

# REVIEW<sup>®</sup> OF OPTOMETRY

November 15, 2015

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## WHAT DO YOU SEE?

NEVUS

MELANOMA

*Our answer, p. 65*

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### Recognize the Signs of Ocular Melanoma

Key features allow you to identify melanomas early and help—even save—your patients.

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**NEW**

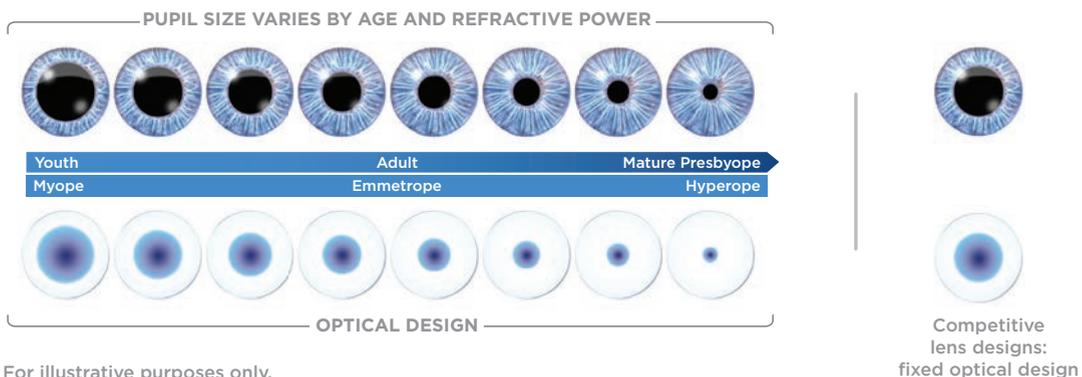
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## IN THE NEWS

Using gene therapy, researchers from the University of Pennsylvania and the University of Florida were able to **preserve sight in dogs** with naturally occurring, late-stage **retinitis pigmentosa**. Overall, they found **gene therapy halted disease-associated cell death** for at least the length of the 2.5-year study. The study, published in *Proceedings of the National Academy of Sciences*, was funded by the National Eye Institute, part of the National Institutes of Health.

Shire has recently completed a Phase III study of **lifitegrast**, OPUS-3, that showed it significantly improved patient-reported symptoms of **dry eye disease** from baseline to day 84, as well as symptom improvement from baseline to days 14 and 42. Shire plans to use these data as part of the resubmission of the New Drug Application (NDA) for lifitegrast in the first quarter of 2016. OPUS-3 is a randomized, double-masked, 12-week Phase III study that enrolled 711 patients to evaluate the efficacy and safety of lifitegrast. Shire continues to plan for a 2016 launch.

A new study, published in the *British Journal of Ophthalmology*, found that patients who reported partial or no improvement in their **dry eye symptoms** also reported higher levels of **systemic and neuropathic ocular pain**. "This study may heighten provider awareness that nervous system sensitization may be contributing to symptoms in patients who do not respond to artificial tears," says **Joanne Shen, MD**, ophthalmology chair and director of the Dry Eye Clinic at the Mayo Clinic.

# Carotenoids Can Reduce Risk of AMD

Consuming more lutein and zeaxanthin could be beneficial for the eyes.

By **Rebecca Hepp, Senior Associate Editor**

**R**esearchers recently discovered that those who consume higher amounts lutein/zeaxanthin—found in red, yellow, orange and dark green fruits and vegetables—have a reduced risk of developing advanced age-related macular degeneration (AMD). Using data from the Nurses' Health Study, conducted from 1984 to 2010, and the Health Professionals Follow-up Study, conducted from 1986 to 2010, they studied a total of 102,046 patients aged 50 and older without AMD, diabetes mellitus, cardiovascular disease or cancer at baseline.

They determined predicted plasma carotenoid scores using repeated food frequency questionnaires. The medical record review revealed 1,361 intermediate and 1,118 advanced AMD cases (primarily neovascular AMD) with a visual acuity of 20/30 or worse.

The results showed a nearly 40% risk reduction for advanced AMD in both women and men when comparing extreme quintiles of predicted plasma lutein/zeaxanthin score. For predicted carotenoid scores such as  $\beta$ -cryptoxanthin,  $\alpha$ -carotene and  $\beta$ -carotene, they found a 25% to 35% lower risk of advanced AMD.

Encouraging the public to eat more fruits and vegetables rich



Photo: Jay Haynie, OD

**Central geographic atrophy seen in a patient with AMD.**

in carotenoids may reduce the incidence of advanced AMD, the researchers concluded in the study.

"Yet the public may not benefit, if retinal health, macular pigment status and nutrition research is not transmitted directly to each patient by their optometrist, so patients know that they are at risk and how to help themselves," says Stuart Richer, OD, PhD, president of the Ocular Nutrition Society. "It is easier to fix the roof before a snow storm, and optometrists are in the unique position to inform patients that they actually have early age-related macular degeneration and/or are low in macular pigment."

Wu J, Cho E, Willett W, et al. Intakes of Lutein, Zeaxanthin, and Other Carotenoids and Age-Related Macular Degeneration During 2 Decades of Prospective Follow-up. *JAMA Ophthalmol*. October 08, 2015. [Epub ahead of print].

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# AI Detects Retinopathy in Diabetics

California HealthCare Foundation (CHCF) used a pattern-recognition learning process—deep learning—to detect diabetic retinopathy (DR), according to an article recently published in the *Economist*. CHCF, in partnership with EyePACS, challenged a community of data scientists to find a way to detect DR in fundus images for a grand prize of \$50,000. Competitors were able to train statistical models of learning to detect signs of retinopathy, even in its more subtle presentations, the article says.

According to Benjamin Graham, PhD, assistant professor at the University of Warwick and winner of the competition, the computer agreed with a doctor's opinion 85% of the time. "Com-

puters could be used to give a second opinion, with differences in diagnosis being flagged for further review, or to highlight areas of interest in images to make it easier for the human grader to process them," Dr. Graham says. "They don't have to be 100% reliable to be useful—human graders certainly are not 100% reliable."

Doctors agree on a diabetic retinopathy diagnosis 84% of the time, Jared Teo of the CHCF says in the article.

Additionally, Dr. Graham's results showed that two computers agreed with each other 93% of the time, higher than the computer-doctor agreement. He suggests two possible explanations for the lack of agreement. "The computers are making systematic errors,

and totally missing information available to the human grader, [...] or the human graders make mistakes, and the computers have learnt to classify the images more accurately than humans. The truth is likely to be a mix of the two."

The possibility of automated screening technologies carries both positives and negatives, according to Steven Ferrucci, OD, chief of optometry at the Sepulveda VA and professor at the Southern California College of Optometry. Nearly 15 years ago, he was involved in a pilot program that evaluated a tele-retinal program designed to remotely review diabetic patients' fundus photos for DR. "It was clear that this system had its plusses, such as allowing care to patients who traditionally would not have access," he says. However, "while we could often assess the retinopathy, it became apparent that this was simply a tool for screening one single aspect of the patient's ocular health, not a full assessment." The same limitation applies to this new technology as well, he says.

A computer program can be taught to look for specific signs of DR, but cannot provide a comprehensive exam, he explains. It may miss things like glaucoma or a peripheral retinal tear, putting the patient at further risk. The program cannot understand the intricacies of patient care either, Dr. Ferrucci says. "Obviously, there are liability issues here that would need to be addressed. Where technology can certainly help take better care of our patients, [...] it must be tempered against its inherent pitfalls."

Photo: EyePACS



Healthy and disease images, such as this fundus image showing diabetic retinopathy, were used to train computers to recognize the condition.



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# Watching Movies Improves Amblyopia

Effective treatments for common children's conditions often fall short of their full potential because they are too tedious for the pediatric cohort. Researchers from McGill University, Southwestern Medical Center and the Retina Foundation of the Southwest may have surmounted this hurdle when it comes to treating amblyopia with contrast-balanced dichoptic therapy.

Their study, published in the *Journal of the American Association for Pediatric Ophthalmology and Strabismus*, found that modifying popular children's movies for dichoptic presentation significantly improved visual acuity. "Children achieved one to four lines of improvement in visual acuity with just six sessions, or nine hours of movie viewing over two weeks," explains Eileen Birch, PhD, co-author.

Eight children between the ages



**Binocular vision brings together the parts of the movie shown separately to the amblyopic and fellow eye.**

of four and 10 viewed dichoptic movies of their choice, out of a selection of 18, three times per week over 14 days. According to the study, an image mask containing a pattern of irregular shapes was multiplied with the movie images seen by the amblyopic eye. An inverse mask was multiplied with the images seen by the non-amblyopic eye. Contrast was reduced enough

to allow binocular vision and then increased by 10% at each visit. Best-corrected visual acuity, random dot stereoacuity and suppression were measured at the onset and after fourteen days.

"This certainly has the potential to change the way we treat amblyopia," says Erin Jenewein, OD, MS, assistant professor at Nova Southeastern University's College of Optometry. "I think the main issue right now is that there is no large randomized controlled trial to show whether or not this method is as good as patching."

The authors hope that controlled studies can confirm their findings and make passive viewing of dichoptic movies a valid therapeutic modality for amblyopia—one that is far more child-friendly.

Li SL, Reynaud A, Hess RF, et al. Dichoptic movie viewing treats childhood amblyopia. *JAAPOS*. 2015 Aug;19(5):401-5.

# Stem Cell Trial Aims to Cure AMD

Last month, a new trial began following the surgical delivery of stem-cell derived retinal pigment epithelial (RPE) cells into the retina of a patient, as part of a collaboration between the London Project to cure blindness, the University College London (UCL) and Pfizer. The trial will evaluate the validity of the procedure as a treatment modality for severe sudden vision loss due to neovascular age-related macular degeneration (AMD). The surgery used a special patch behind the retina to facilitate transplantation of the RPE cells.

Lyndon Da Cruz, PhD, retinal surgeon for the operations and co-leader of the London Project, said

in a UCL press release that there is real potential that people with wet AMD will benefit in the future from transplantation of RPE cells.

The trial will recruit 10 patients in total over a period of 18 months. Each patient will be followed for a year to assess the safety and stability of the cells and whether there is any restoration of vision.

"If successful, this will have huge ramifications," says Jeffrey D. Gerson, OD.

AMD is the leading cause of legal blindness in seniors and there is currently no treatment for geographic atrophy, and this could be a potential treatment for that and also for scarring from wet AMD, he

says. "The visual outcome here will be interesting. Success by vision is different than success by anatomy—patients want to end up with good vision. Only time will tell." ■



Photo: Julie Rodman, OD, MS

**The new trial holds promise for a new treatment modality for wet AMD.**

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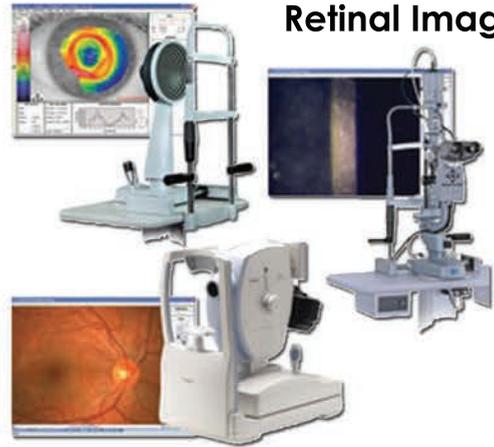
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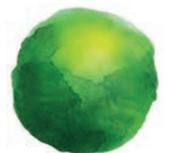


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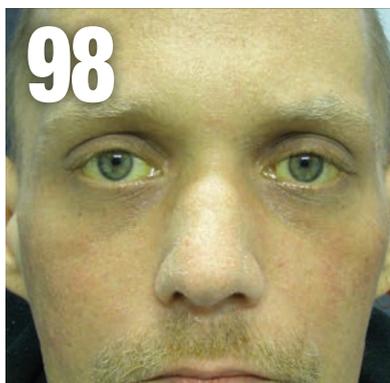
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# A Tale of Two Practices

Optometry can and should take on more. But not at the expense of patient satisfaction. **By Jack Persico, Editor-in-Chief**

**M**y mother and I both needed eye care recently: multifocal contact lenses for me, cataract surgery for her. Thinking about our experiences—mine with my long-time optometrist and hers at an unfamiliar ophthalmology practice—I was struck once again by how different the professions are. It also made me realize that optometrists should be mindful of retaining all that's good about optometry even as they take on more of the care and characteristics of an ophthalmology practice.

In short, I got lots of time, attention and answers. My mom didn't.

With my presbyopia having advanced a bit, I needed a contact lens refit, so I went to the practice I've known for years. They had all my records from prior visits, knew that near vision tasks are a priority in my occupation and were able to update my prescription without much trouble. Free trial lenses and additional contact lens checks were built into the fitting fee. Again and again, they asked me if there was anything else they could do. And my optometrist literally hugged me goodbye when I left.

My mom went in for routine cataract surgery, only to learn she had a macular pucker in one eye, and left with a tricky postoperative prognosis. She's now dealing with aniseikonia that gives her headaches and binocular vision problems; she isn't sure whether her vision can be corrected further or if she just has to "learn to live with it." (She got the distinct impression that the latter was the take-home message.)

She was concerned enough about her surgical outcome that it took a second opinion from a retina specialist at Wills Eye to convince her that the surgery had in fact been done appropriately. While the surgery may not have been subpar, the patient education was. My mom didn't know what to expect, what happened or what comes next.

Obviously, millions of people get exceptional care at ophthalmology practices, and I have no doubt that thousands of patients at that particular practice have as well. But my mom's experience left her frustrated and confused, with a sense that they lacked compassion. Maybe they couldn't have done any better in the surgical suite, but they sure could have chairside and in the dispensary.

## Stay True to Your Roots

This month's focus on building a high-volume practice offers many ideas and insights that can help ODs see more patients. Throughout, our contributors keep returning to the same themes: hire more people, delegate more procedures, charge more money. In other words, be more like ophthalmology.

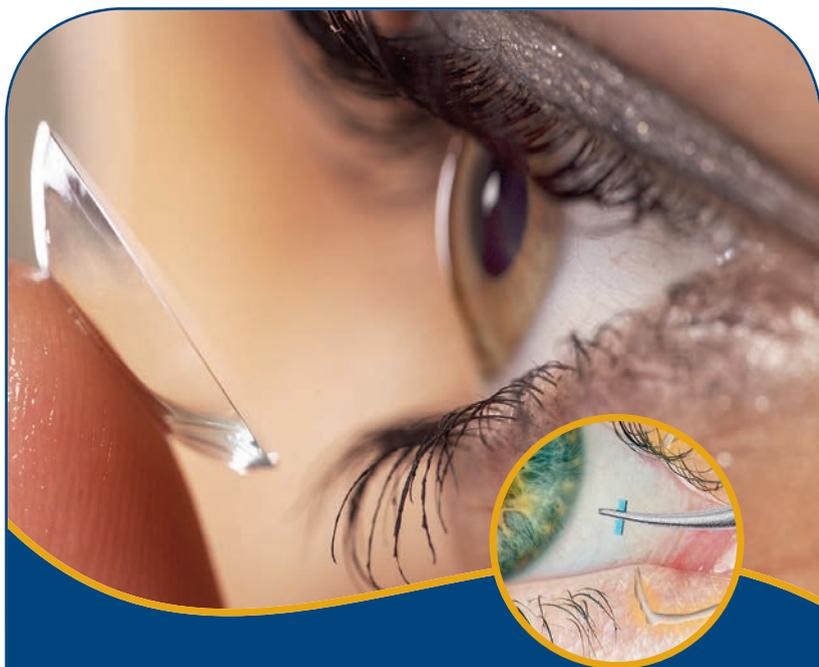
Those are indeed great principles for growth and success. It's where optometry seems inevitably to be headed. There's no other way to meet the future eye care needs of a growing, aging population. Just make sure to keep patient education and satisfaction as paramount as ever. It *is* possible to see more patients without sacrificing what makes optometry unique. ■

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# Are Optometrists Trendy?

Well, trends change, you know, so it's hard to tell. Take a look at where we were and where we are going—I dare ya. **By Montgomery Vickers, OD**

**Y**ou don't see many ODs with LOVE and HATE tattooed on their knuckles these days, although that was very trendy in the '60s and '70s. As the '80s blew by, ODs stuck with trends that mattered: turtleneck dickies and white short-sleeved jackets.

The search for new trends began once someone decided contact lenses shouldn't feel like shards of glass; thus began the era of soft, comfortable lenses—full of bacteria.

But what's trending now, and what about tomorrow? All by myself, I've determined:

## The Top Current and Future Trends in Our Profession

1. Casual Fridays, invented by Happy Hour Thursdays, have evolved into Dress Like a Bum Weekdays. Soon, trendy ODs will make weekends an adventure with Speedo Saturdays.

2. With ophthalmoscopes in hand, optometrists were always breathing on patients, creating the chief complaint, "My eyes are only irritated when you breathe on them." We started eating sugary mints all day, and on the horizon is a trend toward toothless ODs.

3. We used to put engineers in trifocals for better midrange vision. Progressive addition lenses gave them a reason to gripe about their midrange vision again. In the future, we will remind them that engineers have developed every lens design in history, so it's their own fault.

4. Every little town used to have one optometrist, who brought in

some young whippersnapper, who became the one optometrist who brought in another young whippersnapper and, well, you get the trend. In the future, some eyeball testing robot controlled by an evil vision plan monster will need new batteries. Or is that the trend already?

5. Doctors used to refer to the staff as "the girls." We learned that was stupid and chauvinistic and instead referred to them as "the staff." Clever. Now, the girls ARE the doctors and they refer to the staff as "boys, quit texting and finish those recalls!"

6. First came retinoscopy; then came autorefractors, which couldn't tell an astigmat from an ant eater. Soon, laser-guided refractive tracers will produce so much data that once the doctor analyzes 42 pages, the patient will receive the most precise pair of glasses they will ever have remade three times.

7. You used to refer patients to the best ophthalmologist with the crappiest personality. Comanagement became the gold standard, as ophthalmologists realized they knew less about vision than the local shoe repair guy. Soon, they will fight to the death for your refer-

als using flaming punctal plugs.

8. There was an early trend (I'm not lying) that the exam was free and patients only paid for glasses. Thankfully, this has evolved into something very different; after your free exam now, you buy two pairs for less than the price of one!

9. The local optometrist used to see patients at church on Sunday. Then he ran into them at the Rolling Stones concert. Church now sounds like a Rolling Stones concert, we go online to watch it and just delete one another.

10. Optometrists actually used to be in the room turning little dials on devices called phoropters. ODs now delegate this to others, but in the future, patients will decide they want to see through their glasses again. You can prepare for the once-dreaded *Phoropter Finger* by using rotary phones and counting to two.

Gotta be trendy. ■



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# Acute INO: Imaging a Must

When the diagnosis was acute left INO, age of onset made emergent neuroimaging a priority. **By Michael Trottni, OD, and Michael DelGiodice, OD**

An 81-year-old white male presented with acute diplopia, which he noted upon awakening. He reported it as constant, horizontal and worse when looking to the right. Pertinent medical history included hypertension and arrhythmia. Medications included Toprol (Astra Zeneca), Lasix (Sanofi Aventis), potassium and aspirin 81mg. He also had a pacemaker.

Best corrected visual acuities were 20/25 and 20/30 OD,OS. Pupils were round, equal and reactive to light. Intraocular pressures were normal at 15mm Hg in each eye. Extraocular motility testing revealed an adduction deficit in the left eye, with contralateral abducting nystagmus when the patient looked to his right. Anterior and posterior segment exams were unremarkable. There was no

disc edema noted in either eye.

We diagnosed our patient with an acute left internuclear ophthalmoplegia (INO). Given his age and acute onset, the most likely etiology was ischemia. The patient was transported to the emergency room following our recommendation for neuroimaging. MRI was contraindicated because of his pacemaker. A CT was ordered, but failed to show any acute brainstem ischemia. CTA of the head and neck was also ordered, which did not show any significant stenosis.

The patient was admitted under observation for 48 hours and discharged. He returned to our clinic one week later, subsequent to evaluation by his internist and cardiologist, who increased the patient's aspirin to 325mg and started atorvastatin. The patient reported that his diplopia had

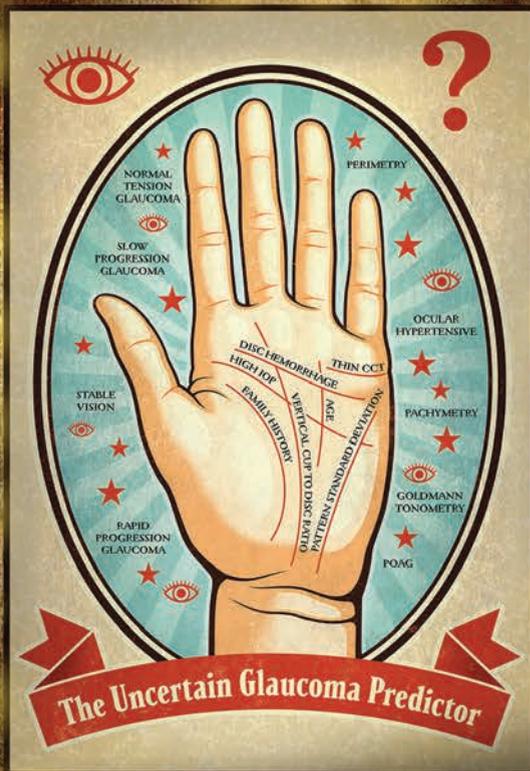
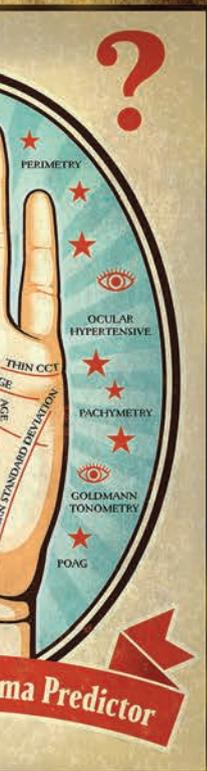
improved significantly. The adduction deficit improved about 80% subsequent to our initial examination. Although our suspicion for myasthenia was low, his normal neuroimaging and failure to show any ischemia or stenosis prompted us to order myasthenia labs just to rule out a masquerading syndrome—results were normal. Our patient followed up one month later with complete resolution of the INO and was doing very well as of his last visit.

## Discussion

Internuclear ophthalmoplegia is a localizing neuro-ophthalmic disorder caused by a disruption of the medial longitudinal fasciculus (MLF). The abducens nucleus contains two groups of neurons: (1) motoneurons that innervate the ipsilateral lateral rectus (LR)



At left and center, this patient showed INO when looking to the right, normal motility when looking to the left. At right, the patient showed an 80% improvement seven days later on follow up.



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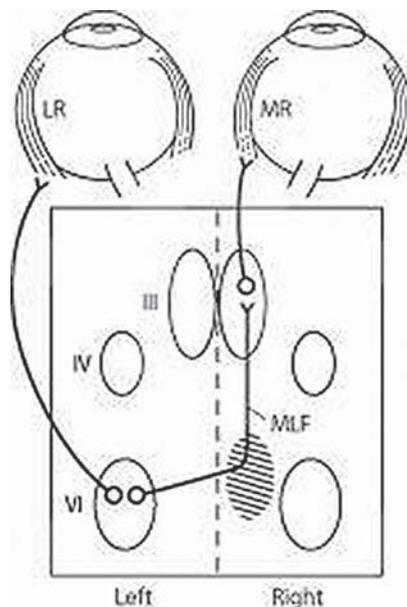
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and (2) internuclear neurons that innervate the contralateral medial rectus (MR) motor neurons via the MLF.<sup>1</sup> Lesions that disrupt the MLF will give rise to an ipsilateral adduction deficit. The deficit can range from a decrease in velocity of adduction to a complete loss. In addition to an ipsilateral adduction deficit, there is often a contralateral abduction nystagmus noted. One explanation for the nystagmus is an adaptive response to overcome the weakness of the medial rectus muscle.<sup>2</sup>

A particular variation of INO termed “one-and-a-half syndrome” occurs when a lesion disrupts the abducens nucleus or the paramedian pontine reticular formation as well as the MLF.<sup>1,3</sup> This results in an ipsilateral gaze palsy and an INO.

Historically, patients with INO will present noting horizontal diplopia. A skew deviation can sometimes be present with INO, so there may be a vertical component as well.<sup>1,3</sup> Convergence is spared in internuclear ophthalmoplegia unless the lesion is also close to the third nerve nucleus.<sup>3</sup> The main causes of INO are demyelination (typically bilateral INO and seen in younger patients) and ischemia (typically unilateral and seen in older individuals).<sup>1,4,5</sup> Less common causes of INO include trauma, tentorial herniation, infection, tumor, hemorrhage and vasculitis.<sup>4</sup>

Given our patient’s age and our expectation of an acute ischemic etiology, emergent neuroimaging was warranted. The preferred imaging modality is MRI unless contraindicated, which was the case for this patient. Although CT imaging was negative, this did not exclude the diagnosis of INO. In one study, 11 patients with INO



**The MLF connects internuclear neurons of the sixth nerve nucleus to the contralateral medial rectus subnucleus.**

underwent MRI, which showed focal or nodular areas of high signal intensity on T2-weighted images in the region of the MLF in 10 of 11 patients.<sup>6</sup> Nine of these 11 patients also underwent CT scan, which failed to show lesions in any patient.<sup>6</sup>

Management of internuclear ophthalmoplegia includes appropriate referrals, depending on the underlying etiology. In cases of ischemic internuclear ophthalmoplegia, patients are typically followed monthly until there is resolution of the palsy. ■

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- Dates, locations, key faculty, number of credit hours available, contact information and registration instructions for each optometric CE meeting scheduled for 2016 (at press time).
- Simple at-a-glance calendars that list every educational event, month by month throughout 2016 for easy reference.
- An online edition will enhance and extend the content with new meetings added throughout the year as details are released.



