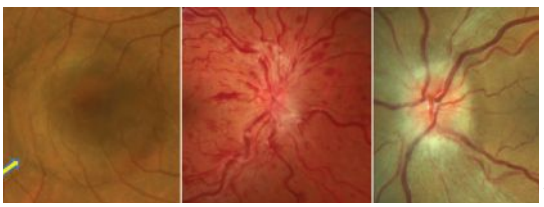

Photo: Mohammad Rafieetary, OD

Study finds elevated risks of (L to R) serous retinal detachment, retinal vein occlusion and ischemic optic neuropathy in patients using ED drugs.

Patients with SRD, RVO and ION were more likely to have hypertension, diabetes, coronary artery disease and sleep apnea. The adjusted incidence rate ratio (IRR) for developing any of the three outcomes was 1.85 (15.5 cases per 10,000 person-years). The adjusted IRRs for each condition were as follows:

- SRD: 2.58 (3.8 cases per 10,000 person-years)
- RVO: 1.44 (8.5 cases per 10,000 person-years)
- ION: 2.02 (3.2 cases per 10,000 person-years)

"These findings suggest that regular users of PDE5Is might have an increased risk for SRD, RVO and ION," the study authors concluded. "Regular users of PDE5Is need to be cognizant of ocular adverse events associated with these drugs and alert their physicians if they experience visual deficits."

Etminan M, Sodhi M, Mikelberg FS, et al. Risk of ocular adverse events associated with use of phosphodiesterase 5 inhibitors in men in the US. JAMA Ophthalmol. April 7, 2022. [Epub ahead of print].

IN BRIEF

Dilating Drops May Affect Glaucoma Measurements. Pupillary dilation is important in conducting an ocular examination or performing intraocular surgery, but **a recent study pointed out that mydriatic agents may impact glaucoma diagnostics by altering vascular density measurements.**

The study included 20 eyes with primary open-angle glaucoma and 20 control eyes. Eyes underwent fundus imaging before and after instillation of topical 0.5% tropicamide and 2.5% phenylephrine, two commonly used topical mydriasis agents.

The researchers reported a statistically significant decrease in the foveal avascular zone area (from mean 0.29mm2 to 0.25mm2) and the foveal avascular zone perimeter (from mean 2.27mm to 2.09mm), as seen on OCT-A after instillation. They noted that **pre- and post-dilation optic nerve head perfusion and flux index were significantly lower in the glaucoma group than the controls.**

"It's long been proposed that glaucomatous eyes have a significant vascular dysregulation and lower ocular perfusion than in normal subjects," the study authors wrote in their paper. **"Pupillary dilation with 0.5% tropicamide and 2.5% phenylephrine resulted in a statistically significant decrease in foveal avascular zone metrics in glaucoma eyes.** This observation emphasizes **the critical role of pupillary status in interpreting glaucomatous vascular alterations detected by OCT-A."**

Ozturker Z, Kurt RA. Effect of mydriatic administration on retinal hemodynamics in glaucoma: an optical coherence tomography angiography study. J Glaucoma. April 14, 2022. [Epub ahead of print].

Dementia-Prone Allele Linked to Faster Neuroretinal Thinning. Like primary open-angle glaucoma (POAG), diseases that bring on symptoms of dementia—including Alzheimer's, frontotemporal dementia and Lewy body disease—result from progressive loss of neurons in the central nervous system, both generally and within the retina, though the nature of this association remains unclear. **The most commonly investigated genetic parameter is apolipoprotein E (*APOE*), the principal genetic determinant of Alzheimer's, Lewy body disease and all-cause dementia.**

A recent study investigated the association between POAG and the genetic risk of dementia by investigating associations between the *APOE E4* allele and structural markers of neuroretinal thinning relevant to glaucoma progression. **The *APOE E4* allele was associated with faster rates of macular ganglion cell/inner plexiform layer (mGCIPL) thinning, particularly in normal-tension glaucoma (NTG) eyes.**

The study included eyes from participants with genotyping data from which *APOE* genotypes could be determined and then compared with an age- and race-matched normative cohort. Structural parameters of neuroretinal atrophy measured using SD-OCT were compared within the cohort on the basis of *APOE E4* allele status.

Rates of mGCIPL thinning were faster in participants carrying one or more copies of the *APOE E4* allele (β coefficient=-0.13µm/year), and this was strongest in eyes affected by NTG (β coefficient=-0.20µm/year). *APOE E4* allele carriers were also more likely to be lost to follow-up and demonstrated a thinner average mGCIPL (70.9µm vs. 71.9µm) and pRNFL (77.6µm vs. 79.2µm) after a minimum of three years of monitoring. The researchers believe their results suggest **the *APOE E4* allele may be a risk factor for retinal ganglion cell degeneration in glaucoma.**

The mechanisms by which mGCIPL thinning may occur in individuals carrying the *APOE E4* allele remain unclear.

"As genome-wide association study data has not identified glaucoma-associated risk variants within the *APOE* gene, **the relevance of *APOE E4*-associated mGCIPL thinning to glaucoma and its visual outcome remains uncertain**," the authors concluded. "Subsequent replication studies within separate cohorts will help to validate and elucidate the relationship between the *APOE E4* allele and glaucoma."

Mullany S, Marshall H, Diaz-Torres S, et al. The APOE E4 allele is associated with faster rates of neuroretinal thinning in a prospective cohort study of suspect and early glaucoma. Ophthalmol Sci. April 19, 2022. [Epub ahead of print].

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FEATURES

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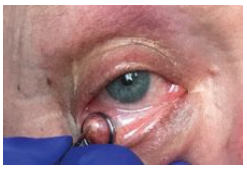

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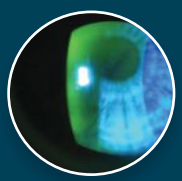

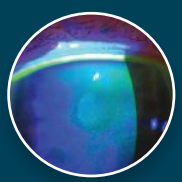

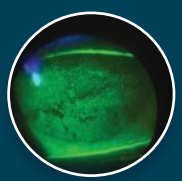

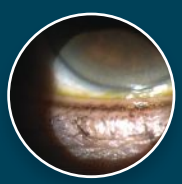

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To treat ocular inflammation and pain following ophthalmic surgery or ocular itching associated with allergic conjunctivitis.

DEXTENZA KEEPS PATIENTS COMPLIANT AND SATISFIED[1-3*]

A hands-free advancement in ophthalmic steroid treatment.[1,4]
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INDICATIONS

DEXTENZA is a corticosteroid indicated for:

- The treatment of ocular inflammation and pain following ophthalmic surgery.
- The treatment of ocular itching associated with allergic conjunctivitis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

WARNINGS AND PRECAUTIONS

Intraocular Pressure 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. Intraocular pressure should be monitored during treatment.

Bacterial Infections - Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection.

Viral Infections - 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 - Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Delayed Healing - Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Other Potential Corticosteroid Complications - The initial prescription and renewal of the medication order of DEXTENZA 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. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

ADVERSE REACTIONS

Ocular Inflammation and Pain Following Ophthalmic Surgery

The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (10%), intraocular pressure increased (6%), visual acuity reduced (2%), cystoid macular edema (1%), corneal edema (1%), eye pain (1%), and conjunctival hyperemia (1%). The most common non-ocular adverse reaction was headache (1%).

Itching Associated with Allergic Conjunctivitis

The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: intraocular pressure increased (3%), lacrimation increased (1%), eye discharge (1%), and visual acuity reduced (1%). The most common non-ocular adverse reaction was headache (1%).

Please see adjacent Brief Summary of full Prescribing Information.

*93% (187/201) DEXTENZA patients were satisfied with the insert in the Phase 3 Study for the treatment of ocular inflammation and pain following ophthalmic surgery.[3]

†73.6% of physicians in Study 1, 76.4% in Study 2, and 79.6% in Study 3, for the treatment of ocular inflammation and pain following ophthalmic surgery, rated DEXTENZA as easy to insert.[2,5]

References: 1. DEXTENZA [package insert]. Bedford, MA: Ocular Therapeutix, Inc; 2021. **2.** Tyson SL, et al. *J Cataract Refract Surg*. 2019;45(2):204-212 [erratum in: 2019;45(6):895]. **3.** Data on File 00837. Ocular Therapeutix, Inc. **4.** Sawhney AS, Inventors, et al. Incept, LLC, Assignee. Drug Delivery Through Hydrogel Plugs. US Patent 8,409,606 B2. April 2, 2013. **5.** Walters T, et al. *J Clin Exp Ophthalmol*. 2016;7(4):1-11.

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REVIEW of OPTOMETRY

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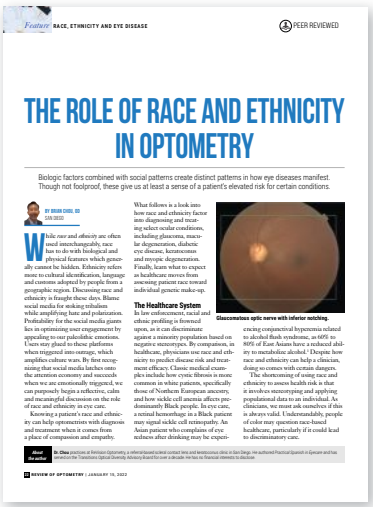
LETTERS TO THE EDITOR

Feedback and ideas from the optometric community.

Recognize Shortcomings in Racial Categories

We should follow expert guidance and understand that race and ethnicity are social constructs that too often over-generalize.

As the Director of Diversity, Equity, Inclusion and Belonging at SUNY College of Optometry, I had the opportunity to read the article, "The Role of Race and Ethnicity in Optometry" (January 2022) by Brian Chou, OD, and am inclined to respond. There are several misleading or inaccurate points mentioned, starting from the first sentence, which states, "While *race* and *ethnicity* are often used interchangeably, race has to do with biological and physical features which generally cannot be hidden…" and carries on from there.


Feature RACE, ETHNICITY AND EYE DISEASE PEER REVIEWED

THE ROLE OF RACE AND ETHNICITY IN OPTOMETRY

Biologic factors combined with social patterns create distinct patterns in how eye diseases manifest. Though not foolproof, these give us at least a sense of a patient's elevated risk for certain conditions.

BY BRIAN CHOU, OD
SUN 2022

While *race* and ethnicity are often used interchangeably, race has to do with biological and physical features which generally cannot be hidden. Ethnicity refers more to cultural identification, language and customs adopted by people from a geographic region. Discussing race and ethnicity is fraught these days. Blame social media for stoking tribalism while amplifying hate and polarization. Profitability for the social media giants lies in optimizing user engagement by appealing to our paleolithic emotions. Users stay glued to these platforms when triggered into outrage, which amplifies culture wars. By first recognizing that social media latches onto the attention economy and succeeds when we are emotionally triggered, we can purposely begin a reflective, calm and meaningful discussion on the role of race and ethnicity in eye care.

Knowing a patient's race and ethnicity can help optometrists with diagnosis and treatment when it comes from a place of compassion and empathy.

What follows is a look into how race and ethnicity factor into diagnosing and treating select ocular conditions, including glaucoma, macular degeneration, diabetic eye disease, keratoconus and myopic degeneration. Finally, learn what to expect as healthcare moves from assessing patient race toward individual genetic make-up.

Glaucomatous optic nerve with inferior notching.

The Healthcare System

In law enforcement, racial and ethnic profiling is frowned upon, as it can discriminate against a minority population based on negative stereotypes. By comparison, in healthcare, physicians use race and ethnicity to predict disease risk and treatment efficacy. Classic medical examples include how cystic fibrosis is more common in white patients, specifically those of Northern European ancestry, and how sickle cell anemia affects predominantly Black people. In eye care, a retinal hemorrhage in a Black patient may signal sickle cell retinopathy. An Asian patient who complains of eye redness after drinking may be experiencing conjunctival hyperemia related to alcohol flush syndrome, as 68% to 80% of East Asians have a reduced ability to metabolize alcohol.[1] Despite how race and ethnicity can help a clinician, doing so comes with certain dangers.

The shortcoming of using race and ethnicity to assess health risk is that it involves stereotyping and applying populational data to an individual. As clinicians, we must ask ourselves if this is always valid. Understandably, people of color may question race-based healthcare, particularly if it could lead to discriminatory care.

About the author: Dr. Chou practices at Envision Optometry, a referral-based scleral contact lens and keratoconus clinic in San Diego. He authored Practical Spanish in Eyecare and has served on the Transitions Optical Diversity Advisory Board for over a decade. He has no financial interests to disclose.

REVIEW OF OPTOMETRY | JANUARY 15, 2022

The most recent AMA guidelines clearly state that race and ethnicity are social constructs without biological or scientific meaning. The Academy and the most up-to-date literature are clear on the fact that race is ill-defined, and often assumed by clinicians based on phenotype without any rigor. Scientists and clinicians are beginning to be aware that "race" has been a proxy for socioeconomic status and other social determinants of health in much of our analysis of data, and are working to reframe what it means in our profession.

With reference to a genetic basis for race-focused medicine, the field of epigenetics has shown that gene expression may also be affected by social determinants of health. Although there are important associations we use to help quickly categorize people based on "race," we must start to recognize that there are many structures and factors behind those associations. Articles will continue to associate certain conditions with race but should also mention the other important factors to take into consideration. I do not think this was adequately done in Dr. Chou's article.

The use of stereotypes of what the typical Asian or Black patient should or should not get screened for or the types of frames you should stock are inaccurate at best. The relationship between Black and Latinx patients and diabetes is rooted in sociological factors widely acknowledged to be present. This article lacks nuance and context.

As a widely read magazine in our profession, *Review* should be on top of the new interpretations of these categories. We cannot reinforce stereotypes; we have moved beyond these practices.

—Joy Harewood, OD
SUNY College of Optometry
New York City

From the Editor: We at the publication share your goal of helping the profession move away from simplistic and outdated modes of thinking about and interacting with patients.

The January issue's theme, explored over the course of seven articles, was the importance of viewing the patient as an individual who comprises a unique set of traits derived from such varied sources as their genetic makeup, health status, socioeconomic experience, cultural/familial upbringing, sexual orientation and more. Dr. Chou's assignment was to review racial and ethnic associations documented in the medical literature and widely used in practice, even if they do rely on generalizations and assumptions.

Either in that article or elsewhere in the issue, we should have acknowledged race as a social construct and the limitations that arise from it; the oversight lies with us on the editorial staff and not Dr. Chou, who wasn't asked to delve into that aspect. He did also touch on the influence of socioeconomic factors and epigenetics in these associations, however.

In short, the aim of the issue was to help optometrists learn to view and relate to each patient as a unique individual. It was an ambitious goal and I don't doubt we could have included more nuance in a number of cases. We look forward to continued exploration of these newer and more challenging topics to help ODs improve their clinical care and cross-cultural fluency.

Rethinking Comanagement

■ In the April issue's letters section, Dr. Don Stover wrote, "I generally don't make money on post-op (comanaged cataract) visits. Wouldn't it be nice if cataract surgery was one fee and the post-op care was another fee? This might support better post-op care."

SHARE YOUR THOUGHTS

Letters are welcome. Write to: editor@reviewofoptometry.com.

Submissions may be edited for length, content or clarity.

This was a hypothesis of mine and was also promulgated by a legal expert in one of our trade papers back in 2017. So, I floated the idea to several of my comanagement referral docs, but they liked the status quo. One of my busiest referrals said no, because he liked to be a more direct part of the surgical care through the Medicare comanagement billing process. I was surprised by this. To me, the OD/MD (or DO) doctor's behavior and the care rendered would be identical. Only the billing codes would be different, and they would be simpler.

I still think Dr. Stover's intuitive idea is good and workable. It seems simpler and more transparent for the patient to return to the referral optometrist's office and for that doctor to bill under the E&M codes or the eye codes, just like for any other patient. Indeed, when a surgeon has an emergency or takes ill, the surgeon's non-comanaged patients are often seen by an unrelated ophthalmologist, who is then allowed to reasonably bill for their services. The bills are reasonable because the visits are brief, and extensive testing is not needed.

—John Maher, MD
Torrance, CA
Instructor at Ketchum University School of Optometry, Anaheim

Tech Training Needed

■ I have a few questions for the colleges of optometry and other educational institutions all across America. How many have certified programs to train people to be an optometric assistant?

In my 46 years' experience as an optometrist, I would say it is difficult if not impossible to find an employee who has any basic eyecare knowledge regarding optics, eye anatomy and the fundamentals of eyeglasses.

Are there no technical colleges that consider a one- to two-year program to teach basic principles of optics and eye care to prepare someone to become a valuable part of the healthcare system? Is the AOA involved in any way to remedy the need for this training?

I see ads by small colleges in my state offering training to be a medical office assistant, pharmacy technician, phlebotomy technician, nurse (of various levels), radiology tech and even massage therapist—but training in eye care is left out. Why? Who is responsible for this lack of important education?

> **"I am lucky to have many experienced and competent assistants and technicians. I would like to have more."**

Every employee that I have in my office has been partially or completely trained by me and my experienced assistants. My optician even has done most of her training herself or by me. I am lucky to have many experienced and competent assistants and technicians. I would like to have more.

The optometry schools or technical colleges need to address this lack of qualified people to work in optometric practices. It has gotten even worse since the pandemic.

—R. Thomas McHugh, OD
Morehead, KY

Hold the Line on Eye Exams

■ I have noticed that many commercial and private practices have become increasingly apathetic about patient care and dilation.

If we are held to the same standards as medicine (ophthalmology), why are we not informing patients who do not want dilation that their optometrist won't examine them if the patient does not allow them to not do their job?

Non-dilated photos are not an acceptable alternative. Widefield imaging is not an acceptable alternative. We are responsible to the patient regarding their eye health when they walk through the door. Widefield imaging is an asset, but it misses the boat when the superior and inferior retina cannot be seen and the doctor does not make an effort to view these areas adequately.

I agree that most patients only want what their vision plan will pay for—eyeglasses and contact lenses. The doctor is the guardian of their eye health and, in many instances, their general health.

I propose that it is time to stop this foolishness. Vision care plans need to change their reimbursement schedules. I feel $40 is reasonable for a refraction. (Consider what ophthalmologists charge, and note that the refraction is done by a technician in many cases.) However, that is not reasonable for a full, dilated examination.

All patients—especially children—deserve the most comprehensive treatment upon initial presentation. Would one consider that examining a child under dilation is of utmost importance? Most cannot report their issues well enough to the examining doctor.

Maybe it is time to turn away a patient who will not let us do our job. We as optometrists are afraid to "rattle the cage" of our patients! If we want additional privileges such as minor noninvasive surgeries, the time has come for us to act like the professionals we are supposed to be and fight back against inadequate eye care. Whether you practice in Florida or Oklahoma, whether you do or do not belong to the state association, your profession is at a significant crossroads. Let's do our job. Make our profession the guardian at the gate. Do not let a patient dictate to you what is right or wrong.

—Russell J. Raye, OD
West Palm Beach, FL

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BY JACK PERSICO
EDITOR-IN-CHIEF
OUTLOOK

All Over the Map

Optometric scope of practice remains a patchwork of laws that change the parameters of care haphazardly from state to state.

This month, we kick off a four-part series on newer optometric privileges conferred through legislative action and how ODs in those states can position themselves to add any such procedures they feel are a good fit. Throughout the series, you'll hear directly from optometrists who have already conquered both the clinical and logistical challenges these new procedures pose.

For the first article, we visually depicted the breadth of optometric scope in several key categories of care using a series of maps (see pages 34-35). Encouragingly, the maps show a high degree of uniformity in optometric privileges for at least the most basic medical eyecare rights: use of diagnostic drops and most garden variety pharmaceutical agents, including glaucoma drugs. Every colored-in state on those maps represents untold hours of lobbying effort and hassle that your colleagues and predecessors had to endure to make it happen. We all owe them a debt of gratitude for their chutzpah.

Still, exceptions and caveats abound:

- All US optometrists can finally prescribe glaucoma meds—but three states still withhold oral drugs in this category.
- ODs in 41 states have the right to inject some medical therapies—but almost half can only do so for patients experiencing anaphylaxis.
- Controlled substances can be prescribed in 47 states—but the state-by-state list of approved drugs would turn that nice, uniform map into a checkerboard pattern if we added all the variance by schedule category.
- Naturally, the more hands-on procedures like minor laser surgery and removal of eyelid lumps and bumps are still hotly contested by ophthalmology, as these are the current front lines of the scope battles.

Optometry's legislative advocates have the wind at their backs right now, as numerous successes over the past few years can attest. Still, the medical lobby remains formidable, recently quashing a bill in Alabama.

Even with momentum going for it, optometry will have to continue to make the same arguments over and over. It's frustrating and, frankly, embarrassing. The way you practice optometry shouldn't be subject to how the political winds are blowing in your state capitol.

For the states pursuing expanded scope, it's encouraging to see the push for "as-taught" laws that would encompass many elements of practice in one shot (those that match the current curricula in optometry colleges). Continued success with this type of bill would obviate the need to go back to the legislature for every new responsibility optometrists seek to be granted. I hope such an approach becomes the new norm in scope expansion efforts. The mantra should be, "If it's learned, it's earned."

The last of the TPA laws (giving ODs basic medication prescribing rights) was passed in 1998—before everyone currently enrolling in optometry college was born. For at least a generation, bright young people have pursued optometry with an understanding that medical care is part and parcel of it. Let's deliver on that expectation for their sake and the betterment of all. ■

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*Prescription market data, Sept. 2021 – S01K without cyclosporine.
†To limit blurriness when using contact lenses, remove contacts, apply drops, then insert contacts.

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BY PAUL M. KARPECKI, OD
CHIEF CLINICAL EDITOR

Clinical Pearls in DED

Follow these steps to build a successful dry eye practice.

It probably doesn't come as a surprise that our profession writes more prescriptions for dry eye disease (DED) than any other condition and that the vast majority of dedicated dry eye clinics are run by optometrists. Having worked in this field for more than 25 years, during most of which I ran a dry eye clinic, I want to share insights to help save you a few years in developing a successful and rewarding dry eye practice.

Where to Start?

It's important to have the base to apply your skills. The first piece of equipment I'd recommend purchasing is a slit lamp imaging system. This technology helps you recall the specific staining from an exam that happened three months prior, is a great educational tool and can increase efficiency, as patients are able to quickly understand what you are diagnosing and managing.

Next, you'll need an instrument for expressing the meibomian glands, such as a Mastrota Meibomian Gland Paddle (Ocusoft), Collins Meibomian Expressor Forceps (Collins) or the Meibomian Gland Evaluator (Johnson & Johnson). In addition, NaFl dye strips and a yellow Wratten #15 filter are essential tools that allow you to see staining of the cornea and the conjunctiva without the need for lissamine green.

Expression is Essential

Imagine deciding to manage glaucoma but refusing to look at the optic nerve. It doesn't make much sense, but that's essentially what's happening if a doctor managing DED doesn't express the meibomian glands. About 86% of all DED has a meibomian gland dysfunction (MGD) component. It takes seconds to do; you simply look at the lower eyelid central to nasal meibomian glands and assess the quality of meibum you express.

> **"DED could be optometry's greatest opportunity, and it starts with your knowledge to simplify the disease and diagnosis."**

Eyelids are Important

Besides MGD, blepharitis is a significant contributor to DED. Examination of the eyelids will uncover *Demodex* collarettes, bacterial biofilm, telangiectatic blood vessels indicative of ocular rosacea and thickened eyelids pointing to chronicity—all which help determine how to best treat this form of DED. Morning symptoms are critical and the usual culprit is inadequate overnight eyelid closure.

Make Diagnosis Easy

The TFOS DEWS II algorithm is actually an easy and effective way to diagnose DED. Begin by looking at risk factors, ensure you have symptoms documented through a questionnaire or the patient's history and confirm with signs such as ocular surface staining or tear break-up time. Once you've made the diagnosis, you need to determine the subtype. Abnormal meibomian gland expression will confirm an evaporative form. Normal expression with a very thin tear meniscus indicates an aqueous-deficient DED.

Treat Each Subtype Differently

Although it's likely that inflammation is present in all forms of dry eye, evaporative DED requires managing obstructed meibomian glands using hydrating compresses and in-office treatments. Aqueous-deficient DED requires managing mucin deficiency (vitamin A *ung*) and aqueous deficiency requires increasing the tear volume (punctal occlusion). For inadequate overnight lid closure, consider lid seals (SleepTite/SleepRite is one example).

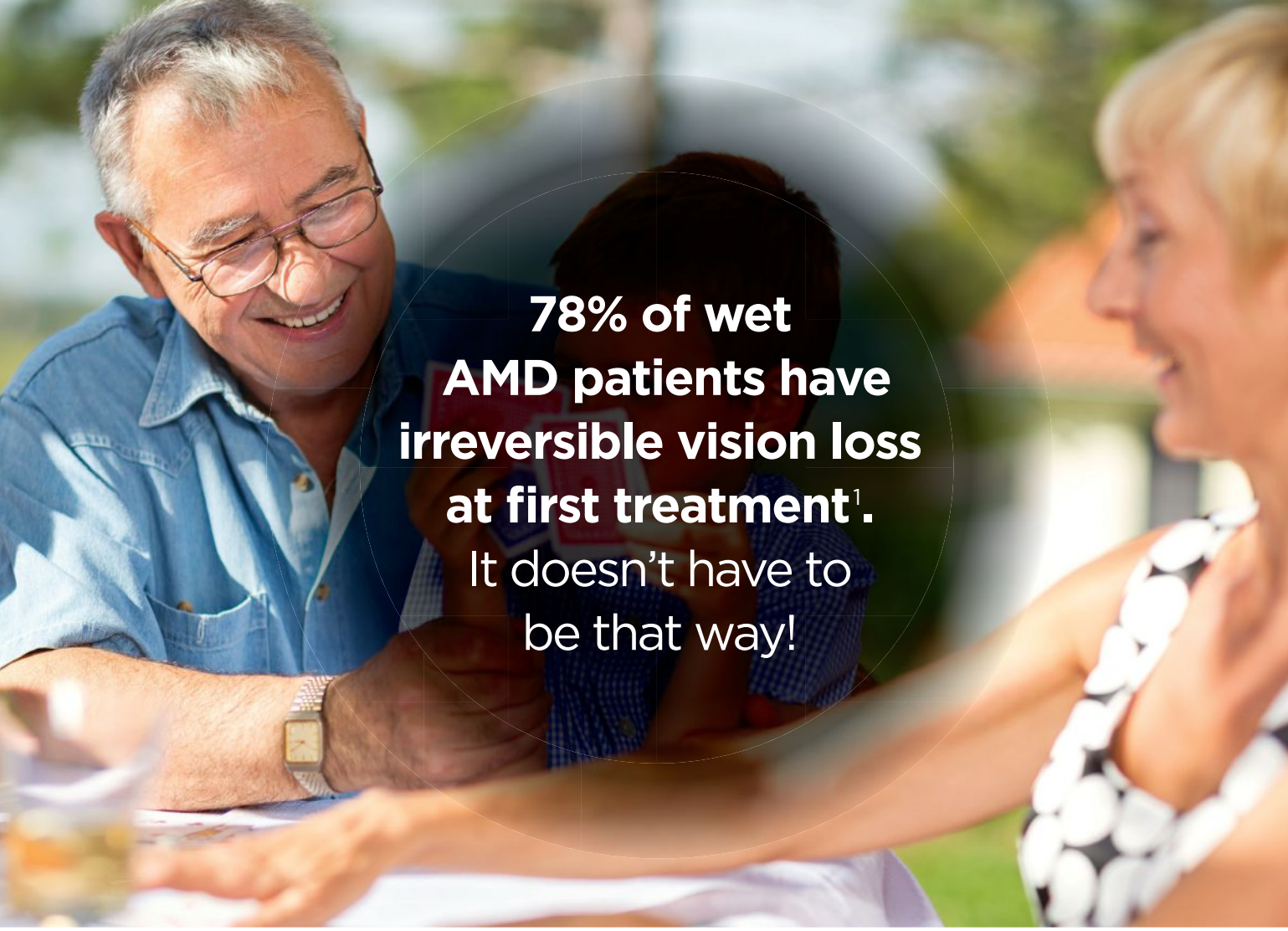
Patient Education

Having the knowledge to effectively manage DED is important, but without properly educating the patient, success is unlikely. I've seen patients confuse medication dosage, use ointments instead of prescription drops twice a day and complain about blurred vision. I've also seen patients discontinue treatment; many times they were lost because they couldn't get oriented as to which structure on the eye we were managing. An education tool worth considering is a platform called Rendia, which features patient-friendly animations, an image library and patient point-of-view options.

DED could be optometry's greatest opportunity, and it starts with your knowledge to simplify the disease and diagnosis. It requires easy but specific treatments for each subtype, meibomian gland expression and a thorough eyelid examination. That's when things get fun and exciting—when you start seeing patients who failed many times experiencing relief and satisfaction in the care of your hands. ■

About Dr. Karpecki

Dr. Karpecki is the director of Cornea and External Disease for Kentucky Eye Institute, associate professor at KYCO and medical director for Keplr Vision and the Dry Eye Institutes of Kentucky and Indiana. He is also chair of the New Technologies & Treatments conferences. He consults for a wide array of ophthalmic clients, including ones discussed in this article. Dr. Karpecki's full disclosure list can be found in the online version of this article at www.reviewofoptometry.com.



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[1]Olsen TW, Feng X, Kasper TJ, Rath PP, Steuer ER. Fluorescein angiographic lesion type frequency in neovascular age-related macular degeneration. Ophthalmology. 2004;111(2):250-255. doi:10.1016/j.ophtha.2003.05.030.

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BY MONTGOMERY VICKERS, OD

CHAIRSIDE

Demands of the Job

Start acting like a business owner or you may not have a business to own.

There are a few things you should be doing to better set yourself up for success. For starters, let's get your schedule under control. As if…

Back in the day, which I can officially say at my age, all was right with the world of eye care. We did what we did, the patient ordered new glasses every year or so and then they wrote a check for what they owed us. We recalled the patient for their yearly exam, and most of the time the cycle started again.

Then along came practice consultants. Now, I really don't have a grudge against them. I love many, if not all, of them. I attended every lecture at every meeting and sat in the front row for giants like Harriet Stein, Richard Kattouf, Neil Gailmard, Gary Gerber and too many others to name here. I always tried to glean at least one new idea at each lecture, and that helped me become a success, no doubt.

One idea that came up over and over again was the concept of preappointing. I would dare to guess that nearly 100% of private practice optometrists have applied this concept one way or another into their practice. It works. It keeps your book full over time.

To keep the math easy (for me), let's say you schedule 10 comprehensive examinations each day. You then preappoint these 10 patients. For the sake of argument, let's say that three people actually keep their preappointment. Now, you only have seven slots left to fill. The next year, typically the same three will be faithful and show up because they are used to the idea. Maybe two more from the other seven will decide to keep their planned appointment, so now you only have five slots to fill. And so on…

That's all well and good, but not all of them will need or want new glasses unless there is a notable change, which happens less often as the patient ages. And, unless you can fit in more patients per day, there becomes fewer spots for new patients and patients who have seen a change or broken their glasses, etc.

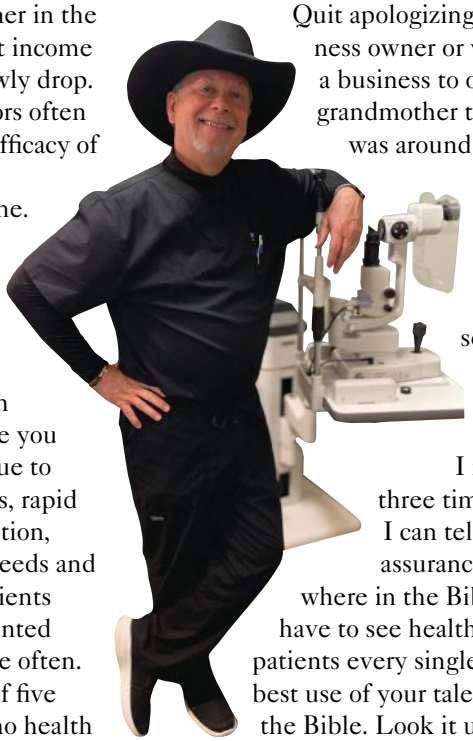
If you are a solo practitioner, or maybe have a partner in the same boat, your net income per patient can slowly drop. At that point, doctors often start to doubt the efficacy of preappointing.

Now, bear with me. This may not be a typically funny Chairside, but it is important. With today's software, you can track which patients need to see you every single year due to eye health concerns, rapid changes in prescription, contact lens refill needs and so forth. These patients should be preappointed yearly, or even more often. But does a family of five emmetropes with no health concerns need to see you yearly? I don't think so.

There is nothing unethical about determining the best recommended appointment frequency for each patient. Makes sense for them. They have other things to do. Makes sense for your practice, too. Staying in business requires that you use your time wisely.

What if a patient wants to use their yearly exam benefit? No problem. They'll call you and you can work them in, but it's perfectly OK not to blow up your day with five emmetropes.

There is an argument that preappointing leads to more no-shows. Doctors who wisely preappoint do not find that to be the rule, just the exception. Yes, you may lose a couple patients from time to time, but if you listen to those practice consultants and preappoint properly, that will not be a major concern.



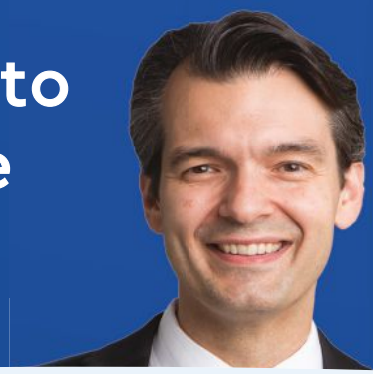
Quit apologizing for being a business owner or you may not have a business to own someday. My grandmother told me when I was around nine years old that if I read the Bible from front to back I would automatically go to Heaven someday. I'm not sure that's how it works, but that year I read it through three times just in case. I can tell you with some assurance that there is nowhere in the Bible that says you have to see healthy, visually stable patients every single year. Not the best use of your talents, and that is in the Bible. Look it up! ■

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

From the experts

Why add a compress to your patients' dry eye treatment?

