Eye on Stroke Prevention, p. 40

June 15, 2013

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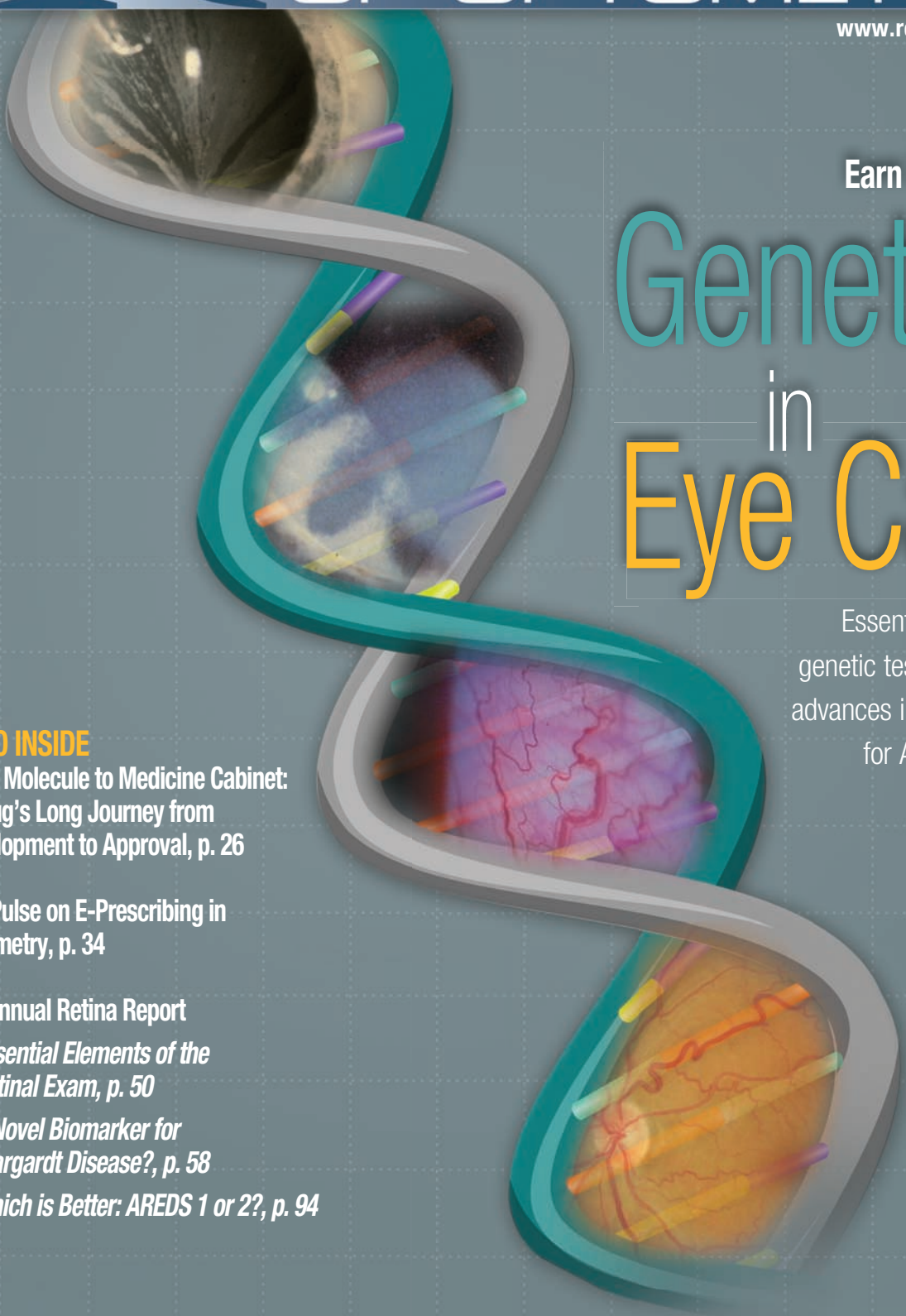

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Essential concepts in genetic testing, plus new advances in gene therapy for AMD and Fabry disease, p.68

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VOL. 150 NO. 6 ■ JUNE 15, 2013

IN THE NEWS

Valeant Pharmaceuticals is in the process of acquiring **Bausch + Lomb** for $8.7 billion. If the deal is OK'd, Bausch + Lomb will retain its name and become a division of Valeant, whose existing ophthalmology businesses will be integrated into the Bausch + Lomb division, creating a global eye health platform with estimated pro forma 2013 net revenue of more than **$3.5 billion**. Until the transaction is finalized, "there will be no immediate changes to day-to-day operations," says Adam Grossberg, B+L's vice president of global communications and branding. He expects the deal to close sometime during the third quarter of this year.

A new study reports that **omega-3s** significantly reduce **dry eye symptoms**. Published online by *Ophthalmology*, the study found that dry eye patients who took two daily omega-3 capsules (each containing 180mg eicosapentaenoic acid and 120mg docosahexaenoic acid) had a 71% improvement in tear film break-up time after one month. Also, their scores on the Ocular Surface Disease Index improved by 26% and their Schirmer's scores improved by 22.3%.

Researchers have developed **spray-on technology** that could be used as a **negative-index flat lens.** This could revolutionize the way optical lenses are made and used, they report in the journal *Nature*. A negative-index flat lens like this could transfer image details that are substantially smaller than the wavelength of light. This could create images of higher resolution than are possible with lenses made of positive-index materials such as glass.

AMD Patient Improves From 20/400 to 20/40

The patient is enrolled in a clinical trial using human embryonic stem cells. **By John Murphy, Executive Editor**

A patient with dry age-related macular degeneration has reportedly shown a remarkable improvement in vision from 20/400 to 20/40. The patient is enrolled in a clinical trial using stem cell therapy.

The news was first reported in an article from Reuters, and later confirmed by the company behind the clinical trial, Advanced Cell Technology.

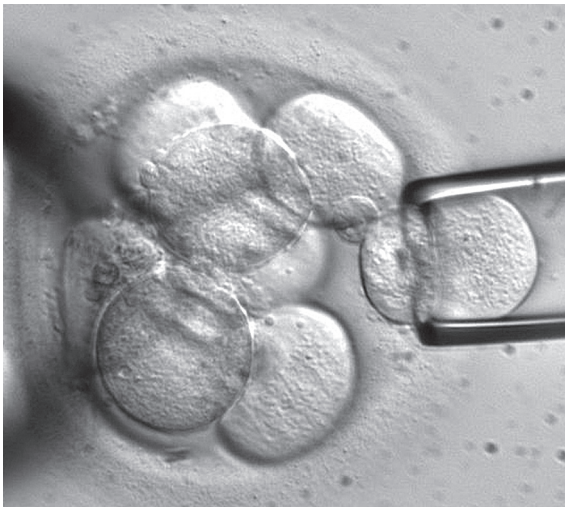

Photo: Advanced Cell Technology

An embryonic stem cell biopsy in progress. This method acquires human stem cells without destroying embryos.

The Phase I/II prospective clinical trial is still underway and otherwise under wraps. The study is investigating transplantation of retinal pigment epithelial (RPE) cells derived from human embryonic stem cells (hESCs) in patients with advanced dry AMD. Two additional clinical trials are also investigating this treatment in patients with Stargardt macular dystrophy.

"The ultimate therapeutic goal will be to treat patients earlier in the disease processes, potentially increasing the likelihood of photoreceptor and central visual rescue," the investigators wrote in a preliminary report in 2012.[1]

News of this patient's dramatic improvement was met with both hopefulness and skepticism by the scientific and ophthalmic communities. The big question: Can this one patient's exceptional results be replicated in others?

"The devil is in the details," says Gordon C. Hendricks, OD, MS, of El Paso, Texas, whose own research involved the regenerative properties of retinal stem cells in fish eyes. "This is very promising research. But what makes it difficult to achieve in humans is exogenously creating those stem cells and then delivering them to the human retina."

1. Schwartz SD, Hubschman JP, Heilwell G, et al. Embryonic stem cell trials for macular degeneration: a preliminary report. Lancet. 2012 Feb 25;379(9817):713-20.

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Prostaglandins Precipitate Ptosis

Use of prostaglandin analogues (PGAs) can cause visually significant eyelid droop, according to a study in a recent issue of *PLoS One*.

In this study, the researchers evaluated 157 current, 15 past and 171 non-PGA users for signs of prostaglandin-associated periorbitopathy. The subjects underwent external digital photography and systematic external adnexal examination, and gave the investigators a history of their glaucoma medication use.

At the conclusion of the study, the researchers determined that patients who currently used bimatoprost 0.03%, travoprost 0.005% or latanoprost 0.004% were much more likely to exhibit upper lid ptosis, levator dysfunction and lower lid retraction than past or non-PGA users. Specifically, current PGA users were 230 times more likely to develop upper-lid dermatochalasis and 249 times more likely to experience periorbital fat loss in the lower lid.

Eye doctors have been anecdotally reporting this problem for a few years now, and smaller case studies and documented it. Ophthalmic drug manufacturers have already changed the product information of PGAs to acknowledge reports of "periorbital and lid changes associated with a deepening of the eyelid sulcus," though not in the list of side effects. But this is the first large cross-sectional study to confirm multiple adverse effects, including lower lid steatoblepharon, upper lid levator dysfunction and upper lid ptosis.

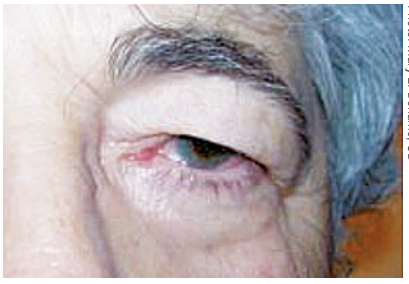

Photo: Mary E. Bonarne, OD

A new study confirms more side effects of prostaglandin analogues: ptosis, periorbital fat loss and sulcus deepening.

"As we continue to use medications as much as we use prostaglandins, it is not unreasonable to come across new adverse events never addressed in the initial safety studies," says Joseph W. Sowka, OD, professor of optometry, director of the Glaucoma Service and chief of the Advanced Care Service at Nova Southeastern University College of Optometry in Ft. Lauderdale, Fla. "But it must be remembered that these findings, while possible, should not negate the widespread use of a medication class that has revolutionized glaucoma therapy."

For his part, "I have never encountered ptosis from prostaglandin use, and no patient has ever reported this to me," he adds. While Dr. Sowka says this research will not alter his prescribing of prostaglandins, he "will not discount any patient report of ptosis or sulcus deepening, and will immediately be prepared to discontinue the medication should such complaints be mentioned."

Shah M, Lee G, Lefebvre DR, et al. A cross-sectional survey of the association between bilateral topical prostaglandin analogue use and ocular adnexal features. PLoS One. 2013 May 1;8(5):e61638.

Blood Vessels in the Eye Linked to IQ

Next time you're checking your patient's retinal health, you might want to see what's going on with their brain, too. The width of retinal blood vessels may indicate brain health and cognitive function long before dementia or other deficits present themselves, according to a study in *Psychological Science*.

Because retinal blood vessels share similar size, structure and function with the blood vessels in the brain, researchers used digital retinal imaging to investigate vascular conditions in the brain. Psychological scientists at Duke University examined data from more than 1,000 people, and found that patients with wider retinal venules were associated with lower IQ scores, even after accounting for various health, lifestyle and environmental risk factors. In addition, subjects with wider retinal venules also showed evidence of general cognitive deficits, with lower scores on numerous measures of neuropsychological functioning.

The researchers suggest that digital retinal imaging may expand beyond eye care and serve as an investigative tool for psychological scientists studying the link between intelligence and health across the lifespan.

Shaley I, Moffitt TE, Wong TY, et al. Retinal vessel caliber and lifelong neuropsychological functioning: retinal imaging as an investigative tool for cognitive epidemiology. Psychol Sci. 2013 May 15.

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If FDA Reclassifies Hydrocodone Pain Meds, Most ODs Won't be Able to Rx

In January, an FDA advisory panel voted in favor of reclassifying hydrocodone-combination drugs from Schedule III to Schedule II. If this comes to pass, optometrists in many states would be left with few options to appropriately treat patients suffering with severe eye pain.

For more than a decade, the Drug Enforcement Administration (DEA) has been advocating the reclassification of hydrocodone-combination pain medications from Schedule III to the more restrictive Schedule II category. This would include such commonly prescribed pain medications as Vicodin (hydrocodone/acetaminophen, AbbVie) and Lortab (hydrocodone/acetaminophen, UCB).

The recent discussion on reclassification began after increasing reports of addiction and illegal abuse of hydrocodone-combination narcotics. Proponents of the reclassification say the abuse and misuse of these drugs is a public health epidemic.

According to the Centers for Disease Control and Prevention (CDC), prescription painkiller overdoses resulted in nearly 15,000 deaths in the US in 2008. In 2009, nearly half a million emergency department visits were due to people misusing or abusing prescription painkillers. In addition, nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs, the CDC says.

The FDA isn't required to follow its advisory panel's decision but, historically speaking, it usually does.

Meanwhile, in March, legislators introduced into Congress a bipartisan bill, called the Safe Prescribing Act of 2013, that would reclassify any substance containing hydrocodone as a Schedule II drug.

In the majority of the 44 states where optometrists are authorized to prescribe certain controlled narcotic substances, ODs are limited to drugs in Schedules III, IV and/or V, which are considered safer and less addictive.

However, in several of these states, optometrists have anticipated this possible switch. They moved quickly to clarify that their current authority to prescribe hydrocodone-combination drugs won't be affected if the reclassification goes through.

The optometric associations in Kentucky, Arkansas and Georgia, where optometrists are prohibited from prescribing Schedule II narcotics, successfully took preemptive steps this year to assure that optometrists will be able to continue to prescribe hydrocodone-combination drugs if they are reclassified. These states approved legislation—HB 8 in Kentucky, enacted on March 19; HB 2210 in Arkansas on April 18; and HB 235 in Georgia on May 6—so that the authority to prescribe hydrocodone-combination drugs is not tied to any particular schedule.

Similar legislation (SB 1454) is pending in Illinois.

After the advisory panel approved reclassification, the FDA later told lawmakers that, if this change is approved, it would require a long process to initiate.

Meanwhile, the Safe Prescribing Act of 2013 has been sent to committee for further consideration.

Top Paying Metropolitan Areas for Optometrists

According to recently released data from the US Bureau of Labor Statistics, these are the top 10 metropolitan areas where optometrists average the highest salaries, as of May 2012.

Metropolitan area	Average annual wage
1. Houma/Bayou Cane/Thibodaux, La.	$201,010
2. Fayetteville, NC	$198,340
3. Toledo, Ohio	$189,390
4. Augusta, Ga./Richmond County, SC	$176,130
5. Miami/Miami Beach/Kendall, Fla.	$170,140
6. Sioux Falls, SD	$169,390
7. Beaumont/Port Arthur, Texas.	$168,660
8. Raleigh/Cary, NC	$164,780
9. Greensboro/High Point, NC	$163,950
10. Bridgeport/Stamford/Norwalk, Conn.	$163,730

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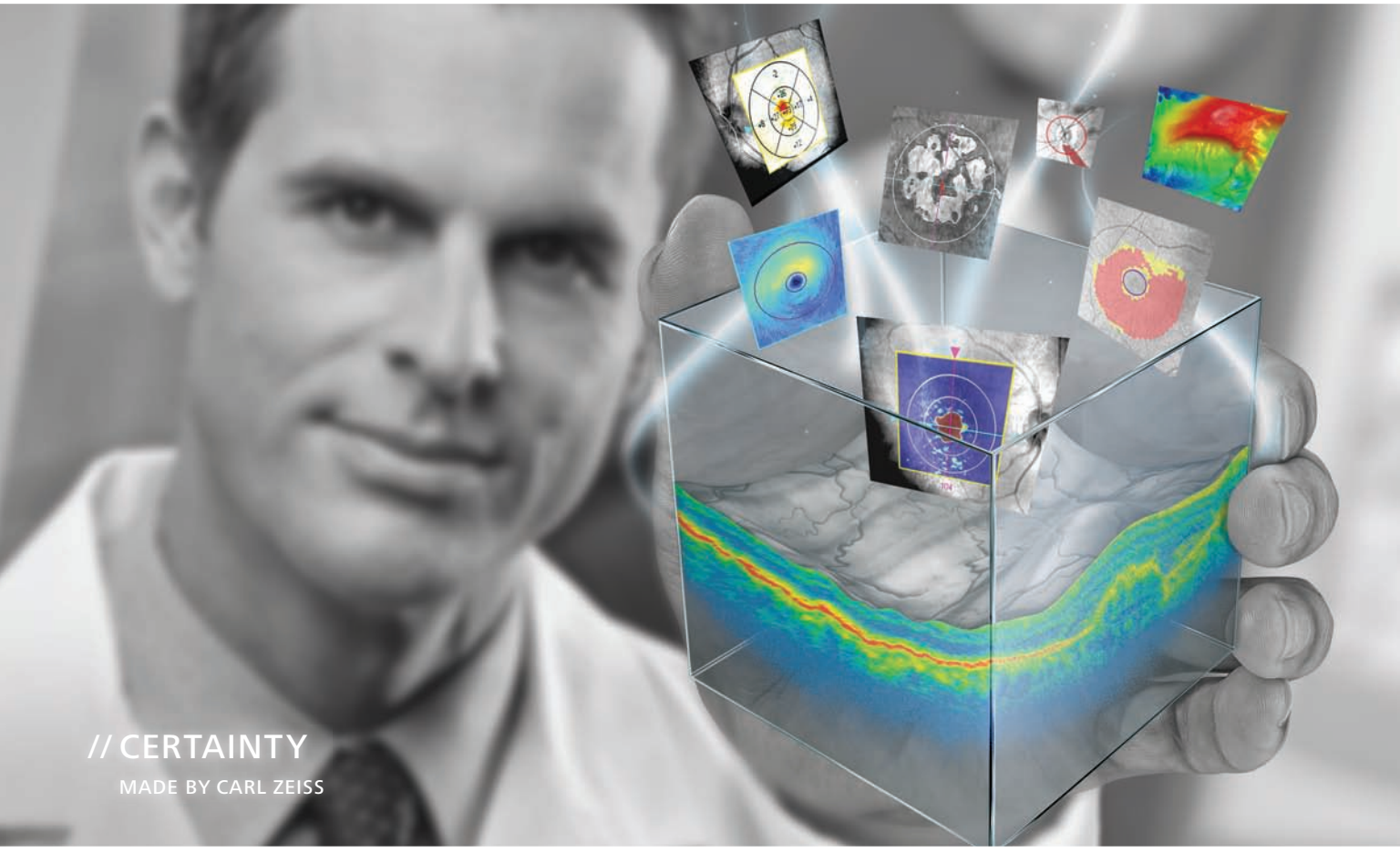

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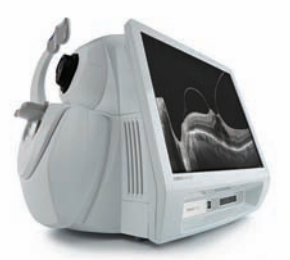

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What to Do With AREDS2?

Ever since the long-awaited results of the Age-Related Eye Disease Study 2 (AREDS2) arrived in early May, optometrists have been sifting through the data to determine what—if any—changes they should make in recommending nutraceuticals to their AMD patients.

And, for some doctors, the initial results of the study prompt more questions than answers on matters of patient care.

Omega-3 Quandry

The primary findings of AREDS2 indicate that neither lutein plus zeaxanthin or DHA plus EPA (omega-3 fatty acids), nor all four components combined, further reduced the risk of progression to AMD when added to the original AREDS formula.[1] However, secondary analyses suggest the combination of lutein and zeaxanthin may be beneficial in select patient populations. The data suggests a reformulation of the AREDS formula that removes beta-carotene and adds lutein and zeaxanthin for patients at risk of AMD progression.

"The results require a lot of sorting through, and are not as cut and dry as the conclusion may imply from the abstract in the *JAMA* (*Journal of the American Medical Association*) article," says optometrist Jeffry Gerson, of Kansas City.

But, he added, "I think the biggest surprise was lack of statistical significance in the benefit of omega-3." Now, he says he won't be quite as adamant to recommend fish oil to all his AMD patients, but "it will still be part of the conversation and likely recommended to many, especially if they don't have regular dietary omega-3 intake."

Stuart Richer, OD, PhD, of the University of Illinois at Chicago, referred to the study as a "landmark achievement." However, he adds, one has to read the published abstract and conclusions with a discerning eye because the *JAMA* article both understates and complicates the data. "The AREDS2 Study Chair Emily Chew, MD, presented two separate ARVO lectures in Seattle that contradicted the *JAMA* article's main conclusion. Unfortunately, the ARVO audience is a much narrower audience than the US public—so much unnecessary confusion has been generated concerning the results, other than to say that lutein/zeaxanthin is a safer choice than high-dose beta carotene in terms of lung cancer risk."

Dr. Richer could not explain the negative EPA/DHA omega-3 results other than to say that the placebo group was already highly nourished with these important eye/brain nutrients. Also, he adds, the AREDS2 results on fish oil contradict AREDS Report #20 as well as the preponderance of evidence showing a clear ocular benefit.[2]

"In my patient population, I will continue to prescribe omega-3 fats because of their beneficial effects on HDL, triglycerides, blood pressure, heart rate, arrhythmias, violent behavior, mood, cognitive function, cardiovascular disease, cancer, and of course, dry eye and blepharitis," Dr. Richer says.

"As a health care provider, this study scares the heck out of me," says Larry J. Alexander, OD, of McKinney, Texas. He characterizes AREDS2 as a poorly controlled study. "Well-nourished, relatively healthy patients in a control group were on AREDS1 and there was no way of knowing whether they had achieved therapeutic dosage of omega-3s or what omega-3s were being taken." Dr. Alexander says he is concerned patients will read the headlines and come away with the idea that they no longer need to take omega-3s.

How Much Zinc?

In addition to the omega-3 findings, optometrist Steven

Imitation Dilation

With today's lifelike prosthetic eyes, it's easier for eye loss victims to blend in—but at night or in bright sunshine, having two different-sized pupils is a giveaway. A new invention features a cosmetic pupil that could give them a boost in confidence.

Researchers at Nottingham Trent University, in the UK, have developed a prosthetic eye prototype that incorporates smart materials to dilate and contract the pupil in response to a light sensor in the device. Because the prototype uses off-the-shelf electronics, the current model is about the size of a grapefruit. The researchers' next step is to miniaturize it to the size of a human eye.

Ferrucci, chief of optometry and residency director at the Sepulveda VA Ambulatory Care Center, in Sepulveda, Calif., was also perplexed that AREDS2 still recommended a daily dosage of 80mg of zinc, despite the study's finding that a lower dosage may have the same effect.

"The study seemed to indicate there was no difference between the higher and lower levels, yet it really didn't recommend that we change the level of zinc at this point," Dr. Ferrucci says. "I'd be interested to see how people interpret that, because it seems to me that if the higher and lower doses are about the same, it makes sense to use less zinc because there is a potential for fewer side effects."

What to Change?

One result of AREDS2 that is clear to Dr. Ferrucci is the substitution of lutein and zeaxanthin for beta-carotene. "That is really going to limit me from prescribing the original AREDS formulation with beta-carotene for the safety profile and for patients who have a lower level of dietary lutein intake."

For Dr. Richer, the results of the AREDS2 study are not going to impact his approach to patient care one iota. "I don't treat individual patients using group statistics and rule-based patient care," Dr. Richer says. "In my opinion, optometrists should attempt to provide a near-optimal result for each of their patients. That means stepping up to the plate, and actually reading Level 1 EBM (evidence-based medicine) science with a discerning eye, as well as Level 2 sciences to obtain a full picture of who will benefit."

Be skeptical but not cynical, he advises. "We are either going to take abstracts as the gospel truth, or start asking each patient what they are eating, measure macular pigment, visual function or some measure of RPE health such as fundus autofluorescence. AREDS2 shows us that it's tough to treat a disease once it becomes advanced, so we better start examining and talking to the children of AMD patients who have a 45% risk of developing AMD. AREDS2 shows us that there is no such thing as an 'average patient.'"

Future Research

Jeffrey Anshel, OD, president of the Ocular Nutrition Society, won't make any changes in his practice based on AREDS2 because he already recommends a full-spectrum multiple vitamin/mineral supplement to all his older patients. He does see AREDS2 as a catalyst for future studies, including more genetic testing (on all subjects, not just one in four of them as in AREDS2), higher doses of vitamin C for cataract effects, and a study that looks at earlier stages of the disease, he says.

"This is just the first report, not the be-all and end-all," Dr. Ferrucci says. "Over the next year, two years, three years, we are going to see additional reports as they begin to look at more of the data. It is important to keep looking at additional studies that come out of this. So this is not the end of AREDS2. It is just the beginning." ■

1. Age-Related Eye Disease Study 2 Research Group. Lutein + zeaxanthin and omega-3 fatty acids for age-related macular degeneration: the Age-Related Eye Disease Study 2 (AREDS2) randomized clinical trial. JAMA. 2013 May 15;309(19):2005-15.
2. SanGiovanni JP, Chew EY, Clemons TE, et al; Age-Related Eye Disease Study Research Group. The relationship of dietary lipid intake and age-related macular degeneration in a case-control study: AREDS Report No. 20. Arch Ophthalmol. 2007 May;125(5):671-9.

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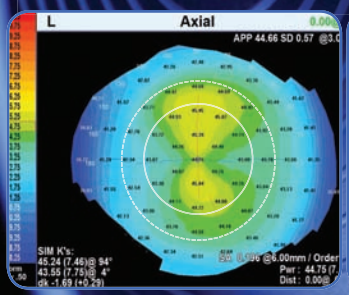

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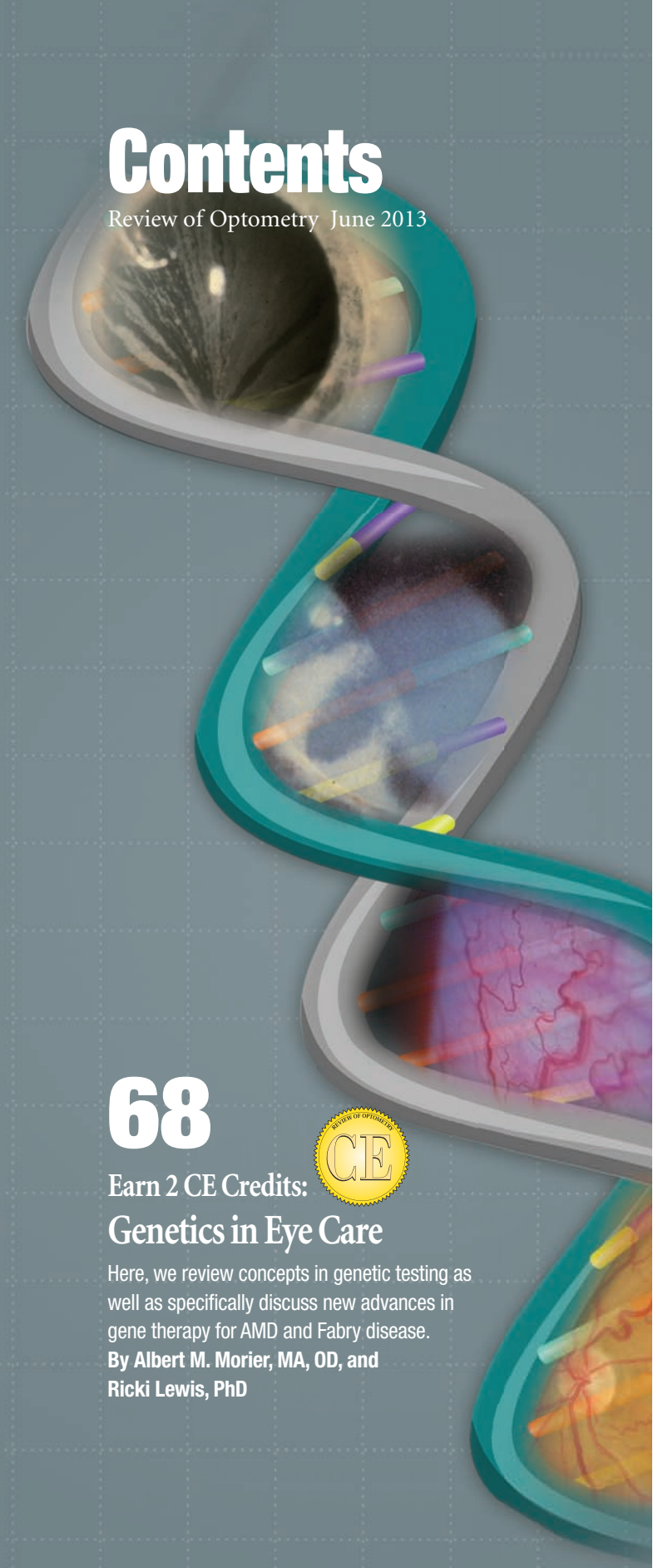

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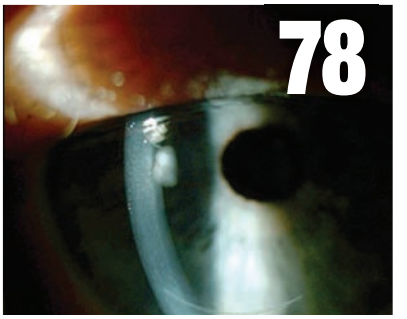

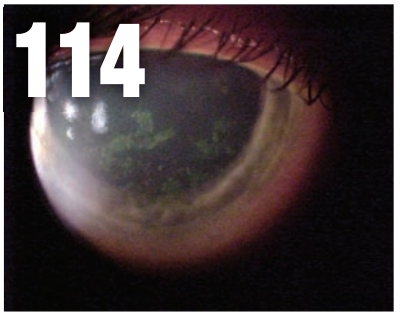

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Dear Eye Care Professional:

During the last several months, Alcon has been developing an exciting national campaign for patients about the importance of eye health and the availability of proven advanced cataract surgery technologies. As a valued partner, we want to let you know how you can get involved and continue to be a resource for your patients who have been diagnosed with cataracts.

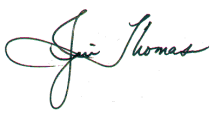
We are excited to announce our new **Cataract Patient Education Resources for Optometrists** that you can begin using in your practice today.

Designed to help enhance the cataract surgery conversations you are already having with your patients, these materials will provide patient-friendly, take-home information they can reference outside of your office.

Visit us online at MyAlcon.com/cataract-patient-education to preview these materials, download copies to your computer, and order printed resources to be shipped directly to your practice.

For a patient whose cataract journey may be just beginning in your office, your guidance will instill confidence in the process and ultimately provide them with an informed decision about their advanced technology options.

Thank you for partnering with us as we continue to educate patients on the proven advancements in cataract surgery technologies.



Jim Thomas
VP & General Manager, Alcon US Surgical

Jim Murphy
VP & General Manager, Alcon US Vision Care

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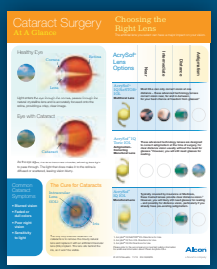
Alcon's Cataract Education Resource Materials will help with your meaningful patient conversations and provide them with confidence before cataract surgery. Select the resources that are right for you, depending on your patient and practice needs.

From Cataracts to Clarity

What You Need to Know

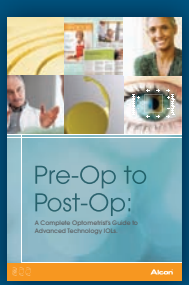
Educating Your Cataract Patients — Optometrist Resources Kit: A packet for optometrists that includes the flashcard, brochure and Focus™ Magazine for patients and one copy of the Pre-op to Post-op Guide for Optometrists.



