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October 2013
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New optometric association launched

Goal is to represent optometric interests

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

Recently, a new organization launched, aiming to represent optometric interests in negotiations with third-party payers, ensure enforcement of existing laws and provider agreements, and improve public perception of optometrists.

According to the organization's Web site, *www.theaado.org*, the American Association of Doctors of Optometry (AADO) is a group of doctors collectively contributing money to an independent organization to give it the ability to do things that an individual doctor or small group of doctors would never have the resources to do on their own, or legally would not be permitted to do as a group.

The organization's first two board members are Art Epstein, OD, FAAO, chair of the communications committee; and Steve Silberberg, OD, chair of the membership committee. Other committee chair positions to be filled include finance, third-party relations, education, and legal/enforcement.

AADO founder Craig Steinberg, OD, JD, says that two things came together that led him to create the organization. The first was conducting online research and coming across the Union of American Physicians and Dentists, and the second was a young bank teller noting his OD credential and commenting that he was in the optical business.

"We know optometrists can't be in unions," he says. "We're independent and can't collectively bargain because of antitrust laws. The history of the Union of American Physi-

See **AADO** on page 5

AMERICAN ASSOCIATION OF DOCTORS OF OPTOMETRY AT A GLANCE

The AADO has three prongs:

- **Begin the process of changing the perception the public has of optometrists**
- **Engage third-party payers in negotiations to improve the terms of provider agreements**
- **Enforce laws and provider agreements, prevent unfair treatment by third-party payers**

> "The AADO is designed to complement organizations like the AOA." — CRAIG STEINBERG, OD, JD

Pharma products voluntarily recalled

Three compounded medications pulled for sterility concerns

By Rose Schneider

Washington, DC—Three pharmaceutical companies have recalled several of their products voluntarily due to sterility concerns and mold.

Avella Specialty Pharmacy has recalled two of its compounded sterile medications—bevacizumab 1.25 mg/0.05 mL PF (Lot no.: 12-20130508@179) and vancomycin PF (BSS) 1% (Lot no.: 12-20130508@181)—because of concerns of sterility assurance with its independent testing laboratory, Front Range Laboratories.

The FDA notified Avella of the issues after a recent inspection of Front Range Labs.

The agency had observed methods used to assess sterility and other qualities, like strength and stability, which could have resulted in the specialty pharmacy receiving inaccurate laboratory test results on the specified lots.

Because of the concerns found, the FDA said the test result obtained by Front Range Labs might not be reliable.

Avella has discontinued its relationship with Front Range Labs as a result of this issue.

To date, the specialty pharmacy has not received any reports of adverse events related to the recall.

The products recalled were dispensed directly to healthcare providers nationwide.

Avella is notifying customers of the voluntary recall by phone and mail. Customers that have any of the medications that are being recalled should immediately discontinue use and return the unused portion to Avella.

Leiter's Compounding Pharmacy has also voluntarily recalled three of its sterile products due to the sterility concerns at Front Range Labs.

See **Recall** on page 5

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

INSIDE: Special Section
Lens Care
Starts on page 25

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References: 1. Data on file, Alcon Research Ltd, 2011. **2.** Lally J, Ketelson H, Borazjani R, et al. A new lens care solution provides moisture and comfort with today's CLs. *Optician* 4/1/2011, Vol 241 Issue 6296, 42-46. **3.** Garofalo R, Lemp J. Clinical trial experience with OPTI-FREE® PureMoist® MPDS. *Contact Lens Spectrum* Special Edition; September 2011:44-48.

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OPTOMETRY TIMES (Print ISSN: 0890-7080, Digital ISSN: 2328-3904) is published monthly (12 issues) by Advanstar Communications Inc., 131 W. First Street, Duluth, MN 55802-2065. Subscription rates: $49 for one year in the United States & Possessions; $59 for one year in Canada and Mexico, and $89 for one year for all other countries. Periodicals Postage paid at Duluth MN 55806 and additional mailing offices. **POSTMASTER:** Please send address changes to OPTOMETRY TIMES, P.O. Box 6089, Duluth, MN 55806-6089. Canadian G.S.T. number: R-124213133RT001, PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Printed in the U.S.A.

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

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

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

Optometry Times

October 2013 • Vol. 5, No. x

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AADO

Continued from page 1

cians and Dentists goes back to the 1970s. It started by representing employed physicians, then began taking members who were not employed and were in private practices. This union found other things it could do that advanced the interests of private practice members, such as negotiating contract terms and conditions that didn't necessarily lead to higher fees. The antitrust laws are designed to protect consumers and promote competition and the adverse effect of not having competition. However, anything you negotiate that benefits competition is not an antitrust violation."

When the bank teller noted that "OD" meant the optical business, Dr. Steinberg says it made him suddenly aware of how many people associate optometry with selling glasses and have no awareness of all that optometrists can do.

"There have been a fair amount of efforts over the years about the need to get eye exams," he says. "But I don't remember anyone promoting what optometrists do, especially the medical side of the practice. There is a very broad perception among the public that if they have an eye injury or pain, they go see a medical doctor, a primary-care physician, or an ophthalmologist. That's a perception that needs to change. That doesn't happen overnight. It takes time. Right now it happens one on one with patients when someone's mom has glaucoma, for example, and we can treat it."

In addition, Dr. Steinberg has noticed a lot of chatter within the profession about vision care and managed care plans affecting practitioners' bottom lines in new ways, such as adding new burdens, restricting the ability to in-office cut and edge spectacle lenses, and referring current patients to other practices.

He says: "What our profession is missing is an entity designed to represent optometric interests, go toe to toe, and say, 'This isn't fair.' We need to see if there's room to negotiate and do it from a position of strength. We need to have the resources to sue them if that what it takes, or hire lobbyists to get laws changed if that's what it takes. I don't have the resources to hire a lobbyist. Several thousand optometrists contributing a few dollars every month would have the resources to get a law changed."

Dr. Steinberg says that he is unaware of another organization with a similar mission. "To some extent, the idea is to pick up where the American Optometric Association (AOA) leaves off. The AOA helped achieve the Harkin amendment. But who's out there to enforce it? If this law is being violated by a plan, who's going to step up and fund forcing the issue and taking them to court if necessary? The AADO is designed to complement organizations like the AOA. The AOA protects us in the legislative community, it gets laws passed to help optometry, but when the laws are ignored, the AOA is not in a position to take the next step."

In a statement, the AOA said: "We are aware that some of the founders of the American Optometric Society are starting another organization and soliciting dues-paying members."**ODT**

Recall

Continued from page 1

The products and lot numbers being recalled are:

- Bevacizumab, Lot no. 08052013@1
- Bevacizumab, Lot no. 08052013@4
- Lidocaine/phenylephrine, Lot no. 07302013@6

Like Avella, the compounding pharmacy has not received any reports of adverse events or reports of contamination. The concerns found also caused the FDA to conclude that the results obtained from the laboratory might not be reliable.

The recalled products were dispensed to healthcare providers between Aug. 5 and Sept. 2 nationwide.

Facilities that have a product that is being recalled should stop using and return them to the compounding pharmacy.

"We are working hard to minimize any impact on our valued customers as we continue to provide high-quality compounded medications to patients," said Charles Leiter, PharmD, president of Leiter's Compounding Pharmacy.

Lastly, Altaire Pharmaceuticals Inc. is voluntarily recalling nine lots of its carboxymethylcellulose sodium 0.5% ophthalmic solution, 30-ml, due to reports of mold.

There have been no reports of adverse effects to consumers thus far.

The pharmaceutical company chose to recall the product after there were complaints of mold found in the 30 mL bottles after use. This caused concerns regarding the product's effectiveness after use and handling of the product by customers.

It has been confirmed by Altaire that all lots of the product were sterile at the time of release, and the preservative was effective when challenged against the USP Preservative Effectiveness Test.

The product recalled is generically known as carboxymethylcellulose sodium 0.5% ophthalmic solution and is labeled as:

- Equate Restore Tears lubricant eye drops, 1 fl oz (30 ml); distributed by Wal-Mart Stores Inc.
- Lubricant eye drops for mild to moderate dry eye, sterile, 1 fl oz (30 ml); distributed by CVS Pharmacy Inc. and Target Corp.

Only the lots listed below are affected and the recall is limited to the product in the 30-ml size:

- 11440, labeled for CVS
- 11441, labeled for CVS
- 12042, labeled for Walmart and CVS
- 12103, labeled for Walmart
- 12203, labeled for Walmart and CVS
- 12207, labeled for Walmart
- 12293, labeled for Walmart
- 12352, labeled for Target and CVS
- 12356, labeled for Target and CVS

Altaire is initiating the recall as a precautionary measure and is notifying customers by phone or letters.

Customers who have any of the products listed should stop use immediately and return it to the place of purchase.**ODT**

In Brief

Vision care providers—are you ready for ACA?

San Diego—Is your practice on track to be compliant with the eye health provisions of the Affordable Care Act (ACA), which take effect Jan. 1, 2014?