Answered by Dr. Mile Brujic, OD, FAAO



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1. Tan J, Ho L, Wong K, et al. Cont Lens Anterior Eye. 2018;41(1):83-87.

RP Prognostication

Genetic testing can provide patients better perspective on how to handle this heritable disease.

Q A patient presents to me for the first time with a classic case of retinitis pigmentosa (RP). I know there is no treatment, but in what other ways can I help counsel this patient?

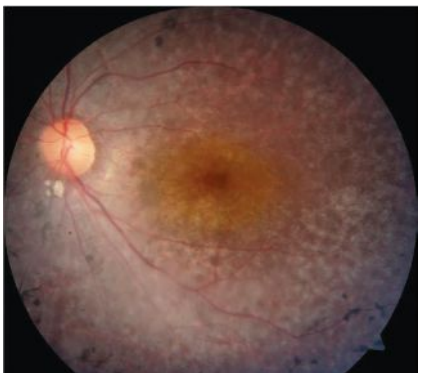
A RP is one of the most common inherited retinal diseases (IRD). "No treatment is currently available, so the key to patient care lies in management," says Himakshi Bhatt, OD, an ocular disease resident at Omni Eye Services of Atlanta. "This is where genetic testing comes into play."

Genetic information can provide insight to inheritance patterns, severity and ultimately disease prognosis. All this information together can help the doctor provide optimal patient care.

Inheritance Outcomes

RP is a group of inherited disorders that results in the degradation of the rod (and eventually cone) photoreceptors. The classic presentation includes the triad of bone spicules, arteriolar narrowing and waxy optic disc pallor.[1] Additionally, posterior subcapsular cataracts, epiretinal membranes and cystoid macular edema can also be present in some cases.[1] Common symptoms include nyctalopia, reduced visual acuity (VA), peripheral visual field loss and, in later stages, photopsia.

Over 50 genes are affected in the disease process, with the most common mutations affecting phototransduction in rods, the retinoid cycle and photoreceptor structure. Commonly affected genes include PRFP31 and RHO for autosomal-dominant inheritance, ABCA4 and USH2A for autosomal recessive inheritance and RPGR for X-linked inheritance.[2]



RP with arteriolar attenuation and bone spicules. Note the peripheral retinal loss with central island of sparing.

The severity and outcome of RP greatly depends on inheritance. Autosomal dominant accounts for about 15% of all RP and is the least severe in presentation. Onset is gradual; the average best-corrected VA is 20/30 for someone under 30 years old. Autosomal recessive RP, the most common variant, has a poorer visual prognosis. Patients usually experience severely diminished vision early in life. X-linked is the rarest form and the most severe. Usually only males are affected, and VA is typically worse than 20/200.

Plan and Manage

Though it may seem daunting, genetic testing is readily available and accessible for patients with RP. For example, Invitae (through Spark Therapeutics) offers free genetic testing for IRDs (www.invitae.com/en/idyourird). Additional testing resources are available with the Foundation Fighting Blindness's My Retina Tracker Program through Blueprint Genetics. Saliva, blood or buccal samples are taken in-office using a pre-ordered collection kit. The specimen is then shipped to a company-specific lab and results come back in a few weeks.

Once mutation and inheritance patterns are discerned, treatment and management of your patient can begin. The only known genetic treatment currently available for RP is for mutations in the RPE65 gene; all other types require mindful management.[2]

"Being diagnosed with an incurable disease is a harsh reality for many to cope with," Dr. Bhatt says. "This information can empower the patient and allow them to come to terms with their diagnosis."

Genetic testing is critical to family planning, especially disease severity and inheritance. Knowing the specific mutation can also be valuable when it comes to future treatment options.

"New clinical trials and experimental gene therapies are always on the horizon, and knowing a patient's specific mutation can open the door to these opportunities," Dr. Bhatt says.

Knowing how severe the final disease state will be or how quickly it will progress provides both the patient and doctor crucial information. "Patients have a way to take their disease in their own hands and no longer fear the unknown," Dr. Bhatt notes. "Testing can also help the provider find the best resources and provide their patient better counsel."

It is key to emphasize that the disease is not the patient's fault and that, as a team, you and the patient will take on the challenge together. ■

1. O'Neal TB, Luther EE. Retinitis pigmentosa. StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2021.

2. Fahim AT, Daiger SP, Weleber RG. Nonsyndromic retinitis pigmentosa overview. GeneReviews. www.ncbi.nlm.nih.gov/books/nbk1417. January 19, 2017. Accessed March 29, 2022.

About Dr. Ajamian **Dr. Ajamian** is the center director of Omni Eye Services of Atlanta. He currently serves as general chairman of the education committee for SECO International and is vice president of the Georgia State Board of Optometry. He has no financial interests to disclose.

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Relieving Allergy Itch with Convenience and Comfort

By Andrew D. Pucker, OD, PhD
Assistant Professor, Department of Optometry & Vision Science,
University of Alabama at Birmingham

Allergens, such as pollen, ragweed, and animal dander, can produce ocular symptoms of itch in as much as 40% of Amercians.[1] Only about 10% of patients with ocular allergies (OA) seek medical care, suggestive of a tendency to self-treat.[2] With anti-allergy OTC sales being 10-fold greater than prescription sales, many patients are approaching pharmacy shelves without a clear doctor recommendation or understanding of which drop might best meet their needs.

While antihistamines and mast cell stabilizers are both effective at relieving symptoms of OA itch, and in some cases signs of conjunctival redness, dual-acting agents, including olopatadine (Pataday® products) and ketotifen (Zaditor®, Alaway®), have combined mast cell stabilizer and antihistamine effects and have been shown to provide better symptom control.[3] Furthermore, among the dual-acting agents available in the United States (US), only three products require once-daily dosing: Pataday Once Daily Relief (olopatadine 0.2%, 16-hour relief), Pataday Once Daily Relief Extra Strength (olopatadine 0.7%, 24-hour relief), and Lastacaft (alcaftadine 0.25%, 16-hour relief).[4] For comparison, the available topical antihistamines (e.g., pheniramine) and mast cell stabilizers (e.g., cromolyn sodium 0.2%) in the US typically require 4 times daily dosing, while most dual acting agents, including ketotifen, require 2-3 times daily dosing.[4] These differences can be important for patients who are busy or polymedicated and have a hard time remembering when to take their medications.

In addition to dosing frequency, topical anti-allergy drops can also differ in their comfort upon application, a characteristic that is driven by how closely the pH of the drug matches the ocular surface. For example, formulations that contain ketotifen and pheniramine maleate have an acidic pH between approximately 4.4 to 5.8. For reference, the average pH of a normal tear film is approximately 7.5, which is closer to the approximate 7.0 pH of olopatadine drugs.[5] This difference in ocular comfort was exhibited in two different studies comparing comfort upon application of Pataday Extra Strength to Alaway (ketotifen 0.025%; Bausch & Lomb, Inc.) or to Visine Allergy Eye Relief Multi-Action (pheniramine maleate 0.3%/naphazoline HCl 0.025%; Johnson & Johnson Consumer, Inc.). Participants in each study felt that Pataday was more comfortable upon application compared to Alaway (N=161; $p<0.001$) or Visine Allergy (N=161; $p<0.003$). In fact, more participants preferred or strongly preferred Pataday Extra Strength over Alaway with respect to overall comfort (64.2% vs. 20.8%), burning (64.8% vs. 15.7%), and stinging (66.7% vs. 17.0%) upon application (Figure 1). Similarly, more participants preferred or strongly preferred Pataday Extra Strength over Visine Allergy with respect to overall comfort (61.8% vs. 21.0%), burning (60.2% vs. 15.8%), and stinging (60.1% vs. 19.0%) upon application (Figure 2).

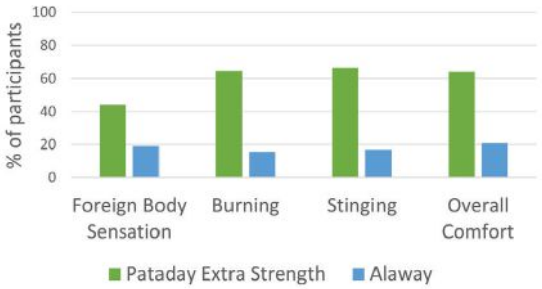

Figure 1. Percentage of participants who "preferred" or "strongly preferred" Pataday Extra Strength or Alaway based on symptoms upon application.

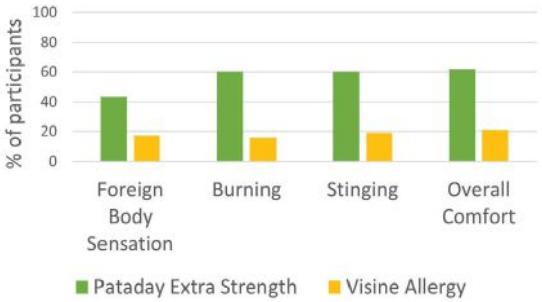

Figure 2. Percentage of participants who "preferred" or "strongly preferred" Pataday Extra Strength or Visine Allergy based on symptoms upon application.

In conclusion, dual-acting agents effectively relieve ocular allergy itch, but Pataday Extra Strength is conveniently available OTC, provides 24-hour ocular allergy relief, and was shown to be more comfortable upon application than two other allergy drops.

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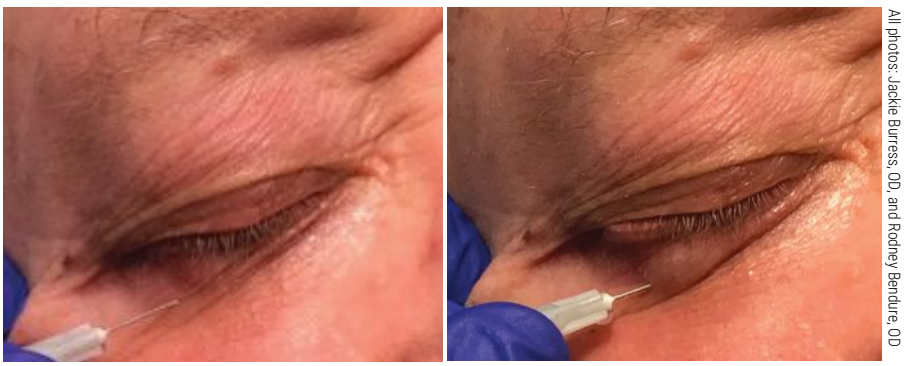
BRINGING INCISIONS AND INJECTIONS TO YOUR CLINIC

This article—the first of a four-part series on optometric scope expansion—discusses how to incorporate these services into your practice flow.

BY CATLIN NALLEY
CONTRIBUTING EDITOR



All photos: Jackie Burress, OD, and Rodney Bendure, OD

On the left, a patient receives an injection of lidocaine prior to removal of a lesion on the palpebral conjunctiva. On the right is the same patient immediately after injection with the bolus of anesthetic visible under the skin.

Optometrists typically know more, and are capable of doing more, than their state licensure will allow, a source of frustration for many and a setback to the efficient delivery of care in United States. Fortunately, especially in the last several years, the laws have been catching up. Multiple states have passed bills to allow more ODs than ever to practice to the full extent of their training and ability, and the momentum is clearly building.

Over the next four months, we'll be digging into some of the newer optometric capabilities with advice from those who already have mastered the ins and outs.

Two practice privileges that a growing number of ODs in the country can embrace are (1) administering certain intralesional injections and (2) performing minor in-office procedures such as removal of lesions in and around the eye. Whether your state already allows you to perform these procedures, is in the process of trying to pass legislation or still has a ways to go to before scope expansion efforts come to fruition, this article will provide guidance on smoothly implementing these services into your practice when it's inevitably time, as well as how to ensure each physician receives the proper training.

Adding Services: The Logistics

Once a state expands its optometric scope of practice, there are many important considerations for practice owners to keep in mind when offering a new service to patients. The first—and arguably the most important—factor to consider is whether additional certification or education is required by that particular state's law.

When offering lesion removal and injections, optometrists who have graduated within the last decade or two have often received the necessary training in school to conduct these procedures, notes Jackie Burress, OD, of Oklahoma, one of the earliest states to get on board with optometric scope expansion. However, for optometric physicians who are more seasoned in the field and did not receive this training as part of their education, additional certification or training courses may be obligatory. Specific requirements will vary from state to state, so it's important to check with the board of optometry in your state before offering these procedures at your practice.

For optometrists who may not legally be required to undergo additional training but nevertheless want to refresh or enhance their clinical skills, shadowing a colleague who is already engaged in the service is a good way

to start. Hands-on CE courses can also be helpful—not only to develop skills but also to better understand the tools as well as the practical components needed to expand clinical services.

Procedure set-up does take time, which could prove challenging in a busy practice. For this reason, Dr. Burress recommends dedicating them to a specific day. "This allows you to focus all of your attention on the procedures instead of fitting them in around standard appointments, which is more efficient and ensures optimal patient care," she says.

Having the right tools at your disposal is also important (see *"Prepping Your Clinic for Incisions and Injections,"* on page 39, for a recommended list); however, don't get caught up in the misconception that starting surgical procedures requires a huge financial investment, urges Richard Castillo, OD, DO, associate dean at Northeastern State University of Oklahoma (NSUOK) College of Optometry and a fierce advocate for optometric scope expansion. "Invest in yourself and your knowledge base," he says. "Remember, you already bring a lot to the table. Your technical skillset and clinical understanding are what will help you successfully integrate these procedures into practice." Dr. Castillo's dual degrees in ophthalmology and optometry give him unique insights into the gaps between the two professions and how best to reconcile them.

For biopsies, you will need to work with your local lab to determine which preparations it will accept, according to Rodney Bendure, OD, another NSUOK optometrist. Upon request, the lab should provide the necessary specimen containers and requisition forms.

Billing and appropriate documentation is another logistical aspect of lesion removal and injections that ODs will have to adapt to in practice. Histopathological evaluation of lesions will be an additional cost to the patient, so it's important to be transparent and let them know what to expect to avoid pained surprise. Dr. Bendure uses the phrase "abundance of caution" when discussing the need for labs or referrals with patients, particularly those who may be hesitant.

HOW TO COPE WITH YOUR NEW SCOPE

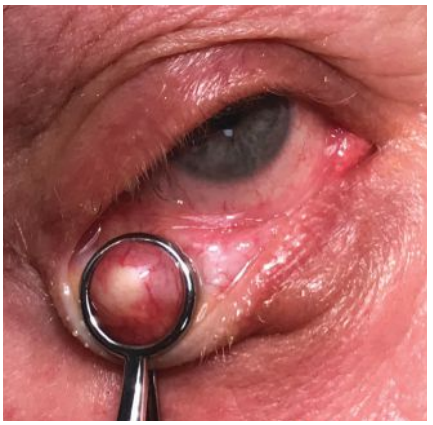
The optometric profession is currently in the midst of a new wave of expanded scope of practice legislation, both proposed and enacted, with many bills aimed at bringing "hands-on" procedures like lesion removal and minor laser surgery to optometry. Others seek to plug the remaining holes in optometric pharmaceutical prescribing rights, notably in oral medication use.

Most recently, Virginia passed legislation enabling its ODs to perform three types of laser surgery—YAG capsulotomy, laser peripheral iridotomy and selective laser trabeculoplasty—while similar efforts in Alabama were stymied by opposition. Though the fight for expanded scope of practice is far from over, ODs can use this growing momentum to enhance not only their own practices but also the profession and eye care at large.

"I have witnessed optometry evolve from a material and retail-based profession to a healthcare service-based profession," notes Dr. Castillo. "The transformation began in the 1970s when optometry started administering eye drops to screen for disease, and since then, the profession has become the largest provider of primary eyecare services in the nation. Today, we have nine states with statutory laser authority and almost 20 states with some level of surgical procedure authority. This progress is only going to continue," he says.

To help you better understand the new and emerging practice privileges, we are publishing a series of four articles that delve into the various categories of scope expansion, offering clinical best practices and discussing the logistics of adding each service. This first article highlights incisions and injections: where to start when integrating these procedures, what tools are needed and how to achieve great outcomes. The remaining three articles in this scope expansion series, which will appear across our next several issues, will include guides to laser surgery, glaucoma treatment and prescribing oral medications.

If you practice in a state where you're already able to offer these services to your patients, this series will provide you with a refresh on the basics of each procedure and give you advice on bettering your practice flow. If you practice in a region where expansion efforts are still underway, each of these four articles will offer information on what you should know and can do to help prepare you and your staff for when it comes time to incorporate these new and exciting services into your clinic.



Before you perform the incision/curettage, the chalazion should be clamped to prevent the mass from moving during the procedure.

Knowing and vocalizing the pros and cons of the various options will help patients feel more secure in your care, especially while these services are still being introduced to your practice.

Clinical Pearls for Incisions and Injections

Lesion removal and anterior segment injections encompass a number of different procedures, including intradermal injection for anesthesia, incision and curettage of chalazion and snip excisions, just to name a few. It is important to consult with your state board to determine which specific procedures are allowed under your state's optometry laws.

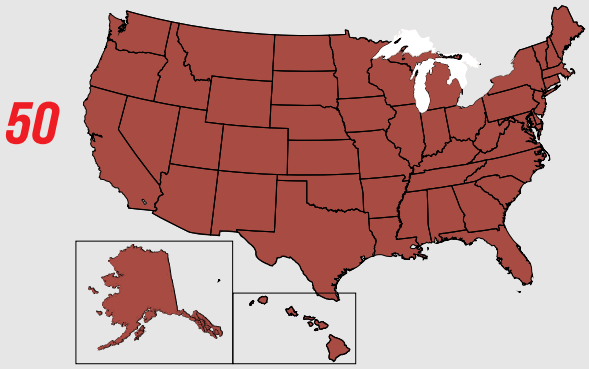
As with any procedure, the clinical work begins with obtaining a thorough medical history and informed consent from the patient, explains Dr. Burress. This history should include past or present medical conditions, drugs and latex allergies and current medications, including both prescription and OTC.

Dr. Burress recommends paying close attention to anticoagulants, such as aspirin, NSAIDs, warfarin, heparin, dipyridamole and clopidogrel, since they can increase the risk of bleeding and prolong healing. Consulting with the patient's primary care provider could help you decide if it is safe to temporarily stop the anticoagulant for lesion removal.

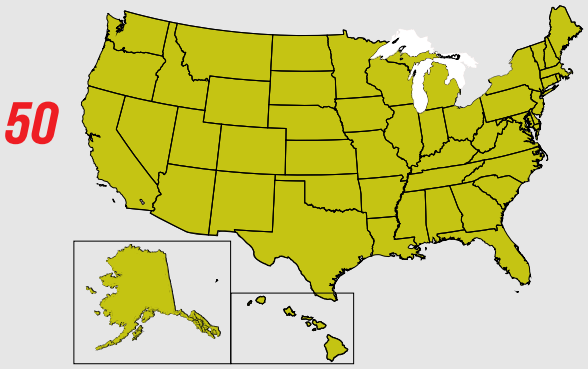
STATUS OF OPTOMETRIC LAWS ACROSS THE UNITED STATES

From Rhode Island's passage of the first diagnostic pharmaceutical agent law in 1971 to Virginia's laser law, enacted just two months ago, the optometry profession has spent over 50 years fighting—and largely winning—battles in state legislatures to allow ODs to better capitalize on their expertise for the good of their communities. These victories

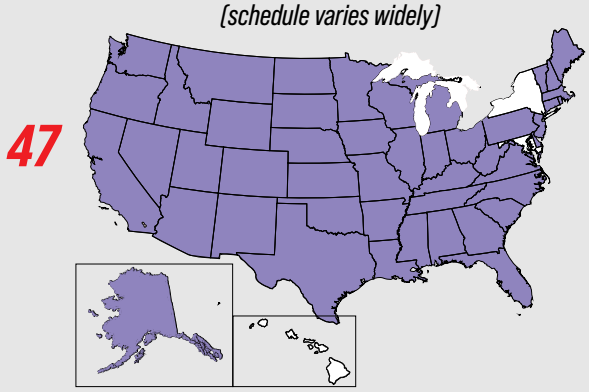
Diagnostic and Therapeutic Pharmaceutical Agents
(unless otherwise specified)



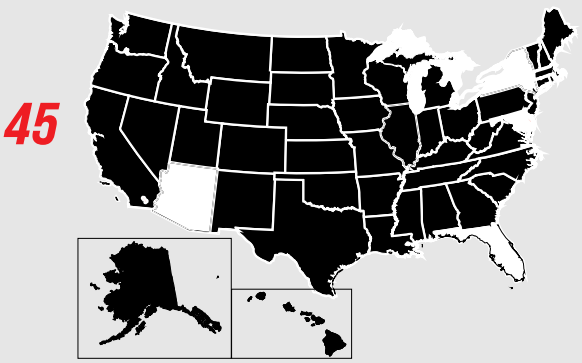
Glaucoma Authority
(topicals only: Florida, Maryland, New York)



Rx Controlled Substances
(schedule varies widely)



Oral Antifungals



Prior to a procedure, Dr. Bendure makes sure to check patient vitals. "I had a young, healthy female in my chair about 12 years ago," he recalls. "She wanted a few skin tags removed around her eyelids. I injected the areas to be treated with Xylocaine with epinephrine." She was doing fine until he massaged the skin to disperse the medication.

"Apparently, I was too aggressive with the digital massage—she had a vasovagal response, turned pale green and passed out," he continues. "Turns out getting her legs and feet elevated and putting a fan on her was all she needed." Checking a patient's vitals beforehand is always a good idea to help predict whether there is a possibility of complications during care that may perhaps be unrelated to the procedure itself.

When Corri Collins, OD, of Lexington, KY, sees a patient for lesion removal, she always takes a pre-op photo to allow for accurate documentation. This allows patients to have a clear, visual comparison of what their eye looked like before and after the procedure.

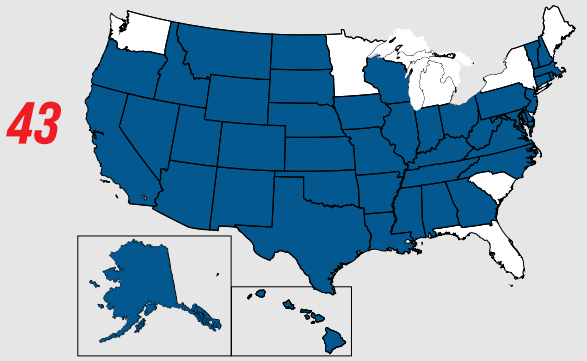
"The majority of lesions I find myself removing are stubborn, irritating skin tags," says Dr. Collins. "These small papillomas typically make their home in the creases of the eyelids where most patients find it to be uncomfortable or irritating." She also adds that lesion size and location can help you determine if a local anesthetic is necessary.

"I typically do not inject local anesthetic if the papilloma is small or very close to the lid margin," Dr. Collins explains. "This is just personal preference due to the pain involved with the injection being the same, if not more, than what is endured with the removal alone."

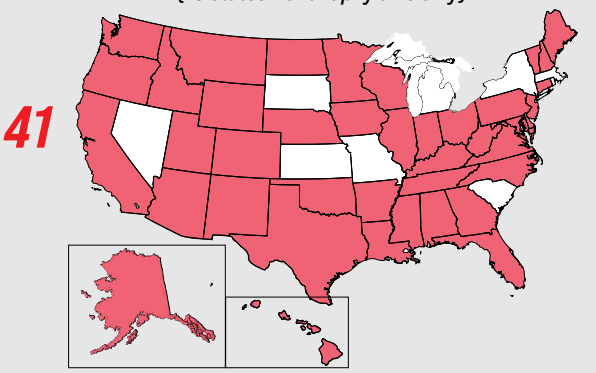
In cases where local anesthetic is warranted or preferred by the patient, it can be helpful to mark the lesion before injecting to ensure the original borders, according to Dr. Collins. "You will be inserting the needle laterally at 5-10 degrees with the bevel up and aspirate to ensure correct location," she explains. Then, after injecting 0.5mL to 1mL of anesthetic, gently massage the area and wait five minutes for the medication to take effect.

have expanded access to eye care, lowered costs and increased patient convenience. Still, opposition has been and will continue to be fierce. A recent expansion bill was struck down in Alabama. Contact the AOA and/or your state association to find out how to help advocate for new privileges and obtain any necessary training.

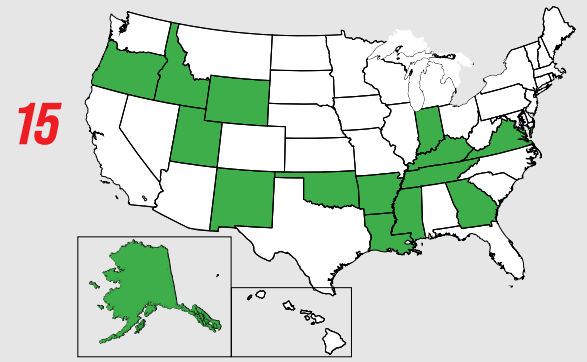
Oral Steroids



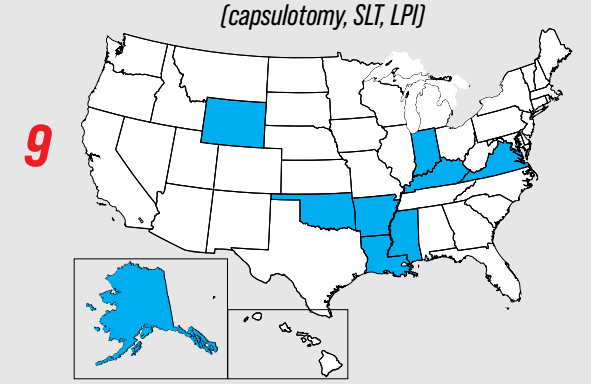
Some Injectable Drugs
(19 states: for anaphylaxis only)



Excision of Lumps and Bumps



In-office Laser Surgery
(capsulotomy, SLT, LPI)

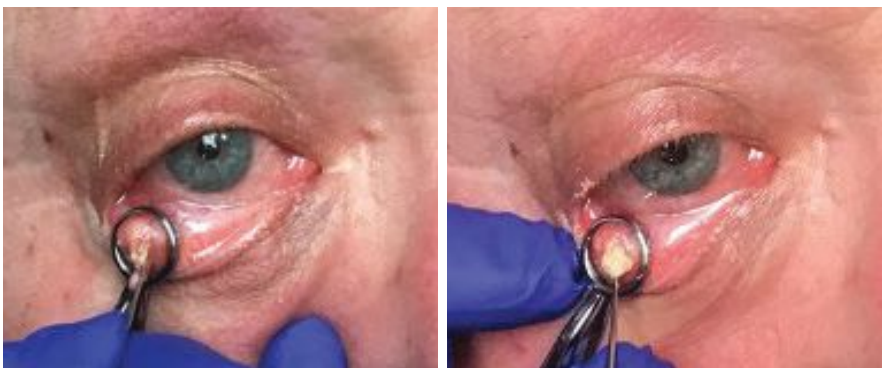


"One stick is best—so inject a portion of the anesthetic (lidocaine, for instance) and, without pulling the needle out of the skin, back it up a bit, then push forward in another direction," advises Dr. Bendure. "Do this a few times until you have infiltrated the entire area beneath the lesion and then remove the needle."

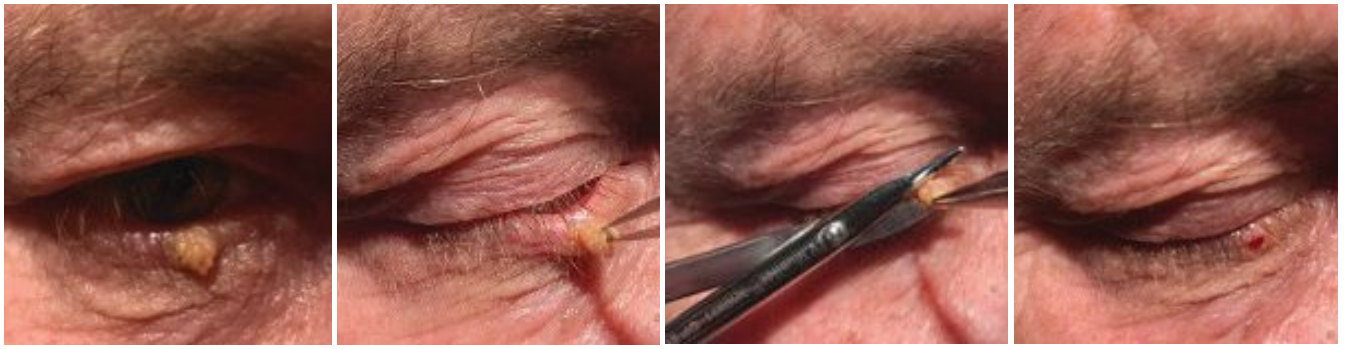
After creating a sterile environment and positioning the necessary equipment close by (a sterile betadine swab, sterile gloves and erythromycin ointment), Dr. Collins says she usually removes these lesions outside of the slit lamp using a headband magnifier. She finds that this method allows for a much larger range of motion while maintaining the same level of clarity.

Dr. Collins takes the following steps for the procedure of removing a lesion around the eye:

1. Wash hands thoroughly and put on sterile gloves.
2. The sterile betadine swab is applied to the lesion and the surrounding area—starting at the lesion and circling out.
3. Once dried, take the tissue forceps (she uses the Adson brand) to pull the lesion away from the skin to



The left image shows granulomatous material extruding from the palpebral conjunctival lesion upon incision. On the right, curettage of the chalazion is expelling the material.



From left to right: Squamous papilloma pre-op; isolation of papilloma using forceps to expose the base; surgical scissors are used to snip the lesion at its base; immediately after lesion removal with snip excision. Note the minimal amount of blood seen in the last image.

LESION REMOVAL: BEST PRACTICES TO REMEMBER

First and foremost, it is important to have a clear understanding of the different types of "lumps and bumps" and the characteristics of skin lesions that imply benign, malignant or uncertain, notes Dr. Bendure.

The standard of care in all 50 states dictates lesions with risk of malignancy be tentatively diagnosed as cancerous and biopsied, notes Dr. Castillo. Most states prohibit ODs from removing a cancerous growth; therefore, referral to an ophthalmic surgeon for excision and biopsy to rule out malignancy is necessary in those cases.

Another key component is anatomy. While ODs have been taught this information, Dr. Bendure urges them to brush up on their knowledge before initiating these procedures in their clinic. "For instance, in the case of triamcinolone injection for a chalazion, you want to make sure you don't cause a central retinal artery occlusion—that really is a possibility," he says. There are anastomoses between the superficial vessels and the ophthalmic artery, he explains.

"If you happen to inject directly into a vessel, you could easily overwhelm the pressure gradient, push the steroid suspension retrograde into the ophthalmic artery and cause blindness," he adds. "So, you should always pull back on the plunger to check for a flash of blood and ensure you aren't going to inject into a vessel."

Other best practices:

- Be prepared to treat emergencies that may arise, including working with EMS if needed in extreme cases.
- Westcott scissors are Dr. Bendure's go-to for most skin tags, but tweezers and a scalpel also work well.
- Radiosurgical units create extremely clean cuts and have the ability to coagulate with the turn of a dial. For eyelid margin lesions, Dr. Bendure has had fantastic aesthetic results, but reminds ODs to use a scleral shell.
- Purchase a vacuum to suck up the tissue plume created with the radiosurgical unit—you don't want to breathe in viral papilloma particles. (A certified HEPA-filtered tissue smoke evacuator is an OSHA requirement.)
- The *Atlas of Primary Eyecare Procedures* is a useful resource for ODs performing these procedures.

get the best view of the base of the lesion. Then, use the Westcott tenotomy scissors to cut the lesion at its base.

4. If a biopsy is warranted, place the specimen in the container, fill out the appropriate paperwork and send it to the practice's local lab.

THE DON'TS OF LESION REMOVAL

Knowing what not to do is just as valuable as knowing what to do. Here are a few missteps to avoid:

- Do not inject Kenalog into darker pigmented patients.
- Never use radiosurgical devices on patients with any electronic implanted devices.
- If you are planning to biopsy a specific lesion, do not use radiosurgery to remove it because the lab is not able to perform a biopsy on tissue that has been subjected to the types of reactive changes RF causes in the tissue.
- Do not inject or cut into a suspected cancerous lesion.

"Usually there is very minimal bleeding involved in these procedures, thus there is very little clean-up to the affected area," says Dr. Collins. "Lastly, I apply erythromycin ointment to the affected area and prescribe the patient a 3.5g tube to continue to use BID until I see them back for their post-op, which is usually one week later."

When removing lesions, it is important to consider how deep you need to go, according to Dr. Bendure. Is it a pedunculated squamous papilloma, for instance, which will likely be a simple snip? Or is it a sessile nevus, which would be better treated with radiosurgical excision to provide a better aesthetic appearance after healing?

Hidrocystoma, also known as a sudoriferous cyst, is another type of lesion Dr. Collins frequently sees in patients at her practice. These lesions can be easily lanced and drained in the office. In most cases, she uses a scalpel blade to open the cyst and then drains the fluid while holding gauze pads to the area to assist with clean-up.

"On some occasions, you will need to use the Westcott scissors to remove additional skin that could be present once the fluid is drained," she said. "Lastly, you will apply erythromycin ointment to the affected area, prescribe it BID to the area and evaluate it at the post-op visit one week later."

For chalazion removal, Dr. Collins prefers to err on the side of caution and makes sure the patient has been using heat masks twice a day for at least three months before considering removal or intralesional injections.

"When determining intralesional injection (Kenalog) vs. incision and curettage, there are a few things you need to consider," she notes. "The steroid injection is only about 75% to

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INDICATIONS AND USAGE
Verkazia® (cyclosporine ophthalmic emulsion) 0.1% is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis in children and adults.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Potential for eye injury and contamination: To avoid the potential for eye injury and contamination, advise patient not to touch the vial tip to the eye or other surfaces.

