Injectable Medications in Ocular Care, *Page 85*

REVIEW® OF OPTOMETRY

March 15, 2017

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DIAGNOSTIC SKILLS AND TECHNIQUES

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This new, noninvasive technology is giving a more detailed view of the retinal vasculature than ever.

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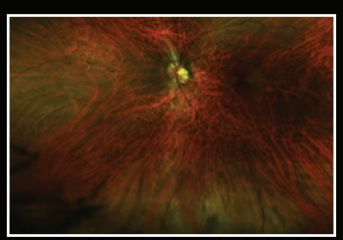

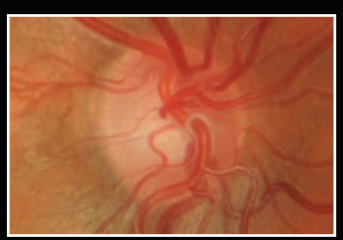

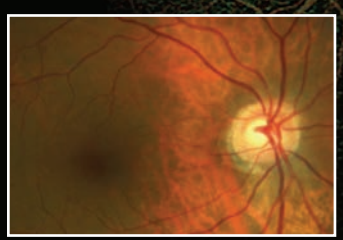

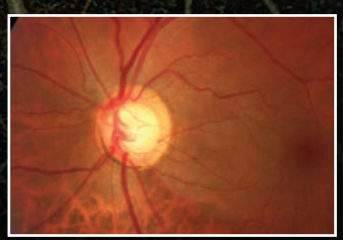

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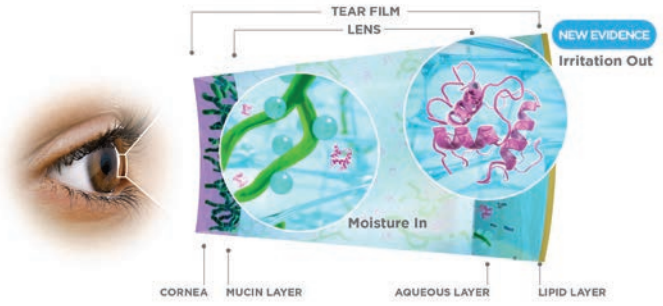

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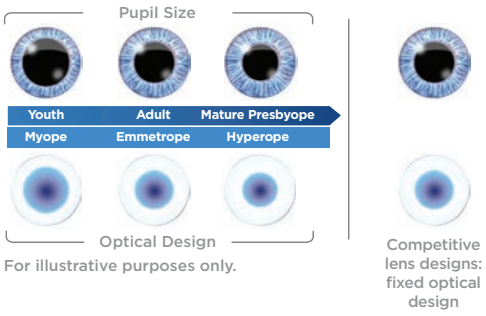

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Reference: 1. Suwala M, Glasier MA, Subbaraman LN, et al. Quantity and conformation of lysozyme deposited on conventional and silicone hydrogel contact lens materials using an in vitro model. *Eye Contact Lens.* 2007;33(3):138-143.

VOL. 154 NO. 3 ■ MARCH 15, 2017

IN THE NEWS

New research suggests cells developed using induced pluripotent stem cells (iPSCs) do not contain more mutations than cell lines created using other methods such as subcloning—a concern that has slowed medical research. Using skin cells from the same donor, investigators created identical copies of the cells using iPSCs and subcloning. When they sequenced the DNA, they found mutations occurred at the same rate in both iPSC and subcloned cells.

Kwon EM, Connelly JP, Hansen NF, et al. iPSCs and fibroblast subclones from the same fibroblast population contain comparable levels of sequence variations. PNAS. 2017;114(8):1964-9.

Laundry detergent pods, with their colorful packaging and easy rupture, are proving hazardous, according to a new study. Researchers found that, between 2012 and 2015, ocular chemical burns associated with laundry pods increased from one dozen to 480 and accounted for 26% of all chemical ocular burn injuries in 2015 among three- and four-year-olds—up from just 0.8% in 2012.

Large increase in eye injuries linked to laundry detergent pods among young children. ScienceDaily. February 21, 2017. Available at www.sciencedaily.com/releases/2017/02/170202122817.htm. Accessed February 21, 2017.

A new RNA interference (RNAi) therapeutic agent may safely block ocular inflammation, according to new research. Used a mouse model, investigators tested a single-strand RNAi agent that suppresses the receptor-associated prorenin system involved in the pathogenesis of uveitis. Results suggest this new molecule was safe and effective, causing significant improvement of both acute uveitis and chronic diabetic inflammation.

Kanda A, Ishizuka ET, Shibata A, et al. A novel single-strand RNAi therapeutic agent targeting (pro)renin receptor suppresses ocular inflammation. Molecular Therapy - Nucleic Acids. January 12, 2017. [Epub ahead of print].

Scope of Practice Battle Rages in NC

ODs in North Carolina may soon have the right to perform laser procedures.

By Rebecca Hepp, Managing Editor

North Carolina many soon join Oklahoma, Kentucky and Louisiana in allowing optometrists to perform select laser procedures. But H.B. 36, which could make it happen, is meeting with significant push-back from ophthalmologists, who raise concerns for patient health and safety.

The bill allows North Carolina ODs to perform procedures such as YAG capsulotomy, laser peripheral iridotomy, selective laser trabeculoplasty and removal and identification of skin lesions around the eye, according to Charles Sikes, OD, North Carolina Optometric Society (NCOS) PAC chairman.[1]

Many ODs recognize this as an inevitable expansion of optometry's scope of practice. "It's the next logical step for us," says Randall Thomas, OD, who practices at the Cabarrus Eye Center in Concord, NC. "West Virginia was the first state to pass therapeutic legislation in 1976, and then it was just like a wave as other states passed similar laws. The next wave in optometric practice is laser procedures."

Supporters of the bill hope its passage will increase access to eye care, provide patients with more convenient treatment options and reduce time and expense—all without compromising patient safety.

"We have a history now, in Louisiana, Oklahoma and Kentucky, of doing these procedures with virtually no negative outcomes," says Jim Sandefur, OD, executive director of the Optometry Association of Louisiana. "In Louisiana, we require all of our doctors to report the number of procedures they have done each year in order to get relicensed, so we have an accurate number of how many procedures were done and their outcomes. In 2015, we did right around 2,000 procedures with zero negative outcomes."

However, opponents also claim optometrists simply don't have the training to safely perform laser procedures, but "that's not exactly correct," Dr. Sandefur says.

Laser procedures are part of the curriculum at optometry schools, said Jill Bryant, OD, president of the NCOS and who works for the National Board of Examiners in Optometry, in a press release. "We are proud of our education."[1]

Dr. Bryant also said the NC Board of Optometry would form a credentialing committee to outline required training if the bill passes, and Dr. Thomas says the National Board of Examiners in Optometry is already including questions on laser procedures on the licensure exam for optometrists.

But if ODs already have the

(continued on page 9)

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Newly Discovered Retinal Cell's Link to Myopia

A retinal ganglion cell recently discovered by scientists may be linked to myopia in children who don't spend enough time outside in natural light.[1] The researchers think the cell, named 'ON delayed,' for its slow reaction to light stimulation, manages eye growth and development in children. According to the study, which used a mouse retina for testing, when the cell dysfunctions, it instructs the eye to grow for too long, causing the retina to fail when focusing on images. This, in turn, results in myopia.

The study attributes the cell's dysfunction to overstimulation caused by the high red/green contrast of indoor lighting, which leads to eye overgrowth. By this logic, too much time spent indoors during childhood could be the trigger for the cell's dysfunction.

While the discovery could eventually prove to be a new key to myopic management, some in the field caution against jumping to conclusions. "The media has been calling this retinal ganglion cell a 'myopia cell,' but we need to be cautious for best patient care," says Monica Jong, PhD, BOptom, senior research fellow at the Brien Holden Vision Institute. "This cell is thought to detect defocus, and is found in the mouse retina, but has not yet been identified in primates or humans."

Defocus has been a target of myopia control efforts, including successes with soft multifocal contact lenses, orthokeratology and executive bifocals. In that regard, Dr. Jong believes the study has opened up new possibilities. "Its potential role in detecting defocus is helpful to further our understanding of one of the mechanisms of myopia," she says.

The researchers hope to eventually find a gene connected to this cell, at which point scientists can alter its activity in a mouse test subject to try to initiate and cure myopia. A human connection for the cell is also prime among areas to address. "Future research on this needs to identify whether the ON delayed retinal ganglion cell directly influences eye growth and whether it is in humans," says Dr. Jong.

In the meantime, encouraging more outdoors time in children can be helpful in controlling myopia, even though the connection is still being formed. "We know that time outdoors can prevent new cases of myopia, but the mechanism by which it works is still unclear. This area of research is growing, and evidence is continually building to inform patient care."

1. Mani A, Schwartz GW. Circuit mechanisms of a retinal ganglion cell with stimulus-dependent response latency and activation beyond its dendrites. Available at www.cell.com/current-biology/abstract/S0960-9822(16)31513-5. Accessed on February 14, 2017.

Screening for DME: Look for the Red

New research, recently published in *Optometry and Vision Science*, suggests focusing on the red channel in color fundus photographs could help reveal diabetes-related eye conditions, especially in racial/ethnic minorities.

Investigators at the Indiana University School of Optometry, Bloomington, looked at color fundus photographs of 2,047 adult patients with diabetes, 148 of whom presented with clinically significant diabetic macular edema and 90% of whom identified themselves as a racial or ethnic minority. Standard, full-color fundus imaging showed 13 patients had cystoid macular edema (CME).

When comparing the standard, full-color fundus images with images divided into the red (long wavelength) and green (shorter wavelength) color channels, the researchers found CME was easier to detect using the red-channel images, which showed 100% agreement with the standard, full-color photographs.

However, the same was not true for the green-channel images, in which five of 13 cases of CME were not visible. All five cases were in patients with dark fundi, the researchers note. The cysts in the red-channel images appeared more numerous and covered roughly twice as much area compared with the green-channel images.

The researchers concluded that separating the red-channel color in retinal images could offer an advantage when screening underserved groups who have a high proportion of dark-eyed patients and higher rates of diabetic eye disease.

Alhamami MA, Elsner AE, Malinovsky VE, et al. Comparison of cysts in red and green images for diabetic macular edema. Optom Vis Sci. 2017;94(2):137.

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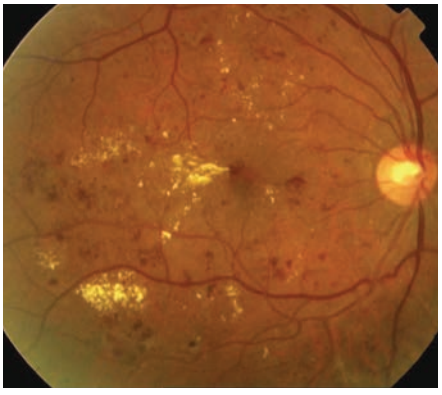
Drug Combo Shows Promise for DR Treatment

A recent study may have uncovered a promising treatment option for patients with diabetic retinopathy (DR). In a rat model, researchers found that a two-drug combination better protected against diabetes-related vision loss compared with a single drug.[1]

The combination of an angiotensin receptor neprilysin inhibitor (ANRI) that contains irbesartin (an angiotensin receptor blocker) and thiorphan (a neprilysin inhibitor and anti-diarrhea compound) was more effective at reducing the symptoms of DR in rat retinas compared with the use of irbesartin alone. Capillary loss was reduced by 68% in the group given ARNI, compared with 43% in the single-drug group. The ARNI group also showed reduced apoptotic cell death by 51%, while the single-drug group showed a reduction of 25%. In addition, the reduction percentages between the ARNI group and the single-drug group were roughly the same after five weeks. Because DR is strongly associated with prolonged diabetes, ARNI's efficacy over time is a promising sign.

While ARNI didn't completely reverse the effects of DR, it noticeably slowed them in rats and gave some promising indications. "The main effect seems to be related to decreasing the amount of inflammation, which could in turn help protect the retinal cells and delay the progression of diabetic retinopathy," says Steven Ferrucci, OD, chief of the Optometry Department at the VA Sepulveda Ambulatory Care Center and professor at the Southern California College of Optometry at Marshall B. Ketchum University.



ANRI may one day help patients avoid the effects of diabetic retinopathy for longer.

As promising as these findings may be, research still needs to address several areas, including long-term effects, side effects and, eventually, tests on the human eye. Still, these results are a step in the right direction for DR patients. "It may someday help millions of diabetic patients affected by retinopathy and its devastating visual complications," says Dr. Ferrucci. "If we could slow down the progression and help patients with diabetes live longer without visual complications, we can really increase these patients' quality of life."

1. Prasad T, Roksnoer LCW, Zhu P, et al. Beneficial effects of combined AT1 receptor/neprilysin inhibition (ARNI) versus AT1 receptor blockade alone in the diabetic eye. Invest Ophthalmol Vis Sci. 2016;57(15):6722–30.

Correction

In the article, "Are You Missing these Optic Neuropathies?" (February 2017), the formula for calculating erythrocyte sedimentation rate (ESR) was incorrect. The corrected text reads: "For ESR, the expected range is equal to the age of a male patient divided by two and the age of a female patient +10 divided by two."

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Laser Laws

(continued from page 4)

knowledge and skills, why is the bill under so much attack? According to Dr. Thomas, it's about protecting one profession from another.

"The opposition from ophthalmology has nothing to do with protecting the public," says Dr. Thomas. "It has to do with protecting their turf. Back when optometry gained the right to prescribe therapeutics in the '70s, ophthalmologists said it would endanger the public, but that certainly hasn't been the case, and the same will be true with these laser procedures."

"The opposition always says the sky is falling when we have an expansion of scope bill, and yet they've always been wrong," adds Dr. Sandefur. "Every one of them has been good for the people and has helped the people, and I think that's the case here again."

Despite significant optimism by optometrists in North Carolina, there's still a lot of work ahead before the bill can pass.

"Optometry, for better or for worse, is a legislated profession," Dr. Thomas says. "We need to ask for what's right and truly patient-centric, because it's all about the patient first. But if we are on the right side of the issue, and always have been, then you need to call your legislator, go by and visit with them and explain the true virtues of the issue."

It will always be a battle, but one well-worth fighting, says Dr. Thomas. "Over the next 20 years, most, if not all, states will pass laser procedure laws," he predicts. "It's just how these things evolve." ■

1. Bonner L. Surgeons don't want optometrists laser-cutting eyes. The News & Observer. February 7, 2017. Available at www.newsobserver.com/news/politics-government/state-politics/article131198204.html. Accessed February 17, 2017.

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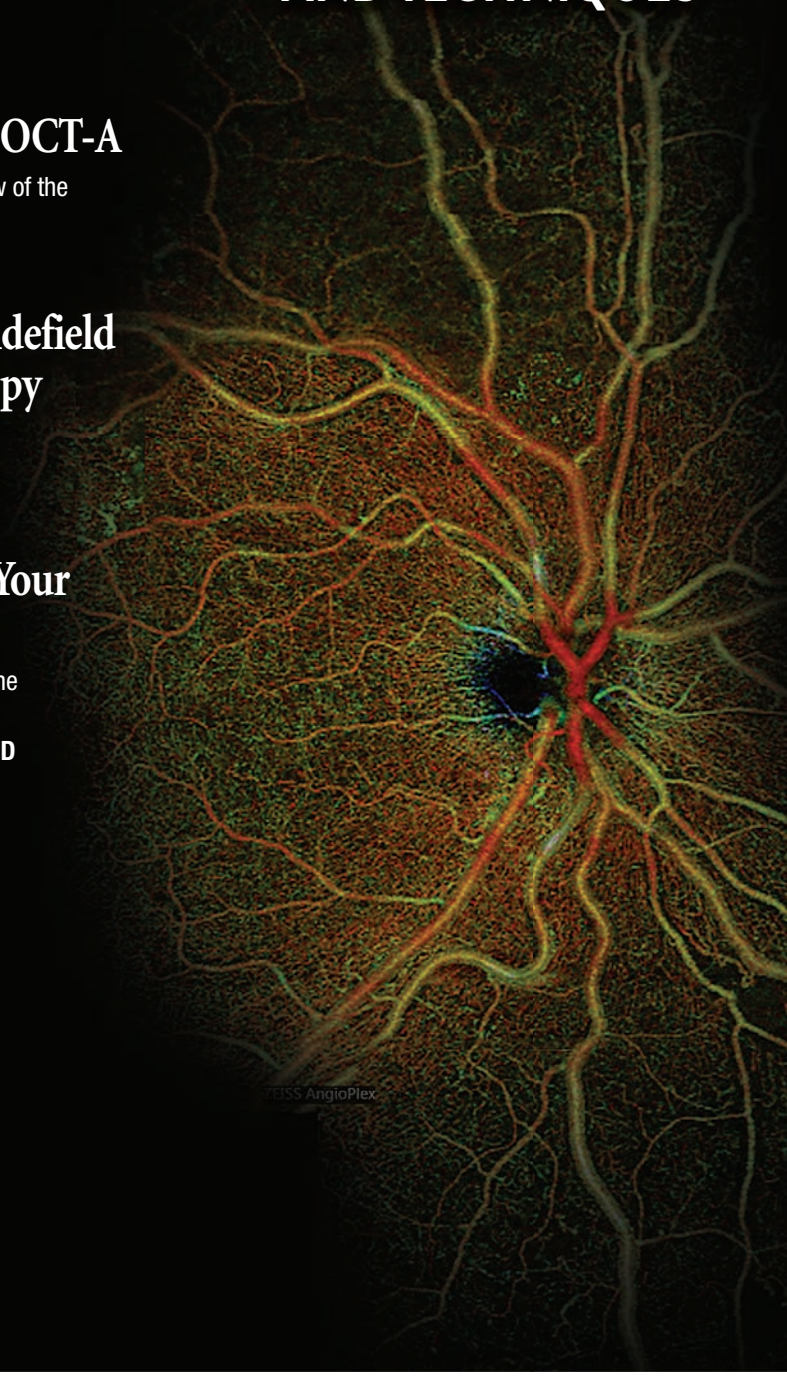

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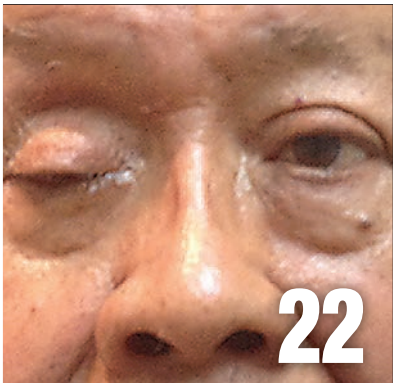

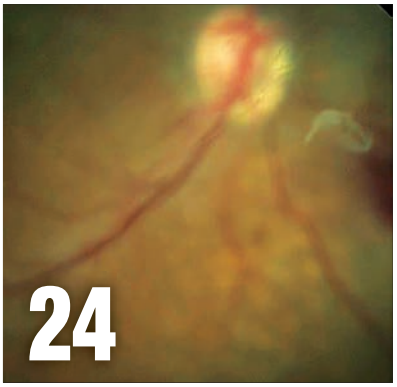

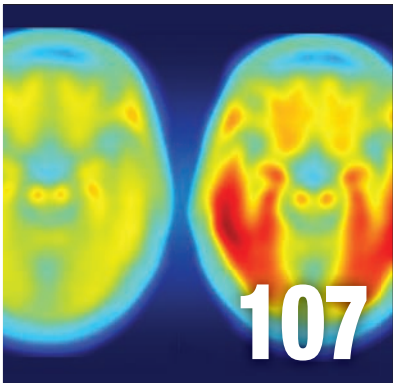

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Outlook

By Jack Persico, Editor-in-Chief

Your Best Device

Technology can help make diagnoses better, faster and more precise, but it's *you* who makes the call.

In this month's issue on diagnostic skills and techniques, there's an interesting dichotomy afoot: *old vs. new*. The series starts off with a thorough, eight-page look at OCT angiography, the very latest addition to an always-evolving technology platform. But there's also a lengthy piece on handheld condensing lenses, one of the oldest technologies for examination of the eye. That article even features an explanation of the optical principles of how lenses work—equations and everything!—reminiscent of the days when this magazine was called *The Optical Journal & Review of Optometry*. (If you're breathless with anticipation and want to get right to the math equations, they're on page 60.)

The contrast between old and new is front and center in our point-counterpoint on ultra-widefield imaging, probably the most polarizing piece of technology optometry has encountered. We thank our contributors, Ken Jeffers, OD, and Paul Ajamian, OD, for each staking out a position and speaking so candidly on the positives and negatives of this disruptive technology. Want to sound off on that, too? Email me at jpersico@jobson.com and we'll share reader reactions in an upcoming letters to the editor section.

Another strain that I hope comes through in this series is the importance of the clinician as the ultimate arbiter of all this data, a theme we might call *man vs. machine*, if you can forgive the gendered language in that phrase. As technology continually gets better, its pronouncements get closer and closer to sounding like objective facts. But doctors should take care not to mistake *data* for *diagnosis*. That's the advice from James Fanelli, OD, and Bill Potter, OD, in their article on so-called "red disease" in glaucoma, the false positives that an OCT scan can generate and might lead the doctor to treat a disease that doesn't exist.

Technology will help you gain insights you might not have had otherwise, but ultimately it's you who makes the call—and takes responsibility for it. Brian Chou, OD, reviews principles of medicolegal protection in his article that closes out the series. Last summer, when we were planning the content for this issue with the editorial board, it was Randall Thomas, OD, who pointed out that a clinician's three most feared words are (or ought to be) "failure to diagnose." That's a heavy burden, and we hope this month's series helps to lighten it a little.

Optometrists are fortunate that the medical device industry has given them so many exceptional tools. But at the recent AFOS meeting during this year's SECO, I was reminded again of just how much the best clinicians can get just by listening. During her talk on tumor diagnosis, Kelly Malloy, OD—a neuro specialist from PCO—gleaned enough pertinent information just from talking with patients that she was pretty sure what she would find in her exam—and what it would mean. That's old-school diagnostic acumen no machine can replace.

Remember, the best diagnostic device you own is the one you have with you all the time—your brain. ■

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By Paul M. Karpecki, OD, Chief Clinical Editor

Diagnos-tech Advances

Greater precision in measuring ocular and visual status helps us spot disease earlier.

The typical exam room, when I began practice, just had some workhorse devices for examination (e.g., slit lamp, phoropter, retinoscope, BIO) and a few specialized devices that generated data on a particular element (e.g., keratometer, tonometer) to augment our findings. Over the course of my career, the exam room has practically exploded with new devices that reveal entire new windows into ocular health and visual performance. The pace of innovation is hard to keep up with, and I'd like to highlight just a few that look to make waves in 2017.

• ***Dry eye.*** Schirmer testing and tear break-up time served optometry well for decades, but it's time to recognize that newer technology adds valuable data these old standbys cannot. Point-of-care diagnostics—e.g., testing for osmolarity (TearLab) and MMP-9 (Rapid Pathogen Screening)—has greatly enhanced the accuracy of dry eye diagnosis, allowing patients to begin therapy earlier and avoid ineffective treatment based on symptoms alone. In 2017, we'll see further developments in biomarker capability. In time, we'll be able to use these advances to hone our diagnoses and gauge the likely patient response to targeted therapies.

Meibography will also become vital. Imaging with the Keratograph M5 (Oculus) with multiple dry eye tests, including non-invasive tear break-up time and meibography, and the CA-800 (Topcon) are greatly assisting with DED diagnostics. TelScreen meibography and video imaging will advance in 2017, and high-res dynamic meibography imaging is now available with LipiScan and LipiView (TearScience).

• ***Glaucoma.*** Wearable tech continues to be a multi-billion dollar industry and will have numerous health applications. The Sensimed Triggerfish contact lens provides non-invasive 24-hour monitoring of changes to the cornea's curvature—a measurement that coorelates with changes in IOP.[1]

Corneal hysteresis, measured by the Ocular Response Analyzer from Reichert, has been shown to be sensitive at predicting visual field progression in glaucoma patients.[2] Recent upgrades to the Icare tonometer added LED indicators for proper alignment, series testing for six rapid test measurements and better alignment and design features.

• ***Retina.*** More than two-thirds of a retina specialist's income comes from medical care, not injections and surgery. This is an area optometry will participate in to a greater extent. Diagnostic advances such as dark adaptometers (AdaptDx, Maculogix) can provide valuable clues three or more years prior to seeing macular drusen and will allow a clinician to begin managing age-related macular degeneration earlier through dietary supplements and lifestyle changes.

OCT angiography, recently introduced by several companies, allows imaging of microvascular changes early in the course of diabetic retinopathy. Optometrists can easily incorporate this new tool into practice without the need for fluorescein angiography.

• ***Refraction/vision testing.*** According to the most recent *Review of Optometry* technology survey, the second most likely device to be purchased in the next 12 months after tear osmolarity was an automated phoropter.[3] It's not a surprise—these technologies continue to advance and streamline efficiency. Current options including systems from Zeiss, Marco and Topcon, and new additions from Reichert and Visionix will provide even greater options. Point-spread-function phoropters (VMax) can measure to 0.10D and even 0.05D and design free-form glasses with that correction.

Two other devices to watch for: the HD Analyzer (Visiometrics), which measures scatter from refracting surfaces to help the clinician choose the best intervention (ocular surface vs. corneal vs. lenticular), and a new technology called NeuroLens (eyeBrain) that can measure eye alignment and provide progressive prism to treat binocular misalignment, computer vision syndrome, frequent headaches and even symptoms of dry eye in patients without DED.

I wish I'd had many of these when starting out! But—better late than never—we're steadily gaining ground on ocular disease diagnosis. ■

Relevant financial disclosures for Dr. Karpecki: eyeBrain, Icare USA, Maculologix, Oculus, Reichert, TearLab, TearScience, TelScreen, Topcon, Vmax, Visionmetrics.

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Time to Get Serious About 2017

It's never too late to make a resolution or two, unless you resolved to stop being late. Then you're up a creek without a paddle. **By Montgomery Vickers, OD**

We are well into 2017 already. We have all had more than two months to catch our collective breath. No more hangovers. No more doomsday worries. The President is The President is The President. Now we can more realistically make our 2017 Late Resolutions. Let's do it!

1. Lose over a 110 pounds. That's not hard as it sounds, really. Just fire that lazy staff member you've been tolerating and overpaying for the past 10 years. You know the one.

2. Get our phoropters cleaned. Please send me the stuff they dig out—I'm knitting an eyelash sweater.

3. Eat better—better cookies, better pizza, better burgers—just like last year.

4. Refer at least one patient in the next year to a fellow optometrist. And no, I don't mean your mom.

5. Accept new patients. You would be surprised how many of your patients will refer new patients if you put up a sign saying, "We are once again accepting new patients!" Hey, it's not misleading. You never once said it wasn't always true.

6. Attend CE to learn something we really don't know anything about. Me? I'm looking at OCT angiography. New grad? Check out retinoscopy.

7. Add at least one piece of advanced equipment to benefit our patients. Me? I'm looking at OCT angiography. New grad? Check out the retinoscope.

8. Double the time and money (yes, you have to give 30 minutes and $10 this year!) we give to the politics of our profession. Who's your state legislator? Just ask Siri!

9. Buy a crisp white coat embroidered with Dr. So-and-so and quit dressing like some shabby punk. OK, that may have been a little rough, but at least stop wearing the *Optometrists Do It In The Dark* T-shirt you got in 1997 at SECO.

10. Be open to new ideas that will benefit our patients and our practice. For one, quit asking if they work on a computer. They do. You are wasting everyone's time.

11. Pay our assistants and staffers exactly what they are worth.

12. Hire only the best assistants and staffers to replace those who quit because we started paying them exactly what they are worth.

13. Be problem solvers for our patients, whether the problem is increased myopia or they don't think they need a yearly exam to buy more contact lenses.

14. Quit griping about new optometry schools and instead gripe about what really matters—that dog next door who won't shut up.

15. Spend a few minutes each day quietly in the lotus position, paying attention only to our breathing and, of course, that damn dog.

16. Respect and obey our government authorities, and I truly mean this. I would say it even if it were not a condition of my parole.

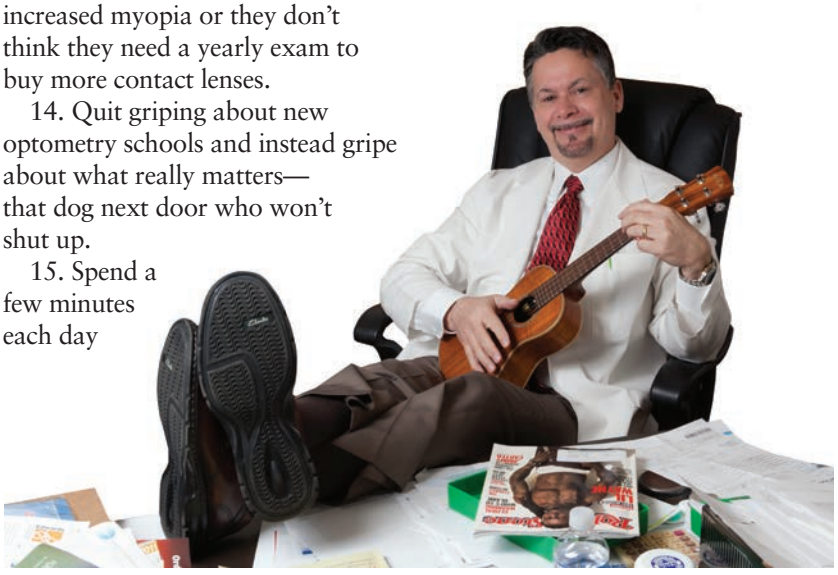
17. Ask every patient, "Are you willing to do what it takes to see as good as you possibly can?" Yes, that is correct English where I come from.

18. Stop marketing with bullet points such as **Contact lenses, *Most insurances accepted, *Fashion frames* and so on, because they make me want to throw up.

19. Smile more, laugh more, hug more, learn more, forgive more—we will therefore be more in 2017.

20. I resolve that #19 is the most insipid thing I will write in 2017.

Now it's your turn. Make 'em see better. ■



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Getting Some Shut Eye

Complete ptosis can mean you're dealing with a neurological issue. Get briefed on the work-up and what comes next. **Edited by Paul C. Ajamian, OD**

Q I have a patient who presented to his family doctor with complete right upper lid ptosis. The doctor diagnosed the patient with conjunctivitis and gave him a topical antibiotic for "stuck shut lid." Beyond a quick look, the eye was never examined. How do I work up this case, and what are some lessons learned for those of us not comfortable with neuro conditions?

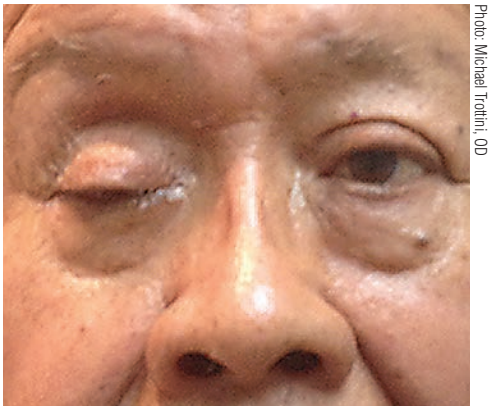

Photo: Michael Trottini, OD

Complete ptosis could indicate the presence of an emergent neurological condition.

A "First, perform an external exam on the patient, which includes watching the patient walk to the exam room," says Trennda L. Rittenbach, OD, of the Palo Alto Medical Foundation in Sunnyvale, Calif. For instance, "if the patient has an unsteady gait, is tilting to one side, is unable to walk unassisted and has never had these issues before, you may be dealing with underlying neurological disease," Dr. Rittenbach advises.

Case history, pupils, EOMs and confrontation fields are the critical exam aspects in cases where there is a suspected neurological etiology, says Dr. Rittenbach. Here, she gets us up to speed on the details of each:

History. Determine the onset and duration of the patient's symptoms, including double vision. A patient experiencing complete ptosis may not present with apparent double vision. Ask about a history of diabetes, hypertension or vascular disease. You may also want to ask if the patient is experiencing any pain or headaches.

Pupils. It's imperative to rule out pupil involvement. A blown pupil is an emergency, without question.

Motilities. These findings are critical to identifying the problematic nerve. Since there is no way you can evaluate motilities with an eye closed, lift the eyelid, instructs Dr. Rittenbach. "In this particular case, the patient had a complete ptosis of the right eyelid. When I lifted up the 'stuck shut lid,' the patient saw two of me and his eye was down and out." Dr. Rittenbach says the patient was unable to adduct the right eye, unable to look up and had limited ability to look down, but abduction was intact and preserved.

Confrontation fields. These were full OD and OS, which helps rule out a stroke or compressive lesion.

Dr. Rittenbach made the diagnosis of a pupil-sparing, complete right third nerve palsy. But, the question still remained: 'What is the cause?' The answer could mean the difference between a trip to the emergency room, a trip to the pharmacy or simply a trip home.

What's Causing the Palsy?

