Be Prepared for Papilledema, *P. 80* • When Your Patient Complains of Headache, *P. 89*

REVIEW of OPTOMETRY®

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A First Look at Therapeutics for Presbyopia
PAGE 105

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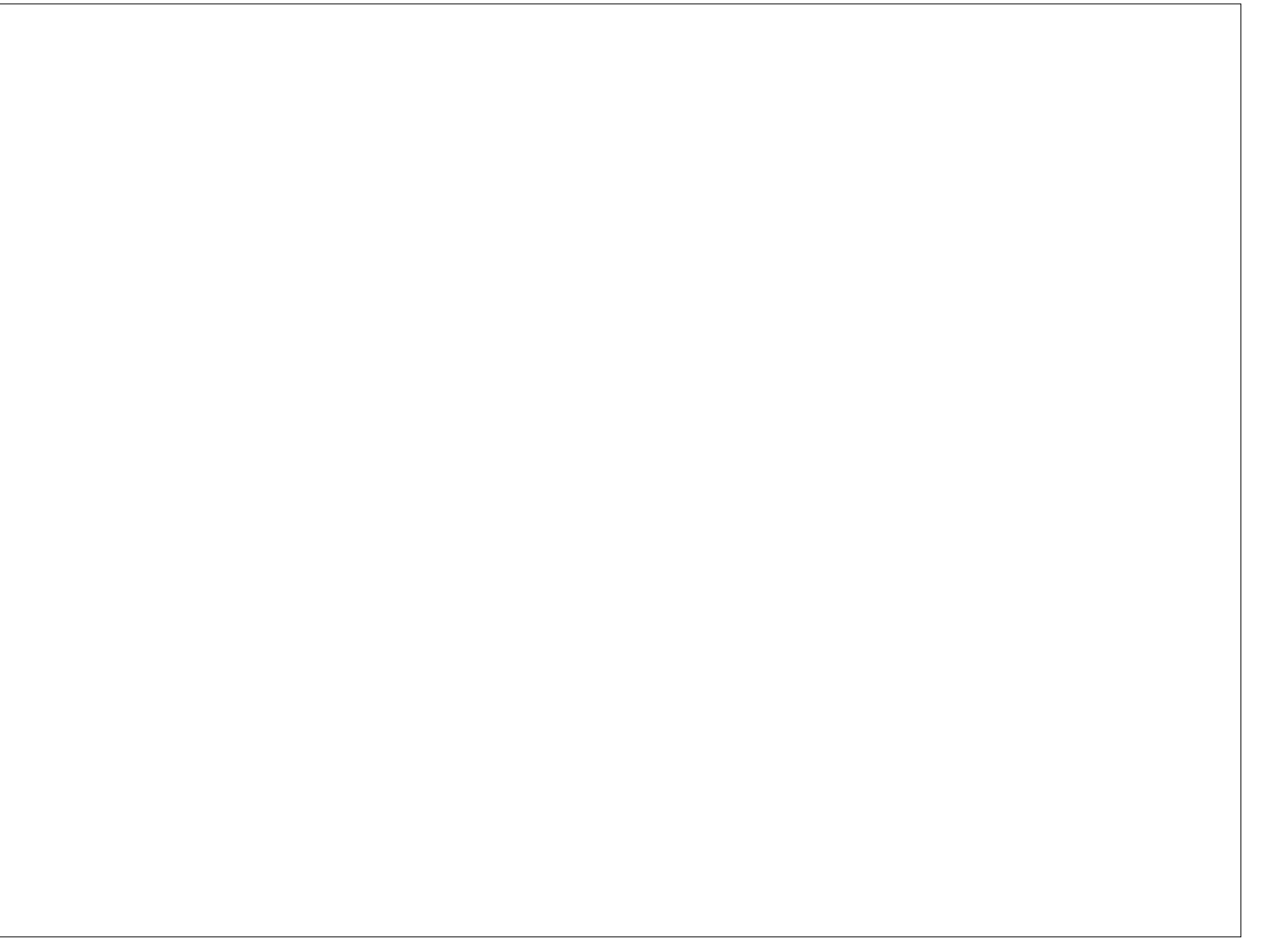

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STRENGTHEN YOUR PRACTICE

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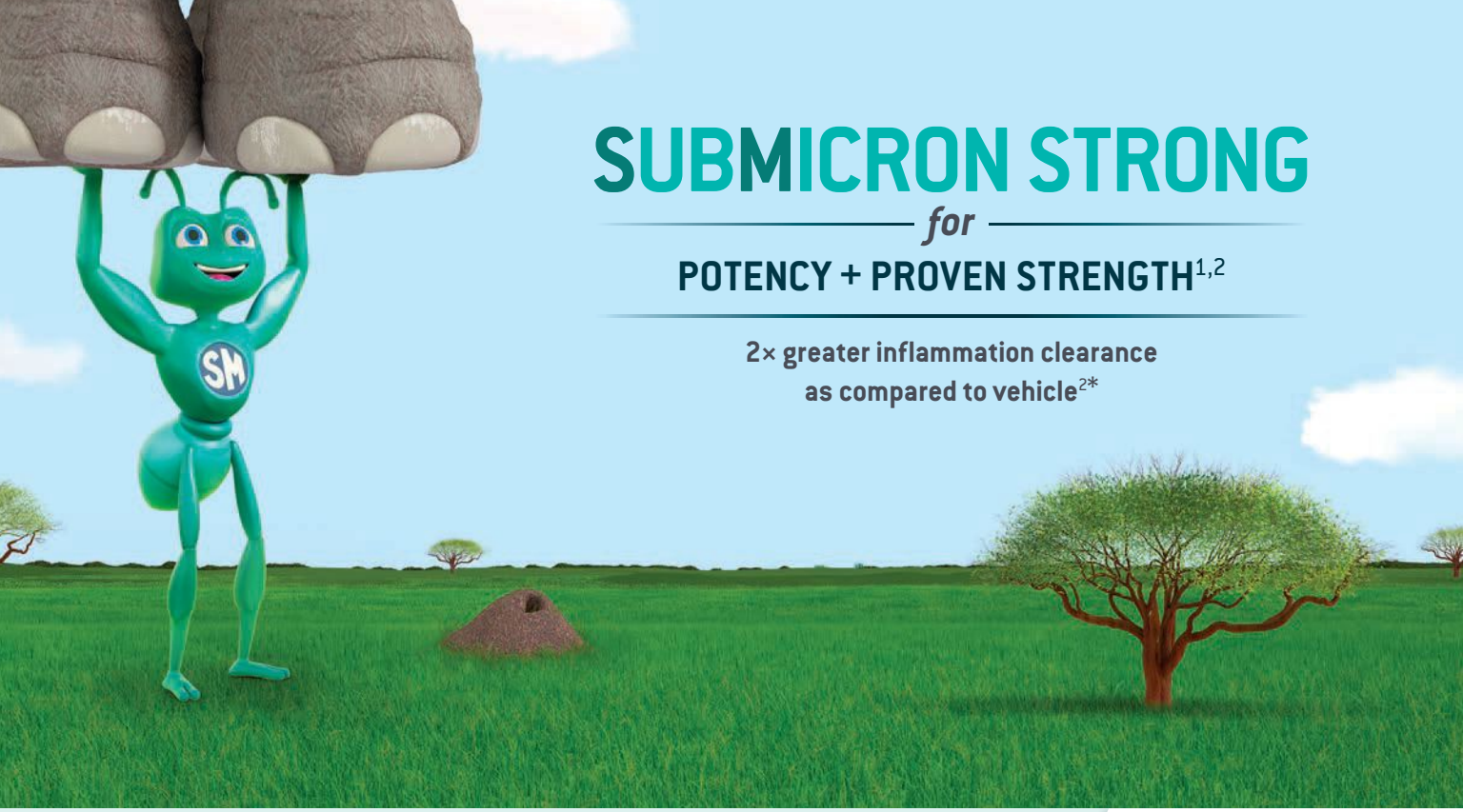

SUBMICRON STRONG

for

POTENCY + PROVEN STRENGTH[1,2]

2× greater inflammation clearance as compared to vehicle[2]*

SM TECHNOLOGY™

- **Engineered with SM Technology™ for efficient penetration at a low BAK level (0.003%)[1,3]**
- **~2× greater penetration** to the aqueous humor than LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%[3]

Clinical significance of these preclinical data has not been established.

LOTEMAX® SM
(loteprednol etabonate ophthalmic gel) 0.38%

SMALL & MIGHTY
SUBMICRON PARTICLES

*PROVEN STRENGTH

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

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

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

Indication

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

Important Safety Information

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

Important Safety Information (cont.)

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

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

Please see brief summary of Prescribing Information on adjacent page.

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

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LOTEMAX® SM
(loteprednol etabonate ophthalmic gel) 0.38%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%

For topical ophthalmic use
Initial U.S. Approval: 1998

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

USE IN SPECIAL POPULATIONS

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

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

Pediatric Use: Safety and effectiveness of LOTEMAX® SM in pediatric patients have not been established.

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

NONCLINICAL TOXICOLOGY

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

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LSM.0032.USA.21 Issued: 2/2021

Diabetic Cataract Patients Benefit From FLACS

Since it uses less phaco energy than traditional surgery, this may be a better option, study says.

Damage to the corneal endothelium during phacoemulsification occurs because of the ultrasonic energy used in the procedure. Effective phaco time and cumulative dissipated energy are thus important risk factors for endothelial cell loss. A recent retrospective study suggests that femtosecond laser-assisted cataract surgery (FLACS) may result in less endothelial cell loss compared with conventional phaco, as FLACS uses less energy to disrupt tissue.

The study, conducted in South Korea, compared endothelial cell loss after phaco and FLACS in patients with diabetes, a systemic disease that not only increases the risk of developing cataracts but also affects the corneal endothelium due to chronic metabolic changes at the cellular level. The researchers found that FLACS appeared to cause less damage than conventional phaco in these patients.

The study included 75 cataract patients (31 with diabetes) who underwent FLACS between 2018 and 2020. The researchers reported no observed differences between groups regarding preoperative and intraoperative parameters, mean postoperative endothelial cell density, hexagonality and cell size.

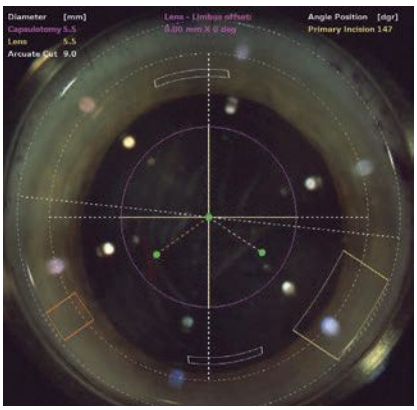

Photo: Justin Schweitzer, OD

The corneas of diabetic patients were found to take longer to recover after endothelial cell loss from FLACS, this study reported.

At one month, but not at three, central corneal thickness was significantly greater in the diabetic group.

Overall, the researchers reported that changes in corneal endothelial cells between the two groups were comparable after FLACS. "The recovery of the cornea in patients with diabetes is longer than in normal controls," the researchers wrote. "Despite good glycemic management, the corneal endothelium in diabetic patients is brittle to surgical trauma and has a weak ability to repair. The eyes of patients with diabetes are subject to various metabolic changes due to hyperglycemia; the aldose reductase in diabetic patients leads to the accumulation of polyols in cells, which act as an osmotic agent causing the swelling of endothelial cells," the authors explained.

"Diabetes also reduces the activity of the Na+/K+ APTase in the corneal endothelium, which produces structural and functional changes in the cornea," they added. "The diabetic endothelium was found to be under greater metabolic stress and had a less functional reserve after conventional phacoemulsification than a normal corneal endothelium."

The lack of difference in corneal endothelial cell damage between groups may be due to the fact that FLACS uses less phacoemulsification energy, resulting in less corneal damage. "FLACS requires less phacoemulsification energy because the laser splits the nucleus," the paper explains. "Because the endothelial cell loss correlates with the amount of energy used, FLACS reduces endothelial cell loss more than conventional phacoemulsification."

Kang K, Song M, Kim K, et al. Corneal endothelial cell changes after femtosecond laser–assisted cataract surgery in diabetic and nondiabetic patients. Eye Contact Lens. July 20, 2021. [Epub ahead of print].

IN BRIEF

Diagnosing glaucoma is often straightforward, but the differential includes some serious conditions, such as compressive optic neuropathy. Researchers recently determined a method that can improve accuracy by looking at **the relationship between two OCT measurements: minimum rim width (MRW) and peripapillary retinal nerve fiber layer (pRNFL) thickness**. The first metric is the shortest distance between Bruch's membrane opening and the internal limiting membrane.

The study included 115 eyes of 77 subjects (34 with compressive optic neuropathy from chiasmal lesions, 21 with glaucoma and 22 controls). **MRW and pRNFL measurements were significantly reduced in both compressive neuropathy and glaucoma compared with controls**. In glaucoma patients, however, MRW was thinner in most measurements than results found in compressive optic neuropathy patients, though an overlap was observed in many parameters. Using the ratio of the two increased the ability to discriminate between compressive optic neuropathy and glaucoma, especially in the nasal disc sector and nasal and temporal averages, researchers found.

"We believe that MRW:pRNFL ratios will prove a useful addition to the differential diagnosis of glaucoma and compressive optic neuropathy," they concluded.

de Souza Andrade T, de Araújo RB, do Nascimento Rocha AA, et al. Bruch's membrane opening minimum rim width and retinal nerve fiber layer helps differentiate compressive optic neuropathy from glaucoma. Am J Ophthalmol. August 25, 2021. [Epub ahead of print].

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Warby Parker Making Big Splash in Eye Care

In addition to a public stock offering, the company plans to open more stores, improve its services and build on customer relationships.

Following the recent launch of the company's updated virtual vision test app and contact lens refill service, Warby Parker announced plans to expand its reach even further into eye care, including more physical stores, upped philanthropy efforts and a more "holistic" approach with a goal of seeking a greater portion of revenue from eye exams and contact lens sales. As part of the company's recent investor day webcast presentation, Warby Parker executives also discussed the company's public stock offering, following its recent filing with the Securities and Exchange Commission (SEC).

This will be a milestone for Warby Parker's next phase of growth, says Brian Chou, OD, of San Diego.

"Expect them to continue ramping up customer acquisition efforts to gain market share in eyeglass sales—but now also with contact lens sales and eye exams," Dr. Chou says.

Implications of growth include increasing competition against other online contact lens sellers like 1-800 Contacts, greater influence with vision plans and future partnerships with laser vision correction networks as Warby Parker expands into services, Dr. Chou predicts.

"An interesting dynamic is to what extent Warby Parker will direct patient traffic to its network of eye care providers vs. encouraging remote prescription renewal," he says.

Company executives suggested several avenues to increase the company's estimated 1% to 2% share of the US eyeglasses market, pointing to a third-party study that estimated Warby Parker could open up to 900 stores in the United States as it expands from 53 markets to more than 100.

Warby Parker's direct stock offering of about 77 million shares took place on the NYSE on September 29. That morning, the opening trade in Warby Parker was priced at $54.05 per share, surpassing the reference price assigned by the NYSE before trading began. Warby Parker shares ended at $54.29 by the end of the day, valuing the company at about $6 billion.

The company had 142 US stores as of the end of its second quarter in June, in addition to three locations in Canada, and it is estimated there are about 41,000 optical outlets currently operating across the United States. Warby Parker expects to open up to 35 new stores this year.

Considering future philanthropic ventures, Warby Parker's stock filing noted that it will become "a public benefit corporation" and has various charitable intentions through a foundation and donation model of giving away eyewear when customers purchase their own set.

Executives suggested the company has many opportunities to improve the ways it engages with customers, including opening more retail stores, investing in pioneering technology such as telemedicine or virtual try-on and improving its buy-a-pair, give-a-pair program.

Photo: Warby Parker

The disruptive company is finding innovative ways to stand out among its competitors in the rising market for remote prescription renewals.

Warby Parker outlines plans for growth, store expansion and evolution to a "holistic" vision care company as it readies public stock offering. Vision Monday. September 13, 2021. www.visionmonday.com/business/retailers/article/warby-parker-outlines-plans-for-growth-store-expansion-and-evolution-to-a-holistic-vision-care-company-as-it-readies-public-stock-offering/?uid=31BD62136C131310AB8C47C61599D876. Accessed September 13, 2021.

IN BRIEF

Tobacco smoking increases health risks and the chances of many diseases, including several ocular diseases such as cataracts and thyroid eye disease. Less is known about the effects of tobacco-free alternative e-cigarettes, however. Looking to bridge this gap, researchers recently analyzed over 1.1 million responses from adults aged 18 and older from the Behavioral Risk Factor Surveillance System to study the association between e-cigarette smoking and perceived visual impairment.

The study concluded there is **an association between e-cigarette use and increased visual impairment**. When it comes to age, **younger people used e-cigarettes more often and older people had higher odds of visual impairment**, with a relatively consistent association of e-cigarette use on visual impairment across the board.

A previous study showed a correlation between e-cigarette use and increased symptomatic dry eye and decreased tear film, theorizing that "the propylene glycol used as solvent for the e-cigarette liquid produces free radicals which damage the lipid layer of the tear film by lipid peroxidation."

In this study, **e-cigarette users were found to have lower tear meniscus heights and tear breakup times,** "which were thought to be from deterioration of the lipid layer, but normal to elevated Schirmer testing indicated increased reflex tearing," the authors noted.

Even though e-cigarettes don't contain tobacco, they share similarities with cigarettes. "Firstly, **e-cigarettes have been shown to create oxidative stress and decrease antioxidants**. Oxidative stress and reduction in antioxidants have been implicated in the development of cataracts, age-related macular degeneration and even glaucoma," the authors explained in their study. "Secondly, **e-cigarettes also contain nicotine, which has been implicated in vasoconstriction in the eye and may increase the risk for glaucoma** via vasoconstriction of episcleral veins or arteries supplying the optic nerve."

While e-cigarette use is associated with increased prevalence of vision impairment, the authors suggest a longitudinal, observational study should be conducted to further investigate this association.

Golla A, Chen A, Tseng VL, et al. Association between e-cigarette use and visual impairment in the United States. Am J Ophthalmol. September 26, 2021. [Epub ahead of print].

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Ocular Conditions and Increased Dementia Risk

Researchers recently discovered that age-related macular degeneration (AMD), cataract and diabetes-related eye disease, but not glaucoma, are associated with an increased risk of dementia. They noted that patients with both ophthalmic and systemic conditions are at higher risk of dementia compared with those with an ophthalmic or systemic condition only.

The analysis included 12,364 adults aged 55 to 73 years from the UK Biobank cohort. Participants were assessed between 2006 and 2010 at baseline and were followed until 2021. Incident dementia was ascertained using hospital inpatient, death record and self-reported data.

Over 1.2 million person-years of follow-up, 2,304 cases of incident dementia were documented. The mean multivariable-adjusted hazard ratios (HRs) for dementia associated with AMD, cataract, diabetes-related eye disease and glaucoma at baseline were 1.26, 1.11, 1.61 and 1.07, respectively. Diabetes, heart disease, stroke and depression at baseline were all found to be associated with an increased risk of dementia.

Of the combination of AMD and a systemic condition, AMD/diabetes was associated with the highest risk for incident dementia (HR: 2.73). Individuals with cataract and a systemic condition were 1.19- to 2.29-times more likely to develop dementia compared with those without. The corresponding risk for diabetes-related eye disease and a systemic condition was 1.50- to 3.24-times higher.

"Vision deprivation may result in reduced activation in central sensory pathways, which is associated with a higher risk of cognitive load and brain structure damage," the researchers noted.

Diabetes, hypertension, heart disease, depression and stroke identified during follow-up mediated the association between cataract and incident dementia, as well as the association between diabetes-related eye disease and incident dementia.

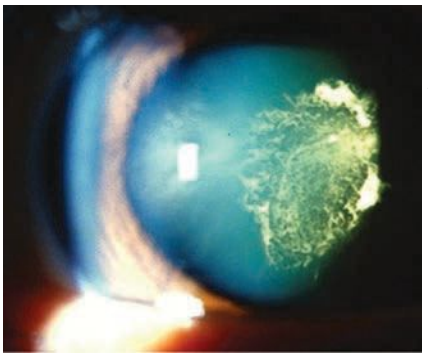

Photo: Julie Tyler, OD

Having a systemic disease along with AMD, cataract or diabetic retinopathy may put some individuals at a higher risk for dementia.

Shang X, Zhu Z, Huang Y, et al. Associations of ophthalmic and systemic conditions with incident dementia in the UK Biobank. Br J Ophthalmol. September 13, 2021. [Epub ahead of print].

Systemic Arterial Pressure Tied to RNFL Loss

Vascular factors affecting the blood supply to the eye have long been suspected of playing a role in glaucoma, which could open the door for additional therapy options. When adjusting for IOP, new research suggests lower arterial and diastolic arterial pressures may be closely linked to faster rates of RNFL loss, indicating that levels of systemic blood pressure may play a significant role in glaucoma progression.

Based on these findings, clinicians should be mindful of not only IOP but also systemic arterial pressure when monitoring the disease state, the study authors explained.

The investigation enrolled roughly 7,500 eyes of about 4,000 subjects from the Duke Glaucoma Registry. The authors investigated the effects of blood pressure on the rate of RNFL loss based on SD-OCT images over time.

Photo: Getty Images

Blood pressure levels play a role in glaucoma progression.

Other considerations included gender, race, diagnosis, central corneal thickness, follow-up intervals and baseline disease severity. The results were based on 157,291 blood pressure visits, 45,408 IOP readings and 30,238 SD-OCT images.

Overall, the mean rate of RNFL change was -0.70µm/year. Considering follow-up results based on univariable models, the research team found no significant link between RNFL loss and mean arterial pressure, systolic arterial pressure or diastolic arterial pressure.

But, when adjusting for IOP at follow-up, faster rates of RNFL thickness change over time were found with each 10mm Hg lower mean arterial pressure (-0.06µm/year) and diastolic arterial pressure (-0.08µm/year). However, this result was not mirrored when it came to systolic arterial pressure (-0.01µm/year). Also, the arterial pressure effects remained significant after adjustment for baseline age, diagnosis, sex, race, follow-up time, disease severity and corneal thickness.

Using the large database of patients under routine care, the study was able to derive precise estimates of the independent effect of blood pressure on rates of structural loss in glaucoma.

Jammal AA, Berchuck SI, Mariottoni EB, et al. Blood pressure and glaucomatous progression in a large clinical population. Ophthalmology. August 30, 2021. [Epub ahead of print].

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Obesity May Raise Risk for Cranial Nerve Palsy

More aggressive medical intervention may be warranted among high-risk patients, research suggests.

Third, fourth and sixth ocular motor cranial nerve palsies (CNPs) can have a significant impact on patients' quality of life by producing diplopia and, even more seriously, by heralding cerebrovascular ischemic events. According to recent studies, there's an association between ocular motor CNP and risk of subsequent stroke in both the general population and among those with diabetes. Researchers recently assessed possible associations between obesity and CNP, concluding that obesity raises the risk of such events (*Table 1*).

The team analyzed a cohort of over four million adults (ages 20 to 90) in South Korea who attended health checkups in 2009 and were followed through December, 2017. During this follow-up period, 5,835 individuals were diagnosed with CNP. The researchers reported that general obesity (defined as BMI ≥25kg/m^2) was associated with an increased risk of CNP, and abdominal obesity (defined as a waist circumference ≥90cm in men and ≥85cm in women) also demonstrated increased hazard ratios. Overall, those with only general obesity, only abdominal obesity or those with both had an increased risk of CNP.

"BMI and waist circumference had positive linear associations with the risk of ocular motor CNP after adjusting for potential confounders such as age and sex and health behaviors such as drinking, smoking and physical activity," the researchers wrote in their paper. "General obesity and abdominal obesity were associated with a 1.25- and 1.24-times increased risk of ocular motor CNP, respectively.

"Obesity is one of the major components of metabolic syndrome and an established risk factor for type 2 diabetes," they continued. "Considering the high intercorrelation between the components of metabolic syndrome, adjustments for hypertension, diabetes and dyslipidemia might lead to underestimation of the harmful effect of obesity on ocular motor CNP."

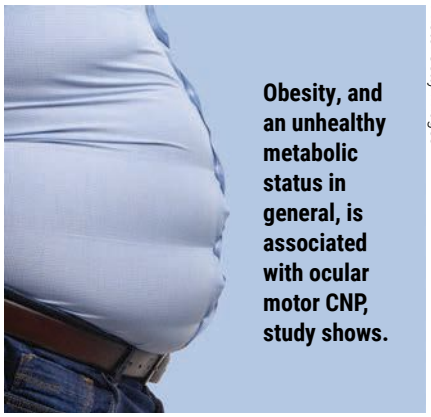

Photo: Getty Images

Obesity, and an unhealthy metabolic status in general, is associated with ocular motor CNP, study shows.

The researchers say the precise mechanism of how obesity increases one's risk of ocular motor CNP is unknown, but there are several potential ways it can affect the development of ocular motor CNP:

1. Obesity is associated with hypertension, diabetes and hyperlipidemia. These are risk factors for ocular motor CNP caused by microvascular ischemia.

2. Experimental and clinical research demonstrates that obesity induces a chronic inflammatory state, which affects neuroinflammatory processes, contributing to neurodegeneration.

3. Caloric excess increases circulation of chylomicron-derived, very low-density lipoprotein triglycerides, which are hydrolyzed to long-chain fatty acids. These lipids are deposited along blood vessels, resulting in atherogenesis. All organs in the body also experience increased lipid load. Animal studies have shown that high-fat diets contribute to inflammatory mediators that can injure and penetrate the blood-nerve barrier and activate neurogenic inflammation. Lipid overload can also stress the nervous system and alter mitochondrial ATP, which is necessary for normal nerve physiology.

The researchers explained that in addition to obesity, an unhealthy metabolic status in general can affect the incidence of ocular motor CNP in people with normal body weight. They also suggested that the combined presence of general and abdominal obesity could have a "synergistic effect" on the development of ocular motor CNP.

"Obesity may be correlated with ocular motor CNP; however, it's also a general indicator of suboptimal health," the researchers wrote. "Ocular motor CNP is one of the various complications that can accompany obesity, but CNP may also suggest that other serious complications such as stroke are imminent or may occur within years in some patients. We suggest that it would be possible to select high-risk patients and attempt more aggressive medical interventions."

Choi DD, Han K, Park K, et al. Association of obesity and incidence of third, fourth, and sixth cranial nerve palsies. Am J Ophthalmol. September 17, 2021. [Epub ahead of print].

TABLE 1. OBESITY AND RISK OF CNP

	Obesity Rate (2015-2016)		Incidence of CNP (per 100,000 person-years)		
	General	*Abdominal*	*Third*	*Fourth*	*Sixth*
Korea	34.2%	20.8%	3.17	3.74	4.66
United States	39.8%	58.9%	4.00	5.73	11.30

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Daily Fish Oil May Protect Against DR

Dietary changes help prevent disease development and progression, study finds.

A study recently confirmed the findings of a handful of others that have demonstrated a possible protective effect of marine polyunsaturated fatty acids (PUFAs), consumed through one's diet, on the prevalence and progression of diabetic retinopathy (DR). Researchers looked at 17 years of diabetic patients' records from the only eye practice in a Norwegian west coast island, where fish products are a readily available dietary staple. Compared with neighboring counties, the population had a relatively low prevalence of vision-threatening DR and visual impairment.

The study participants included 510 patients from the Norwegian island with either type 1 (n=50) or type 2 diabetes (n=460). Self-reported medication, diet supplements, HbA1c and fish consumption were all recorded. In the type 1 and type 2 groups, the median ages were 44.5 and 66 years, respectively, and the median disease duration was 11.5 and eight years, respectively.

The researchers found a very low visual impairment rate among the studied population. No patient had a best-corrected visual acuity (BCVA) of worse than 0.3 (logMAR 0.48) due to DR, and 98% had a BCVA of at least 0.5 (logMAR 0.3) in the better-seeing eye. Less than 0.4% of patients had significant extraocular diabetic comorbidities.

Photo: Julie Torbit, OD

Adding a fish oil supplement or normal amount of fatty acids to one's diet, though controversial, could have the potential to reduce risk of diabetic retinopathy.

"The observation of only 0.4% of severe extraocular microangiopathy as well as preserved best eye visual acuity indicates a generally low level of serious microvasculopathy, including retinopathy," the authors of the study wrote. "In addition, timely medical and ophthalmological care in diabetes patients will effectively help to prevent visual and systemic impairment in one of the leading worldwide causes of blindness and associated morbidity."

A study limitation: patients in the studied region with more severe DR may have been referred directly to the regional university eye clinic, and, therefore, the data of that population could not be included in the analysis. There were also confounding variables at play in this study, making it difficult to confirm a direct link between the consumption of PUFAs and a reduced prevalence and progression of DR.

Overall, these findings, along with evidence from previous studies, suggest that daily intake of fish or fish oils may provide minimal risk protection against diabetic microangiopathy and retinopathy. Likewise, a former study found that "In Japan with a known fish consumption up to fivefold higher than in Western countries (Meyer 2011), the incidence and progression rate of DR seems lower than in Western populations (Kawasaki et al. 2011)," the researchers wrote.

Inform your patients with diabetes who are at risk for DR that the current researchers suggests they could potentially benefit from consuming a normal amount of PUFAs each day either through their diet or supplementation.

Alsbirk KE, Seland JH, Assmus A. Diabetic retinopathy and visual impairment in a Norwegian diabetic coast population with a high dietary intake of fish oils: an observational study. Acta Ophthalmol. September 2, 2021. [Epub ahead of print].

IN BRIEF

The potentially devastating surgical complication of endophthalmitis requires immediate treatment in order to save the eye. A recently published analysis on endophthalmitis rates among Medicare beneficiaries undergoing cataract surgery in the United States reported an **incidence rate of 1.36 per 1,000 cataract surgeries over a nine-year period**.

The study included 14.4 million cataract surgeries performed on Medicare beneficiaries between 2011 and 2019, obtained from Medicare fee-for-service claims (patients 65 years and older). The researchers identified endophthalmitis cases within 90 days of surgery using diagnostic codes. Any patient with a history of endophthalmitis 12 months prior to cataract surgery was excluded from the analysis.

The researchers reported an overall **90-day postoperative endophthalmitis rate of 1.36 per 1,000 surgeries for stand-alone cataract procedures**. They also noted a **decreasing trend for post-op endophthalmitis rates** during the nine-year period. Patients of **older age, male gender or those of Black or Native American race seemed to be at an increased risk for endophthalmitis**. Other risk factors for developing endophthalmitis postoperatively included prior **history of invasive glaucoma surgery, combined cataract and retinal surgery, and various systemic comorbidities**. "It's also possible that a decline in observed endophthalmitis rates reflects changes in billing and/or coding practices and not a true reduction in actual infections," the researchers note. "Further studies exploring racial disparities and surgeon-related characteristics are warranted."

Zafar S, Dun C, Srikumaran D, et al. Endophthalmitis rates among Medicare beneficiaries undergoing cataract surgery between 2011-2019. Ophthalmology. September 16, 2021. [Epub ahead of print].

UPLIFTED

Give Acquired Ptosis Patients an EYE-OPENING Lift With a Daily Drop of Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1%[1]

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

Learn more at Upneeq.com.

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

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

DRUG INTERACTIONS

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

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

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

Reference: 1. Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1%. [Prescribing Information].

RVL PHARMACEUTICALS, INC.

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PM-US-UPN-0197-2 06/21

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(oxymetazoline hydrochloride ophthalmic solution), 0.1%

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

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

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

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

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Ptosis as Presenting Sign of Serious Neurologic Disease

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

5.2 Potential Impacts on Cardiovascular Disease

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

5.3 Potentiation of Vascular Insufficiency

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

5.4 Risk of Angle Closure Glaucoma

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

5.5 Risk of Contamination

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

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

7 DRUG INTERACTIONS

7.1 Anti-hypertensives/Cardiac Glycosides

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

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

7.2 Monoamine Oxidase Inhibitors

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

Data

Animal Data

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

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

8.2 Lactation

Risk Summary

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

10 OVERDOSAGE

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

PATIENT COUNSELING INFORMATION

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

RVL PHARMACEUTICALS, INC.
Manufactured for: RVL Pharmaceuticals, Inc.
Bridgewater, New Jersey 08807

PM-US-UPN-0203 01/21

Myopia Prevention Program Successful

Study found sizable drop in prevalence in preschools—from 15.5% to 10.7%—with the biggest declines in the two years after experimental policies were implemented.

Evidence continues to mount that more time spent outdoors can decrease myopia risk across various populations, particularly in young children. To examine whether increased outdoors time results in a lower myopia prevalence in preschool-aged children, a county in Taiwan launched a program to encourage it in 2014, which lasted through 2020. Over the course of those seven years, the region was able to lower overall myopia prevelance in children from 15.5% to 10.7%, a significant improvement that may have prevented hundreds of students from developing decreased quality of vision.

The effort included annual eye exams for all preschoolers aged five to six years across the county. The research team noted that, "Taiwanese schoolchildren at the age of seven to eight years had one of the highest age-specific prevalence (36.4%) and annual incidence (31.7%) of myopia worldwide," making individuals of this demographic the perfect group to more reliably evaluate the effectiveness of myopia prevention techniques.

The public health bureau that led the program promoted awareness and educational campaigns focusing on myopia prevention strategies, such as ensuring ideal classroom lighting and table height, limiting prolonged near work activities including screen time and encouraging children to be outside for a minimum of 120 minutes each day. The caregiver of each student also filled out a questionnaire about their child's medical information and myopiagenic behaviors, including how much time children spent on electronics and outdoors over the weekend when they weren't physically in school.

Photo: Getty Images

Outdoor time for kids again proves its value in myopia mitigation.

Data from 21,761 students was included in the analysis. The overall prevalence of myopia in preschoolers was 10.7%, with a mean spherical equivalent refractive error of 0.57 in the more myopic eye. From 2014 to 2020, prevalence dropped significantly, from 15.5% to 10.3%. The decline was most significant in the first few years, then became fairly stable for the remainder of the study term. The annual prevalence year by year was as follows: 15.5%, 13.5%, 8.4%, 8.5%, 10%, 9.1% and finally 10.3% in 2020.

When comparing the data from 2019 and 2020, the year when the coronavirus pandemic sent students to learn in virtual classrooms, the researchers detected no significant difference in terms of myopia prevalence. This could be a result of years of educating the students on health-promoting behaviors, such as the numerous benefits of increased time spent being physically active.

The researchers deemed the effort a successful validation of the benefits of outdoor time. "We found that the longer duration of being exposed to these preventive strategies, the less likely to be myopic," they wrote in their paper, published in the journal *Ophthalmology*.

Considering that this school-based outdoor promotion program was able to decrease myopia prevalence by 5.2% in preschoolers, similar programs may have a protective effect on younger populations and encourage them to create lifelong habits that will reduce their myopia risk in years to come, the researchers argued.

Of course, this study does not come without its limitations. "Taken together, the benefits of school-based outdoor promotion program may be more profound in the younger population. However, though highly correlated to the prevalence of myopia, the prevalence of reduced visual acuity might be affected by various causes such as types and degrees of refractive errors, amblyopia, and other pathologies," the researchers pointed out.

They also speculate that promoting outdoor activities during school hours when the daylight is brighter and longer would be more effective on controlling myopia, as current research suggests "Increased exposure to bright ambient light has been considered the contributing factor for the protective mechanism of increased time spent outdoors against myopia."

"This population-based evidence showed high prevalence of preschool myopia and an L-shaped decline after introducing strategies to promote outdoor activities in kindergartens. With undisrupted school-based preventive strategies, the prevalence of myopia can be kept stable even during the COVID-19 pandemic," the team concluded.

Yang YC, Hsu NW, Wang CY, et al. Prevalence trend of myopia after promoting eye care in preschoolers: a serial survey in Taiwan before and during the COVID-19 pandemic. Ophthalmology. August 16, 2021. [Epub ahead of print].

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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. Corneal collagen cross-linking should not be performed on pregnant women.

IMPORTANT SAFETY INFORMATION

Ulcerative keratitis can occur. Patients should be monitored for resolution of epithelial defects.

The most common ocular adverse reaction was corneal opacity (haze). Other ocular side effects include punctate keratitis, corneal striae, dry eye, corneal epithelium defect, eye pain, light sensitivity, reduced visual acuity, and blurred vision.

These are not all of the side effects of the corneal collagen cross-linking treatment. For more information, go to www.livingwithkeratoconus.com to obtain the FDA-approved product labeling.

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

*Photrexa® Viscous and Photrexa® are manufactured for Avedro. The KXL® system is manufactured by Avedro. Avedro is a Glaukos company.

REFERENCE: 1. Photrexa [package insert] Waltham, MA: Glaukos, Inc. 2016.

MA-02165A
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FEATURES

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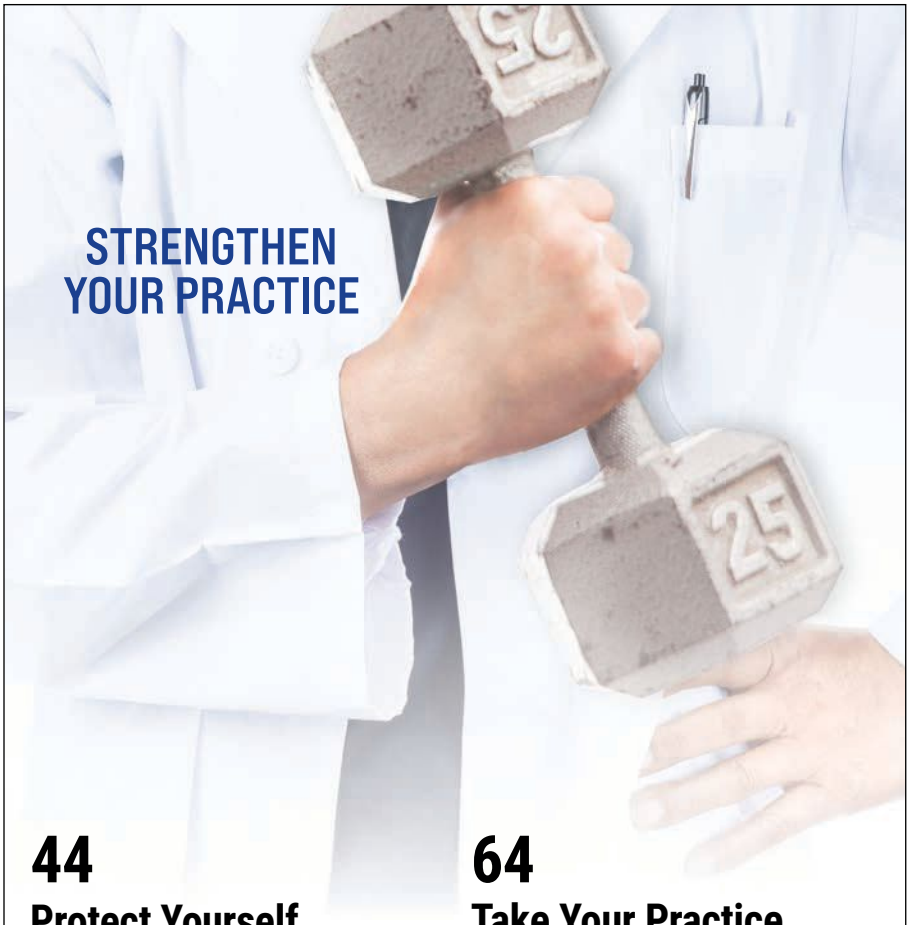

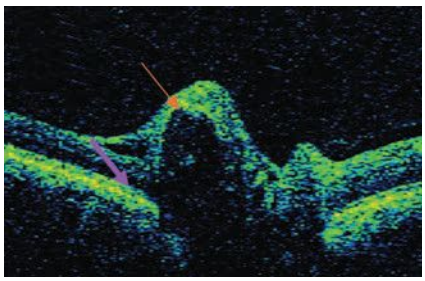

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When patients rely on artificial tears alone, inflammation may persist. Xiidra can disrupt the chronic inflammatory cycle in dry eye disease.* It can provide lasting symptom relief in as little as 2 weeks.[1-5†]

*Xiidra blocks LFA-1 on T cells from binding with ICAM-1 that may be overexpressed on the ocular surface in dry eye disease and may prevent formation of an immunologic synapse which, based on in vitro studies, may inhibit T-cell activation, migration of activated T cells to the ocular surface, and reduce cytokine release. The exact mechanism of action of Xiidra in DED is not known.[1,2,5]

†The safety and efficacy of Xiidra were assessed in four 12-week, randomized, multicenter, double-masked, vehicle controlled studies (N=2133). Patients were dosed twice daily. The mean age was 59 years (range, 19-97 years). The majority of patients were female (76%). Use of artificial tears was not allowed during the studies. The study end points included assessment of signs (based on Inferior fluorescein Corneal Staining Score [ICSS] on a scale of 0 to 4) and symptoms (based on patient-reported EDS on a visual analogue scale of 0 to 100). Effects on symptoms of dry eye disease: a larger reduction in EDS favoring Xiidra was observed in all studies at day 42 and day 84. Xiidra reduced symptoms of eye dryness at 2 weeks (based on EDS) compared to vehicle in 2 out of 4 clinical trials. Effects on signs of dry eye disease: at day 84, a larger reduction in ICSS favoring Xiidra was observed in 3 out of the 4 studies.[1]

Indication

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

Important Safety Information

- Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

Important Safety Information (cont)

- In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.
- To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.
- Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
- Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information about XIIDRA®, please refer to the brief summary of Prescribing Information on adjacent page.

References: 1. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020. **2.** Bron AJ, de Paiva CS, Chauhan SK, et al. TFOS DEWS II Pathophysiology Report. *Ocul Surf.* 2017;15(3):438-510. **3.** US Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 5 (21CFR349). Accessed May 25, 2021. https:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=349&showFR=1 **4.** Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* 2017;15(3):575-628. **5.** Pflugfelder SC, Stern M, Zhang S, Shojaei A. LFA-1/ICAM-1 interaction as a therapeutic target in dry eye disease. *J Ocul Pharmacol Ther.* 2017;33(1):5-12.

