14th Annual Report From ARVO, p. 28

May 15, 2013

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Even if you don't order lab tests yourself, you should know what they measure and how to read the results, p.87

ALSO INSIDE:

FLEXON. JUST WHAT THE

We interviewed over 40 doctors and optical industry professionals at this year's Vision Expo East about

I think Flexon is great for anybody!

▸ James, Optical Industry COO, CA

Flexon's durability is great and I love the warranty.

▸ Frank, Optimetrist Assistant Missouri

The techonology is very important to my customers.

◂ Raul, Optical Industry General Director, Venezuela

We sell a lot of Flexon to the market looking for something light-weight and durable.

◂ Holly, Retail Owner, Arkansas

We love Flexon. It's super lightweight, durable, kid-friendly.

▸ Amelia, Manager, California

Flexon is one of my favorite things to sell to people.

▸ Gene, Optician, New Jersey

My customers find that they can have a frame that's durable and also stylish.

◂ Dora, Optometrist, Virginia

When I show customers Flexon frames bending, they love it. It's an excellent product.

◂ Oswaldo, Optician, NJ

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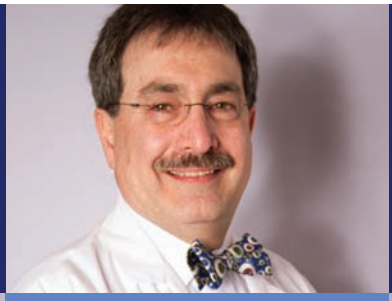
Flexon and here's what a few had to say about the original memory metal...

The durability of Flexon is a great factor in recommending this frame to patients.

Robert, Optometrist, Virginia



Flexon works for all groups of patients.

Polina, Optician, New York

This is a wonderful product and an easy sell - a very easy sell.

Sally, Optical Consultant, Texas

This product is great for any generation. It's a great seller.

Galina, Optician, NY

Flexon works really well for our practice. Patients know they're reliable.

Elsiann, Optician, S. Carolina

I dispense a lot of children's glasses... Flexon is ideal.

Jeet, Optician & Buyer, Pennsylvania

It stands up to a lot of rigors and abuse. That's a big selling point.

David, Optimetrist, New York

I am so confident in Flexon. Anyone and everyone should have [a pair]!

Deb, Eyewear Buyer, Ontario, Canada

Flexon® COLLECTION

VOL. 150 NO. 5 ■ MAY 15, 2013

IN THE NEWS

The American Optometric Association is launching a new **Integrated Eyecare Project Team**, which will analyze existing models of integrated eye care with the intention of identifying specific elements that facilitate the highest-quality, most efficient patient care. Unlike previous versions of integrated eye care models that were chiefly centered upon the best interests of individual ophthalmologists, "optometry's vision for how our professions can work together will be focused on **better patient care and outcomes**," says project team chair Christopher Quinn, OD.

The **World Council of Optometry** presented **Brien Holden, PhD, DSc, LOSc**, of the Brien Holden Vision Institute in Australia, with its highest honor, the **Distinguished Service Award**, on April 21. He is just the sixth individual to receive the award, which recognizes optometrists who have made an outstanding effort to increase access to high-quality vision care. During the last 20 years, the Brien Holden Vision institute has invested more than **$450 million** in research, education and humanitarian funds to create advanced vision correction products and provide quality vision care to people in need throughout the world.

A compound found in **pine bark extract** reduces the risk of cataract formation, according to a study in the March 28 online version of *Current Eye Research*. The researchers reported no short-term side effects of the ingredient, dietary pycnogenol. However, they suggested that long-term, in vitro testing is required before any supplemental recommendations could be made.

AREDS2: Tough to Digest

ODs give initial reactions to the AREDS2 findings and how they may—or may not—affect recommendations for AMD patients. **By Colleen Mullarkey, Senior Editor**

Now that researchers have finally served up the long-awaited results of the Age-Related Eye Disease Study 2 (AREDS2), it's going to take quite a while for the eye care community to digest all of this data and determine what impact, if any, it will have on their current practices.

For some, the big reveal was a little anticlimactic. "Although some parts of the study were intriguing—such as the omega-3 arm not showing a statistical improvement—overall, the study results were not too surprising," says Paul Karpecki, OD, of the Koffler Vision Group in Lexington, Ky.

Others plan to proceed cautiously. "I'm not prepared to make any drastic changes with my AMD patients just yet; I'm interested to see what happens next," says Benjamin Casella, OD, of Augusta, Ga. "We've been hearing about AREDS2 for so many years—you walk into GNC and you see AREDS2 formulations all over the place—but the manufacturers got a little ahead of the science."

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

"The complexity of the design led to variations in the conclusions about the results," says Diana Shectman, OD, associate professor at Nova Southeastern University in Ft. Lauderdale. "We couldn't come up with one simple answer—does it work or not—because there were just too many arms." In the months and years ahead, it seems the data and trends from these subgroup analyses could provide insights that do actually affect clinical care, she says.

However, many optometrists are waiting for the day when the study design focuses more on the preventive level. "AREDS2 has certainly got some value, but I think it's still limited," says Jeffrey Anshel, OD, president and founding director of the Ocular Nutrition Society. "Even before these results were released, I knew they were looking at intermediate and late-stage macular degeneration, which is nice, but it doesn't say anything about early stage. So even before AREDS2 came out, I was waiting for AREDS3 or 4."

To read more details about the findings, see "The Latest on AREDS2 from ARVO 2013," page 68.

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Florida ODs Gain Oral Drugs

It's rare when a war does not end in bloodshed, but such was the case with the so-called "eyeball wars" in Florida. The "war" ended with the passage of HB 239, which permits optometrists in Florida to use oral drugs for eye disease, among other provisions.

"After much soul searching and introspection, everybody looked at it in terms of what's the best for the patient," says Kenneth W. Lawson, OD, legislative chair of the Florida Optometric Association, who has been working on this bill for three years.

The legislation, which was signed by the governor on April 19, achieved unanimous votes in both the state house and senate in favor of its passage. "It shows you can have a peaceful and thoughtful negotiation process that keeps the patient at the front," Dr. Lawson says.

The new law, which takes effect July 1, has several provisions that allow Florida optometrists to better serve their patients:

• ***Allows Rx of oral drugs.*** The bill listed 14 oral drugs that ODs will be able prescribe for eye care; these include analgesics/Schedule III controlled substances, antibiotics, antivirals and glaucoma medications. The legislation also requires that ODs must first participate in a 20-hour online CE review course and exam on oral pharmaceuticals.

• ***Codifies comanagement.*** The legislation mandates state-wide statues regarding comanagement to mirror those of federal guidelines, including informed written consent for comanaged care.

• ***Spells out minor procedures.*** The bill codifies minor "surgical" procedures that fall within the scope of practice for Florida ODs. It doesn't add any new surgeries, but by specifically naming procedures, it removes any doubt that payers may have about whether ODs are licensed to perform them, Dr. Lawson says. These procedures include epilation, naso-lacrimal probing, punctal occlusion, superficial scraping to remove damaged epithelial tissue or superficial foreign bodies, and taking a culture.

The new law also adds language about reporting adverse incidents.

Eyeball wars aside, the end result is not an "optometry bill" but a "patient access to eye health care bill," Dr. Lawson says.

"I'm proud to say that I think Florida's patients are the real winners here," he says. "Now, there's a much higher level of patient safety because you've got another provider to support the patient safety net. And in the economy we're in, you need as many safety nets as possible to prevent patients' eye conditions from rapidly going from bad to worse."

Lazy Eye? Give Tetris a Try!

Playing the popular 1980s video game Tetris could help treat adult amblyopia, according to a study in the April 22 issue of *Current Biology*.

Researchers at the McGill University Health Center in Montreal evaluated 18 adults with amblyopia. Nine subjects played Tetris monocularly with the weaker eye, while the dominant eye was patched. The other nine subjects played dichoptically, where both eyes viewed a separate part of the game. After two weeks, those who played Tetris dichoptically exhibited a dramatic visual improvement in the weaker eye, including enhanced 3-D depth perception. By contrast, subjects in the monocular patching group experienced only modest visual improvement.

Photo: McGill University Health Center

Dr. Hess says that forcing both eyes to work together will increase neuroplasticity and help correct amblyopia in adults.

"The key to improving vision for adults, who currently have no other treatment options, was to set up conditions that would enable the two eyes to cooperate for the first time in a given task," says senior author Robert Hess, PhD, DSc, director of research in the Department of Ophthalmology at McGill.

Li J, Thompson B, Deng D, et al. Dichoptic training enables the adult amblyopic brain to learn. Curr Biol. 2013 Apr 22;23 (8):R308-9.

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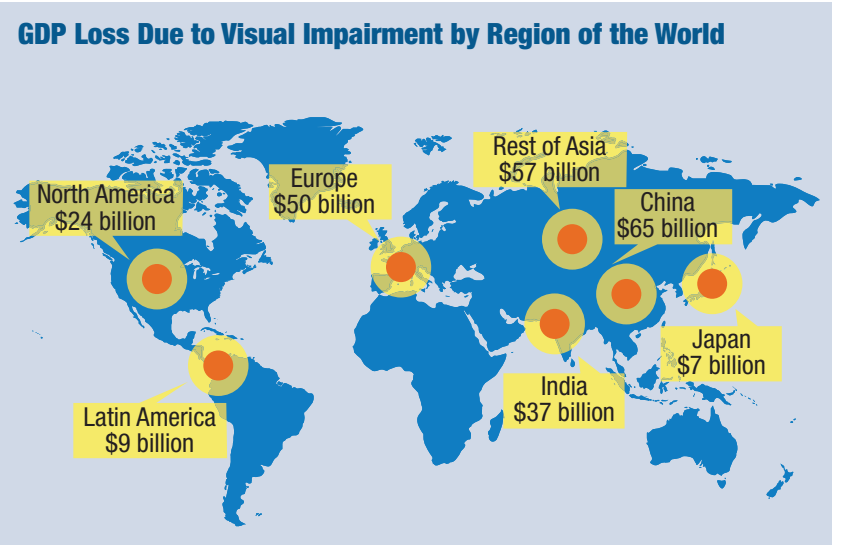
The Cost of Impaired Vision

With an annual loss in productivity totaling $269 billion globally, the cost and prevalence of impaired vision are still underestimated in both developed and emerging countries, according to the Vision Impact Institute.

The Institute estimates that there are just over one billion workers worldwide with uncorrected vision. They say simple measures might drastically reduce the economic and social consequences of impaired vision—even though the cost, level of access to care and awareness differ by country.



Recently launched by Essilor, the Institute's primary missions are to raise awareness about the socioeconomic impact of poor vision and to foster research where needed.

Arthritis Drug Dampens Dry Eye

Topical application of the rheumatoid arthritis drug Kineret (anakinra, Amgen) effectively treats the symptoms of dry eye disease, according to a study in the April 18 online edition of *JAMA Ophthalmology*.

Previous research has shown that dry eye is associated with a significant overexpression of inflammatory cytokines, including interleukin 1 (IL-1). Anakinra, an IL-1 receptor antagonist, effectively suppresses IL-1-mediated inflammation at the level of the ocular surface.

In this randomized, double-masked study, the researchers assessed the safety and efficacy of topical anakinra in 75 individuals with dry eye disease secondary to meibomian gland dysfunction. The subjects were randomized to receive TID administration of 2.5% anakinra, 5.0% anakinra or artificial tears for 12 weeks.

The primary study outcomes included measurement of corneal fluorescein staining (CFS), complete bilateral CFS clearance, tear film break-up time, meibomian gland secretion quality and dry eye-related symptoms (i.e., ocular grittiness, light sensitivity or blurred vision).

After 12 weeks of dosing, subjects who used 2.5% anakinra were four times more likely to exhibit a bilateral reduction in CFS compared to those who received artificial tears. Further, the researchers found that those dosed with 2.5% anakinra experienced a six-fold decrease in dry eye-related symptoms compared to subjects who used artificial tears.

"We began looking at the possible therapeutic effects of IL-1 receptor agonists over 10 years ago in my laboratory," says senior author Reza Dana, MD, MSc, MPH, professor of ophthalmology at Harvard Medical School. But, "we have never seen results such as this before in a trial to treat dry eye disease."

"We possibly have found a safe, well-tolerated eye drop that can treat the underlying cause of dry eye, rather than just temporarily mask the symptoms. The results clearly show us not only that we can possibly help the millions of people affected by dry eye disease worldwide, but that biologics such as this have the potential to provide targeted therapies for other ocular ailments as well," Dr. Dana added.

Amparo F, Dastjerdi MH, Okanobo A, et al. Topical interleukin 1 receptor antagonist for treatment of dry eye disease: A randomized clinical trial. JAMA Ophthalmol. 2013 Apr 18:1-9. [Epub ahead of print]

MYTHS, METHODS AND MEANS FOR SOOTHING END-OF-DAY CONTACT LENS DISCOMFORT

Fig. 1: Headstand in an ice bucket.

Fig. 2: Switch to Avaira®.

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(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

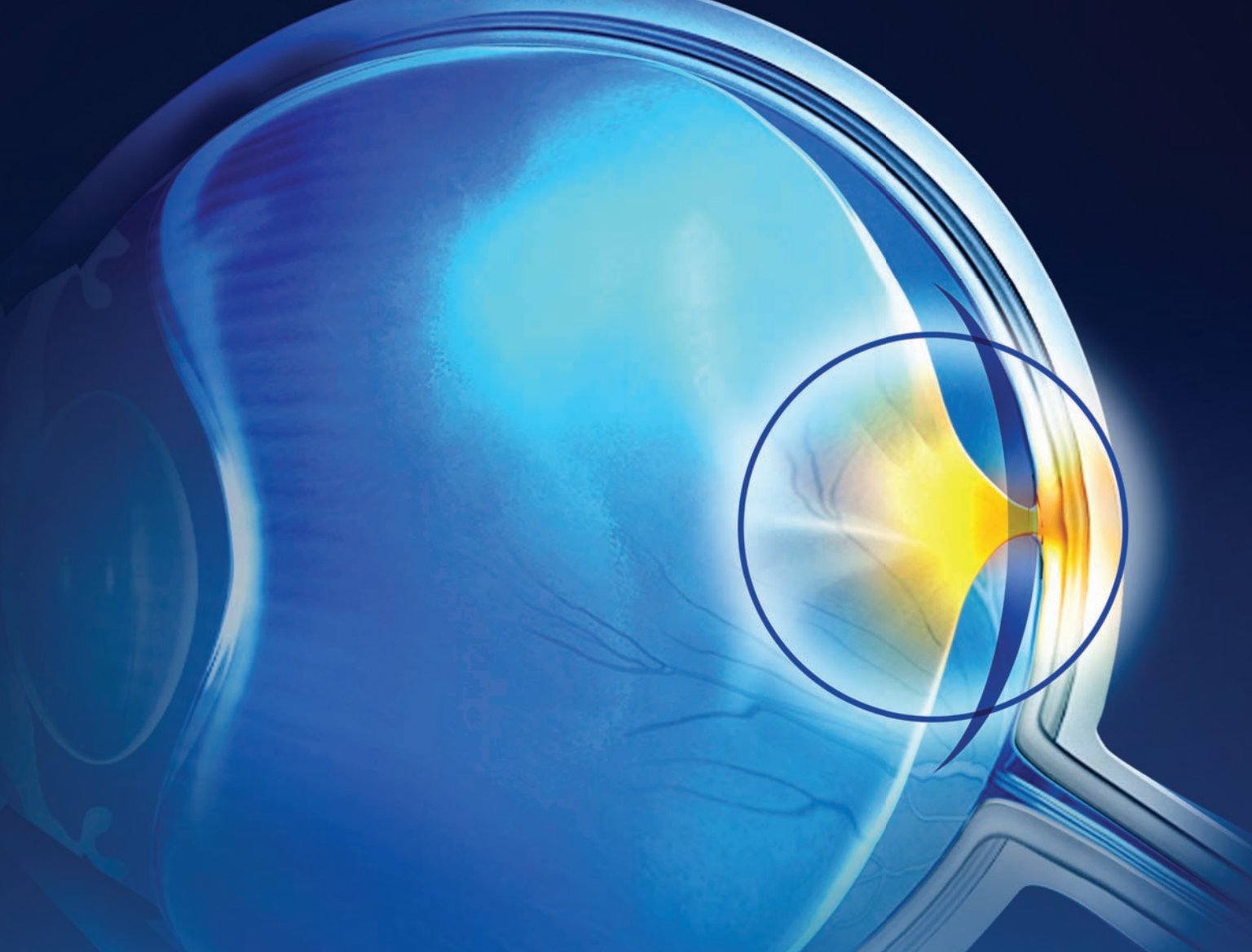
Warnings and Precautions

- 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.

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

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

ThromboGenics®



- 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.

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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.

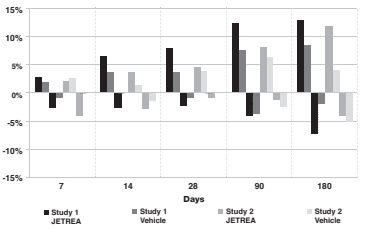
Patients were treated with a single injection of JETREA or vehicle. In both of the studies, the proportion of patients who achieved VMA resolution at Day 28 (i.e., achieved success on the primary endpoint) was significantly higher in the ocriplasmin group compared with the vehicle group through Month 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
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Version 1.0
Initial U.S. Approval: 2012
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04/13 OCRVMA0072 PI D

Expanded Scope of Practice Bills on Deck

From the Bayou to sunny California, ODs are fighting for expanded scope of practice laws in three states during this heated legislative session. Here's a rundown on the latest developments as of press time:

• ***Louisiana.*** A controversial expanded scope of practice law was put on hold earlier this month after the bill's sponsor, Rep. Frank Hoffman, put the bill back on the calendar. House Bill 527 would have allowed optometrists to administer medication by injection as well as perform many eye surgeries, including several eye laser and incisional procedures. The Louisiana House Committee on Health and Welfare approved the bill April 17, but the legislation was never heard on the House floor.

The legislation would have allowed optometrists to administer medication by any appropriate means and perform laser procedures, including Nd:YAG, peripheral iridotomy and selective laser trabeculoplasty, and the optometry board to control the practice of optometry, all with the intent of improving access to care.

• ***Georgia.*** HB 235, which would allow optometrists to prescribe oral steroids for up to 14 days, has gained steam over its Louisiana counterpart. Under the bill, optometrists would also be able to continue to prescribe hydrocodone for up to 48 hours even if the federal government changes it to a schedule II drug.

The legislation also allows the use of different ways to disseminate medication aside from oral and topical mechanisms. This would allow for the prescription of contact lenses that distribute medication, and nasal sprays. However, the legislation maintains a prohibition on the use of injectables and surgery.

Finally, the legislation would change the current law regarding continuing education requirements. Current law exempts those licensed optometrists age 65 and over from having to take continuing education in order to maintain an optometric license in Georgia. The bill would eliminate that exemption.

Georgia governor Nathan Deal signed the bill into law on May 6.

•***California.*** Senate Bill 492 would expand the practice parameters of optometrists who are certified to use therapeutic pharmaceutical agents by removing certain limitations on their practice and adding certain responsibilities, including, but not limited to, the ability to immunize and treat certain diseases, and deleting the specified drugs the optometrist would be authorized to use, and authorizing the optometrist to use all appropriate therapeutic pharmaceutical agents approved by the United States Food and Drug Administration.

SB 492 would also delete limitations on what kinds of diagnostic tests an optometrist could order, and instead would authorize an optometrist to order appropriate laboratory and diagnostic imaging tests.

The bill currently is with the Committee on Appropriations. ■

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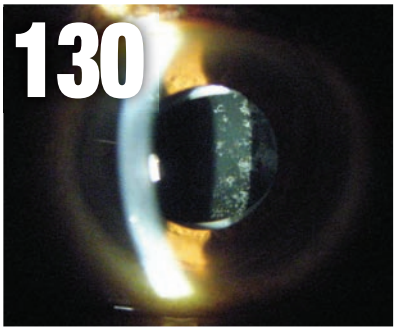

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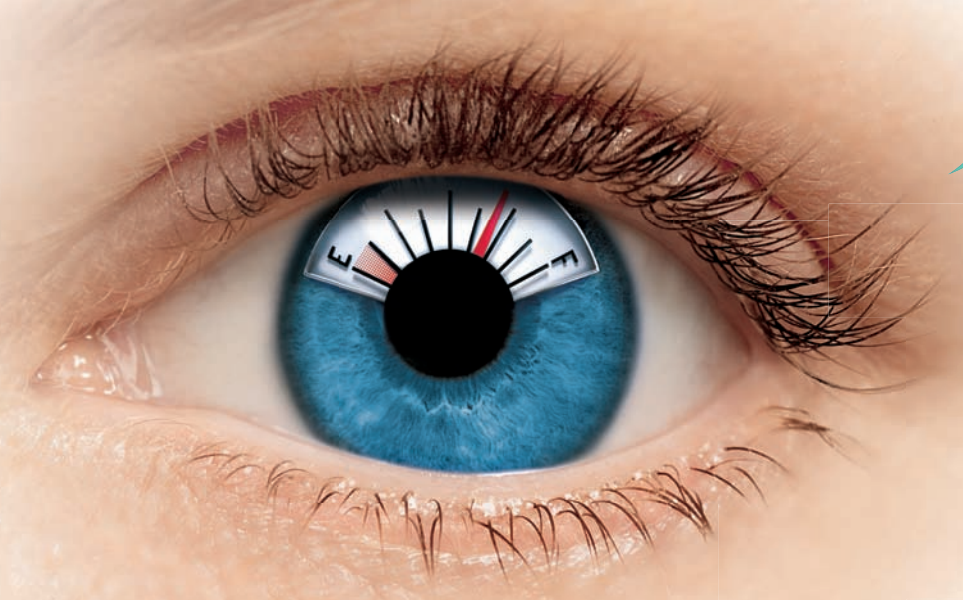

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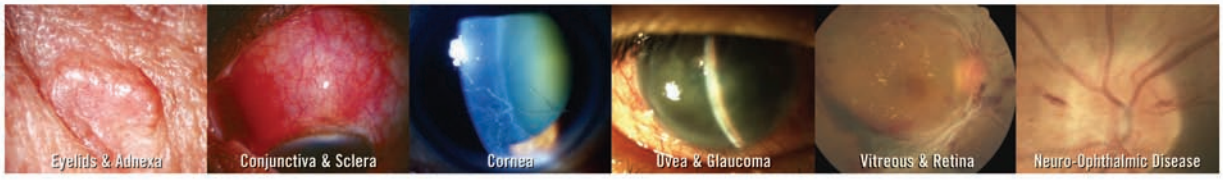

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REVIEW® OF OPTOMETRY

Letters to the Editor

Remembering Rick Bay

We have had the privilege of working with hundreds of professional people over the years, but none surpass the joy of working with Rick Bay [publisher of *Review of Optometry* and *Review of Ophthalmology*, who passed away in December 2012]. While our annual *Clinical Guide to Ophthalmic Drugs* was the work of many people, Rick was always at the helm to oversee this annual project, and it was through our collaborative work on this project that we came to know him.

Rick was one of those people you just enjoy being with. He was funny, witty, had a great sense of humor, but was always focused on making good things happen for *Review of Optometry* and its many educational events. Rick was a man of impeccable integrity, steadfast reliability, and he always had a positive outlook on life. Though his last two years were compromised by his medical condition, it did not dampen his warmth or his spirit. He was always a joy to work with, and we will tremendously miss his ever-smiling face. The continued excellence within the *Review of Optometry* team will be an ongoing reminder to all of us of the blood, sweat and tears that Rick put into making this publication the most popular within the optometric community.

Thank you, Rick, for the privilege of knowing you, and for sharing a bit of your life with us.

—Randall Thomas, OD, MPH
Concord, NC
Ron Melton, OD
Charlotte, NC

This letter was originally submitted in December 2012.

Lessons from Dentistry

AOA's lobbying against stand-alone vision plans in the Health Insurance Exchanges has been nothing short of impressive. AOA often points to dentistry: "If there is a stand-alone dental plan in the Exchange, qualified health plans (QHPs) can drop their pediatric dental benefit … Is this an acceptable future for optometry?" Stand-alone vision plans would render the pediatric vision benefit optional, says AOA.

1. Clarification of the HHS rule. Within the Exchange, QHPs are required to offer the pediatric dental benefit, but purchase is not required. "Outside the Exchange, the rule requires the offer of all 10 benefit categories and purchase of the pediatric dental essential health benefits [EHB] by everyone in the individual and small group markets." There is an "opt-out" only if there is "reasonable assurance" that there will be coverage through a stand-alone dental plan. Effectively, parents have the choice of either a stand-alone dental plan or a dental benefit "bundled" with their QHP. Will parents really opt out of an offered, covered benefit for their children? What about parental responsibility?

2. Affordability. For individuals and families who do not qualify for subsidies and those adults who do not have children, the choice to "opt-out" of the pediatric dental benefit will lower premiums. "The California Dental Association asserts the EHB pediatric dental benefit must be purchased by families with children, but also suggests the state provide flexibility for childless adults. This allows such adults to purchase products that meet their needs in a cost-effective manner. This is important because they will make up a great number of the 'young invincibles' whose engagement in the Exchange will be critical to its success."

3. Medicaid. The American Dental Association is concerned that cost of care exceeds reimbursement, and that their providers cannot meet the considerable needs of that population while losing money on each encounter. "Data show that there is a direct relationship between the level of reimbursement and dentist participation in Medicaid... [The Healthcare Reform Bill] failed to provide basic adult dental benefits under the Medicaid program and failed to address inadequate provider reimbursement and disruptive administrative barriers ... ADA felt that the bill did not provide access to adequate oral health services for many low-income Americans."

4. Meager benefits. ADA has stated, "there are no assurances that this dental coverage will be substantial, and we fear that ... the benefit will be as meager as is currently found in medical plans that promise a dental benefit ... Medical plans have historically ignored or poorly run dental benefit programs, and only offered them to be competitive in the marketplace, not to materially improve oral health among its beneficiaries. They often focus on tactics to decrease utilization, not increase it."

Sound familiar? We should not be surprised at the meager benefits of vision plans that will be bundled with QHP for pediatric vision. We should determine our level of participation. What will be acceptable for our practices? ■

—Lisa Shin, OD
Los Alamos, NM

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Playing the Percentages

ARVO's annual deluge of data once again offers valuable new insights. But health care will always remain more than just a numbers game. **By Jack Persico, Editor-in-Chief**

Prediction is difficult, especially about the future," physicist Niels Bohr said, sounding quite a bit like Yogi Berra. Every doctor knows that all too well. There's no guarantee that the clinical decisions you make will yield the results you expect.

When selecting a medication, how sure can you be that the outcome you anticipate will actually come to pass? Maybe the patient is a nonresponder. Or maybe your diagnostic tests are vulnerable to false positives and negatives.

Even well-funded, high-profile health issues can get waylaid by incorrect or incomplete data. A sobering article in the April 25th *New York Times Magazine* describes a recent reconsideration of the clinical value of routine breast cancer screening. After reviewing three decades of outcomes data, cancer experts reached an uncomfortable conclusion: mammography is more likely to yield false positives that lead to unnecessary surgery than it is to find true early-stage cancers that warrant intervention. Should doctors and advocacy groups now back-pedal from the accepted narrative that early screening is essential? Could they, even if they wanted to, now that the practice is so well entrenched?

With these thorny questions in mind, we turn our attention to the world of ocular research, front and center in this issue as we again review some of the most novel, thought-provoking studies presented earlier this month at ARVO.

The breadth of the subjects on display every year is truly amazing. It's a testament to the tenacity of the research community that so many lines of inquiry are pursued. But how can a busy clinician assimilate so much new information? Which studies are conclusive and which are more speculative?

The biggest news to come out of ARVO was the release of the long-awaited AREDS2 data. The main result may have disappointed—no increased risk reduction by adding omega-3 fatty acids or carotenoids, although safety improved—but the ambitious study showcased can-do science at its best.

The AREDS2 dataset included a whopping 4,203 subjects, from 82 sites, studied for five years. Meanwhile, some of the most interesting ARVO studies reported on work done with just a handful of patients. And of course case reports (where n=1, the loneliest number) have a long tradition in medicine. Always consider sample size when reviewing data, but keep an open mind. If nothing else, small studies prompt reconsideration of popular axioms.

Big Data is Watching You

A new book called *Big Data* explains how "data mining" of enormously large samples, such as Google's five billion searches per day, is transforming many aspects of everyday life. Google can now predict flu outbreaks in real time, faster than the CDC, and translate languages purely based on prediction rather than content.

Can medicine still find room for small studies in a big-data world? Outcomes data will continue to be a driver of health care policy, insurance coverage and medical reimbursements. The clinical decisions you make will increasingly need to be backed by evidence-based medicine, and your performance in the exam room will be factored in to your compensation. Big Data, not Big Brother, is watching you—those PQRS scores are being collected for a reason, you know. Diagnostic tests that don't yield relevant info won't be reimbursed.

But data has its limits. What if new research conflicts with time-honored remedies that have proven their merit in the exam room? "We must not slaughter judgment on the altar of data," *Big Data*'s coauthor Kenneth Cukier eloquently put it on the BBC4 podcast *Start the Week* (which I highly recommend if you like to hear smart British people discuss important stuff). There will always be a need for clinical acumen and intuition.

For a great example of how to walk that line, look no further than this month's special annual supplement, *The Clinical Guide to Ophthalmic Drugs*. Authors Ron Melton and Randall Thomas are renown for their ability to balance scientific rigor with keen clinical instincts honed through decades of practical experience. Thanks to leaders like them, our ARVO report authors plus many others, optometry may be awash in data but has a steady hand on the tiller. ■

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Secrets 'They' Won't Tell You

'They' don't want you to know the real story. 'They' won't tell you the dirt. Who are 'they,' you ask? Maybe the medical elite. Or the Kardashians. **By Montgomery Vickers, OD**

Wisdom... Again, I selflessly offer you special knowledge—secret wisdom I have secretly acquired from some secret sources who shall remain nameless, as requested by Bob ... I mean SAM! Yeah, Sam.

In no particular order, here are some optometric secrets you need to know.

1. Your time is worth what someone else tells you it's worth.

2. Obamacare will change dramatically after Hillary gets LASIK.

3. Some meatballs are not that good. But don't tell my Mom.

4. There's an online chat board for no-shows. Nobody uses it.

5. You should never do anything where the BEST possible outcome is death or, worse, you on You Tube acting a fool.

6. Rich patients always forget their wallet.

7. Contact lens Rx requests are always from past-due patients and brothers.

8. There is nothing heavier than copier paper.

9. The cure for glaucoma was recently discovered in Colorado—by the legislature. However, patients report more frequent side effects of "the munchies."

10. Ophthalmologists who are employed by optometrists will soon be able to join the Paraoptometric Section of the AOA.

11. The ABO and AOS have a secret love child.

12. Always invest in your practice.

12(a). Your practice needs a boat.

13. "Meaningful use" equals "kidney stone."

14. Have at least a couple of frames on the board that are made of 14-karat gold with big diamonds on the temples so your meth addict patients will want to come back, probably when you are not around.

15a. Shameless promotion will become a trend in optometry.

15b. Please "like" me on Facebook.

16. The next trend on the Internet will be online foreign body removal. Customers can buy an official sterile spud, or they can just get the "Value Package" with instructions about how to sterilize a grapefruit spoon.

17. When a patient says "Show me something cheap," hand them a mirror.

18. To shape up, walk briskly during your lunch hour to the pizza place.

19. If you offer free eye examinations, patients will still ask if you accept their vision plan.

20. Don't.

OK, that's today's lesson in optometric wisdom. You decide which of these little gems best applies to your own special situation. Now, I'd like very much to know what wisdom YOU can share, especially if it's about the ABO/AOS baby. ■

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Get Clued in on CLIA Testing

As additional states allow optometrists to perform clinical lab testing in the office, more patients and practices will benefit. **By John Rumpakis, OD, MBA, Clinical Coding Editor**

What is CLIA? The acronym stands for Clinical Lab Improvement Amendments, which Congress passed in 1988 to establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results, regardless of where the test was performed.[1]

This legislation defines a laboratory as "any facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease or ... assessment of health." So, if you register, your office can be a laboratory.

Also, the Centers for Medicare & Medicaid Services (CMS) assumed primary responsibility for financial management operations of the CLIA program. So, you can bill lab tests to Medicare.

Under CLIA, the FDA has authority over commercially marketed in vitro diagnostic tests. The FDA categorizes such tests by their potential for risk to public health. From lower risk to higher risk, these are:

- Waived tests
- Tests of moderate complexity
- Tests of high complexity

While we can order many different kinds of tests that are performed in an outside lab, we need only concern ourselves with the first category for lab tests actually performed in our offices. CLIA-waived tests are simple laboratory examinations and procedures that are cleared by the FDA for home use. These "employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if the test is performed incorrectly," the FDA says.[2]

In 1997, these regulations were further revised to make it clear that tests approved by the FDA for home use automatically qualify for CLIA waiver. And this is where lab testing is relevant to the practicing optometrist. While only a couple CLIA-waived tests are applicable to optometry at this time, they will become more numerous and cover a broader range of applications as technology progresses.

Coding for CLIA

Of course, it's up to your state board of optometry to determine whether running a CLIA-waived test in your office is within your scope of practice. Assuming that it is, there are two things you must do before you can perform and get reimbursed for CLIA-waived tests in your practice. First, your office must be designated as a CLIA-approved laboratory. Second, one of the doctors in your practice must be designated and approved as a clinical lab director. (Go to www.cms.gov/clia to enroll.)

