Earn 2 CE Credits — Top 100 Drugs: Which are *Your* Patients Taking?, **p. 83**

REVIEW® OF OPTOMETRY

SEPTEMBER 15, 2016

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39TH ANNUAL TECHNOLOGY REPORT: FOCUS ON IMAGING

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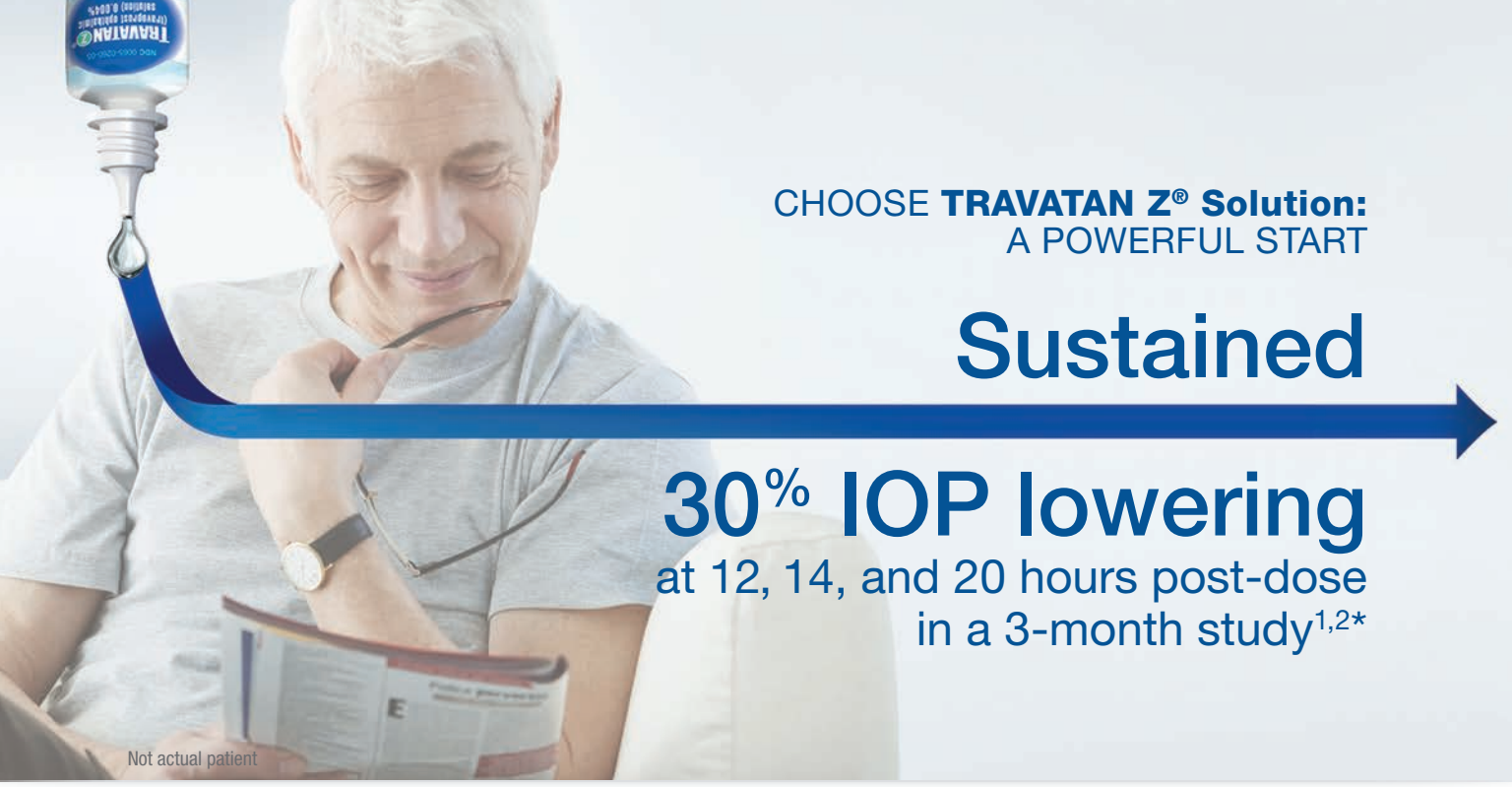

CHOOSE **TRAVATAN Z® Solution:**
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in a 3-month study[1,2*]

TRAVATAN Z® Solution has no FDA-approved therapeutic equivalent available

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INDICATIONS AND USAGE

TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration

The recommended dosage is 1 drop in the affected eye(s) once daily in the evening. TRAVATAN Z® Solution should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the IOP-lowering effect.

TRAVATAN Z® Solution may be used concomitantly with other topical ophthalmic drug products to lower IOP. If more than 1 topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Pigmentation—Travoprost ophthalmic solution has been reported to increase the pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as travoprost is administered. After discontinuation of travoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. The long-term effects of increased pigmentation are not known. While treatment with TRAVATAN Z® Solution can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes—TRAVATAN Z® Solution may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Use With Contact Lenses—Contact lenses should be removed prior to instillation of TRAVATAN Z® Solution and may be reinserted 15 minutes following its administration.

Adverse Reactions

The most common adverse reaction observed in controlled clinical studies with TRAVATAN Z® Solution was ocular hyperemia, which was reported in 30 to 50% of patients. Up to 3% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse reactions reported at an incidence of 5 to 10% in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain, and pruritus. In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

Use in Specific Populations

Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

For additional information about TRAVATAN Z® Solution, please see the brief summary of Prescribing Information on the adjacent page.

*Study Design: Double-masked, randomized, parallel-group, multicenter non-inferiority comparison of the efficacy and safety of travoprost 0.004% preserved with benzalkonium chloride (BAK) to TRAVATAN Z® Solution after 3 months of treatment in patients with open-angle glaucoma or ocular hypertension. Baseline IOPs were 27.0 mm Hg (n=322), 25.5 mm Hg (n=322), and 24.8 mm Hg (n=322) at 8 AM, 10 AM, and 4 PM for TRAVATAN Z® Solution. At the end of Month 3, the TRAVATAN Z® Solution group had mean IOPs (95% CI) of 18.7 mm Hg (-0.4, 0.5), 17.7 mm Hg (-0.4, 0.6), and 17.4 mm Hg (-0.2, 0.8) at 8 AM, 10 AM, and 4 PM, respectively. Statistical equivalent reductions in IOP (95% confidence interval about the treatment differences were entirely within ±1.5 mm Hg) were demonstrated between the treatments at all study visits during the 3 months of treatment.

References: 1. Data on file, 2013. **2.** Lewis RA, Katz GJ, Weiss MJ, et al. Travoprost 0.004% with and without benzalkonium chloride: a comparison of safety and efficacy. *J Glaucoma.* 2007;16(1):98-103.

TRAVATAN Z®
(travoprost ophthalmic solution) 0.004%

Alcon®
a Novartis company

TRAVATAN Z®
(travoprost ophthalmic solution) 0.004%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION
The recommended dosage is one drop in the affected eye(s) once daily in the evening.
TRAVATAN Z® (travoprost ophthalmic solution) should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the intraocular pressure lowering effect.

Reduction of the intraocular pressure starts approximately 2 hours after the first administration with maximum effect reached after 12 hours.

TRAVATAN Z® Solution may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
Pigmentation
Travoprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as travoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of travoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with TRAVATAN Z® (travoprost ophthalmic solution) 0.004% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes
TRAVATAN Z® Solution may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
TRAVATAN Z® Solution should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema
Macular edema, including cystoid macular edema, has been reported during treatment with travoprost ophthalmic solution. TRAVATAN Z® Solution should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Angle-closure, Inflammatory or Neovascular Glaucoma
TRAVATAN Z® Solution has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

Bacterial Keratitis
There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

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

ADVERSE REACTIONS
Clinical Studies Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The most common adverse reaction observed in controlled clinical studies with TRAVATAN® (travoprost ophthalmic solution) 0.004% and TRAVATAN Z® (travoprost ophthalmic solution) 0.004% was ocular hyperemia which was reported in 30 to 50% of patients. Up to 3% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse reactions reported at an incidence of 5 to 10% in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritus. Ocular adverse reactions reported at an incidence of 1 to 4% in clinical studies with TRAVATAN® or TRAVATAN Z® Solutions included abnormal vision, blepharitis, blurred vision, cataract, conjunctivitis, corneal staining, dry eye, iris discoloration, keratitis, lid margin crusting, ocular inflammation, photophobia, subconjunctival hemorrhage and tearing.

Nonocular adverse reactions reported at an incidence of 1 to 5% in these clinical studies were allergy, angina pectoris, anxiety, arthritis, back pain, bradycardia, bronchitis, chest pain, cold/flu syndrome, depression, dyspepsia, gastrointestinal disorder, headache, hypercholesterolemia, hypertension, hypotension, infection, pain, prostate disorder, sinusitis, urinary incontinence and urinary tract infections.

In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C
Teratogenic effects: Travoprost was teratogenic in rats, at an intravenous (IV) dose up to 10 mcg/kg/day (250 times the maximal recommended human ocular dose (MRHOD), evidenced by an increase in the incidence of skeletal malformations as well as external and visceral malformations, such as fused sternebrae, domed head and hydrocephaly. Travoprost was not teratogenic in rats at IV doses up to 3 mcg/kg/day (75 times the MRHOD), or in mice at subcutaneous doses up to 1 mcg/kg/day (25 times the MRHOD). Travoprost produced an increase in post-implantation losses and a decrease in fetal viability in rats at IV doses > 3 mcg/kg/day (75 times the MRHOD) and in mice at subcutaneous doses > 0.3 mcg/kg/day (7.5 times the MRHOD).

In the offspring of female rats that received travoprost subcutaneously from Day 7 of pregnancy to lactation Day 21 at doses of ≥ 0.12 mcg/kg/day (3 times the MRHOD), the incidence of postnatal mortality was increased, and neonatal body weight gain was decreased. Neonatal development was also affected, evidenced by delayed eye opening, pinna detachment and preputial separation, and by decreased motor activity.

There are no adequate and well-controlled studies of TRAVATAN Z® (travoprost ophthalmic solution) 0.004% administration in pregnant women. Because animal reproductive studies are not always predictive of human response, TRAVATAN Z® Solution should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
A study in lactating rats demonstrated that radiolabeled travoprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRAVATAN Z® Solution is administered to a nursing woman.

Pediatric Use
Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

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

Hepatic and Renal Impairment
Travoprost ophthalmic solution 0.004% has been studied in patients with hepatic impairment and also in patients with renal impairment. No clinically relevant changes in hematology, blood chemistry, or urinalysis laboratory data were observed in these patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Two-year carcinogenicity studies in mice and rats at subcutaneous doses of 10, 30, or 100 mcg/kg/day did not show any evidence of carcinogenic potential. However, at 100 mcg/kg/day, male rats were only treated for 82 weeks, and the maximum tolerated dose (MTD) was not reached in the mouse study. The high dose (100 mcg/kg) corresponds to exposure levels over 400 times the human exposure at the maximum recommended human ocular dose (MRHOD) of 0.04 mcg/kg, based on plasma active drug levels. Travoprost was not mutagenic in the Ames test, mouse micronucleus test or rat chromosome aberration assay. A slight increase in the mutant frequency was observed in one of two mouse lymphoma assays in the presence of rat S-9 activation enzymes.

Travoprost did not affect mating or fertility indices in male or female rats at subcutaneous doses up to 10 mcg/kg/day [250 times the maximum recommended human ocular dose of 0.04 mcg/kg/day on a mcg/kg basis (MRHOD)]. At 10 mcg/kg/day, the mean number of corpora lutea was reduced, and the post-implantation losses were increased. These effects were not observed at 3 mcg/kg/day (75 times the MRHOD).

PATIENT COUNSELING INFORMATION
Potential for Pigmentation
Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of TRAVATAN Z® (travoprost ophthalmic solution) 0.004%.

Potential for Eyelash Changes
Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with TRAVATAN Z® Solution. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container
Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

When to Seek Physician Advice
Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of TRAVATAN Z® Solution.

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

Use with Other Ophthalmic Drugs
If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Rx Only
U.S. Patent Nos. 5,631,287; 5,889,052, 6,011,062; 6,235,781; 6,503,497; and 6,849,253

Alcon®

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Fort Worth, Texas 76134 USA

10/15 US-TRZ-15-E-0278

VOL. 153 NO. 9 ■ SEPTEMBER 15, 2016

IN THE NEWS

A handheld device created by engineers and physicians at Duke University has allowed them to **perform scanning laser ophthalmoscopy and optical coherence tomography** of the parafoveal photoreceptor structure **in infants and children without the need for adaptive optics**, according to a study published in *Nature Photonics*. The device, which weighs only 94g, could eventually give a much better picture of how the **retina matures with age**.

A recent systematic review, published by *The Cochrane Library*, found that treating **simple corneal abrasions with a patch may not improve healing or reduce pain**. The review, which included 12 trials and a total of 1,080 participants, found patients receiving a patch may be less likely to have a healed corneal abrasion after 24 hours compared with those not receiving a patch. Further research should focus on better quality trials and examining the effectiveness of patching for large abrasions, the authors conclude.

Allergan recently announced it will acquire ForSight Vision5, a biotechnology company that has developed a **peri-ocular ring designed for extended drug delivery**. The preservative-free, noninvasive ring rests on the surface of the eye and releases bimatoprost over multiple months to lower elevated IOP in glaucoma and ocular hypertensive patients. The first randomized, controlled Phase 2 study comparing the ring to twice-daily timolol drops demonstrated that one administration of the ring provided **sustained IOP reduction for six months** with a reduction of 4mm Hg to 6mm Hg at 12 weeks.

LASIK Trumps CL Wear, Patients Report

Trading in contact lenses for LASIK makes patients happier with their vision years after the procedure.

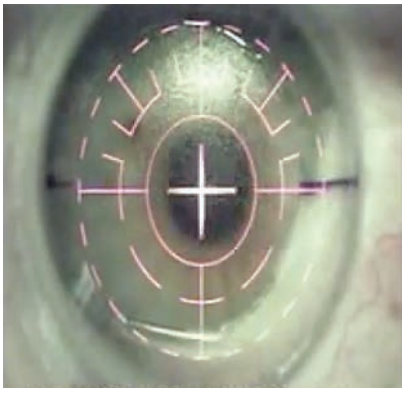
By Rebecca Hepp, Senior Associate Editor

A recent study published in the August issue of *Ophthalmology* found that contact lens wearers who chose to have LASIK were more satisfied with their vision compared with patients who continued with contact lens wear—and their satisfaction increased two and even three years post-procedure.

Using follow-up surveys, the study found contact lens satisfaction declined with time, as 63% of patients initially expressed strong satisfaction with contact lens wear at the beginning of the study, and only 54% expressed the same sentiment by year three.

"This study shows that the control arm of contact lens wearers became less satisfied with their contacts over time, which makes it even more important for us to ask how their current vision correction affects their quality of life," says Walter O. Whitley, OD, of Virginia Eye Consultants. "It reinforces the importance of optometrists staying involved in educating patients on all refractive treatment options available, including LASIK."

LASIK patients in the study consistently expressed strong satisfaction: 88% of former contact lens users and 77% of former glasses wearers reported being strongly satisfied with LASIK at year three, which was consistent with responses at years one and two.



Patient self-reported data suggests LASIK provides better vision long-term compared with contact lens wear.

"With the efficacy, safety and patient satisfaction rates at an all-time high, LASIK surgery will continue to be a popular refractive option," Dr. Whitley says. "Patients need to know what we do, and we need to proactively educate our patients that LASIK is a great option for many. Just like we do for vision and medical eye care, we need to advertise and market our refractive surgery services because if we don't, patients will bypass our practices and go straight to the LASIK center. Optometry needs to be their source of information."

Price MO, Price DA, Bucci FA Jr, et al. Three-year longitudinal survey comparing visual satisfaction with LASIK and contact lenses. Ophthalmology. 2016;123(8):1659-66.

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Overnight IOP Monitoring Reveals OSAS, Glaucoma Link

A new study found an unexpected correlation between obstructive sleep apnea syndrome (OSAS) and glaucoma using a contact lens sensor (CLS) to monitored intraocular pressure (IOP) changes when patients stopped breathing during sleep.

The prospective cohort study involved seven OSAS patients with no ocular disease other than mild cataracts. The subjects underwent continuous, CLS-based IOP monitoring with overnight polysomnography. Nocturnal IOP records were categorized into apnea IOP and nonapnea IOP, and researchers statistically analyzed the differences between IOP levels in these two distinct phases. They concluded that, in patients with OSAS, obstructive apnea led to an immediate IOP decline during nocturnal sleep.

Hypoxic effects were also observed with breathing cessation, causing blood oxygen levels to drop and possibly triggering optic nerve damage. "What's interesting in this study is that, as IOP was measured continuously throughout the night, they found IOP actually decreased during apnea episodes," says James Fanelli, OD. "The authors postulate that this IOP reduction is due to decreased intrathoracic pressure that occurs during episodes of nonbreathing. At the end of the day, though, during episodes of apnea, O_2 levels are decreased, leading to a hypoxic situation, which in turn manifests as the basis of a variety of cardiovascular diseases associated with OSAS. This hypoxic situation, in turn, also affects perfusion and oxygenation of the optic nerve."

Optic nerve damage resulting from hypoxia can occur without a spike in eye pressure—a finding that could clarify the specific nature of glaucoma with normal eye pressure levels. "We also need to keep in mind that other studies have indicated that IOP tends to increase during nighttime sleep and blood pressure tends to decrease at this same time, further compromising perfusion to the optic nerve," Dr. Fanelli says. "Compounding the issue more is the topic of translaminar pressure gradients. During episodes of sleep apnea, intracranial pressure increases as well, and this may have some adverse effects on perfusion to the optic nerve head."

The study calls for more research on IOP-independent etiology, such as episodic hypoxia, that could potentially link OSAS and glaucoma.

Shinmei Y, Nitta T, Saito H, et al. Continuous intraocular pressure monitoring during nocturnal sleep in patients with obstructive sleep apnea syndrome. Invest Ophthalmol Vis Sci. 2016;57(6):2824-30.

1-800 Contacts in the Hot Seat

The online retailer of contact lenses is under fire again, this time from the Federal Trade Commission (FTC). The FTC recently sued 1-800 Contacts, stating the company unlawfully maintains anticompetitive agreements with its rivals that suppress competition in online search advertising. It also restricts truthful and nonmisleading advertising, leading to some consumers paying higher prices for contact lenses, the FTC said in a press release.[1]

The FTC's administrative complaint, issued August 8, alleges 1-800 Contacts entered into bidding agreements with at least 14 competing online contact lens retailers. The agreements effectively eliminate competition to place advertisements on search results pages. The FTC claims they hamper price competition in internet search auctions and constitute an unfair method of competition in violation of federal law.[1]

The 1-800 Contacts agreements were derived from lawsuits the company threatened or brought against competitors for trademark infringement. The company sought to stop computer users from seeing rival ads when using the term 1-800 Contacts.[1] The FTC's complaint claims these *(Continued on p. 8)*


Give a girl the right glasses and she can conquer the world.
My business is successful because of the relationship with my sales reps. Marchon hooks me up with the latest fashion trends in the industry. Marchon me with partnership.
– Ebony Thomas
Optician
Austin, Texas
Marchon me.
MARCHON
FOCUSED ON YOU
Marchon is a registered trademark of Marchon Eyewear Inc. Marchon.com

1-800 Contacts Sued

(Continued from p. 6)
agreements are overly broad and don't safeguard trademark interest.

"The FTC lawsuit against 1-800 Contacts sheds light on their questionable business ethics," says Justin Bazan, OD, of Park Slope Eye in Brooklyn, NY. "For me, it serves as a reminder that 1-800 Contacts puts their focus on profits. While this lawsuit probably will not impact optometrists in any noticeable way, I do hope it can be used as a point of education for our patients."

While the complaint brings the wrongdoing to light, optometrists will have to wait until April 2017 before the hearing, during which 1-800 Contacts is invited to "show cause why an order should not be entered requiring [them] to cease and desist from the violations of law charged in the complaint."[2]

1. The Federal Trade Commission. FTC Sues 1-800 Contacts, Charging that It Harms Competition in Online Search Advertising Auctions and Restricts Truthful Advertising to Consumers. August 8, 2016.
2. The Federal Trade Commission. Complaint, In the Matter of 1-800 Contacts Inc., a corporation. August 8, 2016. Available at www.ftc.gov/system/files/documents/cases/160808_1800contactspt3cmpt.pdf. Accessed August 8, 2016.

Beware of the Burn: Young Children at Highest Risk

One- and two-year-old children are at the highest risk for chemical eye burns, new research suggests. Despite commonly held beliefs that working-age adults were most at risk for chemical eye burns, this study is the first to show toddlers to be at highest risk. These findings point up the need for public education regarding avoidable and serious eye injury.

Factories and other businesses employing the use of chemicals have safety precautions in place, but such measures are not necessarily at the forefront in homes where improperly stored household cleaners and other chemicals put young children at risk. Because chemical burns continue to damage the eye even after contact, this type of eye injury potentially results in irreparable damage to internal structures.

Researchers analyzed four years of data from the Nationwide Emergency Department Sample and found that, while 24-year-olds were at highest risk among adults, one-year-olds were twice as likely to suffer eye burns. The risk drops off significantly once children were old enough to understand the dangers associated with household products.

The most common of these injuries, according to the researchers, results from alkaline agents, rather than from acids. Further, burns stemming from alkaline agents tend to be more dangerous because these agents continue to cause injury the longer they stay on the eye. Reducing these injuries in young people, according to researchers, is as simple as keeping household cleaners and other chemicals out of reach. ■

Haring RS, Sheffield ID, Channa R. Epidemiologic trends of chemical ocular burns in the United States. JAMA Ophthalmol. 2016 Aug 4. [Epub].

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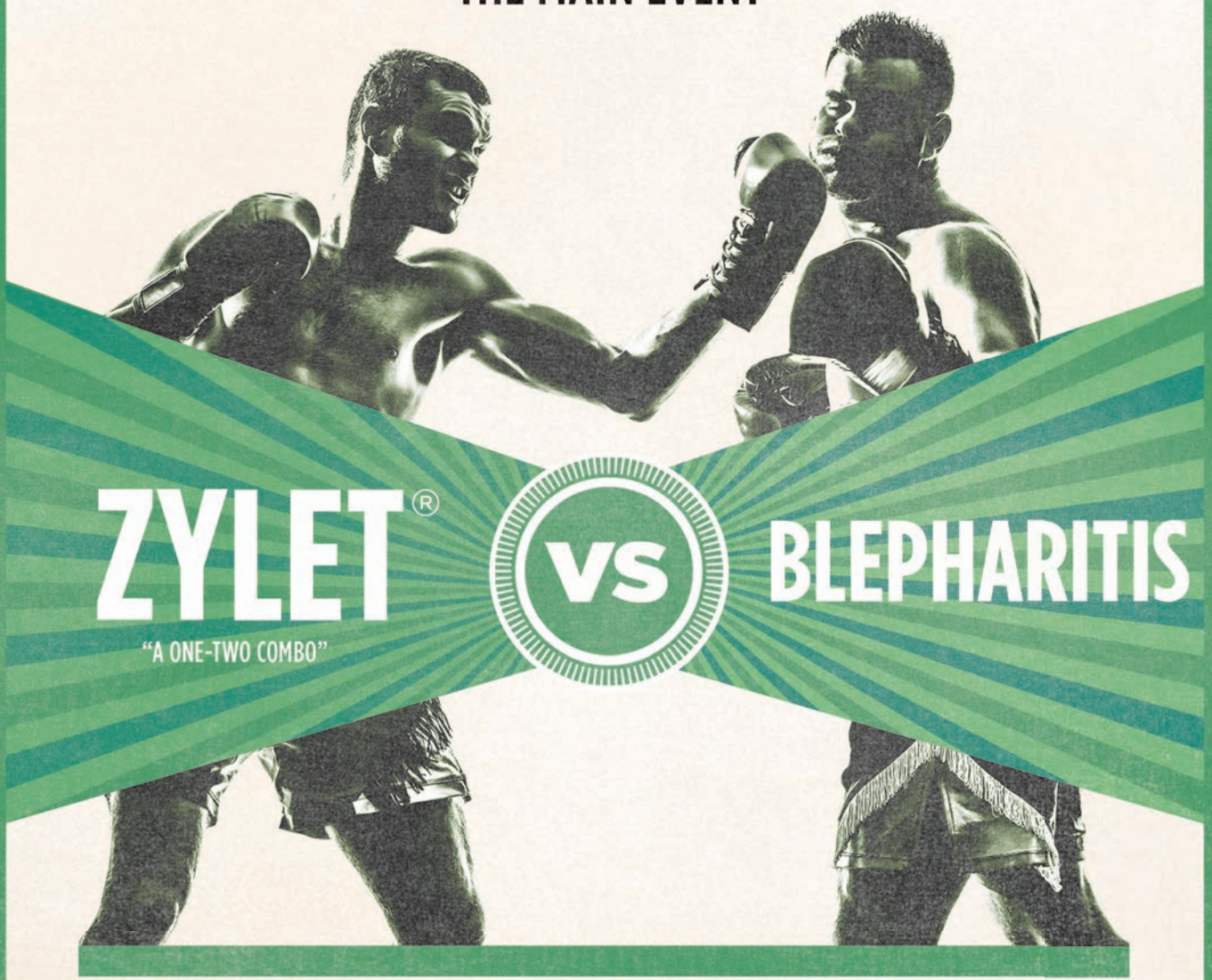

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INDICATIONS AND USAGE

ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension) is a topical anti-infective and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Please see additional Indications and Usage information on adjacent page, including list of indicated organisms.

INDICATIONS AND USAGE (continued)

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

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

The particular anti-infective drug in this product (tobramycin) is active against the following common bacterial eye pathogens: *Staphylococci*, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. *Streptococci*, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*, *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae*, and *H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus* and some *Neisseria* species.

IMPORTANT SAFETY INFORMATION

- ZYLET® 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 this product is used for 10 days or longer, intraocular pressure should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.
- 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 a 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. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Employment of 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 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.
- Most common adverse reactions reported in patients were injection and superficial punctate keratitis, increased intraocular pressure, burning and stinging upon instillation.

Please see Brief Summary of Prescribing Information on the following page.

With a one-two combo in the treatment of blepharitis and other steroid-responsive ocular conditions with the risk of bacterial infection, PRESCRIBE ZYLET® TODAY.

Zylet®
loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension

BAUSCH+LOMB

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

Zylet® (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension)

Initial U.S. Approval: 2004

DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Apply one or two drops of Zylet into the conjunctival sac of the affected eye every four to six hours. During the initial 24 to 48 hours, the dosing may be increased, to every one to two hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

2.2 Prescription Guideline

Not more than 20 mL should be prescribed initially and the prescription should not be refilled without further evaluation [*see Warnings and Precautions (5.3)*].

CONTRAINDICATIONS

4.1 Nonbacterial Etiology

Zylet, as with other steroid anti-infective ophthalmic combination drugs, 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.

WARNINGS AND PRECAUTIONS

5.1 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.

5.2 Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

5.3 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 a slit lamp biomicroscopy and, where appropriate, fluorescein staining.

5.4 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. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

5.5 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).

5.6 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.

5.7 Aminoglycoside Hypersensitivity

Sensitivity to topically applied aminoglycosides may occur in some patients. If hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

ADVERSE REACTIONS

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination.

Zylet:

In a 42 day safety study comparing Zylet to placebo, ocular adverse reactions included injection (approximately 20%) and superficial punctate keratitis (approximately 15%). Increased intraocular pressure was reported in 10% (Zylet) and 4% (placebo) of subjects. Nine percent (9%) of Zylet subjects reported burning and stinging upon instillation.

Ocular reactions reported with an incidence less than 4% include vision disorders, discharge, itching, lacrimation disorder, photophobia, corneal deposits, ocular discomfort, eyelid disorder, and other unspecified eye disorders.

The incidence of non-ocular reactions reported in approximately 14% of subjects was headache; all other non-ocular reactions had an incidence of less than 5%.

Loteprednol etabonate ophthalmic suspension 0.2% - 0.5%:

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.

In a summation of controlled, randomized studies of individuals treated for 28 days or longer with loteprednol etabonate, the incidence of significant elevation of intraocular pressure (≥10 mm Hg) was 2% (15/901) among patients receiving loteprednol etabonate, 7% (11/164) among patients receiving 1% prednisolone acetate and 0.5% (3/583) among patients receiving placebo.

Tobramycin ophthalmic solution 0.3%:

The most frequent adverse reactions to topical tobramycin are hypersensitivity and localized ocular toxicity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics.

Secondary Infection:

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids.

The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.

USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb fixtures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥50 mg/kg/day). Treatment of rats at 0.5 mg/kg/day (6 times the maximum daily clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

Reproductive studies have been performed in rats and rabbits with tobramycin at doses up to 100 mg/kg/day parenterally and have revealed no evidence of impaired fertility or harm to the fetus. There are no adequate and well controlled studies in pregnant women. Zylet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids that appear in human milk could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Zylet is administered to a nursing woman.

8.4 Pediatric Use

Two trials were conducted to evaluate the safety and efficacy of Zylet® (loteprednol etabonate and tobramycin ophthalmic suspension) in pediatric subjects age zero to six years; one was in subjects with lid inflammation and the other was in subjects with blepharoconjunctivitis.

In the lid inflammation trial, Zylet with warm compresses did not demonstrate efficacy compared to vehicle with warm compresses. Patients received warm compress lid treatment plus Zylet or vehicle for 14 days. The majority of patients in both treatment groups showed reduced lid inflammation.

In the blepharoconjunctivitis trial, Zylet did not demonstrate efficacy compared to vehicle, loteprednol etabonate ophthalmic suspension, or tobramycin ophthalmic solution. There was no difference between treatment groups in mean change from baseline blepharoconjunctivitis score at Day 15.

There were no differences in safety assessments between the treatment groups in either trial.

8.5 Geriatric Use

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

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate or tobramycin.

Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma TK assay, a chromosome aberration test in human lymphocytes, or in an *in vivo* mouse micronucleus assay.

Oral treatment of male and female rats at 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (500 and 250 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender. No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at 100 mg/kg/day (1700 times the maximum daily clinical dose).

PATIENT COUNSELING INFORMATION

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses when using Zylet.

MANUFACTURER INFORMATION

BAUSCH & LOMB INCORPORATED

TAMPA, FLORIDA 33637 USA

Zylet is a registered trademark of Bausch & Lomb Incorporated.

Based on 9007705-9004405 Revised 08/2013 US/ZYL/15/0014

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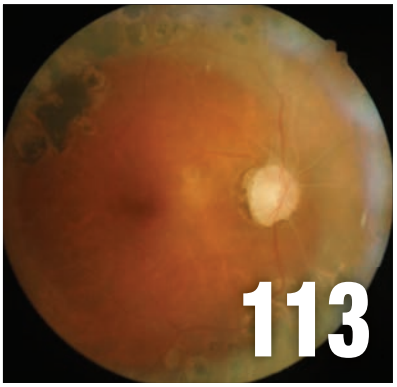

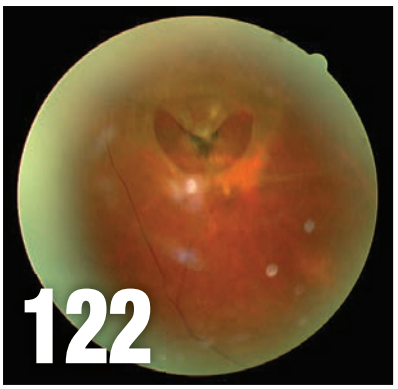

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2 U.S. Patents

- **U.S. Patent No. 9,115,078**:
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  Methods for Improving the Quality of the Meibum Composition of Inflamed or Dysfunctional Meibomian Glands

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[1] Epitropoulos, Alice T, Donnenfeld, Eric D., et al., Effect of Oral Re-esterified Omega-3 Nutritional Supplementation on Dry Eyes. Cornea 2016;0:1-7

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Xiidra improved patient-reported symptoms of eye dryness and improved signs of inferior corneal staining. So help your patients get to know Xiidra.

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Four randomized, double-masked, 12-week trials evaluated the efficacy and safety of Xiidra versus vehicle as assessed by improvement in the signs (measured by Inferior Corneal Staining Score) and/or symptoms (measured by Eye Dryness Score) of Dry Eye Disease (N=2133).

The safety of lifitegrast was evaluated in 5 clinical studies. 1401 patients received at least one dose of lifitegrast (1287 of which received Xiidra). The most common adverse reactions (5-25%) were instillation site irritation, dysgeusia, and reduced visual acuity.

MEET YOU

The only prescription eye drop FDA-approved to treat both the signs and symptoms of Dry Eye Disease

Indication

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

Important Safety Information

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 following page and Full Prescribing Information on Xiidra-ECP.com.

Shire

xiidra™ (lifitegrast ophthalmic solution)5%

Rx Only

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.

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.

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.

Shire

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.

US Patents: 8367701; 9353088; 7314938; 7745460; 7790743; 7928122; 9216174; 8168655; 8084047; 8592450; 9085553 and pending patent applications.
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Outlook

By Jack Persico, Editor-in-Chief

Hard Times for Soft Lenses

Two reports document challenges to long-term success and reinforce the importance of good education.

Contact lenses have been popular ever since their introduction. Although glasses have a longer track record by a few hundred years, many people find them uncomfortable and lacking in peripheral vision. But contact lenses still elicit a gee-whiz feeling the first time a patient puts them on. The problem has never been that initial patient experience; it's the need to keep patients happy and safe long term. And two recent reports suggest, once again, that both those aspects of lens wear come up short.

As reported this month in our news section (*see p. 4*), a new study in the journal *Ophthalmology* shows that LASIK patients had higher satisfaction scores than contact lens wearers. Tellingly, LASIK satisfaction improved over time while contact lens satisfaction declined. Remember, this is for a surgery that costs several thousand dollars, doesn't always deliver 20/20 results and offers no flexibility to change the Rx as the person's visual needs change as they age.

Safety concerns—long thought, or at least hoped, to be declining in the daily disposable era—also persist. In August, the Centers for Disease Control and Prevention issued a report on infectious keratitis in contact lens wear from 2005 to 2015 that reveals threats to eye health with this modality. The study linked one million doctor visits annually and 1,075 cases of corneal infection during the 10-year study period to contact lens wear. Nearly 20% of those cases resulted in scarring that reduced vision. And 25% could have been avoided by more responsible patient behavior.

It's tempting for ODs to see in these numbers a justification to not even bother with contact lenses. Speaking as someone who's worn soft contact lenses for 27 years, I know their shortcomings first-hand. But I also know—and doctors should remember—that positive feelings accompany every negative one.

