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REVIEW® OF OPTOMETRY

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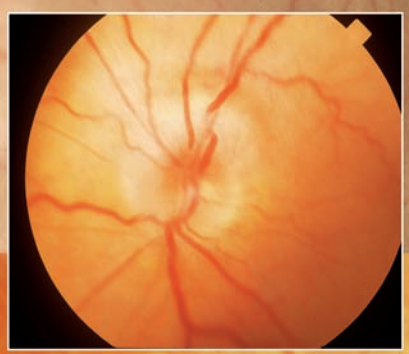

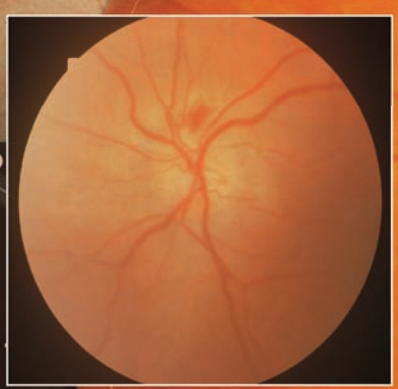

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TobraDex® *ST*

(tobramycin/dexamethasone ophthalmic suspension) 0.3%/0.05%

Indications and Usage: For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant isolates. Streptococci, including some Group A and other beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii,* most *Proteus vulgaris* isolates, *Haemophilus influenzae, H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus* and some *Neisseria* species.

Important Safety Information

Contraindications:

- TOBRADEX® ST Suspension, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- Hypersensitivity to any components of the medication

Warnings & Precautions:

- Intraocular pressure (IOP) increase—prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If used for 10 days or longer, IOP should be monitored.
- Sensitivity to topically applied aminoglycosides may occur
- Cataracts—use of corticosteroids may result in posterior subcapsular cataract formation
- Delayed healing—the use of steroids after cataract surgery may delay healing and

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increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining

- Bacterial infections—prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated
- Viral infections—employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex)
- Fungal infections—fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use
- If product is used in combination with systemic aminoglycoside antibiotics the patient should be monitored for total serum concentration of tobramycin

Please see prescribing information on adjacent page.

TobraDex® *ST*

(tobramycin/dexamethasone ophthalmic suspension) 0.3%/0.05%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TOBRADEX® ST ophthalmic suspension safely and effectively. See full prescribing information for TOBRADEX® ST.

TOBRADEX® ST (tobramycin / dexamethasone ophthalmic suspension) 0.3%/0.05%
Initial U.S. Approval: 1988

----------INDICATIONS AND USAGE----------

TOBRADEX® ST is a topical antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists

----------DOSAGE AND ADMINISTRATION----------

- Instill one drop into the conjunctival sac(s) every 4 to 6 hours. (2.1)
- During the initial 24 to 48 hours, dosage may be increased to one drop every 2 hours. (2.1)
- Frequency should be decreased gradually as warranted by improvement in clinical signs, but care should be taken not to discontinue therapy prematurely. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

TOBRADEX® ST ophthalmic suspension contains 3 mg/mL tobramycin and 0.5 mg/mL dexamethasone.

----------CONTRAINDICATIONS----------

- TOBRADEX® ST, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. (4.1)
- Hypersensitivity to any component of the medication (4.2)

----------WARNINGS AND PRECAUTIONS----------

- Intraocular pressure (IOP) increase-Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored. (5.1).
- Sensitivity to topically applied aminoglycosides may occur. (5.2)
- Cataracts- Use of corticosteroids may result in posterior subcapsular cataract formation. (5.3)
- Delayed healing- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. (5.4)
- Bacterial infections- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. (5.5)
- Viral infections- Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). (5.6)
- Fungal infections- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.7)
- If product is used in combination with systemic aminoglycoside antibiotics the patient should be monitored for total serum concentration of tobramycin. (5.8)

----------ADVERSE REACTIONS----------

Most common adverse reactions to topical ocular tobramycin are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritus, eyelid edema, and conjunctival hyperemia. The reactions due to the steroid component are increases in intraocular pressure with possible development of glaucoma.

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Revised: February 2009

References:

1. TOBRADEX® ST Suspension package insert. **2.** Scoper SV, Kabat AG, Owen GR, et al. Ocular distribution, bactericidal activity and settling characteristics of TobraDex® ST ophthalmic suspension compared with TobraDex® ophthalmic suspension. *Adv Ther.* 2008;25(2):77-88.

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VOL. 149 NO. 5 ■ MAY 15, 2012

IN THE NEWS

ASCRS has established **a new membership category** that will enable certain **optometrists** to apply for **membership** to the organization for the first time. To be eligible for the membership, optometrists must be employed by an ASCRS member, board-certified ophthalmologist. The new category emphasizes a **working partnership** between ophthalmologists and optometrists and encourages arrangements in which employed optometrists—directed and overseen by ophthalmologists—provide a critical role in the delivery of non-surgical eye care.

On June 28 at Optometry's Meeting in Chicago, the **Optometric Historical Society** will honor the life and contributions of **Dr. Irvin Borish**, considered by many as the father of modern optometry. Dr. Borish passed away at he age of 99 on March 3. Known as the architect of modern optometry, Dr. Borish authored the definitive reference text "Clinical Refraction," and was named the most influential O.D. of the 20th century. The tribute to Dr. Borish will be led by his long-time friend, Alden N. Haffner, president emeritus of SUNY College of Optometry.

VSP Global elected **Stuart J. Thomas, O.D.,** as chairman of the board for a term of two years. A practicing optometrist in Athens, Ga., for 28 years, Dr. Thomas has served on the VSP board of directors since 2005 and as vice chairman since 2010. "As a practicing independent optometrist, I look forward to leading the change and support efforts within VSP Global companies to further our mission and strengthen private practice with innovative technologies and programs supporting patient access," he said.

Update on Appalachian College of Optometry

New optometry school to begin classes in Fall of 2014.

By Cheryl G. Murphy, O.D., Contributing Editor

Optometrist Brian Looney is hard at work making one of his dreams a reality—an optometry school in his hometown of Grundy, Va.

Dr. Looney was recently announced as the founding president of the Appalachian College of Optometry. Currently, he is working on the self study, which he will submit to the Accreditation Council on Optometric Education in February 2013 to acquire provisional accreditation for the Appalachian College of Optometry.

Once that accreditation is granted, Dr. Looney will begin hiring faculty and recruiting a class of 48 students, with an expected first day of classes at ACO to begin Fall 2014.

The location for the college would be on the former site for the Appalachian College of Pharmacy. Dr. Looney says the building is 38,000 sq. ft. and is already suitable for use with lecture halls, laboratory space, faculty offices, administrative offices and student areas.

"There would also be new construction, a 20,000-sq. ft. building, which would house the college's eye clinic; however, the new construction will not be started until provisional accreditation is obtained," he says. "Construction would be completed by the time the first class become third-years and are ready to start clinical rotations."

Founding president of the Appalachian College of Optometry, Brian Looney, O.D.

The new school of optometry was announced more than a year ago when the Virginia Coalfield Economic Development Authority approved a $5.6 million loan for the development the college.

For his part, Dr. Looney owns two optometric practices in Grundy and Welch, and plans to eventually integrate his current patient base into the school's eye clinic. He believes the rural area would offer students a wide patient base and a comprehensive clinical education, in which they would be trained to handle any and all situations that may present—because there is currently no ophthalmology presence in the area.

Ocular Tremor Signals Parkinson's Disease

Ocular tremor appears to be an early warning sign for Parkinson's disease (PD), according to a new a study by researchers in Virginia. Measurement of the tremor could even be used to diagnose the disorder—and patients could be provided with therapy—well before more prominent problems manifest.

"All patients with PD exhibited persistent ocular tremor that prevented stability during fixation," the authors concluded. "The pervasiveness and specificity of this feature suggest that modern, precise oculomotor testing could provide a valuable early physiological biomarker for diagnosing PD."

For the study, published online in *Archives of Neurology*, researchers used a video-based binocular eye tracker to compare the oculomotor function of the study group (112 patients diagnosed with PD) against that of the control group (60 age-matched subjects).

The researchers found that all 112 members of the study group demonstrated "persistent instability" when fixating on a target (averaging a fundamental frequency of 5.7Hz, a horizontal amplitude of 0.27˚ and a vertical amplitude of 0.33˚), while just two of the 60 control group participants demonstrated such tremors (and one of those two eventually displayed symptoms of PD).

Researchers also determined that angle of gaze bore no impact on the instability, that the movements were conjugate (i.e., in both eyes), and that each patient's tremors were consistent over the course of each recording—saccades, blinking or other eye movements did not disrupt them.

The researchers also found that the amplitude and frequency of PD patients' visual instability did not correlate with the duration of disease, the United Parkinson's Disease Rating Scale score or the medications being taken. In fact, no differences were seen between those taking medication and those not taking medication for PD.

"The fact that this behavior was universally observed in every tested patient with PD, including unmedicated patients, suggests that ocular tremor is a function of the disease process and not induced by medication," the researchers wrote.

Although the tremor requires special equipment to detect it, "The test is actually very simple so [it]…could be used as a screen by all or many physicians," said study author Mark S. Baron, M.D., of the VA Medical Center in Richmond, Va., in an interview with *MedPage Today*.

"The study clearly demonstrated that patients previously diagnosed with PD, regardless of treatment regimen, displayed unique ocular motility deficits, similar to nystagmus," comments Michael N. Block, O.D., who is in private practice and is a consultant in geriatric nursing facilities in New York. "The authors posit that these deficits could serve as a biomarker for PD."

Then again, Dr. Block says, the study does not establish the predictive value of these oculomotor tests.

Gitchel GT, Wetzel PA, Baron MS. Pervasive ocular tremor in patients with Parkinson disease. Arch Neurol. 2012 Apr 9 [epub ahead of print].

Poor Glaucoma Drop Technique: Good Intentions, Bad Instillations

Nine out of 10 glaucoma patients are not administering their drops correctly, according to a study in the March issue of *Journal of Glaucoma*.

Researchers in India examined a side of patient non-compliance that sometimes is overlooked—the unintentional, improper dosing and instillation of meds. Raghav Gupta, M.D., and colleagues observed and evaluated 70 primary open-angle and primary angle-closure glaucoma patients, ages 35 to 70, who had been self-administering glaucoma meds for at least six months. Individuals suffering from arthritis, tremors and other impairments that might interfere with their ability to correctly instill drops in their eyes were excluded from the study.

The patients were asked to instill one drop from a bottle of artificial tears into one eye using

(continued on page 8)

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Reference: 1. Data on file. Johnson & Johnson Vision Care, Inc. 2011.

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(continued from page 6)

the same technique as they do to instill their glaucoma meds at home. The number of drops they squeezed out of the bottle actually ranged from one to eight drops. Additional results showed:

- 31% of patients "missed the mark," dropping the eye drops on their eyelids or cheeks.
- 75% touched the tip of the bottle to their eye or periocular tissue.
- Just 28% correctly closed their eyes after instilling the drops.
- Just 5% occluded their puncta.

After analyzing these results, Dr. Gupta and colleagues concluded that a mere six of the 70 glaucoma patients tested "were able to correctly instill the eye drop (squeeze out one drop and instill it into the conjunctival sac without bottle tip contact)."

The researchers conceded that there may be limitations inherent in their study, such as behavior modifications that patients exhibit when they know they are being observed. Also, they were not sure if socioeconomic status and literacy of subjects could have influenced the results.

Glaucoma specialist Richard Madonna, M.A., O.D., associate professor at SUNY College of Optometry, agrees with the researchers' emphasis on the importance of doctors proactively demonstrating and teaching the proper technique of eye drop instillation to their glaucoma patients.

"Patients need to be educated (on proper instillation techniques) and it is our job to provide that education, just as we provide education on the medication's side effects or on the results of a visual field," he says.

Dr. Madonna suggests utilizing technicians and staff who normally train patients on contact lens insertion and removal to carefully demonstrate proper drop instillation to glaucoma patients using artificial tears.

He advocates giving glaucoma patients a "pop quiz" on drop instillation at follow-up visits, as suggested in the study. "If patients are asked to demonstrate the technique, an opportunity for teaching may present itself if the patient is having a problem," he says.

Gupta R, Patil B, Shah BM, et al. Evaluating eye drop instillation technique in glaucoma patients. J Glaucoma. 2012 Mar;21(3):189-92.

Glaucoma in the U.S. is Underdiagnosed—and Overdiagnosed

The incidence of new glaucoma diagnoses in the United States varies greatly across different geographic areas, according to a study in the April 3 online version of *Ophthalmology*. The researchers believe that clinicians in certain regions may be more likely to either underdiagnose or overdiagnose various forms of the disease, including both angle-closure glaucoma (ACG) and open-angle glaucoma.

In this study, the researchers examined a random sample of Medicare claims submitted by eye care providers from 2002 to 2008 across nine large geographic regions and 179 subregions.

After completing their data analysis, the researchers determined that individuals who live in New England or the Mid-Atlantic states are approximately 30% more likely to be diagnosed with glaucoma than those who live in the Southeastern states.

In particular, the data suggested that ACG is largely underdiagnosed throughout most of the country. By contrast, the researchers determined that New York City in particular had the highest proportion ACG diagnoses across all analyzed regions—indicating that clinicians there are either overdiagnosing the condition or are detecting it more effectively than eye care providers located elsewhere.

"We're seeing that potentially both physicians and patients in [predominantly rural] areas are not getting the health care that would be obtained in a large, urban setting," said study coauthor Harry Quigley, M.D., professor of ophthalmology and director of the Glaucoma Service at the Wilmer Eye Institute of Johns Hopkins University in Baltimore.

The authors concluded that eye care providers throughout the entire country must improve efforts to perform gonioscopy on a regular basis to ensure a proper, more accurate diagnosis of ACG. Additionally, they noted that elevated ACG diagnosis rates in New York City warrant further investigation.

Cassard SD, Quigley HA, Gower EW, et al. Regional variations and trends in the prevalence of diagnosed glaucoma in the medicare population. Ophthalmology. 2012 Apr 3. [Epub ahead of print]

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[1] Based on a survey of 130 patients who used both Biotrue and OPTI-FREE RepleniSH.
[2] Versus competitive multi-purpose solutions. [3] Based on patient satisfaction study.

AMD Linked to Increased Stroke Risk

Patients with age-related macular degeneration are at an increased risk for both ischemic and hemorrhagic stroke, according to a study in the April 24 online version of *Stroke*.

In this study, researchers evaluated 12,216 individuals aged 45 to 64 years who were enrolled in the Atherosclerosis Risk in Communities study. Overall, 591 participants were diagnosed with AMD (576 dry, 15 wet). After a mean follow-up of 13 years, 548 participants experienced cerebral infarctions, 57 suffered intracerebral hemorrhages and 14 had subarachnoid hemorrhages.

The researchers determined that participants with any form of AMD were approximately 50% more likely to have a stroke than those without evidence of macular disease.

To further complicate matters, one of the most successful treatment options for wet AMD—anti-VEGF therapy—might actually increase an individual's risk for stroke.

"Recently, antivascular endothelial growth factor agents used in the treatment of neovascular age-related macular degeneration have been suggested to increase the risk of intracerebral hemorrhage," the authors wrote. "Based on our findings, it appears that patients with [the eye disease] may already be at an increased risk of intracerebral hemorrhage and, thus, antivascular endothelial growth factor therapy could potentially increase this risk further."

The authors suggested that additional research is required to confirm the potential relationship between anti-VEGF therapy and increased stroke risk.

Ikram MK, Mitchell P, Klein R, et al. Age-related macular degeneration and long-term risk of stroke subtypes. Stroke. 2012 Apr 24. [Epub ahead of print]

Eyes Dry? Try a Cup of Joe

Caffeine could offer some relief for those who suffer with dry eye syndrome—in particular a subset of people with genetic variations in two genes, Japanese researchers say. Apart from knowing that caffeine increases the secretion of saliva and digestive juices, the team was aware that individuals respond differently to caffeine.

The researchers analyzed DNA samples of the participants for two genetic variations that are known to play a role in metabolizing caffeine. Their study results showed that participants with genetic variations in the ADORA2A and CYP1A2 genes had greater tear production after caffeine consumption. ■

Arita R, Yanagi Y, Honda N, et al. Caffeine increases tear volume depending on polymorphisms within the adenosine A2a receptor gene and cytochrome P450 1A2. Ophthalmol. 2012 May;119(5):972-8.

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  - Macular hole[3]
  - Retinal tear/detachment[4]

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www.SymptomaticVMA.com/REV

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1. Schneider EW, Johnson MW. Emerging nonsurgical methods for the treatment of vitreomacular adhesion: a review. *Clin Ophthalmol.* 2011;5:1151-65. **2.** Steidl SM, Hartnett ME. Clinical pathways in vitreoretinal disease. New York: *Thieme Medical Publishers;* 2003. Chapter 17; 263-86. **3.** Gallemore RP, Jumper JM, McCuen BW 2nd, Jaffe GJ, Postel EA, Toth CA. Diagnosis of vitreoretinal adhesions in macular disease with optical coherence tomography. *Retina*. 2000;20(2):115-20. **4.** Mitry D, Fleck BW, Wright AF, Campbell H, Charteris DG. Pathogenesis of Rhegmatogenous Retinal Detachment: Predisposing Anatomy and Cell Biology. *Retina*. 2010 Nov–Dec;30(10):1561–72.

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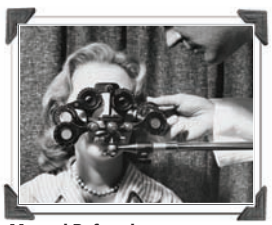

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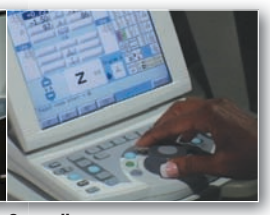

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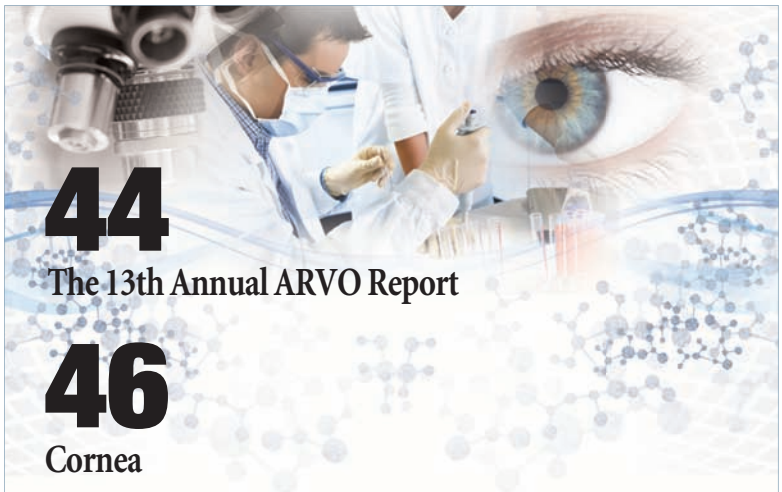

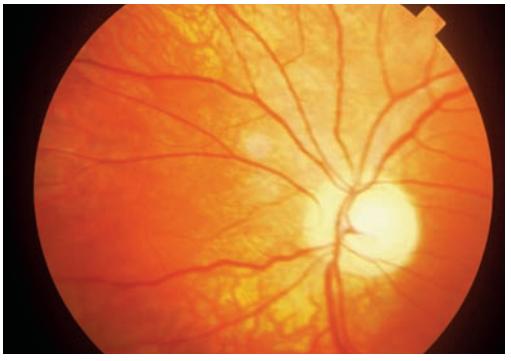

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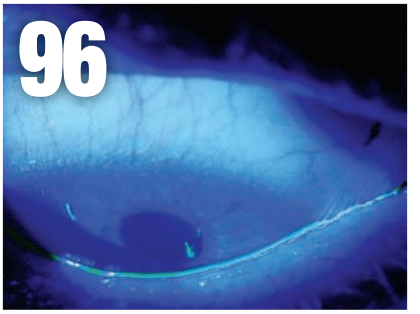

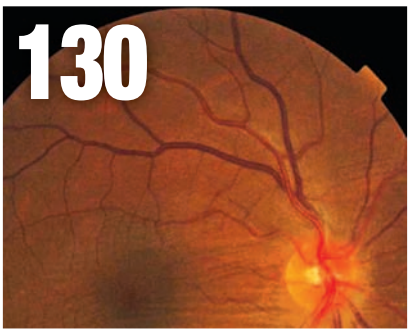

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Letters to the **Editor**

If they really want to 'integrate' the practice, then offer the optometrist(s) equity ownership with equity-based managerial authority.

A More Accurate Estimate

In his article "Steep Competition: LRI vs Toric IOLs" (March 2012), Dr. Bronner states, "Discuss toric IOLs with all patients who have refractive astigmatism. In most cases, this is a fair indication if there will be residual cylinder after [cataract] surgery."

However, more accurately, residual cylinder after cataract surgery is directly related to preoperative corneal cylinder, location of incision and the amount of surgically induced astigmatism (SIA). Postoperative corneal cylinder goes straight to the post-op refractive outcome. Preoperative refractive astigmatism has little bearing. It is those individuals who have little preoperative refractive cylinder in the face of significant corneal cylinder and/or those in which the incision location and SIA result in significant corneal cylinder who truly need counseling.

Here is a good rule of thumb on deciding whether your patient will have significant post-op refractive astigmatism: Begin with the pre-op keratometry readings. Factor in the SIA. If the incision is going to be placed at 12:00, this will flatten the vertical K reading by approximately 0.50D. If the patient has 1.00D of with-the-rule (WTR) astigmatism or less, their post-op corneal cylinder should be 0.50D or less. However, if this patient has pre-op corneal cylinder of 0.50D against-the-rule (ATR) astigmatism, they would be expected to have 1.00D ATR post-op. If the surgical incision is temporal, the math is similar—the meridan of the incision flattens the K reading by about 0.50D. In this case, WTR is increased by surgery and ATR is reduced.

If the referring O.D. wants to more accurately calculate post-op residual astigmatism, he or she may do so with the help of online calculators. Values for pre-op Ks, incision location and SIA are required. The latter two measurements may be obtained from the surgeon who is anticipated to manage the case. Note that it is unnecessary to know the spherical power of the IOL to be implanted in order to calculate the need for a toric IOL. For simplicity, use 20.00D. The online toric calculator will tell you if a toric IOL is indicated and, if so, which power toric to implant. It also calculates residual astigmatism. The online LRI calculator also requires patient age for calculations.

Using the tools outlined above, concerned O.D.s can more accurately counsel their patients on whether they might benefit from an LRI or toric IOL.

—Howell M. Findley, O.D.
Lexington, Ky.

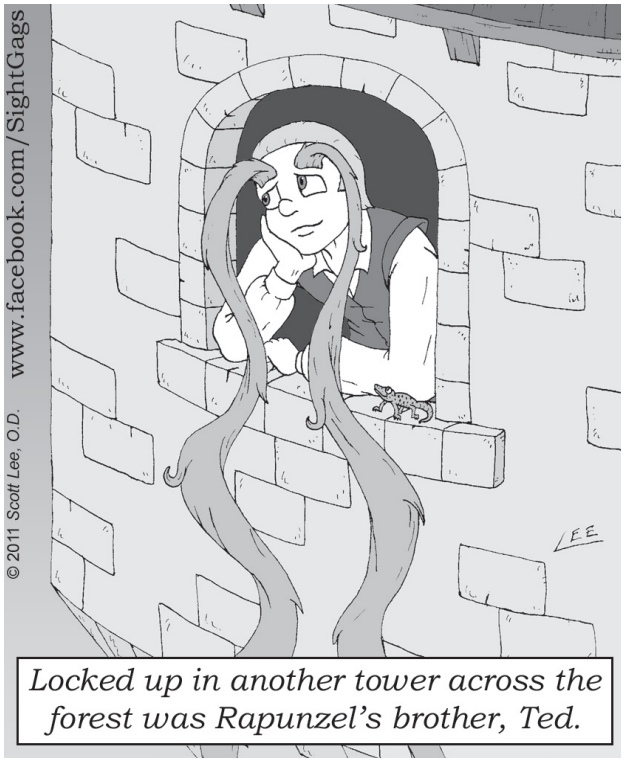
Dr. Bronner responds:

Dr Findley's points are all well made and the article was inappropriately vague in its wording on this topic. The point that I attempted to make is that, in the absence of keratometric or topographic data (which is required to predict postoperative cylinder, as stated in the preceding paragraph of the article), refractive cylinder could be used to guide general discussion—knowing that it may change after acquisition of the aforementioned metrics at the surgery center. The process of estimating postoperative astigmatism was beyond the scope of the article; however, the more information a referring O.D. can gather, the greater his or her role in the targeted outcome will be.

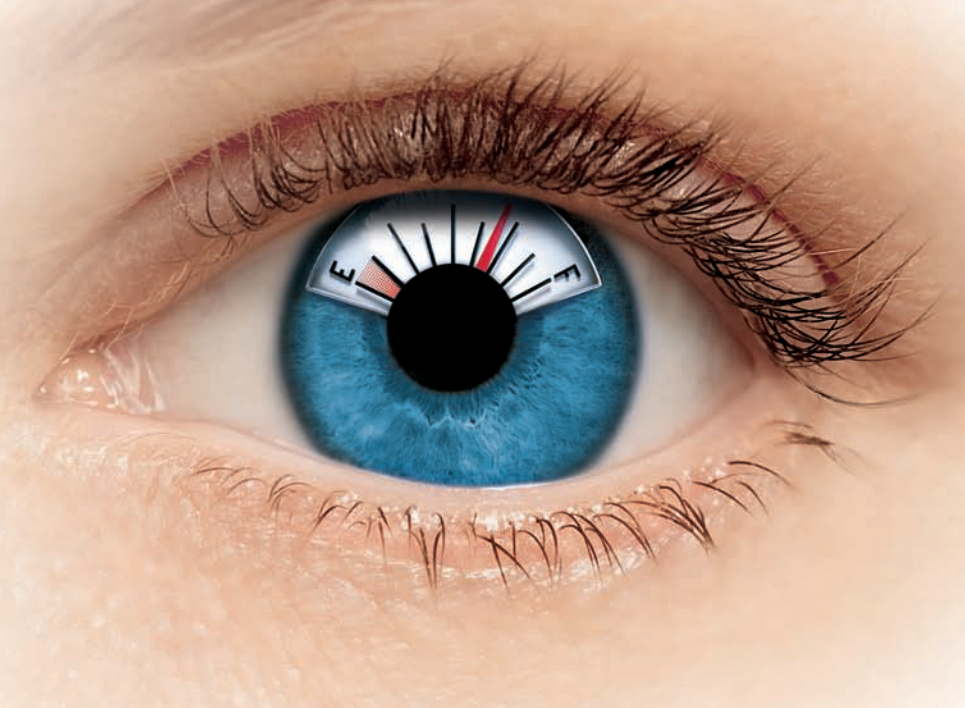
—Aaron Bronner, O.D.
Boise, Idaho

Sight **Gags**

By Scott Lee, O.D.



Locked up in another tower across the forest was Rapunzel's brother, Ted.



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Letters to the Editor

Time for More Shared-Equity Partnerships

Thank you to Derek Cunningham, O.D., and Walt Whitley, O.D., for defining the different forms of "integrated eye care" (*"What is 'Integrated Eye Care?'" March 2012*). Prior to this article, the eye care world has only heard ophthalmology's definition. All models position optometrists to care for their patients to the full extent of the optometrists' license. Well done.

What is never mentioned in our ophthalmology colleagues' versions of integrated eye care is ownership.

Optometrists have been employed by ophthalmologists for years. The ophthalmologist determines income formulas, hiring and firing, work schedules, staffing, equipment purchases and, most importantly, retirement equity in the business. In other words, the ophthalmologist(s) ultimately controls the practice.

Shared-equity partnerships solve this problem. If they really want to "integrate" the practice, then offer the optometrist(s) equity ownership with equity-based managerial authority. They provide this incentive to new "partner ophthalmologists," so they should also offer this to the "partner optometrists." Then, we'll truly experience comprehensive, integrated eye care.

—Randall N. Reichle, O.D.
Bellaire, Texas

Drs. Cunningham and Whitley respond:

Thank you for comments, and we could not agree with you more. Much of the historical hierarchy of the O.D./M.D. business relationship is an unnecessary reflection of scope of practice—or more likely gross earning potential. Just as you mentioned, shared-equity partnerships have rarely been introduced or addressed in regards to integrated eye care. Nonetheless, there are many examples, such as your practice, where this model has been very successful. Optometrists are continuing to demonstrate their increased worth on both the business and clinical side. With the future changes in both the supply and demand of eye care services, we may see many more examples like Eye Centers of Texas integrating eye care. ■

—Derek N. Cunningham, O.D.
Austin, Texas

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Dry Eye Dazzles

Think dry eye is humdrum? Think again. The quest to understand this seemingly simple affliction has inspired more invention than most other areas of optometric practice.

By Amy Hellem, Editor-in-Chief

On the surface, dry eye may seem like one of the most boring topics in eye care. It's not as controversial as injectables; it doesn't call for the use of pricy lasers; and, generally, when you treat it, your patients won't be so impressed by the outcome that they leap into your arms and plant a big, fat kiss on your cheek (as all too many post-op cataract patients have been known to do).

Rather, many of us tend to think of dry eye as a nuisance—from both a treatment and an education standpoint. Yet, the prevalence of this disease requires optometrists and researchers to find new and better ways to address patient complaints and inspires corporations to forge ahead with research.

I vividly recall the first time I realized how important dry eye research is to eye care. It was in 2001 and I was invited to observe a roundtable discussion on the disparity between subjective and objective symptoms. It seemed too rudimentary to warrant a full day of debate. Yet, the meeting was led by some of the most well-respected researchers in eye care and, as I soon discovered, their research was careful, extensive and ahead of its time. Remember, in 2001, there wasn't even a prescription medication available for dry eye. Nonetheless, this disease, for which the best you could offer was an over-the-counter drop, was garnering the attention of optometrists, ophthalmologists and the press.

The next big breakthrough for dry eye came in late 2002, with the approval of Restasis (cyclosporine, Allergan), the first prescription drug indicated for the disease. There was plenty to talk about there. Likewise, at the time, there was much to learn about dry eye as it related to LASIK because laser correction was a huge newsmaker then and the economic climate was not yet grim.

A few years later, in 2007, the very definition of dry eye disease was modified by the Definition and Classification Subcommittee of the International Dry Eye Workshop (DEWS). DEWS determined that dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability, with potential damage to the ocular surface. The DEWS definition also states that dry eye is accompanied by increased tear film osmolarity and ocular surface inflammation.

For several years, conversation about dry eye centered on identifying its cause—inadequate lacrimal layer production (aqueous tear deficiency) or excessive tear film evaporation (evaporative dry eye). This, the researchers said, should help dictate an appropriate treatment plan. But, as we are now learning, there is more to it than that.

Dry eye—particularly evaporative dry eye—is often associated with meibomian gland dysfunction (MGD), a topic that is foremost on the minds of everyone with an interest in contemporary dry eye management, including the author of this month's ARVO Report on Cornea, Joseph P. Shovlin, O.D.

As you know, the International Workshop on Meibomian Gland Dysfunction concluded that MGD is now the leading cause of dry eye. This has spurred a tremendous amount of new research into dry eye in general and MGD in particular.

Dr. Shovlin reports on one study that looked at the effects of anti-inflammatory treatment in MGD. As you'll see in the report, one of the study's most interesting conclusions is that the clinical findings didn't match the patients' subjective ones.

Truly, there is never a dull moment in the world of dry eye management. In addition to this new knowledge of MGD, currently, many of your colleagues are debating more liberal use of steroids for dry eye—a topic on which *Review* will soon be hosting an online debate. (For more go to www.reviewofcontactlenses.com.)

And, next month, *Review* welcomes two special guest authors, Caroline A. Blackie, O.D. Ph.D., and Donald R. Korb, O.D. In their article, "MGD: Getting to the Root Cause of Dry Eye," they call for a substantial shift in thinking with respect to dry eye. ■

Amy Hellem
Editor-in-Chief

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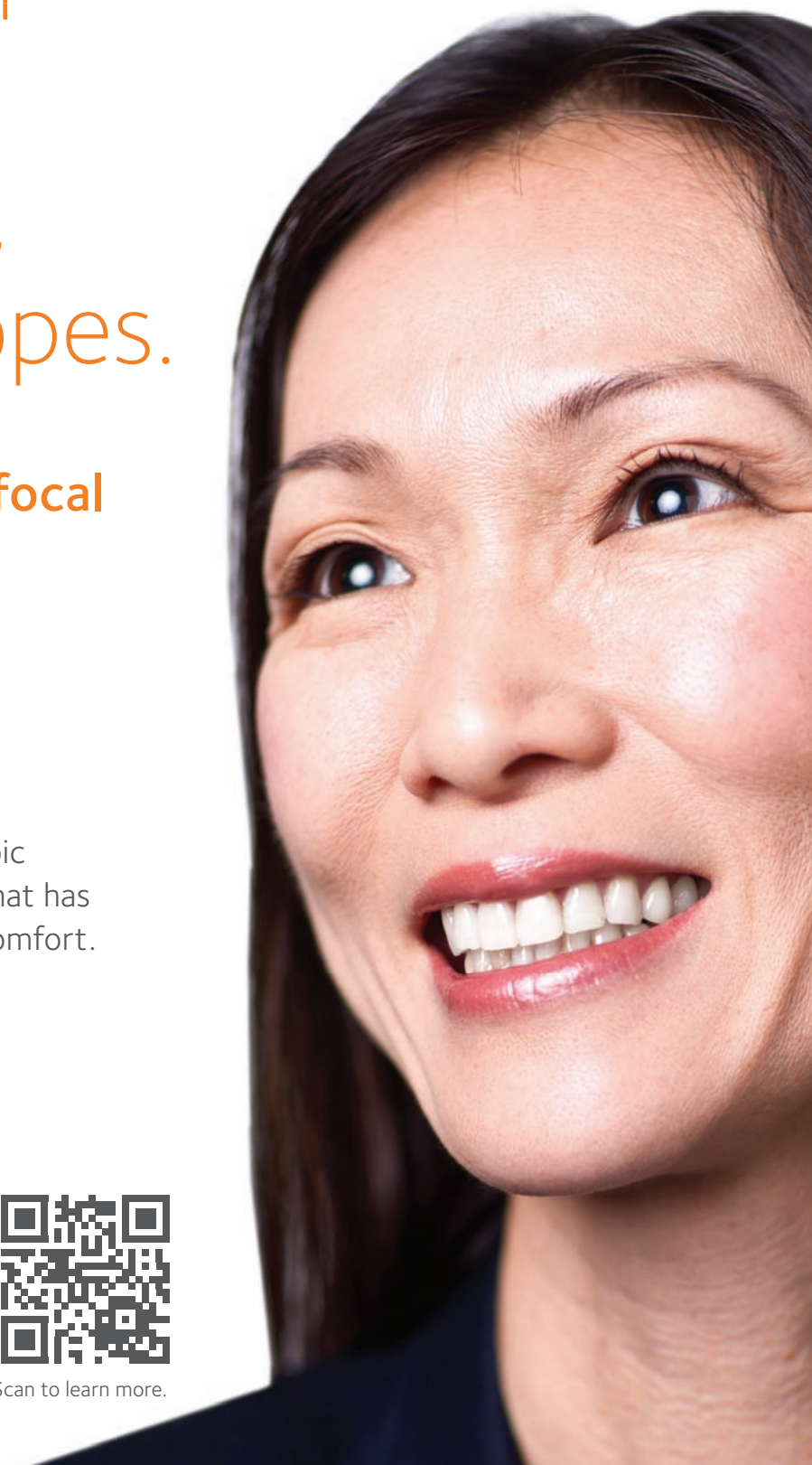

A Pain in the Aspirin

Headaches are common in clinical optometric practice. For me, they usually start around 8 or 9 o'clock in the morning, and last until about 5. **By Montgomery Vickers, O.D.**

Headaches are just a fact of life in clinical optometry. As a matter of fact, headaches are one of the most commonly reported symptoms in eye care. Headaches are mostly unavoidable and nearly undiagnosable.

Oh, I almost forgot. Sometimes patients have headaches, too.

As a matter of fact, nearly everyone in the whole world experiences some form of headache. The majority are related to whom you are related…to. Nothing can trigger head pain like your daughter's first tattoo or your son's most recent speeding ticket. And, wanna understand what it feels like to be hit by a golf ball between the eyes? Try to make a bed to my wife's specifications sometime.

But, work-related headaches are a close second. I have very specific headaches for very specific patients. For instance:

Patient: "I get a headache when I wear my new glasses."

Me: "I get a headache when you speak."

Fortunately, after 32 years of practice, my patients always think I am just funnin' with them.

Har-de-har-har-har…

An Occupational Hazard

Sometimes weather gives me a headache. No, not when a cold front or snow approaches. My headache comes on when it's sunny and mild. I get one when no one shows up—unless, of course they "get a headache when they wear their new glasses." Oh, that patient is always on time.

I have found a few ways to soothe my optometric brain pain. For example, I go to the chiropractor once per month for an adjustment whether I need it or not. OK, I always need it. My chiropractor is my patient. He never wears his glasses. He explained to me that he really doesn't need glasses, so he only wears them when he wants to see something. Glad he's not an airline pilot. Of course, he once adjusted my briefcase instead of my back but I was able to talk him into a discount, so all was forgiven.

Doctors, headaches are just a part of your life, which can only be avoided if you just choose a profession where you never deal with any human beings. Or if you avoid their sensory organs at least, as patients can be quite demanding when you mess with those. If a patient can't see, it's really your fault, after all… I love it when they come in and announce, "My glasses have changed."

Sure, their glasses changed. Pass the acetaminophen!

What if the patient has the headache? Here's my simple, two-step technique for differential diagnosis:

1. Do they have an arrow sticking out of their head AND the headache started right when the arrow hit them in the head AND the headache is located right where the arrow hit them in the head AND this happens every time an arrow hits them in the head in that specific location? If so, there is a 50% chance that the cause is the arrow.

2. Do they have headache with associated nausea, blurred vision, photophobia, photopsias and scotomata? Then there is a 50% chance the cause is still the arrow, even if there is no history of any arrows. The other possibility is the patient is your mom and you are on vacation when she calls.

Maybe you just need to change your mindset. From now on, if your head hurts, it means you are fine. If your head stops hurting, go to the ER because something is horribly wrong with you. ■

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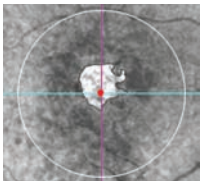

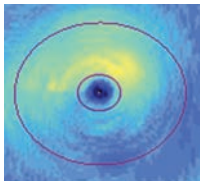

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What's New in Retina Coding

Some CPT codes for retinal disease have changed. But, did you know that utilization guidelines changed, too? **By John Rumpakis, O.D., M.B.A., Clinical Coding Editor**

While optometrists have come a long way in our ability to diagnose and treat common retinal disorders, we still have difficulty in understanding the economics surrounding the appropriate coding and billing for our involvement.