Dr. Rittenbach says it's imperative to order blood work to rule out giant cell arteritis. "A complete blood count with differentials, sedimentation rate and a c-reactive protein are crucial to rule out giant cell arteritis in all third nerve palsy cases in patients older than 50 years," Dr. Rittenbach says.[1]

Taking blood pressure and knowing a diabetes patient's last HbA1c is helpful to determine if the underlying cause is ischemic, says Dr. Rittenbach. If you have evidence that the diabetes is out of control, a referral to the patient's primary care provider or endocrinologist is appropriate. "In addition, I arranged a STAT neuro consult, which isn't always easy, depending on where you practice. The neurologist will most likely order imaging, including a computed tomography angiography test.[2] Most ODs don't work in a hospital setting, so establishing a good working relationship with neurology is critical for when you encounter emergent cases," she says.

Fortunately, in this case, the etiology was ischemic due to elevated blood sugar rather than an intracranial mass or aneurysm. The problem resolved with aggressive blood sugar control after about 12 weeks. ■

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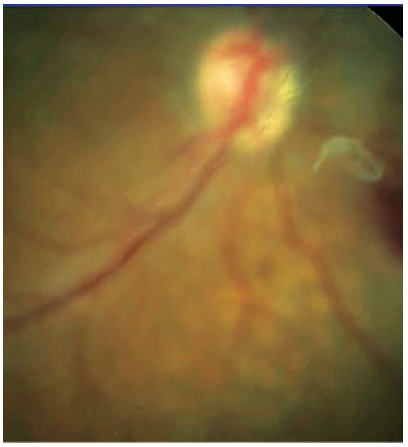
Reflecting on Entoptic Phenomena

Vivid images of the retinal vasculature often appear to our patients during exam. Are they a cause for concern? **By Bisant A. Labib, OD**

Oftentimes, when our patients are sitting behind the slit lamp during a routine examination, we hear them cry, "Wow, I can see the reflection of my blood vessels!" The image that appears to them is an instance of entoptic phenomena (EP), a phrase derived from the Greek words 'inside' and 'light' or 'vision', which describes the ability of an individual to perceive substances endogenous to their own eye, such as retinal vessels or vitreous opacities.[1,2] The presence or absence of different entoptic phenomena can raise red flags for posterior and anterior abnormalities, and even refractive and convergence conditions—making them potential markers of disease presence and progression. This month, let's evaluate what significance, if any, these reflections hold to us as eye care practitioners.

History

Entoptic phenomena were first described by Johann Purkinje in the early 1800s, to describe the fleeting, black afterimage of retinal vasculature, later coined the 'Purkinje tree.'[1] This phenomena occurs due to the location and pattern of the branching retinal vascular 'tree' in front of the photoreceptor layer, casting a shadow that is only induced when the anterior segment of the eye is illuminated.[1] It differs from a real image, particularly in that it does not track with eye or retinal movement due to the direct and constant relationship with the photoreceptor layer.[2] In fact, it is this observation, which led to the conclusion that there must be a rapid mechanism of image creation and erasure as the foundation of normal visual processing.[2]



Here, entoptic phenomenon is perceived as vitreous floater secondary to posterior vitreous detachment.

Screening Applications

In the late 1990s, the application of this afterimage was used clinically to grossly measure potential acuity, as patients' lack of perception of their vessels correlates highly with poor macular function and markedly reduced acuity.[1] It was also helpful in cases where significant media opacities existed, where—if the illumination of a closed eye induced shadows—it correlated with good retinal and macular function.[1,2]

Scanning laser entoptic perimetry. More recent studies recognize this modality as the method to measure entoptic phenomena, as it can offer significant retinal detail as it pertains to foveal capillary detail, the size of the foveal avascular zone (FAZ) and macular blood flow, with greater accuracy than more invasive methods, such as fluorescein angiography.[3,4]

Scanning laser entoptic perimetry is of particular interest to assess diabetic retinopathy, a leading cause of blindness where early detection is a key factor in visual preservation.[3] Studies suggest that this is an effective, noninvasive and portable screening tool to detect retinal dysfunction in diabetic retinopathy, allowing practitioners to identify asymptomatic patients prior to the onset of central vision loss.[3,5] Although this would not replace a retinal exam or photo, it has the potential for patients to train and screen themselves to identify early changes in many retinal diseases.[5]

For example, in a study that used scanning laser entoptic perimetry for the evaluation of age-related macular degeneration (AMD), the training period for patients took no longer than two minutes and, using a computer screen and digital pen, these patients were able to view various stimuli and draw the areas of qualitative difference directly onto their screen. This method was very effective in this case as well, in detecting very early stages of AMD, a time when patients do not typically exhibit any symptoms of the disease.[6]

Clinically Significant EPs

The most commonly observed pathological phenomenon is the shadow cast by vitreous floaters, appearing as either a black spot, in the case of posterior vitreous detachment with Weiss ring, or colorless ellipses thought to be due to embryonic remnants or proteins in the vitreous. These constituents cast a shadow on the retina and elicit the symptomatic presentation.

Moore's lightning streaks. These are also a commonly encountered photopsia, described as the flash of light that many patients experience in cases of anomalous posterior vitreous detachment, where vitreous liquefaction precedes the weakening of vitreoretinal adhesions, resulting in instances of retinal traction.[7]

Blue arc entoptic phenomena. These were first observed by Dr. Purkinje after viewing fire embers in the dark, consist of transient and varying shades of blue arches. Researchers believe they arise in response to the stimulus of the blue-yellow wavelength systems, and follow the distinct anatomy of the nerve fiber layer; potential exists to use this to help practitioners diagnose and monitor very early stages of glaucoma.[7] Other theories speculate that leukocytes, moving within one's own retinal capillaries, mediate the phenomenon.[8] Blue arc EP is inversely correlated with the degree of amblyopia, with studies concluding that its loss varies with the severity of the condition.[5]

Our patients will often report to us with subjective visual disturbances, of either a normal or abnormal cause. Taking a thorough history may reveal underlying ocular pathology. In several cases, these common visual phenomena have the potential to serve as the basis for future implementation of ocular disease screenings and monitoring techniques. ■

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Better or Just Easier?

Technology can be helpful, but remember: the rules haven't caught up yet.

By John Rumpakis, OD, MBA, Clinical Coding Editor

Considering several of this issue's features focus on examination of the posterior pole, an update on the compliance issues we have to follow would be useful. Let's start with some foundational concepts:

1. Dilation of the eye for examination of the posterior pole is part of an examination technique and not a distinct and separate procedure. There is no CPT code for dilating an eye. It is typically interpreted by the courts and insurance carriers as using a pharmaceutical agent to affect pupillary function.

2. According to the CPT, dilation is not mandatory when performing any 920XX code, but is designated "as indicated."[1] Additionally, dilation is part of the definition of all 920XX codes, should it be performed, and is not a separate billable event.

3. When the retinal components (optic discs, including size, cup-to-disc ratio, appearance and nerve fiber layer, as well as posterior segments such as the retina and vessels) of a single-system eye examination are performed using a 992XX evaluation and management code, it must be done through a dilated pupil, unless contraindicated because of age or medical reasons.[2]

4. For any special ophthalmic procedure, whether on the date of service or after, you must provide a statement of medical necessity for the specific tests in your assessment and plan for the office visit.

5. A special ophthalmic test—by virtue of having its own CPT code and having its own specific definition—is not part of any office visit, be it an ophthalmic (920XX), or evaluation and management (992XX) code.

6. All special ophthalmic tests require an interpretation and report distinct and separate from any notes contained in the medical record for the office visit itself. A typical interpretation and report should contain:

- Clinical findings: pertinent findings regarding the test results
- Comparative data: comparison to previous test results (if applicable)
- Clinical management: how the results will affect management of the condition
  - Change, increase or stop medication
  - Recommendation for surgery
  - Recommendation for further diagnostic testing
  - Referral to a specialist or subspecialist for additional treatment

Also, remember that no special ophthalmic test is deemed complete and billable until the interpretation and report is completed.

So, Better or Just Easier?

Now that we have gotten some foundational elements established, let's discuss a common coding and compliance issue for a practice: replacing dilation with fundus imaging. Some clinicians inappropriately use a screening image of the retina as a substitute for dilating the patient. While proponents of retinal imaging will argue that it is much more convenient, the patient prefers it, or it's just plain easier to communicate to the patient, there is not a circumstance that I am aware of for which a routine retinal screening image is either a legal or clinical substitute for dilating the patient.

If you are performing a screening test, the appropriate code to use is S9986—not medically necessary service. Be sure the patient understands it is not medically necessary, they are financially responsible for the test and that it is performed before they see the clinician. Taking a retinal image does not meet the 992XX component requirements for physically examining the retina.

Although the developmental pace of technology for better patient care is phenomenal, the rules have not yet incorporated these advances to a point where we can take advantage of the additional convenience. So, until the rules change, love and embrace your technology, but make sure you don't substitute your clinical examination skills with it; rather, complement your own physical examination. ■

Send questions and comments to rocodingconnection@gmail.com.

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FRONTLINE OCULAR SURFACE DISEASE CARE

Gaining a better understanding of new and advanced technology to diagnose, treat and manage dry eye disease.

By Derek N. Cunningham, OD, FAAO; Kelly Nichols, OD, MPH, PhD, FAAO; Paul Karpecki, OD, FAAO; and Doug Devries, OD, FAAO

The more we study dry eye, the clearer it becomes that it's unwise to make assumptions about risk, severity, signs, symptoms or any other aspect of ocular surface disease based on what we thought we knew about dry eye only a few short years ago. Research including the Beaver Dam Offspring Study (BOSS) startled clinicians when it revealed that age and sex are not always the most accurate predictors of dry eye risk.[1] Though we've long clung to the notion that dry eye is largely an age-related disease, the BOSS study found that healthy adults between the ages of 21 and 34 have about the same incidence of dry eye as their parents. Furthermore, this age group also showed similar dry eye prevalence between men and women. This data should inspire all practitioners to cast a broader net and look more critically for disease without stereotyping based on age and sex.

BOSS also provided a baseline for estimating the level of dry eye disease (DED) in the general population of US adults. Among 3,257 participants, ages 21 to 84 years, the overall prevalence of DED symptoms was 14.5%—which equates to about 30 million people nationwide.

Admittedly, dry eye has long been a source of frustration for clinicians. But we are much better equipped now than we were just a few years back. By looking closely for dry eye in all patients, especially younger ones, we can prevent a lot of suffering—not to mention disease progression. We would never suggest waiting to see field loss before treating a glaucoma patient, so why ignore structural changes and wait for functional loss before addressing dry eye? By addressing the chronic and progressive nature of dry eye, we may be able to keep patients in contact lenses longer, improve cataract or refractive surgical outcomes, and keep dry eye at bay.

THE EVOLUTION OF A DRY EYE DEFINITION

Our intense study of dry eye is relatively new. The first definition of dry eye emerged in 1995, when the NEI/Industry Workshop defined it as a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort.[2] This definition recognized two primary etiologies (aqueous deficiency and

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Goal Statement: On completion of this educational activity, participants should have a strong understanding of the need for a thorough exam of the ocular surface and adnexa, know the steps to proper evaluation of the ocular surface for more definitive diagnoses, and be aware of new research on the role that inflammation plays in DED and new ocular surface disease treatments.

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excessive evaporation), a sign (ocular surface damage, primarily detectable by staining), and a symptom (discomfort) but was otherwise silent with respect to causes, effects or corollaries of the condition.[2,3]

A second definition emerged 12 years later with the DEWS Report, which stated that dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface.[4] What's more, the new definition stated that dry eye is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

In the last 10 years, as we approach the release of DEWS II, so much more has been discovered, and our understanding of diagnostics and new therapeutic approaches is significantly more evolved. Instead of sending patients on their way with nothing more than a boatload of artificial tears, optometrists now recognize that more can be done. We are proactively treating dry eye and are making real headway in understanding how the disease works.

THE PATHOPHYSIOLOGY OF DRY EYE

We can't say with certainty whether dry eye is caused by inflammation, or if inflammation is the result of dry eye. But, either way you look at it, inflammation is part of the dry eye process, and is a hallmark of all ocular irritation.

The other important piece of the inflammation puzzle is the concept that there are two types of inflammation—acute and chronic—with different types of inflammatory markers, cells and mediators that occur in each of these (*see Figure 1*).

FIGURE 1. ACUTE VS. CHRONIC INFLAMMATION

Feature	Acute	Chronic
Onset	Fast: minutes or hours	Slow: days
Cellular Infiltrate	Mainly neutrophils	Monocytes/macrophages and lympohcytes
Tissue injury, fibrosis	Usually mild and self-limited	Often severe and progressive
Local and systemic signs	Prominent	Less prominent; may be subtle

Acute inflammation happens very quickly and often appears very pronounced. Chronic inflammation can be born out of an acute event of any severity when it occurs over time. Such is the case with dry eye.

Inflammatory cells are in our blood supply, normally circulating around the body. When they are activated and called to the scene of irritation, they roll down the blood vessels, sticking to the edges. It is through inflammatory mediators that they then move into the tissue itself, resulting in inflammation.

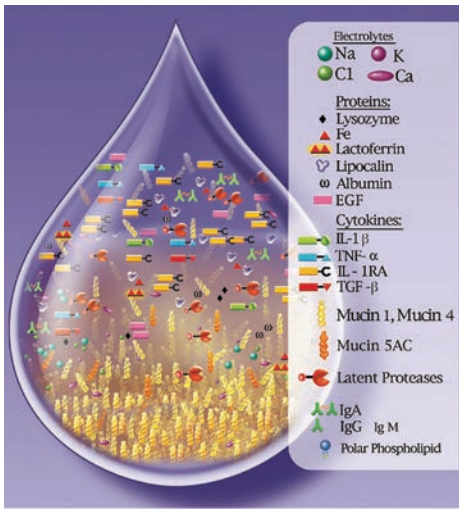
An important point to remember is that, with dry eye in particular, inflammation follows a chronic, well-established pathway. As such, inflammation begets more inflammation. In terms of treatment, patients must be educated about the need for persistent therapy so that the eye is not only quieted, but ultimately is returned to homeostasis.

TEAR FILM COMPLEXITY

The next piece of the dry eye puzzle is the human tear. Tears are exceedingly complex. We've never been able to duplicate them in an artificial product. In fact, there are more than 500 unique proteins in human tears.

In addition to water, healthy tears contain a complex mixture of proteins, mucins and electrolytes (*see Figure 2*). Lysozyme and lactoferrin are the most abundant proteins in tears and also have antimicrobial functions. Immunoglobulins, such as IgA, IgG and IgM, also have protective functions designed to protect the ocular surface.

FIGURE 2. HEALTHY TEARS



Cells are constantly sloughed off and lost from the most superficial layer of ocular epithelia. However, growth factors enable replacement. These very small proteins regulate the process for replacement of epithelial cells and are necessary for wound healing. Many growth factors are present in tears, including EGF (epidermal growth factor).

Maintaining a healthy tear film is a delicate balancing act. The outer lipid layer protects against evaporation. Tear lipids are secreted by the meibomian glands with orifices at the lid margins. The aqueous component in tears is thought to form a gel with soluble mucins that decreases in density toward the lipid layer. It includes a complex mixture of proteins, mucins and electrolytes. Mucins are also a crucial component and are critical for the viscosity of the tear film, stabilizing it against the shear force exerted by each blink cycle.

Tear electrolyte concentrations are also important, as this affects osmolarity, which is important for many aspects of epithelial and nerve cell function.

OCULAR SURFACE DISEASE TRIGGERS

When you consider the many triggers that can affect tears, digital device use is the one environmental factor that stands out most. This rapid shift in lifestyle is exceedingly pervasive and is one of the most plausible explanations we have for the high prevalence of dry eye in younger populations that we saw in the Beaver Dam Offspring Study. Also, looking ahead, we should not underestimate the potential

effects of light-emitting devices on a generation of kids that use them for several hours per day—often in school—from ages two and up.

Although we do not yet have any reliable data to indicate how many hours per day an individual can use a digital device without suffering any lasting effects, it is definitely worth our consideration. What's more, practically speaking, we are already witnessing the fallout. For example, we are beginning to see some patients in their 20s with the meibomian glands of a 70-year-old. Reduced blink rates have dramatically affected these important glands.

Systemic disease is another common ocular surface disease trigger. We commonly think of autoimmune disease as a primary offender in the systemic category, but epidemic disease such as diabetes is equally deserving of our attention. Studies have shown that 50% of patients with diabetes have dry eye.[5] Confocal microscopy consistently shows that the very first structure that's damaged in diabetes is the cornea.[6-9]

Medications are another ocular surface disease trigger. Several systemic medications have drying side effects, most notably antihistamines, hormone replacement therapy, anticholinergics and some sleep aids.

In some cases, food and drink, particularly consumption of alcoholic beverages, can bring on ocular drying. Long-term exposure to dry air, as is found in some locations, can give rise to dry eye, while the windy nature of air-conditioning and forced heat is one of the worst agitators of the condition.

Pollutants, most notably smoke or exhaust, can cause ocular drying as well. Three other prevalent causes of dry eye are refractive surgery, cataract surgery and long-term contact lens wear.

In short, the risk factors keep mounting, leading to eventual ocular surface breakdown and tear film instability.

HOW THE CYCLE OF INFLAMMATION DROVE INNOVATION

When a trigger causes the eye to get stressed, the stressed tissue will express an intracellular adhesion molecule. This intracellular adhesion molecule will then be capable of binding with a T-cell. It is this binding activity that has attracted the interest of researchers when developing new dry eye therapies.

For instance, it was recently discovered that T-cells bind to an adhesion molecule by way of lymphocyte function-associated antigen-1 (LFA-1). LFA-1 is an integrin receptor found on the surface of T-cells and ICAM-1 is its binding partner (*see Figure 3*).[10,11]

The new drug lifitegrast blocks the binding of the adhesion molecule ICAM-1 to the T-cell surface.[12] This, in turn, inhibits T-cell recruitment, activation and cytokine release associated with dry eye.

Our understanding of T-cell behavior grew out of our experience with cyclosporine, which likewise inhibits T-cell activation; however, it does so by allowing apoptosis and blocking the intracellular signal transduction cascade.[13] This earlier research taught us that activated T-cells produce inflammatory cytokines that result in the recruitment of more T-cells and more cytokine production.[14,15]

Our goal as optometrists is to intervene sooner, before this chronic, progressive ocular surface disease spirals further out of control.

DIAGNOSTIC MILESTONES

In the absence of timely diagnosis, dry eye disease will get worse and be more difficult to manage. For this reason, it is our growing responsibility as optometrists to actively look for dry eye in all patients, whether or not they have symptoms or are forthcoming about them. Admittedly, this is not an easy task. Research shows that fewer than 60% of dry eye patients are symptomatic.[16] As such, looking at symptoms alone will likely result in missing a significant percentage of dry eye disease patients, particularly those with early or mild disease.

Fortunately, new diagnostic technology combined with a better understanding of conventional diagnostic methods can aid us in making diagnoses much sooner. Managing a successful dry eye practice 20 years ago would be challenging, if not impossible. Our primary tools at that time were Schirmer strips and artificial tears. It's astounding how far our knowledge, tools and capabilities have evolved in a span of only two decades. Even the seemingly simple things, like surveys and lissamine green, have made treatment more effective because they help us identify dry eye so much earlier, which makes it easier to treat, which in turn helps slow the progression of this chronic disease.

But despite the outstanding technology that we now have at our disposal, it's important to recognize that you should never look at only one marker or test. Depending on your practice setting and resources, the tools you use may vary, but just as you would never rely solely on tonometry to monitor a glaucoma patient, one dry eye test—whether that's staining or osmolarity—should never be relied upon exclusively. Though it may be considered more expensive in the short term, adding additional tests can save you and your patients a lot of time, money and suffering in the long run. Here are some tips on the more popular diagnostic options that we now have to choose from:

• ***Symptom assessment.*** Many clinicians agree that symptom assessment ought to be one of the first and most important measures worth considering in any dry eye evaluation. Whether this is a written survey or a verbal exchange, if a patient indicates that something is wrong, pay attention. Of course, many patients are not forthcoming and will tell you everything is fine. Don't make the mistake of taking this at face value. When you ask probing questions, you'll often discover that there are many times when patients don't feel fine—like after several hours on the computer, on airplanes or when it's windy outside. These are signs of dry eye, and they will not improve on their own. Remember, dry eye is progressive, so the sooner you know, the better. Surveys have come a very long way and have an important place in dry eye diagnosis. For example, the Ocular Surface Disease Index (OSDI) has excellent reliability and validity, as well as good sensitivity and specificity.[17] Although OSDI has some limitations, it effectively discriminates between normal, mild

IS DRY EYE ON THE RISE?

- Dry eye is not found only in older patients, but it is an age-related disease. Consider: More than 100 million adults in the US over the age of 50 have been diagnosed, with another 10 million expected by the year 2020.[41,42]
- The US dry eye population is estimated to be more than 10 times that of other common conditions such as glaucoma.[43]
- Twenty-nine million Americans (9.3%) have diabetes and half of them have dry eye.[44,45] Diabetes rates have been steadily rising for the last 40 years, and there is no indication that this rate is going to decline any time soon.[44,46]
- Digital device use is creeping into almost every part of our lives and has the potential to be a huge driver of dry eye disease in coming years. A recent study by the Vision Council found that, on average, roughly 88% of adults spend more than two hours per day using a digital device, while approximately one in 10 people spend at least three-fourths of their waking hours on a digital device.[47]

to moderate, and severe cases.[2,17] The Standard Patient Evaluation of Eye Dryness (SPEED) and the five-question Dry Eye Questionnaire (DEQ-5) are also commonly used to give objective value to subjective complaints.[18] Other surveys such as Impact of Dry Eye on Everyday Life (IDEEL), National Eye Institute's Visual Function Questionnaire (NEI VFQ-25) and Short Form-36 (SF-36) provide information about the patient's quality of life, which is an important measure in any chronic disease.

• ***Schirmer's and phenol red thread.*** Tear volume testing is a staple in dry eye diagnosis. Although it has drawbacks, few practitioners would feel comfortable diagnosing a case of Sjögren's without it. Schirmer's is the gold-standard tear volume test in research circles, but it requires anesthesia and takes about five minutes. The alternative, phenol red thread, can be performed without anesthesia and takes only takes 15 seconds.

• ***Fluorescein staining.*** This test is useful for assessing the location and possible cause of dry eye. For example, if you see inferior staining, the patient may have incomplete blink, lagophthalmos or closure, whereas patchy, central staining is a good indicator of Sjögren's syndrome. However, keep in mind that, while fluorescein helps with management, it is not valuable as a screening test because it only picks up moderate to advanced disease. It will not detect early dry eye. In essence, waiting for dry eye to appear with fluorescein staining is like waiting for visual field loss before you treat a patient for glaucoma. Another word of caution when using fluorescein: You have to wait a minimum of two to five minutes, depending on the amount instilled, to let the fluorescein clear the eye so you don't get quenching. The cornea will look clear right after you put fluorescein in. If you don't wait, you won't see what's underneath the surface of the tears; all you'll see is the surface fluorescein reacting and sending the light back to you.

• ***Lissamine green and rose bengal.*** These vital dyes can help you pick up moderate and some mild cases of dry eye. Indeed, 1% lissamine green stains dead or devitalized cells and is useful in evaluating conjunctival damage, conjunctivochalsis and the line of Marx along the lid margin.[19] Rose bengal can provide valuable information too, but many patients say it stings.

• ***Corneal topography.*** Although it's not often thought of as a test for diagnosing dry eye, if you're considering referring a patient for cataract surgery, this is an important test to perform and is often a first indicator of dry eye disease in surgical settings. Research shows that topography can detect subtle irregularities on the ocular surface and, as such, is an excellent tool for the detection of dry eye.[20] The appearance of inferior steepening due to epithelial dehydration is a telltale sign that sometimes looks a bit like keratoconus.[21] Other topographical findings of dry eye disease include irregularly shaped placido discs and differences in average keratometry readings between eyes.[20,21]

• ***Osmolarity testing.*** Osmolarity testing indicates whether or not the patient has a higher "salt" content than normal: As the volume of aqueous declines, the solute concentration in tears increases. Hyperosmolar status, whether through decreased tear production or an increased evaporative state, indicates reduced aqueous levels.[22] Some clinicians use osmolarity testing as a screening tool, while others use it to track the disease over time. In either case the test delivers valuable information that you can use to guide treatment. A recent study found that cataract patients who had osmolarity scores within normal limits were within a half diopter of intent, whereas 17% of those with hyperosmolarity would have missed their IOL calculation by more than a diopter.[23]

• ***MMP-9 Testing***. MMP-9 is a proteolytic enzyme produced by stressed epithelial cells, and it has been shown to increase in dry eye patients.[24] This test provides qualitative and quantitative information that can aid the diagnosis of dry eye insofar as it indicates inflammation. A positive reading means that the sample contains more than 40ng/ml, which indicates inflammation. However, the inflammation can be due to a number of causes other than dry eye. That being said, MMP-9 has been correlated with dry eye and is a good indicator that further investigation is warranted.[25]

• ***Non-invasive Keratograph break-up time (NIKBUT).*** NIKBUT uses placido disc ring-based corneal topography to measure initial and average breakup. It does not require the instillation of dye, yet it can help determine tear film quality and it can measure the amount of tears at the lower tear meniscus. Interferometry can also allow you to see par-

ticle spread.

• ***Meibography.*** Meibomian glands plug, swell, become serpiginous, truncate and, ultimately, atrophy.[26] Therefore, the appearance of a capped gland doesn't tell you much.

LIFITEGRAST APPROVAL

In July 2016, the FDA approved the first in a new class of drugs known as lymphocyte function-associated antigen-1 (LFA-1) antagonists. Commercially known as Xiidra (lifitegrast ophthalmic solution 5%, Shire Pharmaceuticals), the new drug is indicated for the treatment of signs and symptoms of DED. Specifically, this small molecule integrin antagonist blocks the binding of ICAM-1 to LFA-1 on the T-cell surface, inhibiting T-cell recruitment and activation associated with DED inflammation.[32,48,49] This preservative-free drop comes in individual vials and is dosed BID.

Lifitegrast went though four separate multicenter, prospective, placebo-controlled, randomized, double-masked FDA clinical trials involving more than 2,000 subjects ranging in age from 19 to 97, with a predominance of female patients, at about 75%.[50] Both the active drug and placebo were administered BID for 84 days, and safety and efficacy were determined between the groups.[12,35-37,51,52]

The study results revealed that the groups using lifitegrast had a statistically significant clinical improvement in signs (inferior corneal staining) and symptoms (eye dryness) compared with placebo. In the OPUS-3 study on symptoms of eye dryness, which involved 355 patients on lifitegrast and 356 on placebo, lifitegrast had a highly statistically significant improvement compared with placebo at day 84 ($p=0.0007$), day 42 ($p<0.0001$) and at 14 days after initiating therapy ($p<0.0001$).[12,35-37,51,52]

The most common (>5%) ocular finding associated with lifitegrast was burning, and the most common (>5%) nonocular finding was dysgeusia, or a change in taste sensation. Most adverse events were reported as being mild to moderate in severity, and transient.[12,35-37,51,52]

Without looking inside the glands, you can't really know how many are lost or viable. Meibomian gland imaging has helped significantly in this regard. It not only provides us with information that helps guide treatment, it also helps us communicate the impact of disease to our patients.

• ***Lipid layer thickness (LLT) assessment.*** An insufficient lipid layer is believed to be the most likely cause of fluctuating vision and is a hallmark of dry eye.[4] Automated assessments of the lipid layer let you know when a patient's dry eye is driven by a deficient lipid layer, which can help guide treatment. For example, if a patient has a deficient lipid layer, treatment should include therapies that encourage meibomian gland expression as well as a lipid-containing artificial tear.

• ***Blink analysis.*** You might be surprised at how many of your patients' dry eye problems are related to their blink patterns. New technology can evaluate routine blink characteristics, including blink rate and partial or incomplete closure. You can use this information and video footage to help educate patients about how blinking contributes to their condition. The information can be used to help encourage treatment compliance and/or blinking exercises.

• ***Microscopy.*** These non-contact devices offer objective data about cell loss in the endothelial cell layer, which is often set in motion by dry eye. Specular microscopes are particularly helpful when monitoring patients over time and to measure improvement with certain therapies. The images can also be valuable for patient education purposes and for encouraging compliance.

FOUR-PRONGED TREATMENT PLAN

Dry eye treatment varies based on the presentation and on what your diagnostic tests uncover. However, our approach to treatment ought to take the lids, glands and ocular surface into consideration. One very effective way to do this and to ensure that all potential offenders are addressed is to initiate a four-pronged treatment plan. By systematically considering the need for treatment in all four areas, you can get your patient on the right path sooner and prevent this chronic disease from getting worse. The four areas that ought to be evaluated and addressed in a patient with dry eye are obstruction, inflammation, biofilm and the tear film.

• ***Obstruction.*** For the obstruction, options include lid margin debridement and scaling, warm hydrating or moist-heat compresses, manual expression and thermal pulsation. The trick to warm compresses is to use a system that can deliver moist heat consistently for several minutes. Another option that's been proven effective for obstruction is LipiFlow thermal pulsation.[27-29]

• ***Bacterial biofilm.*** To clear up the biofilm in patients who have blepharitis, lid scrubs and mechanical treatments like BlephEx can be helpful. Depending on severity, antibiotics may also be indicated.

• ***Inflammation.*** For inflammation associated with MGD, lifitegrast, cyclosporine or omega-3 fatty acids may be suitable. Steroids, azithromycin and oral doxycycline are sometimes helpful too.

• ***Tear film instability.*** The key to effective tear supplementation lies in choosing a product that's appropriate for each patient's unique presentation. A patient with high osmolarity will benefit from a different tear than a patient who is lipid or aqueous deficient with low osmolarity. For example, MGD patients tend to respond well to a lipid-based, osmolarity-lowering tear product.

In some cases, even after you have initiated treatment in the four areas listed above, additional strategies may need to be employed. For example, punctal plugs can benefit many patients, provided they are producing healthy tears. And, for more severe cases, treatments such as autologous serum and amniotic membrane may be beneficial.

TIPS ON TARGETING INFLAMMATION

As our understanding of inflammation has evolved, so,

too, has our ability to address it clinically. Twenty years ago, treating dry eye was frustrating. Most of the time, we used short-term steroids, lubricated the eyes and put plugs in. That was all we had at our disposal. Then, when cyclosporine was introduced, we began to realize that arresting inflammation is at the heart of successful dry eye treatment. More recently, lifitegrast is showing us new ways to inhibit T-cell recruitment and activation associated with dry eye disease inflammation.[30-32]

It is clear that we can't rely on tears for treatment. In fact, research has shown that when artificial tears alone were used for one year, patients experienced a 40% increase in T-cells, which is equivalent to no treatment at all.[33]

Inflammation is present in both aqueous-deficient and evaporative dry eye, and now that there are two pharmaceuticals—cyclosporine and lifitegrast—many clinicians are taking a close look at which therapy to use on individual patients and whether it is ever worthwhile to switch medications.

The efficacy and safety of the newer drug, lifitegrast, has been evaluated in four randomized controlled trials involving more than 2,000 patients.[34-37] And, as we all know from research and clinical experience, cyclosporine likewise has proven to be very safe and effective. With this in mind, it is obvious that, if your patient is already using cyclosporine successfully, there is no reason to change or add medications. But for new cases and for patients who have not responded favorably to cyclosporine, the question becomes when should you consider using steroid induction therapy? If you consider onset of improvement, the need may be reduced in patients who are treated with lifitegrast.

One of the benefits of lifitegrast is that the data show that patients experience improvement in two weeks.[38] This period of time should not be too long for most patients to stick it out, even in the absence of a temporary steroid. But whatever treatment you choose, setting appropriate expectations is essential. Make sure your patient understands that dry eye is a chronic condition that they are going to have their whole life. One way to convey this is by emphasizing the "-itis." Use terms like blepharitis, keratitis and meibomitis. This will help you draw a parallel between dry eye and other diseases that patients are more familiar with, such as arthritis. Patients understand that, even with appropriate treatment, arthritis can flare up at times. The same happens with dry eye.

When patients don't comprehend the chronic, progressive nature of dry eye, they are less likely to adhere to therapy. We've all had patients stop taking cyclosporine because they thought they were healed. In fact, these patients often feel great 30 to 60 days after stopping cyclosporine. However, 90 days down the road, the patient is miserable again and can't make the connection that it has anything to do with the fact that he stopped using the drops. It's a difficult narrative to make a patient understand, but it's a very important one, particularly when you are prescribing cyclosporine.

Make sure your dry eye patients understand that this is a marathon, not a sprint. We can do our best to control it—and we can now do so quite effectively—but we're not yet able to permanently cure dry eye.