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

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

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

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

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

- Hypersensitivity *[see Contraindications (4)]*

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

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

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

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

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

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

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

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

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

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

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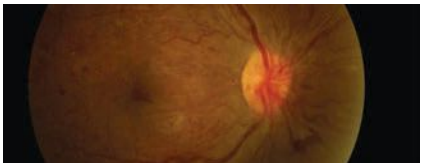
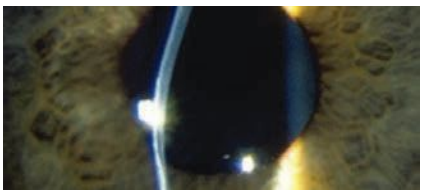
DEPARTMENTS

REVIEW OF OPTOMETRY • OCTOBER 15, 2021





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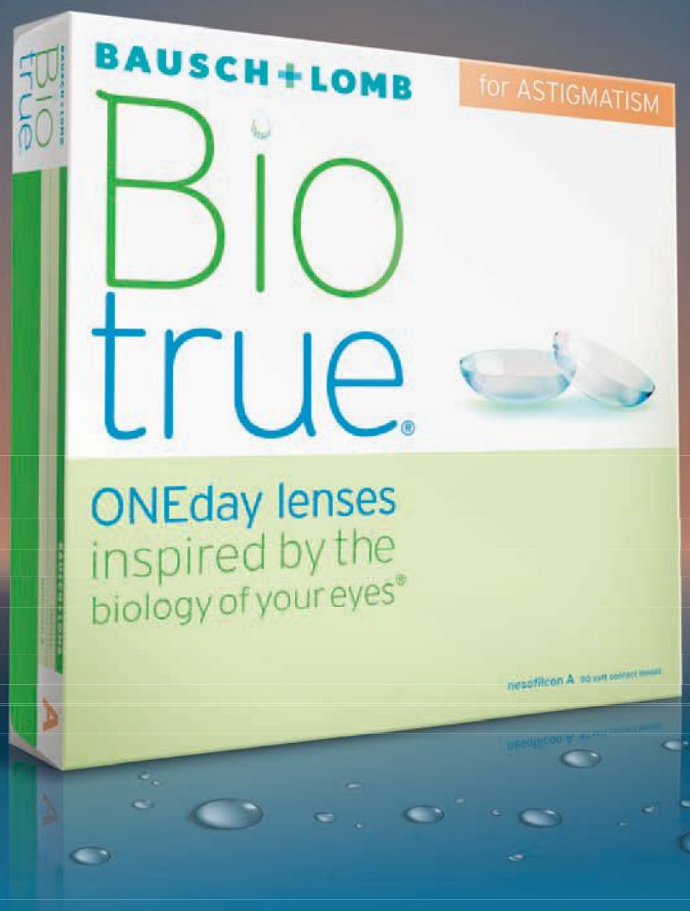

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*Point of sales data from January to June 2021, sourced from third party.

REFERENCES: 1. Results of an online survey with patients who completed an evaluation program for Biotrue® ONEday for Astigmatism contact lenses and wore their trial lenses for ≥4 days (n=1001). **2.** Results from a 7-investigator, multi-site study of Biotrue® ONEday for Astigmatism contact lenses on 123 current non-daily disposable toric soft contact lens wearers. Lenses were worn on a daily wear basis for 1 week.

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REVIEW of OPTOMETRY

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BY JACK PERSICO
EDITOR-IN-CHIEF
OUTLOOK

The Spirit of '71

That year, legislation and innovation gave optometry a broader clinical mandate and soft contact lenses. How are both faring today?

Fifty years ago, two events put in motion seismic changes for optometry: Rhode Island's passage of the first diagnostic pharmaceutical agent (DPA) law and Bausch + Lomb's launch of the first soft contact lens, aptly named Soflens. Each of these 1971 milestones opened up new paths for the profession. And yet, both were also continuations of core components of optometry's DNA—professional reinvention in the case of the former and mastery of optics for the latter.

Plans to bring diagnostic—and eventually therapeutic—drugs to optometry were put in motion three years prior at the famous "LaGuardia meeting" that took place at an unassuming hotel on the grounds of the New York airport. There, Dr. Alden Haffner of SUNY College of Optometry stated, "The optometrist is a primary care provider and the optometrist has a role in the diagnosis and treatment of ocular pathology." Those words are completely uncontroversial today but were radical at the time. In fact, the reason they're uncontroversial today is *because* they were radical then.

Dr. Haffner and the other leaders of the era present at the meeting staked the profession's future on a drive to move optometry beyond refraction and visual correction. It became the organizing principle of the profession from then on. Without their leadership, DPA and TPA laws might never have happened, or at least not with such fervor and sense of common cause.

A reader brings up the LaGuardia meeting this month in a letter to the editor (see page 30), arguing that optometry is at a similar crossroads today and in need of another rallying cry to move the profession forward. I encourage you to read his diagnosis of optometry's current ills and offer your own thoughts.

The spiritual descendants of LaGuardia live on in the work now being done to keep expanding optometric scope of practice, as profiled in a feature article this month that recaps notable progress in recent years (see page 54). ODs are now firmly engaged in the next wave of scope expansion, bringing laser procedures and other methods of direct manipulation of ocular structures into the fold while also plugging a few holes in the therapeutic landscape, like using oral meds and performing glaucoma care with the training wheels off.

Soft contact lenses also have a tenacious individual to thank for their existence, Czech chemist Otto Wichterle, who literally built his first manufacturing apparatus out of an Erector set. B+L transformed those primitive efforts into a new product category and made contact lenses a mainstream phenomenon beginning in 1971. The lenses were primitive by today's standards and complication rates were fairly high, but continual iteration in product design has refined soft lens wear into a relatively uncomplicated affair for most patients. And therein lies the problem. Contact lenses are now perceived to be so trivial that patients are cavalier about safety and receptive to the lures of online Rx fulfillment houses that care about nothing but profit.

Though both of 1971's optometric advances face some growing pains these days, just pause for a moment and reflect on the momentous changes stemming from those days. All that and *Led Zeppelin IV* too? Not a bad year. ■

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LETTERS TO THE EDITOR

Feedback and ideas from the optometric community.

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Submissions may be edited for length, content or clarity.

Femto Fans Fight Back

We take some flak over recent coverage of FLACS.

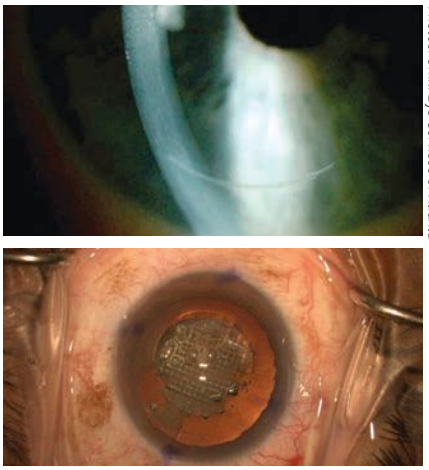
Flawed Study is an Outlier, Misrepresents Clinical Impact

■ We read with interest your news story, "No Clinical Advantage to Femto Cataract Surgery" in the May edition. From our perspective, as a practice that had the first femto laser for cataract surgery (FLACS) in Atlanta in 2013, there are several problems with the journal article summary presented. We wish *Review* had not used such a "sensational" headline; it is oversimplification to state there is no clinical advantage to FLACS over standard phaco.

The article quoted is based on the results of one study in the *British Journal of Ophthalmology*, looking at one narrow aspect of FLACS. Most readers won't take the time to read the manuscript, but if they did they would discover what we did, as one of many leading high-volume cataract practices that embrace FLACS and has clearly seen the advantages for the appropriate patient population:

1. In the study, intrastromal arcuate FLACS incisions were used instead of transepithelial ones, which are more effective and much more widely used. Limbal relaxing incisions (LRIs) are obviously transepithelial, so it demonstrates poor study design to use intrastromal FLACS incisions.

2. The study criteria required patients to have astigmatism >0.9D. Astigmatism correction by corneal incisions is quite unpredictable for that amount of astigmatism, whether by FLACS or LRIs. That is why it is generally accepted that toric intraocular lenses be used instead of corneal incisions for >0.8D of astigmatism. Inclusion criteria for the study should have been eyes under 0.9D, not over 0.9D. Despite this flaw, the study did show significantly less difference vector in the FLACS group vs. LRIs, indicating that laser arcuate incisions were more effective in reducing astigmatism. However, this was not mentioned in *Review*'s summary, a glaring omission.



Photos: Omni Eye Services of Atlanta

The femtosecond laser makes precise arcuate incisions (top), fragments the nucleus (bottom) and automates capsulorhexis formation.

3. The study did not report the percentage of eyes within 0.25D residual refractive error, only that within 0.5D and 1.00D. Numerous studies have documented benefit for FLACS vs. standard within 0.25D—some showing as much as 40% improvement among eyes within 0.25D. Most eyes will be within 0.5D with either procedure because modern IOL calculation formulas and new technology (optical biometers and swept-source OCT biometers) are quite accurate with IOL power selection. However, FLACS has been shown to increase the percent of eyes within 0.25D presumably due to the benefits of added precision of capsulotomy circularity and centration, which may decrease lens tilt and residual refractive error.

4. Post-op endothelial cell counts and central corneal thickness have been shown to be statistically significantly improved in FLACS cases. The *BJO* study's finding that those were not better with FLACS should be further analyzed for possible explanations, because this goes against what almost all other studies have shown when evaluating those outcomes.

5. Phaco energy was also not reported in this study. It has been shown in many studies to be statistically significantly less in FLACS cases. Reduced ultrasound energy means less corneal endothelial cell damage and loss over time. Not reporting phaco energy used is a major flaw in this study design.

We would respectfully request that *Review* publish results from studies which evaluate the issues that we have raised here. Cited at the end of this letter are some studies that support our stance that there are many clinical benefits to FLACS.

A headline that states there is no clinical benefit based on a flawed British study leaves readers with misinformation which can quickly turn to misconceptions as they talk to patients each and every day. Unfortunately, we see in our referral-only practice that there is enough hesitation already by optometrists to get involved in pre-op counseling. Headlines like this will give optometrists the excuse they need to cut off discussions of new technology and premium services, thus depriving patients of factual information based on current studies so that they can make informed decisions about their upcoming surgery.

All studies we cite below, except one, are from *The Journal of Cataract*

and Refractive Surgery, the premier US journal dedicated to such topics. Studies conducted in the US are much more rigorous than in other countries and are considered the gold standard. Each of these studies refutes individual pieces of the *BJO* "broad brush" study and shows a particular benefit of FLACS compared to conventional surgery. These studies reflect a small percentage of those available in the literature showing clinical benefits to FLACS.

We look forward to *Review* presenting the other side of the story so that readers are clearly aware this is a state-of-the-art technology that benefits patients and is very much here to stay.

—Lawrence Woodard, MD
Paul C. Ajamian, OD
Omni Eye Services of Atlanta

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Femto 'Facts'—or Fake News?

■ The June 2021 supplement *Clinical Perspectives on Patient Care* included numerous clinical questions and answers. Among the topics was a section titled "Facts on Femto." The writers stated that "knowledge gleaned from the literature is so enlightening." Their conclusion: "While there is a lot of hype and discussion regarding the 'benefits' (and increased revenue) from femtosecond-assisted cataract surgery, the consensus of the literature opines that such extra expense to the patient does not meet the clinical return on investment."

I congratulate the writers on their exhaustive review of the literature on this topic, which included a total of four references. Moreover, two of these references were published in 2016, one in 2018 and one in January 2020. Each will be addressed below.

I am surprised the writers did not also find a more recent article, "Outcomes of Femtosecond Laser Arcuate Incisions in the Treatment of Low Corneal Astigmatism," published in May 2020.[1] Briefly, this peer-reviewed study shows that in fact use of the femtosecond laser in cataract surgery, including treatment of low amounts of corneal astigmatism, yields a 1.8x greater chance of uncorrected 20/20 distance vision over standard surgery.

1. The first reference noted by the writers, "Femtosecond Laser-Assisted Cataract Surgery Versus Phacoemulsification Cataract Surgery (FACT)," was a study of surgeries between May 2015 and September 2017 in the UK.[2] In this article, we were treated to the knowledge that "based on a *hypothetical cohort*" (emphasis mine) an economic modeling evaluation showed FLACS was not cost-effective (using 2014 data). Also, the surgeons in this study had performed at least 10 supervised FLACS and been certified by laser manufacturers. The article later points out "correspondence suggests the learning curve may include the first 100 cases." Surgeons could treat astigmatism with the laser or not based upon their discretion.

The patients' subjective assessment part of the study included this choice of statements for agreement: "I have no problems seeing; I have some problems seeing; I have extreme problems seeing."

Impressive scientific rigor and worthy of review this article was!

2. The second article referenced by the writers, "Efficacy and Safety of Femtosecond Laser-Assisted Cataract Surgery Compared with Manual Cataract Surgery" (MCS), was a literature search from 2007 to March 2016.[3] Even back then, this review of articles showed a statistically significant lesser phaco time, greater capsular circularity, improved postoperative central corneal thickness and lessened corneal endothelial cell reduction with FLACS. "There was a significantly greater incidence of posterior capsular tears after FLACS relative to MCS," the study notes. "Given that many of the included studies were published early after the introduction of FLACS, the surgeon learning curve may have influenced these results."

In spite of these observations, and the fact that FLACS was approved by the FDA in 2010, those authors suggested "evidence of safety and efficacy of this technology is urgently needed."

3. The third article referenced, "Femtosecond Laser-assisted Cataract Surgery versus Standard Phacoemulsification Cataract Surgery: Study from the European Registry of Quality Outcomes for Cataract and Refractive Surgery," included femto cases performed between December 2013 and May 2015 by surgeons who had done at least 50 femto cases (see above on learning curve) and most of the complications occurred in the first few cases.[4] Of the 2,814 FLACS cases that met the criteria for inclusion, only "127 cases had corneal astigmatism treated by the laser at the time of femtosecond-assisted surgery." Also, a "higher rate of previous corneal refractive surgery in the femtosecond group is, clinically, very significant."

Confirming that FLACS showed better reproducibility in capsular diameter

and centration, better reproducibility of corneal wound construction and less ultrasound energy, the authors somehow reached the conclusion that "this study found no evidence to support claims that femtosecond laser-assisted cataract surgery is a major advance and better than the conventional method."

> **"Due to the cost of equipment and steep learning curve, those who do not want to make the financial and time commitment just find fault with FLACS. But the surgeons who do commit to the technology demonstrate its superiority."**

4. The final article, "Visual and Refractive Outcomes in Manual versus Femtosecond Laser-Assisted Cataract Surgery," reviewed eyes receiving FLACS and MCS from July 2012 to July 2015.[5] Again, in this study astigmatism was only corrected with a toric IOL. To reduce outliers, anyone with greater than 1.5D of corneal astigmatism who elected to have a non-toric IOL was excluded. This does not address those with up to 1.5D.

The study concludes that "no statistically significant difference was found between eyes undergoing FLACS and eyes undergoing MCS with respect to refractive and visual outcomes" but allows that "surgeon learning curves and ongoing FLACS technological improvements may have altered its risk profile in the present day."

With 35 years working in an optometric referral center specializing in cataract and laser surgery, I would like to share the way I see it.

When first introduced, FLACS was supposed to make a poor surgeon good and a good surgeon great. It hasn't turned out that way. Due to the cost of equipment and steep learning curve, those who do not want to make the financial and time commitment just find fault with FLACS. But the surgeons who do commit to the technology demonstrate its superiority.

As an example, one of our surgeons—one author of the study mentioned above—is on record as saying there was no advantage to FLACS. His experience prior to joining our practice led him to this conclusion. However, after joining our group and committing to the technology, he sees it much differently. To prove the point, he (and others) did the research and proved better outcomes with FLACS.

Both surgeons in our practice will readily admit the femtosecond laser makes a more consistently round and properly positioned capsulorhexis than they can do by hand. These are two outstanding cataract surgeons with excellent hands. They would further say that when their turn comes, they want FLACS for their eyes.

I challenge any OD or MD to observe FLACS and MCS performed by suitably experienced surgeons and not conclude FLACS is better. Some faults in studies used to belittle FLACS include the age of the studies (including the infancy of FLACS at that time), the relative inexperience of the surgeons using the FLACS method at the time of the study, the omission of correction for lower amounts of astigmatism—what OD would Rx a pair of glasses that didn't correct low astigmatism?—and perhaps some personal bias.

The innuendo that FLACS is only encouraged to generate higher surgical fees is insulting. What doctor would not offer the newest technology in contact lenses and spectacles because they cost more? Should patients be denied the option for better technology because it costs more? Of course not.

Want a historical analogy? Around 1990, when sutureless cataract surgery came on the scene, there were plenty of haters. I was included in that group. Nowadays, who does not agree that sutureless is superior (given a well-constructed wound) and is surprised to see any of their post-op patients with sutures?

"Facts on femto?" Hardly. Let's keep fake news out of our journals.

—Howell M. Findley, OD
Lexington, KY

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From the Editor: The above letters raise many valid points—and a few spurious ones. None of the 12 studies cited in the first letter were conducted in the US, undermining that letter's critique of the *BJO* study for having been conducted outside the US. The second letter takes the authors of the *Clinical Perspectives* supplement to task for citing only four studies but overlooks the decades of hands-on expertise that also informed their views—an ethos built into the very title of that publication.

When summarizing a journal article for a news story, we take care to note that we are describing the results of a single study. Implicit in this framing is a reliance on readers' knowledge that rarely is any one study the definitive word on a topic. The current issue of this publication includes a news story on positive attributes of FLACS in diabetic patients; we similarly do not expect readers to take that brief summary as the final word on the matter either. Clinicians stitch these and other glimpses of knowledge together into a mosaic. Still, we acknowledge that the headlines used may not always reflect such nuance; we'll aim to do better.

Femto cataract surgery achieves impressive results, but its considerable expense and logistical challenges put greater burdens on surgery centers and patients alike. It's fair to ask for an accounting of value in return. The studies and insights shared in these letters help advance that discussion, and we're grateful for the opportunity to enable a deeper understanding of complex clinical issues.

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Back to the Future

I feel we have reached a critical juncture in our profession's history. I view a number of issues with a mixture of anxiety, concern and disappointment. I believe this to be more than the usual problems we face—it's worrisome because it involves a confluence of multiple strategic threats.

Over 50 years ago, optometry faced a similar crossroads: either the profession needed to move forward by adopting a medical model or face extinction. A group of visionaries met in a hotel room at LaGuardia airport and changed the course of the profession. At the meeting, they decided to advocate for optometrists to play a role in diagnosis and treatment of eye diseases. Three years later, the first DPA bill was passed in Rhode Island and the profession as we now know it was born.

Where we would we be today without the foresight of those individuals?

I think we are at a similar crossroads now. The inevitable changes that are going to occur in our current health delivery system will not spare optometry. The current model is unsustainable. But I believe it's always preferable to be prepared and proactive as opposed to waiting and being forced to react.

Currently, these are the main challenges as I see them:

1. Quality/quantity. At the Academy 2019 meeting in Orlando, I had the opportunity to talk with a number of young ODs involved with residency programs throughout the country. They have serious concerns about the quality of the recent crop of graduates from optometry schools. Apparently, the explosion in new optometry schools has resulted in a decrease in selectivity when accepting students. The ratio of applicants to acceptees is approaching 1:1. When I applied to PCO, there were 14 optometry schools and now there are 23. When I graduated, there were about 27,000 optometrists in the US. Today there are over 41,000.

2. Residencies. This has always been an issue for me. I still maintain that the only difference between OD and MD training is a residency. I appreciate the argument concerning the difficulties facing mandatory residency. I maintain that a solution can be found once a decision is made to move ahead.

In 1968, Alden Haffner, Irv Borish, Norman Wallis and other luminaries met at LaGuardia airport and decided to push for a new era in optometric care. Is it time for another?

3. Reciprocity. This is an embarrassment. It is also anti-competitive. Someday somebody is going to go ahead and also make this an anti-trust issue. Once everything else is addressed, there will be no excuses for this to continue and those states that do will be leaving themselves open to litigation.

4. Multiple certifying boards. Another embarrassment. I see this ultimately as a leadership issue. The leaders of the profession (not necessarily elected) need to come together to resolve this.

5. Artificial intelligence. I see two separate issues here:

First, online autorefraction is an existential issue. This isn't something that's just coming—it's already here. The bottom line is that if your business model is only based on refraction, you're in trouble.

Second, we risk exclusion from diabetic and glaucoma screenings. Diabetic telemedicine is already here. Last time I saw my PCP, there was a big sign in the office offering tele-eye exams for diabetes patients. My concern is not the technology—it's already up and running. My concern is OD access to be providers of this service. It is likely that these types of screening programs (soon to include glaucoma) will only allow MDs and exclude ODs.

6. Vision exams. This is a fundamental issue for the profession that goes back to the time of Prentice. At some point, we are going to have to decide whether we are refractionists or health care providers.

7. As-taught legislation. Eventually, this principle of licensure will need to be addressed or optometry will eventually find itself irrelevant. Going back to the legislature for every new medication or technique is impractical and hinders the advancement of care that scope expansion laws aim to achieve in the first place.

I'm old enough to have personally known several attendees of the LaGuardia meeting. To the best of my knowledge, all were Academy members and many were from academia. I believe that this is where leadership needs to come from again.

We need people to stand up. We need another LaGuardia.

—John J. O'Donnell, Jr., OD, FAAO, Dipl. (Glaucoma)
Harrisburg, PA

Fanelli and Sowka: Greek Gods

I read with interest two articles in the June issue, "Don't Feed the Hand that Bites You" by James Fanelli, OD, and "Not a Brite Idea" by Joseph Sowka, OD, both about surgical misadventures in procedures of dubious medical necessity. I was heartened by the pronouncement of each author and commend their fortitude in reaffirming our duty to abide by the Hippocratic Oath: First, do no harm.

"If there is one act alien to civilized behavior yet applauded by society, it is surgery," opined Richard Selzer, MD, a brilliant surgeon and author, in a 2004 *US News & World Report* article.

In other words, surgery is a necessary evil conferring a big burden on all concerned. Medical necessity should be the omnipresent preoccupation on the mind of caring professionals, as exemplified by the likes of Drs. Fanelli and Sowka.

Kudos to both. I'll frame their inspiring and caring conclusions and will keep honoring my own oath to "do no harm."

—Joseph Hallak, PhD, OD, FAAO
Syosset, NY

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

The Itch to Innovate

New products entering the market can change the way you manage allergic eye disease.

Optometrists have been treating allergic conjunctivitis for decades with agents such as antihistamines/mast cell stabilizers and topical steroids, so the words *new* and *allergic eye disease* don't often end up in the same sentence. But recent advances are likely to have profound impact on our methods and may result in substantial change and faster relief for your patients. From allergy and compounding agents to RASP inhibitors, we discuss these new developments and their benefits below.

New Approvals and Advances

Verkazia (Santen) was recently approved for the treatment of vernal keratoconjunctivitis (VKC). The drug is cyclosporine in a higher concentration (0.1%) than we've previously seen, and a cationic formulation. The latter helps with delivery of therapeutics by creating electrostatic attraction between positively charged droplets of the agent and the negatively charged ocular surface. The higher concentration may also have contributed to Verkazia meeting its primary and key secondary endpoints in the treatment of severe VKC in patients ages four to 18 years old.

Zerviate (cetirizine ophthalmic solution), from Eyevance, became available last year for the treatment of allergic conjunctivitis (AC)—the first antihistamine/mast cell stabilizer prescription medication to enter the market in over two decades. This product is approved for itching associated with AC and has two moisturizers, HPMC and glycerin, in the formulation. Cetirizine, the active ingredient in Zyrtec, is an oral antihistamine highly recommended by physicians, so patients should be familiar with it.

> **Recent advances are likely to have profound impacts and may result in substantial change and relief for your patients.**

OTC Allergy Agents

A new development in the OTC allergy space is a preservative-free antihistamine/mast cell stabilizer version of Alaway (Bausch + Lomb). A preservative-free option can be helpful, especially since as many as 57.7% of allergy patients suffer from clinically significant dryness.[1] Also note that Alcon's Pataday and Pataday Extra Strength (formerly called Pazeo) have moved from prescription to OTC.

A new lid wipe, Ocusoft Lid Scrub Allergy, is another novel idea, as allergens such as pollen and animal dander need to be removed to prevent further allergic responses. Since aggressive scrubbing could amplify allergy symptoms, this product uses a soft pad as well as effective moisturizers. It contains ingredients such as green tea extract, which has been shown to calm the inflammatory response; tea tree oil, which has been shown to relieve itching; and PSG-2, an ingredient used in rosacea creams that reduces redness.

Compounding Agents

New agents can also be obtained via compounding pharmacies, such as ImprimisRx. The most recent one is Elestat (epinastine) HCL 0.05% plus brimonidine 0.025% in a preservative-free multi-dose bottle. The low-dose brimonidine, which is the same as that found in Lumify, helps whiten the eye, making Elestat an effective allergy medication.

The Future: RASP Inhibitors

Reactive aldehyde species (RASP) lead to significant inflammatory responses and are highly elevated in allergic conjunctivitis and dry eye disease. RASP affects NFkB, scavenger receptor A binding and inflammasome activation, which all lead to cytokine release. Reproxalap (Aldeyra Pharmaceuticals), a drug candidate in Phase III FDA testing for both dry eye disease (DED) and AC, is showing evidence of RASP inhibition.

This drug has the potential to work like a corticosteroid without the risks associated with steroids. Reproxalap also significantly suppressed symptoms of itch in AC patients and SANDE scores as well as dryness and discomfort in DED patients. The drug has the potential to be approved for one or both conditions.

We're on the cusp of a new era in allergic eye disease care. Being aware of current and future developments will greatly help your patients who suffer from itching, ocular allergies and even dry eyes. ■

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About Dr. Karpecki

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

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BY MONTGOMERY VICKERS, OD

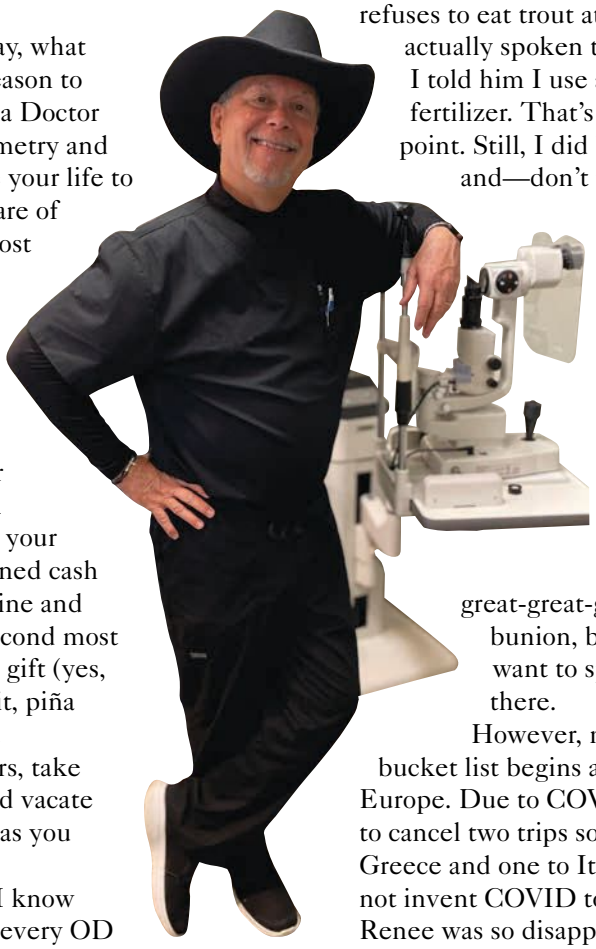
CHAIRSIDE

Hiatus From Home

Looking for a getaway? There are so many places to go and people to see; you just need to know where to start.

Vacation. That's right, I said the "V" word. My family and I got on an airplane and flew someplace sunny and fun. I will admit that I already live someplace sunny and fun so you might surmise that when we choose destinations, we lean toward gloomy and not fun. But there are no oceans in Dallas, although some of our Texas-sized swimming pools are big enough to have two time zones.

Anyway, what better reason to become a Doctor of Optometry and dedicate your life to taking care of God's most precious gift (no, not piña coladas) day after day than to throw your hard-earned cash at sunshine and God's second most precious gift (yes, you got it, piña coladas).



Doctors, take notes and vacate as often as you can.

Now, I know that not every OD considers the beach as his or her first vacation choice. If so, here are some other options to keep in mind:

1. ***Fly fishing***. I bring this up because one of my partners in practice loves to go fly fishing. He goes after the trout all over the western United States. This is something he and I have in common, although I prefer my trout with simple butter, salt and pepper hot out of a skillet. Curiously, he refuses to eat trout at all and hasn't actually spoken to me since I told him I use a trout lawn fertilizer. That's beside the point. Still, I did buy a fly pole and—don't tell John—a nice fry pan too.

2. ***Europe***. I realize that Europe has been around for a lot longer than America. That's all well and good but so has my great-great-grandmother's bunion, but I wouldn't want to spend a week there.

However, my lovely wife's bucket list begins and ends with Europe. Due to COVID, we've had to cancel two trips so far, one to Greece and one to Italy. No, I did not invent COVID to avoid Europe. Renee was so disappointed about the trip to Greece that I found a place just like it that we could visit… Branson, Missouri. The architecture! The history! Actually, it was so fun, and we would go back again if the opportunity presented itself. I love Missourians. They remind me of the greatest people I know… West Virginians.

3. ***Ironman competitions***. I actually know optometrists who consider swimming, biking and running until you puke to be the ultimate vacation destination. I absolutely cannot believe the state board still allows them to practice. They are obviously addicts. And I'll bet each family just loves watching dear old dad spend all day sweating in Speedos. Now, I don't know about you, but that right there sounds like a fun time!

4. ***Wine Country***. Been there, done that. And it was enjoyable. I found an amazing vintage just south of Sonoma. However, after three days all I wanted was a Diet Coke.

5. ***National Parks***. The newest National Park is the New River Gorge area in West Virginia. Once a year, they allow base jumping off the bridge, except during the first wave of COVID when it was cancelled. Something tells me that people who jump off a bridge into whitewater rapids have more to worry about than the virus.

I lump any optometrist who would consider doing this with the crazies in #3. That's just me, though.

Yes, there are a million more vacations to choose from. In order not to get overwhelmed, just whittle down the list and ask yourself, "Which is better: #1 or #2?" Then hit the road—what're you waiting for? ■

About Dr. Vickers

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

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Prescribing for Two

Be aware of the factors at play for pregnant diabetic women.

Q I have a 32-year-old patient with type 1 diabetes who presents for her first eye exam in many years. She is 12 weeks pregnant. What is the latest thinking on safely dilating and prescribing therapeutics if needed?

A During pregnancy, a woman may undergo development of new ocular conditions or modifications of existing ones. One that's most commonly altered during pregnancy is diabetic retinopathy (DR). It has been well documented that patients with pre-existing diabetes, especially type 1, have an increased risk of the development or progression of DR during pregnancy.[1,2] Rates of progression of DR may double during pregnancy, especially if retinopathy was present at conception.[1]

Given this transient increased risk of development or progression of DR during pregnancy and the first year post-partum, Caroline B. Pate, OD, professor and director of residency programs at the University of Alabama at Birmingham School of Optometry, advises to carefully monitor these patients by increasing the frequency of dilated exams.

The Clinical Practice Guidelines of the American Optometric Association recommend that women with diabetes who become pregnant should have a comprehensive eye and vision exam during every trimester with follow-up at six to 12 months postpartum.[1,3,4] Due to the relatively short-lived nature of gestational diabetes, these patients do not carry the same risks of developing retinopathy during pregnancy and do not need to be monitored as frequently during pregnancy as those with pre-existing diabetes.[3,5]

Despite 20/20 best-corrected vision, this type 1 diabetes patient who was seven months pregnant presented with proliferative DR.

Meds During Pregnancy

Although the historical risk of complications to the fetus as a result of using topical ocular diagnostic and therapeutic medications during pregnancy is low, one must still consider the risks and benefits prior to their use in this patient population.[6]

In June 2015, the FDA updated the prescription drug labeling for all new drugs from the "ABCDX" category designation in package inserts.[7] Instead, the prescriber is now responsible for reading the package insert and analyzing the safety data to make an informed decision on the risks and clinical considerations when selecting which medication to use for a patient.

If ever in doubt, Dr. Pate advises, consult the patient's ob-gyn/primary care physician before initiating treatment on a pregnant or nursing patient.

Due to the risks described above to a pregnant patient with pre-existing diabetes, dilation would certainly be warranted for your patient, despite diagnostic dilating agents traditionally holding the category "C" designation, prescribed only when the benefit justified the potential risk to the patient. Mydriacyl (tropicamide, USP) is available in 0.5% and 1% concentrations and could be used to dilate this patient. Avoid longer duration parasympatholytics such as homatropine and atropine due to the increased half-life.[6] If able to dilate with tropicamide alone, avoid phenylephrine due to rare cardiovascular side effects, which have been reported especially with the 10% concentration.[6] Keep in mind: punctal occlusion can help minimize systemic absorption of topical eye drops but do not prevent it completely. "Bottom line, don't be afraid to dilate your pregnant patients," Dr. Pate says.

Counsel all female diabetes patients of childbearing age about the associated risks of pregnancy on the progression or development of DR and the need for frequent monitoring during pregnancy, Dr. Pate says. If severe nonproliferative DR, proliferative DR or diabetic macular edema is detected, refer the patient to a retina specialist for treatment. ■

1. Chew EY, Mills JL, Metzger BE, et al. Metabolic control and progression of retinopathy. The Diabetes in Early Pregnancy Study Group. National Institute of Child Health and Human Development Diabetes in Early Pregnancy Study. Diabetes Care. 1995;18(5):631-7.

2. Sheth BP. Does pregnancy accelerate the rate of progression of diabetic retinopathy?: an update. Curr Diab Rep. 2008; 8:270-3.

3. AOA. Evidence-based Clinical Practice Guideline: Eye Care of the Patient with Diabetes Mellitus. www.aoa.org/AOA/Documents/Practice%20Management/Clinical%20Guidelines/EBO%20Guidelines/Eye%20Care%20of%20the%20Patient%20with%20Diabetes%20Mellitus%2C%20Second%20Edition.pdf. October 4, 2019. Accessed August 27, 2021.

4. Diabetes Control and Complications Trial Research Group. Effect of pregnancy on microvascular complications in the Diabetes Control and Complications Trial. Diabetes Care. 2000;23(8):1084-91.

5. Morrison JL, Hodgson LA, Lim LL, Al-Qureshi S. Diabetic retinopathy in pregnancy: a review. Clin Exp Ophthalmol. 2016;44(4):321-34.

6. Autry J. Pregnancy precautions: how to prescribe safely for new and expectant mothers. Review of Optometry. 2016;153(1): 28-31.

7. FDA Pregnancy and Lactation Labeling (Drugs) Final Rule.www.fda.gov/drugs/labeling-information-drug-products/pregnancy-and-lactation-labeling-drugs-final-rule. Accessed August 27, 2021.

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

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BY MARC B. TAUB, OD, MS, AND PAUL HARRIS, OD

A Glimpse Into the Future

Objective measurements of visual acuity continue to evolve, with a new method showing promising results.

The measurement of visual acuity is the cornerstone of optometry. We do it with every patient at nearly every visit, and it has remained relatively unchanged since Herman Snellen, MD, invented his namesake chart in 1862. Many different types of optotypes have been invented and used since, both clinically and for research purposes, but the procedure has remained the same: we put something up for the patient to see and ask them to tell us what they see.

A good deal of time is spent getting these measurements, and they involve the use of language, either by speaking or signing of some sort, such as when a patient points in the direction of the tumbling "E" or the opening in a Landolt "C." In some instances, such as with the HOTV chart or with Lea symbols, the patient may be given a card with the symbols, only requiring them to touch the symbol on the card to indicate which one they can visualize on the wall down at the end of the room. We don't always know if the measure we got was accurate, yet a lot is riding on the measurement.

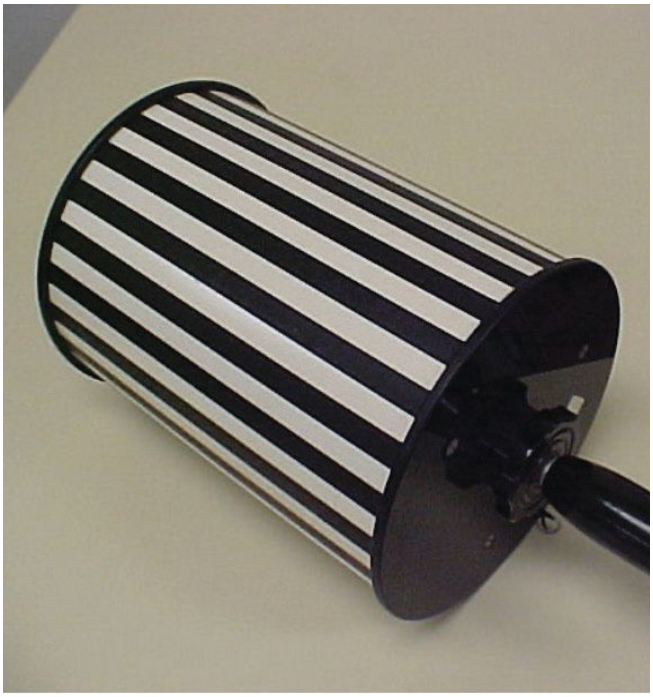

Fig. 1. The drum doesn't offer the best measurement of visual acuity.

Up and Coming

In our sixth floor lab at Southern College of Optometry (SCO), we have worked on several innovations in the measurement of visual acuity, including seminal work on the Dyop invented by Allen Hytowitz, continuously variable size optotype testing for M&S Technologies, validation of the automated electronic ETDRS test and others. However, a new method of testing visual acuity based on an idea, patented by Ben Thompson, PhD, and Jason Turuwhenua, PhD, and developed by Objective Acuity based in New Zealand, is poised to dramatically change how we measure visual acuity. We have conducted two experimental protocols to date using this new technology, with a final protocol in the works before we move the device into the clinic.

Disclosure: Objective Acuity has funded research protocols at SCO, but neither columnist is a paid employee or consultant for the company, nor has any financial interest in it.

The test is based on optokinetic nystagmus. When you read that, you probably think of the drum (*Figure 1*). The drum is clunky, scares many of our patients and, besides being difficult to use, doesn't do a good job pinpointing visual acuity. At best, when the patient doesn't just look at our face as it pops out from behind the drum, we know that they are following the lines. But most drums have lines that are far too wide to be of much use beyond saying that, indeed, the patient can see them.

Drs. Thompson and Turuwhenua's idea was to use a different type of target (*Figure 2*). Against a neutral gray background, the center white circle, with the darker ring around it, has the same overall luminance as the background. A grid of these targets moves either left or right across the screen and a camera

About Drs. Taub and Harris

Dr. Taub is a professor, chief of the Vision Therapy and Rehabilitation service and co-supervisor of the Vision Therapy and Pediatrics residency at Southern College of Optometry (SCO) in Memphis. He specializes in vision therapy, pediatrics and brain injury. **Dr. Harris** is also a professor at SCO. Previously, he was in private practice in Baltimore for 30 years. His interests are in behavioral vision care, vision therapy, pediatrics, brain injury and electrodiagnostics. They have no financial interests to disclose.

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Reference: 1. Jones L, Downie L, Korb D, et al. TFOS Dews II Management and Therapy Report. The Ocular Surface Jul 2017; 575-628.

focuses on the eyes to see if they are tracking the moving targets. There are several different-sized targets, all with the same spacing between them (*Figure 3*).

At the 2019 ARVO meeting, we presented our results in a poster titled, "Visual Acuity Assessment in Adults Using Optokinetic Nystagmus," which demonstrated a very tight relationship between the size of the targets and visual acuity.[1] The system we used for this study was not automated and required the lights to be turned off because it used infrared light to light up the retinal reflex to see the eye movements. Our second study was conducted with an apparatus that now does the analysis in real time, can be done with the lights on and is very fast (*Figure 4*).

This improved method begins by showing moving targets to the patient at the equivalent size for 20/125 for five seconds. If the patient's eye movements indicate the targets were followed, the next size presented is 20/63. If the program did not register target tracking, the moving targets jump up to 20/250. The pattern continues until an appropriate threshold has been determined. This usually takes between 35 and 50 seconds, and the visual acuity equivalent is displayed on the iPad used to control the test.

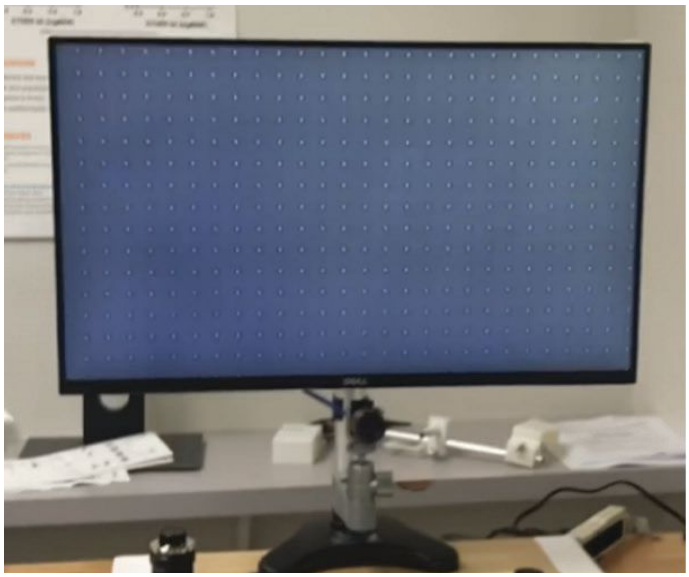

Fig. 4. This is the current configuration of the device we've been looking into as it relates to visual acuity measurement.

A recently conducted study that has not yet been published included 99 subjects (198 eyes) at SCO and found that the measurements were correlated between this system and ETDRS charts, with a 95% confidence interval ranging from 0.71 to 0.86. This has become our go-to test for non-verbal patients. Once it moves into the clinic, we will begin using it with children of all ages.