Coding for retinal disease is easily understood and straightforward. Simply said, code for any office visit where you meet the criterion for providing professional services and then code for the specific procedure(s) performed. The coding for retinal disease consists of nothing more than an E/M visit code in most cases or even using the 920XX codes. Most of our visits are with established patients, so the codes used are 92012, 99213 or 99214 matched with an appropriate ICD-9 diagnostic code based upon meeting the criterion for each visit. And, be sure to code with the highest level of specificity in your diagnosis.

Also recognize that you often are required to code the systemic disease in addition to the ocular manifestations in the diagnosis as well as the medications, as in the case of Plaquenil (hydroxychloroquine, Sanofi-Aventis) therapy.

Retinal disorders are particularly easy to code for, as there are a limited (and repetitive) number of procedures that we actually perform. Most carriers have published policies that follow the CPT very closely, although some have specific policies or guidelines that expand upon the CPT definition for a particular code. So, be sure of a carrier's specific policy regarding billing a code rather than simply relying on the CPT definition. These policies are referred to as Local Coverage Determinations (LCDs), and usually are available on your carrier's website or on a web-based real-time service, such as www.LCDPlus.com *(Disclaimer: that's mine)*.

Of particular importance in retinal disease is the limitation of performing scanning computerized diagnostic imaging (SCODI) on the same visit as a fundus photograph or visual field. According to the National Correct Coding Initiative, visual fields and OCT are allowed on the same day of service, but fundus photography and OCT are not (the sole exception is in Florida).

Some doctors still misunderstand the changes to the scanning laser codes implemented in January 2011. At that time, CPT code 92135 was eliminated and three new codes were implemented: 92132 (anterior segment), 92133 (optic nerve) and 92134 (retina). Many who owned these instruments were more than upset to learn that the definition of this procedure was changed from "unilateral" to "unilateral or bilateral." This means that, rather than getting paid for each eye individually, the reimbursement is now the same whether one or both eyes are done.

What many failed to understand is that the utilization guidelines also had changed. While remaining fairly constant for optic nerve use (twice per year), scanning laser for retina is now indicated as often as once every 28 days for retinal disease (based upon medical necessity) in many areas of the country. This certainly is more in line with a rapidly changing disease state, such as macular degeneration, thus also offsetting the change in laterality status.

Another recent issue is managing the patient on long-term use of toxic medications, such as chloroquine or hydroxychloroquine. In this case, be aware that many LCDs stipulate that you must use SD-OCT (spectral domain) rather than the older TD-OCT (time domain).

Coding for the typical retinal encounter is easy and straightforward. O.D.s have a limited number of diagnostic tests that we can perform. Generally, retinal diseases are not something that will go away or be cured—rather they are managed over time. Keep in mind that you cannot bill a carrier for documenting "no change." Diagnostic tests are only billable if they aid in the treatment/care of the patient as established by medical necessity in the record.

As practitioners, we tend to forget that our patients suffering from chronic retinal conditions can benefit from our experience and expertise. So, be proactive! Treat your patients the way they expect you to: Incorporate full-scope care into your practice, bill appropriately for your services, and reap the rewards in patient satisfaction and financial well-being for doing so. ■

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Making the Most of Antivirals for Treating Herpes Simplex Keratitis

By Jimmy D. Bartlett, O.D., D.Sc.

Worldwide, herpes simplex keratitis represents one of the most common causes of corneal blindness. In the United States alone, approximately $17.7 million is expended annually to treat the estimated 59,000 new and recurrent cases of HSV keratitis occurring among 29,000 individuals each year.[1]

In recent decades, topical trifluridine (Viroptic, Monarch) and oral acyclovir have become the mainstays of therapy for treatment of HSV epithelial keratitis in this country. For stromal keratitis, the use of topical steroids together with a prophylactic antiviral to shorten the duration of active keratitis, and the use of long-term suppressive oral acyclovir to reduce the incidence of recurrent HSV keratitis, have become standard of care.[2] These standards were developed in the 1990s following several well-publicized, randomized clinical trials.[3-6]

This article emphasizes some of the most practical points in treating HSV keratitis and discusses the application of a new drug now available for topical therapy.

Topical Therapy

Although topical trifluridine has been the most widely used antiviral agent for treatment of HSV keratitis in the United States, this drug has several known limitations. First, patient adherence to dosing regimens can be difficult because of the q2h administration frequency. Second, both the trade name product and the generic formulation are preserved with 0.001% thimerosal.[7] Zirgan (ganciclovir ophthalmic gel 0.15%, Bausch + Lomb) had been commercially available outside the United States since 1996, and then received FDA approval in 2009.[8]

Zirgan differs pharmacologically from trifluridine in that it becomes active primarily in virus-infected cells, thus sparing normal tissues from toxicity.[7,8] Also unlike trifluridine, treatment compliance is achieved more easily with ganciclovir because the dosing frequency is one gt q3h while awake until the epithelial keratitis has healed. Thereafter, dosing is one gt tid for another seven days to cover for viral shedding.[7] Unlike trifluridine solution, ganciclovir gel is available as a physician office sample, allowing patients to receive immediate treatment once the diagnosis is made.

Overall, topical ganciclovir gel is well tolerated, does not cause toxic effects in the cornea or on the ocular surface, and does not cause any systemic side effects.[8,9] This medication is at least as effective as topical acyclovir ointment (not available in the U.S.), but there have been no head-to-head studies comparing ganciclovir with trifluridine.[8,10,11]

Oral Therapy

Although topical antiviral therapy is often sufficient when used alone, there are times when adjunctive oral antivirals may be beneficial to improve patient outcomes. The indications for oral acyclovir can be broadly divided into treatment of active viral disease and prophylaxis against recurrence.

In some patients, topical antiviral therapy alone may not be effective in treating active herpetic infections. These circumstances include patients with primary HSV infection, immunocompromised patients, infants and children, and patients with HSV uveitis that is unresponsive to topical steroids.[13] Patients with significant primary HSV infections (blepharoconjunctivitis) may benefit from oral acyclovir. Systemic therapy may shorten the course of the disease, reduce the chance of corneal involvement, and decrease patient morbidity and the likelihood of recurrence.

Immunocompromised patients lack the normal immunologic response that is important in controlling the active virus. For moderately immunocompromised patients, oral acyclovir is probably

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adequate. But, for the severely immunocompromised patient, intravenous acyclovir may become necessary.[13]

Oral acyclovir is quite useful for treating infants and children with infectious HSV epithelial keratitis.[13,14] Oral therapy has several advantages over topical therapy in this patient population. First, it is difficult to administer topical medications to patients in this age group, and second, these children also tend to express a severe immune reaction not typically seen in adults. For these reasons, infectious epithelial keratitis in young patients inadequately treated with topical medications may respond much more quickly to oral therapy.[13]

Another indication for oral acyclovir is in the treatment of HSV uveitis.[6] Administration of oral acyclovir results in therapeutic levels of medication not only in the tear film, but also in the aqueous humor.[15] When used with topical steroids and topical antiviral agents, oral acyclovir can offer an additional benefit to therapy.[6]

For all of these treatments of active HSV infection, the standard adult dosage of oral acyclovir is 400mg five times daily.[16] Also, when topical therapy becomes difficult because of poor adherence to dosing frequency, drug toxicity or foreign body sensation, oral valacyclovir can be an effective and safe option. Adult dosage is generally 500mg two or three times daily.[17,18]

Because recurrent episodes of HSV keratitis can lead to corneal scarring and decreased quality of life, it is important to offer selected patients prophylactic therapy to decrease the risk of future visual impairment. However, studies have shown that herpetic eye disease is costly to prevent and, thus, therapeutic decisions must be made on a case-by-case basis.[1] Past episodes of stromal keratitis with corneal scarring may suggest the need for long-term suppressive therapy. In these cases, oral acyclovir 400mg twice daily may significantly reduce the rate of recurrent HSV epithelial and stromal keratitis. An alternative regimen is oral valacyclovir in a dosage of 500mg once daily, which is as effective and as well tolerated as oral acyclovir.[19] The benefit of prophylactic oral therapy is greatest for patients who have experienced prior HSV stromal disease.[4, 20]

Additionally, oral acyclovir (400mg twice daily) effectively prevents recurrences, decreases episodes of rejection and improves graft survival after penetrating keratoplasty in patients with herpetic eye disease.[21-24] Further, patients with a history of herpetic keratitis who undergo excimer laser procedures for correction of refractive errors or treatment of corneal scars are at increased risk for reactivation. These patients may significantly benefit from prophylactic oral antiviral medication at the time of the laser procedure to decrease the possibility of HSV recurrence.[25]

Following diagnosis of HSV keratitis, we should optimize our patient's care by incorporating new topical antiviral therapy and enlisting the support of oral antiviral agents for the many patients who may benefit from them. Topical ganciclovir ophthalmic gel has a number of clinical advantages compared with older antiviral drugs, and oral acyclovir or valacyclovir may offer beneficial treatment or prevention for many patients with herpetic eye disease.

Research into Adenoviral Conjunctivitis

One of the more interesting aspects of ganciclovir is the promise it holds for treating ocular adenoviral infections.[12] One study of 18 patients with adenoviral conjunctivitis showed that the group treated with topical ganciclovir had a mean recovery time of about eight days compared with 19 days for patients treated with artificial tears. Importantly, those treated with the antiviral drug had far fewer subepithelial infiltrates than those treated with artificial tears.[8] This finding is consistent with our current clinical experience in using topical ganciclovir for patients with EKC. Although not FDA approved for this indication, Zirgan is proving to reduce ocular morbidity and prevent or modify the severity of subepithelial corneal opacities in many of our patients.

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International Vision Expo East Breaks Historical Attendance Records

Preliminary results: 16% more O.D.s at this year's meeting.

By Jane Cole, Contributing Editor

International Vision Expo East drew a record crowd of 16,317 eye care professionals during its annual March show at the Javits Center in New York City, according to unaudited preliminary attendance figures. This represents a 10% jump in attendence compared to 2011 and a new show record.

"We are pleased to report that we broke attendance records dating back to the show's inception in 1986," says Tom Loughran, vice president for Reed Exhibitions, which co-owns International Vision Expo East along with The Vision Council. "Overall feedback indicates that visitors were very satisfied with this year's show. The new split level floor plan, featuring the French Loft on the Level 4 Terrace and combined pavilions and education destination on Level 1, exceeded expectations."

A final third-party audit of International Vision Expo East, which will detail audited attendance figures, will be available in early May 2012.

"Every disruption brings opportunity," says Deborah Castor, vice president of shows and meetings for The Vision Council. "Reed Exhibitions and The Vision Council rose to the challenge when presented with several show floor design constraints due to the ongoing construction at the Javits Center. In the end, the construction provided us with an opportunity to reinvent International Vision Expo East in its 26th year into a totally re-energized event."

This year, the show floor was expanded by an additional 10%. The conference and meeting rooms and exhibits spanned four levels for a combined total of 312,823 square feet. More than 575 exhibitors, including 132 new companies, presented the latest trends in eyewear and advances in eye care technology to eye care professionals and buyers from across the globe.

The informative classroom instruction connected to hands-on knowledge at the expansive exhibits, which allowed attendees to learn about and source the most products in one place, compare and test drive the equipment, and implement new ideas.

This year's International Vision Expo East offered more than 325 hours of continuing education for attendees.

"Our Allergan sales representatives were thrilled with the increased booth traffic at this year's Vision Expo Conference," says Dave Gibson, director of optometric professional relations for Allergan. "We increased our booth size and used interactive screens to highlight our new optometry website, both of which seemed to help drive booth traffic. Additionally, the new

proximity of the educational classrooms to the Medical and Scientific exhibitors provided a great synergy and helped to drive traffic."

Added Kirk Smick, O.D., chairman of the International Vision Expo Conference Advisory Board: "In the 30 years that I have been involved in the optometric education projects, I have never seen more enthusiasm from attendees than this recent Vision Expo East. Exhibitors were beside themselves as streams of eyecare professionals departed the continuing education courses and immediately entered the exhibit hall. The proximity of the conference center to the exhibit hall was a clear advantage for both the eye care professional and the exhibitor."

Vision Expo East featured celebrity designer Marc Ecko.

The latest trends in eyewear were a big hit in the exhibit hall.

In an effort to create a world-class education program, the conference advisory board worked with specialty optical groups, including the Optometric Retina Society, the Optometric Council on Refractive Technology, and the Optometric Nutrition Society, to put together a full program featuring sought-after speakers from a variety of fields. Boasting more than 325 hours of continuing education, the 2012 program was divided into five areas of interest—Allied Health, Business Solutions, Clinical, Contact Lenses and Optical Technology—to make it easier for attendees to create personalized education strategies and practice to the fullest extent of their license.

The expanded CE offerings attracted even more O.D.s this year, representing an increase of 21% of conference attendees compared to last year, according to Vision Expo East estimates. Additionally, there was also an increase in the amount of O.D.s who registered for the exhibit hall, up 7% this year. The total number of O.D.s who attended this year's meeting was 2,968, representing a 16% increase.

"It was another exciting year in New York City at Vision Expo East," says Mark Dunbar, O.D., International Vision Expo Conference Advisory Board Member. "This year in particular there was a 'buzz' unlike I had ever seen before ... you could feel the energy and vibe as you walk(ed) between the continuing education lectures and the exhibit hall. I was impressed to see many of the lectures were full to capacity and the quality of all the lectures this year (was) truly outstanding!"

Also new this year, continuing education was located on Level 1, the same level as the Lenses & Processing Technology, Medical & Scientific and Low Vision Pavilions, as a result of the ongoing Javits Center renovation project. O.D.s were invited to relax and enjoy networking in the all new Optometry Club, which was also located on Level 1. In addition to offering many amenities, including a food stand, the Club played host to a student luncheon on Friday, Doctorfest networking events on Friday and Saturday, and a special Job Search Meet and Greet breakfast on Saturday morning.

"This year's Vision Expo meeting was fabulous. The new location of the educational program allowed attendees to easily stroll between the educational program and the exhibition hall," says Richard Soden, O.D., vice president for clinical affairs at SUNY College of Optometry. "This was a major advantage to previous years. The attendees that I spoke to were enthusiastic about the educational program and felt there were many unique programs offered this time. A huge success!"

Next year, International Vision Expo East will be held from March 14-17, in New York City. Show dates have been confirmed with the Javits Center through 2020 in the March/April timeframe. To view future dates, visit www.visionexpoeast.com/en/For-Attendees/Show-Information. ■

JOSHUA MARC LAHIFF, OD

A Growing Practice Is Built on Happy Patients

Garnering new patients through **word-of-mouth referrals** is more than a great marketing strategy—it is the key to success that endures the test of time.

Successful practices see more patients

Focusing your practice on getting new patients rather than dollars per patient is a more pragmatic—and preferable—business approach. This is true for any practice. In a 2009 study of independent practices, it was reported that the practices with the greatest gross revenue see three times as many patients as the average practice. Furthermore, there is little difference in the gross revenue per exam between rural and urban settings, small and large practices.[1]

Increased patient traffic and improved exam productivity have major impacts on practice revenue. In fact, another 2009 study found that, on average, 52% of a practice's gross revenues come from exam fees alone.[2] This constitutes nearly 2/3 of gross income.[1,2]

According to Dr Josh LaHiff, practicing optometrist in Cheyenne, WY, increasing patient traffic is all about providing patients with an outstanding experience: "You want to be able to provide them [patients] with such an experience that they're going to invest more in your clinic." Dr LaHiff should know. He sees at least 30 patients per day. Which is impressive considering there are 28 other eye care professionals in Cheyenne, a town with a population of only 50,000.

Success is built on a happy patient experience

Increasing patient traffic through referrals is often as simple as delivering excellent service and the healthiest products. "To be the best, you have to use the best. If you wow the patient, treat them like gold, that's how you really generate those referrals," says Dr LaHiff.

That's why Dr LaHiff believes the most effective approach to achieving profitable, long-term patient relationships is to "do what's best for the patient, even if it may not be the most profitable option for the doctor initially, because it is what is right, and the profit will come as an annuity in return visits and the happiness of the patient."

High patient satisfaction inside and outside of the practice is the most effective catalyst for generating new patients. This can be especially true for contact lens patients. A survey of 1086 patients found that those who are happy in their contact lenses are nearly 2x more likely to recommend their eye doctor than those who are unhappy in their lenses.[2]

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The proven method to achieve satisfaction is to use a product with consistently successful results. Dr LaHiff believes that, "When you use a product that you know is going to work time and time again, it cuts your chair time down and it's easier for you, your staff, and your patients to put them in something that's comfortable."

ACUVUE® Brand delivers outstanding comfort and consistent patient satisfaction. In fact, 9 out of 10 ACUVUE® patients are satisfied in their contact lenses.[2]

And happy ACUVUE® wearers refer their eye doctor: 8 out of 10 satisfied ACUVUE® OASYS® Brand Contact Lens and 9 out of 10 1-DAY ACUVUE® MOIST® Brand Contact Lens wearers would recommend their doctor to others.[2]

According to Dr LaHiff, "The more you use a superior product, the better the experience is going to be for the patient." And that's been a proven strategy for the success of his practice. ■

Joshua Marc LaHiff, OD, is a partner and practicing optometrist at Cheyenne Vision Clinic in Cheyenne, WY, and clinical instructor for the Illinois College of Optometry in Chicago, IL. He received his doctor of optometry degree with honors from the Pacific University College of Optometry in Forest Grove, OR.

Dr LaHiff is a member of numerous associations and serves as a speaker and professional consultant for several medical companies, including VISTAKON® Division of Johnson & Johnson Vision Care, Inc. He was compensated for this article.

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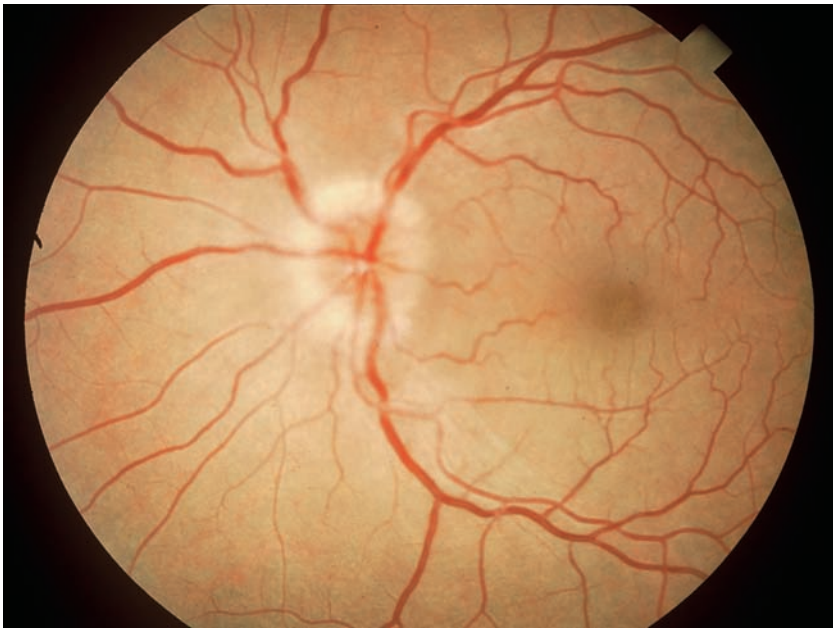
The Many Paths of Acute Optic Neuropathy

When you are dealing with acute optic neuropathies, you are not looking at just one disease—but rather a spectrum of many subtypes. Understanding each one is the key to proper care. **By Douglas Tassi, O.D., and Gary VanderZee, O.D.**

Most likely you have encountered cases of optic neuropathy in your practice over the years, especially considering that it is one of the more common causes of acute vision loss or majorly impaired vision. While optic neuropathy refers to optic nerve damage from any cause, it has many specific subtypes—and they are not all created equal.

In this article, we focus on acute optic neuropathies, which typically present with a very sudden decrease and/or loss of vision in one eye secondary to unilateral optic nerve swelling with a defined afferent pupillary defect (APD). There will be an associated unilateral visual field defect, and the onset typically is very dramatic to the patient.

The most common acute optic neuropathies include ischemic optic neuropathy (ION), optic neuritis and trauma. In patients ages 50 and up, acute anterior ischemic optic neuropathy (AION) is the most common presentation.[1] AION is divided further into non-arteritic (NAION) and arteritic (AAION). AAION is the ocular manifestation of giant cell arteritis (GCA), also known as temporal arteritis. Another variant of ION is posterior ischemic neuropathy (PION), an infarction of the posterior portion of the optic nerve(s). To provide the most effective treatment for patients, it is crucial to understand each of these subtypes, because the underlying cause, disease progression and management varies in each case.[1]



1. The optic nerve will be edematous in about 35% of optic neuritis cases.

Perhaps the most common neuropathy presentation is optic neuritis. Optic neuritis must be considered in cases presenting with

visual disturbances and a unilateral swollen optic nerve in patients younger than age 45. Time is on your side in the diagnosis and treatment of optic neuritis and NAION, but it is your enemy in AAION.

Patients with GCA potentially can go blind in a matter of days—not to mention their increased risk for stroke or myocardial infarction. It is preventable with timely diagnosis and treatment, and for that reason, AAION is considered an ophthalmic emergency. This is why it is critical to clinically differentiate between AAION and NAION (the differential diagnosis of NAION is made via the exclusion of AAION).

In some instances, cost-effective laboratory testing and clinical observation can be used to properly diagnose these optic nerve diseases, without the need for radiology in typical, acute presentations. In atypical presentations, neuroimaging will be indicated. Neuroimaging also will be required in the differential diagnosis of multiple sclerosis (MS) in cases of optic neuritis.

Optic Neuritis

The classic presentation of optic neuritis is a sudden, unilateral loss of vision, with the distinct symptom of pain on eye movement. Typically, the patient is less than 45 years of age. The patient usually has a relative APD, color desaturation, brightness reduction and a unilateral central visual field defect.

The optic nerve will be edematous in about 35% of these cases (*figure 1*).[2] The majority (65%) will have no visible optic nerve edema initially—these cases are known as retrobulbar optic neuritis.[2] Optic neuritis improves over three to six weeks without treatment. The first treatment should not be oral corticosteroids, per the protocol outlined by the Optic Neuritis Treatment Trial (ONTT).[2]

Because the risk of demyelinating disease is high in cases presenting as optic neuritis, patients should receive an MRI with gadolinium. If the MRI is positive for multiple plaque lesions (unidentified bright objects and "railroad tracking"), the patient most likely has MS and can be advised to consult a neurologist regarding treatment options. Image manipulation with fluid attenuated inversion recovery will assist in improved lesion isolation.

Patients with an atypical presentation of optic neuritis, unusual age, chronic occurrences as opposed to acute onset, lack of pain upon extraocular muscle movement and lack of improvement in three weeks potentially have an intracranial mass and should undergo appropriate consultation and neuroimaging.

Optic Neuropathy Basics[19]

The major causes of optic neuropathy include:

- Ischemic optic neuropathy
- Optic neuritis
- Compressive optic neuropathy
- Infiltrative optic neuropathy
- Traumatic optic neuropathy
- Mitochondrial optic neuropathies

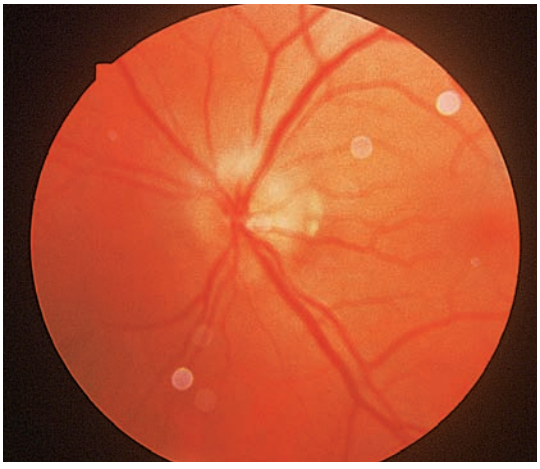
(nutritional optic neuropathies, toxic neuropathies and hereditary optic neuropathies)

Non-Arteritic Anterior Ischemic Optic Neuropathy

NAION is caused by a lack of optic nerve profusion or embolic disease that affects the arteries/arterioles that are supplying the optic nerve. Typically, NAION presents as a sudden, unilateral, painless loss of vision in patients age 50 or older. The patient usually has associated vasculopathic risk factors, including—but not limited to—hypertension, arteriosclerotic diseases, diabetes and nocturnal hypotension.

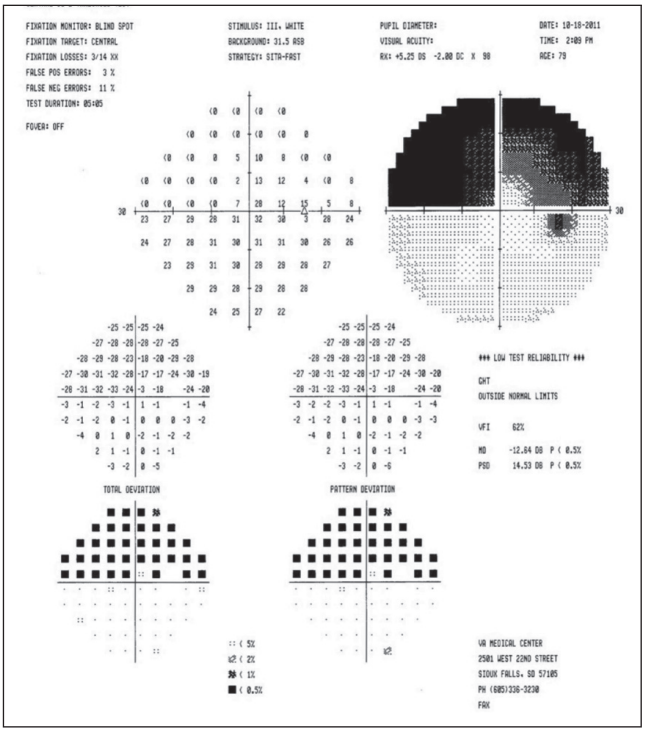
The patient often wakes up with a profound visual disturbance in one eye. Ophthalmoscopically, the patient presents with either segmental or total disc edema (*figure 2*). Splinter hemorrhages of the optic nerve are common. Pupillary testing will show a frank APD in the affected eye. There will be a unilateral visual field defect, which can be superior or inferior, with a classic altitudinal hemianopsia (*figure 3*). Some patients will have an inferior nasal visual field defect in the affected eye.

Patients with NAION will have a normal C-reactive protein and



2. Ophthalmoscopically, the patient presents with either segmental or total disc edema.

erythrocyte sedimentation rate. They also lack the typical constitutional symptoms that are often associated with GCA. Atypical clinical findings include: younger age, lack of acute onset, visual field defect that does fit with typical AION, proptosis, ocular motor paralysis, bilateral findings, and many of the other systemic signs and symptoms of occult neurologic disease. These patients will require consultation with neuroimaging of the brain and orbits with gadolinium enhancement. Bilateral disc edema is papilledema, until proven otherwise with neuroimaging for an intracranial mass. A patient with a swollen optic nerve in one eye and a visual field defect in the other eye is also a brain tumor, until proven otherwise.



3. There will be a unilateral visual field defect with a classic altitudinal hemianopsia.

There is no proven effective treatment for NAION at this time.[3] Some suggested treatments include oral steroid agents to lower intraocular pressure, asprin therapy and intraocular anti-VEGF treatment.[4] The majority of these eyes will progress to optic atrophy with a poor visual outcome (*figure 4*). Some patients will have vision improvement in two weeks, with gradual vision improvement up to six months. If oral steroids are used in the treatment of NAION, the steroid must be started within 14 days of onset.[4]

Fortunately, NAION usually is unilateral. But, there are some cases of bilateral disease, which imparts a devastating visual outcome. In the case of bilateral disease, it will usually affect one eye at a time.

There are reported cases of bilateral simultaneous NAION. However, a national study in 1995 found optic nerve fenestration surgery—which once held promise in NAION—to have profound complications with little benefit, so the study was halted.[5] Currently, the National Institutes of Health has begun a study utilizing neuroprotective agents in the treatment of NAION.

Arteritic Anterior Ischemic Optic Neuropathy

Patients with AION in association with GCA are classified as having AAION. GCA is the leading cause of AAION; less common causes of arteritis are polyarteritis nodosa, lupus erythematosus and herpes zoster.[4] GCA represents a vasculitis of the large- and medium-sized arteries of the head and neck. It has a special predilection to affect the posterior ciliary artery, which is the main blood supply to the optic nerve head. Artery involvement below the aortic arch is rare. Microscopically, there is inflammation of the arterial wall, which is patchy or segmental. This infiltration of giant cells causes a closure of the artery lumen by disruption of the internal elastic lamina.

GCA sometimes presents with classic symptoms, which makes the diagnosis more straightforward. But often, however, the diagnosis is difficult to confirm until the patient has lost vision in one eye. The ocular presentation of AAION in GCA is very similar to NAION. Usually the depth of vision loss is greater and the optic nerve shows a chalky (*figure 5*) or yellow, waxy appearance (*figure 6*).

Splinter hemorrhages of the optic nerve are common. There will be a visual field defect in just one eye that is altitudinal or inferior nasal. Pupillary testing will show an APD of the involved eye. After the optic nerve edema clears, the patient will develop optic atrophy either in a segmental or diffuse pattern. As the optic atrophy progresses, some of these patients will develop optic nerve cupping that looks just like glaucoma—except that the optic nerve pallor is greater than the cupping.[6] Most of these patients end up with very poor vision in the affected eye.

GCA patients can have episodes of amaurosis fugax prior to the

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acute loss of vision. Other less common ocular findings in GCA include retinal artery occlusion, cilio-retinal artery occlusion and sixth nerve palsy. The patient may or may not have a palpable, hard or tender temporal artery. Sohan Singh Hayreh, M.D., M.S., Ph.D., D.Sc., has reported a delay or loss of filling of the short posterior ciliary arteries with fluorescein angiography.[4] The more critical issue will be an index of suspicion from constitutional symptoms, including temporal pain, pain with chewing (jaw claudication), scalp tenderness, headache, neck pain, malaise, weight loss, migratory arthropathy and nocturnal sweating. These patients usually will have only some of these symptoms, and different symptoms will occur at different times in their disease. GCA patients have an increased risk of stroke, cardiovascular disease and aortic aneurysm.

Patients who are diagnosed with polymyalgia rheumatica (PMR) have a 15% to 30% probability of developing GCA.[6] Some studies report that PMR occurs in about 50% of patients with GCA.[7,8] Both conditions exhibit similarities, and many experts believe them to be manifestations of the same disease; others believe GCA and PMR represent two different diseases, supported by human leukocyte antigen typing.[9] There is a clinical sub-group in GCA that will not have constitutional symptoms. These patients usually will not present for medical evaluation until they have lost vision in one eye, and must be evaluated for GCA before they potentially lose vision in both eyes from AAION.

Other Related Conditions

• ***Foster-Kennedy syndrome.*** If symptoms are ignored or the diagnosis for GCA is overlooked, the patient may later present with pseudo-Foster-Kennedy syndrome.[10] This has the clinical appearance of optic atrophy in one eye and papillitis in the fellow eye in the absence of cranial mass. In this presentation, neuroimaging may be needed to rule out Foster-Kennedy syndrome. This presentation also can occur in the infrequent case of bilateral NAION.

In Foster-Kennedy syndrome, optic atrophy is observed in one eye and disc edema in the fellow eye from an intracranial mass lesion.[11] The mass most typically is located in the basal frontal area or a sphenoid wing meningioma. Two simple clinical facts can help clarify the diagnosis. First, the visual field defects relating to ION usually will present with an altitudinal defect in the more recent eye. Second, there will be a clear separation of the visual episodes between the two eyes in ION. In Foster-Kennedy syndrome, the vision loss is—to some degree—bilateral with asymmetry. The visual field defects usually are bizarre or respect the vertical midline.

• ***PION.*** Like the anterior portion of the optic nerve, the posterior portion of the optic nerve can have an acute infarction—but it occurs less frequently. Just as GCA can induce AION, it less frequently can cause PION. Patients with PION present with a sudden loss of vision in one or both eyes.

Typically, the patient with exhibit a central visual field defect alone or in conjunction with other types of visual field defects in the affected eye or eyes. There is an APD, and initially, the optic nerve looks normal, but then turns pale over four to six weeks. There are

Treatment with Multiple Sclerosis

Prior to the Controlled High-Risk Subjects Avonex MS Prevention Study (CHAMPS), the recommended treatment was derived from ONTT—an initially high dosage of intravenous methylprednisolone followed by oral prednisone.[1] The CHAMPS study showed significant treatment benefits with the use of Avonex (interferon beta-1a, Biogen Inc.) following initial IV methylprednisolone.[17] Avonex is delivered intramuscularly on a weekly basis.

This treatment protocol showed a 57% reduction in the mean number of new T2 lesions, a 67% reduction in the number of gadolinium-enhancing lesions and a 91% reduction in T2 lesion volume. The Avonex-treated group showed a 44% reduction in the probability of developing future multiple sclerosis events in a three-year period.[18]

The CHAMPS results were so convincing that it was stopped early to make this treatment option available in MS therapy.[17] Avonex's mechanism of action is unknown at this time. It has been proposed that Avonex works by altering the imbalance in the immune system in those with demyelinating disease. In addition to optic neuritis, young patients with internuclear ophthalmopledgia or sixth nerve palsy who show risk of MS should also be considered for Avonex therapy.[17]

On Sept. 22, 2010, the FDA approved Gilenya (fingolimod, Novartis) capsules for the oral treatment of MS. It is used in MS to reduce relapses and delay disability progression in patients with relapsing forms of MS. It falls within a new class of drugs used in MS treatment that block some blood cells in the lymph nodes, reducing their migration in the brain and spinal cord, which can reduce the severity of MS.

Ophthalmic consultation has been advised with this medication due to reported cases of decreased vision from macular edema. Macular edema typically presents three months after the initiation of treatment with Gilenya.

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ALPHAGAN® P may potentiate syndromes associated with vascular insufficiency. Use with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

ALPHAGAN® P had minimal effect on blood pressure. Caution should be exercised in treating patients with severe cardiovascular disease.

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.

ADVERSE REACTIONS

ALPHAGAN® P adverse reactions (10% to 20%) included allergic conjunctivitis, conjunctival hyperemia, and eye pruritus. Adverse reactions (5% to 9%) included burning sensation, conjunctival folliculosis, hypertension, ocular allergic reaction, oral dryness, and visual disturbance.

DRUG INTERACTIONS

Antihypertensives/Cardiac Glycosides: Because ALPHAGAN® P may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with ALPHAGAN® P is advised.

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

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

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

Please see brief prescribing information on adjacent page.

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SPECIFY 0.1%

Alphagan® P
(brimonidine tartrate ophthalmic solution) 0.1%

ALPHAGAN® P

(brimonidine tartrate ophthalmic solution)
0.1% and 0.15%

BRIEF SUMMARY

Please see **ALPHAGAN® P** package insert for full prescribing information.

INDICATIONS AND USAGE

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% is an alpha adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

CONTRAINDICATIONS

Neonates and Infants (under the age of 2 years)
ALPHAGAN® P is contraindicated in neonates and infants (under the age of 2 years).

Hypersensitivity Reactions
ALPHAGAN® P is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

WARNINGS AND PRECAUTIONS

Potentiation of Vascular Insufficiency
ALPHAGAN® P may potentiate syndromes associated with vascular insufficiency.

ALPHAGAN® P should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

Severe Cardiovascular Disease
Although brimonidine tartrate ophthalmic solution had minimal effect on the blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

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

ADVERSE REACTIONS

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

Adverse reactions occurring in approximately 10-20% of the subjects receiving brimonidine ophthalmic solution (0.1-0.2%) included: allergic conjunctivitis, conjunctival hyperemia, and eye pruritus. Adverse reactions occurring in approximately 5-9% included: burning sensation, conjunctival folliculosis, hypertension, ocular allergic reaction, oral dryness, and visual disturbance.

Adverse reactions occurring in approximately 1-4% of the subjects receiving brimonidine ophthalmic solution (0.1-0.2%) included: abnormal taste, allergic reaction, asthenia, blepharitis, blepharoconjunctivitis, blurred vision, bronchitis, cataract, conjunctival edema, conjunctival hemorrhage, conjunctivitis, cough, dizziness, dyspepsia, dyspnea, epiphora, eye discharge, eye dryness, eye irritation, eye pain, eyelid edema, eyelid erythema, fatigue, flu syndrome, follicular conjunctivitis, foreign body sensation, gastrointestinal disorder, headache, hypercholesterolemia, hypotension, infection (primarily colds and respiratory infections), insomnia, keratitis, lid disorder, pharyngitis, photophobia, rash, rhinitis, sinus infection, sinusitis, somnolence, stinging, superficial punctate keratopathy, tearing, visual field defect, vitreous detachment, vitreous disorder, vitreous floaters, and worsened visual acuity.

The following reactions were reported in less than 1% of subjects: corneal erosion, hordeolum, nasal dryness, and taste perversion.

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

DRUG INTERACTIONS

Antihypertensives/Cardiac Glycosides
Because **ALPHAGAN® P** may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with **ALPHAGAN® P** is advised.

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category B: Teratogenicity studies have been performed in animals.

Brimonidine tartrate was not teratogenic when given orally during gestation days 6 through 15 in rats and days 6 through 18 in rabbits. The highest doses of brimonidine tartrate in rats (2.5 mg /kg/day) and rabbits (5.0 mg/kg/day) achieved AUC exposure values 360- and 20-fold higher, or 260- and 15-fold higher, respectively, than similar values estimated in humans treated with **ALPHAGAN® P** 0.1% or 0.15%, 1 drop in both eyes three times daily.

There are no adequate and well-controlled studies in pregnant women; however, in animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Because animal reproduction studies are not always predictive of human response, **ALPHAGAN® P** should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers
It is not known whether brimonidine tartrate is excreted in human milk, although in animal studies, brimonidine tartrate has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from **ALPHAGAN® P** in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
ALPHAGAN® P is contraindicated in children under the age of 2 years (see **CONTRAINDICATIONS**). During postmarketing surveillance, apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine. The safety and effectiveness of brimonidine tartrate have not been studied in children below the age of 2 years.

In a well-controlled clinical study conducted in pediatric glaucoma patients (ages 2 to 7 years) the most commonly observed adverse reactions with brimonidine tartrate ophthalmic solution 0.2% dosed three times daily were somnolence (50-83% in patients ages 2 to 6 years) and decreased alertness. In pediatric patients 7 years of age (>20 kg), somnolence appears to occur less frequently (25%). Approximately 16% of patients on brimonidine tartrate ophthalmic solution discontinued from the study due to somnolence.