WE CAN DO MORE

Dry eye disease is a chronic, progressive disease that affects millions of people, yet in the United States alone, less than one million are receiving medical treatment.[1,39,40] While there is no cure for dry eye, improved diagnosis and treatment advances can not only provide symptomatic relief, they can also prevent escalation. As such, we would be doing our patients a great disservice if we failed to help shut down the inflammatory cascade and instead clung to old models and followed outdated algorithms. ■

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1. In the Beaver Dam Offspring Study the overall prevalence of DED symptoms was:
a. 4.5%
b. 14.5%
c. 24.5%
d. 34.5%

2. What year did the NEI/Industry Workshop first define dry eye?
a. 1995
b. 2007
c. 2011
d. 2012

3. Which of the following statements is true with regard to dry eye?
a. Inflammation follows a chronic pathway
b. Acute inflammation happens very slowly
c. Inflammation generally subsides quickly without treatment
d. None of the above

4. How many unique proteins exist in human tears?
a. 50 to 150
b. 250 to 350
c. 350 to 500
d. More than 500

5. Normal healthy tears contain a mixture of:
a. Water, proteins, mucins and electrolytes
b. Only water, proteins and electrolytes
c. Only water, proteins and mucins
d. Only water and protein

6. Which of the following proteins are the most abundant in tears?
a. Lactoferrin and albumin
b. Lysozyme and caeruloplasmin
c. Lysozyme and lactoferrin
d. Lactoferrin and lipocalin 1

7. Which of the following immunoglobulins have protective functions designed to protect the ocular surface?
a. IgA, IgG and IgM
b. IgA and IgM
c. IgG and IgM
d. None of the above

8. What percentage of patients with diabetes have dry eye?
a. 15%
b. 25%
c. 50%
d. 75%

9. The first structure that's damaged in diabetes is the:
a. Cornea
b. Heart
c. Skin
d. Kidneys

10. Which of the following systemic medications have drying side effects?
a. Antihistamines
b. Anticholinergics
c. Certain sleep aids
d. All of the above

11. T-cells bind to an adhesion molecule by way of:
a. LFA-1
b. ALF-1
c. FLA-1
d. None of the above

12. Which of the following is an integrin receptor found on the surface of T-cells?
a. ICAM-1
b. LFA-1
c. ALF-1
d. None of the above

13. What is ICAM-1?
a. An adhesion molecule
b. An integrin receptor
c. A new anti-inflammatory drop

CE TEST

d. None of the above

14. What percent of dry eye patients are symptomatic?
a. <60%
b. <70%
c. <80%
d. <90%

15. Which of the following statements is/are true of fluorescein staining?
a. It is useful for assessing the location and possible cause of dry eye
b. It is not valuable as a screening test
c. It only picks up moderate to advanced disease
d. All of the above

16. Which of the following topographical findings should alert you of possible dry eye?
a. The appearance of inferior steepening
b. Irregularly shaped placido discs
c. Differences in average keratometry readings between eyes
d. All of the above

17. A positive MMP-9 reading means that the sample contains more than:
a. 4ng/ml
b. 14ng/ml
c. 24ng/ml
d. 40ng/ml

18. Which medication may be suitable for inflammation associated with MGD?
a. Lifitegrast
b. Cyclosporine
c. Steroids
d. All of the above

19. Research has shown that when artificial tears alone were used for one year, patients experienced a _____ in T-cells.
a. 40% decrease
b. 20% decrease
c. 40% increase
d. 20% increase

20. Data show that lifitegrast patients experience improvement in:
a. Two days
b. Two weeks
c. Two months
d. Lifitegrast improves signs, but not patient symptoms

Examination Answer Sheet

Valid for credit through March 15, 2018

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

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23. Will help you improve patient care: ① ② ③ ④ ⑤
24. Avoided commercial bias/influence: ① ② ③ ④ ⑤
25. How would you rate the overall quality of the material presented? ① ② ③ ④ ⑤
26. Your knowledge of the subject was increased:
◯ Greatly ◯ Somewhat ◯ Little
27. The difficulty of the course was:
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PEER REVIEWED RRA ARTICLE

Imaging Motion: A Review of OCT-A

This new, noninvasive technology is giving us a more detailed view of the retinal vasculature than ever. By Carolyn Majcher, OD, and Susan Ly Johnson, OD

When performing fundus evaluations, you may be tempted to focus on the retina and optic nerve while overlooking the status of the retinal vessels. However, the retinal venules and arterioles can provide vital diagnostic information.

The eye is unique in that it allows for direct, noninvasive visualization of the body's microvasculature. Studying these retinal vessels during clinical examination can give insight into a patient's overall vascular health. Changes in the shape, color and caliber of vessels can represent ocular manifestations of many systemic conditions. Examining the arteriolar-venular caliber ratio can assist in diagnosing vascular abnormalities and associated pathology. A reduced ratio could indicate retinal venular dilation, arteriolar attenuation or both.

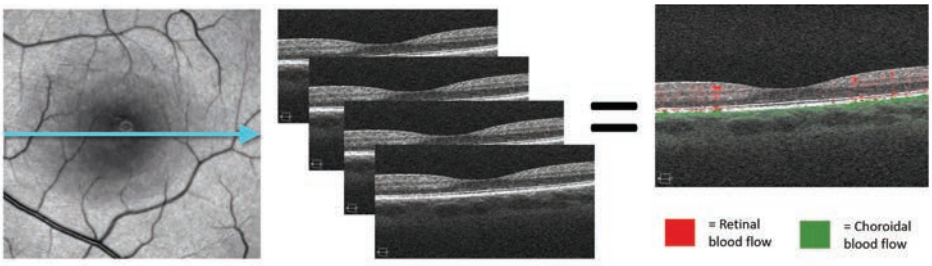

Fig. 1. Above, these images demonstrate the principle of motion contrast, during which the same location is imaged four consecutive times. Differing reflectance patterns between scans represent red blood cell movement and blood flow. In the last image, red represents retinal blood flow and green is choroidal flow.

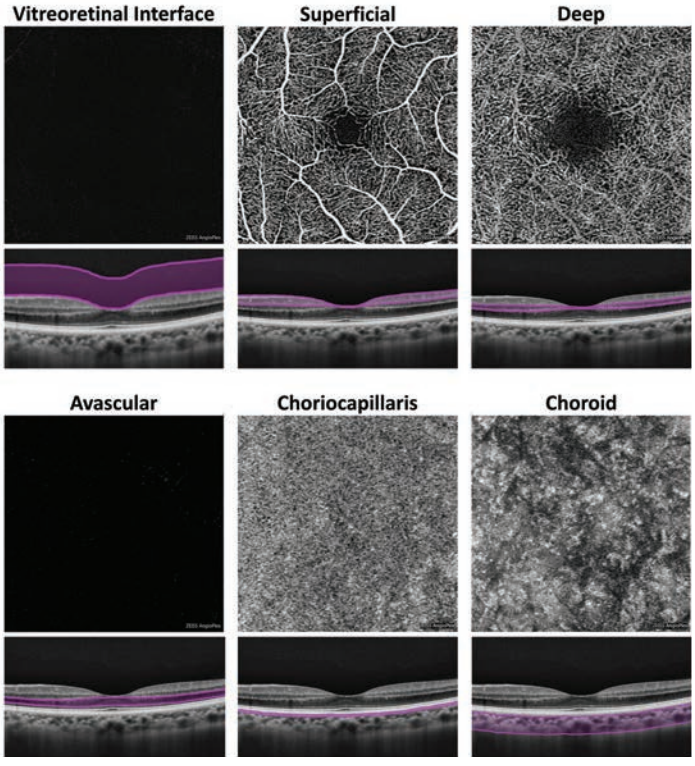

Fig. 2. At left, these *en face* OCT-A images, and corresponding segmentation boundaries, were derived from a 3mm x 3mm macular cube scan in a healthy eye.

Optical coherence tomography angiography (OCT-A) is a noninvasive and dyeless imaging technology that provides volumetric, 3D maps of the retinal and choroidal vascular systems, as well as information on blood flow.[1-3] Because it employs OCT imaging technology, vascular information can be viewed alongside or superimposed upon structural data.[1-3] This allows for precise localization of vascular lesions and for the user to make structural correlations, such as localizing an area of choroidal neovascularization (CNV) to a shallow pigment epithelial detachment.[1-3]

This article—the third in a four-part series on the retinal vasculature—reviews the potential of this budding technology to image maladies of the retinal vasculature system.

Retinal Blood Supply

The neurosensory retina is nourished by a dual blood supply consisting of both the central retinal artery (CRA) and choroidal microcirculatory systems.[4] The CRA supplies the inner layers of the retina and gives rise to two capillary networks:

1. The superficial capillary plexus, located within the nerve fiber layer (NFL) or the ganglion cell layer (GCL).
2. The deep capillary plexus, located within the inner nuclear layer (INL).[4] The choroid supplies the outer retinal layers and consists of three vessel layers (from anterior to posterior):[4]

- Choriocapillaris.
- Sattler's medium-sized vessel layer.
- Haller's large-sized vessel layer.

Technologies

Currently, two FDA-cleared OCT-A systems are commercially available in the US, the AngioPlex (Carl Zeiss Meditec) and the AngioVue (OptoVue).[6,7] Several other systems are either still in development or awaiting FDA clearance, such as the AngioScan (Nidek) and the Triton Swept Source OCT (Topcon).[8,9]

OCT machines with OCT-A capabilities require additional software, but the general hardware and scan acquisition techniques are relatively unchanged. OCT-A imaging is based on the principle of motion contrast portraying differing patterns of reflectance across time due to red blood cell movement within tissue.[1,2]

To detect motion, we must image the exact same retinal location four consecutive times (similar to acquiring four macular cube scans).[1,2] Software then compares these four scans for differences, referred to as the decorrelation signal (*Figure 1*).[1,2] Greater decorrelation signals refer to faster blood flow and result in brighter pixel values on the resultant *en face* OCT-A images.[1,2] Red blood cells that are moving either too slowly or too quickly, such that no reflectance changes are apparent between the consecutive scans, will not be imaged.[1,2] Slow flow is often

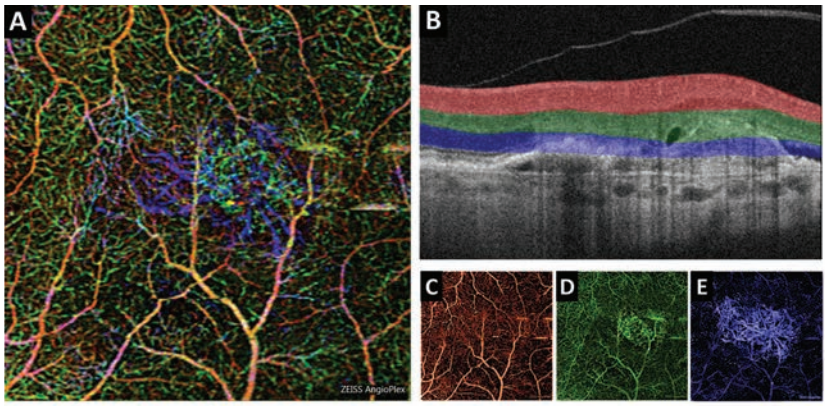

Fig. 3. (A) This color *en face* OCT-A image shows a combination of retinal layers in an eye with a choroidal neovascular membrane. (B) Shows the segmentation boundaries and color codes for each of the individual *en face* OCT-A images below. The *en face* OCT-A images are (C) the superficial retina (D) the deep retina and (E) avascular.

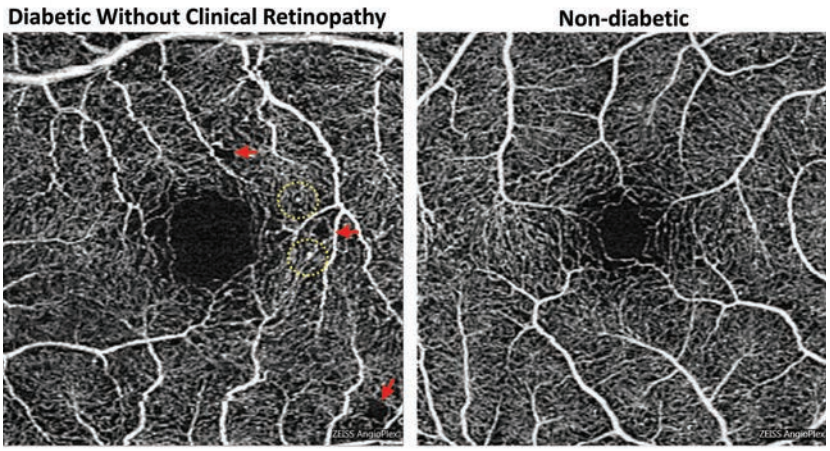

Fig. 4. Foveal enlargement and perifoveal capillary remodeling detected with OCT-A in a diabetic eye without funduscopically visible diabetic retinopathy. Red arrows point to subtle areas of capillary nonperfusion, while yellow circles highlight microaneurysms.

found in extravascular areas that demonstrate late-stage hyperfluorescence patterns with conventional fluorescein angiography (FA).[1,2] For this reason, and since moving fluid in extravascular areas is typically optically empty, OCT-A cannot image conventional FA late-stage hyperfluorescence patterns such as leakage, pooling or staining.[1,2]

Display and Normal Findings

An inherent challenge of OCT-A systems is finding a way to display 3D data in a 2D format that is easy for clinicians to understand and analyze. Each OCT angiogram represents a slab of data, including several retinal layers, compressed into a 2D plane and presented *en face*.[1-3,10] These *en face* OCT angiograms are commonly displayed alongside a corresponding structural *en face* image with identical segmentation boundaries.[1-3,10]

Some differences exist between brands. For instance, the AngioPlex offers six predefined macular *en face* OCT angiograms (*Figure 2*).[1-3,10] The first, and most anterior, is the vitreoretinal interface (VRI) and includes data from the internal limiting membrane (ILM) and 300µm into the vitreous. In a healthy eye, the VRI OCT angiogram should be void of signal, since no vascular movement occurs in the vitreous. The VRI OCT angiogram is particularly useful for detecting and visualizing preretinal neovascularization.

The second *en face* OCT angiogram, available on both commercially available OCT-A platforms, is the superficial retina. The superficial retina OCT angiogram includes vascular data from the NFL, GCL and IPL.[1-3,10] A normal superficial retina OCT angiogram contains the larger vascular branches of the CRA, the superficial capillary plexus of the CRA, and the radial peripapillary capillaries if the scan location is within the peripapillary zone.

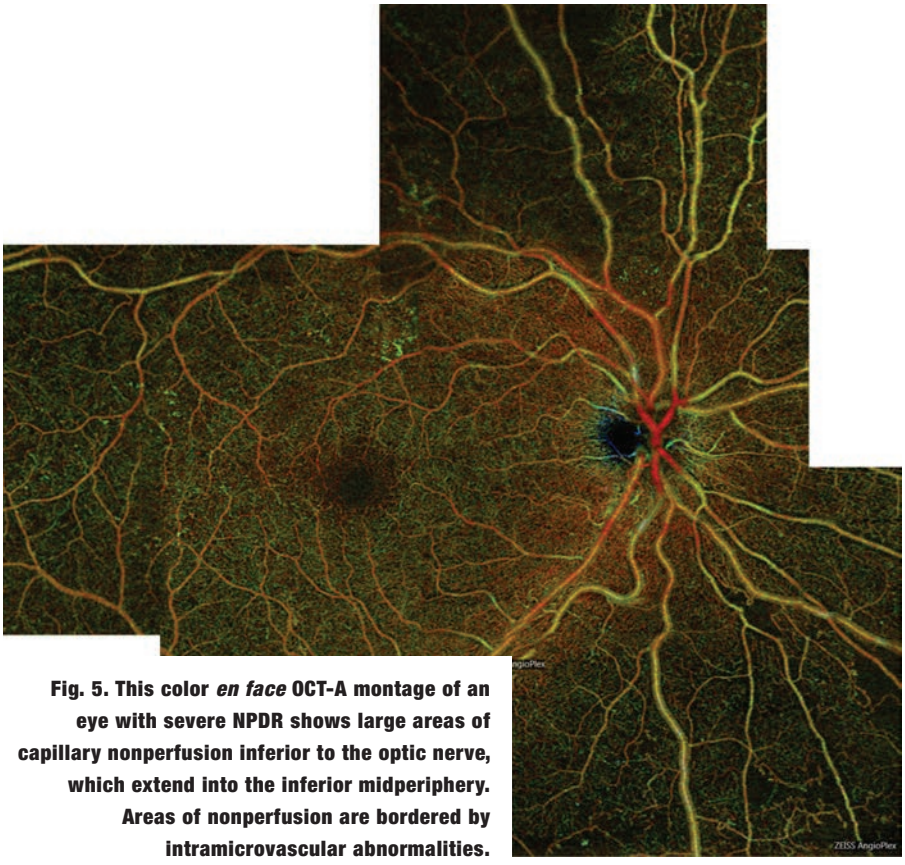

Fig. 5. This color *en face* OCT-A montage of an eye with severe NPDR shows large areas of capillary nonperfusion inferior to the optic nerve, which extend into the inferior midperiphery. Areas of nonperfusion are bordered by intramicrovascular abnormalities.

The third *en face* OCT angiogram, which is also available on both OCT-A platforms, is the deep retina. This angiogram includes vascular data from the inner nuclear and the outer plexiform layers and contains the deep capillary plexus of the CRA. A healthy deep retina OCT angiogram appears as a uniform organization of mini vortexes.[1-3,5,10] The normal foveal avascular zone (FAZ) can be visualized in both the superficial retina and the deep retina OCT angiograms.[11]

The fourth *en face* OCT angiogram includes information regarding the photoreceptors and the retinal pigment epithelium (RPE) and its definition and name differ between platforms. On the AngioPlex, it's called "avascular," and on the AngioVue it's called "outer retina." In a healthy patient, both the AngioPlex avascular and the AngioVue outer retina OCT angiograms should be black or void of signal since the photoreceptors and the RPE are avascular.[1-3,10] These OCT angiograms were specifically designed to aid in detection of CNV.

The fifth *en face* OCT angiogram, available on both platforms, is the choriocapillaris, which includes vascular information from a thin slab, approximately 20µm in thickness, just beneath the posterior aspect of the RPE.

The final *en face* OCT angiogram on the AngioPlex is the choroid,

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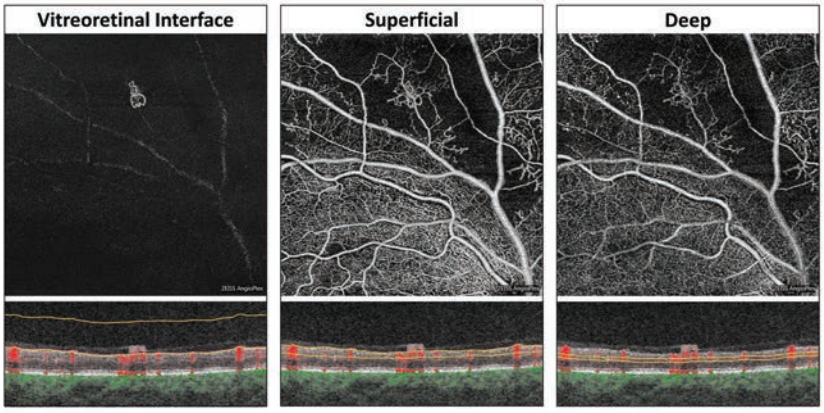

Fig. 6. These three *en face* OCT-A images are displayed with their corresponding segmentation boundaries below. The vitreoretinal interface *en face* OCT-A highlights a small area of neovascularization elsewhere within the superior temporal arcade. The superficial and deep retinal OCT-A scans show extension of the neovascular network within the retina. Massive areas of nonperfusion are seen within the superficial and the deep capillary plexus surrounding the area of neovascularization.

which includes vascular information from a 50µm thick slab beneath the choriocapillaris. Due to fast flow and limited depth penetration, the larger choroidal vessels typically appear dark instead of light as would be expected.[1-3,5,10] Several OCT-A systems, including the OptoVue AngioVue and the Nidek AngioScan, include predefined *en face* angiograms for optic nerve scans and include visualization of the radial peripapillary capillaries.

Another way to display OCT-A volumetric data in a 2D manner is to create a color *en face* image (*Figure 3*).[10] In such an image, multiple *en face* OCT angiograms are color-coded based on depth and superimposed upon each other. The AngioPlex also automatically creates a video of each scan with an *en face* image that changes as a thin segmentation slab is moved from anterior to posterior.

Lastly, the user can superimpose vascular information upon cross sectional B-scans, allowing precise localization of vascular lesions (*Figure 1*).[1-3,10]

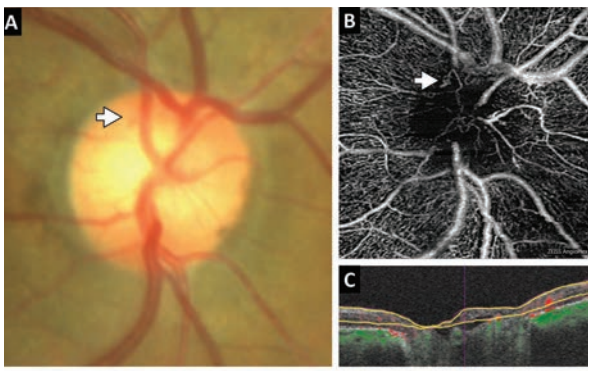

Fig. 7. This patient with diabetes was found to have questionable early neovascularization of the disc. (A) A color photography of the disc with the area in question defined by the white arrow is limited in quality and funduscopic views due to dense posterior capsular opacity. (B) A custom segmentation *en face* OCT-A with the white arrow exposes an early tuft of neovascularization. (C) The segmentation boundaries corresponding to the *en face* OCT-A. Note an anterior layer of tissue within the cup that represents the neovascular membrane.

Comparison with Conventional FA

Since it uses no dye, OCT-A is not truly angiography.[1-3] FA provides information on where dye, either intravascular or extravascular, has traversed over time.[1-4] In contrast, OCT-A provides a snapshot of red blood cell motion at the moment the scan was acquired.[1-3] Because OCT-A cannot capture slow extravascular flow, conventional FA late-stage hyperfluorescence patterns (such as leakage, pooling or staining) cannot be imaged with OCT-A.[1-4] This inability to image late-stage leakage has both disadvantages and advantages.[1-3,5,7] The presence of leakage on FA identifies a breakdown of the blood-retinal barrier and can be used to detect areas of neovascularization or sources of macular edema.[4] OCT-A's disadvantage is that, without leakage, it may be harder to detect neovascular membranes or plan focal laser treatment for macular edema. Leakage, however, frequently obscures details of underlying neovascular membranes and makes precise delineation of neovascular complexes difficult.[1-3,5,7] For this reason, OCT-A provides much higher resolution images of neovascular complexes.[1-3,5,7]

OCT angiography does offer some advantages over FA. For instance, the potential side effects associated with intravenous fluorescein use, and the injection procedure itself, no longer exist.[1-3] OCT-A can be performed even when not medically necessary and can be safely performed in circumstances when FA is contraindicated.[1-4] OCT-A can be performed repeatedly within the same day, which is advantageous for confirming restoration of blood flow

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following treatment for central retinal artery occlusion (CRAO).[1-3,12] The acquisition time for OCT-A is rapid and similar to conventional OCT imaging, while FA requires that late-phase photographs be taken at approximately 10 minutes post injection.[1-4] OCT-A generally provides higher resolution imaging of the microcirculation and capillary beds, providing better delineation of capillary nonperfusion.[1-3]

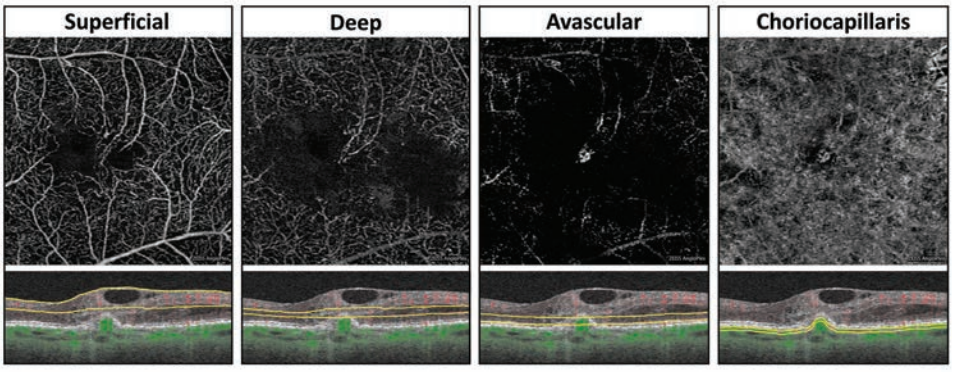

Fig. 8. This *en face* OCT-A with corresponding segmentation boundaries shows an eye with exudative AMD and retinal angiomatous proliferation. Retinal vessels within the superficial and deep retinal angiograms temporal to the fovea can be seen diving down and anastomosing with a circular subRPE choroidal neovascular membrane visualized on the avascular and the choriocapillaris angiograms. Loss of flow signal within the choriocapillaris surrounding the neovascular complex may represent choriocapillaris hypoperfusion.

One of the most beneficial aspects of OCT-A is simultaneous acquisition of conventional OCT structural and vascular information that can be viewed in tandem or superimposed.[1-3] This allows the user to precisely locate vascular lesions and draw structural correlations, helping ODs target more appropriate referrals to the correct specialists.[1-3]

Compared with FA, OCT-A offers a small field of view.[1] Most OCT-A images are only 3mm to 6mm. Although companies are introducing larger scans, these generally sacrifice capillary resolution. Automatic montaging software is available, but additional scans are required.

Also, OCT-A motion detection has fast flow and slow flow cutoffs.[1-3] Vascular structures with very fast flow such as large choroidal vessels are poorly imaged.[1-3,5] Likewise, vascular structures with very slow flow such as microaneurysms, fibrotic CNV membranes, or capillaries within areas of ischemia may be poorly imaged or not imaged at all.[1-3,13] However, despite these limitations the instrument is an excellent auxiliary tool, intended to augment the clinical examination, not replace it.

Finally, OCT angiography and OCT in general are subject to artifacts.[14] Motion and blink artifacts are relatively uncommon due to incorporation of new eye tracking systems on most OCT machines with OCT-A capability. Motion artifacts may appear as horizontal gray or white bars or image doubling or ghosting.[14] Shadowing of larger branches of the CRA often appear on choriocapillaris and choroidal *en face* OCT angiograms.

The most hindering artifacts unique to OCT-A are projection artifacts.[7,14] These are due to the motion of shadows cast by the superficial retinal vasculature onto the photoreceptors and RPE below.[7,14] They appear as a duplication of the superficial retinal vasculature on the photoreceptors and RPE and commonly produce false positive results on the AngioPlex avascular and the AngioVue outer retina *en face* OCT angiograms.[7,14] They may also hinder the user's ability to detect and visualize CNV complexes. Fortunately, software algorithms have been developed to minimize projection artifacts and are expected to continually improve.

OCT-A in Selected Diseases

OCT-A is suitable for use in several conditions routinely seen in optometric practice, including:

Diabetes. For patients with this condition, OCT-A can detect vascular abnormalities prior to the development of funduscopically evident diabetic retinopathy (DR), a condition referred to as "subclinical" diabetic retinopathy.[15] Commonly, the earliest funduscopic finding of nonproliferative diabetic retinopathy (NPDR) is microaneurysm formation, but other early vascular abnormalities, such as enlargement of the FAZ (macular ischemia) or remodeling of the perifoveal capillaries are not obviously apparent with routine fundus examination.[15,16] OCT-A highlights these subtle vascular abnormalities and provides detailed evaluation of the FAZ.[1-3] Until the advent of OCT-A, FA was the only method for detecting macular ischemia in eyes with DR and significant vision loss without observable macular edema.[4,16]

FAZ enlargement and remodeling can be detected in diabetic eyes without funduscopically visible DR using OCT-A (*Figure 4*). One study

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

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ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

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

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

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

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

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast. *Mutagenesis:* Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation. *Impairment of fertility:* Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

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US Patents: 8367701; 9353088; 7314938; 7745460; 7790743; 7928122; 9216174; 8168655; 8084047; 8592450; 9085553; 8927574; 9447077; 9353088 and pending patent applications.
Last Modified: 12/2016 S26218

looked at 61 diabetes patients' eyes that did not have clinically apparent DR.[15] Using OCT-A, they found FAZ remodeling in 36%, capillary nonperfusion in 21% and microaneurysms/venous beading in less than 10% of diabetic eyes.[15] Both FAZ remodeling and nonperfusion were significantly more common among diabetic eyes than normal controls.[15] They and other study groups have also found a significant enlargement of the FAZ in diabetic eyes, suggesting that early macular ischemia may be present before clinical DR development.[11,15] The presence of subclinical DR may predispose the eye to DR development and likely signifies the need for tighter systemic control.[15]

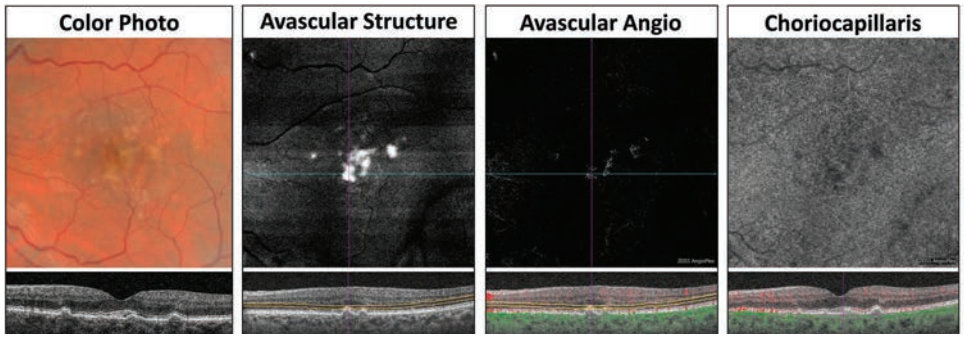

Fig. 9. These images show an eye with nonexudative AMD. From left to right: a color fundus photograph, *en face* structural OCT image using the same segmentation boundaries as the avascular angiogram, avascular *en face* OCT angiogram and choriocapillaris *en face* OCT-A. The avascular angiogram shows areas of false positive reflectance that correspond to areas of drusen on the structural image to the left. These false positive areas represent projection artifacts due to drusenoid RPE elevation that encroaches within the segmentation boundaries seen on the B-scan image below. The choriocapillaris angiogram demonstrates dark areas corresponding to areas of drusen likely due to a combination of shadow artifact and vascular compromise.

Another clinical application of OCT-A in diabetes is the detection and quantification of capillary nonperfusion (*Figures 5 and 6*).[13,17-19] Due to higher microvascular resolution and the lack of obscuring leakage, nonperfusion is better detected and delineated via OCT-A than FA.[17,18] Greater nonperfusion area fuels vascular endothelial growth factor (VEGF) release and is correlated with DR severity.[20,21] Quantifying the degree of nonperfusion may prove a useful tool for predicting the risk of progression to proliferative diabetic retinopathy (PDR) even among eyes within the same DR stage.[21] Individuals with NPDR found to have large areas of nonperfusion with OCT-A should be monitored more closely for the development of PDR and should have their control status reviewed.[21] Recent evidence suggests that anti-VEGF therapy may reverse DR and prove to be a useful treatment to prevent PDR in high risk patients.[21-23]

For patients with diabetes, OCT-A may help detect PDR earlier than was previously possible. The hallmark of PDR is the growth of preretinal neovascularization between the ILM and the posterior hyaloid of the vitreous. Differentiating intraretinal microvascular abnormalities (IRMA) from early neovascularization elsewhere (NVE) can be difficult with ophthalmoscopy alone, even with good stereopsis, yet differentiating severe NPDR from early PDR is important for monitoring and treatment purposes. OCT-A definitively distinguishes IRMA from NVE (*Figure 6*) and aids in detection of early neovascularization of

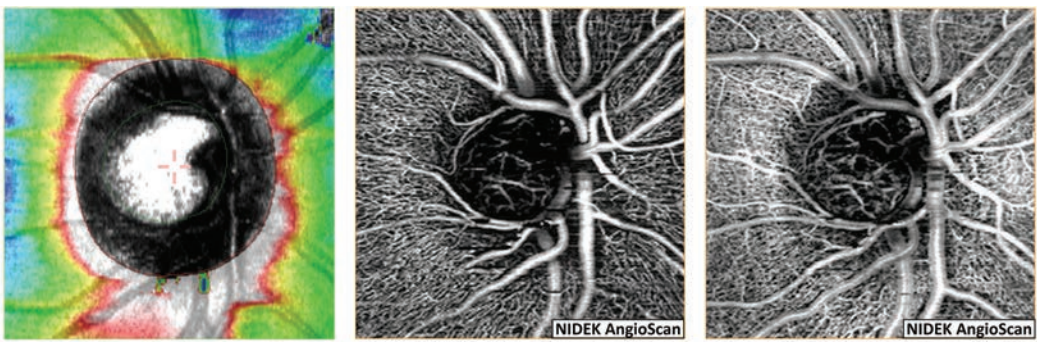

Fig. 10. NFL and *en face* OCT angiograms of an eye with normal tension glaucoma shows the loss of NFL superior nasal (left) with corresponding thinning of the radial peripapillary capillaries (middle). Imaging of the vasculature at the level of the lamina cribrosa and neuroretinal rim (right) demonstrates loss of capillaries within the superior nasal aspect of the cup and rim tissue.