Yes, my eyes get sore near the end of the day *(but I've also had 16 hours of uninterrupted wear)*. Lens handling and insertion can be a frustrating experience *(but that's because the lenses are so thin that I can wear them safely for so long)*. Lens cleaning and disinfection is a messy chore *(but it kept my costs down before I finally switched to daily disposables)*. When I accidently wear my lenses overnight, I wake up with blurry vision and sticky eyes *(but that's because the lenses were so well designed that I can afford to sometimes be careless and forget to take them out)*. And my multifocal contact lenses often perform badly in low light *(but they sure are less conspicuous than reading glasses)*.

As you can see, you can tell the story of contact lens wear entirely in positive terms or in negative ones. My advice: tell both stories. Patients need to hear it all. If you oversell the positives, patients will eventually get disappointed—and maybe a little distrustful. If you dwell only on the negatives, you'll deprive patients of a great experience and your practice of a sales opportunity. Full disclosure and patient commitment will help you *both* over the long haul. ■

Gotta Do the Math

Patients trust my math to correct their vision, and I don't even know if I passed any math classes. This proves I'm good for something, at least. **By Montgomery Vickers, OD**

My kids have always been a lot smarter at math than me. In high school my son used to walk up to the board in AP calculus and fix the teacher's mistakes so the problem would come out right. My daughter aced advanced physics in college despite a professor who apparently believed women were not genetically strong enough for such a "manly endeavor." Jerk.

So imagine my surprise when they both decided they did not want to become optometrists because they were intimidated by the math. (Now I know they just wanted to do something else.)

Yes, math is part of optometry, and the math we do is the physics of optics on steroids—the dreaded physiological optics. Now, I was never any good at math. I am more poet than abacist. I have no clue how I passed any course involving mathematics. In fact, I am not completely sure I actually did pass any course involving mathematics. Through optometry school, I never, ever checked my grade on any test I took in four years. I figured they'd call me if I failed and they never did. They gave me a diploma, so I assume I passed. If not, I hope they're not reading this column, as my 36-year career may veer wildly to my fallback of hot dog vendor.

Just in case, I have decided to use my creative right brain—apparently I have no left brain—to invent some mathematical equations that will keep them busy enough they won't have time to dig through the PCO records to see if I passed math.

Here goes:

- OD years + (Pecan $\pi \times \infty$) = My current weight
- 80° + sunny ÷ # family members appointed = 100% no shows
- (Age + ♂) × 5 = minimum # of days he wears a monthly disposable CL
- (OD schools ÷ # of states) + 1 = 2 [note that the answer will probably change to 3 by 2021]
- Diopters × ∞ = the add power I need these days
- [(# × late patients) ÷ time my plane takes off tonight] × day's income + # dollars I've ever made = alimony I will pay for missing the plane to answer the patient's 47 questions about their dog's left eye @ 7pm
- 92014 fee – $275.00 = per-encounter income derived from that stupid vision plan
- Astigmatism in diopters + ½ of the stars in the universe – # times I've asked which is better, # 1 or #2 = # of times the patient should have said #1 instead of #2
- @#^%*! = my response to "my sister had LASIK and her doctor said she'll never need glasses again"
- Absolute Zero = -273.15°C = temperature I have to keep my office or my staff will quit
- Absolute Zero = $ I get paid if I tell patients they can make payments
- Absolute Zero = worth of my optometric degree if I cross state lines
- Absolute Zero = the chances either presidential candidate will do anything about Medicare

See, math can be important if it's applied properly in your life. And for you folks that think math is easy, I have two words: %#@*() + *@$##! Apply that! ■

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The Infection Connection

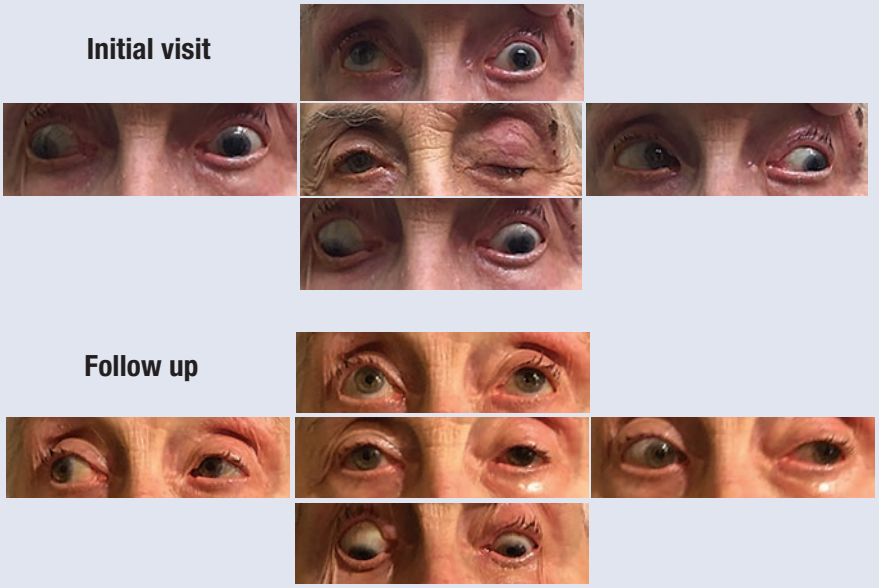
When herpes zoster causes 3rd nerve palsy, patients and practitioners suddenly have to deal with multiple issues. **By Michael Trottini, OD, and Michael DelGiodice, OD**

An 89-year-old white female was referred by her primary care physician for evaluation of an acute herpes zoster infection with diplopia and ptosis. She reported that a rash developed around her left eye and forehead 10 days prior, and that her left eyelid started to droop three days prior. She would experience double vision when she lifted her eyelid. She also reported left eye pain, blurry vision and significant neuralgia around the left side of her head. Her primary doctor started her on Valtrex (valacyclovir hydrochloride, GlaxoSmithKline) and gabapentin. Her medical history was remarkable for hypertension, for which she was taking triamterene/hydrochlorothiazide. Her ocular history included left central retinal vein occlusion since 2013 with chronic macular edema, treated with Ozurdex (dexamethasone intravitreal implant, Allergan) and Eylea (aflibercept, Regeneron) injections.

Her best-corrected visual acuities were 20/25 OD and 20/100 OS. Intraocular pressure was 18mm Hg in each eye. Her pupils were equal, round and reactive to light with no afferent pupillary defect noted. A resolving vesicular rash and erythema was noted along the left ophthalmic branch of the trigeminal nerve. A complete left ptosis was noted. Extraocular motilities showed restricted upgaze, downgaze and adduction of the left eye.

A slit lamp examination of the right eye was unremarkable. The left eye showed 1+ conjunctival injection and ciliary flush with a 1+ anterior uveitis. Her cornea was clear and her posterior segment was quiet. The retinal findings in the left eye were consistent with her report of an old retinal vein occlusion. OCT showed no macular edema.

Initial Visit and Follow up



At initial visit, ptosis with restricted upgaze, downgaze and adduction. At follow up, the ptosis and motilities are significantly improved two weeks later.

Diagnosis & Management

We diagnosed our patient with a complete, pupil-sparing left 3rd nerve palsy secondary to herpes zoster. Antivirals are the mainstay therapy for herpes zoster infections. We typically prefer either valacyclovir or famciclovir over acyclovir because they are more effective in limiting postherpetic neuralgia.[1] She was already taking Valtrex 1g TID per her internist, so we continued her on the current dose. Additionally, because the suggested mechanism for zoster-related oculomotor nerve palsies is inflammatory in nature, we started her on prednisone 60mg QD and treated her uveitis with Durezol (difluprednate ophthalmic emulsion 0.05%, Alcon) QID OS.

Two weeks later, she showed a 60% to 70% improvement in her ptosis and an 80% to 90% improvement in the extraocular movements. Her ocular inflammation was also completely resolved and vision improved to 20/30 in the left eye. We cut the Valtrex to 500mg TID for an additional 10 days and started a prednisone and Durezol taper. Three weeks later, the 3rd nerve palsy had completely resolved with no recurrence. Even with very long tapering of the steroid drops, our patient developed a chronic recurring herpetic uveitis. Because of our concerns for complications, especially with her history of chronic macular edema from a vein occlusion, we decided to treat her with prednisolone acetate QD, which has kept the eye quiet. Her vein occlusion and macular edema have remained stable.

Discussion

When herpes zoster infection affects the ophthalmic branch of the trigeminal nerve, it is referred to as herpes zoster ophthalmicus (HZO).[2] Ocular complications of HZO occur in approximately 50% of cases and commonly include keratitis, pseudodendrite, episcleritis, uveitis and increased IOP.[2,3] Although uncommon, cranial nerve palsies have been seen in patients with HZO. Cranial nerves 3, 4 and 6 have all been reported but cranial nerve 3 is most commonly affected—involved in 47% of all cases.[2,3] On average, the nerve palsy occurs nine and a half days after the onset of rash with a range of two to 42 days.[2] Although the exact mechanism is unclear, research suggests inflammation of the trigeminal nerve could spread to the other cranial nerves within the cavernous sinus.[4] Research also suggests occlusive vasculitis as a culprit.[5]

Though not seen in our patient, oculomotor nerve palsies associated with HZO can affect the pupil. If an aneurysm or space-occupying lesion is suspected, especially with pupillary involvement, MRI and MRA are suggested. Our patient's age, lack of pupillary involvement, and the palsy's timing in relation to the shingles infection and treatment response made aneurysm unlikely in our estimation; therefore, neuroimaging was not performed.

HZO can present with a variety of ocular complications and can be challenging to manage at times. Understanding the various complications and instituting the proper treatment will help improve patient outcomes. ■

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Keepin' it Real

Intraoperative abberometry gives surgeons vital data in real time—while the patient is on the operating table—increasing accuracy. **Edited by Paul C. Ajamian, OD**

Q I have a patient who had LASIK in the '90s and now needs cataract surgery, but I am worried about a refractive surprise. What can I do to improve the outcome?

A "We now have wavefront aberrometry to improve the accuracy of IOL power selection during cataract surgery in postrefractive surgery patients," says Lawrence Woodard, OD, of Omni Eye Services in Atlanta. In contrast to other methods, which only use preoperative corneal and axial length measurements, intraoperative aberrometry determines IOL power after the cataract is removed. "This is important because corneal topography and keratometry readings overestimate the true corneal power in post-LASIK patients. IOL calculation formulas then underestimate IOL power, leaving the patient significantly hyperopic," says Dr. Woodard.

A 2014 study shows that 39% fewer patients' refractions fall outside the intended postoperative target of +/- 0.50D when intraoperative abberometry was used vs. conventional preoperative methodology, notes Dr. Woodard. "This translates into happier patients who are much less likely to need an IOL exchange or enhancement procedure due to significant refractive surprise after cataract surgery."

ORA can be used to effectively increase the accuracy of IOL placement during surgery.

Measuring

It typically takes one to two minutes to obtain the measurements, so the surgical procedure isn't significantly delayed. "Measuring is a painless process for the patient. Data from preoperative biometry is entered into the machine prior to surgery," says Dr. Woodard.

Unfortunately, intraoperative aberrometry is not covered by insurance.

However, Dr. Woodard notes that its use is typically included in some refractive packages offered with premium lenses and laser cataract surgery. "Only a small percentage of cataract surgeons take advantage of this innovative technology, presumably due to the purchase price and monthly click fee they are charged by the company."

Expectations center solely around increasing the accuracy of the refractive target outcome from cataract surgery, according to Robert Pinkert, OD, of Barnet Dulaney Perkins Eye Center in Phoenix. "Though the formulas used to calculate the appropriate IOL come within reach of the target, a real-time measurement that occurs during surgery can increase the predictability of the refractive result," says Dr. Pinkert.

Previous refractive surgeries can impact how far off you land from the refractive target post surgery, Dr. Pinkert explains. "Prior corneal surgeries, such as LASIK and RK, as well as corneal irregularities, may influence the calculations and lead to a refractive surprise—a result far from the intended target for the particular patient," adds Dr. Pinkert.

Finally, patient expectations now focus on advancements in toric and multifocal IOL technology and intraoperative tools to help garner the most accurate refractive results. "Patients are more educated and active, thus their expectations are increasing, with a corresponding rise in the demand for better outcomes," says Dr. Pinkert.

"My own experience did not involve prior LASIK, but I underwent surgery as a refractive lens replacement to improve my uncorrected visual acuity—I was in my fifties and way too young for cataract surgery!" says Dr. Pinkert.

"The toric lens completely neutralized the astigmatism—I am not sure this would have occurred without intraoperative verification of the IOL's power and placement." ■

Coding in a Tech Savvy World

Technology can be a blessing, but understand you aren't the only one using it.

By John Rumpakis, OD, MBA, Clinical Coding Editor

Technology has certainly changed the way we deliver patient care, and it's still changing rapidly. But technology has impacted our practices in other ways too—namely, how carriers look at the care we provide via claims data, ICD-10 and clinical care protocols. These new avenues of scrutiny are helping to develop new economic models of care that very well may be the endgame of health care reform.

A Busy Year

The last year has seen a transformation in how the health care system tracks the care each provider delivers on a daily basis. October 1, 2015 saw the implementation of the long-awaited (and feared) ICD-10 codes, and October 26, 2015 saw the very first release of comparative billing reports provided to optometrists across the country. Recently, many providers have received letters from a major health insurer on the reported overuse of the comprehensive ophthalmological exam codes 92004/92014.

All of this is rooted in the concept of outcomes-based care: rewarding efficient and effective providers while penalizing those who aren't complying with the federal government's requirements for reporting quality outcomes and properly using EHR systems (meaningful use).

Under the Microscope

Right now, carrier computer systems are rapidly compiling data on each and every provider on a variety of issues, including how many visits it took to resolve a specific diagnosis, which code was used and whether or not that level of code was appropriate for that patient presentation. Sound a bit Orwellian? Perhaps, but it's the reality of today's world of cost containment.

You can always use your great in-office technology to diagnose, manage and treat patients—if, of course, you meet the requirements of medical necessity as established by your carrier contract and local standard of care. But it's not even that simple anymore. Algorithms for analyzing clinical care protocols are being developed based on clinical studies and claims data.

Example: Spending Spree

This is what outcomes-based care could look like and how carrier-based analysis could affect future payment systems.

A patient presents with classic dry eye complaints: end-of-day CL discomfort, fluctuating vision when blinking, photophobia and burning. You complete a comprehensive exam because it's been two years since the patient last saw you. You also order a dry eye workup for the following week, consisting of every diagnostic test you can think of. In the meantime, you put the patient on a pharmaceutical agent—not because of clinical signs, but because that's what you heard at a lecture somewhere. Finally, you schedule follow-up visits every two months. At the first follow-up visit, you put an amniotic membrane on both eyes because another lecture said this was a great first-line therapy without any supporting clinical evidence. Overall, you cost the health care system roughly $4,000 in reimbursements.

Here's what's happening behind the scenes in the example: Carriers are looking at the specific CPT code and ICD-10 codes, the frequency of use and the consistency of ancillary testing in combination with pharmacy claims. Why did you perform a comprehensive exam on a patient who presented with complaints of dry eye? That could be considered performing an inappropriate level of care based on the patient complaint. On an ongoing basis, they are comparing your clinical care profile to that of other practitioners of your specialty group and, most importantly, comparing your outcomes.

If you cannot demonstrate that your care profile was necessary based on documented clinical signs and symptoms at each stage of care, and that your overall care was better than someone who achieved the same outcome at a lower cost, you will face some tough questions about what you did, why you did it and what documented clinical standard of care you were following.

With today's technology, we can provide diagnostic and point-of-service care we could only dream of a few years ago. But it also allows carriers to dynamically analyze our care to ensure we are providing the most effective outcomes in the most efficient manner—and we have to pay the price if we aren't measuring up. It's sobering, to be sure, but to claim ignorance of this in today's world won't change the reality. ■

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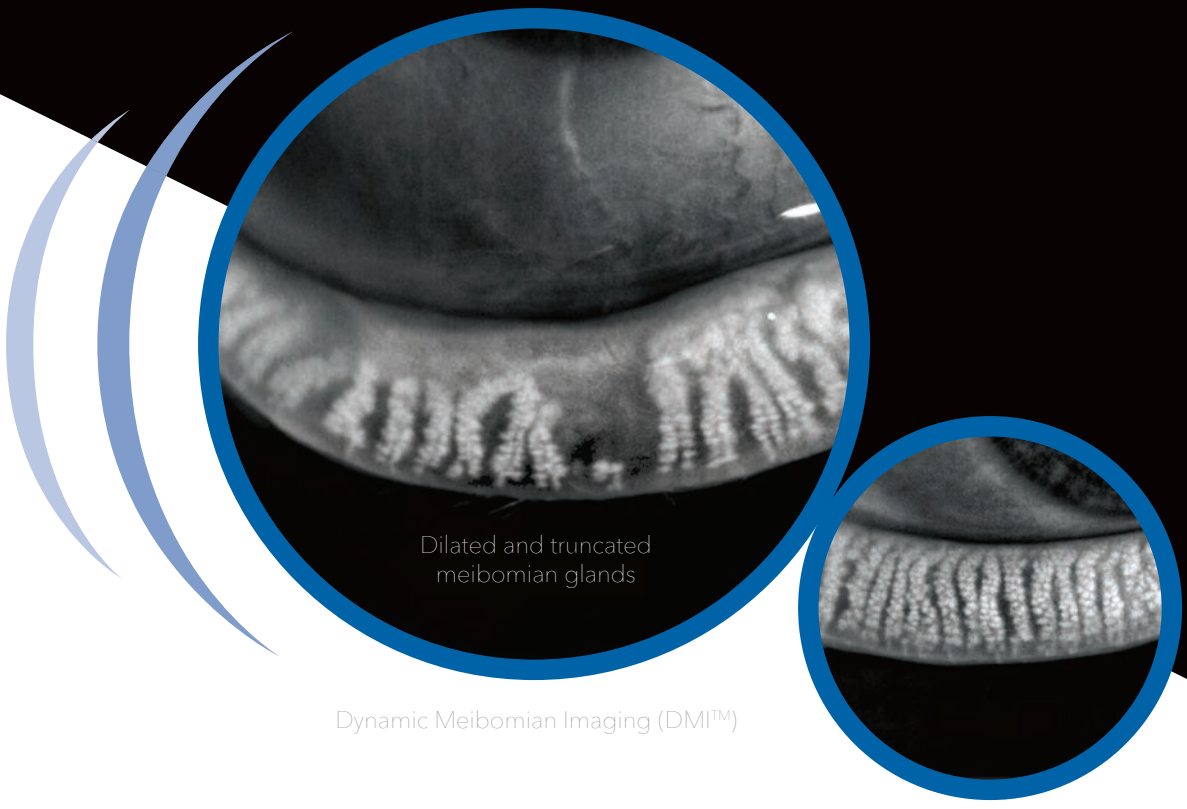

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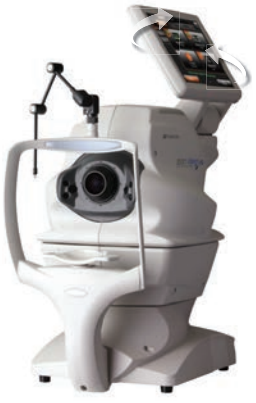

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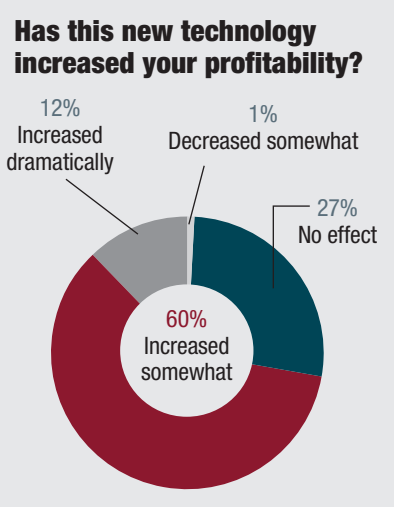
39th Annual Technology Report

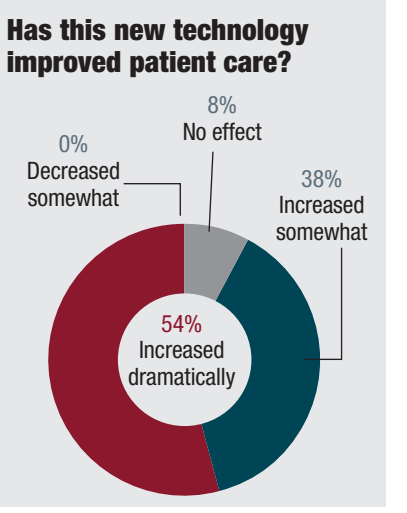
Out With the Old, In With the New

The 2016 technology survey reveals what your colleagues are buying—and how it's changing their practices. **By Rebecca Hepp, Senior Associate Editor**

Technology has become a staple in today's optometric practice; gone are the days when a Snellen eye chart and a phoropter were all you needed to care for the majority of your patients. Today, autorefractors, digital fundus cameras and optical coherence tomographers (OCT) are just a few items that grace your office space and help you provide exceptional patient care. But with this technological boom comes a constant need to upgrade—and often with a big price tag.

What did you invest in this year? How has it impacted your patient care? Your bottom line? We asked, and you answered. See what your colleagues spent their money on this year and what they still have on their wish list in our 2016 Technology Survey.





Must-Have's

Practitioners seem to be sinking their money into the same go-to technology each year, with electronic health records (EHRs), digital fundus cameras, patient callback/reminder systems and tonometers making the top five again. The surprise came with spectral-domain optical coherence tomographers (SD-OCT), in the top five last year at 20% of new purchases, being knocked out of the running by automated refraction systems. Only 13% of respondents purchased an automated refractor in last year's survey, but 23% of this year's survey takers said they invested in one. Those who did so focused on two key benefits: patient experience and exam efficiency.

"It made the flow of the exam much faster and patients' experience much more interesting by actively participating in getting a new pair glasses," one respondent said of her new automated refractor.

"Patients love the technology, and refractions are smoother and take less time," another survey taker said.

It's no surprise patient experience was key with these purchases, as 81% said the impetus for new technology was improving patient care. And improve it did. Whether it was an autorefractor, a retinal imaging system or tonometer, 94% said their technology upgrade improved patient care. The good news is that it also seems to translate to better budgets, as 74% said their new purchase increased profitability as well.

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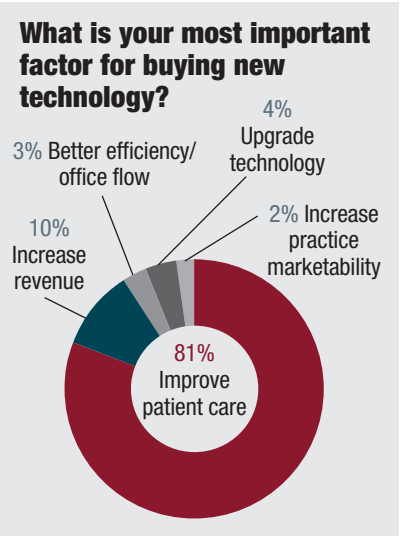
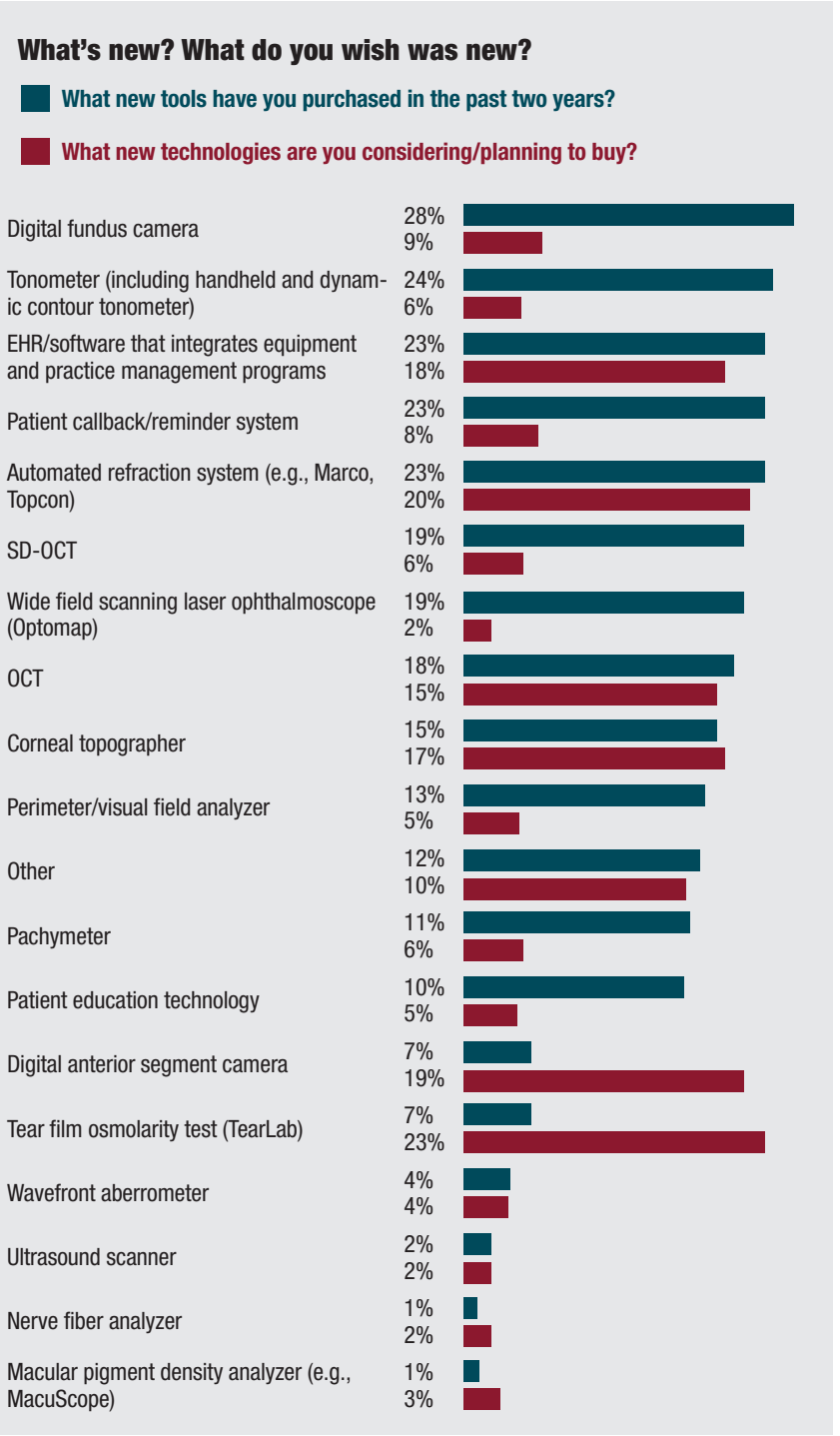
Survey Results





Paying the Piper

Although it's a huge benefit to your practice to have the best technology on the market, it can be tough to designate thousands of dollars for just one piece of equipment—especially considering the sheer number of tools at your disposal. Most survey takers, 41%, said they have limited their new tech budget to less than $10,000 this year, but a lucky 11% will have more than $50,000 to play with.

Others are getting creative to find ways to afford that new visual field analyzer or tonometer. Twenty percent of respondents plan to lease their next major piece of equipment, and 12% said they share equipment with another practice. And with technology advancing at breakneck speed and making that new camera or patient callback system outdated in a few short years, 80% agree that buying new is a better investment than refurbished or used instruments.

The hefty price tag is often easier to swallow when the new toys provide a direct financial benefit to the practice. Many purchases, such as the much-in-vogue autorefractor, increase practice productivity, so you can see more patients in a day. Others, such as an OCT, can help keep patients in the practice by reducing unnecessary referrals.

"The purchase of our OCT has made our patient care better. We've become more efficient in knowing when to follow and when to refer, not to mention it has made practice lots more fun!" one respondent said.

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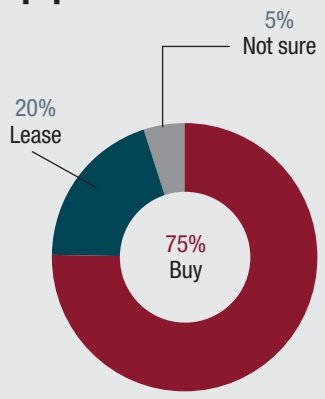
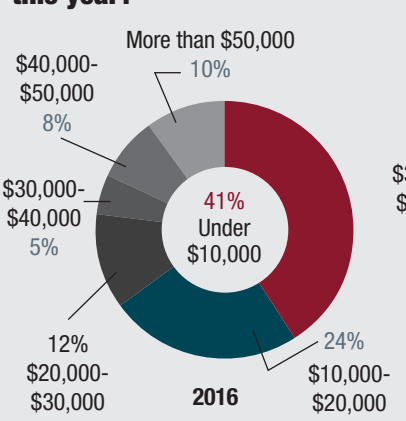
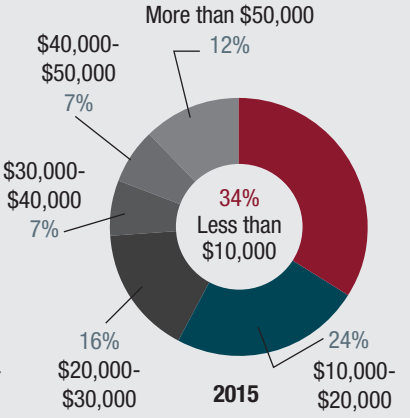
Survey Results

Do you plan to buy or lease your next major piece of equipment?



How much will you be spending on instruments and equipment this year?



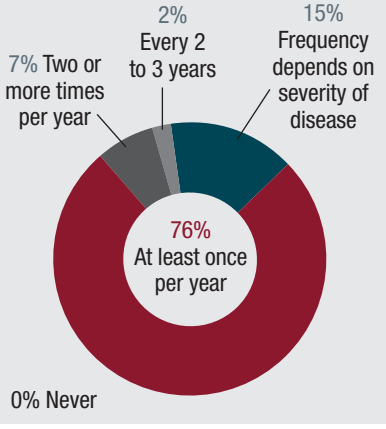


"It certainly has revolutionized the way we practice like no other piece of instrumentation has; we are on our third OCT now and could not imagine practicing without it!"

"Our SD-OCT has allowed the diagnosis of early hydroxychloroquine toxicity, confirmation of macular edema, epiretinal membrane and other causes of reduced visual acuity that previously may have only been suspected and required referral to retinal specialist," another survey taker said. "Also, it's an added diagnostic tool for glaucoma management, especially for those unable to do threshold visual fields."

With rave reviews such as this, it's no wonder nearly 40% of survey takers invested in an OCT or SD-OCT this year.

For patients with eye diseases such as glaucoma or diabetes, how often do you perform a dilated fundus examination?



Front Office Upgrades

Diagnostic technology, such as automated refractors and widefield retinal imagers, may "wow" patients in the exam chair, but the equipment behind the scenes is just as important. Keeping the front office running smoothly is a necessity in a busy practice, and this year 56% of survey respondents made room in their budgets for EHR, a patient callback system or patient education system—all in the name of productivity and employee satisfaction.

"We literally ran out of space for physical files," one survey taker said of his EHR purchase. "Having the data in the cloud has been much more efficient."

Another practitioner is thrilled with her new electronic recall reminders: "We can have staff work on other items besides call patients," she said. "When a doctor is unable to come in to work on a spur of the moment, we text our patients that we need to reschedule and it saves a lot of time and lets the patient know right away their appointment needs to be adjusted. The few times we have had to use this, it has been a lifesaver."

She isn't the only one singing her new callback system's praises. "[Our new] automated patient appointment reminders and recall system dramatically increased revenue," another OD said. "It reduced no-shows by 75% and led to 207 past-due patients making appointments in the first six weeks of use. I am now booked ahead an incredible 880 appointments and they all show up!"

Despite the anecdotal success of these systems, they don't seem to make it onto many optometrists' wish lists. In last year's survey, only 8% of respondents said they would be in the market for a patient callback system in the next year. And yet, far more than 8%, 23% in fact, said they purchased one this year. An EHR or patient callback system might not be the sexiest purchase for your practice, but it provides an invaluable service that many practices say is worth the price—keeping you and your staff on schedule and up-to-date.

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What's on Deck for Next Year?

Even if your practice held off on upgrading this year, it's inevitable you will be making some big purchases in the future. Last year, OCTs topped the wish list, but this year 23% of practitioners have their eye on a more specialized tool: a tear film osmolarity test (Tearlab). Those who already knocked this off the wish list are glad they did. It provides data for both doctors and patients to help monitor dry eye, and its "small reimbursements can add up," one respondent said.

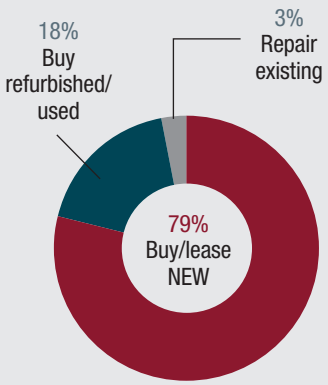
"DES is everywhere," said another respondent who purchased a tear film osmolarity test this year. "It is treatable at all stages, it generates increased revenue and makes patients feel and look better."

Another item on many wish lists is a digital anterior segment camera. While only 7% bought one this year, 19% have moved this one to the top of their list for next year.

Other contenders penciled into next year's budgets are automated refractors (20% are looking to buy one), EHRs (18%) and corneal topographers (17%). But who knows? Maybe those ever-so-useful patient callback systems will sneak into the budget—like they seem to do every year.

The best news from all of your colleagues concerning new technology is that, for the most part, no matter what you spend your money on, it will improve patient care. If you are lucky, and use your new tools correctly, it can also boost your practice's productivity and your bottom line—giving you a little more dough to invest in new technology next year. ■

For your next major piece of equipment, will you…



39th Annual Technology Report

Pearls on Proper Use of Retinal Imaging

Optometrists have a variety of options for discovering and tracking posterior segment pathologies. Here's a guide for when to use which ones. **By Amanda Legge, OD**

Each of the many retinal imaging modalities available on the market today help to aid in the diagnosis of retinal diseases in their own ways. Using these modern wonders, we can monitor progression (or improvement) of retinal pathology and treatment with a degree of clarity we've never seen before. It is the responsibility of the practitioner to determine if, when and how often these imaging modalities are appropriate for diagnosis and management. To do so, we must delineate the type of information each test provides, how it relates to the current state of the patient's retinal disease, as well as its ability to provide a beneficial way of serial monitoring.

This article provides an overview of a variety of retinal imaging devices and how you can use them in your practice.

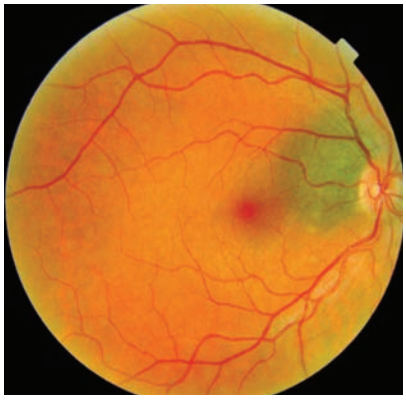


Fig. 1. This fundus image, obtained as a baseline in 2007, shows a new patient with a choroidal nevus.

