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AREDS2 results in

Omega-3 fatty acids did not reduce risk of advanced AMD

By Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Data from the Age-Related Eye Disease Study 2 (AREDS2), recently published in *The Journal of the American Medical Association*, were released last month at the Association of Researchers in Vision and Ophthalmology (ARVO) meeting in Seattle.

Study results showed that adding omega-3 fatty acids DHA and EPA or lutein and zeaxanthin to the original AREDS formula (see "Study Stats," right) did not reduce the risk of advanced age-related macular degeneration (AMD). However, adding lutein and zeaxanthin and removing beta-carotene slightly reduced the risk of advanced AMD.

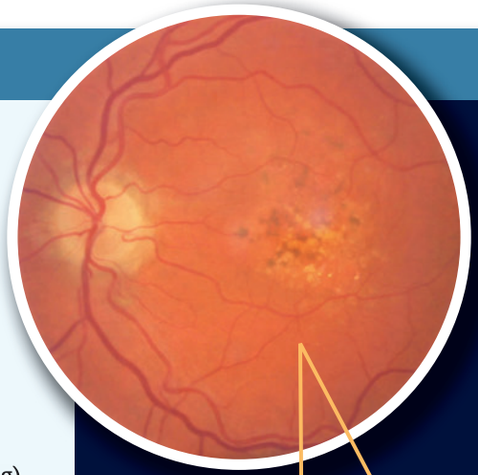
Says Leo Semes, OD, professor of optometry at the University of Alabama-Birmingham School of Optometry: "The substitution of the lutein and zeaxanthin in the 5-to-1 proportion for the beta-carotene seemed to be of benefit. That ought to be the focus for research in the future, and optometrists should focus on this in patients who are at risk. They are patients who are older, with more advanced AMD, and not getting dietary proportions of zeaxanthin and lutein as they should. Those with low levels of zeaxanthin and lutein seemed to benefit most."

Dr. Semes is surprised that omega-3 fatty acids didn't show any benefit. "I saw some preliminary results that suggested they might be of benefit against central atrophy," he said, "but there didn't seem to be any loud and clear message that omega-3s are something to recommend to patients. Of course, patients who take them because of cardiovascular risk should certainly continue. There is a closer link being established between AMD and cardiovascular disease, so there might be some study in the future that looks specifically at that, but we don't get that guidance from AREDS2."

See **AREDS2** on page 5

STUDY STATS

- **5-year duration**
- **4,203 subjects**
- **Subjects aged 50-85 years**
- **Randomized to 1 of 4 formulas:**
  1. Original AREDS formula:
     —500 mg vitamin C
     —400 IU vitamin E
     —15 mg beta-carotene
     —80 mg zinc
     —2 mg copper
  2. AREDS minus beta carotene
  3. AREDS low zinc (25 mg instead of 80 mg)
  4. AREDS minus beta carotene, zinc
- **Randomly assigned to also receive:**
  1. 10 mg lutein + 2 mg zeaxanthin
  2. 1,000 mg omega-3 fatty acids (DHA, EPA)
  3. 10 mg lutein + 2 mg zeaxanthin + 1,000 mg omega-3 fatty acids
  4. Placebo



AREDS2 study take away
The new formula will provide protection to older patients with **advanced AMD** (above) who are lutein- and zeaxanthin-deficient in their diet. Omega-3 fatty acids didn't show any benefit.

Oregon's HB 3000 poised for passage

By Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

At press time, Oregon's House Bill about vision screenings for students (HB 3000) is scheduled for a vote by the House Ways and Means Committee. It is expected to pass. Prior to going before the full Ways and Means Committee, the Ways and Means Subcommitte on Education passed an amended bill.

"This bill requires public school students aged 7 years or younger to have an eye examination or vision screening prior to entering school," says Jim Hale, OD, immediate past president of the Oregon Optometric Physicians Association.

The amended bill allowed families to avoid the eye exam or screening requirement for religious reasons.

Says Dr. Hale: "The current estimate is that this bill will cost the state of Oregon $20,000 per year. The long-term cost savings to the education of children who need vision correction will outweigh the cost to taxpayers."

HB 3000 will move to the House and Senate floors for approval if passed by the full House Ways and Means Committee.**ODT**

INSIDE: Special Section
EHR
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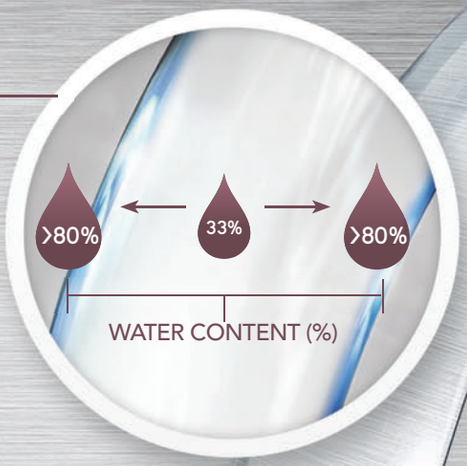
UNIQUE WATER GRADIENT



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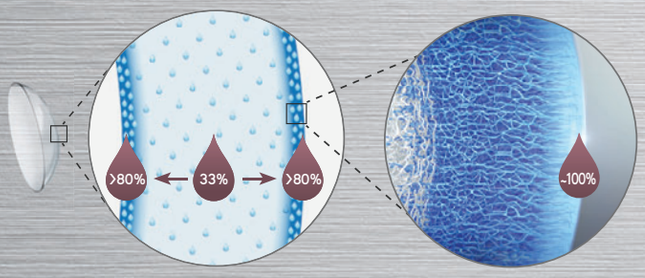

Contact Lens Cross-Section

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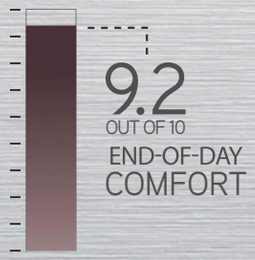

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1. Based on the ratio of lens oxygen transmissibilities among daily disposable contact lenses. Alcon data on file, 2010.
2. Based on critical coefficient of friction measured by inclined plate method; significance demonstrated at the 0.05 level. Alcon data on file, 2011.
3. In a randomized, subject-masked clinical study, n=40. Alcon data on file, 2011.
4. Angelini TE, Nixon RM, Dunn AC, et al. Viscoelasticity and mesh-size at the surface of hydrogels characterized with microrheology. ARVO 2013;E-abstract 500, B0137.

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Optometry Times is an optometry-driven publication that disseminates news and information of a clinical, socioeconomic, and political nature in a timely and accurate manner for members of the optometric community.

In partnership with our readers, we will achieve mutual success by:

- Being a forum for optometrists to communicate their clinical knowledge, insights, and discoveries.
- Providing management information that allows optometrists to enhance and expand their practices.
- Addressing political and socioeconomic issues that may either assist or hinder the optometric community, and reporting those issues and their potential outcomes to our readers.

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AREDS2

Continued from page 1

Cover: Photo courtesy of Leo Semes, OD, FAAO

Dr. Semes also believes the message to consumer media is misleading and cautions optometrists to be prepared for questions from patients. "They're saying that the study provides clarity for the protection against eye disease," he says. "I don't think that clarity emerges. In fact, it's somewhat the opposite. There are a number of arms in the study with differing outcomes. The big take-home message from this study is that if you're lutein- and zeaxanthin-deficient in your diet, you have advanced AMD, and you're older, then this new supplement formula is going to provide a little protection. I don't think the interpretation should be that there's any preventive benefit here. That's very significant."

Although lutein and zeaxanthin appear to be the major drivers for positive outcomes in the AREDS2 study, they did not show any reduced risk of cataract progression, similar to the results of the original AREDS study.**ODT**

Letters

To the Editor

Charging for services

Thanks for Dr. Bowling's editorial about customer service ("Customer service is all about the service," April). One question I have is whether we should be charging everyone for adjustments and minor repairs, not just the online buyers. I suppose that the dealer where you bought the pickup charges for every little thing they do, and they already made a bundle on the purchase. We, on the other hand, make very little on occasion (VSP and other plans), yet are expected to provide free service after the sale.

We currently don't charge for anything—even new nose pads or temple covers—but your editorial has me thinking! Many people ask how much it costs after a repair, and are often surprised when we say, "No charge." Maybe they value our services more than we do!

Michael Spino, OD
Delmont, PA

Primary care helps patients

"Primary-care optometry in the 21st century," by Dr. Michael Ohlson in the May issue, presents the expectations of both an optometrist and a patient who may seek care. The optometrist must prepare fully and apply to practice rapidly expanding knowledge to provide proper care. The OD is often the only healthcare provider seen by a patient over a period of years or perhaps ever. The case history starts as the patient enters the office. Because difficulties with vision many have many etiologies, the OD advises the patient of health issues recognized during the examination, and in particular, those that require care of other modalities. The responsibility is no less than as with other practitioners. This is the optometry Dr. Ohlson preaches, and more important, practices.

Thank you for publishing this well written, succinct article. I hope you will reference it in your other publications.

Albert Nemiroff, OD, FAAO Emer.
Panama City, CA

Share with MDs

I just finished the primary care article by Michael Ohlson, OD. Providing a copy of this article as an example of today's optometric eye care and education would go a long way in answering Dr. Bithika Kheterpal's reservations about optometric quality of care. I wish I had a copy of this article each time an ophthalmologist questions the extent of our education and the quality of our care.

Good work, Michael!

Randall N. Reichle, OD, FAAO
Houston, TX

Required reading

Dr. Mike Ohlson's article about primary care and systemic disease is such a good comprehensive review of all facets of eye care within the larger total body health system that it ought to be required reading for all medical school students, regardless of their specialty, all pharmacists, dentists, dietitians, nurses, and prospective optometry students. Oh, what the heck, health insurance company executives ought to read it too.

Jay Petersma, OD
Johnston, IA

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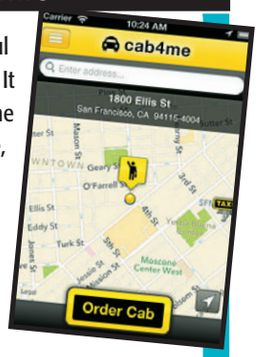

Cab4Me is very helpful for frequent travelers. It allows you to locate the nearest taxi anywhere, anytime. It features a map of wherever you happen to be, and a balloon pops up for you to order a cab through the app. It is especially valuable if you arrive late in a city and there no cabs at the airport or train station.

—Sherry Bass, OD, New York City

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Send your comments to gbailey@advanstar.com.
Letters may be edited for length or clarity.

Pain and gain

Ernest L. Bowling, OD, MS, FAAO,
Chief Optometric Editor

In this issue is an excellent article by Dr. Zach McCarty that discusses Meaningful Use and the need for optometrists to comply with the mandatory EHR guidelines by 2014. In his piece Dr. McCarty noted that, as of his writing, only 3,500 or so ODs had registered for meaningful use. Now, that number isn't surprising since we are a procrastinating lot by nature. I have to admit that I, too, fell in that category.

We've all known that we would have to confront our delays regarding EHR at some point, but there has just been so much going on. *Office fires to put out every day. I just don't have the time. Too much paperwork to complete. Letters to write. Bills to pay. Not enough hours in the day. The staff will balk. Computers will confuse our patients. And I really need to have that root canal…*

What *really* inspired our office to explore EHR wasn't the incentives offered by CMS for implementing EHR. It was the fact that we were drowning in paper. Within a short time, we would have needed to expand our filing capacity yet again to hold all the paperwork. It had to stop, so we began exploring what was available electronically.

Being new to this process, I didn't want to sink a lot of money into this system if it didn't suit our needs. However, from my experiences in years past, I knew what I wanted. It goes without saying that my needs are probably very different from someone else's, but every practice owner should develop his or her own "wish list." First, I wanted a cloud-based system, one that didn't require manual backup every day. We also needed a system with a very short learning curve. The harder a system is to implement, the more frustrated you, and more importantly your staff, will grow. For that reason, I wanted something that would run on an iPad because tablets are an amazingly easy technology to learn. I also didn't want to have to stare at a fixed computer screen at my work desk. Having experience with those set-ups, I think they take away from my patient interaction. I catch myself staring too much at the screen and not spending enough time talking with my patient. I wanted something that was portable and convenient, and I wanted it to be reasonably priced. Perhaps most important, we needed a system that had outstanding customer service. Being neophytes to EHR, we needed a provider that would be patient with us and answer all our questions promptly, because when you have a question you need it answered pretty quickly or else things get backed up in a hurry. This was the most frustrating aspect of my initial foray into EHR, and one I vowed not to repeat. The system also could not slow down the exam process; I don't have time in the middle of a busy day to hunt and peck on a computer keyboard. In my research, one doctor listed this as his main criteria: The EMR data entry could not slow down his exam process one iota.

So, after much online research and talking with colleagues, we decided on a platform. After using the system for a while now, I'm certain it is slowing down my exam process somewhat, but my staff considers it an even tradeoff because they can finally read what is on the exam form. I have to admit the adaptation process has gone much better than expected, probably because most people these days are much more comfortable working with computers than they were a decade ago. That's not to say there haven't been hiccups; there have. The changeover naturally forces you out of your comfort zone, and change can be painful. Yet this technology has so much to offer us, and the integration of these systems is amazing. So, we're trying to join the 21st century in our little office, even if we are kicking and screaming the whole way.

How has your office approached EHR? I'd be interested in hearing your experiences implementing the technology. Feel free to drop me a line at drbowling@windstream.net.**ODT**

Calling all students and residents

Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Students and residents, are you interested in writing for *Optometry Times*? I'd love to see your paper!

Optometry Times is very interested in publishing student and resident papers. I've published three so far in 2013, with the third appearing in this issue. See pg. 28 for the recently anointed Dr. Nick Gubler's take on social media for ODs. Resident Dr. Rim Makhlouf wrote, along with Dr. Joe Sowka, our Special Section piece on secondary glaucomas in the January issue, and student Sara Heikali shared her entrepreneurial view on optometric practice in the February issue.

Write up a case report. Talk about an interesting day in clinic. Share your views on the future of optometry. Discuss a struggle you're having in making a career choice. Outline the reasons why optometry is a great healthcare profession. Wax poetic on that great new contact lens/glaucoma drop/spectacle lens/piece of equipment you just tried. Or even send me something you're working on for a class.

I can give you 5 great reasons to contact me about publishing your paper.

1. *It's great experience.* No, really…it is. Writing for publication is an important skill to learn. I can guide you through the process, along with my colleagues Dr. Ernie Bowling, chief optometric editor, and Dr. Kathy Mastrota, associate optometric editor. Knowing how to write for publication can pay you big dividends down the road in your career.

2. *Plump up your CV now.* Adding published articles early to your CV helps you look good for residency or other graduate school applications. You'll also need a CV for American Academy of Optometry Fellowship or Diplomate consideration, for example, or other industry professional organizations. What about when you are looking to become an associate or partner in practice? Or decide to move into academia? Whatever your professional goals, a well-rounded CV will help. *Optometry Times* can get you started.

3. *Impress your professors or mentors.* Imagine showing them an issue of *Optometry Times* with your article! Better yet, ask your professor or mentor to author with you. Big brownie points.

4. *Big money.* OK, not big money. Good money? Nah, not even that. Enough to feed you for a (short) while.

5. *Bragging rights.* I can't overestimate how important this reason is. Show your mom! And your grandmother! And if you ask nicely, I'll even mail you an extra copy or two for them.

E-mail me at gbailey@advanstar.com or call me (215/412-0214) to talk about how to get started. *Optometry Times* is one of the voices of the profession. We'd like to add you to the chorus.**ODT**

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How many schools are too many?

Two of the most discussed matters in our profession today are the number of new schools opening and whether the increasing number of graduating ODs will add to the perceived oversupply of ODs.

There are 21 optometry schools, public and private, with another proposed school in Virginia tentatively scheduled to enroll its first class in 2014. Four new schools have enrolled students in the past few years; some of those schools are now graduating their first classes.

According to the Association of Schools and Colleges of Optometry (ASCO), in 2012 the 21 current schools had 2,545 individuals apply for the 1,797 first-year spots available. For the 2011-2012 academic year, a total of 6,289 students enrolled in the 20 schools operating then. That represented a 14.6% increase in total enrollment since 2006.[1] With the opening of the two new schools, that number will increase by about 112 students per academic year for a total of about 6,737 optometry students once the two newest schools enroll all four class years. In 2011, there were 1,308 graduates.[1] When all 22 schools start graduating students, that number could easily exceed 1,600 per year, a 22% increase in graduates per year compared with 2011. In 2008, there were 34,800 practicing ODs, and, at the present rate of growth, the projection is 43,200 practicing ODs by 2018, a 24% increase in 10 years.[2]

Several concerns regarding the schools:

- Increasing the applicant pool so schools are not pressured to accept marginally qualified students in order to fill classes
- The level of clinical experience schools will be able to provide to students
- Whether the schools will be able to obtain the necessary skilled teaching staffs.
- The amount of debt incurred by students.

If schools cannot meet the didactic and clinical education requirements for their students, or if schools accept marginally qualified students, we may see the National Board of Examiners in Optometry (NBEO) pass rates begin to decline or graduates barely being able to pass board exams. What effect will that have on the quality of graduates at a time when ODs are taking on a greater role in medical eye care?

According to the American Optometric Association (AOA) Research and Information Center, the average number of patients treated per week per OD in 2012 was 60, or 1.52 patients per hour.[2] Compare that with ophthalmologists who average 125 patients per week, according to Medscape.[3] When you also consider that most ODs now accept reduced exam fees for 61% of their patients[2] due to the prevalence of vision care plans, it has become more difficult to increase, let alone maintain, annual income levels.

With advanced technology and trained paraoptometrics in many OD offices, why is the average number of patients seen per hour so low? Are ODs that inefficient, or is the ratio of total ODs to the pool of patients so high that offices are underutilized? The assumption is that most ODs would easily be able to accommodate more patients per week than they currently see. If so, then the significant increase in total ODs due to the opening of more schools every year would indicate that there will be such a large oversupply of ODs in a few years that it could be detrimental to the health of the profession. The ability of new graduates to find good positions would become more difficult than it currently is.

Some people believe that the aging population, along with the effects of the Affordable Care ACT (ACA), will significantly increase the number of patients seeking care. However, considering that baby boomers—one of the largest groups that make up the older population—are already using eyecare services due to normal age-related eye conditions, that eliminates a significant group of new patients.

An argument could be made that the approximately 30 million people who will have coverage through state health insurance exchanges may already take advantage of the relatively inexpensive basic eye care available through various sources. Will that wave of new eyecare consumers materialize as some have predicted, or are these individuals already receiving care?

Too many schools?

Now for the main question: Are there too many schools graduating too many optometrists, which could cause harm to the profession?

The answer to that seems to be yes:

- Many new graduates are unable to find full-time work in one office, so they must work in 2 or 3 different offices to make a reasonable income.
- As ODs are forced to increase the efficiency and profitability of their practices by seeing more patients per hour in the face of increasing practice expenses and continued erosion of net income per patient, that will further increase the surplus of ODs. The adage, "Work harder to make less" will definitely come into play to a greater extent than it does today.
- As oversupply multiplies, more ODs will be forced to work in commercial positions, which could eventually lead to the profession becoming more like the retail pharmacy industry, where few independent practices exist. Unfortunately, in many commercially affiliated practices, the OD is discouraged from practicing full-scope care in favor of the production of eyeglasses and contact lens prescriptions. Patient care may suffer as a result.

Is there a solution to the problem of too many schools producing too many optometrists? Apparently, at this time there is not.

The AOA has not taken an official position on this issue, and neither has the Accreditation Council on Optometric Education (ACOE), which is responsible for the accrediting schools. Should accrediting standards, especially as they apply to student clinical experiences, be enhanced to make it more difficult to start a new school?

The only solution? Schools unable to find qualified applicants who can finish the curriculum and pass the NBEO exams to become licensed. The applicant pool may shrink dramatically if education becomes cost prohibitive, without the ability for graduates to earn an equitable income. How long will it be before we see optometry schools sued by their graduates for misleading them about job prospects after graduation, as we've seen happen with several law schools?

Only time will tell how this surplus of schools and ODs will affect the profession. Hopefully, some entity with the ability to deal with the problem, presumably the AOA, which has input to both the ACOE and ASCO, will step in before it is too late. At this time, the AOA is either unwilling or unable to step up. It will be interesting to see how the results of the AOA's manpower study are interpreted. **ODT**

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Author Info

Thomas Cheezum, OD, has been in private practice for 35 years in Chesapeake, VA. Dr. Cheezum is a past member of the American Optometric Association (AOA), the Virginia Optometric Association, and the Virginia Board of Optometry. He is currently treasurer of the American Optometric Society.

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When is enough too much?

One OD's perspective on glaucoma therapy

One of my favorite glaucoma patients is a 66-year-old white female with unilateral open-angle glaucoma OS. She moved to Augusta from the Midwest, loves my Georgia accent, and swears she's never shoveling snow again.

When I first saw the patient, I could tell immediately that her Chicago ophthalmologist's diagnosis was correct. OD was essentially unremarkable, with a healthy optic disc and low intraocular pressure (IOP). OS had undergone an argon laser trabeculoplasty (ALT), and she was taking Xalatan (latanoprost, Pfizer) qhs, Cosopt (dorzolamide and timolol, Merck) bid, and Alphagan P (brimonidine tartrate, Allergan) 0.15% tid in that eye. She really didn't like the tid drop because she wore multifocal contact lenses to play bridge during the day and hated having to remove her left lens during lunch. Her IOP OS was 10 mm Hg mid-afternoon. Her left optic cup was about 0.6 x 0.8 with a notch at 5:00, and her right optic cup was about 0.3 x 0.3 with healthy rim tissue. I took baseline dilated fundus photos and invited her to return in a week or two for baseline glaucoma testing, this time in the early morning.