A few things to note regarding coding and billing for CLIA-waived testing. Lab tests are paid from a national laboratory fee schedule and do not follow the RBRVS reimbursement model. The codes are designated in the 8XXXX range in the CPT. Additionally, only those tests that have the "waived" designation can be performed in your office and carry the QW modifier.

CPT codes for the tests that ODs typically perform are:

- **83861-QW—Tear osmolarity** (i.e., TearLab test), defined as microfluidic analysis that uses an integrated collection and analysis device.

If you test both eyes, your claim form would look like this:

83861-QW-LT
83861-QW-RT

- **87809-QW—Adenoviral test** (i.e., AdenoPlus, RPS Inc.), defined as infectious agent antigen detection by immunoassay with direct optical observation.

If you test both eyes, your claim form would look like this:

87809-QW-RT
87809-QW-LT

Additional notes: On your CMS 1500 form, indicate in box 29 that you are *not* using an outside lab, and place your office's CLIA number (provided by CMS) in box 23.

While clinical lab tests are not a significant profit center for a practice, they are proving to be just as valuable to clinical care in an OD's office as they have been for years in a general physician's office. ■

1. How to Obtain a CLIA Certificate of Waiver (brochure). Centers for Medicare & Medicaid Services. 2006 March. Available at: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf. Accessed May 2, 2013.
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Topics covered at this year's meeting range from corneal transplant outcomes to the eagerly-awaited results of AREDS2. **By Michael Hoster, Managing Editor**

Since 1928, the world's thought leaders in eye care have gathered to present their latest study data at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO). Each year, the sheer volume of poster, paper and presentation abstracts is nothing short of astounding—possibly even overwhelming.

That's precisely why *Review* has, yet again, asked four distinguished authors to sift through all the abstracts and highlight the most interesting and clinically relevant material presented at ARVO. And although the annual meeting was not hosted in sunny Ft. Lauderdale for the first time since 1995, the tremendous depth and quality of research still shined brightly.

Here's a brief overview of our authors' top picks in *Review*'s 14th Annual Report from ARVO:

Cornea

Associate Clinical Editor Joseph P. Shovlin, OD, who also edits *Review*'s "Cornea and Contact Lens Q+A," places a priority on clinical study data that can be used to help maximize your patients' corneal health.

He discusses how surgeons and optometrists can better ensure the long-term safety and efficacy of transplant procedures, simply by knowing which patients are at the highest risk for graft failure. Also, he looks at how contact lens wear may affect keratoconus patients who have undergone corneal collagen crosslinking.

Glaucoma

Long-time ARVO Report contributor Robert Cole III, OD, Emeritus Clinical Editor, reviews the diagnostic capabilities of advanced visual field testing, including flicker-defined form and frequency doubling technology perimetry.

Also, he discusses whether the insertion of punctal plugs infused with travoprost could be used as a viable sustained-release drug delivery system.

Cataract and Refractive Surgery

ARVO Report newcomer and Contributing Editor Derek Cunningham, OD, centers upon how optometrists can help optimize refractive outcomes.

Aside from introducing a handful of novel surgical techniques, he primarily focuses upon the pre- and postoperative treatment of dry eye and inflammation with a host of new and emerging topical agents.

Retina

Steven Ferrucci, OD, Editorial Board Member and fellow ARVO Report rookie, provides the most up-to-date research regarding the treatment of diabetic retinopathy, macular edema and age-related macular degeneration—including early study results on a novel systemic agent for geographic atropy.

Further, he previews the long-awaited, and somewhat disappointing, results from AREDS2. ■

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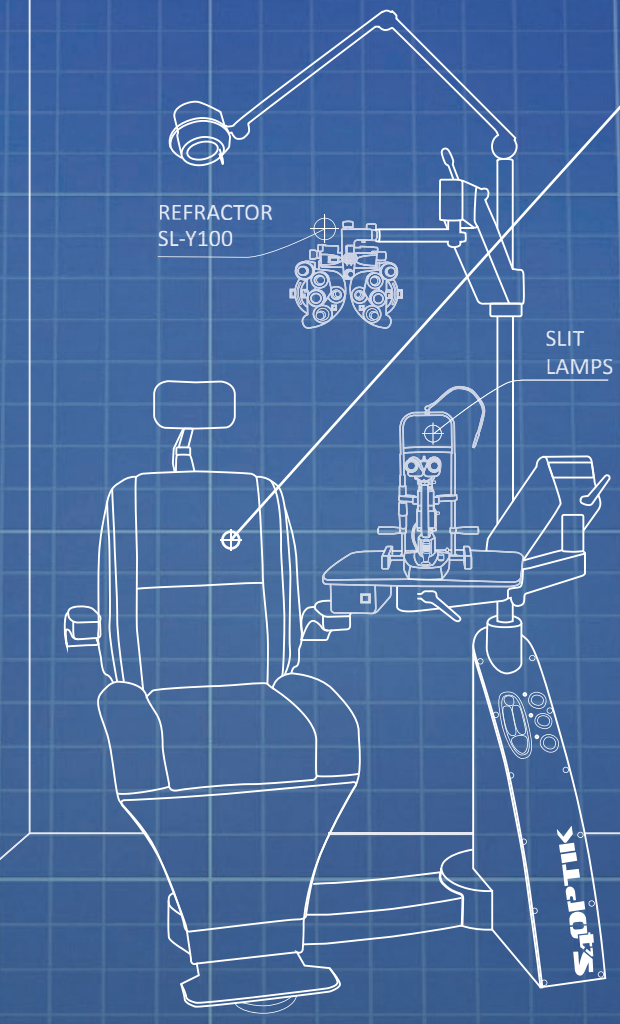

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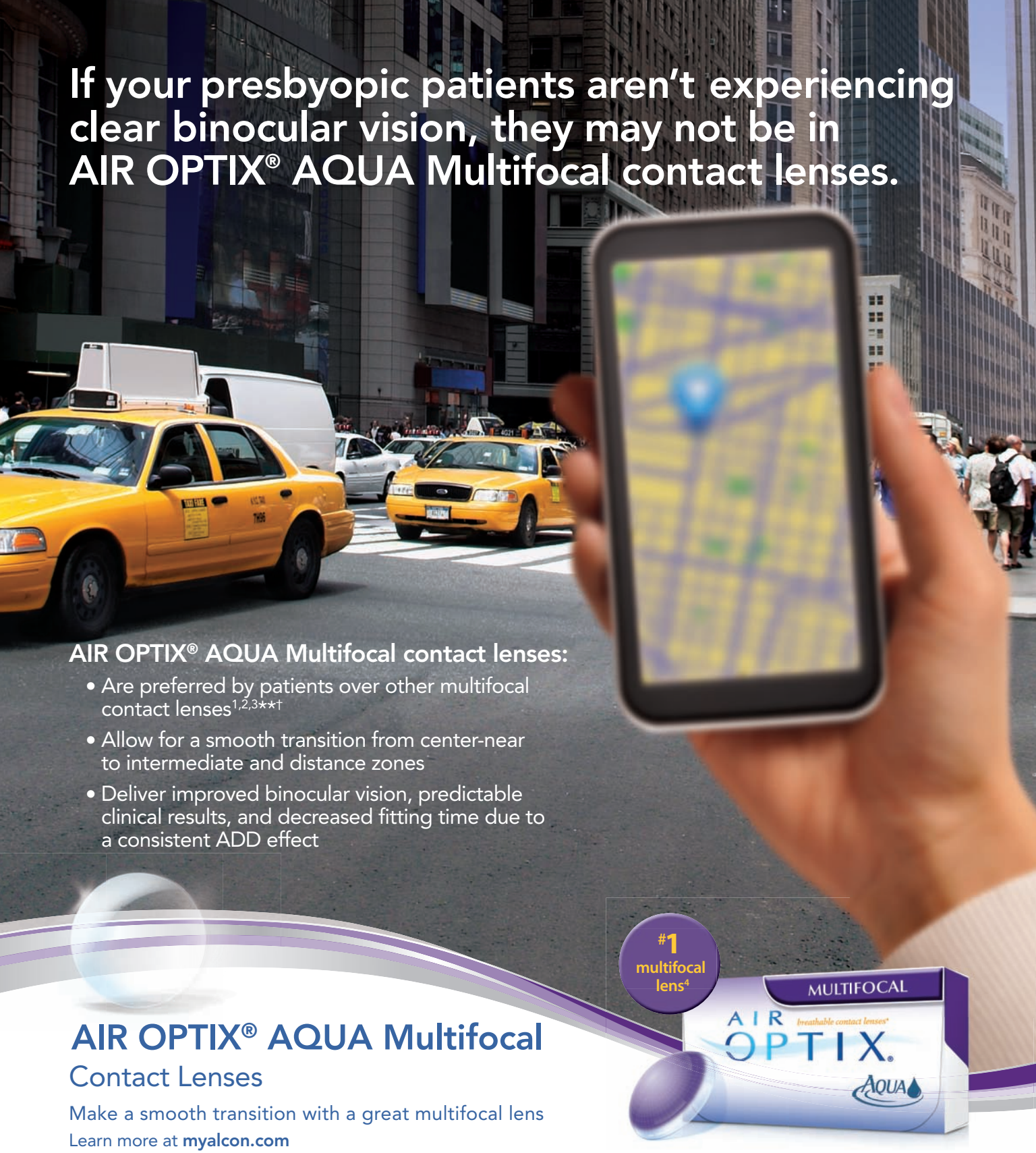

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References: 1. In a randomized, subject-masked clinical study at 20 sites with 252 patients; significance demonstrated at the 0.05 level; Alcon data on file, 2009. **2.** Rappon J. Center-near multifocal innovation: optical and material enhancements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

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Cornea

From improved transplant procedures to scleral and bandage lenses, this year's research focused on optimized corneal health.

By Joseph P. Shovlin, OD, Associate Clinical Editor

Corneal research presented at ARVO has always been a fruitful area of innovation, and this year was no exception—with numerous studies aimed to improve our understanding of graft surgery outcomes, dry eye management and successful lens wear strategies. Highlights are summarized here. (*For additional coverage and commentary that focuses on ways to limit corneal morbidity due to inflammation and infection, be sure to look for this month's* Review of Cornea & Contact Lenses.)

Wait a Second, Femtosecond!

One of the most tantalizing, presumed benefits of femto-assisted cataract surgery is the potential safety gains to be had from the reduction in phaco power used—as the laser handles lens fragmentation and reduces dependence on phaco. Is it borne out in practice? A small study suggests not.[1649/D0284]

In a review of 15 eyes that underwent cataract surgery with or without femto assistance—all performed by the same surgeon and phaco machine—endothelial cell density at one month post-op was only marginally lower in the phaco group (2,696/mm^2 ±233/mm^2) than in the femto group (2,833/mm^2 ±140/mm^2). Peripheral endothelial cell loss was significant in both the phaco group (4%, p=0.004) and the femto group (2%, p=0.005).

The authors concluded that femto-assisted cataract surgery does not significantly differ from traditional phaco in early corneal peripheral endothelial cell loss.

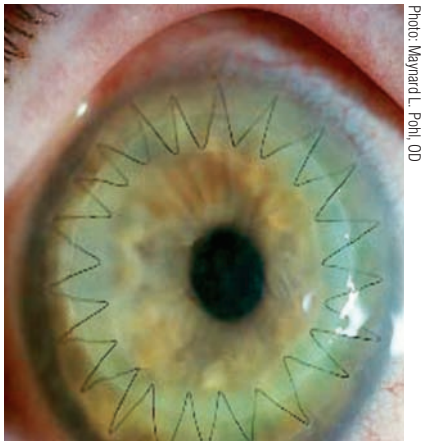

Photo: Maynard L. Pohl, OD

Surgeons who performed more than 15 lamellar procedures per year achieved a markedly better rate of graft survival than those who performed fewer surgeries.

Corneal Transplant Sx Update

Recent advances in lamellar corneal surgery have been a boon to corneal graft patients, but there appears to be a learning curve for surgeons, which ultimately impacts outcomes. In a review of more than 23,000 corneal graft procedures spanning 25 years, a total of 2,983 lamellar grafts were identified: 42% endokeratoplasties (posterior corneal endothelial cell grafts), 39% traditional lamellar keratoplasties and 19% deep anterior lamellar keratoplasties (DALKs).[1753]

Kaplan-Meier graft survival at one year was 74% for endokeratoplasties, 80% for traditional lamellar procedures and 93% for DALKs. Surgeons who performed more than 15 lamellar procedures per year achieved significantly better graft survival than those who performed fewer grafts (p=0.02). A best-corrected acuity of 20/40 or better was achieved in 18% of endokeratoplasties, 34%

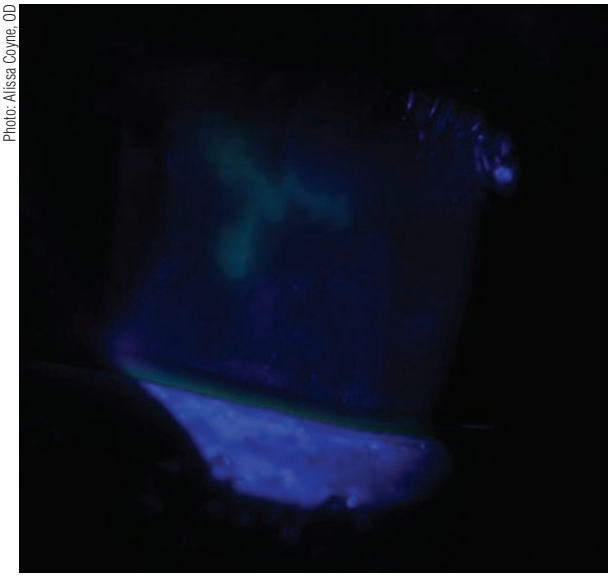

Photo: Alissa Coyne, OD

High-risk patients who receive oral cyclosporine after corneal transplant surgery are at an elevated risk for systemic adverse effects, including herpes keratitis.

of traditional lamellar grafts and in 37% of DALKs. The authors concluded that graft survival and visual acuity outcomes are better for penetrating grafts than for lamellar procedures—even when matched for both clinical indication and the era in which the surgery was performed.

Another study of graft survival compared the clinical outcome of regrafts with first grafts, using data from the Swedish Cornea Transplant Register for patients who underwent penetrating keratoplasty between 2001 and 2008.[3099/D0034] When the original indication was keratoconus or Fuchs' endothelial dystrophy, graft survival was poorer and visual outcome was worse than in first grafts. The second-graft failure rate was threefold higher for the keratoconus patients and twofold higher for those with Fuchs'. However, the outcomes for regrafts in bullous keratopathy patients were similar to first grafts.

When a penetrating keratoplasty is performed in a high-risk patient (i.e., an individual with a history of graft rejection, three or more quadrants of vascularization, presence or history of intraocular inflammation), oral cyclosporine (CSA) is often given postoperatively to aid healing. But, a retrospective analysis of 80 such patients who received oral CSA for an average of 197 days postoperatively found the incidence of systemic adverse effects due to CSA was 45%.[3095/D0030]

The adverse events were as follows: hypertension (15%), elevated liver enzymes (10%), gastrointestinal complaints (8.8%), serum creatinine increase (7.5%), absolute neutrophil count decrease (5.0%) and hirsutism (3.8%).

Also, herpes keratitis occurred more frequently in cases with oral CSA than in those without oral CSA after corneal transplantation. Further, the authors noted that absolute neutrophil count could decline as cumulative doses of CSA increase after about three months or more.

Cell Therapy

Given the precious nature of the endothelium, efforts at preservation are essential. An in vitro study of cell therapy analyzed cadaver endothelial cells and cultured them to improve cell morphology and proliferation rate.[1648/D0283]

Immune-histochemistry testing indicated that cultured cells were positive for zonula occludens-1 and Na,K-ATPase, common markers for human endothelial cells. The cells often demonstrated characteristic hexagonal-like morphology. Time to reach confluence was highly influenced by age, with the youngest donors exhibiting higher proliferative rates. Donor disease also affected culture quality.

The in vitro expansion of human corneal endothelial cells from donor corneas yields a number of suitable cells that could help treat patients otherwise in need of cornea transplantation. The work cited here, and elsewhere, could aid in ongoing efforts to integrate such cells into a host cornea and restore endothelial function.

New MGD Research on Tap

The non-laser—but similar in principle—treatment known as intense-pulsed-light (IPL) therapy, already popular in dermatology, continues to prove its potential as a treatment for meibomian gland dysfunction (MGD). In a retrospective case series, 78 patients with severe dry eye syndrome were treated with IPL and gland expression.[966/B0271] Improvement in tear film break-up time was found in 87% of patients, and 93% reported post-treatment satisfaction with their dry eye symptoms. Adverse events, most typically redness or swelling, were documented in 13% of patients. While preliminary, study results of IPL for dry eye due to meibomian gland dysfunction are promising. A randomized, multi-site trial with a larger sample and treatment comparison groups is currently underway.

To better understand pathophysiology of MGD, a retrospective analysis of 32 eyes looked at tear meniscus characteristics and the location of Marx's line (ML), which is often displaced anteriorly.[925/B0230]

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LUMIGAN® should be used with caution in patients with active intraocular inflammation (eg, uveitis) because the inflammation may be exacerbated. Macular edema, including cystoid macular edema, has been reported with LUMIGAN®. LUMIGAN® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Adverse Reactions: The most common (25%-45%) adverse event with LUMIGAN® was conjunctival hyperemia. Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia. Other common events (> 10%) included growth of eyelashes and ocular pruritus.

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

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LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

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

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with **LUMIGAN®** 0.01% and 0.03% (bimatoprost ophthalmic solution) can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes: LUMIGAN® 0.01% and 0.03% may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: LUMIGAN® 0.01% and 0.03% should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with bimatoprost ophthalmic solution. **LUMIGAN®** 0.01% and 0.03% should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Angle-closure, Inflammatory, or Neovascular Glaucoma: LUMIGAN® 0.01% and 0.03% has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

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

Use With Contact Lenses: Contact lenses should be removed prior to instillation of **LUMIGAN®** 0.01% and 0.03% and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS

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

In clinical studies with bimatoprost ophthalmic solutions (0.01% or 0.03%) the most common adverse reaction was conjunctival hyperemia (range 25%–45%). Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia with 0.01% or 0.03% bimatoprost ophthalmic solutions. Other common reactions (>10%) included growth of eyelashes, and ocular pruritus.

Additional ocular adverse reactions (reported in 1 to 10% of patients) with bimatoprost ophthalmic solutions included ocular dryness, visual disturbance, ocular burning, foreign body sensation, eye pain, pigmentation of the periocular skin, blepharitis, cataract, superficial punctate keratitis, periorbital erythema, ocular irritation, eyelash darkening, eye discharge, tearing, photophobia, allergic conjunctivitis, asthenopia, increases in iris pigmentation, conjunctival edema, conjunctival hemorrhage, and abnormal hair growth. Intraocular inflammation, reported as iritis, was reported in less than 1% of patients.

Systemic adverse reactions reported in approximately 10% of patients with bimatoprost ophthalmic solutions were infections (primarily colds and upper respiratory tract infections). Other systemic adverse reactions (reported in 1 to 5% of patients) included headaches, abnormal liver function tests, and asthenia.

Postmarketing Experience: The following reactions have been identified during postmarketing use of **LUMIGAN®** 0.01% and 0.03% in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to **LUMIGAN®**, or a combination of these factors, include: dizziness, eyelid edema, hypertension, nausea, and periorbital and lid changes associated with a deepening of the eyelid sulcus.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C

Teratogenic effects: In embryo/fetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost which achieved at least 33 or 97 times, respectively, the maximum intended human exposure based on blood AUC levels.

At doses at least 41 times the maximum intended human exposure based on blood AUC levels, the gestation length was reduced in the dams, the incidence of dead fetuses, late resorptions, peri- and postnatal pup mortality was increased, and pup body weights were reduced.

There are no adequate and well-controlled studies of **LUMIGAN®** 0.01% and 0.03% (bimatoprost ophthalmic solution) administration in pregnant women. Because animal reproductive studies are not always predictive of human response **LUMIGAN®** should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether **LUMIGAN®** 0.01% and 0.03% is excreted in human milk, although in animal studies, bimatoprost has been shown to be excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when **LUMIGAN®** is administered to a nursing woman.

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

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

Hepatic Impairment: In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months.

OVERDOSAGE

No information is available on overdosage in humans. If overdose with **LUMIGAN®** 0.01% and 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic.

In oral (by gavage) mouse and rat studies, doses up to 100 mg/kg/day did not produce any toxicity. This dose expressed as mg/m2 is at least 70 times higher than the accidental dose of one bottle of **LUMIGAN®** 0.03% for a 10 kg child.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 2 mg/kg/day and 1 mg/kg/day respectively (at least 192 and 291 times the recommended human exposure based on blood AUC levels respectively) for 104 weeks.

Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the *in vivo* mouse micronucleus tests.

Bimatoprost did not impair fertility in male or female rats up to doses of 0.6 mg/kg/day (at least 103 times the recommended human exposure based on blood AUC levels).

PATIENT COUNSELING INFORMATION

Potential for Pigmentation: Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of **LUMIGAN®** 0.01% and 0.03% (bimatoprost ophthalmic solution).

Potential for Eyelash Changes: Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with **LUMIGAN®** 0.01% and 0.03%. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

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

When to Seek Physician Advice: Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of **LUMIGAN®** 0.01% and 0.03%.

Use with Contact Lenses: Patients should be advised that **LUMIGAN®** 0.01% and 0.03% contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation of **LUMIGAN®** and may be reinserted 15 minutes following its administration.

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

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The furthest anterior migration of ML was measured in three zones: temporal, central and nasal. For each eye, the tear meniscus height, area and length of anterior excursion at the center of the lower eyelid were measured using spectral-domain OCT.

In patients with symptomatic MGD, this study found that central tear meniscus height, area and anterior excursion positively correlate with the furthest anterior migration of ML in the temporal zone, but not in the central or nasal zones.

A possible explanation is age-related changes, such as conjunctivochalasis—which tends to be more pronounced temporally—physically impedes lateral tear migration, leading to increased central tear pooling while also promoting anterior excursion of the tear meniscus temporally by acting as a bridge. By this process, the solute gradient mechanism could contribute to the initiation of MGD. The condition also could be initiated by increased exposure of the meibomian gland orifices to tears, regardless of their osmolarity.

Another MGD study evaluated the influence of the microflora of the eyelid margins in 103 subjects.[926/B0231] The most commonly identified microorganisms were commensal skin bacteria including *Propionibacterium* species (87%) and coagulase-negative staphylococci—mainly *Staphylococcus epidermidis* (80%). Higher numbers of commensal bacteria on the eyelids are associated with clinical measures of decreased meibum quality and function, as well as advanced age in the female population. It remains unknown whether the increased number of bacteria is a causative agent to the compromise of meibomian gland function, or a consequence of either such changes or other systemic factors (e.g., reduced sex hormones in elderly women).

Dry Eye Management

Do even normal, closed eyelids contribute to ocular surface disease by failing to create a necessary protective seal during sleep? Apparently so, according to a study of 148 patients using the Korb-Blackie (KB) lid light test.[942/B0247] In KB testing, a transillumination device is placed against the closed outer upper eyelid while the lids are examined for light leakage emanating from the lid area. Visible light was graded on a 0 to 3 scale, and ocular discomfort on a 0 to 2 scale. The mean light score for each lid region was: temporal 0.3 ±0.5, central 1.0 ±1.0 and nasal 0.5 ±0.7, indicating the central region is the least likely to close completely. Discomfort upon awakening was significantly correlated with the number of lid sections emanating light during the KB lid-light test.

The influence of punctal occlusion on tear film osmolarity in dry eye was the focus of a pilot study that assessed osmolarity at baseline, one week and one month following occlusion.[6024/A0087] Subjective patient assessments of severity and frequency of dry eye symptoms also were collected at each visit, as well as clinician grading of staining, tear film break-up time and meibomian dysfunction.

After punctal occlusion, tear osmolarity and conjunctival/corneal staining showed a statistically significant reduction, and tear film break-up time demonstrated a statistically significant increase. Tear hyperosmolarity is regarded as a hallmark of dry eye disease, the authors note, and tear osmometry stands as a promising diagnostic test to monitor the clinical efficacy of dry eye therapies, such as punctal occlusion.

Lastly, there are some promising new ideas in dry eye treatment involving toll-like receptors (TLR), which may function as catalysts for proinflammatory cytokines and matrix metalloproteinases (MMPs) that lead to ocular surface pathology. This study examined the hypothesis that TLR agonists stimulate the production of MMP-9 in human ocular surface cells.[5999/A0062]

Human and simian corneal epithelial cells were treated with various TLR agonists, then the culture media was analyzed to detect MMP-9 protein secretion. The human cells showed significant increase in MMP-9 from exposure to several different agonists.

These results are the first to show that TLR agonists stimulate the production of MMP-9 in various ocular surface cells. Given that MMP-9 production in dry eye patients is thought to be predictive of dry eye associated corneal ulceration, TLR antagonists may serve as a novel therapeutic option in the treatment of dry eye.

CL-related Dry Eye

When traditional soft lens wears are refit into silicone hydrogel (SiHy) or hydrogel daily disposables (HydDD), which factors about the new lens modality improve their experience? That was the focus of a study supported by Johnson & Johnson that surveyed 598 such patients at baseline, two weeks and four months after the refit.[5458/A0157]

As might be expected, the primary advantages noted were reduction in dryness and discomfort symptoms, lengthening of comfortable wearing time and improvements in ease of use and

compliance with instructions offered by the daily disposable modality.

Symptoms of dryness and discomfort improved more among SiHyDD wearers compared to HydDD wearers, but improvement in the intensity of blurred vision was equivalent for the two lenses. The Contact Lens Dry Eye Questionnaire-8 score improved significantly for all treatment arms at all visits, except for the HydDD group at the four-month visit.

Mean wearing times were unchanged, but mean comfortable wearing time improved by 1.0 to 2.3 hours for all groups, except in former wearers of reusable Hyd or HydDD lenses who were in the HydDD treatment group. Ease of use and compliance with instructions were rated significantly higher at baseline by daily disposable lens wearers compared with reusable lens wearers (compliance: 86% vs. 62%; ease: 93% vs. 60%).

The Versatile Scleral Lens

The fluid reservoir created by a scleral lens makes it a uniquely helpful treatment for ocular surface disease, but lens settling after insertion reduces reservoir depth. To assess the extent of settling, a study examined the change in spacing between the lens and cornea during the first two hours of small-diameter scleral contact lens wear in four patients.[5469/A0168] Scleral lens clearance after initial lens placement was 165µm ±62µm. After two hours of wear, clearance was reduced to 80µm ±23µm, a 50% decrease.

When fitting scleral lenses, sufficient time must be allowed for the lens to reach a stable position before assessing the depth of the post-lens fluid reservoir. If assessed prematurely, lens settling could greatly reduce reservoir volume and increase contact with the cornea—limiting efficacy in patients with severe ocular surface disease.

For many corneal disease patients, scleral lenses are invaluable. However, symptoms of "foggy" vision can hinder success and patient satisfaction. To determine possible causative factors, scleral lens wearers who had to interrupt lens wear at mid-day to eliminate fog were studied.[5483/A0182] Predisposition to dry eye and significantly greater central corneal vault combined with lens edge tightness were implicated.

Of the 15 patients, five were interrupted wearers, averaging 4.45 hours of wear time. Wearing time for the 10 uninterrupted patients averaged 11.75 hours. Uninterrupted wearers had an average dry eye questionnaire (DEQ) score of 28 ±22, while the interrupted wearer's averaged 54 ±11. Sixty percent of both groups exhibited an alignment fit. However, 80% of interrupted wearers exhibited a tight fitting edge compared to 40% of uninterrupted wearers. The average corneal vault for uninterrupted lens wearers was 0.29mm ±0.24mm, while interrupted wearers averaged 0.71mm ±0.44mm.

The best remedy for foggy vision is a reassessment of lens edge fit and adjusting the corneal vault, the authors concluded.

Bandage Lenses

It is estimated that 60% of graft-vs.-host disease (GVHD) patients have ocular involvement with significant compromise in quality of life due to symptoms such as severe photophobia, pain and decreased visual acuity. An ongoing, prospective Phase II clinical trial is using extended soft bandage contact lenses applied to affected eyes with antibiotic coverage for a two-week period.[5440/A0139] To date, the first six patients have all shown improving symptoms/signs, without any occurrence of complications.

Symptomatic changes with the bandage lens therapy are correlated with ocular exams as well as anterior segment OCT, which can be a feasible method to characterize pathological changes related to ocular GVHD. Additionally, wearing of extended soft bandage contact lens can diminish the attrition of corneal tissue from eyelid movement and provide symptomatic relief for patients with ocular GVHD.

CLs After CXL

After keratoconus patients undergo collagen crosslinking (CXL) to stiffen the cornea, how might contact lens wear affect outcomes? That was the specific focus of a study conducted in New Delhi that compared CXL patients with and without subsequent rigid lens wear, as well as a group that wore lenses but had not undergone CXL.[5453/A0152]

All eyes were followed for six months after recruitment. Uncorrected visual acuity improved only in the CXL-and-lens-wear group, from 0.97logMAR ±0.25logMAR to 0.86logMAR ±0.30logMAR at six months. Over-refraction showed a myopic shift of 0.37D in this group, as well. These patients also showed a regression of 0.93D in mean keratometry and 1.99D in maximum keratometry

The authors concluded that rigid lens use after CXL was associated with changes in corneal epithelium and delayed recovery of corneal sub-basal nerve plexus. It is also associated with significant cornea flattening and improved UCVA. ■

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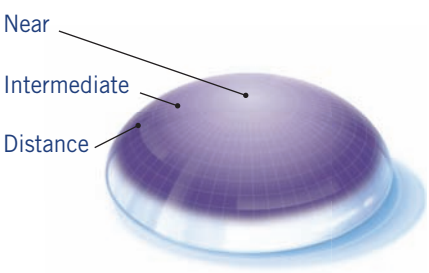
How to Become a Specialty Multifocal Contact Lens Practice

Offering the latest technology, like AIR OPTIX® AQUA Multifocal contact lenses, can help your practice go above and beyond.

We often see contact lens patients from other offices who aren't even aware that multifocal contact lenses are an option to help correct their near vision. Here's where the opportunity arises for you to establish your office as a multifocal specialty practice.

Laying the Groundwork

To build a multifocal specialty practice, it's necessary to become familiar with the different types of multifocal contact lenses that are available. Educate yourself, and don't forget to educate your staff as well. Help them to understand the differences between lenses and teach them about the designs that tend to be the most successful.



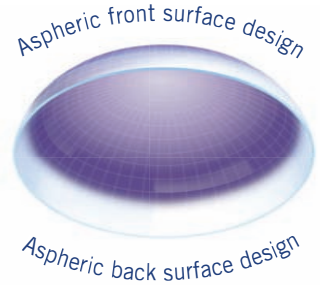
AIR OPTIX® AQUA Multifocal contact lenses have a unique Precision Profile Design that works to provide smooth transitions from near, to intermediate, to distance.

Remember, your staff is often the first contact your patient has in the exam process. **They can help screen for potential candidates and introduce new technology to interested and appropriate patients.** Often, just planting the seed in a patient's mind is enough to pique their interest in trying multifocal contact lenses.

Spread the Word

Get the word out. Let your patients—and the public—know that you are an expert in fitting multifocal contact lenses. Search for opportunities to lecture to civic groups, chambers of commerce or business networking events. Consider writing a public service announcement for your local newspaper about the advances in contact lenses for presbyopia. By educating the public and your patients about presbyopia and how multifocal contact lenses can help, you will define yourself as an expert in the field.

And let's not forget the numerous social media opportunities. With avenues such as Facebook and Twitter, you can reach large audiences with minimal effort. Ask patients whom you have successfully fit to comment or tweet about their experience on your profile or site, as well as on their own. There is a good chance that many of their friends and followers are in the same age group and geographic area. Once the word is out that you successfully fit multifocal contact lenses, your time will be in high demand.



The aspheric front and back surfaces of the AIR OPTIX® AQUA Multifocal contact lens enhance image quality and facilitate fit.

Another component to establishing yourself as a multifocal specialty practice is to **host a multifocal contact lens fitting event in your office**. Use your practice management software to sort the appropriate age group and then e-blast or mail an invitation to this list. Offer incentives to encourage patients to come and make an event out of it, much like you would do for a trunk show. Finally, be sure everyone involved has fun!

KENNETH A. YOUNG, OD

Dr. Young is in group practice in Brentwood, Tenn. He serves as a paid consultant to Alcon.

With today's aging population, there has never been a greater opportunity to differentiate your practice from others in your area. Many baby boomers who grew up with contact lenses are looking to you, their practitioner, to help them with their near vision needs. Fortunately, we now have more choices than ever in multifocal contact lenses, like the AIR OPTIX® AQUA Multifocal contact lens.

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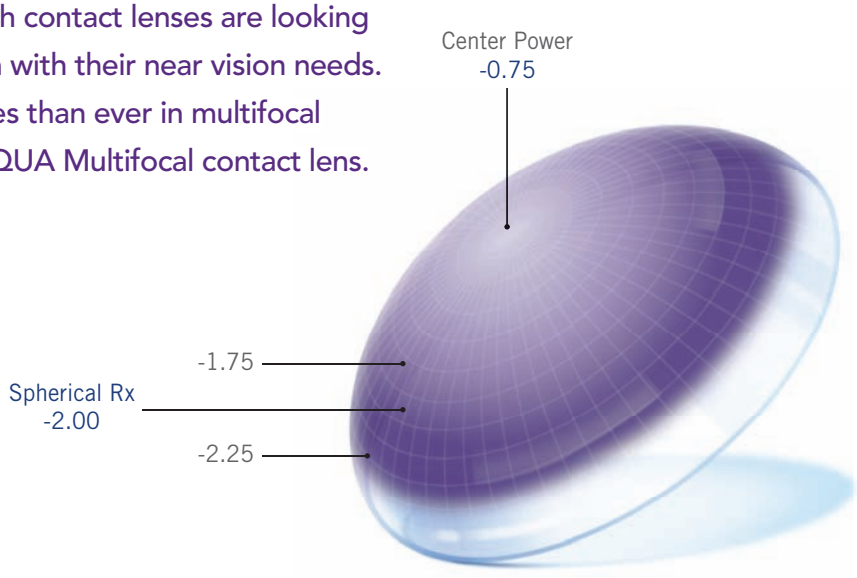

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> **"I find it to be an extremely easy contact lens to fit."**

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Glaucoma

Researchers presented fresh data on new structural metrics, visual fields, blood flow and the latest glaucoma drug.

