Point-Counterpoint: VSP & AOA on Vision and Health Plans, p. 22

February 15, 2012

REVIEW® OF OPTOMETRY

Part 1 of 2

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Pharmaceutical Issue

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VOL. 149 NO. 2 ■ FEBRUARY 15, 2012

IN THE NEWS

The Centers for Medicare and Medicaid Services published instructions for updates to the **clinical laboratory fee schedule** for 2012, including a revised reimbursement rate for the **TearLab Osmolarity Test**, effective January 1, 2012. The **payment code of 83861** that currently applies to the TearLab Osmolarity Test will be cross-walked or paired with **code 84081**.

The **Optical Laboratories Association** (OLA) and **The Vision Council** have signed a final **merger agreement**, naming OLA the new Optical Lab Division of The Vision Council. The activities of both associations will be combined to benefit their respective members. Over the next few months, optical lab division members will receive updates and information about the new programs and services available to them. There will be an in-person opportunity to learn more when the division convenes its next annual member meeting in September 2012, in conjunction with Vision Expo West in Las Vegas.

Alcon is working with the **FDA**, industry cargo theft organizations and law enforcement officials to recover **CIBA Vision contact lenses** that were **stolen** on or about January 9, 2012 while being delivered to an Alcon distribution center in Georgia. The stolen products consist of **FreshLook ColorBlends** contact lenses. Anyone who has information regarding this incident, or has received suspicious or unsolicited offers for the specified products, is encouraged to contact the **FDA Office of Criminal Investigations** at (800) 551-3989 or to visit www.fda.gov/OCI.

Dilated Eye Exams Are More Cost-Effective

For new Medicare enrollees, dilated exam is a better deal than acuity screening. **By Jane Cole, Special Projects Editor**

Replacing visual acuity screenings with dilated eye exams for new Medicare enrollees is "highly cost effective," according to a new study published online in *Archives of Ophthalmology*.

Medicare currently reimburses visual acuity screening for new enrollees during their initial preventive primary care health check.

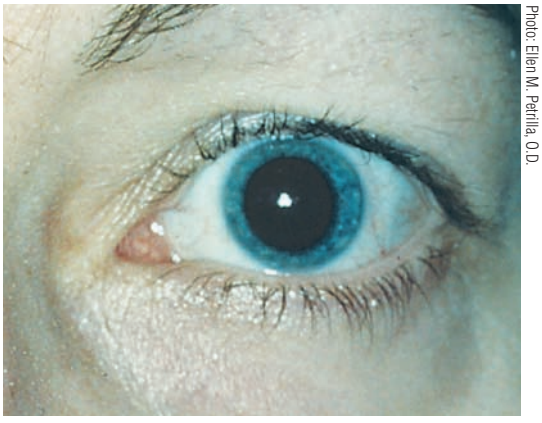

Photo: Ellen M. Petrilla, O.D.

Visual acuity screening for new Medicare enrollees is a "suboptimal use of resources," while dilated eye exams are more cost-effective, researchers found.

In this study, researchers used a cost-effectiveness simulation model with a total of 50,000 simulated patients with demographic characteristics matched to people 65 years old. The study results suggest that, compared with a no-screening policy, dilated eye evaluations increased quality-adjusted life years (QALYs) by 0.008 and increased costs by $94. A visual acuity screening increased QALYs in less than 95% of the simulations and increased total costs by $32 per person. At a willingness-to-pay value of $15,000 or more per QALY gained, a dilated eye evaluation was the policy option most likely to be cost-effective, researchers concluded.

In 2009, the U.S. Preventive Services Task Force reversed its 1996 recommendation in favor of visual acuity screening because of insufficient evidence to support it.

"Our results support the conclusions of the U.S. Preventive Services Task Force that … visual acuity screening in primary care settings cannot be demonstrated to result in meaningfully different outcomes than no screening," researchers wrote.

They added, "Our research suggests that the current policy of visual acuity screening is a suboptimal use of resources and that replacing this policy with coverage of a dilated eye evaluation for all healthy patients entering Medicare would be highly cost-effective."

Rein DB, Wittenborn JS, Zhang X, et al. The Cost-effectiveness of Welcome to Medicare visual acuity screening and a possible alternative Welcome to Medicare eye evaluation among persons without diagnosed diabetes mellitus. Arch Ophthalmol. 2012 Jan 9. [Epub ahead of print]

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Human Stem Cell Therapy Shows Promise for Retinal Diseases

A therapy derived from human embryonic stem cells that was used to treat two visually devastating retinal conditions appears to be both safe and effective, according to a novel study in the January 23 online version of *Lancet*.

In this study, researchers at UCLA's Jules Stein Eye Institute conducted two prospective, open-label clinical trials to assess the safety and tolerability of retinal pigment epithelium (RPE) cells that were derived from human embryonic stem cells. The researchers injected the RPE cells into two subjects—one with Stargardt's macular dystrophy and the other with dry age-related macular degeneration—and followed their progression for four months.

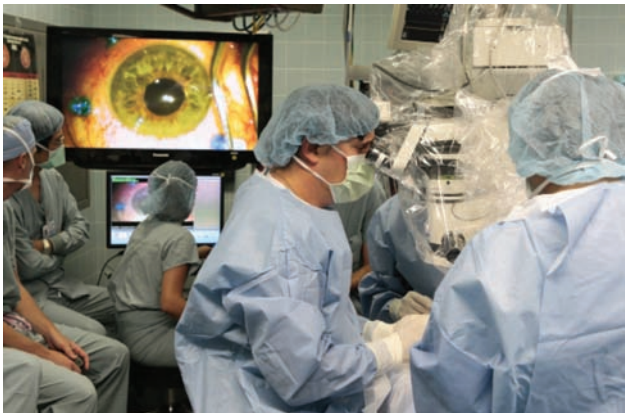


Photo: UCLA Newsroom

Principal investigator Steven Schwartz, M.D., performs the stem cell transplantation procedure.

At four-month follow-up, the researchers noted that the injected cells had properly integrated into the respective hosts' RPE layers and continued to persist throughout the study period. More importantly, both patients experienced an overall improvement in visual quality following cell transplantation.

"Best-corrected visual acuity improved from hand motions to 20/800 (and improved from zero to five letters on the Early Treatment Diabetic Retinopathy Study [ETDRS] visual acuity chart) in the study eye of the patient with Stargardt's macular dystrophy, and vision also seemed to improve in the patient with dry age-related macular degeneration (from 21 ETDRS letters to 28)," the researchers wrote.

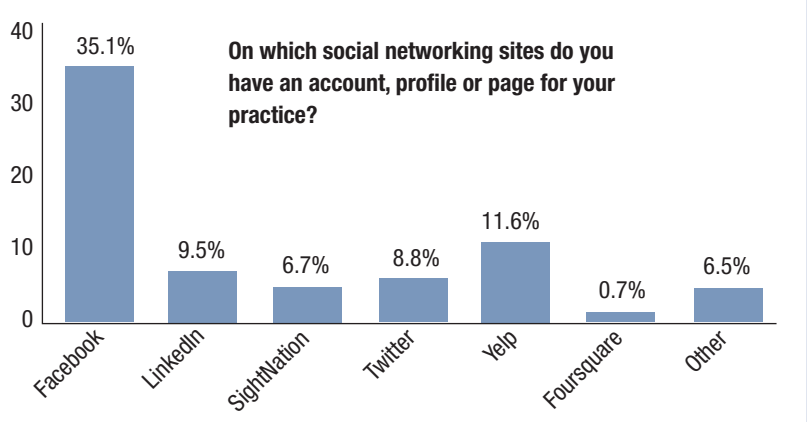
Additionally, the researchers experienced no safety complications associated with the procedure. "We did not identify signs of hyperproliferation, abnormal growth or immune-mediated transplant rejection in either patient during the first four months," they wrote.

In the next several months, the researchers aim to increase the populations of both clinical trials to a total of 24 subjects (12 with Stargardt's and 12 with dry AMD) to further evaluate the procedure's safety and tolerability.

Building upon this early success, the authors ultimately hope to treat patients with such degenerative retinal conditions earlier in the disease process to increase the likelihood of photoreceptor and central visual field rescue.

Schwartz SD, Hubschman JP, Heilwell G, et al. Embryonic stem cell trials for macular degeneration: a preliminary report. Lancet. 2012 Jan 24. [Epub ahead of print]

How Many Eye Care Practices Have a Facebook (or Other) Page?



Source: 2011 ECP Internet Usage & Practice Website Study, Jobson Research. Conducted in Nov/Dec 2011. (www.jobsonresearch.com)

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Adolph Lombart Passes

Optometrist and contact lens pioneer, Adolph Lombart, died December 28, 2011. He was 89 years old.

Lombart, a U.S. Army veteran and graduate of the Pennsylvania State College of Optometry, opened several private practices in Virginia throughout the late 1940s. He especially enjoyed fitting contact lenses, and started a full-time contact lens manufacturing business in 1959. Lombart continued to expand his business and sell contact lenses to his colleagues for more than a decade.

In 1972, he and his two sons—Kenneth and Rick—began selling and distributing other instruments, including slit lamps and lensmeters. Finally, in 1979, Lombart retired from the company, leaving Kenneth and Rick to run Lombart Instruments.

Adolph Lombart was an innovator in the field of contact lens manufacturing and will be missed by many.

Daily Aspirin Linked to Higher Risk of AMD

People age 65 and older who took a daily dose of aspirin had double the risk of developing "wet" AMD compared with those who took it less frequently, according to a recent report from the European Eye Study.

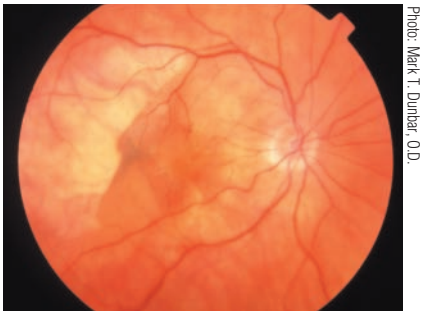

Photo: Mark T. Dunbar, O.D.

Older folks who take a daily dose of aspirin have twice the risk of wet AMD.

The study, which appeared in the January issue of *Ophthalmology*, also found a somewhat elevated risk of early-stage AMD in daily aspirin users. However, investigators found no higher risk for advanced "dry" AMD.

In this study of nearly 4,700 participants, those who reported taking aspirin every day had higher rates of cardiovascular disease, were less likely to be smokers and were older than participants who took aspirin less often.

Because cardiovascular disease itself is a risk factor for AMD, the researchers carefully analyzed whether participants' heart health had impacted the study's outcomes. But even factoring in cardiovascular health, the results still showed higher risk for wet AMD in daily aspirin users.

For primary prevention of coronary heart disease, aspirin provides little net benefit because of its adverse effects, the authors concluded. In addition, other studies highlight the risk of intraocular hemorrhage in patients with wet AMD who take aspirin.

de Jong PT, Chakravarthy U, Rahu M, et al. Associations between aspirin use and aging macula disorder: The European Eye Study. Ophthalmology. 2012 Jan;119(1):112-8.

'Birth Control Glasses' Get the Boot

The Navy Medical Logistics Command announced on January 19 that all active duty and Reserve personnel would be able to select a modernized, more aesthetically appealing "5A" eyeglass frame within the next six months.

This comes as wonderful news to many current military men and women whose only choice had been the standard issue "S9" eyeglass frame—which for decades have called "birth control glasses" or simply "BCGs" due to their unattractive appearance.

The military's standard issue S9 frame—also known as "birth control glasses."

"We are happy to announce that the New Year brings with it a new frame option for all personnel serving on active duty and in the Reserves," said Capt. Matt Newtown, commanding officer of Naval Ophthalmic Support and Training Activity in Yorktown, Va. "Service members have told us that they like the appearance of the new frame. We are confident this frame will increase the likelihood that military personnel will continue to utilize their eyeglasses beyond boot camp."

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RELIANCE INTERNATIONAL

Vision Loss Adds to the Risk for Hearing Loss in Elderly People

Older adults with poorer low-contrast vision also have an increased risk of hearing impairment, according to research in the January issue of *Ophthalmic & Physiological Optics*.

In seeking to determine which vision variables are associated with moderate bilateral hearing loss in an elderly population, a team of scientists at the Smith-Kettlewell Eye Research Institute in San Francisco recently took a look at a cohort of older adults enrolled in a longitudinal study of vision and function in Marin County, California.

They found that among 446 older adults (mean age of 79.9 years), three measures of low-contrast visual acuity were significantly associated with moderate bilateral hearing loss in analyses controlling for age and comorbid conditions: overall low-contrast acuity, low-contrast acuity at low luminance and low contrast and acuity in glare.

"If vision and hearing impairments were independent … we would expect dual sensory loss in 0.7% of people," the authors wrote. "In fact, the prevalence of dual sensory loss was over four times higher (3.1%), indicating that the two kinds of impairment are associated."

While poorer vision for low-contrast targets was associated with an increased risk of hearing impairment in older adults, normal or high-contrast acuity measures were not significantly associated with hearing loss.

"The findings have significance for clinicians, both audiologists and eye care practitioners, in that finding a deficit in one domain (e.g., vision) indicates an increased likelihood of deficits in the other domain (e.g., hearing)," the authors concluded.

They also suggest that, "audiologists consider including a brief test of low-contrast vision, such as low-contrast acuity. Likewise, eye care practitioners should consider performing a screening test of hearing on their patients."

Losing both vision and hearing is debilitating in other ways, the authors add. Dual sensory loss can have greater effects on depression, cognitive function and quality of life compared with sensory hearing or vision loss alone.

Schneck ME, Lott LA, Haegerstrom-Portnoy G, Brabyn JA. Association between hearing and vision impairments in older adults. Ophthalmic Physiol Opt. 2012 Jan;32(1):45-52.

Contact Lenses Deliver Pain Relief

Researchers are developing a new contact lens designed to provide a continuous supply of anesthetic medication to the eye for patients recovering from laser eye surgery.

This new technology uses vitamin E to help release drugs automatically over time, thus eliminating the need for patients to repeatedly use medicine drops. Tests show that the time release of three commonly used anesthetics was extended from slightly less than two hours to up to seven days in some instances.

According to Anuj Chauhan, Ph.D., and his colleagues, the medication-releasing contact lenses may be used for LASIK and photorefractive keratectomy (PRK).

While LASIK is the most common type of laser eye surgery, complications can and do occur if the patient undergoes trauma, such as a hard hit to the face. PRK patients, on the other hand, face a long and painful recovery period where they must wear a bandage contact lens after surgery and place drops of several medications—including anesthetics—into their eyes every few hours. This routine interferes with daily life and increases the risk of drug overdose.

To that end, Dr. Chauhan and his colleagues tested whether anesthetics loaded on this new contact lens could release drugs automatically over time. They found that vitamin E acts as a barrier to keep the anesthetic in place on the eye. In the future, the researchers say these lenses could be used as bandage contact lenses post-PRK surgery.

Peng CC, Burke MT, Chauhan A. Transport of topical anesthetics in vitamin e loaded silicone hydrogel contact lenses. Langmuir. 2012 Jan 17;28(2):1478-87. Epub 2011 Dec 22.

Symptomatic VMA

A Disease That's Gaining Traction

Symptomatic vitreomacular adhesion (VMA) is an increasingly recognized sight-threatening disease of the vitreoretinal interface[1]

VMA:

- May lead to symptoms such as metamorphopsia, decreased visual acuity, and central visual field defect[2]
- Can cause traction resulting in anatomical damage, which may lead to severe visual consequences, including[3,4]
  - Macular hole[3]
  - Retinal tear/detachment[4]

REFERENCES

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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LOTEMAX® OINTMENT

(loteprednol etabonate ophthalmic ointment) 0.5%

POWER IN A PRESERVATIVE-FREE OINTMENT

LOTEMAX® ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Powerful

- Indicated for post-operative inflammation and pain following ocular surgery[1]
- In 2 phase 3, randomized, multicenter, double-masked, parallel-group, 4-week, clinical safety and efficacy evaluations of LOTEMAX® ointment (loteprednol etabonate ophthalmic ointment) 0.5% vs vehicle (mineral oil and white petrolatum) for the treatment of inflammation and pain following cataract surgery (N=805), LOTEMAX® ointment demonstrated statistically significant resolution of anterior chamber cells and flare* (24-32% vs 11-14%) and pain (73-78% vs 41-45%) vs vehicle at post-operative day 8[1,2]
  - <1% of patients in clinical trials experienced intraocular pressure (IOP) elevations ≥10 mm Hg[2]
    - If this product is used for 10 days or longer, IOP should be monitored

Pure

- The first and only 100% preservative-free steroid ointment[1]

Modern

- The first prescription ophthalmic single-agent steroid ointment in over 20 years

*Cell count 0 and no flare.

Important Risk Information about LOTEMAX® ointment

- LOTEMAX® ointment, 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
- 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
- Use of corticosteroids may result in posterior subcapsular cataract formation and may delay healing and increase the incidence of bleb formation after cataract surgery. The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification
- Corticosteroids may increase the hazard of secondary ocular infections. If pain, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated. Fungal culture should be taken when appropriate
- Patients should not wear contact lenses during their course of therapy with LOTEMAX® ointment. LOTEMAX® should not be used in children following ocular surgery as it may interfere with amblyopia treatment. LOTEMAX® is not indicated for intraocular administration
- The most common ocular adverse event, reported in approximately 25% of subjects in clinical studies, is anterior chamber inflammation. Other common adverse events, with an incidence of 4-5%, are conjunctival hyperemia, corneal edema, and eye pain. Many of these events may have been the consequence of the surgical procedure

Please see the Brief Summary of the LOTEMAX® ointment full prescribing information on the reverse side.

References: 1. LOTEMAX ophthalmic ointment Prescribing Information, April 2011. **2.** Comstock TL, Paterno MR, Singh A, Erb T, Davis E. Safety and efficacy of loteprednol etabonate ophthalmic ointment 0.5% for the treatment of inflammation and pain following cataract surgery. *Clin Ophthalmol*. 2011;5:177-186.

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

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ophthalmic ointment, 0.5%

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Brief Summary: Based on full prescribing information revised April 2011

1 INDICATIONS AND USAGE

LOTEMAX® ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

4 CONTRAINDICATIONS

LOTEMAX ointment, 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.

5 WARNINGS AND PRECAUTIONS

5.1 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 even though it may be difficult in children and uncooperative patients.

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 14 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 Contact Lens Wear

Patients should not wear contact lenses during their course of therapy with LOTEMAX ointment.

5.8 Amblyopia

LOTEMAX (loteprednol etabonate ophthalmic ointment), 0.5% should not be used in children following ocular surgery. Its use may interfere with amblyopia treatment by hindering the child's ability to see out of the operated eye (see Pediatric Use, 8.4).

5.9 Topical ophthalmic use only

Lotemax 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.

The most common ocular adverse event reported at approximately 25% in subjects in clinical studies with Lotemax ointment was anterior chamber inflammation. Other common adverse events, with an incidence of 4-5%, were conjunctival hyperemia, corneal edema, and eye pain. Many of these events may have been the consequence of the surgical procedure. The only non-ocular adverse event occurring at ≥ 1% was headache (1.5%).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C.

Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (150 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (25 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥ 5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥ 50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥ 50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (25 times the maximum daily clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

LOTEMAX 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 human milk. Systemically administered steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX ointment is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

LOTEMAX (loteprednol etabonate ophthalmic ointment) 0.5% should not be used in children following ocular surgery. Its use may interfere with amblyopia treatment by hindering the child's ability to see out of the operated eye.

8.5 Geriatric Use

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertilty

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (2500 and 1250 times the maximum daily clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

17 PATIENT COUNSELING INFORMATION

17.1 Risk of Contamination

Patients should be advised not to touch the eyelid or surrounding areas with the tip of the tube. The cap should remain on the tube when not in use

Patients should be advised to wash hands prior to using LOTEMAX ointment.

Do not use if tamper evident skirt is visible on bottom of cap.

17.2 Contact Lens Wear

Patients should also be advised not to wear contact lenses during their course of therapy.

17.3 Risk of Secondary Infection

If pain, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician.

MANUFACTURER INFORMATION

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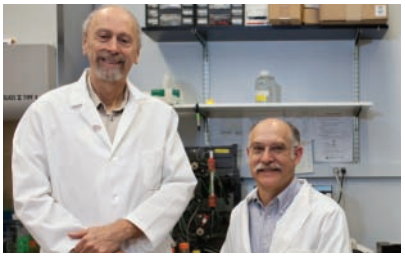
Gene Therapy for RP Works in Dog Model

Researchers at the University of Florida have developed a new gene therapy to treat retinitis pigmentosa (RP), according to a study in the January 23 online edition of the *Proceedings of the National Academy of Sciences*. The therapy is applied by replacing a malfunctioning gene in the eye with a normal copy that supplies the protein necessary for proper photoreceptor function.

"Providing the gene that's missing is one of the ultimate ways of treating the disease and restoring significant visual function," said study coauthor William W. Hauswirth, Ph.D., professor of ophthalmology at the UF College of Medicine and professor of molecular genetics and microbiology at the UF Genetics Institute.

In laboratory testing, the researchers cloned a working copy of the affected gene into a virus that served as a delivery vehicle. They also included a specialized "switch" that would activate the gene once it reached the proper location. After activation, the gene produced a protein that allowed the damaged retinal cells to function normally.



William W. Hauswirth, Ph.D., and Alfred S. Lewin, Ph.D., have successfully treated retinitis pigmentosa in dogs.

Following laboratory testing, the researchers used the gene delivery vehicle to successfully treat X-linked RP in dogs.

"The results are encouraging and the rescue of the damaged photoreceptor cells is quite convincing," said John G. Flannery, Ph.D., professor of neurobiology at the University of California, Berkeley, and an expert on the delivery of replacement genes. "Since this type of study is often the step before applying a treatment to human patients, showing that it works is critical." ■

Beltran WA, Cideciyan AV, Lewin AS, et al. Gene therapy rescues photoreceptor blindness in dogs and paves the way for treating human X-linked retinitis pigmentosa. PNAS. 2012 Jan 23. [E-pub ahead of print]

Eye Do!

Talk about diversifying your services! The Eclectic Eye, in Memphis, which provides optometry services and fashion eyewear, recently hosted an impromptu wedding ceremony for long-time employee Bramlett Dyles and husband David Taylor. Lab production specialist Robb Parker, also an ordained minister, officiated the service as a few unsuspecting customers perused the frame selection.

REVIEW OF OPTOMETRY

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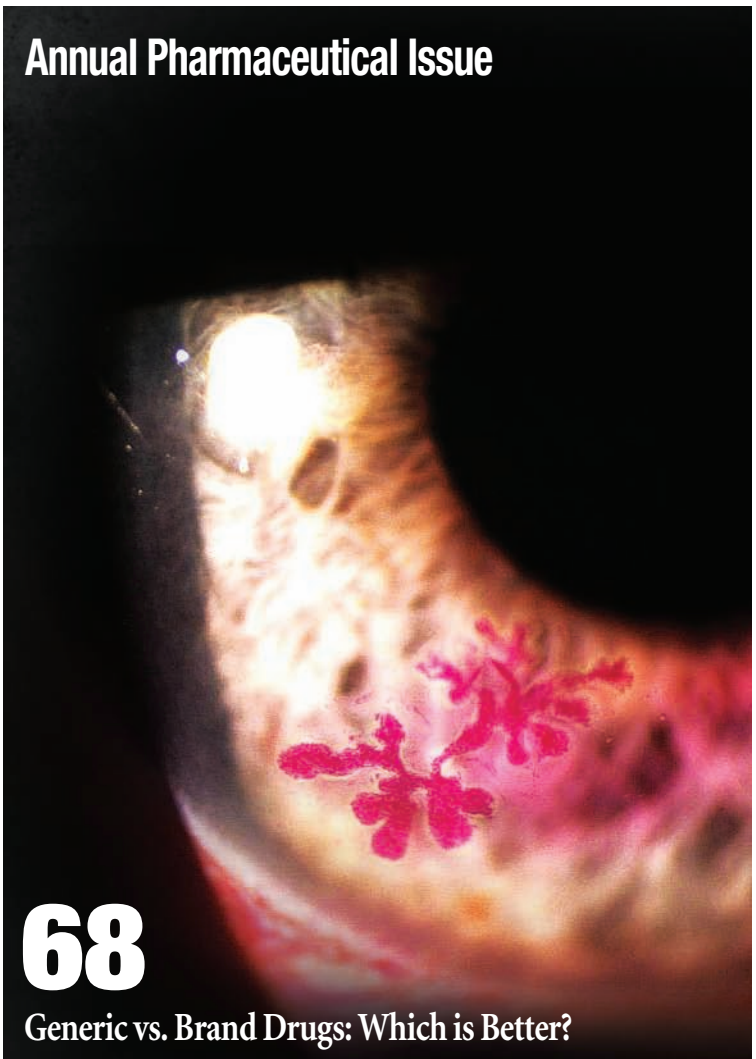

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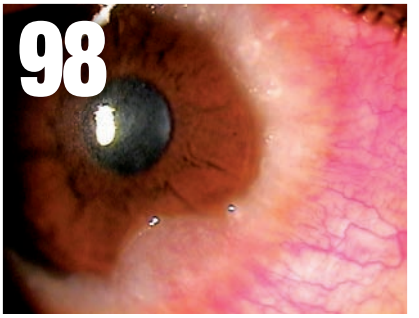

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Brief Summary of Prescribing Information

ATON PHARMA

ATON Pharma, a Division of Valeant Pharmaceuticals North America LLC
Madison, NJ 07940

Rx Only

LACRISERT® (hydroxypropyl cellulose) OPHTHALMIC INSERT

DESCRIPTION

LACRISERT® Ophthalmic Insert is a sterile, translucent, rod-shaped, water soluble, ophthalmic insert made of hydroxypropyl cellulose, for administration into the inferior cul-de-sac of the eye.

Each LACRISERT is 5 mg of hydroxypropyl cellulose. LACRISERT contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long. LACRISERT is supplied in packages of 60 units, together with illustrated instructions and a special applicator for removing LACRISERT from the unit dose blister and inserting it into the eye.

INDICATIONS AND USAGE

LACRISERT is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

CONTRAINDICATIONS

LACRISERT is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.

WARNINGS

Instructions for inserting and removing LACRISERT should be carefully followed.

PRECAUTIONS

General

If improperly placed, LACRISERT may result in corneal abrasion.

Information for Patients

Patients should be advised to follow the instructions for using LACRISERT which accompany the package.

Because this product may produce transient blurring of vision, patients should be instructed to exercise caution when operating hazardous machinery or driving a motor vehicle.

Drug Interactions

Application of hydroxypropyl cellulose ophthalmic inserts to the eyes of unanesthetized rabbits immediately prior to or two hours before instilling pilocarpine, proparacaine HCl (0.5%), or phenylephrine (5%) did not markedly alter the magnitude and/or duration of the miotic, local corneal anesthetic, or mydriatic activity, respectively, of these agents. Under various treatment schedules, the anti-inflammatory effect of ocularly instilled dexamethasone (0.1%) in unanesthetized rabbits with primary uveitis was not affected by the presence of hydroxypropyl cellulose inserts.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Feeding of hydroxypropyl cellulose to rats at levels up to 5% of their diet produced no gross or histopathologic changes or other deleterious effects.

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 following adverse reactions have been reported in patients treated with LACRISERT, but were in most instances mild and transient: transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, edema of the eyelids, and hyperemia.

DOSAGE AND ADMINISTRATION

One LACRISERT ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes. Individual patients may require more flexibility in the use of LACRISERT; some patients may require twice daily use for optimal results.

Clinical experience with LACRISERT indicates that in some patients several weeks may be required before satisfactory improvement of symptoms is achieved.

Issued June 2007

Distributed by:
ATON Pharma,
a Division of Valeant Pharmaceuticals North America LLC
Madison, NJ 07940

Manufactured by:
MERCK & Co., Inc.
West Point, PA 19486 USA

LAC048-1111ROPT

In moderate to severe dry eye syndromes

Only Dissatisfied Patients Need Apply

For patients seeking improvement in comfort and satisfaction:[1]

Continuous lubrication, starting day 1.[2]
Provides ongoing ocular surface protection, long term.[3]

- Results of a large multicenter registry study of over 400 patients showed significant reduction ($p<0.05$) in frequency and severity of dry eye symptoms after one month of therapy with LACRISERT®[1]
- 53% of patients felt that LACRISERT® provided incremental improvements to their existing therapy, including artificial tears[1]

Indications and Usage

LACRISERT® is indicated in patients with moderate to severe Dry Eye syndromes, including keratoconjunctivitis sicca. LACRISERT® is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT® is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

Important Safety Information

LACRISERT® is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose. Instructions for inserting and removing LACRISERT® should be carefully followed. If improperly placed, LACRISERT® may result in corneal abrasion. Because LACRISERT® may cause transient blurred vision, patients should be instructed to exercise caution when driving or operating machinery. Patients should be cautioned against rubbing the eye(s) containing LACRISERT®.

The following adverse reactions have been reported, but were in most instances, mild and temporary: transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, eyelid edema, and hyperemia.

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

* In most patients, one LACRISERT® placed into each eye once daily is effective in providing all-day symptom relief. Some patients may require twice-daily use for optimal results.

References: 1. Koffler BH, McDonald M, Nelinson D, Improved signs and symptoms and quality of life with dry eye syndrome: hydroxypropyl cellulose ophthalmic insert patient registry. *Eye Contact Lens.* 2010;3:170-176. **2.** LACRISERT [package insert] Madison, NJ: ATON Pharma, 2009. **3.** Wander A, Koffler B. Extending the duration of tear film production: review and retrospective case series study of the hydroxypropyl cellulose ophthalmic insert. *Ocul Surf.* 2009;7(3e):154-162.

LACRISERT®
(hydroxypropyl cellulose ophthalmic insert)

Once a Day.*
Continuous Lubrication.
Ongoing Protection.