At that visit, her IOP was 12 mm Hg OU, pachymetry values were average OU, and gonioscopy showed she was open to ciliary body with moderate pigment and a flat iris approach in all quadrants OU. Her OCT scans corresponded to her optic nerve appearance, with a dense inferior wedge defect OS and normal findings OD. Threshold visual fields matched these findings, with a dense superior arcuate scotoma OS and a full field OD.

I obtained her medical records and determined that the highest pre-treatment IOP measured was 28 mm Hg in the affected eye. I also found out that her three different drops were initiated at essentially the same time as her ALT—about 4 years prior to her visit with me. I instructed her to return in 2 months to recheck her IOP and visual field. I also asked her to move her second dose of Cosopt to late afternoon instead of bedtime. She complied and returned 2 months later with unchanged IOPs and a stable, repeatable visual field defect.

So I tried something different. I determined that she was getting an excellent IOP decrease (an almost 60% reduction from her pre-treatment IOP). I instructed her to discontinue Alphagan P and leave everything else the same. She returned in another 2 months with unchanged IOPs (around the same time of day). We plugged along for about a year like this, with her taking Xalatan qhs and Cosopt bid OS and me checking IOPs every few months at different points in the day. She loved me because she could wear her contact lenses uninterrupted during the day, and I never measured an IOP of more than 12 mm Hg.

A year later, her optic nerve appearance, visual field defect, and OCT scans were unchanged from my baseline. I decided maybe I could do her one better. I instructed her to drop down to qam on Cosopt, keeping her on Xalatan qhs. Just like before, her IOP didn't increase, and, just like before, we just kept plugging along. A year later, when there was no detectable structural or functional progression, I decided to see how she did without Cosopt. I instructed her to keep taking the Xalatan qhs OS and no other drops.

We've been going like this for 2 years, and I've never measured IOPs over 12 mm Hg at any point in the day or detected any structural or functional progression. She **loves** me, and I'm only now realizing what a quality-of-life change it's been for her to need only one drop at bedtime.

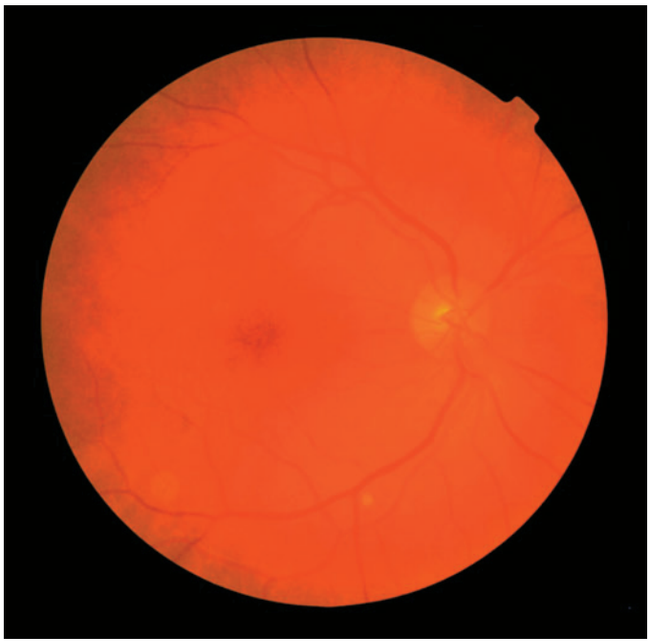
Several variables about this case warrant discussion. First and foremost is the fact that she very likely will not reap the benefits of her laser procedure forever. The time to 50% failure for ALT—and also selective laser trabeculoplasty (SLT)—tends to be around 2 years,[1] and we're almost a decade out on her. Is she currently gaining any IOP reduction from her ALT? Probably not much.

Secondly, was her previous doctor a little trigger-happy when he decided to give her an ALT and a prescription for three different drops at the same time? There are several individual patient factors afoot in light of this question. Take her age, for instance. We want to do everything we need to do in order to preserve her vision for the next 2 or so decades that she'll likely be alive. Do no harm, right? However, when I first saw her I detected obvious perimetric glaucoma, but I didn't see an optic cup of 0.99 with central vision threatened. If I did, I would have kept her on all three drops and would have likely obtained a consult with a glaucoma surgeon just for good measure (maybe we could get her IOP to 9 mm Hg instead of 12 mm Hg?).[2] I would argue that a stepwise approach to dealing with this patient's IOP would be acceptable. Many times in cases of suspected normal-tension glaucoma

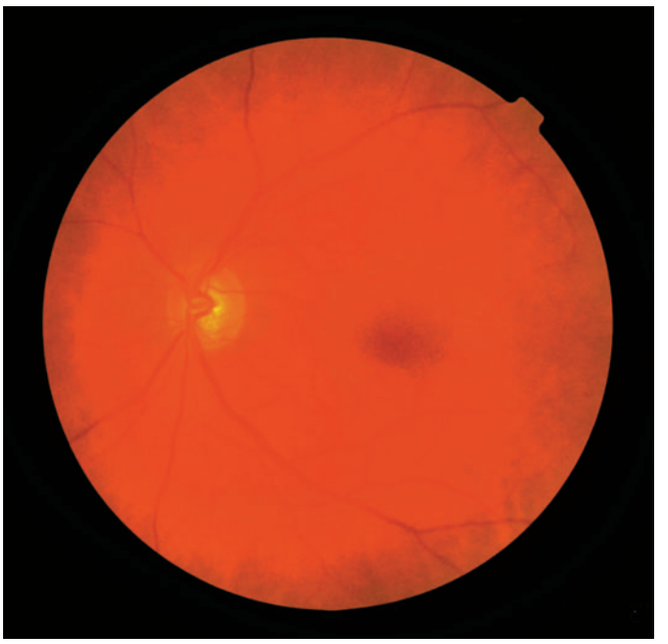
By Benjamin P. Casella, OD, FAAO
Dr. Casella, a 2007 graduate of University of Alabama at Birmingham School of Optometry, practices in Augusta, GA , with his father in his grandfather's practice. He is a member of Allergan's speakers' bureau.

VIDEO

Dr. Ben Casella shares more about his perspective on glaucoma therapy: **http://ow.ly/lFzXJ**



Baseline OD photo for 66-year-old white female with unilateral open-angle glaucoma showing normal rim tissue and normal retinal nerve fiber layer.



Baseline OS photo for 66-year-old white female with unilateral open-angle glaucoma showing a noticeable notch inferotemporally.

(NTG), or sometimes in other forms of glaucoma, I may get a few visual fields and OCTs under my belt before deciding to treat.

Determining efficacy of therapy is extremely important in glaucoma. However, determining who is going to progress and how quickly that progression is going to take place is paramount. It's a matter of figuring out with whom we need to be more aggressive or less aggressive. The do no harm argument holds considerable merit, and the last thing we want is to withhold treatment that could preserve vision. The second-to-last thing we want to do is give someone more than she truly needs. For instance, if I identify a glaucoma patient, put him on a prostaglandin and a combination drop, and vision is preserved throughout his lifetime, then I'm the hero. However, if that patient needed only a prostaglandin, then I've just cost that person unnecessary amounts of time and money.

Extrapolating beyond the patient in this particular case, there are many factors to consider when dealing with how to treat a newly diagnosed—or newly inherited—glaucoma patient. For instance, was the patient ever on corticosteroids for a long time, then taken off because the condition improved? In other words, did steroids cause ocular hypertension leading to detectable glaucoma, and did cessation of the steroids bring the IOP back down to target? Also, was there ever trauma to the affected eye(s)? Or, am I missing subtle "burned out" angle-recession glaucoma?

Another good question to ask a glaucoma patient is: "Did you ever almost die?" Maybe not asked so morbidly blunt, but look into the patient's past for evidence of things such as a hemodynamic crisis. See if something could have caused the ganglion cells of the optic disc to die at one time without causing *progressive* damage.

On the other hand, there will be patients who progress despite achieving a low IOP with multiple drops and even various procedures. There may often be other risk factors, such as various forms of vasospasm, playing a role in ganglion cell death.[3] This is especially true in the presence of NTG, but there's no reason that someone can't have every vascular risk factor in the world and also just happen to have IOPs in the 30s. As one of my former attendings at SUNY once said, "Patients can have as many diseases as they pleases."

Of course I recognize that glaucoma is progressive and needs treatment. I also believe that waiting for someone's glaucoma to become perimetric is waiting too long. However, in most cases, you've got time on your side. You've got time to iron out various risk factors for progression, maybe even time to get a couple of OCTs and visual fields so you can come to an educated conclusion about how aggressive you need to be. Of course, there will always be those patients who present nearly cupped out who truly need the kitchen sink all at once.

I will continue to see this patient, every few months at different points in the day, and I will continue to check carefully for structural and functional progression. If I can prove that her glaucoma is getting worse, we'll start, in a stepwise fashion, additive therapy. However, all I can say for her is "so far, so good."

The number of untreated people out there with glaucoma who are losing functional vision is truly epidemic. However, taking a step back, breathing, collecting structural and functional data, and going over it in a logical manner before initiating treatment will often help you to not only be highly sensitive, but also quite specific, in the care you give to your patients.**ODT**

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When do you diagnose keratoconus?

ODs should provide vision rehabilitation to keratoconus patients at diagnosis

Keratoconus is a naturally occurring weakening of the cornea, characterized by its progressive asymmetric thinning and steepening. Keratoconus typically begins in the teens or 20s, progresses over a decade, and results in significant visual dysfunction, reduced quality of life, and permanent changes in the patient's lifestyle.

The majority of patients with keratoconus eventually end up in an optometrist's office searching for correction for blurred vision. At the onset of the disease, blurry vision is often successfully corrected with spectacles. As the disease progresses, astigmatism increases, and patients are often fit with soft toric contact lenses. Over time, vision progressively worsens due to development of irregular astigmatism. As a result, the patient is often refit into a rigid or hybrid contact lens.

This is the pivot point when some patients receive the diagnosis of keratoconus. The patient has significant loss of best-corrected vision and can no longer wear spectacles for functional vision.

Now is when the optometrist should provide vision rehabilitation to the patient with keratoconus. The optometrist's job is to maintain an acceptable contact lens fit that enables the patient to have functional vision for as many hours as possible. Meanwhile, the disease continues to worsen—the cornea keeps thinning and irregular astigmatism increases, which reduce the patient's tolerance of the contact lenses. And the patient continues to lose vision.

While optometrists work to maintain the patient's functional vision, our overarching goal is to put off surgical intervention for as long as possible. Ultimately, 20% of patients with keratoconus require a corneal transplant to restore visual function, typically due to corneal scarring and contact lens intolerance. When corneal transplantation *is* performed, we provide a better optical system for the patient. However, the patient still requires a lifetime of visual rehabilitation, typically with complex contact lens fitting. Although corneal transplantation has improved with lamellar and femtosecond technology, patients still face significant visual function with reduced quality of life.

It is important to remember that corneal transplantation does not treat the disease of keratoconus; it treats only the resultant irregular astigmatism. Throughout the disease process, the role of the optometrist is a visual rehabilitator. Early diagnosis of keratoconus has had no effect on the clinical treatment choices because our only goal has been to provide maximal vision function and try to avoid the need for corneal transplantation.

By William Tullo, OD
Dr. Tullo is the vice president of clinical services for TLC Vision and adjunct assistant clinical professor at SUNY College of Optometry.

Changing KC treatment

The paradigm is about to change with the advent of the first treatment for keratoconus—collagen cross-linking (CXL). CXL uses a natural photosensitizer riboflavin (vitamin B2) combined with ultraviolet light to reinforce the structural weakness found in the corneal stromal in patients with keratoconus (Figure 1).

While still under investigation in the United States, CXL has been performed for more than a decade outside the U.S. and has been well studied with more than 300 peer-reviewed studies. Following is a summary of what we know about CXL so far:

- 96% of eyes show topographic stability—no progression
- Average corneal flattening of 1.7D of max K
- Amount of flattening reduced in steep cornea
- No change in corneal clarity or index of refraction
- More effective on younger patients
- Reduced side effects, such as stromal haze, on cornea thicker than 400 µm

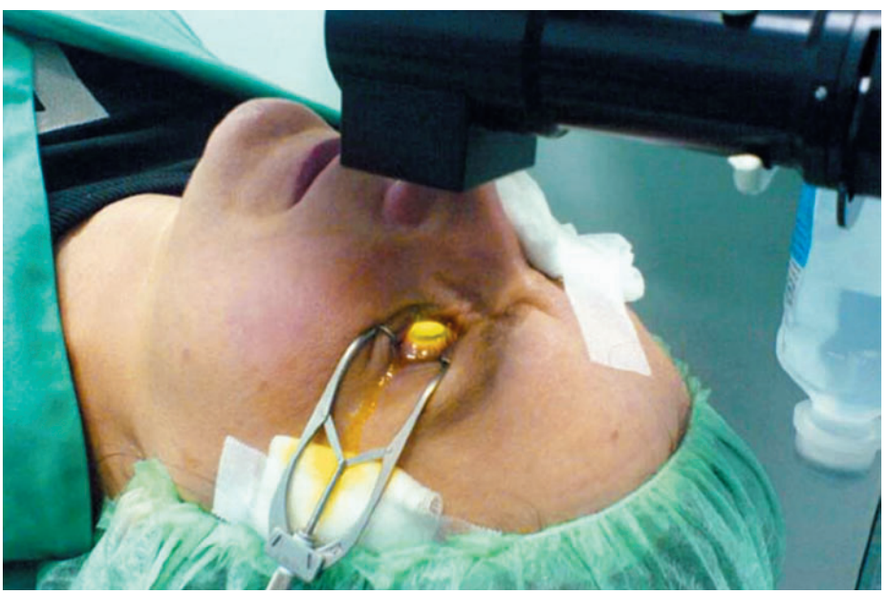


Figure 1. Collagen cross-linking (CXL) uses a natural photosensitizer riboflavin (vitamin B2) combined with ultraviolet light to reinforce the structural weakness found in the corneal stromal in patients with keratoconus.

Now in a Redesigned Bottle

AzaSite
(azithromycin ophthalmic solution) 1%

In the treatment of bacterial conjunctivitis

DEMONSTRATED EFFICACY.

SIMPLE DOSING REGIMEN.

Helps resolve bacterial conjunctivitis

AzaSite is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus mitis* group, *Streptococcus pneumoniae*.

** Efficacy for this organism was studied in fewer than 10 infections.*

The only azithromycin-based eyedrop available.[1]

Recommended dosing

9 DROPS. 7 DAYS.

Bottle not shown at actual size

SELECT IMPORTANT SAFETY INFORMATION

AzaSite is contraindicated in patients with hypersensitivity to any component of this product.

AzaSite is NOT FOR INJECTION. AzaSite is for topical ophthalmic use only and should not be administered systemically, injected subconjunctivally, or introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered azithromycin, serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported rarely. Although rare, fatalities have been reported.

As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

The most frequently reported ocular adverse reaction reported in clinical trials was eye irritation, which occurred in 1% to 2% of patients. Other adverse reactions associated with the use of AzaSite were reported in less than 1% of patients and included ocular reactions (blurred vision, burning, stinging and irritation upon instillation, contact dermatitis, corneal erosion, dry eye, eye pain, itching, ocular discharge, punctate keratitis, visual acuity reduction) and nonocular reactions (dysgeusia, facial swelling, hives, nasal congestion, periocular swelling, rash, sinusitis, urticaria).

There are no adequate and well-controlled studies in pregnant women. Azithromycin should be used during pregnancy only if clearly needed.

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

Safety and effectiveness of AzaSite solution in pediatric patients below 1 year of age have not been established.

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

The recommended dosage regimen for the treatment of bacterial conjunctivitis is: Instill 1 drop in the affected eye(s) twice daily, 8 to 12 hours apart, for the first 2 days and then instill 1 drop in the affected eye(s) once daily for the next 5 days.

Store unopened bottle under refrigeration at 2°C to 8°C (36°F–46°F). Once the bottle is opened, store at 2°C to 25°C (36°F–77°F) for up to 14 days. Discard after the 14 days.

Please see the adjacent Brief Summary of the Prescribing Information.

Reference: 1. Rhee DJ, Rapuano CJ, Papaliodis GN, et al. Pharmaceuticals in ophthalmology. In: PDR Staff. *PDR for Ophthalmic Medicines 2012*. 40th ed. Montvale, NJ: PDR Network; 2011:1–15.

Models.

MERCK

azasite.com

AzaSite®

(azithromycin ophthalmic solution) 1%

Sterile topical ophthalmic drops

Initial U.S. Approval: 2007

Brief Summary of the Prescribing Information for AzaSite.

To report SUSPECTED ADVERSE REACTIONS, contact Inspire Pharmaceuticals, Inc., a subsidiary of Merck & Co., Inc., at 1-800-672-6372 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

AzaSite is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms:

CDC coryneform group G*
Haemophilus influenzae
Staphylococcus aureus
Streptococcus mitis group
Streptococcus pneumoniae

**Efficacy for this organism was studied in fewer than 10 infections.*

DOSAGE AND ADMINISTRATION

The recommended dosage regimen for the treatment of bacterial conjunctivitis is: Instill 1 drop in the affected eye(s) twice daily, eight to twelve hours apart for the first two days and then instill 1 drop in the affected eye(s) once daily for the next five days.

CONTRAINDICATIONS

Hypersensitivity to any component of this product.

WARNINGS AND PRECAUTIONS

Topical Ophthalmic Use Only
NOT FOR INJECTION. AzaSite is indicated for topical ophthalmic use only, and should not be administered systemically, injected subconjunctivally, or introduced directly into the anterior chamber of the eye.

Anaphylaxis and Hypersensitivity With Systemic Use of Azithromycin
In patients receiving systemically administered azithromycin, serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, fatalities have been reported. The potential for anaphylaxis or other hypersensitivity reactions should be considered based on known hypersensitivity to azithromycin when administered systemically.

Growth of Resistant Organisms With Prolonged Use
As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and where appropriate, fluorescein staining.

Avoidance of Contact Lenses
Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

ADVERSE REACTIONS

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

The data described below reflect exposure to AzaSite in 698 patients. The population was between 1 and 87 years old with clinical signs and symptoms of bacterial conjunctivitis. The most frequently reported ocular adverse reaction reported in patients receiving AzaSite was eye irritation. This reaction occurred in approximately 1-2% of patients. Other adverse reactions associated with the use of AzaSite were reported in less than 1% of patients and included ocular reactions (blurred vision, burning, stinging and irritation upon instillation, contact dermatitis, corneal erosion, dry eye, eye pain, itching, ocular discharge, punctate keratitis, visual acuity reduction) and non-ocular reactions (dysgeusia, facial swelling, hives, nasal congestion, periocular swelling, rash, sinusitis, urticaria).

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category B. Reproduction studies have been performed in rats and mice at doses up to 200 mg/kg/day. The highest dose was associated with moderate maternal toxicity. These doses are estimated to be approximately 5,000 times the maximum human ocular daily dose of 2 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

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

Pediatric Use
The safety and effectiveness of AzaSite solution in pediatric patients below 1 year of age have not been established. The efficacy of AzaSite in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials.

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

STORAGE AND HANDLING

Store unopened bottle under refrigeration at 2°C to 8°C (36°F to 46°F). Once the bottle is opened, store at 2°C to 25°C (36°F to 77°F) for up to 14 days. Discard after the 14 days.

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

Patients should be advised to avoid contaminating the applicator tip by allowing it to touch the eye, fingers or other sources.

Patients should be directed to discontinue use and contact a physician if any signs of an allergic reaction occur.

Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by AzaSite or other antibacterial drugs in the future.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

Patients should be advised to thoroughly wash hands prior to using AzaSite.

Patients should be advised to invert the closed bottle (upside down) and shake once before each use. Remove cap with bottle still in the inverted position. Tilt head back, and with bottle inverted, gently squeeze bottle to instill one drop into the affected eye(s).

For more detailed information, please read the Prescribing Information.