ACA compliance requires significant changes to provider enrollment policies and procedures. Among other provisions, the new healthcare laws require that a yearly comprehensive eye exam be covered for individuals age 19 and under. This could mean potentially millions of new patients who previously did not have coverage.

"Both ptometrists and ophthalmologists should be prepared to employ the new laws and ensure that they are included in the various healthcare plans that will become available under these health insurance exchanges," said Sandy T. Feldman, MD, a nationally-recognized ophthalmologist and corneal expert in San Diego.

According to the American Optometric As-

See **ACA** on page 6

ACA

Continued from page 5

sociation (AOA), a few of the top changes for vision care providers as a result of the ACA include:

- The development of a health insurance exchange that will create thousands of newly insured individuals and patients.
- The expansion of Medicaid to individuals who are 133% below the poverty line could mean a potential significant increase in Medicaid patients.
- The formation of Accountable Care Organizations (ACO) and Patient Centered Medical Homes (PCMH) as cost-containment measures could mean potential savings for providers as a result of improved management of a patient's care.

First mobile EHR app for iOS7 from drchrono

Mountain View, CA—drchrono announced the first mobile EHR app to support Apple's iOS7 operating system, which launched recently. This free EHR app allows practitioners to connect with patients and manage their practices, including sharing medical records, electronic prescribing, medical billing, and patient management, all from an iPad. The app supports iOS7, which allows practitioners share files at the point of care via iPad or iPhone via iOS7's AirDrop.

The app allows users to take advantage of three new iOS7 features:

- Airdrop: Providers are able to instantly and wirelessly share documents to any other iOS-enabled device.
- Parallax: drchrono will recognize user's usage patterns and begin preloading patient files.
- Background loading: What is seen on the login screen interacts with how users move their devices. As the user moves, the image shifts as well.

J&J Vision Care accepting research proposals for UV and the eye

Jacksonville, FL—Johnson & Johnson Vision Care, Inc. (JJVCI) is now accepting research proposals related to ultraviolet (UV) radiation and the human eye. Specific areas of interest include the following topics:

- Eye health, including photoageing (cataractogenesis, presbyopia, corneal, retinal, conjunctival/limbal changes)
- Epidemiology of UV-induced ocular disease, including geographic, ethnic, and occupational study. Proposals may include the study of indoor and outdoor UV radiation. Increased risk associated with UV exposure in youth.
- Assessing the protective effect of UV-blocking contact lenses on human ocular tissues including methodology, measurement techniques, and clinical endpoints. Comparative protective effects of contact lenses and spectacles/sunglasses.

Research proposals must be submitted through the JJVCI Investigator Initiated Study (IIS) application process by contacting the clinical research administrator via e-mail at RA-VISUS-IISRequests@its.jnj.com or by calling at +1-904-443-1525. All research proposals must be submitted in English.

For additional information on JJVCI's IIS process and policy and this opportunity, visit *http://www.acuvueprofessional.com/investigator-initiated-studies*

ToriCalc, new cross-cylinder mobile app, lauches

Seattle—Just-launched mobile app ToriCalc quickly calculates cross-cylinder contact lens prescriptions for eyecare practitioners, manufacturers, educators, and contact lens distributors. ToriCalc, resulting from the partnership between Innovative Insights LLC and Abacaus International, is available for individual download or as the basis for a private label entry into mobile application marketing and customer support.

Contact lens specialists need fitting tools and ToriCalc, based on proven sphero-cylinder over-refraction formulas, serves this requirement while providing a mobile application opportunity for businesses or groups desiring to increase their brand awareness and customer support. The app quickly calculates cross cylinder contact lens prescriptions and has been engineered to increase speed and accuracy as well an enhanced user experience. Prescription information may be entered from baseline spectacle refraction or from lens on-eye information. In addition to calculating resultant lens powers, ToriCalc includes a spectacle lens conversion system and a subjective graphical interface to modify axis alignment.

"When we went through the various offerings inside eye care for a highly useful tool practitioners can use every day, a cros- cylinder calculator stood out as the first tier in a customizable suite of mobile application software," said Mark Bertolin, President Innovative Insights LLC.

As a private label option, ToriCalc provides a cost-effective system to build brand awareness and increase exposure in the expanding mobile marketplace. ToriCalc can be branded to meet customer demand and optimized to include client specific features.

ToriCalc is available initially as an iOS application with an Android version following later in 2013. It is available on iTunes and ToriCalc.com.

Study shows safety, effectiveness for non-invasive wet AMD treatmtent

Newark, CA—Two-year results of a therapy for wet age-related macular degeneration show a favorable safety profile and reduced frequency of anti-vascular endothelial growth factor (VEGF) injections in the eye.

Oraya Therapeutics, Inc.'s Stereotactic Radiotherapy uses low-energy, highly targeted X-rays for the treatment of wet AMD. Intended as a one-time procedure, it is non-invasive, rapid, comfortable for the patient, and easy for a trained operator to perform. The total procedure time is typically less than 20 minutes. The IRay radiotherapy system's delivery approach, targeting algorithm, eye stabilization, and tracking methods are proprietary.

The INTREPID study's broadly inclusive cohort of non-naïve wet AMD patients continued to receive the benefit of a 25% mean reduction in anti-VEGF injections over 2 years. Patients identified in the first year as ideal response candidates maintained a 45% mean reduction in anti-VEGF injections through the 2-year visit, with superior vision to the non-treated group. In addition, the overall safety profile was positive, with 1% of treated patients showing evidence of micro-vascular abnormalities due to radiation that could affect vision outcomes.

"A treatment that offers the prospect of fewer injections will be welcomed by clinicians and patients alike, said Timothy L. Jackson, PhD, FRCOphth, King's College Hospital, London, lead investigator for the INTREPID trial. "Importantly, if we select the right patients, vision appears to be better than with anti-VEGF monotherapy. The safety at two years is also encouraging, in that most micro-vascular changes were located away from the fovea, and so did not have an impact on vision."**ODT**

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Energeyes will energize corporate optometry

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

Corporate-affiliated optometrists with Walmart and Sam's Club have formed an association called Energeyes to facilitate networking, collaboration, and education for the benefit of their corporate-affiliated optometric colleagues. The potential number of members is substantial: approximately 3,200, or 11% of practicing optometrists, hold leases with Walmart and Sam's Club alone, and the organization is open to all corporate-affiliated ODs.[1] Such a move has been a long time coming and is no doubt long overdue.

Years ago, corporate optometrists were somewhat of a pariah. They got the cold shoulder from ODs in private practice and often weren't made to feel welcome at local zone meetings. I have to admit, I was probably one of those guys. I once thought that because I had my own building with my name in large letters out front I was somehow better than folks whose chose to work somewhere in a box store. My years teaching optometry students offered a different perspective and showed me the error of my outlook. I've seen a lot of my former students choose to work at commercial places—not only are they surviving, but are thriving in that environment. They practice at a high level and strive to care for their patients the same way we all do.

Optometrists are often lone wolves. It's very easy to feel isolated and alone wherever you practice. I think we cling to zone meetings, study groups, and state and local CE meetings like drowning swimmers cling to a life preserver. We need the intellectual stimulation and social interaction with our peers. We're so busy seeing patients and putting out fires in our practices every day we don't get that nourishment.

"Many of us feel the need for better collaboration, networking, education, and representation that is specific to our needs," said Dr. Mark Uhler, a member of the Energeyes organizing committee. The organization does not see itself as an adversary to the American Optometric Association (AOA), and the AOA supports the association of corporate-affiliated optometrists.[1] I agree: I think it's more that people seek out people of like mind. I commend the folks at Energeyes for identifying a need and filling that need for their affiliated optometrists.

You see, over the years I've come to understand that it doesn't matter *where* you practice, it's *how* you practice. Patients deserve the best optometric care no matter where it's sought, and ODs in commercial locations strive to provide that care. It's no different from the docs who own their own box. It's time to realize outstanding patient care is what defines us as a profession, no matter where you choose to hang your shingle.**ODT**

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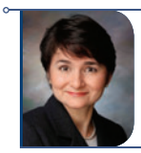
1. Bailey GM. Corporate ODs form association. *Optometry Times*. 2013;5(8):1.

The power of the staple



Katherine M. Mastrota, MS, OD, FAAO
Dr. Mastrota is center director of Omni Eye Surgery in New York City and associate optometric editor of *Optometry Times*.

Most people are amazed to find out that I do not own a driver's license. As a real city girl, I never had the need to drive anywhere because there was always a train, bus, cab, or ferry to get there. Naturally, I take the subway every morning from Brooklyn to Manhattan to get to the office, and at day's end, back to Brooklyn. The 40-minute ride to and fro is the perfect time to review the plans of the day, make my to-do lists, or catch up on reading my personal pile of professional periodicals. I know you have a pile of those, too.