ATON PHARMA ATON Pharma, a Division of Valeant Pharmaceuticals North America LLC Bridgewater, NJ 08807 LAC048-1111ROPT

Letters to the **Editor**

VSP: Allow Stand-Alones Into Exchanges

As part of the Obama administration's health care reform initiative, the Patient Protection and Affordable Care Act was signed into law in 2010. Since then, we've all been working to understand the implications of this new health care model. The really great thing is that it will expand health care coverage, which will allow more people to get the care they need. As an optometrist for over 30 years, this is something I care a great deal about—making sure people have access to health care. I've seen the devastating consequences associated with receiving care late or not at all.

With all of the good things that are associated with health care reform, there are still some unintended consequences that need to be fixed before we move into this new health care model. Under the new law, vision insurance will be provided through Exchanges, which will act as a central marketplace where insurance can be purchased. Although stand-alone vision plans (vision plans which specialize in and provide eye care benefits directly to their members) currently provide 90% of the vision insurance in the U.S., under the current plan they will not be authorized to provide care in the Exchanges. Only medical health care plans will be able to compete for the vision coverage. Ironically, stand-alone dental plans are allowed to offer dental care through the Exchanges.

If the Exchanges move forward as structured, I'll have to provide care to my patients through their health plans. In theory, this sounds great. I'm a doctor and should be treated equal to my medical doctor colleagues. However, there are still a lot of hurdles that have to be overcome before we get to even ground. Medical doctors are at the core of the treatment models called for in the law. Although health plans may decide to allow optometrists on their panel, it is not mandatory. The Harkin Amendment, which has been touted as providing parity for all health care providers, states that health plans are not required to contract with every health care provider and can provide varying reimbursement rates. The amendment provides no guarantees of being treated equal. With the new health care model, I will have to rely on health plans to change their practices and begin treating me the same as their network of medical doctors. While the Harkin Amendment is a good first step, it needs to be strengthened before it has any real meaning.

> *If stand-alone vision plans are not allowed to provide care in the Exchanges, this creates an issue for my practice and countless other practices around the country.*

After caring for my patients all these years, I'm now concerned about the risk of losing them simply because of the way the Exchanges are structured. Stand-alone vision plans have a much higher impact on the number of patients I'm seeing than medical plans do. There are several reasons for this. Not only are there 100 million people in the U.S. relying on vision benefits from stand-alone vision plans, but research shows that these individuals get vision care much more frequently than those who have a benefit through a medical plan. Stand-alone vision plans have more patients and higher utilization than medical plans, and they also direct patients to me. Health plans rarely have a referral model that supports the optometric profession.

If stand-alone vision plans are not allowed to provide care in the Exchanges, this creates an issue for my practice and countless other practices around the country. I completely support optometrists being integrated into the medical health care model. But until I have a guarantee that I will be included on the health plan panels—and treated equal to medical doctors for the same services rendered and have equal access to patients—I can't risk losing the patients that I currently have through stand-alone vision plans. It just makes sense to allow the vision plans to compete for business in the Exchanges the same way medical and dental plans are allowed to do so.

—Tim Jankowski, O.D.
Chairman, VSP Global Board of Directors

AOA: Optometry Should Be Defined By Optometrists

Thanks to several visionary leaders in Congress and the AOA's relentless lobbying efforts, the 2010 health care law is making

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.

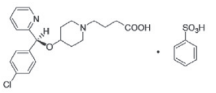
8.5 Geriatric Use

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

healthy vision for America's children a new national health care priority. The legislation specifically recognizes pediatric vision care as essential and requires that health plans cover it starting in 2014.

This means that millions more children who now lack health insurance or whose families struggle with plans with insufficient or segmented benefits will soon be closer than ever to having a range of vision problems diagnosed and treated by their local optometrist.

Throughout the Washington, D.C., battles over health care, the AOA's mission has been to expand patient access to optometric care. We have fought to gain and to hold our profession's seat at the table whenever and wherever health care policy issues are decided. From my trips to the nation's capital for meetings at the White House, the Capitol and the Department of Health and Human Services, I've seen our hard work make the difference.

In fact, the bill that became law two years ago not only makes pediatric vision care essential in health plans, but also includes AOA-backed provisions telling insurers that they can no longer discriminate against us or confuse our patients by covering vision but not all of the medical services we provide.

The battles rage on though, and it will take a Supreme Court decision later this year to begin to cut through some of the uncertainties. No matter what happens, we will need to be vigilant and prepared to do whatever it takes to again defeat organized medicine and insurers who continue their scheming to undo every one of our gains.

The stand-alone plans' outdated business models result in the isolation of the profession of optometry from the rest of health care.

As AOA president, I'm committed to ensuring that neither medicine nor insurers gain the ability to define optometry. Medicine continues to try to tell us and our patients what we are not, while insurers seek to use reimbursement to tell us how and when to provide care. The former is overt and the latter more covert, but both are equally dangerous to our profession.

That is why we must take a stand when health plans try to impose artificial and anti-patient restrictions on our services. This includes the stand-alone plans whose outdated business models result in the isolation of the profession of optometry from the rest of health care, as if somehow vision care must always "stand alone" from primary health care.

Under the new pediatric vision essential benefit, which should be based on a comprehensive eye exam and all necessary follow-up care, the law is aimed at allowing O.D.s to provide our full range of eye health care services while stopping insurers from limiting us to only vision care. This is an important new recognition in Federal law of full-scope optometric eye health care, included to assure the seamless delivery of care for millions of our newest patients as well as to deliver opportunities for optometrists to become providers on the medical plans' health panel.

I still do hear from insurance executives who, while claiming to have our best interests in mind, want a special loophole that would allow them to go back to segregating optometry from the mainstream of health care, requiring us to refer patients when medical eye care is needed. I've let them know that preserving forever a very broken status quo may be very good for their corporate bottom line, but it won't be good for our patients or our practices.

Although there are many uncertainties in the era of health care reform, the integration of vision and eye health care coverage for currently uninsured and underinsured children is a certain step toward expanded access to the full range of care that we provide. It's an advancement that builds on decades of our access and scope of practice gains, and the hard work and visionary thinking of optometric leaders from every state that have made them a reality.

Let's continue looking ahead and continue doing everything necessary to ensure that only optometrists define optometry. For more information on what you can do to help advance our profession, please don't hesitate to contact me or the AOA's Washington, D.C., office. ■

—Dori M. Carlson, O.D.
President, American Optometric Association

This Is Getting Old

When I realized we were doing another story on presbyopia, I nearly ARFD.

By Amy Hellem, Editor-in-Chief

I will let you in on a little secret. The editors here at *Review* cringe every time they're assigned a story on presbyopia. It's not that there's nothing to talk about. It's just that, in most cases, it's all been said before—yet the editor is charged with the creative challenge of packaging it in a way that is fresh and inspiring to readers like you.

Lucky for us, Nathan Bonilla-Warford, O.D., A.B.O.C., submitted something fresh and original for this month's issue. In fact, everything about this article is new—except for the main characters/patients who are, of course, old since they are, after all, presbyopes (there was no avoiding that).

So, what is Dr. Bonilla-Warford's novel idea? He talks about the "new" presbyope. You know, that irritating baby boomer guy who is getting old but refuses to accept or acknowledge it, even though it's evident to anyone who saw him pull up to your door in his shiny new red sports car—the one that he just parked in the only handicapped spot in your lot. That guy.

Anyone will tell you, new presbyopes are no fun. Most of them have a mistaken idea of what presbyopia is. In fact, many think it's a precursor to a horrible medical condition (hence, the "pre-"). Research conducted on behalf of Transitions Optical shows that some 63% of patients think it leads to blindness. So you can understand why a patient might look at you like you're the most insensitive doctor on earth, when you casually reassure him that "this happens to everyone and is just part of getting older."

As Dr. Bonilla-Warford points out, the challenge with presbyopes is to ascertain their stage and understanding of presbyopia, and then present options that they find tolerable. And believe it or not, in some cases, the best course of action is to change nothing. I told you this was new!

When was the last time you were advised not to prescribe a new lens to a presbyope? But, according to Dr. Bonilla-Warford, "if progressive lenses or contacts are prescribed before the patient is mentally prepared, they may go unused—or even worse, may be resented." He compares the patient's grief over the loss of good vision to Kübler-Ross' stages of grief. Again, new.

Thanks Dr. Bonilla-Warford for breathing new life into presbyopia without resorting to referring to it by its new name—age-related focus dysfunction, or ARFD. The American Society of Cataract and Refractive Surgery's product branding experts came up with that gem. I'll give them your number.

Amy Hellem
Editor-in-Chief

July 26-29, 2012

SECO International and Review of Optometry Present

VANCOUVER 2012

This summer, SECO International and Review of Optometry invite optometrists to Vancouver for an exciting four-day continuing education event featuring leading experts in the profession and compelling courses. This unique program, held at the Westin Bayshore Hotel, begins the evening of July 26th and continues during the mornings of July 27th through 29th. This allows attendees plenty of time to spend the remainder of those days with family and friends touring the city of Vancouver and the majestic regions of British Columbia. Group tours will be available.

Featuring 14 Hours of Optometric Continuing Education and Unique Networking and Sight-seeing Opportunities.

Nine courses (8 CEE/TQ Hours) — covering topics such as Cataract surgery, Glaucoma, OCT and corneal crosslinking — will be presented by Dr. Paul Karpecki, Dr. Paul Ajamian, Dr. Kim Reed, Dr. Steven Ferrucci, and Dr. Michael Chaglasian. The conference also features many opportunities for networking and socializing at the Welcome Reception on Thursday, July 26th and the Sponsors' Reception on Saturday, July 28th. Group tours will also be available. Don't let this wonderful opportunity to learn some of the latest developments in optometry while enjoying the international city of Vancouver, BC, pass you by. **Register now!**

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You Can't Afford to Be Rich

You're so money. You're so money, you don't even know it. (But, seriously...how many more pairs of khaki pants do you need?) **By Montgomery Vickers, O.D.**

I told my wife that I'm going to buy a yacht and travel the world for a few months. She sweetly inquired how I was planning to afford that. I patiently (OK, not so patiently) replied (i.e., retorted) that I had seen in the newspaper that the President considers my income to mean I am rich.

Now, if I am rich, why in the world have I gotten out of bed and gone to work every day? If I had actually known I was so wealthy, I would have shipped out to Cannes with DeNiro years ago.

Seriously, when did money become our only goal? Oh, I know…it's easier for a camel to go through the eye of a needle than it is for a rich man to enter the gates of heaven.

But, I am almost certain that nearly all of you/us came from families where Great-grandpa and/or Great-grandma, Grandpa and/or Grandma, Daddy and/or Mommy worked hard, got educated, learned how to build birdhouses… WHATEVER! Then, somebody paid them for what they did. They taught each successive generation to work hard and good things would come. This filtered down to you and me, and here we are: "rich"!

Where do we go from here? Unfortunately, many of us believe that we have no control. Many of you, my colleagues, just think that the government decides your future. If you angrily feel that entitlements make people more and more dependent upon the proverbial State, then what's different about your business plan? Are you subsidized, too? Woe is you if Medicare cuts kick in. Woe is you unless you accept the latest, greatest vision plan. Oh, my, my… woe is you. Oh, and please tell the AOA PAC that you won't donate. That makes sense, right? Take your donation and buy those lottery tickets instead. Hey, somebody's gotta win, right?

The problem is not how much money you make, or want to make. The problem is simply money in general. You see, and I hesitate to tell you this: There is no such thing as money. I believe in Santa, the Easter Bunny, the Tooth Fairy, and that The Donald's hair is real. But I don't believe in money.

So, why do we want what is not real? Doctors, you don't want money. You want food, heating and cooling, khaki pants, cell phones, vacations, washing machines and 3-D beach volleyball. Not money.

Ask yourself these questions:

1. How many pairs of khaki pants can one man own?
2. Your last vacation—weren't you bored after Wednesday?
3. Why text in the first place?
4. Really? You need to Google "How tall is Ryan Seacrest?" while walking with your kids?
5. Look in the mirror. Are you undernourished?
6. Does your current washing machine work?
7. I can forgive the 3-D beach volleyball requirement. That's important.

But, "rich" doctor, please stop with the worry about money, money, money. Put the cell phone down and listen to your kid (if she'll stop texting long enough). Tip your waitress at the diner twenty bucks for your next cup of coffee. Treat your very next patient better than the last one. Smile and relax. Be thankful.

It's just what your daddy told you when you were eight. Work hard. You're going to be just fine.

And, from me to you…VOTE. You cannot afford not to.

Gotta go. Volleyball's on! ■

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Coding **Abstract**

Help! Where's the Code for This?

Here's what you can do when clinical care and medical coding don't match.

By John Rumpakis, O.D., M.B.A., Clinical Coding Editor

Has this ever happened to you? You go to a clinical lecture and hear about a new clinical problem. Then you get back to the office and start to incorporate the new care regimen—but you can't find the right code to use for billing purposes?

I hear about this dilemma all of the time. So, what can you do?

Let's take one of the hotter topics in clinical care: meibomian gland dysfunction (MGD) or meibomian gland disease—or whatever name that you want to call it. After the Tear Film & Ocular Surface Society released its 2011 reports about MGD, optometrists across the nation gained a tremendous clinical awareness of this common entity. But, this excitement was quickly followed by a multitude of questions: "What do I bill for expressing the meibomian glands or probing the ducts?" And, "Which tests or instruments do I use for an appropriate (and accurate) diagnosis?"

Well, here's where reality hits the fan... According to the 2012 ICD-9-CM, there is no such clinical entity for meibomian anything. So, many clinicians have unknowingly been using inaccurate or improper diagnosis codes to describe MGD. Most are improperly using the diagnosis for internal hordeolum (373.12), most likely because someone somewhere told them it is "the code" for meibomitis.

Clinical lecturers are starting to use descriptive terms like anterior blepharitis or posterior blepharitis. But again, according to the ICD-9 codes, neither of those diagnoses exist, either. You will have to be satisfied with the simple diagnosis of plain old blepharitis (373.0) or unspecified blepharitis (373.00) in such cases.

Likewise, regarding procedure codes, no CPT codes currently exist for expressing the meibomian glands or probing of the glands. The current and proper approach when diagnosing or treating MGD is to simply code the appropriate level of a 992XX code or 920X2 code and nothing more.

There is a HCPCS Level III code for a new device (LipiFlow, TearScience) that is in the marketplace, but this code is only appropriate to use if you possess the instrumentation and are using it according to the definition.

As frustrating as it is, our current coding system isn't perfect, but it *is* what we have and are legally bound to use. Please make sure that the medical coding processes that you have in place in your practice are up to date and accurate. This is necessary because we are obligated to accurately describe what we did with the patient and why we did it—and we have to describe it using the diagnosis in the current system that we have.

With efforts by myself and others, perhaps we will see recognition of MGD by the World Health Organization as a valid clinical entity, along with corresponding diagnosis codes, when the upcoming ICD-10 system rolls out in October 2013. ■

Clarification on Bandage Contact Lenses

Here's some further clarification regarding information that appeared in the December 2011 column regarding the use of the new CPT code 92071 for bandage contact lens fits.

There is some disparity among carriers whether this code is to be used for fitting of a bandage contact lens at all. Some carriers have indicated that 92071 is an appropriate code for fitting a bandage contact lens and should be used similarly to the now-defunct 92070. But other carriers have interpreted the CPT definition literally and are indicating that 92071 should *not* be used for that purpose as it is specifically used for fitting a contact lens for the treatment of ocular surface disease (OSD). So what should you do?

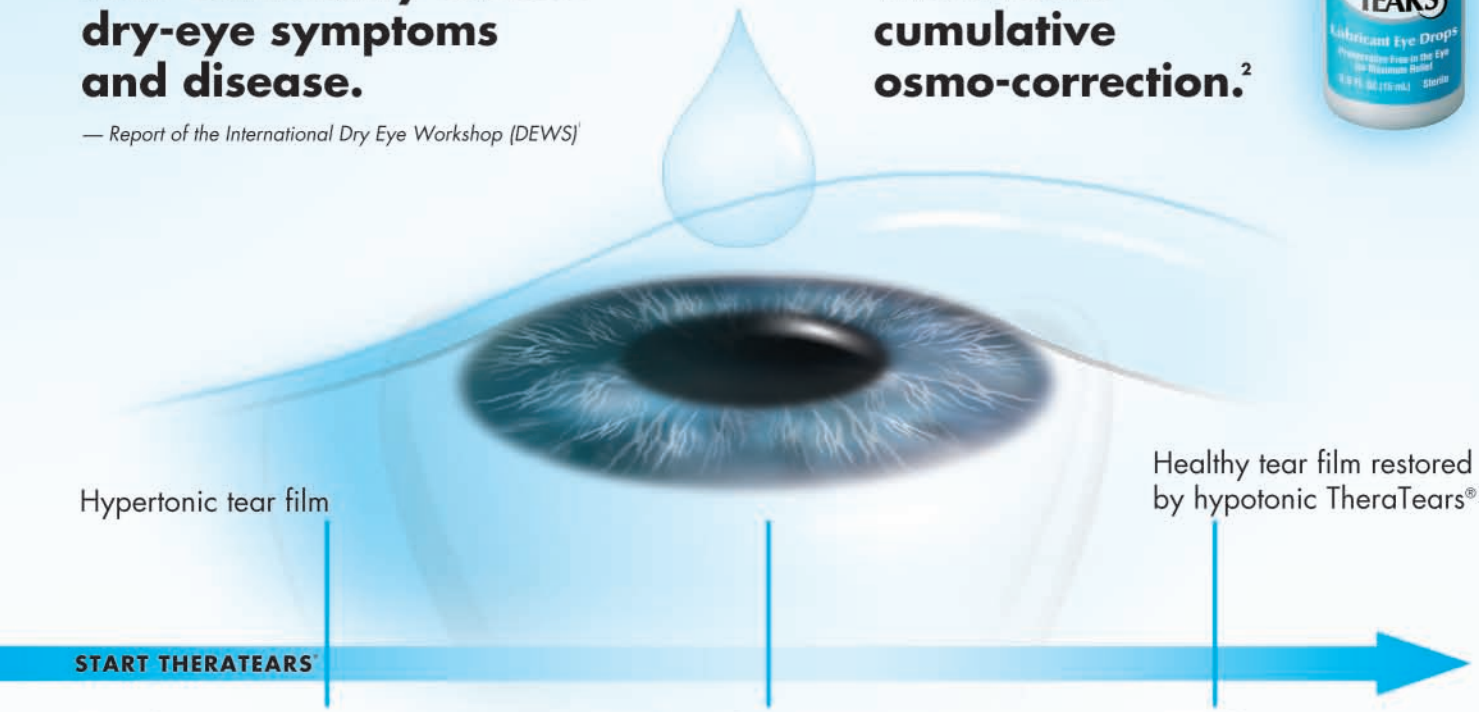
First, contact your carriers and find out where they stand on this issue. If they are accepting 92071 as an expanded version of 92070, and they are including corneal abrasion into their definition of OSD, then proceed just as you did with 92070, with the provision that you can now charge for appropriately billable materials in addition to the fitting code. However, if they are restricting use to treat OSD only and corneal abrasion is *not* included in the more narrow definition, it is recommended that just the office visit be billed without an additional fitting code for the application of the bandage lens.

TheraTears® Lubricant Eye Drops

FACT 1: Increased tear osmolarity causes dry-eye symptoms and disease.

— Report of the International Dry Eye Workshop (DEWS)[1]

FACT 2: q.i.d. TheraTears® = cumulative osmo-correction.[2]



Experts agree — increased tear film osmolarity causes dry-eye irritation and surface disease.[1,3-6] This is what experts have known all along. And there's only one artificial tear brand that's sufficiently hypotonic to lower increased tear film osmolarity — **TheraTears®**. This cumulative lowering of increased tear film osmolarity is called Osmo-correction™. It only comes with hypotonic electrolyte-balanced **TheraTears®** lubricant eye drops. Lubrication, protection *and* Osmo-correction™. Available as a preservative-free drop and liquid gel, in a dropper bottle with a disappearing preservative, and for use with contact lenses.

1 The Ocular Surface. April 2007, 5(2).
2 *modified from:* Gilbard JP, Rossi SR Ophthalmol, Apr 1992, 99(4):600-4.
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Get Ready for Education Plus SECO 2012

By Paul C. Ajamian, O.D., Optometric Education Program Committee Chair

SECO 2012 is not just education, it's "Education Plus." This year's annual Congress in Atlanta, which will be held from Wednesday, Feb. 29 through Sunday, March 4 in Building A of the Georgia World Congress Center, will offer a broad spectrum of new courses designed to help practicing O.D.s and their staff expand their scope of practice.

SECO will keep you ahead of the curve with an exemplary CE experience, which will emphasize future trends and technology, with a focus on what optometric practices may look like in the next decade or beyond.

Education Plus for O.D.s

Optometrists and the entire optometric team will have many opportunities to obtain the continuing education they want and need. There are nearly 400 hours of continuing education for optometrists, opticians, paraoptometrics, ophthalmic technicians and administrative staff.

This extensive line up of education includes Special Sessions, hourly lectures, hands-on workshops, and certification reviews for O.D.s and AOPs.

Special Sessions will provide 16 FREE hours of COPE-approved optometric continuing education for optometrists.

Don't forget to register to attend these FREE Sessions:

- **060 Harnessing the Pluses of Technology**
- **061 Rapid Fire Retinal Rounds**
- **062 Current Quandaries in Glaucoma**
- **063 What Lies Ahead**
- **064 Babies to Boomers: The Keys to Contact Lens Success**
- **200 Teaming Up Against Allergies**
- **065 Down on the Pharm**
- **066 How Do I Co-manage That?**

For attendees who wish to learn more about what will be required to prepare for their ABO board certification exam, SECO will offer Board Review courses on Friday and Saturday.

Of course, education isn't a sole endeavor. There are many advantages to learning as a team. SECO 2012 will provide Joint Education courses for O.D.s and AOPs (staff) that are tailored for optometric team learning.

Be sure to attend Special Sessions such as "What Lies Ahead," to get a glimpse at what you might be doing in the next decade or beyond.

SECO is also featuring its innovative Symposium Series again for 2012 presented by industry leaders, where attendees can enjoy a free meal while getting "inside information" directly from the ophthalmic companies that we work with most.

The Exhibit Hall Experience

In between courses and during the lunch break, SECO encourages attendees to visit one of the largest exhibit halls in optometry. Optometry's Marketplace™ is the profession's most expansive trade show, featuring nearly 300 industry-leading companies. This year, the marketplace will offer the newest in ophthalmic equipment, products and services available in eyecare.

Signature Social Events

SECO 2012 would not be complete without its signature social events and myriad opportunities for networking. Across four days, SECO will host more than 50 affiliate and social events from the opening reception to the Saturday Night "Denim and Diamonds" Party featuring country superstar Laura Bell Bundy that you won't want to miss!

I look forward to seeing you at this year's Congress in Atlanta. For more information or to register, go to: www.seco2012.com. ■

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Reference: 1. Alcon data on file, 2011.

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Ocular Hypertension in Wegener's Granulomatosis

Was this patient's elevated IOP caused by excess oral steroid use or by the underlying condition? **By Jay Ananthan-Nair, O.D., Ph.D., and Kevin Barber, M.D.**

A 40-year-old white female presented with a chief complaint of tearing and some visual blur in her right eye that persisted for a few weeks. She also reported occasional diplopia.

The patient had been diagnosed with Wegener's granulomatosis (WG) a year earlier. Otherwise, her medical and family histories were unremarkable.

Her current medications included 20mg oral prednisone b.i.d. and a monthly infusion of 1,000mg/meter^2 of Cytoxan (cyclophosphamide, Bristol-Myers Squibb).

Diagnostic Data

Her entering visual acuity measured 20/25 O.D. and 20/20 O.S. External examination revealed no abnormalities. Her pupils were equally round and reactive to light and accommodation, with no afferent defect O.U. Extraocular muscles were full, accurate, smooth and extensive in both eyes. Additionally, her confrontation fields were full O.U.

Refraction yielded no improvement in visual acuity. Biomicroscopy showed no abnormalities in the anterior segment O.U. Intraocular pressure measured 24mm Hg O.U.

The right lens showed the early formation of a posterior subcapsular cataract. Dilated fundus examination revealed a healthy optic nerve head with 0.3 x 0.3 cups in addition to well-perfused rim tissue, a healthy nerve fiber layer and macula, and unremarkable peripheral structures.

Treatment and Follow-up

Given the findings, we prescribed Travatan Z (travoprost, Alcon) at bedtime to reduce her intraocular pressure. Additionally, we scheduled her for a three-week follow-up.

At the follow-up visit, our patient noted an increase in all previously reported symptoms. And, although the eye looked normal, her intraocular pressure had increased to 30mm Hg O.D. and 18mm Hg O.S. We decided to add Combigan (brimonidine and timolol, Allergan) b.i.d. to her regimen. We then scheduled the patient for another three-week follow-up.

Just two weeks later, the patient called our office, complaining of increased discomfort. We asked her to come in before her

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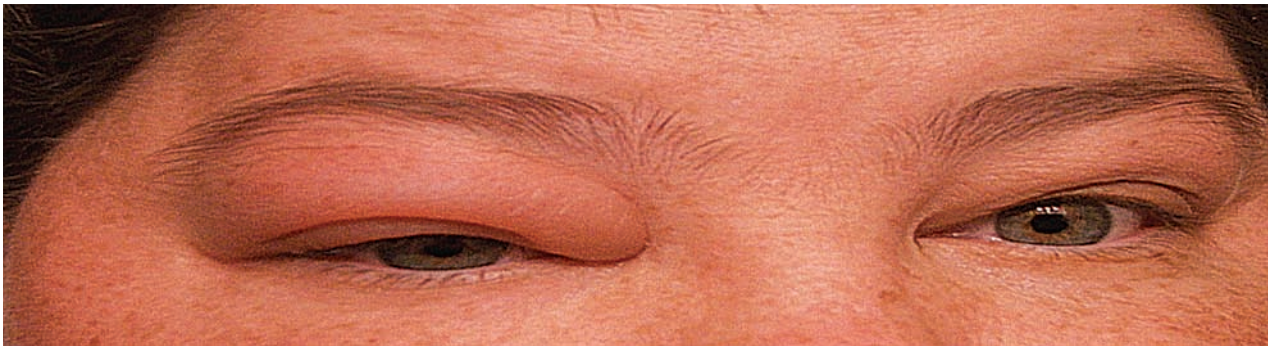

1. Our patient exhibited orbital inflammation and proptosis that was seen primarily in the right eye.

scheduled follow-up appointment. When she arrived at the office, she exhibited a noticeable proptosis (*figure 1*) with restricted motility in the right eye. Additionally, her intraocular pressure now measured 48mm Hg O.D.

We ordered an orbital magnetic resonance imaging scan (*figure 2*), which revealed bilateral orbital granulomas (O.D. > O.S.). After consulting the patient's rheumatologist, we increased her dosage of oral prednisone to 60mg per day and recommended a 33% increase in Cytoxan. Also, we added Azopt (brinzolamide, Alcon) b.i.d. O.D. We again scheduled her for a three-week follow-up.

At this follow-up visit, the patient reported an improvement in both pain and discomfort; however, the increased oral steroid dosing resulted in weight gain, insomnia, poorly controlled hypertension and anxiety.

To avoid the excess steroid use, we selectively injected 1mL triamcinolone acetate (40mg/mL) into the lateral aspect of her right orbit.

In just one week, the orbital granulomas regressed (*figure 3*). Additionally, her intraocular pressure dropped to 16mm Hg O.U. Afterward, the patient remained asymptomatic on a reduced oral steroid regimen. Also, her intraocular pressure remained the same with the use of only topical medications.

Discussion

WG is an arteriolar vasculitis that was first documented in 1931.[1] There are approximately 24 to 157 cases of WG per one million individuals in the United States, with three to 14 new cases per one million individuals reported each year.[1]

Typically, WG presents with multiple organ involvement. Its etiology is primarily unknown, although there have been reports of a genetic predisposition.[2] While the disease is seen in both children and adults, the mean age of detection is 41 years.[3]

The classical form of WG exhibits a triad of necrotizing inflammation in the upper respiratory tract, glomerulonephritis and systemic vasculitis. In one form of WG, systemic involvement is limited to the respiratory tract with an absence of renal involvement.

The pathogenesis is not clearly understood, but autoimmunity is a widely accepted cause. A review of other vasculitides may be helpful in understanding the pathogenesis of WG. Churg-Strauss syndrome and polyarteritis nodosa (PAN) are two such conditions that present similarly to WG, both affecting small to medium arterioles.[1,2]

Immunofluorescence studies show the presence of antineutrophil cytoplasmic auto antibodies (ANCA) in a majority of patients with such cases of vasculitis.[4] There seem to be two different antigens involved—proteinase 3 (PR3) and myeloperoxidase. These antigens are primarily located in the cytoplasm in patients with WG (referred to as cANCA) and in the nuclear and perinuclear areas in patients with PAN.[5,6]

Patients with WG have an increased number of neutrophils that express constitutive PR3. ANCA can activate these neutrophils to release free radicals and lytic enzymes, which can damage vascular endothelial cells and lead to necrosis.

Recent studies in a mice model also have shown the need for PR3 for vasculitis to take place.[5] Although measurement of anti-PR3cANCA gives a more practical way to diagnose and monitor the disease, the specificity of ANCA for WG is a concern.

