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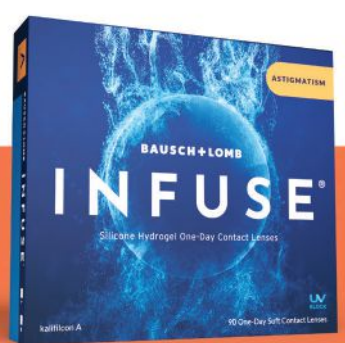

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Study Confirms Safety of Optometric Laser Surgery

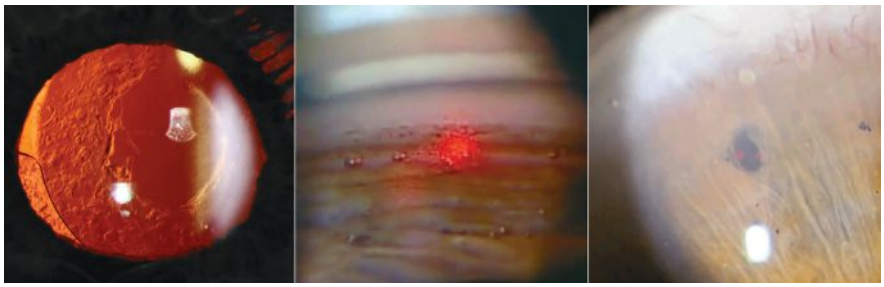
Just two negative outcomes were reported in nearly 150,000 procedures, for a rate of 0.001%.

Optometry's role in eye care is constantly evolving, most notably in the United States, but a growing number of regions around the world are also embracing the profession's use of lasers and other advanced procedures, such as injections and lesion removal. The United Kingdom and New Zealand have both granted ODs these practice privileges, as have 12 US states. Some optometrists, such as those in Oklahoma, have practiced under an expanded scope for more than three decades; yet, limited data exists on the frequency and outcomes of OD-performed procedures and misinformation abounds when the topic is discussed by opponents of scope expansion.

To provide objective data, a group of researchers from the US and Australia recently assessed the delivery of post-graduate education on advanced optometric skills and evaluated the safety of laser procedures performed by optometrists by analyzing the rate of poor outcomes in regions with an expanded practice scope.

Post-graduate programs and requirements for advanced procedures vary from state to state, explains Nate Lighthizer, OD, a prominent leader in optometric laser education and lead author of the present study. While states such as Oklahoma and Louisiana require only the completion of a 32-hour course, others oblige ODs to perform several proctored procedures to gain certification, South Dakota being one example.

Despite these regional differences in training, this study found the number of negative outcomes from OD-performed procedures reported to a state board was next to none. The table provided on the following page summarizes the number of laser procedures performed and negative outcomes reported across different time periods in 10 US states where ODs practice under an expanded scope. Data was obtained from various reputable sources, according to the paper, published recently in *Clinical and Experimental Optometry.*



The incredibly low rate of negative outcomes from optometric lasers reported in this study validates the argument that US optometrists possess the proper skills and education to competently and safely perform these procedures.

"The outcomes of over 146,403 laser procedures performed by optometrists across the US have shown only two negative outcomes, equating to 0.001%," the researchers wrote in their paper. "These metrics outline the effectiveness of these procedures performed by optometrists and show strong support for future optometric scope expansion."

It's important to note that this number isn't reflective of the total quantity of laser procedures ODs have performed in the US since Oklahoma passed the first laser law in 1988. For example, that state stopped requiring the reporting of procedures after 1998 but has maintained a volume of at least 5,000 procedures per year ever since, Dr. Lighthizer estimates. "And I think that would be a conservative estimate, since we are doing way more laser procedures in the past 10 years (2014 to 2024) than we did back in 1988 to 1998," he points out.

Dr. Lighthizer comments that while those who oppose scope expansion often lean on the argument that optometrists are inadequately trained to use lasers and perform minor surgery, this simply isn't true. "Optometrists don't just get a 32-hour course on performing advanced procedures," he explains. "They spent four years in optometry school and are already trained at numerous procedures like eyelid lesions, foreign body removal, punctal plugs and gonioscopy—the essential skill for performing a selective laser trabeculoplasty. Optometrists have already built a tremendous foundation of education, and this is just adding the last piece," he explains.

Dr. Lighthizer draws a parallel to ophthalmologists, making the point that those who "graduated in 1980 or 1990 can do LASIK even though it came about after that time, and the same goes for intravitreal injections,"

given that the required post-graduate training has been completed. In other words, "they built upon their foundation and added a new skill, and optometrists are doing the same thing," he argues.

This study represents the first published data—spanning multiple decades and numerous states—highlighting the competency and safety of ODs performing advanced procedures. "I envision this will be used in nearly every state [scope expansion battle] going forward," Dr. Lighthizer says. "This report shows people the trend happening in optometry schools, the training that happens post-graduation, the states that are doing this and, finally, the outcomes and their metrics, which show a very, very strong track record."

Lighthizer N, Patel K, Cockrell D, et al. Establishment and review of educational programs to train optometrists in laser procedures and injections. Clin Experiment Optom. July 24, 2024. [Epub ahead of print].

TABLE 1. NEGATIVE OUTCOMES OF LASER PROCEDURES PERFORMED BY US OPTOMETRISTS

State	Year	Number of laser surgeries	Number of complaints or negative outcomes
Oklahoma	1988-1998	Over 50,000	1
Kentucky	As of January 2004	Over 60,000	0
Louisiana	As of September 2023	25,807	0
Alaska	2020-current	2,000	0
Arkansas	In 2021	1,135	0
Arkansas	In 2022	1,821	0
Mississippi	In 2021	570	1
Mississippi	In 2022	1,904	0
Mississippi	In 2023	2,054	0
Wyoming	In 2023	1,112	0

Vitamin D Supplement Could Improve DED Symptoms

Its anti-inflammatory and immunomodulatory properties may improve some tear film parameters and subjective ratings, meta-analysis concludes.

Patients suffering from dry eye may find relief with vitamin D supplementation, according to a systematic review and meta-analysis published recently in *Contact Lens and Anterior Eye*. Researchers from China explained in their paper that vitamin D "deficiency exacerbates the ocular inflammatory response in patients with chronic dry eye disease, resulting in altered corneal epithelial contours, damage to Bowman's layer, dendritic cell recruitment and altered subbasal plexiform features. The increase in corneal dendritic cell density and its potential effect on subbasal plexus features may be related to the severity of DED symptoms." They added that deficient levels of this vitamin may also affect nerve fibers, resulting in worse symptoms of ocular pain or foreign body sensation.

The review included a total of eight studies with 439 cases. Studies were independently assessed for quality by two reviewers who also calculated standard mean difference (SMD)—a way of pooling data from different studies—for Schirmer's test, tear film break-up time, corneal fluorescein staining scores, lid hyperemia, Ocular Surface Disease Index (OSDI) and Visual Analog Scale, the latter of which measures subjective pain symptoms. An SMD of 1.00 is used for untreated controls and values above or below indicate treatment effects.

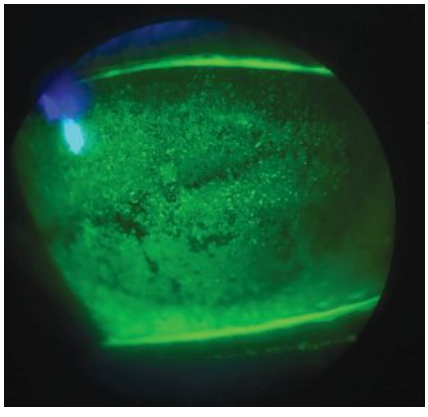


Photo: Pam Theriot, OD

In the meta-analysis, vitamin D doses ranged from 1,000 to 2000 IU (oral) and 200,000 IU (intramuscular injection) once daily. Oral supplementation seemed to produce the greatest effects on dry eye symptoms compared with buccal spray and injection.

Upon analysis, the researchers found that vitamin D supplementation significantly improved tear production by Schirmer testing (SMD: 1.43 vs. controls) and tear film stability by tear break-up time (SMD: 1.19) and reduced lid hyperemia SMD (-0.71), OSDI (SMD: -1.10) and Visual Analog Scale (SMD: -0.32).

"The findings have implications for potential clinical approaches to dry eye therapy and the direction of the patient lifestyle improvement," the researchers concluded in their paper.

Chen Z, Zhang C, Jiang J, et al. The efficacy of vitamin D supplementation in dry eye disease: a systematic review and meta-analysis. Cont Lens and Anterior Eye. July 18, 2024. [Epub ahead of print].

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High tolerability
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INDICATION AND USAGE

VEVYE® (cyclosporine ophthalmic solution) 0.1% is indicated for the treatment of the signs and symptoms of dry eye disease.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Potential for Eye Injury and Contamination** – To avoid the potential for eye injury and/or contamination, patients should not touch the bottle tip to the eye or other surfaces.
- **Use with Contact Lenses** – VEVYE® 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 the administration of VEVYE®.

Adverse Reactions

- In clinical trials with 738 subjects receiving at least 1 dose of VEVYE®, the most common adverse reactions were instillation site reactions (8%) and temporary decreases in visual acuity (3%).
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For additional information about VEVYE®, please see Brief Summary on adjacent page and Full Prescribing Information at vevye.com.

*Ex-vivo porcine corneal penetration study. Clinical relevance is unknown. †In pooled clinical studies. |
1. VEVYE® (cyclosporine ophthalmic solution) 0.1% [package insert], Harrow IP, LLC; 2024. **2.** Restasis® (cyclosporine ophthalmic emulsion) 0.05% [package insert]. Allergan, LLC; 2024. **3.** Cequa® (cyclosporine ophthalmic solution) 0.09% [package insert]. Sun Ophthalmics, LLC; 2024. **4.** Sheppard et al., Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase 2B/3 ESSENCE Study. Cornea 2021;00:1–8. **5.** Akpek et al., Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease The ESSENCE-2 Randomized Clinical Trial. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2023.0709. April 6, 2023. **6.** Data on file.

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Instill one drop of VEVYE® twice a day in each eye approximately 12 hours apart.

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- **Potential for Eye Injury and Contamination –** To avoid the potential for eye injury and/or contamination, patients should not touch the bottle tip to the eye or other surfaces.
- **Use with Contact Lenses –** VEVYE® 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 the administration of VEVYE®.

ADVERSE REACTIONS

Clinical Trial 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 with 738 subjects receiving at least 1 dose of VEVYE®, the most common adverse reactions were instillation site reactions (8%) and temporary decreases in visual acuity (3%).

USE IN SPECIFIC POPULATIONS

PREGNANCY

Risk Summary

There are no adequate and well-controlled studies of VEVYE® 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. VEVYE® doses are approximately 4,700 times lower than recommended oral doses, with blood concentrations being undetectable after topical administration.

Data

Animal Data: Oral administration of cyclosporine oral solution 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 7,250 and 48,000 times higher than the daily maximum recommended human ophthalmic dose (MRHOD) of 0.67 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 4,100 and 14,500 times higher than the MRHOD, respectively).

An oral dose of 45 mg/kg/day cyclosporine (approximately 10,900 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 (3600 times greater than MRHOD).

LACTATION

Risk Summary

Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated. VEVYE® doses are approximately 4,700 times lower than recommended oral doses of cyclosporine, with blood concentrations being undetectable after topical administration. However, caution should be exercised when VEVYE® is administered to a nursing woman.

PEDIATRIC USE

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

GERIATRIC USE

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Evaluation of the potential carcinogenicity of cyclosporine was conducted in male and female mice and rats. In a 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.

In a 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 doses in mice and rats were approximately 120 times higher than the maximum recommended human ophthalmic dose (0.67 mcg/kg/day), normalized to body surface area.

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 (approximately 3,600 times higher than the maximum recommended human ophthalmic dose).

PATIENT COUNSELING INFORMATION

Risk of Contamination

Advise patients to wash their hands well before each use. Advise patients not to allow the dropper tip to touch the eye or any other surface, as this may contaminate the solution.

Contact Lens Wear

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VYE-00002 08/23

MD Groups Respond to Study Linking GLP-1s to NAION

The American Academy of Ophthalmology and North American Neuro-Ophthalmology Society stress that more research is needed to determine whether the association is causal.

In early July, researchers at Harvard University published the results of a recent study that identified an increased risk of nonarteritic anterior ischemic optic neuropathy (NAION) in patients taking semaglutide for type 2 diabetes or weight loss. Semaglutide, a glucagon-like peptide receptor agonist (GLP-1 RA), is the active ingredient in Ozempic and Wegovy (both from Novo Nordisk), two medications being prescribed with increasing frequency across the US, adding to a cause for concern about the study's findings.

The retrospective matched cohort study used data from a single neuro-ophthalmology practice at Massachusetts Eye and Ear in Boston. Among 16,827 patients, 710 had type 2 diabetes; of these, 194 were prescribed semaglutide and 516 were taking a non-GLP-1 RA antidiabetic medication. Additionally, 979 patients in the total cohort were overweight or obese; of these, 361 were prescribed semaglutide and 618 were prescribed non-GLP-1 RA weight-loss medication.

In the type 2 diabetes group, 17 NAION events occurred in patients on semaglutide vs. six in the non-GLP-1 RA cohort. The 36-month cumulative incidence of NAION was significantly higher in those prescribed semaglutide than those on a non-GLP-1 RA, with rates of 8.9% and 1.8%, respectively.

In the cohort of patients who were overweight or obese, a total of 20 NAION events occurred in the semaglutide group vs. three in the non-GLP-1 RA group. The cumulative incidence of NAION for the two medication groups over 36 months was 6.7% and 0.8%, respectively.

Recently, the American Academy of Ophthalmology (AAOph) and the North American Neuro-Ophthalmology Society released a statement responding to the study and commenting on its potential implications for clinical practice. The primary stance of the two organizations is that, while the observed association between semaglutide and NAION of this study is "interesting," more research is warranted to confirm whether the relationship is causal.

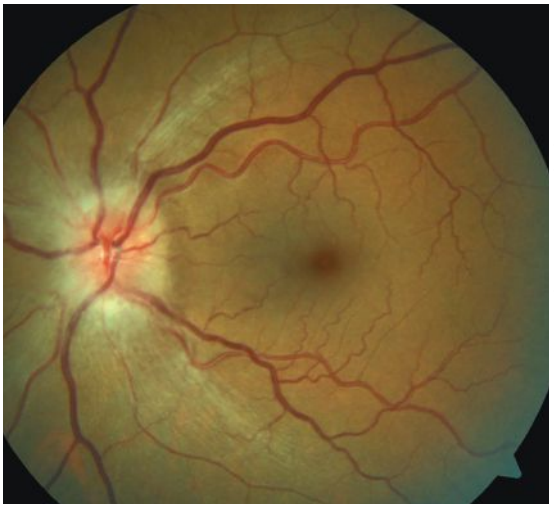

Photo: Michael Trottini, OD, and Candice Tolud, OD

A recent study found an association between the use of semaglutide-a GLP-1 medication for type 2 diabetes and weight loss—and NAION development, though causation remains to be determined.

"The type of study conducted here helps identify potential links between GLP-1 treatment and NAION, but it's not the type of study that can show the treatment caused NAION," states Andrew Lee, MD, a clinical spokesperson for the American Academy of Ophthalmology and a neuro-ophthalmologist at Houston Methodist Hospital, in a recent Vision Monday article. Until more research is conducted, he says "patients should be aware of this information and, in consultation with their care team, make a careful, informed choice based on their individual risk profile."

The AAOph and the North American Neuro-Ophthalmology Society offered several other comments and concerns regarding the design and limitations of the study. For one, they point out that prior to its 2017 FDA approval, semaglutide was rigorously studied in multiple randomized controlled trials around the world. Notably, this is the first study to report an association between semaglutide and NAION.

They also noted that subjects in this study were either overweight, obese or had type 2 diabetes, the latter of which is an established risk factor of NAION, with others including heart disease, history of heart attack, high blood pressure and sleep apnea. However, the study authors did assert that they controlled for these potential confounders in their analysis.

Another potential limitation of the study according to the AAOph and the North American Neuro-Ophthalmology Society was that all patients included were seen at Massachusetts Eye and Ear in Boston. Because the specialty hospital sees a large percentage of NAION patients in the region, this could limit the generalizability of the findings.

The two organizations also point out that semaglutide has previously been linked to other vision changes, such as blurred vision, worsening of diabetic retinopathy and macular complications, though these effects typically subside within three or four months.

Though the AAOph and the North American Neuro-Ophthalmology Society do not recommend that people stop taking semaglutide at this time, they reiterate that further research will help clarify the relationship between the drug and ocular events such as NAION.

Hathaway JT, Shah MP, Hathaway DB, et al. Risk of nonarteritic anterior ischemicopticneuropathy in patients prescribed semaglutide. JAMA Ophthalmol. July 3, 2024. [Epub ahead of print].

Men with DME Show More Inflammation on OCT than Women

Hyperreflective foci and thickening of the inner nuclear layer were more prominent in a recent study. Researchers speculate that estrogen may play a protective role.

The higher incidence of diabetic retinopathy (DR) and likelihood of developing diabetic macular edema (DME) in men compared to women has been established in the literature, and many believe inflammation plays a role in disease progression. A new study published in *Ophthalmology Science* used OCT to identify variations in these characteristics between both men and women with DME and found the male sex was associated with more inflammation-related biomarkers.

Conducted at the Zuckerberg San Francisco General Hospital, the retrospective study included 180 men and 106 women with DME who hadn't received an anti-VEGF injection within the last six months, and researchers performed multivariate regression analyses to control for age, HbA1c levels and central macular thickness. Men had more retinal hyperreflective foci (HRF) (incidence rate 1.19), more hyperreflective choroidal foci (HCF) (1.2 vs. 0.8) and a thicker inner nuclear layer (INL) in the pericentral area (44.6µm vs. 40.7µm). Female patients were found to have a larger extent of disorganization of retinal inner layers (493.5µm in male vs. 588.7µm in female). No significant difference between men and women was found in retinal nerve fiber layer or ganglion cell layer thickness.

In their paper, the authors wrote that HRF is noticeably reduced following anti-VEGF treatment, but an even more significant reduction follows a dexamethasone intravitreal implant, meaning a patient with more HRF at baseline would have more reduction in macular edema and greater improvement in retinal sensitivity after dexamethasone treatment. This led to their hypothesis that "compared to female DME patients, male patients [who] had more HRF suggests increased microglial accumulation and activity in males even with similar control of blood glucose and similar amount of DME. It is possible that due to increased HRF at presentation, male patients could be on average more responsive to corticosteroid treatment, although more studies are needed to confirm this potential therapeutic implication."

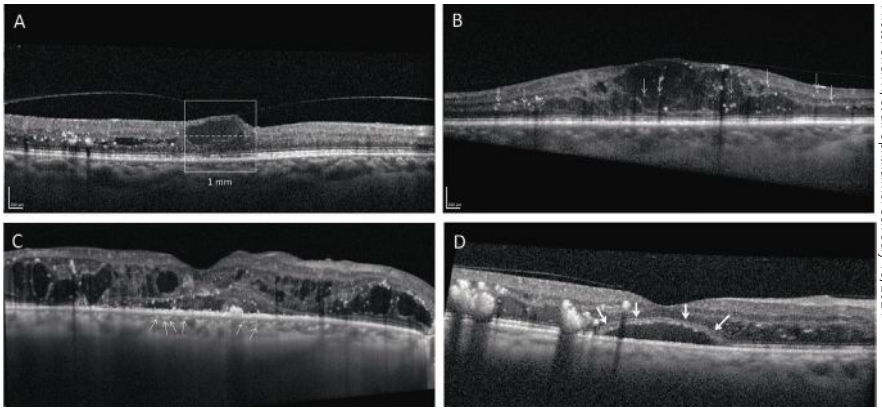

Photo: Chen X, et al. Ophthalmol Sci. July 18, 2024

Researchers suggest that male DME patients may require greater vigilance than women, owning to their more inflammatory response to the condition. This image from the study shows several inflammation-related biomarkers with differential findings for men vs. women: (A) disorganization of retinal inner layers, (B) retinal hyperreflective foci, (C) hyperreflective choroidal foci and (D) subfoveal neuroretinal detachment.

Men also had more HCF when controlled for glycemic levels and the amount of DME, bringing in the matter of microglial cells, which are only found in the inner retina in healthy patients without diabetes. However, as inflammation persists, microglial cells spread posteriorly, creating more HRF in the outer retinal layers in patients with more severe DR. "The majority of eyes in our study with HCF also had HRF, supporting the hypothesis that HCF and HRF are on a spectrum," said the authors. The increased hyperreflective foci in the retina and choroid seen in male DME patients implies increased microglial migration, the researchers wrote, likely due to inflammatory mediators and the breakdown of the external limiting membrane.

As for the biological reasoning behind these differences, sex hormones may be implicated. The authors mention the effect estrogen may have on reducing retinal vessel resistance and how it can protect against the impairment of blood flow in ocular diseases. Although many women in the present study were post-menopausal, other research has found accumulated exposure to estrogen over the lifetime offers protective effects for ocular vascular diseases, contrary to testosterone levels which are associated with the development and progression of DR.

The results of this study suggest that men may potentially require closer follow-ups, concluded the authors. "As HRF and HCF on baseline OCT were correlated with improved responsiveness to corticosteroid treatment in prior studies, there might be a role for a lower threshold for other treatment failures in men to switch to steroid injections for DME, especially when inflammation-related biomarkers are observed on OCT," they said. "Future studies are needed to evaluate the potential implications of these sex-based differences of inflammation-related biomarkers on clinical outcomes and on tailored treatment."

Chen X, Yang W, Fong A, et al. Sex differences in inflammation-related biomarkers detected with optical coherence tomography in patients with diabetic macular edema. Ophthalmol Sci. July 18, 2024. [Epub ahead of print].

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Stress Raises IOP About 4mm Hg in Glaucoma Patients

A new study in *Ophthalmology Glaucoma* had researchers measuring IOP behavior in primary open-angle glaucoma (POAG) patients after using a standardized protocol to induce psychological stress. Included were 39 POAG patients, 18 of which were subjected to the Trier Social Stress Test (TSST)—a simulated job interview followed by mental arithmetic—and 21 controls. All participants were subject to a modified diurnal tension curve one to four weeks before randomization, where IOP was measured three times between 8am and 2pm.

The researchers found no significant differences at baseline between the groups in age, sex, salivary cortisol or mean diurnal test curve IOP. However, there was a difference in mean IOP increase when comparing measurements obtained during the diurnal test curve and immediately after TSST. This was true for both right and left eyes, with increases of 3.8mm Hg and 4.1mm Hg, respectively. Rates of salivary cortisol, salivary amylase, mean arterial pressure and heart rate also increased after the TSST. What's more, 61.1% (11 out of 18) of patients undergoing the stress test experienced an IOP increase greater than 4mm Hg following the test.

Because of this marked difference, the investigators "believe that repetitive stress stimuli in POAG may compromise IOP control and potentially increase the risk of disease progression." This effect occurs in healthy individuals as well, as one previous study noted mean IOP increase of 1.0mm Hg in the right eye and 1.1mm Hg in the left eye following the TSST.

The authors further elaborate that the post-stress IOP elevation was not only statistically significant but also clinically relevant at around 4.0mm Hg; many population-based studies have previously documented high IOP levels to be a risk factor in glaucoma progression.

Besides this trial, some other investigations have been done measuring IOP behavior after anti-stress therapies. One study evaluated effects of mindfulness-based stress reduction on IOP and stress biomarkers in a randomized trial with 90 glaucoma patients. After being assigned either to 21 days of a mindfulness meditation group or control group, results indicated mean IOP reductions from 18.8mm Hg to 12mm Hg in the right eye and 19.0mm Hg to 13.1mm Hg in the left eye of the meditation group.

Photo: Getty Images

It is possible that chronic endogenous elevation of cortisol levels secondary to psychological stress may cause permanent damage to the trabecular meshwork.

The authors explain that these correlations "in conjunction with our results, emphasize the correlation between IOP and stress: not only psychological stress can elevate IOP, but anti-stress therapies may improve IOP control."

Ferreira NS, Costa VP, Miranda JF, et al. Psychological stress and intraocular pressure in glaucoma: a randomized controlled trial. Ophthalmol Glaucoma. July 15, 2024. [Epub ahead of print].

ON Blood Flow Altered in Patients with Sleep Disorder

Patients with obstructive sleep apnea-hypopnea syndrome (OSAS) showed reduced peripapillary vascular density in a recent study. Thus, the researchers propose that measuring optic nerve head vessel density (VD) using OCT angiography could be a useful method for diagnosing and monitoring disease severity.

In this meta-analysis, researchers sought to evaluate retinal microvasculature alterations in OSAS patients. They performed a literature search of several electronic databases, identifying six eligible studies, comprising 479 eyes (333 in the OSAS group and 146 in the control group) for inclusion in the meta-analysis.

Pooled results showed that radial peripapillary capillary (RPC) whole *en face* VD was significantly decreased in the mild-to-moderate OSAS group when compared to the control group. "For RPC peripapillary VD, eyes in mild-to-moderate OSAS showed a trending decrease compared to the controls, and there was a remarkable difference between eyes with severe OSAS and the controls," wrote the study authors in *Journal of Ophthalmology*.

The investigators also analyzed the difference between the severe sleep apnea cohort and controls. They found that RPC inside disc VD was decreased among eyes with severe OSAS vs. patients in the control group.

"To date, this is the first meta-analysis to calculate changes in retinal microvasculature density measured by OCT-A in patients with OSAS and healthy controls," wrote the researchers. "Our results demonstrated that peripapillary vascular density was attenuated in patients with OSAS," they continued. "Moreover, on the basis of these findings and the noninvasive nature of OCT-A imaging facility, we suggest that the measurement of optic nerve head vascular density by OCT-A may presumably serve as a potential biomarker to objectively monitor and diagnose OSAS in the future."

Ji K, Yang Yang Y, Zhang Q, et al. Meta-analysis: characteristics of retinal vasculature in obstructive sleep apnea syndrome humans. J Ophthalmol. July 16, 2024. [Epub ahead of print].

Photo: Getty Images

Findings suggests a connection between peripapillary vascular density and disease severity among patients with OSAS.

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FEATURES

REVIEW OF OPTOMETRY • Vol. 161, No. 8 • AUGUST 15, 2024

48TH ANNUAL CONTACT LENS REPORT

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Could it be KC (KERATOCONUS)?

KC File #3: KC Masquerading as Myopia

Gloria "Gadget" Chiu, OD, FAAO, FSLS, Los Angeles, CA
Dr. Chiu is a paid consultant for Glaukos.

A 33-year-old Asian Indian woman was referred to me for an evaluation. She had a history of soft contact lens wear and although she had always corrected to 20/20 or better, noted that her vision had not been "crisp" for many years. By the time we saw her, she was very unhappy with her vision, particularly in the left eye, complaining of glare and "shadows." She refracted to 20/20 OD and 20/20- OS, with normal to borderline keratometry readings and clear corneas.

Her contact lens history showed frequent small changes in the prescription and progression of myopia and astigmatism between ages 20-31. During that time, the contact lens prescription for the right eye changed from -1.25 sphere to -3.50 -0.75 x 020 and, for the left eye, from -1.00 sphere to -2.75 -1.25 x 140. Given that myopia typically stabilizes by about age 15,[1,2] the degree of myopic progression in this patient's 20s should have been a clue that something was not right.

The patient's medical history included asthma, eczema, and seasonal allergies, for which she was treated with an inhaler, topical creams, anti-allergy shots, and eye drops. Keratoconus is associated with all three of these atopic conditions,[3] although it is not entirely clear whether atopy and keratoconus share common causative factors or whether corneal ectasia is provoked by eye rubbing due to itching associated with allergies.

Corneal topography and tomography was performed in this patient for the first time at age 33, during her first pregnancy. This corneal imaging ultimately confirmed the diagnosis of keratoconus; the left eye (Fig 1) was determined to be worse than the right and progressing. Unfortunately, cross-linking of the left eye had to be delayed due to the patient's pregnancy. Hormonal changes during pregnancy can reduce corneal stiffness and cause or exacerbate an ectatic response.[4] iLink cross-linking is contraindicated during pregnancy because of the unpredictability of corneal changes and unknown effect on the fetus of topical drugs used during and after cross-linking.

Following unsuccessful fits with toric soft and hybrid lenses, a scleral lens was able to eliminate the shadows and higher order aberrations she was experiencing in the left eye. After delivery, the patient underwent FDA-approved iLink® cross-linking in her left eye. Both eyes have now been stable for about 7 years, and she wears toric soft contact lenses OU comfortably. She has been prescribed antihistamine eye drops and counseled to not rub her eyes. We continue to monitor her and have begun monitoring her now 7-year-old son for signs of KC.

This case illustrates that KC can present with 20/20 vision, low myopia and mild astigmatism, and no obvious changes at the slit lamp. Complaints of "shadows" and vision that is not crisp were key clues, especially in an atopic patient with progressing myopia. The delay in treatment due to pregnancy was unfortunate and could have been avoided with earlier diagnosis.

By following the KC clues that are hiding in plain sight, you can help patients get diagnosed and treated earlier, taking one more concern off your patients' plate as they become parents themselves. Visit iDetectives.com to learn more.

KC File #3: THE CLUES

- Late myopia progression
- History of ocular allergies, asthma, and eczema
- Vision not crisp even when corrected to 20/20
- Complaints of shadows

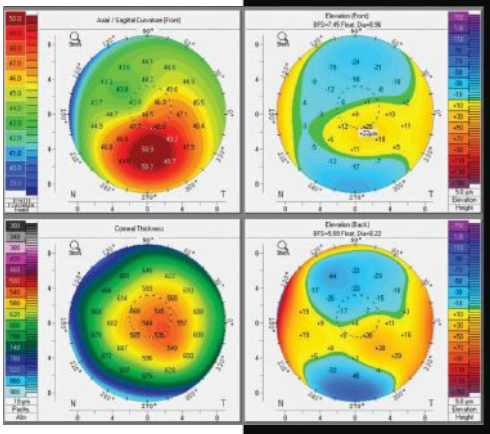

FIGURE 1

REFERENCES: 1. Polling JR, et al. Br J Ophthalmol 2022;106:820-4. **2.** The Comet Group. Invest Ophthalmol Vis Sci 2013;54:7871-84. **3.** Bawazeer AM, et al. Br J Ophthalmol 2000;84:834-6. **4.** Jani D, et al.Clin Exp Optom 2021;104(8):815-25.

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INDICATIONS Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrexa® (riboflavin 5'-phosphate ophthalmic solution) are indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

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You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Following the clues for early KC detection

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Michael Chaglasian, OD, FAAO

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

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

ADVERSE REACTIONS

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

DRUG INTERACTIONS

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

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

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Initial U.S. Approval: 2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 1. Adverse Reactions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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BY JACK PERSICO
EDITOR-IN-CHIEF
OUTLOOK

Setting the Record Straight on Surgery

It turns out optometrists have performed hundreds of thousands of laser procedures without incident.

Opponents of optometric scope expansion rely on fear-mongering arguments that claim, without evidence, that patient safety would be at risk if ODs were given the legal right to perform minor laser procedures like SLT and YAG capsulotomy. You can see why they employ that tactic: it gives them the moral high ground. Who would dare to be against public safety? Of course, baked into that argument is the supposition—you could go ahead and call it a bias or prejudice if you want—that optometrists are inherently unfit for these responsibilities, a premise that has no basis in reality.

We've extensively covered the legislative battles on scope expansion for years, and inevitably the argument comes down to optometric training and what opponents see as inadequacies there. Mind you, they almost never cite any outcomes statistics—because those don't support their premise. Quite the contrary.

As we report this month in our news section, an analysis of nearly 150,000 optometric laser procedures found evidence of just two cases that prompted complaints to the state board about the outcome, for a paltry rate of 0.001%. The study didn't address run of the mill short-term complications like transient IOP spikes, which occur no matter who's pushing the button. Still, there's no hard evidence of a distinction there either.

The lead author of the paper is Nate Lighthizer, OD, one of optometry's tireless champions for these newer responsibilities, as well as a board member and columnist for *Review*. In fact, Dr. Lighthizer's column this month is on how to perform YAG capsulotomy. You can find his clear, concise and authoritative guidance on page 80.

Dr. Lighthizer points out in our news story on the topic that the cumulative volume of all laser procedures performed by ODs since 1988 is much higher than the 146,403 assessed in the study, since Oklahoma dropped its requirement for optometrists to report their laser cases to the state back in 1998. He says at least 5,000 laser procedures are performed each year in Oklahoma alone, "and I think that would be a conservative estimate, since we are doing way more laser procedures in the past 10 years (2014-2024) than we did back in 1988-1998." Some back-of-the-envelope math would nearly double the volume of cases attributable to optometry over the last 36 years.

Claims of insufficient training by optometrists tend to fall apart too when you consider that every optometry college now teaches these procedures, and older ODs who missed out can pursue the necessary training. Ophthalmologists who entered practice before the era of LASIK or anti-VEGF can learn new procedures. So, why can't ODs? The fact of the matter is that they can and do.