By Robert Cole, III, OD, Emeritus Clinical Editor

Anatomical structure studies stood out as a theme at ARVO 2013, perhaps a consequence of glaucoma investigators now taking full advantage of optical coherence tomography innovations that allow for unprecedented visualization and data acquisition of the posterior segment. One can only hope a reliable structural metric for diagnosing and/or measuring glaucoma progression will soon emerge from these nascent efforts.

In the meantime we still have visual fields as a mainstay, which researchers continue to improve upon. Blood flow—sometimes known as intraocular pressure's dark twin—remains largely mysterious, but gave up a few secrets this year. Attendees also perused data on a new class of glaucoma drug, plus an interesting punctal plug implanted in dogs.

Structural Metrics

Using enhanced-depth imaging spectral-domain optical coherence tomography (EDI SD-OCT) and the Humphrey visual field test, researchers at the University of Washington School of Medicine in Seattle found a correlation between lamina cribrosa (LC) morphology and glaucoma severity.[2253/B0057]

Optic nerve head B-scans of 103 glaucoma patients were obtained using EDI SD-OCT. Images were analyzed using the Heidelberg Eye Explorer software. LC depth was defined as the greatest distance between the reference plane (the imaginary extension of Bruch's membrane plane) and the anterior border of the LC, perpendicular to the reference plane. LC thickness was the distance from anterior border to the posterior border of the LC in the center of optic nerve head images.

In this study, researchers found that glaucoma severity shows a significant correlation with LC depth and LC thickness, metrics that may be useful during optic nerve head analysis.

Peripapillary choroidal volume (PCV) appears to be reduced in eyes with glaucoma compared to healthy eyes or ones with ocular hypertension, according to a paper presented by the University of Houston College of Optometry.[2150] A total of 123 subjects participating in a longitudinal, observational clinical research study and diagnosed with primary open-angle glaucoma, ocular hypertension or deemed normal were imaged using SD-OCT, again with enhanced-depth imaging. Whether thinner PCV reflects an inherent risk of POAG or occurs during glaucoma's pathogenesis requires further study.

A new OCT technology that visualizes macular RNFL loss at different stages of glaucoma appears to correlate well with visual fields, according to research teams in Milano and Bergamo, Italy.[4815/D0254] Ten healthy eyes and 10 eyes with varying stages of glaucoma underwent RNFL transversal scans using the incorporated analysis software of the Heidelberg Eye Explorer (version 5.7.0.1).

The new scan's dense volume allows for detection of RNFL loss, from early to advanced stages of

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glaucoma. This visualization follows the same visual field damage shape as anatomical RNFL distribution. The OCT's quicker speed could make this new approach useful in clinical practice, investigators believe.

Another novel OCT measurement, macular retinal ganglion cell analysis via both the Cirrus HD-OCT and RTVue-OCT, appears to work well, according to a Parisian study.[4830/D0269] A total of 167 eyes were split into early glaucoma, moderate-to-advanced glaucoma and healthy groups. The two ganglion cell analyses correlated well with circumpapillary RNFL measurements from each machine respectively, plus both machines showed a similarly high sensitivity and specificity, researchers concluded.

Yet another biological marker—the inner-to-outer retina area ratio—appears to also hold promise as a glaucoma detector, according to a study team at the Jules Stein Eye Institute.[4840/D0279] Forty-one normal subjects and 27 glaucoma patients underwent study. When compared to ganglion cell/inner plexiform layer thickness measurements, the inner-to-outer retina area ratio was found to be significantly predictive of glaucoma. The clinical benefit is that this new measurement does not vary as a function of age or axial length in normal subjects, the study found.

Researchers in Hiroshima attempted to determine how glaucomatous damage affects the thickness of three important structures: retinal nerve fiber layer (NFL); the ganglion cell layer and the inner plexiform layer (GCL+IPL); and the outer retinal layer (ORL).[4851/D0290] Eighty-four glaucoma patients and 36 normal control subjects were studied using OCT. The NFL and GCL+IPL measures in the normal group were significantly thicker than those in the glaucoma group. The outer retinal layer in glaucoma patients was thinner than that in normal subjects, but not to the point of statistical significance. Researchers concluded glaucoma mainly damages the inner retinal layer in the macular area, but that loss of the outer retinal layer may occur too. Also, they suggested that damage to the NFL precedes damage to the GCL+IPL.

Structure vs. Function

We always hear about structural and functional changes that occur as glaucoma progresses. But what about as treatment progresses, when IOP is reduced? A team at Wills Eye Institute looked into this question.[1877/B0131] Forty-seven glaucoma patients with proven pressure-lowering interventions were studied.

Change in IOP was significantly associated with change in cup volume and rim area after the first follow-up visit. Change in functional vision approached significance after the first follow-up visit in patients with the most drastic pressure reduction, but fell just short.

Change in RNFL thickness over time also fell just short of significance among drastic pressure-reduction patients as well. Thus, marked reduction of IOP in glaucomatous eyes caused some early structural changes but no significant changes in functional tests, researchers concluded.

Researchers from Sao Paulo sought to evaluate the correlation between peripapillary retinal nerve fiber layer thickness and visual field indices using different SD-OCTs and visual field perimeters in glaucoma.[2283/B0087] In a total of 44 eyes of 25 patients included in the study, moderate correlations between peripapillary RNFL thickness and visual field indices were found, according to the paper.

A big question in all structure vs. function discussions—which sustains damage first?—was addressed in an interesting way by a multi-site US study team.[4939] They investigated the tendency for the conservation of the binocular visual field in patients with moderate to severe glaucomatous field loss in both eyes.

The resesearchers studied 47 patients with stabilized chronic progressive glaucoma undergoing Humphrey Visual Field 30-2 testing and found a very strong tendency for optimizing the binocular visual field in a manner that defied simple anatomic symmetry considerations. The paper noted that focal axonal injury in one eye may be accompanied by increased activity in the contralateral retinal glia and geniculate layers receiving visual information from the fellow, non-injured eye. Focal bilateral compensation of this kind, mediated by the body's central nervous system, may be involved in the conservation of the binocular visual field in patients with glaucoma, the study observed.

Visual Fields

Optical coherence tomography is a wonderful resource, to be sure, but there is still a great deal of diagnostic value to be had from visual field (VF) testing as well. An international study group made an enhancement to its visual field risk calculator.[2631] Despite good performance in predicting final mean deviation, the

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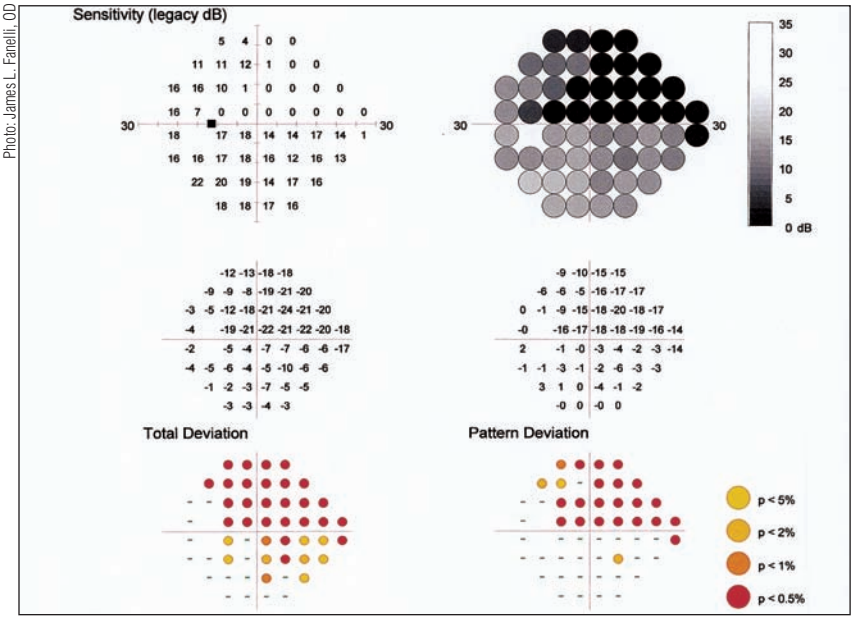

Flicker-defined form perimetry, as demonstrated here on the Heidelberg Edge Perimeter, yields fewer fixation losses and a lower rate of false positives than standard automated perimetry testing.

calculator failed to account for the localized nature of glaucomatous disease and progression, so it could not predict sectorial VF deterioration. Researchers aimed to enhance it by adding visual field topographical information, validating the improvement in a subset of 367 glaucoma patients. The enhanced calculator proved accurate at estimating glaucomatous progression in different sectors, which may be more helpful than global indices for assessing areas of greater risk of progression and estimating the rate of progression in each VF sector, the study suggested.

A US study team found that personalized examination schedules may improve the likelihood of detecting glaucoma progression.[3956/D0244] A total of 571 glaucoma patients underwent evaluation, some receiving a visual field examination and IOP check once a year on a fixed schedule, and some who were examined at intervals based on what the researchers called the Kalman filter, which was validated by data from the Collaborative Initial Glaucoma Treatment Study (CIGTS) and the Advanced Glaucoma Intervention Study (AGIS).

The model forecasts each patient's disease dynamics into the future while incorporating the uncertainty associated with those forecasts. Researchers showed a 27% increase in efficiency in detecting progression among those on personalized schedules.

Flicker-defined form (FDF) perimetry was designed to detect early VF loss in glaucoma. Researchers at Moorfields Eye Hospital in London sought to compare this test with standard automated perimetry (SAP) using a cohort of 137 patients.[3952/D0240] They found the FDF test to be associated with higher false negatives than SAP. However, patients performed better on the FDF in terms of fewer fixation losses and lower false positive rates. Additionally, the FDF test duration was faster, researchers concluded.

Frequency doubling technology (FDT) perimetry can be used to track glaucoma progression, according to a study based in Groningen, Netherlands.[3927/D0225] Among 126 glaucoma patients who were followed for about six years with both the Humphrey Field Analyzer (30-2 SITA) field testing and FDT (C20-1 full threshold), there was a highly significant correlation of results. This suggests that FDT can be used in patients who cannot be reliably tested with SAP.

SLT Lasers

Selective laser trabeculoplasty (SLT) is effective at reducing IOP in both initial and repeat treatments in patients with pseudoexfoliative glaucoma, according to a two-team study based in Massachusetts.[1857/B0111] Investigators studied 56 patients and a total of 79 eyes that underwent as many as three SLT treatments over 11 years.

The percentage of eyes maintaining IOP control without additional SLT (about 50%) and those requiring surgery (about 20%) were similar after the first and second SLT treatments. Although a small group (three of five patients), 60% of eyes required surgery after the third SLT treatment, the study found.

In patients receiving maximal medicinal treatment, SLT as a secondary treatment showed efficacy in reducing or maintaining IOP for three years, according to a study conducted at Wills Eye Institute.[1866/B0120] Eighty-eight glaucoma patients (75 with POAG, six with secondary glaucoma, and seven with normal-pressure

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glaucoma) who received three or four medicinal treatments were followed up after treatment with SLT at one-, three- and five-year intervals. Mean IOP was calculated before receiving laser treatments then compared to the IOP measured at those same intervals. The mean baseline IOP was 18.35mm Hg. The mean at three years was 15.86mm Hg.

Blood Flow

For years it has been postulated that problems with blood flow to the optic nerve head may explain the phenomenon of normal-tension glaucoma. At the heart of these theories is a process called autoregulation. This prompts the question: are certain categories of patients prone to autoregulation dysfunction?

An international study team tackled this question for diabetics.[4472/D0212] They examined the relationship between systemic blood pressure (BP) and ocular perfusion pressures (OPP) with blood flow in the temporal (TPCA) and nasal (NPCA) short posterior ciliary arteries in 75 open-angle glaucoma patients, some with and some without diabetes mellitus.

In diabetics, changes in short posterior ciliary artery blood flow were strongly correlated to changes in BP and OPP. These correlations were weak among those without diabetes; the differences were statistically significant. This data suggests that diabetic glaucoma patients may have impaired vascular autoregulation during fluctuations in systemic BP and OPP, according to the study.

An Indiana University School of Medicine study looked at this question among African Americans.[4470/D0210] The researchers examined differences in the relationship between systemic BP and OPP with localized ocular blood flow in the central retinal artery (CRA) and ophthalmic artery (OA) in 56 glaucoma patients of European descent (ED) and 19 of African descent (AD).

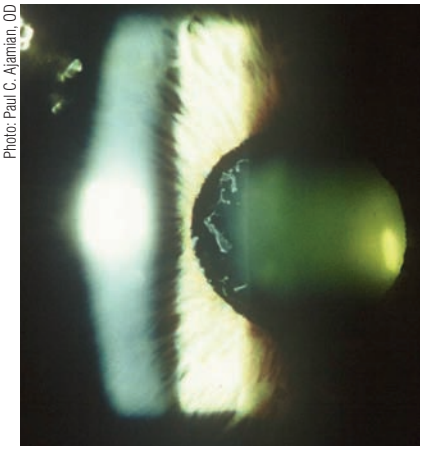

Photo: Paul C. Ajamian, OD

Selective laser trabeculoplasty is effective at lowering IOP in patients with pseudoexfoliative glaucoma, as seen here.

In glaucoma patients of AD, CRA blood flow was more strongly correlated to blood pressure and perfusion pressure than in patients of ED. OA changes were more strongly correlated to ED than AD patients. This indicates that retinal blood flow may not be sufficiently autoregulated during changing blood and perfusion pressure in patients of African descent, according to the study.

Novel Topics

It would not be ARVO without a look at potential new breakthroughs. Here are but a few.

An industry-sponsored US study team investigated the efficacy and tolerability of trabodenoson, a highly-selective adenosine-1 agonist, which is a new class of glaucoma drug.[2621] One hundred and forty-four subjects were randomized to placebo or trabodenoson. The most consistent decreases in IOP were noted at the 500µg dose, the study found, concluding that the drug was well-tolerated, safe and resulted in significant IOP reductions in adults with ocular hypertension or POAG.

Endoscopic cyclophotocoagulation (ECP), a new IOP-lowering procedure that can be combined with cataract surgery, is a safe and simple strategy for the long-term control of mild to moderate glaucoma, a multi-site US study team concluded.[4750/D0134]

The mean baseline IOP in 261 eyes of 163 patients was 17.27mm Hg, which was significantly reduced at every time point from baseline to 66 months, with average IOP at month 66 being 13.63 mmHg among patients who had undergone ECP. That amounts to an average IOP reduction of 21% over 66 months. After ECP, patients on topical medication were 10.5 times more likely to be off of medications at 66 months when compared to baseline, the study found.

It appears punctal plugs made from the drug travoprost can effectively serve as a sustained release modality, at least in canine models thus far, according to an industry-sponsored US study.[5633/C0019] One-, two- and three-month sustained release of travoprost from biodegradable punctal plugs is feasible, the study concluded, and can deliver travoprost into the tear fluid at therapeutic levels. Plug retention is a key attribute to achieve clinical success, and confirmation of plug presence can be performed by physicians or patients, the study noted. Researchers confirmed visualization and retention of the canine plugs. ■

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Cataract & Refractive Surgery

Much of this year's research focused upon surgical refinement and improved postoperative care.

By Derek N. Cunningham, OD, Contributing Editor

Each year at ARVO, dozens of papers and posters are presented on futuristic refractive procedures and prospective IOL materials. While such cutting-edge information is of great interest, maintaining a healthy and quiet ocular surface continues to be optometry's primary role in the refractive care process.

So, in addition to previewing some of the latest surgical procedures and enhanced diagnostic equipment, we'll examine an abundance of research surrounding several new topical agents that will help maximize patients' postoperative outcomes.

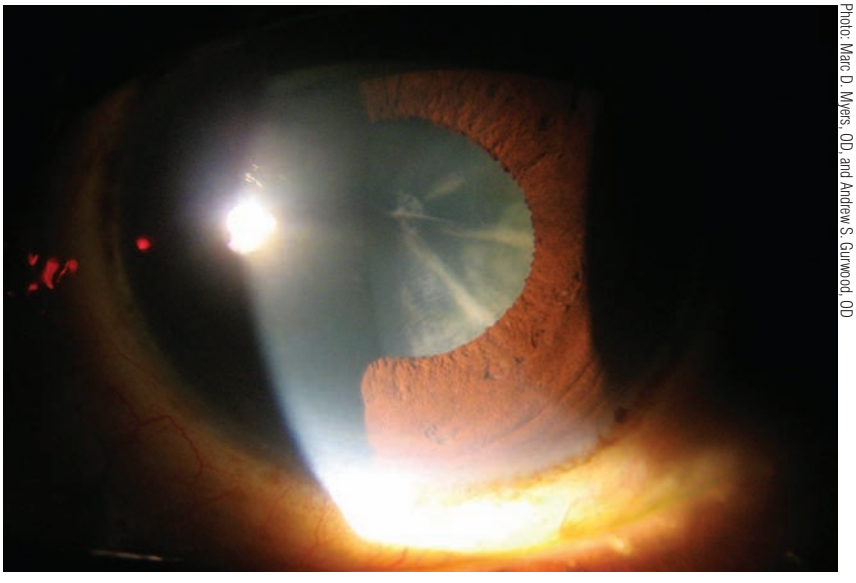

Photo: Marc D. Myers, OD, and Andrew S. Gurwood, OD

Excessive consumption of foods rich in refined sugars, such as white rice, increases an individual's risk of cataracts.

Advances in Epidemiology

Although we are all experienced in acute disease management, it is often helpful to understand both how and why some patients are more likely than others to develop certain ocular conditions. Such information can add valuable guidelines to public health initiatives—particularly with regard to conditions that are precipitated by modifiable lifestyle factors.

For example, we now have a better understanding of how dietary intake can influence the rate of cataract development and progression. An Indian study of 3,723 patients uncovered a significant association between frequent consumption of high-glycemic index foods (e.g., white rice, potatoes, pasta) and cataract development.[895/B0119] To reduce the incidence of cataracts, the researchers recommended consumption of several low-glycemic index cereals in lieu of foods rich in refined sugars.

Additionally, obesity may affect corneal pachymetry measurements during a refractive consultation. A study from the

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[1]Bergmanson J. Clinical Ocular Anatomy and Physiology, 14th ed. Houston , Texas: Texas Eye Research and Technology Center, 2007.

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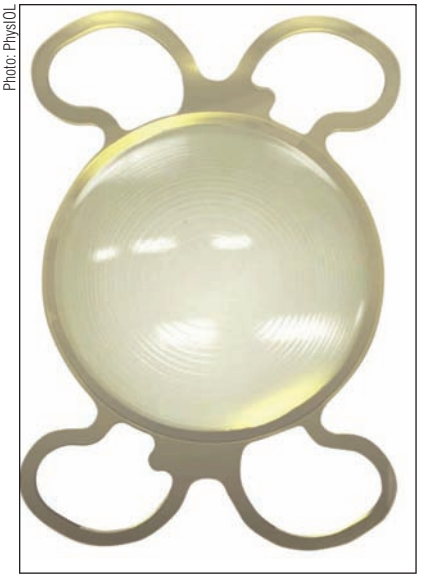
Photo: PhysIOL



The PhysIOL FineVision trifocal IOL demonstrated good contrast sensitivity scores. *(Note: This lens is not commercially available in the US.)*

United Kingdom indicated that peripheral corneal thickness was inversely proportional to body mass index (BMI).[524/B0161] While the study was confined to healthy males with average BMIs, the researchers suggested that body mass index should be added as an input line parameter on corneal analyzers.

Dialed-up Diagnostic Tech

We now may be able to document more accurate and repeatable measurements in patients with abnormal corneas. A new color LED corneal topographer (Cassini, i-Optics) was validated against conventional Placido disk- and Scheimpflug-based topographers in eyes that underwent penetrating keratoplasty.[528/B0165] The device was shown to be more accurate than Placido disk topographers at measuring non-symmetric aberrations, such as astigmatism and quadrafoil. Further, measurements from the color LED topographer were more repeatable than those derived by Scheimpflug-based units. This technology may prove to be especially valuable in refractive surgery clinics that receive a high volume of patients with abnormal corneas.

A Boston-based research group used in vivo confocal microscopy (IVCM) to demonstrate a profound increase in immune dendritic cells and significant decrease in corneal nerves in patients with post-LASIK keratoneuralgia.[3711/371] Despite minimal findings on clinical exam, subclinical changes in sub-basal nerves—as well as increased immune and inflammatory cells—were seen on IVCM.

It's important to note that the IVCM findings correlated well with symptoms. The researchers concluded that IVCM might yield new insights into the pathogenesis of otherwise unexplained corneal pain.

A Focus on Contrast Sensitivity

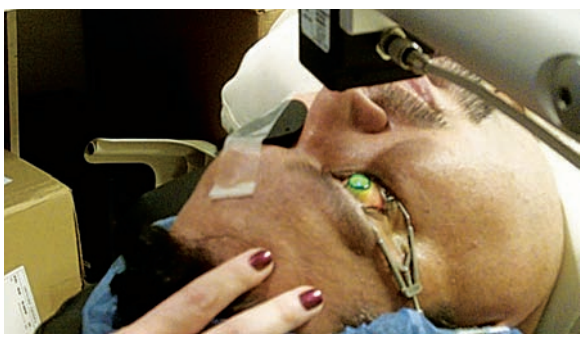
In a Department of Defense-funded joint study between the Wilmer Eye Institute and several military centers, two conventional LASIK technologies were evaluated for postoperative visual performance via contrast sensitivity assessment.[3125/D0060] In this study, wavefront-guided (WFG) surgeries were performed using the VISX Star S4 (Abbott Medical Optics) and wavefront-optimized (WFO) were conducted with the Wavelight Allegretto Wave Eye-Q (Alcon). Corneal flaps were created using the IntraLase (Abbott Medical Optics) femtosecond laser system.

The researchers evaluated best-corrected visual acuity and small-letter (20/25) contrast sensitivity, as well as low luminance/night vision through a night-vision filter. They concluded that high-contrast visual acuity was comparable between WFO and WFG LASIK—as would be anticipated. Perhaps more importantly, however, they found that WFG LASIK appears to be superior to WFO LASIK regarding postoperative night vision performance and low-contrast acuity.

Additionally, visual outcome and patient satisfaction data was presented on a new diffractive trifocal intraocular lens.[841-B0065] The FineVision trifocal IOL (PhysIOL) was evaluated in 50 eyes of 25 patients. The results showed that photopic contrast sensitivity was within the standard normal range. The rate of spectacle independence for all the distances was higher than 85%, and a low percentage of patients reported significant halo or ghosting.

New Developments in CXL

Although corneal collagen crosslinking (CXL) with riboflavin is not approved in the United States, the procedure continues to be routinely performed and extensively studied throughout the world.



Corneal collagen crosslinking, as seen here, may be combined with a topography guidance system to surgically correct refractive error.

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Brien Holden Vision Institute is one of the largest and most successful social enterprises in the history of eye care. By applying commercial strategies to vision research and product development the Institute has generated income for research and public health programs that provide quality eye care solutions and sustainable services for the most disadvantaged people in our world.

The concern for the devastating shortfall in eye care education in developing communities, especially for correction of refractive error, became action in 1998 for those at the Institute. The lack of training institutes and educational opportunities was creating a human resource gap and a critical eye care shortage for hundreds of millions of people in need of services. The concern and willingness to address the issue gave rise to the International Centre for Eyecare Education (ICEE).

Almost 15 years later, and acknowledging that 640 million people are still without access to permanent eye care, concern has galvanised into action again. To advance the process of addressing the challenge, both ICEE and Brien Holden Vision Institute will more closely align, share one common purpose and one name.

Together, we believe if we harness our efforts and broaden our scope we can achieve much more.

Together, we aim to drive, innovate, educate, collaborate, advocate and negotiate what is needed so that hundreds of millions of people worldwide can enjoy the right to sight.

Whether it's research to develop the technology to slow the progress of myopia, investment in new systems for diagnosis of disease, delivery of sustainable access to services or provision of eye care education in the most marginalised and remote communities in the world, the Institute will focus on the quality of vision people experience and equity in eye care access worldwide.

We believe in vision for everyone...everywhere.

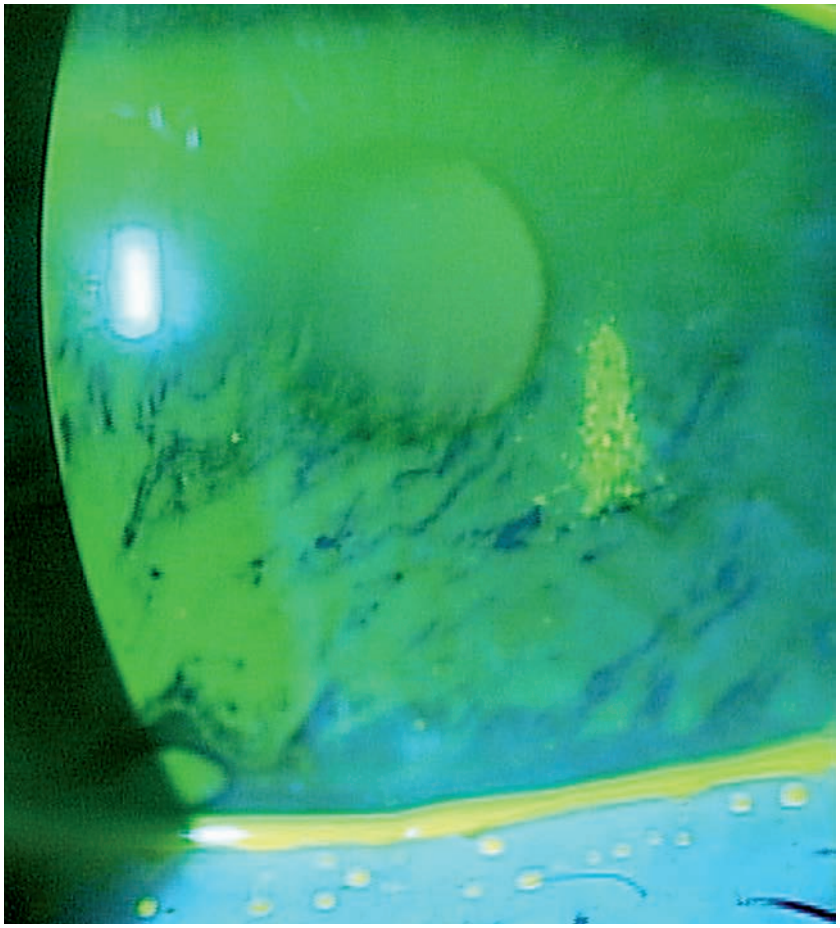
The Durban community in South Africa arrives in hundreds to support the Brien Holden Vision Institutes initiative Drive for Sight, part of the World Sight Day celebrations in October 2012. All attendees were offered free eye examinations, access to free or affordable low cost spectacles and referrals for further eye care where necessary. ***Photo by Graeme Wyllie.***

Brien Holden Vision Institute

Education Research Technology Public Health

Brien Holden Vision Institute Foundation (formerly ICEE) is a Public Health Division of Brien Holden Vision Institute

Photo: Mile Brujic, OD



A topical mixture of 0.2% omega-3 and 0.1% hyaluronic acid could be used to decrease epithelial barrier disruption and corneal staining in dry eye patients.

CXL is highly effective at arresting keratoconus progression secondary to enhanced corneal rigidity. However, when being applied to the corneal tissue, the procedure is fundamentally non-specific.

Some advanced research involving topography guidance was presented that could help transform CXL into a legitimate refractive procedure.[529/B0166] With a stabilizing eye tracker and overlaid topographical data, a digital micromirror could be used to control the applied UVA pattern. Soon, practitioners not only may be able to halt keratoconus, but also provide the patient with freedom from glasses or contact lenses.

In a similar study, researchers from the Cleveland Clinic evaluated the possibility of selective CXL to alter corneal astigmatism.[1620/D0255] In their assessment model, treatments applied orthogonal to the steep axis decreased astigmatism. This could serve as a novel, noninvasive method of astigmatism correction—not only in diseased corneas, but also in healthy eyes.

Improved Patient Safety

Lens exfoliation syndrome (LES) poses significant intraoperative risks during cataract surgery due to weak lens zonules. Femtosecond laser-assisted clear cornea cataract surgery in LES appeared to be safe and effective in a multi-country study involving 65 eyes of 48 consecutive patients.[1818/A0164] The study analyzed uncorrected visual acuity, best spectacle-corrected visual acuity, refraction, cylinder, capsulorhexis diameter, topographic cylinder change and endothelial cell count, as well as possible complications. The researchers suggested that femtosecond laser-assisted cataract surgery might hold an intrinsic advantage of less zonular weakening associated with capsulorhexis and lens fragmentation.

Pre- and Postoperative Dry Eye Treatment

Advanced laser systems, cutting-edge diagnostic technology and enhanced lens materials have dramatically improved the precision and safety of refractive surgical procedures during the last decade. Even so, our patients still regularly experience postoperative dryness and ocular surface inflammation. Fortunately, a handful of novel topical agents may help reduce these deleterious side effects and facilitate optimized visual outcomes.

A multi-university animal study showed that topical omega-3 fatty acid eye drops can improve corneal irregularity, reduce epithelial barrier disruption, and decrease inflammatory cytokines and oxidative stress markers on the ocular surface.[901/B0206]

Following topical administration of 0.2% omega-3 drops, 0.1% hyaluronic acid drops or mixture of both agents, corneal irregularity and fluorescein staining scores were measured at both five- and 10-day follow-up. Levels of interleukin (IL)-1beta, IL-17 and interferon gamma-induced protein (IP)-10 were measured

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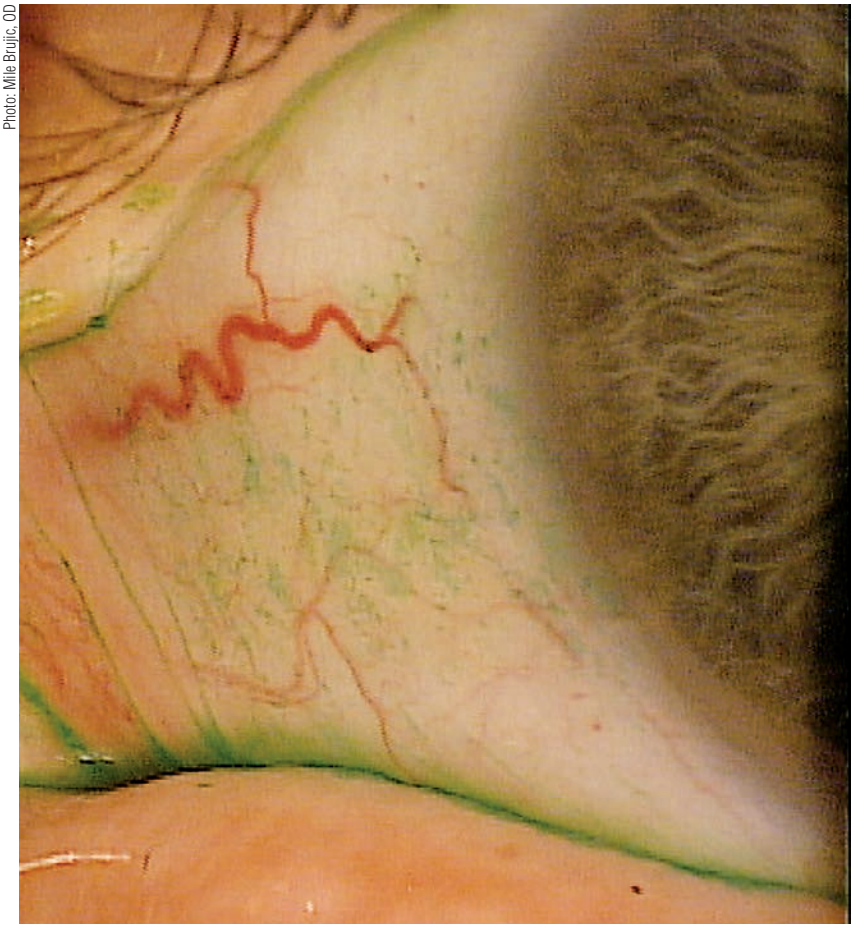

Photo: Mile Brujic, OD

Phase III study data indicated that, compared to placebo, Lifitegrast 5.0% (SARcode Biosciences) dramatically reduced the signs of conjunctival lissamine staining.

in the conjunctiva using a multiplexed immunobead-based assay at 10 days.

Mice treated with the combination 0.2% omega-3 and 0.1% hyaluronic acid mixture showed a significant improvement in corneal irregularity and fluorescein staining compared to mice treated with just 0.1% hyaluronic acid. Further, mice that received the mixture exhibited a significant decrease in IL-1beta, IL-17 and IP-10 levels, compared to the other two dosing groups. These results suggested that a combined mixture of 0.2% omega-3 fatty acid and 0.1% hyaluronic acid can be useful for preoperative treatment of dry eye and corneal irregularity.

