

2019 Income Survey Results: An Up and Down Year, p. 62

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IN THE NEWS

A Korean study determined that **patients with AMD are at a higher risk for Alzheimer's and Parkinson's diseases**, even among those who never smoked, drank alcohol and exercised regularly. The data comes as a warning for eye care providers, considering the increase in life expectancy worldwide will likely increase the prevalence of Alzheimer's disease and Parkinson's disease to increase as well.

Choi S, Jahng WJ, Park SM, Jee D. Association of age-related macular degeneration on Alzheimer's or Parkinson's disease: a retrospective cohort study. *Am J Ophthalmol*. November 9, 2019. [Epub ahead of print].

Your cell phone could be highly contaminated with pathogenic bacteria and may act as a carrier, eventually infecting your eyes. A study found nine bacterial species after swabbing 63 contact lens wearers' conjunctivas, mobile phones and contact lens storage cases. Nine of the mobile phones (26%) and seven (21%) conjunctival samples were contaminated with five different bacterial species.

Waleeda AM, Lua'ib A, Wisamb S, Sanad J. Antimicrobial susceptibility of bacterial isolates from the conjunctiva, storage cases and mobile phones of university students using contact lenses. *Contact Lens & Anterior Eye*. November 10, 2019. [Epub ahead of print].

After analyzing data of 1.86 million individuals from 60 studies, Chinese researchers predict the **number of people affected by amblyopia worldwide will more than double, from 99.2 million today to 221.9 million, by 2040**. The growth will be front-loaded, as the researchers estimate amblyopia rates will rise to 175.2 million cases by 2030.

Fu Z, Hong H, Su Z, et al. Global prevalence of amblyopia and disease burden projections through 2040: a systematic review and meta-analysis. *Br J Ophthalmol*. November 8, 2019. [Epub ahead of print].

AMD Consensus Standards Outlined

Experts make the case for a consistent nomenclature; OCT-A no replacement for FA.

By Mark De Leon, Associate Editor

An international panel of retina specialists, imaging experts and ocular pathologists has developed the framework of a consensus nomenclature system for defining age-related macular degeneration (AMD), which also delineates the subtypes of wet AMD. The team believes establishing a uniform set of definitions will support comparison of diverse patient groups and different studies. Using the proposed classification and terminology, they argue, will improve standardization of AMD investigation and reporting.

The consensus team defined AMD as “a process by which the structure and function of the macula deteriorates over time in association with distinguishing signs and symptoms that typically become clinically evident past 50 years of age and do not appear to be secondary to other processes such as pathologic myopia, central serous chorioretinopathy, monogenetic inherited retinal disease, chorioretinal uveitic syndromes or infections or trauma.” The late phases of the disease include atrophy of the outer retina, thinning and loss of the retinal pigment epithelium (RPE) and macular neovascularization.

Neovascular disease can lead to

leakage, bleeding, scarring and severe vision loss. The panel categorized macular neovascularization into three subtypes: polypoidal choroidal vasculopathy/Type 1, Type 2 and Type 3. The anatomic location of the neovascularization determined by OCT imaging is used to subclassify the vascular component of the disease process.

According to the study group, Type 3 neovascularization is to be used when the vascular complex originates in the retina, Type 2 is used if neovascularization that originates in the choroid breaks through the RPE to reach the subretinal space, while Type 1 is applied when the vessels originate from the choroid and remain under the RPE.

The study group suggests that the consensus standards outlined in this manuscript be used in future AMD studies as well as clinical practice.

The panel also determined that using OCT and OCT angiography does not replace fluorescein angiography or color photography; rather, these additional forms of imaging provide additional data to improve classification.

Spaide RF, Jaffe GJ, Sarraf D, et al., (Consensus on Neovascular AMD Nomenclature Study Group). Consensus nomenclature for reporting neovascular age-related macular degeneration data. *Ophthalmology*. November 14, 2019. [Epub ahead of print].

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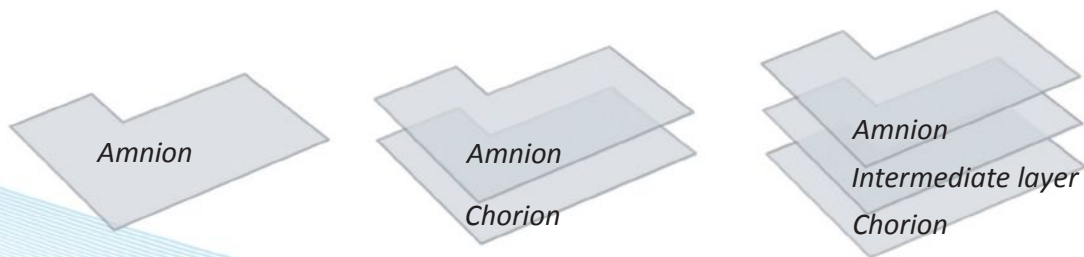


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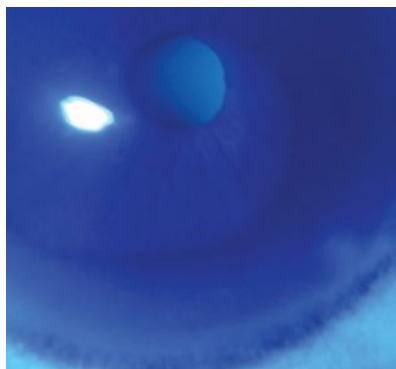
Vulnerable KCN Populations Uncovered

Understanding risk factors and treatment options that are best for your patients will ease the process of managing keratoconus (KCN). Two recent studies revealed aspects to consider about the condition. One discovered increased chance of keratoconus in those with a history of allergic conjunctivitis, and the other found using general anesthesia conducive to uncooperative pediatric patients undergoing corneal crosslinking (CXL).

Beware Eye Rubbing

Researchers in Korea recently discovered many common systemic conditions have no association with KCN in the country's population, with one important exception: allergic conjunctivitis. The researchers looked at data for 1,108,369 individuals, which provided an adjusted incidence rate of 4.47 cases per 100,000 person-years. After matching each patient to five controls, the researchers found those who suffered from allergic conjunctivitis had a 37% increased chance of also being diagnosed with KCN compared with patients who did not have allergic conjunctivitis. The researchers speculate the association is due, in part, to the eye rubbing that often accompanies allergic conjunctivitis.¹

"Eye rubbing, a well-known risk factor for keratoconus, has been reported to not only induce mechanical damage to the cornea but also promote the production of tear inflammatory molecules," the researchers wrote in their paper. They note the findings support the notion that ocular allergy is a significant risk factor for KCN.



Ocular allergy could be a significant risk factor for KCN.

Nonetheless, they found no association between keratoconus and atopy, eczema, asthma, connective tissue disorders, diabetes, sleep apnea or inflammatory bowel disease. While atopy and eczema are seen as a form of allergy, they likely do not cause significant eye rubbing, the researchers wrote.¹

Anesthesia Safe for CXL

Although CXL is routinely performed under local anesthesia in adults and cooperative pediatric patients, younger children and those with developmental delay disorders may require general anesthesia to undergo the procedure. A retrospective case study based in San Francisco demonstrated favorable outcomes using general anesthesia to perform CXL in patients who have developmental delay or display lack of cooperation.²

This is especially relevant given the higher incidence of KCN among patients with Down syndrome. Also, eye rubbing—another risk factor for KCN—is common in patients with developmental delays.

The study reviewed 14 eyes of nine pediatric KCN patients, all

of which had CXL under general anesthesia. All were habitual eye rubbers at baseline, and six patients were developmentally delayed. Compared with unaffected subjects, the developmentally delayed patients were diagnosed and treated at older ages, experienced longer delays from diagnosis to treatment, had lower best-corrected visual acuity (BCVA), higher steep keratometry values, a higher incidence of corneal scarring and monocular vision loss at baseline. However, none of the results were statistically significant.

The researchers noted that no anesthesia or surgical complications occurred. BCVA and keratometry values were stable at six months post-op, with no clinically or statistically significant change observed for either measure. The study also found that eight patients decreased or stopped eye rubbing post-treatment.

The researchers concluded that these findings raise awareness regarding a vulnerable population that may benefit from improved clinical recognition and access to treatment. Early treatment is crucial in pediatric KCN, particularly for patients with developmental delay, for whom later-stage surgical options may not be feasible. They recommended that practitioners pay greater attention to the unique social and care coordination needs of their patients with developmental delay to preserve their vision and quality of life.²

1. Lee HK, Jung EH, Cho BJ. Epidemiological association between systemic diseases and keratoconus in a Korean population: a 10-year nationwide cohort study. *Cornea*. November 21, 2019. [Epub ahead of print].

2. Ahmad TR, Pasricha ND, Rose-Nussbaumer J, et al. Corneal collagen crosslinking under general anesthesia for pediatric patients with keratoconus and developmental delay. *Cornea*. November 7, 2019. [Epub ahead of print].



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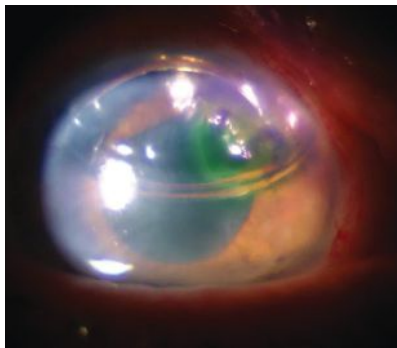


Prescribe Fewer Opioids for Corneal Surgery

Doctors should critically evaluate their patients' pain control needs, study says.

Opioids, which carry a high risk for addiction and overdose, are commonly prescribed after corneal surgery. Researchers from the University of Michigan have determined that easing up on the potent drug reduces patients' opioid use while still providing adequate pain control.

The study used two cohorts of surgery patients to first quantify opioid use and then assess the association of decreasing the number of opioid tablets. The first group (38 patients) received the standard postsurgical opioid prescription—20 tablets of combined acetaminophen 300mg and codeine 30mg. After reviewing the opioid use data from the first cohort, the researchers decreased the number of tablets prescribed at surgery to five, permitting case variation at the



ODs can reduce the chances of opioid misuse after corneal surgery.

surgeon's discretion. This second cohort, comprised of 44 patients, also received a detailed survey about their opioid use, adequacy of pain control and satisfaction.

The first cohort used significantly more tablets than the second cohort (mean 8.3 vs. 4.0) and had significantly more leftover tablets (mean 10.3 vs. 2.9). The survey responses

from the second cohort revealed that 19 of 27 patients reported their pain control as adequate, and six said it was more than needed. Of the 20 participants who had leftover tablets, 17 did not dispose of leftovers, and three threw away or flushed the leftovers.

Researchers hope to encourage safe opioid storage and disposal to minimize dispersion to the community.

The study concluded that practitioners should balance patients' pain control needs with opioid tablet prescribing after ophthalmic surgical procedures. Once they are aware of their patients' opioid use, they can prescribe fewer tablets and reduce the chances of misuse.

Woodward MA, Zhang Y, Tannen B, et al. Association of limiting opioid prescriptions with use of opioids after corneal surgery. *JAMA Ophthalmol.* October 31, 2019. [Epub ahead of print].

ODs Needed in Georgia

American demand for optometry is going to grow over the next 30 years, according to researchers, but that demand won't necessarily be the same for every state. Accordingly, a publication in the *American Journal of Ophthalmology* looked into the state of Georgia's changing demographics and future care requirements.

It used data from the Georgia Governor's Office of Planning and Budget, stratified by age and race, and applied that to the Prevent Blindness America eye disease prevalence values to project the

likely 2050 prevalence of overall vision impairment and blindness, in addition to common ocular diseases.

The investigators found that by 2050, the state of Georgia will be home to approximately a quarter million visually impaired people. Nearly 100,000 of them will be blind and 65% will older than 80 years. This represents a whopping 350% increase in visual impairment for that 80 and older age group.

The team also projects 1.7 million cases of cataracts (2.3 million with refractive error),

250,000 cases of glaucoma and 117,000 cases of macular degeneration. They add that total diabetic retinopathy cases in those older than 40 is expected to grow by 150% by 2040.

"States must have individualized projections to evaluate the unique challenges they will face and prepare for enhanced service delivery, educational campaigns, and advocacy that match the need for their state," the report said.

Kelly E, Wen Q, Haddad D, O'Banion J. Effects of an aging population and racial demographics on eye disease prevalence: projections for Georgia through 2050. *Am J Ophthalmol.* November 9, 2019. [Epub ahead of print].

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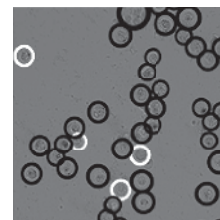
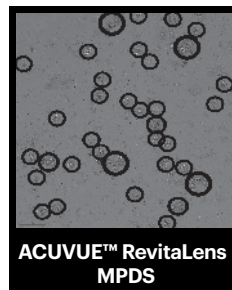


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¹ JJV Data on File 2018. ACUVUE RevitaLens Multipurpose Disinfecting Solution Packaging Claims

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Patients Face Barriers to Neuro Consults

Referrals are delayed and specialist offices are few and far between.

Acute visual disturbances are indicative of a neurological disorder. As such, referring these cases to neuro-ophthalmology sooner rather than later can prevent vision- and potentially life-threatening complications. However, new research shows referrals to neuro-ophthalmology from optometry are too often delayed. In addition, misdiagnosis before referral is a common problem.

The Atlanta-based investigators reviewed 300 cases and compiled information on the patients' demographics. Neuro-ophthalmologists played a major role in directing treatment, such as preserving vi-

sion, preventing life-threatening complications or avoiding harmful treatment in 21% patients in this study—yet obtaining the neuro-ophthalmology consult was a challenge.

The researchers found that patients had to travel a median of 36.5 miles for a neuro-ophthalmology consultation, a potentially significant hardship. Their median time from symptom onset to that consultation was nearly seven months—210 days to be exact. Patients saw a median of two doctors before getting to their neuro-ophthalmology consultation, and 34% of patients in this study

saw multiple providers within the same specialty before even getting a referral. Even after getting that referral, patients often had to wait a median of 34 days before seeing their doctor. Nearly half, 49%, of these patients were initially misdiagnosed before seeing the neuro-ophthalmologist—women were disproportionately misdiagnosed at 57% compared with 35% of men. The team noted mismanagement or delays in care 28% of the time and unnecessary tests in 19% of the patients.

Stunkel L, Mackay D, Bruce B, et al. Referral patterns in neuro-ophthalmology. *J Neuro-Ophthalmol*. October 11, 2019. [Epub ahead of print].

Eyeliner Use Increases MGD, Tear Film Problems

Your patients who routinely use eyeliner may run the risk of developing tear film instability and meibomian gland dysfunction (MGD), a study in *Cornea* suggests.

Researchers from Thailand enrolled 42 healthy females between the ages of 18 and 40 who had no dry eye symptoms. The study divided the patients into two groups: the first included participants who regularly used eyeliner three or more days a week continuously for at least six months. The second group did not wear eyeliner.

Following a questionnaire, the patients underwent several tests, including conjunctival inflammation grading, fluorescein tear break-up time, ocular surface fluorescein staining, Schirmer I, meibomian gland function evaluation, detec-

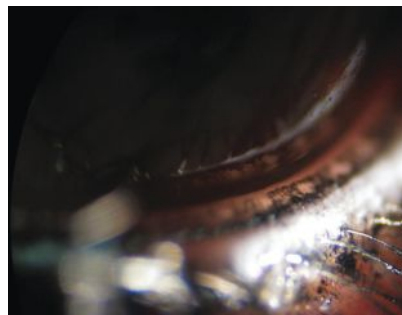


Photo: Elyse Chaglassian, OD

Wearing makeup such as eyeliner could increase the risk for MGD.

tion of eyelid margin abnormalities and *Demodex* detection.

The study found tear break-up time was significantly lower in patients who used eyeliner compared with the controls (3.0 ± 1.9 vs. 5.8 ± 2.1 seconds, respectively). Additionally, meibomian gland grading was notably higher in the eyeliner group, with a higher grade (2/3) reported in 85.7% of patients

who wore eyeliner compared with just 47.6% in the controls. The meiboscore was also higher in the eyeliner group.

Looking at morphological changes for the lid margin, the study found only telangiectasia was significantly higher in the eyeliner group (28.6%) compared with the controls (4.8%).

The researchers also found conjunctival inflammation was four times greater in the women who wore eyeliner (66.7%) compared with those who didn't (14.3%).

However, ocular surface symptoms, fluorescein staining scores, Schirmer I and *Demodex* detection were about the same in both groups.

Prabhasawat P, Chirapapaisan C, Chitkornkijsin C, et al. Eyeliner induces tear film instability and meibomian gland dysfunction. *Cornea*. November 8, 2019. [Epub ahead of print].

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Myopia Control Still a Tough Sell

Just over half of all patients eligible for intervention are prescribed single vision lenses.

A new report in *Contact Lens & Anterior Eye* provided an update to a 2015 survey that examined practitioners' awareness of myopia prevalence and their thoughts on the available treatment strategies. While practitioner concern about myopia and the reported level of activity have increased over the last four years, the recent survey found that the vast majority of practitioners still prescribe single vision interventions to young myopes.

The research team distributed the self-administrated, internet-based questionnaire in eight

languages to reach eye care professionals (optometrists, dispensing opticians, ophthalmologists and eye care specialists) globally.

Of the 1,336 respondents, concern for myopia's prevalence was highest in Asia and lowest in Australasia. Asian clinicians, especially those practicing in China, were more concerned about the increasing prevalence of pediatric myopia in their practices than clinicians in any of the other continents.

Overall, practitioners perceived orthokeratology to be the most effective method of myopia control, followed by pharmaceutical approaches and

approved myopia control soft contact lenses. The least effective perceived methods were single vision distance under-correction and single vision spectacles, as well as single vision soft contact lenses and refractive surgery options. These findings were largely consistent across all continents with some variations.

However, 52% of progressing and/or young myopes were being prescribed single vision spectacles or contact lenses. Although a surprising number, the researchers noted that this was an improvement from the reported 68% in the original study four years ago. The main justifications for practitioners' reluctance to prescribe alternatives to single vision refractive corrections were increased cost (20.6%) and inadequate information (17.6%).

The report concluded that practitioner adoption of appropriate techniques has improved but remains poor overall, noting that myopia control techniques are not being applied early enough in a child's ocular development to provide the best outcomes.

It also found that adequate practitioner education was lacking, along with, in most parts of the world, access to appropriately regulated myopia control products.

The survey group hopes that the publication of the recent global consensus evidence-based guidelines will help inform myopia management in the future. ■

DNA Predicts Future Myopia in Kids

A team of researchers from the United Kingdom suggests genetic information may be helpful in identifying children at high and very high risk for myopia development.

Currently, the best predictor of myopia risk is a low hyperopic refractive error at an age before myopia typically manifests, which suggests a screening regimen of cycloplegic autorefraction would be an effective approach, the study noted. However, cycloplegia in young children can be time-consuming and expensive, and since the transition from moderate to low hyperopia may be part of the process of myopia development, cycloplegic autorefraction screening may be done too late.

In this meta-analysis of three genome-wide association studies, a polygenic risk score derived from 711,984 participants was evaluated in an independent validation sample of 1,516 participants. A measure of statistical validity called area under the receiver operating characteristics (AUROC) curve was 0.67 for predicting myopia and 0.73 for predicting high myopia. Additionally, researchers reported individuals with polygenic risk scores in the top 10% appeared to be at a five- to six-fold higher risk of high myopia.

Still, the study pointed out genetic prediction for myopia in children remains far from perfect. Case in point: the study's best AUROC was 0.75 for predicting moderate myopia, which was less accurate than the previously reported approach of screening for a low level of hyperopia by cycloplegic autorefraction. Sensitivity and specificity of genetic testing also fell short of the previously reported results from cycloplegic autorefraction (0.67 vs. 0.87).

However, there are still benefits to genetic prediction, including the advantage of not requiring eye drops or a specialist clinical assessment, and genetic prediction could also be used to detect children who would benefit from interventions to prevent incident myopia as well as to slow myopia progression, the researchers noted in their paper. The study was funded by a PhD studentship from the College of Optometrists in London.

Mojarrad G, Plotnikov D, Williams C, et al. Association between polygenic risk score and risk of myopia. *JAMA Ophthalmol.* October 31, 2019. [Epub ahead of print].

Wolfsohn JS, Calossi A, Cho P, et al. Global trends in myopia management attitudes and strategies in clinical practice—2019 update. *Cont Lens Anterior Eye.* November 21, 2019. [Epub ahead of print].

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

USE IN SPECIAL POPULATIONS

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

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

Lactation: There are no data on the presence of loteprednol etabonate in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for LOTEMAX[®] 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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2× greater inflammation clearance
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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.

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Important Safety Information (cont.)

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch 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%

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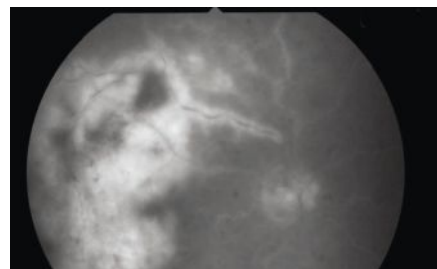
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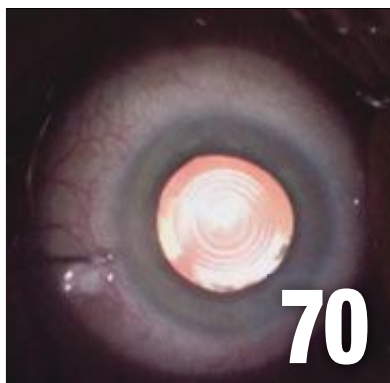
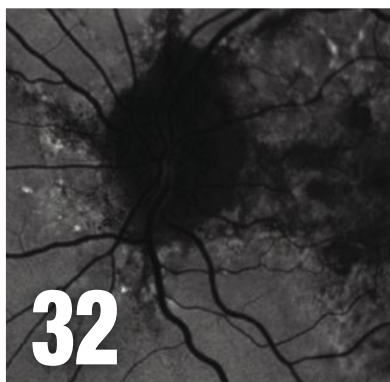
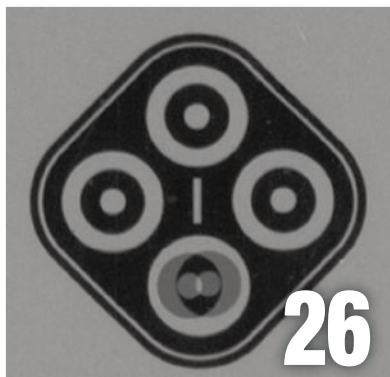
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References:

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4. Food and Drug Administration. Electronic Orange Book. <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>. Accessed June 26, 2018.

Indication

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

Important Safety Information

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

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

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, see accompanying Brief Summary of Safety Information on the adjacent page and Full Prescribing Information on Xiidra-ECP.com.





BRIEF SUMMARY:

Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS

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

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies 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 studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤ 3 months of treatment exposure. 170 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% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

Postmarketing Experience

The following adverse reactions have been identified during postapproval 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 cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported.

USE IN SPECIFIC POPULATIONS

Pregnancy

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 pre-mating 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.

Animal Data

Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation 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.

Lactation

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. 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.

Pediatric Use

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

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.

Mutagenesis: Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.



Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

For more information, go to www.Xiidra.com or call 1-800-828-2088.

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Outlook

By Jack Persico, Editor-in-Chief



Marriage Story

Combining vision and health, like any good relationship, strengthened each. A detractor wants to split them up.

By now you've already read, and ranted about, that opinion piece *The Atlantic* ran in late November. You know, the one with the very neutral and respectful headline: "The Great American Eye-Exam Scam." Nuanced it is not.

The author, Yascha Mounk, recounts losing his glasses on vacation and the "ordeal" (his word) of not being able to get a replacement immediately, which forced him to use a pair of prescription sunglasses for a few days. This real-life *Seinfeld* storyline is an ordeal?

From this experience he spins an argument as facile as it is flawed. Requiring a prescription to buy corrective lenses in America, Mounk says, "creates unreasonable costs—and unjustifiable suffering" for people who can't afford an exam or can't spare the time for one. He acknowledges it does allow previously undetected eye problems to be uncovered, but then immediately downplays this hugely significant service to society by dismissively claiming "it is likely that a much greater number keep wearing glasses that are too weak—or won't wear glasses at all—because they want to avoid the cost, time or stress of a visit to a doctor."