So, I will again ask those MDs who genuflect toward evidence-based medicine to practice what they preach—or at least to give up on a feeble argument that uses "the public good" as a rhetorical device instead of a genuine goal. The truth is that the public good is already well served by the thousands of optometrists who pick up the slack in eyecare by delivering these services to their community in a safe and timely way. ■

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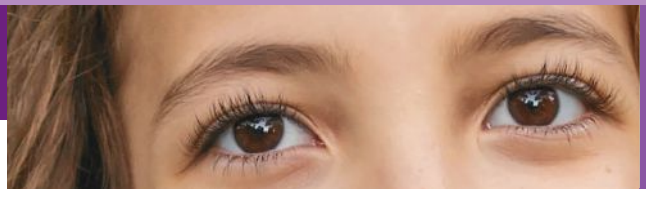

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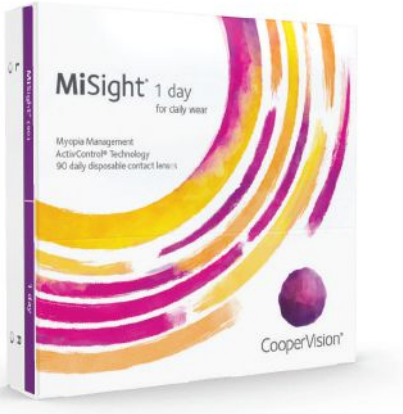

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1. Chamberlain P et al. A 3-year Randomized Clinical Trial of MiSight® Lenses for Myopia Control. Optom Vis Sci. 2019;96(8):556-567

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BY MONTGOMERY VICKERS, OD

CHAIRSIDE

See the World

Jump on a plane and travel for work and play.

When it came to travel, my father had two lines he used throughout his life as a dad and granddad. First, if somebody asked him directions he would ALWAYS say: "You can't get there from here." Pretty accurate observation in 1960s West Virginia.

If we were driving somewhere and griping and complaining about the long, hot journey (no AC… wastes fuel), he would tell us: "It's just over this next hill." Also, apropos for West Virginia travel, I think.

But we traveled best we could with dogs, cats, friends, family and Grandma lying down in the back of the station wagon all the way to wherever.

Optometrists travel. We pay for CE in wonderful locations so we can—we think—write the trip off. For some reason, it gives us solace to think we only had to spend ten grand to save one. And don't forget that us solo practitioners also had to close the office while we were out of town for our new fancy pupillometer wet lab. It's only money.

Then, as the career proceeds, at least for lots of us—including me—we decide we'll drive an hour on Friday afternoon and knock down our CE requirements, hobnob with our colleagues around the coffee pot (or keg) and hightail it back home to reopen on Monday like nothing ever happened.

Travel becomes more for fun. The good kind of travel begins.

Unless you have kids.

When you head to the beach with kids, you are most definitely NOT on vacation. Vacation is when the kids are in school and you can eat lunch without having to break up fights, order more pizza, grill another hot dog and find something for some little mouth to drink because you just found out they hate milk or, even worse, have decided they are vegan this morning.

My wife and I are finally traveling. Only took 70 years of my life for me to have the opportunity to go on vacation where SHE wants to go. Maybe when I'm 80 she will let me decide. She chooses Europe.

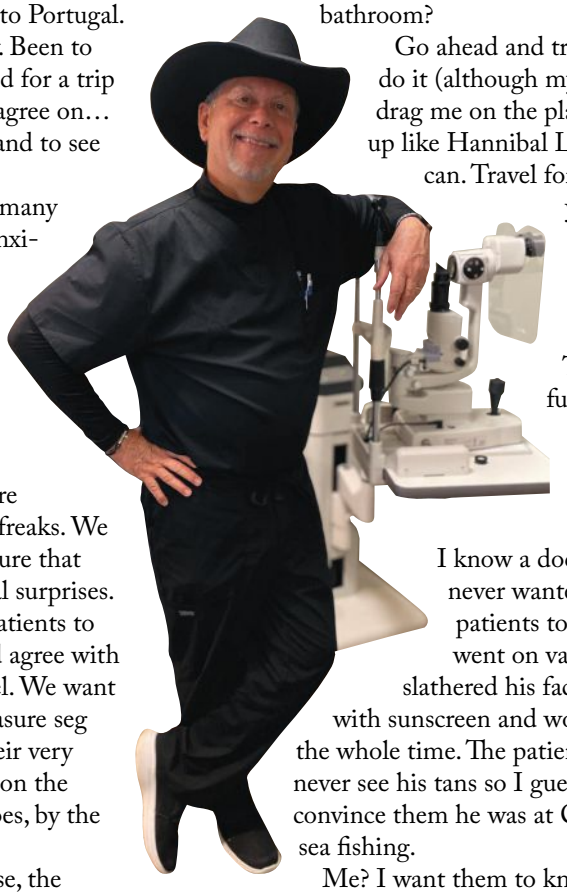
Been to Italy. Been to Greece. Been to Spain. Been to Portugal. Been to Turkey. Been to France. Oh, and for a trip we both could agree on… been to Graceland to see Elvis' stuff.

I have, as do many people, travel anxiety. There are two causes of my travel anxiety.

One is that I am secretly a control freak. Optometrists are mostly control freaks. We want to make sure that there are no real surprises. We want our patients to understand and agree with our best counsel. We want our staff to measure seg heights as if their very lives depended on the result, and it does, by the way.

If nothing else, the fact that we are bred and trained to be control freaks should be evidence enough that we are "real doctors." I guess legislators are scared we will control them so, instead, they control us, even if they think guacamole is an eye disease. To me, good guacamole control is often more tricky than good glaucoma control.

For me, the second cause of travel anxiety is television. Why do all the news stories in the two months before I have to fly somewhere include congressional hearings about how some wing fell off some airplane in the Himalayas so everybody who survived ate each other? Can't we have stories about how 431,000 airplanes took people all over the world and the biggest problem was that guy who tried to vape in the bathroom?



Go ahead and travel. If I can do it (although my wife has to drag me on the plane strapped up like Hannibal Lecter), you can. Travel for CE. It helps you make lists of the stuff your office can do without. Travel for fun. Get the heck out of Dodge every chance you get.

I know a doctor who never wanted his patients to know he went on vacation so he slathered his face and neck with sunscreen and wore gloves the whole time. The patients would never see his tans so I guess he could convince them he was at CE, not deep sea fishing.

Me? I want them to know I was brave enough to get away. ■

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 makers of the #1-prescribed dry eye brand in Europe*

Covering the spectrum of *Dry Eye Relief*

Over-the-counter iVIZIA® lubricant eye drops protect the ocular surface and deliver a unique combination of immediate and long-lasting relief in a **preservative-free** formulation.

- A unique formulation–including povidone (active), trehalose (inactive), and hyaluronic acid (inactive)
- Proprietary, **multi-dose preservative-free (MDPF) bottle**

Safe for use with contact lenses‡

Chronic Dry Eye Patient Usage Study†:

Up to
8 hours
of relief
as well as improved comfort during computer work, reading, and driving[1]

84%
of users reported iVIZIA worked better than their previous eye drops[1]

Recommend iVIZIA and request samples by visiting iVIZIA.com/ECP

Scan here.

*Prescription market data, Dec. 2022 – S01K without cyclosporine.
†In a chronic dry eye patient usage study, participants from a variety of socioeconomic backgrounds answered questions about their experience with iVIZIA lubricant drops. In the study, 203 chronic dry eye patients, 28-80 years old, switched from their dry eye artificial tears to iVIZIA for a month.[1]
‡To limit blurriness when using contact lenses, remove contacts, apply drops, then insert contacts.

Reference: 1. Thea Data on File.

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Théa
let's open our eyes

BY PAUL M. KARPECKI, OD
CHIEF CLINICAL EDITOR

Stop Punishing Doctors

It's time to reform healthcare—where it truly needs it.

The escalating cost of healthcare can clearly be pinpointed to the role of physician benefit managers (PBMs). This group of middlemen, owned by insurance companies, largely avoids transparency and pockets billions of dollars a year—the definition of a conflict of interest. This occurs while drug prices escalate, often to the point that insurers will deny prescriptions written for the newest and best drugs out of "cost concerns."

Who drove up those costs in the first place? And why do regulators feel that targeting *doctors* will lower them?

Getting Hot Under the Collar

It was 104° one day and a pharmaceutical rep asked me to meet with her prior to a promotional program I was conducting that evening. The problem was, after the meeting she was not allowed to drive me the 0.7 miles to the venue that she had to drive to anyway. This would be considered "adding value to a physician," which must be monetized and reported via the Sunshine Act. The problem was that Uber drivers and taxis don't want to accept short-ride fares in remote areas like where I was at the time.

After 25 minutes of trying to get a ride, I started walking in my dress pants, dress shoes and long-sleeve shirt, and carrying my sports coat in one arm and computer bag in the other. I arrived 25 minutes later, sweaty and hot. I wasn't sure if I was heated because of the extreme temperature or because I was thinking about how absurd these regulations were, given that I've personally heard of legislators being whisked off by lobbyists in private jets to Scotland to play golf while they made laws such as this one.

> **"I can't think of a time when any of us looked at a pen from a pharmaceutical company that caused us to change our mind and prescribe that drug."**

Prescribe What's in the Patient's Best Interest

I can't think of a time when any of us looked at a pen from a pharmaceutical company that caused us to change our mind and prescribe that drug. If a therapeutic agent is best for our patient, we are going to do so regardless of which pens may happen to be in the drawer.

Having staff learn about new drugs is also helpful, as they are the ones entering it in the EHR and ensuring it's prescribed properly. In essence, it's a safeguard that helps ensure the doctor's Rx was appropriate. Unfortunately, sending a staff member to attend a program to learn about a new drug is considered "adding value to the doctor" and restricted by many pharma companies.

Abuse by Healthcare Providers

I can't say I have witnessed abuse in eye care, but I do know it has occurred in other medical fields. I understand why regulations were needed but, as with many things, the pendulum has swung too far. The idea of not allowing doctors to learn about pharmaceuticals that patients desperately need because they live in certain states and have to pay for their own meals seems absurd, especially when no such constraints apply to the legislators dining in the finest restaurants who decide what physicians can and can't do.

I can also attest that, as a speaker, it costs me more to leave my practice for a day than the typical honorarium provided for a speaking engagement but, like many, we feel compelled to educate and elevate our profession nonetheless.

Consistent Transparency

While I understand that Sunshine Laws provide transparency to the public, why doesn't this also apply to insurance companies and the PBMs they own? Or, for that matter, the fees the healthcare legislatures receive from lobbying groups, including for their meals, wines, hotels, private jets and golf fees.

In the next reporting quarter—that's three months, mind you—United Healthcare is projected to book over $100 billion in revenue. Much of that comes from PBMs, who often take the majority of revenue on a pharmaceutical Rx. And yet, to the public, the blame lies with doctors and drug companies. The PBMs live in a world of non-transparency; few physicians have even heard of them, let alone our patients. And I don't see PBMs stepping up to inform the public to stop blaming doctors and pharmaceutical companies.

Time for a Change

It's an election year, and it's time to start pushing for reforms that target where the escalating costs truly reside. I can clearly tell you it's not because of doctors, who are providing the best care we can. I'm sure that me walking 0.7 miles in 104° heat to avoid an $8 Uber ride isn't going to make a significant dent in the overall cost of medicine. ■

About Dr. Karpecki

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

Indicated for the treatment of the signs and symptoms of DED

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

Inhibits tear evaporation[1-3]*

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

Rapid and sustained relief[1]†

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

Excellent tolerability[1,4-6]‡

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

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

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

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

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

INDICATION

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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Learn more at MIEBO-ECP.COM

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

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

Initial U.S. Approval: 2023

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

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

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

Data

Animal Data

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

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

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

8.2 Lactation

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

12 CLINICAL PHARMACOLOGY

12.3 Pharmacokinetics

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

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

17 PATIENT COUNSELING INFORMATION

Use with Contact Lenses

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

Administration Instructions

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

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

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Hot and Juicy

Immediate diagnosis and treatment are necessary for this common condition.

Q What are the best ways to deal with suspected preseptal cellulitis?

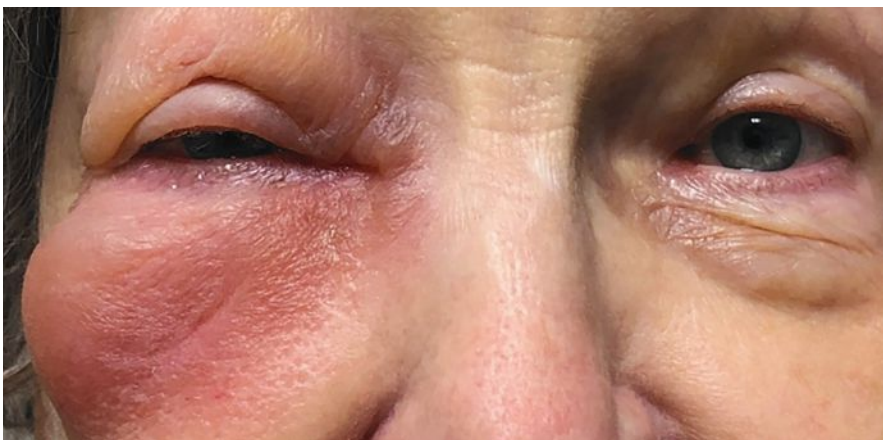
A "It is important to correctly diagnose patients with this inflammatory disease," says Anthony DeWilde, OD, a specialist at VA Telehealth. "Other conditions that may mimic it are mild orbital cellulitis, hordeola, viral infections such as herpes simplex or zoster or epidemic keratoconjunctivitis (EKC) and localized edema from an allergic reaction. Preseptal cellulitis will have more diffuse edema, present with pain and feel warm to the touch."

Preseptal cellulitis is an infection of the skin causing localized erythema, edema and pain. It is important to differentiate preseptal from orbital (postseptal) cellulitis. While both arise from infection, orbital cellulitis has increased risk for infraorbital abscess and cavernous sinus thrombosis.[1,2] Onset of symptoms after a hordeolum, bug bite, eyelid laceration or skin infections with a lack of visual changes suggest a preseptal infection.[1]

A great masquerader can be EKC, which can present with significant lid swelling in advanced cases and lead one to diagnose preseptal cellulitis, but the key finding here is that the eye itself will be significantly injected. True preseptal should present with a white quiet eye.

Patients with orbital cellulitis are more likely to present with history of sinus infection and symptoms including vision loss, diplopia, pain with eye movement, exophthalmos and fever. It is important to note that prepubescent children are at higher risk of orbital cellulitis.[2,3]

Due to the potential for life-threatening complications, orbital cellulitis should be referred to a physician who can image the orbits, hospitalize with IV antibiotics and potentially initiate surgery. While an oculoplastic specialist is best suited to treat these patients, an emergency room physician may be the best referral to start with.[4,5]



Preseptal cellulitis in a patient with an incipient chalazion.

Patient Management

The best treatment for preseptal cellulitis is prompt initiation of oral antibiotics. The most common pathogens are gram-positive *Staphylococcus* and *Streptococcus*. Due to an increase in methicillin-resistant *Staphylococcus aureus* (MRSA), it is recommended that patients receive trimethoprim-sulfamethoxazole (TMP-SMX), clindamycin or doxycycline. However, TMP-SMX and doxycycline do not cover group A *Streptococcus*, and doxycycline is not recommended for children under eight years of age.[4-7]

"Older school treatment includes Keflex (cephalexin, Advancis Pharmaceutical) 500mg BID for mild cases or 500mg QID for more advanced cases," says Dr. DeWilde. The current literature is shifting away from this, however, and pointing toward clindamycin, TMP-SMX plus amoxicillin-clavulanic acid, cefpodoxime or cefdinir.[7] If a patient is immune-compromised, the potential for fungal infection greatly increases.

According to Dr. DeWilde, patients should be monitored closely due to the risk of progression to orbital cellulitis. If symptoms worsen within 24 to 48 hours, prompt referral should be initiated. ■

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

2 TORICS 1 UNMATCHED DESIGN*[1]

MYDAY® DAILY DISPOSABLE TORIC AND BIOFINITY® TORIC LENSES SHARE THE SAME TORIC DESIGN, BREADTH OF PRESCRIPTION OPTIONS—AND THE SAME PERFORMANCE.†[2]

Has the best overall toric lenses.[8]

Has consistently set the bar for innovative toric designs.[9]

Has a toric lens for virtually any patient.[10]

Has the most prescription options for astigmatic patients.[11]

When it comes to fitting astigmatic patients in contact lenses, trust the experts in toric design.[3] With high and unsurpassed clinical performance‡[4] and innovative technology that consistently sets the bar for toric lens design, CooperVision® is a world leader in soft toric contact lenses.§[6]

CooperVision® has the most prescribed toric contact lens portfolio in the U.S.,[7] enabling eye care professionals to prescribe the best toric lens for every patient without compromising on quality.

Compared to Alcon®, Johnson & Johnson®, and Bausch + Lomb®, significantly more eye care professionals agree that CooperVision®.

This feedback is reinforced by the fact that 46% of soft toric contact lens wearers around the world wear CooperVision® lenses.§[6] Biofinity® toric was identified as the most recommended reusable soft toric contact lens by eye care professionals—with over 90% of eye care professionals around the world responding that they trust Biofinity® toric.[5] **And that design—Optimized Toric Lens Geometry™—is also found in MyDay® toric**, enabling practitioners to keep astigmatic patients in the same trusted toric design when transitioning them to a daily disposable modality.†¶[2]

*Unmatched number of patients fit in contact lenses designed with Optimized Toric Lens Geometry in the U.S. (Biofinity toric and MyDay toric). † It is for the ECP to use their professional judgment to determine fitt toric and Avaira Vitality® toric vs. Acuvue Oasys for Astigmatism, Air Optix for Astigmatism, Acuvue Vita for Astigmatism, PureVision Toric, Proclear Toric and Acuvue Advance for Astigmatism. § Combination of 20 Replacement lens and MyDay® daily disposable toric is a 1 Day lens. **In primary gaze. †† Around the clock axes in 10° steps from Plano to -10.00DS, and from +0.25DS to +8.00DS in cylinder powers -0.75D (E-abstract):205296. 3. CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 70% CVI, 45% Alcon, 45% B+L, 55% JJV; p<0.05. 4. CVI data on file, 2020; revi higher than Johnson & Johnson Vision, Alcon and Bausch + Lomb; p<0.05. 6. CVI data on file 2022. 7. CVI data on file, 2019-2021. Based on number of US soft contact lens fits. Includes FRP and 1 day CooperVis CVI, 11% Alcon, 14% B+L, 25% JJV; p<0.05. 9. CVI data on file, 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 41% CVI, 10% Alcon, 17% B+L, 22% JJV; p<0.05. 10. CVI data on file who prescribe toric soft CLs. CVI 65% vs 4% Alcon, 14% B+L and 14% JJV; p<0.05. 12. Sulley A, Young G, Hunt C. Factors in the success of new contact lens wearers. Cont Lens Anterior Eye. Feb 2017; 40(1):15-24. (PureVision Toric), Precision Balance 8|4 lens design (Air Optix for Astigmatism), Accelerated Stabilization Design (Acuvue Advance for Astigmatism) and a prism ballast design (Proclear® toric). 14. CVI data on file 2 2020; review performance from 11 soft toric CL studies that include MyDay toric, Biofinity toric, Avaira Vitality® toric and clariti 1 day toric; n=418 subjects for OTLG lenses and 35 subjects for clariti 1 day. 16. CV monthly SiHy toric prescription options available in the USA reported by the 4 main manufacturers and Biofinity XR toric SKUs. 18. CVI data on file 2021. Based on number of prescription options available in the USA

COOPERVISION® SOFT TORIC CONTACT LENSES PROVIDE:

- **Excellent visual acuity[2]**
- **High levels of subjective vision quality[2]**
- **Excellent rotational recovery*[3]**
- **Consistent, predictable orientation[4]**
- **High levels of fit acceptance[5]**
- **High levels of comfort all day long[5]**

The Optimized Toric Lens Geometry™ Advantage

The Optimized Toric Lens Geometry™ design concept is a multifaceted toric design with a combination of features that together optimize the toric lens wearing experience for the patient with astigmatism. Over a wide range of clinical studies, CooperVision® soft toric contact lenses with Optimized Toric Lens Geometry™ demonstrated strong and unsurpassed clinical performance in the following areas:[12]

- **Rotational Stability**
  Optimized Toric Lens Geometry™ demonstrates excellent rotational recovery and consistent, predictable orientation to deliver unsurpassed toric lens stability.**[13]
- **Vision**
  Biofinity® toric and MyDay® toric contact lenses with Optimized Toric Lens Geometry™ consistently demonstrate excellent visual acuity and high levels of subjective vision quality.[14,15]
- **Fit Success**
  Biofinity® toric and MyDay® toric contact lenses with Optimized Toric Lens Geometry™ provide good-to-excellent fitting characteristics—including fit acceptance, rotational recovery, orientation position, and overall stability.[16]
- **Comfort**
  Biofinity® toric and MyDay® toric contact lenses pair Aquaform® Technology with Optimized Toric Lens Geometry™ to provide wearers with high levels of comfort all day long, thanks to a smooth continuous ballast that minimizes eyelid interaction, combined with naturally wettable material technology.

Parameter Strength

Biofinity® toric has more prescription options than all other monthly replacement SiHy toric brands combined.[17] **MyDay® toric matches Biofinity® toric's core prescription range**, enabling eye care professionals to prescribe the premium performance of MyDay® toric to the vast majority of their patients.††

Lenses with Optimized Toric Lens Geometry™ are available for the broadest range of prescription needs, providing coverage for 99.9% of all astigmatic prescriptions.[18,19]

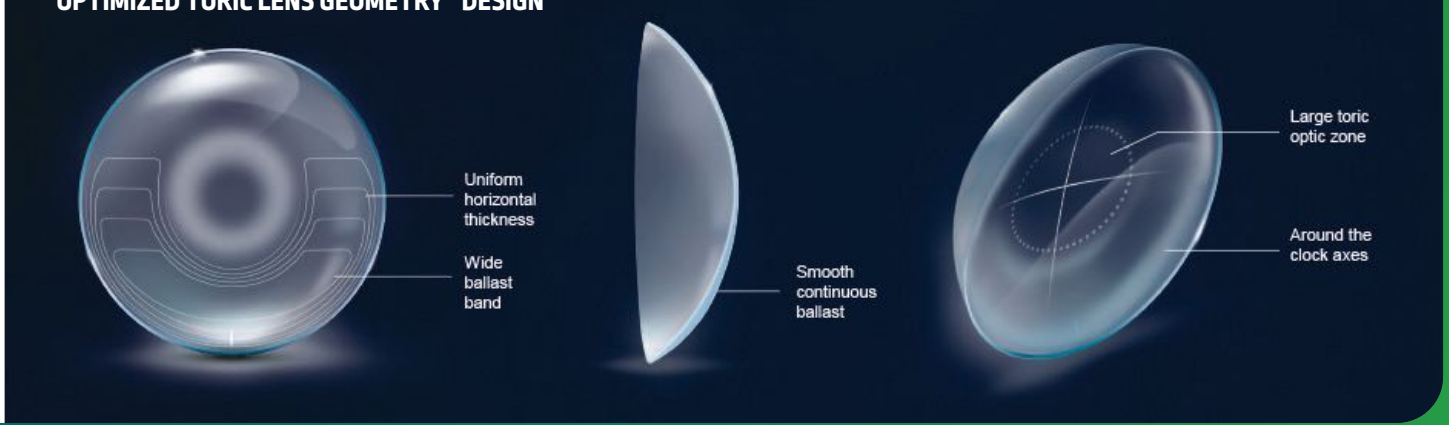
The Toric You Love in Monthly, Also in a Daily Disposable

When moving Biofinity® toric patients into the 1-day modality—look no further than MyDay® toric. Eye care professionals can migrate existing Biofinity® toric wearers into MyDay® toric with confidence, thanks to the consistency of fitting characteristics and good overall fit success with both lenses that utilize Optimized Toric Lens Geometry™. And, MyDay® toric has more parameter options than any other 1 day toric lens.†¶[2]

Read our Optimized Toric Lens Geometry™ white paper to learn more!

CooperVision®

OPTIMIZED TORIC LENS GEOMETRY™ DESIGN



ing characteristics on eye with individual patients. ‡ CVI SiHy toric products are compared individually to at least one of the listed products as follows: clariti® 1 day toric vs. Dailies AquaComfort Plus Toric; Biofinity® 21 market research based on global volume data and internal estimates. | Significantly higher than toric lens brands from Johnson & Johnson Vision, Alcon and Bausch + Lomb; p<0.05. ¶ Biofinity® toric is a Frequent C, -1.25DC, -1.75DC and -2.25DC. **1.** CVI data on file, 2024. U.S. industry reports and internal estimates. **2.** Sulley A & Greenaway N. Success rates with a toric soft contact lens design. Optom Vis Sci 2020;97 ew performance 6 soft toric CL studies with CVI toric CLs; n=242. **5.** CVI data on file 2020. Kubic Online Survey of ECPs in US, Germany, Spain, Japan and South Korea. Total weighted sample n = 549. Significantly ion branded and customer-branded equivalent lenses. US industry reports and internal estimates. **8.** CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 46% e 2020. Kubic masked online survey; n=404 US ODs who prescribe toric soft CLs. 77% CVI, 31% Alcon, 40% B+L, 41% JJV; p<0.05). **11.** CooperVision data on file 2020. Kubic masked online survey; n=404 US ODs doi:10.1016/j.clae.2016.10.002 **13.** Momeni-Moghaddam H et al. Comparison of fitting stability of the different soft toric contact lenses. CLAE 2014;37(5):346-350. Compared to compared to Lo-Torque design 020; review performance from 11 soft toric CL studies that include MyDay toric, Biofinity toric, Avaira Vitality® toric and clariti 1 day toric; 836 eyes for OTLG lenses and 68 eyes for clariti 1 day. **15.** CVI data on file VI data on file, 2020. Review of performance from 11 soft toric studies that include MyDay® toric, clariti® 1 day toric, Biofinity® toric and Avaira Vitality® toric; n=391. **17.** CVI data on file 2021. Based on number of A across all SiHy toric lenses reported by the 4 main manufacturers. **19.** CooperVision data on file 2021. Rx coverage database n=101,973 aged 14 to 70 years. ©2024 CooperVision 16748 06/24

BY JEROME SHERMAN, OD,
AND SHERRY BASS, OD

YOU BE THE JUDGE

Adult Acne Delays HZO Diagnosis

Effective treatment of this condition requires a timely detection and intervention.

A middle-aged woman suffers trauma to her left eye resulting in multiple symptoms and arranges for the next available appointment in a large ophthalmic practice several days later. Review of the electronic medical record (EMR) history of present illness (HPI) taken by a technician documents, "A 53-year-old female presents for an evaluation of pain in her *right eye*. Patient bumped into significant other's collarbone five days ago. She complains about stinging pain and spasms every 10 minutes in the eye. She uses ice four times a day with little relief and Motrin (ibuprofen, Johnson & Johnson) to help with the pain. She states she is light sensitive." Her general health history and previous eye history were both unremarkable.

In the EMR, visual acuity (VA) is recorded as 20/25 in each eye, the external exam listed an eyelid contusion *OD*, but location, size or sketch were not included. Slit lamp exam noted 1+ cells in the left eye only. A dilated fundus exam was recorded as normal, including the statement "flat x 360º, no retinal detachment, no holes." The ophthalmic clinician (Dr. X) arrived at a diagnosis of "traumatic iritis in the left eye" and prescribed steroid eye drops, Pred Forte (prednisolone acetate ophthalmic suspension 1%, Allergan), to be used four times a day in the left eye. The patient was advised to return in a week, and the record does not reveal any indication of what to do if the condition worsened.

Blisters and acne lesions are not noted anywhere in the EMR on this single exam with this ophthalmic clinician. The patient later produced iPhone images of her face dated a day before her exam and two days after her exam. She shared these images early one morning with her sister, a nurse practitioner who practiced more than a thousand miles away. Her sister opined that shingles was highly likely and that treatment with antivirals must begin immediately. An in-person exam several hours later with her primary care practitioner confirmed the diagnosis and the oral antiviral valacyclovir was initiated.

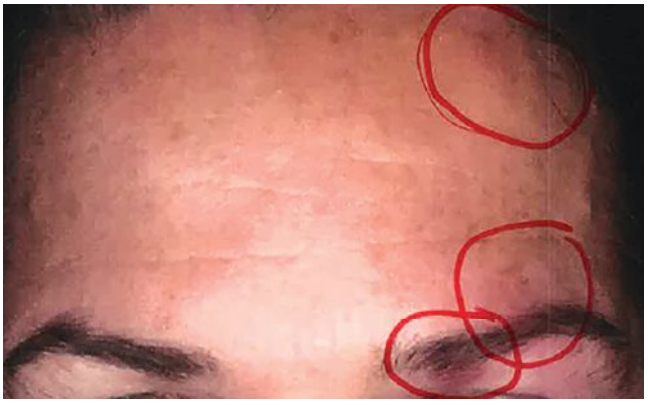


Fig. 1. The patient has acne lesions on both halves of the face but HZO on only the left side, with the circles highlighting rash/blisters. The three red circles were drawn by the neuro-ophthalmologist on the iPhone image taken a day prior to the exam in question.

Later that same day, the patient was evaluated by a different eye clinician in the same group practice. The history on this visit revealed blisters around the left eye two days prior to the last visit when the first eye clinician arrived at a diagnosis of traumatic iritis. This second eye clinician noted vesicular lesions along the brow left eye, diagnosed herpes zoster keratitis and recommended to continue with Pred Forte eye drops QID and the valacyclovir as prescribed by the PCP.

Follow-up was at a major eye hospital a week later. The patient now reported extreme changes in vision OS: "very blurry and double vision." The specialists here confirmed zoster keratitis and glaucoma OS, based upon IOPs of 28mm Hg in that same eye. The patient and her partner relocated to where her sister lived, and a anterior segment specialist took over care. A cataract developed OS, which was surgically removed, and treatment for glaucoma OS continued. Permanent corneal scarring OS resulted in best-corrected VA of 20/50-1 in the left eye with persistence of the "doubling." Along with the visual issues, the patient developed post-herpetic neuralgia (PHN), which continued to be treated by a specialist.

You Be the Judge

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

• Did the patient have subtle vesicles on the first visit

About Drs. Sherman and Bass

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

that were missed because of a rushed exam?

• Did acne lesions on both sides of the face mask the HZO lesions?

• Could the trauma have precipitated the reactivation of the dormant chickenpox virus?

• Did the first eye clinician miss the window of opportunity to treat HZO?

• Is it likely that the patient presented on the first visit with both traumatic iritis and HZO?

Opinions Galore

One of us (JS) was requested to review the case including the iPhone images provided by the patient. A renowned expert in neuro-ophthalmology also reviewed the case for the plaintiff and opined that iPhone images prior to and subsequent to the exam by Dr. X documented three zones of papillomacular rash/blistering on the left side of the face corresponding to the course of the ophthalmic division of the trigeminal nerve (*Figures 1 and 2*).

One expert identified by the plaintiff's attorney was an MD who never practiced medicine but was "an IT professional rendering EMR-related opinions." During his deposition, the man said that "The audit trail shows Dr. X spent seven to eight seconds interacting with the audit trail template, enough time to read the HPI paragraph but not enough time to have typed it." This expert concluded that Dr. X spent seven to eight seconds reading the HPI entered into the EMR by the technician and then closed it, and hence did not add to it or change it. He further testified that there is no evidence that Dr. X documented an *independent history* and that, in that state's Administrative Code, recording of details should be performed by a medical professional. When the technician testified, she admitted she was poorly trained at the time of the exam and was not instructed to ask follow-up questions such as "Is the pain worsening since the trauma?" She also admitted that she confused the eyes and this error was never corrected by the eye clinician.

Three experts for the defense argued that the first iPhone image the day before the exam does not reveal evidence of HZO and that any lesions identified by the neuro-ophthalmologist expert could certainly be common acne. HZO, also known as ophthalmic shingles, is caused by the localized reactivation of the varicella zoster virus in the ophthalmic division of the trigeminal nerve. Previous systemic infection, typically childhood varicella, *i.e.*, chickenpox, results in the virus lying dormant for decades in dorsal root and cranial nerve ganglia. The neuro-ophthalmologist presented literature that trauma can reactivate the dormant virus.

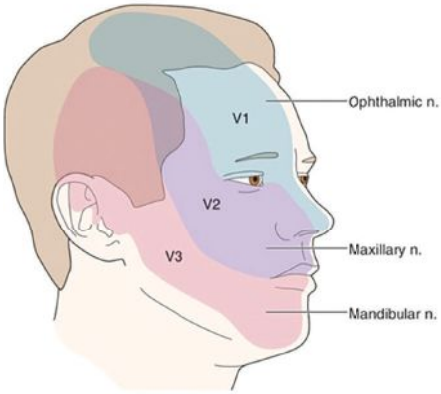


Fig. 2. Mapping of the course of the ophthalmic division of the trigeminal nerve, according to the neuro-ophthalmologist.

Permanent sequelae of HZO may include chronic inflammation, loss of vision and PHN. Antiviral medications such as acyclovir, valacyclovir and famciclovir are the mainstay of therapy and are most effective in preventing ocular involvement and PHN when begun within 72 hours after the onset of the rash.

She Said, She Said

The patient testified that she told the eye clinician that she began to develop blisters two days before the exam. When asked about the time that eye clinician spent with her during the exam, she testified that the exam was very brief and lasted "only a handful of minutes." She also stated "and then I leaned into her and I said I have these weird blisters developing on my eyelid, and then I pointed 'I have a small one on my forehead… she leaned into me and said, 'Yeah, I see that.'" Comments were also made about sensations on her scalp. "I told her… shock-like sensations on my scalp… firecracker sensations" and then she noted, referring to the eye clinician, "she said that sounds like your nerve endings." The patient also stated that she did not obtain the vaccine Shingrix (GlaxoSmithKline).

In contrast, the eye clinician testified that the patient never mentioned the blisters and never mentioned the shock-like sensations on her scalp. Who do you believe? The eye clinician also testified that she obtained an independent history, but it was the same as obtained by the technician and did not add to or change the HPI. This clinician also testified that she had previously diagnosed and treated more than 25 patients with HZO and missing a case would be unlikely.

This case did not settle, and a jury trial was scheduled in the jurisdiction of where the malpractice allegedly occurred. Several days prior to the jury trial, the plaintiff decided to withdraw from the case. Learning that the chances of winning a trial were not favorable and the expenses of both the patient and her significant other to travel to the location of the trial via airplane and hotel accommodations for at least several days, she decided to drop the case.[1] We will never know the verdict of a jury and whether the vaccine Shingrix would have prevented this case of HZO.