Studies show sensitivities ranging from 75% to 90%, but anti-PR3cANCA has become an adjunct, if not primary, method of monitoring the disease. Still, biopsy of the granuloma remains the most reliable diagnostic method.[6]

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  - A significant reduction ($p<0.0001$) in all ocular signs and symptoms, including pain and discomfort, was seen in patients who were switched to a preservative-free formulation.[1]

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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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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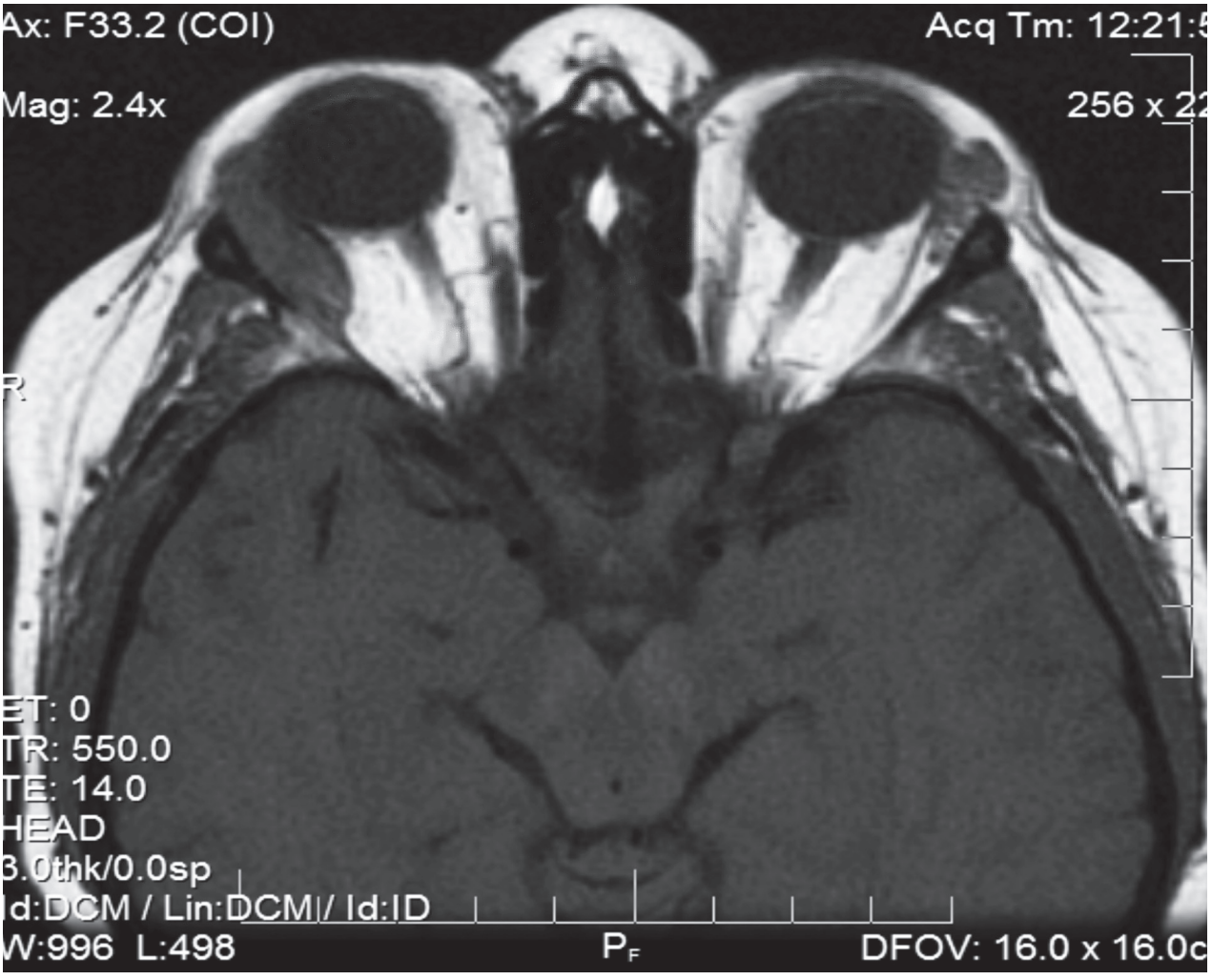


2. Orbital magnetic resonance imaging scan revealed a pronounced granuloma in the right orbit. In addition, we noted the presence of a smaller granuloma in the left lateral orbit.

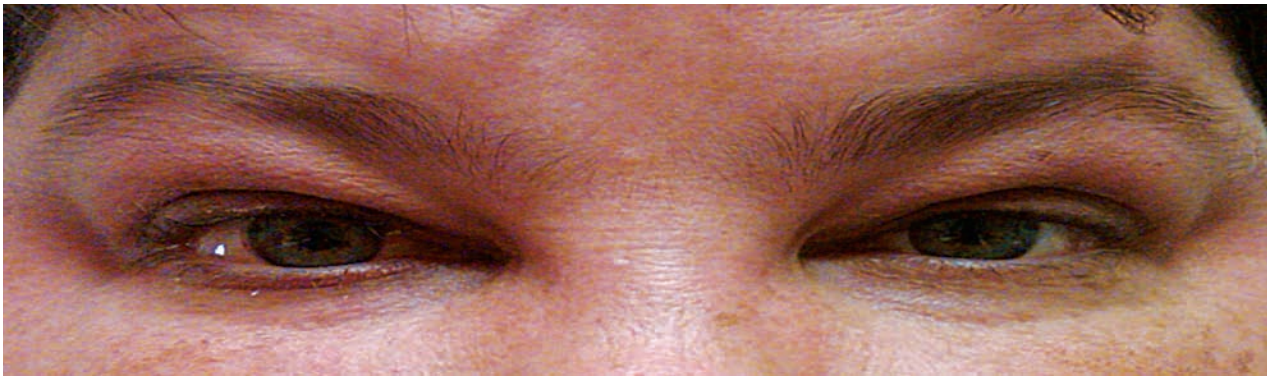
Incidence of ophthalmic involvement can occur in both forms of WG and presents in 28% to 60% of the cases.[7,8] In many cases, ocular involvement actually has lead to the identification of previously undiagnosed WG.

A survey of 140 confirmed cases showed that the most common ophthalmic manifestations were orbital inflammatory disease and necrotizing sclerokeratitis.[8] Also, a review of nine cases from India showed that necrotizing scleritis and peripheral keratopathy were the most common ophthalmic presentations of WG.[9]

Other ophthalmic manifestations reported include scleritis, episcleritis, conjunctivitis, corneal ulceration, uveitis, retinal vasculitis, retinal vascular occlusions, retinal detachments, optic neuropathy, cellulitis, and obstruction of the nasolacrimal duct.[2,10,11] Granulomatosis can occur within the orbit or can infiltrate from the nasal sinuses, resulting in proptosis and secondary ophthalmic complications.[2]

In one case report, orbital involvement resulted in paralysis of the third, fourth and sixth cranial nerves as well as the first division of the fifth cranial nerve and ischemic compression of the optic nerve.[3] Ischemic conditions resulting from vasculitis of the scleral blood vessels can lead to necrosis and even perforation.

In a retrospective study of 49 WG patients in the United Kingdom, 28 individuals exhibited ocular involvement.[12] Of these, 21 had focal involvement with conjunctivitis, episcleritis, scleritis, keratitis, iritis or retinitis.[12] An additional seven patients had



3. Our patient showed marked improvement following an adjustment of her medications and a triamcinolone acetate injection.

orbital involvement.[12]

Further, of the 28 patients with ocular involvement, three died from the disease. This study also indicated that early diagnosis and treatment can result in a better visual prognosis.

In another case from the UK, the authors reported perhaps the first case of extraocular muscle myositis associated with WG as the initial presenting sign.[13] Interestingly, a survey of Slovenian patients examined from 2003 through 2008 indicated that associated ocular manifestations served as the primary diagnosis in 46.7% of WG cases.

Treatment of the underlying systemic condition also helps control the ocular manifestations that do not respond to topical agents. Surgical decompression may be of value in serious orbital involvement with optic neuropathy. Despite the use of systemic immunosuppressants, irreversible ischemic neuropathy has been reported.[3] So, eye care providers must be vigilant and aggressive during treatment to avoid permanent vision loss.

Management of WG is accomplished in conjunction with rheumatologists, pulmonologists, internists and oncologists. A multispecialty approach is critical, because the effects of the disease are so widespread. The mainstay therapy involves immunosuppression with cyclophosphamide and steroids. Cyclophosphamide—a chemotherapeutic agent—and prednisone have been shown to be effective in controlling the disease and its associated ocular manifestations.[14]

In a case like ours, where the patient already is on an oral steroid, the ocular side effects of the systemic condition must be included in the differential diagnosis before implicating the steroid.

Although the patient initially appeared to be a steroid responder, the ocular hypertension was, in fact, largely caused by the orbital granuloma impeding trabecular outflow. Orbital inflammation was caused by the primary granulomas or a spread of the granulomas from the nasal sinuses.[3]

Either way, proptosis and restricted motility are common clinical signs of WG. Optic neuropathy may accompany these symptoms, but was not documented in our patient. Although paralysis of the extraocular muscles has been reported in similar cases, we believe the restrictive ocular motility in our patient probably is a mass effect rather than a frank paralysis.

Steroid use is an essential element of WG management, but the risk of steroid-induced glaucoma is a distinct possibility. So, the use of ocular hypotensive medications may be helpful in controlling this complication, as illustrated in this case.

The chronic nature of WG necessitates long-term steroid use, which can cause multiple side effects that could be life threatening. Therefore, WG patients with a long-standing history of oral steroid use often require constant monitoring and intervention. Localized treatments with triamcinolone acetate may be added to control the orbital granuloma, relieve patient symptoms, and reduce the need for excess oral steroid use.

WG is a serious systemic disease with multiple organ involvement, including the eyes. Patients should be closely monitored for any ocular involvement and treated aggressively to avoid ocular morbidity. Eye care providers should be vigilant, because ocular manifestations sometimes may be the primary and/or only sign of WG.

Although ocular manifestations may take various forms, WG should be included in the

differential diagnosis—especially when there is orbital involvement or scleral necrosis. Localized treatment with triamcinolone acetate may be added to the systemic treatment to control ocular symptoms and avoid excess oral steroid use, particularly when orbital granuloma is involved. ■

Dr. Ananthan-Nair is in private practice in Debary, Fla. Dr. Barber is in private pratice in Orange City, Fla. They have no direct financial interest in any of the products mentioned.

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What To Do With 'New' Presbyopes

What happens when patients realize they have 'short arm syndrome'—and what can you do for them? **By Nathan Bonilla-Warford, O.D., A.B.O.C.**

Presbyopia, although normal and inevitable, is the first unmistakable, irreversible sign for many patients that they are getting older. So, when working with presbyopic patients, it's even more important than usual for us to consider the psychological and emotional implications of our recommendations.

Acknowledging these emotions proactively is important, but it must be done in the right way. Years ago, as an optician, I tried to be light-hearted and positive about presbyopia by saying something like, "This happens to everyone eventually. Congratulations, you've made it. You've earned these bifocals!"

Unfortunately, this never, ever, ever worked.

To our patients, presbyopia is a very big deal. Not only does it have emotional implications for most people, but also it greatly increases their complexity of choices in vision care. Our aging population increasingly demands excellent near vision for viewing computers and other digital devices—and at the same time, they have higher expectations than ever for crisp distance, intermediate and near vision, as well as spectacle independence.

Photos: Cristina Bonilla-Warford

Presbyopia happens to everyone eventually, but that doesn't mean it's routine for the patient in your chair. To patients, presbyopia is the first unmistakable sign of age.

For optometrists, presbyopia management presents an opportunity to increase the bottom line, but it also can consume significant chair time and result in frustrated patients. So, here are some ideas about what to do with patients who are "new" to presbyopia.

Presbyopes by the Numbers

As we all know, presbyopia has a high prevalence. Although age 40 commonly is cited as the onset of presbyopia for epidemiology estimates, the highest incidence (first complaints) actually occurs

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between age 42 and 44.[1]

One study found that more than one billion people in the world were presbyopic as of 2005, and that may reach almost 2 billion by 2050.[2] If presbyopia is defined as a visual condition of everyone over the age of 45, then an estimated 122 million Americans had presbyopia in 2010, according to U.S. Census Bureau figures.[3]

The challenge with presbyopes is to ascertain their level of understanding and stage of acceptance—and then present options that they find tolerable, meet their needs, and are also profitable for our practice.

And, as more baby boomers begin to have trouble at near, this number is only going to go up.

'Presbyopia? What's That?'

Generally speaking, patients don't quite understand what presbyopia is. They may have some notion that vision "changes" as they get older; but for most of their life, they've been unaware that accommodation existed and have thought of vision purely in terms of distance acuity.

Additionally, the term "presbyopia" is confusing to patients. They have told me that because it contains the prefix "pre-," patients may misinterpret it to be the beginning of a medical condition and become concerned.

A 2011 survey of American consumers, conducted on behalf of Transitions Optical, reinforced a great need to educate patients on what presbyopia is, how it affects vision and which treatment options are best. More than eight in 10 Americans (83%) say they are not familiar with presbyopia—and more than six in 10 (63%) mistakenly believe that it can lead to blindness.[4] (To that end, the American Society of Cataract and Refractive Surgery hired a product-branding agency to come up with a better, clearer term for presbyopia.[5] The result: "age-related focus dysfunction." Perhaps not surprisingly, "ARFD" hasn't really caught on with either the eye care community or the public.)

Even more concerning is that, independent of what it is called, patients do not understand how to deal with presbyopia appropriately. According to the Transitions survey, even if people experience trouble seeing up close, one in three said that they would not schedule an appointment with their eye doctor.[4] And fewer than four in 10 (38%) said that they would purchase prescription eyewear from their eye doctor. Instead, nearly one in five said they would do eye exercises (19%) or take vitamins (18%) to try to improve their eyesight.[4]

Clearly, we have a lot work to do in educating our patients about presbyopia and the options available to them. As with any treatment decision, patient selection is important. Because presbyopia management always involves some level of give and take, we cannot simply hand patients a prescription. We must discern what their beliefs and expectations are. (*See "Grief Over the Loss of Good Vision," page 46.*)

Patients do not realize that an optometrist's skill is largely in the psychology of vision. They often think that we gather data about their eyes and simply give them the corresponding prescription. The challenge with presbyopes is to ascertain their stage and understanding of presbyopia, and then present options that they find tolerable, meet their needs, and are also profitable for our practice.

Options for New Presbyopes

While earlier generations of presbyopes may have simply learned to deal with lined bifocals or progressives as a necessary evil, today's baby boomers have much higher expectations. Fortunately, there are now many options for managing presbyopia.

• ***Do nothing.*** If the patient is either in denial or mildly annoyed, often the best course of action is to

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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.

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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.

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; Clinical Study Report 05-003-11. **4.** Data on file, Allergan, Inc., 2005; Clinical Study Report 05-003-13. **5.** MediMedia Formulary Compass, November 2011.

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change nothing. If progressive lenses or contacts are prescribed before the patient is mentally prepared, they may go unused—or even worse, may be resented. This is especially true for myopes who can simply remove their glasses to see very small text. This uncorrected view often looks and feels more natural than multifocal correction, even if the measured near vision acuity is better.

• ***Glasses.*** The use of spectacles in some form is so ubiquitous for presbyopes that, like gray hair, glasses are a classic element of the mental picture of an "old person."

The fact is, for most presbyopes, they work. While over-the-counter readers are mass-produced with cheap materials, they do allow patients who don't require distance correction to read a menu and use a phone. This may be adequate for patients who are merely annoyed or simply accepting of presbyopia. Even so, be sure to educate them about the benefits of customized single-vision near prescriptions, quality lens materials and coatings, and optical-quality frames.

One key part of the process of accepting presbyopia is the patient's understanding that a single pair of glasses simply will not meet all of his needs. For patients with a distance prescription, the selection of multiple single-vision prescriptions, lined bifocal or trifocal prescriptions, or progressive-addition

Grief Over the Loss of Good Vision

Presbyopia progresses slowly over many years. And, because it truly is a loss of the visual freedom of seeing comfortably up close, I find it useful to consider new presbyopes' progress as "stages of presbyopia," which I have adopted from Kübler-Ross' stages of grief:

• **Denial**. The patient who does indeed have trouble at near, but refuses to admit it. This may be minor or infrequent enough that it does not interfere with work, hobbies or home life. Ideally, these patients are best left as is. Because presbyopia options involve some level of trade-off, it is not helpful to create a problem for them, regardless how small.

• **Annoyance**. The patient who acknowledges he has trouble, but just doesn't care enough to make changes.

• **Bargaining**. The patient who believes that, with enough time, money and effort, he can have the vision that he had 20 years ago. While these patients are very motivated, they may also have unrealistic expectations.

• **Acceptance**. The patient who realizes that vision isn't what it used to be, but with the right choices, she can still work and play as she used to do.

lenses (PALs) for everyday use is based on a combination of lifestyle and desire.

With new digitally-surfaced PALs, most patients rapidly adapt to them; but patients whose primary concern is to have the very widest width of reading area may be better suited to lined bifocals. Traditional PALs are not designed to optimize intermediate vision, so office workers should be educated on the benefits of near variable focus or "computer PALs." And don't forget about pre-presbyopic patients who are at risk for computer vision syndrome—they can benefit from some of these lenses, too.

High-tech options, such as Superfocus lenses (above) or emPower! eyewear (left) may appeal to patients who are reluctant to give in to presbyopia.

Additionally, there are new developments in multifocal lens technology. The electronic emPower! eyewear (PixelOptics) makes use of LCD lenses to provide additional plus power for near viewing. The Superfocus lens is manually adjusted by a slider on the bridge of the frame. These advanced options may appeal to high-tech, "bargaining" patients who are reluctant to give in to presbyopia; they also set your practice apart, and provide unique word-of-mouth advertising.

• ***Contact lenses.*** As with glasses, there are now many contact lens options for presbyopes: soft and RGP, simultaneous distance and near designs, and even multifocal toric contact lenses.

Historically, many presbyopic contact lens wearers have been prescribed monovision. While this is still useful, our patients only have two eyes and often need three areas of vision correction: distance, intermediate and near. Use of multifocal contacts can provide greater range of clear vision while preserving binocular vision.

Finally, spectacles to wear over the contacts, either to improve distance or near vision, are always an option when needed.

• ***Surgical procedures.*** Just as optometric practices benefit from the broad range of presbyopia options, so do ophthalmology practices and surgeons now offer a wider array of procedures to meet their needs. For patients who have a successful history of monovision contact lens wear, monovision LASIK may be an option. Multifocal intraocular lenses are used with success for patients requiring cataract surgery and are increasingly used for patients without cataracts (clear lens exchange).

Marketing To Presbyopes

Marketing to presbyopes can be difficult. Because patients take presbyopia personally, adhering to the axiom "under-promise, over-deliver" is important.

Low presbyopes, who have generally had great distance vision—and been proud of it—will find everything blurry far away. Myopes, who could see great up close without correction, will not understand why they can't see great up close. High astigmatism complicates everything. And, complaints of dryness or discomfort with contacts are more common.

Despite all of this, it is possible to effectively communicate that there are presbyopia treatment options and that you are an expert in this area.

• ***Exam room education.*** As with all optometric products and services, the conversation that occurs in the exam room is the most effective. During this time, we discuss specific recommendations and the benefits of each prescription. Although presbyopia is a universal condition, it doesn't feel that way to the patient. Try to convey how the patient's situation is special or unique so that he or she is engaged in the process, rather than just making an accession to "getting old."

• ***Internal marketing.*** There's no reason to wait until patients enter the exam room. The medical history questionnaire presents an excellent opportunity to ask about near vision difficulties and options. Pamphlets, posters, waiting room video screens and on-hold messages can all be used to highlight specific products that you frequently

recommend. Many companies produce direct-to-consumer marketing materials that can also be used (but review them carefully to ensure they do not "over promise" and are consistent with your overall marketing strategy).

• ***External marketing.*** To reach new presbyopic patients, feature your new products and services on your website or blog. Take advantage of media coverage of new developments in technology by linking to the story and explaining that you offer the product.

For example, a significant amount of news coverage has featured the new emPower! lenses. Add links to the coverage on your website, Facebook page or Twitter feed, and put your own twist on it. This "buzz" can be used to position your office as high tech, and may lead to media opportunities for you as the vision expert. These segments can then be saved and used for future campaigns.

• ***Word of mouth.*** Satisfied patients produce the best marketing. When a patient is overjoyed with the vision in their multifocal contact lenses or IOLs, their friends and family take notice. You can promote this by encouraging a patient to leave a review of their experience online for other patients to see.

Presbyopia may not be the most exciting condition for us to deal with, but there are more methods for managing it now than at any other time in history. By taking the time and effort to consider all of the options, optometrists can improve the quality of life of our presbyopic patients by making them feel like active participants in this multifaceted high-tech process—and not so old, after all! ■

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Looking at SiHy Lenses from Every Angle

When trying to determine if a silicone hydrogel contact lens is right for your patient, four key factors will help you to decide if it's a good fit.

By David L. Kading, O.D., and Katherine Shen, O.D.

The introduction of the silicone hydrogel (SiHy) lens modality in 1999 opened a whole new world of options for optometrists to recommend and prescribe to patients. Initially intended for extended-wear, SiHy lenses started being used for daily wear around 2003.[1]

Since then, they have secured an increasingly important role in the market and in practice—now accounting for nearly two-thirds of all lens fits and refits.[2] Several studies have concluded that patients achieve greater comfort with SiHy lenses when compared to their hydrogel counterparts. SiHy lenses have shown similar comfort upon insertion, but sustained comfortable wear throughout the day.[3-6]

Despite all the innovations in SiHy lenses, contact lens comfort remains a major issue for patients and optometrists. In a survey of nearly 900 patients, 52.7% of contact lens wearers, 17.4% of spectacle wearers and 7.3% of emmetropes reported dry eye.[7] This poses a significant challenge for patients who seek a high level of comfort with continuous wear of their contact lenses.

Because a significant portion of our contact lens patient base utilizes SiHy lenses, it's vital to understand the inherent hydrophobic properties and to alleviate the issues that patients may encounter because of them.

First, give the lenses a head start by having a uniform, healthy tear film. Maximize comfort by utilizing the appropriate lens, lens-solution combination, care schedule and patient behavior modifications. Remember, it can take some time and experimentation with different options to find a comfortable lens that fits the patient's lifestyle and clinical needs.

When it comes to finding the right fit with a silicone hydrogel lens, let's look at the four most important factors you should consider: the ocular surface, the lens and materials, the solution and its biocompatibility, and patient compliance.

The Ocular Surface

It's not a surprise that patients with a compromised ocular surface find contact lenses difficult to wear. But, by identifying specific markers, we can help our patients achieve more successful, more comfortable lens wear. Throughout the ocular examination, it's crucial to keep all aspects of the ocular surface in mind and to take

For patients with decreased tear production presumed to be due to ocular inflammation associated with chronic Dry Eye

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note of how one component can have a negative effect on the next.

Blepharitis has several factors that need to be evaluated. First, you'll want to look for any signs of anterior blepharitis—the classic red eyelid, often accompanied by crust and flakes. This condition can have a dramatic effect on the patient's overall ocular comfort, and contact lens wearers may not be able to differentiate this type of discomfort from that which they may experience with their typical contact lens wear. Often, you can pinpoint anterior blepharitis because patients experience a generalized irritation and an itchy sensation.

Perhaps the more significant component of blepharitis that contact lens wearers encounter is posterior blepharitis or meibomian gland dysfunction (MGD). In March 2011, the International Meibomian Gland Dysfunction Workshop published a report that was created with the collaboration of more than 50 experts over two years. It defines MGD as "a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion."[8]

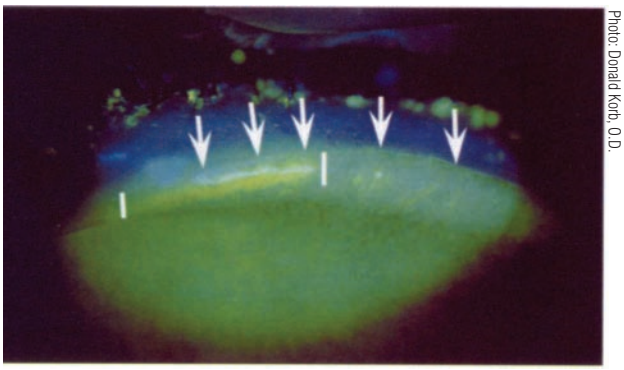


Photo: Donald Korb, O.D.

Lid wiper epitheliopathy may increase the sensitivity of the cornea and traumatize the corneal epithelium.

This may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation and ocular surface disease. Although treatment of MGD is still debated, appropriate interventions should be determined based on severity and symptoms. Common treatment options include the use of warm compresses, omega-3 fatty acids, topical azithromycin, oral tetracyclines, gland expression or probing, topical cyclosporine and artificial tears.

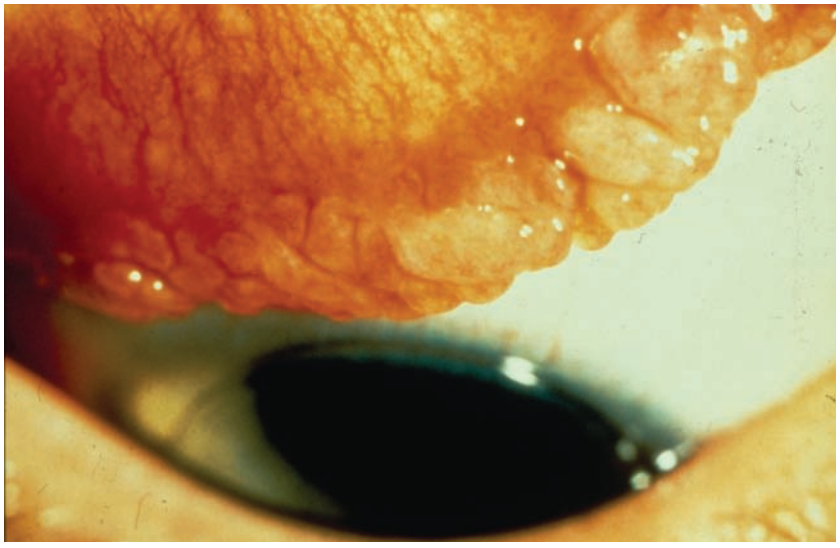
In addition to evaluating the lids for blepharitis, you should carefully perform a lid eversion to look for signs of giant papillary conjunctivitis (GPC) or

lid wiper epitheliopathy (LWE). Evidence of GPC on the upper eyelid often indicates hypersensitivity or mechanical damage from contact lens wear.

This lid wiper region is the area of the lid that slides over the ocular surface, cleaning and restoring the protective tear layer. One study showed that 76% of contact lens wearers who were symptomatic for dry eye had staining in this area, indicating LWE.[9,10] This condition may traumatize the corneal epithelium and increase the sensitivity of the cornea, so patients with LWE need lenses or solutions that decrease mechanical stress.[10] It can help to switch the patient to a contact lens that has a smoother surface, recommend that they rub the lenses during cleaning, and suggest a new solution for a more wettable lens surface (with a lower coefficient of friction) that decreases protein and lipid build up.

Beyond the lids, it's important to assess the quality and quantity of the tear film. Through the use of a phenol red threat test or simple evaluation of the tear meniscus, a skilled clinician can evaluate a patient's volume of tears. But perhaps even more important than the volume is the quality of the tears. You can determine the tear quality by evaluating tear film break-up time and tear osmolarity, as well as examining the corneal surface. Patients with decreased quantity and quality may benefit from artificial tears, punctual plugs, Lacrisert (Aton Pharma) inserts or topical cyclosporine.

Finally, inspect the cornea for staining. Some patients may have corneal staining due to contact lens wear or improper contact lens solution use, while others may have developed staining due to dry eye disease. You can better understand the etiology by looking at the location, depth and amount of staining present. Many optometrists use artificial tears, topical cyclosporine or anti-inflammatory drops to decrease staining.



Evidence of giant papillary conjunctivitis on the upper eyelid frequently indicates hypersensitivity or mechanical damage from contact lens wear.

Lens Material

In the late 1800s, the first successful contact lenses were fitted. Made from glass, they caused considerable eye irritation and were not wearable for an extended period. It wasn't until the 1930s that contact lenses became more convenient when William Feinbloom, O.D., Ph.D., introduced the first rigid corneal contact lens with polymethyl methacrylate (PMMA), a hard plastic alternative to glass. However, one of the most significant adverse effects to these "hard" lenses was the lack of oxygen permeability, because they did not allow any oxygen to be transmitted to the cornea. In the 1970s, the first rigid gas-permeable (RGP) lenses became available, offering improved oxygen permeability.

Since then, the industry has continued to experiment with polymer composition in order to enhance their quality and allow more oxygen permeability. After decades of research and hypothesis, the first readily available silicone hydrogel lenses hit the market in 1999. With the introduction of silicone as the major carrier for oxygen, the incidence of corneal edema and chronic oxygen deprivation decreased considerably.

However, silicone presents one major problem—it is innately hydrophobic. This is an issue for a lens that must remain constantly wettable on the surface of the eye. In order to partially compensate for the dryness, hydrogels were added to make the lens moister. But, even with the addition of hydrogels, the lens surface still remains extremely hydrophobic, which makes the lens unbearable to wear.

Fortunately, researchers discovered that surface-wetting agents, plasma treatments or material chemistry to hide the silicone could make the lenses more comfortable.[11] (*See "Maintaining Moisture," page 55.*)

Contact Lenses

Four companies—Johnson & Johnson, Bausch + Lomb, CIBA Vision and CooperVision—manufacture the vast majority of SiHy contact lenses sold in the United States. They represent both the two-week and one-month modalities. Most recently, Johnson & Johnson released its 1-Day Acuvue TruEye (narafilcon B dk/t 61.1) lens to the market, signaling the beginning of a new phase in silicone hydrogel lenses: the single-use SiHy product.

Although there were initial concerns about the high cost of single-use high oxygen permeable lenses and questions about whether there was need for such a product, the market received them very favorably. The industry will likely continue to see further enhancement of this modality, with other manufacturers releasing similar products.

One of the most exciting innovations the SiHy industry saw over the past two years was the introduction of custom, lathable SiHy lenses.

One of the most exciting innovations the SiHy industry saw over the past two years was the introduction of custom, lathable SiHy lenses. Although spherical, the O_2OPTIX Custom lenses previously available from CIBA Vision (discontinued in 2011) had limitations. In early 2011, Contamac introduced the Definitive material (Efrofilcon A dk 60), which is available in the United States through proprietary lens designs from four manufacturers—Art Optical, Metro Optics, X-Cel Contact Lens and Unilens. These companies manufacture custom lenses from silicone hydrogel materials in various designs, including sphere, toric, multifocal, toric multifocals, reverse geometry and keratoconus.

Wettability

For a long time, many in eye care considered contact lens solutions and lens materials two separate entities with very little effect on each other, but the introduction of SiHy lenses was a game-changer. Within the cornea, a layer of mucin hides the hydrophobic cell membrane. When this layer is disrupted, the tears interact causing a lower tear film break-up time or corneal staining.