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

Special Populations
ALPHAGAN® P has not been studied in patients with hepatic impairment.

ALPHAGAN® P has not been studied in patients with renal impairment. The effect of dialysis on brimonidine pharmacokinetics in patients with renal failure is not known.

OVERDOSAGE

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility
No compound-related carcinogenic effects were observed in either mice or rats following a 21-month and 24-month study, respectively. In these studies, dietary administration of brimonidine tartrate at doses up to 2.5 mg/kg/day in mice and 1 mg/kg/day in rats achieved 150 and 120 times or 90 and 80 times, respectively, the plasma C_{max} drug concentration in humans treated with one drop of **ALPHAGAN® P** 0.1% or 0.15% into both eyes 3 times per day, the recommended daily human dose.

Brimonidine tartrate was not mutagenic or clastogenic in a series of in vitro and in vivo studies including the Ames bacterial reversion test, chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, and three in vivo studies in CD-1 mice: a host-mediated assay, cytogenetic study, and dominant lethal assay.

Reproduction and fertility studies in rats with brimonidine tartrate demonstrated no adverse effect on male or female fertility at doses which achieve up to approximately 125 and 90 times the systemic exposure following the maximum recommended human ophthalmic dose of **ALPHAGAN® P** 0.1% or 0.15%, respectively.

PATIENT COUNSELING INFORMATION

Patients should be instructed that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions (see **WARNINGS AND PRECAUTIONS**). Always replace the cap after using. If solution changes color or becomes cloudy, do not use. Do not use the product after the expiration date marked on the bottle.

Patients also should be advised that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

As with other similar medications, **ALPHAGAN® P** may cause fatigue and/or drowsiness in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness.

Rx Only

Revised: 12/2010

Based on package insert 71816US13B

APC67YM10

Alphagan P
(brimonidine tartrate ophthalmic solution) 0.1% & 0.15%

three forms of PION: arteritic (APION), non-arteritic (NAPION) and surgical.[4]

APION is managed just like AAION; however, there is no effective treatment for NAPION. Surgical PION occurs most often in patients who have had non-ocular surgery of longer duration, or have had significant blood loss. PION also occurs in patients who have had a major hemorrhagic event from trauma or a ruptured blood vessel, producing a shock-induced neuropathy. There are no effective treatments for surgical PION, only preventative measures.

Some patients with NAPION can retain functional vision, but patients with APION or surgical PION usually are left with very poor vision in the affected eye(s). PION is a diagnosis by exclusion, and other causes must first be eliminated in the differential diagnosis.[12]

Among many others, differential diagnoses might include central nervous system disease from cerebral mass, cerebral vascular accident, cerebral aneurysm, subdural hemorrhage and meningitis. Ocular etiologies also would need to be ruled out including central retinal artery occlusion, central retinal vein occlusion, retinal detachment and other visible causes of potential eye disease determined by a comprehensive ye examination. The diagnosis of surgical PION is usually more straightforward as the patient recovers from surgery with profound vision loss.

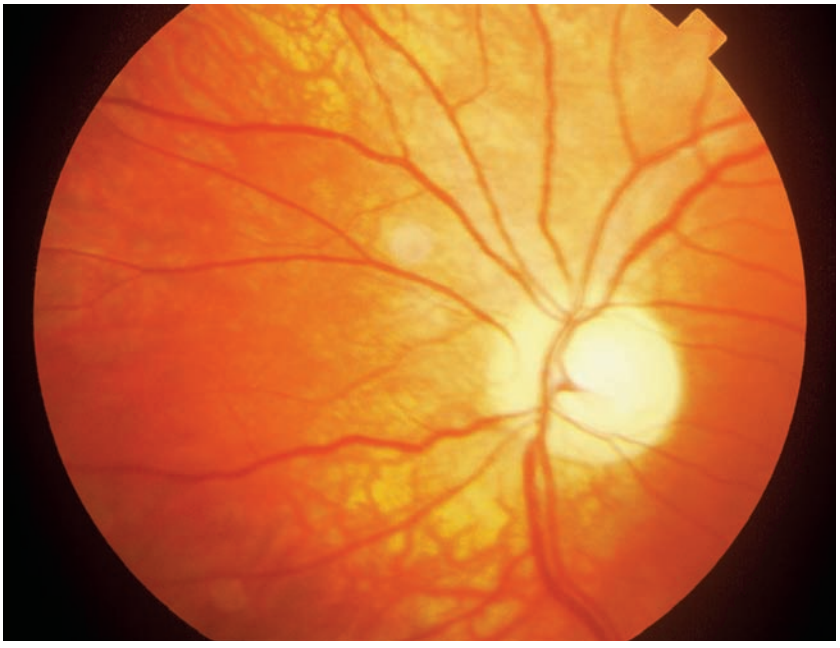
GCA Work-Up

All patients with AION will require a GCA work-up for diagnosis, or diagnosis by exclusion in NAION. All patients suspected of having AION should have blood work done. The work up for GCA should include complete blood count with differential and platelets, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). CRP has gained significant respect as a more specific predictor of GCA; however, at this time, both ESR and CRP should be included in the blood work. All patients with an abnormal ESR and/or elevated CRP also should have a temporal artery biopsy. Some patients with GCA can have normal or only mildly elevated ESR in the earlier stage of their disease. If the patient is anemic, the ESR can show a false negative value, which is the reason these patient should also have a complete blood count with the lab work.

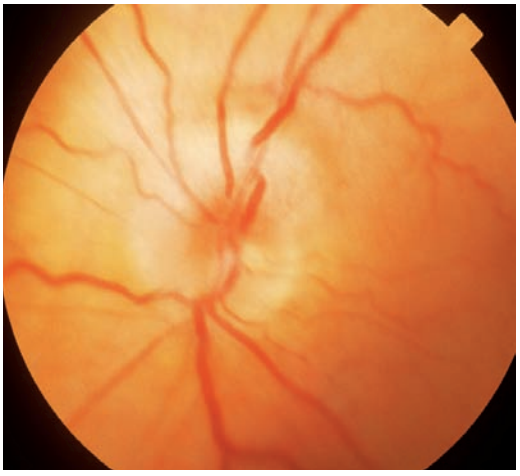
It is important to recognize that many other conditions can cause an elevated ESR and CRP, including chronic renal failure, infection, polyarteritis nodosa, PMR, systemic lupus erythematosus, rheumatoid arthritis, rheumatic fever, ulcerative colitis, regional ileitis, cardiac disease, malignant neoplasm and proteinemias.[13]

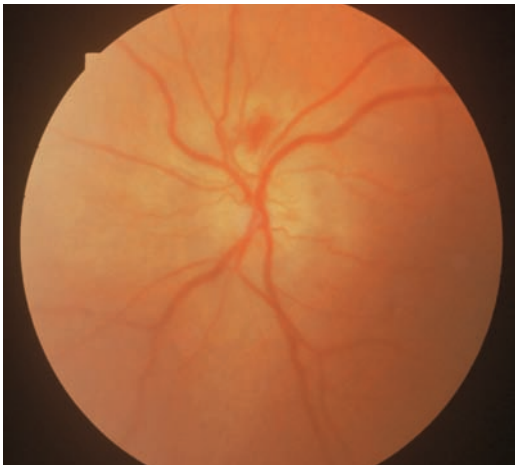
If your index of suspicion is high for GCA, a temporal artery biopsy should be performed. If the first temporal artery biopsy is negative, but the index of suspicion remains high for GCA, these patients should be considered for a second temporal artery biopsy on the contralateral side. It is important to note that there is debate about contralateral temporal artery biopsies. The probability of the unilateral biopsy being negative with a positive biopsy on the contralateral side is 1% to 5%, depending on the study.[14]

The temporal artery biopsy should obtain a minimum 2cm to 2.5cm section of artery. To improve the yield of the biopsy, some advise a specimen of 3cm to 5cm if possible, which will help minimize "skip areas" for inaccurate pathology. Others recommend the patient should have a bilateral temporal artery biopsy with 5cm sections. Some studies have shown a 13% increase in positive biopsy for GCA with simultaneous bilat-



4. NAION often progresses to optic atrophy with a poor visual outcome.





5, 6. Usually the depth of vision loss in AAION is greater and the optic nerve shows a chalky (left) or yellow, waxy appearance (right).

eral temporal artery biopsies.[15]

In reality, the surgeon performing the biopsy will dictate the protocol based on what seems best for each individual patient and the surgeon's individual philosophies. Temporal artery biopsy should be performed within two weeks of starting steroid treatment.[16] It is important to note that some patients with GCA can have a negative temporal artery biopsy, because the temporal arteries are not always involved in GCA. For this reason, some patients will be managed for GCA even with a negative temporal artery biopsy. This would be based on at-risk clinical findings, including constitutional symptoms, age, abnormal ESR, abnormal CRP and the presentation of an acute AION.

Treatment of GCA and AAION

The treatment of AAION requires systemic steroids. Patients with AION who are highly suspect of GCA should be started on high-dosage oral steroids (60mg to 100mg) immediately, until a decision can be made in the differential diagnosis. Some clinicians prefer IV steroids initially in the treatment of GCA. These patients are hospitalized and treated with 250mg of methylprednisolone every six hours, for a total of 12 doses. After that, they are treated with oral steroids on a tapering schedule.

A delay in high-dose steroid treatment can result in bilateral blindness in a patient with GCA. If the patient has GCA, long-term oral steroids will be required. The oral steroid dosage will be reduced gradually and titrated based on ESR and CRP levels. Oral steroids never should be adjusted based on the patient's symptoms or a standard timetable—the rate of reduction must be patient specific. The patient's internist will be the one to best manage this disease in most cases. Rheumatology consultation and management can be very beneficial in these cases of GCA. Certainly, periodic follow-up with the patient's eye doctor is important.

Investigation of New Testing in GCA

There is a definite need for improved objective testing in GCA. Currently, several imaging techniques are under investigation to aid in the diagnosis of GCA. These tests include magnetic resonance imaging with contrast media of the vessels, duplex ultrasound and positron emission tomography scanning. A more specific, objective test would be very beneficial in evaluating GCA, because current testing can leave questions about how to manage patients who have a negative temporal artery biopsy but remain highly suspect of having GCA. Similarly, current lab tests can fall short of reaching a definitive diagnosis in patients who are suspected of having GCA. Therefore, laboratory testing that is more specific for GCA also would be very beneficial.

This article should help you better understand the diagnosis and management of the unilateral, acute swollen optic nerve. Some of these neuropathies require no treatment, while others require possible treatment but are not considered an ophthalmic emergency. Most importantly, one subtype of acute optic neuropathy is a true ophthalmic emergency requiring immediate treatment to prevent blindness—which in most cases is avoidable with timely diagnosis and treatment.

Optometrists must be prepared to manage patients with acute optic neuropathies. Some patients will require a team approach of different specialists working together for a timely diagnosis and appropriate treatment. When you encounter a

case relating to optic nerve diseases in which the diagnosis remains a mystery, cover yourself and the patient with neuroimaging. ■

Dr. Tassi practices hospital-based optometry at the VA Medical Center in Sioux Falls, S.D. Dr. VanderZee practices hospital-based optometry at the same facility, where he serves as chief of optometry, and also is a fellow of the American Academy of Optometry.

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Report From ARVO

Our experts in cornea, retina, cataract and refractive surgery, and glaucoma have pored through hundreds of posters, papers and presentations from the annual Association for Research in Vision and Ophthalmology (ARVO) meeting in Ft. Lauderdale, Fla.—mindful of the unique needs of practicing optometrists in a variety of settings. Our thought leaders have compiled synopses of the data and insights that are most relevant to you.

In *Review*'s 13th Annual ARVO Report, their customized information capsules will update you on the latest clinical advances, studies, office-based treatments and surgical procedures in the following areas:

• ***Cornea.*** Associate Clinical Editor Joseph P. Shovlin, O.D., editor of our "Cornea and Contact Lens Q+A" column, discusses how to reduce the risk of microbial keratitis through improved contact lens case hygiene. He also reviews the evaluation of limbal and scleral changes created by contact lenses and the effects of contact-lens-induced mechanical force on central corneal sensitivity. Among numerous advances in dry eye disease, Dr. Shovlin reports that protein biomarkers for the condition were identified in post-menopausal women by using label-free quantitative proteomics. He also focuses on host immune response, anti-inflammatory agents and other treatments that should be considered when managing meibomian gland dysfunction. Finally, Dr. Shovlin provides new insights on posterior lamellar surgery and other corneal procedures.

• ***Retina.*** Contributing editor Mark T. Dunbar, O.D., author of our "Retina Quiz" column, adds to the growing body of data spawned by last year's Comparison of Age-Related Macular Degeneration Treatment Trials (CATT) by discussing new insights on the effect of retinal anatomy on outcomes. He also reviews the implications of genetic predisposition to age-related macular degeneration (AMD), based on CATT data. In addition, he comments on encouraging new findings on anti-VEGF Trap-Eye research (intravitreal aflibercept, [Eylea, Regeneron Pharmaceuticals]) related to the care of patients with AMD and diabetic macular edema. Not so encouraging, though, is the news he has to share on the MARINA and ANCHOR follow-up studies. Meanwhile, a variety of new and worthwhile perspectives on vitreo-retinal care are unveiled.

• ***Cataract and Refractive Surgery.*** Clinical and Education Conference Director Paul M. Karpecki, O.D., coauthor of our "Research Review" column, explores penetrating procedures that appear to optimize visual outcomes while treating diseased corneas. He addresses improvements in more conventional refractive surgical procedures. Dr. Karpecki also reviews novel ideas for preventing cataracts, offers updates on the femtosecond laser and suggests new strategies for managing your postoperative patients.

• ***Glaucoma.*** Co-chief clinical editor Robert Cole III, O.D., reviews the differences between generic and brand-name prostaglandin analogues. He also provides insightful discussions of 24-hour intraocular pressure control, peak morning IOP, patient adherence to prescribed regimens, ocular surface health, exercise and prevention, structure, function, monitoring, assessing nerve rim, blood flow and diagnostic technologies. ■

To view any of the abstracts cited in the ARVO report that follows, go to www.arvo.org.

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1. Based on subjective ratings at one week, on a scale of 1 to 10 with 1 = poor and 10 = excellent. In a randomized, subject-masked-to-sponsor clinical study at 19 sites with 233 patients; significance demonstrated at 0.05 level; Alcon data on file, 2011.

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* Results may vary. See USA package insert for details.

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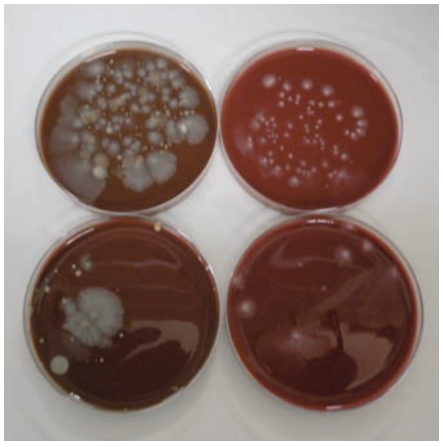
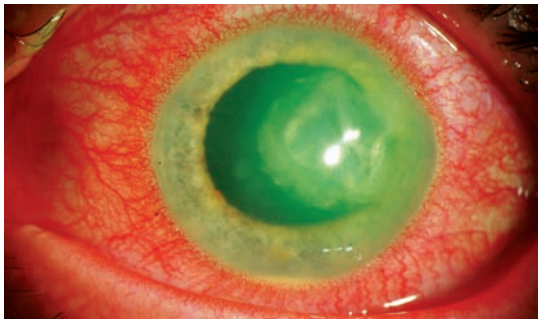
Cornea

The effect of contact lenses on the eye was high on the agenda at ARVO 2012. Dry eye also commanded attention, as did meibomian gland dysfunction and cutting edge corneal procedures. **By Joseph P. Shovlin, O.D., Associate Clinical Editor**

Researchers offered new contact lens insights that focused on lens/storage case-induced contamination, the influence of mechanical force, and other important matters. Studies also quantified the effects of dry eye on ocular tissue, investigated meibomian gland dysfunction, and evaluated new corneal procedures.





This year's ARVO research sought to reduce the incidence of microbial keratitis, by delving deeper into microbial colonization of lens cases—like those seen here.

New Data on Contact Lens Wear

Lack of contact lens case hygiene has often been shown in epidemiology research to be associated with increased risk of microbial keratitis. The aim of yet two more trials was to examine the microbial colonization of lens cases during the use of lens care products containing dual disinfectants.[693/A4]

A pair of non-contemporaneous, prospective, single-group, bilaterally designed, open-labeled clinical studies employed the same protocol to evaluate the microbial contamination of contact lens cases when used with balafilcon A lenses in conjunction with RevitaLens OcuTec (polyquaterium-1 and Alexidine, Abbott Medical Optics) in one study or in conjunction with Biotrue (polyquaternium-1 and PHMB, Bausch + Lomb) in another study. Forty subjects were enrolled in each of the studies, and lens cases (approximately 70 from each trial) were collected after one month of use. The cases were cultured with the use of standard techniques to identify microbes.

Use of lens care products containing polyquaterium-1 and Alexidine or polyquaternium-1 and PHMB resulted in a low frequency of contamination of contact lens cases by gram-negative bacteria, suggesting these lens care products may help reduce the incidence of a primary source of bacterial contamination during contact lens wear.

In other contact lens research, it was found that commercially available scleral lenses can help manage many conditions that compromise the ocular surface.[4715/A26] Although

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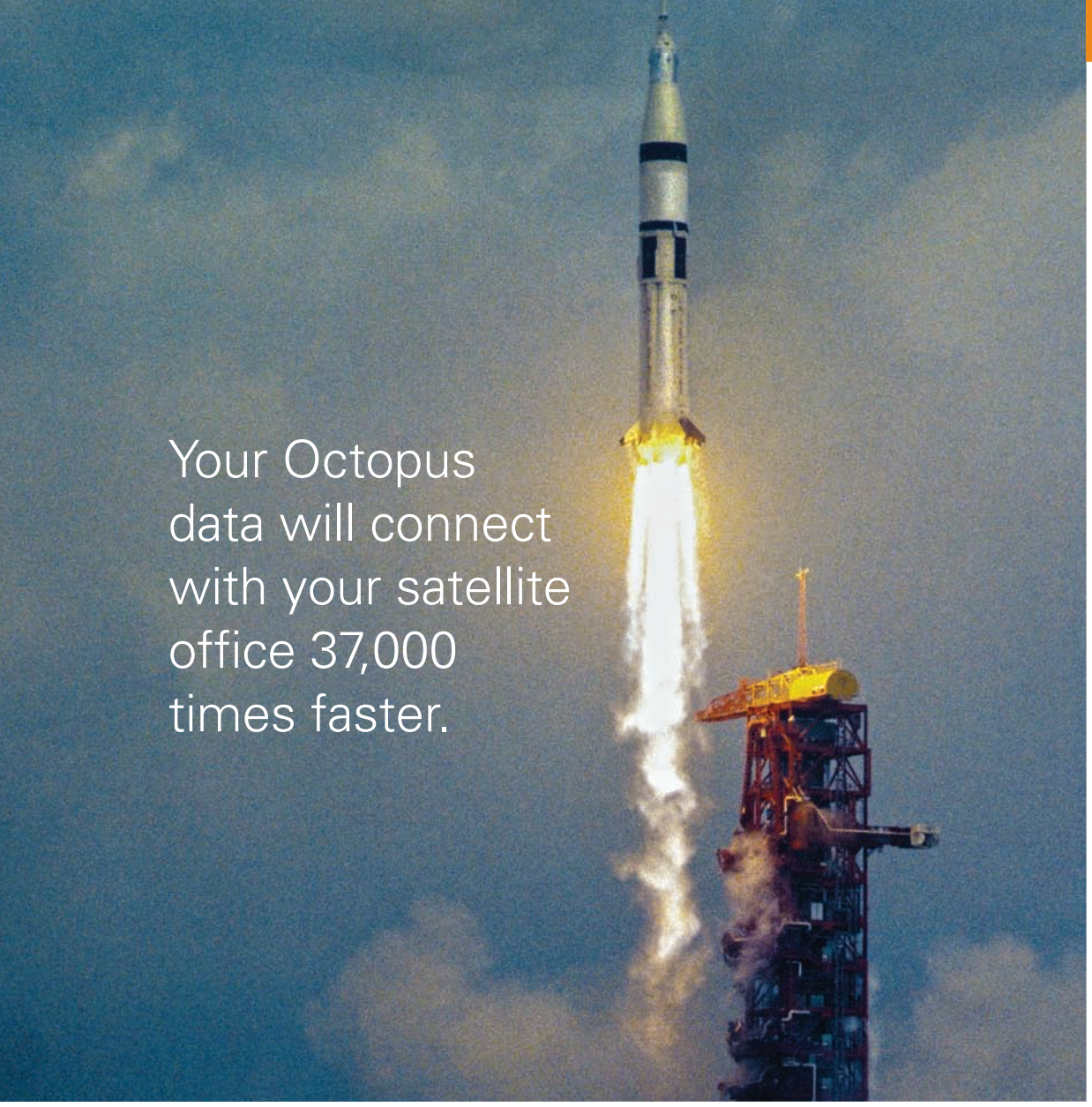

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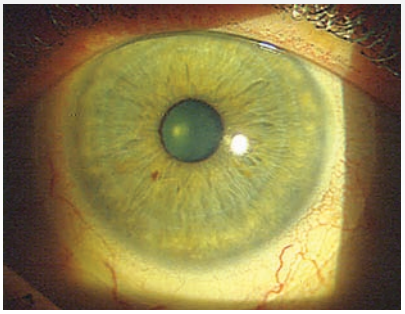
the primary goal of scleral lens wear in the studied patient population was ocular surface protection, the researchers also found that visual acuity improved for most in the group. The research focused on the use of the Jupiter Scleral Lens (Visionary Optics/Essilor Contact Lenses).

Rigid gas permeable scleral lenses rest entirely upon the sclera and completely vault the cornea and limbus, maintaining a fluid reservoir between the lens and the cornea. These unique fitting characteristics allow the devices to protect the ocular surface, the researchers reported. Data were collected at the Mayo Clinic in Rochester, Minn., through a retrospective chart review of patients with ocular surface disease who were fitted with these lenses between June 2006 and November 2011. The scleral lenses had been prescribed for 114 patients (185 eyes). Lenses were prescribed for assorted reasons, including chronic graft versus host disease, exposure keratopathy, neurotrophic keratopathy, limbal stem cell deficiency and Sjögren's syndrome, to name a few.

After patients wear any type of contact lenses, notable limbal and scleral changes are known to occur. A study at the School of Optometry, Queensland University of Technology, Brisbane, Australia, used anterior segment optical coherence tomography (AS-OCT) to evaluate these changes.[4729/A40] Nasal and temporal horizontal 5mm B-scans (centered on the limbus) were taken for six subjects using a commercial AS-OCT before and after six hours of contact lens wear for three types of lenses (hydrogel sphere, silicone hydrogel sphere and silicone hydrogel toric). At least one day of no contact lens wear was introduced between periods of lens wear.



Scleral lenses rest entirely upon the sclera and completely vault the cornea and limbus, maintaining a fluid reservoir between the lens and the cornea. These unique fitting characteristics allow the devices to protect the ocular surface.

Significant changes in the limbal/scleral region were observed after contact lens wear, while only limited corneal changes were observed. This limited study showed that AS-OCT can potentially be used as a powerful tool for observing the effects of contact lenses on the ocular surface.

Effects of Mechanical Force

The influences of hypoxia and mechanical force on corneal sensitivity during contact lens wear are currently unclear. In Sydney, Australia, investigators looked into the short-term influence of mechanical force exerted by contact lenses on central corneal sensitivity. Eighteen patients (seven males, 11 females, ages 23.6±4.8 years old) wore silicone hydrogel (SCL), rigid (RGP) or orthokeratology (OK) contact lenses. Lenses were matched in Dk/t (46 ISO units), but assumed to exert different levels of mechanical force on the corneal surface. The lenses were worn for a single overnight wear (eight hours) in the right eye only.

Central corneal sensitivity was found to be reduced after a single overnight wear of OK lenses, as measured using the Cochet-Bonnet aesthesiometer. This finding suggested that the mechanical force exerted by contact lenses may be a key influence on corneal sensitivity. It also indicated that Cochet-Bonnet and non-contact corneal aesthesiometer instruments may measure different aspects of corneal sensitivity.

Extended wear patients may be able to reduce risks of complications by faithfully cleaning their lenses each morning, another study found. The retrospective analysis in Sydney, Australia, and Hyderabad, India, was designed to determine if cleaning or replacing lenses in the morning or evening—during continuous wear—influenced the rate of corneal erosions.[6092/D913]

Continuous contact lens wear related to ocular mechanical adverse events could be reduced by changes in cleaning or replacement modality, researchers found. Changes could also be related to elimination of the overnight debris accumulation achieved through a morning replacement/cleaning modality.

In another study, researchers in Boston and Iowa City, Iowa, used laser in vivo confocal microscopy to evaluate subclinical immune responses to various contact lenses and contact lens solutions.[6112/D933] The multicenter, randomized, double-blinded, clinical trial focused on 65 naive contact wearers (130 eyes) who had been fitted with silicone hydrogel contact lenses (PureVision [Bausch + Lomb], Oasys [Vistakon] or Biofinity [CooperVision]) and who had been enrolled into one of three contact lens solution groups (OPTI-FREE RepleniSH [Alcon], Clear Care [Alcon] or ReNu MultiPlus [Bausch + Lomb]).

Increased ocular surface staining and minimal ocular injection were observed in all groups. Conjuncti-

SWITCH TO THE POWER OF BEPREVE

For the treatment of itching associated with allergic conjunctivitis

Turn off itch—turn on comfort.

Discover the power to turn off ocular itching associated with allergic conjunctivitis–even for severe patients.

BEPREVE (bepotastine besilate ophthalmic solution) is indicated for the treatment of itching associated with allergic conjunctivitis. 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.

Prescribe the Power.™

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ISTA Pharmaceuticals®
www.istavision.com

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

----------INDICATIONS AND USAGE----------

BEPREVE is a histamine H_1 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)

----------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 ISTA Pharmaceuticals, Inc. at 1-877-788-2020, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 01/2010

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

None.

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

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.

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 radiolabeled 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 µg-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.

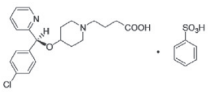
8.5 Geriatric Use

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 67425-007-50)
10 mL (NDC 67425-007-75)

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.

Rx only

Manufactured for: ISTA Pharmaceuticals®, Inc.
Irvine, CA 92618

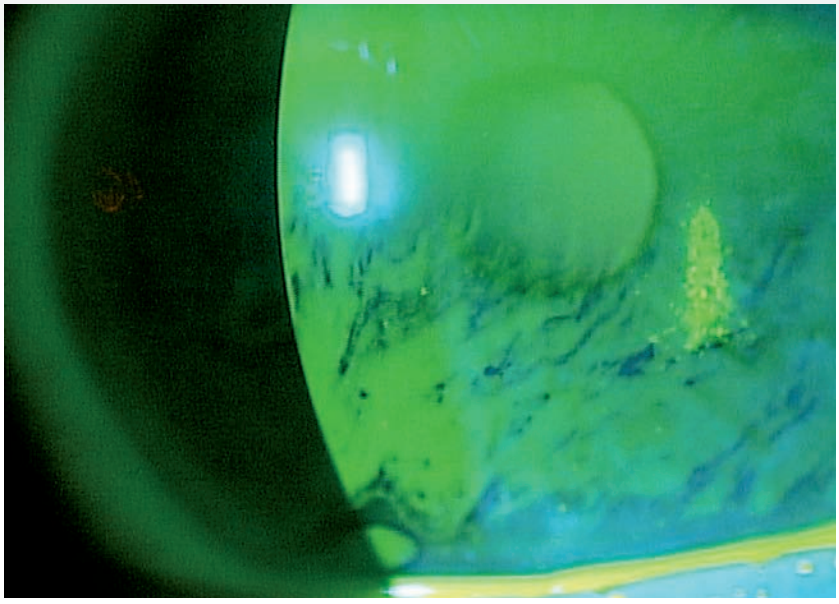
By: Bausch & Lomb Incorporated
Tampa, FL 33637

Under license from:
Senju Pharmaceutical Co., Ltd.
Osaka, Japan 541-004

BRV859-7/10

val staining correlated to peripheral dendritic cell density (r>0.40 for all quadrants).

ReNu MultiPlus demonstrated significantly increased staining for all conjunctival, limbal and cornea areas, correlating with the highest increase in dendritic cell density in the central cornea (58%) and nasal (26%) and temporal (24%) quadrants at six weeks, compared to OPTI-FREE RepleniSH and Clear Care. Laser in vivo confocal miscroscopy revealed increased immune cell infiltration in all groups after one week of contact lens wear. Corneal and conjunctival staining were detected after six weeks of wear.



In an effort to create new treatments for patients with ocular surface disease, protein biomarkers for dry eye were identified in post-menopausal women.

Dry Eye Advances

Protein biomarkers for dry eye disease were identified in post-menopausal women by using label-free quantitative proteomics.[413] Investigators from Ohio State University School of Optometry and the College of Optometry, University of Texas, tried this approach to analyze protein extracted from the Schirmer strips from normal patients (n=25) and patients with post-menopausal dry eye (n=25). Each sample was individually digested with trypsin and then analyzed by liquid chromatography–mass spectrometry.

Approximately 400 unique proteins were identified. Proteins of interest—lysozyme, lipocalin and mammoglobin B—demonstrated numerous functions and protective roles, including front-line defense, tear film stability, lipid scavengers, and products of inflammation.

In another study at the School of Optometry, Indiana University, and University of Waterloo, Ontario, Canada, researchers sought evidence that fluorescent dye quenched the tear film and affected its interpretation.[4258/A135] They measured changes in tear film fluorescence over time during tear break-up (TBU) and thinning, along with associated sensory descriptors in 16 patients with a range of dry eye symptoms.

In each patient, one eye was kept open as long as possible, while the patient indicated level of discomfort on a 0 to 10 scale and described sensations. An arbitrary cutoff of 5% TBU at the end of each trial was used to divide subjects into two groups—TBU vs. tear thinning.

A decrease in tear film fluorescence over time was best explained by the phenomenon of fluorescent dye quenching as the tear film thinned because of evaporation. However, the rate of change in fluorescence was much higher when associated with rapid TBU. Associated sensations were greater, suggesting that TBU and thinning operate by different mechanisms and exert different levels of stress on the ocular surface.

Meibomian Gland Dysfunction

One study in Boston focused on the host immune response and effects of anti-inflammatory treatment in meibomian gland dysfunction.[593/A61] Laser in vivo confocal microscopy was used to analyze images of the palpebral conjunctiva and meibomian glands of one eye of five healthy individuals and both eyes of 11 patients with a clinical diagnosis of meibomian gland dysfunction. Anti-inflammatory treatment was prescribed based on laser in vivo confocal microscopy findings, resulting in follow-up visits for six patients.

Confocal microscopy indicated that meibomian gland dysfunction was associated with increased conjunctival and intraglandular inflammation. Anti-inflammatory therapy improved both clinical signs and imaging parameters, but it was followed by a lag in symptomatic relief.

Searching for causes of meibomian gland dysfunction, investigators in Tampa, Fla., identified

fibrotic obstruction as a major factor.[605/A73] Intraductal meibomian gland probing was designed to evaluate frequency of a popping noise and tactile relief of intraductal resistance. Gritty sensations were also associated with keratinized cell debris believed to be contributing to obstructive meibomian gland dysfunction. Of 15,642 glands probed, 41% involved popping, 24% involved gritty sensations and 35% exhibited neither of these characteristics. Up to 74% of upper glands and 50% of lower glands revealed some degree of detectable intraductal resistance.

Experts at the University of Texas took a retrospective look at the effectiveness of long-term treatments of meibomian gland dysfunction.[608/A76] Their study of 82 patients showed that the current treatment approach had a positive impact on patients' signs and symptoms. Current treatments are aimed at unplugging the meibomian glands, altering meibum, and controlling inflammation on a short-term basis, typically during a period of days to weeks. Efficacy of the treatments was assessed by basal tear testing and ratings of 0 to 4 (0=none, 4=severe) for anterior blepharitis, lid margin vascularity, meibomian gland obstruction and meibum turbidity.

Statistically significant improvements were noted for anterior blepharitis and meibomian glands at all time points during the two-year study period. Anterior blepharitis scores improved by 0.79 and 0.78 points after three months and by 1.00 and 0.92 in the three-to-six-month follow-up group. Meibomian gland obstruction improved by 0.68 in the lower left lid in the zero-to-three month month group at 1.43 and at 1.86 points after the first year of follow up.

Updates on Corneal Procedures

Debate persists over whether graft thickness determines functional outcome in posterior lamellar surgery. One important study that shed new light on the subject compared descemet membrane endothelial keratoplasty (DMEK) outcomes to descemet stripping automated endothelial keratoplasty (DSAEK) at the University of Erlangen-Nuremberg, Erlangen, Germany.[3137]

The study looked at a single-center, retrospective, consecutive case series of 38 consecutive patients undergoing DMEK and 35 consecutive patients undergoing DSAEK for Fuchs endothelial dystrophy or pseudophakic bullous keratopathy. Three months after DMEK, 83% of the eyes reached a visual acuity of 20/40 or better, which increased to 95% six months after surgery. Thirty-six percent of eyes reached a visual acuity of 20/25 or better three months after DMEK. This proportion increased to 50% six months after surgery.

Several studies investigated MGD, including its dignosis, cause and treatments.

Meanwhile, three months after DSAEK, 28% of eyes reached a visual acuity of 20/40 or better, which increased to 43% six months after surgery. Therefore, DMEK was found to provide faster and more complete visual rehabilitation six months after surgery when compared to DSAEK. Endothelial cell survival was not significantly different between either group, within a six-month follow-up period.

Researchers in Portland, Ore., used anterior corneal topography to measure improvements in anterior corneal topography for up to two years after DSAEK.[3139] From a prospective data registry of corneal transplant recipients, researchers identified 75 eyes of 58 patients who received DSAEK for Fuchs' corneal endothelial dystrophy or pseudophakic bullous keratopathy. These patients had no ocular comorbidities known to limit visual acuity and had complete datasets for three years of post-operative follow-up.

Best spectacle-corrected visual acuity improved at each time point, but not every interval revealed statistical significance. Mean Snellen best corrected visual acuity was 20/51 pre-operatively, 20/30 at six months, 20/29 at 12 months, 20/25 at 24 months, and 20/24 at 36 months.

Researchers studied ReLEx smile (Carl Zeiss Meditec AG), a new femtosecond laser-based, small-incision lenticule extraction procedure that addresses moderate and high myopia.[5575] A total of 379 eyes (198 patients) were treated for myopia (spherical equivalent ranging from -13.13D to -1.63D, mean -7.28D) with ReLEx smile and prospectively followed for three months.

ReLEx smile is a flapless, all-in-one refractive procedure. Refractive predictability, safety and patient satisfaction at three months seemed equal to ReLEx flex and femtosecond-LASIK. Optimizing laser energy settings and surgeon experience was confirmed to be important to minimize initial inferior results. ■

INTRODUCING

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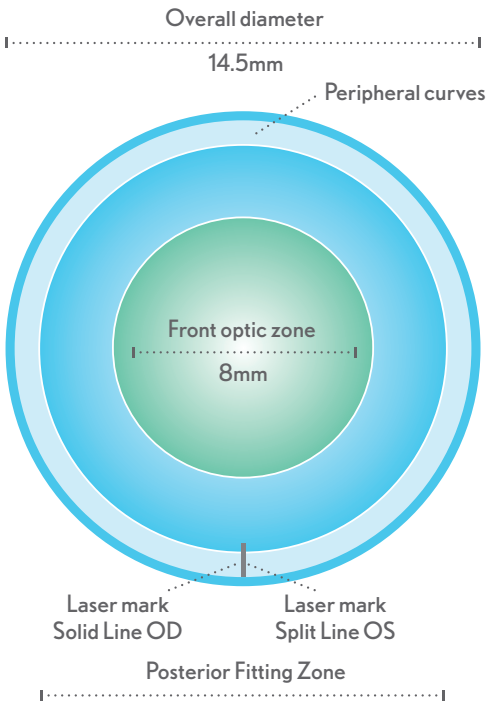

A revolutionary design for keratoconus and other irregular corneas.

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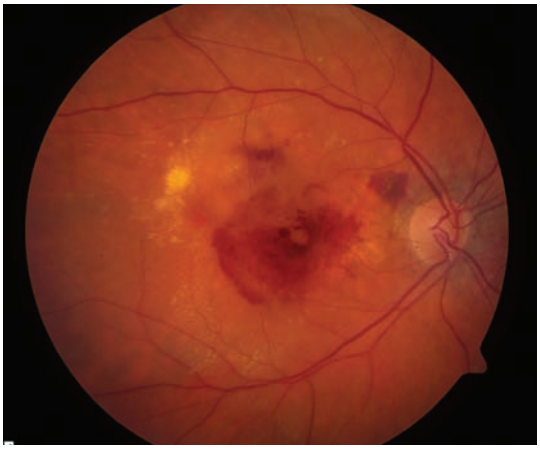
Metro Optics	800-223-1858

Retina

Researchers revealed new insights from established studies in AMD and diabetic retinopathy at ARVO 2012. Pioneering work on retinal-vitreal treatments, genetics, sleep apnea and other topics provided many additional learning opportunities.

By Mark T. Dunbar, O.D., Contributing Editor

Researchers rolled up their sleeves and produced important analyses of the Comparison of Age-Related Macular Degeneration Treatment Trial (CATT) and the MARINA and ANCHOR studies. VEGF Trap-Eye, sleep apnea, and other topics also stimulated rich discussion of future interventions in the posterior segment.



Research at ARVO followed up on the CATT study, which confirmed that Avastin is just as effective as Lucentis for the treatment of neovascular AMD, as seen in this patient. In this new research, however, clinicians are starting to see post-treatment differences in outcome.

Milestone Trial Continues Its Influence

Following up on the landmark findings of CATT, researchers confirmed that the reduction of central neovascular (CNV) lesion sizes after injection with ranibizumab was similar to the reduction experienced after injection with bevacizumab.[2893/A338] However, they were also starting to see post-treatment differences in outcome that were determined by retinal anatomy.

In a review of 1,185 patients after 52 weeks of treatment, the researchers found anti-vascular endothelial growth factor (anti-VEGF) therapy reduced lesion activity and improved visual acuity in all treatment groups. However, at all time points, those with residual OCT-determined intraretinal fluid had worse visual acuity than those without fluid. In addition, abnormally thin or thick retinas revealed worse visual acuity. Monthly ranibizumab dosing resulted in more eyes with no fluid and lower mean retinal thickness, although the long-term significance of this finding was still unknown. These results raised important treatment implications in eyes undergoing anti-VEGF therapy for neovascular age-related macular degeneration (AMD).