PHN can be minimized by timely intervention. The standard of care for HZO is that antiviral therapy should be initiated within 72 hours after the onset of blisters to prevent or minimize injury and long-term sequela from the virus. ■

1. Levin G. What are the odds of winning a medical lawsuit? The Levin Firm. July 18, 2023. www.levininjuryfirm.com/what-are-the-odds-of-winning-a-medical-malpractice-suit. Accessed July 15, 2024.

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

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IT'S THE OCULAR SURFACE-SPARING NASAL SPRAY FOR DRY EYE[1]

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Indication

Tyrvaya® (varenicline solution) nasal spray is indicated for the treatment of the signs and symptoms of dry eye disease.

Important Safety Information

The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation.

Please see Brief Summary of Prescribing Information on the next page and the full Prescribing Information at Tyrvaya-pro.com.

Reference: 1. Tyrvaya. Prescribing Information. Oyster Point Pharma.

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INDICATIONS AND USAGE

TYRVAYA® (varenicline solution) nasal spray is a cholinergic agonist indicated for the treatment of the signs and symptoms of dry eye disease.

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 three clinical trials of dry eye disease conducted with varenicline solution nasal spray, 349 patients received at least 1 dose of TYRVAYA. The majority of patients had 31 days of treatment exposure, with a maximum exposure of 105 days.

The most common adverse reactions reported in 82% of TYRVAYA treated patients was sneezing. Other common adverse reactions that were reported in >5% of patients include cough (16%), throat irritation (13%), and instillation-site (nose) irritation (8%).

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: There are no available data on TYRVAYA use in pregnant women to inform any drug associated risks. In animal reproduction studies, varenicline did not produce malformations at clinically relevant doses.

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

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

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

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

The lack of clinical data during lactation precludes a clear determination of the risk of TYRVAYA to an infant during lactation; however, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TYRVAYA and any potential adverse effects on the breastfed child from TYRVAYA.

Pediatric Use: Safety and efficacy of TYRVAYA in pediatric patients have not been established.

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

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VIATRIS™

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

Is This Actually Amblyopia?

Make sure to exclude any other reasons why a decrease in acuity might occur.

When Marc and I look for topics for this column, we often circle back to questions such as, "With what concepts do our students most often struggle?" or "What topic would be a useful refresher?" Since we're all lifelong students, it makes sense to us that our fellow practicing docs might also be interested in discussions tackling these topics. One topic that has popped up rather often is that of knowing when and how to diagnose amblyopia.

We've all learned that amblyopia is a "diagnosis of exclusion," but what does that really mean? I recently heard a colleague describe it as not only a diagnosis of ***ex***clusion, but also of ***in***clusion (many thanks to Dr. Morgan Ollinger for the phrase!), and I love this way of putting it; not only do we as practitioners need to rule out the bad stuff, but we have to make sure that there is a reason for the reduced function (most often visual acuity) that we see before we call something amblyopia. We offer here a refresher of those findings that are required for the diagnosis to be made.

Amblyogenic Factors

To understand these, it makes sense to remind ourselves of what amblyopia is—and what it isn't. As commonly understood, amblyopia is "an acquired unilateral or bilateral decrease in visual acuity for which no obvious structural or pathologic causes can be detected."[1] There are many other decreases in function due to amblyopia in both the worse- and better-seeing eyes, but these will have to be addressed in another column. Amblyopia is the result of some disruption to the developing visual system during infancy or early childhood and therefore will not be the result of injury or insult later in life. For example, a traumatic cataract at age 35 brought on by a car accident may cause a decrease in acuity, but that decrease is not considered amblyopia. There are several major classifications of amblyopia—organic, psychogenic and functional—with the latter being the category that we will discuss here. To break things down even further, within the classification of functional amblyopia, we have refractive (either anisometropic or isoametropic), strabismic and deprivational subclasses.

The most important thing that we need to do as practitioners when we have a patient with decreased acuity is answer the "why?" question. Why is the acuity reduced? Do we have an obvious reason—for example, some readily visible pathology? Is there uncorrected refractive error? Has the patient ever been able to achieve better acuity in the past? There are numerous other questions that can be asked, and we tend to go through a bit of a mental checklist during our exams that answers many (if not most) of them. We perform chair skills, we refract, we carefully assess ocular health. Once we do these things, we often are able to help the patient achieve good acuity or at least have the answers we need to explain any remaining deficits.

But what about when we don't have an explanation? Are we looking at amblyopia? For each of the above-mentioned categories (strabismic, refractive or deprivational), there are certain findings that we need to see if we are going to diagnose amblyopia. Since I am an organizer, I love having things displayed logically as well as creating lists and tables, so *Table 1* puts the amblyogenic factors all in one place for easy reference. Without one or more of these findings, we can't diagnose amblyopia, so keep digging for answers. Even with a factor or two showing up in your exam data, remember that not every patient will have reduced acuity as a result. All findings should be evaluated within the broader context of the whole patient. Let's look at a few of these cases to illustrate the importance of the amblyogenic factors.

Case 1

This patient is a 15-year-old girl who presented to our clinic with the chief complaint of longstanding blurry vision in both eyes. She reported that she had glasses at some point in the past (she couldn't remember when), but they were lost. As this was her first visit with us, we had no record of any previous prescription. Entering unaided acuities were 20/80 OD and 20/60-1 OS with pinhole acuity of 20/50 in each eye. At near, she achieved 20/32 OD and 20/40 OS. Refraction revealed moderate compound hyperopic astigmatism (+3.50 -1.25x180 OD, +3.25 -1.00x010 OS), which gave a best-corrected

About Drs. Taub and Schnell

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

acuity of 20/50 in each eye. Cycloplegia showed additional hyperopia (+6.50D OD, +5.50D OS), with similar cylinder. Pupils, color vision and confrontation visual fields were all normal, as was ocular health with dilated examination.

Is this amblyopia? We have ruled out obvious retinal or optic nerve pathology and we have an amblyogenic factor in the refractive findings. Given this, we were comfortable prescribing—a trial frame of +3.50 -1.00x180 OD/OS showed 20/25 OU visual acuity—and diagnosing binocular dysfunction, but we held off on calling this bilateral refractive amblyopia for the time being. Why? She needs to adapt to her new prescription and show us that this isn't simply a case of uncorrected refractive error. The patient is scheduled for a two-month follow-up in order to assess her progress.

Photo: Seth Taub

The most common complaint related to amblyopia is blurry vision.

Case 2

A 13-year-old boy came to us with a previous diagnosis of refractive amblyopia. He had been diagnosed with the condition at least two years prior and had been wearing glasses and patching. He had also begun a program of vision therapy with limited improvement so far. Entering visual acuities with his current prescription (+2.50D OD, +1.75D OS) were 20/50-1 OD and 20/20+3 OS. Refraction at the most recent visit showed little change; an updated prescription of +3.00D OD, +2.00D OS was released, with best-corrected acuity of 20/40 OD, 20/20+3 OS. Based on this information, I was skeptical that we really had a case of amblyopia—the difference in hyperopia is technically large enough, but it seemed like too much of an acuity deficit for only a 1.00D difference—so we went digging for more information.

As with the patient in Case 1, pupils, color vision and confrontation visual fields were all normal. Ocular health with dilated exam was also negative for any obvious pathology. Stereo testing was reduced, however, and cover testing showed 10 exophoria at distance and near. Near point of convergence was quite receded, to 11cm/17cm on three attempts. The patient suppressed the right eye on both near base-in and near base-out vergence testing. After all of this, a repeat cover test was performed, since something still didn't add up—a phoria is not amblyogenic. This time, a small but constant right exotropia was found, of approximately eight to 10 prism diopters. Aha, now we had an explanation! While the anisometropia was only barely enough to cause refractive amblyopia OD, the presence of a constant right XT provided the amblyogenic factor that allowed us to diagnose strabismic amblyopia in the right eye. With a shift in therapeutic activities and goals in his vision therapy program, he has started making much better progress.

TABLE 1. AMBLYOGENIC FACTORS[2-4]

Refractive		
Anisometropic		*Isoametropic*
+1.00D	Hyperopia	+3.00D to +5.00D
-2.00D to -3.00D	Myopia	-6.00D to -8.00D
-1.50D	Astigmatism (WTR)	-2.50D
Strabismic		
Some form of strabismus is required: - Esotropia - Exotropia - Hypertropia	- Constant turns are more likely to cause amblyopia than intermittent ones - Unilateral turns are more likely to cause amblyopia than alternating ones	
Deprivational		
Something that blocked the visual axis during early development is required: - Congenital cataract - Congenital ptosis - Congenital/infantile corneal opacity or scar	- Remember, the later an event occurs to block the visual axis, the less likely it is to cause amblyopia	

Case 3

This patient actually just presented to clinic this morning, as I'm finishing this column. This 15-year-old girl complained of longstanding distance blur in both eyes with her current glasses. Her entering acuities were 20/60 OD, 20/40 OS; as with our other two patients, pupils, color vision and confrontation visual field were normal. Upon refraction, we found +3.00 -5.00x010 OD and +3.50 -6.00x170 OS, which was similar to what she was already wearing. A new prescription was given since her old frame was bent and her lenses were badly scratched. Her best-corrected

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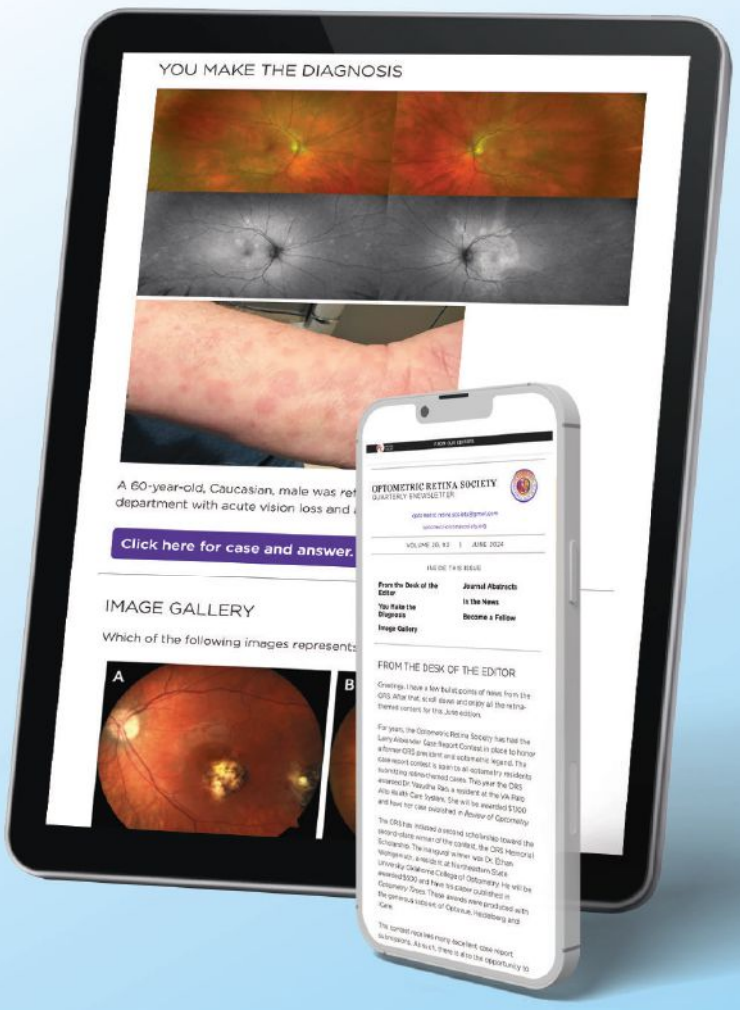

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visual acuity did not change much and her near acuity was also decreased to approximately 20/50, so much of the typical near-point testing was deferred to a follow-up in eight weeks, although ocular alignment was shown to be grossly intact on cover testing with a non-accommodative target. Ocular health with dilation was normal.

So, what do we have in this case? Can we call this amblyopia? Unlike with Case 2, this patient did not come in with a diagnosis in place. She certainly has an amblyogenic factor with such high astigmatism, and the level of reduction in acuity makes sense, except for the fact that she has been wearing a similar prescription for some time. Several questions arise: Has her wear time been consistent with her old prescription? Did she ever truly adapt to it? Is there any pathology that we were unable to find today? (I'm pointing at you, cornea! A topography is warranted with this much astigmatism.)

Given that we still have unanswered questions such as these, we can't be certain at this time that this is truly amblyopia. Remember, we have to ***ex***clude all of the potential pathological findings first, as well as determine whether the patient is in their best refractive correction. For this patient, while we did assess suspected refractive amblyopia OD/OS, we also referred her for a corneal evaluation and set up a follow-up exam. We will re-evaluate her acuity and binocularity at that time, as well as the findings from the corneal evaluation. If she adapts well to her glasses and still has reduced visual acuity—and assuming that her corneas are determined to be otherwise healthy (*e.g.*, free from keratoconus)—we can feel much more comfortable calling this amblyopia.

Takeaways

We've talked a bit about what amblyopia is and have looked at several cases as examples. As I mentioned at the beginning, though, it's vital to remember what amblyopia *isn't*. It is not a catch-all, a diagnosis to be used when you aren't sure what has caused a patient's reduced acuity. Calling unexplained acuity loss "amblyopia" is a recipe for disaster for the patient when that isn't accurate (not to mention a significant potential legal issue for the doctor), so we have to guard ourselves against the fallback of using "amblyopia" and not pursuing the situation further. Make sure you rule out pathology, make sure that you have at least one amblyogenic factor before calling something amblyopia (some patients have several) and make sure you follow up appropriately. Your patients will benefit from your attention to detail. ■

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MY SEVEN SECRETS TO SPECIALTY CONTACT LENS SUCCESS

Learn the principles that will allow you to integrate this modality into your practice.

BY SUSAN GROMACKI, OD, MS
FULTON, MD

Despite the wide range of successful mass market products, many patients continue to need specialty contact lens (CL) care. However, it's not always easy to build a thriving practice. I have started two of them: one in an ophthalmology group and the other in an optometric private practice. There is potential for anyone who enjoys the challenge of specialty contact lenses and who is willing to put in the effort. Here are some tips to help you make it happen.

1. Expertise and Education

Specialty CL patients need and deserve a high level of care. They may have disfigured corneas, endured unwanted surgical complications or suffer from conditions that hitherto could not be ameliorated.[1] Many of these people are hurting emotionally and need our empathy as much as our prowess. Others simply have a tricky prescription that's poorly served by off-the-shelf contact lenses.

Who are the patients that you will be serving? Their diagnoses include: keratoconus, keratoglobus, pellucid marginal degeneration, corneal dystrophies and degenerations, corneal scarring due to prior trauma or infection, post-corneal transplantation, dry eye disease, ocular surface disease, post-refractive surgery (LASIK, PRK, RK), irregular astigmatism, high astigmatism, presbyopia, children with myopia, normal cornea patients unsuccessful with other CL modalities, exposure keratitis, high ametropia, anisometropia and iris anomalies (*e.g.*, aniridia, coloboma) (*Figure 1*).

How you develop this skillset depends on your training. Fortunately, my contact lens education during optometry school was strong, and I bolstered that with additional cornea and contact lens coursework for my Master of Science in Physiological Optics. My research project and master's thesis were on the topic of keratoconus. Then during my residency, I spent one afternoon per week fitting irregular corneas in a specialty contact lens clinic. Others may spend an entire year in an accredited cornea/contact lens residency. Upon completion, they are ready to see any type of CL patient and should be confident enough to fit lenses.

If you did not develop enough advanced experience in these areas during your training, there are plenty of opportunities to do so after graduation.

> **Word-of-mouth can also be a practice-builder. Following the referrals, good working relationships with the referring doctors help sustain the best care for the patient—and lead to future referrals.**

These can include the following:

• ***Use your laboratory.*** This can include both the account representatives and the telephone-based consultants. They can help you with the nuances of fitting their lenses as well as practice management. Many laboratories also sponsor webinars and in-office or group wet labs with hands-on training.

About the author

Dr. Gromacki is a fellow of the American Academy of Optometry and a diplomate in the Cornea, Contact Lens and Refractive Technologies section. She serves as the director of the Contact Lens Service at a subspecialty group practice in Maryland. In the past year, she has received consulting fees from Alcon, Bausch + Lomb SVP, Glaukos, Johnson & Johnson Vision Care and Tarsus, as well as speaking fees from Bausch + Lomb SVP, GPLI, Glaukos, Johnson & Johnson Vision Care, PSS Eyecare and Wink Productions.

• ***Observe a busy specialty contact lens practice.*** I have hosted many colleagues over the years. The practical information learned from observing even a half day of specialty lens fits will be valuable. Seek out someone who sees them all day, every day. Those of us who do this for a living are happy to help.

• ***Invite a specialty CL expert to your practice.*** Sometimes a laboratory can help you set this up. I personally have enjoyed assisting my colleagues with some of their most challenging fits.

• ***Immerse yourself by reading journal and magazine articles***. *Review of Cornea and Contact Lenses* is jam-packed with detailed information five times per year.

• ***Dedicate an entire continuing education conference to attending CL courses***. Many of the larger meetings, *e.g.*, the American Academy of Optometry's (AAO) or Optometry's Meeting, offer several days-worth of CL courses. Other meetings cover all types of specialty lens topics in one conference. While there, take a "hands-on" fitting workshop or an interactive course. If you do this for several years, you will become an expert in the design and fitting of these lenses.

• ***Consult a textbook.*** The comprehensive texts review every type of specialty contact lens, as well as all types of CL fittings.[2-4] However, email newsletters often provide the most current information for the clinician, as they provide links to the latest research, summary articles and new technologies.

• ***For elite competency, pursue a higher certification***. Although these programs may initially seem challenging, peer review/collaboration is the only way to become the best of the best. For overall knowledge (you can always select contact lens cases to write), pursue the Fellowship in the AAO. For just scleral lenses, consider the Fellowship in the Scleral Lens Education Society (SLES). For a comprehensive specialty lens experience, the Diplomate of the AAO Section on Cornea, Contact Lenses and Refractive Technologies offers the best process in the US. What's great about these programs is the ability to meet others—whether candidates like yourself or existing Fellows/Diplomates—who share your passion for specialty contact lenses.

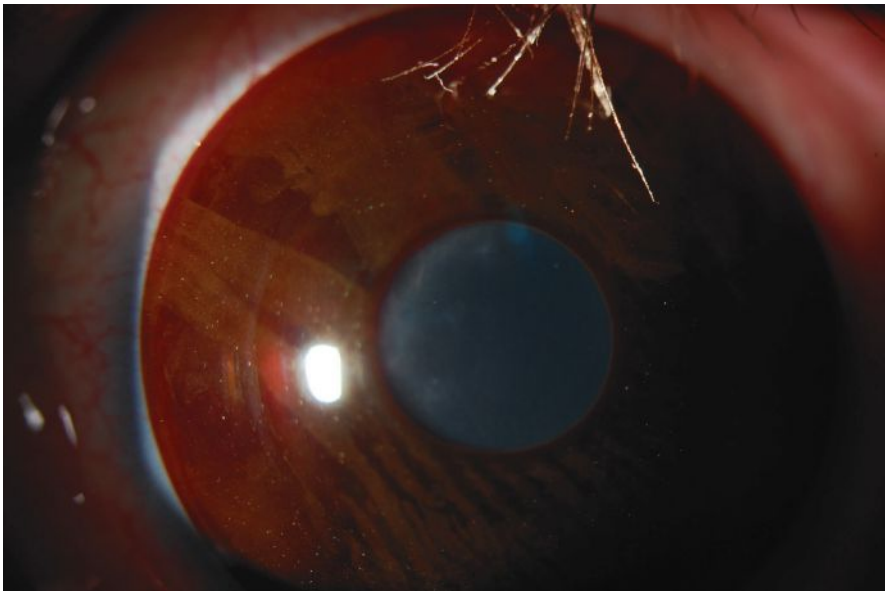

Fig. 1. A soft prosthetic contact lens for aniridia.

2. Good Relationships

If you want to help patients who need specialty lenses, they need to find a way to your chair. Good referral sources include optometrists, cornea specialists, general ophthalmologists, oculoplastic surgeons, neuro-ophthalmologists, oncologists, endocrinologists, rheumatologists, hematologists, otolaryngologists, pediatricians, primary care providers, opticians and the colleagues and patients of your own practice.

To spread the word regarding your offerings, use personal practice visits, letters, emails, phone calls, texts, your website and social media (for example, a local Facebook page). You can also advertise using print media, television and radio. Make sure that your practice appears on the doctor locator page of organizations like the Gas Permeable Lens Institute (GPLI), SLS and National Keratoconus Foundation (NKCF). These groups also provide excellent practitioner and/or patient education. Word-of-mouth can also be a practice-builder. For example, an OD colleague on maternity leave asked me if I would see her specialty CL patients while she was out. Another optometrist friend recently retired and asked if I would take on her keratoconus patients.

Following the referrals, good working relationships with the referring doctors help sustain the best care for the patient—and lead to future referrals. Collegial communication is so important. For example, I frequently exchange text messages with the ophthalmologists with whom I comanage. Once the fitting is complete, I send a summary report to the referring provider, thanking them and providing an update.

Another benefit to joining a group like AAO Diplomate is the built-in network of experts from throughout the country and world. When a colleague's patient moves into my area, they know they will be in good hands with me and vice versa.

3. Diagnostic Lenses

Although we are fitting more and more specialty lenses empirically, their complexities often dictate an initial on-eye fitting. That saves a visit for the patient and chair time for your practice. For a full-scope specialty contact lens practice, at least one type of fitting set is needed in each of these categories:

- Corneal spherical GP
- Corneal keratoconic GP
- Corneal reverse geometry GP
- Scleral GP
- Multifocal corneal GP: aspheric*
- Multifocal corneal GP: translating*
- Multifocal soft: center distance
- Multifocal soft: center near
- Multifocal soft: myopia control
- Orthokeratology GP*
- Keratoconic soft
- Hybrid

**if recommended by your lab*

4. Practice Support

It is important that your practice is fully on board with supporting a specialty CL service. There must be adequate spacing and good employees to help. In addition, the staff need to be sensitive towards the patients' emotional needs. Many of them can't see well with glasses due to their serious ocular condition and require a good deal of patience. If they call to replace a lost or broken contact lens, their request must be addressed immediately.

If you are an associate and want to start this service, communicate your interest and passion in specialty contact lenses to your employer immediately. Of course, this might begin at the interview when you describe your expertise in this area and how it can better serve and add value to the practice.

5. Scheduling Considerations

The practice must understand that these visits are not routine. They take longer, and more attention must be made to their scheduling. For scleral lens dispensing visits, a 30-minute lens settling period must be built into the schedule. In my practice, those patients are given an appointment time 30 minutes prior to when they will see me. I then overlap appointments to ensure maximum efficiency. For the initial patient evaluation, meanwhile, we book 30 to 45 minutes, and tell them that between the testing, fitting and lens settling, they may be in the office for up to two hours. This visit may include:

- Complete history of contact lens wear (prior records with current contact lens parameters are important).
- Thorough history of contact lens care, since sometimes it is poor CL care and compliance, rather than the fit, that led to discomfort.
- Corneal topography/tomography.
- Refraction.
- Pachymetry/specular microscopy.
- External ocular photography.
- Visual acuities and entrance testing.
- Slit lamp examination with sodium fluorescein and lid eversion.
- Measurement of horizontal visible iris diameter (HVID).
- Contact lens trial fitting.
- Comprehensive education/reassurance regarding the patient's condition, including handouts.

Other testing on the first day that may be used includes keratometry, aberrometry, OCT, meibography, axial length measurement (for myopia management) and scleral profilometry.

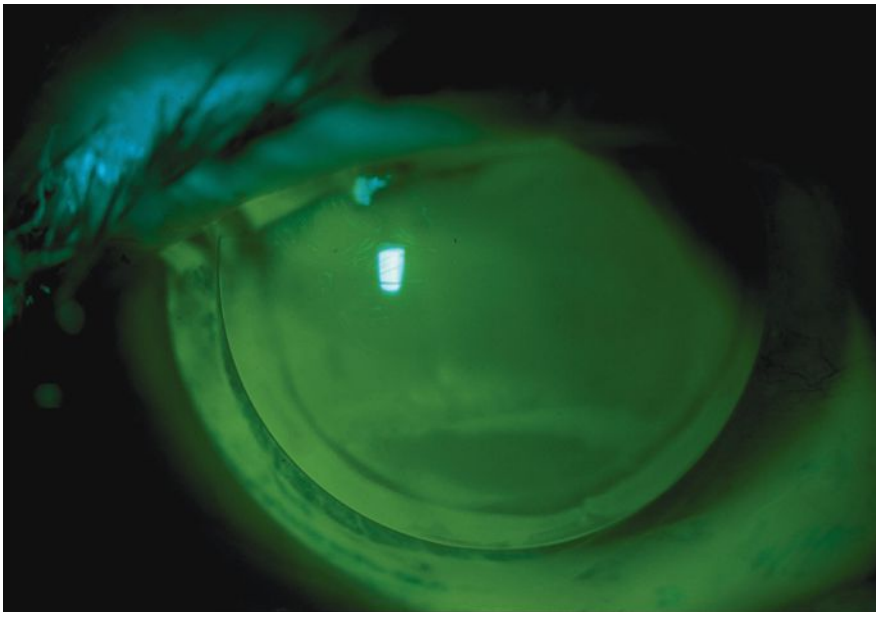

Fig. 2. No specialty CL practice is complete without a concentration in corneal GP contact lenses.

6. Layout/Supplies

Your office should ideally possess a nice, comfortable, clean, well-lit room dedicated to CL training and education. The supplies you will need include:

- A stand-up and a flat mirror, the latter for helping apply scleral lenses.
- GP and soft CL rinsing and soaking solutions.
- Preservative-free solution to fill a scleral lens.
- Large and small contact lens suction cups/DMV insertion/removal tools.
- Handout explaining insertion, removal and care.
- Sodium fluorescein.
- Extra contact lens cases.
- A scleral lens insertion stand.
- A handheld cobalt blue light.
- Chairs for the patient and staff member.
- Gloves and plexiglass shield (post-pandemic).
- GP daily cleaner and hydrogen peroxide for the disinfection of reusable trial lenses.

Many advanced contact lens practices also possess a radiuscope, lensometer, hand magnifier, laboratory-strength contact lens cleaner, and/or a modification unit with polish, suction cups and spinner tools. It's difficult to say when exactly these should be incorporated into your practice, but I think you can't have the best specialty CL practice without them.

7. A Motivated, Empowered Staff

Often, what separates the great practices from the good ones is the staff. When

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Fig. 3. It is important to demonstrate items that facilitate scleral lens insertion; without them, some patients may discontinue lens wear.

interviewing, select them for their empathy and their positive disposition. The skills they need can be trained.[5]

Your staff members are an extension of you. With a positive encounter, the patient's takeaway will be a good impression of the practice and a positive attitude toward contact lenses.[6-8] For example, it is important that you impart to staff your philosophy on CL care and follow-ups so that your patients will receive the message that you want conveyed. During case history, they should ask patients how they clean their lenses "from the time they start until the time they finish;" then compassionately correct them if they're deviating from your instructions. Although patients may be initially embarrassed by their noncompliance, they ultimately appreciate how much we care about their eyes.[6]

A good staff member is vital to successfully completing the contact lens application/removal/education visit (*Figure 3*). It is the patient's first experience applying contact lenses (or a new type of lenses, such as sclerals), and they may be nervous. If it doesn't go well, they are more likely to drop out of contact lenses, even if the vision and fit are excellent. This encounter isn't easy at first, and this is especially true for specialty CL patients, as they may struggle to see. A good technician uses a positive attitude, patience, contact lens knowledge and a good sense of humor to put the patient at ease. A successful dispensing visit lays the foundation for years of healthy contact lens wear.[5] Often, a close bond will form between the technician and patient during the insertion and removal session, which is beneficial to both parties—and to the practice. Analogous to a dental hygienist in a dentist's office, your technician may spend more time with your patients than you do.

At my practice, insertion and removal typically are not done on the first day, but rather when the patient comes back to pick up their lens. Remember they have been there for up to two hours and are exhausted after that first day. Also, some patients elect not to order the CL at all on the first day after we have completed the testing. So, performing insertion and removal on that day is not prudent.

Train at least one staff member to understand the medical and vision insurance plans that you accept. It is beneficial to verify benefits prior to the first visit and then obtain pre-authorization for potential coverage of medically necessary contact lenses. This is especially important for vision plans, where materials are more likely to be completely or partially covered. In my practice, I initially provided my specialty contact lens coordinator videos, articles, courses and webinars. The information may be overwhelming at first, but a well-trained and capable staff member will master it. The ultimate goal is for them to be more familiar with coding and billing than the doctor. The practice will reap the benefits.

Specialty contact lens designs include parameters that spherical lenses do not have. And what's more, the terminology for these numbers may differ from lab to lab. A staff member must understand the technical terms and abbreviations well enough to order the lenses accurately, because every parameter matters with these lenses.

A large practice may have four separate individuals performing these important functions; in a small practice, it may be the same person, with help from the doctor. Regardless of how many staff members are involved, their attention to detail is vital to the success of any specialty contact lens practice.

Once they gain some experience, involve them. Ask them for their input. Some of their ideas may impress you. Then reward them for their contributions. I recently nominated my technicians for a national award (2023 Contact Lens Institute; www.contactlensinstitute.org/resources/awards), which they received. We hosted an in-office reception for them, inviting family, friends and referring doctors.

Worth the Effort

The rewards of fitting specialty contact lenses go beyond financial. These patients continue to challenge and inspire me. It is gratifying to restore sight, correct vision, enhance comfort, improve appearance and prevent myopia progression. These lenses have brought immense satisfaction not only to my patients but also to their doctor. ■

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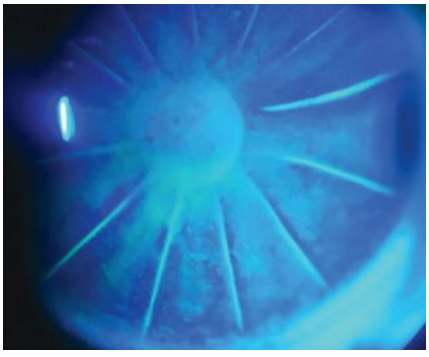
MAKE SPECIALTY LENSES THRIVE IN YOUR PRACTICE

It's more than just a matter of obtaining the lenses. Here's a look at the tools and talents you'll need.

BY KEVIN CHAN, OD, MS, AND STEVEN SORKIN, OD
VIENNA, VA; FAIRFIELD, NJ

When considering new services to incorporate into an optometric practice, specialty contact lenses (CLs) have certainly been one of the most implemented, as this niche matches our refractive skillsets very well. For many practitioners, adding specialty CL services can create a new focal point, making their practice stand out with a new category of patients whose vision was otherwise considered "just the way it is." By providing custom lens fits to these patients, it can indeed widen the potential of what specialty lenses can offer—not simply for vision, but also to enhance quality of life.

As with many specialty fields, the implementation of custom CLs does not take off on its own organically; rather, it requires strategic planning fueled with passion and commitment in advocating these services to patients. Here are several key aspects for which you can build a specialty lens service and make it thrive in your practice.



Slit lamp image of a patient status post radial keratotomy.

Know Where the Heart Belongs

To get started with specialty CLs, you first need to feel passionate about it. Read as much as you can from journals and periodicals to get familiar with the technology and products. Attend conferences such as Global Specialty Lens Symposium, International Congress of Scleral Contact Lenses, Optometry's Meeting, American Academy of Optometry, Vision by Design (by the American Academy of Orthokeratology and Myopia Control) as well as the International Keratoconus Academy. State and local optometric societies also provide valuable in-person education. Participating in hands-on workshops can be incredibly helpful in meeting with the various contact lens and equipment companies, along with the ability to network with colleagues and find a mentor or two to assist you in this journey.

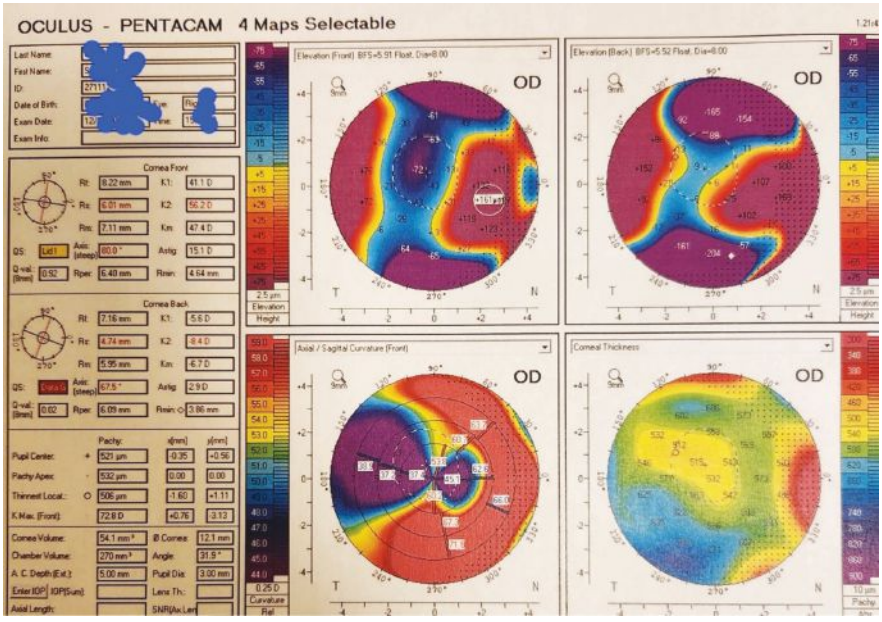
You will find that those of us in the specialty CL community are very welcoming and resourceful in helping beginning practitioners succeed. Residents or practitioners can also ask to visit some practices and shadow a more experienced colleague to observe

About the authors

Dr. Chan is the senior clinical director of Treehouse Eyes. He was the recipient of the Global Specialty Lens Symposium 2024 Rising Star Award in recognition of his leading role in cornea and contact lenses and was also named a Healio honoree in 2023. He lectures nationally and internationally about contact lenses and myopia management and presented the TEDx talk, 'Myopia–Global Epidemic.' He is a Fellow of the American Academy of Optometry and earned the International Academy Certification in Myopia Management. He serves as a Professional Affairs Consultant for Johnson & Johnson Vision and Essilor's Myopia Taskforce. Financial disclosures include Euclid Vision Corporation, Topcon Healthcare, PECAA and Conexiant. **Dr. Sorkin** is director of specialty contact lens services at Corneal Associates of New Jersey. He lectures nationally and internationally on contact lenses, ocular therapeutics and corneal disease. He serves as president of the Essex County Optometric Society and serves as a member of the board of directors of the New Jersey Society of Optometric Physicians (NJSOP), also serving as a member of the medical advisory board of the International Keratoconus Academy (IKA). He is a Fellow of the Scleral Lens Education Society (SLES) and is adjunct clinical faculty at Salus University and the New England College of Optometry. He was named New Jersey Optometrist of the Year in 2018 by NJSOP. Financial disclosures include Avellino, Bausch + Lomb SVP, BostonSight, Dompé, the IKA, Santen, the SLES and Tarsus.

their exam flow, see some patients and engage in a wet-lab setting. This happens quite frequently in our offices.