Rx only

Inspire Pharmaceuticals, Inc., a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

Manufactured by: Catalent Pharma Solutions, LLC
Woodstock, IL 60098

U.S. Patent Nos.: 6,159,458; 6,239,113; 6,569,443; 6,861,411; 7,056,893;
and Patents Pending

Revised: 09/2012

OS-82431207R001

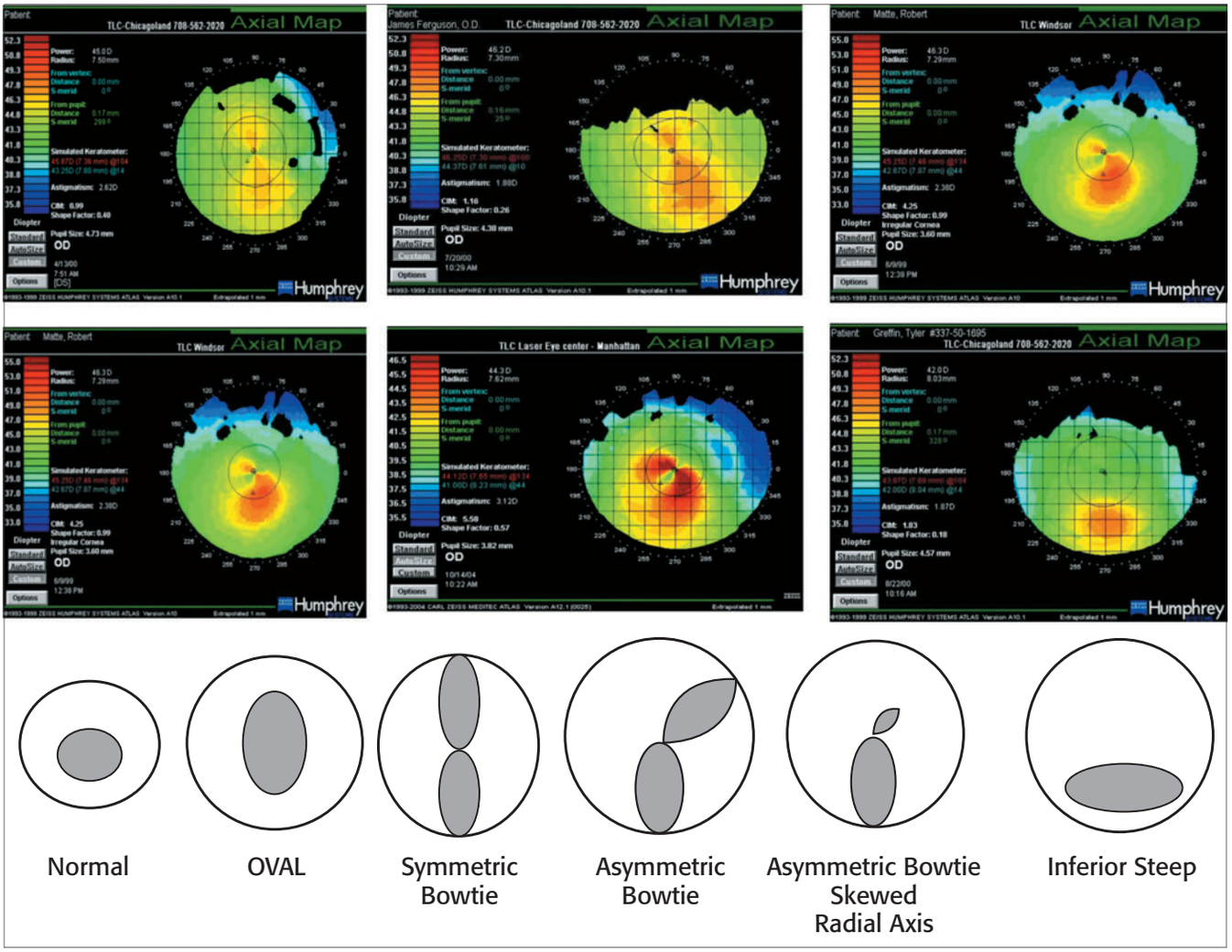


Figure 2. Topographic progression of keratoconus, top and bottom. All patients with keratoconus begin with normal corneal topography, gradually progressing from symmetric bowtie (regular astigmatism) to asymmetric inferior steep astigmatism with skewed (irregular astigmatism) radial axis.

- Improves best corrected visual acuity and uncorrected visual acuity by regularizing corneal shape

The most effective form of CXL may be the original Dresden protocol, which requires epithelial removal. Recent improvements in trans-epithelial (epi-on) CXL may provide similar effect with faster visual recovery, less pain, reduced risk of stromal haze with reduced risk of infection, and slow re-epithelialization. Regardless of the method, CXL stops the progression of keratoconus, working best on young, thick, and flat corneas. The earlier the detection and diagnosis of keratoconus, the more effective and safer the CXL treatment.

Outside the U.S. it is no longer acceptable to watch patients with keratoconus lose best-corrected vision. As soon as keratoconus is detected—sometimes as young as 12 years old—CXL is recommended to prevent vision loss. Early detection of keratoconus using topography screening has become the norm, resulting in many countries almost eliminating the need for corneal transplantation due to advanced keratoconus.

> Collagen cross-linking (CXL) has been performed for more than a decade outside the U.S. and has been well studied with more than 300 peer-reviewed studies.
>
> **William Tullo, OD**

It is important to remember that topography can detect keratoconus only once the disease has begun to thin and steepen the cornea. Also, all patients with keratoconus begin with normal corneal topography, gradually progressing from symmetric bowtie (regular astigmatism) to asymmetric inferior steep astigmatism with skewed (irregular astigmatism) radial axis (Figure 2). Future advances in keratoconus detection will continue to improve early diagnosis. Both biomechanical analysis of the cornea and genetic testing promise to detect keratoconus well before topographic changes occur and vision is lost.

Next-generation improvements in CXL methodology—including selective CXL, topo-guided advanced surface ablation, and CXL combined with Intacs—ensure the future of keratoconus treatment will provide stricken patients with an improved prognosis for normal vision and quality of life.

So, when do *you* diagnose your patients with keratoconus? **ODT**

Putting the manage in co-manage

Working together to take the best care of your patients

Co-manage. A doltish term if you think of the compound nature of the word. The etymology shows co (koh) is a prefix used (1) to form nouns meaning joint, mutual, or common, and (2) to form adjectives meaning jointly or mutually. The second part of the term is manage (**man**-ij), a verb meaning be in charge of; administer; run; or supervise.

Individually, the words create a sense of mutual care, shared, divided, and mutually respected. By joining the words, the term has been used surrounding patient care for decades. Yet now more than ever it the term seems to have lost a lot—if not all—of the original intent. There are a myriad of layers of patient-centric management concerns when we work with other physicians to ensure proper care and services. However, this does not always mean that each case is going to take a lot of chair time or require a tremendous amount of effort. To provide the best co-management of care for our patients, it necessitates a desire to nurture this relationship with the mutual provider.

By Marc R. Bloomenstein,OD, FAAO
Dr. Bloomenstein is director of optometric services at Schwartz Laser Eye Center in Scottsdale, AZ.
E-mail him at mbloomenstein@gmail.com.

Know your co (equal)

Whether you share the care of your patient with a surgeon or another OD, understand their philosophies, treatment protocol, and their staff. Co-management is not just simply sending a patient to another office and allowing that office to take control of the process. It is paramount that you meet with this doctor's partners (if any), as well as his or her staff, know the lay of their land and—most importantly—know what your expectations will be. This meeting also sets the ground rules for specific procedures, surgical options, philosophies, quirks, and even hours of operation.

I've said many times that surgeons are like hired guns. You need to interview the best possible "gun" you can trust with your patients. The notion that you are only as good as your weakest link extends beyond the person answering your phone all the way to the facility that you think can help your patient.

Have your surgeon on speed dial

There should never be a question that goes unanswered. The lines of communication should always be open. There needs to be a reciprocal understanding that, if something goes awry—which happens from time to time—you will receive a call and vice versa. A great example of communication is the toric IOL, which I discussed in my February column. A rotation of the toric lens is unlikely, but it *is* possible. Yet without prior knowledge of the axis of implantation, you would never know. As the primary caregiver for our patients, we may have more intimate knowledge of what will benefit the patient based on previous attempts to solve a problem. A policy of, "Call me before you change anything," is a real sign of mutual equality.

The paper trail

Patients like to have tangible signs of cooperation. Having printed materials explaining where the patient is going, who the patient is seeing, and what he or she should expect creates that understanding. I recommend printing information on your letterhead that provides details about your partner who will assist you in caring for this patient. Take the time to find out what preoperative regimen is needed for the surgery, such as the recovery, pricing, and insurance coverage; have this material readily available. Surgical centers want the referrals, so they are often wiling to provide these materials with your hours, phone numbers, and addresses to strengthen the bond of partnership.

The timetable

"We are going to see you back 1 week after your surgery and then after 1 month. Let's set up those appointments before you leave." Those words are reassuring to the patient. When your patient knows exactly when he or she is coming back and what you will be doing, the ambiguity of the care is removed. I cannot state this any more simply—The role of each caregiver should be detailed ahead of time.

Co (together) management (taking care of our patient) is meant to help, not be a deterrent or a veiled financial agreement. This cooperation between optometry and other medical professions means working together to take the best care of our patients. In doing so, we *co*llectively *co*-articulate this notion of *co*ordinating care of our patients and act as their *co*-pilot in this crazy *co*-existence.**ODT**

co-man·age [koh-man-ij]

verb (used with an object), verb (used without object), **co-man·aged, co-man·ag·ing.**

To manage jointly.

YOUR PATIENTS SAY

Lens care makes a difference

Listen to your patients. I did, and I learned a lot.

After I asked my patients to try OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution, I was intrigued by what they said. I was so intrigued that I started writing down what they said.

I first experienced OPTI-FREE® PureMoist® almost 2 years ago during a post-market patient comparison survey sponsored by Alcon. At the initial visit, patients filled out a questionnaire about their experiences with their current contact lens solution. Some patients were using another product manufactured by Alcon, and some patients were using competitors' products. Patients were then given a bottle of OPTI-FREE® PureMoist® and told to use it for the next 2 weeks before answering another questionnaire.

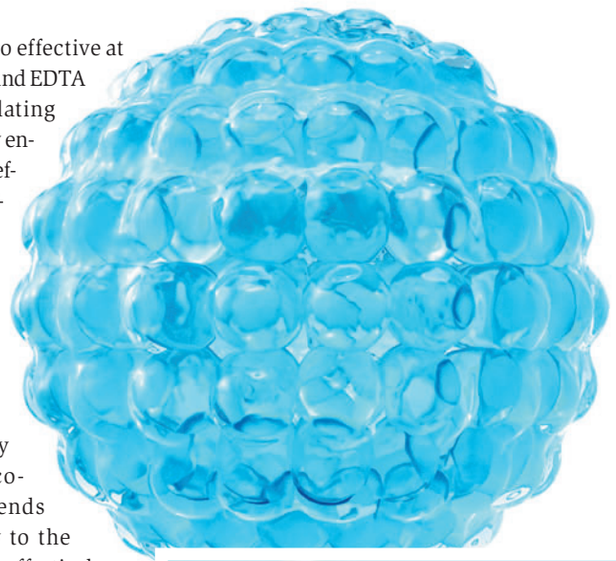
Christopher Stansbury, OD

For the next 6 months, I would consistently dispense OPTI-FREE® PureMoist® to my contact lens patients, instruct them to use it, and inform them that I would be asking about their experiences when they returned for follow-up. I will present the most frequently reported comments along with the science to support the validity of each comment.

"My LENSES SEEM to stay cleaner with the new contact lens solution."

Why didn't the previous generation of multi-purpose solutions do a good job keeping SiHy contact lenses clean? That question can best be answered by looking once again at the molecular structure of SiHy contact lenses. The hydrophobic nature of the dimethylsiloxane polymer moieties makes them very attractive to lipids.[1] They still attract some proteins to their hydrophilic regions, but they are predominately affected by lipids. The lipids may first appear as grayish globules on the surface of the contact lens, but as the deposits increase, the globules may coalesce into a mesh-like film.

The multi-purpose solutions that were on the market when SiHy contact lenses were launched were designed with hydrogel lenses in mind. There was no specific component in multi-purpose solutions to address the lipid deposits. That's where OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution has the real advantage. It was designed from the start as a multi-purpose disinfecting solution for SiHy contact lenses.[2] The tried and true combination of citrate and TETRONIC®† 1304 were kept from OPTI-FREE® RepleniSH® Solution because they were so effective at cleaning hydrogels, and EDTA was added as a chelating agent. EDTA not only enhances the cleaning effects of citrate/TETRONIC® 1304, but it also has an additive disinfecting effect with POLYQUAD® and ALDOX® preservatives. The best weapon against lipid deposits is actually the EOBO block copolymer. The BO ends bind competitively to the hydrophobic regions, effectively blocking the attachment of lipid molecules.[3]



Top Image: Proprietary HydraGlyde® MoistureMatrix.

Bottom Image: HydraGlyde® MoistureMatrix embeds on and within soft contact lenses for an outstanding lens-wearing experience.

The OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution Challenge

I have been pleased with the results I've achieved from switching my patients to OPTI-FREE® PureMoist MPDS. The responses I have heard from patients have been overwhelmingly positive and encouraging. Now, my challenge to you is to carry out a comparison study in your own practice. Dispense an OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution starter kit to your next 50 contact lens patients, schedule them for a 2-week follow-up visit, and ask them about their experiences with the new contact lens solution. If you accept this challenge, I would like to hear about your results. E-mail me at cstansbury@wv-eye.com to tell me how it works for you.

Dr. Stansbury is part of a four-doctor group operating five clinics in southern West Virginia.

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3D printing—the great equalizer in eyewear manufacturing

Design, develop, and implement your own frame line

I was never impressed with the 3D-printed cheap, plastic, gimmicky doohickies and other useless—albeit geekishly intriguing—gadgets that I had seen. A recent post in the Optometry and Technology Facebook group, *https://www.facebook.com/groups/optometry.technology*, changed that. I watched a YouTube video of OD Jeff Goodhew's son Cam, an 11th grader, 3D printing his own frames. I was impressed. My initial reaction was, "Wow, that's really cool but, yikes—those are cheap, plastic, gimmicky, big, red frames that I would never wear or want to sell." However, there was a deeper emotion looming. It was one of potential. It was the excitement of possibilities. It was the recognition of an inflection point in the design and manufacturing process. This is disruptive technology, and it will have an impact.

Watch Cam Goodhew 3D printing his own eyeglass frame at *www.bit.ly/3dframes*.

Did you feel it? Or perhaps that video made you nervous. You certainly had an emotional response because eyewear is still very much at the core of optometry, and 3D printing certainly represents a change in how eyewear is made. Change often can be uncomfortable or exciting, because change leads to progress. When the first PCs came to market, many of us were myopic in our view of what they could help us accomplish. Much like our initial reaction to PCs, many of us might downplay the potential of 3D printing. I used my first few computers to play games and for word processing. A few decades later, my Internet-connected computer is a critical artery in my life. I know 3D printing is not going to be as revolutionary or as important as the PC, but I do foresee it having its place in our world.

Small-scale manufacturing

So, what exactly is going on in the video? What you are watching is a type of 3D printing known as additive manufacturing. Material is layered, and the layers are fused on top of each other, until a complete 3D product has been made. Contrast this with subtractive manufacturing, the more familiar way of cutting out a design from a block of material.

Surprisingly, 3D printing is not a new concept. In fact, it has been around for 3 decades, but has never really been in the public eye. Why? It has been inefficient, inaccessible, slow, and often expensive. Today, the reality is that those barriers have broken down, and consumers can even now buy a very basic 3D printer for around $500.

By Justin Bazan, OD, is a 2004 SUNY grad and the owner of Vision Source Park Slope Eye in Brooklyn. Reach him on his Facebook page.

In the video we see Cam using a free data set for frames he found at Thingiverse, *www.thingiverse.com*. Using a free, simple computer program called MarkerWare, he put finishing design touches on the digital plans. He then uploaded these plans into his 3D printer. Cam uses the $2,000 MakerBot Replicator 2 3D printer, seen here: *http://store.makerbot.com/replicator2.html*. The printer then deposits the melted plastic material, layer upon layer, in an additive process. The kicker is that the frames consumed only $4 worth of materials!

So, you may think geeks are the only people using or even interested in 3D printing. Well, a little research has already given us an industry example to learn from. Here is what I found. PQ Eyewear, *http://pq-eyewear.com*, works with a 3D printing company to produce its line of frames. They have unique styles that often appear to be impossible with traditional manufacturing process, yet are easily done with 3D printing. For a detailed look at this operation, read, "Is 3D printing about to hit the mainstream?" at *www.guardian.co.uk/technology/2013/apr/30/3d-printing-mainstream-technology*.

So there is already an impact. For the first time in history, the possibility of an entrepreneur or sole proprietor being able to design and manufacture a frame line on a small scale is a reality. A small-scale frame line was never before feasible in view of competition from current frame manufacturers, which often require orders that have minimums in the hundreds of frames. With 3D printing, we can truly design, develop, and implement our own frame line.

Another area of potential involves creating individual frames. Customizable. Personalized. Specialized. Unique. Frames that are truly yours because you can be involved with them from the concept to design through manufacturing. The idea of bespoke eyewear is a reality. One day soon, your clients could come in and design their own frames. I should say *hopefully* come in, because I'm sure as I write this, there are companies developing platform-to-process online orders, printing at a local shop, or even implementing the technology in a vending machine. **ODT**

3D demonstration

Want to see how Camden Goodhew used his 3D printer to print his own eyeglass frame? Watch the video: www.bit.ly/3dframes.

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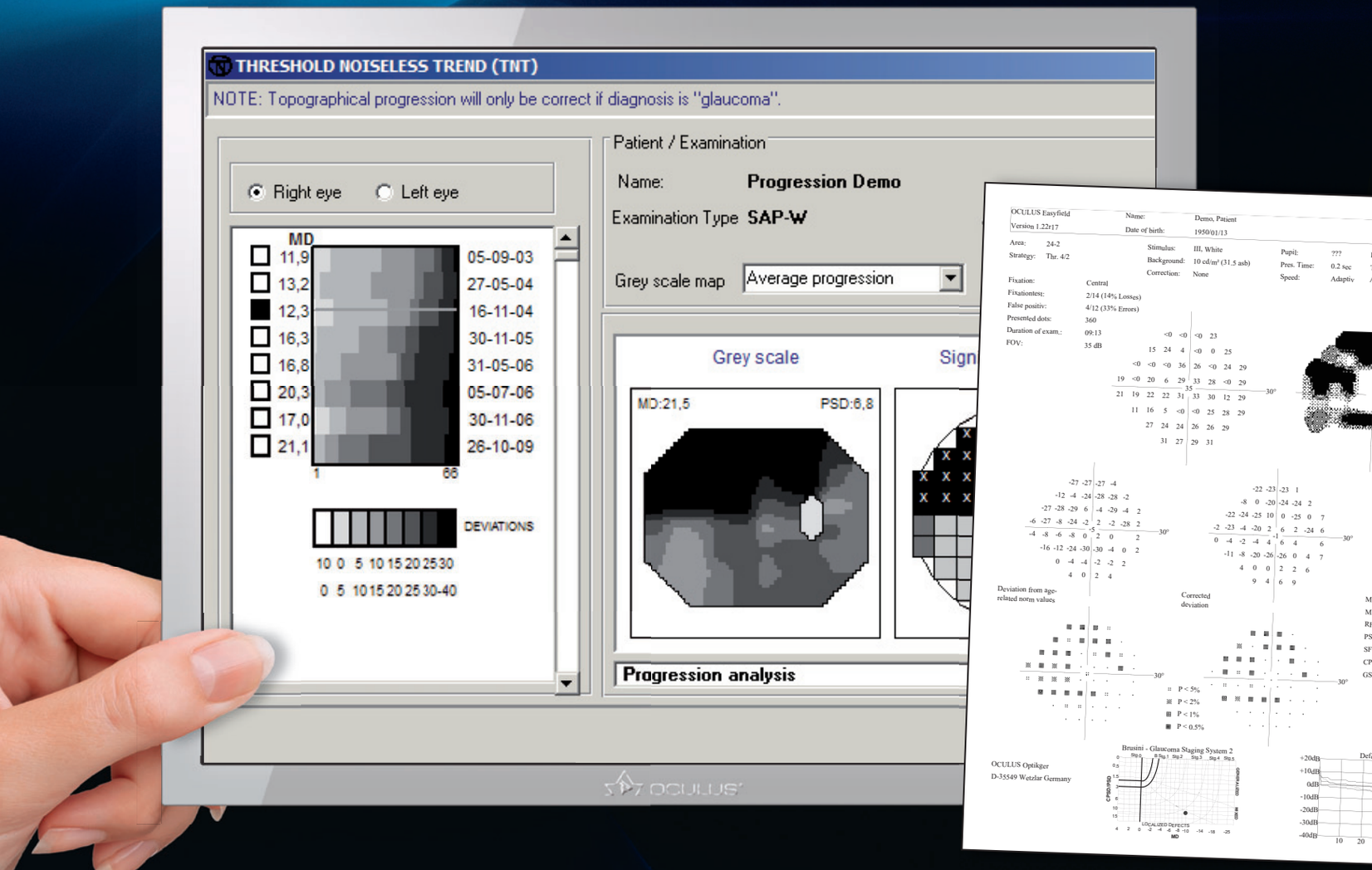

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Ocular manifestations of diabetes: Some clues for eyecare professionals

Optometrists often see signs of diabetes in undiagnosed patients

By Paul Chous

Diabetes is the leading cause of new blindness in Americans under age 74, the leading cause of end-stage renal disease and non-traumatic amputation, and the sixth leading cause of death in the United States. Each year, more than 200,000 U.S. deaths are reported as being caused by diabetes or its complications.[1] Recent work has shown diabetes to be strongly associated with several types of cancer[2] and Alzheimer's disease.[3] In 2012, diabetes care cost the U.S. economy $245 billion, a 41% increase from 2007.[4] By the year 2020, Americans with diabetes or prediabetes could cost the U.S. healthcare system $3.35 trillion.[5] The American Diabetes Association estimates that 25.8 million Americans have diabetes,[6] and another 79 million have pre-diabetes,[6] the majority of whom will develop type 2 diabetes without intervention.[6] Moreover, as many as 7 million Americans have undiagnosed diabetes right now.[6]

Optometrists are well aware of these statistics because we see the ophthalmic manifestations of diabetes on a daily basis, often in patients who have yet to be formally diagnosed.