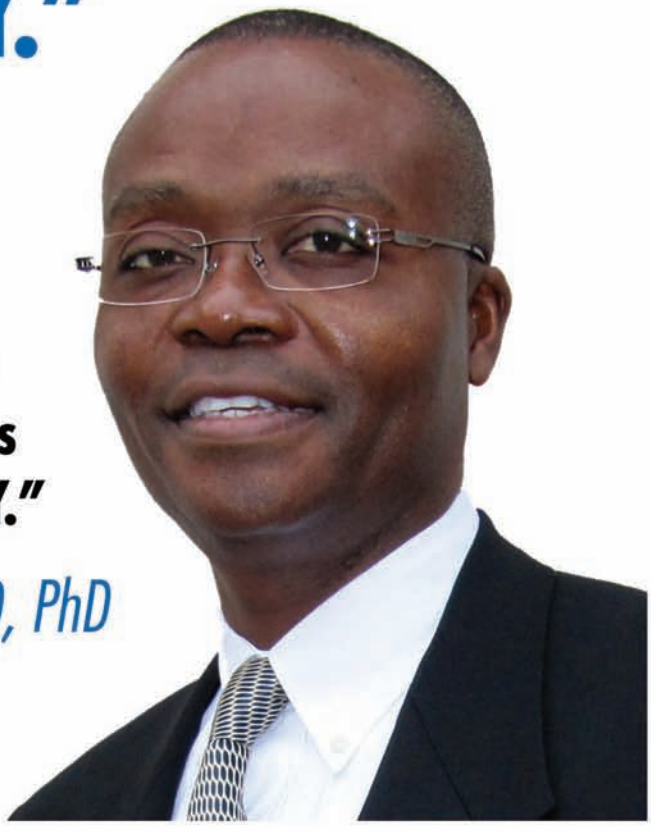
In another CATT follow-up report, anti-VEGF agents were found to possibly have a systemic impact on the proliferation of AMD in the fellow, unaffected eye.[3680] This is important data for optometrists, helping to inform their efforts in continuously monitoring for the appearance or progression of disease in contralateral eyes.

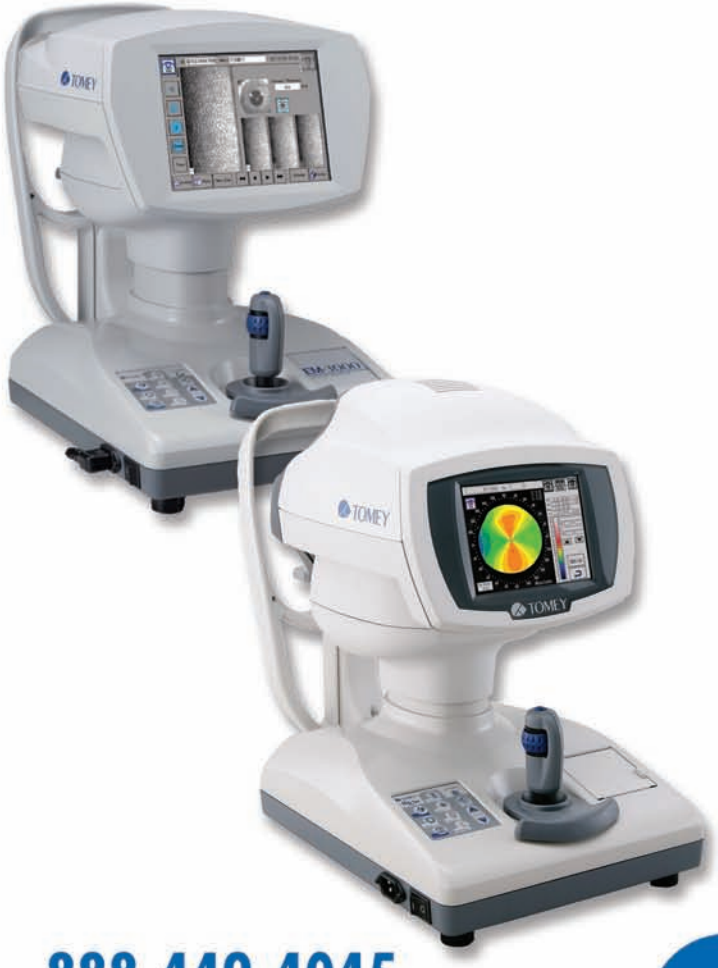
Among 1,185 CATT patients, 61% showed no signs of CNV in

"AFTER AN EXTENSIVE SEARCH, I CHOSE TOMEY."

"When it came time to make a selection of a Specular Microscope and or an Autorefractor/Topographer to upgrade our diagnostic services to our patients, I chose TOMEY."

– Dr. A. Philip Aitsebaomo, OD, PhD





"A few years ago when I decided it was time to upgrade my medical services to my patients, I started a project that evaluated various medical devices. I was not so concerned with the cost but was mostly interested in how the device performed.

"One of the devices I was very much interested was a Specular microscope. There were a few on the market and after an extensive evaluating process; I selected the Tomey Specular Microscope. This device was relatively new on the market, but what I especially liked on the unit was the fact that it took 15 shots in the time other units took one. This feature almost guaranteed that I would obtain a good photo every time.

"Based on these and other features, I chose TOMEY. Surprisingly it was the least expensive unit. I purchased the most advanced device for less, and the staff really appreciate the ease of use."

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the fellow eye at enrollment. At one year, CNV had developed in 8% of 365 eyes of patients who had been treated with ranibizumab and seven percent of 362 patients who had been treated with bevacizumab. After adjusting for known risk factors for CNV and drug dosing regimen, the estimated hazard ratio associated with treatment for bevacizumab was 0.92 (95% confidence interval [0.54, 1.56]). As a result, the authors concluded that CNV incidence rates in the fellow eyes of patients treated with anti-VEGF agents could indicate the systemic effects of the drugs. Through one year, ranibizumab and bevacizumab had similar effects on the incidence of CNV in the fellow eye.

Genetic Implications

Another follow-up on CATT looked at response to anti-VEGF agents among patients who had primary genetic factors for AMD.[3682] The response in these patients was virtually identical to the response in patients who were not genetically predisposed to AMD. To reach this conclusion, researchers evaluated 75% of 1,116 patients participating in CATT at 43 clinical centers. Each patient was genotyped for single nucleotide polymorphisms (SNPs) rs1061170 (CFH), rs10490924 (ARMS2), rs11200638 (HTRA1), and rs2230199 (C3), using TaqMan SNP genotyping assays. These results provided long-term hope for the visual outcome of patients with CFH2 or ARMS2 genetic variants.

Despite this promising conclusion, another study offered a troubling and completely opposite finding.[3683] Researchers in this case determined that genetically predisposed patients experienced onset of AMD at an earlier age and often responded poorly to treatment with ranibizumab, compared to patients without the genetic variants.[3683]

> "In one study, genetically predisposed patients experienced onset of AMD at an earlier age and often responded poorly to treatment with ranibizumab, compared to patients without the genetic variants."

Researchers evaluated 420 eyes of 397 unrelated Caucasian neovascular AMD patients who had been treated only with intravitreal 0.5 mg ranibizumab injections. Each participant underwent best-corrected visual acuity testing before and after treatment with three ranibizumab injections. Genotyping of SNPs in the CFH, ARMS2, VEGF, kinase insert domain receptor (KDR), low-density lipoprotein receptor-related protein 5 (LPR5) and FZD4 was performed.

In addition, a very important study showcased early genetic treatment for patients with Leber congenital amaurosis.[4642] Most patients experienced long-term visual gains with the use of an experimental oral therapy, QLT091001. The therapy was used for patients whose condition was associated with lecithin/retinol acyltransferase (LRAT) or retinal pigment epithelial 65 protein (RPE65) mutations.

Trap-Eye Data Released

Pivotal data from the latest anti-VEGF Trap-Eye study were released. These results suggest that every-other-month dosing of intravitreal aflibercept (Eylea, Regeneron Pharmaceuticals) is just as effective as monthly injections of ranibizumab (Lucentis, Genentech/Roche).[2042/D1060]

A total of 2,457 patients with AMD from VIEW 1 and VIEW 2 were randomized to four treatment groups: ranibizumab 0.5mg every four weeks and aflibercept 2mg every four weeks, aflibercept 0.5mg every four weeks, and aflibercept 2mg every eight weeks (after three initial monthly doses).

In outcomes of ≥ 15 letters at the 52nd week, cumulative incidence curves for the four dosing regimens did not differ. Improvement in vision was observed early in all treatment groups.

Another VEGF Trap-Eye study examined the safety and efficacy of the drug for treating cystoid macular edema secondary to central retinal vein occlusion (CRVO).[6929] The one-year GALILEO study—a double-masked, multi-center, controlled phase III study—looked at 177 patients who were randomized to 2mg of intravitreal aflibercept or

What is VEGF Trap-Eye?

On June 17, the FDA's Dermatologic and Ophthalmic Drugs Advisory Committee voted unanimously to recommend approval of Eylea (aflibercept ophthalmic solution, Regeneron Pharmaceuticals)—an injectible drug for the treatment of the neovascular form of age-related macular degeneration, or wet AMD. Eylea, also known as VEGF Trap-Eye, is a fully human fusion protein consisting of portions of VEGF receptors 1 and 2 that bind all forms of VEGF-A, along with the related Placental Growth Factor (PlGF). Eylea is a specific and highly potent blocker of these growth factors. The drug is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

7 STUDIES
1,563 PATIENTS
1 POOLED RESULT

30% SUSTAINED

IOP lowering for up to a full day[1]

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Visit www.travatanz.com/7studies1result

Scan the QR code using your smartphone, or ask your local sales representative for a free copy of the published study.

INDICATIONS AND USAGE:
TRAVATAN Z® Solution is a prostaglandin analog indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration:
One drop in the affected eye(s) once daily in the evening.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:
Pigmentation: Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent.

Eyelash Changes: Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible.

Adverse Reactions:
Most common adverse reaction (30% to 50%) is conjunctival hyperemia.

Use In Specific Populations:
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.

For additional information please refer to the accompanying brief summary of prescribing information on adjacent page.

Reference:
1. Dubiner HB, Noecker R. Sustained intraocular pressure reduction throughout the day with travoprost ophthalmic solution 0.004%. *Clin Ophthalmol.* 2012;6:525-531.

Alcon®

TRAVATAN Z®
(travoprost ophthalmic solution) 0.004%

TRAVATAN Z®

(travoprost ophthalmic solution) 0.004%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is indicated for the reduction of elevated 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) once daily in the evening.
TRAVATAN Z® (travoprost ophthalmic solution) should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the intraocular pressure lowering effect.

Reduction of the intraocular pressure starts approximately 2 hours after the first administration with maximum effect reached after 12 hours.

TRAVATAN Z® Solution may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
Pigmentation
Travoprost 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 travoprost 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 travoprost, 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 TRAVATAN Z® (travoprost ophthalmic solution) 0.004% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes
TRAVATAN Z® Solution 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
TRAVATAN Z® Solution 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 travoprost ophthalmic solution. TRAVATAN Z® Solution 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
TRAVATAN Z® Solution 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 TRAVATAN Z® 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. The most common adverse reaction observed in controlled clinical studies with TRAVATAN® (travoprost ophthalmic solution) 0.004% and TRAVATAN Z® (travoprost ophthalmic solution) 0.004% was ocular hyperemia which was reported in 30 to 50% of patients. Up to 3% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse reactions reported at an incidence of 5 to 10% in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritus. Ocular adverse reactions reported at an incidence of 1 to 4% in clinical studies with TRAVATAN® or TRAVATAN Z® Solutions included abnormal vision, blepharitis, blurred vision, cataract, conjunctivitis, corneal staining, dry eye, iris discoloration, keratitis, lid margin crusting, ocular inflammation, photophobia, subconjunctival hemorrhage and tearing.

Nonocular adverse reactions reported at an incidence of 1 to 5% in these clinical studies were allergy, angina pectoris, anxiety, arthritis, back pain, bradycardia, bronchitis, chest pain, cold/flu syndrome, depression, dyspepsia, gastrointestinal disorder, headache, hypercholesterolemia, hypertension, hypotension, infection, pain, prostate disorder, sinusitis, urinary incontinence and urinary tract infections.

In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C
Teratogenic effects: Travoprost was teratogenic in rats, at an intravenous (IV) dose up to 10 mcg/kg/day (250 times the maximal recommended human ocular dose (MRHOD), evidenced by an increase in the incidence of skeletal malformations as well as external and visceral malformations, such as fused sternebrae, domed head and hydrocephaly. Travoprost was not teratogenic in rats at IV doses up to 3 mcg/kg/day (75 times the MRHOD), or in mice at subcutaneous doses up to 1 mcg/kg/day (25 times the MRHOD). Travoprost produced an increase in post-implantation losses and a decrease in fetal viability in rats at IV doses > 3 mcg/kg/day (75 times the MRHOD) and in mice at subcutaneous doses > 0.3 mcg/kg/day (7.5 times the MRHOD).

In the offspring of female rats that received travoprost subcutaneously from Day 7 of pregnancy to lactation Day 21 at doses of ≥ 0.12 mcg/kg/day (3 times the MRHOD), the incidence of postnatal mortality was increased, and neonatal body weight gain was decreased. Neonatal development was also affected, evidenced by delayed eye opening, pinna detachment and preputial separation, and by decreased motor activity.

There are no adequate and well-controlled studies of TRAVATAN Z® (travoprost ophthalmic solution) 0.004% administration in pregnant women. Because animal reproductive studies are not always predictive of human response, TRAVATAN Z® Solution should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
A study in lactating rats demonstrated that radiolabeled travoprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRAVATAN Z® Solution 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 and Renal Impairment
Travoprost ophthalmic solution 0.004% has been studied in patients with hepatic impairment and also in patients with renal impairment. No clinically relevant changes in hematology, blood chemistry, or urinalysis laboratory data were observed in these patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Two-year carcinogenicity studies in mice and rats at subcutaneous doses of 10, 30, or 100 mcg/kg/day did not show any evidence of carcinogenic potential. However, at 100 mcg/kg/day, male rats were only treated for 82 weeks, and the maximum tolerated dose (MTD) was not reached in the mouse study. The high dose (100 mcg/kg) corresponds to exposure levels over 400 times the human exposure at the maximum recommended human ocular dose (MRHOD) of 0.04 mcg/kg, based on plasma active drug levels. Travoprost was not mutagenic in the Ames test, mouse micronucleus test or rat chromosome aberration assay. A slight increase in the mutant frequency was observed in one of two mouse lymphoma assays in the presence of rat S-9 activation enzymes.

Travoprost did not affect mating or fertility indices in male or female rats at subcutaneous doses up to 10 mcg/kg/day [250 times the maximum recommended human ocular dose of 0.04 mcg/kg/day on a mcg/kg basis (MRHOD)]. At 10 mcg/kg/day, the mean number of corpora lutea was reduced, and the post-implantation losses were increased. These effects were not observed at 3 mcg/kg/day (75 times the MRHOD).

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 TRAVATAN Z® (travoprost ophthalmic solution) 0.004%.

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 TRAVATAN Z® Solution. 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 TRAVATAN Z® Solution.

Use with Contact Lenses
Contact lenses should be removed prior to instillation of TRAVATAN Z® Solution and may be reinserted 15 minutes following its administration.

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

Rx Only
U.S. Patent Nos. 5,631,287; 5,889,052, 6,011,062; 6,235,781; 6,503,497; and 6,849,253

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4/12 TRV12070JAD

sham injections every four weeks. Beginning at week 24 through week 52, patients in the aflibercept group were treated on an as-needed (PRN) basis with sham injections during non-treatment visits.

After 52 weeks, 60.2% of patients in the aflibercept group had gained at least 15 ETDRS letters from baseline, compared to 32.4% of patients in the sham group. These results corroborated previous results from the sister COPERNICUS study, suggesting that intravitreal aflibercept injection could be an effective treatment for macular edema secondary to CRVO.

Long-term MARINA and ANCHOR Results

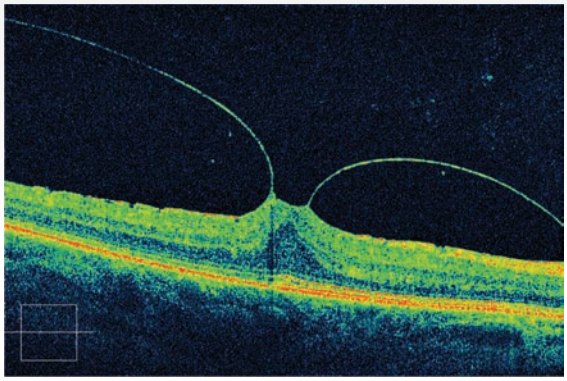
Seven-year data from MARINA and ANCHOR were released, suggesting that most patients on long-term anti-VEGF therapy continued to demonstrate significant disease progress or blindness.[3679]

Fourteen U.S. clinical trial sites recruited 65 patients originally treated in the ANCHOR and MARINA trials (enrolled between March 2003 and September 2004) and further treated with ranibizumab in the HORIZON extension study. At the time of this most recent analysis, the cohort was being reviewed seven to eight years after initiation of intravitreal ranibizumab treatment. For the primary endpoint, 37% of original study eyes had ETDRS visual acuity of 20/70 or better. The mean visual acuity in study eyes was 20/125. Within the cohort, subgroups showed favorable outcomes, with good vision (≥ 20/40) in 23% of eyes and durable CNV quiescence in 35%. By contrast, another group showed poor outcomes; 37% of eyes had vision of 20/200 or worse. Ongoing exudative disease activity, defined as evidence of CNV leakage or hemorrhage at study visit or within the previous 6 months, was found in 54% of study eyes, and 23% required ongoing treatment (ranibizumab or other AMD treatments).

A report on the COMPLETE study, representing extremely important early work on a complement-inhibitor drug, was released. Complement-inhibiting agents represent the newest and most significant therapeutic treatments for early AMD.[2045/D1063]

In this prospective, double-masked study, patients with drusen in the absence of geographic atro-

phy were randomized 2:1 to intravenous (IV) eculizumab or placebo in a double-masked fashion. Fifty percent of patients in the eculizumab group received a low-dose regimen of 600mg weekly for four weeks, followed by a maintenance period of 900mg every two weeks until week 26. The other 50% received a high dose of 900mg weekly for four weeks, followed by 1,200mg every two weeks until week 26.



Ocriplasmin could provide a minimally invasive pharmacologic approach to treat patients like this one who have VMT syndrome.

The COMPLETE study represents the first coordinated use of systemic complement inhibition for the treatment of dry AMD and systemic complement inhibition. Eculizumab was well tolerated through six months.

Sleep Apnea and Bevacizumab

Researchers found that untreated obstructive sleep apnea hinders functional and anatomical response to bevacizumab in AMD.[2925/A370] The treatment of sleep apnea is a popular topic across multiple disciplines of medicine, particularly in eye care (glaucoma, ocular surface disease and, now, AMD). These results suggest that optometrists should become more knowledgeable about sleep apnea, the overall impact of the condition and how to treat and manage it with other healthcare professionals.

Twelve patients with untreated obstructive sleep apnea were treated with intravitreal bevacizumab (1.25 mg/0.05ml) injections every six weeks for clinical and angiographic evidence of exudative AMD. Clinical examinations and OCT every six weeks were used to assess the anatomical and functional outcome for up to 90 weeks. The treatment of obstructive sleep apnea with continuous positive airway pressure yielded a subsequent impressive anatomical response, but functional improvement did not follow. Indentifying and treating underlying obstructive sleep apnea earlier in the management of exudative AMD may provide better functional outcomes.

New Approaches to Retinal-vitreal Disease

A new treatment for retinal-vitreal disease was shown to be well tolerated.[1337] The data suggested promising potential, despite the study's limited size. ALG-1001 is a synthetic anti-integrin oligopeptide. The first human clinical safety and efficacy data on this new class of anti-angiogenic compounds in the eye was presented.

Studies to date have shown that ALG-1001 inhibits integrin receptors in vitro and, in vivo, arrests aberrant blood vessel growth meditated by αvß3, αvß5, α2ß1 and α5ß1. These are integrin sites that are expressed in neovascular ocular tissue in patients with wet AMD and diabetic retinopathy.

Fifteen patients with end-stage diabetic macular edema completed this open label study. Baseline best- corrected visual acuity (BCVA) was ≥ 20/100. Patients had not undergone anti-VEGF treatment or focal laser treatment within 90 days. Many were refractory to bevacizumab and previous photocoagulation. Despite the small study size, the results demonstrated clinically significant efficacy, including improvements in BCVA and OCT-measured central macular thickness. The clinical improvements endured to the end of the study, at least 90 days past the last intravitreal treatment in nearly all study subjects who demonstrated improvements.

Ocriplasmin Moves Forward

Phase III of the MIVI-TRUST study provided further evidence that ocriplasmin could effectively remove vitreomacular adhesion (VMA) as well as foster the repair of full-thickness macular holes without surgical intervention.[2754] Also, the treatment appears both safe and well tolerated.

The MIVI-TRUST program, which consisted of two large, phase III clinical trials, investigated a single intravitreal injection, 125µg (100µl) of ocriplasmin, compared to a single 100µl placebo injection for the pharmacological treatment of symptomatic VMA.

A single intravitreal dose of 125µg of ocriplasmin achieved resolution of VMA in approximately 30% of patients. Resolution of this anatomic pathology resulted in clinically significant visual acuity benefits in patients with vitreomacular traction (VMT) syndrome. Treatment was well tolerated by patients. Ocriplasmin could provide a minimally invasive pharmacologic approach to treat patients with VMT syndrome.

For patients with itching due to allergic conjunctivitis...

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•

Lasts all day: Effective through 16 hours[2,3]

•

87% of Commercial lives covered[4,*]

INDICATIONS AND USAGE

LASTACAFT® is an H_1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

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**®. 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.

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

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Offering a 3 mL Bottle

*Covered with prior authorization/step edit. Total lives = 168,704,665. Based on data valid through December 2011.

References: 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. **4.** MediMedia Formulary Compass, December 2011.

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LASTACAFT®

(alcaftadine ophthalmic solution) 0.25%

No Sx Required for VMT?

A report on 36 eyes from Bascom Palmer suggested that patients with mild to moderate VMT syndrome did not require surgical intervention.[5220/D1273] The clinical course of VMT for eyes that did not undergo surgery was relatively stable over 16 months of mean follow-up. Visual acuities at the initial and final follow-up visits were similar. The study identified a low rate of progression from mild to severe grades of VMT that required vitreoretinal surgery.

Comparing Technologies

A study that compared SD-OCT, camera-based fundus autofluorescence (AF), confocal scanning laser ophthalmoscope AF and fluorescein angiographic (FA) imaging raised potentially lucrative implications for imaging device companies. A total of 30 patients were enrolled in a geographic atrophy (GA) cohort. While GA can be measured using different imaging modalities, each modality measures a different property of GA. On average, the comparison found that areas of GA measured with AF and FA were smaller than the areas measured by SD-OCT images. Whether these different imaging modalities yield similar enlargement rates remained to be determined.

These results undoubtedly will be scrutinized by industry in search of breakthrough diagnostic and monitoring technology. Nonetheless, current data continues to suggest that the use of multiple imaging devices will likely be more accurate and clinically useful than relying on one single modality.

Positive long-term results were reported for Second Sight's Argus II, a retinal prosthesis.[6953] All 30 patients, who had bare light perception or worse because of retinitis pigmentosa, received Second Sight Argus II implants.

New Ways of Monitoring

Advances in treatments for AMD and diabetic retinopathy suggest that frequent disease monitoring is crucial for timely intervention. Recently, a new handheld shape discrimination hyperacuity (hSDH) test iPhone app was designed for visual function self-monitoring in patients with maculopathy.[2914/A359]

This appears to be a promising app for at-home monitoring. More apps are becoming available to provide useful clinical information to the user. This app could help patients determine if their condition is progressing, and persuade them to schedule an appointment for a clinical assessment. ■

Getting Patients to Comply with Lens Replacement

By Craig Wood, OD

What many patients fail to recognize is the correlation between reduced contact lens satisfaction and over-extending the life of their contact lenses. We have many patients who have grown frustrated with their contact lenses and inquire about laser vision correction or consider giving up on lenses all together. I like to ask these people about their lens replacement habits, lens care solutions they have used, and how often they sleep in their lenses. This can open dialogue and it's evident that most patients really don't want to give up their contact lenses – they just want something that works for them. So we take these as opportunities to educate patients on preferred lens replacement schedules and appropriate lens care solutions.

I don't believe there is one single indicator that will tell if a patient is being compliant with lens replacement. Certainly I look at their chart and take note of how long it has been since their previous visit. My staff will also make notations in the chart indicating the number of boxes of lenses that have been ordered. But with the presence of online ordering and big box stores selling lenses – it can be hard to gauge how frequently someone is actually replacing lenses.

I comment to the patient when they are in the exam chair about the presence of neovascularization or other microscopic changes that I may see and use that as a point of discussion. One tool I use extensively in my practice is corneal topography. We obtain topographies on all of our contact lens patients and then compare these scans annually. This is a great way for the doctor to point out subtle (and sometimes not so subtle) changes in the corneal shape and emphasize the medical nature of what happens to the eye when wearing contact lenses. I often use the evidence of topographical change to refit patients to a different lens.

In my practice the most compliant patients are our daily disposable lens wearers. Compliance diminishes with 2 week replacement lens wearers because they simply forget when to replace them. With DAILIES® brand lenses, it is quite obvious that they need to be replaced daily and when they aren't, the lenses become uncomfortable. With monthly replacement lens wearers, it is easy for people to associate paying their bills, or using the 1st of each month as a reference point to remind them to change their lenses. If you ask wearers of 2 week replacement lenses, they will often state they simply forget when to replace the lenses.

I follow the manufacturer's recommended replacement schedule almost without fail and I review the replacement schedule when discussing contact lens care with my patients during the annual exam. I have also trained my staff to remind the patients of proper lens replacement when they are discussing lens care solutions. We have our patients return for a one-week contact lens check and at that time again reinforce when to replace their lenses.

Cataract & Refractive Surgery

New research focuses on penetrating corneal procedures, cataract prevention and a variety of innovations that could eventually benefit patients.

By Paul M. Karpecki, O.D., Clinical and Conference Education Advisor

Thinking has literally gotten deeper in refractive surgery with the release of studies on penetrating procedures that appear to optimize visual outcomes while treating diseased corneas. Conventional refractive surgery also continues to move forward on the research front, focusing on the needs of presbyopes and the importance of osmolarity for refractive surgery candidates. Of course, cataract—the leading cause of blindness worldwide that is expected to affect an estimated 40 million people by 2020—remained a primary concern. Important studies focused on prevention.

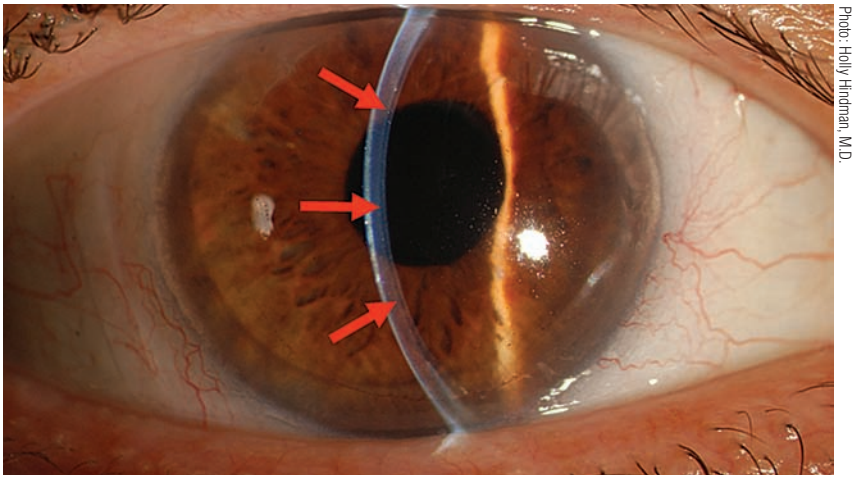

Photo: Holly Hindman, M.D.

New research suggests that the optical quality might be better in DALK because of less peripheral irregularities. This photograph illustrates a post-surgical DALK eye following suture removal. The arrows identify the graft-host interface.

Improving Penetrating Corneal Procedures

Deep anterior lamellar keratoplasty (DALK) does not involve the full transplantation used during penetrating keratoplasty (PKP). The patient's endothelium is left in place, resulting in less risk of rejection, faster healing and improved tissue stability.

DALK has not always produced ideal optical results. However, surgeons from Seoul, Korea, reported positive visual outcomes on keratoconus patients who had undergone DALK.[13/A156]

The medical records of 26 transplantation patients were retrospectively reviewed, revealing the results of nine DALK procedures with same-size grafting, five PKP procedures with same-size grafting and 12 PKP procedures with 0.25mm oversize grafting (PKPo) for keratoconus. Astigmatism tended to be lower in DALK than in PKP or PKPo, a difference that was marginally significant. Corneal irregularity indices measured at 3mm or 5mm in the DALK group were less than those in the PKP groups at the final follow-up. Highlighting these findings, the surgeons said the optical outcomes of DALK with same-size grafts for keratoconus were comparable to those of PKP. The

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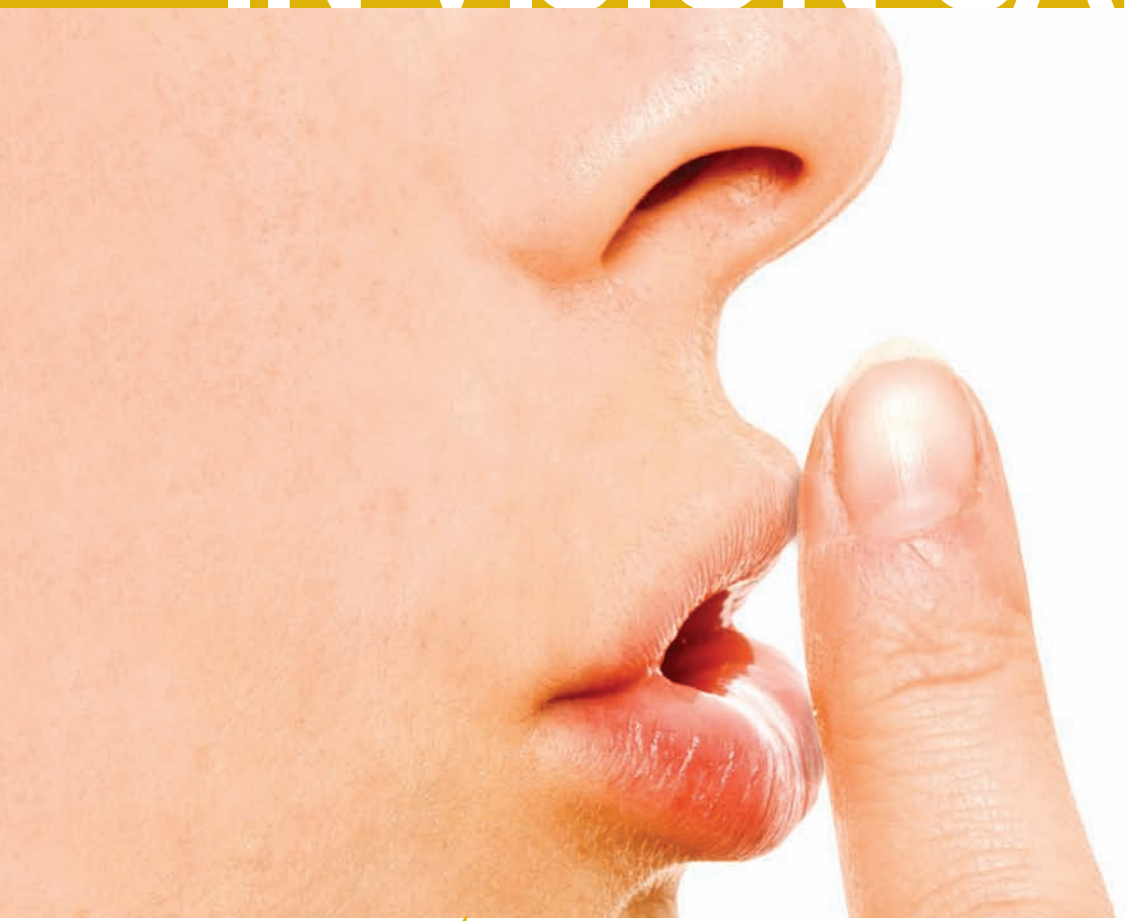

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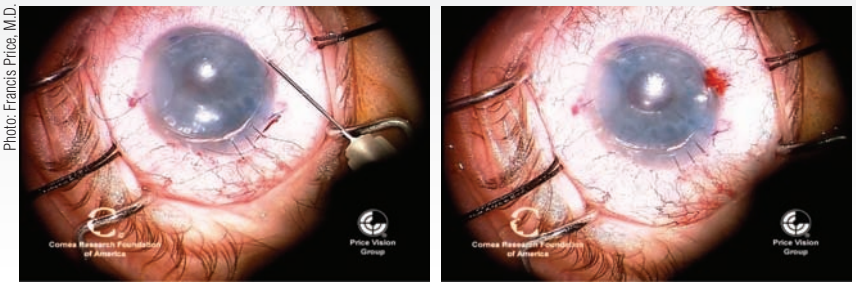

DMEK was used with some success for corneal endothelial diseases. Once the graft is unrolled, air is injected to push the graft up to the host stroma (left). DMEK is complete, with the endothelial graft in good position (right).

optical quality might be better in DALK because of less peripheral irregularities.

In a related study, Descemet's membrane endothelial keratoplasty (DMEK) was used with some success for corneal endothelial diseases through the selective replacement diseased endothelium.[20/A163] The case series involved nine consecutive patients and relied on intraoperative OCT (iOCT) to visualize the graft within the anterior chamber during orientation and attachment to the posterior cornea.

The research, based in Germany, found that the use of iOCT helped locate and orientate DMEK grafts within the recipient's anterior chamber. This procedure, although challenging, appeared to offer the potential for good visual acuity because no interface was present in the stroma, such as what would be found in Descemet's scraping endothelial keratoplasty (DSEK).

A new surgical procedure, superficial anterior lamellar keratoplasty (SALK), transplants only the anterior corneal stroma in the treatment of corneal dystrophies, such as epithelial basement membrane dystrophy, stromal dystrophy, and lattice dystrophy.

One study showed that the procedure can greatly improve vision, producing results that peak six months after surgery.[18/A161]

Conventional Refractive Surgery

As always, numerous reports covered conventional surgical correction of vision. One examined the benefits of corneal inlays for the correction of presybyopia.[1720] The inlays can be implanted in the non-dominant eyes of emmetropes or ametropes concurrently with LASIK. Three approaches were reported to be in various stages of clinical investigation:

1. Near centered multifocal effect by means of anterior corneal surface reshaping.
2. Bifocal approach using an inlay with intrinsic power.
3. Extension of depth-of-focus by means of a pinhole.

Researchers say all three are improvements over standard monovision because of improved distance vision retention in the treated eye.

Another study evaluated stereopsis in patients implanted monocularly with the KAMRA small aperture corneal inlay.[1392/A64] Under the findings, the KAMRA small aperture corneal inlay did not affect stereopsis and contrast sensitivity remained within normal limits.

A study of 128 refractive surgery patients from eight sites showed the importance of measuring osmolarity with the TearLab device before refractive surgery. The study also revealed the importance of treating hyperosmolarity with drops (Blink Tears) to achieve a faster quicker recovery.[1286] Patients with preoperative hyperosmolarity (≥ 308 mOsm/L) demonstrated significantly worse refractive outcomes at three months than their normal counterparts. For hyperosmolar patients, continuing postoperative therapy for at least three months may be important.

Preventing Cataracts?

A lot of discussion at ARVO centered on the possibility of preventing or delaying cataract onset with drops and oral agents. A study out of New Zealand and Germany looked at ex vivo permeation of cystine across bovine corneas. Seeking to develop an antioxidant drop, the researchers added ethylenediaminetetraacetic acid (EDTA), which opens tight junctions of bovine corneas to facilitate increased penetration of the drops into cystine, the limiting factor for glutathione synthesis.

Over a 24-hour period, 45nmol of cystine permeated across the bovine cornea. This amount almost tripled (118nmol over 24 hours) when the researchers incorporated 0.5% EDTA. Further penetration enhancers in combination with other delivery approaches, such as in situ gel eye drops, will be further evaluated before testing the most promising formulations in vivo.

A dietary supplement called sulforaphane is also being investigated for cataract prevention. According to one study, it can protect the human lens cells against oxidative stress and may delay the onset of cataracts.[1066/D1271] In an experiment that used the human lens epithelial cell line FHL124, application of 30μm H2O2 to FHL124 cells caused a reduction in cell viability and increased cytotoxicity and

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INDICATIONS AND USAGE

Preservative-free TIMOPTIC® in OCUDOSE® is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Preservative-free TIMOPTIC® in OCUDOSE® may be used when a patient is sensitive to the preservative in Timoptic (timolol maleate ophthalmic solution), benzalkonium chloride, or when use of a preservative-free topical medication is advisable.

IMPORTANT SAFETY INFORMATION

Timoptic is contraindicated in patients with: bronchial asthma; a history of bronchial asthma; severe chronic obstructive pulmonary disease; sinus bradycardia; second or third degree atrioventricular block; overt cardiac failure; cardiogenic shock; hypersensitivity to any component of this product.

This drug is absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. Severe respiratory or cardiac reactions, including death, have been reported following systemic or ophthalmic administration of timolol maleate. Timoptic should be used with caution in patients with cerebrovascular insufficiency.

The most frequently reported adverse experiences have been burning and stinging upon instillation.

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

Reference 1: Jaenen N, Baudouin C, Pouliquen P, et al, Ocular symptoms and signs with preserved and preservative-free glaucoma medications. *Eur J Ophthalmol.* 2007;17(3):341-349

IOP=intraocular pressure

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Brief Summary of Prescribing Information

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in OCUDOSE®
(DISPENSER)

CONTRAINDICATIONS

Preservative-free TIMOPTIC in OCUDOSE is contraindicated in patients with (1) bronchial asthma; (2) a history of bronchial asthma; (3) severe chronic obstructive pulmonary disease (see WARNINGS); (4) sinus bradycardia; (5) second or third degree atrioventricular block; (6) overt cardiac failure (see WARNINGS); (7) cardiogenic shock; or (8) hypersensitivity to any component of this product.

WARNINGS

As with many topically applied ophthalmic drugs, this drug is absorbed systemically.