Cataract Surgery Flashcard for Patients: A quick guide for patients on cataracts and intraocular lens options.

Cataract Surgery General Brochure for Patients: (See attached insert) This brochure provides patients with a comprehensive overview of cataracts, what to expect during a procedure and differences in intraocular lenses.

Focus™ Magazine for Patients: A magazine that provides an introduction to cataract surgery through patient stories, advanced technology options and informative health articles in an easy-to-read magazine for patients.



Pre-op to Post-op Guide for Optometrists: Informative guide for optometrists to facilitate conversations with patients about advanced technology lenses—from pre-op to post-op stage. Please note this is not patient education take-away material.

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Life Begins at 23

Genetic testing reveals much about our health risks, but raises the stakes for doctors. Will patients be convinced their DNA is their destiny? **By Jack Persico, Editor-in-Chief**

It took 10 years and $3 billion to map the human genome for the first time. I ordered mine on the internet for $99, and will have the results before Labor Day.

One of the fascinating—and worrisome—consequences of the Human Genome Project's success at sequencing every human DNA base pair is the opportunity we all now have to peer at our own genetic fingerprints. Considered science fiction only a decade ago when the project concluded, personal genotyping cost several thousand dollars until recently. Now, it can be ordered for less than a week's worth of groceries. "Retail genomics" is a reality.

It's being popularized by web sites like 23andMe.com (named for the 23 chromosome pairs in every human cell), where I ordered my genetic profile. They're sending me a sample collection tube to spit in and mail back, then in a few weeks I'll get a report on my DNA genotype. It's technically not a full sequencing (as in the Human Genome Project), just a *Cliffs Notes* version that quantifies my predispositions for 250 conditions, including glaucoma and AMD, but also everything from Parkinson's to atrial fibrillation to liver disease.

Needless to say, I'm a bit worried about the results. My great aunt has AMD, and is nearly blind from it. If the test shows I'm at an elevated risk for the disease, I can adjust my diet, start taking an AREDS vitamin and get eye exams more frequently—all the usual strategies. I also can, and probably will, panic.

It's easy to look at an elevated genetic predisposition for a certain disease and assume the worst. In such cases, incomplete information is probably more troubling than none at all; such knowledge can become a lifelong burden. And yet, knowing one's propensity for various diseases does allow for early intervention, family planning and other measures that justify the unease such revelations cause.

But the funny thing is, I didn't even especially *want* the disease screening data; I ordered the test because it will provide my ethnicity breakdown and ancestral lineage (as more people sign up, your global familial connections are uncovered). But 23andMe doesn't separate out its health screening and ancestry services. So, bear in mind that some of your patients will be learning potentially monumental things about their genetic health profile without even expecting it.

Mendelian Meddling

Has industry rushed into retail genomics without due concern for ethical issues and proper patient education? For the consumer-based services, perhaps. The genetic tests available to medical professionals are more nuanced in both the way they assess risk and how they present the results. And, they keep you as the gatekeeper of the data.

This month's cover story (*see "Genetics in Eye Care," page 68*) provides an excellent primer on key concepts in genetic testing and the prospects for gene therapy in heritable ocular diseases. But beyond the science, you'll also need to orchestrate the delicate art of genetic counseling, working in concert with primary care physicians to assuage your patients' fears and put the results in perspective.

Is our DNA our destiny? Those 23 telltale chromosome pairs will become ever more relevant to your patient care. The continual rise of genetics as an integral part of medical risk assessment dovetails nicely with another medical megatrend: the drive to encourage preventive measures rather than after-the-fact treatment. Optometrists do more routine eye disease screening than anybody, of course, so it'll fall to you to incorporate genetic risk modeling into your practice.

Also in this issue, retina expert Jerome Sherman, OD, describes familial involvement of Stargardt disease presenting with a biomarker found via SD-OCT. The one-two punch of genetic testing and advanced imaging is beginning to transform screening, diagnosis and management. Expect more to come.

That's a brave new world, and an incongruous one—with ODs now having to deftly shift gears from discussing single nucleotide polymorphisms to anti-reflective lens coatings. Talk about an expanded scope of practice! You're going all the way to the molecular level.

As for me, when my results come back, I think I might just give the health risk data—sight unseen—to my PCP, so that she can advise me. Sometimes, ignorance is bliss. ■

The Varilux S Series™: Nanoptix Technology™ — A Revolutionary Approach to Fundamental Progressive Lens Structure

Three groundbreaking technologies underlie the extraordinary benefits of new Varilux S Series™ lenses:

- **Nanoptix Technology™: A breakthrough technology that virtually eliminates "swim" compared to other premium progressive lenses. Nanoptix Technology™ reengineers the basic shape of the progressive lens by considering the lens as a set of many optical elements, allowing designers to minimize image deformation while maintaining the power progression.**
- **SynchronEyes Technology™: A powerful, innovative technology that integrates prescription data from both eyes into each lens, optimizing binocular visual fields and giving wearers expansive vision.**
- **4D Technology™: A revolution in lens personalization that enhances overall visual response times by ensuring the sharpest vision in the leading dominant eye™. (Available only on Varilux S 4D™ lenses.)**

This paper will introduce the contribution of Nanoptix Technology™ to the elimination of the "swim effect."

Defining "Swim"

The "swim effect" some progressive lens wearers experience during dynamic visual tasks has long challenged lens designers. Despite decades of work, every progressive lens design to date has induced some degree of "swim." Lens designers' attempts to reduce "swim" have all been hampered by the fact that, up to now, the strategies employed to limit "swim" have had the unwanted side effect of reducing fields of clear vision.

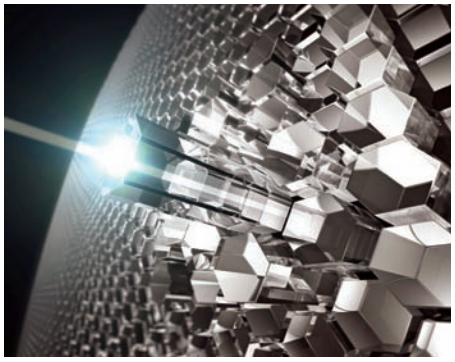

FIGURE 1 Varilux S Series™ lenses are calculated from many tiny optical elements.

Nanoptix Technology™ completely rethinks the lens design process—with the result that Varilux S Series™ lenses virtually eliminate "swim" compared to all other progressive lens designs and still provide expansive vision.

The Origin of "Swim"

By definition, progressive lens power increases continuously from the distance to the near portions of the lens. But this variation of power at the surface of the lens induces image distortion, which is most pronounced in the lower part of the lens where power is greatest.

In static conditions the wearer will experience image deformation: straight lines viewed through the bottom of the lens may appear curved due to prismatic deviation. In dynamic binocular vision—ie, when either the wearer or objects in the visual field are moving—this effect is amplified, and the wearer may experience "swim," as objects appear to move unnaturally in the visual environment.

The "swim effect" is roughly proportional to the increase in prismatic deviation between upper and lower parts of the lens. This can be measured by looking at the difference in horizontal displacement of the image of a vertical line as seen through these two parts of the lens. The displacement, Δx, is a function of the shape of the lens and the power difference from top to bottom. Dividing Δx by the maximum power variation, ΔP, gives us a value, Δd, called the "end-to-end normalized deformation."

Δd is an objective measure of the lens' tendency to distort and can be used as an indicator of the lens' tendency to produce "swim." To minimize "swim," the Δd value of a progressive lens should be close to 0, as it would be in a single-vision lens.

Breaking the Paradigm

Instead of considering the lens as a single, continuous curve, Nanoptix Technology™ reengineers the lens, conceptualizing it as composed of many optical elements (Figure 1). By controlling the length and the position of each element, Nanoptix Technology™ calculates the power and design needed *at each point* to correct the given prescription. Once each element is determined, Varilux S Series™ lenses are built, element by element (Figure 2). The result is a fundamental restructuring of progressive lens geometry that enables the control of prismatic deviation at the element level, virtually eliminating "swim" compared to other progressive lenses.

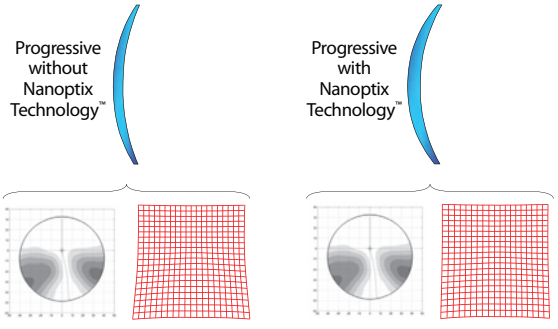

FIGURE 2 Using dynamic vision in a virtual reality environment, subjects compared their perception of a grid as it would appear through a progressive lens either with or without optimization aimed at elimination of "swim." Among subjects with a preference, 73% preferred the optimized design.

Nanoptix Technology™ provides stable, virtually "swim"-free vision. Combining this with SynchronEyes Technology™, which creates lenses optimized for binocular vision, enables Varilux S Series™ lenses to give wearers virtually unlimited vision in progressive lenses. ■

For additional information:

www.Varilux.com/variluxSSeries – Technical Information

Optometry is Still a Man's Game

Optometry, as a profession, is still a man's game. The women are beating us senseless, obviously, but it's still a man's game! **By Montgomery Vickers, OD**

When I was kicked out of Pennsylvania College of Optometry—thankfully with diploma in hand—guys dominated the profession of optometry. I'm not saying that was a good thing, that's just the way it was. The guys were a bunch of nerdy lab rats. The women were beautiful, cheery and smart. Once we got out into the profession, how could we guys compete with that? As a group, we were outmanned (pardon the pun).

Since then, it's been easy to see the growth and contributions of our female colleagues. Funny how we good ol' boys actually seemed surprised as we realized the women were moving the profession's evolution, not us.

But, ladies, please allow me to remind you (and us) that men optometrists still have much to offer our profession! Here are many examples, although I will admit there are, of course, exceptions:

• ***Men optometrists fix broken drawers.*** More accurately, we patch them together so they look OK to the patients, even though they don't actually open and close. Who cares? All that's in there are old, broken, hand instrument handles and 1980s-era glaucoma pamphlets.

• ***Men optometrists spend more time with patients.*** Now, we don't spend time actually examining these patients. That's not what I mean. But we can throw off the whole schedule just BS-ing about fishin' or cars, and don't get me started about how much time we spend braggin' about our new grill. By the way, it uses natural gas and has eight burners!

• ***Men optometrists schmooze Moms better, and Moms determine who your patients are.*** Come on, you know it's true. Men have been trained since caveman days to kiss up to Mom. One only has to carefully examine the Petroglyphic chiseling of the Schmomagnen Era's hairy ape-like creatures hopelessly trying to fold fur clothes to know why we try so hard to keep Momma happy. It's in our DNA. That and prostate enlargement.

• ***Men optometrists still use direct ophthalmoscopes.*** Not all of us, but the vast majority do because we are old enough to still think OCT represents the month when we drink beer and eat Weiner schnitzel. This is a medical skill worth keeping, kinda like bloodletting for the plague.

• ***Men optometrists carry the paper.*** There are only two reasons an optometrist could possibly file a Worker's Comp claim, and both of them involve copy paper. Hey, paper is actually wood, so a ream of paper equals about five logs and, besides, paper cuts can be dangerous (ref. "bloodletting" in previous paragraph for more information).

• ***Men optometrists can pretend everything at the office is peachy keen.*** We are awesome at ignoring the staffers who come to work late, the deliveries that get lost, the phones that don't work, and the bills that don't get paid. You want to get things done at the office? Have a woman optometrist. You want to chat about cigars? Men. You want to improve efficiencies? Women. You want to gripe about Obamacare? Men. You know who you are!

Me? It should be obvious to you that I hold women optometrists in high regard and I give the men a hard time. On the other hand, with a few exceptions, I would rather hunt woolly mammoths with the guys. Woolly mammoth burgers are great for grillin'! ■

New DAILIES TOTAL1® Water Gradient Contact Lenses: Comfort Redefined

A new era in contact lenses for a new era in comfort. — **Mile Brujic, OD**

When I graduated from optometry school in 2002, silicone hydrogel lenses had been available for several years, but most of the lenses we fit were still hydrogels. Over the last decade we have seen a major transition in soft contact lens prescribing, motivated by the hope that increasing oxygen flow to the cornea would enhance ocular health and comfort.

Oxygen Permeability

Unique among tissues, the avascular cornea gets much of its oxygen directly from the air, and, to varying degrees, contact lenses can impede that process. Over time, diminished corneal oxygen flow can result in physiological changes, including edema, epithelial microcysts, limbal hyperemia, and neovascularization.[1]

The demand for greater oxygen transmissibility led to the addition of silicone, an extremely oxygen permeable material, to the hydrogel lens matrix. Silicone hydrogel solved the oxygen transmissibility problem, and the incidence of serious hypoxia-related complications was reduced to almost zero.[1,2]

Silicone and Comfort

Unfortunately, while silicone is highly oxygen permeable, it is also extremely hydrophobic. Even embedded in a hydrogel matrix, hydrophobic silicone moieties can migrate to the lens–air interface. At the lens surface, tiny hydrophobic areas can form and coalesce, reducing surface lubrication and potentially creating discomfort during blink.

To address this challenge, material scientists tried surface treatments to encapsulate the silicone and added wetting agents to the lens matrix to improve surface moisture. These strategies have worked well, but a subset of patients continues to remain uncomfortable.

A New Approach: The Water Gradient

The novel material (delefilcon A), from which DAILIES TOTAL1® contact lenses are made, has brought a new era in contact lens comfort. The first and only water gradient contact lenses, DAILIES TOTAL1® contact lenses are 33% water at their core, but over 80% water in the 6 microns between the core and the surface.[4]* The result is that DAILIES TOTAL1® contact lenses combine outstanding surface lubricity for comfort throughout the day with high oxygen transmissibility (Dk/t of 156 at –3.00 D), and essentially no silicone at the surface.

Thanks to the water gradient, the remarkable surface of DAILIES TOTAL1® contact lenses is exceptionally lubricious, offering a smooth, wet surface for the lids to slide over during blink. Indeed, DAILIES TOTAL1® contact lenses have the lowest coefficient of friction of any daily disposable contact lenses tested.[5] The result is outstanding comfort from beginning to end of day.

In an ongoing multicenter European clinical study (n = 280), patients preferred DAILIES TOTAL1® contact lenses to their habitual lenses by a ratio of 13 to 1.[6]** That startlingly high level of preference was replicated in my own patients' enthusiastic reactions to these lenses.

A High-performance Product

When I introduce DAILIES TOTAL1® water gradient contact lenses, patients are naturally curious about what makes them different from the ones they currently wear. I describe the revolutionary water gradient concept, emphasizing that the low water content core makes the lenses highly breathable, while the highly lubricious surface makes them exceptionally comfortable.

COMFORT COUNTS

Comfort issues are surprisingly common among contact lens wearers—even ones who never complain about discomfort. Industry studies show us that the overwhelming majority of patients with discomfort symptoms simply don't tell us about them—even when we ask. I have found that when I ask patients about their lens-wearing experience, they typically answer "good" or "fine." But when I ask them to rank it on a scale of zero to 10, they will rate it as a 6 or 7.

To me, 6 or 7 out of 10 is an opportunity to improve a patient's wearing experience. We know that lack of comfort is the number one reason patients give up on contact lens wear.[3] I want my patients to truly enjoy contact lens wear and to be happy with the lenses I prescribe. Their health, and that of my practice, depends on it.

* In vitro measurement of unworn lenses.
** Percentage of wearers agreeing with statement "I prefer these lenses to my previous contact lenses."

Mile Brujic, OD, is a partner of Premier Vision Group, a four location optometric practice in Northwest Ohio.

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Special Ophthalmic Testing

You can perform some tests on the same day as the office visit—as long as you record the medical necessity. **By John Rumpakis, OD, MBA, Clinical Coding Editor**

Most of the diagnostic technology that has been developed for eye care practices within the last decade has been in the area of "special ophthalmic tests." These tests have specific rules when performing, recording and coding them. Special ophthalmic tests are contained in a separate section of the Current Procedural Terminology (CPT) coding system, and are described as:[1]

- Services in which a special evaluation of part of the visual system is made, which go beyond those included under general ophthalmological services or in which special treatment is given.
- Special ophthalmological services may be reported in addition to the general ophthalmological service or evaluation and management services.

So, what does that mean? In reality, this means that any test that has a specific definition as a separate and distinct procedure, by virtue of having its own CPT code, is not part of the regular office visit, which is under a general ophthalmologic code (920XX) or an evaluation/management code (992XX).

For example, let's say that a patient presented with a chief complaint of distorted vision. In the course of your physical exam, you dilated the patient, looked at the macula, and noted some pigmentary changes and drusen. Based upon your physical exam, you order an OCT of the retina. You would bill the office visit with the appropriate CPT code for office visits (920XX or 992XX) and then bill the OCT (92314). Both would be billable because they represent distinct and separate components of the encounter.

Thus, these tests can be ordered and performed by the physician on the same date of service as the office visit, as long as they are performed in accordance with the National Correct Coding Initiative Edits and meet all requirements specific to your geographic location for medical necessity.

Most audit failures for special ophthalmic procedures are generated by not providing adequate or appropriate medical necessity for performing the test in the medical record. In other words, don't perform the test simply because you want to do it or are just establishing a baseline.

More on Modifiers

Special ophthalmic codes are composed of two separate and distinct components: professional and technical. If you perform both the technical and professional components in your practice, you don't separate the code into the individual components, but report the code in its entirety. The two modifiers that separate a code are:

- ***-26 for Professional Component.*** Certain procedures are a combination of a physician professional component and a technical component. When the physician component is reported separately, identify this service by adding modifier -26.[2]
- ***-TC for Technical Component.*** When the equipment or technician performs the test, this is identified by adding modifier "TC" to the procedure code identified for the technical component charge.[2] Note that the technical component represents both the equipment and the staff person performing the test, so trying to bill for staff time in addi-

Clarification

Last month's column, "Get Clued in on CLIA Testing," encouraged readers to perform and be reimbursed for CLIA-waived tests in their own offices. This was not meant to imply that optometrists cannot obtain CLIA certification to perform "moderate complexity" lab tests in their offices. Although uncommon for ODs, it is possible to make your office a CLIA lab, as long as it complies with your state license.

Special Tests: Reimbursement Before and After MPPR

	CPT code 92285	CPT code 92025	Before MPPR	After MPPR
Professional Component (-26)	$3.07	$19.75	$22.82	$22.82
Technical Component (-TC)	$18.41	$18.75	$37.16	$33.48
Total	**$21.48**	**$38.50**	**$59.98**	**$56.30**
		Total reduction in this example		6%

tion to the test itself is improper and would raise a red flag.

Make Way for MPPR

Other contemporary issues surrounding these tests are being subject to the new CMS rule called the Multiple Procedure Payment Reduction (MPPR). This means that if you perform multiple special ophthalmic procedures on the same day, then full payment is made for the TC service with the highest payment under the Medicare Physician Fee Schedule. Payment is made at 80% for subsequent TC services provided by the same physician (or by multiple physicians in the same group practice, i.e., same Group NPI) to the same patient on the same day.

As you can see in the example on the opposite page, the CPT code 92025 would be paid in full and the technical component of 92285 would be paid at 80%.

This rule applies to all ophthalmic special procedure tests as well as most ophthalmic ultrasonography tests.[3]

While many of these special ophthalmic procedures are commonplace in our practices and we've been submitting them for what seems like forever, never forget that keeping up on the changes keeps you out of hot water! ■

Please send your comments to CodingAbstract@gmail.com.

'Claim/Service Lacks Information'

Does this phrase look familiar to you: "CO-16. Claim/service lacks information which is needed for adjudication"? If this appears frequently on your EOBs, then you may not be aware of new requirements for filing claims for special ophthalmic testing.

You now need to place the name and NPI of the referring physician (even if it is yourself) in box 17 of the CMS 1500 form to allow the carrier to properly process it.

Claim Adjustment Reason Codes. Washington Publishing Company, 2013. www.wpc-edi.com/reference/codelists/healthcare/claim-adjustment-reason-codes. Accessed May 20, 2103.

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From Molecule to Medicine Cabinet:

A Drug's Long Journey from Development to Approval

For every 10,000 drug compounds developed, only one will achieve FDA approval. Here's how it happens. **By Bruce E. Onofrey, OD, RPh**

Step right up, ladies and gentlemen, and buy some Hamlin's Wizard Oil! It's the "best pain remedy on Earth." As advertised, "There is no sore it will not heal! No pain it will not subdue!" Among its many benefits, it cures rheumatism, sore throat, headache, toothache, backache, as well as cramps, colic, diarrhea and cancer. (Never mind that it's made of 50 to 70% alcohol as well as camphor, ammonia, chloroform, sassafras, cloves and turpentine.)

About a century ago, Hamlin's Wizard Oil was one of the most popular patent medicines—and possibly one of the *least* harmful—of its kind. Back then, there were no requirements that a remedy prove its safety and efficacy, or even reveal its ingredients.

While our current drug approval process is by no means perfect, the US Food and Drug Administration has arguably some of the world's most rigorous procedures for determining whether a drug is safe, consistent and effective. Nowadays, we take for granted that the many pharmaceuticals we use provide a positive effect without causing harm (if taken as directed). We prescribe drugs every day, yet rarely do we consider how the drug came into existence. This article provides an inside look at this laborious but necessary process.

The Drug Approval Process

Here's a breakdown of how a drug undergoes the FDA's approval process, which takes an average of eight to 12 years. Bear in mind that the FDA itself does not test drugs; its role is to review test data and to approve or disapprove a drug to be marketed for a specific medical use.

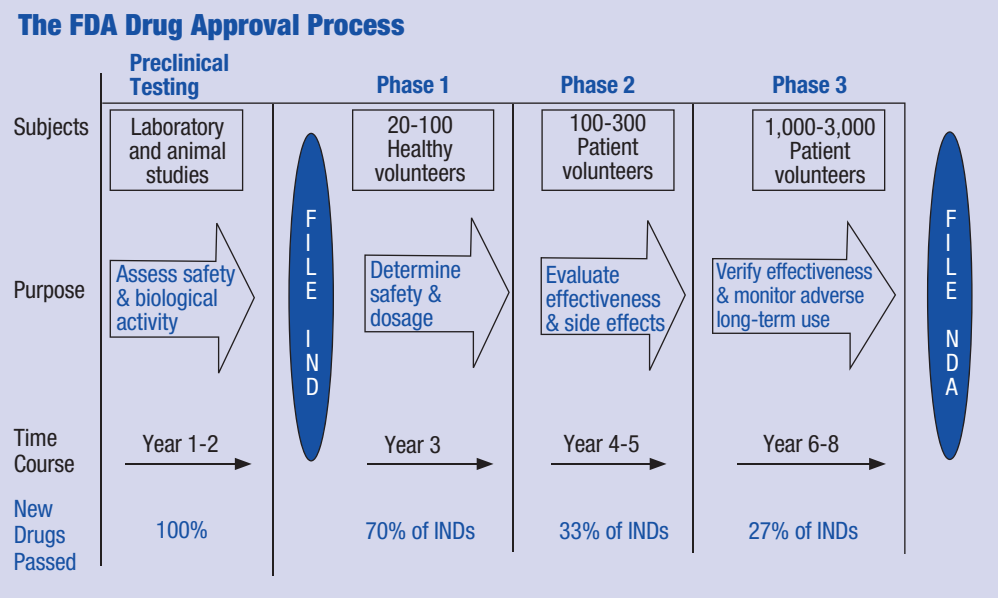
• ***Preclinical studies.*** The process begins with the identification of a unique molecule that is believed to have promise in treating human disease. Preclinical testing involves toxicology, pharmacokinetics and dosing studies conducted on animals (often rodents and dogs) to help establish dosing limits and potential adverse effects. It is critical that potential drug adverse effects are identified prior to the commencement of human testing. (*See "The FDA Drug Approval Process," opposite.*)

• ***Investigational application.*** After obtaining promising data from preclinical studies, the pharmaceutical company must first file an Investigational New Drug Application (IND) in order to begin the clinical testing on humans. The IND document is a roadmap of the proposed study. It includes

the study protocol, the relevant data from the pre-clinical studies, drug manufacturing data and, most importantly, the informed consent document and other data relevant to the recruitment of human subjects. The FDA has 30 days to review and approve the IND application.

• ***Phase I studies.*** The Phase I study examines the pharmacologic actions and safe dosage range of a drug. Two numbers are very important: Therapeutic Index (TI) and No Observable Adverse Effect Level (NOAEL). The TI is the ratio of the lethal dose in 50% of test subjects (LD50) to the effective dose in 50% of test subjects (ED50). Any ratio below 20 is considered dangerous. Because lethal doses are never used in human studies, the NOAEL is a useful analog to the TI for human trials.

Phase I studies normally recruit a small number of healthy human volunteers. Dosages start at very low levels (well below NOAEL) and are gradually increased. Blood levels are measured and bioavailability is established. Drug half-life and protein binding are measured to assist in establishing proper dosing levels and intervals for future trials. These studies are particularly focused on identifying drug side effects. To help recognize the true side effects of the test drug, Phase I studies usually include a placebo test group. Under a double-blind protocol, neither the investigator nor the subject knows if they received the placebo or active study drug.



It takes a new drug eight or more years of testing before gaining FDA approval.

• ***Phase II studies.*** Phase II studies not only help identify unsafe medications and drug side effects, but also begin to identify drug efficacy. For this reason, the selected test subjects have the condition for which the drug is intended. This means Phase II studies are true safety/efficacy trials, so this particular study can make or break a drug. By their nature, Phase II studies evaluate a small group of individuals. If efficacy and safety cannot be established at this level, then it is impossible for the drug study to proceed with a larger population of test subjects.

A critical component of a Phase II study is the establishment of a treatment dose. This includes both the amount of drug and its proper dosing interval. Dose the patient too low and the drug demonstrates no efficacy; too high and it produces unacceptable toxic side effects. One technique to establish a "best dose" is to randomize test subjects into low-, medium- and high-dose groups. This is a more efficient method of quickly identifying dosages that are unacceptably low or high. All Phase II studies are double blind, with the control group receiving a placebo dosage.

• ***Phase III.*** If Phase II studies demonstrate drug efficacy and safety, then this most expansive phase of drug testing is justified. Phase III studies involve a large number of patients who have the disease that the study drug intends to control or cure. A critical element that differentiates Phase III from Phase II studies is the dosage form. The test dose in Phase III must be in the form that is intended to be approved and marketed to the public. So, dosing information from Phase II trials is critical in designing the final dosage form.

Next in importance is the protocol of the study. Proper patient selection is critical. Investigators must establish inclusion and exclusion criteria, and carefully define the drug indication. The goals of therapy ("endpoints") must also be well delineated. Test populations and control groups need to be large enough to yield statistical relevance,

A Brief History of the FDA

At the beginning of the 20th century, there was absolutely no oversight of pharmaceutical companies' claims of drug efficacy, safety or purity of ingredients. Here's how the government has since evolved to protect the public and to hold the drug industry accountable:

• ***1906.*** The publication of Upton Sinclair's book "The Jungle," an exposé of the meatpacking industry, triggered the federal government to pass the Pure Food and Drug Act (also known as the Wiley Act). This legislation created a new federal agency: The Food, Drug and Insecticide Administration (later changed to the FDA in 1931). The Wiley Act dictated only that the ingredients in a product displayed purity—it did not require the product to be tested for safety or efficacy.

• ***1938.*** False claims of efficacy continued until an infamous incident occurred that caused the deaths of more than 100 people, mostly children. A drug company sold an anti-infective sulfanilamide elixir in a poisonous vehicle similar to ethylene glycol (the main ingredient in automotive antifreeze). Subsequently, President Roosevelt signed the Federal Food, Drug and Cosmetic Act in June 1938. The main purpose of this legislation was to force manufacturers to ensure both drug purity and safety. There still was no requirement to prove efficacy, but manufacturers were prevented from making fraudulent claims.

• ***1951.*** The Durham-Humphrey amendment specified that certain drugs could only be prescribed under medical supervision, thus separating over-the-counter agents (OTCs) from legend (i.e., prescription) drugs. Their sale is restricted to licensed prescribers.

• ***1962.*** Thousands of children in Europe were born without limbs after pregnant mothers used the sedative thalidomide. Fortunately, the use of this drug had been rejected in the United States. Nevertheless, the disaster led to the Kefauver-Harris Amendment. This required, for the first time, that pharmaceutical companies prove efficacy and safety prior to marketing a drug.

• ***1984.*** The Hatch-Waxman Act allowed competing companies to market generic versions of drugs at the end of their period of exclusivity. The law allows the sale and marketing of these generics without repeating the rigorous preclinical testing process required of new drug agents. It also extended the exclusive period for branded products to five years after initial approval.

and the groups must be matched by age, gender and other pertinent factors to ensure statistical credibility.

To improve statistical credibility in certain drug trials, multiple, parallel Phase III studies are performed. Additionally, an extension of a Phase III study may occur, with subjects continuing drug therapy under "open label" conditions, where the actual treated subjects are identified.

In addition to safety and efficacy, the Phase III studies must demonstrate, via animal studies, acceptable levels of the drug's mutagenic potential, or the tendency to induce cancer in patients who receive the drug.

At the formal completion of the Phase III trial, the data are evaluated and the safety and efficacy profile of the drug is established, as well as the initial recommended dosage amount and frequency. Drug side effects, warnings and contraindications are also established. Most importantly, the initial drug indication is identified.

• *NDA.* At the conclusion of Phase III studies (assuming these prove successful), the pharmaceutical company files a New Drug Application (NDA) with the FDA. All study information—including efficacy and safety information from drug trials, manufacturing data and pharmaceutical data—must be included in this extensive document.

• *Phase IV studies.* Following FDA approval, Phase IV studies (called post-approval or post-marketing studies) have several purposes. First, their design must mirror that of the other preclinical studies, although the rigor of design is less intense. A Phase IV study can be used to expand the indications for a drug that was approved for limited applications, or it can be a comparator study (a study intended to demonstrate clinical superiority over a competitor's product).

Generic Drugs

A drug patent in the US lasts 20 years, and during that time other manufacturers cannot produce the same agent. But once a drug has reached the end of its 20-year patented life, it can be produced and marketed by other companies, under certain circumstances, in a generic form. Just as for new, branded drugs, the FDA is also responsible for the approval of generic (or "copycat") forms of approved pharmaceutical agents.

The Drug Price Competition and Patent Term Restoration Act of 1984—more commonly known as the Hatch-Waxman Act—was designed to promote the availability of generic drugs. It accomplished this by increasing financial incentives for new drug development and by abbreviating the process of generic drug approval.