ADVERSE REACTIONS
The most common adverse reactions reported in greater than 5% of patients were eye pain (12%) and eye pruritus (8%), which were usually transitory and occurred during instillation.

You are encouraged to report adverse reactions of prescription drugs to Santen at 1-855-7-SANTEN (1-855-772-6836). Or you may contact the U.S. Food and Drug Administration (FDA) directly. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Brief Summary on adjacent page and Full Prescribing Information at verkazia.com.

REFERENCES: 1. Verkazia [package insert]. Emeryville, CA: Santen Inc.; 2021. **2.** Leonardi A, Doan S, Amrane M, et al; for VEKTIS Study Group. A randomized, controlled trial of cyclosporine A cationic emulsion in pediatric vernal keratoconjunctivitis: the VEKTIS study. *Ophthalmology*. 2019;126(5):671-681. doi:10.1016/j.ophtha.2018.12.027 **3.** Bremond-Gignac D, Doan S, Amrane M, et al; for VEKTIS Study Group. Twelve-month results of cyclosporine A cationic emulsion in a randomized study in patients with pediatric vernal keratoconjunctivitis. *Am J Ophthalmol*. 2020;212:116-126. doi:10.1016/j.ajo.2019.11.020 **4.** US Department of Health and Human Services. *Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations*. 42nd ed. US Government Publishing Office; 2022. Accessed March 16, 2022. https://www.fda.gov/media/71474/download

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cyclosporine ophthalmic emulsion 0.1%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
Verkazia ophthalmic emulsion (0.1% (1mg/mL) cyclosporine) is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

GENERAL DOSING INFORMATION
Contact lenses should be removed before applying Verkazia and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 10 minutes apart to avoid diluting products. Administer Verkazia 10 minutes prior to using any eye ointment, gel or other viscous eye drops.

DOSAGE AND ADMINISTRATION
Instill one drop of Verkazia, 4 times daily (morning, noon, afternoon, and evening) into each affected eye.

Treatment can be discontinued after signs and symptoms are resolved and can be reinitiated if there is a recurrence.

CONTRAINDICATIONS
None.

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

ADVERSE EVENTS
Table 1: Adverse Reactions Reported in ≥ 1% of Patients Receiving Verkazia

	(N=135)
Eye Disorders	
Eye pain[a]	12%
Eye pruritus[b]	8%
Ocular discomfort[c]	6%
Visual acuity reduced	5%
Ocular hyperemia	4%
Systemic	
Cough	5%
Headache	4%
Upper respiratory tract infection	2%
a Including eye pain and instillation site pain b Including eye pruritus and instillation site pruritus c Including foreign body sensation and ocular discomfort	

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
There are no adequate and well-controlled studies of Verkazia 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 [*see Data*].

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 320 and 2150 times higher than the daily maximum recommended human ophthalmic dose (MRHOD) of 0.015 mg/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 185 and 650 times higher than the MRHOD, respectively).

An oral dose of 45 mg/kg/day cyclosporine (approximately 485 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 mothers or offspring were observed at oral doses of up to 15 mg/kg/day (160 times greater than MRHOD).

Pediatric Use
Verkazia's safety and effectiveness has been established in patients from 4 through 18 years of age.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis
Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value. The low dose in mice is approximately 5 times greater than MRHOD.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low dose in rats is approximately 5 times greater than MRHOD.

Mutagenesis
In genetic toxicity tests, cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. Cyclosporine was positive in an in vitro sister chromatid exchange (SCE) assay using human lymphocytes.

Impairment of Fertility
Oral administration of cyclosporine to rats for 12 weeks (male) and 2 weeks (female) prior to mating produced no adverse effects on fertility at doses up to 15 mg/kg/day (160 times higher than MRHOD).

CLINICAL STUDIES
The safety and efficacy of Verkazia for the treatment of VKC was evaluated in two randomized, multi-center, double-masked, vehicle-controlled, clinical trials (VEKTIS Study; NCT01751126 and NOVATIVE Study; NCT00328653).

A total of 168 and 118 patients were enrolled in the VEKTIS and NOVATIVE studies for the efficacy analyses, respectively. Patients' age ranged from 4 through 17 years (mean age 9 years) in VEKTIS and 4 through 21 years (mean age 9 years) in NOVATIVE, with most patients being between 4 and 11 years of age (76% in VEKTIS and 80% in NOVATIVE) and male (79% in VEKTIS and 81% in NOVATIVE). Most of the patients had both limbal and tarsal forms of VKC (65% in VEKTIS and 74% in NOVATIVE). In both studies, patients had experienced VKC for a mean of 3 years prior to enrollment and all patients had a history of at least one recurrence of VKC in the year prior to study entry.

STORAGE AND HANDLING
Do not freeze Verkazia. Store at 20°C to 25°C (68°F to 77°F). After opening the aluminum pouch, the single-dose vial should be kept in the pouch to protect from light and avoid evaporation. Any opened individual single-dose vial with any remaining emulsion should be discarded immediately after use.

PP-VKC-US-0024

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90% effective with 25% of patients needing a second injection, whereas incision and curettage is typically over 90% effective."

Another consideration is skin color. If the patient has darker pigmented skin, Kenalog could cause lightening of the tissue; for that reason, it's typically contraindicated in this patient population, says Dr. Collins.

Just like any procedure, performing intralesional injection begins by establishing a sterile environment—with properly sanitized or disposable tools—followed by application of the betadine to the affected area and then either external or internal injection. "If you administer an injection externally, this will require you to inject tangentially to the globe; internal injections will require a clamp to evert the lid to inject," explains Dr. Collins. "You will be injecting 0.2-0.4cc of 10-20mg/mL, applying gentle pressure afterwards and advising the patient to use erythromycin ointment BID for one week."

Incision and curettage require a clamp to evert the lid, a scalpel to create a vertical incision (about 2-3mm away from the lid margin) and involve a curette to remove the internal contents, she outlines. "Lastly, forceps/Wescott scissors will be used to remove the fibrotic capsule to ensure it does not return. Once again, apply gentle pressure and prescribe erythromycin ointment BID for one week."

Although the procedures described above are among the most common, gaining incision and injection privileges opens up broad new vistas that require the OD to recognize their capabilities—and their limitations. Be sure to have a protocol in place for appropriate referral of cases beyond your wheelhouse, as well as time in your schedule to continually work on building your skills and educating yourself on safety and best practices.

PREPPING YOUR CLINIC FOR INCISIONS AND INJECTIONS

Successful incorporation of new procedures depends, in part, on having the necessary tools at your disposal. For instance, it is important to have specific procedure consent forms as well as pathology vials and forms, according to Dr. Collins. To offer lesion removal and injections, the initial set-up shouldn't break the bank. Tools to have on hand include:

- Specimen containers
- Sterile betadine swabs
- Sterile towels
- Eye patches/pads
- 4x4 gauze pads
- 1" paper tape
- Syringe/needles (typically ½ to 1 inch with 25-27 gauge)
- Adson tissue forceps
- Scalpel (No. 3 or 4) with blades (11 or 15)
- Sharps container
- Chalazion clamps with curettes
- Westcott scissors
- Headband magnifier
- Anterior segment camera
- Local anesthetic (1% lidocaine with epinephrine 1:100,000 and 8.4% bicarb)
- Kenalog (10-40m/mL) or triamcinolone
- Ointments (preferably erythromycin)
- High-temperature cautery
- Autoclave with sterilization packs

Depending on the types of lesions ODs at your practice are planning to remove, a radiosurgical unit may be a beneficial addition to your clinic. Another consideration is whether to invest in reusable or disposable tools. Dr. Bendure brings up the point that advantages can be seen with either option as you compare initial costs vs. the time required to clean and sanitize surgical instruments. Ultimately, he notes, it's up to the optometrist to determine what works best for their individual practice and the patients they care for.

Looking Ahead

As the current wave of scope expansion continues to gain momentum across the country, ODs are in the perfect position to take advantage of this progress for the benefit of their patients, practices and profession. By practicing to the fullest extent of their scope, optometrists are able to provide their patients with the highest level of care possible.

"As primary eye care providers we have the responsibility to give our patients the best access to timely, comprehensive care," notes Dr. Burress. "And so, if it is within our scope to provide additional services that can save our patients time and money, we need to. This is especially important in rural areas that may have limited facilities close by. The more we can do in-office to meet our patients' needs and improve the quality and convenience of their care, the better."

Optometrists who currently don't have the ability to perform these procedures in their state have a key role to play in changing that. Get involved with your professional organizations and help raise awareness among the community and legislators. "Building a relationship with your state representatives is crucial," says Dr. Castillo. "Become a resource for legislators and participate in the grassroots efforts in your state." In order for the voice of optometry to overtake that of the opposition, those who work directly in the field must be active advocates for expansion laws.

For those ODs whose scope of practice has expanded and are considering adding a new service, Dr. Collins encourages them to take the leap. "Our profession has fought to expand our scope to meet the same level as our education and training, so get out there and capitalize on the opportunities given to us," she says. "By integrating this into your practice, you will be providing top-tier optometric care and will be able to continue giving your patients the level of care they deserve." ■

PEER REVIEWED

VISUAL HALLUCINATIONS IN THE DEMENTIA SPECTRUM

Be proactive in asking patients questions and understand the risks they certainly face.

BY SARA WEIDMAYER, OD
ANN ARBOR, MI

ILLUSTRATIONS BY PAULA McDOWELL, OD
BIG RAPIDS, MI

Optometrists are the frontline workers in eye care and should be the first source patients turn to for reliable and accurate information about eye health and vision. We also should be providing patient education before problems arise or questions are asked. Finally, we should help patients recognize the circumstances under which they should contact us and help them understand what could happen.

Certainly, the information we give is broadly contextual—we educate aging patients about cataracts, we educate diabetic patients about retinopathy—so who would you preemptively educate about visual hallucinations? How do you frame a conversation around them? How often do you talk to your patients about visual hallucinations in general, especially when they didn't bring it up? My guess would be "not enough."

A major area where visual hallucination becomes relevant is in the context of neurodegenerative diseases on the dementia spectrum, all of which involve irreversible and progressive neuronal loss.[1] Here, we'll focus on visual hallucinations in the context of common dementia spectrum disorders.

Classification and Causes

Visual hallucinations are visual perceptions that occur without a corresponding visual stimulus; they occur due to neural activity without visual input. They can be simple (*e.g.*, photopsias, lines, dots, shapes or checkerboard patterns) or complex (formed images, *e.g.*, people, animals, objects).[2] There are even more minor forms of visual hallucinations such as a sensation or perception of a presence (*e.g.*, a person or animal standing behind them), a passage (*e.g.*, a the sensation of a dog passing by) or an illusion (*e.g.*, an actual object being seen as another object for a time, like a book momentarily appearing to be a bird).[3]

Minor visual hallucinations are transitory, and other hallucination episodes are typically short-lived; complex visual hallucinations usually last less than five minutes, can be static or kinetic and can occur any time throughout the day; most patients, even those with dementia, maintain understanding that these sightings are in fact hallucinations.[3,4]

Eyecare providers should be well-versed on Charles Bonnet syndrome (CBS), which involves complex visual hallucinations in cognitively sound individuals in the context of acquired visual impairment, but many are far less familiar with hallucinations in other settings.

Visual hallucinations in schizophrenia or other psychiatric disorders and in hallucinogen-induced states seem straightforward enough; but these stereotypical hallucinations—such as geometric patterns (*e.g.*, checkerboard, cobwebs, tunnel, spiral) that reduplicate and/or change in size/shape or in object composition—also occur in non-psychiatric conditions such as epilepsy or narcolepsy, due to tumors or strokes involving the visual pathway, brainstem or thalamus, and even in normal individuals just before falling asleep.[5,6]

About the author and illustrator

Dr. Weidmayer practices at the LTC Charles S. Kettles Medical Center, VA Ann Arbor Healthcare System in Ann Arbor, MI. She is also a clinical assistant professor for the Department of Ophthalmology and Visual Sciences, WK Kellogg Eye Center of the University of Michigan. **Dr. McDowell** is chief of pediatrics, pediatric residency supervisor and professor at Michigan College of Optometry at Ferris State University in Big Rapids, MI. She is an avid painter in her free time. They have no financial disclosures.

While the exact mechanisms of the dysfunctional visual information processing that produces visual hallucinations still eludes researchers, several areas along the visual pathway—spanning from the outer retina and optic nerve to the frontal, parietal and temporal cortices—have all been implicated.[7] Irritation to any of these areas may be to blame for visual hallucinations, but the type of irritation can vary from photoreceptor dysfunction to inflammation or ischemia, compression, medications, recreational drugs or migraines, among others, depending on the visual hallucination-provoking disorder.[8]

TABLE 1. VISUAL HALLUCINATION TYPES

Type	Examples
Minor	
Presence	Perception of a person/animal standing behind/nearby
Passage	Sensation of a person/animal passing by
Illusion	One object briefly looking like another object
Simple	Photopsias, lines, dots, shapes, checkerboard
Complex	Formed images (people, animals, objects)

In CBS, visual hallucinations have been attributed to a "release phenomenon" that occurs from deafferenation of the cerebral cortex's visual association areas after acquired visual impairment causes defective visual input.[6] While the precise source of the irritation leading to visual hallucination in the dementia spectrum is not well-defined, it is understood to be different than the release phenomenon in CBS. Much work remains to fully understand the pathophysiology of visual hallucinations in neurodegenerative disorders.

CBS should be touched on with every visually impaired patient since visual hallucinations in CBS occur in about 11% of people with severe vision loss, but don't miss another broad demographic of patients at even higher risk: those on the dementia spectrum.[9]

Dementia Spectrum

The most common dementias include Alzheimer's disease (AD), Parkinson's disease with dementia (PDD) and dementia with Lewy bodies (DLB); classification of these diseases is very complex but largely boils down to which proteins are misfolded. Amyloid-β extracellular plaques and hyperphosphorylated tau proteins causing intracellular neurofibrillary tangles (NFT) are characteristic of AD, whereas PDD and DLB demonstrate α-synuclein deposition in Lewy bodies and neurites.[1]

Clinically, patients with AD typically have a form of cognitive impairment whose domains include memory, language and perceptual processing deficits.[1] Parkinsonian motor dysfunction comprises typical features of Parkinson's disease (PD) such as rigidity, bradykinesia, gait impairment and rest tremor.[10] When cognitive function has become impaired enough that it affects social, occupational or basic activities of daily living, the criteria has been met to diagnose dementia.[10] The prevalence of dementia in PD is up to 78%; mortality follows the dementia diagnosis by about four years, on average.[10,11]

One minor visual hallucination—illusion—involves the patient transiently seeing one object as another, such as a book for a bird.

Clinical features of PDD and DLB overlap and include cognitive difficulties chiefly involving attention, executive dysfunction, memory impairment and visuospatial abnormalities in the context of the parkinsonian motor dysfunction.[1,10] PDD and DLB are differentiated from each other by the timing of whether parkinsonism or dementia develop first: those with parkinsonism who develop dementia less than one year after motor symptoms have PDD, whereas DLB includes those who develop dementia before parkinsonism or who develop dementia and parkinsonism within one year of each other.[1,10]

These patients—our patients on the dementia spectrum—need to hear from you about visual hallucinations. This phenomenon has been reported in up to 25% of those with AD.[12] In early stages of AD, minor visual hallucinations are the much more prevalent type to occur, and they may begin quite early in the disease process; other visual hallucination forms are not likely in early AD but are associated with moderate AD and more severe AD dementia.[4]

In patients with PD, visual hallucinations are reported in about 16% to 40%—more so in those with PDD where they're seen in up to 65%.[3,13] Minor hallucinations are the most frequent hallucinatory symptom in PD.[4] Interestingly, these minor visual hallucinations can also be experienced by patients—up to 30% of them—months to even several years before they develop any motor symptoms of PD.[14] The main predictive factor for having visual hallucinations in treated PD patients is cognitive impairment; others include older age, duration of disease, depressive symptoms, sleep-wake cycle disturbances and more severely affected motor status.[3,15] In PDD and DLB, complex hallucinations have been associated with increasing density and the distribution of Lewy bodies

TABLE 2. VISUAL HALLUCINATIONS AND NEURO DISEASES

	Alzheimer's Disease	Parkinson's Disease	Parkinson's Dementia	Dementia with Lewy Bodies
Characteristic findings	Neurofibrillary tangles of amyloid-β extracellular plaques and hyperphysphorylated tau proteins	Lewy bodies and neurites with α-synuclein deposits		
		Parkinsonian motor dysfunction		
			Dementia develops less than one year after motor symptoms	Dementia develops before motor symptoms or within one year of motor symptoms
Frequency of patients who have VH	Up to 25%	16% to 40%	65%	Up to 80%
Predominant VH type	Minor VH forms in early AD; other VH forms in later AD stages	Minor VH		Complex
Temporal development and key features of VH	Minor VH may occur at the beginning of early AD stages	Up to 30% may have minor VH months to years prior to motor symptoms		Complex VH are a typical early presenting feature of DLB

and NFTs in the temporal cortex in particular.[16]

Not surprisingly, complex visual hallucinations tend to worsen with time, both regarding frequency and severity, and are unfortunately a risk factor for dementia and a higher rate of mortality.[17-19] Visual hallucinations are overwhelmingly common in DLB, where they occur in up to 80% of patients.[20] In fact, recurrent complex visual hallucinations are one core diagnostic criteria for DLB and, along with early dementia, are a typical presenting feature of the disease.[10] While illusions are also common in DBL, they are less specific than the complex hallucinations that are diagnostically helpful.[10]

Patient Inquiry

Visual hallucinations are under-reported by patients, likely for many reasons. Minor ones are often quickly dismissed by patients and are often not reported at all, largely because they may not be particularly bothersome. On the other hand, some patients may be afraid of stigma or have concern for cognitive decline when they experience a hallucination, so they may not share these symptoms with their healthcare providers. Because visual hallucinations can be quite complex and very well-formed, while surprisingly sometimes perceived as pleasant, they can also be very distressing to patients.

In one study of patients with minor visual hallucinations, they had been occurring for a mean duration of nearly one year and were not mentioned by the patients until they were explicitly asked.[3] Other studies have similarly demonstrated that these patients do not volunteer experiencing them unless they're prompted by leading questions or a direct inquiry.[21] The bottom line is that we should be directly asking our at-risk patients—those on the dementia spectrum—if they have had any hallucinatory experiences.

Case One

An 80-year-old man presented, in part due to "floaters." On further questioning about what they looked like, these were not vitreous floaters as I had expected; what he described as "floaters" was the sensation of a full-sized and -shaped person passing by on the right side (passage visual hallucination). They had been occurring about once per month over the past year.

He had no previous diagnosis of any form of neurodegenerative process. He denied tremors and couldn't comment on gait changes such as shuffling, reduced arm swinging and rigidity because he couldn't walk much due to other health issues. He denied any noticeable changes in cognition. His eye exam was non-contributory. His primary care physician was consulted and the patient was scheduled for an evaluation of his motor function, reflexes and cognition to evaluate for a correlating diagnosis; early PD would be highly suspected and early AD would also be a consideration.

Takeaways: (1) Ask good clarifying history questions to elicit what the patient is really trying to tell you—ask them to describe in detail what they mean so you hear what they're communicating. (2) Minor visual hallucinations can precede motor symptoms in PD and can present early in AD—if a patient is reporting these hallucinations, recommend a further workup.

Discussion. While more formal interview templates are available regarding visual hallucinations, such as the North-East Visual Hallucinations Interview, eyecare clinicians can start with simple probing questions to classify any problem as relevant, such as onset, frequency, intensity and associated features; however, consider also asking about the complexity of the hallucination, and any associated thoughts, emotions and behaviors.[2]

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Important Safety Information

WARNINGS AND PRECAUTIONS

Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.

ADVERSE REACTIONS

The most common adverse reaction in clinical trials that occurred more frequently with OXERVATE was eye pain (16% of patients). Other adverse reactions included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, and increase in tears (1%-10% of patients).

Please see additional Important Safety Information on accompanying page and full Prescribing Information, including patient information, at OXERVATE.com/prescribing-information.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Dompé at 1-833-366-7387 or Usmedinfo@dompe.com.

TREAT NK TODAY
OXERVATE.com/HCP

*Study NGF0212 (REPARO): 52 patients per group; European patients with NK in one eye; 72% of patients completely healed; key findings were after 8 weeks of treatment; 6 times daily; vehicle response rate 33.3%.[2] Study NGF0214: 24 patients per group; US patients with NK in one or both eyes; 65.2% completely healed; vehicle response rate 16.7%.[2,7]

†Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea after 8 weeks of OXERVATE treatment.[2]

References: 1. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol.* 2014;8:571-579. **2.** OXERVATE (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. Boston, MA: Dompé U.S. Inc.; 2019. **3.** Voelker R. New drug treats rare, debilitating neurotrophic keratitis. *JAMA*. 2018;320:1309. **4.** Mastropasqua L, Massaro-Giordano G, Nubile M, Sacchetti M. Understanding the pathogenesis of neurotrophic keratitis: the role of corneal nerves. *J Cell Physiol*. 2017;232:717-724. **5.** Muzi S, Colafrancesco V, Sornelli F, et al. Nerve growth factor in the developing and adult lacrimal glands of rat with and without inherited retinitis pigmentosa. *Cornea*. 2010;29:1163-1168. **6.** Data on file. Dompé U.S. Inc.; 2021. NGF0212. **7.** Pflugfelder SC, Massaro-Giordano M, Perez VL, Hamrah P, Deng SX, Espandar L, et al. Topical recombinant human nerve growth factor (cenegermin) for neurotrophic keratopathy. *Ophthalmology*. 2020;127:14-26.

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US-OXE-1900180.02 02/21

oxervate®
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

Brief Summary of Safety

Consult the full Prescribing Information for complete product information.

INDICATIONS AND USAGE

OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

Recommended Dosage and Dose Administration

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

ADVERSE REACTIONS

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

In two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1-10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

Animal Data

In embryofetal development studies, daily subcutaneous administration of cenegermin-bkbj to pregnant rats and rabbits throughout the period of organogenesis produced a slight increase in post-implantation loss at doses greater than or equal to 42 mcg/kg/day (267 times the MRHOD). A no observed adverse effect level (NOAEL) was not established for post-implantation loss in either species. In rats, hydrocephaly and ureter anomalies were each observed in one fetus at 267 mcg/kg/day (1709 times the MRHOD). In rabbits, cardiovascular malformations, including ventricular and atrial septal defects, enlarged heart and aortic arch dilation were each observed in one fetus at 83 mcg/kg/day (534 times the MRHOD). No fetal malformations were observed in rats and rabbits at doses of 133 mcg/kg/day and 42 mcg/kg/day, respectively. In a pre- and postnatal development study, daily subcutaneous administration of cenegermin-bkbj to pregnant rats during the period of organogenesis and lactation did not affect parturition and was not associated with adverse toxicity in offspring at doses up to 267 mcg/kg/day. In parental rats and rabbits, an immunogenic response to cenegermin-bkbj was observed. Given that cenegermin-bkbj is a heterologous protein in animals, this response may not be relevant to humans.

Lactation

There are no data on the presence of OXERVATE in human milk, the effects on 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 OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older [*see Clinical Studies (14)*].

Geriatric Use

Of the total number of subjects in clinical studies of OXERVATE, 43.5 % were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis and Mutagenesis Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj.

Impairment of fertility Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male or female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD). In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).

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Being empathetic to the patient's experience by attentively listening and explaining what is occurring may provide emotional relief to the patient that there likely is a physiologic reason in addition to pointing them to additional help.

Case Two

A 74-year-old presented for a comprehensive exam. He had a history of treated PD, diagnosed 11 years prior, which was managed by neurology. When I asked him directly about visual hallucinations, he endorsed them. They had first started three years ago after an increase in Sinemet (carbidopa/levodopa, Merck) dosage, where he described thinking someone was sitting at a picnic table across the street but would then realize it was a garbage can (illusion). It occurred about weekly at first. He had told his neurologist about it at the time, and amantadine was started; the hallucinations were then only occasional.

However, in the past nine to 10 months prior to seeing me, he was seeing formed shapes and animals (complex visual hallucination) along with a more constant palinopsia that was noticeably worsening in complexity and frequency. He had seen two local optometrists in his hometown specifically regarding this but wasn't given any insight as to what was happening, so he wasn't even going to mention it. He also had developed worsening intense nightmares that were causing him to thrash quite violently in his sleep. I discussed the hallucination in the context of PD with him and his wife and consulted with his neurologist who decreased his Sinemet dosage.

When a patient experiences the minor visual hallucination known as presence, they often mistake shadows for people.

Initially, he did feel the change helped with lessening the frequency of the hallucination during the day; however, months later they were again worsening and had progressed to very frequent, more complex and very troublesome. He also noticed more illusions: "I can turn the chair into a bear or the computer screen into a hat." Because of this, he stopped driving. Additionally, his sleep symptoms were continuing to worsen, so much so that he feared for his wife's safety.

Amantadine was then stopped by his neurologist. Six months later, his daytime visual hallucinations had improved, but he would still occasionally misinterpret shadows as people and see illusions out of his window, such as park benches. Overall, this was a welcomed improvement. Meanwhile, however, his sleep symptoms had become more violent and severe. Next, mirtazapine was stopped, melatonin was increased and an updated consult with Sleep Medicine was ordered due to the REM sleep behavior disorder. This change in medication did further improve his daytime visual hallucinations, and perhaps lessened the frequency but not intensity of his RBD. By the next six-month interval with neurology, he was demonstrating increased irritability, anger, frustration and confusion in the evenings. Donepezil was added, and continued management is ongoing.

Takeaways: (1) He asked two eye doctors about his visual hallucinations and wasn't given an answer—don't be that doctor. (2) He didn't volunteer to me that he had experienced hallucinations but told me all about them when I asked—so, ask! (3) Visual hallucinations can be very troublesome to patients, both emotionally and functionally—they led this patient to stop driving. (4) Medication changes can help, but it's tricky to balance motor function symptoms, hallucinations, REM sleep behavior disorder and more—be sure to direct these patients to neurology for medication management and share salient information such as details and duration of patient-reported symptoms and relevant exam findings. (5) Complex visual hallucinations tend to worsen, and are a risk factor for dementia—this case developed functional changes in mood and mental status about two years after the onset of worsening complex visual hallucinations.

Discussion. How I tend to approach this clinically in patients with known AD, PD, PDD or DLB is first by offering basic information about visual hallucinations in these conditions, then asking if they have experienced the phenomenon. It might sound something like this:

"I see that you have Parkinson's. Interestingly, a high percentage of these patients eventually develop what's called visual hallucinations, which means seeing or perceiving things that aren't actually there. Sometimes these are more shadow-like shapes or patterns in the vision, or sometimes even just a sensation or feeling like someone is standing near you or passing by you, but isn't really there; however, sometimes they can become quite complex and realistic, like animals or people. There are medications available that may help if these develop. Have you ever experienced anything like this?"

You might just be surprised by what you hear, and how often you hear it.

Case Three

A 74-year-old male presented who had a history of symptoms including mild tremors, urinary incontinence, gait instability and cognitive impairment. Two years prior, after neuropsychological testing, neurology felt these symptoms were likely independent with multifactorial etiologies, not indicative of a neurodegenerative process at the time; however, about one year later, he developed visual hallucinations.

In Patients With Diabetic Eye Disease (DR and DME),

HELPING TO PROTECT VISION STARTS WITH YOU

IF YOU SEE OR SUSPECT DIABETIC RETINOPATHY

EDUCATE PATIENTS[1]

- Your early and frequent discussions about progression of disease, timely referral, and potential treatment options can empower patients[1]

REFER APPROPRIATE PATIENTS[1]

- The AOA recommends referring patients with severe NPDR and PDR within 2 to 4 weeks, and patients with higher-risk PDR with or without macular edema within 24 to 48 hours[1]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

Please see Important Safety Information throughout and Brief Summary of the full Prescribing Information on the following page.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

Brought to you by **REGENERON®**

FOLLOW UP WITH PATIENTS

- Encourage referred patients to promptly visit a retina specialist

CONTINUE TO MONITOR PATIENTS[1]

- The AOA recommends frequent monitoring of patients[1]
  - At least every 6 to 9 months in patients with moderate NPDR and more frequently for patients with greater disease severity

The more you know about anti-VEGF agents and other potential treatments for DR, the better you can help inform your patients. Find out more by visiting diabeticretinaldisease.com.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

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

anti-VEGF, anti–vascular endothelial growth factor; AOA, American Optometric Association; NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.

Reference: 1. Eye care of the patient with diabetes mellitus. American Optometric Association. Accessed April 2, 2021. http://aoa.uberflip.com/i/1183026-evidence-based-clinical-practice-guideline-eye-care-of-the-patient-with-diabetes-mellitus-second-edition/

07/2021
EYL.21.03.0229

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

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

1 INDICATIONS AND USAGE
EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

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

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections
EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation
EYLEA is contraindicated in patients with active intraocular inflammation.

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

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments
Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure
Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

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

6 ADVERSE REACTIONS
The following potentially serious adverse reactions are described elsewhere in the labeling:
- Hypersensitivity [*see Contraindications (4.3)*]
- Endophthalmitis and retinal detachments [*see Warnings and Precautions (5.1)*]
- Increase in intraocular pressure [*see Warnings and Precautions (5.2)*]
- Thromboembolic events [*see Warnings and Precautions (5.3)*]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.
A total of 2980 patients treated with EYLEA constituted the safety population in eight phase 3 studies. Among those, 2379 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEW1 and VIEW2) for 24 months (with active control in year 1).
Safety data observed in the EYLEA group in a 52-week, double-masked, Phase 2 study were consistent with these results.

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

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

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

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

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

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

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

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

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

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

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

6.2 Immunogenicity
As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.
In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].
Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data
Animal Data
In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg.
Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

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

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

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

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

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

17 PATIENT COUNSELING INFORMATION
In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [*see Warnings and Precautions (5.1)*].
Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

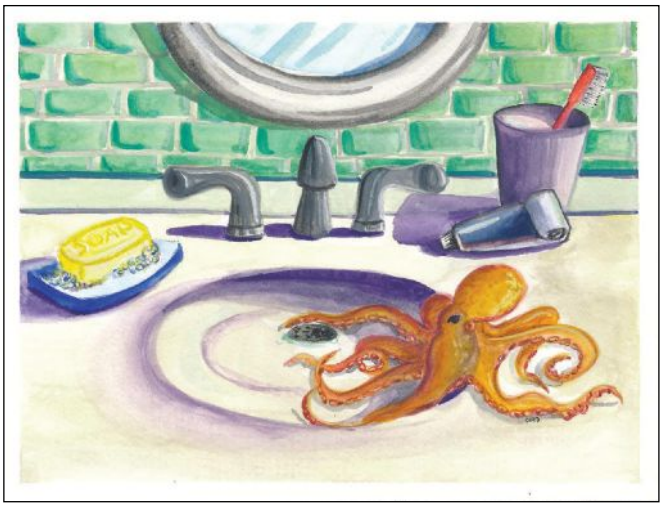
REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

Issue Date: 08/2019
Initial U.S. Approval: 2011

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

EYL.20.09.0052



Complex hallucinations involve formed images and can occur any time throughout the day.

These initially presented only upon awakening when he'd see spiders on the nearby wall. He even would get out of bed and try to hit them before realizing they were not there. They only happened in that setting and would last about 60 to 90 seconds.

At that point, with relatively early development of complex visual hallucinations, his symptom constellation became particularly concerning for DLB so carbidopa/levodopa was started. I saw him about a year later, and when I inquired about his hallucinations, he said he had been seeing "like a mouse or a squirrel in my house. I went after it and got it into the corner, but it wasn't even there. I see mice and stuff like that, and it's not there at all. Sometimes I see a spider that is not even there." The squirrels and mice were full-sized and very realistic appearing, and the spiders were the diameter of a cup. Because he saw them so often, he was no longer reacting to them. He continues to follow with neurology for management but was very grateful for the information and reassurance that these hallucinations are common in the context of DLB.

Takeaways: (1) Visual hallucinations are a helpful symptom diagnostically—in this case, it finally allowed the neurologist to connect the symptom constellation into a unifying diagnosis. (2) Patients appreciate compassionate listening, information and reassurance about what they are experiencing.

Management

As there have been no large-scale studies regarding treatment for visual hallucinations, case report, anecdotal and consensus literature are relied upon.[5] It is definitely not one-size-fits-all, and response to various medication classes varies from patient to patient, and depending on its cause.[5] Dopamine replacement medications may precipitate or exacerbate hallucinations, but dose adjustments or medication class changes can often help.[10]

Various abnormalities on office-based tests such as electroretinogram (ERG), visual evoked potential (VEP) and optical coherence tomography (OCT) have been demonstrated in certain subsets of this population, but these abnormalities have not yet proven to be diagnostic or specific to the dementia spectrum, so are of limited utility—and are not routinely recommended as of now in dementia spectrum patients.[13,22,23] In addition to a comprehensive dilated eye exam, ERG, VEP, OCT and visual field testing may be relevant to evaluate for clues that may point to or help rule out other sources of visual hallucinations.

Takeaways

Optometrists should be asking about symptoms of visual hallucinations and educating all patients on the dementia spectrum about the possibility. Preemptively educating patients about this possibility can soothe a lot of surprise and fear if and when they do develop and lets them know that treatments do exist. I would challenge you to ask—and educate—every patient (and/or their caregivers) who has a relevant medical history concerning visual hallucinations. ■

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COMBATING DRY EYE THROUGH COMMUNICATION

Proper education will lead both you and your patients to successful outcomes.

BY SELINA MCGEE, OD
EDMOND, OK

It goes without saying that having the right diagnostic tools in your office is important to treat dry eye, but there's something else that's just as critical to ensuring a successful outcome for all of your patients: communication. If they don't fully "hear" what we say, they'll fail to understand and commit to treat their condition. Understanding chronicity and the patient commitment to themselves is necessary for any treatment to be effective. Considering that only about 12% of adults in the United States have good health literacy, we have to be very intentional about how we communicate.[1]

What exactly is health literacy? It's the patient's ability to collect and understand information on their health status so they can make the best decisions for their unique situation.