This system is not yet commercially available but should be a technology that is licensed to many different vendors of visual acuity testing platforms. When optometrists around the world can get accurate visual acuity measures with or without lenses over a range of 20/10 to 20/2000 in under a minute without having to have the patient do anything other than look at a screen, the bedrock measure of visual performance we all use to measure the efficacy of our treatments will rise to a new level of sophistication and help shed the yoke of Snellen's initial invention. ■

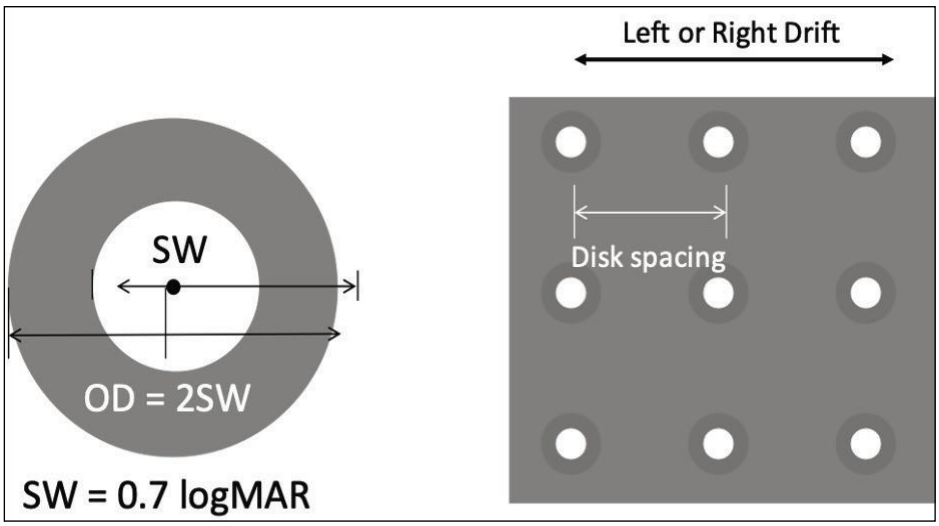

Fig. 2. A grid of these targets moves across the screen to determine if a patient is able to track their movement.

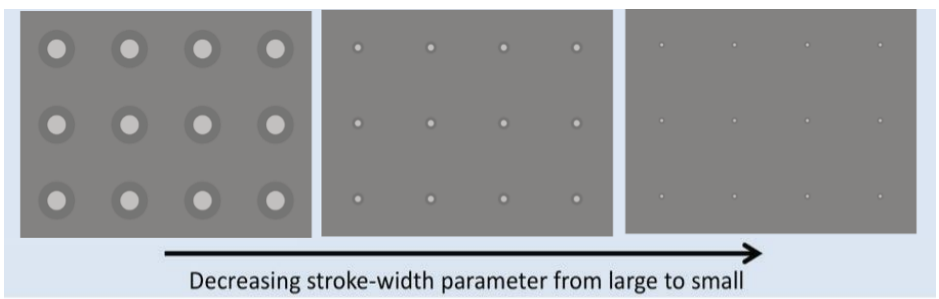

Fig. 3. These three varying sizes of targets all appear with the same distance between them.

1. Harris PA, Garner T, Sangi, M. et al. Visual acuity assessment in adults using optokinetic nystagmus. Invest Ophthalmol Vis Sci. 2019;60:5907.

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References: 1. Bron AJ, et al. *Ocul Surf*. 2017;15(3):438-510. doi:10.1016/j.tos.2017.05.011 **2.** Jones L, et al. *Ocul Surf*. 2017;15(3):575-628. doi:10.1016/j.jtos.2017.05.006

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BY JOHN RUMPAKIS, OD, MBA
CLINICAL CODING EDITOR

SWOT Your Way to a Stronger Practice

Self-examination and awareness are key to preventing an audit.

Much of my time is spent either helping practitioners be proactive in developing an internal audit prevention program or providing defense-related activities in audit proceedings. The former often helps avoid the latter.

Part of any business strategy is based upon a simple SWOT analysis—*strengths*, *weaknesses*, *opportunities* and *threats*. Having an internal process for coding and medical record compliance to which we can apply a SWOT analysis is also fundamental for creating a strong practice.

Investigate, review, analyze and report exactly where you and your office team stand. You may even find that you are doing many things well—a bonus.

Collect and Reflect

Often, there are three main issues in an audit for a practice. A lack of medical necessity noted in record for the type and level of visit or for special ophthalmic procedures and surgical services. There could be improper coding of office visits based on poor record keeping of time or medical decision-making (MDM). Sometimes, there is improper use of modifiers -25 and -59 by when clinical use is not met or the definition of the modifier is not met.

To collect information, start with a random sample. Maybe pull every fifth record from your medical records until you have a sample of 20 or 25. From that cohort, pull actual claims as well as associated financial records. Also make

> **Identifying strengths and weaknesses provides a foundation for opportunities.**

sure to have the current AMA CPT book, ICD-10 library, current policies for your zip code from your contracted medical carriers, CMS LCDs, etc.

Once you've collected everything, evaluate the following areas:

a. Was the patient status (new or established) calculated properly?

b. Did you properly determine the chief complaint that brought the patient in on that specific day?

c. If using E&M codes, did you perform a medically appropriate history and examination commensurate with the patient's presentation?

d. Did you properly document and sum total time if using time as the E&M code criterion?

e. Did you properly document your MDM if using that as the E&M code criterion?

f. Was the type (920XX or 992XX) and level of the exam appropriate for the specific patient presentation?

g. Did you properly determine all diagnoses specific to your examination and map them properly to the correct CPT code?

h. Did you properly determine and record medical necessity for each and every special ophthalmic test ordered and performed?

i. Did you properly create an interpretation & report (I&R) for each test performed?

j. Did you research the CCI edits to make sure that you can actually perform the tests indicated on the same day prior to doing the tests?

1. If using a modifier, do you meet the definition?

k. If you are having the patient back for a surgical procedure, did you review the surgical preamble defining a surgical package and what is included in that?

l. If using a modifier, did you read all documentation necessary to determine if your clinical application has met the definition of using this modifier?

m. Did you complete an operative report for every surgical procedure performed?

Moving Forward

A SWOT analysis of this information is now easy. What were your identified strengths? Did you consistently have a chief complaint listed on every visit? Did you do a great job in completing an I&R for every special ophthalmic test? What were your identified weaknesses? Perhaps you could have done a better job in cross-referencing the CCI edits prior to testing or recording time in your medical record.

Properly identifying these two sides provides the foundation for your opportunities. What can you correct? Who is responsible for monitoring these changes? By going through this exercise, you can reduce the threat of criminal, civil and financial exposure the practice may have due to improper coding and compliance practices.

Building a successful practice is not just about making money through proper clinical care and appropriate coding and billing; it is also about keeping the money you have made. ■

Send your coding questions to rocodingconnection@gmail.com.

About Dr. Rumpakis

Dr. Rumpakis is president and CEO of Practice Resource Management, a firm that provides consulting, appraisal and management services for healthcare professionals and industry partners. As a full-time consultant, he provides services to a wide array of ophthalmic clients. Dr. Rumpakis's full disclosure list can be found in the online version of this article at www.reviewofoptometry.com.

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ERIC J CONLEY, OD, MJ
HUNTINGTON, NY

Each day, health care professionals evaluate, diagnose and manage medical conditions knowing there is the possibility for malpractice litigation. In eye care, optometrists encounter many ocular conditions with systemic etiologies and many systemic pathologies that have ocular signs and symptoms, which when missed can have devastating consequences.

The provider's ability to properly connect the dots of a patient's complaints starts with careful observation of each part of the eye and thorough documentation. The greater the volume, the more tempted a provider may be to cut corners, skip tests and document incompletely. This opens the door to missed or erroneous diagnoses and, in some cases, improper treatment and failure to refer in a timely manner.

Developing a "legal protections" protocol for the office can significantly reduce your risk of being sued. To achieve that, you'll need to: (1) effectively recognize the areas of eye care most susceptible to legal peril (2) thoroughly understand how to navigate the contractual doctor/patient relationship; (3) know communication dos and don'ts to abide by with any patient who may have been potentially harmed and (4) promptly and properly respond to a formal legal summons.

Why ODs Get Sued

What legal issues should be most concerning to optometrists practicing in the 21st century healthcare setting? Optometric malpractice in years past was significantly different than our current day concerns.

Consider a 1941 case from an appellate court in Georgia, where "the Optometrist had not exercised reasonable care and skill in his examination of the eyes of his patient, a schoolboy, and in the fitting of glasses on the eyes."[1] The court's ruling described the injury, or tort, of the plaintiff "[as] suffer[ing] headaches and nausea and [being] 'backward' in his school work." The court ultimately awarded $75.00 to the plaintiff.[1]

Compare that relatively benign injury and nominal award with a more recent ruling for "failure to refer," whereby a plaintiff suffering from significant nearsightedness was not evaluated until the Monday after suffering from and reporting symptoms of floaters and flashes of light on the previous day. What did it cost the provider for that mistake? The macula-off retinal detachment with severe and permanent visual impairment in one eye resulted in a jury award of $2.5 million to the plaintiff.

These types of judgments rendered against providers, or more often settled out of court by professional liability insurance companies on behalf of providers, are extremely stressful and demoralizing. And, each settlement or judgment, even when paid by insurance companies, eventually exerts costs to providers in the way of increasing malpractice premiums. Having a triage system and "after-hours" plan *before* incidents occur is just one of the many procedural changes optometrists should establish in clinical practice to avoid medical harm and lawsuits.

First, know which local hospitals have surgical retina providers on duty 24 hours per day, seven days per week (typically teaching hospitals) or establish a direct connection with your preferred retina practice whereby patients

About the author

Dr. Conley is the founder of Conley Eye Care in Huntington, NY. He obtained his Master of Jurisprudence at Loyola University Chicago School of Law and is a fellow of the American Academy of Optometry. He lectures nationally on topics such as glaucoma, nutraceutical science, dry eye disease, imaging advancements in eye care and medical malpractice. He is is a paid consultant for Guardion Health Sciences.

can be triaged directly by the specialist. Additionally, institute a triage phone questionnaire to remove "judgment calls" by staff when fielding calls. As a result, instructions are explicit based on the intake answers provided by the patient and delayed evaluations are eliminated.

Failure to Diagnose

In eye care, most negligence cases arise from a "failure to diagnose," particularly around patients with glaucoma. Why? Because glaucoma typically presents without symptoms and the clinical signs can be missed if the patient's optic nerve, neuroretinal rim and retinal nerve fiber layer analysis are performed improperly, particularly without pupil mydriasis.

Consider the risk of a non-mydriatic evaluation in the following case (*Figures 1-3*). A non-stereoscopic optic nerve evaluation and the patient's initial visual field does not indicate any glaucoma or significant loss of vision. However, careful stereoscopic examination of the optic nerve and optical coherence tomography (OCT) highlight early inferior optic nerve damage, ganglion cell loss and reduced retinal nerve fiber layer thickness consistent with the inferior-temporal thinning/sloping of the neuroretinal rim tissue.

Undilated viewing and reliance on subjective visual field data, or worse yet, "normal-range" intraocular pressure readings, might cause a provider to *fail to diagnose* the glaucomatous optic neuropathy present in this case.

In eye care, nearly all serious incidences of "missed" diagnoses are tied to examining patients without dilated fundus examinations using slit lamp and binocular indirect ophthalmoscopy techniques. In glaucoma care, significantly greater congruency of the "actual" cup-to-disc ratio with interpreted ratios is found in dilated evaluations versus undilated examinations.[2]

One of the easiest ways to avoid claims of misdiagnosis of intraocular disease, including retinal breaks, tears and detachments, open-angle glaucoma and malignancies (ocular and brain tumors) is to routinely use diagnostic agents for dilation of the pupil during ocular examinations.

Unfortunately, providers occasionally fail to dilate patients due to patient complaints about post-dilation blur and photosensitivity as well as the increased examination time added to the visits. Designing practice protocols and procedures around actively dilating patients annually allows for the most effective ocular examinations and reduces malpractice risk significantly.

Keeping current on the latest technologies and treatment options through continuing education courses and colleague collaborations will, undoubtedly, prevent application of outmoded standards as new and improved options are introduced and adopted by the profession.

An audit of patient records and state board complaints initiated by patients against providers highlights both documentation errors as well as clinical decision making shortcomings that lead to litigation.

The areas of greatest concern that repeatedly arise include: (1) providers recognizing and documenting a clinical finding as "different" or concerning (*e.g.*, "possible optic nerve pallor") but not initiating steps to investigate further (*i.e.*, imaging, blood work, referral, etc.), (2) documenting a finding that is significant (*e.g.*, "new-onset floaters") but not initiating the proper expanded documentation or testing (*i.e.*, questioning for associated findings such as flashes or veil/curtain effect and performing dilated fundus evaluations or referral) and (3) performing a complete and thorough evaluation with proper assessment and plan but failing to fully document information collected during the course of the examination.

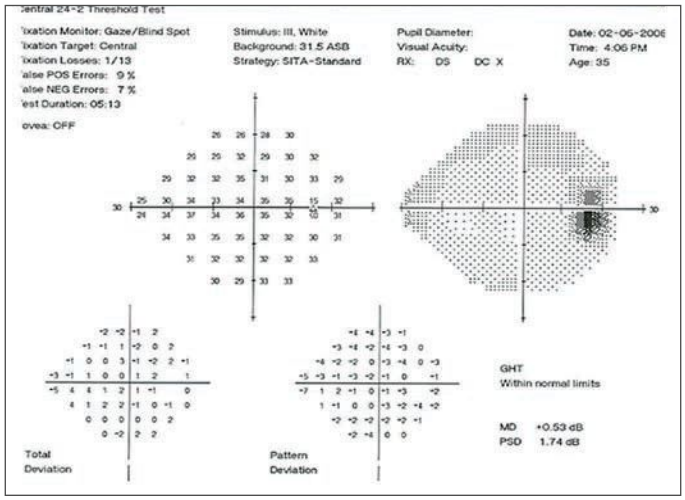

Fig. 1. Patient's results on 24-2 SAP VF appears "normal" however there is masking of an actual early glaucomatous defect due to the patient's high "false positive" responses (9%).

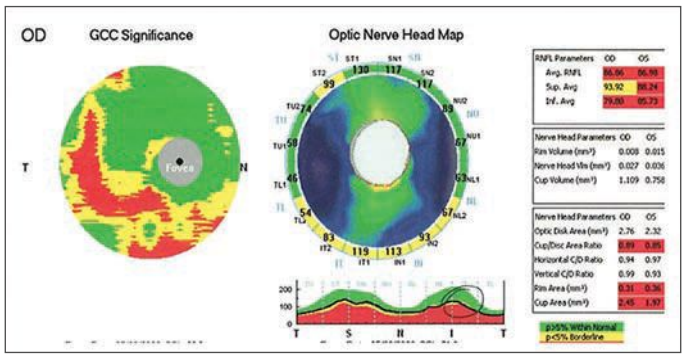

Fig. 2. Patient's OCT OD demonstrates large ratio cupping with inferior thinning of the RNFL and corresponding GCC consistent with glaucomatous optic nerve atrophy.

Defining Negligence

Now before you panic and double-up all your malpractice coverages, understand that the legal standard for negligence requires four main elements that *all* must be satisfied before a judgment can be rendered: (1) Duty of Care, (2) Breach of Duty, (3) Injury and (4) Causation.

Christopher Lievens, OD, MS, FAAO
The Eye Center at Southern College of Optometry
Memphis, Tennessee
Dr. Lievens is a paid consultant for Alcon.

With a Unique Water Gradient Surface Using CELLIGENT® Technology, TOTAL30® Contact Lenses Provide an Experience That Feels Like Nothing, Even at Day 30[1]

I've had the pleasure and challenge of educating future optometrists for a quarter of a century. Optometry students have a desire for knowledge, and we do our best as educators to transform that desire into a habit of lifelong learning. Patient care is constantly evolving as technology improves and new treatment strategies emerge. Teaching is most rewarding when truly novel science and technology can help our patients.

In 2013, Alcon launched DAILIES TOTAL1® – a new lens material in a brand-new category of soft lenses. Now, Alcon is introducing **TOTAL30®** monthly replacement contact lenses and I am just as impressed as I was 8 years ago. Built upon the scientific backbone of Water Gradient Technology, TOTAL30® contact lenses use biomimicry as the basis for its construct. It is gratifying to share this innovation with the optometrists of tomorrow.

Many patients prefer reusable lenses–in fact, in 2020, the reusable category accounted for over 60% of all contact lens prescriptions in the United States.[2] Generally, my preference when a patient prefers reusable lenses is a monthly replacement lens over a two-week replacement lens because they are associated with better replacement compliance.[3]

These patients deserve innovation, but most recent contact lens advancements have focused on daily disposables. Introducing TOTAL30® reusable contact lenses from Alcon. TOTAL30® lenses are composed of lehfilcon A, a Water Gradient material that features a high-oxygen-transmissibility silicone hydrogel core (Dk/t=154 @ –3.00D) that gradually transitions to almost 100% water at the surface. This Water Gradient remains durable over 30 days of daily wear and nightly cleaning, disinfection and storage.[4–7] (*Figure 1*) The surface of the lenses is enhanced with CELLIGENT® Technology, a truly biomimetic lens chemistry that provides important features necessary for using Water Gradient technology in a monthly replacement lens. Biomimetic is a key word here, because TOTAL30® lenses are inspired by ocular biology, and their surface is designed to mimic the corneal surface.

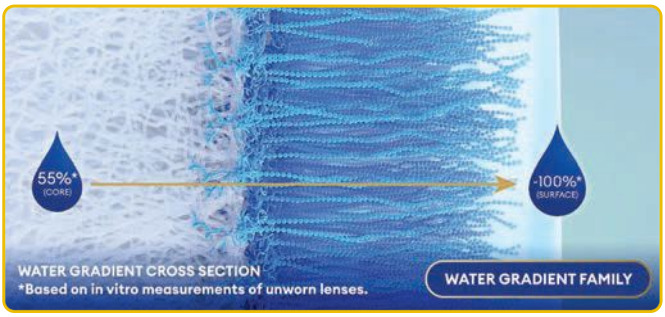

FIGURE 1: The Water Gradient of TOTAL30® contact lenses[6,7]

A Closer Look at the Surface of the Cornea

The corneal epithelium is complex, with important characteristics and mechanisms that allow it to be wettable and help protect it from foreign debris and pathogen adhesion. Microscopically, the corneal epithelium is brush-like with microvilli that project out from the surface epithelial cells, onto which glycocalyx adheres as feathery extensions. The glycocalyx–comprised primarily of mucin secretions from goblet cells–is hydrophilic, and so attracts water. Thus, in large part, glycocalyx provides moisture to the corneal epithelium. It is also important to note that the microvilli and glycocalyx float freely and are constantly in motion, which helps to sweep away foreign particles.[8,9]

Like the cornea, a monthly replacement contact lens requires excellent wettability, and should resist adhesion of bacteria and contamination with large, sticky molecules such as proteins and lipids.

CELLIGENT® Technology and the Power of Biomimicry

TOTAL30® is the latest addition to Alcon's groundbreaking permanent water surface lens family, previously available only in the daily disposable category.

Alcon has optimized the Water Gradient Technology of DAILIES TOTAL1® for monthly wear, through the addition of CELLIGENT® Technology. CELLIGENT® is based on 2-Methacryloyloxyethyl phosphorylcholine (MPC), a biocompatible hydrophilic polymer demonstrating resistance to protein and bacterial adhesion.[10,11] When used in the Water Gradient surface of TOTAL30® contact lenses, MPC forms polymer nanofibers with properties similar to the glycocalyx extensions of the corneal epithelium, including hydrophilicity[10,12] and constant, dynamic motility.[5,7,12] Put simply, these nanofibers mimic the glycocalyx to provide a constant soft and gentle brushing motion that helps lubricate the lens surface. (*Figure 2*) Furthermore, MPC nanofibers have a neutral charge to help repel foreign hydrophobic particles.[12]

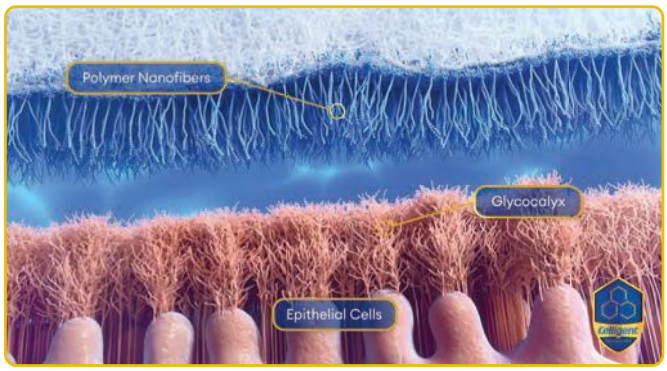

FIGURE 2: CELLIGENT® Technology lens chemistry creates polymer nanofibers at the lens surface to mimic the glycocalyx formed on the microvilli of corneal epithelial cells

Using CELLIGENT® Technology lens chemistry to create the Water Gradient surface makes TOTAL30® an extremely soft[13], lubricious[14] lens that helps resist contaminants like bacteria[15,16] and lipids.[17] Water Gradient Technology enables superior in vitro lens-surface moisture stability.[18]** TOTAL30® lenses also feature Class 1 UV blocking (more than 90% of UVA and 99% of UVB).[19,20,*]

Consider Prescribing TOTAL30® for Your Patients in Reusable Lenses

I have been blown away with the science and technology of TOTAL30® contact lenses. Having a lens designed through biomimicry to resemble the cornea is impressive to say the least. Interns and students alike share my excitement, and we look forward to years of prescribing this lens for our patients.

TOTAL30® Technical Specifications

MATERIAL lehfilcon A	**CENTER THICKNESS (@–3.00D, mm)** 0.08	**CORE MODULUS (MPa)** 0.6
DIAMETER (mm) 14.2	**HANDLING TINT** VISITINT®	**SURFACE MODULUS (MPa)** 0.046
Dk/t 154@ –3.00D	**SURFACE WATER CONTENT** ~100%	**PACKAGING** 6-ct. box and 1-ct. trial pack
BASE CURVE (mm) 8.4	**CORE WATER CONTENT** 55%	**LIGHT PROPERTIES** Class I UV absorption* and HEVL filtration†
POWER RANGE +8.00D to +6.50D (0.50D steps); +6.00D to +0.25D (0.25D steps); -0.25D to -8.00D (0.25D steps); -8.50D to -12.00D (0.50D steps)		**WEARING SCHEDULE** Daily wear only

*UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. The patient should continue to use UV absorbing eyewear as directed.

**Based on in vitro studies wherein wettability was measured using the iDDrop System. All lenses were tested in an identical manner, soaked in a PBS (phosphate-buffered saline solution) for 16 ± 2 hours ($p<0.05$)

†There is no demonstrated clinical benefit to a 34% reduction in visible light at wavelengths below 450 nm.

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In legal proceedings, this is often a very difficult threshold to meet, and many lawsuits fail on inconclusive causation findings or disputes on standards.

In fact, there has rarely, if ever, been more than 50 total optometric malpractice judgments in any given year across the entire United States—an amazing statistic considering ODs are the leading providers of primary eye care services. With more than 35,000 full-time employed ODs practicing in 7,000+ communities and 4,300+ towns having ODs serve as the only source of primary eye care, such a minimal number of lawsuits is all the more impressive.[3] Contributing to the exceptionally low incidences of malpractice is the fact that optometrists: (1) do not perform intraocular surgery, (2) endure a rigorous optometric doctoral program for entry to practice and (3) benefit from the "all or none" requirements of negligence in legal proceedings.

Typically, the elements in cases determining legal outcomes mainly revolve around Breach of Duty and Causation findings since the "standards" of eye care are generally well-established. As the injury is typically evident (loss of visual acuity, visual field or both), plaintiffs will be claiming some level of loss of function/ability to bring suit.

If our lack of action, delayed action(s) or improper action(s), as their provider, was directly responsible for the injuries that followed, then the only remaining "lifeline" in obtaining a "not guilty" verdict is whether or not we were following the "standard of care" throughout the doctor/patient exchange without breaching that duty.

In the event the injury suffered by the patient was inevitable regardless of the care that was applied at the time of presentation to the doctor's care, there will not be an enforceable negligence ruling and the plaintiff's case will be unsuccessful.

In current case law, the standard of care is established as the care that would typically be rendered by those who provide "reasonable and ordinary care," skill and diligence as physicians and surgeons in good standing practicing "in the same neighborhood," in the same general line of practice, [who] ordinarily have and exercise in like cases. It is not measured against the most knowledgeable [expert] of peers/colleagues in the profession but it has and continues to evolve as technology and treatment protocols evolve.[4]

Consider that before collagen crosslinking (CXL) become FDA approved, our standard of care in corneal ectasia cases (keratoconus/pellucid marginal degeneration/post-refractive surgery) was to manage "vision" with contact lenses until apical corneal scarring necessitated corneal transplant surgery. That protocol is no longer acceptable since CXL can arrest ectatic advancement and prevent loss of vision normally associated with scar development.

A provider who would fail to refer for CXL would be negligent and open to malpractice litigation. In the end, our practice decisions are compared with the average physician in the same line of practice and alternative treatments or experimental techniques are acceptable only if a respectable minority recognizes it as "reasonable medicine" or if all other standard treatments have failed and serious consequences are imminent.

In the world of eye care, the Injury component of negligence can be as minimal as asthenopia-related symptoms, as demonstrated previously, to severe visual impairment or even resultant death (failure to diagnose malignancies/tumors).

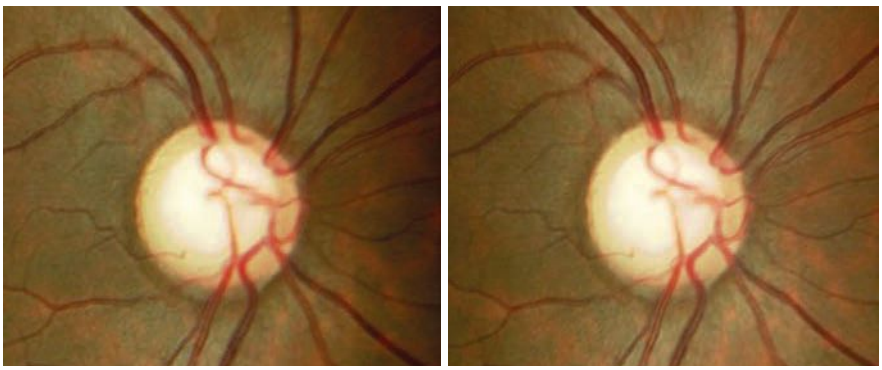

Fig. 3. Patient's right eye stereoscopic optic nerve images. Notable is the inferior temporal sloping and thinning of the neuroretinal rim tissue that would be difficult to detect without stereoscopic viewing.

Put into Practice

So, having established a macro view of the malpractice minefield, it's probably prudent to reflect on how we most often become entangled in legal jeopardy in our practices day-to-day along with the mechanisms to mitigate that risk:

Contractual Relationships

The doctor/patient relationship is a consensual one wherein the patient knowingly seeks the assistance of a physician and the physician knowingly accepts them as a patient. However, once we have established that relationship, we are responsible for providing healthcare in a manner consistent within the "standard of care" of the eye care community.

We can only "disengage" from the established doctor/patient relationship when: (1) the patient is cured or dies, (2) when the physician and patient mutually consent to termination, (3) when the patient dismisses the physician or (4) when the physician withdraws from the doctor/patient contract.[5]

Now, of course, for a number of reasons, a relationship between the doctor (or the doctor's staff) and a patient may no longer be suitable (*e.g.*, behavioral issues, treatment non-compliance), and it is best if the parties go their separate ways. It will be necessary for the clinician to initiate a rational discussion expressing how issues in the relationship are making

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care counterproductive and that a referral to another provider is necessary where the patient might have better success and outcomes.

This referral ultimately needs to be confirmed, in written form, that your colleague has assumed the care of the patient to avoid abandonment and breach of contract charges. As a rule, have your office manager/front desk staff make the appointment for the outgoing patient while they are still at your office to be sure you have provided sufficient time and access for the patient to find a replacement provider. Lastly, obtain documentation that another physician is now actively managing the patient and you'll satisfy your legal obligations under the law.

How to Respond to a Summons

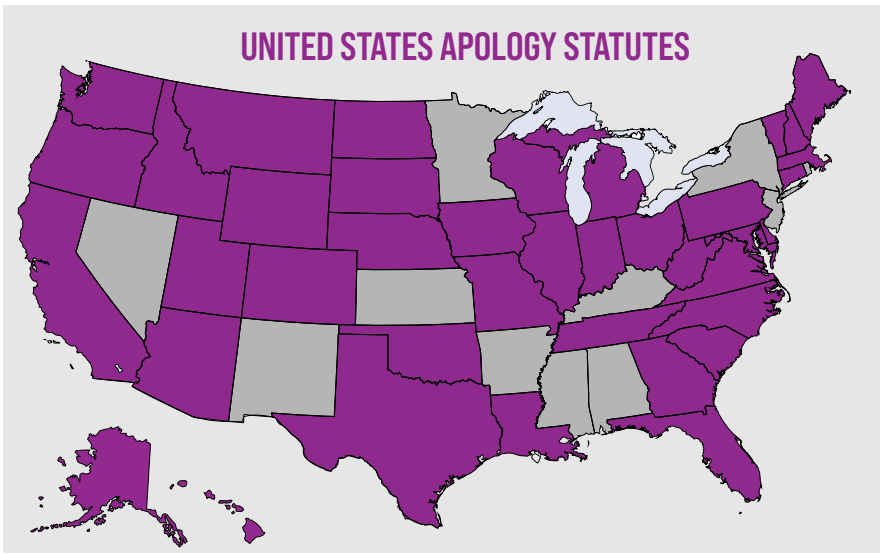
Formal legal summons, records requests by attorneys and/or patients or informal complaint letters regarding one of your patients requires the following actions: (1) immediately contact with your malpractice carrier (legal summons require responses of guilty/not guilty typically within 30 days or risk of a default judgment against you) and a personal malpractice attorney, (2) take a deep breath—this is why you have malpractice insurance and (3) realize that while this will be a source of stress and frustration, you will continue to care for patients and protect your livelihood.

In the event that an amicable solution cannot be arrived at, your insurance provider will also be assigning its in-house counsel to manage your case, but having your own personal representation is always sound advice.

Finally, a system to prevent medical chart records and billing information from ever leaving your office without your review (see below) is important every day but even more critical during these potential legal proceedings.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislates that our patients have a right to a copy of their medical record; however, no statute dictates that the review or release needs to be immediate, and usually up to 30 days is allowable before running afoul of the law.[4] Providers can and should provide records to comanaging physicians in a timely or expedient fashion especially if the patient is in an emergent or urgent health crisis, but beyond that, a process for review and then release is critical.

Completing records accurately and completely at the time of service can avoid omissions and/or mistakes that occur when backfilled long after the visit has occurred and memories are blurred.



Adapted from National Conference of State Legislatures

Fig. 4. US map highlighting the 39 states and territories currently with legislation enacting "I'm Sorry" statutes and or provisions.

Documentation and Preparation

Incomplete or inaccurate charts (paper or electronic) are the low-hanging fruit for malpractice litigators. If it's not written, it didn't happen.

Did you have a discussion about potential visual loss in the event the patient is noncompliant with medication usage but didn't document the discussion? Well, it didn't happen in the eyes of the court. Did you modify or "clean up" a medical record (paper or electronic) after receiving a "discovery" patient record request from the plaintiff's attorney (they likely already attempted to obtain a copy of the chart from your front desk staff on an earlier benign request)? If so, you've just handed the suing party an automatic victory even if the changes were an accurate representation of those visit(s).

Enforce an office-wide, written, firm chart and form policy (punishable by immediate termination) that no copy of any patient record requested by anyone (*e.g.*, patients, proxies, colleague providers, government entities, plaintiff's attorneys) is ever released without prior review and authorization from each and every doctor within the practice that has contributed to the medical record *and* an in-house document placed at the fore of the chart (paper or EMR) describing the request type (*e.g.*, notes, images, billing), requestor(s) and the authorized release date.

It's always best to make a habit of completing patient visit medical records by the end of the business day, if not by the end of the actual encounter for the greatest accuracy and precision. The end result is confidence knowing that the records and materials are accurate and represent the full and complete story of the patient's rendered care. For most optometrists providing excellent care to their patients, there is nothing more important in those legal proceedings.

After-incident Communication

A poor patient outcome resulting in visual loss or reduction is not necessarily medical malpractice. In fact, many poor

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outcomes occur while under the care of expert clinicians managing cases meeting or exceeding every standard of care. In other words, some poor outcomes are not preventable despite the best treatments and care.

What is preventable is poor communication between providers and patients. And, while patients ultimately know that doctors are human and capable of errors, it is not perfection they are seeking.

A significant contributing factor that induces a patient towards medical malpractice proceedings is the unsatisfactory communication before, during and after a perceived or actual patient injury. Patient polling, depositions, interrogatories and casual conversations all point to patient frustrations and, more importantly, anger originating from a provider's minimization, trivialization, dismissal or outright avoidance of patient complaints after an outcome or incident has resulted in a poor outcome.

The adverse event, unfortunate and sometimes vision impairing, is not the impetus for initiating most lawsuits but rather the feeling that the doctor does not care, particularly when the silence afterwards is deafening to them. The doctor/patient relationship is ultimately based on trust and communication and once that foundation has been eroded, the patient may look to force that communication and "get answers" for their concerns in any manner possible—only at this juncture will they use the courts and attorneys as their conduit rather than a phone call to the office.

To get ahead of this potential litigation, enact an "office grievance communication policy." Define a written policy playbook instructing all members of the office team how to properly respond (or not respond) to patient complaints (minor and major) based on the following principles and research.

First, no policy has been more beneficial at preventing medical malpractice cases than "I'm sorry" laws that allow providers to apologize for poor outcomes suffered by patients with those statements not being held against the clinician in later court proceedings. Check with your insurance carrier and state association regarding the status of "I'm Sorry" legislation and advice on patient communication before embarking down this path.

At last glance, 39 US states and territories have some form of legal protection for physicians who apologize to patients after an adverse event and additional states have legislation pending (*Figure 4*).[6] Even in states which have not yet passed legislation preventing apologies from being used against providers, it is clear that an open dialogue between doctor and patient, even one in which the doctor provides empathy without an admission of an error, results in far fewer lawsuits being initiated.

The cover of your grievance communication policy book should include the following two statements that should always be a part of any dialogue between the distressed patient and the accountable doctor: "I regret that you have had a bad experience with your _____. Neither one of us expected you to have these problems. I regret this has happened to you" and "I am ultimately responsible for your care. I am going to delve deeper into this matter to fully understand how it happened. I am going to stay in touch with you and share all the information with you as soon as I learn how this occurred."

From this point forward, any and all scheduled phone conversations need to occur weekly between the patient and doctor until the patient is satisfied with the efforts undertaken to remedy the injury. Patients want to be sure that action has been taken to prevent a repeat error with them and any other future patients. It is critical that the interaction is performed between parties physically seated at the same level and not substituted with the practice's or insurance company's attorney, an uninvolved practice partner, office manager, etc.

Furthermore, do not permit staff (*e.g.*, front desk, technical support and managers) to discuss the situation with the involved patient (or any other patients inside or outside the office) except to say that "I'm not aware of the specific concerns you are having, but I know that Dr. _____ is going to discuss everything with you in the exam room."

Following a principle of truthful but limited disclosure, expressing how "sorry you are that the negative outcome happened" without taking blame for the complication allows for a joint grieving process between the doctor and patient and the patient's family members.

An explanation of what happened and what future treatment options exist to potentially remedy the problem are critical for expressing care and maintain the doctor-patient relationship.

Finally, inform the patient and their family how you plan to use what you learn from your patient's experience to try to prevent others from having the same or a similar problem in the future with other patients.

Takeaways

Ultimately, the patient understands that the physician is human and imperfect, but they will not tolerate dishonesty. Establishing all of the protocols listed within are certainly effective measures in reducing malpractice litigation events; however, developing a trusted doctor-patient relationship with our patients that nurtures open communication has proven to be the best tool yet.

As much as what's been discussed has helped reduce lawsuits, always consult with your malpractice carrier before expressing regret and implementing these policies. ■

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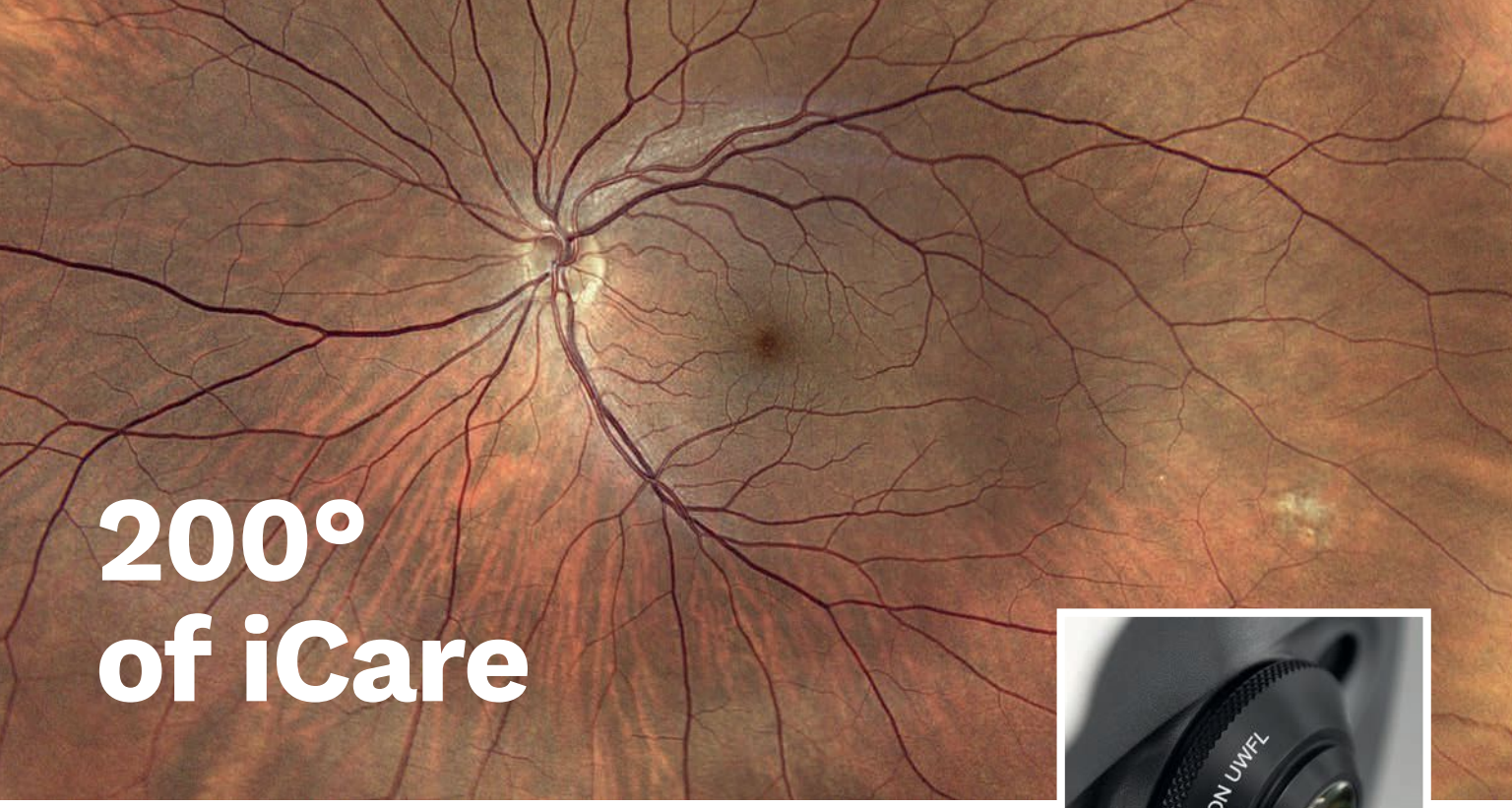

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SCOPING OUT OPTOMETRY'S NEXT ERA

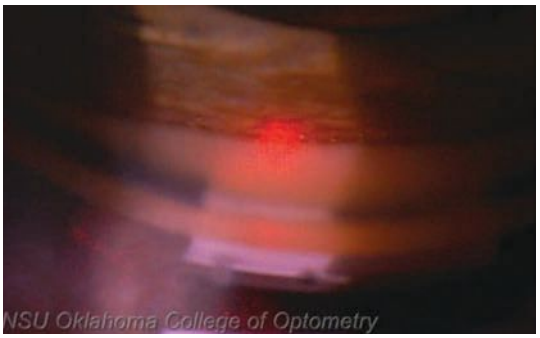
Momentum has been building to extend practice privileges for ODs, making eye care more accessible than ever before. Here's where these efforts stand in 2021.

BY LEANNE SPIEGLE
ASSOCIATE EDITOR

Expanding the scope of practice for optometrists in the United States is an ongoing process made difficult by the fact that the profession is legislated on a state-by-state basis. Yet, especially over the last decade, many states have been successful in passing legislation that extends practice privileges of optometrists, which, in turn, is improving access to care. The American Optometric Association (AOA) reports that 99% of the US population has access to a doctor of optometry, meaning that the passage of these bills could allow hundreds of thousands of people to access potentially vision-saving treatment without having to travel far from their homes or see a different doctor.[1] However, only four states (Alaska, Kentucky, Louisiana and Oklahoma) currently allow optometrists to perform every procedure outlined in their education and training.[2]

It wasn't until 1971 that Rhode Island became the first to authorize the use of diagnostic drugs, followed by West Virginia and North Carolina, before which optometrists had little elbow room to do much other than visual field testing.[3] Fast forward to today and more and more states are allowing optometrists to perform laser and minor procedures, administer various injections, prescribe a growing number of medications and controlled substances and manage more patients independently without having to consult with or refer patients to an ophthalmologist.

Photo: Nathan Lighthizer, OD



To date, six states allow optometrists to use SLT to lower intraocular pressure in glaucoma patients (Oklahoma, Kentucky, Louisiana, Alaska, Arkansas and Wyoming).

Glaucoma management is one category of patient care that has strongly benefited from expansion laws. As of 2021, every state in the country can treat glaucoma topically. In addition, seven states are now allowed to perform at least one type of laser procedure (Oklahoma, Kentucky, Louisiana, Alaska, Arkansas, Mississippi and Wyoming).

"The reason why more states are granting optometrists authority to perform different procedures is twofold: the first is that the knowledge, education and training of optometry reflects that they should have the authority in their scope of practice to provide those services to their patients, and the other is the safety history modeled by previous practice changes," says Nebraska's Christopher Wolfe, OD, chair of the AOA State Government Relations Committee.

"Glaucoma management has been in the profession for 20, 30 years or longer in some states," notes Dr. Wolfe. "It's difficult for someone to say ODs are not managing glaucoma appropriately and not trained on it. The same sort of thing is happening with other procedures; we can offer patients care through safe procedures that are much more accessible." Dr. Wolfe also points out that the way licensure laws are written is an important part of ensuring ODs will be able to use new medications and treatment options in patient care when they become available.