America, he argues, should be more like countries that allow opticians to dispense glasses or contacts directly. No need to muck around with the "red tape" (again, his wording) of seeing a doctor. "So why does the United States require people who want to purchase something as simple as a curved piece of plastic to get a prescription, preceded by a costly medical exam?" he asks.

Well, for starters, it's not "as simple as a curved piece of plastic." Mounk treats corrective lenses like any other consumer good. I can walk into a store and buy a pair of shoes with no hassles. Think how absurd it would be if I had to see a podiatrist first. That's the sort of argument he's making. Of course, even if one were to go along with this line of reasoning, we all know that determining optimal lens power for any given patient is far more subjective than what an autorefractor spits out.

But the bigger thing he's missing here is the interdependence between eye health and vision. The corrective lenses and the "costly" medical exam are not two distinct things; rather, they are two pieces of the same product: comprehensive care.

We all know the difference between *eye care* and *vision care*—the former considers the organ's health and the latter its function. After beginning strictly on the vision side, optometry now fully integrates these two, and the whole is greater than the sum of its parts as a result. This has been one of the most consequential advances of optometry's evolution into primary care providers.

But the author thinks this couple needs a divorce. He values convenience over quality, is cavalier toward health and flat-out oblivious about wellness and prevention. The routine exams he so denigrates give ODs vital access to patients over the course of a lifetime and a chance to steer them toward healthier habits. Absolving patients of personal responsibility in favor of instant gratification—now that would be an ordeal. ■

Technology in balance



Health



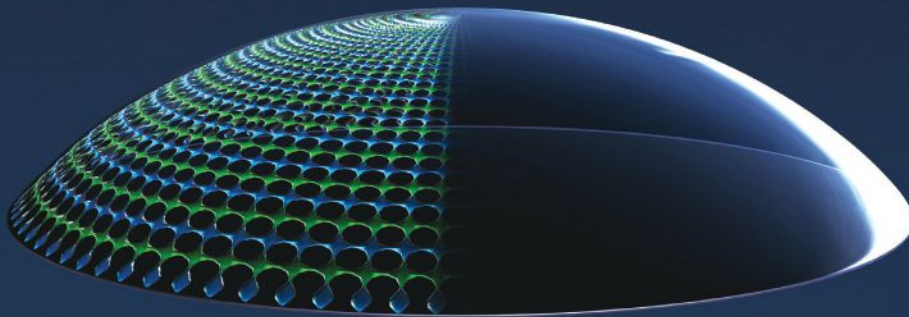
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Don't Miss the Boat

Optometry must embrace several new opportunities to help patients with presbyopia.

By Paul M. Karpecki, OD, Chief Clinical Editor

Comanagement has had a bad rap, and rightfully so. When premium intraocular lenses (IOLs) hit the market, many optometrists were left with the same minimal Medicare fee, even though these IOLs required far more work and chair time, both before and after surgery. No wonder only 7% of all cataract surgeries today involve premium IOLs. Even new and improved technologies such as extended depth-of-focus and a new trifocal IOL have not moved the dial much. To be fair, some surgical practices offering premium IOLs provide ODs adequate fees for the time, effort and additional testing. So how do we make sure this is true for all comanagement relationships?

Get Educated

Companies rolling out innovative technologies must educate both surgeons and ODs. Approximately 88% of all comprehensive eye exams are conducted by optometry, and patients are far more likely to trust their OD than a surgeon they just met. When the primary care optometrist makes an IOL recommendation in our office, the likelihood of the patient pursuing this is north of 95%. Optometrists would be more comfortable recommending an IOL if they were properly educated on its merits, limitations and safety data.

Fortunately, premium IOL companies have begun educating optometry—perhaps a little late and a little less than what's required, but we are getting there.

Get On Board

Education will be a must when two surgical technologies launch in 2020.

The success of RxSight's light adjustable lens (LAL) hinges on optometric inclusion because it requires extremely accurate refractive measurements and other refractive decisions such as the amount of monovision and whether or not to include full distance correction. In addition, the lens allows for further correction after surgery—the optometrist's domain. The IOL has a photoreactive ultraviolet (UV) absorbing material that allows for the refractive error to be modified after implantation using a UV light source.

To fine-tune the Rx, ODs will rely on contact lens trials for monovision, trial lenses, precise refractions and discussions on what to correct, at what distance and even whether to address small amounts (0.50D) of astigmatism. This IOL is similar to monofocal lenses on the market and will be similar in cost and reimbursement as current cataract surgery, but patients will pay for the light delivery device enhancements.

Clinical trials show that patients receiving the RxSight LAL achieved uncorrected vision of 20/20 or better twice as often as those receiving a monofocal lens, and nearly 92% of patients receiving the LAL achieved results within 0.50D of the intended target.¹ The company understands optometry's crucial role, and I expect surgeons, primary eye care providers and patients will benefit equally from the effort, time and commit-

ment this premium IOL will require.

A second surgical technology I hope we'll see in 2020 is the ReFocus VisAbility implant for presbyopia. Young eyes that can accommodate have zonules that are taut in static position; as the lens grows throughout life and enlarges, the zonules become loose and can't flex the crystalline lens. These scleral micro-inserts are placed to expand the zonular space. Data from one of the investigational sites shows more than 90% of patients with the implants regain reading capabilities to that of newspaper print or better. There is no surgery in the visual axis—or even the cornea, for that matter—so the risk of visual loss is minimal. This is another procedure for which surgeons will need to work closely with optometry to ensure proper patient selection and education on the surgical procedure, expectations, not to mention the proper peri- and postoperative care required to achieve these results.

Great presbyopia solutions are ahead, and ODs must educate themselves and prepare their offices to provide the perioperative care required. Your knowledge and skills will solidify your patient's trust in doing what is best for them when recommending these innovative surgical advances. ■

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

1. Chayet A. A single center exploratory study to evaluate the use of the RxSight Light Adjustable Lens (LAL) and the Light Delivery Device (LDD) to improve visual outcomes. (unpublished data).

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What is It About 20-somethings?

Patients want to be able to see their Instagram posts, not your OCT readouts.

By Montgomery Vickers, OD

What is the most important test in eye care? All you mad scientists are jumping in with fundus photography, OCT, visual fields and on and on. After all, these help us enhance and protect our patients' eye health. What's more important than that?

Well, after all the tests are run and you have destroyed your patient's will to live with seemingly endless data collection, do you know what they really care about? *Can they see.*

Seeing 20/Whatever Works

So, the most important test is good ol' visual acuity (VA). I don't know if Snellen and his buddies were vaping CBD or what, but they decided 20/20 is what a "normal" person should be able to see. Interestingly, with computers now running (or "ruining") our lives, no one reads a black 20/20 on a white background in a dimly lit room. Thus, the goal of 20/20 has become 20/happy.

My first eye exam as a kid didn't even include a Snellen chart. Our family physician, Dr. Peck, figured if I could read the headlines of the *Montgomery Herald* taped on the wall, that would be good enough. He was right.

I have many patients who are, at best, 20/40 and correctable to 20/10 who would rather have a toenail removed by a lawnmower than have to wear glasses.

I often ask this seemingly simple question (this is considered correct English where I come from): "Do you wanna see as good as you can

see?" Of course 100% of patients immediately reply, "Yes!" Bull.

I follow up with: "What if you had to swim across the Kanawha River when it's 10 degrees outside and there's 14 inches of snow on the ground? Still wanna see as good as you can see?" "No."

VA only means something to us. Patients just want to be 20 years younger, not to see as best they can. Our job is to convince them that they want to spot a bus before it slams into their car and it's good to not feel like death warmed over after straining at a computer all day.

Once I had been in practice for something like 25 years, I decided to finally listen to the patient. If they didn't complain at all about their distance vision, even when measuring 20/60, unless they drove a church bus, I spent about 18 seconds planting a small seed about distance visual needs for future reference; I spent the rest of my time working on what they *do* gripe about.

Handle VAs With Care

But, insurance companies love VAs and expect at least some attempt to record them.

So we do.

However, *never,*

ever, allow a staff member to take a VA in these circumstances:

1. A multifocal contact lens follow-up visit. A 20/happy patient doesn't realize their left eye is only 20/30-2. Leave them in bliss.

2. Myopia control children. If dad's with them, you'll have a lot of 'splainin to do if Suzi subjectively reports, "That looks fuzzy." Avoid.

3. *Any* recheck in children. Just make a professional judgment and recheck their Rx with 20/40 or bigger. I'm not joking.

You can do VAs, if you want, on any post-op patient, but stick them behind a foggy phoropter and start from known blur. Never burst their bubble with 20/20 off the bat.

VA testing is, no doubt, the most important test we do; not because it helps the patient, but because it can make or break you if not handled with aplomb. ■



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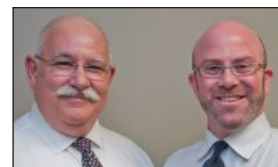
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Out of Our Depth

Beware binocular vision testing that overestimates stereopsis, concealing a visual disorder capable of correction. **By Marc B. Taub, OD, MS, and Paul Harris, OD**

The response to stereo testing indicates how well a patient's binocular system is functioning. If stereo is present, we know the patient is using the information flowing through both of their eyes. One way to optimize your patient's needs is to perform refraction with their habitual prescription and then with their new prescription to see if stereo improved. If it did, then you should feel confident the new prescription will benefit the patient. But, not so fast.

The Evolution of Stereo

Stereo tests have evolved from the good old days when clinicians didn't know the difference between local and global stereo—all we knew was the Stereo Fly (Figure 1). Show it to people for the first time and watch their reaction. We all remember telling our patients to “pinch the wings” and watching as they recoiled from the image jumping off the page. Fun times! But the real test was the Wirt circles.

When conducting the Wirt circle test, few of us concern ourselves with monocular cues to depth. The

lower circles in the diamond with the “1” in the center look fuzzy or appear in twos when viewed without the stereo glasses (Figure 2). With the stereo glasses on, only one of the two circles shifts to the right or left, depending on which

eye the person is looking through centrally. These monocular cues to depth tend to work well until about 70 seconds of arc on the Wirt circle test. Measures up to 70 seconds of arc may or may not be actual measures of binocular stereopsis and may represent excellent use of monocular cues.

Then came random dot tests, of which there are two different kinds. In one, the Wirt circles lie on top of the random dot pattern background (Figure 3). Here again, the monocular cues are easily discernible. Of the three circles, one clearly looks

blurred without the stereo glasses. Put the glasses on, cover one eye—or suppress the central vision through one eye—and now one of the circles has shifted slightly. You can guess well down to 70 seconds of arc without really having good binoc-

ularity or, therefore, good stereopsis.

Global stereo targets, on the other hand, are all done with random dot patterns (Figure 4). The background shows the same dots in the same place to both eyes. If you are truly binocular, when figures appear, the dots in that area will shift right in one eye and left in the other, relative to the unshifted dots in the background. Depending on the direction of shift, the person will perceive the dots forming the figure, circles in this instance, as shifting closer or further than the plane of the test.

In each of the circles are four circles, three of which are pushed inward behind the plane of the test and one of which is shifted out closer to the observer by the same amount the other three are inset. Being able to correctly identify the nearer circle is a good sign. The monocular cues, which some claim are still present, are much harder to detect under these circumstances.



Fig. 1. The full Stereo Fly test book with Wirt circles on the left.

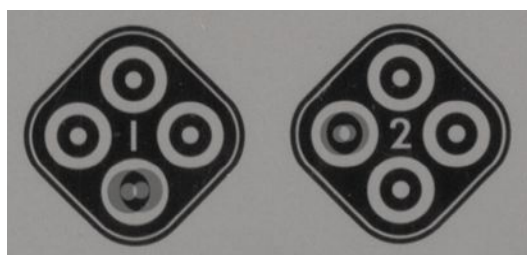


Fig. 2. The first two Wirt circles.

One study found that several participants were able to get to about 70 seconds of arc on the Wirt circles but were worse than 400 seconds of arc on the global Random Dot 3 test.¹ Another showed that there are no monocular cues to depth with full random dot tests, which are all global.² These researchers discovered some non-stereoscopic cues that could be used to deceive the test, but they were unique to the design of the Stereo Butterfly test used in their work.²

Before the advent of global stereo testing, we assumed the measurements from the standard tests were accurate. However, now we know that Wirt circles have fairly strong cues that may falsely lead us into believing the prescription we are about to give is a good one, at least as far as binocularity is concerned.

Upon further review, however, we realized that we were overestimating the level of binocular performance of some of our patients. It is important to make sure we don't throw the baby out with the bathwater, so to speak. In this case, the baby is improvement in binocularity and stereopsis, and the bathwater is tests that do not always tell the full

story. What we should be doing is continuing to use stereopsis to measure the level of binocular improvement and confirm our refraction. Let's take a look at a case example to see how this applies.

Case Example

A nine-year-old was referred in for a vision therapy evaluation secondary to the diagnosis of amblyopia.

Her uncorrected visual acuities were 20/20 OD and 20/30 OS. Her manifest refractions were +0.75 OD and +3.00 OS. The visual acuity in her right eye was still 20/20 with the +0.75, but her left eye only improved to 20/25- with the +3.00. Prescribing was deferred to us following the vision therapy evaluation, but the referring doctor had indicated his desire to give full plus in both eyes.

At the initial evaluation, we used Wirt circles and recorded 70 seconds of arc. This is a routine part of our chair test, which occurs before the refractive data from the rest of the testing is available. Knowing that the patient could have used monocular cues to attain this result, we recommended the global stereopsis test. Without lenses, the patient only made it to 400 seconds of arc on the large global shapes. This shows that she had a functioning binocular and stereo-capable system but could not see the stereo without any plus.

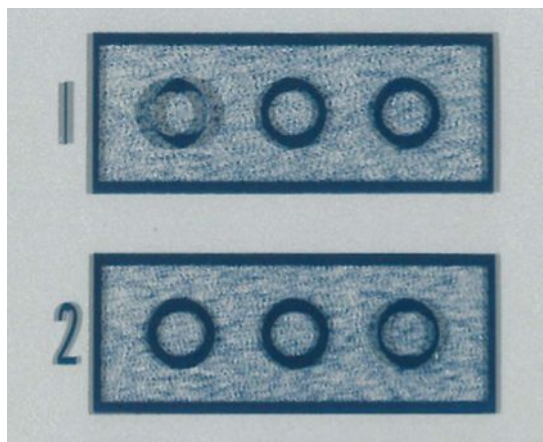


Fig. 3. Wirt circles with random dot background.

We then suggested the patient put +1.25 over her left eye only and repeat the test. The results were surprising, as the stereopsis results came out to 30 seconds of arc with the fully global stereo test. For demonstration purposes, we also did stereo testing through +2.25 and +3.00 over the patient's left eye. There was no further improvement with more plus.

There are many other factors that must be taken into consideration to derive the amount of plus we should prescribe. We can see that partial plus may yield a large improvement in stereo, but the addition of more plus may change nothing. So don't be fooled into thinking your patient has good stereo with the prescription you are about to give as measured by the Wirt circles. Using a global stereopsis test will help you help your patient attain a higher degree of binocularity and, therefore, better visual performance. ■

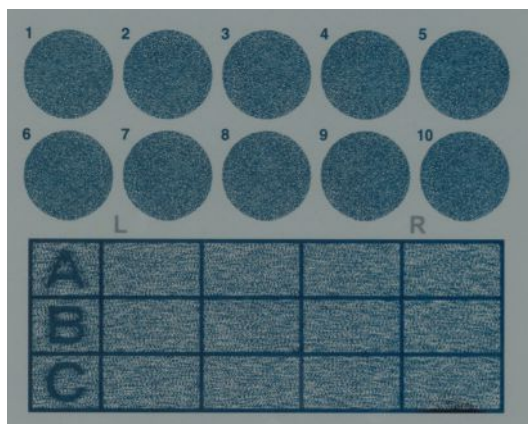


Fig. 4. The global Random Dot 3 test.

1. Bodack M, Wilcox J, Harris PA. Comparison of three tests of stereoacuity. Poster presented at the American Academy of Optometry; New Orleans, LA; 2015.
2. Chopin A, Chan SW, Guellai B, et al. Binocular non-stereoscopic cues can deceive clinical tests of stereopsis. *Sci Rep.* 2019;9(1):5789.

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INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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



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

ADVERSE REACTIONS

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

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

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

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CONTRAINDICATIONS

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

Use with Contact Lenses

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

ADVERSE REACTIONS

Clinical Trials Experience

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

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

Data

Animal Data

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

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

Lactation

Risk Summary

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

Pediatric Use

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

Geriatric Use

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

PATIENT COUNSELING INFORMATION

Handling the Vial

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

Use with Contact Lenses

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

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

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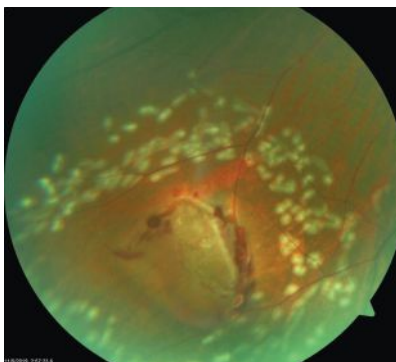
Edited by Paul C. Ajamian, OD

Q I frequently have patients who are on Flomax (tamsulosin, Boehringer Ingelheim), have diabetes or are darkly pigmented and don't dilate well. I am frustrated with my inability to get out to the periphery with binocular indirect ophthalmoscopy (BIO) and to scleral depress when necessary. Any suggestions?

A Not all clinical exams or patients are the same, so we can't expect to be able to use all of the same tools with every patient, according to Jeffrey Gerson, OD, of Grin Eye Care in Leawood, KS. "My standard lens for use with my BIO is a 20D, but I often use a 30D lens as needed," Dr. Gerson says.

With a 30D lens, the field-of-view is wider, and it is often easier to get a good view into a smaller pupil. This is becoming increasingly more important with poor dilators, either from diabetes, Flomax use or other issues. The larger field (60 degrees vs. 75 degrees) can give better perspective, with the trade-off being a lesser degree of magnification (3.13x vs. 2.15x). A little practice goes a long way when dealing with this magnification issue, according to Dr. Gerson.

"The 30D allows for the shortest working distance with the greatest field-of-view," Dr. Gerson says. Another advantage is that the 30D has a smaller diameter lens, which allows for easier manipulation for a doctor with smaller hands or when dealing with a patient with deeper inset or smaller eyes. The 30D is also ideal for kids who are not the most cooperative.



Using a 30D lens can get you into a smaller pupil and out to the ora serrata.

Scleral Depression

Besides the lenses used, Dr. Gerson recommends other techniques that can be helpful for a successful peripheral retinal examination, such as proper choice of dilating drops. Dr. Gerson uses a combination of 1% tropicamide and 2.5% phenylephrine for maximum dilation. "If one set doesn't do it, instill another," he states. "If possible, I always recline my patients, which helps get better views in the periphery," Dr. Gerson says. A better view of the ora serrata means that scleral depression will be easier to perform.

"The lack of confidence some

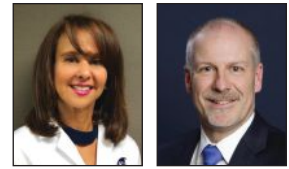
have with scleral depression stems from lack of practice or fear of hurting the patient," he says. Dr. Gerson believes that each of these factors contributes to the other. "With some practice and a 30D lens, scleral depression becomes easier and more comfortable for patients," he adds. Start with a long cotton swab, and graduate to a metal depressor if you need to. The more you do it, the more second nature it will become.

Scleral depression provides a dynamic view of the retina, which is critical when searching for retinal breaks in patients with symptoms like flashes and floaters. "Before one diagnoses a benign posterior vitreous detachment, one must rule out peripheral breaks, and that calls for scleral depression," Dr. Gerson says.

Imaging and Dilation

Traditional fundus cameras only capture approximately 45 degrees. Ultra-widefield imaging is defined as a single capture that includes the far periphery of the retina in all four quadrants. This is a good screening tool that tips you off as to when and where to take a closer look with BIO and 30D.

If the image is normal but the symptoms tell a different story, protect yourself and your patient by dilating and taking a closer look. The most thorough retinal exam is probably a combination of the two modalities. Don't give your patients the message that dilation is bad and ultra-widefield is good. "Clinically, I want to use every tool at my disposal," Dr. Gerson says. ■



A Break in the Membrane

Angioid streaks may be harbingers of an underlying systemic condition. Here's how you know. **By Jay M. Haynie, OD, Diana Shechtman, OD, and Himanshu Banda, MD**

Angioid streaks—defects in Bruch's membrane—can cause visual disturbances in multiple ways.¹ The streaks may traverse the fovea, leading to retinal pigment epithelium (RPE) disruption. In addition, mild trauma to the eye may cause the choroid to rupture at these areas, leading to submacular hemorrhage. Secondary choroidal neovascularization is also possible.

Angioid streaks have many systemic associations, as summarized by the 'PEPSI' mnemonic: *P*seudoxanthoma *E*lasticum, *P*aget's disease, *S*ickle-cell/thalassemia/spherocytosis, *I*diopathic. Of note, Ehlers-Danlos syndrome, once part of the mnemonic, is no longer commonly believed to be associated with angioid streaks.²

Pseudoxanthoma elasticum is an inherited multi-system disorder characterized by ectopic mineralization and fragmentation of elastic fibers in the skin, the elastic laminae of blood vessels and Bruch's membrane in the eye.³ Defects in an ATP-binding cassette (ABC) transporter gene in *ABCC6* on chromosome 16 are responsible for the disease.⁴

In addition to angioid streaks, other ophthalmic manifestations of this disease include a 'peau d'orange' fundus appearance, which may appear as mottled dark spots on a lighter background.

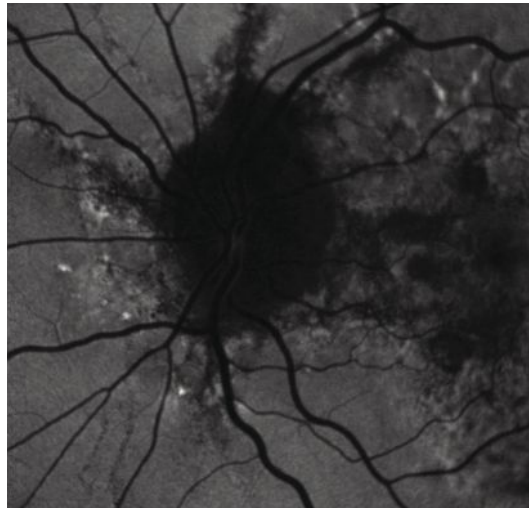


Fig. 1. The patient's fundus autofluorescence demonstrates hyperfluorescent streaks radiating from the optic nerve that correspond clinically with angioid streaks.

describes seeing a 'wave' near the center of her vision. She stated that she had similar symptoms in her right eye several years ago and was treated for wet age-related macular degeneration. She denies any major medical problems. Her 12-point review of systems was otherwise negative, other than skin changes for most of her adult life.

Her best-corrected visual acuity was 20/40 in right eye and 20/50 in the left eye. No relative afferent pupillary defect was noted. Confrontation visual fields and extraocular motility were intact. Her anterior segment examination was otherwise unremarkable.

The dilated fundus examination revealed orange-red linear irregularities extending radially from the optic nerve into the peripheral fun-

On a Losing Streak

Case by Drs. Haynie and Banda
A 57-year-old female presented with a one-week history of a painless distortion in the left eye. She

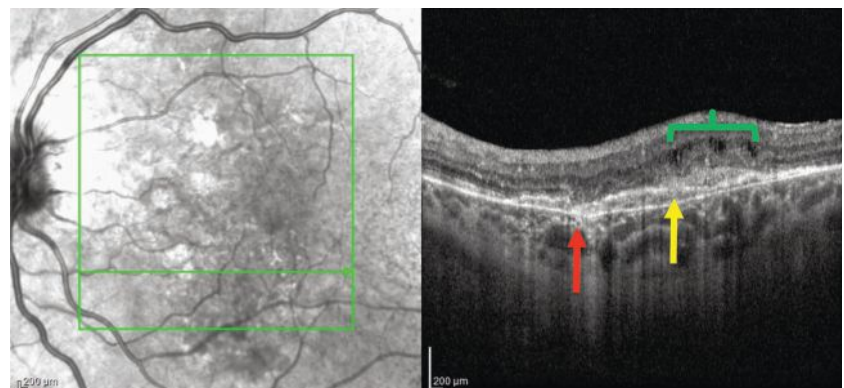


Fig. 2. OCT of the left eye demonstrates a break in Bruch's membrane (red arrow), a shallow pigment epithelial detachment with overlying subretinal hyper-reflective material (yellow arrow) and cystoid macular edema (green bracket).

dus in both eyes. These linear changes were better visualized on fundus autofluorescence (FAF), more obviously demarcated in the left eye (Figure 1). Spectral-domain optical coherence tomography (SD-OCT) of the right macula revealed changes such as RPE irregularities; however, no intraretinal or subretinal fluid was noted. In the left eye, SD-OCT showed a break in Bruch's membrane, sub-retinal hyper-reflective material and associated intraretinal fluid (Figure 2). Fluorescein angiography (FA) of the right eye showed a perifoveal lesion with early hyperfluorescence and late leakage, consistent with a choroidal neovascular membrane (CNVM) (Figure 3).