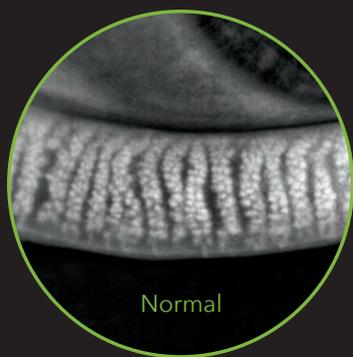
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# Too Many Tears: Is it Dry Eye?

Patients with a number of underlying conditions experience epiphora. How do you diagnose, educate and treat these patients? **By Paul M. Karpecki, OD**

**W**atery eyes, known as epiphora, seems like a misnomer for dry eye disease (DED), which can be very confusing to patients. It's imperative that we first determine the cause of the epiphora so we can properly educate patients and provide them the best treatment options. If it is caused by dry eye disease, or more specifically lipid layer deficiency causing the lacrimal gland to upregulate, then it becomes very important to educate the patient that their eyes are tearing due to a lack or decrease of one of the components of the tear film. If it's not caused by dry eye, the appropriate management or referral must be made.

## Causes

Epiphora is typically a multifactorial issue with many causes.<sup>1</sup> Four general categories include: (1) lid apposition issues, (2) nasolacrimal duct obstruction or stenosis, (3) dry eye disease and (4) a broad category we'll define as something you'd see on a slit lamp examination such as trichiasis or allergic conjunctivitis. A large-scale study showed that epiphora causes included lower lid malposition (33.3%), nasolacrimal/canalicular obstruction (29%), multifactorial (22%), punctal stenosis (11%) and reflex tearing (4.7%).<sup>1</sup> It also showed that women tended to experience epiphora at a younger age than men and the primary cause of their epiphora was punctal stenosis compared with men (34.6% vs. 22.4%); however, more men



**A diagnosis of ectropion, as seen here, may warrant surgical tightening.**

had eyelid malposition than women (39.5% vs. 27.9%).<sup>1</sup> Let's look at all the potential causes.

**Slit Lamp Findings.** The first step is to rule out the non-dry eye causes. During your slit lamp exam look for a turned-in lash (trichiasis) that requires epilation or a foreign body.

One very important cause of excessive tearing is conjunctivochalasis, or folds in the conjunctiva due to a loss of Tenon's.<sup>2</sup> Conjunctivochalasis can often advance to the point of resting on the lower eyelid. If this is present, the patient requires a surgical procedure to tighten the conjunctival tissue via resection or cautery. Most cases of conjunctivochalasis can be monitored, but once it causes a foreign body sensation or persistent epiphora, it should be surgically treated.

**Lower Lid Malposition.** The presence of ectropion or entropion also warrants a referral to an oculoplastic surgeon for repair. Ectropion and entropion are typically diagnosed on presentation; however, pre-clinical or early cases of lid laxity may cause epiphora sooner. You can conduct

two tests to reveal early cases of ectropion or entropion in patients with epiphora. To induce entropion, have a patient forcefully blink or close their eyes and note if the eyelid turns in. To check for lid laxity or early ectropion, pull the lower lid away from the globe and see how quickly it snaps back. If it remains out for an extended period of time, this is a diagnosis of lower lid laxity and may require surgical tightening in cases of persistent epiphora. This seems to be very effective, although ectropion may potentially recur.<sup>3</sup>

**Nasolacrimal Duct Obstruction.** The third category is obstruction of the nasolacrimal duct system preventing tears from draining. In the past, tests such as the Jones test I and II were used to help determine if the nasolacrimal duct (NLD) system was clear or not. Today, you can simply instill sodium fluorescein (NaFl) dye and leave it in place for five to 10 minutes. In a person with an open canal, the dye should drain in that time (five minutes for a non-dry eye disease patient and 10 minutes for a patient with DED because of their slower clearance). After five or 10 minutes the clinician should gently press upward along the lower lacrimal sac; if NaFl dye regurgitates back through the punctum, this is a positive sign of obstruction. The patient should then receive a dilation and irrigation procedure. If that does not open the NLD, refer to an oculoplastic surgeon for dacryocystorhinostomy.

**Evaporative Dry Eye.** Finally, if

all of these tests and findings are negative, your next step is ruling out evaporative dry eye. Effective testing includes osmolarity testing, tear film break-up time, meibomian gland expression, lipid layer interferometry or meibography. If evaporative dry eye is indeed present, have the patient begin a lipid-based tear every two to four hours per day and an anti-inflammatory medication such as a corticosteroid or cyclosporine and see if the tearing subsides.<sup>4</sup>

Explain to the patient that they are deficient in one of the layers of the tear film, known as the oil layer, and the body is trying to compensate for this by over-producing aqueous; by treating the inflammation and supplementing the oil layer, you will soon know if evaporative dry eye is the cause. If true evaporative dry eye is present, it should be treated long-term and should include options to address obstruc-

tion such as commercial warm compresses, manual expression or thermal pulsation treatments, cyclosporine, omega-fatty acids, lid hygiene and tear supplementation.<sup>5</sup> In non-responsive conditions, and although not performed routinely, studies have shown a benefit to injecting the lacrimal gland with botulinum toxin.<sup>6</sup> Although the results are temporary, the patient satisfaction rates are very high.

Although there are other causes of chronic epiphora, these four categories likely account for more than 95% of the potential underlying pathologies.<sup>7</sup> By testing for each one and taking the appropriate management steps, you can help patients find relief from the irritation and frustration of epiphora. ■

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**Conjunctivochalasis, a common cause of excessive tearing, may require surgical tightening of the conjunctival tissue.**

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### **INDICATIONS AND USAGE**

ZYLET<sup>®</sup> (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 conjunctivides 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.

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## 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

## DOSE 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 ( $\geq 10$  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  $\geq 5$  mg/kg/day doses, and cleft palate and umbilical hernia at  $\geq 50$  mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with  $\geq 50$  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  $\geq 5$  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

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# Hit the Books

When a hard-working academic presents with dry eye and a history of LASIK, how do you determine the cause—and how can you help? **Edited by Paul C. Ajamian, OD**

**Q** I have a 22-year-old patient who is now a grad student with a history of LASIK, performed two years prior. She still needs glasses and her eyes are constantly hurting her. She is on frequent tear replacement therapy and Restasis but reports no improvement. How can I help her?

**A** “Graduate students have demanding workloads in terms of reading,” says Justin Kwan, OD, of Southern California College of Optometry. LASIK can disrupt binocular vision and manifest as dry eye symptoms, so investigate the integrity of the binocular vision and accommodation systems before meibomian gland evaluation, he says.

Dominick Opitz, OD, of Illinois College of Optometry (ICO) adds that many patients pursue LASIK due to contact lens (CL) intolerance. “Several studies show a relationship between CL wear MGD, so certainly evaluate the quality and quantity of MG secretions.”

Dr. Opitz’s colleague at ICO, Jennifer Harthan, OD, agrees. “Pay close attention to the lids for signs of active MGD,” Dr. Harthan says. “Also, look for cylindrical dandruff, indicating *Demodex*” involvement in lid disease. Leslie O’Dell, OD, director of the Dry Eye Center of Pennsylvania at Wheatlyn Eye Care, says MG expression helps determine MGD severity. Dr. Opitz adds that “if the patient suffers from aqueous-deficient dry eye pre-LASIK, this is likely to be exacerbated [by the surgery].” Studies suggest patients rarely suffer from only one subtype

of ocular surface disease. Both aqueous-deficient and evaporative dry eye tend to be present.

## Questionnaires—and Answers

“For this patient, start with a dry eye questionnaire,” says Dr. O’Dell. The Standard Patient Evaluation of Eye Dryness (SPEED) survey is great because it is both fast and validated, but the Ocular Surface Disease Index (OSDI) is being used again thanks to free new app, the Dry Eye OSDI Questionnaire, she says.

“Questionnaires will be helpful in quantifying the patient’s symptoms and their response to treatment,” says Dr. Opitz.

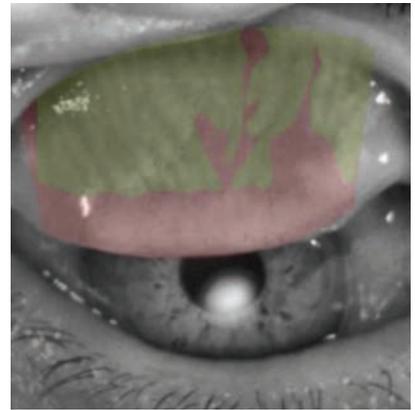
According to Dr. O’Dell, treatment would really depend on the exam. “If there is no inflammation present and the meibomian glands are healthy, consider punctal occlusion in addition to Restasis (Allergan). If inflammation and

## Is it Sjögren’s?

“Patients with aqueous-deficient dry eye with or without MGD should be evaluated for autoimmune disease like Sjögren’s,” notes Dr. Opitz.

Dr. O’Dell points out that the presence of dry mouth helps uncover the potential for systemic involvement. “We recently did a study showing a high correlation between dry eyes and dry mouth in 563 patients,” she says.<sup>1</sup>

Dr. Harthan says to consider blood work for an autoimmune component and perform in-office Sjö testing for Sjögren’s. Studies suggest testing may allow for earlier detection of Sjögren’s, Dr. Opitz says.



**Meibography shows Grade 2 meibomian gland dysfunction.**

MGD are identified, use at-home lid debridement followed by 10 minutes of warm compresses,” she says.

Dr. Opitz recommends adjunctive therapies to reduce inflammation. “Whether the diagnosis is aqueous, evaporative or both, consider using anti-inflammatory medications with Restasis, like omega 3s, Lotemax gel (Bausch + Lomb), as well as oral or topical azithromycin,” he says.

“This patient will likely need eyelid margin debridement scaling, in-office forced expression with the Mastrota paddle and oral azithromycin to kick-start her meibomian glands,” says Dr. Kwan. “Omega-3 supplementation and Retaine MGD ophthalmic emulsion (Ocusoft) may help.”

Dr. O’Dell recommends in-office MG expression. “Of course, if *Demodex* is identified, treatment is crucial to symptom relief.” ■

1. Kwan J, O’Dell L. Hom MM. Relationship between dry eye and dry mouth symptoms. Paper presented at the 94th Annual AAO Meeting, October 6th, 2015; New Orleans, LA.

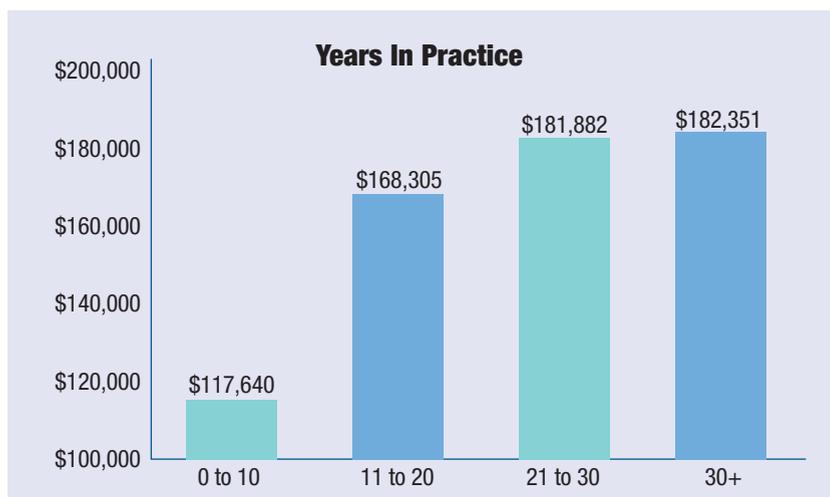
## 2015 INCOME SURVEY: Love What You Do

Optometrists are doing well for themselves, but the paycheck isn't the only thing driving them. **By Rebecca Hepp, Senior Associate Editor**

“I love what I do! The income is secondary,” says Grace Buenaventura, OD, of San Diego, in response to our 2015 Income Survey. And she isn't the only survey respondent to express this sentiment. Beyond the rewarding nature of the work, survey respondents praise the profession for providing an excellent professional/personal life balance and advancement opportunities through its various career paths.

The good news, according to this year's survey results, is that optometrists are also generally well compensated for their dedication to their patients and profession.

Below, take a look at the highlights from this year's Income Survey to see just how the profession is doing—and how you compare. Nearly 900 optometrists responded from across the country, giving us a glimpse into annual salaries, based



on everything from employment status and practice setting to years of practice, gender and region.

### Salary Basics

The average annual income for all survey takers—both full-time (91%) and part-time (9%) prac-

tioners—is \$144,155. Full-time optometrists, both self-employed (51%) and employed (49%), reported an average annual salary of \$150,123, a small 1% increase from last year's results. Part-timers average \$81,937.

Our reported annual wage for

full-time practitioners came in a little high, considering the Bureau of Labor Statistics (BLS) mean wage for 2014 is \$113,010.<sup>1</sup> However, the BLS does not include self-employed optometrists, who often report higher wages. By excluding self-employed survey takers, our average salary drops to \$116,068, just 3% higher than the BLS average salary.

The suggestion that self-employed practitioners can make more money is what often leads young clinicians down the path of practice ownership.

“I have a strong base salary but I realize that, as an employee, growth can only be so much,” says Syed Hussain, OD, who works in Laurel, Md. “I hope to transition to practice ownership in a few years.”

And no wonder, considering self-employed optometrists seem to be

the heavy hitters of the profession, at least in terms of money in the bank. Their annual salary averages \$182,428, according to our survey—36% more than employed doctors. Added to that, many solo practitioners say they have greater flexibility with their schedules and

can work fewer days or hours a week, or make adjustments to accommodate their family needs.

“I’m able to balance work and play by seeing patients Monday, Tuesday and Wednesday only,” says Kay Royal, OD, a solo optometrist in Toccoa, Ga. “What’s not to love?”

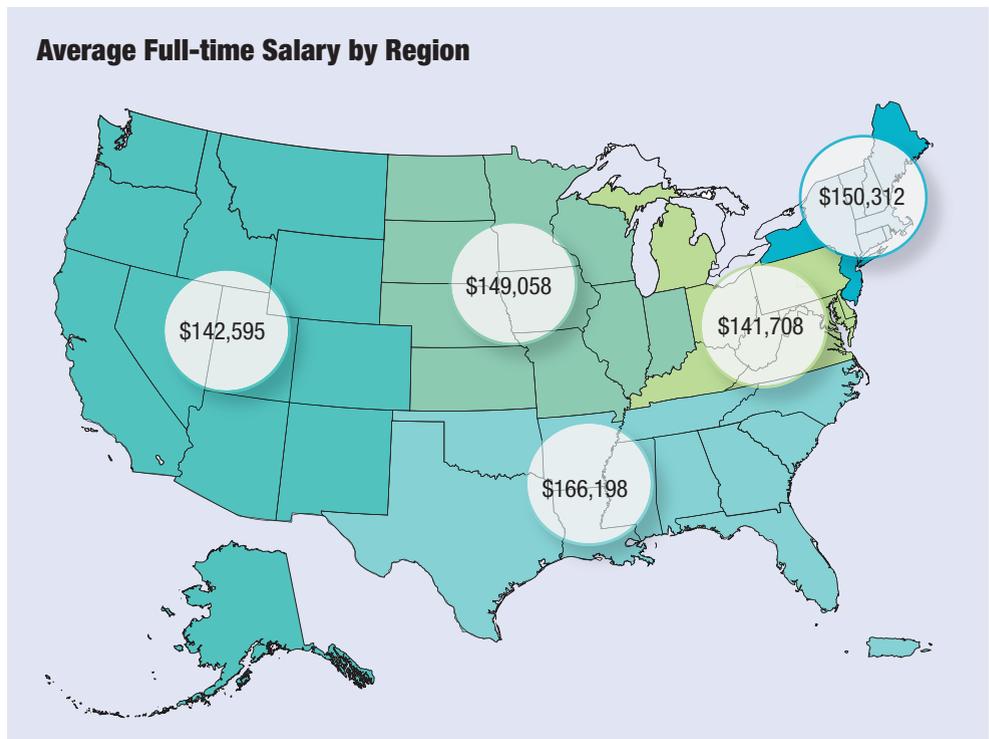
For some, owning their own practices has lent to an easier transition into retirement.

“I reduced my hours at my choice, and my salary has remained steady overall,” says Steven R. Wilkins, OD, a solo practitioner in Virginia Beach, Va. “The private practice is only operating on a four-day work week. After 30+ years of practice, I just decided to slow down for the last five.” And why not? He earned it!

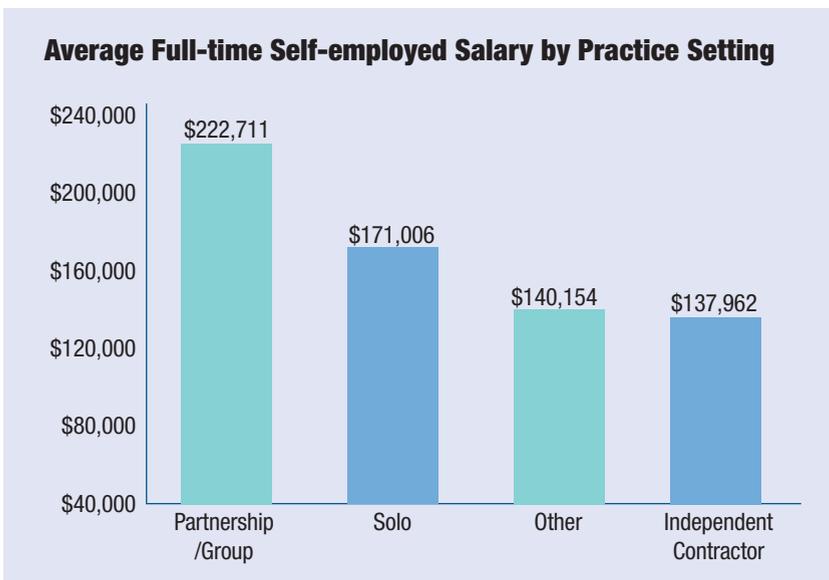
### Where You Work Matters

Whether you own your own practice or not isn’t the end of the story. Your practice setting can have a

### Average Full-time Salary by Region

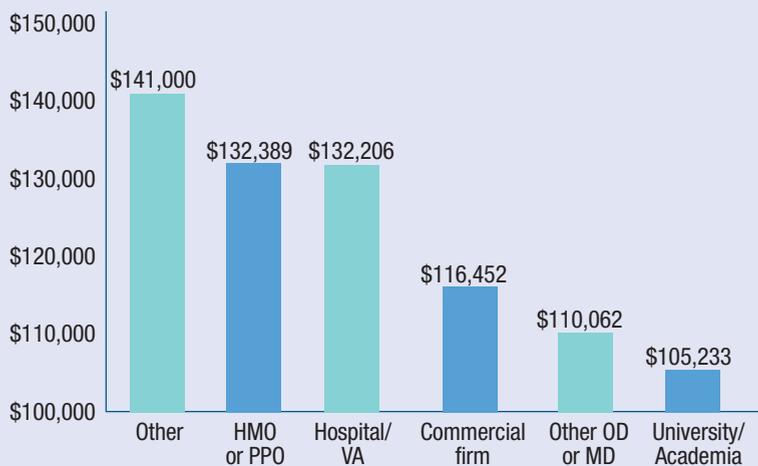


### Average Full-time Self-employed Salary by Practice Setting



# Salary Survey

## Average Full-time Employed Salary by Practice Setting



huge impact on your salary as well. Self-employed optometrists who work within a partnership or group (31% of all self-employed optometrists) reported a 23% higher salary than solo practitioners, and the highest average salary of any

**“Optometry allows me to make a great living and spend time with my family.”**

— Daniel Koenig, OD

group at \$222,711. There was also a 38% pay disparity between these practitioners and independent contractors, who reported the lowest annual average salary within the self-employed category of \$137,962.

For employed doctors, there was a slightly smaller disparity of 21% between the highest and lowest reported salaries—the highest was nearly a tie between those working for an HMO or PPO (who reported an average of \$132,389) and those in the hospital or VA setting (who reported an average of \$132,206), and those in academia reported the lowest at \$105,233.

## Location, Location, Location

In addition to variations in income due to practice setting, the region in which you live affects your take-home, too. Our survey takers provided a relatively fair representation of each region, with 13% in the

Northeast, 16% in the Mid-Atlantic and Lower Great Lakes, 23% in the South, 19% in the Midwest and 29% in the West.

Practitioners in the South reported the highest annual salary of \$166,198, which was 15% more than the salary reported by those practicing in the Mid-Atlantic and Lower Great Lakes region. Those practitioners averaged the lowest salary of \$141,708, followed closely by optometrists in the West, who averaged \$142,595. So it comes as no surprise that a self-employed optometrist from Texas reported the highest single salary of \$900,000.

## Experience Pays

Another statistical no-brainer highlighted by this year’s survey is the financial benefit that comes from years in practice. Salaries rise with experience, and the survey results showed an average increase of 35% between practitioners in the field for 0-10 years vs. those practicing for 30+ years. In fact, the average salary for optometrists practicing for 30 years or more was \$182,351, second only to the salary reported by self-employed optometrists in a partnership or group practice.

## The Gender Gap

Unfortunately, this year’s survey provided a grim reminder that pay disparity still exists between men and women—in fact, it grew significantly from last year. Last year, men working full-time reported an average salary 59% higher than women working full-time; this year, the gap widened to 68%.

But, like last year, the survey’s demographics can, at least in part, explain some of the difference. For instance, only 7% of optometrists in the field for 30 years or more are women—and they still reported an average salary 33% lower than their male counterparts with the same experience level. That same gap was at 46% last year. In addition,

## Average Full-time Salary by Gender





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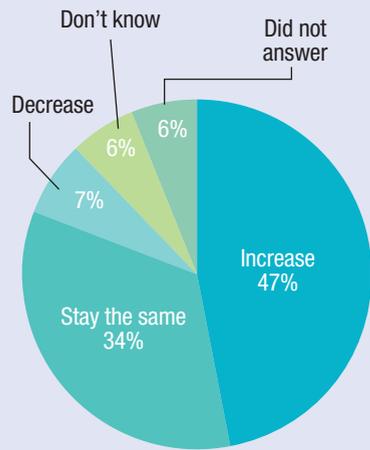
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# Salary Survey

## Next year, what do you expect of your net income or salary?



tion, 45% of survey takers have been in the field 10 years or less, 57% of whom are women. In this demographic, women reported an average salary of \$108,755, 16% lower than men with the same experience. Compensation seems to be evening out, at least somewhat, for the younger generation, considering last year's disparity was 29%.

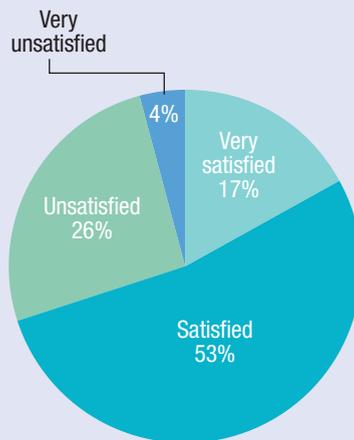
Regardless of the glimmer of hope, the overall gap in pay is still substantial, and in desperate need of a deeper discussion beyond the scope of this reader survey.

## Satisfaction

As a whole, optometrists are happy with their financial situation. Seventy percent said they are satisfied or very satisfied with their salary, and only 4% claimed they are very unsatisfied. For those who are satisfied, optometry seems to provide them the financial backing and flexibility necessary to support their chosen lifestyle. For those who are unsatisfied, student loan debt and lower reimbursements were the two biggest concerns.

But the future looks bright for most. Almost half of respondents

## How satisfied are you with your current income?



expect their income to increase over the next year, and many have a plan to help make that happen.

"My income is strictly based on how many patients I see in an employed setting," says Justin Johnson, OD, of Belvidere, Ill. "I hope to generate word of mouth referrals for exceptional patient care."

**"My income continues to grow about 10% per year, and this allows me to save for retirement and donate 10% to Optometry Giving Sight."**

— Greg Pearl, OD

"Increasing my patient examinations from optical plans to medical eye examinations with ancillary testing results in a considerable increase in revenue per patient," says Brian Kahn, OD, of Atlanta. "Because we can see only so many patients per hour and per day, maximizing the medical model in optometry provides the source of enhanced net income."

"This year, we added a vision therapy optometrist to our practice

and a medical optometrist, who will concentrate on glaucoma and dry eye disease," says Dawn Stratton, OD, of Lexington, Ky. "We have already seen an 18% increase in gross income over a four-month period compared to last year, and our net is keeping up."

Other plans for revenue generation include: better practice marketing with referrals, website redesign; upgrading technology; taking on extra hours; opening a new practice or transitioning into solo practice.

## Giving Back

While the survey asked optometrists to hone in on the financials of their career, some still found a way to remind us of the loftier goals that drive their dedication to patients and the profession. Many optometrists, including A.J. DeVivo, OD, from Ashtabula, Ohio, hope to spend more time volunteering, and not just where they live.

"My daughter and I are planning to go to Haiti in January with

an OD team on a mission trip," he says. "I am not interested in increasing income, I am going to do more volunteer work for the profession."

But, it's still nice to know the profession can financially support practitioners' passion to help others, both at home and abroad. ■

1. Bureau of Labor Statistics. Occupational Employment and Wages, May 2014: 29-1041 Optometrists. [www.bls.gov/oes/current/oes291041.htm](http://www.bls.gov/oes/current/oes291041.htm).

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# POWER UP Your Practice

Thinking about increasing patient volume? Answer these five questions first.

By **Bill Kekevan, Senior Editor**

**O**ptomety is an ever-changing and evolving discipline. Shouldn't it naturally follow that the profession's approach to patient flow changes along with it? Some enterprising doctors see that question as a challenge—one they're eager to rise to.

The American Optometric Association's 2014 Eye Care Workforce study, commonly known as the "manpower study," noted that optometrists, collectively, have excess capacity and can see on average about 20 more patients per week.<sup>1</sup> But figuring out how to begin building a practice's volume may leave some feeling confused. An important first step in undertaking any project is knowing the right questions to ask.