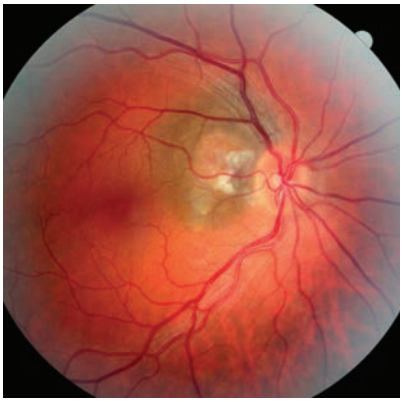


Fig. 2. The same patient, seen in 2015, displays visible changes to the nevus.

Basic Imaging

Fundus photographs capture the current funduscopic appearance of the retina, macula, vasculature and optic nerve. Many fundus cameras allow full color as well as red-free and green-free filters to visualize inner and outer retinal layers. Many cameras also allow side-by-side comparison, or overlapped imaging that aligns successive retinal photos, to assess subtle changes to the size and shape of lesions. Many cameras also have measuring calipers within the software to measure length, diameter, perimeter and area of retinal pathology.

Fundus photography can also image mid-peripheral and far-peripheral lesions and then stitch the various images together, creating a collage of systematic peripheral sweeps. The latest scanning laser ophthalmoscope uses confocal laser scanning microscopy to deliver high-resolution, widefield images. The images created by the laser wavelengths can also be separated into red-free and green-free images. To date, these cameras cannot give a full 360 degree view to the *ora serrata*, so they cannot replace clinical funduscopy to identify retinal lesions, but they can be quite useful to photodocument and monitor peripheral lesions sequentially.

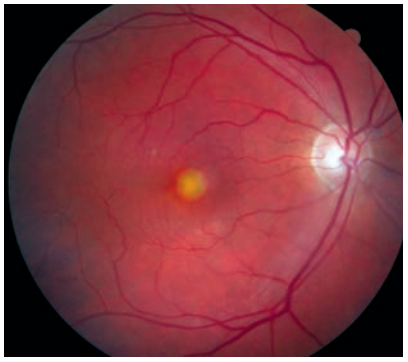
Obtaining baseline fundus photos may prove invaluable if changes to a patient's retinal lesions develop between visits. *Figures 1 and 2*,

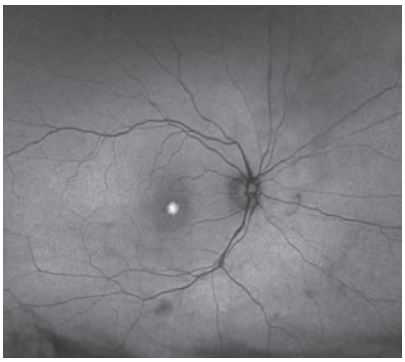
for example, show a patient with a choroidal nevus adjacent to the optic nerve head that appears normal. *Figure 1* was obtained in 2007, as a baseline. In 2015, the patient returned for a routine, comprehensive examination and the photos showed a definite change (*Figure 2*). It was exceedingly helpful to compare his baseline 2007 image to the current clinical picture to help guide the diagnosis. Because the size of the choroidal nevus remained the same and there was only a central elevated lesion, we determined—with the aid of additional tests—that the diagnosis was peripapillary choroidal neovascular membrane. It was, quite coincidentally, located within the same, unchanged, choroidal nevus. The most concerning differential diagnosis we considered was choroidal melanoma, but because the size of the nevus itself had not changed compared to the baseline image, we considered this less likely.

It is also possible to take fundus photographs in three dimensions. Stereoscopic fundus photography has the distinct advantage of imaging depth of the retina and optic nerve compared to conventional photography. It allows the clinician to evaluate excavation of the optic nerve in glaucoma or amount of swelling in papilledema. Especially with tumors, retinal neovascular nets and edema of the retina or optic nerve head, stereoscopic photography captures the binocular clinical view to monitor these conditions over time for depth changes that two dimensional imaging cannot. In fact, for the patient in *Figures 1 and 2*, stereoscopic photography would have been particularly helpful in following this patient over time. One year after diagnosis, the size and shape of the choroidal neovascular net remains the same, but appears significantly shallower compared to previous images, as it continues to resolve untreated. Serial two-dimensional photography does not easily depict this improvement.

Although fundus photography, compared to newer imaging technology, does not often yield new information above clinical examination findings, it can be invaluable for retinal disease progression and if a patient moves to another doctor for continuity of care. Baseline imaging should be obtained on any retinal finding with potential for change. Re-imaging should be used if you suspect a change from the baseline and should then be analyzed in a side-by-side, or overlapping, comparison with previous images with computerized measurements to confirm and properly manage any pathology.

Certainly, fundus photography can be overused





Figs. 3 and 4. This is an expected finding for AOVD with a large hyper FAF area of the vitelliform lesion without any diffuse change to the macular autofluorescence.

if imaging a stable retinal finding more than once a year—especially when change is unlikely. Overall, baseline and periodic imaging can aid in prompt diagnosis and treatment intervention if discrepancy is subtly measured with the tools now available in most photographic software.

A Metabolic Evaluation

A noninvasive imaging modality for retinal pigment epithelium (RPE) metabolic function is fundus autofluorescence (FAF). The yellow fluorescence emitted is a result of lipofuscin when stimulated with blue light in the range of 488nm. Lipofuscin is a retinal fluorophore that ultimately accumulates in RPE lysozomes during phagocytosis of photoreceptor outer segments. This physiology allows indirect interpretation of the metabolic activity of the RPE.[1] Both confocal scanning laser ophthalmoscopy and standard fundus photography can be used to record autofluorescence (AF).

FAF of a healthy retina appears as a uniform, granular, slightly hyperfluorescent signal. This is due to levels of lipofuscin present in RPE lysozomes during normal phagocytosis and metabolism. The optic nerve and blood vessels are black, due to blockage of the signal. The central fovea is also dark due to the absorbing pigment (xanthophyll) of the central macula.

Loss of photoreceptors results in decreased autofluorescence because the metabolic demand on the RPE is diminished or eliminated—indicating a dead or dying retina with poor visual prognosis in that location. Hypoautofluorescence is also seen in pathology that blocks the normal signal such as vitreal or preretinal hemorrhage.

An increase in AF is due to rapid turnover of the photoreceptors or an abnormality in the phagosomal uptake of lipofuscin from them. Therefore, an increase in AF denotes a sick or stressed RPE and active retinal disease.[2] Other causes of increased AF include: fluorophores that are not within the RPE lysozomes, most commonly drusen of the optic nerve head; astrocytic hamartomas; chronic hemorrhage; and deposition in Best's disease or adult onset vitelliform macular dystrophy.[3]

Similar to color fundus photography, FAF is useful for baseline, as well as serial, imaging to help identify hyperautofluorescent or hypoautofluorescent lesions and monitor their size, shape and location over time. Baseline FAF imaging is especially useful for retinal diseases likely to cause metabolic change to the RPE. In early stages of many diseases, the fundus may appear normal during funduscopic examination and colored fundus photography, but FAF has the ability to show dysfunctioning RPE health at the metabolic level. FAF is useful in any retinal disease that affects the integrity of the RPE and should be used in all cases for both baseline and periodic monitoring, the frequency of which is case dependent. Functional deterioration of the retina can occur much earlier than structural changes, which are detected clinically later in the disease process. As such, it should be used more liberally than conventional photography to allow the clinician to assess the disease state at both an anatomic and metabolic level.

FAF is exceedingly useful in diseases of RPE dysfunction such as Stargart's disease and pattern dystrophies that cause hyper FAF; diseases of RPE atrophy, such as geographic atrophy; hereditary RPE or macular dystrophies that cause hypo FAF; subretinal autofluorescent accumulation disorders such as vitelliform dystrophies and central serous chorioretinopathy; window defects in the cases of white dot syndromes and macular telangiectasia; and other diseases of increased lipofuscin deposition including optic disc drusen and astrocytic hamartomas. It is also now a recommended objective modality of monitoring for Plaquenil maculopathy, along with multifocal ERG and spectral domain OCT. Hyper FAF is likely to precede visual acuity or visual field loss due to macular toxicity.[4]

FAF can also help differentiate between clinically similar looking retinal diseases, or to confirm a suspected diagnosis. An example

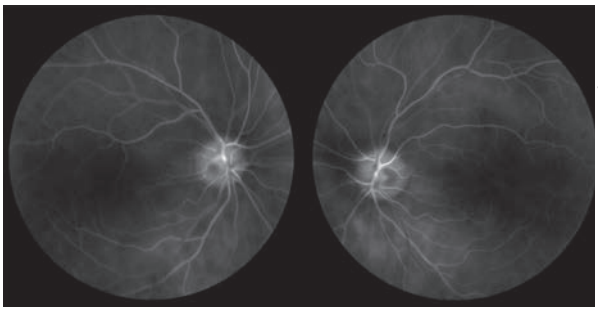


Photo: Dorothy Hitchmoth, OD

Fig. 5. This multispectral imaging photo shows two healthy eyes. With this system, the wavelengths of LED sourced light are used to highlight the oxyhemoglobin molecule in blood. If oxy heme is present, the image are will appear white.

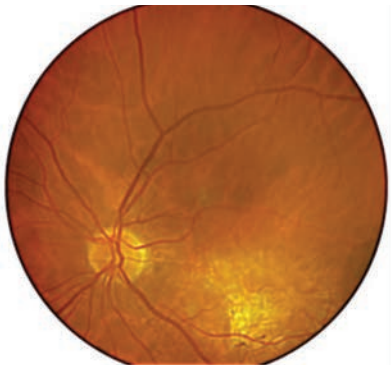
is adult onset vitelliform dystrophy (AOVD) versus age-related macular degeneration (AMD). Both have risk for choroidal neovascular membranes (CNVM) that should be monitored carefully, but AMD is much more likely to progress to severe vision loss so it should be monitored more closely and AREDS therapy should be initiated. Similar to fundus photography, the software for many FAF cameras allow for caliper measurements. That way, if any hypofluorescence or hyperfluorescence is imaged, it can be measured and monitored over time.

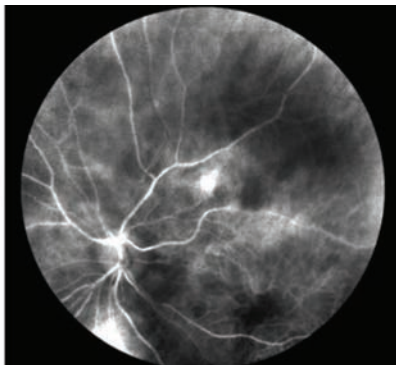
Figures 3 and *4* show a patient who, funduscopically, has a large, central, yellow, elevated lesion, but also has pinpoint surrounding drusen. FAF can help determine if the retinal dysfunction is concentrated solely in the lipofuscin-filled yellow lesion—diagnostic for AOVD—or if it is more diffuse with mixed hypoautofluorescence and hyperfluorescence, indicating AMD is more likely. In this case AOVD was confirmed with FAF and other diagnostic techniques, and the patient is being monitored and managed accordingly.

Peeling Back The Layers

Multispectral imaging (MSI) is another noninvasive imaging technique that allows individual assessment of retinal layers and choroid based on their absorption spectra (*Figure 5*). Monochromatic LED wavelengths ranging from 450nm to 800nm dissect the *in vivo* retina and choroid into spectral slices.[5] This allows a gradual examination of differing depths of tissue to a microscopic degree unavailable with funduscopy, fundus photography or FAF.

MSI takes advantage of five light-absorbing molecules in the eye called chromophores. These chromophores are retinal hemoglobins, choroidal hemoglobins, choroidal melanin, RPE melanin and





Figs. 6 and 7. Perfusion mapping (right) compared with a color fundus photo. The area of hyperperfusion superior indicates leakage and CNVM, which was confirmed with FA.

macular pigment.[6] Each chromophore absorbs a different wavelength of light and can be imaged separately with MSI technology. Generally, longer wavelengths—including those beyond the human visible spectrum—image deeper elements of the posterior segment. A compilation of scans shows a topographical map of each layer of the retina from the inner limiting membrane through the choroid. These *en face* progressive images enhance our ability to localize and interpret retinal pathology.

MSI allows a detailed analysis of the RPE and choroid without interference from the anterior retinal structures, which is helpful in evaluating early outer retinal diseases. Unlike FAF, which extrapolates RPE health from its metabolic activity, MSI can directly visualize RPE structural changes. This is especially beneficial in early AMD cases when the RPE undergoes subtle physical changes only visable through MSI. Focal hyperpigmentation, seen in long wavelength spectral slices, is often not visualized with funduscopy, color photography, FAF or OCT. MSI is especially helpful in evaluating macular pigment, which has a protective role in the retina and is important in the development and progression of AMD. MSI allows the practitioner to examine variation in pigment distribution to identify individuals at risk of developing visual loss and to change treatment accordingly. In addition, MSI can image lipofuscin and melanin, giving it credible applications for a wide variety of inner and outer retinal diseases and choroidal pathology including retinitis pigmentosa; congenital retinal pigment epithelial hypertrophy (CHRPE); hyperpigmentation after reabsorption of fluid as in central serous chorioretinopathy (CSCR) and adult-onset vitelliform dystrophy (AOVD); choroidal nevi and melanoma; and for drug induced retinal toxicity due to Plaquenil (hydroxychloroquine, Sanofi-Aventis), as it has an affinity for melanin.[7]

Once retinal disease is apparent, MSI can identify subtle progression that standard methods cannot. These differences can be used to track disease progression in three-dimensional space: length, width and exact depth within retinal layers.

In addition to retinal imaging, the Retinal Health Assessment (RHA) MSI (Annidis Health Systems) also offers a perfusion map feature that can identify exudative retinopathy. Perfusion mapping examines oxygenated—as opposed to deoxygenated—hemoglobin to assess change in retinal vasculature (*Figures 6* and *7*). It has the ability to identify early choroidal neovascularization noninvasively in an optometric setting, unlike fluorescein angiography.

In the normal eye, retinal arteries appear brighter (hypersaturated) compared with veins because of their oxygenation level. The choriocapillaris is also imaged with this technique, which has been described as a virtual indocyanine green (ICG). If leakage is present from a neovascular membrane, the area appears hypersaturated and the net can be visualized. The hypersaturation in perfusion mapping in exudative AMD tends to agree with late-phase fluorescein angiography leakage and thus an active CNVM.

MSI can be performed to evaluate any stage of retinal or choroidal disease. In early stages, unexpected structural alterations may be found that cannot be viewed with either conventional imaging or funduscopy. It can distinguish overlapping or occult disease and can evaluate retinal vasculature abnormalities.

Because it is capable of detecting these invisible funduscopic changes, it can be used as a screening device for certain patient populations, specifically those at risk for macular degeneration, diabetic retinopathy or macular edema, and in children with a family history of hereditary macular degeneration. In these cases it is prudent to offer this as part of an annual comprehensive examination for earliest detection and intervention to improve long-term outcomes.

Optical Coherence Tomography

OCT is extremely helpful with retinal—specifically macular—diagnoses. It has enhanced identification and treatment of subtle and subclinical signs of a multitude of retinal

disease and it also aids in differentiating disease entities that are similar in clinical appearance. Certainly the advent of spectral domain (SD), compared with time domain (TD), OCT has made diagnoses even more concrete with high definition technology and deep choroidal imaging. New OCT software has the ability to examine the inner and outer retina simultaneously or separately and can show *en face* imaging for macular surface disease such as epiretinal membrane.

OCT is a pseudohistologic study in cross-section. Although it has not replaced fluorescein angiography for the identification and localization of CNVM in neovascular AMD, it has decreased the use of this somewhat invasive procedure.[8] It can accurately detect even subtle fluid accumulation under or within the retina that can't always be visualized clinically.

For example, a patient presented with no reported symptoms for her annual comprehensive examination. Upon dilation, a large microaneurysm with exudate was noted close to the foveal avascular zone (FAZ) in her right eye. Central FAZ fluid could not be visualized during funduscopy, but because of the likelihood of macular edema being present due to the amount of exudate seen, an OCT was ordered (*Figure 8*). The OCT confirmed subtle cystic spaces centrally in her right eye. She was referred to a retinologist who agreed with the diagnosis. Because subtle edema was evident on OCT, focal laser treatment was promptly recommended to prevent further leakage, fluid accumulation and possible permanent deterioration to her central vision. The macular edema and microaneurysm resolved without permanent consequence to her vision. If the OCT did not show macular edema, treatment would have been deferred, and monitoring would have been more appropriate.

Because of the many benefits of OCT, it should be used to obtain a baseline on all macular disease states. Most OCT instruments have software to calculate thickness change to microscopically measure macular edema, thickening or atrophy between serial scans. OCT has proven more sensitive in identifying diabetic macular edema than a clinician during funduscopy and fluorescein angiography.[9,10] It is clinically useful in a wide variety of macular diseases, including; vitreomacular traction, epiretinal membrane, RPE detachments, macular degeneration, Central serous chorioretinopathy (CSCR), vitelliform dystrophy, hereditary macular dystrophies, any form of macular edema and toxic maculopathy. It will often identify microscopic macular disturbances before it progresses

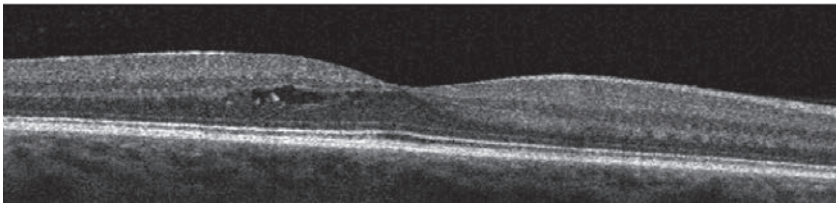


Fig. 8. This image of subclinical central macular edema is due to a temporal macular large microaneurysm and can only be detected with OCT. It would not visible on funduscopy or fundus photography,

to being funduscopically visible.

Similar to FAF, SD-OCT is now a recommended testing guideline to diagnose Plaquenil maculopathy prior to visual acuity loss, color vision or visual field deficit.[4] It also has great benefits for glaucoma patients by measuring both retinal nerve fiber layer thickness and calculating change over time, as well as ganglion cell complex thickness—which is becoming ever more important in the diagnosis and management of glaucoma.

Additionally, OCT imaging of the cornea, iris and angle is now more advanced and more detailed than ever before and, as a result, is used on a more frequent basis to improve upon our ability to manage anterior segment diseases.

OCT Offspring

OCT has been improving since its advent. First generation OCT was TD-OCT, which translated the path length of the reference arm for depth information about the retina longitudinally with time. SD-OCT, which measures the inferometric signal as a function of optical frequencies, allows faster imaging with increased detail and greater number of images per scan compared with TD-OCT with less artifacts and noise.[11] However, SD-OCT is still somewhat insensitive to higher frequencies, which is why the quality of the signal decreases with depth of the posterior segment.

To compensate for this, enhanced depth imaging (EDI-OCT) was made to move the peak of sensitivity inward, allowing for imaging beneath the RPE into the choroid and lamina cribrosa. Imaging of the choroid is helpful in several retinal pathologies including measurements of choroidal changes, such as nevi and melanoma, as well as retinal diseases that have a direct effect on the choroid. Notably, investigators have found the choroid is significantly thickened in CSCR, leading scientists to believe that increased hydrostatic pressure in the choroid is a direct cause.[12] Age-related choroidal atrophy, which was also associated with loss of visible blood vessels, was discovered with EDI-OCT studies.[13] Patients with age-related choroidal atrophy may be at a higher risk to develop glaucoma or macular degeneration.[13]

OCT technology continues to evolve and improve today. Now called the third generation of OCT, swept source OCT (SS-OCT) scans through a series of wavelenghts and interprets the spectral components in time as opposed to spatial separation. This provides low artifacts while achieving exceptional quality at extremely high frequencies. The result is a deeper range of imaging into the eye, a higher axial resolution and faster scanning speed. This larger range of imaging allows the same sensitivity over the entire scan window, which allows the vitreous, retina, choroid and lamina cribrosa to be visualized at the same time. SS-OCT also has the capability for widefield scanning to image both the disc and macula in a single scan. This benefit makes imaging off-axis pathology, such as choroidal nevi, much easier with a larger target area. As compared with SD-OCT—which segments full thickness, inner and outer retina—SS-OCT can automatically segment the retina into seven layers: internal limiting membrane, retinal nerve fiber layer, macular ganglion cell layer, inner segment-outer segment junction, RPE, Bruch's membrane and choroid, making it easy to delineate the precise anatomic location of deficits.[14] The new generation of OCT provides better image quality, more easily interpreted and more repeatable than previous models.

Both SD-OCT and SS-OCT are being used to image retinal blood flow known as OCT-angiography (OCT-A) without the use of intravenously injected fluorescein or indocyanine green. Speed of imaging is particularly vital to the quality of an OCT-A image, which is one reason why SS-OCT will be of great benefit to optometrists as this technology becomes more widespread. OCT-A uses an algorithm known as split-spectrum amplitude-decorrelation angiography to detect motion in blood vessels by the variation in reflected OCT signal amplitude between consecutive scans. This algorithm can quantify data on both flow index—a measure of capillary flow velocity—and blood vessel density. Clinically, it detects capillary dropout as well as neovascularization. It differs from both FA and ICGA, as it does not measure leakage from blood vessels; rather, it images exact delineation and size measurements of aberrant blood vessels (such as seen with choroidal

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neovascularization), or lack thereof. It is also able to correspond blood flow and measurement information in tandem with OCT B-scans. The clinician can scroll through an OCT cube, just as in SD-OCT 3D imaging, to view the precise location of pathology. While OCT-A is able to image both retinal and choroidal microvasculature, FA is better for retinal abnormalities and ICGA is more ideal in choroidal imaging.[15]

Conditions best studied with this novel technology include macular degeneration, diabetic retinopathy, macular edema, and retinal vein and artery occlusions. Although this is a new technique, it is likely to play a large role in the management of all ocular diseases that affect the vasculature of the retina or choroid.

Furthermore, because it is less invasive than either FA or ICGA, it will be more frequently employed, likely aiding in identifying neovascularization or blood vessel dropout much easier throughout the population than ever before.

OCT is such a dynamic tool in optometric practice that it can and should be used on almost all retinal conditions as baseline. The timing of retesting is determined on a case-by-case basis. Because it is such a versatile instrument that yields information not able to be visualized with funduscopy, it is exceedingly useful for serial monitoring to determine prompt initiation or change to treatment.

Retinal Oximetery

This new, noninvasive technology is designed to calculate relative oxygen saturation of retinal blood vessels. The ratio between a wavelength of light sensitive to oxygen saturation and a wavelength control that calibrates light intensity is linearly related to hemoglobin oxygen saturation.[16] Specifically, it calculates retinal vessel oxygen saturation and vessel width, which has been shown to be different in a variety of retinal diseases, including: exudative AMD, retinitis pigmentosa and in retinal vascular diseases such as central retinal vein occlusion (CRVO) and central retinal artery occlusion (CRAO).[17-20]

Although this is a relatively new technology, studies show dual wavelength oximetry can help doctors identify diseases that affect retinal vasculature.[21] Retinal oxygen saturation is lower in venules affected by CRVO, variable in BRVO, lower in retinal arterioles during CRAO and is increased in diabetic retinopathy, according to investigators.[21] Clinically, it can be helpful in identifying the extent of retinal vascular disease to better determine a prompt treatment plan and discuss a more accurate prognosis. Because of the simple graphics in the software, it is also easier for patient education than fluorescein angiography.

Retinal imaging has greatly enhanced the diagnosis and management of a multitude of ocular disease. Baseline imaging in the appropriate modalities can be invaluable. Some imaging technology has the ability to capture retinal function before it affects funduscopic structure. Others can, in detail, image single layers of retinal tissue and identify defects that are invisible during a dilated fundus examination. Noninvasive imaging is also starting to help clinicians diagnose retinal vasculature status, and may someday be able to take the place of invasive fluorescein angiography.

It is vital to understand the clinical utility of each imaging modality in order to appropriately order, interpret and repeat imaging in the future. In doing so, it can benefit the patient by improving clinical diagnosis and management without unnecessary overuse. ■

Dr. Legge is in private practice at Wyomissing Optometric Center in Pennsylvania and has an advanced retinal studies certificate through Salus University.

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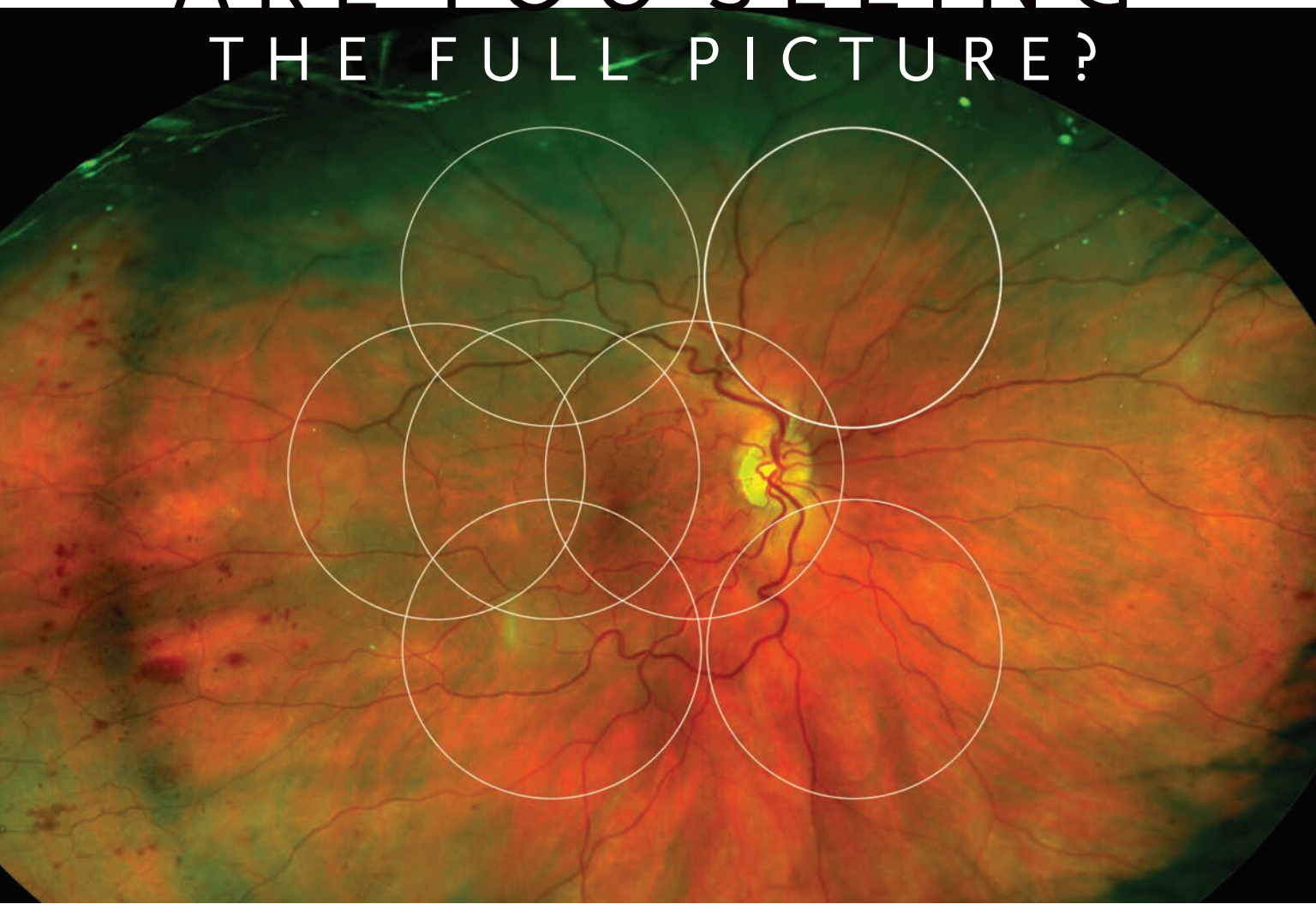

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39th Annual Technology Report

How I Learned to Stop Worrying and LOVE EHR

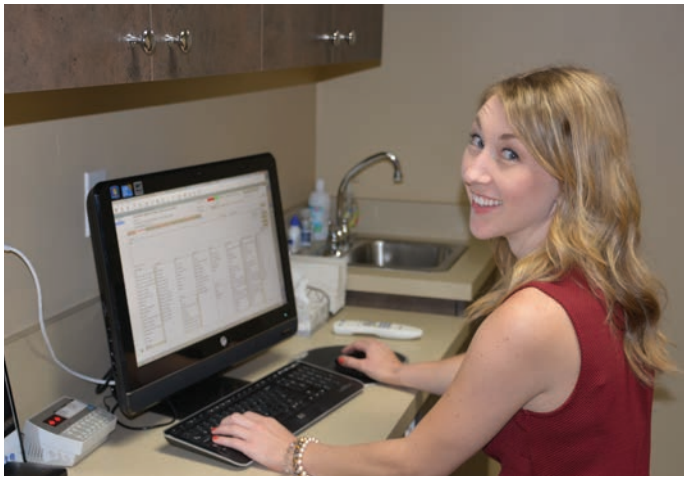
Tech wizards discuss their biggest hurdles and how you can clear them when it's your turn. **By Jane Cole, Contributing Editor**

If you're still longing for the days when you could pick up a pen and write down your patient's macular degeneration progress, or if you've warmed up to your software but aren't quite thrilled, it's time to face the facts: electronic health records (EHR) aren't going anywhere.

With the federal push for Meaningful Use (MU) compliance and the recent conversion to ICD-10 codes, optometrists are becoming increasingly more reliant on their EHR systems. As such, seasoned users say buckle up for EHR's long ride and don't lag behind when it comes to your electronic record keeping.

"These systems have become very powerful. They're not just EHR, they are the hub of your business," says Jason Miller, OD, of Powell, Ohio.

This article features the wisdom of optometrists—who've been through EHR red tape, lawsuits and more—on how to troubleshoot software bumps and overcome frustrations so you can use this technology to its greatest benefit.



Kimberly Michel, OD, who practices at Eyelux Optometry, along with Brian Chou, OD, operates the team's EHR.

All EHR-induced Trauma

The biggest benefit of EHR for Brian Spittle, OD, of Midlothian, Va., is how it helps the doctors at his growing practice all get on the same page, especially since his practice recently expanded from two to four doctors. EHR provided him the efficiencies of continuity and consistency of documentation, he says. "We have a centralized data management system where all aspects of our practice come back to this one hub, and everyone is on the same talking points page," says Dr. Spittle. While his practice has grown, so has his EHR system, which today has its own command central room, consisting of seven servers in a climate-controlled setting.

Of course, the seasoned pros remember the early growing pains of EHR. Brian Chou, OD, of San Diego, Calif., implemented his first system in 2006 and refers to the experience as "traumatic."

"One doctor reverted back to paper, a staff member quit, patients

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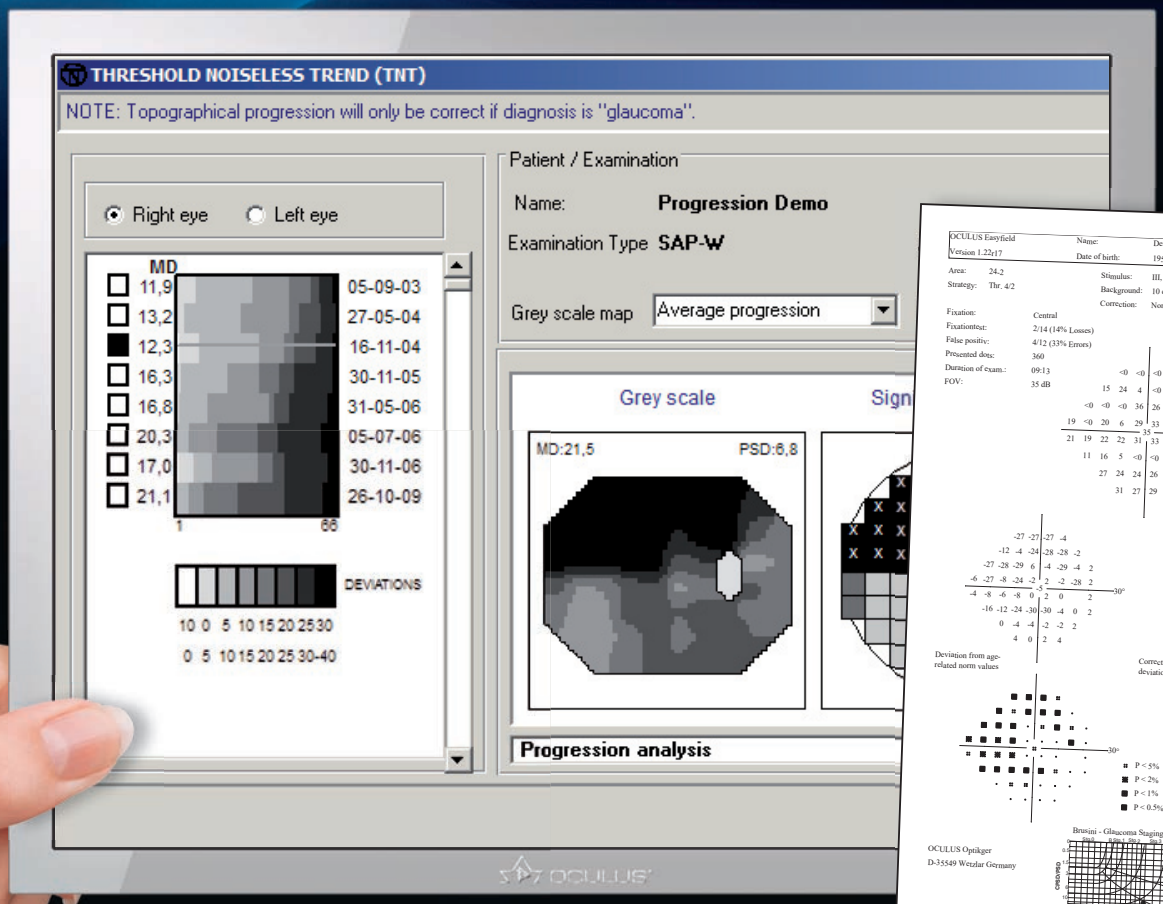

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were unhappy due to mistakes, it took longer for staff and doctors to figure out their usual functions and collections took a big, but temporary, hit," he recalls.

When Dr. Chou moved to his current practice in 2011, the transition was a cinch since his new team was experienced with EHR, and there was good teamwork amongst the doctors and staff, he says.

EHR's Bad Reputation

Scott Jens, OD, of Middleton, Wis., who is also the CEO of RevolutionEHR, estimates 75% of optometrists are using EHR today, and this percentage consists of early adapters who wanted to get rid of paper records, those who migrated to EHR because of MU and the latest recruits who got on board to help with conversion to ICD-10.

Whether its increased usage is out of necessity or choice, Dr. Jens says the main perceived obstacle of EHR is the belief that software has not automated practices as much as doctors had hoped.