Dr. McGee carefully communicates with her patient as they create a plan and discuss the steps that have to be taken to combat dry eye.

Since dry eye is highly prevalent and a chronic disease, this article will share how I present concepts of dry eye, build ocular surface health literacy and convey the responsibilities of the patient in a way that encourages adherence to my therapeutic plan.

About the author

Dr. McGee is founder and owner of BeSpoke Vision, a boutique private practice that offers patients a wide range of optometric care via its dry eye center, specialty contact lens clinic and aesthetics suite. She is also an adjunct assistant professor at the Northeastern State University College of Optometry and on faculty at the Oklahoma Medical Research Foundation at its Sjögren's clinic. She is a Fellow of the American Academy of Optometry, a Diplomate of the American Board of Optometry and is past president of the Oklahoma Association of Optometric Physicians. Dr. McGee consults for Allergan, Kala Pharmaceuticals and Novartis Pharmaceuticals.

Communication is Key

As author Stephen Covey once said, "Begin with the end in mind." The first step is to figure out what you want to accomplish with your dry eye patients. Developing a system for communication is very important. It's not just what you say but how you say it. Ask yourself the following questions:

- Do I have a communication system?
- If so, where are the gaps?
- What's working?
- More importantly, what's *not* working?

I have found the key to communication in our office is consistently working on the same language delivered in a way that the patient wants the information. Words matter, delivery matters and known processes are vital; a breakdown anywhere along that chain diminishes your return on investment.

Imagine a patient hearing different words used by different team members: one person says *dry eye*, another says *ocular surface disease* and someone else says *unstable tear film*. How confused would the patient be when they left the office?

Remember, it's not just you as the doctor delivering messaging. Every touchpoint in the office (and prior to the patient entering the office) is an opportunity to communicate. As you consider that, ask yourself these questions:

- Does my team understand the importance of dry eye?
- Do they know the consequences?
- Do they have the willingness to participate?

Education Roadmap

I cannot overstate how important beginning the education process with your team first dictates how successful you will be when educating your patients.

In my office, we created a roadmap of the patient journey to determine where we needed to talk about dry eye. Once that was completed, we discussed and practiced what would be said and by whom.

Dr. McGee's technicans are properly educated on dry eye, and in turn, help teach patients what they need to know during appointments.

First, we started with our digital footprint. We developed a wealth of information on our website for patients visiting us online before they came into the office, and we also direct patients back to the website if they need more information after their visit.

Next, our director of first impressions checks in the patient with a personalized greeting and a lifestyle questionnaire which includes sections specifically driven to gather symptoms of dry eye and educate the patient. When the patient is handed this form, our staff member also lets them know how prevalent and underdiagnosed dry eye is and why it's so important they answer honestly.

Next stop on the roadmap is the technician. I have invested in supertechs in my office, meaning the technician that works up the patient also scribes for me with the patient. I like this system because anything that occurs during the workup doesn't get lost in translation once I come into the exam, and I believe there is better continuity of care with this system. My technicians educate our patients every step of the way, explaining every diagnostic tool, what it is and why we perform it.

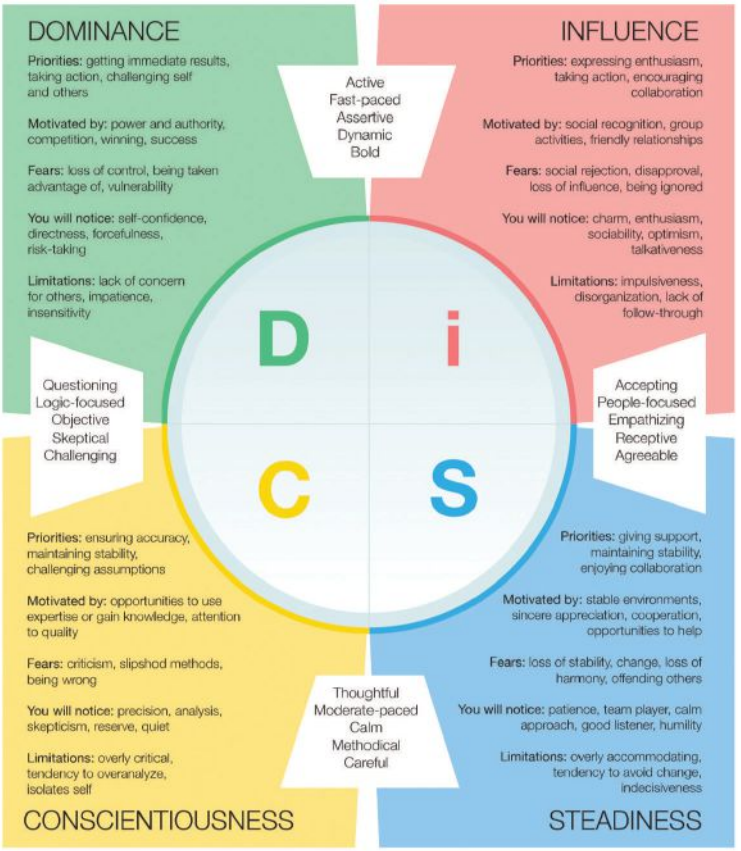
The way they ask questions to the patient is also key. How we phrase the questions can either expand the conversation or shut it down. Try to ask the questions so that "fine," "yes" or "no" are not available answers. An example is, "Do you experience x, y or z?" The answer that is too easily given is yes, no or maybe. If the patient does answer yes, you can certainly expand on that with follow-ups like, "Tell me more," "When does that occur?" or "What have you done about it?"

What happens if they answer no? You've effectively shut that conversation down. If you change that question with just one word, it makes a subtle difference: "When do you experience x, y and z?" The patient is going to be required to think about when that does happen. Maybe they only experience eyes that burn periodically or vision that fluctuates toward the end of the day. Once they elucidate their particular experience, everything that you talk about is driven toward helping that pain point.

When you become the person solving your patients' symptoms, the conversation becomes two-sided. If we don't do the legwork up to this point to find out what the patients' pain points really are, all we do is try to convince someone to adhere to solu-

tions for a problem they don't even recognize they have. We have all had that experience in the chair with a patient who clearly has signs of dry eye, but because we never tied it to them personally—giving them the why and how it's effecting their typical day—those conversations lead to frustration for both the doctor and the patient.

During examinations, I rely heavily on diagnostic tools to help me educate each patient. My tech workups help me expand upon the patient's chief complaint and how I can best help them achieve an optimized vision and ocular surface plan. We use standing orders when a patient answers two or more symptom questions to perform MMP-9 and tear osmolarity testing; this is all performed before I walk into the room.



The DISC personality test can be an important tool when communicating with and understanding your patients.

The refraction is a key component to not only helping patients achieve their best vision possible but also gives us many clues to their personality type as well as keeping your ears open for symptoms of dry eye. I'm listening for things like, "Wait, let me blink. Now it's clearer." That is a direct clue there is a problem that needs to be addressed. Explain to the patient why that blink is so important and remind them how their vision cleared when they blink. If we educate along the way, this helps the patient retain more information as well as save precious chair time.

Personality Profiles

Why do I care what type of personality my patient has? My goal is to truly connect with each patient, and to do that efficiently I lean on tools such as the DISC personality test. I have found that when I engage my listening skills and communicate with patients in the way they want to be communicated with, they feel heard, understood and are more likely to adhere to our dry eye plan because we've worked through it together. The way in which I educate each patient is different even though the content is the same. The tools I use to educate also cover all personality types so that there is something there for everyone and I can further customize it to each patient.

To simplify DISC, think of it this way: there are four types and most people have one strong tendency followed by a second. We each exhibit all four types at different times, but leaning into one may require more energy for that person. Think about the introvert at a party: they can be sociable, but may find the experience to be draining, and they will need to recharge before being at their best again. Each letter of the acronym stands for a personality; let's review a simplified version:

• ***D (dominance)*** individuals are doers and they want information quickly without a lot of detail. They are the patients during the refraction that answer before you even explain what you want done, and answers are clear and concise.

• ***I (influence)*** people are those who like to talk, are often the life of the party and they are the patient that is still talking to you as you place the phoropter if front of their face. Typically, you can barely get a question in as they chat.

• ***S (steadiness)*** types are your "feelers." They don't like change and are very careful about the decisions they make. They will also use "feeling" language; listen hard for those cues. Often, behind the phoropter it comes out as, "I don't want to choose, this is so hard. I feel like I failed this test."

• ***C (conscientiousness)***—the thinkers. These are the patients that need *all* of the information before making an informed decision. They may ask questions like, "Should I be looking at the O or the H? Should I choose the letters that are clearer or the ones that are easier to see?"

Based on the patient's personality type, I then communicate towards that. As I move through the rest of the exam using meibography, photography, vital dye (lissamine green and sodium fluorescein), functionality of meibomian glands as well as ocular surface, I use what I've learned about the patient to explain as I go and educate.

When Blepharitis/MGD Strikes,

STOP FLARES FAST

- **>50% reduction in symptoms of blepharitis/blepharoconjunctivitis in 1 week of dosing. No IOP spikes reported during first week of treatment[1,a]**
- **Greater bactericidal activity—more effective at killing MRSA than TobraDex* (>99.9% kill rate vs 0%)[2]**
- **Delivers 12.5× higher tobramycin concentration in ocular tissue compared to TobraDex[2]**

RESCUE YOUR PATIENTS FAST.
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Indications and Usage

For steroid responsive inflammatory ocular conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe and chronic anterior uveitis, corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies for which a corticosteroid is indicated and where the risk of superficial bacterial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

Important Safety Information

CONTRAINDICATIONS:

Most viral disease of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures. Hypersensitivity to any components of the medication.

WARNINGS & PRECAUTIONS:

- IOP increase – Prolonged use may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. IOP should be monitored.
- **Aminoglycoside sensitivity** – Sensitivity to topically applied aminoglycosides may occur.
- **Cataracts** – Posterior subcapsular cataract formation may occur.
- **Delayed healing** – May delay healing and increase the incidence of bleb formation. Perforations of the cornea or sclera have occurred. Slit lamp biomicroscopy, and fluorescein staining should be conducted.
- **Bacterial infections** – May suppress host response and increase secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- **Viral infections** – Use with history of herpes simplex requires great caution. The course and severity of many viral infections of the eye (including herpes simplex) may be exacerbated.
- **Fungal infections** – Fungal infections of the cornea may occur and should be considered in any persistent corneal ulceration.
- **Use with systemic aminoglycosides** – Total serum concentration of tobramycin should be monitored.

ADVERSE REACTIONS:

The most frequent adverse reactions (<4%) to topical ocular tobramycin are hypersensitivity and localized ocular toxicity, including eye pain, eyelid pruritus, eyelid edema, and conjunctival hyperemia.

The reactions due to the steroid component are increased intraocular pressure with possible development of glaucoma, and infrequent optic nerve disorder; subcap-sular cataract; and impaired healing.

The development of secondary infection has occurred. Fungal infections of the cornea may occur. Secondary bacterial ocular infection following suppression of host responses also occurs.

Non-ocular adverse events (0.5% to 1%) included headache and increased blood pressure.

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

[a]Randomized, investigator-masked, active-controlled, parallel-group trial conducted at 7 private practice clinical sites in the United States with 122 adult patients who had moderate to severe blepharitis/blepharoconjunctivitis.[1]

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TST-US-220017 03/22

TobraDex® ST
(tobramycin/dexamethasone ophthalmic suspension) 0.3%/0.05%
FORMULATED WITH XanGen®

TOBRADEX® ST (tobramycin/dexamethasone ophthalmic suspension) 0.3%/0.05%

Brief Summary

This Brief Summary does not include all the information needed to use TOBRADEX ST safely and effectively. Please see Full Prescribing Information for TOBRADEX ST at MyTobraDexST.com.

INDICATIONS AND USAGE
TOBRADEX ST is a topical antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

DOSAGE AND ADMINISTRATION
Recommended Dosing: Instill one drop into the conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, dosage may be increased to one drop every 2 hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

CONTRAINDICATIONS
Nonbacterial Etiology: TOBRADEX ST 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.

Hypersensitivity: Hypersensitivity to any component of the medication.

WARNINGS AND PRECAUTIONS
IOP increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. IOP should be monitored.

Aminoglycoside sensitivity: Sensitivity to topically applied aminoglycosides may occur.

Cataracts: May result in posterior subcapsular cataract formation.

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

Bacterial infections: May suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

Viral infections: Treatment in 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 with long-term use. Fungal invasion must be considered in any persistent corneal ulceration.

Use with systemic aminoglycosides: Use with systemic aminoglycoside antibiotics requires monitoring for total serum concentration of tobramycin.

ADVERSE REACTIONS
The most frequent adverse reactions to topical ocular tobramycin (TOBREX®) are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritis, eyelid edema, and conjunctival hyperemia. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics.

Non-ocular adverse events occurring at an incidence of 0.5% to 1% included headache and increased blood pressure.

The reactions due to the steroid component are: increased intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve disorder; subcapsular cataract; and impaired healing.

Secondary Infection: The development of secondary infection has occurred. Fungal infections of the cornea are particularly prone to develop with long-term use. Fungal invasion must be considered in any persistent corneal ulceration. Secondary bacterial ocular infection following suppression of host responses also occurs.

USE IN SPECIFIC POPULATIONS
Pregnancy and Nursing Mothers
There are no adequate and well controlled studies in pregnant women. TOBRADEX® ST ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when TOBRADEX® ST is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

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

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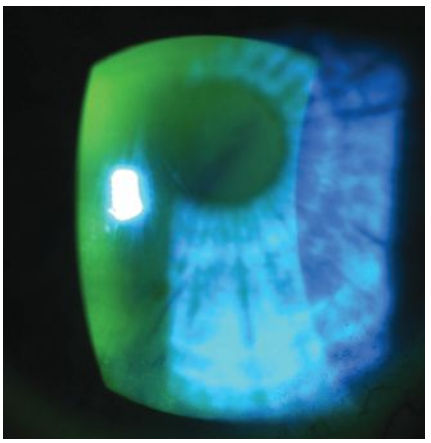
Technicans discuss dry eye treatment options with patients.



Dry eye patients need ongoing patient education and encouragement to stay the course of treatment and self-care.

For those who are in the "D" category, I don't dwell and overexplain—I get right to the point. For those in the "I" category, I lean back and let them talk. For those in the "S" category, I lean in and make sure they are comfortable with the conversation, I speak slower and I shift my body language to convey a safe space. I pointedly ask for feedback from them. For those in the "C" category, I put on my patience hat and allow them to ask questions. I slow down and lean back in my chair instead of sitting on the edge of it ready to leap out of the room and on to the next patient.

All of these details matter to that patient. The words you choose, your body language and the "how" of your communication, along with the actual information, together make up the patient experience. In order for the patient to hear your dry eye education and what you want them to learn, you have to do it in way that is meaningful to them.

If you're thinking this sounds like a lot of work, it is. It's also worth the investment and will greatly improve your patients' experience and the outcome.

Managing Dry Eye Properly

Once the exam is complete, I give patients written information to take home. This includes a handout with clear photos and explanations of our therapeutic options, with everything from visual hygiene, home therapy (warm compresses, lid seals), medications (Xiidra, Restasis, Cequa) and in-office procedures (LipiView, iLux, TearCare). I simply check what that patient is going to do between now and the next time I see them.

For a new dry eye patient, I am careful to explain what to expect. Dry eye is a chronic disease that we will manage together; we will start with step therapy and follow up in four weeks to see if we need to add additional therapies or if the patient is fully managed. It's important to follow up—I never let a dry eye patient go longer than six months, even when well-managed.

Before leaving the room, I am careful to go through what prescriptions I write (not recommendations—remove that word from your patient dialogues) and ask, "Do you have any questions for me? Did we accomplish everything you wanted to achieve?" Then, my scribe takes over, walking the patient through more detail and answering any other questions that may arise. They finish with tying everything back to the "why."

For myself and the other doctors that work in my practice, we have a standard protocol based on what level of dry eye disease the patient has. We have four levels of disease and we all are using our diagnostic tools and therapeutics in the same way, with the same language. This is very important for continuity of care and I want our patients to have the same experience no matter which doctor they see.

Takeaways

When you first start putting these kinds of systems into place, it can daunting, but layering education throughout the entire patient experience and empowering your team to build the systems with you are what make this doable. It may feel clunky and uncomfortable, but that's when you know you're doing the right thing. Eventually, you will become unconsciously competent and create your system.

Effectively educating our patients and our team will give patients the control to take better care of themselves. Communication is a lifelong skill that we all must be intentional about and continue to improve upon to give our patients, practices and profession every opportunity for success. ■

1. America's Health Literacy: why we need accessible health information. www.ahrq.gov/sites/default/files/wysiwyg/health-literacy/dhhs-2008-issue-brief.pdf. Accessed April 26, 2022.

HOW TO USE DRY EYE QUESTIONNAIRES IN YOUR PRACTICE

These handy tools can help you better understand patients' symptoms to guide a diagnosis and formulate treatment.

BY LEANNE SPIEGLE
ASSOCIATE EDITOR

Busy doctors and distracted patients don't exactly relish the thought of adding one more step to an optometric visit, but the notion of screening patients for dry eye with a survey tool has merit, experts say. Asking patients to devote a bit of forethought to the state of their ocular surface comfort before their exam can elicit conversations that might not otherwise occur, allowing you to identify some cases that would have gone unaddressed. And when managing a condition as multifactorial as dry eye, keeping a record of when patients feel better or worse helps to identify possible triggers, narrow down the list of potential diagnoses and evaluate response to treatment.

That's where dry eye questionnaires come in. Since the mid-1980s, when the first symptom survey—the McMonnies questionnaire—was developed, various others have been created and validated as practical screening tools for dry eye disease (DED). This article will explore how to best implement such questionnaires into your practice and walks you through the pros, cons and clinical indications of the various surveys used today to assess this complex condition.

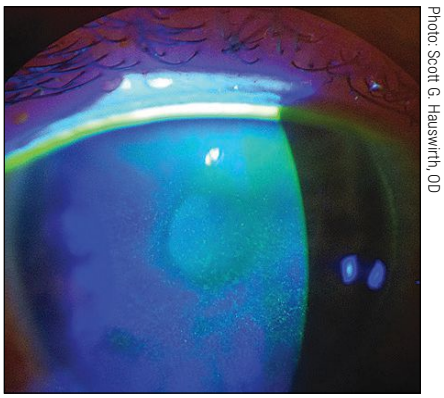


Photo: Scott G. Hauswirth, OD

Because signs and symptoms of dry eye don't always correlate, a clinical exam should always be used to confirm the findings of a questionnaire.

Why and When Should You Use Questionnaires?

When a patient comes to your practice complaining of eye dryness, the actual culprit could be one of many possibilities. Having the ability to know the basic information about the case—such as symptom severity, frequency, pain level and potential triggers—even before the person sits down in your chair is incredibly valuable and can help steer your clinical evaluation in the right direction.

Despite worries that surveys might slow down office flow, "dry eye questionnaires are actually huge time-saving tools," says dry eye guru Paul Karpecki, OD, of Lexington, KY. "Patients can fill them out online before they come into the office, and the score can be transferred into your electronic medical records. There's a lot of value in implementing something that doesn't require staff to administer. That helps increase your efficiencies and diagnostic capabilities."

About the Contributors

Dr. Karpecki is the medical director for KeplR Vision and the Dry Eye Institutes of Kentucky and Indiana. He is the Chief Clinical Editor for Review of Optometry and chair of the New Technologies & Treatments conferences. A fixture in optometric clinical education, he consults for a wide array of ophthalmic clients, including ones discussed in this article. Dr. Karpecki's full list of disclosures can be found in the online version of this article. **Dr. Sicks** is an associate professor at ICO and a clinical attending in the Cornea Center for Clinical Excellence at the Illinois Eye Institute. She lectures and conducts research on specialty contact lenses. **Dr. Theriot** practices at a multi-specialty eye clinic in Shreveport, LA. Her clinical practice covers a broad spectrum of ocular care with a unique clinical focus on ocular surface disease and dry eye. She is a consultant for Novartis and a key opinion leader for Sun Pharmaceuticals and Kala Pharmaceuticals. **Dr. Pucker** is currently the senior director of Drug Development at Lexitas Pharma Services. He is also active in clinical practice providing myopia management and contact lens care. Dr. Pucker is a Fellow and Diplomate of the American Academy of Optometry, Fellow of the Scleral Lens Education Society, and Fellow of the British Contact Lens Association. **Dr. Shovlin,** a senior optometrist at Northeastern Eye Institute in Scranton, PA, is a fellow and past president of the American Academy of Optometry and a clinical editor of Review of Optometry and Review of Cornea & Contact Lenses. He consults for Kala, Aerie, AbbVie, Novartis, Hubble and Bausch + Lomb and is on the medical advisory panel for Lentechs.

In addition to having patients complete the questionnaire beforehand, Dr. Karpecki asks them two questions once they enter the room: what is their worst symptom, and when is it worse? "First, I'll glance at the score, and if that indicates the patient may have DED, I'll go through the completed questionnaire and see what it says. Then, I'll ask those two key questions. Now, I have the information I need to pinpoint which kind of dry eye—or alternative condition—I might be dealing with, and I can go ahead with the examination and diagnosis."

Another option is to have the patient fill out the questionnaire as they sit in the waiting room, which is what Pam Theriot, OD, of Shreveport, LA, does at her practice. "I can see pros and cons to distributing the survey in either of these ways. If the patient completes it at home, they wouldn't be able to ask a question or get help if they got stuck on or didn't understand something. Also, it fills up the time when they would otherwise just be sitting in the waiting room."

Repeating the survey at subsequent visits allows you to quantify how the patient is feeling and responding to treatment. "The biggest benefit of questionnaires is that most of them provide you and the patient with a number that you can use to keep track of what level of improvement is occurring over time," says Dr. Karpecki. "For example, if a patient scores a 15 on the Standard Patient Evaluation of Eye Dryness (SPEED) test, and when they return they score an 8, we know they are at least headed in the right direction."

Dr. Theriot adds that patients are usually very number-oriented. "Not all of them are, but often they're very interested in knowing if they're making progress. I can tell them if they look better, but the questionnaires help them figure out if they feel better."

Lastly, Dr. Karpecki notes that some patients who wear contact lenses may not provide truthful responses when asked in the exam room to describe their symptoms for fear of having to give up their lenses. "Most patients tend to be more honest about symptoms on a questionnaire, which is less intimidating than face-to-face questioning and can help you address the issue in a way that allows them to also keep their lenses."

When Aren't Questionnaires All That Helpful?

Subjective tests can inform doctors on factors of a condition that can't be observed during a physical exam, such as the level of pain a patient is experiencing or disruption it is causing in their life; however, the tests are not fool-proof, and in some circumstances, the results can be misleading.

For example, take a neurotrophic patient who has been dealing with dry eye for many years and no longer experiences bothersome symptoms due to the gradual downregulation of ocular nerves that has occurred. Though this patient's questionnaire would likely suggest they don't have dry eye, they may actually show signs of disease upon examination. Relying heavily on a questionnaire as clinical evidence without factoring in the physical findings would fail to detect disease in some patients such as those with nerve damage, which, according to Dr. Karpecki, happens more often than it should.

"Dry eye is one of the rare diseases where signs and symptoms don't correlate," says Dr. Karpecki. "If you look at macular degeneration, the worse the disease, the more vision loss the patient has. In glaucoma, the worse the disease, the more peripheral vision loss that is present. But in some cases of dry eye, as it progresses the patient could actually experience fewer symptoms. For these individuals, having them complete surveys about how their eyes feel doesn't help us a lot in terms of severity. Most people and researchers think a high score on symptoms equates to more severe dry eye, but many times, low scores can still occur with severe disease."

Dr. Theriot also notes that patients with disdain for paperwork who are simply not interested in answering the questions could give untruthful responses and produce a false positive or negative result on the test. Questionnaires that include too many questions could have the same effect and deter honest and thorough completion, which jeopardizes the accuracy of the score. At the same time, as Joseph Shovlin, OD, of Scranton, PA, points out, there may also be a downside to surveys that contain too few questions. "If a busy practice does not allow for lengthy surveys, a discordance between what the clinician feels is important and what the patient is experiencing or trying to convey may allow for patient symptoms to go untreated," says Dr. Shovlin.

Another point, made by Dr. Sicks, is that sometimes not every item on

HOW TO OBTAIN THE SURVEYS

While most dry eye questionnaires can be used in clinical settings at no cost, there are exceptions. For surveys that are copyrighted, you'll need to contact a local rep of the company or organization to inquire about how to gain access or rights to distribute the survey at your practice. We have included links on our website to downloadable PDFs of each of the freely available ones mentioned in this article.

Some questionnaires offer alternative methods of access. The OSDI can be completed using an app by Allergan called "Dry Eye OSDI Questionnaire." One catch: it's currently only available on Apple devices.

"Having a patient fill out the survey beforehand on their phone and then having them send or bring in their score could be really efficient," ICO associate professor Lindsay Sicks, OD, points out. The app could also save time by calculating the scores for you, she adds.

"Plus, if you have an iPad at your practice, you could download the app on the device and have the patient fill the survey out that way while they're in the waiting room. Then, your technician could enter that result right into the EMR," says Dr. Sicks. Because not every patient owns an Apple device, this may be the more accessible option if you opt to go this route to use the OSDI.

For the remainder of the surveys that aren't app-compatible or accessible to the public via the internet, be sure to reach out to the owner or developer to inquire about usage restrictions.

the questionnaire will apply to each patient. "One question on the Ocular Surface Disease Index (OSDI), for instance, asks about driving at night and another asks about using an ATM," she says. "Not every patient drives and not every patient uses an ATM, so they might answer those questions 'no, it's not bothering me any of the time,' which will pull their score down so that the dry eye looks to be less severe." It is important to note, however, that most questionnaires, including the OSDI, do offer an "N/A" option for situations like these.

Dr. Sicks adds that this dilemma is commonly seen with younger patients, as most questionnaires tend to have questions geared toward adults. "It's actually hard to administer these tests for kids, because [using the previous example from the OSDI], they don't drive at night or work with an ATM. So, is the OSDI really validated for kids? Technically not," she points out.

Andrew Pucker, OD, PhD—formerly of UAB School of Optometry before a recent move to industry—says that 90% of the patients he sees currently are children and that he personally would choose not to distribute these questionnaires to those under 10 years old. "They usually aren't able

STORING THE DATA

Keeping a dated record of patients' scores from each dry eye questionnaire can help you detect signs of improvement or symptom progression, as well as determine their response to a certain treatment. No matter how you decide to administer the surveys, whether that be virtually, on paper or face-to-face, you should record at least the patient's score—or better yet, a scanned image of the entire survey—into your EMR or another data collection system, which may depend on the customization of the EMR at your practice, says Dr. Sicks.

"We use a NextGen system and have built a grid specifically for ocular surface disease, which includes a section where you can input the OSDI score and the date, and it keeps track over time," she notes. "Another way to do it would be to put the survey score in the impression part of your impression and plan." Whichever method you choose to store the data, be sure that it is easy to access and shown chronologically for easy comparison of scores over time."

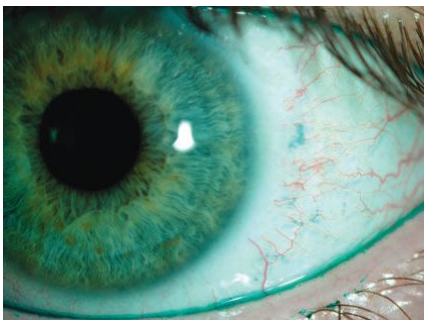


Photo: Michelle Hessen, OD

Dry eye surveys can inform you about factors such as frequency and severity of patients' symptoms, which you wouldn't know simply by looking at their eyes.

to explain to you what's going on," says Dr. Pucker. "Instead, you could ask basic questions about individual symptoms—such as burning, dryness, foreign body sensation, itching, watering—to help you determine a diagnosis." However, Dr. Pucker notes that in these cases with young patients, you miss out on the value of surveys that allow you to track progression.

In addition, as COVID-19 has dramatically changed many people's everyday routines, Dr. Sicks notes that "people's answers to questions about habits or activities might be skewed or different than they were a year or two ago."

One final consideration of questionnaires is their potential to lead to overdiagnosis of dry eye.

"It's important to not get bogged down into thinking that all symptoms that sound like dry eye including those picked up by surveys are truly dry eye, especially when there is no symptomatic relief with seemingly appropriate

Photo: iStock

Depending on how customizable your EMR system is, this may be an ideal place to store patients' questionnaire scores from each visit.

treatments," Dr. Shovlin explains. "Suggesting patients have dry eye may be one of our worst mistakes when only a few signs and/or symptoms point in that direction. There are days where everyone coming into the office feels they have 'dry eyes.'" He notes that when a patient shows no improvement, other differential diagnoses should be considered, such as conjunctivochalasis, environmental irritative conjunctivitis or even ocular misalignment, to name a few.

In any of the cases above, questionnaires may not be as valuable or reliable of a tool in dry eye assessment. Dr. Theriot emphasizes that "you have to rely more on what you're seeing than on what they're feeling." Still, for many patients, questionnaires are a useful tool and can play an important role in clinical decision-making, she says.

How Do You Choose Which Test To Distribute?

There are a number of research-backed tests that can be administered to patients with dry eye. Generally, patients, as well as physicians, want something that takes little time to complete, is easy to understand and will provide them with a numbered score or categorization to gauge the severity of symptoms. To make a good selection for your patients, Dr. Shovlin says that "clinicians have to decide why they find these questionnaires valuable, as well as how to implement these validated tools into their practice in order not to be disruptive to patient flow."

For Dr. Pucker, efficiency is key. "The shorter the survey and the fewer response options, the better," he says. "For one, people get survey fatigue and really don't like long surveys." Secondly, he says, "It's better to have fewer options—for example, mild, moderate and severe—as opposed to having 10 shades of grey. If you make the options more black and white, you'll get better responses because mild, moderate or severe responses are slightly less subjective."

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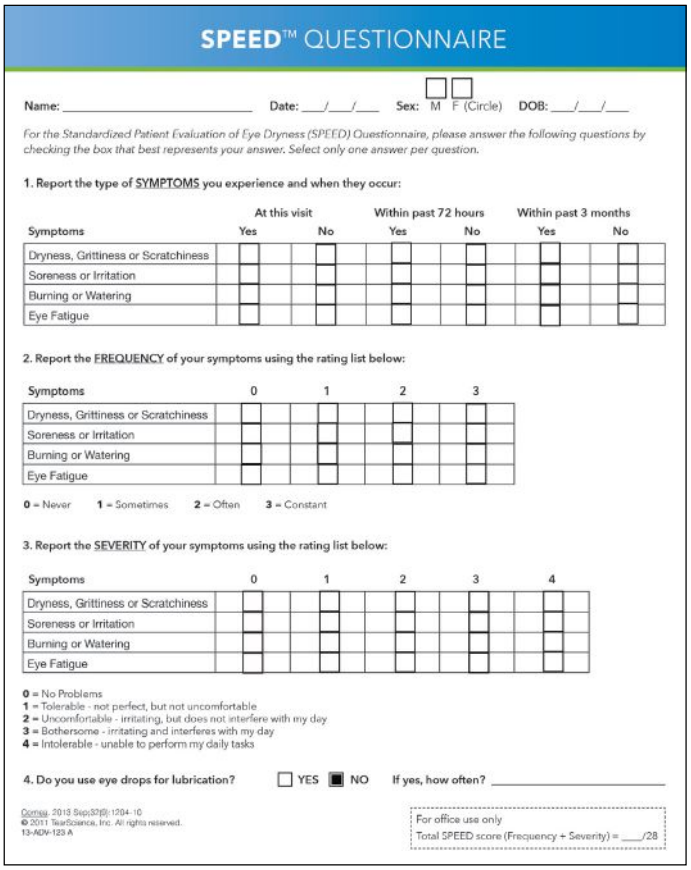
†Based on the AREDS and AREDS2 clinical studies.
[1]Data on file for #1 Dr. Recommended Brand, Bausch + Lomb. [2]National Eye Institute. National Institutes of Health; September 2015. Accessed November 4, 2020. https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_AMD_English_Sept2015_PRINT.pdf [3]Age-Related Eye Disease Study 2 Research group. *JAMA.* 2013;309(19): 2005-15. doi:10.1001/jama.2013.4997

Selecting a test that asks patients how symptoms are affecting their day-to-day life can give you insight into the severity of the condition and how aggressively to treat it. A recent review of 24 different dry eye questionnaires concluded that the following six address health-related quality of life and were recommended by the study's researchers for patient evaluation: OSDI, Impact of Dry Eye in Everyday Life, Dry Eye-Related Quality-of-Life Score, University of North Carolina Dry Eye Management Scale, Dry Eye-Related Quality of Life and the 25-Item National Eye Institute Visual Function Questionnaire.[1]

The list of questionnaires used in clinical practice settings might look a little different. Below are some of the tests that optometrists use today to assess the growing population of dry eye patients.



SPEED™ QUESTIONNAIRE

Name: _____ Date: ___/___/___ Sex: M F (Circle) DOB: ___/___/___

For the Standardized Patient Evaluation of Eye Dryness (SPEED) Questionnaire, please answer the following questions by checking the box that best represents your answer. Select only one answer per question.