The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported following systemic or ophthalmic administration of timolol maleate (see CONTRAINDICATIONS).

Cardiac Failure

Sympathetic stimulation may be essential for support of the circulation in individuals with diminished myocardial contractility, and its inhibition by beta-adrenergic receptor blockade may precipitate more severe failure.

In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of cardiac failure, Preservative-free TIMOPTIC in OCUDOSE should be discontinued.

Obstructive Pulmonary Disease

Patients with chronic obstructive pulmonary disease (e.g., chronic bronchitis, emphysema) of mild or moderate severity, bronchospastic disease, or a history of bronchospastic disease (other than bronchial asthma or a history of bronchial asthma, in which TIMOPTIC in OCUDOSE is contraindicated [see CONTRAINDICATIONS]) should, in general, not receive beta-blockers, including Preservative-free TIMOPTIC in OCUDOSE.

Major Surgery

The necessity or desirability of withdrawal of beta-adrenergic blocking agents prior to major surgery is controversial. Beta-adrenergic receptor blockade impairs the ability of the heart to respond to beta-adrenergically mediated reflex stimuli. This may augment the risk of general anesthesia in surgical procedures. Some patients receiving beta-adrenergic receptor blocking agents have experienced protracted severe hypotension during anesthesia. Difficulty in restarting and maintaining the heartbeat has also been reported. For these reasons, in patients undergoing elective surgery, some authorities recommend gradual withdrawal of beta-adrenergic receptor blocking agents.

If necessary during surgery, the effects of beta-adrenergic blocking agents may be reversed by sufficient doses of adrenergic agonists.

Diabetes Mellitus

Beta-adrenergic blocking agents should be administered with caution in patients subject to spontaneous hypoglycemia or to diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Beta-adrenergic receptor blocking agents may mask the signs and symptoms of acute hypoglycemia.

Thyrotoxicosis

Beta-adrenergic blocking agents may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta-adrenergic blocking agents that might precipitate a thyroid storm.

PRECAUTIONS

General

Because of potential effects of beta-adrenergic blocking agents on blood pressure and pulse, these agents should be used with caution in patients with cerebrovascular insufficiency. If signs or symptoms suggesting reduced cerebral blood flow develop following initiation of therapy with Preservative-free TIMOPTIC in OCUDOSE, alternative therapy should be considered.

Choroidal detachment after filtration procedures has been reported with the administration of aqueous suppressant therapy (e.g. timolol).

Angle-closure glaucoma: In patients with angle-closure glaucoma, the immediate objective of treatment is to reopen the angle. This requires constricting the pupil. Timolol maleate has little or no effect on the pupil. TIMOPTIC in OCUDOSE should not be used alone in the treatment of angle-closure glaucoma.

Anaphylaxis: While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge with such allergens. Such patients may be unresponsive to the usual doses of epinephrine used to treat anaphylactic reactions.

Muscle Weakness: Beta-adrenergic blockade has been reported to potentiate muscle weakness consistent with certain myasthenic symptoms (e.g., diplopia, ptosis, and generalized weakness). Timolol has been reported rarely to increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.

Information for Patients

Patients should be instructed about the use of Preservative-free TIMOPTIC in OCUDOSE.

Since sterility cannot be maintained after the individual unit is opened, patients should be instructed to use the product immediately after opening, and to discard the individual unit and any remaining contents immediately after use.

Patients with bronchial asthma, a history of bronchial asthma, severe chronic obstructive pulmonary disease, sinus bradycardia, second or third degree atrioventricular block, or cardiac failure should be advised not to take this product. (See CONTRAINDICATIONS.)

Drug Interactions

Although TIMOPTIC (timolol maleate ophthalmic solution) used alone has little or no effect on pupil size, mydriasis resulting from concomitant therapy with TIMOPTIC (timolol maleate ophthalmic solution) and epinephrine has been reported occasionally.

Beta-adrenergic blocking agents: Patients who are receiving a beta-adrenergic blocking agent orally and Preservative-free TIMOPTIC in OCUDOSE should be observed for potential additive effects of betablockade, both systemic and on intraocular pressure. The concomitant use of two topical beta-adrenergic blocking agents is not recommended.

Calcium antagonists: Caution should be used in the coadministration of beta-adrenergic blocking agents, such as Preservative-free TIMOPTIC in OCUDOSE, and oral or intravenous calcium antagonists, because of possible atrioventricular conduction disturbances, left ventricular failure, and hypotension. In patients with impaired cardiac function, coadministration should be avoided.

Catecholamine-depleting drugs: Close observation of the patient is recommended when a beta blocker is administered to patients receiving catecholamine-depleting drugs such as reserpine, because of possible additive effects and the production of hypotension and/or marked bradycardia, which may result in vertigo, syncope, or postural hypotension.

Digitalis and calcium antagonists: The concomitant use of beta-adrenergic blocking agents with digitalis and calcium antagonists may have additive effects in prolonging atrioventricular conduction time.

CYP2D6 inhibitors: Potentiated systemic beta-blockade (e.g., decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g., quinidine, SSRIs) and timolol.

Clonidine: Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. There have been no reports of exacerbation of rebound hypertension with ophthalmic timolol maleate.

Injectable epinephrine: (See PRECAUTIONS, General, Anaphylaxis)

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a two-year oral study of timolol maleate administered orally to rats, there was a statistically significant increase in the incidence of adrenal pheochromocytomas in male rats administered 300 mg/kg/day (approximately 42,000 times the systemic exposure following the maximum recommended human ophthalmic dose). Similar differences were not observed in rats administered oral doses equivalent to approximately 14,000 times the maximum recommended human ophthalmic dose.

In a lifetime oral study in mice, there were statistically significant increases in the incidence of benign and malignant pulmonary tumors, benign uterine polyps and mammary adenocarcinomas in female mice at 500 mg/kg/day (approximately 71,000 times the systemic exposure following the maximum recommended human ophthalmic dose), but not at 5 or 50 mg/kg/day (approximately 700 or 7,000 times, respectively, the systemic exposure following the maximum recommended human ophthalmic dose). In a subsequent study in female mice, in which postmortem examinations were limited to the uterus and the lungs, a statistically significant increase in the incidence of pulmonary tumors was again observed at 500 mg/kg/day.

The increased occurrence of mammary adenocarcinomas was associated with elevations in serum prolactin which occurred in female mice administered oral timolol at 500 mg/kg/day, but not at doses of 5 or 50 mg/kg/day. An increased incidence of mammary adenocarcinomas in rodents has been associated with administration of several other therapeutic agents that elevate serum prolactin, but no correlation between serum prolactin levels and mammary tumors has been established in humans. Furthermore, in adult human female subjects who received oral dosages of up to 60 mg of timolol maleate (the maximum recommended human oral dosage), there were no clinically meaningful changes in serum prolactin.

Timolol maleate was devoid of mutagenic potential when tested *in vivo* (mouse) in the micronucleus test and cytogenetic assay (doses up to 800 mg/kg) and *in vitro* in a neoplastic cell transformation assay (up to 100 mcg/mL). In Ames tests the highest concentrations of timolol employed, 5,000 or 10,000 mcg/plate, were associated with statistically significant elevations of revertants observed with tester strain TA100 (in seven replicate assays), but not in the remaining three strains. In the assays with tester strain TA100, no consistent dose response relationship was observed, and the ratio of test to control revertants did not reach 2. A ratio of 2 is usually considered the criterion for a positive Ames test.

Reproduction and fertility studies in rats demonstrated no adverse effect on male or female fertility at doses up to 21,000 times the systemic exposure following the maximum recommended human ophthalmic dose.

Pregnancy: Teratogenic Effects — Pregnancy Category C.: Teratogenicity studies with timolol in mice, rats and rabbits at oral doses up to 50 mg/kg/day (7,000 times the systemic exposure following the maximum recommended human ophthalmic dose) demonstrated no evidence of fetal malformations. Although delayed fetal ossification was observed at this dose in rats, there were no adverse effects on postnatal development of offspring. Doses of 1000 mg/kg/day (142,000 times the systemic exposure following the maximum recommended human ophthalmic dose) were maternotoxic in mice and resulted in an increased number of fetal resorptions. Increased fetal resorptions were also seen in rabbits at doses of 14,000 times the systemic exposure following the maximum recommended human ophthalmic dose, in this case without apparent maternotoxicity.

There are no adequate and well-controlled studies in pregnant women. Preservative-free TIMOPTIC in OCUDOSE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Timolol maleate has been detected in human milk following oral and ophthalmic drug administration. Because of the potential for serious adverse reactions from timolol in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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

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

ADVERSE REACTIONS

The most frequently reported adverse experiences have been burning and stinging upon instillation (approximately one in eight patients).

The following additional adverse experiences have been reported less frequently with ocular administration of this or other timolol maleate formulations:

BODY AS A WHOLE: Headache, asthenia/fatigue, and chest pain.

CARDIOVASCULAR: Bradycardia, arrhythmia, hypotension, hypertension, syncope, heart block, cerebral vascular accident, cerebral ischemia, cardiac failure, worsening of angina pectoris, palpitation, cardiac arrest, pulmonary edema, edema, claudication, Raynaud's phenomenon, and cold hands and feet.

DIGESTIVE: Nausea, diarrhea, dyspepsia, anorexia, and dry mouth.

IMMUNOLOGIC: Systemic lupus erythematosus.

NERVOUS SYSTEM/PSYCHIATRIC: Dizziness, increase in signs and symptoms of myasthenia gravis, paresthesia, somnolence, insomnia, nightmares, behavioral changes and psychic disturbances including depression, confusion, hallucinations, anxiety, disorientation, nervousness, and memory loss.

SKIN: Alopecia and psoriasiform rash or exacerbation of psoriasis.

HYPERSENSITIVITY: Signs and symptoms of systemic allergic reactions including anaphylaxis, angioedema, urticaria, and localized and generalized rash.

RESPIRATORY: Bronchospasm (predominantly in patients with preexisting bronchospastic disease), respiratory failure, dyspnea, nasal congestion, cough and upper respiratory infections.

ENDOCRINE: Masked symptoms of hypoglycemia in diabetic patients (see WARNINGS).

SPECIAL SENSES: Signs and symptoms of ocular irritation including conjunctivitis, blepharitis, keratitis, ocular pain, discharge (e.g., crusting), foreign body sensation, itching and tearing, and dry eyes; ptosis; decreased corneal sensitivity; cystoid macular edema; visual disturbances including refractive changes and diplopia; pseudopemphigoid; choroidal detachment following filtration surgery (see PRECAUTIONS, General); and tinnitus.

UROGENITAL: Retroperitoneal fibrosis, decreased libido, impotence, and Peyronie's disease.

The following additional adverse effects have been reported in clinical experience with ORAL timolol maleate or other ORAL beta blocking agents, and may be considered potential effects of ophthalmic timolol maleate: *Allergic:* Erythematous rash, fever combined with aching and sore throat, laryngospasm with respiratory distress; *Body as a Whole:* Extremity pain, decreased exercise tolerance, weight loss; *Cardiovascular:* Worsening of arterial insufficiency, vasodilatation; *Digestive:* Gastrointestinal pain, hepatomegaly, vomiting, mesenteric arterial thrombosis, ischemic colitis; *Hematologic:* Non-thrombocytopenic purpura; thrombocytopenic purpura; agranulocytosis; *Endocrine:* Hyperglycemia, hypoglycemia; *Skin:* Pruritus, skin irritation, increased pigmentation, sweating; *Musculoskeletal:* Arthralgia; *Nervous System/Psychiatric:* Vertigo, local weakness, diminished concentration, reversible mental depression progressing to catatonia, an acute reversible syndrome characterized by disorientation for time and place, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics; *Respiratory:* Rales, bronchial obstruction; *Urogenital:* Urination difficulties.

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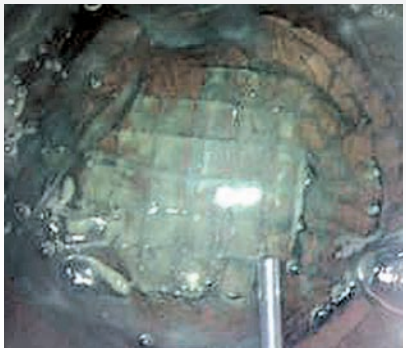
apoptosis. These effects were significantly inhibited by 24-hour pre-treatment with 1µm of sulforaphane. The use of 30µm H2O2 also caused an elevation in lactate dehydrogenase (LDH) levels in the medium relative to control, which were suppressed by sulforaphane treatment.

The molecule guggulsterone is also being studied as a possible agent in cataract prevention. An in vitro cell culture model was used to investigate the effects of guggulsterone on prevention of toxicity in human lens epithelial cells.[1070/D1275] Researchers observed H2O2-induced dose and time-dependent decline in the cells' viability, which was prevented by guggulsterone. Guggulsterone also suppressed a dose-dependent and significant increase in LDH release from human lens epithelial cells, suggesting H2O2-induced alteration of membrane integrity as well as cell death.

Meanwhile, researchers at McMaster University in Ontario, Canada, have looked into a method for possibly preventing posterior capsular opacification (PCO) after cataract surgery.[1069/D1274] Inhibition of matrix metalloproteinases by the antibiotic sulfadiazine has been shown to potentially decrease the incidence of PCO. Now, the investigators must determine the most effective therapeutic dose, which will be crucial when considering further tests involving in vivo studies and drug delivery devices such as IOLs.

Updates on Femtosecond Lasers

A femtosecond laser can be used to correct astigmatism via intrastromal arcuate incisions, ensuring that no break in the tissue occurs and that the entire procedure is performed within the corneal stroma. In one study involving rabbit and human cadaver eyes, the laser was shown to allow for the creation of a single, intrastromal incision, unlike a free hand or mechanical diamond blade incision.[6622/A611] No morphologic changes were detected above and below these intrastromal incisions. Benefits included decreased risk of infection, no epithelial plug formation, and no need for topical antibiotics.



Femtosecond lasers were a hot topic at ARVO, as their utility continues to expand. This photo demonstrates lens fragmentation performed by the LensAR femtosecond laser system.

OCT features were found to be similar across all studies. Advantages over the use of diamond blades include predictability of incision depth, arc length and ability to modify the side-cut angle.

Another study showed the benefits of rapid healing and precision when using the femtoscond laser.[1505/A461] The goal of the California-based trial was to review the initial results of an intrastromal arcuate keratotomy (ISAK) performed with an IntraLase femtosecond laser (iFS, Abbott Medical Optics).

In this prospective single center study, two groups of patients with astigmatism (naturally occurring or post-cataract surgery) were treated with the femtosecond laser, which was used to perform arcuate cuts completely placed within the corneal stroma on the steep axis.

Twenty-one eyes had been treated with this method and completely followed. Seventeen patients showed naturally occurring astigmatism, most of them selected prior to cataract surgery. Four additional patients presented with astigmatism following cataract surgery. The iFS-laser allowed the creation of precise, purely intrastromal incision patterns that were not readily achievable by standard diamond blade techniques. These preliminary outcomes indicated an excellent safety profile, the possibility of highly precise pattern placement and very rapid recovery and stability of vision.

LASIK with the femtosecond laser was shown to provide outcomes equal to those associated with the mechanical microkeratome. In a randomized, paired-eye study sponsored by the National Institutes of Health, LASIK with the femtosecond laser was shown to provide outcomes equal to those associated with the mechanical microkeratome. Twenty-one patients underwent LASIK for myopia or myopic astigmatism.[1491/A447] Eyes were randomized by ocular dominance to LASIK with the flap created by a femtosecond laser (15 kHz [IntraLase FS, IntraLase]) in one eye and to LASIK with the flap created by a mechanical microkeratome (Hansatome, Bausch + Lomb) in the fellow eye.

Researchers found no effect on the endothelium of patients treated with the femtosecond versus those treated with the mechanical microkeratome. Five years after surgery, corneas that had undergone either method of flap creation could be accepted as donor tissue for endothelial keratoplasty.

Managing Postoperative Patients

Once more, a study has shown the benefit of using brominidine (Alphagan) to keep pupil size small to eliminate or reduce postoperative night vision problems in patients who have undergone surgical procedures. Thirty candidates for LASIK between 20 and 40 years of age in Turkey were included in the trial.

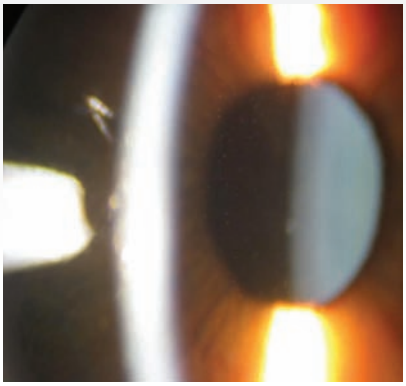
OPD-Scan (Nidek ARK-10000) was used for baseline and serial measurements at low mesopic and photopic luminance levels (10cd/m2 and 100cd/m2) 30 minutes after instillation of one drop of brimonidine tartrate 0.2% in one eye versus administration of a placebo in the contralateral eye.

At all time intervals, brimonidine tartrate 0.2% produced a moderate miotic effect ranging from 5.65±1.01mm to 6.48±1.01mm, which was most significant 90 minutes after instillation at low mesopic conditions.

Meanwhile, research explored the use of a new formulation of loteprednol etabonate gel 0.5% for post-cataract inflammation and pain.[6690/D710] Two multicenter, randomized, double-masked studies were conducted. In each study, patients with anterior chamber cell (ACC) severity greater than or equal to grade 2 after cataract surgery were randomized to receive the gel or a vehicle q.i.d. for 14 days.

The intention to treat population included 406 patients (203 per treatment group) in the first study and 407 patients (n=206 for loteprednol gel 0.5%, n=201 for vehicle) in the second study.

In the first study, 30.5% and 16.3% of patients in the loteprednol gel and vehicle groups, respectively, experienced complete resolution of ACC at day eight; whereas 72.9% and 41.9% patients, respectively, had no (grade 0) pain at day eight. In the second study, 31.1% and 13.9% of patients in the loteprednol gel and vehicle groups, respectively, benefitted from complete resolution of ACC at day eight; whereas 75.7% and 45.8% patients, respectively, had no pain at day eight.



Research seeks to reduce post-cataract inflammation.

Another study based in Inglewood and Torrance, Calif., evaluated the effects of a low concentration of modified bromfenac (Bromday, ISTA Pharmaceuticals) for inflammation and pain associated with cataract surgery.[6684/D704] Patients were randomized to receive either bromfenac ophthalmic solution (n=110) or placebo (n=110), dosed once daily, one day before cataract surgery, on the day of surgery, and continuing through 14 days post-surgery.

A significantly larger proportion of patients in the bromfenac group had cleared ocular inflammation by day 15, compared to the placebo group. The number of patients who were pain-free at days one, three, eight and 15 was also significantly higher in the bromfenac group, compared to the number in the placebo group. From a safety standpoint, the incidence of adverse events was significantly lower in the bromfenac group compared to the placebo group.

A third medication that showed good results with lower dosing and a tolerable safety profile was difluprednate (Durezol, Alcon) for glaucoma patients after cataract surgery.[6695/D715] A retrospective chart review of 65 patients was performed on glaucoma patients who underwent cataract surgery by one surgeon between June 2010 and June 2011 in Bronx, N.Y. Only those who were treated with difluprednate 0.05% immediately post-operatively at four times daily and then tapered according to level of inflammation were included in the study.

Difluprednate 0.05% was found to be an alternative to generic prednisolone acetate 1%, possibly offering more drop uniformity and requiring less frequent dosing for anterior uveitis.

The effects of systemic medication on ocular health were also reviewed. The association between intraoperative floppy iris syndrome (IFIS) and the use of medication for benign prostatic hyperplasia (BPH), such as tamsulosin (Flomax, Boehringer Ingelheim), and the use of some hypertensive medications, is well established.

Now, a study at the University of Texas has suggested that the use of warfarin (Coumadin, Bristol-Myers Squibb) may also result in IFIS.[6707/D727] Thirteen eyes of nine patients who had taken or were actively taking warfarin were identified as having IFIS during phacoemulsification surgery.

This complication makes cataract surgery significantly more difficult, requiring surgeons to operate through a much smaller pupil. As a result, surgeons may require additional instruments to assist them in the procedure. ■

Glaucoma

New insights on topical therapy, prevention, structure, function and diagnostic technologies highlighted a diverse presentation of topics.

By Robert Cole, III, O.D., Co-Chief Clinical Editor

Provocative comparisons among glaucoma medications drew much attention at ARVO 2012. Visitors to this milestone forum designed to encourage and assist research, training, publication and dissemination of knowledge in vision and ophthalmology also benefitted from an updated look at exercise and prevention.

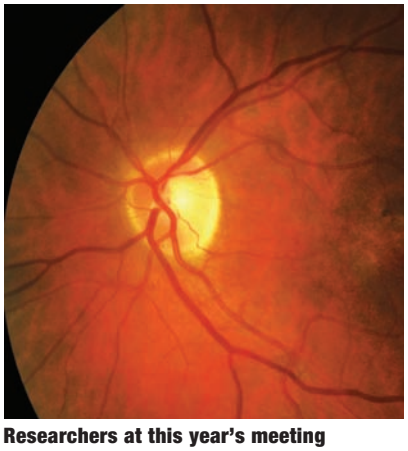
Researchers tackled structure and function from several vantage points, including diagnostic technologies and nerve perfusion. In addition, fresh perspectives were presented on monitoring and disease process, as well as overall diagnostics.

New Insights on Topical Therapy

With the increased use of generic glaucoma drops, one study helped explain the inconsistencies in these agents that we see clinically. Researchers in New Delhi compared the physical properties of three commercially available generic brands of latanoprost with Xalatan (Pfizer).[5096/A237] The aim of the study was to compare the eye drop volume dispensed, total number of drops dispensed per vial and physical properties (pH, density and relative viscosity) of 2.5ml vials of the medications. On the basis of pH estimation and relative viscosity, the researchers estimated absolute drug concentration per drop.

Significant differences were found among the drop size, number of drops per bottle and physical properties of the generic brands compared to Xalatan. The researchers said the study underscored the unmet need for better quality control in the production of generic prostaglandin analogues. The findings also raised implications for the IOP lowering efficacy, adverse effect profile and cost of glaucoma therapy associated with generics.

In Thessaloniki, Greece, and Brescia, Italy, the 24-hour efficacy of preservative-free tafluprost (Zioptan, Merck) and preservative-containing latanoprost (Xalatan) were compared in patients with primary open-angle glaucoma (POAG) or ocular hypertension (OHT).[5104/A245] The 24-hour IOP control was obtained when both agents were administered as first-choice therapy. The study, a prospective, observer-masked, crossover comparison, included consecutive, newly-diagnosed patients with POAG or OHT who had baseline IOP between 24mm Hg and 33mm Hg. Thirty-eight patients were randomized to either latanoprost or tafluprost administered in the evening for three months. Patients were then switched to the opposite therapy



Researchers at this year's meeting investigated whether generic glaucoma medications are truly a suitable substitute for their brand name counterparts.

Monthly Multifocal Pearl

Multifocal Fitting Success

By Randall Fuerst, OD, FAAO

According to the literature, more than 150 million Americans use corrective eyewear[1]—and more than 112 million are presbyopic.[2] Of these, only 8% of presbyopes wear contact lenses (monovision [3.5%] or bifocal or progressive contact lenses [2.2%]).[3]

For years, we have had a limited choice of effective multifocal lenses with which to fit our presbyopic patients. In my 29 years in practice, I have worked with numerous contact lenses—all with inadequate success. With the newer designs, an increasing number of us are fitting multifocal lenses with higher rates of success. I finally have lenses with which to fit my presbyopic patients.

SIMPLE STEPS TO SUCCESS

A 2003 survey of contact lens wearers between the ages of 35 and 55 found that 91% of these wearers were committed to continuing to wear contacts over glasses.[4] Several studies have also documented that despite good monofocal acuity at distance and near, the majority of monovision patients would prefer more normal binocular vision, if given the choice.[5] Fortunately for us, we now have the tools to make these presbyopic patients happy! Advances in technology have resulted in multifocal lenses that make fitting easier. The following are my recommendations for successfully fitting patients with multifocal contact lenses such as the AIR OPTIX® AQUA Multifocal contact lenses.

Be an inquiring mind. Ask your patients who use bilateral distance contact lens + reading glasses, as well as your monovision contact lens patients if they would be willing to try multifocal contact lenses. You're almost guaranteed to succeed with these patients—especially if you determine that some or all of their day-to-day tasks and visual demands could be facilitated by a multifocal contact lens.

Prepare your patients. While toric and spherical lenses work almost immediately when fit correctly, multifocal contact lenses may take time. Explain to patients that neuroadaptation is common with multifocal contact lenses. We see this with progressive addition spectacle lenses and certainly with multifocal intraocular lenses. Pre-set patients to understand that the simultaneous focusing in and out between distance and near foci is normal and part of the adaptation process. If the patient has adequate distance acuity and comfort, give them a week to begin to explore the improvement in both distance and near acuity—as well as a diminishing observance of ghosting—this is neuroadaptation. Further explain that full adaptation will likely take a few weeks.

Describe the process. Explain that fitting multifocal contact lenses is a process that will require a number of office visits, due to neuroadaptation and the absolute requirement that 0.25D difference, while often of little consequence to a spherical or toric lens wearer, can be incredibly impacting with a multifocal lens. Be up front in letting patients know the charges for this packaged fitting plus follow-up. Many ODs shy away from fitting multifocals because of the perceived increased work. See it as an advantage: the troubleshooting and working with patients gives you the opportunity to be a doctor.

Understand the varied multifocal contact lens design attributes. My most successful gas permeable design, hybrid lens design and soft lens design involves a center near zone that aspherically transitions to distance vision in the periphery of the lens. This is the design attribute of the AIR OPTIX® AQUA Multifocal lens, and it is a great first lens of choice. It provides a smooth transition as eyes move naturally from one focal distance to another. Knowing the differing designs is important when describing the varied options and challenges ahead of time with your prospective multifocal contact lens patient.

A PERFECT EXAMPLE

Sherri, a 45-year-old special education teacher who spends approximately three to four hours each day in front of her computer, has worn soft contact lenses for 20 years. She has been in monovision for the past three years and while not particularly unhappy, Sherri isn't overly thrilled with her vision, either. She complained that when she drives, because her left eye has been fitted for near vision, she does not see the driver's side door mirror clearly and has to rapidly turn her head.

When asked, she was open to moving up to binocular vision and multifocal soft contact lenses. I fit Sherri with AIR OPTIX® AQUA Multifocal lenses. Because she was already a +2.00 add, I fit her full distance vision with a medium add in both eyes. After confirming acceptable distance acuity monocularly and binocularly, I asked her to look at her cell phone. When this proved satisfactory, I pulled out the near point chart. After reviewing the progression she could likely expect to occur, I asked to see her again in two weeks. Sure enough, after some fine-tuning, Sherri is a multifocal contact lens wearer and is significantly happier than she was in monovision lenses. She says she is more comfortable and feels like her eyes aren't "battling" back and forth anymore—especially when she is tired.

Dr. Fuerst is a partner in a 3-office, 8-doctor practice in the Sacramento area. He is a principal in an ophthalmic biomedical devices company and has lectured nationally and internationally. He is also actively involved in the AOA's Contact Lens and Cornea Council.

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2. Koffler BH. Management of presbyopia with soft contact lenses. Ophthalmol. 2002;216 (Suppl 1):34–51.
3. Alcon data on file, 2005.
4. Edmunds and Reindel (2003), as cited in Tan J. Contact Lens Options for Presbyopia. http://www.siliconehydrogels.org/editorials/previous_editorial_jackie_tan.asp. (Accessed April 2012).
5. Richdale K, Mitchell GL, Zadnik K. Comparison of multifocal and monovision soft contact lens corrections in patients with low-astigmatic presbyopia. Optom Vis Sci. 2006;83(5):266–273.

for another three months.

Tafluprost, when employed as first-choice therapy, achieved statistically similar 24-hour IOP reduction when compared to latanoprost. The study highlighted the importance of complete assessment of efficacy over 24 hours.

Researchers in Milan and Rome evaluated the effects of bimatoprost 0.1% (Lumigan, Allergan) and timolol 0.5% on circadian IOP and blood pressure based on an interim analysis of 20 patients.[5105/A246]

Both treatments were associated with statistically significant reductions in IOP compared to baseline (-3.8mm Hg, with timolol 0.5%; -4.8mm Hg, with bimatoprost 0.1%). IOP was also statistically significantly lower after treatment with bimatoprost 0.1%. Bimatoprost 0.1% once at night was found to be more effective than timolol 0.5% twice daily in reducing the IOP at all time points of the 24-hour curve. Night-time IOP under timolol 0.5% seemed not to be different than IOP after washout. Heart rate and blood pressure were significantly reduced by timolol 0.5%.

Studying Adherence and Ocular Surface Health

Investigators from the University of Colorado and Aristotle University of Thessaloniki, Greece used electronic monitoring to assess patients' adherence to glaucoma therapy regimens and ocular surface health. They compared the effects of latanoprost/timolol fixed vs. latanoprost/timolol unfixed therapy in glaucoma.[5097/A238]

The prospective six-month, parallel, observational study involved 142 consecutive well-controlled patients with open-angle glaucoma (OAG) or OHT who received either unfixed therapy (latanoprost) once in the evening and timolol twice daily or latanoprost/timolol fixed combination (Xalacom, Pfizer) therapy once in the evening.

Can aerobic exercise protect against glaucoma?

Patients in the unfixed group demonstrated worse vertical cup-to-disc ratio (0.65 vs. 0.58) and worse mean visual field defect (5,9 dB vs. 3,8 dB) at baseline. The unfixed group also demonstrated higher mean IOP at six months (16.6mm Hg vs. 15.0mm Hg).

The adherence rate was significantly better in the fixed combination group at three months (75.6% vs. 61.2%) and six months (73.0% vs. 57.3%) of follow up. Signs of ocular surface disease were significantly worse in the unfixed group at baseline. The trial demonstrated a significantly superior rate of adherence and ocular surface health in the fixed combination treatment group, verifying superior benefits for the first time in a trial. Hopefully, this fixed combination will soon be available to us here in the United States.

Exercise and Prevention

Can aerobic exercise be a prescription for prevention of glaucoma? Canadian researchers sought an answer to this long-debated question in a meta-analysis to compare the effect of exercise parameters on IOP levels.[5070/A211] They analyzed 10 studies, focusing on sedentary or normally-active participants with normal baseline IOP (10mm Hg to 21mm Hg) who had completed a single bout of mild aerobic exercise (producing a 40% heart rate) to moderate aerobic exercise (50% to 70% heart rate) ranging from two to 60 minutes in duration.

Their findings? IOP reduction from exercise was within the range that is most useful to those at risk of POAG. Prescription of even a mild daily aerobic exercise regime could be an effective method to keep slightly elevated IOP levels within a normal range.

Considering Structure and Function

Seeking to identify the best functional and structural indicators of glaucoma progression, investigators at the University of Pittsburgh and the New England Eye Center evaluated the visual field (VF) and optic nerve head (ONH) parameters of 110 eyes of 60 subjects

BECAUSE inflammation HAPPENS

Make DUREZOL® Emulsion your steroid for post-op care.

Unique molecular design optimizes potency and penetration[1-4]

Covered on more than 82% of national formularies[5]

IMPORTANT SAFETY INFORMATION:

Indications and Usage: DUREZOL® Emulsion is a topical corticosteroid that is indicated for the treatment of inflammation and pain associated with ocular surgery.

Dosage and Administration: Instill one drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.

Contraindications: DUREZOL® Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

Warnings and Precautions:

- *Intraocular pressure (IOP) increase* – Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.
- *Cataracts* – Use of corticosteroids may result in posterior subcapsular cataract formation.
- *Delayed healing* – The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- *Bacterial infections* – Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- *Viral infections* – Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- *Fungal infections* – Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

Adverse Events: Ocular adverse reactions occurring in 5-15% of subjects in clinical studies with DUREZOL® Emulsion included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.

Please see full prescribing information on adjacent page.

Alcon®

 1/11 DUR11500JAD U.S. Patent No. 6,114,319

DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all of the information needed to use Durezol® safely and effectively.
See full prescribing information for Durezol.

DUREZOL® (difluprednate ophthalmic emulsion) 0.05%

Initial U.S. approval: 2008

----------INDICATIONS AND USAGE----------

Durezol is a topical corticosteroid that is indicated for the treatment of inflammation and pain associated with ocular surgery. **(1)**

----------DOSAGE AND ADMINISTRATION----------

Instill one drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response. **(2)**

----------DOSAGE FORMS AND STRENGTHS----------

Durezol contains 0.05% difluprednate, as a sterile preserved ophthalmic emulsion for topical ophthalmic use only. **(3)**

----------CONTRAINDICATIONS----------

Durezol, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. **(4)**

----------WARNINGS AND PRECAUTIONS----------

- Intraocular pressure (IOP) increase - Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored. **(5.1)**
- Cataracts - Use of corticosteroids may result in posterior subcapsular cataract formation. **(5.2)**
- Delayed healing - The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. **(5.3)**
- Bacterial infections - Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. **(5.4)**
- Viral infections - Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). **(5.5)**
- Fungal infections - Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. **(5.6)**

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised date: March 2010

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Durezol (difluprednate ophthalmic emulsion) 0.05%, a topical corticosteroid, is indicated for the treatment of inflammation and pain associated with ocular surgery.

2 DOSAGE AND ADMINISTRATION

Instill one drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.

3 DOSAGE STRENGTHS

Durezol contains 0.05% difluprednate as a sterile preserved emulsion for topical ophthalmic administration.

4 CONTRAINDICATIONS

The use of Durezol, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

5 WARNINGS AND PRECAUTIONS

5.1 IOP Increase

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.

5.2 Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

5.3 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

5.4 Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

5.5 Viral Infections

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

5.6 Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

5.7 Topical ophthalmic use only

Durezol is not indicated for intraocular administration.

6 ADVERSE REACTIONS

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Ocular adverse reactions occurring in 5–15% of subjects in clinical studies with Durezol included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis. Other ocular adverse reactions occurring in 1–5% of subjects included reduced visual acuity, punctate keratitis, eye inflammation, and iritis. Ocular adverse events occurring in < 1% of subjects included application site discomfort or irritation, corneal pigmentation and striae, episcleritis, eye pruritis, eyelid irritation and crusting, foreign body sensation, increased lacrimation, macular edema, scleral hyperemia, and uveitis. Most of these events may have been the consequence of the surgical procedure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

Pregnancy Category C. Difluprednate has been shown to be embryotoxic (decrease in embryonic body weight and a delay in embryonic ossification) and teratogenic (cleft palate and skeletal) anomalies when administered subcutaneously to rabbits during organogenesis at a dose of 1–10 µg/kg/day. The no-observed-effect-level (NOEL) for these effects was 1 µg/kg/day, and 10 µg/kg/day was considered to be a teratogenic dose that was concurrently found in the toxic dose range for fetuses and pregnant females. Treatment of rats with 10 µg/kg/day subcutaneously during organogenesis did not result in any reproductive toxicity, nor was it maternally toxic. At 100 µg/kg/day after subcutaneous administration in rats, there was a decrease in fetal weights and delay in ossification, and effects on weight gain in the pregnant females. It is difficult to extrapolate these doses of difluprednate to maximum daily human doses of Durezol, since Durezol is administered topically with minimal systemic absorption, and difluprednate blood levels were not measured in the reproductive animal studies. However, since use of difluprednate during human pregnancy has not been evaluated and cannot rule out the possibility of harm, Durezol should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

8.3 Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Durezol is administered to a nursing woman.

8.4 Pediatric Use

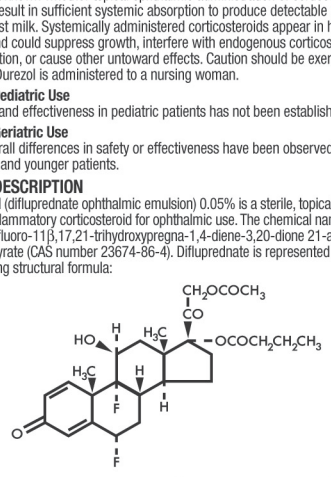
Safety and effectiveness in pediatric patients has not been established.

8.5 Geriatric Use

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

11 DESCRIPTION

Durezol (difluprednate ophthalmic emulsion) 0.05% is a sterile, topical anti-inflammatory corticosteroid for ophthalmic use. The chemical name is 6α,9difluoro-11β,17,21-trihydroxypregna-1,4-diene-3,20-dione 21-acetate 17-butyrate (CAS number 23674-86-4). Difluprednate is represented by the following structural formula:



Difluprednate has a molecular weight of 508.56, and the empirical formula is C27H34F2O7. Each mL contains: ACTIVE: difluprednate 0.5 mg (0.05%); INACTIVE: boric acid, castor oil, glycerin, polysorbate 80, purified water, sodium acetate, sodium EDTA, sodium hydroxide (to adjust the pH to 5.2 to 5.8). The emulsion is essentially isotonic with a tonicity of 304 to 411 mOsm/kg. PRESERVATIVE: sorbic acid 0.1%.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids inhibit the inflammatory response to a variety of inciting agents that may delay or slow healing. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotreines by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2. Difluprednate is structurally similar to other corticosteroids.

12.3 Pharmacokinetics

Difluprednate undergoes deacetylation in vivo to 6α,9-difluoroprednisolone 17-butyrate (DFB), an active metabolite of difluprednate. Clinical pharmacokinetic studies of difluprednate after repeat ocular instillation of 2 drops of difluprednate (0.01% or 0.05%) QID for 7 days showed that DFB levels in blood were below the quantification limit (50 ng/mL) at all time points for all subjects, indicating the systemic absorption of difluprednate after ocular instillation of Durezol is limited.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

Difluprednate was not genotoxic in vitro in the Ames test, and in cultured mammalian cells CHL/IU (a fibroblastic cell line derived from the lungs of newborn female Chinese hamsters). An in vivo micronucleus test of difluprednate in mice was also negative. Treatment of male and female rats with subcutaneous difluprednate up to 10 µg/kg/day prior to and during mating did not impair fertility in either gender. Long term studies have not been conducted to evaluate the carcinogenic potential of difluprednate.

13.2 Animal Toxicology and/or Pharmacology

In multiple studies performed in rodents and non-rodents, subchronic and chronic toxicity tests of difluprednate showed systemic effects such as suppression of body weight gain; a decrease in lymphocyte count; atrophy of the lymphatic glands and adrenal gland; and for local effects, thinning of the skin; all of which were due to the pharmacologic action of the molecule and are well known glucocorticosteroid effects. Most, if not all of these effects were reversible after drug withdrawal. The NOEL for the subchronic and chronic toxicity tests were consistent between species and ranged from 1–1.25 µg/kg per day.