Diabetic eye disease refers to conditions prevalent among patients with diagnosed or undiagnosed diabetes that are attributable, either directly or indirectly, to hyperglycemia—cataracts, glaucoma, ocular surface disease, nonarteritic ischemic optic neuropathy, cranial mononeuropathy, extraocular muscle palsy, and most importantly, diabetic retinopathy. Diabetes patients are also at higher risk for other retinal-vascular disorders as a function of concomitant dyslipidemia and hypertension, including retinal vein and artery occlusion.

Take-Home Message

Optometrists too often see the ophthalmic manifestations of diabetes—cataracts, glaucoma, ocular surface disease, nonarteritic ischemic optic neuropathy, cranial mononeuropathy, extraocular muscle palsy, and diabetic retinopathy. Patients with diabetes are also at high risk for other retinal-vascular disorders, including retinal vein and artery occlusion.

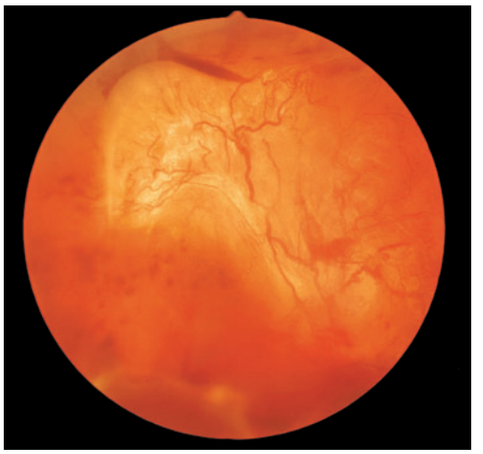
Diabetes and the aging eye

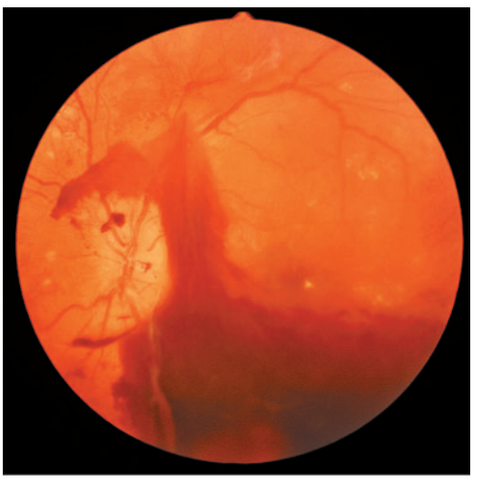
The quintessential ophthalmic finding in undiagnosed diabetes is fluctuating refractive error. Both myopic and hyperopic shifts have been reported due to lenticular changes caused by hyperglycemia,[7] but the majority of studies show a myopic shift with subsequent reversal toward hyperopia after control of blood glucose.[8-10] The mechanisms responsible for this phenomenon include changes in regional refractive index, lens curvature, and hydration. Cataract development and progression in diabetes occur at a younger age and a faster rate due to glycation of lens proteins, osmotic stress, and disorganization of collagen.[11]

Recently, a device (ClearPath DS-120, Freedom Meditech Inc.) for measuring advanced glycation end products (AGEs) as a function of crystalline lens autofluorescence received FDA clearance. The device gives eyecare professionals insight into long-term glycemic stress in patients with both diagnosed and undiagnosed diabetes.

The association between diabetes and open-angle glaucoma is hotly debated.[12] Glycation of laminar collagen, as well as poorer optic nerve perfusion, may increase risk of damage from ocular hypertension. However, it is likely that higher rates of diagnosis in diabetes patients is confounded by glucose-induced increases in corneal rigidity, resulting in over-detection of OHTN,[13] as well as detection bias in a population being scrutinized for disease of the posterior segment.

There is no doubt diabetes increases the risk of both neovascular glaucoma secondary to ischemia,[14] and iatrogenic glaucoma due to use of corticosteroids for the treatment of retinopathy and macular edema.[15] Other optic nerve diseases more commonly seen in diabetes include non-arteritic anterior ischemic optic neuropathy[16] (co-association among NAION, sleep apnea, and diabetes increases this risk) and so-called diabetic papillopathy—typically unilateral disk swelling caused by vascular leakage around

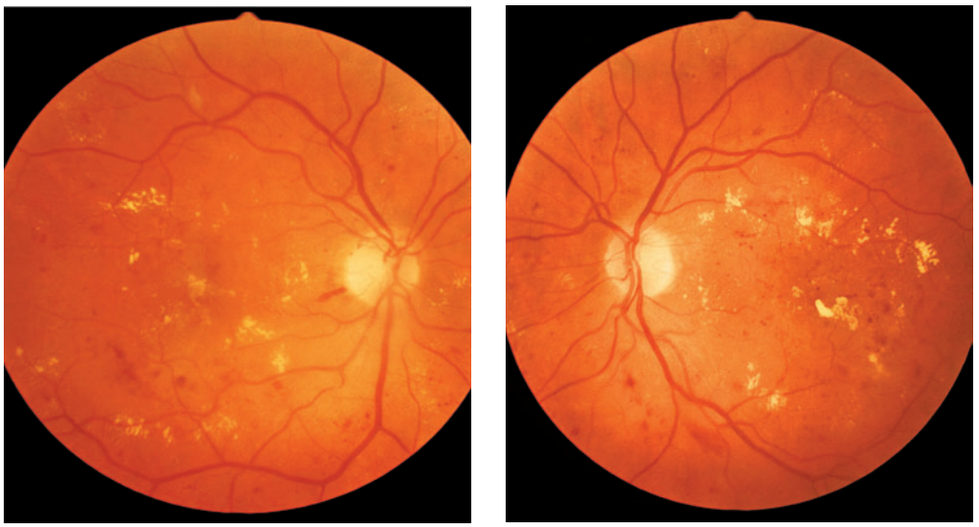




Proliferative diabetic retinopathy with vitreous hemorrhage and fibrovascular traction. (Photos courtesy Dr. Paul Chous)

VIDEO

Visit **http://ow.ly/lB75V** to hear more from Dr. Paul Chous on the importance of treating diabetic patients.



Center involved diabetic macular edema. (Photos courtesy Dr. Paul Chous)

the optic nerve head, with good recovery of vision in most cases.

Ocular surface disease and use of artificial tear supplements are more common in diabetes patients than in the general population.[17] This phenomenon is mediated by increased glucose in tears and meibomian secretions, as well as morphologic changes in corneal nerves and hemidesmosomal attachments that increase risk of corneal erosion. Severity of keratoconjunctivitis sicca appears to correlate with glucose control and severity of retinopathy.[18] A major Spanish study found that diabetes doubled the risk of asymptomatic meibomian gland dysfunction, a finding that may underscore diminished corneal sensation.[19] Another retrospective study of nearly 160,000 patients over 10 years found diabetes to significantly increase the risk of herpetic eye disease,[20] possibly due to impaired corneal immune response. Diabetes is also associated with reduced endothelial cell counts.[21] Though the vast majority of people with diabetes can successfully wear contact lenses,[22] these processes support conservative prescription and careful follow-up by optometrists.

Isolated cranial nerve palsy is about seven times more common in diabetes, presumably due to microvascular infarct.[23] CN III, IV, VI, and VII are most commonly affected, and recovery of function is the rule within 6 months.[24] Multiple CN palsies in diabetes rarely occur and warrant neuroimaging to rule out compressive lesion. Corneal hypoesthesia can result from sensory neuropathy of CN V, a finding that increases the risk of dry eye as well as neurotrophic keratitis.[25,26] Idiopathic ptosis is associated with increased risk of insulin resistance,[27] as are acanthosis nigricans[26] (hyperpigmentation caused by hyperinsulinemia), skin tags, and demodex folliculorum[29] of the eyelids.

Effects of diabetic retinopathy

Diabetic retinopathy (DR) is the single most important ocular complication of diabetes, with a wide spectrum of presentations and severity. Evidence suggests DR is a neurovascular disease, with changes in retinal nerve fiber layer thickness and ganglion cell function preceding the vascular changes identified by dilated eye examination.[30] Functionally, these processes may result in abnormal color vision (acquired tritan and tetartan defects), reduced contrast sensitivity,[31] and loss of perimetric sensitivity.[32] Abnormalities in multifocal electroretinogram response are known to precede clinically detectable retinopathy and even predict future sites of retinal-vascular damage.[33]

A host of processes have been implicated in the pathobiology of DR, including hyperglycemic oxidative stress, hypertension, inflammatory dyslipidemia, and release of inflammatory cytokines that mediate blood-retinal barrier breakdown, apoptosis of retinal pericytes, capillary closure, and ischemia that triggers neovascularization.[34] Optometrists are well aware of the various fundus lesions seen in DR; the key is to remember which findings presage the highest risk of sight-threatening retinopathy (extensive intra-retinal hemorrhage or microaneurysm formation; vein beading; and IRMA) and those that immediately threaten vision—retinal thickening that involves or approaches the macular center; neovascularization of the optic nerve, retina, or anterior chamber angle; and pre-retinal or vitreous hemorrhage, especially with fibrovascular proliferation.

The Freedom Meditech ClearPath DS-120 measures lens fluorescence, a marker of long-germ glycemic stress.

The prevalence of diabetes among patients with hypertension is high, and vice versa. So it is not surprising that hypertensive retinopathy is more common in diabetes patients, may accelerate diabetic retinopathy, and may muddy the waters regarding the underlying etiology of retinopathy in patients with both conditions.[35] From the standpoint of diagnostic suspicion of undiagnosed type 2 diabetes, it is interesting to note that generalized retinal arteriolar narrowing, a classic finding of mild hypertensive retinopathy, independently raises the risk of diabetes about 70%.[36] It is also important to realize that diabetes is a risk factor for retinal vascular occlusive disease, more commonly venous but also arterial occlusions.[37] Patients experiencing these events often have hypertension and cardiovascular disease that frequently co-mingle with diabetes.

As we have seen, diabetes affects the eye in a myriad of ways, including alterations in visual function as well as structure. These ocular changes are important because they also reflect systemic metabolic insult, are associated with other complications of diabetes including kidney and cardiovascular disease, and put the optometrist on the front line in detecting diabetes in those who have not yet been diagnosed.**ODT**

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Author Info

Dr. Chous completed his undergraduate education at Brown University and University of California, Irvine, and then received his MA and OD degrees with highest honors from University of California, Berkeley. He has a private practice specializing in diabetes eyecare and education in Tacoma, WA.

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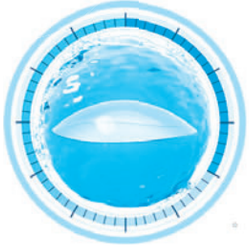

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Stage 2 Meaningful Use: Are you ready?

Requirements for stages in Meaningful Use have changed. Stay current on what you need to know.

By Zachary S. McCarty, OD

According to the U.S. Center for Medicare and Medicaid Services (CMS) records, some 3,570 optometrists have attested for Electronic Health Record (EHR) incentives totaling close to $57 million. By the end of April 2013, 12,087 optometrist have registered for the EHR incentive program. Of these, some 8,204 ODs have already received $145,030,796 in incentive payments. With incentives scheduled to decline in future years and penalties kicking in for practitioners who fail to adopt and attest to Meaningful Use for EHRs, more clinicians are looking to purchase and implement such systems. The biggest question on everyone's mind is: Are you ready for Stage 2 Meaningful Use requirements in 2014?

What are the stages of Meaningful Use?

To help make adoption and use of EHRs easier, in addition to receiving incentive payments, CMS established criteria for Meaningful Use in stages. Stage 1 is the easiest level to obtain; Stage 3 will be the most difficult. Each stage of Meaningful Use has a distinct purpose with the goal of advancing the overall health of our patients.

The goal of Stage 1 is to capture health data in a coded format. Stage 2 applies the data to patient care and expands the exchange of information between providers and other healthcare entities. Finally, Stage 3—the exact measures are still in preliminary stages—will focus on Clinical Decision Support (CDS) application during point of care to help improve healthcare outcomes and provide patients with self-management tools and their comprehensive health data.

The stage that a practice should be following depends on when a practice installed and first attested to using its EHR system. Up through 2013, all practices, whether on an existing EHR system or a new installation, are in Stage 1. The only difference is the length of time required to attest—90 days for practices just installing and attesting for the first time, or the entire calendar year for those practices that already attested to Meaningful Use in a previous year.

Take-Home Message

Many practices will move to Stage 2 Meaningful Use criteria in 2014. Learn about the changes from Stage 1 to Stage 2 and how to compy with additional Objectives in Stage 2.

In 2014, any practice that has attested to using an EHR in 2011 or 2012 will be required to follow Stage 2 Meaningful Use criteria. Practices installing and attesting to meaningful use of EHRs in 2013 and 2014 will still be under the updated Stage 1 Meaningful Use criteria and will report on Stage 2 criteria starting in 2015. Because the entire process becomes more complicated the longer a system is installed and used, CMS recently launched an online process calculator. Practitioners can input data about when their EHR was installed and when they first attested; the Web site will calculate and display the path to Meaningful Use and stage by calendar year. Go to *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Participation-Timeline.html*.

Why should I implement EHR and report Meaningful Use?

Currently, successful reporting and attesting to Meaningful Use criteria results in an EHR incentive payment by CMS to the eligible practitioner, based on either submitted allowable Medicare charges or standard, set payment for the Medicaid incentive pathway. This incentive disappears in 2015 and becomes a payment reduction (penalty) for practitioners not successfully reporting EHR Meaningful Use criteria. Those practitioners who don't successfully report criteria for patients seen in 2013 will receive an automatic 1% adjustment to CMS payments in 2015. This penalty increases to 2% in 2016 and 2017, then rises to 3% in 2018. The penalties can continue to increase up to 5% if 75% of practitioners nationally are not "meaningful EHR users." This payment adjustment will be combined with other payment adjustments for not reporting PQRS and e-prescribing. A 1% penalty could quickly grow to 3% in 1 year if a practitioner is not performing all three things: PQRS, e-prescribing, and Meaningful Use). The other point to consider: the longer a practitioner waits to attest to Meaningful Use, the harder the staged criteria become as evidenced by the recent changes.

Stage 1 has changed for 2013

Several criteria used to meet Meaningful Use Stage 1 have been updated for 2013.

First is the objective concerning CPOE (computerized physician order entry). Practitioners may elect to use alternate reporting criteria. Typically, reporting is based on a percentage of patients for which a medication has been prescribed electronically—30% for Stage 1. Instead, practitioners can now report based on the total number of scripts created during the EHR reporting period, rather than the number of unique patients.

For the objective related to recording vital signs, there are now optional criteria that may be used in 2013 (it becomes required for Stage 1 reporting in 2014). Blood pressure must be measured only for patients aged 3 years and older, and height and weight are required reporting for patients of all ages (compared with the current verbiage of the criteria that states all three measurements are required on patients aged 2 years and older). The exclusion still applies that if all 3 measures are not relevant to a specialty, then the practitioner is not required to report on this measure. Because CMS has not specifically addressed which specialties are exempt from

VIDEO

Dr. Zachary McCarty talks you through Stage 2 Meaningful Use and what you need to know. **http://ow.ly/lFI5u**

this reporting measure, the decision is left to the discretion of the reporting practitioner.

For physicians waiting to implement EHRs until 2014 or later, they are still under Stage 1 criteria. However, another measure changes just for this group. Current criteria for an objective require providing an electronic copy of a patient's health information within 3 business days of **request**. The revised objective requires online access to a patient's health information **without request** within 4 business days of the information being made available to the provider.

The remainder of Stage 1 Objectives remains unchanged.

Differences between Stages 1 and 2

There are several key differences between Stage 1 and Stage 2 criteria. First, many Stage 1 Menu objectives (for example, optional—practice picks 5 of 10 to report) become Core (mandatory) in Stage 2. Stage 1 has 15 Core Objectives, and 5 of 10 Menu Objectives were required, 1 of which had to be related to public health. In Stage 2, 17 Core Objectives will be required, and 3 of 6 Menu Objectives must be reported. Many Stage 2 Menu Objectives are new.

In general, compliance with new criteria for Stage 2 requires a patient portal. Also, every EHR system must be certified for 2014 Stage 2 Objectives. As such, providers will be required to update current systems to receive this new required functionality. It will be important for practices and providers to work closely with their software vendors to ensure that each installation is current and can meet Stage 2 Objectives.

What is different about Stage 2 Objectives?

For many objectives, the percentage of patients for which a provider must meet criteria and report on increases.

- CPOE requirement increases from 30% of medications/unique patients to 60% of medications, 30% of lab, and 30% of radiology orders.
- E-Rx Objective increases from 40% of medications to 50%.
- Recording demographics spikes from 50% to 80% of unique patients.
- Recording vital signs (if not excluded) goes from 50% to 80% of unique patients.
- Recording smoking status jumps from 50% to 80% of unique patients.
- Instead of implementing only 1 Clinical Decision Support (CDS), 5 CDSs must be implemented within the EHR system.
- Clinical summaries must be provided for 50% of office visits within 1 day, decreased from 3 business days).

The Stages of Meaningful Use

The overarching goal of Meaningful Use is to optimize patient care.

To help make adoption and use of EHRs easier, CMS established criteria for achieving Meaningful Use in stages.

STAGE 1 **[Difficulty: Simple]** Capturing patient health data in a coded format.

STAGE 2 **[Difficulty: Moderate]** Apply data to patient care and enhance information exchange between providers and other healthcare entities.

STAGE 3 **[Difficulty: High]** Enhance healthcare outcomes and provide patients with self-management tools and comprehensive health data.

- 55% of lab test results must be entered; the requirement is now a Core Objective.
- Patient reminders drop from 20% to 10%, mainly because the Objective status changes from Menu to Core.

Several Objectives from Stage 1 are still present; however, they have been combined with other Core Objectives. For instance:

- Performing drug-drug and drug-allergy checks.
- Maintaining an active problem list, medication list, and medication allergy list has been combined into a single Objective.
- Performing drug-formulary checks is part of the E-Rx Objective.

New Stage 2 Objectives

Several Stage 2 Objectives and Measures will require more effort by both the physician and staff, as well as the patient.

First, besides making health information available electronically to 50% of patients within 4 business days of the information being received by the physician, 5% of unique patients, or their authorized representative, must view, download, or transmit their health information to a third party. This Objective demonstrates the need for a patient portal in which the patient's information can be securely uploaded and accessed by the patient. This portal will also need to keep track of which patients view and then transmit information to other persons.

Next, the transition of care Objective has been modified. Not only is it a Stage 2 Core Objective, but there are additional requirements besides providing a summary of care record for more than 50% of transitions of care. For 10% of these transitions and referrals, this information must be transmitted electronically either through Certified EHR Technology (CEHRT), or through a Health Information Exchange (HIE). Further, at least one of these electronic transmissions of the summary of care record must be either between EHRs designed by different developers or a successful test with the CMS-designated test EHR.

The final new Stage 2 Core Objective is secure patient messaging. A secure message must be sent using the electronic messaging function of certified EHR technology to 5% of unique patients. This is the other Objective that would require a patient portal.

Stage 2 Menu Objectives

Five of the 6 Stage 2 Menu Objectives are new. Only 3 Menu Objectives must be successfully reported. Unfortunately, starting in 2014, a Menu Objective/Measure cannot be reported as an exemption. These new Objectives are:

- Enter at least one electronic progress note created, edited, and signed by the physician for more than 30% of unique patients.
- More than 20% of all scans and tests ordered by the practitioner resulting in an image are incorporated into the EHR. Every optometrist should consider reporting this measure given the amount of tests that ODs perform, such as visual fields, corneal topographies, and OCTs.
- Have structured data entered in the EHR for one or more first-degree relatives for more than 20% of all unique patients.
- Submission of cancer case information from CEHRT to a cancer registry.
- Submission of specific case information from CEHRT to a specialized registry.

Clearly, Stage 2 Meaningful Use increases both the amount of data collected on patients and its use for communicating and coordinating care with the patient and other providers.

The corollary is that the volume of data and its management will throw a burden on the provider and his or her office staff. Ultimately, though, once EHR protocol becomes routine, patients will begin to recognize better healthcare outcomes and greater shared responsibility in their well being.**ODT**

Author Info

Dr. McCarty is director of clinic operations, health information, and IT at SouthEast Eye Specialists in Chattanooga, TN. E-mail him at zmccarty@southeasteye.com

EHRs and the new healthcare game

A 5-step continuum for eyecare practitioners that only begins with electronic health records

By Alistair Jackson, MEd

Most of us have now conceded that the transformation of health care is here to stay. Yet, we aren't entirely sure where it is taking us, or why we should play ball.

Healthcare reform, as we call the new game, is indeed here to stay. In fact, reform-type changes have been around for more than 20 years. Many professionals — media professionals included —have mistakenly confused health*care* reform with health *insurance* reform. As long as Obamacare was in question, we thought health*care* reform was also up for grabs. Not so, but it meant that many of us fell behind the change curve.

Some eyecare providers (ECPs) faced another dilemma: the Medicare question. Many ECPs asked, "If I don't see many Medicare patients and my business is more refract-and-refer, am I really in the healthcare game? Do the EHR incentives even apply or matter to me?"