"In some cases, people are saying, 'I've never heard anyone say they are thrilled with their software,'" Dr. Jens says. "I can tell you that's not true, but that perception can be a big barrier to entry." Another obstacle to EHR is that patients may pick up on their doctor's unenthusiastic attitude, rather than embrace the education it enables, he adds.

Still, Dr. Jens believes those who've gotten on board with EHR know it is a very powerful tool for both the patient and the practice. For patients, it provides easily accessible information such as prescriptions, receipts and their personal health care records, in addition to the ability to schedule appointments through their personal portal, he says. And in turn, the software benefits the practice through gained efficiencies, including freeing up staff from running routine tasks such as recall reports for scheduling and appointment reminders that now are automated. These efficiencies reduce staff expenses and can refocus staff's efforts on patient care. Additionally, the software ties the patient data to other health care providers, linking critical information such as medication history and previous diagnoses, he adds.

Brian Spittle, OD, opted to go with this server based system rather than a cloud. His servers are housed in a climate controlled room.

Surviving An MU Audit

In addition to choosing and implementing an EHR system, another big challenge is the fact that many are far behind in MU, Dr. Miller says. "CMS phased in various MU criteria along the way. It is going to take a high amount of commitment to meet each specific MU area," he adds.

For those who've gone through MU audits, experts give one word of advice: documentation.

TeShawna Sutton, OD, of London, Ky., has survived not one, but two, attestation audits by the Centers for Medicare & Medicaid Services (CMS).

"The first audit was extremely scary," she says. "Of course, that one was from our first reporting year and was, therefore, for the most money."

But the initial audit helped her learn some valuable lessons moving forward, she says. "I hadn't been quite as diligent with screenshots and creating a paper trail to prove that what I had reported was true up until that point," she says. "That, of course, left a lot of questions open from the auditing firm; but luckily we were able to produce enough documentation to prove we had sufficiently met MU requirements."

Since then, Dr. Sutton says her practice has been extremely diligent in its attestation process, including being vigilant on photo-documentation. Additionally, she hired an outside firm to do her security risk analysis (SRA) to ensure her practice has correctly prepared backup documentation.

Despite her efforts, her practice faced a round-two audit this year all because of a typo, she says. The second audit focused on an initial SRA that had the date of the previous year on the header. Fortunately, the company she hired had recorded and time-stamped phone calls and screenshots to prove the SRA had been completed in the correct reporting year. "It was a simple typographical error, but it carried big potential problems. Luckily, with experience, we have learned how to survive better," she says.

While audits may be triggered by the way you bill a visit on a claim, many CMS audits are selected randomly, Dr. Jens says.

"Today, there isn't a way to avoid an audit, but the way to succeed is to do MU by the book, and that means not taking shortcuts," Dr. Jens says.

Corneal Hysteresis is more associated with visual field progression than CCT or IOP.[1-3]

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References: 1. Medeiros FA, Meira-Freitas D, Lisboa R, Kuang TM, Zangwill LM, Weinreb RN. Corneal hysteresis as a risk factor for glaucoma progression: a prospective longitudinal study. Ophthalmology. 2013 Aug;120(8):1533-40. **2.** De Moraes CV, Hill V, Tello C, Liebmann JM, Ritch R. Lower corneal hysteresis is associated with more rapid glaucomatous visual fi eld progression. J Glaucoma. 2012 Apr-May;21(4):209-13. **3.** Aashish Anand, MD, Carlos Gustavo De Moraes, MD, Christopher C Teng, MD, Celso Tello, MD, Jeffrey M Liebmann, MD Robert Ritch, MD. Lower Corneal Hysteresis Predicts Laterality in Asymmetric Open Angle Glaucoma, IOVS Papers in Press. Published on June 23, 2010 as Manuscript iovs.10-5580.

Staff: Train All or Select Few?

Most optometrists recommend you get your entire staff on board with EHR training. And most vendors will provide it, ranging from on-site—using a paid trainer, which is typically the most expensive—to do-it-yourself online videos and webinars, Dr. Chou says. "The training needs for each practice will vary from one to another. It requires careful and regimented planning to successfully pull off. It is definitely better to err on the side of overtraining than undertraining," he says.

For Dr. Jens, training starts with the doctor. He says his EHR company has witnessed the best results when doctors agree to go through the training process with their staff. Given the widespread practice involvement of EHR—from the front desk to the back office, optical to contact lenses, and doctors to technicians—everyone needs to do their part when it comes to education, he adds.

At Dr. Spittle's practice, every member of his staff is trained, but only in the precise aspects of their job that pertain to EHR. "The people who work in the exam rooms know a lot more about health records than the front desk," he says. "Our system has been integrated to different parts of our day on the same system. We're all integrated, but everyone knows what they should do (on EHR) to do their job."

Working Out Workflow Kinks

Initially, implementing the new software will impact workflow and productivity, doctors say. As such, many doctors have opted to cut down the practice's schedule during the initial roll out.

TeShawna Sutton, OD, gives staff member Sarah Lambdin some tips on using the EHR system.

At Dr. Spittle's practice, when he launched his second EHR system, he cut his patient volume in half for the first few days. "That's one of those costs you don't budget for ahead of time," he says.

Adds Dr. Sutton, "I believe EHR has ultimately helped with workflow and productivity over the long term. It was cumbersome at first, as we were learning the program, but I believe now it's a bonus. In the early days, we did some explaining to our patients that we were moving a little slower because of the computers, but I believe patients were seeing EHR being used all across health care, and they were accustomed to it."

The Necessity of Specificity

With an updated EHR system, the recent conversion from ICD-9 to ICD-10 codes should not be an issue, Dr. Chou says. "With a decent EHR, coding is generally facilitated, since the EHR should auto suggest the appropriate code and allow the user to bring forth coding from prior exams," Dr. Chou says.

For Dr. Sutton, coding has been the best thing about EHR. "Our software codes are based on what you build within the exam. The switch from ICD-9 to ICD-10 went much more smoothly than expected because of EHR," she says.

Still, don't get complacent about coding or what your EHR may be programmed to suggest as you document your patient's visit. Otherwise, it could cost you.

With some new ICD-10 codes coming out this year, it is important for doctors to stay abreast of them, Dr. Jens says. While CMS and private payers were more lenient this year with ICD-10 codes, more specific eye codes, especially ones for chronic eye diseases, are on deck, and Dr. Jens cautions doctors to be as specific as possible with coding, or they will likely start to see claims rejected in 2017.

"I urge doctors to say, 'Okay, I made the conversion, but now I might have to update my codes once again to get to the most specific version,'" Dr. Jens says.

Since Dr. Jens recently served as an expert witness on an EHR malpractice case, he stresses doctors should be as specific as possible when it comes to coding and documenting patient visits.

"The paradox with EHR is that the recordings are highly legible but sometimes inaccurate." Dr. Chou says. "This is because EHR makes it so easy to create 'normal' findings to meet various exam criteria. But if the findings aren't actually normal, then it's data fabrication."

He gives the example of EHR that automatically copies the entry of eye pressure for the right eye to the

left eye. "Presumably, the software engineers thought they were helping practitioners save time," Dr. Chou says. "But in doing so, this can create false data. In this previous example, if the IOP of the left eye is not taken, the EHR user must delete the copied IOP reading in the field for the left eye, or else it appears as if the eye pressure in the left eye was actually taken, even if it wasn't."

Dr. Chou, who has recently served as an expert witness in several medical malpractice cases where EHR was used, has seen how this type of error has caused major problems. In these lawsuits, there was conflicting information because normal data was automatically populated and the prior exam information was copied forward because, essentially, it was an easy shortcut, althought innacurate.

There are other situations where properly documenting a finding, such as screening for a visual field defect, is so cumbersome and time consuming, that the practitioner is tempted to just record a normal finding, Dr. Chou adds. "A well-designed EHR uses practitioner feedback to guide development of their software so that these sorts of burdens are minimized without compromising the accuracy of documentation."

"It's not difficult to use EHR to make your records look incredibly strong if you just use them to their fullest and not take shortcuts," Dr. Jens adds. "I compel optometrists to look at medical records as their way of staying actively involved in the future of medical care. But in the end, it's about making sure a patient's wellness is well tracked," Dr. Jens says.

Software in the practice is really meant to improve patient care and outcomes, and with that comes an expectation to diligently document a medical service as specifically as possible, Dr. Jens says. "I fear that without the panacea for data input, many doctors won't appreciate the value of documenting everything to the most granular degree. I trust this industry to make advances to make data entry easier and easier over time, and that doctors of optometry remember that it's not just about good outcomes management, but that the medical record in an EHR is still the determinant in medicolegal situations. It's not the testimony on the stand that matters. It's what the record says."

EHR for many might not be perfect, but it has become an ally to most practices. "I may have said at one time that I'd love to see us go back to when we didn't have computerized records," Dr. Sutton says. "But now, I would definitely say there's no way I would want to go back to paper at this point." ■

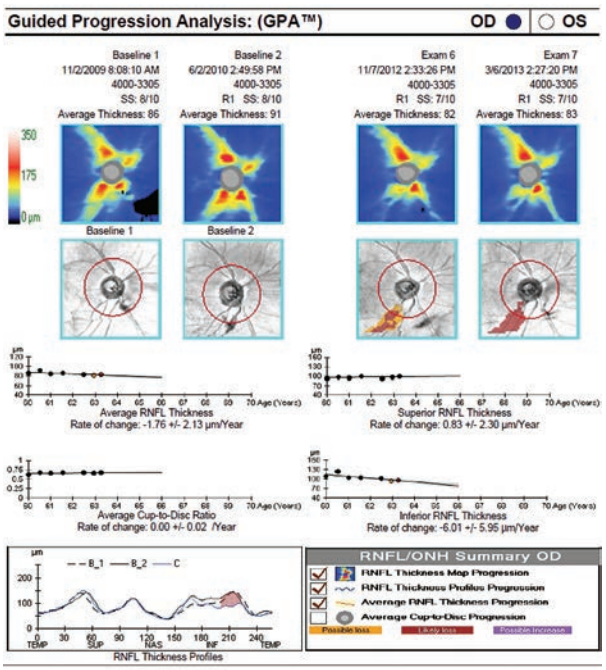
39th Annual Technology Report

The Best Tech for Tracking Glaucoma Progression

OCT is the new gold standard for diagnosing and monitoring glaucoma. Here's how to use it in clinical practice. **By Danica J. Marrelli, OD**

Glaucoma is a chronic, progressive disease of retinal ganglion cells that results in characteristic structural changes to the optic nerve and retinal nerve fiber layer (RNFL), as well as corresponding visual field loss. Glaucoma affects nearly three million people in the United States today, with numbers likely to reach more than six million by 2050.[1] While the rate of blindness from glaucoma in the United States has decreased significantly in the past 20 years—likely due to improved diagnostic and treatment modalities—glaucoma remains a common cause of permanent blindness and disability.[2] Early detection is key to slowing progression, and clinicians have many tools at their fingertips to help them with this.

This article highlights how eye care practitioners can use optical coherence tomography (OCT) to detect structural progression in glaucoma.



Case one is a 66-year-old glaucoma patient. The RNFL thickness map shows a decrease in thickness inferiorly (loss of reds and yellows), which is also identified in the deviation map, with the development of a clear wedge RNFL defect over several years (event analysis). Average and inferior RNFL thickness trend analyses show significant negative trends over time. The RNFL thickness profile (TSNIT) also shows confirmed inferior progression.

Glaucoma Progression

Detecting progressive changes in glaucoma is an important, yet difficult, aspect of disease management. Progression detection is challenging for a variety of reasons, including: the slow but variable rate of progression among patients; the inherent variability of testing such as visual fields and OCT; the lack of agreement between test results; and the lack of consensus on what defines progression. Most glaucoma patients exhibit slow progression of structure and function over many years. However, a subset of glaucoma patients will show rapid progression and are at risk of significant visual disability or blindness.

To reduce the likelihood of visual disability, once clinicians have made the diagnosis of glaucoma and have initiated treatment, they should focus primarily on whether the

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disease is stable or whether there are progressive changes that require an increase in therapy.

Risk Factors For Progression

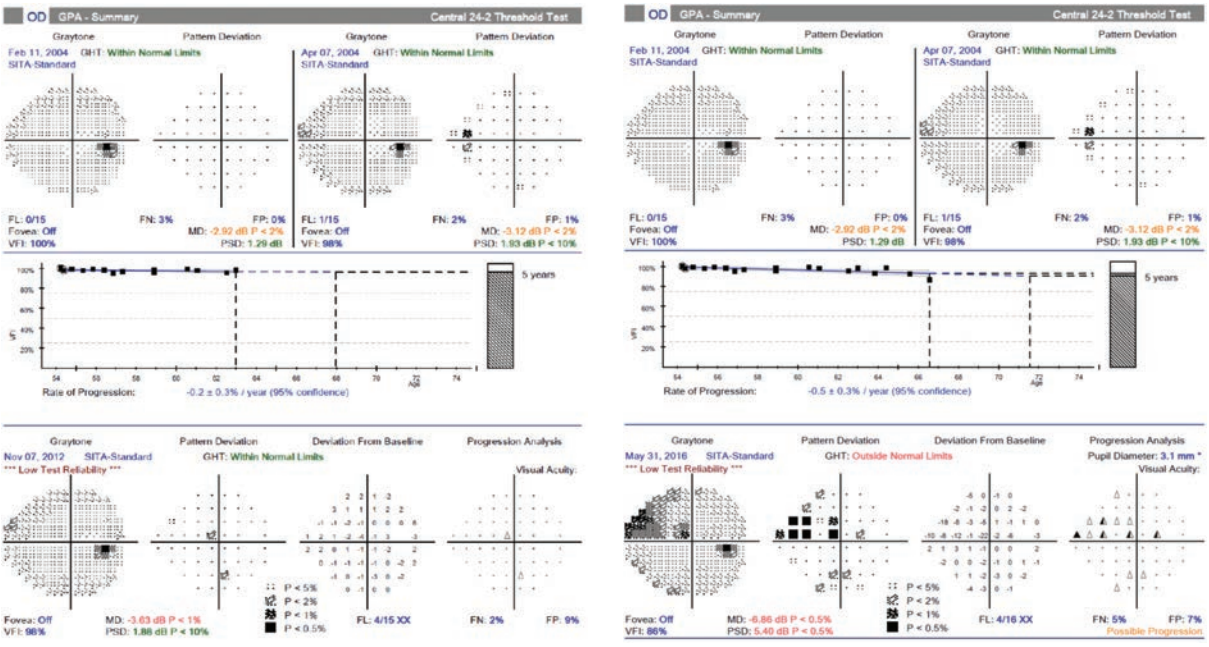
Just as risk factor assessment is important in the diagnosis of glaucoma, it can also be used to identify glaucoma patients with the highest risk of progression. Research has identified a number of risk factors for progression, including higher intraocular pressure, pseudoexfoliation, older age, lower ocular perfusion pressure, advanced disease at time of presentation and the presence of an optic disc hemorrhage.[3] Patients with significant risk factors for progression should be followed more closely to ensure the treatment plan is sufficient.

Tools For Detecting Progression

According to the World Glaucoma Association's Progression of Glaucoma consensus publication, both functional and structural testing should be conducted throughout the course of the disease.[3] While visual fields and optic disc photography have been considered the gold standard for detecting progression, no one particular test is perfect for detecting progression. Furthermore, there is not always agreement among tests or those interpreting the tests. Although structural changes are thought to precede and even predict functional changes, that is not always the case.

Clinicians have used automated perimetry for decades to detect functional progression in glaucoma patients. Despite the subjective nature of the testing and the importance of patient attention and cognitive abilities, it remains a critical component of glaucoma testing. Because structural changes often occur before functional deficits, structural assessment is important even when visual function is normal. Structural progression can be detected using a variety of tools, including optic disc and RNFL photography and OCT.

Optic disc and fundus photography remains an important tool in the diagnosis and management of glaucoma. Changes in neuroretinal rim appearance—such as focal or diffuse neural rim thinning, enlargement of the optic cup, changes in peripapillary atrophy and disc hemorrhage development—can be detected through serial optic nerve photography. These changes are often very subtle and require careful evaluation of sequential photographs; comparison of C/D ratio, written descriptions of the optic nerve, or even drawings are not sensitive enough to detect subtle changes. In eyes with sufficient pigmentation, serial photography can help identify RNFL defects and progressive changes, which are also difficult to



For case one, at the time that progression of the inferior RNFL loss was confirmed, the most recent visual field, left, showed no progression. However, over the next three years, she developed a corresponding superior visual field defect, right.

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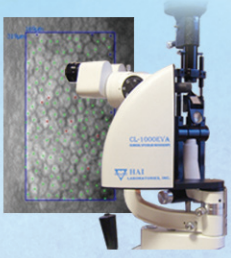

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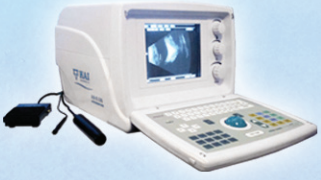

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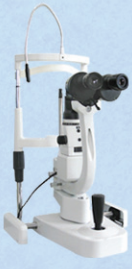

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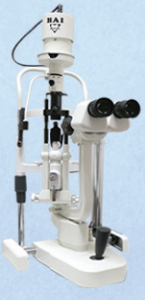

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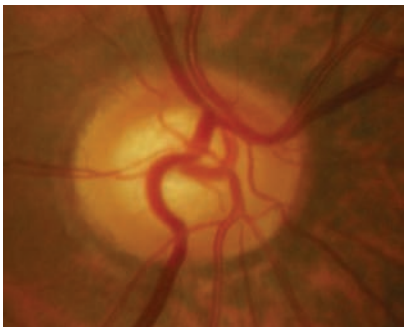
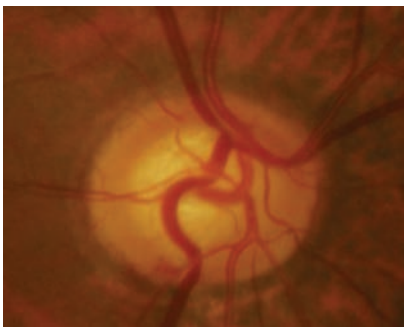
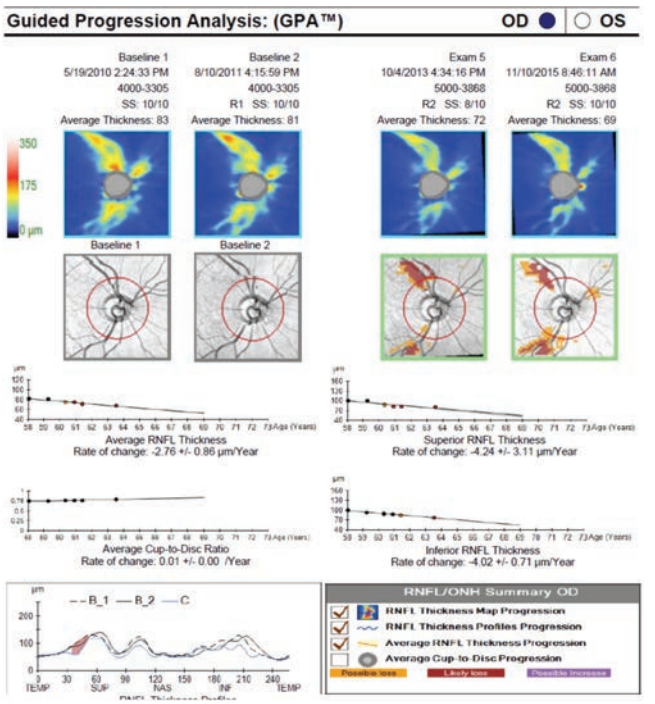




Case two is a 66-year-old patient with normal tension glaucoma. Serial optic nerve photographs of the right eye demonstrate a disc hemorrhage inferiorly with corresponding thinning of the neuroretinal rim, along with more subtle thinning of the superior rim indicated by a change in the course of the blood vessel at 11:00.



Case two's RNFL thickness map shows loss of superior and inferior RNFL over five years. Average, superior and inferior RNFL show a significant rate of decline. Both superior and inferior RNFL show loss on the TSNIT curve, although statistical significance is only noted superiorly.

appreciate.

Beyond these tried-and-true tools, OCT has gained wide acceptance in clinical practice since its introduction in the early 1990s. Today's spectral domain (SD-OCT) instruments provide high resolution and highly repeatable images that can be used in the diagnosis of glaucoma and detection of structural progression. Historically, clinicians have used optic nerve and RNFL parameters to diagnose and follow glaucoma patients. OCT can measure optic disc parameters such as disc and rim area, cup-to-disc ratio (average and vertical), minimum rim width and cup volume. RNFL measurements include average thickness and thickness subdivided by quadrant.

More recently, macular imaging with OCT has emerged as an important parameter in the diagnosis of glaucoma. Currently, several commercially available OCT instruments have a glaucoma protocol that involves macular imaging. These instruments vary in the way they analyze the macula (various inner retina segmentation algorithms versus full thickness symmetry analysis). There are several advantages to using macular scans compared to optic nerve and RNFL parameters. At a fundamental level, glaucoma is a disease of retinal ganglion cells. Since the macula contains more than 50% of the ganglion cells of the entire retina, a macular scan will sample the majority of retinal ganglion cells. In addition, while the optic disc and peripapillary region have highly variable structural characteristics among normal and glaucoma patients, there is much less variability in the macular region.[4,5]

Research shows macular OCT scans have a similar ability to detect glaucoma as average RNFL thickness scans. Detecting and following glaucoma progression using macular thickness is the newest area of interest, and the research is still emerging. It is important to remember that using macular OCT testing in glaucoma diagnosis and progression detection is limited to patients without concomitant macular disease such as age-related macular degeneration, epiretinal membranes and macular edema.

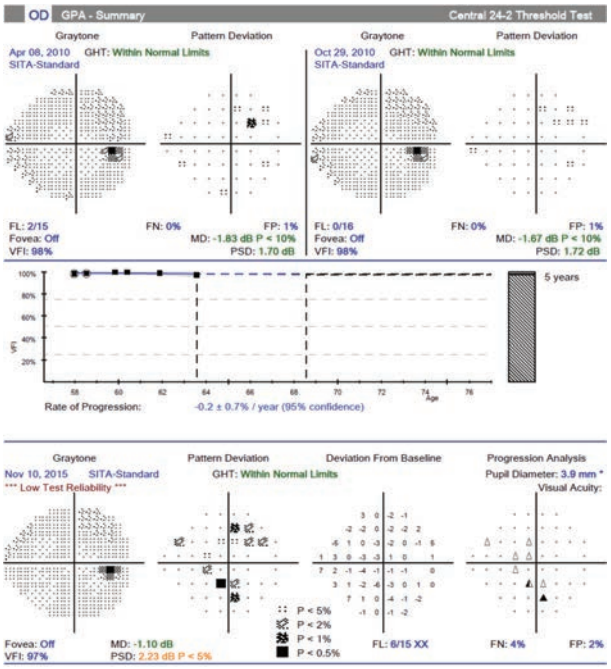
Substantial structural damage may occur before a visual field defect; researchers estimate that OCT could detect glaucomatous changes as early as eight years before a visual field defect develops in glaucoma suspects.[6] Other studies show that OCT changes are correlated with and can predict the development of visual field progression in glaucoma. One study found that glaucoma patients with progressive RNFL thinning had a higher risk of visual field progression compared with those without progressive thinning.[7]

OCT Progression Software

Glaucoma progression software incorporates statistical analysis of sequential OCT scans to detect progressive changes. While different instruments analyze and present the data differently, there are two basic types of analysis: event analysis (EA) and trend analysis (TA).

EA compares a single follow-up test to baseline test(s). Progression is detected when the difference between baseline and a subsequent exam exceeds a predetermined threshold, based primarily on test-retest variability. In simple terms, EA answers the question, "Has there been a change from baseline?" For most instruments, the first time a significant difference from baseline is seen, the change is indicated in yellow, which is considered *possible progression*. If the same change is maintained on consecutive scans, it is indicated in red. For accurate progression analysis, it is critical that the images be aligned for serial evaluation; newer instruments employ eye tracking and other registration strategies to ensure the same areas are compared with each scan. An advantage of EA is that it does not require a large number of tests for analysis; however, it is more susceptible to artifact than TA.

TA performs regression analysis between a particular parameter and time, giving a slope that indicates the rate of change. In simple terms, TA answers the question "How quickly is this patient changing?" TA may be performed with optic disc parameters such as rim area or cup-to-disc ratio, or with RNFL parameters such as average thickness, superior thickness and inferior thickness. Progression is noted when the slope (rate of change) reaches statistical significance. Like with EA, the first exam with a significant slope is typically indicated in yellow; if the slope remains significant with repeat testing, it is indicated in red. Confidence intervals are provided, with tighter confidence intervals indicating a more reliable slope. TA is less susceptible to sudden change and artifact, and the slope is more reliable as the number of follow-up scans increases. Disadvantages of TA include the large number of tests necessary to create a reliable slope and the fact that it may be relatively insensitive to small, focal changes. Recently, in both a simulated progression model and in a study of glaucoma patients, TA performed better than EA in detecting progression.[7,8]



Over the same period of time with case two, there is no confirmed visual field progression, although numerous points tested have changed from baseline (clinician observation indicated good fixation throughout the test).

Challenges

Clinicians are well aware of the difficulties of interpreting subjective testing such as perimetry, and the objective nature of OCT testing is appealing. Although the test itself is objective, interpretation is subjective and influenced by practitioner experience. In addition, there are limitations and caveats to OCT interpretation, such as: measurement variability, age-related (non-disease related) changes, other ocular diseases, signal-to-noise ratio, instrument/image artifacts and the stage of the disease.

Measurement variability. The clinician must discriminate between instrument measurement variability, normal age-related changes and true disease-related changes. Measurement reproducibility with SD-OCT is excellent, as the test-retest variability for an average RNFL measurement is approximately 3.5µm to 5µm.[9] However, when evaluating quadrants, sectors or clock hours, the variability increases as much as twofold. Fortunately, the latest instruments have faster scanning, improved image registration and technology such as eye tracking that have reduced the impact of test-retest variability.

Age-related changes. Keep in mind that every change seen in an OCT scan is not necessarily a disease-related change. Multiple studies have demonstrated age-related thinning of both RNFL and

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macula.[10-13] Cross-sectional studies suggest an age-related decrease in average RNFL of about 0.2µm to 0.33µm per year.[10] Longitudinal studies demonstrate a slightly larger decrease of approximately 0.52µm per year, and suggest that the magnitude of the natural decline varies as a function of baseline RNFL thickness, with patients with higher baseline RNFL thickness showing significantly larger changes over time.[10] Studies have also reported age-related changes in macular thickness of about -0.25µm per year.[11]

Rates of change have been studied in glaucoma suspects as well as non-progressive and progressive glaucoma patients. In a group of glaucoma suspects followed for an average of 2.2 years, one study found that the rate of global RNFL thickness loss was more than twice as fast (-2.02µm/year vs. -0.82µm/year) in subjects who developed visual field loss compared with those who did not develop field loss.[12] Even the glaucoma suspects who did not develop a visual field defect had a rate of RNFL change that exceeded the expected age-related change, although the follow-up in this study was relatively short.[12] Other studies show the rate of RNFL change in progressive glaucoma is nearly twice as fast as non-progressive glaucoma (-2.12µm/year vs. -1.18µm/year).[13]

Other diseases. The impact of concomitant macular disease renders macular OCT scans ineffective in glaucoma. Other conditions may impact the optic nerve and RNFL measurements, as well. While it is not surprising that the presence of an epiretinal membrane would influence macular thickness scans, one study also found epiretinal membranes were a common source of artifacts in RNFL scans.[14]

The evolution of posterior vitreous detachment (PVD) also affects RNFL scans, as focal traction at the vitreoretinal interface may cause the RNFL to look thicker. As the PVD progresses and the traction is released, the RNFL measurement becomes thinner.[14] Without careful evaluation, this thinning may be misinterpreted as progression.

Uveitis can also impact RNFL scans. Patients with this condition have thicker RNFL during periods of inflammation and thinner RNFL during periods of inactivity; this thinning after resolution may be mistaken for disease-related loss.[15]

In addition, other optic neuropathies and retinal conditions can impact RNFL thickness. It is important to consider non-glaucomatous causes of thinning when progression is suspected.

Signal-to-noise ratio. Anything that obstructs the path of light in the acquisition of an OCT image may reduce the signal-to-noise ratio, which is associated with thinner RNFL measurements.[16] Signal strength can be reduced with the presence of dry eye or media opacities such as cataracts or vitreous floaters. When sequential scans have worsening signal strengths, thinning can be misinterpreted as disease-related progression; thus, signal strength should always be considered when analyzing serial scans.

Artifacts. Blink artifacts and motion artifacts can be misinterpreted as progression if not properly identified on the *en face* image.[17] Artifacts may lead to improper segmentation of RNFL or inner retinal layers on macular scans; some instruments allow for manual segmentation upon discovery of an error, but others do not. Research estimates that 15% to 36% of glaucoma patient scans contain some type of artifact.[14] Recognizing and accounting for these artifacts is crucial to accurate progression detection.

Stage of the disease. This has a significant impact on OCT relevance. The RNFL layer contains blood vessels, glial tissue and ganglion cell axons; even in eyes with no light perception due to glaucoma, the RNFL does not fall below 30µm; the *floor* effect on most commercial instruments is considered to be around 45µm to 50µm. As the RNFL approaches this floor in advanced glaucoma, the thickness is more heavily influenced by other structural components, such as blood vessels, and less by actual RNFL thickness, making progression detection more difficult.[16]

Patients with mild to moderate glaucoma may show significant rates of change in both RNFL and macular/ganglion cell layer thickness. In a study of advanced glaucoma patients, however, there was a significant difference in the rate of change of macular thickness, but not RNFL thickness, between progressive and non-progressive patients.[18] This study highlights both the limitations of RNFL OCT and the potential benefits of macular OCT in more advanced disease. In a recently published study evaluating severe glaucoma patients, macular ganglion cell-inner plexiform layer was able to detect change, adding evidence that macular scans may be useful late in the disease process.[19]

Types of Glaucoma Changes

Specific patterns of RNFL progression have been identified in glaucoma.[20] The most common type of RNFL change is an expansion or widening of an existing RNFL defect. The next

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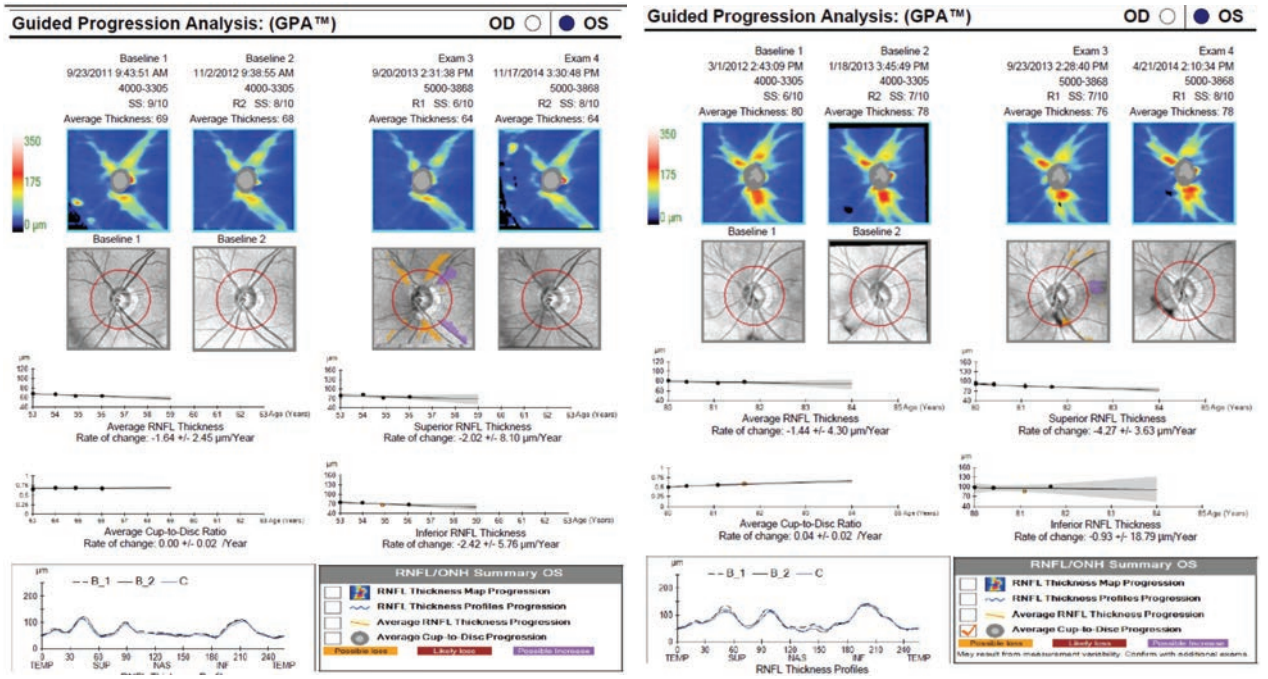

Beware of artifacts. In the patient on the left, note the reduced signal strength and motion artifact (discontinuity of blood vessels) on exam three. When the scan was repeated, the signal strength was improved and the suspected change was not confirmed. In the patient on the right, note the high variability of the inferior RNFL measurement, most likely the result of the vitreous floater impacting the scan.

is the development of new RNFL defects, followed by a deepening of an existing defect (often in conjunction with expansion).

The most common location of change is in the inferotemporal quadrant, approximately 2mm from the center of the disc. This location is important because this is outside of the circle scan used by commercial instruments. Therefore, clinicians cannot look solely at the RNFL circle scan profile (TSNIT curve), as it may miss these early changes. Clinicians should look at both the circle scan profile and the RNFL thickness/deviation maps to get a better sense of overall change.

With optic disc parameters, rim area is more sensitive than the vertical C/D ratio, probably because rim area takes into account the entire rim rather than a single axis. There is often poor agreement between RNFL, disc and macular parameters in progression analysis. Corroborating changes seen on multiple parameters is a strong indicator that the change is real and not an artifact.

Progression: Now What?

Along with automated perimetry and stereo optic disc photos, clinicians should obtain OCT (RNFL and macular protocols) at the time of diagnosis. To detect the rapidly progressing patients, four to six visual fields are recommended during the first two years following diagnosis.[3] No firm guidelines have been developed regarding the frequency of OCT testing, but a rule of thumb is to obtain scans at roughly the same rate as visual fields. After two years, if the patient appears to be stable, the frequency of testing can be decreased. If progression is suspected, the frequency of examinations can be increased.