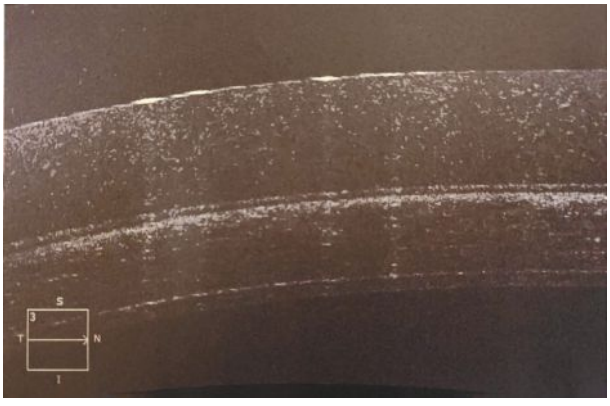
Online education has certainly flourished over the past few years. Organizations such as the Scleral Lens Education Society and the Gas Permeable Lens Institute have an abundance of online resources and provide monthly online webinars to expand your knowledge. These organizations also have in-person events and workshops to further your clinical acumen and experience. Many online CE providers also provide virtual courses such as Woo University, Eyes on Eyecare and CE Wire throughout the year, both on contact lenses and cornea/anterior segment conditions.



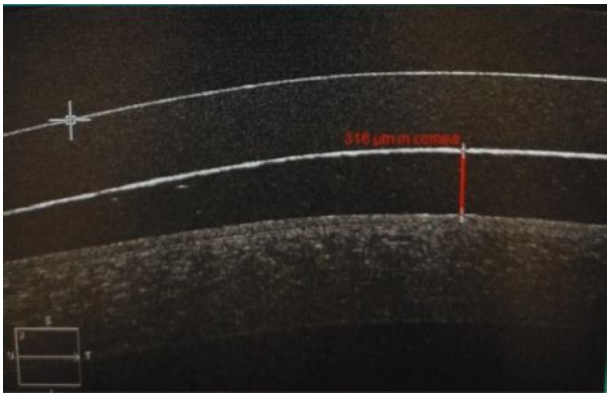
Topography image of a patient with severe irregular astigmatism post-PK.

Know Your Audience

Familiarity with your patient base and how to cater specialty lens services to different patient demographics is key. Simply talking about specialty lenses without the context of why for patients is like selling a Cadillac to a teenager without a driver's license. Be sure to impart to your patients that the virtues of specialty contact lenses go beyond just the core aspect of vision correction—what makes specialty lenses "special" is their therapeutic potential for patients of all ages.



Anterior segment OCT of a specialty soft keratoconus contact lens on the eye demonstrating the thickness of the lens.



OCT image of a scleral lens evaluating lens vault over the cornea.

For children, orthokeratology (ortho-K) is one of the most effective yet underrated rigid gas permeable (GP) lens modalities in the specialty lens toolbox.[1] By using a reverse geometric design, ortho-K lenses can uniquely reshape the corneal contour for patients while sleeping. With the prevalence of childhood myopia accelerating, most ortho-K lenses have been specifically designed for myopia management, and this is the type most young patients are prescribed.[2] In comparison with conventional spectacles and single vision contact lenses, what makes ortho-K a unique experience for children and their parents is that an ortho-K lens isn't just a vision correction device—it can help them achieve independence in many daily activities or functions. Moreover, it can unlock possibilities they could hardly imagine with their current vision correction.

To achieve optimal distance clarity for patients with myopia, the central cornea is flattened based on the patient's refractive error along with a compression factor (typically +0.50D by default) to allow clear and lasting unaided vision during daytime hours. Fascinatingly, robust clinical data shows that optic zone sizes and higher-order aberrations (HOAs) play emerging roles in slowing axial length progression in children.[3-6] When optic zone was reduced, some studies showed that it positively correlated with the mid-peripheral steepening effect on the cornea, thereby yielding a greater amount of relative peripheral refraction generated. Nevertheless, it is important to note that this outcome is not universal, as large pupil size has been shown to increase the exposure

of peripheral defocus signals as well, thereby halting greater axial length elongation.

The ortho-K outcome can also be subject to change based on patient's age, level of myopia and other behavioral factors. HOAs, notably spherical aberration, have demonstrated clinically significant benefits in slowing axial length progression.[5] While the exact mechanism is yet inconclusive, some theories suggest that HOAs are closely associated with peripheral defocus, which can directly impact the retinal image quality. Interestingly, the human retina appears to respond to and interpret retinal blur as a positive "go" signal that can help reduce axial length growth.

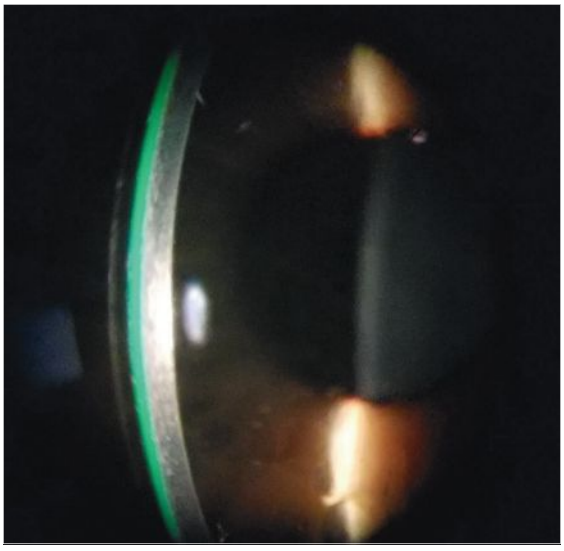
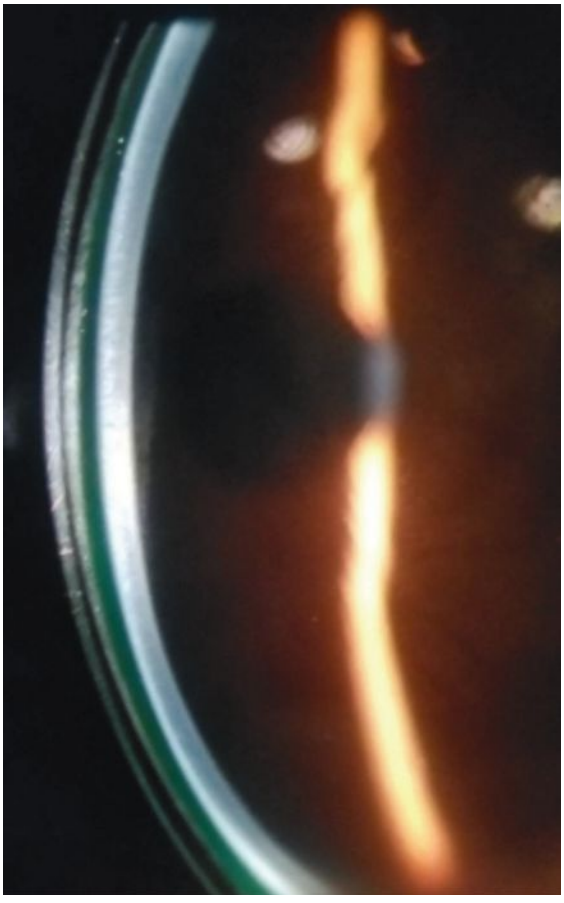


Image of a scleral lens on a post corneal transplant eye.



Demonstration of scleral lens vault using fluorescein dye.

However, the use of ortho-K lenses is not limited to children or adults with myopia. Patients with astigmatism, hyperopia or those reaching presbyopic age who are in need of reading glasses may also be eligible for ortho-K lens wear for full distance correction or modified monovision. With the versatility of corneal remolding techniques by ortho-K, we fully believe and live by the 'no-one-size-fits-all' principle. By that nature, it truly encompasses the ability to indeed alter corneal shapes the way intended and, therefore, help patients achieve their desired vision for their lifestyles.

As an example, an eight-year-old child with progressive myopia would benefit from an ortho-K lens design with a distinct and uniform mid-peripheral steepening effect (also known as the bull's-eye red ring) combined with a relatively small back optic zone size; this design will yield a greater level of myopic defocus signals and HOAs. To illustrate ortho-K's versatility, consider also a 50-year-old patient who has been emmetropic all her life and is now emerging as a presbyope. She started experiencing reading difficulties at work as an accountant while also suffering from chronic dry eye symptoms and wanted to be more independent of glasses or contact lenses. Use of a hyperopic ortho-K lens design (*i.e.,* central steepening and mid-peripheral flattening) with a modified monovision approach could help fulfill her unique vision needs. Offering this approach in turn will build loyalty.

In our collective clinical experience, success and patient loyalty are not built solely by following monetary incentives. Rather, it is the journey of the specialty lens experience you provide that makes an overwhelmingly positive or even a life-changing outcome for patients that will foster trust and support. Doing well with specialty CLs isn't simply about the science of the lenses; listening to your patients' visual needs and helping them achieve their treatment goals is the art of mastering specialty lenses for all patients.

Knowledge and Relationship with Lab Manufacturers

Many laboratories provide in-office wet labs and consultation. During the early phase of the learning process, lab consultants are great assets in guiding practitioners to navigate the roadmap of lens design and offer troubleshooting advice. Make sure your laboratory has a robust return policy, as you will need to make more lens changes at the beginning. Choose lens designs that allow the ability to customize lens parameters. Also be aware of added charges for lens customization, lens exchange fees as well as shipping costs when deciding on contact lens laboratories that you would like to partner with. Labs are also useful in providing patient education material.

The process of becoming an astute clinician with specialty lenses takes time and effort to feel comfortable in diagnosing and managing anterior segment complications that frequently occur when taking care of complex eyes. Keratoconus is the most

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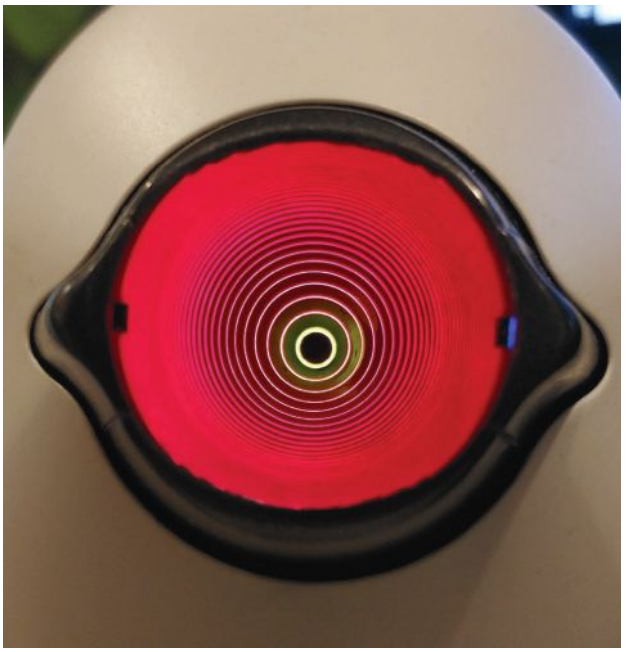


Placido disc corneal topography seen from a patient's bird eye view. Placido disc evaluation is valuable in assessing the corneal contour and the quality of ocular surface. It can guide the selection of specialty CL design.

prominent corneal disease requiring specialty contact lenses, but other conditions such as corneal dystrophies, corneal scarring, corneal transplants, irregular astigmatism and ocular surface disease also are a major part of specialty lens practice, so choosing your partnered laboratory should work for what kind of patients you will see.

Lens Types

A specialty CL-driven practice also needs to offer multiple contact lens modalities. Scleral lenses are rightfully positioned as the primary option for most patients, but other options, including custom soft lenses, corneal GP lenses and hybrid lenses, are integral parts of a complete specialty CL practice. A subset of a specialty lens practice is prosthetic lenses for disfigured eyes and for functional needs. You should consider the patient's needs, clinical findings, previous contact lens experience, eye anatomy, dexterity and finances to prescribe the appropriate lens modality and provide the best care for your patients.

When considering scleral lenses for patients with presbyopia, practitioners can sometimes be too focused on making a perfect fit, owing to the weight carried by the term 'specialty contact lens.' While it is certainly a vital factor to achieve successful clinical outcomes, it is also key to keeping patients informed and discussing with them what they want to achieve in daily life. They should also be cognizant of other possible scenarios for which patients' expectations may warrant adjustment or alignment. For example, what is the patient's occupation—are they a truck driver or computer engineer? What priority in life does the patient have? Does the patient mind compromising a bit of clarity at distance in exchange for more independence from reading glasses? All these questions merit further consideration when it comes to prescribing scleral lenses for patients with presbyopia.

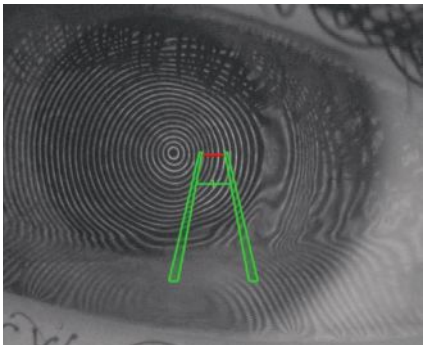
Hybrid lenses can be used in patients with very discerning vision requirements as they provide crisp vision and comfort with the GP center and soft skirt combination. They are available as single vision, extended depth-of-focus and multifocal optics along with a version geared for the irregular cornea. Most hybrid lenses exist as six-month replacements. When used effectively, these lenses can distinguish you from other providers, as they are only available from doctor's offices.

Cosmetic lenses are commonly perceived as multicolor lenses for appeal. However, cosmetic colored lenses have been documented in use for occlusion therapy to ameliorate migraine, photophobia—particularly for patients with iris atrophy or ocular albinism—diplopia as well as amblyopia.[7]

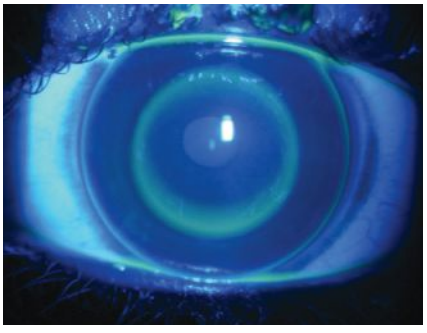
Get to Know Your Gadgets

Corneal topography and tomography have increasingly become indispensable tools with which to excel in specialty lens care. As easy as it seems to use these technologies, though, they are not necessarily recognized for their versatile functionality. We'll break it down and explore the nuances of how to maximize the utility of these devices.

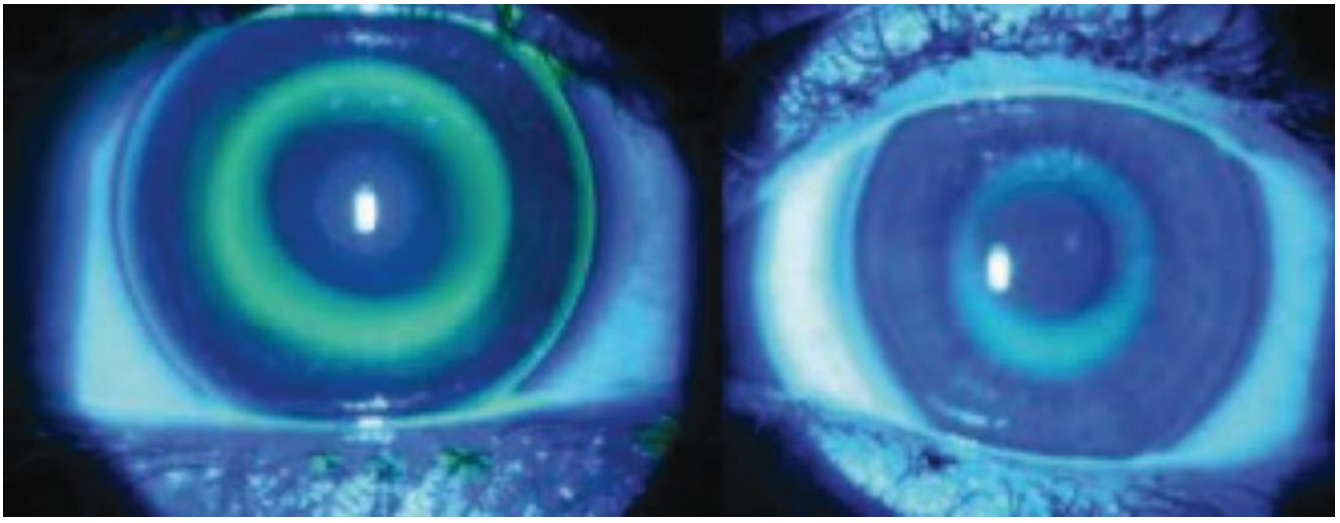
First, you need to invest in your practice. A slit lamp biomicroscope and fluorescein dye are all that is technically required to evaluate a contact lens; however, to provide the most up-to-date care, upgrading to an anterior segment OCT (AS-OCT) will allow for more precise on-eye lens analysis. We find AS-OCT helpful when troubleshooting and would recommend it for those new to specialty



Decentration and distortion of mires in a corneal topography *in vivo*. Angle kappa should be considered. Guiding patients to blink and turning their heads contralateral to the eye measured helps address the issue.



Optimal NaFl distribution for an orthokeratology lens fit in a young adult. Relatively larger back optic zone diameter can be considered to optimize the clarity of distance vision.



Comparison of the back optic zone diameter (BOZD) between 6.0mm and 4.8mm. Selection of a relatively smaller BOZD for children has shown to augment the amount of peripheral defocus signaling, which is believed to help slow axial length progression.

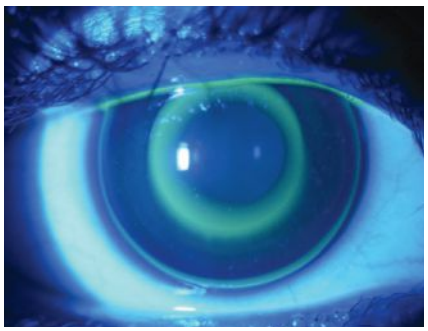
lens care, as it reinforces what you are seeing with the slit lamp. Having slit lamp imaging from a phone or camera adapter and AS-OCT images to transmit to laboratories can be very helpful when needing to make changes to lens parameters, following anterior segment conditions and for patient education.

Topography, and preferably tomography, is important in diagnosing and managing corneal conditions. These technologies also give you valuable insight into the shape and corneal contour to assist you in designing your contact lenses, such as prolate vs. oblate shape, horizontal visible iris diameter (HVID) and corneal eccentricity. Specular microscopy instruments are important in diagnosing and following patients with endothelial disease and corneal transplants. Evaluating endothelial cell counts and viability of endothelial cells can help you determine the most appropriate CL modality or whether to refer for corneal endothelial surgical interventions, such as posterior lamellar surgery, that can address both Descemet's membrane and endothelial deficit when indicated.

Corneoscleral imaging devices, collectively known as scleral profilometers, are great tools to possess and have become a vital part of specialty lens practice. It benefits clinicians to better understand scleral shape, which aids in designing specific types of specialty CLs, such as scleral and ortho-K lenses. In addition, aberrometry is emerging as yet another technological advancement to incorporate HOA correction in our lenses for those patients that require higher quality vision not possible with standard scleral lens optics.

Corneal Topography

Capturing good corneal topographic images gets you halfway to successful outcomes. Essentially, it is just like building a solid foundation when making a cake. While any topography can provide practitioners a general overview of the corneal contour, it is fundamentally crucial to minimize visual interferences by the lid apertures.



Optimal NaFl distribution for an ortho-K lens fit in a child. Note that the mid-peripheral ring with NaFl pooling is designed to be more coincided with the pupillary margin to optimize the projected mid-peripheral defocus signal compared to the fit for young adults.

Gently holding patient's upper and lower lids manually without pressing against the conjunctiva or soft orbital tissues during the capture of topographical images can accurately yield full exposure of the limbal-to-limbal aperture to help determine the lens diameter for any type of specialty lenses. In general, ortho-K lens diameter is approximately 0.5mm to 0.8mm smaller than the HVID. The average diameter ranges from 10.6mm to 11.0mm in most cases. At times, though, it can be customized as a trans-limbal design with a diameter beyond the limbus (greater than 11.5mm) for atypical corneal toricity or induced astigmatism to optimize lens stability and comfort.[8]

The use of corneal topography extends beyond the realm of GP and ortho-K lenses. When fitting multifocal or custom soft lenses, it has been customary for practitioners to have patients wear a trial pair and evaluate the overall fit in the slit lamp. While it is an essential step to assess lens movement, lens-lid interaction and fluid exchange underneath the lenses, what we can do to take this assessment a step further is to evaluate multifocal or custom soft lenses via corneal topographical imaging *in vivo*. After a trial lens is placed onto the patient's eyes, wait for a minute and capture serial corneal topographical images. It can provide

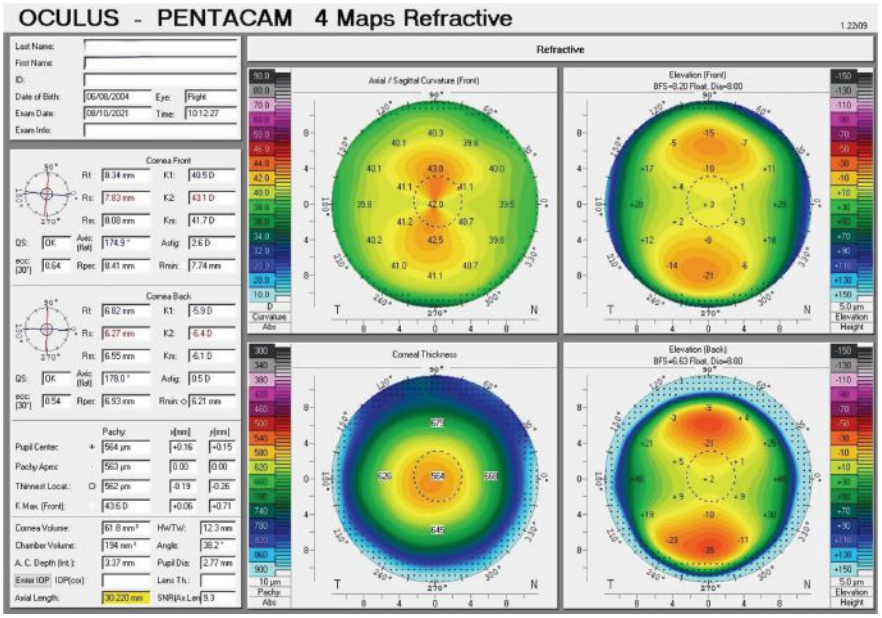
you four key pieces of information: distribution of multifocality, centration of multifocality in reference to the visual axis, neutralization of toricity and power distribution vs. baseline via comparison maps. All this information (though not exclusive to those mentioned) can be tremendously helpful in guiding whether a revision should be made and how it should be made.

Moreover, it can help guide when to fit patients with decentered pupils for a custom decentered optical multifocal design, as compared with commercially available multifocal soft lenses.

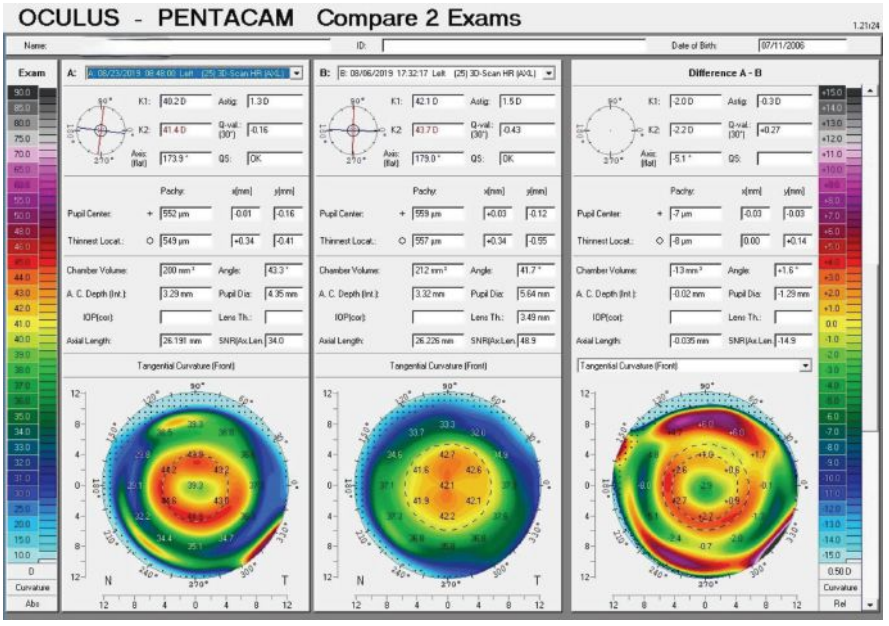
OCT

The use of OCT has become increasingly more prevalent in the realm of scleral lens fitting and troubleshooting. Thorough knowledge of how the central and peripheral cornea changes in response to keratoconus and its progression can be useful in understanding how limbal clearance on the sclera should be accommodated in a scleral troubleshooting regimen.[9]

The advent of OCT can also be applied to measure the sagittal depth of the eye, which can help guide practitioners to determine patient candidacy for a commercially available soft CL or custom soft lens. While seemingly unconventional, studies found that soft lenses behave and interact with the eyes differently despite having the same base curves and in conditions with various temperatures.[10,11] The differences in sagittal depth values among various spherical and toric lens designs help practitioners recognize how to account for each lens design based on its unique characteristics and make adjustments accordingly.



An overview of a four-map comparison depicting keratometry, pachymetry, anterior and posterior elevation.



An overview of a two-map tangential comparison between the baseline and the treatment phase, showing the overall centration effect and axial length status.

Office Logistics and Billing

In addition to technological and scientific considerations, staff too plays a vital role in the success of a specialty CL practice. Staff should be kept up-to-date on lens technology, testing and care. They need to be thorough in lens ordering, lens processing, schedule logistics as well as lens exchanges and to reconcile invoices and monthly statements. Being comfortable with lens application and removal training and lens care products is paramount. They are not simply your technicians; they should possess personalities amenable to engaging with patients who may warrant advanced assessments, follow-up visits and guidance for lens care regimens. We give our patients samples of all products and provide them with a handout about lens care and where to purchase additional lens care solutions. A laminated card with application and removal instructions is also given at the contact lens dispense visit. Lens care is reinforced at every CL progress visit.

Make sure that your front desk support staff also stay abreast on the nuances of specialty CL services you provide in your office. Your staff should

This child is having a corneal topography scan performed at an interim follow-up visit.

Another child was seen having a corneal tomography to reveal the anterior and posterior corneal status upon fitting with ortho-K lenses.

be confident and able to answer basic questions about specialty lenses and the services offered. Update your website to highlight these services so patients are aware and come prepared with questions prior to consultation.

At times, specialty lenses can be tricky and challenging with billing and coding. Rules and regulations frequently change, so keep up-to-date on individual medical and vision care plans if you participate with them. Read your provider manuals very carefully as well as the agreement documents that you have signed.

It is essential to be transparent with patients regarding billing and payment policies. Also be comfortable with medical billing and coding, as this is critical to avoid trouble down the line and to, of course, maximize payment. Document everything in writing and provide patients with a signed copy prior to commencing the lens fitting process. Spell out all of your policies including returns, cancelation of the fitting process or switching lens modalities. Be cognizant of the warranty period and make the patient aware of this as well.

Referral Network

One of the main sources of patients to specialty CL practices are referrals from ophthalmology, optometry and other medical specialties; most eyecare practitioners do not provide specialty lens services in their practice. It is important to offer many different modalities and options to patients. Corneal GP lenses particularly are becoming less and less a part of most optometry practices. Corneal GP lenses uniquely provide many advantages compared with other CL types, including vision benefits, ease of insertion and removal, less costly lens care, typically lower cost to both provider and patient and excellent corneal physiology.

In our respective practices, we often arrange lunch-and-learn seminars and share about specialty CL services with other medical professionals. It creates great networking opportunities with people in other multidisciplinary settings and build the referral network. With the strong referral network, it helps distinguish us in our geographic regions and beyond to provide these services.

Takeaways

One of the greatest merits provided by specialty contact lenses is that they truly impact patients' lives. To provide the best care for your patients, it requires a combination of knowledge, learning aptitude and dedication on your part. You do need to have a passion for specialty CLs to thrive. While they are seemingly categorized as simply "contact lenses," they are also key, life-changing investments for which you have to be willing and motivated to dive into should you aim to make it impactful for patients while profitable for your practice. For that, practitioners should stay familiar with lens costs and chair costs. If you are losing the ROI doing specialty lenses, you will lose interest and footing very quickly. If you stay on top of it, treating these patients can be both humbling and rewarding with great returns. ■

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AN OVERVIEW OF OPTICS IN SOFT CONTACT LENSES

Understanding how various designs affect vision will help you match patients with the best-suited option for their needs.

BY NICHOLAS GIDOSH, OD
PHILADELPHIA

Soft contact lenses have certainly come a long way from the original HEMA materials of the 1950s based on Lim and Wichterle's work.[1] One of the biggest transformations we have seen is the variety of options now available in the optics of these lenses. Patients were once told they couldn't wear contacts because of astigmatism and presbyopes were advised to rely on reading glasses. Today, soft lenses come in various add powers of center-distance and center-near designs, correct up to 6.00D of cylinder, use prism-ballasting methods and are even being recommended for pediatric myopia management.

Contact lenses are a cornerstone of many eyecare practices. Therefore, it is essential that patients' needs are met with the lenses we prescribe to improve satisfaction and reduce risk of dropout. A major focus for patient lens satisfaction is comfort, influenced by issues with ocular surface dryness and the effect of contact lens wear on the tear film. Many new soft lens options feature improved wetting agents and lens surface treatments to satisfy this need.[2]

However, some patients are more likely to be dissatisfied with their vision in contact lenses than others; these can include presbyopes, patients with high or uncommon prescriptions and individuals with astigmatism. A good starting manifest refraction is an essential first step to ensure the best visual outcome in contact lenses. Vertex distance should also be considered, especially in cases of higher refractive errors. After an initial lens is selected and applied to the eye, the next essential part of lens evaluation is checking for centration.

Some patients, particularly those with large pupils, can experience symptoms of glare and ghosting in lower levels of light. Soft lens designs usually have around a 9mm optic zone, but if the lens decenters, this can affect visual quality even in single vision designs. Centration can be improved by adjusting the sagittal depth of the lens as a

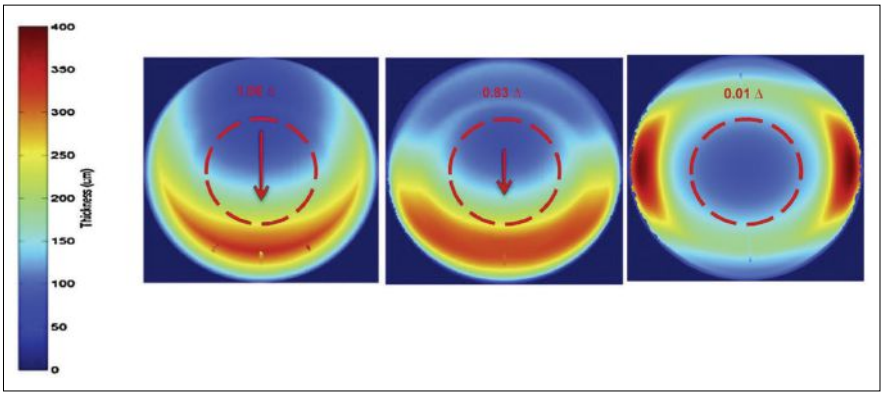

Photo: Sulley A, et al

Fig. 1. Thickening of lens zones in three various types of toric stabilization: prism-ballast (left), peri-ballast (center), thin zone (right).[7]

About the author

Dr. Gidosh is an associate professor at Pennsylvania College of Optometry (PCO). He serves as chief of the Cornea and Contact Lens Service at The Eye Institute and has presented lectures and workshops in PCO's Advanced Studies Program and International Program on topics including scleral and hybrid lenses, irregular corneas and contact lens fitting. He is a fellow of the American Academy of Optometry and has served as a clinical investigator for studies involving hybrid, scleral, multifocal and orthokeratology lenses, presenting lectures and posters at national and international conferences on these topics.

function of both base curve and diameter. One study has measured sagittal depth of various soft daily and monthly lenses, and these variables can be adjusted to improve fit and centration.[3]

Parameters are far more modifiable when entering the realm of custom lenses; in general, these are unique in that there is a wide range of powers, diameters and base curves available. These are chosen based on the material, keratometric values and horizontal visible iris diameter. This is particularly useful if the patient has a large corneal diameter. The optic zones can also be customized between 6mm and 12mm. Examples include but are not limited to Intelliwave (Art Optical), Revive (Bausch + Lomb), NaturaSoft (Advanced Vision Technologies), MetroSoft (Metro Optics) and SpecialEyes.[4]

A newer concept in soft lens optics, represented by products like MyDay and Biofinity Energys (CooperVision), is to help patients struggling with digital eye fatigue. One report found seven out of 10 patients have experienced symptoms of digital eye strain and about four out of 10 patients experience these symptoms multiple times a week. This may be a result of 79% of these patients spending over three hours per day on their smartphones. There are now single vision soft lenses using a +0.30D add, which is designed to help with eye strain.[5] A report found eight out of 10 patients felt an improvement in eye tiredness with these lenses with nine out of 10 reporting clear vision.[6]

In the remainder of this article, let's review the optics of modern toric and multifocal soft contact lenses and how each may affect visual performance and comfort of wear.