The patient was diagnosed with angioid streaks and a new choroidal neovascular membrane in the left eye. She had characteristic skin findings on her neck consistent with the diagnosis of pseudoxanthoma elasticum (Figure 4). The patient elected for treatment with anti-VEGF agents in the left eye.

Shifting Focus

Commentary by Dr. Shechtman

Angioid streaks are bilateral blood vessel-like cracks emanating from the optic nerve. Although angioid streaks can be idiopathic, there is often an underlying cause, which the driving force when managing these patients.

Clinicians must determine the presence of such etiologies, as well as address the ocular complications. System workup may be specific based on the clinical presentation, such as the case provided. The three most frequently encountered systemic associations

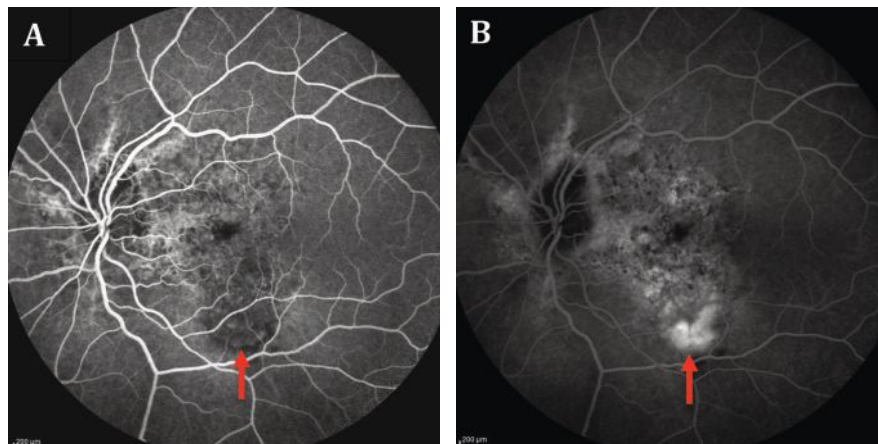


Fig. 3. The patient's fluorescein angiography of the left eye (A) shows early hyperfluorescence noted inferior to fovea with late leakage (B). Angioid streaks surrounding the nerve can also be seen as staining.

are pseudoxanthoma elasticum, Paget's disease of bone and sickle cell hemoglobinopathies; thus, workup should focus first on these conditions.

Optometrists should communicate with the patient's primary care provider to ensure the patient receives the proper testing. Along with a complete comprehensive medical exam, the primary care provider should consider a skin biopsy, serum alkaline phosphatase/calcium/phosphate and hemoglobin electrophoresis, among other testing when necessary.

As for treatment, angioid streaks are merely observed for secondary complications such as CNVM. Both FA and SD-OCT are helpful tools used to assess these complications. Clinicians should ask patients to follow a home Amsler grid and return to the clinic if they experience any new visual symptoms. CNVM is typically treated with standard anti-VEGF therapy.

Of note, common differentials include lacquer cracks, choroidal rupture and streaks seen in patients with histoplasmosis. Careful evaluation using FA, FAF or red-free photography, in addition to correlating history (i.e., history of trauma) and location (presence of white streaks near the macula in a high myope), helps to reveal the proper diagnosis. ■

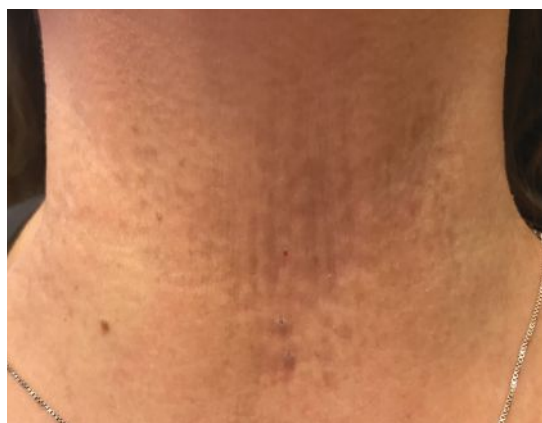


Fig. 4. A color photo of the patient's skin findings associated with pseudoxanthoma elasticum depicts the 'peau d'orange' appearance.

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Changes Afoot For Retinal Exams

Be on the lookout for these new codes and definitions in 2020.

By John Rumpakis, OD, MBA, Clinical Coding Editor

The new year is nearly upon us, and with it comes changes in many CPT procedures, codes and definitions. One of the most noteworthy is the change with extended ophthalmoscopy.

The Definition

Extended ophthalmoscopy is a dilated assessment of the posterior segment using indirect ophthalmoscopy or slit lamp biomicroscopy and an additional diagnostic tool, such as a 3-mirror lens, 20-diopter lens, 90-diopter lens or scleral depression, and includes a detailed drawing of the retina. This provides a high-intensity illumination and a stereoscopic, wide-field view of the fundus for detection and/or evaluation of vitreoretinal pathology.¹ Extended ophthalmoscopy codes are generally reserved for the meticulous evaluation of the eye and with detailed documentation of a severe ophthalmologic problem needing continued follow-up that cannot be sufficiently evaluated with photos.

Codes of the Past

Historically, extended ophthalmoscopy was defined by two CPT codes:

- 92225: Ophthalmoscopy, extended, with retinal drawing (e.g., retinal detachment, melanoma), with interpretation and report (I&R); initial.
- 92226: Ophthalmoscopy, extended, with retinal drawing (e.g., retinal detachment, melanoma), with I&R; subsequent.

Both codes are unilateral in

nature, and medical necessity for each eye must be clearly established in the record. The codes also required a specifically sized drawing, traditionally with “colored pencils,” to denote various anatomical structures and markers and must include an I&R to be a completed test.

According to CMS statistics, these two procedures rank in the top five retinal diagnostic procedures, thus flagging them for the potential for significant waste and abuse.² Documentation for the codes generally required:

- The complaint or symptomatology necessitating the extended exam.
- Notation that the eye examined was dilated and the drug used.
- The method of examination.
- A detailed drawing of the retina showing the patient’s retinal anatomy, including the pathology found and a legible narrative report of the findings.

- An assessment of the change from previous exams when performing follow-up services (92226).

- If the provider of the service differs from the ordering/referring physician, the referring provider must maintain hard copy documentation. The physician must state the clinical indication/medical necessity for the ophthalmoscopy in the exam order.

Documentation in the medical record for a diagnosis of glaucoma must include a detailed drawing of the optic nerve and documentation of cupping, disc rim, pallor, slope and any pathology surrounding the optic nerve.

New Codes and Definitions

Starting in January 2020, extended ophthalmoscopy will be described by two new codes that now include the region of the retina examined and a unilateral/bilateral status:³

- 92201: Ophthalmoscopy, extended, with retinal drawing and scleral depression of peripheral retinal disease (e.g., retinal tear, retinal detachment, retinal tumor) with I&R, unilateral or bilateral.

- 92202: Ophthalmoscopy, extended, with drawing of optic nerve or macula (e.g., glaucoma, macular pathology, tumor) with I&R, unilateral or bilateral.

Note that 92201 *requires* the use of scleral depression, whereas the older codes did not specify any one technique. The new codes still require detailed drawings of the areas of exam and concern.

The CPT continues to refine definitions of various procedures to ensure physicians have the tools to properly translate the medically necessary services they provide to patients, work in alignment with the ICD-10 and prevent opportunities for waste and abuse. Keeping up to date with these changes in your practice allows you to provide the care your patients require and keeps your practice safe from audit. ■

Send your coding questions to rocodingconnection@gmail.com.

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“ I didn't realize
STARS
were little dots that twinkled ”

—Misty L, *RPE65* gene therapy recipient

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25th Annual Surgery Report

How to Succeed in Cataract Comanagement

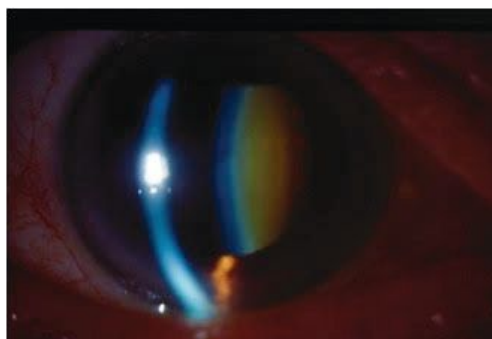
These tips can help you stay integral to the care team—and it all starts with open communication. **By Robert Stutman, OD, MBA**

By 2050, the number of people in the United States with cataracts is expected to double from 24 million to about 50 million.¹ This growing need for cataract surgery will occur simultaneously with a well-publicized shortage of nearly 122,000 physicians by the year 2032—and ophthalmology is one of the subspecialties that will be in the highest demand.²

There couldn't be a better time for us to collaborate more regularly and comprehensively with our ophthalmology colleagues to meet our cataract patients' needs. To provide the best possible results for our patients, surgeons will need to spend more time in the operating room, while ODs take charge of preoperative counseling and postoperative management.

Choosing a Surgeon

Trust is the cornerstone of any comanagement relationship and is



When a patient has an advanced cataract ready for surgery, you need to have a surgeon ready for your referral.

equally paramount when patients' outcomes are at stake. When seeking out a surgeon, first ask other local and trusted optometric colleagues where they send their patients. Additionally, a surgeon who already works in a collaborative practice with ODs will most likely be happy to comanage patients with you.

Before referring patients to a surgeon, first get to know that surgeon, their staff, affiliate doctors (ODs

and MDs), and anyone else who will be involved in taking care of patients. Visit and observe the preoperative consult, the day of surgery and postoperative workflow. A referral office will likely require this for ODs who actively comanage surgery. This will also give you first-hand knowledge of the patient's journey, so you can better prepare them prior to their referral.

You should also take the time to meet with and interview the surgeon. It is imperative that you agree on the surgical plans for your patient. Here you can ask a number of important questions to make sure you are on the same page:

- At what point will you recommend surgery?
- What type of cataract surgery do you offer patients, traditional or femtosecond laser?
- What types of intraocular lenses do you offer? What do you have the most experience with and how will this

impact the options available to patients? Do you offer toric monofocal IOLs as an alternative to patients with corneal cylinder? Do you offer multifocal IOLs? If so, what type?

- Who qualifies for surgery?
- What is the patient's out-of-pocket expense?
- Do you treat patients with concomitant diseases such as glaucoma or Fuchs' dystrophy?
- Do you offer minimally invasive glaucoma surgery (MIGS) or other corneal procedures? Which ones? If yes, what are the results?

Discuss the refractive aspect of the cataract surgery and be comfortable with the IOL selection process, including the surgeon's IOL preferences (monofocal, toric, multifocal, trifocal and extended-depth-of-focus). Be sure to agree on how best to educate patients on each of these options and make sure there is a clear path for the surgeon to receive your refractive recommendations at the time of the initial consultation, as this is integral to the preoperative discussion.

Before entering into a comanagement relationship, agree with the surgeon's office in advance regarding the division of clinical labor to streamline the process for patients. This should include a protocol for routine postoperative management and a proactive plan for less common but more urgent issues that arise, ensuring patient safety and continuity of care following a procedure. This is an opportune moment to take responsibility for the preoperative and postoperative care.

In addition to meeting with the surgeon, get to know the administrative staff of the consulting surgeon. Office managers and administrators from both referring and consulting offices play a pivotal

role in maintaining the comanagement relationship, as transferring clinical information between offices is vital to maintaining continuity of care. Simplifying this process will guarantee a seamless transition back to your office. Additionally, don't forget to establish billing and coding processes prior to any referral so you get reimbursed properly for services you provide.

Laser vs. Traditional Surgery

Not only should you align your philosophies with the surgeon regarding the type of cataract surgery offered, you should also know how patients are educated on the different types of surgery. Both the referring optometrist and consulting surgeon have a responsibility to educate patients on their shared viewpoint as well as the reasons for recommending one procedure over another.

Femtosecond laser-assisted cataract surgery has been available for more than seven years, with thousands of surgeons using one of many available technology platforms. Optometrists recommending cataract surgery should

be well versed on the advantages of this technology and be comfortable discussing with patients.

The light energy employed by the femtosecond laser assists the surgeon in creating the incisions into the eye, the capsulorhexis, the phacofragmentation and corneal arcuates for astigmatism management. This allows for reduction in energy and manipulation by the surgeon when in the operating room. It can also lead to faster recovery times with less postoperative restrictions for patients. The femtosecond laser can even lead to more consistent effective lens positioning when placing the IOL, allowing for higher predictability in refractive outcomes for patients.

Preoperative examination. A thorough and detailed preoperative exam is the most important component of making the appropriate recommendation for the refractive component of the cataract surgery. When determining whether a patient will benefit most from a traditional monofocal spherical IOL or a specialty toric or multifocal IOL, you should diligently identify

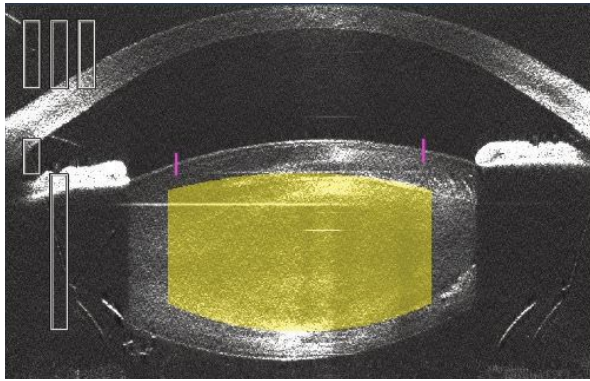
Which MIGS is Ideal?

In the case of a glaucoma suspect with acceptable IOP, a stand-alone cataract surgery may be indicated. While the exact mechanism is unclear, most believe removing the cataract alone helps with increasing outflow.^{3,4} These patients' IOP can therefore be monitored closely after surgery and treated if and when necessary.

A well-controlled patient, who has been treated by one or a combination of modalities, including laser trabeculoplasty or topical medications, is the perfect candidate for a MIGS procedure. However, not all patients need the same degree of IOP-lowering effect, and not all surgeons perform all procedures.

Most of the MIGS procedures performed by cataract surgeons today are focused on using an *ab interno* approach to increase trabecular outflow following phacoemulsification. Some of the more commonly used procedures in this category include the iStent Inject (Glaukos), Kahook Dual Blade (New World Medical), Hydrus Microstent (Ivantis) and Omni Surgical System (Sight Sciences).

Each of these procedures are unique in their own right, yet they all require the same general operating room protocol, which involves the surgeon performing an angle procedure with intraoperative gonioscopy usually following a standard phacoemulsification.⁵



This OCT image shows the lens during a femtosecond laser cataract procedure.

and manage any ocular surface conditions that can potentially affect the outcome of cataract surgery. In particular, ocular surface disease and significant dry eye may require aggressive treatment before and after surgery. Additionally, other corneal considerations include pterygia, corneal dystrophies (both anterior basement membrane and Fuchs'), post-refractive corneal irregularities and Salzmann's nodules. All of these may limit visual acuity following cataract surgery and should be addressed with the patient beforehand.

Likewise, patients with significant visual field changes from glaucoma or reduced visual acuity from retinal disease may also have post-cataract visual limitations. Again, you should prepare the patient and communicate with the surgeon prior to their initial preoperative evaluation.

MIGS Considerations

For glaucoma or ocular hypertension patients who are ready for cataract surgery, the process has become a little more complicated with MIGS. This addition to the surgical process affords patients a great opportunity to reduce their dependence on IOP-lowering medications.³ Once you know your surgeon's capabilities, MIGS prefer-

ences and candidacy protocols, you can educate your patients and make timely and appropriate referrals.

Prior to referring a patient for a surgical consult, assess the patient's disease severity and stability and make an appropriate recommendation to both the patient and the

comanaging surgeon. Depending on their individual needs, you may recommend phacoemulsification alone or combined with either a MIGS or a filtering procedure.

MIGS procedures have transformed the treatment protocol for glaucoma patients undergoing cataract surgery because of their ability to achieve consistent IOP control, independent of patient compliance, while lowering the incidence of both side effects and surgical complications.³ A variety of procedures are available (with several more in trials) that achieve IOP control by:

1. Increasing trabecular outflow
2. Reducing aqueous production
3. Increasing subconjunctival filtration

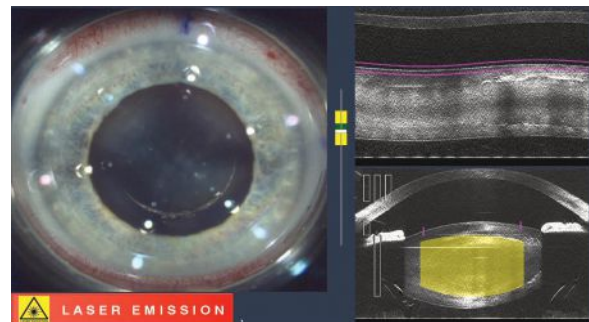
Not only do these procedures provide safe and effective IOP control in combination with cataract surgery, they are also more accessible to surgeons because they do not require the use of large, expensive devices.⁴ Instead, many of the current options are easily kept in stock in the operating suite with little capital expense to the surgical center.

Choosing the Right IOL

The comanagement of cataract surgery unequivocally calls for a refractive discussion between you and the surgeon. As the practitioner recommending surgery, you know best the visual requirements of the patient seeking a surgical consultation, while the surgeon may have never met them. You have the established relationship and understand the patient's personality, occupation, hobbies and lifestyle.

Thus, you are in the best position to counsel patients on the optimal IOL options to fit their needs, characteristics and expectations. This is augmented by your robust knowledge of the surgeon's IOL preferences discussed during your initial comanagement interview, which allows you to make proper recommendations consistent with the information the MD will provide.

This is especially important when suggesting a premium IOL, such as a toric or presbyopia-correcting IOL, considering these are out-of-pocket expenses for patients. Here you must collaborate with the surgeon to establish the criteria for patient candidacy for a premium IOL. Not every patient is a good candidate for every technology. Part of the preoperative consultation should include educating patients on available technology and discussing if they would be good candidates for the advanced options.



Here, the femtosecond laser is creating a capsulorhexis.



As the patient's primary eye care provider, you are best suited to recommend the IOL, whether a multifocal, above, or a toric option, at right.



For example, if a patient has less than 1.00D of corneal astigmatism, they would not be an ideal candidate for a toric monofocal IOL. The lowest amount of cylinder available on most toric IOLs in the United States is 1.50D at the IOL plane. Accounting for effective lens positioning, this will neutralize 1.00D of cylinder at the corneal plane. If a patient has less, they would be a better candidate for a standard spherical IOL.

For presbyopia-correcting IOLs, your discussion with the comanaging surgeon will be more in depth with many different options. They are available in accommodating, bifocal (which can vary in add powers of +4, +3, +2.50), extended-depth-of-focus (EDOF) and newly FDA-approved trifocal designs. Each of these IOLs will act differently in the eye, and it is important to know which IOL your surgeon will offer to your patient so that you can prepare them accordingly.

To set your patients up for successful outcomes, you must recommend the best IOL options for each patient, whether they have presbyopia or not. You can identify ideal candidates for a presbyopia-

correcting IOL with a focus on these three issues:

Motivation. A patient who is excited and motivated to be less dependent on their glasses or contact lenses is the first characteristic to look for. A patient who has worn glasses all of their life and is happy continuing to do so may not have the inclination to change.

Realistic expectations. Help the patient understand exactly what the IOL can and cannot do. The patient must be aware of any limitations before committing to surgery. Explaining this postoperatively will be perceived as a surgical failure, and patients will be unhappy. For example, even with a multifocal IOL, a patient may find they need to use glasses for certain tasks.

Depending on the chosen IOL, there will likely be a “sweet spot” for near vision tasks at a given working distance. This means patients may need readers if they are attempting a near task closer or further than this “sweet spot” focal distance. In addition, most multifocal IOLs are light dependent, so patients need to understand that optimal lighting will help them. If, however, they don't have control

of the lighting (e.g., in a dimly lit restaurant), they may need readers to assist.

Challenging Patients

Open communication with your consulting surgeon will make it easier to manage even the most challenging clinical situations, including patients who are post-refractive surgery, post-retinal detachment surgery or a patient with only one cataract that will need a balance Rx in their IOL. For these patients, you are truly in the best position to educate the consultant and drive the decision-making process for the refractive plan prior to the patient meeting the surgeon for the initial consultation.

As more patients present ready for cataract surgery and more surgeons are spending a greater portion of their time in the operating room, optometrists are poised to expand their role managing preoperative cataract consultations and postoperative surgical care. It is imperative that the optometrist maintains an open line of communication between their office, the patient and the consulting surgeon's office. Making sure that all parties are on the same page will ensure a seamless transition to accomplish a happy postoperative outcome. ■

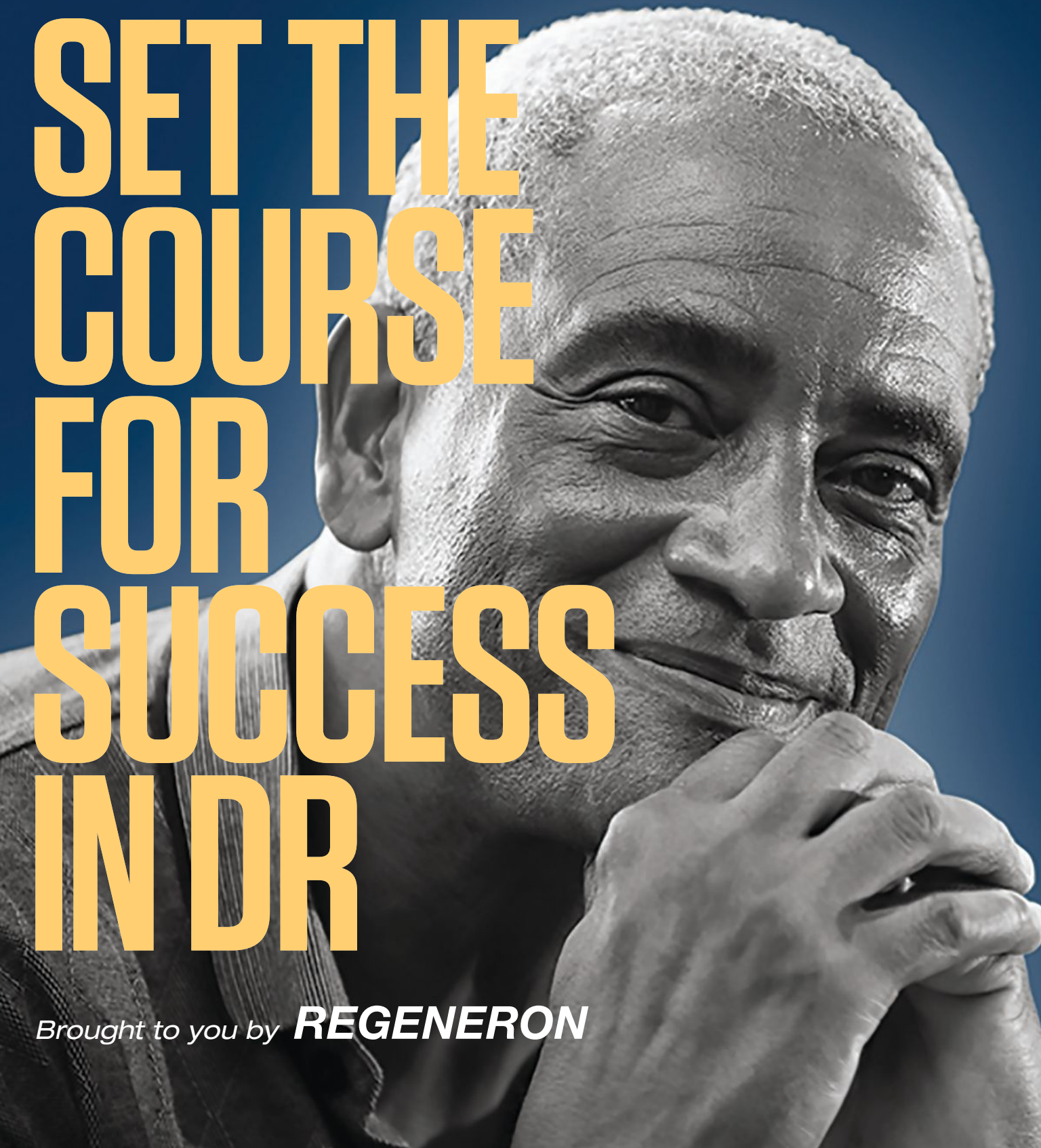
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- Your early and frequent discussions about disease progression, treatment options, and referral will empower patients, which could help them avoid significant vision loss^{3,4}



According to the AOA, you should refer patients with³:

- Severe nonproliferative DR (NPDR) within 2 to 4 weeks
- Proliferative DR (PDR) within 2 to 4 weeks
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Ensure patients have followed up with a retina specialist who can treat DR



Monitor your patients with DR^{3,4}

The AOA recommends frequent monitoring of patients³

- At least every 6 to 8 months in patients with moderate NPDR and more frequently for patients with greater disease severity³

Refer patients to a specialist who can treat DR^{3,4}

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AOA = American Optometric Association.