When patients are not wearing contact lenses, they have a thick tear film covering their corneal surface.

Contact lenses are not just an extension of the cornea; the rich tear film must split in order to create an anterior and posterior lens interface. Thus, a patient's base tear film break-up time usually is lower when wearing contact lenses.

Contact lenses have both hydrophilic and hydrophobic properties. The long chain organic polymers contain both hydrophilic and hydrophobic groups, which cluster in relatively dry or wet areas. In essence, the state of the ocular surface will dictate the chemistry of the lens surface.[12] When the eye is dry (hydrophobic), then the organic hydrophobic lens properties cluster at the surface.

For example, if a patient has a decreased tear film break-up time, the surface environment will draw the hydrophobic polymers of the lens to the surface. This will create a lens that becomes increasingly dry as the day goes on. The hydrophobic polymers are now attracted to a hydrophobic surface and become a very stable interface. It would require a significant amount of energy to break this bond. In addition to attracting other dry areas, the lens surface is now attracted to lipids, which can bind and create a dirty and uncomfortable lens as the day goes on.

Conversely, if a contact lens surface is very moist, through a quality tear film and moist lens surface, then the hydrophilic polymers will rotate to the surface, which creates a more comfortable lens-wearing experience. Lens solution manufacturers have incorporated the latest technological advances to create solutions designed to decrease lipids and proteins, while maintaining a moist wettable surface that lasts all day. By sustaining a wettable, moist surface, the hydrophilic components of the lens will be drawn to the surface and the hydrophobic polymers will stay hidden.[12]

Maintaining Moisture

Several contact lens manufacturers have set their brands apart from one another by using unique formulas to offer better wettability.

- Johnson & Johnson incorporates a wetting agent into the matrix of their Acuvue Advance with Hydraclear (galyfilcon A dk/t 85.0) and Acuvue Oasys with Hydraclear Plus (senofilcon A dk/t 147.1).
- Bausch + Lomb's PureVision (balafilcon A dk/t 110.0) and PureVision 2 HD (balafilcon A dk/t 130.0) line of lenses utilizes a plasma surface treatment.
- CIBA Vision's Air Optix Night and Day (lotrafilcon A dk/t 175.0) and Air Optix Aqua (lotrafilcon B dk/t 137.5) maintain their wettability by incorporating a plasma coating.
- CooperVision's Biofinity (comfilcon A dk/t 160.0) and Avaira (enfilcon A dk/t 125) utilize a manufacturing technique that isolates the silicone chains inside the matrix of the lens.

* The toric and multifocal designs from each of these manufacturers incorporate the same wetting system as their sphere counterparts.

Solution Biocompatibility

A 2002 study revealed issues with certain SiHy lens materials and multipurpose solutions (MPS).[13] The awareness that not all lens solution combinations are compatible has led to an influx of research and product development. During a contact lens exam, it's essential to evaluate the eye for any perilimbal injection, generalized hyperemia or corneal staining.

Also, examine the cornea for any signs of corneal infiltrates or prior peripheral scars that could relate to a contact lens-induced peripheral ulcer (CLPU). In some cases, it may be necessary to discontinue contact lens wear until the condition clears, and then switch the patient to a contact lens solution that is more compatible. In recent years, many optometrists have taken a much more active role in recommending contact lens solutions.

By specifically asking patients which solution they use and how they use it, optometrists can get a better handle on how to choose the most appropriate solution for the patient. When making a solution recommendation, explain to patients that it's important for their health and comfort to use the lens-solution combination you have prescribed.

Patient Compliance

Just about every optometrist has become accustomed to seeing health and comfort issues that crop up in patients who do not care for

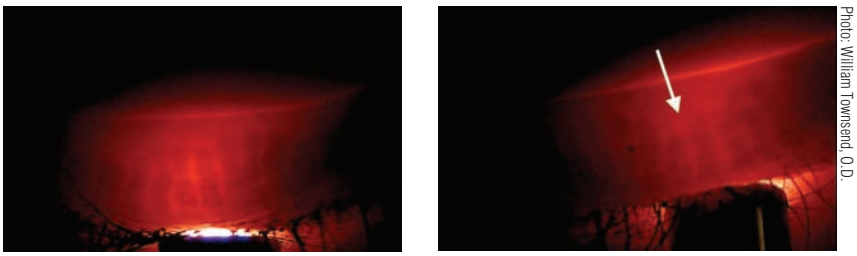
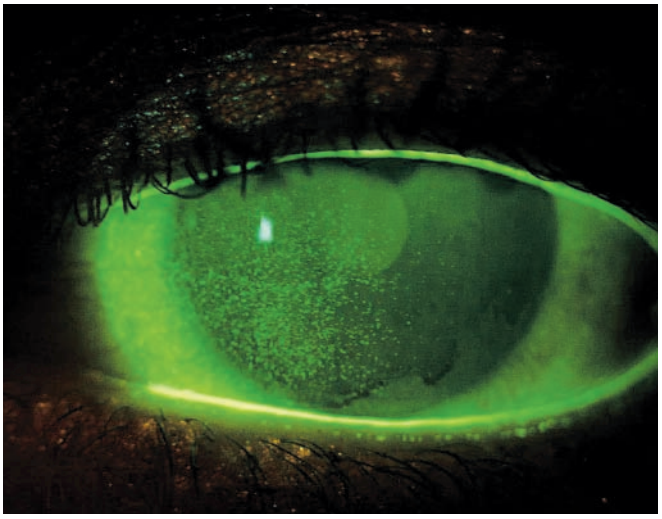


Photo: William Townsend, O.D.

A biomicroscopic photograph of eyelid transillumination of normal meibomian glands (left). Contact lens-associated meibomian gland loss is more common in the upper eyelids (right).

their lenses correctly. Because lens contamination frequently stems from the hands, hand washing should be stressed during initial lens training.



Some patients may have corneal staining due to contact lens wear or improper contact lens solution use, while others may have developed staining due to dry eye disease.

One study found that 35% of patients do not wash their hands prior to lens insertion or removal, and 42% wash their hands but leave them wet with tap water.[14] Placing a contaminated lens into the eye following a thorough lens cleaning is counterproductive. Teaching patients a system that stresses hand washing is critical for lens cleanliness and wettability, which are essential factors in successful SiHy lens wear.

In the same study, researchers discovered that 52% of patients place their lenses directly in the case following removal.[14] With SiHy lenses having inherent wettability issues, it's vital for patients to diligently follow the manufacturer's recommendation for cleaning. This is not only important for cleaning the lipids that can build up, but also to replenish the wettability of the lens surface.

Contact lens replacement schedules vary depending on the lens type used. In one study, compliance with the manufacturer's recommended replacement frequency (MRRF) was 88% for daily disposable lenses, 72% for monthly replacement lenses and 48% for two-week lenses.[3]

When asked: "What was the primary reason that you wear your lenses longer than recommended?" Fifty-one percent of respondents said the primary reason was "Forgot day to replace."[3] In another study, patient comfort and vision was evaluated in relation to the compliance of lens replacement in one-month and two-week lenses.[15] The authors found that patients achieved a higher level of end-of-day comfort and better vision when they followed the MRRF. They noted that patients must replace their SiHy lenses to achieve the best subjective performance.[15]

When it comes to compliance, we can't call our patients on a daily basis to emphasize the importance of following our prescriptions and recommendations; however, we can look for simplified lens recommendations, habits and products that promote compliance while we have them in the exam room. By doing this, we can promote a safer, more comfortable experience for our SiHy lens-wearing patients. ■

Dr. Kading owns Specialty Eyecare Group, a Seattle-based practice with multiple locations. His emphasis is on specialty contact lenses and new technologies.

Dr. Shen is an associate at Specialty Eyecare Group, where she specializes in pediatrics, binocular vision and ocular pathology.

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Case Report

The Heart of the Problem

As illustrated in this case, branch retinal artery occlusions are most often caused by emboli in patients with cardiovascular risk factors.

By Jeff Cohen, O.D., and Susannah Marcus-Freeman, O.D.

A 71-year-old black male presented to the Gainesville Veteran's Affairs ophthalmology clinic complaining of vision loss in the inferior field of his left eye, which had persisted for two days. He stated that his vision was "dark at first, but now blurry—like looking through water." He denied any pain, trauma or discharge from his left eye, and said that he did not have any flashes, floaters or a curtain coming into his vision. In addition, he denied any jaw claudication, scalp tenderness, fatigue or headaches that were consistent with giant cell arteritis.

The patient's medical history was significant for hypertension, hyperlipidemia, cardiomyopathy, insulin-dependent diabetes mellitus, benign prostatic hyperplasia and deep vein thrombosis. His current medications included 0.125mg digoxin q.a.m. and 200mg metoprolol succinate q.d. for cardiomyopathy; 10mg glipizide b.i.d. and 100 units/mL insulin for type 2 insulin-dependent diabetes; 25mg hydrochlorothiazide/37.5mg triamterene q.d., 100mg losartan q.d., 40mg lisinopril q.d., and 30mg nifedipine t.i.d. for hypertension; 20mg rosuvastatin q.d. for hyperlipidemia; 2mg terazosin for benign prostatic hyperplasia; and 81mg aspirin q.d. for stroke and heart attack prevention.

His last eye exam was more than two years prior, and revealed mild non-proliferative diabetic retinopathy, mild hypertensive retinopathy, an epiretinal membrane and symptomatic dry eye syndrome in both eyes.

Diagnostic Data

Best-corrected visual acuity was 20/25 O.D. and 20/40- O.S. Confrontation fields were full in the right eye, but severely constricted in the inferior half of his left eye. Amsler grid testing was normal in the right eye, but revealed an inferior scotoma in the left eye. Anterior segment evaluation by slit lamp showed a few sebaceous cysts on both lower lids; quiet bulbar conjunctivae; mild corneal arcus

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without keratopathy in both eyes; deep and quiet anterior chambers without cells or flare and brown, flat and intact irides—without any rubeosis. On Goldmann applanation testing, his intraocular pressure (IOP) measured 14mm Hg O.U. We dilated the patient with one drop of phenylephrine 2.5% and one drop of tropicamide 1%.

We evaluated the posterior segment using a slit lamp, a 90D lens and binocular indirect ophthalmoscopy with a 20D lens. The crystalline lens showed 2+ nuclear sclerotic cataracts and 2+ anterior cortical cataracts O.U.

The fundus examination of the right eye revealed a clear vitreous, a 0.35/0.35 cup/disc ratio with good perfusion of the neuroretinal rim, and an artery/vein ratio of about 1/2 with mild arteriolar attenuation. The macula was flat, and the periphery was flat and intact with scattered areas of white without pressure.

The fundus examination of the left eye revealed a clear vitreous; a 0.45/0.45 cup/disc ratio with mild temporal pallor of the disc, an artery/vein ratio of 1/2 with mild arteriolar attenuation, and a sclerosed vessel, box-carring and refractile plaques emanating from the superior portion of the optic nerve head (*figure 1*). The macula of his left eye appeared diffusely pale and edematous superior to the fovea, and the periphery was flat and intact with scattered areas of white without pressure.

A fundus examination of the right and left eyes revealed Hollenhorst plaques causing blockage of the superior temporal artery with surrounding retinal edema.

Differential Diagnoses

The differential diagnoses in this case included:

• ***Central retinal artery occlusion*** (CRAO), which usually manifests as superficial whitening of the retina in the posterior pole and a cherry red spot in the center of the macula. Visual acuity is normally finger counting or worse, with a marked afferent pupillary defect (APD).[1]

• ***Branch retinal artery occlusion*** (BRAO), which presents as a focal, wedge-shaped area of retinal whitening with a retinal emboli (or Hollenhorst plaque) visible in 62% of cases. Patients are usually in their seventh decade, and typically have hypertension, carotid occlusive disease and/or diabetes mellitus.[1]

• ***Ophthalmic artery occlusion***, which presents with marked constriction of retinal vessels and marked retinal edema often without a cherry red spot. Visual acuity is severely reduced to the level of light perception or even no light perception.[1]

• ***Inflammatory or infectious retinitis***, which may manifest as areas of retinal whitening or edema caused by a variety of infectious (herpes simplex virus, candidiasis, cytomegalovirus or toxoplasmosis) or inflammatory agents (Vogt-Koyanagi-Harada syndrome, sarcoidosis, serpiginous choroidopathy or Behçet's disease).[1,2]

Diagnosis

Because the patient's best-corrected visual acuity was 20/40 O.S. and there was no evidence of a cherry red spot in the macula, a diagnosis of CRAO or ophthalmic artery occlusion were excluded. Based on the findings of visible retinal emboli in the superior temporal arcade, a coinciding inferior altitudinal visual field defect and an area of retinal whitening within the distribution of a branch retinal arteriole, we diagnosed the patient with a BRAO O.S.

We performed spectral-domain optical coherence tomography (SD-OCT) and confirmed a large area of edema located just superior to the macula O.S. We then sent the patient directly to a retinologist for immediate evaluation. Intravenous fluorescein angiography (IVFA) showed normal perfusion in the right eye, and significantly delayed filling with an evident plaque in the superior arcade of his left eye (*figure 2*).

We alerted his primary care physician of the patient's BRAO, and the retinologist recommended a complete cardiovascular evaluation, including an echocardiogram and carotid Doppler study.

We scheduled the patient to return to the retina clinic in one month for follow-up care. IVFA showed significantly delayed filling

FOR PATIENTS IN NEED OF ADJUNCTIVE IOP LOWERING

EXTEND YOUR REACH

with ALPHAGAN® P 0.1%

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ALPHAGAN® P is contraindicated in neonates and infants (under the age of 2 years) and in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

WARNINGS AND PRECAUTIONS

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.

Alphagan® P
(brimonidine tartrate ophthalmic solution) 0.1%

ALLERGAN

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%

with an evident plaque located in the superior arcade of his left eye.

Follow-up Care

Visit 1

The patient returned to the retina clinic six weeks later. His best-corrected vision was 20/25- O.D. and 20/30-2 O.S. As measured by Tonopen (Reichert), IOP was 12mm Hg O.D. and 11mm Hg O.S.

Anterior segment was unremarkable, except for moderate nuclear sclerotic and cortical cataracts O.U. The irides were flat and intact, brown, and without rubeosis. Gonioscopy of the left eye revealed an open angle visible to the ciliary body band, mild iris processes and no evidence of neovascularization.

Dilated fundus exam of the left eye revealed a clear vitreous cavity, and a 0.45v/0.45h optic nerve with mild temporal pallor of the disc. The vessels looked attenuated with a severely sclerosed retinal artery emanating from the superior optic nerve head.

The macula appeared pale with about two disc diameters surrounding edema superior to the foveal avascular zone. The periphery was flat and intact, with scattered areas of white without pressure.

The patient was scheduled for a carotid Doppler test two weeks from the visit. Again, the retinal specialist recommended obtaining an echocardiogram. The patient was advised to control his blood pressure, blood sugar and cholesterol to prevent further complications. We scheduled him to return to the retina clinic in six weeks.

Visit 2

The patient returned to the ophthalmology clinic one month later complaining of a black-brownish floating spot he had in his left eye for four days. He denied the presence of any pain, flashes, curtain in his vision or new visual field loss. His best-corrected vision was 20/25- O.D. and 20/40+2 O.S. As measured by Tonopen, his IOP was 13mm Hg O.D. and 11mm Hg O.S. The anterior segment of the left eye was unremarkable except for the aforementioned cataracts, and there was no rubeosis present.

A dilated fundus exam of the left eye now revealed a 1/6 disc diameter preretinal hemorrhage located just inferior to the optic nerve head, with an adjacent retinal tuft and small particle vitreous hemorrhage. The optic nerve head now displayed some sectoral pallor inferiorly and temporally without shunt vessels present. The macula still appeared swollen just superiorly, and the periphery was flat and intact with no evidence of tears, breaks, holes or retinal detachment.

The carotid Doppler test completed two weeks prior revealed <49% stenosis of the right and left internal carotid arteries. The patient's primary care physician was again alerted about the risk of mortality in patients with retinal artery occlusions, and further evaluation including echocardiogram and embolic work-up was recommended. We educated the patient on his exam findings and scheduled him to return to the retina clinic in one month.

The ophthalmologist recommended possible sectoral retinal photocoagulation if neovascularization became apparent once the vitreous hemorrhage resolved. We instructed the patient to return to the clinic immediately if he noticed any new floaters or changes in vision.

Visit 3

The patient returned to the ophthalmology clinic one month later for follow-up. He denied any changes in vision since the last visit. His best-corrected vision was 20/40 O.D. and O.S. Measured by Tonopen, his IOP was 14mm Hg O.D. and 15mm Hg O.S. The anterior segment of the left eye was unchanged.

A dilated fundus exam of the left eye now revealed possible neovascularization of the disc inferiorly, a cotton wool spot just nasal to the optic nerve head, and scattered dot and blot hemorrhages in the posterior pole. The macula still appeared swollen just superiorly, and the periphery was flat and intact with no evidence of tears, breaks, holes or retinal detachment.

We counseled the patient on the exam findings. The retinal specialist did not perform any retinal photocoagulation at this time. He wanted to evaluate the patient in two months to monitor for any worsening of the presumed neovascularization. We advised the patient to return to the clinic immediately if his symptoms changed.

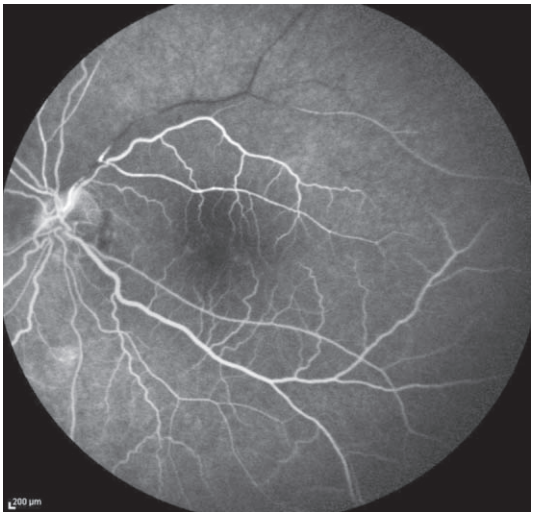
Discussion

Clinical features

BRAOs are caused by a blockage in a branch of the central retinal artery leading to retinal ischemia in the affected area. They represent approximately 38% of all acute retinal artery obstructions.[3] The main cause of this acute event is often an embolus that has traveled from another part of the body, becoming trapped in a vessel too narrow for passage.[4] The point where the blockage occurs dictates the nomenclature (branch, twig, hemiretinal or central retinal artery occlusion). If the embolus were to become lodged

at the lamina cribrosa, a central retinal artery occlusion would result.

Sometimes, however, the embolus is small enough to traverse the narrowing of the central retinal artery at the lamina cribrosa and become stuck in the smaller-caliber retinal arteries, resulting in a BRAO.[4] Once this occurs, anoxia takes place in the inner two-thirds of the retina, including the nerve fiber layer, ganglion cell layer, inner plexiform layer and the inner portion of the inner nuclear layer. The outer third of the retina remains uncompromised, as its perfusion is supplied by the choroid. A study on rhesus monkeys proved that irreversible retinal necrosis occurs after 105 minutes of ischemia, but showed good recovery prior to 97 to 98 minutes of ischemia.[5]



A magnified view of the affected artery.

Symptoms typically are sudden, unilateral and painless and include partial loss of vision. One study showed that ocular arterial occlusions can occur at any time; however, 65.1% of the surveyed population noticed visual deterioration during the daytime (between waking up and going to sleep).[6] Patients often complain of a visual defect that corresponds with the site of the occlusion. A visual field test typically will show a superior or inferior altitudinal defect. Pupil examination may show an APD, depending on the size of the retinal infarction.

A careful case history may reveal that the patient had experienced previous episodes of amaurosis fugax, prior cerebrovascular accidents or other types of transient ischemic attacks. Visual acuity can range from 20/15 to finger counting, depending on the extent of macular involvement. The visual prognosis after a BRAO is favorable; one study found that 89% of eyes initially presenting with best-corrected visual acuity of 20/40 or better retained that vision after 14 months follow-up time.[7]

Depending on the timing, a dilated fundus exam of a fresh lesion will show a wedge-shaped area of superficial whitening within the zone affected by the BRAO.[2] This phenomenon occurs due to ganglion cell necrosis, resulting in intracellular edema. Over several weeks, the retinal whitening resolves and the retina regains a relatively normal appearance. Although a rare finding, collateral blood vessels may form in the weeks and months following a vascular occlusion. These anomalous vessels represent an anastomosis between the obstructed arteriole and adjacent healthy arterioles in an attempt to re-perfuse the retina.[8] BRAOs usually occur at bifurcations, most commonly in the superior temporal retina.[9] Retinal or iris neovascularization is fairly uncommon, unless ocular ischemic conditions, such as diabetes mellitus or carotid occlusive disease, are present.[1]

Fundus fluorescein angiography will show delayed or absent filling in the affected branch, delayed arteriovenous transit time, reduced arterial caliber (attenuation) and segmental "box-carring" or "cattle-trucking" of the blood column.[10] Also, the appearance of retrograde filling of the occluded branch retinal artery can help determine the prognosis of the vascular occlusion.[11] Retrograde filling indicates a means of collateral circulation from the adjacent arterioles and capillaries.[11] Despite this, retinal degeneration in the affected area still occurs because the blood supplied by the capillaries is incapable of delivering an adequate supply of oxygenated blood.[12] Even though it is called a "branch retinal artery occlusion," the circulation is often markedly delayed, but never totally interrupted.[12]

In addition to fluorescein angiography, noninvasive instruments such as OCT and SD-OCT can be used to histopathologically monitor changes in the retina. OCT scans of a BRAO show high reflectivity corresponding to the edematous inner retinal layer and a hyporeflective signal corresponding to the photoreceptor layer.[13] The OCT can identify shrinkage and thinning (from neural cell loss) to a final thickness of 60% of a normal healthy retina.[14] This finding can be used clinically, as a visual field defect can correspond to an atrophied retinal area despite a normal ophthalmoscopic appearance long after a BRAO has occurred.[14]

However, SD-OCT is much better in detecting pathological changes in the individual layers of the retina. It can be used

to monitor changes in the foveal inner-segment-outer-segment line, which can be helpful in monitoring structural integrity of the photoreceptor layer despite atrophic changes in the inner retinal layers.[13] Additionally, our Spectralis (Heidelberg Engineering) SD-OCT unit is equipped with TruTrack technology, which allows imaging of identical points on the retina at different time periods, with high correlation.[13]

Multifocal electroretinograms (MERGSs) can also identify damaged areas of the retina in patients with a BRAO. Both the first- and second-order MERGs are useful in evaluating retinal function; however, the second-order MERGs are more sensitive in detecting damage to the inner nuclear layer, inner plexiform layer, the ganglion cells and the nerve fiber layers.[15] Although MERGs are not commonly used in all clinical settings, they are highly useful since a BRAO damages the inner two-thirds of the retina.

Etiology

By far, the most common cause of a BRAO is an embolus. The three most common types of emboli are cholesterol, calcific and platelet-fibrin.[12] Other less common types include emboli from tumors, inflammation, bacteria, parasites, fungi, amniotic fluid or impurities injected into the bloodstream from intravenous drug use.[12]

The carotid artery and the heart are the two most common sources. In the carotid artery, emboli often originate from atheromatous disease (plaque). In the heart, emboli often come from aortic and mitral valvular lesions, tumors of the left atrium, myxomas or patent foramen ovales.[16] Once the embolus dislodges from a vessel wall, it travels through the bloodstream until it reaches a site where it is too large to pass through. In this case, the emboli were small enough to pass through the lamina cribrosa and not cause a CRAO, but large enough to occlude a branch retinal artery.

The cholesterol embolus is the most common type of retinal embolus seen.[17] These emboli often appear slightly larger than the blood vessel they are within, and are usually clumped as multiple tiny yellow crystals at the bifurcation.[17] They often reflect brightly, depending on the angle of the light source. At times, they may not be visible ophthalmoscopically, but will shine a golden-orange with light digital pressure on the eye.[18]

Cholesterol emboli will travel distally until they disappear from the branch retinal artery over the course of hours, days or weeks. Periarteriolar sheathing may be visible, indicating the earlier presence of a cholesterol embolus.[18] When sheathing occurs at an arteriolar bifurcation, it is referred to as "pants leg sheathing," which is pathognomonic of prior embolism.

Emboli are most frequently seen in the temporal retina by a 7:1 ratio, more so superiorly than inferiorly.[17]Calcific emboli appear as solid, dirty yellowish-white colored lesions that do not shine with induced pressure. They have a tendency to become lodged in first- or second-order arteries, and often overlie the optic disc.[18] They are larger than cholesterol emboli and more likely to occlude a vessel totally, remaining within the vessel forever. For that reason, they are more likely to produce a total or sectoral permanent loss of vision.

Platelet-fibrin plaques appear as dull, gray-white, mobile materials that tend to defragment as they travel throughout the vasculature. Also called "fisher plugs," these emboli are difficult to observe due to their migratory behavior. Patients with platelet-fibrin plaques may be asymptomatic, may complain of amaurosis fugax or may have a BRAO.[19] They presumably arise from ulcerative plaque of the ipsilateral internal carotid artery or from abnormal heart valves.

Laboratory Testing

Patients who present with either a CRAO or BRAO need an investigative workup to determine the underlying etiology. If the patient is 50 years or older, often the erythrocyte sedimentation rate (ESR) is ordered to rule out GCA. The clinician should also ask about cardinal symptoms of giant cell arteritis that include antecedent headache, jaw claudication, scalp tenderness, joint aches, recent weight loss or fever. Although the patient may deny any of those symptoms, the ESR should be ordered. Westergren ESR testing is the most reliable method, and the normal values for men are age divided by two and age plus 10 divided by two, for women. BRAO associated with GCA is relatively uncommon.

If the ESR is elevated or there is clinical suspicion of GCA, a temporal artery biopsy should be performed. Additionally, a C-reactive protein (an acute phase protein released in the bloodstream by the liver) is often ordered to determine the level of inflammation. A recent study reported that high levels of C-reactive protein correlate more with atherosclerosis and future risk of a life-threatening vascular event, and was not significantly elevated in patients with a retinal

artery occlusion.[20] The significance of increased C-reactive protein in patients with a retinal artery occlusion is probably due to risk factors such as essential hypertension, heart disease, hyperlipidemia and diabetes mellitus that can contribute to the vascular occlusive event.[20]

Systemic workup should also include checking blood pressure and pulse, carotid palpation and auscultation, fasting blood sugar, glycosylated hemoglobin, complete blood cell count with differential, and prothrombin time/partial thromboplastin time (PT/PTT). If the patient is less than age 50 or has appropriate risk factors, also consider a lipid profile, anti-nuclear antibody, rheumatoid factor, fluorescent treponemal antibody, serum protein electrophoresis, hemoglobin electrophoresis and anti-phospholipid antibodies.[2]

A carotid artery evaluation with Doppler ultrasonography and cardiac evaluation with echocardiography is warranted, because these patients likely have systemic comorbidities. Patients with both the presence of a visible retinal embolus and a BRAO have been shown to have a worsened survival prognosis.[21] A recent study indicated that echocardiographic studies positively identified potential sources of emboli in the heart or aortic arch in 16 of 73 patients with retinal arterial occlusive events.[22]

Treatment and Management

Although there is not a single proven modality of treatment for a BRAO, there have been numerous hypothesized and attempted treatments aimed at increasing the perfusion pressure of the retinal circulation or dislodging the disrupting emboli. Retinal perfusion pressure may be increased by reducing the IOP, dilating the ophthalmic and central retinal arteries, or increasing the ophthalmic artery pressure.[10] Oral acetazolamide (Diamox 500mg tablets, Barr Pharmaceuticals) can reduce the IOP as low as 5mm Hg very quickly, and has shown some benefit in the acute stage.

Anterior chamber paracentesis can also lower IOP dramatically; however, this modality is more controversial. A maximum increase in retinal perfusion of only 20% has been reported from animal studies; additionally, ophthalmologists may feel discouraged to perform this procedure due to the risk of complications and the need to repeat the paracentesis every two hours to maintain low IOP.[10] Digital ocular massage, retrobulbar administration of vasodilating drugs and inhalation of carbon dioxide (from breathing into a paper bag or the premixed preparation carbogen) have been used to treat the acute stages of BRAO by activating the retinal auto-regulatory mechanisms.

The evidence shows that BRAOs are most often caused by emboli in patients with cardiovascular risk factors. Theoretically, visual recovery should be possible if started within the first few hours of the acute phase; however, most patients do not present in that narrow time period, and it is nearly impossible to recover ganglion cell loss after that critical period. Although there is still no proven treatment, optometrists should investigate for any carotid or cardiac conditions, because these patients have a significantly increased risk for stroke, heart attack or even death. ■

Dr. Cohen completed his residency at the Malcom Randall VA Medical Center in Gainesville, Fla., in June 2010. He now practices in a commercial setting in West Los Angeles. Dr. Marcus-Freeman is a staff optometrist and optometry residency coordinator at the Malcom Randall VA Medical Center.

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Annual Pharmaceutical Issue

Generic vs. Brand Drugs: Which is Better?

The cost savings of generic latanoprost may improve compliance, for example, but does the generic "equivalent" work as well as the brand-name drug?

By Edward Chu, O.D., and Ania Hamp, O.D.

Which is better: a $100 bottle of brand-name Xalatan or a $25 bottle of generic latanoprost? Seems like an easy question with an obvious answer, right? Your patient and the patient's pharmacist may certainly think so, and have no qualms choosing the much cheaper generic. However, should you be as cost-conscious? After all, if the generic does not work properly, then even the $25 is a waste—and the patient's vision may be at risk. Sometimes, you do indeed get what you pay for.

On the other hand, generic drugs work well enough most of the time and they offer very real cost savings—not only to individual patients, but also to the health care system as a whole.

When is it best to prescribe the generic or the brand-name drug? It's a confounding question. But with a little more information—which we'll cover in this article—hopefully you will have a better grasp on how to answer it for individual patients.