When progression is suspected based on OCT, clinicians should take a systematic approach to make appropriate clinical decisions.[3] Here are the steps a clinician can take:

1. Repeat the test. This will confirm that the suspected change is real rather than due to artifact.
2. If the suspected change is verified, decide whether or not the change is typical of the changes seen in glaucoma versus a factor of age or other disease process.
3. If the change appears to be glaucomatous, ascertain the rate at which the progression has occurred. If using trend analysis, this information is provided in terms of microns per year; with event analysis,

the clinician should consider the time it took for the event, or change, to occur. Assessing the rate of change relative to the patient's life expectancy and stage of the disease is important in deciding how aggressively, or even whether, to modify therapy.

Remember, a statistically significant change is not always clinically meaningful. For example, a slow, structural change in a patient advanced in age with minimal visual field loss might not necessitate any change in therapy, as it is unlikely to cause visual disability in the patient's lifetime. Rapid progression in a younger patient, or progression in a patient with more advanced disease, is more likely an indicator for amplifying therapy with additional medications, laser trabeculoplasty or surgical intervention. Confirming that a change is glaucomatous and that the rate of change is clinically meaningful before changing therapy helps to avoid overtreatment.

When contemplating a change in therapy, the next step's impact is pivotal. The impact of adding a second medication or switching from a single agent to a fixed combination medication is significantly lower than the risks associated with surgical intervention. Finally, if therapy is increased, update the baseline for all testing (visual fields, OCT and photography) so future changes are compared to an appropriate baseline.

OCT has become instrumental in our ability to diagnose glaucoma and detect progression. By understanding the ways in which OCT can detect change, as well as recognizing its limitations, clinicians can use this technology to its fullest capability. ■

Dr. Marrelli is a clinical professor and director of the Ocular Diagnostic Service at the University of Houston College of Optometry.

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Dissecting DME

A clinician's role in diagnosing and managing diabetic macular edema.

By Jarett Mazzarella, OD, Justin Cole, OD, and Susan Yee, OD

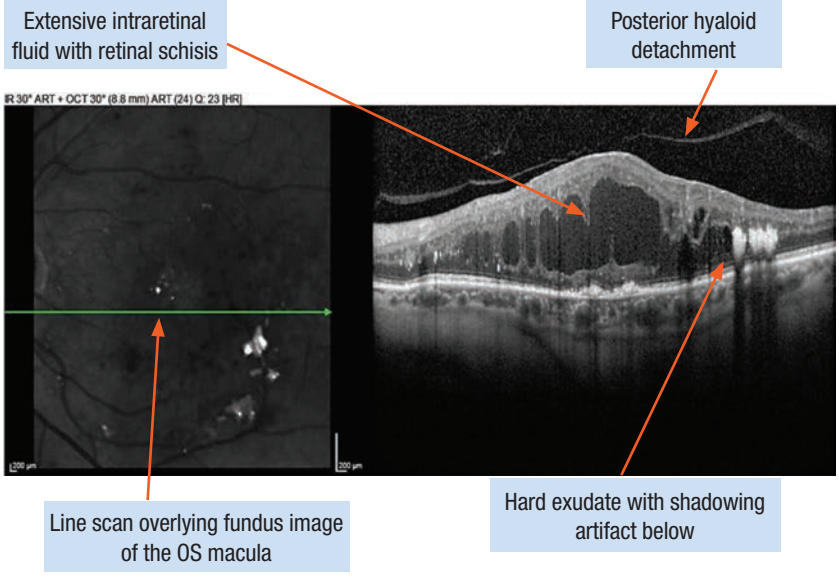
Diabetic macular edema (DME) is a sight-threatening condition and the most common cause of visual loss in patients with diabetes mellitus (DM).[1,2] It has a prevalence of 3.8% in diabetic patients over the age of 40, regardless of gender.[3] However, elevated hemoglobin A1c and longer duration of DM have a direct association with the prevalence of DME.[3] Comorbidities—including hyperlipidemia, hypertension and renal disease—as well as medications such as thiazolidinediones can increase the risk of DME.[4,5] By understanding the pathophysiology of DME, early detection and intervention can occur, thereby halting the progression of DME and reducing the risk of permanent vision loss.[1,6]

Pathophysiology

DME is the result of chronic microvascular compromise and can develop by an inflammatory or ischemic mechanism. High plasma glucose levels cause the breakdown of the blood-retinal barrier through the loss of pericytes. This leads to loss of endothelial cell function and release of vascular endothelial growth factor (VEGF).[7] This growth factor leads to capillary leakage, causing the accumulation of extracellular fluid in the macula.[8,9] VEGF also causes activation of inflammatory molecules and is implicated in neuronal apoptosis and capillary non-perfusion.[1]

Classification

DME is defined as retinal thickening or hard exudates at least one disc diameter to the center of the macula.[11,12] Clinically significant macular edema (CSME), introduced by the Early Treatment Diabetic Retinopathy Study (ETDRS), is defined as DME meeting at least one of three criteria: thickening at or



Diffuse diabetic macular edema captured with spectral-domain OCT line scans.

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Classifications of DME by Imaging Modality[11,13,36,37]

OCT	Diffuse	Cystoid: further divided into mild, moderate or severe based on distance of exudates/thickening from the center of fovea	Posterior hyaloid/ vitreofoveal traction	Serous retinal detachment
FA	Focal: localized leakage from microaneurysms/ dilated capillaries	Diffuse: involves entire circumference of fovea	Diffuse cystoid: diffuse leakage, the dye is within the cystic area of macula in late phase of FA	
Subretinal fluid area vitreoretinal interface abnormalities etiology (SAVE) Protocol (OCT/FA)	Focal or multifocal: definable leakage source in FA, edema in OCT	Non-focal: no definable leakage source in FA, edema in OCT	Macular or peripheral ischemia: defined as capillary non-perfusion in FA	Atrophic edema: retinal cystoid degeneration w/o Müller cells or disruption in horizontal layer centrally

within 500µm of foveal center, hard exudates within 500µm of foveal center with adjacent thickening, or at least one disk diameter of thickening with part of it located within one disc diameter of foveal center.[11-13] Treatment is typically required when DME meets the criteria based on ETDRS evidence.[12]

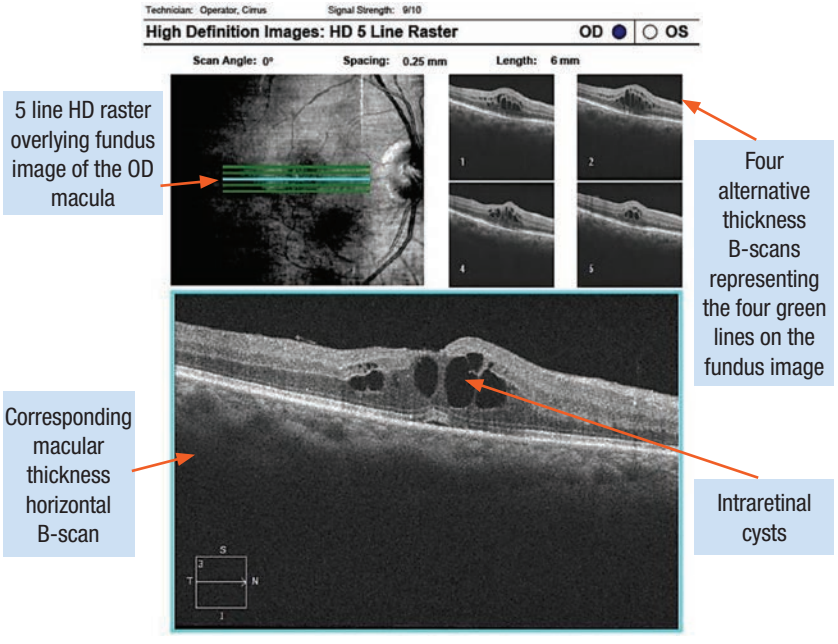
Evaluation Techniques and Imaging Modalities

Early detection of DME can lead to prompt treatment and reduced risk of permanent vision loss. It can also provide information on how the disease progresses and the response to treatment. Some early detection techniques include:

Slit lamp examination with a contact fundus lens. With the advent of advanced imaging devices, clinicians may overlook the opportunity to define DME during a fundus evaluation. Retinal vascular clues such as bending of the vessels, proximity of hemorrhage/microaneurysms to the macula or presence of hard exudate can alert an astute clinician to the presence of DME. Using a contact fundus lens to evaluate retinal thickness (RT) and elevation secondary to intraretinal or subretinal fluid is also a viable option. Whether the DME is diffuse or focal will determine how easily it is identified on clinical exam.

Conventional color fundus photography. Fundus photos are still useful for monitoring both progression of DR and the response to treatment.[13] Fundus photographs are particularly useful with recent advancements in telemedicine, specifically for high risk patients in rural areas to aid in early diagnosis and intervention.[13]

Fluorescein angiography with widefield functionality. Fluorescein angiography (FA) historically has been considered the gold standard in the diagnosis of DME, as it can illustrate capillary non-perfusion and leakage in the retina.[9] Recent advances with widefield FA improve views of the posterior pole and the peripheral fundus, aiding in accurate diagnosis of early ischemia and proliferative diabetic retinopathy. This is vital, as recent studies have shown that peripheral ischemia may



Cystoid diabetic macula edema captured with SD-OCT line scans.

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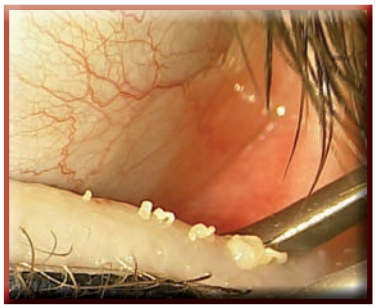

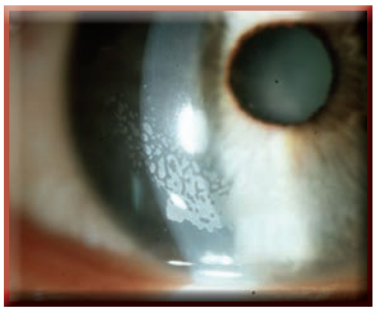

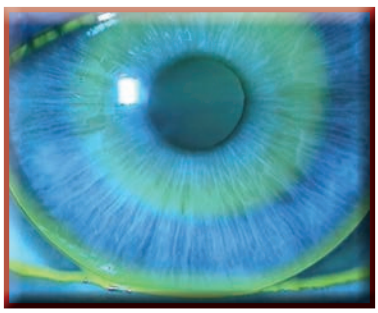

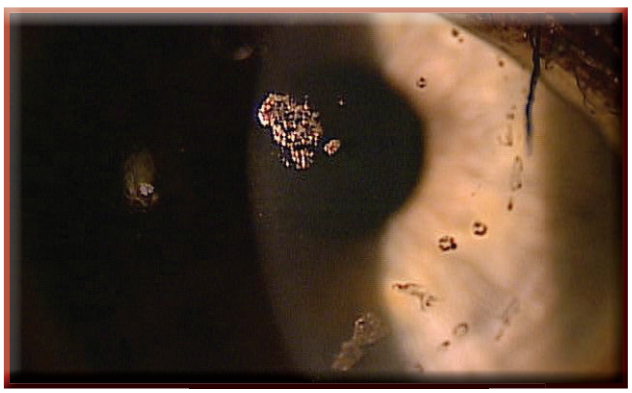

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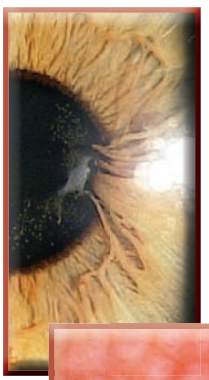

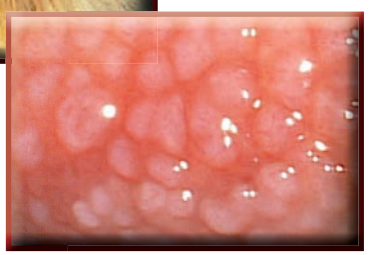

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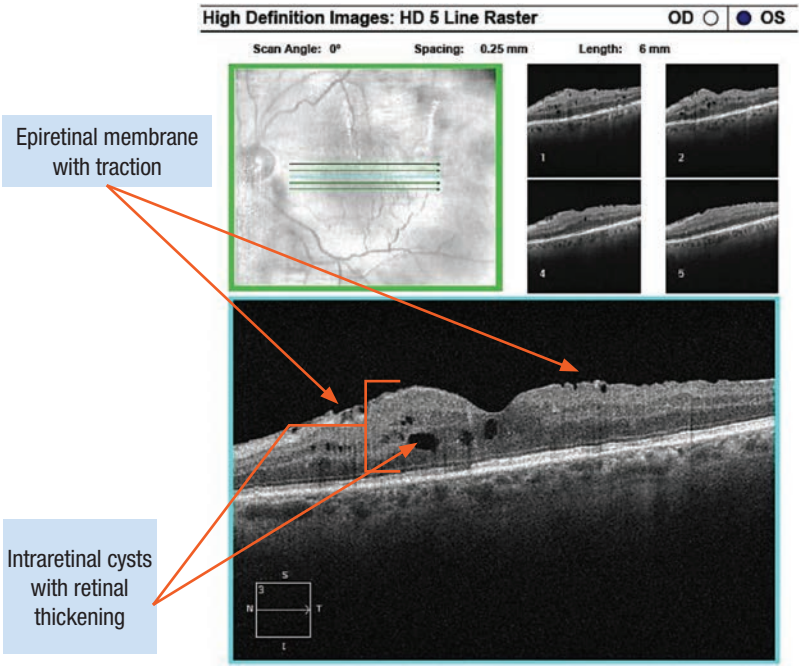
be related to the presence and significance of DME.[13]

Clinicians should be aware that adverse events can occur during FA testing, such as: allergic anaphylaxis, local tissue necrosis, nausea, vomiting, GI distress, cardiopulmonary reactions, headaches, convulsions and thrombophlebitis at the injection site. Clinicians should also be cautious when evaluating pregnant or nursing mothers. The invasiveness of this procedure and the development of OCT-angiography (OCT-A) will reduce the use of FA in the diagnosis and management of DME.[9] However, because widefield imaging is currently a limitation for OCT-A, FA remains a valuable diagnostic option for evaluating DME.

Spectral domain (SD) and swept source (SS) OCT. OCT has quickly become the new gold standard for monitoring DME.[14] It can quantify volume and thickness to evaluate resolution over time with treatment and can be used to image hard exudate and intraretinal blood within the retinal layers. OCT can define vitreomacular traction and provide an accurate evaluation on the anatomical integrity of the retina, the inner/outer segment junction line and the external limiting membrane.[14] Current algorithms can segment out particular retinal layers for individual evaluation, and macular change analysis functions are ideal for looking at thickness differences over time. SS-OCT advancements have provided better visualization of the choroid and choroidal scleral interface. Studies show that subfoveal choroidal thickness is reduced in patients with DME.[15] In the future, this could provide a better understanding of the disease process and may lead to possible alternative treatment sites. SS-OCT can also be beneficial in evaluating the vitreoretina interface in patients with diabetes. Recent studies demonstrate adhesion between the posterior hyaloid and the retina in patients with DME not observed with prior technology.[13]



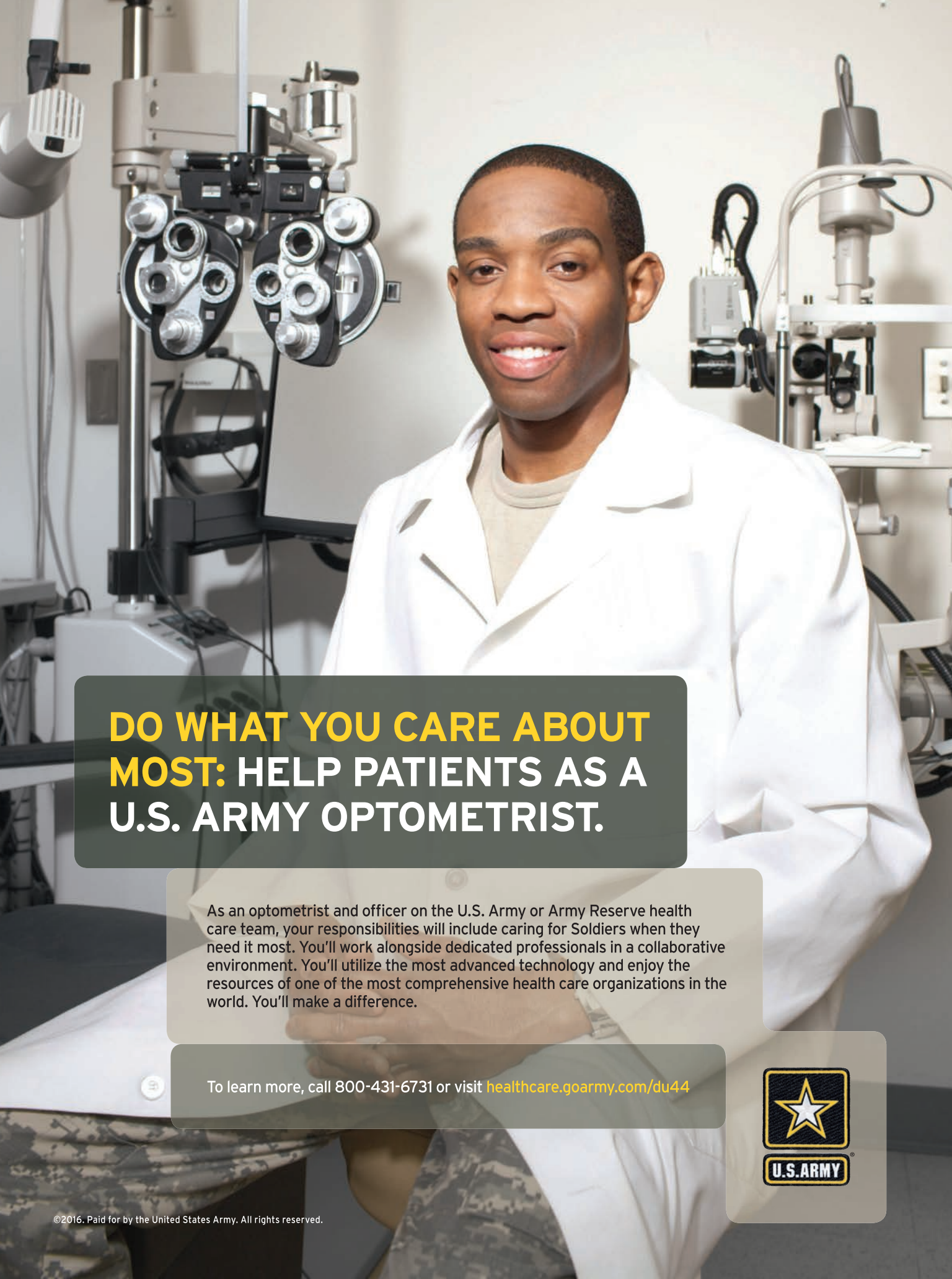
DME associated with traction from an epiretinal membrane.

OCT-angiography. OCT-A is a newer imaging modality that can identify the depth of the retina and choroid. It can detect capillary dilation or truncation, increased foveal avascular zones and capillary dropout or non-perfusion in the retina. This quick, non-invasive, in-office test can define the inner and outer capillary plexus. The choroidal vasculature is also easily identifiable, which has been a disadvantage of FA and why indocyanine green angiography (ICG) is preferred to define choroidal disease. While FA and ICG demonstrate pathology through the presence of leakage and pooling of dye from vessels, OCT-A shows retinal vasculature anomalies and corresponding anatomical changes to the retina associated with DME not obscured by dye leakage.[16] Studies show OCT-A can identify the location of microaneurysms adjacent to retinal fluid.[16]

One major limitation of current OCT-A technology is a smaller scan area compared with widefield FA and fundus photography. Also, projection artifacts from inner retinal layers can be projected to deeper layers of the scan, which can make interpretation and delineation of lesions difficult. This technology is also very sensitive to movement and blink artifacts.[14]

Management and Referral

Once macular edema is detected, determining the exact etiology of the ocular presentation is key. Differential diagnoses of DME may include pseudophakic cystoid macular edema, a central or branch retinal vein occlusion with macular edema, uveitic macular edema, or macular edema associated with an epiretinal membrane or vitreomacular traction. Once clinicians determine the edema is of diabetic origin, they can refer the patient for treatment or monitor



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based on current ophthalmological and optometric practice guidelines.

The preferred practice patterns published by the American Academy of Ophthalmology list ETDRS protocol for defining CSME as a threshold to determine timing and necessity of treatment due to the risk of moderate vision loss as defined as a doubling of the visual angle.[17] It is also imperative to determine if the DME is involving the center of the macula, which studies show has a 10 times greater risk of moderate vision loss at one year compared with eyes not involving the center of the macula. In cases where the patient may refuse or postpone treatment, three to four month evaluations are recommended to monitor for progression of clinical findings and effects on visual acuity.[17] The evidence-based clinical practice guidelines published by the American Optometric Association (AOA) suggest if DME is present but does not meet CSME criteria, clinicians should monitor within two to four months.[18]

The AOA clinical practice guidelines also indicate that the frequency of eye examinations should be determined based upon the type of diabetes, duration of the disease, age and the predicted ability of the patients to adhere to their treatment plans. Other comorbidities and ocular findings must also be considered in determining referral and follow-up assessments.[18] In women who are diabetic, care must be taken to monitor these patients closely due to the risk of progression of diabetic retinopathy and diabetic macular edema during pregnancy.[19]

DME Treatment Effects, Dosing and Cost[2,41-45]

	Average Increased BCVA	Dosing	~Cost per/ dosage
Anti-VEGF intravitreal injections			
Lucentis (ranibizumab)	~12-15 letters, ~35-45% had >15 letters @ 2 yrs	Monthly (0.3 mg)	~$1200
Avastin (bevacizumab)	~9 letters @ 2yrs, 32% gained 15 letters @ 2 yrs	Monthly (1.25 mg)	~$50
Eylea (aflibercept)	10-12 letters, ~33% >15 letters @ 12 months	Bi-monthly (2mg) after five initial doses	~$1950
Corticosteroids			
Iluvien (fluocinolone acetonide) intravitreal implant	7-8 letters @ 3yrs, ~29% >15 letters @ 3 yrs	One implant, ~3 yrs	~$8000
Ozurdex (dexamethasone) intravitreal implant	~8 letters @ 3 yrs, ~22% >15 letters at 3 yrs	One implant, ~6 months	~$2000

As with any guidelines, clinicians must not solely depend upon them to formulate treatment plans. Established relationships with retinal specialists will continue to be the cornerstone in making timely referrals and determining follow-up criteria based on the specific treatment modality and each specialist's comanagement criteria.

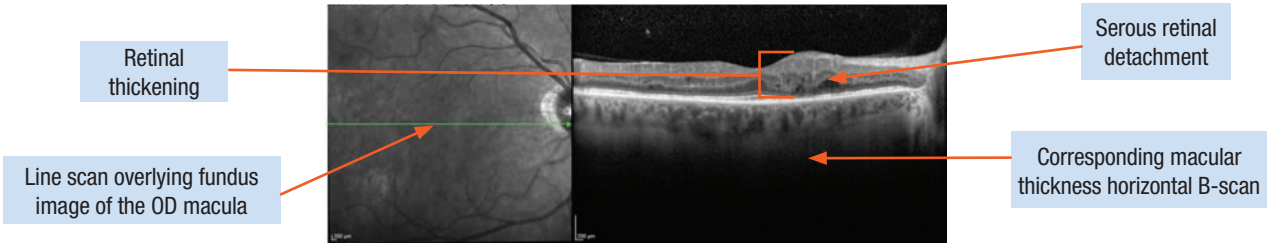
Treatment Options

The first step in treatment is to counsel patients on lifestyle modifications such as diet and the systemic control of comorbidities such as blood pressure and cholesterol with tight control of glucose levels.[20] The American Diabetic Association currently suggests hemoglobin A1c levels less than 7% for non-pregnant adults.[21] The Diabetes Control and Complications Trial in the 1980s demonstrated a 23% reduction in macular edema with intensive blood sugar control.[22]

Currently, there are four evidence-based therapies for DME: focal and grid laser, intravitreal anti-VEGF injection, intravitreal steroid injection and implant and surgical intervention.[23]

Laser photocoagulation. In 1971, the Diabetic Retinopathy Study (DRS) determined that when treating eyes with DME, performing focal photocoagulation prior to panretinal treatment reduces risk of progression of DME.[7] Also, when patients undergo panretinal laser, divided treatment sessions with lower intensity burns may aid in reducing visual loss.[22]

In the 1980s, ETDRS showed that



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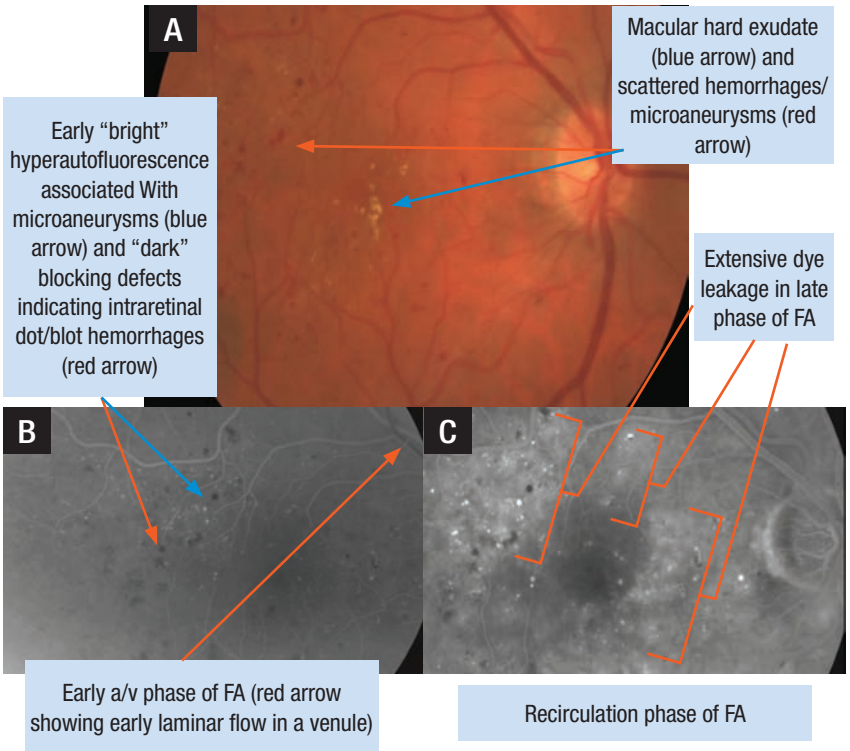

A. Retinal photograph of a patient's right eye with DME. B. FA photo of early arteriovenous (a/v) phase OD. C. FA photo of later phase (recirculation) demonstrating extensive leakage of dye in the macula OD.

treating macular edema using macular laser photocoagulation reduced the risk of moderate vision loss, defined by doubling of the visual angle, by 50%, over three years.[22] However, patients with entering visual acuity worse than 20/40 had a lesser likelihood of visual improvement after laser treatment.[6]

Newer therapies such as micropulse laser and laser guided by FA or OCT have been evaluated to reduce damage to the retina during treatment with greater precision and less energy on the retina.[24]

Intravitreal anti-VEGF injection. Anti-VEGF medications have revolutionized DME treatment. The first anti-VEGF medication FDA approved for the treatment of macular edema was intravitreal Lucentis (ranibizumab, Genentech). Studies show an improvement in best-corrected visual acuity (BCVA) vs. laser, sham and combination therapies.[25] Many retinal specialists use off-label Avastin (bevacizumab, Genentech) to treat DME, mostly for financial reasons. Avastin, FDA approved for the treatment of several forms of cancer, acts by a similar mechanism as Lucentis, and studies show it has a similar response, at a fraction of the cost.[26] The perceived benefit with Eylea (aflibercept, Regeneron), the latest drug FDA approved for the treatment of DME, is the increased binding of multiple VEGF domains, which would decrease the frequency of intravitreal injections. The DA VINCI study demonstrated that all Eylea groups showed improved BCVA and decreased central RT compared with laser. Other trials showed that five monthly injections, followed by bimonthly injections, had similar increases in BCVA and decreases in central RT, when compared with laser.[27]

The DRCR.net protocol T study compared the efficacy of intravitreal Eylea, Avastin and Lucentis for DME and found an average increase in BCVA of 13 letters, 10 letters and 11 letters, respectively, with similar safety and side effect profiles.[30] The study noted that when initial VA was 20/40 or better no medication had superiority over another; however, when the VA was worse than 20/40 at presentation, Eylea performed better in terms of recovery of vision.[28]

Intravitreal steroid injection and implants. Because DME may shift from a VEGF-mediated mechanism in the acute phases to an inflammatory mechanism in chronic cases, steroids are a good alternative treatment option for cases of refractory DME, especially in pseudophakic patients.[29,30] Current delivery options are peribulbar or intravitreal injection with triamcinolone or fluocinolone acetonide. This mode of treatment suffers from short duration of action, usually one month, and the need for repeated treatments.

An intraocular steroid implant device allows for a slow, sustained release of the drug. The two FDA approved intravitreal implants for DME are Iluvien (fluocinolone acetonide, Alimira Sciences) and Ozurdex (dexamethasone intravitreal implant, Allergan). Clinical trials show Ozurdex can be effective for up to six months, and Iluvien may provide efficacy for up to three years.[29,31] Studies show that steroid implants can also work well in combination with other modalities such as laser or surgical intervention.[29,32] Most implant candidates have a longstanding history of DME and have likely had macular laser

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therapy and multiple anti-VEGF injections.[33]

Intraocular surgical intervention. In cases of DME with vitreoretinal traction, a pars plana vitrectomy (PPV) with or without membrane peel is a viable treatment option.[34] In cases of diffuse DME with the presence of subretinal fluid, studies show that PPV was benefical.[35] Surgical intervention is not equally effective in all patients with DME, and after vitrectomy there are limitations of increased diffusion and quicker clearance times of drugs by intravitreal injections.[34] Alternative therapies such as steroid implants may provide a sustained method of therapy in this group of patients for chronic care after PPV.

Although these therapies have known quantifiable results, they also come with financial, socio-economical and quality of life burdens, such as medication costs, the frequency of the dosing schedule and the decrease in activities of daily living.

Comanagement

The timeline for patient follow up after treatment is based on several factors. Depending on the exact mechanism causing the DME, the response to treatment and the duration of treatment may vary between patients. Other confounding factors such as epiretinal membranes or vitreomacular traction can lead to the need for repeated treatments or the use of multiple treatment modalities, especially in cases of chronic (greater than three-year duration) DME or recalcitrant DME. The location of the DME in the macula (+/- center involvement), the pattern of DME (localized or diffuse) and the retinal perfusion (retinal ischemia) may all alter the treatment course and prognosis. Significant reduction in acuity at initial presentation, other ocular comorbidities and treatment side effects must also be considered for comanagement with your retinal specialist.

As the prevalence of diabetes continues to rise in the United States—it increased 382% from 1988 to 2014—the number of individuals with macular edema will consequently rise, increasing the public health burden.[3] In 2013, The American Diabetes Association estimated that the United States spends $245 billion every year in health care services and loss of work production in patients afflicted with DM.[21]

Advances in imaging technology have allowed clinicians to screen diabetes patients and detect DME even before visual compromise. Early detection is crucial in improving patients' long-term quality of life and reducing the economic burden. The primary eye care providers' relationship with the referring retinal specialist is integral, as it ensures patients receive the prompt, prudent and individualized care they need. Future research into innovative drug delivery will further change the landscape of DME treatment and management. ■

Drs. Mazzarella, Cole and Yee are staff optometrists in The Salisbury VA Health Care System, Salisbury, NC.

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DME Treatment Potential Side Effects[31,36,39,40]

Treatment	Side Effects
Focal/grid laser photocoagulation	Risk of foveal burns, subretinal fibrosis, laser scars, central/paracentral scotoma, CNVM, reduced color vision, loss of vision
Anti-VEGF	Endophthalmitis, uveitis, vitreous hemorrhage (VH), retinal tears/detachment, cardiovascular effects from HTN, hypertensive emergencies, arterial thromboembolic events, GI perforation
Intravitreal steroid (injections/implants)	Early cataract formation, elevated IOP, endophthalmitis, VH, retinal tears/detachment
Intravitreal NSAID (injection/implant)	Endophthalmitis, vitreous hemorrhage, retinal tears/detachment
Combination: intravitreal w/laser	See above
Pars plana vitrectomy	Endophthalmitis, retinal tears/detachment, vitreous hemorrhage, elevated IOP, cataract

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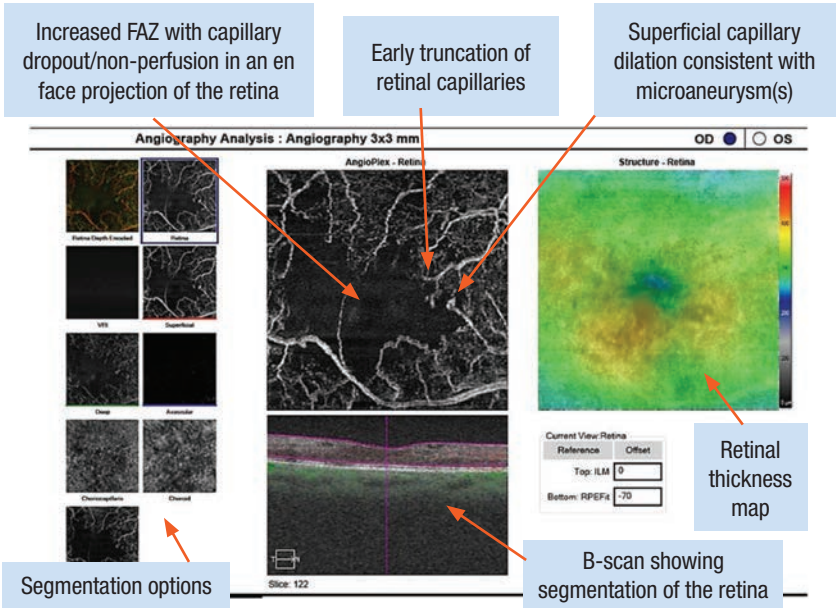

OCT-A with Cirrus OCT Angioplex highlighting a 3x3mm box around the OD macula. The image shows an increased foveal avascular zone with capillary dropout and truncation. Focal dilations of capillary vessels are notated in locations of microaneurysm(s).