Toric Lenses

There are now more soft lens designs than ever for the astigmatic patient, with daily disposable lens cylinder ranges up to 2.75D correction and monthly lens ranges up to 5.75D. Modern toric designs stabilize the lens on-eye through the options of prism-ballast, peri-ballast and thin zone designs (also referred to as double slab-off or dynamic stabilization). Peri-ballast designs such as the Biofinity Toric (CooperVision) and prism-ballast designs like Air Optix for Astigmatism (Alcon), both used in studies, are similar in that they both thin the superior portion of the lens to create a stabilization effect. The thin-zone design uses the thickness of the contact lens and four thinned zones of stability to create minimal thickness under the lids.

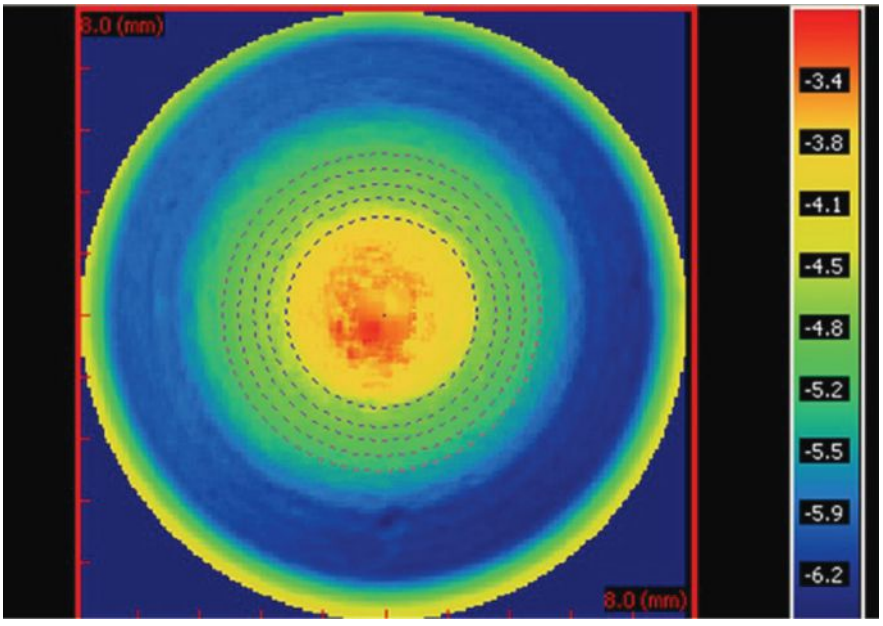

Fig. 2. A center-near soft multifocal lens with the power map measured by the NIMO TR1504.[11]

One study found a difference in the vertical prism measured in the optic zone of toric lenses with different stabilization methods. *Figure 1* shows the three different designs with a map of the lens thickness in different zones. The prism-ballast technique on the left creates a denser thin zone superior with a thin zone of prism that extends from the inferior quadrant up along the lateral aspects of the lens. The study found these designs typically have the most vertical prism within the optic zone. The middle map is of the peri-ballast design. Here, the superior thinned zone is more spread out along the top half of the lens, while a thick area is condensed to the bottom. These designs had a moderate amount of optical prism with a mean value between 0.75 and 0.77 prism diopters between the two designs in the study. The final option on the right of *Figure 1*—the thin-zone design—showed little to no measurable prism within the optic zone with a mean value of 0.01 prism diopters.[7]

This optical prism data could be clinically impactful, especially when fitting toric lenses monocularly. Fitting a ballasted design in one eye could create vertical imbalance for a patient; studies have found that over 0.5 prism diopters of vertical disparity could cause symptoms of eye strain, visual discomfort, decreased stereopsis and even nausea and motion sickness in some patients.[8-10] Labs that manufacture custom soft torics can also allow for customization in the amount of prism in the lens. Increasing this parameter can provide better stability of the cylinder correction.

Multifocals

Presbyopic patients have a plethora of soft lens options in daily, biweekly and monthly replacement modalities. Most use aspheric, center-near optics due to pupil constriction at near to deliver improved visual acuity up close. Fit guides vary across companies and designs, given the variance between multifocal lenses in add power, zone size and the

rate at which this power changes across the zone. This has been demonstrated through instrumentation that can measure the power across the optic zone of different contact lenses. One such device, the NIMO TR1504 (Lambda-X), has demonstrated these design differences across multiple studies.

Figure 2 shows a center-near aspheric multifocal soft lens and where the near addition power is concentrated. In this figure, the outer blue zone represents the distance power, around -6.00D. There is then a progressive blending inward to generate the +2.50D add, the red color measuring -3.50D in the central zone. Here, it can be appreciated that the full add is reached across only about 2mm of the lens center. This is a fairly typical near-zone size across many multifocal designs.[11]

These power profiles can also be viewed graphically to show the measured power at different positions across the lens. The chord is a bisection of the center of the lens where the left side of the plot at 0mm is the geometric center of the lens. The graphs measure 4mm from the center to show the changing power across the multifocal's profile.

Figure 3 shows the contrast between a concentric design and a center-near aspheric. The top graph shows greater fluctuation of power where the central zone is the distance power of -6.00D. Repeated measurements show the change of the power, consistently reaching up to -3.50D because of the +2.50D addition to then change back to the distance power as it changes between the rings until reaching the edge of the optic zone. The bottom graph shows the add power is reached in the center of the lens, starting at -3.50D, which then smoothly blends out to 2.5mm to 3.0mm, where the lens achieves a distance power of -6.00D.

Studies like this underscore the importance of zone size and show how multifocal optics are some of the most susceptible to lens decentration. Due to the power changing across different zones, a lens that is not centered over the visual axis will have issues providing the desired visual outcome.[11]

Power profiles such as those in *Figure 3* can show how large distance or near zones are and the transition between them. This information is useful when accounting for the patient's pupil size, visual demands and illumination of their typical environment. A patient with smaller pupils may have more difficulty at distance if the multifocal design has a large center-near addition zone. This optic may also be problematic for a patient more concerned about their distance vision, such as a truck driver. Conversely, a multifocal with a smaller center-near zone may make it more difficult for patients to see up close if they have particularly large pupils or critical near-vision demands, such as reading medicine bottles in a pharmacy.[12]

Due to the complexity of multifocal optics and each patient's unique visual demands, these designs can sometimes be viewed as challenging fits. When providers encounter suboptimal visual performance after following the manufacturer's fitting guide recommendations, the lens centration should be critically reexamined and pupil size considered.

Custom soft multifocal designs have an advantage of variable base curves and diameters to improve centration. Many also allow the customization of center-distance or center-near zones along with zone size flexibility. This can be extremely helpful during troubleshooting. Even beyond this is the ability for some designs to incorporate decentered optics. By measuring the amount of the central zone's decentration from the middle of the pupil, some designs can move the optics of the contact lens back into alignment with the visual axis. This process is often aided through topography. After adjusting the topography scale and narrowing it, one can measure the decentration and axis by clicking in the center of the

Photo: Kim E, et al

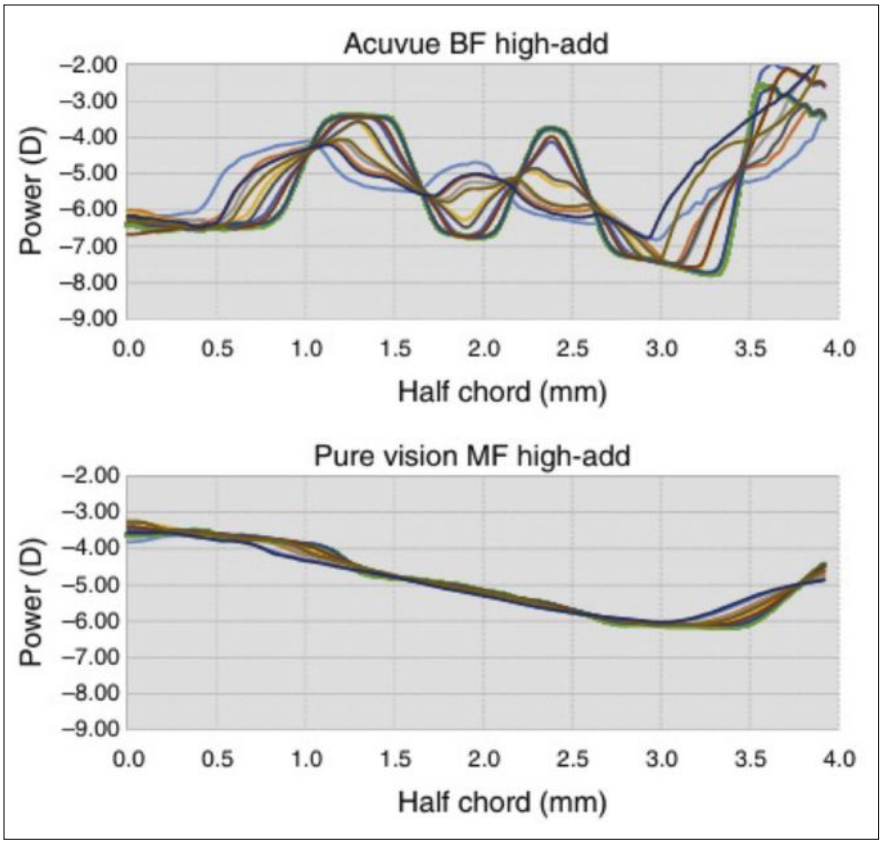

Fig. 3. The graphical profile of a concentric center-distance soft multifocal (top) compared with a center-near aspheric design (bottom). This graphs the power across the lens from the center out to the edge of the optic zone.

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Fig. 4. The Zernike plot, highlighting visually disturbing coma. This Xwave aberrometer (Ovitz) can send the data to labs for custom lens manufacturing to correct higher-order aberrations.[15]

optic—red color for center-near and blue color for center-distance.[13]

An alternative option in simultaneous vision now exists in the form of extended depth-of-focus (EDOF) optics, such as those in NaturalVue contact lenses (Visioneering Technologies). These power profiles use an aperiodic, non-harmonic change in power. As a result, they are less influenced by pupil size and lens decentration. The EDOF power profile creates an optical "pinhole effect," thereby allowing a range of clear vision rather than one or two focal points.[14]

The Future of Optics

With so many improved contact lens designs over the years, it is apparent that competition breeds innovation. Patients no longer need to hear, "Contacts won't work for you because of your astigmatism," and many are given the opportunity to try multifocal lenses instead of resorting to monovision or over-spectacles.

Given the wide array of viable soft lens options on the market now, what's next? How can things possibly get better? Soft contact lenses may start to see a shift in private practices into a more customized route. Consumers seem to respond positively to things made "just for them," which can be illustrated through the "Starbucks model." Services and businesses like this popular coffee chain provide a custom product or experience for that individual (in the case of Starbucks, each customer's order is named after them).

If a patient has unmet visual needs within your practice, consider the expanding options of custom soft lens designs, particularly for highly astigmatic individuals and presbyopes. There may even be a breakthrough in optical innovations like what is occurring in the scleral lens space with higher-order aberration correction. There are now instruments that can measure visual problems like trefoil and coma to send to a lab for optical customization with that lens (*Figure 4*). The measurement even accounts for lens decentration and rotation.[15]

Takeaways

A rewarding challenge of eyecare is delivering the best possible outcomes to our patients. Thankfully, there are many great tools for providing the best visual experience in soft contact lenses for our patients. Consideration of ballasting and prism can help stabilize toric lenses, and remembering to evaluate pupil size and lens centration can improve multifocal performance for presbyopes. ■

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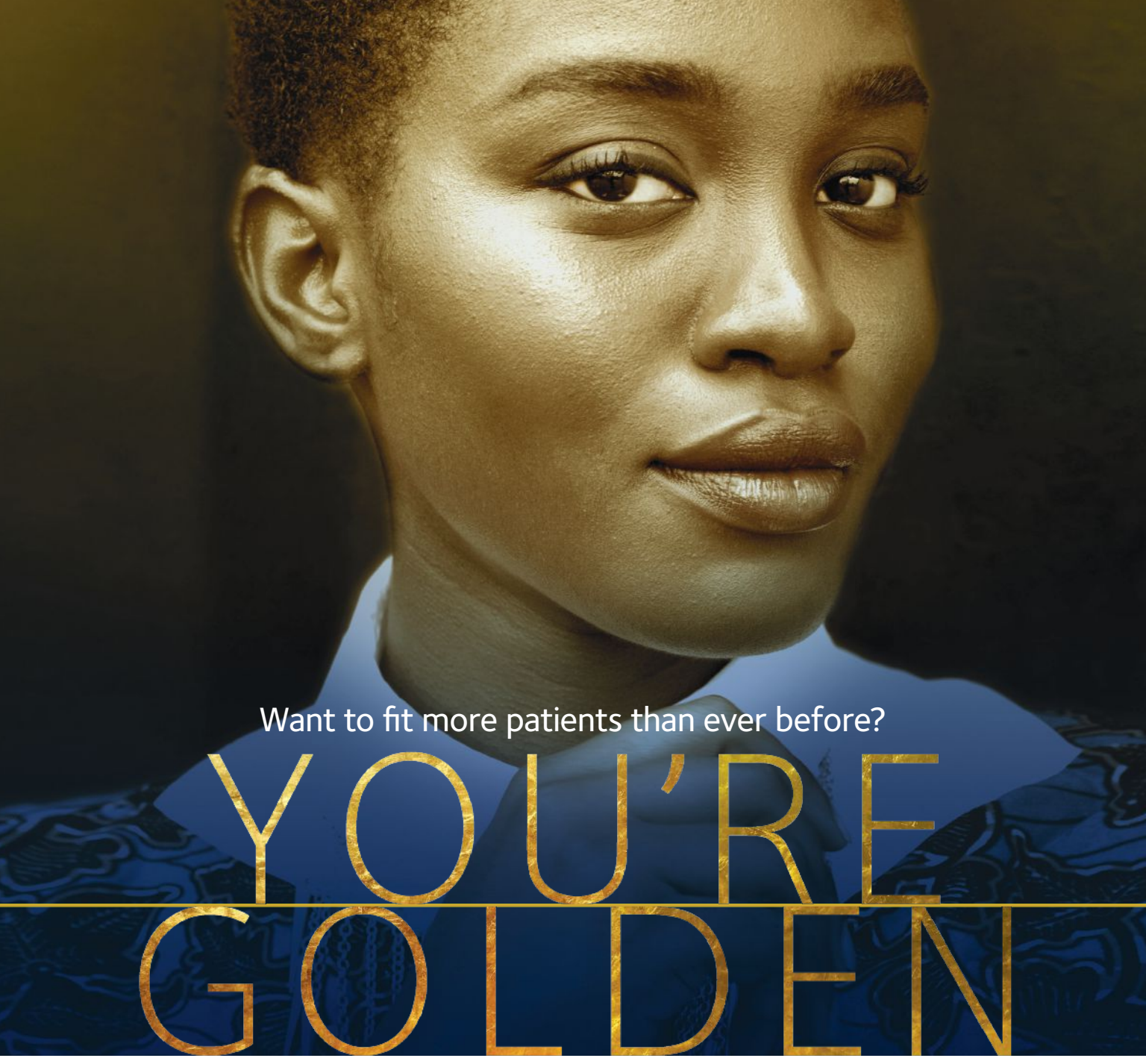

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CONTACT LENS COMPLICATIONS: RECOGNITION, PREVENTION AND MANAGEMENT

From mild dry eye to vision-threatening microbial keratitis, here's how to detect impending trouble, avoid similar issues in other patients and intervene to sidestep a potentially devastating outcome.

BY ROYA ATTAR, OD
JACKSON, MS

Contact lenses have been consistently popular for decades as an alternative to spectacle lens correction that offers convenience, improved aesthetics and the ability to accommodate a wide range of vision demands. Despite their benefits—and the great strides made by manufacturers in improving the safety profile of their products—improper use and poor hygiene can lead to a variety of complications. Recognizing and managing these is crucial to maintaining the ocular health of our patients. Contact lens complications can range from mild discomfort to severe ocular conditions that may threaten vision. Here, we will delve into several common complications associated with contact lens wear, describe methods for prevention and present options for treatment.

Dry Eyes

This condition takes the cake as one of the most common issues among contact lens users, though its cause can vary. To provide these patients relief and discourage dropout, the first step for clinicians is to identify the cause of the discomfort, then decide how to proceed, whether that involves recommending artificial tears or opting for a lens with more hydrating properties.

Recognition. Symptoms of contact lens-related dry eye include dryness, irritation, redness and a gritty sensation in the eyes. Patients may also report fluctuating vision and discomfort after prolonged wear, which are leading causes of contact lens dropout. Dry eye can arise from chronic lack of sufficient lubrication and moisture on the surface of the eye, which is influenced by several factors including, but not limited to, autoimmune conditions, medication use, meibomian gland dysfunction and improper lens use and hygiene.[1-3] Identifying one or more of these during a patient workup should raise your suspicion for both primary dry eye and irritation during contact lens wear.

Prevention. To prevent symptoms in these patients, recommend using high-quality lenses that allow for better oxygen permeability. Encourage patients to follow proper lens hygiene and limit wear time. Regular use of lubricating eye drops can also help maintain tear film stability, if patients are willing to tolerate such a regimen. Switching to daily disposable lenses can reduce the risk of dry eye by minimizing the buildup of deposits and ensuring a fresh, clean lens surface every day.[1]

Management. For mild cases, over-the-counter artificial tears can provide relief—again, provided that patients are willing to commit to the expense and inconvenience. More severe cases may require prescription eye drops, such as cyclosporine or lifitegrast. To maintain contact lens wear, opt for a product with

About the author

Dr. Attar is an associate professor and director of optometric services at the University of Mississippi Medical Center in Jackson, MS. She is the sole optometrist at the state's esteemed medical school and holds dual doctorates in optometry and health administration, complemented by an MBA. Dr. Attar is a fellow of the American Academy of Optometry, chairs the AAO Retina Special Interest Group and is the vice chair of the American Optometric Association Leadership Development Committee. Her achievements have been recognized through numerous awards, including Mississippi Young OD of the Year, SECO Young OD of the Year, AOA Young OD of the Year and Women in Optometry Young OD of the Year. Dr. Attar is on advisory boards for Heidelberg Engineering, Apellis and OcuTerra Therapeutics and is on the speaker bureau for Tarsus Pharmaceuticals.

high water content and/or the least disruptive experience possible for the ocular surface.

Beyond contact lens use, it's important to investigate other contributory factors to dry eye, such as autoimmune conditions (*i.e.*, Sjögren's syndrome), the use of certain medications (antihistamines, antidepressants and diuretics), meibomian gland dysfunction, compliance with the replacement schedule of lenses and the methods used to clean and store the lenses. A comprehensive approach to identifying and managing these factors can significantly improve the patient's dry eye symptoms and overall eye health.[1,3]

Conjunctivitis

This term encompasses a spectrum of diseases and disorders that primarily affect the conjunctiva and typically arise from an underlying allergy or infection. While rare, the condition could result in serious ocular complications in severe cases, underscoring the need for immediate workup and treatment.

Recognition. Conjunctivitis can be caused by bacterial, viral (*Figure 1*) or allergic reactions and is often associated with improper lens hygiene, extended wear times or allergic reactions to lens materials or solutions. Symptoms include redness, swelling, itching, watery or mucous discharge and a gritty sensation in the eyes. Giant papillary conjunctivitis (GPC) is a severe form that can occur due to chronic lens wear and significant deposits, characterized by large papillae on the upper eyelid.[2-4]

Prevention. To prevent conjunctivitis, emphasize proper lens hygiene, including washing hands before handling lenses, using fresh disinfecting solution and avoiding contact with water while wearing lenses. Adhering to prescribed replacement schedules and using daily disposable lenses can significantly reduce the risk of contamination and allergic reactions.[3,4]

Management. Instruct patients to discontinue contact lens use until the condition has resolved. Treatment depends on the type of conjunctivitis. If the infection is bacterial, it can be treated with antibiotic eye drops. Viral conjunctivitis, being self-limiting, can be managed with lubricating eye drops and cold compresses. Also, advise patients about the contagious nature of viral conjunctivitis. Allergic conjunctivitis is treated with antihistamine or mast cell stabilizer eye drops.

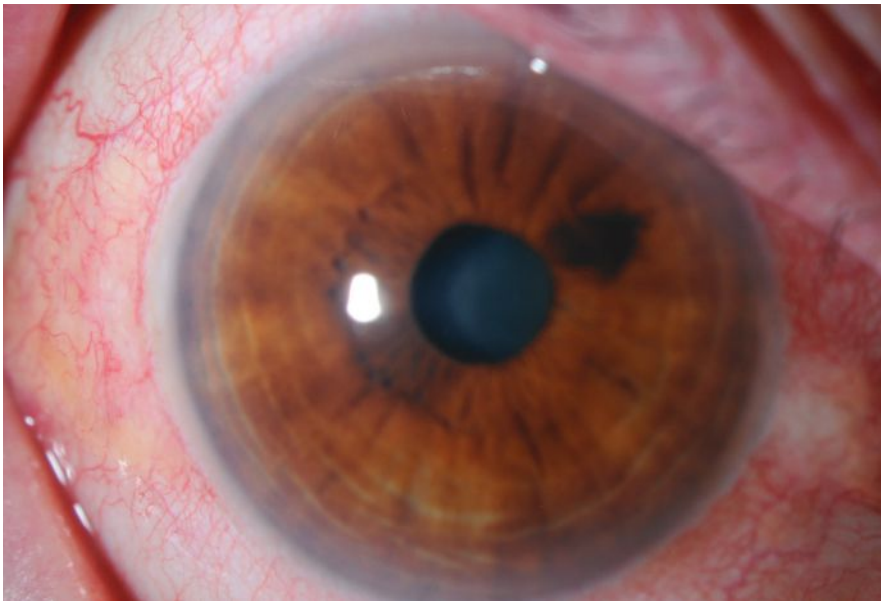

Fig. 1. The affected eye of this patient exhibits characteristic signs of viral conjunctivitis, commonly known as pink eye. The conjunctival blood vessels are visibly dilated, contributing to the overall redness.

For patients with GPC, recommend switching to daily disposable lenses, using peroxide disinfection or reducing wearing time to minimize allergen exposure and lens deposits once condition resolves. In severe cases, a short course of topical corticosteroids may be necessary. If not managed appropriately, conjunctivitis in contact lens wearers can lead to more severe conditions. Persistent or recurrent conjunctivitis should prompt a reevaluation of the patient's contact lens hygiene practices, lens material and solution compatibility.[3,4]

Corneal Neovascularization

This possible complication of contact lens wear results from the ingrowth of blood vessels from the limbal vascular plexus into the cornea. The risk of corneal opacification increases as the condition progresses, threatening the patient's vision. However, in the early stages, patients may be asymptomatic; thus, clinicians must be well-versed in signs and symptoms to be able to intervene before a patient's vision starts to decline.

Recognition. Corneal neovascularization can result from a wide range of ocular pathologies and conditions including but not limited to inflammatory disorders, chemical injuries, limbal stem cell deficiency, allergies, trauma, surgery, corneal infections, autoimmune diseases, corneal graft rejection, congenital diseases, ischemia, degeneration and systemic conditions such as diabetes mellitus and vitamin A deficiency.

In contact lens users, a common cause of corneal neovascularization is a lack of oxygen, or hypoxia. Epithelial edema can also occur secondary to hypoxia. Several factors can cause chronic hypoxia from contact lens use including contact lens overwear, poor care or sensitivity to contact lens solutions. Symptoms include redness and irritation, or the patient may be asymptomatic.

Neovascularization can be superficial, deep, sectoral or involve 360° of the cornea. In contact lens users, a small amount (1mm to 2mm) of peripheral superficial vascularization is common; however, having growth or progression of more than 2mm or involving a middle or deeper stroma is not com-

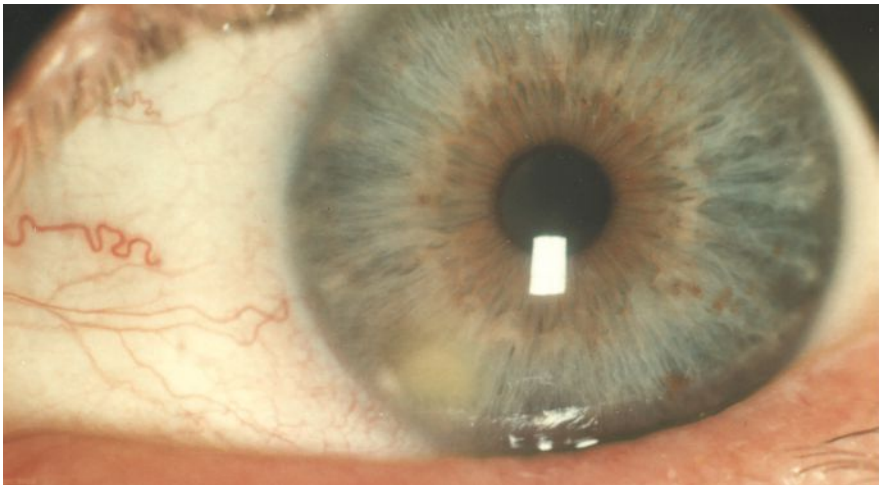

Fig. 2. Note the marginal infiltrate located at the periphery of the cornea, appearing as a small, localized white or grayish opacity, distinctly positioned near the limbus of the eye. Surrounding the infiltrate is a mild conjunctival injection, indicating a localized inflammatory response. This condition is typically associated with inflammatory processes, such as ocular surface disease or contact lens-related complications.

mon. Although rare, deep stromal vessel growth is of greater concern and can lead to significant complications. Vessel growth into the visual axis, although exceptionally rare, can lead to visual impairment via intracorneal hemorrhage, lipid exudation and scarring, all of which potentially compromise the patient's vision.[2,5]

Prevention. Look for signs of a tight-fitting lens or conjunctival drag. Tight lenses tend to be comfortable initially, so it's important to carefully evaluate lens fit. An excessively tight lens will show minimal or no post-blink movement. Perform the digital push-up test by raising the lower eyelid margin with the thumb to move the lens upward and then assessing speed of recentering and amount of digital force necessary to move the lens upward. A tight lens will be difficult to move during the test or the lens will recenter slowly. Also, look for conjunctival drag during the blink or push-up test. Encourage patients to adhere to appropriate wear schedules and avoid overnight lens wear as well as give their eyes regular breaks from lens wear.[5]

Management. Treatment may include switching to a better fitting lens, updating to lenses with higher oxygen permeability or reducing lens wear time. Overnight wear of contact lenses is uncommon these days, but patients should be strongly advised to limit lens wear to waking hours. In advanced cases, patients may need to stop wearing contact lenses altogether. Topical corticosteroids can be used to aid in vessel regression. In severe cases or when there is vessel growth into the visual axis, refer the patient to a cornea specialist.[2,5]

Sterile Corneal Infiltrates

Treatment for this complication depends directly on its origin, which may vary from case to case. Clinicians should familiarize themselves with the wide array of signs and symptoms, initiate the appropriate management plan as soon as possible and counsel patients on proper lens hygiene to avoid recurrence.

Recognition. These white or grayish opacities can be epithelial, subepithelial or anterior stromal, often resulting from an inflammatory response to contact lens wear, especially extended wear (*Figures 2 and 3*). Other risk factors include, but are not limited to, hypoxia, poor contact lens hygiene and lens case contamination. Symptoms can include mild to moderate pain, redness, tearing, photophobia and reduced visual acuity.

It is important to note that corneal infiltrates can be sterile or infectious in origin. Differentiation is critical to ensure appropriate treatment and prevent complications. Often, the patient history, symptoms and clinical signs are key factors in distinguishing between sterile and infectious infiltrates.[2,3,6,7] Under the slit lamp, sterile corneal infiltrates are typically seen as small, localized spots in the peripheral cornea with little to no epithelial staining and can be associated with other signs of inflammation, such as conjunctival injection.[2,3,6,7]

Prevention. Avoiding corneal infiltrates involves proper lens hygiene, forgoing overnight wear and ensuring appropriate lens fit and material. Encourage patients to adhere strictly to lens replacement schedules and to avoid using expired or damaged lenses and solutions. Daily disposable lenses can reduce the risk by eliminating the need for cleaning and minimizing the chance of contamination.[2,3,6]

Management. Regardless of the etiology of the infiltrate, patients should be instructed to immediately discontinue contact lens use to prevent further irritation and allow the cornea to heal. Sterile infiltrates resulting from inflammation of the cornea can be treated with topical steroids. However, if there is a suspicion of a bacterial infection or if the infiltrates are accompanied by epithelial defects, antibiotic drops should be prescribed; a commercially available fluoroquinolone is usually adequate. Lubricating eye drops can help alleviate discomfort and promote healing by maintaining a moist ocular surface.

The patient should be monitored closely to confirm resolution of infiltrates and to ensure there are no additional complications. If infiltrates recur, reassess the lens material, fit, wearing modality, cleaning/disinfecting solution and patient's compliance with care instructions.[2,3,6]

Corneal Abrasion

Characterized by scratches or injuries to the surface epithelium of the cornea, corneal abrasions represent the most common form of ocular trauma and often arise due to improper lens handling or wearing damaged lenses (particularly for GP lens patients). Once an abrasion is identified, prompt action helps minimize a patient's risk of developing a potentially vision-threatening infection.

Recognition. Symptoms of corneal abrasion include sudden onset of severe eye pain, tearing, redness, light sensitivity and a gritty sensation. Patients may have difficulty keeping the eye open, making examination difficult.[3,8]

Prevention. Educate patients on proper lens handling and hygiene, emphasizing the need for thorough hand washing before inserting or removing lenses, and spend extra time reviewing proper insertion and removal techniques to avoid scratching the cornea. It is also important to recommend regular replacement of lenses according to the prescribed schedule and discourage use of damaged or torn lenses.[3,8]

Management. Patients should be treated with topical antibiotics to prevent infections—a fluoroquinolone or aminoglycoside is the drug of choice due to *Pseudomonas* coverage. Ointment formulations should be used for comfort while healing and for overnight use. Cycloplegics can also be administered in the office for pain control due to discomfort from ciliary spasm. Use lubricating eye drops or ointments to provide relief and promote healing. The patient should be monitored daily until resolved.[3,8]

Microbial Keratitis

This painful, sight-threatening infection moves fast—and so should you. Here's guidance on diagnosing, preventing and managing this condition in contact lens wearers.

Recognition. Microbial keratitis (MK) can result from bacterial, viral, fungal or amoebic infections, as well as noninfectious sources like trauma or extended contact lens wear (*Figure 4*). In contact lens wear, the etiology is most often bacterial.

Signs and symptoms include pain, redness, blurred vision, photophobia, tearing, discharge, tear film debris and anterior chamber reaction. Patients may also notice a white or grayish spot on the cornea and experience a gritty or foreign body sensation in the eye. Visual acuity can be significantly reduced in severe cases.

MK is one of the most serious complications of wearing contact lenses. For an infection of the cornea to occur, the offending organism must bind to and penetrate the corneal epithelium. Contact lens–induced hypoxia can cause compromised corneal epithelial integrity, impaired wound healing and increased bacterial binding, which may predispose a patient to infection. Patients will experience moderate to severe pain, photophobia, redness and discharge.