Based on Bioequivalence

While the initial brand-name company must submit to rigorous drug testing and lengthy clinical trials when applying to the Food and Drug Administration (FDA), companies that produce generic medications merely submit to an abbreviated form of the approval process. Safety and efficacy do not have

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to be proven or established with generics because thorough testing on the branded medication has presumably already been conducted. Companies merely have to show the FDA that their drugs are bioequivalent to the brand.[1] Currently, in order to prove bioequivalence, scientists need to prove that the generic is in an acceptable +/- range of labeled concentration. Typically, this is accomplished by ensuring that the generic version releases its active ingredient in the bloodstream at the same speed and in the same amount as the branded drug.[1]

While this is relatively easy to measure with systemic medications, bioequivalence of ophthalmic drugs cannot reliably be tested in the same way. Moreover, bloodstream concentrations of an ophthalmic medication applied directly to the eye are likely not important in assessing its efficacy. So, the FDA's only stipulations for ophthalmic generic medications is that they contain the same concentration of the active ingredient, dosage and route of administration.[2]

Without true bioequivalence testing for ophthalmic medications, eye care practitioners must assume that they work equally well; however, we all know this is not always the case. Most eye care providers likely remember the series of patients in the early 2000s who experienced corneal melts associated with the use of generic diclofenac ophthalmic solution (as opposed to the brand-name Voltaren) after ocular surgery. In one article, three in five patients who experienced a corneal melt were taking generic diclofenac, and four patients eventually progressed to corneal perforation that required a transplant.[3]

Potential Problems with Generics

Doctors and health policy analysts largely agree that generic medications can bring significant savings to health care costs. A 2002 study by the Schneider Institute for Health Policy at Brandeis University indicated that if generic usage was increased by Medicare recipients, there could be theoretical savings in billions of health care dollars.[4] A 2005 report estimated that for every 1% increase in generic drug use, overall spending on prescription drugs would be reduced between $1.3 to $4 billion annually.[5]

Generic medications are only required to have the same concentration of the active ingredient—so the inactive ingredients and the preservatives are often different.

On the other hand, it is possible that doctor follow-up visits may increase in number and/or frequency if the insurance company or the patient makes the decision to switch to generic medications. This could effectively nullify the health care savings.

Especially with glaucoma medications, some practitioners may be more inclined to bring patients back sooner to check the efficacy and tolerability of the generic medication than they normally would if no switch had occurred. Due to the increasing number of generic manufacturers and the potential for differing efficacy between generics, one glaucoma specialist has gone as far as to recommend tracking each type of generic by having their patients bring in the bottles to each visit. By doing this, he can track each type of generic and watch for patterns of efficacy and tolerability.[6]

While the FDA sets definitive guidelines for generic drugs produced in the United States, overseas manufacturing factories may not be monitored as closely. Although a firm's application to the FDA must include a full description of the facilities it uses for manufacturing, testing and packaging, there may be budgetary restrictions that prevent every facility overseas from being inspected on the same schedule as those in the U.S.[7]

There is also concern over the ingredients in generic medications coming from possible sources with less oversight, such as India and China. For example, a 2005 study found that 20% of generic ciprofloxacin eye drops purchased in India were under-potent, and some preparations of the antibiotic content were low enough to negatively affect treatment outcomes.[8]

With generic medications, an increase in allergy symptoms from one month to the next can occur if there is a difference among manufacturers in the preservatives and/or inactive ingredients they use. If the pharmacy receives the medication from differing companies on a month to month basis, this could potentially result in more ocular surface toxicity, poor tolerability and patients returning for a "red eye" visit.

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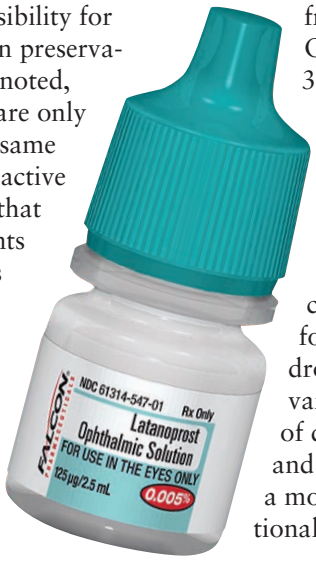
We only need to look as far back as the issues related to Travatan (travoprost, Alcon) preserved with benzalkonium chloride (BAK) to see the possibility for problems with certain preservatives.[9] As previously noted, generic medications are only required to have the same concentration of the active ingredient, meaning that the inactive ingredients and the preservatives are often different. Consequently, an increased number of office visits to check efficacy and tolerability of a generic medication could theoretically cause eye care costs to increase, and offset the savings from the drug's lower price.[6]



The growing number of generic manufacturers may lead to inconsistent bottle appearances and increased patient uncertainty about proper compliance. Producers of generic medications must follow manufacturing standards and comply with labeling regulations, which prohibit generic medication bottles from looking similar to their brand-name counterparts.[10] This may ultimately cause confusion among patients if there is a different cap color, different label color or varying bottle size from month to month. One study found that 36% of individuals said they would be upset or worried if the color or appearance of their medication bottle changed in any form.[11]

Some generic medications have also been found to have different dropper sizes, which may vary the drop size, number of doses in the container, and ultimately the cost of a month's supply.[12] Additionally, concern has been expressed about the plastics used in medication bottles and quality control and what this means in terms of efficacy.[6]

We need to recognize the significance of our role in patient education regarding these potential differences and make sure our patients contact us if they have any questions about their treatment.

Generic Medications: How Do They Come to Market?

Development of innovative drugs is expensive, and without recovering the investment through patent protection, much of the pharmaceutical industry's research and development would stop or slow significantly.[4] Pharmaceutical Research and Manufacturers of America (PhRMA) reports that U.S. biopharmaceutical research companies invested a record $67.4 billion in 2010 in the process of developing and researching new medications and vaccines.[24] The cost to develop just one new drug averages almost $1 billion.

In other words, generic medications are possible only as a result of the large investment and time taken by another company for research and development. So, before generics are put on the market, patent protection is typically given to the developer for an 11-year period so that it may fairly recoup its investment expenses.

Studies on Generics

• ***Glaucoma drops.*** Currently, the generic ophthalmic medication making the most headlines is latanoprost 0.005%, the trade version of Xalatan (Pfizer). Currently, "The Orange Book," the FDA's text containing "Approved Drug Products with Therapeutic Equivalence," lists seven approved manufacturers of generic latanoprost.[13]

The efficacy of generic glaucoma medications is of particular interest in the ophthalmic community. Although the generic may be less expensive and may provide significant savings, there is some concern that generic glaucoma medications do not have the same effect as their trade versions, and the result could be progression of the disease and loss of vision.[14]

However, a recent study that compared generic latanoprost to Xalatan found that both treatments demonstrated comparable safety and tolerability among patients.[15] Take note, though, that 99.6% of the patients in the study were white, so these results may not be the same in African Americans, Asians and Hispanics. Also, one could argue that there may have been investigator bias because Bausch + Lomb, the producer of the generic, conducted the study.

Previously, there had been only one other study conducted on a generic formulation of latanoprost in 2007.[16] The study consisted of 30 patients who were randomized into two groups; they received either Xalatan or a generic latanoprost (Latoprost [Sun Pharmaceuticals], produced in India) for the first 12 weeks, then switched to the other drug for the last 12 weeks. The investigators found that patients who were crossed over from Latoprost to Xalatan experienced a further decrease in IOP. In contrast, when subjects were crossed over from Xalatan

to Latoprost, IOP rose more than 1mm Hg on average. Overall, the generic, which is formulated at a higher pH than the branded product, was found to be less efficacious at lowering IOP.[16]

Concerns have also been raised regarding the prescribing of the generic version of timolol gel-forming solution. Researchers have shown that retention time on the ocular surface differs between various extended-release gel vehicles. Specifically, the gellan gum found in Timoptic-XE (timolol maleate ophthalmic gel-forming solution, Merck) may allow the brand-name medication to have longer surface contact, better absorption and beta-blocker activity intraocularly.[17] In a 2002 study, the branded version of timolol gel-forming solution based in gellan gum was shown to lower IOP better than its generic counterpart based in xanthan gum.[18] Consequently, some individuals in the medical field have proposed that considerations, such as particle size and other properties of a suspension must be evaluated for generic equivalence.[19]

• ***Steroid drops.*** Several studies and cases in recent years have also illustrated the need to exercise caution and vigilance when treating inflammation with ophthalmic steroids. Allergan has noted in its memorandums to doctors that the micro-fine suspension in its Pred Forte (prednisolone acetate) is more uniform, remains longer in the conjunctival sac and minimizes mechanical irritation to the eye compared to generic prednisolone acetate.[20]

A 2007 study looked at the differences in particle size between Pred Forte, EconoPred Plus and generic prednisolone acetate 1%.[21] The assumption was that larger particles would settle out of the suspension at a faster rate, sink to the bottom, and require greater shaking by the patient. The results of the study found that the generic form of prednisolone acetate had a greater tendency for particles to agglomerate, which subsequently led to inconsistent dosage concentration.[21] In addition, the authors wrote, the larger particle sizes may potentially clog the tip of the medication bottle during instillation and further alter dosage consistency and concentration. In contrast, the particle sizes in Pred Forte were smaller and more uniform, which allowed them to stay in suspension longer and gave a more precise dosage of the drop.[21]

At least one study found that generic prednisolone acetate has larger particles, which settle out of the suspension at a faster rate, sink to the bottom, and require greater shaking by the patient.

Optometrists should consider that products with poorly suspended ingredients can potentially compromise the treatment of highly inflamed eyes.

Patient Perspective

• ***Cost and compliance.*** Theoretically, generic medications should improve management and patient compliance because the obstacle of cost has been removed. With a more affordable prostaglandin analog now available, patients previously on generic timolol, generic dorzolamide or those who had refused treatment may elect to take generic latano-

prost. This kind of switch between classes of glaucoma mediations should also lead to significantly greater compliance due to the prostaglandin's once-daily dosage schedule.

• ***Inferiority complex.*** Another potential issue is that patients may be resistant to going on a generic medication because they perceive them as inferior to their branded counterpart.[22] Generics are often considered second-rate medications due to perceived poor compliance with standard manufacturing practices, lack of patient knowledge about generics, and influence of the brand-name company.[22,23] According to a study in New Zealand, less than half of participants interviewed perceived generic medications to be safe, effective and equal in quality compared to their branded counterpart.[11]

Furthermore, the New Zealand study found that younger patients who had a better knowledge and understanding of drug differences were more likely than those with poor understanding of the drugs to say they would use a generic drug in both major and minor illnesses.[11] We need to educate our patients so they can make an informed decision about their treatment and be willing to try a generic medication if the situation is appropriate. This is particularly true in the elderly who may be on multiple medications, as well as those with low socioeconomic status who could benefit from the savings.

• ***Patient preferences.*** We often need to consider our patient's personality and past experience when deciding between generic and brand drugs as well. One important question to ask our patients is whether they have taken generics before and what the outcome was. If the patient had a poor experience, they may be biased towards branded medications and willing to pay the higher price.

The severity of the disease can also influence how willing a patient is to take a generic medication. According to the same study in New Zealand, individuals surveyed were more prepared to change to a generic for a minor illness than for a major illness (79% vs. 58.7%).[11] In a severe disease like glaucoma, which has the potential for permanent vision loss, patients may be less willing to switch to a generic.

Which Story to Believe?

The true safety and effectiveness of generic medications cannot be certain without head-to-head clinical trials comparing topical ophthalmic brand-name drugs to their generic counterparts, but currently the

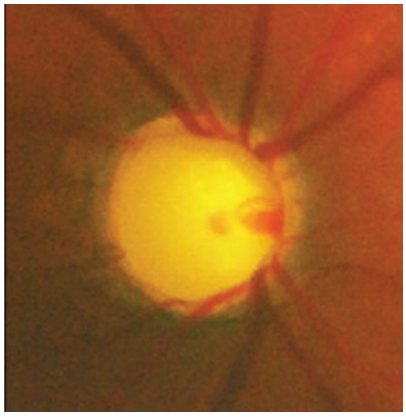
data is limited.[19] For now, here's what we do:

In patients with ocular inflammation secondary to iritis, given the aforementioned research, we prefer to prescribe Pred Forte over a generic whenever possible.

Similarly, due to the lack of information regarding the efficacy of generic glaucoma medications, in patients with advanced or end-stage glaucoma who are at high risk for progression and vision loss, we give strong consideration to staying with the brand-name medication that has the patient's IOPs under good control. We do not want to risk losing control of the disease or cause ocular toxicity by switching from brand to generic. Preparing a stock letter for the insurance carrier, which states that your patient has "advanced or end-stage vision-threatening glaucoma" and has been stable on his or her current medications, will be helpful if and when this situation arises. Another option is to switch patients to a branded drug for which there is no generic available at the time (i.e., switch the patient from Xalatan to a different brand-name prostaglandin), as long as similar efficacy is achieved.

Overall, we need to educate our patients on the potential for allergy and poor efficacy with generic medications. Also, more office visits may be required to evaluate the IOP-lowering effect between generic and branded glaucoma medications, as well as other ophthalmic drugs.

In addition, we need to tell patients to contact us if they experience any adverse effects after switching to a generic medication. As long as efficacy is comparable and there are no allergic reactions, generics provide an affordable alternative treatment option that should be utilized and prescribed to our patients.



A patient with advanced or end-stage glaucoma, who is at high risk for progression and vision loss, should probably stick with the brand-name medication to keep IOP under good control.

As eye care providers, we need to remember that when choosing between generics and brand medications, there are two sides to the story. ■

Dr. Chu and Dr. Hamp see large populations of patients with advanced disease. They each lecture on glaucoma and other clinical topics. They have no financial or proprietary interests in any of the aforementioned medications and/or companies.

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Azopt®

(brinzolamide ophthalmic suspension) 1%

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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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:
1. Liu JHK, Weinreb RN. Monitoring intraocular pressure for 24 h. *Br J Ophthalmol*. doi:10.1136/bjo.2010.199737. **2.** Bagga H, Liu JH, Weinreb RN. Intraocular pressure measurements throughout the 24 h. *Curr Opin Ophthalmol*. 2009;20(2):79-83. **3.** Liu JHK, Zhang X, Kripke DF, Weinreb RN. Twenty-four-hour intraocular pressure pattern associated with early glaucomatous changes. *Invest Ophthalmol Vis Sci*. 2003;44(4):1586-1590. **4.** Liu JHK, Medeiros FA, Slight JR, Weinreb RN. Comparing diurnal and nocturnal effects of brinzolamide and timolol on intraocular pressure in patients receiving latanoprost monotherapy. *Ophthalmology*. 2009;116(3):449-454.

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Annual Pharmaceutical Issue

Pain Management in the Optometric Practice

When patients are in pain, over-the-counter or topical medications usually ease discomfort. But sometimes, an oral narcotic is necessary to reduce the pain.

By Steven Ferrucci, O.D., and Marc Bloomenstein, O.D.

As optometrists, we will occasionally come across patients who require pain management. Although the need for pain relief is most often acute and lasts perhaps just 24 to 48 hours or less, patients certainly appreciate the cessation of discomfort. Incidences that necessitate pain control include corneal abrasions, foreign bodies, trauma, or after refractive or cataract surgery. Pain may also be associated with inflammation—most notably intraocular pain, such as that associated with episcleritis or preseptal cellulitis. In certain circumstances, a bandage contact lens, ophthalmic ointments or pressure patching may be enough to aid in patient comfort and augment the healing process.

More often, topical agents, such as non-steroidal agents (NSAIDs), with or without cycloplegics may be adequate. Yet in severe cases, an oral agent in the form of a narcotic is needed to reduce the pain.

This article reviews the various agents used for pain relief in the optometric practice, as well as some pearls and pitfalls to treating pain.

Know What You Are Treating

Before initiating any treatment for pain management, you need to do a thorough medical history that particularly focuses on allergies and current medications. Interactions of drugs and allergic response can

Release Date: February 2012
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Goal Statement: Optometrists occasionally encounter patients who require pain management. Often, these patients can be treated with over-the-counter medications or common topical ophthalmic drugs. To that end, this course reviews both topical and oral medications that are appropriate for pain relief in the optometric practice. Narcotic agents, in particular, are also discussed.
Faculty/Editorial Board: Steven Ferrucci, O.D., and Marc Bloomenstein, O.D.
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Disclosure Statement: Dr. Ferrucci is on the advisory board for Arctic DX, Alcon, Allergan and Reichert. Dr. Bloomenstein is a consultant and on the speakers' bureau for Abbott Medical Optics, Allergan, Alcon Laboratories, Bausch + Lomb, Ista Pharmaceuticals, RPS and Reichert, and on the speakers' bureau for Merck and Odyssey Labs. The authors have no financial interest in any products aside from their consulting agreements.

aggravate an already unfortunate problem. Along these same lines, determine if your patient has any medical issues that may limit your ability to prescribe the appropriate treatment or recommended dose (e.g., issues with metabolizing or clearing the meds).

It is imperative to determine the true cause of the pain, and treat it accordingly. Otherwise, all we are doing is masking the pain, without truly remedying the problem. The pain may be something that your patient has experienced before, so during your history remember the mnemonic FOLDAR: Frequency, Onset, Location, Duration, Association and Relief. Asking these questions can help to localize the discomfort or give you a good indication of the treatment options already attempted to placate the pain.

The nature of the pain, as well as its severity, should also be assessed. Gauging the pain is helpful and can be accomplished by subjectively asking the patient to assess their pain on a scale from 0 ("no pain") to 10 ("the worst pain ever"). While each person has a different threshold of pain, it is important to make sure that as we treat the pain and the underlying condition, the patient's relative discomfort is decreasing, not increasing. Although the irritation may sometimes get worse before it gets better, if the pain is increasing with treatment then we have to assume we either misdiagnosed or mistreated the condition. This indicates that we need to change the treatment protocol.

Topical Meds

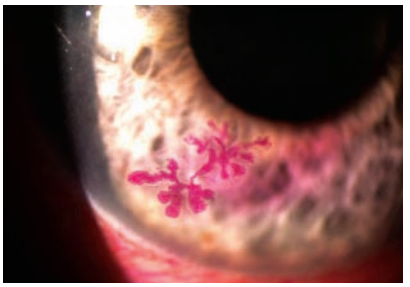
The first line of pain management often can be initiated with a topical medication. The advantage with topical formulations—aside from the medication reaching the superficial tissue (episclera, cornea, etc.) in higher concentrations—is that there are fewer side effects and they are more easily manageable for the patient.

Ideally, we could simply treat ocular pain with 0.5% proparacaine to deaden the cornea-rich nerves and improve the surface pain. However, the toxicity and potential abuse of this class of medication prohibits that practice, and frankly is not the standard of care.

Yet, there has been a movement of late, spurred by the discomfort induced by surface ablation surgeries, to use a diluted proparacaine for the analgesic effects. Investigators in Canada conducted a small, randomized, masked study of adults with corneal injuries.[1] Participants were treated with either 0.05% proparacaine or an artificial tear placebo. The proparacaine arm had a significant improvement in pain reduction. The investigators found no ocular complications or signs of delayed healing in either group, and concluded that the use of diluted proparacaine may be an efficacious analgesic for these acute corneal injuries.

(As described in this study, the proparacaine was diluted by a factor of 10, and this can be accomplished by a pharmacy.[1] However, similar results can be achieved by using a 3mL sample of artificial tears diluted with two to three drops of proparacaine 0.5% solution.)

When this diluted drug is put into practice, patients who receive it should be cautioned about the significant potential for abuse and potential cornea-related complications. Perhaps even educate the patient to "not use" these drops—unless absolutely necessary. Just knowing that they have it available to decrease or terminate the acute pain may provide a psychological benefit for patients to get them through the worst of the pain, without having to actually use it. Be sure to ask your patients to bring back the diluted bottle at a follow-up



Does a case of herpes simplex keratitis require some sort of treatment for pain? If the eye is hurting, the answer is yes.

appointment (you may be surprised to see that the bottle is still full), and discard the remaining drops upon completion of the treatment.

• ***Artificial tears.*** Lubricating the ocular surface helps reduce discomfort that may be a concomitant reaction to the inflamed tissue. Moreover, certain treatment options, such as topical antivirals, may induce some irritation or dryness that only a lubricating drop can alleviate. So, the use of artificial tears can provide a minor sense of relief.

• ***NSAIDs.*** The primary mechanism of action responsible for nonsteroidal anti-inflammatory drugs (NSAID) and their analgesic effect is the inhibition of prostaglandin synthesis by competitive blocking of cyclooxygenase (COX).[2] COX is an enzyme that is responsible for the production of inflammatory mediators, such as prostaglandins. The use of a topical NSAID, frequently used in surgery patients, can reduce inflammation, maintain pupil dilation and induce an analgesic effect. This triad is most useful in the successful management of ocular pain.

Because this class does not work on the same enzymes as steroids, there is little concern of any sight threatening long-term complications. Although some cases of delayed wound healing and corneal melts have been reported, the use of an NSAID for long-term pain

States That Permit Optometrists to Prescribe Controlled (Narcotic) Legend Drugs

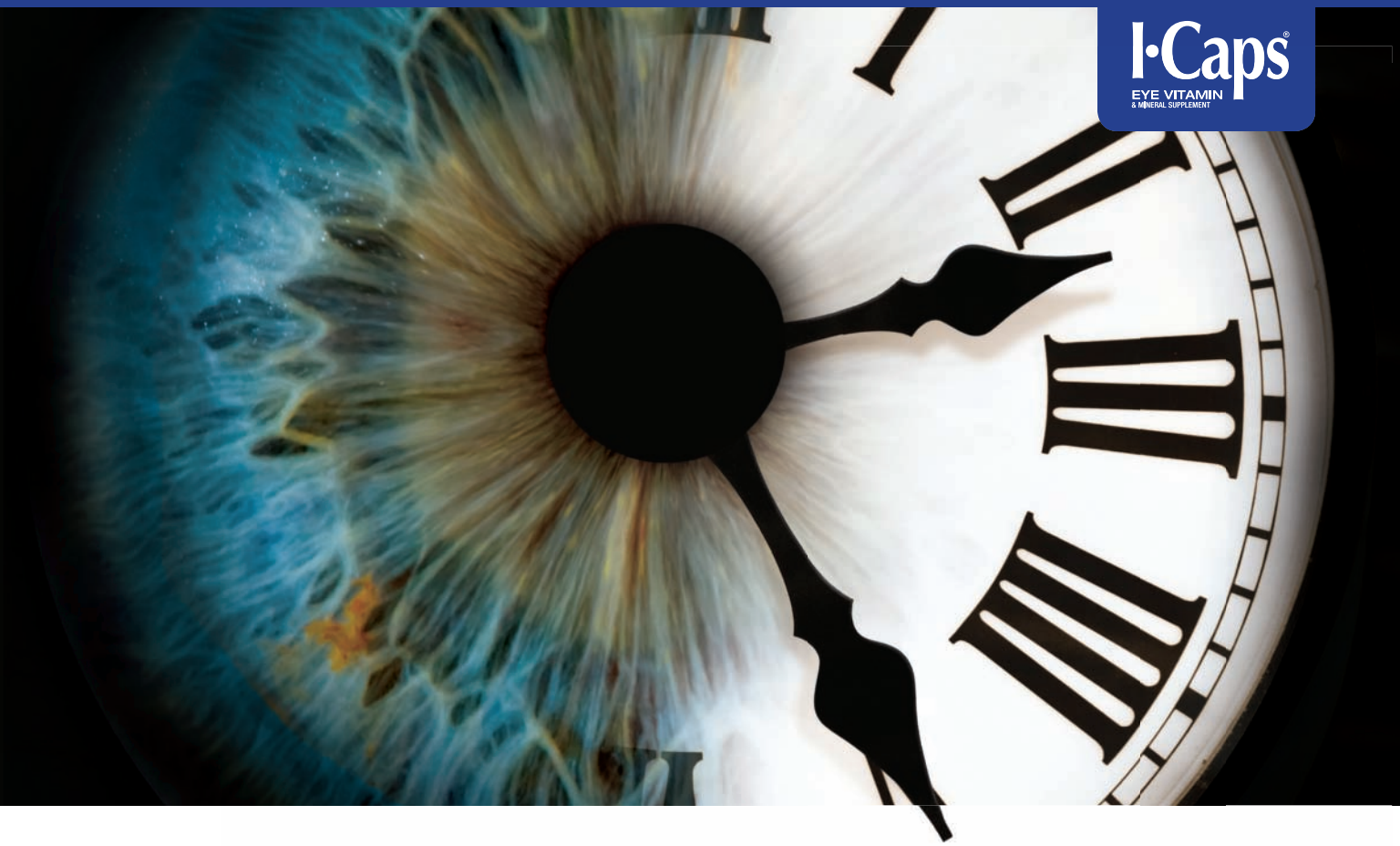
STATE	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
ALASKA [17]			X	X	X
ALABAMA [7]			X	X	X
ARIZONA			X		
ARKANSAS			X	X	X
CALIFORNIA [10][11]			X		
COLORADO			X	X	X
CONNECTICUT		X	X	X	X
GEORGIA [5]			X	X	X
IDAHO		X	X	X	X
ILLINOIS [16]			X	X	X
IOWA		X	X	X	X
KANSAS		X	X	X	X
KENTUCKY [8]			X	X	X
LOUISIANA [15]			X	X	X
MAINE [18]			X	X	X
MICHIGAN [13]			X	X	X
MINNESOTA				X	
MISSISSIPPI				X	X
MISSOURI		X	X	X	X
MONTANA [2]		X	X	X	
NEBRASKA [2][6]		X	X	X	X
NEVADA [8]			X	X	
NEW HAMPSHIRE [3]			X	X	
NEW JERSEY			X	X	X
NEW MEXICO [2]			X	X	X
NORTH CAROLINA		X	X	X	X
NORTH DAKOTA [9]			X		
OHIO			X		
OKLAHOMA			X	X	X
OREGON [12]			X	X	X
PENNSYLVANIA			X	X	X
RHODE ISLAND			X	X	X
SOUTH CAROLINA			X	X	X
SOUTH DAKOTA [2]		X	X	X	X
TENNESSEE [4]		X	X	X	X
TEXAS [6][10]		X	X	X	X
UTAH [8]			X	X	X
VERMONT			X	X	X
VIRGINIA [2][8]			X		
WASHINGTON [14]			X	X	X
WEST VIRGINIA [10]			X	X	X
WISCONSIN [2]			X	X	X
WYOMING			X	X	X

Source: AOA State Government Relations Center
Last Revised April 28, 2011

1. Reserved.
2. Treatment for ocular pain and inflammation.
3. Treatment with only those oral analgesic drugs included in the formulary.
4. Therapeutically-certified ODs may utilize any pharmaceutical agent rational to the treatment of eye disease.
5. Treatment with controlled analgesic drugs over 72 hours may not be done without consultation with the patient's physician.
6. Within the Schedule II category - topical only is permitted (this would be the one controlled drug available for diagnostic purposes)
7. Within the Schedule III category - no agents containing dihydrocodeinone ("hydrocodone"), other Schedule III drugs limited to Rx not to exceed 96 hours.
8. Prescriptions limited to dosages for no more than 72 hours.
9. Treatment with acetaminophen plus 30mg of codeine only.
10. Prescription of analgesics for a duration of no more than 3 days.
11. Compounds containing codeine or hydrocodone only.
12. Treatment with Schedule III analgesics longer than 7 days requires consultation with an MD.
13. Plus may prescribe dihydrocodeinone combination drugs, no matter what class they are scheduled in.
14. Prescription for controlled narcotic substance may not be for more than 7 days for a single condition, trauma, episode.
15. Rx of narcotic for 48 hours only. May be followed with one additional 48 hour Rx if warranted by follow-up exam.
16. Prescriptions limited to analgesics in dosages for no more than 72 hours.
17. Prescriptions limited to 4 days quantity.
18. Prescriptions limited to one 5 day supply of analgesics in Schedules III, IV, and V.

State optometry acts specifically prohibiting optometrists from prescribing controlled (narcotic) legend drugs: Delaware, Hawaii, Indiana, and Massachusetts (when referring to this list of states which specifically prohibit the prescription of controlled drugs, remember that other states not listed here authorizing "topical agents only" or "specific categories only" could essentially prohibit the use of controlled narcotic drugs as well.)

Help promote healthy eyes.*



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[1] Luthe, R. Supplemental Information. *Ophthalmology Management*. November, 2010.

management is beneficial; also, the contributing factors to these corneal complications may be overuse of the medication or concomitant systemic factors, such as diabetes.[3] Patients who report low-grade discomfort, ocular or periocular allergy or medicamentosa secondary to other medications, as well as acute pain, can appreciate the analgesic effects.

Unfortunately, the earlier NSAID formulations sting or burn upon instillation, so many doctors (and patients) avoid this line of treatment. However, one strategy to help patients with the burn upon instillation is to keep the drop in the refrigerator. When the drop is instilled, it reduces the burning sensation and provides pain relief like a cold compress.

For many years, the stalwart NSAIDs have been Voltaren (diclofenac 0.1%, Novartis) and Acular LS (ketorolac tromethamine 0.4%, Allergan). Although both show a decrease in corneal sensitivity, these drops require a q.i.d. dosage and have the added deficiency of inducing that uncomfortable sting. Because we want to ameliorate the pain, not add to it, these side effects may be a deterrent.

The newer ophthalmic NSAIDs do not carry the same stinging side effect and are more readily used for pain relief.

Acuvail (ketorolac tromethamine 0.45%, Allergan) is the latest NSAID to be approved by the FDA. This formulation is preservative free and is supplied in individual ampules that are useful for the transient nature of this treatment. This NSAID is dosed b.i.d. and is indicated for perioperative use one day prior to cataract surgery. There has been some concern that this drop is cost prohibitive. But for patients who may have recurring pain issues, such as recurrent corneal erosions, the availability of a b.i.d.-dosed analgesic that is preservative free may justify the price.

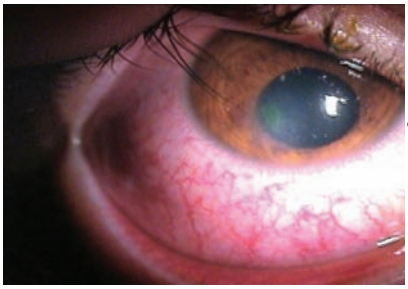


Photo: Derek Cunningham, O.D.