Here, several experts give their take on how to build patient volume, and what questions doctors ought to ask.

## What's the Best Practice Model For Me?

"First of all, you need to define 'high-volume,'" says Jack Shaeffer, OD, president and CEO of the 16-location Shaeffer Eye Center of Alabama. Many people, he says, just use it to mean "a well-run practice that makes money." Define your terms, and your goals, right up front. To him, the most important part is making sure you don't sacrifice patient care in the process.

Dr. Shaeffer's practice is medically focused, but that's not necessarily the right model for everyone. "Some people are going to want a more medically based practice, some are going to want a more refractive-based practice and both models are acceptable," he says. He stresses that if practitioners prefer to focus more on spectacles and contact lenses, that's simply a different level of care.

In fact, there are several models of eye care practice, and it's incumbent upon the OD to select the one most likely to provide a path to success. Various options also exist for practitioners who are not prepared to be full-time business owners. Being your own boss sounds great, but it requires capital investment, risk and managerial know-how. For this reason, employment—by another OD, an MD or a corporate franchise—suits many just fine.

According to Kirk Smick, OD, co-founder of Clayton Eye Center in Morrow, Ga., the different optometric practice models are setting the discipline itself on the trajectory toward becoming two distinct, and equally necessary, professions. "One profession is where you go when you break your glasses on Saturday" and need a quick fix, so "you run to the mall with the

express purpose of getting a refraction and a new pair of glasses.” The other is a medically based practice, which Drs. Smick and Shaeffer use.

Practices focused on vision care and dispensing may deprive themselves of growth opportunities in medical care, Dr. Smick says. And therein lies the future of optometry, as he sees it. “From an economic point of view, reimbursements are going down and so traditional optometry is not nearly as financially rewarding as it was 10 or 20 years ago. But, by incorporating medical procedures, your income can come back because you’re providing a lot more services to the same number of patients.”

### How Can I Be More Efficient?

One need not run a 16-location practice like Shaeffer Eye to embrace the lessons of a high-volume practice. Even small locations with only a handful of personnel can root out inefficiencies. In fact, one of those inefficiencies may involve that personnel.

“You can’t run that kind of practice without high quality staff,” Dr. Shaeffer says. “And you have to have staff training and enhancement programs because the staff has to grow and has to learn.” To keep your staff highly trained is an investment, just like new technology is an investment.

Being efficient doesn’t mean it’s time for doctors or their staff to cut corners, says Dr. Shaeffer. “You have to want to deliver the highest quality of care that you can possibly give and become very efficient at managing that care. You can’t say ‘OK, I’m only going to dilate these patients’—all patients need to be dilated,” he says. “All patients in my estimation should also be offered a visual field screening”

and a comprehensive medical exam if warranted, regardless of the copay or the deductible. “It’s about the disease process and not about what insurance the patient has.

Those are the boundaries you have to set for yourself and your staff.”

The real secret is in delegation. The more you’re able to delegate to staff, the more efficient your practice is going to become. That’s why Dr. Smick’s practice boasts a staff of 85—in addition to seven full-time optometrists and four full-time ophthalmologists.

One step you can take to tighten up efficiency is to ensure your staff members are multi-talented and cross-trained for various responsibilities, says ophthalmic consultant Bryan Rogoff, OD. He says ODs should ensure that everyone in the practice is contributing “to the utmost capacity.”

“Our secret to growth was adding more [insurance] plans and more doctors and staff,” says Dr. Smick. “I have a lot of friends who have a three-week backlog. That’s fine for them, but the patient who calls can’t wait three weeks. So, they call my practice, because we have availability today.”

### What Makes Me Unique?

In a crowded market, optometric practices need differentiating factors that make them stand out. Some may develop expertise in contact lenses, pediatrics or low vision. Others embrace surgical eye care. “A key element, if you want to grow, is being able to offer ophthalmological services,” says Dr. Smick. Many solo optometrists simply have an ophthalmologist come into their practice once every week or two, saving up those patients who need such services. Others refer to nearby MD practices and comanage patients

actively. No matter how care is delivered, offering that wider scope of care means you’re going to attract more patients, according to Dr. Smick.

The fact is, the discipline is changing. With Kentucky, Oklahoma and Idaho all permitting ODs to perform some laser procedures, the privileges are, indeed, expanding. Perhaps due to the increasing need for eye care as the baby boomer population eases into retirement age, or perhaps due in part to the decline in new ophthalmologists (a recent study determined that “there continues to be a gradual erosion of the role of ophthalmic medical education in the standard medical school curriculum”), optometry is slowly but surely expanding its scope of practice.<sup>2</sup> But it’s also partnering with ophthalmology to provide top-quality patient care.

“As we look forward to the next 10 to 15 years, there’s going to be a real shortage of ophthalmologists,” says Dr. Smick, given the projections for increased rates of cataract, AMD and other age-related eye diseases—routine care simply can’t be managed by MDs at their current capacity. “Optometrists who practice the medical model are really going to become busy. They’re going to be seeing a lot more glaucoma patients and doing the bulk of the pre- and postoperative care,” Dr. Smick says. He adds that many of the big surgical practices have optometrists working side by side with them. “That’s how the manpower distribution is going to be able to work out,” he predicts.

Partnering with ophthalmology is nothing new, but it’s something that optometrists may benefit from more than ever in the very near future. Doing so can provide your patients a level of care your com-

petitors cannot. The first step is to set up an old-fashioned face-to-face meeting.

“It’s networking 101,” Dr. Rogoff says. “Set up a lunch. Engage with that person. And, keep up that relationship. Suddenly, MDs will be sending patients your way.”

## **How Can I Best Accommodate Patients?**

If you’re finding yourself with downtime for a significant portion of the day, your problem might not be your schedule so much as it is your patients’ schedules.

Many practices could add a couple of late nights per week, maybe staying open until 7pm, and open a few hours Saturday to wrest back clientele lost to big mega-chains who can afford to be available more often, says Dr. Rogoff. “A lot of middle class people work two jobs” and simply can’t see you during normal business hours. “You can choose to be either proactive or reactive about it,” he says.

Incidentally, Dr. Rogoff adds, when you’re thinking about increasing hours, that might be the right time to also consider bringing a new OD aboard who will be eager to have the work and provide you a well-deserved rest.

To best accommodate them, you have to know your patients, and that means studying the demographics of your area. To previous generations, that might have required a consultation with the local chamber of commerce, but these days such research is often just a click away, says Dr. Rogoff, as analytics are abundant in the digital era.

Those demographics could help you decide which model to practice, or where to practice. For instance, if your community’s demographics skew to the young

and healthy, the medical model might not be appropriate. However, that population may be ripe for dry eye or specialty contact lenses. Studying your demographics can reveal something as simple as whether your area has a large percentage of young athletes whose parents want to invest in sports goggles and safety lenses.

In addition, you should consider your patient base’s access to medical care. “There is still a significant population in the United States that live in rural towns of 10,000 or less,” says Dr. Smick.

That patient base may not have as much selection, but they will have eye disease. “If those doctors are still going to be successful, they’ll have to provide a variety of services.”

## **How Can I Improve Revenue?**

Reimbursement rates are low, and it can be frustrating to know that optometry is reimbursed at a lower rate than ophthalmology for some of the same services. With all the other burdens insurance places on optometrists, it’s enough to make some want to drop insurance altogether and go private-pay only.

Dr. Rogoff advises otherwise. If you drop vision plans, he says, you’re really doing a disservice. “How are you going to be able to gain that market share back if you’re losing 10% or 20% of patients? Even if it’s not an ideal reimbursement, you might have to spend two to three times more on marketing trying to capture that share back,” he says.

In addition, “there’s a sort-of fear factor of managed care,” according to Dr. Schaeffer. On its website, his practice offers to accept a wide variety of plans and promises to assist patients in determining the best use of their insur-

ance benefits.

He adds that the dispensary at a medical-based or integrated health-based practice carries the dual benefit of providing patients with increased care and providing physicians more opportunities to increase revenue. “If you’re going to operate at this level of practice, first of all, you’re going to have to have the product,” Dr. Schaeffer explains. “You shouldn’t put the same contact lenses on every patient.” Rather, be well versed in all options and tailor the care to each individual. “And you have to have staff who understand that just because a person sees 20/20 and says they feel OK, that doesn’t mean [what they’re wearing] is the best product.” Careful attention to detail in on-eye performance will ensure long-term success—and justify fees commensurate with your level of care.

“Now you have an eye exam, you have a contact lens evaluation and you have a contact lens follow up, and that is required in a high level of care practice,” says Dr. Schaeffer. “It’s not optional. It’s required to be comprehensive. That’s the minimum a doctor can do. And you should have fees tied into that.”

Contact lens technology is currently at a point where every patient should be offered multifocal lenses, “but sometimes the multifocal evaluation can take three to four visits to make sure you have the perfect prescription,” according to Dr. Schaeffer. This often deters ODs. Bill for each or bundle them together—but charge for your expertise.

## **Bravery, in a New World**

What Dr. Smick and others are noticing is that the majority of optometrists no longer come

## Coding Connection

By John Rumpakis, OD, MBA, Clinical Coding Editor



# The Busy Practice of the Future

A lot is changing in today's optometry practice. Be sure you are staying up to speed on coding regulations.

The U.S. health care system is undergoing a seismic change, and the traditional model of optometric practice must change in order to survive. It is my opinion that the optometrist of the future (today, really), must be able to see more patients per hour, for less cost and with higher quality outcomes. These are the foundational tenets of health care reform as we move from the traditional fee for service model into a bundled model, or ACO model listed as Alternative Payment Models for Value Based Health Care. Fifteen patients per day could easily shift to 30 patients per day, so how you make this move is critical to your long-term success.

### Delegation

If we think about this from a business prospective, that means the traditional optometrist must learn how to delegate more effectively. For the higher volume at less cost with higher quality model to succeed, doctors must allow trained non-OD personnel to do more. Therein lies the potential issues from a coding perspective.

Many optometrists today do delegate and have found some cost efficiencies in doing so, but how does that affect coding? When delegating, it is important to remember that there are certain rules you have to follow from a medical records and coding perspective in addition to your individual state optometric laws.

The widespread use of electronic medical records (EMRs) has created more uniformity with respect to the patient encounter, as well as a more rigid and exact audit trail that records when someone does anything, so be aware. With respect to the patient encounter, the 920XX codes do not specify by rule who can take the history, perform the refraction, collect data assessing visual function, etc. We do know, however, that the physician must perform the physical examination and is the one who has authority to

create a prescription (but not the only one, in some states).

The 992XX codes, however, have a different set of rules. The evaluation and management guidelines stipulate that, while a staff member can record many aspects of the history, the physician must record the history of present illness (HPI) itself. In a typical clinical situation, the staff member must log out of the EMR, and the physician must log in to properly input the HPI. If you are using a scribe, then the notation must be something along the lines of "HPI performed by Dr. Acme, recorded by Jane Doe, scribe."

### Timing

With respect to special ophthalmic testing, many doctors are ordering and performing tests prior to actually seeing the patient. While this may be appropriate for specific types of tests, such as visual fields and OCT, it would not be appropriate for fundus photography (specifically 92250), anterior segment photography (92285) or special anterior segment photography (92286). These types of images require that the physician examine the patient first and determine the medical necessity for the recording of the image before ordering the image, performing the test and interpreting it accordingly. Keep in mind that your digital camera has a time/date stamp associated with every image captured, same as your EMR, so your electronic bread crumb trail is very clear.

Building the optometric practice of the future requires a completely different mindset—one that embraces delegation to overcome the challenges of the faster, cheaper, higher quality mandate. It also raises concerns of making these changes while also considering the rules that are in place. Doing your due diligence with respect to delegation and the medical record requirements prior to making process changes will only help to ensure your success while mitigating associated risk.

into the discipline to take over their family business. The new crop of optometrists appear more likely than previous generations to embrace employment and, for those who choose that path, plenty of options will be available. However, this generational shift should

not be seen as the beginning of the end of private optometric practice. It takes a good deal of planning, but by evaluating your patient base, the services you're able to offer and your methods of delivering them, you can still find room to let your entrepreneurial spirit and

individualist drive lead you to success. ■

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# Top 10 Staff Management Tips

Improving your offices' productivity can be key to happier patients and a healthier bottom line. **By Gina M. Wesley, OD**

**I**n-office productivity, no matter what type or size of practice you have, is the basic tenet of practice success. An office that produces efficiently fosters a practice that can continue to grow and offer patients the best care and technology. Here are 10 management tips that helped grow my practice from zero to seven figures in just seven years:



**Being prepared for each patient before they sit in the exam chair can improve patient satisfaction—and your office's productivity.**

## 1. Be Prepared for Your Patients

If you want to have successful patient interactions and the financial benefits that come with them, you and your staff must prepare. I set aside time before each patient day to go through my patient charts and write notes to myself

and staff prior to that appointment. I delegate to my staff, via scheduling notes, all different types of preparation for that particular patient. For instance, was one of the patient's family members in for an appointment recently? If so, we can acknowledge we remember that bit of information, making

the initial greeting more personal. This can set the tone for the exam. (Make sure you have permission to share this information first. In my office, my HIPAA signature line states that the patient gives us permission to share necessary information with immediate family.) I delegate what testing I want done on the patient, including the mydriatic agents I need, photos, dry eye testing, inquiries into contact lens wear and habits, etc.

It's specific to that patient. Perhaps I noticed we were supposed to see this patient back for glaucoma testing, but the patient failed to schedule or show. I include notes for the staff to inquire about this. What if the patient has an active treatment plan for dry eye? I ask staff to



**It's more efficient for staff to spend 30 seconds scheduling next year's appointment at check out rather than five minutes one week later doing the same thing, but having to look up all the data again.**

attend to that patient's routine to elicit why they may or may not be having success with that treatment regimen, even before I see them.

The same applies to optical recommendations. Is the patient's chief complaint regarding poor near vision, yet they failed to comply with purchasing PAL's last year? Delegate a technician to begin the discussion about this during pretesting. Or, perhaps you remember (or recorded) that last year they said they would most likely get new sunglasses this year. I will definitely note for my front desk staff to assist the patient in looking prior to the exam starting.

In knowing our patients, we show that we understand them and their vision needs. When we attend to our patients in the most specific and efficient way possible by being prepared, we see a surge in per patient revenues. We make every hour with our patients count, which can be a very productive strategy.<sup>1</sup>

## 2. Analyze Goals

Perhaps your first thought is,

“What goals?!” You should set goals for your practice, be they small or large, and track and analyze your practice's efforts to reach those goals on a regular basis.

After setting those goals, don't be afraid to adjust them and find out why you are, or are not, reaching your goals. As an example, perhaps you have been tracking the results of your recent attempt to sell more contact lenses. You are surpassing your goal of selling annual supplies by three or four more each week. Adjust the goal to reflect your current strategy success, and aim for the next level. Because you and your staff are more effective than anticipated, you can adjust accordingly and discuss the methods that have led you to surpass your expectations. Conversely, if you are reaching lower numbers than expected after a few weeks or months of analysis, adjust the goal and meet with staff to find out why the goal wasn't met. There may be a legitimate reason (fewer contact lens wearers in the last few weeks than average) that helps you realistically understand and amend

your initial target.

We often get caught up in the day-to-day needs of patient care and practice administration. If we can spend some time actually analyzing what's going on, we make our patient time that much more productive.<sup>2</sup>

## 3. Manage the Schedule

Managing your patient schedule effectively is an often overlooked and underestimated component of successful practice management.<sup>3</sup> Each patient who walks in the door is worth a certain dollar value every year (per patient average revenue).<sup>4</sup> A pre-appointing system (preferably electronic) is important for maintaining a more regular interval between eye exams than relying on recall postcards, emails or phone calls to get a patient to the office. If you rely on patients scheduling themselves once you remind them they are due, they often come to your office every 18 months rather than every 12. With this method, they have a little more than three exams in a five-year time frame, instead of the expected five. That can lead to a loss of thousands of dollars for your practice over the course of time.

Another advantage of pre-appointing is that my staff found it's far less time consuming to confirm or reschedule a pre-appointed patient than to have that patient schedule on their own. Patient-reliant scheduling results in more recall notices and calls, draining valuable staff time.

It takes my staff about 30 seconds to one minute to pre-appoint a patient at checkout for the same approximate day and time next year with our EMR system. The time spent by staff going back into the record to pre-appoint that patient a week or more later is

# Practice Productivity

about five minutes, once notes are reviewed and we prepare the scheduling information appropriately (*tip #1*). For just a week's worth of patients missed in the pre-appointing process, the difference is about one staff hour of work vs. five hours. This adds up to thousands of dollars in inefficient use of staff time over the course of the year.

Of course, nothing will eliminate unpredictable events such as cancellations and last-minute no-shows. You can minimize the financial hit from these by using a waiting list of patients who want to see you ASAP. Maybe they already have an appointment scheduled, but would like to be notified if they can come in sooner. Or perhaps they want a prime time spot that's booked weeks out in advance, and can come in at the last minute if a spot opens up. Doctor time is the most expensive staff time to have idle. Using this type of schedule management system and waiting list, I very rarely have an open spot in my schedule.

## 4. Streamline CL Fitting, Follow-Up and Ordering

One of the most productive ways to ensure your contact lens patients order their lenses through you and schedule regular exams is by putting a streamlined process in place.<sup>5</sup>

When a contact lens patient is in the office for their annual exam, we have pricing already prepared by staff, outlining the annual supply cost of the current brand of lenses they are wearing. If they are not changing lens modality or brand, the staff member offers the information to the patient at checkout with the assumption that they will purchase a year's supply.

If, during the exam, you end up refitting the patient into a new brand, checkout pricing will now include the previous brand as well as the new brand. We include this information on a sheet of paper the patient can take home and scan it into that patient's documents for reference. Staff will schedule a follow-up email/text/phone call or contact lens check visit with that patient in a week or two to finalize the new Rx and order. By implementing these steps, we are giving patients all the data they need, yet not losing them to follow-up. This

causes less delay with ordering contact lenses, and doesn't postpone next year's appointment due to surplus supply.

## 5. Train Staff

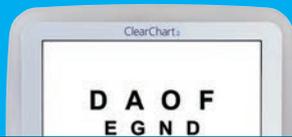
Efficiencies don't remain effective simply because they are in place. You must train and re-train on particular tasks, and often. It's not enough to train someone once on a particular office task. If left to their own devices, most staff often begin to interpret their own version of how best to complete that task. While this may not be a bad thing in principle, the idea is consistency in the patient experience, and if one staff member differs greatly from another in how they perform a certain task—checking a patient in and out, for example—it can create confusion at best, and poor customer service at worst. Added to the possible patient-related issues are the financial implications that can ensue. If one staff member's checkout process, as an example, results in a delay of payment or missed fees, this is financially detrimental to the practice. To avoid this, delegate a lead trainer in each area, review the processes and desired office workflow with them and make sure these policies are reviewed several times per year with appropriate staff.

## 6. Create a Procedural Manual

Have you ever had a staff member go on vacation or leave your practice altogether and panicked, realizing they were the only one who knew how to do something? If this has happened, you are in definite need of a procedural, or How-To, manual. This will outline how staff members should complete every single task in your office, no matter how mundane. At the very least,



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it saves you from having to figure something out on your own. Most importantly, though, it helps other staff members remember what to do in the absence of a key staff member, or if that staff member is preoccupied with patient concerns. Having a procedural manual allows your office to run smoothly regardless of the day's staffing schedule, thus promoting the highest levels of productivity and efficiency.

## 7. Hold Regular Staff Meetings

Scheduling regular staff meetings is vital to ensuring staff is on the same page, policies are reviewed in a timely manner, office messages are delivered and training is carried through. We focus on a "why" question in my office at every meeting, which creates our core office culture.<sup>6</sup> I present one or two real or likely-to-occur scenarios, and we as a team discuss how we can meet our "why" in that particular situation. This is our first agenda item for each meeting, before we move on to the business items, training, policies, etc. that are also integral to our meetings. We sometimes have vendors in the office to train on new products and technology. My office meeting usually takes two hours every Monday morning. We have a never-ending list of topics to discuss and it's become critical to help integrate necessary changes while maintaining our office dynamics and workflow. I often let staff run the meeting, as they have excellent insight in the day-to-day needs of office life.<sup>7</sup>

## 8. Manage Patient Time in Office

Research has analyzed patient time spent in office and it's correlation to sales in all areas, not

just optical.<sup>8</sup> It seems there are varying opinions, but the ideal time falls somewhere between 45 and 60 minutes. Anything longer than that, and sales generally seem to decline. After spending a few months analyzing my office's patient flow, we noted a few things:

**Entrance activities.** This portion of the visit has a *huge* time variable. Established patients can move through this more quickly, but even a small change such as sharing new insurance benefits can alter that. Additionally, new patients who have not bothered to follow our advice in filling out forms before they arrive add anywhere from five to 15 minutes to their pre-appointment time. What we've done to countermand some of these slow-downs is to ensure we are not repeating questions among staff. For instance, asking patients the reason for their visit both at the front desk and during pretesting makes patients repeat what could be a lengthy explanation. Additionally, we've incorporated tablets for signing documents as well as protocol for pulling new patients back sooner into pre-tests if they are struggling to fill out forms.

**Testing and exam.** This time will vary most among doctors depending on your delegation preferences and your style of exam, but opportunities certainly exist for efficiencies. Something as simple as having the technician pull all pictures and networked tests forward so they are ready for you to show the patient can save one to two minutes per patient because you aren't fumbling. If you see 20 to 30 patients per day, this can add up significantly. We are continually looking in this area for greater proficiency.

**Doctor hand-off/optical.** Our observations in this area focused

on the dilation of patients' eyes. Such an integral portion of the exam is critical for my practice's standard of care, yet can really hinder a sale in optical due to blurry vision—which often leads to slower decisions or no end sale at all. We've attempted to improve this area's efficiency by encouraging browsing before the exam, or offering the use of daily disposable contact lenses when browsing. (We do not do a full fitting, and the lenses are placed on eye by staff and removed by staff).

Paying attention to each step has pared down average entrance to optical time to around 40 minutes for most of our patients, which is our goal.

## 9. Share Information with Staff and Patients

You may be the primary information delivery vehicle in the office, but that doesn't mean you can't delegate pre-approved information sharing to your staff. Use educational clips within the office and your website, and give your staff the freedom to access and share them with patients.

Today's technology allows you to easily create your own clips to post on your website, showcase in the office or both. Tell the history of your practice, or feature what's new in the practice. Doing so will help patients feel they are an active part of the success of your practice, which can foster patient loyalty. A low-tech option would be to organize informational binders for the reception area. I find our patients looking through our binders more than I ever thought they would. It's a great way to focus on the services and products your practice offers, and you can even offer promotions within the binders for those who are savvy researchers.

## 10. Mix Up The Merchandise

Have your displays of optical goods, contact lenses and other ophthalmic products looked the same for years? Or for even just one year? Successful merchandisers realize the need to reorganize, re-display and mix it up to keep products looking fresh and new. You can improve your office productivity by implementing some great merchandising tactics. If you can help sell something simply by how it's displayed or presented, that display becomes the most effective "employee" in the office.

That "employee" needs to be tended to, and diversification is important. Like you sometimes, patients will often look at a typical "wall of frames" and just feel "blah." Great merchandisers diversify their displays to showcase layers, textures and highlight various products. Essentially, they want to

spark some interest. Often, you can learn from your own favorite stores how to effectively merchandise. Pay attention to what grabs your attention. Make it interesting, and your patients will respond. And then change it up.

As with any new practice management strategies, not only you, but also your staff, have to be onboard with these new ideas. I would suggest rolling out ideas at an office meeting, and know you need to be honest about what's expected for all involved when you implement any change.<sup>8</sup> Time spent improving productivity is perhaps the hardest first step to take, but is well worth the outcome. ■

*Dr. Wesley is an active member of the American Optometric Association and a fellow of the American Academy of Optometry. She was awarded the 2013 Early Pro-*

*fessional Achievement Award from The Ohio State University College of Optometry and was Minnesota's 2011 Young Optometrist of the Year. Her Vision Source practice serves primary care, contact lens and pediatric patients.*

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# ARE YOU READY TO Take On an ASSOCIATE?

From what to pay to reasons why you should—or shouldn't—hire, consider the following when you're debating whether to add a new doctor to your practice.

By Jane Cole, Contributing Editor

**A**t the age of 55, Eric White, OD, knew it was time to come up with an eventual exit strategy. Dr. White has been practicing solo for the past 25 years, and although he didn't have immediate retirement plans, he realized it was finally time to hire another doctor.

The recent addition of Dr. White's new associate, Michael Morgan, OD, a former patient Dr. White recruited while the junior doctor was still in optometry school, has given Dr. White the chance to travel and lecture without worrying about coverage.

"I've been solo for my whole career, and I realized it's important to have somebody to cover for me. Also, because of my age, I'm getting to the point where I want to start thinking about slowing down," he says. The decision clicked when Dr.

White found an excellent potential associate he could groom to possibly take over the practice when he's finally ready to retire.

Whether you're nearing retirement or looking to see more patients with an already full schedule, there's much to consider before taking the plunge and hiring an associate.

## What's Your Motivation?

Practice management consultant Gary Gerber, OD, from the Power Practice, says the number one motivation a doctor should have in mind when considering taking on an additional doctor is quality of life. Doctors should take into account how hard they want to work, how many hours they want to work and how much they want to be compensated for their work, he says.

"There's a lot of bad advice out there that dictates you should only

bring on another doctor if your practice is grossing X amount of dollars," he says. Six years ago, Dr. Gerber offers as an example, a prospective client with two young children reached out to him to help with her practice, which was only open 2.5 days a week. The doctor wanted the practice to be more profitable and didn't want to continue to turn away patients, but she wasn't willing to work more days.