Slit lamp findings will show a focal, irregular stromal infiltrate greater than 1.5mm in size in the central, midperipheral or peripheral cornea, along with diffuse infiltration and an overlying epithelial defect. Other findings include lid edema, diffuse general and limbal conjunctival injection, anterior chamber reaction and possible hypopyon. Without proper antimicrobial treatment, patients will worsen rapidly.[2,3,9-11]

Prevention. As with so many of these complications, the best way to ensure prevention is to educate patients on the importance of proper lens hygiene, avoiding overnight wear (unless using lenses

For a Deeper Dive

Each of the topics discussed in this broad overview warrants additional study. In the online version of this article, you'll find links to the following resources from our archives:

- Contact Lens Wear and Its Disruption of the Tear Film
- Dissecting the Soft Contact Lens
- Managing Contact Lens-associated Red Eye
- Hot Topics in Bacterial Keratitis
- Understanding Corneal Ulcers and Infiltrates
- Four Contact Lens Complications to Combat

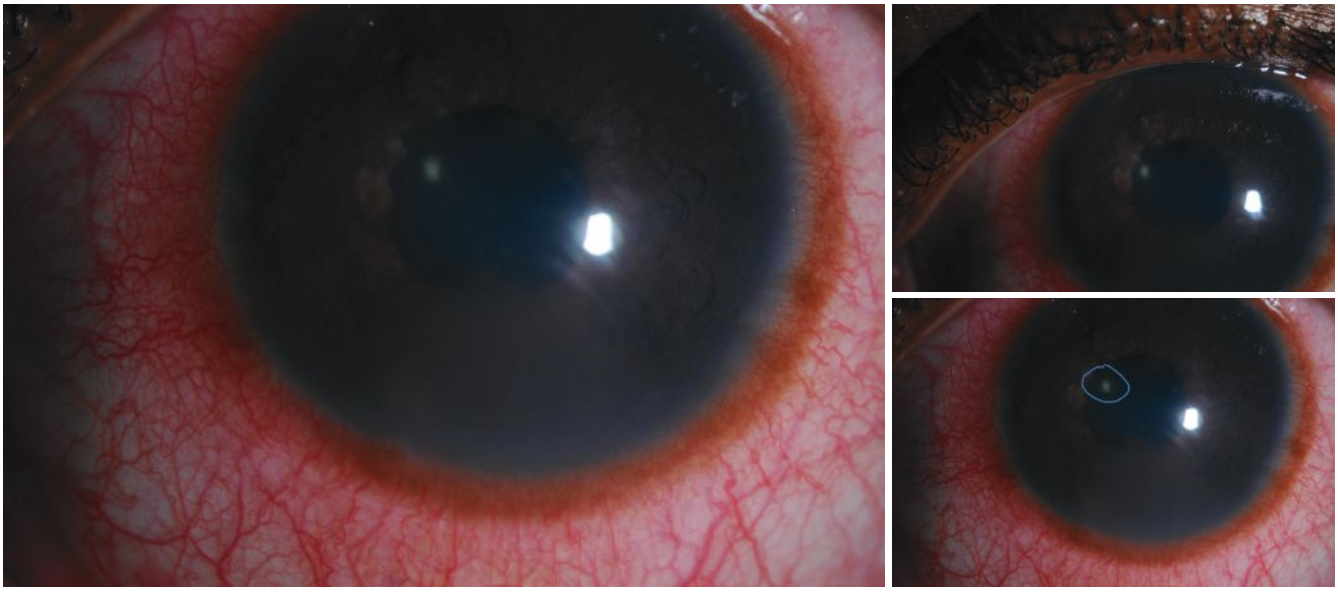

Fig. 3. A close-up view of a patient's eye reveals an infectious corneal infiltrate with a moderately severe conjunctival injection. The cornea appears slightly hazy, with a distinct grayish-white spot indicating the presence of an infiltrate.

Photo: University of Iowa

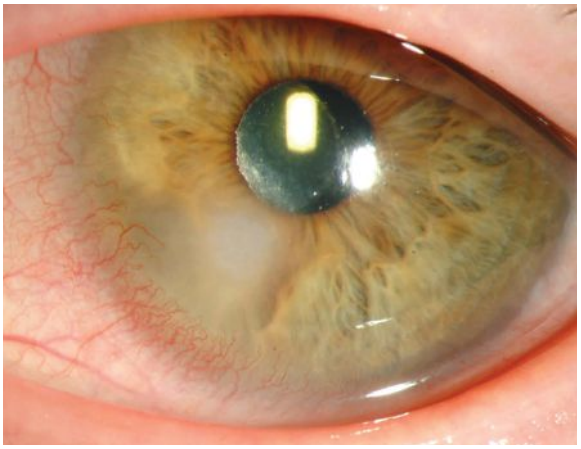

Fig. 4. Extended contact lens wear and poor hygiene practices, such as using tap water to clean lenses, can result in MK, often of a bacterial etiology.

specifically designed for it) and avoiding contact with nonsterile water while wearing lenses. Daily disposable lenses can significantly reduce the risk of infection by eliminating the need for cleaning and reducing the chance of contamination. In addition, solution efficacy is important, especially for those not using daily disposables. Ensuring the use of effective and appropriate contact lens solutions can help reduce the risk of infection.[2,9-11]

Management. Regular and prompt evaluation of patients presenting with keratitis is essential to determine the appropriate treatment and prevent long-term complications. Discontinuing contact lens use immediately is critical. When treating noninfectious keratitis, lubricating drops or ointments alleviate discomfort and promote healing, anti-inflammatory drugs reduce redness and discomfort and prophylactic antibiotics prevent secondary infections.

For noninfectious keratitis, such as contact lens–induced red eye without an infectious component, superficial punctate keratitis and some autoimmune-related keratitis, steroids are appropriate to reduce inflammation and alleviate symptoms. Monitor the patient closely for signs of improvement and potential side effects such as increased intraocular pressure or secondary infections. For suspected herpetic infections, start topical antivirals.

For infectious keratitis, prompt treatment with appropriate antimicrobial agents is essential. In cases of bacterial keratitis, broad-spectrum antibiotic eye drops such as fluoroquinolones (*e.g.*, moxifloxacin) are the first line of treatment. In more severe or unresponsive cases, fortified aminoglycosides or cefazolin may be necessary.

Establishing a definitive diagnosis through cultures and corneal scrapings is crucial to guide therapy. Not all cases of MK are cultured at diagnosis; however, culturing should be considered for centrally located lesions, lesions larger than 2mm, cases where empirical fluoroquinolone therapy has failed and any monocular or immunocompromised patient. If your office is not equipped to culture, referral to a cornea specialist is appropriate.

Regardless of culturing, immediate treatment with a fluoroquinolone is essential. If a patient was cultured, the treatment regimen may be altered based on species and sensitivity reports. Steroids should generally be avoided initially until the infection is controlled with appropriate antibiotics. Once the infection is under control, steroids can be introduced to reduce inflammation and prevent scarring, but this should only be done under close supervision.

Acanthamoeba keratitis should be considered in patients with known exposure to fresh water (*e.g.*, swimming in a lake) or tap water, disproportionate pain relative to clinical appearance or cases not responding to antibiotics. Close follow-up is essential to monitor healing and prevent complications. Referral to a cornea specialist is warranted if you suspect any of the following:

- atypical or complicated cases, such as suspected fungal or *Acanthamoeba*
- if the keratitis does not respond to initial treatment within a reasonable time frame
- if the keratitis is severe with extensive corneal involvement or along the visual axis
- if there is a high risk of complications such as corneal scarring, neovascularization or perforation

Cases that may require long-term immunosuppressive therapy, specialized medical management or surgical intervention (*i.e.*, corneal transplantation) should also be managed by a cornea specialist.[2,3,9,10]

Takeaways

Contact lenses offer clear vision and convenience but not without potential complications, most of which result from poor patient compliance and hygiene. These complications can be effectively managed through proper recognition, prevention and prompt intervention. Carefully assess each case's severity, response to treatment and potential complications to determine the best course of action. Furthermore, educate patients regularly on the importance of proper lens care, adherence to wear schedules and regular eye exams. By doing so, eyecare providers can significantly reduce the incidence of contact lens complications and help patients maintain optimum ocular health and vision. ■

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A STEPWISE APPROACH TO DIAGNOSING DRY EYE DISEASE

Identifying this condition requires a systematic assessment using multiple techniques.

BY HAMZA SHAH, OD, MS
HOUSTON

With the incidence of ocular surface disease (OSD) on the rise, evaluating the relevant structures is a crucial aspect of every eye examination. Dry eye disease (DED) ranks among the most prevalent ocular conditions worldwide, with evaporative DED being the most common form.[1,2]

When approaching dry eye management, it is important to keep in mind that other ocular surface diseases can influence its course. For this reason, be sure to perform a comprehensive ocular surface assessment on every patient with dry eye signs or symptoms. Without thorough assessment, misdiagnosis can lead to insufficient or misdirected treatment and persistent symptoms for the patient.

Establishing a standardized protocol for evaluating OSD patients is useful for the busy clinician. A systematic approach not only provides technicians with clear guidelines but also helps doctors avoid overlooking key details. Like glaucoma, OSD is a chronic, multifactorial condition requiring systematic assessment and ongoing treatment.

Dry eye occurs due to tear film instability, hyperosmolarity and ocular surface inflammation, resulting in damage to the ocular surface.[1] Classified by the Tear Film and Ocular Surface Society's Dry Eye Workshop (DEWS II) Definition and Classification Report, the condition can be broken down into two primary categories: aqueous-deficient dry eye and evaporative dry eye.[1] When performing a dry eye workup, not only is it important to diagnose the condition when present, but it is just as important to rule out dry eye masqueraders.

Step One: Case History

Gathering a comprehensive medical history can offer clinicians valuable insights into diagnosing and managing a patient's DED. This includes details about their age, occupation, systemic health conditions, medications (both systemic and ocular), history of surgeries (both ophthalmic and systemic) and use of contact lenses. Symptoms of dry eye can vary widely; patients may present as asymptomatic or experience symptoms that

Ocular Surface Disease Index© (OSDI©)[3]

Ask your patient 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	
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	
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.

Fig. 1. Example of the OSDI questionnaire.

About the authors

Dr. Shah graduated from the Illinois College of Optometry before practicing full-scope optometry in the Chicagoland area. He later joined the Center for Sight and Dry Eye Institute in Carmel, Indiana, where he completed a residency in ocular disease. He is currently a clinical assistant professor at the University of Houston College of Optometry. His primary focus is in perioperative care, glaucoma and ocular surface disease. He has no financial disclosures.

may be constant or intermittent, such as decreased vision, irritation, redness, foreign body sensation, burning, tearing, sharp pain and photophobia.[3]

Systemic conditions. Many systemic conditions can contribute to DED, such as Sjögren's syndrome, Parkinson's disease, androgenic deficiency, thyroid disease and diabetes.[4] Autoimmune conditions including rheumatoid arthritis, lupus, systemic sclerosis and dermatomyositis can lead to secondary Sjögren's syndrome.[5] Sjögren's is a common cause for aqueous-deficient dry eye.[6] It involves the secretory glands, leading to dry mouth, and can also affect the vaginal, gastric and respiratory membranes.[3] Laboratory testing to consider when a clinician suspects a systemic etiology are Ro/SS-A, La/SS-B, rheumatoid factor (Rh factor), antinuclear antibodies (ANA), antibodies salivary gland protein 1 (anti-SP-1), carbonic anhydrase 6 (anti-CA6) and parotid secretory protein (anti-PSP), all of which are comprised within the Sjö test.[3] In cases of high suspicion of Sjögren's but negative blood testing, repeat blood testing or order a salivary gland biopsy.[7]

Medications. Another significant contributor to DED is medication use,

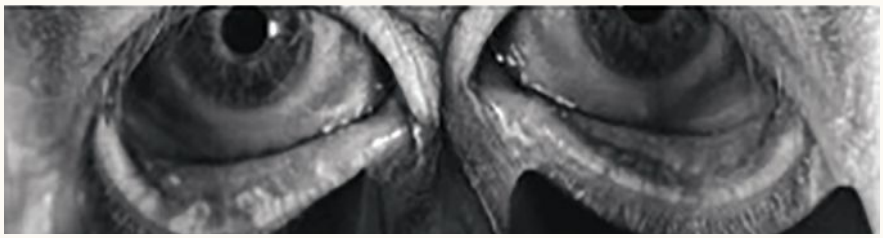

Fig. 2. Bilateral meibography with truncation and presence of tortuosity and segmentation.

with approximately 22 of the top 100 best-selling systemic drugs known to cause DED.[8] Among these meds are antihistamines, antihypertensives, antiarrhythmics, antipsychotics, bronchodilators, antispasmodics/antimuscarinics, antineoplastics, antidepressants, antimalarials, antivirals, thiazide diuretics, cannabinoids, analgesics, chelating agents, systemic hormones, nonsteroidal anti-inflammatory, corticosteroids, anticholinergic, isotretinoin and chemotherapy agents.[3,9] Additionally, topical medications containing preservatives are also recognized contributors to DED, with BAK-containing topical medications being the worst for the ocular surface.[10]

Other factors to consider are menopausal status, smoking status, hormone replacement therapy, vitamin A or omega-3 fatty acid deficiency and history of radiation therapy.[4]

Step Two: Dry Eye Questionnaires

There are several questionnaires available that can be used to get a subjective, quantified understanding of a patient's symptomology before even talking with them. The questionnaires can allow clinicians to gain information regarding symptom severity, frequency, level and triggers.

Some commonly used are Ocular Surface Disease Index (OSDI), Standard Patient Evaluation of Eye Dryness (SPEED), National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) and the Dry Eye Questionnaire-5 (DEQ-5). These questionnaires provide an unbiased number that can be used to monitor the subjective progress. Patients can sometimes be intimidated when discussing their symptoms with the doctor and can

A Stepwise Approach to Diagnosing Dry Eye Disease

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

Release Date: August 15, 2024

Expiration Date: August 15, 2027

Estimated Time to Complete Activity: two hours

Target Audience: This activity is intended for optometrists interested in effectively addressing DED and ensuring optimal outcomes.

JOINTLY ACCREDITED PROVIDER™ INTERPROFESSIONAL CONTINUING EDUCATION

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

- Systematically evaluate and identify dry eye disease.
- Conduct a comprehensive patient case history when DED is suspected.
- Effectively use dry eye questionnaires to support the care of these patients.
- Recognize when specific testing is necessary for a thorough dry eye evaluation.

Faculty: Hamza Shah, OD

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unconsciously lessen the severity of their DED.

The OSDI is a validated symptom survey often used for assessing DED severity in research (*Figure 1*).[11] It is scored on a scale of 0 to 100, with higher scores indicating more severe cases. The questionnaire consists of three categories: ocular symptoms, visual-related function and environmental triggers. Each category comprises four questions, allowing patients to respond with a score ranging from 0 to 4 or select "N/A" for each question. The OSDI score is calculated through the following formula: (sum of score)*25/(# of questions answered). A normal OSDI score could range from 0 to 12. Dry eye is diagnosed as mild if the score is between 12 to 22, moderate if between 23 and 32 and severe if exceeding 33.[12]

Step Three: Tear Film Biomarker Assessment

Although not required for the diagnosis of DED, osmolarity and MMP-9 testing offer additional tools to help establish a diagnosis.

Tear osmolarity measurements provide a quantified assessment of solute particles within a patient's tear film. Beyond clinical value, osmolarity findings provide a quantified tool that aids patient education. The TearLab osmometer (Bausch + Lomb), ScoutPro osmometer (Bausch + Lomb) and I-Pen osmolarity system (I-Med Pharma) are devices that measure tear osmolarity.[13] TearLab analyzes a 50µL tear sample to determine tear osmolarity.[14] Values of 308mOsm/L and above, or an asymmetry of at least 8mOsm/L between the eyes, are considered abnormal. Readings between 308mOsm/L and 316mOsm/L indicate mild DED, while values above 316mOsm/L indicate severe disease. Tear hyperosmolarity increases with the severity of dry eye disease.[15]

Hyperosmolarity in tears is due to a relative decrease in aqueous levels and an increase in solids within the tears.[16] This state triggers the inflammatory cascade, leading to epithelial cell dysfunction and death, along with changes in mucin expression.[1,8] Patients consequently experience chronic epithelial stress, tear instability and ocular irritation.[17] It is important to consider osmolarity as a diagnostic tool among other tests, rather than the gold standard for diagnosing DED.

The DEWS II report concluded that tear osmolarity is a crucial test in diagnosing DED.[1] Even though precorneal tears can be more difficult to collect, it is important to note that precorneal tear film osmolarity is significantly higher than that of the tear meniscus in DED, with values reaching as high as 800mOsm/L to 900mOsm/L.[18,19] Note that one study indicated osmolarity results can sometimes be misleading, showing no significant difference between healthy and dry eye patients, and some healthy patients having higher osmolarity than the normal 308mOsm/L.[20] Osmolarity can be considered an indirect test for ocular inflammation, but the results should be interpreted in conjunction with other findings.

Ideally, osmolarity should be paired with MMP-9 testing, which provides a direct indication of ocular inflammation. In-office MMP-9 rapid testing takes about 10 minutes to deliver either a negative or positive result, rather than a quantified value. The test uses a matrix

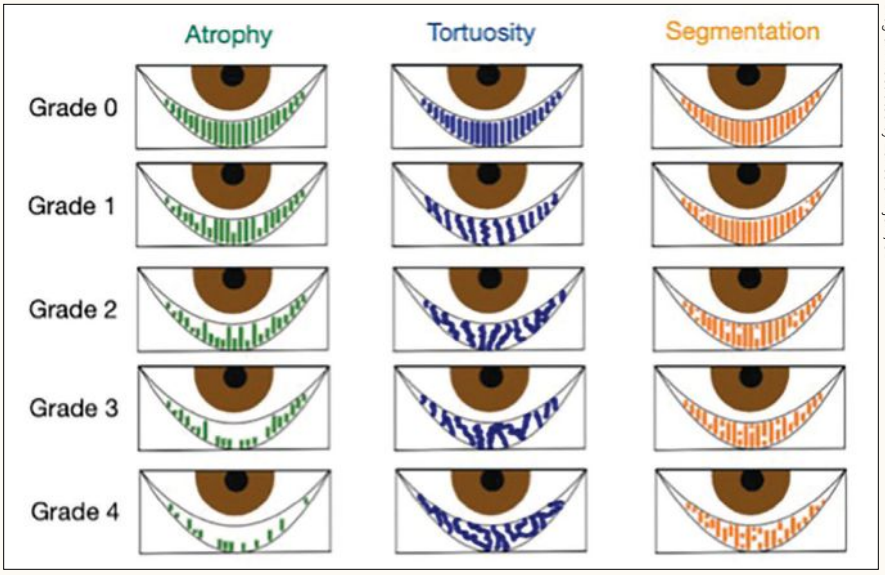

Diagram illustrated by Zuneera Anjum, OD

Fig. 3. Puly 5-grade scale for gland atrophy, Halleran grading scale for tortuosity and the segmentation grading scale.

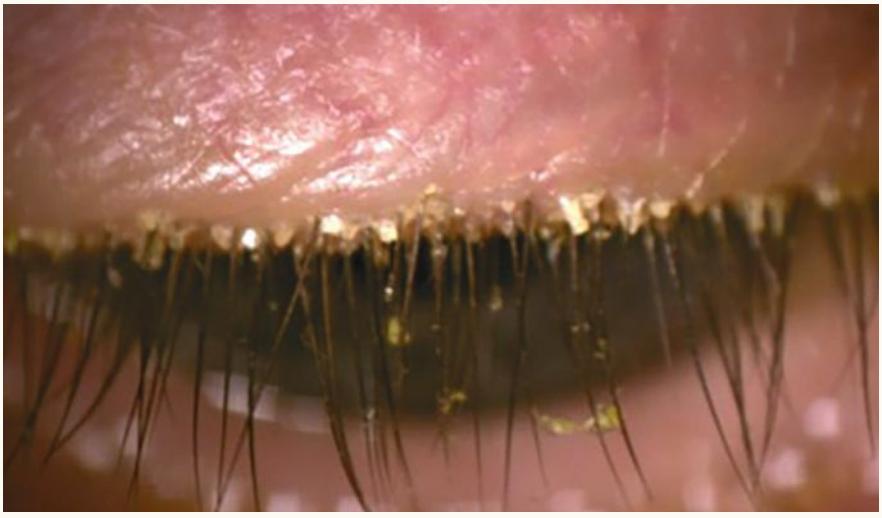

Fig. 4. Presence of *Demodex* with the patient looking down.

metalloproteinase-9 (MMP-9) concentration of 40ng/mL as the cutoff; any concentration above this value results in a positive result, while concentrations below it yield a negative result.[21]

MMP-9 is induced by interleukins, tumor necrosis factor, tumor growth factor and the inflammatory cascade, making it an ideal marker for inflammation.[22,23] A study showed that MMP-9 concentrations correlate with patients' symptoms, tear break-up time (TBUT), corneal staining and conjunctival staining.[24] Although the InflammaDry test does not provide a numerical concentration, knowing that inflammation is increased can help in formulating an accurate diagnosis and treatment plan. Positive MMP-9 results can also occur in other inflammatory conditions like allergies, chronic blepharitis and conjunctivochalasis.[25,26] Therefore, it is important not to use this test as a standalone diagnostic tool, considering its positive results can be due to etiologies other than dry eye disease.

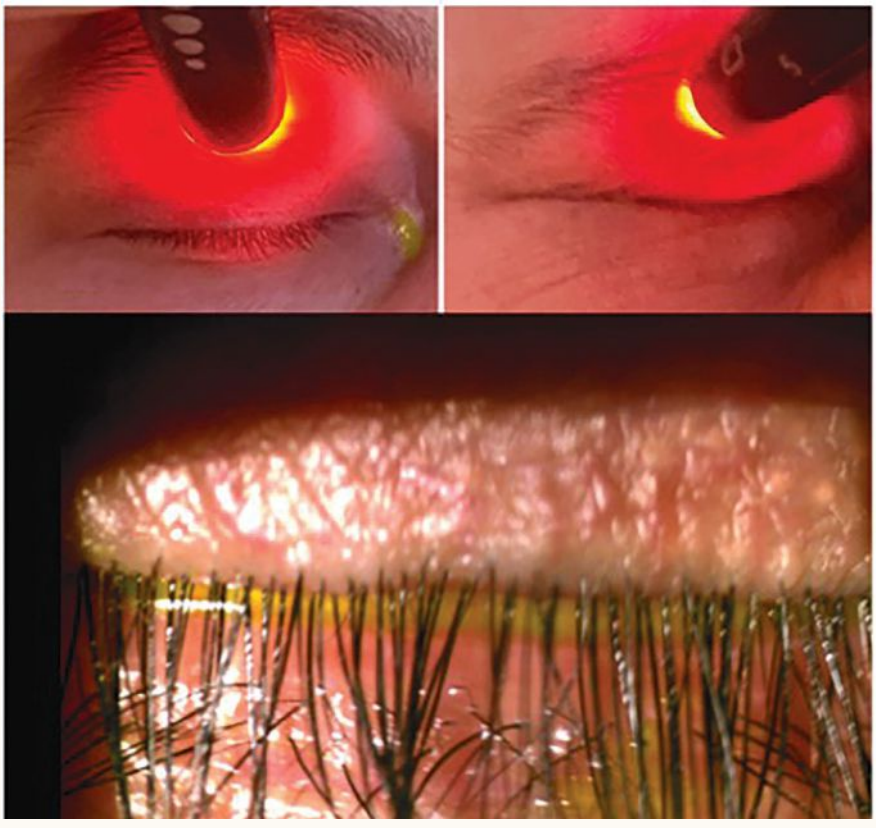

Fig. 5. Korb Blackie test reveals light leakage centrally indicating lagophthalmos (top left). Patient demonstrates no light leakage while squeezing (top right). Slit lamp photo depicting improper lid closure (bottom).

Step Four: Meibography

Although this too is not required for the diagnosis or management of DED, meibography is a great tool to assess meibomian gland quality and quantity. It also provides patients a visual representation of their gland architecture, helping them better understand their anatomy and the stage of their disease.

Various instruments facilitate meibography, including LipiView/LipiScan (Johnson & Johnson Vision), Keratograph 5M (Oculus), iLux (Alcon) and Myah (Topcon). Additionally, standalone options—anterior segment cameras with infrared capabilities—are also available to visualize the meibomian glands. Obtaining meibography images provides valuable information for the physician and serves as an excellent tool to educate patients about the condition of their glands.

When interpreting a meibography, it is important to grade the quality and quantity of the glands by analyzing three key factors: atrophy, tortuosity and segmentation, each of which can be graded from 0 to 4 (*Figures 2 and 3*).

Atrophy, described by the Pult 5-grade scale, measures the loss of meibomian glands, ranging from partial to complete loss from the orifice to the fornix.[27] Tortuosity, assessed using the Halleran grading scale, is present if a gland bends at a 45° angle from the midline or if there are multiple bends of any degree within a gland.[28] Segmentation, evaluated using a segmentation grading scale, describes the broken appearance of the glands, often indicated by a division within a gland marked by a black line.[29] These grading systems provide a quick and standardized method for documenting the quality of meibomian glands as shown on the meibography.

Step Five: Lids and Lashes

Evaluation of the eyelids and lashes should be the first step during a slit lamp examination when performing a dry eye evaluation. Information obtained from this examination can either directly contribute to diagnosing DED or help identify another condition that may be causing the patient's symptoms. Examining the position of the lashes and lids can help rule out trichiasis, entropion and ectropion, any of which can disrupt the ocular surface. Lid abnormalities such as entropion and ectropion are more commonly seen in the elderly and are more frequently observed in female patients.[30,31]

Anterior blepharitis and *Demodex* are closely associated with meibomian gland dysfunction (MGD).[32,33] *Demodex* is classically identified by collarettes at the base of the lashes, whereas anterior blepharitis presents with more generalized crusting and scaling along the lid margins, rather than being concentrated at the base of the eyelashes.

Anterior blepharitis. This condition is a result of overgrowth of bacteria and its associated biofilm, resulting in increased concentration of exotoxins

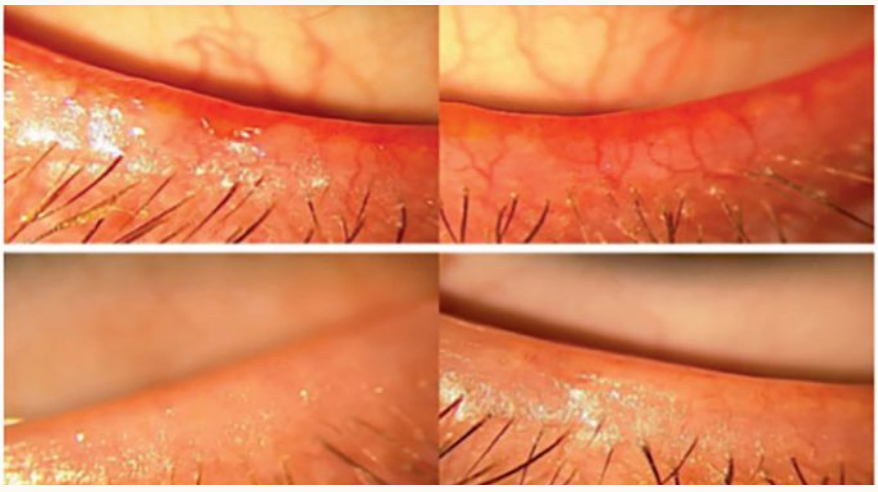

Fig. 6. Lower eyelids with telangiectasia before and after intense pulse light treatment.

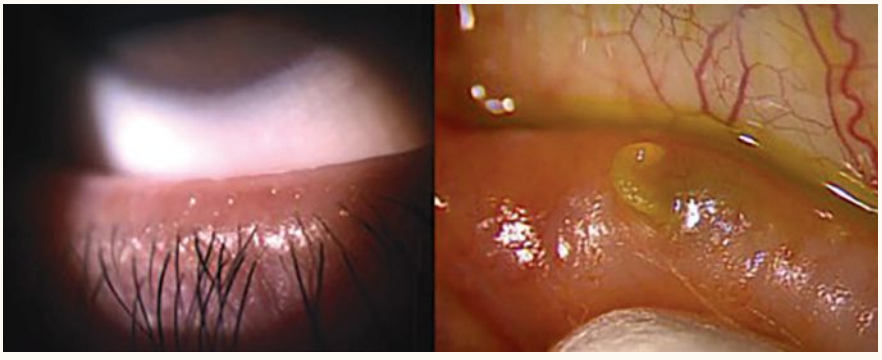

Fig. 7. Proper release of meibum through blinking, grade 0 (left). Expression of hardened meibum, grade 3+ (right).

and lipases along the lid margin.[34] If not treated, this chronic inflammation leads to increased MGD, telangiectasia and hyperkeratinization.[26,35,36]

Demodex. One study found a 60% prevalence of *Demodex* infestation in the eyelids of patients with MGD, compared to 18% in controls.[37] OSDI scores, corneal staining, chalazion presence, reduced TBUT and MGD are much more commonly seen in patients with *Demodex*.[38-40] As *Demodex* go through their two-week life cycle, their remains contribute to the physical blockage of meibomian gland orifices and cause changes to the gland architecture over time.[39,40] To obtain the best view when examining for blepharitis or *Demodex*, direct the patient to look down, allowing for a direct view of the base of the lashes (*Figure 4*). Chronic blepharitis and *Demodex* infestation cause chronic inflammation, leading to lid margin keratinization and, in later stages, even ectropion or entropion.[26]

When evaluating the lids, it is also important to check for incomplete blinking and nocturnal lagophthalmos. This can be done either with or without the slit lamp. Decreased blink frequency and incomplete blinking is increasingly seen with the rise in digital screen use.[41] The average American adult spends over 10 hours per day in front of a digital screen, making it essential to look for incomplete blinking in all patients.[42] Incomplete blinking has been linked to a twofold increase in the risk of developing DED and is associated with increased OSDI scores, MGD and reduced TBUT.[43,44] Lagophthalmos can often be coupled with incomplete blinking. The Korb-Blackie test evaluates the level of lid closure (*Figure 5*). Patients with lagophthalmos have trouble keeping their eyes closed throughout their sleep, leading to increased tear evaporation. As a result, they usually report symptoms being worst upon awaking.[45]

Ocular rosacea. It is also important to notice any telangiectatic blood vessels along the lid margin (*Figure 6*). It is theorized that ocular rosacea is caused by increased inflammation, which triggers the expression of certain cytokines and antimicrobial molecules like cathelicidin, which has both vasoactive and proinflammatory properties. There is an increase in vascular endothelial growth factor (VEGF) within the skin, explaining the excessive vascularization seen with ocular rosacea.[46,47] This can be graded from a scale of 0 to 3:[48]

0 = no telangiectasia
1+ = mild
2+ = moderate
3+ = severe

Step Six: Meibomian Glands

Meibum is the substance secreted by the meibomian glands. In eyes without MGD, meibum has a melting point of around 32° C.[49] However, the melting point of meibum can increase up to 45° C.[38,50] This phenomenon explains why in cold temperatures, such as during winter, the meibum can harden, preventing its proper release into the tear film, thereby increasing tear evaporation. MGD is a leading cause of evaporative dry eye, which is the most common form of DED.[46]

For a thorough evaluation of the meibomian glands, it's essential for the physician to perform meibomian gland expression. This allows for the assessment of both the quality of meibum and the efficiency of its release (*Figure 7*). Meibum quality can be graded on a scale ranging from 0 to 3+. Grade 0 indicates clear meibum, considered normal, while grade 1 represents waxy or cloudy meibum with diffusely turbid fluid secretions. Grade 2 signifies granular meibum, characterized by turbid fluid secretions containing particulate matter, and Grade 3+ denotes opaque or inspissated meibum, which may have a semi-solid plug-like consistency requiring extra pressure for expression.[51]

When examining the glands, the presence of notching at the lid margin indicates areas of complete gland dropout.[4] Additionally, meibomian foam or frothing (saponification) may be observed in patients with MGD. Frothing of the tears occurs when microbial flora produce biofilm, releasing exotoxins and lipase, leading to inflammation at the lid margin. This process breaks down tear lipids into soaps and free fatty acids, resulting in saponification of the tear film.[33,52]

Step Seven: Corneal Sensitivity

During every initial dry eye consultation, corneal sensitivity testing should be conducted before the instillation of any topical anesthetic. This test can be performed with a Cochet-Bonnet esthesiometer or with the use of a cotton tip or dental floss. It is important to assess all four peripheral quadrants (nasal, temporal, superior, inferior) and the central cornea.[53]

Deficient corneal sensitivity is an indicator for dysfunction of the nasociliary branch of the trigeminal cranial nerve. Early neurotrophic keratitis (NK) can present with a keratitis that looks similar to that seen with DED. Although traditional dry eye treatment does benefit patients with NK, it is not necessarily treating the root cause and, for that reason, early identification and appropriate management is necessary. NK classically presents with reduced corneal sensation and impaired corneal healing, which can lead to corneal ulceration.[54]

Step Eight: Tear Quality and Ocular Surface

Tear quality and ocular surface assessment is pivotal in the diagnosis of DED. Using vital dyes and conducting tests such as Schirmer and Jones can provide valuable information for an accurate diagnosis.

Tear film. Normal tear meniscus height ranges from 0.2mm to 0.5mm.[55,56] A meniscus of less than 0.2mm can indicate aqueous-deficient DED.[57] If you don't wish to quantify the tear meniscus height, it is a good habit to grade it as low, average or high when viewed under the slit lamp (*Figure 8)*.

Schirmer 1 test, without anesthetic, is another method to obtain a quantitative value of tear production. A Schirmer strip is placed into the lower fornix for five minutes, measuring both basal and reflex tearing. Schirmer 1 can also be conducted with the addition of an anesthetic drop, if trying to measure just basal tear volume. A measurement of less than 10mm wetting is considered abnormal.[46]

Dry eye patients may experience epiphora, but it's crucial to rule out other causes.[58] Ensure the puncta are patent, the lid architecture is intact without ectropion, and there is no blockage within the lacrimal system. Jones 1 and 2 tests are invaluable for assessing suspected lacrimal system obstructions.[59] In the Jones 1 test, fluorescein dye is instilled in the fornix; if dye is present upon the patient blowing their nose, it indicates a positive result. If Jones 1 is negative, Jones 2 can be performed by dilating the puncta and irrigating the lacrimal system with a cannula. Sensation or the taste of saline confirms the patency of the lacrimal system.[60]

Ocular surface. Vital dye staining is a crucial component of a dry eye assessment. Several dyes can be used for evaluating the ocular surface, including sodium fluorescein (NaFl), lissamine green and rose bengal.