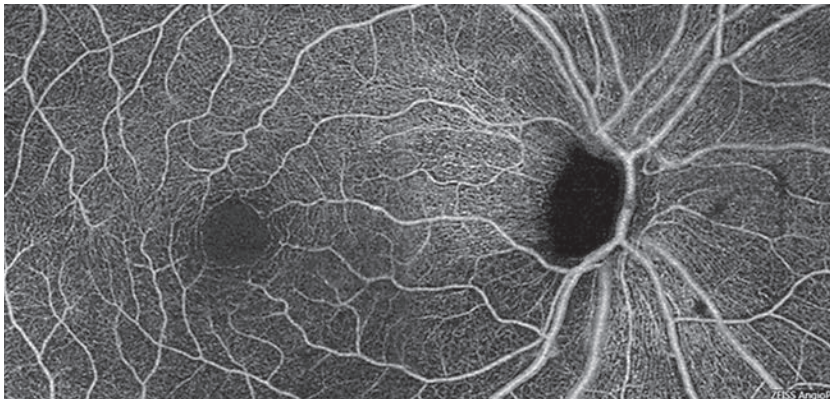

Fig. 11. A superficial retina *en face* OCT-A montage of an eye with primary open angle glaucoma and severe thinning of the inferior NFL. OCT-A reveals darkening of the image representing loss of radial peripapillary capillaries and the superficial capillary plexus in a wedge shape fashion and extending into the macular region.

the disc (*Figure 7*). With early NVE, the lesion will be present in the VRI *en face* OCT angiogram, while IRMA, which is confined to the retina, will be absent. Due to higher microvascular resolution and the lack of obscuring leakage, areas of neovascularization can be precisely delineated and measured.[19] This will allow for future automated quantification of neovascularization that can be used to track treatment responses and assess the need for retreatment.[24]

While OCT-A is useful in questionable cases, it should not be viewed as a replacement for the clinical examination.

AMD. A significant clinical utility of OCT-A in AMD is its ability to aid in the differentiation of nonexudative vs. exudative forms. Conventional structural OCT provides valuable information regarding the presence of CNV membranes by allowing the clinician to visualize secondary manifestations of CNV such as fluid accumulation as well as retinal and subretinal thickening.[1,28] The addition of OCT-A provides another tool for CNV detection since it allows the membrane itself to be visualized. Direct visualization of the CNV membrane allows for classification of CNV membranes into occult/subRPE, classic/subretinal, or retinal angiomatous proliferation (RAP) subtypes (*Figure 8*).[28,29] OCT-A also allows for precise localization and size determination. For optometrists, earlier detection means earlier referral for definitive treatment. Future longitudinal studies may also be able to identify CNV precursors and high-risk features so that conversion to exudative forms of the disease can be postponed or avoided altogether.

Anticipated analytic software updates will provide quantitative information regarding CNV flow and area that will be valuable for monitoring and quantifying response to treatment.[28,31-33] In addition, OCT-A is a helpful complement to conventional structural OCT, FA, fundus examination and visual acuity testing when trying to determine whether retreatment is warranted during a "treat as needed or treat and extend" phase of anti-VEGF management.[31-33]

CNV membranes typically appear on the avascular and choriocapillaris OCT angiograms, and the presence of any bright area on the avascular OCT angiogram alerts the user that a CNV complex may be present. Note that nonexudative AMD with large drusen commonly produces false positive bright signal areas on the avascular angiogram due to projection artifact (*Figure 9*). These false positive areas occur because the photoreceptors/RPE containing the projection artifact signal become elevated from drusen formation and become included in the segmentation.

Glaucoma. Increasing evidence that vascular insufficiency plays an important role in glaucoma has made OCT-A a useful tool for quantitatively evaluating optic disc and peripapillary perfusion in glaucoma or suspect patients.[36,37]

OCT-A provides detailed optic nerve head microcirculation structural and flow imagery, which, in normal subjects, presents as a dense microvascular network. However, in eyes with glaucoma, OCT-A shows visible attenuation of the optic disc vasculature globally and focally prior to visual field loss with 100% sensitivity and specificity, whereas, the difference in microvasculature between normal and glaucomatous eyes could not be visualized via disc photographs (*Figure 10*).[36,37]

Peripapillary vessel density is the percentage of area occupied by the large vessels and microvasculature in the peripapillary region. Investigators have revealed a mean peripapillary vessel density in glaucomatous eyes of 80.6%, which is significantly less than the 93.0% found in normal eyes.[39]

OCT-A vessel density measurements may have similar diagnostic accuracy to retinal nerve fiber layer (RNFL) thickness measurements for differentiating between healthy and glaucoma eyes. These results suggest that OCT-A measurements may be a tool for detecting damage to

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tissues relevant to the pathophysiology of open-angle glaucoma (*Figures 10 and 11*).[37]

Researchers found that the OCT-A flow index was reduced by 35% before visual field loss in glaucoma patients compared with normal.[39] They also found that flow index was significantly correlated with the severity of glaucoma, visual field mean deviation and pattern standard deviation, RNFL, and ganglion cell complex thickness in glaucomatous eyes.[38,40] Hence, quantitative OCT-A may have potential usefulness in the diagnosis, staging and monitoring of glaucoma.[37,39]

A Bright Future

OCT-A provides highly detailed microvascular imagery.[1-3] The information it can obtain is volumetric and allows for depth resolution of lesions. It also provides tandem vascular and structural information so clinicians can draw valuable correlations between the two.[1-3] The major clinical applications of OCT-A include:

1. Detection and quantification of retinal nonperfusion as well as high resolution evaluation of the FAZ enabling identification of macular ischemia in retinal diseases such diabetic retinopathy, venous occlusive disease, and arterial occlusive disease.

2. Detection of early diabetic retinal vascular changes prior to development of clinically evident DR.

3. Detection and quantification of preretinal and CNV.

4. Detection and quantification of neural retinal rim and peripapillary perfusion compromise in optic nerve diseases such as glaucoma.[1,11,15,18,19,28,31-33,37-43]

OCT-A may not completely replace FA, but it will serve as a complement to FA to provide valuable depth and structural information.[1-3] ■

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Dr. Johnson is a resident at the Rosenberg School of Optometry.

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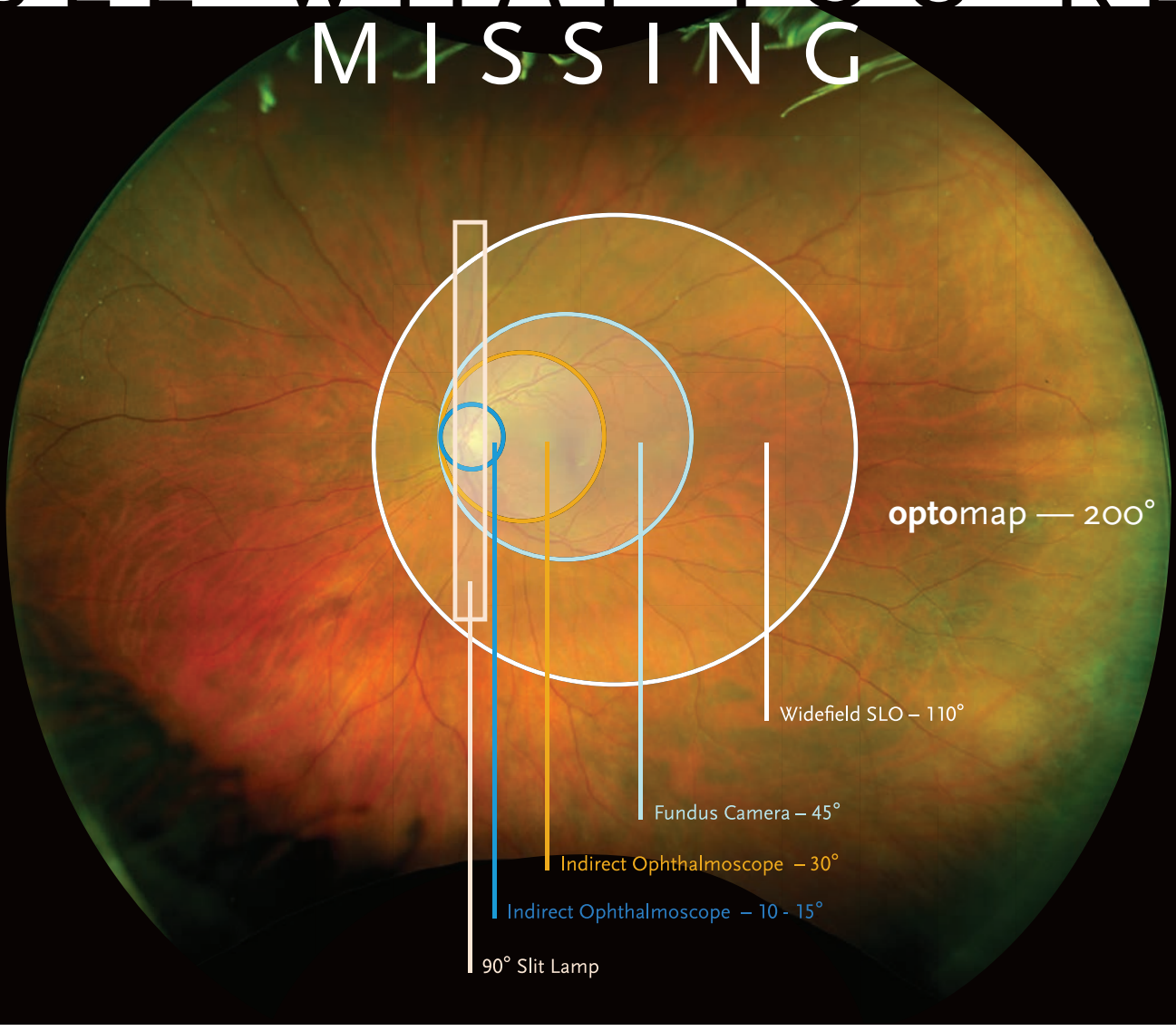

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Ultra-Widefield Imaging vs. Dilated Funduscopy

A dilated exam is the standard of care—but is it always practical?

By Ken Jeffers, OD, and Paul C. Ajamian, OD

IN FAVOR

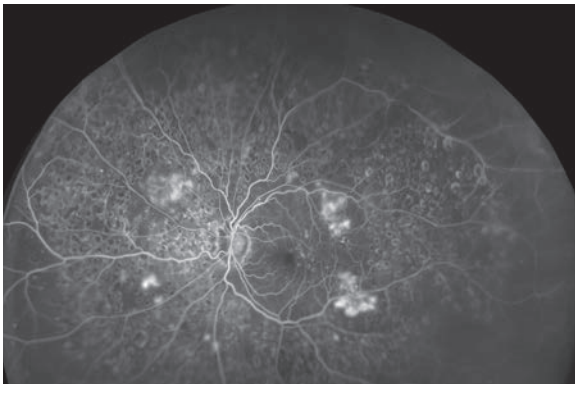
Technology Improves Care, Convenience and Communication

By Ken Jeffers, OD

I use ultra-widefield imaging (UWFI) as an alternative to, and sometimes even a replacement for, dilation in many of my patients.

There, I said it. If you're a member of an optometric social media site, you've probably already formed an opinion of me based on this first sentence, and it may not be a positive one. I'm not asking you to agree with me. Rather, I'm asking you to hear me out with an open mind. This article is not a scholarly treatise comparing UWFI's clinical accuracy in a retinal exam to that of a dilated fundus exam, because there are plenty of those already written. I'm writing as a typical private practice optometrist who happens to believe in the technology because I've been using it nearly every day in practice for the past five years.

Photo: Optos



UWFI can provide expansive views of the retina and help document the progression of myriad conditions, such as diabetic retinopathy, seen here in its severe form.

Before I state my case as to why I support the use of UWFI, I want to make a few things clear:

1. Dilation is still the standard of care to which an optometrist will be held in a court of law.[1]

2. No technology can replace a good case history and clinical examination.

3. UWFI is an excellent tool to have at our disposal—as is a bottle of tropicamide.

4. I have no financial agreements or endorsements to disclose. I own an Optos Daytona, but there are other UWFI devices to choose from.

5. In all patients for whom I use UWFI, I still look at their optic nerve and macula with a fundus lens at the slit lamp for an undilated binocular view.

Now that those are off of my chest, let me tell you how I use the ultra-widefield imaging modality

and how it has benefited both my patients and practice.

Five Pros of UWFI

I have five basic reasons for you to consider UWFI in your office:

1. Patients don't like being dilated. If you care about what your patients think and what motivates them to seek—or avoid—care, it would be unwise to ignore this fact.

Granted, we've all seen patients who exaggerate the side effects of dilation. I've heard everything from, "The last time I was dilated, I was blind for three days" to "I haven't been able to see the same since the last eye doctor dilated me and I'll never let anyone do that to me again." Our patients can be, shall we say, dramatic. So, if you had an option to make their eye exams easier, wouldn't you want to consider it? UWFI certainly has the potential to revolutionize how we practice. It's an ingenious technology and patients love it. I have had several patients make an appointment in my office because they heard about UWFI and did an Internet search to find an office that provides this diagnostic modality. When these patients present to my office, I'm always careful to tell them that UWFI does not work for everyone, and I may still need to dilate their eyes.

2. Patients are impressed with the technology. When my technicians capture the ultra-widefield image, patients often ask what the device does. They are curious about it. When I show them the image of their own eye and compare it with images from the library of pathology, they are often blown away with what we can see. When I show them pictures of patients with choroidal melanomas, diabetic retinopathy, hypertensive retinopathy, papilledema and other pathology, they often comment, "I didn't even know you could see those types of problems in an eye exam." UWFI gives me an opportunity to show them first-hand what these conditions look like and educate them about the importance of regular eye examinations.

I truly believe UWFI has improved my patients' compliance with their eye exam frequency. Although I often explain what I'm doing and what I can see during a dilated fundus examination, it doesn't seem to have the same impact on compliance as the patient "examining" their own retina with me.

3. In certain cases, UWFI can be superior to a dilated exam using a conventional fundus lens at the slit lamp or with a binocular indirect ophthalmoscope. Before you hit "send" on the hate email you just composed, I also think a dilated fundus examination is superior to UWFI in certain cases. Ideally, doing both is best. Truthfully, certain pathologies can be better seen with UWFI, while others can be better seen through dilated pupils.

Any pathology requiring a three-dimensional view of the fundus (e.g., papilledema, macular edema or any retinal lesion with risk factors for malignancy, including elevation) requires a good dilated exam—plus UWFI.[2-4] Because UWFI provides up to a 200-degree temporal and nasal imaging field and can image up to 82% of the retina, it is often better—30% better, in one study—at locating peripheral retinal lesions such as tears, holes, nevi and hemes than a dilated exam.[5,6]

Research also suggests UWFI can be advantageous when examining patients with diabetes. One study found UWFI, compared with

standard techniques, identified retinal nonperfusion and neovascularization in an additional 10% of eyes, while other researchers found diabetic retinopathy was identified 17% more frequently in non-mydriatric UWFI compared with the ETDRS standard.[7-9]

Seeing the entire retina at once provides a distinct advantage within the context of diagnosing peripheral lesions.[5] It's not easy to miss retinal pathology with UWFI, as long as you obtain good quality images.

4. UWFI provides a permanent, digital image in the patient's chart for future reference. How many times have you found something on a dilated fundus examination and wondered how long it had been there? No one enjoys that anxious moment when we think to ourselves, "Is this new or did I miss it last year?" UWFI nearly eliminates this doubt. And I don't know about you, but my ultra-widefield images are a little better than my retinal drawings.

5. UWFI can be profitable. The device is costly to purchase, but I've found that it pays for itself if you believe in the technology like I do. The capture rate in my office is between 70% and 80%, and I charge a nominal fee for this service. This income is not susceptible to the chargebacks, discounts or contractual fees we have become all too accustomed to in optometry today. There is nothing wrong with making money on a service that benefits the patient and that they want.

The benefit is not just financial, either: It also saves time. We all know dilating is probably the biggest bottleneck in our office flow. I save, on average, 20 minutes on each eye exam when I use the ultra-widefield imaging modality instead of dilation.

The Power of Belief

But remember, the decision to bring any new technology into your office should never be financially motivated. Before I adopt new equipment in my office, I make sure it meets two criteria: It must benefit my patients in some way, and it must be able to pay for itself and, at some point in time, become profitable.

If you add this technology to your office, it is critical that you believe in it. Some optometrists are not on board with UWFI, and I respect that. You have to decide if it fits your practice culture and your own clinical philosophy. For UWFI to be successful in your practice, you have to make sure your staff understands it and they all have the same "script" when explaining it to patients. Do not delegate the education of UWFI to your staff entirely, though, as the recommendation ultimately needs to come from you, the doctor, to use the modality. Talk to patients about it yourself. They deserve more than a photocopied handout mixed in with the bundle of admissions papers they get in the waiting room.

As ultra-widefield imaging is optional, this is the exact script I use with my patients:

"The next portion of the exam is the internal eye health exam. This is the part of the exam where we look for eye health problems as well as general health problems that can be detected through your eye exam. The traditional way to perform this exam is with dilation (I then explain what dilation is and does), *which is a service covered by your insurance but is less convenient for you. We now have an alternative to dilation called ultra-widefield imaging, which costs extra but is faster and more convenient. In most cases, UWFI is sufficient, but it depends on the quality of the images we are able to capture. If the images are not usable in my opinion, I will have to dilate you and you will not be charged for UWFI in this case. Which do you prefer today?"*

Misleading a patient to think that UWFI is a replacement for dilation is unethical and ultimately reflects poorly on our profession. I only use UWFI for routine care or for capturing pathology. I never use UWFI alone when a patient presents with symptomatology clearly requiring a dilated exam to properly evaluate.

I am not oblivious to the critics' claims about UWFI, and I agree with many of them. While I support the use of UWFI, it still comes with limitations and disadvantages.[5,10] For example, good quality images rely on patient cooperation; some training is needed to capture good quality images; eyelid and eyelash artifacts can obstruct the view, especially of the superior and inferior retina; images can be blurry due to media opacities; the camera can create artifacts; and so on. Other than the last reason, these limitations could arguably present during a dilated fundus examination as well.

Never has a medical device in optometry inspired such riveting debate! I personally believe this topic is so emotional to many of us because some of our colleagues are misleading our patients into thinking that it is a replacement for dilation.

Few would argue that UWFI is not a useful technology, and when presented to our patients properly and ethically, it can be used as an alternative to dilation in many of our patients.

Dr. Jeffers is an attending optometrist at Professional Eyecare Associates in Casa Grande, Ariz.

IN OPPOSITION

All That Glitters is Not Gold

By Paul C. Ajamian, OD

Would you allow a surgeon to operate on you with one eye occluded? I wouldn't. Stereopsis gives a medical specialist a better appreciation of the depth and contour of clinical entities. It's simply too valuable to the outcome to be cast aside under the guise of convenience—or worse, profit.

None of our 35-year-old Omni Atlanta comanagement centers own a UWFI device, because the model doesn't really work for a practice like ours and I am not happy about what it teaches our patients. We dilate every patient who needs it, and they expect it, so there is usually no argument between patient and clinician.

Understandably, there are increasing numbers of patients who will chose a primary care practice that does have UWFI and does not dilate. This puts the practice that does not have the instrument at a disadvantage, so some practices have relented and brought the instrument in as a screening device to attract patients.[11] This gives the doctor the chance to at least explain to the patient face-to-face the necessity of dilation in their particular case.

It's safe to say there's nothing wrong with a device to screen the fundus. However, when the screener picks up something suspicious or questionable in appearance, dilation is well still the standard of care to further delineate the problem.[11]

The care model I take exception to can be exemplified by the following scenario: The patient presents to the front desk to sign in for their annual exam and the receptionist says: "Would you like to be mapped today? The test costs $45 and will allow us to forego dilation, a procedure that causes pain and light sensitivity and blurred vision for a number of hours after the exam." What would you say if it were presented that way? Not only does it put the patient in a position to choose their own medical testing protocols, it also implicitly puts forth the notion that dilation is bad. If they choose UWFI and later you determine that they still need to be dilated, you're now in the awkward position of having to convince them to do something that you told them their $45 would prevent. I know this may seem like an exaggeration, but patients hear what they want to hear, and this approach of offering a "dilation-free" exam may cause you to have to swim upstream at some point in the future.

In our comanagement practice, patients sometimes will present from other optometrists and will request UWFI. For instance, one who recently presented for a cataract evaluation physically blocked me as I was about to dilate her and said, "Dr. X never dilates me! Aren't you going to map me like he does?" She truly believed that our exam was inferior to his because we were doing a dilated exam instead of UWFI, and nothing could be said that would change her mind.[12]

It's critical to advise patients that UWFI is not a substitute for a dilated exam. Unless we sufficiently drive this point home, we are going to teach an entire generation of patients they don't need to be dilated and, worse, that dilation has

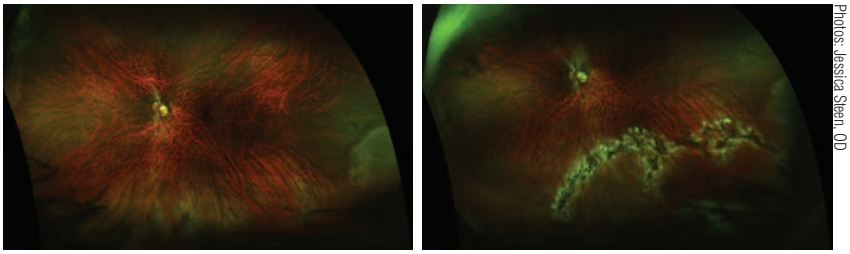
terrible side effects and is no longer the standard of care. If we take care to treat UWFI as a screening modality, no problem. But when we put too much stock in it, problems are going to arise.

Clinical Cases-in-point

As a clinician, one qualm I have is that using UWFI can cause false positives—something we have seen in our referral setting more than once. I have had a number of patients sent to us for retinal detachment (RD), macular holes, schisis and branch artery occlusions who, in fact, had artifacts on UWFI—clinically speaking, nothing—but were told they had a potential major eye condition requiring surgery. And it's not just false positives that pose risks for our patients and practices; clearly, false negatives would be even worse.

The missed glaucoma patient. Failure to dilate puts patient and clinician at significant risk for missing glaucoma.[2] Recently, a 72-year-old patient was referred for a cataract evaluation, with no mention of any other problems. She had been seen yearly with examinations conducted using an Optomap (Optos), but no dilated funduscopy. Our evaluation revealed that the patient had 0.9 cups and 15-degree field remaining due to end-stage chronic open-angle glaucoma. In the context of my clinical practice, the biggest reasons to dilate are to look at the optic nerve and rule out glaucoma, regardless of the IOP or family history. The only way to evaluate the nerve is through a dilated pupil with a handheld lens. Mapping with UWFI falls far short if you are relying on it to rule out this potentially devastating disease.

RD false positives. At least two patients have presented recently to our clinic with a diagnosis of retinal detachment subsequent to imaging with UWFI. These patients were, to be quite honest, scared to death—and rightly so, as they were sent to us for surgery. When we dilated them, their retinas were flat and showed no signs of RD.



Photos: Jessica Shean, OD

This retinal break with retinal detachment, seen post-treatment (right), was diagnosed using dilated funduscopy, but was not apparent pre-treatment (left) using UWFI.

So, what gives? The most obvious outstanding issue that these cases illustrate is that UWFI was not used as an adjunctive modality or a screening tool that can garner initial red flags, which would then be investigated further using the standard of care, dilation. As with all technology, incorrect findings are possible, and to send patients to another professional without dilating should be avoided at all costs.

Research shows UWFI has poor imaging for the detection of retinal holes, tears and postoperative scarring, especially in the inferior and superior periphery.[10] The cost of failing to dilate with suspicious findings, particularly if you suspect pathologies such as these, can be measured in terms of harm to the patient. We have the responsibility to practice in a manner that yields the best possible ocular and systemic outcomes for our patients. Practitioners are expected to allay patient's fears—not create them. When we do, without any defensible reason, it is simply bad practice.

The profession needs to emphasize that dilation is not bad and something to be avoided. There is nothing wrong with using "convenient" modalities to bring patients into the office for a dilated exam. But, practitioners need to realize that UWFI, when it serves that purpose, is simply not a replacement to dilated funduscopy.

Professional Backsliding

After many years of working tirelessly to expand our scope of practice to include dilating drops, our profession in some ways seems to be going backwards by teaching patients, one-by-one, that this procedure is unnecessary and avoidable. We are undermining years of work in the legislature and classroom by doing what we think is more convenient and expedient for our patients.

In some cases, it is. Would I dilate a 1D myope contact lens wearer every single year? No, probably not, and UWFI might be good to do in those alternating non-dilation years. But, to sell it as a substitute is harmful and irresponsible.[13] The big question that exists is whether you, a specialist in the discipline of eye care, believe dilation is perceived by the patient as negative—in essence, a problem UWFI solves. If you do, patients will pick up on it and adopt those same beliefs.

While wider images have their value, they also mean less magnification, and many doctors can't make heads or tails of what they are seeing due to minimization. But, ODs will tell me that they find things on UWFI that they wouldn't have seen otherwise. Yes, of course this is

the case. But, I would say they may not have looked carefully enough, because they knew that UWFI would catch their misses. This I find analogous to the trend among young ODs and MDs in how they approach the macula: take a five-second look at the anatomy and say, "Let's order an OCT." We need to look carefully with our eyes, and if an epiretinal membrane is detected, then the OCT is appropriate to document and measure the finding. Otherwise, we are headed down a path of "automated" exams where the instruments have taken over the process.

With online sites such as Opternative promoting "eye exams" without going to the doctor, UWFI could become yet another form of ancillary testing spun as a telemedicine tool that teaches patients that a face-to-face exam is not necessary.[13] Our vital, irreplaceable role is to absorb all the diagnostic data we can and offer an assessment—that's the "art" of medicine, and no machine can replace it. Then, we may order tests to document, measure and establish baselines for those conditions first observed with the clinician's eye.[14,15]

Stay True to Your Principles

For sure, UWFI is a great modality for documentation and can be a useful adjunct to established protocols of care. But too often the clinical case for it gets conflated with financial rationalizations. We sometimes see the gee-whiz appeal of a shiny new piece of technology—*patients will love it, we'll look so high tech*—and get led astray contemplating the revenue stream it might bring in. But it's wise to remember your Shakespeare: all that glitters is not gold.

The purpose of adjunctive modalities is not to steer patients to a test with the primary purpose of making money. A screening test is fine as long as it leads to a detailed fundus exam, instead of acting as a replacement for one. Make sure you are thinking solely about the clinical value that any device brings to your practice and your patients.[13,14]

My practice has been dilating patients for 38 years. When patients are educated on the necessity of a procedure, it is not perceived as inconvenient. If we teach our patients that dilation is a bad thing so that we can upsell them an a la carte test, it's a disservice to our patients and our profession—and, in my opinion, unethical.[13]

If the test ultimately increases compliance with regular dilated eye exams, so be it. But don't lose sight of the main objective: compliance with the standard of care. ■

Dr. Ajamian is the center director of Omni Eye Services of Atlanta.

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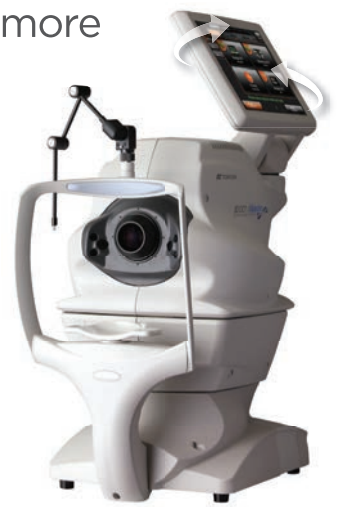

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TOPCON

Condensing Lenses: Sharpen Your Skills in Choosing and Using

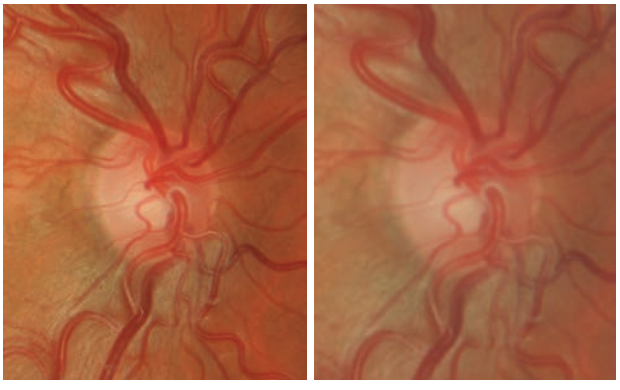
These devices remain vital to everyday practice. Are you making the most of them?

By Philip E. Walling, OD, Joseph Pole, PhD, Paul Karpecki, OD, Nick Colatrella, OD, and Jeffrey Varanelli, OD

We are very fortunate that in our profession, unlike most other medical fields, it is possible to noninvasively examine the organ of interest. This "window" to the eye provides so much information about the patient's general well being. As optometrists, we have an obligation to detect and manage a multitude of eye and related health problems, and our choice of equipment to fulfill this duty is crucial. Although exciting high-tech devices, such as OCT, have revolutionized the way we detect and monitor eye disease, the newer equipment has not invalidated the humble handheld lens. Condensing lenses have the benefit of being readily available, relatively low cost and highly portable. This article will discuss the different types of diagnostic and therapeutic lenses, why optometrists may find these techniques helpful and what devices have become available more recently.

There are myriad condensing lenses available today for use with the slit lamp or the binocular indirect ophthalmoscope (BIO). In essence, the lenses are broken down into high magnification lenses, used to visualize great detail, and wide-angle lenses, used to cover a large area in a single view. Some are best used with dilated pupils and others through small pupils. We will break down each type of lens and offer some recommendations based on our experience.

The most commonly used lenses are indirect, also known as "aspheric" and "condensing" lenses, which are classically used at a slit lamp—for example, 78D or 90D lenses—or with a head mounted binocular indirect ophthalmoscope (e.g., 20D or 28D lenses). These are the traditional optics familiar to all eye care practitioners. They work very well and are available in a range of powers and designs.



Increased magnification (right) results in a "hazier" view.

Indirect Ophthalmoscopy Lenses

Slit lamp indirect ophthalmoscopy has become the standard diagnostic procedure for comprehensive eye examination. Volk Optical introduced the 60D lens in the early 1980s and, in subsequent years, extended the range of lenses for the slit lamp by adding additional powers. Over time, indirect ophthalmoscopy has come to replace the previously widespread use of direct ophthalmoscopy, and with good reason. Advantages include

Table 1. Indirect Lenses and Their Typical Use

Power	Purpose	Application
90D	View the posterior pole using a slit lamp	Good general purpose lens. Alternative to 78D if the practitioner elects to use just one lens.
78D	View the posterior pole using a slit lamp	Good all-around lens. Ideal option if thepractitioner uses a single lens.
60D	View the posterior pole using a slit lamp	Ideal for optic nerve head examination as lens offers higher magnification near 1x.
28D	View the retina including periphery using a head-mounted BIO	Lower magnification than 20D. Ideal for pediatric examination, when scleral indentation is required and for patients with nystagmus. Useful when slit lamp examination is not possible.
20D	View the retina including periphery using a head-mounted BIO	Higher magnification than 28D. Ideal for pediatric examination, when scleral indentation is required and for patients with nystagmus. Useful when slit lamp examination is not possible.

a larger field of view, a comfortable working distance between practitioner and patient, and most importantly a stereoscopic view, which enhances depth perception and helps provide a more comprehensive examination.

These lenses form a real, inverted image of the retina in between the lens and the practitioner. The technique is not always easy to master, but the benefits are notable once the user becomes proficient. Since the image is inverted and reversed, making a sketch of the retina on paper can be readily achieved by turning the page upside down and drawing what is seen, allowing for a simple conversion when the page is properly reoriented. Another tip for successful examination is to view the periphery sequentially and leave the macula until last, as taking patient comfort into account is likely to improve compliance.

Since the power of the optic dictates the magnification and field of view (see *"Crunching the Numbers: Magnification and Field of View," p. 60*), different lenses have distinct characteristics, which allow the doctor to select the best lens per their preference and the specific task to be addressed. Let's consider their value for a variety of tasks.

Head-mounted BIO. When using the BIO, the type of condensing lens is as important as turning the light on. The advances in technology over the last few years have enabled a much more efficient and detailed

examination of the retina, macula and optic nerve. Each has their advantages and disadvantages.

The main workhorse lens for use with the BIO is the 20D lens. This relatively low-powered lens (2.2D, 20D, Volk Optical; 20D Ocular Instruments; Diamond 20D Katena) is a compromise between magnification and field of view. Seeing subtle hemorrhages in the posterior pole with a red-free filter and analyzing peripheral retinal anomalies with scleral depression are its best qualities. It works best with a fully dilated pupil.

Advances in design have minimized reflections, allowing unobstructed views. Ocular Instruments has an attachment for its Maxfield 20D lens called the Saxena Retinal Grid 520, which fits onto the front side of the lens. It has a grid pattern of monofilament lines spaced at 5.20mm, which helps in estimating the size of retinal lesions, choroidal nevi and other anomalies in need of documentation by comparing the grid size with the optic nerve head. If a camera is not available, estimating the size with the grid provides a reliable measurement, which can be referenced at subsequent visits to rule out progression. Volk has developed a series of lenses with low dispersion glass and anti-reflective coating to further minimize reflections. The Digital ClearMag is designed to replace a 14/15D lens because of its increased magnification and the Digital ClearField is designed to replace a 20D/2.2 lens.