1. Report the type of SYMPTOMS you experience and when they occur:

Symptoms	At this visit Yes	At this visit No	Within past 72 hours Yes	Within past 72 hours No	Within past 3 months Yes	Within past 3 months No
Dryness, Grittiness or Scratchiness	☐	☐	☐	☐	☐	☐
Soreness or Irritation	☐	☐	☐	☐	☐	☐
Burning or Watering	☐	☐	☐	☐	☐	☐
Eye Fatigue	☐	☐	☐	☐	☐	☐

2. Report the FREQUENCY of your symptoms using the rating list below:

Symptoms	0	1	2	3
Dryness, Grittiness or Scratchiness	☐	☐	☐	☐
Soreness or Irritation	☐	☐	☐	☐
Burning or Watering	☐	☐	☐	☐
Eye Fatigue	☐	☐	☐	☐

0 = Never **1** = Sometimes **2** = Often **3** = Constant

3. Report the SEVERITY of your symptoms using the rating list below:

Symptoms	0	1	2	3	4
Dryness, Grittiness or Scratchiness	☐	☐	☐	☐	☐
Soreness or Irritation	☐	☐	☐	☐	☐
Burning or Watering	☐	☐	☐	☐	☐
Eye Fatigue	☐	☐	☐	☐	☐

0 = No Problems
1 = Tolerable - not perfect, but not uncomfortable
2 = Uncomfortable - irritating, but does not interfere with my day
3 = Bothersome - irritating and interferes with my day
4 = Intolerable - unable to perform my daily tasks

4. Do you use eye drops for lubrication? ☐ YES ■ NO If yes, how often? _____

Cornea. 2013 Sep;32(9):1204-10
© 2011 TearScience, Inc. All rights reserved.
13-ADV-123 A

For office use only
Total SPEED score (Frequency + Severity) = ___/28

The SPEED Questionnaire, consisting of four sections, is among the most common surveys used in practice today to assess dry eye.

Standard Patient Evaluation of Eye Dryness (SPEED)

One widely used questionnaire is the SPEED test (developed by TearScience, now a part of Johnson & Johnson Vision), which is brief and easily allows patients and physicians to observe progress or changes in eye dryness and symptoms over time. Divided into four sections, the questionnaire touches on symptom timing, frequency and severity and then provides a numbered score between zero and 28, with zero indicating lack of symptoms.

The symptoms assessed in the SPEED test include dryness, grittiness, scratchiness, irritation, burning, watering, soreness and eye fatigue.[2] The first section asks about the presence of these symptoms and how recently they began, and the second asks about the frequency of the symptoms. The third section asks patients to report the severity of each symptom, and the final section questions patients on whether and how often they use eye drops for lubrication.

A study that looked at the SPEED questionnaire's ability to detect dry eye found it to be a repeatable and valid instrument for the measurement of symptoms.[3] It also determined that the test scores were significantly correlated to ocular surface staining and clinical measures of meibomian gland function, including meibomian gland score and meibomian glands yielding liquid secretion score.[3]

Dr. Pucker, who participated in a Rasch analysis of the SPEED questionnaire, says the test showed positive results and accuracy in screening for symptoms. "The metrics of the test are good," he says. "It's mostly a unidimensional device with meaningful questions that aren't redundant, so it's very specific for detecting dry eye."

Dr. Karpecki explains that on the SPEED test, "anything above a six is considered positive, but really anything over eight is going to be very conclusive for DED." He notes that for most of his patients, the questions on SPEED offer the information necessary to specify which type of dry eye could be present.

Dr. Theriot says that she distributes the SPEED test to every patient who comes into her office for a dry eye assessment and repeats it every time they come back. She offers two reasons for why she also prefers this test over many of the others.

First, "to have a number to give to the patient at each visit to let them know whether they're improving," says Dr. Theriot, and secondly because of its ability to distinguish between the different types of dry eye. It questions patients on more specific symptoms than many other tests, which helps point to the presence of a particular condition. For example, based on her clinical experience, Dr. Theriot suggests that "if a patient reports burning and watering, it's more likely to indicate evaporative dry eye, whereas if they are experiencing dryness, scratchiness or grittiness, that might indicate aqueous-deficient dry eye," she says. "If they report eye fatigue, it could be because the patient needs to have an adjustment made to their glasses or contact lens prescription power or has ocular misalignment."

Ocular Surface Disease Index (OSDI)

Another common survey is the OSDI (Allergan), frequently used as a reliable method of dry eye assessment and quantification in optometric research

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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 following page.

References: 1. US Patent 9,937,225 B2. **2.** Cholkar K, Patel A, Vadlapudi AD, Mitra AK. Novel nanomicellar formulation approaches for anterior and posterior segment ocular drug delivery. *Recent Pat Nanomed.* 2012;2(2):82-95. **3.** Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.

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PM-US-CQA-0831 08/2021

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.

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Cranbury, NJ 08512

PLR-00020 2018

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and clinical trials. The 12-item survey questions respondents on three categories relating to dry eye: ocular symptoms, vision-related function and environmental triggers.[2] Patients then rate their responses based on the frequency of the occurrence over the last week from zero to four, with zero indicating "none of the time" and four indicating "all of the time."

The OSDI produces a quantifiable score between 0 and 100, with higher numbers suggesting more severe disease. A normal score for patients without dry eye would be 12 or below, while a score of 13 to 22 represents mild disease, 23 to 32 represents moderate disease and patients with a score over 33 are characterized as having severe dry eye.[2]

Studies have shown that OSDI has good specificity (0.83) and moderate sensitivity (0.60) when differentiating between patients with and without DED.[2]

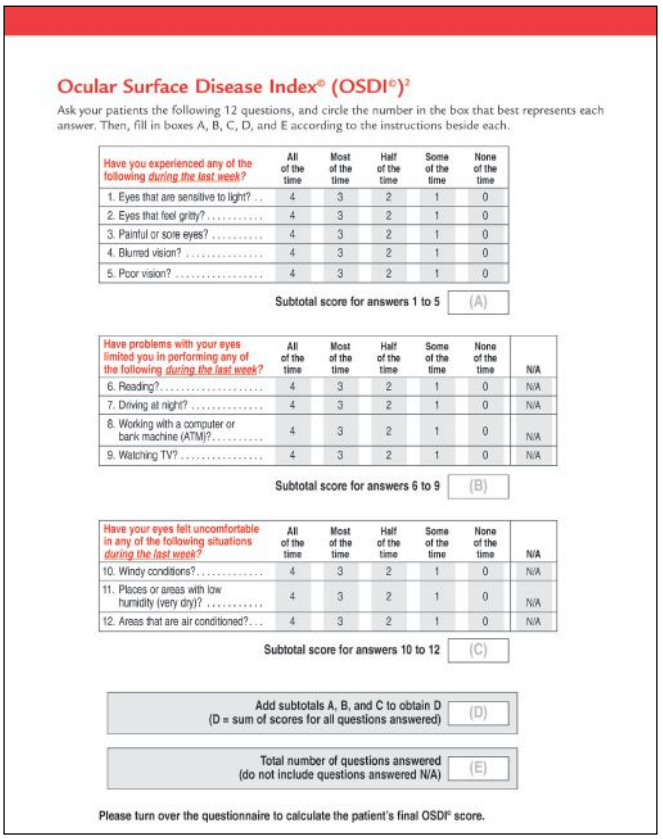
"The OSDI is very multi-dimensional," explains Dr. Pucker, who researched the validity of the questionnaire in another analysis. "It tests symptoms, environment and then tasks, so it's closer to an overall quality of life measurement than many others and screens patients for more than just dry eye," he notes.

In addition, Dr. Theriot says that along with the SPEED questionnaire, she distributes the OSDI survey at a patient's first dry eye evaluation. "One of the beautiful things about these questionnaires is that they have been scientifically proven over large patient populations to truly indicate dry eye, but also, in the case of the OSDI, they can give a subset of the severity of the disease," she says. "That's why I like to give this questionnaire to patients at the initial exam to be able to gauge where they are on the spectrum of mild, moderate or severe disease."

Dry Eye Questionnaire (DEQ-5)

A condensed version of the original 21-item DEQ, this one measures symptom severity over the last month. The test contains only five questions, making it one of the quickest to complete and grade. Though it's much newer and contains half the questions of the OSDI, a recent study comparing the performance of both tests found that the total scores of each were significantly correlated.[4] The study reported the reliability of DEQ-5 and OSDI to be 0.92 and 0.82, respectively, and concluded that the DEQ-5 can provide a valid measurement of dry eye symptoms.

The survey asks patients to rate the severity of eye discomfort, dryness and wateriness each from 0 to 4, with 0 indicating "never" and 4 indicating "constantly." The test-taker is then asked about the intensity of the symptom, with a score of 0 meaning it is not intense at all, and a score of 5 meaning



Ocular Surface Disease Index® (OSDI®)[2]

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?	4	3	2	1	0	N/A

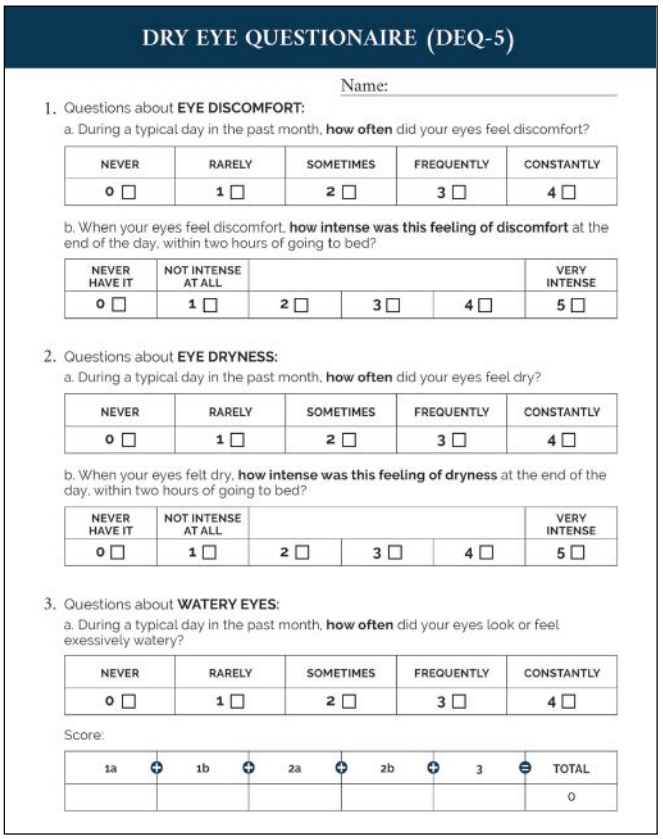
Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D (D = sum of scores for all questions answered) (D)

Total number of questions answered (do not include questions answered N/A) (E)

Please turn over the questionnaire to calculate the patient's final OSDI® score.

The OSDI Questionnaire includes items that ask patients about how their dry eye affects daily activities such as reading or using a computer.



DRY EYE QUESTIONAIRE (DEQ-5)

Name:

1. Questions about **EYE DISCOMFORT:**

a. During a typical day in the past month, **how often** did your eyes feel discomfort?

NEVER	RARELY	SOMETIMES	FREQUENTLY	CONSTANTLY
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

b. When your eyes feel discomfort, **how intense was this feeling of discomfort** at the end of the day, within two hours of going to bed?

NEVER HAVE IT	NOT INTENSE AT ALL				VERY INTENSE
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

2. Questions about **EYE DRYNESS:**

a. During a typical day in the past month, **how often** did your eyes feel dry?

NEVER	RARELY	SOMETIMES	FREQUENTLY	CONSTANTLY
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

b. When your eyes felt dry, **how intense was this feeling of dryness** at the end of the day, within two hours of going to bed?

NEVER HAVE IT	NOT INTENSE AT ALL				VERY INTENSE
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

3. Questions about **WATERY EYES:**

a. During a typical day in the past month, **how often** did your eyes look or feel exessively watery?

NEVER	RARELY	SOMETIMES	FREQUENTLY	CONSTANTLY
0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Score:

1a	⊕	1b	⊕	2a	⊕	2b	⊕	3	⊖	TOTAL
										0

The DEQ-5 Questionnaire is a shorter version of the DEQ, which has long been used as a valid measurement of dry eye symptom frequency and severity.

it is very intense. The total score is a number between 0 and 22.

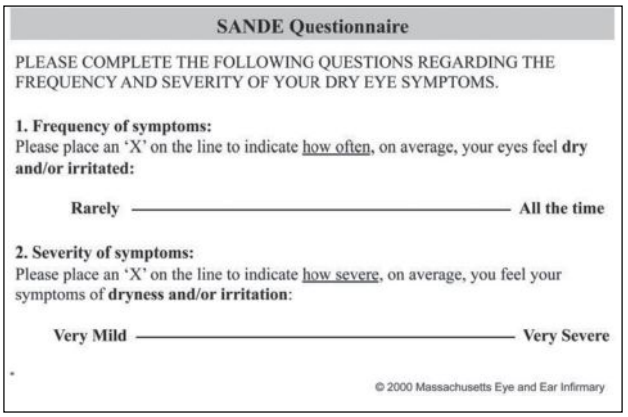
One unique advantage of the DEQ-5 is its ability to differentiate between Sjögren's syndrome and non-Sjögren's dry eye. A score above 6 suggests DED and a score ≥12 suggests Sjögren's syndrome.[1]

"We use the DEQ-5 on occasion in our practice and have had good success with it," says Dr. Karpecki. "The reason why we don't rely on it more is that the SPEED test is just the one we use most routinely and it's become habitual, but the DEQ-5 is still a great option."

Dry Eye-Related Quality-of-Life Score (DEQS)

Originally developed in Japan, the DEQS is one that focuses more specifically on patient quality of life. The survey consists of 15 items and was developed to assess symptoms and their effect on daily living throughout the previous week. It asks patients to rate the frequency and severity of various ocular symptoms on a scale of 0 to 4 from "not at all" to "always" and "not at all" to "very much."[1]

The first six questions focus on ocular symptoms, while the other nine focus on how the patient's daily life has been affected. It questions patients on things like light sensitivity and difficulty using screens, whether their work is being impacted and whether they are feeling depressed as a result of their symptoms. A quality-of-life score ranging from 0 to 100 is then calculated with the cutoff value for DED being 15 points. A psychometric analysis showed that the test has good internal consistency, test-retest reliability, discriminant validity and responsiveness to change.[5]



SANDE Questionnaire

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS.

1. Frequency of symptoms:
Please place an 'X' on the line to indicate how often, on average, your eyes feel **dry and/or irritated:**

Rarely ——— **All the time**

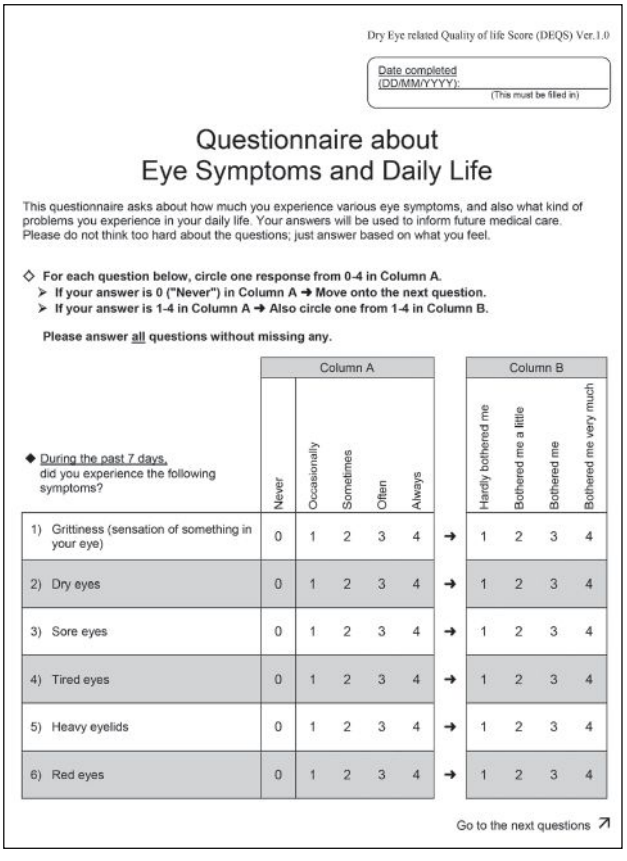
2. Severity of symptoms:
Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of **dryness and/or irritation**:

Very Mild ——— **Very Severe**

With only two questions, the SANDE Questionnaire is one of the most efficient surveys and uses a visual analog scale.

Symptom Assessment Questionnaire in Dry Eye (SANDE)

This is among the shortest of the tests, containing only two questions presented on a visual analog scale. Patients



Dry Eye related Quality of life Score (DEQS) Ver.1.0

Date completed (DD/MM/YYYY): (This must be filled in)

Questionnaire about Eye Symptoms and Daily Life

This questionnaire asks about how much you experience various eye symptoms, and also what kind of problems you experience in your daily life. Your answers will be used to inform future medical care. Please do not think too hard about the questions; just answer based on what you feel.

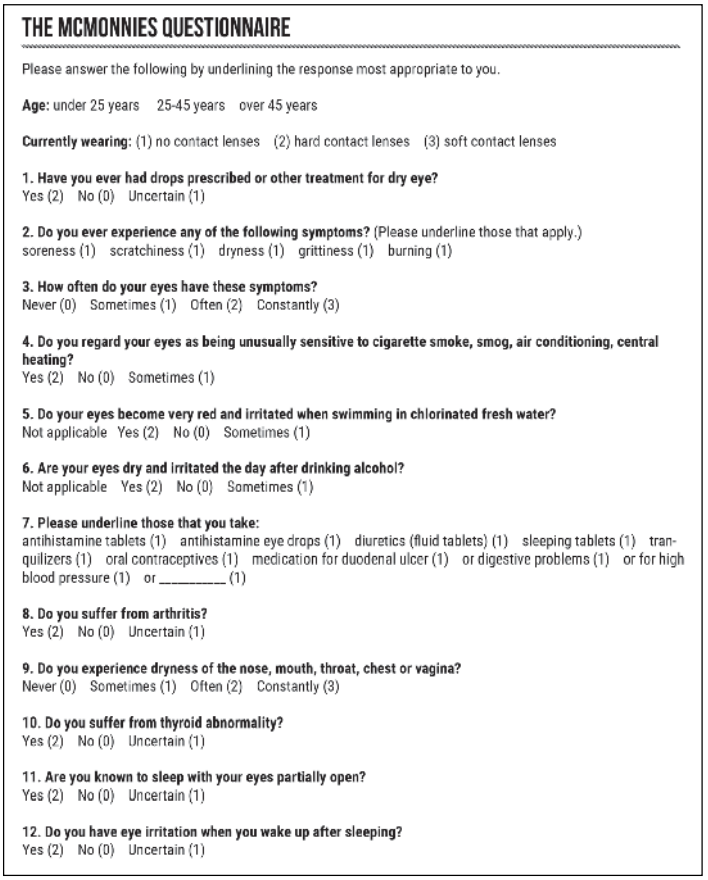
◇ **For each question below, circle one response from 0-4 in Column A.**
➢ **If your answer is 0 ("Never") in Column A ➔ Move onto the next question.**
➢ **If your answer is 1-4 in Column A ➔ Also circle one from 1-4 in Column B.**

Please answer all questions without missing any.

◆ During the past 7 days, did you experience the following symptoms?	Column A: Never	Occasionally	Sometimes	Often	Always		Column B: Hardly bothered me	Bothered me a little	Bothered me	Bothered me very much
1) Grittiness (sensation of something in your eye)	0	1	2	3	4	➔	1	2	3	4
2) Dry eyes	0	1	2	3	4	➔	1	2	3	4
3) Sore eyes	0	1	2	3	4	➔	1	2	3	4
4) Tired eyes	0	1	2	3	4	➔	1	2	3	4
5) Heavy eyelids	0	1	2	3	4	➔	1	2	3	4
6) Red eyes	0	1	2	3	4	➔	1	2	3	4

Go to the next questions ↗

The DEQS Questionnaire is similar to the DEQ and DEQ-5, although it incorporates more questions about a patient's quality of life.



THE MCMONNIES QUESTIONNAIRE

Please answer the following by underlining the response most appropriate to you.

Age: under 25 years 25-45 years over 45 years

Currently wearing: (1) no contact lenses (2) hard contact lenses (3) soft contact lenses

1. Have you ever had drops prescribed or other treatment for dry eye?
Yes (2) No (0) Uncertain (1)

2. Do you ever experience any of the following symptoms? (Please underline those that apply.)
soreness (1) scratchiness (1) dryness (1) grittiness (1) burning (1)

3. How often do your eyes have these symptoms?
Never (0) Sometimes (1) Often (2) Constantly (3)

4. Do you regard your eyes as being unusually sensitive to cigarette smoke, smog, air conditioning, central heating?
Yes (2) No (0) Sometimes (1)

5. Do your eyes become very red and irritated when swimming in chlorinated fresh water?
Not applicable Yes (2) No (0) Sometimes (1)

6. Are your eyes dry and irritated the day after drinking alcohol?
Not applicable Yes (2) No (0) Sometimes (1)

7. Please underline those that you take:
antihistamine tablets (1) antihistamine eye drops (1) diuretics (fluid tablets) (1) sleeping tablets (1) tranquilizers (1) oral contraceptives (1) medication for duodenal ulcer (1) or digestive problems (1) or for high blood pressure (1) or _____ (1)

8. Do you suffer from arthritis?
Yes (2) No (0) Uncertain (1)

9. Do you experience dryness of the nose, mouth, throat, chest or vagina?
Never (0) Sometimes (1) Often (2) Constantly (3)

10. Do you suffer from thyroid abnormality?
Yes (2) No (0) Uncertain (1)

11. Are you known to sleep with your eyes partially open?
Yes (2) No (0) Uncertain (1)

12. Do you have eye irritation when you wake up after sleeping?
Yes (2) No (0) Uncertain (1)

The McMonnies Questionnaire is the oldest of the surveys. It's also incorporated into the Keratograph 5M.

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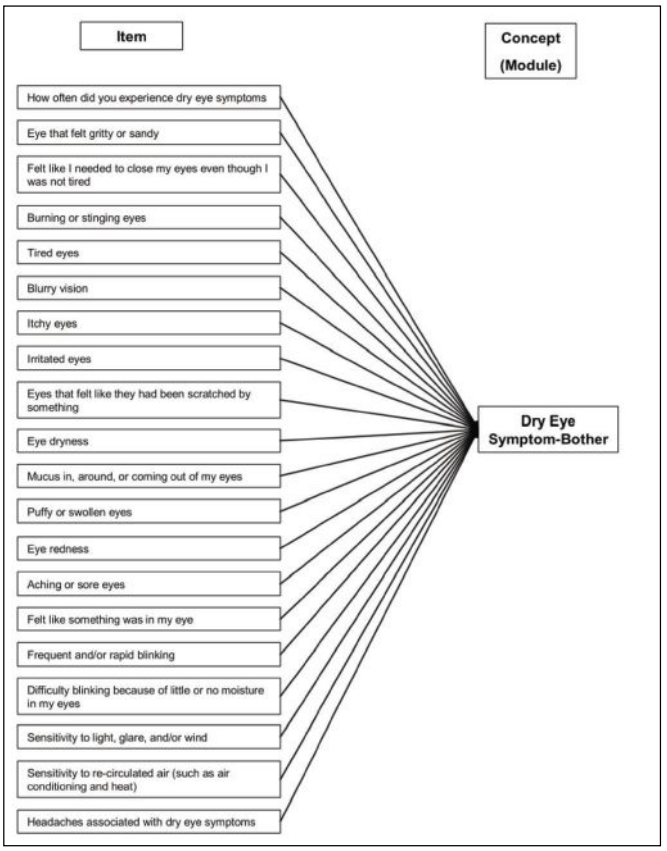
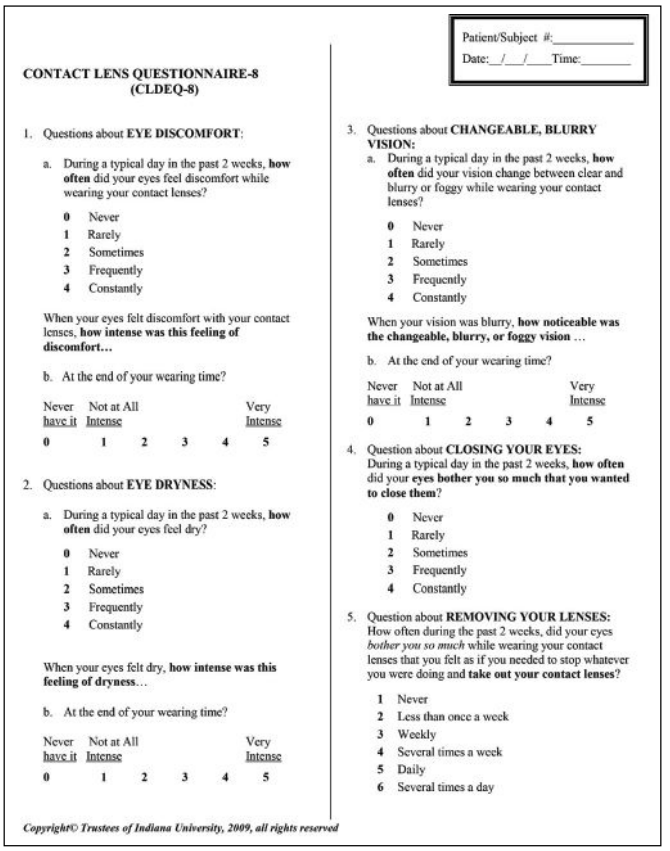


The IDEEL Questionnaire is three pages and 57 questions long.



Patient/Subject #:_____
Date:__/__/____Time:_____

CONTACT LENS QUESTIONNAIRE-8 (CLDEQ-8)

1. Questions about **EYE DISCOMFORT**:
   a. During a typical day in the past 2 weeks, **how often** did your eyes feel discomfort while wearing your contact lenses?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort…**
   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

2. Questions about **EYE DRYNESS**:
   a. During a typical day in the past 2 weeks, **how often** did your eyes feel dry?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   When your eyes felt dry, **how intense was this feeling of dryness**…
   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

3. Questions about **CHANGEABLE, BLURRY VISION:**
   a. During a typical day in the past 2 weeks, **how often** did your vision change between clear and blurry or foggy while wearing your contact lenses?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   When your vision was blurry, **how noticeable was the changeable, blurry, or foggy vision** …
   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	1	2	3	4	5

4. Question about **CLOSING YOUR EYES:** During a typical day in the past 2 weeks, **how often** did your **eyes bother you so much that you wanted to close them**?
   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

5. Question about **REMOVING YOUR LENSES:** How often during the past 2 weeks, did your eyes *bother you so much* while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and **take out your contact lenses**?
   1 Never
   2 Less than once a week
   3 Weekly
   4 Several times a week
   5 Daily
   6 Several times a day

CLDEQ-8 is well-suited to assessing dry eye in contact lens wearers.

rate the frequency and severity of ocular dryness or irritation by placing an "X" on a line between "rarely/mild" and "all the time/very severe." In a study that compared this questionnaire with the OSDI, researchers found that SANDE showed a significant correlation and minor differences in scores compared with the OSDI and indicated that the test was short, quick and reliable.[6]

"Visual analog scales like SANDE are super useful in practice and can help you very effectively see the progression over time," notes Dr. Pucker. "It's a very short and simple test that has good metrics, and it's validated, but I don't see it used often enough in practice."

McMonnies Dry Eye Questionnaire

Developed in 1986 by Charles McMonnies, this one is among the earliest screening tools for DED. The 12-question test asks patients to describe the frequency and severity of various symptoms, habits and coexisting conditions associated with dry eye by selecting one of several options listed for each item. The results produce a score between 0 and 25, with a score of 14.5 or higher indicating DED.[1]

Despite having been around the longest, the McMonnies has been shown to have poor internal consistency and inadequately studied validity and reliability.[1] Sensitivity of the test has been reported to be between 87% and 98% and specificity between 87% and 97%.[7] Authors of a Rasch analysis on the test's validity had two major concerns. "First, there is no standardized scoring protocol. Second, there is uncertainty about whether the questionnaire can be used to grade disease severity," they wrote.[7] For these reasons, it's not typically the top choice for use in optometry practices today.

However, in conjunction with other screening tools, this survey can still be useful in patient assessment. Dr. Sicks points out one particular advantage of using this test.

"The McMonnies questionnaire is actually incorporated into the Keratograph 5M," says Dr. Sicks. "If you have the device, you can run through the entire dry eye analysis. It goes through all of the questions while the patient is sitting there, so you can ask them for their responses face-to-face."

Impact of Dry Eye on Everyday Life (IDEEL)

This comprehensive questionnaire, developed by Alcon, includes 57 items and three separate modules, covering questions on dry eye symptoms, impact on daily life and satisfaction with treatment effectiveness and treatment-related inconvenience. Though the test may take longer than others for patients to fill out and physicians to grade, it could offer useful insight into the severity of your patient's condition, the burden that the disease is placing on them and their satisfaction with the care they are receiving. Results from a psychometric analysis done to develop and validate IDEEL indicated that

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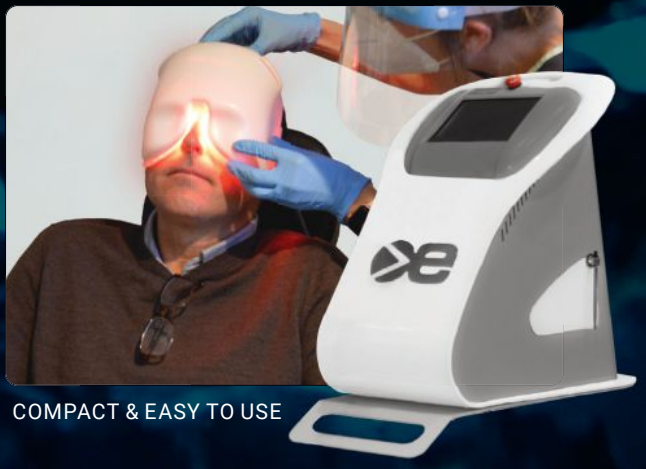

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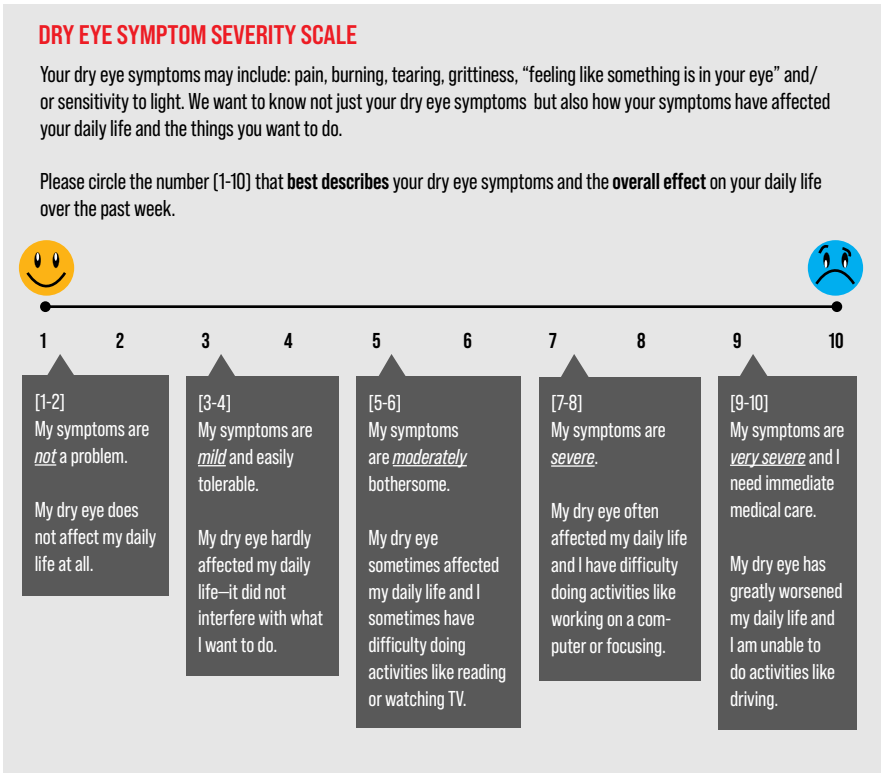

The UNC DEMS contains just one question presented along a visual analog scale.

the test met the criteria for item discriminant validity, internal consistency reliability, test-retest reliability and floor/ceiling effects.[8]

It's important to note that in order to distribute this survey to patients in your practice, you will have to purchase it from Alcon with a price tag of a few thousand dollars.

Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)

Certain dry eye questionnaires are specifically designed for contact lens wearers, such as the CLDEQ-8. This survey—currently property of Indiana University—includes five questions that ask patients about eye discomfort, eye dryness, changeable or blurry vision and how often the patient has to close their eyes or remove their lenses to relieve the bothersome symptoms.

"I'll use the CLDEQ-8 whenever I'm suspecting that a patient is unhappy with their contact lenses so I can quantify how unhappy they are," says Dr. Pucker. "When it's a score of 12 or more, that suggests you should make some kind of change, such as in wear schedule, lens material or contact solution."

A study comparing SPEED with the CLDEQ-8 found that scores of both were associated with self-reported dry eye in contact lens wearers, suggesting that either test could be used to assess this subset of dry eye patients. The SPEED questionnaire was shown to outperform the CLDEQ-8 in one area particularly: the former was able to quantify multiple symptoms while the latter quantified only those of dry eye.[9]

University of North Carolina Dry Eye Management Scale (UNC DEMS)

This single-item questionnaire, copyrighted by the University of North Carolina, asks patients to circle the number between 1 and 10 that best describes how bothersome their dry eye symptoms have been over the previous week. The survey also has an optional section at the bottom where patients can write anything they want the doctor to know about their eyes. Dr. Shovlin says that the UNC DEMS is his first choice if he decides to give a survey to a patient. "It's very simple, direct and pretty reliable from a severity perspective," he says.

Takeaways

Dry eye questionnaires can be a very beneficial tool to help you better understand your patient's condition and how it's impacting their day-to-day life. It can also increase the efficiency of your practice by allowing you to obtain patient data before the start of the appointment, which leaves more time to ask follow-up questions and perform the clinical exam.

"Although the results of these symptom surveys don't always correlate to the clinical signs when we're dealing with dry eye, they can help by offering a starting point and directing to more specific care and assessment of the patient," says Dr. Sicks. "But you're still going to have to ask your patients other questions about their specific environment and what's been bothering them. It's not the end all be all." ■

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Development and validation of the Dry Eye-Related Quality-of-Life Score questionnaire. JAMA Ophthalmol. 2013;131(10):1331-1338.