Reading in a crowded subway car is a bit of an art form. Most daily newspapers, especially *The New York Times*, not unlike *Optometry Times*, are physically expansive—oversized pages chock full of information. *The New York Times*, not unlike *Optometry Times*, opens to shoulder's length, making it impossible to read unless some creative origami takes place. Before handheld devices became commonplace, I would be fascinated at how many different ways a reader could fold the *Times* to make it compact for reading and commuter sensitive.

At this point, you must be wondering where I am going with this. Well, here's a little-discussed fact about *Optometry Times*. The print version of *Optometry Times* (of course it's available electronically) is constructed perfectly for those of us who love paper and enjoy flipping the pages of a hard copy and relish tearing out intriguing articles and the like. *Optometry Times* can go everywhere. How can that be, you must be thinking, when it is larger than standard size? **It's the power of the staple**.

Yes, the power of the staple. *Optometry Times* can fold. Try folding a bound periodical, and you have a lumpy, fanned-page mess. Folded once, *Optometry Times* is smaller (and lighter) than an iPad and can fit into any purse. Folded twice, it can fit into your pocket. *Optometry Times* can go anywhere to be ready at any moment for a quick read, whether waiting for your car to be washed (not a time waster for me, but perhaps for you doctors who drive) or any other opportunity to occupy your valuable time.

Folded once, *Optometry Times* is smaller (and lighter) than an iPad and can fit into any purse. Folded twice, it can fit into your pocket, ready for a quick read.

Optometry Times, like *The New York Times*, is "All the News That's Fit to Print." I encourage you to pick up your copy and practice origami on your own. You will not be disappointed with the content, and I am certain you will learn something new every time you explore its pages.

Contact me at KatherineMastrota@msn.com with any comments, concerns, subway questions, or origami instructions.**ODT**

BLUE LIGHT, VISION, AND THE EYE

By developing an experimental framework to distinguish beneficial blue light rays from harmful ones, Essilor has effectively created a new field: photobiology research.

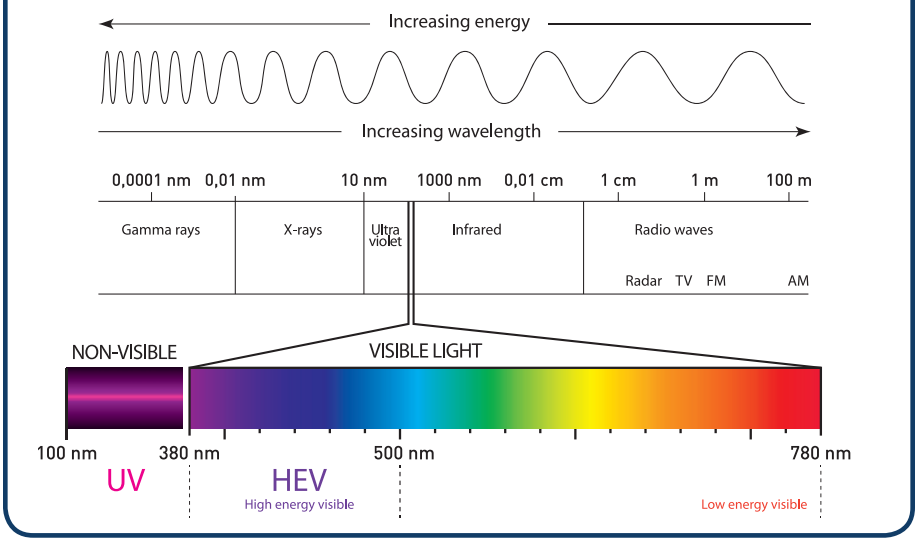
The electromagnetic spectrum encompasses every possible wavelengths of radiation in our universe. At one end lie the tight, high-energy gamma rays that are so powerful that exposure to these rays can cause cancer in living creatures; while far away on the opposite end lie the long, low-energy frequencies that cause nothing more harmful than AM radio. Near the center of this vast continuum, sandwiched between ultraviolet and infrared energy, runs a very thin sliver of bandwidth that we see as visible light and colors—also known as optical radiation, which ranges from about 380 nanometers (nm) to 780 nm. (See Figure 1.)

Within optical radiation, the colors that are blue and bluish, from violet to turquoise, take up a lot of space, about 380 to 500 nm. They have tighter wavelengths and pack greater energy than greens, reds and yellows. Thus blue light is sometimes referred to as high-energy visible (HEV) light.

Blue light tends to occur at higher frequencies outdoors via sunlight and at lower ones indoors, where, until recently, most illumination was provided by incandescent light sources, which burn at higher red and yellow frequencies than the sun.

It is known that prolonged exposure to outdoor radiation (both visible and non-visible light) can result in cumulative damage to eye tissues, both anterior and posterior. Ultraviolet radiations are harmful to the cornea and crystalline lens and are associated with cataract development. HEV light is a known risk factor for age-related macular degeneration (AMD). It can induce and accelerate photochemical reactions and cell photo-damage, largely mediated by the accumulation of reactive oxygen species in the retina, researchers believe.

Figure 1. Electromagnetic spectrum and zoom on visible and blue light



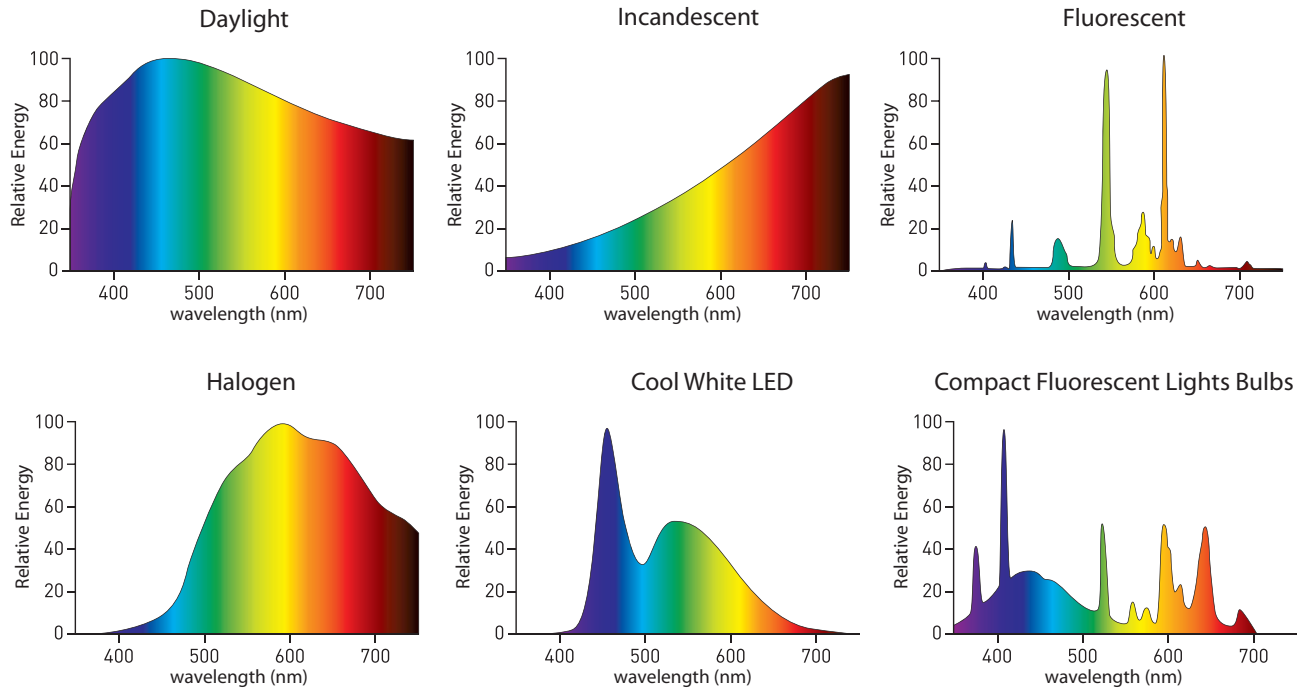
And yet we also know that exposure to HEV light has a beneficial effect as well. It plays an important role in non-visual functions, such as circadian rhythms involving sleep-wake cycles, as well as cognitive, psychomotor, and hormonal balance.

Although they have a great deal in common, these two areas of scientific inquiry—the study of HEV light's positive effects on the one hand and its negative impact on the other—have up until now operated largely independently of each other. But recently, Essilor's R&D department, working in conjunction with the Paris Vision Institute, unveiled data vthat maps out a very precise retinal phototoxic spectrum within HEV radiation. For the first time ever, researchers can measure the precise physiological conditions of illumination using an *in vitro* model. This paves the way for a whole new discovery of corrective lenses that filter out harmful HEV frequencies while allowing beneficial ones, to pass through to the eyes untouched.

Blue Light Sources

Every light source emits a spectrum that can be expressed as a function of a monochromatic wavelength and shown on a graph. For example, Figure 2 represents the spectra in the visible range of typical sunlight, an incandescent bulb, a fluorescent lamp, a halogen lamp, and a cool white light-emitting diode (LED).