The lower dioptric power lenses (MaculaPlus 5.5x and 15D, Volk Optical; 16D, Ocular Instruments), which have greater magnification, are good for evaluating the posterior pole including a clear, stereoscopic view of the macula, optic nerve and nerve fiber layer. They also come in handy when a patient is unable to sit behind the slit lamp and a more detailed view of the optic nerve in needed—for instance, to estimate rim tissue in glaucoma or the macula to rule out macular edema. The only disadvantage to these lenses is the long working distance from the cornea. Long fingers are needed to steady the lenses; however, practitioners can use two hands and place the ulnar side of the palm of one hand on the patient's forehead, while the other hand rests on top of it.

Crunching the Numbers: Magnification and Field of View

Indirect ophthalmoscopy is performed when the examiner views the image of a patient's fundus through a condensing lens. Handheld lenses typically range in power from +14.00D to +40.00D, while condensing lenses included in a slit lamp may have a power as high as +120.00D. The resulting magnification is:

$$M = -\frac{P}{C} \times M_E$$

where P is the total dioptric power of the patient's eye and C is the power of the condensing lens.

M_E represents the amount of additional angular magnification needed for the examiner to clearly view the image produced by the condensing lens. M_E is usually computed or quoted in reference to a standard viewing distance of 25cm (4D). The method of computing M_E depends on how the examiner views the lens image. If the examiner performs handheld indirect ophthalmoscopy and has a sufficient amount of accommodation to view this image, then:

$$M_E = \frac{A}{4}$$

where A is the amount the examiner accommodates in diopters. If the examiner is presbyopic, A represents the add power used by the examiner for near viewing.

Consider a presbyopic examiner performing handheld BIO on an emmetropic patient. The examiner wears a +23.50D add. The refracting components of this patient's eye (cornea and crystalline lens) may be modeled by a +60.00D thin lens. When the examiner holds a +16.00D condensing lens in front of the eye and views the image through the add, the magnification is:

$$M = -\frac{+60.00\ D}{+16.00\ D} \times \frac{+2.5\ D}{4} = -2.34x$$

It should be noted that as the condensing lens power increases, the amount of magnification decreases. While the above formula assumes that the patient is emmetropic, the presence of refractive error has little to no effect on the size of the lens image.

If indirect ophthalmoscopy is performed with a slit lamp, then M_E simply represents the amount of auxiliary magnification provided by the device. For example, consider the examiner viewing the emmetropic patient described above. She replaces the handheld condensing lens with a +90.00D lens in a slit lamp set at 10x magnification. The magnification in this scenario becomes:

$$M = -\frac{+60.00\ D}{+90.00\ D} \times 10 = -6.67x$$

If the magnification of an optical system increases, the maximum possible size of the field of view (FOV) will decrease. For indirect ophthalmoscopy, the field of view is determined by the diameter of the condensing lens, its location with respect to the patient's eye, and the power of the patient's eye (P):

$$FOV = \frac{\text{condensing lens diameter}}{\text{eye to condensing lens distance}} \times \frac{1}{P}$$

To achieve the largest possible field of view, the distance from the lens to the eye must be approximately equal to the focal length of the lens, although the position of the examiner will make this distance slightly larger.

Consider again the examiner performing handheld indirect ophthalmoscopy on an emmetropic patient with a +60.00D eye. The +16.00D condensing lens has a diameter of 50mm. The examiner holds this lens 7.26cm in front of the patient's eye. The resulting field of view is:

$$FOV = \frac{5.0\ cm}{7.2\ cm} \times \frac{1}{60.00\ D} = 0.012\ m = 12mm$$

The medium dioptric powered lenses provide a larger field of view while sacrificing some degree of magnification.

The medium dioptric powered lenses (28D, 30D Volk Optical, 30D Ocular Instruments; Diamond 28D, Katena) are ideal for patients with small pupils or a constricted, opaque capsulorhexis opening of the anterior capsule following cataract surgery. They provide a larger field of view while sacrificing some magnification. You have to be even more discriminating when examining the fundus because of the lack of magnification. Ocular Instruments also has an attachment for its Maxfield 28D lens called the Saxena Retinal Grid 428, for help in estimating the size of lesion and nevi.

Very high-powered 40D lenses work well for retinal screenings, especially in patient populations where seeing into the eye is a challenge in itself. A large swath of retina can be seen at one time to rule out any obvious disease.

At the slit lamp. Typically, the 78D with 0.77x magnification is a versatile all-around lens; if practitioners are to own just one lens, this may well be the best choice. The 90D (0.64x) is an alternative option, as it too is an appropriate general-purpose lens. The 60D lens is especially suitable for disc imaging since it offers higher magnification of approximately 1x; the unit magnification also means that no conversion is required when measuring disc size. The 20D and 28D lenses are ideal when more magnification is required, or when a longer working distance is desired. These lenses are preferable when patients can't work with the slit lamp, for children where a panoramic view is valuable and viewing time is limited, and for situations where imaging is challenging such as nystagmus or when scleral indentation is required *(Table 1)*.

All indirect lenses have the advantage of creating an image is relatively independent of the power of the eye

Table 2. Condensing Lenses Comparison Chart

Note: different lens manufacturers use different eye models to calculate magnification and field of view, hence the specifications are not directly comparable.

BINOCULAR INDIRECT OPHTHALMOSCOPY CONDENSING LENSES					
Manufacturer	**Lens**	**Field of View**	**Image Magnification**	**Working Distance**	**Best Use**
Katena	Diamond 20D	53	3.0x	48mm	General fundus exam
Katena	Diamond 28D	53	2.1x	35mm	General fundus exam
Ocular Instruments	MaxField 20D	50	2.97x	47mm	General fundus exam
Ocular Instruments	MaxField 30D	63	1.97x	26mm	Small pupil/large fundus area
Ocular Instruments	MaxField 40D	82	1.49x	14mm	Small pupil/large fundus area, pediatric exams
SVT	20D	46/60	3.13x	50mm	General fundus exam
SVT	30D	58/75	2.15x	30mm	Small pupil/large fundus area
Volk	Macula Plus 5.5	36/43	5.50x	80mm	High detailed view of disc, macula and post pole
Volk	15D	36/47	4.11x	72mm	High detailed view of disc, macula and post pole
Volk	Digital ClearMag	38/49	3.89x	60mm	High detailed view of disc, macula and post pole
Volk	20D	46/60	3.13x	50mm	General panretinal fundus exam
Volk	Digital ClearField	55/72	2.79x	37mm	General panretinal fundus exam
Volk	Panretinal 2.2	57/73	2.68x	40mm	General panretinal fundus exam
Volk	30D	58/75	2.15x	30mm	Small pupil/large fundus area
Volk	40D	69/90	1.67x	20mm	Small pupil/large fundus area; good in pediatric exams
SLIT LAMP CONDENSING LENSES					
Manufacturer	**Lens**	**Field of View**	**Image Magnification**	**Working Distance**	**Best Use**
Katena	Diamond 60D	68	0.96x	14mm	ONH and macula; posterior pole
Katena	Diamond 78D	80	0.77x	10mm	General fundus exam. Small pupil/large fundus area
Katena	Diamond 90D	75	0.64x	8mm	Panretinal fundus exam. Small pupil/large fundus area
Ocular Instruments	MaxField 60D	85	1.00x	10mm	ONH and macula; posterior pole
Ocular Instruments	MaxField High Mag 78D	88	0.98x	10mm	General posterior pole exam
Ocular Instruments	MaxField Standard 90D	94	0.75x	5mm	Panretinal fundus exam
SVT	60D	68/131	1.15x	10 to 13mm	Posterior pole exam
SVT	115D	95/155	0.76x	7mm	Small pupil/large fundus area
Volk	Digital High Mag	57/70	1.30x	13mm	Posterior pole, macula
Volk	60D	68/81	1.15x	13mm	ONH and macula; posterior pole
Volk	Digital 1.0x Imaging	60/72	1.0x	12mm	General posterior pole exam; photography
Volk	Super 66	80/96	1.0x	11mm	Posterior pole, macula
Volk	78D	81/97	0.93x	8mm	General posterior pole exam
Volk	Super Field	95/116	0.76x	7mm	Panretinal fundus exam
Volk	90D	74/89	0.76x	7mm	Panretinal fundus exam
Volk	Digital Wide Field	103/124	0.72x	4 to 5mm	Panretinal fundus exam

and so this technique is preferable for patients with high a refractive error. Significant astigmatism of more than five diopters, particularly if it is oblique, will noticeably impact the image. The only way to improve the quality of imaging further is to use a diagnostic lens that contacts the eye, as this will neutralize the irregularities in the cornea.

Selection factors. When choosing a lens, some of the key performance aspects to keep in mind include image quality, amount of light required, ease of imaging through the limiting pupil and the ergonomics of clinical use. Lens ergonomics specifically focus on the way it handles, the ease of control, the lens weight and general handling comfort. Much of this depends upon individual

The 20D lens is a good compromise between magnification and field of view.

preference and previous experience. Traditionally indirect lenses have been made from glass and have a lens holder with knurling. This tried-and-true design is a favorite with many practitioners.

Some newer lenses have a different appearance, with a silicone grip (designed to improve lens control); these are more lightweight due to the materials used. The PMMA lens is lighter than a traditional glass lens and it is protected from scratches by a hard coating made of evaporated diamond.

Lenses for small pupils. New optical designs claim to improve imaging through small pupils, such as for patients whose pupils do not dilate well. Lenses from Katena use a steeper front surface to move the ray bundle forward into the pupil plane. This design is meant to be more efficient than designs that position the ray bundle further back in the eye, closer to the nodal point.

In practice, the efficiency in the illumination pathway means that lower light levels can be used during the examination. This may improve patient comfort and cooperation, particularly with children. Additionally, for those patients whose pupils do not dilate well—for example, individuals with diabetes or patients taking alpha-blockers such as tamsulosin—imaging the retina or at least the macula is usually still possible.

Fundus Biomicroscopy Lenses

These devices are essential in the evaluation of the optic nerve in glaucoma, maculopathy and peripheral retinal disease. After performing BIO and finding an anomaly, using condensing lenses designed for the slit-lamp allows for an "up-close" look at the condition.

The optic nerve is best examined using a low-power biomicroscopy lens (e.g., 60D, Super 66 (66D), Volk Optical; 60D Ocular Instruments; Diamond 60D, Katena). Such a lens allows for greater magnification without having to use the high magnification of the biomicroscope, which results in a hazy view as the magnification of the slit lamp approaches the diffraction limits of light. Having a crisp image gives a detailed, clear view of the neuroretinal rim tissue that is vital in diagnosing and managing glaucoma.

The macula is also visualized well with the low-powered lenses. When macular changes are suspected, using a lower-power lens allows a detailed view of the inner and outer retina, especially the retinal pigment epithelium (RPE). Visualizing the granularity of the RPE is an acquired skill but a necessary one. Subtle RPE changes can be one of the first signs of macular disease.

Use low dioptric power lenses for a clear, stereoscopic view of the macula, optic nerve and nerve fiber layer.

Photo: Ocular Instruments

The Saxena Retinal Grid can help in estimating the size of lesions and nevi.

Peripheral fundus lesions are seen well with a high-powered biomicroscopy lens (e.g., 90D, SuperField, SuperVitreoFundus, Volk Optical; 90D, panfundus, Ocular Instruments; Diamond 90D, Katena). They allow the practitioner to see in great detail anomalies that may still be questionable after performing indirect ophthalmoscopy. The views possible from the BIO, scleral depression and the peripheral fundus lens gives the practitioner the information needed to make a specific diagnosis.

Diagnostic Contact Lenses

While binocular indirect lenses offer significant benefits, another tremendously valuable way of imaging the retina is to use a contact diagnostic lens. Lenses such as Volk's SuperQuad 160, Ocular Instruments Mainster PRP 165 or a Katena disposable Retina 180 provide access to even the most peripheral retina—a good view out to the ora serrata can be achieved. These lenses are surprisingly easy to use, assisted by the stability of the lens on the eye and more control over the eye and lids. While it is somewhat inconvenient to anesthetize the eye and use contact fluid, the imaging quality and access to ocular structures make the effort worthwhile.

For the anterior segment, contact lenses are required to view the anterior chamber since the mirrors within the lens are required to overcome the cornea's total internal reflection.

Gonioscopy. This technique is the key to accurate and timely diagnosis of glaucoma and is an important skill that all optometrists should hone. For example, a 4-mirror lens allows imaging of all four quadrants of the anterior chamber angle without excessive rotation of the lens since the illumination of the slit lamp can be efficiently scanned across each mirror. This lens has two additional advantages: it can image the central 30° of the posterior pole and full lens visualization can be achieved without using contact fluid.

An alternative to the customary 4-mirror lens is a 3-mirror lens. This one will access four different zones within the eye. Consequently, it is considered an "all-purpose lens," as this device used on its own allows a

Infection Control for Contact Lenses

For lenses that touch the eye, there appears to be a trend towards disposable products. Both Volk and Katena offer single-use lenses in individual sterile pouches. They are popular in hospitals because of the time, cost and logistics of disinfecting traditional reusable lenses. The convenience of an immediately available sterile lens in a busy environment is very often welcome.

With infection control always on the agenda in clinical environments, disposable medical devices have their place. Office-based practices may choose to use disposable lenses on "challenging" patients—for example, those with known hepatitis, HIV or a history of drug use. Practices may also benefit from the efficiencies in staff time and removal of disinfection chemicals. Single-use lenses are also a cost-effective way of trying a new type of lens without investing hundreds of dollars.

Photo: Katena

Katena's 4-mirror single-use gonio lens.

comprehensive eye exam. It does take time to master the rotation of the mirrors along with movement of the slit lamp beam and the subsequent interpretation, but once achieved, this is an ideal lens for a thorough examination. This is evidenced by the 3-mirror lens remaining in routine eye care with minimal changes to the optics for the last 50 years.

Diagnostic Lenses for SLT. With an increasing number of states expanding the scope of practice to allow optometrists to perform certain laser procedures, it is worth reviewing the lenses associated with argon and selective laser trabeculoplasty (SLT), Nd:YAG capsulotomy and Nd:YAG laser peripheral iridotomy. Again, each of the three main manufacturers offer suitable lenses for SLT; Ocular Instrument's Latina, Volk's single mirror and Katena's single mirror lenses are all examples of this utility. The Katena single mirror lens is available both with and without a handle. For capsulotomy, the best known lenses are Volk's reusable capsulotomy or their new single use lens, or Katena's single-use capsulotomy.

A broad selection of lenses is available to meet every clinical need and budget. These diagnostic and therapeutic lenses have stood the test of time, and the reusable style having been widely used over the last five decades. Lenses have recently undergone their own evolution due to modern manufacturing. This makes disposable lenses feasible and it is likely that they will become increasingly popular. Optometrists now have a wider range of lenses to choose from to address the various needs of their practices. ■

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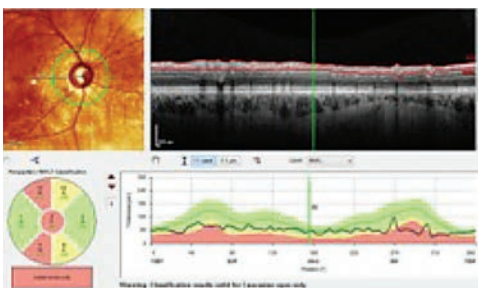
Red Disease: Is it Haunting Your Glaucoma Diagnoses?

New imaging modalities are game-changers for glaucoma care, but beware of false positives. **By William B. Potter, OD, and James L. Fanelli, OD**

Technological changes are continually improving our diagnostics and clinical care, especially for patients with glaucoma. Yet, technologies such as automated perimetry, tonometry and optical coherence tomography (OCT) come with a few drawbacks, the most important of which is the risk of misinterpreting the data due to false positives and false negatives. One study found the referral rate—from optometrists to ophthalmologists, as well as general ophthalmologists to glaucoma specialists—for a false positive reading for glaucoma patients ranges from 29% to 68%.[1] The same study also found 71% of referrals were made on a single suspicious reason (elevated intraocular pressure [IOP], visual field results or disc appearance) at six months.[1]



Both the Garway-Heath sectors, lower left, and the TSNIT graph, lower right, show an RNFL that is considered, statistically, outside of normal limits (in red), compared with the reference database. Clinicians must compare these findings with actual anatomical changes. In this case, these areas do, in fact, show damage.

Optometrists have an enormous responsibility to avoid over- and under-treatment in glaucoma care. Side effects of treatment are multiple in nature and severity; for example, beta-blocking ophthalmic drops can have significant cardiac and circulatory side effects, chronic glaucoma treatment can cause ocular surface disease (OSD) with a variety of implicated agents, and topical treatments have been known to cause cataracts.[2-4] One of the most important steps in avoiding overtreatment is steering clear of "red disease"—where non-existent disease is incorrectly indicated by instrumentation—when implementing new technologies intended to help inform treatment decisions.

Here, we discuss the ramifications of red disease and overtreatment for patients with glaucoma.

Know Your Tools

As with any technology, users must first understand two primary principles: what the technology does and, just as importantly, what the technology means—is the test reliable, does is correlate with the clinical findings, is it repeatable? For example, pre-perimetric glaucoma implies you have compelling evidence of optic nerve damage consistent with glaucomatous damage, yet there are no discernible visual field defects. Although it's generally accepted that 40% or more of ganglion cells need to be damaged before a visual field defect is noted, this generalization was based on evaluating a glaucoma suspect with standard automated white-on-white perimetry (SAP WOW).[5,6] Today, selective perimetry, targeting M-type ganglion cells, seems to be able to detect visual field abnormalities earlier than SAP WOW. So when it comes to SAP strategies, pre-perimetric glaucoma does exists. But perhaps we should be using selective perimetry in these cases instead. The point is to know what your technology does and doesn't do.

The same thing can be said for optic nerve imaging technologies, with a whole host of variances across instrument manufacturers. Each instrument's resolution, repeatability, image registration, post-image acquisition data processing and reference database all play into that technology's ability to provide accurate diagnostic data.

The Good and the Bad of OCT

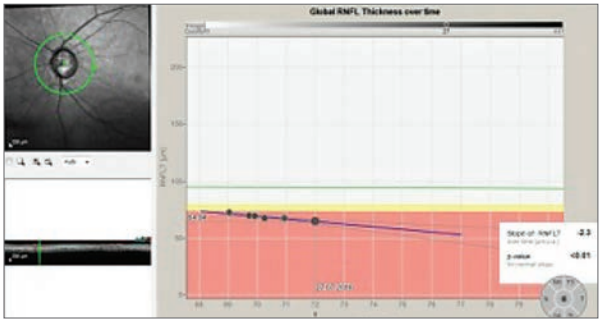
The development of optic nerve and nerve fiber layer scanning devices has changed how glaucoma is diagnosed and monitored. OCTs supplement clinical optic nerve assessment with reproducible, quantitative measurements of the optic nerve head (ONH), retinal nerve fiber layer (RNFL) and macula.[2] But this new-found information comes with its own set of technology-related concerns, as research suggests OCTs have a false positive rate of 15% to 36%.[7]

As with visual fields, an OCT reading provides a large amount of information and, while each parameter may provide valuable information, improper interpretation increases the chance of getting a false positive or false negative and drawing a wrong conclusion. For example, with OCT scanning, RNFL is the most specific parameter, with sensitivity equal to, or better than, ganglion cell and ONH analysis; yet clinicians must understand how it plays into the whole clinical picture to avoid misinterpreting the reading. One study found the overall incidence of false positives for the Cirrus (Zeiss) RNFL clock-hour map, quadrant map or deviation map at a <5% level was 39%, and the incidence of false positives for Spectralis (Heidelberg Engineering) RNFL sector or quadrant analysis was 18%.[7]

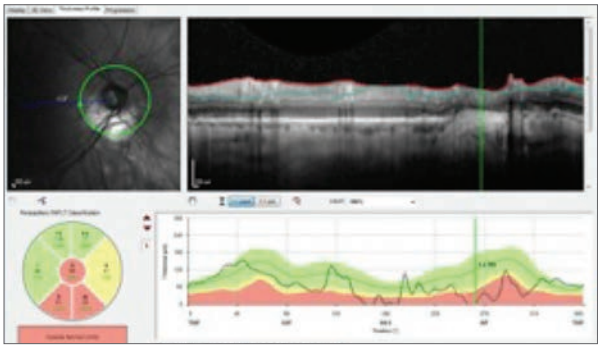
Beware the Database

Each OCT device is accompanied by a normative database associated with several parameters such as the RNFL scan (the TSNIT graph) and the macula thickness scans. At times, the database may be misleading or even inappropriate. Current OCT reference databases (RDBs) have 95% to 99% specificity cut-offs; however, they are dependent on the inclusion/exclusion criteria of the study protocol and have been carefully assessed by technicians, investigators and reading centers.[6] RDBs also do not include comorbidities and are within certain myopic constraints. But these RDBs are nothing more than statistical ranges for the index being analyzed.[8]

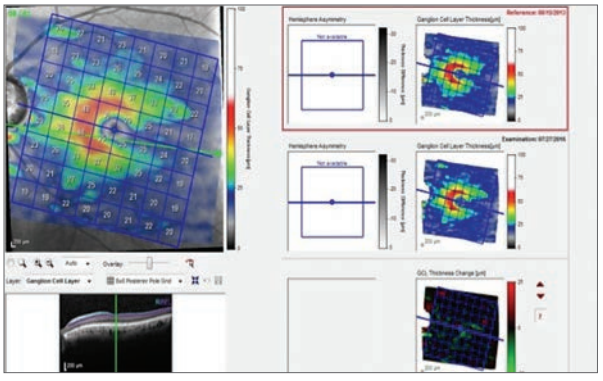
All too often, clinicians make diagnoses based upon the RDB comparisons, leading to red disease—flagging an individual as having glaucoma simply when the objective OCT image, or a portion thereof, lies outside the RDB. Invariably, as busy clinicians, we look for a quick,



This series of RNFL scans over a three-year period demonstrates progressive RNFL thinning. The downward slope of the global optic nerve trend, on the right, indicates progressive loss of tissue, indicative of worsening disease.



The presence of peripapillary atrophy is confounding the RNFL circle scan of a patient with advanced glaucomatous disease. The questionable change to the RNFL inferiorly in the area of greatest peripapillary atrophy suggests the patient progressed, further evidenced in the TSNIT indicated by the vertical line.



This scan of the GCL in a patient with advanced disease indicates ganglion cell loss in the inferior temporal region, which results in a superior arcuate defect with a nasal step, as seen on the left. The two scans on the right are of the same area separated by a three-year period. The change analysis, lower right, shows a slight decrease in GCL thickness, occurring along the horizontal raphe both superiorly and inferiorly.

accurate summary of the OCT report, and naturally our eyes gravitate to the red, yellow and green areas of the printouts—but those colors mean nothing more than that a particular index (RNFL scan, for example) falls within a relative normal, borderline or abnormal range, respectively. They do not tell us whether disease is or is not present. Therefore, it is imperative for the clinician to correlate this data (for example, a parameter on an OCT that is flagged as abnormal) with the overall clinical picture to see if the OCT findings make sense.

With glaucoma, clinicians must answer two questions for all patients:

(1) Is there a condition that needs to be treated or monitored? (Asked only during the initial work up.)

(2) Is the patient stable? (Asked at every follow-up visit and is independent of the answer to #1.)

While too much emphasis is placed on the RDBs, in our opinion, that data is only significant in the initial patient workup. The RDB should not even be considered in follow-up visits, as change over time becomes the primary marker of progression.

In the initial work-up, clinicians need to know whether or not the patient's optic nerve characteristics fall within a like database of individuals without glaucoma. Although the RDB does not determine the presence or absence of disease, it does gives us a feel for where our patient falls in the normal bell curve distribution of data points of the index we are studying. Whether or not the patient is within the normal range, the initial visit concludes with a decision to either actively manage or passively observe. During all subsequent visits, clinicians must determine if there is change to the structure or function over time, and the RDBs have no relevance—the patient becomes their own reference.

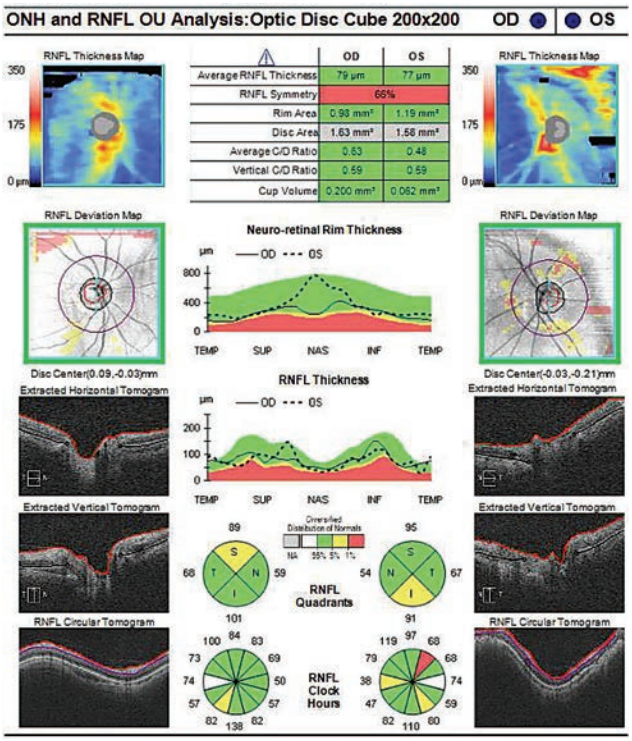
Documenting Progression

As glaucoma involves the progressive loss of retinal nerve fibers and optic rim tissue, repeat measurements are key

Tall Tales in Tonometry

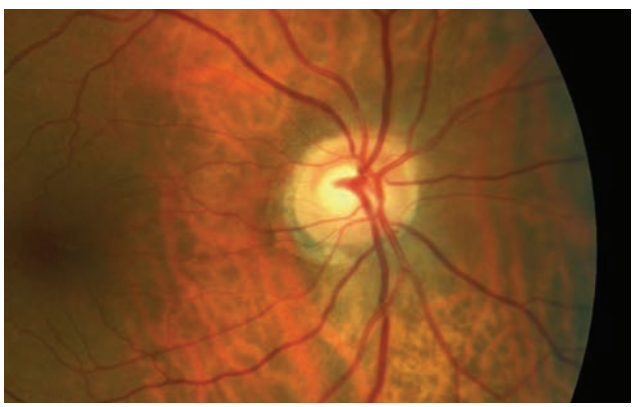
Measuring intraocular pressure (IOP) has generated some controversy in recent years, in part because advances in diagnostic technology allow us to better account for central corneal thickness (CCT) and rigidity when analyzing a patient's IOP. Thicker corneas tend to give higher readings on applanation tonometry, causing undue concern if a cornea is thicker than average and IOP readings are high.[1] Conversely, in the presence of thinner corneas, applanation tensions generally under-report actual IOP.

Some practitioners insist on "correcting" the IOP based on corneal thickness. However, correcting IOP using CCT measurements is fraught with dangers and can lead to a false positive or false negative



Images: Dan Carver, OD

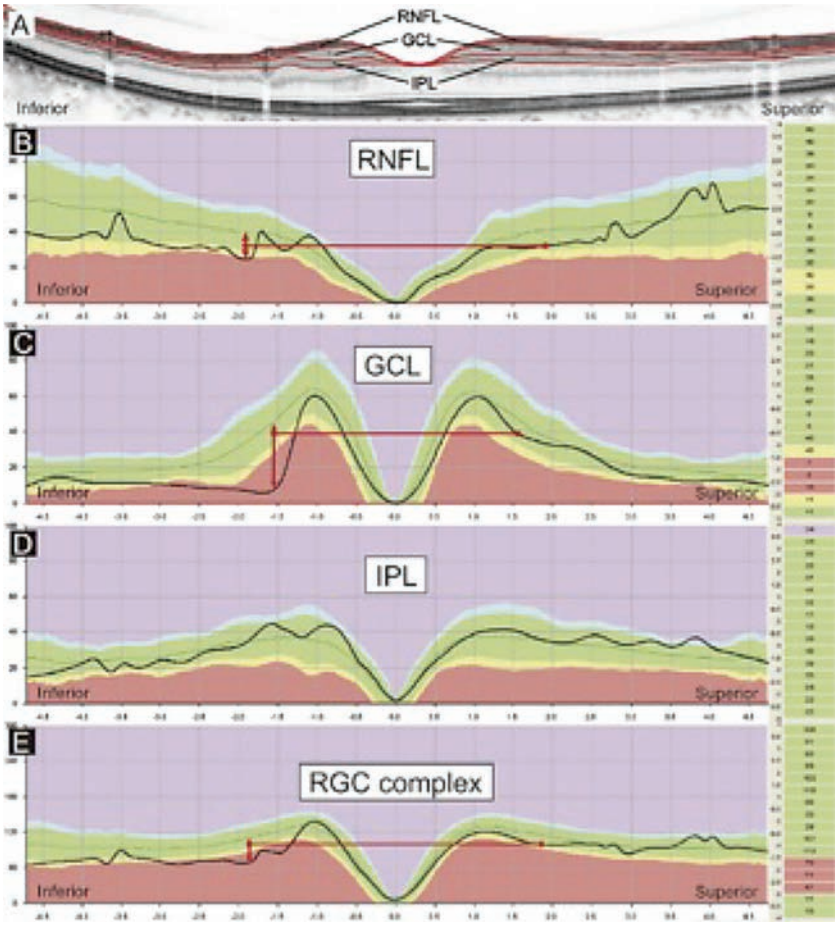
Does the cup-to-disc ratio in the OCT above match the photo below? In fact, the OCT overestimates the clinical c/d ratio.



reading. First, no one nomogram has been found to be accurate, and most of the well-known studies (AGIS, OHTS, EMGT, etc.) did not use a nomogram to convert IOP reading based on CCT. Second, converting IOPs based on CCT becomes a moot point when considering the therapeutic effect of treatment—target IOP—rarely changes significantly after correcting the reading using CCT. For example, assuming a desired reduction in IOP of 20%, an untreated applanation pressure of 30mm Hg has a target IOP of 24mm Hg, while its converted IOP readings of 28mm Hg has a target of just 23mm Hg.

1. Bhan A, Browning AC, Shah S, et al. Effect of corneal thickness on intraocular pressure measurements with the pneumotonometer, Goldmann applanation tonometer, and Tono-Pen. Invest Ophthalmol Vis Sci. 2002;43:1389-92.

This image represents several indices that may be examined in an OCT printout—RNFL, GCL, IPL and the RGC complex (GCC)—compared with a relative database. The image suggests that the most discernable variation from the RDB may be seen in GCL scans and least discernable in the IPL scans. Knowing your instrument is critical in interpreting this data. Does your OCT scanner image only the GCL, or does it image the GCL+IPL (GCC)? Interpreting data obtained by two different technologies (as in the case where a patient changes providers) can be exceedingly difficult.



to identifying and managing change over time. The most common pattern of developing retinal nerve fiber defects is widening of the defect.[9]

Evaluation of the cup-to-disc (c/d) ratio has been a mainstay in the consideration of glaucoma progression. While human examiners are subject to variability, our instrumentation cannot be considered flawless, either. Modern scanning instruments measure linear cup size and volume with apparent precision that may not agree with the clinical exam. Scleral crescents and peripapillary atrophy, for example, can cause the margin of the disc to appear ill defined, both to the examiner and to the scanning instrument. This tends to cause a larger than usual disc measurement and can subjectively affect the c/d ratio. A tilted disc, resulting from an oblique insertion of the optic nerve, could alter a scan due to parallax. Ideally, the optic nerve should be measured 90 degrees to the direction of the scan. Clinicians must be comfortable with their imaging instrument to ensure proper interpretation of its data.

Of particular interest for tracking progression is the current study of ganglion cell loss. Spectral domain OCT instruments can detect subtle changes in macular ganglion

Visual Fields: Facts and Fiction

While instrumentation errors are not common with visual fields (VFs), practitioners should still be wary of red disease when using them, especially if patient errors and fixation losses mimic defects in the visual field. VFs are dependent on the patient's ability to navigate through the test, and though the testing strategies are controlled, patient responses to VF testing are quite variable. It's extremely important to evaluate the error indices such as false positives, false negatives and fixation losses. Further, anatomical variations such as scotomas from a large nose, heavy eyebrows or droopy eyelids can influence the validity of the test.

The practitioner must always consider glaucoma's pathology, as the field defect must make sense with the physical examination of the optic nerve. For example, the nasal step VF defect must honor the horizontal midline, based on nerve fiber layer anatomy. Less structured defects would be more suspicious as artifacts, and should prompt practitioners to repeat the test. Even when using the correct testing strategy (selective vs. SAP), field interpretation can be clouded by confounding issues such as other disease states, a lack of defects when you expect them or a confusing defect.