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25th Annual Surgery Report

Picking a Premium IOL For Every Patient

Matching the right lens with the right eye requires a personal connection.

By Victoria Roan, OD

Cataract surgery is one of the most common procedures across the globe and the number one surgery (of any stripe) performed in the United States. But with an expanding pool of potential postoperative outcomes, patients have a higher demand than ever for precision. Today's intraocular lens (IOL) technology, while imperfect, benefits from an array of recent innovations. While none replicate the eye's natural ability to accommodate and refocus at varying distances as in a pre-presbyopic eye, the newest slate of IOLs can give patients more independence from glasses than ever before.

The optometrist's role in preparing patients for cataract surgery includes a robust understanding of these available IOL options and how to best match a patient to the technology that fits their priorities. As good as the newest lenses may be, they still impose trade-offs among near, intermediate and dis-

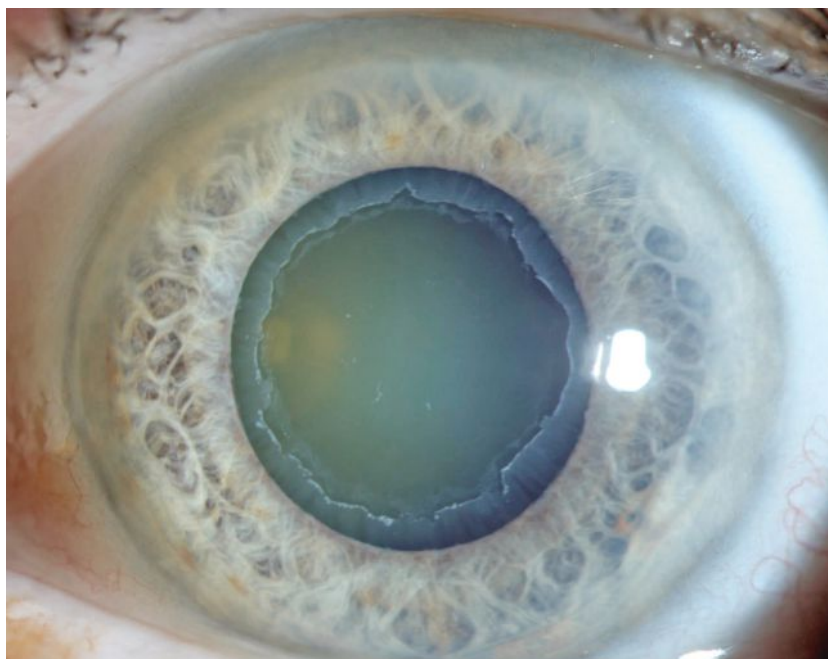


Photo: Aaron Bonner, OD

Pseudoexfoliation can cause difficulty in IOL placement. Due to association with weak zonules, specialty lenses are contraindicated in these patients.

tance vision. All patients are likely to experience improved vision after the procedure, and many can achieve excellent postoperative acu-

ity at multiple focal lengths—if we do our jobs well in patient selection and pre-op education. This article will give an overview of the process.

First Things First

Initial consultation for cataract surgery should include best-corrected acuity, glare testing and a history that details the patient's lifestyle. To get an understanding of their expectations, start by discussing how reduced acuity affects their day-to-day functioning. No "absolute" acuity will qualify a patient for insurance reimbursement, but a good rule of thumb is to begin discussing the future need for cataract surgery when the patient is beginning to struggle with those daily activities with no improvement despite glasses or contact lenses.

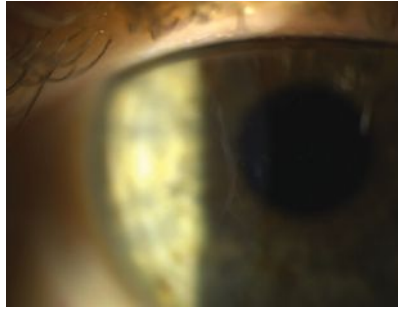
Recent research shows that when patients recognize postoperative visual improvements, they are more satisfied with the surgery—especially when they regain unaided near vision for reading after the cataract is removed.¹ Younger patients, who still have some remaining accommodative ability left before the surgery, tend to rank their satisfaction lower postoperatively compared with those in their 70s or older.^{1,2}

If the patient does not present with any glare issues from the cataract, the potential for "trading symptoms" is also a concern.² As initial dysphotopsia following surgery is not uncommon, patients also must be educated preoperatively about the potential for glare, arcs, streaks and halos initially after surgery.

In addition, proper reassurance during the healing period that neuroadaptation improves with time will help minimize patient stress during the recovery process.

Toric IOLs

Of the two broad categories of premium IOLs—toric and presbyopic—the former is more likely to succeed. However, while 52% of



Even subtle EBMD may disrupt aberrometry measurements and ultimately patient's visual outcome with a toric or premium IOL.

patients *can* be treated with a toric IOL, only 7% of patients receive one.³ Of course, the first step is figuring out which patients are in that 52% who qualify.³

Whether incompatibility is due to personality quirks that make adaptation difficult or preexisting ocular conditions that limit best-corrected visual acuity (BCVA), setting reasonable vision goals is the first step.^{4,6}

Recent research shows 'Type A' patients are more likely to fare poorly with a premium lens.⁴ A patient who has a long history of maladaptation to progressive lenses and updated prescriptions yearly may not be able to appreciate the gain of less dependence on glasses. Instead, these patients will more likely nitpick at the small aberrations and dysphotopsias associated with these lenses. Conversely, those with more agreeable or open personalities (Type B) tend to adapt better to the new lenses, whether standard or premium.⁴

Obvious ocular morbidities (e.g., macular degeneration, ocular surface disease, diabetic retinopathy, glaucoma) are contraindicated and easily explained to patients.⁵ More subtle findings tend to require more explanation as to why a premium lens would not be a proper match.

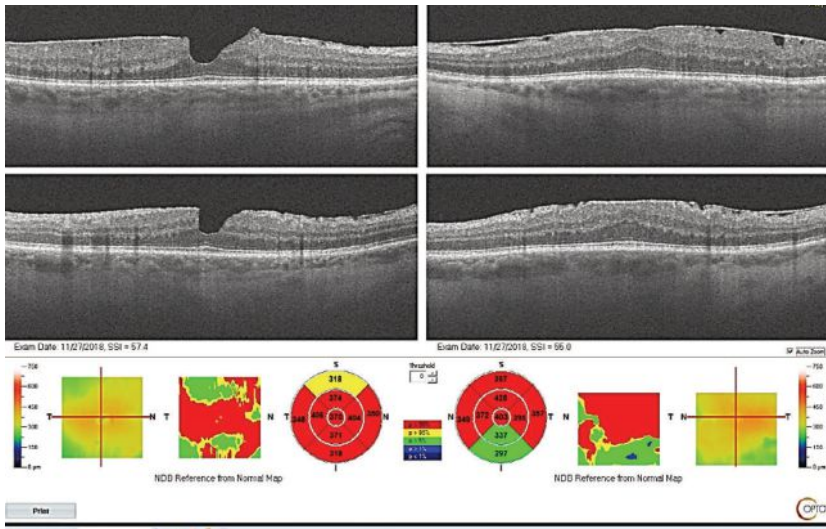
These can include forme fruste keratoconus, mild epiretinal membrane and epithelial basement membrane dystrophy (EBMD), for which the patient has no symptoms.

One study earlier this year found that EBMD can result in inaccurate biometric keratometry measurements used for IOL selection, leading to post-op refractive inaccuracies and patient dissatisfaction.^{4,7} Instead, the patient should be educated on the diagnosis and potentially offered phototherapeutic keratectomy to smooth out the corneal surface. However, if corneal opacity persists, many of these patients will be poor premium lens candidates.

Before cataract surgery, be sure to evaluate all patients with corneal topography. Instead of educating your patient on toric IOL candidacy based on refractive cylinder, using corneal topography offers more accurate information when calculating IOLs. You can compare your corneal topography findings to your autorefractor Ks to see if the patient would likely be a candidate for an astigmatism-correcting lens at the time of surgery. If the two measurements are not within half a diopter, the typical IOL increment, careful evaluation of the cornea may be warranted. As mentioned above, subtle changes like EBMD or dry eye can distort keratometric readings and, ultimately, post-op results.⁷ Management of such treatable corneal findings should be addressed before proceeding with cataract surgery measurements.

Furthermore, it is prudent to notify patients if they are at higher risk for zonular dehiscence at the time of surgery due to history of trauma, history of retinal detachment repair with silicone oil or presence of pseudoexfoliation.

Lens Selection



Epiretinal membrane is a contraindication for proceeding with premium IOLs as the patient's acuity post-operatively is likely limited. In addition, patients are at elevated risk for post-operative cystoid macular edema.

With weakened zonular integrity, orienting the axis accurately or centering the lens in a poorly secured bag will be difficult. Luckily, a capsular tension ring is typically placed into the capsular bag to help stabilize the structures enough to accommodate a toric IOL.⁸

After evaluating for these contraindications and establishing need for astigmatism correction, it's time to guide the toric-candidate through their options. Depending on the patient's preferred endpoint or chosen residual prescription, the benefits of electing a toric IOL may vary. If sharp distance vision without correction is their priority, then proceeding with a toric IOL is important in achieving their lifestyle goals. But careful discussion is needed to emphasize loss of intermediate and near function in the single-focus lens. In addition, individuals with career environments that may enhance sensitivity to glare, arcs, and other aberrations may benefit to neutralize their astigmatism to minimize ghosting and streaks with focal lights.⁶

What may also be a crucial factor in a patient's decision making is the financial burden of opting for a non-insurance-covered lens. Careful consideration of the cost/benefit tradeoffs of toric IOLs in patients hoping to retain near function will depend on the patient's blur tolerance. Astigmatism below 1.50D may not negatively affect their near acuity and a spectacle Rx at distance will be required to achieve the best results anyway. If proceeding with a specialty lens comes at too high of a financial burden for the patient, the preoperative evaluation serves as an opportunity to create an alternative plan to achieve their goals once they are stable from cataract surgery.⁶ After evaluating for these contraindications, it's time to guide the toric candidate through their options.

Femtosecond laser limbal relaxing incisions (LRI) may be recommended to better manage small (<1.25D) amounts of corneal astigmatism. Though more accurate than its manual predecessor, performing the LRI with a laser

at an incorrect axis can still occur and cannot be undone, resulting in increased or irregular astigmatism. Additional risks of LRIs include regression and wound leak, which makes toric IOLs the safer alternative even given the risk 10 degrees or more of rotation in a small number of cases (less than 3%).^{9,10}

An enhancement procedure like LASIK or PRK post-cataract extraction can also accurately treat residual refractive error when needed.¹¹ In cases where the patient presents with more than 5D of corneal toricity and no other irregular corneal findings, a toric IOL to eliminate the majority of the prescription is done first, followed by a laser enhancement to fine-tune vision with much less tissue removal. Similar considerations need to be made when treating more than 2.5D of astigmatism matched with toric multifocal or extended-depth-of-focus lenses.

It's not just a matter of opinion that optometry should be first to introduce patients to this information—research backs the idea. If the patient is feeling well cared for and well-informed beginning with their primary eye care provider, overall satisfaction tends to score higher, according to a *Journal of Cataract and Refractive Surgery* study.^{5,12} Anecdotally, we have found that the better ODs prepare a patient, the smoother the process, and the better it reflects on the optometrist. Repetition of information over time allows the patient to slowly absorb and process the information that will heavily impact their quality of life in the future.

IOLs for Presbyopia

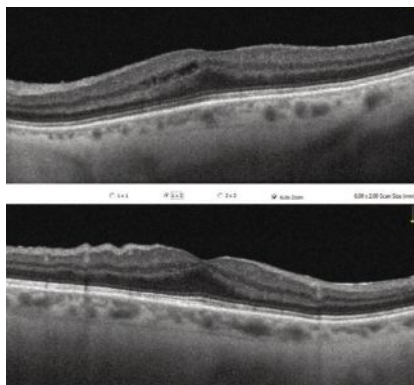
There are several categories of presbyopia-correcting IOLs on the market:

Diffraction multifocals. These lenses use several optical zones with different powers to establish separate focal points. While multifocals will offer better distance and near function (+2.50D range), some patients complain of a lack in clarity for intermediate activities. These include the Tecnis Multifocal (Johnson & Johnson Vision) and AcrySof IQ Restor (Alcon).

Extended-depth-of-focus IOLs. The Tecnis Symphony IOL (Johnson & Johnson Vision) lays claim to this category as an improvement upon conventional multifocal IOL performance. The lens uses chromatic aberration to create smoother transitions between its optical zones and fewer “dead zones” where vision is non-functional between set focal points. Surgeons estimate it provides around +1.50D of range, requiring the patient to wear readers for detailed near activities like threading a needle or beading.

Accommodating or pseudo-accommodating IOLs. In this approach, used in the Crystalens AO and Trulign Toric from Bausch + Lomb, a flexible lens bows forward, increasing the focusing power enough to improve near function of about +1.00D or more.

Trifocal IOLs. Though popular overseas for several years, this option has only recently come to our shores when Alcon launched its PanOptix IOL a few months ago. The design is said to deliver improved quality of distance, intermediate and near function compared to previous generations of multifocal IOLs.¹³ PanOptix has three target focal points at optical infinity, 60cm and 40cm. It comes in both spherical and toric platforms, as do the Restor 2.5 and Restor 3.0. However, PanOptix has unique technology to use more of the incoming light.



Irvine-Gass syndrome 1.5 months following cataract surgery. Prompt treatment with an NSAID and steroid typically results in a good prognosis and full resolution in a few weeks.

Monovision. As with contact lenses, monofocal IOLs can be chosen to establish one eye for distance and one eye for near or intermediate. If the patient’s non-dominant eye has good tolerance for blur, combining a dominant single-focus IOL with a non-dominant diffractive lens may allow the patient further freedom from spectacle wear.

Mix-and-match. Taking it a step further, personalizing vision with a multifocal lens in one eye for better near function paired with an EDOF or trifocal lens in the other may allow full range of vision by supplementing the intermediate zone. The possibilities are endless, but careful assessment of clinical findings is important in ruling out those with contraindicated findings.¹⁴

The goal is to minimize patients’ need for corrective lenses according to their distinct lifestyle requirements. Unfortunately, there is no lens that can completely guarantee absolute freedom from glasses 100% of the time. As the primary care provider, it is important to emphasize a personalized strategy that best matches the patient’s goals while establishing limitations.

What’s to Come?

Newer IOL technology in the pipeline looks to shake up the status quo yet again. Below are but a few of the hopeful disruptors.

1. Light-Adjustable Lens (RxSight). This was FDA approved this year, but is not yet on the market. It’s the first lens that allows postoperative adjustments to address uncorrected visual acuity or even undecided visual endpoints. The lens is made of a photoreactive silicone that allows optical changes to be induced postoperatively.²¹

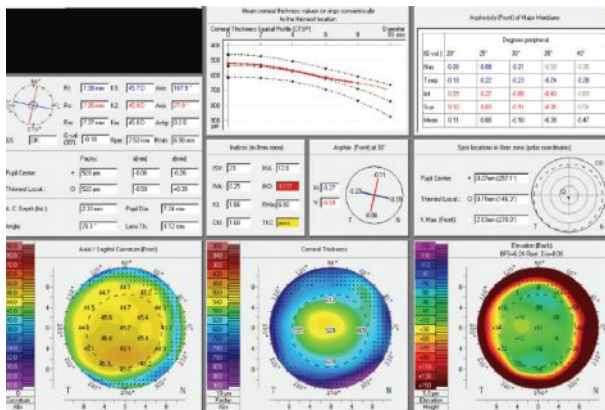
2. Eyhance monofocal IOL (Johnson & Johnson Vision). This lens aims to target the monofocal market with a mild extension toward intermediate vision using an aspheric lens design and broader defocus curve rather than a diffractive design. The purported benefit is improved “sweet spots” postoperatively compared to current monofocal IOLs. This lens may be optimal for those who do not mind wearing readers for near function and some intermediate tasks, but do not want to deal with adapting to diffractive halos and decreased contrast sensitivity. While not yet FDA approved, it has been released into the European market since February 2019.²²

3. IC-8 Small Aperture Lens (AcuFocus). This lens uses the same technology as the Kamra corneal inlay to extend the depth of focus via pinhole effect. The lens is currently proceeding with clinical trials in the U.S. estimated to be completed in May of 2020. European studies have shown up to 2.25D range of focus.^{23,24}

Reasons for Dissatisfaction

Even if you’ve done your job right prior to cataract surgery—evaluated patients thoroughly for ocular surface disease, explained the benefits and shortcomings of their chosen lens option and prepared them for a neural adaptation period—the patient may still experience dissatisfaction with a premium IOL. Luckily, many of the following postoperative complications are treatable.

Forme fruste keratoconus can be subtle and is often missed in routine eye exams. Tools such as the Pentacam help identify those with irregular astigmatism as these patients are contraindicated for toric and presbyopia-fixing IOLs.



It Starts With Us

Unfortunately, no matter how much we try, there is no way of determining which patients will absolutely adapt well to a premium lens. Most information is gained through the process of discussing patients' expectations and visual goals. Keep in mind that, although someone is clinically a good candidate for a premium lens on paper, their lifestyle and personality may exclude them. The more you can understand their hobbies, occupational requirements, and are able to determine which visual functions are most important to change, the more likely they will be matched with the proper IOL.

Though patients are becoming more accustomed to doing their own research, they may only be reading the manufacturer information, which tends to leave out the potential negatives of their product. It is essential that the eye care provider educate the patient about the compromise and gains of the options. If they are unable to give up sharp near function without need for glasses, then they may ultimately be a better candidate for monofocal IOLs with near endpoints or monovision if they have a history of success using soft contact lenses. The additional chair time that it takes in the initial discussion will save you and the patient a lot of time and frustration in trying to fix or adapt to an "unexpected" visual outcome.

Individuals with higher distance visual demands (e.g., sharp shooters, photographers, long haul truck drivers, historical emmetropes) tend to struggle with the lower contrast sensitivity and halving effects of the presbyopia-correcting IOLs. Instead, they tend to prefer the sharpness of monofocal lenses, certainly opting for astigmatism

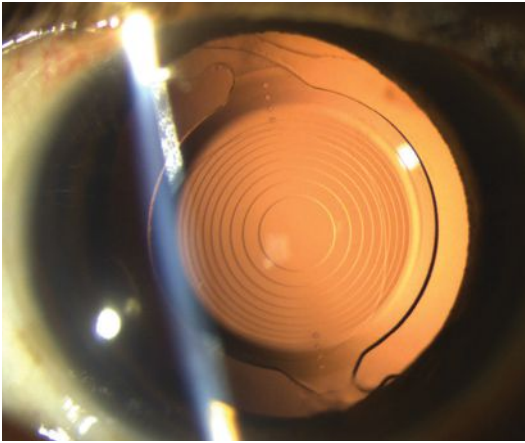
Most easily detected is residual refractive error. Once stability of the cornea is established with topography and manifest refraction, the patient can enhance their acuity with LASIK or PRK, which is much more customizable and predictable compared to cataract surgery. Enhancement procedures are often reviewed with patients who have a history of more than two years.

Secondly, and most easily treated, is posterior capsular opacification, which can occur in up to 40% of patient following cataract surgery.¹⁵ Hazing of the posterior capsule is typically more common in younger patients, as well as those with diabetes, history of uveitis, and traumatic cataracts.¹⁶⁻¹⁹ The typical complaint consists of slow return of glare and blur in vision after a period of clarity following cataract surgery.

Preparing the patient ahead of time about the risks and potential treatments alleviates the misunderstanding that the original cataract surgery "didn't work." Instead, the YAG capsulotomy becomes an anticipated step in clearer vision. Time of treatment may vary based on surgical clinics, but the general rule is that it's safe to proceed once there is enough peripheral capsule scarring and fibrosis to secure the intraocular lens, which may take up to three months.

A more frustrating post-op complication is cystoid macular edema, also known as Irvine-Gass syndrome. Preventative care with a non-steroidal anti-inflammatory drug, in addition to the typical steroid and antibiotic combination, is used to minimize inflammatory reaction by disrupting the prostaglandin cascade. Fortunately, vision loss is usually temporary and responds quickly to restarting topical anti-inflammatory therapy. More severe or stubborn cases may require intravitreal injections with retina specialist. The most important thing as a primary eye care provider is to catch the presentation early as visual prognosis is better the sooner treatment is initiated.²⁰

Lastly, even if there are no post-op complications, the patient may still be upset. The abundance of information that the patient considers at the cataract evaluation may lead to key concepts being forgotten—for example, the loss of near function in monofocal IOL use. In addition, they may hear "miracle" stories from friends and family members that are not realistic for their own case. Therefore, repetition of information over several visits with their primary eye care provider is important in allowing the patient to absorb the important key points fully before surgery.



This patient's Toric Symphony IOL was implanted one day before this photo was taken.

correction to neutralize astigmatic aberrations. In particular, those who spend a lot of time in scotopic settings; for example, truck drivers often have to drive long distances at night. Postoperative halos and starbursts from multifocal and extended depth of focus lenses may make it very difficult for them to perform their job safely.

On the other end of the spectrum, it is easy to fall into the trap of prioritizing distance vision for all patients. Myopic patients who enjoy near tasks such as crafting, reading, computer use or hairstyling may prefer to remain with an intermediate (-1.25D) or near (-2.50D) endpoint. This is a great opportunity to trial different options using soft contact lenses to simulate the loss of these working distances if they opt for distance vision.

As the primary eye care provider, consider beginning the process of determining lens selection early, when cataracts are first detected but before the patient is symptomatic. Build rapport and patient loyalty by addressing their long-term needs early on. Begin the conversation on what their ideal vision

would be within the limitations of the current technology. Start trialing different modes of vision from monovision to multifocal to single focus or even a multifocal/single focus combination.

The early conversation and the ability for the patient to functionally trial their options will make the whole process a lot less foreign and confusing when it actually comes time for surgery. Trialing

each option for a week with your patient will help them easily rule out the option of monovision or premium lenses if they are unable to adapt.

At times, the different lens options and packages that are reviewed at the time of surgery can be overwhelming. Our job as the primary care doctor of optometry is to guide them to the right choice. In the words of Malcolm Gladwell, we, as doctors, are “in the relationship business.” We have the opportunity to spend more time with a patient in an exam setting than other health care professions listening and learning their needs and goals. Furthermore, we have the amazing privilege of altering the way they see the world in the blink of an eye by providing personalized lifestyle vision. ■

Dr. Roan is a staff optometrist at Pacific Cataract & Laser Institute in Bellevue, WA.