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7. Gothwal VK, Pesudovs K, Wright TA, McMonnies

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Take your practice from beginner to advanced with these steps.

BY ALEXANDRA WIECHMANN, OD
SAN ANTONIO, TX

How often do you find yourself with a patient in your chair with an exhaustive list of dry eye symptoms, not knowing where to begin? It can be overwhelming for both you and the patient, which is why it's imperative to have proper knowledge of dry eye causes and treatments in your diagnostic toolkit. After all, as eyecare professionals, it's our job to produce happy patients.

Dry eye disease (DED) is a multifactorial condition that can complicate treatment; we must first determine the underlying causes and then marry them with treatment options that make sense for the patient's lifestyle, budget and expectations. Do symptoms arise from too much screen time, an undiagnosed systemic disease or a medication they failed to list on their paperwork? Does this patient simply need prescription drops or do they require placement of an amniotic membrane or thermal pulsation device treatments? The list of symptoms is as long as the available treatments.

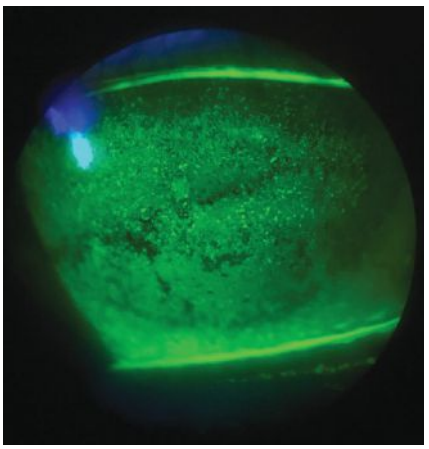

Fig. 1. Slit lamp image of diffuse punctate corneal staining.

Our aim in this article is to help you incorporate dry eye treatment into your practice while graduating your management from basic to advanced, without having to purchase expensive equipment. In the end, you will have happier patients while also increasing your practice revenue.

Adding Dry Eye to Your Practice

The Tear Film and Ocular Surface Society Dry Eye Workshop II (TFOS DEWS II) report provides evidence-based rationale for diagnosis and treatment and gives those new to DED a more organized approach. The TFOS DEWS II diagnostic methodology report provides a comprehensive review of tests to be used for diagnosis, monitoring and to guide treatment. Coupled with the Management and Therapy report, the collective work ensures the most targeted therapy and monitoring plan.

Because you are treating a condition that requires more chair time and different billing practices, don't try to fit it all into one visit; have them return for a follow-up when they need additional care. If the patient originally presented for routine care using their vision plan, they will need to return for a separate visit for the additional testing to be billed through their insurance.

Get to Know Your Patients

Make sure you've gathered comprehensive information from your patient. Are their symptoms occupational, whether it's too much computer time or working in harsh environmental conditions? Do they have other symptoms such as dry mouth or eye pain, or have they

About the author

Dr. Wiechmann is an assistant adjunct clinical professor at the University of the Incarnate Word Rosenberg School of Optometry and faculty of the Refractive Surgery Alliance Grands Rounds Collaborative Care Series. She practices at Parkhurst NuVision, an OD-MD integrated care practice that specializes in refractive surgery and is a Fellow of the American Academy of Optometry. She has no financial disclosures.

had recent bloodwork to rule out autoimmune conditions? They could also be taking certain oral medications, which may interfere with goblet cells, meibomian glands and ocular surfaces of the conjunctiva and cornea (*Table 1*).[1] Is your patient on topical glaucoma medications? A study found these induced meibomian gland dysfunction (MGD) and were associated with a 50% incidence of dry eye.[2]

Thoroughly getting to know your patient helps involve them in their treatment, understand how their daily routine contributes to their discomfort and allows you to find the best regimen to improve their condition.

Education is Key

Using diagnostics helps add a greater level of understanding of these patients. Showing or explaining their results allows them to be more accepting to your treatment recommendations. This could be done with your phone at the slit lamp or you could invest in a corneal topographer with keratograph that allows you to evaluate meibography, non-invasive tear break-up time (TBUT) and tear meniscus height (*Figure 1*). When patients are shown these images, they typically understand what is happening on the ocular surface and it allows them to be part of their own dry eye treatment journey.

Treatment Regimen

The next step is determining what treatments are best for your patients, which range from beginner to intermediate to advanced.

Fig. 2. Tyrvaya is the first FDA-approved nasal spray to treat DED.

TABLE 1. SYSTEMIC MEDICATIONS THAT MAY CAUSE DRY MOUTH AND DRY EYES

Adjuncts to anesthesia	Antimuscarinics	Chelating agents
Analgesics	Antineoplastics	Decongestants
Antiandrogens	Antiparkinsonians	Diuretics
Antiarrthythmics	Antipsychotics	Neurotoxins
Anticholinergics	Antipyretic agents	Opioids
Antidepressants	Antirheumatic agents	Psychedelic agents
Antiemetics	Antispasmodics	Retinoids
Antihistamines	Antivirals	Sedatives and hypnotics
Antihypertensives	Anxiolytics	
Antileprosy agents	Bronchodilators	

Fraunfelder FT, Sciubba JJ, Mathers WD. The role of medications in causing dry eye. Jour Ophthamol. 2012;2012:285851.

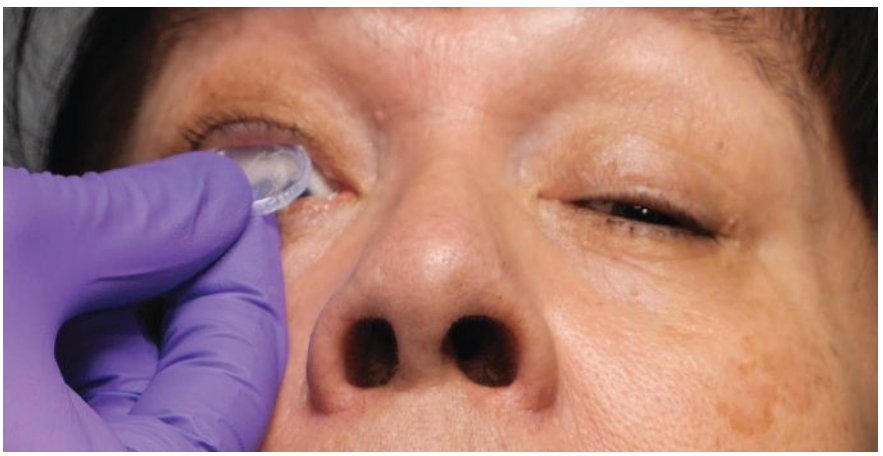

Photo credit: Doan Huynh Kwak, OD

Fig. 3. Prokera Slim being inserted on a patient. It is a corneal bandage device that reduces inflammation, prevents scarring and helps the ocular surface heal.

TIER 1 (BEGINNER)

- *Prescription eye drops.* These include cyclosporine (Restasis [0.05%], Allergan), Cequa (0.9%, [Sun Pharmaceuticals]), Klarity-C (0.1%) and lifitegrast (Xiidra, Novartis).
- *Ointments.* These include Refresh PM, Systane Nighttime, erythromycin and Gen-Teal Tears.
- *Warm compresses.* A popular option is the Bruder Moist Heat Eye Compress.
- *Lid scrubs/cleansers.* These include Avenova, Ocusoft, We Love Eyes, Zocular, Optase and Cliradex.
- *Tea tree eye cleansers.* These include Cliradex, We Love Eyes and Eye Eco.
- *Steroids.* These include loteprednol (Eysuvis [0.25%], Kala Pharmaceuticals), Lotemax SM (0.38%, Bausch + Lomb) and Alrex (0.2%, Bausch + Lomb).
- *Nasal spray.* There's now a treatment called Tyrvaya (varenicline, Oyster Point Pharmaceuticals).
- *Eye seals/sleep masks.* Options include Eye Eco and Sleep Tite.

Start basic with a slit lamp and begin assessing the lids and lashes where you first see ocular surface inflammation. Approximately 20% of patients have ocular findings before dermatologic evidence of rosacea, (which will be further discussed in Tier 3).[3] Warm compresses and lid scrubs are easy treatments that patients can add to their daily routine.

A significant number have *Demodex* infestation, including about 45%

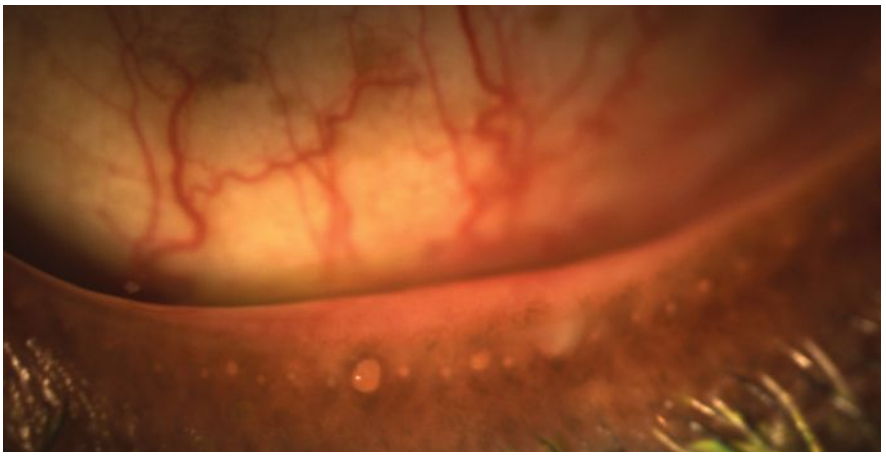

Photo: Katherine Sanford, OD

Fig. 4. Obstructed meibomian glands respond to digital pressure by releasing thickened, cloudy meibum.

of patients with blepharitis, 84% of patients 60 and older and 100% of patients over the age of 70.[4,5] Patients with rosacea have nine times the average rate of infestation.[6] Keep in mind that inflamed eyelid margins and mechanical irritation of the lids are not always present.

Another thing to look out for is nocturnal lagopthalmos, the inability to close the eyelids while sleeping. We always ask patients if their dryness worse is the morning. If so, we consider overnight therapies such as ointment or eye seals from Eye Eco.

Tyrvaya, the first FDA-approved nasal spray for the treatment of DED, activates the trigeminal parasympathetic pathway, resulting in improved basal tear film production (*Figure 2*). A study showed that, at week four, 47% of patients improved their Schirmer's score by equal to or more than 10mm from baseline, compared with 14% and 28% of vehicle-treated patients, respectively.[7]

Inflammation plays a significant and central role in the pathogenesis of dry eye.[8] Steroids can be our friend for a short-term therapy, including Eysuvis, which is the first steroid to be FDA-approved for dry eye flare-ups.

The hardest part about treating patients is setting expectations. Often they feel like we should be able to fix 50 years of dry eye with a few drops for a few weeks. However, a study showed that lifitegrast demonstrated significant improvement in patient's signs and symptoms who suffered from inflammatory MGD.[9]

Prescribing cyclosporine or lifitegrast won't create an overnight fix, though. Inform your patients that dry eye is a war, a chronic progressive disease and that these drops, most of the time, require long-term commitment.

Make it convenient for your patients by selling products like warm compresses, lid scrubs/cleansers, ointments or artificial tears in your office. Stock brands you believe in and think are the best fit for your patients; specifying specific brands and products increase patient buy-in and compliance.

TIER 2 (INTERMEDIATE)

- *Amniotic membranes.* Options include the cryopreserved Prokera (BioTissue), as well as several dehydrated membranes (*e.g.*, BioDOptix, Integra Lifesciences; AmbioDisk, Katena; AcellFX, Akorn).
- *Therapeutic meibomian gland expression.* Mastrota Meibomian Gland Paddle (Medi Instruments), Collins Meibomian Expressor Forceps (Sigma Pharmaceuticals) and Meibomian Gland Evaluator (Johnson & Johnson).
- *Microexfoliation devices.* (BlephEx).
- *Punctal plugs.*
  - » Temporary occlusion. These include Vera180 (Lacrivera) and Soft Plug Extended Duration (Oasis Medical).
  - » Permanent occlusion. These include SmartPlug (Medennium) and FormFit (Oasis Medical).
  - » Surgical closure. This includes cauterization, punctal plug suturing and canalicular ligation).

You can get a jump start on treating the ocular surface with amniotic membranes. In a dry eye study with 160 participants, 95% said cryopreserved amniotic membranes healed their

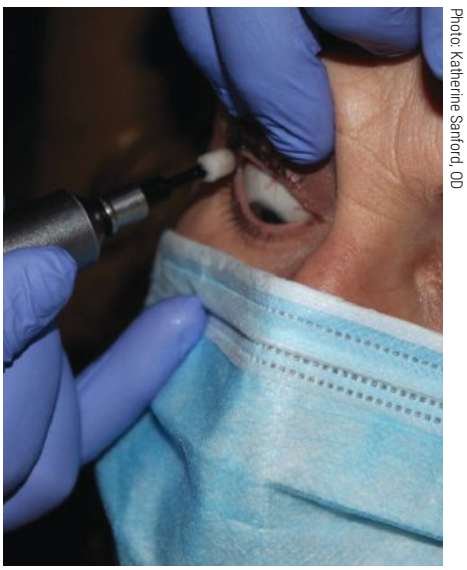

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Fig. 5. The BlephEx device for in-office removal of eyelid scurf and bacterial debris, which can cause inflammatory lid disease. The rotating pad buffs away the biofilm and other lid debris to prevent blepharitis.

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IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: Glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infection following suppression of host response, and perforation of the globe may occur.

Please see the Full Prescribing Information on the next page.

Reference: 1. Leibowitz HM, Hyndiuk RA, Lindsey C, et al. Fluorometholone acetate: clinical evaluation in the treatment of external ocular inflammation. *Ann Ophthalmol.* 1984;16(12):1110-1115.

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Brief Summary

INDICATIONS AND USAGE
FLAREX (fluorometholone acetate ophthalmic suspension) is indicated for use in the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

DOSAGE AND ADMINISTRATION
Shake Well Before Using. One to two drops instilled into the conjunctival sac(s) four times daily. During the initial 24 to 48 hours, the dosage may be safely increased to two drops every two hours. If no improvement after two weeks, consult physician. Care should be taken not to discontinue therapy prematurely.

CONTRAINDICATIONS
Contraindicated in acute superficial herpes simplex keratitis, vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva; mycobacterial infection of the eye; fungal diseases; acute purulent untreated infections, which like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid; and in those persons who have known hypersensitivity to any component of this preparation.

WARNINGS AND PRECAUTIONS
Topical Ophthalmic Use Only
For topical ophthalmic use only. Not for injection.

Intraocular Pressure Increase
Prolonged use may result in glaucoma, damage to the optic nerve, and defects in visual acuity and visual field. It is advisable that the intraocular pressure be checked frequently.

Cataracts
Use of corticosteroids may result in cataract formation.

Delayed Healing
Topical ophthalmic corticosteroids may slow corneal wound healing. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with chronic use of topical steroids.

Viral Infections
Use in the treatment of herpes simplex infection requires great caution.

Bacterial Infections
Use of corticosteroids may suppress the host response and thus aid in the establishment of secondary ocular infections. Acute purulent infections of the eye may be masked or exacerbated by the presence of steroid medication.

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.

Contamination
Do not touch dropper tip to any surface, as this may contaminate the suspension.

Contact Lens Wear
Contact lenses should be removed during instillation of FLAREX but may be reinserted after 15 minutes.

Temporarily Blurred Vision
Vision may be temporarily blurred following dosing with FLAREX. Care should be exercised in operating machinery or driving a motor vehicle.

ADVERSE REACTIONS
Clinical Trials Experience
Glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infection following suppression of host response, and perforation of the globe may occur.

Postmarketing Experience
The following reaction has been identified during postmarketing use of FLAREX in clinical practice. Because reactions are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reaction, which has been chosen for inclusion due to either its seriousness, frequency of reporting, possible causal connection to FLAREX, or a combination of these factors, includes dysgeusia.

USE IN SPECIFIC POPULATIONS
Pregnancy
Fluorometholone has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human ocular dose. Fluorometholone was applied ocularly to rabbits daily on days 6-18 of gestation, and dose-related fetal loss and fetal abnormalities including cleft palate, deformed rib cage, anomalous limbs, and neural abnormalities, such as encephalocele, craniorachischisis, and spina bifida, were observed. There are no adequate and well-controlled studies of fluorometholone in pregnant women, and it is not known whether fluorometholone can cause fetal harm when administered to a pregnant woman. Fluorometholone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLAREX is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
No studies have been conducted in animals or in humans to evaluate the possibility of these effects with fluorometholone.

PATIENT COUNSELING INFORMATION
Risk of Contamination
Do not touch dropper tip to any surface, as this may contaminate the suspension.

Use with Contact Lenses
The preservative in FLAREX, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of FLAREX but may be reinserted 15 minutes after instillation.

Temporarily Blurred Vision
Patients should be advised that their vision may be temporarily blurred following dosing with FLAREX. Care should be exercised in operating machinery or driving a motor vehicle.

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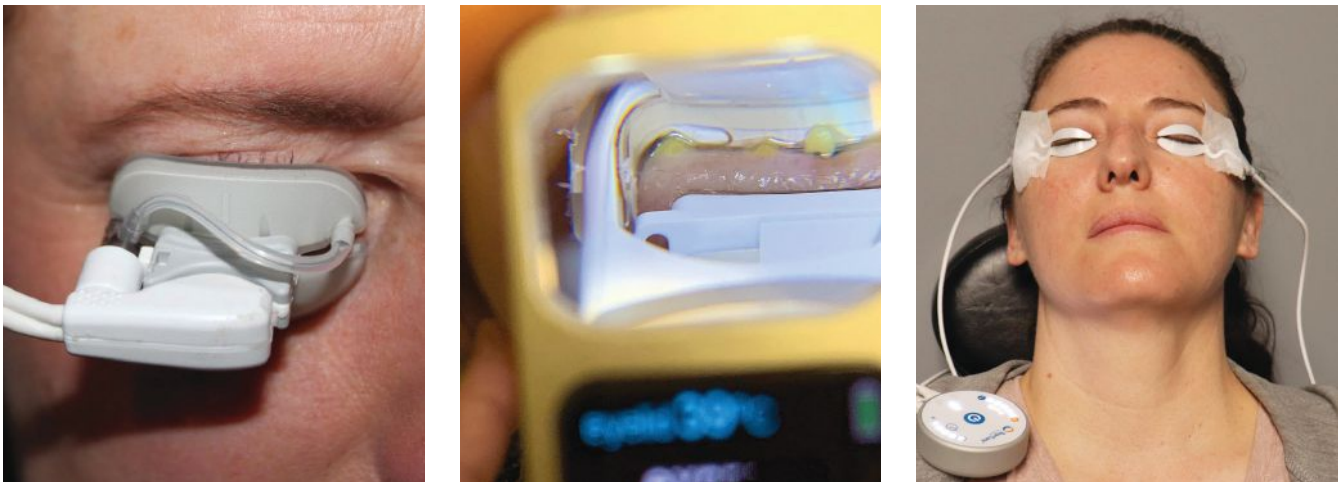

Fig. 6. In-office procedures to heat and express the meibomian glands are gaining favor. From left to right: LipiFlow, iLux and TearCare.

eye and 81% said it improved their vision.[10] Usually, amniotic membranes are used clinically one eye at a time since they obscure vision. Prokera Clear heals the cornea and maintains visual acuity with the inclusion of a clear central aperture. Additionally, consider that if you find the cornea to be moderately to severely dry, it may require you to use more than one membrane treatment.

To help keep tears on the surface longer, consider using punctal plugs, which block the openings to the drainage ducts to improve ocular surface tear retention.

It's been shown that hyperkeratinization of the meibomian gland duct is a primary cause of MGD; once the ducts are obstructed, the glands themselves atrophy (*Figure 4*).[11] Historically, doctors have first tried therapeutic expression of the glands to increase quality and promote healthy meibum production. This could be attempted with a topical anesthetic and an expressor, such as the Mastrota Meibomian Gland Paddle.

Blepharoexfoliation is a painless procedure performed in-office that cleans the eyelids margins, removing bacteria and biofilm (*Figure 5*). BlephEx has been shown to improve eyelid health: increasing TBUT, reducing inflammation and enhancing meibomian gland function.[12] It is also a reasonable clinical approach for use on noncompliant MGD patients. We could consider doing therapeutic expression and/or BlephEx with a thermal treatment, which brings us to our advanced level.

TIER 3 (ADVANCED)

- *Thermal pulsation devices.* These include TearCare (Sight Sciences), LipiFlow (Johnson & Johnson Vision), Systane iLux (Alcon), Thermoflo (MiBo Medical Group) and EyeXpress (Holbar Medical Products).
- *Intense Pulse Light Therapy (IPL).* These include Lumenis Optima IPL (Lumenis) and LacryStim IPL (Quantel Medical).
- *Low-level Light Therapy (LLLT).* These include Eye-Light (Espansione Group) and Equinox LLLT (Marco).
- *Radio Frequency energy application.* A device called TempSure (Cynosure) enables this.
- *Scleral lenses.* These create a temporary reservoir for medication and lubricants and include DigiForm (TruForm Optics and Contamac), Onefit (Blanchard Contact Lenses), Boston IV (Bausch + Lomb) and PROSE (BostonSight).

We have arrived at the point of adding equipment to your practice to truly designate ourselves as a comprehensive dry eye clinic. When advancing into Tier 3 treatment options, consider the increased financial commitment for both your practice and patients. While some treatment options can be billable with correct diagnosis, many are not. Before purchasing new equipment, it's important to study the cost, typical reimbursement or out-of-pocket costs for the patient, as well as proper diagnosis requirements. Once you have the whole picture, it's easier to decide whether your clinic will benefit from adding extra equipment and procedures.

Warm compress care at home can be challenging for patients to keep the glands heated up for a sufficient amount of time and at the right temperature. New technology has created the opportunity for thermal pulsation devices to make this less challenging. (*Figure 6*). These wearable eyelid paddles provide targeted and adjustable thermal energy and pressure to the meibomian glands. The Olympia clinical trial data for TearCare showed a statistically significant improvement in both TBUT and meibomian gland secretion score, as well as a statistically significant decrease in Ocular Surface Disease Index score.[13]

Another newer technology is LLLT, which uses specially designed LED light to gently apply periorbital heat to the eyelids to treat MGD, blepharitis, chalazia and *Demodex*. Treatment consists of four consecutive applications, which last 15 minutes; the sessions are separated by 48 to 72 hours. It's been shown that LLLT increases the amount of tear

Photo credit: Katherine Sanford, OD

Fig. 7. Dr. Wiechmann demonstrates the use of IPL on a patient.

volume and decreases neutrophils and the level of inflammatory cytokines significantly in non-human trials.[14]

Radio frequency energy application is a non-invasive treatment that stimulates collagen production by delivering high frequency electrical currents, which generates heat to the surface of the skin. The heat promotes not only improvement in skin tone but also reduces inflammation around the eye and improves lipid expressions into the tears. It only takes around 10 to 20 minutes to complete.

IPL has been used in dermatology for several years as a treatment for rosacea and now has been incorporated into eye doctor's offices to treat ocular rosacea (*Figure 7*). The light emitted causes blood cells in the abnormal telangiectasias to absorb the light, coagulate and close the blood vessels. Rosacea is a condition where these abnormal blood vessels secrete inflammatory mediators over time that damage the meibomian glands.[15] Ultrasound gel is applied to the face from tragus to tragus, including the nose. Complete two full passes across the ultrasound gel and then you can then express the patient's upper and lower glands. The protocol calls for four visits repeated about every 30 days. After these initial treatments are completed, the patient can then return for maintenance in the future when they become more symptomatic.

Let's Get Down to Business

When deciding to bring any new dry eye treatment into your office, it's important to consider the cost of acquisition and return on investment. Another thing to consider is adding marketing and advertising to acquire dry eye patients. Questions to ask:

- Do you have a page on your website dedicated to dry eye treatments?
- Do you use email marketing to target your dry eye patients, letting them know about the latest treatments?
- What systems are you using to make sure your patients are returning for their follow-up visits?
- Do you offer financing for non-billable treatments, and do you have someone in your office who goes over pricing? It's critical to have someone in your clinic who can explain the potential out-of-pocket expense for patients, depending on their insurance plan's allowables and deductibles.
- Do you have a system to follow-up if they don't sign up for anything?

All of these, if done well, can lead to a profitable dry eye practice, regardless of the treatments that you have in your office.

Become Committed

Some may believe treating dry eye is a hassle, as it requires more chair

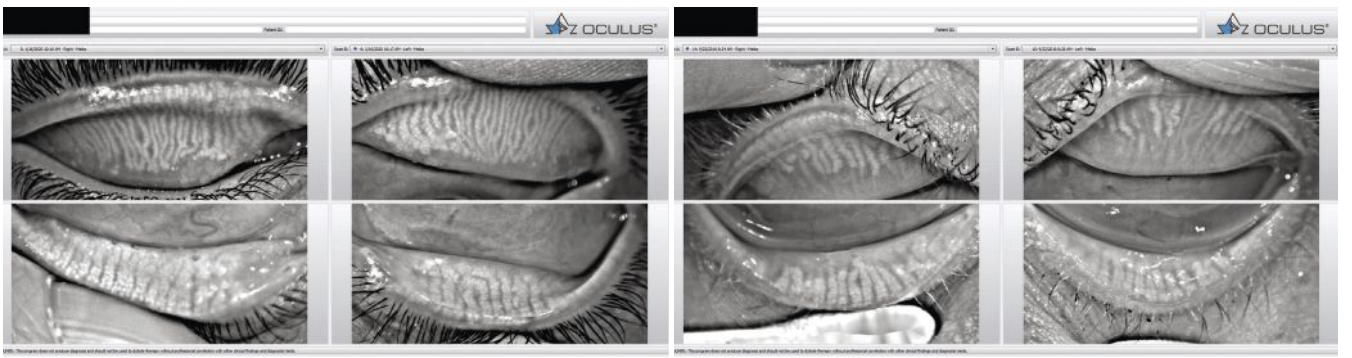

Fig. 8. Meibography imaging of the upper and lower lid meibomian glands.

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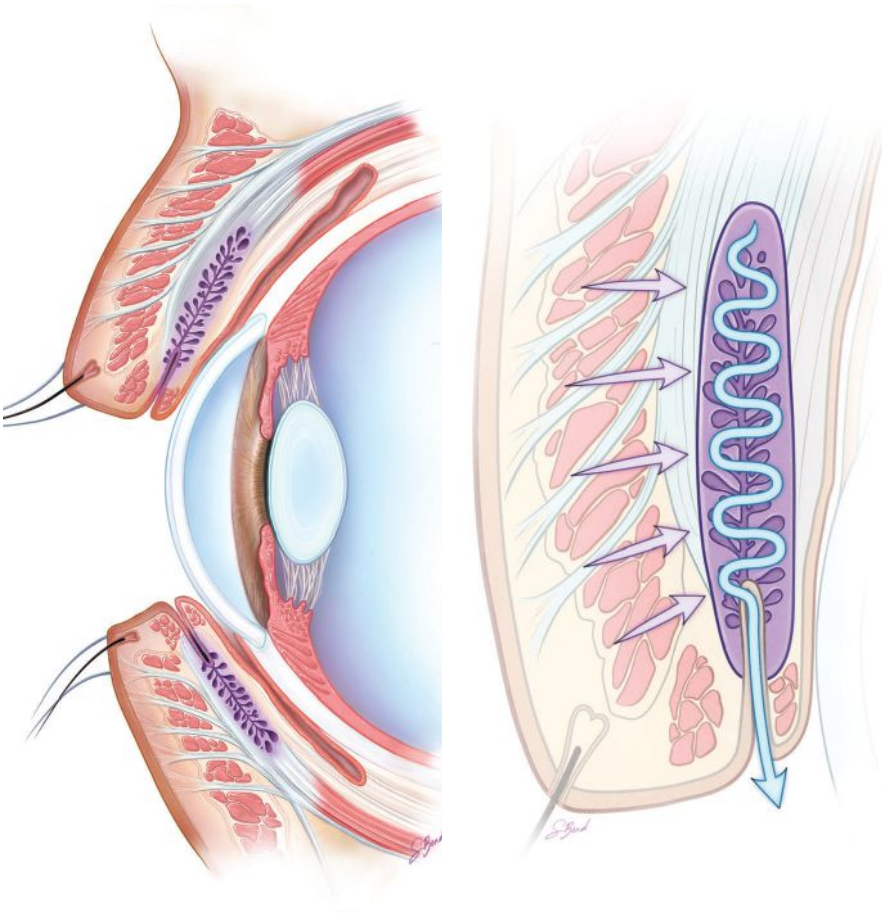

Fig. 9. Maintaining or restoring meibomian gland health is a central component of long-term interventions for dry eye. When the orifices are free of obstruction, adequate lipid release to the ocular surface upon blinking is again possible, improving tear stability.

time and think it won't pay off in the end, but I feel this isn't the case any more. DED is increasingly more common and the more you treat it, the easier it gets. Don't wait until the condition becomes severe, as this makes it much more challenging and frustrating for you and your patients.

Our profession is changing and we need to increase our awareness of the treatments we are capable of providing; we can become patient's go-to doctor for dry eye care. This is also an easy way to shift to a more medical practice model. Once you are committed and experienced in medical billing, you can expand your offerings, further growing your revenue. You've now graduated from being a primary care optometrist to a medical optometric practice. At this level, revenue growth can become exponential.

Takeaways

Never stop learning! Technologies and treatments are always improving and keeping up with these advancements is what sets you apart from your peers. There are ample continuing education courses on DED as well as workshops conducted by leaders in the dry eye landscape.

Remind yourself and your patient that you can't throw the kitchen sink at DED all at once. Start with a few treatment options and get your patient into a routine. Then, reassess their new daily symptoms and see what needs to be added or removed. Not every treatment works for everyone—don't be afraid to change it up. Remind them that DED is never "cured" forever; you are managing their symptoms and preventing them from becoming more severe.

Dry eye management requires a positive attitude. Many of my patients come to me thinking they have tried everything under the sun and are about to give up and accept that pain and suffering is their only option. There are many factors that can cause their problems and trying to fix them all might not be practical, but if you take the time to treat the things within your control, it can be the most rewarding time spent with someone in your chair.

Once you bring your patients relief, they can end up being some of the most grateful people leaving your practice, eventually referring their friends and family. Become a dry eye hero—your patients will thank you! ■

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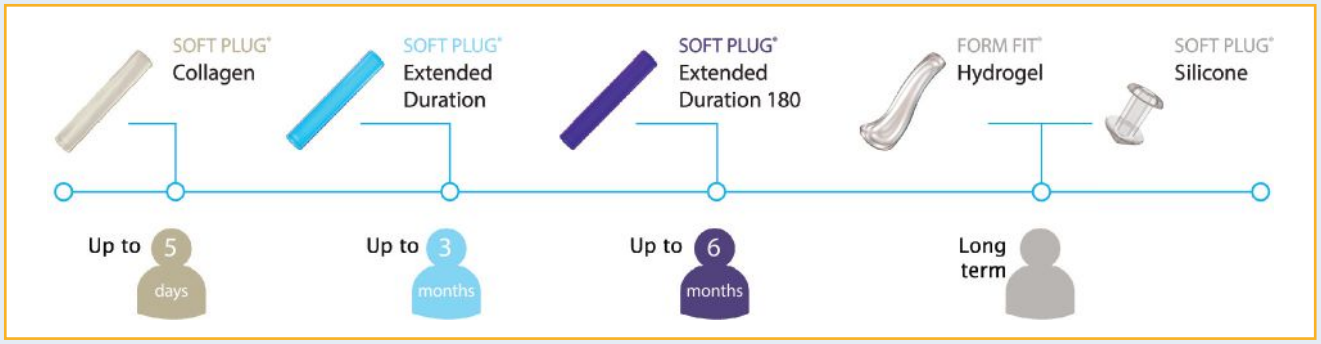

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FOUR HIDDEN LIFESTYLE RISKS ASSOCIATED WITH DRY EYE

How ODs can help their patients reduce the expression of DED in their daily lives.

BY TRACY DOLL, OD
BEAVERTON, OR

Dry eye is one of the most common ocular issues an optometrist will encounter in their practice. The classic risk factors for ocular surface dryness have been well discussed and documented for over a decade, thanks in part to the oft-quoted body of evidence-based papers reported by the Tear Film and Ocular Surface Society (TFOS) DEWS I and DEWS II reports.[1,2] Older age, female sex, history of ocular surgery, contact lens wear and comorbid systemic disease are well-known culprits of ocular surface dryness. The classic dry eye patient is still women over the age of 50.

While some risk factors cannot be changed, newer investigations are seeking ways to prevent ocular surface dryness from being compounded by preventable lifestyle risk factors. TFOS is currently investigating these modifiable risks, which will be discussed in the group's upcoming workshop, "A Lifestyle Epidemic: Ocular Surface Disease."[3]

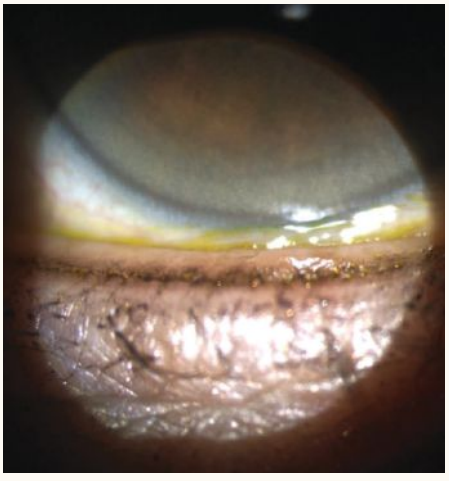

Fig. 1. Tight-lining/water-lining with eyeliner.