In most situations, clinicians should repeat the VF testing when initial results don't correspond to the clinical picture. In the OHTS design, VFs were repeated three times in the presence of defects before the defect was considered real.[1]

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cell layer thickness and may portend glaucomatous development by several years.[10] However, even our best technology can sometimes produce errors that could potentially lead to overtreatment of glaucoma suspects.[11] One study looked at 538 eyes and found 9.7% showed segmentation errors in macular ganglion cell inner plexiform layer thickness measurement and roughly half of the errors were not reproducible.[12]

Additionally, the early warning of the ganglion cell loss may lead to treatment of individuals whose lifespan will not outlast the development of the disease. Although this new diagnostic criteria shows promise, we are not at a point where consideration of the ganglion cell complex should be the sole indicator in glaucoma treatment, especially in the context of concurrent macular disease, such as macular degeneration.

Glaucoma is a progressive disease that is easy to misrepresent if we rely too heavily on single instrument measurements and fail to consider imperfections in serial results. Diagnosis and treatment remain quite subjective in many cases, and the consideration of false positive and false negative results is critical to avoid over-treating. To avoid the trap of red disease, clinicians should always consider the spectrum of signs and symptoms, with emphasis on treating the individual patient and not the technologic finding. ■

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Dr. Fanelli is in private practice in Wilmington, NC, writes Review of Optometry*'s "Glaucoma Grand Rounds" column and lectures on glaucoma and other clinical topics.*

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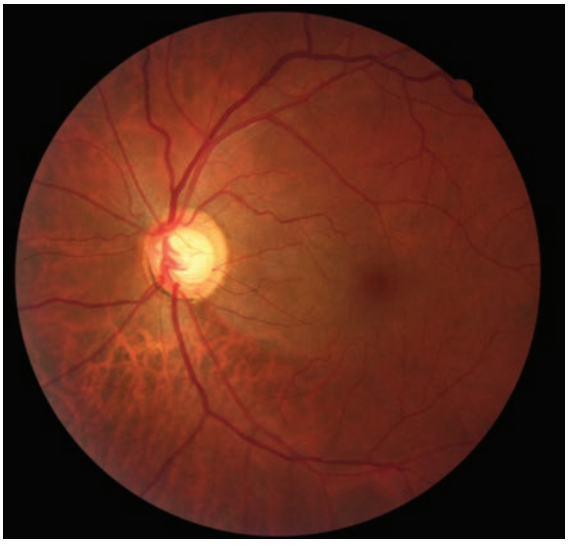
Protect Yourself From Medicolegal Risk

Even the best practitioners run the risk of being sued. Here's how you can avoid a suit—and survive if it does happen. **By Brian Chou, OD**

Getting sued for malpractice is a no-win situation. Even if you're not at fault, you still lose your time and suffer from the emotional toll and overall distraction.

Fortunately, malpractice payments on behalf of optometrists are rare; on average, there are less than 34 cases nationally each year, and half of them are less than $50,000.[1] But for each malpractice payment, there are even more claims. In ophthalmology, from 1985 to 2007, for every malpractice indemnity payment there were roughly four claims.[2] Over the course of a 35-year career, 95% of ophthalmologists will have one claim against them, and more than half can expect two or three.[3] While optometry may never incur the same level of risk, ODs must remain diligent as practitioners provide more and more medical services.

The general principles of how to protect yourself apply no matter the circumstances. However, the top three allegations all concern claims of lapses in diagnostic services, making this aspect of care particularly significant, especially given optometry's role as the first point of contact for many patients. According to the National Provider Data Bank, the most common allegation in optometric malpractice—more than 35% of cases—is failure to diagnose.[1] The next four most common allegations are delay in diagnosis, wrong or misdiagnosis, improper management and failure/delay in referral or consultation. In total, these five allegations account for two-thirds of all cases.[1] Recent articles suggest glaucoma, retinal detachment and tumors are the conditions underlying most optometric malpractice claims.[4-6]



Overlooking an inferior nerve fiber layer defect such as this could lead to litigation for failure to diagnose.

This article discusses how you can minimize your risk against malpractice in general, with emphasis on the optometrist's role as diagnostician and initiator of an episode of care. Remember that a missed diagnosis in and of itself does not constitute malpractice, just as a correct diagnosis does not dispel medicolegal risk. Rather, perceived negligence with resulting damages is what triggers a claim.

Evolving Standard of Care

With scope of practice expansion and an ever-widening array of diagnostic modalities and treatments, standard of care is a moving target. It's generally established by an expert witness who describes what a reasonably prudent practitioner would have done under a similar circumstance. This can often make or break a case, so it's important your

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"Standard of care can even be changed by a single judge in the event of litigation, as in *Helling v. Carey*, where the care given was well within the medical standard at the time, but the judge, in his ruling, literally changed the standard with his decision, i.e., requiring tonometry on patients even under age 40 since the test is inexpensive and harmless," says Pamela Miller, OD, JD, of Highland, Calif.

For example, we may see an increase in suits regarding missed or delayed diagnosis of progressive keratoconus and post-LASIK ectasia due to the evolving standard of care created by the approval of the first corneal collagen crosslinking (CXL) system. Designed to slow or halt the progression of these conditions, CXL may prevent further loss of best-spectacle corrected visual acuity (BSCVA) if used at the earliest signs of progressing keratoconus or post-LASIK ectasia.[7,8] Missing an early diagnosis for these conditions could lead to a malpractice suit, given this new opportunity to slow or halt progression of the disease in a milder state.

Best Practices

There are several precautionary steps you can take to protect yourself from malpractice suits.

(1) Assume a likeable chairside manner. Some of us are blessed with this natural demeanor, but some are not. Although personality is largely immutable, you can work on traits and habits conducive to communicating warmth and compassion. In one study, resident physicians received empathy training modules, after which patients rated a significantly improved physician empathy.[9] Patient surveys can offer valuable feedback in guiding you. A strong patient-doctor relationship is protective against malpractice claims. "Patients don't like suing doctors that they like," says Michael G. Harris, OD, JD, MS, clinical professor emeritus at the UC Berkeley School of Optometry and attorney at law.

(2) Carefully document and ensure good communication. If your exam records don't document a diagnostic test, it's assumed that it was not done. Your duty as a practitioner is to maintain an accurate and complete record, which can be challenging in the age of electronic health records (EHR). It's also important to communicate your diagnosis clearly to the patient, especially if there is potential for vision loss. For inconsequential findings, such as a benign iris nevus, it's a judgment call whether to mention it.

Poor Outcomes Don't Always Equal Malpractice

In a malpractice suit, the plaintiff is burdened with establishing four criteria: duty for the doctor to render care to the patient, negligence (i.e., breach of the standard of care), damages or injury (i.e., vision loss, disfigurement, disability) and a causal relationship between the negligence and damages.

Suppose you diagnose bilateral amblyopia in a patient who is nearly emmetropic with 20/40 BSCVA. Four years later, the patient has light-perception vision in each eye and is diagnosed with retinitis pigmentosa by another doctor. Although you did not meet the standard of care by offering a logical diagnosis and the patient experienced visual damage leading to light-perception vision, there would not be proximate cause. Had you correctly diagnosed retinitis pigmentosa, the visual outcome would have been the same, since there currently is no effective treatment. Hence there would not be malpractice for failure to diagnose.

"It is important to document your advice and instructions regarding follow-up care," Dr. Harris adds.

(3) Determine the cause of any reduced BSCVA, abnormal findings or worsening symptoms. For example, if you have a patient who presents with intraocular pressure (IOP) of 28mm Hg OD and 17mm Hg OS, then has IOP of 15mm Hg OU the next day, it is not acceptable to let the patient return in 12 months—you need to find out why there was an abnormal IOP to avoid missing a crucial diagnosis. In many instances, retinal imaging alone is not sufficient to rule out retinal pathology, as dilated examination is the standard.[10]

(4) Routinely administer automated screening visual fields, tonometry and dilated eye examination. A disproportionate number of conditions practitioners allegedly failed to diagnose could have been detected with these three measures. Liberal use of pupil dilation is perhaps the single most important action an optometrist can do to reduce the likelihood of a misdiagnosis that results in a malpractice claim.[6]

(5) Err on the side of over-referring. If your patient's diagnosis is out of your expertise or comfort level, document the reason for referral and the name of the practitioner (if known) or type of specialist, and explain the rationale for the referral to your patient. It's always a good idea to provide the doctor a referral letter or a copy of your exam findings and diagnosis. Especially with high-risk conditions, such as a macula-on retinal detachment or paracentral microbial keratitis, make sure you or your staff confirms the appointment was made and document the appointment time in your records. According to Dr. Miller, "When there is no consultation

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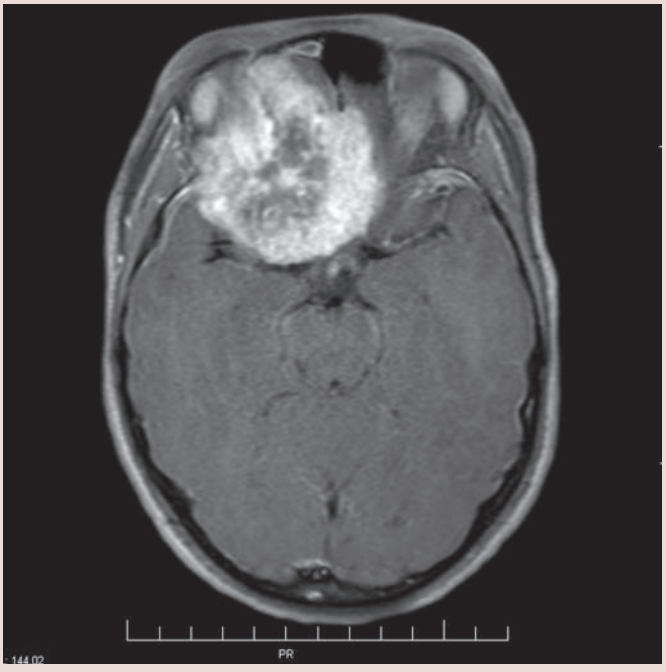
Case 1: Reduced Vision Due to Brain Tumor

A nine-year-old male was brought to an optometrist by his mother due to decreased distance vision and eyes getting "tired." Unaided visual acuities were 20/30 in each eye, correcting to 20/20 in each eye with a low astigmatic prescription. Pupil reflexes were normal with no afferent pupillary defect, confrontation visual fields were full, and non-contact tonometry yielded 16mm Hg OD and 17mm Hg OS. Biomicroscopy was unremarkable, and undilated funduscopy showed cup-to-disc ratios of 0.2 in each eye and normal posterior segments.

The next year, he returned with broken glasses and a complaint of headaches. BSCVA was 20/200 OD and 20/20 OS. Pupils were recorded as equal, round and reactive to light and accommodation with no afferent pupillary defect. Confrontation fields were full and non-contact tonometry as 9mm Hg OD, 13mm Hg OS. Biomicroscopy was unremarkable, and undilated funduscopy was recorded with cup-to-disc ratios of 0.2 in each eye and normal posterior segments. The optometrist diagnosed possible amblyopia in the right eye and accommodative spasm.



The patient's emergency MRI reveals the tumor—a few years too late.

The following year, he returned but was not examined because the public health insurance would not cover the costs of the exam. A year later, the patient was examined by a pediatric neuro-ophthalmologist on referral by his primary care physician. An emergently ordered MRI showed a mass larger than a golf ball pressing against his right optic nerve. Multiple surgeries successfully removed the meningioma, but he ended up with no light perception in the right eye.

The patient's family filed a malpractice claim against the optometrist. During discovery, the defendant OD produced a referral note indicating that he had referred the boy to ophthalmology. The patient's mother denied receiving a referral or receiving any communication about the urgency of identifying the cause of her son's reduced vision.

As the plaintiff's expert witness, I opined that the optometrist failed to meet the standard of care due to an inadequate attempt to identify the cause of BSCVA dropping from 20/20 to 20/200 over a year. Ambylopia was not a reasonable diagnosis since the patient previously had 20/20 acuity in that eye with no anisometropia, strabismus or media opacity. Accommodative spasm also was not a reasonable diagnosis given the unilateral nature of reduced vision and poor BSCVA.

Regardless of whether or not an appropriate referral was made to an ophthalmologist, the OD should have performed a dilated eye examination, automated visual fields, rechecked for a relative afferent pupillary defect and ensured he was seen by an ophthalmologist while conveying urgency to the parent. Earlier detection of the meningioma would likely have averted this patient's catastrophic vision loss.

This case settled for an undisclosed amount.

report received after the patient is referred, it is always a good idea to follow up with the patient and the physician."

*(6) **Administer informed consent and document when patients decline dilation when medically indicated.*** Dilation is crucial to confirm myriad diagnoses. If the patient recognizes the increased risk and makes an informed decision to decline dilation, thereby hindering your ability to provide a definitive diagnosis, this should be memorialized by the patient's signature with a date. "In some cases, you may want to use a specific informed consent document and have it signed by the patient and witnessed," says Dr. Harris. Of course, the patient must be legally able to give consent; in the event the patient is a minor or impaired, the parent or guardian should sign the form.

*(7) **Stay up-to-date.*** Clinicians should remain current with continuing education and certifications, as diagnostics evolve with new technology, clinical practice guidelines and court precedents. For example, the availability of anti-VEGF injections for treating wet age-related macular degeneration now opens up the

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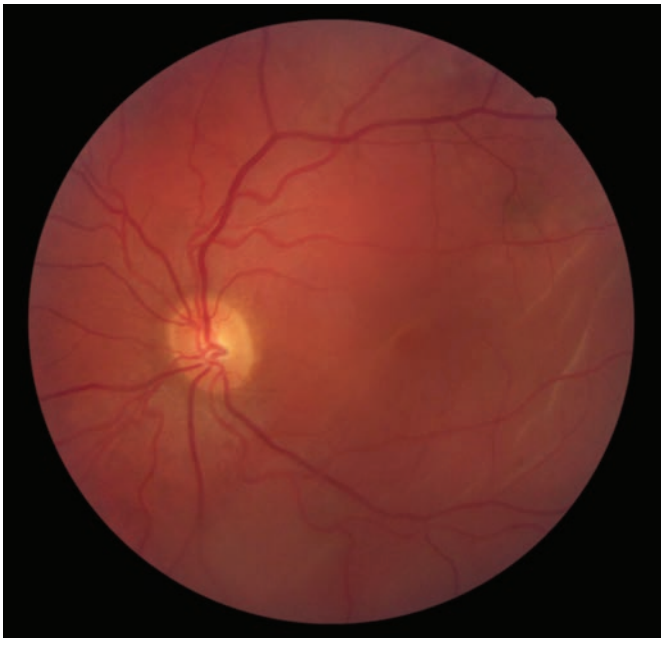
possibility of increased malpractice exposure for ODs who fail to diagnose this in a timely fashion.[11]

(8) Have adequate professional liability insurance. Most practitioners should have at least a $2 million occurrence limit and a $4 million aggregate limit. A personal umbrella policy will not cover excess liability beyond your professional liability insurance. When you end or switch your professional liability insurance, it is wise to obtain or confirm the existence of "tail coverage," which extends the time after you drop the policy when you can still report claims brought against you. "If you retire, make certain you are still covered for any actions that may arise out of the time you actually saw patients," says Dr. Miller. "Beware of the statute of limitations, especially with respect to minors you saw during your practice years."



Research suggests retinal detachment, as seen here, is a common condition underlying optometric malpractice claims.

If You Are Sued

The patient, their attorney, or your state board may notify you of a malpractice suit for failure to diagnose. In these situations, contact your professional liability insurance carrier without delay and provide the requested documentation. Never contact the patient or the patient's attorney without first consulting your professional liability insurance to avoid jeopardizing your case. Any information you share can be used against you. Your professional liability insurance will assign you an attorney to guide your legal defense.

"You may not agree with the advice given to you by the insurance company's attorney, especially if you are advised to settle a case which you think has no merit," says Dr. Harris. "You can hire your own private attorney, but this is usually extremely expensive and not worthwhile. It is usually best to heed the insurance company's attorney's advice even if you disagree with it."

Should You Apologize?

If a patient has a poor outcome, it can be tempting to apologize. However, it's best to seek your legal counsel's opinion first. Apologizing when you did nothing wrong may compromise your defense. In a survey of nearly 1,400 physicians who were sued, when asked, "Would saying 'I'm sorry' have helped?" 93% answered "no."[1] A better approach may be to express compassion for your patient's situation. In the majority of instances, any communication after a claim is made between you and the patient should be through each party's legal counsel.

Still, "it is important to remember that the assigned attorney's client is actually the insurance company, not you," says Dr. Miller. "You may wish to at least consult with your own attorney to ensure that you are being properly represented and that your interests are protected."

While you review your patient's records, know that adding supplemental notes or making deletions to the records after learning about the suit is fraught with danger. Such changes to the records are discoverable and can look suspicious. "Tampering with records can lead to other serious legal action and sanctions from your state board," says Dr. Harris.

However, if you do recall pertinent information, Dr. Miller says, "it's best to add it as a separate informational sheet that is dated, signed and includes the reason for the addendum. This makes it clear that it is not part of the original patient record, but allows for your input."

Expect a Marathon, Not a Sprint

Malpractice suits are time-consuming and disruptive to your schedule, as 78% last more than a year, and 39% last more than three years.[12] Additionally, 28% of physicians sued spent more than 40 hours in preparation of their case and 30% of those going to trial spent 40 hours or more in court and trial-related meetings.[12]

But most cases will settle. In an analysis of 518 optometric cases,

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Case 2: Symptoms from Macular Edema Blamed on LASIK

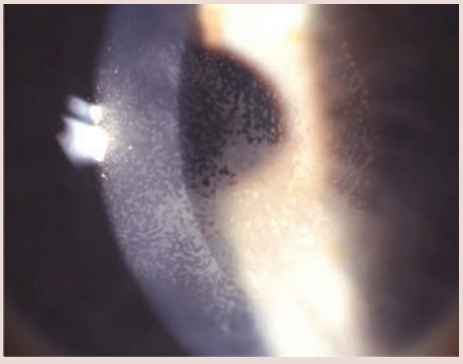
A 35-year-old woman underwent uncomplicated, successful bilateral LASIK for moderate myopia. Her ocular history was significant for a retinal condition as a teenager, which she remembered as macular degeneration. However, the preoperative dilated eye examination failed to show any retinal pathology. At the one-month postoperative visit, unaided visual acuities were 20/20 in each eye, and biomicroscopy was unremarkable aside from meibomian gland secretions under the left flap. At the three-month postoperative visit, unaided visual acuities had not changed. Biomicroscopy was unremarkable except for epithelial ingrowth under the left flap edge periphery.

At nine months postoperatively, the patient presented complaining of "split vision" in the left eye with symptomatic onset about one month prior. Unaided visual acuities were 20/20 in each eye. Amsler grid for the right eye was normal, but metamorphopsia was present in the left eye. The patient was referred to a retinal specialist.

Two weeks later, complaining of seeing "letters broken in half" out of the left eye, the patient was examined by an ophthalmologist in another practice. Unaided visual acuities were the same, and biomicroscopy showed some superficial scarring of the left cornea. Optical coherence tomography (OCT) showed the left fovea was approximately 50µm thicker than the right eye. The ophthalmologist diagnosed macular edema OS and started her on topical nonsteroidal anti-inflammatory drops. Six weeks later, a retinal specialist confirmed the diagnosis of macular edema in the left eye. One year after the retinal specialist consult, the patient returned for follow up, still complaining of distorted vision in the left eye. Unaided visual acuities were still 20/20 in each eye and the corneas appeared the same. OCT confirmed persisting macular edema in the left eye.

The patient filed a complaint claiming damages in excess of $500,000 against the optometrist who provided her postoperative care, alleging negligence and failing to refer her for treatment of epithelial ingrowth.

As the expert witness for the defendant optometrist, I opined that the optometrist met the standard in providing postoperative care for this patient.



Most cases of epithelial ingrowth only require monitoring. However, severe cases that threaten vision, as shown here, require referral.

Most cases of epithelial ingrowth are clinically insignificant and non-progressive. In such cases, monitoring is usually sufficient and referral is not required. However, if epithelial ingrowth is progressive and forming nests near the visual axis, it is appropriate to refer the patient back to the refractive surgeon to lift the flap, remove the cells and prevent keratolysis. In this case, I found that the patient's symptoms were attributable mostly, if not entirely, to macular edema and not epithelial ingrowth or other interface debris.

As this case is pending, additional information may come forth.

98% were the result of negotiated settlements and only 2% the result of court judgments.[1]

Closing Arguments

Unfortunately, good doctors sometimes get sued for malpractice. It's not possible to eliminate all medicolegal risk, but these measures can minimize your exposure. Patients generally don't expect perfection from their doctor. We are all human and make mistakes. Yet, our patients expect us to be competent and render reasonably prudent care, and rightfully so. ■

Dr. Chou serves as an expert witness for litigation involving optometric standard of care. He is a partner at EyeLux Optometry in San Diego and writes on a diverse range of industry topics.

Disclaimer: The content in this article is for general information only and does not constitute legal or professional advice or an opinion of any kind.

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Injectable Medications in Ocular Care

Optometrists can make use of these treatments using the following protocols.

By Brandon Runyon, OD, Blair Lonsberry, OD, and Nathan Lighthizer, OD

"You're going to put a needle where? You are the glasses and contacts doctor, not the injections doctor." In the words of football coach Lee Corso, "Not so fast, my friend." With scope of practice expanding in many states, it may be only a matter of time before injections are a regular part of an optometrist's daily grind. Naturally, optometrists are curious about them.

This article reviews the four most common injections currently performed in eye care: subcutaneous/intradermal, intravenous, subconjunctival and intramuscular (IM) injections.

Subcutaneous/Intradermal Injections

Clinically speaking, the most common injection that optometrists are performing is a subcutaneous or intradermal injection. Anesthetics are the primary class of medications used in eye care, injected via intradermal or subcutaneous routes.[1-2] These medications include local anesthetics used prior to in-office procedures—for instance, benign lump removal.

The two most common local anesthetics used in eye care are

This 10cc syringe is filled with 1% lidocaine with epinephrine and uses a 30g half-inch needle for intradermal injection.

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Goal Statement: With the aging population, the need to treat ocular disease—especially more advanced cases that may require the use of injectable medications—will likely be required of many optometrists. Patients need their local eye care provider to be comfortable and familiar with these injections. Because optometrists are just beginning to administer injections as scope of practice expands, there is a general lack of education or training in such injections. The goal of this article is to provide optometrists with a comprehensive overview of the most common injections that optometrists perform, and to improve their clinical knowledge and comfort level when performing clinical procedures around the eye.

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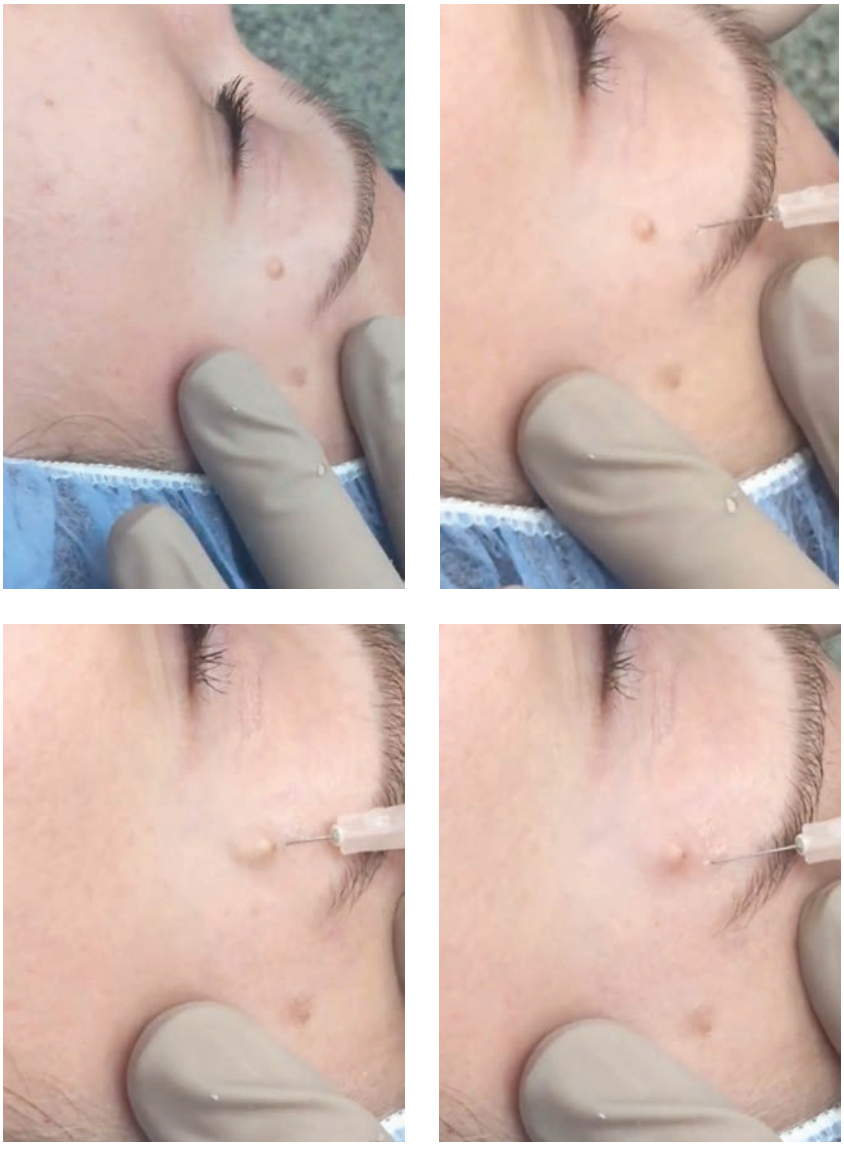
Xylocaine (lidocaine, Astra Zeneca) and Marcaine (bupivacaine, Pfizer).[1-4] For lidodaine, the concentration used around the ocular adnexa is usually 0.5%, 1.0% or 2.0%.[1-4] Never inject 4.0% lidocaine, because the higher concentration increases the risk of anesthetic-related complications. Lidocaine has an onset of action in 30 seconds to one minute, with a duration of around 30 to 60 minutes.[1-4] Lidocaine with epinephrine, i.e., 0.5mL of 1% lidocaine with epinephrine 1:100,000, lasts about twice as long due to the vasoconstrictive effects of the epinephrine. The lidocaine and epinephrine come in a combination and often don't require mixing. The maximum allowable dose of lidocaine for an adult is 30mL.[5] This is one reason why local anesthesia with lidocaine is so safe. An entire lid can be anesthetized with less than 1mL in most cases. Even if multiple areas require numbing—for example, in the case of a multiple papilloma removal—it would be unusual to exceed 2mL, so the maximum toxic dose should never be approached.

Contraindications

Avoid anesthetic use in patients who have contaminated wounds—i.e., any wound you did not create yourself under sterile conditions. Additionally, avoid anesthetic use in patients with peripheral vascular disease, cerebrovascular or cardiovascular disease, immunocompromising diseases or nerve blocks. When contraindications do not exist, most practitioners will reach for lidocaine with epinephrine. It is advantageous to use when working on the eyelid and face due to the area's extensive vascularization. It will often make the job easier during lesion removal, as there will be less bleeding, less swelling and the duration of the anesthesia effect will be increased.



Top left, keep the skin taut immediately before and during the injection. Top right, note the approximately 10- to 20-degree angle of the 30g needle above the skin plane. Bottom left, as the doctor performs the intradermal injection, note the bolus of anesthetic underneath the lesion. Bottom right, the anesthetic is placed underneath the lesion. Always inject as the needle is being withdrawn.

Defining Injection Types

- *Subcutaneous* – Any injection below the dermis in the subcutaneous space.
- *Intradermal* – Any injection into the dermal space (which is below the epidermis).

Two points of clarification when differentiating subcutaneous and intradermal injections:

- Since there is no defined subcutaneous tissue plane in the eyelids, injections into the eyelid are placed in the dermal plane, hence, they are most correctly referred to as intradermal.
- A defined subcutaneous plane appears again beyond the rim of the orbit in the skin of the face enabling the administration of true subcutaneous injections.

If, however, epinephrine is contraindicated, use lidocaine without epinephrine. Contraindications of epinephrine include angle-closure glaucoma and pregnancy or labor.[4,5] It can diminish vascular flow, so if a patient has peripheral vascular disease, that could further reduce the already reduced blood flow. Never use epinephrine in contaminated wounds because it decreases blood flow, which decreases the wound's natural defenses, potentially increasing the risk of infection. Lidocaine without epinephrine used in eye care is usually in a concentration of 1.0% or 2.0%.[4,5]

Bupivacaine, most often found in 0.25% concentration, has a slower onset, but is a longer lasting anesthetic agent than lidocaine. It may require approximately five minutes to take effect, but it usually lasts around twice as long as lidocaine.[5,6] It is also possible to mix with lidocaine, getting the dual benefit of the quick-acting lidocaine and the longer-lasting bupivacaine. They are often combined in a 50/50 mixture. Research shows no significant difference in onset and duration of action when comparing 0.25% bupivacaine by itself vs. when used in combination with 1% lidocaine.[5] However, addition of epinephrine can shorten the onset and significantly increase the duration of action when used with either anesthetic or with the mixture of the two, which is still similar to the onset and duration of action for lidocaine with epinephrine, indicating that lidocaine with epinephrine should be the go-to anesthetic combination when possible.[6]

Pros and Cons

Advantages of local anesthetic injections include ease of administration, the ability to put the medication directly where it is needed and the ability to control the quantity. Local anesthetic injections are safe and reliable for in-office use. They are more reliable than topical anesthetic creams or gels, which often need 30 to 45 minutes to activate and may not give a full anesthetic effect.[5,7] In addition, their inclusion of epinephrine gives them vasoconstrictor capabilities.[5] This will provide some amount of hemostasis, which will help minimize bleeding, bruising or swelling.

Disadvantages of local anesthetic injections include discomfort or pain during the injection, especially in the eyelid or face due to the density of free nerve endings in the tissue. Patients can exhibit a certain "fear reaction" with the thought of a needle and injection around the eye. Most often patients will describe a small needle stick or "bee sting" when the needle penetrates through the epidermis and will feel the most pain or burn as the anesthetic is injected. Once the anesthetic takes effect, the discomfort is largely over. The anatomy can be distorted from the injected anesthetic, which can make it more difficult to visualize the tissue in its normal state for lump and bump removal. However, since we often inject very small amounts of local anesthesia, often 0.3cc to 0.5cc, tissue distortion is minimal.

Other risks of local anesthesia include allergic reaction, infection, bleeding from needle trauma, ischemic damage to the tissue if epinephrine is used and systemic absorption, eliciting rare side effects such as tremor, tinnitus, visual disturbance, mental status change, seizure and circumoral numbness.

Most anesthetics are either esters or amides. Esters, such as procaine, novocaine and tetracaine, are particularly notorious allergy-inducing agents.[8,9] The topical anesthetic drops that we use in eye care are esters, which are especially effective in numbing mucous membranes, but often are avoided in injections because they are known allergens, whereas allergies to amide compounds, such as lidocaine and bupivacaine, are much less common.[8,9] Usually, when an allergic reaction occurs to an amide anesthetic, it is due to preservatives in the solution, such as methylparaben, which is used in a wide selection of anesthetics.[8,9] Of particular importance, there is no cross reactivity between the amide and ester class anesthetics. Your patient who had an allergic reaction to an ester-based anesthetic (novocaine) at the dentist may have no issues when numbing the papilloma with an amide-based anesthetic (lidocaine).[8,9]

Other contraindications include any history of cardiovascular reactions, including hypotension, bradycardia, arrhythmia and respiratory depression from prior anesthetics.[8,9]

Patient Comfort

Local anesthetics are weak bases; however, to prolong shelf life, they are prepared in acidic solutions. Consequently, it stings when injected. The pH is usually between four and five in the bottle. At that pH, there are two species of lidocaine molecules: one is the charged or polar molecule, and the other is the uncharged or nonpolar molecule. There is a predominance of the charged molecule: about 10 times as much charged/polar lidocaine ion as uncharged/nonpolar lidocaine. Of particular importance, it is the uncharged/nonpolar lidocaine molecule that is able to cross the neuronal membrane, block the sodium channels and precipitate the anesthesia. So when injecting anesthetic out of the bottle, we are injecting an acidic solution with 10 times as much inactive charged/polar anesthetic as the active uncharged/nonpolar form. During the injection, the tissue's natural buffers have to alter that from a

pH of four to five to a pH of 7.4. As that occurs, more of the active, nonpolar molecule becomes available to provide the anesthesia.

If the pH is raised before the injection, it alters the ratio of inactive to active anesthetic. If the pH is raised up to 7.4, it decreases the ratio from 10/1 to 4/1. Now there would only be four times as much nonactive anesthetic compared with active anesthetic. The injection should sting less because more active anesthetic is being injected at a more neutral pH, while at the same time not having to wait for the tissue's natural buffers to increase the pH. Preparing a solution of nine parts anesthetic to one part sodium bicarbonate before injection will accomplish this by raising the pH of the injectable anesthetic, which puts more anesthetic in the active, unpolar form, which, in turn, will more quickly numb the pain of the injection.