The law allows generics to obtain FDA approval by submitting bioequivalence studies (as opposed to the more costly clinical data required to approve a totally new drug), and it extends the marketing exclusivity of branded drugs by up to five years (which is in addition to the 20-year patent duration of the original molecule). This extension compensates the developer for the additional time and money required

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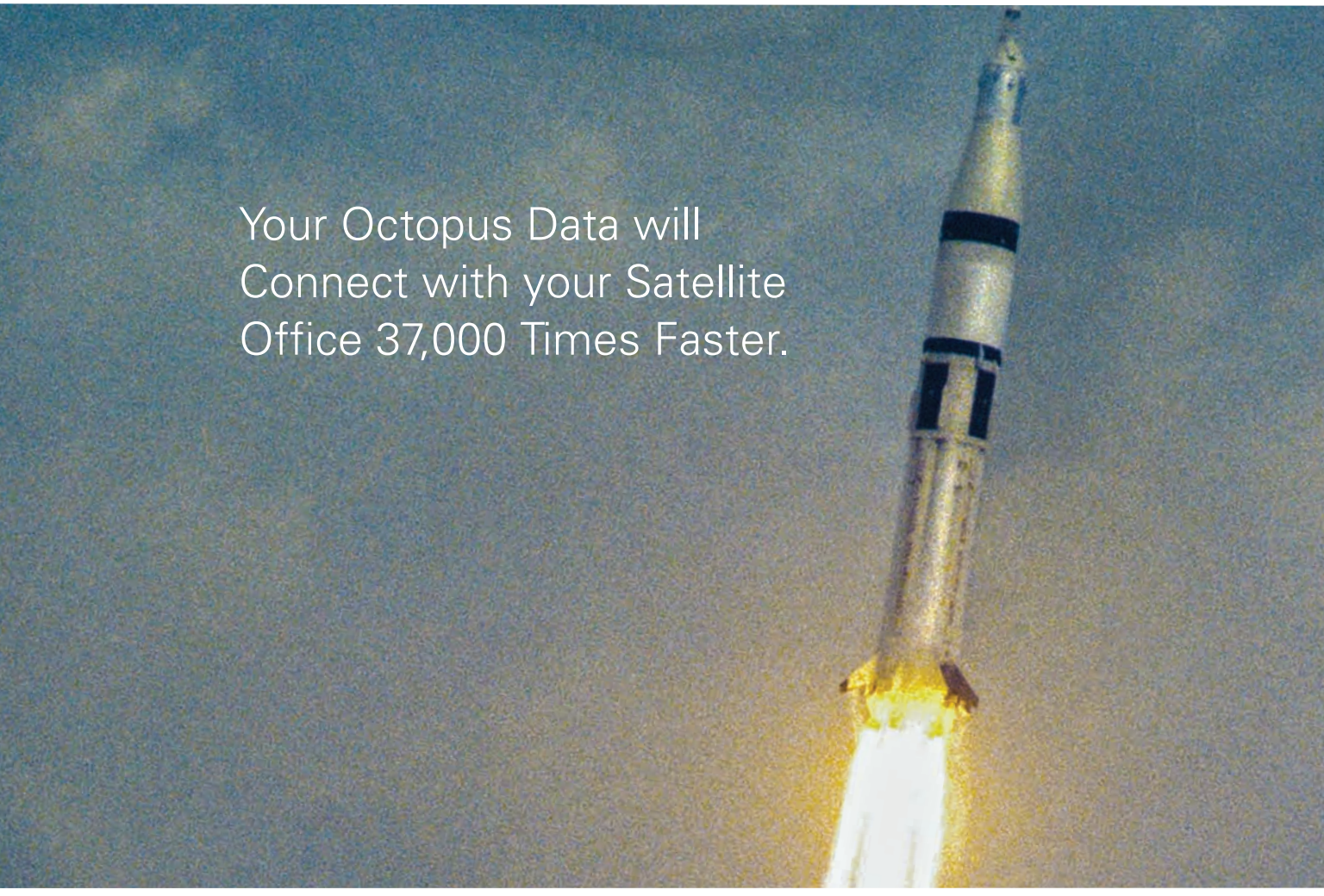

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How to Report Adverse Events

Multiple generic drug manufacturers, abbreviated testing, counterfeit drugs and the occasional idiopathic response to branded drugs require a reporting system that can rapidly identify undesirable adverse and/or toxic effects of pharmaceutical agents. MedWatch, also known as the FDA Adverse Event Reporting System (FAERS), is the program responsible for reviewing reports of serious drug reactions, quality issues, therapeutic inequivalence/failure and product use errors that result in harm to patients. This reporting process not only involves pharmaceutical agents, but also includes medical devices, dietary supplements, infant formula and cosmetics.

Practitioners and patients can report issues on the FDA website (www.fda.gov/Safety/MedWatch/HowToReport/default.htm), via a mail-in form (form FDA 3500B) or by calling 1-800-FDA-1088.

to bring a new therapeutic agent to market.

A controversial and often abused component of this law allows the original pharmaceutical company to have an automatic stay of 30 months to challenge the generic manufacturer's right to copy the branded drug. This is commonly used to stall the generic company's ability to sell a cheaper version of the drug and maintain exclusivity over the sales of the drug.

Generic Drug Equivalence

The FDA will approve a generic version of a drug following the filing of an Abbreviated New Drug Application (ANDA) if the generic version is determined to be both therapeutically and pharmaceutically equivalent. It must also demonstrate bioequivalence. The specific meanings of these terms are critical to the use of a generic agent that delivers the same therapeutic benefits as the original, branded agent.

• ***Pharmaceutical equivalence.*** This implies that the generic contains the same active ingredients, the same dosage form and strength, and the same route of administration as the original drug. According to the FDA, generic ophthalmic solutions are required to have the same active and inactive ingredients in the same concentrations.

• ***Bioequivalence.*** This term means that the drug follows the same pharmacokinetic profile as the original—its absorption, distribution, metabolism and excretion can be expected to be the same as the reference drug. This implies that the drug reaches the same blood levels and half-life (bioavailability) of the original drug.

However, topical (locally-applied) agents—including ophthalmic, otic (ear) and parenteral (injectable) solutions—do not have to meet this requirement. Generic manufacturers can request a waiver of bioequivalence for topical products.

The Hatch-Waxman Act provides an incentive to generic drug manufacturers to be the first to file an ANDA. The first company to file a successful ANDA is allowed to exclusively market the new generic drug for 180 days. This advantage has led to a new class of generic drug—the "authorized" generic. This is a practice whereby the original drug manufacturer agrees to license the drug to a specific generic manufacturer, thereby retaining some control of the drug and profits derived from the sale of the generic form.

Drug Withdrawals and Recalls

Believe it or not, once the FDA approves a drug, it cannot withdraw it from the market. The FDA must negotiate with the manufacturer to voluntarily remove the pharmaceutical agent in question.

One of the most recent and important withdrawal actions was against the blockbuster NSAID Vioxx (rofecoxib, Merck). After Vioxx was approved and became widely used for its analgesic and anti-inflammatory benefits, the incidence of cardiovascular complications dramatically increased in patients who used it. At the request of the FDA, Merck withdrew the drug.

The sister drug of Vioxx, Celebrex (celecoxib, Pfizer), was allowed to stay on the market only after its manufacturer dramatically altered the package insert with a "black box" warning. This warning requires the patient to be counseled about a drug's serious side effects and requires that the physician obtain the patient's informed consent to use the drug.

Patients do not select their own treatments. They depend upon and trust that their physicians will prescribe drug therapies that are both safe and effective; that is, drug treatments that have the potential to produce greater benefits than risks. So, it's important that clinicians understand how the FDA functions to protect patients from medications that can produce significant harm. It is equally important that prescribers understand FDA reporting mechanisms to bring adverse drug effects to the FDA's attention. ■

Dr. Onofrey is a clinical professor and the executive director of CE programs at the University of Houston College of Optometry, and a frequent lecturer on ocular disease management and pharmaceutical agents.

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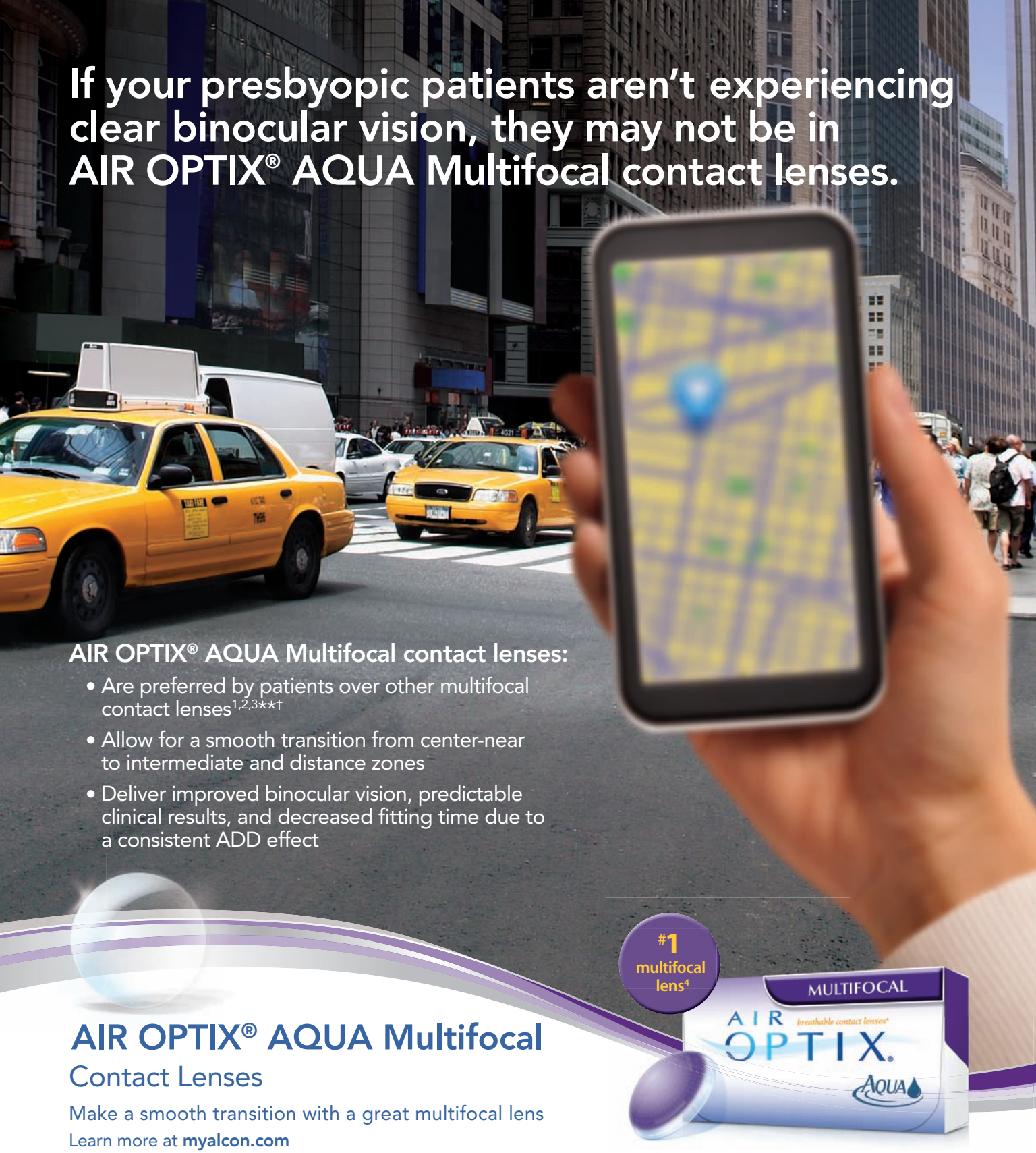

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References: 1. In a randomized, subject-masked clinical study at 20 sites with 252 patients; significance demonstrated at the 0.05 level; Alcon data on file, 2009. **2.** Rappon J. Center-near multifocal innovation: optical and material enhancements lead to more satisfied presbyopic patients. *Optom Vis Sci.* 2009;86:E-abstract 095557. **3.** In a randomized, subject-masked clinical trial at 6 sites with 47 patients; significance demonstrated at the 0.05 level; Alcon data on file, 2008. **4.** Based on a third-party industry report, 12 months ending October 2012; Alcon data on file.

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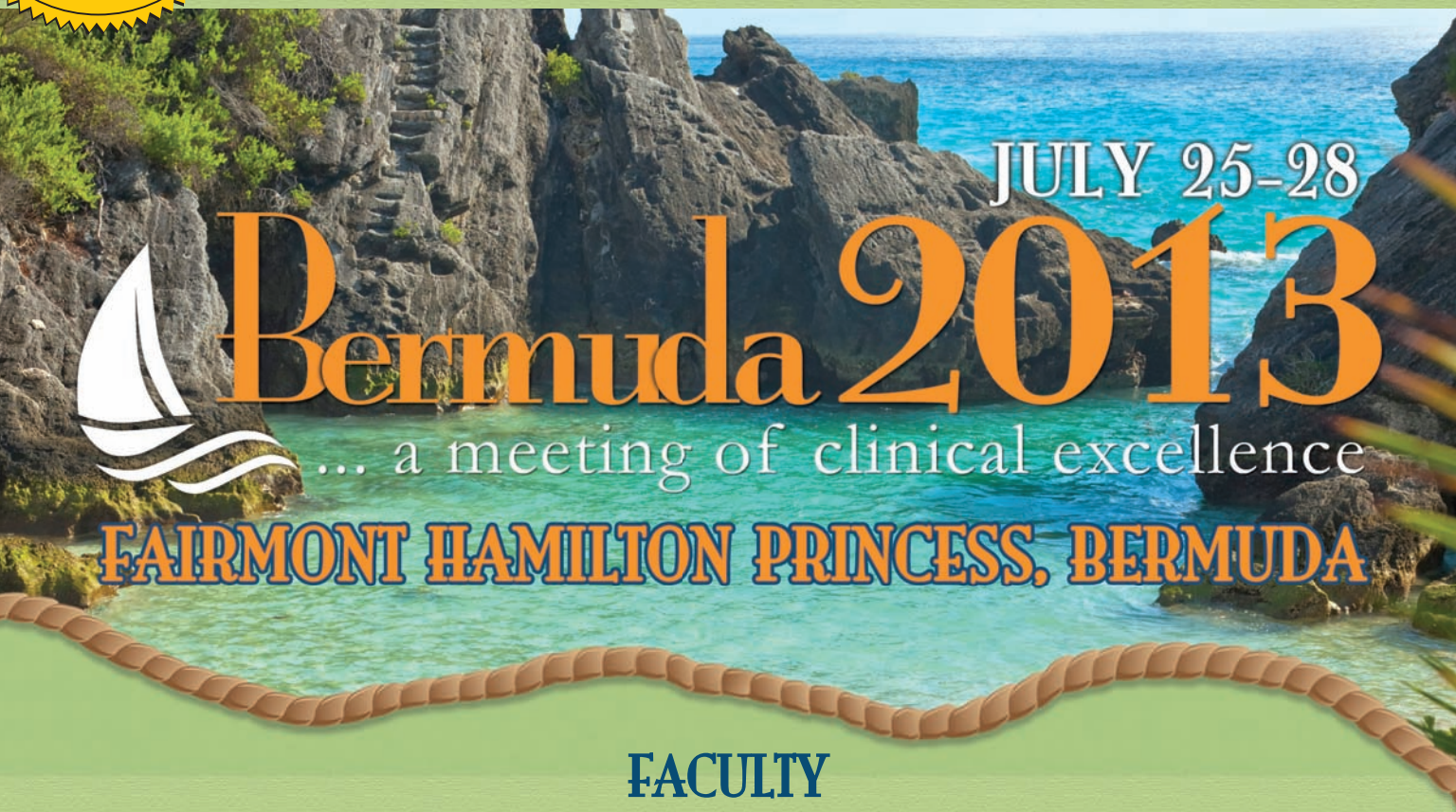

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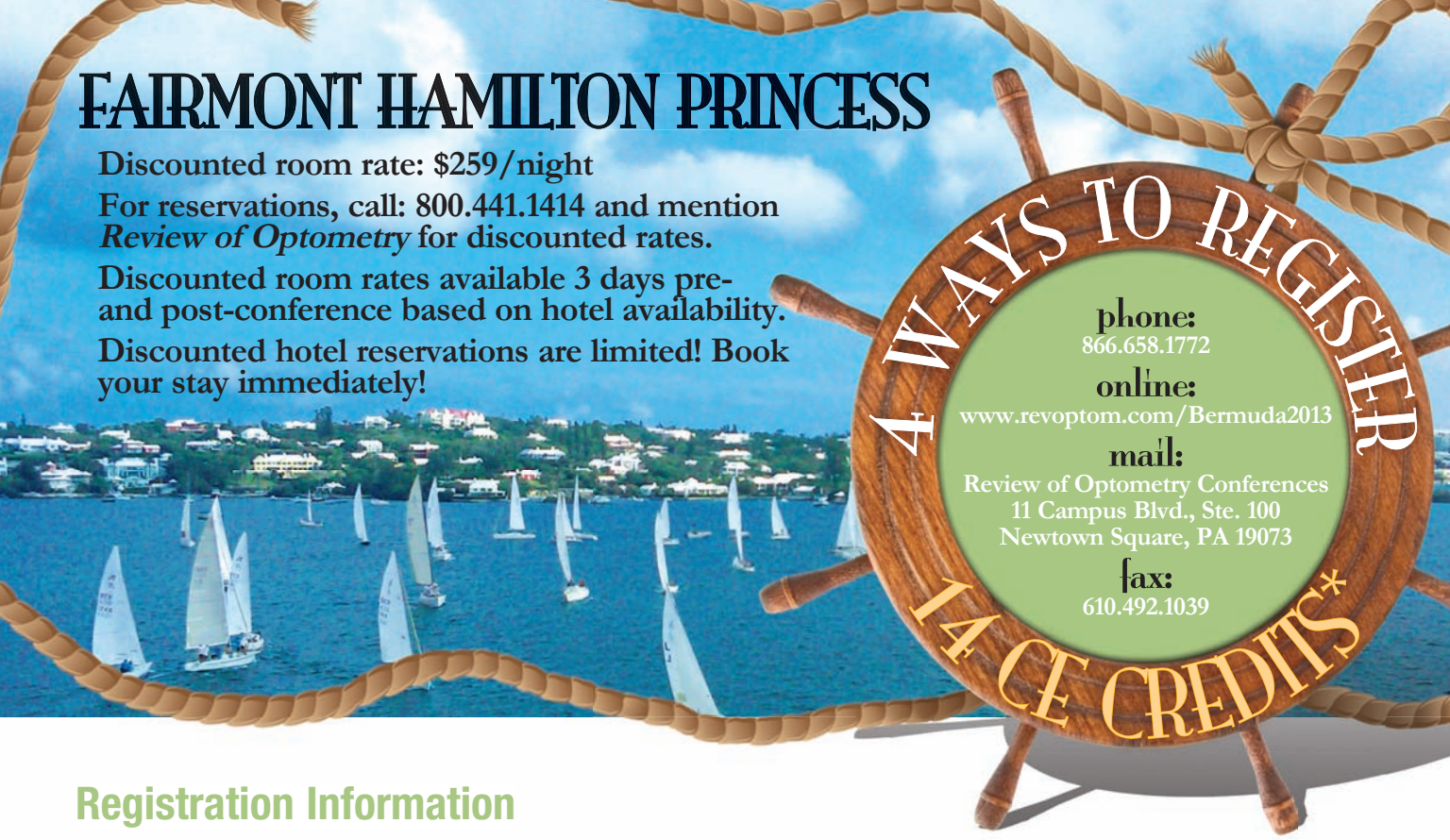

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The Pulse on e-Prescribing in Optometry

E-prescribing isn't novel anymore, but it's not an established standard in optometry practices yet either. How is eRx working for the average OD?

By Colleen Mullarkey, Senior Editor/Web Editor

Just as optometrist John Warren and his family had settled into their front-row seats at the Kennedy Center in Washington, DC, he received a phone call from a frantic patient back in Racine, Wis., with a nasty eyelid infection. With just 15 minutes to go before the curtains opened for Rumpelstiltskin, he got the details from the patient and logged onto his e-prescribing system from his iPhone.

As the lights began to dim, the eRx was on its way to the patient's local pharmacy. "It's just amazing. E-prescribing allows me to meet my patients' needs—even when I'm hundreds of miles away," says Dr. Warren, who made the switch to eRx about three years ago. "Coming from the old paper Rx pad, it certainly saves you some hassles."

With each year that passes, more providers are putting down their pen and pad in favor of the click of a button. More than 380,000 office-based US physicians were e-prescribing by the end of 2012, and nearly half (44%) of all prescriptions dispensed last year were routed electronically, according to Surescripts, the nation's largest e-prescribing network.[1]

"It's a sign of the times and the general shift toward technology and mobile devices/communications," says Carmen Catizone, MS, RPh, DPh, executive director of the National Association of Boards of Pharmacy. "It seems to be happening across the board in health care, as we trend towards electronic medical records and identify ways to reduce prescription errors caused by illegible handwriting and miscommunications."

Less Time in the Pharmacy Line

In addition to cutting down on prescription errors, e-prescribing saves time for many ODs and improves convenience for both them and their patients. "From a patient perspective, they don't have to go to a pharmacy, wait for the prescription to be filled, and then pick it up," says Mile Brujic, OD, a partner of Premier Vision Group, a four-location optometric practice in northwest Ohio. "This whole process starts before they even step out of our office."

Make sure that your patient has realistic expectations, though. As Dr. Brujic's wife, a pharmacist, likes to remind him, the Rx still goes into a queue at the pharmacy the same way a paper script would. "At this point I educate people on it, just because I sent it through doesn't mean it will get filled immediately," he laughs. But it's still likely to be much faster.

With 788 million prescriptions routed electronically last year—a 38% increase from 570 million in 2011, more patients are enjoying the benefits of e-prescribing.[1] It means less paper for them to tote around, including discount cards from manufacturers. "Right now, a lot of companies have their drug reps hand you some coupons to give to your patients to cap their copay or out-of-pocket expense," Dr. Warren says. But how often do you or the patient forget to grab that little sheet of paper? Some manufacturers have those discounts set up to send electronically when a doctor prescribes one of the applicable drugs. When the patient gets to the pharmacy, the discount has already been applied.

Why eRx?

National e-prescribing lecturer Jay W. Henry, OD, MS, who founded ehrguru.net, says some of the big reasons to e-prescribe include:

- Error reduction.
- Formulary checking (to lower patient costs).
- Time savings for doctor and patient.
- Simplified refill process.
- Protection of patient privacy (certified systems are HIPAA-compliant and you don't have to worry about someone in the room seeing the written Rx).
- Forgery protection—you don't need to have Rx pads in the exam rooms.
- Reduction of drug-drug duplication errors.
- Automatic drug allergy checking.
- Automatic drug-drug interaction checking.

More than 380,000 office-based US physicians were e-prescribing by the end of 2012, and nearly half (44%) of all prescriptions dispensed last year were routed electronically.

You'll spend a lot less time on the phone with the pharmacy, too. "Undoubtedly it improves accuracy for me and saves follow-up calls—is that Tobrex or Tobradex?" Dr. Warren says. "There's a lot less confusion about the drugs and the dosing." And instead of having to field faxes or phone calls for prescription refills, you'll receive those electronically as well, which allows you to respond more quickly and easily monitor the status.

Watch Where You're Clicking

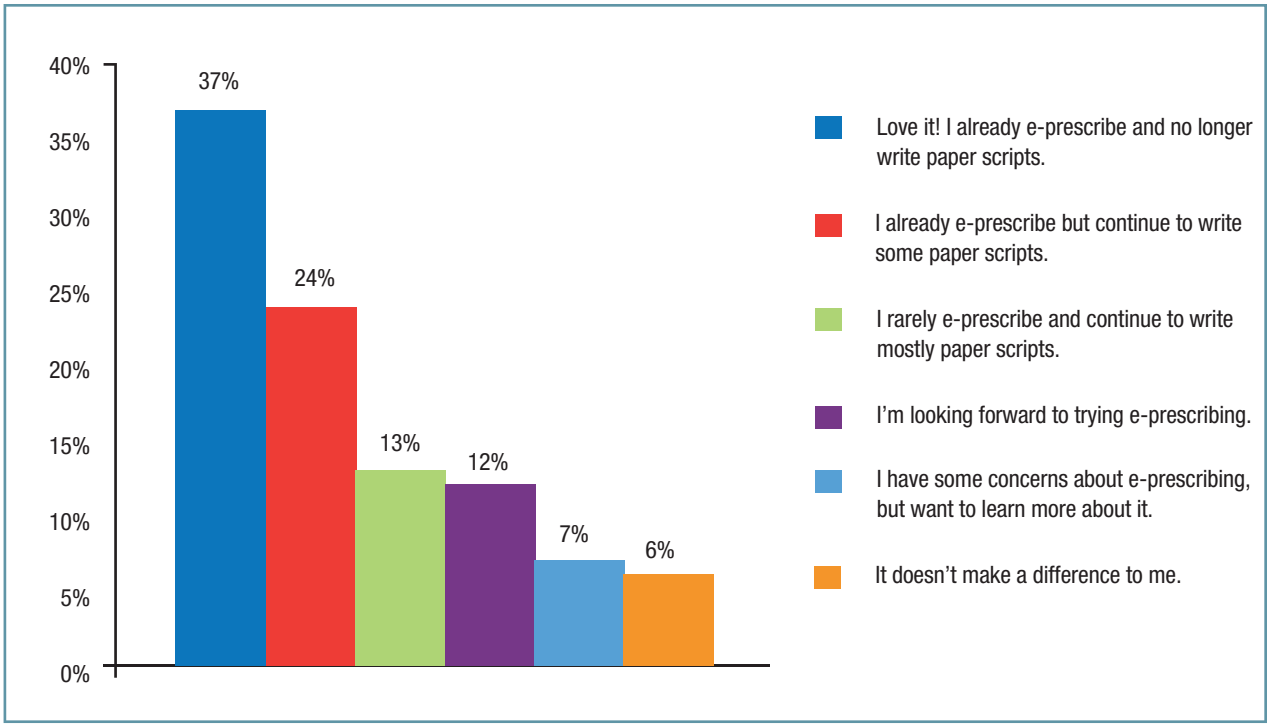
While this convenience has significant benefits, it also can be easy to make a mistake. With 93% of community pharmacies able to accept e-prescribing, the jam-packed, drop-down menu of pharmacies can blur together.[1] Dr. Brujic recalls clicking on Wal*greens* instead of Wal*mart* a couple times. "Now the patient is at Walmart asking about the prescription, and Walgreens is calling our office saying we have this prescription from your office and no information on this patient," he says. "It's an easy fix, just a matter of rerouting the eRx, but it's a little inconvenient for the patient."

But, sometimes drop-down mishaps can have much more serious consequences. "The drop-down menus can limit choices available to the doctor and have been shown to result in prescribing errors from doctors selecting the wrong drug," Dr. Catizone says. With such a quick and easy system, it's important to take your time and make sure that click of a button is the right one.

As long as you're vigilant, these limited choice may actually increase

How Do You Feel About E-Prescribing in Your Practice?

In a *Review of Optometry* online poll, we asked our readers how they feel about implementing e-prescribing in their practices. The majority of the 500 respondents report already using eRx, while most of the paper-and-pad users expressed an interest in trying electronic prescribing and learning more about it.



accuracy and decrease follow-up from the pharmacy. "[The system] keeps you from selecting drugs that just aren't available in certain dosages," Dr. Warren says. "If a drug only comes in 250mg tablets, it only lets you choose 250mg tablets from the drop-down menu."

When you create a prescription in an eRx system, it automatically checks for known drug allergies and drug-to-drug interactions, and raises a red flag if you select a drug that could create a potential problem. "In primary eye care, there's very little we're going to give a patient that's going to kill them if they're taking something else," Dr. Warren says. "If you're an internist treating hypertension, that's another story. So for me, the biggest benefit of e-prescribing is the formulary checking."

In the old days, you might write a paper prescription, give it to the patient and then 20 minutes to two days later, you get a call from a patient saying, "I can't afford a $150 drug." Then you have to make multiple calls back and forth with the pharmacist, trying to find a suitable drug that is covered. Unfortunately, this scenario could play out quite a few times before you find a good fit—and by that point, everyone's time and patience may be running out.

Today, with more optometrists e-prescribing, this type of situation is much less prevalent. "With eRx systems, at the point of creating the Rx, the system will tell you if the drug is on the formulary or not," says Jay W. Henry, OD, MS, the first optometrist in the country to e-prescribe and a partner at Hermann & Henry Eyecare, in Pickerington, Ohio. "If it is not, it will automatically offer you other drug options in the same classification that are covered, allowing you to select a covered medication at that time, saving everyone time and money."

On the other hand, if the more expensive drug is the best option, it allows you to talk with the patient and explain that the price tag may be a little higher but it's the best option for their health.

A Matter of Cost and Convenience

Like a lot of technology today, e-prescribing may come at a price—specifically, a price of about $600

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to $650 per year for most EHR-integrated eRx systems. "I didn't think it would be worth the price tag at first, but it saves me plenty of time in the exam room and improves the patient experience enough, that I consider it money well spent," Dr. Warren says. "My average patient age is about 59 to 60, and over half of my visits are medically related—so, in my case, it's really a no-brainer."

But that's not necessarily the case for every optometry practice. When deciding what type of eRx system, if any, is worth the investment for your office, look at your prescribing patterns. If, for example, you have a pediatric practice that does mostly vision therapy and writes one prescription a week, it's probably not something that makes sense practically or financially.

If you want to dip your toe in the water, you might want to try a free standalone system online first. Usually you won't a pay for these systems—but they will cost you some convenience. Before making the switch to EHR-based e-prescribing, Dr. Brujic's practice used a free, online standalone program. "The e-prescribing was a separate island, and it was a little bit cumbersome to use," he says. And because a standalone system wouldn't automatically communicate with any of your other systems, you'll need to re-enter all of the prescription information into your EHR or paper chart.

"Transitioning between the systems (with a standalone program) is a challenge and may rely on memory or the jotting of notes rather than having all of the needed information available for review when prescribing the appropriate medications," Dr. Catizone says. "The integrated systems offer significant advantages and increased patient safety—besides the workflow considerations, there is the ability to consider all of the patient factors at the time of prescribing instead of closing one system and then accessing another system to e-prescribe." It's no surprise then that a whopping 87% of prescribers are e-prescribing using an EHR as opposed to a standalone system.[1]

With an integrated system—where an eRx module is built into an EHR—you typically pay an annual fee to use it, but that investment will likely save you some time and hassle. It saves a lot of data entry because you can just select eRx when you are in the patient's encounter. It will already have your basic information and the patient's, so you select a pharmacy and drug, then send it and sign off. "When you sign off, the integrated system will download the prescription you just wrote into your EHR, saving all the double entry and reducing errors," Dr. Henry explains. "The process is significantly easier."

So if e-prescribing works this well, why aren't 100% of doctors using it? Well, they're getting there—currently more than two out of three office-based physicians are e-prescribing, but there are still a few docs dragging their heels.[1] "For some, the barrier to adoption is change. None of us like change, but once we get used to a new system and a new workflow, we are fine," Dr. Henry says. "I have been e-prescribing for a long time now, and the process is so much easier for me than handwriting or calling a pharmacy. I can't imagine doing it any other way." ■

1. Surescripts. National Progress Report on E-Prescribing and Safe-Rx Rankings Year 2012. Available at: www.surescripts.com/about-e-prescribing/progress-reports/national-progress-reports. Accessed May 30, 2013.

How Does eRx Fit into the CMS Puzzle?

By Jay W. Henry, OD, MS

E-prescribing is a core objective of meaningful use—that means, to meet meaningful use as defined by the Centers for Medicare & Medicaid Services Incentive Programs, you must use eRx.

- For stage 1, you must eRx more than 40% of permissible prescriptions written. You can be exempt from this requirement if you write fewer than 100 prescriptions during the meaningful use reporting period, or if you do not have a pharmacy within your organization and there are no pharmacies that accept electronic prescriptions within 10 miles of your practice location at the start of your EHR reporting period.
- For stage 2, more than 50% of prescriptions must be compared to a drug formulary and transmitted electronically. Again, you can gain exemption if you write fewer than 100 prescriptions during the meaningful use reporting period, or if you do not have a pharmacy within your organization and there are no pharmacies that accept electronic prescriptions within 10 miles of your practice location at the start of your EHR reporting period.