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MIGS Today and Tomorrow

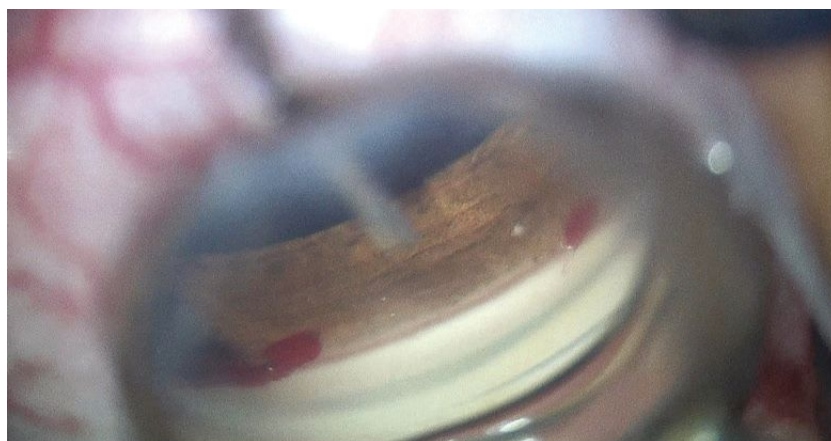
Referring ODs must be up to date on all developments that could benefit their patients. **By Rachel Caywood, OD**

Glaucoma management has been rapidly changing in recent years. An increase in surgical glaucoma treatment options has made it difficult to navigate the constantly changing terrain of glaucoma management. A 2017 survey of glaucoma surgeons showed that minimally invasive glaucoma surgeries (MIGS) are on the rise, with 22% of cataract surgeries performed by glaucoma specialists including a MIGS procedure.¹ But with more than 10 different MIGS on the market in the United States, how do you know which one would benefit your patient? This article discusses the recent studies highlighting the benefits and risks of several MIGS procedures to help you better counsel patients on their options.

Trabecular Meshwork Bypass

Several procedures seek to increase aqueous outflow with this method:

iStent (Glaukos). This device remains a good treatment option for patients with mild-to-moderate glaucoma who use one to three medications and require cataract surgery. As the first FDA-approved trabecu-



iStent inject insertion directly following cataract surgery. To see a video of this procedure online, visit www.reviewofoptometry.com.

lar meshwork (TM) bypass MIGS device, many surgeons are comfortable with it, which is why it is frequently used today. Several studies show greater intraocular pressure (IOP) and medication reduction in patients with primary open-angle glaucoma (POAG) who receive the iStent combined with cataract surgery than in glaucoma patients who had cataract surgery alone.²

One recent study shows the original iStent is slightly more effective than the iStent inject (Glaukos) in lowering IOP; however, the results were not statistically significant.³

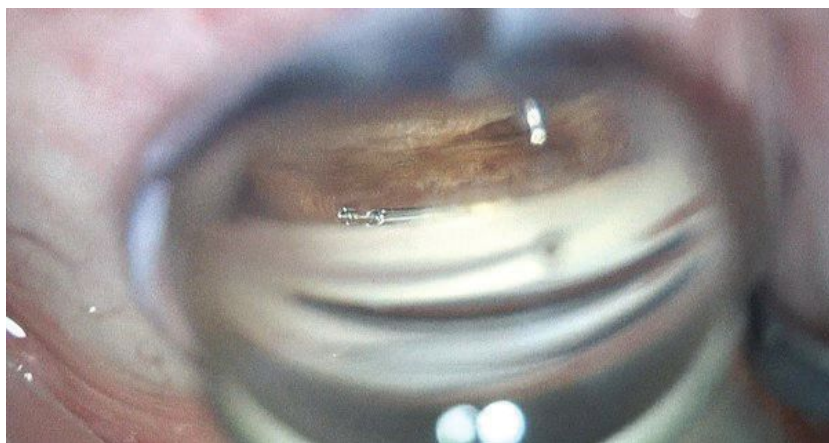
This study also shows intraoperative bleeding and postoperative hyphema are about twice as common in the iStent group compared with the iStent inject group, but these complications were not significant and self-resolved without sequelae.

iStent inject. This second-generation TM bypass device is similar in appearance to a punctal plug. The surgeon inserts the device into the nasal angle of the TM during cataract surgery. Due to the ease of insertion, the iStent inject is gaining popularity among surgeons. One study shows favorable two-year

IOP reduction outcomes with an iStent inject combined with cataract surgery vs. cataract surgery alone. Unmedicated IOP two years post-op was reduced by 7.0 ± 4.0 mm Hg in those with the combined treatment vs. 5.4 ± 3.7 mm Hg in those with cataract surgery alone.⁴ Complications are rare, but the most common include malposition of the stent as well as with blood reflux during and after the procedure.⁵

One study shows the iStent inject combined with cataract surgery to be effective in the treatment of primary and secondary glaucoma, including POAG, ocular hypertension, angle closure glaucoma, pseudoexfoliative, normal tension and combined mechanism glaucoma. This study included patients with mild, moderate and severe glaucoma. IOP decreased from 19.95 ± 3.7 mm Hg to 16.75 ± 2.2 mm Hg and medications were reduced from 1.3 ± 0.66 mm Hg to 0.3 ± 0.57 mm Hg. All patients had at least 20% IOP reduction from baseline. The study reported no adverse events.⁶

Hydrus (Ivantis). This 8mm bypass device also serves as a three clock-hour Schlemm's canal scaffold. A prospective multicenter randomized trial compared patients who



Hydrus insertion directly following cataract extraction. To see a video of this procedure online, visit www.reviewofoptometry.com.

underwent Hydrus implantation and cataract surgery vs. cataract surgery alone. Two years after surgery, IOP was reduced by 7.6 ± 4.1 mm Hg in the Hydrus group compared with 5.3 ± 3.9 mm Hg in the group with cataract surgery alone.⁷ There were 1.4 fewer medications in the combined procedure group compared with 1.0 fewer medications in the cataract surgery-only group.

The most common intraoperative adverse events observed in the study were device malposition (1.6%) and hyphema (1.1%), but there were no reported long-term sequelae from these complications. Nonobstructive peripheral anterior synechiae

(PAS) was the most common postoperative complication (14.9%). A concern among surgeons is the difficulty of insertion of the device due to its length; however, one study shows that the learning curve of insertion by an experienced glaucoma surgeon is negligible.⁸ The results of this study show promise of Hydrus's use increasing among general cataract surgeons.

Complications. The most common postoperative complications of iStent, iStent inject and Hydrus are hyphema, stent malposition or obstruction and IOP elevation. Hyphema after surgery is most often transient and

MIGS: iStent Leads the Pack

Minimally invasive surgeries have gained momentum in recent years, offering a new approach for some glaucoma patients. But with so many differing procedures and devices, it can be hard to keep up with usage patterns among surgeons. The American Glaucoma Society (AGS)-IRIS Registry study may help, as it provides insight into the demographic differences in three areas: MIGS procedure usage, effectiveness and adverse outcomes/safety concerns.

In total, 383,942 patients (591,116 eyes; 88.69%) received cataract surgery alone, while 50,970 patients (75,358 eyes; 11.31%) underwent combined cataract and MIGS procedures. Most (51,897 eyes) received the iStent, followed by endoscopic cyclophotocoagulation (BVI Medical) (15,714 eyes), according to Mildred M.G. Olivier, MD, who presented the findings during the 2019 American Academy of Ophthalmology annual meeting.

The data also shows the highest rates of MIGS usage tend to occur in patients who are male, black, older than age 60 and from the Midwest. Additionally, they typically had mild to moderate disease, were covered by Medicare and seen by a non-glaucoma specialist, Dr. Olivier noted.

The findings highlight the growing popularity of this approach, with an increase in MIGS use from 5.2% to 14.9% during the study period (2013 to 2017). Dr. Olivier acknowledged the limitations of the study, including no visual field or OCT data, dependence on the ICD-10 codes to determine glaucoma severity and specific procedures were not necessarily known due to overlapping procedure codes for angle surgery.

self-resolving. If recurrent or severe hyphema occurs, the device may require removal. Stent obstruction is an infrequent complication but can lead to device failure. Early obstruction is typically due to device malposition; whereas, chronic inflammation can lead to PAS and later obstruction. If the obstruction is observable, the lumen may be treated with a YAG laser. Few studies have reported severe but transient elevated IOP after iStent insertion.⁹ Observing elevated IOP one day after surgery may warrant anterior segment decompression to lower IOP.

Trabeculotomy

These procedures target the trabecular meshwork/Schlemm's canal:

Trabectome (Microsurgical Technology). The FDA approved this MIGS in 2004 for partial trabeculotomy in patients with mild to moderate glaucoma with or without cataract surgery. The Trabectome device cauterizes and aspirates the TM tissue anywhere from 90 to 180 degrees on the nasal angle. One study shows Trabectome is effective in uveitic glaucoma patients where other trabeculotomy procedures may not be as effective. Removal of excess tissue reduces the risk of PAS formation in the angle.¹⁰ Another study shows sustained long-term IOP reduction from 20.0 ± 5.6 mm Hg pre-op to 15.6 ± 4.6 mm Hg post-op and medication reduction from 1.8 ± 1.2 to 1.0 ± 1.2 at five years post-op.¹¹

Reported potential complications of Trabectome are blood reflux



Ab interno canaloplasty directly following cataract surgery. To see a video of this procedure online, visit www.reviewofoptometry.com.

into the anterior chamber, hyphema and partial goniosynechiae. None of these were clinically significant in the treatment of 101 patients with POAG.¹² Some surgeons avoid Trabectome due to the thermal damage to the angle compared with other trabeculotomy procedures. A new probe is under development to reduce this damage. Trabectome was the first FDA-approved MIGS and may not be as popular in some areas due to the development of newer MIGS procedures and stents.

Kahook Dual Blade (New World Medical). This procedure has two advantages: (1) reduced cost compared with other procedures and (2) full removal of the TM tissue, up to 180 degrees, without thermal damage. Kahook can be performed alone or during cataract extraction. One recent study shows favorable results of Kahook as a stand-alone procedure for POAG, where the mean IOP was reduced from 23.5 ± 1.1 mm Hg to 15.0 ± 0.6 mm Hg six months after the procedure.¹³ Hyphema is an expected surgical complication and typically self-resolves within a few days to weeks.

Goniotome (Microsurgical Technology). This device is like the Trabectome with aspiration and irrigation ports but excises

the TM in the same fashion as the Kahook. This allows for better surgical views and homeostasis during the procedure and aids in removal of excised trabecular tissue. The IOP-lowering effect of trabeculotomy performed with Goniotome would mirror those of Kahook.

Gonioscopy-assisted transluminal trabeculotomy (GATT). For many years, this was considered a treatment for congenital glaucoma, but it is now an effective treatment for POAG in adults. This procedure consists of inserting a suture or catheter through Schlemm's canal and extracting the suture (or device), which then unroofs the entire TM 360 degrees. One recent study shows significant IOP reduction two years after GATT by an average of 9.2 mm Hg in patients with POAG and medications were reduced an average of 1.43. The same study shows secondary glaucoma patients' IOP reduced by 14.1 mm Hg and two fewer medications per patient on average.¹⁴

The main advantage of this procedure is that it treats 360 degrees of the angle, where other methods of trabeculotomy only treat up to 180 degrees. Because GATT can be performed without specialty equipment, it may be the most cost-effective MIGS and a key factor why its use has increased among surgeons. Potential disadvantages



To see videos of procedures involving the iStent Inject, the Hydrus and ab interno canaloplasty, performed by Andrew Bailey, MD, visit www.reviewofoptometry.com or scan the QR code.

include remnants of the TM that may adhere to the adjacent tissues and cause PAS. In studies where this complication was observed, the effects were not clinically significant. One study showed that up to 16% of patients do not have patent Schlemm's canal 360 degrees. Limited Schlemm's canal patency will limit the treatable area of TM with GATT, potentially reducing the effectiveness of the procedure in these patients.¹⁵

An alternative to performing GATT alone is by combining Trabectome with GATT to treat the angle, also known as Trabectome-initiated GATT. The surgeon performs a 90-degree trabeculotomy with Trabectome and then treats the residual 270 degrees of the TM with GATT. This procedure was developed to ensure at least 90 degrees of the angle would be treated if Schlemm's canal is not open to perform a complete GATT.¹⁶

Ab interno canaloplasty (ABiC,

iTrack). This is a modification of traditional canaloplasty, as it achieves the same viscodilation of Schlemm's canal with an internal approach. Studies shows similar outcomes with and without the suture in traditional canaloplasty.¹⁷ ABiC is the only MIGS procedure that treats all structures of the aqueous outflow system. During the procedure, adhesions in the TM are broken, the Schlemm's canal is dilated and collector channels are irrigated. Unlike many of the MIGS procedures, ABiC can be repeated.

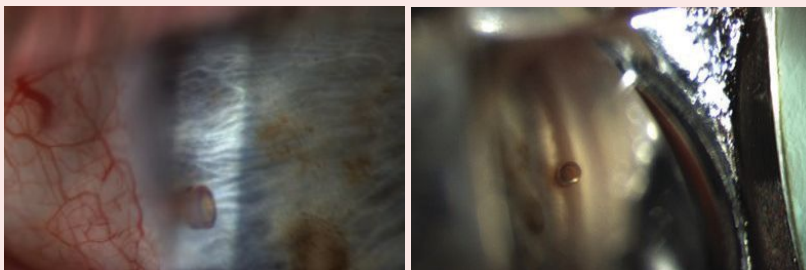
Few studies evaluating the results of ABiC have been published, but one recent study shows IOP reduction from 18.5 ± 3.4 mm Hg to 13.8 ± 2.0 mm Hg after surgery. Medications were also reduced from 2.4 to 0.25 on average.¹⁸ Another ABiC study shows similar outcomes in POAG patients treated with ABiC in one eye and traditional canaloplasty in the other.¹⁹ Complications associated with

Suprachoroidal Stents

Currently, suprachoroidal MIGS devices are not available in the United States. CyPass (Alcon), a suprachoroidal stent, was voluntarily removed from the market in August 2018 due to increased endothelial cell loss noted in some patients five years after implantation.

The American Society of Cataract and Refractive Surgeons task force recommended clinicians monitor eyes that have a CyPass stent to watch for visually significant complications from endothelial cell loss. Repositioning or removing the device is discouraged; instead, the surgeon may attempt to clip the proximal end of the device, reducing any protrusion into the anterior chamber.

American Society of Cataract and Refractive Surgery. Preliminary ASCRS CyPass withdrawal consensus statement. www.ascrs.org/CyPass_Statement. Accessed October 26, 2019.



An appropriately positioned CyPass stent in the nasal angle, as shown here, in a patient with a healthy endothelium is unlikely to cause corneal edema.

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ABiC are rare, and further long-term studies are needed to determine any associated significant complications.

Omni (Sight Sciences). This device is designed to viscodilate Schlemm's canal and collector channels and perform a trabeculotomy simultaneously. With this device, the surgeon can choose to treat 180 or 360 degrees of the angle with Visco 360 and/or Trab 360 (Sight Sciences).

Cyclophotocoagulation

Endocyclophotocoagulation (ECP, BVI Medical) reduces aqueous outflow and is the only MIGS with indications in neovascular and angle-closure glaucoma. Because ECP directly treats the ciliary processes, some surgeons feel it is less traumatic than transscleral cyclophotocoagulation (CPC). ECP can be performed with or without cataract extraction; however, it is better suited for pseudophakic eyes or during cataract extraction because the energy applied to the eye may induce cataract development.

Research shows combining phaco and ECP can open the angle in the plateau iris by shrinking the ciliary processes.²⁰ This combination can be more effective in chronic angle-closure patients vs. POAG patients in both lowering IOP and medications.²¹ Due to possible complications such as inflammation, cystoid macula edema, cataract development, hypotony and phthisis bulbi, practitioners are advised to perform ECP with the least amount of energy to achieve effective treatment.

CPC uses diode laser energy applied to the external sclera approximately 1.5mm posterior to the limbus with the Cyclo G6 Glaucoma Laser System (Iridex). One study showed CPC to have three modes of action: reducing aqueous production, increasing uveoscleral outflow and causing a pilocarpine-

type effect. Although not considered a MIGS procedure by some (CPC is performed externally), it can be an effective means of lowering IOP by reducing aqueous outflow. CPC can also effectively deal with refractory glaucoma and narrow-angle glaucoma.²² Potential complications are hypotony, phthisis bulbi and chronic inflammation, all of which can be reduced by titrating the amount of energy exposed to the eye. However, more studies are needed on this procedure with published guidelines for treatment titration, as all reported complications are dose-dependent.²³

Subconjunctiva

The Xen gel stent (Allergan) is a hydrophilic 6mm tube placed ab-internally to create a subconjunctival bleb. Many surgeons consider Xen to be a MIGS plus procedure due to the bleb formation, which comes with increased risk of complications compared with other MIGS. Xen is FDA approved for insertion in patients with refractory glaucoma as an independent procedure or during cataract surgery. One recent study shows a significant reduction in IOP from 22.5 ± 4.2 mm Hg to 13.4 ± 1.3 mm Hg four years post-operatively. Medication use also decreased in the treatment group from an average of 2.4 ± 1.3 before surgery to 1.2 ± 1.3 after surgery.²⁴

Another study shows that 43% of Xen gel stent blebs required needling postoperatively to break fibrotic adhesions and aid in reforming the bleb.²⁵ Many general surgeons may not feel comfortable with bleb needling, so a glaucoma specialist usually performs this procedure.

Reported complications with the Xen gel stent are malignant glaucoma, conjunctival wound leak, hyphema, vitreous hemorrhage, hypotony maculopathy, choroidal effusion stent obstruction, exposed

stent and dellen formation.²⁶ In light of the potential risks associated with the complications of the Xen gel stent, these are best managed by the surgeon who implanted the stent. In October 2019, Allergan announced a voluntary recall of 15 lots of Xen implants due to residual polishing materials on the needle sleeve from the manufacturing process. The recall was for unused stents, and explanting devices is not advised at this time.²⁷

Future of MIGS

Many other devices are still under investigation:

- Standalone procedures for iStent and iStent inject are in clinical trials.
- The iStent infinite (Glaukos), a device housing three stents similar to the iStent inject, is currently going through FDA trials for use in refractory glaucoma. When approved, this device will allow for iStent implantation as a standalone procedure.
- The iStent supra is a suprachoroidal device currently in the final stages of the FDA approval process. Glaukos anticipates its release sometime in 2020. This device will fill the void CyPass left; however, some surgeons may be leery of potential complications caused by suprachoroidal stents.
- The MicroShunt (Santen, Glaukos) is an *ab externo* subconjunctival stent that is currently seeking FDA approval. After approval, this device will be a good alternative to Xen gel stent.
- The SolX Gold Shunt (SolX) is a suprachoroidal device in clinical trials for FDA approval.
- iDose (Glaukos) is a medication implant device in clinical trials for long-term drug

administration *in vivo* into the anterior chamber. The time benefit for iDose will be limited when the drug release is exhausted, but it may be used in cases where medication compliance is an issue.

- The Beacon Aqueous Microshunt (MicroOptx) is a novel device that filters aqueous from the anterior chamber to the surface of the eye. The device is implanted in the cornea stroma, is designed to maintain the IOP at 12mm Hg and shows great promise for a new MIGS device.

Glaucoma surgeons' proficiency varies greatly on the procedures they perform, from no MIGS to several. Surgeons usually become proficient in a few procedures rather than trying to master them all.²⁸ Comanaging optometrists should know which MIGS procedures are available before referring patients.

Glaucoma treatment options are ever changing, and optometrists must be knowledgeable on all of the MIGS on the market to provide the best possible care to each patient. ■

Dr. Caywood is a staff optometrist at the Oklahoma City VA Medical Center.

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A Workup Protocol for Transient Vision Loss

When a patient's vision switches on and off, it's time for a serious investigation. Here's what to look for and where to refer. **By Christina Tran, BS, and Leonid Skorin Jr., DO, OD, MS**

Your patient reports that their vision went dark for a couple of seconds in one eye and then went back to normal. What's your next move? Optometrists are tasked with determining the etiology of sudden, reversible bouts of vision loss. Patients need proper workup due to the wide range of underlying conditions associated with transient monocular vision loss (TMVL). Clinicians must ask critical questions, make careful observations and order appropriate tests to narrow the list of differential diagnoses so that the patient can receive prompt treatment and management (*Figure 1*).

This article provides a by-the-numbers overview of the information you'll want to collect, both historical and clinical, how to obtain it and how to interpret it to protect your patients' vision.

Four Points of Historical Information

Asking about the patients' experience with these episodes is vital in guiding your next step. The first thing you'll want to do is get

patients to discuss these four aspects of their TMVL.

Monocular/Binocular. The examiner should inquire if the vision loss was in one or both eyes. If it was in one eye, it may be difficult for the patient to accurately recall which eye it was. Transient binocular vision loss (TBVL) can be caused by atypical migraines, papilledema and seizures.¹⁻⁴ TMVL can be caused by giant cell arteritis (GCA), retinal artery occlusion and thromboembolic events.⁴ Both binocular and monocular transient vision loss can occur with or without any ocular health abnormalities.¹⁻⁴ In cases where you observe no ocular pathological findings, it is critical to perform testing such as blood pressure measurement, carotid auscultation and carotid ultrasound to assess the circulatory system.

Duration. Episodes of TMVL can range from a couple of seconds to up to 24 hours.¹ It may be difficult for a patient to accurately recall how long the visual disturbance lasted. Regardless, an estimate can help differentiate the cause. TMVL related to migraines tends to last longer and

have a gradual onset with a duration of up to one hour.²

Papilledema is a bilateral thromboembolic event that tends to cause quick, one- to two-second bouts of vision loss.¹ Thromboembolic-causes of TMVL can last from one to 15 minutes.³

Provoked/Unprovoked. Ask your patient about what they were doing when the vision loss occurred and be sure to verify any recent changes to medications. TMVL can be provoked by a change in the dosage of medications for hypertension.¹ Reduced blood perfusion of the optic nerve head during a sudden postural change can also result in brief dimming or loss of vision.¹ Delayed recovery following the viewing of a bright light source such as car headlights is another example of provoked TMVL.¹

Unprovoked episodes of vision loss are generally more concerning because of the association with thromboembolic events and vascular conditions.

Visual Phenomena. When a patient experiences unprovoked TMVL, the examiner should ask if

the patient also experienced brief flashes of light, stationary flickering of light, zigzag lines, colored lights or geometric shapes.

TMVL accompanied by these visual phenomena can be due to a migraine, especially if typical features of a migraine are present.¹ Flashing lights can also be a sign of retinal detachment or retinal photopsia caused by vitreoretinal traction. TMVL is a diagnosis of exclusion that requires all organic causes to be ruled out.