Subcutaneous/Intradermal Injections Protocol

1. Wear protective gloves, maintain asepsis and take appropriate needle stick precautions throughout the procedure.

2. Clean the top of the medication vial with an alcohol prep pad.

3. Draw up medication with the 18g needle by injecting into the vial an amount of air that is equal to or slightly larger than the amount of medication desired.

4. Withdraw the plunger to a level that is slightly more than the desired amount of medication. The medication vial should be either horizontal or inverted to minimize air in the syringe.

5. Remove the 18g needle and place it in the sharps box. Replace the needle with the finer 27g or 30g needle.

6. Invert the needle and push inward on the plunger to remove any air bubbles. You may additionally need to tap the syringe with your fingers.

7. Clean the injection site with an alcohol prep pad and allow it to air dry.

8. Keeping the skin taut at the injection site, pierce the skin with the needle with the bevel of the needle up. The angle of the needle as it enters the skin should be approximately 15 degrees to 30 degrees above the skin plane.

9. Once the needle is under the skin, pass the needle through the skin to the area requiring the injection.

10. Before injecting, pull back on the plunger to ensure the needle is not in a blood vessel.

11. Inject the medication at a steady rate as you are withdrawing the needle under the lump or bump.

12. Withdraw the needle and immediately place the needle and syringe into the sharps container.

IV Protocol

Intravenous (IV) injections are used primarily only for diagnostic purposes in ophthalmic care. Fluorescein angiography (FA) and indocyanine green (ICG) angiography are the two procedures most commonly carried out via IV injection (rarely, a tensilon test will be performed when myasthenia gravis is suspected).[10] The obvious benefit of the IV route is the instant absorption of the drug into the vascular system, allowing FA to visualize the integrity of the choroidal/retinal vasculature. However, the main disadvantage is that instant absorption also increases the likelihood of side effects.

The majority of potential side effects in ophthalmic procedures are easily managed; however, potentially life-threatening complications, such as anaphylactic shock, are also possible and require life-saving protocols.[11,12] Emergency medical kits contain treatment/management products for a variety of emergency events including anaphylactic shock, vasovagal syncope and other emergency situations. A valid CPR certification should also be held by anyone providing IV injections.

Prior to performing the procedure, have all supplies on hand. This is especially important if performing an FA, as the dye will reach the choroid within 10 seconds, providing the "choroidal flush" phase of the angiography. Two concentrations of fluorescein are available for injection (5cc of 10% or 2cc of 25%). A 23g to 25g butterfly needle infusion set, tourniquet, 3cc to 5cc syringe, alcohol pads, bandages and, to be on the safe side, an emesis basin (or a handy garbage can) should be prepared before the injection.

Find a stable vein in which to inject the dye. Injecting fluid into a vein is more difficult than removing blood, as the blood vessel has to remain stable and not rupture when the fluid is injected. Typically, the veins on the underside of the arm in the antecubital space (median cubital vein, cephalic vein or basilic vein) are used, but if those are not available, then the back of the hand can be used. The blood vessels on the hand often look more prominent and easier to visualize but they are much more unstable and tend to roll and are more likely to rupture when the dye is injected.

Once a vein is identified, a tourniquet is applied above the area that is to be injected (on the biceps if the antecubital veins are to be used or on the forearm if the hand veins are to be used) to increase the blood in the vein, making it more visible. Try to develop a "feel" for the veins by palpating them to determine how stable they are and exactly where they are located. Clean the area with an alcohol pad and let it air dry. The butterfly infusion kit has convenient "wings" to grasp to have more control over the needle. The bevel of

the needle is typically bevel up when performing the procedure. Insert the needle into the vein at a 45-degree angle until the needle has penetrated the vein. At this point, you will likely see a "flash" of blood into the tube indicating that the needle is in the vein. The needle is then leveled out parallel to the arm or hand and inserted into the blood vessel and then taped down. Please note that, just because you visualize the "flash" of blood, it does not necessarily mean that you have stable venous access. It is important that the needle is leveled out and inserted into the blood vessel. Once a stable insertion of the needle is achieved, the tourniquet can be removed. Remove the tourniquet prior to pushing the dye or it will potentially increase the chance of rupturing the blood vessel (extravasation).

With the infusion kit stable, the syringe with the fluorescein dye drawn up into it can be attached. The dye push typically occurs over two to six seconds for the entire bolus of dye. Complication rates for rapid vs. a slow dye push have been shown to be similar.[13,14] However, a very slow dye administration over 15 to 25 seconds did demonstrate lower complication rates but also made the initial phase of the angiography unrecordable.[15] It is crucial to watch for extravasation (blowing) of the blood vessel as the dye is pushed. If the blood vessel blows, then the dye is being injected into the surrounding tissue and not the vein.

The most common complications that a patient can experience after the dye is injected include nausea (most likely complication generally about 30 seconds after the injection), vomiting, pruritus (itch), and urticaria (hives).[16] Anaphylaxis, syncope (fainting) and myocardial infarction (heart attack) are also possible but extremely rare and unlikely.[2,3] It is important to educate the patient that they are likely to see a yellowing of the skin typically around the injection site, and their urine will be a dark yellowish-orange, both of which are temporary.

After the injection is complete, remove the needle and discard it into a sharps container. Cover the injection site with gauze and a bandage. Remember, it is the responsibility of the person giving the injection to always ensure they know where the tip of the needle is from the time the cap is removed until it is in the sharps container.

Subconjunctival Injections

Despite the patient's natural fear of a "needle coming near my eye," periocular and intraocular injections have evolved to a level of widespread use in the realm of eye care for a variety of indications. Subconjunctival injections can be among the most useful tools in your procedural toolbox and are effective in creating a depot of medication that is continuously leached onto the ocular surface through the conjunctiva. As with any other procedure in optometry, your first attempt may seem shaky by your own perception, but the keys to success are a calm demeanor, appropriate setup and patient education. If you are performing these procedures less frequently, it does not mean that you're not capable or qualified. You can always practice subconjunctival injections of sterile saline with a cow or sheep eye, a fellow colleague in your area, or even a willing family member or relative.

Common Subconjunctival Medications and Dosages

- Xylocaine (1% lidocaine with or without epinephrine): 0.5mL to 1mL
- Kenalog-40 (triamcinolone suspension 40mg/1ml vial): 20mg to 40mg
- Ceftriaxone (500mg vial): 100mg
- Vancomycin (500mg vial): 25mg

One of the skills you need to master to perform subconjunctival injections correctly is creating a dilution. With the exception of lidocaine, most medications will come in a vial in powder form. This allows for adjustment of the dosage based on the indication. Triamcinolone (Kenalog), for example, comes in multiple concentrations, but most commonly can be found in Kenalog-40 formulation, which reads "40mg/1mL" on the bottle. This makes it extremely easy to calculate how much medication to give the patient.

If you want 20mg of medication, inject 1mL of sterile saline into the vial making 40mg/1mL, draw up the entire 1mL of fluid, and then inject only 0.5mL of the solution, which is half or 20mg; (40mg/1 mL) x (0.5 mL) = 20mg.

If you were to inject only 0.5mL into the vial, you need to inject only 0.25mL to achieve the desired dose of 20mg. (40mg/0.5 mL) x (0.25 mL) = 20mg.

Other medications, such as the antibiotics ceftriaxone or vancomycin, commonly come in larger vials in 500mg powder forms, which must be diluted to the appropriate dosage. This can be a rate-limiting step, unless you've got an old chemistry textbook handy or you've done the calculation ahead of time. The conjunctiva can hold a surprising amount of fluid, but the amount of fluid delivered in a subconjunctival injection should range between 0.25mL and 1.0mL.

Across the literature, there are many indications for subconjunctival injections, and injections are not always reserved for the most severe cases. Most commonly, optometrists think of subconjunctival steroid and antibiotic injections for conditions such as anterior uveitis and infectious corneal ulcers. It might be surprising to know that this type of injection may also be used for treatment

of pseudophakic or uveitic cystoid macular edema as well as other conditions such as scleritis, in some situations.[17-19] Other indications might include medication noncompliance, patients who are physically unable to instill their own eye drops, a systemic contraindication to oral treatment (such as diabetes), or patients who cannot afford to purchase the needed medications. For example, a 1mL vial of Kenalog-40, which is typically used for anterior or intermediate uveitis, can be obtained online for about $10.

From a patient's standpoint, there is generally a fair amount of anxiety leading up to the procedure. There are a number of ways to combat this anxiety (including oral anxiolytics), but periocular and intraocular injections are performed multiple times each day in other eye care settings (e.g., retina, hospital clinics) without these medications. When faced with this issue, many times the key to delivering a successful and safe injection lies almost completely in the patient education.

A Patient Presents…

Consider this scenario: A patient with Type II diabetes presents with moderate to severe uveitis in one eye. In the early stages of your discussion with the patient, calmly describe the condition and the significant risks associated with it, such as potential for permanent vision loss, blindness, scarring, recurrence, macular edema, etc. You might say "Mrs. Jones, you have a very significant amount of inflammation present in your eye called iritis. Iritis can result in cataracts, glaucoma, macular edema and other complications that can cause acute vision loss. If not treated appropriately, it can recur and the risks for complications are even higher."

Maintain a serious demeanor with a relaxed tone throughout the discussion and try to minimize patient questions or other interruptions until you have completed your preliminary education. Next, calmly explain the treatment and why you feel a subconjunctival injection of medication would be extremely helpful. For instance, say "the treatment for this condition requires around-the-clock steroid delivery to the surface of your eye and also keeping the eye dilated for an extended period of time. Given the situation, I think we can best resolve the iritis with the help of an injection of medication under the tissue that covers the white part of your eye. This will ensure that your eye is receiving that around-the-clock steroid."

At this point, the patient's usual reaction is fear, but this is the key moment in your conversation when you should sympathize with your patient whether they visibly express fear or not. "I understand that this is probably not what you expected to hear today. Fortunately, as intimidating as this sounds, this is unlike other injections you may have had, and there is relatively little discomfort involved in the procedure. We have a natural instinct to close our eyes when anything is near our eyes, but I have a special device that will help you keep the eye open for the procedure. The tissue that I will inject today will be completely numb, and because I will have you looking away from the area I will be injecting, you will not be able to see it happen. Sometimes people notice a 'pressure sensation' as the medication is injected, but there should not be any pain. When the anesthetic wears off, you might later notice some foreign body sensation."

You can stop now to answer any questions. You have addressed both of the common fears: pain and the fear of "something coming close to my eye." Answer the questions to the best of your ability and include discussion of any alternatives now that you have explained why an injection is the best mode of treatment for them. If the patient seems receptive, continue into the written informed consent portion of the discussion, which should cover the major risks, benefits, alternatives and complications associated with the procedure. Finally, follow-up with common experiences following the procedure. "Mrs. Jones, I think that you would benefit greatly from this injection, as it continuously releases the needed medication onto the surface of the eye even while you're sleeping. We could treat this with systemic steroids or topical eye drops alone, but this is less than ideal because treating with topical eye drops alone will take several weeks to completely resolve the signs and symptoms of iritis and the oral steroids can significantly raise your blood sugar."

However, as with any medical treatment or procedure, there are risks. Many of the major complications—increased eye pressure which may cause glaucoma, accelerated cataract formation, infection and, in

Subconjunctival Injection Materials List

- Topical ophthalmic anesthetic (proparacaine, tetracaine)
- Topical broad spectrum ophthalmic antibiotic such as fluoroquinolone or PolyTrim (polymyxin B sulfate and trimethoprim ophthalmic solution, Allergan)
- Desired injectable medication
- Alcohol prep pads
- Eyelid speculum
- 0.12mm or 0.3mm 1x2 micro-ophthalmic toothed forceps
- 2.0cc, 2.5cc or 3.0cc syringe
- 18g 1.5" needle for drawing up medication
- 25g or 27g 0.5" needle for injection of medication
- +/- 4% lidocaine and sterile cotton swab
- +/- technician or assistant

rare cases, possible loss of vision—are the same or similar to those associated with simply having iritis. Sometimes a blood vessel might break during the procedure, which may make the eye look slightly red after the procedure, but this will resolve on its own without treatment. Most commonly, people will experience some foreign body sensation from the depot of medication. They may even notice the medication if you look in the mirror and pull your eyelids up or down.

As optometrists, we pride ourselves in good outcomes, being patient advocates and providing the best patient-centered evidence-based care that we can. Subconjunctival injections, when applied in the appropriate situation, can provide an additional treatment modality and dramatically improve outcomes.

Subconjunctival Injections Protocol

1. Wear protective gloves, maintain asepsis and take appropriate needle stick precautions throughout the procedure.

2. Clean the top of the medication vial with an alcohol prep pad.

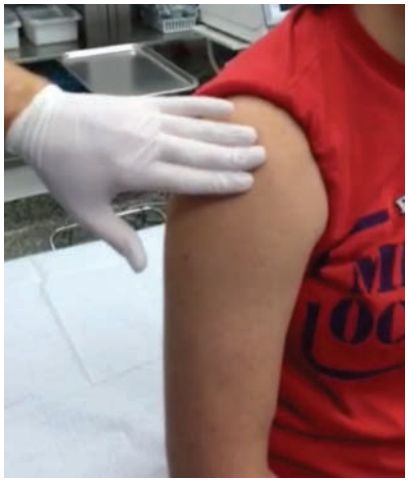
3. Draw up medication with the 18g needle by injecting an amount of air that is equal to or slightly larger than the amount of medication desired.

4. Withdraw the plunger to a level that is slightly more than the desired amount of medication. The medication vial should be either horizontal or inverted to minimize air in the syringe.

5. Remove the 18g needle and place it in the sharps box. Replace the needle with the finer 27g needle.

6. Invert the needle and push inward on the plunger to remove any air bubbles. You may additionally need to tap the syringe with your fingers.

7. Select the location by gross observation, which is approximately 5mm (0.5cm) posterior to the limbus and avoids conjunctival vasculature and extraocular muscle insertions to prevent subconjunctival hemorrhage and injection into an extraocular muscle. (Note: typically this is the superior temporal or inferior temporal locations of the globe and posterior enough to cover the subconjunctival medication deposit with the upper or lower eyelid, depending on the location).



The first step for an intramuscular injection is to select the proper location.

8. Instill two drops of topical anesthetic into the affected eye.

(Optional: You may additionally soak a sterile cotton swab in 4% lidocaine and hold it to the desired injection site to aid in patient comfort. *Never* inject 4% lidocaine into any tissue, as it is meant only for topical use.)

9. Instill one drop of topical broad-spectrum ophthalmic antibiotic eye drop.

10. Insert an eyelid speculum to the affected eye by having the patient look down and securing the upper eyelid first. The lower eyelid can be secured next by having the patient look straight ahead or slightly upward.

11. Ask the patient to look in the opposite direction of your selected injected site (look superior nasal for inferior temporal location and vice versa).

12. Using your non-dominant hand, grasp the conjunctiva at the selected injection site and lift outward, forming a "tent" shape of the conjunctiva with the sterile 1x2 toothed forceps.

(Critical point: Keep a firm grasp on the conjunctiva. Holding tension on the conjunctiva will also help maintain the patient's gaze in some capacity.)

13. The injection should be made at an angle parallel to the globe. Gently insert the needle bevel up into the empty space below the "tented" conjunctiva.

14. Pierce the "tented" conjunctiva with the needle and inject the medication. Quickly withdraw the needle following completion of the injection. Visualize that the needle has not penetrated the globe. (Note: Tenting of the conjunctiva will form a large pocket of empty space for injecting the medication. This should make it easy to inject the medication and quickly withdraw the needle following completion of the injection, which makes globe perforation unlikely.)

15. Instill another drop of a topical broad-spectrum antibiotic eye drop.

16. Remove eyelid speculum.

Muscle Up

Intramuscular injections may be used less commonly than other types of injections in eye care, but they can be great primary treatments as well as effective adjunctive therapy to oral medications. Muscles are highly vascular tissue and larger than subcutaneous tissues, meaning there is more surface area for absorption. This generally leads to quicker absorption and onset of the medication's effects but can vary greatly between agents. Additionally, the duration of action

may be shorter or longer than oral medications, but again this is dependent on the drug.

By far, the most important indication for IM injections is for immediate lifesaving treatment of anaphylaxis in the office. Many physicians' offices may stock an EpiPen for these rare anaphylactic events, but with the recent significant price hike to more than $500 per EpiPen, many practitioners may be stocking 1mL ampules of 1mg/1mL epinephrine (previously labeled 1:1000) in office due to the significant cost savings (generally less than $5).

IM injections can be particularly useful in other clinical scenarios aside from anaphylaxis as well. For example, per the current CDC treatment guidelines, patients with conjunctivitis secondary to gonorrhea must receive dual therapy with IM ceftriaxone and oral azithromycin or doxycycline.[20] From a clinical standpoint, there are other clinical cases where in-office IM injections of anti-emetics, antibiotics, or other medications may be quite useful. For example, a patient who presents with active nausea and vomiting but needs symptomatic relief to complete your evaluation. Other cases to consider involve severe allergic reactions warranting diphenhydramine or epinephrine, more serious soft tissue infections, and select immunizations such as the flu shot.

When giving an IM injection, there are three considerations for the practitioner: medication dosage, location and technique. The medication and amount to be given will largely dictate the location in which you will give the injection, but please remember you will likely have to perform dilution calculations based on how the medication is stored. Some common IM medications and dosages for basic clinical practice are:

- Epinephrine: anaphylaxis; 1mg/1mL; 0.2mg to 0.5mg q5-15m PRN if no clinical improvement.[21]
- Ketorolac: acute moderate to severe pain; 30mg q6h if >110 pounds.[22]
- Promethazine: nausea/vomiting; 12.5mg to 25mg q4-6h.[23]
- Ceftriaxone: gonorrhea infection; 250mg once (plus oral azithromycin or doxycycline).[20]
- Diphenhydramine: severe allergic reaction; 25mg to 50mg per dose, can give up to 100mg in a single dose.[24]

With regards to location, the most commonly used injection sites are: upper arm (deltoid), outer thigh (vastus lateralis; site of EpiPen delivery), and the buttocks (ventrogluteal).[25,26] Because of the small volume of medication being administered, nearly all of the common medications listed above will be delivered to the deltoid muscle. One to two milliliters of medication is the current recommendation for this location. If you need to administer more than this amount, consider the vastus lateralis, which allows for up to 5mL of medication to be safely administered. If you have a registered nurse nearby (as some hospital-based clinics do), they can be extremely helpful when selecting an injection site or they can even deliver the injection for you.

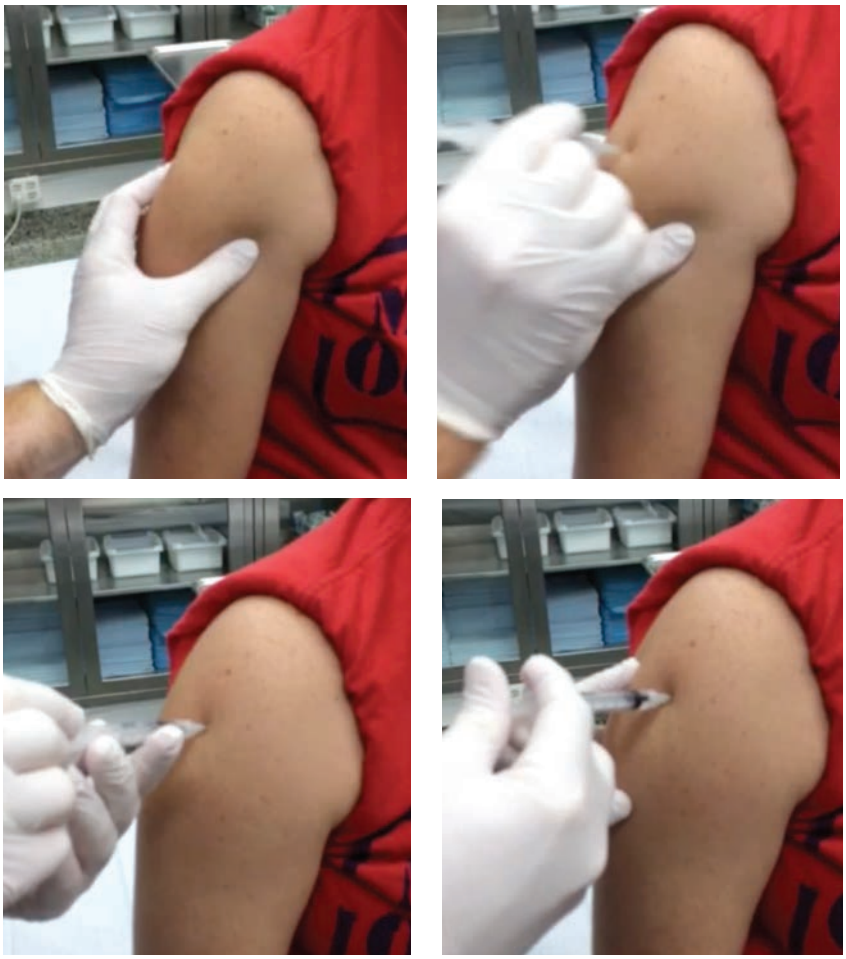
Current evidence in the nursing literature suggests that the "Z-track" technique should be used for IM injections because it decreases pain on injection and prevents leakage of medication into subcutaneous fat where it may not be absorbed.[25] This method involves pulling the skin taut in one direction prior to injection, aspirating, and injecting the medication at 90 degrees over five to 10 seconds. Lastly, withdraw the needle quickly, release the skin, and cover with a cotton swab or bandage. Rubbing the injection site is not recommended with this method.

Intramuscular Injection Materials List

- Desired medication to be injected
- Alcohol prep pads
- 1.0cc to 2.0cc syringe
- 18g 1.5" needle for drawing up medication
- 25g to 27g 1" to 1.5" needle for injection of medication (0.75" for children)
- Cotton swab and bandage
- 0.9% sterile saline (if needed for creating a solution).

Intramuscular Deltoid Injection Protocol

1. Wear protective gloves, maintain asepsis and take appropriate needle stick precautions throughout the procedure.
2. Clean the top of the medication vial with an alcohol prep pad.
3. Draw up medication with the 18g needle by injecting an amount of air equal to or slightly larger than the amount of medication desired.
4. Withdraw the plunger to a level that is slightly more than the desired amount of medication. The drug vial should be either horizontal or inverted to minimize air in the syringe.
5. Remove the 18g needle and place it in the sharps box. Replace it with the finer 25g or 27g needle.
6. Invert the needle and push inward on the plunger to remove any air bubbles. You may additionally need to tap the syringe with your fingers.
7. While sitting or standing, have the patient relax their arms at their sides. Find the acromial process (the bony prominence where the humerus meets the shoulder joint).
8. Place two fingers across the lateral portion of the humerus in the area immediately below the acromial process.
9. The target location for the deltoid injection should be the area just below the bottom finger (about 1" to 1.5" below the bony promi-



Top left, pinching the muscle can help allow easy access for the medication. Top right, as the needle enters the skin for an IM injection, note how the maneuvering is similar to that of throwing a dart. Bottom left, the doctor pulls back on the plunger just before injection to ensure the needle is not in a blood vessel. Bottom right, the medication is injected at a slow and steady rate.

nence).

10. Clean the injection site with an alcohol prep pad and allow it to air dry.

11. Find an area just lateral to the injection site and pull the skin laterally in one direction only with your nondominant hand. Pulling the skin in only one direction will decrease leakage of the medication into subcutaneous fat.

12. Pierce the skin at a 90 degree angle with the needle and quickly advance the needle into the muscle. The end of the needle connected to the syringe (the hub of the needle) should come into contact with the skin. This will ensure the needle is deep enough and into the muscle.

13. Inject the drug over five to 10 seconds while maintaining the skin taut with your non-dominant hand.

14. Remove the needle quickly at a 90 degree angle and release the lateral tension on the skin from your non-dominant hand.

15. Immediately cover with a cotton swab and bandage.

Injections are becoming more widespread in optometric practices across the nation. Having the knowledge and skill set to perform injections will expand your therapeutic toolbox for treating patients. But, it will also impress those patients enough to leave the clear impression that, not only are you the "glasses and contacts doctor," but you're also a medical professional they can entrust to perform injections. ■

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OSC QUIZ

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1. Which of the following concentrations of lidocaine should never be injected into the eyelid?
a. 0.5%.
b. 1.0%.
c. 2.0%.
d. 4.0%.

2. The maximum allowable dose of lidocaine without epinephrine for an adult is:
a. 1mL.
b. 5mL.
c. 30mL.
d. 100mL.

3. The usual amount of anesthetic that is injected into an eyelid when performing a lump/bump removal is:
a. 0.3mL to 0.5mL.
b. 1mL to 2mL.
c. 3mL to 5mL.
d. 10mL to 12mL.

4. What is the usual pH of the anesthetic solution in the bottle or vial, assuming the solution was not buffered?
a. One to two.
b. Four to five.
c. Seven to eight.
d. 10 to 11.

5. Which of the following statements concerning subcutaneous/intradermal injections is false?
a. It is the most common injection that optometrists perform.
b. Allergies are more common in ester anesthetics (novocaine) compared with amide anesthetics (lidocaine).
c. When performing subcutaneous/intradermal injections in and around the eyelid, the needle should enter the skin at an approximately a 45-degree to 60-degree angle.
d. Epinephrine in the anesthetic solution provides some degree of hemostasis and will help minimize bleeding, bruising and swelling.

6. Which of the following is *not* a common purpose of IV injection in ophthalmic care?
a. Fluorescein angiography.
b. Indocyanine green angiography.
c. Diagnostic testing of ocular conditions.
d. Therapeutic management of ocular conditions.

7. Which of the following is the most likely complication/side effect of the injection of sodium fluorescein dye during a fluorescein angiography?
a. Syncope (fainting).
b. Myocardial infarction.
c. Nausea.
d. Anaphylaxis.

8. At what time period do most patients experience the side effects of the injection of sodium fluorescein during a fluorescein angiography?
a. 10 seconds.
b. 30 seconds.
c. Two minutes.
d. Five minutes.

9. Which of the following is *incorrect* with respect to the IV injection procedure?
a. Antecubital veins are most commonly used.
b. "Flash" of blood during injection process indicates stable venous access.
c. Bevel-up needle insertion is most common.
d. Extravasation indicates improper venous access or blown vessel.

10. The injection of sodium dye during a fluorescein angiography is over what time period?
a. Two to six seconds.
b. Eight to 10 seconds.
c. 15 to 20 seconds.
d. 30 seconds.

11. During a subconjunctival injection, medication is continuously delivered to the ocular surface via:
a. Deposition onto the surface of the eye through the conjunctiva.
b. Diffusion into episcleral veins.
c. Direct absorption into episcleral arteries.
d. Reverse osmosis as a result of diffusion of medication into aqueous humor.

12. When preparing a subconjunctival injection, you should dilute most medications in powder form with:
a. 0.9% sterile saline.
b. lactated ringer's solution.
c. 1% lidocaine with epinephrine.
d. 1% lidocaine without epinephrine.

13. When administering a subconjunctival injection, the most ideal location for injection:
a. Is inferior or inferior temporal.
b. Has little to no vascularity.
c. Can be hidden by the eyelid.
d. All of the above.

14. When performing a subconjunctival injection of 40mg of Kenalog, which of the following is a possible side effect?
a. Increased IOP and/or glaucoma.
b. Accelerated cataract formation.
c. Secondary infection.
d. All of the above.

15. What is the maximum volume of medication recommended for injection into the subconjunctival space?
a. 0.1mL.
b. 1.0mL.
c. 3.0mL.
d. 5.0mL.

OSC QUIZ

16. According to current literature in nursing, what is the preferred delivery method for intramuscular injections?
a. Spread and bunch method.
b. Z-track method.
c. Point and shoot method.
d. None of the above.

17. All of the following are advantages of the Z-track method of intramuscular injections except:
a. Delays time to medication absorption.
b. Limits absorption into subcutaneous fat.
c. Decreases pain on injection.
d. All of the above.

18. Which of the following muscles is not a preferred site for intramuscular delivery of medications?
a. Deltoid.
b. Vastus lateralis.
c. Ventrogluteal.
d. Sternocleidomastoid.

19. What is the recommended first-line medication and dosage to be injected intramuscularly for the treatment of anaphylaxis?
a. 0.2mL to 0.5mL of 0.1mg/mL epinephrine every five to 15 minutes as needed if no clinical improvement.
b. 0.2mL to 0.5mL of 1.0mg/mL epinephrine every five to 15 minutes as needed if no clinical improvement.
c. 25mg of diphenhydramine every five to 15 minutes as needed if no clinical improvement.
d. 100mg of diphenhydramine every five to 15 minutes as needed if no clinical improvement.

20. What is the current CDC guideline for the treatment of gonorrhea-related infections?
a. 250mg IM ceftriaxone plus 1g oral azithromycin once.
b. 500mg IM ceftriaxone plus 100mg oral doxycycline for five days.
c. 1g oral azithromycin once plus 100mg oral doxycycline for five days.
d. 250mg IM azithromycin plus 250mg oral ceftriaxone once.

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3.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
4.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
5.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
6.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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Vision Expo East 2017:

Find Your New York State of Mind

With more than 320 hours of education, VEE is a must for optometrists looking to learn.

By Jane Cole, Contributing Editor

Vision Expo East (VEE) has become a heavy-hitter among clinical education meetings, and 2017's CE lineup will not disappoint.

"This year's program offers more than 320 hours of education covering everything from diagnostic testing and equipment and surgical treatment to inventory management, specialty lenses and staff development," said Mark Dunbar, OD, co-chairman, conference advisory board. "Vision Expo offers the unique opportunity to enhance your knowledge in these core areas to expand the quality and consistency of care for your patients."

New for 2017 is a scleral lens track that will offer six hours of CE credit. This includes a comprehensive discussion of the fitting and evaluation of scleral lenses and a hands-on workshop. Topics will include lens designs, overall fitting philosophy, the comprehensive fitting process, scleral lens modifications, problem solving, lens ordering and more.

Another highlight for VEE 2017 are Blue Light Sessions, in which blue light basics, both indoors and outdoors, as well as the latest research findings will be discussed.

Dr. Scot Morris kicked off last year's Global Contact Lens Forum by moderating a leadership panel.

Budget-Friendly Learning

This year's VEE, which will be held from March 30 to April 2 at the Jacob Javits Convention Center in New York City, is offering plenty of opportunities for free education. Start planning your clinical education at VEE with some of the following courses:

Global Contact Lens Forum: Attend this forum to earn four hours of free CE credit and gain insight into current issues optometrists face as contact lens practitioners. Thought leaders in the profession will share their views on the future of the contact lens practice. Courses will include "State of the Contact Lens Industry in 2017—Things to Come...R&D and Developing Technologies," "Evidence Based Eye Care and Clinical Practice: A Review of Research in Clinical Practice," and "Contact Lens Practice Settings—A Spectrum of Opportunity."

Ocular Surface Disease and Wellness Symposium: Offering three hours of free CE credit, this symposium will focus on why an optometry practice should mirror a preventative care model. Attendees will gain expertise in recognizing dry eye diseases and clinical aspects of the ocular surface from diagnosis to treatment to help them expand the quality and consistency of patient care. A featured course will be "The Dry Eye Institute: The 'WHY' and the Integrated Health Care Model," presented by Jack Schaeffer, OD, Paul Karpecki, OD, Marc Bloomenstein, OD, and Richard Adler, MD. The four doctors will also team up to present "Ocular Surface Disease: The Diagnosis, Treatment, and the Clinical Aspects of Ocular Surface Disease."

Vision Series for 2017: Grab a bite to eat and continue your learning over lunch. A total of five CE credit hours will be available for this new series. Courses currently on deck include "Ocular Allergy Update" by Arthur Epstein, OD, "Innovation in Contact Lenses" by Ian Ben Gaddie, OD, and Gina Wesley, OD, as well as "Building Your

Practice with OCT" and "Diabetic Eye Disease Diagnosis and Management Strategies for Patients," both by Dr. Dunbar and Rishi Singh, MD.

Free Google Talks: Join your fellow ODs in the Marketing Stadium to hear from Google experts on how search engine marketing will grow your eye care business and build a digital strategy to attract patients.

Free Classes in the Medical & Scientific Theater: Learn about the latest in cornea, eye care analytics and dry eye management during this series of free sessions. Courses include: "Corneal Cross-Linking in the US: What You Need to Know," by Clark Chang, OD, Paul Karpecki, OD, Alexandra Nicklin, OD, and Grace Lytle, OD; "21st Century Grand Rounds: Eye Care Analytics—Improving Your Patient's Visual Outcomes," presented by Thomas A. Wong, OD, director of new technologies, SUNY Optometry; and "A Contemporary Approach to Dry Eye Management: Secrets of Practice Success" by Arthur Epstein, OD.

Update Your Optical Shop

VEE will also offer 18 hours of CE credit during its retail program. "Vision Expo is a true fashion destination for opticians and buyers to look, touch and immerse themselves in a world of options to keep them competitive in today's retail landscape," says Dr. Gaddie, co-chairman of the Conference Advisory Board.