In addition, the eRx incentive program by CMS in 2013 will give a 0.5% incentive to doctors. This translates to a 0.5% bonus on all your allowable Medicare billings for the year. In order to qualify, you must be a successful e-prescriber, which means submitting 25 eRx prescriptions to Medicare patients when they also have an office visit over the year, and then submitting the CPT II code G8553 on the CMS 1500 claim form upon billing to notify CMS that you did eRx.

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Eye on Stroke Prevention

Many of our patients at risk for stroke don't know the first signs of it. Primary care optometrists can detect, and even help patients avoid, a stroke. **By Edward Chu, OD**

The third leading cause of death and the primary cause of adult disability and hospital admissions in the United States, stroke is a serious health concern that should be high on our watch list—whether we're seeing a patient for a medical visit or a routine eye exam. If a patient comes in with transient monocular vision loss, binocular vision loss, homonymous hemianopsia or acute diplopia, we need to recognize that they could be suffering from a transient ischemic attack (TIA) or stroke, and act promptly.

Irreversible tissue injury and death can occur within three hours of a stroke, so time is of the essence in getting these patients the urgent attention they need in a hospital setting.

Better yet, we need to talk to our patients about stroke *before* we reach this point. As primary eye care providers, are we educating our patients appropriately and adequately regarding stroke risk and its signs and symptoms? Let's take a look at some of the warning signs that we should be relaying to our patients, as well as how stroke correlates to the eye specifically.

Blood Flow, Interrupted

A stroke (more formally called a cerebrovascular accident, or CVA) is caused by an interruption in blood flow through the brain. Ischemic strokes, which account for approximately 87% of cases, occur when a blood vessel is obstructed by a blood clot or embolus that came from a different location.[1] Typical treatment involves a tissue plasminogen activator (TPA)—a "clot buster."

Hemorrhagic strokes, on the other hand, usually stem from a rupture of a weakened blood vessel, such as with an aneurysm or arterial-venous malformation. The leaked blood compresses adjacent areas and tissue, and can lead to a painful headache, nausea and vomiting. (These symptoms can occur with an ischemic stroke, but are more likely to present with a hemorrhagic stroke.)

The scary fact is patients who suffer from a stroke often do not recognize that they are having a stroke, nor do they seek treatment or medical attention in a timely fashion. According to one study, only 22% of stroke victims who called for an ambulance recognized

Act FAST When You See Symptoms

If you suspect your patient is showing signs of a possible stroke or transient ischemic attack, this quick and easy-to-remember acronym can provide you with the questions to ask that can determine if they need immediate help.

- **F**ace. Ask the patient to smile. Does one side of the face droop?
- **A**rms. Ask the patient to raise both arms. Does one arm drift downward?
- **S**peech. Ask the patient to repeat a simple phrase. Do you notice any slurring or strange qualities?
- **T**ime. If you see any of the signs above, call 9-1-1 immediately. Prompt attention could prevent permanent damage or save your patient's life.

Adapted from the National Stroke Association: www.stroke.org.

For the reduction of IOP in patients with POAG or OHTN

When it's important to consider ocular and systemic side effects...

An alternate route to IOP reduction

- Effective at lowering IOP throughout the day and over the long term[1-3]
- Excellent systemic safety profile including no deleterious effects on CV or pulmonary function in clinical studies[1]
- Established ocular side effects profile: In clinical trials comparing RESCULA and timolol,* both were generally well tolerated regarding ocular adverse events, with similar incidence of hyperemia and similar changes to eyelash length and density[1,4,5]
  - The only events seen significantly more often with RESCULA than with timolol were burning and stinging and burning/stinging upon instillation; these events were generally mild and transient[2,4]
- No labeled drug-drug interactions[1,4]

Indication

RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Important Safety Information

RESCULA is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

RESCULA has been reported to increase pigmentation of the iris, periorbital tissues, and eyelashes. Patients should be advised about the potential for increased brown iris pigmentation which is likely to be permanent.

RESCULA should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular edema, including cystoid macular edema, has been reported. RESCULA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

*In pooled safety analyses of pivotal trials comparing RESCULA with timolol maleate 0.5%.[4]

Please see Brief Summary on reverse and full Prescribing Information, available from your Sucampo representative.

Rescula®
(Unoprostone isopropyl
ophthalmic solution) 0.15%

Brief Summary of Prescribing Information for RESCULA.

INDICATIONS AND USAGE
Rescula (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION
The recommended dosage is one drop in the affected eye(s) twice daily.

Rescula may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If two drugs are used, they should be administered at least five (5) minutes apart.

CONTRAINDICATIONS
Rescula is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

WARNINGS AND PRECAUTIONS
Iris Pigmentation
Unoprostone isopropyl ophthalmic solution may gradually increase the pigmentation of the iris. The pigmentation change is believed to be due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. The long term effects of increased pigmentation are not known. Iris color changes seen with administration of unoprostone isopropyl ophthalmic solution may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. Treatment with Rescula solution can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula should be informed of the possibility of increased pigmentation.

Lid Pigmentation
Unoprostone isopropyl has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as unoprostone isopropyl is administered, but has been reported to be reversible upon discontinuation of unoprostone isopropyl ophthalmic solution in most patients.

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

Macular Edema
Macular edema, including cystoid macular edema, has been reported. Rescula should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Contamination of Tip and Solution
To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses
Rescula contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

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

In clinical studies, the most common ocular adverse reactions with use of Rescula were burning/stinging, burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes, and injection. These were reported in approximately 10–25% of patients. Approximately 10–14% of patients were observed to have an increase in the length of eyelashes (≥ 1 mm) at 12 months, while 7% of patients were observed to have a decrease in the length of eyelashes.

Ocular adverse reactions occurring in approximately 5–10% of patients were abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder.

Ocular adverse reactions occurring in approximately 1–5% of patients were blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.

The most frequently reported nonocular adverse reaction associated with the use of Rescula in the clinical trials was flu-like syndrome that was observed in approximately 6% of patients. Nonocular adverse reactions reported in the 1–5% of patients were accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis.

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

Voluntary reports of adverse reactions occurring with the use of Rescula include corneal erosion.

There have been rare spontaneous reports with a different formulation of unoprostone isopropyl (0.12%) of chemosis, dry mouth, nausea, vomiting and palpitations.

USE IN SPECIFIC POPULATIONS
Pregnancy Category C - There are no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, RESCULA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use - the safety and efficacy of RESCULA in pediatric patients have not been established.

It is not known whether RESCULA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RESCULA is administered to a nursing woman.

No overall differences in safety or effectiveness of RESCULA have been observed between elderly and other adult populations.

CLINICAL PHARMACOLOGY
Mechanism of Action
Rescula is believed to reduce elevated intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork. Unoprostone isopropyl (UI) may have a local effect on BK (Big Potassium) channels and CIC-2 chloride channels, but the exact mechanism is unknown at this time.

STORAGE AND HANDLING
Store between 2°–25°C (36°–77°F).

For more detailed information please read the Prescribing Information.

Marketed by:

Sucampo Pharma Americas, LLC
Bethesda, MD 20814

Revised 01/2013

References: **1.** RESCULA [package insert]. Bethesda, MD: Sucampo Pharmaceuticals, Inc; 2012. **2.** Data on file. CSR C97-UIOS-004. Sucampo Pharmaceuticals, Inc. **3.** Data on file. CSR C97-UIOS-005. Sucampo Pharmaceuticals, Inc. **4.** Data on file. Integrated summary of clinical safety. Sucampo Pharmaceuticals, Inc. **5.** McCarey BE, Kapik BM, Kane FE; Unoprostone Monotherapy Study Group. Low incidence of iris pigmentation and eyelash changes in 2 randomized clinical trials with unoprostone isopropyl 0.15%. *Ophthalmology.* 2004;111(8):1480-1488.

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the problem was a stroke and called within one hour of symptom onset.[2]

This is why it's crucial to educate patients about the common clinical symptoms of stroke, including:

- Weakness or paralysis on one side of the body (face, arm, leg).
- Slurred speech.
- Confusion.
- Loss of balance.
- Tingling, burning or numbness of the skin.
- Headache.
- Vision loss.

Risk factors for stroke include, but are not limited to, family history, age (>55 years), race (African Americans have the highest risk), sex (male), hypertension, diabetes, high cholesterol, cigarette smoking, cardiovascular disease, obesity, sleep apnea, atrial fibrillation and giant cell arteritis. So it's particularly important to talk with patients who fall within one or more of those categories.

In addition, one of the most important risk factors for a stroke is a transient ischemic attack (TIA) or mini-stroke. (*See "'Mini-strokes' Are a Significant Warning Sign."*)

Evidence shows education does make a difference. Survey participants reported that the knowledge that stroke is serious and treatable is what prompted them to call 9-1-1 and get help.[2,3]

Transient Monocular Vision Loss

Several studies have identified transient monocular vision loss (TMVL) as the single greatest predictor of hemodynamically significant stenosis on a carotid ultrasound.[4-6] Any time that a patient reports TMVL, consider the possibility that carotid artery disease is responsible. Patients tend to report painless total or sectoral loss of vision lasting from a few seconds to a few hours, which resolves completely. During an eye exam, you may find an explanation for the transient vision loss; however, the patient's ocular health may also be unremarkable.

In any case of TMVL, consider the patient's overall health and order a carotid ultrasound to evaluate the patient for significant blockage. Perhaps even more important, while the patient is still in the exam chair, it is our responsibility as primary eye care providers to ask pertinent questions to rule out a possible TIA. (*See "Act FAST When You See Symptoms," page 40.*) Because symptoms of TIA mirror those of stroke, it is also possible that these questions may help you diagnose an acute stroke.

The difficult part in this triage process is determining whether the patient needs to go to the emergency room immediately or if he or she can schedule an appointment with their primary care provider in a few days.

You don't want to unnecessarily worry your patients, but you also don't want to mismanage a patient and risk permanent neurologic damage.

Carotid Artery Disease

Many eye findings that worry optometrists about stroke risk often relate to the carotid artery—either as a source of plaque (retinal emboli, artery occlusion) or as a result of significant carotid artery blockage (venous stasis retinopathy, TMVL). Carotid artery stenosis is a major cause of morbidity and mortality, and the eye may be the first place it manifests.

While TMVL is a symptom that may prompt a patient to seek medical care, venous stasis retinopathy (VSR) may not have any significant symptoms and routine eye exams are crucial for its detection.

Venous stasis retinopathy is caused by prolonged ischemia secondary to internal carotid artery stenosis. Unlike ocular ischemic syndrome, venous stasis retinopathy only has posterior segment involvement. Some of the common signs include dilation of retinal veins, mid-peripheral dot-and-blot hemorrhages, venous beading,

'Mini-strokes' Are a Significant Warning Sign

Similar to a stroke, a transient ischemic attack (TIA), commonly called a "mini-stroke," requires urgent evaluation because the symptoms are indistinguishable from a stroke. Unlike stroke, TIA is only a temporary disruption in blood flow and causes no permanent damage to the patient. However, according to one study, the probability of suffering a stroke following a TIA is approximately 29.3% for the first five years, so preventive measures need to be taken to decrease the potential for a future ischemic event.[27] The EXPRESS study found that starting proven medications and therapies within 24 hours of symptom onset reduces the risk of having a stroke within three months by 80%.[28]

It's also important to note that there's poor recognition of the term "TIA" among the general public. In a telephone survey of more than 10,000 adults conducted by the National Stroke Association, only 8.2% of those polled knew the definition of a TIA and only 8.6% could identify a typical symptom. The population at greatest risk—the elderly—were the least knowledgeable regarding TIA and its symptoms.[29]

Another telephone survey of TIA patients found that 44.4% delayed medical attention more than 24 hours and, of those who knew they were having a TIA, only 42.2% sought medical attention on an urgent basis (within one hour of onset).[30]

flame hemorrhages and microaneurysms. In a study of 110 patients with symptomatic carotid artery occlusion, 100% had mid-peripheral hemorrhages, so this is a finding that has to be present to make this diagnosis.[7]

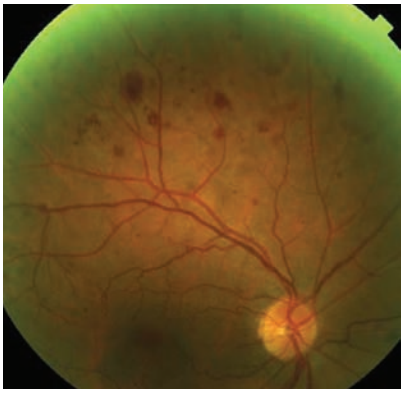
When hemorrhages are seen outside the posterior pole, carotid artery disease should be considered as a potential underlying cause. Specifically, the study found that 69% of patients with VSR had between one to five mid-peripheral hemorrhages per quadrant.[7] Thus, from a management standpoint, these are individuals who should have a carotid ultrasound ordered to detect hemodynamically significant stenosis and educated regarding stroke risk.

Ocular ischemic syndrome (OIS) is similar to VSR, except the anterior segment is also affected by carotid artery blockage and severe chronic panocular vascular compromise. Because of its direct link to carotid stenosis, individuals with OIS are at risk for TMVL and TIA or may have already suffered a previous episode.[8] The OIS triad of findings includes mid-peripheral hemorrhages, dilated retinal veins and iris neovascularization. In one study, 67% of OIS patients presented at their initial examination with neovascularization of the iris.[9]

Individuals with OIS can experience progressive vision loss from macular edema and/or ischemia as well as complications from neovascularization of the disc, retina, iris and angle. In particular, OIS patients are at high risk for neovascular glaucoma.

One study found that 35% of patients have neovascularization of the iris and IOP greater than 22mm Hg at presentation.[10] In addition to iris and angle neovascularization, anterior segment involvement in OIS patients may include corneal edema, anterior uveitis and conjunctival injection.

In one study, the five-year mortality rate of patients with OIS was found to be 40% compared to 11% of controls.[8] Specifically, 63% died of cardiac disease while 19% died from stroke.[8] These study results suggest that individuals with OIS would benefit from education about the signs of stroke as well the urgency with which it needs to be addressed.



1. Mid-peripheral hemorrhages, as seen here, may be a sign of carotid artery disease and may prompt further testing.

In addition to educating patients regarding stroke, eye findings consistent with carotid artery disease should also prompt you to order a carotid ultrasound to evaluate for hemodynamically significant stenosis (*figure 1*). Typically, a 60% to 70% blockage may necessitate a vascular consult to see if the patient is a good candidate for carotid artery surgery. If a patient is not found to have significant carotid artery blockage, but is symptomatic for TMVL or TIA, consider a consult sooner.

Retinal Emboli

Retinal emboli are another risk factor for stroke that requires proper education and work-up in our patients. Emboli can be asymptomatic, but can also cause more severe visual sequelae in cases of retinal artery occlusion. Most emboli are either cholesterol, calcific or fibrino-platelet in nature, with the majority being of cholesterol composition. You should order proper imaging to evaluate the carotid artery and the heart as the source of the retinal emboli. One study found that there was an abnormal echocardiogram in 62% of central retinal artery occlusions (CRAO) and 44% of branch retinal artery occlusions (BRAO).[11] Similarly, there was plaque present on carotid doppler in 71% of CRAOs and 66% of BRAOs.[11]

Cholesterol or Hollenhorst plaques tend to be refractile, yellow or white in color, round in shape, and found at a retinal arterial bifurcation. They originate in the carotid arteries and tend to be transient in nature. In the Beaver Dam Eye Study, 90% of them disappeared over a five-year period.[12] In addition, cholesterol plaques tend to be associated with TMVL rather than permanent vision loss.[13]

Dr. Robert Hollenhorst, in his landmark study on cholesterol plaques, found that 15% of patients who had the plaques died within one year, 29% died by year three and 54% died within seven years.[14] In addition, more than one-third of patients developed stroke or suffered from TIA during the study follow-up.[14] Fortunately, medications and treatments have improved since 1966, but the study still shows that cholesterol plaques are a sign of an unhealthy cardiovascular system and increase the risk for stroke.

Calcific emboli tend to originate from damaged heart valves. Specifically, calcific aortic stenosis and mitral/aortic valve disease can lead

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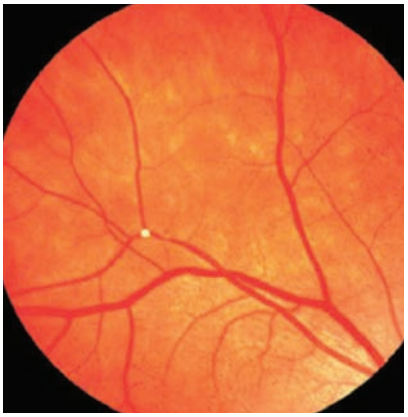
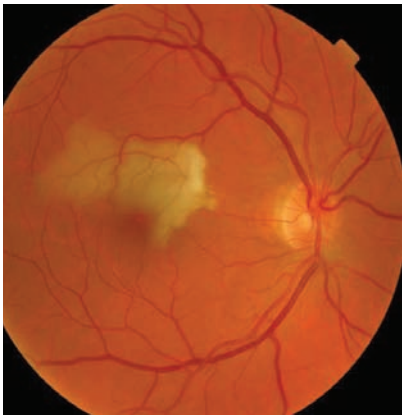


2. In the Beaver Dam Eye Study, the presence of retinal emboli was shown to be associated with a threefold greater risk of fatal stroke over eight years.[18]



3. A study in Taiwan found retinal arterial occlusions increase risk of subsequent stroke, particularly within the first six months following the occlusion.[16]

to the flat, white, non-refractile emboli we see in the eye. These emboli tend to become lodged at blood vessels of the optic nerve and are more likely to lead to permanent vision loss.[13] Fibrino-platelet plaques can originate from both the carotid artery and the heart. They tend to be dull gray-white plugs that are long in shape and smooth in appearance. Although typically mobile, these plaques can cause retinal arterial occlusions when they become stuck or lodged within a vessel.[13]

With regards to stroke risk, the Beaver Dam Eye Study found that retinal emboli were associated with a threefold greater risk of fatal stroke over eight years (*figure 2*).[12] The Blue Mountain Eye Study found that over 12 years, 30% of patients with retinal emboli died—with 4% of the deaths resulting from stroke. There was a moderate threefold increase in stroke-related mortality rates in patients with emboli.[15] In general, patients with emboli have a higher mortality rate compared to those without emboli.

Studies have also shown that patients with retinal arterial occlusion (RAO) are also at higher risk for stroke. Patients with RAO have a higher prevalence of TIA as well as stroke.[11] Recently, a population-based study in Taiwan found that 19.6% of RAO patients went on to suffer a stroke, while only 10% of control group patients suffered a stroke (*figure 3*).[16] Stroke risk was particularly high in the first month following the artery occlusion and most strokes occurred within six months, suggesting the need to educate patients at the time of the retinal finding. The study also found that patients with CRAO had higher rates of stroke than patients with BRAO.[16]

In the presence of retinal emboli, with or without artery occlusion, optometrists need to properly educate patients about their increased stroke risk and the need for urgent medical attention if they experience them. Moreover, order a carotid doppler and echocardiogram to find the source of the emboli and refer appropriately with detection of any abnormalities to the appropriate specialist.

Hypertension

Elevated blood pressure can increase the risk of stroke through atherosclerosis of the vessels over time; this may lead to blockage of small vessels in the brain and ischemia. Hypertension can also weaken blood vessels and cause an aneurysm, which can disturb blood flow. In the eye, early microvascular changes from hypertension, such as arteriolar narrowing, artery-vein nicking and artery opacification, have been shown to increase the risk of stroke. In the Atherosclerosis Risk in Communities (ARIC) Study, artery-vein nicking and artery narrowing were shown to increase the odds of MRI-defined subclinical infarction by nearly twofold.[17]

As the severity of hypertension increases, there can be further breakdown of the blood-retina barrier and "moderate" findings, such as flame-shaped hemorrhages, cotton-wool spots and exudates. Similarly, cotton-wool spots and hemorrhages have been shown to increase relative risk of incident stroke two to three times compared to individuals without these retinal findings.[18]

"Severe" hypertensive retinopathy can occur when elevated blood pressure causes an increase in intracranial pressure and optic nerve swelling. Severe hypertension can also lead to infarction of segments of the choriocapillaris. Siegrist's streaks refer to linear RPE hyperplasia over infracted choroidal arterioles, and Elschnig spots are a sign of non-perfused choriocapillaries. Uncontrolled hypertension has been shown to increase the risk of stroke four- to sixfold, so this is another group we need to educate (*figure 4*).

Hypertension can also lead to retinal-arterial macroaneurysms. Elevated blood pressure can cause the smooth muscle lining arteries to be replaced with collagen, making the arterial wall less elastic and more susceptible to aneurysm

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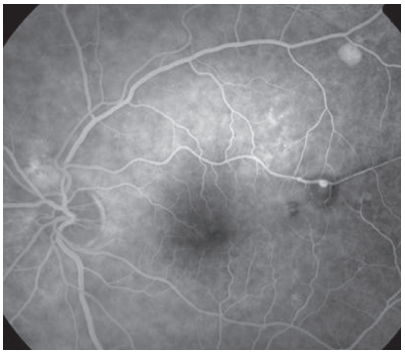
formation. This is typically found in older female patients and is associated with high blood pressure in up to 79% of cases.[19]

Diabetes

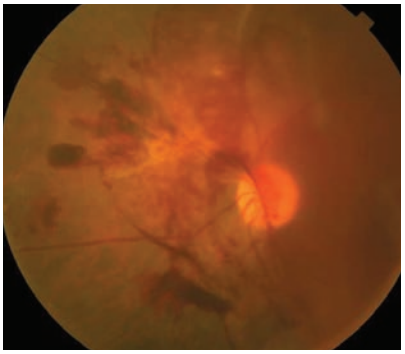
Diabetes increases the risk for stroke by inhibiting blood flow and fostering ischemia. In the eye, diabetic retinopathy is commonly detected in individuals who have poorly controlled blood sugars or have had the disease more than 10 years. The ARIC study found the risk of incident ischemic stroke was two to three times higher in individuals with non-proliferative diabetic retinopathy vs. individuals without diabetic retinopathy.[17] In addition, the level of diabetic retinopathy also seemed to correlate with stroke risk. Of the 1,305 individuals in the study who had no diabetic retinopathy, only 3.9% went on to suffer an ischemic stroke. In contrast, 9.6% of individuals with mild to moderate diabetic retinopathy and 11.4% of individuals with severe diabetic retinopathy went on to suffer a stroke.[20]

Diabetics who have proliferative diabetic retinopathy (PDR) are not only at risk for devastating ocular sequelae if not properly treated, they are also at increased risk for stroke. The Wisconsin Epidemiological Study in Diabetic Retinopathy found the risk of the stroke was six times higher in patients with PDR, and the risk of stroke mortality was double compared to patients without PDR (*figure 5*).[21,22]

Asymmetric diabetic retinopathy is found in approximately 5% to 10% of diabetic patients and can also be a sign of carotid disease and increased stroke risk.[23,24] In previous studies, "asymmetry" has been defined as PDR in one eye with no retinopathy in the fellow eye, or as a two to three grade difference between the eyes. The literature has been somewhat inconsistent. In the seminal study on this topic, Andrew Gay, MD, and Arthur Rosenbaum, MD, found that in the majority of their subjects, severe carotid stenosis was found ipsilateral to the eye with less retinopathy.[25] They theorized that carotid disease retards progression of retinopathy in the ipsilateral eye or accelerates it in the contralateral eye.[25]



4. Fluorescein angiography illustrating a retinal arterial macroaneurysm (RAM), resulting from hypertension. Uncontrolled blood pressure can increase the risk of stroke four- to sixfold.



5. In the Wisconsin Epidemiological Study in Diabetic Retinopathy, the risk of stroke was found to be six times higher in patients who had proliferative diabetic retinopathy.[26]

Since then, two significant studies have found that the connection is not that definitive. The Duker group found that it was "50/50" whether the ipsilateral or contralateral eye with PDR had more severe carotid stenosis.[23] They argued that the technique used in the Gay study, ophthalmodynamometry, was not direct evidence of carotid stenosis.[23] Their findings were supported by another study from Japan, which proposed that ocular ischemic syndrome can be additive to diabetic retinopathy and that PDR is more likely to be on the same side as the carotid stenosis in cases of asymmetric retinopathy.[26]

Case-by-Case Basis

While ocular manifestations of carotid artery disease (TMVL, VSR, OIS, retinal emboli) have a clear connection with increased future stroke risk and warrant patient education in almost all cases, the need to educate patients with microvascular signs (diabetic and hypertensive retinopathy) may not be as clear for some practitioners.

While artery-vein nicking and mild non-proliferative diabetic retinopathy have been shown to increase risk for future stroke in certain studies, if the blood pressure and/or blood sugars are well-controlled, some ODs may not feel compelled to educate their patient regarding stroke. Instead, they may elect to educate the patient on blood sugar and/or blood pressure control, which is likely adequate for low-risk patients.

Ultimately, the need to educate our patients about stroke risk and signs of stroke should be taken on a patient-by-patient basis and depends on patient personality as well as doctor comfort. Older patients with multiple vasculopathies who are not compliant with their medications are likely better candidates for education compared to relatively younger and healthier individuals who are more compliant with their treatments.

Overall, the role of the primary care optometrist can be paramount in detecting current stroke as well as preventing future incidents. With the majority of at-risk patients poorly educated about the signs of stroke as well as the need for urgent care when it occurs, we can help our patients to recognize these signs and to act appropriately. ■

Dr. Chu practices at the Salisbury VA Medical Center in Salisbury, NC.

The ABCDs of a Transient Ischemic Attack

Within the last decade, significant research has validated a simple acronym (ABCD) to help identify TIA patients at highest risk for stroke: Age, Blood pressure, Clinical symptoms, and Duration of symptoms. These risk factors are each assigned a point value:

- **Age > 60 = 1 point**
- **Blood pressure systolic > 140 and/or diastolic > 90 = 1 point**
- **Clinical symptoms**
  - Unilateral weakness/numbness = 2 points
  - Speech disturbance w/o weakness = 1 point
- **Duration of symptoms**
  - Less than 10 minutes = 0 points
  - Between 10 to 60 minutes = 1 point
  - Greater than 60 minutes = 2 points

Out of a possible six-point scale, higher ABCD scores are correlated with higher risk of future stroke. Specifically, one study found that 95% of patients who had strokes that occurred within seven days of a TIA had ABCD scores of 5.31. Another study looked at the risk of stroke within 30 days following TIA and found that an ABCD score of 5 was associated with an eightfold greater risk.[32]

More recently, another group investigated whether adding "Diabetes" to the scale would also help predict stroke risk in TIA patients. Not surprisingly, the ABCD^2 score was validated for two-, seven-, 30- and 90-day risk of stroke after TIA for scores 4 and higher.[33,34] It's also been shown that patients with higher ABCD^2 scores had more severe stokes, more severe resulting disability and longer hospital stays.[35]

The current international guidelines from the American Stroke Association recommend immediate hospitalization and diagnostic evaluation of TIA patients with an ABCD^2 score of 3 or higher within 24 hours of symptom onset. If you have a patient in your chair who you suspect of having a moderate to high risk of TIA, it is vital that you get them urgent medical care without delay. (Note that even with low ABCD^2 scores, there is still risk of future stroke and these patients need a full diagnostic work-up within two days after a TIA.)

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4th Annual Retina Report

Essential Elements of The Retinal Exam

What should be included in the primary care optometrist's diagnostic retinal examination? **By Michael Trottini, OD, and Candice Tolud, OD**

The management of posterior segment diseases has changed dramatically over the past several decades. Advanced retinal imaging technologies, coupled with increased understanding of macular disorders and the importance of the optometric role in detection, have provided us with real-time, quantitative and qualitative analysis of pathology. How we understand retinal changes, and ultimately manage our patients, is rapidly evolving.

So, how exactly have these technologies changed the way we evaluate our patients? Is it time to get rid of our ophthalmoscopes? How has retinal imaging changed the way we look at the fundus? And, what techniques and technologies must we incorporate into our practices to appropriately manage our patients?

To answer these questions, we've enlisted the help of a few leaders in optometric retina care for their insights.

Dilation and Lenses

As our patients get older, their risk for eye diseases increases, which requires more frequent dilated exams. But what about younger, healthier patients? How often should they be dilated?

The American Optometric Association's Clinical Practice Guidelines recommend a comprehensive exam in asymptomatic, risk-free patients every two years between the ages of six to 60, and then annual exams thereafter.[1] While there are no specifics on frequency of dilation in the risk-free patient, the guidelines recommend using the initial dilated examination to guide the timing of subsequent dilations.

Jeffry Gerson, OD, of WestGlen

Direct ophthalmoscopy seems old fashioned, but it still has its place in the retina exam.

Don't Ditch the Direct Ophthalmoscope

While the direct ophthalmoscope has essentially lost its first-at-bat position for retinal examinations, it should not be forgotten.

"Direct ophthalmoscopy is becoming a lost art," Dr. Ferrucci says. "But, even with all the new equipment available—BIOs, fundus lenses, OCT, digital imaging—we should not fully abandon the direct ophthalmoscope. It still plays a useful role in some cases due to its ease of use, its capability to focus through the media and reveal some media opacities that may be missed with non-contact slit lamp lenses, and its ability to give a non-inverted image with decent magnification. It's been a useful tool for a long time, and still has its place." It can be especially useful in patients confined to a wheelchair and unable to sit at a slit lamp.

Eyecare & Omni Eye Centers of Kansas City, recommends a dilated retinal exam on all new patients. Then, assuming this baseline exam shows no pathology, Dr. Gerson generally dilates at intervals of every few years in young, healthy patients who have no family history of retinal disease.

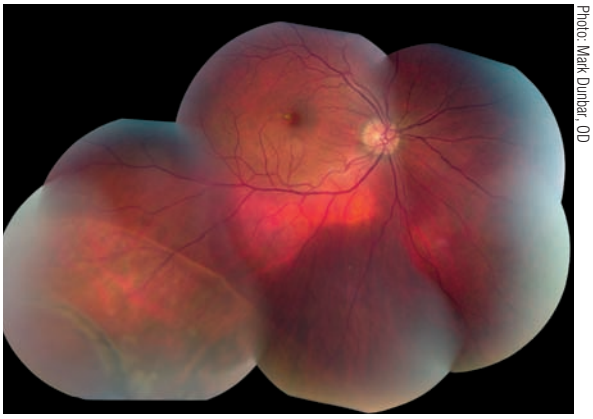


Photo: Mark Dunbar, OD

Dilation and fundus photography are important elements of the retinal exam that, in many ways, cannot be replaced.

For viewing the retina, newer generation non-contact slit lamp lenses are gaining increased popularity. In particular, the Digital Wide Field Lens (Volk Optical) seems to be a favorite among the doctors we interviewed. It has the ability to provide views past the equator, which is useful when performing a non-dilated exam. "It is a big step up from the traditional 90D and 78D lenses, offering better optics and less internal reflectivity," says Steven Ferrucci, OD, chief of optometry at the VA Ambulatory Care Center in Sepulveda, Calif. Another valuable lens is the Digital High Mag (Volk Optical), which allows for a more magnified and stereoscopic view of the macula and optic nerve. *(See "Don't Ditch the Direct Ophthalmoscope," page 50.)*

Fundus Photos and Optomap

Fundus photography is useful for clinical photo-documentation of various retinal pathologies, such as optic nerve disorders, maculopathies, diabetic retinopathy and choroidal nevi.

"Although fundus photography doesn't have quite the detail of newer imaging systems, it still provides important information on progression of retinal disease and is still a very important part of the retinal exam," says Mark Dunbar,

OD, director of optometric services at Bascom Palmer Eye Institute, in Miami.