In *every* case, health reform matters for eye care. However, it is not about the stimulus money. Reform matters with or without incentive grants, regardless of either carrots or sticks.

The ECP continuum

There is an end game in healthcare reform. It is wrapped around key tenets such as portability, interoperability, and transparency. Those concepts are rolling out before our eyes under the guise of the HIPAA Omnibus Rule, new laws concerning the exchange of Protected Health Information (PHI), and the appearance of hospital-compare and physician-compare Web sites, not to mention the advent of various patient portals and big-data platforms.

What does this mean for ECPs? The following 5-step continuum helps us see the big picture, one that only *begins* with EHRs.

STEP 1 Implement and use certified EHRs.

Electronic health records are where it all starts. Health care is forsaking paper charts; electronic records are the new *de facto* standard. Despite their shortcomings and ongoing evolution, EHRs signal an adapt-to-survive game. If you are hanging on to paper ways, tell yourself, "no EHRs, no patients."

Take-Home Message

Physicians want to know what ECPs know and can contribute to the care team. ODs must embrace their unique place in providing higher quality at lower cost, another mantra and key tenet of healthcare reform.

Why certified EHRs? While only certified EHRs can guide you through the Meaningful Use process, the certification criteria also spell out what we may call the future survival standards, the rules of the new game. These are the capabilities you will need in order to remain relevant in the business of health care.

STEP 2 Communicate electronically.

EHRs are not about your handwriting; they are about the secure electronic exchange of health data. Call it exchange, call it secure messaging, or direct transport, this is portability and interoperability being fleshed out in real time. This is what Stage 2 of Meaningful Use is all about. Stage 1 was about laying a foundation of EHRs. Stage 2 is about moving beyond EHRs.

As a side note on electronic communications, patient messaging should not be confused with secure messaging. Several industry partners today offer practice-management interfaces for patient-facing marketing communications: appointment reminders, recalls, product offerings, and patient education. They may use e-mail, text messages, or automated phone messages. Patient messaging platforms do not deal with PHI and are not subject to the HIPAA laws, nor do the vendors want them to be. Such offerings do not constitute secure messaging, which is set apart by its clinical nature.

Secure messaging integrates with EHRs and applies specifically to the transport of PHI, the most obvious form of which is the Continuity of Care Document in Stage 1 Meaningful Use, also known as a Summary of Care, or a transition/referral of care formatted to the Consolidated Clinical Document Architecture standard in Stage 2 Meaningful Use.

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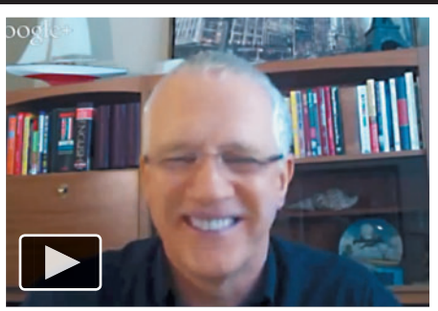

Alistair Jackson discusses a fraction of what he knows about healthcare reform and electronic health records. **http://ow.ly/lFMtt**

STEP 3 Position your practice for team delivery of care.

Why exchange patient data? Another big play in the new healthcare game is a move away from silos of care to team-based delivery of care, or care teams. It could be said that HMOs have tried and failed at this already, but remember that HMOs did not have the benefit of the HITECH Act or a federally-funded Nationwide Health Information Network.

One CMS Innovations pilot program worthy of your attention is the Comprehensive Primary Care Initiative (CPCI)[1]. The CPCI is taking the Medical Home concept into the offices of your local primary care physicians (PCPs), equipping and incentivizing them to establish care teams for the complete care—including eye care—of chronic patients. Note that most patients will quickly qualify for complete care coordination.

Inherent in positioning your practice for team-based care is a business culture transformation. A transition is needed not only for technology, but also for people. It will not suffice simply to upgrade your IT infrastructure. Work to prepare your staff as well. The work under way by TransforMED[2] for the American Academy of Family Physicians is instructive, a mature model of how PCPs are converting their practices to a patient-centered medical home model.

STEP 4 Acceptance on care teams.

Is there any question that you need to be part of those care teams? Your eligibility to play begins with EHRs.

See **Game** on page 26

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Game

Continued from page 24

There is a secure communications requirement here, which some eyecare EHRs have already met or will soon meet. By October 2014, Stage 2 Certification will require **all** EHRs to demonstrate health information exchange capability for care coordination.

Your use of EHRs that meet these and other new survival requirements has nothing to do with whether or not you attested to Meaningful Use or received incentive grants. The standards apply to all providers with or without the stimulus money. I call these survival requirements because, without them, your business cannot survive the demands of the new healthcare game.

STEP 5 Access to patients and payments. The final step in the ECP continuum is to ensure you do what it takes to retain access to your patients and also to the reimbursements you deserve for the improved patient outcomes you help deliver.

Lest I blow a whistle too early in the game, let me re-emphasize that this is a continuum—we are looking ahead to the end of the continuum, and there is yet time to play.

Access to patients is a serious matter, of course. We must not assume, "once a patient, always a patient," or that nothing can happen to steal away your patients. The new game has new rules. At issue here is your technology, not your professionalism. You need the right equipment to stay connected and play the game.

As for payments, another fundamental shift is in the works, a shift away from fee-for-service toward pay-for-performance (P4P). This shift was signaled in July 2007 by the Physician Quality Reporting Initiative (PQRI), essentially a pay-for-reporting pilot program. Today, the program has evolved into the Physician Quality Reporting System (PQRS) and dovetails with the Meaningful Use requirement to report Clinical Quality Measures (CQMs).

CQMs, in turn, are the stuff of registries that collect and curate condition-specific health data at the patient population level. One goal of registries is to enable the development of performance measures and best-practice protocols that, in turn, help improve patient outcomes. It is such advances—again, all fueled by EHRs—that will give rise to P4P reimbursement models.

5 steps to EHR and beyond…

Meaningful Use (MU) Stage 1 was about the rise of EHRs. Stage 2 journeys beyond EHRs. This 5-step continuum outline helps show the big picture that only began with EHRs.

- ☐ **STEP 1** **Implement and use certified EHRs.** Electronic records are the new standard for relevancy in the healthcare business.
- ☐ **STEP 2** **Communicate electronically.** This includes the secure electronic exchange of health data.
- ☐ **STEP 3** **Position your practice for team delivery of care.** Healthcare has moved to the care team model—a team-based delivery of care.
- ☐ **STEP 4** **Acceptance on care teams.** You need to be part of those care teams.
- ☐ **STEP 5** **Access to patients and payments.** Do what it takes to retain your patients and the reimbursements you deserve.

Expect P4P reimbursement models to be well contested. Yet, they provide hope against a paper-based fee-for-service model that has proved to be incapable of recognizing and rewarding providers whose care is exemplary. Mediocre, duplicate, and even fraudulent care have been rewarded equally. Advances in health IT will change that, improving reimbursements for those who deserve them, and improving outcomes for all patients.

Beyond EHRs

So, where are we today regarding EHRs? Across the optometry profession, we are seeing continuous adoption of EHRs. The December 2012 EHR Incentive Program report from CMS tells us that 3,934 optometrists have been paid to date, while 10,943 have been registered to date. Those are encouraging numbers, but there is also see a sizeable gap to be closed.

EHRs are Step 1. Step 2 and more take us beyond EHRs. Just as we cannot understand healthcare reform by looking only inside eye care, we cannot understand the end game of reform by focusing our gaze on EHRs. EHRs will remain a constant for providers in their day-to-day work of improving patient outcomes, but there is so much more as well.

> By October 2014, Stage 2 Certification will require **all** EHRs to demonstrate health information exchange capability for care coordination.

To play or not to play?

As a profession, we must know that we belong in the healthcare game. Physicians from all walks of health care want to know what ECPs know and can contribute to the care team. As providers at the preventive end of the eye care spectrum, optometrists must embrace their unique place in providing higher quality at lower cost, another mantra and key tenet of healthcare reform. Let's play! **ODT**

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Author Info

Alistair Jackson, MEd, began his second career when he joined the eyecare software industry. He developed a special interest in EHRs, particularly the impact healthcare reform would have on independent practices. Jackson now writes, speaks and advises through his own consultancy, Eye Care Advice. Learn more at *www.eyecareadvice.net*.

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STUDENT STANDPOINT

Using social media to improve patient care and outcomes

The Internet is the new 'word-of-mouth' referral system

By Nicholas Gubler, OD

Social media is a great tool for networking and bringing people together, not to mention a free and easy way to build your optometry practice. Social media entities are built primarily for communication. Sharing ideas, creating awareness, and coordinating activities are a few of the activities that a person can devote some time doing. Social media is a versatile creature of intrigue that develops into what we create, whether it be establishing a social awareness campaign, joining a cause, or finding a few friends to volunteer with. Social media has a lot to offer a philanthropic individual with just the click of a mouse.


Dr. Gubler

Many optometry practices have realized the benefits of social media and have started marketing strategies to attract new customers. The marketing effort of private practice offices has begun equalizing patient exposure that was formerly attainable only with big budgets and large advertising departments. No matter your stance as a practitioner, whether you are involved in corporate optometry or private practice, the benefits of social media are something everyone can use to bolster patient care and outcomes.

Creating an online presence

The real question is how optometry (or any business) can implement the structure of social media outlets like Facebook, Twitter, and Linked In while not leaving out some of the newer boulevards of Google Plus and Pinterest. Not every practice needs to make a Pinterest business page, and not all practitioners need to revive their dead MySpace profiles to be successful. Practitioners should develop an online presence of their own because patients write online reviews all the time.

How your practice can use social media

- **Find one social media platform and become an expert.**
- **If unsure where to start, choose a mainstream platform like Facebook or Google+.**
- **Followers are more interested in who you are than what you sell, so share what you do and what you believe.**
- **Share other people's links and tips.**
- **Whatever you post, it should be meaningful to patients and help improve the quality of care.**

Take-Home Message

Social media offers marketing benefits to optometric practices. Effort with social media equalizes patient exposure that was formerly attainable only with big budgets and large advertising departments.

Web sites like Yelp may warrant a visit from busy practitioners because patients are constantly leaving reviews about their healthcare experiences, both good and bad. No matter how busy your schedule, it would be wise to take a moment and peruse the Internet to see what has been written about your service as a healthcare provider. The challenge has already begun, and practitioners must defend their own reputation from the scrutiny of patient perception. Whether or not a review is fair is mostly irrelevant. Business consumers reading reviews are rarely given additional information from review Web sites before reaching final decisions. Review sources, such as Angie's List, strive to dig deeper when looking for a doctor online. Angie's List claims its evaluations are better than free review sites for 4 basic principles:[1]

- No anonymous reviews
- Certified data collection process
- Complaint resolution team
- Company/providers respond to reports

Remember, when responding to reviews, be courteous and honest, but keep it short. The last thing most patients want to read is an extended story. Defend yourself and be done with it, and when appropriate offer the patient an opportunity for you to make things right. Though the customer is not always right, he should feel you are interested in him; listening and trying to offer the best service possible can go a long way to improving customer satisfaction.

The ability to navigate review sites like Yelp or Angie's List is an important venture worthwhile to help ensure quality customer service online. If a practitioner doesn't have time or want to worry about this aspect of the practice, it can easily be delegated to an

See **Social media** on page 30

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Social media

Continued from page 28

office manager or an office assistant better suited for the job. While it is not all about marketing, developing a presence online can help ensure your customers know they are getting exceptional service that will be consistent with the growth of your practice. The better you become at responding to customer comments, the more efficient you will be at keeping the referrals from online review sites. It has been said by many practitioners today that the best way to grow a practice is by word of mouth, so remember that a review site is the Internet's version of what people have done for years.

Engaging patients

Coordinating activities is another activity that can keep patients involved with a practice. Whether it is letting the patients choose the color of your next office paint job or a few pieces of art to add to the office, a Pinterest business account can add atmosphere to an office. Patient involvement in an office gives them ownership of the practice. Patients feel more welcome and comfortable in a place that they helped create. A sense of accomplishment creates the opportunity to build relationships of trust and commitment.

In the past, optometrists wrote feature stories in the newspaper or shared a newsletter. Today, optometrists need to be on the Web sharing ideas and conversing with their population base. Publishing articles (online) is still an excellent way for an optometrist to become an established expert practitioner. Blogs are another wonderful way to create awareness and educate patients. They help communicate information in a way that speaks volumes to patients. Just imagine the joy in sharing your passion for optometry on your blog and educating patients about disease prevention or the latest contact lens design. Staying up to date with social networking conveys knowledge of new technology and current trends in the industry. Patients appreciate the efforts of practitioners who are current on all things optometry.

Along with educating patients comes the passion for the profession of optometry. One fun way to share this passion is Instagram, an online portal for pictures. Instead of inviting patients over for a slide show of your most recent mission trip, consider posting a link on Facebook to Instagram. That could be just the beginning of optometrists using social media.

> 'A practitioner must be ready to embrace change and be willing to expect success through new corridors. Optometrists should familiarize themselves with at least one form of social media and become an expert.'
>
> Nicholas Gubler, OD

Looking ahead

The future of social media and optometry extends beyond what we know today. Current research across America is moving toward video gaming platforms for solving some of the most complex problems in our society. An article by Dayton Fandray outlines the advances individuals are making with scientific gaming.[2] The technology, termed "gamification," involves video game enthusiasts working to unlock the mysteries of protein molecules that have eluded the smartest supercomputers. Gabe Zichermann, a guru of the craze states, "The world is full of idealistic people with great ideas and a vision for how things could be better." He continues, "[Humans] have a 'last mile' problem of sustaining people's engagement long enough to complete a problem."[2]

Optometrists deal with this on a daily basis with almost every savvy patient equipped with an iPhone or Android device. Who is to say that patients couldn't educate themselves about eye disease via social media? Many patients already play farming games on Facebook, run a business online, or have led a battle surge. Fandray believes "the immersive nature of the online experience…has created exciting new possibilities for engaging students in learning activities."[2] Online games for anatomy are already available for optometry students, and perhaps these could extend to help patients learn about the eyes and what doctors recommend.

The key for any changing climate is preparation. The future waits for no one and needs no invitation before it changes the way we communicate. A practitioner must be ready to embrace change, and be willing to expect success through new corridors. Optometrists should familiarize themselves with at least one form of social media and become an expert…or at least step up above an amateur level of understanding and embrace the ideas that fit their mode of practice best.

Practitioners would do well to start with one of the mainstream networks, such as Facebook, or a broad network like Google Plus, and begin following a few meaningful groups and individuals that match their goals. Followers are more interested in who you are than what you sell, so share what you do and what you believe. If you are stuck, here are a couple of things recommended by one social media blogger: share other people's links and tips, your ideas, and educational information.[3] Sites like All About Vision, or Medscape are also great references that can be used to help educate patients. Whatever practitioners decide to post, it should be meaningful to patients and help improve the quality of care. With all the ways to share, it should be easy to inspire those around us to a better tomorrow. There is no time better than the present to begin a new tradition to improve patient care and outcomes with social media.**ODT**

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Note: *Dr. Nicholas Gubler's essay won this year's American Optometric Society Dr. Harvey Yamamoto Award. Dr. Gubler recently graduated in the inaugural class at Arizona College of Optometry, Midwestern University, Glendale. Contact him at ngubler82@midwestern.edu.*

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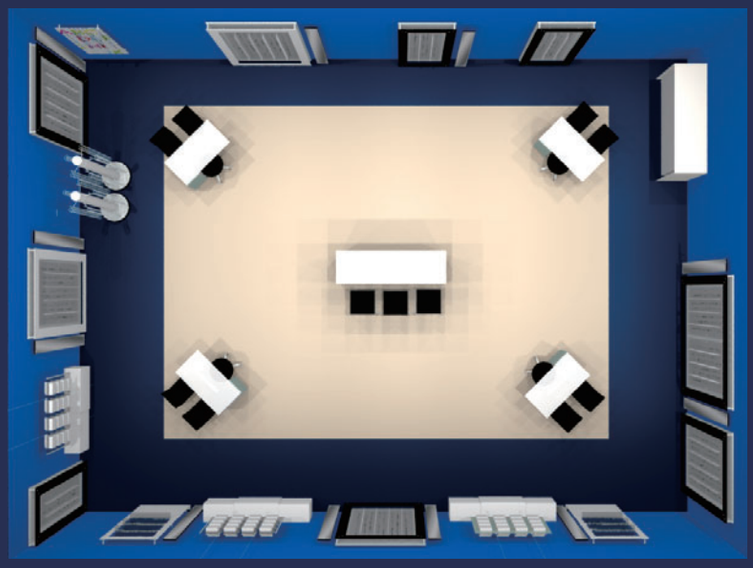

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SOFTWARE

August 2013

Aug. 1-4, 2013
AKOA Annual Summer Conference
Fairbanks, AK
E-mail: AKOA@alaska.com
www.akoa.org
Sponsored by Alaska Optometric Association

Aug. 2-3, 2013
WOA Summer Education Event
Sheboygan, WI
Contact: Joleen Breunig
Phone: 608/824-2200
E-mail: joleen@woa-eyes.org
www.woa-eyes.org
Sponsored by Wisconsin Optometric Association

Aug. 2-4, 2013
SWFOA Annual Educational Retreat
Sanibel, FL
Contact: Brad Middaugh, OD
Phone: 239/481-7799
E-mail: swfoa@att.net
www.swfoa.com
Sponsored by Southwest Florida Optometric Association

Aug. 3-4, 2013
Colorado Vision Summit
Denver, CO
Phone: 303/863-9778
www.coloradovisionsummit.org
Sponsored by Colorado Optometric Association

Aug. 9-10, 2013
Annual Island Retreat
Key West, FL
Contact: Gloria Ayan
Phone: 786/405-9723
E-mail: ocularhealthfoundation@gmail.com
Sponsored by Foundation for Ocular Health and Aran Eye Associates

Aug. 18, 2013
NSU Super Sunday
Orlando, FL
Contact: Vanessa McDonald
Phone: 954/262-4224
E-mail: oceaa@nova.edu
http://optometry.nova.edu
Sponsored by Nova Southeastern University

Aug. 22-25, 2013
SCOPA Annual Meeting
Myrtle Beach, SC
www.sceyedoctors.com
Sponsored by South Carolina Optometric Physicians Association

September 2013

Sept. 19-21, 2013
Envision Conference
Minneapolis, MN
E-mail: info@envisionconference.org
www.envisionconference.org
Sponsored by Envision

Sept. 19-22, 2013
GWCO Annual Congress
Portland, OR
Phone: 503/654-1062
www.gwco.org
Sponsored by Great Western Council of Optometry

Sept. 20-22, 2013
National Opticians Conference
Cincinnati, OH
Contact: 703/719-5800
E-mail: mail@abo-ncle.org
www.abo-ncle.org
Sponsored by American Board of Opticianry and National Contact Lens Examiners

Sept. 21-22, 2013
NSU Fall Conference: Glaucoma Update
Fort Lauderdale, FL
Contact: Vanessa McDonald
Phone: 954/262-4224
E-mail: oceaa@nova.edu
http://optometry.nova.edu
Sponsored by Nova Southeastern University

Sept. 25-29, 2013
WOA Convention and Annual Meeting
Wisconsin Dells, WI
Contact: Joleen Breunig
Phone: 608/824-2200
E-mail: joleen@woa-eyes.org
www.woa-eyes.org
Sponsored by Wisconsin Optometric Association

Sept. 26-27, 2013
SDOS Fall Conference
Rapid City, SD
Contact: Deb Mortenson
Phone: 605/224-8199
E-mail: Sdeyes3@pie.midco.net
www.sdeyes.org
Sponsored by South Dakota Optometric Society

Sept. 27-29, 2013
KOA Annual Fall Conference
Louisville, KY
Phone: 502/875-3516
E-mail: sarah@kyeyes.org
www.kyeyes.org
Sponsored by Kentucky Optometric Association

Sept. 29-Oct. 1, 2013
NDOA Annual Congress and Exhibition
Fargo, ND
Phone: 701/258-6766
E-mail: ndoa@btinet.net
www.ndeyecare.com
Sponsored by North Dakota Optometric Association

October 2013

Oct. 2-5, 2013
International Vision Expo West
Sands Expo Center, Las Vegas, NV
www.visionexpowest.com
Sponsored by Reed Exhibitions and The Vision Council

Oct. 5-7, 2013
CAO Annual Education Conference
Groton, CT
Contact: Lynn Sedlak, CAE, MBA
Phone: 860/529-1900
E-mail: lsedlak@cteyes.org
www.cteyes.org
Sponsored by Connecticut Association of Optometrists

Oct. 8-12, 2013
COVD Annual Meeting
Orlando, FL
Phone: 330/995-0718
www.covd.org
Sponsored by College of Optometrists in Vision Development

Oct. 10, 2013
World Sight Day
www.who.int
Sponsored by World Health Organization (WHO) and International Agency for the Prevention of Blindness (IAPB)

Oct. 11-12, 2013
WOA Northwoods Education Event
Hayward, WI
Contact: Joleen Breunig
Phone: 608/824-2200
E-mail: joleen@woa-eyes.org
www.woa-eyes.org
Sponsored by Wisconsin Optometric Association

Oct. 17-18, 2013
IOA Hawkeye Institute
Cedar Rapids, IA
Phone: 800/444-1772
http://iowaoptometry.org
Sponsored by Iowa Optometric Association

Oct. 19-21, 23-25, 2013
CE in Italy: Florence, Tuscany
Florence and Tuscany, Italy
Contact: James L. Fanelli, OD
Phone: 910/452-7225
E-mail: JamesFanelli@CEinItaly.com
http://CEinItaly.com

Oct. 23–26, 2013
AAO Annual Academy
Seattle, WA
www.aaopt.org
Sponsored by American Academy of Optometry

Fishing

Continued from page 37

Four years later, he purchased a 20-foot motorboat, which he named Daddy's Toy. Because it was more seaworthy than his previous craft, he ventured farther from shore and began deep rig fishing, catching red snapper, grouper, king mackerel, and black fin and yellow fin tuna.