A Finnish study analyzed the potential use of topical cis-urocanic acid (cis-UCA) in a murine model of dry eye in mice.[902/B0207] Compared to the both the vehicle and Restasis (cyclosporine, Allergan) treatment groups, the researchers found that 1.0% cis-UCA was most effective in reducing corneal fluorescein staining. Interestingly, mice treated with Restasis showed no statistical separation throughout the experiment, and did not exhibit a significant reduction in corneal staining at day 17 of treatment. They concluded that topical treatment with 1.0% cis-UCA significantly reduced corneal staining in a preclinical model of dry eye disease.

A murine study conducted at the Brien Holden Vision Institute indicated that topical application of L-carnitine could limit the progression and severity dry eye.[921/B0226] Eye drops containing L-carnitine have been shown to produce rapid and consistent improvements in the signs and symptoms of dry eye disease. The researchers reported that L-carnitine could help maintain human corneal epithelial cell volume under hyperosmotic stress, as well as ameliorate aspects of hyperosmotic stress-induced apoptosis.

A Japanese study evaluated the anti-inflammatory effects of rebamipide in human corneal epithelial cells.[911/B0216] Dry eye causes tear hyperosmolality, which stimulates an inflammatory cascade and disrupts corneal barrier function. Rebamipide—which exhibits mucin secretagogue activity—is used regularly as a dry eye treatment in Japan.

The researchers documented the effects of rebamipide on barrier function and cytokine expression in a human corneal epithelial cell line. They found that, in conjunction with its mucin secretagogue activity, rebamipide effectively treats dry eye via up-regulation of barrier function and anti-inflammatory effects.

In a separate study, researchers analyzed the clinical effect of rebamipide on post-LASIK dry eye.[945/B0250] This prospective study evaluated 32 eyes of 16 patients with LASIK-associated dry eye who currently used artificial tears or hyaluronic acid eye drops. In addition to their current topical therapy, the subjects received 2.0% rebamipide eye drops QID for four weeks.

For allergic conjunctivitis[1]

THE POWER TO CALM THE ITCH

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INDICATION AND USAGE

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

IMPORTANT RISK INFORMATION

BEPREVE® is contraindicated in patients with a history of hypersensitivity reactions to bepotastine or any of the other ingredients. BEPREVE® is for topical ophthalmic use only. To minimize risk of contamination, do not touch the dropper tip to any surface. Keep the bottle closed when not in use. BEPREVE® should not be used to treat contact lens–related irritation. Remove contact lenses prior to instillation of BEPREVE®.

The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions occurring in 2%-5% of patients were eye irritation, headache, and nasopharyngitis.

Made by the trusted eye-care specialists at BAUSCH+LOMB

Please see the accompanying prescribing information for BEPREVE® on the following page.

Reference: 1. BEPREVE [package insert]. Irvine, CA: ISTA Pharmaceuticals, Inc; 2012.

BAUSCH+LOMB

For product-related questions and concerns, call **1-800-323-0000** or visit **www.bepreve.com**.

BEPREVE®
(bepotastine besilate ophthalmic solution) 1.5%

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% safely and effectively. See full prescribing information for BEPREVE®.

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5%
Initial U.S. Approval: 2009

----------RECENT MAJOR CHANGES----------
Contraindications (4) 06/2012

----------INDICATIONS AND USAGE----------
BEPREVE® is a histamine H1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis. (1)

----------DOSAGE AND ADMINISTRATION----------
Instill one drop into the affected eye(s) twice a day (BID). (2)

----------DOSAGE FORMS AND STRENGTHS--------
Solution containing bepotastine besilate, 1.5%. (3)

----------CONTRAINDICATIONS----------
Hypersensitivity to any component of this product. (4)

----------WARNINGS AND PRECAUTIONS----------
- To minimize the risk of contamination, do not touch dropper tip to any surface. Keep bottle tightly closed when not in use. (5.1)
- BEPREVE should not be used to treat contact lens-related irritation. (5.2)
- Remove contact lenses prior to instillation of BEPREVE. (5.2)

----------ADVERSE REACTIONS----------
The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions which occurred in 2-5% of subjects were eye irritation, headache, and nasopharyngitis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated. at 1-800-323-0000, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION

Revised: 10/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

2 DOSAGE AND ADMINISTRATION
Instill one drop of BEPREVE into the affected eye(s) twice a day (BID).

3 DOSAGE FORMS AND STRENGTHS
Topical ophthalmic solution containing bepotastine besilate 1.5%.

4 CONTRAINDICATIONS
Bepreve is contraindicated in patients with a history of hypersensitivity reactions to bepotastine or any of the other ingredients *[see Adverse Reactions (6.2)]*.

5 WARNINGS AND PRECAUTIONS
5.1 Contamination of Tip and Solution
To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

5.2 Contact Lens Use
Patients should be advised not to wear a contact lens if their eye is red. BEPREVE should not be used to treat contact lens-related irritation.

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

5.3 Topical Ophthalmic Use Only
BEPREVE is for topical ophthalmic use only.

6 ADVERSE REACTIONS
6.1 Clinical Trials 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 common reported adverse reaction occurring in approximately 25% of subjects was a mild taste following instillation. Other adverse reactions occurring in 2-5% of subjects were eye irritation, headache, and nasopharyngitis.

6.2 Post Marketing Experience
Hypersensitivity reactions have been reported rarely during the post-marketing use of BEPREVE. Because these reactions are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequency or establish a casual relationship to drug exposure. The hypersensitivity reactions include itching, body rash, and swelling of lips, tongue and/or throat.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C: Teratogenicity studies have been performed in animals. Bepotastine besilate was not found to be teratogenic in rats during organogenesis and fetal development at oral doses up to 200 mg/kg/day (representing a systemic concentration approximately 3,300 times that anticipated for topical ocular use in humans), but did show some potential for causing skeletal abnormalities at 1,000 mg/kg/day. There were no teratogenic effects seen in rabbits at oral doses up to 500 mg/kg/day given during organogenesis and fetal development (>13,000 times the dose in humans on a mg/kg basis). Evidence of infertility was seen in rats given oral bepotastine besilate 1,000 mg/kg/day; however, no evidence of infertility was observed in rats given 200 mg/kg/day (approximately 3,300 times the topical ocular use in humans). The concentration of radio-labeled bepotastine besilate was similar in fetal liver and maternal blood plasma following a single 3 mg/kg oral dose. The concentration in other fetal tissues was one-third to one-tenth the concentration in maternal blood plasma.

An increase in stillborns and decreased growth and development were observed in pups born from rats given oral doses of 1,000 mg/kg/day during perinatal and lactation periods. There were no observed effects in rats treated with 100 mg/kg/day.

There are no adequate and well-controlled studies of bepotastine besilate in pregnant women. Because animal reproduction studies are not always predictive of human response, BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

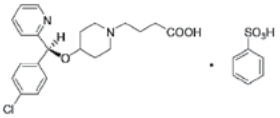
8.3 Nursing Mothers
Following a single 3 mg/kg oral dose of radiolabeled bepotastine besilate to nursing rats 11 days after delivery, the maximum concentration of radioactivity in milk was 0.40 mcg-eq/mL 1 hour after administration; at 48 hours after administration the concentration was below detection limits. The milk concentration was higher than the maternal blood plasma concentration at each time of measurement.

It is not known if bepotastine besilate is excreted in human milk. Caution should be exercised when BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is administered to a nursing woman.

8.4 Pediatric Use
Safety and efficacy of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% have not been established in pediatric patients under 2 years of age. Efficacy in pediatric patients under 10 years of age was extrapolated from clinical trials conducted in pediatric patients greater than 10 years of age and from adults.

8.5 Geriatric Use
No overall difference in safety or effectiveness has been observed between elderly and younger patients.

11 DESCRIPTION
BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is a sterile, topically administered drug for ophthalmic use. Each mL of BEPREVE contains 15 mg bepotastine besilate.
Bepotastine besilate is designated chemically as (+) -4-[[(S)-p-chloro-alpha -2-pyridylbenzyl]oxy]-1-piperidine butyric acid monobenzenesulfonate.
The chemical structure for bepotastine besilate is:



Bepotastine besilate is a white or pale yellowish crystalline powder. The molecular weight of bepotastine besilate is 547.06 daltons. BEPREVE® ophthalmic solution is supplied as a sterile, aqueous 1.5% solution, with a pH of 6.8.
The osmolality of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is approximately 290 mOsm/kg.
Each mL of BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% contains:
Active: Bepotastine besilate 15 mg (equivalent to 10.7 mg bepotastine)
Preservative: benzalkonium chloride 0.005%
Inactives: monobasic sodium phosphate dihydrate, sodium chloride, sodium hydroxide to adjust pH, and water for injection, USP.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Bepotastine is a topically active, direct H_1-receptor antagonist and an inhibitor of the release of histamine from mast cells.

12.3 Pharmacokinetics
Absorption: The extent of systemic exposure to bepotastine following topical ophthalmic administration of bepotastine besilate 1% and 1.5% ophthalmic solutions was evaluated in 12 healthy adults. Following one drop of 1% or 1.5% bepotastine besilate ophthalmic solution to both eyes four times daily (QID) for seven days, bepotastine plasma concentrations peaked at approximately one to two hours post-instillation. Maximum plasma concentration for the 1% and 1.5% strengths were 5.1 ± 2.5 ng/mL and 7.3 ± 1.9 ng/mL, respectively. Plasma concentration at 24 hours post-instillation were below the quantifiable limit (2 ng/mL) in 11/12 subjects in the two dose groups.

Distribution: The extent of protein binding of bepotastine is approximately 55% and independent of bepotastine concentration.

Metabolism: *In vitro* metabolism studies with human liver microsomes demonstrated that bepotastine is minimally metabolized by CYP450 isozymes.

In vitro studies demonstrated that bepotastine besilate does not inhibit the metabolism of various cytochrome P450 substrate via inhibition of CYP3A4, CYP2C9, and CYP2C19. The effect of bepotastine besilate on the metabolism of substrates of CYP1A2, CYP2C8, CYP2D6 was not studied. Bepotastine besilate has a low potential for drug interaction via inhibition of CYP3A4, CYP2C9, and CYP2C19.

Excretion: The main route of elimination of bepotastine besilate is urinary excretion (with approximately 75-90% excreted unchanged in urine).

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility
Long-term dietary studies in mice and rats were conducted to evaluate the carcinogenic potential of bepotastine besilate. Bepotastine besilate did not significantly induce neoplasms in mice receiving a nominal dose of up to 200 mg/kg/day for 21 months or rats receiving a nominal dose of up to 97 mg/kg/day for 24 months. These dose levels represent systemic exposures approximating 350 and 200 times that achieved with human topical ocular use. The no observable adverse effect levels for bepotastine besilate based on nominal dose levels in carcinogenicity tests were 18.7 to 19.9 mg/kg/day in mice and 9.6 to 9.8 mg/kg/day in rats (representing exposure margins of approximately 60 and 20 times the systemic exposure anticipated for topical ocular use in humans).

There was no evidence of genotoxicity in the Ames test, in CHO cells (chromosome aberrations), in mouse hepatocytes (unscheduled DNA synthesis), or in the mouse micronucleus test.

When oral bepotastine was administered to male and female rats at doses up to 1,000 mg/kg/day, there was a slight reduction in fertility index and surviving fetuses. Infertility was not seen in rats given 200 mg/kg/day oral bepotastine besilate (approximately 3,300 times the systemic concentration anticipated for topical ocular use in humans).

14 CLINICAL STUDIES
Clinical efficacy was evaluated in 2 conjunctival allergen challenge (CAC) studies (237 patients). BEPREVE (bepotastine besilate ophthalmic solution) 1.5% was more effective than its vehicle for relieving ocular itching induced by an ocular allergen challenge, both at a CAC 15 minutes post-dosing and a CAC 8 hours post dosing of BEPREVE.

The safety of BEPREVE was evaluated in a randomized clinical study of 861 subjects over a period of 6 weeks.

16 HOW SUPPLIED/STORAGE AND HANDLING
BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is supplied in a white low density polyethylene plastic squeeze bottle with a white controlled dropper tip and a white polypropylene cap in the following size:
5 mL (NDC 24208-629-02)
10 mL (NDC 24208-629-01)

STORAGE
Store at 15° – 25°C (59° – 77°F).

17 PATIENT COUNSELING INFORMATION
17.1 Topical Ophthalmic Use Only
For topical ophthalmic administration only.

17.2 Sterility of Dropper Tip
Patients should be advised to not touch dropper tip to any surface, as this may contaminate the contents.

17.3 Concomitant Use of Contact Lenses
Patients should be advised not to wear a contact lens if their eye is red. Patients should be advised that BEPREVE should not be used to treat contact lens-related irritation.

Patients should also be advised to remove contact lenses prior to instillation of BEPREVE. The preservative in BEPREVE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of BEPREVE.

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Tampa, FL 33637
Under license from:
Senju Pharmaceutical Co., Ltd.
Osaka, Japan 541-0046

Tear secretion was examined via Schirmer testing with anesthesia both before rebamipide treatment and at four-week follow-up. Additionally, the researchers measured tear film break-up time, fluorescein staining and lissamine green staining before treatment and at both one- and four-week follow-up.

The researchers determined that the addition of 2.0% rebamipide improved ocular surface function and dry eye symptoms. More specifically, they noted that increased mucin secretion in the tear film effectively improved LASIK-associated dry eye following rebamipide use.

A recently completed Phase III FDA study was presented on a new agent for dry eye disease—Lifitegrast 5.0% ophthalmic solution (SARcode Biosciences).[2669/309] This may be the closest-to-market dry eye formulation that we've seen in years, and could hold major promise for the management of both pre- and postoperative ocular surface disease.

Lifitegrast is an investigational drug that targets integrin lymphocyte antigen-1 (LFA-1) and inhibits binding to intracellular adhesion molecule-1. LFA-1/ICAM-1 interactions are essential to the regulation of T-cell-mediated inflammation.

The study evaluated 588 dry eye patients over 84 days, measuring corneal staining and ocular symptoms. Compared to placebo, Lifitegrast ophthalmic solution demonstrated a superior ability to reduce corneal fluorescein and conjunctival lissamine staining—both key clinical parameters of ocular surface disease. Further, reductions in staining were associated with significant improvements in key symptoms. The researchers determined that Lifitegrast appears safe and well-tolerated when administered BID for at least 84 days.

Enhanced Postoperative Healing

Medical treatment following refractive surgery often involves the use of several medications. Many of the most commonly used drugs are preserved with benzalkonium chloride (BAK)—which is known to impair the integrity of tear film lipid layer and the corneal epithelial membranes.

One study showed that hyaluronic acid was able to efficiently suppress the adverse effects of BAK on the meibomian and corneal lipid films.[944/B0249] The researchers were able to demonstrate this by instilling pure BAK into the lipid films. The interaction yielded impaired lipid film spreading, increased surface pressure-area hysteresis and partial lipid displacement from the ocular surface.

The inclusion of hyaluronic acid in the lipid film's subphase minimized these adverse effects. Once a concentration ≥ 0.1% of hyaluronic acid was added, normal lipid film properties were maintained for the entire BAK concentration range. This could have immediate consequences for current patient care, and likely will lead to new formulations of eye drops intended for postoperative care.

Meanwhile, a French study evaluated the effects of hyperosmolar conditions and increased BAK toxicity on corneal wound healing efficacy.[6041/A0104] Cytotoxicity, cell migration and proliferation were analyzed after a 30-minute exposure to 0.02% BAK in a normal osmolarity state (275mOsm/L), 0.02% BAK in three different hyperosmolar states (356mOsm/L, 406mOsm/L and 505mOsm/L) or phosphate-buffered saline. The researchers noted that BAK-induced hyperosmolarity and/or BAK toxicity impairs the corneal healing process and exacerbates dry eye conditions.

During the last several years, there has been industry-wide interest in the formulation of topical postoperative medications that exhibited reduced dosing intervals and limited side effect profiles. In a Phase III FDA trial, researchers evaluated the anti-inflammatory effects of a low-concentration formula of bromfenac in cataract surgery patients.[125/C0130]

Subjects underwent unilateral cataract surgery (phacoemulsification or extracapsular cataract extraction) with posterior chamber IOL implantation and were randomized to receive either the low-concentration bromfenac ophthalmic solution or placebo once daily.

Dosing began one day before cataract surgery and was continued postoperatively for 14 days. At day three, 27.9% of subjects in the bromfenac group achieved trace ocular inflammation vs. just 13.8% in the placebo group. By day 15, 71.2% of patients on bromfenac therapy exhibited trace inflammation vs. 39.4% of patients in the placebo group.

The researchers also determined that, when compared to placebo, QD low-concentration bromfenac ophthalmic solution yielded a lower overall incidence of ocular adverse events in postoperative cataract surgery patients. (*Note: Since the initial submission of this study to ARVO, this specific formulation of bromfenac has been FDA approved as Prolensa [bromfenac ophthalmic solution 0.07%, Bausch + Lomb]*). ■

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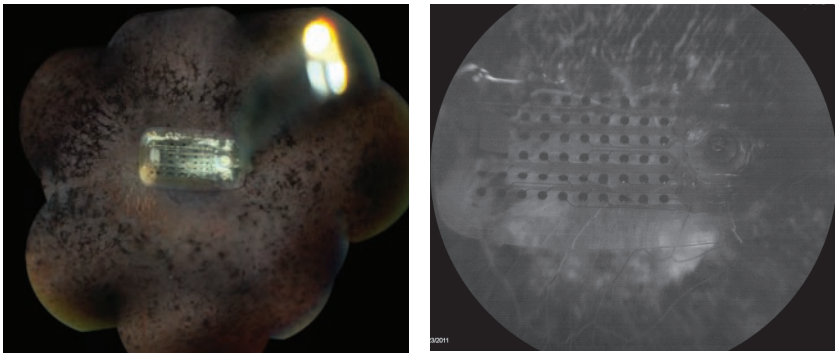
Retina

It's an exciting time in the retina field. Researchers at ARVO 2013 reported on newly identified genetic factors in AMD and novel treatments for the disease, as well as FDA approval of a retinal prosthesis for RP and a new anti-VEGF agent for wet AMD.

By Steven Ferrucci, OD, Editorial Review Board Member

If your interests lie in macular and vitreoretinal disease, then this year's ARVO meeting surely did not disappoint. For the first time, a full-day retina subspecialty symposium was held just before ARVO—giving retinal specialists and general eye care practitioners an additional opportunity to hear about the latest and greatest in retina from a roster of world-renowned experts.

It was the perfect way to gear up for the many sessions at ARVO that reviewed the constantly evolving landscape of treatments and imaging technology and introduced new avenues of retinal research. Attendees were eager to hear the long-awaited results of the Age-Related Eye Disease Study 2 (*See "The Latest on AREDS2 at ARVO 2013," page 68).* Other hot topics this year included the role of Eylea in age-related macular degeneration (AMD), the genetics of AMD and several novel treatment approaches to AMD. Presentations also highlighted a new retinal prosthesis that may offer help to patients with retinitis pigmentosa (RP), as well as new ways to treat macula edema.



The Argus II Implant (left) attaches to the retinal surface with a tack. The cable that both powers the chip and conducts the image signal from the episcleral housing is seen temporally. An early frame of a fluorescein angiogram (right) in a patient with the Argus II Implant demonstrates some persistent macular perfusion. Images: Elaine Leibenbaum, Julia Haller, MD, and Carl Regillo, MD.

Retinal Prosthesis

It was a milestone moment for retinal technology in February when the FDA approved the first implanted device to treat adults with advanced RP. The Argus II Electronic Retinal Prosthesis System (Second Sight Medical Products)—which has been cleared in Europe since 2011—should be commercially available in the US later this year. For now, it's been granted "humanitarian use," an approval pathway limited to devices that treat or diagnose fewer than 4,000 people in the US each year.

A few studies evaluated this prosthesis, hopefully paving the way for its more widespread use. One study looked at the safety profile

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of 16 patients in Europe who had received the implant.[1040/C0017] The patients were followed on average for 6.2 months, and reported no surgical or serious, device-related adverse effects. Ten patients experienced no surgery or device-related adverse events at all, whereas the other six reported minor adverse effects, such as IOP elevation, nausea, fainting, conjunctival irritation and a retinal tear.

A second study found that the Argus II implant has good long-term reliability, with only one failure in 30 subjects (each with an average of 4.2 years of use, representing more than 125 cumulative patient years).[1037/C0014] Further, accelerated lifetime testing demonstrated that finished implants have more than a 10-year lifetime in accelerated testing. Another study confirmed these results, echoing previous tests that demonstrated the ability of the prosthesis to provide visual function over several years.[349]

Diabetic Retinopathy

Researchers evaluated 759 patients from the RISE/RIDE Phase III trials to see if Lucentis (intravitreal ranibizumab, Genentech) had an effect on the severity of a patient's diabetic retinopathy.[4028] Results showed that a greater proportion of patients in the ranibizumab arm had a two- or three-step regression of diabetic retinopathy on the ETDRS scale vs. those in the sham group. A three-step improvement was achieved at 36 months in 3.3% of the sham group, compared to 15.0% and 13.2% in the 0.3mg and 0.5mg treated eyes, respectively. Over the course of 36 months, 33.9% of the sham-treated eyes developed proliferative diabetic retinopathy, as opposed to only 12.8% and 15.1% of the ranibizumab-treated eyes.

Another study evaluated the safety and efficacy of Macugen (intravitreal pegaptanib, OSI Pharmaceuticals Inc.) combined with panretinal photocoagulation (PRP) vs. PRP alone in the regression of retinal neovascularization in eyes with high-risk proliferative disease.[2439/C0140] At six months, the combination of pegaptanib with PRP showed better preservation of best-corrected vision, greater decrease in retinal thickness and maintained visual field better than PRP alone, but showed no major difference in neovascular regression.

A second study of 30 patients compared combination therapy of ranibizumab with PRP vs. PRP alone in treatment-naïve proliferative diabetic retinopathy (PDR).[5761/D0008] This study uncovered a greater change in best-corrected vision, a larger decrease in central retinal thickness and a lower incidence of vitreous hemorrhage in the combination treated group—again suggesting that anti-VEGF agents in conjunction with PRP may be preferred to PRP alone.

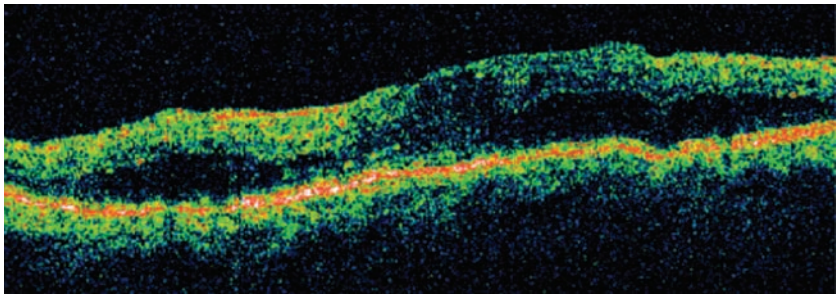
Additionally, a retrospective study of 78 patients seemed to indicate that metformin may reduce the rate of PDR in type 2 diabetes patients.[2249/C0150] In the non-metformin group, 15 patients (45.5%) developed PDR as compared to just 12 patients (27.3%) in the metformin-treated group, indicating a trend of less PDR in the metformin-treated group. A larger study is recommended.

Macular Edema

Several studies are investigating alternative approaches to treat macular edema—either secondary to diabetes or vein occlusion. The MOZART study evaluated the safety and efficacy of an intravitreal dexamethasone implant (Ozurdex, Allergan) in 59 patients with visual impairment from diabetic macula edema (DME).[2387/C0088] Investigators noted that, over the six months, central retinal thickness was reduced and acuity improved—28% of patients had 20/40 or better acuity vs. just 6% at baseline. They observed IOP greater than 25mm in 7% of patients, with 4% of patients developing cataracts. No endophthalmitis was reported.

A second study showed positive results using a different intravitreal dexamethasone implant injection (DEX-I), with a gain of more than 10 letters in 27% of cases at two months and 24% at four months.[2382/C0084] However, this study showed that recurrence of edema was observed in 76% of cases at four months, leading to re-treatment in more than one-third of cases.

Another study evaluated Ozurdex in patients with macular



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edema from vein occlusions. Forty eyes were treated with Ozurdex and were followed for six to 24 months.[254-D0099] Overall, 94% showed initial regression on OCT, lasting an average of 4.2 months, with two lines of improvement. Overall, 59% improved 14.2 letters on average, while 10% worsened and 31% remained the same. Approximately 19% had elevated IOP and were treated with drops. In eyes that were not previously treated, the results were even better—86% showed improvement. Half of the patients required retreatment, with an average of 1.6 treatments per year. The results seem to indicate that Ozurdex may be an effective treatment in such patients—even those who did not respond well to anti-VEGF agents.

Other research looked at the role of laser, as well as anti-VEGF in combination with laser, in the treatment of macular edema. The LLOMD study evaluated 15 eyes of 13 patients with reduced visual acuity secondary to diabetic macular edema who had a mean VA of 20/100.[2396/C0097] At six months, the mean VA gain was 12.6 ETDRS letters, with the central retinal thickness decreasing an average of 76.7µm in patients who received laser in combination with ranibizumab. Additionally, 37.5% of patients required a second injection at six months. However, with the addition of laser, the study showed that the number of injections needed over the first year was greatly reduced compared to previous studies of injections alone. In total, the researchers determined that approximately 10 injections are needed during the first year. Further, they concluded that adding macula grid laser to ranibizumab injection may reduce the economic burden of treatment.

The Latest on AREDS2 at ARVO 2013

The Age-Related Eye Disease Study 2 (AREDS2) Research Team presented the results of the multi-center randomized, controlled clinical trial of oral supplementation with lutein/zeaxanthin (10mg/2mg) and/or omega-3 long-chain polyunsaturated fatty acids (1,000mg) for the treatment of AMD and cataract at the ARVO meeting.

Conducted at 82 clinical sites across the US from 2006 to 2012, the trial included 4,203 participants, ages 50 to 85. The AREDS2 subjects consented to either take the original AREDS formulation or a randomly assigned variation of the AREDS formulation.

The main outcome measurement was progression to advanced AMD, neovascular or central geographic atrophy. Progression to cataract surgery and progression of lens opacity was a secondary outcome.The addition of lutein and zeaxanthin, DHA and EPA, or both to the AREDS formulation in primary analysis did not further reduce the risk of progression to advanced AMD. However, because of increased incidence of lung cancer in former smokers, lutein with zeaxanthin may be an appropriate carotenoid substitute of beta-carotene in the original AREDS formulation.

The comparison of low-dose vs. high-dose zinc showed no evidence of a statistically significant effect, so a clinical recommendation cannot be reached. Lastly, daily supplementation with lutein/zeaxanthin had no statistically significant overall effect on rates of cataract surgery or vision loss. It will take some time to digest these results and see how they should be implemented in practice.

Two additional studies revealed that reduced-energy focal macular photocoagulation could have advantages over traditional focal macular laser. [2375/C0076,2416/C0117] Both seemed to indicate that, by reducing the laser exposure when performing the procedure, there were decreases in CRT and increases in vision—with potentially less collateral damage and inflammation to surrounding viable tissue. More research is needed to investigate whether reduced-energy focal macular photocoagulation could replace more traditional laser therapy as the standard.

Eye on Eylea

Several reports evaluated Eylea (aflibercept, Regeneron Pharmaceuticals), the latest FDA-approved anti-VEGF agent for the treatment of wet AMD. A number of these looked at the role of Eylea in patients whose choroidal neovascularization did not respond to other agents, namely Lucentis (ranibizumab, Genentech) and Avastin (bevacizumab, Genentech/Roche).

One study evaluated 41 eyes of 34 such patients—77% of these patients had a good response to Eylea after one month, demonstrating decrease in central retinal thickness and absorption of subretinal fluid.[4176/A0094] Best-corrected visual acuity improved in these patients to 20/74, from 20/122.5 at baseline.

A second study evaluated 60 eyes of 52 patients that did not respond after five consecutive injections of the other agents.[3806/B0116] After three Eylea injections, 28 eyes (46.7%) displayed improved acuity, while 18 eyes (30%) showed decreased acuity, and 14 (23.3%) had no change in acuity at three months.

Lastly, a study evaluated 19 eyes of 17 patients receiving Eylea as primary therapy, with dosing as needed.[3817/B0127] Over a 20-week period, patients received on average 1.84 injections, with an interval between injections of approximately 11 weeks. Five of these patients were determined to be non-responders to other

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anti-VEGF agents. Of these five, four responded positively to Eylea, indicating again that Eylea may be an effective alternative for patients who do not respond to other agents. Also, this study seems to indicate that the interval to repeat injections may be longer with Eylea than the other agents.

However, a separate study looked at the costs associated with Eylea.[3838/B0148] The researchers hypothesized that, despite fewer injections, the cost of treatment per patient would actually increase. The study reviewed the records of 30 patients treated for wet AMD from 2011 to 2012 at the Cincinnati Eye Institute. The average duration between Avastin or Lucentis injections was 29 days, as opposed to 34 days with Eylea injections. No complications were noted in any groups. Total cost over the six months was $3,700 for Avastin, $96,000 for Lucentis and $366,300 for Eylea. This study suggests that while Eylea may reduce the frequency of injections, office visits and possibly complications, it appears to add considerable health care costs per patient.

While Eylea may reduce the frequency of injections, office visits and possibly complications, it appears to add considerable health care costs per patient.

New AMD Treatments

Several studies evaluated novel treatments for AMD. One study investigated the safety and feasibility of an episcleral brachytherapy device (SMD-1) for wet AMD.[3787/B0097] Six patients received radiation for five and a half minutes to the macular CNV using a brachytherapy probe adjacent to the macular sclera via a subtenon retrobulbar approach. Patients also received concomitant anti-VEGF injections, as needed. The procedure was readily performed and well tolerated, with no adverse effects. At three months, all patients experienced improved best-corrected vision, with a mean gain of 19 ETDRS letters. At 12 months, three patients continued to demonstrate improved vision of seven letters on average, and two of those patients did not require any additional injections. All patients had reduced macular thickness compared to baseline, but two patients did demonstrate a reduction in vision.

Another study evaluated the safety of 1% CLT-005 topical eye drops, designed to inhibit Stat3, which has been associated with neovascular and inflammatory processes in animal studies.[1716] The researchers determined that the drug was able to deliver the active ingredient to the RPE/choroid in animal eyes, without adverse effects—paving the way for additional studies regarding its role in the treatment of AMD or geographic atrophy (GA).

Australian researchers looked at the progression of early AMD after treatment with nanosecond pulse laser compared to patients with a natural history of AMD.[4146/A0064] They treated 48 patients with bilateral high-risk AMD with ultra-low energy laser in 12 spots around the macula of one eye. At 12 months, three of the 48 treated participants progressed to GA, while seven of the 70 control group progressed. At 24 months, four in the treated group and nine in the control groups progressed to GA, suggesting that a single course of nanosecond laser intervention may potentially reduce the odds of progression to advanced AMD. A larger randomized controlled study is now underway.

Another study evaluated the safety and tolerability of an extrafoveal subretinal injection called rAAV.sFlt-1, an anti-VEGF gene therapy for AMD, in elderly patients.[4504] Twelve patients underwent the procedure with minor adverse effects and no evidence of local or systemic toxicity. The researchers noted that this injection should be further evaluated as a potential strategy for long-term anti-VEGF therapy.

Research continues on Emixustat HCL, a novel orally administered agent in development for the treatment of GA associated with dry AMD.[4506] Emixustat HCL is a rod visual cycle modulator that inhibits isomerase activity and reduces retinal toxins, such as A2E, which damages the RPE and overlying photoreceptors. Four dose levels and two dose regimens were examined in 72 patients who were followed for 90 days. No adverse systemic effects of concern were noted, with just two patients experiencing treatment-related events. All ocular adverse effects resolved upon drug cessation, and were mild with no severe events observed. Results were encouraging, and a long-term Phase II study in now underway to evaluate its role in GA patients.

Other studies looked at using existing therapy more effectively. A team of researchers in Italy evaluated whether ketorolac eye drops combined with ranibizumab intravitreal injections would provide additional efficacy over ranibizumab alone in wet AMD. [4175/A0093] Sixty eyes were divided into

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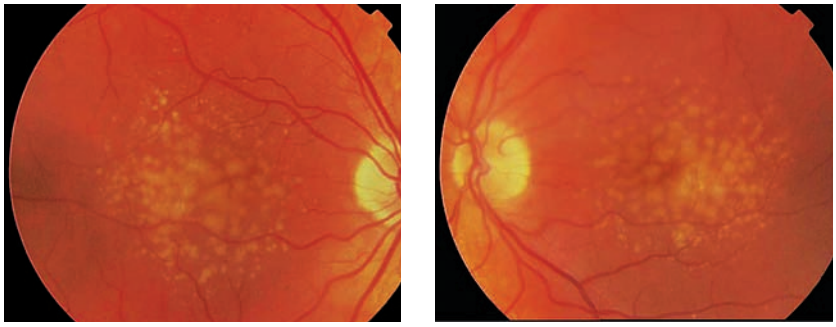
two groups: one received ranibizumab alone, and one was treated with ranibizumab plus ketorolac BID for six months. At the end of six months, there was no statistically significant difference in best-corrected vision or number of injections required. However, the mean six-month change in central macular thickness was 146.53µm in the combination group, while the change was 106.88µm in the ranibizumab-only group. This is the first study to identify an additional effect of ketorolac eye drops combined with ranibizumab. More studies would be needed before a change in current protocol would be appropriate.