Of note, fundus imaging is particularly useful for multiple-doctor practices that share follow-up of patient care because it decreases, at least to some extent, interpreter-related variability in disease monitoring, Dr. Ferrucci says.

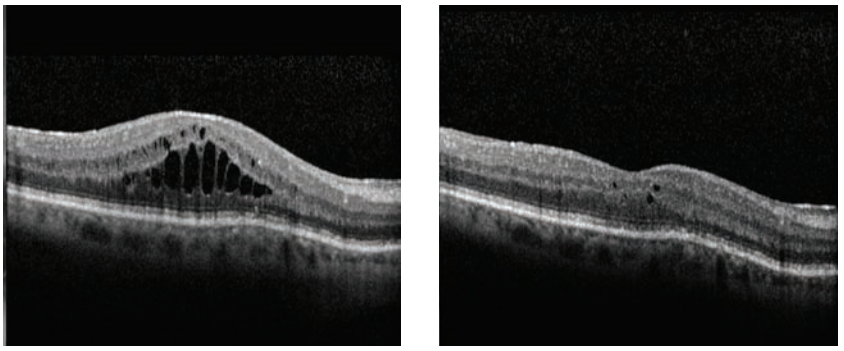
Widefield retinal imaging, such as the Optomap (Optos), allows for nearly full diagnostic views of the fundus without the need for dilation. But the technology has become a topic of debate among eye doctors, some of whom question whether it replaces a dilated fundus exam, and if such imaging technology can be used to monitor retinal pathology.

Even the doctors we interviewed held different opinions on the use of widefield imaging. In the end, however, they formed a general consensus: Even with the improved magnification and contrast, widefield imaging should not be used solely in the management of retinal disease, but as an adjunct to dilated retinal exams. "There's still something about actually looking inside your patients' eyes with a 90D or 78D lens that cannot be replaced," Dr. Ferrucci says.

Optical Coherence Tomography

Optical coherence tomography (OCT) provides cross-sectional views of internal tissue previously only achievable by histological studies. Thus, OCT has been described as a method for non-invasive tissue "biopsy."[2]

Almost as fast as it takes to acquire a macular scan, the OCT has changed the way we look at the retina. With its detailed and instantaneous imaging of retinal structures, the OCT has quickly surpassed many of its technological antecedents for monitoring retinal disease. "We can now see types of disease and disease processes that we could really only surmise before. It's really given us a whole new level of diagnosis," Dr. Ferrucci says.



OCT reveals macular edema in a patient one month after cataract surgery (left). One month after topical steroid and NSAID treatment (right), the edema shows significant improvement on OCT.

The earlier generation time-domain OCT (TD-OCT) uses a reference mirror that measures the time it takes for light to be reflected, acquiring approximately 400 scans per second. This results in longer acquisition times and lower resolution compared with the newer generation spectral-domain OCT (SD-OCT). The latter is able to acquire a significantly greater number of scans per second at a markedly higher resolution.

The leading manufacturers of SD-OCT are Carl Zeiss Meditec, Heidelberg, Optovue and Topcon, all of which have hardware and software differences. However, no single brand has a clear-cut advantage over the other instruments, according to the doctors we interviewed.

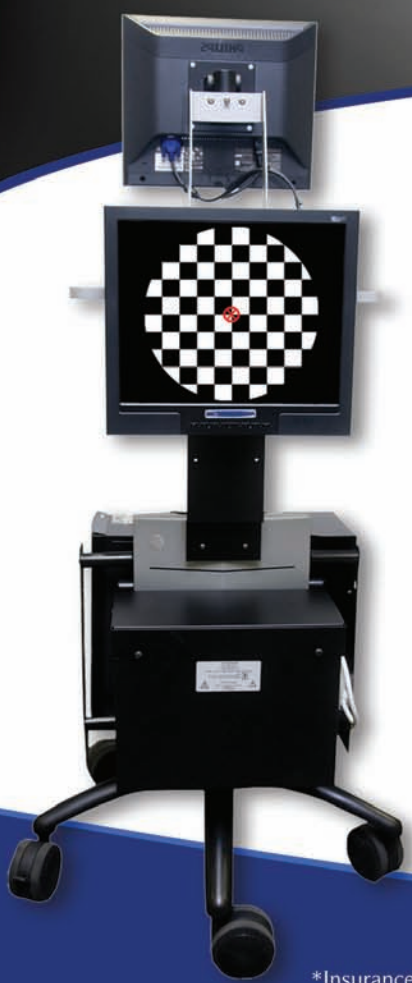
"From an optometric perspective, OCT has provided a way to look at the retina and correlate what you are seeing clinically to what is happening anatomically," Dr. Dunbar says. Specifically, SD-OCT has made it much easier to manage various retinal pathologies such as macular degeneration, epiretinal membranes and central serous chorioretinopathy.

In managing macular degeneration, OCT has the ability to objectively monitor the quantity and volume of drusen. Dr. Dunbar says the use of OCT for tracking macular degeneration is akin to the use of visual fields in following glaucoma. That is, "OCT allows us to quantify and document any changes or progression of drusen over time with serial imaging," he says.

Speaking of glaucoma, OCT is also being used for optic nerve evaluation. Glaucoma analysis databases can follow progression of optic neuropathy due to glaucoma.

Another novel development: Vitreomacular traction was once a diagnosis optometrists and ophthalmologists could only surmise, but now it can easily be identified with OCT.[3]

OCT is also being used with fundus fluorescein angiography to follow wet macular degeneration and macular edema. Indeed, OCT has led retina specialists to rely much less on fluorescein angiography, Dr. Dunbar says. For instance, with the advent of OCT, the use of fluorescein angiography has declined



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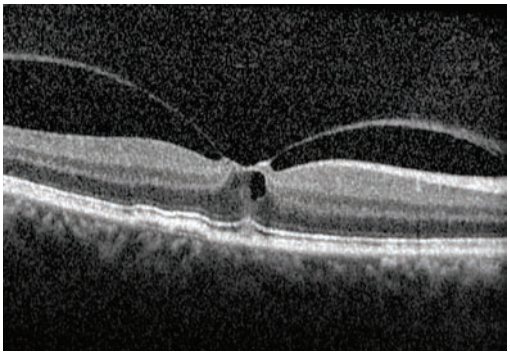
by approximately 70% to 80% at Bascom Palmer Eye Institute, he estimates.

Plus, new uses for OCT are being found all the time. For example, current research has linked multiple sclerosis and optic nerve fiber layer loss, which can be measured and followed on serial OCT studies.[4]



OCT shows us images not easily visualized before, such as this vitreomacular traction.

It's important, however, to not rely solely on the results of OCT without placing it in context. It should only be used when there is a clear indication. "The most important things are taking a careful history, listening to your patient and actually doing a good exam," Dr. Ferrucci says. "So, as fantastic as OCTs are, we can't throw everything else we've been doing out of the window and rely only on them. OCTs are another piece of the clinical puzzle. Granted, OCT is an important and impressive piece, but it shouldn't be the only piece and it shouldn't overrun our common sense."

Novel Retinal Innovations

These recent innovations in retinal diagnosis and monitoring are by no means "essential elements" of the retinal exam, but they do show promise and usefulness in certain patients.

• ***Preferential Hyperacuity Perimetery (PHP).*** The Foresee PHP (Reichert) is used to monitor macular changes in patients with AMD. It can detect elevations in the retinal pigment epithelium consistent with conversion from dry to wet AMD within the central 14 degrees of the visual field. PHP testing allows not only for quantification of the degree of distortion, but also identifies the location of the visual distortion as well an estimation of its severity.

PHP is also available as a home monitoring system (ForeseeHome, Notal Vision) that uses a phone line to transmit patients' responses to a monitoring center, which then notifies both the patient and the doctor if there is a change. It has shown good sensitivity and specificity for monitoring the development of CNV. It's a tool that Dr. Gerson finds increasingly more helpful than the standard Amsler grid for his AMD patients to use for self-monitoring.

"It's not for every patient," Dr. Gerson says. "First, because it requires good hand-eye coordination, which is a concern for some older patients. I generally see if patients can perform the test in office before placing an order for the home monitoring device. Also, because the test isn't covered by insurance, it can be hard to afford, especially for those patients on a fixed income."

• ***Macula Risk.*** As treatments for macular degeneration continue to develop and improve, so must our ability to identify patients who are at high risk for progression. Macula Risk (Arctic Dx) is a simple, in-office test for specific genetic markers associated with progression to advanced macular degeneration. The procedure entails obtaining a sample of the patient's DNA by oral swab taken in the office. The results can determine a patient's risk of developing geographic atrophy or choroidal neovascularization.

"I think that knowing a patient's risk is important," Dr. Ferrucci says. "By knowing which patients are at high risk, you can counsel them earlier and more aggressively. Also, if you have a patient who is high risk, you are going to want to see them a little more frequently than a low-risk patient."

Fundus Autofluorescence

Fundus autofluorescence (FAF) is becoming a hot topic in the optometric world. More and more manufacturers are producing retinal cameras, fundus imagers and OCTs that include autofluorescence. It has become of particular interest in managing patients with macular degeneration. FAF allows for the visualization and distribution of lipofuscin, which may predict the progression of macular degeneration.[5]

Autofluorescence is not just for macular degeneration, Dr. Dunbar says. He also uses FAF in patients with central serous chorioretinopathy to show damage within the retinal pigment epithelium that wouldn't be visible on fundus photography or OCT.

What should be included in the retinal diagnostic arsenal of a primary care optometrist? All of our experts agree that, at the very least, a primary care optometry practice should be equipped with a fundus camera.

Dr. Gerson also suggests that optometrists have an OCT "because it's becoming standard of care in many diseases." For instance, the multi-functionality of the OCT in detecting and following macular pathology, optic nerve disorders, hydroxychloroquine maculopathy and even neurological disease (such as multiple sclerosis) makes it an invaluable tool. "The OCT is becoming as common as

the phoropter in the optometric office," Dr. Dunbar says. Even a busy solo practice can justify purchasing a unit.

"Not everyone can afford every instrument, and that's OK," Dr. Gerson says. "But it's important for optometrists to be aware of what technologies are out there and why their patients will benefit from them. Not having a certain device doesn't mean that your patient doesn't deserve it. So, know where to send your patient to have that particular testing done. If another OD down the street has what your patient needs, you can always send the patient to them for that test." ■

Dr. Trottini is in practice at Outlook Eyecare, in Monroe Township, NJ. Dr. Tolud is in practice at South Jersey Eye Physicians, in Cream Ridge, NJ.

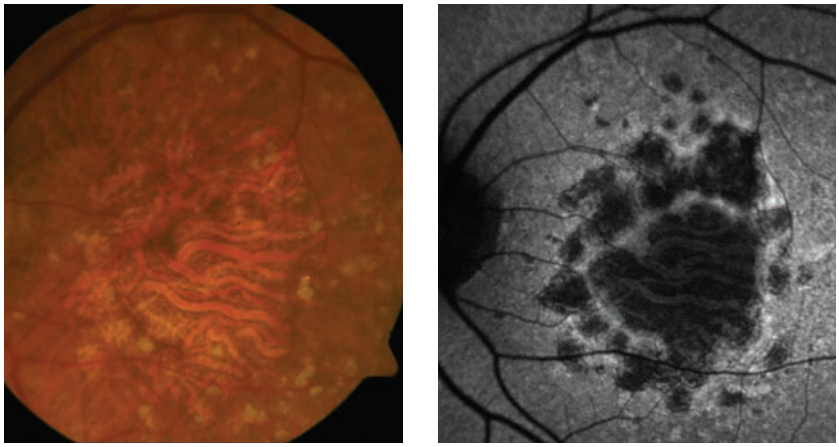


Photo: Mark Dunbar, OD

Highlighted areas on fundus autofluorescence image show drusen, while darkened areas show geographic atrophy.

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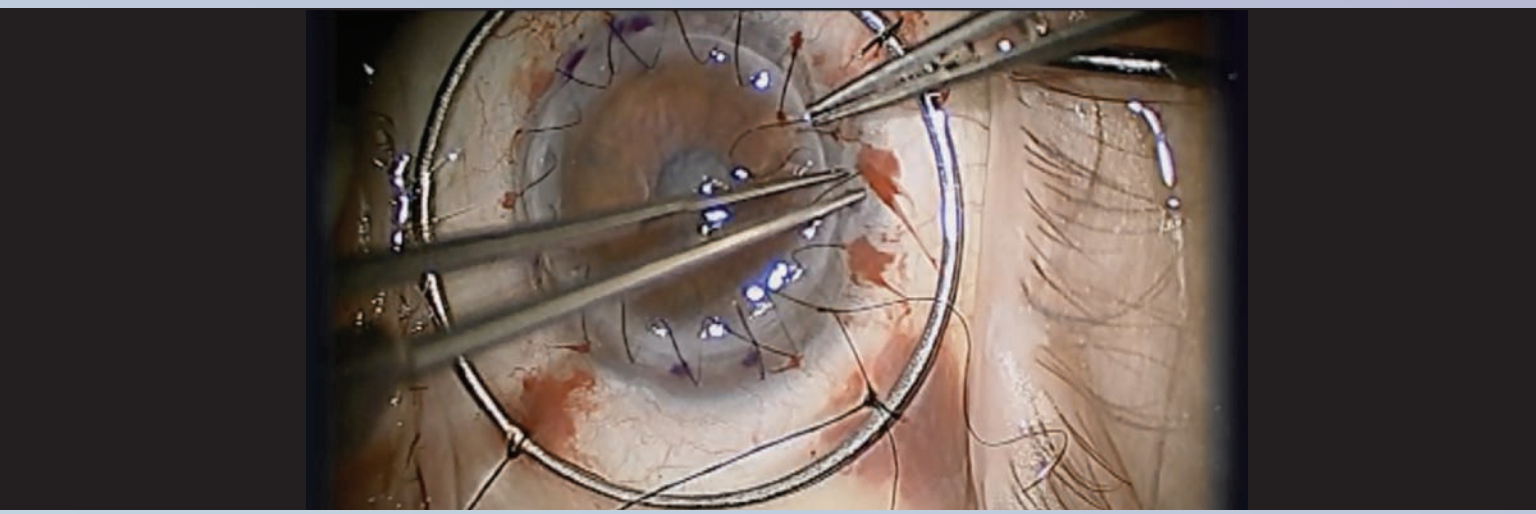
Surgical Minute

By Derek N. Cunningham, OD, and Walter O. Whitley, OD, MBA



See the view through the operating microscopes of some of the best eye surgeons in the US, with expert commentary from comanaging optometrists.

Surgical Minute

PK: Right on the Button

When all else fails, penetrating keratoplasty offers a chance for better acuity.

By Derek N. Cunningham, OD, and Walter O. Whitley, OD, MBA

On The Web >> View a narrated video of penetrating keratoplasty.

Penetrating keratoplasty (PK) is a full-thickness transplant in which the damaged central cornea (7mm to 9mm) is removed and replaced with donor tissue. Compared with other types of tissue transplants, it has a long and outstanding record of success; more than 46,000 corneal transplants were performed in 2011, according to Eye Bank Association of America.

The most common indications for penetrating keratoplasty are regrafting, keratoconus, Fuchs' endothelial dystrophy, pseudophakic bullous keratopathy, perforated corneas, traumatic scars and viral keratitis.

The advantages of penetrating keratoplasty include the full removal of damaged corneal tissue, improved optical clarity, restored corneal anatomy, ease of performance compared to other corneal transplant procedures, improved cosmetic appearance and the potential for good optical results.

Some disadvantages are a higher risk of graft rejection, post-op astigmatism, suture management, intraocular complications and traumatic corneal rupture.

Variations of the procedure include deep anterior lamellar keratoplasty (DALK), Descemet's stripping endothelial keratoplasty (DSEK) and Descemet's membrane endothelial keratoplasty (DMEK). The choice of procedure (PK or one of the above variations) depends on which corneal layers have been affected.

The procedure begins with the preparation of the donor tissue. A trephine (a circular cutting device) is used to cut the donor cornea, followed by trephination of a similar sized portion (7mm to 9mm) of the patient's cornea. Once the recipient's corneal button has been removed, the anterior chamber is filled with balanced salt solution or sodium hyaluronate and the donor button is placed into position.

Four cardinal sutures of 10-0 nylon are placed at 90° intervals in the donor graft, just above Descemet's membrane. The sutures are then passed into the recipient's cornea at the same level, at approximately 1.5mm into the host tissue. Once the needle is passed though, the suture is tied and buried. After the cardinal sutures are in place, suturing can be completed with a single running suture or interrupted sutures.

Postoperatively, patients are prescribed topical antibiotics for one to two weeks as well as topical steroids, which are tapered over several months. Many times, patients are kept on low-dose topical steroids to reduce the risk of graft rejection and failure. Sutures can be removed as soon as two to three months, if needed. Or, if a patient has little astigmatism and the sutures are not causing any problems, they can be left in place for many years.

As comanaging optometrists, our main concern is the long term management and visual function. Postoperatively, corneas may take anywhere from 18 to 24 months to fully stabilize, so be sure to continuously monitor patients for adequate visual acuity and functional vision. Communicate with your corneal specialist to decide when patients are sufficiently stable for contact lenses. A specialty contact lens (GP or hybrid) may be considered as soon as three months after surgery, but may need several changes and modifications once the sutures are removed. ■

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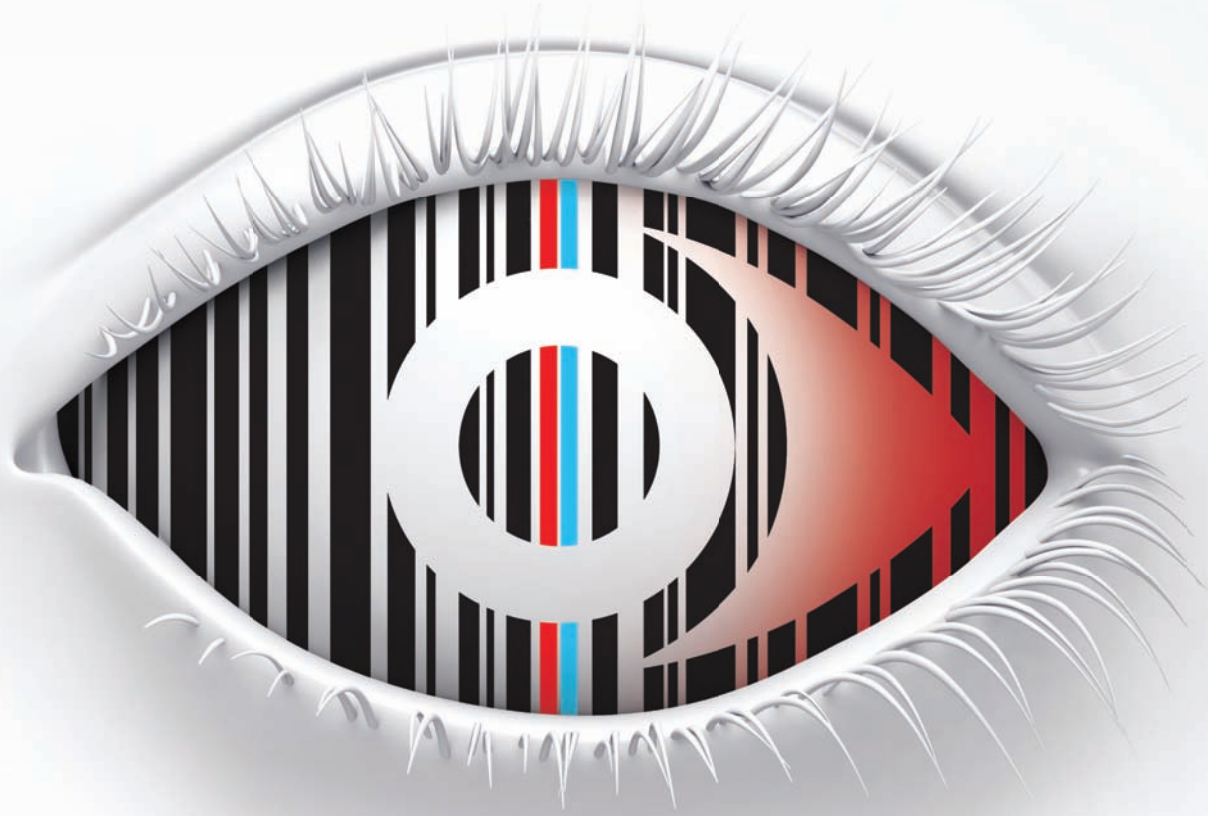

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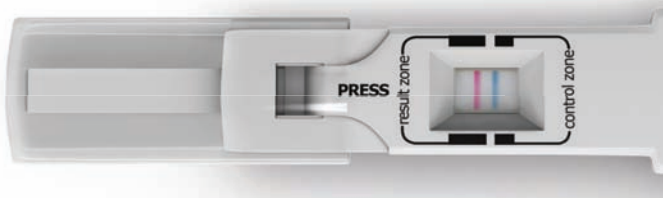

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Case Report

4th Annual Retina Report

A Novel Biomarker for Stargardt Disease?

In this case series, the high-resolution capacity of SD-OCT was used to provide what could be the earliest retinal indication of this visually devastating genetic condition.

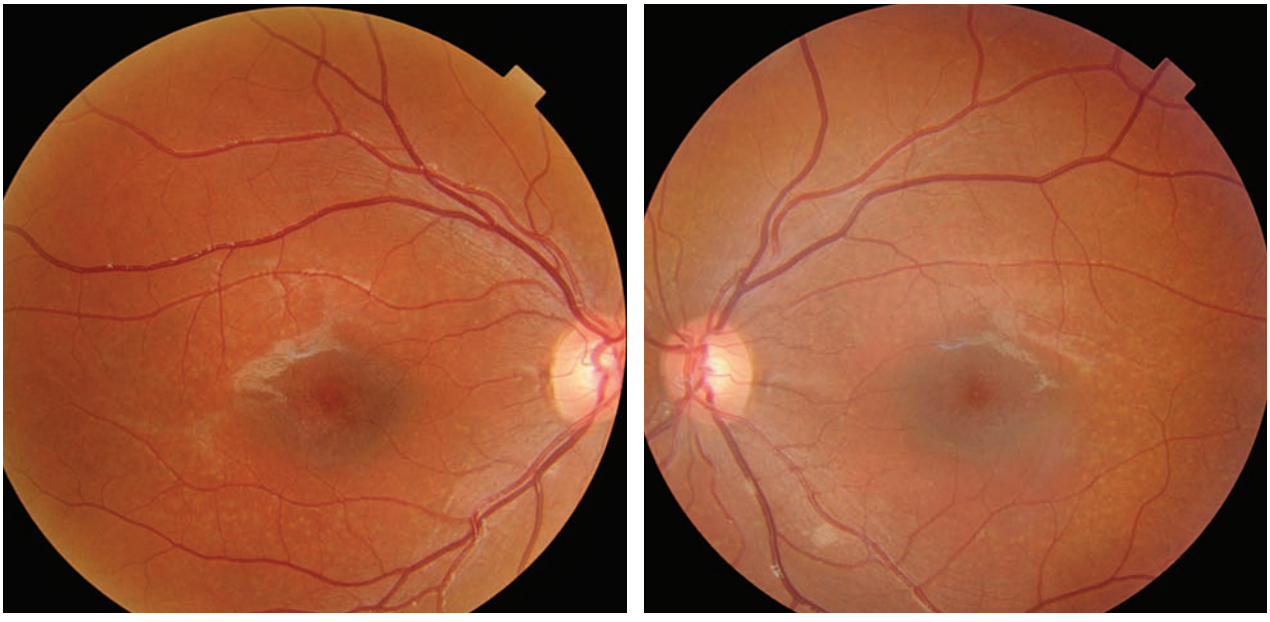
By Jerome Sherman, OD

More than 100 years ago, German ophthalmologist Karl Stargardt initially described the features of what is now known as the most common form of juvenile macular dystrophy.[1]

Stargardt disease—with or without the deep white/yellow retinal lesions, or the so-called flecks of fundus flavimaculatus—is an inherited autosomal recessive trait caused by mutations in the *ABCA4* gene.[2,3]

Symptoms usually begin in the first two decades of life, and final visual acuity generally stabilizes between 20/200 and 20/400.[4]

Both spectral domain optical coherence tomography (SD-OCT) and fundus autofluorescence (FAF) permit clinicians to detect and potentially manage Stargardt disease earlier than ever before. Using these imaging modalities, I've documented what I believe to be the earliest ocular abnor-



Fundus photographs of the eight-year-old son who presented with a visual acuity of 20/200 OU (OD left, OS right).

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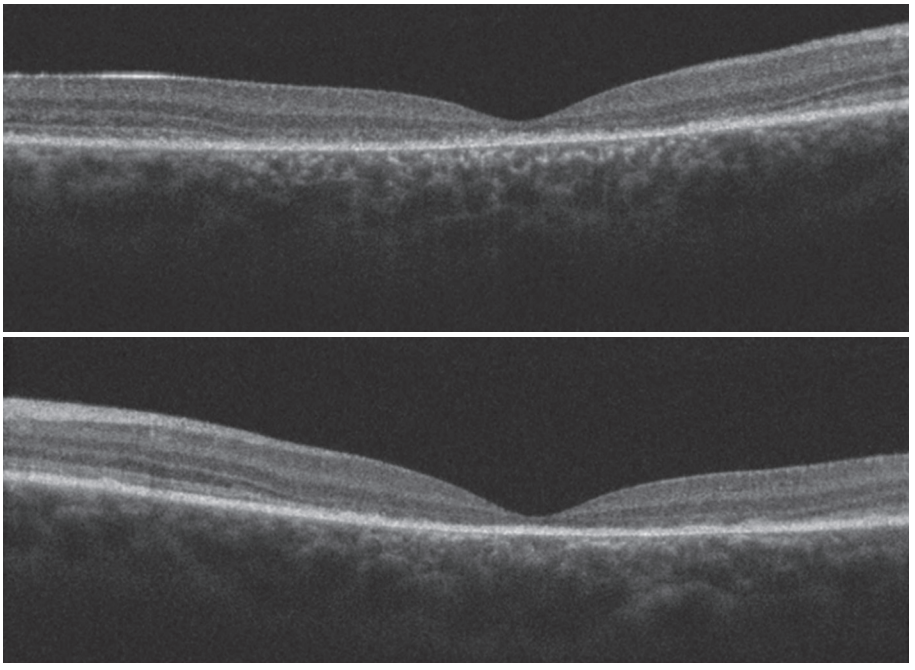
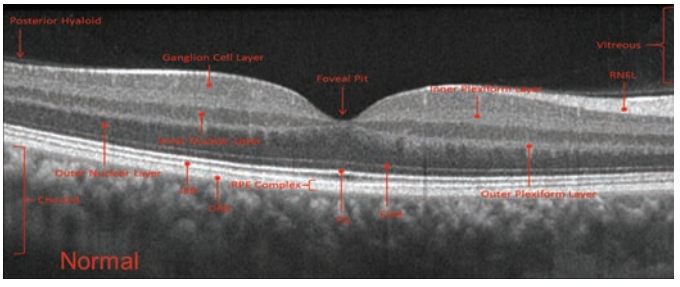




Spectral-domain optical coherence tomography scans of the son (OD top, OS middle), compared to a normal scan in a healthy individual (bottom).

mality associated with Stargardt disease—a thickened, irregular, hyper-reflective external limiting membrane (ELM).

These findings are described in the following case series.

Family History

Upon referral, a mother presented with her three children: an eight-year-old son, a five-year-old daughter and a four-year-old daughter. Although her daughters had no visual symptoms and were never evaluated, her eight-year-old son complained of progressive, bilateral visual acuity reduction at distance and near over a three-year duration. He also complained of some difficulty with both color and night vision.

The mother reported that although 15 ODs and MDs examined her son over this period, no practitioner offered any organic explanation of his visual complaints. (She reported that several clinicians hinted at an underlying psychogenic cause.)

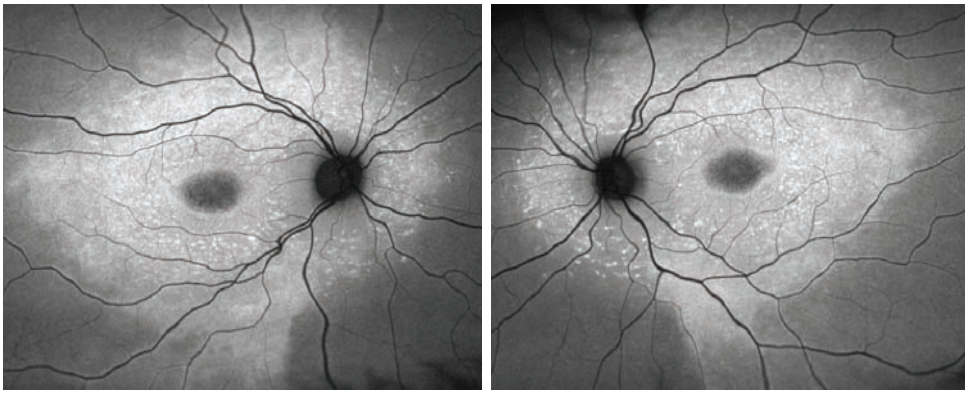
Careful questioning failed to reveal any family history of eye problems or contributory systemic disease.

Case I

The eight-year-old son's best-corrected visual acuity measured 20/200 OU. We performed funduscopy and SD-OCT OU.

On SD-OCT, we observed macular thinning in his right eye. Also, we noted a general absence of the photoreceptor integrity line (PIL). It appeared that the son's outer retina was collapsing onto the retinal pigment epithelium (RPE) in the entire central zone.

The PIL was somewhat preserved outside the macula; however, it should be present in the entire scan. We uncovered very similar SD-OCT findings in the son's left eye.



Fundus autofluorescence images of the son (OD left, OS right).