Then a fishing tournament sponsored by the Southern King Mackerel Association came to town. Dr. Kleamenakis and several of his buddies decided to enter their first competition, sometimes called a rodeo. There was just one problem: They didn't know much about mackerel. Worse yet, Dr. Kleamenakis' 20-foot boat could barely compete in ocean waters against the 35-foot boats of competing fishermen.

Not easily intimidated, the friends entered the competition anyway, catching a 25-pound mackerel. "We were really excited, all proud of ourselves with our chests pushed out," he said. "As our boat was docking, I lifted up the fish to show everyone. I heard the announcer say, 'And Daddy's Toy just pulled in with a small king mackerel.' Our egos were so deflated."

Throughout the years, Dr. Kleamenakis has learned a variety of techniques to catch different species of fish.

Dr. Kleamenakis knows he's not the only optometrist who enjoys fishing, and now he organizes annual optometry meetings which include a fishing component.

Rodeos, tournaments, and conferences

Throughout the years, Dr. Kleamenakis has learned a variety of techniques to catch different species of fish, which is part of the sport's attraction. In the mid-1990s, he purchased a 24-foot boat so he and his fishing friends would stand a better chance in tournament competition. Dr. Kleamenakis explained that fishermen must enter many state or regional tournaments and consistently perform well in order to accumulate enough points to qualify for national tournaments.

While he and his friends won first prize in a statewide fishing tournament, earning $3,500 for catching the largest combined speckled trout, red fish, and flounder, their hopes are still high for winning a national tournament. Dr. Kleamenakis said that in 2004, they placed sixth at the Coastal Conservation Association's national redfish tournament held in Slidell, LA. More than 100 fishermen competed for the $25,000 grand prize and, more importantly, bragging rights, he said.

The rules were simple: try to catch the heaviest redfish that wasn't over 27-inches long and keep it alive so it could be released into the ocean after being weighed.

Early on in the competition, Dr. Kleamenakis and his friends were in first place. Still, one fishing partner grew concerned when their fish lost some scales during the struggle to remove it from the boat's holding container, thereby reducing its weight. "Those missing scales knocked us down thousands of dollars," he said. "We wound up in sixth place, collecting $8,000."

Because Dr. Kleamenakis knew he wasn't the only optometrist who loved fishing, he began organizing annual optometry meetings that included fishing trips. Some 12 optometrists attended the first conference, and double that number registered for the following year's event.

"We tell our fishing stories and our lies," he said. "The camaraderie makes it fun, as well as doing something natural that's been pretty much the American way of life since Daniel Boone." **ODT**

FYI

Mike Kleamenakis, OD
Phone: 504/913-8477
E-mail: v.s.@gentilly.nocoxmail.com

Photos courtesy Michael Kleamenakis, OD

Optometrist is hooked on fishing

New Orleans practitioner catches the big ones and reels in other ODs

A few years back, Michael Kleamenakis, OD, excitedly called his family and friends to share some big news: "Our son was born, and I just bought a new boat!"

It was tough for people on the receiving end of the call to tell which newborn excited him more. Actually, it was a tie, recalled Dr. Kleamenakis, a private practitioner in New Orleans.

Dr. Kleamenakis, a native of the Big Easy, is a natural-born fisherman. He caught his first fish—a half-pound perch—when he was just 3 years old. Since then, not a week has gone by when he hasn't baited a hook, dropped a fishing line in water, or ate fish he caught the same day for dinner. For more than 40 years, Dr. Kleamenakis has been the quintessential fisherman, always trying to catch the next fish.

Family affair

Dr. Kleamenakis said his father introduced him to the sport. He remembers spending many Saturdays with dad and his younger brother, catching fish in local marshes and lakes. When he turned 10, his father taught him how to fillet fish, then hand it over to the family chef—his mother.

"I don't know of anything else that compares to fishing," Dr. Kleamenakis said, adding that nothing is more exciting than feeling a tug on his fishing line and waiting to see what's on the other end. "Fishing is in its own category of fun."

While attending optometry school at the University of Houston College of Optometry, he purchased a pirogue—a 12-foot long, 40-pound, flat-bottomed canoe—that he used for fishing in the marshes off Galveston Bay. But the pirogue, which was designed for shallow waters, had its limitations. Because both Dr. Kleamenakis and his wife enjoy fishing, they shopped around for a 16-foot motorboat. "When my son was born, the deal was already struck to buy the boat, so I simply closed the sale," he said.

Competitive fishing

After graduating from optometry school, Dr. Kleamenakis and his family moved back to New Orleans where he started his practice.

See **Fishing** on page 36

For more than 40 years, Dr. Kleamenakis has baited a hook, dropped a line in the water, or eaten his own catch for dinner—every week.

BAUSCH+LOMB

PROLENSA™ (bromfenac ophthalmic solution) 0.07%

Brief Summary

INDICATIONS AND USAGE

PROLENSA (bromfenac ophthalmic solution) 0.07% is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

DOSAGE AND ADMINISTRATION

Recommended Dosing

One drop of PROLENSA ophthalmic solution should be applied to the affected eye once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.

Use with Other Topical Ophthalmic Medications

PROLENSA ophthalmic solution may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics. Drops should be administered at least 5 minutes apart.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Sulfite Allergic Reactions

Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Slow or Delayed Healing

All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including bromfenac, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Potential for Cross-Sensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including bromfenac. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

Increased Bleeding Time

With some NSAIDs, including bromfenac, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

It is recommended that PROLENSA ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Keratitis and Corneal Reactions

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including bromfenac, and should be closely monitored for corneal health.

Post-marketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.

Contact Lens Wear

PROLENSA should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

ADVERSE REACTIONS

Clinical Trial Experience

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

The most commonly reported adverse reactions following use of PROLENSA following cataract surgery include: anterior chamber inflammation, foreign body sensation, eye pain, photophobia and vision blurred. These reactions were reported in 3 to 8% of patients.

USE IN SPECIFIC POPULATIONS

Pregnancy

Treatment of rats at oral doses up to 0.9 mg/kg/day (systemic exposure 90 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and rabbits at oral doses up to 7.5 mg/kg/day (150 times the predicted human systemic exposure) produced no treatment-related malformations in reproduction studies. However, embryo-fetal lethality and maternal toxicity were produced in rats and rabbits at 0.9 mg/kg/day and 7.5 mg/kg/day, respectively. In rats, bromfenac treatment caused delayed parturition at 0.3 mg/kg/day (30 times the predicted human exposure), and caused dystocia, increased neonatal mortality and reduced postnatal growth at 0.9 mg/kg/day.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of PROLENSA ophthalmic solution during late pregnancy should be avoided.

Nursing Mothers

Caution should be exercised when PROLENSA is administered to a nursing woman.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 18 have not been established.

Geriatric Use

There is no evidence that the efficacy or safety profiles for PROLENSA differ in patients 70 years of age and older compared to younger adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (systemic exposure 30 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and 5 mg/kg/day (340 times the predicted human systemic exposure), respectively, revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and micronucleus tests.

Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively (systemic exposure 90 and 30 times the predicted human exposure, respectively).

PATIENT COUNSELING INFORMATION

Slowed or Delayed Healing

Advise patients of the possibility that slow or delayed healing may occur while using NSAIDs.

Sterility of Dropper Tip

Advise patients to replace bottle cap after using and to not touch dropper tip to any surface, as this may contaminate the contents.

Advise patients that a single bottle of PROLENSA, be used to treat only one eye.

Concomitant Use of Contact Lenses

Advise patients to remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

Concomitant Topical Ocular Therapy

If more than one topical ophthalmic medication is being used, the medicines should be administered at least 5 minutes apart

Rx Only

Manufactured by: Bausch & Lomb Incorporated, Tampa, FL 33637
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Osaka, Japan 541-0046

Introducing an advanced formulation of BROMDAY® (bromfenac ophthalmic solution) 0.09%

PROLENSA™
POWERED FOR PENETRATION

PROLENSA™ delivers potency and penetration with QD efficacy[1,2]

- **Advanced formulation delivers corneal penetration[1-3]**
- **Proven efficacy at a lower concentration[1]**

Available in 1.6-mL and 3-mL bottle sizes

IMPORTANT RISK INFORMATION ABOUT PROLENSA™

Indications and Usage
PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Dosage and Administration
Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Please see brief summary of full Prescribing Information on adjacent page.

References: 1. PROLENSA™ Prescribing Information, April 2013. **2.** Data on file, Bausch & Lomb Incorporated. **3.** Baklayan GA, Patterson HM, Song CK, Gow JA, McNamara TR. 24-hour evaluation of the ocular distribution of ^{14}C-labeled bromfenac following topical instillation into the eyes of New Zealand White rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398.

BAUSCH + LOMB

Warnings and Precautions
- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

Adverse Reactions
The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

PROLENSA™
(bromfenac ophthalmic solution) 0.07%

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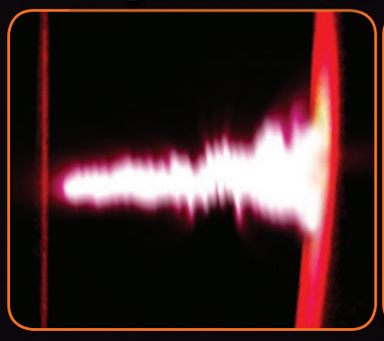

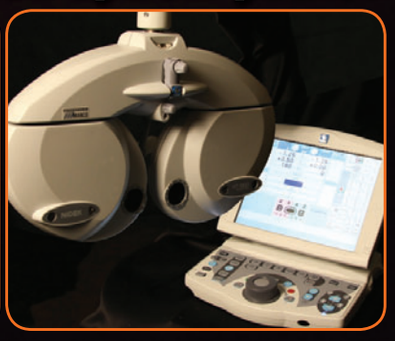

The OPD-Scan III shows you, and your patient, a clear image of their optical pathway. 2520 data points provide over 20 wavefront diagnostics in 20 seconds. Combined with the TRS-5100, either rapid refinements or full refractions complete the picture of their total visual system.

HOA [µm]: @4.00mm / Order = 4 L

	T. Sph	T. Coma	T. Tre	HO
Total:	0.020	0.040	0.025	0.059
Cornea:	0.061	0.108	0.073	0.155
Internal:	0.041	0.085	0.091	0.156

Refraction: VD = 13.75mm

	Sph	Cyl	Axis	RMS
WF@4.00	+1.00	-0.50	105	0.07D
WF@5.42	+0.75	-0.50	111	0.19D
Diff	-0.25	0.00	6	

When the OPD-Scan III indicates 'WF', only a basic refinement is required – saving 5-7 minutes per patient.

In addition, you'll know:

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- Which patients have night driving issues and may require a second Rx
- Which patients have higher-order aberrations that may not be correctable
- How to successfully elevate the total patient experience

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*Data based on national averages.

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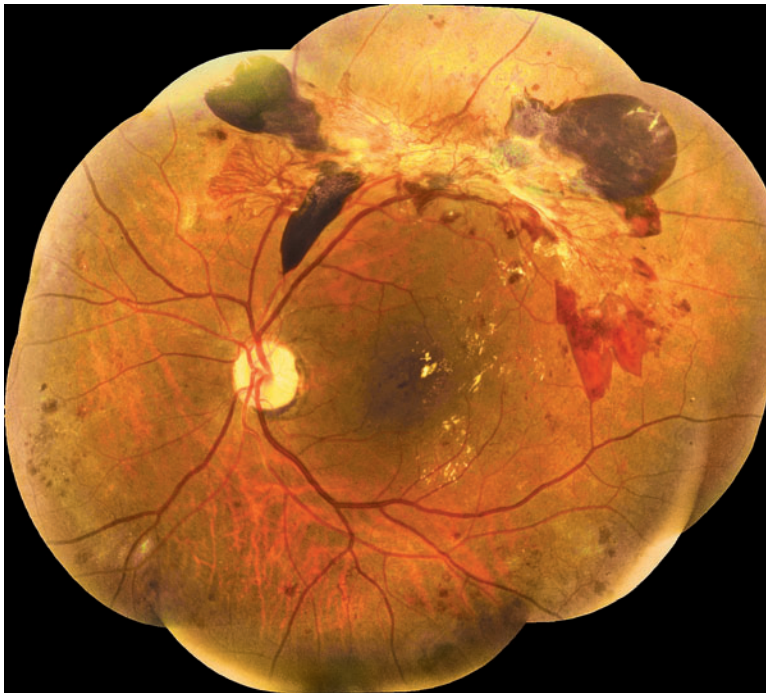


Proliferative diabetic retinopathy

By Mark E. Tafoya, OD, MD

The field of retina is exciting. It is continually changing. Opportunities abound. What's more, the treatment options we can offer our patients are forever increasing. When I was in optometry school and would diagnose a macular hole, I would tell the patient that nothing could be done and there was a chance that the same thing could happen in his fellow eye. But, now I can successfully surgically repair many macular holes.

In my office, I see people from all walks of life and of all ages. My patients span the gamut from premature newborns who are only days old all the way to great-grandparents who are in their early 100s. Retinal conditions affect all races. And here in Hawaii we have a melting pot of ethnicities represented. Retinal disease can also affect all socioeconomic groups. So the diversity in patients is very interesting to me.

In addition to the diversity of my patient base, my typical day at Pacific Retina Care is forever changing. One would think that I have set clinic days and set surgery days that were the same day every week. But because I am on call 24 hours per day and 7 days per week, I can be called in at any time and on any day. About one third of my surgical cases are unscheduled emergencies that I perform after clinic in the evening or on weekends. Because I treat every patient as an individual, even the encounter varies from patient to patient. Surprisingly, there is quite a variety of retinal diseases.

Out of all the patients I see, there are four most common categories of disease that I encounter.

Diabetic retinopathy

Diabetic eye disease is the most common condition that I encounter. All of us know that diabetes is of epidemic proportions. According to the American Diabetes Association (ADA), diabetes affects more than 25 million Americans.[1] Sadly, many patients with diabetes are undiagnosed; by the time the patient sees me, he or she has severe diabetic eye disease. The ADA

See **Retina** on Page 4

INSIDE:

Cataract

The cataract patient's journey

Cataract removal has been, and will likely remain for some time to come, a cornerstone of eye care and a major source of revenue for most ophthalmic practices.

Anyone who works in the eyecare field should have at least a passing understanding of how cataracts develop, the surgery that removes them, the postoperative routine, and the rapidly evolving technology of intraocular lenses (IOLs).

PAGE **10**

ONE INJECTION, EARLY INTERVENTION.

TAKE ACTION WITH JETREA®
(ocriplasmin) Intravitreal Injection, 2.5 mg/mL

The **FIRST** and **ONLY** pharmacologic treatment for symptomatic Vitreomacular Adhesion (VMA).[1]

Indication

JETREA (ocriplasmin) Intravitreal Injection, 2.5 mg/mL, is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion.

Important Safety Information

Warnings and Precautions

- A decrease of ≥ 3 lines of best-corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with JETREA and 3.2% of patients treated with vehicle in the controlled trials. The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention. Patients should be monitored appropriately.
- Intravitreal injections are associated with intraocular inflammation/infection, intraocular hemorrhage and increased intraocular pressure (IOP). Patients should be monitored and instructed to report any symptoms without delay. In the controlled trials, intraocular inflammation occurred in 7.1% of patients injected with JETREA vs 3.7% of patients injected with vehicle. Most of the post-injection intraocular inflammation events were mild and transient. If the contralateral eye requires treatment with JETREA, it is not recommended within 7 days of the initial injection in order to monitor the post-injection course in the injected eye.
- Potential for lens subluxation.
- In the controlled trials, the incidence of retinal detachment was 0.9% in the JETREA group and 1.6% in the vehicle group, while the incidence of retinal tear (without detachment) was 1.1% in the JETREA group and 2.7% in the vehicle group. Most of these events occurred during or after vitrectomy in both groups.
- Dyschromatopsia (generally described as yellowish vision) was reported in 2% of all patients injected with JETREA. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

Adverse Reactions

- The most commonly reported reactions (≥ 5%) in patients treated with JETREA were vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, and retinal edema.

VISIT **JETREACARE.COM** FOR
REIMBURSEMENT AND ORDERING INFORMATION

LEARN MORE AT JETREA.COM

Please see Brief Summary of full Prescribing Information on adjacent page.

ThromboGenics®

JETREA™
(ocriplasmin)
Intravitreal Injection, 2.5 mg/mL

Reference: 1. JETREA [package insert]. Iselin, NJ: ThromboGenics, Inc.; 2012.

05/13 OCRVMA0072 JA1 J

JETREA™
(ocriplasmin)
Intravitreal Injection, 2.5 mg/mL

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

Please see the JETREA® package insert for full Prescribing Information.

1 INDICATIONS AND USAGE
JETREA is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion.

2 DOSAGE AND ADMINISTRATION
2.1 General Dosing Information
Must be diluted before use. For single-use ophthalmic intravitreal injection only. JETREA must only be administered by a qualified physician.

2.2 Dosing
The recommended dose is 0.125 mg (0.1 mL of the diluted solution) administered by intravitreal injection to the affected eye once as a single dose.

2.3 Preparation for Administration
Remove the vial (2.5 mg/mL corresponding to 0.5 mg ocriplasmin) from the freezer and allow to thaw at room temperature (within a few minutes). Once completely thawed, remove the protective polypropylene flip-off cap from the vial. The top of the vial should be disinfected with an alcohol wipe. Using aseptic technique, add 0.2 mL of 0.9% w/v Sodium Chloride Injection, USP (sterile, preservative-free) into the JETREA vial and gently swirl the vial until the solutions are mixed.

Visually inspect the vial for particulate matter. Only a clear, colorless solution without visible particles should be used. Using aseptic technique, withdraw all of the diluted solution using a sterile #19 gauge needle (slightly tilt the vial to ease withdrawal) and discard the needle after withdrawal of the vial contents. Do not use this needle for the intravitreal injection.

Replace the needle with a sterile #30 gauge needle, carefully expel the air bubbles and excess drug from the syringe and adjust the dose to the 0.1 mL mark on the syringe (corresponding to 0.125 mg ocriplasmin). THE SOLUTION SHOULD BE USED IMMEDIATELY AS IT CONTAINS NO PRESERVATIVES. Discard the vial and any unused portion of the diluted solution after single use.

2.4 Administration and Monitoring
The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include the use of sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a broad spectrum microbiocide should be administered according to standard medical practice.

The injection needle should be inserted 3.5 - 4.0 mm posterior to the limbus aiming towards the center of the vitreous cavity, avoiding the horizontal meridian. The injection volume of 0.1 mL is then delivered into the mid-vitreous.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., eye pain, redness of the eye, photophobia, blurred or decreased vision) without delay *[see Patient Counseling Information]*.

Each vial should only be used to provide a single injection for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, and injection needles should be changed before JETREA is administered to the other eye, however, treatment with JETREA in the other eye is not recommended within 7 days of the initial injection in order to monitor the post-injection course including the potential for decreased vision in the injected eye.

Repeated administration of JETREA in the same eye is not recommended *[see Nonclinical Toxicology]*.

After injection, any unused product must be discarded.

No special dosage modification is required for any of the populations that have been studied (e.g. gender, elderly).

3 DOSAGE FORMS AND STRENGTHS
Single-use glass vial containing JETREA 0.5 mg in 0.2 mL solution for intravitreal injection (2.5 mg/mL).

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS
5.1 Decreased Vision
A decrease of ≥ 3 line of best corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with JETREA and 3.2% of patients treated with vehicle in the controlled trials *[see Clinical Studies]*.

The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention. Patients should be monitored appropriately *[see Dosage and Administration]*.

5.2 Intravitreal Injection Procedure Associated Effects
Intravitreal injections are associated with intraocular inflammation / infection, intraocular hemorrhage and increased intraocular pressure (IOP). In the controlled trials, intraocular inflammation occurred in 7.1% of patients injected with JETREA vs. 3.7% of patients injected with vehicle. Most of the post-injection intraocular inflammation events were mild and transient. Intraocular hemorrhage occurred in 2.4% vs. 3.7% of patients injected with JETREA vs. vehicle, respectively. Increased intraocular pressure occurred in 4.1% vs. 5.3% of patients injected with JETREA vs. vehicle, respectively.

5.3 Potential for Lens Subluxation
One case of lens subluxation was reported in a patient who received an intravitreal injection of 0.175 mg (1.4 times higher than the recommended dose). Lens subluxation was observed in three animal species (monkey, rabbit, minipig) following a single intravitreal injection that achieved vitreous concentrations of ocriplasmin 1.4 times higher than achieved with the recommended treatment dose. Administration of a second intravitreal dose in monkeys, 28 days apart, produced lens subluxation in 100% of the treated eyes *[see Nonclinical Toxicology]*.