A BB hit this eye. Now that's gotta hurt!

Nevanac (nepafenac 0.1%, Alcon) is a unique NSAID that is a prodrug. The suspension first touches the cornea as nepafenac, which delivers the analgesic to the surface without discomfort associated with other NSAIDs. As it penetrates the intraocular tissues, an enzyme converts nepafenac molecules into the COX-inhibitor amfenac.[4] Alcon reports that this mechanism of action gives Nevanac a target-specific activity, maximizing the efficacy at the intended ocular sites where pain and inflammation reside.

Bromday (bromfenac 0.09%, Ista) is a once-a-day selective NSAID that is indicated for the treatment of pain and ocular inflammation following cataract surgery. Ista reports that this drop is the most selective and potent COX-2 inhibitor. The q.d. dosing may be the perfect solution for the acute pain that your patients are experiencing and, from a prophylactic aspect, may increase patient compliance.

All NSAIDs have the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. So, use caution when treating individuals who have previously exhibited sensitivities to these drugs. Moreover, with the potential for corneal toxicity and melting issues, these drops should be used with precaution when there is a corneal breach. If there is an epithelial compromise that lasts longer than a week of treatment, cease the use of the NSAID.

The NSAIDs are specifically indicated for the treatment of pain and inflammation in and around cataract surgery; thus, alternative use would be considered an off-label treatment. This may become necessary to explain to the pharmacy or the patient.

• ***Cylcoplegics.*** Often, ocular pain is related to an intraocular inflammatory component, or a superficial corneal problem that translates internally. An example is a patient with a foreign body on the epithelium that also induces an iritis or internal inflammation. In these instances, the use of a cycloplegic agent can help to reduce the excruciating pain your patient is experiencing. Depending on the duration and extent of cycloplegia and mydriasis desired (as well as taking into account that heavily pigmented irises may require higher strengths), the exact concentration, dosage and type of cycloplegic should be determined on a per-case basis.

Cycloplegics block acetylcholine, a stimulatory neurotransmitter of the autonomic nervous system. Because acetylcholine induces contraction of the iris and ciliary body, the cycloplegic does the exact opposite by temporarily inducing pupil dilation and paralysis of the ciliary body. The relaxation of the ciliary spasm induces a reduction in the pain and stabilizes the blood-aqueous barrier, which reduces the anterior chamber inflammation.

Atropine, derived from the atropa belladonna (deadly nightshade) plant, is the most potent cycloplegic agent available, with a duration lasting up to 12 days. Atropine is available in 0.5%, 1% and 2% ophthalmic solutions and a 1% ophthalmic ointment, with a rec-

ommended dosage of b.i.d. to t.i.d. Long-lasting cycloplegia may be necessary in extreme cases of iritis, and using such a strong cycloplegic will also help prevent posterior synechiae formation.

Scopolamine is available in 0.25% ophthalmic solution and is dosed b.i.d. The choice of scopolamine vs. that of the more potent atropine should be based on the severity of the patient's inflammation.

Homatropine, another cycloplegic agent, is available in 2% and 5% concentrations. With only about 10% the potency of atropine, this is a very effective drop for those acute inflammatory pain reactions. It tends to have a cycloplegic recovery in one to three days after use.

When a patient presents with a traumatic corneal injury, such as an abrasion, consider the use of cyclopentolate instead. Cyclopentolate is available in 0.5%, 1% or 2% concentrations. Because this drop is short-acting, its role is to hold the potential inflammatory mediators in the blood vessels and not release them into the anterior chamber. So, if you have no other drops at hand, cyclopentolate is an acceptable Band-Aid until you can use a stronger cycloplegic.

• ***Topical steroids.*** The use of steroids as adjunctive pain modulators is limited to the cessation of the inflammation in the eye. As stated earlier, it is important to find cause of the discomfort and treat it accordingly. But, whether that cause is secondary or idiopathic, steroids can help treat the underlying inflammation that is producing the pain.

Steroids have a high side-effect profile and should be limited to short-term treatment options. Patients need to be followed more closely to measure the intraocular pressure (IOP), which may be raised secondary to the medication. Although some data suggest that selective steroids, such as ester-based steroids, have a lower prevalence of IOP spiking, a good rule of thumb is to measure the IOP bi-weekly every time a steroid is prescribed, regardless of the dosing and concentration. There are, however, some differences in ophthalmic steroids, and making a decision of which would be the most effective for the patient's inflammatory pain should be taken into account.

Loteprednol etabonate is an ester-based steroid marketed by Bausch + Lomb in two concentrations of topical formulations: Alrex (loteprednol etabonate 0.2%) and Lotemax (loteprednol etabonate 0.5%), as well as an ointment (loteprednol etabonate 0.5%).

Loteprednol has proven effective in the reduction of ocular inflammation. Subsequently, in a post hoc analysis of data collected from two published pivotal clinical trials, Lotemax provided statistically significant relief of postoperative pain following cataract surgery.[5] This translates into superior use for pain management in your patients with mild inflammatory conditions.

Durezol (difluprednate 0.05% emulsion, Alcon) is the first and only FDA-approved steroid indicated for the treatment of pain following cataract surgery. The recommended dosage is one drop, b.i.d to q.i.d., postoperatively.

Durezol has been shown to be as effective q.i.d. as prednisolone acetate administered eight times a day in resolving inflammation and pain associated with endogenous anterior uveitis.[6] This suggests that Durezol can be effectively used at a lower dosage than other steroids.

Prescriptive Pearls for Narcotics

Play it safe when writing a prescription for narcotics.

- Prescribe the drug on a 24-hour basis with no refills. This ensures the patient will need to return to your office if more pain relief is necessary.
- In addition to writing the number of tablets you want dispensed, such as 12, you should also write out in parentheses the word "TWELVE" to avoid any tampering with your prescription.
- Be sure to include your contact information and sufficient patient information to prevent anyone else from using this prescription for narcotics.

Rod Cone, O.D.
321 Main Street
Columbus, OH
(610) 555-1234
Optom Lic # 12345
DEA Lic # XXOXOX

Name: John D'oh DOB: 08/08/1968

Address: 742 Evergreen Terrace

Rx: Tylenol #3

Sig: 1 - 2 tablets p.o. q 4 - 6 hrs

Disp: 12 (TWELVE)

Refills: None

Generic substitution: yes

Signature: Rod Cone, O.D.

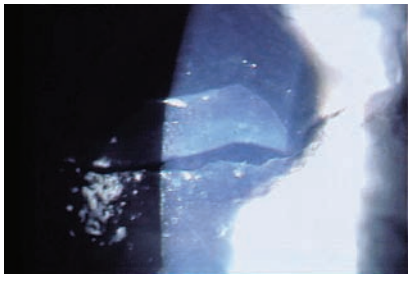
Oral Meds

Before initiating any oral pain management, a more thorough medical history of the patient is warranted. Be sure to ask about alcohol use, antidepressant use, smoking, history of stomach ulcers and pregnancy in appropriate patients, because these may be contraindications for certain treatments. Also, be sure to ask about any current medications as well as over-the-counter (OTC) preparations that the patient may be taking—especially warfarin, digoxin and antidepressants, because these have interactions with many other medications. Additionally, check the patient's medical history for kidney or liver disease, as medications may be metabolized and cleared less quickly with liver or renal status. Lastly, make sure to inquire about a history of previous allergy to any medications, especially aspirin, and document accordingly.

In general, start with the simplest, most cost-effective treatment and work up, depending on the patient's level of pain, symptoms, etc. So, OTC agents are often the first line treatment for mild to moderate pain. Yet, caution your patients about the notion of "more is better," because the side effects of these medications, although OTC, may be significant.

• ***Over-the-counter options.*** There are several OTC preparations that can be recommended for pain management.

Aspirin (acetylsalicylic acid) is available in a variety of forms and is very inexpensive. However, it is not great for pain relief, and a low dose (81mg/day) is generally used more for stroke, myocardial infarction and blood clot prevention than for true pain relief. Dosage for analgesia is typically 650mg to 975mg every four hours. It is contraindicated in patients with a history of aspirin allergy, bleeding ulcers or other bleeding disorders as well as in patients who consume more than three alcoholic beverages a day, or are pregnant as it is category D medication (positive evidence of risk). Another consideration: Avoid aspirin in patients less than 18 years of age or with viral illnesses, such as the flu or chicken pox, due to concerns of Reye's syndrome.



When a patient presents with a traumatic corneal injury, such as an abrasion, consider the use of cyclopentolate.

Acetaminophen is also available in many preparations, such as brand-name Tylenol (McNeil) or as a generic. It is much better at relieving pain than aspirin, but does not have any platelet or anti-inflammatory properties like aspirin or NSAIDs. The new recommended dosage is 650mg to 975mg every four hours for pain relief, with a maximum daily dose of 3,000mg to prevent liver toxicity. It is safe to use during pregnancy, with bleeding disorders, and in children with viral infections because there is no danger of Reye's syndrome, as with aspirin. It is contraindicated in patients with liver disease, alcoholism or a history of acetaminophen hypersensitivity.

Over-the-counter NSAIDs are readily available as well, and are effective for mild to moderate pain relief. They have the added benefit of anti-inflammatory control; due to this dual effect, they are often a good choice for a patient with ocular pain from iritis, for example.

Ibuprofen is available OTC as brand-name Motrin (McNeil) or as ageneric. It can be dosed from 200mg to 800mg every four hours, with a maximum daily dose of 2,400 mg. The side effects of ibuprofen—stomach upset and GI toxicity—can be lessened if the daily dose is kept under 1,600mg per day.

Naproxen sodium is another OTC NSAID option, available as Aleve (Bayer Healthcare) and as a generic. Dosage is 220mg every eight to 12 hours, with a maximum dose of 1,500mg per day. Many doctors recommend two pills as a loading dose and then one pill every eight to 12 hours thereafter, with no more than three pills in a 24-hour period.

Contraindications to all the NSAIDs include GI bleeding, avid alcohol use and pregnancy (because it is category C, an unknown risk). Also, they should be avoided in patients with a known hypersensitivity to NSAIDs and used in caution with patients with an aspirin allergy, as there may be a crossover effect.

There are also many NSAIDs available by prescription only, such as naproxen. Its recommended dose is 500mg initially, then 250mg every six to eight hours thereafter for reduction of pain and inflammation.

Indomethacin is also a commonly used NSAID for the pain, tenderness, swelling and stiffness caused by arthritis, but it has no indication for general pain. However, it is used frequently in eye care for the treatment of scleritis, typically 25mg to 50mg three times a day.

• ***Narcotics.*** When greater pain relief is needed, the next step is a narcotic. Narcotics should be used judiciously; but when used appropriately, they are great options for patients in moderate to severe pain. Rules governing prescribing of narcotics by optometrists vary state by state, so be familiar with your particular state's rules. As an example, an optometrist in California can prescribe Schedule III narcotics if there

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is a direct indication for ocular pain. (*See "States That Permit Optometrists to Prescribe Controlled [Narcotic] Legend Drugs," page 80.*)

Codeine is a very useful narcotic for mild to moderate pain relief. It is not typically prescribed by itself, but rather in conjunction with either aspirin or Tylenol. When combined with aspirin, it has the added benefit of inflammatory control. However, when combined with Tylenol, the codeine and the Tylenol work on separate areas of the central nervous system to produce a synergistic effect and very good pain relief.

The most common form of codeine is Tylenol #3, which has 30mg of codeine and 300mg of acetaminophen. (Tylenol #1 has 15mg codeine and Tylenol #4 has 60mg of codeine—each with the same amount of acetaminophen, 300mg). Its recommended dose is one to two tablets every four to six hours, with a maximum daily dose of 360mg codeine and 4,000mg Tylenol.

Empirin (Glaxo Wellcome) with codeine #3 is 30mg of codeine combined with 325mg of aspirin. Empirin with codeine #4 is 60mg codeine with 325mg aspirin. Recommended dose of either is one tablet every four to six hours, with a maximum daily dose of 360mg of codeine.

Codeine can be fairly sedating, so advise caution, especially if a patient has not used it previously. Also, GI disturbances are common, with constipation being the most reported side effect.

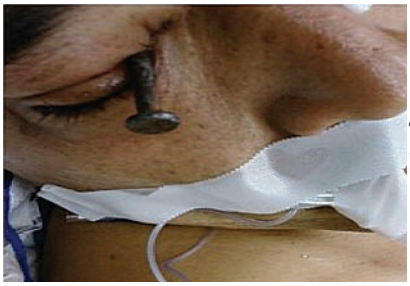

Photo: Derek Cunningham, O.D.

This patient got nailed! Pain management is definitely in order.

Hydrocodone is about six times as potent as codeine, and may cause less constipation and sedation than codeine. Like codeine, hydrocodone is a Schedule III drug and is commonly co-formulated with either Tylenol or ibuprofen. The most commonly prescribed form is Vicodin (Abbott Laboratories), which is 5mg hydrocodone with 500mg acetaminophen. Recommended dose is one to two tabs every four to six hours, with a maximum dose of eight tablets per day, or 4,000 mg acetaminophen.

It is also available as Vicodin ES (extra strength), which is 7.5mg hydrocodone and 750mg acetaminophen, with a maximum dose of five tablets per day. Vicodin HP (high potency) is 10mg hydrocodone with 660mg acetaminophen, with a maximum of six tablets per day.

Hydrocodone also can be combined with ibuprofen for added inflammatory control in the form of Vicoprofen (Abbott Laboratories), which is 7.5mg hydrocodone and 200mg ibuprofen, given one to two tabs every four to six hours, with a maximum dose of five tablets per day.

Tramadol is a synthetic analogue of codeine; but it is non-narcotic, so it is not DEA classified. Tramadol has similar potency as Tylenol #3, but its abuse and addiction potential is very low. It has minimal side effects, including dizziness, headaches, nausea, vomiting and drowsiness. However, it has many interactions with other drugs, including tegretol, digoxin, warfarin and others. Also, it should be avoided in patients with a history of seizures. Recommended dose is 50mg to 100mg every four to six hours with a maximum dose of 400mg a day. (Individuals 75 years and older should be limited to 300mg a day.) When combined with acetaminophen, it is called Ultacet (37.5 tramadol/325mg acetaminophen, Ortho-McNeil-Janssen) with a recommended dose of one to two tablets every four to five hours.

Side effects of these narcotics include drowsiness, respiratory depression, liver toxicity, renal failure and urinary retention, nausea and vomiting, and abuse or addiction potential. However, when used appropriately for the short term, many of these side effects are never realized. Further, addiction and abuse potential is very low when used for such a short period of time.

The treatment of pain is not limited to on-label indications, and finding the right dosing should be

There is No 'Correct' Analgesic for Each Condition

Which pain reliever is best for a case of iritis? Or for corneal abrasion? Or post-cataract surgery? It all depends on the patient's pain. The best agent for a particular case doesn't depend on the ocular condition, but on the severity of pain.

- For **mild pain**, OTC analgesics such as Tylenol or ibuprofen are often all that are needed. Also, they are inexpensive, readily available and relatively safe.
- For **moderate pain**, Tylenol #3, one to two tablets every four to six hours, is a good choice.
- In **more moderate to severe** cases, one to two tablets of Vicodin (hydrocodone 5mg/acetaminophen 500mg, Abbott Laboratories) every four to six hours is often helpful.

In cases when an agent stronger than Vicodin is needed, a referral for Percocet (oxycodone/acetaminophen, Endo Pharmaceuticals) or Percodan (oxycodone/aspirin, Endo Pharmaceuticals) may be needed because this is outside of optometrists' scope of practice in most states.

individualized. A realistic goal is to provide relief of the discomfort the fastest way possible with the least amount of side effects. Bear in mind that there is sometimes a disconnect between the severity of the pain and the physical signs. Yet, we as clinicians need to balance both when helping patients get back to status quo.

Looking for a topical solution is optimal and yet is not always possible. Combining treatments may be the best solution; so don't be afraid to write multiple prescriptions to alleviate your patient's discomfort.

At the end of the day, your patient just wants to feel better. ■

Dr. Ferrucci is chief of optometry and residency director at the Sepulveda VA Ambulatory Care Center and Nursing Home in North Hills, Calif. He is also an associate professor at Southern California College of Optometry. Dr. Bloomenstein is the director of optometric services at Schwartz Laser Eye Center in Scottsdale, Ariz. He is the immediate past president of the Optometric Council on Refractive Technology.

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OSC QUIZ

You can obtain transcript-quality continuing education credit through the Optometric Study Center. Complete the test form *(page 88)*, and return it with the $35 fee to: Optometric CE, P.O. Box 488, Canal Street Station, New York, NY 10013. To be eligible, please return the card within one year of publication.

You can also access the test form and submit your answers and payment via credit card at *Review of Optometry Online*, www.revoptom.com.

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

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

1. All of the following are examples of conditions appropriate for pain management EXCEPT:
a. Corneal abrasion.
b. Bacterial conjunctivitis.
c. Post cataract surgery.
d. Post refractive surgery.

2. A useful mnemonic to characterize pain is:
a. FOLDAR.
b. PEPSI.
c. NOSPECS.
d. CLARE.

3. Before initiating any pain management, you should:
a. Determine the underlying cause of the pain.
b. Have the patient rate the pain in accordance with a pain scale.
c. Determine what the patient has tried already that has/has not been helpful.
d. All of the above.

4. At least one randomized trial has demonstrated that:
a. NSAIDs are effective pain managers.
b. Diluted proparacaine can be effective for pain reduction.
c. Steroids are all different.
d. Surface ablation is painful and needs specific medications.

5. The primary mechanism of action of a non-steroidal anti-inflammatory drug is to:
a. Block histamine release.
b. Increase prostaglandin production.
c. Inhibit cyclooxygenase.
d. Stabilize mast cells.

6. What is NOT an example of a topical pain reliever?
a. Diluted proparacaine.
b. Homatropine.
c. Diclofenac.
d. Moxifloxacin.

7. When do you typically bring a patient back for follow-up after prescribing topical steroids?
a. One day.
b. Two weeks.
c. One month.
d. Two months.

8. Cease using an NSAID if there is epithelial compromise that lasts longer than:
a. One day.
b. Two days.
c. One week.
d. One month.

9. What is the most potent cycloplegic available?
a. Atropine.
b. Scopolamine.
c. Homatropine.
d. Cyclopentolate.

10. Before initiating any oral pain relief, you should:
a. Ask about any current medicine use, including OTC preparations.
b. Ask about any history of allergies to medications, especially aspirin.
c. Ask if your patient is currently pregnant.
d. All of the above.

11. In general, when treating pain it is best to start with:
a. The strongest medication you can.
b. The newest medication available.
c. The simplest, most cost-effective option.
d. The most expensive option.

12. Aspirin should be avoided in children under age 18 with a viral syndrome due to:
a. Reye's syndrome.
b. Down's syndrome.
c. Duane's syndrome.
d. Moebius' syndrome.

13. Which statement regarding Tylenol is TRUE:
a. It has anti-platelet functions similar to aspirin or NSAIDs.

OSC QUIZ

b. It needs to be avoided in children under age 18 with a viral illness.
c. It is a much better pain reliever than aspirin.
d. It can be used safely in patients with liver disease or a history of alcoholism.

14. Contraindications for NSAIDs include all of the following EXCEPT:
a. Gastrointestinal bleeding.
b. History of allergy to aspirin, due to potential crossover effect.
c. Pregnancy.
d. Active iritis.

15. In states that allow optometrists to prescribe narcotics, from which schedule can most O.D.s prescribe?
a. Schedule I.
b. Schedule II.
c. Schedule III.
d. All schedules.

16. Tylenol #3 consists of
a. 15mg of codeine and 300mg of acetaminophen.
b. 30mg of codeine and 300mg of acetaminophen.
c. 300mg of codeine and 30mg of acetaminophen.
d. 60mg of codeine and 300mg of acetaminophen.

17. All of these statements concerning hydrocodone are true EXCEPT:
a. It is six times as potent as codeine.
b. It may cause less constipation and drowsiness than codeine.
c. It is typically co-formulated with Tylenol or ibuprofen.
d. It is schedule II.

18. Tramadol is:
a. A schedule III narcotic agent.
b. Similar in potency to Tylenol #3.
c. Known to have a very high abuse potential.
d. Can be used safely in patients with a history of seizures.

19. Which of the following is a useful safeguard when writing for narcotic agents?
a. Prescribe on a 24-hour basis.
b. Write for no refills.
c. Write out the number of pills you wish dispensed (e.g., "TWELVE.")
d. All of the above.

20. Side effects of narcotics include all of the following EXCEPT:
a. Diarrhea.
b. Drowsiness.
c. Nausea and vomiting.
d. Abuse or addiction potential.

Examination Answer Sheet

Valid for credit through February 1, 2015

This exam can be taken online at www.revoptom.com. Upon passing the exam, you can view your results immediately. You can also view your test history at any time from the website.

Pain Management in the Optometric Practice

Directions: Select one answer for each question in the exam and completely darken the appropriate circle. A minimum score of 70% is required to earn credit.

Mail to: Jobson - Optometric CE, PO Box 488, Canal Street Station, New York, NY 10013

Payment: Remit $35 with this exam. Make check payable to Jobson Medical Information LLC.

COPE approval for 2 hours of CE credit is pending for this course.

This course is joint-sponsored by the Pennsylvania College of Optometry

There is an eight-to-ten week processing time for this exam.

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

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

Rate the effectiveness of how well the activity:

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

How long did it take to complete this course? _____

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Suggested topics for future CE articles: _____

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By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

Signature _____ Date _____

Lesson 108063 RO-PCO-0212

FIRST-LINE

LUMIGAN® 0.01%

(bimatoprost ophthalmic solution) 0.01%

For patients starting or changing PGA therapy

A drop with low dropout

Efficacy with low overall discontinuation rate:
8.1% (15/186) with LUMIGAN® 0.01%
and 13.4% (25/187) with LUMIGAN® 0.03%[1,2]

Indication: LUMIGAN® 0.01% and 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

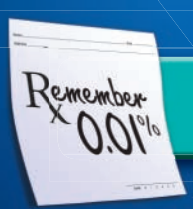
Important Safety Information

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.



Prescribe LUMIGAN® 0.01%

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

ALLERGAN

LUMIGAN® 0.01% AND 0.03%
(bimatoprost ophthalmic solution)

INDICATIONS AND USAGE
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.

APC81RP11 based on 71807US12B.

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Billie Taylor, CPOT

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INTERNATIONAL VISION EXPO & CONFERENCE NEW YORK

Vision Expo East: New Programs, Expanded CE

More than 60 hours of business-focused education courses will be offered.

This year, eye care professionals can expect even more from International Vision Expo East, including 325 hours of continuing education from sought-after speakers, 60 hours of education focused solely on business and more than 450 exhibitors featuring the latest in technology and frames.

International Vision Expo East is projecting 15,000 eye care professionals will attend the show, which will be held from March 22-25 in the Jacob K. Javits Convention Center in New York City.

International Vision Expo East will feature the latest in frames and technology from more than 450 exhibitors.

An Eye on CE

Vision Expo East's Conference Advisory Board has worked with specialty optical groups, including the Optometric Retina Society, the Optometric Council on Refractive Technology and the Ocular Nutrition Society, to put together a full program featuring expert speakers from a variety of fields. The program has been 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.

International Vision Expo & Conference continues to be the only show to present more than 60 hours of exclusive, business focused education courses for the optical profession, such as Visionomics™, Boot Camps and E-technology, Frame Buyers Certificate, and Social Media and Internet Marketing. Back by popular demand, these courses are designed to help professionals manage the business end of their practice while increasing efficiency, improving practice management, and providing comprehensive and engaging patient care.

In conjunction with Optometry Board Certified, attendees can select from 20 hours of review courses specifically designed to prepare optometrists for the Board Certification Exam. The 2012 conference program also brings back the acclaimed Management & Business Academy™ (MBA), which includes two three-hour modules: one dedicated to financials and private practice benchmarks and the second focused on marketing and merchandising. This successful program is sponsored by Essilor and CIBA Vision, and is endorsed by the American Optometric Association.

The Medical & Scientific Theater, located in the Lenses & Processing Technology Pavilion on Level 1, will also offer a special series of free, supplier-endorsed educational sessions on Friday and Saturday.

New this year, continuing education will be 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.

Strategic Partnerships

Additionally, International Vision Expo East has formed strategic partnerships with several state associations that will be sponsoring several education sessions and events. The state associations include the New Jersey Society of Optometric Physicians, the Delaware Optometric Association, the Maryland Optometric Association, the New York State Optometric Association and the Pennsylvania Optometric Association.

The sponsored sessions and events include:

International Vision Expo East is projecting 15,000 eye care professionals will attend the show.

• The Pediatric Red Eye (Course 1325), Thursday, March 22, 4:30 p.m. to 5:30 p.m. Presented by Ida Chung, O.D. Arranged through the cooperative efforts of New York State Optometric Association and the College of Optometrists in Vision Development.

• Vision and Balance: An Optometric Survival Guide (Course 2217), Friday, March 23, 9:45 a.m. to 11:45 a.m. Presented by Neera Kapoor, O.D., Michael McGovern, O.D. Sponsored by the New York State Optometric Association.

• Student Lunch (3028), Friday, March 23, 12:00 p.m. to 2:30 p.m., Room #1A28. Sponsored by the New York State Optometric Association and the Pennsylvania Optometric Association.

• Current Concepts of Myopic Development and Treatment (Course 2428), Friday, March 23, 4:00 p.m. to 6:00 p.m. Presented by Jeffery Cooper, O.D. Arranged through the cooperative efforts of New York State Optometric Association and the College of Optometrists in Vision Development.

• Basic Medical Coding 2012-What Every Doctor Needs to Know (Course 3228), Saturday, March 24, 9:45 a.m. to 11:45 a.m. Presented by Richard Soden, O.D. Sponsored by the New York State Optometric Association.

• Advanced Medical Coding 2012—What Every Doctor Needs to Know (Course 3328), Saturday, March 24, 2:45 p.m. to 4:45 p.m. Presented by Richard Soden, O.D. Sponsored by the New York State Optometric Association.

• Pearls from the Posterior Segment: Interactive Grand Rounds (Course 3310), Saturday, March 24, 2:45 p.m. to 4:45 p.m. Presented by Bill Marcolini, O.D. Sponsored by the New Jersey Society of Optometric Physicians.

New Optometry Club and Vision Bucks Program

In addition to the educational opportunities, optometrists are invited to join their peers and network and unwind in the new Optometry Club, located on Level 1 in room #1A20. Boxed lunches will be available on Saturday for attendees to enjoy in between CE and shopping the show floor. O.D.s who pre-order at the time of registration can save $10 on each meal. The Club will also play host to several other key events including a student luncheon on Friday, Doctorfest networking events with free beer and wine from 5:30 p.m. to 6:30 p.m. on Friday and Saturday and a special Job Search Meet and Greet breakfast from 8:00 a.m. to 9:30 a.m. on Saturday.

Also new in 2012 is the Vision Bucks program, which will give a $500 purchase reward to the first 40 optometrist who spend $5,000 or more on the show floor.

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REVIEW® OF OPTOMETRY

'I Want Laser Cataract Surgery!'

Femtosecond laser cataract surgery is coming—and patients want it. But it's not for every cataract patient. Here's what you need to know. **Edited by Paul C. Ajamian, O.D.**

Q **I just got a letter from a local surgeon that he is now doing cataract surgery with the femtosecond laser. Is this a better procedure for my patients?**

A "Yes, it's better in some ways, but like everything else, there are plusses and minuses," says Jeffrey Hood, O.D., of Carolina Eyecare Physicians, in Charleston, S.C. "It's not necessarily for every cataract patient."

Laser cataract surgery does not replace phacoemulsification. "It does allow the surgeon to fragment the lens with less energy. The capsulorhexis is perfectly circular, centered and reproducible, which helps with refractive outcomes. The cornea wounds are very precise, which may help with the outcomes as well. A big advantage is that it allows the surgeon a better way to fine-tune the astigmatic correction. Overall, it gives the surgeon and the patient more opportunities to have a better refractive outcome."

For astigmatism control, the femto laser allows the surgeon to place an unopened arcuate in the cornea, Dr. Hood says. Then if the patient needs a postoperative adjustment for residual astigmatism, the surgeon can do it by opening up that arcuate in the exam room at a later time. "Let's say the patient has 0.50D of post-op astigmatism. Instead of giving the patient glasses, the O.D. can send the patient back to the surgeon, and cylinder can be corrected," he says.

There are two downsides to laser cataract surgery thus far: one is cosmetic (a minor concern) and one is financial (a major concern).

The cosmetic concern is that patients usually appear with injection and small subconjunctival hemorrhages at the one-day post-op visit. "It's due to the docking of the instrument against the conjunctiva," says Dr. Hood. It usually resolves within a few weeks, and it's nothing to be worried about.

The financial concern is a bigger issue. Medicare reimbursement will not change if the surgical method used includes the laser, Dr. Hood says. It is an out-of-pocket expense that must be part of a premium procedure—in other words, it can be billed with any type of IOL as long as the patient understands that it is for the correction of astigmatism.

Will the patient pay a premium price to "have surgery with the laser," which may decrease their chances of wearing glasses after cataract surgery? That's a question that the O.D. can (and should) discuss before the patient is referred.

Specifically, Medicare reimbursement for cataract surgery doesn't change according to the surgical methods—the reimbursement is the same whether the capsulotomy is made with a cystotome or femto laser. Also, providers may not "balance bill" a Medicare patient for any additional fees to perform the covered components of cataract surgery with a laser.

But, cataract patients can be billed for any additional services used specifically to implant premium refractive IOLs, as well as any associated incremental professional and technical services. However, the patient must consent to the additional out-of-pocket costs in advance.

Q **How will my role change in the pre- and postoperative care?**

A The extra work will be on the front end, to educate the patient about the additional solutions to their wants and needs, Dr. Hood says.

"Patients walk in our door and say, 'All I know is, I want that laser cataract surgery!'" he explains. "But they don't know what it does. They don't even know why they want it." So the optometrist's first job is to ground the patient's expectations. Rather than offering the patient a menu of different procedures and IOLs, doctors should ask cataract patients what their visual goals are, Dr. Hood says.