Pathology in Practice

As co-chairs, Drs. Dunbar and Gaddie have offered up their own personal "Chairmen's Top Picks" you won't want to miss:

Headache Applications for Optometric Practice: This course, presented by Bradley Sutton, OD, will cover different types of headaches arising from various etiologies. Dr. Sutton will emphasize headache disorders that can present to your optometric practice. Topics will include migraines, cluster headaches, idiopathic intracranial hypertension, temporomandibular joint syndrome, meningitis, tension headaches, hypertensive headaches, stroke-related headaches and cranial neuralgias.

We Can Save Vision—Understanding of the Corneal Shape and Mechanics in Keratoconus: If you're still diagnosing keratoconus by waiting to see the "red spot" on your topography, then you need to attend this course. Corneal mapping technology is rapidly evolving, and landmark peer-reviewed studies have redefined how doctors evaluate the cornea and corneal shape. New corneal biomechanical evaluation devices can predict who is more likely to develop keratoconus and keratoectasia. Come and learn from experts Barry Eiden, OD, and Andrew Morgenstern, OD, how to evaluate and treat this all-too-common disease.

Glaucoma Pearls and Grand Rounds: Take a look at a series of glaucoma cases and learn about important issues related to the disease. Murray Fingeret, OD, Michael Chaglasian, OD, and Robert Wooldridge, OD, will present patient information, photographs, OCT images and visual fields to illustrate when therapy is indicated, when to modify therapy and signs that glaucoma is progressing.

Intrepid Talks: Members of The Intrepid Eye Society—thought leaders with the goal of promoting excellence and growth in the field—share on topics related to future medical therapeutics, care delivery platforms, diagnostics, collaborative care models, practice development and more. Drs. Dunbar and Gaddie are particularly interested in "Mode of Practice Options for Optometrists," moderated by Michael Cooper, OD, and Mark Schaeffer, OD, and with panelists Justin Schweitzer, OD, Melissa Barnett, OD, Leslie O'Dell, OD, and Whitney Hauser, OD.

Oculoplastic and Aesthetic Eye Care in an Optometric Practice—Opportunity Abounds! Learn about a variety of surgical options such as blepharoplasty, eyelid bag repair, dermal fillers, Botox and more. Moderator Louise Sclafani, OD, and panelists Dr. Eiden, Walter Whitley, OD, and Kathleen Albrecht, MD, will share their own clinical experiences in bringing aesthetic eye care services to the optometric practice.

What Would Larry Do? As a tribute to a pioneer in optometric education, specifically the posterior segment, this lecture will feature enigmatic cases and offer logical, pragmatic approaches to solving them, just like Larry Alexander, OD, would. Leo Semes, OD, Scot Morris, OD, and Jeffry Gerson, OD, will present.

I'm Right—He's Crazy: Diabetes and AMD from the Trenches—Part 1: Get a better understanding of practical strategies for patients with diabetes. This course will start by covering the biology underlying diabetes. The discussion will then turn to the actual systemic disease and finish with ocular disease. Paul Chous, OD, and Dr. Gerson will present.

I'm Right—He's Crazy: Diabetes and AMD from the Trenches—Part 2: Drs. Chous and Gerson will team up again to use both science and case examples to help attendees gain a more solid grasp on practical strategies for patients with AMD. Diagnostic technologies, treatment options and case examples of AMD will all be explored.

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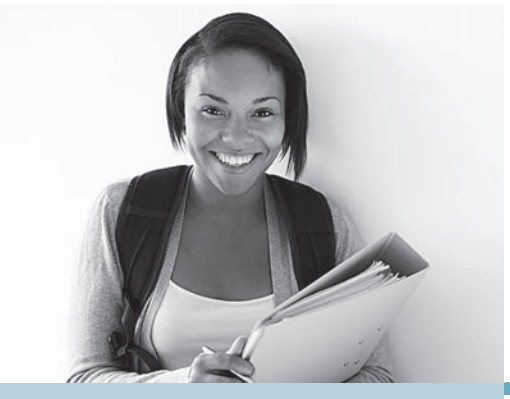

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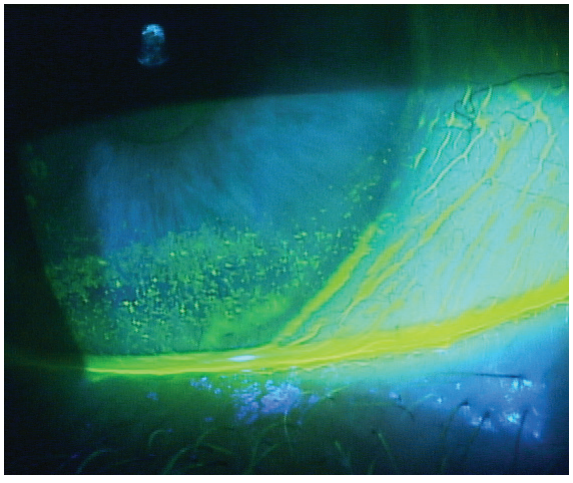
Plug into Dry Eye Therapy

Don't overlook the benefits of punctal occlusion for your DED patients. New technologies have made it better than ever. **By Paul M. Karpecki, OD**

Dye eye disease (DED) is a prevalent and chronic ocular surface disorder that affects patients of all ages.[1] Although dry eye is not curable, with proper diagnosis and the variety of treatment options available, we can help our patients manage the disease and find relief. One of the treatment options often overlooked by clinicians is punctal occlusion. However, significant advances in this treatment modality make it a worthwhile option for many patients seeking relief.



Patients with inferior corneal staining secondary to lagophthalmos, as seen here, are good candidates for punctal occlusion.

DED Treatment: A Combined Effort

In response to the rising prevalence of DED, manufacturers have brought a variety of new pharmacological treatment options to market, including tear substitutes, eyelid therapeutics, dietary supplements and anti-inflammatory agents.[1]

But successful treatment of DED typically requires multiple treatment platforms targeting each patient's particular combination of symptoms, signs and severity. For instance, tear replacement—although highly effective—is rarely successful when used as the sole treatment.[2] However, when combined with other therapies, such as changes to the patient's environment, the use of anti-inflammatory medications, treatment of the obstructed glands and biofilm control, patients are more likely to achieve improvement.

With so much to choose from, we tend to overlook the tried-and-true lacrimal occlusion for the treatment of DED and contact lens intolerance secondary to dry eye. It can increase the efficacy of ocular co-treatment medications and lubricants by allowing medications to stay on the eye longer or increasing contact time.

Plugging it Up

For some patients, punctal plugs should be the first line of treatment. Patients with neurotrophic dry eye are ideal candidates for punctal occlusion, as are patients with contact lens intolerance due to early DED. Neurotrophic dry eye, often caused by conditions such as herpes zoster ophthalmicus or diabetes, often affects patient's nerves, resulting in poor communication between the lacrimal functional unit and the brain. Patients typically do not have an inflammatory, or any, response, which is why the eye continues to remain desiccated or have a persistent epithelial defect.[3,4] Therefore, it's likely punctal plugs would simply elevate the tear volume, which is critical to improving this form of DED.[5]

Punctal plugs can be a particularly well-suited option for those with lagophthalmos with inferior corneal staining, as the elevation of the tear lake after punctal occlusion is often enough to clear the lower area of ocular irritation.

Finally, punctal plugs provide a means by which ODs can address drop noncompliance. Research shows punctal occlusion can increase the efficacy of drops and increase therapeutic effect by allowing a greater contact time of the medications.[6] In one study, patients were randomized to cyclosporine alone, punctal plugs alone and punctal plugs with cyclosporine. Although all three groups improved, the group that had both therapeutics and punctal plugs had the longest period of ocular surface health and improved symptoms, suggesting treatment may be additive.[6]

No Plug, Please

As with all treatment modalities, there are contraindications to

punctal occlusion. Patients with an active infection, abnormal drainage of the lacrimal system or sensitivity to the material are not candidates. Clinicians should also avoid punctal plug use in cases of allergic conjunctivitis, where occluding the punctae could result in the allergens remaining on the ocular surface and possibly increasing the allergic response. Punctal plugs are not optimal for patients with significant blepharitis who need the biofilm removed with mechanical treatments such as Blephex (RySurg) and lid scrubs.

Finally, clinicians should first treat advanced levels of inflammation on the ocular surface with topical therapies, omega fatty acids or oral doxycycline before considering punctal occlusion. Once inflammation is controlled or the biofilm is treated, punctal plugs are once again a possible treatment option.

New Technologies

New innovations have made punctal occlusion a therapeutic option for any number of indications. Absorbable plugs that dissolve over an approximately 90- or 180-day period—e.g., Comfortear Lacrisolve 180 absorbable punctum plugs (Paragon BioTeck), Extend absorbable synthetic implants (Beaver-Visitec), Quintess six-month dissolvable lacrimal plug (OcuSoft)—can provide a huge benefit to patients in need of DED relief.

The plugs are easy to insert in office and sit completely under the surface, posing little risk to the patient. While an excellent treatment tool for DED, they can also serve as a diagnostic tool to help clinicians determine the patient's response to occlusion therapy. Patients who respond well to the 180-day plug are often good candidates for long-term silicone punctal plugs.

However, I have found that many patients notice continued relief even after the 90- or 180-day plugs absorb, and I simply replace them with another extended duration plug months later if symptoms return.

Safety and Efficacy

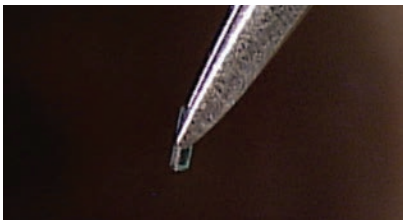
Multiple studies confirm the efficacy of punctal plugs compared with topical treatment alone. A prospective double-masked study demonstrated a 94.2% reduction in dry eye symptoms and 93% reduction in conjunctival symptoms eight weeks after lacrimal occlusion.[7] The control group remained unchanged. Additionally, nearly 77% of the occlusion therapy subjects were virtually symptom free, and 100% of the participants no longer required moisturizing drops.[7]

A 2016 study evaluating 29 patients with moderate dry eye also showed significant symptomatic relief and reduced fluorescein staining in all except the inferior corneal zone three weeks following punctal occlusion.[8] Although patients had significant symptomatic improvement and improved staining, tear analysis showed minimal effect on tear cytokines and MMP-9 levels. This suggests a need for dual treatment (plugs and anti-inflammatory medications) earlier in dry eye management.[8]

Research is underway on drug-eluting punctal plugs that contain either corticosteroids or cyclosporine. We may in the future have an option that provides punctal occlusion with slow-release therapeutic medications.

An observational study of silicone plugs indicated a satisfactory retention rate of 84.2% after three months, 69.5% after one year and 55.8% after a median of two years (17 to 93 months) with few complications.[9]

Further, with a mean retention period of 85 weeks, patients opting for punctal plugs can look forward to living an extended period relatively free of dry eye symptoms.[10]



Bruder punctal plug forceps have a grove for easily grasping the plugs and are particularly useful for collagen and extended duration plugs.

With a plethora of new options to address dry eye symptoms, we should not overlook the benefits of occlusion therapy. Patients suffering from chronic DED will embrace the opportunity for a long-term treatment option and, quite likely, rejoice at the prospect of eliminating or reducing the frequency of instilling lubricating agents. ■

Dr. Karpecki is a consultant to Beaver-Visitec, Blephex, Ocular Therapeutix, OcuSoft, Bruder and Paragon BioTeck.

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Concussion and Chronic Traumatic Encephalopathy

Optometrists should be on the lookout for symptoms of CTE in patients with a history of repetitive head trauma, expecially those who play contact sports.

By Melinda Wolter, OD, Carlo J. Pelino, OD, and Joseph J. Pizzimenti, OD

Chronic traumatic encephalopathy (CTE) is a progressive neurodegenerative disease that is associated with repetitive mild traumatic brain injury (mTBI).[1] Affected individuals report a variety of symptoms and show a distinct pattern of pathological changes.[1]

CTE has been depicted in both documentaries and mainstream cinema and continues to make headlines among news broadcasts and popular press, including *Sports Illustrated*, *ESPN*, *National Geographic*, *Forbes* and *USA Today*.[2-4] Tragic suicides in high-profile athletes later found to have CTE (on autopsy)—including professional football players Dave Duerson and Junior Seau and, more recently, BMX rider Dave Mirra—have pushed this condition to the forefront.[2-5]

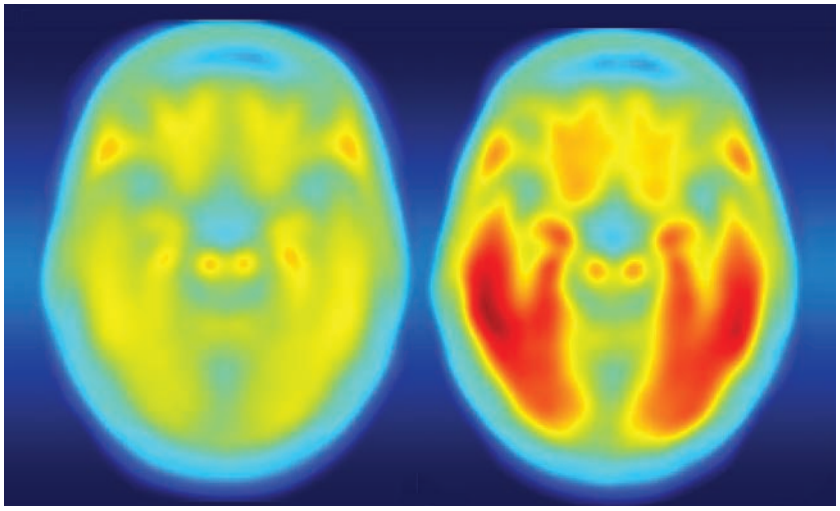

Photo: National Science Foundation

Defective tau protein, as seen on the right positron emission tomography image, accumulates in the brains of patients with Alzheimer's disease, Parkinson's disease and CTE.

Sports and CTE

The clinical symptoms of CTE were first described nearly a century ago in boxers, and the disease was originally known as "punch drunk" or "dementia pugilistica."[6] It is only recently that research has associated modern sports, such as American football, soccer, ice hockey, motocross, BMX and rugby, with a similar deterioration.[7,8]

Symptoms of CTE include changes in behavior (e.g., explosivity, violence, impulsivity) and mood (e.g., depression, suicidality, irritability), memory loss, diminished concentration, impaired motor functioning (e.g., parkinsonism, dysarthria, gait changes) and dementia.[9]

The clinical features of CTE are varied and typically manifest years or even decades after the initial episode of repetitive mTBI. Although the majority of patients report a history of concussions, this is not a prerequisite for diagnosis, suggesting that sub-concussive head injuries are sufficient to lead to the development of CTE.[1]

As with other neurodegenerative diseases, CTE can only be diagnosed with certainty by neuropathological examination of brain tissue.

Concussions and CTE

In its Practice Parameter, the American Academy of Neurology defines concussion as "trauma-induced alteration in mental status that may or may not involve loss of consciousness."[10] The terms *concussion* and *mild traumatic brain injury* refer to different injury constructs and should not be used interchangeably.

In the Zurich Consensus Statement on Concussion in Sport, researchers defined concussion as a complex pathophysiological process affecting the brain, induced by traumatic biomechanical forces.[11]

Several common features of concussion that may be useful for

clinicians in defining the nature of a concussive head injury include:[11]

1. Concussion may be caused either by a direct hit to the head, face or neck or a hit elsewhere on the body with an impulsive force transmitted to the head.
2. Concussion typically results in the rapid onset of short-term impairment of neurologic function that resolves spontaneously.
3. Concussion may result in neuropathological changes, but the acute clinical symptoms largely reflect a functional disturbance rather than a structural injury.
4. Concussion results in a graded set of clinical symptoms that may or may not involve loss of consciousness. Resolution of the clinical and cognitive symptoms typically follows a sequential course. In a small percentage of cases, however, post-concussive symptoms may be prolonged.
5. Standard structural neuroimaging studies show no abnormality in concussion.

Overall, the number of years of exposure—not the number of concussions—is significantly associated with worse pathology in CTE.[1,7,10] This suggests the chronic nature of head trauma, irrespective of concussive symptoms, is the most important driver of disease.[1,12]

Research also suggests CTE and continued exposure to head trauma is associated with other neurodegenerations, including Alzheimer's disease.[1]

CTE, Concussions and the Eye

Concussions can cause any number of symptoms, including dizziness, nausea, headache, sleep problems, cognitive difficulties (i.e., feeling in a fog) and irritability.[1,11]

Ocular symptoms can include visual blur, visual field loss, diplopia and photosensitivity.[1,11]

Research has found that CTE in particular can have a significant impact on ocular health. In a study of 10 eyes of deceased individuals with varying stages of CTE, researchers found pathology in the retina, mostly in the ganglion cell layer, throughout the different stages of the disease, with the most severe retinal pathology occurring in the most severe CTE stages.[13] Ophthalmic sequelae associated with concussion and TBI may be sight threatening and visually debilitating.

The Tau of CTE

Alzheimer's disease, Parkinson's disease and now CTE have all been associated with tau proteins that have become defective.[12,14,15] Tau proteins perform the important function of stabilizing microtubules. When these proteins become defective and fail to adequately stabilize microtubules, neuropathologies may develop.[12]

Research suggests abnormal tau pathology in CTE occurs uniquely in those regions of the brain that are most susceptible to stress during trauma.[7,9]

In CTE, an accumulation of hyperphosphorylated tau (p-tau) forms within neurons and glia in a distinctive pattern. The abnormal tau accumulates in an irregular and patchy distribution that is perivascular and concentrated within the depths of sulci. In addition, the superficial cortical layers are preferentially involved compared with the deeper layers. This unique pattern of tau pathology is likely a result of force concentration during traumatic injury.[1,12]

CTE is therefore a tauopathy characterized by the deposition of p-tau protein as neurofibrillary tangles, astrocytic tangles and neurites in striking clusters around small blood vessels of the cortex, typically at the sulcal depths.

Patients with severely affected cases may show p-tau pathology throughout the brain.

Our next column will dig deeper into the possible ocular complications of CTE, along with testing protocols optometrists can incorporate into their practice to screen for this potentially devastating condition. ■

Dr. Wolter is in private practice in the Northeast region of Pennsylvania.

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A Fresh Take on Cataract Care

New options aim to take the hassle out of postoperative care.

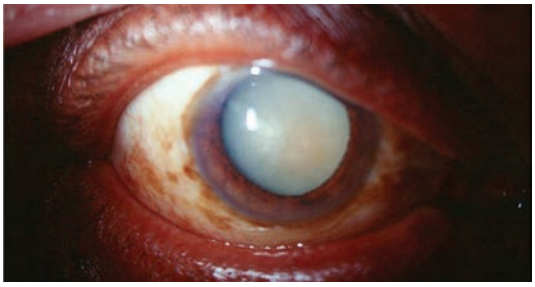
By Alan G. Kabat, OD, and Joseph W. Sowka, OD

In last month's column, we discussed the potential benefits and pitfalls of "dropless" cataract surgery. Although promising, only a small percentage of surgeons have embraced this technique, and some patients, due to the nature of their condition or associated comorbidities, are simply not candidates. Luckily, several companies have developed a variety of additional techniques that aim to improve postoperative cataract care for these patients.

Less is More

The same company that helped bring dropless surgery to the masses, Imprimis Pharmaceuticals, has also developed a number of compounded drugs designed to streamline post-op management of both cataract and refractive surgery. Currently, most surgeons employ three separate drops in their post-op regimen: a topical antibiotic, corticosteroid and nonsteroidal anti-inflammatory drug (NSAID). When considering the current market leaders in these categories—i.e., Besivance (besifloxacin 0.6%, Bausch + Lomb), Durezol (difluprednate 0.05%, Alcon) and Prolensa (bromfenac 0.07%, Bausch + Lomb)—the out-of-pocket expense for patients can be upwards of $500. Generic medications can reduce costs considerably, but do little or nothing to simplify the postoperative regimen.

The use of multiple drops, often with differing frequencies, can be confusing for patients and lead not only to callbacks and questions but, potentially, to toxicity and other medical complications.[1]



Removal of a dense cataract, such as the one seen here, can require the patient to commit to a drop schedule that may be confusing. Luckily, several options can help eliminate, reduce or assist with the need for post-op drops.

Currently, Imprimis manufactures three compounded formulations for topical use. Branded as LessDrops, the products include:

- Pred-Gati (prednisolone acetate 1% and gatifloxacin 0.5%)
- Pred-Nepaf (prednisolone acetate 1% and nepafenac 0.1%)
- Pred-Gati-Nepaf (prednisolone acetate 1%, gatifloxacin 0.5% and nepafenac 0.1%)

Each of these products is supplied in a 3mL bottle, sufficient for two weeks of therapy at QID dosing. The list price for the two-drug combinations is $25 each; for the three-drug combination, the price is $30.[2] LessDrops must be ordered through the physician's office, but may be shipped either to the doctor or directly to the patient.[2]

Two other American companies have recently introduced similar products. APS Pharmacy currently offers a line of products called SmartDrops. This line also consists of three combination agents:[3]

- prednisolone 1% with moxifloxacin 0.5%
- prednisolone 1% with ketorolac 0.4%
- prednisolone 1% with moxifloxacin 0.5% and ketorolac 0.4%

Per their website, SmartDrops is a patent-pending pharmaceutical solution matrix technology created to stabilize multiple active ingredients that do not typically mix. The technology micronizes the particles to enhance solubility, create uniform distribution, balance the pH and maintain the specific gravity to obtain one complete isotonic solution.[3] At present, these products are available and licensed in 45 states.

Another company in this race, Ocular Science, has created a product line under the name Droplet, which includes four postoperative drop formulas:[4]

- Pred-Moxi (prednisolone phosphate 1% and moxifloxacin 0.5%)
- Pred-Ketor (prednisolone acetate 1% and ketorolac tromethamine 0.5%)
- Pred-Moxi-Ketor (prednisolone acetate 1%, moxifloxacin 0.5% and ketorolac tromethamine 0.5%)
- Pred-Levo (prednisolone sodium phosphate 1.5% and levofloxacin1.5%)

The Droplet formulations are supplied in 6mL bottles and cost approximately $50 per bottle.[4]

Punctal Implants

In another effort to simplify the postoperative experience for physicians and patients, Ocular Therapeutix has developed Dextenza, a 0.4mg dexamethasone implant for intracanalicular use, indicated for the treatment of ocular pain after ophthalmic surgery. Although not yet approved for use in the US, Dextenza completed Phase III clinical trials and submitted the results to the Food and Drug Administration (FDA) in September 2015. Despite failing to receive approval, the drug-eluting implant met its primary endpoint regarding the elimination of postoperative pain on day eight following surgery, as compared with the placebo/control group.[5,6] Additionally, a study shows the proportion of patients with an absence of anterior chamber cells was significantly greater in the dexamethasone implant group on days 14 and 30 postoperatively than in the control group.[6] Ocular Therapeutix continues to pursue approval for Dextenza. On January 23, the company announced that it had resubmitted a new drug application to the FDA for Dextenza. They are concurrently pursuing other indications for the device too, including ocular allergy and dry eye disease.[7,8]

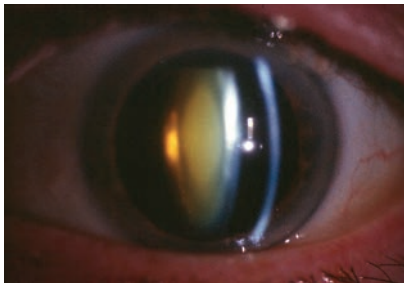
Eye Drops on Your iPhone

Finally, for those who don't wish to deviate from the current standard of postoperative medications, but still wish to help simplify drop use for their patients—there's an app for that. In fact, there are several available for the Apple iPhone and Android devices. For instance, the Easy Drops app (Milan Eye) allows patients to access the surgeon's individual profile, select the medication regimen for their surgery and set reminders for drop instillation. It also offers practice contact information, patient portal access, videos about the practice, appointment reminders that interface with the phone's calendar and a progress monitor.

While this app is free for patients, physicians and their practices must have an active account for their patients to use it. Doctors can register at easydropsapp.com. Fees for their basic package are $150/month or $1500/year (per doctor for one to four docs/practice).

Apps that are free for both the patient and doctor offer less personalized service, but can still help patients track progress with their

drop regimen. One such app is Eye Dr from the Queensland Eye Institute. This simple program permits up to four medication reminders per day, which can be personalized to include the name of the drops. There are additional options within this app for patients with glaucoma and macular degeneration, including a script reminder, appointment reminder and Amsler grid. Similarly, Round Health's Medicine Reminder and Pill Tracker allows patients to enter their medications—drops, pills, inhalers, etc.—and set reminders for when and how to administer them. The app can also remind the patient when it's time to order refills (although this feature is more applicable to pills than other forms of medication). Finally, EyeDropTimer (Matthew Hayson) can help patients maximize topical drug absorption. As the name suggests, patients use this app to ensure that they keep their eyes closed for a set period between eye drops, signaling that the time has concluded by activating a chime on the phone.



This patient displaying white nuclear scatter will face a drop regimen for which they may not have the skills to follow. A variety of modern options are designed to assist.

Easy Access, Happy Patients

Patients today demand greater convenience when it comes to elective procedures such as cataract surgery. The doctors who perform these surgeries, and those who provide postoperative care, need to create greater value and employ new technologies to ensure patient satisfaction and practice success. ■

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■ **2.** *Annual Cornea & Contact Lens Symposium.* Marshall B. Ketchum University, Fullerton, CA. Hosted by: Marshall B. Ketchum University. CE hours: 8. To register, email Antoinette Smith at asmith@ketchum.edu, call (714) 872-5684 or go to www.ketchum.edu/ce.

■ **5.** *OD Excellence Information Meeting.* Office of Steve Chander, Chicago. Hosted by: OD Excellence. Key faculty: Steve Chander. CE hours: 2. To register, email Anthony Senander at asenander@odexcellence.com, call (707) 433-5542 or go to www.odexcellence.com.

■ **5-9.** *15th Annual Education Conference.* Hilton Embassy Suites, Myrtle Beach, SC. Hosted by: New Jersey Academy of Optometry. Key faculty: Joseph Shovlin, Eric Schmidt. CE hours: 16. To register, email Dennis Lyons at dhl2020@aol.com or call (732) 920-0110.

■ **6.** *Envision University Low Vision Grand Rounds.* Envision University, Wichita, KS. Hosted by: Envision University. CE hours: 2. To register, email Michael Epp at michael.epp@envisonus.com, call (316) 440-1515 or go to www.envisionuniversity.org.

■ **7-8.** *St. George Spring Quarterly Conference and Meeting.* The Inn at Entrada, St. George, UT. Hosted by Utah Optometric Association. CE hours: 4. To register, email Alyssa White at alyssa@utaheyedoc.org, call (801) 364-9103 or go to www.utaheyedoc.org.

■ **8-9.** *Optometric CE Annual Symposium.* Las Vegas Marriott, Las Vegas. Hosted by: Optometric CE, Inc. Key faculty: Ernie Bowling, Bryan Wolynski, Dave Hansen, Sherrol Reynolds, Bryan Rogoff. CE hours: 12. To register, email Joel Rothschild at admin@optometricce.org, call (909) 255-0464 or go to www.optometricce.org.

■ **9.** *MSO Annual Meeting.* Four Points Norwood, Norwood, MA. Hosted by: Massachusetts Society of Optometrists. Key faculty: Ron Melton, Randall Thomas, Mark Dunbar. CE hours: 8. To register, email Kalyn Burke at kalyn@maoptometry.org.

To list your meeting, please send the details to:
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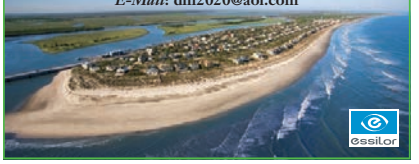

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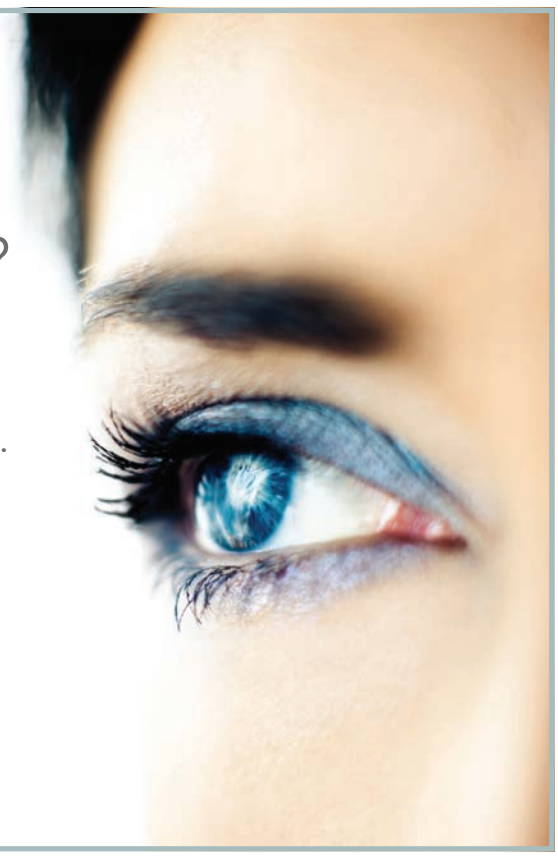

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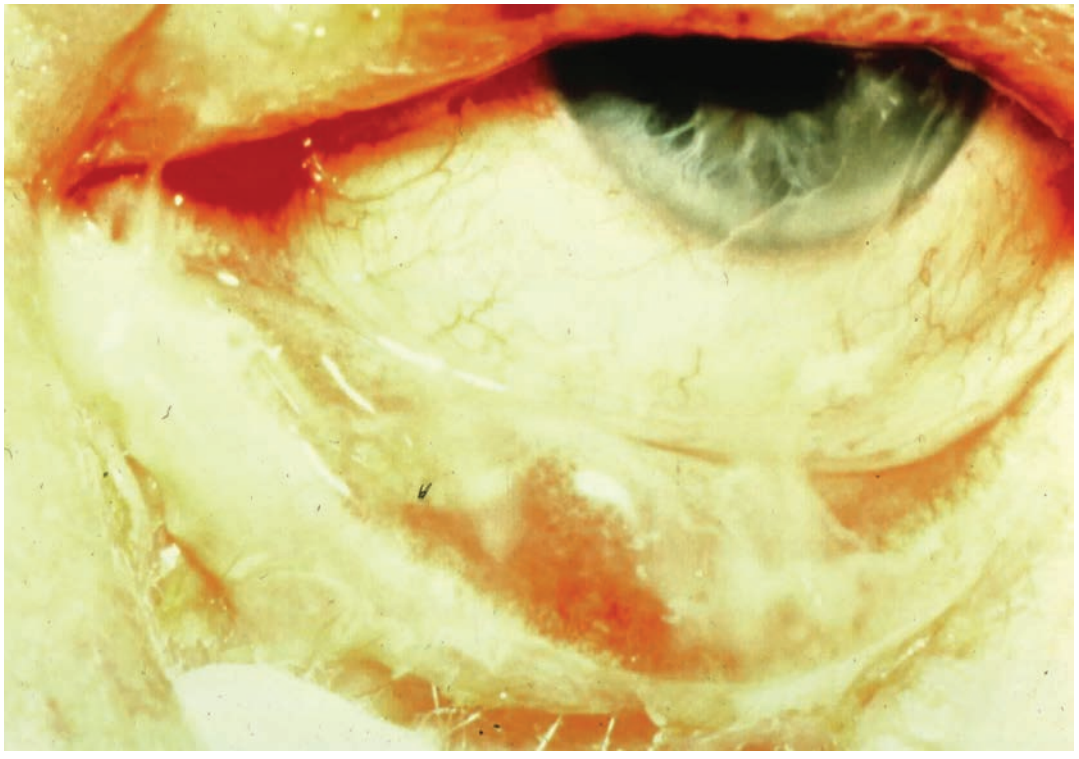
Diagnostic **Quiz**

A Sticky Situation

By Andrew S. Gurwood, OD



In addition to the red, irritated anterior segment, this 25-year-old female patient had been experiencing several symptoms including visual blurriness and sticky eyelashes upon waking, as well as watery discharge throughout the day. Can these complaints, combined with this photo, reveal the underlying cause of her distress?

History

A 25-year-old Caucasian female presented to the office with a chief complaint of a red, irritated right eye, which she had experienced for three days.

She said that, upon waking, she experienced visual cloudiness and her eyelashes would stick together. She also noted a watery discharge throughout the day.

Her systemic history was unremarkable, and she denied taking medicines or having allergies of any kind.

Diagnostic Data

Her best-corrected entering visual acuities were 20/30 OD and 20/20 OS at distance and near with no improvement upon pinhole. Her external examination was normal with no evidence of afferent pupil defect. The biomicroscopic examination of the right eye's anterior segment is demonstrated in the photograph. Goldmann applanation tonometry measured 15mm Hg OU. There were no posterior pole or peripheral pathologies OU.

Your Diagnosis

Does this case require additional tests? What is your diagnosis? How would you manage this patient? What is the patient's most likely prognosis? To find out, please visit us online at www.reviewofoptometry.com. ■

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