"The first thing we did was get her an associate," Dr. Gerber says. "Here's a little, tiny part-time practice [that needed help], yet most formulas say you need to make \$800,000 a year before you should hire someone. She wasn't even close to that; yet in this case, it was the right decision to hire someone."

Brian Chou, OD, whose practice brought on a new doctor over a year ago to allow for growth, suggests

doctors consider hiring an associate if their schedules are consistently booked beyond a week and there is no further capacity to increase exam volume even with better staff delegation, use of technology or office design changes. “While it’s a good problem to have, patients that can’t get in on a timely basis will go elsewhere, which results in lost potential revenue,” Dr. Chou says.

Another key reason to bring on a new doctor is the potential of additional revenue related to expanding hours or new services, Dr. Chou says. For instance, you could hire someone to work on Saturdays and Sundays, or someone with residency training in specialty areas such as glaucoma, low vision or vision therapy, he says.

This scenario has paid off for Dr. White, whose practice expanded hours and is now open an additional day once a month. However, the biggest asset Dr. White’s new associate has brought into the office is “young blood,” he says. “His generation is coming to see him. Additionally, Dr. Morgan has brought more expertise on the medical aspects that I lack; but in turn, I’m teaching him doctor-driven contact lens dispensing.”

Most doctors focus on the practice income and patient load, but another doctor may bring in a different patient population and give you more time to manage the practice, says Peter Shaw-McMinn, OD, who has served as the chairman of the AOA Practice Management Committee and the Association of Practice Management Educators. “A young doctor tends to attract younger patients. A doctor who specializes in VT, low vision, sports vision or glaucoma may bring in patients you would not normally see,” he says.

One caveat to consider is whether or not hiring additional staff would



**Dr. White, of Complete Family Vision Care in San Diego, with his new associate, Michael Morgan, OD.**

suffice, Dr. Gerber says. “Most doctors hire associates too soon. What they should probably do is hire more staff before they hire another doctor. They usually pull the associate trigger too early.” In some cases, hiring and training staff to take on some of the duties you are not delegating could be the best solution.

“If everything is aligned and it’s a quality of life decision, and the doctor says, ‘My staff is great, but I really think I need somebody else,’ then it is indeed time to hire another doctor, as long as you understand the reasons why you are making this decision,” Dr. Gerber says.

### How Much Should You Pay?

The employed optometrist is typically the highest staffing expense. Therefore, owner-doctors must carefully perform their financial due diligence to make sure all the numbers work, Dr. Chou says. To compensate the new doctor, it’s best to talk with several other OD employers in the community to find the going rate. “In projecting how much revenue will be brought in, keep in mind that the new associate is not expected to produce as well as the established

doctor, and that there is also variability from associate to associate,” he adds.

Dr. Shaw-McMinn recommends paying the doctor based on productivity, so the more they bring in, the more they get paid. “Twenty-five percent of gross income is a good start, but that will apply to private pay. For vision plans, it will need to be a higher percentage of professional fees and a variable percentage for add-ons, depending upon the plan,” he says.

The adage, “You get what you pay for,” is true in this case, Dr. Gerber says. “You want someone who is a rock star who is going to represent the practice and go out in the community and market. They’ve got to be pretty amazing people, so pay them more than they can get elsewhere. Find the going rate and pay a little bit more. This way, you can be more selective,” he says.

### Do You Need to Offer Equity?

Equity may be appropriate for the business-minded OD to incentivize growth, but perhaps not for the OD who’s happy just being a worker-bee and takes no interest in additional responsibilities, Dr. Chou says.

“There’s no reason to give equity to the OD unless you want a partner to assist in managing the practice,” Dr. Shaw-McMinn says. “If you are capable of managing the practice, hire independent contractors to see patients or an employee-doctor.”

For Dr. Gerber, equity should be considered on a case-by-case basis. “The equity gets back to the initial reason you’re hiring a doctor. If you’re hiring a doctor because you want some kind of exit plan in place, then equity probably makes sense. If you’re hiring because you just want to work less, remember there are many doctors who have no aspirations of being a partner,” he says.

Dr. White looks at his new associate as his future and has already discussed Dr. Morgan taking over the practice one day. “We sat down and came up with a five-year plan. I don’t expect him to buy in right away because it’s a marriage. You have to make sure you’re compatible. We are extremely compatible, but I also know he’s in debt up to his eyeballs from school. So right now, I want him to work with me

for maybe five more years and then decide if it’s right for him to buy into the practice. But, my thoughts are now that he is going to be my exit strategy, so when I’m ready to retire, by that time, he will have already bought into the practice.”

## Do You Need to Expand the Practice?

Hiring a new OD will likely mean your practice can accommodate an

influx of new patients. With this in mind, meeting added patient volume also requires additional staff, Dr. Chou says. The rule-of-thumb is that approximately four hours of staff time is required for each hour of optometrist time, he adds.

“Bottlenecks in the office need to be identified, and this can be offset by staggering doctor hours or building out a new exam lane and pre-exam space,” he says.

### More Than a Handshake: Get it Down in Writing

You’ve made the decision to bring on an associate, and your new OD has accepted the job. Congratulations, but you haven’t completed the hiring process yet, experts say.

Finalizing the employment agreement is the final step, which should be reviewed in most cases by a lawyer, they add.

“Definitely don’t cut and paste an agreement from Google; get a real lawyer who knows your state laws to do this for you. There’s a lot of risk if you do it the wrong way,” Dr. Gerber says.

Besides the general information on salary, start date, hours and vacation, you may want to consider the following for your employment agreement when taking on a new associate:

**Non-Compete Clause:** Depending on state laws, a non-compete, non-solicitation clause should be included with “reasonable” terms, Dr. Gerber says. “It’s not reasonable to say, ‘If you leave here, you can’t practice within a hundred miles for a hundred years.’” The contract won’t be enforceable if you’re not reasonable, he says.

Still, the practice owner needs protection if and when the associate leaves, so the contract should spell out that the associate will not be entitled to patient records, they will not be allowed to contact patients, and they will not be allowed to set up a practice within a reasonable distance or there will be a penalty, says Pamela Miller, OD, JD, DPNAP. Remember to check with your legal counsel as to the appropriate terminology that should be used in your state. Depending on the terminology, the “penalty” may or may not be valid or reasonable, she adds.

**Spell Out Specifics:** The more information you include in the contract, the better. Particulars such as who’s paying for things like CE, insurance and state association dues, as well as the amount of vacation time, should all be included, Dr. Gerber says.

**Tailor to the Individual:** Dr. Miller suggests custom-fitting the contract to the specific employee. “Determine if they are going to be full-time, part-time or fill-in, because there are differences,” she says. If someone is hired on a fill-in basis for a day or two a month, a written contract is not that critical. In these cases, if you prefer to have a contract in place, you can create a working one by going back to e-mail correspondence and including the basics of

what was agreed upon and discussed, she says.

**Future Ownership:** Another key component that should be included is whether the new employee is going to buy the practice or work their way from associate to partner or purchaser. “There are different intents. Some employees will never reach that status, so it would be a different contract,” Dr. Miller says. Depending on the expectations, spell these out in the contract.

Even if the new associate is not planning currently to buy the practice but is full-time and there is a remote possibility they would take over the practice, language should be included in the employment agreement that the first right of purchase would go to the associate, Dr. Miller says. “If you are bringing in an associate, make sure there is some form of safety protection there, and they have first right of the practice. It will help ease both your mind and that of your associate,” she adds.

If the new associate will eventually become a potential owner or partner, you may want to include a life insurance clause, Dr. Miller says. Under these special circumstances, in the event the senior partner dies, the new doctor will have money to buy the practice.

**Potential of Damages:** If you hire, for example, a fill-in doctor and the person doesn’t show up, it may cost you. Staff still needs to be paid and patients will need to be rescheduled. In this case, a damage clause in the contract would cover the senior OD, Dr. Miller says. “The senior doctor can pursue legal action, but it’s really up to the doctor, and the matter would probably be settled in small claims court if the practice owner decided to pursue the matter.”

**Transparency:** The senior doctor needs to be aware of the new associate’s level of licensure, professional liability coverage, whether the doctor has been censured or if their credentials have ever been pulled by a third party, Dr. Miller says. “You also want to know if they were ever accused of Medicare, Medicaid or insurance fraud,” she adds.

The doctor should check with their state board of optometry and with their own legal counsel when it comes to these issues, as they can differ significantly from state to state, Dr. Miller says.



**EyeLux in San Diego recently added a new associate. Pictured from the left is Jacquelin Le, OD; Kelvin Nguyen, OD; new associate Kimberly Michel, OD; and Brian Chou, OD.**

Adding hours may be the easiest solution. “If you’re not open Saturdays, experiment and be open, for example, on Saturdays or Thursday nights,” Dr. Gerber says.

If you practice in a commuter market, also consider adding earlier hours in the morning, he suggests. Dr. Gerber has clients whose practices open at 6am because they are located in commuter towns. If the senior doctor doesn’t want to get to work before the sun rises, ask the newly hired junior doctor to work from 6am until noon on Tuesdays and Thursdays, for example, Dr. Gerber says.

### Can You Keep the New Doctor Busy?

Even when the new associate isn’t seeing patients, you can still keep their schedules productive. Dr. Gerber suggests the owner-doctor build time into the new hire’s schedule for practice building and education. Suggest they work three days a week, but see patients for only two-and-a-half days. “You’ll pay them for three full days, but on that other

half day, you tell them they are going to be working on developing the practice.”

For a new associate with a specialty in sports vision, this could include talking to teachers, putting together a program for high school athletes, or managing the practice’s social media presence.

“They need dedicated time to start building the practice from the first day they start working. It’s a great way to make them busier faster,” Dr. Gerber says.

### Are You Ready to Share?

Being a solo practitioner for 25 years, one of the biggest challenges for Dr. White was sharing his long-time patients. Even though Dr. White had known his new associate since Dr. Morgan was three years old, letting Dr. Morgan see his patients wasn’t necessarily easy at first. “I’d look at his schedule and say, ‘Oh, he’s seeing that patient.’ But it’s okay now,” Dr. White says.

Sometimes the transition is made easier by greeting long-time patients in the exam or waiting room and

letting them know they are going to have an exemplary experience with the new doctor. This worked for Dr. White when a long-time patient came to see his associate instead of him, since she didn’t want to wait until Dr. White had availability in his schedule. “I went out, gave her a hug, and let her know she’d love Dr. Morgan and she was in good hands. She said she wouldn’t be here if she thought otherwise,” he says.

“Many practice management experts will give you a number to use when your practice can handle another doctor, but I think everyone should have a second doctor in their practice,” Dr. Shaw-McMinn concludes. “There are times you won’t be able to be there, and you can be covered in case of emergency or illness or vacation. Even if you don’t have a full schedule, it’s worth having another doctor there one day a week. While the doctor is seeing patients, you have time to manage the practice and train staff properly. The biggest hurdle is finding someone you are comfortable with.” ■

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# THE COLORFUL WORLD OF OPTOMETRY COME TO LIFE

Optometrists show off bold new office designs that integrate form with function. **By Rebecca Hepp, Senior Associate Editor**

When you envision your dream office, what do you see? More space and light? The latest OCT machine in its very own testing area? A ruthlessly organized contact lens fitting room? Optometrists from across the country shared their dream offices come to life for *Review of Optometry's* 2015 Office Design Contest, and the winners prove that *different* is often a very good thing.

All of our contestants showed dedication to both their patients' needs and aesthetic appeal, but three practices stood out for their creativity and functionality, according to our expert judging team.

Color took center stage in this year's contest. The winner and both runners up incorporated bolder color palettes to add a little spice to the daily routine. But aesthetics wasn't the only factor that set these contestants

apart for our judges. Entries were also judged based on function, ergonomics and incorporation of optometric equipment, and the winners came through with much-needed upgrades, staff-friendly workspaces and patient-centered layouts.

See how three practices blended the latest technology with unique office designs to provide both their patients and staff with the ultimate optometry experience.

## MEET THE JUDGES



Craig Miller, OD, owner of Eye Columbus, in Columbus, Ohio  
2013 Office Design Winner



Teri Hung, OD, and Michael Hung, OD,  
owners of Eye Elements in Dunwoody, Ga.  
2013 Office Design Winner



Sharokh Kapadia, OD, owner of St. John's Eye Associates in Ponte Vedra, Fla.  
2013 Office Design Winner



# Winner

**Specs Downtown, Florence, Ala.**  
**Barry Basden, OD, owner**



Dr. Basden had no idea what he was getting into when he decided to renovate his 7,400sq. ft. office space in Florence, Ala. Once a dry goods store, tailor shop, bank and then an attorney's office, the building's original brick walls were hidden beneath layers of older material—including horsehair plaster. But stripping everything down to find the original character of the building paid off for Dr. Basden.



“This is a very creative and artistic space; every room has so many different design interests,” said contest judges Teri and Michael Hung, both ODs. “By retaining the historic nature of the building with the use of traditional brick and wood flooring/framework, the owners were able to maintain warmth in a very art deco space.”

Patients enter into a cozy and inviting waiting area with original hard-



wood floors and teal walls that contrast nicely with the practice's red logo and exposed brick. After grabbing a cup of coffee or a quick break in the massage chair, patients are enticed to enter a relaxing and colorful optical space. Designer frames are displayed along with moose, deer, antelope and other animal head replicas, creating a fun and eclectic shopping experience. The staff calls it the Trophy Room.

"The choice of materials and colors provides a funky retail environment, which is perfect for a designer eyewear retail environment," said contest judge Craig Miller, OD. "There is nothing sterile about this practice."

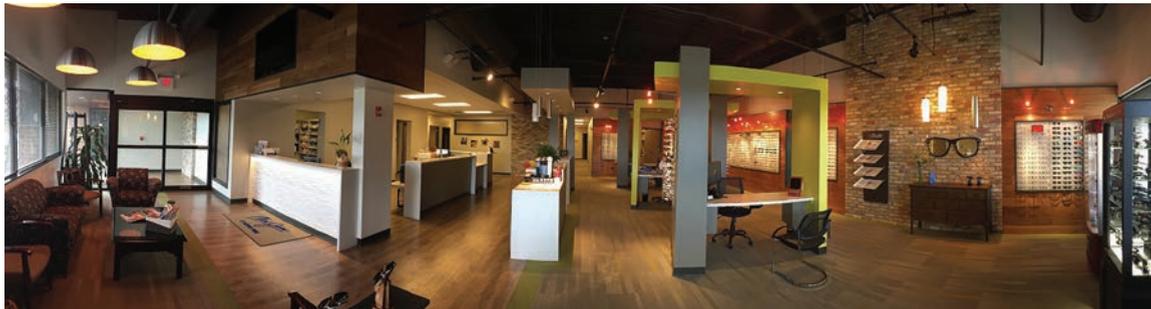
It's not all fun and games in Dr. Basden's practice, however. Each of his exam rooms is equipped with state-of-the-art equipment, including electronic visual acuity panels and a slit lamp camera. He did, of course, add a little character to his exam rooms—patients won't soon forget the experience if they were seen in the plane, hipster or block exam rooms.

"They brought the fun back into optometry!" was the first thing that came to mind when I saw the photos of this practice," said contest judge Sharokh Kapadia, OD. "Their attention to detail is second to no other practice I have seen, from the unique and eclectic exam rooms, to the cool 'trophy room' and the functional loft meeting area."



# 1st Runner Up

Midwest Eye, Downers Grove, Ill.  
Todd A. Robert, OD, owner



Exposed brick is once again the centerpiece for the first runner up, Midwest Eye. Dr. Robert incorporated a bold lime green and orange color scheme with an open loft design, giving patients a uniquely modern experience.

“The fun colors, varying textures, modern lighting, brick wall and lofty ceiling all bring attractive visual interest into this smart office design,” said Drs. Teri and Michael Hung.

“I like the non-traditional use of materials and color that make this environment one that stands out,” Dr. Miller added.

But the judges were raving about more than just the colors. The optical kiosks spread throughout the front office provide an unusual solution for the need for patient privacy in such an open space. “I like the clean, open-concept feel to this practice,” said Dr. Kapadia. “Purchasing eye wear in a private kiosk type of setting is a real distinguishing plus that their patients must appreciate.”

“Though the office has an open concept, there are zones within the design that give patients privacy and separation of office tasks,” said Drs. Teri and Michael Hung. “The smart kiosks in the optical allow for more private discussion, and the patient intake area is private but still open and accessible to the rest of the practice.”

The entire office is wheelchair accessible, and the front desk is readily identifiable and offers multiple counter heights for staff and patient comfort. Dr. Robert and his design team took into





**Dr. Robert chose to remove the drop ceiling, giving the office a “loft” feel.**

account the technology needs of the younger generation as well and incorporated a data bar to give patients and representatives much-needed space to stay connected.

“Having a data bar to recharge phones and computers can be very accommodating to patients in today’s modern mobile world,” said Drs. Teri and Michael Hung.

Added to these front office perks is a well-organized back office with updated diagnostic tools.

“We purchased a new OCT and added it to a separate imaging room, allowing for a private intake area,” said Pam Peters, practice manager. “The pretest area was set up with instruments and patient flow in mind, with additional room to grow. The larger contact lens room allows for more trials with easier access. All of our equipment is where we need it!”

Above and beyond the patient-friendly design and high-tech testing, patients are struck by their optometrists’ dedication to the profession. Photos of their mission trips line the hallways, adding aesthetic appeal and a powerful conversation starter.





## 2nd Runner Up

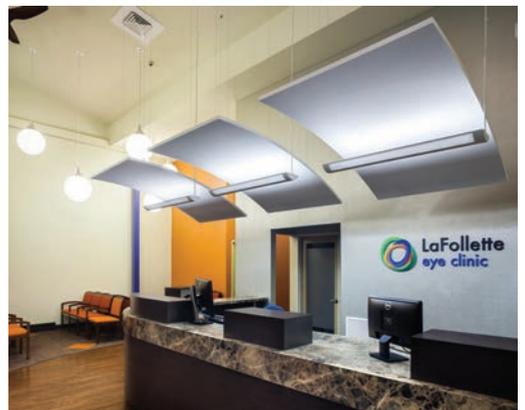
LaFollette Eye Clinic and The Eyewear Gallery, LaFollette, Tenn.  
Andrew Howard, OD, and Elizabeth Howard, OD, owners

**D**rs. Andrew and Elizabeth Howard made their dream office a reality when they opened a new office in LaFollette, Tenn. The theme, “A Celebration of Vision,” helped turn the 10,000 square foot building into an efficient, patient-friendly and aesthetically stunning optometric practice.

“It’s a comfortable, beautiful and happy place,” said Dr. Andrew Howard. “It’s a joy to offer this space to our staff and community.”

The exterior’s picture windows provide patients a preview of the interior and the lighting that changes color seasonally. The color scheme is incorporated throughout the space and does more than provide a clean, modern look.

“The color palette of bright blues, oranges and greens adds life throughout the space, while still representing the logo colors of the



practice,” said Drs. Teri and Michael Hung.

The colors, incorporated into the flooring, were designed to subtly define spaces as well, according to Dr. Andrew Howard. They help patients navigate the office loop from the lobby, through testing and exams to the eye wear gallery without backtracking.

And with 16 exam rooms, patient flow was bound to pose a problem. But a unique layout consisting of four pods with four rooms each ensures staff efficiency and patient comfort.

While Drs. Andrew and Elizabeth Howard wanted the office to be a work of art, they also wanted to create the ultimate patient experience. The seven new testing rooms allow space for workups, visual fields, preferential hyperacuity testing, VEP/ERG and topography. Two retinal imaging devices are strategically located in the middle of all pods, as retinal imaging is their most common diagnostic test. All of this means



patients flow effortlessly through their appointment—and staff don’t waste steps either.

“This practice has a lot of presence—great curbside appeal with the inside having an open, bright and airy feel to it,” said Dr. Kapadia. “The owners have put a lot of thought into maximizing efficiencies and improving the patient’s experience from the use of 16 exam rooms organized into four separate pods and circular patient flow to the spacious and inviting optical.” ■



# Nutrition and Glaucoma:

## EXPLORING THE LINK

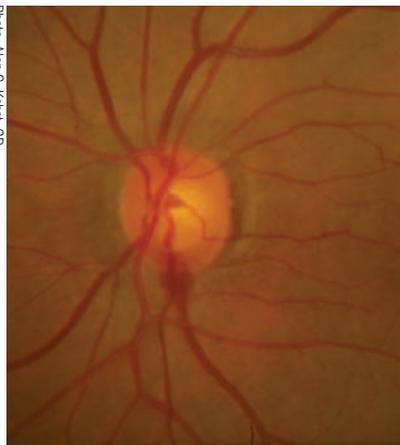


Numerous studies reveal that nutrition can play a big role in glaucoma development and management. **By Kimberly Reed, OD**

**B**ack in the 1980s, a “glaucoma workup” typically consisted of perimetry testing, gonioscopy, detailed hand drawings of the optic nerve and multiple IOP measurements. Our understanding of glaucoma has evolved significantly over the intervening years and, thanks to advances in technology, we can now achieve a much finer-grained assessment of ocular structures. Currently, the standard of care for glaucoma evaluation includes pachymetry, nerve fiber layer and optic nerve analysis, as well as evaluation of blood pressure. That list may soon expand to include other assessments, including a nutritional analysis and possibly even genetic testing.

Here, we explore the relationship

Photo: Alan G. Kalat, OD



**Nutritional substances may serve as adjuvant therapies for patients with glaucoma to help minimize hemorrhaging at the optic disc.**

between nutrition and glaucoma and its possible impact on your patients and your practice.

### Intraocular Pressure

Evidence that elevated IOP increases the chance of glaucomatous optic nerve damage is plentiful.<sup>1-4</sup> For example, the Early Manifest Glaucoma Trial (EMGT) shows that the hazard ratio for progression increased by 11% for every 1mm Hg increase in IOP.<sup>5</sup> The Barbados Eye Study found that among persons who developed glaucoma, nearly half (46%) had baseline IOPs greater than 22mm Hg. Similar to the trends found in the EMGT, the Barbados Eye Study also found that the risk of open angle glaucoma (OAG) increased by 12% with each 1mm Hg increase in IOP. For persons with baseline IOP under 17mm Hg, incidence of OAG was 1.8%, but for those with baseline IOP greater than 25mm

Hg, the incidence was 22.3%.<sup>2</sup> Research shows that for a person whose IOP is above 21mm Hg, the risk of developing glaucoma is 16 times higher than for a person with IOP lower than 16mm Hg.<sup>6</sup> High IOP is still the biggest risk factor to consider, but it's not the only one.

## Other Factors

Despite the well-established link between increased IOP and glaucomatous nerve damage, it is certainly not an exclusive relationship. A significant proportion of patients with IOP greater than 21mm Hg do not ever develop glaucoma.<sup>6-10</sup>

Also, many patients with glaucoma don't have an elevated IOP.<sup>6,10</sup> In fact, up to one half of patients with glaucoma have IOP of 20mm Hg or lower at initial diagnosis.<sup>6,10</sup> Close to 20% of patients in the Baltimore Eye Survey had an IOP of less than 21mm Hg on each of their first three glaucoma visits.<sup>11,12</sup> Normal tension glaucoma (NTG) is even more common in Asian populations.<sup>13,14</sup>

Further, significant racial differences exist in the prevalence of glaucoma. The Baltimore Eye Survey reported that African Americans had a prevalence of primary open-angle glaucoma (POAG) that was 4.3 times higher than in Caucasians.<sup>11,15</sup> Latinos older than age 60 have a risk of glaucoma development approximately the same as for African Americans.<sup>16</sup>

This leaves us wondering why some patients with IOP in the mid-20s suffer severe nerve damage, while others don't. We had other questions too. Why do some patients with IOP in the high teens remain disease-free, while others with the same IOP suffer progressive field loss? Why do African Americans and Latinos suffer more severe nerve damage than Cauca-

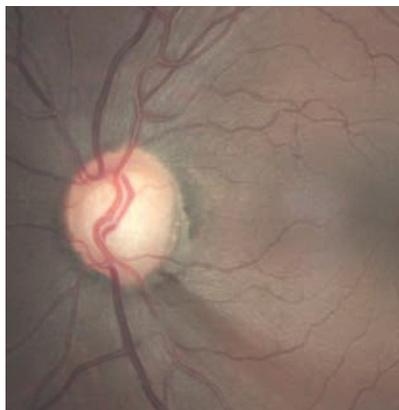


Photo: Joseph W. Sowma, OD

### Glaucomatous optic disc hemorrhage and associated, adjacent RNFL defect in a glaucoma patient.

sians, even after correcting for central corneal thickness differences? Why do some patients have an aggressively progressive form, while others seem to have a more stable or even non-progressive profile?

## Non-IOP Mechanisms

Clearly, the relationship between IOP and glaucomatous damage is not linear. Other mechanisms are indisputably involved in this complex disease. Vascular dysregulation and oxidative stress are two proposed mechanisms that may lead to glaucomatous ganglion cell apoptosis, or programmed cell death.<sup>17</sup>

Accumulation of advanced glycation endproducts (AGEs) within the retina and optic nerve head in glaucomatous eyes is another proposed mechanism in the pathogenesis of glaucoma. Increased rigidity of the lamina cribrosa is one possible direct consequence of AGE accumulation. The glaucomatous trabecular meshwork may also undergo earlier senescence under the influence of AGEs, compared with normal eyes.<sup>18</sup>

Alterations in glutamate and heat shock proteins are reported in glaucomatous eyes compared with normal eyes.<sup>19,20</sup> Genetics almost

certainly play a role in glaucoma development, and some evidence shows that nutritional deficiencies may also contribute.<sup>21,22</sup> Decreased cerebrospinal fluid pressure is seen more commonly in patients with NTG, suggesting a possible connection. What is not entirely clear is whether each of these factors is individually to blame in different subsets of patients, or whether some—or all—of them combine and intertwine with each other to create a final common pathway culminating in glaucomatous visual field loss. Two of these proposed factors—vascular dysregulation and oxidative stress—may be modifiable with nutrition. Let's look at these mechanisms in greater detail.