The standard dye for ophthalmic assessment is NaFl.[2] It is important to use a very small amount to avoid excess dye and improper assessment. Avoid the use of a combined sodium fluorescein and anesthetic drop due to its anesthetic properties so the assessment is not affected. Also, avoid the introduction of excess dye into the tear film. NaFl theoretically can stain normal healthy cells but has a much higher affinity for areas where there is a disruption of the cell-to-cell

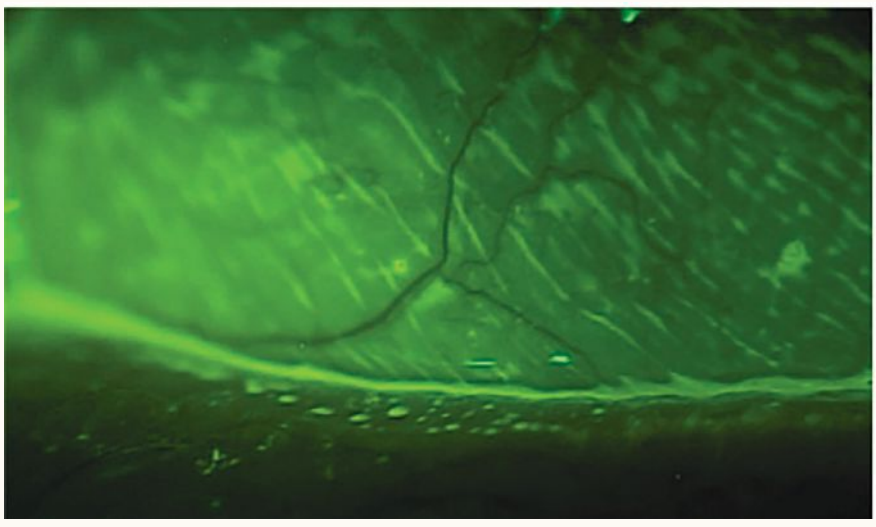

Fig. 8. Low tear meniscus.

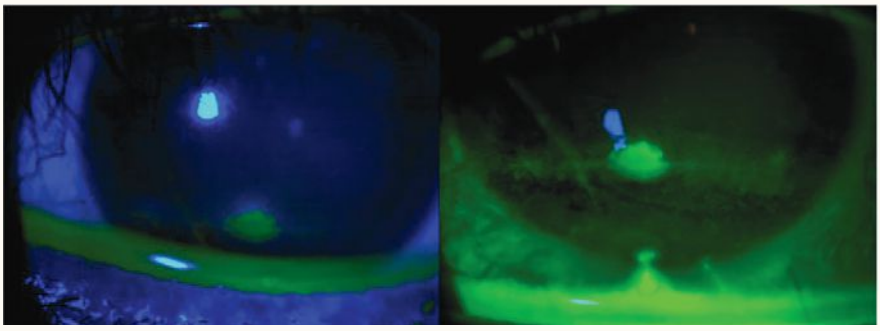

Fig. 9. Ocular surface viewing with just cobalt blue light (left) with a Wratten filter.

junctions.[2,50] The staining is best appreciated with a Wratten filter in conjunction with cobalt blue light, and conjunctival staining can also be better appreciated with the filter (*Figure 9*). NaFl can also be used to calculate the TBUT, which allows for the assessment of tear stability and evaporative DED. A TBUT greater than 10 seconds is considered normal, less than five seconds is low and anything in between is marginal.[61]

Lissamine green and rose bengal are two other, less-used vital dyes for ophthalmic staining assessment. Lissamine green stains epithelial corneal and conjunctival cells that are unprotected by mucin or glycocalyx, along with degenerated and dead cells.[62] Due to its better contrast than NaFl, lissamine green is excellent for assessing conjunctival staining and for lid wiper epitheliopathy without the need for a Wratten filter. However, a study concluded NaFl staining with a Wratten filter to be more sensitive in detecting conjunctival staining than lissamine green, while also allowing for corneal assessment.[63] Rose bengal is less commonly used due to its toxicity and stinging upon instillation. Similar to lissamine green, it stains degenerated and dead cells.[64] There have been some findings indicating that rose bengal, along with NaFl, can also stain normal healthy epithelial cells.[65]

Understanding staining patterns can often help narrow the differential diagnoses (*Figure 10*).[3,66] Superior corneal and/or conjunctival staining, as shown in *Figure 10A*, can be due to superior limbic keratoconjunctivitis, trichiasis or a foreign body. *Figure 10B* illustrates inferior staining, which can be due to lagophthalmos or incomplete blinking. An inferior-central band, depicted in *Figure 10C*, can result from exposure or NK. Diffuse staining, shown in *Figure 10D*, can indicate viral conjunctivitis or a toxic reaction.[3] Temporal conjunctival staining, as seen in *Figure 10E*, is often associated with Sjögren's syndrome.[67] Lastly, *Figure 10F* shows nasal conjunctival staining, which can be one of the first areas affected in DED patients.[64]

While assessing the cornea and conjunctiva for staining, it is important to look for conjunctivochalasis (CCH). This condition, which is the result of loss of elasticity within the conjunctiva, most commonly affects the inferotemporal bulbar conjunctiva.[68] Patients with CCH can present with symptoms similar to DED, which worsen in downgaze. These patients also tend to experience blurry vision and discomfort that does not resolve with blinking. This is because the upper eyelid, instead of collecting tears, contacts the loose conjunctiva and is unable to spread the tears onto the corneal surface properly.[69]

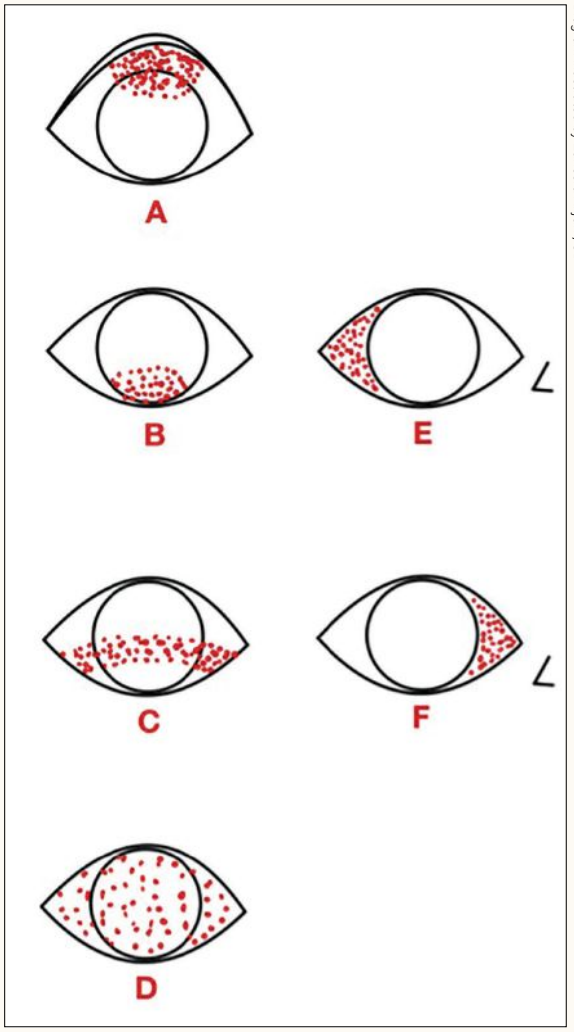

Diagram illustrated by Zuneera Anjum, OD

Fig. 10. Common ocular surface staining patterns.

Final Remarks & Discussion

The follow-up schedule is as important as the initial workup and prescribed treatment for managing DED. Given that dry eye is a chronic condition, it should be treated with the same long-term care approach as other chronic ocular conditions. Patients should be seen at appropriate intervals based on the severity of their condition. Regular follow-ups and repeat diagnostic testing are essential to ensure that DED does not worsen and to catch any progression early, allowing for timely management.

The most essential tools for managing dry eye include a slit-lamp, sodium fluorescein strips and a method for capturing slit-lamp photos. It is important to document photos for comparison and even more important for patient education.

The prevalence of DED necessities a mode for its assessment during every comprehensive exam. It should be managed and treated like any other serious ocular condition. Clinicians now have a wide array of treatment options, and more are on the horizon. An accurate diagnosis is essential before initiation of treatment, given addressing the underline condition rather than just the symptoms will yield the best outcome for the patient. By establishing a stepwise approach, clinicians can effectively address DED, ensuring optimal outcomes and improved quality of life for 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, Attn.: CE Processing, Jobson Healthcare Information, LLC/WebMD, 283-299 Market Street, 2 Gateway Center, 4th Floor, Newark, NJ 07102. 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 medication class is NOT known to cause DED?
A. Antihypertensives.
B. Chemotherapy agents.
C. Antidepressants.
D. HMG-CoA reductase inhibitors.

2. Which gland is biopsied to confirm suspicion of Sjögren's syndrome?
A. Salivary gland.
B. Thyroid glands.
C. Pituitary gland.
D. None of the above.

3. Which of the following is the most common type of DED?
A. Aqueous deficient.
B. Evaporative.
C. Mucin deficient.
D. None of the above.

4. Which of the following systemic conditions is commonly associated with DED?
A. Hypertension.
B. Sjögren's syndrome.
C. Asthma.
D. Migraine.

5. Which layer of the tear film is most responsible for reducing evaporation?
A. Lipid layer.
B. Aqueous layer.
C. Mucin layer.
D. All layers equally.

6. What is considered an abnormal TBUT?
A. >10 seconds.
B. <10 seconds.
C. <12 seconds.
D. >20 seconds.

7. What is/are the best way(s) to evaluate improper eyelid closure?
A. With a Wratten filter.
B. Korb-Blackie.
C. Viewing lid closure under the slit lamp.
D. Both B and C.

8. Where is corneal staining most likely to occur in patients with neurotrophic keratitis?
A. Superior.
B. Nasally.
C. Inferior-central.
D. Temporally.

9. Which of the following vital dyes can also stain normal, healthy cells?
A. Sodium fluorescein (NaFl).
B. Lissamine green.
C. Rose bengal.
D. Both A and C.

10. What is the MMP-9 concentration threshold for a positive InflammaDry test result?
A. >40 ng/mL.
B. >35 ng/mL.
C. >100 ng/mL.
D. >500 ng/mL.

11. How long should the Schirmer strip be left in place during a Schirmer test?
A. Two minutes.
B. Three minutes.
C. Four minutes.
D. Five minutes.

12. What is the significance of notching or scalloping at the eyelid margin?
A. Indication of telangiectasia.
B. Area of complete gland dropout.
C. Presence of ***Demodex***.
D. Sign of inflammation.

13. Which of the following systemic conditions does NOT typically contribute to DED?
A. Diabetes.
B. Thyroid disease.
C. Asthma.
D. Rheumatoid arthritis.

14. What is the function of cathelicidin in ocular rosacea?
A. Anti-inflammatory and vasodilator.
B. Pro-inflammatory and vasoactive.
C. Antimicrobial and anti-inflammatory.
D. None of the above.

15. What is the purpose of the Korb-Blackie test?
A. Measure tear osmolarity.
B. Assess lid closure.
C. Evaluate corneal sensitivity.
D. Assess gland expression.

16. Which meibomian gland characteristic CANNOT be assessed with meibography?
A. Gland atrophy.
B. Gland tortuosity.
C. Gland segmentation.
D. Gland expression.

17. What is the main mechanism through which CCH leads to dryness of the corneal surface?
A. The excess conjunctiva sitting on the lower lid causes inflammation of the lid leading to MGD.
B. Upper eyelid makes contacts with loose conjunctiva and is unable to spread the tears throughout the corneal surface.
C. The excess conjunctiva blocks tear production.
D. The excess conjunctiva rubs against the corneal surface leading to dysfunction of the corneal epithelial cells.

18. Which cranial nerve is being evaluated in the corneal sensitivity testing done to confirm the presence of neurotrophic keratitis?
A. CN III (oculomotor nerve).
B. CN V (trigeminal nerve).
C. CN VII (facial nerve).
D. None of the above.

19. How long is the life cycle of *Demodex*?
A. Two weeks.
B. Six weeks.
C. One week.
D. 10 weeks.

20. What difference in inter-eye osmolarity is indicative of a dysfunctional tear film?
A. ≥10.
B. ≥8.
C. ≥20.
D. ≥308.

Examination Answer Sheet

A Stepwise Approach to Diagnosing Dry Eye Disease

Valid for credit through August 15, 2027

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

Directions: Select one answer for each question in the exam and completely darken the appropriate circle. A minimum score of 70% is required to earn credit.

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Answers to CE exam:

1. Ⓐ Ⓑ Ⓒ Ⓓ
2. Ⓐ Ⓑ Ⓒ Ⓓ
3. Ⓐ Ⓑ Ⓒ Ⓓ
4. Ⓐ Ⓑ Ⓒ Ⓓ
5. Ⓐ Ⓑ Ⓒ Ⓓ
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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. Systematically evaluate and identify dry eye disease. ① ② ③ ④ ⑤
22. Conduct a comprehensive patient case history when DED is suspected. ① ② ③ ④ ⑤
23. Effectively use dry eye questionnaires to support the care of these patients. ① ② ③ ④ ⑤
24. Recognize when specific testing is necessary for a thorough dry eye evaluation. ① ② ③ ④ ⑤

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

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

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

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

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

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

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

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

Ⓐ Very confident Ⓑ Somewhat confident Ⓒ Unsure Ⓓ Not confident

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

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

30. Additional comments on this course: _____

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

First Name
Last Name
E-Mail
The following is your: ☐ Home Address ☐ Business Address
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City State
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Telephone # - -
Fax # - -
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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 125287 RO-OSC-0824

BY PAUL M. KARPECKI, OD
CHIEF CLINICAL EDITOR

OSD Management in Glaucoma Patients

How to minimize the use of drops while treating both conditions.

While many patients with glaucoma experience ocular surface disease (OSD) issues, adding another bottle to a glaucoma patient already on chronic medications could result in a loss of compliance and the potential for intraocular pressure rise. However, not treating the OSD can also lead to patients discontinuing their glaucoma medications secondary to pain and discomfort. How do we solve this dilemma?

Implications of Topical Glaucoma Agents on the Ocular Surface

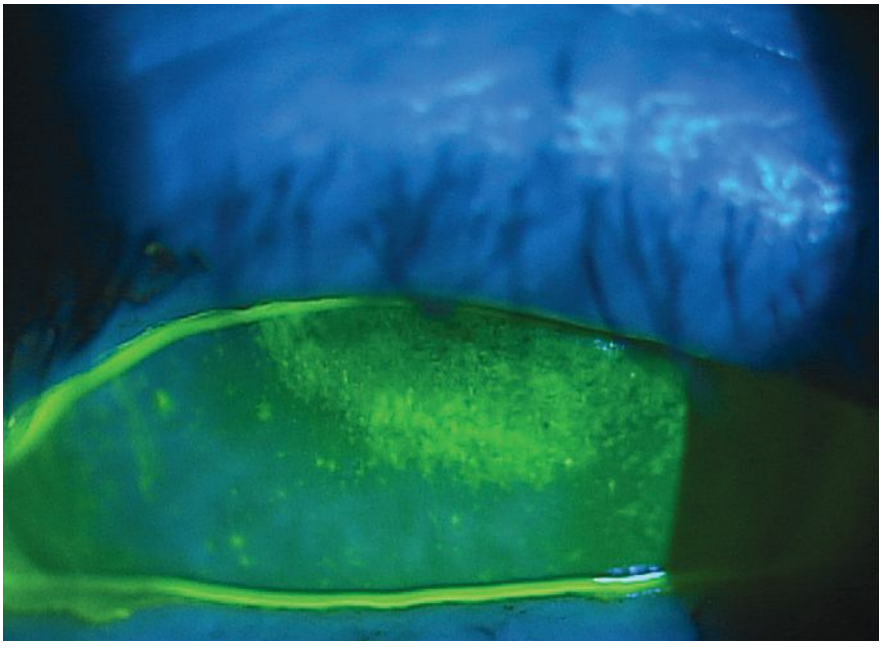
A key clinical consideration for topical antiglaucoma medications is their potential to cause or exacerbate OSD. Though they are a first-line treatment in glaucoma therapy, prostaglandin analog have been associated with a high rate of meibomian gland dysfunction.[1] It is critical that eyecare practitioners (ECPs) understand the chronic effects of these drugs for patients, and consequently, for patient adherence.

An additional contributor to OSD in patients with glaucoma-induced dry eye is chronic exposure to formulations containing preservatives such as benzalkonium chloride (BAK). Nonspecific to any class of antiglaucoma agents, BAK is an inflammatory element that can damage the ocular surface epithelium, disrupt the tear film and even lead to punctate keratitis of the cornea.[2] Some preservative-free glaucoma medications are an option, although payor coverage is variable. These include Iyuzeh (latanoprost 0.005%, Thea Pharma), Zioptan (tafluprost 0.0015%) and Cosopt PF (dorzolamide/timolol ophthalmic solution 2%/0.5%). Another option, such as selective laser trabeculoplasty, may not address ocular surface symptoms but can help reduce drop burden.[3] MIGS—if cataract surgery is needed—or injecting bimatoprost SR (Durysta, Abbvie) are other options; however, some patients may not be candidates or not have access.

Owing to their side effect profile, topical antiglaucoma agents often present a challenge to medication adherence. Patients may be noncompliant or even self-discontinue their chronic glaucoma medications due to discomfort, irritation and/or blurred vision.[4] Beyond reinforcing patient education, ECPs should understand that management of dry eye disease (DED) in patients with glaucoma require a different set of treatment considerations.

Shift in Clinical Approach

The neurotrophic effects from chronic use of proinflammatory drops and preservatives can be a differentiating factor in how patients present with glaucoma-induced dry eye. Whereas DED symptoms commonly include dryness and irritation in the general population, patients with chronic glaucoma typically report blurred vision, irritation and painful discomfort, specifically when instilling antiglaucoma drops. Another



Neurotrophic keratitis in a patient with longstanding use of topical glaucoma agents.

About Dr. Karpecki

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

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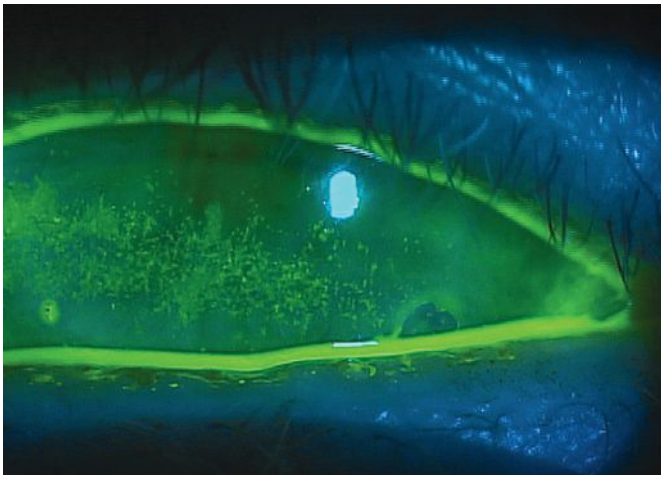

Glaucoma-induced dry eye in a patient using multiple BAK-preserved therapies.

This patient with glaucoma-induced dry eye and a thin tear meniscus could benefit from punctual occlusion.

set of unique differences in this group is that patients often have pre-existing conjunctival hyperemia from glaucoma drops and/or report photophobia.

While steroid drops are often used in dry eye patients with superficial punctate keratitis, long-term use of steroid drops would be a contraindication in patients with glaucoma. Yet ECPs should also think broadly about reducing the eye drop burden, or at the very least, the implications of an additional eye drop in a glaucoma regimen that already incorporates multiple daily administrations. In-office procedures can be an effective way to manage patients with glaucoma-induced OSD.

If targeting the meibomian glands, thermal expression procedures such as intense pulse light therapy and low-level laser therapy or thermal expression procedures (TearClear, iLux or LipiFlow) help avoid noncompliance. Alternatively, punctal plugs can be an excellent treatment for patients with DED to help with dry eye and have also been shown to increase the effectiveness of glaucoma medications.[5,6] To avoid irritation on the ocular surface, consider punctal plugs that reside in the vertical canal only or fill the entire lacrimal system. Such examples are the 180 dissolving punctal plugs with tapered ends (Oasis Medical), form-fitting punctal plugs (Oasis Medical) or lacrimal fillers (Lacrifill, Nordic Pharmaceuticals).

Avoiding the Ocular Surface

Prescription therapies such as varenicline (Tyrvaya, Viatris Pharmaceuticals) are neurostimulators that use the nasal route to promote a basal tear reflex, replenishing all three layers of the team film. External stimulators iTear 100 (Olympic Ophthalmics) can also be ordered that also have good success in stimulating basal tear production when needed.

Amniotic Membrane

In light of some of the current limitations of inflammation treatment, amniotic membrane can be an excellent in-office option.[7] For example, cryopreserved material (Prokera, BioTissue) maintains key anti-inflammatory components that form the heavy-chain, high molecular weight hyaluronic acid/pentraxin 3 (HC-HA/PTX 3) matrix for corneal wound healing.[8] Patients with a trabeculectomy bleb may not be suitable for treatment with CAM in part due to irritation concerns. In this case, there are dehydrated formulations that maintain many anti-inflammatory components and growth factors (*e.g.*, Apollo, Atlas Medical). The rapid effects (typically inserted for three to four days in the case of cryopreserved amnion) make it a favorable option in glaucoma-induced dry eye management.

More commonly, patients with glaucoma-induced dry eye who are affected through the meibomian glands stand to benefit from a targeted approach.

Implementing Best Treatment Practices

Like any chronic disease, OSD is more effectively managed with early treatment. In cases of glaucoma-induced OSD, the cause or stimuli of dry eye symptoms will typically remain in place for the rest of many patients' lives with the use of IOP-lowering drops. Early disease identification combined with aggressive treatment that minimizes the use of drops and preservatives is an ideal way of managing this large subset of patients. ■

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30

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INDICATION

RYZUMVI™ (phentolamine ophthalmic solution) 0.75% is indicated for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

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

Adverse Reactions

The most common adverse reactions that have been reported are instillation site discomfort (16%), conjunctival hyperemia (12%), and dysgeusia (6%).

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CONTRAINDICATIONS: None.

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

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

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

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

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

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

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

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BY NATE LIGHTHIZER, OD

Cloudy Gives Way to Clear

YAG laser capsulotomy is an in-office ophthalmic procedure that has been giving sight back to patients for decades.

"Doc, I think my cataracts have come back." We have all heard that statement before, especially after cataract surgery. Yttrium aluminum garnet (YAG) laser capsulotomy, a procedure that came about in the late 1970s, is an in-office intervention that is being performed more and more by optometrists as scope of practice advances across the nation. It is one of the most rewarding procedures eyecare providers perform and likely represents the number one laser procedure that optometrists have been completing over the past decade. Here are the nuts and bolts of the procedure.

Indications and Contraindications

Knowing when to do vs. when not to do a procedure is critical for any treating doctor. YAG laser capsulotomy is indicated following cataract surgery when posterior capsular opacification (PCO) has caused vision to fall to the point where it affects activities of daily living. Generally, patients often have visual acuities of 20/25, 20/30 or worse, but glare symptoms or other affected activities of daily living may drive a patient to seek care before vision has fallen on the Snellen acuity chart.

Contraindications include active inflammation within the eye, significant corneal or other media opacities that affect viewing of the posterior capsule and a patient that is unable to hold steady or fixate appropriately to undergo the procedure. Any active retinal conditions—such as macular edema, macular hole or vitreomacular traction, among others—should be properly assessed. Also, determine whether a retinal consult should be obtained before performing the YAG capsulotomy, as there is the rare risk of worsening macular or retinal conditions when a laser procedure is performed inside the eye. In my experience, the report back from the retina specialist quite often includes a statement like "clear up and open the posterior capsule so I can better assess the retinal condition." Regardless, caution is always recommended especially in early cases.

Potential Complications

Fortunately, these are rare with YAG laser capsulotomy. Rare complications, including the approximate rate of occurrence based on the literature and clinical experience, as well as proper management if the complication occurs, include:[1-5]

• ***Intraocular pressure (IOP) spike, 5% to 15%.*** The literature shows an IOP spike rate of approximately 10% following capsulotomy; however, with pre- and postoperative in-office use of brimonidine, clinical experience shows the rate of IOP spike to be in the range of 1% to 5%.

• ***Inflammation/uveitis, 1% to 10%.*** The rate of a clinically significant iritis following a YAG capsulotomy is very low. The more energy used for the procedure, the higher the likelihood of an inflammatory response. This can be controlled in the postoperative period with a topical steroid if needed.

• ***Intraocular (IOL) lens pitting, 8% to 33%.*** Proper focus of the laser and

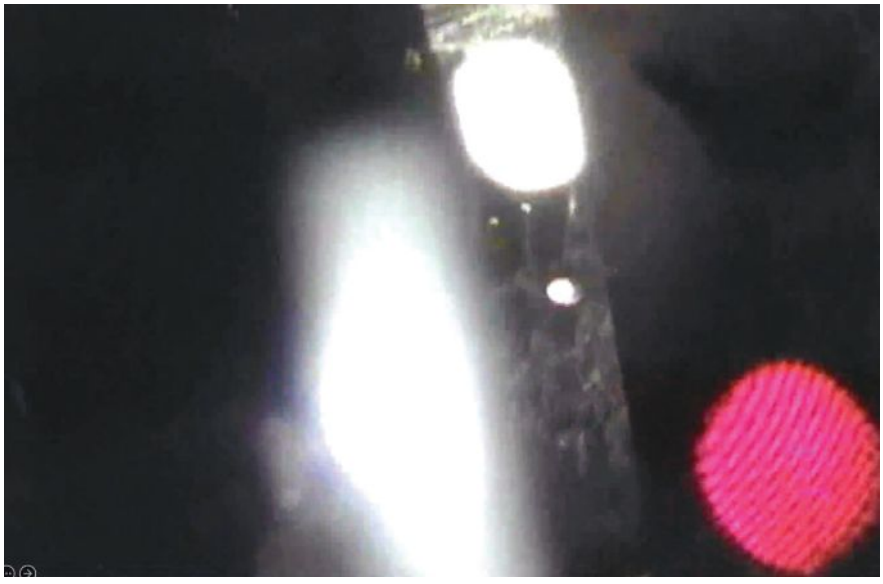

Fig. 1. Peripheral lens pit seen while doing a YAG capsulotomy. This indicates laser energy was focused too far anteriorly. Acuity was not affected due to the peripheral location.

About Dr. Lighthizer

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

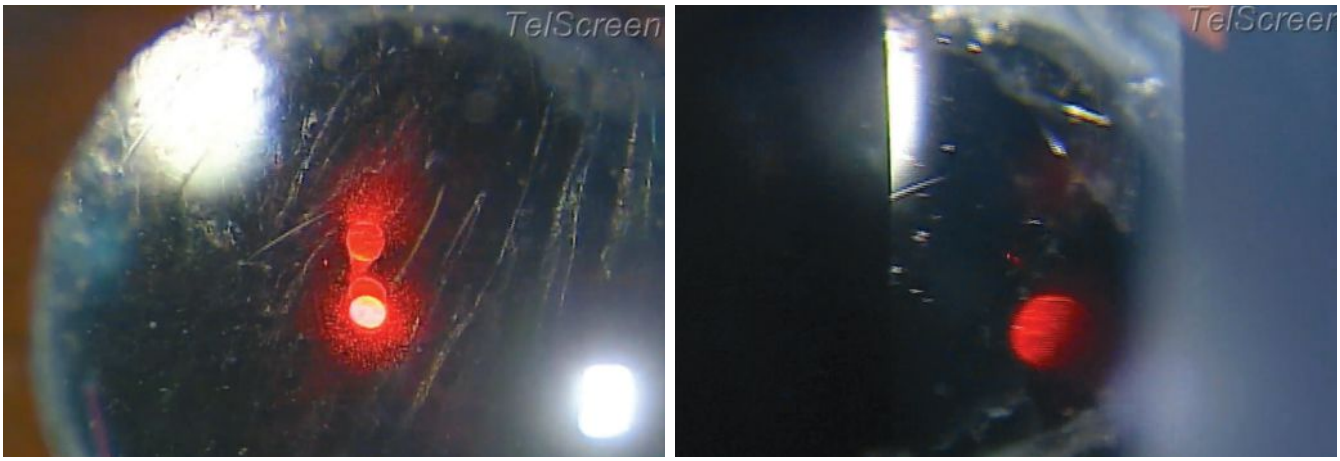

Photo: NSU Oklahoma College of Optometry

Fig. 2. Preoperative appearance of a standard grade 2 PCO (left), as well as the appearance of the capsule at the end of the procedure (right). Notice the nicely opened capsule. Visual acuity improved from 20/40 to 20/20.

correct offset settings will minimize this potential complication (*Figure 1*).

• ***Floaters, 10% to 20%.*** Based on clinical experience. A temporary increase in floaters is fairly common after a YAG; however, the floaters most often subside in a matter of days to weeks.

• ***Cystoid macular edema, 0% to 2.9%.*** Very rare complication which can be treated with topical steroid and/or topical non-steroidal drops.

• ***Retinal tears/breaks/detachments, 0% to 2.3%.*** Very rare complication that can occur anywhere from days to a year plus following a YAG capsulotomy. Proper diagnosis and prompt referral to a retinal specialist is warranted.

Procedural Technique

Let's review how to perform YAG capsulotomy.

1. Complete a thorough dilated fundus exam including posterior pole and peripheral retinal evaluation.

2. Preoperative drops include topical ophthalmic brimonidine one to two drops in the eye to be treated 10 to 15 minutes prior to the procedure to help blunt the risk of an IOP spike, along with topical ophthalmic proparacaine immediately prior to the procedure in both eyes to eliminate a blink reflex. A consent form should be reviewed and signed before every procedure.

3. The use of a YAG capsulotomy laser lens is physician preference, with ophthalmology surveys showing approximately half of ophthalmologists prefer the use of a laser lens, while the other half prefers to do the procedure without a laser lens. I prefer to use a laser lens to give control and stability of the eye and provide a better view of the posterior capsule, especially if any ocular surface disease is present. Cushioning solution, such as Genteal gel (hypromellose 0.3%, Novartis), is necessary if a laser lens is used. Downsides of using a laser lens include another step that needs to be done (putting the laser lens on the eye), as well as another interface for glare to develop along with bubbles to form in the cushioning solution.

4. Laser settings are critical to properly perform any laser procedure. Three main settings can be adjusted by the physician as the YAG laser is being set up to perform a YAG capsulotomy.

Energy (in mJ). Typically, energy setting varies based on physician preference and thickness and density of the PCO. It is recommended to start in the range of 1.5mJ to 2.0mJ. I use 1.6mJ for a standard grade 1 to 2+ PCO.

Offset (in microns). Using a posterior offset is important to minimize the likelihood of lens pitting during the procedure. The recommendation is somewhere between 150µm and 300µm of posterior offset when performing a standard YAG laser posterior capsulotomy. This setting is again a physician preference. The type of IOL material can also play a role in how much offset is used, with clinical experience showing that silicone IOLs (such as the light-adjustable lens) are perhaps slightly more prone to pitting, and therefore some recommend increasing the offset by an extra 50µm to 100µm whenever treating silicone IOLs.

Burst mode (single, double or triple shot). Typically, YAG capsulotomies are performed on single shot mode as that is all that is needed. Double shot or triple shot are typically reserved for YAG laser peripheral iridotomies in darker irises.

One critical note: a timeout should be performed by the doctor and one other individual (*e.g.*, staff member, student, resident) after the laser settings have been dialed in and before the procedure begins to double check and ensure that the right laser mode/setting is selected along with the correct and intended energy level, offset and burst mode. A timeout should be performed prior to every procedure.

5. The YAG laser capsulotomy pattern or technique is also dependent on physician preference. YAG capsulotomy techniques or patterns include cruciate/modified cruciate (cross-like), circular, hinge/horseshoe, spiral, star and postage stamp.

Of these types of patterns, the cruciate/cross-like and circular are the most common and most popular among treating eyecare providers. Ophthalmology

surveys show that the cruciate technique is more than double the next most popular pattern, which is the circular technique. One study reported that "Both the cross-like and circular YAG capsulotomy techniques induce similar visual and IOP changes. The circular technique is associated with a higher amount of energy used and more floater symptoms."[6]

I prefer the cross-like pattern starting near the top center of the PCO and working my way straight down the vertical meridian. Once the vertical meridian is complete and open, the horizontal part of the cross pattern is done, starting near the center and working outwards towards the periphery in both the left and right directions (*Figures 2 and 3*). If the capsule is agreeable, the four flaps that are formed from the cross-like technique will fold back on their own instantaneously and won't require many further shots to move the flaps away from the visual axis. Often, the flaps won't fold back on their own instantaneously, and a few more shots at each flap will be required to assist each flap in folding back and out of the visual axis.

6. The typical number of shots for a YAG capsulotomy is often somewhere between 20 and 60, although some cases require more or fewer shots depending on the thickness and density of the PCO. Our record is a seven-shot capsulotomy by Greg O'Brien, OD, during his residency approximately 15 years ago. Beat that!