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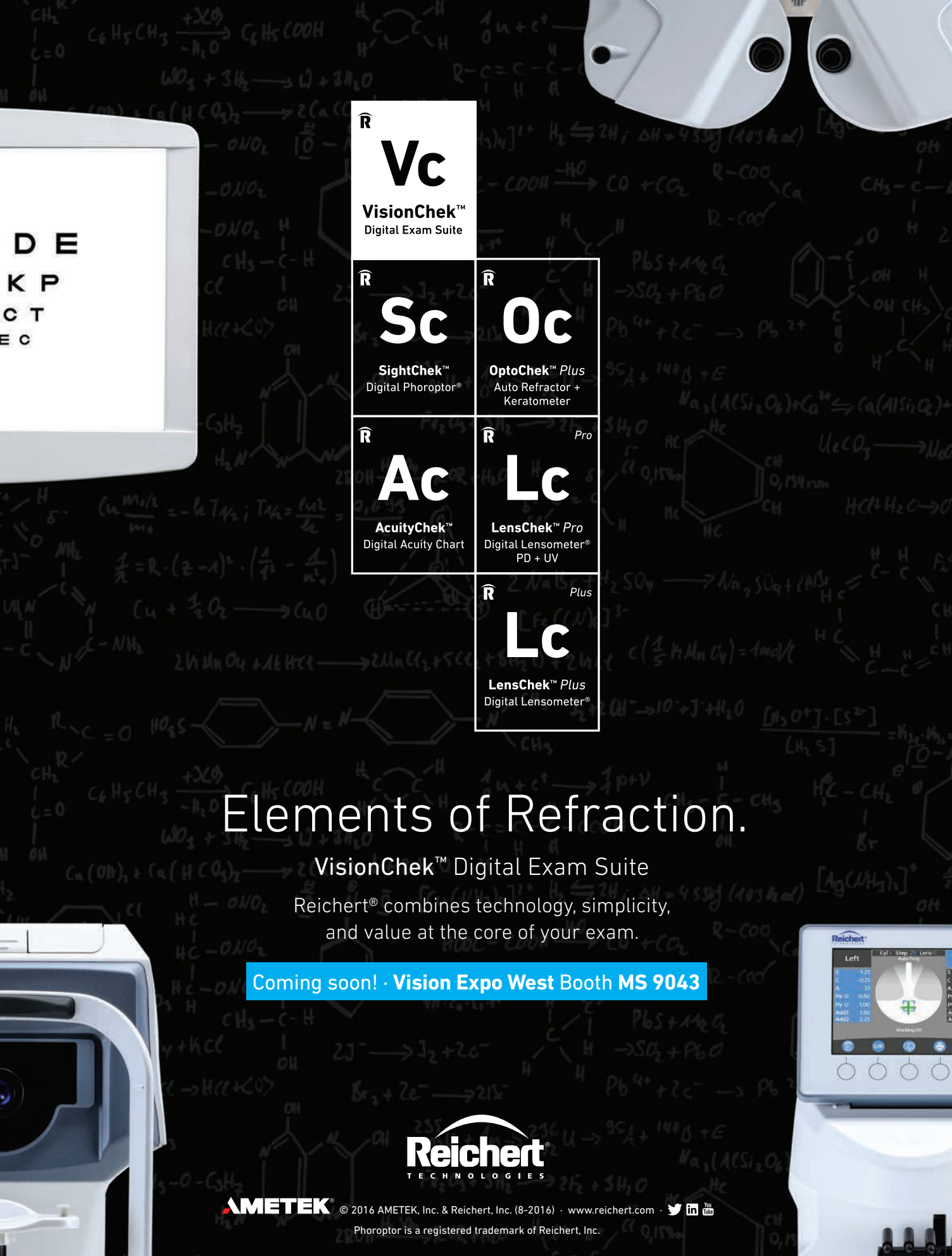
International Council of Ophthalmology: Guidelines for Observable Findings of DME[38]

+/- DME	Retinal Findings	Retinal Location
(-) DME	(-) thickening or exudates in the posterior pole	X
(+) DME	(+) thickening or exudates in the posterior pole	X
Mild DME	(+) thickening or exudates in the posterior pole	Outside central macula (diameter 1000µm)
Moderate DME	(+) thickening or exudates in the posterior pole	Inside central macula (diameter 1000µm) Not involving the center (fovea)
Severe DME	(+) thickening or exudates in the posterior pole	Inside central macula (diameter 1000µm) Involving the center (fovea)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Top 100 Drugs: Which Are *Your* Patients Taking?

The eye doesn't exist in a vacuum. Knowing the most commonly used medications by indication can help you provide the best possible care. **By Len V. Koh, PhD, OD, MBA**

As primary eye care practitioners, our patient population covers the breadth of the human lifespan, and we are busy clinical bees applying our expertise to a wide range of conditions to provide care for our diverse cohort.

Although we as optometrists prioritize vision, we also need to consider the whole health of our patients. The eyes are extensions of the brain, and the ocular system is an integral part of the body. But patients often view the eyes as isolated entities, which is made clear when they present to the office without their current prescriptions or a medication history in hand. In our modern holistic and systems-based approach to eye care, we are on alert for patients who take systemic medications with the potential to cause adverse reactions within the ocular system. To help preserve their vision, we need to first know what our patients are taking.

The Top 100

Although the FDA approves dozens of new drugs each year, it is rare for any particular new drug to become a blockbuster in the market in the first few years. Focusing on the top 100 prescribed medications ensures we cover the meds we are likely to see on a daily basis in the clinic. *Table 2* lists the top 10 therapeutic classes by prescription.[1] *Table 1* contains the top 100 drugs in the United States from April 2014 through March 2015, according to their ranking by research firm IMS Health.[2] This article highlights many of the more common drugs you may encounter in your practice and their potential impact on ocular health. Use it as a systemic Rx refresher and to stay informed of new developments and new and existing clinical key points.

Note: This top 100 list contains only the most prescribed branded drugs, so it is by no means a comprehensive accounting of the drugs our patients are taking—generics and over-the-counter drugs, of course, are taken by many patients. Bear this distinction in mind for all discussions of volume/popularity in the ensuing article. Furthermore, the notable systemic and adverse reactions discussed in the article are excerpted from the packaging inserts for each respective drug, as submitted to the FDA and

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Expiration Date: September 15, 2019
Goal Statement: Medical intervention on many disease states currently relies on pharmolcogical modalities. This course provides an overview of the most prescribed branded drugs from 2014-2015. It includes summaries of their risks to the eye as well as the systemic risks. Mechanisms of action are described in brief, and the top 100 drugs are categorized in terms of their primary indications.
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accessible via DailyMed.[3]

Possibly the most important point to remember within the context of the top 100 is that a number of drugs are known, potentially, to cause reversible or irreversible visual impairment.[4]

Diabetes medications. Treatments for diabetes account for the most prescriptions in the United States, with more than 64 million, including multiple forms of insulin, various classes of hypoglycemic drugs and medications to treat pain from nerve or muscle impairment. This is not surprising—it is estimated that 29.1 million Americans, or 9.3% of the population, suffered from diabetes in 2012.[5] The number of new cases has been projected to grow each year by 1.4 million.[5]

A common medication taken by many of our diabetes patients is Lyrica (pregabalin, Pfizer), approved for epilepsy and the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia and neuropathic pain associated with spinal cord injury. Approximately 10 million prescriptions were written in the United States for Lyrica during the 2014-2015 period of the IMS study.[2]

Adverse effects. Hypoglycemia is a primary concern for patients taking various forms of insulin and insulin secretagogues such as sulfonylureas. Early symptoms of hypoglycemia include pounding heart, racing pulse, pale skin, sweating, trembling, anxiety, dizziness and weakness. A few options to treat hypoglycemia in-office include glucose tablets, hard candies and a half-cup of fruit juice or soft drink. Each of these contains about 15 grams of fast-acting carbohydrate. Educate your patients with diabetes on the importance of medical nutrition therapy and regular annual eye exams.[6] In controlled

Table 1. Top 100 Most Commonly Prescribed Branded Drugs[2]

Rank	Prescriptions	Brand name	Generic name	Indications
1	21,561,481	Synthroid	levothyroxine	Hypothyroidism
2	21,478,776	Crestor	rosuvastatin	Hyperlipidemia
3	18,203,939	Ventolin HFA	albuterol sulfate	Bronchospasm
4	15,298,228	Nexium	esomeprazole	GERD
5	13,776,325	Advair Diskus	fluticasone + salmeterol	Asthma
6	10,939,840	Lantus Solostar	insulin glargine	Diabetes
7	10,413,999	Vyvanse	lisdexamfetamine	ADHD, binge eating
8	10,022,365	Lyrica	pregabalin	Epilepsy, pain
9	9,635,935	Spiriva Handihaler	tiotropium bromide	COPD
10	9,148,946	Januvia	sitagliptin	Diabetes
11	9,145,153	Lantus	insulin glargine	Diabetes
12	9,099,978	Abilify	aripiprazole	Schizophrenia, MDD
13	8,265,594	Symbicort	budesonide + formoterol	Asthma
14	8,025,275	Tamiflu	oseltamivir	Influenza
15	7,472,719	Cialis	tadalafil	ED, BPH
16	7,104,074	Viagra	sildenafil citrate	Erectile dysfunction
17	6,985,631	Suboxone	buprenorphine + naloxone	Opioid dependence
18	6,925,137	Zetia	ezetimibe	Hyperlipidemia
19	6,739,752	Xarelto	rivaroxaban	Stroke, DVT, PE
20	6,461,435	Bystolic	nebivolol	Hypertension
21	6,449,730	Celebrex	celecoxib	Arthritis
22	6,432,382	Nasonex	mometasone	Rhinitis
23	5,961,360	Namenda	memantine HCl	Alzheimer's
24	5,736,650	Flovent HFA	fluticasone	Asthma
25	5,347,532	Oxycontin	oxycodone	Severe pain
26	5,224,025	Diovan	valsartan	Hypertension
27	5,128,576	Westhroid	thyroid dessicated	Hypothyroidism
28	5,123,676	Voltaren Gel	diclofenac	Osteoarthritis
29	4,917,514	Nuvaring	etonogestrel + ethinyl estradiol	Contraception
30	4,650,167	Afluria	influenza vaccine	Influenza
31	4,620,902	Dexilant	dexlansoprazole	Esophagitis
32	4,483,555	Benicar	olmesartan	Hypertension
33	4,385,623	Proventil HFA	albuterol	Asthma
34	4,209,193	Humalog	insulin lispro	Diabetes
35	4,179,914	Novolog Flexpen	insulin aspart	Diabetes
36	3,968,615	Novolog	insulin aspart	Diabetes
37	3,686,182	Vesicare	solifenacin succinate	Overactive bladder
38	3,462,987	Premarin	conjugated estrogen	OB/GYN and urological indications
39	3,352,383	Benicar HCT	olmesartan + HCT	Hypertension
40	3,335,659	Lo Loestrin Fe	norethindrone + ethinyl estradiol + ferrous	Contraception
41	3,298,208	Lumigan	bimatoprost	Glaucoma
42	3,157,234	Namenda XR	memantine HCl	Alzheimer's
43	3,043,015	Humalog Kwikpen	insulin lispro	Diabetes
44	3,027,293	Janumet	sitagliptin + metformin	Diabetes
45	2,905,818	Pataday	olopatadine HCl	Allergic conjunctivitis
46	2,900,301	Ortho-Tri-Cyclen Lo	norgestimate + ethinyl estradiol	Contraception
47	2,861,717	Travatan Z	travoprost	Glaucoma
48	2,846,891	Combivent Respimat	ipratropium + albuterol	COPD
49	2,811,156	Toprol-XL	metoprolol	Hypertension
50	2,769,837	Pristiq	desvenlafaxine	MDD

Rank	Prescriptions	Brand name	Generic name	Indications
51	2,711,901	Invokana	canagliflozin tablet	Diabetes
52	2,555,803	Minastrin 24 Fe	norethindrone + ethinyl estradiol	Contraception
53	2,418,649	Strattera	atomoxetine HCl	ADHD
54	2,390,205	Seroquel XR	quetiapine	Schizophrenia, MDD
55	2,384,517	Vytorin	ezetimibe + simvastatin	Hyperlipidemia
56	2,334,004	Focalin XR	dexmethylphenidate	ADHD
57	2,307,692	Dulera	mometasone + formoterol	Asthma
58	2,283,328	Levemir Flexpen	insulin detemir	Diabetes
59	2,279,662	Zostavax	zoster vaccine live	Herpes zoster
60	2,271,799	Avodart	dutasteride	BPH
61	2,257,507	Pradaxa	dabigatran	Stroke, DVT, PE
62	2,208,377	Chantix	varenicline	Smoking cessation
63	2,179,340	Eliquis	apixaban	Stroke
64	2,173,082	Humira	adalimumab injection	Autoimmunity
65	2,164,191	Levemir Flextouch	insulin detemir	Diabetes
66	2,100,856	Levemir	insulin detemir	Diabetes
67	2,078,063	Victoza 3 Pak	liraglutide	Diabetes
68	1,909,750	Combigan	brimonidine + timolol	Glaucoma
69	1,825,705	Exelon	rivastigmine tartrate	Alzheimer's
70	1,744,708	Tradjenta	linagliptin	Diabetes
71	1,738,728	Premarin Vaginal	conjugated estrogen	Atrophic vaginitis, dyspareunia
72	1,691,819	Enbrel	etanercept	Autoimmunity
73	1,691,615	Onglyza	saxagliptin	Diabetes
74	1,661,050	Ranexa	ranolazine	Angina
75	1,651,083	Truvada	emtricitabine + tenofovir	HIV
76	1,644,996	Welchol	colesevelam	Hyperlipidemia
77	1,639,652	Linzess	linaclotide	IBS-constipation
78	1,635,230	Latuda	lurasidone	Schizophrenia, bipolar
79	1,483,322	Alphagan P	brimonidine	Glaucoma
80	1,425,156	Viibryd	vilazodone	MDD
81	1,406,934	Effient	prasugrel	Stroke
82	1,376,523	Norvir	ritonavir	HIV
83	1,371,937	Amitiza	lubiprostone	Constipation
84	1,338,802	Azor	amlodipine + olmesartan	Hypertension
85	1,310,993	Advair HFA	fluticasone + salmeterol	Asthma
86	1,293,249	Uloric	febuxostat	Gout
87	1,245,330	Lotemax	loteprednol	Ocular inflammation
88	1,230,040	Myrbetriq	mirabegron	Overactive bladder
89	1,219,923	Asmanex Twisthaler	mometasone	Asthma
90	1,212,887	Epiduo	adapalene + benzoyl peroxide	Acne vulgaris
91	1,204,025	Xopenex HFA	levalbuterol	Asthma
92	1,189,206	Durezol	difuprednate	Ocular inflammation
93	1,181,134	Patanol	olapatadine	Allergic conjunctivitis
94	1,147,295	Atripla	efavirenz + emtricitabine + tenofovir	HIV
95	1,144,739	Aggrenox	aspirin + dipyridamole	Stroke
96	1,134,532	Exforge	amlodipine + valsartan	Hypertension
97	1,110,123	Humulin R	insulin regular	Diabetes
98	1,110,008	Carafate	sucralfate	Duodenal ulcer
99	1,069,219	Novolog Flex pen Mix 70/30	insulin aspart	Diabetes
100	1,035,265	Relpax	eletriptan	Acute migraine

studies, blurred vision was reported in 7% of patients, and visual field changes were detected in 13% of patients treated with Lyrica.[3]

Opiate medications. Moderate and severe pain are commonly treated with μ-opioid full agonists such as Oxycontin (oxycodone, Purdue Pharma), which had more than 5.3 million prescriptions in the study year.[2]

Adverse effects. Boxed warnings for Oxycontin include addiction, abuse and misuse, and life-threatening respiratory depression. Suboxone (Indivior)—a combination of buprenorphine, a μ-opioid receptor partial agonist and naloxone, a μ-opioid receptor antagonist—had nearly seven million prescriptions in the United States for the treatment of opioid dependence.[1] In some states, such as Ohio and Pennsylvania, first responders carry emergency opioid overdose kits and administer Narcan (naloxone hydrochloride, Adapt Pharma) to revive opioid addicts from an overdose.

Respiratory drugs. Collectively, these drugs, which primarily include β_2-adrenergic agonists (BA) and corticosteroids, comprised more than 56 million American prescriptions in 2014-2015.[2] β_2-adrenergic agonists can be short- or long-acting (LABA) and, like corticosteroids, are used to treat asthma. Muscarinic antagonists such as Spiriva (tiotropium, Boehringer Ingelheim) and Atrovent (ipratropium bromide HFA, Boehringer Ingelheim) are more effective at opening the airways than both corticosteroids and BA in patients with chronic obstructive pulmonary disease (COPD) and emphysema.[3]

Adverse effects. The potential ocular side effects of muscarinic antagonistic drugs are similar to cycloplegics, including mydriasis, blurred vision and angle closure. Because the potential ocular side

effects of long-term corticosteroid use include increased intraocular pressure (IOP) and posterior subcapsular cataract, we should measure IOP and dilate patients with histories of respiratory disorders to thoroughly evaluate the lenses and optic nerves. LABAs have black-box warnings for the increased risk of asthma-related death. Thus, patients should be educated on the potential side effects of LABAs such as confusion, dizziness, arrhythmia, body pain, trembling and seizures—all of which require emergency attention.

Hyperlipidemia medications. These include statins such as Crestor (rosuvastatin calcium, AstraZeneca) and cholesterol absorption inhibitors such as Zetia (ezetimibe, Merck). Often, drugs from these two classes are sold in combination. Welchol (colesevelam, Daiichi Sankyo), a bile acid sequestrant, is indicated for the treatment of both high cholesterol and Type 2 diabetes. Over 32 million prescriptions for statins alone or in combination were written to reduce blood cholesterol in the United States in the 2014-2015 period.[1]

Adverse effects. Patients on statins need to be reminded of the risks for myopathy, including rhabdomyolysis, which manifests as muscle pain, tenderness or weakness. Zetia in combination with statins can elevate liver enzymes; thus, liver function tests should be performed at the initiation of therapy. Welchol may decrease the absorption of fat-soluble vitamins A, D, E and K, so patients should take vitamin supplements at least four hours prior to their normal dose. Since hyperlipidemia increases the risk for retinal arterial and vein occlusions, a comprehensive eye exam is recommended.

Antihypertensive drugs. Calcium channel blockers, angiotensin receptor antagonists and β-blockers, on the whole, have been the most prescribed drugs for the past five years, yielding close to 25 million US prescriptions in 2014-2015.[2] This number would be even higher if the rankings were to include the generic forms, as most of the thiazide diuretics, angiotensin converting enzyme (ACE) inhibitors and β-blockers are available as generic drugs. β-blockers are one of the most commonly prescribed drugs on the market because they are widely used for a variety of cardiovascular diseases, including hypertension, angina pectoris and heart failure. Of course, optometrists are familiar with its topical formulation, timolol, for the treatment of glaucoma.

Adverse effects. It's important to pay close attention to this large group of patients by taking blood pressure and perfoming a retinal exam because of their risk for stroke or retinal vein occlusion secondary to hypertensive vascular changes such as arteriovenous nicking.

Fetal toxicity is a boxed warning for angiotensin receptor antagonists such as Benicar (olmesartan medoxomil, Daiichi-Sankyo), so patients who are pregnant should not take the drug. Similarly, drugs that act directly on the renin-angiotensin system, such as the ACE inhibitor Zestril (lisinopril, AstraZeneca), can cause injury and death to the fetus.

The boxed warning for β-blocking agents indicates that these drugs must be tapered off over one to two weeks with careful monitoring to prevent exacerbations of angina pectoris and myocardial infarction. The most common adverse reactions with systemic β-blockers tend to be mild and transient, manifesting as tiredness, dizziness, depression and bradycardia. Furthermore, β-blockers may mask tachycardia, an early sympathetic symptom in hypoglycemic diabetes patients.

Thyroid medications. Synthroid (levothyroxine sodium tablets USP, AbbVie) was the most commonly prescribed branded drug in the 2014-2015 study year, with more than 21.5 million US prescriptions.[2] It is approved for hypothyroidism and pituitary thyroid stimulating hormone suppression. Hypothyroidism is a broad category consisting of primary (thyroidal), secondary (pituitary), tertiary (hypothalamic) and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy or from the effects of surgery, radiation or drugs, with or without presence of goiter.

As practitioners, we must be alert for thyroid eye disease and diagnose it early in our patients. Exophthalmometry at an initial visit can serve as a baseline for future comparison. Patients can be educated on the early symptoms of thyroid eye disease such as dry eye, redness, light sensitivity, lid retraction and eye protrusion. Furthermore, thyroid eye disease occurs three times as often in females than in males, and it can arise even when a patient is euthyroid.[7]

Adverse effects. Thyroid hormones should not be used for weight loss or to treat obesity because overdose can be serious or life threatening, especially when taken together with sympathomimetic amines, which are used to suppress the appetite.

Anti-ulcerants. These are the eighth most commonly prescribed drugs by indication.[2] Nexium (esomeprazole magnesium, AstraZeneca) and Dexilant (dexlansoprazole, Takeda Pharmaceuticals) account for over 19 million prescriptions in the United States.[2] Other commonly prescribed anti-ulcerant drugs such as ranitidine and omeprazole available in generic forms. Carafate (sucralfate, Aptalis Pharmaceutical Technologies), available in suspension, is also an anti-ulcerant

Table 2. Top 10 Therapeutic Classes by Prescriptions[1]

Dispensed Prescriptions (Millions)		2010	2011	2012	2013	2014
1	Antihypertensives	652	649	691	701	705
2	Mental health	481	495	511	523	537
3	Pain	462	462	470	482	480
4	Antibacterials	271	274	272	269	267
5	Lipid regulators	255	255	266	264	263
6	Antidiabetes	173	174	186	193	201
7	Nervous system disorders	142	148	157	168	179
8	Anti-ulcerants	147	150	159	166	170
9	Respiratory	153	153	157	162	169
10	Thyroid therapies	110	113	122	127	130

with more than one million prescriptions.[2] It is only indicated for short-term treatment—up to eight weeks for an active duodenal ulcer.

Adverse effects. Chronic use of proton pump inhibitors for more than a year can increase the risk of osteoporosis-related fractures of the hip, wrist and spine.[3] Furthermore, conjunctivitis and abnormal vision have been reported with incidence of less than 1%.[3] Constipation was the most frequent complaint with Carafate use (2%).[3] Diabetes patients are at risk of hyperglycemia when using this drug.[3]

Combination oral contraceptives (COC). An estrogen (estradiol) and a progestogen (progestin) are often combined to suppress ovulation and increase cervical mucus to inhibit sperm penetration. Over 15 million prescriptions for branded COCs, such as Lo Loestrin Fe (norethindrone acetate & ethinyl estradiol, Allergan) were written in the study year.[2] However, the number of patients taking COCs is significantly higher, considering the top 100 does not account for generic versions of these medications.

Adverse effects. The boxed warning on COCs includes cigarette smoking and its ability to increase the risk for serious cardiovascular events such as stroke and myocardial infarction. Patients taking COCs should be aware of potential serious side effects that could be easily remembered by the mnemonic 'ACHES': **A**bdominal pain, **C**hest pain, **H**eadaches (severe), **E**ye problems and **S**welling of the legs and thighs. Dry eye and retinal vein thrombosis have been associated with COCs as well.[3]

Arthritis and osteoarthritis medications. Brand-name drugs for this indication were doled out to over 15 million Americans, not including the many generic versions available.[2] Celebrex (celecoxib, Pfizer) and Voltaren Gel (diclofenac sodium topical gel, Novartis) are the nonsteroidal anti-inflammatory drugs (NSAIDs) that make the top 100 branded list. Two branded drugs commonly used to treat arthritis are tissue necrosis factor alpha (TNF-α) inhibitors Enbrel (etanercept, Amgen) and Humira (adalimumab, AbbVie).

Adverse effects. The boxed warning for Celebrex indicates that the drug increases the risk for myocardial infarction and stroke. Additionally, Celebrex is a sulfonamide that may cause serious adverse skin events such as Stevens-Johnson syndrome. All NSAIDs can cause serious gastrointestinal adverse events, including bleeding, ulceration and perforation of the stomach or intestines.

A few other side effects of systemic NSAIDs worth knowing: they can worsen pre-existing hypertension, decrease renal blood flow and induce bronchospasm. Finally, keep in mind the risk of Reye's syndrome, a very rare but serious disease affecting primarily the brain and liver with symptoms of drowsiness, confusion, seizures, coma and, in severe cases, death. These usually develop three to seven days after the viral illness starts. It most likely occurs in children younger than 15 years of age.[8] The exact etiology is unknown, but it has been reported in patients who took aspirin and recently had chicken pox, a cold or flu.[8]

For TNF-α inhibitors, serious infections and malignancy are the boxed warnings because they are immune suppressants, exposing patients to opportunistic infections. Most patients who developed these infections were taking concomitant immune suppressants such as methotrexate or corticosteroids. Lymphoma and other malignancies have been reported in patients treated

with TNF-α inhibitors.[3] As for ocular side effects, optic neuritis and cataract are potential adverse effects. Furthermore, patients with arthritis also have increased risk of uveitis.

Psychiatric medications. Central nervous system (CNS) stimulants such as Vyvanse (lisdexamfetamine dimesylate, Shire) and Focalin XR (dexmethylphenidate hydrochloride, Novartis) are indicated for attention deficit hyperactivity disorder (ADHD), as is Strattera (atomoxetine, Eli Lilly).

Schizophrenia affects about 1% of Americans, with onset occurring mainly between the ages of 16 and 30.[9] Atypical antipsychotics such as Abilify (aripiprazole, Otsuka America Pharmaceuticals), Seroquel XR (quetiapine fumarate, AstraZeneca) and Latuda (lurasidone, Sunovion Pharmaceuticals) are the drugs of choice for schizophrenia; however, they are also indicated, and may be prescribed for, other psychological concerns such as bipolar I disorder, major depressive disorder (MDD) and autistic disorder.

MDD is characterized by having at least two weeks of a major depressive episode that causes significant distress and disability. It is not associated any history of mania or hypomania as in bipolar disorder. The annual community prevalence rate is about 7% in the United States, affecting three times more young patients—i.e., those 18 to 29 years old—than patients over 60 years of age.[10]

Pristiq (desvenlafaxine, Pfizer), a serotonin and norepinephrine reuptake inhibitor (SNRI), and Viibryd (vilazodone, Allergan), a 5HT1A partial agonist, are two branded drugs for MDD. Selective serotonin reuptake inhibitors (SSRIs) such as Prozac (fluoxetine, Eli Lilly), Paxil (paroxetine, GlaxoSmithKline), Zoloft (sertraline, Pfizer) are also indicated for treating MDD, along with many generic versions.

Adverse effects. CNS stimulants are amphetamine derivatives and have a high potential for abuse and dependence. They have been associated with weight loss and slowing of growth rate in pediatric patients; thus, close monitoring of growth (weight and height) in pediatric patients is recommended. Blurred vision, mydriasis and difficulties with visual accommodation have been reported as post-marketing experiences. Strattera, which is not a derivative of amphetamine, has a low potential for abuse but an increased risk of suicidal ideation in short-term studies in children or adolescents with ADHD. Families and caregivers are advised to monitor for unusual changes in behavior, especially during the initial few months of therapy.

The boxed warning for atypical antipsychotics indicates that elderly patients are at increased risk of death due to dementia-related psychosis and suicidal thoughts and behaviors. Antipsychotic drugs work by blocking dopamine receptors, and in rare cases, can cause tardive dyskinesia and neuroleptic malignant syndrome, a rare but potentially fatal condition manifesting as hyperpyrexia, muscle rigidity, altered mental status and autonomic instability (i.e., irregular blood pressure and heartbeat).

The ocular side effects of typical or older antipsychotics such as phenothiazines (chlorpromazine and thioridazine) are widely known for their deposits in the retina, lens and cornea.[11] Although atypical or newer antipsychotics are less harmful to the eye, they have more metabolic side effects such as hyperglycemia, dyslipidemia and weight gain.

The boxed warning for MDD drugs states that, according to studies of short-term use (i.e., few months) antidepressants increase the risk of suicidal thoughts and behavior in children, adolescents and young adults. When caring for patients of all ages who are taking antidepressants, be sure to monitor closely for adverse psychiatric effects. Advise families and caregivers of the need for close observation and communication with the prescriber.

Alzheimer's disease (AD). Therapies include Namenda (memantine HCl, Allergan), a glutamatergic receptor blocker, and Exelon (rivastigmine, Novartis), a cholinesterase inhibitor, with about 11 million prescriptions between 2014 and 2015.

Adverse effects. Various visual anomalies, including color vision, visual fields, stereopsis and contrast sensitivity, have been reported in patients with AD, but they are hard to replicate consistently.[12] It is likely that AD deteriorates visual function, and it may be difficult for patients to describe visual problems as dementia worsens, so we must pay attention to patients' complaints and do the best we can to optimize their visual function and improve their quality of life. Caregivers can play an essential role in observing and recording any

The Top Five Drugs by Class

The top five therapeutic classes by prescription (both branded and generic) for the past five years in order of frequency are antihypertensives, mental health, pain, antibacterials and lipid regulators (*Table 2* lists the top 10 drugs by class).[1] This ranking correlates well with disease prevalence in the United States, and we should take this into consideration when treating patients. For instance, we should pay more attention to hypertension by taking blood pressure in-office and be on the lookout for early signs of hypertensive retinopathy. Additionally, we could do more for our patients by reviewing their medications and screening for early mental health issues via questionnaires available from Mental Health America.[5]

Practitioner and Patient Resources

For practitioners: Dailymed (https://dailymed.nlm.nih.gov), a website run by the US National Library of Medicine, contains 80,188 drug listings as submitted to the FDA.[3]

For patients: Patient assistance program resources can help the public access assistance or discounts to costly drugs. These are run by nonprofit organizations such as Partnership for Prescription Assistance (www.pparx.org), NeedyMeds (www.needymeds.org), RxAssists (rxassist.org) and others. Moreover, many drug companies run their own patient assistance programs, so you can direct patients to the company's web site and apply for the discounts.[4]

difficulty with vision-related tasks and report to the eye care provider.[12] Cholinesterase inhibitors (e.g., Exelon) enhance the cholinergic system and can induce miosis.

Erectile dysfunction medications. Viagra (sildenafil citrate, Pfizer) and Cialis (tadalafil, Eli Lilly) are phosphodiesterase-5 (PDE-5) inhibitors indicated for the treatment of erectile dysfunction (ED). Cialis is also approved for the treatment of benign prostatic hyperplasia. Thus, it is prudent that we do not assume all patients are taking these medications primarily for ED.

Adverse effects. Patients need to be reminded that ED medications potentiate the hypotensive effect of nitrates, such as nitroglycerin for angina. Color vision disturbances have been associated with PDE-5 inhibitors because they have the ability to also block PDE-6 in the retina. Non-arteritic anterior ischemic optic neuropathy (NAION) has been reported as a possible result of PDE-5 inhibitors, but it could also be a coincidence, since elderly patients have increased risk of NAION.[3] Nevertheless, patients with prior history of NAION should be warned of increased risk of recurrence.

Benign prostatic hyperplasia (BHP). This occurs in almost all men as they age, and about half of all men over the age of 75 have some symptoms, so the number of patients taking Avodart (dutasteride, GlaxoSmithKline), a 5α-reductase inhibitor, may be significant. Vesicare (solifenacin succinate, Astellas Pharma), a muscarinic antagonist, and Myrbetriq (mirabegron, Astellas Pharma), a β_3-adrenergic agonist, are approved for the treatment of overactive bladder, with symptoms of a sudden, strong and uncontrollable urge to urinate.

Adverse effects. Like other muscarinic antagonists, Vesicare can cause blurry vision, dry eye and angle closure. We are familiar with Flomax (tamsulosin, Boehringer Ingelheim), an 1-adrenoceptor blocker that has been associated with floppy iris syndrome, which can complicate cataract surgery.

Anticoagulants. Brand-name drugs indicated to prevent stroke accounted for nearly 11 million prescriptions in the IMS study.[2] They include factor Xa inhibitors such as Pradaxa (dabigatran, Boehringer Ingelheim) and thrombin inhibitors such as Eliquis (apixaban, Bristol-Myers Squibb) for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation, and platelet aggregation inhibitors such as Effient (prasugrel, Eli Lilly) for maintaining anticoagulation in the treatment of deep vein thrombosis and pulmonary embolism.

Adverse effects. These drugs increase the risk for bleeding, so patients may need to avoid elective dental work or elective surgical procedures. Additionally, premature discontinuation of oral anticoagulants can increase the risk of thrombotic events. Some patients may present to your office with severe subconjunctival hemorrhage secondary to adverse effects. The International Normalized Ratio (INR) is typically 0.9 to about 1.1 for healthy individuals. On warfarin therapy, the INR elevates to between 2 and 3.5.[13] But INR may not be accurate in assessing the effectiveness of newer anticoagulants such as Pradaxa or Xarelto (rivaroxaban, Janssen Pharmaceuticals); more effective tests tailored to these novel drugs are being developed.[13,14]

Glaucoma medications. These commonly prescribed drugs are near and dear to our specialty. More than 9.5 million brand-name prescriptions were given out in the study year to decrease IOP in glaucoma patients.[2] Lumigan (bimatoprost ophthalmic solution, Allergan), Travatan Z (travoprost ophthalmic solution, Alcon), Alphagan P (brimonidine tartrate ophthalmic solution, Allergan) and Combigan (brimonidine tartrate/timolol maleate ophthalmic solution, Allergan) are the top four branded drugs for glaucoma.

Adverse effects. Brimonidine can cause allergic conjunctivitis and conjunctival hyperemia, whereas prostaglandin analogs such as bimatoprost can cause conjunctival hyperemia, itchy eyes, eyelash growth and skin hyperpigmentation. Another side effect of long-term prostaglandin analog use is prostaglandin-associated periorbitopathy, which results in very deep superior sulcus and a 'sunken' eye appearance.[15]

Various ophthalmic medications. Other ophthalmic drugs that make the top 100 ranking are Patanol (olopatadine, Alcon) and Pataday (olopatadine, Alcon), with over four million prescriptions in the United States for the treatment of ocular itching associated with allergic conjunctivitis in the study year.[2]

Durezol (difluprednate ophthalmic emulsion, Alcon), the newest topical steroid, and the corticosteroid Lotemax (loteprednol etabonate,

Bausch + Lomb) garnered more than one million prescriptions each for the treatment of inflammation and pain associated with ocular surgery.[2]

Adverse effects. Some of the most common side effects of olopatadine are cold-like symptoms and pharyngitis in about 10% of patients. Burning or stinging, conjunctivitis, hyperemia and keratitis are other potential ocular adverse effects. Patients should wait at least 10 minutes after instilling olopatadine before inserting contact lenses because the benzalkonium chloride preservative can be absorbed by soft lenses.

As for steroids, we know they are contraindicated in active ocular infections such as herpes simplex keratitis, fungal keratitis and bacterial keratitis. Prolonged steroid use can lead to increases in IOP and the formation of posterior subcapsular cataract, although perhaps less so with Lotemax.

HIV antivirals. For patients who have access to therapy, HIV infection can be managed as a chronic disease.[16] Although AIDS-related illnesses are decreasing, cardiovascular disease and cancer are increasing in HIV patients because of long-term immunodeficiency and the cumulative toxicities incurred from antivirals.[16] Norvir (ritonavir, AbbVie) and two other combination antivirals, Truvada (emtricitabine/tenofovir disoproxil fumarate, Gilead) and Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate, Bristol-Myers Squibb) are the commonly prescribed branded antivirals.