"A lot of people say, 'I've been wearing glasses for 80 years and I don't mind wearing them—but I want the laser!' Well, that patient isn't a good candidate for the laser because he will not perceive any benefit from the procedure," he says. "Instead, a patient who is interested in being less dependent on glasses after the procedure, and is willing to pay out-of-pocket to do so, is a better candidate for this premium procedure."

About 50 of these lasers are now in use in the U.S. So, O.D.s will need to keep informed of ongoing studies to find out if these lasers live up to their prestige and appeal. ■

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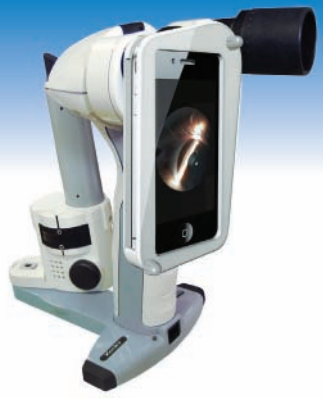

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Spring is in the Air

With the right treatment approach, patients with vernal conjunctivitis can enjoy the springtime and keep their symptoms under control. **Edited by Joseph P. Shovlin, O.D.**

Q What's the best approach for younger kids with severe flare-ups of vernal conjunctivitis that include corneal findings? Is it okay to use cyclosporine or tacrolimus? If employing a tiered approach, how do you use steroids?

A While not the most common expression of allergic eye disease, vernal conjunctivitis is a distinct clinical entity that is seen occasionally with corneal findings. Seasonal in nature, this expression of severe allergic disease presents mostly in prepubescent males, ages six to 12. Some of these cases, although worse in the spring, can run through summer into fall, requiring longer-term therapy.

Flare-ups are chronic and recurrent, but typically subside once the patient has reached puberty.[1] Symptoms include light sensitivity; blepharospasm; profound itching (which can be almost debilitating); and a vast amount of excess, stringy, ropy mucus. Also, the limbal and paralimbal tissues will have a milky, gelatinous appearance. Generally, it's sectorial, but occasionally it involves the entire limbal circumference. Recalcitrant shield ulcers are also troubling and potentially sight-threatening when they occur.

Look through the patient's chart and talk with them about the history so you can base your prescribing on this past experience. Some doctors have had success with cyclosporine, a low-potency immunomodulator, and tacrolimus, a non-steroidal immunosuppressant. Cyclosporine 0.05% (Restasis, Allergan) used b.i.d. or more often (or 0.03% tacrolimus ointment b.i.d.) can reduce the need for ongoing steroid usage or minimize the amount of steroid with any long-term therapy or refractory case.

Caution: If tacrolimus is used, monthly blood work with appropriate lab tests is needed. However, treatment of vernal conjunctivitis with either of these medications is an off-label ophthalmic use, which is why practitioners often shy away from using them.

"What the patient must have early on is aggressive use of a steroid, and there's likely to be a protracted use of the medication," says Randall Thomas, O.D., M.P.H., who works with a group practice in Concord, N.C. "So you want to go with an ester-based corticosteroid, because it's safe and highly clinically effective." Two concentrations are available—loteprednol etabonate 0.2% (Alrex, Bausch + Lomb) or 0.5% (Lotemax, Bausch + Lomb).

Dr. Thomas usually prescribes the higher concentration, with dosing every two hours for three to four days to aggressively get the allergic reaction under control. "Once you've done that, it should calm the storm, and then you can start tapering the Lotemax down, usually over a one- to four-week period," he says.

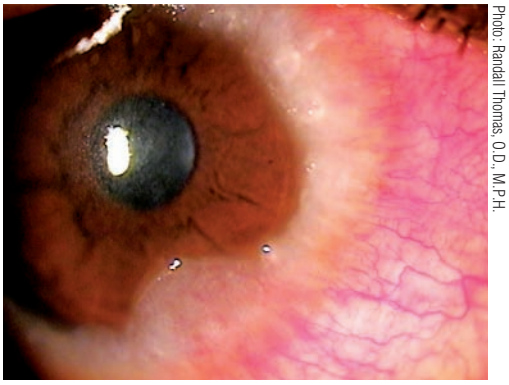

Photo: Randall Thomas, O.D., M.P.H.

Common presentation of limbal vernal conjuctivitis.

To make sure the symptoms have been eradicated, have the patient come into the office one to two weeks after treatment is initiated. Carefully monitor pressure because, even though loteprednol etabonate has a very safe clinical profile, it does have the potential to raise IOP—particularly in children. Dr. Thomas recommends moving the patient down to the 0.2% concentration earlier if there is rise in pressure, and the symptoms appear to be improving.

Once the patient has achieved control, it can be helpful to add an antihistamine/mast cell stabilizer or use one concommitantly to keep the symptoms at bay.[2] In addition, the patient should use cold compresses, and consult with an allergist to learn about environmental modifications to avoid or decrease exposure to allergens and triggers in the home. ■

1. Kari O, Saari KM. Updates in the treatment of ocular allergies. J Asthma Allergy. 2010 Nov 24;3:149-58.
2. Melton R, Thomas R. Vernal keratoconjunctivitis. Clin Refract Optom. 2005;16(2):50-51.

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Reference: 1. Data on file. Johnson & Johnson Vision Care, Inc. 2009.

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Nerve Sends Mixed Signals

This patient's right optic nerve has both neuroretinal rim loss and optic nerve pallor. Does he have one condition, or two? **By James L. Fanelli, O.D.**

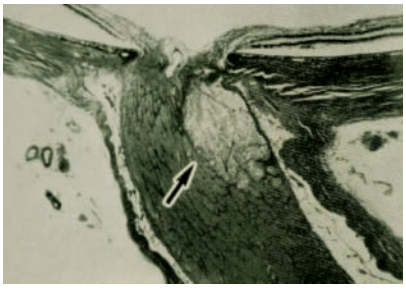
A 74-year-old white male presented in January 2012 as a new patient. His primary care physician referred him to us for a complete ophthalmic evaluation, primarily because of a history of diabetes and post-cerebral aneurismal repair damage to the right eye.

Current medications included Synthroid (levothyroxine sodium, Abbott), Lopressor (metoprolol tartrate, Novartis), Diovan (valsartan, Novartis), Tricor (fenofibrate, Abbott), Niaspan (niacin, Abbott), pravastatin and metformin. He reported no drug allergies. The patient said that he has had type 2 diabetes mellitus for five years, and was started on diabetic medications only because of slightly abnormal glucose levels. That morning, his fasting blood glucose was 106mg/dl; he was unaware of his A1C level.

He underwent coronary artery stenting three years ago, as well as a cardiac ablation for arrhythmia several years prior to stent insertion.

The patient further reported that he underwent a procedure in 1999 to repair a cerebral aneurysm (procedure and specific site unknown); during the surgery, the right optic nerve was "deprived of oxygen," he said, and he has since had a nasal field defect in the right eye. Other than this, he had no complaints related to his vision.

He had bilateral cataract surgery in 2006, and his last visit to an eye care provider was a follow-up to his cataract surgery.



This micrograph shows an ischemic optic neuropathy, similar to what we suspect in this patient's case. The arrow points to the area of infarct—where the optic nerve is supplied by the short posterior ciliary arteries.

Diagnostic Data

Entering visual acuity was 20/30-1 O.D. and 20/30-2 O.S. Pupils were round and reactive to light, with a +2 afferent defect (APD) noted O.D. Extraocular motilities were full in all positions of gaze. Best-corrected visual acuity was 20/30+1 O.D. and 20/20-1 O.S. through hyperopic astigmatic correction.

Slit lamp exam of his anterior segments was unremarkable. Intraocular pressure measured 17mm Hg O.D. and 18mm Hg O.S. at 9:58 a.m. Threshold visual field testing in the right eye revealed a dense scotoma above and below the midline, located primarily in the nasal field encroaching on superior fixation, but clearly not respecting the vertical midline. The visual field in the left eye was normal.

Dilated exam showed that the posterior chamber IOLs in both eyes were centered in the capsular bags. The right optic nerve was moderately pale in all quadrants, especially noticeable in the temporal aspect of the disc. His cup-to-disc ratio O.D. appeared to be 0.55 x 0.75, with thinning of the inferotemporal neuroretinal rim. The optic nerve of the left eye was characterized by a plush and well-perfused neuroretinal rim, and a cup-to-disc ratio of 0.40 x 0.40. Both nerves were of average size.

The retinal vasculature was characterized by mild hypertensive and arteriolar sclerotic retinopathy O.U., consistent with his medical history. The right macula had a small, diffuse epiretinal membrane involving the foveal avascular zone, along with fine retinal pigment epithelial (RPE) granulation consistent with his age. The left macula was remarkable only for symmetric RPE granulation. There were no findings in either eye associated with his nonproliferative diabetic retinopathy.

His peripheral retinal examination was unremarkable O.U. We obtained fundus photos as well as B-scan ultrasonography O.U., primarily aimed at evaluating the physical characteristics of the postlaminar anterior optic nerves. Optic nerves in both scans were symmetric and normal.

Now, how do you proceed? When do you see him back, and for what?

Discussion

Although this patient has a complex history, there is no evidence from the preliminary visit that there is any imminent threat to his vision.

Certainly, there are unanswered questions—foremost of which is the status of the right optic nerve. He presented with a visual field defect and an APD in the same eye, but his history suggests that these findings coincided with each other as complications related to his cerebral aneurysm repair. And, most importantly, his history indicated that the visual field defects in the right eye were stable.

But, are they *really* stable? Also, was there anything in the examination that suggests possible progressive visual field loss? The answer to this question drives the scheduled follow-up visits.

Optic nerve ischemia occurs after many types of surgery. Whether through blood loss, extended operative time, associated cardiovascular and pulmonary co-morbidities or trauma, the optic nerve depends on proper oxygenation for normal functioning. Abnormalities in this process are the basis of the non-glaucomatous optic neuropathies.

But the *non-glaucomatous* optic neuropathies result in optic nerve damage fundamentally different than that of *glaucomatous* optic neuropathy.

In cases of *non-glaucomatous optic neuropathies*, the visible end result of the optic nerve damage is typically optic disc pallor and optic atrophy. But, in such cases, the neuroretinal rims typically do not become thinned. While they become pale and atrophic over time, the ganglion cells of the neuroretinal rim usually remain in place.

In *glaucomatous optic neuropathy*, however, the rim tissue remains pink and perfused, but there is characteristic loss of neuroretinal rim and nerve fibers.

The key to this patient's future visits, at least in the immediate future, relate to the fact that his right optic nerve is characterized by both neuroretinal rim loss consistent with glaucoma *and* optic nerve pallor. While it's very likely that the optic disc pallor indicates a posterior ischemic optic neuropathy, which probably occurred as a result of the intracranial aneurysm repair, we still need to account for the etiology of the neuroretinal rim loss.

We scheduled the patient for further evaluation three weeks after his initial presentation. This will include color vision tests, Heidelberg Edge Perimeter visual fields, corneal pachymetry, gonioscopy, Heidelberg Retina Tomograph-3 optic nerve imaging and stereo-optic nerve imaging.

Does this patient have two co-existing optic nerve morbidities? Possibly. When will we find out? Very soon. ■

Pause the Plaquenil?

This rheumatoid arthritis patient presented with blurred vision in both eyes. Was her history of Plaquenil use to blame? **By Mark T. Dunbar, O.D.**

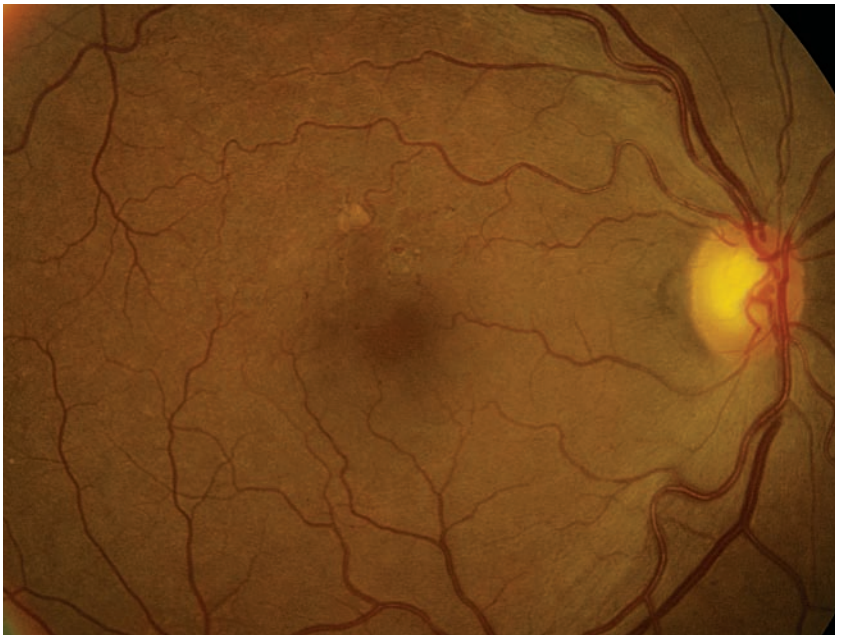
A 60-year-old Hispanic female presented for an annual evaluation. The patient reported that her vision was slightly blurred in both eyes. Additionally, she noted that her eyes felt dry.

Her medical history was significant for hypertension and rheumatoid arthritis. She was taking several medications, including an antihypertensive agent and 200mg Plaquenil (hydroxychloroquine, Sanofi-Aventis) b.i.d. The patient reported that she had been taking Plaquenil for the past two years. Her ocular history was unremarkable.

On examination, her best-corrected visual acuity measured 20/20 O.U. Her pupils were equally round and reactive to light, with no afferent defect. Confrontation visual fields were full to careful finger counting O.U., and ocular motility testing was normal.

Amsler grid testing was normal O.U. Color vision testing was normal (15/15 plates were correct). The anterior segment examination was remarkable for a scanty tear film and mild punctate epithelial erosions. Her intraocular pressure measured 15mm Hg O.U.

On dilated fundus examination, her optic nerves appeared healthy with a small cup and good rim coloration and perfusion O.U. The vessels were of normal caliber, and her peripheral retinae were unremarkable. Of interest, we noted changes that were located slightly superior to the right macula (*figure 1*). The left eye was remarkable only for a few drusen. We also performed a spectral-domain optical coherence tomography (SD-OCT) scan (*figure 2*).



1. Fundus image of the posterior pole and macula of our patient's right eye.

Take the Retina Quiz

1. Which test was truly unnecessary to perform?
   a. SD-OCT.
   b. Color vision.
   c. Amsler grid.
   d. Both B and C.

2. What additional testing is necessary to appropriately manage this patient?
   a. 10-2 visual field.
   b. Pattern electroretinogram (ERG).
   c. Fundus autofluorescence (FAF).
   d. Electro-oculogram.

3. What does the SD-OCT scan reveal?
   a. Normal anatomy.
   b. Loss of the photoreceptor integrity layer (PIL).
   c. Mild cystoid macular edema (CME).
   d. Choroidal neovascular membrane (CNV).

4. What do the findings in the right macula represent?
   a. Old branch retinal vein occlusion (BRVO).
   b. Hydroxychloroquine toxicity.
   c. Wet age-related macular degeneration.
   d. Macular telangiectasia.

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References: 1. CIBA VISION date on file, 2009. 2. In a survey of 589 optometrists in the U.S.; CIBA VISION data on file, 2009. 3. Based on the ratio of lens oxygen transmissibilities; CIBA VISION data on file, 2009, 2010. 4. In a randomized, double-masked clinical study at 10 sites with 103 patients; CIBA VISION data on file, 2007. 5. Based on the prevalence of refractive errors presenting to U.S. ODs surveyed in 1999 and calculation of residual astigmatism (of ≤ 0.62D); CIBA VISION data on file, 2009. 6. Rappon J, Bergenske P. AIR OPTIX AQUA MULTIFOCAL contact lenses in practice. *Contact Lens Spectrum*. 2010;25(3):S7-9. 7. In a survey of 221 eye care practitioners in the U.S. who fit over 2000 patients with AIR OPTIX AQUA MULTIFOCAL contact lenses; significance demonstrated at the 0.05 level; CIBA VISION data on file, 2009.

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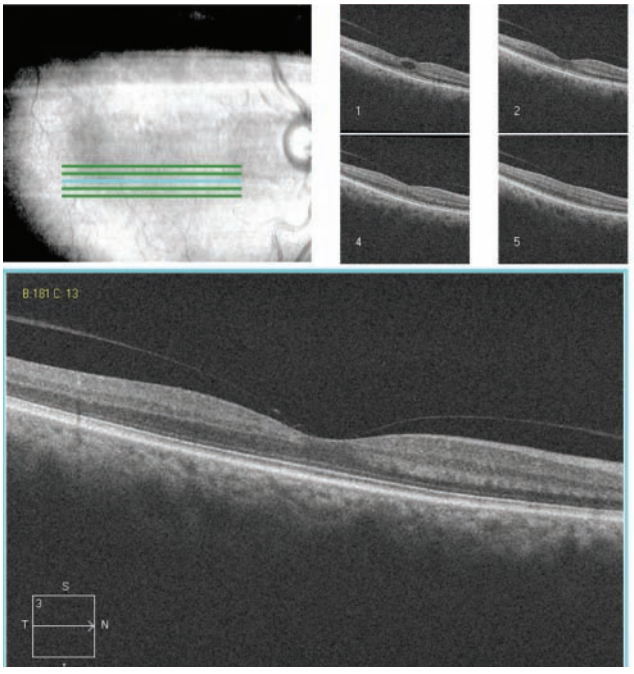

2. The SD-OCT scan of our patient's right eye. What do you notice?

5. How should we manage our patient?

a. Recommend discontinuation of Plaquenil.

b. Close observation.

c. Anti-vascular endothelial growth factor (VEGF) therapy.

d. Anti-VEGF therapy and discontinuation of Plaquenil.

For answers, go to page 130.

Discussion

There are several small microaneurysms located slightly superior to the right macula. The microaneurysms are seen as small, red bulbs with some fine telangiectatic vessels. Additionally, there are some retinal veins that are sheathed or perhaps even sclerosed. Could this be the result of Plaquenil use?

Retinal toxicity caused by Plaquenil is quite rare considering the large number of people who use this drug. Nonetheless, clinicians (and most patients) are keenly aware of the potential ocular complications of this medication.

Patients who present with Plaquenil toxicity typically exhibit depigmentation that is located circumferentially around the macula, giving it a "bull's eye" pattern. Consequently, this clinical finding is often termed bull's eye maculopathy.

Bull's eye maculopathy will yield the appearance of a ring-shaped scotoma on threshold visual field testing. This explains why patients on Plaquenil therapy should be followed with 10-2 visual fields. Unfortunately, once these changes are seen, the toxicity may already be fairly advanced.

For years, the single greatest problem that clinicians have faced is an inability to detect associated retinal changes earlier. But, with the advent of SD-OCT and other specialized ancillary tests (e.g., FAF and pattern ERG), these changes can be detected significantly earlier even before they are seen funduscopically and perhaps before they ever appear on visual field testing.

In early 2011, Michael Marmor, M.D., and colleagues published revised recommendations for screening patients who are on Plaquenil therapy.[1] While the older recommendations focused on the maximum daily dose for a patient, the revised guidelines emphasized cumulative dose as the most critical factor for developing associated retinal toxicity.[2,3]

The traditional protocol for following patients on Plaquenil therapy consisted of baseline photography as well as annual color vision testing, Amsler grid and 10-2 visual fields annually.[2,3] Under the new guidelines, color vision and Amsler grid testing are no longer considered acceptable screening methods so they have been removed from the protocol.[2,3] However, 10-2 visual fields are still important. In addition, the authors recommended that visual fields be supplemented with any one of the following tests: multifocal ERG, SD-OCT or FAF.[1] (The authors specifically noted that time-domain OCT was not sensitive enough to detect early changes.[1])

Dr. Marmor's research team also recommended that screening should be performed within the first year of initiating therapy, and then annually after five years of Plaquenil use. The risk for retinal toxicity begins once the patient has used Plaquenil for five to seven years and/or has taken a cumulative dose of more than 1,000g. Patients with renal or hepatic dysfunction are at an increased risk of toxicity.[1] Other risk factors for retinal toxicity include short stature, obesity, advanced age and/or a pre-existing macular pathology.[1]

So, what does this mean for our patient? Are the retinal changes a result of Plaquenil use? Our patient has been using Plaquenil for just two years, so it is unlikely that secondary retinal toxicity would manifest so quickly. In addition, the fundus changes are not typical for Plaquenil toxicity. The microaneurysms, fine telangiectatic retinal vessels and retinal vein sheathing suggest that, at one point in time,

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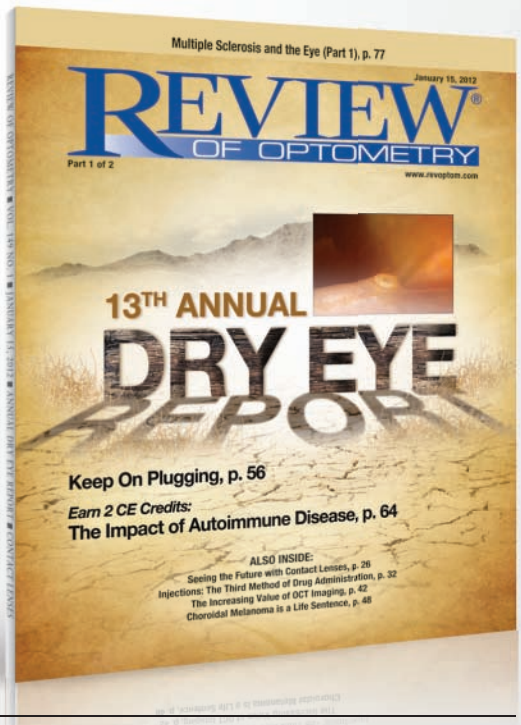

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our patient may have had an ischemic event involving her right eye. Indeed, the patient was diagnosed with a small BRVO seven years earlier. The occlusion never really affected her vision, so treatment wasn't warranted.

Interestingly, she is still functioning very well with 20/20 visual acuity today. The SD-OCT shows a normal foveal contour without any macular edema. However, just superior to the fovea, one of the five raster lines shows mild CME. This likely is the result of slow leaking from the microaneurysms and capillaries.

Do we need to treat this patient? Given that her acuity is good and the CME does not involve her fovea, she can be monitored. If we were truly concerned with retinal toxicity, we would begin to see disruption at the level of the PIL. On careful inspection, we can see that the PIL is completely normal.

Because the patient has previous macular pathology, should we make a recommendation to stop the Plaquenil? It's an important question to address, because preexisting macular pathology is a risk factor for the development of retinal toxicity according to the new screening recommendations.

We elected not to discontinue the Plaquenil therapy; however, we will follow her annually with 10-2 visual fields, SD-OCT and FAF. We gave the patient a written report and referred her to a rheumatologist for evaluation. ■

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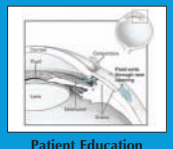
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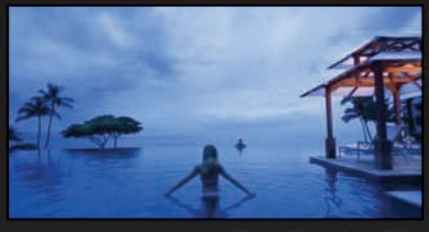

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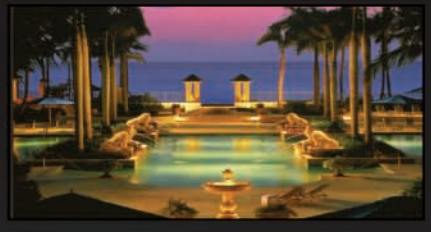

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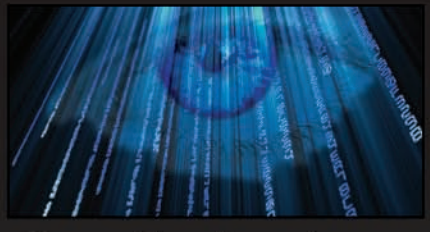

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MGD is Taking Heat

The LipiFlow Thermal Pulsation System may be a more effective treatment for MGD than conventional hot compress therapy. **By Alan G. Kabat, O.D., and Joseph W. Sowka, O.D.**

Over the past six years of writing this column, we've published numerous articles that have discussed dry eye and meibomian gland dysfunction (MGD). For one of us (Dr. Kabat), this field of study is a passion. For the other (Dr. Sowka), it is an all-too-common patient complaint, and a potential barrier to effective long-term glaucoma therapy.

There have been—and will continue to be—numerous strategies for dry eye management. These include simple lubrication therapy, nutritional intervention, the use of topical pharmaceutical agents and even surgical procedures such as conjunctivoplasty.[1] However, with the recognition of MGD as perhaps the most frequent cause of dry eye disease, our attention recently has turned to new ways to manage this old adversary.[2]

Classic MGD Management

One of the most well-established and widely accepted MGD treatments involves lid hyperthermia (e.g., warm compresses) combined with digital massage to help express sequestered meibum from the glands.

Indeed, some experts maintain that, despite the recent introduction of topical immunomodulatory agents and even direct probing of meibomian glands, the use of heat and therapeutic gland expression is the best and most practical treatment option for MGD.[3-7]

Of course, the classic technique of using warm compresses on a daily basis can be cumbersome, disruptive and tedious for many patients, and clinicians realize that such prescribed treatment often fails because of poor compliance. To that end, a variety of devices have been developed to help facilitate this therapy.[8-13]

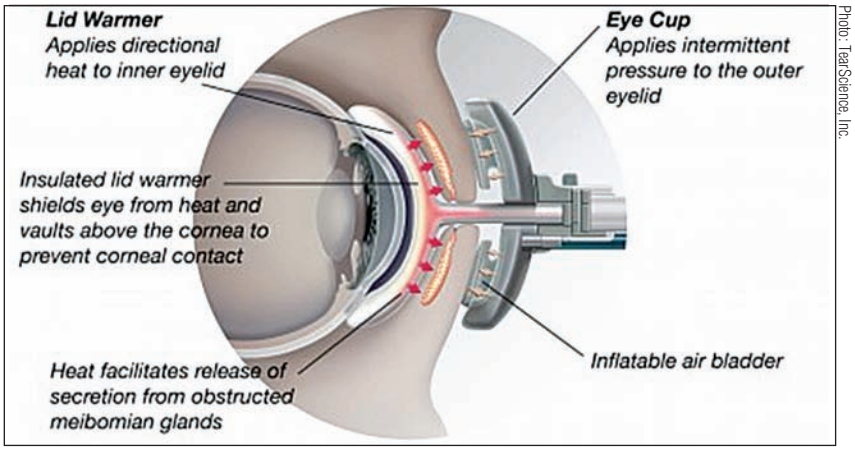

Photo: TearScience, Inc.

Diagram of the LipiFlow Thermal Pulsation System.

A Better Mousetrap

In our high-tech society, patients may have little faith in something as simple as hot compresses, but may readily gravitate to a new "device." One recent innovation, the LipiFlow Thermal Pulsation System (TearScience, Inc.), first garnered the attention of the general eye care community about 18 months ago, following the publication of a case report in *Cornea*.[13]

The article detailed the case of a 39-year-old patient with severe evaporative dry eye secondary to MGD who was treated with a prototypical device, which was designed to alleviate meibomian gland obstruction through a combination of precision-controlled heat delivery and pulsating pressure on the eyelids.[13]

According to the study, a single, 12-minute treatment session per eye successfully restored function in 33% of the individual meibomian glands, doubled the tear film break-up time, and decreased symptom scores by approximately 80% for the entire follow-up period of three months.[13]

Then, about a year ago, a second publication reported the results of 14 subjects enrolled in a multicenter trial that utilized the same device.[14] Once again, the treatment successfully improved meibomian gland secretions and expressibility, tear film break-up time, corneal staining and the overall symptom score beyond the three-month follow-up.[14]

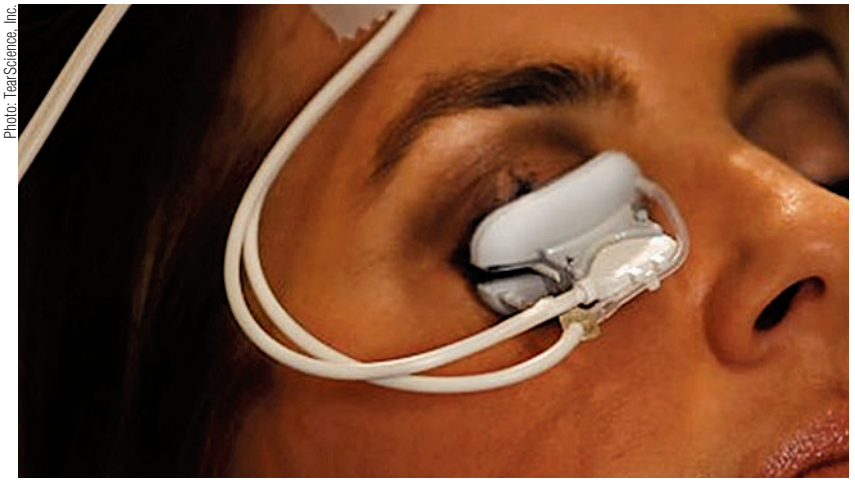

Photo: TearScience, Inc.

External view of the LipiFlow Thermal Pulsation System.

Larger studies of a longer duration (that are not yet published) show similar efficacy and even longer maintenance of therapeutic effect. According to information obtained from TearScience, a subcohort of 30 patients was followed for one year after a single LipiFlow session. The subjects continued to show statistically significant improvements in mean meibomian gland secretion scores, mean tear film break-up time and subjective symptoms (based on the Standard Patient Evaluation of Eye Dryness [SPEED] and Ocular Surface Disease Index [OSDI] questionnaires) at both nine- and 12-month follow-up.[15,16]

How Does it Work?

What makes the LipiFlow system unique is its design. Although it employs nothing more than directed heat and massage to achieve its effect, LipiFlow exhibits a remarkable feat of engineering as well as a revolutionary approach to this seemingly antiquated form of therapy. The first distinctive feature of this system is the inclusion of a heating element that is directed toward the meibomian glands from the palpebral side (inside) of the lid, rather than the dermal side. This is a logical consideration, because the glands are physically situated much closer to the conjunctival surface than to the skin of the lids.