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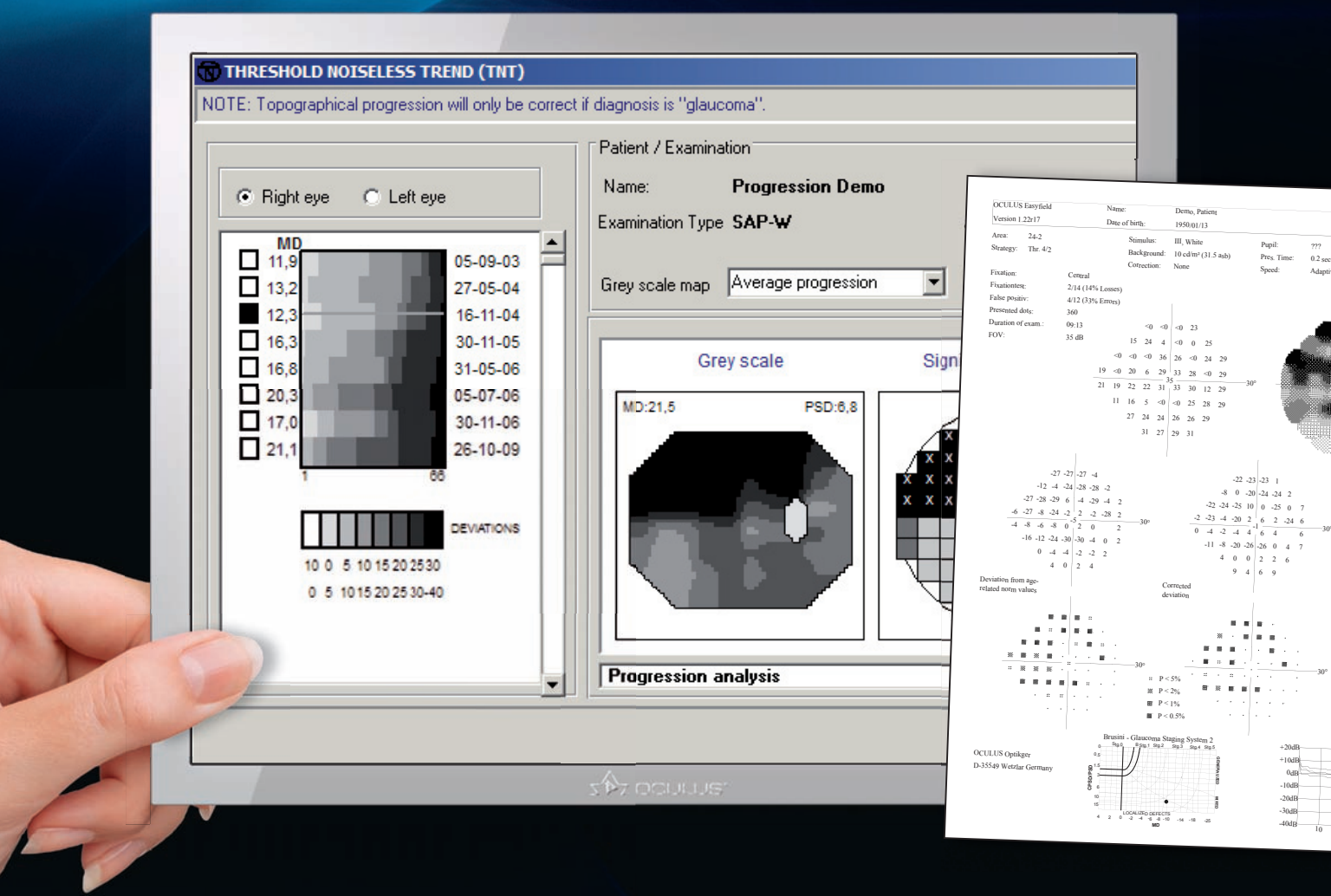

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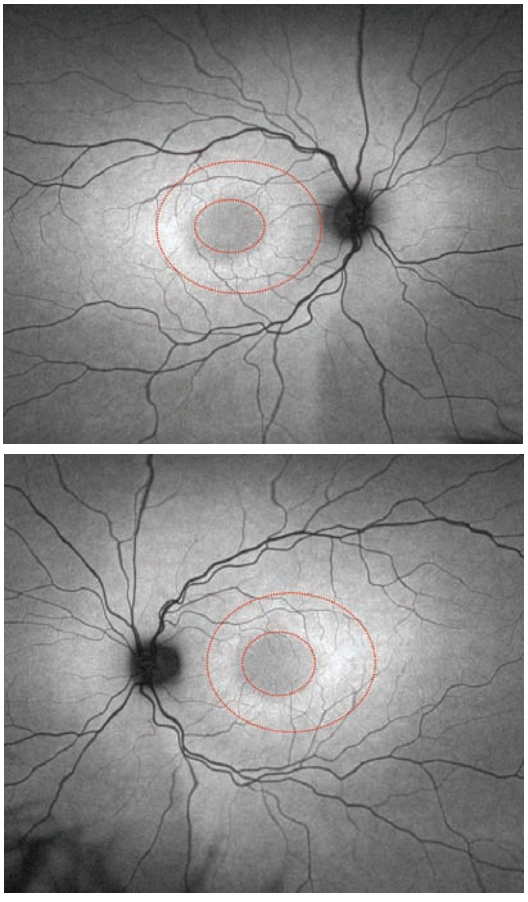
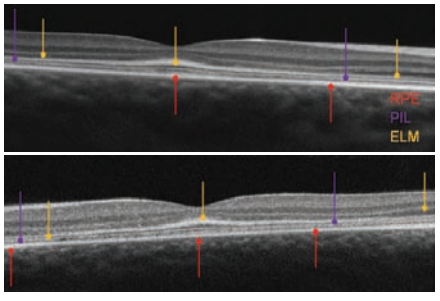


FAF images of the five-year-old daughter (OD top, OS bottom). Note the bull's eye around both maculae.

Both the FAF images and the SD-OCT scans reveal marked abnormalities in the outer retinas of both eyes. Hyper- and hypo-FAF findings suggested a primary abnormality of the RPE, with secondary involvement of the overlying photoreceptors.



OCT scans of the five-year-old daughter (OD top, OS bottom).

Flash ERG results were low/normal in amplitude, and not delayed under photopic and scotopic conditions OU. Such normal or near-normal ERG results effectively ruled out an overall cone-rod dystrophy.

We diagnosed the son with probable Stargardt disease and fundus flavimaculatus.

Case II

The five-year-old daughter exhibited no definitive symptoms of Stargardt disease. Her best-corrected visual acuity measured 20/25 OU, which is considered normal in four- and five-year-olds. The fundus images revealed normal, white, glistening reflections off the ILM in both eyes—an expected finding in young children. So, we interpreted the fundus evaluation as essentially normal OU. However, FAF testing revealed a subtle bull's eye in both maculas.

In contrast to her brother, the five-year-old sister exhibited normal, intact retinal layering—although the PIL was somewhat attenuated. Further, the ELM was thickened, irregular and grossly hyper-reflective. In healthy individuals, the ELM appears very subtle and perhaps one-fifth to one-tenth as thick and reflective as the PIL. In both eyes, her ELM was thicker and more reflective than the PIL. Specifically, the abnormal ELM was most markedly evident in the macula.

Case III

The four-year-old daughter's best-corrected visual acuity also measured 20/25 OU. Like her older sister, we documented characteristic ILM reflections on the fundus evaluation of both eyes.

With parental consent, we used chocolate to bribe the girl and improve her cooperation for the SD-OCT scan. Her images were very similar to those obtained of the older sister—her PIL was somewhat thinned, and the ELM was thickened, irregular and hyper-reflective OU.

Discussion

In comparison to their brother—who exhibited a thin macula and compromised outer retinal structures—the two sisters had intact retinal layers, but an abnormally thickened ELM. The apparent irregular thickening and hyper-reflective appearance on the OCT potentially was due to adjacent layer degeneration, with cellular debris accumulating on the ELM.[5] The ELM—likely formed by the footplates of the Müller cells—is structural in nature and supportive of the retina's neural components.

In the two sisters, the apparent ELM thickening likely was due to the close proximity of cellular debris deposits. The outer nuclear layer (ONL) normally is comprised of dense, closely packed nuclei of cones and rods, and hence is hyporeflective.

As the nuclei degenerate, they are less densely packed and occupy a larger space. But as this occurs, the entire ONL becomes less hyporeflective and more hyper-reflective. This newly hyper-reflective zone appears as an extension of the hyper-reflective ELM. This hypothesis

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is supported by some rare histopathological specimens.[6]

After a thorough evaluation and comparison of these three siblings, it seemed increasingly evident that the abnormal ELM appearance might be the earliest clinical indication of Stargardt disease.

To date, we have not observed a similar finding in retinitis pigmentosa or any other retinal degenerations. Indeed, this apparent thickened, irregular and hyper-reflective ELM may be a biomarker for very early Stargardt disease—even before the onset of symptoms and acuity reduction.

Another potential explanation for associated ELM thickening is a defect in the *ABCA4* gene. In patients with Stargardt disease, a compromised *ABCA4* gene allows toxic vitamin A dimers to accumulate in the photoreceptors.[7]

Follow-Up

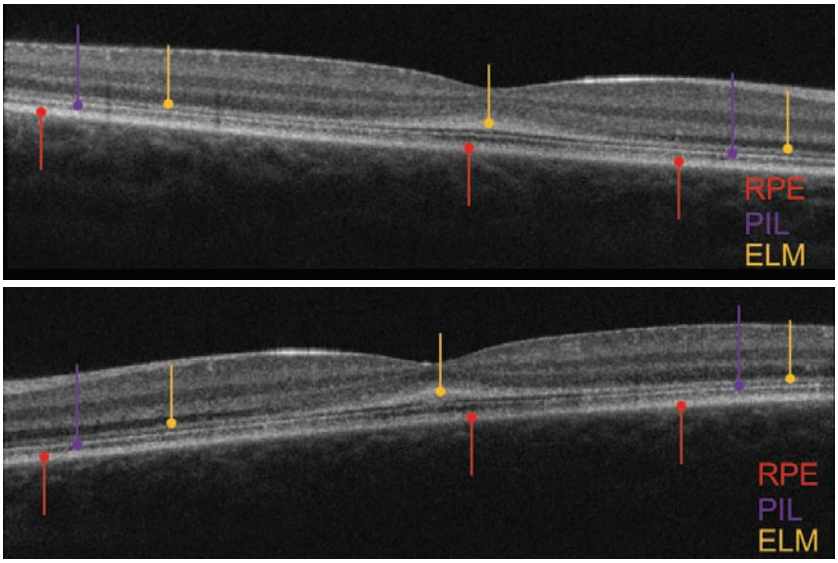
All three siblings were evaluated four months after their initial visit. FAF imaging revealed bilateral progression in the eight-year-old son. His preliminary genetic testing results revealed the presence of at least one *ABCA4* gene abnormality, which has been associated with Stargardt disease.

After meeting with an executive from Alkeus Pharmaceuticals, the mother agreed to allow her three children to be enrolled in a study testing its oral, chemically modified vitamin A supplement, ALK-001. It is anticipated that FDA testing of ALK-001 will begin within this calendar year.

Interestingly, both parents had normal fundus evaluations and SD-OCT scans. Because Stargardt disease typically has an autosomal recessive inheritance pattern, both the mother and father most likely had one abnormal gene. Unfortunately, in this particular instance, all three children inherited the abnormal recessive gene from both parents. ■

Management Tips for Stargardt Patients

- Early diagnosis of Stargardt disease may provide researchers with additional time to develop and test advanced therapies and management strategies.
- Genetic confirmation, enrollment into a central registry and publication of natural history data may help locate patients who are most appropriate for clinical trials and/or genetic counseling.
- Oral treatment, such as ALK-001 from Alkeus Pharmaceuticals, may prevent the formation of toxic vitamin A dimers in the retina.[7] Earliest drug activity may be monitored by fundus photography, FAF imaging and OCT scans.
- Stargardt patients should not use high-dose vitamin A supplements. Dietary consumption of vegetables and fruits rich in vitamin A is permissible, however.
- If you suspect that a patient potentially has Stargardt disease, contact Dr. Sherman at j.sherman@sunyopt.edu for a consultation.



OCT scans of the four-year-old daughter (OD top, OS bottom).

Dr. Sherman is a distinguished teaching professor at State University of New York College of Optometry and the Schnurmacher Institute of Vision Research. He also practices at The Eye Institute and Laser Center, New York City.

Thanks to Arnold Sherman, OD, and Jennifer Lee for their contributions to this article.

To view additional images and an expanded discussion, go to www.retinarevealed.com and click on Case #55 in the archive.

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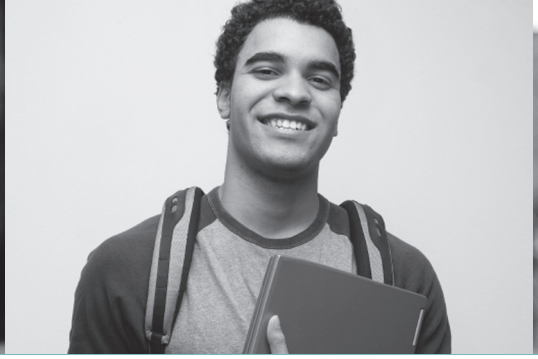


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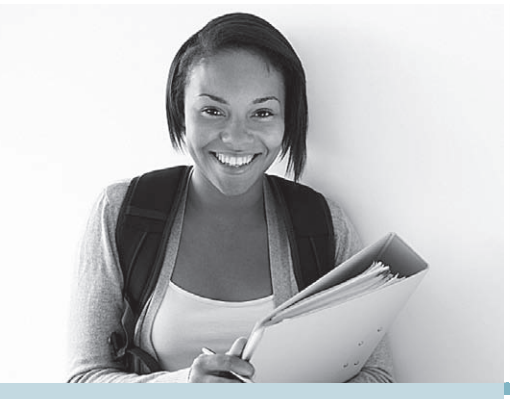

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Genetics in Eye Care

Here, we review concepts in genetic testing as well as specifically discuss new advances in gene therapy for AMD and Fabry disease.

By Albert M. Morier, MA, OD, and Ricki Lewis, PhD

Advancements in genetics and molecular biology have expanded exponentially during the last 60 years. Enhanced instrumentation and computing power have changed the landscape of molecular research. Until recently, such studies in eye care generally centered upon an understanding of Mendelian genetics (dominant and recessive disorders) and population genetics (knowing which conditions are more prevalent in certain populations).

Because gene sequencing has become more streamlined and less expensive during the last decade, researchers have amassed a wealth of critical information to help facilitate the diagnosis and treatment of several major ocular disorders. Here, we will help the practicing optometrist garner a better understanding of human genetics and how it is becoming an essential element of contemporary eye care.

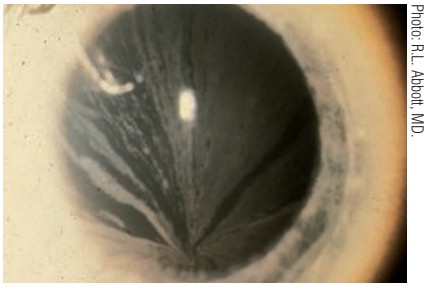

Photo: R.L. Abbott, MD.

Corneal verticillata in Fabry disease.

The Basics of Gene Studies

Sequencing the first human genome took more than a decade. Now, applying next-generation methods that use microfluidics to sequence many copies of its small segments, a human genome can be sequenced in just days. Thousands of people already have had either their exomes (the 1.5% of the genome that encodes proteins and accounts for 85% of inherited diseases) or their complete genomic construct sequenced.

During the late 1980s and 1990s, genetic linkage studies were considered to be an important tool for determining the prevalence of common single-gene disorders, such as sickle cell disease and Marfan syndrome. Shortly after the turn of the millennium, however, researchers moved away from genetic linkage studies and began conducting

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genome-wide association studies (GWASs) to evaluate more specific genetic associations and variants found in populations of patients believed to have the same disease.

In the GWAS approach, fluorescently labeled probes are used to highlight single-base sites in the genome, where more than 1% of the population exhibits variability. These sites are called single-nucleotide polymorphisms (SNPs). Bioinformatic algorithms search the data for SNP patterns that are much more prevalent among the individuals with the trait in question. However, many of the earliest GWASs returned weak and inconclusive results because the approach simply detected genetic associations, not underlying disease causes. Nonetheless, to this day, the GWAS technique remains a powerful tool to interrogate sequenced genomes for the chromosomal sites where specific genes of interest are likely to exist.

Results from the first successful GWAS ever conducted were published in *Science* in 2005. In this study, Robert J. Klein, PhD, and associates evaluated 96 patients with polymorphisms associated with age-related macular degeneration (AMD) and 50 control subjects.[1] They determined that, among 116,204 SNPs genotyped, an intronic and common variant in the *complement factor H* (*CFH*) gene was present in those with AMD.[1] More specifically, in individuals homozygous for the risk allele, the likelihood of AMD was increased by a factor of 7.4.[1]

There are more than 25 genes reported to influence the risk of AMD, including *CFH*, *ARMS2* and *HTRA1*.[2] Environmental factors, such as smoking and excessive sunlight exposure, play a major role in the onset of AMD as well.[3-7] Smoking typically increases an individual's likelihood of developing AMD by two to three times.[5] The exact mechanism of retinal damage due to smoking is unknown, but long-term oxidative insult has been suggested.[6] Other environmental factors linked to the onset of AMD include excessive alcohol consumption and infections by certain pathogens (e.g., *Chlamydia pneumoniae*).[7-11]

Genetic Variation and Mutation

Every individual has hundreds of genetic variants—most of which are recessive.[12] Unfortunately, however, the language used to describe these variants can be somewhat confusing.

A mutation is a change in the DNA sequence from what is most commonly found in a particular population (and often is referred to as the "wild type" phenotype). It is considered a type of polymorphism (which simply means "many forms") that is present in less than 1% of a population.

There are several types of mutations. A point mutation is an alteration of a single base. It is considered "nonsense" if it generates a stop codon that truncates the encoded protein, or "missense" if it substitutes one amino acid type for another. A missense mutation only affects the phenotype if it alters a protein in a way that impacts its function in a detectable manner. Another type of point mutation affects a splice site, which is the DNA sequence at which noncoding parts of pre-messenger RNAs (introns) are cut out. Altering a splice site can add or remove segments to a messenger RNA, altering the size of the encoded protein.

Chromosome-level mutations include deletions and duplications as well as rearrangements (inversions and translocations). The genome is also peppered with many copy number variants (CNVs), which range from repeats of just a few nucleotides to vast, million-base duplications or deletions. Chromosomal microarray tests using comparative genome hybridization detect the CNVs that are correlated to such conditions as autism and developmental delay. A type of CNV mutation that causes more than a dozen neurological disorders is the expanded repeat, which typically is a triplet or quadruplet.

Keith H. Baratz, MD, and William Brown, OD, of the Mayo Clinic Department of Ophthalmology and associates have discovered a strong association between the *transcription factor 4* gene (*TCF4*) on chromosome 18 and Fuchs' corneal dystrophy.[13] They performed a GWAS to compare 100 affected study participants with 200 controls. The GWAS simultaneously evaluated 330,000 alleles between the affected and unaffected subjects. The strength of the association between Fuchs' and the variation at the *TCF4* gene was unprecedented. The researchers determined that the *TCF4* gene may be responsible for 75% of Fuchs' corneal dystrophy cases.[13]

Monogenic Vs. Multifactorial Disorders

For many years, human genetics was chiefly associated with monogenic (or Mendelian) traits and diseases. Since then, we've learned that the most common health conditions are, in fact, multifactorial—meaning that they are caused by at least one gene-related complication and one or more ancillary/environmental factors.

• ***Monogenic conditions.*** The classic "modes of inheritance" for monogenic traits are autosomal recessive (e.g., Usher syndrome),

Recommendations on Genetic Testing

In 2012, the American Academy of Ophthalmology published its "Recommendations for Genetic Testing of Inherited Eye Diseases," which emphasize the importance of distinguishing monogenic from multifactorial ocular diseases, and also advise when it is appropriate to order a genetic test.[54] Some of the specific recommendations include:

1. Offer genetic testing if symptoms match those of a known monogenic disorder, such as retinitis pigmentosa.

2. Use tests from Clinical Laboratories Improvement Amendment (CLIA)-approved labs. Consult databases and the literature to interpret results.

3. Provide patients with their test results so that they can research clinical trial opportunities.

4. Discourage patients from using direct-to-consumer genetic tests—many of which do not provide physician expertise or genetic counseling services.

5. Suggest sequencing exomes and genomes only in a research setting, until these approaches are integrated into medical practice.

6. Do not order a genetic test for a multifactorial disorder because individual gene variants contribute only partially (and unevenly) to overall risk.

7. Do not test asymptomatic patients under age 18 for untreatable disorders.

Keep in mind that there is no universal consensus for in-office genetic testing of AMD. Additionally, more comprehensive guidelines are anticipated in the near future.

autosomal dominant (e.g., some forms of Stargardt macular dystrophy) and X-linked recessive (e.g., red/green colorblindness). An autosomal condition affects both sexes. An allele (gene variant) is dominant if the associated trait requires only one copy. An allele is recessive, however, if the trait requires two inherited copies.

For any particular gene, a homozygote has two identical alleles, while a heterozygote inherits a normal allele and a mutant allele. Individuals who have two different variants of a gene are termed "compound heterozygotes." A male carrier of an X-linked gene mutation is hemizygous, because he has only one gene copy. Genetic counselors consult family history charts (pedigrees) and apply Mendel's laws to predict the likelihood that certain individuals inherit a particular monogenic condition.

• ***Multifactorial conditions.*** In contrast to the predictable monogenic inheritance, multifactorial traits and conditions are determined by many factors—each contributing to different aspects of the phenotype. They do not recur with predictable frequency, and are not amenable to gene therapy in the way that monogenic traits are (unless the applied therapy targets a common phenotype that is shared by different forms of the condition, such as the ability of anti-VEGF agents to control blood vessel growth in neovascular AMD).

Nuances of Phenotype

Genetic heterogeneity refers to the same or very similar phenotypes (clinical presentations) that correspond to genotypes in different genes. The Leber congenital amauroses (LCAs) offer a compelling example of this phenomenon. The LCAs are considered early-onset, severe subtypes of RP—although there is some disagreement about classifying them as distinct disorders. All of these disorders are considered retinal dystrophies.

Because the biochemical pathways that functionally link the retinal pigment epithelium (RPE) to the photoreceptors are complex, many proteins (including the enzymes that catalyze the reactions) and their genes are implicated in the 18 types of LCA associated with specific genes. Simply stated, Leber congenital amaurosis can occur in many ways.

Sixteen of the 18 recognized monogenic forms of LCA are inherited in an autosomal recessive manner. Genetic tests can help confirm a clinical diagnosis when phenotypes overlap and range in both severity and course. For example—mutations in *GUCY2D* cause very poor vision but no night blindness and a normal-appearing fundus, whereas mutations in *RDH12* cause night blindness and a characteristic shredded/fishnet retinal appearance.

Several terms are used to describe nuances of gene expression:

• ***Pleiotropy*** is the term applied to a genetic disease that affects more than one organ system. Fabry disease, for example, affects the heart, kidney and brain, and may exhibit several ocular manifestations. It is an X-linked, recessive deficiency of alpha galactosidase A (a lysosomal enzyme).

• ***Variable expressivity*** refers to different degrees of severity in the same genotype among individuals.

• ***Incomplete penetrance*** references the percentage of people with a specific genotype who actually develop the associated phenotype. Degree of penetrance reflects disease severity. Huntington's, for example, is one of the most highly penetrant inherited diseases. If he or she lives long enough, every individual who inherits the expanded triplet repeat mutation eventually develops symptoms of Huntington's. In contrast, the autosomal dominant trait polydactyly (extra digits) is incompletely penetrant, because some individuals who have

affected parents and children develop the normal number of digits.

Gene and Stem Cell Therapy

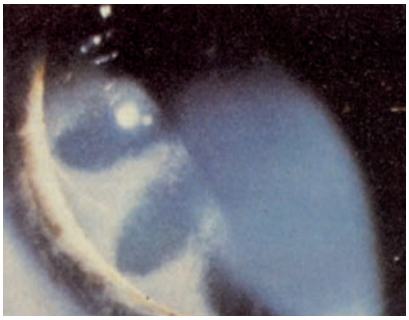
Gene therapy is indicated for pathologies that have not yet destroyed cells. When cells have degenerated, however, replacing them with healthy versions is a more logical approach.

Since 2007, more than 230 patients have received gene therapy for LCA2.[14,15] Most of these treatment procedures have been extremely successful. In gene therapy for LCA2, approximately 15 billion adeno-associated viruses carrying the wild type human *RPE65* gene are introduced into the subretinal space.

For retinal dystrophies in which the RPE and/or photoreceptors are degenerating or depleted, a stem cell approach may be more promising. For example, two Phase I/II prospective clinical trials are underway to treat Stargardt macular dystrophy and dry AMD with RPE cells derived from human embryonic stem cells.[16] The procedure appears to be safe, and dramatically effective, in some of the few patients treated so far.

Human embryonic stem cells are a controversial, and perhaps unnecessary, source of healthy cells. RPE derived from induced pluripotent stem cells that are cultured from the patient's own fibroblasts—and are therefore autologous—are another therapeutic option. In addition, the RPE itself appears to harbor its own stem cells that may one day be activated to heal from within.

Sally Temple, PhD, and Jeffrey Stern, MD, PhD, are pioneering an investigation of RPE stem cells (RPESCs).[17] They culture adult RPE from medical waste, isolate individual cells and apply biochemicals that enable the cells to function as stem cells. This process facilitates the generation and self-renewal of thousands of RPE cells in the dish. These cells might be used in allogeneic transplants or in drug discovery.



An example of 'propeller cataract' associated with Fabry disease. Of the two types of lenticular changes found in patients with Fabry disease, one is a granular anterior capsular or subcapsular deposit that radiates out from the periphery in a pattern that has been described as akin to a propeller.[49]

Genetic Testing for AMD

In-office genetic testing for macular degeneration is gaining in popularity. Choroidal neovascularization (CNV) is responsible for approximately 90% of severe vision loss related to AMD.[18,19] It occurs when abnormal blood vessels migrate through Bruch's membrane. Subsequent hemorrhaging causes irreparable damage to photoreceptors as well as rapid vision loss.[20,21]

As primary eye care providers, a key challenge is how to accurately identify subsets of patients who are at the highest risk for conversion to CNV. The etiology of AMD is complex, with genetic considerations prominently factoring into the disease pathogenesis. Researchers affiliated with the US Twin Study of AMD concluded that genetic factors account for approximately 46% to 71% of macular variation and overall disease severity.[22]

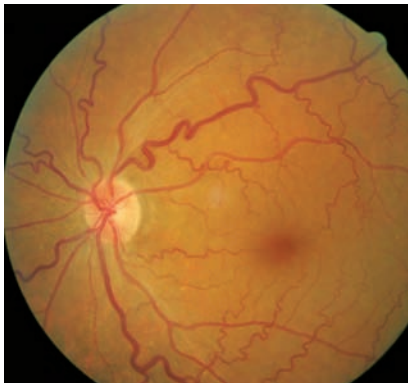
In recent years, several polymorphisms in genes involved in the complement pathway, lipid metabolism, extracellular matrix remodeling and oxidative stress have been associated with AMD. This suggests that AMD has several molecular mechanisms.

Multiple research groups have developed gene-based AMD risk prediction models that can incorporate and account for various demographic and environmental factors.[23-27] The first-generation genetic tests for AMD, such as Macula Risk (ArcticDx), did not incorporate a clinical assessment, making it difficult for clinicians to interpret genetic risk within the context of current disease status.

The second-generation genetic tests for AMD account for current disease status, genetic risk and lifestyle factors when calculating a comprehensive risk score. The latest such tests are Macula Risk NXG (ArcticDx) and RetnaGene (Sequenom).

• ***Macula Risk NXG*** analyzes 15 AMD-associated variations in 12 different genes including *CFH*, *C3* and *ARMS2*—all of which were included in its first generation test. Leveraging recent discoveries of novel AMD-associated genes, Macula Risk NXG includes the cholesterol metabolism genes (*CETP*, *LIPC*, *ABCA1* and *APOE*), as well as the extracellular matrix remodelling genes (*TIMP3* and *COL8A1*). Other complement pathway genes (*CFI*, *C2*, *CFB*) also are included.

The ordering clinician is required to provide information about drusen size and presence of CNV or geographic atrophy in each eye. Furthermore, the test requires physicians to include the patient's age, height, weight and smoking history. The DNA sample is obtained through a cheek swab. The results predict an individual's risk of progression to advanced AMD within two, five and 10 years, and patients



Retinal blood vessel tortuosity in a Fabry patient. Conjunctival and retinal blood vessels may exhibit tortuosity and aneurysmal dilatations. The pathophysiology primarily is caused by Gb3 accumulation within the vessel walls, resulting in endothelial cell dysfunction, abnormal blood flow and hypercoagulability. While blood vessel tortuosity is often seen among all Fabry patients, aneurysmal dilatations are not. Such dilatations are a sign that the disease is at a more advanced level.[55]

are categorized into one of five risk groups (patients in risk Group Five are at the highest risk). Macula Risk NXG has a reported sensitivity and specificity of greater than 80% and a 10-year predictive accuracy of 0.895.[25]

• ***RetnaGene*** is indicated to predict the risk of wet AMD in white patients aged 55 years or more who already have signs of early or intermediate AMD. This test incorporates macular phenotype (expressed as the AREDS Simple Scale Score), age and smoking history. Additionally, RetnaGene evaluates for 12 genetic variations in eight genes (*CFH*, *CFHR4*, *CFHR5*, *C3*, *C2*, *CFB*, *ARMS2* and *F13B*).[28] Like Macula Risk NXG, the DNA analysis is performed with a cheek swab.

RetnaGene calculates the risk of progression to CNV within two, five and 10 years, and categorizes the patient as high, moderate or low risk. The test is reported to have a 10-year predictive accuracy of 0.96.[29]

Anti-VEGF therapy offers wet AMD patients hope for a previously untreatable disease. Despite unequivocal evidence indicating that treatment must be administered soon after conversion to wet AMD, many patients still are mismanaged.[30-32] Fortunately, the next generation of genetic tests represent a powerful tool that we can use to screen our high-risk patients, monitor them closely and refer them to a retina specialist immediately upon disease conversion.

Genetic Considerations in Fabry Disease

Ocular manifestations of genetic diseases can help eye care providers more readily identify life-threatening conditions, such as Fabry disease—a single-gene, X-linked lysosomal storage disorder that causes progressive complications within the kidneys, brain and heart.

Fabry disease is a debilitating and eventually fatal condition that was first described by Johannes Fabry in Germany and William Anderson in England at the end of the nineteenth century.[33] It is one of more than 50 lysosomal storage disorders, and occurs in an estimated one in 40,000 men.[1,34,35] The incidence in women has been estimated to be twice as high as that in men, but its true prevalence in women is unknown.[36]

Measured enzyme activity levels of less than 2% can be found in many hemizygous men who subsequently become prone to life-threatening complications in vital organs and other morbidities secondary to Fabry disease. Evidence-based research has confirmed that most mutation-positive women will experience signs and/or symptoms of the disease, although possibly later than age-matched men.[37-39]

The initial symptoms of Fabry disease can include angiokeratomas (telangiectatic cutaneous lesions), acroparesthesia (severe pain in hands and feet), hypohidrosis (inability to sweat) and gastrointestinal complications.[40] These are not fatal consequences of the disease, but they may have a significant impact on the patient's quality of life.

Ocular manifestations of Fabry disease have been published by several investigators.[40-51] Any ocular signs of the disease suggest that a fatal, insidious condition is lurking within the patient's genome, slowly damaging his or her kidneys, heart and brain.

The most commonly reported ocular finding is corneal verticillata, a bilateral, whorl-like pattern of radiating, cream-colored lines usually found in the inferior cornea. These deposits can range from faint to pronounced, and are located at the level of Bowman's membrane. They can be seen as early as six months of age and are fully apparent by age 10.[41,50]

A number of drugs also may result in corneal verticillata, including amiodarone, chloroquine, indomethacin, chloropromazine, naproxen, ibuprofen and tamoxifen.[51] Corneal whorling from both Fabry disease and amiodarone occur at the same level within the cornea.[52,53] It is important to note that patients who present with corneal whorling on amiodarone therapy may additionally have hypertrophic cardiomyopathy as a result of Fabry disease. So, it's crucial not to simply attribute the presentation to amiodarone use, especially if the patient is young.

Remember that ocular manifestations of Fabry disease often are present at a very young age, well before the signs and symptoms

of renal disease, stroke or hypertrophic cardiomyopathy develop. Thus, early diagnosis by an eye care provider—in conjunction with enzyme replacement therapy—may reduce the morbidity and mortality associated with the condition.