The picture of ocular surface dryness is changing and becoming more inclusive of broader patient types, including younger individuals. This article seeks to highlight four lifestyle risk factors that may be present for both classic and non-classic patients alike. The vicious cycle of chronic ocular surface dryness can be initiated by regular ocular surface irritation. The daily lifestyle habits described in this article all lend themselves to habitual ocular irritation.

Risk Factor #1: Cosmetics

The most common eye cosmetics in the marketplace continue to be mascara and eyeliner, followed by eyebrow makeup and eyeshadow.[4] And thanks to the Zoom effect, we are aware of our appearances now more than ever before.[5] Never before have individuals had to work and socialize with a virtual mirror in place. Multiple surveys have indicated increased interest in improving the physical appearance of the eyes through both cosmetics (skincare/makeup), cosmetic enhancements and surgical means.[5-8]

Sadly, consumers have been led to trust marketing terms that have no specific regulation or definition in the

About the author

Dr. Doll spent 15 years in academia and now practices at Sunset Eye Clinic in Beaverton, OR, where she is the director of ocular surface care services. She also serves on the American Academy of Optometry Anterior Segment Section leadership team and is a member of the Intrepid Eye Society and the Tear Film and Ocular Surface Society. She has a passion for lecturing, writing and conducting research on ocular surface dryness and eye beauty. Dr. Doll receives fees from Dompé, Oyster Point, Science-Based Health, Kala, Cynosure and Sun Pharma.

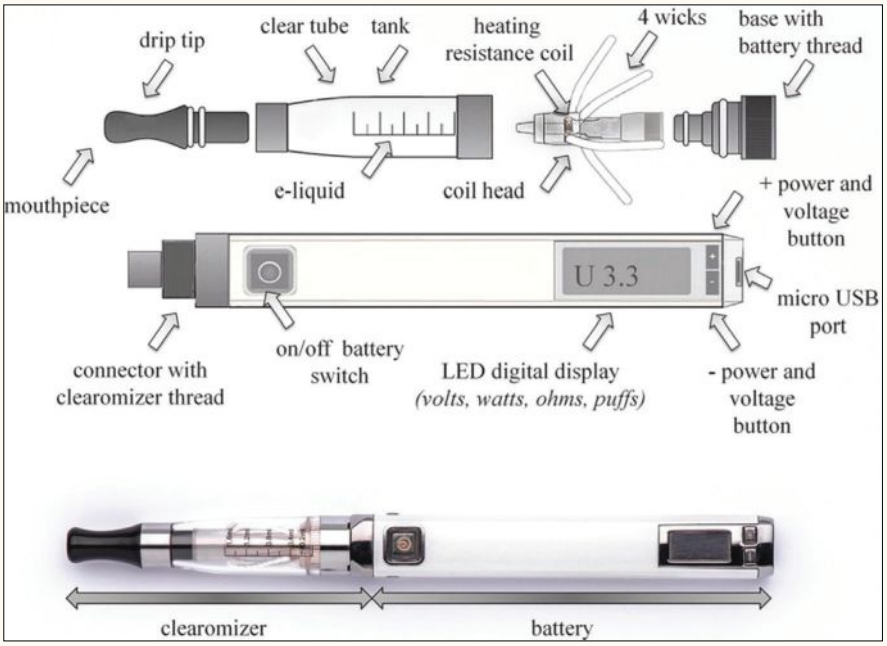

Fig. 2. The basic construction of a vaping mod.[75]

United States cosmetics and makeup marketplace. The following terms are not currently standardized in the United States: *hypoallergic*, *clinically tested*, *doctor recommended*, *natural* and *pH balanced*.[8-16] With no standards, health benefits cannot be verified. In fact, only 11 ingredients have been banned from cosmetics in this country compared with the nearly 1,300 substances banned in the European Union.[9] The burden currently lies with the consumer to read the ingredients listed on product packaging to determine cosmetic safety.

With multiple scientific and lay terms for individual cosmetic ingredients, this task can be particularly daunting. The eyecare provider can be helpful in educating patients about the most common eye cosmetic irritants and offering credible resources. It should be noted that interactions between individual ingredients and the impact of layering cosmetics have not been well documented or investigated. This is an area that needs further study.

There are a number of cosmetic ingredients that can be considered ocular surface offenders, and it is important that patients be made aware of the associated risks. Before purchasing an eye cosmetic, recheck the packaging for known allergies and irritants. Manufacturers can change ingredients in cosmetics without warning. Fragrance as an ingredient can be particularly tricky, as they are considered proprietary and their exact composition is not required to be listed.[23-32] A healthier option for ocular cosmetics can be to choose fragrance-free products. Preservatives are helpful to prevent bacterial growth in cosmetics but can also kill off the natural and healthy flora responsible for maintaining proper lipid barrier function of the skin on the eyelids.[33-49] Choosing cosmetics with more frequent replacement and lower levels of preservatives is a better balance vs. cosmetics with multiple harsh preservatives.

Other, less eye-irritating cosmetic swap-outs can be encouraged. One example would be to choose a one-ingredient oil (argan or jojoba oil) as an eye makeup remover instead of a 14-ingredient oil-free option packed with multiple preservatives, dyes and fragrances. Colorful cosmetics should also be used in moderation. A general rule to follow: the more colorful, the higher the potential for causing eye irritation. It's better to stick with neutral tones of brown and taupe vs.

Release Date: May 15, 2022

Expiration Date: May 15, 2025

Estimated Time to Complete Activity: two hours

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

- Recognize the different factors that contribute to dry eye disease.
- Explain how a patient's lifestyle can exacerbate the condition.
- Educate patients on changes that can help reduce the expression of DED.
- Communicate effectively to patients about dry eye disease.

Target Audience: This activity is intended for optometrists engaged in managing dry eye.

Accreditation Statement: In support of improving patient care, this activity has been planned and implemented by PIM and the Review Education Group. PIM 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 CE for the healthcare team. PIM is accredited by COPE to provide CE to optometrists.

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TABLE 1. COSMETIC INGREDIENT RESOURCES[17-22]

Websites for Ingredient Checking	Phone Apps for Ingredient Checking
ewg.org/skindeep/	Think Dirty Makeup App
clearya.com	Ingredio Beta App
m.checkcosmetics.net	Ingred App

TABLE 2. POTENTIAL COSMETIC OCULAR OFFENDERS

Cosmetic Ocular Offenders	Common Names
Fragrances[23-32]	• Fragrances can be proprietary, so there may not be a listed name other than "fragrance" • The suffix *-ol* is common in products promoted as "natural" or "organic" (*e.g.*, citronellol, geraniol and linalool) and can cause contact dermatitis
Preservatives[33-49]	• Parabens: butylparaben, ethylparaben, methylparaben, propylparaben • Formaldehydes: ureas, quaternium-15, sodium hydroxymethylglycinate, DMDM hydantoin, bronopol (2-bromo-2-nitropropane-1,3-diol), 5-bromo-5-nitro-1,3-dioxane • Combination of ethylhexylglycerin and phenoxyethanol: the bactericidal action of this combination is potentiated, making them much stronger together • Benzalkonium chloride (BAK): if a patient has allergies to eyedrops, look for this in cosmetics too
Pigments[23,24, 40-59]	Undiagnosed metal allergies can result in chronic irritation. Potential sources: iron oxides, titanium dioxide, copper, aluminum, ultramarine blue/violet/pink, manganese violet, carmine, chromium oxide, iron blue, bismuth oxychloride
Lash Growth Serums[60-67]	Prostaglandin-based serums can exacerbate ocular surface inflammation. May include: isopropyl cloprostenate, ethylcloprostenolomide, methylamido dihydro noralfaprostal, 17-pheyl trinor prostaglandin E serinol amide

TABLE 3. SAFER ALTERNATIVES

Category	Better Choices
Pigments	• Browns and taupe shades instead of bright colors • Never place pigmented products over the top of meibomian glands
Fragrances	• Fragrance-free options instead of undisclosed fragrances
Preservatives	• Frequent replacement cosmetics (three to six months) • Either ethylhexylglycerin or phenoxyethanol
Removers	• Simple oils: jojoba, argan • Micellar removers without fragrances or preservatives

blues, pinks and purples.[23,24,40-59] It's also a much healthier idea to avoid placing pigmented products over the top of the meibomian glands, as they can contain waxes and irritating pigments. Tight-lining or water-lining with eyeliner should be moved a few centimeters away from the gland openings.

The addition of ocular cosmetic enhancements has compounded the potential for ocular surface irritation. The growing trend of false eyelashes is dominating the eye beauty market. Eyelashes are not simply beauty adornments but rather serve the very specific anatomical function of diverting debris from the ocular surface. The ideal eyelash length determined to be helpful in mammals (animals and humans alike) is one-third the eye width.[68] Altering this ratio could result in a wind tunnel effect, funneling allergens, dust and debris right to the ocular surface.[68] Before healthcare providers consider capitalizing on this trend, careful thought should be given to anatomical function. When considering options for safer cosmetic lash and lid enhancement, the healthiest choices are temporary, removable and applied by experienced and licensed aestheticians. Generally, beauty enhancements requiring licensure should not be DIY.

Most people do not discard cosmetics appropriately, and cosmetics can become contaminated with skin flora. Thirty percent of single-user mascaras are contaminated with overgrowth of bacteria at the three-month mark.[69] For this reason, all liquid cosmetics should be replaced at least every three months. Powders are also not immune to bacterial growth and should be replaced every four to six months.

Additionally, cleaning applicators is very important to avoid overgrowth of micro-organisms and invasion from non-native species, including fungus.[70-73] Infected cosmetic tools present a risk for soft tissue infections if the epidermis is not intact. Makeup sponges harbor the most bacteria due

to their large surface area and ability to hold moisture. Weekly cleaning of cosmetic applicator tools (*e.g.*, brushes, sponges) with most types of soaps or alcohol-based cleansers has been shown to be adequate in reducing microbial levels of *Staphylococcus* and *Streptococcus* species on cosmetic applicators.[74] All cleaned brushes ideally should be stored in cool, dry locations.

Risk Factor #2: Vaping

The origination of the e-cigarette/vaping module came from a good place: the desire to deliver nicotine without the harmful effects from the carcinogenic ingredients in classic tobacco cigarettes. The original devices were even made to look like classic cigarettes. However, they have evolved over time to look less like a cigarette and to be more discreet; some even look like pens, AirPod cases or USB flash drives. Regardless of technology, all vaping mods have a basic construction: a metallic coil is immersed in vaping fluid containing the substance of choice, most commonly nicotine (cannabinoids are also common).[75-77] A battery sends an electric current through the coil, resulting in heating and vaporization of the juice, which is then inhaled. The strength of the e-cigarette/vape battery (lithium-ion) output is what determines the amount of nicotine and vapor that is produced with every inhale and exhale.

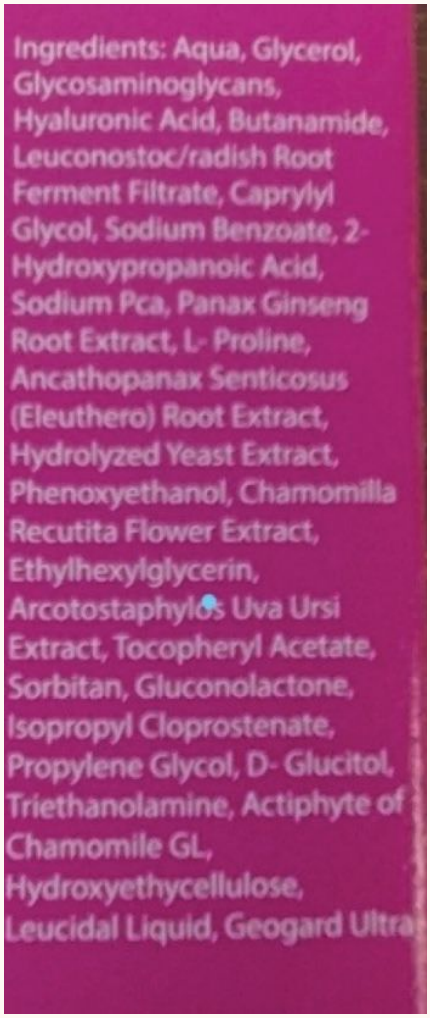

Fig. 3. Be mindful of harmful substances on a cosmetic product's ingredient list.

Sadly, while these devices are arguably less harmful than tobacco cigarettes, they are not without health risks. Like cosmetics, there is poor regulation of the over 80 known ingredients in vaping juice. The most common juices have nicotine solubilized in propylene glycol or glycerin. Nicotine alone in water vapor feels very harsh, resulting in a peppery sensation on the back of the throat. Unfortunately, vaping juice solvents have been associated with a lung condition mimicking pneumonia, known as EVALI (e-cigarette or vaping-associated lung injury).[78-80] The heated metallic coils can also leach metals into the vaping juice, resulting in metal deposition in the lungs.

These known toxic and carcinogenic ingredients, when exhaled, can also make their way to the ocular surface. Vaping has been positively associated with disrupting the lipid layer of the tear film, causing ocular surface dryness.[81-87] Reduction in noninvasive corneal tear breakup time and tear breakup time has been associated with vaping. Higher voltage with more chemical release has been correlated with worsening symptoms, Shirmer score and tear stability.[81-87]

Fig. 4. The Sleep Tite Sleep Rite shield is a newer option for managing lagophthalmos.[112]

In addition to the impact on the tear film, there lies the potential for severe vision loss with improper modification of vaping mods. Batteries that are improperly combined with combustion units to create higher levels of delivered nicotine (or other substances) could result in device explosion. There are documented cases of explosive foreign bodies, including metallic shrapnel imbedding in the ocular tissues.[88-90] Patients need to be reminded of this risk and to never combine non-approved device components.

The eyecare provider should be very specific when taking case history. It is important to ask about vaping in addition to smoking because patients may not identify vaping and smoking as the same act. In the early days of vaping modules, the marketing was very clearly aimed at a younger population, using candy flavors, bright colors and young models in marketing. Since the appearance of vaping devices in the mid-2010s, many states have adopted laws mandating that vaping device and juice companies eliminate colorful packaging and flavoring that would appeal to minors. Unfortunately, these laws may have come too late. A survey in 2021 indicated that 11.3% of high school students (1.72 million)

TABLE 4. EYE COSMETIC BEST PRACTICES

Lash Enhancement	Better Practices	Better Marketing
False Lashes	• Use for special occasions instead of daily • Use partial lashes/wisps, natural lengths • Do not reuse	• Natural Lengths • Wisps • Accent
Lash Extensions	• Use for special occasions instead of daily • Use partial fill, natural lengths • Use a licensed and experienced esthetician • Clean daily with hypochlorous acid (oil-based cleaners will loosen bonds) or lash cleansers	• Esthetician/cosmetology license • Reference list • Education and products for cleaning lashes
Adhesives used in Application of False Lashes/Eyelash Extensions and Double Eyelid Tape	• Consider formaldehyde-free and latex-free options • Consider oxymetazoline hydrochloride ophthalmic solution 0.1% for ptosis instead of daily eyelid gluing	• Formaldehyde-free • Latex-free
Lash Serums	• Use prostaglandin-free options that have peptides or short chains of amino acids, the building blocks of proteins: myristoyl pentapeptide-12/-16/-17, myristoyl octapeptide-1, copper tripeptide-1	• Prostaglandin-free • Drug-free
Tattooed/Permanent Eyeliner	• Do not repeat due to positive association with meibomian gland dysfunction and gland atrophy • Use healthier eyeliner as a better choice	• Esthetician/cosmetology license • Separate permanent makeup artist certification • Eyelid-specific pigments • Reference list
Lash Perms/Lifts/Tints	• Use for special occasions instead of regular treatments • Go to an experienced, professional esthetician and never DIY • Patch-test for sensitivity • Avoid if allergic to hair dye or perming solution (the ingredients are identical for lashes and hair) • Use healthier mascara as a better choice	• Esthetician/cosmetology license • Reference list • Sensitive eye options

and 2.8% of middle school students (320,000) reported current e-cigarette use.[91] Since 2014, e-cigarettes/vaping modules have been the most common nicotine delivery option for teens and young adults.[91] These groups should be questioned about vaping as the potential for early nicotine abuse exists. Smoking is often not associated with the fruity flavors delivered in vapors.[91,92] Roughly 85% of middle school and high school students will choose flavored options for vaping, with fruit flavors being the most popular option across all demographics.[92] In addition to educating patients on the ocular risks associated with vaping, optometrists should also be prepared to provide resources to help individuals who are interested in cessation.

Risk Factor #3: Screen Time

Even the most robust tear film cannot fight the evaporative stress induced by excessive screen time. The actual amount of screen time associated with inducing dryness is shockingly low. Research revealed a correlation of as little as two hours of screen time daily with dry eye.[93] A study of young adult computer users demonstrated statistically significant poorer symptomology correlated with increased screen use.[94] The average adult in the United States spends around three to four hours daily on their smartphone, personal computer and other digital activities.[95]

Evaporative stress occurs due to a lack of protective blinking during digital device use. Multiple studies have demonstrated that the regular resting blink rate of 17 to 23 blinks per minute is reduced to between 3.6 to 10 blinks per minute when on screens.[96-98] Eyes simply are not being covered enough during screen

time. Lack of blinking has also been positively associated with meibomian gland dysfunction and dry eye.[99-103] The mechanism by which protective meibum is secreted onto the lid margin to be incorporated into the tears requires a complete blink. The muscles of Riolan (termination of the orbicularis oculi in the eyelid) contract with the complete blink, releasing meibum from the terminal ducts of the meibomian glands.[104] The oil is then picked up by the upper eyelid and spread across the surface of the eye for incorporation in the tear film.[104] Incomplete blinking equates to no meibum in the tear film, gland obstruction and inflammatory sequelae.

The combination of exposure coupled with inadequate volumes of meibum is a recipe for evaporative dry eye. Regular breaks and complete blinking can help to combat screen-associated dryness. There are a variety of free or inexpensive apps that can be installed onto both computers and smartphones that remind users to take healthy breaks and blink completely. Other workspace dry eye practices include humidifiers, air vent deflectors and moisture chamber/wind-blocking eyewear.

Even our younger patients are at risk, with children from eight to 12 years old spending four to six hours a day on screens, and teens facing up to nine hours of daily exposure.[105] The American Academy of Child and Adolescent Psychology recommends all children take frequent breaks and stop all screen activity 30 to 60 minutes prior to going to sleep at night.[104]

TABLE 5. HARMFUL INGREDIENTS IN VAPING

Vapor Additive	Examples	Toxicity
Carbonyl Compounds	Formaldehyde, acetaldehyde, acrolein	Cytotoxic, carcinogenic, irritant, pulmonary emphysema, dermatitis
Volatile Organic Compounds	Benzene, toluene, aniline	Carcinogenic, hematotoxic, neurotoxic, irritant
Heavy Metals	Cadmium, lead, mercury, arsenic	Carcinogenic, nephrotoxic, neurotoxic, hematotoxic
Other Metals	Nickel, tin, chromium, manganese	Lung irritant
Vitamins	Vitamin E	Identified in association with EVALI
Tobacco-Specific Nitrosamines	NNK, NNK	Carcinogenic
Flavors	Unknown substances as they are considered proprietary	Unknown

Educating patients and their parents on the risks associated with excessive screen time is becoming increasingly important with the introduction of more and more digital devices.

Risk Factor #4: Sleep Issues

Screen-induced sleep perturbations, in addition to primary sleep disorders and medication-induced sleep problems, can also be major risk factors for dryness. Primary sleep disorders have been associated with a cycle of ocular surface damage and dry eye disease symptoms.[106,107] Sleep disorders have been shown to lead to "decreased aqueous tear secretion, increased corneal epithelial cell defects, corneal sensitivity and apoptosis and induced squamous metaplasia of the corneal epithelium in animal models.[107] There is normal diurnal variation in tear secretion, and this balance is interrupted by poor sleep.[108] Obstructive sleep apnea (OSA) not only disrupts normal sleep but is also associated with decreased blood supply to the eye. A lack of normal blood supply leads to hypoxia and inflammation, with subsequent ocular surface damage.[109] OSA is also associated with floppy eyelid syndrome, which could cause further nighttime irritation.[110]

The case history can illuminate whether patients have sleep risk fac-

TABLE 6. RESOURCES FOR VAPING CESSATION

Websites	Apps
www.drugwatch.com/e-cigarettes/how-to-quit-vaping/	Quit Start
www.lung.org/quit-smoking/helping-teens-quit/talk-about-vaping	QuitGuide
truthinitiative.org/thisisquitting	NoVape—Crush Cravings
smokefree.gov/tools-tips/text-programs	Quash
www.becomeanex.org/the-day-you-quit/	

TABLE 7. REMINDER APPS TO BREAK, BLINK

Computer Apps	Phone Apps
Eyelo	Blink: Blink & Co
Dry Eye Zone Blinkers	BLINK: Eye Blinking Reminder
Work Rave	Blinks: Don't Forget to Blink
Dejal Time Out	DryiRelief
EyePro 3.1	Donald Korb Blink Training

tors for eye dryness. Any patient who is not obtaining help for sleep disorders should be encouraged to investigate undiagnosed sleep problems. A great place to refer patients to help start the conversation about poor sleep with their internal health provider is sleepeducation.org/patients.

A patient who wakes in the morning or throughout the night with symptoms of dryness should be examined for nocturnal lagophthalmos. While sleeping with partially open eyes can occur from top to bottom, anatomical variations and disease states like thyroid ophthalmopathy can also lead to gaps from front to back, like a dental overbite. Shining a penlight or transilluminator on the closed eyelid and examining the lid margin for escaping light can help to identify patients who may be at risk of ocular surface exposure at night.[111] A new solution for nighttime exposure, in addition to nighttime lubricants and sleep shields, is the Sleep Tite Sleep Rite shield (*Figure 4*). These shields help to keep the eyelids closed and the ocular surface protected at night. Alternating from right to left every other night can help break the cycle of morning dryness.[112]

Takeaways

Excessive screen time, vaping/e-cigarette use, unhealthy eye cosmetics/enhancements and poor sleep can lead to daily chronic ocular irritation. These ocular surface dryness risk factors are primarily identifiable through a patient case history. Without attention to the lifestyle contributions to dry eye, the disease cannot be effectively treated. Digital resources are available to help guide eyecare practitioners and all patient types on healthier lifestyle options that promote and protect ocular surface health. It is important that optometrists are aware of modifiable risk factors of dry eye and how to best educate and support their patients. ■

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OPTOMETRIC STUDY CENTER QUIZ

To obtain CE credit through the Optometric Study Center, complete the test form on the following page and return it with the $35 fee to: Jobson Healthcare Information, LLC, Attn.: CE Processing, 395 Hudson Street, 3rd Floor New York, New York 10014. To be eligible, please return the card within three years of publication. You can also access the test form and submit your answers and payment via credit card online at revieweducationgroup.com. You must achieve a score of 70 or higher to receive credit. Allow four weeks for processing. For each Optometric Study Center course you pass, you earn two hours of credit. Please check with your state licensing board to see if this approval counts toward your CE requirement for relicensure.

1. Which patient age demographic is currently most at risk for dry eye according to the latest data by TFOS DEWS II?
a. Men <20.
b. Women 30-40.
c. Men >60.
d. Women >50.

2. Which cosmetic labeling term is regulated by the United States government?
a. Clinically proven.
b. pH balanced.
c. Hypoallergenic.
d. None of the above.

3. Which cosmetic ingredient category is proprietary and does not have to disclose its exact ingredients?
a. Preservatives.
b. Fragrances.
c. Pigments.
d. Solvents.

4. Which is the ideal healthy lash length to help divert debris from the ocular surface?
a. Lashes that are two-thirds eye width.
b. Lashes that are one-half eye width.
c. Lashes that are one-third eye width.
d. All lash lengths are healthy lengths.

5. Which component of a vaping module is responsible for the amount of nicotine in the inhaled vapor?
a. Coil.
b. Battery.
c. Mouthpiece.
d. E-liquid or juice.

6. Vaping has been associated with which ocular surface finding?
a. Reduced tear breakup time.
b. Central corneal staining.
c. Conjunctival injection.
d. Corneal infiltrates.

7. Which epithelial toxic preservative is found in both cosmetics and vaping e-juice?
a. Formaldehyde.
b. BAK.
c. Phenoxyethanol.
d. Ethylhexylglycerin.

8. Which percentage of high school-aged teens indicated they were currently vaping in a 2021 survey?
a. 2.8%.
b. 5.6%.
c. 11.3%.
d. 21.2%.

9. Research indicates that dry eye is associated with a minimum of how many hours of screen time?
a. 1 hour.
b. 2 hours.
c. 4 hours.
d. 6 hours.

10. Which is true of blinking with digital device use?
a. The blink rate drops from 17 to 23 blinks per minute down to between 3.6 to 10 blinks per minute.
b. The blink rate increases to 20 to 32 blinks per minute up from between 5.7 to 15 blinks per minute.
c. Blinks become approximately 30% incomplete.
d. The blink is completely eliminated.

11. Which anatomical action releases meibum from the meibomian glands?
a. Switching from primary to up-gaze.
b. A complete blink.
c. Reflex lacrimal tearing.
d. Saccades.

12. A 2020 survey of United States children indicated that teens experience how many hours of daily screen time (smartphone, computer, television, tablets and other devices)?
a. 5 hours.
b. 7 hours.
c. 9 hours.
d. 11 hours.

13. Reduced sleep led to which corneal change in animal models?
a. Corneal epithelial cell defects.
b. Corneal cell apoptosis.
c. Squamous metaplasia of the corneal epithelium.
d. All of the above.

14. Which sleep disorder is associated with reduced blood flow to the eye?
a. OSA.
b. Primary insomnia.
c. Blue light-induced sleep disorder.
d. Nocturnal lagophthalmos.

15. Which in-office tool is helpful in the diagnosis of nocturnal lagophthalmos?
a. PD ruler.
b. Penlight/transilluminator.
c. Occluder.
d. Pinhole occluder.

16. When should screen time be stopped prior to sleep, according to the American Academy of Child and Adolescent Psychology?
a. 30-60 minutes prior to sleep.
b. 60-90 minutes prior to sleep.
c. 2-3 hours prior to sleep.
d. 4-5 hours prior to sleep.

17. Which lid hygiene ingredient is least likely to damage the glue bond for eyelash extensions?
a. Hypochlorous acid.
b. Tea tree oil.
c. Jojoba oil.
d. Argan oil.

18. How often should mascara be replaced to avoid bacterial contamination in a single user?
a. 1 month.
b. 3 months.
c. 6 months.
d. 1 year.

19. EVALI has been linked to which ingredient(s) in vaping liquid/juice?
a. Solvents.
b. Vitamin E.
c. Flavors.
d. Both a and b.

20. Which of the following is a prostaglandin analog ingredient found in OTC eyelash growth serums?
a. Myristoyl pentapeptide-12/-16/-17.
b. Myristoyl octapeptide-1.
c. Copper tripeptide-1.
d. Isopropyl cloprostenate.

Examination Answer Sheet

Four Hidden Lifestyle Risks Associated with Dry Eye

Valid for credit through May 15, 2025

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Answers to CE exam:

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

Post-activity evaluation questions:

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

21. Recognize the different factors that contribute to dry eye disease. ① ② ③ ④ ⑤
22. Explain how a patient's lifestyle can exacerbate the condition. ① ② ③ ④ ⑤
23. Educate patients on changes that can help reduce the expression of DED. ① ② ③ ④ ⑤
24. Communicate effectively to patients about dry eye disease. ① ② ③ ④ ⑤

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

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

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

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

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

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

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

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

Ⓐ Very confident Ⓑ Somewhat confident Ⓒ Unsure Ⓓ Not confident

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

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

30. Additional comments on this course: _____

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

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Rate the quality of the material provided:

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

31. The content was evidence-based. ① ② ③ ④ ⑤
32. The content was balanced and free of bias. ① ② ③ ④ ⑤
33. The presentation was clear and effective. ① ② ③ ④ ⑤

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

Signature _____ Date _____ Lesson 122768 RO-OSC-0522

Herpes Hassles

A history of HSK is not always a contraindication for CXL; active infection is.

Q Is UV exposure in corneal cross-linking (CXL) a contraindication if the patient has a known history of herpes simplex keratitis (HSK)?

A "CXL has become an essential tool in preventing progression of corneal steepening in individuals with corneal ectasia, such as keratoconus," say Sara Stockwell, OD, and Mitch Ibach, OD, of Vance Thompson Vision. The procedure is performed by anesthetizing the cornea, debriding the central 8mm to 9mm, instilling a riboflavin solution, exposing the eye to UV-A light and inserting a bandage contact lens.[1]

Drs. Stockwell and Ibach note that while the goal of CXL is to prevent further progression of ectasia, many patients experience an improvement in corneal curvature as well, which can lead to improved best-corrected visual acuity.[2] They add that CXL is safe and effective when performed correctly; however, as with any ocular surgery, there are complications and adverse effects that can occur, including corneal haze, infection (bacterial/fungal/viral), ectasia progression, best-corrected vision loss, dryness and photophobia.[2]

CXL Contraindications

Some clinicians are leery of recommending CXL to patients with a history of herpes viral infection due to the risk of developing HSK postoperatively, according to Drs. Stockwell and Ibach. There have been reports of HSK infections post-CXL even in individuals with no prior history of HSK.[3] It is suspected that exposure to UV-A during the procedure leads to reactivation of the latent herpes simplex virus and subsequent corneal infection, which can occur after any ocular laser surgery likely as a result of stress and/or damage to the corneal nerves.[4] In such cases, individuals who were treated appropriately with oral antivirals were not left with any long-term visual or ocular complications, demonstrating the importance of timely postoperative examination to monitor for potential complications.[3,4]

Despite the risk of developing HSK after CXL, a history of HSK is not always a contraindication for CXL, note Drs. Stockwell and Ibach. If a patient is in need of CXL and has a history of HSK or herpes zoster virus, the doctor duo suggests treating them prophylactically with oral antivirals one month before and six months after the procedure in order to prevent recurrence.[3] They typically prescribe valacyclovir 500mg QD to BID or acyclovir 400mg BID. However, if a patient has an active HSK infection, CXL should be postponed until the infection has completely cleared.

The doctors say that, ultimately, the decision to perform CXL should not be hindered by a history of HSK unless a patient has an active infection. The patient and physician should weigh the risks and benefits together to make the best decision. It's important to remember that HSK can typically be treated effectively and without any serious complications if diagnosed in a timely manner.[1] Oral antivirals, which are the most common treatment option for HSK, are safe to use in most healthy individuals. ■

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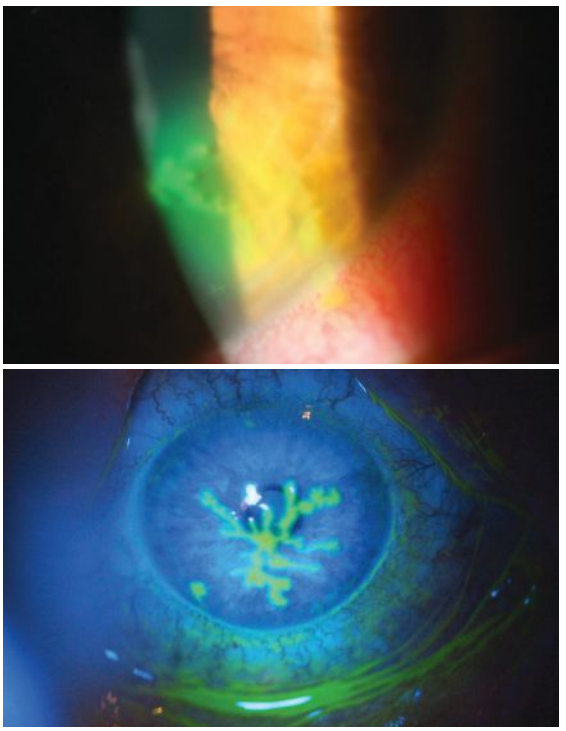

Dendritic HSK with and without cobalt blue filter.

About Dr. Shovlin

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

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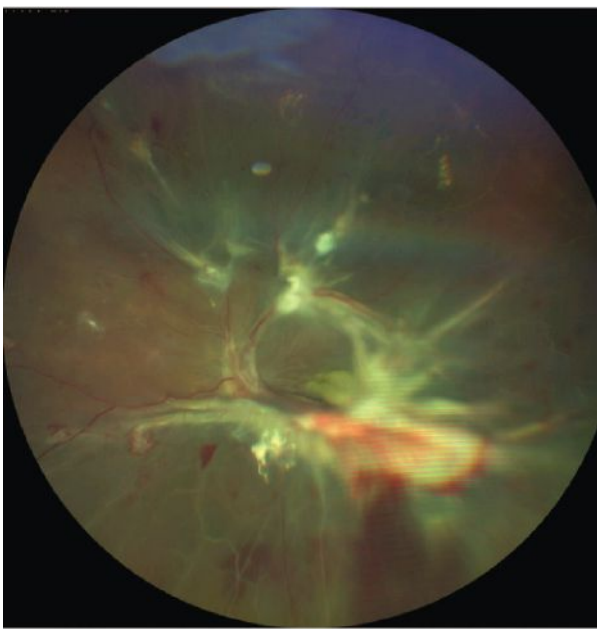
BY BISANT A. LABIB, OD

Neovascularization: A Small Solution to a Big Problem

Quick identification and effective treatment of proliferative retinal disease is necessary for optimal outcomes.

Proliferative retinal diseases are one of the leading causes of vision loss worldwide. Many treatments are aimed at reversing these conditions and preserving visual function. However, in order to do so, timely diagnosis and management is vital. As complications can be severe, more effective therapeutic solutions are continuously being evaluated.

It is important that the eyecare practitioner be able to accurately identify these treatable proliferative processes as early as possible. As such, understanding how and why they arise is crucial.



Severe neovascularization with hemorrhage and fibrous proliferation in diabetic retinopathy, leading to tractional retinal detachment.