Two separate studies evaluated photodynamic therapy in combination with anti-VEGF injections.[4509,3790/B0100] Both indicated that this therapeutic combination might be an effective way of improving acuity in patients with wet AMD, while perhaps reducing the overall number of treatments needed. In one of the studies, 96.2% of eyes lost fewer than 15 letters, and 27.3% gained 15 or more letters.

Genetics in AMD

Genetics in eye care have been garnering a lot of attention lately, specifically the role of genetics in AMD.

One study evaluated data from the 100 Genomes Project to confirm the contribution of known genetic risk factors for AMD.[6166/C0051] This investigation revealed that, in the population of European descent, CFH has the largest attributable risk (25.6%), followed by ARMS 2 (22.5%), then C3 (9.1%) and CST3 (5.8%). In other populations, the risk allele in ARMS2 is the major contributor to risk, followed by CFH. In Asian and African populations, CST3 takes precedent over C3 as the third strongest contributor to AMD risk.



This patient is at high risk for AMD due to multiple confluent drusen in both eyes. Perhaps genetic testing could one day identify patients like this earlier.

In Spanish patients, a study found that CFH and CB genes, combined with environmental risk factors such as smoking and body mass index, were associated with an increased risk of GA.[6183/C0068] A second abstract confirmed the role of CFH gene in AMD risk in a cohort of Brazilian AMD patients.[6175/C0060] In another study evaluating the genetic contribution of AMD in 38 Armenian patients, researchers found no genetic differences in the risk alleles compared to a Caucasian population.[6196/C0081] All of this research indicates the genetic factors that could influence the development or AMD may be very similar across different groups.

Interestingly, some of these same studies seem to suggest that the HDL-related CETP gene may be associated with AMD in African Americans, pointing to a potential risk modifier in lipid pathways.[6168/C0053]

An abstract submitted by Johanna Seddon, MD, ScM, identified three new genes that may add to the predictive power of risk models for progression to advanced AMD. [6178/C0063] They are the R1210c mutation in CFH, and variants to the genes COL8A1 and RAD51B. She suggested that these new genes will be useful for AMD surveillance in the future, along with genes that have already been identified and established factors such as drusen size, baseline AMD status, demographics and environmental factors (including smoking, age and body mass index).

Additional studies attempted to see if there was a link between genetic profile and response to treatment. One study evaluated the genetic profile of 835 patients from the CATT (Comparison of AMD Treatment Trial) trial to determine if certain genotypes responded better to treatment than others.[6187/C0072] Results revealed there were no strong associations between the studied genotypes and response to anti-VEGF treatment.

A second study evaluated the IVAN study and also was unable to find any associations between genetic profiles and response to anti-VEGF treatment.[6185/C0070] However, another study of 43 patients seemed to indicate that patients with high-risk alleles for AMD responded more poorly to treatments than those with low-risk alleles.[6186/C0071]

This link of genetic profiles to treatment response may continue to be investigated, as this could bring us closer to personalized treatment of AMD—based on genetic factors and other components. ■

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Case Report

Diagnosis and Management of Carotid Artery Disease

This patient with type 2 diabetes and hypertension presented with a twig retinal artery occlusion secondary to cholesterol emboli. How should he be managed?

By Richard J. Zimbalist, OD

A Hollenhorst plaque is a relatively common retinal finding in the geriatric population. Patients often are visually asymptomatic and present with retinal emboli from plaque ulceration in the internal carotid artery. Carotid duplex is a high-quality, first-line test that identifies the degree of lumen narrowing. Recommendations for medical therapy or surgical intervention are largely based on the amount of stenosis, and may be further guided by diagnostic imaging modalities.

Here, we review the case of a 62-year-old white male who presented with multiple Hollenhorst plaques, a twig retinal artery occlusion and hemodynamically significant internal carotid stenosis.

History

A 62-year-old white male presented to Harry S. Truman Memorial Veterans' Hospital optometry clinic in Columbia, Mo., for a routine diabetic eye exam on March 22, 2011. The patient's only complaint was visually distracting scratches on his glasses.

His systemic history was remarkable for lower back pain, hypertension, hypercholesterolemia and a 10-year history of type 2 diabetes mellitus. His current medications included 50mcg fluticasone nasal spray, 600mg gemfibrozil, 20mg glipizide, 12.5mg hydrochlorothiazide, 80mg lisinopril, 2,000mg metformin hcl, 1,000mg naproxen, 30mg pioglitazone and 30mg tramadol hcl.

At a routine check-up with his primary care physician one month earlier, his blood pressure measured 157/71mm Hg. His most recent hemoglobin A1C measurement was 6.8% from a previous primary care appointment in November of 2010.

At his last ocular evaluation one year earlier, the patient exhibited incipient cataracts, mild dermatochalasis, compound hyperopic astigmatism and an unremarkable dilated fundus examination. His family history was unremarkable for known ocular disorders.

Diagnostic Data

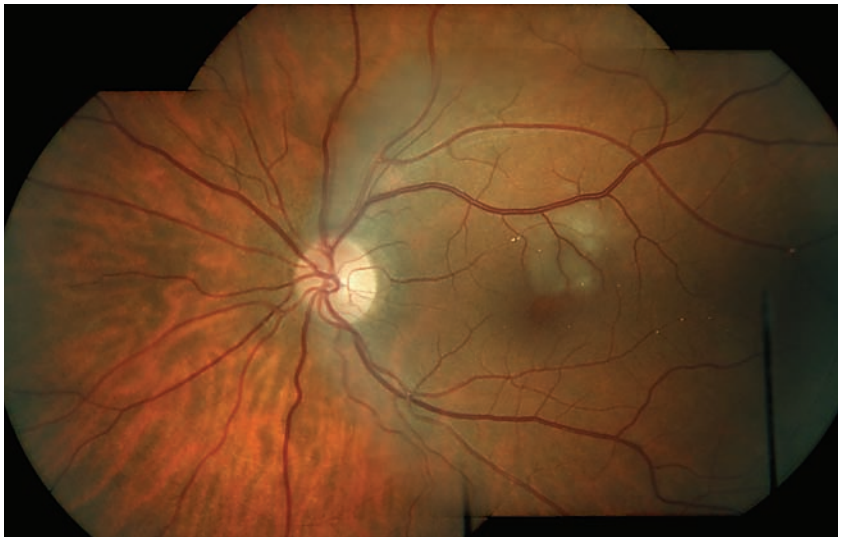
Best-corrected visual acuity was 20/20 OU. Extraocular motility was full and unrestricted in both eyes. Confrontation fields were unremarkable OD; however, we noted a small scotoma located inferior to fixation OS. The defect was repeatable on Amsler grid testing.

Pupils were equal, round and reactive to light, without evidence of afferent defect OU. Slit-lamp exam was remarkable for mild dermatochalasis. The anterior chamber was deep and quiet in both eyes. Intraocular pressure measured 17mm Hg OD and 15mm Hg OS. Dilated slit-lamp examination revealed trace nuclear sclerotic lenticular opacities in both eyes.

Funduscopy was performed with a 78D lens and showed a 0.15 x 0.15 cup-to-disc ratio, with healthy neuroretinal rim tissue in both eyes. The right fundus was unremarkable except for a resolving retinal microinfarct located along the superotemporal arcade.

The left eye exhibited 13 separate retinal emboli lodged in the superior and inferior temporal retinal arterioles (*figure 1*). Many of the retinal emboli were refractile and located at arterial bifurcations. We also documented a 1DD area of white, mildly edematous retina located superior to the fovea. There was no evidence of vitreal or retinal inflammation. The peripheral retina was flat and intact bilaterally. Carotid auscultation did not reveal a bruit on either internal carotid artery.

The patient was referred for a lipid panel, carotid duplex and vascular surgery consult, given the high suspicion for hemodynamically significant stenosis in the left internal carotid artery.



1. Color fundus photo montage of our patient's left eye at initial presentation on March 22, 2011. We noted multiple Hollenhorst plaques located throughout the temporal arcades. Further, we documented a twig retinal artery occlusion located superior to the fovea.

Differential Diagnoses

The differential diagnoses for retinal arterial emboli in this case included:

• ***Calcific emboli.*** Nonscintillating, white in appearance, and typically present in the central retinal artery due to their large size. Such entities may remain in the retinal vasculature permanently, because they do not dissolve. They are associated with heart valve or aorta calcification. Transesophageal echocardiogram is needed to confirm the diagnosis.

• ***Fibrinoplatelet emboli.*** Dull white in appearance and often present as long, smooth emboli simulating a plug in the retinal arteriole. They are most commonly associated with carotid thrombosis.

• ***Cholesterol emboli/Hollenhorst plaque.*** Highly refractile, crystal-like emboli that typically are seen at arteriole bifurcations. The emboli can be visually asymptomatic, because they often do not cause a significant obstruction of the retinal arteriole. Also known as Hollenhorst plaques, cholesterol emboli originate from atheromatous lesions in the ipsilateral carotid artery or aorta.

• ***Talc emboli.*** Associated with intravenous drug injection and free-base cocaine use. The talc particles are small and white, and frequently found parafoveally.

• ***Tumor cells.*** Commonly caused by metastatic lesions, these proliferative neoplastic cells may separate from the lesion and lodge in the retinal arterioles.

• ***Septic emboli.*** These deposits are associated with bacterial endocarditis.

• ***Fat emboli.*** An uncommon cause of emboli due to long bone fractures. They are associated with Purtcher's retinopathy. Concomitant scattered retinal microinfarcts and hemorrhages typically are associated with the condition.

Diagnosis

We diagnosed the patient with a twig retinal artery occlusion secondary to Hollenhorst plaques. On initial examination, the emboli appeared refractile and were located in multiple arterial bifurcations. Although multiple types of emboli can present in the retinal vasculature system, the findings were most consistent with atheromatous changes in the carotid artery. If carotid duplex results were non-contributory, additional testing would have been conducted.

Follow-up and Treatment

• ***Follow up #1.*** A local vascular surgeon evaluated the patient approximately three weeks after the initial visit. A carotid duplex was performed, which revealed no significant stenosis in the right carotid artery system. The left

internal carotid artery had a peak systolic velocity of 247cm/sec, an end diastolic velocity of 81cm/sec and greater than 70% stenosis. The surgeon recommended a carotid endarterectomy (CEA), to which the patient consented.

He underwent a CEA of the left internal carotid artery on April 21, 2011. The procedure was performed without perioperative complications. A repeat carotid duplex two weeks later revealed a clear and patent internal carotid artery. Carotid duplex imaging was recommended at one-year follow up.

• ***Follow up #2.*** The patient returned to the eye clinic on June 22, 2011 for bilateral dilation. Visual acuity remained 20/20 in each eye with spectacle correction. Once again, he denied experiencing any visual complaints. Further, he suggested that he felt better since undergoing the CEA.

All entrance testing and anterior segment findings were unchanged. Dilated fundus examination was unremarkable OD. The left fundus, however, exhibited a retinal microinfarct located along the superotemporal arcade as well as an isolated Hollenhorst plaque located nasal to the optic nerve head (*figure 2*). There was no evidence of plaques lodged in the temporal retinal arcades.

• ***Follow up #3.*** He returned on December 19, 2011 for bilateral dilation. Visual acuity was 20/20-2 OU with spectacle correction. The patient again denied visual complaints since undergoing the CEA eight months earlier.

All entrance testing and anterior segment findings remained unchanged from the initial exam. The fundus was unremarkable in both eyes. No hemorrhages, microinfarcts or emboli were detected in either eye.

Discussion

Ophthalmologist Robert W. Hollenhorst first described cholesterol emboli in the retinal arterioles in 1958.[1] A Hollenhorst plaque is an embolus formed from cholesterol deposition that typically originates from the ipsilateral carotid artery. They appear as refractile, crystal-like emboli and usually are lodged at arteriole bifurcations. Patients are largely asymptomatic due to plaque malleability as well as persistent vascular perfusion around the emboli.

Hollenhorst plaques often are discovered incidentally during funduscopy. Frequently, the plaques dislodge and are not noted on subsequent examinations.[2] Patients may experience amaurosis fugax if the plaque becomes lodged in a retinal arteriole for a transient period. Cases also can present with simultaneous evidence of a retinal artery occlusion and corresponding visual scotomas. Retinal artery occlusions occur if the embolus size is larger than the caliber of the vessel it enters—thereby preventing perfusion to a specific portion of the retina. Retinal ischemia results distal to the arteriole blockage.[2]

Many patients with cholesterol emboli are of geriatric age and have comorbid vascular conditions. The occurrence of Hollenhorst plaques and retinal artery occlusions has long concerned clinicians because of its potential neurologic involvement. A carotid duplex is the primary modality of carotid artery imaging, because it is a non-invasive procedure. Either CEA or carotid angioplasty and stenting (CAS) typically are performed in patients with hemodynamically significant stenosis.

• ***Pathophysiology.*** Atherosclerosis is a form of arteriosclerosis, during which the intimal layer of the vascular column in both medium and large arteries hardens secondary to progressive plaque formation.

Although the exact mechanism of atherosclerosis remains unknown, clinicians generally agree that hypertension, hyperlipidemia, diabetes and cigarette smoking are associated risk factors. Further, diets rich in cholesterol (particularly low-density lipoproteins) appear to alter the permeability of the arterial wall endothelium. Circulating monocytes are then able to adhere to the compromised surface, allowing the passage of lipoproteins through active transport.

Lipoproteins filter through the basement membrane and simultaneously draw the monocytes through the endothelial wall into the intimal layer. The monocyte converts into a macrophage and phagocytizes the lipoproteins to form a "foam cell." Foam cells accumulate in the tunica intima and create a roughened/irregular endothelial surface that facilitates platelet aggregation.

Biochemical signals for fibrous connective tissue are released by platelets, causing the adherence of material and formation of a fibrous cap and atheroma.[4] The fibrous cap prevents the necrotic center of an atheroma from leaking into the vessel lumen. If the cap ruptures, however, a thrombus can form. This process subsequently allows emboli to enter distal arterioles.

Plaque accumulation tends to occur at arterial bifurcations, where blood flow velocity, lumen size, and shearing stress are decreased. A similar anatomical construction is believed to facilitate Hollenhorst plaque deposition in the retina, given that the plaques

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Indication

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

Important Safety Information

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

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

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

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

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

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

Rescula®
(Unoprostone isopropyl
ophthalmic solution) 0.15%

Brief Summary of Prescribing Information for RESCULA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

For more detailed information please read the Prescribing Information.

Marketed by:

Sucampo Pharma Americas, LLC
Bethesda, MD 20814

Revised 01/2013

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

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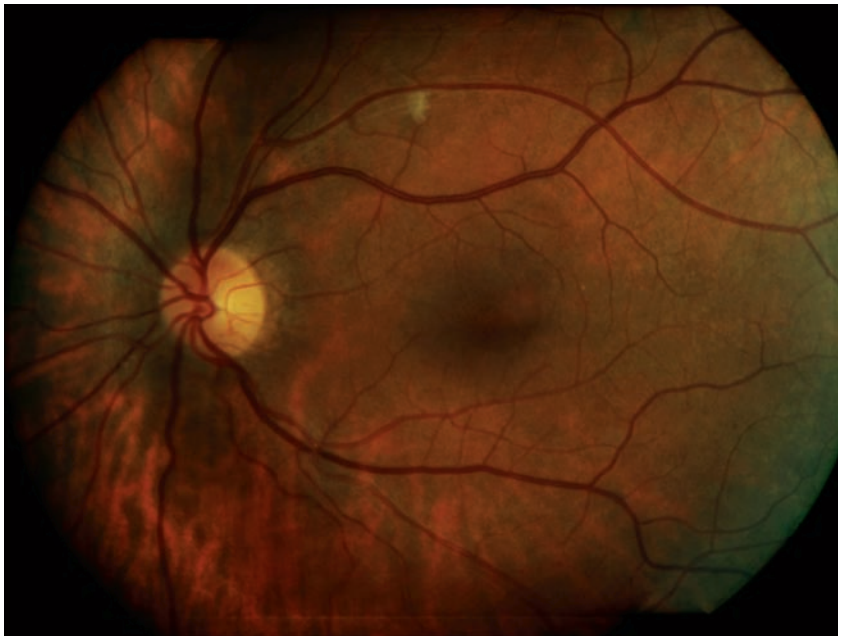
commonly are noted at retinal arterioles bifurcations.[5] To better understand how retinal emboli occur, knowledge of the extracranial arterial system is essential. The left common carotid stems from the subclavian artery, whereas the right common carotid artery arises directly from the aortic arch. The common carotid branches into the internal and external carotid arteries to perfuse separate regions in the brain.

The first branch of the internal carotid artery is the ophthalmic artery, which ultimately forms the central retinal and posterior ciliary arteries.[6] Occlusions secondary to emboli typically occur in the central retinal artery and its branches. Researchers have postulated that cholesterol plaques are seen in the retina due to their small size and decreased velocity while traveling through the internal carotid system.[7] Considering the small diameter of the ophthalmic artery, larger emboli with increased velocities simply may bypass the ophthalmic branch.

• ***Diagnostic testing.*** The presence of a Hollenhorst plaque on funduscopy typically merits further evaluation to rule out underlying systemic vascular disease. Minimal baseline work-up for ophthalmic providers consists of a lipid panel, carotid auscultation and carotid duplex. Transesophageal echocardiography and computed tomographic angiography (CTA) also may be necessary for further evaluation, particularly if the initial work-up is negative or the findings are atypical.

A carotid duplex is a noninvasive imaging technique that uses both B-scan ultrasonagraphy and doppler ultrasonography to evaluate the common, internal and external carotid arteries. Duplex imaging rapidly alternates between the two methods, providing the technician with an accurate determination of blood flow velocity and arterial plaque formation.[9] Although the procedure is heavily dependent on the technician, duplex imaging is highly accurate when compared to the gold standard of arteriography.[10]



2. Color fundus photo montage of the left eye at follow up #1 on June 22, 2011. Note the isolated microinfarct located along the superior temporal arcade as well as the resolved Hollenhorst plaques.

Evaluation of the carotid arteries provides information about the peak systolic velocity, end diastolic velocity, diameter reduction, plaque size and morphology, spectral characteristics, and direction of vertebral flow. It is typical to note an increased peak systolic velocity with a larger degree of stenosis (as the vessel lumen decreases, blood is forced through at a higher velocity).

Significant internal carotid artery stenosis is characterized by a vessel diameter reduction of 80% to 99%, a peak systolic velocity greater than 125cm/sec, an end diastolic velocity greater than 140cm/sec and extensive spectral broadening.[9]

CTA typically is performed to accurately determine the degree of carotid stenosis prior to surgical intervention. The procedure uses an intravenous contrast material, which facilitates clear imaging of the arterial lumen. CTA provides thin-slice images in different planes, which can be compiled into a single, three-dimension image. Measurements for stenosis determination are made via the narrowest portion of the stenosed lumen as well as distally (where the lumen is believed to be normal).[11]

When performed on patients with stenosis percentages between 70% and 99%, CTA has a sensitivity of 85% and specificity of 93%.[12] Such testing is especially beneficial when duplex results are suggestive of total occlusion.

The majority of retinal cholesterol emboli typically originate

A Review of Ocular Ischemic Syndrome

No discussion of the carotid system would be complete without discussing ocular ischemic syndrome (OIS). Widespread ischemia to the eye may result when the carotid artery is at least 90% occluded. Patients may experience decreased vision, periorbital eye pain, headache, amaurosis fugax and extended visual recovery after photostress. Anterior segment findings may include episcleral injection, corneal edema, iris neovascularization and uveitis with increased flare in the anterior chamber. Posterior segment signs of OIS include arteriolar narrowing, venous dilation without tortuosity, midperipheral retinal hemorrhages, microinfarcts and optic disc/retinal neovascularization.[31,32] Although the most common symptom of OIS is decreased vision, patients may present with mixed signs and symptoms. Because many of these findings are noted in other ocular conditions, clinicians should consider OIS when ocular findings are asymmetrical.

The intraocular pressure can range from low to high, depending on the state and duration of OIS. Low unilateral eye pressure is indicative of hypoperfusion to the ipsilateral ciliary body. Significantly elevated intraocular pressure may be due to neovascular glaucoma from widespread ocular ischemia. Although neovascular glaucoma should initially be treated with topical medical therapy, surgical intervention may be necessary if the intraocular pressure is not reduced to an appropriate level.[31]

The treatment of OIS is targeted at fixing the underlying etiology of the carotid artery or other atherosclerotic sites. Surgical procedures include carotid endarterectomy (CEA) and carotid angioplasty and stenting (CAS). While there are no large clinical studies documenting the neovascular and visual changes after CEA or CAS, some case reports and small-scale studies have shown resolution of neovascularization within several days of CEA. Other case reports have also shown that OIS retinopathy without neovascularization can improve following CEA. It is important to note that surgical intervention has never been shown to reverse chronic neovascular glaucoma.[33-35]

Local ocular treatment is targeted at retinal and iris neovascularization. Panretinal photocoagulation (PRP) has produced mixed results when used to treat OIS. PRP has been shown to successfully reduce ocular neovascularization, but has a minimal effect on visual acuity due to chronic ischemia of the retina.[36-39] Intravitreal injections of anti-vascular endothelial growth factor also have been found to reduce retinopathy, iris neovascularization and neovascular glaucoma secondary to OIS.[40,41]

One study revealed that two individuals with iris neovascularization and cystoid macular edema exhibited a drastic improvement in signs and symptoms following initial bevacizumab injection. Despite clinical improvement of the macular edema, the authors documented no improvement in best-corrected visual acuity.[40]

from the internal carotid artery. Be certain to consider transesophageal echocardiography in young patients and when an emboli of cardiac origin is suspected.[13]

Although the majority of cardiac emboli will be calcific or fibroid, the aortic arch also may develop atheromas.[14] In contrast to Hollenhorst plaques, larger cardiac emboli often are more visually devastating because they tend to lodge in the central retinal artery.

Carotid artery evaluation with duplex ultrasonography may be ordered for ocular etiologies such as transient monocular vision loss, retinal venous occlusions, retinal artery occlusions, optic atrophy, peripheral retinal hemorrhaging, asymmetric diabetic retinopathy, venous stasis retinopathy, normal-tension glaucoma, retina emboli and ocular ischemic syndrome (*see "A Review of Ocular Ischemic Syndrome," above*).[15,16]

Given this extensive list of conditions, you must be aware of the positive predictive value of the findings as they relate to the likelihood of significant carotid stenosis.

Vicki Lyons-Wait, OD, and associates summarized the incidence of hemodynamically significant stenosis based solely on ocular risk factors.[15] Of particular interest to this report, the prevalence of hemodynamically significant internal carotid artery stenosis—as found with duplex imaging—has been shown to range from 7% to 20% for asymptomatic retinal emboli and 20% to 25% for branch retinal artery occlusions.[15-20]

Ultimately, Dr. Lyons-Wait's research team recommended a baseline duplex for asymptomatic patients over the age of 60 with comorbid systemic vascular conditions and evidence of pertinent retinal findings.[15]

Heath K. McCullough, MD, and associates found similar moderate positive predictive values of carotid stenosis for the ocular signs/symptoms of amaurosis fugax (18.2%), Hollenhorst plaques (20.0%) and venous stasis retinopathy (20.0%).[21]

Treatment Options

The treatment decision for carotid stenosis largely is based on the degree of stenosis and history of symptoms. Patients with less than 50% stenosis typically are managed medically with the use of anti-platelet aggregates, while those with more than 70% stenosis may be considered surgical candidates.

• ***Therapeutic intervention.*** Each antiplatelet medication features a different mechanism of action. Some of the more common antiplatelet medications include

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INDICATIONS AND USAGE

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MECHANISM OF ACTION

Alcaftadine is an H_1 histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation have also been demonstrated.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Patients should be advised not to wear a contact lens if their eye is red.

LASTACAFT® should not be used to treat contact lens-related irritation.

Remove contact lenses prior to instillation of LASTACAFT® (alcaftadine ophthalmic solution) 0.25%. The preservative in LASTACAFT®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of LASTACAFT®.

LASTACAFT® is for topical ophthalmic use only.

ADVERSE REACTIONS

The most frequent ocular adverse reactions, occurring in < 4% of LASTACAFT® treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness, and eye pruritus.

The most frequent non-ocular adverse reactions, occurring in < 3% of subjects with LASTACAFT® treated eyes, were nasopharyngitis, headache, and influenza. Some of these events were similar to the underlying disease being studied.

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1. LASTACAFT® Prescribing Information. **2.** Torkildsen G, Shedden A. The safety and efficacy of alcaftadine 0.25% ophthalmic solution for the prevention of itching associated with allergic conjunctivitis. *Curr Med Res Opin.* 2011;27(3):623-631. **3.** Data on file, Allergan, Inc., 2005.

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aspirin (COX-2 inhibitor), clopidogrel (adenosine diphosphate [ADP] receptor inhibitor) and dipyridamole (ADP reuptake inhibitor). Despite varying mechanisms, the primary goal of any antiplatelet medication is to reduce the aggregation of platelets near a diseased site and the limit the formation of additional atheromas. Antiplatelet therapy has been shown to reduce the five-year stroke rate by approximately 50% in asymptomatic stenosis.[22] Anticoagulants also have been evaluated as primary medical therapy; however, there has been no data supporting the superiority of such medications (e.g., warfarin) over conventional antiplatelet therapy.

Intense cholesterol lowering has long been postulated to reduce the likelihood of both fatal and non-fatal strokes. Subgroup analysis in the Stroke Prevention by Aggressive Reduction in Cholesterol Levels trial indicated that intense lipid reduction with atorvastatin reduced the risk of both cerebrovascular and cardiovascular events in patients with carotid stenosis.[23] Despite the retrospective and non-randomized nature of this review, the data suggest that patients with known carotid stenosis may benefit from statin use as well as antiplatelet therapy.

• ***Surgical intervention.*** Carotid endarterectomy is performed under general or localized anesthesia. After an incision is made along the diseased arterial portion, a tubing shunt is placed between the proximal and distal ends to permit blood flow to the brain during the procedure. The atheromatous plaque is then excised and the artery is closed.[24]

Carotid angioplasty and stenting is another procedure that is gaining popularity due to the surgical risks associated with endarterectomy. CAS consists of an arteriogram of the carotid artery followed by placement of a filter known as a cerebral protective device, which prevents debris and emboli from traveling to the ipsilateral cerebral hemisphere. The balloon is then inserted to dilate the artery and a stent is inserted to recanalize the blood flow.[24,25]

A landmark study comparing the two procedures was completed in 2010. Although CEA and CAS were both found to be safe and effective in treating carotid artery stenosis, there was a higher risk of myocardial infarction following CEA and a greater risk of stroke after CAS.[26]

Both therapeutic and surgical treatments have advantages and disadvantages. Studies have examined the most appropriate treatment, given the degree of stenosis, symptomatology and medical status. The North American Symptomatic Carotid

Endarterectomy Trial showed that surgical intervention was markedly more effective than medical therapy in patients with 70% to 99% stenosis.[27] However, in those with just 50% to 69% stenosis, the benefits of surgery dropped considerably. Further, there was no documented benefit of CEA in patients with less 50% stenosis. Instead, the researchers recommended medical therapy for these individuals.[27] Similar results were obtained in symptomatic patients in the European Carotid Surgical Trial.[28]

The Asymptomatic Carotid Atherosclerosis Study and Asymptomatic Carotid Surgery Trial showed a risk reduction of 53% and 46%, respectively, when CEA was performed on patients with minimum stenosis of 60%.[29,30] Guidelines from these studies only recommend CEA when the risk of perioperative stroke, myocardial infarction or mortality was low. The authors determined that patients with less than 60% stenosis are best managed on medical therapy alone, until they become symptomatic or the degree of stenosis increases to more appropriate surgical levels.[29,30]

This case illustrates the significance of retinal cholesterol emboli and their relation to carotid artery disease. Patient history, retinal findings and imaging studies help determine whether surgical intervention may be beneficial to a patient. Clinicians should consider a duplex ultrasound for individuals who present with ocular signs, neurologic symptoms or comorbid vascular conditions. Although CEA typically is not indicated for asymptomatic patients who exhibit less than 60% stenosis, medical therapy should be considered to prevent further plaque accumulation and increased stenosis. Both CEA and CAS have associated perioperative risks, but are relatively safe options for individuals who require surgical intervention for hemodynamically significant internal carotid stenosis. ■

Dr. Zimbalist practices at the Harry S. Truman Memorial Veterans' Hospital in Columbia, Mo.

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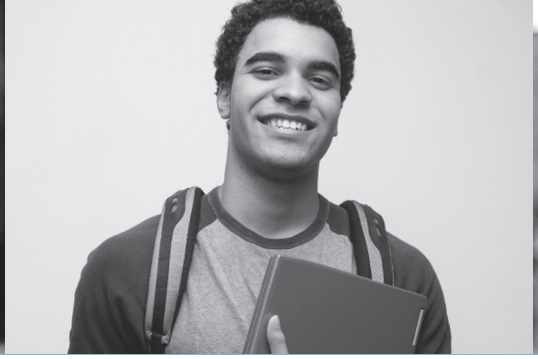


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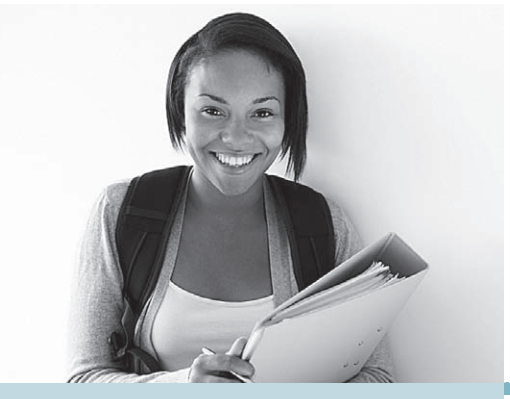

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Rick Bay served as the publisher of The *Review* Group since 1991.

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Medical Laboratory Testing for Optometrists

Even if you don't order lab tests yourself, you should know what they measure and how to read the results. **By Amy Dinardo, OD, MBA, and Douglas Coon, OD**

Optometrists play a key role in preventing, diagnosing and comanaging systemic disease. Because we have become even more proactive in the health care delivery system—particularly in disease prevention and health care improvement—medical laboratory tests will continue to be important factors to consider in conjunction with a comprehensive eye examination.

Medical laboratory tests are important tools for the diagnosis and management of diseases, many of which have serious ocular manifestations. Optometrists should possess a working knowledge of such testing in order to understand the complete clinical picture.

While we frequently encounter medical laboratory tests in everyday practice, their ability to order and interpret such tests is defined by the scope of practice for each state.[1]

Whether you order the laboratory tests independently or through the primary care physician, the individual who receives the results must communicate the information to all involved health

Name:			Date Performed:	5/6/2010
DOB/Sex/State:			Date Collected:	05/03/2010 04:00 PM
			Date Last Meal:	05/03/2010 10:45 AM
Examiner:	PTM		Date Received:	5/7/2010 12:13:11AM
Ticket No.:	8028522035			
		Abnormal	Normal	Range
CARDIAC RISK				
CHOLESTEROL			161.00	120.00 - 240.00 mg/dL
CHOLESTEROL/HDL RATIO			2.39	1.50 - 5.00
HIGH DENSITY LIPOPROTEIN(HDL)			67.30	35.00 - 75.00 mg/dL
LOW DENSITY LIPOPROTEIN (LDL)			78.70	60.00 - 190.00 mg/dL
TRIGLYCERIDES			75.00	10.00 - 200.00 mg/dL
CHEMISTRIES				
ALBUMIN			4.40	3.50 - 5.50 g/dL
ALKALINE PHOSPHATASE			49.00	30.00 - 120.00 U/L
BLOOD UREA NITROGEN (BUN)			17.00	6.00 - 25.00 mg/dL
CREATININE			0.85	0.60 - 1.50 mg/dL
FRUCTOSAMINE		1.82		1.20 - 1.79 mmol/L
GAMMA GLUTAMYLTRANSFERASE			9.00	2.00 - 65.00 U/L
GLOBULIN			2.80	1.00 - 4.00 g/dL
GLUCOSE		61.00		70.00 - 125.00 mg/dL
HEMOGLOBIN A1C			5.10	3.00 - 6.00 %
SGOT (AST)			25.00	0.00 - 41.00 U/L
SGPT (ALT)			22.00	0.00 - 45.00 U/L
TOTAL BILIRUBIN			0.52	0.10 - 1.20 mg/dL
TOTAL PROTEIN			7.20	6.00 - 8.50 g/dL

1. This sample lab report shows both normal and abnormal results, as well as acceptable reference ranges for each testing category.