## Vascular Dysregulation

Vascular dysregulation, commonly defined as glaucoma with IOP consistently below 21mm Hg, is believed to be a significant contributor to glaucomatous progression in normal tension glaucoma.<sup>23-25</sup> Although systemic hypotension is a recognized risk factor for NTG, investigators believe a more critical indicator is the diastolic perfusion pressure (DPP), which takes IOP into account. DPP is calculated as the difference between diastolic blood pressure and IOP. For example, a patient with systemic blood pressure of 110/65 and IOP of 15mm Hg would have a DPP value of 65-15=50. Values less than 55mm Hg have been associated with a two- to six-fold increase in glaucoma.<sup>26-27</sup> The Barbados Eye Study found that lower systolic BP, and particularly lower ocular perfusion pressures, doubled the risk of glaucoma.<sup>28</sup> A recent study compared the ocular blood flow of individuals of African descent with the ocular blood flow of individuals of European descent with open

angle glaucoma, and found significantly lower blood flow values in all retrobulbar blood vessels in African descent patients.<sup>29</sup>

Regulation of blood flow in small vessels is accomplished in large part by two substances that are endogenously produced. Endothelin-1 (ET-1) is a potent vasoconstrictor, while nitric oxide (NO) is a vasodilator. Studies show both to be abnormal in glaucoma patients.<sup>30</sup> One theory is that in susceptible patients, a delayed response to oxygen demand results in prolonged ischemia and an exaggerated reperfusion response. That reperfusion, rather than the initial hypoxia, is thought to be injurious to the optic nerve.<sup>31</sup> Clinical “soft signs” which may represent visible manifestations of irregular ocular perfusion in these patients include beta zone peripapillary atrophy and optic disc hemorrhages, the latter of which herald a higher likelihood of visual field loss.<sup>32,33</sup> Normalization of ET-1 and NO is an attractive, but elusive, target for pharmaceutical intervention.<sup>34</sup>

## Oxidative Stress

Retinal ganglion cells require a great deal of energy compared with other tissues and cells. The mitochondria of these ganglion cells are responsible for their energy production, and consequently produce relatively larger amounts of reactive oxygen species (ROS), or free radicals—one of these being the superoxide radical. Endogenously produced superoxide dismutases (SOD-1, -2, and -3) are responsible for neutralizing superoxide. Zinc and copper are essential in the structure and function of SOD-1 and SOD-3, which function as an antioxidant within cell cytoplasm and in extracellular spaces, respectively. Manganese is required for SOD-2, which is

thought to function exclusively in the mitochondrial space. A reduction in the quantity or quality of these enzymes has been linked to a variety of diseases, and mutations in genes coding for even a single amino acid related to SOD can have a devastating effect on health.<sup>35</sup>

Increased oxidative stress is implicated in open angle glaucoma.<sup>36-37</sup> Assuming it does contribute significantly to the pathogenesis of the disease, it seems reasonable to assume that increasing total antioxidant capacity could provide protection in glaucoma patients. How to accomplish that is a therapeutic challenge.

## Nutritional Strategies

Several nutritional substances have shown promise as adjuvant therapies in glaucoma by targeting the vascular dysregulation model, the oxidative stress model or both, of glaucoma pathogenesis.<sup>38-48</sup>

### *Ginkgo biloba*

*Ginkgo biloba* is possibly the most-studied among nutritional therapies in glaucoma. In one study, *ginkgo biloba*, dosed at 40mg TID, was shown to improve blood flow to the peripapillary area.<sup>38</sup> *Ginkgo biloba* likely has antioxidant properties as well.<sup>39</sup> Importantly, *ginkgo biloba*—unlike currently available pharmacological agents—appears to function in both lipophilic and hydrophilic environments, allowing it to reach the inner mitochondrial membranes that are highly vulnerable to oxidative damage.<sup>40</sup> *Ginkgo biloba* supplementation does carry a risk of adverse effects, the most serious of which is increased risk of bleeding. Other reported side effects include increased blood pressure when combined with thiazide diuretics and one case of coma in a patient taking the antidepressant trazodone.<sup>41</sup>

### *Black currant anthocyanins*

Black currants contain a complex spectrum of anthocyanins and have been shown to normalize abnormal serum endothelin-1 levels in patients with glaucoma.<sup>42,43</sup> Further, IOP-lowering effects may be achieved with oral administration of 50mg a day of black currant anthocyanins.<sup>44</sup> A study also reported improvements in ocular blood flow and reduction in visual field progression compared to patients given placebo.<sup>45</sup>

### *Mirtogenol*

This proprietary blend of standardized bilberry extract Mirtoselect and Pycnogenol, a French maritime pine bark extract, was shown to reduce IOP and increase systolic and diastolic ocular blood flow, thereby increasing the diastolic perfusion pressure.<sup>46</sup> A study of 79 subjects in 2010 compared Mirtogenol alone with latanoprost alone, and a combination of both.<sup>47</sup> Although both Mirtogenol and latanoprost alone were beneficial, a synergistic relationship was found in the combination group for intraocular pressure reduction as well as increases in systolic and diastolic blood flow, especially after several weeks of treatment.<sup>47</sup> No side effects from Mirtogenol have been reported in the literature to date.

### *Manganese*

A recent study found that blood manganese levels were negatively associated, while mercury levels were positively associated, with the odds of glaucoma diagnosis in a South Korean population.<sup>48</sup> This is suggestive, but not conclusive, that low levels of manganese may contribute to the pathogenesis of glaucoma, possibly connected with reduced function of SOD-2 to neutralize superoxide at the level of the inner mitochondrial membrane.



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# Glaucoma Management

## Other nutrients

Several other substances have been studied less extensively, but may possibly show some promise in adjuvant therapy for glaucoma. These include resveratrol, magnesium, ubiquinone, melatonin and bilberry extract. Coffee is a well-known antioxidant and scavenger of the superoxide radical. Green, white and black teas all have antioxidant capacity and may potentially reach therapeutic levels at the retinal ganglion cells. Further study of these substances is warranted.<sup>49</sup>

## Today's Glaucoma Patient

Even without considering nutritional strategies, taking blood pressure on all patients with glaucoma is good clinical practice. Calculation of diastolic perfusion pressure may help to identify patients at risk for more rapid progression, prompting more aggressive treatment and follow up. In addition, it is especially important to consider these risks in hypertensive patients taking blood pressure-lowering medications, as exaggerated nocturnal hypotension must be avoided.<sup>50</sup> On the other hand, patients who do not display a drop in blood pressure overnight, the so-called “non-dippers,” are significantly more at risk of death from a cardiovascular event than those who display a more typical diurnal curve. Modification of treatment regimens may need to be discussed with the patient's other health care providers, with 24-hour blood pressure measurement, before medications are altered to avoid putting patients at systemic risk.

Ideally, patients with poor nutritional status could be readily identified and targeted for intervention. But how can you identify which patients need intervention? Should those patients, once identified, be advised to take a multivitamin/min-

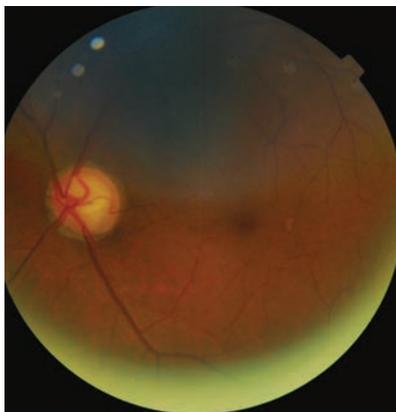


Photo: Justin Cole, OD

**Optic nerve thinning due to glaucoma.**

eral supplement (MVM), or instead, take specific supplements targeted towards glaucoma?

## Glaucoma Prevention in Practice

A good starting point is to do a baseline dietary analysis. This is sound clinical practice for all patients and can easily be done by a staff member prior to examination. A diet lower in fruits and vegetables, especially berries and dark leafy greens, is unquestionably associated with higher prevalence of a multitude of both systemic and ocular diseases. The recommendation to incorporate more of these whole foods into the diet, based on an informal food frequency survey, is theoretically ideal, but unfortunately not likely to be met with 100% compliance.

A slightly better approach is to capture indirect measures of nutrient levels, which can be done non-invasively in the office. Macular pigment optical density (MPOD) testing is a subjective test that is designed to measure xanthophyll (lutein and zeaxanthin) levels at the macula. Although xanthophylls have not, to date, been directly implicated in glaucoma in large clinical trials, this may serve as a proxy measurement of general

nutrition intake, since foods containing lutein and zeaxanthin (spinach, kale, orange and yellow peppers, and pumpkin, to name just a few) also offer significant antioxidant properties and trace mineral levels. Transdermal nutrient testing gives an estimate of carotenoids in the skin. Both of these techniques can be easily performed by staff members, provide immediate results, establish a treatment baseline, and can increase compliance with your suggested supplementation regimen. Having a baseline and a target allows both practitioner and patient to monitor improvement and can be a strong motivator at follow-up visits. Bear in mind that these tests are estimating levels of only a portion of the substances that may ultimately improve a patient's outcomes with respect to glaucoma, and do not offer a direct measure of nutrients more directly linked to glaucoma. Mineral levels—including manganese, magnesium and zinc—are not addressed.

Another method is to test the patient's blood, serum or cellular membranes for specific nutrient profiles. Standard laboratory analysis is available for many individual nutrients, and several independent companies offer comprehensive nutritional testing. An advantage to the latter route is that nutritional supplementation advice is often included with the results; however, insurance rarely covers such testing, and patients must be aware that the information provided is not designed to replace medical care.

None of these approaches is likely to provide any information regarding the advisability of the two substances with the most evidence supporting their use in glaucoma, namely *ginkgo biloba* and Mirto-genol. Discuss the potential risks and

benefits of these substances with your patients, and provide them with detailed information about how to purchase any product(s) you recommend.

Finally, we can consider genetic and epigenetic factors in our evaluation and management of our patients. Remember that a positive family history of glaucoma is a well-known risk factor for the disease. It may be that the hereditary component in the pathophysiology of glaucoma may be at least partly due to genetic defects that lead to inadequate endogenous antioxidants or vasoregulatory agents. If so, those patients might need relatively higher or lower levels of specific nutrients to compensate for altered function. This is a rapidly emerging area that is not without controversy. Given the wide availability of genetic testing and its interpretation, however, patients are increasingly able to inexpensively access to their own genetic 'map,' which is likely to prompt many questions about approaches to minimize risk of disease.

Astute clinicians will remain abreast of developments in this area in order to address these questions responsibly.

Currently, while determining individual nutrient needs and intake levels is possible and arguably strongly advisable, it is not yet standard of care in the optometric practice.

This landscape is rapidly evolving, and many experts predict that testing of this sort will be commonplace as we move toward individualized medicine in all aspects of health care. ■

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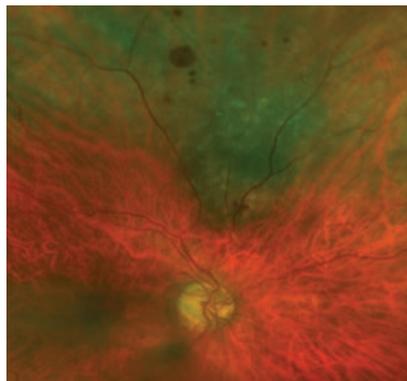
# Recognize the Signs of Ocular Melanoma

Key features allow you to identify melanomas early and help—even save—your patients. **By Sara Weidmeyer, OD**

In the past, enucleation was the standard treatment for uveal melanoma (UM). However, it became apparent that early detection and prompt referral for treatment could reduce mortality and allow less invasive, globe-sparing treatment modalities. The role of the primary eye care provider is integral for early detection.

## Uveal Melanomas

Melanomas are malignant tumors that occur when pigment-producing melanocytes abnormally over-proliferate and gain resistance to apoptosis.<sup>1,2</sup> Ninety-five percent of ocular melanomas (OM) are uveal, while conjunctival OM's constitute the remaining 5%.<sup>2</sup> Rarely, OM formation occurs in the eyelid or orbit.<sup>3</sup> The uveal tract is composed of the anteriorly-located iris and the posteriorly-located ciliary body and



**This photo shows an 8mm x 6mm mottled melanotic choroidal nevus with no appreciable thickening in the superior midperiphery, with overlying drusen and intraretinal hemorrhaging. There are also intraretinal hemorrhages extending into the superior periphery. The lesion has no evidence of orange pigment or subretinal fluid. Surprisingly, this choroidal nevus has remained stable in size and thickness for several years, and is being monitored by an ocular oncologist due to its size.**

choroid. Approximately 90% of UMs occur in the choroid.<sup>1,4,5</sup> The remaining 9% of cases occur in the ciliary body and iris (7% and 2%, respectively).<sup>1,4,5</sup> These can develop from a pre-existing lesion, such as a choroidal or iris nevus.<sup>1</sup>

Uveal melanomas are the most common primary intraocular malignancy in adults. In fact, they are second only to childhood retinoblastoma as the most common primary intraocular malignancy.<sup>1,4,6</sup> However, with only between four and 20 per one million cases per year globally, UM is still very rare.<sup>1,6</sup> It has been estimated that just shy of 7,100 patients develop UM globally per year, with around 2,500 of those being North Americans. The rare conjunctival OM presents in 200 North Americans annually.<sup>3</sup>

The incidence of UM is found almost entirely in the Caucasian

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**Goal Statement:** The appearance of ocular melanomas make them hard to identify without the proper clinical insight, and some occur frequently enough to warrant education regarding their identification and treatment. This course provides a detailed overview of choroidal, ciliary body, iris and conjunctival melanomas, including clinical presentation, risk factors, differentials, prognostics and treatment options.

**Faculty/Editorial Board:** Sara Weidmeyer, OD

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population—98% of cases.<sup>6-7</sup> They can occur at any age, though the median onset is between 55 and 60 years old and only 1% of cases occur in people under 20. Iris melanomas tend to appear at a younger age. On average, an iris melanoma diagnosis occurs in the patient's early 40s.<sup>7-8</sup> UM is slightly more prevalent in men than women.<sup>4,6,9,10</sup>

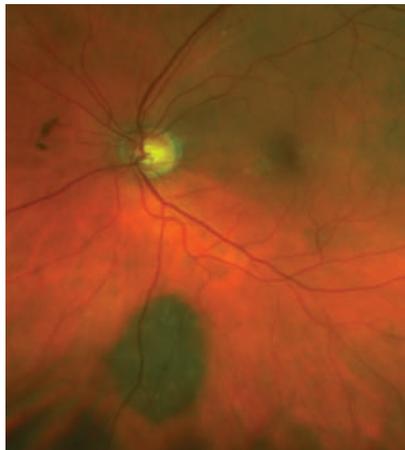
### Clinical Presentation

The morphology of posterior UM varies substantially with respect to shape, size and color. Coloration can range from amelanotic (about 15% of cases) to darkly pigmented (about 55%), and the pigmentation is often mottled (about 30%).<sup>1,3-4</sup> They may be shallow and diffuse (5%), but are often irregular solid masses that are either abruptly elevated in the form of a dome (75%), or are mushroom-shaped (20%) if they erupt through Bruch's membrane. They also may become multilobular with growth.<sup>1,5,11</sup> Choroidal melanomas are grouped as small (0 to 3mm), medium (3.1 to 8mm) or large (greater than 8.1mm), based on thicknesses.<sup>3,5</sup>

Iris melanomas are pigmented more than 80% of the time, and almost half (45%) appear in the inferior quadrant.<sup>3</sup> They may appear thin and diffuse, in a transparent "tapioca" pattern infiltrating the iris, or nodular with the appearance of feeder vessels.<sup>3</sup>

Patients with melanomas may present with a variety of symptoms, depending on the size, location and extent of the lesion. Patients may be asymptomatic, but frequently present with blurry vision. Floaters, photopsias and visual field loss corresponding to the location of the lesion may also occur.<sup>1</sup>

The patient may experience pain if the lesion compresses ciliary nerves, or from increased intraocu-



**Photo of choroidal nevus, approximately 4mm v. x 3mm h. with overlying drusen.**

lar pressure following secondary angle closure. Pain may also arise from iris melanoma seeding into the trabecular meshwork, obstructing aqueous outflow, or from tumor necrosis. However, all of these circumstances are uncommon.<sup>1,3-4,12</sup>

### Ancillary Testing

While clinical observation is generally adequate for diagnosis, ancillary testing may be helpful.

On B-scan, choroidal melanomas usually appear as solid masses, which exhibit bright anterior acoustic reflection with low internal and basal reflectivity.<sup>12-13</sup> On A-scan, low internal reflectivity is seen within the tumor, and oscillation in echo height within the lesion indicates vascularity.<sup>12-13</sup> A- and B-scans also aid in accurate tumor size and thickness measurements.

Optical coherence tomography (OCT) and enhanced depth imaging OCT (EDI-OCT) can be quite useful. One study found that choroidal UM usually shows a smooth-domed topography, often with overlying subretinal fluid (SRF) and "shaggy" photoreceptors, which likely represents photoreceptor edema.<sup>14</sup> They also show physical compression of the choriocapillaris due to the lesion

### Table 1. Iris Melanoma High Risk Profile

- Age < 40 years old
- Blood in anterior chamber
- Clock hours of iris involved
- Diffuse configuration
- Ectropion uveae
- Feathery margins

itself and dark posterior shadowing due to the density of melanin.<sup>14-15</sup>

Anterior segment OCT imaging can be used for iris melanomas. With this, the surface appears furrowed and the internal reflectivity is variable. However, note that for pigmented iris melanomas, just as with posterior segment OCT, posterior shadowing occurs and the extent of the lesion is often difficult to assess.<sup>16</sup>

Fundus autofluorescence (FAF) highlights metabolically stressed RPE and, in uveal melanoma, usually shows focal hyperautofluorescence, especially at the borders of the tumor or in areas of SRF or lipofuscin ("orange pigment," as described below).<sup>17</sup> However, the intensity of autofluorescence can vary, and the same pattern may be seen in several other non-UM lesions.<sup>18</sup>

Fluorescein angiography (FA) does not yield pathognomonic signs for uveal melanoma because findings will vary based on the lesion's pigmentation, vascularity, overlying RPE integrity, etc.<sup>12</sup> Thus, FA alone is not very useful in diagnosing UM.

On magnetic resonance imaging (MRI), melanomas generally appear hyperintense on T1-weighted images and hypointense on T2-weighted images due to melanin's intrinsic T1 and T2 shortening effects; this does not hold true, however, for amelanotic or lightly pigmented melanomas. MRI is also helpful for determining tumor size and extent of involvement. Ciliary body involvement, extrascleral spread and

increasing degree of pigmentation (as gauged by increasing T1 hyperintensity and T2 hypointensity) all carry poorer prognostic implications. Finally, computed tomography (CT) usually shows nonspecific hyperdensity.<sup>4</sup>

### Clinical and FNAB Diagnosis

Most melanomas can be diagnosed clinically. For example, the Collaborative Ocular Melanoma Study (COMS) found that more than 99.5% of large choroidal melanomas were correctly diagnosed clinically.<sup>19</sup>

For smaller or atypical melanomas, or if the tumor type is less clinically obvious, cytopathology of samples obtained via fine-needle aspiration biopsy (FNAB) will differentiate the tumor with up to 95% accuracy.<sup>11,19</sup> Diagnostic FNAB is the most reliable means of differentiating atypical fundus lesions; however, it is only required in approximately 1% to 2% of cases of presumed UM and is usually done at the time of tumor treatment.<sup>19-21</sup> FNAB samples may be obtained via trans-corneal, trans-scleral or trans-vitreous approaches. Trans-scleral and trans-vitreous FNAB is generally preferred for pre- and post-equatorial tumors, respectively.<sup>11,19</sup> Histology of the solid mass may also be evaluated in enucleated eyes, and excellent correlation, at or near 100%, has been shown between histologic and cytologic diagnosis.<sup>19</sup>

**Table 2. Melanoma Mnemonic**

Characteristic	High Risk
Thickness	>2mm
Fluid	Any
Symptoms	Any
Orange Pigment	Any
Margin	Within 3mm of disc
Ultrasound	Hollow
Halo	Absent
Drusen	Absent

### Classification and Prognostics

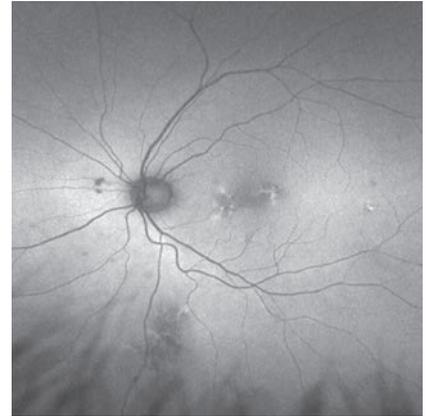
Uveal melanomas are divided into three histological types: spindle type A, spindle type B, and epithelioid type. Within these histological types, there are four classifications as described by Callender's modified classification:<sup>1</sup>

1. Spindle type tumors
2. Epithelioid cell
3. Mixed (spindle and epithelioid)
4. Necrotic

Most uveal melanomas are of the spindle (35% to 45%) or mixed cell types (45% to 63%). Purely epithelioid cell-type melanomas are rare (1.75% to 5%), and necrotic melanomas, for which the predominant cell type is indiscernible, are also rare (5% or less).<sup>1,19</sup> Histologically, epithelioid cell categorization and high mitotic count are among the features most predictive of melanoma-related mortality.<sup>2,22</sup>

The American Joint Committee on Cancer (AJCC) has established an anatomic tumor classification system for anterior and posterior uveal melanomas. Iris melanomas are staged T1-T4 based on amount of extra-iris extension. Posterior melanomas are classified on a T1-T4 scaling criterion based on increasing size, basal diameter and thickness; they are further subcategorized as stage I-IV depending on ciliary body involvement and extra-ocular extension.<sup>5,9</sup>

Many techniques are used in molecular testing for chromosomal alterations of UM samples, which are obtained post-enucleation, post-local resection or via FNAB.<sup>2</sup> Analysis of chromosomal information from uveal melanomas has identified critical mutations: aberrations in chromosomes 3 (complete or partial loss), 8q (gains) and, to a lesser extent, loss of both 1p and 6q. Polysomy 6p (gains) and disomy 3 are generally associated with longer



**Fundus autofluorescence of choroidal nevus showing overlying patchy hyperautofluorescence.**

survival rates for uveal melanoma, while monosomy 3 is associated with poor prognosis.<sup>2,23</sup> These gross aberrations are not seen in conjunctival melanoma.<sup>2</sup> GNAQ, GNA11, BAP1 and other gene mutations are commonly found, and these genetic markers correlate with increased mortality, particularly in combination with monosomy 3.<sup>2,20,23</sup>

Gene expression profiling (GEP) of tumor RNA is helpful for prognostication in primary uveal melanomas. A commercially available assay, Decision Dx-UM (Castle Biosciences), classifies the UM into two metastatic risk classes:

- Class 1, with 1B subtype, which classifies UM as low risk and intermediate-risk, respectively.
- Class 2, UM with high risk.<sup>2,21</sup>

At eight years, the survival rate for class 1 is 95%, whereas it is only 31% for class 2.<sup>5</sup>

Chromosomal analysis and GEP can produce accurate metastasis risk assessments (75% to 95% accurately stratified risk), but the most predictive genetic factor appears to be complete or partial loss of chromosome 3. Those with a normal chromosomal status have a higher rate of survival.<sup>2,23</sup> Assessing chromosomal status, in addition to

considering AJCC staging offers the best melanoma-related mortality prediction.<sup>23</sup>

### Risk Factors for Formation

There are several identified risk factors for the development of UM. According to one study, the most important risk factors for UM development are pre-existing choroidal nevi and ocular- or oculodermal melanocytosis. Melanocytosis, also known as “nevus of Ota,” manifests as grayish pigmentation in the skin, sclera and uvea, and carries a 1/400 lifetime risk of uveal OM development in Caucasians.<sup>5</sup> Three percent of patients with UM have ocular melanocytosis.<sup>10</sup> Patients with uveal melanoma are at about two to three times higher risk of metastasis if they have ocular or oculodermal melanocytosis.<sup>3</sup>

Caucasian ethnicity and older age are well-recognized risks.<sup>6,9</sup> Additionally, fair skin, poor ability to tan, and those with little ocular pigmentation are at higher risk. A poorer prognosis with UM has also been linked to light iris color, particularly those with light irises but increased choroidal pigmentation.<sup>3,6</sup> Choroidal nevi, which are found in 7% of the Caucasian population, are also an important risk factor, as melanomas may develop directly from them. Roughly one in 8,845 choroidal nevi transform into melanomas.<sup>6,20</sup>

Ultraviolet light exposure has long been suspected to play a role in the formation of uveal melanoma.

Evidence is mounting that blue light may be a strong risk factor for UM formation, particularly in the setting of pre-existing choroidal nevi.<sup>6</sup> For example, arc welding exposure, which is a source of blue ultraviolet light, is significantly associated with UM formation.<sup>3,5-6</sup> Prophylactic UV protection is advisable, to help reduce the risks of both OM and a number of other ocular diseases.