We are only now learning how to better use genetic information to help make accurate, timely diagnoses for inherited diseases. Soon, this information will help researchers develop novel interventions. In the meantime, eye care providers should acquire a working knowledge of genetic inheritance patterns for the most common sight-threatening conditions. ■

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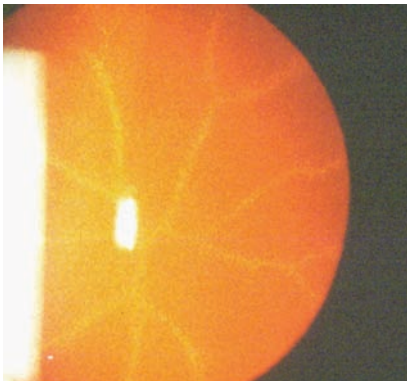

Fabry cataract. The second lenticular change associated with Fabry disease is a whitish, faint, linear cataract at or near the posterior capsule. This presentation, first described 1965, was termed a 'Fabry cataract' because it was unique to the condition.[51] Because the cataract is translucent, it is best observed via retro-illumination.

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1. An exome is:
a. The 1.5% of the genome that encodes for proteins.
b. The 98.5% of the genome that encodes for proteins.
c. Another name for the genome.
d. A gene not found in the nucleus of eukaryotes.

2. What is a genome-wide association study (GWAS)?
a. An incidence analysis of a particular genotype within a population.
b. An examination of many common genetic variants in different individuals to determine if a given variant is associated with a certain condition.
c. An incidence analysis of a particular phenotype within a population.
d. All of the above.

3. Single-nucleotide polymorphisms (SNPs) are specific sites in the genome where more than _____ of the population exhibits variability.
a. 1%.
b. 5%.
c. 10%.
d. 20%.

4. A variant in which gene is likely to influence an individual's risk of AMD development?
a. *Complement factor H*.
b. *ARMS2*.
c. *HTRA1*.
d. All of the above.

5. In addition to genetic factors, which environmental influence increases an individual's risk of AMD?
a. Moderate red wine consumption.
b. Active *Chlamydia pneumoniae* infection.
c. Warm climates.
d. None of the above.

6. What is a "wild type" gene?
a. The phenotype expressed by the recessive allele.
b. The phenotype expressed by the dominant allele.
c. The phenotype that most commonly occurs in nature.
d. The phenotype that occurs in less than 1% of the population.

7. The GWAS conducted by Keith Baratz, MD, and William Brown, OD, indicated that the *TCF4* gene may be responsible for what percentage of Fuchs' corneal dystrophy cases.
a. 25%.
b. 50%.
c. 75%.
d. 100%.

8. Which inherited condition is NOT classified as monogenic?
a. Usher syndrome.
b. Cleft palate.
c. Stargardt macular dystrophy.
d. Red/green colorblindness.

9. What is the term for an individual who exhibits two different variants of a gene?
a. Heterozygote.
b. Compound heterozygote.
c. Homozygote.
d. Compound homozygote.

10. How many recognized forms of Leber congenital amaurosis are inherited in an autosomal recessive capacity?
a. Eight.
b. 12.
c. 16.
d. 18.

11. Which inherited condition exhibits an extremely high degree of penetrance?
a. Polydactyly.
b. Gaucher disease.
c. Huntington's disease.
d. Colon cancer.

12. In which instance might stem cell therapy be more appropriate than gene therapy?
a. When cells are degenerated.
b. If the disease is monogenic.
c. When cells are intact, but missing a single enzyme.
d. If the disease is multifactorial.

13. The US Twin Study of AMD indicated that genetic factors account for as much as _____ of macular variation and disease severity.
a. 46%.
b. 54%.
c. 71%.
d. 82%.

14. Macula Risk NXG analyzes which of the following factors:
a. Cholesterol metabolism genes (i.e., *CETP* and *LIPC*).
b. Extracellular matrix remodeling genes (e.g., *TIMP3* and *COL8A1*).
c. Complement pathway genes (e.g., *CFI*, *C2* and *CFB*).
d. All of the above.

15. Fabry disease is a single-gene disorder of:
a. X-linked inheritance.
b. Y-linked inheritance.
c. Autosomal-dominant inheritance.
d. Autosomal-recessive inheritance.

16. What symptom is NOT commonly associated with early Fabry disease?
a. Angiokeratomas.
b. Acroparesthesia.
c. Alopecia.
d. Hypohidrosis.

17. What is the most common ocular manifestation of Fabry disease?
a. Propeller cataracts.
b. Conjunctival tortuosity.
c. Fabry cataracts.
d. Corneal verticillata.

OSC QUIZ

18. Which medication is associated with corneal whorling?
a. Amiodarone.
b. Chloroquine.
c. Naproxen.
d. All of the above.

19. What complication is NOT typically associated with Fabry disease?
a. Hypertrophic cardiomyopathy.
b. Renal disease.
c. Stroke.
d. Liver disease.

20. According to the American Academy of Ophthalmology's 2012 recommendations on genetic testing, which suggestion is FALSE?
a. It is advisable to test asymptomatic patients aged less than 18 years for untreatable disorders.
b. Use tests from Clinical Laboratories Improvement Amendment (CLIA)-approved labs.
c. Provide patients with their test results, so that they can research clinical trial opportunities.
d. Do not order a genetic test for a multifactorial disorder.

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18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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Better Than the Blade

Bladeless laser cataract surgery costs more, but offers the potential for better results and less inflammation than the traditional procedure. **Edited by Paul C. Ajamian, OD**

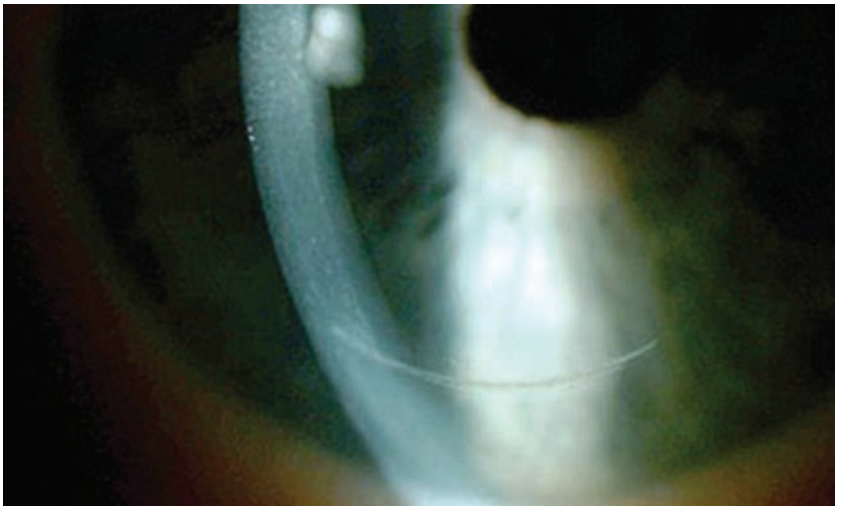
Q Patients are asking about bladeless laser cataract surgery. What do I tell them?

A "When patients ask about bladeless cataract surgery, I explain that it is the wave of the future for cataract surgery," says Andrea Knouff, OD, of Omni Eye Services in Atlanta. Traditional cataract surgery, by comparison, hasn't changed much in more than 30 years—it's still performed by using a small blade held by a human hand.

"Now, with bladeless cataract surgery, the femtosecond laser makes all the incisions and breaks up the cataract in under a minute," Dr. Knouff says. "So far, the laser has shown that it's more accurate than a blade in the surgeon's hand, so it has the potential for a sharper and more precise visual outcome."

Specifically, "you can customize the incisions for each specific eye to a much greater degree than any surgeon can do," says cataract and corneal surgeon Lawrence Woodard, MD, also of Omni Eye Services. "Also, the laser is able to treat astigmatism in the cornea during the cataract surgery with much more accuracy than we're currently able to achieve using a blade."

The laser's ability to break up the cataract also has benefits. "The studies are showing we're able to remove the cataract with a lot less energy inside the eye compared to the standard procedure," Dr. Woodard says. "So, we think this could be healthier for the eye in the long term because were using less energy to remove the cataract."



The femtosecond laser can perform precise arcuate incisions.

However, be sure to tell the patient that this is a premium service not covered by insurance.

"Then patients always ask, 'Is it worth it for me to spend extra money to get it done with the laser?' Because of the benefits, I say, 'Yes, it is. If it's something you can afford, there's no reason not to have it done with the laser,'" Dr. Woodard says.

Q What should I look for postoperatively? Is the post-op care much different?

A The postoperative concerns are the same as with conventional cataract surgery, but there are some subtle differences.

"Postoperatively, you'll see a series of perfect cuts where the primary and secondary incisions were made," Dr. Knouff says. "If cylinder has been treated, you'll note the precise corneal relaxing incisions. You'll also see a perfectly round circular area where the anterior capsulotomy was made."

Overall, the laser yields a more accurate and precise outcome with typically less anterior segment inflammation.

"Sometimes the eye is a little red after surgery because the suction from the laser's eyepiece can cause a subconjunctival hemorrhage," Dr. Woodard says. But this usually goes away in a few days or a week with no treatment necessary.

Lastly, "One benefit that we're finding is that more patients are getting 20/20 after surgery without the need for glasses," he says. "Because this laser is more precise in making the opening incisions and more precise with treating astigmatism, more patients are less dependent on glasses afterward compared to traditional cataract surgery." ■

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The Phantom Menace

Don't discount dry eye complaints without objective signs in your post-LASIK patients. It could indicate a deeper issue. **Edited by Joseph P. Shovlin, OD**

Q I have treated several post-LASIK patients in recent years with unrelenting symptoms of dryness who don't respond to fairly aggressive therapy. My local corneal surgeon calls this the "phantom" corneal phenomenon, as they have very few, if any, objective signs. Are there any new thoughts or treatments available for these unfortunate few?

A Patients with a history of corneal surgery may report dry eye symptoms, including complaints of foreign body sensation and burning/irritation, yet present with a relatively normal tear film and no corneal staining.

A 2007 study suggests that corneal nerves sustain a degree of damage during refractive surgery, and resulting changes in membrane ion channel expression at the injured and regenerating nerve fibers can lead to spontaneous nerve impulse firing.[1] The author speculates that the brain reads these abnormal sensory discharges as ocular surface dryness, despite only a modest disturbance of tear secretion.

"The major challenge is how to treat these patients to help with their complaints—my typical course is still to treat them as if they have dry eye, with anti-inflammatory drops such as topical steroids and Restasis (cyclosporine, Allergan)," says Miami's William Trattler, MD, who specializes in refractive, corneal and cataract eye surgery. He also recommends topical NSAIDs, such as bromfenac, ketorolac or nepafenac, and oral pain medications for patients experiencing serious discomfort. These medications all act on slightly differing arms of the inflammatory cascade.

Research has also suggested that drugs like anticonvulsants, such as Neurontin (gabapentin, Pfizer) and Lyrica (pregabalin, Pfizer)—that reduce abnormal activity in injured nerves—may be a potential treatment for sensations of dry eye after refractive surgery.[1]

"Some patients may have minimal response to [conventional] treatment recommendations, and in those challenging cases, I will recommend that they see a neurologist or a pain management specialist," Dr. Trattler says.

"There appeared to be more substance to the patient's claims than simply passing it off as a psychological oddity."

Another possibility, although rare, is occipital neuralgia. Randall Fuerst, OD, of Citrus Heights, Calif. encountered one such case several years ago. The patient complained of extreme pain, dry eye-like symptoms and blurred vision. Re-treatment with LASIK cleared up the visual issues, but did little to stifle the pain. The patient began to complain of a deep, boring pain in and around his left eye, and began to experience depression and loss of sleep. "There appeared to be more substance to the patient's claims than simply passing it off as a psychological oddity," Dr. Fuerst explains.

Dr. Fuerst happened to recount the patient's issue to an ophthalmologist at Walter Reed Army Medical Center, who suggested it could be a case of occipital neuralgia. "He recommended we bring the patient in and palpate the lower occipital region of the scalp for a 'very tender and painful' area," Dr. Fuerst says. If found, "a 50/50 mix of lidocaine and triamcinolone should be injected into this spot."

The patient did indeed have a tender/painful spot at the base of his left occipital region—which he had not previously mentioned because he felt it was unrelated. They injected the area, and two days later, the patient reported a significant reduction in pain. He returned two weeks later, and was given a second injection—and has not had symptoms since.

"Since then, I've been involved in treating four other patients with symptoms of phantom pain, irritation that waxes and wanes, and a tender locus at the base of either the right side or left side of the occipital region of their scalp," Dr. Fuerst says. "Treatment has been successful in all of these cases, which in turn has made me extremely grateful for my chance encounter with someone who knew about this condition—and how to treat it." ■

1. Belmonte C. Eye dryness sensations after refractive surgery: impaired tear secretion or "phantom" cornea? J Refract Surg. 2007 Jun;23(6):598-602.

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TMI? No Such Thing!

A 72-year-old suspect apparently converts to glaucoma—at least according to certain tests. So, do you begin treatment now? **By James L. Fanelli, OD**

In 2005, a 64-year-old white female presented to the office as a new patient with complaints of blur at near and distance. She reported that she had not seen an eye care provider in several years. She was taking no medications, other than OTC vitamin supplements.

Diagnostic Data

Refraction yielded 20/20 acuity OD and OS through an increased hyperopic, astigmatic correction. Pupils and extraocular motilities were full. Slit lamp exam of her anterior segments was essentially unremarkable.

Intraocular pressure measured 23mm Hg OD and 22mm Hg OS at 10:00 a.m. Upon dilation, her crystalline lenses showed incipient nuclear sclerosis, though not interfering with vision. Scattered vitreous floaters were visible.

I estimated her cup-to-disc ratios as 0.50 x 0.55 OD and 0.50 x 0.60 OS. The superotemporal neuroretinal rim was somewhat thinned OD and the inferotemporal neuroretinal rim was thinned OS. Her retinal vascular, macular and peripheral retinal examinations were normal. We took stereo-optic disc photos at this visit.

Given her optic nerve appearance and IOPs in the low 20s, I asked her to return in one month for a glaucoma workup—including baseline visual fields, Heidelberg Retina Tomograph-3 (HRT-3, Heidelberg Engineering) imaging, gonioscopy and pachymetry.

She returned for follow-up, as scheduled. Pachymetry measured 538µm OD and 535µm OS. Her IOP was 22mm Hg OD and OS at 9:05 a.m. Gonioscopy showed open angles OU to the scleral spur and ciliary body, with minimal trabecular pigmentation. There were no angle abnormalities in either eye. HRT-3 imaging confirmed thinned neuroretinal rims superotemporally OD and inferotemporally OS. Standard white-on-white perimetry showed no glaucomatous field defects OU.

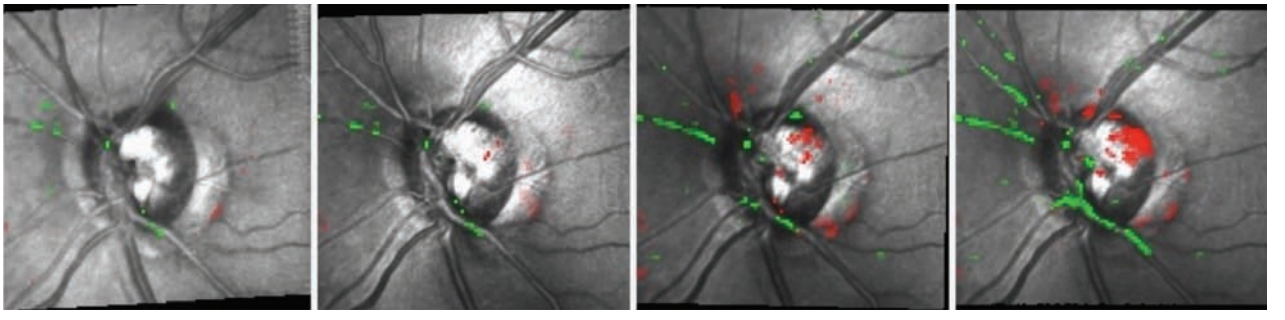
Given the lack of family history for glaucoma, and no other risk factors, the patient appeared to be at risk—albeit low risk—for developing glaucoma.

For the next several years, I followed this patient closely. Ultimately, she developed hypertension, hypercholesterolemia and gastroesophageal reflux disease.

During this time, her IOP averaged in the low 20s OD and OS, varying from 18mm Hg to 25mm Hg OD and from 16mm Hg to 25mm Hg OS. HRT-3 Topographic Change Analysis confirmed that her nerve fiber layer and neuroretinal rims remained stable in both eyes. Visual fields also remained stable and clear in both eyes.

In 2010, the patient underwent visual field studies on Heidelberg Edge Perimeter (HEP, Heidelberg Engineering), which also confirmed no glaucomatous field loss in either eye. Her optic nerves have remained stable clinically—until recently.

In January 2013, she presented for a scheduled follow-up with a large nerve fiber layer hemorrhage located at 12 o'clock OS. Her IOP was essentially unchanged at that visit, as were HEP field studies.



Over five months, Topographic Change Analysis shows progressive damage to the superotemporal neuroretinal rim OS following a disc hemorrhage at the same location.

Discussion

Certainly, the development of a disc hemorrhage in either a glaucoma suspect or a patient with frank glaucoma raises the concern of instability. But, is a disc hemorrhage enough of a clinical finding by itself —with no other discernable changes to the optic nerve or visual fields—to initiate therapy?

While the answer to that question can vary from provider to provider, I think the majority of us would tend *not* to initiate therapy in this case, especially when all other indices are stable. (Which comes first: disc hemorrhage or optic nerve head progression? Research suggests that structural optic nerve head progression actually presages disc hemorrhage, not the other way around.[1])

That said, I also think that the majority of us would watch this patient more closely from this point on. Perhaps more frequent fields and optic nerve imaging are in order, and/or perhaps more frequent office visits. Either way, the development of the disc hemorrhage calls into question the overall stability of the patient's status.

In situations like these, we should not simply dismiss a hemorrhage as a common event in a patient with glaucoma. Nor should we jump the gun and radically alter the management course. Our plan should be to watch very carefully for any inkling of change to the optic nerve, neuroretinal rim, nerve fiber layer or visual field in each eye.

This is where our newer technology comes in to play. With advances in perimetry and optic nerve imaging, detecting change over time has become easier. Be aware, of course, that not all optic nerve imaging devices consistently yield the same results in the same eye. (*See "Don't Just 'Treat the Red,'" below.*)

Structure/function analysis OS indicates damage to the superotemporal neuroretinal rim, yet the corresponding visual field sector is normal.

For instance, what one instrument calls "normal" may be flagged as "not normal" by a different technology. And, not only are there differences across the industry and across categories of instruments, sometimes even using the same type of instrument over time can give confounding results. That is, the same type of technology (either fields or imaging) may not agree with previous reports of the same eye with the same test.

So, for imaging technologies, image registration becomes incredibly important in assuring that subsequent tests take images in *exactly* the same location as the baseline image. Some instruments do a better job of this than others.

Don't Just 'Treat the Red'

Some doctors have had a tendency recently to put too much faith in optic nerve imaging as a diagnostic tool, resulting in what has been described as "treating the red" or simply treating "red disease." These terms are derived from imaging instruments whose abnormal results are shown in red, which readily identify this area for the clinician. Unfortunately, some clinicians may rely too heavily on an aberrant finding (which could be an artifact), and they "treat the red" rather than actually treating the glaucoma.

Asrani SG. OCT and glaucoma: Artifact alert. Rev Ophthalmol. 2013 Feb;20(2):57-61.

Management

What does this mean for our patient?

As it turned out, this she eventually did develop demonstrable changes—as measured by tomography, but not by visual fields—to the superotemporal quadrant of her neuroretinal rim OS (where the disc hemorrhage occurred).

Also, from a structure/function perspective, HEP does not yet show functional change at the area of the neuroretinal rim compromise, and OCT still shows the retinal nerve fiber layer adjacent to the compromised neuroretinal rim to be normal. In other words, the only demonstrable change is seen in the neuroretinal rim, not on OCT or on HEP fields.

Given these inconsistencies, what do you do?

Remember, that the development of a disc hemorrhage should cause us to look very critically for any changes in structure or function, or both. So, because at least one method demonstrated structural change over time, I decided to start the patient on therapy, with Zioptan (tafluprost, Merck) HS OS.

Moving forward, we'll continue to look with a critical level of suspicion for change over time in structure and/or function. Time will tell whether she will be stable enough with this treatment plan. ■

1. Realini T. Disc hemorrhage and glaucoma progression. Eye World. 2009 Aug; 14(8):60-61.

PVD Confirms the Worst

This patient presented with significant blur and a posterior vitreous detachment in her right eye. What does this mean? **By Mark T. Dunbar, OD**

A 63-year-old Hispanic female presented with blurred vision in her right eye that had persisted for approximately eight months. She reported that the visual distortion progressed over a period of several weeks, which now prohibited her from reading with her right eye.

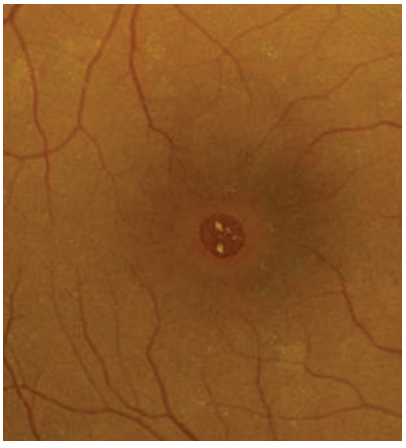
She denied any history of ocular injury, surgery or infection. Her medical history was remarkable for controlled hypertension.

Best-corrected visual acuity measured 20/200 OD and 20/20 OS. Confrontation visual fields were full to careful finger counting OU. Pupils were equally round and reactive, with no evidence of afferent defect. Ocular motility testing was normal. The anterior segment examinations of both eyes were unremarkable. Intraocular pressure measured 14mm Hg OU.

The optic nerves in each eye were healthy, with good rim coloration and perfusion. Dilated fundus exam revealed a posterior vitreous detachment (PVD) in her right eye. The right macula exhibited obvious changes (*figure 1*). The vessels and periphery were normal. Additionally, we performed a spectral-domain optical coherence tomography (SD-OCT) scan (*figure 2*) OD. The left eye, however, was completely unremarkable.

Take the Retina Quiz

1. Based on the clinical exam, what is the correct diagnosis?
   a. Lamellar macular hole.



1. Our patient's right macula exhibits a peculiar lesion.

   b. Cystoid macular edema (CME).
   c. Stage III, full-thickness macular hole (FTMH).
   d. Stage IV FTMH.

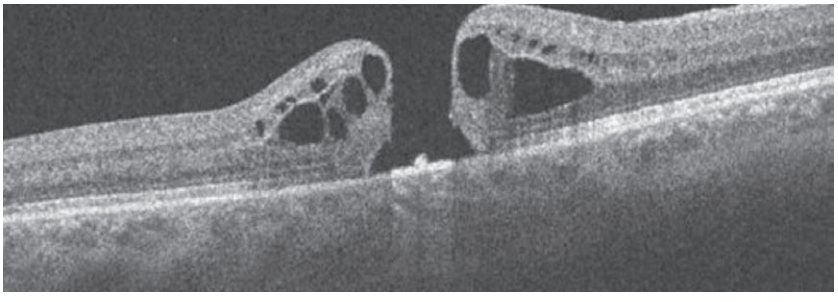
2. What does the SD-OCT scan reveal?
   a. Epiretinal membrane with a pseudohole.
   b. Lamellar hole with CME.
   c. Neurosensory detachment with evident CME.
   d. FTMH.

3. How should this patient be managed?
   a. Observation.
   b. Pars plana vitrectomy (PPV) with internal limiting membrane (ILM) peel, gas bubble injection and face-down positioning.
   c. Intravitreal anti-VEGF injection.
   d. Laser photocoagulation.

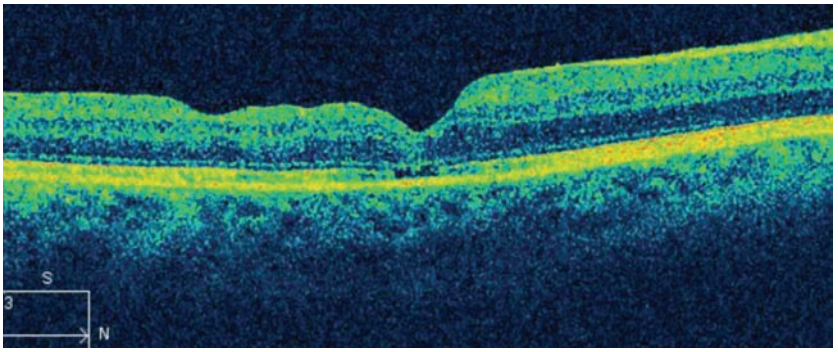
4. Which agent could be used to treat our patient's condition?
   a. Eylea (aflibercept, Regeneron Pharmaceuticals, Inc.).
   b. Jetrea (ocriplasmin, ThromboGenics).
   c. Avastin (bevacizumab, Genentech/Roche).
   d. ACU-4429 (emixustat hydrochloride, Acucela).

5. How would you describe the finding illustrated in figure 3?
   a. Normal macular structure.
   b. Epiretinal membrane.
   c. Foveal "pseudocyst."
   d. Incomplete inner/outer segment junction at the fovea.

For answers, go to page 114.



2. SD-OCT scan of her right macula. What do you notice?



3. Three months after undergoing PPV, our patient experienced complete FTMH closure.

Discussion

Our patient has a classic full-thickness macular hole in her right eye. On clinical examination, we documented a round, well-circumscribed, full-thickness retinal defect. Associated yellow deposits could be seen at the base of the hole, and an accompanying cuff of fluid located around the hole was indicative of a serous retinal detachment.

The presence of a PVD was slightly unusual, however. The existence of a PVD categorizes this as a Stage IV presentation, which occurs in approximately 25% of all FTMH cases. It is important to note that the vast majority of FTMHs are Stage III.

J. Donald M. Gass, MD, described the progressive stages of idiopathic macular hole formation based upon biomicroscopic observations.[1] He postulated that macular holes developed as a result of cortical vitreous shrinkage, which resulted in tangential traction on the macula.

Indeed, this is still thought to be what occurs in patients with idiopathic macular hole development. However, with the development of OCT, we now have a much better understanding of the pathogenesis and clinical spectrum of macular hole formation:

- In a *Stage I macular hole*, there is loss of the foveal depression, which is seen as a yellow spot or ring in the center of the fovea. A foveal "pseudocyst" is evident on OCT, which represents a large, optically empty space within the retina. This presentation results from posterior cortical vitreous contraction.
- In a *Stage II macular hole*, the patient exhibits a full-thickness retinal defect that usually measures less than 400µm in thickness.
- *Stage III macular holes* are larger, measuring 400µm to 600µm, with a surrounding rim of retinal detachment that ranges between 1,000µm and 1,500µm. In some Stage III holes, there is no evidence of a cortical vitreous detachment. In these instances, the hole is caused by tangential traction. However, in cases where the macular hole manifests from an incomplete PVD, perifoveal vitreous detachment occurs. Here, the vitreous is attached in the center of the fovea but detached around the macula.
- A *Stage IV macular hole* occurs when there is an obvious PVD. Most of these holes develop as a result of trauma. In fact, it is rare to observe an idiopathic Stage IV macular hole—which is exactly what occurred in our patient.

The next question: How should we intervene? PPV with ILM peel, gas bubble injection and face-down positioning has emerged as a highly successful treatment for FTMHs. The outcomes often are better when the hole is operated upon as soon as the full-thickness defect has occurred. On the other hand, the prognosis for visual improvement is not as good for holes present longer than one year—and is even worse for holes present longer than two years. Fortunately, our patient's symptoms began about eight months ago, so we believed that she had a good chance of anatomic hole closure and visual recovery.

Jetrea is another potential treatment option. Ocriplasmin is a molecule created from plasminogen. It is a proteolytic enzyme that can induce a PVD by partially dissolving the protein structures contained within the vitreous. This action results in a pharmacologic lysis between the vitreous cortex and the retina. In the pivotal FDA trials of Jetrea, 40.6% of patients exhibited FTMH closure with a single intravitreal injection vs. just 10.6% in the placebo group.[2] Unfortunately, the treatment is expensive—priced at nearly $3,000 per injection.

Our patient elected to undergo PPV. Three months after the surgery, her macular hole closed completely and her vision improved to 20/60 OD. However, there was some lingering disruption in the outer retinal layers at the level of the inner/outer segment junction. This likely explains why her vision wasn't better than 20/60. Nevertheless, over time, we hope that the integrity of her outer retina will improve and yield further visual recovery. ■

1. Agarwal A. Macular dysfunction caused by vitreous and vitreoretinal interface abnormalities. In: Gass' Atlas of Macular Diseases, 5th ed. Vol. 1. Philadelphia: Elsevier Saunders; 2012:628-712.
2. Stalmans P, Benz MS, Gandorfer A, et al. Enzymatic vitreolysis with ocriplasmin for vitreomacular traction and macular holes. N Engl J Med. 2012 Aug 16;367(7):606-15.

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Topical NSAID Update

The latest agents, Prolensa and Ilevro, are improved formulations of current standbys for postoperative pain management. **By Alan G. Kabat, OD, and Joseph W. Sowka, OD**

Topical non-steroidal anti-inflammatory drugs, or NSAIDs as we typically call them, have been a valuable addition to the ophthalmic pharmaceutical arena for more than 25 years.

In the body, NSAIDs work to diminish inflammation and mediate pain by inhibiting the cyclooxygenase (COX) enzymes. These enzymes catalyze the conversion of arachidonic acid into prostaglandins and thromboxanes—both powerful mediators of inflammation.

While not as potent a class of anti-inflammatory drugs as the corticosteroids, NSAIDs still possess a significant ability to ameliorate pain and reduce the signs of ocular inflammation, including postoperative cells and flare within the anterior chamber.[1,2]

The Earliest Topical NSAIDs

The first commercially available topical NSAID to receive FDA approval was Ocufen (flurbiprofen sodium 0.03%, Allergan) in 1986. Ocufen's only indication was for inhibiting intraocular miosis during cataract extraction. But physicians who used this drug soon realized that it had an additional benefit—Ocufen also helped control some of the inflammation and pain following surgery.

When Voltaren (diclofenac sodium 0.1%, Novartis Ophthalmics) received approval in 1991, it was the first topical NSAID to carry a specific indication for postoperative pain. Then, Acular (ketorolac tromethamine 0.5%, Allergan) was granted FDA clearance in late 1992. While Acular was initially approved for the treatment of seasonal allergic conjunctivitis, it later secured approval for postoperative inflammation.

NSAIDs in Eye Care

Primary care optometrists use this class of medications far less frequently than our surgical counterparts in ophthalmology—particularly because the approved indication for these drugs is almost exclusively for the management of postoperative complications. Topical NSAIDs are currently accepted as the standard of care for postoperative management of cataract surgery, along with prophylactic antibiotics and corticosteroids.[3]

However, there are a number of off-label applications for topical NSAIDs, such as temporary relief of ocular pain due to superficial corneal insult. Because of their ability to inhibit prostaglandin synthesis, these drugs help to rapidly and effectively break the pain cycle.[2]

NSAIDs are used for corneal abrasions, corneal foreign bodies, recurrent corneal erosions and chemical keratitis, among others. Additionally, many optometrists are actively involved in the comanagement of surgical patients.

So, it's important to understand the proper use of topical NSAIDs, including appropriate dosing and potential side effects. Knowledge of these drugs' attributes also can help us make better decisions about drug selection and recommendation.

New Kids on the Block

Over the years, improved formulation strategies have resulted in increased potency and diminished dosing requirements for this class of drugs, yielding more convenient and effective regimens. More recently, the FDA approved two new NSAIDs, Prolensa (bromfenac sodium 0.07%, Bausch + Lomb) and Ilevro (nepafenac 0.3%, Alcon).