Release Date: May 2013
Expiration Date: May 1, 2016
Goal Statement: Medical laboratory tests are important tools for the diagnosis and management of diseases, many of which have serious ocular manifestations. As optometrists continue to be recognized as valuable members of the health care system and our scope of practice continues to grow, it is even more important that we understand the significance of our role in the prevention, diagnosis and management of systemic diseases.
Faculty/Editorial Board: Amy Dinardo, OD, and Douglas Coon, OD
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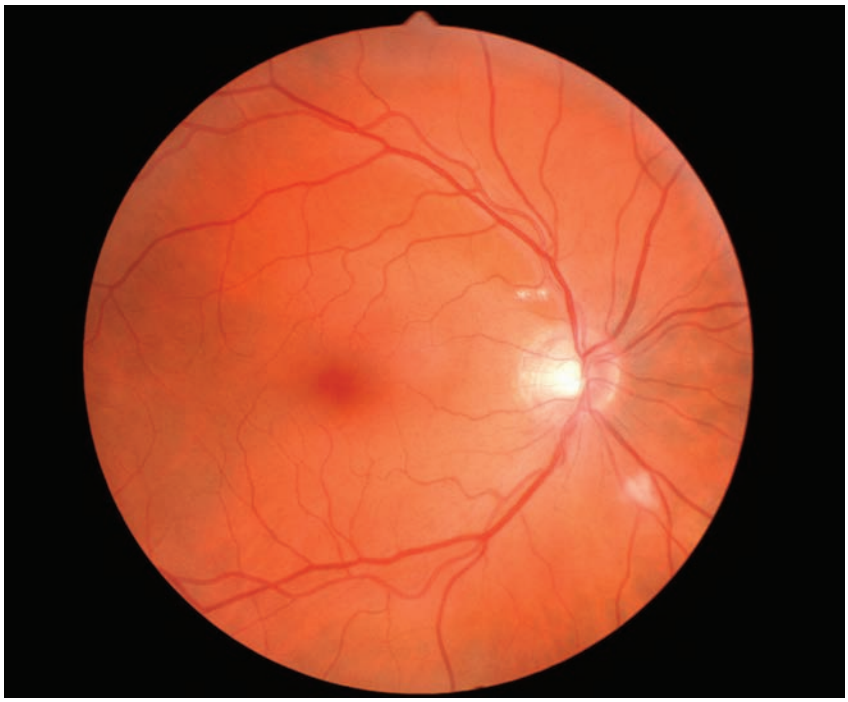
Disclosure Statement: Drs. Dinardo and Coon have no relationships to disclose.



2. This patient with anemia exhibited cotton-wool spots.

care providers in order to provide optimal care.

Laboratory tests are performed at an accredited facility upon the written request from an "authorized individual." A written request can be as simple as a handwritten prescription, a preprinted order from the laboratory or a transmission through electronic health records. (Check with your laboratory of choice to determine the preferred method of ordering lab tests.)

For most of the tests described in this article, blood is acquired via venipuncture (drawn from a vein below the elbow) or by finger stick (taking a small sample of blood from the finger). Patients may need special instructions, such as fasting for a certain number of hours prior to the test.[2,3]

Laboratory reports include the result with a set of reference ranges for each test. Reference ranges are based on "normal" values for the average population. When appropriate, the ranges are further classified by other variables, such as age and gender. The report is usually designed in such a way to draw attention to data that falls outside of the reference ranges for a particular test(s). It is important that the physician analyze both positive and negative results in the context of the entire clinical picture *(figure 1)*.[3]

CBC with Differential

One of the most commonly ordered and extremely useful medical laboratory tests, a complete blood count with differential (CBC with diff), provides specific information about red blood cells, white blood cells and platelets. A CBC with differential includes the following:

• ***Red blood cell count (RBC).*** RBC count is simply the number of erythrocytes (in millions) per cubic millimeter (mm^3) or microliter (µL). It does not give the detailed information necessary to determine how well RBCs are functioning.

• ***Hemoglobin (Hb).*** This represents the amount of oxygen-carrying protein (hemoglobin) in a sample and reflects the number of RBCs present.

• ***Hematocrit.*** Provides a value related to the percentage of total blood volume that is comprised of red blood cells. It is closely related to hemoglobin levels.

• ***Red blood cell indices.*** Helpful in classifying anemias, these indices provide information such as RBC size, weight and hemoglobin concentration.

• ***White blood cell count (WBC) and differential.*** A WBC count reflects the number of WBCs per µL. The differential provides detailed information about the types of WBCs present, along with percentages. This information is useful in the differential diagnosis of certain disease states.

• ***Platelet count.*** This represents the number of platelets per µL and is useful in the diagnosis and management of blood clotting disorders and other diseases.[4,5]

A CBC with differential may be ordered for several conditions that exhibit ocular manifestations. It is most helpful for patients with persistent infections, recurrent inflammation, or in those who exhibit signs of anemia or leukemia.[5] Typically, a CBC with diff is part of a battery of tests performed prior to surgery. It also can be used to monitor patients for negative side effects associated with certain medications. For example, a baseline CBC is recommended prior to initiating oral acetazolamide and at regular intervals during therapy.[6]

In cases of recurrent or bilateral uveitis, a CBC may be useful in identifying a possible non-specific systemic etiology. For example, an

elevated WBC count (leukocytosis) may be present with underlying bacterial infections. An elevated lymphocyte count (lymphocytosis) may be present with viral infections. Parasitic causes of uveitis may reveal elevated eosinophils (eosinophilia).

A CBC also can be ordered to assess for complications that may result from an associated systemic pathology, such as ankylosing spondylitis or inflammatory bowel disease (e.g., anemia).[3,5,9]

In cases of retinopathy, the presence of cotton-wool spots and/or retinal hemorrhages of unknown etiology in a patient without a documented history of diabetes mellitus or hypertension should prompt eye care providers to order a CBC to rule out anemia (*figure 2*). Additionally, the CBC could detect polycythemia (elevated RBC count), which is present in serious diseases such as leukemia.[3]

Blood Glucose

Insulin normalizes blood glucose and promotes glycogen synthesis by stimulating cellular uptake of glucose. Insulin also signals the liver to cease glucose production. Hyperglycemia can be a result of beta cell autoimmune destruction and the inability to produce insulin (e.g., type 1 diabetes). The condition also can result from the inability to use insulin to regulate blood glucose, as seen in patients with insulin resistance or type 2 diabetes. Ultimately, hyperglycemia is a major cause of both systemic and ocular complications.[7,8]

Numerous studies support the importance of maintaining tight glucose control to normal or near-normal values for the prevention of ophthalmic complications.[8,9] So, fasting blood glucose, random (plasma) glucose and glycosylated hemoglobin are essential metrics in the diagnosis and treatment of patients with diabetes mellitus.[7,8,10]

• ***Fasting blood glucose (FBG).*** Fasting plasma glucose is the amount of glucose in the blood at the time of collection after the patient has refrained from eating or drinking anything but water for at least eight hours. Physicians frequently use this test to diagnose diabetes. Blood samples are best conducted in the morning shortly upon awakening.[10] On the other hand, random (plasma) glucose indicates blood glucose levels without fasting. Because blood glucose increases after eating, this measurement is expected to be slightly higher than fasting plasma glucose—depending on the time of the patient's last meal. If a patient has symptoms of severe hyperglycemia, he or she can be diagnosed with diabetes based on a random plasma glucose of greater than or equal to 200mg/dL.[7,8,10]

• ***Two-hour postprandial glucose.*** Two-hour postprandial glucose—the measure of serum glucose two hours after a meal—can be used as a "glucose challenge" to assist in the diagnosis of diabetes. In particular, this test is used to assist in the diagnosis of gestational diabetes. In healthy patients, blood glucose should normalize within two hours of eating. If serum glucose remains elevated two hours after a meal, diabetes is strongly suspected.[7,8,10]

• ***Glycosylated hemoglobin test (HbA1c).*** This test reflects the percentage of free glucose bound to hemoglobin in red blood cells. Because the average lifespan of a red blood cell is three months, this test is a good estimation of the patient's average blood glucose over that time period. Not only is the HbA1c used to diagnose diabetes, but it is frequently used by physicians to determine the effectiveness of treatment and the level of patient compliance. HbA1c is acquired two to four times a year, depending on the patient's status and physician's preference.[8] Be aware that HbA1c can be misleading in patients with hemoglobinopathies or various forms of anemia, such as sickle cell.[7,10]

Because patients are more familiar with blood glucose results, the American Diabetes Association established a new metric, estimated average glucose (eAG). This calculation easily translates the patient's HbA1c percentage into an average glucose (mg/dL) that patients can understand.

For example, if a patient's HbA1c is 9%, his or her blood glucose has been averaging 212mg/dL over the last three months.[8] Translating a patient's HbA1c into an eAG reading can be extremely helpful in practice as a patient education tool. (*To see how it works, visit http://professional.diabetes.org/GlucoseCalculator.aspx.*)

Blood Glucose Reference Ranges[7]

Fasting blood glucose (mg/dL)
Normal: <100
Pre-diabetes: 100-125
Diabetes: >126

Two-hour postprandial glucose (mg/dL)
Normal: 70-141
Pre-diabetes: 140-200
Diabetes: >200

Glycosylated hemoglobin
Normal: 5.7%
Pre-diabetes: 5.7%-6.4%
Diabetes: >6.5%

Estimated average glucose (eAG)
28.7 x (A1C) - 46.7 = eAG

Lipid Panel Reference Ranges[11]

LDL lipoproteins (mg/dL)
Optimal: <100
Near optimal: 100-129
Borderline high: 130-159
High: >160

HDL lipoproteins (mg/dL)
Low: <40
High: ≥60

Triglycerides (mg/dL)
Optimal: <150
Near optimal: 150-199
Borderline high: 200-499
High: >500

Total cholesterol (mg/dL)
Desirable: <200
Borderline High: 200-239
High: >240

The American Diabetes Association recommends that all asymptomatic patients over age 45 undergo a diabetes screening. Younger patients should be screened if they are overweight (BMI greater than or equal to 25 kg/m^2), obese or have additional risk factors for diabetes.[8] Because patients with prediabetes have an increased risk of disease progression, it is recommended that they be counseled on effective strategies to improve their health, such as weight loss and physical activity.

The reference ranges that all health care professionals currently use to diagnose diabetes are based on the prevalence of retinopathy in the diabetic population.[7] Diabetes is confirmed if any one of the laboratory studies is increased on two separate occasions. It is also confirmed if two different laboratory tests, FBG and HbA1c for example, are increased on one occasion.[7] (*See "Blood Glucose Reference Ranges," page 89.*)

If a patient exhibits any signs or symptoms of hyperglycemia, it is important to inquire about the specific blood glucose tests discussed above. Some important signs or symptoms to be aware of are increased thirst or hunger (polydipsia/polyphagia), more frequent urination (polyuria) or refractive error shifts.[7,8]

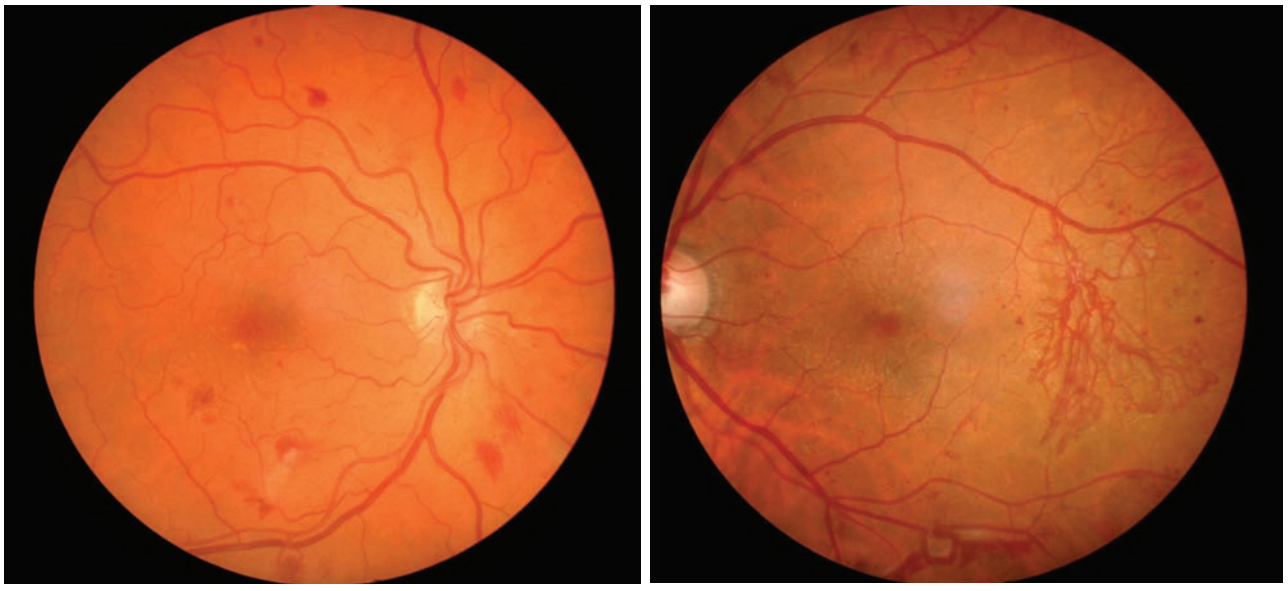
The presence of retinal microaneurysms, cotton-wool spots, retinal hemorrhages or neovascularization in a patient not previously diagnosed with diabetes may prompt an investigation of the patient's blood glucose (*figures 3 and 4*).[9]

Lipid Profile

Produced by the liver and ingested from food, cholesterol is actually an important component of cellular structures, bile acids and steroid hormones. However, high cholesterol (hypercholesterolemia) is strongly associated with cardiovascular disease and its associated life- and vision-threatening consequences.[11]

For a complete lipid profile, patients must refrain from eating for nine to 12 hours prior to the test.[3] A lipid profile consists of the measurement of the following lipoproteins:

• ***Low-density lipoprotein (LDL).*** LDLs are known as "bad" cholesterol because they bind to arteries and increase the patient's risk for diseases, such as hypertension and atherosclerosis. Most cholesterol-lowering therapies are targeted at reducing LDL.



3, 4. This patient with a history of elevated glucose readings presented with diabetic retinopathy (OD left, OS right).

• ***High-density lipoprotein (HDL).*** Known as the "good" cholesterol, HDLs are cardioprotective because they remove cholesterol from the arteries and transport it back to the liver.

• ***Trigycerides.*** Triglycerides can be particularly high due to physical inactivity, smoking, obesity and a high-carbohydrate diet. These factors also increase the risk of cardiovascular disease.

• ***Total cholesterol.*** When used alone, total cholesterol is an insufficient indicator for the diagnosis, treatment and management of dyslipidemia. However, it can be helpful when used with other data. For example, the total cholesterol/HDL ratio is helpful in assessing a patient's risk for heart disease.

• ***Very low-density lipoproteins (VLDL).*** Triglyceride-laden VLDLs are another form of "bad" cholesterol. This value may be included in a lipid panel and is estimated using the triglyceride value.[11]

The National Heart, Lung and Blood Institute recommends that adults over the age of 20 be screened with a lipid profile at least once every five years.[11] (*See "Lipid Panel Reference Ranges," page 90.*)

Inflammatory Markers

Both acute and chronic inflammatory disease states cause an increase in plasma protein. As a result, RBCs tend to become positively charged and stick to each other in clumps. Erythrocyte sedimentation rate (ESR), or "sed rate," is the rate at which RBCs settle out of uncoagulated blood in one hour. The upper limit for males under age 50 is 20mm/hr and the upper limit for females under age 50 is 15mm/hr. For males and females over age 50, the upper limit is 20mm/hr and 30mm/hr, respectively.[5,13]

C-reactive protein (CRP), another acute-phase protein, is produced by the liver in response to inflammation and infection. CRP should be <1mg/dL, no matter the patient's age or sex.[5,13]

Both ESR and CRP are sensitive—albeit non-specific—indicators of inflammation. Both markers, particularly ESR, increase naturally with age. The ESR test is fairly inexpensive, rapid and easy to perform. But it is affected by many variables, such as temperature, medication, pregnancy and smoking. Because CRP is not affected by blood cell shape/size, plasma composition or fluid status, it can be a more accurate representation of inflammation.[13]

Consider an ESR and/or CRP in patients with signs of inflammatory or autoimmune diseases, such as systemic lupus erythematosus (SLE), sarcoidosis or rheumatoid arthritis.[5] ESR is most commonly used in the diagnosis of giant cell arteritis, yet its diagnostic sensitivity for this disease increases to more than 99% when combined with a CRP.[14]

The presence of anterior ischemic optic neuropathy (ION, figure) or a central retinal artery occlusion (CRAO) warrants ESR and/or CRP testing, especially if the patient exhibits concurrent symptoms of giant cell arteritis (*figures 5 and 6*).[9]

Autoimmune Diseases

Autoimmune diseases involve the development of antibodies that inevitably damage the individual's own tissue. Sometimes, ophthalmic manifestations are the first sign of an autoimmune disease. Signs range from dry eye or episcleritis to recurrent uveitis or retinal vasculitis.[9] Whenever an autoimmune disease is suspected, certain laboratory tests may assist in the diagnosis.

• ***Antinuclear antibodies (ANA).*** Antinuclear antibodies cause tissue damage by targeting cellular DNA and nuclear material. Ninety-five percent of patients with SLE have high levels of ANA,

Lipids and the Eye

Consider ordering a lipid profile for patients with these ocular conditions:

• **Lipemia retinalis.** Serum triglyceride levels higher than 2,000mg/dL can lead to this relatively rare condition, in which retinal blood vessels appear creamy or salmon-colored. Although lipemia retinalis can be asymptomatic and generally does not affect vision permanently, it is a harbinger of a potentially fatal systemic condition.[12]

• **Amarosis fugax**. Consider a lipid panel if patients exhibit transient monocular loss of vision (amarosis fugax), because of its association with atherosclerosis.[9]

• **Hollenhorst plaques**. Retinal emboli visible within the retinal arterioles indicate an increased risk of stroke-related death. Lipid control plays a significant role in preventing strokes.[2]

• **Retinal vascular occlusions.** Retinal vein/artery occlusions in patients without known hypertension, hyperlipidemia and/or diabetes should be investigated further. Hyperlipidemia is a common risk factor associated with retinal vein occlusions.[9]

• **Xanthelasma.** High cholesterol is reported in about 50% of people with xanthelasma, which are yellow, lipid-laden deposits located underneath the skin around the eyelids.[9]

• **Corneal arcus in younger patients.** The peripheral corneal deposits in corneal arcus mainly are composed of low-density lipoproteins. Patients—particularly men under age 50—with premature corneal arcus have a four-fold increased relative risk of mortality from cardiovascular disease and coronary heart disease.[9]

Eye-Related Autoimmune Diseases

The following ocular conditions are examples that warrant testing for autoimmune diseases:

- **Uveitis.** Recurrent or bilateral uveitis should raise suspicion for an associated systemic disease. In such cases, consider testing for conditions such as rheumatoid arthritis, systemic lupus erythematosus (SLE), sarcoidosis or HLA-B27 syndromes.
- **Retinal vasculitis.** SLE may affect almost any part of the visual pathway. The presence of retinal vascular sheathing in a patient without known SLE should prompt testing.

so this test is commonly ordered to assist in the diagnosis.[2,3] However, 15% of healthy people have a positive ANA. A positive ANA result also can indicate other autoimmune diseases, such as Sjögren's syndrome (40% to 70%) or scleroderma (60% to 90%).[5]

- ***Rheumatoid factor (RF).*** This IgM antibody is directed against IgG. It is present in healthy patients, and increases in value with age. As the name suggests, the increased presence of RF can reflect rheumatoid arthritis (RA). However, a positive RF is not necessarily diagnostic of RA; it can also suggest SLE, Sjögren's syndrome, sarcoidosis and tuberculosis.[2,3,5]
- ***Human leukocyte antigens (HLA).*** Human leukocyte antigens are located on the surface of leukocytes, platelets and other tissue cells.[2] Out of all of the classes and subtypes of HLA known to exist, the HLA-B27 allele is the most pertinent to optometric practice due to its relationship with autoimmune diseases. HLA-B27 is positive in 90% of patients with ankylosing spondylitis, 75% with Reiter's syndrome (reactive arthritis) and 50% of patients with Crohn's disease.[2,5]

Other disorders associated with abnormal immunological responses include sarcoidosis and myasthenia gravis (MG). Up to 78% of patients with sarcoidosis exhibit non-specific ocular complications, such as granulomatous uveitis and retinal perivasculitis, for example.

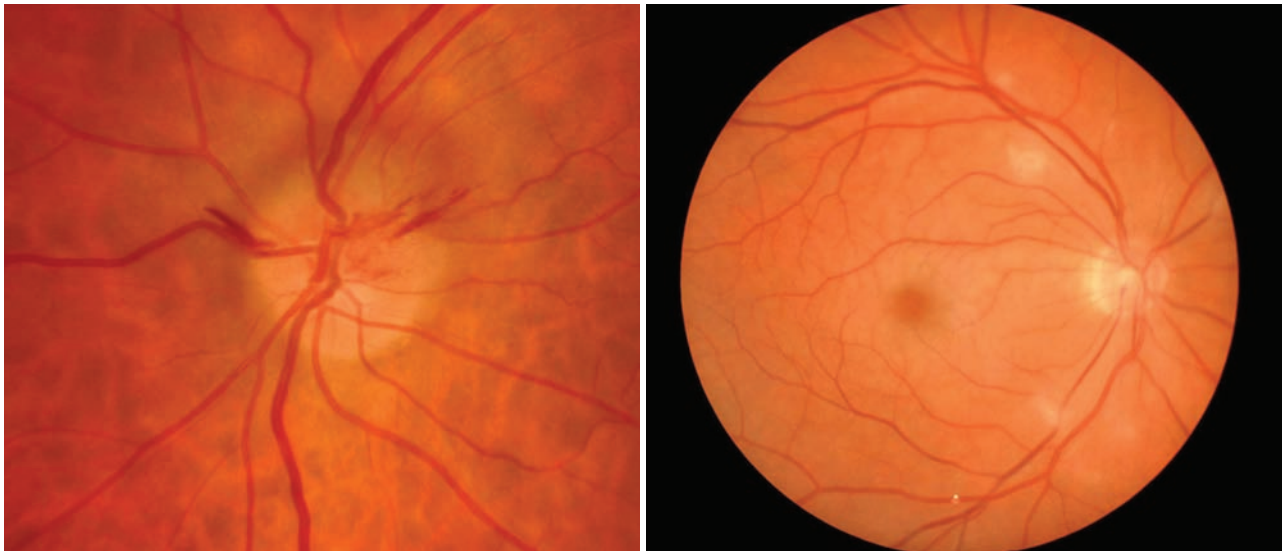
Along with radiological imaging, serum angiotensin-converting enzyme (ACE) testing is used to diagnose and monitor this disease. Serum ACE is elevated over 40µg/L in 60% of patients diagnosed with active sarcoidosis.[2,9] Patients with MG are likely to present with ptosis and/or diplopia secondary to an inherent defect in neuromuscular transmitter secretion. The diagnosis of MG can be aided with a serum assay for acetylcholine receptor antibodies, a specific protein found in many of these patients.[5,9]

Infectious Diseases

Enzyme-linked immunosorbent assays (ELISAs) are highly sensitive and specific tests for detecting the presence of antibodies in a sample. ELISAs are recommended to diagnose infectious conditions, such as human immunodeficiency virus (HIV), toxocariasis and Lyme disease.

A Western blot is a type of assay used to detect specific proteins in a blood or tissue sample. It is regularly employed as a confirmatory test for HIV after a positive ELISA.[2]

The venereal disease research laboratory and rapid plasma



5, 6. The optic nerve of a patient with anterior ischemic optic neuropathy (left). Fundus photograph of a patient with a central retinal vein occlusion (right).

reagin are tests used for the initial screening of an active syphilis infection. They are also used for monitoring a patient's response to treatment. Common confirmatory tests for syphilis are fluorescent treponemal antibody absorption or *Treponema pallidum* particle agglutination.

A positive test indicates that the patient had syphilis at some time, but it cannot distinguish between past and present infection. Multiple variables can lead to false positive tests for syphilis, including advanced age, pregnancy, SLE and thyroiditis.[15]

Consider laboratory testing for infectious diseases in the following situations:

• ***Granulomatous anterior uveitis or vitritis.*** Syphilitic infection is commonly related to a nonspecific iritis or iridocyclitis. Localized or diffuse vitritis can be present in conditions such as toxocariasis, Lyme disease and cytomegalovirus associated with AIDS.

• ***Retinal cotton-wool spots.*** Retinal cotton-wool spots in a patient without known diabetes mellitus, hypertension or anemia may prompt ELISA and/or western blot in patients at risk for HIV (*figure 7*).

• ***Unexplained retinitis or neuritis.*** Chorioretinitis or neuroretinitis of unknown origin can signify one of many infectious diseases, such as toxoplasmosis, toxocariasis or cat scratch disease.[9]

Blood Clotting

The most common blood clotting study encountered in an eye care setting is the prothrombin time (PT) or "pro time." Laboratories measure the length of time it takes for a sample of blood to clot and convert it into an international normalized ratio (INR). Along with other tests, a PT may be ordered to diagnose unexplained bleeding or bruising, such as recurrent subconjunctival or pre-retinal hemorrhages, for example. It may also be used for screening purposes prior to surgery. A periodic PT is necessary to monitor patients taking anticoagulants, such as warfarin.

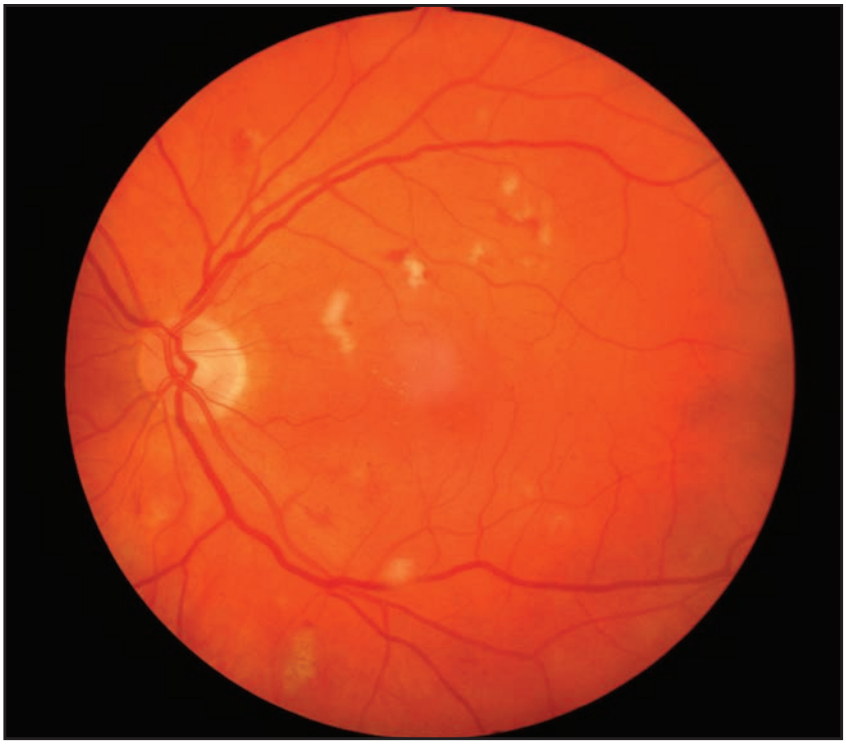
The reference ranges for PT are approximately 10 to 13 seconds or an INR of 0.8 to 1.1 (although these ranges can vary at each lab). For patients on anticoagulant therapy, an INR of 2 to 3 is adequate for most individuals, or as high as 3.5 for high-risk patients. An INR greater than 4.5 indicates a high risk of hemorrhage.

Be aware that a wide variety of foods, supplements and medications can affect anticoagulant therapy and PT. These include fish oil, fluoroquinolones, tetracyclines and acetaminophen. Also, this test can be inaccurate in patients with liver disease.[2,16]

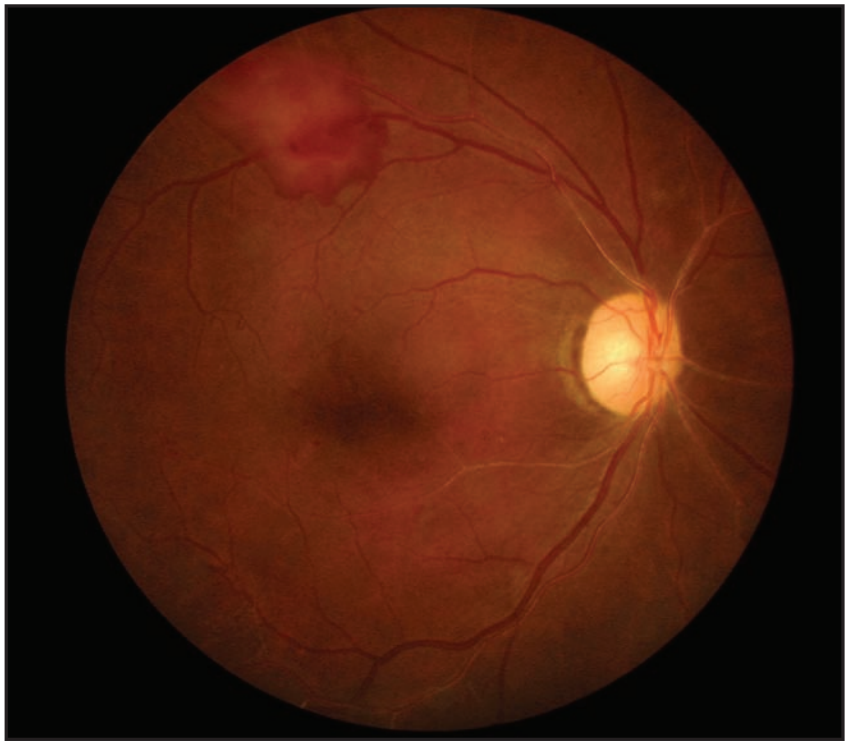
Thyroid

Normally, the endocrine system works on a continuous feedback loop where thyroid-stimulating hormone (TSH), released by the pituitary gland, prompts the thyroid to release T3 and T4. The presence of T3 and T4 signals the pituitary gland to decrease the release of TSH. In hyperthyroidism, or Graves' disease, an overactive thyroid gland secretes excessive T3 and T4, which results in low TSH. Because T3 and T4 are decreased in hypothyroidism, the pituitary secretes more TSH.[17,18]

Ultrasensitive serum TSH studies have the highest sensitivity and specificity to screen for both hypo- and hyperthyroidism. An additional test can be ordered to detect the presence of free serum T4. Typical reference ranges for TSH vary from 0.3mIU/L to as high as 5.0mIU/L, and 0.8ng/dL to 1.8ng/dL for free serum T4. Both



7. This patient exhibited evidence of HIV retinopathy.



8. Salmon patch lesion in a patient with sickle cell retinopathy.

tests can be skewed by the use of various medications, including amiodarone, corticosteroids, aspirin, furosemide and lithium.[19]

Consider TSH, free T4 and/or orbital imaging in any patient exhibiting signs of Graves' disease, such as proptosis, extraocular muscle restrictions, lid retraction, compressive optic neuropathy or dry eye from corneal exposure.[5,9] Experts have not reached a consensus on the age and frequency at which screening for thyroid diseases in adults should be conducted. But current clinical practice guidelines suggest testing patients over age 60.[18]

Sickle Cell

Fortunately, the majority of infants in the United States are screened for sickle cell disease (SCD). But the mandatory neonatal screening systems are not infallible, and some patients with milder forms of SCD may be unaware of their condition.

Peripheral retinal neovascularization, vitreous hemorrhages, salmon-colored retinal hemorrhages and angioid streaks are commonly associated with sickle cell anemia (*figure 8*). Because of the increased incidence of severe IOP spikes, be sure to ask about SCD in patients with hyphema. Patients with SCD should not receive carbonic anhydrase inhibitors due to the risk of systemic acidosis and painful vaso-oclusive crisis.[9]

A hemoglobin S solubility test detects the presence of hemoglobin S (sickle cell trait). A test is positive if the solution becomes opaque or turbid when a reducing agent is added to whole blood. It is a good screening test for patients over six months of age, but it cannot distinguish SCD and sickle cell trait. Hemoglobin electrophoresis is used to distinguish between the different variants of SCD.[2,3]

Renal Function

Urea is synthesized by the liver and transported to the kidney for excretion. So, blood urea nitrogen (BUN) is a good test of both kidney and liver function. Serum creatinine, a waste product of muscle metabolism, is another excellent indicator of renal function. Creatinine levels also can be included in a urinalysis.

The reference ranges for adult BUN are 5mg/dL to 20mg/dL, and 0.2mg/dL to 1.0mg/dL for serum creatinine. Anything above these levels suggests kidney disease, degenerative muscle diseases, drug interactions or a high-protein diet, among others.[2,3,5]

Renal function tests are indicated in patients with certain genetic diseases that have ophthalmic manifestations. Alport syndrome is associated with a characteristic dot-and-fleck retinopathy, congenital cataracts, and anterior or posterior lenticonus.

Vortex keratopathy causes deposits to form in the corneal epithelium that present in a symmetrical, whorl-like pattern. Medications such as amiodarone, tamoxifen and chloroquine can cause this condition. However, vortex keratopathy also is a potential sign of Fabry's disease.[9]

Multiple studies show a high correlation between diabetic retinopathy and renal disease. The American Diabetes Association recommends measuring serum creatinine in all diabetic adults at least once a year.[8] Hypertension is the second most common cause of renal failure in the United States, after diabetes. Hypertensive patients should have a serum creatinine test at least once a year.[20]

Liver Function

Aspartate aminotransferase (AST), alanine aminotransferase

(ALT) and gamma-glutamyl transferase (GGT) are enzymes associated with heart and liver damage. Although varied, the reference ranges for AST/ALT usually are between 7U/L to 46U/L, and 5IU/L to 38IU/L for GGT.

Increased alkaline phosphatase above 120IU/L can be an indicator of liver or bone disease. Total bilirubin, a byproduct of hemoglobin metabolism, should be less than 1.3mg/dL in a healthy adult.[2]

Liver function tests and imaging are indicated in patients with a history of choroidal melanoma, which has a 90% to 95% rate of metastasis to the liver.

Liver function tests are also included in the battery of examinations that are indicated for the diagnosis and management of Wilson's disease, a genetic disorder of copper metabolism. Patients with Wilson's disease may present with evidence of a distinct Kayser-Fleisher ring of copper deposition on Descemet's membrane in the corneal periphery.[9]

As optometrists continue to be recognized as valuable members of the health care system and our scope of practice expands further, it is even more important that we understand the significance of our role in the prevention, diagnosis and management of systemic diseases.