14 CLINICAL STUDIES

14.1 Postoperative Ocular Inflammation and Pain

Clinical efficacy was evaluated in 2 randomized, double-masked, placebo-controlled trials in which subjects with an anterior chamber cell grade ≥ "2" (a cell count of 11 or higher) after cataract surgery were assigned to Durezol or placebo (vehicle) following surgery. One drop of Durezol or vehicle was self instilled either 2 (BID) or 4 (QID) times per day for 14 days, beginning the day after surgery. The presence of complete clearing (a cell count of 0) was assessed 8 and 15 days post-surgery using a slit lamp binocular microscope. In the intent-to-treat analyses of both studies, a significant benefit was seen in the QID Durezol-treated group in ocular inflammation and reduction of pain when compared with placebo. The consolidated clinical trial results are provided below.

Ocular Inflammation and Pain Endpoints (Studies Pooled)

	Durezol QID (n = 107)		Vehicle (n = 220)	
Day	8	15	8	15
Anterior Chamber cell clearing (% subjects)	24 (22%)*	44 (41%)*	17 (7%)	25 (11%)
Pain free (% subjects)	62 (58%)*	67 (63%)*	59 (27%)	76 (35%)

*Statistically significantly better than vehicle, p<0.01

16 HOW SUPPLIED/STORAGE AND HANDLING

Durezol (difluprednate ophthalmic emulsion) 0.05% is a sterile, aqueous topical ophthalmic emulsion supplied in an opaque plastic bottle with a controlled drop tip and a pink cap in the following size: 5 mL in a 5 mL bottle (NDC 42826-601-05).

Storage

Store at 15-25°C (59-77°F). Do not freeze. Protect from light. When not in use keep the bottles in the protective carton.

17 PATIENT COUNSELING INFORMATION

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the emulsion. If pain develops or if redness, itching, or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing a preservative, patients should be advised not to wear contact lenses when using Durezol.

Revised: March 2010

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3. Ponec M, Kempenaar J, Shroot B, Caron JC. Glucocorticoids: binding affinity and lipophilicity. *J Pharm Sci.* 1986;75(10):973-975.
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5. Fingertip Formulary. November 2010.

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(including 24 healthy, 48 glaucoma suspects and 38 glaucomatous eyes). The patients had undergone comprehensive ocular examination and four or more visits involving VF testing (Carl Zeiss Meditec), spectral-domain optical coherence tomography (SD-OCT) (RTVue-100, Optovue) and scanning laser ophthalmoscopy (SLO) (HRT III, Heidelberg Engineering).[219/A460]

For VF, the Visual Field Index (VFI) showed statistically significantly better correlation with the common latent progression than both mean deviation and pattern standard deviation. For SD-OCT, the parameters with the highest correlation with latent progression were cup area and rim area and statistically significantly better than other measured parameters. SLO also showed cup area and rim area to be the parameters most correlated with latent progression.

Cup and rim area were found to be the most useful structural measurements of progression, while VFI was the most useful functional parameter. Even though SD-OCT and HRT quantified ONH structure, there was a poor correlation between the devices in detecting progression.

Blood Flow and Glaucoma

Changes in retrobulbar blood flow may correlate to changes in the optic disc in patients with glaucoma, according to clinicians who coordinated a research effort in Indiana and Kaunas, Lithuania.[247/A488] Ninety-eight patients with OAG were examined at baseline and after two years of follow-up for retrobulbar blood flow and optic nerve structure, as measured by color Doppler imaging and OCT, respectively.

Decreased perfusion in the retina and optic nerve were associated with increased optic cup area in this cohort of patients. Decreasing retinal blood flow may increase optic nerve damage, as defined by optic cup area, in patients with OAG, a researcher noted. We are still waiting for a reliable, affordable device for the private office.

In the state of New York, the efficacy of the Amsler grid was evaluated for detecting glaucomatous central visual field defects.[177/A418] Ninety-six eyes of glaucoma patients who had either a normal or abnormal 10-2 VF finding for both eyes within the previous four months were included in the study. The results of the Amsler grid

tests were found to approximate the 10-2 VF results. Therefore, the Amsler grid was determined to be a possible useful supplement to 10-2 VF testing for evaluating and monitoring central VF loss in glaucoma.

Monitoring and Understanding Disease Process

The utility of a new diagnostic indicator, age-adjusted concurrent pressure to cornea index (CPCI), was tested as a means for discriminating between glaucoma and non-glaucoma.[4176] Researchers in Singapore, China, and Australia defined CPCI as the age-adjusted ratio between untreated intraocular pressure and central corneal thickness (CCT) in mm, measured within two hours of each other. In a population-based, cross-sectional study, the distribution of CPCI in 294 normal controls with normal visual fields, 124 with normal-tension glaucoma, 11 with OHT with normal visual fields, and 14 with POAG was determined.

The CPCI was determined to have better discriminatory ability for glaucoma than IOP and CCT alone. CPCI may be a useful summary indicator of glaucoma risk. Longitudinal studies are needed to prove its prognostic value.

Assessing Nerve Rim

Rim assessment lacks a solid anatomical basis. Clinical disc margin does not provide a reliable outer border of rim tissue because of clinically and photographically invisible extensions of Bruch's membrane (BM) inside the disc margin.[1745] As a result, rim tissue orientation in ONH also cannot be determined.

To address this issue, investigators in Halifax, Nova Scotia, Canada and Portland, Ore., introduced a BM opening-minimum rim width (BMO-MRW) measurement that quantified the rim from its true anatomical outer border and accounted for its variable trajectory in the measurement plane. Glaucoma patients (n = 107) and normal controls (n = 48) underwent Spectralis SD-OCT (Heidelberg Engineering) imaging (24 B-scans centered on the optic nerve head).

Greater than three-fold higher sensitivity at 95% specificity in early glaucoma of BMO-MRW was found, compared to results found with current methods. This was clinically significant, indicating the possiblity of a new structural marker for the detection and risk-profiling of glaucoma.

Estimating Morning IOP Peak

An alternative way of estimating morning IOP peak in glaucoma patients—the water-drinking test— was the focus of a cross-sectional study in Porto Alegre, Brazil.[5050/A191] Forty-five adult glaucoma patients (90 eyes) had their IOP checked by hand-held applanation tonometry between 6 a.m. and 7 a.m. at home, immediately after awaking and while still lying in bed. Patients were advised to fast for one hour and to arrive at the clinic 15 minutes before additional IOP testing, avoiding activities that could lead to accommodation.

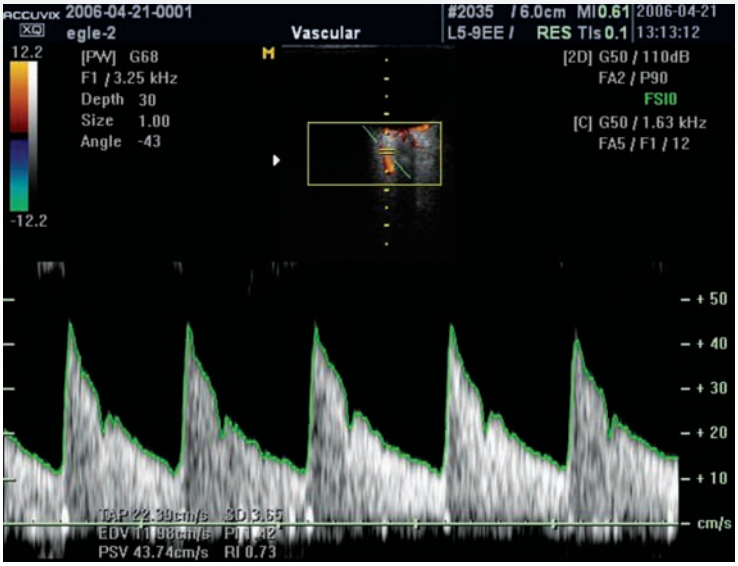
They then drank 500ml of room-temperature water in five minutes and had their IOP measured in the sitting position. Afterward, they laid down under dim light for 15 minutes in a quiet place before IOP was measured again. Reproducible results showed that IOP verified at wake-up time in bed had excellent agreement with IOP in the clinic under these conditions, raising the possibility of an easy, fast and reliable method of appraising morning IOP peak in glaucoma patients.

Exploring Diagnostic Technologies

Researchers from the Wilmer Eye Institute in Baltimore, Md., assessed the ability of pupillography to discriminate glaucoma patients from persons without glaucoma.[5621] Three approaches were evaluated:

1. Detecting a relative afferent pupillary defect (RAPD) between the two eyes.

2. Comparing pupil responses to



Doppler imaging was used to determine whether changes in blood flow correlate with changes in the optic disc.

stimuli aimed at different parts of the retina within the same eye.

3. Comparing overall pupillary responses of eyes with glaucoma to responses of normal eyes.

The RAPiD (Konan Medical), a binocular pupillographic device, recorded latency and amplitude of pupil responses. Thirty controls and 104 glaucoma patients from a single clinic were enrolled. Patients with glaucoma had a significantly larger RAPiD result compared to controls. Researchers identified five parameters, suggesting that a prototype pupillography device may be able to discriminate glaucoma from normal eyes with relatively high specificity and sensitivity. This device may prove ideal for screening.

In an observational cohort study that looked at 134 eyes from 88 patients, researchers in La Jolla, Calif., compared the diagnostic accuracy of the Spectralis and the HRT for detection of glaucoma in patients suspected of having glaucoma.[5620] Patients were recruited from the Diagnostic Innovations in Glaucoma Study (DIGS). Forty-eight eyes with progressive glaucomatous optic nerve change and 86 eyes without any evidence of progressive damage to the optic nerve were included.

All eyes underwent retinal nerve fiber layer imaging with the Spectralis and topographic imaging with HRT within six months. The researchers concluded that RNFL assessment with the Spectralis performed better than optic disc topographic parameters obtained by the HRT when diagnosing glaucoma in glaucoma suspects.

Finally, researchers in St. Louis, MO, determined that IOP and perimetric mean deviation were higher in winter than during summer, although there was no evidence of a causative relation.[1751] The findings could shed light on the disease process, as well as help reduce clinical test-retest variability.

IOP measurements and visual fields were evaluated from 33,873 visits over 12.5 years (median) by 1,636 participants in the Ocular Hypertension Treatment Study (OHTS). The 22 clinics participating in the OHTS were classified into six regions with similar climates (Atlantic, Central, North, Pacific Northwest, Southeast, and West), based on the magnitude and timing of seasonal variations in precipitation, temperature and sunlight hours. ■

PAULA R. NEWSOME, OD, FAAO

Building a Thriving Practice

How daily disposable lenses can **help your practice grow**

More optometrists are moving toward daily disposable lenses and learning that what's healthier for their patients is also healthier for their practice.

Creating a daily disposable practice is achievable

Transforming your contact lens practice to focus on daily disposable lenses can seem like a daunting prospect, but as Paula Newsome, OD and President of Advantage Vision Center in Charlotte, NC, can attest, the conversion was simple: "When we decided to actively engage in daily disposables, we first looked at who we thought could most benefit from the lens. Then we started seeing the health benefits for all our patients. From a health perspective, putting on a fresh lens every day is the absolute best option for our patients." With health as a starting point, every decision made thereafter became easier.

Address the "cost" concern

Dr Newsome admits that she was initially concerned with how patients would react to the cost: "I was thinking in my mind that it was very cost prohibitive." What she found, however, was quite different. She discovered that the leading daily disposable, 1-DAY ACUVUE® MOIST® Brand Contact Lenses, cost less than a dollar per eye, per day. "I think that's a very reasonable amount if you're talking about somebody's sight," she said. And when she presents the health benefits of daily disposables up front, her patients agree that their eye health and their vision are worth the cost.

Create a competitive advantage

Dr Newsome has seen that giving patients the option of daily disposable lenses has given her a competitive advantage: "Promoting daily disposable contact lenses has been a win-win for our practice. The experience my patients have in the lenses has certainly made our practice stand out in the market." A benefit to standing out in a competitive market is building a reputation and increasing word-of-mouth referrals. Increased referrals are not only a benefit to her practice, but an assessment of her care and a true indicator of happy patients. "Patients are excited, enthusiastic, and they go back to their work and share the good news with others," she says. To date, there has been a 20 percent growth in her daily disposable contact lens business from the same time last year.

Advice to fellow ODs

Dr Newsome has some simple advice for fellow ODs who are considering building a daily disposable practice.

I. **Engage your staff;** as they have a lot of contact with patients, it is important to get them involved in the process

II. **Invite a sales rep** to conduct a lunch and learn to educate the staff

III. **Utilize point-of-purchase and educational materials** to support daily disposables

"I would tell fellow ODs to make sure you include daily disposable lenses in your armamentarium," suggests Dr Newsome. Daily disposable contact lenses are optimal for patients for a number of reasons, including health, convenience, and compliance. There are many benefits to a practice as well. Daily disposable patients have better recall and are less likely to go to other places to purchase contact lenses, according to Dr Newsome.

"I talk to all of my contact lens patients about daily disposables because I believe in it that strongly." Her philosophy is "change is good" and, in her practice, it is paying off. Dr Newsome concludes, "The health benefit that we provide for patients, in addition to the economic benefit to the practice, is a win-win for everyone." ■

Paula R. Newsome, OD, is President of the Advantage Vision Center in Charlotte, NC. She received her doctorate in optometry from the University of Alabama at Birmingham. Dr Newsome is a member of the North Carolina Optometric Society and the American Optometric Society. She is also actively involved in the National Optometric Society, the Piedmont Optometric Society, the Charlotte Medical Society, and is a Fellow of the American Academy of Optometry.

Dr Newsome is a member of numerous associations and serves as a speaker and professional consultant for several medical companies, including VISTAKON® Division of Johnson & Johnson Vision Care, Inc. She was compensated for this article.

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Give Athletes a Shot at Better Vision

Whether they shoot foul shots or target rifles, your athletic patients require the best vision to stay at the top of their game. **By Graham B. Erickson, O.D.**

Good vision is a critical factor in sports performance, because visual information is the dominant sensory system when performing practically any perceptual-motor task.[1-4]

Some researchers contend that athletes possess superior visual systems that allow them to see and process critical visual information more effectively than "non-athletes" and novice athletes.[4-7] Others, however, argue that athletes do not possess superior visual system physiology, but that elite athletes are able to use available visual information more efficiently than novices in a competitive sports environment.[8-10]

In either case, optometrists can provide targeted visual assessment, unique refractive options and even sports vision training to help these patients achieve peak performance.

Here, we'll examine the visual skills that are most pertinent to your athletic patients, as well as discuss the best vision-correction options for athletes who participate in a variety of different sports.

What is Sports Vision?

The term "sports vision" has been used to describe a host of eye care services that are provided to athletes. Practitioners working in this area usually are involved with one or more of the following professional activities:[11]

- Prevention and management of sports-related eye injuries.
- Assessment and remediation of functional vision deficiencies that may negatively impact competitive consistency.
- Specialized contact lens services with emphasis on environmental factors in sports, position of gaze factors, emergency care and attainment of maximum visual acuity.
- Performance-based ophthalmic eyewear services that address visual and environmental demands.
- Assessment of specific sports-related visual abilities.
- Enhancement training of specific visual abilities that are

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Goal Statement: Optometrists can provide targeted visual assessment, unique refractive options and even sports vision training to help athlete patients achieve peak performance. This article examines the visual skills that are most pertinent to your athletic patients, as well as reviews the best vision-correction options for athletes who participate in a variety of different sports.
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considered to be essential for competitive consistency in a specific sport activity.

• Consultation with athletes, coaches, trainers and teams regarding visual factors and strategies related to consistent peak athletic performance.

Most of our patients are active participants in sports or recreational activities, and many of these individuals are dedicated to the pursuit of athletic excellence. A critical, but often neglected, aspect of peak human performance is optimal visual function. So, all optometrists must consider visual performance factors when providing one or more of the aforementioned services to athletic patients.

Evaluation of Visual Performance Skills

The vision and visual perceptual skills identified as important for sports performance include: static and dynamic acuities, contrast sensitivity, distance stereopsis, accommodative-vergence facility, span of perception, central eye-hand reaction and response speeds, and peripheral eye-hand response speed.[11,12] Two extensive review articles concluded that athletes have demonstrated better visual abilities than non-athletes, and that top-tier athletes—those who are most successful—often have visual abilities that are superior to lower-level or less successful athletes.[5,6] Some aspects of these skills commonly are assessed as part of a routine vision exam, but many vision skills are not evaluated for various reasons (e.g., there is little or no standardization of assessment procedures and/or limited or outdated diagnostic instrumentation).

To effectively provide specialized vision care to an athlete, you should first identify which vision factors are essential to successful performance in the individual's sport(s) of choice.[12,13] For example, a dynamic and reactive sport, such as basketball, has very different visual demands than the static precision requirements of target shooting. The vision assessment should then include methods to evaluate the quality of those skills in the most appropriate, accurate and reproducible manner. The following visual skills have been frequently identified as important across many sports disciplines:

• ***Static visual acuity (SVA).*** Assessment of visual performance skills routinely begins with a measurement of SVA. Compromised SVA can negatively affect other areas of visual performance.[11] Previous research has found mixed results regarding SVA in athlete populations.

For example, when SVA is assessed using chart systems (with 20/20 as the best acuity measureable), there is no statistically significant difference in the visual ability of athletes compared to non-athletes.[14-16] Even when a best acuity demand of 20/15 is presented, one study found that 81% of professional baseball players could achieve that level.[17] The researchers subsequently modified their assessment method to achieve acuity demands down to 20/7.5, reporting overall mean SVAs of approximately 20/13, with several athletes exhibiting SVAs of 20/9.2 or better.[17]

• ***Dynamic visual acuity (DVA).*** DVA generally is defined as the ability of the visual system to resolve detail when there is relative movement between the target and the observer.[6,11] Many sports involve extensive object movement, including balls, pucks, competitors, teammates, etc. Often, at elite levels of sport, the velocity of movement between the athlete and the target is tremendously high, so athletes need to accurately perceive and identify critical target features during dynamic situations.

One literature review indicated that athletes demonstrate superior DVA abilities compared to non-athletes, and that elite athletes have better DVA than amateur or non-elite athletes do.[5] This suggests that there is an important link between elite athletes and DVA ability.

On the other hand, a separate report documented no significant differences in performance on a DVA test between elite and sub-elite youth soccer players.[18] (However, their use of a predictable rotator device to measure this function may not have been environmentally appropriate to simulate the visual task demands of a dynamic, large-field sport such as soccer.) Although many researchers agree about the importance of DVA in sports, this visual skill often is not assessed in clinical practice due to limitations in available commercial instruments.[6]

• ***Contrast sensitivity (CS).*** CS measures the visual system's ability to process spatial or temporal information about objects and their backgrounds under various lighting conditions. Measuring an athlete's CS is important because most sports involve interpreting visual information at contrast levels below what is measured with a typical visual acuity chart.[11] Performance of athletes on CS testing is significantly better than non-athletes across all spatial frequencies evaluated.[11,19,20] CS may be improved or degraded with contact lens wear or refractive surgery.

Many commercial systems are available to measure CS.[16] Several devices use linear grating patterns that vary in spatial frequency, contrast level and, possibly, orientation. Others use letters or numbers

of different contrast levels and/or sizes. CS measurements usually involve determination of a threshold contrast level at specific spatial frequencies, and reduced sensitivity may relate to performance inconsistency in some sports.

• ***Stereopsis.*** Determining distance and spatial localization of an object is a necessity for athletes in many sports. While these judgments can be made using monocular depth cues, superior binocular depth perception is more advantageous for an athlete.[21]

Research on the assessment of stereopsis has produced mixed results; some studies found no difference between athlete and non-athlete populations; whereas, other studies found better performance in athletes.[11,17,21] The difference in these findings may be due to the lack of standardized testing procedures, the use of simulated depth targets, and the limitations of the instruments to measure threshold stereoacuity.[6]

Previous studies employed near stereo tests or testing at far with vectographic projection slides or a Howard-Dolman apparatus.[11] Considering that many sports are dynamic, athletes would likely perform better with a dynamic stereopsis assessment, because static testing may not reveal much difference between athletes and non-athletes.

• ***Accommodative-vergence facility.*** Competitive sports rarely occur at one distance. Most athletes need to look between far, intermediate and near distances extremely quickly, requiring rapid accommodative-vergence responses. This visual skill can be assessed using "distance rock testing." A study using this test presented normative data for a population of elite athletes, but did not compare performance with that of non-athletes.[11]

Guidelines for Refractive Compensation in Athletes

Refractive Status	Consider Prescribing at:
Myopia	-0.25D or more
Hyperopia	+1.00D or more
Astigmatism	0.50D or more*
Anisometropia	0.50D or more†

* Against-the-rule astigmatism and oblique astigmatism are more detrimental than with-the-rule astigmatism.
† Consider meridional effects with asymmetric astigmatism.

• ***Perception span.*** Perception span, or central visual recognition accuracy, uses tachistoscopic presentation to measure the speed and span of recognition. Several studies have investigated speed of recognition abilities in athletes who play baseball, cricket, volleyball, tennis and other "fast ball" sports.[22-25] Most studies have found that experienced athletes can evaluate sport-relevant information more rapidly than inexperienced observers.[22-25]

Other studies have investigated both the speed and span of recognition by evaluating the ability to recall a sequence of numbers presented tachistoscopically for 1/50 of a second and found no difference in athletes compared with non-athletes.[11,14]

However, one particular report found significant differences in performance for both span and speed of recognition, which were also present when distraction factors were added to simulate competition conditions.[26] When considering these differences in research results, it indicates that the use of numerical stimuli may confound the assessment of recognition speed in athletes.[26]

Thus, the use of target parameters that more closely simulate the visual information processed in sport situations can yield better discrimination of perception span abilities that correlate with sports performance.[26]

• ***Central eye-hand reaction and response time.*** Visual-motor reaction and response speeds are critical to performance. Reaction time is the elapsed time between the onset of a visual stimulus and the initiation of a motor response. Response time is the total time required by the visual system to process a stimulus plus the time needed to complete the motor response.

Several studies report that athletes in various sports have faster reaction times compared to non-athletes, and that reaction time is a discriminator between expertise levels.[27-30] However, other studies have not reproduced this difference.[31,32] A gender bias also has been reported, with males achieving faster times than females on average.[11,33]

Interestingly, eye-hand reaction time can be improved with brief training regimens, making this a potentially valuable assessment and/or goal for the athlete.[11]

• ***Peripheral eye-hand response.*** Overall ability to process and respond to visual stimuli strongly enhances an athlete's eye-hand coordination.[6] The typical instrumentation used for evaluating eye-hand coordination has been a two-dimensional panel with an array of lights mounted on a wall, such as the Wayne Saccadic

Fixator (Wayne Engineering). When using this device, the athlete is required to press a randomly lit button as rapidly as possible with one hand. Then, another button is lit in a random position on the instrument and the reaction time reflex cycle is repeated for the selected test time period. The panel is set at the athlete's arm length and is larger than the central visual field, thus assessing a peripheral eye-hand response.

The Wayne Saccadic Fixator is typically programmed to test in two primary modes: visual proaction time (a self-paced mode for a set time period in which each light remains lit until the button is pressed, then the next random light is lit); and visual reaction time (an instrument-paced stimulus presentation in which each light stays lit for a preset amount of time [0.75 seconds] before automatically switching to another light, whether or not the button is pressed).

One study found better visual proaction times in youth athletes than non-athletes, while another study found no such difference between adult athletes and non-athletes.[14,34] Visual reaction time has been compared in both athletes and non-athletes in only one study, in which athletes performed better than non-athletes.[14]

Nike SPARQ Testing

The Nike SPARQ Sensory Training Station is designed to test vision skills that previously have been identified as important for sports, including SVA, DVA, CS, distance stereopsis, accommodative-vergence facility, span of perception, central eye-hand reaction and response speeds, and peripheral eye-hand response speed. It is designed to provide a customized "sensory performance profile" that graphically represents the athlete's visual strengths and weaknesses by comparing performance to a database of peers. Each profile presents the top four opportunities for intervention and/or enhancement based on performance. For example, if measurements of visual acuity and CS are reduced, a comprehensive eye exam is recommended.

The results of one study indicated that many of the Nike SPARQ Sensory Training Station assessments demonstrate repeatability as well as no learning effect over time.[35] The measures that did improve across sessions (including accommodative-vergence facility, central eye-hand reaction and response speeds, and peripheral eye-hand response speed) demonstrated an expected learning effect due to the motor response characteristics being assessed.

Refractive Compensation for Athletes

Athletes who currently use vision correction require an evaluation to determine if the prescription is providing optimal visual performance for the specific sport demands. A task analysis of the sport will assist in determining the specific visual demands, and a careful refractive analysis can establish the best refractive compensation for use in that sport. For example, a myopic baseball player may benefit from an additional 0.25D of minus to improve contrast judgment or when playing in twilight conditions. Such prescriptions are sport-specific, and are not intended for general use.

Ultimately, you should continue the subjective refraction until the best visual acuity is reached. Do not stop the refraction at 20/20, because the athlete may be capable of seeing 20/10 or better. In some sports, such as major league baseball, 20/20 visual acuity is below average.[13,17] For many athletes, we need to raise the bar above 20/20 in order to provide optimal vision.

Guidelines have been published to assist the practitioner in determining when refractive compensation should be considered (*see "Guidelines for Refractive Compensation in Athletes," page 85*).[12,36] Any patient with myopia of -0.25D or greater should be counseled on the possible benefits of refractive compensation (although correction of less than -0.50D is not available with contact lenses).

Astigmatism has a similar effect on visual resolution, especially against-the-rule and oblique astigmatism. Refractive compensation should be considered with -0.50D or more astigmatism, although with-the-rule astigmatism compensation may not yield as much improvement on clinical evaluation.

Low amounts of hyperopia are often well tolerated without correction; however, hyperopia of +1.00D or greater may require a significant amount of effort from the athlete to achieve and maintain clarity. Judicious refractive compensation may reduce the accommodative effort needed for the athlete to achieve optimal image clarity. Low amounts of anisometropia are not always compensated for, especially when the refractive errors are low. Anisometropia of 0.50D or more can have a detrimental impact on depth perception, and some athletes may be sensitive to that effect.[5,6] Additionally, the effects of meridional anisometropia should be considered in athletes with asymmetric astigmatism.

Balancing the image quality through refractive compensation will enhance sensory fusion and improve the quality of spatial

localization judgments. These guidelines are useful for the practitioner to trigger the discussion of the potential benefits of a refractive prescription. Ultimately, however, the athlete makes the decision whether to experiment with a prescription.

Contact Lenses vs. Spectacles

Spectacles are not commonly recommended for use in sports. The main concern is that most eyewear does not offer the impact resistance necessary to protect the wearer from the possible hazards encountered in many such activities. The American National Standards Institute (ANSI) performance standards for dress and industrial-strength (safety) eyewear are not applicable in most sports.

Instead, the American Society for Testing of Materials (ASTM) has developed performance standards for eye and head protection in many sports. ASTM performance standards are established for protective eyewear in each sport individually, and the forces potentially encountered in a sport are used to determine appropriate testing parameters.

Even if the athlete selects appropriate protective eyewear, consider the potential effects from optical aberrations of the lenses. Monochromatic lens aberrations can degrade the optical image transmitted through the off-center portions of the lens, and distortion can decrease the useful field of view through a lens. The reduction in the useful field of view can have a detrimental impact on performance in sports. For example, a right-handed tennis player viewing the ball toss during a serve looks through the left field portions of his or her spectacle lenses, and the image can be significantly altered by large refractive errors secondary to these aberrations.

On the other hand, field-of-view aberrations, visual field restriction, optical distortion, frame comfort, frame stability, surface reflections, lens fogging and precipitation issues with spectacle lenses largely can be avoided by moving the optics onto the cornea. Contact lenses eliminate the induced prismatic effects that are evident with most spectacle lenses. The potential visual field impediment created by eyewear frames also is eliminated with contact use, as are the issues of lens reflection and fogging that compromise visual performance with eyewear.

In comparison to spectacle use, the peripheral visual field is increased by approximately 15% with contact lens wear.[2] Contacts are an excellent vision-correction option for highly dynamic sports (*see "Dynamic Reactive Sports," page 88*), because no frame can be dislodged and no lenses can fog

Nike Ignites a SPARQ

The Nike SPARQ Sensory Training Station consists of a single computer and two high-resolution LCD monitors (both 0.28mm dot pitch)—one 22-inch diagonal display and one 42-inch diagonal touch-sensitive display. A hand-held Apple iPod Touch is used in several assessments to measure responses. A liquid crystal shutter system creates simulated depth through a wireless link to the computer for stereopsis testing at far. Custom software controls the displays, input acquisition and test procedures, based on subject responses. Pre-recorded instructions are automatically played at the start of each assessment to maintain consistency for each evaluation.

Dynamic Reactive Sports

Baseball	Motor racing
Softball	Racquet sports
Basketball	Skating
Boxing	Skeet and trap shooting
Cycling	Skiing
Diving	Soccer
Fencing	Surfing
Football	Swimming
Gymnastics	Track and field events
Hockey	Water polo
Kayaking	Wrestling
Martial arts	Volleyball

over. Although contact lens comfort is an obvious issue to contend with, frames pose significantly greater limitations for the majority of athletes.

Take note, however, that both target shooters and archers may actually prefer spectacles to contact lenses. The main advantage is the stability of clear vision obtained with spectacle lenses. Because peripheral vision is not a significant factor in most aiming sports, the enhanced visual field does not offer a significant benefit. The shooter or archer typically is not bothered by lens aberrations off the optical center. However, in athletes with strong prescriptions, the lenses may need to be fit with the optical centers set at the particular eye position used when aiming.

Hydrogel Lens Applications

Due to better comfort and stability, soft contact lenses typically are preferred to gas-permeable lenses for use in sports. The main considerations for hydrogel lenses are the material composition, water content, diameter and thickness. In general, lenses with a higher water content tend to dehydrate faster than low to medium water content lenses.[36] Therefore, thicker, low to medium water content lenses or silicone hydrogel lenses should be used for athletes who have dehydration problems.[36]

Additionally, it has been suggested that the significantly increased oxygen permeability with silicone hydrogel lenses contributes to improved comfort and decreased symptoms of dryness. High water content lens materials or silicone hydrogel lenses may be needed for prolonged lens wear situations, in which oxygen transmission is a crucial factor. Larger-diameter lenses also are recommended for better stability and hydration.

These lens recommendations apply to sports in which considerable wind or airflow hits the athlete's face. Some endurance sports require a lens modality for extended use. In sports such as high-altitude mountaineering, long-distance sailing or long-distance motor racing, the athlete experiences extreme environmental conditions over an extended period of time, requiring excellent visual performance throughout the event while maintaining good ocular health.

Contact lenses for athletic use should fit more tightly than traditional fitting practices dictate. The lens should exhibit minimal movement after a blink as well as maintain a good centering position in extreme gaze directions.

Single-Use Lenses

Any athlete can benefit from single-use lenses—from the weekend athlete, who seeks the comfort of a disposable lens, to the professional athlete who prefers immaculately clean and fresh lenses before starting a competition and a quick replacement of lenses at any time during competition.

Single-use contact lenses can be a particularly useful for water sports. They offer an advantage over prescription masks or goggles, because peripheral vision is not as restricted. Nonetheless, you cannot overlook the main concerns regarding contact lens wear in the water—namely lens loss and increased risk for microbial infection.

Orthokeratology

Orthokeratology is another option to reduce myopia and astigmatism with specially designed rigid lenses. What could potentially put an athlete at a disadvantage is the increased presence of higher-order aberrations and spherical aberration that may occur after initiating orthokeratology.[37,38]

The increase of higher-order aberrations may cause a reduction in low-contrast visual acuity during the daytime, and this reduction is more significant in patients with larger pupil sizes.[38]

However, orthokeratology remains an attractive option for athletes, especially young, myopic or astigmatic athletes who are not yet eligible for refractive surgery.

Visual Performance Training

Literature reviews have indicated that there is sufficient scientific support for the efficacy of vision therapy in modifying and improving visual system disorders.[4,12] The athlete who possesses average, or even above average, vision skills presents a compelling and controversial challenge. Can the vision skills of this athlete be enhanced above the current level, and would this result in demonstrable improvements in sports performance?

Several studies have reported positive effects of vision training programs on sports-specific tasks, while other studies have not identified improvement in performance.[39-43] The differences in study results are speculated to be caused by differing athletic skill levels (novice vs. expert subjects) and the

use of general vs. specific vision training programs.[12]

Additionally, research design factors in all these studies weakened the results and conclusions, indicating the need for further study in this area of sports vision.

All the visual performance skills described here have been shown to be amenable to training.[4] There are eye care professionals who provide this service. And, more recently, optometrists have collaborated with sports trainers to provide this service as part of personalized sports training. The sports trainers are taught the vision skill performance procedures similar to vision therapists, and are instructed to integrate these practices into the physical training program under the direction of the optometrist.

In this model, the athlete receives pre- and post-training assessments with the optometrist, making the O.D. part of the training team for the athlete. The Nike SPARQ Sensory Testing and Training Stations have digitized training programs for some aspects of visual performance, providing athletes the opportunity to train in eye care practices or at a sports training facility.

There is a vast array of refractive correction options available for athletic patients, and eye care professionals now have many new technologies to choose from in order to help meet the special demands encountered in athletic and recreational activities. We are uniquely suited to assist in the selection of the best eyewear designs, performance tints, contact lens parameters and protection for our athletes' eyes.

Additional vision training services to remediate and enhance critical visual performance factors should be discussed with the athlete as a management option. Most of the patients that we examine are routinely active in some sports and recreational pursuits. Not only do elite athletes reap performance advantages from our services, but patients from all walks of life can benefit from improvement in visual function across all aspects of daily life.

Once your reputation is established as an eye doctor who fulfills the visual needs of athletes, word-of-mouth marketing will bring a wealth of new athletic patients with vision care needs to your practice. ■

Dr. Erickson is a professor at Pacific University College of Optometry. He has served as past-chair of the American Optometric Association Sports Vision Section and the Binocular Vision, Perception and Pediatric Optometry Section of the American Academy of Optometry. He lectures both nationally and internationally on the topics of sports vision, pediatrics and binocular vision. Dr. Erickson is a paid consultant to Nike, Inc.

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OSC QUIZ

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1. A review of the literature regarding the visual attributes of athletes shows a consensus on all of the following conclusions EXCEPT:
a. Athletes possess superior visual physiology compared to non-athletes.
b. Athletes are able to use visual information better in sports.
c. Many aspects of visual performance are not routinely evaluated in an eye exam.
d. Some of the instrumentation for measuring visual performance is outdated or unavailable.

2. A study of static visual acuity (SVA) in professional baseball players found that:
a. 20/20 is average visual acuity in these athletes.
b. Less than 20% of individuals could see 20/15.
c. Mean visual acuity was approximately 20/13.
d. No players were able to see better than 20/10.

3. Most studies of dynamic visual acuity (DVA) in athlete populations have found better performance than in non-athletes. One study of youth soccer players did not find this result. What was the reason suggested for this difference in results?
a. DVA is not important to play soccer.
b. The soccer ball is a large target.
c. Using letters as DVA stimuli is inappropriate.
d. Using a predictable rotator device to measure DVA is inappropriate for soccer players.

4. What primary limitation do athletes with reduced contrast sensitivity (CS) experience?
a. Glare recovery.
b. Inconsistent performance.
c. Photosensitivity.
d. Fatigue.

5. What is NOT a common challenge associated with the assessment of stereopsis in athletes?
a. Dynamic stereopsis is difficult to assess clinically.
b. Threshold levels of stereopsis are difficult to measure at far.
c. Testing can be conducted at near distances and extrapolated to far distances.
d. Most assessment tools simulate the appearance of stereopsis.

6. What visual skill is often assessed using "distance rock testing?"
a. DVA.
b. Stereopsis.
c. Accommodative-vergence facility.
d. Peripheral eye-hand response.

7. What was discussed as a possible confounding factor in measuring perception span in athletes?
a. Use of shape patterns as stimuli.
b. Use of number sequences as stimuli.
c. Use of sport-relevant images as stimuli.
d. All of the above.

8. Which of the following assessments shows a gender bias, where males perform better than females on average?
a. Central eye-hand reaction and response time.
b. Perception span.
c. DVA.
d. CS.

9. Protective eyewear for participation in sports should meet what industry standard?
a. ANSI Z80.1.
b. ANSI Z80.3.
c. ANSI Z87.1.
d. ASTM.

10. What is NOT an advantage of contact lenses over spectacle correction in athletes?
a. No restriction on peripheral vision from a frame.
b. No distortion of vision when looking in non-primary gaze positions.
c. Superior CS.
d. No problems with lens fogging.

11. It is estimated that athletes who wear contact lenses vs. spectacles receive an approximate increase in peripheral visual field by what percentage?
a. 20%.
b. 15%.
c. 10%.
d. 5%.

12. Which athletes may actually prefer spectacle correction over contact lens wear?
a. Motor racers.
b. Target shooters and archers.
c. Volleyball players.
d. Fencers.

13. All of the following contact lens types are suggested to minimize dehydration EXCEPT:
a. Silicone hydrogel.
b. High water content.
c. Medium water content.
d. Low water content.

14. All recommendations are appropriate for contact lens prescribing in athletes EXCEPT:
a. Soft lenses typically are preferred over gas permeable lenses.
b. Single-use lenses are useful for water sports.
c. Larger-diameter lenses may be better for stability and hydration.

OSC QUIZ

d. More lens movement is preferred to accommodate head shifting.

15. Why may athletes who choose refractive compensation with orthokeratology notice reduced visual performance during the daytime?
a. Reduced stereopsis.
b. Accommodative infacility.
c. Higher-order aberrations.
d. Dry eye symptoms.

16. Orthokeratology may be a good option for which category of athletes?
a. Moderate to high astigmats.
b. Young, low to moderate myopes.
c. Young, low to moderate hyperopes.
d. Presbyopes.

17. A recent collaboration to provide visual performance training to athletes involves the optometrist partnering with:
a. Chiropractors.
b. Ophthalmologists.
c. Physical therapists.
d. Sports trainers.

18. The recommended refractive prescribing guidelines for athletes with hyperopia begin at:
a. +0.50D.
b. +1.00D.
c. +1.50D.
d. +2.00D.

19. The recommended refractive prescribing guidelines for athletes with anisometropia begin at:
a. 0.50D.
b. 1.00D.
c. 1.50D.
d. 2.00D.

20. When considering visual tasking demands, which is NOT a dynamic, reactive sport?
a. Baseball.
b. Skiing.
c. Basketball.
d. Golf.