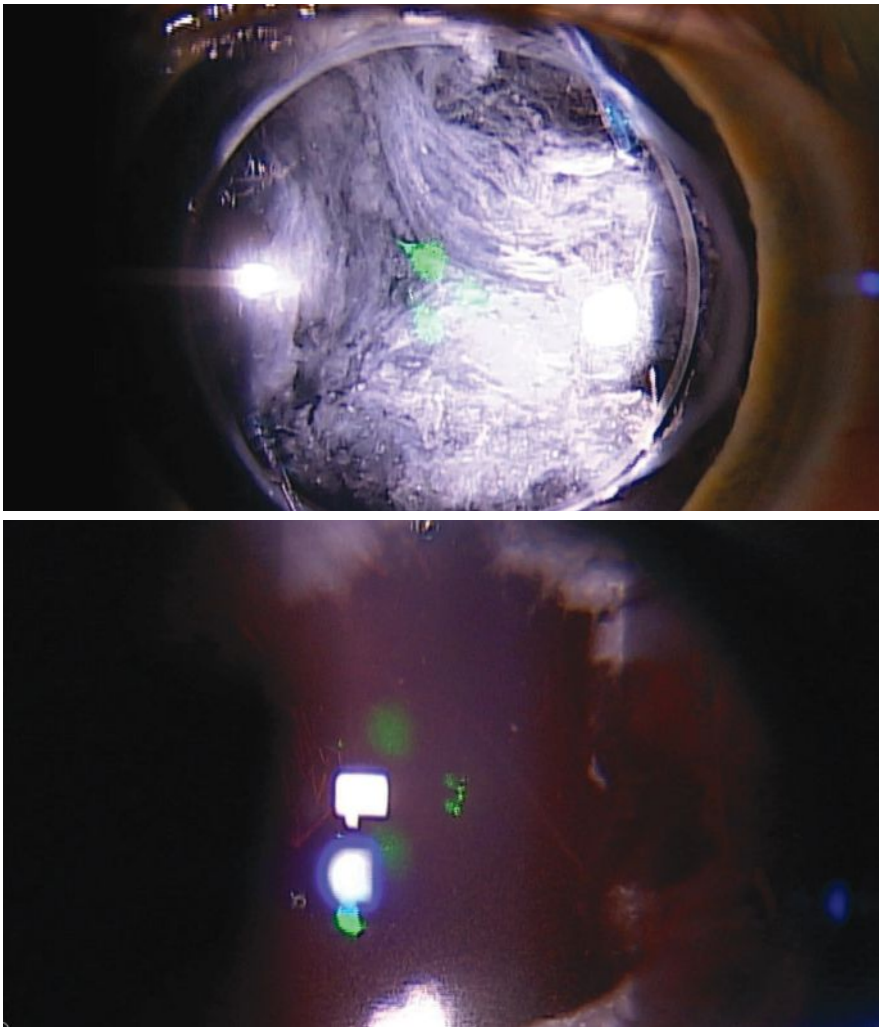

Fig. 3. Preoperative appearance of a significant grade 4 PCO (top), as well as the appearance of the capsule at the end of the procedure (bottom). Visual acuity improved from hand motion to 20/30.

7. Once the YAG capsulotomy is complete, one to two drops of topical ophthalmic brimonidine are instilled in the treated eye again to control for any postoperative IOP spike. We check the patient's IOP 30 to 60 minutes after the procedure, and if the IOP is similar to preoperative levels, we release the patient until the one-week follow-up visit. We currently do not put the patient on a postoperative steroid eye drop; however, depending on practitioner preference and number of shots needed to clear the PCO, a topical steroid two to four times daily for three to five days could be prescribed.

Takeaways

YAG laser capsulotomy is almost always a quick in-office procedure that greatly helps patients see better and improve on their activities of daily living. The literature has shown that YAG laser capsulotomies are effective treatments to improve patient vision that can be safely and effectively performed by ODs.[7] Optometrists nationwide are encouraged to adopt this procedure if scope of practice allows in your state or be very familiar with the comanagement aspects of the procedure if current scope does not allow it. YAG laser capsulotomy is one of the most rewarding procedures for eye doctors, and, most importantly, one of the most immediately gratifying and helpful procedures for patients. ■

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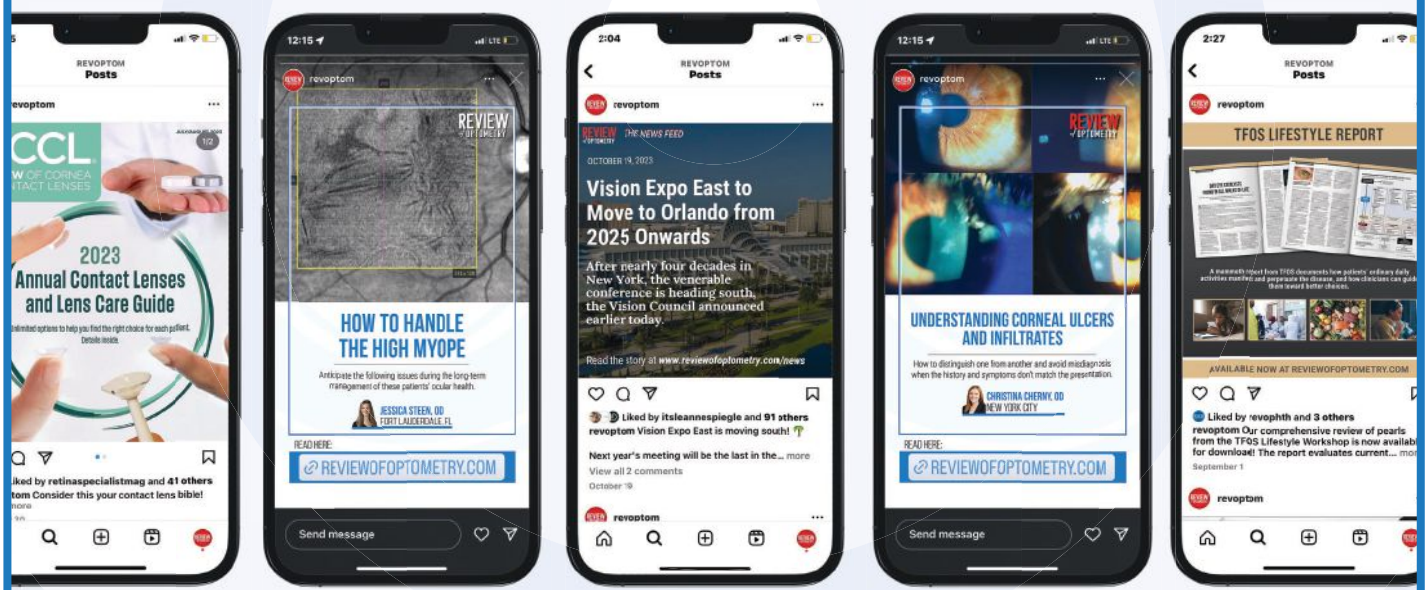
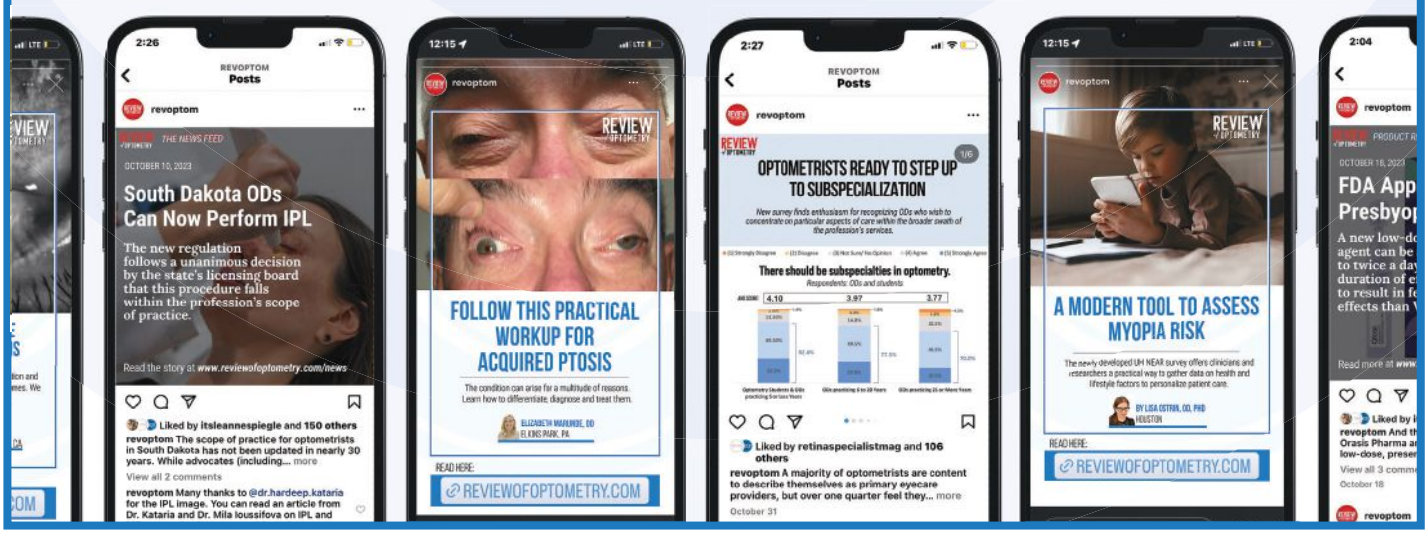




Move Over, PK

DMEK and DSEK are now the most commonly performed keratoplasty procedures.

BY JOSHUA BLACK, OD
VIRGINIA BEACH, VA

In our June column, we discussed post-op management of penetrating keratoplasty (PK)—the first corneal transplant procedure, dating back to 1905. While many cornea surgeons still perform this procedure today, it's no longer the most common for corneal transplants. In this month's column—part two in our mini series on keratoplasty procedures—we'll discuss two surgical techniques that have recently surpassed PK in popularity among physicians.

The corneal endothelium is a fragile but vital layer of cells responsible for maintaining corneal clarity by transporting water out of the stroma. These cells do not replicate, leaving the cornea susceptible to developing edema should the endothelium become diseased due to conditions such as Fuchs' dystrophy.

Full-thickness PK involves removal of healthy anterior corneal layers to treat a solely posterior disease, often resulting in suboptimal vision and leaving patients susceptible to a host of complications.

In 1956, the first report of a posterior lamellar keratoplasty was published, which involved excising only the diseased posterior corneal layers and replacing it with healthy donor posterior tissue.[1] However, the idea was not further developed until the 1990s and early 2000s when a flurry of new techniques was attempted. Eventually, it was discovered that an air bubble injected into the anterior chamber can be used to push donor tissue against the host cornea.[2]

DSEK and DMEK

Various technique adjustments eventually led to Descemet stripping endothelial keratoplasty (DSEK), which has become widely accepted for treating endothelial disease given the improved visual outcomes compared to PK.[3]

In 2006, the first successful Descemet membrane endothelial keratoplasty (DMEK) was performed.[4] This technique selectively replaces the Descemet membrane and endothelium with a donor replacement disc that is roughly 10µm thick. DMEK allows for near-complete restoration of corneal anatomy; however, the procedure does involve a different skill set than DSEK to manipulate the incredibly thin donor membrane. Due to these technical challenges, DSEK was a more popular option until recently.

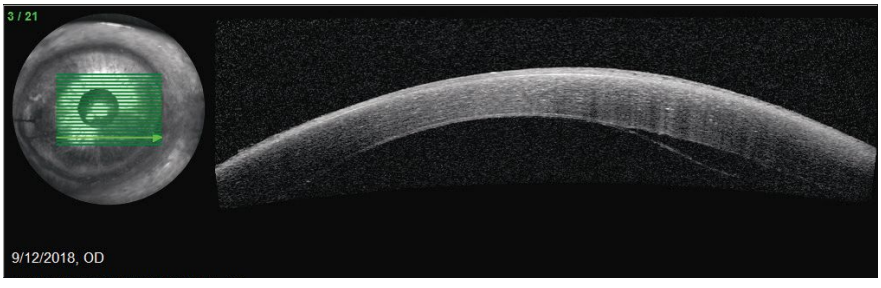
Currently, DSEK and DMEK are both commonly performed in the United States thanks to the efforts of eye banks. Cornea surgeons are now able to receive donor tissue that is fully processed and may even be preloaded into injector devices. The 2023 Eye Banking Statistical report showed that DMEK was, for the first time, the most common keratoplasty procedure performed followed by DSEK and then PK.[5] This highlights a recent trend toward DMEK surgery given its overall superior visual outcomes.[6]

Surgical Techniques

In general, endothelial keratoplasty procedures involve creating a paracentesis and main incision site. The recipient Descemet membrane and endothelium are scored 360° and a circular button of tissue is removed; this is known as a descemetorhexis. The prepared donor tissue is then inserted into the eye and apposed to recipient cornea. Temporal sutures are often used to close the main wound. An air bubble is injected underneath the graft to fill the anterior chamber. To prevent this bubble from causing pupillary block, an inferior iridectomy is performed, which may be done intraoperatively or preoperatively using a laser, or the eye may be dilated at the conclusion of the case.

Common Complications

With both procedures, graft dislocation is the most common complication.[7,8] Many of these small detachments resolve spontaneously; however, more



AS-OCT can be a useful tool in pre- and postoperative management. Shown here is an inferior dehiscence of DMEK graft.

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

About Drs. Cunningham and Whitley

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

extensive cases sometimes require an additional air injection to reattach the graft. Occasionally, the grafts never clear despite graft attachment, leading to primary graft failure. Over time, the grafts undergo endothelial cell loss, and the cornea may eventually become edematous, leading to secondary graft failure.[9] Graft rejection may also rarely occur.

Refractive considerations are also important. DSEK typically induces a hyperopic shift of about 1.00D to -1.50D, while DMEK induces a smaller shift of roughly 0.50D to 0.75D. Frequently, DSEK and DMEK are combined with cataract surgery, and the hyperopic shifts are accounted for during intraocular lens calculations. Very little, if any, irregular astigmatism is induced negating the need for rigid contact lenses, unlike PK.

In summary, DMEK has become the surgery of choice, as it has a greater potential to achieve excellent visual outcomes with lower risk of graft rejection. DSEK is more commonly reserved for complex cases, which pose challenges for graft unfolding. ■

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ABOUT THE AUTHOR

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BY RAMI ABOUMOURAD, OD

RETINA QUIZ

Spot Inspection

How do you stratify risk for this patient?

A 78-year-old Hispanic male presented for a new patient exam following uncomplicated cataract surgery 12 months prior; he had no visual complaints. Past medical history included coronary artery disease and stage IV metastatic lung cancer diagnosed 10 years prior. He received numerous rounds of chemotherapy and radiation since diagnosis and is still undergoing active treatment with pembrolizumab, docetaxel and ramucirumab under the care of his oncology team.

Best-corrected visual acuity was 20/25+2 OD and 20/20 OS, intraocular pressure was 11mm Hg OD and 10mm Hg OS, pupils were equally round and reactive without a relative afferent pupillary defect, extraocular motilities were full in all gazes and confrontation visual fields were full to finger counting in both eyes. Slit lamp examination revealed well-positioned intraocular lenses OU and trace posterior capsular opacification OD.

Take the Retina Quiz

1. What is the most likely diagnosis?
a. Choroidal melanoma.
b. Choroidal metastasis.
c. Choroidal nevus.
d. Congenital hypertrophy of the RPE.

2. Which of the following statements is true regarding this lesion?
a. Already malignant with high risk of metastasis.
b. Already malignant with low risk of metastasis.
c. Benign with high risk of transformation.
d. Benign with low risk of transformation.

*3. Which of the following clinical findings **is** a risk for malignancy?*
a. 3mm basal diameter.
b. 3mm thickness.
c. Thinning of the overlying retina.
d. Presence of drusen.

4. Which of the following imaging modalities is frequently used to assess this condition?
a. B-scan ultrasound.
b. OCT.
c. Fundus autofluorescence (FAF).
d. All of the above.

5. What is the most appropriate management of this patient?
a. Enucleation.
b. Fine needle aspiration biopsy.
c. Plaque brachytherapy.
d. Repeat examination in six months.

For answers to the quiz, turn to page 90.

Diagnosis

Fundus examination showed peripheral reticular degeneration OU and a 2.5-disc diameter hyperpigmented peripapillary lesion. The lesion was flat with overlying drusen, but no orange pigment or subretinal fluid (*Figures 1A and B*). OCT showed that the macula was flat OU (*Figures 2A and B*). OCT through the lesion showed homogeneous choroidal hyperreflectivity with overlying subretinal pigment epithelial (RPE) deposits and confirmed that the lesion was flat with no associated subretinal fluid; the lesion measured 3mm at greatest basal diameter on the OCT module (*Figure 2C*). FAF showed peripheral reticular degeneration OU without any abnormal peripapillary autofluorescence (*Figures 3A and B*).

Discussion

Choroidal nevi are the most common primary intraocular tumors and are benign in nature.[1] There is no gender predilection, and prevalence is estimated to be 5% to 25%, though highly variable based on the sampled population demographic.[1-3] For example, prevalence is estimated to be 5.6% in a Caucasian population, 2.7% in a Hispanic population and 2.1% in a Black population; however, the overall estimated prevalence of choroidal nevi in adults over age 40 in the United States is 4.7%.[2,3]

A series of 3,806 patients showed that 95% were Caucasian with a median age of 62.5, with the odds of having a choroidal nevus being 10-times higher in Caucasians and five-times higher in Hispanic vs.Black patients.[3,4]

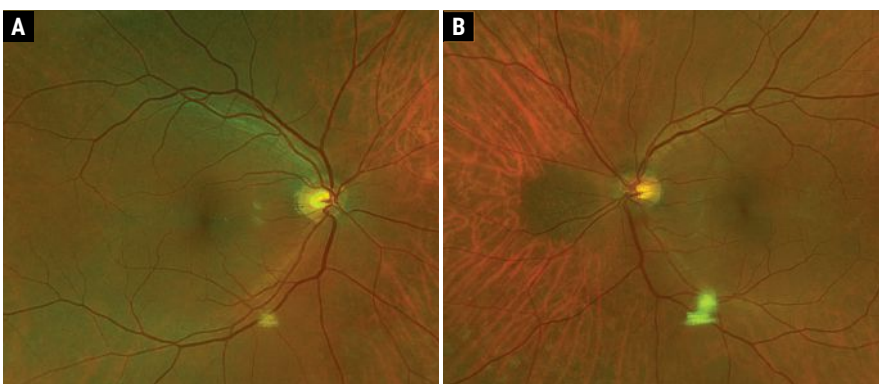

Fig. 1. Optos fundus photo of the right (A) and left (B) eye.

About the author

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

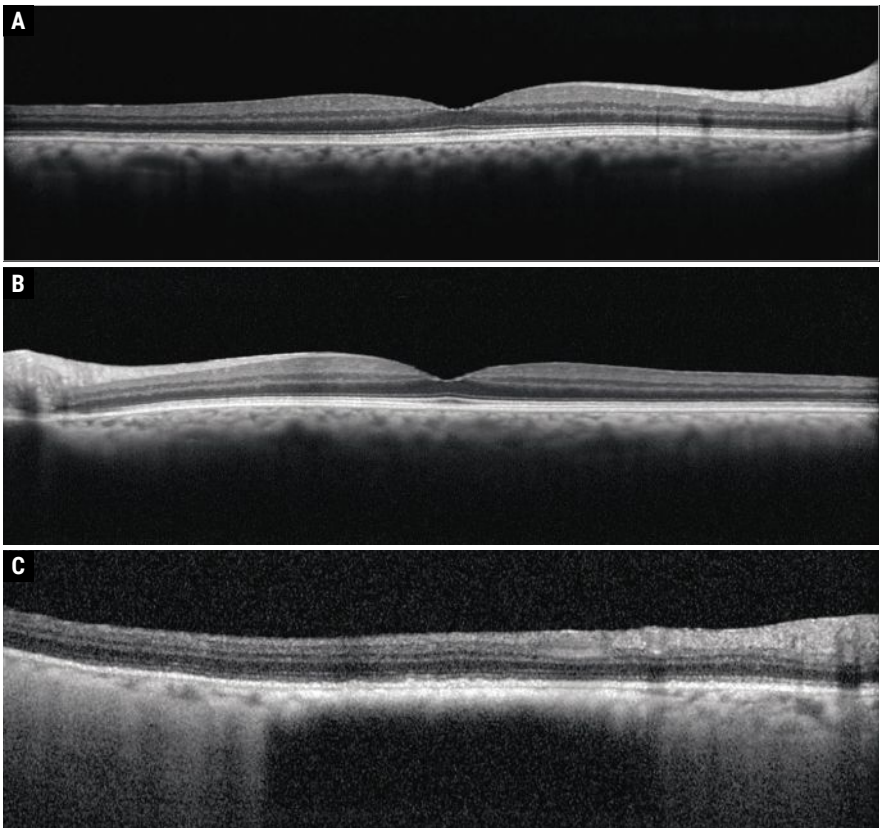

Fig. 2. Heidelberg OCT of the right macula (A), left macula (B) and peripapillary lesion (C).

Clinical Features

Choroidal nevi are commonly found as incidental findings on routine fundoscopy. They are typically well-circumscribed choroidal lesions <2mm in thickness and <5mm in diameter.[1] They may be melanocytic (pigmented) or amelanotic (nonpigmented).[1] Although nevi are benign, there exists an inherent risk of transformation to melanoma which carries with it the possibility of associated morbidity and mortality via metastasis.[1]

Clinical Assessment of Risk Factors

One study extensively published on the topic of choroidal nevus and established the mnemonic we now use routinely when assessing choroidal nevi to stratify risk of malignant transformation: *To Find Small Ocular Melanoma-Using Helpful Hints Daily* (TFSOM-UHHD).[5,6] Clinical risk factors for malignant transformation include: thickness >2mm; presence of subretinal fluid; presence of symptoms; presence of orange pigment (lipofuscin); posterior tumor margin <3mm from optic disc; ultrasound hollowness; absence of depigmented halo surrounding lesion; absence of drusen.[5-7] Low-risk clinical features include the presence of overlying drusen or RPE alterations, suggesting chronicity and representing overlying degenerative changes.[1]

In 1995, another study found that the clinical features of small melanocytic choroidal lesions portending greatest risk of metastatic disease were tumor location (posterior margin touching the optic disc), increased tumor thickness, symptomatic blurry vision and documented tumor growth.[6] However, the authors refuted this more recently in a 2019 analysis that showed proximity to disc, absence of drusen and absence of depigmented halo were not significant.[4] The aforementioned risk factors are actually most likely indicative of tumors that have already undergone malignant transformation rather than factors that precede it.[6] Documented growth carries an eight-times greater risk of metastatic disease than non-growing tumors.[6]

The mnemonic was therefore revised in 2019 to reflect lesion diameter: *To Find Small Ocular Melanoma Doing Imaging* (TFSOM-DIM).[4] The advent of multimodal imaging has further refined our ability to structurally assess these lesions in greater detail. OCT is excellent for identifying and monitoring drusen progression and overlying RPE changes, and it can also demonstrate overlying thinning and cystoid degenerative changes of the retina, which suggest chronicity.[4] The clinical finding of orange pigment is well-demonstrated as hyperAF on FAF imaging.[4] B-scan ultrasound is useful for detecting low echogenicity (hollowness) but is limited in its utility for thinner tumors.[4,8]

Enhanced-depth imaging (EDI) spectral-domain OCT allows for improved imaging capability of the choroid and provides an axial resolution of approximately 3µm to 4µm compared to 50µm to 200µm with ultrasound imaging.[9] Ultrasound tends to overestimate tumor thickness for flatter lesions, which is likely due to the imprecision associated with lower resolution and inability to accurately distinguish the junction of the overlying retina and underlying sclera.[9] However, limitations of OCT include patient cooperation, degree of lesion pigmentation, media clarity and anterior location.[8] In general, EDI-OCT is perhaps more useful and sensitive at monitoring small, flat, posterior lesions than ultrasound and/or clinical exam alone.[8]

Management, Prognosis and Risk of Transformation

It is recommended that choroidal nevi be evaluated twice in the first year they are observed, followed by annual examinations if noted to be stable in the first year. Ophthalmic and systemic morbidity and mortality due to choroidal nevi typically occur in the presence of subretinal fluid, choroidal neovascularization and malignant transformation.[2,4] In rare cases (~1%), choroidal nevi may grow exudative neovascular membranes that can require therapy.[4] Furthermore, all nevi carry potential for malignant transformation and should be followed accordingly. Kaplan-Meier estimates showed that in

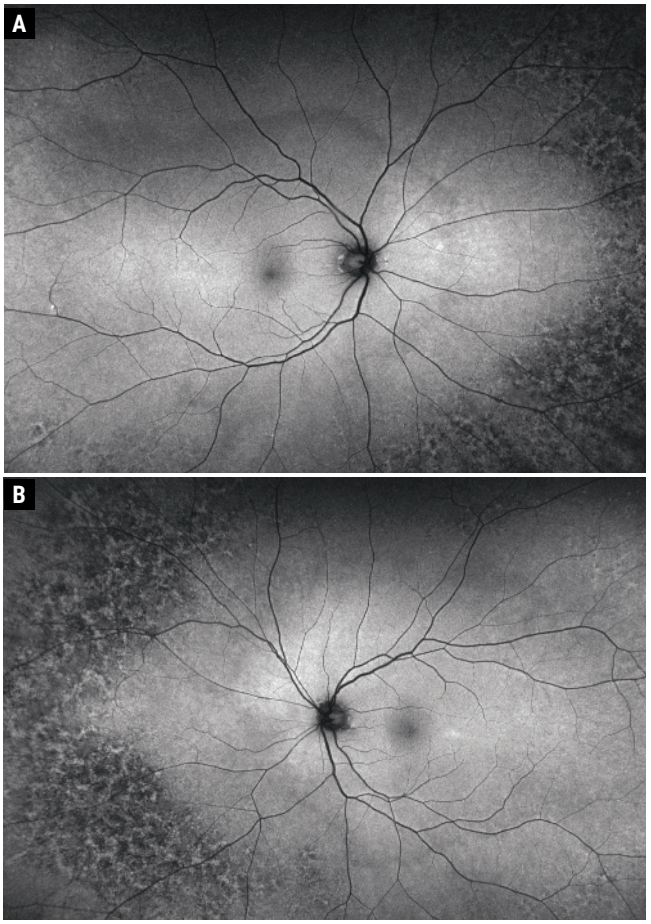

Fig. 3. Optos fundus autofluorescence of the right (A) and left (B) eye.

five years, patients with zero to five risk factors carried a 1.1%, 11%, 22%, 34%, 51% and 55% risk, respectively, of malignant transformation.[4]

Our patient has been followed for two years without demonstrable change in lesion size, presence of subretinal fluid or development of orange pigment. ■

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BY ANDREW S. GURWOOD, OD

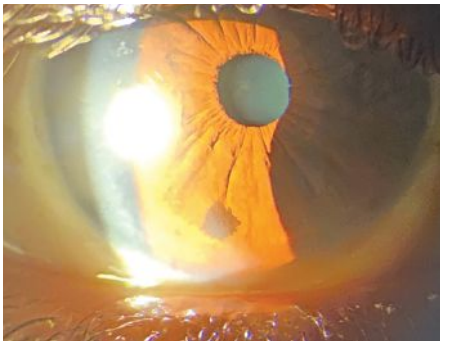
DIAGNOSTIC QUIZ

A Pigmentation Puzzle

When you see a suspicious lesion, do you have a plan for assessment and monitoring?

An 87-year-old Black woman was referred to the eye clinic for a cataract evaluation. She wanted a second opinion regarding the necessity of cataract removal, OU. Her systemic history was remarkable for hypertension, which was well controlled with oral medication daily. She denied allergies of any kind.

Her best-corrected entering visual acuities were 20/30 OU at distance and near. Her external examination was normal and there was no afferent pupil defect. The pertinent finding OD, discovered during the biomicroscopic exam of the anterior segment, is demonstrated in the photo. Goldmann applanation tonometry measured 15mm Hg OU. The dilated fundus exam findings were normal.



Slit lamp exam of the patient revealed these findings. What might be the prognosis?

Additional studies included photodocumentation and referral to an ocular oncologist to ensure no additional testing such as ultrasonography or biopsy was required.

Your Diagnosis

What would be your diagnosis based on the findings presented? What's the likely prognosis? To find out, read the online version of this article at www.reviewofoptometry.com. ■

Dr. Gurwood thanks Dr. Nick Karbach for his contributions to this case.

About Dr. Gurwood

Dr. Gurwood is a professor of clinical sciences at The Eye Institute of the Pennsylvania College of Optometry at Salus University. He is a co-chief of Primary Care Suite 3. He is attending medical staff in the department of ophthalmology at Albert Einstein Medical Center, Philadelphia. He has no financial interests to disclose.

Retina Quiz Answers—Q1: c, Q2: d, Q3: b, Q4: d, Q5: d

XDEMVY® (lotilaner ophthalmic solution) 0.25%, for topical ophthalmic use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see the XDEMVY® package insert for full Prescribing Information.

INDICATIONS AND USAGE
XDEMVY is indicated for the treatment of *Demodex* blepharitis.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Risk of Contamination Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with Contact Lenses Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS
Because clinical studies 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.

XDEMVY was evaluated in 833 patients with *Demodex* blepharitis in two randomized, double-masked, vehicle-controlled studies (Saturn-1 and Saturn-2) with 42 days of treatment. The most common ocular adverse reaction observed in controlled clinical studies with XDEMVY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary There are no available data on XDEMVY use in pregnant women to inform any drug associated risk; however, systemic exposure to lotilaner from ocular administration is low. In animal reproduction studies, lotilaner did not produce malformations at clinically relevant doses.

Data *Animal Data* In an oral embryofetal developmental study in pregnant rats dosed during organogenesis from gestation days 6-19, increased post-implantation loss, reduced fetal pup weight, and incomplete skeletal ossification were observed at 50 mg/kg/day (approximately 1390 times the recommended human ophthalmic dose (RHOD) on a body surface area basis) in the presence of maternal toxicity (i.e., decreased body weight and food consumption). A rare malformation of situs inversus of the thoracic and abdominal viscera occurred in 1 fetus from a pregnant rat receiving 50 mg/kg/day; whether this finding was treatment-related could not be excluded. No maternal or embryofetal toxicity was observed at 18 mg/kg/day (approximately 501 times the RHOD on a body surface area basis). In an oral embryofetal development study in pregnant rabbits dosed during organogenesis from gestation days 7-19, no embryofetal toxicity or teratogenic findings were observed at 20 mg/kg/day (approximately 580-times the RHOD on an AUC basis), even in the presence of maternal toxicity (i.e., decreased food consumption and body weight).

In an oral two-generation reproductive toxicity study, F0 male and female rats were administered lotilaner at doses up to 40 mg/kg/day for 10 weeks before pairing and during the 2-week pairing period (3 weeks for males). Dosing for F0 females continued through lactation day 22. F1 male and female rats were administered lotilaner at 1 and 5 mg/kg/day post-weaning from day 23 for 10 weeks before pairing and during the 2-week pairing period (3 weeks for males). Dosing for F1 parenteral females continued through lactation day 22. There were no clear adverse effects on the F1 generation, and a slightly lower mean body weight during lactation was noted for F2 pups at 5 mg/kg/day. The no observed adverse effect level (NOAEL) was determined to be 5 mg/kg/day (approximately 139 times the RHOD on a body surface area basis).

Lactation: Risk Summary There are no data on the presence of XDEMVY in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lotilaner following 6 weeks of topical ocular administration is low and is >99% plasma protein bound, thus it is not known whether measurable levels of lotilaner would be present in maternal milk following topical ocular administration. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XDEMVY and any potential adverse effects on the breast-fed child from XDEMVY.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 18 years have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lotilaner.

Mutagenesis Lotilaner was not genotoxic in the following assays: Ames assay for bacterial gene mutation, *in vitro* chromosomal aberration assay in cultured human peripheral blood lymphocytes, and *in vivo* rat micronucleus test.

Impairment of fertility In a two-generation study of reproductive performance in rats, F0 male and female rats were administered lotilaner at oral doses of 40 mg/kg/day for 80 days reduced to 20 mg/kg/day for 47-50 supplementary days. Reduced pregnancy rates and decreased implantation rates were observed in F0 females at doses 20 mg/kg/day) (approximately 556 times the RHOD on a body surface area basis), which were also associated with maternal toxicity (i.e., decreased body weight and food consumption). No effects on fertility were observed in F0 females at the dose of 5 mg/kg/day (approximately 139 times the MRHOD on a body surface area basis). No effects on fertility were observed in F0 males at the oral dose of 20 mg/kg/day (approximately 556 times the RHOD on a body surface area basis), and no effects on fertility were observed in F1 males and females at the oral dose of 5 mg/kg/day (approximately 139 times the RHOD on a body surface area basis).

PATIENT COUNSELING INFORMATION
Handling the Container Instruct patients to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

When to Seek Physician Advice Advise patients that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of XDEMVY.

Use with Contact Lenses Advise patients that XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

Use with Other Ophthalmic Drugs Advise patients that if more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes between applications.

Missed Dose Advise patients that if one dose is missed, treatment should continue with the next dose.

RX only

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- **Acts specifically via mite GABA-gated chloride channels to...**
- **Target, paralyze, and kill *Demodex* mites**

GABA=gamma-aminobutyric acid.

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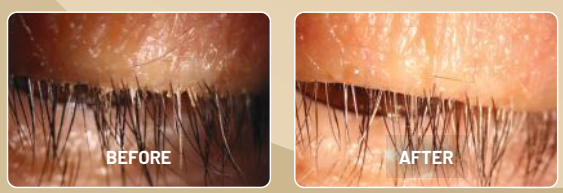

44% and 55% of patients taking XDEMVY in SATURN-1 (N=209) and SATURN-2 (N=193), respectively, achieved a significant improvement in their eyelids (reduction of collarettes to no more than 2 collarettes per upper lid) at Day 43 vs 7% (N=204) and 12% (N=200) of patients taking vehicle ($P<0.01$ in each trial).[1]*

All images are of actual patients who participated in clinical trials for Tarsus Pharmaceuticals.

INDICATIONS AND USAGE

XDEMVY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of *Demodex* blepharitis.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS

Risk of Contamination: Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with Contact Lenses: XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS: The most common adverse reaction with XDEMVY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

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

References: 1. XDEMVY [prescribing information]. Tarsus Pharmaceuticals, Inc; 2023. **2.** Gao YY et al. *Invest Ophthalmol Vis Sci*. 2005;46(9):3089-3094. **3.** Yeu E et al. *Cornea*. 2022;42:435-443. **4.** Toutain CE et al. *Parasit Vectors*. 2017;10(1):522.

*The safety and efficacy of XDEMVY for the treatment of DB were evaluated in a total of 833 patients (415 of whom received XDEMVY) in two 6-week, randomized, multicenter, double-masked, vehicle-controlled studies (SATURN-1 and SATURN-2). Patients were randomized to either XDEMVY or vehicle at a 1:1 ratio, dosed twice daily in each eye for 6 weeks. All patients enrolled were diagnosed with DB. The primary efficacy endpoint was defined as the proportion of patients with collarette reduction to no more than 2 collarettes per upper eyelid at Day 43.

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