Detailed knowledge of the laboratory tests frequently used by health care practitioners is critical to patient care and can be an incredibly powerful tool for the eye care practitioner. ■

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Lab Testing in Your Office

As the emphasis in health care becomes more patient-centered, focusing on the early detection of diseases, point-of-care screening devices that give immediate results in-office are expected to play a larger role. Point-of-care tests are beneficial for providing: immediate feedback, proactive patient education, improved patient compliance and increased collaboration between health care providers.[21]

Point-of-care devices exist for detecting C-reactive protein, cholesterol, human immunodeficiency virus (HIV), and others. Blood glucose is frequently monitored by diabetic patients, but it can be acquired in-office with a glucometer. In fact, frequent self-monitoring of blood glucose (SMBG) is reported to be a beneficial component of effective therapy—particularly in patients controlled with insulin.[8,21]

When recording a patient's blood glucose in mg/dL, whether self-reported or acquired in-office, be sure to note when the patient has last eaten. Similarly, HbA1c can also be checked at home or in-office using point-of-care instruments. The test is quick and reimbursable by many medical insurance plans.[22]

Experts agree that point-of-care devices do not replace standardized laboratory tests because their accuracy and practicality has come into question. Even so, some point-of-care devices may be extremely useful and relevant in certain optometric practices. For example, offices with a large population of diabetic patients would benefit from the use of a glucometer and HbA1c analyzer.

If you're considering adding point-of-care testing to your practice, be sure to check with state board requirements and your malpractice insurance to ensure that it is not considered outside of an optometrist's scope of practice. Also, consider factors such as cost, accuracy, training, safety, billing and equipment maintenance.

Additionally, most point-of-care tests require the medical office to apply for a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver through the Centers for Medicare and Medicaid Services. The tests usually include acquiring a small sample of bodily fluids, so it is critical to observe safety precautions for the prevention of spreading diseases.[5]

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OSC QUIZ

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You must achieve a score of 70 or higher to receive credit. Allow eight to 10 weeks for processing. For each Optometric Study Center course you pass, you earn 2 hours of transcript-quality credit from Pennsylvania College of Optometry and double credit toward the AOA Optometric Recognition Award—Category 1.

Please check with your state licensing board to see if this approval counts toward your CE requirement for relicensure.

1. Which information is most helpful in classifying the type of anemia?
a. Red blood cell count.
b. Hemoglobin.
c. Hematocrit.
d. Red blood cell indices.

2. In a complete blood cell count (CBC) with differential, the "differential" provides information about what specific blood component?
a. Blood plasma.
b. Red blood cells (RBC).
c. White blood cells (WBC).
d. Platelets.

3. For a fasting blood glucose test, patients must refrain from eating or drinking anything but water for at least how many hours beforehand?
a. Two.
b. Four.
c. Six.
d. Eight.

4. In a healthy patient, a two-hour postprandial glucose level should be:
a. <100 mg/dL.
b. <140 mg/dL.
c. <220 mg/dL.
d. <300 mg/dL.

5. According to the American Diabetes Association, asymptomatic patients without risk factors for diabetes should be screened at what age?
a. 25.
b. 35.
c. 45.
d. 55.

6. The estimated average glucose (eAG) is a direct reflection of the patient's:
a. Fasting blood glucose (FBG).
b. Two-hour postprandial glucose.
c. Random plasma glucose.
d. Hemoglobin A1c (HbA1c).

7. For diabetic patients, which test best determines the effectiveness of treatment?
a. FBG.
b. Two-hour postprandial glucose.
c. Random plasma glucose.
d. HbA1c.

8. Because of its cardioprotective properties, which lipoprotein in a lipid panel is considered the "good cholesterol?"
a. High-density lipoprotein (HDL).
b. Low-density lipoprotein (LDL).
c. Very low-density lipoprotein (VLDL).
d. Triglyceride.

9. When used alone, which element of a lipid panel is the LEAST helpful?
a. Total cholesterol.
b. Triglyceride.
c. HDL.
d. LDL.

10. Based on current recommendations, how often should patients be screened for high cholesterol?
a. At the age of 45, then every 10 years.
b. At the age of 35, then every 10 years.
c. At the age of 30, then every five years.
d. At the age of 20, then every five years.

11. Which two tests should be ordered together to aid in the diagnosis of giant cell arteritis?
a. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP).
b. ESR and rheumatoid factor (RF).
c. CRP and antinuclear antibody (ANA).
d. ANA and RF.

12. Increased antinuclear antibodies can be indicative of what systemic condition?
a. Sjögren's syndrome.
b. Scleroderma.
c. Systemic lupus erythematosus.
d. All of the above.

13. What is the most common blood clotting test encountered in an eye care setting?
a. Red blood cell indices.
b. Prothrombin time (PT).
c. ESR.
d. Hemoglobin S solubility test.

14. An increased risk of hemorrhaging occurs at an international normalized ratio (INR) above what value?
a. 2.5.
b. 3.5.
c. 4.5.
d. 5.5.

15. Which laboratory test has the highest sensitivity and specificity for detecting thyroid disease?
a. Serum T3.
b. Serum T4.
c. Ultrasensitive serum thyroid-stimulating hormone (TSH).
d. Ultrasensitive serum T3 and T4.

16. Thyroid studies can be skewed in patients taking all of the following medications, EXCEPT:
a. Amiodarone.
b. Fluoroquinolones.
c. Aspirin.
d. Corticosteroids.

OSC QUIZ

17. The American Diabetes Association recommends that diabetic patients have this renal function test at least once a year:
a. Serum creatinine.
b. Alkaline phosphatase (ALP).
c. Blood urea nitrogen (BUN).
d. HbA1c.

18. What is the second most common cause of renal failure in the United States?
a. Diabetes mellitus.
b. Hypertension.
c. Fabry's disease.
d. High cholesterol.

19. Uveal melanomas have a high rate of metastasis to which organ?
a. Breasts.
b. Kidneys.
c. Lungs.
d. Liver.

20. Which test of liver function can also be an indicator of bone disease?
a. Aspartate aminotransferase (AST).
b. Alanine aminotransferase (ALT).
c. BUN.
d. ALP.

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Effective September 2012, we will send the results of any CE post-course test that is manually submitted (via mail or fax) to the email address provided on your answer sheet.

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1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor

Rate the effectiveness of how well the activity:

21. Met the goal statement: ① ② ③ ④ ⑤
22. Related to your practice needs: ① ② ③ ④ ⑤
23. Will help you improve patient care: ① ② ③ ④ ⑤
24. Avoided commercial bias/influence: ① ② ③ ④ ⑤
25. How would you rate the overall quality of the material presented? ① ② ③ ④ ⑤
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◯ Greatly ◯ Somewhat ◯ Little
27. The difficulty of the course was:
◯ Complex ◯ Appropriate ◯ Basic

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Lesson 109174 RO-OSC-0513

Highlights of Vision Expo East

Among the glitz and glasses, this year's meeting also encouraged eye care practitioners to send patients this message: 'Think About Your Eyes.' **By Cheryl G. Murphy, OD**

This year's Expo showcased the newest frames and lenses—as well as the latest in 'eye tech,' such as the Z3 GPS MOD ski goggles with built-in GPS.

At *Vision Monday*'s Eye² Zone, group editor Andy Karp tests out Cinemizer multimedia glasses.

This year's Vision Expo East, which drew nearly 15,500 attendees from all over the United States and more than 90 countries, featured at least two notable events out of dozens of interesting happenings.

One was the expansion of The Vision Council's Think About Your Eyes public awareness campaign and its partnership with the American Optometric Association.

The other was Vision Monday's collection of exhibits in the Eye² Zone, which gave showgoers a glimpse into the future of eyewear and visual technologies. It also provided a chance for some practice owners to do some valuable comparison shopping for ophthalmic instruments.

'Think About Your Eyes'

At Vision Expo East, the Vision Council announced its new partnership with the AOA for a relaunch of its Think About Your Eyes national campaign (www.thinkaboutyoureyes.com).

Their goal is to educate the public about the benefits of eye health and the importance of getting an annual comprehensive eye exam. It ran in several test markets in 2010, reaching nearly 25% of Americans, the Vision Council reported. Those markets saw an 8% growth in the number of eye exams performed, which translated to an additional 120 patient visits for each partici-

pating practice per year in those areas.

"The first Think About Your Eyes campaign resulted in more than 3.4 million incremental eye exams in our test markets and more than 367,000 previously undiagnosed cases of eye disease," said Ed Greene, chief executive officer of the Vision Council. "With results like that, imagine the impact we can have on a national scale as we combine the strengths of the Vision Council, the leading industry association, and the AOA, the leading professional association."

In the second half of 2013, Think About Your Eyes will begin advertising on national television, print, radio, Internet and social media outlets. It will also include a 'doctor locator' as part of its patient outreach. Doctors can join for an annual membership fee to be included in the doctor locator directory and will be able to track results of the tool in real time.

Vision Expo East drew 15,500 attendees to New York's Javits Center this year.

Representatives of Optos, Inc., demonstrate the Optomap for James Loskot, OD, of Abingdon, Md.

Get in the Zone

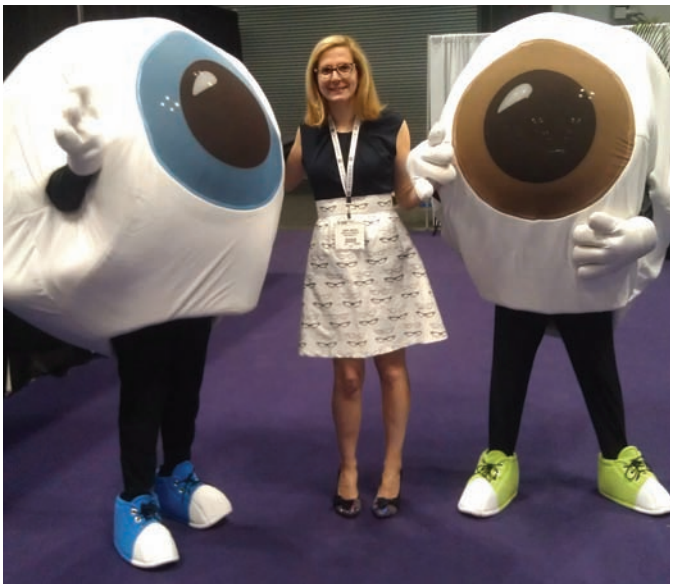
Among the many booths inside the exhibit hall, one area previewed the latest inventions in eyewear technology. Google Glass was noticeably absent, but plenty of other innovative devices were on display in *Vision Monday*'s brand new Eye^2 Zone.

The futuristic-looking, silver Cinemizer (Carl Zeiss) video glasses resemble opaque, virtual reality glasses that display 3D movies with stereo sound. These could be used, for example, by an airplane passenger as an immersive replacement for the current in-flight seatback screens.

For those who would like to go from watching movies to making them, Pivothead glasses (Aurora & Durango) can take HD video, capture stills, record wind-resistant audio, and more.

Adventure seekers looking for something even more interactive could check out the Z3 GPS MOD ski goggles (Zeal Optics), which not only have a built-in GPS but can also record speed, altitude, temperature, distance and more. These are shown on its widescreen in-goggle viewfinder display. The device also has Bluetooth to connect with the user's smartphone to view texts, show maps and locate friends.

As visual technologies in glasses, contact lenses and eyewear expand, eye care professionals need to keep a close watch on this exploding market to help navigate our patients through it.



Contributing editor Cheryl Murphy, OD, sported her eyeglasses skirt and had a ball with a couple well-rounded friends.

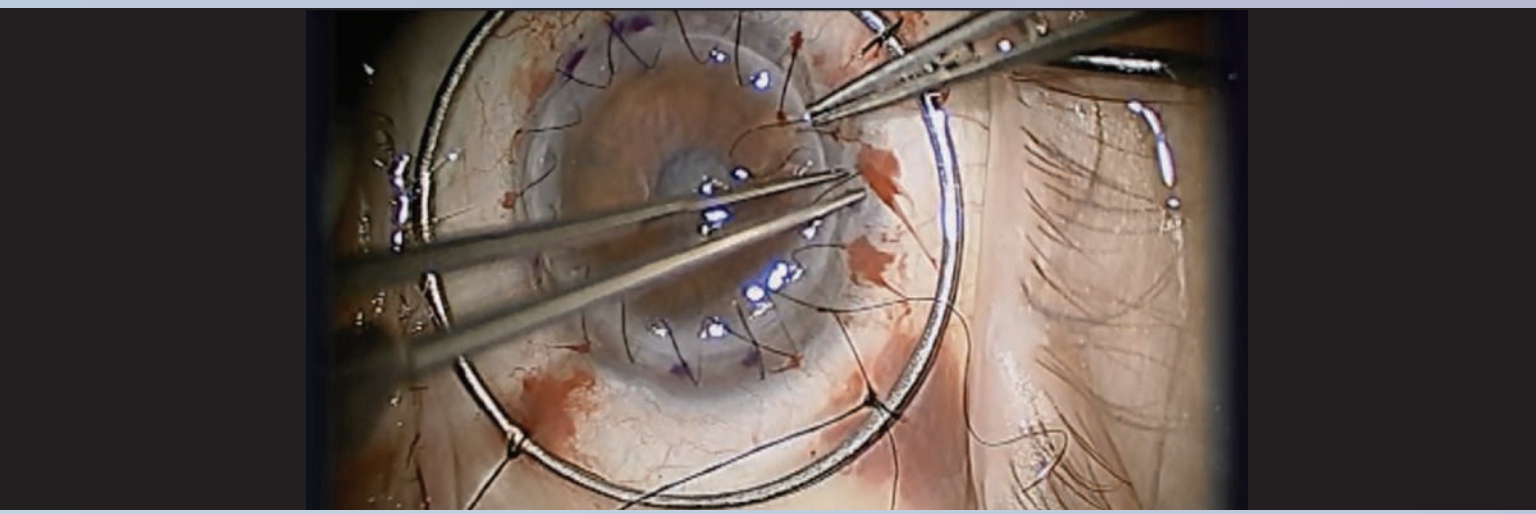
Easy-to-Compare Eye Care Tech

Among Expo's array of 575 exhibitors, the Med Sci Pavilion was abuzz with doctors and eye care professionals from all over the nation testing out the latest diagnostic equipment.

James Loskot, OD, of Abingdon, Md., came not only for the one-stop shopping and side-by-side comparison of products that the vast exhibit hall provides, but also because it's a place to "get rejuvenated and learn a lot." Vision Expo East provided him and others with an opportunity that thumbing through pamphlets cannot: a hands-on demonstration and a chance to ask questions directly to representatives and experts. ■

Surgical Minute

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



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

Surgical Minute

PK: Right on the Button

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

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

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

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

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

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

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

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

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

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

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

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

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When the Lens Won't Leave

On occasion, lens material is found in the eye after cataract surgery. How do you get this unwelcome 'guest' to leave? **Edited by Paul C. Ajamian, OD**

Q I occasionally see patients with retained lens material after cataract surgery. Do I handle them any differently post-op?

A "Yes, you do," says Howell Findley, OD, center director of Commonwealth Eye Surgery, a comanagement and ocular surgery center in Lexington, Ky.

"Retained lens material in the anterior segment is an uncommon occurrence after uncomplicated cataract surgery," Dr. Findley says. "It occurs when all of the lens cortex or nucleus is not evacuated at surgery. It may be more common in patients with high myopia or small pupils, where lens remnants may hide in the posterior chamber. It may present as early as within one week post-op or as late as 15 years after surgery. When it occurs, retained lens material may result in corneal edema and iritis."

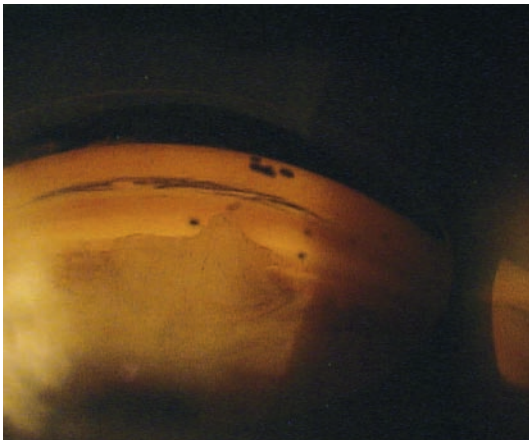
So, for any patient who presents with sudden-onset decreased vision, iritis or corneal edema (particularly when corneal edema is not expected), consider the possibility of retained lens material. "If not evident on slit-lamp exam, perform gonioscopy to rule out retained lens material in the angle," Dr. Findley says.

If you find retained lens material, the first step is to increase the topical steroid, he says. "The patient is probably already on prednisolone at QID dosing, so I would increase it to every two hours or maybe switch to Durezol (difluprednate 0.05%, Alcon), which can be dosed QID. Also, if the patient is using generic prednisolone, I would switch them to the name brand."

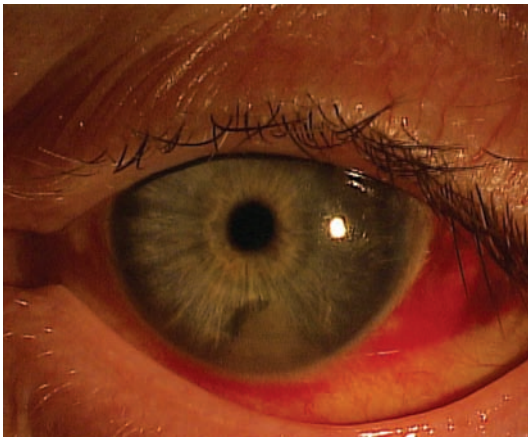
Be aware that the retained lens material can be lens cortex or lens nucleus; it can be difficult to tell them apart. "Cortical material may resolve with steroids, but nuclear likely will not," Dr. Findley says.

In any event, when confronted with retained lens material, contact the surgeon about the situation and coordinate the approach to resolution. For instance, sometimes the associated iritis won't respond to topical meds, so evacuation of the retained lens material by anterior chamber washout is required, Dr. Findley says.

Significant retained lens material, even without corneal edema, may also best be treated with AC washout, he says. However, immediate washout is not required. Patients with retained lens material that won't respond to topical steroids should be scheduled to return to the surgeon on an urgent basis. But keep up the increased steroid frequency in the meantime, Dr. Findley adds. ■



A 67-year-old white male was referred for sudden vision loss OS. He had phacoemulsification 10 years earlier. Slit lamp exam showed corneal edema and retained lens material in the inferior angle. Posterior capsule IOL remained in the capsular bag. Gonioscopy confirmed retained lens material in the inferior angle.



A 63-year-old white male was referred for the presence of flocculent, whitish material in the anterior segment one week after uneventful phacoemulsification with IOL implantation OS. He was on atropine preoperatively due to miosis. Slit-lamp exam revealed a clear cornea with retained lens material in the inferior angle. IOL was in the bag. Gonioscopy confirmed lens material in the inferior angle.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Post-CXL: Under Pressure?

While increases in measured IOP have been reported in post-CXL keratoconic eyes, it's still unclear whether or not it's a 'real' rise. **Edited by Joseph P. Shovlin, OD**

Q I recently saw a patient who had collagen crosslinking (CXL) for keratoconus and his intraocular pressure seems to have increased. Is it typical for CXL to cause a rise in IOP? What type of device would provide the most accurate measure of IOP in these patients?

A "An increase in measured IOP after CXL treatment is a typical finding in keratoconic patients, which has also been shown in relevant published studies," says Michael A. Grentzelos, MD, who coauthored a study that reported a significant increase in Goldmann applanation tonometry measurements of IOP in a prospective case series of 55 eyes in 55 patients in Greece.[1] "However, it is not clear what the reason for this finding is; we cannot be certain if the increase in measured IOP is an overestimation, as we believe, or an increase in 'true' IOP, or both," he explains.

Used to halt the progression of keratoconus, CXL substantially stiffens the cornea by creating chemical bonds within or between collagen fibrils and proteoglycans.[2] And properties of the cornea—including thickness and biomechanical strength—are known to influence measured intraocular pressure.[3]

"While the thinner corneas found in eyes with keratoconus or prior LASIK lead to underestimation of IOP, several studies have suggested that the change in biomechanical properties of the cornea that are induced by crosslinking may result in slight overestimation of IOP," says Grace Lytle, OD, MS, director of professional education at Avedro, a medical device company that makes CXL technology, in Waltham, Mass. "However, topical steroids are frequently incorporated into the postoperative regimen for crosslinking, and care should be taken to differentiate an overestimation of IOP from true IOP increase due to steroid response or other etiologies."

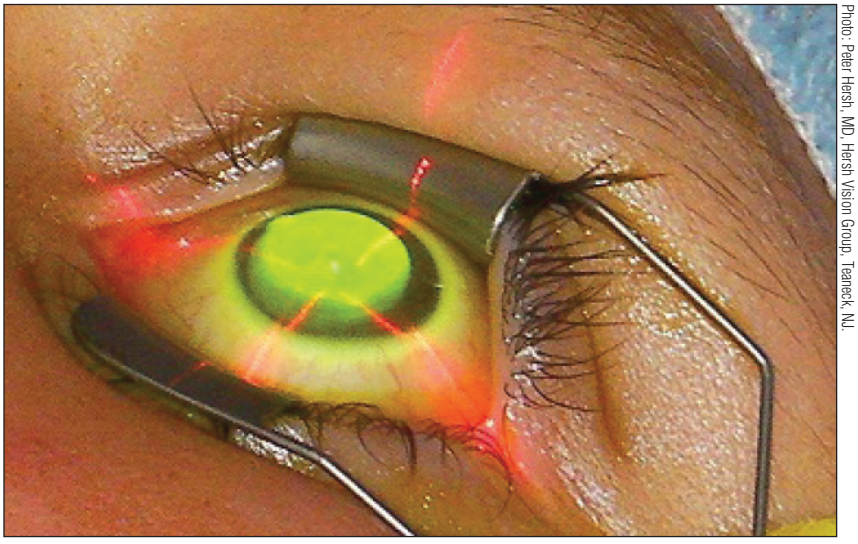

Photo: Peter Hersh, MD, Hersh Vision Group, Teaneck, NJ.

An intraoperative photo of a keratoconic patient undergoing a corneal collagen crosslinking procedure.

While there is not yet an established standard of care for measuring IOP following CXL, current literature suggests that methods of tonometry that compensate for biomechanical properties of the cornea (such as the Pascal tonometer, Ziemer Ophthalmic Systems) may provide more accurate measurement than Tonopen (Reichert Inc.) or Goldmann applanation tonometry.[1,4]

"It seems that a dynamic contour tonometer should probably provide the most accurate measurement of intraocular pressure in these patients postoperatively, but this has not been proven yet," Dr. Grentzelos says. ■

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Hold the Gluten, Please

Because ocular complications may occur secondary to conditions associated with celiac disease, being aware of CD can help you to be proactive in your patients' care.

By Joseph Pizzimenti, OD, and Carlo Pelino, OD

Years ago, most of the general public had never even heard of celiac disease—but today awareness of this increasingly common digestive condition has grown as quickly as the gluten-free sections in local supermarkets. An immune-mediated, chronic inflammatory disorder of the small intestine, celiac disease (CD) is nothing new, but it is definitely more prevalent.

Nearly five times as many Americans have CD now than in the 1950s.[1] Estimates suggest that close to 2 million people in the US, or 1% of non-Hispanic Americans, suffer with this debilitating digestive disease. So it's very likely that you may encounter a patient in your office whose immune system reacts to gluten, a protein found in wheat, barley rye, and to a much lesser extent, oats.

While CD hasn't been directly correlated with eye disease, there are a number of secondary ocular complications in many of the higher-risk populations. Being aware of a patient's celiac disease can enable you to be more vigilant and prepared to deal with some of the ancillary complications that may arise.

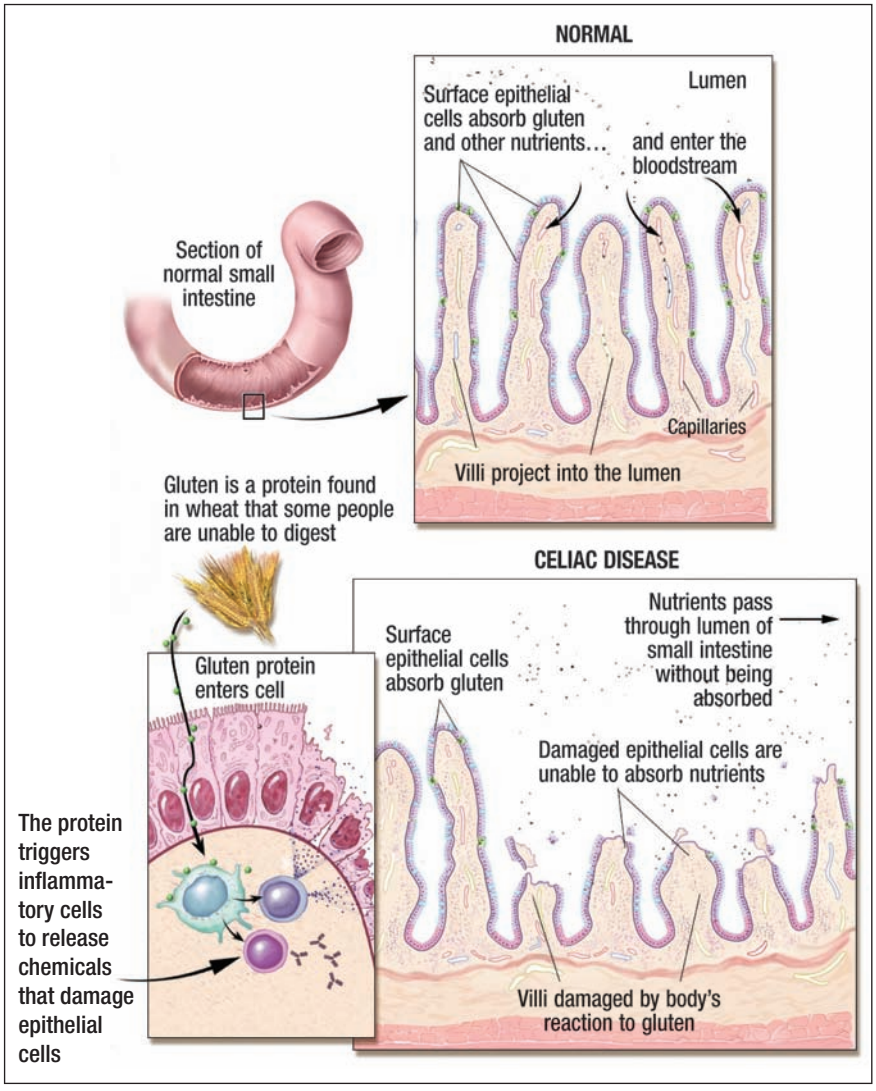

Image Courtesy: U.S. Pharmacist

The medical illustration above details the immune reaction that people with celiac disease have when they ingest gluten, damaging the small intestine.

A Few Basics to Digest

Associated with human leukocyte antigen (HLA) DQ2 and DQ8 haplotypes, CD can occur in individuals with a certain genetic background.[2] For these people, eating foods with gluten ultimately causes mucosal damage to the villi lining the intestine, keeping it from properly absorbing nutrients.

The clinical presentation of CD is age-dependent and quite varied. Classic features in the first few

years of life are malnutrition, diarrhea, abdominal pain and distension. Children and adolescents frequently present with short stature and delayed onset of puberty.[2,3]

Conversely, many patients with CD present at a later age with more subtle symptoms, so the diagnosis may be delayed. They may be symptomatic for years prior to their diagnosis, and are often initially misdiagnosed with irritable bowel syndrome. Adults have diarrhea as a major symptom of CD in approximately 50% of cases.[4] Other gastrointestinal symptoms may include abdominal pain, diarrhea or constipation, bloating and excessive gas.

Patients identified with CD by screening due to genetic and other risk factors are often asymptomatic or mildly symptomatic.[4] Due to heightened awareness and increased screening efforts, this population is rapidly growing. Some experts believe that something in the environment seems to be triggering the various genetic and biological factors that drive CD.[2-4]

Diagnostic Work-up for CD

A gastroenterology consult should be obtained when CD is suspected, and/or to screen individuals considered high risk. In addition to a detailed history and physical examination, serologic testing is performed.

There are multiple antibodies found in CD, but endomysial IgA (EMA) and transglutaminase (TG) IgA autoantibodies are the most sensitive and specific.[2] If serologic testing is positive, intestinal biopsy via endoscopy of the small intestine is required for confirmation.[2,4,5]

IgA deficiency is increased in people with CD. If the patient is IgA deficient, tissue transglutaminase IgG can be measured.

When CD is suspected clinically in the presence of IgA deficiency, upper intestinal endoscopy with biopsy should be considered, regardless of the autoantibody results.[4]

Associated Conditions and Secondary Complications

Patients with celiac disease have an increased risk of certain malignancies, the most feared complication of CD.[3] Adenocarcinoma of the small intestine is rare, though the risk for this carcinoma is increased in people with CD.

Case Report

• **History.** A 40-year-old white female presented complaining of gradual, bilateral blur and increased glare while driving at night. The patient was only recently diagnosed with celiac disease, although she had suffered intermittent bouts of diarrhea, bloating, upset stomach and weight loss for most of her adult life.

Her systemic history was remarkable for type 1 diabetes of 28 years duration, which was being treated with insulin. She reported improved glycemic control following the start of a gluten-free diet.

• **Diagnostic data.** Refraction improved her best-corrected visual acuities from 20/40 OD and OS to 20/25 OD and OS. BCVA was 20/25 due to cortical cataract on the visual axis in each eye. Clinical examination showed mild cortical lens opacities. Dilated funduscopy ruled out signs of diabetic retinopathy.

• **Management.** A new spectacle prescription with anti-reflective lenses was issued. The patient was educated about the relationship between celiac disease and type 1 diabetes. She was advised to continue with her primary physician's dietary recommendations, as better glycemic control may help her avoid ocular and other complications.

Populations at Increased Risk for CD[2-6]

In these populations, many of which have significant ocular complications, the rates of celiac disease range from 5%-10%.

- Type 1 diabetes
- Autoimmune thyroid disease (both hyper- and hypothyroidism)
- Turner and Down syndromes
- Rheumatoid arthritis
- Sjögren's syndrome

When CD is not recognized and/or treated, complications commonly develop, including iron and other nutritional deficiencies, osteopenic bone disease and growth retardation in children. There are also issues related to fertility: increased rates of infertility and spontaneous abortions.[2,3]

Several conditions are found with an increased frequency in CD, though not thought to be due to gluten ingestion. The known association between CD and type 1 diabetes is likely related to a shared genetic risk.[5] Autoimmune thyroid disease also shares genetic risk factors with CD. In addition, CD has been found at an increased rate in patients with both Turner and Down syndromes.[2,3,6]

Direct ocular complications of CD have not been identified; however, ocular complications may occur secondary to associated conditions, such as type 1 diabetes (early cataract as in our case report, as well as diabetic retinopathy and diabetic macular edema) and anemia (optic neuropathy).

If not properly diagnosed or treated, celiac disease may cause a patient's diabetic retinopathy to progress. Malabsorption of vitamins A and E may result in a pigmentary retinal degeneration not unlike retinitis pigmentosa.

Treatment Approaches

Lifelong avoidance of gluten is the primary treatment for CD. Consultation with a dietician for strict gluten-free diet education is essential in both treatment and follow-up. Certain grains, such as oats, can be contaminated with wheat during growing and processing, so dietitians generally recommend avoiding oats unless they are specifically labeled gluten-free.[2,3]

Lactose intolerance may be a side effect of CD, since the damaged small intestine cannot break down the lactose molecule. Patients should avoid dairy products until the intestinal symptoms have improved, and use dietary substances such as folate, iron, calcium and vitamins in the early stage of the disease as well.[2]

Serologic testing is used to monitor therapy, as antibody levels are expected to decline with treatment. A small subset of treated patients may fail to respond to a gluten-free diet. In some, corticosteroids might be helpful (in which case, you will want to monitor the patient's intraocular pressure).[6] In those that fail to respond to steroids, other comorbidities, such as abnormalities of the small intestine, have to be ruled out.

Early serologic diagnosis and dietary treatment in celiac disease can prevent severe, sometimes life-threatening, complications. ■

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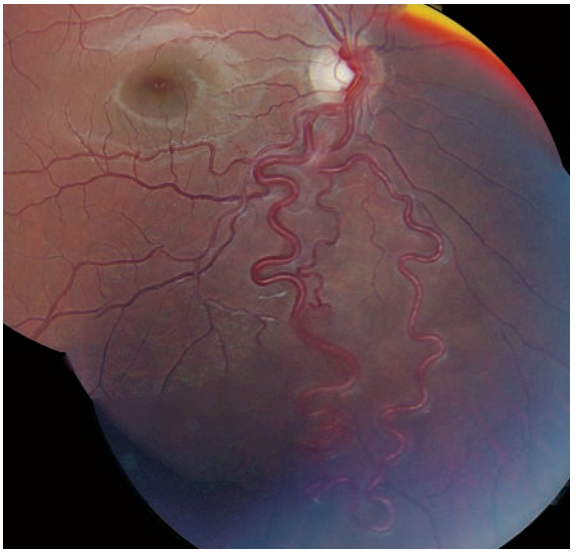
A Torturous Condition

This young patient presented with decreased distance vision and a suspected diagnosis of Marfan syndrome. What do *you* think? **By Mark T. Dunbar, OD**

A 15-year-old Hispanic male presented following a referral from his pediatrician. Recently, the patient noted difficulty with his distance vision. At the time of the examination, he was undergoing genetic testing for a potential diagnosis of Marfan syndrome.