• ***Prolensa***. Bromfenac sodium has been a popular NSAID choice since 2005, when Xibrom (Bausch + Lomb) was first introduced in the United States. The halogenation of the bromfenac molecule with bromine is believed to impart

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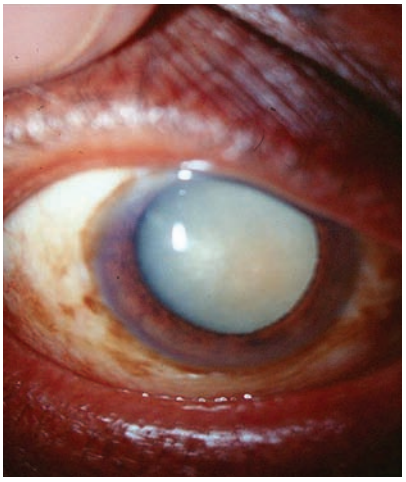

Prolensa and Ilevro are the newest options for topical pain management following cataract extraction.

increased potency and penetration into the ocular tissues. Prolensa actually contains a slightly lower concentration of bromfenac than its predecessors (Bromday and Xibrom both contained 0.09%). Like the previous formulations, it is preserved with 0.005% benzalkonium chloride (BAK).

Prolensa is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.[4] The pH of Prolensa is 7.8, which is more physiologically neutral than that of Xibrom or Bromday (both 8.3).[4-6] According to the manufacturer, this pH modification makes the bromfenac molecule more lipophilic and further improves penetration through the cornea.[7]

Although there currently are no head-to-head studies comparing Prolensa and Bromday, both once-daily formulations have been shown to be effective in managing postoperative inflammation in cataract patients.[8]

• ***Ilevro.*** Alcon's Ilevro is a newer version of Nevanac (nepafenac sodium 0.1%, Alcon). Nepafenac is a prodrug of the more potent anti-inflammatory agent amfenac.[9] In the body, prodrugs are converted to a more active drug state through enzymatic processes.[10] Because nepafenac is a lipophilic, neutral molecule, some researchers have hypothesized that it may have greater corneal permeability than other NSAIDs that have acidic structures.[9,11,12]

Ilevro is indicated for the treatment of pain and inflammation associated with cataract surgery.[13] In clinical trials, Ilevro dosed once daily was superior to its vehicle at completely clearing inflammation by day 14 post-op.[14] In a similarly structured trial, Ilevro dosed once daily was found to be equivalent to Nevanac dosed TID.[15] Both Ilevro and Nevanac are preserved with 0.005% BAK.

In addition to offering a 200% greater concentration of the active drug than its predecessor (0.3% vs. 0.1%), Ilevro has a number of other favorable attributes when compared to Nevanac. It has a lower pH (6.8 vs. 7.4), reduced molecule size, and demonstrates faster dissolution when instilled onto the ocular surface.[16] Also, it contains several inactive ingredients that may help improve comfort, tolerability and ocular surface contact time—including guar gum, propylene glycol and carboxymethylcellulose.[13]

Although not one of the classes of drugs more commonly prescribed by optometrists, NSAIDs are a valuable addition to our pharmaceutical armamentarium and a crucial component of postoperative cataract management.

Additionally, NSAIDs help control intraoperative miosis, pain, inflammatory surgical complications, and perhaps even iatrogenic cystoid macular edema.[17]

In order to better serve our patients and communicate with our ophthalmologic colleagues, increased familiarity with the newest agents is essential. ■

Drs. Kabat and Sowka are consultants to Alcon. They have no direct financial interest in any of the products mentioned.

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Which is Better: AREDS 1 or 2?

The results from AREDS2 are in! But will this study change the way you care for your patients with AMD? **By Diana L. Shechtman, OD, and Paul M. Karpecki, OD**

Age-related macular degeneration (AMD) is a leading cause of vision loss in elderly, white Americans.[1,2] Cumulative oxidative stress plays a role in the disease. So, it seems reasonable to suggest that dietary antioxidants and nutraceuticals will effectively combat the disease.

During the last 20 years, several major studies have repeatedly demonstrated the benefits of nutritional supplementation in patients with existing AMD.[3-12] Of these, AREDS exerted the most widespread, long-standing influence on clinical eye care and industry-based marketing. Can we expect a comparable impact from the long-awaited AREDS2 trial? Let's take a look.

AREDS

The Age-Related Eye Disease Study was the first large-scale clinical trial to evaluate the efficacy of high-dose antioxidants on the progression of AMD. Its results showed that increased intake of antioxidants and zinc lowered the risk for disease progression by 25% in patients with intermediate or advanced AMD.[6-8] Further analysis from AREDS suggested that higher dietary intake of lutein and zeaxanthin (L/Z), in addition to omega-3 fatty acids, decreased the risk of developing advanced AMD.[10,11]

Regarding adverse effects, subsequent research from AREDS found an increased incidence of genitourinary disorders associated with high-dose zinc supplementation.[6] Additionally, research from other studies indicated that elevated intake levels of beta-carotene increased smokers' risk for lung cancer.[13] In addition to the dietary intake information from AREDS, the aforementioned safety considerations played a significant role in the testing parameters for AREDS2.

AREDS2

This five-year trial evaluated more than 4,000 subjects with intermediate AMD. Most participants were educated, well-nourished, elderly whites who already were taking a multivitamin. Sixty-five of the subjects had large bilateral drusen, while the remaining individuals had at least late AMD in one eye (either geographic atrophy or wet AMD).

The study's primary goal was to determine if the addition of 10mg lutein, 2mg zeaxanthin and/or 1,000mg omega-3 long-chain fatty acids (350mg DHA and 650mg EPA) to the original AREDS formulation would further reduce the risk of progression to advanced AMD.

Additionally, the study evaluated the effects of refining the AREDS formula by eliminating beta-carotene and reducing the zinc dosage.[12] Secondary outcomes included the effects of lutein, zeaxanthin and omega-3 fatty acids on the progression to moderate vision loss associated with AMD, as well as the prevalence of cataracts.[12]

The study design initially randomized approximately 1,000 subjects into four arms: original AREDS formulation (control); L/Z; omega-3 fatty acids; and a combination of L/Z with omega-3 fatty acids. A second classification further randomized the groups to receive a control or modified AREDS formula. The modified AREDS formula included either the presence or absence of beta-carotene, and either a high or low dose of zinc. *(Note: There was no true placebo group, because all control subjects still took some form of an AREDS supplement. This was an ethical necessity, given that the AREDS formula was proven to be effective in the management of intermediate AMD.)*

What Did We Learn?

The primary results of AREDS2 revealed that, when comparing the control group to the treated arms (L/Z; omega-3; L/Z and omega-3 combination), there was no significant reduction in the risk of progression toward advanced AMD. AREDS2 was an elobarate study with a complex design, involving secondary randomization and analyses. Some of the most pertinent statistical analyses are summarized below:[12,14,15]

- The addition of L/Z to the AREDS formula was associated with a 10% decrease in the risk of progression to AMD. This exploratory analysis evaluated the primary effects of taking L/Z vs. not taking L/Z.

When evaluating specific subgroups, it was determined that the addition of L/Z to an AREDS formula without beta-carotene yielded an 18% reduction in the risk of progression to advanced AMD.

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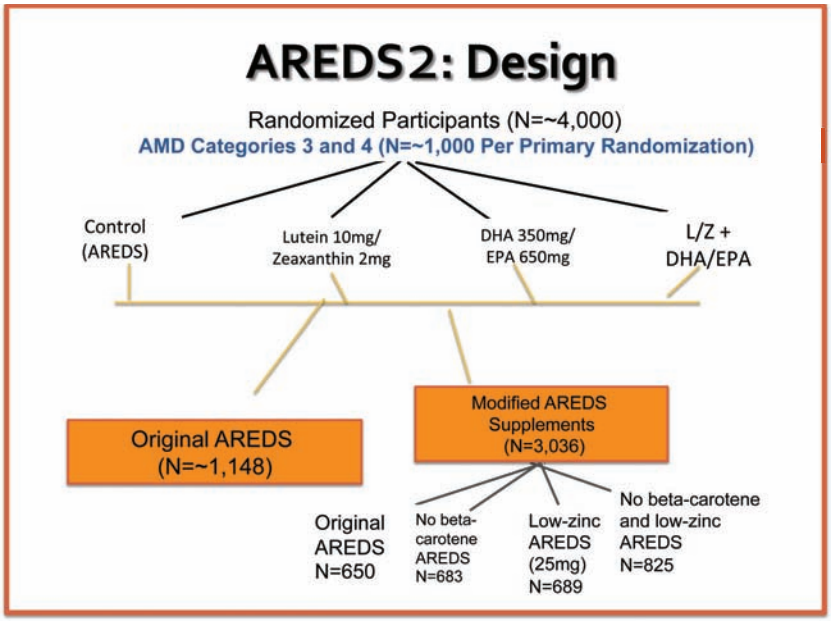

• In another subgroup, patients in the lowest quintile of dietary intake for L/Z exhibited a 26% reduction in progression toward advanced AMD. Hence, the researchers determined that patients who would benefit the most from L/Z supplementation are those with the lowest dietary intake levels of L/Z.

• Omega-3 fatty acid supplementation did not yield a statistically significant reduction in the progression of AMD.

• Regarding adverse effects, there were no differences in mortality across all groups. Additionally, a subgroup analysis revealed that there were no differences in genitourinary tract infection incidence between the low- and high-zinc groups. However, beta-carotene supplementation was shown to double the risk of lung cancer in former smokers.

• Overall secondary analysis of AREDS2 did not indicate any benefit of L/Z supplementation on cataract progression.

• Although serum levels of lutein increased two-fold among subjects in the L/Z groups, a subgroup analysis showed that the increase was tempered when L/Z was given simultaneously with an AREDS formula that contained beta-carotene.

The Initial Verdict

The AREDS2 results suggest that lutein and zeaxanthin have a role in AMD management, and should replace beta-carotene in the original AREDS formula. With regard to omega-3 fatty acids, perhaps eye care providers should evaluate individual needs before recommending supplementation. Further studies that more directly scrutinize the effects of these nutritional supplements will clarify their true impact on AMD progression.

It is important to remember that our role as eye care providers also should include a proactive approach, ensuring decreased disease prevalence and progression. It is our duty to take preventive measurements whenever possible. So, patient management should emphasize counseling with regards to appropriate diet and nutrition. Although this was not the assessed in AREDS2, the eye care provider should consider proper supplementation (such as carotenoids) for at-risk or early-stage patients when deemed necessary.

Further analysis of the AREDS2 data could provide more specific information and potentially signify the advent of a new era in personalized medicine. Going forward, decisions on proper patient management may be made on an individual basis—and may even include genetic testing. ■

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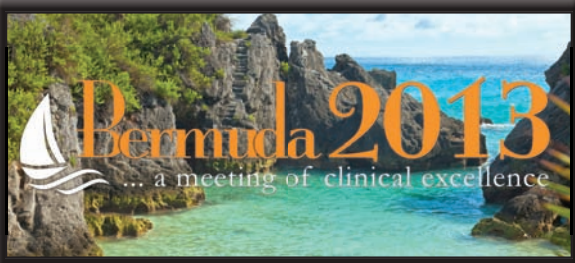

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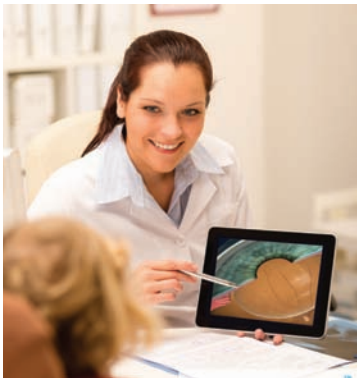

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The service is free for both professionals and students, but registration is required. Users can log in with their current website login information or register directly within the app.

Visit www.therightcontact.com.

Digital Measurement Device

Shamir SPARK

Using the iPad camera, the new SPARK 3D measuring tool from Shamir automatically calculates all frame measurements based on one picture.

The device fits over an iPad and requires users to download Shamir's app onto their iPad. It doesn't require any additional artificial light sources and eliminates the need for bulky measuring clips.

SPARK (Single-shot Panorameter Augmented Reality Kit) replaces Shamir's previous Panorameter Kit, a manual measurement tool that determined panoramic angle, pantoscopic tilt and vertex distance. This new device takes all of those measurements as well as the fitting height, mono PD, HBOX, VBOX and DBL with one picture.

Visit www.shamirlens.com.

Eyewear Accessories

Ficklets Eyewear Charms

If you're looking for a way to make your pediatric patients more excited about wearing glasses, Ficklets interchangeable eyewear charms may do the trick. Creator Ros Guerrero came up with the idea to make her daughter feel more comfortable and confident in her glasses. It's also a money saver for families—allowing kids to give their frames a fresh, updated look without buying a whole new pair of glasses. But these little add-ons can increase profit for the optical, too, with the right placement and promotion.

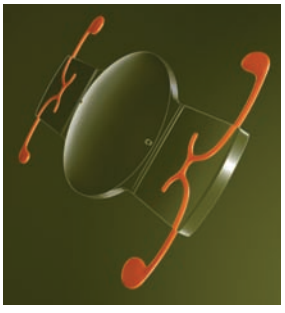
Derived from the word "fickle," Ficklets allow patients to accessorize and personalize any pair of eyeglasses. With more than 100 charm styles, Ficklets come in a variety of shapes, colors and themes—including sports, animals and even holidays—that allow kids to make their own fashion statement with their glasses. They can be mixed, matched, doubled-up and added to the temple or even the nosepiece of the glasses.

Visit www.flickets.com.

Intraocular Lenses

Trulign Toric

Bausch + Lomb recently received FDA approval for the Trulign Toric posterior chamber intraocular lens, a toric IOL that corrects for astigmatism and has the additional capacity to deliver improved vision across a natural range of focus. It demonstrated improved uncorrected near, intermediate and distance vision in FDA clinical trials.



The Trulign Toric IOL is best suited to patients who have astigmatism and wish to have improved uncorrected near, intermediate and distance vision after cataract surgery. The unique haptic design provides excellent rotational stability, with 96.1% of lenses rotating less than 5° from the day of surgery to four to six months post-op, according to study results.

The Trulign Toric lens is available in cylindrical powers of 1.25D, 2.00D and 2.75D (at the IOL plane), and can correct astigmatism between 0.83D and 2.50D.

Visit www.bausch.com.

Diagnostic Technology

Octopus/Optovue Bundle

Haag-Streit USA and Optovue have joined forces to bundle Haag-Streit's Octopus perimeter with Optovue's optical coherence tomography (OCT) technology. The Octopus 900, a 90° full-field projection

perimeter, allows for testing in all levels of disease—early detection, tracking progression or performing the most sensitive examinations at the end stage of disease.

RTVue was the first FDA-cleared spectral-domain OCT launched in the US, and also the first OCT device approved for both corneal and retinal imaging. The iVue is the compact version of the RTVue OCT, offering the same scanning speed and resolution as the larger system—which includes scanning and reports for retina, retina nerve fiber and cornea assessment by the clinician.

Optovue will be responsible for sales, installation and training of the combined Octopus/OCT offering in the US, and Haag-Streit will handle ongoing clinical support and technical service.

Visit www.haag-streit-usa.com or www.optovue.com.

Cosmetics for Sensitive Eyes

Zoria Boost

Zoria Boost Lash Intensifying Serum is the first in Ocusoft's new line of cosmetic products for sensitive eyes. The line will provide practitioners with a wider range of offerings to complement fashion frames, contacts, blepharoplasties and botulinum toxin injections.

Featuring polypeptide technology developed by ophthalmologist and biochemist Lili Fan, MD, Zoria Boost naturally enhances and supports the eyelash growth cycle for dramatically longer, fuller and darker-looking eyelashes, the company says. It is safe for contact lens wearers and those with sensitive eyes.

Through an exclusive distribution agreement between Ocusoft and Dr. Fan, Zoria Boost will be marketed to and distributed by eye care professionals without a prescription. Also available in the cosmetics line is Zoria mascara—a flake-free, hypoallergenic formula for sensitive eyes—as well as Zoria make-up remover and facial skin cleanser.

Zoria Boost will be offered through Ocusoft's new skin care division and may be ordered online or from your local Ocusoft representative.

Visit www.ocusoft.com. ■

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

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EXPRESSION OPAQUE-PLANO	21.95	20.95	**19.95**
NEW LOWER PRICE! FREQUENCY 55% & ASPHERICS	14.95	12.95	**10.95**
PROCLEAR 8.6 & 8.2	22.92	21.00	**19.25**
PROCLEAR 1 DAY 90 PACK	38.95	37.50	**36.50**
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Meetings + Conferences

June 2013

■ **26-30.** *Optometry's Meeting.* San Diego Convention Center, San Diego. Hosted by: American Optometric Association and American Optometric Student Association. To register, call (866) 229-3691 or visit www.optometrysmeeting.org.

July 2013

■ **1-5.** *CE in Belize 2013.* Belize Yacht Club Resort & Marina, Ambergris Caye, Belize. Hosted by: International Academy of Optometry. Meeting chair: Edward Paul, OD, PhD. CE hours: 16. Contact Elizabeth Cramond at elizabeth.landfalleye@gmail.com or (910) 256-6364. visit www.CEinBelize.com.

■ **10.** *2013 Summer Continuing Education.* Time: 9:00 a.m. to 4:30 p.m. The Breakers by the Ocean, Spring Lake, NJ. Hosted by: New Jersey Society of Optometric Physicians. Featured speakers: Carlo Pelino, OD, and William Potter, OD. CE hours: 7. Visit www.njsop.org.

■ **10-14.** *45th Annual NOA Convention.* Loews New Orleans Hotel, New Orleans, La. Hosted by: National Optometric Association. Visit www.nationaloptometricassociation.com or call (877) 394-2020.

■ **11-13.** *2013 International Vision Conference.* Manchester Grand Hyatt, San Diego. Sponsored by: OD Excellence. CE hours: 17. Contact Johanna Lieblein at info@odexcellence.com. Visit www.odexcellence.com.

■ **17.** *2013 Summer Seminar.* Ritz Charles, Carmel, Ind. Hosted by: Indiana Optometric Association. Featured speakers: Milton M. Hom, OD, Leo P. Semes, OD, and James E. Hunter, OD. CE hours: 7. Visit www.ioa.org/2013-summer-seminar.html.

■ **17-20.** *5th World Glaucoma Congress.* Convention Centre, Vancouver. Hosted by: World Glaucoma Association and Optometric Glaucoma Society. Visit www.worldglaucoma.org.

■ **18-21.** *23rd Annual Victoria Conference.* Delta Ocean Pointe Resort, Victoria, British Columbia. Presented by: Pacific University College of Optometry. Visit www.pacificu.edu/optometry/ce/.

■ **25-27.** *Northern Rockies Optometric Conference.* Snow King Resort and Conference Pavilion, Jackson Hole, Wyo. Featured speakers: Jerry Sherman, OD, Jack Schaeffer, OD, Jay Henry, OD, Philip Gross, OD, and Stuart Richer, OD. Email director@nrocmeeting.com or visit www.nrocmeeting.com.

■ **25-28.** *Bermuda 2013.* Fairmont Hamilton Princess, Bermuda. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, OD. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

■ **26-27.** *2013 Gold Coast Summer Conference.* Hilton Sandestin Resort, Destin, Fla. Sponsored by: Alabama Optometric Association and UAB School of Optometry Alumni Association. Visit www.alaopt.org.

■ **26-28.** *Nova See St. Simons.* The King and Prince Beach & Golf Resort, St. Simons, Ga. Sponsored by: Nova Southeastern University College of Optometry and Luxottica. CE hours: 17. Contact Vanessa McDonald, manager of continuing education, at oceaa@nova.edu. Visit http://optometry.nova.edu/ce.

August 2013

■ **1-4.** *2013 Annual Continuing Education Conference.* Wedgewood Resort, Fairbanks, Alaska. Hosted by: Alaska Optometric Association. Email akoa@alaska.com or call (907) 770-3777. Visit www.akoa.org.

■ **2-3.** *Summer Education Event.* Blue Harbor Resort, Sheboygan, Wis. Hosted by: Wisconsin Optometric Association. Email joleen@woa-eyes.org or call (608) 824-2200. Visit www.woa-eyes.org.

■ **3-4.** *Colorado Vision Summit.* Crowne Plaza Hotel Denver International Airport, Denver, Colo. Hosted by: Colorado Optometric Association. Visit www.coloradovisionsummit.org or call (303) 863-9778.

■ **3-5.** *Annual Educational Retreat 2013.* South Seas Island Resort, Sanibel, Fla. Hosted by: Southwest Florida Optometric Association Inc. CE hours: 14. Contact Brad Middaugh, OD, at swfoa@att.net or (239) 481-7799. Visit www.swfoa.com.

■ **18.** *Super Sunday 2013.* NSU Orlando Campus. Hosted by: Nova Southeastern University College of Optometry. Faculty: Paul Chous, OD, MA, and Kimberly Reed, OD. CE hours: 8. Contact Vanessa McDonald at oceaa@nova.edu or (954) 262-4224. Visit http://optometry.nova.edu/ce.

■ **22-25.** *106th SCOPA Annual Meeting.* Myrtle Beach Marriott Resort & Spa at Grand Dunnes, Myrtle Beach, SC. Hosted by: South Carolina Optometric Physicians Association. CE hours: 21. Visit http://southcarolina.aoa.org.

September 2013

■ **8-9.** *Northeast Optometric Congress.* Westford Regency Inn and Conference Center, Westford, Mass. Email Kathleen Prucnal, OD, at drkaprucnal@msn.com or visit www.oepf.org.

■ **19-21.** *Envision Conference.* Hyatt Regency Minneapolis, Minneapolis, Minn. Email info@envisionconference.org or call (316) 440-1530. Visit www.envisionconference.org.

■ **19-22.** *GWCO Congress 2013: Focused on the Future.* Oregon Convention Center, Portland. Hosted by: Great Western Council of Optometry. Featured speaker: Jim Trunick, OD. Contact Wayne Oman, deputy director, at gwco@gwco.org or (503) 654-1062. Visit www.gwco.org.

■ **20-22.** *New Technology & Treatments West Coast 2013.* Marriott Del Mar, San Diego. Hosted by: *Review of Optometry.* Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

■ **20-22.** *44th Annual Colorado Vision Training Conference.* YMCA of the Rockies, Estes Park, Colo. Contact Jamie Anderson, OD, FCOVD, (303) 325-2019 or jamie@highlinevisioncenter.com. Visit www.visioncare.org.

■ **21-22.** *Fall Conference 2013.* Steele Auditorium, NSU Campus, Orlando, Fla. Hosted by: Nova Southeastern University College of Optometry. Program Director: Joseph Sowka, OD. Contact Vanessa McDonald at oceaa@nova.edu. Visit http://optometry.nova.edu/ce.

■ **22.** *CE Forum XVII.* The Hotel Hershey, Hershey, Pa. Hosted by: Central Pennsylvania Optometric Society. CE hours: 6. Email Mary Good, OD, at cposrsvp@gmail.com.

October 2013

■ **2.** *6th Annual Prevent Blindness America Swing Fore Sight Golf Tournament.* Bali Hai Golf Club in Las Vegas. Contact Danielle Disch at ddisch@preventblindness.org or (312) 363-6022. Visit preventblindness.org/swingforesight.

■ **2-5.** *International Vision Expo & Conference West 2013.* Sands Expo & Convention Center, Las Vegas. Call (800) 811-7151 or visit www.visionexpowest.com.

■ **6-7.** *SECO London 2013.* Hosted by: SECO International and the Association of Optometrists. CE hours: 12. Visit www.secointernational.com/london-2013.html.

■ **8-12.** *COVD 43rd Annual Meeting.* Rosen Shingle Creek, Orlando, Fla. Hosted by: College of Optometrists in Vision Development. Visit www.covd.org or call (330) 995-0718.

■ **10-11, 11-13.** *VOSH International Meeting/COPR Annual Conference.* Ritz Carlton Hotel, San Juan, Puerto Rico. Hosted by: VOSH International and Colegio De Optómetras de Puerto Rico (COPR). Visit www.covd.org or call (330) 995-0718.

■ **12-13.** *3rd Annual Forum on Ocular Disease.* WDW Swan and Dolphin Resort in Orlando, Fla. Hosted by: PSS EyeCare. CE hours: 18. Contact Sonia at education@psseyecare.com or go to www.PSSeyecare.com and click on "Orlando."

■ **19-21, 23-25.** *CE in Italy: Florence and/or Castiglion Fiorentino, Tuscany.* To register for one or both of these programs, contact James Fanelli, OD, at jamesfanelli@ceinitaly.com or call (910) 452-7225. Visit www.ceinitaly.com.

■ **23-26.** *Academy 2013 Seattle.* Washington State Convention Center, Seattle. Hosted by: American Academy of Optometry. Visit www.aaopt.org/meetings/academy2013.

November 2013

■ **22-24.** *New Technology & Treatments East Coast 2013.* Westin, Alexandria, Va. Hosted by: *Review of Optometry*. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences. ■

To list your meeting, please send the details to:

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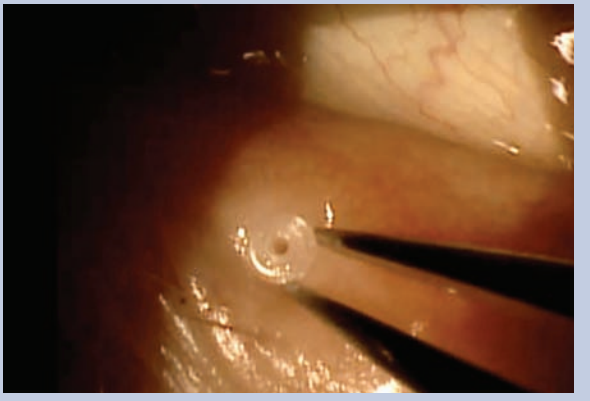
Advertisers Index


The Resurgence of Punctal Occlusion

Don't call it a comeback, but this modality has gained prominence of late—especially as ODs perform more post-op care.

By Derek N. Cunningham, OD, and Walter O. Whitley, OD, MBA



Go to www.revoptom.com or scan the QR code at left to see video footage of the procedure.

On The Web ›› View a narrated video of a punctal plug insertion procedure.

Although it seems that plugs are not discussed as frequently these days, punctal occlusion continues to be a mainstay option for patients with ocular surface inflammatory diseases like dry eye, allergy and blepharitis once the inflammation is controlled. Other considerations for punctal occlusion include contact lens wearers with complaints of dryness, acute corneal conditions, glaucoma, and cataract and refractive surgery.

Not commonly considered a surgery, punctal occlusion is indeed a minor surgical procedure. Diagnoses that support its medical necessity include tear film insufficiency, superficial keratitis, keratoconjunctivitis sicca and rheumatoid arthritis.

The question remains: Where did all the plugs go? Traditionally, punctal occlusion had been a frequently used second-line treatment (after artificial tears) for patients suffering from dry eye disease. Results were often variable, with some patients showing vast improvement in symptoms while others felt the plugs made no difference at all. As we learned more about the role of inflammation as the underlying cause of dry eye disease, use of anti-inflammatory and immunomodulating medications became the mainstay of therapy, eclipsing punctal occlusion in many cases. According to the ITF guidelines, punctal plugs should be considered for Severity Level 3, along with tetracyclines. On the other hand, the Dry Eye Workshop report suggests that plugs may be beneficial in earlier stages of the disease.

There are several types of plugs, varying by design, duration, location, size and material. Temporary canalicular collagen plugs dissolve in one week. Semi-permanent canalicular plugs, made from either acrylic or silicone material, last for several months. Partial occlusion can be performed with silicone punctal plugs that have a fenestrated central area to allow the passage of some tears. Lastly, permanent occlusion can be performed with silicone material and inserted into the canaliculus or punctal area. Another alternative for permanent occlusion is thermal cautery.

With the exception of cauterization, punctal occlusion is reversible. Regarding most types of plugs, the safety profile is very high; epiphora, conjunctival irritation and extrusion typically are the most common—yet infrequent—complications.

Other rare complications include canaliculitis and dacryocystitis, which are caused by common bacterial pathogens, such as *Actinomyces israelii*, *Staphylococci*, *Streptococci* and diphtheroids. In the event of complications, patients may require plug removal as well as anti-inflammatories and antibiotics. Rarely, surgical removal of plugs is indicated.

Patient education is important whenever discussing treatment options for dry eye disease. Stress to patients that punctal occlusion is safe, quick, reversible and widely performed; however, it will not cure their disease. Inform patients why you are performing temporary (diagnostic) vs. permanent occlusion along with the risks, benefits and alternatives to the procedure. For those on topical therapy, explain that plugs may help increase the contact time of medications, will help them retain their natural tears, and will not interfere with their normal tear production. ■

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Diagnostic **Quiz**

Three Months, Three Problems

By Andrew S. Gurwood, OD

History

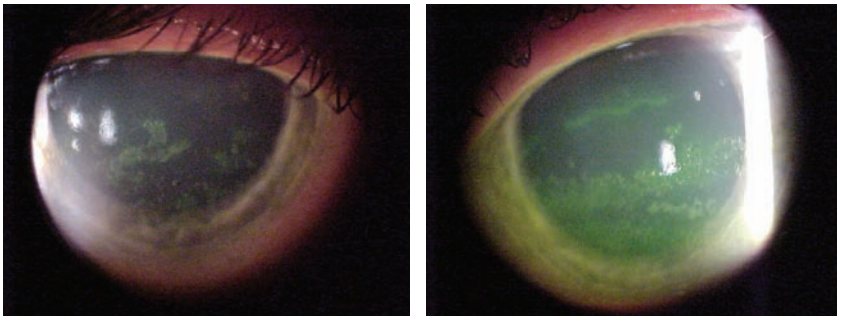
A 27-year-old black female presented following an ER visit for a chief complaint of a painful left eye, which had persisted for one hour. The patient explained that this had happened twice before—both times upon waking in the morning.

Further, she informed us that these episodes seemed to begin following a fingernail injury to her left eye three months earlier. She had no contributory systemic history, and no known allergies.

Diagnostic Data

Her best-corrected visual acuity was 20/20 OD and 20/40 OS at distance and near. External examination findings were normal, with no evidence of afferent pupillary defect in either eye.

Her intraocular pressure measured 14mm Hg OU. The dilated fundus examination was normal. The pertinent biomicroscopic examination findings are illustrated in the photographs.



Slit-lamp images of our 27-year-old patient (OD left, OS right) who presented emergently with a painful left eye. What is your diagnosis?

Your Diagnosis

How would you approach this case? Does the patient require any additional testing? What is your diagnosis?

How would you manage or treat this patient? What is the likely prognosis?

To find out, please visit www.revoptom.com. Click on the cover icon for this month's issue, and then click "Diagnostic Quiz" under the table of contents. ■

Thanks to Marc D. Myers, OD, of Coatesville, Pa., for contributing to this case.

Retina Quiz Answers *(from page 87):* 1) d; 2) d; 3) b; 4) b; 5) d.

Next Month in the Mag

Our July issue features the 19th Annual Glaucoma Report. Topics include:

- *Does Normotensive Glaucoma Really Exist?*
- *Rho-kinase Inhibitors for Glaucoma: What Will They Offer?*
- *A Look at Microinvasive Glaucoma Surgery*
- *Optometric Study Center: OCT Imaging for Glaucoma—What Does it Reveal?* (earn 2 CE credits)

Also in July:

- *What's New in Toric Soft Lenses?*

And...

- Don't miss the *Ophthalmic Product Guide* and the *Annual Contact Lenses and Lens Care Guide*.

Feedback

Review of Optometry welcomes questions and comments. E-mail Jack Persico, editor-in-chief, jpersico@jobson.com, with "Letter to the Editor" as the subject line.

Or, write to *Review of Optometry*, 11 Campus Blvd., Suite 100, Newtown Square, PA 19073.

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References
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