5.4 Retinal Breaks
In the controlled trials, the incidence of retinal detachment was 0.9% in the JETREA group and 1.6% in the vehicle group, while the incidence of retinal tear (without detachment) was 1.1% in the JETREA group and 2.7% in the vehicle group. Most of these events occurred during or after vitrectomy in both groups. The incidence of retinal detachment that occurred pre-vitrectomy was 0.4% in the JETREA group and none in the vehicle group, while the incidence of retinal tear (without detachment) that occurred pre-vitrectomy was none in the JETREA group and 0.5% in the vehicle group.

5.5 Dyschromatopsia
Dyschromatopsia (generally described as yellowish vision) was reported in 2% of all patients injected with JETREA. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

6 ADVERSE REACTIONS
The following adverse reactions are described below and elsewhere in the labeling:

- Decreased Vision *[see Warnings and Precautions]*
- Intravitreal Injection Procedure Associated Effects *[see Warnings and Precautions and Dosage and Administration]*
- Potential for Lens Subluxation *[see Warnings and Precautions]*
- Retinal Breaks *[see Warnings and Precautions and Dosage and Administration]*

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates in one clinical trial of a drug cannot be directly compared with rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.

Approximately 800 patients have been treated with an intravitreal injection of JETREA. Of these, 465 patients received an intravitreal injection of ocriplasmin 0.125 mg (187 patients received vehicle) in the 2 vehicle-controlled studies (Study 1 and Study 2).

The most common adverse reactions (incidence 5% - 20% listed in descending order of frequency) in the vehicle-controlled clinical studies were: vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, and retinal edema.

Less common adverse reactions observed in the studies at a frequency of 2% - < 5% in patients treated with JETREA included macular edema, increased intraocular pressure, anterior chamber cell, photophobia, vitreous detachment, ocular discomfort, iritis, cataract, dry eye, metamorphopsia, conjunctival hyperemia, and retinal degeneration.

Dyschromatopsia was reported in 2% of patients injected with JETREA, with the majority of cases reported from two uncontrolled clinical studies. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. Immunogenicity for this product has not been evaluated.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy: Teratogenic Effects
Pregnancy Category C. Animal reproduction studies have not been conducted with ocriplasmin. There are no adequate and well-controlled studies of ocriplasmin in pregnant women. It is not known whether ocriplasmin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The systemic exposure to ocriplasmin is expected to be low after intravitreal injection of a single 0.125 mg dose. Assuming 100% systemic absorption (and a plasma volume of 2700 mL), the estimated plasma concentration is 46 ng/mL. JETREA should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers
It is not known whether ocriplasmin is excreted in human milk. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, caution should be exercised when JETREA is administered to a nursing woman.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use
In the clinical studies, 384 and 145 patients were ≥ 65 years and of these 192 and 73 patients were ≥ 75 years in the JETREA and vehicle groups respectively. No significant differences in efficacy or safety were seen with increasing age in these studies.

10 OVERDOSAGE
The clinical data on the effects of JETREA overdose are limited. One case of accidental overdose of 0.250 mg ocriplasmin (twice the recommended dose) was reported to be associated with inflammation and a decrease in visual acuity.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No carcinogenicity, mutagenicity or reproductive and developmental toxicity studies were conducted with ocriplasmin.

13.2 Animal Toxicology and/or Pharmacology
The ocular toxicity of ocriplasmin after a single intravitreal dose has been evaluated in rabbits, monkeys and minipigs. Ocriplasmin induced an inflammatory response and transient ERG changes in rabbits and monkeys, which tended to resolve over time. Lens subluxation was observed in the 3 species at ocriplasmin concentrations in the vitreous at or above 41 mcg/mL, a concentration 1.4-fold above the intended clinical concentration in the vitreous of 29 mcg/mL. Intraocular hemorrhage was observed in rabbits and monkeys.

A second intravitreal administration of ocriplasmin (28 days apart) in monkeys at doses of 75 mcg/eye (41 mcg/mL vitreous) or 125 mcg/eye (68 mcg/mL vitreous) was associated with lens subluxation in all ocriplasmin treated eyes. Sustained increases in IOP occurred in two animals with lens subluxation. Microscopic findings in the eye included vitreous liquefaction, degeneration/disruption of the hyaloideo-capsular ligament (with loss of ciliary zonular fibers), lens degeneration, mononuclear cell infiltration of the vitreous, and vacuolation of the retinal inner nuclear cell layer. These doses are 1.4-fold and 2.3-fold the intended clinical concentration in the vitreous of 29 mcg/mL, respectively.

14 CLINICAL STUDIES
The efficacy and safety of JETREA was demonstrated in two multicenter, randomized, double masked, vehicle-controlled, 6 month studies in patients with symptomatic vitreomacular adhesion (VMA). A total of 652 patients (JETREA 464, vehicle 188) were randomized in these 2 studies. Randomization was 2:1 (JETREA:vehicle) in Study 1 and 3:1 in Study 2.

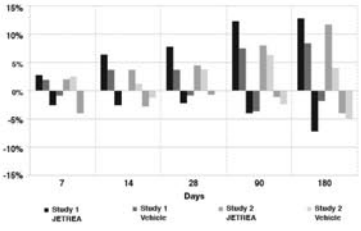
Patients were treated with a single injection of JETREA or vehicle. In both of the studies, the proportion of patients who achieved VMA resolution at Day 28 (i.e., achieved success on the primary endpoint) was significantly higher in the ocriplasmin group compared with the vehicle group through Month 6.

The number of patients with at least 3 lines increase in visual acuity was numerically higher in the ocriplasmin group compared to vehicle in both trials, however, the number of patients with at least a 3 lines decrease in visual acuity was also higher in the ocriplasmin group in one of the studies (Table 1 and Figure 1).

Table 1: Categorical Change from Baseline in BCVA at Month 6, Irrespective of Vitrectomy (Study 1 and Study 2)

Study 1			
	JETREA	Vehicle	Difference
	N=219	N=107	(95% CI)
≥ 3 line Improvement in BCVA			
Month 6	28 (12.8%)	9 (8.4%)	4.4 (-2.5, 11.2)
> 3 line Worsening in BCVA			
Month 6	16 (7.3%)	2 (1.9%)	5.4 (1.1, 9.7)
Study 2			
	JETREA	Vehicle	Difference
	N=245	N=81	(95% CI)
≥ 3 line Improvement in BCVA			
Month 6	29 (11.8%)	3 (3.8%)	8.1 (2.3, 13.9)
> 3 line Worsening in BCVA			
Month 6	10 (4.1%)	4 (5.0%)	-0.9 (-6.3, 4.5)

Figure 1: Percentage of Patients with Gain or Loss of ≥ 3 Lines of BCVA at Protocol-Specified Visits



16 HOW SUPPLIED/STORAGE AND HANDLING
Each vial of JETREA contains 0.5 mg ocriplasmin in 0.2 mL citric-buffered solution (2.5 mg/mL). JETREA is supplied in a 2 mL glass vial with a latex free rubber stopper. Vials are for single use only.

Storage
Store frozen at or below -4°F (-20°C). Protect the vials from light by storing in the original package until time of use.

17 PATIENT COUNSELING INFORMATION
In the days following JETREA administration, patients are at risk of developing intraocular inflammation/infection. Advise patients to seek immediate care from an ophthalmologist if the eye becomes red, sensitive to light, painful, or develops a change in vision *[see Warnings and Precautions]*.

Patients may experience temporary visual impairment after receiving an intravitreal injection of JETREA *[see Warnings and Precautions]*. Advise patients to not drive or operate heavy machinery until this visual impairment has resolved. If visual impairment persists or decreases further, advise patients to seek care from an ophthalmologist.

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Version 1.0
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Retina

Continued from page 1

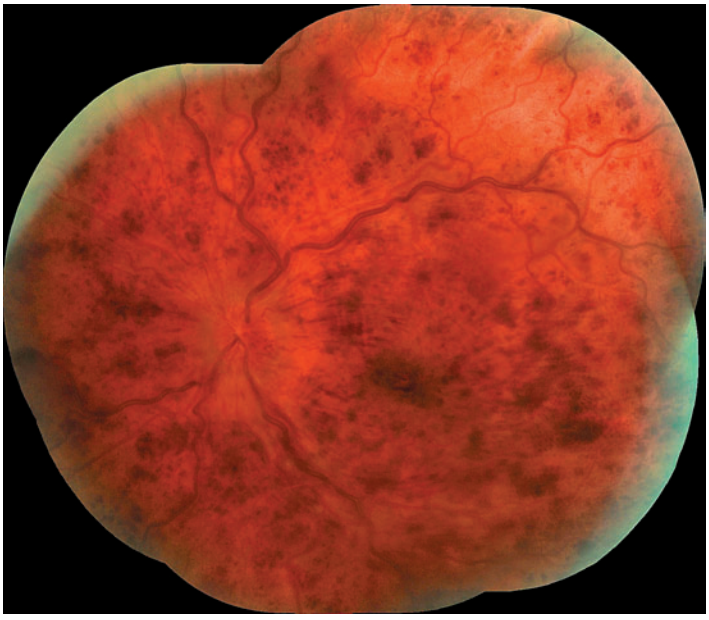
also says diabetes is the leading cause of new blindness in the U.S.[2]

In early diabetic retinopathy, we follow patients closely with dilated fundus exam, HD-OCT, fluorescence angiography, and B-scan imagery when indicated. As the disease progresses, patients may require closer monitoring, intravitreal injection, and laser treatment, all of which I perform in-office. If patients develop a non-clearing vitreous hemorrhage or tractional retinal detachment, then surgical intervention is offered. Also, macular edema can occur, which can be improved by anti-VEGF injections, steroids, or laser treatment.

The two main categories of diabetic retinopathy—proliferative and non-proliferative—differ in the formation of neovascularization. In proliferative disease, new blood vessels form at the optic nerve, elsewhere on the retina, or on the iris. These vessels are weak and leaky. Neovascularization of the retina leads to tractional retinal detachment. Neovascularization of the iris can cause a form of glaucoma. Either type of retinopathy can also involve macular edema.

Age-related Macular Degeneration

Age-related macular degeneration (AMD) affects 19 million Americans.[3] The majority has dry AMD. Currently, there is research on various treatments for dry AMD, but there are no FDA-approved treatments available at this time. More than 1.7 million patients have the wet form.[4] Wet AMD is characterized by leaking fluid or blood as a result of neovascularization. Fortunately, most cases of wet AMD have a positive outcome with anti-VEGF agents administered to the eye via intravitreal injection. I perform this procedure many times during the day to affected patients, often on a monthly basis.



Central retinal vein occlusion (CRVO)

There are many anti-VEGF medications available to choose from, such as Lucentis (ranibizumab, Genentech), Avastin (bevacizumab, Genentech), and Eylea (aflibercept, Regeneron). Information from the recent CATT Trial, which compared the use of Lucentis with Avastin head to head for the treatment of wet AMD, resulted in finding them to be equally effective when given monthly.[5] Eylea is the newest agent available, and it can be administered every other month rather than monthly. It has been found to be equally effective compared with monthly dosing of Lucentis for wet AMD.[5]

My goal for treating wet AMD is to get the macular region dry in OCT—no swelling due to intra- or sub-retinal fluid. I used clinical examination, HD-OCT, and fluorescein angiography to evaluate the response to these anti-VEGF agents. The field of retinal pharmacology is rapidly evolving. Several companies are currently testing their medication in the hopes that they can find a longer acting and more potent agent with an improved delivery vehicle. In the future, a combination of medications, each doing its own role, looks to provide the best promise for treating AMD.

Vascular occlusive disease

Retinal vein occlusion (RVO) is the second most common retinal vascular disease following diabetic retinopathy.[6] The spectrum of RVO includes central retinal vein occlusion (CRVO), hemi-retinal vein occlusion (HRVO), and branch retinal vein occlusion (BRVO). Patients with RVO often develop sudden painless loss of vision. Risk factors include hypertension, diabetes, age, anatomical predisposition, smoking, hyperlipidemia, hypercoagulable states, and glaucoma/elevated intraocular pressure.[7] VEGF plays a key role in the evolution and progression of RVO disease. Some of the highest levels of VEGF are often present in RVO patients. The mechanism of vision loss can be due to macular edema, neovascularization, and macular ischemia.[8] Neovascularization can

lead to neovascular glaucoma, vitreous hemorrhage, and tractional retinal detachment. Fortunately, there are more treatment options for RVO-associated macular edema today than in the past. Due to the high levels of VEGF present in this disease, anti-VEGF agents are quite effective. In addition, combination therapy, consisting of anti-VEGF injections, steroids, and laser, seems to provide the most effective mode of treatment in my office.

Anatomical disease

Treatments of retinal anatomical changes—retinal detachments, retinal tears, macular holes, and epiretinal membrane—most often involve surgery. However, the enzyme Jetrea (ocriplasmin) has been FDA approved for symptomatic vitreomacular adhesion (VMA). The ability to treat VMA with an injectable agent is attractive due to reduced risk compared with surgery. It has been shown to have a positive outcome in some patients. This new medication can be used in some macular hole cases and, if successful, the patient will avoid having to position face-down, as is the case after macular hole surgery.[9] Jetrea could also be used in cases of diabetic macular edema that show VMA.

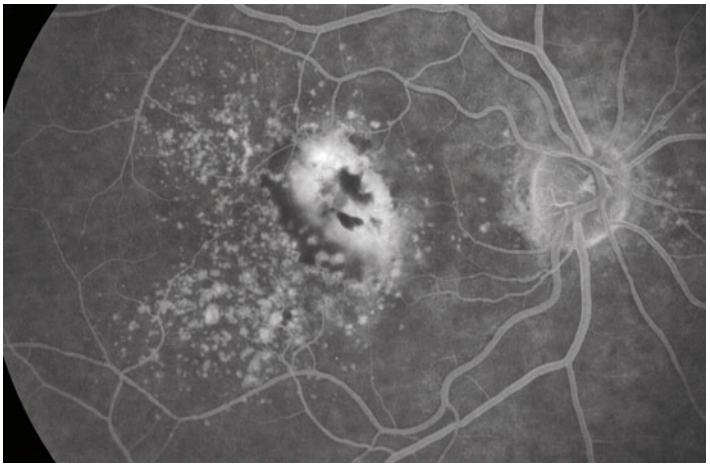
Working with an eyecare professional

Dr. Mark E. Tafoya relies on his assistants to help him manage retina patients in many ways, including:

- Taking a thorough case history, performing preliminary testing, performing all diagnostic testing, and scribing
- Preparing patients for treatment and assisting with procedures
- If surgery is required, educating patients in preparation for consent with the doctor; scheduling the case with the hospital; ensuring that all paperwork is prepared
- Facilitating communications with patients, hospitals, other doctors' offices, and pharmacies

Retinal detachments and retinal tears, if detected early, can be treated in-office with pneumatic retinopexy and laser/cryotherapy. The best case for pneumatic retinopexy is a patient with a single retinal break in the superior retina. These patients often recover faster than those that must go to surgery for vitrectomy with or without scleral buckle. Small-gauge instrumentation for vitrectomy has become available over the past 10 years, and I use it in every vitrectomy case that I perform. Small-gauge, disposable instruments and newer vitrectomy instruments have produced more efficient retinal surgery than when I was a resident and retina fellow. I am able to perform complex retinal detachment repairs, macular hole repairs, and epiretinal membrane removal in less time and with less trauma. Clearly, these new technologies and treatments lead to better outcomes and faster recovery times for our patients.

Retina is an exciting specialty. With the help of my assistants, I can effectively manage my patients and address their retinal needs.◗



Courtesy of Mark E. Tafoya, OD, MD

Wet age-related macular degeneration fluorescence angiography

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Dr. Tafoya is in private practice in Waipahu, HI.

ADVANCE YOUR CAREER THROUGH CERTIFICATION

By Liz Meszaros

If you're an ophthalmic assistant or technician wondering about your career options, consider the many ophthalmic certification options open to you. Broader employment opportunities, enhanced job mobility, and increased earning power are just some of the benefits of becoming a certified ophthalmic assistant or technician. Public recognition and an enhanced acceptance by future managed healthcare systems are also benefits.

Your first step to becoming certified should be a visit to the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO) Web site, *www.jcahpo.org*. JCAHPO offers certification and continuing education to all ophthalmic allied health personnel. For everyone interested, this process involves 6 steps:

- **Fulfill required education and work experience**
- **Apply for initial certification**
- **Successfully complete the exam for initial certification**
- **Keep up with required continuing education credits**
- **Apply for re-certification every 3 years**
- **Advance to the next level of certification**

JCAPHO provides 3 levels of certification, with each requiring pre-set eligibility requirements and successfully passing an exam. The 3 levels begin with an entry-level certification and proceed to advanced-level certification:

Take-Home Message

Ophthalmic assistants and technicians can expand their career options by earning ophthalmic certifications. Diverse employment opportunities, enhanced job mobility, and increased earning power are just some of the benefits of becoming a certified ophthalmic assistant or technician.

Certified Ophthalmic Assistant (COA): This is the core level of certification. Some of the more common tasks performed by COAs include:

- **Measuring visual acuity**
- **Instilling ocular medications**
- **Taking medical and family histories**
- **Performing manifest refractometry**
- **Instructing patients about medications, tests, and procedures**
- **Coordinating patient flow**
- **Measuring IOP using applanation tonometry**
- **Taking part in telephone triage**
- **Measuring pinhole acuity**
- **Measuring, comparing, and testing the pupils**

Certified Ophthalmic Technician (COT): This intermediate level of certification is different from COA certification in that instead of 6 months to 1 year of training required for COA certification, COT certification is 1 to 2 years long. COTs have more responsibilities and technical skills than COAs, as well as more experience. In general, COTs have worked as either a COA for at least 1 year or graduated from training programs offered by the Commission on Accreditation of Ophthalmic Medical Programs (CoA-OMP), Certified Medical Assistant (CMA), or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredited training program.

Certified Ophthalmic Medical Technologist (COMT): Working at the highest levels of JCAHPO certification, the COMT can perform additional jobs including obtaining ophthalmic photographs, using ultrasound, and providing instruction and supervision of other ophthalmic personnel. COMTs have a higher level of responsibility and expertise than either COAs or COTs and are expected to have the ability to make clinical and technical judgments. Training generally lasts 2 or more years.

Go on to subspecialize

Once certified at any of these levels, ophthalmic healthcare providers can also become certified in subspecialty areas, such as ophthalmic surgical assisting (OSA). OSAs assist ophthalmologists through the entire surgical process, including pre-op, post-op, and follow-up patient care. OSAs are required to be knowledgeable in:

- **Pre-operative patient preparation**
- **Surgical instrument use**

See **Certification** on page 8

For more than 20 years, Liz Meszaros has been covering medical news. Reach her at lizm32@ptd.net.


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Certification

Continued from page 6

- **Aseptic technique**
- **Surgical procedures**
- **Surgical complications**
- **Surgical pharmacology.**

The JCAHPO has made available the subspecialty certification guidelines for OSA, which are available at *www.jcahpo.org/certification/osa.aspx*, as well as the "Ophthalmic Surgical Assisting Independent Study Course," available at *www.jcahpo.org/certification/osa.aspx*.

Specialty certifications are also available in the following subspecialties:

Registered ophthalmic ultrasound biometrist (ROUB): ROUB certificate holders specialize in A-scan biometry of the eye and assist ophthalmologists in the analysis of imaging for diagnostic and treatment purposes. They administer intraocular lens (IOP) power calculations, perform instrument settings, and must have a strong knowledge of the basic physics and keratometry of the eye and exam techniques and procedures related to biometry.

Certified diagnostic ophthalmic sonographer (CDOS): CDOS certificate holders perform critical tasks related to B-scan sonography in clinical settings under the supervision and direction of ophthalmologists. They must have superior knowledge of the anatomy and physiology of the eye and orbit, as well as the ability to perform sonographic exams to analyze the various components of the eye to help diagnose patients.

More about certification opportunities

For ophthalmic assistants and technicians interested in certification, a wealth of information is available from several sources. For example, to discover more about certification and requirements, go to the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO) Web site, *www.jcahpo.org/certification/coa.aspx* or *www.jcahpo.org/certification/cot.aspx*.

In addition, the 2013 edition of JCAHPO's "Criteria for Certification and Recertification" is available at *www.jcahpo.org/certification/pdfs/CriteriaforCert_FULL.pdf*.

Other informative Web sites:

- **American Society of Ophthalmic Administrators** (ASOA): *www.asoa.org/coe*.
- **Association of Technical Personnel in Ophthalmology** (ATPO): *www.atpo.org/ATPO/Home/ATPO/Default.aspx*.
- **ACTIONed premier e-learning network for ophthalmic professionals:** *http://action.jcahpo.org/*.
- **Commission on Accreditation of Ophthalmic Medical Programs** (CoA-OMP): *www.coa-omp.org/*.
- **Discover Eye Careers:** www.discovereyecareers.org/.
- **JCAHPO/ATPO annual continuing education program:** www.jcahpo.org/ace2013/.

Corporate certified ophthalmic assistant (CCOA): CCOA certificate holders are industry sales representatives who connect with administrators, physicians, and other healthcare personnel and work in the corporate segment of the eyecare field.