Genetic factors such as abnormal alterations in chromosome 3, 6 and 8 and GNAI1 mutations are other risk factors, as previously noted.<sup>6</sup>

### Differential Diagnosis of Choroidal Melanoma

There are a plethora of differential diagnoses to consider when a lesion looks suspicious for choroidal melanoma.<sup>1</sup>

- **Choroidal nevi.** These are present in about 7% of the Caucasian population. Fortunately, <1% of them transform into melanomas, but funduscopically differentiating nevi from a small choroidal UM can be challenging.<sup>12,20</sup> OCT findings are often similar to melanomas, but longstanding nevi generally show chronic overlying RPE and outer retinal atrophic changes.<sup>14</sup>

Clinically, several characteristics of choroidal nevi put them at greater risk for malignant transformation. The mnemonic “TFSOM-UHHD,” which stands for “To Find Small Ocular Melanoma—Using Helpful Hints Daily” (Table 2)—may aid in the crucial early

detection of UM. The presence of each characteristic raises the risk of malignant transformation from nevus to melanoma threefold, and the presence of three or more of these characteristics is an almost certain indication of melanoma.<sup>3,5</sup>

Lipofuscin, composed of lipids, proteins and small chromophores, accumulates in the RPE due to metabolic aberration, where the retinal photoreceptor outer segments are incompletely digested, or turn over more quickly than the RPE can phagocytose them. Lipofuscin accumulation may appear as diffusely granular, or form in coalesced areas. This occurrence is better known as “orange pigment,” and is best appreciated on FAF, where it brightly fluoresces. The presence of lipofuscin is a prominent risk factor for malignancy—choroidal nevi with orange pigment are highly suspicious. Tumors with SRF also have a higher risk of growth and are more likely to be malignant.<sup>17</sup>

Rarely, choroidal melanomas may exhibit a diffuse growth pattern. This diffuse UM is flat with  $\leq 3$ mm thickness, or <20% ratio of thickness-to-base size. These diffuse melanomas only represent about 3% of uveal melanomas, but they carry a 3.84 times increased risk of metastasis vs. non-diffuse melanoma.<sup>3</sup> Diffuse and other small melanomas are quite dangerous, and unfortunately, may easily be misdiagnosed as a benign nevus.

- **Choroidal metastatic tumors.** Metastatic choroidal tumors (with their primary malignancy elsewhere in the body) tend to be multifocal (averaging two per eye) and often have SRF.<sup>11</sup> On average, two out of three primary sites are known, although up to one of out three are not.<sup>11</sup> Globe metastases, which originate from primary lung or breast cancer, are usually present in the choroid due to its rich blood

### Iris and Ciliary Body Melanomas

Since iris melanomas usually develop from iris nevi, an iris nevus is the most common differential when evaluating for iris melanoma. Remembering the letters “ABCDEF” can help the clinician differentiate between the two. Iris OM is more likely given any of these characteristics (Table 1).<sup>3</sup>

Ciliary body melanomas may be difficult to detect, as they may remain hidden behind the iris unless they are large, or if they grow through the sclera to produce a visible pigmented episcleral extension. Visible sentinel vessels may form overlying an otherwise hidden tumor, and should prompt further investigation.<sup>3</sup>

supply.<sup>4,12</sup> While the lesions may be hard to clinically differentiate from primary uveal melanoma, the symptoms tend to manifest and progress much more quickly.<sup>4</sup> EDI-OCT generally shows a bumpier surface topography than primary UM, but like UM, often demonstrates overlying subretinal fluid and shaggy photoreceptors.<sup>14</sup>

- **Melanocytoma.** Unlike choroidal melanoma, melanocytomas (also known as hyperpigmented melanocellular nevi) are almost always benign tumors. They are rare and are generally found in patients between 30 and 50 years of age who have dark skin.<sup>13</sup>

Melanocytomas are darkly pigmented and may occur in the choroid, usually at or near the optic nerve and less frequently in anterior structures such as the sclera, conjunctiva, ciliary body or iris.<sup>13,17</sup>

They are usually small (<1 disc diameter) and exhibit mild growth in only 10% to 15% of cases. These dense masses are usually avascular and show high internal reflectivity on B-scan, whereas choroidal melanomas are usually more vascular and exhibit low internal reflectivity.

Choroidal fluorescence is generally blocked on FA, because of the heavy pigmentation and lack of vascularity that characterize melanocytomas.<sup>13</sup> Also, they are hypo-fluorescent on FAF due to a lack of lipofuscin, in stark contrast to FAF data in uveal melanoma.<sup>17</sup> These lesions also differ histologically from melanomas. When bleached, uniform large cells with a small nucleus, abundant cytoplasm and a clear cytoplasmic membrane are visible. Even with these differences, melanocytomas are still difficult to differentiate from melanomas both clinically and radiologically. B-scan and FA findings can vary in a way that mimic choroidal melanomas, so patients with melanocytomas may,

## Conjunctival Melanoma

Conjunctival melanomas account for 5% of ocular melanomas and 2% of all ocular malignant tumors. It is the second most common primary conjunctival malignancy after squamous cell carcinoma. The median age of onset is 60. It occurs in 0.2 to 0.8 per million Caucasians annually; it is seldom reported in non-Caucasians. Usually, conjunctival OM is found in the interpalpebral bulbar conjunctiva, and carries a poorer prognosis if it is elsewhere.<sup>2</sup>

Differentials include racial melanosis, conjunctival nevi and primary acquired melanosis (PAM).<sup>3</sup> Conjunctival melanomas may arise de novo (up to 17%), from pre-existing nevi (up to 25%) or as PAM (up to 76%).<sup>2-3</sup> About 10% of PAMs transform to conjunctival melanoma.<sup>3</sup> The features of conjunctival OM can vary greatly: from flat to nodular, from amelanotic to darkly pigmented, single to multiple tumors, and the margins may vary; cell type also varies and, like uveal and cutaneous melanomas, may be epithelioid, spindle or a mixture of the two.<sup>2</sup> Conjunctival melanomas are classified by the AJCC into T1-T4 based on size and extent of spread. Like UM, increasing rates of metastasis and death occur with increasing class.<sup>3</sup> Genetic and histologic outlook for conjunctival OM is not well established.<sup>2</sup> Treatment generally involves wide excision with a dry, irrigation-free, "no touch" approach to prevent seeding, followed by topical chemotherapy with mitomycin C, or cryotherapy.<sup>2-3</sup> Local recurrence may present in more than 50% of cases.<sup>2</sup> Orbital extension necessitates exenteration.<sup>3</sup>

Metastasis via the lymphatic system develops in 20% to 30% of cases, usually to regional lymph nodes, brain, lung and liver, and is more likely to occur if the tumor has a thickness of >2mm, ulceration, or mitotic counts of >1/mm.<sup>2</sup> The 10-year survival rate is approximately 70% to 75%. Frequent monitoring, at least two to three times per year, with lymph node palpation and annual brain MRI and chest x-ray are advised.<sup>2</sup>

unfortunately, undergo unnecessary treatment for their benign lesion.<sup>13</sup>

- **Disciform macular degeneration.** Disciform scarring, subretinal hemorrhaging and the turbid, creamy exudation often seen with age-related macular degeneration (AMD) may cause choroidal elevations and a clinical picture that mimics uveal melanoma. The presence of AMD in the contralateral eye, along with OCT imaging or other ancillary testing, will help differentiate between AMD and uveal melanoma.

- **Peripheral exudative hemorrhagic chorioretinopathy (PEHCR).** This retinal degeneration affects elderly patients and appears as an elevated dark mass. On FA, the affected area will show blockage due to hemorrhaging. It appears dense on ultrasound and will usually resolve with time.<sup>5,11</sup>

- **Congenital hypertrophy of the retinal pigment epithelium (CHRPE).** These darkly pigmented,

flat lesions may be quite variable in size and often have hypo-pigmented lacunae within their borders. They do not grow with time and are benign.

- **Choroidal hemangioma.** These are benign dilations of the choroidal vasculature and appear as red to orange elevations.<sup>10</sup>

EDI-OCT reveals smooth, dome-shaped topography and enlargement of the affected choroidal vessel lumen.<sup>14</sup> FA indicates a vascular filling pattern and B-scan shows high internal reflectivity.<sup>23</sup>

Other potentially confusing differential diagnoses include choroidal detachment, granulomas, sclero-choroidal calcifications, vortex vein varix and choroidal osteomas.<sup>5</sup>

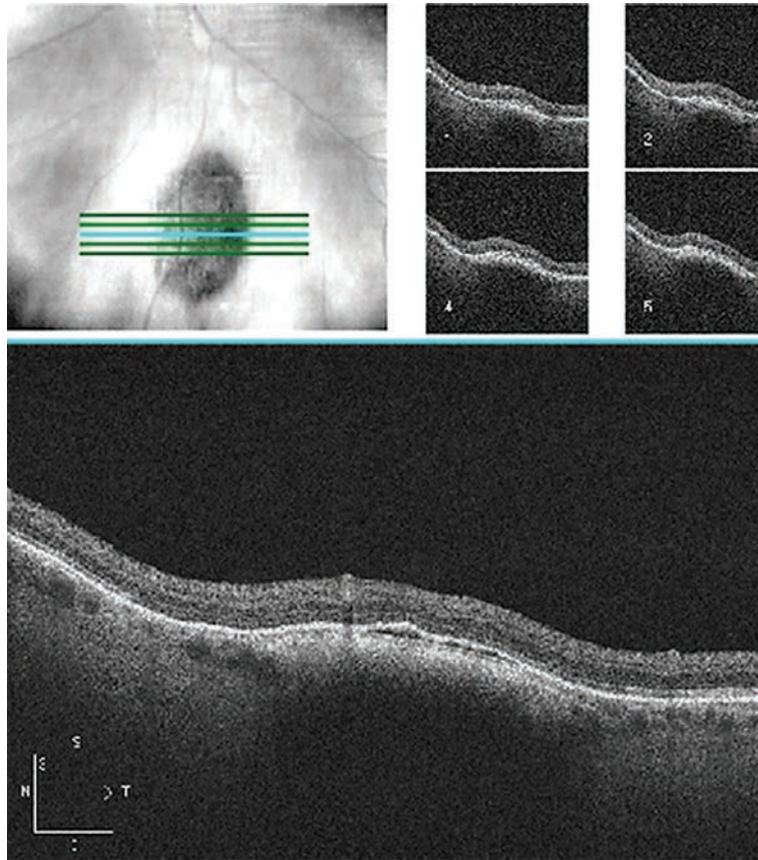
## Treatment Options

Several considerations are made when considering treatment for uveal melanoma: tumor size, location, proximity to the fovea and optic nerve, overall systemic health

considerations and patient preference.<sup>25</sup> The most frequent treatments for posterior UM are enucleation and focal radiotherapy (either proton beam or plaque radiotherapy).<sup>3</sup> However, since the COMS revealed that treatment with enucleation or brachytherapy yielded equivalent mortality rates for medium-sized melanomas, globe-sparing procedures are performed when early detection makes them possible.<sup>25</sup>

- **Plaque radiotherapy/brachytherapy.** Plaque brachytherapy (otherwise known as plaque radiotherapy) involves placing a radioactive implant or “plaque” into or overlying the cancerous tissue. Iodine-125 and ruthenium-106 isotopes are most commonly used, and around 98% of tumors are locally controlled.<sup>3</sup> These plaques are very customizable and can fit almost any ocular site and tumor size (up to 18mm in diameter and 12mm thickness). Some tumors may be technically difficult for plaque placement over their entirety, particularly those that are large or near to the optic nerve.<sup>3,20,25</sup>

- **Charged particle irradiation.** Proton beam therapy (PBT) and stereotactic radiosurgery (SRS) are effective for cases of larger, or more inaccessible choroidal melanomas, such as very posterior or juxtapapillary melanomas where plaque radiotherapy may not be possible.



**OCT of choroidal nevus showing lesion thickening and thin band of SRF.**

The SRS procedure generally involves retrobulbar anesthesia to immobilize the eye, application of a stereotactic frame, MRI to localize the tumor followed by a large dose of gamma radiation to the lesion.

Tantalum markers (non-metallic clips) are often sutured to the sclera around a posterior lesion to aid in the visualization of the treatment area during the treatment during PBT. Proton beams can then be very precisely focused to deliver radiation to the tumor, largely sparing surrounding tissue. However, the proton beam does deliver radiation to a broader area than SRS. Whereas SRS radiation is usually given in one dose, PBT's larger radiation dose is generally fractionated into multiple sessions.<sup>25</sup>

PBT demonstrates up to 97% control of local tumors.<sup>3</sup> Poorer

visual outcomes are generally expected with tumors that are located less than two disc diameters from the fovea or optic disc. One large clinical study comparing SRS and PBT for the treatment of choroidal melanomas found that, for melanomas touching the optic nerve, patients who underwent SRS were more likely to incur severe visual loss. However, PBT and SRS have both proven efficacious and yield comparable rates in regards to tumor control and globe preservation (about 96%).<sup>25</sup>

Radiation retinopathy is a potential complication of both SRS and PBT; other

potential complications include optic neuropathy and neovascular glaucoma.<sup>3,25</sup> Secondary enucleation may be necessary, and rates have been reported at 2.4% to 14% post-SRS and 3.7% to 14% post-PBT.<sup>25</sup>

- **Local resection.** Uveal melanomas are sometimes locally resected via a procedure that involves excising the entire UM en-bloc—as a full, intact single specimen. Radiotherapy is sometimes used after resection to prevent recurrence.<sup>3,25</sup> Tumor seeding is unlikely with local resection, but generally minimal manipulation is attempted.<sup>20</sup> This procedure is often used for iris melanomas.

- **Enucleation or Exenteration.** Advanced melanomas necessitate enucleation. These include tumors >10mm thick, >18mm in basal diameter, those surrounding the optic nerve, or those causing second-

ary glaucoma. The procedure is done under general anesthesia, and the extraocular muscles are spared to assist with cosmetic prosthetic movement over the volume-replacing implant post operatively. Exenteration of the orbit is usually not necessary unless there are larger degrees of extraocular tumor extension.<sup>3</sup>

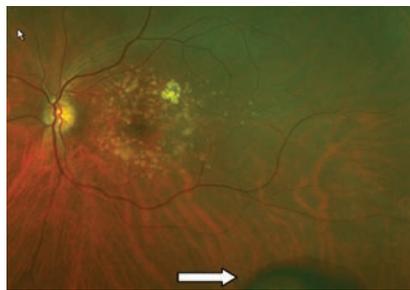
• **Transpupillary thermotherapy.** TTT uses a diode laser focused through a contact lens, and can treat small choroidal melanomas (<3mm thickness), especially darkly pigmented ones, that do not make contact with the fovea or optic disc.<sup>20,25</sup> This modality offers precisely targeted treatment with immediate tumor necrosis, and may be a good selection for elderly patients whose tumor meets the recommended treatment criteria. It can be used as monotherapy, but is now usually done in conjunction with plaque radiotherapy.<sup>3,20</sup> Potential side effects include retinal hemorrhaging, vein occlusions or traction, and tumor recurrence in up to 8% of cases.<sup>3</sup>

Iris melanomas are generally surgically resected, but plaque radiotherapy is often employed, especially if there is a lot of tumor seeding; enucleation may also be necessary.<sup>3,4</sup>

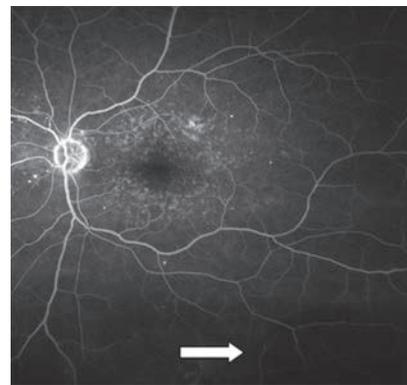
Observation, while not advised in most cases, may be a reasonable management plan in some patients—the very elderly, frail or those with serious comorbidities may opt out of treatment.

## Prognosis

Iris uveal melanoma, the least common of all UM, is relatively non-aggressive and has the best prognosis regarding mortality, especially for younger patients.<sup>3,10,26</sup> On the contrary, ciliary body melanomas have the worst prognosis. As previously noted, UM in older patients, larger UM size, diffuse melanoma, extraocular extension, epithelioid cell type, and chromo-



**PEHCR and the corresponding fluorescein angiogram, which indicates choroidal blockage due to hemorrhaging.**



somal mutations all carry poorer prognosis. Despite tumor size and other risk factors, genetic analysis of the tumor carries significant weight in regards to obtaining an accurate prognosis.<sup>2-3,22</sup> Again, complete or partial loss of chromosome 3 is most prognostic for mortality.

Overall, prognosis for UM is poor, with a five-year mortality rate around 40%, and an eventual 50% 10-year mortality rate, primarily due to aggressive metastasis.<sup>6,23</sup> Choroidal melanomas metastasize hematogenously (via bloodstream), as the choroid does not have a developed lymphatic system.<sup>1</sup> The liver is the most frequent site of metastasis; up to 90% of patients with metastasis have liver involvement.<sup>1,4</sup> Prognosis is very poor once liver metastasis is detected, with a median survival duration of only 2.2 to 12.5 months.<sup>6</sup> Other metastatic sites include lung, skin and bone.<sup>3,4</sup> Molecular genetics are used for prognostication regarding risk of metastatic disease, but, unfortunately, there is little effective treatment for metastatic UM.<sup>2</sup>

The rate of metastasis and death in uveal melanoma increases with respect to T1-T4 staging criteria by two-, four- and eight-fold, respectively.<sup>3,5</sup> Though the metastatic risk is much lower in small melanomas, even small choroidal melanomas do pose a metastatic risk. On average, metastasis is presumed to occur

when the UM has a basal diameter of 3mm and a thickness of 1.5mm—at a time when it may be assumed to be a choroidal nevus.<sup>5,22</sup> This, again, emphasizes how key early detection is for uveal melanoma. Each millimeter of increase in tumor thickness increases the metastatic risk by 5%.<sup>5</sup>

Generally speaking, oncologic physicals twice per year with liver function tests, and annual liver imaging (MRI or ultrasound) and chest x-ray are advised to monitor for metastasis.<sup>3</sup>

Early identification of UM is key, especially given that there is a harrowing difference in metastatic prognosis based on tumor thickness, so differentiating them from other mimickers may save a patient's life. Evolving diagnostic testing not only helps to determine metastatic potential, but in the future may offer more individualized, targeted management strategies to improve survival. ■

*Dr. Weidmayer practices at the VA Ann Arbor Healthcare System in Ann Arbor, Mich. She is also a clinical instructor for the University of Michigan Department of Ophthalmology and Visual Sciences.*

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### OSC QUIZ

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1. Most ocular melanomas occur in the:
  - a. Iris
  - b. Ciliary body
  - c. Choroid
  - d. Conjunctiva
2. Most iris melanomas occur in the:
  - a. Superior quadrant
  - b. Inferior quadrant
  - c. Nasal quadrant
  - d. Temporal quadrant
3. Why do choroidal melanomas show posterior shadowing on OCT?
  - a. They are physically dense tumors
  - b. Due to the density of melanin within the tumor
  - c. They are very reflective
  - d. Due to their thickness

4. What is not a histological classification of uveal melanoma?

- a. Spindle type
- b. Epitheloid type
- c. Basal cell type
- d. Mixed (spindle and epitheloid) cell type

5. What chromosome is not often found to have aberrations in uveal melanoma?

- a. Chromosome 3
- b. Chromosome 8
- c. Chromosome 6
- d. Chromosome 2

6. Which gene expression profiling class portends the best survival rate?

- a. Class 1
- b. Class 1b
- c. Class 2
- d. Class 2b

7. Which of the following is the most important risk factor for uveal melanoma formation?

- a. Increasing age
- b. Fair skin
- c. Ultraviolet exposure
- d. Oculodermal melanocytosis

8. Which of the following is a less concerning characteristic of an iris nevus?

- a. Nodular configuration
- b. Hyphema

c. Feathery margins d. Large area involved

9. What conjunctival finding is particularly concerning for melanoma?

- a. Conjunctival injection
- b. Pinguecula
- c. Sentinel vessel
- d. Papillae

10. Which of the following is a low risk feature when differentiating choroidal nevus from choroidal melanoma?

- a. Drusen
- b. Lipofuscin
- c. Subretinal fluid
- d. Thickening

11. How does lipofuscin (“orange pigment”) appear on fundus autofluorescence compared to normal surrounding retina?

- a. Hyperautofluorescent
- b. Hypoautofluorescent
- c. Isoautofluorescent
- d. Blocked autofluorescence

12. Which is true of diffuse configuration choroidal melanoma?

- a. They are usually >3 mm thick
- b. They are higher risk for metastasis vs. non-diffuse melanoma
- c. They are very common
- d. They are thicker than they are wide

13. Plaque radiotherapy may not work well for uveal melanoma if:

- a. The tumor is small
- b. The tumor is in the ciliary body
- c. The tumor is at or near the optic disc

## OSC QUIZ

- d. The tumor is irregularly shaped
14. Which is not a complication of charged particle irradiation?
- Radiation retinopathy
  - Optic neuropathy
  - Neovascular glaucoma
  - Corneal edema
15. What procedure is frequently used for iris melanomas?
- Local resection
  - Enucleation
  - Exenteration
  - Transpupillary thermotherapy
16. Transpupillary thermotherapy may be a good option if the tumor is:
- Near the fovea
  - Near the optic disc
  - >3 mm thick
  - Darkly pigmented
17. Prognosis for uveal melanoma is better with:
- Ciliary body involvement
  - Younger patients
  - Larger melanomas
  - Epitheloid cell type melanomas
18. What is the most common site of metastasis for uveal melanoma?
- Skin
  - Bone
  - Liver
  - Lung
19. Each millimeter of increase in tumor thickness increases its metastatic risk by:
- 1%
  - 5%
  - 10%
  - 20%
20. What tests are recommended to screen for uveal melanoma metastasis?
- Liver function labs
  - Liver imaging
  - Chest X-ray
  - All of the above

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- Avoided commercial bias/influence: ① ② ③ ④ ⑤
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# A Drop in the Bucket

Should a pregnant graft patient be taken off steroids?

Edited by Joseph P. Shovlin, OD

**Q** I have a 28-year-old graft patient following keratoconus lens intolerance who is now pregnant. She's been on topical steroids for the past 12 months. I generally leave these patients on low-dose steroids indefinitely; however, in the case of her pregnancy, should I stop her steroids?

**A** "If a patient is on topical corticosteroids once a day or every other day, then the amount of absorption of corticosteroid is so low to non-detectable that it is not of much concern," says Kathy Tran, OD, chief of the Cornea, Contact Lenses and Refractive Surgery department at the UC Berkeley School of Optometry. "However, I still advise a patient to pinch the corner of their eyes for two minutes after administration of the medication during the first trimester," to occlude the puncta. The concern, she says, is steroid exposure during the first six to 12 weeks of embryogenesis. "Many medications have the most serious effects on fetal development during the first trimester of pregnancy."

There are approximately 6.5 million pregnancies annually in the United States, and approximately 64% of women are prescribed a drug during pregnancy.<sup>1,2</sup> The FDA categorizes medications, including eye drops, according to the level of potential risk to a fetus if taken during pregnancy. Topical corticosteroids fall within Category C, Dr. Tran says, meaning studies have demonstrated an adverse effect on the fetus in animal models; data on

humans is still inconclusive.

Though the original labeling system has been in place since 1979, recent changes effective June 30, 2015 now address previously missed criteria.

James Aquavella, MD, of the University of Rochester Medical Center, notes that researchers have shown relatively frequent applications of dermatological steroid preparations in pregnant mice were followed by cleft palate changes; however, he adds that he typically prescribes one daily drop of topical steroid followed by punctal compression and has not seen any adverse effects during pregnancy.<sup>3</sup> "My advice is to inform the patient of the risks (unknown) and benefits (i.e., reducing the incidence of graft rejection). If she agrees, continue the low-dose application," he says. "Since most practitioners agree the risk is greater during the first trimester, an alternative would be to slowly taper and stop while observing frequently during this period."

If the patient must use the medication three to four times per day (e.g., early in the post-op course or if the risk of graft rejection is elevated), use greater caution. Dr. Tran recommends nasolacrimal occlusion after each drop to minimize systemic absorption. "I also encourage them to drink a glass of water after each drop is administered," she says. Some clinicians might be more comfortable inserting

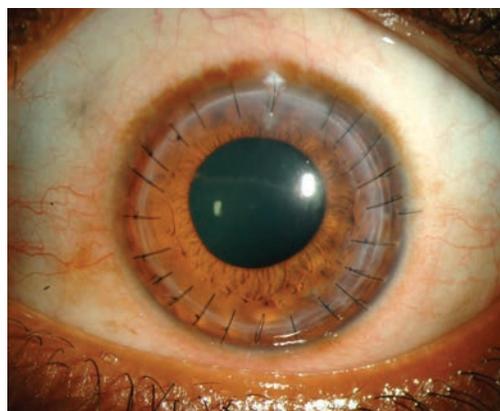


Photo: Christine W. Smith, OD

**Corneal transplantation requires long-term topical steroid use to prevent rejection. But what about in patients who become pregnant?**

punctal plugs during the pregnancy to minimize absorption. Regardless of the method you choose, conduct and document a discussion with the patient's obstetrician.

"Prescribing during pregnancy is always a risk-benefit consideration," Dr. Tran says, who advises optometrists to "carefully weigh the benefit of treatment for any condition in a pregnant patient against the possible risks," however remote, to the developing fetus. Discuss your concerns and offer your best clinical recommendation. If she agrees to use the medication, "document the discussion in the chart and that the benefit of the medication outweighs the risk of teratogenicity." ■

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# See You at the (Neuromuscular) Junction: Part 1

Myasthenia gravis must always be in your differential diagnosis when diplopia, ptosis or both are present. **By Carlo J. Pelino, OD, and Joseph J. Pizzimenti, OD**

**M**yasthenia gravis (MG) is an autoimmune disease that affects the neuromuscular junction and is characterized by fluctuating weakness of the skeletal (voluntary) muscle groups of the body.<sup>1,2</sup> Its name comes from the Greek and Latin words meaning *grave muscular weakness*.<sup>1</sup> Myasthenia gravis is now recognized as one of the best-defined forms of autoimmune disease.

Ocular myasthenia gravis is a form of the disease in which the extraocular muscles and those muscles that control the eyelids are easily fatigued and weakened.<sup>2</sup> Ptosis and extraocular muscle motility deficits are often the first indicators of MG.<sup>1</sup> Ninety percent of patients with generalized myasthenia also have ocular involvement. However, in 20% to 30%

of MG patients, the condition is confined to the eyes.