Adverse effects. The drug labels warn of lactic acidosis (low blood pH) and severe hepatomegaly with steatosis (fat liver). Optometrists should be alert for signs of severe liver problems manifested as yellow eyes. Furthermore, patients with HIV are at increased risk of eye infections, ocular malignancy and HIV retinopathy.

Vaccines and antivirals. The herpes zoster vaccine Zostavax (Merck) was administered to more than 2.2 million Americans to prevent shingles in individuals 50 years of age and older in the study year.[2] It is a live vaccine and is not recommended for individuals who are immunosuppressed or immunodeficient. Optometrists should educate older patients about the vaccine because herpes zoster ophthalmicus can cause severe pain and threaten vision.

Over 12.6 million vaccines were given to prevent or treat influenza in the form of the influenza vaccines Afluria (BioCSL) and Tamiflu (oseltamivir phosphate, Genentech). During 31 seasons between the years 1976 and 2007, flu-associated deaths in the United States ranged from a low of about 3,000 to a high of about 49,000. People 65 years of age and older accounted for 80% to 90% of the flu-related deaths.[17]

Rounding Out the Top 100

The above drug categories comprise the bulk of the top 100 branded medications cited by IMS Health.[2] Other notable drugs and their indications are as follows. All figures are taken from the IMS data and represent US-only prescribing patterns.[2]

Smoking cessation. Chantix (varenicline, Pfizer) made the list with over 2.2 million prescriptions.[2] It is a nicotinic receptor partial agonist that can lead to changes in behavior, hostility, agitation and suicide ideation.

Chronic angina. Ranexa (ranolazine, Gilead), a sodium current inhibitor, is used to treat adults with chronic angina and can be used with other cardiovascular drugs.

Irritable bowel syndrome (IBS). Linzess (linaclotide, Allergan), a guanylate cyclase agonist, treats IBS with constipation (IBS-C) and chronic idiopathic constipation (CIC). The most common side effect is diarrhea within the first two weeks of treatment. Amitiza (lubiprostone, Takeda Pharmaceuticals), for CIC, is a chloride channel activator.

Gout. Uloric (febuxostat, Takeda Pharmaceuticals), a xanthine oxidase inhibitor, was prescribed more than 1.2 million times for the management of chronic hyperuricemia in patients with gout during the year studied.[2] It is contraindicated in patients prescribed azathioprine or mercaptopurine, as it increases the risk of cardiovascular thromboembolic events and hepatic failure.

Acne. Epiduo (Galderma Laboratories) is a combination of adapalene (a retinoic acid nuclear receptor agonist) and benzoyl peroxide (an oxidizing agent with bactericidal effect) and is the most prescribed branded topical acne agent in the world.[18] Eyelid edema, contact dermatitis and conjunctivitis have been identified in post-marketing experience.

Migraine. Relpax (eletriptan HBr, Pfizer), a 5HT1B/1D receptor agonist, is indicated for the acute treatment of migraine. Since it is a serotonin agonist, serotonin syndrome may occur, particularly during co-administration with selective SSRIs and other antidepressants. Serotonin syndrome symptoms include agitation, hallucinations, coma, irregular heartbeat and blood pressure and hyperthermia.

By highlighting these drugs, we gain essential knowledge pertinent to us as primary care optometrists. Additionally, though the rankings in *Table 1* would be different if generic drugs were included, the general principles of care described in this article are relevant to generic drugs in corresponding classes. ■

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OSC QUIZ

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1. Which drug class is the most commonly prescribed in the last few years?
a. Anticoagulants.
b. Antihypertensives.
c. Anti-ulcerants.
d. Thyroid therapies.

2. Which of the following drugs is indicated for neuropathic pain associated with diabetic peripheral neuropathy?
a. Januvia (sitagliptin).
b. Lyrica (pregabalin).
c. Humira (adalimumab).
d. Abilify (aripiprazole).

3. This is a μ-opioid antagonist available as emergency opioid overdose kit:
a. Oxycontin (oxycodone).
b. Bystolic (nebivolol).
c. Zetia (ezetimibe).
d. Narcan (naloxone).

4. Which is a long-acting β_2-adrenergic agonists (LABA), which has a black-box warning of increased risk of asthma-related death?
a. Flovent (fluticasone).
b. Pataday (olapatadine).
c. Severent (salmeterol).
d. Praxada (dabigatran).

5. This muscarinic antagonist used to treat COPD can cause ocular side effects similar to atropine:
a. Spiriva (tiotropium).
b. Pristiq (desvenlafaxine).
c. Viibryd (vilazodone).
d. Enbrel (etanercept).

6. Which potentially serious side effect do patients need to be warned of when taking a statin class of drug for hyperlipidemia?
a. Dry eye.
b. Muscle pain.
c. Headache.
d. Constipation.

7. Which antihyperlipidemic drug can interfere with fat-soluble vitamin absorption?
a. Crestor (rovustatin).
b. Lotemax (loteprednol).
c. Welchol (colesevelam).
d. Diovan (valsartan).

8. This cholesterol absorption inhibitor is often combined with the statin class of drugs in the treatment of hyperlipidemia:
a. Zetia (ezetimibe).
b. Benicar (olmesartan).
c. Vesicare (solifenacin).
d. Nasonex (mometasone).

9. Which of the following drugs is an angiotensin converting enzyme inhibitor?
a. Vyvanse (lisdexamfetamine).
b. Januvia (sitagliptin).
c. Zestril (lisinopril).
d. Cialis (tadalafil).

10. Which class of antihypertensives can cause fetal toxicity?
a. Calcium channel blockers.
b. β-blockers.
c. Thiazide diuretics.
d. Angiotensin receptor antagonists.

11. All of the followings are common adverse reactions to β-blockers, except:
a. Tachycardia.
b. Tiredness.
c. Dizziness.
d. Depression.

12. This is the most commonly prescribed drug for patients with thyroid disorder:
a. Viagra (sildenafil).
b. Strattera (atomoxetine).
c. Crestor (rosuvastatin).
d. Synthroid (levothyroxine).

13. Which of these is a proton pump inhibitor, chronic use of which can increase the risk of osteoporosis-related fractures of the hip, wrist or spine?
a. Nexium (esomeprazole).
b. Chantix (varenicline).
c. Ventolin (albuterol).
d. Myrbetriq (mirabegron).

14. Reye's syndrome, a very rare but serious disease affecting primarily the brain and liver with symptoms of drowsiness, can happen in the young with which class of medication?

OSC QUIZ

a. β-blockers.
b. NSAIDs.
c. Corticosteroids.
d. PPIs.

15. Which of the following ADHD drugs is less addictive than the others?
a. Strattera (atomoxetine).
b. Nexium (esomeprazole).
c. Focalin (dexmethyphenidate).
d. Viagra (sildenafil).

16. Which of these is a serotonin and norepinephrine reuptake inhibitor (SNRI)?
a. Eliquis (epixaban).
b. Pristiq (desvenlafaxine).
c. Namenda (memantine).
d. Nasonex (mometasone).

17. Which ophthalmic drug can cause hypertrichosis and skin hyperpigmentation?
a. Alphagan P (brimonidine).
b. Durezol (difluprednate).
c. Lumigan (bimatoprost).
d. Pataday (olapatadine).

18. Which of the following medications is used to prevent shingles?
a. Zostavax (zoster vaccine live).
b. Tamiflu (oseltamivir).
c. Afluria (influenza vaccine).
d. Norvir (ritonavir).

19. Which of the following is an NSAID for the treatment of arthritis?
a. Latuda (lurasidone).
b. Cebebrex (celecoxib).
c. Enbrel (etanercept).
d. Focalin (dexmethyphenidate).

20. This combination drug is the most prescribed topical acne agent in the world:
a. Epiduo (adapalene + benzoyl peroxide).
b. Vytorin (ezetimibe + simvastatin).
c. Uloric (febuxostat).
d. Humulin R (insulin regular).

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5.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
12.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
16.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
17.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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Is That Conjunctival Lesion Cancerous?

Easily mistaken for a benign pinguecula or pterygium, conjunctival intraepithelial neoplasm is far more ominous. You can avoid invasive procedures and still ensure effective treatment. **By Aaron Bronner, OD**

The interpalpebral space of the conjunctiva frequently develops irregular tissue changes that are, mostly, minimally pathologic or not pathologic at all. This location is exposed to ultraviolet (UV) radiation and atmospheric irritants and is susceptible to dryness; thus, lesions such as pingueculae and pterygia are commonly encountered ocular surface irregularities and generally draw minimal attention on exam.

Squamous neoplastic disease, however, is occasionally encountered. Invasive conjunctival squamous cell carcinoma is often histologically preceded by conjunctival intraepithelial neoplasm (CIN), which represents the most frequently encountered conjunctival neoplastic growth. These lesions—often misdiagnosed as more typical ocular surface growths—are slowly progressive, locally invasive and have no metastatic potential. However, they may occasionally cause significant local ocular surface damage and can progress to the more invasive squamous cell carcinoma. Both the diagnosis and treatment of CIN can be challenging. This article offers insights for ODs who may not encounter CIN too often and would like a clinical overview.

CIN Development

The genesis of an epithelial cancerous cell population, or carcinoma, requires a series of changes to the cells' behavior. Cells that exhibit this dysplasia show disorganized growth and maturation, resulting in an overabundance of immature cells which is contrasted by a concomitant relative paucity of mature cells of this line. While dysplasia is a reversible process, dysplastic cells may then undergo further mutation, resulting in neoplastic transformation, whereby the cells become insensitive to growth inhibitors and become invasive.

Neoplastic carcinomas may be locally confined by basement membrane—known as carcinoma *in situ*—or may be invasive, characterized by the lesion breaking through the respective basement membrane and spreading locally. This staging, however, does not refer to two separate entities; rather, carcinoma *in situ* represents a preliminary step along the same continuum of neoplasia. If left alone, carcinoma *in situ* may eventually become invasive.

While it is possible for squamous carcinoma to skip the step of CIN, it is frequently the midpoint in the disease's etiology. CIN is an abnormal line of conjunctival (and possibly corneal) epithelial cells and represents either simple dysplasia (partial thickness of epithelial tissue) or carcinoma *in situ* when the lesion is full thickness.[1-4] CIN is part of the spectrum of neoplastic disorders of the conjunctiva and cornea known collectively as ocular surface squamous neoplasia (OSSN). If CIN becomes invasive by breaking through basement membrane, it is reclassified as invasive squamous cell carcinoma (SCC).

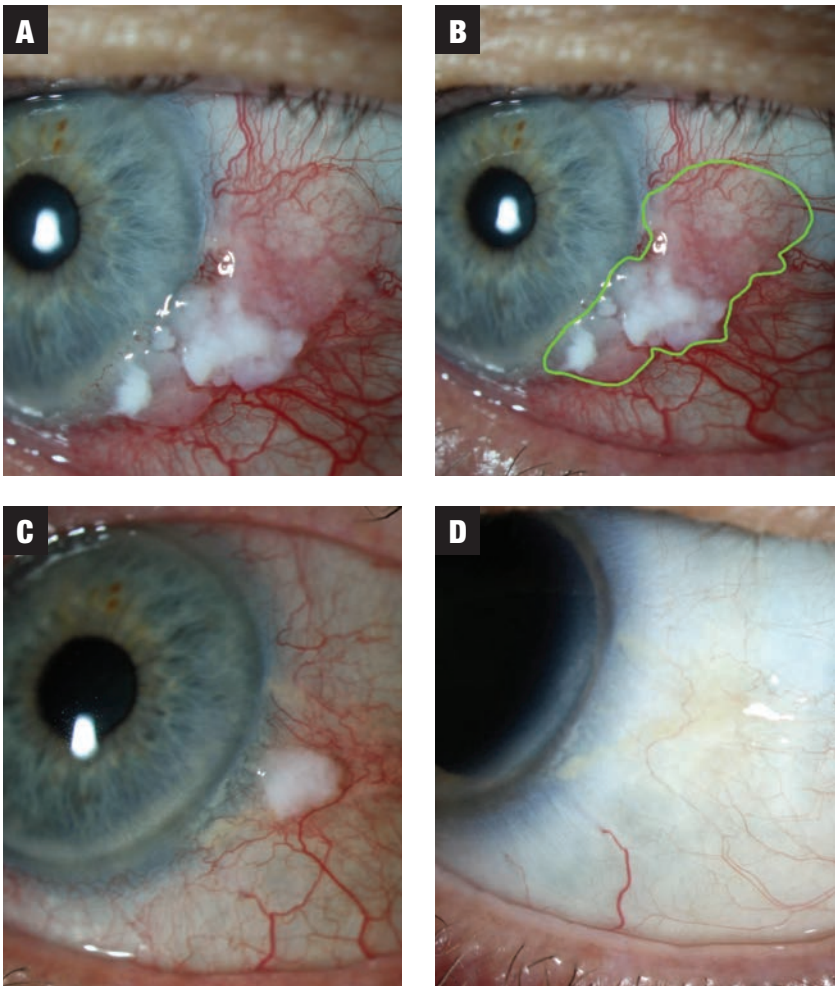


Fig. 1a. This lesion has both leukoplakic and gelatinous zones. Treatment was initiated at MMC-0.02% QID. Fig. 1b. Full estimated extent of lesion highlighted. Fig. 1c. After first three-week course of MMC 0.02%, lesion shows dramatic reduction in size. Patient was placed on a "wash out" period of two weeks and instructed to anticipate a second course of MMC Fig. 1d. Lesion showed complete resolution following washout.

Though uncommon, CIN is the most frequently encountered conjunctival neoplasm in the United States.[4] Risk factors for the development of CIN, and all forms of OSSN, are UV exposure (particularly UV-B), male gender, exposure to petroleum products, heavy tobacco smoke, human immune deficiency virus (HIV) and human papillomavirus (HPV) type 16, though this last risk remains controversial.[1,3-5] CIN prognosis is usually good, except in cases when the growth is unusually large. Once the lesion breaks basement membrane and becomes invasive, prognosis is worse and often calls for aggressive treatment such as enucleation or exteneration. Even in these cases, risk of distant metastasis is low.

Clinical Presentation

The clinical appearance of CIN is that of an abnormal, slightly elevated, fleshy mass, typically located at the interpalpebral limbal

zone (95% of all lesions).[6] The predilection for this area is likely due to its features. UV-B exposure is greatest in the interpalpebral zone, and the stem cell zone of the limbus is a transitional space between the corneal and conjunctival epithelium. This transition zone likely confers special risk to the tissue for undergoing dysplasia.

The conjunctival lesions may be gelatinous, papillary or, less commonly, leukoplakic, which occurs as a result of hyperkeratosis. These lesions are usually well defined and will show some degree of feeder vasculature.[3,7,8] Ninety-five percent of cases will involve the limbus.[6] Corneal manifestations show similar whitening and can exhibit gray, fimbriated (i.e., finger-like) epithelial projections from the limbus. Classically, the lesions will demonstrate positive staining or stippling with rose bengal, which can be useful in the clinical differentiation of CIN from other conjunctival lesions.[8,9]

Despite relatively prominent findings on paper, CIN and SCC lesions can be challenging to differentiate from more normal growths of the conjunctiva, such as pingueculae, pterygia and nevi. This can lead to misdiagnosis in up to 60% of cases, even when evaluated by experienced clinicians—making biopsy with histologic assessment potentially valuable.[3]

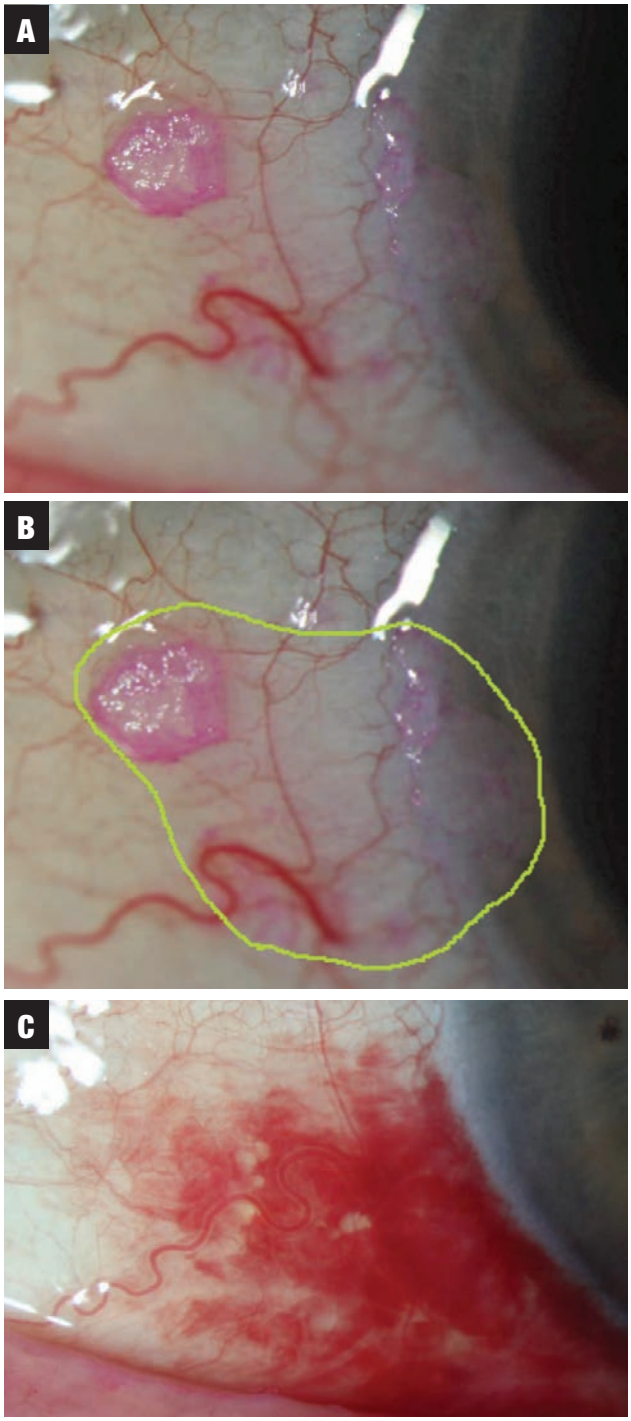
Diagnostic Testing

Historically, testing included excisional biopsy performed at the time of surgical removal. However, physicians are now using chemotherapy as a primary treatment modality, which may limit access for biopsy.

A newer diagnostic tool is impression cytology, which is performed by applying a filter paper to the lesion, removing the superficial epithelium and allowing minimally invasive histological studies. This is roughly 80% sensitive, though false negatives remain its weakness, because the collecting paper may be stymied by excess keratosis of the lesion; repeat attempts are generally more successful.[8] One study shows ultra-high resolution OCT, though not currently available, is very sensitive in the differentiation of OSSN and pterygium on the basis of the lesion's epithelial thickness.[10]

Treatment

The traditional treatment of CIN is excision with margins of 1mm to 5mm, depending on the extent and history of primary and recurrent lesions. Corneal involvement is debrided with a surgical blade, and



Figs. 2a-c (from top to bottom). Case 2 involved a small suspected CIN lesion discovered incidentally on exam. Treatment was initiated at INFa2b qid until 10mL bottle was empty. The estimated total extent of neoplastic margins is highlighted in green. Finally, resolution was seen, with concurrent SCH related to Valsalva (not medication induced). Treatment required one month at one million IU qid and then 10 days qid at three million IU of INF-a2b.

cryotherapy is applied to the bed and conjunctival edges. The sclera is left bare. This is usually successful, but recurrences are reported between 10% and 52%, depending on the rate of clear surgical margins as determined by postoperative histology.[6-11] The rate drops to 5% if clear margins are achieved; unfortunately, studies show it is difficult to guarantee clear margins.[8,9] These numbers would seem to support the use of the widest margins possible; however, there are consequences of extensive conjunctival excision: cicatricial changes, limbal stem cell deficiency, scleral melt, significant disturbance to the tear film and irregular changes in corneal astigmatism.

Topical Options

More recently, topical chemotherapeutics have become popular to manage CIN, as they have the benefit of treating the entire ocular surface and, when used judiciously, seem to be well tolerated.

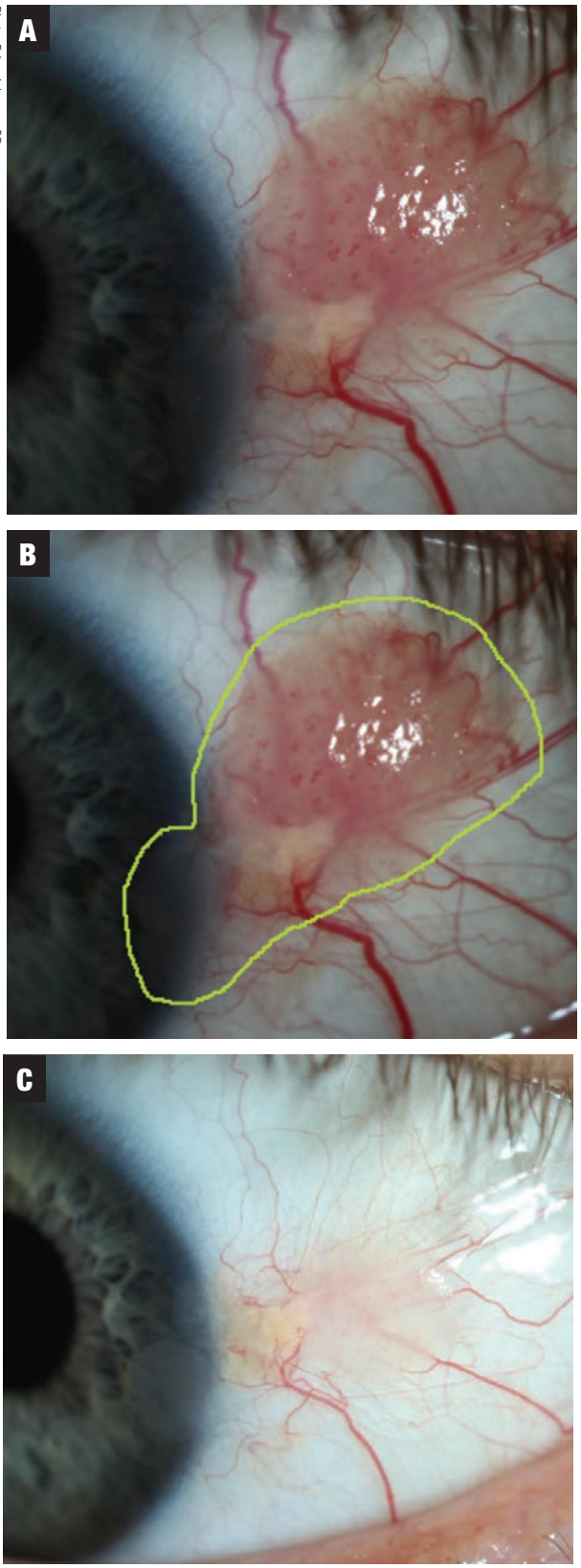
Mitomycin. Discovered in the 1950s, mitomycins are fermentation byproducts of *Streptomyces caespitosus*. Mitomycin-C (MMC), the last of these molecules discovered, is an antimetabolite used outside of eye care as an anti-tumor chemotherapy agent.[12,13] MMC works as an alkylating agent that prevents DNA splitting during cellular mitosis, an alteration that is extremely toxic.[1] Even one of these crosslinks can be fatal to a cell.[13] Additionally, MMC may generate reactive oxygen species and increase the synthesis of tumor necrosis factor (TNF).

Though it has its roots in oncology, MMC use has become more widespread, particularly within eye care, in attempts to limit excessive postoperative scar formation. Optometrists who comanage surgery patients may be familiar with its intraoperative use to prevent scarring in patients who have undergone a glaucoma filtering procedure and its use in PRK to prevent corneal haze. Since its first OSSN-associated use in the mid 1990s, MMC has proven efficacious, with success rates between 82% and 100%. Dosing is typically 0.04% concentration given QID in one-week-on, one-week-off cycles, or a 0.02% concentration is continuously dosed in four-week treatments.[4] Medication toxicity is greater with prolonged treatments or higher concentrations

As MMC is an especially potent, potentially dangerous medication, its side effects—limbal stem cell deficiency and scleral melt, for example—may be severe. More frequently encountered side such as corneal and conjunctival epitheliopathy and conjunctival injection are transient.[4,14] When used, MMC requires careful follow up and cessation of medication when any significant side effect is suspected.

5-Fluorouracil (5-FU). This is another antimetabolite used in the treatment of dermatologic tumors, and also by glaucoma surgeons. Its mechanism blocks DNA synthesis by interfering with the enzyme thymidylate synthase. In the treatment of OSSN, 5-FU is generally dosed at a concentration of 1% QID one-month-on, one-month-off until resolution. Most cases resolve with one or two cycles, though some take as long as five. Epithelial toxicity, resulting in erosion or sloughing, is common. In one study, the treatment duration was set as the time until sloughing occurred, with time off treatment lasting until re-epithelialization. Despite this painful complication, side effects of 5-FU do not seem to be as severe as MMC, and recurrence rates are generally reported as equivalent.[4,14]

Photo: Brian Johnson, OD



Interferon alpha 2b (INF-a2b). Interferons are a subgroup of naturally occurring inflammatory proteins known as cytokines. They are produced by activated immune cells and have variable antineoplastic, antiviral and antimicrobial effects. The first reported use of INF-a2b in 1994 yielded successful resolution of a CIN lesion with its topical use.[5] Since then, INF-a2b has been used both topically and subconjunctivally, with good effect, in the treatment of OSSN.

Perilesional dosing has the greatest efficacy, with 87% to 100% resolution over a five-week period (with injections given up to three times per week).[4,14,15] Multiple injections are necessary to obtain this level of efficacy, which results in up to 100% of patients developing systemic myalgias and fever.[5,14] Topical dosing is roughly equivalent to MMC in effectiveness.[14,15] It is given at a concentration of one million international units (IU) per millimeter and dosed QID for one month beyond clinical resolution. When resolution does not occur, the concentration may be increased to up to three million IU, also QID. Generally, regardless of the treatment concentration, compounding pharmacies will prepare the bottle from a single preparation of one million IU. This one million IU preparation can be concentrated further by reducing the amount of carrier to the bottle. Side effects of topical INF-a2b are mild, with hyperemia and follicular conjunctivitis being frequently reported; keratitis is reported less commonly.[4]

Topical vs. Surgery

Though biopsy and surgical excision were the historic treatment of choice, topical chemotherapeutics, which have some theoretical benefits over surgery, have gained some acceptance as front line therapy. With surgery, it is impossible to guarantee clear margins—a feature required for the best prognosis. The greater the amount of tissue removed to ensure clear margins, the greater the potential for long-term disruption of the ocular surface. Topical agents treat the entire ocular surface, eliminating the need to identify margins and allowing effective treatment of neoplastic cellular populations that could not be plainly identified with microscopic analysis—a benefit that

Fig. 3a. Case 3 involved moderate-sized presumed papillomatous CIN. Patient was started on treatment INF-a2B three million IU X 10 days. Fig. 3b. Estimated total lesion size. Fig. 3c. Post treatment. Near complete resolution of growth with continued irregular corneal epithelium. Against advisement, the patient opted to observe at this time.

may lead to the pairing of topical agents with surgical excision as a total treatment protocol for large lesions. The drawback to topical therapy, of course, is that since the entire ocular surface is exposed to the medication—technically an overtreatment—complications may arise and, in the case of MMC in particular, those complications though rare, may be severe.

As far as efficacy is concerned, all topical chemotherapy agents for the management of OSSN perform reasonably well. INF-a2b has undergone head-to-head efficacy studies against surgical resection and has been shown to eliminate the lesion at comparable rates, and recurrence rates may actually be lower for INF-a2b relative to resection.[4] Follow-up studies report that its use is more appropriate in simple or small lesions, while surgery is preferable in cases of more advanced lesions, though topical therapy may be preferable for recurrent lesions.[4,15]

MMC generally has the shortest treatment course, but is the most toxic and carries the greatest risk of complications. 5-FU has a middling side effect profile and treatment duration; it is also the least expensive of the group. INF-a2b has superior tolerability, but is often associated with longer treatment and greater cost.[4,13-16]

Cost certainly may be a consideration when deciding to use topical chemotherapeutics. Insurance companies will sometimes refuse to cover these medications, reporting their use as experimental. In short courses of treatment and comparing only total healthcare expenditure, topical chemotherapeutics are less expensive than surgery; however, they can exceed the expense of surgery after several courses.

This possible stumbling block aside, given the efficacy, ability to avoid surgery and general tolerability, when used in a monitored fashion topical chemotherapeutics appear to be a good option for the treatment of conjunctival intraepithelial neoplasm lesions. ■

Dr. Bronner is a staff optometrist with Pacific Cataract and Laser Institute in Kennewick, Wash.

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A Global Scourge

Mosquitoes are one of the deadliest animals in the world because of their ability to carry and spread disease. **By Carlo J. Pelino, OD, and Joseph J. Pizzimenti, OD**

Billions of people around the world are at risk from bacteria and viruses transmitted by mosquitoes, ticks, fleas and other vectors. Vector-borne infection results in some of the world's most destructive diseases—many of which have emerged as increasing threats to human health in this age of globalization.

Photo: CDC

The *Aedes* species of mosquito is a vector for several diseases.

Meet the Vectors

Vector-borne diseases are especially difficult to prevent, predict and control. Only a few have vaccines. Additionally, almost all vector-borne pathogens are *zoonoses*, meaning they can live in animals as well as in humans. An *arbovirus* is defined as any of a group of viruses that are transmitted by arthropods such as mosquitoes and ticks—which are notoriously difficult to reach, physically, and often develop resistance to insecticides. The most widely known vector-borne diseases in the United States are Lyme disease, West Nile virus (WNV) and Rocky Mountain spotted fever.[1]

Mosquitoes. Numerous species of mosquitoes feed on the blood of various types of hosts, mainly vertebrates, including mammals, birds, reptiles and amphibians. Mosquito-transmitted infection causes millions of deaths worldwide every year. Zika virus, dengue fever, chikungunya virus, yellow fever, malaria and WNV are just some of the life-threatening diseases associated with mosquitoes.[2] Species within the *Aedes* genus (primarily *Ae. aegypti* and *Ae. albopictus*) carry several of these diseases (*Table 1*).

As global travel and changing land use increase, the risk of rare or new vector-borne pathogens emerging and crossing borders also increases.

West Nile Virus

WNV, which was unknown in the United States before 1999, infected 5,674 Americans in 2012.[1,3] Now, WNV is one the most important mosquito-transmitted viruses native to the United States. It is a seasonal epidemic in North America, usually flaring up during the summer until the first frost.

WNV causes life-threatening complications in approximately 1% of infected persons, with increased morbidity and mortality in individuals older than 50.[1,3] Neurologic sequelae include severe muscle weakness, with approximately 10% of patients developing a complete flaccid paralysis.[3]

Reported types of WNV-related ophthalmic involvement are listed in Table 2.[3] Most ocular signs may be treated with a topical and/or systemic steroid, but seem to be self-limited in the majority of cases. Prognosis of ophthalmic complications in WNV is generally favorable. In rare instances, ocular involvement has led to a permanent decrease in acuity and visual fields.

Table 1. Diseases Transmitted by *Aedes* Mosquitoes[1,2]

- Chikungunya
- Dirofilariasis
- Dengue fever
- West Nile virus
- Yellow fever
- Zika virus

Dengue

Globally speaking, dengue is the most common arboviral disease, with 40% of the world's population living in areas with known dengue virus transmission.[4] Dengue is typically a self-limiting disease with an overall mortality rate of less than 1%.[1,4] A small percentage of patients previously infected by one dengue serotype develop bleeding and vascular endothelial leakage

upon infection with a second dengue serotype. This very serious syndrome is known as severe dengue or dengue hemorrhagic fever.

Reported types of dengue-related ophthalmic involvement are listed in Table 2. Most patients with visual symptoms and signs recover spontaneously without any treatment. Patients with severe vision loss or bilateral involvement have been successfully treated with systemic steroids and occasionally immunoglobulins.[4] Prognosis of dengue-related ophthalmic complications is generally favorable.

The case-fatality rate of patients with severe dengue varies with the timing and quality of clinical care. When treated, dengue hemorrhagic fever has a mortality rate of 2% to 5%, but when left untreated, the mortality rate is as high as 50%.[1,4] Dengue virus has emerged as a major health problem in Puerto Rico.

Surveillance, Protection, Detection, Action

The CDC Division of Vector-Borne Diseases (DVBD) strives to protect our nation from diseases transmitted by mosquitoes, ticks and fleas. Some of these diseases have long been present in the United States while others have emerged more recently. The DVBD plays a unique role, housing much of the world's expertise in the diagnosis, prevention and control of these diseases.[5] A major part of the DVBD's ongoing work is disease tracking, laboratory studies, education and technical assistance and response. The DVBD also deals with the increasing problem of travel-associated infections and the threat of exotic arbovirus importation.

The CDC developed and leads ArboNET, the national surveillance system that monitors mosquito-borne infections in humans, birds and other animals. This information allows the CDC and its partners in local and state health departments, other government agencies and private industry to prepare for and quickly respond to epidemics.[6] Early detection and intervention is critical for making sound decisions about the need for insecticide spraying and other protective community interventions.

Zika Virus

Our next article will be a detailed review of Zika virus. Zika-infected babies with microcephaly are at risk for potential ocular complications listed in Table 2. Infected adults have presented with clinical signs of uveitis and conjunctivitis.[2,7,8] ■

Zika and the 2016 Summer Olympics

Brazil is the epicenter of Zika. The World Health Organization (WHO) has declared Zika virus a global health emergency. There has been considerable debate, even among medical experts, about whether Rio de Janeiro adequately addressed the issue for the 2016 Olympics. Several high profile athletes, including top ranked golfers Jason Day and Rory McIlroy, cited fear of Zika as the primary reason for deciding not to participate in the games. WHO issued guidelines for athletes as well as others who were in Brazil for the Olympics and Paralympics. The recommendations included using insect repellent, practicing safer sex or abstinence and staying home if pregnant. The official statement is available at www.who.int/mediacentre/news/statements/2016/zika-olympics/en/.

Table 2. Ophthalmic Significance of *Aedes*-involved Infection[1-4]

West Nile Virus
- Retinal hemes in posterior pole
- Macular edema
- Retinal vasculitis
- Optic neuropathy

Dengue
- Chorioretinitis
- Anterior uveitis
- Retinal vasculitis
- Optic neuritis
- Abducens nerve palsy

Zika Virus

Adults
- Uveitis
- Conjunctivitis

Infants with microcephaly
- Macular pigment mottling, loss of foveal reflex
- Chorioretinal atrophy and scarring
- Hemorrhagic retinopathy
- Torpedo maculopathy
- Optic nerve hypoplasia
- Iris coloboma
- Lens subluxation

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Paul M. Karpecki, OD, FAAO works in corneal services and currently serves as Clinical Director, Advanced Ocular Surface Disease at Kentucky Eye Institute in Lexington KY., and is the Past President of the Optometric Cornea, Cataract and Refractive Society.
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Derek Cunningham, OD	Thursday, September 8	9pm EST
Paul M. Karpecki, OD	Tuesday, September 13	7pm EST
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Is His Prognosis… Favre-able?