"For example, suppose a law states that you can treat glaucoma with a

beta-blocker. If a different medication like prostaglandin comes around, then you wouldn't have access to that new medication that's been around for 20 years and is safer and less of a treatment burden for the patient, and you might be going back to the legislature to battle for that," Dr. Wolfe explains. "Rather, what the law might say is to allow for the treatment of glaucoma. That way, any new medication that comes around relative to the treatment of glaucoma would then be available to physicians and to their patients."

Expanding privileges not only allows optometrists to use the training and skills they are already capable of, but it also lets ODs care for more patients in-office, offer a wider variety of treatment options and, consequently, improve the vision and eye health of more people. Let's explore some of the scope expansion bills that have passed over the last two decades and how they're being implemented in the practice of optometry across the states.

Hands-on Optometry: Newcomers Aplenty

In just the last three years, eight states mounted legislative efforts to expand scope for their ODs—and most succeeded. Many of these next-gen laws allow optometrists to manipulate ocular structures directly, bringing invasive surgical procedures—*e.g.*, intralesional steroid injection, curettage, foreign body removal, selective laser trabeculoplasty (SLT) and YAG capsulotomy—to optometry.

Arkansas. One defining battle of the current scope era took place here two years ago. The state changed its definition of optometry—literally—in March 2019 with the passage of HB 1251, which had been reworked following its initial rejection a month prior. The practice of optometry in Arkansas now encompasses some minor ophthalmic surgeries, including procedures of the lid, adnexa or visual system, as well as the use of ophthalmic lasers (making it the fifth state to do so).

Before the bill passed, ODs in Arkansas were not allowed to perform any procedure that required anything other than a topical anesthetic, and, according to the president of the Arkansas Optometric Association, Joe Sugg, OD, the road to changing that legislation was anything but smooth.

"The challenges we faced from our opposition were truly relentless and unprecedented," Dr. Sugg recalls. "Every step of the way, we faced the well-funded and organized efforts from medicine and ophthalmology, under the name 'Safe Surgery Arkansas.' The group even challenged the scope law after it was signed by the governor and began collecting signatures to place the new law on the November 2020 general election ballot," he says. Partly because most of the collected signatures turned out to be unqualified canvassers, a petition granted in favor of optometry was able to push the act forward. Since it went into effect, the benefits of the bill for both practices and patients have been made apparent.

"A friend and colleague of mine in another rural practice had a glaucoma patient who was left debilitated by a stroke and could no longer walk to the office or instill his eye drops," Dr. Sugg shares. "This OD arranged transportation for the patient to come to the office and performed SLT on him, helping save his vision. These are the types of stories about the care we optometrists provide in our offices that our opposition takes for granted, but fortunately more and more state legislatures are understanding how beneficial these expanded scope laws can be for our patients."

Maryland. In March 2020, an exciting scope of practice law (HB 447/SB 447) went into effect here, giving optometrists more prescribing authority and removing several requirements for ophthalmology referrals. ODs in the Old Line State are finally permitted to prescribe most topical agents and oral pharmaceuticals. They also no longer have to refer patients to an ophthalmologist for open-angle glaucoma treatment, corneal and conjunctival foreign body removal or to order labs, cultures or blood tests.

Vermont. In a rare loss, the Office of Professional Regulation under Vermont's Secretary of State decided in late January 2020 that it would not allow optometrists in the state to perform the advanced procedures being proposed by the Vermont Optometric Association (VOA), including various forms of laser treatment and injections. This jurisdiction came despite several states having recently passed similar scope of practice expansion laws for ODs (Oklahoma, Kentucky, Alaska and Louisiana).

As justification for opposing the law, the state referred to a *JAMA Ophthalmology* 2016 report that suggested the incidence of repeat laser trabeculoplasty procedures doubles when done by an optometrist rather than an ophthalmologist; however, critics point out that the study has several limitations and does not provide a sound argument for depriving Vermont ODs of expanded practice privileges. The growing and successful track record of scope of practice laws in the United States also demonstrates the great potential of the proposed legislation, which will surely not be the VOA's last effort to advocate for ODs and their patients.

UNCLE SAM FAVORS SCOPE LAWS

The federal government showed its support of expanded practice laws with the release of a 2018 report titled *Reforming America's Healthcare System Through Choice and Competition*. The document, advocating the rights of non-medical clinicians such as optometrists, included the following guidelines: (1) allow clinicians to practice at the "top of their license," (2) allow non-physicians to be paid directly and (3) eliminate supervision requirements between physicians and "care extenders" (like ODs).

The report also covered the potential of telehealth, regarding technology as a way to increase competition and accessibility, even across state lines. It states that telehealth is most effective when it replicates in-person care, evaluates conditions using digital images and allows for quicker information acquisition than would be possible with in-person visits.

AOA Applauds Report Calling for States to Improve Safe Patient Access to Critical Eye Health Services. AOA. December 12, 2018. www.aoa.org/about-the-aoa/press-room/press-releases/report-calls-on-states-to-review-scope-laws?sso=y. Accessed September 21, 2021.

Optimizing OCT Imaging

By Jay M. Haynie, OD, FAAO

Imaging technologies play an important role in our profession, and the ability to visualize tissue and evidence of disease in detail is one of the cornerstones of our jobs. High-quality images are critical to reaching a more confident diagnosis, and ultimately, delivering better patient outcomes through more informed disease management. At the eyeRISE 2021 virtual conference, I discussed "Advancements in Optical Coherence Tomography (OCT) Imaging Devices" with several of my colleagues. We agreed that image quality is necessary for accurate interpretation and analysis, yet there still are challenges to yielding such optimized images.

When considering OCT imaging devices, the clinical usefulness of a scan can be affected by three parameters: 1) the scan area (field of view); 2) the scan density (resolution); and 3) the scan time for image acquisition. If we hold any one of these parameters' constant, the other two factors can be inversely affected. For example, if we want a fast scan acquisition with high resolution then we are limited in scan area. Inherently, there has always been a need to make some tradeoff when selecting the scan pattern on our OCTs—until now.

In an effort to eliminate the need for eye care providers to have to choose between scan area and scan density, Topcon Healthcare (Tokyo, Japan) developed PixelSmart™ technology for the DRI OCT Triton, Topcon's Swept Source OCT (SS-OCT) platform. At its core, PixelSmart is designed to deliver the best of both worlds—the image quality of a high-density line scan and the wide coverage of a dense cube scan—without sacrificing scan speed.

PixelSmart's new image processing algorithm is elevating visualization of the retina by delivering the clarity of averaged images throughout the entire volume scan—reducing speckle noise and improving contrast. The technology is a post-processing technique, meaning scan time is not affected, and Triton scans previously captured on the device can be reprocessed to further enhance scan quality.

This step forward in OCT imaging aims to provide clinicians with the highest possible image quality to help them better identify and differentiate between pathologies, with the goal of improving patient care and outcomes.

In the following discussion, I share my first impressions with PixelSmart technology after evaluating it in my clinic.

OCT IN CLINICAL PRACTICE

What is your typical imaging protocol in clinic?

Dr. Haynie: Our office protocol entails volumetric scans on all new patients. In addition, if we are dealing with a patient with age-related macular degeneration, we generally use high-resolution scan patterns to get a better view of potential neovascular membranes and subretinal fluid. For our diabetic patients or those with retinal vascular disease, we rely primarily on volumetric scans.

What percentage of your patients have cataracts or other media opacities and how is SS-OCT technology impacting your care of these patients?

Dr. Haynie: About 30 percent of our patients have significant media opacities. When you are trying to diagnose, manage and stabilize retinal disease prior to cataract surgery, it can be challenging to evaluate whether a patient is ready to go forward with the procedure. For that reason, we use SS-OCT technology to penetrate through media opacities and help us make that assessment.

When assessing patient findings, why is it still important to look through the B-scans for every patient rather than just reviewing OCT reports?

Dr. Haynie: I think one of the upsides of OCT technology is the algorithmic data it gives us, but that can also be a downside with regard to, for example, "red disease." You can look at a thickness map and see a large area of increased retinal thickening—it shows up as red areas on these reports—but you really don't know what has caused that. So, just like when you see a lesion on a fundus photo, you need to look at the live tissue. The problem with relying on thickness maps alone becomes apparent when a patient has a retinal cotton-wool spot or a significant intraretinal hemorrhage. Those conditions will create a very large area of increased retinal thickness. However, cotton-wool spots can improve over time, so it's important to go through the B-scans to try to isolate and identify the origin of the pathology that has resulted in elevation or thinning on the individual retinal thickness map.

How has PixelSmart helped to optimize your clinical workflow?

Dr. Haynie: Most technologies today offer faster and faster scans, so speed is readily available. But without PixelSmart technology, interpreting the raw data and multiple scans can be challenging. With PixelSmart, you get speed, large volumetric data scans, and high-quality images. As a result, you have the information you need from one scan rather than having to take that patient through multiple scans, such as raster scans, 5-line scans, and radial scans. That is extremely helpful in optimizing clinic workflow because we're inundated with retinal disease cases. Every patient coming in is getting OCT imaging, but now we only need one scan to get all of the information we need.

APPLYING PIXELSMART TO PATIENT CASES

CASE STUDY 1: Central Serous Chorioretinopathy: PixelSmart Enhances the View of the Choroid

A 74-year-old woman was referred to my clinic for management of Central Serous Chorioretinopathy (CSC) in the right eye. She described a gray smudge in the central vision of her right eye that appeared to have grown larger over the previous six weeks. She had a medical history of hypertension and her ocular history was unremarkable. When thinking about the typical demographic of patients with CSC, this patient was a little bit older than we typically see, and her visual symptoms raised suspicion as to whether this was the correct diagnosis.

Looking at the original B-scan of the patient's right eye in **Figure 1**, there is a presumed neurosensory retinal de-

tachment, which is the shallow pocket of subretinal fluid.

When PixelSmart is toggled on as shown in **Figure 2**, we can view the high-resolution neurosensory detachment and choroidal scleral junction. Diseases of the pachychoroid, which include CSC, don't tend to exhibit this razor-thin choroid as in our patient. Yet, PixelSmart reveals thinning of the choroid indicating that a closer look is necessary to identify the source of the subretinal fluid.

Figure 1. Images: Jay M. Haynie, OD, FAAO

Figure 2.

In this case, it is necessary to scroll through the OCT B-scans starting with the superior B-scan (**Figure 3**) just above the fovea. We now see an area of RPE disturbance, a break in Bruch's membrane, subretinal thickening as well as the presence of a shallow, irregular retinal pigment epithelial detachment known as the "double-layer sign." These are all indications of a choroidal neovascular membrane (CNV) that has migrated through Bruch's membrane and is growing into the subretinal space.

Figure 3.

In this case, the utilization of PixelSmart helped us to differentiate between CSC and CNV, which is critical as the etiology, management, and the long-term prognosis of the two conditions is quite different. The patient went on to receive serial anti-VEGF injections and has done very well.

CASE STUDY 2: Lamellar Macular Hole or MacTel? PixelSmart Helps Make the Diagnosis

A 75-year-old woman was referred to our clinic for management of bilateral lamellar macular holes. Her chief complaint was that she was missing letters while reading and recently noticed areas of central distortion in each eye. The patient's medical history was unremarkable and her ocular history revealed she was pseudophakic, having undergone cataract surgery three years prior.

Looking at the patient's standard imaging in **Figure 1**, the B-scan through the central foveal area reveals a cavitation defect within the inner retina. This led to the initial diagnosis of a lamellar macular hole. However, on closer evaluation of the areas surrounding the cavitation defect, nothing stands out as being abnormal.

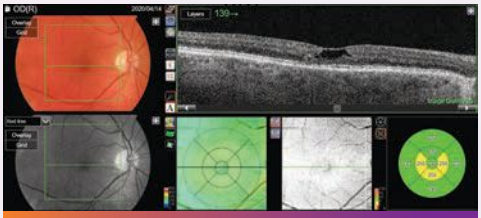


Figure 1.

Standard imaging of the fellow eye in **Figure 2** reveals a similar image, with a cavitation defect within the inner retina with adjacent structures and the RPE appearing intact.

Toggling on PixelSmart in **Figure 3** to view the initial line scan of the right eye, we see a cavitation defect that looks very similar to the original OCT scan. However, just to the left of the cavitation, a hyperreflective lesion within the deep retinal layer is apparent. More importantly, the ellipsoid zone and the IPL layer are disrupted in the temporal perifoveal region.

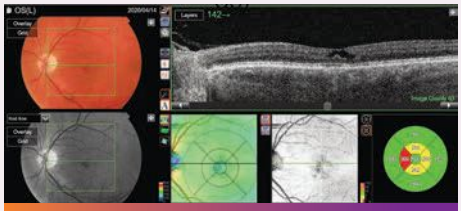


Figure 2.

Imaging of the fellow eye using PixelSmart in **Figure 4** highlights the cavitation defect in addition to the disruption of the outer retinal complex and a drape of the internal limiting membrane on the surface, which are characteristic features of Type 2 Macular Telangiectasia (MacTel). Because of this technology, we moved from an initial diagnosis of a lamellar macular hole to the appropriate diagnosis, which is Type 2 Macular Telangiectasia.

Figure 3.

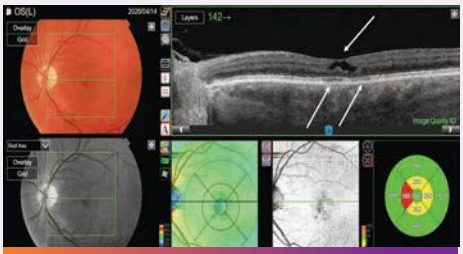


Figure 4.

This differential diagnosis is particularly important because a lamellar macular hole typically carries a fairly good prognosis: it is not amenable to surgery, patients generally have stable vision, and the condition rarely progresses to a full thickness hole. Type 2 Macular Telangiectasia has a far different prognosis; patients may develop visual symptoms (as this patient did) but also serious complications, such as choroidal neovascular membranes, can occur.

As these cases demonstrate, high-quality imaging was necessary to make the more accurate diagnoses and determine the appropriate treatment plan for the patient. Innovations like PixelSmart are game-changing technology that bring immediate value to a clinical practice. ●

Jay M. Haynie, OD, FAAO, practices at Sound Retina in Tacoma, Wash., and is a nationally recognized speaker on new technology and management of retina and macular diseases.

Iowa. In June 2020, the House passed a bill allowing Iowa optometrists to treat certain ocular conditions with injections. HF 310 gave the state's ODs the right to administer subconjunctival injections to treat ocular conditions, intralesional injections to treat chalazia, botulinum toxin (including for cosmetic purposes) and injections to counteract an anaphylactic reaction. While newer OD graduates will have the education and clinical training required to administer these injections, the Iowa Optometric Association (IOA) is offering workshops for those needing to acquire the new skillset, and even offered one prior to the bill's passage to prepare the state's ODs for what was to come.

In order for a licensed OD in Iowa to begin using these injections, the state's board of optometry put forward the following training requirements:

- Complete 24 hours of approved educational training pertaining to injections.
- At least four of the 24 hours must be clinical training, and at least five of the 24 hours must address administration and side effects of injection treatment for botulinum toxin and chalazia.

Brian Kirschling, OD, who served as IOA's president from April 2020-2021, says that the bill passed the House three times in the years leading up to 2020 and received widespread bipartisan support, but the COVID-19 pandemic did temporarily take top priority at the House. He notes that despite it being a long process, building relationships with state legislators is a crucial part of advocating for increased practice privileges that will expand access to care across the state population.

"After three or four years, I think some people start to think, 'Well, this is never going to happen,'" Dr. Kirschling says. "Then, to have [the bill pass], despite the fact that COVID was an immediate priority for everybody in the world, is a testament to not only that sweat equity and financial support in those relationships, but also a testament to the respect for optometry in the state of Iowa."

Dr. Kirschling says the IOA has upcoming workshops scheduled for the start of 2022 to allow more optometrists in the state to complete the training necessary to begin administering the injections. While this bill will certainly allow more of Iowa's residents to access critical care without having to travel far, he explains that the efforts will be ongoing for scope of practice expansion.

"You can never sit back and rest on your laurels for too long; you have got to think: how do we how remain an attractive state for young people to want to practice in, and how do we provide the best care for the most Iowans across the state?" says Dr. Kirschling. Some counties have only one or two eyecare providers for the entire region, he notes, and "chances are that it's going to be an optometrist in large portions of Iowa." As a result, "it's very important that when new procedures or medications become available, we're always making sure that we are included in those discussions and thinking about how to provide access to care for the vast majority of the state population," he says.

Pennsylvania. For the first time in 18 years, the Keystone State expanded the scope of practice for optometrists in October 2020 when Gov. Tom Wolf signed HB 2561, an amendment to the state's Optometric Practice and Licensure Act first passed in 1980. Among other new privileges, the amendment gives ODs much more authority to examine, diagnose and treat patients in-office by removing restrictions such as the requirement for the secretary of health to approve medications before doctors write a prescription. The bill grants the state's board of optometry the exclusive right to manage and determine the optometric formulary, meaning patients will have access to needed medications sooner and more conveniently.

Mississippi. This past spring, Mississippi passed a law that now allows its optometrists to prescribe oral steroids and use certain injectable agents, including local anesthesia in some procedures, as well as permits them to excise and remove chalazia and noncancerous growths in and around the eyelid. The bill was approved by Gov. Tate Reeves in March 2021, prior to which, it was amended to allow for any OD credentialed by the state board to perform laser capsulotomy procedures.

"We are proud to be one of the first states to be able to perform these types of procedures, and we are very

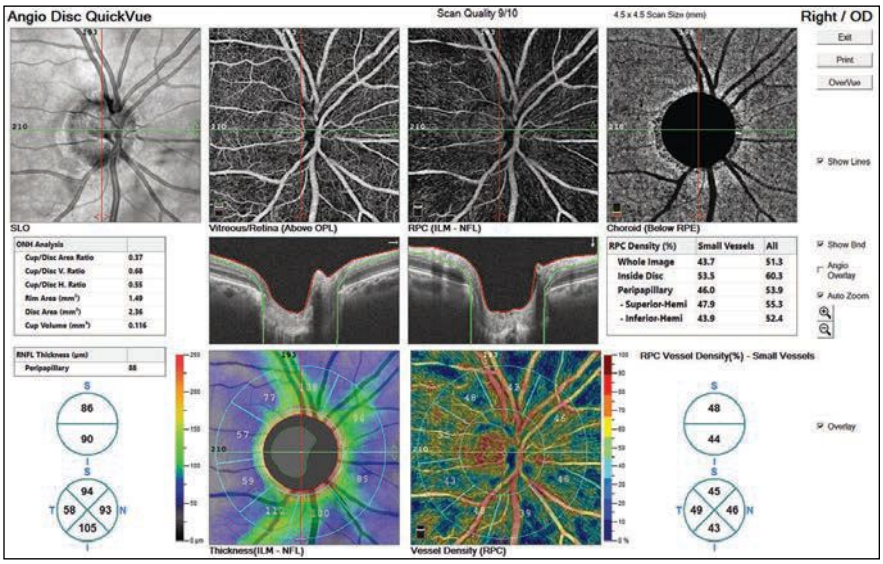


Photo: Ryan Schott, OD

It was only this past summer that all 50 states achieved autonomy in glaucoma care, when a Texas law freed ODs there from having to comanage all aspects with an MD. Above: an AngioVue OCT-A scan identifies capillary dropout that corresponds to RNFL dropout.

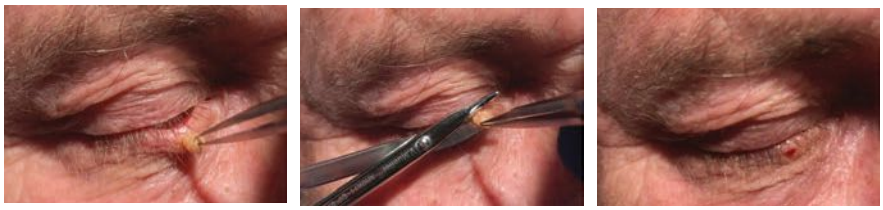
grateful for the states that came before us," says Ryan Wally, OD, legislative chair of the Mississippi Optometric Association. "We have had people from Louisiana, Arkansas, Oklahoma and Kentucky all reach out to us to help us with our efforts. If I had one piece of advice for other states going forward, I would encourage them to reach out to the states that have been successful, because the advice and expertise they can offer is valuable."

Dr. Wally explains that for ODs in Mississippi to be able to perform the added procedures and start prescribing oral steroids, they must first complete mandated training, including a continuing education (CE) course and an eight-hour preceptorship with an ophthalmologist or licensed, credentialed optometrist, followed by a state board exam and clinical skills assessment, during which the OD must perform a laser capsulotomy procedure.

"We already have almost 150 optometrists statewide who are credentialed in these procedures. As soon as the bill passed, our state board went to work to begin that process," says Dr. Wally. "[The practice expansion] has really helped with access to care and being able to offer excellent eye care statewide."

Wyoming. Only a few weeks after Mississippi's bill passed, optometrists in Wyoming received their big win when Gov. Mark Gordon signed the scope expansion bill, HB 39, on April 2 of this year. The state's ODs, practicing in 22 of 23 counties, can now perform YAG laser capsulotomy, SLT, laser iridotomy and lesion removal, as well as enjoying more prescribing authority. The last scope of practice update for Wyoming ODs was 26 years ago in 1995, highlighting the significant need for this legislation that better aligns practice rights with current education and training.

Kari Cline, executive director of the Wyoming Optometric Association (WOA), says that Wyoming ODs must complete certain CE courses and a period of proctoring to be able to perform the specific procedures. "I would say about 95% of practicing optometrists in the state of Wyoming have completed those courses," she says. Ms. Cline notes that a lot of the graduating students are coming out of school with training in the new procedures and may only need to take a refresher course depending on the skills and education they received.



Photos: Jackie Burress, OD, Rodney Bendure, OD, and Lisa Kedzuf, OD

Lesion removal is one procedure being added to practice scope in a growing number of states that gives patients quicker access to care with the ability to be treated in-office. Above: excision of a squamous papilloma in an optometric office.

Dana Day, OD, past president and current legislative chair of the WOA, says that optometrists and their patients alike in Wyoming are excited about the services they can now offer in-office. "I was able to present the option to a couple of my patients recently to have their laser procedures done in the office or have them referred to another practicing physician, and they were excited to be able to just stay here and have it done in our office when they used to have to go somewhere else," says Dr. Day.

He continues, "Our optometrists are excited; as you can see, 95% of them, or close to that, have already done the certification and are looking forward to incorporating these expanded privileges into their practices for the betterment of patient care." Dr. Day encourages any ODs in Wyoming who haven't yet taken the certification to do so and embrace the new opportunities.

Texas. The Lone Star State was the lone hold-out on independent glaucoma care until this past June, when Gov. Greg Abbott signed SB 993, giving ODs in the state the authority to manage most forms of glaucoma independently without the requirement of comanagement with an ophthalmologist. With the exception of Schedule I and II controlled substances, Texas ODs can also now treat eye conditions with oral meds.

"This bill is not only great for optometrists, but ophthalmologists too," says Houston's Jill Autry, OD. "Many patients would never even see an eye doctor if they had to find an ophthalmology office. As optometry becomes more medical, more medical issues are found, and many are going to need to be referred to ophthalmology. As people look at optometrists as their primary eye care physicians, it's not only patients and optometrists that gain, but ophthalmologists, primary-care practitioners (PCPs), endocrinologists and rheumatologists—I think it's really better for everybody."

Now that ODs in Texas can prescribe antivirals, patients could avoid negative outcomes from conditions that otherwise may not be treated in time due to barriers to access of the drug, Dr. Autry explains. "Antivirals are pretty commonly used to treat ocular disease. The alternatives are very expensive, and many times are not readily available at pharmacies. Oftentimes, you really need to start those antivirals within 24 to 72 hours, and by the time you get the patient in to see an ophthalmologist or their PCP, visual outcomes may suffer." Thankfully, patients seeking critical antiviral treatment in Texas will no longer need to go to such lengths.

The state's board of optometry did not mandate specific training for ODs to begin taking advantage of the expanded privileges since the law went into effect on September 1, but there are CE courses for those who wish to learn about the various medications they may now be prescribing to their patients. Dr. Autry says that Texas ODs would love to eventually be able to perform laser and surgical

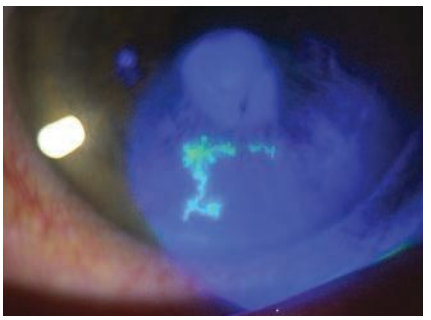


Photo: Lisa Martén, MD

As antivirals can be hard to access, giving ODs the authority to prescribe them helps reach more patients in need.

procedures like a growing number of states around them, but negotiations in this recent bill may prevent that from happening for at least the next several years.

Next-Gen Scope Veterans

Let's check in with some of the early success stories in the current wave of hands-on optometric procedure laws to see if their experiences may point the way toward what to expect for the roll-outs now happening in more recently updated states.

"Optometrists have been very pleased with the laws that allow them to practice full scope and they end up working more effectively with their ophthalmology colleagues/surgeons because of the clearly defined areas of practice scope," notes Kentucky's Paul Karpecki, OD, a longtime champion of optometric scope expansion and greater involvement in medical care. "The specialists are seeing more appropriate patients that need to be in their office and optometry is seeing the primary care patients that need to be monitored for diabetic retinopathy or glaucoma, as examples."

Michigan. The last adjustment to Michigan's scope of practice for optometrists happened back in late 2002 with the signing of HB 5552, coined the "Therapeutic Care Legislation." The bill's passage meant ODs were no longer required to consult with an ophthalmologist prior to treating glaucoma, allowing for speedier treatment and a more seamless process for both physicians and patients.

The legislation also granted Michigan ODs the right to prescribe oral drugs, including Schedule III, IV and V controlled narcotic substances. Since then, the scope of practice in Michigan has been at a standstill but continues to be monitored, says Jeff Towns, executive director of the Michigan Optometric Association.

"We have a lot of frustrated recent graduates in the state that really aren't able to practice the scope of optometry they are being taught and trained to provide, which unfortunately means a lot of our graduates are leaving the state for others that allow them to practice at a level commensurate with their training and education," says Towns. "In a way, Michigan taxpayers are helping to pay for the education and training of doctors who are going to apply that training outside the borders of our state. Like any state, we need to be looking to the future."

Because of the nature of the work, it's easier for optometrists than it is for ophthalmologists to practice successfully in less populated and rural areas of a state, notes Towns. He says that while the demand for eye care is growing as the population increases, "We need to look at who is the most likely provider to help meet that demand, and optometrists are in a perfect spot to do that."

Oklahoma. Optometrists in this southern state have been performing laser procedures since 1998, practicing in the first state permitting them to do so with one of the best scope of practice laws in the country. Six years later in October 2004, Gov. Brad Henry signed a rule that also made it the only state at the time allowing optometrists to perform over 100 types of surgeries, including those using a scalpel. The regulation gave ODs the ability to cut the eyelid or eye surface to remove cancer lesions, administer medication via injections in the center of the eye and inject Botox around the eye. Since no other states' ODs at the time were allowed to perform such delicate procedures, the rule was met with controversy initially; however, as years pass and states nationwide are implementing similar laws, the safety history and benefits of optometrists performing these procedures can hardly be disputed.

Kentucky. In February 2011, Kentucky joined Oklahoma as only the second state at the time allowing optometrists to perform laser procedures when the Better Access to Quality Eye Care bill (SB 110) was signed into law by Gov. Steve Beshear with bipartisan support. The bill allows optometrists to use the most current methods of drug administration, including certain injections and drug-dispensing contact lenses, as well as perform minor surgical procedures to correct ocular abnormalities.

While the training for these procedures is built into the curriculum for today's optometry students, the bill requires all ODs who haven't already to complete necessary training and certification requirements before performing each class of procedures.

This past summer, the Bluegrass State also conferred onto the state's optometrists the right to dispense pharmaceutical agents in-office.

Dr. Karpecki, who practices in Lexington, notes that "the overarching issue is that, other than in some major metropolitan cities, there is a severe shortage of ophthalmologists, resulting in optometry having to provide greater patient access and in-office services."

Indiana. On January 1, 2014, the scope of practice expanded for Indiana optometrists when the state lifted the prohibition against ODs performing injections. A more recent law that passed in 2020 also added Indiana optometrists to the list of providers authorized to engage in telemedicine and issue prescriptions to patients over the phone, a practice privilege being granted to ODs in an increasing number of states around the country, especially following the intense demand for telemedicine brought on by the COVID-19 pandemic.

Nebraska. In May 2014, the state's Better Access to Quality Eye Care bill was signed into law by Gov. Dave

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Heineman. The legislation lifted former restrictions and gave optometrists the ability to prescribe several oral drugs including steroids, glaucoma medications and immunosuppressives. It also authorized potentially life-saving injections that treat anaphylaxis.

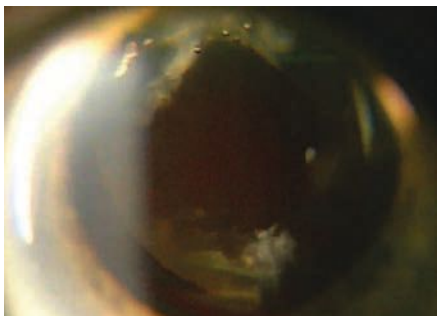
Because such a large portion of the state is rural, extending prescribing authority for ODs has afforded many Nebraskans the opportunity to receive certain treatments in-office, as opposed to jumping through hoops to access care that patients may desperately want or need, notes Dr. Wolfe, who also serves as the legislative chair for the Nebraska Optometric Association.

"Since 1998, when ODs in Nebraska were first allowed to begin treating and managing glaucoma, no complaints have been sent to the board, nor have any actions had to be made relating to the treatment and management of glaucoma or expanded authority, which really speaks to the safety of the profession for providing those services to patients," says Dr. Wolfe. He adds that no additional training was required for ODs to begin administering care based on the updated regulations of the 2014 bill since every optometrist in the state with a therapeutic license has been trained and tested on these medications since the early 1990s.

Louisiana. Gov. Bobby Jindal signed HB 1065 in June 2014 permitting Louisiana optometrists to perform various ophthalmic procedures including YAG laser capsulotomy and laser peripheral iridotomy. The bill, initially met with controversy after a similar effort was shot down the year before, also began allowing ODs in the state to prescribe Schedule III drugs. The legislation made Louisiana the third state in the country to allow ODs to use lasers.

Alaska. Optometrists in The Last Frontier had reason to celebrate in July 2017 when the "Optometry and Optometrists" bill (HB 103) was signed into law by Gov. Bill Walker, giving the Alaska Board of Examiners in Optometry the authority to write regulations that allow the state's ODs to practice everything they've been taught in optometry school, including use lasers and perform surgical procedures. Alaska is the largest state in the country, yet also ranks fourth in states with the lowest population. In a region where people and communities are so dispersed, giving optometrists more practice privileges makes treatment accessible for thousands of Alaskans who may not have been able to access it before.

Virginia. In spring 2018, Virginia enacted SB 511, authorizing optometrists to administer limited injections of Schedule IV steroids for chalazia treatment. Prior to the law that went into effect on July 1, 2018, ODs in the Old Dominion State could only prescribe Schedule II hydrocodone combination products (hydrocodone plus acetaminophen) and Schedules III and IV controlled substances and devices. The new law requires that optometrists in the state pass certain training requirements and be board and TPA certified to be able to administer steroid injections.



Photos: Kelly Boucher, OD, Brittany Ellis, OD, and Nathan Lighthizer, OD

Today, capsulotomies can be performed in optometry offices in seven states. Oklahoma was the first state to authorize ODs to do so. At left, Oklahoma's Nathan Lighthizer, OD, prepares to treat a patient. At right, we see the resulting central clearance postoperatively.

Final Thoughts

Scope of practice in the field of optometry in the United States is moving in a positive and exciting direction for doctors, healthcare workers, patients and communities, especially those in less populated areas of the country. The more people who have their eyes examined regularly and consider optometrists their primary eye care providers, the more diseases and instances of vision loss or blindness that may be prevented.

The bottom line: there are more cataract surgeries than there are surgeons, notes Dr. Karpecki, leaving an underserved patient base for minor procedures, advanced treatments like SLT, YAGs and iridotomy lasers.

"We still need to work with ophthalmology for surgical procedures and tertiary care—and in some cases, secondary care—but aside from that, optometry can manage most ophthalmic conditions and needs to stay educated and aware of them." ■

BIG RETAILERS FIGHT BACK

In 2018 in Oklahoma, large retail chains, primarily Walmart, began to fight against prescription eyewear being sold in their stores and allowing optometrists to open practices in commercial settings. Public voters ruled in favor of the retailers when questioned about the matter in a ballot question in the 2018 midterm elections. However, Walmart and the Oklahoma Association of Optometric Physicians ended up agreeing on a compromise: ODs could offer independent eye care services and prescription eyewear within retail facilities, so long as it is a separate legal entity owned and operated by the OD. The legislation was amended twice and eventually approved by Gov. Kevin Stitt in May 2019.

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TAKE YOUR PRACTICE TO NEW HEIGHTS

Adding new services and an expanded level of care for your patients' benefit, as well as your own, is within reach. Here's what to keep in mind.

BY CATLIN NALLEY
CONTRIBUTING EDITOR

As the field of optometry continues to grow, expanding the care provided at your practice is a way to not only stand out but also level up as an eyecare professional. It can be a challenging undertaking, but with careful consideration and a clear plan of attack, these changes can take your practice to new heights and enhance the level of care for your patients.

There are a number of benefits to adding new services, including revenue generation and professional growth. "Revenue from optical sales is dwindling for many of our colleagues due to competitive pressures," says Paul Chous, OD, of Tacoma, WA. "Putting specialty care in place is a way to offset those losses. It also makes practicing optometry more fun and satisfying."

"Not only does expanding the care you provide help differentiate yourself from other optometry practices, it also breaks up the routine," adds Brooke Messer, OD, of Sioux Falls, SD. "It's a new challenge that requires you to stretch your brain in different ways and learn something new. It is also very rewarding because it allows you to offer another level of care to your patients that can have a significant impact on their quality of life."

Photo: Julie Torbit, OD, Anna Kathryn Bedwell, OD, Daniel Bollier, OD, Brad Sutton, OD

When including diabetes management, multiple imaging modalities—to catch signs of diabetic retinopathy, for example, as seen here—are important to have in your practice.

When considering adding a specialty service into your practice, it is important to lay the groundwork and set yourself up for success. This includes choosing an aspect of care that is the right fit for you as an optometrist, as well as your practice and patients. Here we explore a few of the many specialty areas you can integrate to not only enhance the care your patients receive, but also your own professional growth and career satisfaction.

Key Considerations

No matter the specialty service you are exploring for your practice, there are key considerations that should not be overlooked. First and foremost, do you have a passion for this new aspect of care?

"To be successful, you need a genuine interest," says Dr. Messer. "If you don't care to manage the disease, you won't—regardless of the equipment or investment you make. And so, before you add anything new, you have to decide whether or not you want to delve into this specific area of care."

Equally important is having an educated staff that is prepared to support you in this new endeavor. "You must provide your team with the necessary

education while also making sure they believe in the value of these services because they will often be the ones fielding initial questions and engaging with patients," explains Dr. Messer.

Additionally, you need to know where your patients are going to come from, she notes. Are you already seeing patients who need this service? When it comes to new patients, how will you generate referrals? A clear plan will help set you up for success and ensure you make the most of your investment.

There are a number of other important questions to ask yourself, according to Dr. Chous. How prevalent is the condition for which specialty services will be provided? What are the financial costs of implementing these services? This could include acquisition of instrumentation and the time commitment required to learn new skills as well as reimbursement. How does it compare to income generated by your customary goods and services? Can additional services be billed as medical rather than vision care services?

"When considering additional services of care in practice, analyze your patient base to make sure we have the need for the service," recommends Carol Parker, OD, of Louisville, KY. "Next, make sure you can incorporate it into your daily work schedule. Will you need added personnel to be able to effectively incorporate it? Lastly, is this something that you feel is not only beneficial to the patient, but for your practice growth and is focused in the direction of your practice's mission statement?"

Avenues for Growth

There is a plethora of opportunities for optometrists to expand their practice and the care they provide, from specialty contact lenses, ocular surface disease, vision rehabilitation and binocular vision to diabetes management, pediatrics, myopia control and low vision to name a few.

"We continue to expand in the medical arena of glaucoma, retina, lasers and some in-office surgical procedures. Presbyopia treatments are being researched and may be available soon," says Dr. Parker. "Specialty contact lenses are rapidly increasing with the newer products evolving. The dry eye industry continues to grow with newer interventions for MGD, new pharmaceutical treatments and OTC supplements.

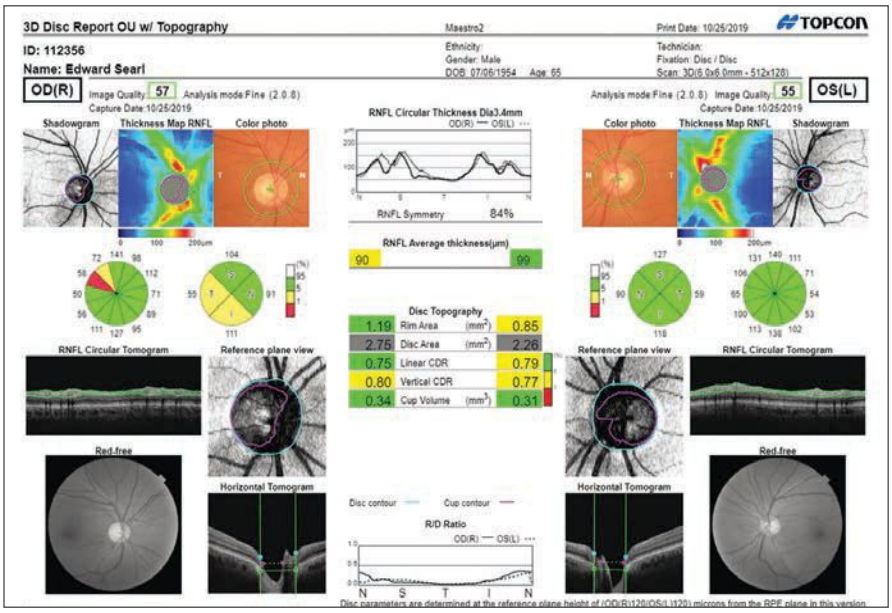

Photo: Ryan Schott, OD

Investing in the right equipment, such as OCT, is essential to success when adding glaucoma to your practice.

"When adding a new addition to your clinic, gather all the information, do your training and figure out how you will add it to your existing schedule," she continues. "Once you are ready to offer the service, be prepared to accommodate how fast word of mouth travels."

Diabetes management. If you are interested in adding diabetes care into your repertoire, Dr. Chous, who specializes in diabetes eye care, recommends investing the time necessary to learn everything you can about the diagnosis and pathobiology of the disease at large and, more specifically, diabetes-related eye disease.

"The AOA's *Evidence-Based Clinical Practice Guidelines for the Care of Patients with Diabetes Mellitus*, 2nd edition, is a great place to start, but I would also strongly recommend consistent perusal of the medical literature and CE courses focused specifically on diabetes," he suggests.

Successful implementation of a specialty service, like diabetes management, depends on access to the right instrumentation. This includes multiple imaging modalities—specifically, retinal photography and SD-OCT, according to Dr Chous. Less expensive but just as important tools to have in your practice include in-office blood glucose meter with single-use lancets, rapid-acting carbohydrate to treat acute hypoglycemia that is prevalent in those on insulin and/or sulfonylurea therapy.

The right equipment—and the knowledge of how to use it—are key factors when it comes to positioning yourself as an expert and successfully building a new service into your practice. "I have gotten dozens of patient referrals because I knew the diagnostic criteria for diagnosis of diabetes management and how to respond to low blood glucoses in my office," notes Dr. Chous.

A broad understanding of nutritional/lifestyle impacts on diabetes is also crucial and helps set you apart from other providers. "Patients are thirsty for practical advice about better diabetes management, and evidence shows

that the overwhelming majority are not receiving any formal diabetes education, so understanding diabetes and being simpatico with knowledgeable diabetes providers in your community is very helpful," explains Dr. Chous. "All it takes is a few diabetes-savvy primary care providers or endocrinologists who have confidence in you to grow your practice."

Incorporating any new specialty service requires time to learn and grow. It also comes with difficulties. "In the diabetes arena, many ODs face ignorance from physicians about what we know and do," says Dr. Chous. "The way to combat this is one physician at a time, showing the rest of the diabetes care team that we cannot only detect, stage and appropriately refer diabetic retinopathy, but also add value to their care by delivering consistent and complementary messages."

Glaucoma. With an aging population and growing disease prevalence, now is the time to embrace management of these patients. While caring for glaucoma patients can be a challenge, it is also a rewarding and lucrative opportunity.

As with the implementation of any new specialty, it begins with investing in education and the right equipment. To properly assess these patients, Deepak Gupta, OD, of Milford, CT, recommends having—at the very least: applanation tonometer, gonioscope, fundus camera and a threshold visual field analyzer.[1]

This can be a costly undertaking, which is why it is important—as previously mentioned—to have a strong commitment to this area of care, as well as a comprehensive understanding of your budget and the needs of their patients and practice.

When initiating patient acquisition, Eric Schmidt, OD, president of Omni Eye Specialists in Wilmington, NC, suggests sharing services with current patients as well as local practices. Establishing your practice as safe and trustworthy will help set you apart and encourage other physicians to send you referrals.[2]

A challenging aspect of glaucoma management is patient education. Ensuring patients understand the disease and its sight-threatening implications is key when it comes to compliance. If your patient understands the seriousness of their condition, they are more likely to adhere to treatment, which leads to better outcomes.

Laser therapy, in particular selective laser trabeculoplasty, is becoming a first-line treatment option for certain glaucoma patients.[3] If you practice in a state that allows to perform such procedures, this is another way to set yourself apart and grow your practice.

Specialty contact lenses. This growing area of optometry is an excellent option if you have an interest in contact lenses and a desire to enhance your practice with a specialty offering. But where to start? Dr. Messer, who specializes in fitting patients with corneal and scleral lenses, recommends reaching out and building relationships with the specialty laboratories. The Gas Permeable Lens Institute offers a directory that can help you find a partner lab. Many labs offer the full toolbox of specialty lenses, from scleral gas permeable lenses to custom soft options. When selecting a partner lab, first consider the lenses you'll be using the most and visit with the consultants on their available training to bring you up to speed. If you're just starting, Dr. Messer also suggests connecting with one or two labs and then building from there as needed.