Figure 2. Spectra of classical light sources



Depending on atmospheric conditions, time of day, geography, etc., the blue light portion of sunlight is 25-30% percent.

Existing artificial light sources are based on one of two processes: incandescence or luminescence. In incandescent light sources, that is, incandescent bulbs (of the Thomas Edison variety) and halogen lamps, a filament is heated and emits a light radiation.

In luminescent light sources, which include compact fluorescent lamps (CFL), fluorescent bulbs, and LEDs, the atoms of a gas or a semiconductor are excited via a discharge or a carrier recombination, leading to the emission of visible radiation.

Luminescent light sources tend to contain a greater portion of blue light. For example, compact fluorescent lamps contain 26% blue light, and cool white LEDs emit at least 35%. By contrast, traditional incandescent lamps emit only 3% blue light.

Until recently, traditional artificial light was provided mostly by incandescent lamps. However, such older light sources are now being rapidly replaced by products based on LEDs, which have a longer lifetime, lower energy consumption, and less negative environmental impact. In Europe, it is predicted that by 2016 traditional incandescent light sources will no longer be available for domestic lighting. Leaders in the lighting industry believe that by 2020, more than 90% of all light sources worldwide will be based on solid state lighting products and LEDs. We can see this all around us as luminescent light sources progressively conquer office environments, TV screens, computer monitors, mobile phones, tablets, etc.

This trend significantly increases exposure to these new LED-based artificial light sources, consequently elevating the proportion of total blue light that reaches the eye.

Blue Light and Vision

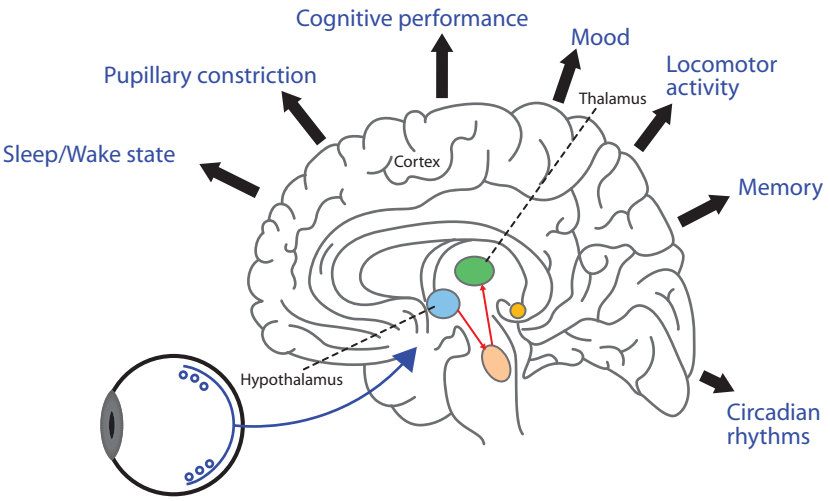
To function properly, rod and cone photoreceptors must constantly regenerate. Retinal pigment epithelium (RPE) cells play a critical role in this regeneration. Without RPE cells, rods and cones cannot survive. Several retinal pathologies can be linked to RPE and photoreceptor degeneration, including AMD, retinitis pigmentosa, and Stargardt's disease.

Over the last 20 years, many studies have linked the role of sunlight exposure to the prevalence of AMD. For example, the EUREYE study found significant associations between blue light exposure and neovascular AMD in individuals having the lowest antioxidant levels.[1] Another study performed on 838 fishermen in the Chesapeake Bay area showed patients with advanced AMD had been exposed to high levels of blue light over the preceding two decades.[2]

Furthermore, granules that accumulate in the RPE cells in the early stages of AMD are made up of a substance called lipofuscin. Lipofuscin is produced by an incomplete phagocytosis of the photoreceptor's outer segments and can be activated by specific protons, with a maximum absorption in the blue spectral range.

How does this occur? During very prolonged or extreme light exposure, an accumulation of all-trans-retinal (ATR) can occur in the photoreceptor outer segments (POS). The ATR is photosensitive to light ranging from violet to blue, with an absorption profile decreasing from 400 nm to 500 nm. When the antioxidant defenses begin to falter, as they do in advanced age, this ATR photo-activation can induce an

Figure 3. Non-visual biological functions controlled by light



oxidative stress in the POS. When the POS are oxidized, they cannot be correctly phagocytized by RPE cells. This incomplete intracellular digestion generates lipofuscin granules in the RPE. The end result of all these processes is RPE degeneration and photoreceptor death.

Preventative Measures

AMD is a serious worldwide problem, one expected to worsen as life expectancies increase and mean population ages continue to rise. The worldwide AMD population was roughly estimated at 100 million people in 2012, and if demographic trends continue at current rates, this number will double in the next 30 years.

While great advances have occurred over the past 10 years in the treatment of AMD, especially in the field of anti-vascular endothelial growth factor (VEGF) injection therapy, the longevity of treatment benefits remains frustratingly short, and there seems to be no endpoint to the frequent intra-vitreal injections required to maintain it. Any measures that could be taken to prevent the onset of this blinding disease would no doubt be enthusiastically welcomed by the ophthalmic community.

One area in which preventative measures might be particularly effective is dry AMD, where anti-oxidative dietary supplements, containing lutein or zeaxanthin, have yielded positive results.

Another degenerative disease in which preventative options would be welcome is retinitis pigmentosa. Like AMD, retinitis pigmentosa is characterized by RPE and photoreceptor degeneration. Progressive rod atrophy causes a slow peripheral vision loss in both eyes. Cones are also affected at later stages of the disease. No treatment solutions for this disease in advanced stage have yet been commercialized.

Stargardt's disease is an inherited juvenile form of macular degeneration that causes progressive central vision loss. The pathological features of Stargardt's include the accumulation of fluorescent lipofuscin pigments in the RPE and the degeneration of photoreceptors.[3,4] Some *in vivo* studies on Stargardt's disease models suggest that light exposure increases the formation of lipofuscin granules. For instance, researchers have observed that mice kept in dark environments demonstrated almost no lipofuscin deposits.

Beyond the lack of therapeutic treatments for patients suffering from degenerative retinal diseases, a dearth of preventive solutions coupled with a generally late diagnosis explain the irreversible and numerous negative effects on vision.

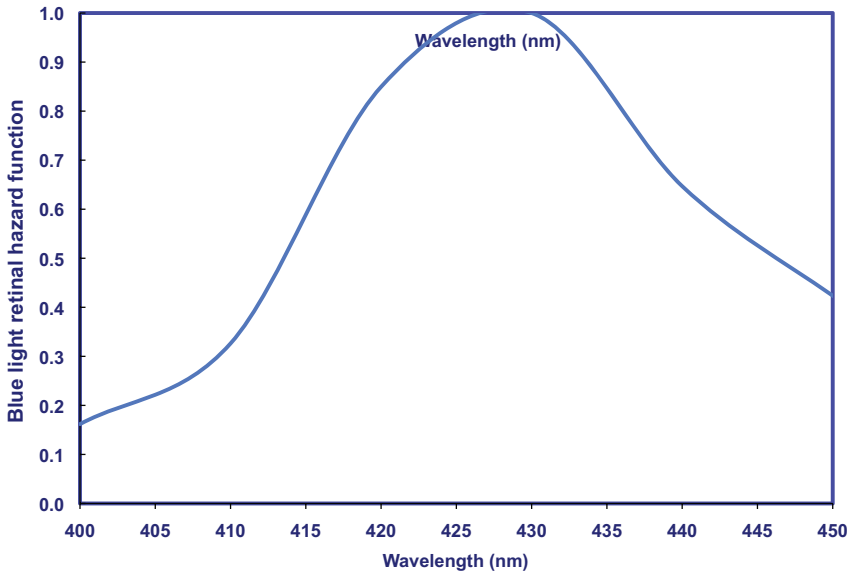
Blue Light and Non-visual Functions

While it is obvious that light regulates the visual process, photons received by the eye can also affect many non-visual biological functions. These non-visual

KEY TAKEAWAYS

- Essilor is the first ophthalmic industry player to conduct *in vitro* photobiology research with 10 nm ranges of HEV exposure.
- For the first time, the most toxic wavelength range within blue light is identified in physiological sunlight conditions using a swine AMD cell model.
- Wavelength-dependent apoptosis (cell death) is evidenced, associated to lifelong cumulative toxicity.
- RPE cell apoptosis is evidenced between 415 nm and 455 nm (435 +/-20nm), the Blue-Violet range.
- Preventive solutions are necessary to slow down the continuous aging and pathological process.
- The innovation of the photobiology research, carried out by Paris Vision Institute and Essilor, is based on 4 aspects:
  1. Use of an *in vitro* model of AMD and aging using A2E photosensitization on primary swine RPE cells.
  2. Calculation of physiological sunlight exposure at retinal level.
  3. Sophisticated LED-fibered cell illumination device to scan blue spectral range.
  4. RPE cell exposure to 10 nm illumination bands in physiological sunlight conditions.