His entering visual acuity measured 20/40 OU. With a small myopic correction, his vision improved to 20/20 OU. Confrontation visual fields were full to careful finger counting OU. His pupils were equally round and reactive, without evidence of afferent defect.

Extraocular motility testing was normal. The slit-lamp examination was unremarkable. His intraocular pressure measured 13mm Hg OU. Dilated fundus examination of the right eye revealed obvious changes (*figure 1*).



1. Fundus photograph of the right eye shows a very interesting vessel pattern exiting the optic nerve. What is the correct diagnosis?

Take the Retina Quiz

1. How would you describe the remarkable blood vessel pattern observed in figure 1?
   a. Venous tortuosity and engorgement.
   b. Arteriovenous (AV) malformation.
   c. Dilated afferent and efferent vessel.
   d. Blood vessel sheathing.

2. What does this finding represent?
   a. Hemangioma.
   b. Retinal angioma.
   c. Neovascularization.
   d. Genetic disorder.

3. What is the correct diagnosis?
   a. Combined hamartoma of the retinal pigment epithelium.
   b. Capillary hemangioma of the retina.
   c. Racemose hemangioma of the retina.
   d. Von Hippel-Lindau disease.

4. What further testing is warranted?
   a. Neuroimaging.
   b. Blood pressure measurement.
   c. Ultrasonography.
   d. Chest X-ray.

5. What significant ocular finding would you expect to see if the patient had Marfan syndrome?
   a. Choroidal hemangioma.
   b. Optic nerve glioma.
   c. Port wine staining.
   d. Lens subluxation.

For answers, go to page 130.

Discussion

The prominent dilated retinal artery and vein seen exiting the optic nerve of the patient's right eye represents an abnormal congenital AV malformation. This particular finding is termed Racemose hemangioma of the retina (also referred to as Wyburn-Mason syndrome). This condition is one of the phakomatoses—a collection of disorders characterized by systemic hamartomas of the eye, brain, skin, and sometimes the viscera and bones.[1] Even though Racemose is classified as a "hemangioma," there is no distinct tumor present.

Interestingly, 30% of patients with this condition also have similar vascular malformations located elsewhere in the body—most commonly in the midbrain.[1] In some cases, retinal lesions may be an extension of an intracranial vessel abnormality that has extended anteriorly along both the visual pathway and the optic nerve toward the retina.

The ocular/retinal manifestations of Racemose hemangioma include one or more dilated, tortuous arteries that emerge from the optic disc and extend into the retina. The

arteries typically form a distinct AV communication with a similarly dilated vein, as was seen in our patient. The AV anastomoses exhibit variable alterations in capillary and arteriolar networks, and visual symptoms are related to the size, extent and location of the abnormal vascular process. The AV malformations can vary dramatically, presenting as only subtle alterations located within the capillary system to more profound anatomical changes (as seen in this case).

In some patients, the AV anastomoses can involve the entire fundus. Such massive presentations have been described as resembling a "bag of worms," and are often associated with more severe vision loss. More advanced retinal lesions also have a higher incidence of central nervous system involvement.

Racemose hemangiomas usually are non-progressive. Orbital AV malformations may be associated with mild proptosis, conjunctival vascular dilatation or a bruit.

Except for fluorescein angiography (FA), ancillary testing contributes little information to the diagnosis. The FA exhibits early, rapid arteriole filling as the eye passes through the AV communication back toward the optic disc with a short transit time. In stark contrast to capillary hemangioma, no leakage is observed from the retinal vessels during its late phases.

Neurologic symptoms may be present, depending on lesion size, location and configuration. Patients can exhibit mental changes, headaches, seizures, visual field abnormalities and cranial nerve palsies. Other systemic complications include subarachnoid hemorrhage, hydrocephalus, cognitive deficiencies and gingival hemorrhages secondary to AV malformations in the maxilla/mandible.

In most cases of Racemose hemangioma, the retinal vascular lesions remain stable and are not treated. A neurologic evaluation is recommended, including an MRI or CT scan to rule out central nervous system (CNS) involvement.

Our patient's MRI showed no CNS involvement. Also, the genetic testing for Marfan syndrome was normal. So, exempting annual eye examinations, our patient will not require any additional follow-up care going forward. ■

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Rescula to the Rescue?

An old glaucoma medication stages a comeback in the United States.

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

A 55-year-old man was diagnosed with early primary open-angle glaucoma OD and ocular hypertension OS. He had minimal field loss in the right eye, but no visual problems in the left eye.

His central corneal thickness measured 530µm OU, and his intraocular pressure was 25mm Hg OD and 24mm Hg OS. His general health was remarkable for elevated cholesterol levels, which were controlled with a statin drug, and chronic obstructive pulmonary disease (COPD), which was controlled with an inhaler.

We started him on a prostaglandin analog. While the resultant IOP reduction was significant, so was the associated hyperemia. So, we tried another prostaglandin analog and noted similar intolerability.

Considering his COPD, topical beta-blockers were not a viable option—either alone or in fixed combination agents. Seemingly, that left topical carbonic anhydrase inhibitors and alpha-2 adrenergic agonists as the remaining choices in medical therapy.

At least, those medication classes *were* our last choices until the re-release of Rescula (unoprostone isopropyl 0.15%, Sucampo Pharmaceuticals)—a topical ophthalmic solution indicated for lowering IOP in patients with glaucoma or ocular hypertension. In this month's column, we'll take a fresh look at Rescula.

A Glance at Prostones

Prostones are a class of naturally occurring compounds that result from enzymatic catalysis of eicosanoids and docosanoids by 15-PGDH. Prostones are believed to be activators of cellular ion channels that promote fluid secretion and enhance cell protection, including the recovery of cellular barrier function. This activity gives prostones wide-ranging therapeutic potential.

As an example, lubiprostone is a bicyclic fatty acid derivative that locally activates type 2 chloride channels (ClC-2) without activation of prostaglandin receptors.[1,2] It is considered to have fundamentally different cellular effects than prostaglandins. Lubiprostone is clinically available as Amitiza (Sucampo Pharmaceuticals), which is indicated to treat constipation-predominant irritable bowel syndrome.[2]

Rescula's Debut

Rescula initially was FDA approved in 2000 to lower IOP in patients with glaucoma and ocular hypertension who were either intolerant of other medications or needed greater pressure reduction than their current drug therapy provided. The labeled dosing frequency was BID.

Unoprostone was developed from a prostaglandin metabolite, but the compound itself was considered to be a docosanoid with properties principally different from prostaglandin analogs. At the time of approval, it was believed that the mechanism of action functioned via increased aqueous outflow, but the true action never was fully understood.

Rescula disappeared from the US market in the mid-2000s, presumably due to competition from true prostaglandin analogs—which offered impressive pressure reduction and once-daily dosing.

An Encore Performance

On December 7, 2012, the FDA approved a supplemental new drug application for Rescula with the same previously established indications and dosing. Since 2000, there has been further study and insight into the mechanism of unoprostone. The medication is no longer considered to be a prostaglandin analog in the prostaglandin family, but rather a docosanoid in the prostone family.

Unoprostone's effects were studied on calcium-activated big potassium (BK) channels in the human trabecular meshwork, as well as on prostaglandin receptors. It was seen that unoprostone was a potent BK channel activator, but had no effect on prostaglandin receptors. Further study on the effects of unoprostone showed that it had a distinctly different mechanism of action than latanoprost. (It was unclear if unoprostone affected the BK channel directly or through an unidentified mechanism in this study.[4]) Although not

clearly understood, it appears that the effects of unoprostone on BK and ClC-2 channels act to increase aqueous outflow through the trabecular meshwork—a mechanism currently enjoyed only by miotics.

Clinical Effects

Rescula appears to exert an average IOP reduction of 3mm Hg to 4mm Hg throughout the diurnal cycle in patients with a mean baseline IOP of approximately 23mm Hg. Further, Rescula has been seen as an acceptable alternative to topical beta-blocker use, or as an effective adjunct for patients who already use beta-blockers.[5,6]

When evaluating the additive effects of unoprostone 0.15% with brimonidine 0.2% in patients who are already using timolol maleate 0.5%, researchers observed similar efficacy and safety between the two adjunctive medications throughout the daytime diurnal curve.[7] Upon comparing the effects of monotherapy with either unoprostone 0.15% or brimonidine 0.2%, it was noted that twice-daily brimonidine demonstrated a statistically greater peak reduction in IOP than unoprostone.[8] Still, it is worth noting that unoprostone decreased IOP over the complete 12-hour daytime dosing cycle, whereas brimonidine did not.[8]

Safety Considerations

It appears that Rescula has an encouraging safety profile. There are no known adverse cardiovascular or pulmonary effects associated with Rescula use, and no noted drug interactions. Regarding local ocular adverse effects, Rescula compares favorably with timolol maleate. Hyperemia incidence secondary to Rescula use is similar to that associated with timolol maleate. The only adverse ocular effect seen more frequently with Rescula compared to timolol maleate is transient stinging/burning upon instillation.

There is a 1% rate of iris color changes in patients who use Rescula.[9] Additionally, multiple studies have documented a low rate of increased eyelid periocular skin pigmentation and upper eyelid sulcus deepening after unoprostone use.[10,11]

We now have a "new" topical option to lower IOP. Rescula can impart a sustained, modest IOP reduction throughout the diurnal cycle with an ocular safety profile similar to that of timolol maleate, but without the systemic contraindications and adversities of beta-blockers. Further, Rescula may offer an option to increase aqueous outflow through the trabecular meshwork without the local ocular adverse effects of miotics, and can be added to conventional beta-blocker therapy.

At this time, it is not clear if Rescula will have an additive effect with prostaglandin analogs. Nonetheless, Rescula may be a viable option for select patients who need a modest IOP reduction and are intolerant of true prostaglandin therapy or have systemic contraindications to beta-blockers. ■

Dr. Sowka is a member of Sucampo Pharmaceutical's advisory board. Neither he nor Dr. Kabat has direct financial interest in any of the products mentioned.

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An Alternative to PPV

Recently approved Jetrea could be a less invasive treatment option for vitreomacular traction syndrome. **By Diana L. Shechtman, OD, and Paul M. Karpecki, OD**

A 67-year-old Hispanic male presented with a history of visual distortion in his left eye. His best-corrected visual acuity measured 20/20 OD and 20/30 OS. Amsler grid testing was positive for metamorphopsia OS.

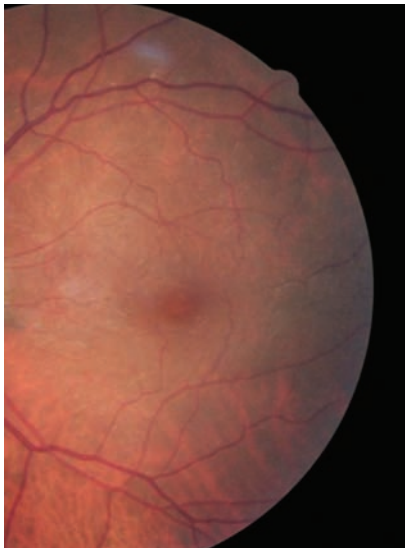
Dilated fundus exam revealed wrinkling within the left macula (*figure 1*). A spectral-domain optical coherence tomography (SD-OCT) scan of the left eye revealed the presence of vitreomacular traction (VMT) syndrome (*figure 2*). What are his management options?

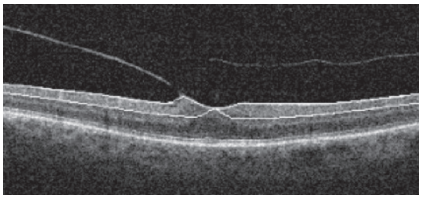
PVD and VMT

A posterior vitreous detachment (PVD) is a normal physiologic process that invariably occurs with advanced age. Age-related biochemical changes result in vitreal liquefaction and weakening of the vitreoretinal interface. This process contributes to the development of a PVD. Such detachments often are associated with a complete separation of the vitreous cortex from the internal limiting membrane (ILM). Sometimes, however, a partial PVD may result. In these instances, the remaining adherence to an area of firm vitreoretinal attachment may yield a number of distinct conditions—including VMT syndrome.

VMT is a macular entity associated with an incomplete PVD. The partial vitreomacular adhesion induces tractional forces resulting in both structural and functional damage. There are an array of variable symptoms, which may include metamorphopsia, decreased visual acuity and photopsia. The capacity of OCT to provide high-resolution images of the vitreal-retinal interface has fostered a better understanding of VMT.

VMT represents a broad spectrum of retinal diseases, including cystoid macular edema (CME), epiretinal membranes (ERMs) and macular hole (MH) formation.[1,2] The natural disease course is variable. Depending on the individual case, patients may remain stable; experience a spontaneous, complete PVD; or continue to progress.[3,4]





1, 2. Dilated fundus exam (left) and OCT scan (bottom) of our patient's left eye. Should he be monitored for VMT progression, or is he a potential candidate for intravitreal Jetrea?

Traditional Intervention

Although many cases simply are monitored, disease progression and associated visual decline often make pars plana vitrectomy (PPV) a necessity. Progression may lead to visual distortion, vision loss and/or further deterioration of the retinal structures—as well as associated complications.

PPV has been shown to provide a dramatic normalization of the macular contour and a subsequent improvement in symptoms.[5] Just like any surgical procedure, however, PPV carries inherent risks—including cataracts, retinal detachment, residual vision loss and infection. Further, the postoperative recovery period can be both taxing and woefully inconvenient for the patient.

Intravitreal Microplasmin

Previous studies have shown that autologous plasmin enzyme had lysing capabilities, which could help induce a PVD.[6] Microplasmin is a recombinant protease plasmin with proteolytic properties against fibronectin and lamin (components of the vitreoretinal interference). It functions as a thrombolytic agent and causes a pharmacological vitreolysis. The introduction of microplasmin into the vitreous would, in essence, induce a nonsurgical PVD. The enzymatic agents alter the biochemistry of vitreous, yielding both

vitreous liquefaction and a separation between the vitreous cortex and ILM.

Two multicenter Phase III clinical studies (the MIVI-TRUST trials) evaluated the safety and efficacy of a single 0.125mg intravitreal injection of microplasmin for the treatment of VMT.[7] Inclusion criteria included observation of VMT via OCT and associated visual acuity of 20/25 or worse.

Approximately 650 individuals with various maculopathies, including VMT, ERMs and MHs, were evaluated. Patients were randomly assigned to receive either microplasmin or a placebo injection, and were evaluated during the subsequent six months. VMT resolution was noted in 26.5% of those in the treatment group, compared to 10% in the placebo group.[7] Additionally, MH closure was documented in 40.6% of the treated group vs. just 10.6% of the placebo group.[7]

Ocular side effects associated with microplasmin injection were minimal and transient. (In fact, most side effects were local and associated with the intravitreal injection itself.) The most common adverse effects included floaters, mild pain and conjuctival hemorrhage. Serious adverse effects, such as retinal detachment, only were observed in 2% of the treated group vs. 4% in the placebo group.[7]

The trial data collected by the MIVI-TRUST researchers facilitated FDA approval of Jetrea in January 2013. For the first time ever, our patients now have more than one potential treatment option for symptomatic VMT. But will Jetrea, in fact, change the standard of care for those with VMT syndrome? Only time will tell. ■

Drs. Shechtman and Karpecki have no direct financial interest in any of the products mentioned.

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Contact Lenses

1-Day Acuvue TruEye

Vistakon recently introduced 1-Day Acuvue TruEye (narafilcon A) silicone hydrogel daily disposable lenses to the US market. The narafilcon A product will gradually replace 1-Day Acuvue TruEye (narafilcon B), which was launched in the US in 2010. The narafilcon B product was only being used in the US and a few Caribbean countries, while the narafilcon A product, launched in 2008, has become the standard throughout Europe, Japan and other international markets.

While both versions share most of the same material properties, they are different products. One key difference is that the narafilcon A product is available in two base curves (8.5 and 9.0), allowing more patients to be fit with this lens, and has a DK/t of 118 for increased oxygen transmissibility with minimal impact to modulus.

1-Day Acuvue TruEye (narafilcon A) lenses, which are only sold in packs of 90, are now available at some US offices, with distribution expected to grow throughout the coming months.

Visit www.acuvueprofessional.com.

iSight Contact Lens Line

GP Specialists rebranded its entire custom made-to-order soft contact lens product line with the name iSight. This includes the designs the company acquired through its purchase of American BioCurve in 2011. The company says it now offers "one of the largest portfolios of made-to-order products in the industry," which include:

- iSight DW sphere and toric contact lenses
- iSight Gold sphere and toric contact lenses
- iSight SiHy silicone hydrogel sphere and toric contact lenses
- iSight MCL multifocal sphere and toric contact lenses
- iSight Aphakic contact lenses
- iSight Pediatric contact lenses

Visit www.gpspecialists.com.

Exam Room Equipment

Kinetic Intelligent Exam Console

Eye Designs recently unveiled its Kinetic Intelligent Exam Console, a new exam lane system designed to address the daily requirements of the medical profession and meet the challenges presented by constant use of the exam room desk, sink, computer and other essential components.

The solid-surface countertop with radius corners, solid-surface sink bowls and hands-free electronic faucet are included to facilitate best sanitation and hygiene practices. Constructed with a water-resistant core, the sink bases won't be damaged by plumbing leaks or accidental overflow, the company says.

Built-in wire management keeps all wiring and cords out of sight under the cabinet and the built-in computer/printer station cabinets are equipped with ventilation ports. The console features a locking medical record drawer for HIPAA compliance, and locking medicine cabinet and drawers to secure extra supplies and medicine. The smart office accessory

Frames

Dragon Mansfield

The Mansfield, the latest offering from Dragon for Spring 2013, fuses modern simplicity with a timeless silhouette. Largely inspired by Hollywood sex symbol Jayne Mansfield, the virtually frameless design features a four-base polycarbonate shield lens, stamped metal plaque inlay on the temple and external metal rivets.

The frame is available in a variety of cool hues, including matte black, matte tortoise, Palm Springs pool, and black and white.

Visit www.dragonalliance.com.

Fendi Spring/Summer 2013 Collection

The Fendi Spring/Summer 2013 Eyewear Collection marries elegant designs with creativity in colors and materials. The Fendi logos are interpreted in a number of different ways, incorporating metal accents, Swarovski jewels and temple cutouts.

Women

FS5331

• *FS5331.* Inspired by the chic 2Jours oversized leather tote bag, this design features butterfly-shaped lenses and a stylish metal detail that runs along the brow line. It's available in black, gray, cream, Havana and vintage/Havana.

FS5284

• *FS5284/F1018.* FS5284, the optical version of F1018, incorporates a zyl frame with large square lenses. Patterned frame fronts connect to contrasting colored temples that are wood-inspired for a unique look. They are available in black, striped brown/gold, marble brown and Havana green.

F1018

F1030

• *F1030.* A strong, dark zyl accents colorful frame fronts along the brow line, and the temples feature the iconic Fendi Pequin pattern and small metal accent pieces. This style is available in black/Havana, black/brown, black/red, Havana/beige and Havana/rose.

F1036

• *F1036.* Geek chic describes this injected frame, with classic large square frame fronts offset by contrasting colored temples. The "F" Fendi logo starts at the temple endpiece and runs halfway down the temple to add sophistication. It's available in black, classic black, brown, Havana, blonde Havana and bordeaux.

Men

FS5335

• *FS5335.* Inspired by the classic wayfarer shape, this masculine frame features square lenses surrounded by brilliant zyl. Unique features like a keyhole nose bridge and yellow hinges make this frame stand out. It's available in black, Havana and vintage Havana.

F1027

• *F1027.* Classic large square frame fronts in solid colors make this men's optical extremely wearable. Striped, wood inspired temples complete with the Fendi logo and yellow hinges add a stylish feel to this men's optical frame with classic, large square frame fronts. It's available in black, Havana, green gradient and dark red gradient.

Visit www.marchon.com.

wall panel includes chart holders, a bulletin board, phone holder, literature holders, tissue and glove dispensers and shelves for additional supplies.

Electronic ophthalmic control panel integration and an optional trial lens drawer are also available. Visit www.eyedesigns.com.

Low Vision

Ocutech SightScope Flip

The new SightScope from Ocutech could provide a new option for patients who have had visual impairment since birth, as well as for seniors suffering from macular degeneration. These specially designed glasses allow for convenient switching of line-of-sight between the carrier lenses and the telescope with just a slight head tilt. Patients can simply flip

the telescope out of the way when it's not required.

For patients with negligible distance prescriptions, you may either attach the SightScope clip-on demonstrator onto their own distance eyeglasses or use the SightScope mounted on the demonstrator frame. For patients with significant distance refractive error, attach the SightScope clip-on demonstrator onto their own distance eyeglasses.

- 1.7x is indicated for visual acuity of 20/50 or better for viewing distances beyond five feet away (32.5° binocular field of view/26° monocular field of view).
- 2.2x is indicated for

visual acuity of 20/80 or better for viewing distances beyond six feet away (22.5° binocular field of view/ 18° monocular field of view).

The SightScope is completely adjustable, has standard and custom frame options, a wide field of view and a built-in sunshield that reduces glare and reflections. You can prescribe for bioptic or full-diameter positions as well as binocular or monocular options.

Visit www.ocutech.com.

Exams/Dispensing

AP-7000 Automated Perimeter

Kowa's next-generation automated perimeter, the AP-7000, offers an extensive variety of test strategies and screening programs. Full-threshold modes offer macular, central and peripheral coverage up to 80°, while screening modes provide swift evaluation of the visual field for relative or absolute scotomas. To shorten test times, quick modes are available for both threshold and screening modes, according to Kowa.

Special features include perimetry on fundus images, easy touch-screen operation with a tabbed user interface, kinetic perimetry, chronological analysis over time and advanced network connectivity. By automatically correlating the fundus image (from a fundus camera, OCT or SLO) with the static visual field, early detection of glaucoma is possible, the company says.

Visit www.kowa-usa.com.

EHR Integration

MaximEyes/Reichert

With new built-in bidirectional integration between First Insight's MaximEyes EHR software and Reichert's Auto Phoroptor RS Refraction System, eye care providers will save time and improve efficiency, the companies say.

This integration allows users to quickly move through the refraction process by uploading lensometer or autorefractor data directly into a MaximEyes EHR patient exam record, then exporting the final data (i.e., manifest refractions, pupillary distance and unaided VA) from MaximEyes EHR to Reichert's Auto Phoroptor RS Refraction System.

Visit www.first-insight.com. ■

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Meetings + Conferences

May 2013

■ **9-10.** *117th Annual Meeting and Spring Seminar.* DeVos Place, Grand Rapids, Mich. Hosted by: Michigan Optometric Association. Contact Amy Possavino at amy@themoa.org or call (517) 482-0616. Visit www.themoa.org.

■ **11-18.** *AEA Optometric Cruise Seminar.* Alaska-Inside Passage–Aboard the Star Princess. Itinerary: Seattle, Juneau, Skagway, Glacier Bay National Park, Ketchikan, Victoria, Seattle. Email aeacruises@aol.com or call (888) 638-6009. Visit www.optometriccruiseseminars.com.

■ **17-19.** *2013 AZOA Spring Congress.* Hilton Tucson El Conquistador Golf & Tennis Resort, Tucson, Ariz. Hosted by: Arizona Optometric Association. Contact Kate Diedrickson at kate@azoa.org or call (602) 279-0055. Visit www.azoa.org.

■ **17-19.** *Nova Southeastern University's 17th Annual Eye Care Conference & Alumni Reunion.* NSU College of Optometry, Fort Lauderdale, Fla. Contact Vanessa McDonald at oceaa@nova.edu or visit http://optometry.nova.edu/ce.

■ **May 31-June 1.** *East Coast Optometric Glaucoma Symposium.* DoubleTree by Hilton Bethesda, Md. Hosted by: *Review of Optometry.* Meeting chair: Murray Fingeret, OD. CE hours: 12. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

June 2013

■ **7-9.** *Ocular Symposium: Pearls in Ocular Diagnosis.* Holiday Inn Golden Gateway, San Francisco. CE hours: 24. Contact Lorraine Geary at ocularsymp@aol.com or call (415) 278-9940.

■ **13-16.** *Maui 2013.* Wailea Beach Marriott Resort & Spa, Maui, Hawaii. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, OD. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

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

July 2013

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

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

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

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

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

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

■ **26-28.** *Nova See St. Simons.* The King and Prince Beach & Golf Resort, St. Simons, Ga. Sponsored by: Nova Southeastern University College of Optometry and Luxottica. Faculty: David Loshin,OD, PhD; Rim Makhlouf, OD; Nicole Patterson, OD; Diana Shechtman, OD; Joseph Sowka, OD; and Robert McCullough, OD. CE hours: 17. Contact Vanessa McDonald, manager of continuing education, at oceaa@nova.edu or (954) 262-4224. Visit http://optometry.nova.edu/ce.

August 2013

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

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

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

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

September 2013

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

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

■ **19-22.** *GWCO Congress 2013: Focused on the Future.* Oregon Convention Center, Portland. Hosted by: Great Western

Council of Optometry. Featured speaker: Jim Trunick, OD. Contact Wayne Oman, deputy director, at gwco@gwco.org or (503) 654-1062. Visit www.gwco.org.

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

■ **21-22.** *Fall Conference 2013.* Steele Auditorium, NSU Campus, Orlando, Fla. Hosted by: Nova Southeastern University College of Optometry. Program Director: Joseph Sowka, OD. Contact Vanessa McDonald, manager of continuing education, at oceaa@nova.edu or (954) 262-4224. Visit http://optometry.nova.edu/ce.

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

October 2013

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

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

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

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

■ **12-13.** *3rd Annual Forum on Ocular Disease.* WDW Swan and Dolphin Resort in Orlando, Fla. Hosted by: PSS EyeCare. CE hours: 18. Featured speakers: Randall Thomas, OD; Ron Melton, OD; Murray Fingeret, OD; Deepak Gupta, OD. Contact Sonia at education@psseyecare.com or go to www.PSSEyeCare.com and click on "Orlando."

November 2013

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

To list your meeting, please send the details to:

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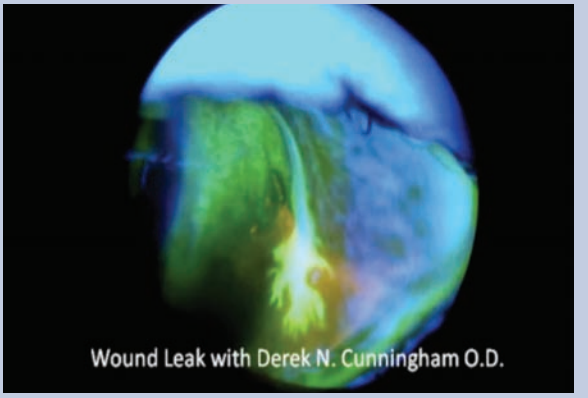
How to Handle Wound Leakage

It's usually self-limiting, and prognosis is excellent. But you do play a vital role.

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



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

On The Web ›› View a narrated video of a wound leakage visualized with fluorescein.

Short-term, postoperative complications of cataract surgery are something every comanaging optometrist should be comfortable with.

Postoperative lens exchange complications are best categorized by the timeframe in which they typically occur. At the one-day post-op exam, the major complications to look for are increased IOP and corneal wound leakage (sometimes leading to decreased IOP). Although increased IOP is much more common than wound leakage, it is not viewed as serious due to its self-limiting nature. Endophthalmitis, the most devastating of all complications, typically does not present until three to seven days after cataract surgery.

Although there are several different techniques for performing cataract surgery, modern phaco has—by far—been the most widely adopted. To minimize tissue disruption, most surgeons will use a corneal incision roughly 3mm to 4mm in length. This serves the dual purpose of permitting phaco probe entry and facilitating subsequent intraocular lens delivery. A second, side-port corneal incision is much smaller and undergoes far less manipulation.

Key clinical signs that you may have a wound leak on your hands include poor vision, low eye pressure (below 8mm Hg), complaints of epiphora, shallow anterior chamber, large corneal folds, choroidal effusion and optic nerve edema. If any of these are noted, be especially diligent to ensure good wound closure. Although any full-thickness corneal incision can leak, the vast majority of the time, it will be confined to the phaco incision.

The easiest and best way to identify wound leakage is with the instillation of fluorescein. Generally, close inspection of the wound under cobalt blue light will show leaking intraocular fluid between blink with no special manipulation. If wound leakage is not seen clearly but is still suspected, "paint" the wound with a fluorescein strip, as shown in the video. This deposits substantial amounts of dye around the wound and enhances visualization of any leakage.

Management of wound leakage will vary based on the cause, timing, severity and general appearance. The majority of leaks will be visible in the first day or two after surgery, and will be self-sealing if mild. If wound leakage is moderate but the anterior chamber is still formed, use a bandage contact lens to decrease lid interaction and promote re-epithelialization. Other potential strategies at this point include decreasing steroid use, adding cycloplegia and initiating topical aqueous inhibitors. If the anterior chamber is flat or the IOP is consistently very low, have the patient see the surgeon for surgical repair.

Postoperative wound leakage after cataract surgery is typically a condition that can be managed well by comanaging optometrists. Reassure patients by explaining the condition's self-resolving nature and excellent visual prognosis. We prefer to see any patient with wound leak on a daily basis until the wound is fully closed, and continue broad-spectrum topical antibiotic therapy for several days after the wound is fully closed. *(Note: it is essential to remind the patient about the importance of using their antibiotic eye drops as long as they are functionally exposed to the infection risks of an open globe.)* ■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Diagnostic **Quiz**

Time to Issue a 'YAG Order?'

By Andrew S. Gurwood, OD

History

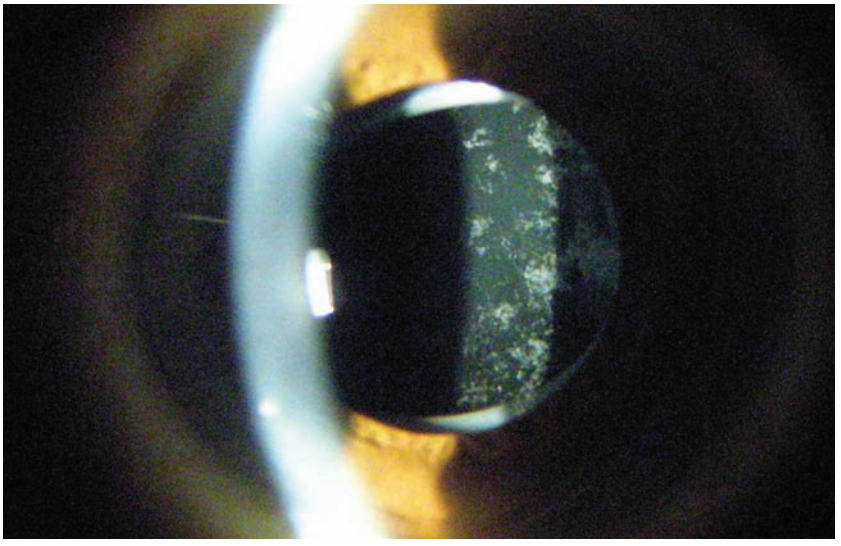
A 73-year-old black female presented for a routine follow-up examination six months after undergoing phacoemulsification with intraocular lens implantation in her right eye.

The patient explained that, while she was very happy with the outcome of the procedure, she noticed more glare at night and believed that her distance vision was not as good as it was immediately following the operation. She attributed this difficulty to the cataract in her fellow eye, and expressed a desire to have it removed.

The patient completed her postoperative dosing regimen, and denied use of any other medications. She reported no known allergies of any kind.

Diagnostic Data

Her best-uncorrected visual acuity was 20/40 OD, and her best-corrected visual acuity measured 20/25 OS. The external examination findings were normal, with no evidence of relative afferent pupillary defect.



Slit-lamp view of our 73-year-old patient's right eye. What do you notice?

Refraction revealed slight astigmatism in her right eye and mild myopia in her left eye, which was negligibly different than her habitual correction.

The anterior segment examination was normal. Intraocular pressure measured 17mm Hg OU. The dilated fundus examination was unremarkable and noncontributory. The pertinent slit-lamp findings are illustrated in the photograph.

Your Diagnosis

How would you approach this case? Does the patient require any additional tests? What is your diagnosis? How would you manage this patient? What is the likely prognosis?

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

Retina Quiz Answers *(from page 108):* 1) b; 2) a; 3) c; 4) a; 5) d.

Next Month in the Mag

Our June issue features the 4th Annual Retina Report. Topics include:

- *A Glimpse at the Modern-day Retinal Examination*
- *Controversies in Macular Pigment and Nutrition*
- *The Genetics of Ocular Disease* (earn 2 CE credits)

REVIEW OF OPTOMETRY (ISSN 0147-7633) IS PUBLISHED MONTHLY, 12 TIMES A YEAR BY JOBSON MEDICAL INFORMATION LLC, 100 AVENUE OF THE AMERICAS, NEW YORK, NY 10013-1678. PERIODICALS POSTAGE PAID AT NEW YORK, NY AND ADDITIONAL MAILING OFFICES. POSTMASTER: SEND ADDRESS CHANGES TO REVIEW OF OPTOMETRY, PO BOX 2025, SKOKIE, IL 60076. SUBSCRIPTION PRICES: US: ONE YEAR $56; TWO YEARS $97, CANADA: ONE YEAR $88, TWO YEARS $160, INT'L: ONE YEAR $209, TWO YEARS $299. FOR SUBSCRIPTION INFORMATION CALL TOLL-FREE (877) 529-1746 (USA ONLY); OUTSIDE USA, CALL (847) 763-9630 OR FAX (847) 763-9631. PUBLICATIONS MAIL AGREEMENT NO: 40612608. CANADA RETURNS TO BE SENT TO BLEUCHIP INTERNATIONAL, P.O. BOX 25542, LONDON, ON N6C 6B2.

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