Normal Blood Supply

Proliferative retinal diseases are generally classified as either causing retinal or choroidal neovascularization. In order to understand their mechanisms, it is first necessary to distinguish normal retinal angiogenesis and blood supply. As we already know, for vision to occur, light needs to reach the photoreceptors. Because of this, the outer retina is largely avascular, as blood vessels would prohibit image formation if located immediately in front of the photoreceptors. Instead, the entire retina is nourished by a dual blood supply: blood vessels within the inner retinal layers and the choroid.

The vasculature of the inner retina is located far enough anteriorly to the photoreceptors that light is able to navigate around it.[1] This system is made up of deep and superficial capillary beds that are responsible for nourishing the inner two thirds of the retina. By contrast, the outer one third of the retina is supplied by the choroidal vasculature.[1] These two distinct blood supplies are separated by the retinal pigmented epithelium.

Because of this dual supply, neovascularization in proliferative disease processes can arise either from the primary inner vasculature— termed *retinal neovascularization*—or the vasculature in the choroid, called *choroidal (or subretinal) neovascularization*. In either case, these new vessels invade areas where vessels are not normally present.[2]

Protective Measures

Neovascularization is a protective mechanism that many tissues throughout the body have in response to injury. For example, wound repair in the skin involves the formation of new blood vessels to compensate for those that have been damaged.[1] In the retina, disease processes that cause damage to normal retinal vasculature, leading to ischemia and retinal nonperfusion, typically stimulate the growth of neovascularization.

A key contributor that has been heavily studied in this process is vascular endothelial growth factor (VEGF). While normally present in healthy eyes, VEGF is highly expressed in proliferative disease, triggering the growth of neovascularization. When photoreceptors and neurons are deprived of oxygen and nutrients that are usually supplied by healthy vessels, the resultant hypoxia triggers VEGF release.[3] VEGF is known to stimulate and mediate vasculogenesis, endothelial cell migration and tube formation.[4]

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

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Retinal Neovascularization

Although these new blood vessels are formed to compensate for a lack of oxygen and nutrients, instead of repairing the problem they exacerbate it. This is attributed to the differences in the structure of neovascularization as compared with normal, healthy retinal vasculature.

Unlike regular retinal vessels, neovascularization is composed of thin-caliber vessels that lack tight junctions.[1,2] One may recall that tight junctions of the retinal vasculature are a key feature, comprising one of the blood/retinal barriers.[1] As such, these new blood vessels are very prone to leakage and exude plasma into the nearby tissue and vitreous. This causes the vitreous gel to degenerate, contract and collapse, ultimately leading to devastating visual complications such as vitreous hemorrhages and tractional retinal detachment.[1,4] Common etiologies that give rise to proliferative retinal disease include diabetic retinopathy, retinopathy of prematurity, retinal vein occlusion, sickle cell or other hemoglobinopathies and Eales disease.[1,2,5]

To identify retinal neovascularization, key features on fundus exam help distinguish it from normal retinal vasculature. Besides the smaller and thinner caliber—appearing as fine tufts or fronds—retinal neovascularization is often accompanied by connective or fibrotic tissues that increase in intensity over time. It may appear near the disc (NVD) or elsewhere (NVE), growing either superficially toward the vitreous or down beneath the retina.[2]

Because of the architecture of retinal neovascularization, fluorescein angiography (FA) shows leakage of dye from these vessels into the extravascular space. Another distinct feature on FA: the neovascular vessels are often located adjacent to areas of poor capillary perfusion to compensate for this pathology.[2,6,7]

A newer noninvasive method in the works to identify NVE and NVD is OCT angiography (OCT-A). Studies suggest *en face* OCT-A may visualize these abnormal growths as exuberant vascular proliferation or intense growth of small blood vessels located at the margin of new blood vessels, indicating active proliferation.[6]

> **Besides the smaller and thinner caliber—appearing as fine tufts or fronds—retinal neovascularization is often accompanied by connective or fibrotic tissues that increase in intensity over time.**

Subretinal Neovascularization

The other piece of the dual blood supply, the outer choroid, is also a site of neovascularization. This is known as subretinal neovascularization, which suggests the new blood vessels grow beneath the retina in the subretinal sensory space.

Subretinal neovascularization can be further subdivided into two categories, depending on the origin of these vessels. The first is retinal angiomatous proliferation, which arises from the deep capillary plexus of the inner retinal vasculature before making its way through the outer retina and into the subretinal space. Choroidal neovascularization, on the other hand, arises from the actual choroidal blood vessels, penetrating Bruch's membrane and ending in the subretinal space. Regardless of subtype or origin, both forms of subretinal neovascularization are complications of wet (exudative) age-related macular degeneration, among other, less common diseases.

On retinal examination, subretinal neovascularization appears as a greenish or grayish lesion, which may or may not be associated with retinal hemorrhages, exudate or edema. Leakage is also present on FA. Using OCT-A, subretinal neovascularization can be seen as a "seafan" or vascular complex within the outer retina, which is otherwise devoid of blood vessels. These complexes are often located in areas where there is less than optimal perfusion.[8]

Treatment

Since we understand how and why neovascularization arises, we are able to identify primary therapeutic targets. The mainstay of treatment for several decades has been the use of panretinal photocoagulation. This laser therapy aims to destroy areas in the peripheral retina in the hopes of diminishing VEGF release, thereby regressing neovascularization. Though effective, it is not without side effects, such as reduced peripheral vision, loss of night vision, pain, blur and macular edema.[7]

Anti-VEGF agents are also available through intravitreal injection, again attempting to retard the stimulus of neovascularization. Currently available anti-VEGF drugs include pegaptanib, bevacizumab, ranibizumab, aflibercept, brolucizumab and faricimab, along with some biosimilars.

As we continue to research stimuli for neovascular formation, therapeutic targets are more easily identifiable. However, one thing is for certain: identifying these conditions quickly and accurately is critical in ensuring the best treatment outcome. ■

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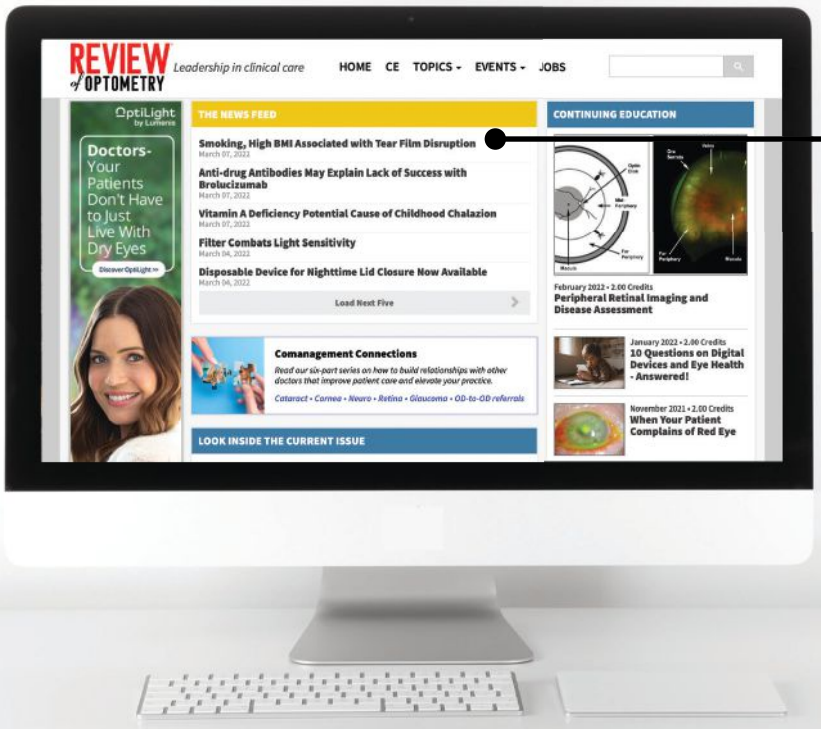

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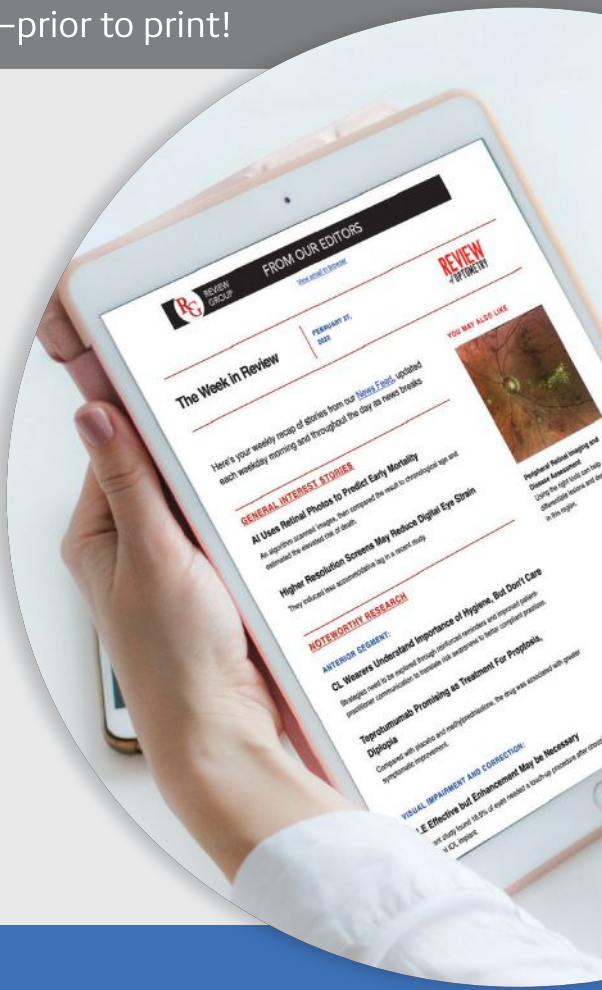

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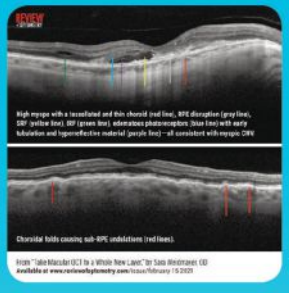

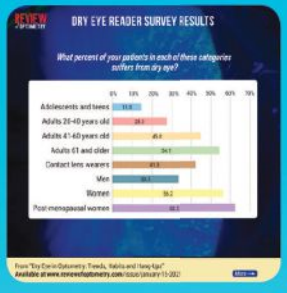

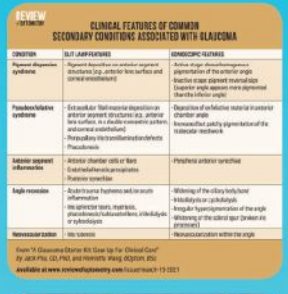

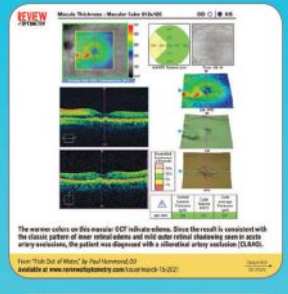

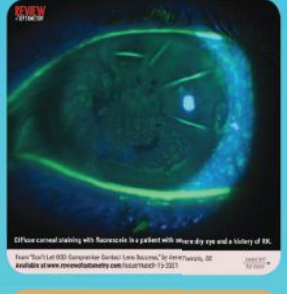

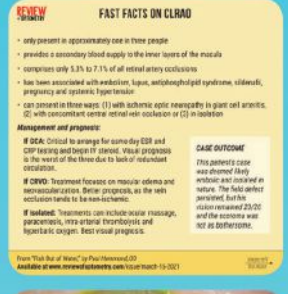

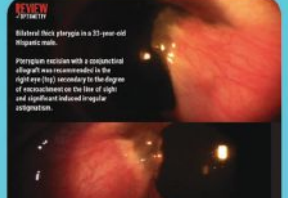

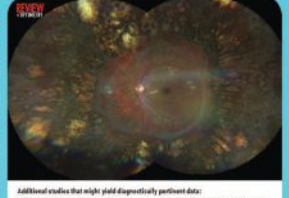

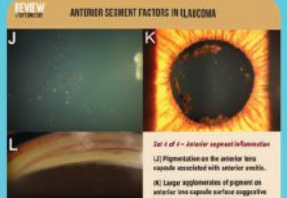

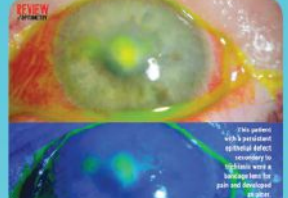

BY ALISON BOZUNG, OD

URGENT CARE

Bullae or Bust

Here's what's on the differential for unilateral corneal edema in a white and quiet eye.

A 37-year-old Hispanic male presented to the emergency department with complaints of blurred vision in his left eye for six months. He reported that his vision had drastically worsened over the preceding week. He denied any active pain or inflammation in his eye, though he did note an episode of photophobia and redness that had occurred in the weeks leading up to his rapid vision decline.

The patient's entering visual acuities were 20/20 in the right eye and counting fingers at three feet in the left. His intraocular pressures were 17mm Hg OD and 16mm Hg OS, and there was no afferent pupillary defect. The slit lamp and fundus examinations of the right eye were unremarkable. The conjunctiva of the left eye was white and quiet without foreign body presence. The cornea was diffusely hazy with subtle stromal thickening throughout the central region. There were numerous large epithelial bullae but no infiltrate or keratic precipitates (KPs) (*Figure 1*). The anterior chamber was deep and formed, and there were no appreciable cells or hypopyon. The dilated fundus examination of the left eye was grossly normal. Additional imaging was completed with anterior segment OCT (*Figure 2*).

A thorough review of the patient's personal and family ophthalmic history was taken. The patient denied any contact lens wear, prior ophthalmic surgery or ocular trauma. He was not taking any oral or topical ophthalmic medications, but he did endorse a history of perioral cold sores. He denied knowledge of any family history of ocular disorders or surgery.

Differential Dive

In cases such as this one, it is helpful to review common causes of corneal edema. First, consider the possibility of a degenerative disorder of the cornea. Fuchs' endothelial dystrophy is the most common endothelial disorder. These patients are typically older and experience a gradual decline in their vision bilaterally.[1] The condition causes accelerated loss of endothelial cells over a patient's lifespan, at a rate which may lead to pathologic characteristics. Clinical exam reveals the presence of endothelial guttae, stromal thickening and epithelial bullae in advanced cases. As mentioned before, our patient did not have any history of such disorders.

Specular microscopy was completed to evaluate the endothelial health of the asymptomatic eye (*Figure 3*). The cell count was within normal limits for his age, and the cells were mostly hexagonal as one would expect in a healthy eye. The central cornea was slightly thin at 514µm, eliminating the possibility of subclinical edema. Other endothelial disorders that can cause corneal edema include posterior polymorphous dystrophy (PPMD), congenital hereditary endothelial dystrophy (CHED) and iridocorneal endothelial (ICE) syndrome. In our patient, there were no clinical signs of any abnormalities of the contralateral eye, ruling out PPMD and CHED. ICE syndrome typically presents as a unilateral condition, but it is associated with iris atrophy and elevated intraocular pressure, two features not seen in our patient.

Corneal edema can also present secondary to ocular trauma and surgery. Pseudophakic bullous keratopathy (PBK) occurs after cataract surgery and leads to irreversible corneal swelling due to loss of endothelial cells during surgery. Though the overall chances of developing this condition are low, factors that lead to an increased risk of PBK include pre-existing endothelial compromise, increased phacoemulsification energy, combined anterior vitrectomy, direct endothelial damage from surgical instruments and anterior chamber intraocular lens placement.[2]

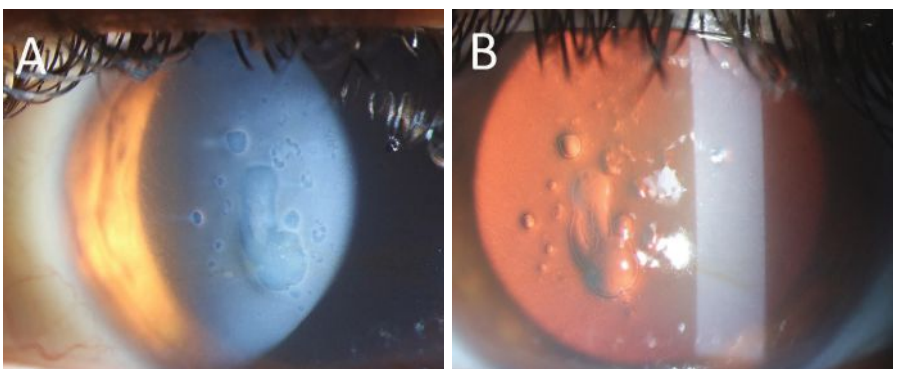

Fig. 1. Slit lamp examination on direct (A) and retro (B) illumination reveals large, scattered epithelial bullae with mild corneal haze. Note the quiet conjunctiva (A).

About Dr. Bozung

Dr. Bozung works in the Ophthalmic Emergency Department of the Bascom Palmer Eye Institute (BPEI) in Miami and serves as the clinical site director of the Optometric Student Externship Program as well as the associate director of the Optometric Residence Program at BPEI. She has no financial interests to disclose.

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Ocular trauma can cause refractory corneal edema, particularly when there is direct damage to the endothelium or a rupture in Descemet's membrane. It is also common to see temporary corneal swelling in cases of corneal abrasions, but this typically resolves as soon as the epithelial defect closes. Our patient denied any ocular surgery or trauma, ruling out these etiologies.

Corneal edema can also result from infectious keratitis. Associated clinical findings include the presence of an infiltrate, epithelial defect, redness, photophobia and anterior chamber inflammation. In our patient, there was no infiltrate, defect or inflammation present, ruling out microbial keratitis.

Viral infections such as herpes simplex virus (HSV) can also cause corneal edema. Herpetic keratitis is most clearly recognized when epithelial involvement (*e.g.*, a dendrite) is present. The absence of dendrites, however, does not exclude a viral infection. HSV may manifest as stromal keratitis or endotheliitis. Stromal HSV often presents with corneal edema, haze and deep corneal neovascularization. Herpetic endotheliitis typically presents with a red, photophobic eye that has keratic precipitates underlying the area of stromal edema. In many cases, the KPs may be difficult to visualize initially due to corneal clouding.[3]

So, What's the Deal?

Our patient's clinical presentation was unique in that he had significant epithelial bullae but in an otherwise white and quiet eye. He reported an episode of redness and photophobia that preceded his visit to the emergency department, but those symptoms had resolved by the time he sought care. Given the patient's age, unilaterality and prior history of cold sores, a suspected diagnosis of herpes simplex endotheliitis was made. The patient was started on valacyclovir 500mg three times daily, sodium chloride drops four to six times daily and preservative-free artificial tears four times daily.

At a five-day follow-up, his vision had improved to 20/150. At that time, prednisolone acetate was added four times daily. One month after his initial presentation, the patient's corneal edema had completely resolved, and his vision was 20/30 without correction. He was tapered off the topical corticosteroids, and the valacyclovir was discontinued. Despite lacking classic findings of herpetic keratitis, the exam and course of improvement supported a herpetic component.

Similar cases have been reported, including a 62-year-old female who presented with unilateral corneal edema and epithelial bullae but lacked anterior chamber inflammation, KPs or elevated intraocular pressure. Topical steroids alone did not improve the clinical findings. The patient therefore underwent an aqueous tap confirming HSV and went on to receive successful treatment with topical corticosteroids and oral antivirals.[4]

Another case involved a 60-year-old male with unilateral corneal edema and bullae in an otherwise quiet eye. There were no KPs or anterior chamber cells, but intraocular pressure was elevated in the affected eye at the initial visit. At follow-up, he was noted to have developed epithelial dendrites, and corneal cultures were positive for HSV.[5]

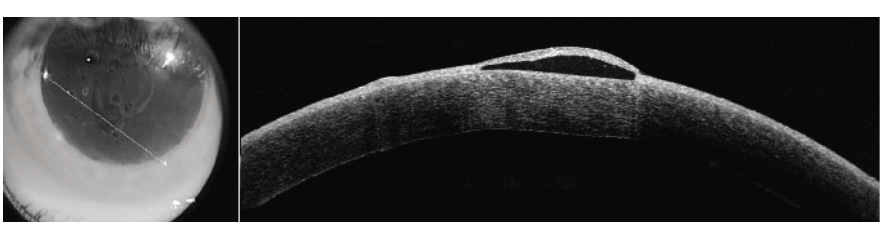

Fig. 2. Anterior segment OCT through the cornea reveals prominent epithelial bullae and minimal stromal thickening. There were no endothelial KPs visible on any OCT images.

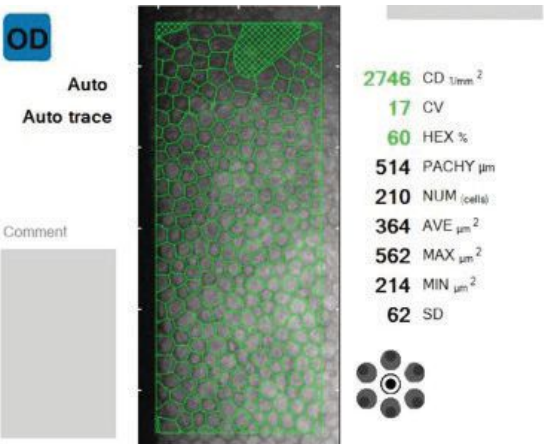

Fig. 3. Specular microscopy was performed in the patient's fellow eye, revealing healthy endothelial cells without corneal edema. Endothelial cell analysis was attempted OS, but data was unable to be collected.

A third case of corneal bullae from viral endotheliitis in a quiet eye revealed cytomegalovirus as the causative agent, further illustrating that not all disease processes present with classic findings.[6]

Take-home Message

This column highlights the diverse clinical manifestations possible with herpes simplex keratitis. When faced with a divergent clinical picture, it is helpful to think logically through the differential diagnoses. Many etiologies can be ruled out, leaving the practitioner with a narrow list of suspects to work through.

In this case specifically, the patient was treated empirically given the known history of HSV and the larger clinical picture. He continues to be monitored for recurrence but was doing well at the most recent follow-up. ■

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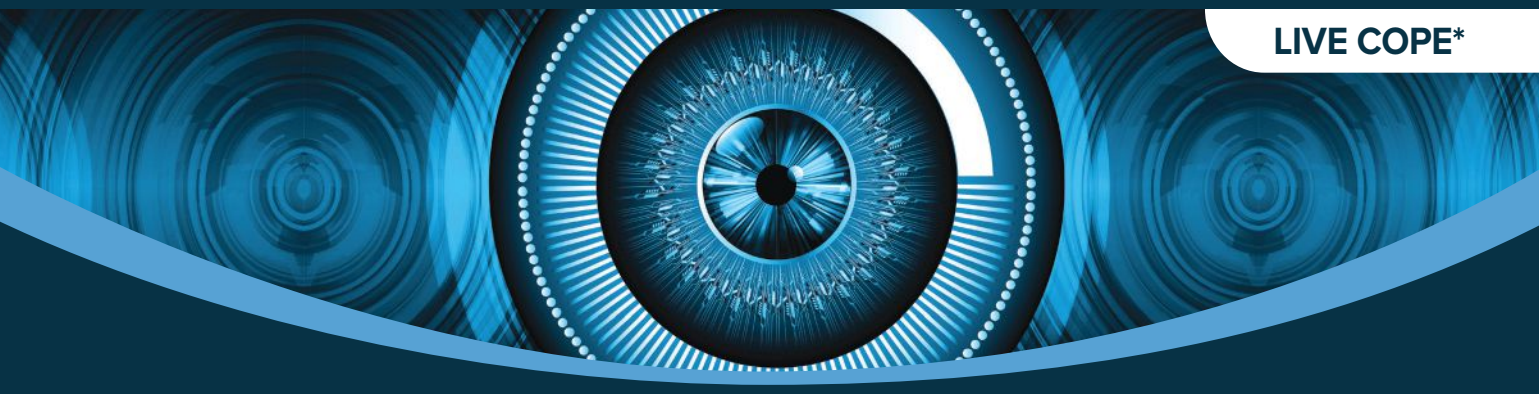

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▶ NEW TECH

Next-gen Self-tonometer Cleared by FDA

In-office tonometry readings only show you a brief snapshot of a patient's intraocular pressure (IOP), which varies considerably throughout the day and night. With the increased interest in self-tonometers such as iCare Home, it's now possible to document a patient's IOP readings around the clock without requiring them to travel to the office. The newest incarnation, called iCare Home2, allows IOP measurements to be taken while a patient is sitting or lying down, making it more accessible and user-friendly than the previous model, according to a company press release.

As with the original iCare Home, the new model uses cloud-based software called iCare Clinic to store IOP data that eyecare professionals can access 24/7 to help make appropriate treatment and management decisions. The company also notes that patients can review and monitor their own measurements using a mobile app called Patient2, which allows data to be saved from the tonometer to the patient's smartphone via Bluetooth.

iCare says its latest handheld self-tonometer enables remote IOP monitoring during a time when the need for virtual healthcare is increasing and may also provide valuable clinical data that's otherwise unobtainable through periodic in-person appointments.

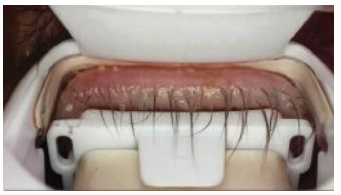
New Camera Adapter for BQ 900 Slit Lamp

Slit-lamp biomicroscopy is a fundamental diagnostic tool essential to daily practice. While examining patients' eyes helps you make clinical decisions in the moment, digitally documenting your findings can help with tracking progression and informing long-term treatment and management. One new slit lamp camera attachment from Haag-Streit designed for this purpose—the Imaging Module 910 for the BQ 900 slit lamp—can capture sharp clinical images during an exam with the click of a button, according to developers.

The module can be used in one of two ways: "stand alone" mode, which allows images to be stored directly in the EMR system, or "EyeSuite" mode, which enables features such as image editing through custom software the company provides. For the best image quality and illumination possible, the device includes smart features such as auto-exposure mode and automatic aperture control, a press release from Haag-Streit explains. The company adds that an image selection algorithm filters and chooses the best images.

Alcon Updates its MGD Thermal Pulsation System

Warming the eyelids and applying pressure to express the glands has long been a popular treatment for meibomian gland dysfunction—a leading contributor to dry eye—using either home remedies or newer in-office procedures. Alcon recently released an updated model of its meibomian gland expression device, called Systane iLux2, and says this version can customize heat and compression settings to give the doctor more control over the intervention. Alcon says the iLux2 can treat both eyes in eight to 12 minutes total.



The device also now includes a camera that captures photos and videos of the procedure and its effects on the meibomian glands, the company says, in hopes of improving patient adherence with medical recommendations and overall satisfaction with your care. Immediately after treatment, you can show the patient the affected areas of their eyelids and the changes that took place during the treatment.

▶ THERAPEUTICS

Topical Immunomodulator FDA-approved for VKC

Vernal keratoconjunctivitis (VKC) is uncomfortable to its young patients and can damage the ocular surface if left untreated. A variety of steroids and antihistamines are typically prescribed to manage the rare condition. A new, recently approved therapeutic—Verkazia—is a cyclosporine 0.1% emulsion that blocks release of pro-inflammatory cytokines, thereby suppressing the immune system and reducing inflammation, manufacturer Santen says.

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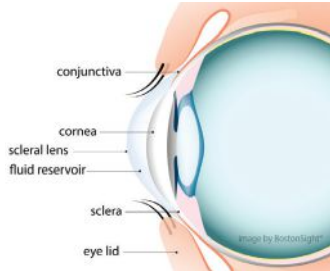
Clinical trials of Verkazia demonstrated improvements in corneal inflammation (keratitis score) and ocular itching, a press release explained. The company also noted that the most common side effects, occurring in more than 5% of patients and typically during instillation, were eye pain (12%) and eye itch (8%).

In addition to providing VKC patients with symptomatic relief, Verkazia may also mitigate their chance of developing vision-threatening complications such as shield ulcers, according to Santen.

▶ CONTACT LENSES

BostonSight Scleral Campaign for Patient Education

You may be getting more patient inquiries about scleral contact lenses with the launch of a new marketing campaign last month, which intends to provide accessible materials to educate more patients on scleral lenses. Called the BostonSight Scleral campaign, its goal is to help increase patients' awareness of the potential benefits of this modality. Through various handouts available via its website, the company offers information and resources on topics such as "What is a is a scleral lens?", "Anatomy of a scleral lens" and a "Healthy Lens Habits Guide." The three conditions that scleral lenses are commonly used to treat that the campaign will focus on are dry eye disease, keratoconus and post-LASIK ectasia.



BostonSight wrote in a press release that its campaign aims to help promote confident decision-making by equipping patients with the knowledge they need to select a lens that meets their needs. The company also notes that its educational materials may encourage more patients to strike up a conversation about scleral lenses with their eyecare provider.

Six Lens Designs Added to Eye Surface Profiler

Since the launch of a recent software update—called Prime 6.1—the Eye Surface Profiler (ESP) from Eaglet Eye now features over 60 lens algorithms and works with over 25 labs to ensure a wide range of lens designs are available to fit patients' specific needs. Lens designs that may be fit with the newest ESP model include scleral, ortho-K, hybrid, soft and corneal gas permeable. The additional algorithms that are now incorporated into the ESP software will allow you to offer more of your patients a customizable fit from the comfort of your clinic, the company notes. ■

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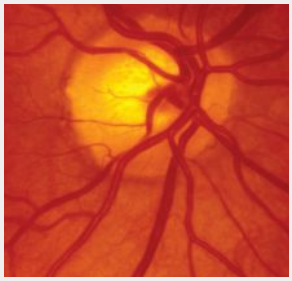

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REVIEW Education GROUP

BY ANDREW S. GURWOOD, OD

DIAGNOSTIC QUIZ

History Lesson

How to proceed when a patient's report of their medical status doesn't match your clinical assessment.

A 52-year-old African American female reported for an annual eye exam. Her chief complaint was difficulty with reading. She indicated she had an ocular history of medullated nerve fibers in the right eye diagnosed by another practitioner many years ago. She also indicated she had a family history of glaucoma (grandmother). Her systemic history was significant for hypertension, for which she was properly medicated. She denied allergies of any kind.

Clinical Findings

Her best-corrected entering visual acuities were 20/20 OU at distance and near. Her external examination was normal with no evidence of color deficiency, brightness loss, field abnormality or afferent pupillary defect. Refraction was negligible, with improvement at near with a small increase in add power. Biomicroscopy uncovered normal and healthy anterior segment tissues with Goldmann applanation tonometry measuring 19mm Hg OU.

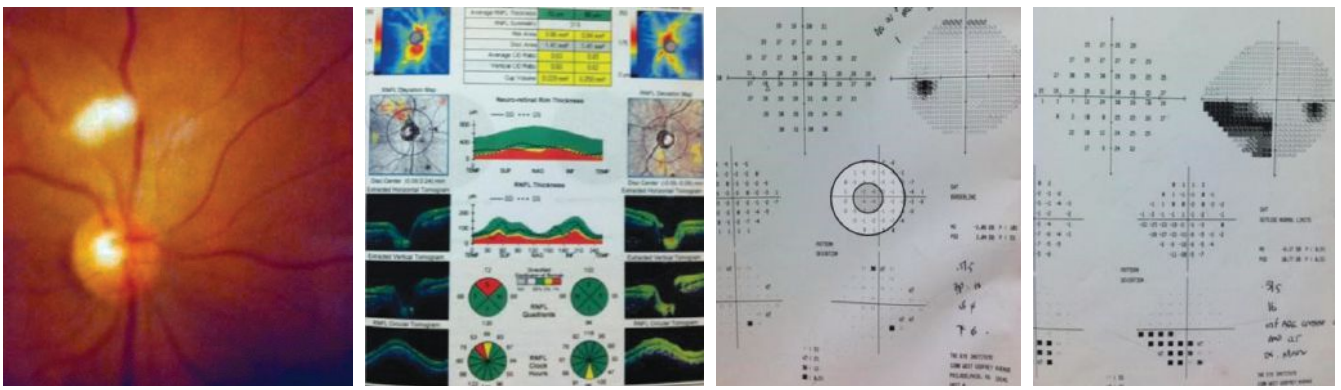
Her dilated funduscopic exam was within normal limits; the photograph below, from old records, demonstrates the "medullated nerve fibers" seen by the previous practitioner. Her cup-to-disc ratios were slightly asymmetric, measuring 0.4/0.4 OD and 0.4/0.55 OS.

For More Information

Additional testing included requesting the previous records and obtaining visual fields, OCT and photos to establish a baseline in case she was considered to be a borderline glaucoma suspect based upon the asymmetric C/D ratio and family history. Measurement of central corneal thickness (pachymetry) to understand the relative conversion risk to treatable glaucoma and gonioscopy to understand angle status is also recommended.

Your Diagnosis

What would be your diagnosis in this case? What is the patient's likely prognosis? To find out, please read the online version of this article at www.reviewofoptometry.com. ■



Examination and diagnostic findings in our patient. How to these correspond to her history and chief complaint?

About Dr. Gurwood Dr. Gurwood is a professor of clinical sciences at The Eye Institute of the Pennsylvania College of Optometry at Salus University. He is a co-chief of Primary Care Suite 3. He is attending medical staff in the department of ophthalmology at Albert Einstein Medical Center, Philadelphia. He has no financial interests to disclose.

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Reference: 1. Chamberlain P, et al. A 3-year randomized clinical trial of MiSight® lenses for myopia control. *Optom Vis Sci.* 2019;96(8):556-67.

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References: 1. Alcon data on file, 2021. **2.** Silverstein S, Yeu E, Tauber J, et al. Symptom Relief Following a Single Dose of Propylene Glycol-Hydroxypropyl Guar Nanoemulsion in Patients with Dry Eye Disease: A phase IV, Multicenter Trial. *Clin Opthalmol.* 2020;14:3167-3177. **3.** Craig JP, Nelson JD, Azar DT, et al. TFOS DEWS II report executive summary. *Ocul Surf.* 2017;15:802-812. **4.** Alcon data on file, 2021.

Alcon