Another certification option is the Certified Ophthalmic Executive (COE). COE applicants must have at least 3 years of healthcare administration experience, 1 or more years of ophthalmic practice management experience, and a working knowledge of administrative duties in 7 content areas, including:

- **Basic ophthalmic knowledge**
- **Finance and accounting**
- **Business operations**
- **Marketing**
- **Risk management and regulatory compliance**
- **Human resources**
- **Management information systems**

COE applicants must complete the COE examination at a Pearson Vue Testing Center, of which there are approximately 5,000 throughout the country, or at the American Society of Ophthalmic Administrators (ASOA) Congress on Ophthalmic Practice Management held each spring.

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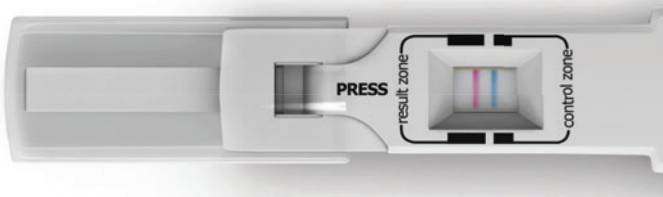

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THE CATARACT PATIENT'S JOURNEY

Take a quick tour through this common surgery

By Frank Celia

Cataract removal is the most frequently performed surgery in the United States, with some 3 million patients undergoing the procedure each year.[1] It is also one of the most successful surgical procedures, producing very favorable visual outcomes and few adverse side effects. It has been, and will likely remain for some time to come, a cornerstone of eye care and a major source of revenue for most ophthalmic practices.

Anyone who works in the eyecare field should have at least a passing understanding of how cataracts develop, the surgery that removes them, the postoperative routine, and the rapidly evolving technology of intraocular lenses (IOLs). Following is a brief sketch of what today's patients with cataracts can expect.

Frank Celia is a freelance healthcare writer based in the Philadelphia area. Reach him at frankcelia@aol.com.

Symptoms and diagnosis

The lens of the human eye—a clear, flexible orb made mostly of water and protein—sits directly behind the iris and pupil. It focuses incoming light on the retina. Muscles around the lens cause it to change shape when we focus on objects near or far. For some unknown reason, around age 40, these muscles start to fail. This is why people in this age group and older have trouble reading small print, a refractive condition called presbyopia.

Another result of aging: proteins in the lens begin to clump together, causing some areas of the lens to become cloudy, creating a cataract. As the cataract grows, the cloudiness increases and vision declines. The surgeon breaks up this lens into pieces, removes them, and then inserts a clear plastic IOL, which will mimic the function of a natural lens.

Early cataracts may cause changes in vision that prompt a person to seek medical care. A cataract can be diagnosed during a routine eye examination or in the course of treatment for other ocular conditions. Changes will be gradual in the beginning. Sight may be cloudy or slightly blurry. Sunlight or lamplight may appear too bright or glaring. During nighttime driving, oncoming headlights may seem to contain more glare than previously. Colors may lose their luster.

Depending on the location of the growing cataract, near vision may actually improve somewhat in the early stages. However, this "second sight" is temporary, quickly replaced by vision impairment. Other differently positioned cataracts may induce few symp-

Take-Home Message

Cataract surgery, the most frequently performed surgery in the United States, is about as complication-free as a surgical procedure can get. Staying informed about this eyecare mainstay can help you better communicate to patients, thereby increasing your value to patients and employers alike.

toms early on, but then cause dramatic impairment after they become well developed. Strong multifocal spectacles, different lighting, and magnification may help alleviate early, pre-surgery symptoms.

Surgery—risks, results, complications

A cataract surgery procedure, free from complications, lasts only about 10 minutes. Most patients feel only slight discomfort afterward, and what little pain there is can be managed with over-the-counter medications such as acetaminophen. Most surgeons prescribe anti-inflammatory and antibiotic drops that the patient instills for about a week after surgery. Many patients recover all their vision in a few hours, but for others it may take up to a week before cloudy, blurry, or distorted vision subsides.

The most serious side effect associated with cataract surgery is infection, known as endophthalmitis, but it is extremely rare. Only about 1 eye in 1,000 becomes infected. However, because infection can cause blindness, it is still a risk eyecare practitioners take seriously. In addition to antibiotic therapy, patients are asked to avoid hot tubs and swimming pools, exposure to irritants such as grime, dust, or wind, and eye-rubbing.

If both of a patient's eyes have cataracts, the surgeon may wait 2 days to 2 weeks to perform the second surgery. Without complications, patients undergoing cataract surgery should take no more than a month to fully recover.

IOL options

Most patients will receive monofocal IOLs, that is, lenses that will produce only one kind of refraction, either distance correction

The most serious side effect associated with cataract surgery—endophthalmitis—is extremely rare. Only about 1 eye in 1,000 becomes infected. However, because infection can cause blindness, it is still a risk eyecare practitioners take seriously.

or near correction. Most patients must choose between the two. In rare cases, a combination of intermediate, near, and distance vision can be achieved by implanting a distance lens in one eye and a near lens in the other, creating monovision—vision that is not totally binocular (using both eyes at once). But, if the patient has no previous experience with monovision correction, it can be a difficult skill to learn in older age.

Several multifocal and one accommodative IOLs are approved for use in the U.S. These so-called premium lenses employ various optical strategies to give the patient some level of near, intermediate, and far vision. However, all the premium lenses currently available induce some degree of visual compromise and are known to produce side effects, such as nighttime glare and halos. Nevertheless, some patients are still willing to pay the $2,500 or so extra per surgery to reduce dependence on reading spectacles.

One of the most frequent questions new cataract patients ask is why Medicare and private insurance does not cover the cost of premium IOLs. The reason is due to the Centers for Medicare and Medicaid Services (CMS) regulatory ruling several years ago that the vision correction offered by premium lenses was tantamount to a refractive surgery procedure, such as LASIK, therefore surgeons could charge extra for it. In any case, premium IOLs require additional surgical expertise and follow-up care—and the lenses themselves are more expensive—eyecare practitioners earn that extra fee.

The next big IOL innovation expected to arrive in the U.S. is a premium toric lens that corrects for astigmatism. The technology has been available in Europe for some time and has produced favorable outcomes there. Several toric IOLs recently received FDA approval in the U.S.

Prevent Blindness America estimates there are more cataract cases worldwide than glaucoma, macular degeneration, and diabetic retinopathy combined.[1] Unlike those other diseases, the treatment for cataracts is well established and about as complication-free as a surgical procedure can get. No doubt, innovations will continue to occur, but the fundamental aspects of the surgery will likely remain constant. Staying informed about this eyecare mainstay can help you better communicate to patients, thereby increasing your value to patients and employers alike.

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IMPROVE PATIENT FLOW BY USING COMMUNICATION, FLEXIBILITY, CONSISTENCY

By Janet L. Carter, OD, FAAO

Dr. Carter is in private practice in Reno, NV.

Take-Home Message

Streamlining the patient flow process can help build a high-performing practice. Implementing and enforcing three factors—communication, flexibility, and consistency—can enhance patient flow, thereby increasing the success and profitability of a practice.

All of us have experienced it: a day where the doctor just can't seem to run on time, the waiting room is full, and everyone is unhappy at having to wait. Few things are more frustrating for any optometric practice. Fortunately, with a little planning and a lot of patience, these days can be greatly reduced and your patients' experience enhanced.

Three things are required to improve patient flow and keep the practice on schedule: communication, flexibility, and consistency.

Communication begins when the patient makes the appointment. Your scheduler needs to clearly establish why the patient wants an appointment in order to allow the proper time. A patient might say, "I'm coming because I want the doc to check my glasses," when he or she really means, "I think my glasses need an adjustment." On the other hand, that statement could just as easily mean "I haven't had an eye examination in 5 years, and I am really not seeing well." A good EHR (electronic health records) system could help you here. Your EHR would allow you to quickly look up a patient's record to verify the most recent visit; that would tell you if a comprehensive eye examination is warranted. If the patient is new to your office, ask about his or her most recent eye examination and where it was done. I 've had patients tell me "Oh, I had an eye exam last week," only to uncover that the "examination" was really just a screening at the DMV.

If your scheduler knows exactly why patients are coming , then the scheduler can more easily advise the patients how long they should plan to be at your office so the patients can plan accordingly. Let the patient know ahead of time if the exam will require dilation; this avoids long conversations about it on the day of the appointment and may prevent the patient from rescheduling the dilation because of post-appointment plans. If the patient is interested in contact lenses, but has never worn them before, he or she will need to allow time to learn application and removal; if it's late in the day or if you are short-staffed, the patient may need a second visit for this. Knowing these things ahead of time can greatly reduce frustration for all concerned.

Planning ahead

The scheduler can also greatly assist patient flow by getting as much information as possible about vision plans or medical insurance prior to the appointment. Have a list handy of plans or procedures that may require pre-authorization so that it can be taken care of prior to the scheduled visit, thereby shortening wait times. Many practices e-mail required paperwork to patients in advance to be filled out ahead of time. Planning ahead is also very useful if you can note any special circumstances, such as language or mobility difficulties, right on the schedule. Many practices have one room that is wheelchair friendly, so such notes can insure that the proper room is available at the right time. Also, if you have a technician or optician who speaks a second language, you can be sure that person will be available when a particular patient needs assistance.

Good communication between the doctor and staff is also important. If I have a meeting or special event, I inform my staff ahead of time. That way they know it is important to me to finish on time and will schedule accordingly. Talk with the doctor and be sure you understand how much time to allow for specific types of appointments. If a patient calls and says he or she might be a little late, take a moment to ask the doctor's advice on possibly rescheduling. Try to show the doctor the schedule at the beginning of the day. Often, the doctor will recognize patient

names as folks who might take a little longer to examine or require a little extra care. After you have been with the practice for a while, you might also recognize those names and schedule accordingly. If you are in a group practice, remember that every doctor is different. In that situation, you might need to vary the schedule based on the doctors' individual needs. This can be especially true if you have doctors who specialize in different clinical areas. A low-vision practitioner will have far different scheduling needs than someone who sees mostly young and healthy patients for routine vision care.

Flexibility keeps the pace brisk

Everyone involved in the practice needs to have the authority to change things up once as needed. For example, it's 9:35 and your 9:30 appointment hasn't shown, but the 10 o'clock patient just finished her paperwork. The technicians should feel free to get her started with pretesting. The 9:30 might not even show, but if the patient does eventually make it, he can expect a little longer wait in return for being tardy. Your tech can always tell the 10 o'clock patient that she might have to wait a little while after the pretesting to see the doctor. This creates a perfect opportunity for your tech to suggest the patient browse your optical during the wait. Always have at least one optician in the optical area to help unexpectedly early patients. Patients appreciate the chance to look at frames before being dilated or poked, plus it diverts the patients' attention from having to wait.

It is advantageous if you can have several waiting areas within your office space. That way, the tech can do pre-testing as patients are checked in, then direct them to wait for the doctor in a different area. Patients will then feel the appointment is in progress, and the perception of time waited may be less. Of course, always have interesting reading material or patient education videos in all the waiting areas. These secondary waiting areas can also be a useful place for patients to wait while they are dilating.

Optimal patient flow requires:

1. Communication
2. Flexibility
3. Consistency

Flexibility is also the key to setting your schedule for the day. Most practices have set times for examinations and briefer time slots in between for quicker checks such as emergencies and contact lens follow-ups. However, your scheduler should be empowered to change these around a bit without necessarily adding appointments as warranted. If, for example, you have a family of three coming in together, and there is an open quick check slot between the exam appointment times, move the examinations together and the quick check to the end of that combined time slot. It is often much easier for the doctor to see all the family members together, because health histories and the like can be discussed at the same time. Nothing will disrupt patient flower faster than having the doctor interrupt several family members' examinations by running to another room—or worse yet requesting the room be vacated—to see a contact lens check who was scheduled in between and doesn't have time on a busy workday to wait until the entire family is seen. Avoid that scenario by moving the quick check spot to later.

Consistency enforces perimeters

As important as it is for all staff involved with the patient to be flexible with timing and scheduling concerns, consistency is just as crucial to maintaining proper patient flow. Staff will feel more comfortable in being proactive and flexible by knowing there are consistent rules to guide them. This goes back to communication.

Ask your doctor to set guidelines for changing and rearranging appointments, and then stick to them. If the doctor will insist on rescheduling if a patient is late, know the drop dead time beyond which the patient cannot show up and be seen. In other words, if the doctor won't see patients who are more than 15 minutes late, the rule isn't 15 minutes for some people and 20 for others. Of course, this shouldn't apply to true emergencies. If the doctor knows that she can count on staff to enforce her rules, she will be more comfortable with giving staff the authority to be flexible within those boundaries. Keep in mind that to make the process work effectively, the doctor needs to be consistent in her own instructions.

All of your patients deserve the same consideration. Make sure that there aren't different sets of rules for different patients or staff. If everyone communicates this properly, your office will run smoothly and everyone will be happier.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD) and Macular Edema following Central Retinal Vein Occlusion (CRVO).

DOSAGE AND ADMINISTRATION

FOR OPHTHALMIC INTRAVITREAL INJECTION ONLY. EYLEA must only be administered by a qualified physician.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks (*see Clinical Studies*).

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (monthly).

Preparation for Administration

EYLEA should be inspected visually prior to administration. If particulates, cloudiness, or discoloration are visible, the vial must not be used. Using aseptic technique, the intravitreal injection should be performed with a 30-gauge x ½-inch injection needle.

The glass vial is for single use only. Remove the protective plastic cap from the vial. Clean the top of the vial with an alcohol wipe. Remove the 19-gauge x 1½-inch, 5-micron, filter needle from its pouch and remove the 1-mL syringe supplied in the carton from its pouch. Attach the filter needle to the syringe by twisting it onto the Luer lock syringe tip. Push the filter needle into the center of the vial stopper until the needle touches the bottom edge of the vial. Using aseptic technique withdraw all of the EYLEA vial contents into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle. Remove the filter needle from the syringe and properly dispose of the filter needle. **Note:** Filter needle is **not** to be used for intravitreal injection. Remove the 30-gauge x ½-inch injection needle from the plastic pouch and attach the injection needle to the syringe by firmly twisting the injection needle onto the Luer lock syringe tip.

When ready to administer EYLEA, remove the plastic needle shield from the needle. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top. To eliminate all of the bubbles and to expel excess drug, SLOWLY depress the plunger so that the plunger tip aligns with the line that marks 0.05 mL on the syringe.

Administration

The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include surgical hand disinfection and the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a topical broad–spectrum microbicide should be given prior to the injection.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., eye pain, redness of the eye, photophobia, blurring of vision) without delay (*see Patient Counseling Information*).

Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before EYLEA is administered to the other eye.

After injection, any unused product must be discarded.

No special dosage modification is required for any of the populations that have been studied (e.g., gender, elderly).

DOSAGE FORMS AND STRENGTHS

Single-use, glass vial designed to provide 0.05 mL of 40 mg/mL solution for intravitreal injection.

CONTRAINDICATIONS

EYLEA is contraindicated in patients with

- Ocular or periocular infection
- Active intraocular inflammation
- Known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as severe intraocular inflammation

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments (*see Adverse Reactions*). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (*see Dosage and Administration and Patient Counseling Information*).

Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA (*see Adverse Reactions*). Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (*see Dosage and Administration*).

Thromboembolic Events. There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence in the VIEW1 and VIEW2 wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA (*see Clinical Studies*). The incidence in the COPERNICUS and GALILEO CRVO studies during the first 6 months was 0% (0/218) in patients treated with EYLEA 2 mg every 4 weeks compared with 1.4% (2/142) in patients receiving sham treatment (*see Clinical Studies*).

ADVERSE REACTIONS

The following adverse reactions are discussed in detail in other sections of the labeling:

- Endophthalmitis and retinal detachments (*see Warnings and Precautions*)
- Increased intraocular pressure (*see Warnings and Precautions*)
- Thromboembolic events (*see Warnings and Precautions*)

The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Injection Procedure. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, increased intraocular pressure and vitreous detachment.

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

A total of 2042 patients treated with EYLEA constituted the safety population in four phase 3 studies. Among those, 1441 patients were treated with the recommended dose of 2 mg.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months (*see Clinical Studies*).

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

Adverse Reactions	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%
Eye pain	9%	9%
Cataract	7%	7%
Vitreous detachment	6%	6%
Vitreous floaters	6%	7%
Intraocular pressure increased	5%	7%
Conjunctival hyperemia	4%	8%
Corneal erosion	4%	5%
Detachment of the retinal pigment epithelium	3%	3%
Injection site pain	3%	3%
Foreign body sensation in eyes	3%	4%
Lacrimation increased	3%	1%
Vision blurred	2%	2%
Retinal pigment epithelium tear	2%	1%
Injection site hemorrhage	1%	2%
Eyelid edema	1%	2%
Corneal edema	1%	1%

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were retinal detachment, retinal tear, and endophthalmitis. Hypersensitivity has also been reported in less than 1% of the patients treated with EYLEA.

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The data described below reflect exposure to EYLEA in 218 patients with macular edema following CRVO treated with 2 mg dose in 2 double-masked, controlled clinical studies (COPERNICUS and GALILEO) for 6 months (*see Clinical Studies*).

Table 2: Most Common Adverse Reactions (≥1%) in CRVO Studies

Adverse Reactions	EYLEA (N=218)	Control (N=142)
Eye pain	13%	5%
Conjunctival hemorrhage	12%	11%
Intraocular pressure increased	8%	6%
Corneal erosion	5%	4%
Vitreous floaters	5%	1%
Conjunctival hyperemia	5%	3%
Foreign body sensation in eyes	3%	5%
Vitreous detachment	3%	4%
Lacrimation increased	3%	4%
Injection site pain	3%	1%
Vision blurred	1%	<1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were cataract, eyelid edema, corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD and CRVO studies, the pre-treatment incidence of immunoreactivity to EYLEA was 1% to 3% across treatment groups. After dosing with EYLEA for 52 weeks (wet AMD), or 24 weeks (CRVO), antibodies to EYLEA were detected in a similar percentage range of patients. Both in the wet AMD and in the CRVO studies, there were no differences in efficacy or safety between patients with or without immunoreactivity.

Postmarketing Experience. The following adverse reaction has been identified during postapproval use of EYLEA: intraocular inflammation. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category C. Aflibercept produced embryo-fetal toxicity when administered during organogenesis in pregnant rabbits at intravenous doses of 3 to 60 mg/kg. A series of external, visceral, and skeletal malformations were observed in the fetuses. The maternal No Observed Adverse Effect Level (NOAEL) was 3 mg/kg, whereas the fetal NOAEL was below 3 mg/kg. At this dose, the systemic exposures based on Cmax and AUC for free aflibercept were approximately 2900 times and 600 times higher, respectively, when compared to corresponding values observed in humans after an intravitreal dose of 2 mg. There are no adequate and well-controlled studies in pregnant women. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is unknown whether aflibercept is excreted in human milk. Because many drugs are excreted in human milk, a risk to the breastfed child cannot be excluded. EYLEA is not recommended during breastfeeding. A decision must be made whether to discontinue nursing or to discontinue treatment with EYLEA, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of EYLEA in pediatric patients have not been established.

Geriatric Use. In the clinical studies, approximately 85% (1728/2034) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 58% (1177/2034) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

Patients with Renal Impairment. Pharmacokinetic analysis of a subgroup of patients (n=492) in one Phase 3 study, of which 43% had renal impairment (mild n=120, moderate n=74, and severe n=16), revealed no differences with respect to plasma concentrations of free aflibercept after intravitreal administration every 4 or 8 weeks. No dose adjustment based on renal impairment status is needed for either wet AMD or CRVO patients.

PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, the patient should seek immediate care from an ophthalmologist (*see Warnings and Precautions*).

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations (*see Adverse Reactions*). Patients should be advised not to drive or use machinery until visual function has recovered sufficiently.

REGENERON

Manufactured by: Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
U.S. License Number 1760

Issue Date: September 21, 2012
Initial U.S. Approval: 2011
Regeneron U.S. Patents 7,306,799; 7,531,173; 7,608,261; 7,070,959; 7,374,757; 7,374,758, and other pending patents

FOR THE TREATMENT OF WET AMD*

Permanent **J-code** has been issued for EYLEA® (aflibercept) Injection **effective January 1, 2013**

HCPCS Code	Description	Billing Units
J0178	Injection, aflibercept, 1 mg	2‡

‡With a per 1 mg descriptor, it is important to accurately indicate "2" billing units on the claim form for each 2 mg injection.

TIME BETWEEN TREATMENTS®†

More Information available at www.EYLEA.com

**Neovascular (wet) Age-related Macular Degeneration*

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA

- †EYLEA® (aflibercept) Injection is indicated for the treatment of patients with neovascular (Wet) Age-related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.
- EYLEA is indicated for the treatment of patients with Macular Edema following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly).

IMPORTANT SAFETY INFORMATION FOR EYLEA

- EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported during the post approval use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs in the VIEW 1 and VIEW 2 wet AMD studies in patients treated with EYLEA was 1.8% during the first year. The incidence of ATEs in the COPERNICUS and GALILEO CRVO studies was 0% in patients treated with EYLEA compared with 1.4% in patients receiving sham control during the first six months.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.
- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, increased intraocular pressure, and vitreous detachment.

Please see brief summary of full Prescribing Information on the following page.

REGENERON

11/2012 LEA-0065F-4

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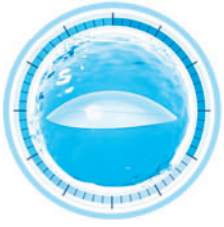

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