Figure 4. Relative blue spectral function efficiency, blue light risk function



irradiance detection tasks are triggered by a third photoreceptor, discovered in 2002, called intrinsically photosensitive retinal ganglion cells, or ipRGC. These cells contain a melanopsin associated pigment.[5] Melanopsin pigment absorbs around 480 nm ± 15 nm, (about what we see as turquoise) which is now commonly known as the "chronobiological spectral band."

Non-visual photoresponse is essential for circadian rhythms in many non-visual functions, encompassing sleep/wake state (melatonin synthesis), pupil light reflex, cognitive performance, mood, locomotor activity, memory, and body temperature, among other bodily functions. (See Figure 3.)

Chronobiological disruptions can cause sleep disorders, gastrointestinal disorders, depression, anxiety—and even increased risks of cancer for shift workers, according to studies (HAS-French Haute Autorité de Santé 2012 report).

Thus, it is now widely believed that exposure to blue light within the chronobiological spectral band should be maintained to ensure a good synchronization and regulation of non-visual biological functions.

Experimental Model

The achievement of Essilor and the Paris Vision Institute has been to establish an *in vitro* experimental model that produces accurate, reproducible photobiology results. This model consists of an illumination device that allows researchers to convey light on very restricted, narrow wavelengths, parsing the visual light spectrum into 10-nanometer bands. Each band is guided by an optic fiber toward a cell incubator, which contains swine cells. This allows researchers to precisely control the degree of illumination for each wavelength.

Researchers have extracted from this *in vitro* model a formula to calculate blue light risk. It describes the biological risk linked to the photochemical degradation of RPE cells when the retina is exposed within certain blue light ranges. (See Figure 4.)

Moreover, the newly established selective photo-toxicity spectrum creates the starting points for two very practical areas of research: the invention of selective photo-protection ophthalmic filters and the calculation of how well these filters function.

Summary

The 4-year rigorous research work, jointly released by scientists from Essilor's R&D department and Paris Vision Institute, shows that RPE cell apoptosis is specifically amplified in a 40 nm narrow range within the Blue-Violet light spectrum, from 415 nm to 455 nm, centered at 435 nm. The identification of this precise "toxic band" represents the heart of this scientific discovery.

Thus, we now have specific criteria for selective photo-protection. Essilor has developed a truly new category of ophthalmic lenses—Crizal® Prevencia™ No-Glare lenses. This new technology can simultaneously selectively filter harmful light—Blue-Violet and UV light—while passing through all beneficial light and still maintaining lens transparency.

Furthermore, the unique illumination system is currently being used to measure the cell protection brought by various blue filtering lenses. Hence, for the first time, lens protective efficacy can be evaluated under *in vitro* physiological sunlight conditions, based on objective measurements of cell viability.

This evidence, though preliminary, strongly suggests that new filters could aid in preventing patients from premature AMD onset, and possibly other diseases as well.

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What's important to you?

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

As I shared in one of my first editorials, I have been part of the optometric community for almost 25 years. A big chunk of that time has been spent in the contact lens and corneal arena. Since I arrived at *Optometry Times* in August 2012 to captain this ship (it's been a year already??), I have enlarged my focus to spend more time within the entire profession of optometry than ever before.

I like it!

I'm finding that optometrists have many topics on their mind. Here are a few:

- Board certification (we need it)
- Board certification (we don't need it)
- Electronic health records (EHR) and meaningful use (MU)
- Changes to vision care plans
- Too many vision care plans
- Changes to overall health care, including HIPAA and Affordable Care Act (or Obamacare)
- Audits
- New professional organizations
- Too many optometry schools
- Too many optometrists
- Lack of cohesiveness in the profession

I came up with that list after thinking about it for, oh, maybe 5 seconds.

Some doctors worry a lot about their patients buying glasses over the Internet. Others, not so much. They're too busy trying to train new staffers. Some doctors are fielding questions from just about every patient in their Medicare-based practices about AREDS and what it means to them, while others are working hard to gather support to pass an expanded scope of practice bill in their state.

Clearly there's a lot to talk about and a lot for us to write about. But what I want to know is: What is important to *you*? We want our publication to reflect what is important to the optometrists walking into exam rooms every day. And the only way we can do that is for you to tell us.

E-mail me (gbailey@advanstar.com) to tell me your top three concerns in optometry today.**ODT**

Letters

To the Editor

If we just listen

People sometimes ask me if I find the repetitive "which is better?" aspect of optometry boring ("Which is better: one or two?" by Ernie Bowling, OD, FAAO; *News Flash* August 21, 2013). I tell them no because every patient has a story to tell if we just listen. Thank you for saying that so well.

Janet Carter, OD, FAAO
Las Vegas

Free adjustments = donation

In response to Michael Spino's letter to the editor ("Charging for services," June 2013) we also do not charge for repairs/adjustments. When patients ask about how much it costs for a repair, we explain that we do provide this service free of charge, but we appreciate a donation to be made to Optometry Giving Sight, *www.givingsight.org* (our charity of choice). We find that patients are quite generous and are pleased to support a practice that has a social conscience. Optometry Giving Sight will send you a donation box if your practice wants to participate in this way.

Pui-Yee Ho, OD
Brooklin, Ontario

For the record

Thank you for including a statement from the American Optometric Society (AOS) regarding the AOS v American Board of Optometry (ABO) litigation on the cover of the August issue ("Judge rules against AOS in bankruptcy case"). However, there were a significant number of mis-statements made by Dr. Paul Ajamian. In fact, the ABO did not win every legal battle.

The actual case was lost on one issue only: the inability of the AOS to prove future damages under the Lanham Act. The judge clearly stated that any certificate issued by any board is the same as board certification (BC) and did not grant any special recognition or credence to the ABO program. The actual ABO testimony stated that the ABO BC optometrist is no more competent than the non-ABO BC optometrist. All court documents, testimony, and depositions from both sides are still on the AOS Web site.

Dr. Ajamian also testified that 3 years in practice is the equivalent of a residency program, although no proof of that was ever presented. This is truly a serious misstatement and quite detrimental to any of the excellent residency programs being pursued by our colleagues.

Furthermore, the AOS went into Chapter 11 with a reorganization plan, specifically intending to pay the judgment and costs in full. The fact is that the AOS did indeed submit a valid and feasible plan to pay that amount in full, and it was outright objected by the ABO. The ABO then filed to force the AOS into Chapter 7 liquidation. Dr. Ajamian also stated from the podium at the American Optometric Association (AOA) House of Delegates that it was the ABO's intent to completely destroy the AOS—the ABO has continued to expend monies to ensure that end.

The original and permanent injunction still stands against the ABO. To date through the July exam, about 1,650 people have taken and passed their process—a very small minority of optometric doctors (fewer than 5%).

In addition, the ABO has been adamant about suing the AOS litigation counsel for malpractice and has continued to pursue that avenue.

The actions of the ABO and the AOA support of the ABO are are reprehensible and repeatedly so. It is particularly disturbing that the AOA President Elect is still on the ABO board and was originally the head of that board. The ABO is housed in the AOA building, and numerous connections and funding from the AOA have occurred over the past several years. As a 40-plus-year AOA member, I am deeply disappointed in the actions of some of the AOA leadership, which continue to create a rift within the profession, despite many overtures from the AOS to attempt to help heal this rift, even encouraging our members to support the state and national PACs and their state associations.

Pamela J. Miller, OD, FAAO, JD, DPNAP
President, American Optometric Society

New organizations and respect in optometry

The emergence of many new organizations in such a short time seems to me an ominous sign. New groups form when existing ones don't meet the needs of their members. I see this a clear warning to those in leadership roles, and I urge them to embrace rank-and-file perspective and change. If this doesn't happen soon, they and the organizations they lead risk becoming irrelevant and perhaps even extinct.

We live in an age where communication is almost instantaneous, and nearly everyone has a loud and clear voice. It amazes me that some organizations remain so insular. I think the days of power being concentrated in the hands of a few are coming to an end. Why aren't we using readily available technology to empower our members to voice their concerns, then act on addressing those needs and desires? If the organization doesn't represent its membership, who then does it represent? Continued resistance to changes that would facilitate stronger membership involvement is absolutely ludicrous.

It's never been more clear that the profession needs to develop greater respect for itself and come together to work as one unified force. Obviously one group can't do everything. The American Optometric Association (AOA), The Optometric Society (TOS), and our state organizations are essential for representing us politically and publically. There's a clear role for the American Academy of Optometry (AAO) in representing us academically and furthering the science of what we do. Association of Regulatory Boards in Optometry (ARBO) is critical for bringing order to the myriad state boards, CE requirements, and laws. And there is an absolute need for the new American Association of Doctors of Optometry (AADO) in representing ODs and their patients' interests in our tumultuous relationships with managed care and third-party payers—which will become increasingly important. Moreover, our organizations must work together, not compete for power and position. This has to be about the profession, and more importantly, our patients.

It's never been more clear that the profession needs to develop greater respect for itself and come together to work as one unified force.