Like any other niche, knowledge is invaluable, and taking the time to attend meetings in the specialty of your choice is important. "Take advantage of the specialty meetings for continuing education," says Dr. Messer, noting that it's important to spend time in the exhibit hall as well. "This is an opportunity to talk and connect with laboratory representatives, so when you do call to order a lens, they will recall your conversation and spend extra time to make sure you understand and are confident in the fitting process. In short, the laboratory consultants are such a great resource."

Successfully integrating this service also depends on patient communication and education. "It is crucial to have discussions with your patients," notes Dr. Messer. "When you identify a patient who would be a good candidate for specialty lenses, talk to them about their options. Start with the cases you feel most comfortable with and then as you build your expertise and confidence you can tackle more challenging patients.

"You just have to commit to talking about it," she emphasizes. "And the same goes for your team. Educate them on the patients who may benefit, so they can flag them on the schedule and you can be ready with a game plan and materials to educate them on the new service."

It's important to find a balance that includes clinical expertise and practice management, according to Dr. Messer. Therefore, organization is critical as each lab has different requirements to maintain your warranty and credits with them, she explains. As you grow, it could be worthwhile to have a staff member who is fully dedicated to

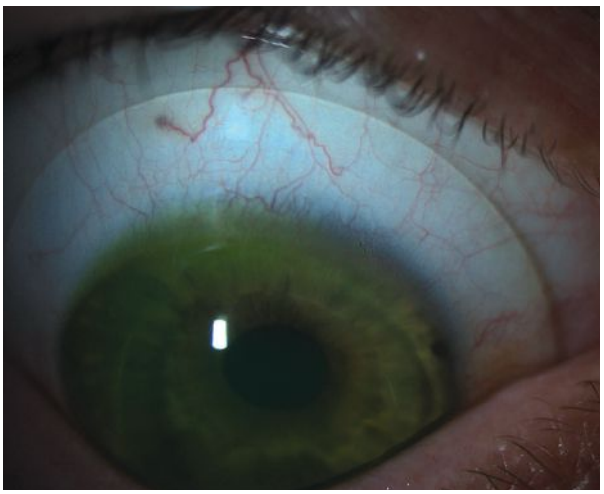

Photo: Jeffrey Sterling, OD

Scleral lenses are one of the many specialty items you can offer your patients.

The Promise of a New Era in *DEMODEX* BLEPHARITIS Treatment

By Selina McGee, OD, FAAO, Dipl. ABO; Paul M. Karpecki, OD, FAAO; and Ben Gaddie, OD

Demodex blepharitis is a significant public health challenge that rests largely on the shoulders of optometry. This condition is extremely prevalent and highly consequential in terms of patients' quality of life. In fact, the prevalence of *Demodex* blepharitis in the United States may be as high as 25 million.[1,2] Furthermore, beyond the physical symptoms, eight out of 10 patients who have *Demodex* blepharitis say the condition has a negative impact on their daily lives.[3] Specifically, they report difficulty wearing makeup, constantly worrying about their eyes, difficulty driving at night, and a negative appearance of the eyes or eyelids (see Figure 1).[3]

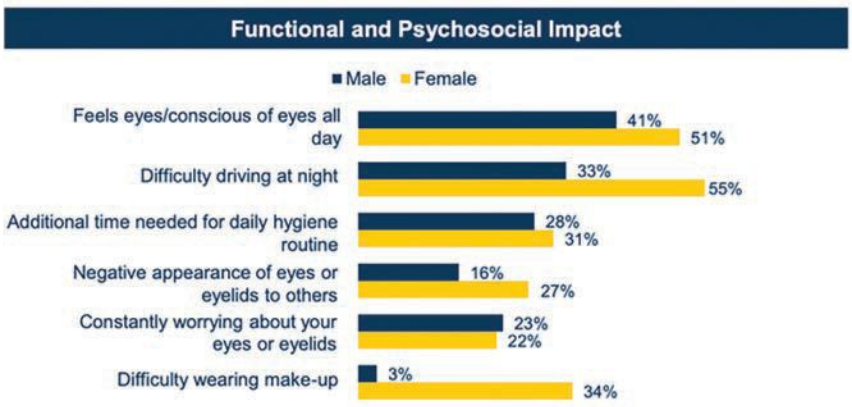

Figure 1.[3]

Historically, our ability to manage *Demodex* blepharitis has been limited to OTC products, but this may soon change, with the investigational treatment TP-03 (lotilaner 0.25% ophthalmic solution; Tarsus Pharmaceuticals). As the data reveal in study after study, TP-03 has demonstrated

Selina McGee, OD, FAAO, Dipl. ABO
BeSpoke Vision

Paul M. Karpecki, OD, FAAO
Kentucky Eye Institute

Ben Gaddie, OD
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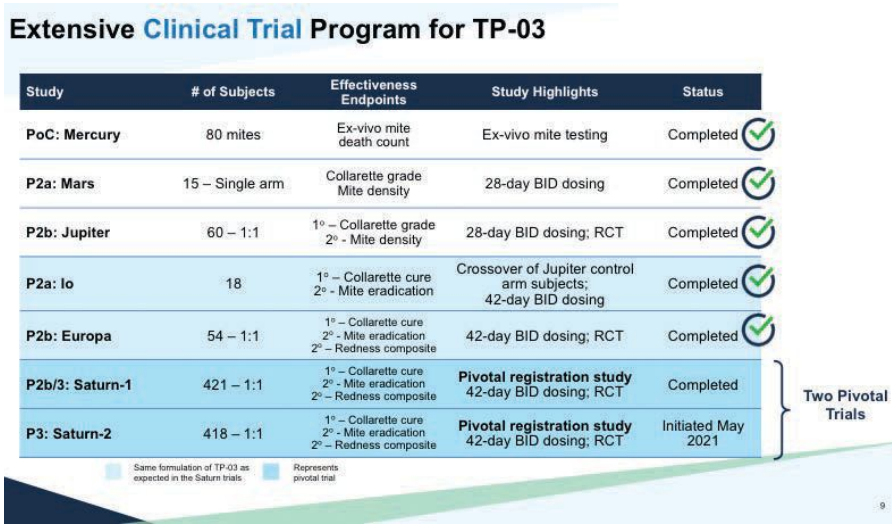

Figure 2 Source: Tarsus Pharmaceuticals data on file.

IMPACTS OF *DEMODEX* MITES

Here are some of the ways *Demodex* mites negatively impact patients:[5-8]

1. The mites' claws cause mechanical insult.
2. Mites lay eggs in lash follicles, causing irritation, follicular distension, misdirected lashes, and madarosis.
3. Bacteria live on the surface of the mite and within the mite's gut, causing an inflammatory response.
4. The mites excrete digestive enzymes as they feed. When they die, they leave behind digestive waste and collarettes, causing irritation, hyperemia, inflammation, and hyperplasia

positive results both in terms of safety and efficacy (see Figure 2).

THE IMPORTANCE OF TREATMENT

Demodex mites are particularly insidious because they lead to disease in several different ways and they are the most common ectoparasite in the human body.[4]

The mites' cycle of insult illuminates why we so often witness the tell-tale pathognomonic sign of collarettes in patients who have *Demodex* blepharitis. Importantly, 58% of patients presenting at eyecare offices have collarettes,[1,2,6] and in some studies, 100% of patients presenting with collarettes had *Demodex* blepharitis.[6] The collarettes emerge when the mites feed on patients' skin—and partially digested cells combine with keratin, mite waste, and eggs.[5,8] The resulting collarettes appear at the base of the lash and migrate upwards as the hair grows.

TREATMENT HISTORY

As the leading cause of blepharitis in the United States,[9,10] the need for treatment is great, yet no FDA-approved drugs currently exist for *Demodex* blepharitis.[11] Many of the drugs that have been proposed (such as sulfur or mercury oxide ointments,[12] iodized solutions,[6] and pilocarpine gel[6]) have not been proven effective, while the efficacy of several other approaches, (e.g., oral antiparasitics such as ivermectin, metronidazole, and tea tree oil solutions) show only variable success.[11]

Fortunately for patients, a new treatment has been proposed. Lotilaner is approved for use in oral form for the treatment of fleas and ticks in pets, and is now under

investigation as a topical formula for humans.[11] Known as TP-03, this topical formulation of preserved lotilaner is dispensed from a multidose eyedrop solution bottle for the treatment of *Demodex* blepharitis (see Figure 3). In terms of mechanism of action, the drug causes paralysis and death of the mites. Suggested dosing is b.i.d. for six weeks.

POSITIVE FINDINGS FOR A NEW APPROACH

The first four Phase 2 clinical trials looking at TP-03 all showed the drug to be well-tolerated, safe, and effective (see Figure 2). Both Mars and Jupiter demonstrated that it reduced collarettes and *Demodex* density after 28 days of treatment, beginning as early as day 14 of treatment, with effects lasting at least 90 days.[13,14] In both of these investigations, patients reported the drop to be comfortable with no treatment-related adverse effects (AEs).

The Phase 2a Io and the Phase 2b Europa studies likewise found positive results.[15] In Io, collarette cure was achieved in 72% of participants, and mite eradication was achieved in 78% of participants at day 42. In the Europa trial, collarette cure was reached in 80% of participants on TP-03 compared with 16% on vehicle ($p<.001$) at day 42, and mite eradication was reached

Product Form	Multi-dose eye drop solution bottle, preserved
Targeted Use	Treatment of Demodex blepharitis
MOA	Paralysis and death of Demodex mites
Diagnosis	Collarettes identified in standard eye examination
Dosing	BID* for 6 weeks
Efficacy Goal	1º collarette cure rate, 2º mite eradication, 2º redness + collarette cure rate
Safety Goal	Well-tolerated safety profile

Figure 3. TP-03 At a Glance

Source: Tarsus Pharmaceuticals data on file.

in 73% of participants on TP-03 compared with 21% on vehicle (p=.003) at day 42. Again, in these two studies, the drug was well-tolerated, with no serious AEs or treatment discontinuations due to AEs.

ONE STEP CLOSER

More positive news arrived in June when the Phase 2b/3 Saturn-1 trial results were announced, again revealing statistically significant complete collarette cure at day 43 in patients treated with TP-03 compared to vehicle (p<0.0001).[16] Furthermore, the study showed mite eradication at day 43 (p<0.0001), and composite cure based on complete collarette and erythema cures at day 43 (p<0.0001). In addition, significant, clinically meaningful improvements were observed within two weeks across multiple endpoints. As in earlier trials, TP-03 was well-tolerated with a safety profile similar to vehicle, and no treatment-related discontinuations were reported.

Saturn-1 is the first of two pivotal trials. Topline results for the second pivotal trial, Saturn-2, are expected early in 2022. Combined, the two trials are expected to be used as the basis to support submission of a New Drug Application to the FDA, providing clinically-proven treatment for millions of patients who suffer with *Demodex* blepharitis.

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Photo: Maria Walker, OD, MS

As the myopia population grows, adding mitigation efforts to your practice gives you the opportunity to provide long-term benefits for your patients.

managing the logistics of the specialty lens process.

Another consideration is your time. Ordering lenses can be a long process and the more patients you have wearing specialty lenses, the more time you need to order lenses via phone or email. Dr. Messer recommends blocking off time during the day to ensure you don't get behind. "You'll need time to consult with the lab during their business hours," she says. "I set aside time in my schedule before or after lunch to make those calls."

Myopia control. With an increased focus on the hazards of myopia, consider implementing myopia control into your practice. Several treatment options are available, including atropine drops, orthokeratology lenses, soft multifocal contact lenses and even spectacle lenses (*e.g.*, Essilor's new Stellest product).

If you have a desire to implement this service into your practice, the first step is learning everything you can about myopia management, both from a clinical and business perspective, according to expert consultant Gary Gerber, OD.[2] All staff members must have the training so they can effectively explain myopia and its treatment to parents.

Investing in technology is also vital. Tools that could help you optimize myopia management include corneal topography, open-field autorefraction, peripheral autorefraction and wavefront aberrometry.[2]

While managing myopia can be time consuming, it is a rewarding endeavor that not only enhances the care you provide, but can also offer significant, long-term benefits for patients. These benefits should be emphasized to parents, according to Kevin Chan, OD, of Vienna, VA, who also suggests that optometrists conduct pre-testing with younger patients instead of relying on technicians. This allows you the opportunity to develop a strong relationship with the child and their parents from the start.[2]

Strategic Approach

Adding a new aspect of care into a practice can be difficult, so it's important to adopt a strategic approach. This includes recognizing that incorporation of any new service takes time and there will be a learning curve for everyone involved.

"When expanding services, it is hard to just make yourself do it. You need to make sure the staff is on board with the new services being offered and make sure you have a plan of how you will be announcing them and implementing them into the schedule," says Dr. Parker. "Everyone needs to be trained and appreciate what is being offered or they will not offer them to the patients. If your staff is not educated and doesn't truly believe in what is being offered, they will not use it or make anyone aware of the new products and services."

It is also crucial to allow yourself the time necessary to learn and improve your skills. Beginning a new service with your most difficult case is a recipe for failure. "Your best candidates for your new skills should be those with mild to moderate levels of the condition you're managing," says Dr. Messer. "For instance, you probably don't want learn orthokeratology on a patient with high myopia. Starting with a less challenging patient increases your likelihood of success while helping you gain confidence and hone your skills."

Don't be hesitant to ask for help. Find a mentor who can help you on your journey into any type of optometric specialty care, Dr. Chous urges. It is also important to recognize that while having the right technology is a key component, it's not the only factor necessary for your success.

"Technology is great and impressive, but won't generate referrals de novo," notes Dr. Chous. "My advice is to invite friendly (or at least open-minded) potential referral sources to your office to demonstrate what you offer and why it will help their patients. Give it time, and eventually those same referral sources will be sending you their patients and requesting your services for themselves and their family members."

Expanding the services you provide as an optometrist are beneficial to not only you and your patients, but the profession as a whole.

"It is beneficial for survival in private practice," says Dr. Parker. "Reimbursements are continually being reduced and we must find new avenues of revenue. Yet, they need to feel these are serving a purpose and need for the patients. If not, it will show, and patients will distrust the provider and may leave the practice and go elsewhere. So, it is a fine line between expanding to benefit the patient and expanding to benefit the provider. It must be mutually inclusive." ■

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HOW TO HIRE, TRAIN AND RETAIN STAFF IN A FIERCE LABOR MARKET

Flexibility, pay increases and employee happiness can optimally position a practice for low turnover and attract the best and the brightest in the field.

BY JANE COLE
CONTRIBUTING EDITOR

Hiring used to be a straightforward process: an employer would take out an ad or ask for a referral from a trusted source, sift through a stack of applications, conduct several interviews and then make an offer to the best candidate. However, due to the current labor shortage—coupled with the trend of employers having to bump up employee pay since COVID—hiring has gone from business as usual to a headache for many companies, including optometric practices.

For Dori Carlson, OD, of Heartland Eye Care in Grafton, ND, her biggest challenge in hiring and retaining staff has been the current lack of a workforce.

"We finally are fully staffed after over three years of struggling to find the right people," says the former AOA president. "We would advertise and have two applicants who weren't qualified. So, we'd pull the advertising and try again later. This summer, we finally had qualified applicants."

In New Hampshire, hiring and retaining good staff is equally as challenging, says Scott Huffer, OD, a partner at Drs. Helfman, Lasky & Associates in Nashua.

"There are a lot of job openings, and our staff members are being offered jobs everywhere they go," Dr. Huffer says. "We particularly have difficulty with opticians, as there are very few well-trained opticians in our area."

Just like a buyers' or sellers' market in real estate, today's hiring landscape is an employees' market, says optometrist and CEO of the Power Practice, Bethany Fishbein.

In its August jobs report, the National Federation of Independent Businesses found that 50% of owners had job openings they couldn't fill, a record high for the second consecutive month.[1] Additionally, the number of unfilled job openings remains far above the 45-year historical average of 22%.[1]

Despite the daunting statistics, ODs are finding ways to remain competitive.

"It's important to take good care of your staff, be a great place to work and put effort into creating a positive office culture and environment where people want to be and will enjoy the time they spend at your practice. Now more than ever, an employee's life outside of the office is extra stressful," says Dr. Fishbein, who co-owns two practices in Somerset, NJ.

Market Your Practice

In today's ultra-competitive hiring market, it's critical that businesses spell out an answer to the implicit question, "Why us?" in their help-

Photo: Clint Taylor, OD

It's important to ensure each of your staff members are happy in their role, and step in if they're not.

wanted ads, as opposed to previous years when it was the interviewee's job to convince you, "Why them?" says Dr. Fishbein.

When advertising for a position, Dr. Fishbein suggests including information on what makes your practice stand out, including your work culture, employee benefits and extra perks such as weekends or school vacations off.

"Whatever is unique about working for you, include that in the initial ad to attract applicants to you over the other options they have," Dr. Fishbein says.

For example, Dr. Fishbein recently made her office even more staff-friendly by cutting hours. Prior to COVID, her office was open every other Sunday. Following the pandemic's onset, a few of her staff members didn't return because they had young children and needed to be home. Due to the sudden staffing shortage, her practice eliminated night and weekend hours, a popular trend Dr. Fishbein is hearing from her clients as well. Other practices are experimenting with four-day work weeks, with longer hours but the promise of three-day weekends, she says.

To remain competitive, Dr. Huffer is considering changing his practice's benefit structure, since he says employees seem focused on their hourly wage and not their total compensation.

"We pay 75% of health insurance premiums, in addition to offering profit sharing and generous time off policies, but employees seem focused on their salary," Dr. Huffer explains. "I think we may be better served to move to paying a higher wage while maintaining the total compensation. I think employees notice that much more."

Additionally, a practice owner should keep hiring on the forefront of their mind, he says. This includes networking at local association meetings and asking colleagues how happy they are at their jobs. This is particularly important because adding a doctor to a practice can take time, he says.

Photo: Clint Taylor, OD

Dr. Taylor has little turnover in his practice, which he attributes to the family atmosphere he says is part of the office culture.

Another potential resource for identifying new hires: existing employees.

"We've found that our current staff members are our best resource for finding new employees," says Clint Taylor, OD, owner of Taylor Eye Center in Carmi, IL. "The nine members of our team have a wide network of friends, family and acquaintances, and they have served as a pipeline of sorts for potential new employees."

Regardless, no matter how thorough of an interview and background check you conduct, there's still a question of how well a given candidate will perform and fit in, Dr. Taylor adds.

"I've had candidates knock their interview out of the park and receive glowing recommendations from references, and then underperform after they were hired. And the opposite has been true—candidates we've had doubts about during the interview process have turned out to be real all-stars once they were given a chance and hired. Only after a few months of having the new employee in the office regularly do you start to get a feel for their true potential," Dr. Taylor says.

Dr. Carlson has added personality testing to her hiring process. "It gives us a little more information about the person that may not reflect in an interview," she says.

For Ken Krivacic, OD, MBA, of Irving, TX, his philosophy has always been to hire for personality and not as much for skill, as he believes employees can be trained.

"A person with a positive attitude who likes showing up for work outweighs potentially not having the skill level you're looking for," says Dr. Krivacic, who spent three decades as the sole owner of a private practice and continues to see patients through his new partnership with MyEyeDr. "I felt that hiring approach served us well for over 30 years."

Beyond the usual hiring tools, Dr. Taylor created his own test to assess prospective employees' talents and personalities.

"After their interview, I ask myself this question, 'If I was going to be on a three-hour flight, would I choose to sit next to this person or not?' I've found that the answer to that question tells me a lot about whether or not they'll fit in with our culture," he says.

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Photo: Clint Taylor, OD

Make sure to allocate staff vs. doctor responsibilities to create a better office workflow.

Staff Retention Tips

One in four workers may be seeking out opportunities with a new employer once the pandemic threat has subsided, indicating talent migration could be imminent as employees look for increased flexibility and opportunities to grow their careers, according to Prudential Financials Pulse on the American Workers Survey.[2]

One strategy to promote employee retention is to offer staff bonus incentives both on a monthly and annual basis, Dr. Krivacic says. Bonuses should be simple and easy for employees to understand, reasonable to obtain and motivational, he suggests.

"Only offering a yearly incentive may not be as effective as a monthly bonus, as staff can get distracted," he adds. Monthly bonuses can also be discussed during weekly meetings, which can provide a forum for employees to know where they stand.

Another tip in employee retention: learn to trust those who work for you, he adds.

"If you let your staff take charge at times and make some decisions, it can help them grow as employees and value their job more," Dr. Krivacic says. "Sometimes, staff have made decisions I wouldn't have made, and in those cases, we'd talk afterward. But I didn't want them to be scared to make a decision. It's not a big deal; the practice isn't going to close if a wrong decision is made. I think any successful business has learned to trust its employees. If the employee is empowered to make decisions, it's often better for the patients too."

Dr. Huffer had a few employees who were considering leaving for another job that offered more money. In these cases, he sat down with the individuals and discussed what it would take to convince them to stay. In some instances, he was able to retain an employee by offering a raise or a change in job responsibilities, including a transition from full- to part-time.

In today's working environment, everyone is short-staffed, and many employees are overworked, Dr. Huffer adds. It's important to make sure staff are thanked and encouraged, and many employees benefit from positive feedback, he says.

"Occasionally, we will buy our staff lunch or provide an ice cream break. It's critical to maintain good morale, or the problem can spiral. You need to be a good place to work," he says. Dr. Huffer also makes an effort to recognize birthdays and employment anniversary dates.

Retention of good employees can mean more than salary adjustments, Dr. Carlson adds. Her practice has five employees who have been with her for at least 20 years. Ultimately, retention of employees comes down to culture, she feels.

Dr. Carlson says her practice is a fun place to work where staff are treated like family. Her practice also offers a generous benefits package, including 100% coverage of employees' health insurance and schedule flexibility.

"People bring their lives with them to the office. They can't leave them at the door, as much as we would like them to do just that," Dr. Carlson

SHOULD STAFF REFRACT?

Once hired, now the focus shifts to which tasks staff should handle, and which the doctor should take charge of. Every practice divvies up patient testing differently, with "who handles refraction" remaining a point of debate.

Dr. Carlson passes the baton as much as possible to staff. Clinically, she believes employees are responsible for all pretesting, including history, acuities, entrance testing, autorefraction, dark adapt screening and Optomap imaging (Optos), in addition to contact lens training and education and all optical functions. On the business side, her staff takes on invoice processing, insurance billing, contact lens and optical orders, marketing and social media.

"I believe refractions are part of the data gathering process, and for several years, we had staff do refractions," Dr. Carlson says. Her practice uses Marco refraction systems, and staff received training directly from the company, she explains. However, doctors always have the final say in the prescription.

Dr. Carlson's practice stopped having techs refract a few years ago when a few long-term employees left. "At that time, it made more sense to install more digital refraction units in the exam rooms, rather than train people when our staffing was in a state of flux," she says.

Likewise, Dr. Taylor delegates many exam tasks to his staff. When the tech pages him to enter the exam room, all pretesting has been performed and entered into the chart and the patient's habitual glasses prescription has been added to the phoropter.

"I currently refract our patients, but would be open to having technicians refract, given the right training and equipment," he says.

There is no right or wrong answer to whether staff should do refractions, Dr. Krivacic believes.

"It's okay to delegate the task and have the OD do the final review," he says. Still, Dr. Krivacic has received negative feedback regarding staff refracting them instead of the doctor.

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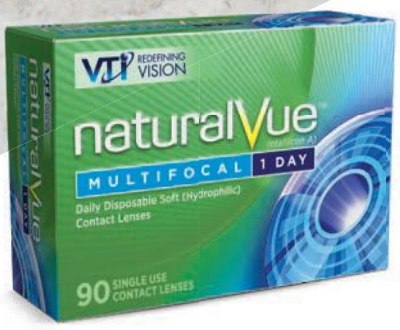

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explains. "We've learned that offering flexibility with regard to work hours is one of the benefits they appreciate the most. We all cover for each other."

COVID's Impact

Dr. Fishbein noted a trend of staff burnout, which has heightened during COVID; staying in tune with employees' mental health is important, she says.

"People are dealing with a lot of issues right now. Employees may have health concerns or their children are starting school, and at any given moment, the school can shut down and your staff member may need to be home with their kids for two weeks. As an employer, you must be sensitive to what else is going on in your staff's lives," she says.

Flexibility, when it can be offered, is key in keeping staff happy.

If a staff member requires more flexibility, Dr. Fishbein suggests looking for opportunities where the employee can remain productive while working from home, a win-win scenario. This could include answering phones, checking insurance or working on a project.

"Right now, everybody on a team needs to be more understanding of each other," Dr. Fishbein suggests.

COVID is also forcing practices to adapt in other areas, with virus exposure causing people to quarantine and vaccine mandates potentially posing another wrinkle in hiring and retaining staff.

"I am a little concerned about one or two employees that may leave rather than be vaccinated," Dr. Huffer says.

Another ripple effect of COVID: increased salaries.

"With a tighter labor market, we're hiring people away from another job. So, we've had to increase starting salaries to attract employees, which then means we've had to increase salaries across the board," Dr. Carlson adds.

Dr. Huffer also had to increase pay for many employees. "In our area, there are help-wanted signs with high starting hourly wages posted seemingly everywhere," he says.

You Get Out What You Put In

In the current labor market, staff training is as important as ever for both the employee and the practice. A recent article in the Harvard Business Review suggests when employers favor hiring over training, the labor market can't keep up.[3] Instead, many organizations compete for the top, job-ready talent rather than help incumbents or younger underserved and underrepresented groups develop the skills they need to fill tomorrow's roles.[3]

At Dr. Carlson's practice, she says weekly staff meetings have helped immensely in the training process. "We find it takes less time to train people when we have uninterrupted time to explain technical skills, culture and philosophy of care," she adds. Dr. Carlson also takes advantage of online training modules.

Photo: Clint Taylor, OD

Fully empowered and well-trained staff can devote more time with patients, particularly kids, freeing up the OD.

Of course, training isn't a one-size-fits-all approach.

"For training, it's about finding what you need someone to learn and then accommodating how much more the individual wants to learn," Dr. Fishbein says. "There are employees who really see continuous growth as an amazing perk and a reason they want to work at your office." For this type of employee, you will want to create continuous learning opportunities, she notes.

On the other hand, there might be another employee in the same position with a different personality who may get stressed over the thought of additional training and prefer to do the job they were hired for and nothing more, Dr. Fishbein adds.

"This person isn't a terrible employee, but you need to have conversations with staff to understand who wants to be pushed, and for those who don't want that challenge, give them room to tell you when their situation changes. An employee may have other issues going on in their lives outside of work and not want to take on additional responsibilities at that moment," Dr. Fishbein says.

Final Thoughts

Dr. Krivacic considers staff as an asset and not a cost. If you have a good staff member, they're going to more than make up what you're paying them and be a benefit to the practice, he says.

"Often, we don't appreciate our employees like we should," Dr. Krivacic says. "With the current labor market and the fact that it's hard to find good people, I think we're seeing employers valuing their staff more." ■

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Papilledema is a condition that presents with bilateral optic nerve head edema due to increased intracranial pressure (ICP). This condition can be life-threatening and thus a medical emergency, so having a plan set in mind will help the optometrist.

History Considerations

There are a number of pertinent case history questions that the clinician should ask in cases of suspected papilledema (*Figure 1*). First, ask about common symptoms and signs of increased intracranial pressure including headaches, transient visual obscurations, pulsatile tinnitus, nausea, vomiting and diplopia.[1] Headaches are an especially common symptom associated with papilledema. The pain is often described as diffuse, may radiate down the posterior portion of the neck, and is characteristically more severe upon wakening in the morning and when laying down.

Transient visual obscurations are typically graying or blackening of the vision that only lasts a few seconds and are more common with a change in position.[1] Therefore, the clinician should ask the patient, "Do you notice a change in your vision when you bend over to pick things up or get up from laying down?"[2]

When asking about pulsatile tinnitus, describe the phenomenon as a whooshing sound with a rhythmic beat.[3] It is important to differentiate this complaint from ringing in the ears (tinnitus) that can occur in conditions not related to increased ICP, such as hearing loss and Meniere's disease. In contrast, pulsatile tinnitus is a sound synchronous to the patient's pulse due to abnormal blood flow from increased ICP.

Papilledema can be secondary to numerous etiologies including, but not limited to, intracranial mass, venous sinus thrombosis and idiopathic intracranial hypertension (IIH).[1] There are some questions that should be asked to assess for factors that place a patient at more risk for such etiologies.

If a patient's papilledema is secondary to intracranial mass lesion, asking about neurologic symptoms, such as weakness and loss of sensation, may provide localizing details. Also consider inquiring about possible cranial nerve deficits, such as dysphagia and dysphonia, as these could point towards a brainstem lesion. Lastly, symptoms related to balance or gait issue could suggest cerebellar pathology to the optometrist.

Cerebral venous sinus thrombosis (CVST) occurs when a blood clot obstructs the cerebral venous drainage system, which in turn can then increase ICP.[4] Signs and symptoms in patients with CVST depend on the location of the thrombus and resulting axonal injury and/or increased ICP. Therefore, presentations are variable ranging from mild headache to nausea, vomiting, focal or even diffuse neurologic deficits. Ask your patient history questions to assess for risk factors of CVST.[5] These include underlying blood clotting disorders, such as sickle cell and thrombophilia, use of certain medications such as oral contraceptives, and infectious diseases.[4]

While rare, given the ongoing pandemic, clinicians may also consider

About the authors **Dr. Maglione** works in the neuro-ophthalmic disease services at The Eye Institute and teaches didactically in neuro-anatomy and neuro-ophthlamic disease courses at the Pennsylvania College of Optometry at Salus University. She is a Fellow of the American Academy of Optometry. **Dr. Marunde** is a neuro-ophthalmic disease resident at The Eye Institute at Salus University. They have no any financial interests to disclose.

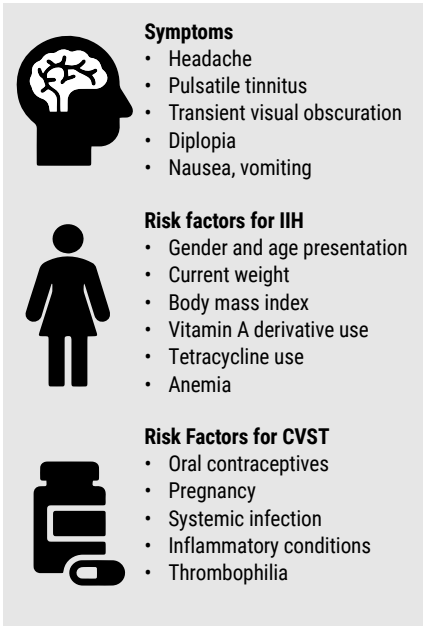

Fig. 1. Pertinent symptom and history questions to consider for papilledema.

the association between coronavirus disease 2019 (COVID-19) and underlying thrombosis in papilledema patients with this infection.[6] Other conditions that predispose patients to a hypercoagulable state include pregnancy, cancer and inflammatory conditions, such as lupus.

IIH commonly presents in females of childbearing age that are 10% or more above their ideal body weight. In these patients, neuroimaging must rule out structural etiologies such as mass or hydrocephalus. However, on neuroimaging, there are signs that can indicate increased ICP in the absence of structural lesions. These can include an empty sella, flattened posterior globe and dilated and tortuous subarachnoid space around the optic nerves.

Additionally, patients with IIH should have a normal cerebrospinal fluid analysis and an increased opening pressure on lumbar puncture.[1] Since weight is a modifiable factor in IIH, it is important to ask about the patient's current weight and monitor for changes at follow-up exams. Clinicians should also inquire about anemic states and the use of vitamin A derivatives and tetracyclines as these may be associated with IIH.[7-9]

Afferent Examination

A full assessment of afferent function is vital in any patient with papilledema. Clinicians must establish baseline visual function as treatment protocol may differ in cases with vision loss versus cases without. A baseline assessment may also contribute to determining effectiveness of treatment and monitoring for long-term damage.

A list of afferent testing to consider are seen in *Figure 2*. Patients will often present with relatively normal afferent function and the absence of afferent abnormalities should not exclude the diagnosis of papilledema. However, if assessed carefully, one might note subtle afferent findings, such as an enlarged blind spot which can be present even in early cases of papilledema.

One can consider assessing blind spot on confrontation fields by comparing the size of your own (so long as it is normal) to the size to the patient's. The blind spot size averages 5.5° horizontal and 7.5° vertical.[10] In cases of chronic papilledema, abnormal afferent functions may further manifest and are extremely important to identify as treatment may need to be modified. The long-term pressure on the optic nerves causes retinal nerve fiber layer (RNFL) damage resulting in findings such as reduced visual acuity, color vision and visual field defects.[11]

Efferent Assessment

Providers will want to note if there is any efferent abnormality, such as a cranial nerve (CN) palsy III, IV and/or VI palsy, in patients with papilledema as this could help to localize a potential space occupying lesion. CN VI is particularly susceptible to increased ICP due to its path through Durello's canal. Thus, even patients without brainstem lesions may present with this palsy when increased ICP leads to compression of the nerve in this region. It is important to note that in addition to the optic nerve dysfunction, CN VI palsies are the only other acceptable abnormality on the neurologic examination in patients with the diagnosis of IIH.[1,4]

A combination of ductions and cover tests in multiple positions of gaze can help identify even the mildest of deficits. While performing ductions, be sure to ask the patient to extend their gaze as far as possible. The examiner should shift their own viewpoint to be sure to assess for any evidence of scleral show carefully (*Figure 3*).

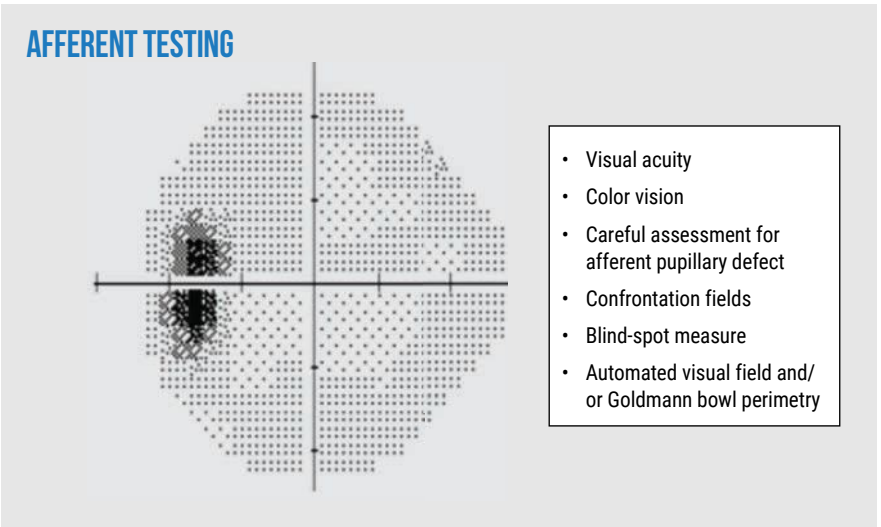

Fig. 2. Pertinent afferent tests to perform in patients with suspected or confirmed papilledema. Consider these tests during both baseline and follow-up examinations for comprehensive monitoring. Note the enlarged blind spot on automated 24-2 visual field seen in the left eye of a patient.

	Up Gaze 3 Eso	
Right Gaze 35 to 40 Eso	Primary Gaze 18 Eso	Left Gaze 4 Exo
	Down Gaze 10 Eso	

Fig. 3. This patient from this efferent assessment presented with diplopia and was diagnosed with a CN VI palsy. Careful ductions demonstrated a subtle right abduction deficit. Cover testing demonstrated an increasing eso-deviation in right gaze, consistent with the patient's right CN IV palsy.

Cover testing in multiple positions of gaze can be performed at distance to assess the patient for comitancy. Perform this testing without the patient's glasses as they can block patients eccentric viewing and/or produce prismatic effect that can compromise results. Non-comitant deviations on cover testing can suggest a CN palsy. For instance, an increasing eso-deviation on lateral gaze can suggest a CN VI palsy ipsilateral to the direction of increasing misalignment.

Funduscopic Assessment

Papilledema has certain fundoscopic characteristics that should be carefully assessed for. A stepwise approach to assessing the optic nerve head on dilated exam will help determine if the patient has disc edema. First, assess each quadrant of the optic disc for any elevation. Next, assess the margins of the optic disc, evaluate for any margins that are blurry or indistinct. Further assess the margins for vessel obscuration; look at the small vessels at the edge of the margin and determine if there are segments missing of the vessel.[12]

Staying close to the margin of the optic nerve head on the temporal side, look for Paton's lines, which are concentric folds of the retina.[13] After full assessment of the optic nerve head, the fundoscopic findings can be graded from 0 to 5 in relation to the Frisen scale.[14]

The presence or absence of spontaneous venous pulsations (SVPs) is an important finding when assessing patients with possible papilledema. SVPs are caused by variations in the pressure gradient along the retinal vein as it emerges through the lamina cribrosa. It has been found that when a patient's cerebral spinal fluid (CSF) pressure is higher than 190mm H_2O, the CSF pulse pressure rises to equal the intraocular pressure causing the SVP to cease.[15] Therefore, the presence of an SVP does suggest normalized ICP. However, approximately 10% of the normal population does not exhibit a physiologic SVP.

Thus the absence of an SVP should not be interpreted as definitive increased ICP. SVPs may be subtle and limited to a small segment of one vein; therefore, the provider must carefully assess for its presence on dilated examination. SVP should follow the rhythmic movement of the cardiac cycle and, if questionable, a provider should not rely on SVP to confirm or deny a diagnosis of increased ICP.[15]

Ancillary Testing

The use of optical coherence tomography (OCT) imaging of the peripapillary retinal nerve fiber layer (RNFL) and ganglion cell complex (GCC) in patients with elevated neuro-retinal rim can be useful in a multitude of ways. While the diagnosis of papilledema is likely made from the funduscopic view in moderate to severe cases, OCT can be a useful baseline assessment for future monitoring. However, in severe cases of papilledema, the scan may not be able to penetrate to deeper values and thus results may be less accurate.[16]

When assessing the peripapillary RNFL of a child, in which the OCT does not have a normative database currently, a clinician should reference values in literature to help determine if their patient's OCT results are abnormal. One study found that the mean peripapillary RNFL thickness in children ages five to 15 in North America was 107.6µm.[17] However, the RNFL thickness value alone is unlikely to be sufficient enough to differentiate cases of mild papilledema from pseudo-papilledema.[18] Fortunately, there are a number of other signs on OCT images that may help to support the clinician's diagnosis.

It has been theorized that the force of increased subarachnoid pressure in patients with papilledema may result in an anterior displacement of structures in the peripapillary region. Specifically, Bruch's membrane (BM) and the retinal pigmented epithelium (RPE) have been shown to have an increased angle toward the vitreous in these patients, while BM and RPE in patients with disc swelling unrelated to intracranial hypertension was angled away from the vitreous.[19]

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Additionally, measurements of the inward displacement of Bruch's membrane have been shown to be statistically significant in being able to differentiate mild papilledema from pseudo-papilledema.[20]

However, there is no current standardized algorithm for analysis of the angle in which BM/RPE are located. Clinicians can currently assess a patient's peripapillary anatomy using cross-sectional OCT images, such as with a raster scan, and if there is definite protrusion of BM/RPE towards the vitreous, then the diagnosis of papilledema should be presumed. Until standardized algorithms are clinically available, the absence of deflection should not rule out papilledema.

The biomechanical forces of increased ICP give rise to concentric curvilinear folds of retina adjacent to the optic disc. Superficial folds of RNFL, known as peripapillary wrinkles or Paton's lines, strongly suggest the diagnosis of papilledema and are often assessed with dilated funduscopic examination. OCT imaging of the peripapillary RNFL can be a useful adjunct in looking for this anatomical change.[21] Specifically, *en face* vitreoretinal interface (VRI) OCT images may be able to highlight peripapillary wrinkles which are otherwise difficult to see funduscopically (*Figure 4)*. OCT can also help to confirm the presence of papilledema in patients without peripapillary wrinkles in primary gaze. It has been demonstrated that placing the eye in the adducted state can elicit their presence and detection, including with OCT imaging.[22]

OCT may help to discern optic disc drusen (ODD) which, when buried, is a well-known mimicker of papilledema. ODD have been defined as signal poor lesions with overlying hyperreflective cap (*Figure 5A*).[23] Peripapillary hyperreflective ovoid mass-like structures (PHOMS) have also been associated with ODD.[24] However, clinicians must always be suspicious of papilledema overlying ODD, and it is important to note that PHOMS have now been identified in cases of papilledema and other pathologies.[25] The presence of superficial ODD can also be highlighted on fundus autofluorescence (FAF) as bright concentric lesions (*Figure 5B*).

Other ancillary tests to consider on patients with ODD and/or papilledema include ultrasound of the optic nerve and fluorescein angiography (FA). In orbital ultrasonography, the optic nerve sheath width (ONSW) widens with increased ICP. Increased ICP also causes a change in the ONSW in primary gaze vs. upon 30° of abduction. Drusen will present as ovoid hyperreflective structures.[26] With FA, drusen present as bright ovoid structures, staining in early and late stages and papilledema presents as leakage in the peripapillary region.

FA may be the modality of choice in pediatric patients, as their optic disc drusen are more likely to be buried, thus making detection on OCT and FAF more difficult.[27]

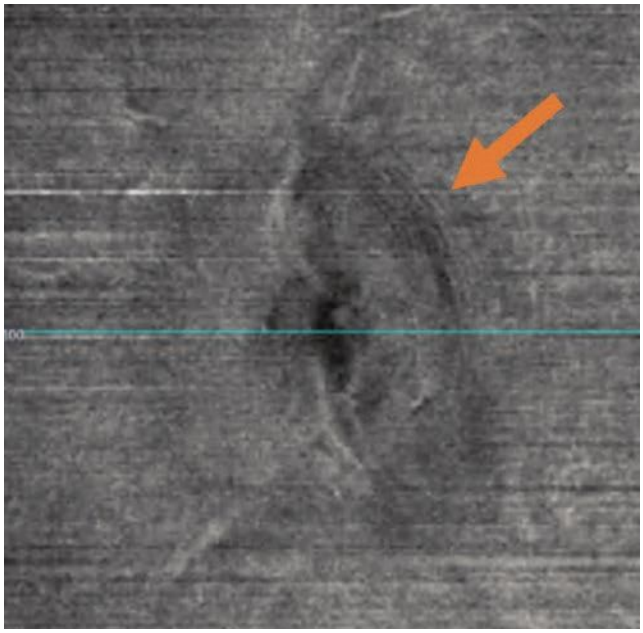

Fig. 4. Peripapillary wrinkles seen on *en face* VRI OCT imaging.