Migraine

The exact pathophysiology of migraines remain unknown, but research suggests that these patients may have overactive neurons in their brains and brainstems resulting in vascular fluctuations, aura and pain.² The prevalence of migraines

with aura is highest in 30- to 50-year-old Caucasian women.² Research shows that 70% to 90% of patients with migraines have a positive family history.² Patients with migraines have a higher risk of stroke, especially those who experience aura.² The distinguishing feature of a migraine from ischemia or seizure is prodromal tingling and numbness, which can start five to 30 minutes before visual aura.¹ Headache commonly follows aura and is typically unilateral and throbbing in nature.² The headaches may be accompanied by nausea, vomiting, photophobia and phonophobia.²

The most common type of aura with migraine is a type of visual phenomena called scintillating scotoma.¹ This is often described as sparkling zigzag lines with adjacent blurry, wavy, or missing areas of

vision. Other forms of TMVL with migraines are hemianopsias and monocular vision loss.⁵ In young patients, transient hemianopsias are more often related to migraines than to an embolic transient ischemic attack.⁵ Transient monocular vision loss due to a migraine will more frequently present with positive visual symptoms in contrast to totally blacked-out monocular vision loss due to an embolus.⁵

All patients with new migraines and visual aura should have their visual fields assessed. Neuroimaging should be performed as well, especially for patients with a new onset or increased frequency of symptoms. Blood work such as erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) is critical in elderly patients with TMVL headache symptoms to exclude GCA.²

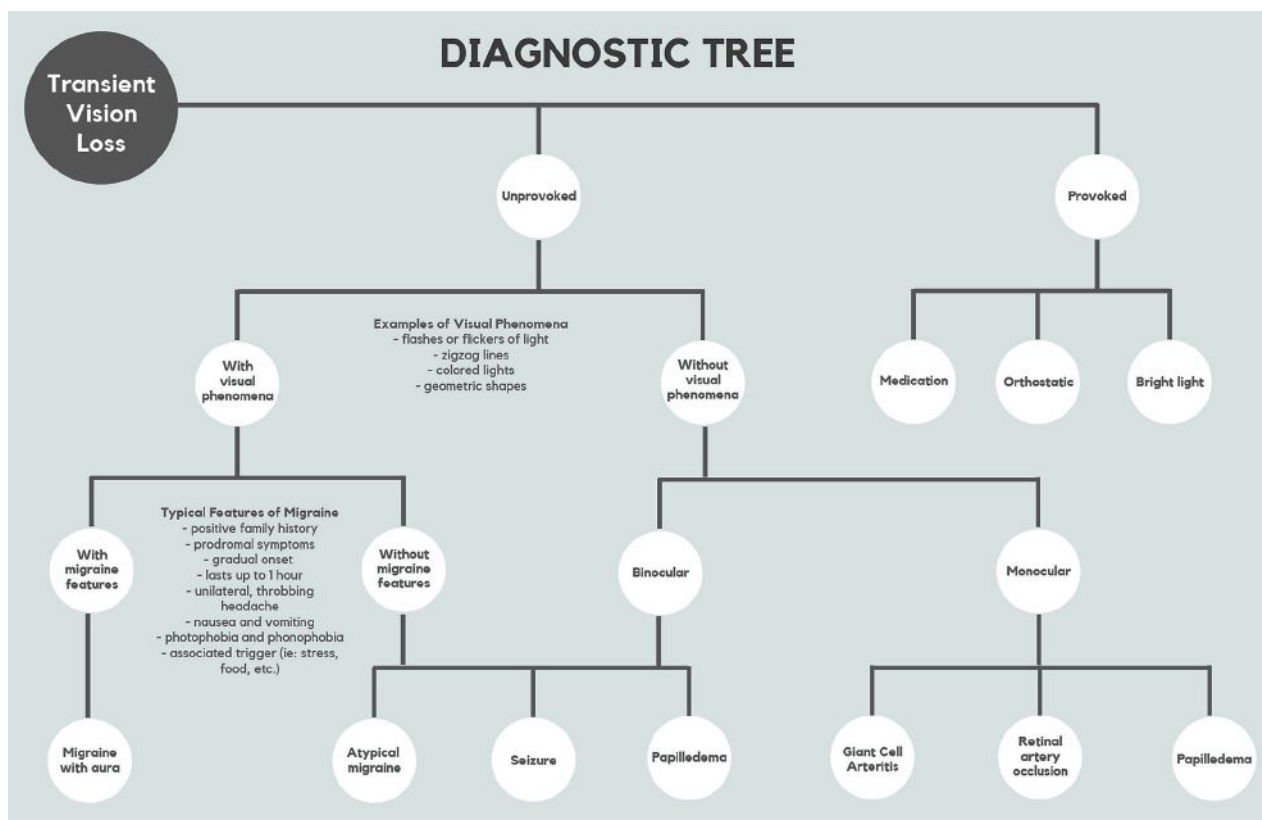


Fig. 1. This flow chart offers a way to navigate TMVL's various presentations.

Since migraine itself is a diagnosis of exclusion, it cannot be identified without appropriate neurologic testing and imaging. If this is suspected, a neurologic referral should be made to pursue the appropriate work up.

Treatment depends on the severity and frequency of the migraines. Non-pharmacologic treatment includes eliminating trigger factors, stress management and biofeedback. Physical techniques such as massage, acupuncture, osteopathic or chiropractic manipulation can be beneficial in certain cases. A number of transcutaneous electrical nerve stimulation devices are now available for migraine treatment. Pharmacologic treatment is divided into acute (abortive) therapy and prophylactic (preventative) therapy. Acute therapies include simple and combination analgesics, non-steroidal anti-inflammatory drugs, steroids, ergot products and selective serotonin receptor agonists known as triptans. Monoclonal antibodies are very target-specific agents that modulate the calcitonin gene-related peptide neurotransmitter.²

Giant Cell Arteritis

This inflammatory disease affects medium-to-large vessels with a predilection for arteries of the head, including the ophthalmic artery and superficial temporal artery. Layers of the elastic lamina within the vessels are destroyed by lymphocytes and multinucleated giant cells and inflammation causes narrowing of vessel lumens.⁶ The prevalence of GCA is three times higher in women than men and most patients are 70 years or older.⁶ It is uncommon for patients to have GCA if they are younger than 50.⁶ Research suggests a genetic component may be in play, due to a higher incidence of GCA in

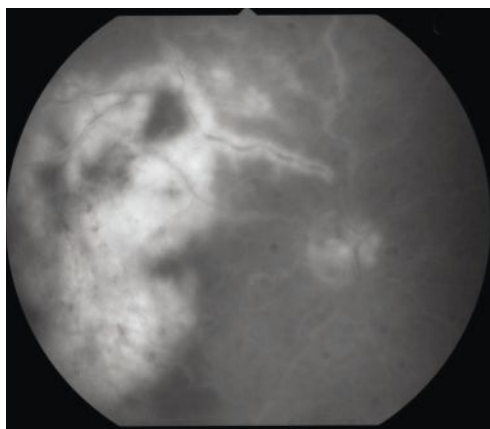


Fig. 3. Fluorescein angiography, seen here, can help identify filling defects of the retinal arteries caused by an occlusion.

Caucasians and an association with HLA antigens.⁶

Optic nerve infarction tends to manifest as multiple episodes of TMVL before potentially inducing permanent blindness.⁵ Multiple episodes of TMVL are more likely due to GCA than an embolic cause.⁵ Transient binocular diplopia and other visual phenomena have been reported in addition to TMVL.⁶ Approximately 80% to 90% of vision loss in patients who have GCA is due to anterior ischemic optic neuropathy (AION) and the second eye tends to become affected within days in 75% of untreated patients.⁶

Between 16% and 26% of patients will have visual complications without any systemic symptoms, but the examiner should inquire about headaches, scalp tenderness, jaw claudication when chewing or talking, fever, weight loss and polymyalgia rheumatica.^{5,6} The most common of these symptoms are headaches and jaw claudication. Interestingly, research shows that patients with jaw claudication may predict a higher risk of vision loss.⁶

GCA is an ophthalmic emergency whose diagnosis is definitively estab-

lished with a positive temporal artery biopsy which can be completed by most general ophthalmologists (*Figure 2*).

The fundus of these patients usually appears normal, but cotton-wool spots may be present, indicating infarction of the retinal nerve fiber layer (RNFL).⁵ Fluorescein angiography may show choroidal filling defects including delayed filling or patchy defects of perfusion.⁶

Optic disc edema can result in a chalky, white appearance of the disc with AION. Diagnosis of GCA is highly likely with simultaneous presence of AION and central retinal artery occlusion (CRAO).⁶

In addition to performing a dilated fundus exam, the examiner should palpate the scalp and jaw muscles to evaluate for any tenderness and a potentially prominent, pulseless temporal artery.⁶ Blood tests should include erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and complete blood count (CBC) with differential.

An abnormal ESR is usually greater than 90mm/hour, and an abnormal CRP is greater than 2.45mg/dl.⁶ CRP is a more sensitive test than ESR for diagnosis of GCA although the combination of ESR and CRP is 97% specific for the diagnosis of GCA.⁶ It is highly unlikely that a patient will have vision loss with a normal ESR, normal CRP and no systemic symptoms. CBC with differential may reveal normochromic normocytic anemia, elevated platelet count or increased inflammatory components in GCA patients.^{6,7}

Patients with GCA are routinely placed on high-dose intravenous corticosteroids to control inflammation and manage symptoms.⁶ Vision loss due to AION is considered a

neuro-ophthalmic emergency that needs immediate intervention to prevent blindness and involvement of the other eye. These patients are started on 1g to 2g of intravenous methylprednisolone for three to five days.⁶ This is followed by 1mg/kg of oral prednisone per day which will be tapered slowly over six to 12 months.⁶ ESR and systemic symptoms should improve quickly after the first dose of steroids, but the visual prognosis often remains poor. Symptoms can recur following the initial corticosteroid treatment, vision loss can progress even when on corticosteroid therapy and vision is rarely recovered.⁶ Recent studies show a reduction in relapse rates with the addition of the steroid-sparing interleukin-6-receptor antagonist tocilizumab.^{6,8}

Retinal Artery Occlusion

Temporary interruption of retinal circulation can cause TMVL, also known as amaurosis fugax.⁵ Interruptions are usually due to cholesterol, platelet-fibrin or calcific emboli.⁹ Blockages can result in a central retinal artery occlusion (CRAO) or a branch retinal artery occlusion (BRAO), which can lead to permanent severe vision loss.^{5,10} One study shows that more than 40% of patients with a CRAO had a plaque located in their internal carotid artery near where the ophthalmic artery originates.⁵ Retinal artery occlusions are most common in males and patients in their 60s.¹⁰ Risk factors for retinal artery occlusion include carotid disease and cardiac disease.¹ Diabetes, hypertension, high cholesterol, certain blood conditions and smoking are also risk factors.^{5,10} Artery occlusion today is considered an active 'stroke in the eye' and requires immediate admission to the hospital with evaluation from a certified stroke team.



Fig. 2. A GCA diagnosis can be established with a positive temporal artery biopsy.

Temporal Artery Biopsy Up Close

The temporal artery is marked after being located by palpation and Doppler ultrasound. An incision is made through the skin and subcuticular tissue directly over the artery. Dissection is performed with cautery and blunt dissection. The artery is then exposed. It may appear thickened, gray, or mottled compared to a normal artery.⁶ The specimen to be biopsied is measured. It is recommended that specimens are at least 2cm to 3cm in length due to potential skip lesions.⁶ The distal and proximal ends of the artery are clamped with titanium clips. The specimen is excised. The incision is closed with dissolvable subcutaneous sutures and the skin with Dermabond. Steri-strips are applied followed by a Telfa pad and pressure dressing. The specimen is sent to pathology to be analyzed for signs of inflammation, including epithelioid cells and giant cells.⁶ It is rare to have a false-positive temporal artery biopsy.



To see a video of this procedure, visit www.reviewofoptometry.com, or scan the QR code.

Vision loss caused by a retinal artery occlusion typically has an abrupt painless onset.⁵ The episode generally lasts for one to 15 minutes until the blockage disperses and blood flow is restored.⁵ The episode of TMVL is usually described as darkening rather than blurring of vision. If vision returns it does so slowly over minutes.⁵ Only about 1% to 2% of cases affect both eyes.¹⁰ If the acuity returns the patient may realize they have developed permanent visual field defects that can be altitudinal, peripheral or central.⁵ Nasal visual field defects are common because emboli tend to get trapped in the temporal retinal circulation.⁵

With CRAO, the fundus will have a "cherry red spot" at the center of the macula, and the rest of the retina will appear pale due to the lack of blood supply.^{5,10}

With BRAO, you'll see an area of pale retina that corresponds to the blocked vessel (*Figure 3*).¹⁰ Paleness of the retina tends to last around four to six weeks before fading away as the tissue atrophies.¹⁰ Fluorescein angiography can identify any filling defects of the retinal arteries. In addition, a measurement of the patient's blood pressure should be obtained. For carotid emboli, the carotid artery can be assessed with conventional angiography, a Doppler ultrasound, magnetic

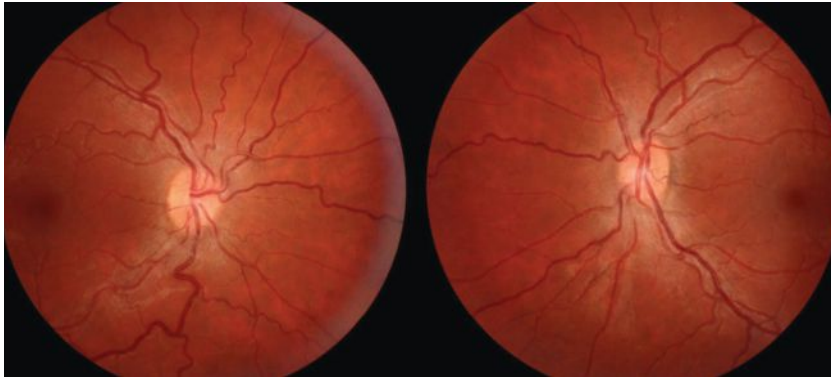


Fig. 4. Conditions that increase the production, or decrease the outflow, of cerebral spinal fluid can lead to papilledema, as seen in this patient's fundus.

resonance angiography or computer tomography angiography.⁵ Cardiac evaluation including electrocardiography and 24-hour heart monitoring is warranted in cases of cardiac emboli.⁵ Neuroimaging of the head may also be indicated to look for any emboli in the brain.⁵

There is no standard treatment for retinal artery occlusions. Suggested therapies attempt to dislodge the embolus with ocular massage, hyperventilation by breathing into a paper bag, which may cause dilation of the vessels, and lowering intraocular pressure with paracentesis or medication.¹⁰ These treatments must be implemented within

four to six hours after the onset of symptoms to be effective.¹⁰ A recent study found that intravenous PGE1 infusion, a prostaglandin infusion therapy, could statistically significantly recover vision in patients with acute CRAO.¹¹ Management of a patient with retinal artery occlusion is focused on reducing the risk of stroke and other vascular events. Medications include statins and antiplatelet therapy with aspirin.⁵ In addition, patients are advised to control any underlying hypertension and blood glucose levels, quit smoking and lose weight to reduce the risk of another retinal artery occlusion or a future stroke.⁵

Case Report: Patient With Transient Vision Loss

An 82-year-old man presented to the eye clinic with a concern about recent episodes of transient vision loss. The patient explained that vision in his right eye would go completely black for about half an hour, and then his vision would recover after lying down to rest. The patient also reported a history of vertical diplopia that had occurred sporadically in the past few months. The patient denied any visual phenomena or pain related to the vision loss, but he did report jaw discomfort that occurred occasionally while eating.

Review of systems was significant for sarcoidosis, for which the patient was currently taking 25mg of prednisone. The patient reported that his family physician recently tapered the prednisone from 30mg to 25mg, and this coincided with the occurrence of his transient vision loss.

No evidence of any ocular involvement was found upon examination. Blood tests were ordered by his family physician, and the results showed elevated ESR, elevated CRP and slightly elevated platelet, neutrophil and monocyte counts. We performed a temporal artery biopsy on the right side since visual symptoms were in his right eye. The results came back positive for giant cell arteritis (Figure 5). As a result, the dosage of prednisone was increased to 40mg per day by his family physician to manage the patient's symptoms and prevent vision loss.

Papilledema

This condition is characterized by swollen optic discs which occur due to increased intracranial pressure (ICP). This ICP increase can disrupt axoplasmic flow through the optic nerve and result in the leakage of cellular contents around the optic disc (Figure 4).¹²

Papilledema may result from pathologies such as intracranial mass, choroid plexus papilloma, obstructive hydrocephalus, hemorrhagic cerebrovascular accident and venous sinus thrombosis. It may also occur idiopathically as in idiopathic intracranial hypertension (IIH).

IIH mostly affects overweight females of child-bearing age between 15 and 44 years old, but it can affect all ages and genders.¹³ No proven cause is known, hence the idiopathic etiology of the condition. The proposed pathophysiology is a combination of a decreased absorption or increased production of CSF related to vascular, hormonal, or cellular mechanisms.¹³

TMVL is not usually the presenting symptom in patients with papilledema, but it is a common symptom, occurring in up to 70% of IIH cases.¹³ Vision loss can be in one or both eyes and can cause a partial or complete visual field defect.

Vision changes are often described as a monocular or bilateral "graying out," with episodes usually only lasting a couple seconds.¹⁴ Patients with papilledema may also experience binocular horizontal diplopia due to a lateral rectus (CN VI) palsy.¹³ Visual phenomena such as flashes of light have been reported in 54% of cases and permanent vision loss in 32% of untreated cases.¹³ Chronic, untreated papilledema can lead to field defects that mimic the damage caused by glaucoma.¹⁵

Headaches occur in 98% of cases of papilledema.¹³ They can be in any

location and occur daily. Headaches may be accompanied by nausea, vomiting, light sensitivity, pulsatile tinnitus, and neck and back pain.¹³ The headache with IIH is usually worse in morning and may have a positional component.

The evaluation of a patient who presents with signs and symptoms of IIH includes dilated fundus examination, visual field assessment, neuroimaging, lumbar puncture, CSF analysis and CBC, best accomplished by the neurologist or neuro-ophthalmologist. In-office assessment with an optical coherence tomographer can demonstrate a swollen nerve fiber layer.

The severity of papilledema seen on dilated fundus examination may correspond with the severity of vision loss.¹³ An assessment of the patient's visual field will likely reveal an enlarged blind spot or inferonasal field loss.¹³ Magnetic resonance imaging (MRI) with venography (MRV) can help rule out various other causes of increased ICP such as dural venous sinus thrombosis. If MRI is contraindicated, computed tomography (CT) can be done instead. Abnormal opening pressures greater than 25cm H₂O in adults and 28cm H₂O in children up to age 18 may suggest a diagnosis of IIH.¹³ An analysis of CSF should be conducted as well as a CBC to further rule out other causes of intracranial hypertension. Diagnosis of IIH is ultimately established using the Modified Dandy Criteria.¹³

Lumbar puncture can temporarily relieve symptoms or completely resolve papilledema in a patient with IIH.¹³ Patients should be advised to lose 5% to 10% of body weight and modify their diets to increase the chances of remission.¹³ Pharmacologic agents such as acetazolamide and furosemide aim to decrease the production of CSF and may have

a diuretic component for increasing outflow of CSF. Topiramate can be prescribed for migraine prophylaxis, and it also has a carbonic anhydrase inhibitor component that can help the patient with weight loss.¹³

Steroids can help quickly lower ICP as well but can lead to rebound weight gain and ICP increase when taken off the steroids.¹³ For these reasons, steroids should only be prescribed in severe cases of vision loss and in cases that do not respond to other medications.

Surgery is another option for certain refractory cases. In optic nerve sheath decompression, slits are made in the optic nerve sheath to increase the outflow of CSF and decrease pressure exerted on optic nerve.¹³ A different surgery called CSF diversion uses a shunt and is more effective at reducing headaches than vision loss.¹³ It may take months to years to treat this condition. Patients may still have papilledema, increased ICP, and visual field defects even with treatment.

Transient vision loss is a common visual complaint of patients, and, in certain cases, a prompt diagnosis and initiation of treatment and management could be critical to not only the patient's vision but their overall health. There are many factors to consider when managing such a patient and optometrists need to be ready to do so efficiently. Optometrists should know what information and tests are pertinent for a diagnosis and then decide whether the patient should make a visit to

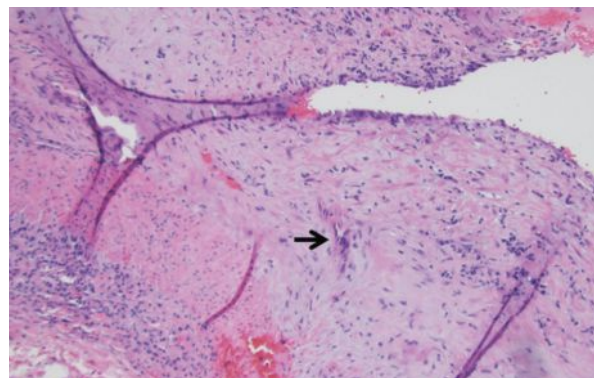


Fig. 5. Histology shows a specimen affected by temporal arteritis (the arrow indicates a multinucleated giant cell).

another medical specialist or the emergency room for the care that the patient needs. ■

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Dr. Skorin practices at the Mayo Clinic Health System in Albert Lea, Minnesota.

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2019 Income Survey: An Up and Down Year

Overall, it wasn't the best year for optometry, but certain groups did better than others.

By Catherine Manthorp, Associate Editor

As the year draws to a close, now is a good time to take stock of the financial ups and downs of 2019. This year's annual income survey saw optometrist participation grow to nearly 900 respondents who shared that their income rose, albeit incrementally, over the past year to an average of \$170,341—an increase of almost 1% from 2018. While this is good news for the profession, this year's rate is the lowest it's been in the last five years: it was 9% from 2015 to 2016, 4% from 2016 to 2017 and 3% from 2017 to 2018.

Hopefully 2020 will turn the tide of this downward trend.

This year's survey was comprised of slightly more part-time participants than last year's, making up 11% of the total respondents compared with 9% in 2018. Those 11% also fared better than their full-time colleagues this year. Full-time workers averaged an income of \$175,765 in 2019—a mere 0.35% rise over the last year—and part-timers made \$127,185 on average, an 11% surge from 2018.

As always, be mindful that while we ask the same survey questions,

the responses we compare from year to year come from different individuals, making trend analysis tricky, especially among a smaller cohort. The results are representative of the profession but aren't as accurate as they could be.

The More the Merrier

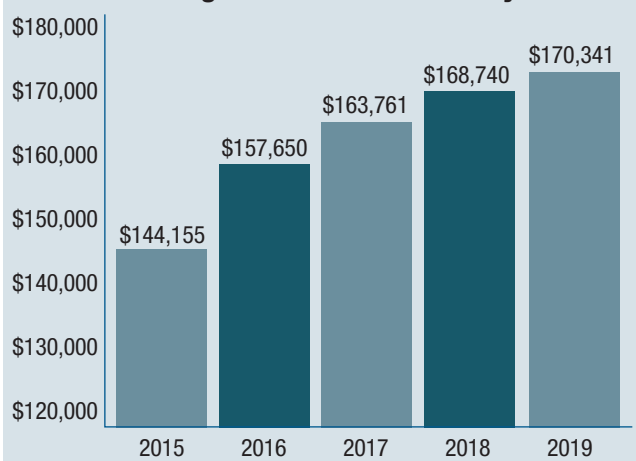
Years of experience and money made almost always coincide, and this year was no different. Entry-level respondents with zero to 10 years of experience comprised 35% of this year's survey participants and earned an average of \$144,013, a 10% jump from the average income beginners made in 2018.

The average income leap from the first experience bracket to the next one, 11 to 20 years (23% of respondents had this intermediate level of experience), was a sizable 18% to \$170,180. This also represents a 3% increase from 2018.

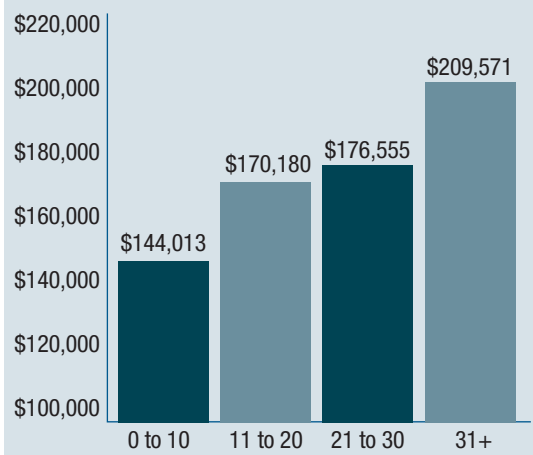
Financial progress stalled a bit for those with 21 to 30 years of experience who experienced a mid-career plateau. These clinicians made up 21% of respondents and earned an average of \$176,555, just 4% more than those with 11 to 20 years of experience. It's also a less-than-desirable 11% decrease from the average income this experience group reported in 2018.

While last year's seasoned clinicians made less than their counterparts with slightly fewer years of experience, this year's 21% of participants who have been practic-

Average Income From Year-to-year



Average Income by Years in Practice



ing for more than 30 years earned an average of \$209,571. That's a 19% jump for 10 more years of experience and a 7% increase from the average income veterans reported in 2018. While not all optometrists at different experience levels were on the right track, this group certainly was—a testament that all the years you put in do pay off.

In Charge and Living Large

Working for yourself is the dream for many. For survey respondents, it's also a profitable dream. While the majority of respondents (57%) are employed, those who are self-employed came out on top in 2019, earning an average of \$220,206, a 66% increase from those who are employed (\$132,967 on average)—similar to the 67% difference between the two categories last year. While this is a significant monetary gap, both groups saw their average income rise from 2018, with employees making 3% and self-employed workers making 2% more than last year.

Of those who are employed, 52% work for another OD or MD, 21% for a commercial firm, 9% for a hospital/VA, 6% for an HMO or a PPO and 5% for a university. Seven

percent of respondents chose the “other” option and reported taking the military, government, industry, nonprofit or private equity route, to name a few. These percentages were similar to last year's.

Employees who chose the “other” option were the least profitable, making an average of \$116,333 in 2019. This category fell a few ranks compared with last year's results.

Similar to the last two years, working for another OD or MD (\$126,887) or a university (\$129,355) were lower-paying gigs. Those who work for a commercial firm earned \$139,341 on average—comparable with 2018. Moving up from the least profitable work environment last year, those employed by a hospital/VA made an average of \$150,829 in 2019.

At the top of the employed chain for another year in a row were HMO or PPO employees who made an average of \$162,481—level with the average income their counterparts earned in 2018.