Several years ago, researchers dissected the issue of warm compresses for the treatment of MGD in an effort to determine the precise temperature and duration necessary to render a therapeutic impact on the meibomian gland secretions. They concluded that patients needed to achieve and maintain a temperature of 45°C (113°F) for at least four minutes on the outer lid surface several times daily to be even somewhat effective.[17]

Additionally, the authors indicated that conventional warm compress therapy, while beneficial, is difficult if not entirely impractical for most patients.[17] The LipiFlow device addresses the physical limitations of heating the inner eyelid surfaces by employing a large shell (similar to a scleral lens) that contains both warming and insulating components.

It is designed to safely and comfortably vault the cornea and direct constant, controlled heat to the glands while protecting the surfaces both in proximity of and in contact with the device. The instrument may be inserted very easily, much like a gonioscopy lens. The shell then maintains a consistent temperature of exactly 42.5°C (109°F) around the inner surface of the eyelids, which has been shown to effectively heat all of the meibomian glands in both the upper and lower lids.[13]

The instrument's second major component is an inflatable silicone air bladder that covers the external surface of the eyelid after the device has been inserted. During the 12-minute treatment cycle, the bladder inflates and deflates rhythmically—applying pressure from the distal region of the lids to the proximal region near the lid margins, which simulates the motion that is recommended for gland self-expression.

Both the upper and lower lids are squeezed simultaneously between the inner heated surface of the shell and the outer air bladders, which expresses the sequestered meibum from the glands in a precise, controlled fashion.

Still New to the U.S.

The LipiFlow Thermal Pulsation System has been available in Europe and Canada for some time, but just recently received FDA approval in July 2011. The instrument is still not widely available because of its high price tag.

Still, noted experts who have worked with the device are extremely positive. Alan N. Carlson, M.D., chief of Cornea, External Disease and Refractive Surgery Services at Duke University Eye Center, was an early supporter and remains a strong advocate for the LipiFlow system, as does Stephen S. Lane, M.D., managing partner of Associated

Eye Care in St. Paul and adjunct clinical professor at the University of Minnesota in Minneapolis.[18,19]

Of course, the most compelling part of this treatment seems to be its endurance. If future studies confirm the early research, it may eventually be possible to treat MGD and evaporative dry eye with brief, periodic in-office therapy rather than relying on a variety of daily, patient-initiated interventions.

While there is no "magic bullet" for patients with dry eye, new innovations allow us to achieve improved results with a larger percentage of our patients. Only by staying abreast of the latest treatments and technologies can we remain competitive in the ever-changing field of eye care. ■

Drs. Kabat and Sowka have no direct financial interest in any of the products or companies mentioned in this article.

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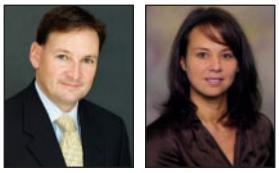

Ointments in Clinical Practice

Here, we examine the latest research surrounding the clinical utility of ophthalmic ointments. **By Paul M. Karpecki, O.D., and Diana L. Shechtman, O.D.**

The primary benefits of ophthalmic ointments include increased medication contact time and the potential to provide an added barrier to the ocular surface. More specifically, ointments may provide additional surface protection for patients with exposure keratopathy from Bell's palsy, trauma, infection, eyelid tumors or incomplete blink.[1,2] Ophthalmic ointments have been particularly effective for patients who suffer from nocturnal lagophthalmos.[3] Ointments are also routinely used after various surgical procedures and in neonatal applications.[4,5]

Perhaps one of the most common uses for ophthalmic ointments is to treat lid diseases, such as blepharitis, contact dermatitis and atopic dermatitis.[6,7] Other areas of application may include allergic eye diseases—giant papillary conjunctivitis, vernal keratoconjunctivitis, atopic keratoconjunctivitis and even more severe forms of seasonal allergic conjunctivitis.[8-11]

Several corneal conditions—including filamentary keratitis, keratoconjunctivitis sicca, corneal staining and corneal abrasions—often are effectively treated with ophthalmic ointments. In fact, one study indicated that ophthalmic ointments appear to be superior to pressure patching for traumatic corneal abrasions.[14] So, in cases where a bandage lens may not be an option, an ophthalmic ointment likely is the next best alternative.

There are, however, a few disadvantages to the use of ophthalmic ointments. For example, many patients will experience temporarily blurred vision and tear film instability following application. Also, because of the extended contact time, the ocular surface could be exposed to preservative agents for a longer period. Lastly, the use of ophthalmic ointments will not work effectively with contact lens use or bandage lenses.[15]

Lotemax Ointment

In late 2011, Bausch + Lomb introduced preservative-free Lotemax ointment (loteprednol etabonate ophthalmic ointment 0.5%) for the treatment of inflammation and pain following ocular surgery. Safety and efficacy trials were conducted to compare Lotemax ointment to the delivery vehicle for the treatment of inflammation and pain following cataract surgery in 805 patients.[16] Efficacy outcomes included the proportion of patients with complete resolution of anterior chamber inflammation, as well as the number of patients with no pain eight days after surgery.

Safety outcomes evaluated adverse events, ocular symptoms, intraocular pressure changes and visual acuity. Significantly more patients who received Lotemax ointment experienced complete resolution of anterior chamber inflammation and reported no pain eight days after surgery than those who received the vehicle.[16]

Additionally, fewer patients who used Lotemax ointment required rescue medications secondary to associated adverse events. The most common adverse events included anterior chamber inflammation, photophobia, corneal edema, conjunctival hyperemia, eye pain and iritis.[16] Mean IOP decreased in both treatment groups; however, four of 805 patients exhibited a pressure increase of more than 10mm Hg—three of whom received Lotemax ointment.[16]

Truly Preservative Free?

It is essential to note that nonaqueous formulations do not support microbial growth. A certain level of water content must be present for microorganisms to grow. Lotemax ointment simply does not reach that level, and therefore does not require the addition of preservatives.

Researchers have categorized a host of microorganisms with respect to their capacity to grow and produce metabolites under various conditions.[17] Bausch + Lomb conducted its own safety study that included several lots of Lotemax ointment. The ointment was inoculated with various microorganisms, including *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli*, *Fusarium solani*, *Serratia marcescens*, *Stenotrophomonas maltophilia* and *Bipolaris australiensis*.[18]

The test units were stored at 20ºC to 25ºC, and the samples were tested at seven, 14 and 28 days postinoculation by plating serial dilutions of sample aliquots on appropriate growth media and counting colony-forming units.[18] Results showed that microorganism growth was not supported in any of the Lotemax ointment lots at all three time intervals.[18]

A Note on Preservatives

So, why is it so critical to mention that Lotemax ointment does not contain preservatives agents? Simply put,

all non-dissolving preservatives in ocular preparations, such as benzalkonium chloride (BAK), show some toxicity. BAK is the most commonly used preservative in ophthalmic preparations.[19] It is a quaternary ammonium compound, which is considered a detergent.

Studies have shown that BAK exhibits the ability to alter cell membrane permeability, causing the cell to rupture.[18,19] Other research on BAK has shown that the degree of epithelial damage—and the speed which it occurs—depends on its tissue concentration.[5,19]

This phenomenon was less noticeable with lower percentages of BAK. It is interesting to note that other preservatives, including boric acid, chlorhexidine, chlorobutanol, ethylenediaminetetraacetic acid and paraben, do not affect cell viability.[20]

We must evaluate all therapeutic options in practice, based on both clinical experience and current research. Being aware of new ophthalmic ointments, and understanding their advantages and disadvantages, can help you determine how to best utilize them in clinical practice. ■

Dr. Karpecki is a consultant to Bausch + Lomb. Neither he nor Dr. Shechtman have any direct financial interest in the products mentioned.

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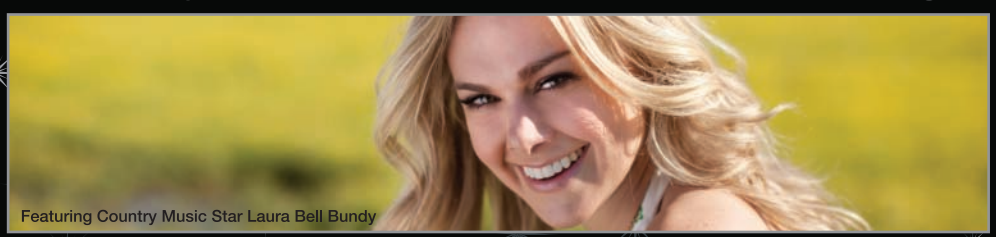
Saturday, March 3, 2012, 8:30 PM–Midnight



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Product **Review**

Contact Lenses

Specialty Line

ABB Concise received FDA clearance to produce an entire line of specialty contact lenses in silicone hydrogel 60Dk, 74% H_2O Definitive material. This includes indications for use in toric, multifocal, multifocal toric and irregular cornea lenses as well as the KeraSoft IC Lens manufactured under the Bausch + Lomb license and offered exclusively in Definitive material. ABB plans to launch the new product line in the first quarter of 2012.

Intelliwave Custom Soft Lens Multipacks

Art Optical recently introduced new, easy-to-dispense multipacks of its Intelliwave custom soft lens designs and rolled out a discounted pricing program. The convenient multipack with new lower pricing supports easy and economical lens replacement for patients and aids in compliance.

Offered in Definitive silicone hydrogel material as a quarterly replacement option or in traditional hydrogel materials on a semi-annual replacement schedule, Intelliwave lenses are available in two-packs, three-packs and four-packs. For additional product details, visit www.artoptical.com.

KeraSoft IC Lenses

KeraSoft IC silicone hydrogel contact lenses are now available in the United States from Bausch + Lomb, through a global licensing agreement with UltraVision CLPL. These lenses are designed to fit irregular corneas, *(continued on page 118)*

Frames

Aspex Grilamid TR90

The Aspex Grilamid TR90 was developed with thermoplastic polyamide, a new, advanced polymer developed exclusively for Aspex that is 20% lighter than other plastics. Frames using TR90 are now available in all Aspex brand lines, including EasyClip, Manhattan Design Studio and Takumi Magnetic Eyewear. In addition to being flexible, durable and lightweight, frames made from TR90 are temperature resistant, the company says. TR90 frames are also non-allergenic and block damaging UV exposure. For more information, visit www.aspexeyewear.com.

Carrera Champion Sunglasses

Worn by Gym Class Heroes lead singer Travie McCoy, Carrerra's Champion sunglasses appeared in the band's latest music video "Ass Back Home." Sleeping on buses and in hotel rooms in different cities every night, the documentary-style video showcases the hard, taxing lifestyle of an artist while on tour. The Carerra "Champion" sunglass model is inspired by the original design first introduced in the early 1980s and produced in Safilo Group's Optyl, a lightweight, hypoallergenic material. Visit carreraworld.com.

Frames

Costa Double Haul

Serious anglers will appreciate Costa's signature vent system in Double Haul's frame front to alleviate lens fog in extreme weather conditions, as well as full-eye coverage to allow full range of vision while on the water. Double Haul features a large fitting frame with Hydrolite no-slip nose pads, sturdy integral hinges and durable co-injected molded temples for a comfortable fit. The new style is available in tortoise, black and the new translucent crystal frame colors.

Anglers can customize Double Haul in Costa's patented 580 lenses in either glass or polycarbonate (580P). The new style will retail from $179 to $249 depending on lens customization, and will be available at www.costadelmar.com and at authorized Costa retail outlets.

Karl Lagerfeld Eyewear Collection

Marchon debuted the Karl Lagerfeld Fall/Winter collection for men and women this season. Shapes from the women's sunwear collection are vintage-inspired and amplified by use of colors—dark hues that graduate to light and then are infused with a contrasting color burst or rich tortoise shells and horns. The men's collection showcases retro shapes with modern color gradients and the K temple exemplifies skilled craftsmanship. The collection features ophthalmic and sunwear styles, including:

KL747S

- K747S. A thin, polished metal bar is inlayed at the temples, beginning at the end pieces and continuing to the mid temples, punctuated by the "KL" logo. Lagerfeld enhances the depth of design by setting the inlayed metal against color gradients, specifically a purple/violet gradient and grey/orange gradient to enhance the cat eye shape.

KL748S

- KL748S. This sister style to the KL747S is a modified butterfly, evident on the slightly waved brows crafted from rich zyl. Thin, polished metal beginning at end pieces and continuing down the temples toward the "KL" logo is prevalent set against black, Havana, light tortoise and sand colorations.

Office Design

Optical Displays

The new Impressions Collection of Modular Wall Displays, from Fashion Optical Displays, showcases eyewear with distinctive styling that is designed to transform any wall into a profit center. Intended for both new and established practices, the Impressions Collection features a variety of elements that include horizontal and vertical framed display back panels, graphic display panels and mirrors.

These custom-built display panels can be placed in various configurations that uniquely fit each dispensary. Select one or more display panels that hold only seven frames or panels that hold as many as 42 frames. Each display panel and mirror is framed in a selection of styles, including Brushed Stainless, Aged Pewter, Rosewood and Walnut. Visit www.fashionopitical.com.

(continued from page 116)

including keratoconus, post-laser refractive surgery, Pellucid Marginal Degeneration and other complex corneal irregularities. Each KeraSoft IC lens is custom-made to match the patient's individual needs, and can offer increased wear time and improved comfort.

Eye care professionals who are interested in KeraSoft IC lenses for their patients should visit www.KeraSofttraining.com to complete the necessary training for KeraSoft IC lens fitting. Once training is completed, contact Art Optical, the first lab channel partner, to get trial set information and to place KeraSoft IC orders.

BAUSCH+LOMB KERASOFT® IC

Website Enhancements

VirtualTryOn

Polarized sunglass maker Maui Jim has added VirtualTryOn to its website. The new system provides enhanced information about each sunglass style and allows customers to see themselves in a pair of glasses and then post the images to Facebook. It has two options—VirtualFitLive and VirtualFitPhoto.

VirtualFitLive is the live webcam option that projects a live image of the user's face; then the system superimposes sunglasses onto the image. If users turn their face, the glasses move with them. VirtualFitPhoto lets users upload photos of their face, either by snapping photos through their computer's webcam or by uploading a photo from their files. The cho-

sen sunglasses will appear on the photo, and can be saved or shared with friends on Facebook. To try it out, visit www.mauijim.com/tryonlive.html.

MBA Site Relaunch

The Management & Business Academy's website, sponsored by Alcon and Essilor, has undergone a dramatic redesign to provide a more usable and attractive environment for accessing tools for optometric practice growth. The revitalized site features a new organizational flow that provides easy access to a wealth of detailed reports, articles, surveys, calculators, staff workshops, monographs and other resources.

Existing content is highlighted, and new content is added to the site on a weekly basis with the posting of two MBA e-newsletters: MBA Essentials and MBA Intelligence. An enhanced search function allows users to access highly detailed metrics and best practices that can be applied to measure and improve practice performance. The MBA website is open to all who register at www.MBA-ce.com.

Thermal Pulsation System

Next-Generation TearScience LipiFlow

TearScience, Inc. recently received FDA clearance for its second-generation LipiFlow Thermal Pulsation System, which treats evaporative dry eye by liquefying and evacuating obstructions in the meibomian glands. This system includes a more robust graphical user interface and allows physicians to treat both eyes simultaneously.

Time savings achieved by performing a bilateral treatment is beneficial for both busy physicians and patients alike. Users can also store a record of the treatment on the device and on EMR servers, eliminating the need to manually document the treatment in patient records. The new LipiFlow console displays the treatment temperature, pressure sequence and treatment time remaining.

This second-generation product will be commercially available in March 2012. Physicians currently using TearScience's first-generation LipiFlow will be upgraded to the new system. Visit www.tearscience.com.

Eyewear Case

Eco-friendly Folding Case

Marchon recently introduced a new eco-friendly folding case for all house-brand collections, helping to reduce the global carbon footprint. The simple, effective and innovative design of each case aims to reduce carbon emissions caused by transportation, production and storage.

The foldable case, which is approximately one-tenth of the volume of the average eyewear case when shipping, offers wearers a sleek silhouette when closed.

This functional, eco-friendly eyewear case is part of Marchon's ongoing commitment to environmental protection and worldwide social campaigns. The company plans to selectively extend the new case program to the designer-brand portfolio. House-brand case deliveries will begin in spring 2012. Visit www.marchon.com. ■

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Speakers: Jimmy Bartlett, OD; Walter Choate, OD; Jack Schaeffer, OD; Diana Shectman, OD; Robert Wooldridge, OD

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- Posterior Segment Disease Diagnosis & Management
- Technological Innovations in Eyecare
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- Surgical Co-Management
- Ocular Manifestations of Systemic Disease
- Ocular Surface Disease Diagnosis & Treatment

For more information or to register, go to
www.revoptom.com/PuertoRico2012

or contact Lois DiDomenico at
ReviewMeetings@Jobson.com or 866-658-1772.

*COPE approval is pending. Check with your state licensing board to find out if this counts toward your CE requirements for re-licensure.

Schedule

Thursday, July 19, 2012

2:00pm – 4:00pm	Visit Sponsors & Registration
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
9:30am – 11:30am	CE Courses

Schedule is subject to change.

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4 Ways to Register

Online: www.revoptom.com/PuertoRico2012

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11 Campus Blvd, Ste. 100
Newtown Square, PA 19073

Fax: 610-492-1039

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Registration Information

Name _____ License # (License numbers are now required for HCP reporting and will only be used for this purpose.) _____

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Mailing Address _____ City _____ State _____ Zip Code _____

Telephone _____ Fax _____ Email _____

Name Badge Information (please print clearly)

My Name _____

My Guest _____ Additional Guests _____

Payment Information

	Rate per person		No. in party		Subtotal
OD Registration - $595 **($100 OFF by March 1, 2012 - only $495)** (includes 14 hours of CE, breakfasts, and reception)	$595	x	_____	=	$_____
Additional Guest(s) - $45 (12 years and older, includes reception)	$45	x	_____	=	$_____
Optional Catamaran/Snorkeling Activity, Saturday, July 21 - $125 (includes lunch)	$125	x	_____	=	$_____
			TOTAL	=	$_____

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CONFERENCE CANCELLATION POLICY

- Full refund on registration fee until June 21, 2012
- 50% refund on registration fee until July 5, 2012
- No refund past July 5, 2012

For more information or to register, contact Lois DiDomenico at ReviewMeetings@Jobson.com or 866-658-1772.

jmi
REVIEW® OF OPTOMETRY

Meetings + Conferences

February 2012

■ **24-26.** *Annual AOS Meeting and CE Conference.* Westin Kierland Resort and Spa, Scottsdale, Ariz. Hosted by: The American Optometric Society. COPE CE hours: 14. For details and registration, visit www.optometricsociety.org.

■ **29-March 4.** *SECO 2012.* Building A, Georgia World Congress Center, Atlanta. Hosted by: SECO International, LLC. CE hours: 300+. Call (770) 452-0600 or e-mail registration@secostaff.com. For more information, visit www.seco2012.com.

March 2012

■ **1-3.** *Big Sky Ski Conference.* Huntley Lodge, Big Sky Conference Center, Big Sky, Mont. Hosted by: The Montana Optometric Association. CE hours: 13. E-mail sweingartner@rmsmanagement.com or call (406) 443-1160. For more information, visit www.mteyes.com.

■ **4-9.** *26th Annual Eye Ski Conference.* The Lodge at Mountain Village, Park City, Utah. CE hours: 20. Contact Tim Kime, O.D., Meeting Director, at tandbkime@buckeye-express.com. For more information, visit www.eyeskiutah.com.

■ **11.** *MOA 5th Annual Evidence-Based Care in Optometry Conference.* Tilghman Auditorium, Johns Hopkins Medical Campus, Baltimore, Md. Hosted by: The Maryland Optometric Association. CE hours: 7. Contact Kristen Philips at (410) 727-7800 or e-mail moa@assnhqtrs.com. For more information, visit http://maryland.aoa.org/x20759.xml.

■ **11-12.** *75th Great Lakes Optometric Congress.* Chicago/Northbrook Hilton, Northbrook, Ill. Hosted by: The Optometric Extension Program Foundation. CE hours: 13. Contact John Loesch, O.D., at drjohnod1@gmail.com. For more information, visit www.oepf.org.

■ **22-25.** *International Vision Expo & Conference East 2012.* Jacob K. Javits Convention Center, New York, N.Y. CE hours: 325+ hours. For more information, call (800) 811-7151 or visit www.visionexpoeast.com.

■ **30-31.** *25th Anniversary of the Cogan Ophthalmic History Society.* National Library of Medicine, Bethesda, Md. Contact George Bohigian, M.D., president, at bohigian@att.net or visit www.cogansociety.org for more information.

■ **30-April 1.** *Primary Eye Care Update.* Hill University Center, UAB Campus, Birmingham, Ala. Hosted by: University of Alabama at Birmingham School of Optometry. CE hours: 18. Call (205) 934-5701 or e-mail cbratton@uab.edu. For more information, visit www.uab.edu/optometry.

■ **31-April 1.** *6th Annual Conference on Comprehensive Eye Care.* Sheraton Hotel (formerly Crowne Plaza), Niagra Falls, N.Y. Hosted by: PSS EyeCare. CE hours: 16. Call (203) 415-3087 or e-mail education@psseyecare.com. For more information, visit www.psseyecare.com.

April 2012

■ **11-12.** *2012 WOA Spring Seminar.* Country Springs Hotel, Waukesha, Wis. Hosted by: The Wisconsin Optometric Association. For more information, call (800) 678-5357 or visit www.woa-eyes.org.

■ **12-14.** *OptoWest 2012.* Renaissance Esmeralda Resort and Spa, Indian Wells, Calif. For more information, call (800) 877-5738 or e-mail events@coavision.org. Visit www.optowest.com.

■ **13-14.** *OAOP Annual Spring Congress.* Embassy Suites & Conference Center, Norman, Okla. Hosted by: the Oklahoma Association of Optometric Physicians. CE hours: 21. For more information, visit www.oaop.org.

■ **14-15.** *4th Annual Symposium on Ocular Disease.* Crowne Plaza Hotel, Tysons Corner, Va. Hosted by: PSS EyeCare. CE hours: 16. Call (203) 415-3087 or e-mail education@psseyecare.com. For more information, visit www.psseyecare.com.

■ **14-15.** *Miami Nice Symposium.* Colonnade Hotel, Coral Gables, Fla. Presented by: Miami-Dade Optometric Physician Association. CE hours: 17. For more information, contact Dr. Steve Morris at (305) 668-7700 or MPOPA.board@gmail.com. Visit www.MiamiEyes.org.

■ **20-21.** *Educational Meeting 2012.* Mission Inn, Howey-in-the-Hills, Fla. Hosted by: the Florida Chapter of the American Academy of Optometry. CE hours: 10. For more information, contact Arthur T. Young, O.D., at eyeguy4123@msn.com or (239) 542-4627.

■ **20-22.** *WFOA 2012 Spring Seminar.* Sandestin Hilton Beach Resort, Destin, Fla. Hosted by: the West Florida Optometric Association. CE hours: 18. For more information, contact Tom Streeter at (850) 279-4361 or opttom@hotmail.com. Visit http://wfoameeting.com.

■ **21-22.** *20th Annual Suncoast Educational Seminar.* Hyatt Regency Clearwater Beach Resort, Clearwater Beach, Fla. CE hours: 12. Hosted by: Pinellas Optometric Association. Contact Bruce Cochran, O.D., at (727) 446-8186 or IDoc1@aol.com.

■ **25-29.** *10th Annual New Jersey Chapter—American Academy of Optometry.* Kingston Plantation, Myrtle Beach, S.C. CE hours: 16. For more information, contact Dennis H. Lyons, O.D., at (732) 920-0110 or dhl2020@aol.com.

May 2012

■ **3-5.** *Mountain West Council of Optomestrists Annual Congress.* Caesar's Palace, Las Vegas. Hosted by: Mountain West Council of Optometrists. For more information, contact Tracy Abel, CMP, at (888) 376-6926 or tracyabel@earthlink.net. Visit www.mwco.org.

■ **18-20.** *Nova Southeastern University's 16th Annual Clinical Eye Care Conference & Alumni Reunion.* NSU College of Optometry. CE hours: TBD. Contact Vanessa McDonald, M.S.,

Manager of Continuing Education, at (954) 262-4224 or oceaa@nova.edu. Visit http://optometry.nova.edu/ce for more information.

June 2012

■ **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. For more info, 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. For more information, visit www.revoptom.com/conferences.

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@vision-care.org. For more information, visit www.visioncare.org.

■ **19-22.** *Caribbean 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. For more information, visit www.revoptom.com/conferences.

August 2012

■ **3-5.** *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. For more information, visit www.swfoa.com.

September 2012

■ **21-23.** *New Technology and Treatments in Vision Care.* California. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, O.D. CE hours: 15. For more information, contact Lois DiDomenico at ReviewMeetings@jobson.com or (866) 658-1772. For more information, visit www.revoptom.com/conferences. ■

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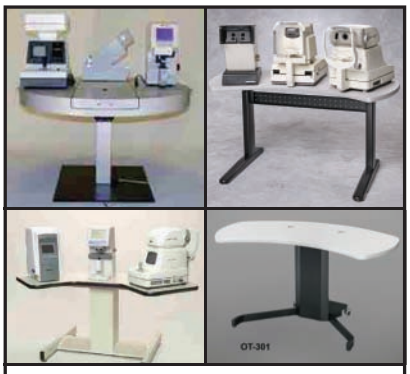

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See full prescribing information for Durezol.

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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

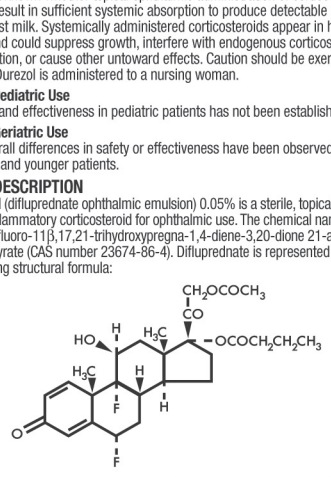
Safety and effectiveness in pediatric patients has not been established.

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

References:

1. Bikowski J, Pillai R, Shroot B. The position not the presence of the halogen in corticosteroids influences potency and side effects. *J Drugs Dermatol.* 2006;5(2):125-130.
2. Tajika T, Isowaki A, Sakaki H. Ocular distribution of difluprednate ophthalmic emulsion 0.05% in rabbits [published online ahead of print December 1, 2010]. *J Ocul Pharmacol Ther.* doi:10.1089/jop.2010.0093.
3. Ponec M, Kempenaar J, Shroot B, Caron JC. Glucocorticoids: binding affinity and lipophilicity. *J Pharm Sci.* 1986;75(10):973-975.
4. Korenfeld MS, Silverstein SM, Cooke DL, Vogel R, Crockett RS; Difluprednate Ophthalmic Emulsion 0.05% (Durezol) Study Group. Difluprednate ophthalmic emulsion 0.05% for postoperative inflammation and pain. *J Cataract Refract Surg.* 2009;35(1):26-34.
5. Fingertip Formulary. November 2010.

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Diagnostic **Quiz**

Something to Cry About

By Andrew S. Gurwood, O.D.

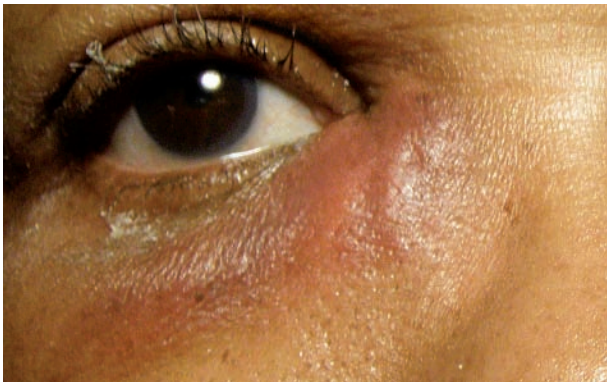
History

A 67-year-old black female presented to the emergency department with a chief complaint of a red, painful right eye. She also reported increased tearing O.D. Her systemic history was unremarkable, and she reported no known allergies or current medications.

Diagnostic Data

Her best-corrected entering visual acuity measured 20/25 O.D. and 20/20 O.S. Anterior segment examination revealed the presence of epiphora and mucopurulent discharge, which was oozing from the inferior punctum. The patient suggested that the application of pressure over the site of inflammation was painful and increased the volume of discharge. We noted no anterior chamber reaction in her right eye.

Her pupils were equally round and reactive, with no evidence of afferent defect. Intraocular pressure measured 16mm Hg O.U. Additionally, the dilated fundus examination of both eyes was normal—with quiet nerves, grounds and peripheries.



Our patient presented with a red, painful right eye as well as increased tearing. What is your diagnosis?

The pertinent external examination findings are illustrated in the photograph.

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 102):* 1) d; 2) a; 3) c; 4) a; 5) b.

Next Month in the Mag

Our March issue features the 17th Annual Comanagement Report. Topics include:

- *Integrated Eye Care in the 21st Century*
- *Comanagement of Limbal Relaxing Procedures*

Also in March:

- *Optometric Study Center: An Overview of Visual Hallucinations* (earn 2 CE credits)
- *How to Use Autologous Serum to Treat Severe Dry Eye*
- *O.D. Identifies Own Stroke*
- *The Impact of Systemic Allergy Drugs on the Eye*

And...

- Don't miss the March issues of *Review of Cornea & Contact Lenses* and *Women in Optometry*!

Feedback

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

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

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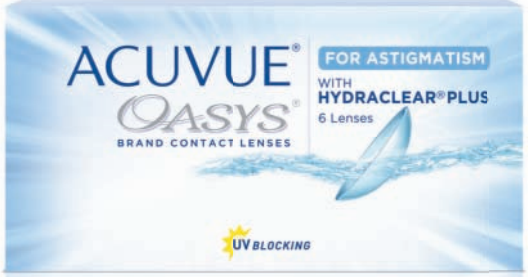

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Reference: 1. Data on file. Johnson & Johnson Vision Care, Inc. 2008.

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

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

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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%