Management Strategies

If all of the signs are pointing to pseudo-papilledema without overlying papilledema, the clinician should consider asking the patient to return for close monitoring within one to two months. Stability of all findings, including afferent, efferent and ancillary tests, on subsequent examination may help to support the suspected diagnosis of pseudo-papilledema.

On the contrary, if there is suspicion of papilledema, the patient must be sent immediately to the hospital for further evaluation and neuroimaging, preferably magnetic resonance imaging (MRI) of the brain with and without contrast to rule out intracranial mass and magnetic resonance venogram (MRV) to assess for venous sinus thrombosis. Additionally, arterial imaging will help rule out arteriovenous malformations, especially in male patients in which no other etiology has been identified.[28] If not contraindicated, lumbar puncture with opening pressure and analysis of contents, to rule out some etiologies such as infection, should then be considered.[4] Ultimately, the differentiation between pseudo-papilledema and mild papilledema often remains a diagnostic challenge, but it is important that the clinician always considers that papilledema may have serious underlying etiologies, and additional evaluation and treatment must not be delayed.

Once a patient is definitively diagnosed with papilledema, our role as eye care providers does not end. As mentioned previously, OCT imaging can be helpful in the long-term monitoring of patients who have established care with neurology and begun treatment. Clinicians must always interpret subsequent OCT scans and their trends with caution.

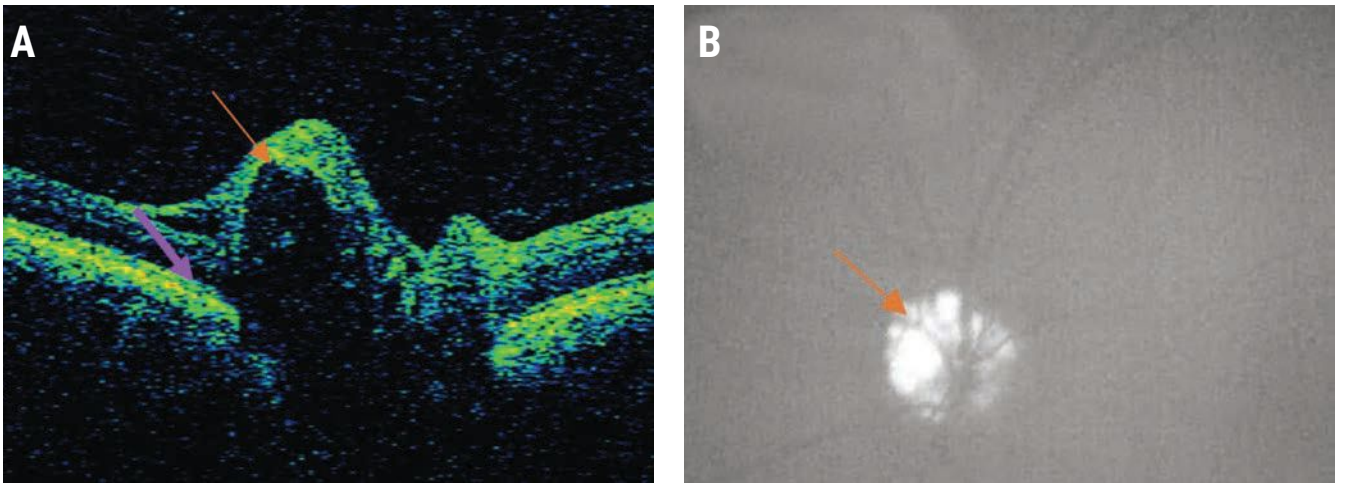

Fig. 5. A patient with pseudo-papilledema: (A) Note the ODD (orange arrow) in this OCT image, characterized by a signal poor lesion with a hyper-reflective cap. Also seen is the downward deflection of BM/RPE in a patient without papilledema denoted by the purple arrow. (B) Superficial ODD in the same patient seen as bright lesions on fundus autofluorescence.

While decreasing RNFL values may signify improving papilledema, this change must be differentiated from papilledema-related atrophy. Analysis of the ganglion cell complex is often a helpful discriminator, as thinning can be an early sign of papilledema related optic atrophy.[29] The presence of GCC thinning may be associated with a visual field defect, and as more aggressive treatment is often warranted in patients with visual field defects and loss, providers must continually monitor for these changes.

In addition to GCC analysis, reanalysis of the BM/RPE angle may provide useful. It has been shown that the angle of BM/RPE changes promptly following lumbar puncture in patients with increased ICP.[30] Patients with decreasing RNFL values secondary to papilledema related optic atrophy may still exhibit a positive BM/RPE angle towards the vitreous signifying that the patient still has active increased ICP.[31]

Takeaways

While it's true that cases of papilledema may seem challenging, optometrists can increase their diagnostic confidence and improve patient outcomes with a thorough case history, careful examination and analysis of ancillary testing, such as OCT. ■

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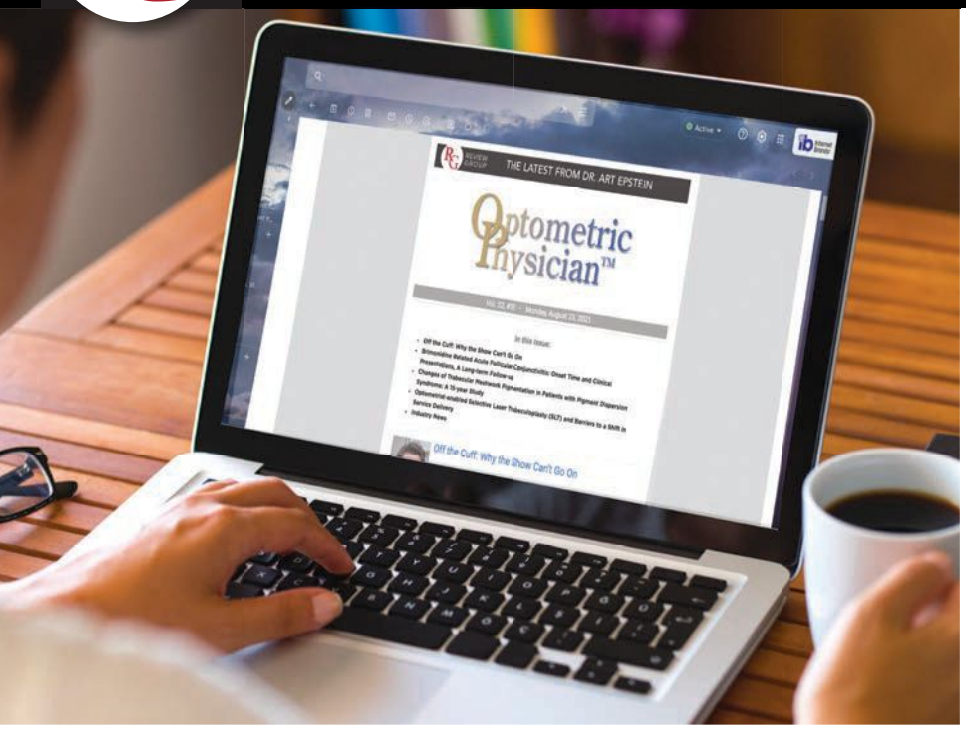

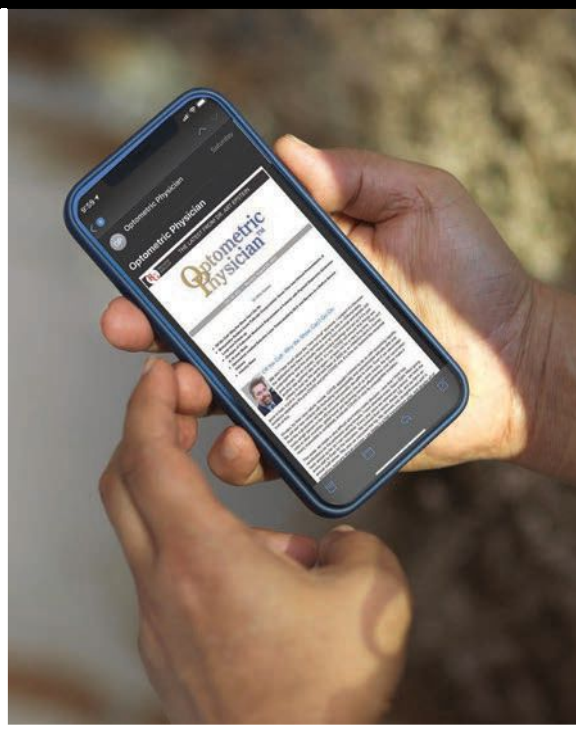

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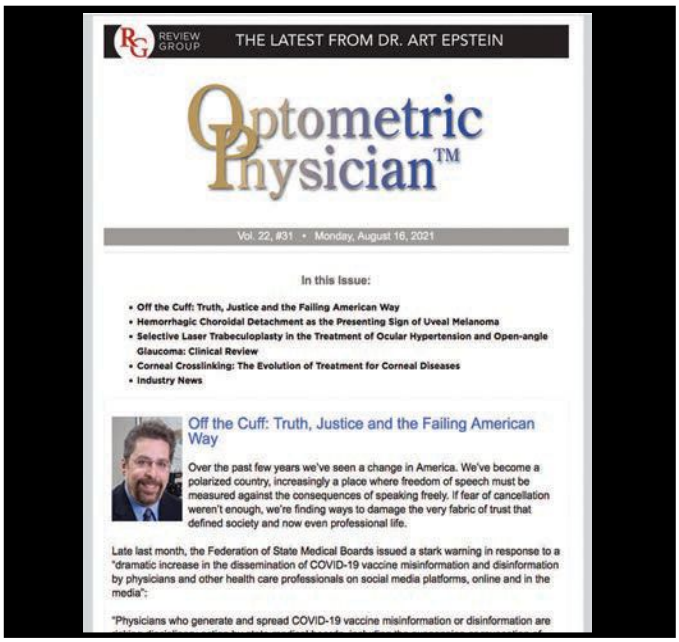

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WHEN YOUR PATIENT COMPLAINS OF HEADACHE

Learn what this signifies and what to do about it.

BY KHADIJA SHAHID, OD, MPH
IOWA CITY

Headache, or cephalgia, is one of the most prevalent disorders in the world. Over half the population younger than 20 experiences headache at some point in their lives. By the time of adulthood, headache has occurred in over 90% of the total population, making it the most disabling neurologic disorder worldwide.[1]

The complex, subjective nature of cephalgia makes it challenging to manage, yet its pervasive and severe characteristics have led people to seek treatment as far back as the earliest documented time in human existence. Today, headache is still a common presenting complaint in the emergency department (ED) and the single most common neurologic complaint in pediatric ED visits.[2,3]

Patients with headache are routinely referred to eye care physicians for consultation. Similarly, patients experiencing headache, or the associated visual and ocular symptoms, are more likely to present to us with questions and concerns. As optometrists, we needn't feel the burden to act as a neurologist to our patient; rather, we should be familiar enough with the disorder to be part of the management team and triage appropriately when an emergent referral is indicated.

Headaches can be caused by something as simple as the wrong eyeglass prescription, or as urgent as a neuro-degenerative disorder. Determining which one is sitting in your chair might take some practice—and a thorough patient history.

This article will help clinicians understand the many etiologies behind a headache, not all of which require a

TABLE 1. MIGRAINE WITHOUT AURA[7]

A. At least five attacks fulfilling criteria B through D
B. Headache lasts four to 72 hours (untreated or unsuccessfully treated)
C. Headache has at least two of the following four:
1. Unilateral location
2. Pulsating quality
3. Moderate or severe pain intensity
4. Aggravation due to or causing avoidance of routine physical activity
D. During headache, at least one of the following:
1. Nausea and/or vomiting
2. Photophobia and phonophobia

About the author **Dr. Shahid** is a clinical associate professor in the Department of Ophthalmology and Visual Sciences at the University of Iowa's Carver College of Medicine, where she provides comprehensive eye care and vision rehabilitation. She has no financial interests to disclose.

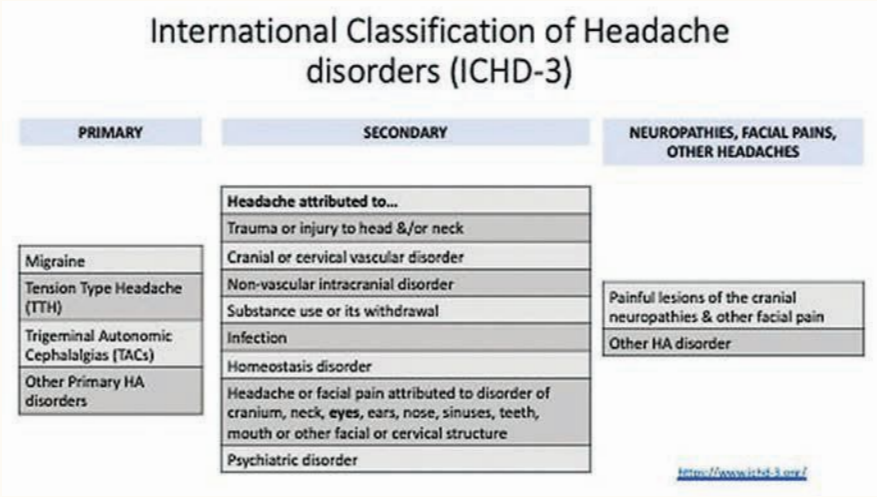

Fig. 1. Headaches are primary or secondary depending on the etiology.

referral to a neuro specialist. We will also discuss the more serious conditions that may give rise to headache and how clinicians can identify them early to ensure a quick referral when necessary.

The OD's Role

Headaches can be divided into primary and secondary types based on the underlying disorder, as outlined by the International Classification of Headache Disorders' third edition (ICHD-3) (*Figure 1*).

Primary headaches are caused by dysfunction of pain-sensitive structures in the head. They comprise most headaches and include four major categories: migraine, tension-type headache, trigeminal autonomic cephalalgias (TAC) which include cluster headaches and other primary headache disorders.

The ICHD-3 defines secondary headaches as those related to underlying disorders such as trauma, infection, malignancy or uncorrected refractive error—the most relevant to eye care providers.

It's important to consider the following in our role as optometrists when it comes to the headache workup:

Is the headache vision-related? Consider uncorrected or miscorrected refractive error, accommodative or binocular disorders, and computer vision syndrome. Patients will complain of frontal or temporal pain and asthenopia, worse during the work or school week and generally relieved by rest. Work, school and recreational screen viewing have increased exponentially, so even if the visual component isn't the primary cause, it can be a significant contributor, warranting the need for best refractive correction and visual hygiene at all times.

An important population to consider in this category are those suffering from traumatic brain injury. Over half of these patients report chronic headache along with increased dry eye and symptoms of fragile binocular systems, all of which can be addressed through optometric care.[4]

Does it originate in the eye? Consider corneal disorders such as dry eye, foreign body, abrasion, keratitis and herpetic eye disease, as well as angle closure and inflammation/uveitis. Headaches originating from the eye typically present as unilateral head pain or brow ache. Look for associated photophobia, decreased vision, nausea/vomiting and a red, painful eye.

Is it an emergent or urgent case? Look for concerning signs and symptoms such as intractable migraine (persistent, debilitating migraine lasting more than 72 hours, which is also referred to as status migrainosus), neurological changes including

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

- Understand the etiologies behind headaches that present with an ophthalmic component.
- Ask the right questions when a patient complains of headaches.
- Understand how optometric services can mitigate complaints of headaches.
- Identify the more serious conditions that may present with a headache.
- Determine whether or not a referral to a specialist is needed.

Target Audience: This activity is intended for optometrists engaged in managing patients who present with headaches.

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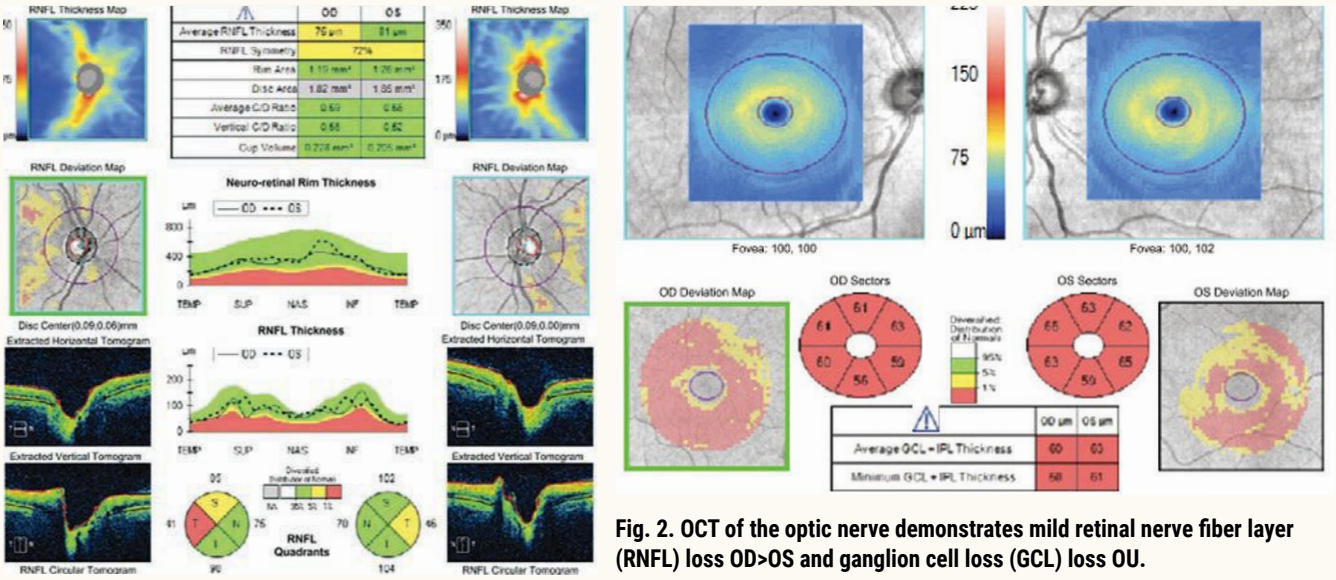

Fig. 2. OCT of the optic nerve demonstrates mild retinal nerve fiber layer (RNFL) loss OD>OS and ganglion cell loss (GCL) loss OU.

pupillary abnormalities and/or cranial nerve (CN) palsies, associated fever or infection and history of recent trauma. ODs should also watch out for cases of rapid-onset (arising and peaking within a few minutes) or "first-or-worst" headaches, especially in patients who are pregnant, immunocompromised or over the age of 50.

Primary Headache

These types of headaches are the most common. As such, it is important that ODs recognize how to approach patients who present with them.

Migraines. This type of headache is the third most prevalent disorder in the world and the third leading cause of disability in people under the age of 50. The typical migraine

Case Study #1

HPI
A 62-year-old female presented with a chief complaint of new, recent-onset light flashes in both eyes. She described very intense, sun-shaped flashes with edges that moved. They progressed across her vision and then stopped after 10 minutes. There was no pain or headache following the visual symptoms. She noted a history of visual flashes in the past, but they were always prior to a headache.

Patient's Ocular, Medical History (POH, PMH)
Cataracts OU
Migraines with visual aura

Medications
Cholecalciferol (vitamin D3) 500unit/5mL

VA With Correction
20/20 OD, 20/20 OS

Pupils, EOM, Confrontation VFs
Normal OD, OS

IOP
14mm Hg OD, 15mm Hg OS

Slit Lamp Examination
1+ nuclear sclerotic cataract OU
Vitreous syneresis OU
No posterior vitreous detachment OU
All other structures normal

Dilated Fundus Examination
Cup-to-disc: 0.2 OD, 0.15 OS
All other structures normal

Discussion
The patient was diagnosed with typical aura without headache.[5] This case features the classic description of the migraine-associated visual aura known as scintillating scotoma: a zigzag or angulated figure, usually with shimmering (scintillating) colored, black or silver edges, that appears near the point of fixation and surrounds an area not well seen. There is gradual enlargement or spread to the right or left side that leaves a total or relative scotoma in its wake until breaking up and completely resolving over 15 to 30 minutes. Typical aura can also include sensory or speech/language symptoms, but these are less common.

Also reassuring was the patient's prior history of migraine with aura. It's not uncommon for migraines to change over a person's lifetime. Many migraine sufferers report improvement of headache symptoms around age 50, with only the aura remaining thereafter.[27] However, if the presentation is new, i.e., the visual aura presents for the first time in a patient over age 40, or if atypical features of the aura are described, further evaluation is warranted to rule out other causes (*Table 9*).

sufferer is 25 to 55 years old and female (3:1 female-to-male ratio) with a family history of migraine.[5]

There are several types and subtypes of migraine outlined in ICHD-3, and many patients experience more than one over their lifetime. The most common is migraine without aura, occurring in over 60% of migraine sufferers, followed by migraine with aura, affecting approximately 30% (*Tables 1 and 2*).[6]

The typical migraine can occur in four phases which can begin up to two days prior to the headache attack and continue up to two days following (*Table 3*).

The aura phase is characterized by recurrent attacks of usually unilateral, fully reversible, visual, sensory or other central nervous system

Case Study #2

HPI
A 58-year-old female presented due to vision changes and headache. She woke up with decreased vision in her left eye that persisted for two to three days, describing it as "looking through Vaseline." She had associated left side facial numbness and weakness lasting several hours, followed by a left-sided headache that resolved with sleep. The facial numbness returned a second day, prompting her to present to the local ED.

ED exam notes reporteded mild left side facial numbness and loss of sensation with mild slack in smile. Her left arm and leg demonstrated muscle weakness. Differentials of concern included transient ischemic attack, cerebrovascular accident (CVA), retinal migraine and migraine with atypical aura.

POH, PMH
Dry eye, sick sinus syndrome s/p pacemaker, hypertension, type two diabetes, osteoarthritis, stress

Family History
Negative for neurological problems

Medications
Lexapro, metformin, vitamin B12, escitalopram oxalate, lorazepam, omeprazole

Vitals
Heart rate: 77bpm
BP: 151/88mm Hg

VA With Correction
20/30 and no improvement with pinhole OD, 20/25 OS

Pupils, EOM, Confrontation VFs
Normal OD, OS

Manifest Refraction (subjective)
No improvement in vision OU

IOP
14mm Hg OD, 13mm Hg OS

Slit Lamp Examination
Lens, trace nuclear sclerosis OU
All other structures normal

Dilated Fundus Examination
Slight arteriolar narrowing OS
Cup-to-disc: 0.60 OD, 0.55 OS
All other structures normal

Additional Testing
Complete blood count, partial thromboplastin time, international normalized ratio, transesophageal echocardiogram: normal
CT: no acute intracranial abnormality
CTA head and neck: mild atherosclerotic disease with 0% stenosis, no occlusion or aneurysm
OCT: mild RNFL loss OD>OS, GCL loss OU (*Figure 2*)
Goldmann VF: normal VF with I2e and I4e isopter OU (*Figure 3*)

Discussion
The patient was diagnosed with probable ischemic CVA, unable to confirm with MRI because of the pacemaker. She was placed on daily aspirin 81mg, counseled on BP and blood glucose control and scheduled for follow-up with neurology and her PCP for a formal sleep study.

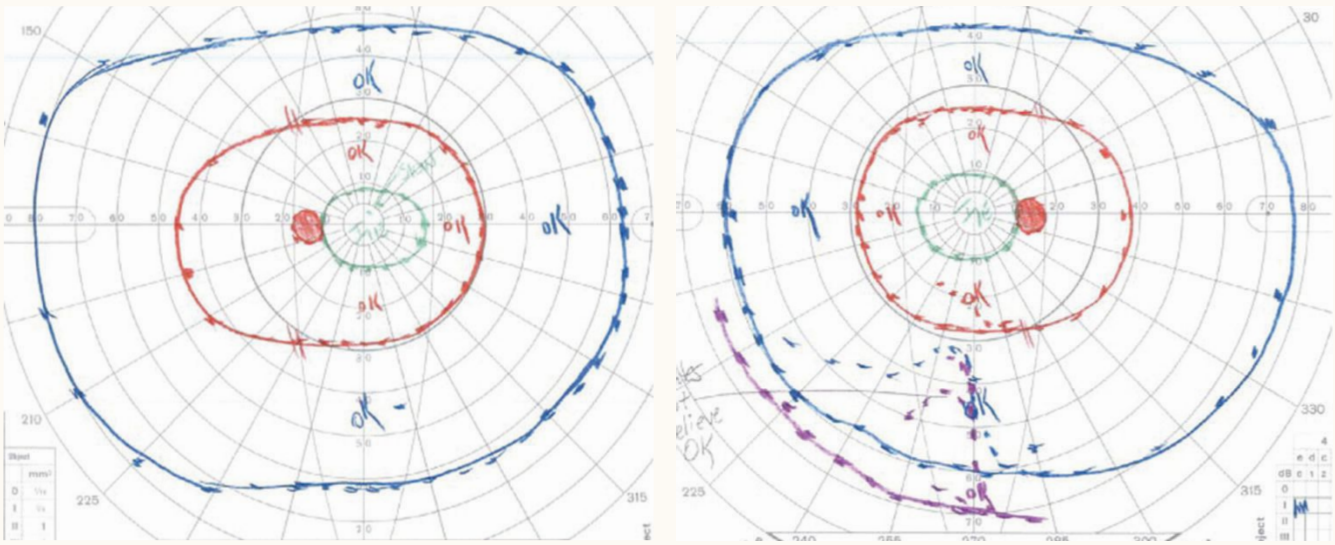

Fig. 3. Goldmann VF testing demonstrates normal VFs with I2e and I4e isopter OU.

symptoms. These tend to develop gradually, persist for up to an hour and then fully resolve, although they can continue into the headache. More than one aura type can occur, generally in succession. The most frequent is visual aura, occurring in over 90% at least some of the time, followed by sensory (pins and needles) and speech aura (aphasia).[7]

When atypical aura characteristics are described by patients or when rare complications of migraine present, a comprehensive eye exam and a prompt referral for additional neuroimaging or other workup is necessary to rule out infarction or other concerning differentials.

Women have a unique relationship with migraine. They are at higher risk of migraine with more severity

TABLE 2. MIGRAINE WITH AURA[7]

A. At least two attacks fulfilling criteria B and C
B. One or more of the following fully reversible aura symptoms:
1. Visual
2. Sensory
3. Speech and/or language
4. Motor*
5. Brainstem*
6. Retinal*
C. At least three of the following six characteristics:
1. At least one aura symptom spreads gradually ≥5 minutes
2. Two or more aura symptoms occur in succession
3. Each individual aura symptom lasts five to 60 minutes
4. At least one aura symptom is unilateral
5. At least one aura symptom is positive
6. The aura is accompanied, or followed within 60 minutes, by headache
**Not typical aura*

TABLE 3. MIGRAINE PHASES

Prodromal phase (up to two days prior)	-Hyperactivity -Hypoactivity/fatigue -Depression -Difficulty concentrating -Stiff neck -Photo and/or phonophobia -Nausea -Blurred vision -Yawning -Pallor
Aura phase (if present)	-Visual -Sensory -Speech/language
Headache	-(+/-) Cranial autonomic symptoms -Lacrimation -Conjunctival injection -Facial swelling and/or flushing or sweating -Ptosis -Gritty eye symptoms -Nasal congestion/rhinorrhea -Periorbital edema
Postdromal phase (up to two days following)	-Same as prodromal phase

Case Study #3

HPI
A 38-year-old male presented to the ED with a chief complaint of very severe headache for the past three to four weeks. He described an excruciating, throbbing, right-sided headache that radiated to the right eye, teeth and jaw, with associated rhinorrhea. "It's as if a boxer was jabbing me over and over." The pain was rated up to 10/10 severity, lasted about two hours or less each time and had occured several times a day, every day, for the past month. The patient could not find relief—rest or any attempt to remain made it worse. His wife reported that she could tell when he was having an episode because his right eye looked "sunken and droopy," and his face got red prior to and during the episode.

POH, PMH
No ocular history, hypothyroidism, headache as described earlier for the past two years, chronic smoker (cigars, cigarettes) for 20 years

Family History
Negative

Medications
Synthroid 125mcg

VA Without Correction
20/20 OD, 20/20 OS

Pupils, EOM, Confrontation VFs
Normal OD, OS

IOP
14mm Hg OD, 15mm Hg OS

Slit Lamp Examination and Dilated Fundus Examination
Lid ptosis OD
All other structures normal

Additional Testing
ESR, MRI, MRA: normal

Diagnosis
Cluster headache

Case Study #4

HPI
A 36-year-old female presented with new headaches and decreased vision, worse OS. She also noted a change in the appearance of her left eye. "It looks hazy." She described a unilateral, left-sided headache that started two weeks ago, lasted a few days and was accompanied by vomiting and nausea. She had left eye aching, tenderness and pain with movement. After a few days, the headache resolved, but her hazy vision and aching eye persisted. She was diagnosed with migraine and told to follow up with her eye doctor about the complaints of vision loss.

POH, PMH
Leber's congenital amaurosis OU, headaches, no history of migraine, depression

Medications
Venlafaxine

VA With Correction
5/160 OD, hand motion at 2ft OS

Previous VA (four months earlier)
20/160 OD, 20/160 OS

Pupils
4mm dark, 3mm light, no RAPD OD
4mm dark, 4mm light, fixed OS

EOM
Full OD, OS
Nystagmus

Confrontation VFs
Unable OD, OS

IOP
15mm Hg OD, 55mm Hg OS

Slit Lamp Examination
Cornea: central haze, edema OS
Anterior chamber: diffusely shallow with narrow angle OD, angle closure OS
Iris: anteriorly displaced OD, temporal irido-corneal touch, fixed pupil OS
1+ nuclear sclerosis
All other structures normal

Dilated Fundus Examination
Cup-to-disc: 0.55 OD, 0.65 OS
Retina: diffuse atrophy of RPE OU
All other structures normal

Additional Testing
Gonioscopy: no structures visible OU
Anterior segment ultrasound: shallow anterior chamber, narrow angle, lens displaced forward, ciliary body rotated anteriorly (*Figure 4*)

Diagnosis
Acute ACG associated with SSRI use

and frequency compared with men, in part due to hormonal correlations. Ten percent report more severe symptoms or increased attacks during menstruation, while 70% note improvement during pregnancy.[8]

There is an increased risk of stroke in males and females with chronic migraine, but especially in women with migraine aura and history of smoking. This risk may be further exacerbated by estrogen-containing oral contraceptives.[9]

As optometrists, we can counsel patients with chronic migraine to identify and minimize headache triggers and to maintain healthy lifestyles via optimal nutrition, hydration and weight, as well as adequate and regular sleep schedule and stress management (mindfulness practice, meditation, walking, etc.), all of which are proven to mitigate headache.[10]

Retinal migraines. Much less common, but more likely to present to us, is retinal migraine. A retinal, ocular or ophthalmic migraine is a series of repeated attacks of unilateral visual disturbance (*Table 4*). The visual disturbance is always monocular, more commonly negative (dimming, scotomas or blindness) and often followed by ipsilateral headache. As this migraine type is very rare, the diagnosis is one of exclusion and can only be made after all other causes of transient monocular vision loss are ruled out.

TABLE 4. RETINAL, OCULAR OR OPHTHALMIC MIGRAINE[7]

Attacks fulfilling criteria for migraine with aura and criterion B
A. Aura characterized by both of the following:
1. Fully reversible, monocular, positive and/or negative visual phenomena (e.g., scintillations, scotoma or blindness) confirmed during an attack by either or both of the following:
i. Clinical visual field examination
ii. Patient's drawing of a monocular field defect
2. At least two of the following:
i. Spreading gradually ≥five minutes
ii. Symptoms last five to 60 minutes
iii. Accompanied, or followed within 60 minutes, by headache
B. Other causes of amaurosis fugax have been excluded

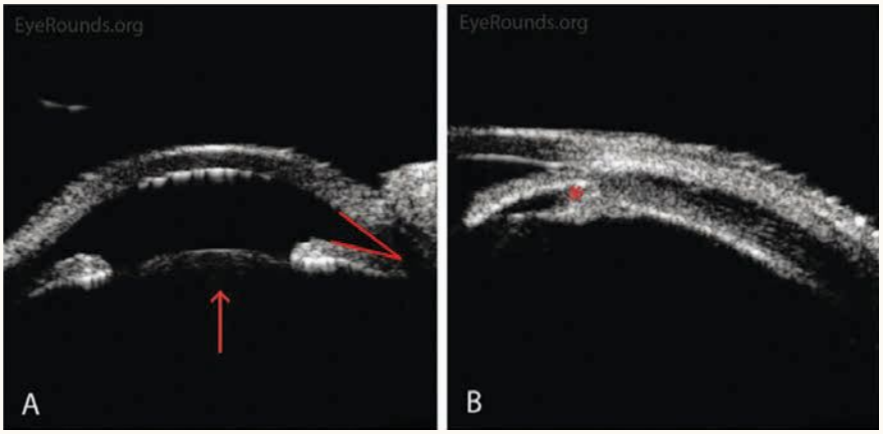

Fig. 4. Anterior segment ultrasound shows a shallow anterior chamber, narrow angle, forward-displaced lens and anteriorly rotated ciliary body.

If you suspect your patient has experienced a retinal migraine, document important details of the history of present illness (HPI) and perform a thorough ophthalmic exam with particular attention to pupils, extraocular motility (EOM) and visual fields (VFs) through testing such as dynamic, Goldmann-type VF or static, Humphrey-type VF (*Table 5*).[11] Record the aura either by having the patient draw the defect or via VF testing if the aura is present during examination.

The posterior pole should be evaluated for optic nerve changes such as increased cupping (glaucoma), edema or pallor (demyelination, compression or ischemic optic neuropathy), presence of drusen (high suspicion for choroidal neovascular membrane or vascular occlusion) and a crowded disc (increased risk of vascular occlusion). Presence of macular edema and/or compromise of vascular arcades suggests central retinal artery or vein occlusion and/or other carotid artery disease or ischemia.

If the patient is experiencing a retinal migraine during the exam, you may note one or all of the following:[12]

- (+) RAPD during or after the attack
- (+) Benign episodic pupillary dilation, *i.e.*, spontaneous pupil dilation for seconds, minutes or hours
- Disc and macular pallor
- Vasoconstriction of arteriolar and venules (segmental or diffuse), which is the most common observation during an attack

Most importantly, even in the absence of ophthalmic or other findings, refer to the appropriate specialist for careful workup before making the diagnosis of retinal migraine. Direct communication should be initiated with the patient's primary care provider (PCP), cardiologist or neurologist, with a suggestion to include the following in the workup: carotid testing such as carotid and cardiac auscultation, carotid Doppler study and cardiac echogram, as well as transesophageal echography and imaging of the brain, orbit and cerebral vasculature.

Patient/family history and additional symptoms may warrant further testing to rule out, for example, giant cell arteritis (GCA), collagen vascular disease, hypercoagulable states, vasculitis or obstructive sleep apnea (OSA), which can be a cause of first or recurrent stroke and can also occur as a new condition following a stroke.[13]

TABLE 5. RETINAL MIGRAINE

HPI	Typical Features	Concerning Features
Personal or family history	Migraines	Atherosclerotic, inflammatory, polymyalgia rheumatica, collagen vascular disease, hypercoagulable states and/or vasculitis
Frequency	One episode, rare occurrence	Repeated visual episodes in the same day or once daily for more than one day
Age of onset	Age 20 to 39*	First occurrence over age 50
Laterality	Monocular vision loss	Bilateral (e.g., hemianopia may make it hard for patient to recognize nasal loss in one eye)
Duration	Five to 60 minutes	Very short: stasis from disc edema or disc drusen Very long: embolic cause
Associated symptoms	Smoker, increased stress, after exercise/exertion	Malaise, jaw claudication, scalp tenderness, weakness, paresthesia, slurred speech or other neurologic symptoms
Relief	Completely resolves	Persistent defect

**Retinal migraine has been documented as young as age seven; in fact, about 7% of childhood migraines are retinal*[2]

TABLE 6. CLUSTER HEADACHE[7]

A. Severe to very severe unilateral orbital or supraorbital and/or temporal pain that lasts 15 to 180 minutes (untreated)
B. Either or both of the following:
1. At least one (ipsilateral to headache)
i. Conjunctival injection and/or lacrimation
ii. Nasal congestion and/or rhinorrhea
iii. Eyelid edema
iv. Forehead and facial sweating
v. Miosis and/or ptosis (Horner's)
2. A sense of restlessness or agitation
C. Occurs every other day up to eight times daily, for several days to weeks or months

A thorough, unremarkable workup confirms the final diagnosis of retinal, ocular or ophthalmic migraine, but our job is not yet done. Retinal migraine patients are at higher risk for central retinal artery occlusion, central retinal vein occlusion, branch retinal artery occlusion, retinal hemorrhages and/or edema, vitreous hemorrhage, choroidal ischemia, ischemic optic neuropathy and very rarely, permanent vision loss.[11] Routine follow-up is necessary, especially when risk factors exist that can increase the possibility of complications.

The terms "retinal," "ocular" and "ophthalmic" can be used interchangeably; however, they are not to be confused with other migraine aura; specifically, typical aura with or without migraine. Both retinal (ocular or ophthalmic) migraine and typical aura can present with or without headache, and both can have overlapping presentations, but there are key differences in their typical presentation to help guide when a patient should be referred out for further evaluation of retinal migraine. These features include monocular/unilateral, negative aura, complete or incomplete loss of vision, dimming, altitudinal defects and central VF. In comparison, typical visual aura (with or without headache) usually presents with the following: bilateral, positive aura, flashes, scintillations and peripheral VF.

Recognizing the rare migraine complications that require referral is critical. These include status migrainosus, migraine aura-triggered seizure, persistent aura, visual snow, positive lesions on neuroimaging and ischemic lesions on neuroimaging.[14]

Additionally, retinal migraine should not be confused with previously termed ophthalmoplegic migraine, now more appropriately classified as recurrent painful ophthalmoplegic neuropathy. This disorder involves repeated paresis attacks of one or more ocular cranial motor nerves (III, IV, VI) with ipsilateral headache when brain lesion has been excluded.[5]

It is estimated that over half of patients with chronic migraine, defined as occurring more than 15 days per month, develop medication overuse headache (MOH), though it's likely overlooked and misdiagnosed.[15] Analgesics, triptans or opiate medications

Case Study #5

HPI
A 17-year-old female presented for an eye exam due to new, persistent headaches and vision changes. For the past month, she had been aggravated by several low-grade headaches occurring almost daily. She also reported associated blurred vision which made it difficult for her to focus for seconds to minutes.

POH, PMH
No ocular history
Migraine since age 13

Medications
Minocycline 100mg

Vitals
BP: 126/69mm Hg
BMI: 25.63

VA Without Correction
OD 20/20 OD, 20/20 OS

Manifest Refraction
+0.25 sph, VA 20/20 OD
+0.75 sph, VA 20/20 OS

Pupils, EOM, Confrontation VFs
Normal

IOP
15mm Hg OD, 14mm Hg OS

Slit Lamp Examination
All structures normal

Dilated Fundus Examination
Disc: diffuse edema OU, small disc hemorrhage OD
Cup-to-disc: 0.10 OD, 0.10 OS
All other structures normal

Additional Testing
Color photos: grade two to three disc edema with small disc hemorrhage OD, grade two disc edema OS
Humphrey VF 24-2: enlarged blind spot OU
OCT: significant increased RNFL OD>OS
B-scan: marked elevation with signs of increased subarachnoid fluid in retrobulbar optic nerve, no evidence of disc drusen OU
MRI: no mass
MRV: moderate narrowing of bilateral transverse sinus
LP: opening pressure 261mm H_2O

Diagnosis
IIH of unclear etiology vs. intracranial hypertension secondary to metabolic, toxic or hormonal cause; in this case, minocycline

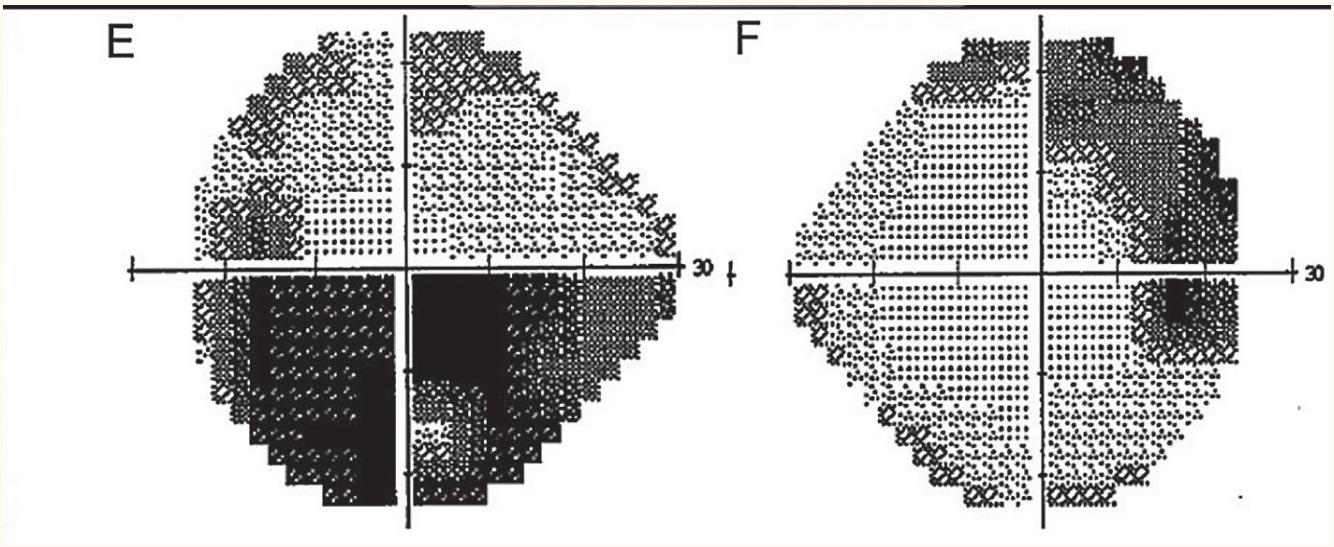

Fig. 5. Humphrey VF 24-2 testing (greyscale) demonstrates a dense, superior arcuate defect in the right eye and a dense, inferior altitudinal defect in the left.

used more than 10 to 15 days per month for more than three months are responsible. The headache usually resolves once overuse is discontinued, but not without side effects. Refer any suspected MOH back to the PCP to help treat the condition.