On the other hand, looking at those who are self-employed, 54% practice on their own, 29% are members of partnerships or groups and 16% are independent contractors. Less than

1% chose the “other” option.

As it was the past two years, working as an independent contractor was the least profitable option and only paid an average of \$137,853 in 2019. Those who work on their own made \$215,245 on average—a 10% boost from last year. The only respondent who chose the “other” option owns a franchise and earned an average of \$260,000 this year.

Rising above the rest in 2019 were self-employed optometrists who work in partnerships or groups, making an average of \$275,984, up 4% from 2018.

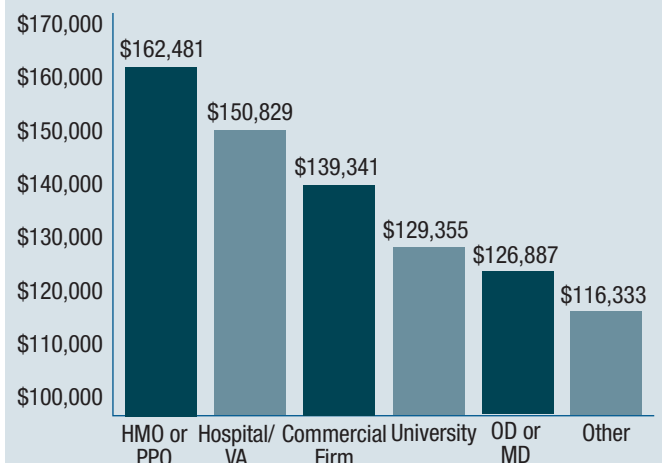
If the Price is Right, Hop on a Flight

While moving comes with its own baggage—literally—it might be worth it if you could make 17% more by calling a new place home.

Shaking things up, the Mid-Atlantic/Lower Great Lakes region was this year's most lucrative place to practice, with workers earning an average income of \$187,142, 18% more than respondents from this part of the country claimed in 2018.

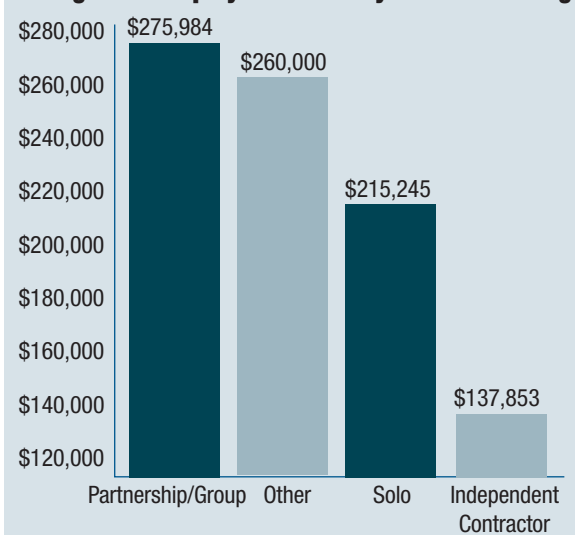
Earning an average of 7% less than those in the highest-paying region, practitioners in the South

Average Employed Income by Practice Setting



Income Survey

Average Self-employed Income by Practice Setting



were bumped down to the next highest income—\$174,519 on average, 8% less than 2018.

Neck-and-neck for the third and fourth most profitable areas of the country, respectively, were the Midwest (\$168,507) and the West (\$168,334), earning right around what they made last year. Practitioners in the Northeast were once again the least profitable, only making an average of \$159,555. However, this still represents a 4% rise from the average income reported in this region in 2018.

Gender Gap Grapple

The gender income gap has been a topic of conversation and controversy for as long as men and women have been in the workforce together. While progress has been made across the board—the disparity between men and women closed by 3% last year—it hasn't been enough to keep optometry from moving backward. Not taking full-time or part-time into account, men made 47% more than women in 2019, which means the gap widened by 10% over the past 12 months.

This year, men out-earned women

than women at the same experience level, who sat at \$131,632 on average, 2% less than last year. This represents another substantial step backwards for the category as a whole—the gap widened from 10% in 2017 to 42% in 2018 and by a similar amount this past year. This is the largest income disparity between men and women at each experience level in 2019.

The next highest income gap was between men and women with 21 to 30 years of experience. Men earned an average of \$203,165, 50% more than women with the same level of experience, who reported an average income of \$135,251. This widening gap—it was 12% in 2018—looks even worse when we throw in comparisons of what men and women with 21 to 30 years under their belts

on average \$199,068 to \$134,967 and made up the majority of respondents at 55%. Further distancing both groups, men made 4% more than their counterparts did in 2018 while women made 3% less.

At an average income of \$223,909—18% more than last year—men who have been practicing for more than 30 years earned 70% more

earned between last year and this year—13% more and 16% less, respectively.

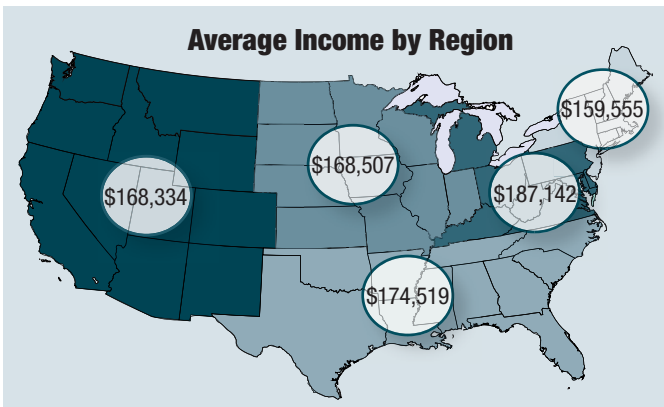
The income difference between men and women with 11 to 20 years of experience was similar at 47%, with men earning an average of \$204,456 and women, \$139,560. This disparity is up from 40% last year, with men making a similar income and women seeing their drop by 4% compared with 2018.

The less experience, the less disparity, this year's survey found. The smallest income disparity, 21%, belonged to novices with zero to 10 years in the field, with men earning \$161,088 on average and women, \$132,628. The men reported making 9% less than 2018 and the women, 6% more, closing the gap by 20% over the last year.

Looking at the Bigger Picture

With this year's financial results in the books, the majority of respondents seemed to be in good spirits, as more than 65% reported feeling satisfied or very satisfied with their income for the second year in a row. Respondents generally agreed that the amount of money they make is commensurate with their work and worth. Their annual take-home also gives them flexibility and security in their daily lives, lets them save for retirement and allows them not

Average Income by Region



Average Income by Gender



to worry about the future. Many believe the income they earn as an optometrist is the reason they're able to live comfortably, with one respondent saying it "allows me to have a quality of life I'm very satisfied with." Recent graduates reported that they are making more than they expected and are pleased with the field's profitability.

Keeping up with the generally positive attitude, almost 85% of respondents indicated they were satisfied or very satisfied with their career choice. Most named the income they make, the work-life balance they are able to strike and the opportunities available to them as the best benefits of the job. The majority said helping make a difference in others' lives is the greatest perk of all. "I decided to become an optometrist when I was 12 years old—it's all I've ever wanted to do," said one respondent.

However, some do not believe they are bringing in nearly as much as they should be with the amount of effort they put into their job and their experience level. These practitioners said they are concerned about their ability to pay off loans and the lack of raises or bonuses they've seen thus far in their careers. "It is getting harder and harder to grow a practice with all the administrative challenges, pressure from online competitors and increased

staffing costs," a respondent said.

Many are not pleased with the push to see more patients and run more tests, the cost of getting started in the profession in the first place and the ever-changing insurance requirements, with one respondent calling optometrists "glorified salesmen." Others stated the profession is becoming too commercialized and it's no surprise that it's losing respect. "Optometry has been great to me. However, I'm glad I'm retiring. I do not feel like the changes coming in the future, especially government involvement, will be pleasant," another remarked.

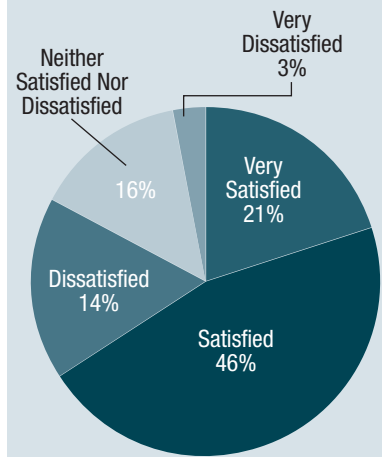
While there were some who expressed dissatisfaction, the percentages fell as the rankings became more pessimistic toward how respondents felt about their income and career choice—good signs all around—and many remained optimistic about the year to come. Of this year's respondents, 53% expect their income to increase, 40% don't expect a change at all and only 7% expect it to decrease in the future.

Eyes on the Prize

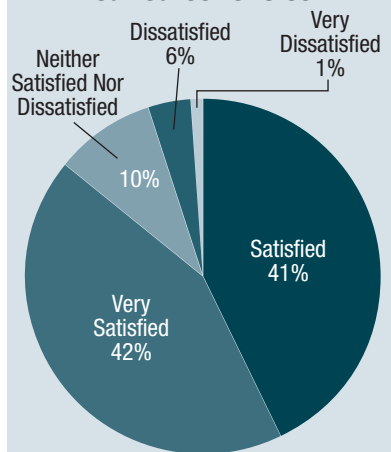
As is usually the case, some optometrists did better than others in 2019, keeping in mind factors like experience level, employment status, location and gender. We saw the mid-career plateau reappear and the gender income gap widen. The upside is that the average income continues to increase.

And optometrists are a resourceful bunch never shy of a challenge. To propel the field forward and boost their salary, many respondents have plans to increase patient awareness and volume through marketing and referrals and improve efficiency and accuracy through remodeling and staff additions. Others want to invest in equipment, specialize and expand their locations and services. ■

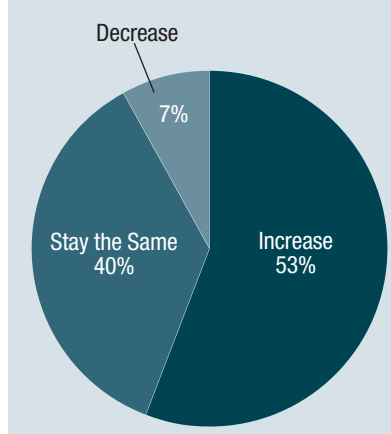
How Satisfied Are You With Your Current Income?



How Satisfied Are You With Your Career Choice?



Next Year, You Expect Your Income To...





Iron Man in the OR

Don't automatically rule out laser refractive surgery for patients with hemochromatosis.

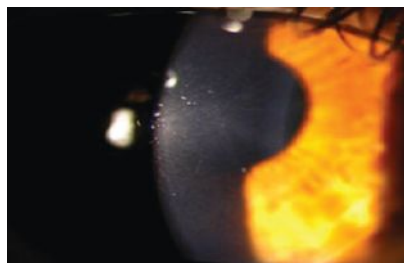
Edited by Joseph P. Shovlin, OD

Q My patient has hemochromatosis and is interested in LASIK.

There are no indications of ocular surface dryness, corneal disease or cataracts. Are there any known contraindications or concerns? Should we proceed with the surgery?

A Pigmented iron lines and deposits can occur in the corneas of healthy patients and patients with corneal pathologies, according to Vance Thompson, MD, director of refractive surgery at Vance Thompson Vision, and Mitch Ibach, OD, who practices at Vance Thompson Vision. They note that metallic foreign bodies can also leave rust rings and deposit iron in the cornea.

Hemochromatosis is a condition in which there is a buildup of iron in the body.¹ In genetic hemochromatosis, the intestines absorb too much dietary iron, which then builds up throughout the body's organs.² Acquired hemochromatosis is usually secondary to anemia—excess breakdown of red blood cells—or over-absorption caused by iron transfusions.² The human body can't excrete excess iron, and systemic damage typically takes the form of



A PRK patient two weeks post-op.

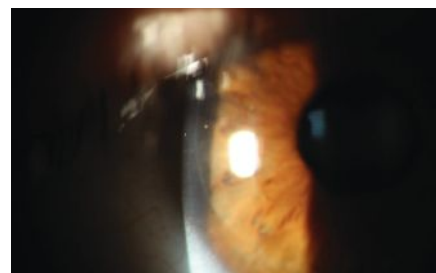
toxic oxygen free radicals that then lead to oxidative damage.³

Setting Up For Success

Prior to corneal laser refractive surgery, eye doctors must establish that the patient's tear film is healthy enough to aid in immediate healing and long-term refractive preservation, state Drs. Thompson and Ibach. Iron transport proteins lactoferrin and ferritin are both readily found in the tear film and may be dysregulated in hemochromatosis.³ Despite their iron-binding nature, over 90% of lactoferrin proteins remain unbound to iron in normal homeostasis.³ In rabbit corneas, unsaturated lactoferrin can protect against oxidative damage.³

Lactoferrin in its non-iron-bound form exhibits bactericidal properties and anti-biofilm activity.³ Analogous to lactoferrin, ferritin is also capable of warding off oxidative damage.³ In hemochromatosis patients, Drs. Thompson and Ibach say, it is possible that the positive attributes of these iron proteins are depleted but unclear if hemochromatosis has a negative effect on tear film quality or quantity.

The eye's second main refractive structure is the crystalline lens, which has three refractive stages: optically clear with sufficient accommodation, optically clear with insufficient accommodation (presbyopia) and opaque/cloudy with insufficient accommodation (cataract). The pathogenic cause of cataracts is not



A clear, well-adhered LASIK flap seen one day postoperatively.

fully understood, but evidence suggests oxidative damage plays a role.³ Drs. Thompson and Ibach highlight the importance of preoperatively educating hemochromatosis patients on the possibility of early cataract formation, which could shorten the refractive lifespan of corneal refractive surgery.

Satisfaction rates for LASIK have risen to 98%, making this elective procedure one of the most successful.⁴ Drs. Thompson and Ibach emphasize that corneal refractive surgery, like any procedure, presents risks that patients must thoroughly understand ahead of time. They believe hemochromatosis patients can safely undergo laser refractive surgery and should expect outcomes on par with the published literature. In the United States, they add, FDA-approved options including LASIK, PRK and SMILE can all confidently be recommended to this patient. ■

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Shed Some Light on DED

New IPL technology can help you meet the needs of this growing patient population.

By Paul M. Karpecki, OD

Now that we know meibomian gland dysfunction (MGD) is a common contributor to ocular surface disease, we can apply a number of new treatments that directly address the unique biology affected. From supplements and lid hygiene to in-office debridement and expression therapies, MGD treatment continues to evolve.

One approach, intense pulsed light (IPL) therapy—an off-label use of an FDA-approved device—has become more mainstream for patients with confirmed MGD, particularly if they also present with rosacea. The technology is now on its second iteration with the advent of low-level light therapy (LLLT), a new two-step approach.

What We Know about IPL

The value of IPL in dry eye was first identified in 2002, when patients treated for skin problems reported improvement in their dry eye symptoms as well.¹ The finding was good news, as more than 80% of rosacea patients have concomitant MGD.²

IPL treatments are performed with 500nm to 1,200nm light pulses for 20 to 30 minutes and can be repeated every three to five weeks. IPL can achieve clinical improvement via several potential mechanisms:³

- Thrombosis of abnormal blood vessels below the skin surrounding the eyes.



Paul Karpecki, OD
Patients with hyperemia and telangiectatic vessels are ideal IPL candidates.

- Heating the meibomian glands and liquefying the meibum.
- Activation of fibroblasts and enhancing the synthesis of new collagen fibers.
- Eradication of *Demodex* and decreasing the bacterial load on the eyelids.
- Interference with the inflammatory cycle by regulation of anti-inflammatory agents and matrix metalloproteinases.
- Reducing the turnover of skin epithelial cells and decreasing the risk of physical obstruction of the meibomian glands.
- Changes in the levels of reactive oxidative species.

IPL therapy is generally considered safe; however, traditional treatment should not be considered in patients with darker skin tones (Fitzpatrick skin types of 5 or 6) due to the risk of melanin damage and

resultant hypopigmentation.⁴

Two Therapies in One

Combined light therapy involves the application of both IPL and LLLT.⁵ LLLT is a different kind of photobiomodulation that also had its beginnings in dermatology and is now demonstrating efficacy in MGD, specifically in terms of improved tear break-up time.^{5,6}

While IPL treatment offers thermal-based effects, LLLT is athermal, and researchers believe it has additive effects on the lids and periorbital area.⁵ The presumed mechanism is photoactivation.^{5,7} The ability to apply LLLT to the upper lid, where it is generally considered unsafe to apply IPL, may further contribute to its MGD therapy success.⁵

A recent study of 460 eyes evaluated the effects of combined light therapy on patients who were unresponsive to previous medical management.⁵ The combined treatment consisted of intense short pulses of light on the area of the face around the eye followed by longer exposure to low-level red light on the cheek and over the closed lids.⁵

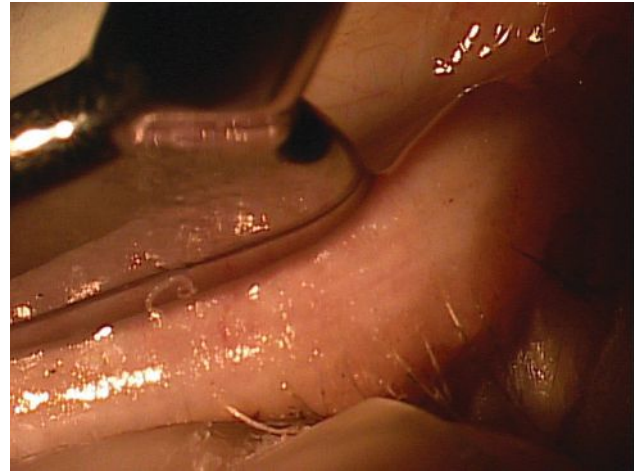
The researchers found that mean Ocular Surface Disease Index (OSDI) scores were significantly lower after combined treatment.⁵ Pre-treatment, 70.4% of patients



Paul Karpecki, OD

TSI

Telangiectasia and blepharitis in a patient with rosacea.



Paste-like meibomian expression in a patient with MGD.

had OSDI scores indicative of dry eye; after, only 29.1% did.⁵ The researchers also observed a one-step or greater reduction in MGD grading in 70% of eyes, with 28% of eyes having a two-step or greater reduction.⁵ Tear break-up time was ≤6 seconds in 86.7% of eyes pre-treatment, which dropped to 33.9% of eyes after treatment.⁵ There were no ocular or facial adverse events or side effects related to treatment.⁵

Beyond efficacy and safety, practical benefits may also inspire use of combined light therapy. Specifically,

the therapy adjusts energy levels for optimum effects based on the patient's level of MGD and their Fitzpatrick skin scale score.⁵

Furthermore, the currently available device used for this combination therapy, Eye-Light (Topcon), requires no gel thanks to a built-in cooling system of forced air that maintains the temperature of the crystal at a non-traumatic level for the patient's skin type.⁵ This may allow treatment of any patient, regardless of their Fitzpatrick skin type.

Time will tell how treatment will change with the approval of this new form of light therapy, but one thing is certain: With so many tools at our disposal, we are well equipped to treat both the signs and symptoms of dry eye and MGD with greater ease and efficacy than ever before. ■

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

IPL Procedure Basics

Although there is some variation in protocol, a standard IPL procedure begins by placing protective IPL shields over the eyes. All IPL devices, with the exception of the Eye-Light, require applying ultrasound gel to the skin to keep the treatment area cool.⁴ Clinicians should only treat the skin inferior and lateral to the lower eyelid margin, as there is risk of light penetration through the eyelid and absorption within the intraocular structures with upper eyelid treatment.⁴ For systems that require coupling gel, clinicians should remove the ultrasound gel after two passes on each side and apply a hot compress along the eyelids for two to three minutes.⁴

Research also shows expressing the meibomian glands following IPL treatment can be beneficial.^{8,9} In fact, meibum expressibility improvement might be a good therapeutic target of IPL treatment in patients with MGD and dry eye and could be an indicator of ocular surface inflammation during IPL treatment.¹⁰ In a recent study of 30 patients who underwent three IPL sessions, patients with low meibum expressibility and tear film instability experienced greater improvement in symptoms after IPL treatment.¹⁰ The improvement in meibum expressibility was also associated with a decrease in tear inflammatory cytokine levels.¹⁰

Finally, a topical steroid may be prescribed for two to three days following the procedure.⁴

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Triple 20/20

The first trifocal IOL FDA-approved for presbyopia is achieving exciting visual acuity potential. **By Katherine Rachon, OD**

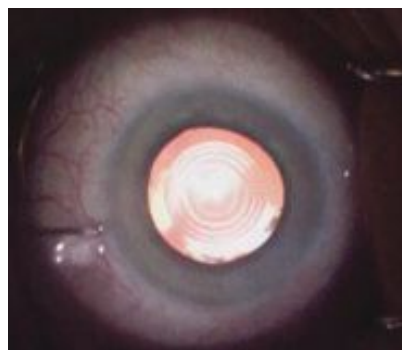
There's always a catch when discussing cataract surgery with a patient who wants to be "glasses-free." Despite the success of today's multifocal intraocular lenses (IOLs), some patients may still need glasses. Avid readers or those who rely on computers may find even a premium IOL's range lacking. With its approval earlier this year, the AcrySof IQ PanOptix (Alcon) is the latest IOL trying to help patients put away their readers for good. The lens is designed to extend the range of near and intermediate vision without sacrificing distance vision.

Lens Details

The PanOptix is a biconvex acrylic lens that uses diffractive optics in its central 4.5mm to create an intermediate focal point of 60.0cm (+1.65D) and a near point of 40.0cm (+2.35D). The lens filters UV and blue light and includes negative aberrations on its anterior surface to counteract the positive aberrations of the cornea.¹ Alcon's technology, which focuses 88% of the light on the retina, even in a 3.0mm pupil, is designed to provide a crisp image independent of pupil size.² The toric implant can correct up to 2.82D of corneal astigmatism.¹

Research Findings

While under investigation, researchers measured uncorrected binocular vision at the six-month follow up for 256 eyes that received the PanOptix and found 92% of patients saw 20/25 or better at dis-



Most patients (94%) are very satisfied with the new PanOptix trifocal IOL.

tance, 94% at 66.0cm and 91% at 40.0cm.¹ In a small study of various lens designs, the PanOptix achieved near vision of 20/32+.³

Researchers also compared the PanOptix with the Restor IOL (Alcon) "blend," which uses a +2.5D lens in the dominant eye and +3.0D in the other to enhance intermediate vision. They found uncorrected binocular distance acuity was 20/20 with PanOptix and 20/25 with Restor. Intermediate acuities were 20/25 and 20/32, while near vision measured 20/20 and 20/25, respectively.⁴

When surveyed on visual satisfaction, 94% of patients were "very satisfied," 98% would recommend the lens and 99% would choose the PanOptix lens again if they had a choice.¹ In response to how often they needed glasses, 81% of patients answered "never" for distance, 94% for arm's length and 84% for near.

Although the visual acuities and contentment are promising, the study's exclusion criteria included

conditions such as iritis, glaucoma and previous refractive surgery. Complaints of glare and halos were minimal—only 4.8% of patients were symptomatic at six months. While 13% showed posterior opacification at six months, the study did not include whether Nd:YAG capsulotomy was necessary.¹ As use of PanOptix grows, we will see longer-term data and a more realistic expectation for patients excluded from the first investigation.

The enhanced visual acuities achieved with the trifocal make for an exciting option for patients. Still, this lens is not a cure-all and should be avoided in patients who are sensitive to glare or have macular disease or untreated ocular surface disease. In addition, patients can expect a "premium IOL" charge ranging in the low thousands per eye. Educating patients on this new option can help them make an informed decision that might increase their quality of life. ■

Katherine Rachon practices at Virginia Eye Consultants, a referral-based tertiary care center in Norfolk, VA.

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Piecing It All Together

Glaucoma care must rely first on clinical acumen and second on imaging technology.

By James L. Fanelli, OD

When glaucoma patients move in to your area and wish to establish care with you, some will have a long history of closely monitored disease, whereas others will be recently diagnosed and bring with them, essentially, no assurance that they are stable. In either case, it's imperative that you are prepared to evaluate and manage them. Given that most cases of glaucoma fall in to the mild-to-moderate category, glaucoma is the consummate debilitating disease manageable by optometrists.

Technological advances, particularly those in optic nerve imaging, have played a huge role in expanding our ability to detect disease at earlier stages than previously possible.