Optometry has evolved into the primary eyecare profession in the U.S. and will be a key part of the healthcare delivery system in the future. The greatest risk for our profession comes from within. We must work together cohesively to ensure our place in the future of health care.**ODT**

Author Info

Art Epstein, OD, FAAO, is in practice in Phoenix and was recently named as a board member for the American Association for Doctors of Optometry. E-mail him at artepstein@gmail.com.

MY FAVORITE APP

Retina Risk

This app—a clinically validated risk calculator for sight-threatening diabetic retinopathy— is useful to clinicians for patient education. It generates a color-coded speedometer graphic depicting annualized risk for sight-threatening retinopathy based on a combination of established risks like A1C and blood pressure. This allows the ECP to manipulate inputs and show patients visually how much their individual risk changes with better (or worse) metabolic control. It has gotten my patients' attention. It also conveniently creates a printable report.

—A. Paul Chous, OD
Memphis

In Brief

October is Home Eye Safety Awareness Month

Chicago—Each year in the United States, more than 2.5 million eye injuries occur, and 50,000 people permanently lose part or all of their vision, according to the American Academy of Ophthalmology. A recent report from Prevent Blindness America shows that the annual costs related to eye injuries are more than $1.3 billion.

Because more eye injuries occur in and around the home, Prevent Blindness America has declared October as Home Eye Safety Awareness Month to help educate the public. Find information for your patients on the organization's dedicated Web page: *PreventBlindness.org/eye-safety-home*.

Eye injuries can occur from a variety of common sources, such as flying debris from lawn mowers or trimmers or splashes from household cleaners, paints, or solvents. Prevent Blindness America urges everyone to wear protective eyewear approved by the American National Standards Institute (ANSI) when performing household activities. The eyewear should have the "Z-87" logo stamped on the frames.

Knowing what to do for an eye emergency can save valuable time and possibly prevent vision loss. Prevent Blindness America offers a free First Aid for Eye Emergencies sticker in both English and Spanish that can be placed on the inside of a medicine cabinet. Basic eye injury first aid instructions include:

Chemical burns

- Immediately flush the eye with water or any other drinkable liquid. Hold the eye under a faucet or shower, or pour water into the eye using a clean container. Keep the eye open and as wide as possible while flushing. Continue flushing for at least 15 minutes.
- ***Do not*** use an eyecup. ***Do not*** bandage the eye.
- If a contact lens is in the eye, begin flushing over the lens immediately. This may wash away the lens.
- Seek immediate medical treatment after flushing.

Specks in the eye

- ***Do not*** rub the eye.
- Allow tears wash the speck out or use an eyewash.
- Try lifting the upper eyelid outward and down over the lower lid.
- If the speck does not wash out, keep the eye closed, bandage it lightly, and see a doctor.**ODT**

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ALLERGAN

Staff communication made easy

My office communication process may give you some ideas

Working on communication each day helps the entire staff—including doctors—to improve. Committing to better communication and implementing a plan to make it happen are keys to success.

As I talk to doctors about the struggles within their practices, one topic comes up over and over. It is so common that you can count on it being an issue in every single practice: staff communication. Getting everyone on the same page and keeping them there is a constant struggle for practices of every size.

There is only one way to get good at staff communication: practice. You must commit to improving communication—if you want to improve it. Once you are committed, you must put systems in place to keep the momentum going so the benefit does not fade away.

Michael Rothschild, OD
Dr. Rothschild is director of What's Next-Leadership OD; a consultant for Alcon, Optos, and Vision Source; a member of the speakers' bureau for VSP; and a clinical researcher for CIBA Vision.

What works for us

In our office, we have tried many methods to stay in touch with each other. Here is our current regimen.

Tip of the day

Each staffer has a practice e-mail account, and daily we receive a "Tip of the Day." This is a collection of tidbits of information that we should all know but are easy to forget. For instance, today's was, "*If contact lens brand for a patient is unknown, choose the word "unknown" in the CL brand section in EMR*." Rather than nagging your staff over small items like this, a helpful daily e-mail serves as a pleasant reminder for everyone. The item is on a checklist, and the tips are scheduled out for the entire year.

Bulletin board

Directly above our time clock is a dry erase board. Every afternoon, the clinic leader maps out the next day's morning patients by listing which tech will begin which visit. In our office, the morning can be particularly chaotic. Even if we don't go by the plan, having a plan that everyone sees has a tremendous effect of keeping us on track.

Checklists

Sets of checklists are a critical point to making sure routine office tasks are completed every day. Most doctors are amazed at how many steps are necessary to simply open their offices. Turning on a computer usually involves three or four steps. (I encourage you to count the computers in your office.) But there are also lights, equipment covers, dusting, cleaning, resupplying rooms, turning on/off the air conditioner or heat…

Leadership team/plan for the day

The leaders of every department get together with the doctors as each day starts and simply answer the question, "What's up today?" The only answer that is not allowed is, "Nothing." (That is also a rule at my house with my teenage kids.) We are busier than expected, somebody called in sick, we had a bunch of cancellations, we need to get the new people trained. There's always something going on.

Basic meeting

This is a daily meeting that everyone in the office attends. It is the longest standing communication tool we use, and it is truly a part of our culture simply because we have insisted on it. We have 20 basic rules for our staff to abide by in every patient interaction. During the meeting, we review one of the rules and discuss why it is a part of our practice mission. Staff members are responsible for conducting these meetings, so individual presentation skills are honed at the same time.

Everybody Needs to Know sheets

Sometimes we hear the question, "When did we start doing it this way?" Which is followed up with, "Nobody told me." Whenever we make a change to our process that everyone must know, we complete an "*Everyone Needs to Know*" sheet. It has every staff member's name on it, and we all sign it—including the doctors.

Staff meeting

In addition to our daily Basic Meeting, we close the office once a week for an hour to discuss our overall plan for the practice. We look at our goals and check our progress. We also use these opportunities to keep abreast of changes in the industry.

Leadership development

A leadership team is the collection of staff members from each area of the practice who take responsibility for day-to-day decisions. These can be tough and require an ability to make judgment calls—and a freedom to make those calls. The leadership team meets regularly to discuss how to grow and improve.

Retreats

Twice per year, the office closes for 1 to 2 days to dig in deep about where the practice is going and how it should change. Together we discuss what we can do better and to set the direction. This is when we set the goals that we evaluate at our weekly meetings.

Smaller tasks work

This might look like an overwhelming list of tasks, but it's much easier to digest when broken into smaller tasks with a little happening every single day.

Communication systems have to be varied and updated, but you must commit to working on it every day. **ODT**

BESIVANCE® (besifloxacin ophthalmic suspension) 0.6%: Potency and Broad-spectrum Activity for the Treatment of Bacterial Conjunctivitis

Ron Melton, OD, FAAO

ABSTRACT Bacterial conjunctivitis is a common ocular infection that, although usually self-limited, can result in severe cases and develop vision-threatening complications. Diagnosis of bacterial conjunctivitis is generally clinical, and most cases can be managed with empirical antibiotic therapy. Use of a potent, broad spectrum topical antibiotic maximizes the chances of rapid, successful resolution. BESIVANCE® (besifloxacin ophthalmic suspension) 0.6%, a fluoroquinolone developed specifically for topical ocular use and approved for the treatment of bacterial conjunctivitis, provides such an antibiotic choice. BESIVANCE® is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: *Aerococcus viridans**, CDC coryneform group G, *Corynebacterium pseudodiphtheriticum**, *Corynebacterium striatum**, *Haemophilus influenzae*, *Moraxella catarrhalis**, *Moraxella lacunata**, *Pseudomonas aeruginosa**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis**, *Staphylococcus lugdunensis**, *Staphylococcus warneri**, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius**.

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

As a double halogenated topical chlorofluoroquinolone, BESIVANCE® demonstrates potent activity against a range of important ocular pathogens, including strains of methicillin-resistant staphylococci, and susceptible isolates of *Pseuedomonas aeruginosa*. Formulated in a mucoadhesive vehicle, BESIVANCE® also has excellent ocular surface residence time, making it a superb choice for the treatment of bacterial conjunctivitis.

See Important Risk Information about BESIVANCE®.

Important Risk Information for BESIVANCE®

- BESIVANCE® is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.
- As with other anti-infectives, prolonged use of BESIVANCE® may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.
- Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with BESIVANCE®.
- The most common adverse event reported in 2% of patients treated with BESIVANCE® was conjunctival redness. Other adverse events reported in patients receiving BESIVANCE® occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.
- BESIVANCE® is not intended to be administered systemically. Quinolones administered systemically have been associated with hypersensitivity reactions, even following a single dose. Patients should be advised to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.
- Safety and effectiveness in infants below one year of age have not been established.