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7.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
8.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
9.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
10.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
11.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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13.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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15.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
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17.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
18.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
19.	Ⓐ	Ⓑ	Ⓒ	Ⓓ
20.	Ⓐ	Ⓑ	Ⓒ	Ⓓ

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24. Avoided commercial bias/influence: ① ② ③ ④ ⑤
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References: 1. Based on third-party industry report, Alcon data on file, Jan 2010-Sep 2011. **2.** Woods J, Woods C, Fonn D. Early symptomatic presbyopes—What correction modality works best? *Eye Contact Lens.* 2009;35(5):221-226. **3.** Rappon J. Center-near multifocal innovation: optical and material enhancements lead to more satisfied presbyopic patients. *Optom Vis Science.* 2009;86:E-abstract 095557. **4.** 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. **5.** Rappon J, Bergenske P. AIR OPTIX® AQUA Multifocal contact lenses in practice. *Contact Lens Spectrum.* 2010;25(3):S7-S9.

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Depressed and Dizzy

A bipolar patient, on a handful of psychotropic meds, presented with vague visual complaints. What, if anything, can you do for her? **Edited by Paul C. Ajamian, O.D.**

Q I saw a 42-year-old female with nonspecific visual complaints, dizziness and headaches. Her exam revealed 20/20 acuity (O.D., O.S.) with diffuse, nonspecific field defects on FDT. She has been diagnosed with bipolar disorder and is currently taking Depakote (divalproex sodium, Abbott Laboratories), Lexapro (escitalopram oxalate, Forest Laboratories) and trazodone. She also casually mentions a history of alcohol abuse. Where do I go from here?

A "It's concerning when a patient has a history of mental issues, psychotropic medications and alcohol abuse," says optometrist and registered pharmacist Jill Autry, of the Eye Center of Texas.

But don't automatically jump to conclusions that a complicated psychophysical etiology is to blame for the patient's problems. Something as simple as dry eye or early presbyopia, exacerbated by her medication, could be the likely cause of this patient's complaints. As always, perform a thorough evaluation of the anterior and posterior segment.

Dr. Autry explains: "This patient's list of medications have significant effects on the central nervous system. Depakote is an anti-epileptic drug, but is also approved for bipolar disease and migraine. Lexapro is a selective serotonin re-uptake inhibitor (SSRI) antidepressant, and trazodone is a serotonin antagonist reuptake inhibitor (SARI) antidepressant. These meds and others, like anti-anxiety medications and ADHD drugs, have a plethora of side effects listed on the package insert, such as blurred vision, dizziness, fatigue, headache, and so on. So, it's difficult to tell which drug may be causing this patient's problem. They may even be working synergistically to cause side effects. A lot of the heavy CNS mechanistic meds have very high cholinergic properties, which can cause cycloplegia (or decreased accommodation) or increased ocular dryness."

Alcohol abuse is another story, Dr. Autry says. A current or previous history of alcohol abuse can result in optic nerve toxicity, sometimes referred to as "toxic amblyopia," which could cause the patient's vision problems. This would manifest as central or cecocentral visual field defects.

So what should your exam include?

- Dry eye testing.
- Accommodative testing.
- Relative afferent pupillary defect testing.
- A careful optic nerve evaluation, looking for nerve swelling or pallor to implicate or rule out optic nerve disease.
- Full-threshold (20-2) visual field test, especially looking for central or cecocentral defects, indicative of optic nerve disease.
- Color vision plates in each eye, as loss of color vision is another indicator of problems with the nerve.
- An optic nerve fiber layer analysis.

"If the exam shows that the patient merely has dry eye or an accommodative problem, then the solution is simple," Dr. Autry says. "You treat the dry eye, or prescribe her a pair of reading glasses or change her reading add."

However, if the patient has optic nerve involvement or repeatable visual field defects, then refer her to a neuro-ophthalmologist for further testing. "This should include an MRI to rule out any other neuro issues, as well as an ERG to check the retina, and a VEP to evaluate optic nerve conduction," she says.

On the other hand, the exam might show that the patient is perfectly normal, with no obvious signs. In that case, Dr. Autry says, tell the patient: "'All of your exam findings are normal. But I want to watch this and make sure it isn't something that's progressive. So I'd like to bring you back in four to six months and repeat some of these tests, and see if there is a decline in your vision or a decline in your visual field.'"

Lastly, "*Never* tell the patient her antidepressant or bipolar medication might be, for example, causing her dry eye or other visual side effects. Because she might take it upon herself to discontinue it. And that can be very dangerous for a person with mental issues," Dr. Autry says. "Our role is to do as much testing as we need to do in our office to explain the acuity loss and symptoms, and then take that information and refer that on if necessary." ■

Treat FK the Right Way

There's no shortage of pain management options for severe corneal injuries. It's just a matter of choosing the best one for your patient. **Edited by Joseph P. Shovlin, O.D.**

Q I have recently seen several patients with filamentary keratitis (FK). In general, they are difficult to manage because of their refractory state. Would contact lenses be therapeutic? Are there any new treatment options?

A FK can be a chronic, persistent and devastating condition, but if you are diligent with diagnosis and management, you can limit the number and severity of recurrences.[1] "The key to treating filamentary keratitis is to address the underlying condition that causes the corneal filaments to form," says Craig Thomas, O.D., a private practitioner at First Eye Care in Dallas.

For moderate to severe FK, current best practices include the use of multiple eye drops and bandage contact lenses. "Bandage contact lenses protect the damaged epithelium from the shearing effects of the eyelids; this allows the damaged basal cells of the epithelium to attach to Bowman's membrane," Dr. Thomas says. "Smooth attachment of the basal epithelial cells to Bowman's membrane prevents the formation of new receptor sites for the corneal filaments."

Topical pharmacologic treatment options include artificial tears, steroids, immunomodulators and 5% hypertonic solution. Preservative-free artificial tears lubricate the cornea and relieve ocular discomfort, while steroids can modify or reduce the number of mucus receptor sites by inhibiting inflammatory cells and fibroblasts at the base of the corneal filament. Immunomodulator eye drops reduce dry eye-induced inflammation and increase aqueous production. Finally, 5% hypertonic solution decreases the formation of corneal filaments by inhibiting receptor site formation and increasing the tear-to-mucus ratio of the pre-corneal tear film.

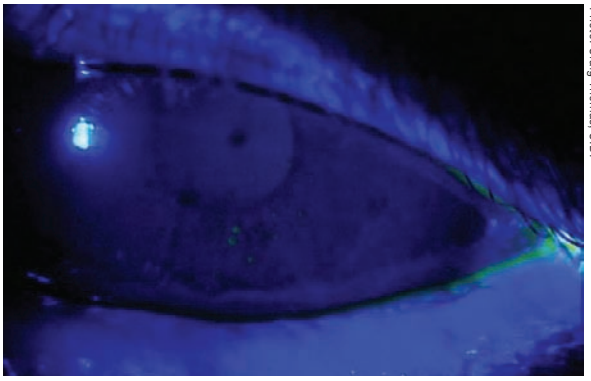

Photo: Craig Thomas, O.D.

If untreated, the focal epithelial defects (seen above) stained with fluorescein dye, will serve as attachment points for corneal filaments.

"Two days of overnight bandage contact lens wear, in-office cycloplegia, Pred Forte (prednisolone acetate, Allergan) three times per day and unpreserved artificial tears three times per day [will typically] resolve the filamentary keratitis and ocular discomfort by the third day," Dr. Thomas says. "After that, unpreserved artificial tears and 5% hyperosmotic solution would usually comprise the maintenance therapy. Punctal plugs could be added to the treatment regimen if the condition returned or if symptoms persisted."

Lately, there's been a lot of buzz about a new potential treatment for FK—Botox (onabotulinumtoxin A, Allergan) injections. In a recent study, researchers examined 33 eyes of 17 patients who had FK that was resistant to conventional medical therapy.[2] All eyelids were subcutaneously injected with Botox (10U/0.1ml). The results showed that the filaments completely resolved in 88% of the eyes after the initial injection. While 42% of eyes showed sustained improvements after the first injection, 58% required additional injections during follow-up because of recurring symptoms and filaments on the cornea. However, larger trials will be necessary to verify these results before this treatment is ready for prime time.

Regardless of which treatment strategy you choose, it's important to talk with your patients about the often-chronic nature of this condition. Let them know that, while prolonged therapy may be necessary, you will work together to find a customized plan that will ease their symptoms and improve their comfort. ■

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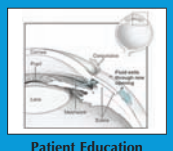

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Add Color to Your Diet

Macular pigments (Part 1): Xanthophylls may not only protect the retina, but also enhance its function. **By Carlo J. Pelino, O.D., and Joseph J. Pizzimenti, O.D.**

Xanthophylls are a subclass of carotenoids, a large group of plant pigments responsible for the colors of bright fruits and vegetables. Although more than 600 carotenoids are found in nature, just 40 to 50 are consumed in the typical diet, and only 14 have been detected in serum.[1] Of these 14, just lutein, zeaxanthin and their metabolites are located in the macula. Macular pigment (MP) serves as a filter that absorbs blue light and has been shown to act as a potent antioxidant, quashing free radicals associated with the pathogenesis of age-related macular degeneration (AMD).[2]

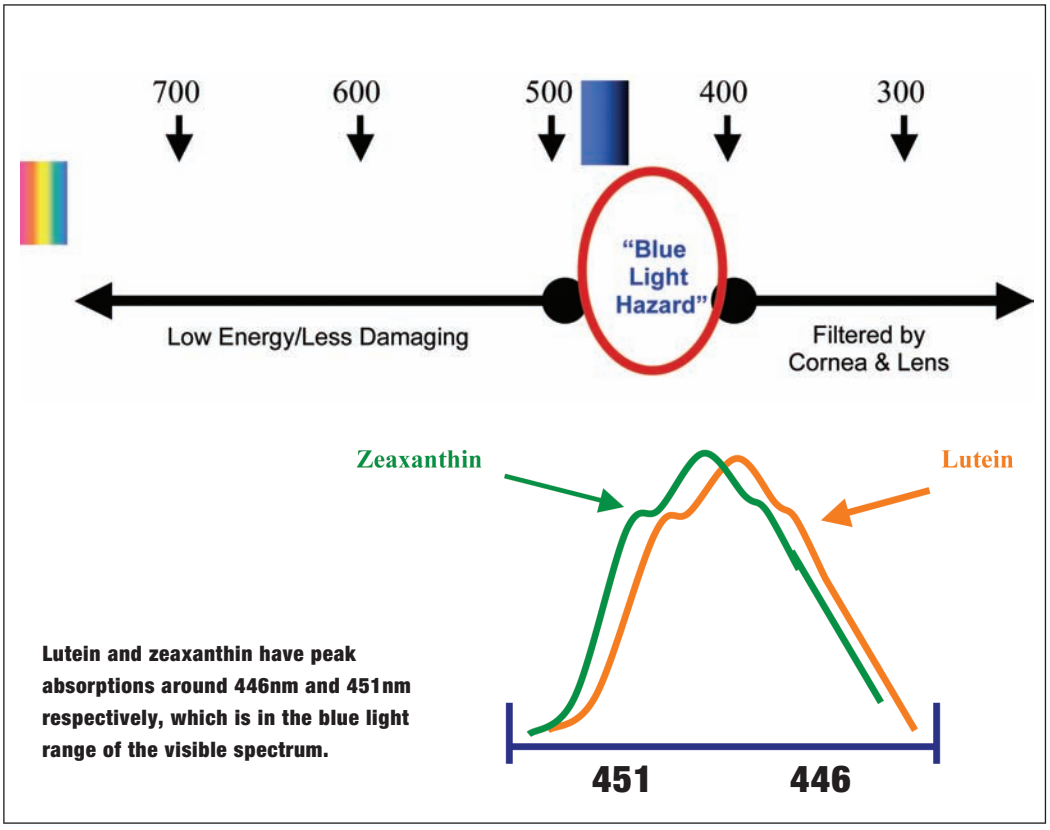
Lutein and zeaxanthin are found in egg yolk, yellow fruits and vegetables, and in dark green leafy vegetables like spinach, kale and collard greens. Low levels of lutein and zeaxanthin in the diet, serum or retina may result in an increased risk of AMD.[2,3] Much of the early MP research—including supplementation studies—focused on lutein exclusively. More recent epidemiological evidence suggests that zeaxanthin may be of equal importance in protecting the fovea.[3,4]

Nutritional therapy with dietary and/or supplemental MP, along with other potentially beneficial agents (such as omega-3 fatty acids), is one means of proactive intervention. In our nutrition-based efforts to preserve patients' macular health, we also may be enhancing their visual function.

Clinical Application of MPOD

The amount of MP in the retina can be quantified in a clinical setting. The most studied method is a psychophysical technique called heterochromatic flicker photometry (HFP), which uses flickering blue and green light targets to yield a measurement reported in density units as macular pigment optical density (MPOD). Lower MPOD can be associated with increased risk for AMD, as well as several other risk factors for AMD (including poor diet, smoking, low serum

UV/Visible Spectrum of Lutein & Zeaxanthin



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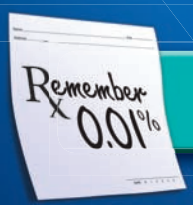
Warnings and Precautions: LUMIGAN® causes changes to pigmented tissues, mostly increased pigmentation of the iris, eyelid, and eyelashes as long as LUMIGAN® is administered. Iris color change may not be noticeable for several months to years. After discontinuation of bimatoprost, iris pigmentation is likely to be permanent, while eyelid and eyelash changes have been reported to be reversible in some patients. Patients should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

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 Prescribing Information on adjacent page.

1. LUMIGAN® 0.01% and 0.03% Prescribing Information.
2. Katz LJ et al. *Am J Ophthalmol.* 2010;149(4):661-671.



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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 (eg, 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 event 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 events (> 10%) included growth of eyelashes and ocular pruritus.

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

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 that 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/m^2 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: 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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carotenoid concentration and high body mass index).[5]

The optometrist is an important resource for patients seeking to achieve optimum retinal health and protection. We start by advising patients to eat a balanced diet that is high in fish and whole grains, emphasizing fruits, vegetables (especially greens) and fat-free or low-fat dairy products.

The diet should also include lean meats, poultry, beans, eggs and nuts. It should be low in saturated fats, trans fats, cholesterol, salt (sodium) and added sugars.[6] A broad-spectrum multivitamin may be advisable for patients who are unable to achieve these dietary goals. Some multivitamin products contain lutein and zeaxanthin, in addition to other vitamins and minerals that are important in ocular health (such as vitamin C, vitamin E and zinc).

For patients at risk for AMD due to genetic, personal, systemic or environmental factors, or those who show early signs of the disease, we supplement with both zeaxanthin and lutein. First, we obtain a baseline MPOD measurement with heterochromatic flicker photometry. It is generally appropriate to administer a dosage of 4mg to 10mg of zeaxanthin per day, depending upon the patient's diet (especially green vegetable intake), body mass, MPOD and other health factors.[2,4]

For lutein, 6mg to 20mg per day typically is suitable, again depending upon the various patient characteristics.[3,4] We usually supplement for six months before rechecking the MPOD.

If you have questions about whether or not a vitamin supplement is appropriate for a particular patient, contact the patient's primary care physician, pharmacist or a nutritionist before proceeding.

Improved Visual Function

A growing body of evidence suggests that the antioxidant and blue-light filtering properties of MP may be associated with improved visual function.[3,7] Lutein and zeaxanthin may attenuate photophobia or discomfort associated with intense short-wavelength targets and may impact the threshold for photophobia under normal viewing conditions.[3]

Recent findings demonstrated that supplementation with lutein and zeaxanthin increased MPOD in a healthy population and led to an improved tolerance to glare and decreased photo-stress recovery time.[3,7] Likely via its blue-light filtering property, MP contributes to better visual acuity, glare recovery and contrast sensitivity in healthy individuals as well as those with age-related eye diseases.[8,9] High levels of MP additionally attenuate chromatic aberration and photophobia.[10]

The Zeaxanthin and Visual Function Study evaluated MPOD, visual acuity, contrast sensitivity, shape discrimination, color vision, glare recovery, central kinetic perimetry and lipofuscin pattern changes following supplementation with 9mg lutein, 8mg zeaxanthin or a combination of the two xanthophylls per day for 12 months.[3]

In the zeaxanthin group, high-contrast visual acuity improved by 8.5 letters/1.5 lines and foveal shape discrimination sharpened from 0.97 to 0.57.[3] The zeaxanthin group had the largest percentage of subjects who had clearing of their kinetic visual field central scotomas. In addition, these patients reported an improvement in night driving skill.[3]

Numerous studies suggest that retinal lutein and zeaxanthin may protect the macula from light-induced damage.

The light-filtering properties of macular pigment also may influence visual comfort, function and performance. A patient's MPOD can potentially serve as a biomarker not only for predicting the risk for eye disease, but also for visual function.

Stay tuned for Part 2 of this column, which will appear in the July 2012 issue. In that piece, we'll discuss the role of macular pigments in systemic wellness. ■

Disclosure: Drs. Pelino and Pizzimenti have no proprietary interest in any instrument, food product, vitamin or supplement. Dr. Pizzimenti serves on the scientific advisory board for ZeaVision.

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4:00pm – 6:15pm	CE Courses
6:15pm – 7:15pm	Welcome Reception

Friday, July 20, 2012

6:30am – 7:00am	Breakfast with Sponsors
7:00am – 9:00am	CE Courses
9:00am – 9:30am	Break with Sponsors
9:30am – 12:00pm	CE Courses

Saturday, July 21, 2012

6:30am – 7:00am	Breakfast with Sponsors
7:00am – 9:00am	CE Courses
9:00am – 9:30am	Break with Sponsors
9:30am – 12:00pm	CE Courses

Sunday, July 22, 2012

6:30am – 7:00am	Breakfast with Sponsors
7:00am – 9:00am	CE Courses
9:00am – 9:30am	Break with Sponsors
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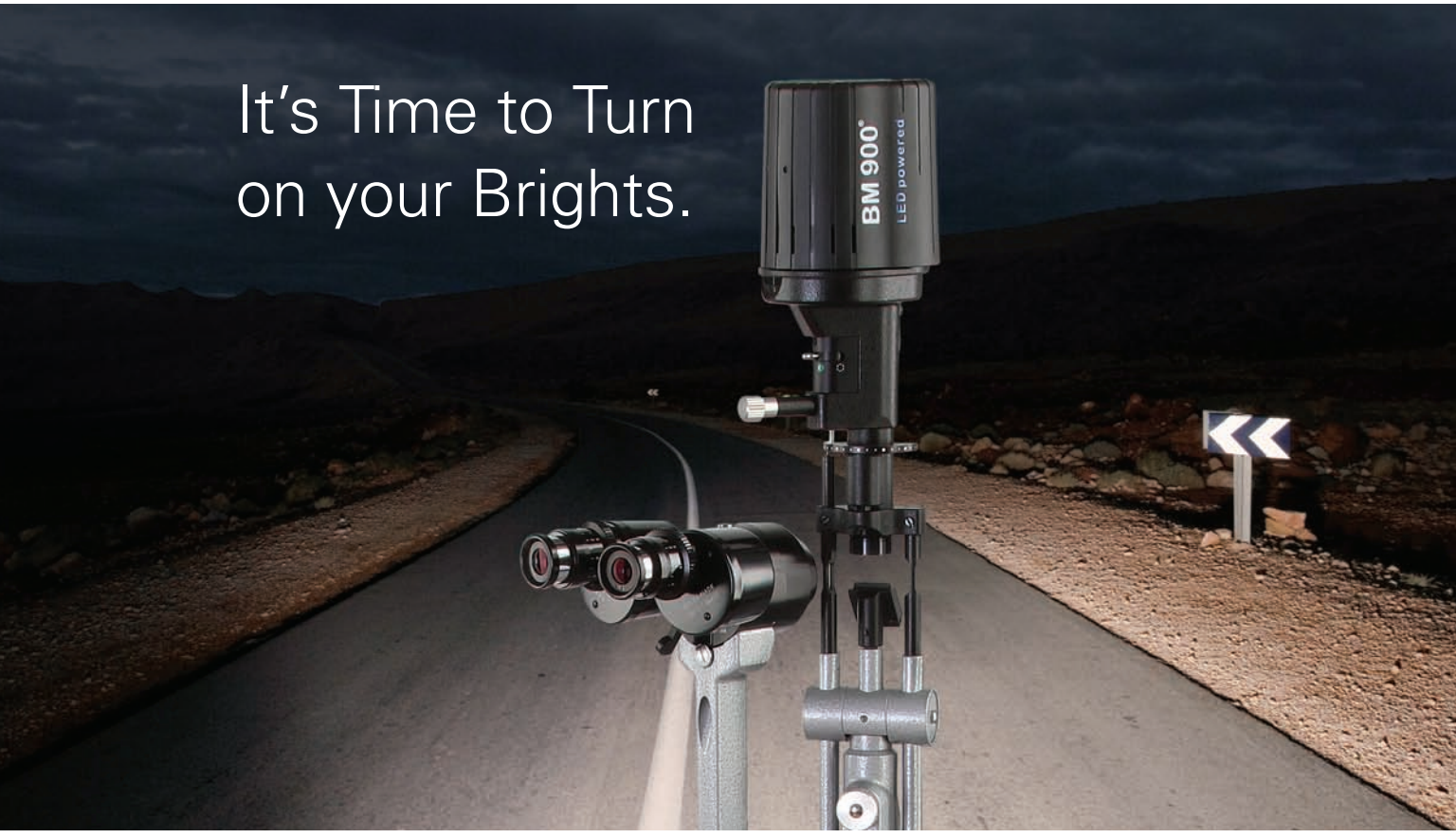

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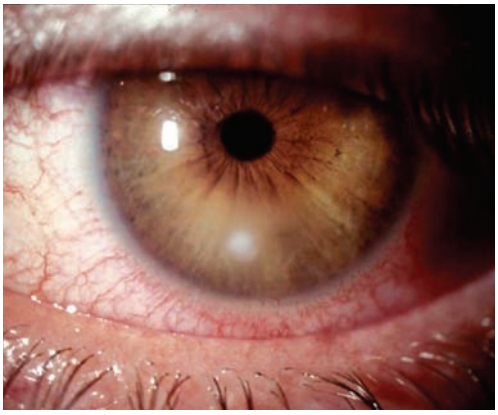
Build a Therapeutic Practice

Now, more than ever, is the time for optometry to embrace medical management.

By Joseph W. Sowka, O.D., and Alan G. Kabat, O.D.

Throughout the years that we have written this column, we have tackled the therapeutic management of numerous conditions. However, we really never have addressed the underlying reasons for therapeutically managing patients with ocular disease.

Attending a recent continuing education lecture helped formulate the idea for this month's column. The speaker was delivering an excellent lecture on managing anterior segment diseases and was presenting a particularly serious case of bacterial keratitis. The diagnosis and management was exceptional, and was well supported by evidence-based literature.



This patient with infectious bacterial keratitis required expert ophthalmic care.

However, one member of the audience became upset with the lecturer and spoke out. He verbally reprimanded the speaker for, in his opinion, advocating that the audience (and all optometrists in general) accept the management of a condition with such a high risk of visual morbidity.

The audience member contended that it was irresponsible for any speaker to advocate that optometrists attempt to treat a potentially visually devastating condition—such as a centrally located bacterial keratitis—and, by doing so, would merely subject optometrists to the possibility of medical malpractice litigation, should the patient's outcome be poor.

Clearly, the speaker was not advocating that any member of the audience practice beyond his or her personal comfort level. Rather, the speaker was factually detailing the diagnosis and the current state of disease management. Yet, the audience member continued to challenge the speaker and contended that therapeutic practice puts optometrists at risk of medico-legal suits with little, if anything, to gain.

Realities of Optometric Malpractice

Having served as expert witnesses in numerous optometric malpractice cases, we certainly can attest that there is no possible way to eliminate the risk of litigation, short of ceasing clinical care altogether. Fortunately, cases of malpractice in optometry are uncommon. In an 18-year span between 1991 and 2008, there were 609 payments related to optometric malpractice made in the United States.[1] This translates to roughly 34 cases per year, with the majority of involved parties settling for a relatively low figure of $50,000 or less.[1] Since 1991, claims against optometrists accounted for just 0.19% of payments made nationally.[1] Although very rare, the risk of a malpractice suit being filed potentially exists for every patient encounter with every optometrist.

Revisiting the aforementioned example of bacterial keratitis, the audience member suggested that patients with such conditions immediately should be referred to eliminate the risk of a malpractice suit, should the outcome be poor. However, simply referring such patients will not eliminate your risk. Instead, the risk is present as soon as the patient enters your practice.

Regarding sight-threatening bacterial keratitis, should an optometrist refer the patient in anything less than an urgent, same-day basis, there could be a suit over a delayed referral.

If an optometrist immediately refers the patient to a general ophthalmologist, there could be an allegation that the referral was improper and that the patient should have been sent directly to a corneal specialist.

Finally, if an optometrist informs a plaintiff's attorney that there was a high risk of visual morbidity with a centrally located bacterial infection that necessitated an immediate referral to a corneal specialist, there can be an allegation that, by not immediately starting the patient on

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antibiotic therapy prior to the referral, care was withheld, leading to attendant visual morbidity. While these scenarios may seem unreasonable or unbelievable, we have seen such allegations used by plaintiffs' attorneys often.

In reality, a practitioner's best defense against allegations of medical malpractice is to understand and adhere to the current standards of practice, as advocated and published by organizations such as the American Optometric Association and the American Academy of Ophthalmology. Additionally, scrupulous documentation of all aspects of a patient's care is absolutely mandatory. Your records are your best defense. We have seen many cases damaged or even lost simply by poor record keeping.

Many practitioners are unaware of the true nature of alleged malpractice by optometrists. There is the mistaken belief that the majority of suits involve the inappropriate use of therapeutic medications. In fact, however, most cases fall into the categories of: failure to diagnose, delay in diagnosis and misdiagnosis.[1]

These are acts of omission, not commission; that is, the practitioner allegedly didn't diagnose promptly or properly, rather than causing harm through therapeutic intervention. These errors of omission can occur in both therapeutic and nontherapeutic practices equally. So, fear of medical malpractice litigation is not a viable reason to avoid building a therapeutic practice.

The Changing Environment of Optometric Practice

Optometry's traditional "bread and butter"—namely, refractive care—is in peril. Opticians are lobbying heavily for refractive privileges in many states. Larger ophthalmology offices routinely fit and dispense spectacles and contact lenses today (a practice that was virtually unheard of 20 years ago). We have also seen a massive shift in contact lens practice and profitability over the last two decades.

We recall a time when contact lenses were sold in individual glass vials and preciously cared for by a patient for a year or more, due to their expense. At one time, "contact lens insurance" was sold to help patients cope with the cost of damaged and lost lenses. During this time, contact lenses themselves were significant sources of revenue.

Today, all of that has disappeared with the overwhelming change to disposable lenses, causing the practitioner's profit margins for these devices to plummet. Patients are increasingly using the Internet and wholesale distributors to obtain their replacement lenses.

Online Spectacles

Perhaps the greatest motivation for building a therapeutic practice (or any specialty optometric practice, such as complex contact lens fitting, low vision rehabilitation, or pediatric vision and vision therapy) is patients' ability to now purchase their spectacles via the Internet.

Traditionally, patients received spectacles from trained professionals such as opticians, optometrists and ophthalmologists. Such professionals took detailed measurements, including segment height and interpupillary distance, to complete the spectacle order. Once finished, the spectacles were verified to have been made according to the required specifications and were placed on the patient's face and adjusted for the optimal fit and use.

For all of this labor, the dispensing professional rightfully profited from the spectacles through a significant cost markup.

However, tradition is beginning to give way to technology in the spectacle arena. In 2007, 5% of surveyed patients reported receiving spectacles from an online source.[2] Additionally, that year, 1.7% of all spectacles were ordered and delivered directly to the patient from online retailers.[2] (It was estimated that 2.8% of all spectacle prescriptions were ordered and delivered directly to patients in 2010.[2])

While those numbers may not be overtly concerning, practitioners are undoubtedly noticing that more patients are now requesting segment height and interpupillary distance be included in their spectacle prescriptions. There has to be some degree of concern that the profitability of spectacles may follow the trend that occurred with contact lenses.

Building a Therapeutic Practice

Therapeutic care is profitable, provided that there is acknowledgement of and adherence to a few basic principles:

• *Capitalize on your time and services*. Simply put: The practitioner must not devalue their professional services or time. Many optometrists are so grounded in material sales that they fail to capitalize on their most valuable assets—namely their diagnostic knowledge and clinical skills.

Fees for service should be set at an appropriate level commensurate with the complexity of the case and the time invested in managing the condition. Fees should be charged for each and every visit, be it consultation or follow-up. Too often, optometrists charge for the initial visit, but advise patients that "there will be no charge for the follow-up." This is a recipe inconsistent

with professional respect, reward or financial compensation. No other healthcare profession, be it veterinary medicine or chiropractic, follows such a recipe.

• *Bill for separate procedures.* Another infrequently practiced policy is billing appropriately for separate procedures. Epilating an inward-turned eyelash may seem insignificant because of its mild complexity (as compared to a glaucoma work-up, for example).

But, in reality, it took time and practice to understand how to properly approach the eyelash, remove it and avoid complications. Remember—you paid someone money and time to teach you these techniques, and it took great effort and repetition to master them. It is not appropriate to simply "give them away."

• *Don't forget the Rx.* Another critical point on building a therapeutic practice is to always write prescriptions. This may sound basic, but many optometrists simply do not use their Rx pads as often as they should. In fact, many rely on samples for the bulk of their treatment.

While this may save the patient a few dollars, it does little to establish the practice as a center for excellence. Remember the old adage, "That which costs me nothing is worth nothing." Utilized improperly, samples can change patients' perceptions from expertise to expectation.

Optometrists who espouse that the profession should adhere to refractive care and avoid therapeutic need to see how optometry is changing. Therapeutic care does not increase medico-legal exposure. Additionally, it seems reasonable to believe that spectacle dispensing will become less profitable in the near future, just as contact lenses did years ago.

Yet, it is highly unlikely that the necessity of therapeutic ocular disease management will diminish any time soon.

The best reason that we can advocate to practice therapeutic optometry is simple. Remember, even in today's connected world, a patient still cannot be treated for a case of sight-threatening bacterial keratitis over the Internet! ■

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VEATCH OPHTHALMIC INSTRUMENTS

One Eye's Better Than None

This patient presented with 20/400 vision in his right eye. Now, he's losing the vision in his left eye too. Can we help restore his sight? **By Mark T. Dunbar, O.D.**

A 46-year-old Hispanic male presented with an eight-year history of reduced visual acuity in his right eye. He had seen several eye care providers over the years, but had always been confused as to why his vision was reduced. More recently, he began to notice blurry vision in his left eye. Because this is his only functioning eye, he became extremely concerned and scheduled an evaluation. His medical history was significant for a brain aneurysm that required cranial surgery about five years ago.

On examination, his best-corrected visual acuity measured 20/400 O.D. and 20/30 O.S. Extraocular motility testing was normal. His confrontation visual fields were full to careful finger counting O.U.

His pupils were equally round and reactive to light and accommodation, with no evidence of afferent defect. Amsler grid testing revealed a dense central scotoma in the right eye and diffuse metamorphopsia in the left eye. The anterior segment was unremarkable.

On dilated fundus examination, the patient's vitreous appeared clear O.U. He had small cups with good rim coloration and perfusion in both eyes. Examination of the right macula showed nonspecific retinal pigment epithelium (RPE) mottling (*figure 1*). We also noted RPE changes located temporally. In addition, we documented significant changes in the left macula (*figure 2*).

We obtained a spectral-domain optical coherence tomography (SD-OCT) scan of both maculae (*figures 3 and 4*). Also, we performed fundus autofluorescence (FAF) on the patient's right eye (*figure 5*).

Take the Retina Quiz

1. What does the SD-OCT of the right eye reveal?

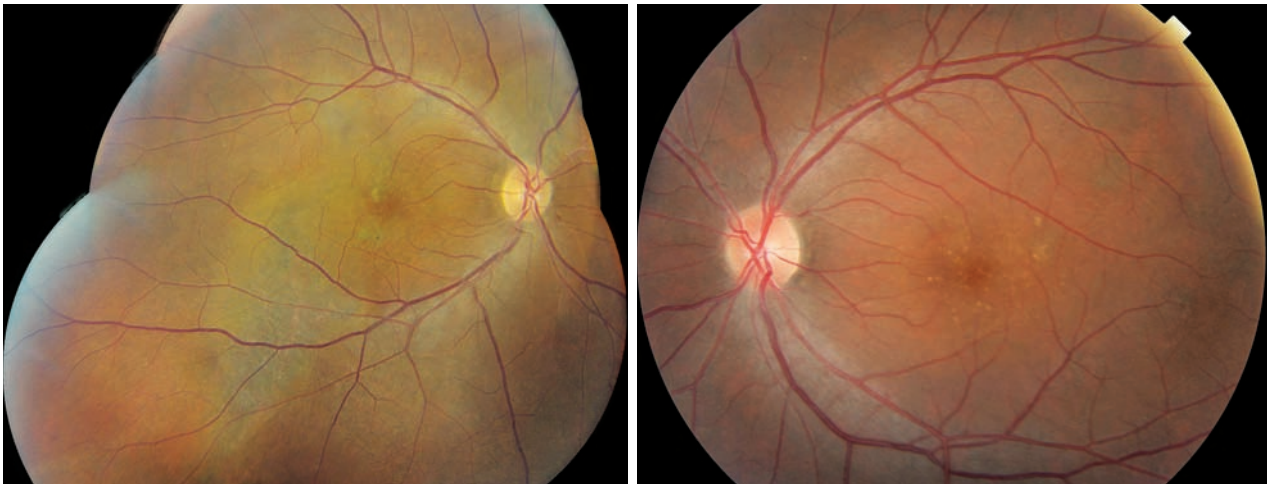
a. Occult neurosensory detachment and loss of the photoreceptor integrity layer (PIL).
b. Occult choroidal neovascularization (CNV).
c. Polypoidal choroidal lesions.
d. Occult persistent epithelial defect (PED).

2. What does the SD-OCT of the left eye reveal?

a. Shallow neurosensory detachment.
b. Shallow RPE detachment.
c. Occult CNV.
d. Polypoidal choroidal lesions.

3. What does the FAF scan of the patient's right eye reveal?

a. Occult CNV.
b. Nonspecific atrophy of the RPE and photoreceptors.
c. Widespread RPE destruction and a trough line.
d. Loss of the RPE secondary to



1, 2. Wide-field fundus photograph shows unusual changes in his right macula (left). Also, what do you notice about our patient's left eye?

When night falls, IOP rises.[1-3]

AZOPT® Suspension, an adjunctive partner to a PGA that has IOP-lowering efficacy all day and all night[4]

INDICATIONS AND USAGE
AZOPT® Brinzolamide Ophthalmic Suspension 1% is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

DOSAGE AND ADMINISTRATION
- Instill one drop in the affected eye(s) three times daily
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
- Hypersensitivity to any component of this product

WARNINGS AND PRECAUTIONS
- Sulfonamide hypersensitivity reactions
- Corneal edema may occur in patients with low endothelial cell counts

ADVERSE REACTIONS
Most common adverse reactions are blurred vision and bitter, sour or unusual taste.

Before prescribing AZOPT® Suspension, please read full prescribing information on adjacent page.

References:
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Azopt® (brinzolamide ophthalmic suspension) 1%

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AZOPT® (brinzolamide ophthalmic suspension) 1% is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

2 DOSAGE AND ADMINISTRATION

The recommended dose is one drop of AZOPT® (brinzolamide ophthalmic suspension) 1% in the affected eye(s) three times daily. If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart.

3 DOSAGE FORMS AND STRENGTHS

Solution containing 10 mg/mL brinzolamide.

4 CONTRAINDICATIONS

AZOPT® (brinzolamide ophthalmic suspension) 1% is contraindicated in patients who are hypersensitive to any component of this product.

5 WARNINGS AND PRECAUTIONS

5.1 Sulfonamide Hypersensitivity Reactions

AZOPT® (brinzolamide ophthalmic suspension) 1% is a sulfonamide and although administered topically it is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of AZOPT® (brinzolamide ophthalmic suspension) 1%. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration.
If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

5.2 Corneal Endothelium

Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing AZOPT® (brinzolamide ophthalmic suspension) 1% to this group of patients.

5.3 Severe Renal Impairment

AZOPT® (brinzolamide ophthalmic suspension) 1% has not been studied in patients with severe renal impairment (CrCl < 30 mL/min). Because AZOPT® (brinzolamide ophthalmic suspension) 1% and its metabolite are excreted predominantly by the kidney, AZOPT® (brinzolamide ophthalmic suspension) 1% is not recommended in such patients.

5.4 Acute Angle-Closure Glaucoma

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. AZOPT® (brinzolamide ophthalmic suspension) 1% has not been studied in patients with acute angle-closure glaucoma.

5.5 Contact Lens Wear

The preservative in AZOPT® (brinzolamide ophthalmic suspension) 1%, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of AZOPT® (brinzolamide ophthalmic suspension) 1%, but may be reinserted 15 minutes after instillation.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

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

In clinical studies of AZOPT® (brinzolamide ophthalmic suspension) 1%, the most frequently reported adverse events reported in 5-10% of patients were blurred vision and bitter, sour or unusual taste. Adverse events occurring in 1-5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

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

7 DRUG INTERACTIONS

7.1 Oral Carbonic Anhydrase Inhibitors

There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and AZOPT® (brinzolamide ophthalmic suspension) 1%. The concomitant administration of AZOPT® (brinzolamide ophthalmic suspension) 1% and oral carbonic anhydrase inhibitors is not recommended.

7.2 High-Dose Salicylate Therapy

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Developmental toxicity studies with brinzolamide in rabbits at oral doses of 1, 3, and 6 mg/kg/day (20, 62, and 125 times the recommended human ophthalmic dose) produced maternal toxicity at 6 mg/kg/day and a significant increase in the number of fetal variations, such as accessory skull bones, which was only slightly higher than the historic value at 1 and 6 mg/kg. In rats, statistically decreased body weights of fetuses from dams receiving oral doses of 18 mg/kg/day (375 times the recommended human ophthalmic dose) during gestation were proportional to the reduced maternal weight gain, with no statistically significant effects on organ or tissue development. Increases in unossified sternebrae, reduced ossification of the skull, and unossified hyoid that occurred at 6 and 18 mg/kg were not statistically significant. No treatment-related malformations were seen. Following oral administration of ^{14}C-brinzolamide to pregnant rats, radioactivity was found to cross the placenta and was present in the fetal tissues and blood.

There are no adequate and well-controlled studies in pregnant women. AZOPT® (brinzolamide ophthalmic suspension) 1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring at an oral dose of 15 mg/kg/day (312 times the recommended human ophthalmic dose) were seen during lactation. No other effects were observed. However, following oral administration of ^{14}C-brinzolamide to lactating rats, radioactivity was found in milk at concentrations below those in the blood and plasma.