Other muscles, such as those that control facial expression, chewing, talking and swallowing, are often involved in the disorder. The prevalence of MG in the United States is estimated to be about 20/100,000, although it is likely under-diagnosed.<sup>1-3</sup> MG can occur in all races, both genders and at any age. It most commonly affects young adult women under 40 and older men over 60.<sup>1-3</sup>

## Case Summary

A healthy 59-year-old white male presented with complaints of right upper eyelid droop and painless diplopia on right lateral and up-gaze of five month's duration. When diplopic, he reported that the two images were displaced ver-

tically. His symptoms tended to be worse in the evening. Upon further probing, the patient reported some degree of weakness and fatigue in his arms and legs.

Ophthalmic workup revealed bilateral superior lid ptosis (worse OD) that increased after sustained up-gaze. Binocularity testing revealed a right hypotropia and underaction of the right eye in superior right gaze. Application of an ice pack to the right eye for five minutes led to subjective resolution of the diplopia and an objective improvement in both the ptosis and extraocular movements.

A tentative diagnosis of ocular MG with suspected general MG was established. The patient was referred to a neurology clinic, and acetylcholine receptor (AChR) autoantibodies were subsequently found to be positive. He was successfully treated with pyridostigmine, which relieved the signs and symptoms.

## Causes and Symptoms

In most cases of MG, the etiology occurs from autoantibodies binding to acetylcholine receptors at the neuromuscular junction. Cellular immune responses against the receptor are also found.<sup>2,3</sup> Complement fixation may occur, causing symptoms by direct injury to the post-synaptic membrane, degradation of the receptors themselves or

## The Neuromuscular Junction



**Electron micrograph showing a cross section through the neuromuscular junction. The "T" denotes the axon terminal, and "M" indicates the muscle fiber. The arrow shows junctional folds with basal lamina. Postsynaptic densities are visible on the tips between the folds.**

In order for the body to generate voluntary movement, a nerve impulse originates in the corticospinal tract of the brain, travels to a nerve ending in a muscle and causes it to release acetylcholine. The acetylcholine then travels across the space to the muscle fiber side of the neuromuscular junction, where it attaches to multiple receptor sites. The muscle contracts when enough of the receptor sites have been activated by the acetylcholine.

inhibition of the binding and function of acetylcholine.<sup>2</sup>

The importance of T cells in the pathogenesis of MG is becoming increasingly apparent. The thymus is the central organ in T cell-mediated immunity, and thymic abnormalities such as thymic hyperplasia or thymoma are well recognized in myasthenic patients.

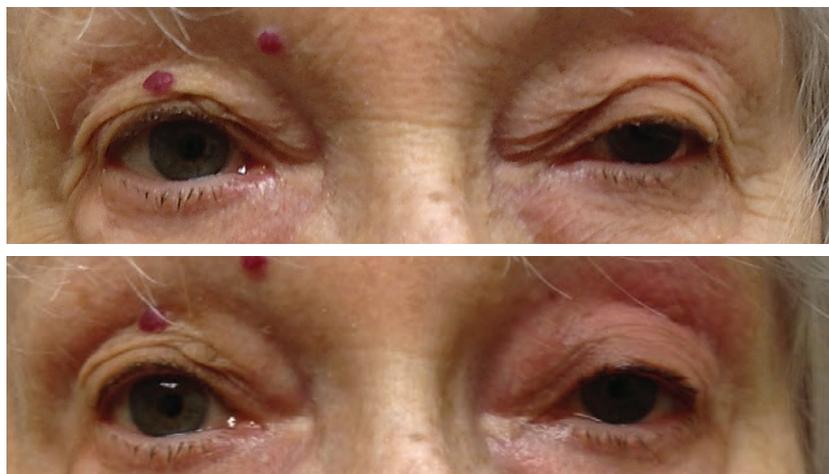
## Put the Freeze on Ocular MG

Establishing a diagnosis of isolated ocular myasthenia can be difficult. Symptomatic response to acetylcholinesterase medications may be equivocal, and AChR auto-antibodies may be absent in up to 30% of those who exhibit ocular symptoms for more than two years. No test for myasthenia gravis is 100% sensitive or specific.<sup>3</sup>

In 1960, Scottish neurologist John A. Simpson hypothesized that MG “is an ‘auto-immune’ response of muscle in which an antibody to end-plate protein may be formed.”<sup>4</sup> The clinical observation that symptoms may improve with cold and worsen with heat and the electrophysiological finding that neuromuscular transmission may improve with local cooling form the rationale for the use of the ‘ice pack test’ in the diagnosis of MG.<sup>5</sup> The ice pack test is performed by applying an ice pack (or holding an ice cube wrapped in a towel) over the levator palpebrae superioris muscle of a ptotic eye for two to five minutes.

A number of studies have reported improvement of myasthenic ptosis following an ice pack test.<sup>6,7</sup> The test is both sensitive and specific for the diagnosis of myasthenia, having no effect on ptosis of other causes, such as oculomotor nerve palsy.

The exact mechanism by which cooling improves myasthenic



Photos: Michael Tralini, OD

**Above, myasthenia gravis OS. Below, ptosis improves a little after the ice pack test.**

muscle function has not been completely explained. Cooling is believed to affect the neuromuscular junction both by decreasing cholinesterase activity and by prompting efficacy of acetylcholine at eliciting depolarizations at the end plate.<sup>1,2,6,7</sup> Researchers in 1979 reported that myasthenic ptosis improved transiently in six eyes after application of ice for five to 10 minutes. Two patients with non-myasthenic ptosis did not show signs of improvement.<sup>8</sup>

More recent research tested 156 patients with an ice pack and edrophonium (Tensilon) with an interval of 15 minutes. Patients were instructed to hold an ice-filled plastic glove on the closed ptotic eyelid. Before and after two min-

utes of ice application, the distance between the upper and lower margin was measured. Patients with positive test results—an increase of 2mm or higher—were considered controls. The ice pack test was positive in all 61 patients who had a positive Tensilon test and in none of the 95 patients with a negative Tensilon test.<sup>9</sup>

If you suspect myasthenia gravis, as you should for patients with ptosis, diplopia or both, the ice pack test is a simple, fast, specific and sensitive option for diagnosis.

In Part 2, we will discuss the diagnosis and treatment of MG. ■

### Common Symptoms of MG

- Ptosis
- Blurred vision
- Diplopia
- Slurred speech
- Difficulty chewing and swallowing
- Weakness in the arms, legs, hands, fingers and neck
- Chronic overall muscle fatigue
- Difficulty breathing
- Unstable gait

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# Acute Vision Loss: Lessons Learned

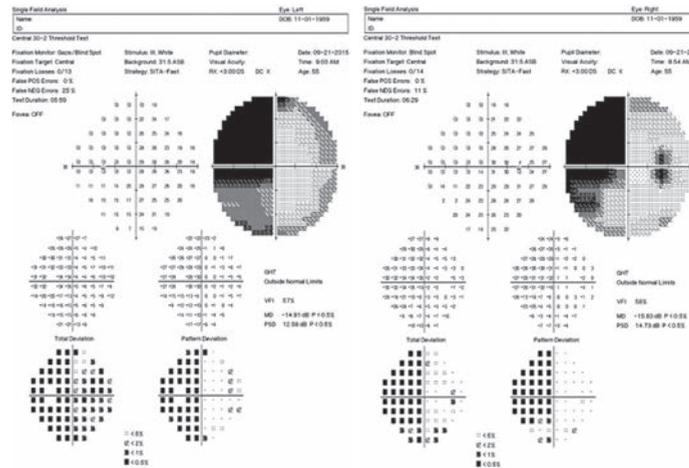
It may be tempting to go with your first diagnosis, but a closer look can reveal multiple pathologies. **By Alan G. Kabat, OD, and Joseph W. Sowka, OD**

A 55-year-old black male with a history of Type 2 diabetes and hypertension presented urgently for evaluation. A regular patient to the clinic, he had been seen six months ago for a comprehensive examination and diagnosed with moderate nonproliferative diabetic retinopathy (DR) in both eyes. At today's visit, he reported a two-day history of vision loss, which developed abruptly. He said he experienced unusual flashes of light, followed by a sudden "darkening" affecting his left eye.

## Evaluation

Examination revealed corrected acuity of 20/25 OU. Pupils were normally reactive and ocular motilities were unrestricted. Visual field testing by confrontation demonstrated severe depression of the superior temporal quadrant of the left eye, but was also noted to affect the superior nasal quadrant of the right eye. Biomicroscopy revealed healthy anterior segment structures; dilated funduscopy showed moderate nonproliferative DR, but no evidence of neovascular scaffolding, vitreous hemorrhage or retinal detachment in either eye. Ultimately, an automated field analysis was performed, demonstrating a dense, homonymous hemianopic defect of the left visual field, denser above than below the horizontal midline.

Although the patient's chief complaint seemed to indicate a retinal etiology, testing quickly confirmed this was a neuro-ophthalmic event.



**This 55-year-old diabetic patient's field analysis shows a dense, homonymous hemianopic defect of the left visual field, denser above than below the horizontal midline.**

Wise clinicians analyze patients' complaints within the context of the ocular and medical history to arrive at a logical presumptive diagnosis. Sometimes, however, the most obvious diagnosis is not the correct one. We learned this principle from professor Lou Catania, OD, quoting Hickam's dictum: "The patient may have as many diseases as he or she pleases."

In this case, DR complications or rhegmatogenous retinal detachment appeared likely, but a thorough evaluation revealed another suspect: cerebrovascular disease.

## A Roadmap to the Brain

Visual field testing provides insight into the integrity of the visual pathway. The visual pathway is exquisitely organized as it traverses the entire length of the brain, from an area just beneath the frontal lobe to the tip of the occipital cortex. Nerve fibers originating in the nasal retina cross at the level

of the optic chiasm, traveling with contralateral temporal fibers to the lateral geniculate nucleus where they synapse. Post-geniculate fibers split into superior and inferior pathways, traveling through the parietal and temporal lobes, respectively, as they course posteriorly in the brain. As they reach the occipital lobe (the primary visual cortex), the superior and inferior fibers are reunited.

Because of this extraordinarily detailed and consistent arrangement, lesions of the visual pathway result in predictable and repeatable visual field defects. The late Larry Gray, OD, used to tell us "visual fields read like a roadmap to the brain." The implication is, if you can understand the architecture of the pathways and the nuances of visual field defects, you can potentially pinpoint the precise location of the intracranial pathology.

As we know, purely unilateral field defects typically reflect pre-chiasmal lesions, either within the

retina or optic nerve. Lesions of the chiasm—most commonly pituitary gland tumors or craniopharyngiomas—result in bitemporal, heteronymous field defects. Post-chiasmal lesions result in homonymous field defects, i.e., affecting the same side (right or left) of the visual field and respecting the vertical midline. Damage to the optic radiations in the temporal or parietal lobe results in a quadrantanopia, impacting the superior or inferior field, respectively. These field defects will cross neither the vertical midline nor the horizontal midline. Lesions of the occipital lobe result in homonymous hemianopias, contralateral to the side of the lesion (i.e., a right-sided field defect with a left-sided lesion and vice-versa).

Also important in the localization of visual field defects is the concept of congruity. Congruity refers to the similarity in shape and depth of the visual field defect in each eye. In essence, the more the field loss in one eye appears to be a “carbon copy” of the other, the greater the level of congruity.

For pathology affecting the post-chiasmal pathways, the accepted convention is that greater congruity is associated with more posteriorly located lesions.<sup>1</sup> However, this is not an absolute rule. One study demonstrates congruous visual field defects encountered in ≥50% of lesions to the optic tract or optic radiations, although 84% of occipital lobe lesions produced congruous field defects.<sup>2</sup> Also, the vast majority of incongruous visual field defects occur with lesions to the optic radiations, which are located more anteriorly.<sup>2</sup> One important caveat to this rule is that only incomplete homonymous hemianopias may be described as congruous or incongruous. By definition, an

incomplete hemianopia spares at least part of the vision on the affected side. Complete homonymous hemianopias have no localizing value, except to say that they are post-chiasmal.<sup>1</sup>

## Findings

Our patient was found to have an incomplete, moderately congruous, left homonymous hemianopia, denser above than below the horizontal midline. Due to the abrupt onset of symptoms, we suspected a cerebrovascular accident affecting the posterior optic radiations or anterior occipital cortex. The pattern of the visual field defect is also more indicative of stroke than other intracranial abnormalities, such as traumatic brain injury, cerebral hemorrhage or compressive tumor.<sup>2</sup> The patient was advised that he had likely suffered an isolated stroke which caused him to experience vision loss. He later revealed he'd been suffering from a headache on the right side, behind his ear (the occipital region).

## Further Recommendations

The patient was referred to his primary care physician with a request for an MRI with contrast of the area in question, to be performed within 24 to 48 hours. Additionally, a comprehensive neurological evaluation was requested to rule out any additional compromise. Once confirmed, treatment goals for isolated stroke are aimed at controlling modifiable risk factors that could predispose to subsequent CVAs. This includes tighter control of comorbidities such as diabetes, hypertension, hypercholesterolemia, hyperlipidemia and obesity. The use of aspirin as a platelet anti-aggregant may be advisable in those with significant intracranial arterial ste-

nosis.<sup>3</sup> Smoking cessation (including avoidance of second-hand smoke), a low-fat diet and regular exercise are also typically encouraged.<sup>4</sup>

Optometric management depends on the extent of field loss and the degree of recovery following the stroke. According to research, the majority of recovery occurs within the first 60 days after the initial event, and recovery after six months is highly unlikely.<sup>5</sup> Patients with residual field deficit following stroke may benefit from vision rehabilitation, including such elements as prismatic correction and compensatory training to improve visual search abilities.<sup>1</sup> Vision restorative training (VRT) may provide a mechanism to regain visual function at the border of the visual field defect, although studies with this system have yielded conflicting and inconclusive results.<sup>6,7</sup> ■

*Our thanks to the following individuals for helping to inspire this article: Mr. Matthew Hennen (SCO '16), Dr. Leah Stevens and Dr. Robert Goodwin (via ODs on Facebook).*

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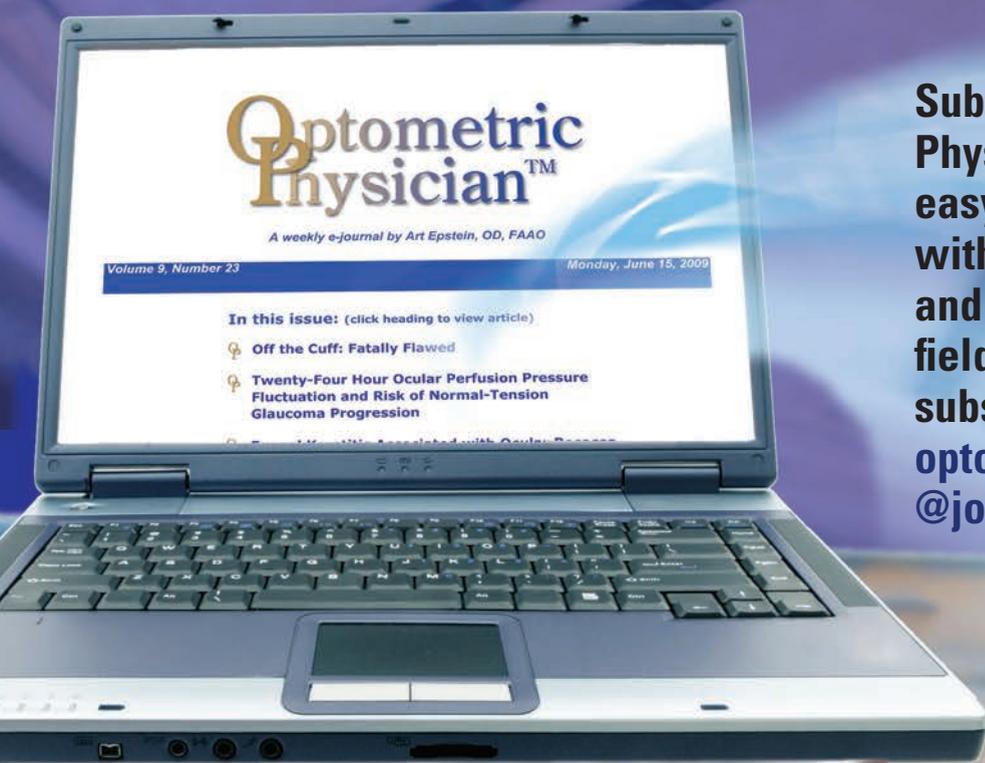


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## ICE, ICE, Baby

A new combination procedure can help patients undergoing cataract surgery who have open-angle glaucoma. **By Justin Schweitzer, OD**

When we hear “ICE,” we think of Iceman from the blockbuster *Top Gun* or the hip-hop single “Ice Ice Baby.” Recently in eye care, however, the term refers to a new procedure combining the placement of an iStent trabecular micro-bypass stent (Glaukos), cataract surgery and endocyclophotocoagulation (ECP) for patients with cataracts and open-angle glaucoma. Combining a trabecular micro-bypass stent, which increases aqueous outflow, with ECP, which decreases aqueous production, can be an effective option for glaucoma patients.

While cataract surgery alone can lower IOP, more advanced glaucoma patients need more aggressive IOP lowering.<sup>1</sup> Combining minimally invasive glaucoma surgeries and cataract surgery can potentially provide this, and a greater safety profile than traditional filtration surgeries.

### iStent

The insertion of a single stent and, at times, multiple stents (although not FDA approved) through the same corneal incision used during cataract surgery serves as a bypass through the trabecular meshwork. This allows greater physiological outflow and, therefore, lower IOP. A study revealed that 66% of eyes treated with cataract surgery and a glau-



**After iStent implantation, the surgeon inserts the ECP probe for the final step.**

coma stent achieved a greater than 20% reduction in IOP without medications vs. 48% of eyes treated with cataract surgery alone.<sup>2</sup> In addition, the overall safety profile was similar to cataract surgery alone.<sup>2,3</sup>

### Endocyclophotocoagulation

ECP uses a diode laser and video imaging integrated into a fiber-optic system delivered through a probe to ablate the ciliary body processes. The coagulation and scarring of the ciliary body processes leads to a decrease in aqueous production, resulting in a reduction in IOP. A study revealed patients who underwent either phacoemulsification alone or phacoemulsification combined with ECP showed greater benefit in the combined group with no increased risk of complications.<sup>4</sup>

### Advantages

These surgeries complement each other well and address both inflow and outflow of aqueous. Patients with mild to moderate open-angle glaucoma and a cataract who are using multiple IOP-lowering medica-

tions are generally ideal candidates. Patient satisfaction can be high with ICE, as no external sutures, common with trabeculectomies, are placed and postoperative visual recovery is rapid. ICE also carries no risk of bleb-related infections or bleb leaks.

### Postoperative Care

Postoperatively, ICE is managed with a typical post-cataract regimen of topical steroid, NSAID, plus a topical antibiotic for prophylaxis. IOP may fluctuate due to steroid use and viscoelastic issues. As IOP improves and stabilizes, the patient may reduce their dependence on glaucoma drops. The emergence of antibiotic-steroid injections, such as TriMoxiVanc/TriMoxi, is another option some eye care centers use. The injection of this combination medication can help avoid the postoperative inflammation common with ECP. ■

*Dr. Schweitzer is a cornea, glaucoma, cataract and refractive surgery specialist at Vance Thompson Vision in Sioux Falls, SD.*

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**THE OPTOMETRIC RETINA SOCIETY  
AND REVIEW OF OPTOMETRY PRESENT:**

# RETINA UPDATE 2015



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Joseph Pizzimenti, OD



Brad Sutton, OD

## Featured Faculty



Hajir Dadgostar, MD, PhD  
Distinguished Retinal Surgeon



Stuart Richer, OD



Jeffrey Austin, OD



Jeffry Gerson, OD



Steve Ferrucci, OD

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“The mission of the Optometric Retina Society (ORS) is to promote the advancement of vitreoretinal knowledge for clinicians, ophthalmic educators, residents, and students. The ORS is dedicated to posterior segment disease prevention, diagnosis, management and co-management.”

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- Nutrition and Genetics in Retinal Wellness
- New Paradigms in Retinal Vascular Disease
- Vitreoretinal Grand Rounds
- Medical and Surgical Retina Update
- Macular Holes and Epiretinal Membranes
- What's New in Retinal Imaging

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# Product Review

## Practice Management

### Optometry-Specific EMR

Clinicians now have an EMR system designed specifically for eye care practices.

MDoffice recently launched ODOoffice, which incorporates business rules in the workflow based on ideas, input and insights gleaned from eye care professionals, the company says.

This product was designed to cater to a huge demand from optometrists who wanted an EMR system adapted to their specific needs, including opticals, refractive disorder management, patient records and comanagement for complete treatment, according to the company.

Visit [www.ODOoffice.com](http://www.ODOoffice.com).

### Dispensary Training Platform

Eye care practitioners and staff looking to improve their dispensary skills can consider Zeiss' new Zeiss Academy Vision Care, an online campus to help ECPs develop office skills.

The course content falls into three areas:

- Optical science courses: fundamentals of optics, fitting and dispensing.
- Product courses: the latest products and technologies with an emphasis on matching products to patient needs.
- Selling courses: enhance patient interactions, better meet patient needs and increase premium product sales, according to Zeiss.

The site tracks progress and allows you to pick up where you left off and provides personalized certificates for courses completed.

Visit [www.zeiss.com/e-learning](http://www.zeiss.com/e-learning).

## Diagnostic Technology

### Ocular Allergy Diagnostic Test

Eye care providers looking for a convenient way to manage allergy and distinguish ocular surface disease



pathology can consider the Doctor's Allergy Formula no-needle diagnostic test, recently acquired by Bausch + Lomb. Eye care providers can use the test

to identify the source of ocular allergies in-office to help determine the most appropriate treatment for patients, the company says.

Visit [www.drallergyformula.com](http://www.drallergyformula.com).

### Automated Specular Microscope

Topcon Medical Systems' SP-1P fully automated specular microscope, designed for analysis of the corneal endothelium, is available now.

A 10.4in. rotating touch panel monitor allows for instrument operation from almost any position without a lever. Some of the SP-1P's features include:

- Wide-angle photography mode.
- Automatic measurement and analysis of the endothelium.
- Easy-to-read screen, analysis software and a color histogram after the analysis.

Visit [www.topconmedical.com](http://www.topconmedical.com).



## Contact Lenses

### Tear-infused Contact Lenses

Patients looking for a new option in comfort can now try the new Acuvue Oasys 1-Day with HydraLuxe Technology by Johnson & Johnson. The new lens uses tear-like molecules to mimic the eye's natural mucins, the company says.

According to Johnson & Johnson, four technology advances help address the need for day-long comfort during modern life's daily demands:

- Tear-infused material integrates with the wearers' own tear film.
- Electrolyte-balanced packaging solution.
- Enlarged optics to help patients see clearly even when pupils may be enlarged due to low light.
- Increased lens diameter for full corneal limbus coverage during blinking.

Visit [www.acuvueprofessional.com/products](http://www.acuvueprofessional.com/products).



### New Plus Powers

Hyperopic patients can now try the new plus power Dailies Total1 contact lenses by Alcon. The daily disposable lenses, with Alcon's water gradient technology, are designed to mimic the cornea's environment, according to Alcon. Dailies Total1 are available with a power range of -0.50D to -6.00D in 0.25 steps and -6.50D to -10.00D in 0.50 steps. The latest release adds +0.50D to +6.00D in 0.25D steps.

Visit [www.dailies.com](http://www.dailies.com).

## November 2015

■ **21-22.** *Everything Therapeutic – San Antonio.* Westin Riverwalk Hotel, San Antonio, TX. Hosted by: University of Houston College of Optometry. Key faculty: Bruce Onofrey. CE hours: 16. To register, email [optce@uh.edu](mailto:optce@uh.edu), call (713) 743-1900 or go to [ce.opt.uh.edu/](http://ce.opt.uh.edu/).

■ **22.** *Clinical Chiefs Optometry Update.* Marshall B. Ketchum University, Fullerton, CA. Hosted by: SCCO at Marshall B. Ketchum University. Key faculty: Mark Sawamura. CE hours: 8. To register, email [ce@ketchum.edu](mailto:ce@ketchum.edu), call (714) 449-7495 or go to [www.ketchum.edu/ce](http://www.ketchum.edu/ce).

## December 2015

■ **2-6.** *OEP Clinical Curriculum: VT/Visual Dysfunctions.* Office of Robert Lewis, Phoenix. Hosted by: OEP Foundation. Key faculty: Robert Lewis. CE hours: 35. To register, email Theresa Krejci at [TheresaKrejciOEP@verizon.net](mailto:TheresaKrejciOEP@verizon.net) or go to [www.oepf.org](http://www.oepf.org).

■ **5.** *Retina Update 2015.* Anaheim, CA. Hosted by: *Review of Optometry* and Optometric Retina Society. Key faculty: Brad Sutton, Joseph Pizzimenti. CE hours: 12. To register, email Lois DiDomenico at [ReviewMeetings@jobson.com](mailto:ReviewMeetings@jobson.com), call (866) 658-1772 or go to [www.reviewofoptometry.com](http://www.reviewofoptometry.com).

■ **5-6.** *Malinovsky Ocular Disease Seminar.* Bloomington, IN. Hosted by: IU School of Optometry. Key faculty: Todd Peabody, Jeff Perotti, Don Lyon, Tony Van Alstine, Patty Henderson. CE hours: 14. To register, email Cheryl Oldfield at [coldfiel@indiana.edu](mailto:coldfiel@indiana.edu) or go to [www.opt.indiana.edu/ce/seminars.htm](http://www.opt.indiana.edu/ce/seminars.htm).

■ **5-6.** *32nd Annual Cornea, Contact Lens & Contemporary Vision Care Symposium.* Westin Memorial City Hotel, Houston. Hosted by: University of Houston College of Optometry. Key faculty: Jan Bergmanson. CE hours: 16. To register, email [optce@uh.edu](mailto:optce@uh.edu), call (713) 743-1900 or go to [ce.opt.uh.edu/](http://ce.opt.uh.edu/).