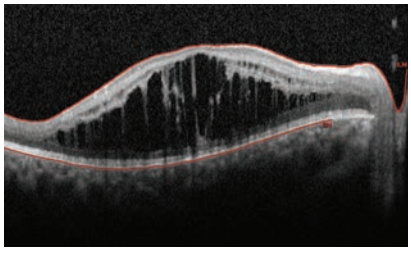
The last three months for this teenager were a blur. Well, for his vision anyway.

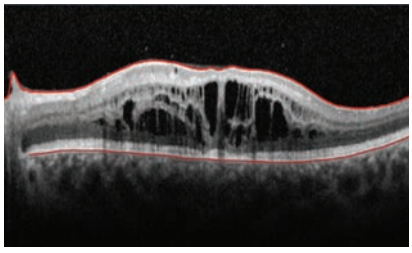
By Philip Kim, OD, and Mark Dunbar, OD

A 19-year-old male initially presented to the emergency eye clinic complaining of progressive blurred vision in the right eye that started three months earlier. He also reported a long history of decreased night vision affecting both eyes. The patient was not taking medication. His social history is noncontributory.

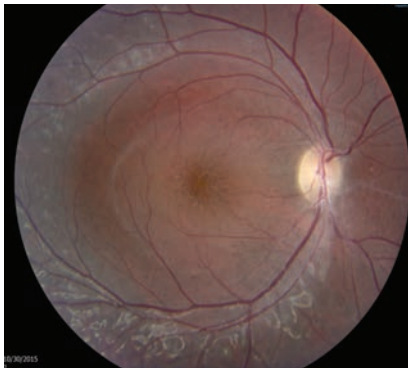
Upon examination, his visual acuity was measured to be 20/400 OD and 20/80 OS with no improvement after refraction. Extraocular motilities showed full range of motion. His confrontation fields were full-to-finger count in each eye. Pupils were round and reactive to light with no afferent defect. His color vision with the Ishihara plates was reduced to 5/9 plates OD and 6/9 plates OS. His intraocular pressures (IOP) were 16mm Hg OD and 17mm Hg OS.

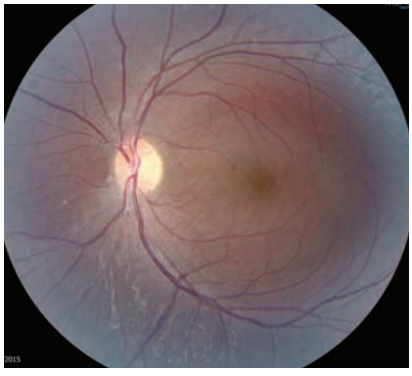
Anterior segment examination yielded normal limits. In addition to an OCT of the retina *(Figures 1a and 1b)*, we obtained fundus images *(Figures 2a and 2b)* that displayed optic nerves that were normal in appearance, but showed the presence of white pigmentary changes of the retinal pigment epithelium (RPE) along the arcades and macular changes (*Figures 3a and 3b*). Intravenous fluorescein angiography (FA) (*Figures 4a and 4b*) were also obtained.





Figs. 1a and 2b. This 19-year-old patient presented with progressive blurring in the right eye and decreased night vision. What can these OCT findings tell you?





Figs. 2a and 2b. Our patient's optic discs appeared normal, but do these fundus images point to the cause of his issue?

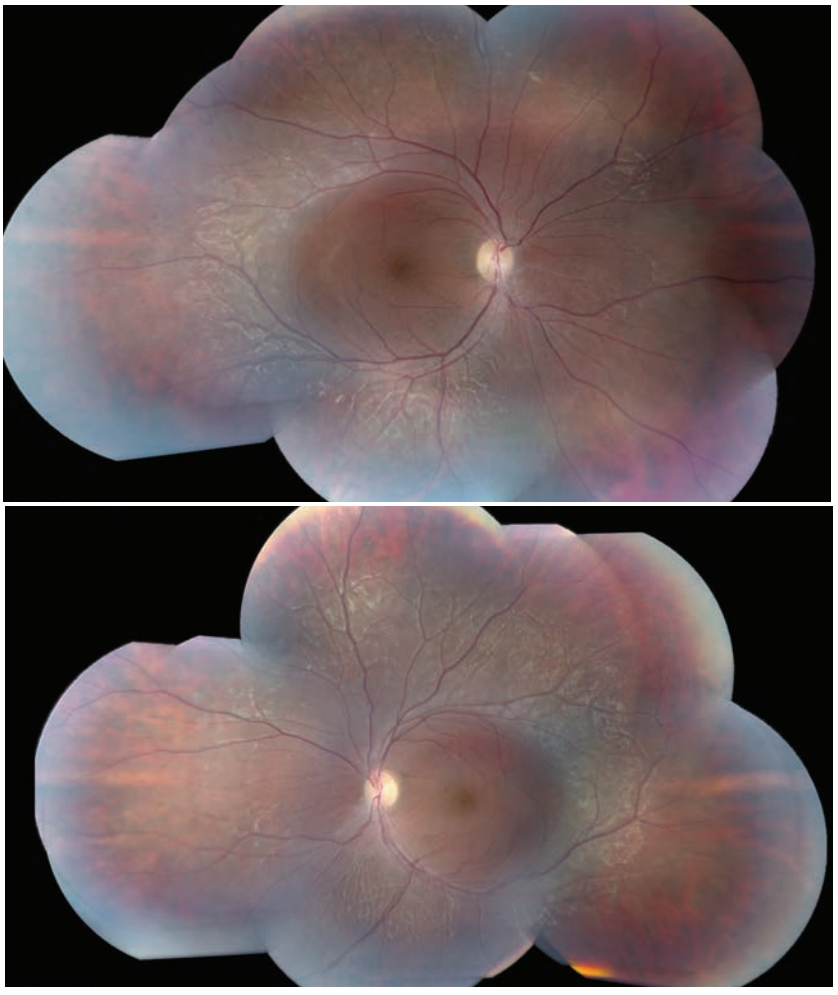
Take the Quiz

1. What does the OCT reveal?
a. Vitreoretinal traction.
b. Retinal thickening with cystoid changes of the inner retina.
c. Retinoschisis of the nerve fiber layer.
d. All of the above.

2. What does the intravenous fluorescein angiography show?
a. Significant leakage of fluorescein in both the eyes.
b. Significant pooling of fluorescein in one of the eyes.
c. Areas of hypofluorescence that correlate with blockage of the retina from blood.
d. No significant leakage.

3. What is the likely diagnosis?
a. Enhanced S-cone syndrome/ Goldmann-Favre Syndrome.
b. Retinitis pigmentosa.
c. North Carolina macular dystrophy.
d. Choroideremia.

4. What additional test would be most helpful to confirm the diagnosis?
a. Fine needle biopsy.
b. Fundus autofluorescence.
c. ERG/genetic testing.



Figs. 3a and 3b. These fundus images of the left (above) and right eyes show white pigmentary changes of the RPE along the arcades as well as macular changes.

d. B-scan ultrasonography.

5. What are some possible treatment options for this patient?
a. Oral or topical carbonic anhydrase inhibitor.
b. Photodynamic therapy.
c. Radiation.
d. Vitrectomy/membrane peel.

Discussion

The OCT of the retina showed profound macular cystoid changes with no leakage on the FA. This supported the conclusion that a non-leaking cystoid macular edema or a macular retinoschisis was present in the patient. In addition, the ERG showed reduced cone response and near absent rod response with increased cone responses under a blue stimulus. In following with symptoms of night blindness, reduced color vision and annular white pigmentary changes of the RPE along the vessels, the patient was suspected to have enhanced S-cone syndrome (ESCS).

Researchers postulate that enhanced S-cone syndrome and Goldmann-Favre syndrome (ESCS/GFS) fall under a spectrum of a single vitreoretinal degeneration.[1] The inheritance pattern is autosomal recessive via a mutation in nuclear receptor gene NR2E3. The NR2E3 mutation encodes for a ligand-dependent transcription factor that is expressed in the photoreceptors and is involved in suppressing the expression of certain genes of rods and cones, and suppressing cone differentiation in early embryogenesis.[1] The resulting mutation then causes an increased number of S-cones at the expense of other photoreceptors, and also may create a weakness in cellular adhesion, according to research speculation.[2] The abundance of S-cones causes the characteristic increased sensitivity to short wavelengths during ERG testing, while the weakness in cellular adhesion is related to the development of cystoid macular changes, researchers believe.[2]

ESCS, along with its characteristic response to short wavelengths, typically shows a profoundly abnormal ERG with an absence of rod-driven response and can lead to severe depression of both the cone and rod response.[3] In cases when the responses are extinguished and suspicion of the diagnosis still remains, genetic testing may provide further insight in supporting the diagnosis. In our patient's case, following the conventional full-field ERG, the patient underwent an additional ERG test known as the S-cone protocol (*Figure 5*). This protocol involves saturating the L- and M- cones, such that only the functions of S-cones are tested. Under certain specific intensities, our patient exhibited a response with an increased amplitude of approximately two to three fold outside the normative values, supporting the evidence of S-cone sensitivity and our initial diagnosis.

The most commonly reported symptoms of ESCS include night blindness and progressive visual

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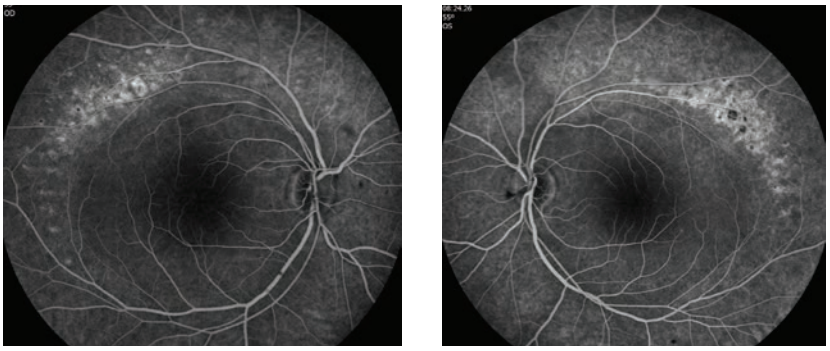

Figs. 4a and 4b. Do our patient's intravenous FA images reveal anything about his likely diagnosis?

acuity loss.[4] Clinical findings of ESCS/GFS are atypical pigmentation degeneration of the RPE in the mid periphery that may be accompanied by dendritic whitish retinal vessels, vitreous humor degeneration such as the appearance of an optically empty vitreous, and the presence of vitreous veils, foveal and peripheral retinoschisis, posterior subcapsular cataract and cystoid macular edema. The distinction between GFS from ESCS is that the former falls on the severe end of the wide disease spectrum.[4]

The use of oral and topical acetazolamide has long been proposed as a possible treatment of macular edema secondary to hereditary retinal dystrophies.[2] The clinical effect of a carbonic anhydrase inhibitor is said to act on the membrane receptors of the RPE, where it may acidify the subretinal space, decrease its volume as well as help stabilize cellular adhesion between the retina and the RPE.[2] However, this theory remains in question, given cases of ineffective outcomes of both topical and oral carbonic anhydrase inhibitors having rather ineffective outcomes.[5] Other proposed treatments that have been investigated in the treatment of macular edema and retinoschisis include grid laser photocoagulation, cyclosporine A and observation.[6-8] A general consensus on primary treatment still remains to be established.

Following the examination, the patient subsequently had genetic testing and had a positive finding for a heterozygous mutation in the NR2E3 gene. In addition, the patient was also started on 500mg of oral acetazolamide daily. At the patient's two-month follow-up visit, the OCT displayed an improvement in the cystoid macular edema in each eye, with improved visual acuities of 20/30 OD and 20/50 OS. ■

Dr. Kim practices at Nova Southeastern University in Ft. Lauderdale, where he is also a faculty instructor.

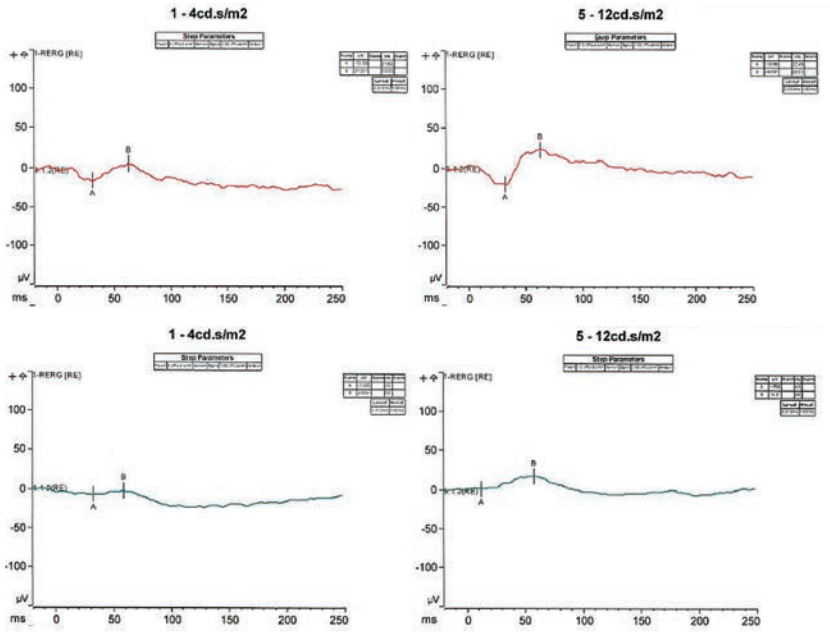

Fig. 5. S-cone protocol testing involves saturating the L and M cones, such that only the functions of S-cones are tested. Under certain specific intensities, our patient exhibited a response with an increased amplitude of approximately two to three fold outside the normative values.

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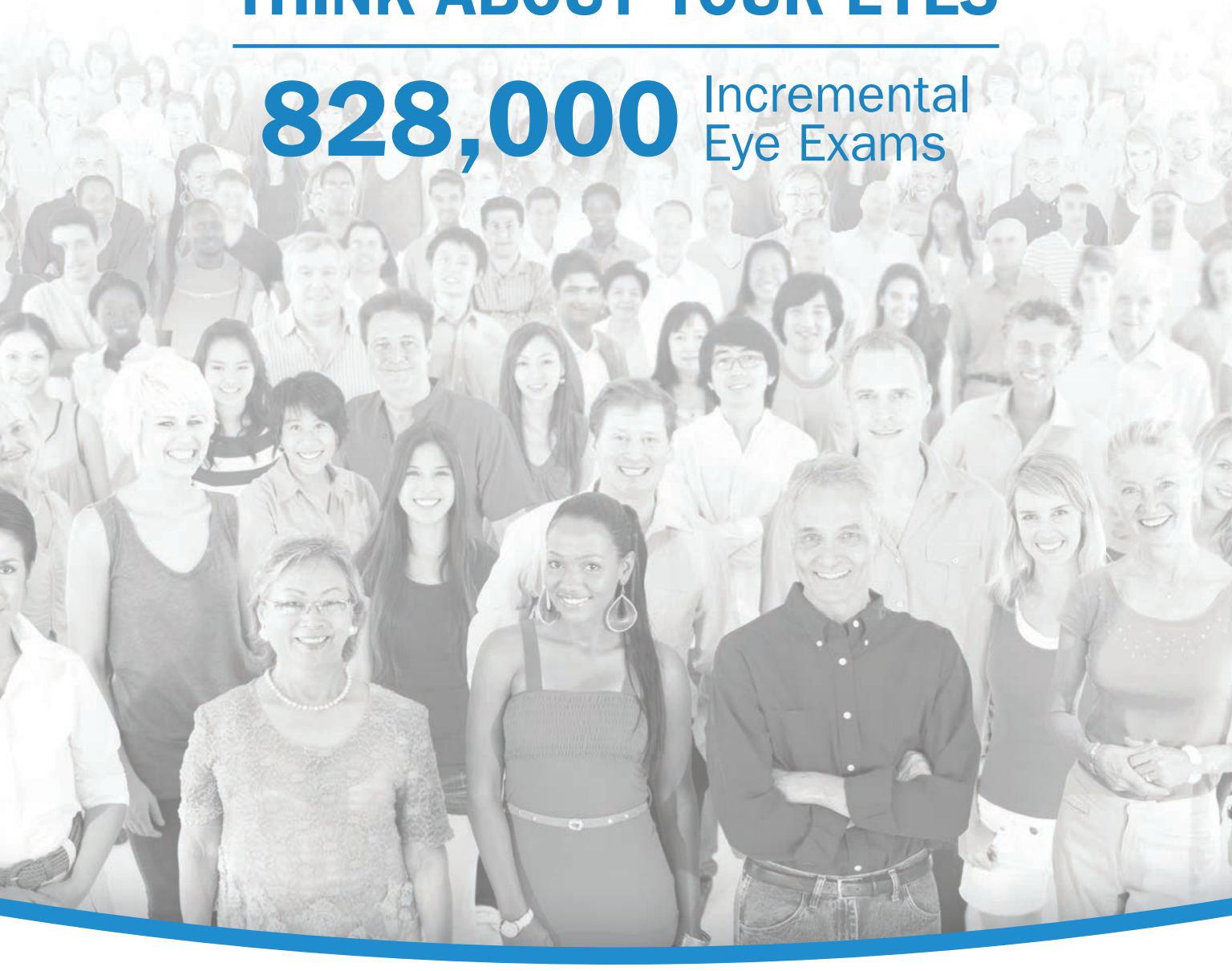

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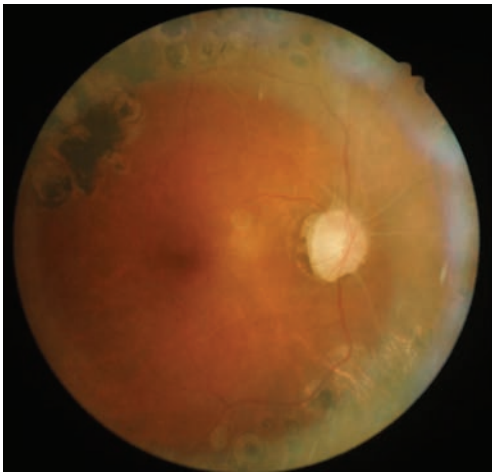
The Over/Under of Glaucoma

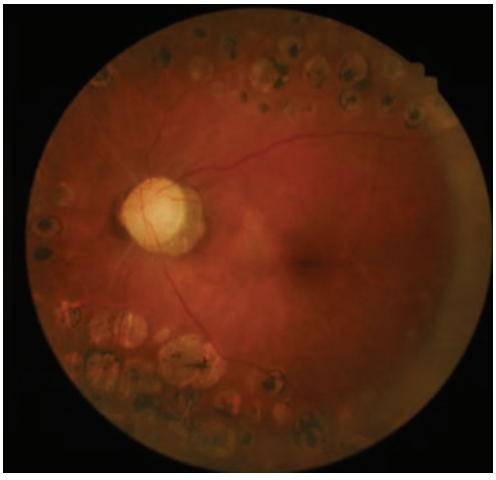
Correctly diagnosing this disease can be a challenge.

By Alan G. Kabat, OD, and Joseph W. Sowka, OD

Glaucoma is insidious in its slow progression and its virtual absence of symptoms in the early stages. We eye care practitioners bear the burden of detecting this disease and intervening before visual function is compromised.

We routinely perform tonometry and fundus examinations on all patients to screen for glaucoma, regardless of the patient's age, ocular or medical history. When patients have elevated intraocular pressure (IOP) or apparent cupping of the optic discs, we aggressively initiate additional evaluation of these "glaucoma suspects." This zeal may seem warranted, given both the disease's progressive nature and the fact that roughly half of those who suffer from glaucoma are reportedly undiagnosed.[1-4] But, glaucoma affects less than 3% of the adult population in the United States, according to epidemiologic studies.[1,2] Further, consider a recent report by Fotis Topouzis, MD, PhD. Speaking at the European Glaucoma Society Congress in Prague regarding a clinical investigation of 2,554 subjects 60 years or older, he said, "Only one-third of the patients who had been previously diagnosed with glaucoma had the diagnosis confirmed in the study. The vast majority were undergoing treatment, and a smaller proportion had had laser or surgery."[5] In other words, many so-called glaucoma patients who had been seen and treated did not have the disease at all when evaluated retrospectively. This raises an intriguing question: are we really underdiagnosing glaucoma? Or, could we actually be overdiagnosing the disease?





Posterior pole images from a 58-year-old black female patient.

Case in Point

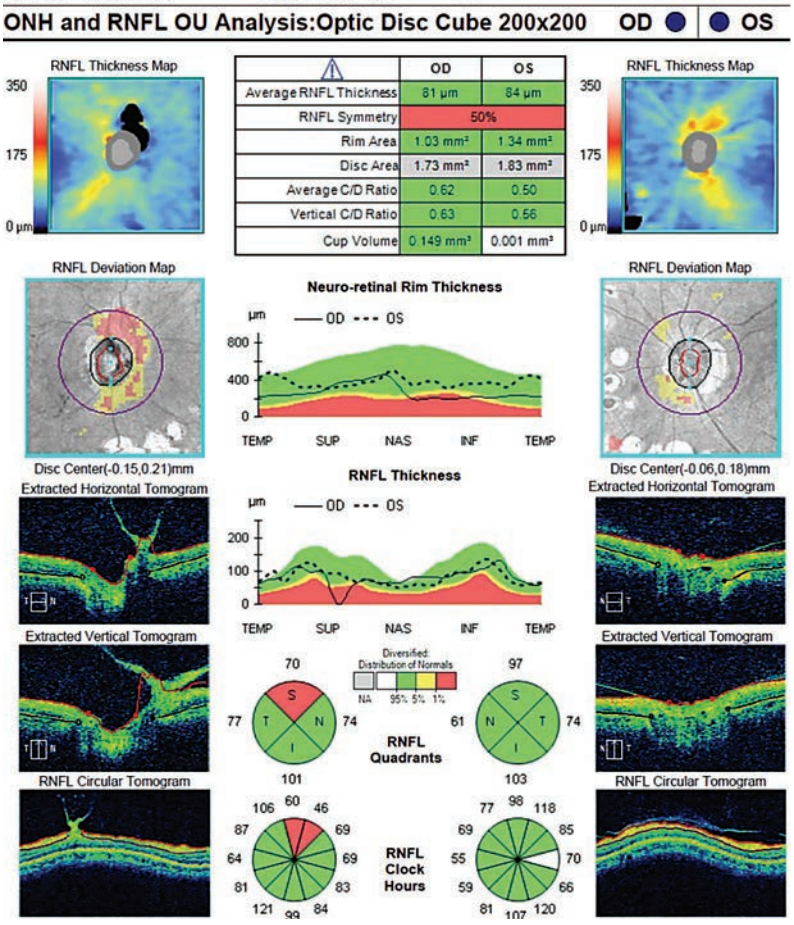
A 58-year-old black woman presented for a comprehensive evaluation upon referral from her primary care physician. Due to her declining health and complex therapeutic regimen (she was taking approximately 20 medications daily), she had been placed in a skilled nursing facility. She reported a five-year history of glaucoma, for which she was currently using two topical medications (travoprost 0.004% QHS and dorzolamide 2%/timolol maleate 0.5% BID OU) as prescribed by another eye care provider. She had undergone successful cataract extraction in both eyes, approximately one year prior.

Her medical history was positive for Type 2 diabetes, diagnosed at age 23, and treated with insulin. The diabetes had led to proliferative retinopathy for which she'd received panretinal photocoagulation (PRP) in both eyes 10 years earlier. She also had end-stage renal disease, for which she was undergoing kidney dialysis three times a week. A variety of other systemic medications and supplements were prescribed for associated conditions, such as hypertension, coronary artery disease, hypercholesterolemia, Parkinson's disease, hyperparathyroidism and constipation.

Upon examination, best corrected acuities were 20/40 OD

and 20/30 OS. Her visual fields were markedly constricted in both eyes. Extraocular motilities were full, and pupils—while sluggish—reacted bilaterally to light, with no afferent pupillary defect. Examination revealed a healthy anterior segment, with clear media and no evidence of iris neovascularization. IOP was 16mm Hg OD and 17mm Hg OS. Funduscopy revealed extensive scarring of the mid-peripheral retina in both eyes from prior PRP, and vascular changes consistent with advanced renal disease.

The optic nerves displayed mild pallor (consistent with PRP) and peripapillary atrophy temporally. Moderate, shallow and symmetrical cupping (C/D=0.55) was observed in both eyes, and there was no evidence of disc hemorrhages or retinal nerve fiber layer (RNFL) defects. Optical coherence tomography (OCT) of the nerves was within normal limits, and aside from a small area of signal loss due to a remnant of fibrotic tissue, the RNFL was intact. Based upon these findings, the patient was instructed to discontinue her glaucoma medications and return in one month for reassessment. At follow-up, IOP was 20mm Hg OD and 21mm Hg OS. Pachymetry measurements revealed central corneal thickness of 530µm OD and 520µm OS. Currently, she is being monitored quarterly, without topical medications.



	OD	OS
Average RNFL Thickness	81 µm	84 µm
RNFL Symmetry	50%	
Rim Area	1.03 mm²	1.34 mm²
Disc Area	1.73 mm²	1.83 mm²
Average C/D Ratio	0.62	0.50
Vertical C/D Ratio	0.63	0.56
Cup Volume	0.149 mm³	0.001 mm³

OCT readings from the same patient.

Where Are We Going Wrong?

There are a number of reasons why practitioners may rush to diagnose glaucoma or incorporate more therapy than is actually required. Unquestionably, the greatest among these is a fear of committing malpractice and subsequently being the target of litigation. Additionally, practitioners may lack the tools and experience necessary to conduct a thorough and accurate assessment of these patients; indeed, some physicians are known to rely solely on tonometry as a basis for their treatment.[3] On the other hand, some practitioners may rely too heavily on newer technology, such as OCT or scanning laser polarimetry.[6] Using the results of these tests to the exclusion of basic diagnostic considerations (e.g., tonometry, gonioscopy, optic nerve head appearance and visual field assessment) often leads to an erroneous conclusion. Finally, some doctors base their treatment recommendations on the premise that certain glaucoma therapies are prophylactic or "protective" in some way. Unfortunately, without clinical evidence that "neuroprotection" in glaucoma is a reality, this management strategy is likely ill-conceived.[7]

The Harm in Overdiagnosis

One certainly could make the argument that it's safer—from a clinical/legal perspective at least—to initiate IOP-lowering therapy for all those who demonstrate glaucomatous risk factors. Certainly, no ethical practitioner would care to see a patient lose vision from a manageable disorder. However, the implications of overdiagnosis and overtreatment are substantial and must also be considered. A major concern is the growing economic burden of glaucoma therapy, which amounts to roughly $5.8 billion

annually.[8] If 50% (or more) of these patients don't actually require medical intervention, the cost savings to our patients and third party payers is substantial.[3,9] Additionally, one must weigh the impact on quality of life in terms of obtaining and using medications. Topical IOP-lowering agents, even those requiring just once or twice daily administration, can be inconvenient to use and complicate the patient's overall drug regimen. Finally, any medical or surgical therapy may predispose toward additional risks and side effects, which must be borne by the patient; if glaucoma is truly not present, then these risks are borne needlessly.

We recommend patience and diligence in making a glaucoma diagnosis or amplifying therapy. Experts agree not all suspects require immediate treatment.[10] As easy as it may be to write an initial prescription for latanoprost or brimonidine, we need always be certain that such therapy is actually in the patient's best interest. Likewise, when a patient is new to the office and offers a history of glaucoma that was treated by another physician, we must maintain a healthy degree of skepticism. Always verify that the diagnosis and that the current treatment strategy is appropriate. Stopping medications for two to four weeks is perfectly acceptable in cases that may seem unusual or questionable.

In the end, remember that glaucoma is not a disease of days and weeks, but rather of months and years. With rare exceptions, we can well afford the extra time it takes to be competent, caring and compassionate providers. ■

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Product Review

Ophthalmic Instruments

SD-OCT

Topcon's new 3D OCT-1 Maestro system is designed to deliver a high resolution, color, non-mydriatic image with the latest SD-OCT technology. The device features a rotating touch panel and fully automated (alignment, focus and capture) operation, the company says.

After the OCT image within the fundus image is indicated, a 12mm x 9mm scan, along with automated segmentation, provides measurement and topographical maps of the optic nerve and macula, according to Topcon.

A compare function, automatic segmentation of RNFL, total retina, GCL + IPL and GCL + IPL + RNFL with an extensive reference database are included, according to the company.

Visit www.topconmedical.com.

Lenses and Finishing

UV Protection Lens

Super Optical now offers a new lens for UV reduction. The BlueShield blue light lenses will be released at Vision Expo West in Las Vegas.

A limited number of lenses in a few bases cover the entire FastGrind range: -9.00 to +8.00 sphere and up to three cylinder.

BlueShield helps block over 95% of AMD- and eyestrain-causing blue light and, on average, over 85% of other blue light, according to the company.

Visit Super Optical at Vision Expo West, Booth #LP11086.

Hard Coating

FastCoater, a new tabletop hard-coating machine, will be available for presale at Vision Expo West.

FastCoater costs less than its closest competitor while still focusing on a quality hard-coat product, according to the manufacturer, Super Optical. An independent lab test of its hardest coat saw the highest rating for adhesion, thickness and coating coverage, according to the company. It is also the smallest on the market, according to Super Optical.

Visit Super Optical at Vision Expo West, booth #LP11086.

Frames Webinar Series

ABB Optical Group is offering a webinar series about educating patients on UV protection and helping optometrists increase premium sunglasses sales.

Presented by Alessandro Baronti of Luxottica, the series is free for ABB Optical Group's Primary Eyecare Network members and $15 per webinar for nonmembers. Each class is from 12:30pm to 1:30pm PDT. The remaining installments of the series are:

- September 14, *Art of Retailing*
- October 12, *The Art of Assortment Planning*
- November 9, *The Patient Handoff*

Visit PrimaryEye.net.

Ocular Nutrition

Supplements

Patients have a new supplement option for ocular health. PreserVision AREDS 2 formula + multivitamin, released in June, is beta carotene-free and contains a high level of vitamin D to support the needs of older adults, according to Bausch + Lomb. The supplement is now available in major retailers, including Walgreens, Rite Aid, Kroger and Amazon.

Visit www.preservision.com.

Contact Lenses

Monthly Lenses

Optometrists can now offer patients Johnson & Johnson's Acuvue Vita monthly replacement contact lenses. The new, non-coated silicone hydrogel lens, launched in June, is designed to help maintain lens hydration, enhance comfort and provide UV protection, according to the company.

The lens material is designed to integrate beneficial lipids while maintaining a low deposition profile and reduced evaporation rates.

Visit www.acuvue.com.

Rebate Program

Bausch + Lomb has updated its contact lens rebate website. It now works on all digital devices and features a scan-and-upload function that allows patients to submit rebate forms online or by mail. Customer service representatives will be available via live chat, e-mail or phone, according to the company.

After receiving an eye exam, the mail-in rebate offer will save patients up to $130 on select Bausch + Lomb contact lenses until December 31, 2016.

Visit www.BauschRebates.com. ■

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Contact owner Dr. William Hoot (817) 925-6918 (wrhoot@att.net) or office manager Joanne Watters at (360) 590-4636, (jkwttrs@comcast.net) or at office phone (360) 533-5800 Monday or Tuesday

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NOTICE: After August 1, 2003, all applicants for ABCMO board certification must have completed an ACOE residency in medical optometry and passed the Advanced Competence in Medical Optometry examination of the NBEO.

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Diagnostic **Quiz**

An Eye for Flare

By Andrew S. Gurwood, OD

History

A 67-year-old black female reported to the office with a chief complaint of painful eyes, more so in the left eye than the right, for the previous week.

She explained she was experiencing pain, redness and photophobia in both of her eyes, but the discomfort in the left eye had become unbearable.

Her systemic history was remarkable for hypetension, which was properly medicated. She denied allergies of any kind.

Diagnostic Data

Her best corrected entering visual acuities were 20/20 OD and 20/20 OS at distance.

We performed an external examination and the results were normal with no evidence of afferent pupil defect. The biomicroscopic examination of the anterior segment of both of her eyes showed no iris neovascularization.

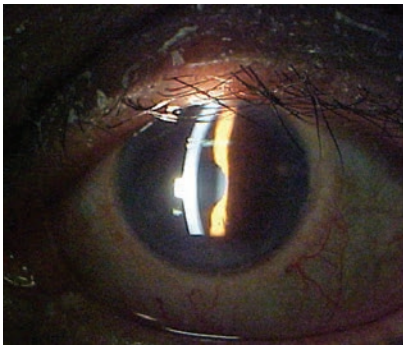

Fig. 1. The anterior segment of our 67-year-old patient's left eye.

The pertinent anterior segment findings include the cell flare in the left eye (*Figure 1*). Goldmann applanation tonometry measured 15mm Hg OU.

The pertinent clinical findings in the posterior segment of the patient's left eye are demonstrated in *Figure 2*.

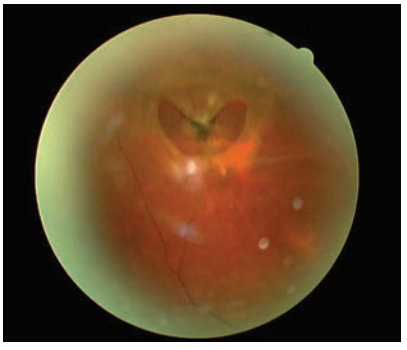

Fig. 2. The posterior segment of the same eye. The patient had experienced pain for approximately one week.

Your Diagnosis

Does this case require any additional tests? How would you manage this patient? What is the likely prognosis? What does this patient's history and clinical findings tell you about her most likely diagnosis?

To find out, please visit www.reviewofoptometry.com. ■

Next Month in the Mag

In October, *Review of Optometry* will present its 22nd annual glaucoma report.

Topics include:

- *Acute Angle-Closure Glaucoma: Are You Ready?*
- *Topical and Oral Medication Use in Postoperative Glaucoma Patients.*
- *Essential Procedures: How to Perform Gonioscopy.*
- *Optometric Study Center: Controversies in Glaucoma Medical Management* (earn 2 CE credits).

Also in this issue:

- *An Atlas of Conjunctival and Scleral Anomalies*
- *Spotlight on Demodex Therapy: Eliminating the Mite-y Menace*

Retina Quiz Answers *(from page 107):* 1) b; 2) d; 3) a; 4) c; 5) a.

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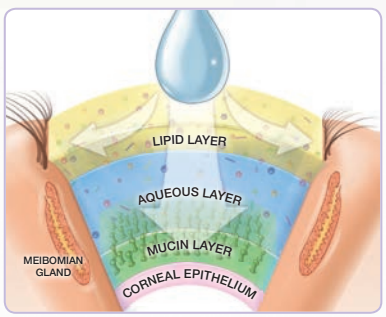

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