Cluster headaches. This condition is the more common of an otherwise rare headache disorder group TAC, which is broadly characterized by unilateral headache with ipsilateral and prominent cranial, parasympathetic autonomic features. TAC sufferers are more likely to present to us because of involvement of the eye or periorbital region (*Table 6*).

This disorder appears around age 20 to 40. Unlike the other primary headaches, it is more common in males. Attacks can occur up to eight times daily, repeating on the same side of the head over four to 16 week bouts, once or twice a year. The remission period between these attacks can last months to years but 15% of sufferers have very short or no remission.[16]

Secondary Headache

These types of headaches have the potential for significant morbidity and mortality, but only a minority (20% or less) of patients presenting for headache have the secondary type, and an even smaller portion are true emergencies. Use the mnemonic SNNOOP10 as a guide for those red flags that warrant immediate referral to rule out emergent underlying disorders (*Table 7*).[17]

Angle closure glaucoma (ACG). This is an important etiology of secondary headache in the ED setting. The association of SSRI and tricyclic antidepressant medications and ACG is low but, given the high prevalence of antidepressant use, one should be suspicious in any patient with new-onset, unilateral headaches and a history of antidepressant medication use. Other medications that can potentially cause ACG include botulinum toxin, anticholinergic agents, antipsychotic agents and sulfa-based agents including topiramate, an antiepileptic medication that is also often prescribed for migraines.

Idiopathic intracranial hypertension (IIH). Drug-induced intracranial hypertension is a known complication in long-term use of anabolic steroids, amiodarone, lithium carbonate, nalidixic acid, thyroid hormone replacement therapy, tetracycline antibiotics, high-dose vitamin A derivatives, estrogen-progestin oral contraceptives and, more recently, antipsychotic medication-induced weight gain, a prominent side effect of first- and second-generation antipsychotics.[18]

The condition usually has a favorable outcome with spontaneous resolution of papilledema and good visual prognosis once the causative agent is discontinued. Risk factors for more significant vision loss include younger age, higher opening pressure and more severe papilledema.[19] When no inducing agent can be identified, the condition is considered IIH (*Table 8*).

Headache is the most common symptom in IIH, but it presents with a wide variety of characteristics. Some patients describe severe, daily, throbbing headaches that can last for hours and are worsened by postural change, while others may only be mildly symptomatic with vague symptoms.

Transient visual loss, described as obscurations, blurring or darkening, is the second most common symptom, followed by pulsatile tinnitus.[20] Other ocular symptoms frequently reported include pain behind the eye or with eye movement and diplopia from CN VI palsy.

IIH is a diagnosis of exclusion that requires negative MRI and positive LP findings. The goal is to treat underlying disease, preserve vision and minimize headache morbidity. Recurrence of IIH is associated with weight gain, so lifestyle interventions

Case Study #6

HPI
The patient in case study #5 presented three years later in the ED for new, progressively worsening headaches for the past two days. The headaches were very severe, pounding and generalized to the entire head with progressive worsening, rated 9/10. She was tearful from the pain. Any type of movement exacerbated it. She could not find relief with medication, rest, massage or ice or warm compress.

She also noted severe neck pain and stiffness. Her mother said she had a fever of 103°F one night. In addition, the patient reported nasal congestion, sore throat and nausea.

PMH
Migraine since age 13, drug-induced IIH and papilledema at age 17

Medications
Sertraline, tretinoin 0.025% cream

Vitals
BP: 112/75mm Hg
Temperature: 99.7°F

Additional Testing
LP: opening pressure was normal but analysis of CSF was positive for enterovirus PCR

Diagnosis
Aseptic (viral) meningitis without encephalitis

for consistent and permanent weight loss are important.

Results from the IIH Treatment Trial demonstrated the importance of maximally tolerated acetazolamide (up to 4g daily) combined with a low-sodium weight loss diet to significantly improve papilledema, lower cerebrospinal fluid (CSF) pressure and improve general and visual quality of life scores. There are still no trials to guide therapy in patients with moderate to severe vision loss who may need surgery.[21]

If idiopathic intracranial hypertension is suspected or optic disc edema is noted, the following should be documented:

1. Blood pressure (BP)
   a. Rule out malignant hypertension, defined as >180/120
2. Ophthalmic examination
   a. Visual acuity (VA)
   b. Pupils
   c. EOM
      i. CN VI palsy is more likely to occur
      ii. Less frequently CN III, IV palsy
   d. VF testing
      i. Using dynamic, Goldmann-type or static Humphrey-type
   e. Intraocular pressure (IOP)
      i. Exclude hypotony, a rare cause of papilledema[22]
   f. Dilated fundus exam
   g. Color fundus photos and/or optic nerve OCT to document edema
3. Neurological examination
   a. CN VII, IX, XII can also be involved in IIH[23]
4. Neuroimaging
   a. Urgent MRI (with and without contrast) or CT, whichever is available within 24 hours
   b. CT or MR venography to exclude cerebral venous sinus thrombosis within 24 hours
5. Once all imaging is confirmed normal, LP >25cm CSF is indicative of IIH[20]

Meningitis. Headache is the most common presenting symptom of meningitis. The head pain is described as either global or localized to the nuchal area with associated neck stiffness. The classic triad of symptoms associated with meningitis headache—head pain, neck stiffness and fever—are only seen in about half of patients, but at least one occurs in the majority and over 95% present with at least two of the following: head pain, neck stiffness, fever and altered mental status.[2]

Pending the extent of the infection, there can be neurological symptoms including lethargy, distraction, alterations in mental status, seizure or postictal state. Ophthalmic evaluation may reveal associated optic nerve

TABLE 7. RED FLAGS (SNNOOP10)

Systemic symptoms, including fever
Neoplasm in history
Neurologic deficit or dysfunction
Onset of headache is sudden or abrupt
Older age (over 50 years)
Pattern change or recent onset of headache
Positional headache
Precipitated by sneezing, coughing or exercise
Papilledema
Progressive headache with atypical presentation
Pregnancy or puerperium
Painful eye with autonomic features
Post-traumatic onset of headache
Pathology of immune system such as HIV/immunocompromised
Painkiller overuse or new drug at onset of headache

edema or CN VI palsy from increased intracranial pressure.

Meningitis headache is an emergency. There should be no hesitation in the urgent referral for emergent blood cultures, possible CT before LP and analysis of CSF. Causative agents are bacterial, viral, fungal, parasitic or noninfectious. Bacterial agents are the most concerning since they have the highest mortality rate (approximately 15%).[2] Also urgent is differentiating meningitis (inflammation of meninges surrounding the brain and spinal cord) from encephalitis (inflammation of the brain), which presents with more severe neurological symptoms. The prognosis is much worse with encephalitic involvement.

GCA. This condition is a true ocular emergency that requires immediate consultation and treatment. The risk of GCA increases over age 55 but is most common over age 70, with a three-times higher incidence in females. The most commonly reported symptoms are headache, jaw claudication, anorexia/weight loss and scalp tenderness. Other commonly reported symptoms are malaise, myalgia, fever and neck pain.[24]

The absence of systemic symptoms does not rule out GCA, nor does normal ESR or CRP testing. About 20% of biopsy-positive GCA cases reported vision loss as their sole complaint. Similarly, temporal artery biopsies carry high rates of both false positives and false negatives.[25]

The main goal of treatment is to prevent further vision loss in the affected eye, decrease the risk to the fellow eye (over half of patients present with contralateral involvement if left untreated) and prevent CVA, heart attack, other cerebral events and dementia.[25] Therefore, prompt, high-dose prednisone (1mg/kg per day) is recommended while awaiting test and biopsy results.

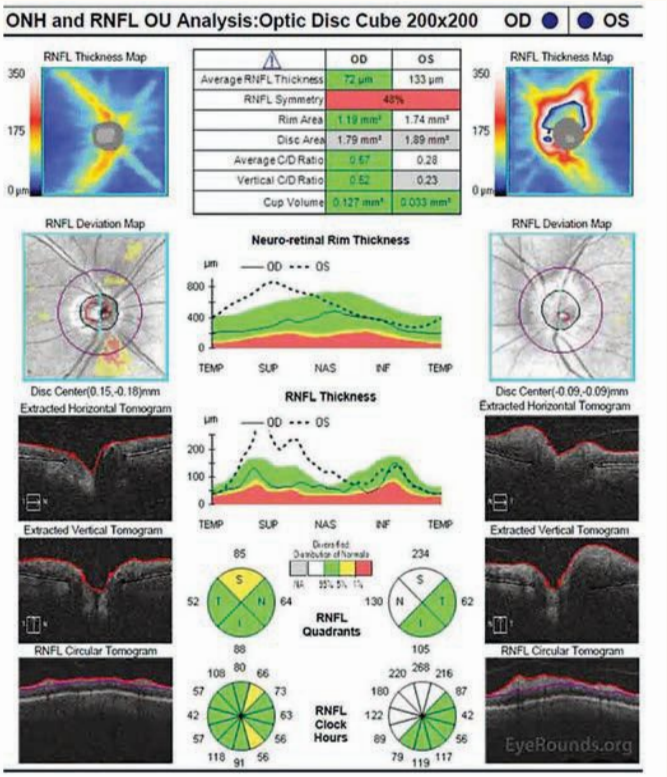

Fig. 6. OCT of the optic nerve shows significantly increased RNFL and neuroretinal rim thickness in the superior and nasal rims OS.

Case Study #7

HPI
An 84-year-old male present for eye pain, headache and vision loss OS. He had an ongoing headache for the past two months with pain behind his left eye. He noted that the lower half of his vision in the left eye was "cloudy." He denied floaters, flashes, diplopia, jaw claudication, fever and weight loss. He recalled scalp pain when combing his hair.

POH, PMH
Cataract surgery OU, POAG, type 2 diabetes, hypertension, hyperlipidemia, OSA, polymyalgia rheumatica, seronegative rheumatoid arthritis

Medications
Hydroxychloroquine 400mg, amlodipine, losartan

VA With Correction
20/20 OD, 20/60 and no improvement with pinhole OS

Pupils
(+) APD OS

EOM
Normal, (-) diplopia

Confrontation VFs
Inferior defect OS

IOP
18mm Hg OD, 19mm Hg OS

Slit Lamp Examination
PC IOL in OU, clear and centered
All other structures normal

Dilated Fundus Examination
Disc edema at superior rim OS
Cup-to-disc: 0.30 OD, 0.15 OS
Macula: several small hard drusen in both eyes
All other structures normal

Additional Testing
Humphrey VF 24-2 (grey scale): superior arcuate defect OD, inferior altitudinal defect OS (*Figure 5*)
OCT: significantly increased RNFL and neuroretinal rim thickness in superior and nasal disc OS (*Figure 6*)
ESR: 48mm/hour
CRP: 0.52mg/dL
Temporal artery biopsy: positive

Diagnosis
Arteritic anterior ischemic optic neuropathy OS

TABLE 8. HEADACHE ATTRIBUTED TO IIH

A. New headache or significant worsening of pre-existing headache fulfilling criterion C
B. Both of the following:
1. IIH has been diagnosed
2. CSF pressure exceeds 250mm (280mm in obese children)
C. Either or both:
1. Headache has developed or significantly increased in temporal relation to IIH, or led to its discovery
2. Headache is accompanied by either or both:
i. Pulsatile tinnitus
ii. Papilledema
Diagnosing IIH requires a negative MRI and a positive LP

TABLE 9. ATYPICAL FEATURES OF AURA REQUIRING FURTHER INVESTIGATION

Side-locked
More than one occurrence in a single day
Lack of expansion or lack of change in appearance
Persistent aura that does not completely resolve
Duration <five minutes or >60 minutes
Atypical visual aura: foggy vision, looking through water, complex visual hallucinations
Negative visual symptoms: hemi- or quadrantanopia, scotoma
Retinal aura symptoms: progressive tunnel vision, total loss or dimming of vision
Negative sensory symptoms: numbness
Brainstem aura: dysarthria, vertigo, tinnitus, hypoacusis, diplopia, ataxia
Motor aura or hemiplegic migraine: motor weakness
Any other associated neurological findings
Headache prior to visual aura

Summary

With such a prevalent, universal disorder like headache, it may seem like our role as eye care providers is small. The cases outlined in this article illustrate otherwise. In a review of patients presenting to the ED for headache, 8.5% had relevant ocular fundus abnormalities (retinal hemorrhages, disc edema, disc pallor and grade III/IV hypertensive retinopathy). Of those, 41% had normal neuroimaging studies.[26] The authors extrapolate that over 250,000 of the more than three million patients presenting to the ED for headache in the United States have pertinent ocular findings, not including important anterior segment and refractive findings. This highlights the importance of our role in providing comprehensive ophthalmic care for patients suffering from headache. ■

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1. A migraine with "typical aura" includes which of following findings?
a. Intense sun-shaped flashing lights with moving edges noted on both sides of vision prior to or during the headache lasting 30 minutes.
b. Pins and needles sensation on one side prior to or during the headache lasting 15 minutes.
c. Stiff neck and blurred vision prior to the headache.
d. All of the above.

2. Which cases of migraine aura do NOT warrant further investigation?
a. A 20-year-old patient with progressive tunnel vision prior to migraine.
b. A 30-year-old patient presenting with scintillating scotoma without headache and a prior history of migraine with aura.
c. A 40-year-old patient with new-onset scintillating scotoma with no prior history of migraine.
d. A 50-year-old patient with motor weakness followed by migraine and a prior history of migraine without aura.

3. Which of the following is NOT an example of a secondary headache?
a. Meningitis headache.
b. Cluster headache.
c. MOH.
d. Angle closure headache.

4. Which is one of the most common causes of disability in young adults and one of the most prevalent disorders in the world?
a. IIH.
b. Migraine.
c. Cluster headache.
d. Meningitis.

5. Which finding would be MOST concerning during a headache consult?
a. History of migraine with aura.
b. History of HIV.
c. Scintillating scotoma.
d. Nausea.

6. Which of the following investigations would be appropriate in suspected retinal migraine?
a. Carotid imaging.
b. MRI.
c. Formal VF test.
d. All of the above.

7. ACG is associated with each of the following EXCEPT:
a. Antidepressant medications.
b. Retinal migraine.
c. Botulinum toxin.
d. Antipsychotic medications.

8. Which type of headache is MOST likely to have an associated CN palsy?
a. IIH.
b. Retinal migraine.
c. Recurrent painful ophthalmoplegic neuropathy.
d. Both a and c.

9. Which of the following is associated with confirmed retinal migraine?
a. Increased risk of retinal vascular occlusion.
b. Vasodilation during retinal migraine attack.
c. Slurred speech.
d. Motor weakness.

10. Formal diagnosis of IIH MUST include this finding:
a. CSF pressure <250mm.
b. Negative MRI.
c. Positive CSF in LP.
d. All of the above.

11. Which type of meningitis headache carries the highest mortality rate?
a. Viral.
b. Bacterial.
c. Fungal.
d. Parasitic.

12. Which of the following is NOT characteristic of a typical migraine headache?
a. Family history of migraine.
b. Female gender.
c. Severe, pulsating headache.
d. Persistent aura that is measurable with VFs.

13. Which of the following statements is true?
a. Headaches presenting to the ED rarely have ocular findings.
b. MRI is indicated in any patient with a new-onset headache.
c. All new headache patients need a neurology consult.
d. Refraction is a necessary part of investigation in patients with a headache.

14. Atypical migraine aura includes which of the following?
a. Scintillating scotoma.
b. Headache following migraine aura.
c. Duration 15 minutes.
d. Repeated scotomas and flashes three to four times daily.

15. The IIH Treatment Trial suggests which of the following treatments for IIH?
a. Short-term weight loss.
b. Minimal dose of acetazolamide to minimize side effects.
c. Maximum tolerated dose of acetazolamide.
d. Surgery.

16. Which of the following would help support the diagnosis of headache associated with IIH?
a. Optic nerve OCT demonstrating neuroretinal rim thinning and RNFL loss in both eyes.
b. Humphrey VF demonstrating bilateral enlarged blind spots.
c. BP of 189/132.
d. B-scan demonstrating buried calcified bodies in optic disc.

17. Which of the following is more likely associated with a cluster headache?
a. Female gender.
b. Older age.
c. Visual aura.
d. Horner's syndrome.

18. Which of the following is TRUE regarding retinal migraine?
a. It is always bilateral.
b. It can also be referred to as ocular migraine.
c. It is a very common headache type.
d. It is always followed by a headache.

19. Which of the following is NOT associated with chronic migraine?
a. Increased risk of stroke.
b. Positive neuroimaging.
c. MOH.
d. Cluster headache.

20. In a suspected GCA headache, which of the following is applicable?
a. Normal lab work (ESR, CRP) adequately rules out GCA.
b. Prompt steroid treatment should be initiated.
c. Typical patients are 20- to 40-year-old males.
d. All of the above.

Examination Answer Sheet

When Your Patient Complains of Headache

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14. Ⓐ Ⓑ Ⓒ Ⓓ
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16. Ⓐ Ⓑ Ⓒ Ⓓ
17. Ⓐ Ⓑ Ⓒ Ⓓ
18. Ⓐ Ⓑ Ⓒ Ⓓ
19. Ⓐ Ⓑ Ⓒ Ⓓ
20. Ⓐ Ⓑ Ⓒ Ⓓ

Post-activity evaluation questions:

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

21. Understand the etiologies behind headaches that present with an ophthalmic component. ① ② ③ ④ ⑤
22. Ask the right questions when a patient complains of headaches. ① ② ③ ④ ⑤
23. Understand how optometric services can mitigate complaints of headaches. ① ② ③ ④ ⑤
24. Identify the more serious conditions that may present with a headache. ① ② ③ ④ ⑤
25. Determine whether or not a referral to a specialist is needed. ① ② ③ ④ ⑤

26. 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.

27. 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): ☐

28. 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: _____

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

Ⓐ Very confident Ⓑ Somewhat confident Ⓒ Unsure Ⓓ Not confident

30. 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: _____

31. Additional comments on this course: _____

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32. The content was evidence-based. ① ② ③ ④ ⑤
33. The content was balanced and free of bias. ① ② ③ ④ ⑤
34. 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.

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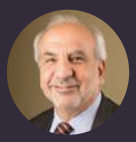

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PEER-REVIEWED

A First Look at Therapeutics for Presbyopia

Gina Wesley, OD, FAAO

Paul M. Karpecki, OD, FAAO

An overview of the growing list of options for presbyopia management.

By Gina Wesley, OD, FAAO, and Paul M. Karpecki, OD, FAAO

Presbyopia is front and center in most practices because it affects a wide age range of people, and patients are very vocal about their symptoms and how they affect their quality of life. After all, we are living long lives and presbyopia symptoms begin to appear around age 40.[1,2] As the world's population grows older, optometrists must be prepared to intervene and treat patients in a manner that is practical, effective and personalized to the lifestyle needs of the individual. In this regard, optometrists have a huge opportunity to make a difference. In the United States alone, approximately 128 million people are presbyopic.[3,4,5] Globally, 1.8 billion people are affected.[6]

In the US, most presbyopic patients wear some sort of vision correction. But as most eyecare providers will attest, patients express tremendous frustration with most of the options they try, spectacles in particular. According to the Vision Council, almost 31 million adults purchase about 51.2 million pairs of readers per year.[7] These are active patients who lead busy lives and who plan to work into their 70s. They also spend most of their days experiencing the negative effects of presbyopia. For example, Americans check their phones 96 times per day.[8] That's just one device. In total, US adults spend in excess of 11 hours daily interacting with media.[9,10] For those patients whose vision correction doesn't allow them to easily switch visual functioning distance, this can be extremely frustrating.

If you're having conversations with these patients in your office, you know

A First Look At Therapeutics For Presbyopia

This activity is supported by unrestricted educational grant from Orasis.
Faculty: Gina Wesley, OD, and Paul M. Karpecki, OD
Release Date: October 15, 2021
Expiration Date: October 15, 2022
Estimated time to complete activity: 2 hours
Goal Statement: This course will provide a comprehensive overview of existing and emerging presbyopia mitigation options.
Educational Objectives: After completing this activity, the participant should:
1. Better understand the presbyopic population today and its unique needs.
2. Have knowledge of existing presbyopia mitigation options.
3. Gain awareness of emerging pharmaceutical presbyopic candidates.
4. Understand the basic mechanisms of action for emerging presbyopic candidates.

Target Audience
This activity is intended for optometrists who provide primary care optometry services, including but not limited to medical optometric services.
Faculty/Editorial Board: Paul M. Karpecki, OD and Gina Wesley, OD
Continuing Education Credit:
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that they want and expect more. Yet, the limited options we have to improve their quality of life don't do much in the way of engendering loyalty to our practices. Patients likely commiserate about this lack of choices with family and friends as they wait impatiently for new technology to end their frustration. This is why it is so important that we remain fully informed about new options for presbyopes—because patients may hear about them as soon as we do, so we must be prepared. We experienced this with cataract surgery, and it's even more pronounced with presbyopia correction.

This monograph aims to provide optometrists with the information needed to field patients' questions, respond to their demands in a safe and clinically appropriate fashion, and prescribe or recommend solutions from the diverse and growing armamentarium of presbyopia-correcting options, ranging from spectacles and contact lenses to surgery and emerging pharmaceuticals.

Indeed, we are well-versed in most presbyopia-correcting approaches. But as new therapies emerge, clinicians must also be prepared to guide and educate patients in this evolving treatment landscape. As pharmacologic agents for presbyopia become clinically approved for use in patients, we must quickly ready ourselves to make treatment decisions and counsel patients about their choices.

THE PATIENT EXPERIENCE

Dynamic vision is much more complicated than static vision. With ametropia, the cornea doesn't change. You only need to correct for distance and accommodation provides the near. Presbyopia is dynamic and has multiple points of focus with moving components. Replicating or simulating this natural dynamic is challenging, and patients are very sensitive to the frequent changes they experience in their vision and ability to focus. They often relay to their eye doctor what appear to be overnight changes (e.g., they went to bed able to read a book and woke up needing a new prescription). These changes don't happen that fast, but for many patients, that's how it feels. This phenomenon highlights one of the most meaningful ways that we can help presbyopic patients; namely, preparing them for what's about to happen. If we mention it ahead of time, patients are more likely to slowly notice the changes vs. experience what feels like rapid vision loss and extreme disappointment.

Binocular vision issues drive many patient complaints in presbyopia patients. For example, consider the convergent insufficient patient who can no longer accommodate to compensate for their near point of convergence. When patients are convergent insufficient, their accommodation can help build the ratio necessary to be comfortable at near. But with age, these patients start to lose their hyperfocus ability to compensate and start to complain a bit more about asthenopia, often in their mid- to late-30s. Run a quick cover test on these patients and if you notice an issue, have an early conversation about expectations moving forward so they understand they may need help sooner than other presbyopes.

Another group to pay extra attention to is post-LASIK former myopes with symptoms of asthenopia. Before surgery, these patients had built in, base-in prism in their minus lens glasses to help them with convergence issues, but post-LASIK, that's suddenly gone. When these patients are in their late 30s, they often start experiencing near vision issues, which is a little sooner than you would think, but it makes sense because LASIK surgery has taken away their prismatic "crutch."

Finally, accommodative insufficient patients are likely to experience earlier symptoms. These patients never had the ability to focus properly at the appropriate time and age, and need more help sooner. Here again, we have to be ready to explain this to our patients because they don't understand why they are feeling so much more uncomfortable than other people who are the same age.

Patients with early-onset symptoms of presbyopia may be very motivated to achieve comfortable vision. This begins with a conversation about what's happening physiologically and an explanation about what we can do to help.

Patients with early-onset symptoms of presbyopia may be very motivated to achieve comfortable vision. This begins with a conversation about what's happening physiologically and an explanation about what we can do to help.

TREATMENT OPTION OVERVIEW

As you know, there are a variety of vision correction options for presbyopes, including spectacles. Within the spectacle arena, there are reading glasses, progressives, bifocal/trifocal and anti-fatigue lenses. With contact lenses, we can choose between multifocals, which allow for continued binocularity, monovision as a fallback, or modified monovision using a combination of multifocal and spherical designs. In the surgical realm, we've considered

accommodating lenses, multifocal IOLs, extended depth of focus IOLs, trifocal IOLs, adjustable IOLs, corneal inlays and scleral expansion.

The IOL options have proven to be a frontrunner in this category and are increasingly selected as a presbyopia-correcting option for cataract patients. In some instances, as with contact lenses, monovision also is still utilized and can provide very sharp point near vision. However, this often comes at the expense of intermediate vision, which in this day and age is critical to functioning with our many handheld tools and devices. The challenge with most IOLs is that you only get one chance to get it right, and you don't know for sure how the patient is going to react until after the lens is already in their eye. In other words, your biometry and other preoperative measurements have to be spot on, which can be challenging in a patient population with so much ocular surface disease because these tear films can create a lot variability in the eye's refractive surface.

Conversely, adjustable lenses are less reliant on preoperative measurements. Instead, you refine the prescription after the lens is in the eye. This is achieved using an adjustable beam light delivery device, which is used in-office and causes macromers in the path of the light to be photopolymerized. The unpolymerized macromers move into the exposed area causing precise shape and power change. Next, the entire lens is exposed to light to polymerize all of the remaining macromers. The outcome is a precise change in the lens power to match the patient's individual prescription. In essence, refraction is optimized after healing is complete, and the patient gets to trial the refractive outcome. The light treatments are painless, noninvasive and last about 90 seconds. Most patients have two to three treatments, the first of which is at least 17 days after surgery. The subsequent treatments are for refinement purposes. Clinical trials show patients receiving the RxSight Light Adjusting Lens achieved uncorrected vision of 20/20 or better twice as often as those receiving a monofocal lens, and nearly 92% of patients receiving the light adjusting lens achieved results within 0.50D of the intended target.[11]

One disadvantage of light-adjusting lens technology is that patients must wear UV protective glasses outdoors for the first few weeks until they decide that their vision is exactly as they want it and you lock in the final prescription. As soon as they are satisfied, you can finalize the prescription, and patients can discontinue wearing the UV protecting eyewear.

In addition to spectacles, contact lenses and surgical techniques, a number of new pharmaceutical agents are being investigated for the treatment of presbyopia. They are based on one of two main mechanisms of action—pupil modulation or lens softening. Pupil modulation utilizes pupillary miotics, which exert a pinhole effect and increase the depth of field.[12] The lens softening approach is based on the assumption that lens stiffening and loss of flexibility are presbyopia's main causes.[13] As such, these drops selectively target and disrupt the disulfide bonds in the lens.

LENS SOFTENING APPROACH

A presbyopic lens can result from several different etiologies; however, excessive crosslinking is considered a leading potential cause of increased lens stiffening, which results in the loss of accommodative focusing power. In short, in order for the eye to focus on nearby objects, the lens must be flexible and viscous enough to change shape by thickening at its center in order to accommodate. Lens fiber cells are filled with a 30% solution of protein, known as cytosol (soluble) lens protein. A normal functioning lens fiber cell allows for cytosol displacement, thus facilitating accommodation and enabling the lens to focus on nearby objects. Oxidation is a normal challenge to all body tissues, including the lens fiber cells. Oxidation leads to crosslinking of cells and the aggregation of proteins. Normally, we have processes to break these bonds, but as we age, the enzymes that do this can't keep up with the number of crosslinked proteins, so the aggregation builds up. This compromises the lens fiber cell's ability to displace cytosol and, therefore, its ability to accommodate.

The experimental drug in this category, UNR844 (lipoic acid choline ester [LACE] 1.5%, Novartis) is a prodrug that's administered twice-daily. Previously called EV06 ophthalmic solution, this drop penetrates the cornea and is metabolized into choline and lipoic acid, two naturally occurring substances. Next, enzymes within lens fiber cells chemically reduce lipoic acid to active dihydrolipoic acid. Dihydrolipoic acid chemically reduces disulfide bonds. These disulfide bonds are cleaved, or chemically reduced, in lens fiber cells and the choline exerts a cationic surfactant action on protein aggregation. Crystallins are repaired and cytosol displacement is restored. As such, UNR844 may potentially restore the natural ability of the human crystalline lens to reduce aberrant chemical bonds and cross-links, thus regaining lens flexibility and restoring accommodation and focal power. This therapeutic approach should not disrupt the fiber structure of the lens or any natural proteins. Therefore, UNR844 will not likely result in optical distortions, which could potentially result from mechanical or laser treatment approaches.

In a Phase 1/2 study, 50 patients received one drop twice daily.[14,15,16] At day 91, distance-corrected near visual acuity (DCNVA) was 20/40 in 82% of the treated patients and 20/32 in 68% of treated patients. Also of note, 22% of patients experienced an improvement of three lines after 90 consecutive days of twice-daily treatment. With increased use the improvement was sustained in 67% of patients at 7 months post-treatment.[17,18]

More recently, a Phase 2 study of 78 patients ages 45 to 55 years did not meet its primary objective insofar as there was no significant difference in mean change in DCNVA between UNR844 and placebo.[19] The authors

noted that this may be due to variability in DCNVA measures. When a post hoc non-parametric analysis was performed, the median difference between UNR844 and placebo was four letters, which is more in line with the earlier results. A Phase 2b dose-finding study is planned.

PUPIL MODULATION APPROACH

Dilated pupils narrow depth of focus and create blur. By making the pupil smaller, we allow for a range of depth of focus, and when we create a pinhole, we improve image quality by blocking stray light. Of course, we also restrict peripheral vision, making placement very important. Only a small pupil at, or extremely close to, the iris plane can extend depth of focus without restricting peripheral focus.[20] The traditional miotic is the muscarinic receptor agonist pilocarpine, which causes miosis and ciliary muscle contraction.

Several pupil modulation drugs in the pipeline may receive approval in the next few years, some of which utilize pilocarpine, sometimes in combination with other agents. The leading miotics under investigation include:

• **AGN-190584.** (1.25% pilocarpine, AbbVie/Allergan). After assessing different concentrations of pilocarpine with and without oxymetazoline, researchers have optimized a formulation upon which new Phase 3 trial data is based.[21] Gemini 1 and Gemini 2 are placebo-controlled randomized trials that include a total of 750 patients.[22,23] AGN-190584 or vehicle were administered once-daily bilaterally for 30 days. In both studies, the primary endpoints were met. Specifically, there was a statistically significant 3-line or more gain in distance-corrected near visual acuity out to day 30 at hour 3 in low-light conditions and without a loss of distance vision. No treatment-emergent serious adverse events were observed.

• **Brimochol (brimonidine and carbachol, Visus Therapeutics).** This combination of carbachol, a parasympathomimetic, and brimonidine, an alpha-2 adrenergic agonist, has entered Phase 2 trials. It is unique in that the effect is believed to last 8 to 12 hours thanks to the higher dose carbachol.[24] However, headaches and brow aches are thought to be mitigated due to the combination with brimonidine. Five clinical studies have already been conducted, with the most recent reporting on 57 subjects and showing statistically significant improvement in near visual acuity of a 5 Jaeger-line or greater gain.[25]

• **CSF-1 (low-dose pilocarpine, Orasis Pharmaceuticals).** With a concentration of less than 1% pilocarpine, this parasympathomimetic is currently in Phase 3 trials. Six hundred subjects are enrolled in two multicenter, double-masked, parallel-group clinical trials dubbed NEAR-1 and NEAR- 2 (300 subjects per study).[26,27] A unique feature of CSF-1 is the vehicle, which is both lubricious and preservative-free, which may be beneficial given the prevalence of dry eye in aging populations. The primary and secondary outcomes of the Phase 3 investigations mimic those studied in phase 2b,[28] with some additions including the impact on night vision and other safety and tolerability measurements. In the earlier investigation of 166 patients on b.i.d. dosing, 47% achieved ≥3 line improvement and 80% achieved a ≥2 line improvement.[29] Treatment-related adverse events were mild and temporary, with no negative impact on distance or night vision.

• **MicroLine (1% or 2% pilocarpine, Eyenovia).** Now in Phase 3 trials, this agent is administered via the company's proprietary Optejet dispenser that delivers about 8 microliters of 1% or 2% pilocarpine.[30] For reference, a typical drop is between 30 and 50 microliters. Earlier investigations have shown that a statistically significant proportion of subjects treated with MicroLine had a 3-line or more improvement in distance-corrected near visual acuity vs. placebo in low-light conditions at 2 hours post-treatment and that the drug was well-tolerated. All adverse events were mild.

• **Nyxol (0.75% phentolamine and 0.4% pilocarpine, Ocuphire Pharma).** This combination drug began Phase 2 proof-of-concept trial enrollment in VEGA-1 earlier this year, with the expectation of reporting on data from 152 participants.[31] It is believed that Nyxol (preservative-free phentolamine) can last a significant period of time to offset the shorter duration of the low-dose pilocarpine. Earlier studies indicate that Nyxol alone reduced pupil diameter by approximately 20% and significantly improved near visual acuity by one line for >24 hours after an evening instillation.

• **PRX-100 (aceclidine, LENZ Therapeutics).** Aceclidine is a parasympathomimetic like pilocarpine. This muscarinic acetylcholine receptor agonist causes pupil constriction in the sphincter muscle of the iris and causes miosis without stimulating accommodation. In Phase

Dilated pupils narrow depth of focus and create blur. By making the pupil smaller, we allow for a range of depth of focus, and when we create a pinhole, we improve image quality by blocking stray light. Of course, we also restrict peripheral vision, making placement very important.

2b trials (n=58), this novel treatment was well-tolerated, with 47.2% of participants gaining 3 lines of near vision acuity and more than 90% gaining at least 2 lines of near visual acuity.[32,33] About half of the patients receiving the drug maintained the 2-line improvement for up to 7 hours following initial installation. According to the company, aceclidine can treat a broad range of refractive error, from -4.50D to +1.50D and up to 2.00D of astigmatism.[34]

ADAPTING TO PRESBYOPIA

Fundamentally, patients are seeking functional vision without too much hassle (which, of course, is relative). Some patients need 20/20 all the time to be happy, which may not be possible without making adjustments to how they interact with the environment. However, most patients are used to modifying their lighting or the fonts on their computers. The challenge for eye care providers is determining the right strategy for each individual patient. Unfortunately, this can be hit-or-miss before a patient is ready for cataract surgery. The promise of therapeutics opens up a whole new realm of possibilities that may be more convenient and aesthetically acceptable to many presbyopes. But, whatever option the patient chooses, it must be comfortable and safe. As new data emerges on drops, this should be top of mind.

Optometrists have a long history of treating presbyopia with glasses and contact lenses, but for patients who are not willing or able to undergo surgical procedures, no pharmacologic treatments have been available. As this evolving pipeline develops, there is growing anticipation for this method of treatment.

One way we can position ourselves is to make patients aware of the emerging possibilities and let them know that we are the leading experts in presbyopia treatment. In addition, we can let them know that soon we will have more options for more circumstances and lifestyle needs. That said, by no means does the introduction of drops imply that glasses and contact lenses are going away. On the contrary, therapeutics are additive. They are not going to work perfectly for every patient's eyes in every situation. However, they may offer freedom that wasn't previously available, which is welcome news for clinicians and patients alike.

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A First Look at Therapeutics for Presbyopia

CE QUIZ

To obtain continuing education credit, complete the test and form on the following pages and return them to: Jobson Healthcare Information, LLC, Attn.: CE Processing, 395 Hudson Street, 3rd Floor New York, New York 10014. You can also access the test form and submit your answers online at: revieweducationgroup.com under the Supported CE tab. You must achieve a score of 70 or higher to receive credit. Allow four weeks for processing. A passing score will earn you 2 hours of credit. Please check with your state licensing board to see if this approval counts toward your CE requirement for relicensure.

1. Presbyopia symptoms begin to appear around age _____.
a. 30
b. 40
c. 50
d. 60

2. In the United States, approximately _____ people are presbyopic.
a. 28 million
b. 108 million
c. 128 million
d. 208 million

3. Globally, _____ people are affected by presbyopia.
a. 800 million
b. 1 billion
c. 1.8 billion
d. 2.8 billion

4. US adults spend in excess of _____ hour(s) daily interacting with media
a. 1
b. 2
c. 11
d. 22

5. Which of the following is true of ametropia?
a. You only need to correct for distance and accommodation provides the near
b. You only need to correct for near and accommodation provides the distance
c. You always need to correct for near and for distance
d. You never need to correct for near or for distance

6. Presbyopia is:
a. Static
b. Dynamic
c. Characterized by rapid onset
d. Stable over time

7. Which of the following patient groups are likely to experience presbyopia symptoms early?
a. Convergent insufficient patients
b. Post-LASIK former myopes
c. Accommodative insufficient patients
d. All of the above

8. Post-LASIK former myopes may experience asthenopia due to _____ .
a. Near vision issues
b. Distance vision issues
c. Delayed neuroadaptation
d. Glaucoma

9. Which of the following was *not* mentioned as a way to mitigate the effects of presbyopia:
a. Light-adjusting lenses
b. Pharmaceuticals
c. Eye muscle exercises
d. Monovision

10. IOL options are increasingly selected as a

presbyopia-correcting option for cataract patients. In some instances, monovision also is still utilized and can provide very sharp point near vision. However, this often comes at the expense of _____ ?
a. Intermediate vision
b. Near vision
c. Near and distance vision
d. Near and intermediate vision

11. Adjustable lenses are _____ on preoperative measurements than other IOL designs.
a. More reliant
b. Less reliant
c. Equally reliant
d. Not at all reliant

12. Which of the following is *not* true of light adjusting IOLs?
a. Refraction is optimized after healing is complete
b. Patients get to trial refractive outcomes
c. The light delivery device is used in the operating room to achieve the final prescription
d. Patients must wear UV protective glasses outdoors for several weeks

13. Pupil modulation approaches to presbyopia correction utilize _____.
a. Analgesics
b. NSAIDs
c. Antibiotics
d. Miotics

14. The _____ approach to pharmaceutical presbyopia correction is based on the assumption that lens stiffening and loss of flexibility are presbyopia's main causes.
a. Lens softening
b. Lens hardening
c. Lens removal
d. Lens stabilization

15. Lens fiber cells are filled with a _____ solution of protein, known as cytosol (soluble) lens protein.
a. 10%
b. 20%
c. 30%
d. 40%

16. Which of the following is *not* true of oxidation?
a. It is a challenge to lens fiber cells
b. It helps lens fiber cells in presbyopes
c. It leads to crosslinking of cells
d. It leads to aggregation of proteins

17. Which of the following is *not* true of pupil modulation?
a. It allows for a range of depth of focus
b. It improves image quality by blocking stray light
c. It improves image quality by allowing extra light
d. It can restrict peripheral vision

18. Pilocarpine causes miosis and _____ .
a. Lens hardening
b. Crosslinking
c. Ciliary muscle contraction
d. Aggregation of proteins

19. Which of the following is *not* a leading miotic under investigation for presbyopia treatment?
a. Brimonidine and carbachol
b. Low-dose pilocarpine
c. 3% pilocarpine
d. Aceclidine

20. Which of the following most accurately describes CSF-1?
a. Low-dose pilocarpine in a lubricious and preservative-free vehicle
b. Utilizes a dispenser that delivers about 8 microliters of 2% pilocarpine
c. Is a combination of brimonidine and carbachol
d. Contains phentolamine to offset the shorter duration of the low-dose pilocarpine

Examination Answer Sheet

A First Look at Therapeutics for Presbyopia
Valid for credit through October 15, 2022

Online: This exam can be taken online at: www.revieweducationgroup.com under the Supported CE tab. 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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Credit: This course is COPE approved for 2 hours of CE credit. Course ID is: 74374-GO.

Processing: There is a four-week processing time for this exam.

Salus University has reviewed and approved this activity, which is administered by Review Education Group and distributed by Review of Optometry.

Answers to CE exam:

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

Post-activity evaluation questions:

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

21. Overview of presbyopic population today and its unique needs. ① ② ③ ④ ⑤
22. Knowledge of existing presbyopia mitigation options. ① ② ③ ④ ⑤
23. Awareness of emerging pharmaceutical presbyopic candidates. ① ② ③ ④ ⑤
24. Understanding of the basic mechanisms of action for emerging presbyopic candidates. ① ② ③ ④ ⑤

25. Based on 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? _____

_____

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 in the future?

Ⓐ Lack of time to stay abreast of updates on emerging pharmaceutical options for presbyopia
Ⓑ Clinician lack of interest in using emerging pharmaceutical options for presbyopia
Ⓒ Patient lack of interest in using pharmaceutical options for presbyopia
Ⓓ Clinician need for marketplace validation of pharmaceutical options for presbyopia
Ⓔ Patient need for marketplace validation of pharmaceutical options for presbyopia

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First Name
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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

30. The content was evidence-based. ① ② ③ ④ ⑤
31. The content was balanced and free of bias. ① ② ③ ④ ⑤
32. The presentation was clear and effective. ① ② ③ ④ ⑤
33. Additional comments on this course: _____

_____

_____

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 121962 RO-AS-1021

Go With the Flow

Corneal hysteresis may help spot glaucoma in KCN patients.

Q Can corneal hysteresis (CH) aid intraocular pressure (IOP) assessment in keratoconus (KCN)?

A "Hysteresis is a measurement characterizing how something responds to the loading and unloading of an applied force," says Paymaun Asnaashari, OD, who practices in northern California. "It is not a constant property, like thickness or weight, but a measurement that is dependent on the elastic properties and viscosity of a material or system." The cornea is a viscoelastic tissue, and CH reflects its ability to absorb and dissipate energy.[1]

Discussion

There is growing evidence regarding CH and its relationship to optic nerve changes, but the exact mechanism of how a lower CH may contribute to development or progression of glaucoma still remains unclear, as the intrinsic properties of the eye that CH aims to measure are not well understood, Dr. Asnaashari says.

However, study findings support the hypothesis that CH serves as a surrogate biomarker of the viscoelastic properties of the lamina cribrosa, posterior sclera and other optic nerve structures.[2] The idea that a lower CH is associated with lower optic nerve biomechanical rigidity supports the theory that it can lead to posterior displacement of the lamina cribrosa, he notes. A lower CH may indicate a decreased ability of the posterior tissues to compensate for IOP changes.[2] An association between lower CH and higher vertical c/d ratios with optic disc hemorrhages has also been reported.[3] This suggests the biomechanical properties of the cornea are important in glaucomatous optic changes.

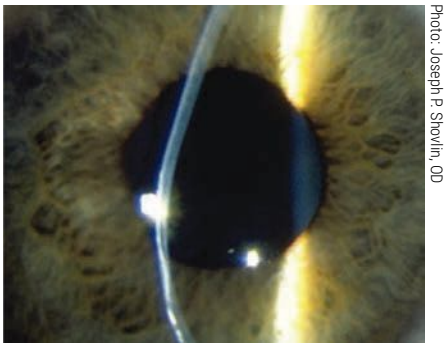

Photo: Joseph P. Shovlin, OD

Studies have observed lower CH in KCN, which may be an indicator for glaucoma risk.