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

8.4 Pediatric Use

A three-month controlled clinical study was conducted in which AZOPT® (brinzolamide ophthalmic suspension) 1% was dosed only twice a day in pediatric patients 4 weeks to 5 years of age. Patients were not required to discontinue their IOP-lowering medication(s) until initiation of monotherapy with AZOPT®. IOP-lowering efficacy was not demonstrated in this study in which the mean decrease in elevated IOP was between 0 and 2 mmHg. Five out of
32 patients demonstrated an increase in corneal diameter of one millimeter.

8.5 Geriatric Use

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

10 OVERDOSAGE

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity data on brinzolamide are not available. The following tests for mutagenic potential were negative: (1) *in vivo* mouse micronucleus assay; (2) *in vivo* sister chromatid exchange assay; and (3) Ames *E. coli* test. The *in vitro* mouse lymphoma forward mutation assay was negative in the absence of activation, but positive in the presence of microsomal activation. In reproduction studies of brinzolamide in rats, there were no adverse effects on the fertility or reproductive capacity of males or females at doses up to 18 mg/kg/day (375 times the recommended human ophthalmic dose).

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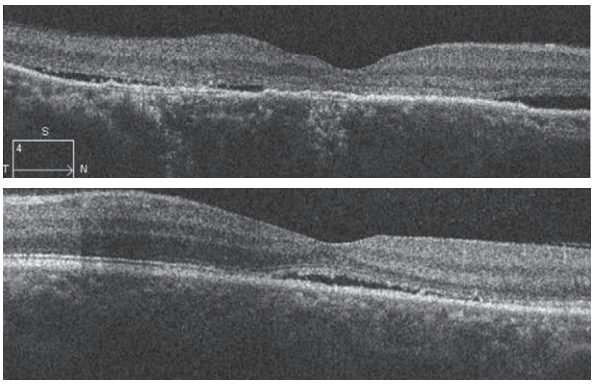

3, 4. Spectral domain optical coherence tomography scan revealed some interesting findings (O.D. top, O.S. bottom).

lipofuscin accumulation.

4. What is the most likely diagnosis?
a. Stargardt's macular dystrophy.
b. Chronic idiopathic central serous choroidopathy (ICSC).
c. Occult CNV.
d. Polypoidal choroidal vasculopathy.

5. How do you believe the retinal specialist managed this patient?
a. Observation with protective eyewear.
b. Intravitreal anti-VEGF therapy.
c. Photodynamic therapy (PDT).
d. Laser treatment O.S.

For answers, go to page 130.

Discussion

Our patient has chronic ICSC in both eyes. The right eye exhibited nonspecific RPE changes in the macula. On clinical examination, there was no evidence of subretinal fluid; however, the SD-OCT clearly shows shallow puddles of fluid scattered throughout the macula. Interestingly, the fovea seems to be spared. But, that probably wasn't always the case because the SD-OCT scan reveals extensive loss of the PIL, which partially explains the 20/400 visual acuity.

The larger area of RPE mottling located temporal to the right macula that was seen on wide-field color photography is of particular interest. The presentation appears as a linear area of RPE mottling that extends inferiorly. This represents a trough line that developed as a result of fluid leakage from the serous detachment.

The FAF scan of the right eye is also quite remarkable, because it clearly illustrates the extent of RPE degeneration located throughout the macula and posterior pole in a radiating, star-like pattern. The trough line that is seen extending inferiorly also is better appreciated on FAF.

FAF is a noninvasive photographic method of documenting pathological changes within the retina and the RPE. In patients with AMD, FAF commonly is used to evaluate the effects of lipofuscin accumulation within the RPE. In this case, the use of both FAF and SD-OCT helps us understand what happened in the patient's right eye, uncovering the presence of persistent fluid, damage and destruction to the RPE and photoreceptors.

The clinical examination of his left macula revealed a shallow neurosensory detachment, which we confirmed on SD-OCT. Further, we noted fine, yellow precipitates located on the inner retinal surface. Fortunately, his visual acuity remained widely unaffected O.S.

Most cases of ICSC resolve naturally without any treatment. However, recurrences develop in approximately 33% to 50% cases within one year.[1] It is interesting to note that 10% of patients will experience three or more episodes or ICSC.[1] Clearly, our patient falls into this category.

Given the history of progressive vision loss in his right eye, as well as the presence of a shallow serous detachment in his left eye, we referred our patient to a retinal specialist. The patient was seen within a two-week period. The retinal specialist confirmed the findings that we saw in the patient's right eye. Interestingly, however, the serous detachment in his left eye had completely resolved at the time of his appointment. Nonetheless, the retinal specialist elected to follow the patient, without treatment, and instructed him to return in six weeks. ■

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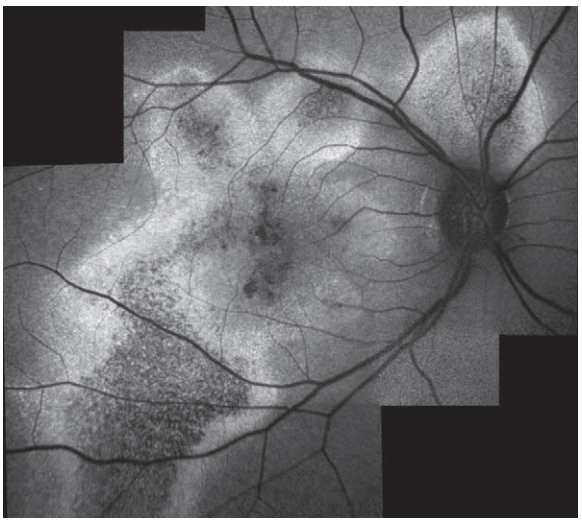

5. A fundus autofluorescence scan of the patient's right eye. How do you explain these findings?

Supplements Are Not Enough

Nutritional supplementation in conjunction with a balanced diet will help protect your patients against AMD. **Edited by Diana L. Shechtman, O.D., and Paul M. Karpecki, O.D.**

It is widely understood that specific nutritional supplements can positively impact disease prevalence and progression, as well as visual outcome in patients with age-related macular degeneration (AMD). Yet, many nutritionists generally insist that actual food intake—rather than supplement use—may be the best source of nutrients to combat disease and promote wellness. In essence, nutritional supplements are just that: a *supplement to*—not a *substitute for*—a well-balanced, nutritious diet and healthy lifestyle.

So, what impact does a patient's diet have on the likelihood that he or she will develop a progressive, sight-threatening condition, such as AMD?

The Research

Due to a wealth of evidence from several major studies including AREDS, TOZAL, the Lutein Antioxidant Supplementation Trial (LAST) and LAST II, we know the potential benefits of nutrient-based interventions for AMD.[1-4] AREDS was somewhat unique among these studies because, in addition to looking at the protective effect of specific nutritional supplements against AMD, its researchers collected extensive information regarding the dietary intake habits of the study population.

• ***AREDS report #22.*** Many individuals associate the "AREDS formula" with the research that was published in the original 2001 report, which suggested that "high levels of antioxidants and zinc" lowered the risk of vision loss from AMD and disease progression by 25%.[5] However, more than 20 subsequent AREDS reports have further investigated the impact of nutritional supplementation and dietary alteration on ocular health.

In 2007, the AREDS research group released its 22nd report, which concluded that patients who have a higher dietary intake of the carotenoids lutein and zeaxanthin were at lower risk for the development of neovascular AMD, geographic atrophy, and large or extensive intermediate drusen.[5] Additionally, the report indicated that increased intake levels of lutein and zeaxanthin decreased the progression of AMD, regardless of disease stage.

• ***AREDS report #23.*** In 2008, the AREDS researchers published data that suggested patients with bilateral drusen were 50% less likely to progress to central geographic atrophy following high dietary intake levels of omega-3 fatty acids (specifically DHA and EPA).[6] It is important to note that the study was not specifically designed to determine how much EPA and DHA was "sufficient" to prevent disease progression.

• ***NHANES.*** The Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES) evaluates overall wellness, nutrition and associated lifestyle habits (e.g., alcohol use, sleep disorders, smoking status) in American adults and children. The NHANES database is a valuable source of information that can be used to compare existing study results and/or stimulate further investigational trends.

One recent study analyzed NHANES data to look for trends between the food intake of different cultural groups and the associated risk for AMD development.[7] The researchers concluded that Mexican Americans—who are at a relatively lower risk for AMD development than whites—had diets with a higher zeaxanthin to lutein intake ratio compared to individuals from other ethnic populations.

Nutrition in Clinical Practice

It is evident that overall ocular health and the prevention of degenerative macular disease are strongly linked to nutritional input, both in the form of food and dietary supplementation. And while we have a wealth of literature in these areas, it is sometimes challenging to incorporate all of this evidence into clinical practice—particularly when it comes to nutritional consultation. The sheer volume of information is intimidating. Further, it's difficult to stay abreast of the most current study data, especially when some of the findings seem contradictory.

Our own unpublished survey data seemed to suggest that, while most optometrists do offer some form of nutritional counseling to their patients, many do not—due in large part due to a lack of sufficient knowledge about the subject.[8] Interestingly, however, more survey

participants reported making the recommendation to "eat a variety of colorful fruits and vegetables every day" than "take an AREDS- or even an AREDS 2-formulated daily supplement." More good news: Most practitioners who responded to our survey reported that they recommend smoking cessation to their patients with AMD.[8] While these are positive trends, our results also clearly indicate a continued need to better integrate nutrition-based research findings into clinical practice.

We also have to consider the limitations associated with poor patient compliance. Although many individuals are aware of the benefits of eating adequate amounts of fruits and vegetables, a recent study showed that achieving—and sustaining—increased dietary intake levels of fruits and vegetables cannot be accomplished with behavioral interventions (goal setting, reminders, etc.) alone.[9] Information from the NHANES database has shown that the average fruit and vegetable intake for American adults remains below recommended levels. More specifically, average daily intake levels of lutein via food sources is less than 2mg—far below the required levels to combat degenerative diseases, such as AMD.[9] Even with the support of nutritional counseling, the average low-income American adult consumes an average of just 1.1 servings of lutein per day.[9]

What Can We Do?

Too often, patients who are at risk for AMD simply are instructed to take a multivitamin that contains lutein or an AREDS-formulated supplement.[8] However, this advice might not be suitable for each patient, and may even be contraindicated (i.e., excess beta carotene intake in smokers). Further, patients are then faced with a bewildering array of supplement choices at their local retailers, with little to no information about the potential health benefits and risks, indications for use or dosing instructions.

So, it is critical that we actively partner with our patients to help them make informed choices about dietary consumption and nutritional supplement selection. Most importantly, we need to take a proactive stance and begin asking the right questions regarding our patients' dietary and lifestyle habits before recommending any associated modifications. Keep in mind that such advice should be provided on an individual basis, rather than as a generalization for all patients.

Ultimately, however, being familiar with the research—and then analyzing and applying it in the context of the individual patient's needs—will help you better incorporate nutritional education into optometric practice. ■

Thanks to Kimberly K. Reed, O.D., associate professor at Nova Southeastern University, for contributing this article.

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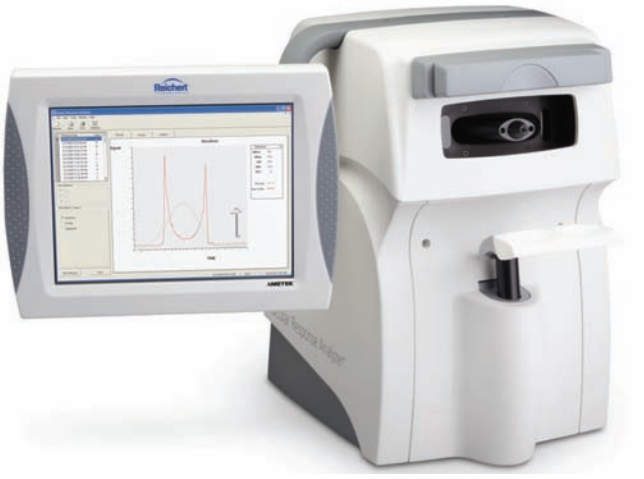
Product **Review**

Diagnostic Technology

All-In-One Ocular Response Analyzer

The new all-in-one Ocular Response Analyzer from Reichert Technologies eliminates the need for a separate PC and optimizes space utilization. It's designed to provide better overall signal quality and improved measurement repeatability for more reliable results.

With left/right mounting, 180° rotating, tilt screen and an intuitive touch-screen user interface, the new device is easier for clinicians to use, the company says. It also features an internal CPU, on-board operating system and 160GB hard drive and also is available with an optional motorized chin-rest. For more information, visit www.reichert.com.



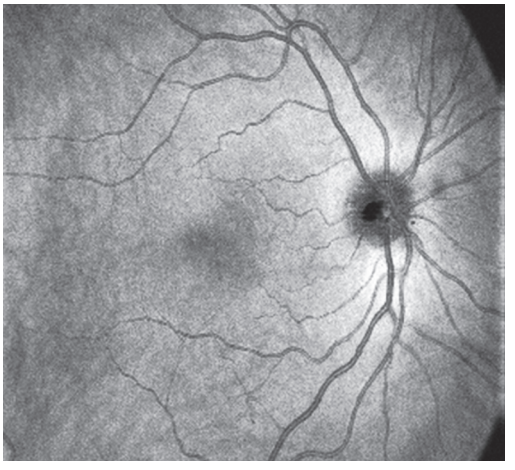
Imaging Technology

Optovue RTVue XR FD-OCT

Optovue received FDA 510(k) clearance for the updated XR version of their RTVue FD-OCT system, which brings 70,000 A-scans/second to spectral-domain OCT. With real-time tracking and the updated SharpVue feature, the speed of the RTVue XR can reduce the incidence of motion artifacts while allowing for greater scan averaging output, the company says.

The new updated system also includes motion correction widefield 3D, a high-density data cube that is designed to provide a nearly motion-free image.

The XR version is scheduled to be available in the third quarter of 2012. For more information, visit www.optovue.com.



RTVue XR FD-OCT features motion-correction widefield 3D, up to 12mm by 12mm.

Lenses

ADDvantage Digital Progressive Lens

Super Systems will now carry trademark recognition for their ADDvantage line of premium high-definition progressive lenses. The lens is marked and measured for digital accuracy, allowing for a precision finish, the company says. It offers an affordable price point and is available in regular and short corridor, with or without a Premium AR Coating and Sunsensor technology.

Regular corridor progressives are intended to fit larger frames and have a longer progression to add power; short corridor progressives are designed to fit smaller modern frames, with a quicker progression to add power, compensating for lost space with the smaller design. ADDvantage also is available with Sunsensor technology by Corning, which changes its tint based on UV light. For more information, visit www.superoptical.com.

Contact Lenses

CooperVision Avaira Toric

The FDA recently granted a Special 510(k) clearance for CooperVision's Avaira Toric two-week

Frames

Nike Sunwear with Transitions Optical

Nike Vision has partnered with Transitions Optical to introduce new Nike MAX Transitions adaptive sunglasses, available in two styles and two lens colors. The violet color of the *Golf Tint* is designed to improve the contour recognition on the greens and increase ball pop. On the other hand, the green color of the *Outdoor Tint* is engineered to brighten the shadows, increase contrast and enhance the visual spectrum in natural environments—like hiking trails.

Nike MAX Transitions sunglasses are available in the Show X2 and SQ, two of Nike's most popular sunglass styles.

- ***Show X2*** features adjustable temples and an adjustable ventilated nose to offer a high level of stability and reduce fogging.
- ***SQ*** is designed to provide wide coverage with minimal visual interference.

In addition to Show X2 and SQ, the Nike MAX Transitions lens also is offered as an accessory lens in styles Skylon Ace, Skylon Ace Pro and Show X2 Pro. All of which are made from polycarbonate material and block 100% of UV rays. For more information, visit www.nikevision.com/transitions.

YSL 2345/s
Matte Black/Grey Horn/Grey

YSL 6366/s
Matte Havana/Beige/Greige

YSL Spring/Summer Eyewear 2012

As part of its eyewear offerings for spring/summer 2012, Yves Saint Laurent introduces its Capsule collection, manufactured by Safilo, composed of original and modern sunglasses and optical frames.

The look is designed to be retro and sophisticated, with materials that are light and resistant.

The multi-layered acetate models feature animal prints and unique combinations of colors, which have been exclusively developed for this edition.

The cat eye or aviator frames are available at Yves Saint Laurent flagship stores, select boutiques and various optical stores around the world.

For more information, visit www.safilo.com.

silicone hydrogel contact lenses for astigmatism. The company re-launched Avaira Toric, with shipments available for select distribution beginning early this month. The lenses have an optimized ballast design for lens stability, designed to provide patients with excellent visual acuity. The consistent fit across the power range offers eye care practitioners a great option for a wide range of astigmatic patients.

Avaira contact lenses are designed to attract and retain moisture within the lens material without the need for surface treatment or wetting agents. This is thanks to Aquaform Comfort Science, which makes it the only two-week silicone hydrogel toric that is naturally wettable, the company says. For more information, visit www.coopervision.com.

Dry Eye Therapy

Ocusoft Retaine MGD

A new therapy for individuals suffering from dry eye syndrome and meibomian gland dysfunction, Ocusoft Retaine MGD Ophthalmic Emulsion is packaged in 30 single-dose vials and will be the first product in a complete line of Retaine brand artificial tears. It is the only preservative-free, oil-in-water emulsion that moisturizes, lubricates and protects moderate to severe dry eyes, the company says.

It uses Novasorb Technology, a proprietary cationic process of binding positively charged ions to the negatively charged ocular surface, to prolong corneal contact time and enhance comfort. The hypotonicity of the emulsion adds moisture by lowering the salt concentration of tears, while the lipid component lubricates and protects the surface of the eye.

Special discount pricing is available to doctors dispensing from their office; however, patients also may order online directly at www.retainebrand.com. For more information, visit www.ocusoft.com/retainemgd.

Office Supplies

Instrument Identification Tape

Wilson Ophthalmic now offers a new way to identify and color code your instruments. The ID sheet tape comes in 54 different colors and designs—stripes, solids, stars and many others are available to clearly identify each instrument.

These sheet tapes come in full 8.5" x 11" pages of the same pattern or color, and have (44) 2-inch strips, (44) one-and-a-half-inch strips and (220) one-inch strips per page.

For more information or to place an order, visit www.WilsonOphthalmic.com.

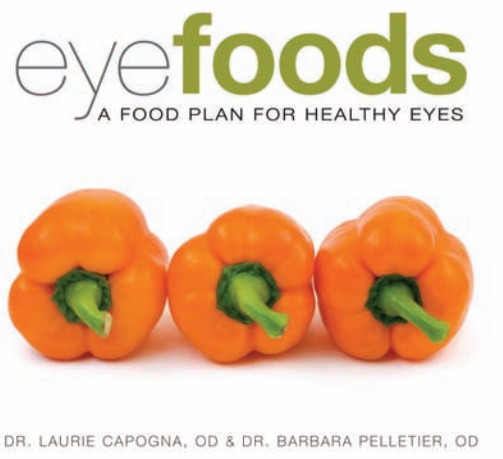
Books and Reference Materials

Eyefoods, A Food Plan for Healthy Eyes

As a way to educate people regarding the benefits of good nutrition on vision, Laurie Capogna, O.D., and Barbara Pelletier, O.D., developed and published *Eyefoods, A Food Plan for Healthy Eyes*—now in its fourth printing.

Developed after years of research, the book gives patients the necessary knowledge to make food and lifestyle choices that will help preserve their eye health. Based on current scientific research, filled with tips and photos in an easy-to-read format, it's a great book to have in any waiting room, the authors say.

To purchase copies of *Eyefoods*, visit www.eyefoods.com. To learn more about retailing Eyefoods in your optometry practice, e-mail sales@eyefoods.com.



The Illustrated Full Color Atlas of the Eye, Eye Care & Eye Surgery

On the anniversary of his 35th year illustrating ophthalmic conditions and procedures, ophthalmic artist Stephen F. Gordon releases the Illustrated Full Color Atlas of the Eye, Eye Care & Eye Surgery. Edited by Columbia Eye Consultants' Timothy Holekamp,

Web Resources

Transitions Vantage Lenses Website

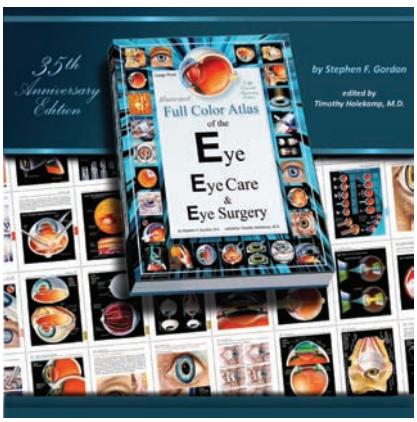
Transitions Optical, Inc. officially launched the trade website for new Transitions Vantage lenses at TransitionsVantage.com. Transitions Vantage lenses officially became available to consumers on May 1 in a variety of materials and exclusively in grey.

The site is designed to help industry professionals better understand the product and how to recommend it to patients. Visitors to the site can access product information, instructional videos, educational tools and marketing materials surrounding Transitions Vantage lenses.

After successfully completing a short quiz, eye care professionals also can sign up to receive a complimentary Transitions Vantage launch kit designed to meet their needs.

The launch kit will include a Transitions Vantage lens lorgnette sample, a glare simulator, consumer brochures, a recommendation guide, frequently asked questions and a final inspection guide with film.

M.D., its didactic ophthalmic illustrations depict three decades of eye care history, breakthroughs and innovations to date, including the latest AMD injection approaches.



The atlas was created for the educational needs of a wide range of audiences—including seasoned physicians, new staff, students and patients—as a full-reference compendium to enhance their understanding of all ocular concepts. It comes fully indexed and includes color-tabbed page edges for quick reference.

The book is available in two versions: a premium version on gloss paper for doctors' use and personal archives, as well as a low vision, large-print edition on low-gloss, non-reflective paper for patients. Educational institution and student discounts are available. For more information, visit sgordon.com.

Eyewear Donation

Eye Make a Difference

Eye Make a Difference, a new eyewear donation program launched by Marchon, works to give individuals the ability to live fuller lives by donating gently used eyewear. Each donated prescription frame is refurbished through the Folsom Project for the Visually Impaired and boxed for optometrists and other health care professionals to take with them on sight-related international mission trips.

For more information on how to participate in the program, visit www.marchon.com/EyeMakeADifference. ■

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- 50% refund on registration fee until June 7, 2012
- No refund past June 7, 2012

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REVIEW® OF OPTOMETRY

Meetings + Conferences

June 2012

■ **1-3.** *Essentials in Eye Care: Board Certification Exam Preparation and Continuing Education.* Western University College of Optometry, Pomona, Calif. Call (909) 706-3493 or e-mail ceoptometry@westernu.edu. Visit www.westernu.edu/optometry-continuing-education.

■ **2-3.** *Regional Clinical Seminar: Maximizing Stereopsis in Patients with Strabismus or Amblyopia.* Metro Washington DC (Gainesville, Va.). Sponsored by: The Optometric Extension Program Foundation. Speaker: David Cook, O.D. CE hours: 12. Contact Tod Davis, O.D., at toddavis@verizon.net.

■ **8-10.** *OAL 75th Anniversary Celebration Convention.* Lafayette Hilton, Lafayette, La. Hosted by: The Optometry Association of Louisiana. CE hours: 16. Contact James D. Sandefur, O.D., Executive Director, at (318) 335-0675 or optla@bellsouth.net.

■ **8-10.** *19th Annual Ocular Disease Update.* Chateau on the Lake, Branson, Mo. Hosted by: Northeastern State University Oklahoma College of Optometry. CE hours: 13. Contact Ashley Beason Manes, CME coordinator, at (918) 444-4033 or beason01@nsuok.edu. Visit http://optometry.nsuok.edu/ContinuingEducation.aspx.

■ **10.** *MOA CE Event.* Conference Center at the Maritime Institute, Linthicum Heights, Md. Hosted by: The Maryland Optometric Association. Guest speakers: William Tullo, O.D., and Jim Owen, O.D., M.B.A. CE hours: 7. Call (410) 727-7800, e-mail moa@assnhqtrs.com, or visit www.marylandeyes.org.

■ **10-24.** *Majestic China 2012.* Hosted by: iTravelCE, LLC. CE hours: 20. Contact Dr. Bridgitte Shen Lee at (832) 390-1393 or info@itravelce.com. Visit www.itravelce.com.

■ **21-24.** *Maui 2012.* Wailea Beach Marriott Resort & Spa, Maui, Hawaii. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, O.D. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

■ **27-July 1.** *Optometry's Meeting.* McCormick Place West, Chicago. Hosted by: The American Optometric Association and the American Optometric Student Association. To register, call (866) 229-3691 or visit www.optometrysmeeting.org.

July 2012

■ **2-6.** *CE in Belize.* Sunbreeze Hotel, Ambergris Caye, Belize. Hosted by: The International Academy of Optometry. Contact Edward Paul, Jr., O.D., Ph.D., Education Director, at (910) 256-6364 or e-mail epauljr@aol.com. Visit www.CEinBelize.com.

■ **12-15.** *Colorado Vision Summit.* The Steamboat Grand, Steamboat Springs, Colo. Hosted by: Colorado Optometric Association. Call (877) 691-2095 or e-mail CVSummit@visioncare.org. Visit www.visioncare.org.

■ **13-15.** *OEP/SCO Conference on Clinical Vision Care: Time, Rhythm and the Visual Process.* Southern College of Optometry, Memphis, Tenn. Sponsored by: SCO and The Optometric Extension Program Foundation. Call OEP at (949) 250-8070, or e-mail Howard Bacon, O.D., at hbbacon@familyoptometry.net.

■ **18-22.** *44th Annual NOA Convention.* Hyatt Regency, Toronto. Hosted by: The National Optometric Association. Keynote Speaker: Joseph Pizzimenti, O.D. CE hours: 13. Visit http://www.nationaloptometricassociation.com/convention.html.

■ **19-22.** *Puerto Rico 2012.* Ritz Carlton, San Juan, Puerto Rico. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, O.D. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

■ **19-22.** *Northern Rockies Optometric Conference.* Snow King Resort, Jackson Hole, Wyo. CE hours: 16. E-mail Mrs. Marian Schulz at wyoschulz@yahoo.com or visit www.nrocmeeting.com.

■ **26-29.** *SECO Vancouver 2012.* The Westin Bayshore, Vancouver, British Columbia. CE hours: 14. E-mail info@secostaff.com or visit www.seco2012.com/vancouver.

August 2012

■ **3-5.** *32nd Annual Educational Retreat 2012.* South Seas Island Resort, Sanibel, Fla. Hosted by: Southwest Florida Optometric Association Inc. CE hours: 12. Contact Brad Middaugh, O.D., at (239) 481-7799 or swfoa@att.net. Visit www.swfoa.com.

■ **19.** *Orlando Super Sunday #1.* Orlando Campus, NOVA Southeastern University, Orlando, Fla. CE hours: 8. Contact Vanessa McDonald, M.S., at (954) 262-4224 or oceaa@nova.edu. Visit http://optometry.nova.edu/ce/supersunday.

■ **23-25.** *Idaho Optometric Physicians Association Annual Congress.* The Grove Hotel, Boise, Idaho. Contact Randy Andregg, O.D., executive director, at randregg@frontiernet.net or (208) 461-0001. Visit http://idaho.aoa.org.

■ **23-26.** *105th SCOPA Annual Meeting.* Myrtle Beach Marriott Resort & Spa at Grande Dunes, Myrtle Beach, S.C. Hosted by: The South Carolina Optometric Physicians Association. CE hours: 20. Visit http://southcarolina.aoa.org.

September 2012

■ **5-8.** *International Vision Expo & Conference West 2012.* Sands Expo & Convention Center, Las Vegas. Call (800) 811-7151 or visit www.visionexpowest.com.

■ **6-9.** *72nd Annual Middle Atlantic Optometric Congress.* Doubletree Hotel and Convention Center, Pittsburgh/Monroeville, Pa. Under the auspices of: The Optometric Extension Program Foundation & the Western Pennsylvania Optometric Society. CE hours: 12. E-mail Barry Cohen, O.D., at barryc51@gmail.com.

■ **6-10.** *The Art and Science of Optometric Care: A Behavioral Perspective.* Grand Rapids, Mich. Held by: The Optometric Extension Program Foundation. CE hours: 35. E-mail Theresa Krejci at TheresaKrejciOEP@verizon.net or visit www.oepf.org.

■ **12-15.** *Envision Conference.* Hilton St. Louis at the Ballpark, St. Louis. E-mail info@envisionconference.org or call (316) 440-1530. Visit www.envisionconference.org.

■ **13-14.** *South Dakota Optometry Society Fall Conference.* Hilton Garden Inn, Sioux Falls, S.D. Call Deb Mortenson at (605) 224-8199 or e-mail deb.mortenson@pie.midco.net. Visit www.sdeyes.org.

■ **14-16.** *SWCO 2012.* InterContinental Hotel, Dallas. Sponsored by: The Southwest Council of Optometry. Call Niki Bedell at (713) 743-1856 or e-mail nbedell2@uh.edu. Visit www.swco.org.

■ **14-16, 18-20.** *CE in Italy: Florence and/or Castiglion Florentino, Tuscany.* To register for one or both programs, contact James L. Fanelli, O.D., at (910) 452-7225 or jamesfanelli@CEinItaly.com. Visit www.CEinItaly.com.

■ **21-23.** *New Technology and Treatments in Vision Care.* California. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, O.D. CE hours: 15. Contact Lois DiDomenico at ReviewMeetings@jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences.

■ **27.** *CPOS CE Forum XVI.* The Hotel Hershey, Hershey, Pa. Hosted by: The Central Pennsylvania Optometric Society. Featured speakers: Ron Melton, O.D., and Randall Thomas, O.D., M.P.H. CE hours: 6. E-mail Mary Good, O.D., at cposrsvp@gmail.com.

■ **27-30.** *GWCO Congress 2012.* Oregon Convention Center, Portland. Hosted by: The Great Western Council of Optometry. CE hours: 59. Visit http://www.gwco.org/Congress.html.

October 2012

■ **4-7.** *EastWest Eye Conference.* Cleveland Convention Center, Cleveland. Hosted by: The Ohio Optometric Association. Call (800) 999-4939 or e-mail info@ooa.org. Visit www.eastwesteye.org.

■ **6-7.** *PSS 2012: 2nd Annual Forum on Ocular Disease.* The Castle Hotel & Resort, Orlando, Fla. Hosted by: PSS EyeCare. CE hours: 18. Call (203) 415-3087 or e-mail education@psseyecare.com. Visit www.psseyecare.com.

■ **12.** *HVOS Fall Seminar.* The Grandview, Poughkeepsie, N.Y. Hosted by: The Hudson Valley Optometric Society. Contact Robert Greenbaum, O.D., at robertgreenbaum58@gmail.com or (845) 473-0220. Visit www.hvos.org.

■ **24-27.** *Academy 2012 Phoenix.* Phoenix Convention Center. Hosted by: The American Academy of Optometry. Visit www.aaopt.org/meetings/academy2012. ■

To list your meeting, contact:
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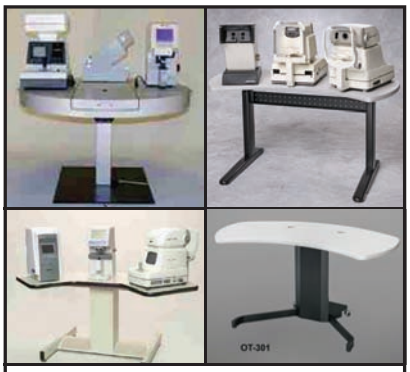

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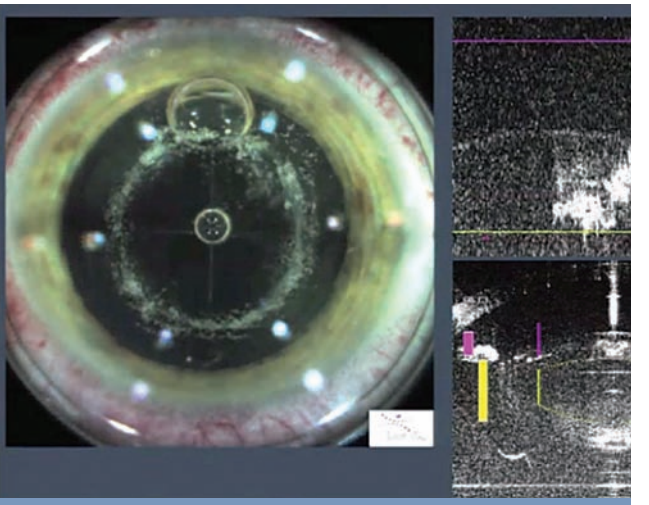
Femto-Phaco

Are we witnessing the next revolution in cataract surgery? Read on for what every O.D. needs to know about it, and visit *Review of Optometry* online for a video demonstration of the procedure.

By Derek N. Cunningham, O.D., and Walter O. Whitley, O.D., M.B.A.



Go to www.revoptom.com to see video footage of this fascinating femto laser cataract procedure.

On The Web ›› See how this technology produces more consistent and safer results.

Cataract surgery may witness the largest technology jump since Dr. Charles Kelman invented phacoemulsification more than 45 years ago. The femtosecond laser used for LASIK surgery has been modified to perform many of the integral steps of cataract surgery. It can fragment the lens, perform an anterior capsulotomy, create all required corneal incisions and create limbal relaxing incisions. And it does it in that order—the exact opposite sequence than traditional scalpel surgery—to ensure accuracy and avoid issues of gas bubble formation.

What does this mean for optometry? It has some specific advantages for our patients: It allows for centered and perfectly formed capsulorhexis, as well as well formed, water tight corneal incisions.[1,2]

The importance of a well-centered and perfectly formed capsulorhexis is more critical than ever because of the growing use of premium IOLs. With both accommodative and multifocal IOLs—particularly those that are pupil dependent—the performance of the lens can be hampered by an imperfect or decentered capsulorhexis, resulting in glare, halos and night driving problems. The size of the capsulorhexis is also very important in optimizing the performance of accommodating IOLs.

When comanaging optometrists are screening for postoperative visual complaints in patients who received premium IOLs, a sub-optimal capsulorhexis can be subtle and difficult to detect. If symptoms are severe, a lens exchange could be considered; however, there is significant risk in this procedure.

Well formed, water tight corneal incisions are also important. Greater stability and reproducibility of corneal incisions may lead to a decrease in rates of endophthalmitis and hypotony. When comanging these patients postoperatively, you may notice very precise incisions.

There are some current limitations and disadvantages of the surgery at this time. The lasers are expensive and require a per usage charge and, currently, Medicare and most insurance companies will not cover the added cost of using this laser.

To make things even more complicated, surgeons who participate in Medicare cannot directly charge patients for the use of this laser during cataract surgery because of the "golden scalpel rule." The golden scalpel rule basically states that if you can do the same procedure with a less expensive tool, such as a $20 dollar scalpel, you cannot charge any of your patients directly for the use of a more expensive tool like a laser.

But, while cost is currently impeding national adoption, any technology that produces more consistent and safer results eventually gains widespread acceptance. ■

1. Nagy Z. Comparative Analysis of Laser Assisted and Manual Capsulorhexis During Phacoemulsification. Paper presented at the European Society of Cataract and Refractive Surgeons, September 2010; Paris.
2. Masket S, Sarayba M, Ignacio T, Fram N. Femtosecond laser-assisted cataract incisions: architectural stability and reproducibility. J Cataract Refract Surg. 2010 Jun;36(6):1048-9.

ACADEMY 2012 PHOENIX

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Meeting and hotel registration opens May 7, 2012

www.aaopt.org

Diagnostic **Quiz**

Thyroid Disease Under Control?

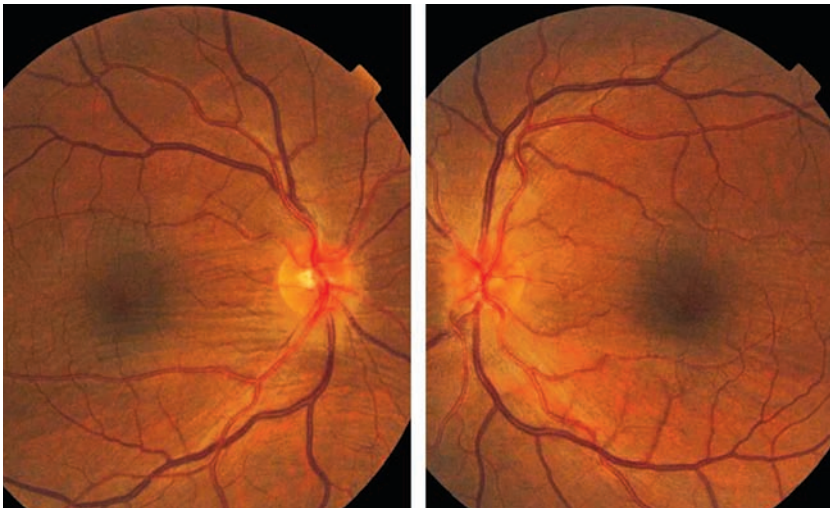
By Andrew S. Gurwood, O.D.

History

A 45-year-old white male presented with a chief complaint of worsening diplopia and general "eye discomfort." While it was not officially documented in his ocular history, the patient explained that he underwent orbital decompression surgery twice to relieve congestion in his left eye secondary to thyroid-related, infiltrative disease of the muscles.

At this visit, he also wanted his spectacle prescription (which contained prism to alleviate double vision) checked and updated.

Additionally, his medical status was being followed closely by an endocrinologist, who determined that his thyroid function was within normal parameters. Nonetheless, the patient explained that his orbital disease seemed to be progressing, despite proper medical management.



Fundus images (O.D. left, O.S. right) of our 45-year-old patient who presented with worsening diplopia and discomfort. His medical history was significant for thyroid disease. What is the likely diagnosis in this case?

Diagnostic Data

Best-corrected visual acuity through +2.25DS spectacles measured 20/40 O.D. and 20/50 O.S., which had decreased from 20/30 O.U. at his last visit. External examination uncovered limited ocular motilities throughout all directions of gaze, with full confrontational fields and no evidence of afferent pupillary defect O.U.

We were unable to significantly increase his visual acuity via refraction. Biomicroscopy revealed inferior sodium fluorescein dye uptake located inferiorly on the both the bulbar conjunctiva and cornea (O.S. > O.D.). The anterior chambers, irides and lenses were clear. His intraocular pressure measured 16mm Hg O.U.

Because the patient's visual acuity was reduced, we performed a dilated fundus examination. The pertinent findings are illustrated in the photographs.

Your Diagnosis

How would you approach this case? Does this patient require any additional tests? What is your diagnosis? How would you manage this patient? What's the likely prognosis?

To find out, 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 110):* 1) a; 2) a; 3) c; 4) b; 5) a.

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