Bacterial conjunctivitis is a common ocular surface infection. Each year, one in every eight US children comes down with acute conjunctivitis, most of which is bacterial; and bacterial conjunctivitis accounts for about 1% of all primary care office visits.[1] In the US, the incidence of bacterial conjunctivitis is estimated at about 1.3%.[2]

Typically, bacterial conjunctivitis is acute and self-limited. It can resolve spontaneously, but topical antibiotic therapy offers a number of benefits.[3] Antibiotic treatment can shorten the course of the disease, enabling a faster return to school or work. Faster resolution also reduces the risk of transmission and the potential for a lingering moderate or severe bacterial conjunctivitis causing serious complications.

Spectrum of Activity and Potency

The organisms that most often cause bacterial conjunctivitis include *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Staphylococcus epidermidis*.[4] Among these, *S. aureus* is typically the most aggressive organism, and the combination of virulence and drug resistance makes methicillin-resistant *S. aureus* (MRSA) an organism of great concern. Although MRSA has moved out into the community, healthcare workers remain at high risk of MRSA colonization because of its prevalence in hospital settings.[5]

When confronted by a case of bacterial conjunctivitis, the gold standard for determining the causative pathogen is to culture the conjunctiva. Routine culture of every case of conjunctivitis is impractical in general practice settings, however; and patients with bacterial conjunctivitis diagnosed from signs and symptoms are typically treated empirically with topical ophthalmic antibiotics.

To achieve quick and effective bacterial eradication with empirical therapy, it

Please see the full prescribing information for BESIVANCE® on page 4.

is critical to choose an agent with a wide spectrum of antimicrobial activity.

A Powerful Fluoroquinolone

Current generation fluoroquinolones are the antimicrobial agents most often used to manage ocular infections, including bacterial conjunctivitis, in large part because they have a broad spectrum of activity and are generally well tolerated. Despite overall effectiveness of the class, fluoroquinolone resistance is a growing problem, and there has been a concerning rise in the prevalence of MRSA-caused ocular infections.[6] To meet the long-term threat of bacterial resistance, a continuous stream of novel agents will be necessary. In the short term, clinicians can be advised to treat bacterial conjunctivitis empirically with currently available agents that have the potency necessary to neutralize even resistant organisms.

BESIVANCE® (besifloxacin ophthalmic suspension) 0.6% was developed specifically for ophthalmic use and approved for the treatment of bacterial conjunctivitis in 2009.[7] Like other fluoroquinolones, its bactericidal activity is a result of inhibitory effects on topoisomerase II (DNA gyrase) and topoisomerase IV, two bacterial enzymes that are essential for DNA replication.[7] Older fluoroquinolones targeted primarily topoisomerase IV, whereas later generation fluoroquinolones have increased affinity for topoisomerase II.[8]

Similar to gatifloxacin and moxifloxacin, which are cyclopropyl fluoroquinolones, the BESIVANCE® molecule contains an N-cyclopropyl group that confers broad-spectrum antimicrobial activity.[9] It acts against gram-positive and gram-negative organisms commonly associated with bacterial conjunctivitis.[4]

What sets BESIVANCE® apart is the addition of a chlorine atom at the C-8 position, which makes BESIVANCE® an 8-chlorofluoroquinolone. It is the first and only double-halogenated ocular fluoroquinolone available in the US. The chlorine addition provides improved potency against both bacterial topoisomerases.[9,10] This more balanced dual-binding mechanism may also increase its potency across the bacterial spectrum.[10] Additionally, BESIVANCE® has no systemic equivalent, eliminating the risk of resistance from systemic use.[9] In vitro resistance to BESIVANCE® occurs at a general frequency of $< 3.3 \times 10^{-10}$ for *S. aureus* and $< 7 \times 10^{-10}$ for *S. pneumoniae*.[7]

Bacterial Conjunctivitis: Case Study

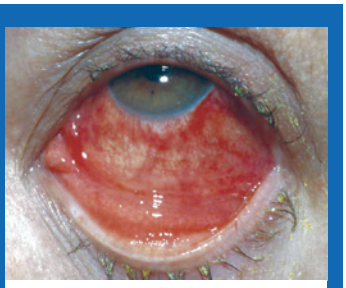

Fig 1 Bacterial conjunctivitis with a MRSA-positive culture. *(All images courtesy of Ron Melton, OD, FAAO.)*

A 57-year-old female nurse at local hospital presented with a 3-day history of occasional watering, with significant discharge from both eyes on the morning of the office visit (Figure 1). On examination her best corrected vision was 20/30 OU. She had 3+ bulbar conjunctival injection (with injection somewhat more intense on the inferior bulbar conjunctiva). Both corneas were clear, and there was no preauricular node swelling on either side. The patient was tested for the presence of adenovirus (using the 10-minute AdenoPlus test [Nicox]), and specimens were taken for culture.

The adenovirus test was negative, and the patient was started on BESIVANCE® and followed up in 3 days. On follow-up, there was a 75% improvement in the bulbar conjunctival injection. The culture came back positive for scant MRSA. The patient was sent home and told to continue BESIVANCE® three times a day for 4 more days.

Relative Potency

BESIVANCE® demonstrates efficient killing of the common isolates in bacterial conjunctivitis.[11] A review of minimum inhibitory concentration (MIC) values indicates that BESIVANCE® has excellent potency against both gram-positive and gram-negative bacteria.[4]

In vitro studies find BESIVANCE® also has significant potency against resistant strains, including MRSA and ciprofloxacin-resistant staphylococci, which is not true of all common topical antibiotics or even of all other fluoroquinolones.[4,12]

Besifloxacin demonstrates low MIC_{50} and MIC_{90} values against MRSA (0.5 µg/mL and 4 µg/mL, respectively), which are comparable to those of vancomycin (MIC_{50} = 1 µg/mL; MIC_{90} = 4 µg/mL), a glycopeptide antibiotic regularly used for the treatment of MRSA infections because of its potency against the highly resistant organism.[6]

While it is not always possible to establish the clinical significance of in vitro data, bacterial conjunctivitis clinical trials have shown excellent therapeutic efficacy and tolerability of BESIVANCE® in adults and children of at least 1 year of age.[13-16]

In one recent study, treatment with besifloxacin brought about rapid microbial eradication in cases of bacterial conjunctivitis culture-positive for MRSA and methicillin-resistant *S. epidermidis* (MRSE)—even where isolates were also ciprofloxacin-resistant.[17] Microbial eradication does not always correlate with clinical outcome in an antiinfective trial. In vitro reports from this study found the MIC_{90} values for besifloxacin to be 2 µg/mL against ciprofloxacin-resistant MRSA isolates, and 4 µg/mL against ciprofloxacin-resistant MRSE isolates.[17] The clinical significance of in vitro data has not been established.

In my experience, BESIVANCE® is highly effective in treating bacterial conjunctivitis, which I see as a reflection of its potent activity against both susceptible *and* resistant bacterial strains (see Case Study box).

Formulation Attributes

BESIVANCE® is formulated in a mucoadhesive polymer that enhances drug retention on the ocular surface.[18] Extended residence time may result in increased drug concentration on the surface of the eye, and, consequently, improved efficacy for concentration-dependent antibiotics like BESIVANCE®, whose efficacy is greatest when concentrations are high at the site of infection.

Measurement of human tear concentration after a single instillation has shown that BESIVANCE® remains on the ocular surface through 24 hours; at 12 hours after instillation, the tear concentrations still exceeded its MIC_{90} values against a number of significant organisms.[8] BESIVANCE® is approved for instillation

Please see Important Risk Information on page 1 and the full prescribing information for BESIVANCE® on page 4.

Bacterial Conjunctivitis: Differential Diagnosis

Before initiating antibiotic treatment, it is important to confirm the diagnosis of bacterial conjunctivitis. Viral conjunctivitis should not be treated with antibiotics. Bacterial conjunctivitis can occur unilaterally or bilaterally. Most often, it is isolated to one eye and characterized by a mild mucopurulent discharge that is typically worse upon awakening than later in the day.

Conjunctival hyperemia can be mild, moderate, or severe (Figure 2A). In mild cases, conjunctival hyperemia will typically be greater inferiorly than superiorly, an indication of greater bacterial activity in the inferior conjunctiva and a distinguishing factor for bacterial conjunctivitis. Mild cases of bacterial conjunctivitis are also often characterized by abundant floating microparticulate debris in the inferior lacrimal lake, an important finding that can distinguish low-grade bacterial conjunctivitis from adenoviral infection.

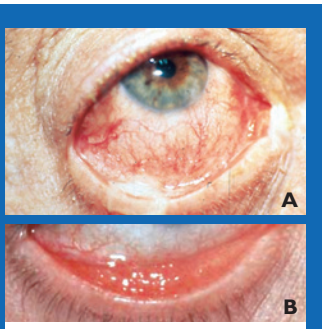

Fig 2 A Bacterial conjunctivitis with grade 2 hyperemia, more pronounced toward the inferior fornices, and less so near the limbus, and moderate mucopurulent discharge. **B** Conjunctival follicles.

Adenoviral conjunctivitis is often transient, starting in one eye and rapidly moving to the other. A weepy serous discharge is common. More severe cases can present with follicular conjunctivitis, which is rarely, if ever, seen in bacterial conjunctivitis (Figure 2B).

of one drop in the affected eye(s) 3 times a day, 4 to 12 hours apart, for 7 days.