■ **6.** *Annual GP Lens Symposium.* Marshall B. Ketchum University, Fullerton, CA. Hosted by: SCCO at Marshall B. Ketchum University. Key faculty: Barry Weissman, Brooke Messer. CE hours: 8. To register, email [ce@ketchum.edu](mailto:ce@ketchum.edu), call (714) 449-7495 or go to [www.ketchum.edu/ce](http://www.ketchum.edu/ce).

■ **26-Jan. 2.** *Seminar in Paradise.* MSC Cruise Line's Divina, Western Caribbean Cruise, Departs Miami, FL. Hosted by: Dr. Travel Seminars/The New Jersey Society of Optometric Physicians. CE hours: 16. To register, email Robert Pascal at [info@DrTravel.com](mailto:info@DrTravel.com), call (800) 436-1028 or go to [DrTravel.com](http://DrTravel.com).

## January 2016

■ **9.** *Glaucoma Symposium 2016.* Willows Lodge, Woodinville, WA. Hosted by: Pacific University College of Optometry. Key faculty: Howard Barnebey, Murray Fingeret. CE hours: 7. To register, email Martina Fredericks at [frederim@pacificu.edu](mailto:frederim@pacificu.edu), call (503) 352-2207 or go to [www.pacificu.edu](http://www.pacificu.edu).

■ **9.** *2016 Coding Update.* Embassy Suites Little Rock, Little Rock, AK. Hosted by: Arkansas Optometric Association. Key faculty: John McGreal. CE hours: 5. To register, email Vicki Farmer at [aroa@arkansasoptometric.org](mailto:aroa@arkansasoptometric.org), call (501) 661-7675 or go to [arkansasoptometric.org](http://arkansasoptometric.org).

■ **11.** *2016 Legislative Conference.* Capitol Plaza Hotel, Jefferson City, MO. Hosted by: Missouri Optometric Association. Key faculty: Alan Cleinman. CE hours: 3. To register, contact Lee Ann Barrett at [moaed@moeyecare.org](mailto:moaed@moeyecare.org), call (573) 635-6151 or go to [www.moeyecare.org](http://www.moeyecare.org).

■ **16-17.** *Gold Coast Educational Retreat.* Hyatt Regency Pier 66, Fort Lauderdale, FL. Hosted by: Broward County Optometric Association. Key faculty: Randall Thomas, Ron Melton, Tim Murray, Roger Prouty, Cory Collier, Joseph Sowka, Joseph Pizzimenti. CE hours: 17. To register, email [bcoa@browardeyes.org](mailto:bcoa@browardeyes.org) or go to [browardeyes.org](http://browardeyes.org).

■ **16-18.** *Kraskin Invitational Skeffington Symposium on Vision (KISS).* Hyatt Regency, Bethesda, MD. Hosted by: Optometric Extension Program Foundation (OEPF). CE hours: 19. To register, email Jeffrey Kraskin at [jlkraskin@rcn.com](mailto:jlkraskin@rcn.com), call (202) 363-4450 or go to [www.skeffingtonsymposium.org](http://www.skeffingtonsymposium.org).

■ **17.** *IOA Winter CE Series.* Westin Chicago North Shore, Wheeling, IL. Hosted by: Illinois Optometric Association. Key faculty: Len Messner. CE hours: 6. To register, email Charlene Marsh at [ioabb@ioaweb.org](mailto:ioabb@ioaweb.org) or go to [www.ioaweb.org](http://www.ioaweb.org).

■ **17-23.** *2016 Island Eyes Conference.* Sheraton Maui Resort, Lahaina, Maui, HI. Hosted by: Pacific University. Key faculty: Denise Goodwin, Nathan Lighthizer, Leo Skorin, Stanley Teplick, Samuel Kim. CE hours: 29. To register, email Jeanne Oliver at [jeanne@pacificu.edu](mailto:jeanne@pacificu.edu), call (503) 352-2740 or go to [www.pacificu.edu/IslandEyes](http://www.pacificu.edu/IslandEyes).

■ **24.** *IOA Winter CE Series.* Hyatt Regency O'Hare, Rosemont, IL. Hosted by: Illinois Optometric Association. Key faculty: Paul Karpecki. CE hours: 6. To register, email Charlene Marsh at [ioabb@ioaweb.org](mailto:ioabb@ioaweb.org), call (217) 525-8012 or go to [www.ioaweb.org](http://www.ioaweb.org).

■ **30.** *Georgia Optometric Association Super CE.* Georgia International Convention Center, College Park, GA. Hosted by: Georgia Optometric Association. CE hours: 8. To register, email Vanessa Grosso at [VanessaGOA@aol.com](mailto:VanessaGOA@aol.com), call (770) 961-9866 x-1 or go to <http://hleachgoa.wix.com/goaeyes>.

■ **31.** *VOA 1 Day CE Conference.* Richmond Marriott West, Glen Allen, VA. Hosted by: Virginia Optometric Association. CE hours: 4. To register, email Bo Keeney at [Office@thevoa.org](mailto:Office@thevoa.org), call (804) 643-0309 or go to [www.thevoa.org](http://www.thevoa.org).

## February 2016

■ **3-4.** *Michigan Optometric Association Winter Seminar.* Kellogg Hotel and Conference Center of Michigan State

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University, East Lansing, MI. Hosted by: Michigan Optometric Association. Key faculty: Steven Ferrucci, Marc Bloomenstein. CE hours: 12. To register, email Amy Root at [amy@themoa.org](mailto:amy@themoa.org), call (517) 482-0616 or go to [www.themoa.org](http://www.themoa.org).

■ **8.** *IOP Winter CE.* The Grove Hotel, Boise, ID. Hosted by: Idaho Optometric Physicians. CE hours: 4. To register, email Randy Andregg at [execdir@iopinc.org](mailto:execdir@iopinc.org), call (208) 461-0001 or go to [Idaho.aoa.org](http://Idaho.aoa.org).

■ **12-14.** *Heart of America Contact Lens Society.* Sheraton Crown Center, Kansas City, MO. Hosted by: HOACLS. Key faculty: Paul Ajamian, Michael Chaglasian, Joseph Sowka, Valerie Kattouf, Jeffry Gerson. CE hours: 77 total, 15 per OD. To register, email Ron Fiegel at [registration2@thehoaccls.org](mailto:registration2@thehoaccls.org) or go to [www.hoaccls.org](http://www.hoaccls.org).

■ **12-16.** *SkiVision.* Westin Snowmass Resort, Snowmass Village, CO. Hosted by: SkiVision, Review of Optometry. Key faculty: Murray Fingeret, John Flanagan, Ian Ben Gaddie, Jack Schaeffer, Jay Haynie, Kathy Dumbleton. CE hours: 20. To register, email Lois DiDomenico at [ldidomenico@jobson.com](mailto:ldidomenico@jobson.com), call (610) 492-1018 or go to [www.skivision.com](http://www.skivision.com).

■ **13.** *OAL Mid-Winter CE Conference.* DoubleTree Hotel, Lafayette, LA. Hosted by: Optometry Association of Louisiana. CE hours: 8. To register, email Jim Sandefur at [optla@bellsouth.net](mailto:optla@bellsouth.net), call (318) 613-1392 or go to [www.optla.org](http://www.optla.org).

■ **13-20.** *Innovations in Eye Care.* Western Caribbean Cruise from Fort Lauderdale, FL. Hosted by: Dr. Travel Seminars, LLC. Key faculty: Robert Wooldridge. CE hours: 16. To register, email Robert Pascal at [DrTravel@aol.com](mailto:DrTravel@aol.com), call (800) 436-1028 or go to [www.drtravel.com/optometristsSeminars.html](http://www.drtravel.com/optometristsSeminars.html).

■ **14.** *IOA Winter CE Series.* Marriott Bloomington-Normal Convention Center, Bloomington/Normal, IL. Hosted by: Illinois Optometric Association. Key faculty: Michael Chaglasian. CE hours: 6. To register, email Charlene Marsh at [ioabb@ioaweb.org](mailto:ioabb@ioaweb.org), call 217-525-8012 or go to [www.ioaweb.org](http://www.ioaweb.org).

■ **14-24.** *AEA Cruises Canary Island's Optometric Cruise Seminar.* Aboard NCL Epic, Barcelona, Spain. Hosted by: AEA Cruises. CE hours: 10. To register, email Marge McGrath at [aea-cruises@aol.com](mailto:aea-cruises@aol.com), call (888) 638-6009 or go to [www.optometric-cruiseseminars.com](http://www.optometric-cruiseseminars.com).

■ **19-21.** *32nd Annual Palm Beach Winter Seminar.* Hilton West Palm Beach, Florida. Hosted by: Palm Beach County Optometric Association. CE hours: 20+. To register, email [PBWinterSeminar@gmail.com](mailto:PBWinterSeminar@gmail.com) or go to [www.pbcoa.org](http://www.pbcoa.org).

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## BRIEF SUMMARY OF PRESCRIBING INFORMATION INDICATIONS AND USAGE

SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

### DOSE AND ADMINISTRATION

The recommended dose is one drop of SIMBRINZA® Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA® Suspension 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.

### DOSE FORMS AND STRENGTHS

Suspension containing 10 mg/mL brinzolamide and 2 mg/mL brimonidine tartrate.

### CONTRAINDICATIONS

**Hypersensitivity** - SIMBRINZA® Suspension is contraindicated in patients who are hypersensitive to any component of this product.

**Neonates and Infants (under the age of 2 years)** - SIMBRINZA® Suspension is contraindicated in neonates and infants (under the age of 2 years) *see Use in Specific Populations*

### WARNINGS AND PRECAUTIONS

**Sulfonamide Hypersensitivity Reactions** - SIMBRINZA® Suspension contains brinzolamide, a sulfonamide, and although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of SIMBRINZA® Suspension. Fatalities have occurred due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation *[see Patient Counseling Information]*

**Corneal Endothelium** - Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing SIMBRINZA® Suspension to this group of patients.

**Severe Renal Impairment** - SIMBRINZA® Suspension has not been specifically studied in patients with severe renal impairment (CrCl < 30 mL/min). Since brinzolamide and its metabolite are excreted predominantly by the kidney, SIMBRINZA® Suspension is not recommended in such patients.

**Acute Angle-Closure Glaucoma** - The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. SIMBRINZA® Suspension has not been studied in patients with acute angle-closure glaucoma.

**Contact Lens Wear** - The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension but may be reinserted 15 minutes after instillation *[see Patient Counseling Information]*.

**Severe Cardiovascular Disease** - Brimonidine tartrate, a component of SIMBRINZA® Suspension, has a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

**Severe Hepatic Impairment** - Because brimonidine tartrate, a component of SIMBRINZA® Suspension, has not been studied in patients with hepatic impairment, caution should be exercised in such patients.

**Potential of Vascular Insufficiency** - Brimonidine tartrate, a component of SIMBRINZA® Suspension, may potentiate syndromes associated with vascular insufficiency. SIMBRINZA® Suspension should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

**Contamination of Topical Ophthalmic Products After Use** - There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface *[see Patient Counseling Information]*.

### 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 the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

**SIMBRINZA® Suspension** - In two clinical trials of 3 months duration 435 patients were treated with SIMBRINZA® Suspension, and 915 were treated with the two individual components. The most frequently reported adverse reactions in patients treated with SIMBRINZA® Suspension occurring in approximately 3 to 5% of patients in descending order of incidence were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Rates of adverse reactions reported with the individual components were comparable. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA® Suspension patients.

Other adverse reactions that have been reported with the individual components during clinical trials are listed below.

**Brinzolamide 1%** - In clinical studies of brinzolamide ophthalmic suspension 1%, the most frequently reported adverse reactions

reported in 5 to 10% of patients were blurred vision and bitter, sour or unusual taste. Adverse reactions occurring in 1 to 5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

The following adverse reactions were reported at an incidence below 1%: allergic reactions, alopecia, chest pain, conjunctivitis, diarrhea, diplopia, dizziness, dry mouth, dyspnea, dyspepsia, eye fatigue, hypertonia, keratoconjunctivitis, keratopathy, kidney pain, lid margin crusting or sticky sensation, nausea, pharyngitis, tearing and urticaria.

**Brimonidine Tartrate 0.2%** - In clinical studies of brimonidine tartrate 0.2%, adverse reactions occurring in approximately 10 to 30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Reactions occurring in approximately 3 to 9% of the subjects, in descending order included corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain.

The following adverse reactions were reported in less than 3% of the patients: lid crusting, conjunctival hemorrhage, abnormal taste, insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.

**Postmarketing Experience** - The following reactions have been identified during postmarketing use of brimonidine tartrate ophthalmic solutions in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to brimonidine tartrate ophthalmic solutions, or a combination of these factors, include: bradycardia, hypersensitivity, iritis, keratoconjunctivitis sicca, miosis, nausea, skin reactions (including erythema, eyelid pruritus, rash, and vasodilation), and tachycardia.

Apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine tartrate ophthalmic solutions *[see Contraindications]*.

### DRUG INTERACTIONS

**Oral Carbonic Anhydrase Inhibitors** - There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and brinzolamide ophthalmic suspension 1%, a component of SIMBRINZA® Suspension. The concomitant administration of SIMBRINZA® Suspension and oral carbonic anhydrase inhibitors is not recommended.

**High-Dose Salicylate Therapy** - Carbonic anhydrase inhibitors may produce acid-base and electrolyte alterations. These alterations were not reported in the clinical trials with brinzolamide ophthalmic suspension 1%. However, in patients treated with oral carbonic anhydrase inhibitors, rare instances of acid-base alterations have occurred with high-dose salicylate therapy. Therefore, the potential for such drug interactions should be considered in patients receiving SIMBRINZA® Suspension.

**CNS Depressants** - Although specific drug interaction studies have not been conducted with SIMBRINZA® Suspension, the possibility of an additive or potentiating effect with CNS depressants (alcohol, opiates, barbiturates, sedatives, or anesthetics) should be considered.

**Antihypertensives/Cardiac Glycosides** - Because brimonidine tartrate, a component of SIMBRINZA® Suspension, may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with SIMBRINZA® Suspension is advised.

**Tricyclic Antidepressants** - Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with SIMBRINZA® Suspension in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

**Monoamine Oxidase Inhibitors** - Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine tartrate and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

### USE IN SPECIFIC POPULATIONS

**Pregnancy** - *Pregnancy Category C*: Developmental toxicity studies with brinzolamide in rabbits at oral doses of 1, 3, and 6 mg/kg/day (20, 60, and 120 times the recommended human ophthalmic dose) produced maternal toxicity at 6 mg/kg/day and a significant increase in the number of fetal variations, such as accessory skull bones, which was only slightly higher than the historic value at 1 and 6 mg/kg. In rats, statistically decreased body weights of fetuses from dams receiving oral doses of 18 mg/kg/day (180 times the recommended human ophthalmic dose) during gestation were proportional to the reduced maternal weight gain, with no statistically significant effects on organ or tissue development. Increases in unossified sternebrae, reduced ossification of the skull, and unossified hyoid that occurred at 6 and 18 mg/kg were not statistically significant. No treatment-related malformations were seen. Following oral administration of <sup>14</sup>C-brinzolamide to pregnant rats, radioactivity was found to cross the placenta and was present in the fetal tissues and blood.

Developmental toxicity studies performed in rats with oral doses of 0.66 mg brimonidine base/kg revealed no evidence of harm to the fetus. Dosing at this level resulted in a plasma drug concentration

approximately 100 times higher than that seen in humans at the recommended human ophthalmic dose. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent.

There are no adequate and well-controlled studies in pregnant women. SIMBRINZA® Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers** - In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring at an oral dose of 15 mg/kg/day (150 times the recommended human ophthalmic dose) were observed during lactation. No other effects were observed. However, following oral administration of <sup>14</sup>C-brinzolamide to lactating rats, radioactivity was found in milk at concentrations below those in the blood and plasma. In animal studies, brimonidine was excreted in breast milk.

It is not known whether brinzolamide and brimonidine tartrate are excreted in human milk following topical ocular administration. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use** - The individual component, brinzolamide, has been studied in pediatric glaucoma patients 4 weeks to 5 years of age. The individual component, brimonidine tartrate, has been studied in pediatric patients 2 to 7 years old. Somnolence (50-83%) and decreased alertness was seen in patients 2 to 6 years old. SIMBRINZA® Suspension is contraindicated in children under the age of 2 years *[see Contraindications]*.

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

### OVERDOSAGE

Although no human data are available, electrolyte imbalance, development of an acidotic state, and possible nervous system effects may occur following an oral overdose of brinzolamide. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Very limited information exists on accidental ingestion of brimonidine in adults; the only adverse event reported to date has been hypotension. Symptoms of brimonidine overdose have been reported in neonates, infants, and children receiving brimonidine as part of medical treatment of congenital glaucoma or by accidental oral ingestion. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

### PATIENT COUNSELING INFORMATION

**Sulfonamide Reactions** - Advise patients that if serious or unusual ocular or systemic reactions or signs of hypersensitivity occur, they should discontinue the use of the product and consult their physician.

**Temporary Blurred Vision** - Vision may be temporarily blurred following dosing with SIMBRINZA® Suspension. Care should be exercised in operating machinery or driving a motor vehicle.

**Effect on Ability to Drive and Use Machinery** - As with other drugs in this class, SIMBRINZA® Suspension may cause fatigue and/or drowsiness in some patients. Caution patients who engage in hazardous activities of the potential for a decrease in mental alertness.

**Avoiding Contamination of the Product** - Instruct patients that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions *[see Warnings and Precautions]*. Always replace the cap after use. If solution changes color or becomes cloudy, do not use. Do not use the product after the expiration date marked on the bottle.

**Intercurrent Ocular Conditions** - Advise patients that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

**Concomitant Topical Ocular Therapy** - If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

**Contact Lens Wear** - The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension, but may be reinserted 15 minutes after instillation.

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6,316,441

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## Yellow: Proceed With Caution

By Andrew S. Gurwood, OD

### History

A 34-year-old white male was admitted to the hospital after being referred for an ophthalmic consult by his internal medicine team. The patient reported no ocular or visual complaints and had an unremarkable ocular history.

His medical history was positive for alcohol-induced cirrhosis of the liver. The remainder of his surgical and medical histories were non-contributory. The patient was not currently taking medication and denied any drug allergies.

### Diagnostic Data

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

The pertinent external findings

are documented in the photograph. The biomicroscopic examination of the anterior segment was unremarkable and Goldmann applanation tonometry measured 15mm Hg OU.

The dilated fundus examination was within normal limits with normal cupping measuring 0.2/0.2 and quiet peripheries.

### Your Diagnosis

Does this case require any additional tests? What does this patient's history and clinical findings tell you about his likely diagnosis? How would you manage this patient? What's the patient's likely prognosis? To find out, please visit us online at [www.reviewofoptometry.com](http://www.reviewofoptometry.com). ■



**This 34-year-old male patient presented with yellowed eyes and skin, but 20/20 vision in both eyes. Can his history aid in his diagnosis?**

### Next Month in the Mag

In December, *Review of Optometry* focuses on pediatrics in its 20th annual comanagement report. Topics include:

- *ACA Children's Vision Health Benefit: Boom or Bust?*

Learn how you can better serve the millions of children in the United States with undetected vision problems who now have access to a comprehensive ophthalmic examination.

- *Systemic Management of Pediatric Ocular Disease*

Dosing of systemic medications for the pediatric population is not a simple linear calculation based on the size of an individual. Read more about what you must consider when dosing systemic medications for children and young adults.

- *Amblyopia: When to Treat, When to Refer?*

Amblyopia is a condition that is often diagnosed at a patient's first eye examination and can be managed in a general optometric practice. Learn how to diagnose and manage this condition, as well as educate patients on the importance of treating amblyopia.

- *How to Coordinate Care for Congenital Retinal Disorders*

Managing diseases of the retina that present in the youngest patients requires attention to details. Here's a look at how to follow up on these unique patients.

Also in this issue:

- *Comanaging Traumatic Brain Injury*

Visual symptoms of TBI can impair rehabilitation and create significant restrictions with occupational, educational and other activities of daily living. Hone your knowledge of potential visual and ophthalmic changes following TBI.

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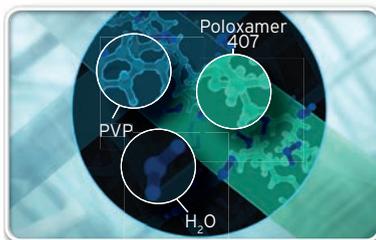
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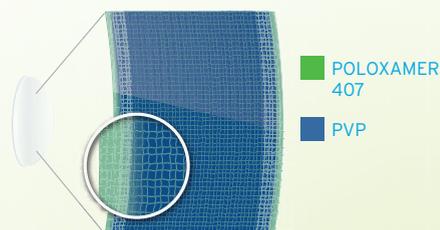
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\* **WARNING:** UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. You should continue to use UV-absorbing eyewear as directed. NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders.

**REFERENCE: 1.** Multiple-Packaged Lenses Comparison, Tyler's Quarterly - Professional Edition, September 2013 **2.** Twenty-two subjects participated in a randomized, double masked, contralateral eye study to evaluate water loss of Biotrue ONEday, 1-Day Acuvue Moist, 1-Day Acuvue TruEye contact lenses. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry wet). The percent water loss was then calculated for each lens from the wet and dry weights.

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See better. Live better.

# ADD SIMBRINZA® Suspension to a PGA for Even Lower IOP<sup>1\*</sup>

## INDICATIONS AND USAGE

SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination indicated in the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

### Dosage and Administration

The recommended dose is one drop of SIMBRINZA® Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA® Suspension 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.

## IMPORTANT SAFETY INFORMATION

### Contraindications

SIMBRINZA® Suspension is contraindicated in patients who are hypersensitive to any component of this product and neonates and infants under the age of 2 years.

### Warnings and Precautions

**Sulfonamide Hypersensitivity Reactions**—Brinzolamide is a sulfonamide, and although administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

**Corneal Endothelium**—There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

**Severe Hepatic or Renal Impairment (CrCl <30 mL/min)**—SIMBRINZA® Suspension has not been specifically studied in these patients and is not recommended.

**Contact Lens Wear**—The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension but may be reinserted 15 minutes after instillation.

**Severe Cardiovascular Disease**—Brimonidine tartrate, a component of SIMBRINZA® Suspension, had a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

### Adverse Reactions

#### SIMBRINZA® Suspension

In two clinical trials of 3 months' duration with SIMBRINZA® Suspension, the most frequent reactions associated with its use occurring in approximately 3-5% of patients in descending order of incidence included: blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Adverse reaction rates with SIMBRINZA® Suspension were comparable to those of the individual components. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA® Suspension patients.

## Prescribe SIMBRINZA® Suspension as adjunctive therapy to a PGA for appropriate patients

SIMBRINZA® Suspension should be taken at least five (5) minutes apart from other topical ophthalmic drugs

Learn more at [myalcon.com/simbrinza](http://myalcon.com/simbrinza)

For additional information about SIMBRINZA® Suspension, please see Brief Summary of full Prescribing Information on adjacent page.

Reference: 1. Data on file, 2014.

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Up to  
7.1 mm Hg  
additional IOP  
reduction from  
baseline when  
added to a PGA<sup>1</sup>

5.6<sup>†</sup> mm Hg additional mean diurnal IOP lowering observed from baseline when added to a PGA<sup>1</sup>



Treatment Arm	IOP Time Points (mm Hg) <sup>1†</sup>				
	Baseline <sup>§</sup>	8 AM	10 AM	3 PM	5 PM
PGA + SIMBRINZA® Suspension (N=83)	Baseline <sup>§</sup>	24.5	22.9	21.7	21.6
	Week 6	19.4	15.8	17.2	15.6
PGA + Vehicle (N=92)	Baseline <sup>§</sup>	24.3	22.6	21.3	21.2
	Week 6	21.5	20.3	20.0	20.1

<sup>1</sup>Least squares means at each Week 6 time point. Treatment differences (mm Hg) and *P*-values at Week 6 time points between treatment groups were: -2.14, *P*=0.0002; -4.56, *P*<0.0001; -2.84, *P*<0.0001; -4.42, *P*<0.0001.

<sup>§</sup>Baseline (PGA Monotherapy).

Treatment Arm	Mean Diurnal IOP (mm Hg) <sup>1†</sup>	
	Baseline <sup>§</sup>	Week 6
PGA + SIMBRINZA® Suspension (N=83)	Baseline <sup>§</sup>	22.7
	Week 6	17.1
PGA + Vehicle (N=92)	Baseline <sup>§</sup>	22.4
	Week 6	20.5

<sup>1</sup>Treatment difference (mm Hg) and *P*-value at Week 6 was -3.4, *P*<0.0001.

<sup>†</sup>Baseline (PGA Monotherapy).

**Study Design:** A prospective, randomized, multicenter, double-blind, parallel-group study of 189 patients with open-angle glaucoma and/or ocular hypertension receiving treatment with a PGA. PGA treatment consisted of either travoprost, latanoprost, or bimatoprost. Patients in the study were randomized to adjunctive treatment with SIMBRINZA® Suspension (N=88) or vehicle (N=94). The primary efficacy endpoint was mean diurnal IOP (IOP averaged over all daily time points) at Week 6 between treatment groups. Key secondary endpoints included IOP at Week 6 for each daily time point (8 AM, 10 AM, 3 PM, and 5 PM) and mean diurnal IOP change from baseline to Week 6 between treatment groups.<sup>1</sup>

<sup>†</sup>PGA study-group treatment consisted of either travoprost, latanoprost, or bimatoprost.

<sup>1</sup>Treatment difference (mm Hg) and *P*-value at Week 6 was -3.7, *P*<0.0001.

**SIMBRINZA®**  
(brinzolamide/brimonidine  
tartrate ophthalmic suspension)  
1%/0.2%