CH has been shown to be lower in glaucoma, with studies demonstrating that a lower CH is a risk factor for visual field progression and retinal nerve fiber layer thinning.[4-8] Accordingly, patients with a higher CH may not exhibit the same IOP-lowering effects across the same therapies—pressure reduction in a patient with a high CH may be significantly less.[9]

It can be tempting to start a patient on a second drop if their IOP does not reach its target, but if the patient has a high CH, we can expect a lower risk of progression and less of an effect on IOP. Another study showed further evidence of an inverse association between CH and magnitude of IOP reduction post-MIGS.[10] Within the same study, there was an increased need for repeat surgeries or other interventions for patients with a lower CH.[10]

Multiple studies have found that CH is lower in KCN eyes and that the measurement decreases with increasing corneal steepening and thinning as the disease becomes more severe.[4,11,12] It has been supported that CH also naturally drops with age.[13] Other studies have suggested that the LASIK flap creation and corneal thinning weaken the cornea and reduce CH, potentially leading to the development of new parameters for screening candidates for refractive surgery.[14,15] However, it is not yet supported that patients with corneal ectasia disease who are glaucoma patients or suspects have a lower CH than patients with corneal ectasia disease alone.[16] ■

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About Dr. Shovlin

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

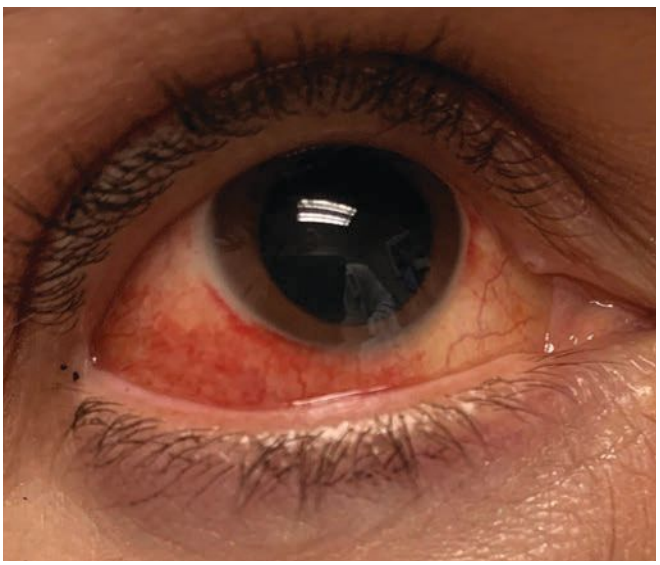
BY JOSEPH W. SOWKA, OD

Not as Bad as it Seems

Episcleritis needs proper diagnosis and treatment to alleviate a patient's worries.

A 53-year-old woman presented urgently with a moderately painful red right eye of two days duration. She reported some associated tearing but no other discharge. She denied itching or recent illnesses. It seemed to be neither better nor worse than when she first noticed the pain, which she had awoken with. This was a first occurrence for her. Her medical history was significant only for unspecified thyroid dysfunction.

Her corrected visual acuity was 20/20 in each eye. She manifested a sectorial redness in her right eye, and the remainder of her external evaluation was normal. Her intraocular pressure was 22mm Hg OU. A dilated fundus exam revealed optic disc cupping of 0.3/0.3 in each eye and normal retinal findings OU. Following dilation, in which 2.5% phenylephrine was employed as part of the regiment, her redness has significantly reduced but did not completely dissipate. Based upon her symptoms and clinical examination, she was diagnosed with episcleritis.



Sectoral injection in episcleritis.

In the Red

Episcleritis is a superficial inflammation involving the conjunctiva and episcleral region.[1,2] The episclera is a highly vascularized ocular tunic that encircles the globe between the overlying conjunctiva and the underlying sclera.[3,4] The inflammatory response remains localized to the superficial episcleral vascular network with nongranulomatous inflammation and vascular dilatation with perivascular infiltration.[3-5] Episcleritis commonly appears as a sectorial injection involving both the episcleral tissues and overlying conjunctiva, usually concentrated in either the nasal or temporal quadrant.

Typically, there is no discharge but tearing may be common.[1,2] Any significant discharge should prompt consideration of other possible entities rather than episcleritis. Significant serous discharge may indicate a viral conjunctivitis, but the eye is usually diffusely rather than sectorally red. Mucopurulent discharge and eyes that are stuck shut upon awakening points to a bacterial infection. Tearing and significant itching prompt thoughts of allergic conjunctivitis and patient rubbing may induce sectorial injection. True episcleritis occurs in response to noxious stimuli or secondary to an underlying systemic disease.[3,4] Quite commonly, episcleritis reveals no underlying etiology and remains idiopathic.

Episcleritis typically appears acutely with patients often reporting that they woke up with a red eye. Superior injection has the potential to go unnoticed and may be completely masked by the upper eye lid. Most cases are unilateral; however, it may occur bilaterally in cases of toxic exposure or underlying systemic disease.

There may be a translucent white nodule within the inflamed area. When this finding is present, it is called nodular epscleritis. Nodular episcleritis represents a focal concentration of inflammation. The nodule adheres to underlying tissue and is distinguished from conjunctival cysts and phylectenules by its subsequent lack of mobility with the conjunctiva. Patients may complain of mild pain or tenderness to the affected region, pain upon manipulation or a stabbing sensation upon moving the eyes. Due to lack of corneal involvement, visual acuity is unaffected. Though the cornea is inherently unaffected, longstanding or recurrent episcleritis may precipitate dellen formation. Though uncommon, it is possible anterior chamber cells may be seen in more pronounced cases.

Care must be taken to distinguish episcleritis from the more severe

About Dr. Sowka **Dr. Sowka** is an attending optometric physician at Center for Sight in Sarasota, FL, where he focuses on glaucoma management and neuro-ophthalmic disease. He is a consultant and advisory board member for Carl Zeiss Meditec and Bausch Health.

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condition scleritis, which may appear superficially similar. Ocular injection is typically deeper with scleritis and the eye will not blanch with 2.5% phenylephrine as it would in episcleritis. Pain is much more common and severe in scleritis compared to episcleritis. Some patients with scleritis complain of a boring type of pain which does not occur in episcleritis. Additionally, vision is more likely to be reduced in scleritis due to more widespread inflammation whereas there should be no significant vision loss in episcleritis unless there is a mild concurrent keratopathy.

Not every case of sectorial injection is true episcleritis. Trichiasis or other observable irritation, may mechanically induce a "pseudo-episcleritis." Careful history and examination should identify potential mechanical causes of sectorial injection that may be mistaken for true episcleritis. Treating these entities without first removing the cause may result in management failure or, at least, unnecessary prolonged treatment. Signs and symptoms should be considered before prescribing any medications.

Treatment

Most cases of episcleritis will blanch with the application of topical 2.5% phenylephrine, which aids in diagnosis.[3] In contrast, deeper ocular inflammation such as seen in scleritis and uveitis will not result in blanching, and pharmacologic use does not affect the clinical appearance.

Episcleritis may be idiopathic or in association with some underlying systemic disease. Among those conditions associated with chronic or recurrent episcleritis include rheumatoid arthritis, polyarteritis nodosa, systemic lupus erythematosus, inflammatory bowel disease, sarcoidosis, Wegener's granulomatosis, tuberculosis, Lyme disease, gout, herpes zoster and syphilis.[6-9] Inflammatory bowel disease is a strong consideration when encountering patients with episcleritis.[10]

Most cases of episcleritis are self-limiting, resolving spontaneously within two to three weeks even in the absence of treatment.[11] Patients who are symptomatic or disturbed by cosmetic appearance benefit from a regimen of cold compresses, lubricants, topical nonsteroidal anti-inflammatory drugs and topical corticosteroids.[11] As inflammation in episcleritis is relatively superficial, virtually all topical steroids are acceptable, including fluorometholone, rimexolone, loteprednol, prednisolone and difluprednate. Dosing on both the topical NSAID and topical steroid typically range from BID to Q4H. Cycloplegia is rarely necessary.

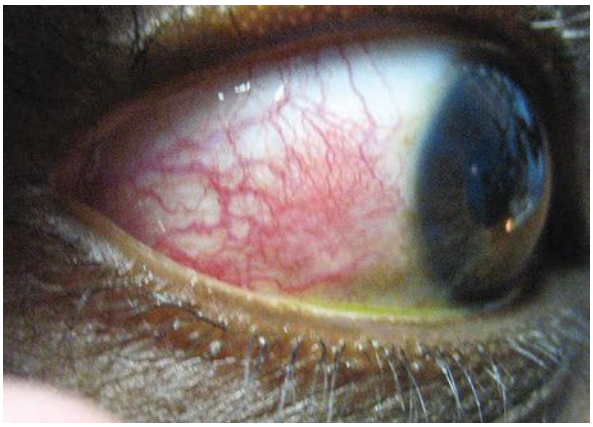

Photo: Ernie Bowling,OD

Episcleritis can present with complaints of discomfort or irritation (rather than true eye pain), redness and edema to the affected area over the sclera.

Recalcitrant or severe cases associated with systemic disease may require oral therapy which could include ibuprofen (600mg to 800mg BID to QID), naproxyn sodium (250mg to 500mg TID) or indomethacin (25mg to 75mg BID).[1,11] Follow-up on these cases should be weekly until resolution or marked improvement. Patients placed on steroids of any kind are at risk for steroid-induced elevation of intraocular pressure, which should be monitored and addressed with glaucoma medications if necessary. Prolonged cases of episcleritis are atypical and should prompt consideration of other diagnoses or increased likelihood of an underlying systemic association.

Due to the association with systemic disorders, patients with exaggerated, recalcitrant or recurrent events should be referred for a medical evaluation with either an internist or rheumatologist. Recommendations should be made for a complete autoimmune profile and assessment of the aforementioned systemic associations with emphasis on inflammatory bowel disease.

The patient presented here was educated about her condition and prescribed topical prednisolone acetate 1% QID. She missed her scheduled follow-up appointment but telephoned a week later to say that her discomfort and redness resolved. She was instructed to initiate a brief steroid taper.

Takeaways

Although there are many things to keep in mind when encountering episcleritis, it is a condition similar to subconjunctival hemorrhage in that it typically looks worse than it is and is self-limiting in most cases. ■

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REVIEW of OPTOMETRY

BY PAUL M. KARPECKI, OD
CHIEF CLINICAL EDITOR

A Disease For All Seasons

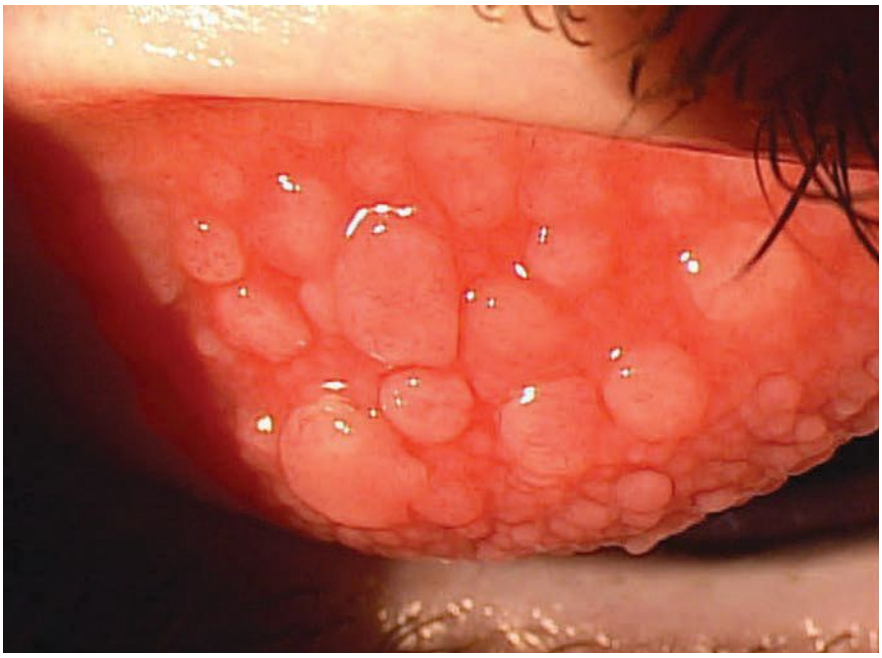
Don't be fooled by its name: vernal keratoconjunctivitis can cause problems year-round. Heed these pearls to aid care.

Vernal keratoconjunctivitis (VKC) has long challenged eye care professionals, particularly due to its chronicity. This bilateral, allergic inflammatory disease is often labeled as seasonal, despite the fact that patients frequently have recurrences throughout the year—often with serious consequences, including loss of vision.[1] Management of VKC must be continuous with a heavy emphasis on patient education, focusing on prompt treatment for acute exacerbations.

Epidemiology and Pathogenesis

VKC generally first presents at an early age—usually between ages four and seven—but it can manifest in infancy.[2] Although it usually resolves after puberty, VKC is also sometimes seen well into adulthood.[3,4] In fact, although adults with VKC demonstrate the same clinical manifestations, the inflammatory response tends to be higher, which increases risk of fibrotic sequelae.[5] In either case, VKC primarily (thought not exclusively) affects young males who live in arid climates, leading some researchers to believe that it may involve a genetic predisposition.[2]

Occasionally, VKC is associated with atopy, implicating a host of environmental factors such as wind and pollen.[2,6] However, it's often said that the term "vernal" is a misnomer since about 23% of cases are perennial and nearly 16% of seasonal cases evolve into a perennial variant in a mean of three years' time.[7] Furthermore, research shows that as many as 60% of VKC sufferers have had a recurrence during the winter months.[7]



Vernal keratoconjunctivitis before treatment started. Management of this condition and long-term care is essential, as recurrence is a top concern.

> **Be on the lookout for ropy discharge, conjunctival congestion and even corneal involvement in severe cases.**

Signs, Symptoms and Classification

Clinical signs, symptoms and medical history are far more useful in guiding VKC diagnosis than other tests, such as skin prick.[2] VKC is classified according to the part of the conjunctiva predominantly involved—bulbar/limbal, palpebral or mixed. In most cases, the disease primarily involves the tarsal and bulbar conjunctivae.[3] Papillary hyperplasia can range in size from 0.1mm to 5mm, sometimes with a cobblestone appearance.[8]

In the case of limbal VKC, you'll likely note opaque, gelatinous confluent papillae and Horner-Trantas dots.[3] Many VKC cases are misdiagnosed as allergic conjunctivitis because the signs, such as eosinophilic elevations, may only involve one or two clock hours of the limbus. The number of cases would likely be higher if clinicians closely observed the limbus in all children presenting with severe ocular allergic reactions.

Be on the lookout for ropy discharge, conjunctival congestion and

About Dr. Karpecki

Dr. Karpecki is medical director for Keplr Vision and the Dry Eye Institutes of Kentucky and Indiana. He is the Chief Clinical Editor for *Review of Optometry* and chair of the New Technologies & Treatments conferences. A fixture in optometric clinical education, he consults for a wide array of ophthalmic clients, including ones discussed in this article. Dr. Karpecki's full disclosure list can be found in the online version of this article at www.reviewofoptometry.com.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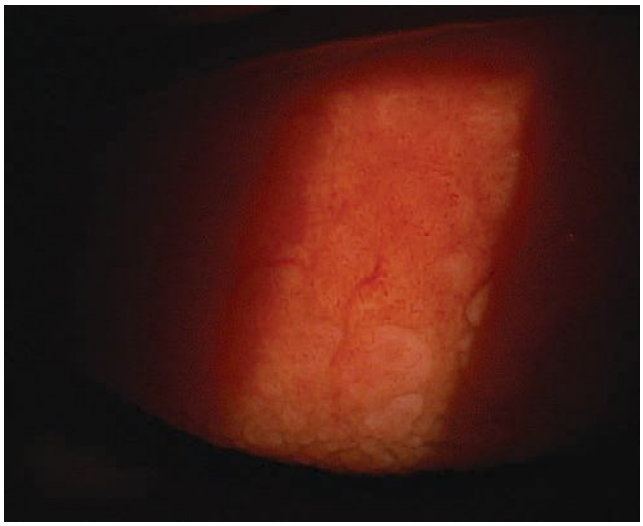
even corneal involvement in severe cases. Patients will likely complain of itching, discharge, watery eyes, photophobia and foreign body sensation. Keep in mind that the itching can be debilitating and complaints about pain and extreme light sensitivity should alert you to potential corneal involvement.[2]

Recurrence is a top concern since it can result in complications, including keratoconus, shield ulcers, chronic dry eye, limbal stem cell deficiency and lid complications due primarily to chronic inflammation, eye rubbing and long-term steroid use.[2]



Vernal keratoconjunctivitis after treatment.

Disease Management

Acute VKC is often managed with topical antihistamine/mast cell stabilizers or steroids, but the larger concern—as previously mentioned—is recurrence, which can lead to severe complications that detract from quality of life as well as a child's future potential.[2] As such, effective long-term care is essential and must include educating patients and parents about the likelihood of recurrence and the need for prompt intervention.

Long-term therapy is best managed with calcineurin inhibitors, which include tacrolimus and cyclosporine. These are immune modulators that work to block IL-2 mediated Th2 lymphocyte proliferation, two critical components in the pathogenesis of VKC. Previously, doctors had the choice of using a commercial cyclosporine but at a much lower dose. More typical would be to compound these therapeutics.

Earlier this year a new drug called Verkazia was approved by the FDA for VKC. Verkazia is a higher concentration of cyclosporine (CsA) at 0.01% that comes in a unique oil-in-water, cationic emulsion. This second-generation oil emulsion is the same technology used in Retaine MGD drops that have been effective in MGD and evaporative dry eye disease management, and uses charged particles to increase bioavailability. The drug is dosed QID and indicated for children and adults with VKC. Recommended dosage is one drop four times a day, and can be discontinued after signs and symptoms are resolved. It can be reinitiated if there is a recurrence.

In Phase III clinical studies, the efficacy of high-dose CsA cationic emulsion in treating allergy symptoms, superficial punctate keratitis and overall quality of life scores was demonstrated in patients with severe cases. Verkazia improved keratitis, symptoms and quality of life scores in patients with severe VKC. There was also improvement in photophobia, tearing, itching and mucous discharge was greater with Verkazia QID and BID vs. vehicle over four months, although QID was the most effective. In the long-term, overall corneal fluorescein staining, visual analog symptoms and quality of life scores remained stable for up to 12 months with Verkazia. Adverse events were mild or moderate, with instillation site pain being most common. Verkazia was also well tolerated.[1]

Traditional therapies include topical mast cell stabilizers, topical antihistamines, dual-acting allergy drops, NSAIDs, corticosteroids, tacrolimus and lubricants.[2] Supratarsal steroid injection or systemic therapy also may be indicated in some cases.[2] Surgery may also be indicated to treat complications such as giant papillae, shield ulcers, keratoconus, LSCD or corneal opacity.[2]

As primary eye care providers, we must closely observe all patients with severe signs or symptoms of allergic conjunctivitis to rule out VKC. Focusing on the long-term care for VKC patients is of utmost importance, in addition to the acute, episodic intervention that relies on topical corticosteroids. Since this is a disease that primarily affects children, we must also consider developmental consequences, particularly in light of the fact that VKC can limit joyful activities such as school, sports and vacations, ultimately leading to psychological and relationship issues.[1] ■

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BY JAMES L. FANELLI, OD

Don't Complicate Things

Neurodegenerative disorders such as Alzheimer's can make glaucoma management more challenging and contribute to disease progression.

I saw a 92-year-old Caucasian female in June 2021 for a scheduled glaucoma progress evaluation. She was initially seen in 2009 as a new patient with complaints related to slightly decreased vision.

Case

Prior to her first presentation at my clinic, her most recent visit to an eye care provider had occurred about one year earlier, at which point she was told she had cataracts that did not require surgery and to follow-up in one year.

The patient's left eye demonstrates advanced neuroretinal rim loss, peripapillary atrophy and macular changes. From an OCT perspective, given the peripapillary atrophy and early macular disease, the neuroretinal rim and Bruch's membrane opening are the structures where we should look to observe more reliable glaucomatous changes.

At her initial visit with me, the patient's entering visual acuities were 20/60 OD and OS, and she was best corrected to 20/40- OD and OS. Pupils were equal, round and reactive to light and accommodation with no afferent pupillary defect, and extraocular muscles were full OU. Her anterior segments were unremarkable with open angles by Van Herick slit lamp estimation.

Through dilated pupils, she was found to have nuclear and cortical cataracts slightly worse OS than OD, along with some macular changes OS>OD consistent with very early macular degeneration. No subretinal abnormalities were found. Her cup to disc ratios were 0.70/0.75 OD and 0.80/0.85 OS with moderate peripapillary atrophy OD>OS, and her optic nerves were judged to be average in size. Her retinal vascular evaluation was consistent with what you would expect to see in an 80-year-old individual, and her peripheral retinal evaluations were normal.

Pachymetry readings were 500µm OD and 483µm OS. Applanation tensions were 15mm Hg OD and 16mm Hg OS. Fundus photos were obtained.

The patient's initial visit put a potential glaucoma diagnosis OU on my radar, and she was scheduled for a complete glaucoma evaluation including visual fields, gonioscopy and OCT imaging.

The patient complied with my requests for follow-up and was diagnosed with normal-tension glaucoma. Structural damage was confirmed on objective optic nerve and retinal nerve fiber layer (RNFL) imaging, and bilateral arcuate field defects were found on relatively reliable threshold field studies.

She was started on a prostaglandin 1 drop OU HS and tolerated the medication well. Unfortunately, it did not result in a reliable, consistent lowering of intraocular pressure (IOP), and she was ultimately switched to another medication that she is still using today.

Discussion

Scenarios like this play out in each of our offices regularly. A new patient presents with undiagnosed glaucoma and you make the diagnosis and render appropriate care. Your initial care is geared toward confirming the diagnosis, and subsequent life-long care is focused on keeping the patient visually satisfied and stable throughout their life. Fortunately, for both the patient and the practitioner, we are blessed with a plethora of available instruments, medications, studies and in-office and surgical techniques that can be used to stave off further glaucomatous damage.

In many cases, including this one, the patient will undergo other procedures, such as cataract surgery, that also help preserve vision. With the advent of minimally invasive glaucoma surgery (MIGS) devices, even better outcomes can be achieved.

About Dr. Fanelli

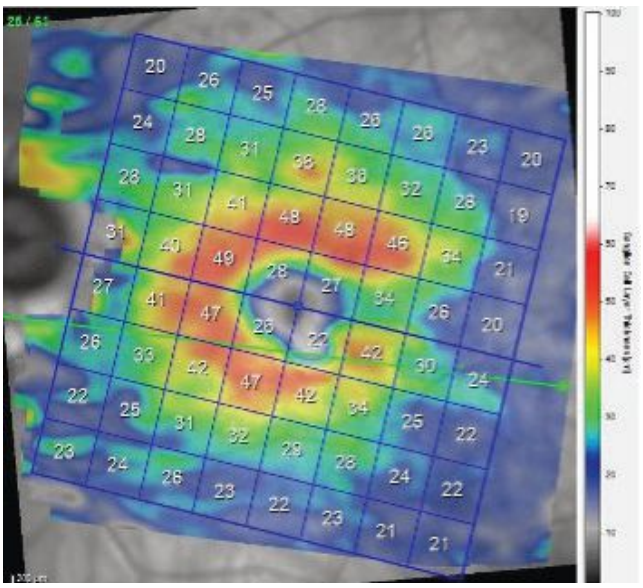
Dr. Fanelli is in private practice in North Carolina and is the founder and director of the Cape Fear Eye Institute in Wilmington, NC. He is chairman of the EyeSki Optometric Conference and the CE in Italy/Europe Conference. He is an adjunct faculty member of PCO, Western U and UAB School of Optometry.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

In this patient's case, since we were able to achieve adequate IOP control before the development of MIGS devices used in conjunction with lens extraction, her cataract surgery was a straightforward phacoemulsification with standard intraocular lens implantation. Postoperative acuities were good at 20/25 OD and 20/30 OS.

Keep in mind that age-related macular degeneration (AMD) may lurk in the background in cases like this and should be monitored closely. Fortunately, in this patient's case, her AMD remained mild and non-angiogenic.

For nine of the 12 years I've cared for this patient, things went rather smoothly. But eventually, that began to change. She seemed to have a shorter temper and attention span, and it became challenging for her to answer relatively simple questions. Not surprisingly, she was diagnosed with Alzheimer's disease (AD) three years ago, and since then, it had progressed significantly. Up until that point, she had been entirely stable from a glaucoma perspective.

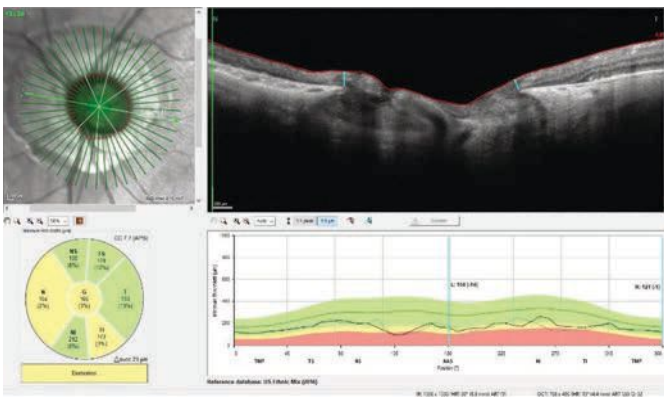
Neurodegenerative disorders such as AD can cause structural changes in the posterior pole when imaged with OCT technology.[1,2] RNFL loss, especially in the papillomacular bundle, is perhaps a biomarker of early neurodegeneration.[1,3] Optic atrophy has also been reported. Whether AD can worsen glaucoma has not yet been confirmed. But AD can certainly play a role in a patient's ability to comply with medication schedules. When compliance becomes a problem, often we'll move toward procedures such as selective laser trabeculoplasty to reduce medication burden and thereby facilitate compliance. AD can also cause patients to forget about appointments. This particular patient's husband has been wonderful in making sure her prostaglandin is administered OU HS and she never misses an appointment.



While the patient's neuroretinal rim shows significant damage, the macular ganglion cell layer has remained reasonably healthy.

When it comes to the shortened attention span that often results from AD, getting through various tests in the office can become burdensome, and test results may be uninterpretable. A good example of this is visual field testing; unfortunately, that was one of the first tests we eliminated from our patient's office visits.

As AD progresses, in addition to attention span and cognitive issues, physical limitations begin to prohibit detailed evaluation. Even a quick OCT scan becomes a challenge for the patient. These tests are no longer attainable in our patient. We are now down to six-month visits, during which we are able to obtain IOPs using a Perkins tonometer and take a quick look at her fundus and optic nerves.



Note that the circumpapillary RNFL area is affected by the peripapillary atrophy, whereas the neuroretinal rim, showing significant glaucomatous damage, is relatively stable.

Given that she has advanced glaucoma, every micron counts from an OCT perspective. But in reality, there is no way to ascertain subtle changes seen on OCT anymore; I can only look for gross changes, and gross changes to her optic nerves will carry a consequent burden of vision loss.

Fortunately, her IOPs, neuroretinal rims and gross vision have all remained stable. What has not remained stable is her neurodegenerative disease. She still lives at home, with outside help concerning some activities of daily living. And though from my perspective her quality of life has changed, I'm not so sure that from her perspective it has changed all that much. But I do know that not changing what our office visits look like insofar as testing and frequency would certainly have had a detrimental effect on her quality of life. It's all about the patient, and sometimes keeping things simple is the best medicine. ■

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2. Polo V, Garcia-Martin E, Bambo MP, et al. Reliability and validity of Cirrus and Spectralis optical coherence tomography for detecting retinal atrophy in Alzheimer's disease. Eye (Lond). 2014;28(6):680-90.

3. Doustar J, Torbati T, Black KL, et al. Optical coherence tomography in Alzheimer's disease and other neurodegenerative diseases. Front Neurol. 2017;8:701.

Special Delivery

The Durysta implant eases glaucoma hassles—for a time.

BY JESSICA SCHIFFBAUER, OD
NORFOLK, VA

In glaucoma care, the momentum right now is with options that reduce reliance on the patient. Laser trabeculoplasty as a first-line therapy, minimally invasive glaucoma surgery at the time of cataract surgery and combination drugs that put two or more agents in one bottle all aim to achieve IOP control in a patient-friendly way, recognizing this group's struggles with adherence.

The newest idea—intracameral sustained-release of medication—is now upon us. Durysta (Allergan) is an injectable pellet of 10mcg bimatoprost that delivers a small amount of drug in the anterior chamber that lasts up to 15 weeks in clinical studies, though the effect on IOP is said to extend beyond that. Other intracameral injections currently being studied will follow in time.

Nonetheless, we now have a novel drug delivery device that has shown efficacy in lowering IOP while having an excellent safety profile. Below we discuss what optometrists need to know when comanaging Durysta with our surgical colleagues.

Choosing the Ideal Patient

Practitioners should thoroughly evaluate the anterior chamber structures for suitability. In pseudophakes, the IOL should cover the capsulotomy and the posterior capsule should be intact. Durysta can be used in patients with pigmentary dispersion or pseudoexfoliation, but one must ensure integrity of the lens.[1] Contraindications include active or suspected ocular or periocular infections, history of intraocular inflammation, endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior lens capsule and prostaglandin allergy.[1]

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

Gonioscopy prior to insertion should ensure there is enough space in the angle to fit the implant to avoid contact with the corneal endothelium. Using the Shaffer grading system, an angle of grade 3 or 4 should allow sufficient space for implantation. Extreme caution should be used in those with narrow angles or anatomical scarring.[2]

Photo: Walt Whitley, OD

Durysta delivers bimatoprost into a patient's anterior chamber.

Implanting the Device

Intracameral implants can be injected under topical anesthesia either at the slit lamp or in an operating room.[2] Using a clear corneal paracentesis entry—typically temporal—the 28-gauge needle/injector is inserted in the anterior chamber, aimed inferiorly and the implant is injected.[2] Then, the injector is slowly removed and the insertion site is tamponaded with a cotton-tip applicator.[2]

Most surgeons won't prescribe an antibiotic following implantation as there is little evidence they make a difference in preventing endophthalmitis. Patients are typically seen a week later and, if recovering well, will follow-up in two to three months. The implant biodegrades over time.

Potential Adverse Reactions

Adverse reactions include hypersensitivity, corneal complications (*e.g.*, edema, endothelial cell loss), macular edema, intraocular inflammation, pigmentation and endophthalmitis.[1] Conjunctival hyperemia, seen in 27% of patients, was the most common reported ocular adverse reaction in clinical trials.[1] Others noted include foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, blurred vision, irritation and dry eye.[3] Headaches were the most common non-ocular adverse reaction.[3]

Though questions remain about the feasibility of—and insurance coverage for—repeat injections after the initial implant dissolves, even a short-term break from meds is welcome. With a reported 32% drop in IOP, Durysta expands treatment options for glaucoma patients, especially those who may be hypersensitive and/or have poor compliance or ocular surface disease.[3] ■

1. Craven ER. Tips and tricks for Durysta injection. www.glaucomaphysician.net/issues/2020/september-2020/tips-and-tricks-for-durysta-injection. September 1, 2020. Accessed September 16, 2021.

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ABOUT THE AUTHOR

Dr. Schiffbauer practices at Virginia Eye Consultants in Norfolk, VA. She is a consultant for Bausch + Lomb and a speaker for Eyevance Pharmaceutials.

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

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New items to improve clinical care and strengthen your practice.

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▶ DIAGNOSTIC EQUIPMENT

Device For Front-to-Back Ocular Assessment

A new multi-modal device can perform various assessments that may help you detect early signs of cataracts, glaucoma, retinal and corneal pathologies, the manufacturer suggests. The Visionix VX650 from Luneau Technology combines into one device the functionality of the following equipment: autorefractor, keratometer, aberrometer, topographer, pachymeter, Scheimpflug camera, tonometer and a 45-degree fundus camera, states a company press release. Capturing such data using only a single device reduces patient movement through the practice, improving workflow efficiency, Luneau suggests, as screenings could be done in the pre-test room.

Since the VX650 is EMR-ready and HIPAA compliant, the data produced can be reviewed and shared locally or remotely, says the company.

Keep Your Distance, Get Your Data

An auto phoropter called the Vision-S 700 refraction station by Essilor Instruments allows for remotely controlled—and hence COVID-safe—testing, requiring no physical contact at all between you and the patient, says the company.

Like the company's Vision-R 700 manual phoropter, this new device also uses a unique "liquid lens" optical module and software algorithms that allow simultaneous and continuous variations of lens power by automatically compensating for the effect that any change in sphere, cylinder and axis has on the other dimensions. Essilor calls this "digital infinite refraction" and says it cuts time from the refraction process—potentially down to three minutes—without sacrificing accuracy.

To save space in the practice, the Vision-S 700 also eliminates the need for physical separation between the patient and chart by creating an "immersive" refraction experience that simulates the appropriate amount of distance for vision testing, a company press release explains. Vertex distance and monocular pupillary distance can be adjusted and patient position monitored from afar by the doctor or tech. The test gives patients the option to respond to lens changes with "I don't know/they appear equal" to encourage accurate, informed results, giving patients and ODs greater confidence in the prescription, the company says.

▶ THERAPEUTIC AIDS

Overnight Single-Use Device Keeps Eyelids Shut

A new option may offer an alternative to conventional ointments for treating patients with dry eye disease (DED) who experience nighttime lid closure issues. As the first product from start-up company Ophthalmic Resources Partners, the SleepTite/SleepRite works by allowing eyelids to remain sealed shut during sleep to protect the cornea and conjunctiva from exposure to fluids, airborne contaminants and excessive drying, resulting in a reduction of DED and meibomian gland dysfunction symptoms, say the product's developers. They also note that reducing oxidative stress by eliminating overnight exposure improves efficacy of topical and procedural treatments as well.

SleepTite/SleepRite has a porous and latex-free design and will be available for patients with both regular and sensitive skin types in boxes of 30, a company press release explains. The daily disposable devices feature a non-irritating adhesive designed to stay in place all night and not pull on lashes or skin, and a tab on the outer edge also makes for easy removal, the release explains. Patients who wish to alternate eyes every other night will still see clinical improvement, the company says.

Low Vision Smart Glasses Powered by Cell Phone

The new Eye4 augmented reality glasses by Eyedaptic may help your low vision patients better perform daily tasks like reading and using a computer. An upgrade to previous models, the Eye4 allows the glasses to be tethered to a smartphone, giving it dual functionality as both a wearable and handheld magnifier, the company explains. Since most of Eye4's technology is in the phone's all-in-one interface, the glasses are light and compact, weighing just three ounces, says an Eyedaptic press release. Powered by a cell phone tether (using either the patient's own device or the one that comes with Eye4), the glasses feature two high-resolution cameras aided by image processing technology, the company notes. Other features include auto zoom mode, image stabilization and contrast enhancement.

The company says that, in clinical trials, patients wearing the smart glasses had a fivefold greater ability to perform daily activities. This hands-free eyewear solution may help people with retina-related vision challenges, including AMD, lead more independent lives, Eyedaptic suggests. ■

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MICHAEL HOSTER
(610) 492-1028
mhoster@jobson.com

EXECUTIVE DIRECTOR
JAMES HENNE
(610) 492-1017
jhenne@jobson.com

SENIOR MANAGER, STRATEGIC ACCOUNTS
MICHELE BARRETT
(610) 492-1014
mbarrett@jobson.com

REGIONAL SALES MANAGER
JONATHAN DARDINE
(610) 492-1030
jdardine@jobson.com

PRODUCTION MANAGER
FARRAH APONTE
212-274-7057 faponte@Jobson.com

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Better Never Than Late?

A patient undergoes a seemingly uneventful cataract operation—then things take a turn for the worse.

A 74-year woman presented to the office with a chief complaint of "blurred vision for months." She said the issue had gradually become worse over time. Her ocular history was positive for cataract removal with intraocular lens implantation three years prior. She did not report any pain. She denied trauma, systemic disease and allergies of any kind.

Diagnostic Data

Her best-corrected entering visual acuities were 20/30 OD and 20/30 OS. Her external examination was unremarkable with no evidence of afferent pupillary defect. The biomicroscopic examination was normal with no posterior capsular opacification and a centered lens. Her Goldmann applanation tonometry measured 17mm Hg OU.

Additional studies included color photodocumentation, laser interferometry to assess best capable function, optical coherence tomography (OCT) to understand retinal status, OCT angiography to rule out choroidal neovascularization and fluorescein angiography to rule out the presence of choroidal neovascularization and/or retinal pigment epithelial cell damage or leakage.

The pertinent posterior segment findings are demonstrated below.

Your Diagnosis

What would be your diagnosis in this case? What is the patient's likely prognosis? To find out, please read the online version of this article at www.reviewofoptometry.com. ■

What do these findings suggest about the patient? How would you approach management?

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.

NEXT MONTH IN THE MAG

In November, we present a series on the health of the ocular surface. Articles will include:

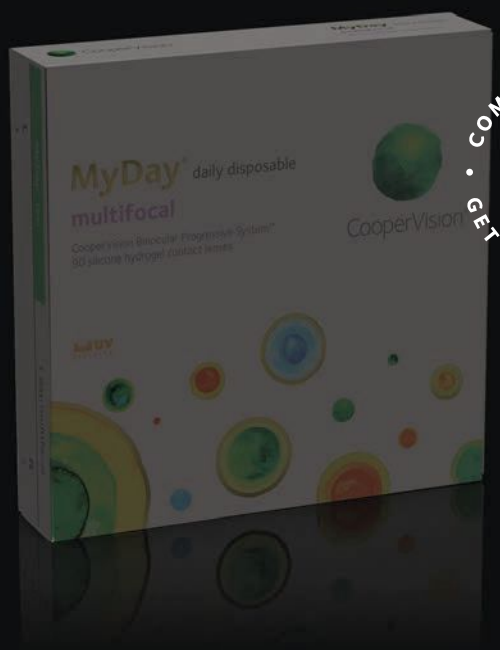
- The Conjunctiva Up Close: A Visual Guide to Pathology
- Blepharitis: New Approaches to an Old Problem
- Dry Eye: Where Do We Stand with Omega-3 Supplements?
- Managing Mask-induced Ocular Surface Changes
- When the Patient Complains of Red Eye

Also in this issue:

- Office Design Contest: Freshen Up Your Practice

Presbyopia VS. You

Presbyopia is the ultimate opponent in the exam lane—and the newest multifocal contact lens is about to change the game.



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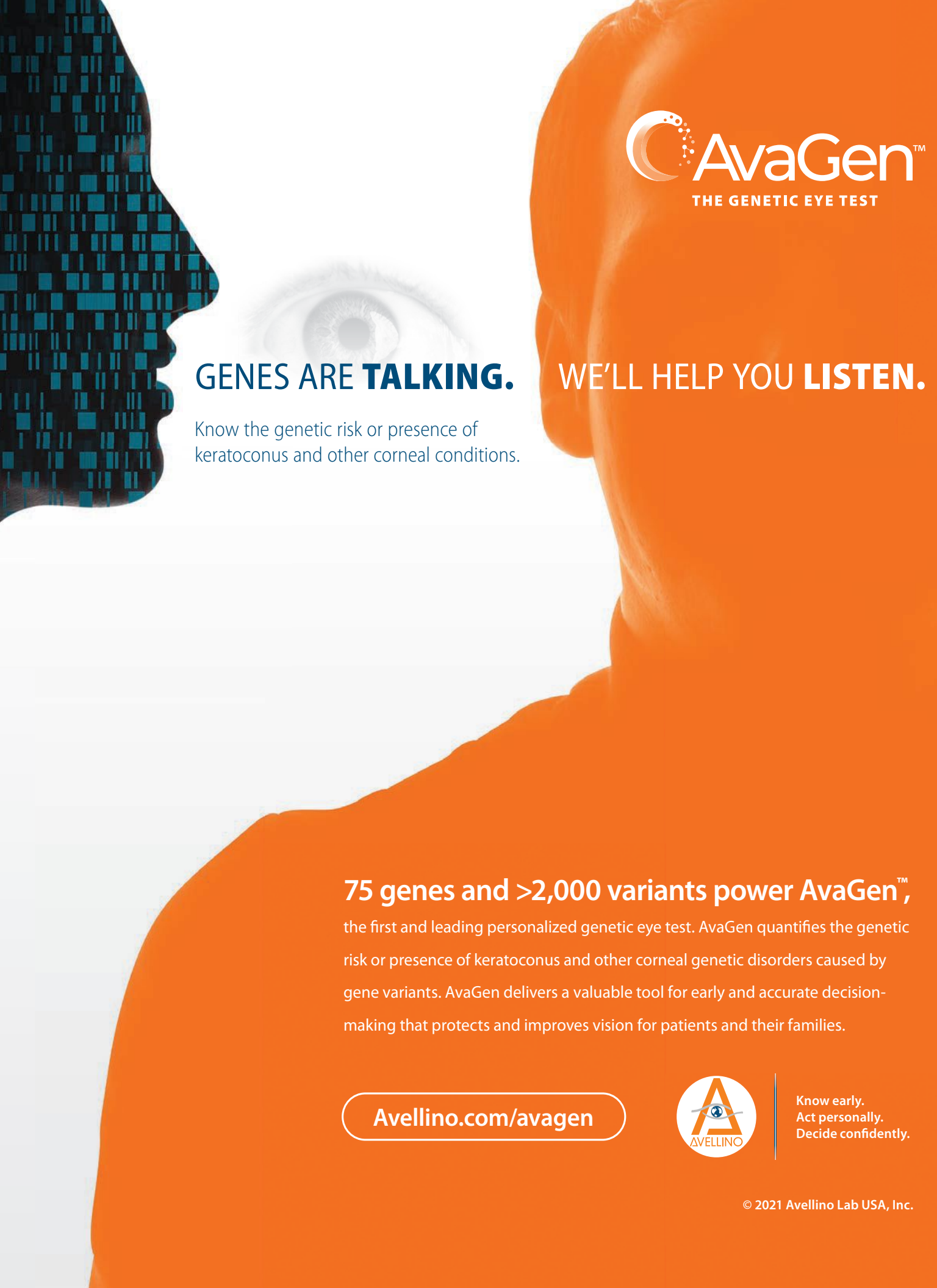
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