But these devices also come with an almost overwhelming amount of data to sift through. Sometimes the data is daunting and doesn't necessarily 'fit' with what we are seeing clinically, clouding the issue. But at the end of the day, no instrument can outrank clinical judgment.

Diagnostic Data

Several technological developments can help us put the pieces of the glaucoma puzzle together. Over the past several years—at the Optometric Glaucoma Society meetings, in particular—world-renowned experts have offered insight into instruments that can help us with

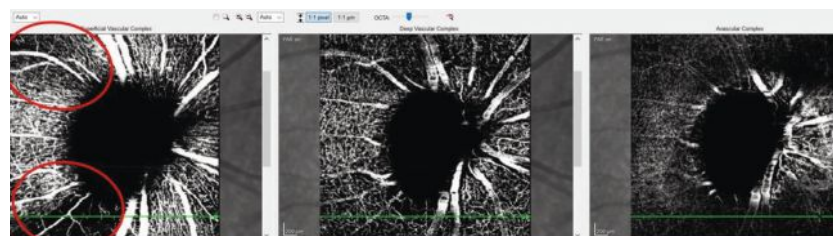


Fig. 1. These OCT-A images show a patient with advanced glaucoma. Note the areas of decreased vascular density (circled in red). They coincide nicely with the superior temporal and inferior temporal RNFL sectors that are preferentially damaged in glaucoma.

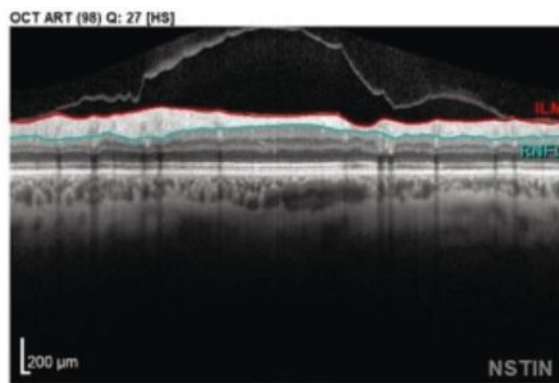
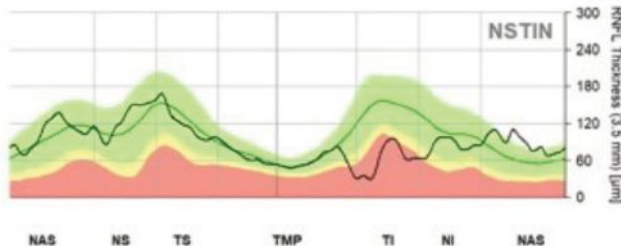


Fig. 2. This peripapillary RNFL circle B scan image and NSTIN plot shows a patient with glaucomatous structural damage in the inferotemporal sector. Note the contiguity of the entire temporal RNFL scan in this format.



day-to-day clinical evaluations. But sometimes, simply looking at the optic nerve in a different way can help complete the picture.

Recently, a new patient presented with a history of glaucoma over

nearly two decades. His disease was advanced enough that imaging was not necessary to tell us if he has disease, but it is imperative in telling us if his disease is worsening.

A review of the patient's records

demonstrated visual field defects consistent with the extent of glaucomatous damage in both eyes. OCT imaging was obtained and the processing of the images present a good opportunity to discuss new and upcoming ways that we will be looking at OCT scans in the near future.

Tools of the Trade

One of the relatively recent advances in OCT imaging centers around identifying Bruch's membrane opening (BMO) in the optic disc and using its edge as a landmark to evaluate the thickness of the more medial tissue, the ganglion cells. The concept of minimum rim width (MRW) is a measure of the ganglion cell thickness in the neuroretinal rim of the optic nerve as measured from the BMO to the shortest point of the innermost edge of the ganglion cells. This thickness is termed the BMO-MRW.

OCT angiography (OCT-A) is a relatively new adjunct to OCT that helps us visualize various anatomical layers of retinal and optic nerve vasculature. While this is helpful, researchers are still evaluating what constitutes a normal vascular appearance. Patients with glaucomatous damage will have concurrent ganglion cell and retinal nerve fiber layer (RNFL) aberrations (i.e., loss and reduction of tissue volume), and reduced tissue volume requires less vascular supply to nourish the remaining tissue. But what is not clear is which comes first in the course of the disease: reduced RNFL volume or a reduction in associated vascular supply to the area. The answer simply is unknown—and may potentially be a bit of both. So, while OCT-A is helpful in making sense of the clinical picture, the metrics are not yet specific enough to pinpoint exact diagnostic decisions (Figure 1).

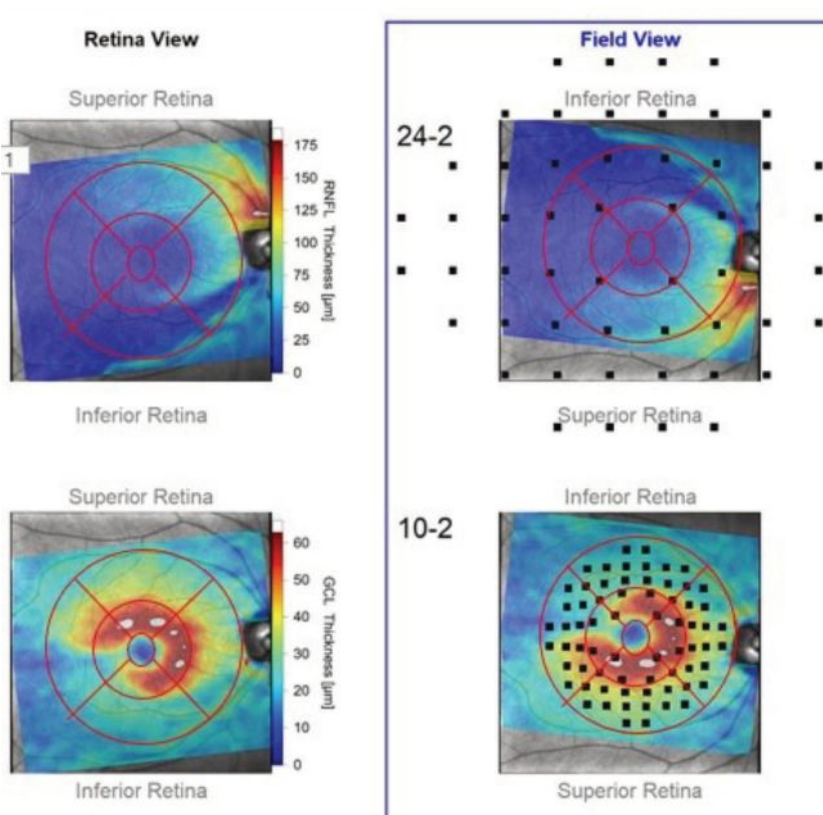


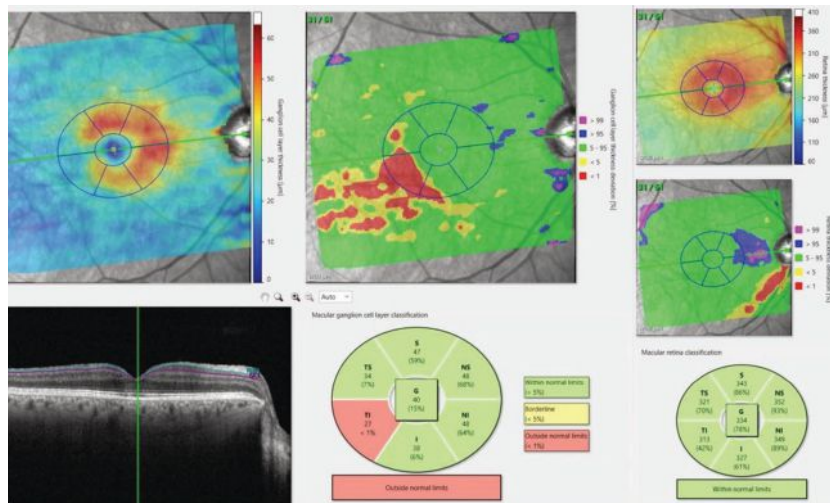
Fig. 3. These RNFL diameter circle scans show the patient's right eye. Note the stability of the innermost RNFL circle scan of the most recent visit compared with the baseline visit obtained 18 months earlier. Where there is a difference between the scans, the thickness differences overlay major peripoptic retinal blood vessels.

The Order of Operations

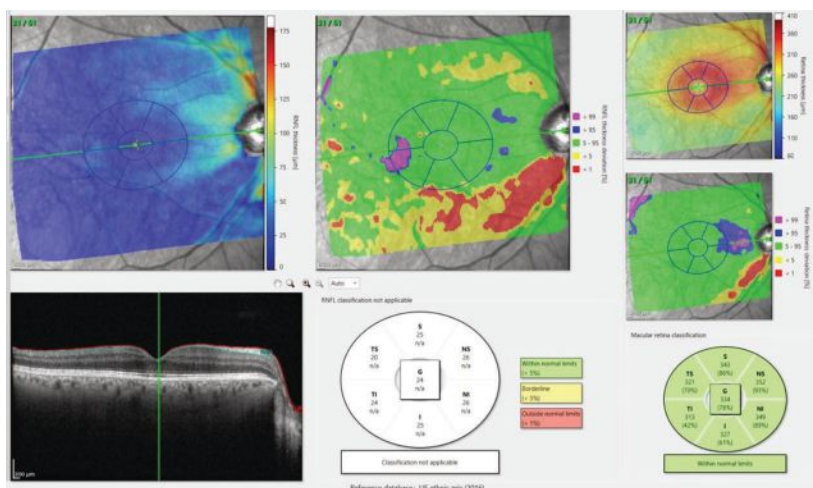
In the near future, we'll be seeing changes in how we visualize the peripoptic neuroretinal rim scans. We've already moved from one RNFL circle scan to three, each with varying diameters, enabling us to look at the RNFL further away from the optic nerve than previously. But all RNFL circle scans have been predicated upon the order in which the scans were obtained: temporal, superior, nasal, inferior and, finally, back to the temporal sector—this is visualized as the TSNIT graph, which, in a healthy non glaucomatous eye, will have a classic “double hump” appearance, with the humps coinciding with the ST and IT sectors

of the peripoptic RNFL, which typically are the thickest sectors.

But in reality, starting our RNFL circle scan in the middle of the macular fibers and ending in this same area puts the macular RNFL data at the lateral ends of the TSNIT graph. Since more than half of the ganglion cells originate in the macula early glaucomatous loss can be detected in the macula. With this in mind, instead of plotting the RNFL with the macular fibers on each end of the plot, some research is showing an advantage to starting the scan nasally and making a full, uninterrupted sweep through the temporal and macular fibers (NSTIN) where glaucoma can be detected.¹



Figs. 4a and 4b. The deviation map in 4a (above) highlights an area in the temporal, inferior macula of loss of ganglion cell bodies, which matches up nicely with figure 4b (below), which shows the comparable damaged RNFL axons in the same eye.



Note in imaging a familiar look to the NSTIN plotting, but with the added benefit of the superior temporal, the temporal and the inferior temporal RNFL all located adjacent to each other (Figure 2). Furthermore, research now overlaps the points tested in a 24-2 or a 10-2 visual field to the anatomically matched macular regions.¹ This is especially valuable as it allows us to use structural data gathered from OCT scans to help target the type of visual field strategy for individual patients.

Take, for example, this “retina view” map of the RNFL and ganglion cell layer thicknesses as they appear anatomically in a patient’s right eye (Figure 3). In the adjacent “field view,” the anatomical maps are turned upside down (to match the points tested in a visual field exam), over which the testing points of both a 24-2 and 10-2 strategies are superimposed. You can see in the retina views, both ganglion cell somatic loss as well as corresponding RNFL loss. But when overlaying the field testing

points in the field view, you can see that only four or five points in the 24-2 testing strategy would indicate a defect, whereas we’d see many more test defective in a 10-2 strategy.

Deviation Maps

Coinciding with this recent research, the development of deviation maps of ganglion cell thickness and RNFL thickness measures in the macula as compared with a reference database.¹ Given the high resolution available with OCT, it makes sense to look specifically at RNFL and ganglion cell layers in the macula when looking at glaucomatous eyes.

While the ganglion cell complex (GCC) has been commonly referenced in discussion of glaucoma pathogenesis, the ability to look solely at the ganglion cell layer becomes incredibly important in detecting early disease. The ganglion cell layer consists of the cell bodies of the ganglion cells, and the RNFL consists of the axons of these same cells. By visualizing these layers and comparing them with a reference database, optometrists can easily appreciate deviation from the norm (Figure 4).

Glaucoma remains a puzzle, and the pieces don’t always fit together. But with the energy behind new ideas and techniques, optometry is getting to the point where the technology is going to be facilitate fitting those pieces together. With the right marriage of our individual clinical expertise, our collective research and advanced technologies, our ability to care for glaucoma patients will ultimately be more precise. ■

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Product Review

Contact Lenses

Myopia Control Now On-label

Optometrists fitting pediatric patients with myopia control lenses will soon have an on-label indication with the recent FDA approval of CooperVision's MiSight 1 day contact lens. The omafilcon A lens is designed for children ages eight to 12 who have a myopia prescription from -0.25D to -6.00D. According to CooperVision, the lens's design results in clear distance, intermediate and near vision with peripheral treatment zones that create myopic retinal defocus.



MiSight 1 day will launch in the United States as part of CooperVision's myopia management initiative in March 2020, according to a company release.

New Scleral Lens Design Software

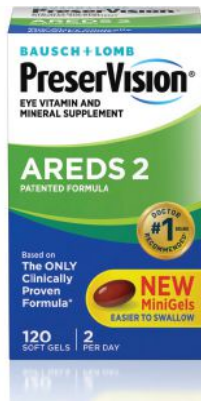
Clinicians who find scleral lens design concepts to be a challenge can consider EyePrint Prosthetics' new ScanFitPro software, which seeks to improve accuracy and confidence in the results.

The algorithm uses the Pentacam's Corneal Scleral Profile report, generated by 250 Scheimpflug images covering a diameter of up to 17mm. All images are taken in a straight-on gaze, preventing off-axis elevation disparities, the company says. ScanFitPro automatically designs a lens in 3D space and gives the user the ability to customize from there. The topographical data is combined with an iris image overlay to allow the physician to visualize the device on the eye.

Nutrition

AMD Protection That's Easy to Swallow

If your patients in need of an AREDS vitamin complain of difficulty swallowing bulky pills—and use that as an excuse for non-compliance—now you can recommend a more gentle option. Bausch + Lomb recently launched PreserVision AREDS 2 Formula minigel vitamins.



Aside from that change, there are no differences in the ingredients or recommended uses compared with the older formulation, B+L says.

PreserVision AREDS 2 minigel eye vitamins are available at major retailers nationwide at a suggested retail price of \$32.99 for a 120-count bottle, according to B+L. ■

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Macro Management

Imaging helps unveil an unusual presentation in an otherwise healthy teenage patient.

By David Schaeffer, OD, and Mark T. Dunbar, OD

A 16-year-old Caucasian male presented for routine comprehensive eye exam and contact lens evaluation. He reported no vision problems and just wanted to update his contact lens prescription.

His best-corrected visual acuities were 20/25 OD, 20/20 OS. Confrontation fields were full-to-finger count, extraocular muscles exhibited full range of motion and pupils were equal, round and reactive to light without afferent pupillary defect.

Slit lamp examination was unremarkable. Intraocular pressures were 19mm Hg OD and 17mm Hg OS via iCare tonometer (iCare). A dilated fundus exam revealed retinal vascular changes (Figure 1). The red-free image of the right eye is also available (Figure 1b). Optical coherence tomography (OCT) of the right eye's macula was performed (Figure 2).

Take the Quiz

- How would you best describe the vascular findings in Figure 1?
 - Retinal neovascularization.
 - Shunt vessels (collaterals).
 - Dilated and aberrant macular vessel crossing horizontal raphe.
 - Retinal hemangioma.
- How would you characterize the findings at the junction of inner and outer retina in the OCT of the right eye in Figure 2?
 - Hard exudates.
 - Large vessels in deep capillary

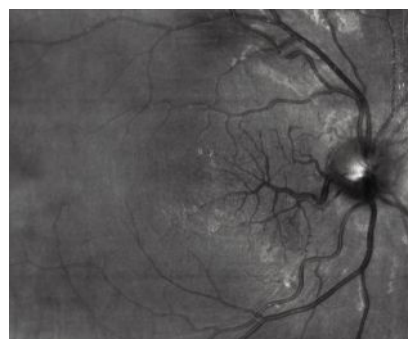
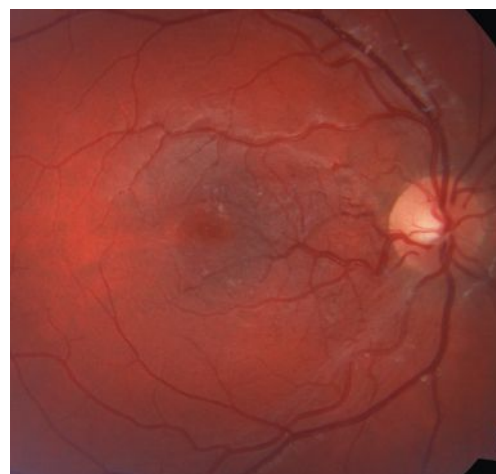


Fig. 1a. and 1b. This fundus (above) and the red-free image of our 16-year-old patient's right eye shows an unusual retinal finding. Can you identify the patient's condition?

- plexus.
 - Foveal cyst.
 - Both b and c.
- What is the correct diagnosis?
 - Retinal venous malformation (congenital retinal macrovessel).
 - Retinal capillary hemangioma.
 - Branch retinal vein occlusion.
 - Neovascularization.

- What other testing would you order?
 - Genetic testing.
 - Blood pressure.
 - Carotid imaging.
 - Neuroimaging.
- What other clinical condition/finding is associated with this retinal finding?
 - Vascular malformation of the brain.
 - Von Hippel-Lindau syndrome.
 - Strawberry hemangioma.
 - Port wine stain.

For answers, see page 82.

Diagnosis

This patient presented with a large aberrant vessel in his right eye, which we determined was a retinal venous malformation (RVM), also known as congenital retinal macrovessel. RVM is a dilated, aberrant vein that traverses the foveal region and crosses the horizontal raphe.^{1,2} It can originate either as a branch of one of the arcades, from the central retinal vein or from its immediate branches at the disc. It presents unilaterally and is usually found incidentally, due to minimal or no effect on visual acuity.^{1,2}

RVM is rare, with an estimated incidence of 1:200,000, though that may be an underestimation since patients are typically asymptomatic.² RVM is non-progressive, and visual/ocular prognosis is excellent. However, recent studies show a cor-

relation between RVM and vascular malformations of the brain, which can have significant complications.^{2,3} Our patient was promptly sent for brain MRI.

Visual acuity may be affected in cases where:

- (1) Tributaries of the abnormal vessel cross over the foveola.
- (2) There is a presence of a foveolar cyst.
- (3) There are changes to foveal avascular zone.^{1,4}

Some cases report retinal hemorrhage or central serous retinopathy associated with RVM, but these may be coincidental or due to other underlying etiologies.^{2,4} Though acuity may not be affected in most patients, one study determined that retinal sensitivity can be reduced in the area of the aberrant vessels despite normal Snellen acuity.⁵

Discussion

In our case, the slightly reduced acuity is possibly due to the epiretinal membrane-like structural changes, foveal cyst and abnormal vessels within the foveola. Though neither fluorescein angiography nor OCT angiography has been done on this patient, large vessels are visible in the deep capillary plexus on OCT within the fovea, and it is plausible that small tributaries of these vessels course through the foveola.

Fluorescein angiography of RVM reveals early filling and late emptying. Sometimes there are areas of capillary non-perfusion adjacent to the aberrant vessel or remodeling of the foveal avascular zone. Microaneurysm-like changes can also be seen. However, in none of these cases is there leakage from the RVM.^{1,4} Because there is no leakage, it is proposed that foveal cysts form secondary to perfusion abnormalities and that the microaneurysm-like

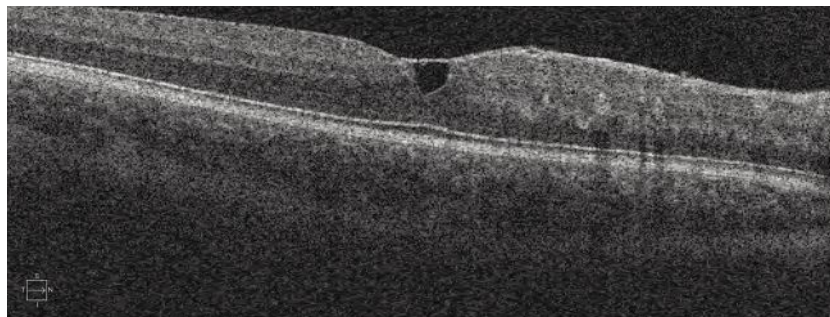


Fig. 2. We also obtained this SD-OCT image of the macula of the patient's right eye.

changes are just large vessels viewed *en face*.¹

A proposed etiology is that RVM originates in the 15th or 16th week of gestation when pre-endothelial mesenchymal cells invade nerve fiber layer from the hyaloid artery at the optic disc. These cells eventually differentiate and mature into blood vessels and, researchers believe, during the maturation process one of these vessels enlarges and positions inappropriately.^{1,6} The stimulus for this event is unknown.^{1,6}

Most importantly, a significant correlation exists between RVM and vascular malformations of the brain. One retrospective study looked at 49 patients across the globe determined to have RVM. In the 12 who were found to have either a venous or cavernous malformation of the brain, the abnormality was ipsilateral in 85% and in the frontal lobe in 75%.²

This study suggests a rate of 24% of vascular malformation of the brain in the presence of an RVM, but this may be an underestimation since only 27 patients had neuroimaging done and 44% of those MRIs had vascular abnormalities.² Compared with a rate of 0.2% to 6.0% of brain venous malformations in the general public, this study clearly demonstrates a strong correlation between RVM and venous malformation of the brain.² Based on these

neurologic findings and retinal vessel appearance, researchers believe RVM may be a milder variant of racemose angiomas (Wyburn-Mason syndrome).^{4,6}

Recent publications encourage using the term *retinal venous malformation* rather than *congenital retinal macrovessel* to highlight the correlation between RVM and venous malformation of the brain and to emphasize the importance of ordering neuroimaging.^{2,4}

At this time, our patient has yet to undergo neuroimaging and is currently scheduled for a CT angiography and brain MRI. ■

Dr. Schaeffer graduated from the Illinois College of Optometry in 2017, and completed his residency training in ocular disease at Bascom Palmer Eye Institute. He is currently providing primary eye care with MyEyeDr in Birmingham, AL.

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Of Grave Concern?

By Andrew S. Gurwood, OD

History

A 66-year-old woman came to the office with a chief complaint of dry, scratchy eyes which she had been experiencing for the previous six months. She explained that the problem had been worsening despite her general practitioner treating her with artificial tear drops.

She had no known previous ocular disease and reported a systemic history of hypertension for which she was properly medicated with lisinopril. She reported no allergies.

Diagnostic Data

Her best-corrected visual acuities were 20/30 OD and 20/30 OS at distance and 20/40 at near, both eyes. External examination was normal and there was no evidence of afferent pupillary defect. Refraction revealed symmetrical, spherical myopia with a changes in the carrier and add that yielded 20/25 acuity at distance and near. The pertinent



What can this patient's anterior segment presentation tell you about the likely cause of her dry and scratchy eyes?

anterior segment findings are demonstrated in the photograph. Intraocular pressures were measured with Goldman applanation at 19mm Hg, OU. The dilated fundus examination revealed normal posterior poles, without evidence of choroidal folds, hypertensive retinopathy or peripheral pathology.

Your Diagnosis

Does the case presented require any additional tests, history or information? Based on the information provided, what would be your diagnosis? What is the patient's likely prognosis? To find out, please visit us at www.reviewofoptometry.com. ■

Retina Quiz Answers (from page 78): 1) c; 2) d; 3) a; 4) d; 5) a.

Next Month in the Mag

Coming in January, *Review of Optometry* will present an issue on vision care.

Topics include:

- *How to Build a Myopia Control Clinic*
- *Better Ways to Perform VAs*

- *Treating Binocular Vision Problems in Children and Adults*
- *How Presbyopia Management is Changing*
- *Low Vision: When to Recommend*

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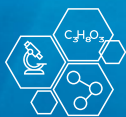
- *Who Really Has Dry Eye Disease?* (Earn 2 CE Credits)

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