Expanded Label

In 2012, the US FDA granted additional labeling indications for BESIVANCE® (besifloxacin ophthalmic suspension) 0.6%, including indications to treat bacterial conjunctivitis caused by susceptible isolates of *Aerococcus viridians*, *Moraxella catarrhalis*, *Pseudomonas aeruginosa*, and *Staphylococcus warneri*.[7] BESIVANCE® provides practitioners a potent topical antibiotic indicated for most of the pathogens relevant to bacterial conjunctivitis. The approval for *P. aeruginosa*, in particular, should be reassuring to practitioners, as it represents an official recognition of the activity BESIVANCE® shows against this often highly virulent gram-negative organism.

P. aeruginosa is a concern not just because of its virulence but because of its ability to invade the cornea, particularly in contact lens wearers.[19] BESIVANCE® offers proven activity against *P. aeruginosa* conjunctivitis. Indeed, a recent post hoc analysis of four clinical studies showed that treatment with BESIVANCE® leads to fast microbial eradication and high rates of clinical resolution in patients with bacterial conjunctivitis caused by *P. aeruginosa*.[19] Clinical resolution was defined as the absence of both ocular discharge and bulbar conjunctival injection.

Conclusions

Topical antibiotic therapy is beneficial in patients with bacterial conjunctivitis. In empirical therapy—the typical treatment for bacterial conjunctivitis—it is important to use a potent, broad-spectrum agent. BESIVANCE® has demonstrated excellent therapeutic efficacy in the treatment of bacterial conjunctivitis.[14-16,19] The potent bactericidal activity of BESIVANCE® against a wide range of significant ocular pathogens, including resistant strains, makes it a valuable component of the ocular antibiotic armamentarium.

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BAUSCH+LOMB
Besivance®
besifloxacin ophthalmic suspension, 0.6%

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Besivance® (besifloxacin ophthalmic suspension) 0.6%
Sterile topical ophthalmic drops
Initial U.S. Approval: 2009

---------- RECENT MAJOR CHANGES ----------
Indications and Usage (1) 09/2012
---------- INDICATIONS AND USAGE ----------
Besivance® (besifloxacin ophthalmic suspension) 0.6%, is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria:
*Aerococcus viridans**, CDC coryneform group G, *Corynebacterium pseudodiphtheriticum**, *Corynebacterium striatum**, *Haemophilus influenzae*, *Moraxella catarrhalis**, *Moraxella lacunata**, *Pseudomonas aeruginosa**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis**, *Staphylococcus lugdunensis**, *Staphylococcus warneri**, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius**
*Efficacy for this organism was studied in fewer than 10 infections. (1)

---------- DOSAGE AND ADMINISTRATION----------
Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days. (2)
---------- DOSAGE FORMS AND STRENGTHS----------
7.5 mL size bottle filled with 5 mL of besifloxacin ophthalmic suspension, 0.6% (3)
----------CONTRAINDICATIONS----------
None (4)
----------WARNINGS AND PRECAUTIONS ----------
Topical Ophthalmic Use Only. (5.1)
Growth of Resistant Organisms with Prolonged Use. (5.2)
Avoidance of Contact Lenses. Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance. (5.3)
---------- ADVERSE REACTIONS ----------
The most common adverse reaction reported in 2% of patients treated with Besivance was conjunctival redness. (6)

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

See 17 for PATIENT COUNSELING INFORMATION
Revised: 09/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Besivance® (besifloxacin ophthalmic suspension) 0.6%, is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria:
*Aerococcus viridans**
CDC coryneform group G
*Corynebacterium pseudodiphtheriticum**
*Corynebacterium striatum**
Haemophilus influenzae
*Moraxella catarrhalis**
*Moraxella lacunata**
*Pseudomonas aeruginosa**
Staphylococcus aureus
Staphylococcus epidermidis
*Staphylococcus hominis**
*Staphylococcus lugdunensis**
*Staphylococcus warneri**
Streptococcus mitis group
Streptococcus oralis
Streptococcus pneumoniae
*Streptococcus salivarius**
*Efficacy for this organism was studied in fewer than 10 infections.

2 DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once before use.
Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

3 DOSAGE FORMS AND STRENGTHS

7.5 mL bottle filled with 5 mL of besifloxacin ophthalmic suspension, 0.6%.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Topical Ophthalmic Use Only

NOT FOR INJECTION INTO THE EYE.
Besivance is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

5.2 Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use of Besivance (besifloxacin ophthalmic suspension) 0.6% may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining.

5.3 Avoidance of Contact Lenses

Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance.

6 ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with the rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.
The data described below reflect exposure to Besivance in approximately 1,000 patients between 1 and 98 years old with clinical signs and symptoms of bacterial conjunctivitis.
The most frequently reported ocular adverse reaction was conjunctival redness, reported in approximately 2% of patients.
Other adverse reactions reported in patients receiving Besivance occuring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C.
Oral doses of besifloxacin up to 1000 mg/kg/day were not associated with visceral or skeletal malformations in rat pups in a study of embryo-fetal development, although this dose was associated with maternal toxicity (reduced body weight gain and food consumption) and maternal mortality. Increased post-implantation loss, decreased fetal body weights, and decreased fetal ossification were also observed. At this dose, the mean C_{max} in the rat dams was approximately 20 mcg/mL, >45,000 times the mean plasma concentrations measured in humans. The No Observed Adverse Effect Level (NOAEL) for this embryo-fetal development study was 100 mg/kg/day (C_{max}, 5 mcg/mL, >11,000 times the mean plasma concentrations measured in humans).
In a prenatal and postnatal development study in rats, the NOAELs for both fetal and maternal toxicity were also 100 mg/kg/day. At 1000 mg/kg/day, the pups weighed significantly less than controls and had a reduced neonatal survival rate. Attainment of developmental landmarks and sexual maturation were delayed, although surviving pups from this dose group that were reared to maturity did not demonstrate deficits in behavior, including activity, learning and memory, and their reproductive capacity appeared normal.
Since there are no adequate and well-controlled studies in pregnant women, Besivance should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

Besifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Besivance is administered to a nursing mother.

8.4 Pediatric Use

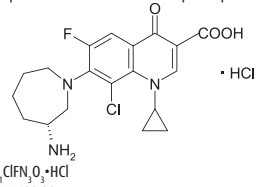
The safety and effectiveness of Besivance® in infants below one year of age have not been established. The efficacy of Besivance in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials *[see CLINICAL STUDIES (14)]*.
There is no evidence that the ophthalmic administration of quinolones has any effect on weight bearing joints, even though systemic administration of some quinolones has been shown to cause arthropathy in immature animals.

8.5 Geriatric Use

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

11 DESCRIPTION

Besivance (besifloxacin ophthalmic suspension) 0.6%, is a sterile ophthalmic suspension of besifloxacin formulated with DuraSite®† (polycarbophil, edetate disodium dihydrate and sodium chloride). Each mL of Besivance contains 6.63 mg besifloxacin hydrochloride equivalent to 6 mg besifloxacin base. It is an 8-chloro fluoroquinolone anti-infective for topical ophthalmic use.



$C_{19}H_{21}ClFN_3O_3 \cdot HCl$
Mol Wt 430.30
Chemical Name: (+)-7-[(3R)-3-aminohexahydro-1H-azepin-1-yl]-8-chloro-1- cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid hydrochloride.
Besifloxacin hydrochloride is a white to pale yellowish-white powder.

Each mL Contains:
Active: besifloxacin 0.6% (6 mg/mL);
Preservative: benzalkonium chloride 0.01%
Inactives: polycarbophil, mannitol, poloxamer 407, sodium chloride, edetate disodium dihydrate, sodium hydroxide and water for injection.
Besivance is an isotonic suspension with an osmolality of approximately 290 mOsm/kg.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Besifloxacin is a fluoroquinolone antibacterial *[see CLINICAL PHARMACOLOGY (12.4)]*.

12.3 Pharmacokinetics

Plasma concentrations of besifloxacin were measured in adult patients with suspected bacterial conjunctivitis who received Besivance bilaterally three times a day (16 doses total). Following the first and last dose, the maximum plasma besifloxacin concentration in each patient was less than 1.3 ng/mL. The mean besifloxacin C_{max} was 0.37 ng/mL on day 1 and 0.43 ng/mL on day 6. The average elimination half-life of besifloxacin in plasma following multiple dosing was estimated to be 7 hours.

12.4 Microbiology

Besifloxacin is an 8-chloro fluoroquinolone with a N-1 cyclopropyl group. The compound has activity against Gram-positive and Gram-negative bacteria due to the inhibition of both bacterial DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme required for replication, transcription and repair of bacterial DNA. Topoisomerase IV is an essential enzyme required for partitioning of the chromosomal DNA during bacterial cell division. Besifloxacin is bactericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentrations (MICs).
The mechanism of action of fluoroquinolones, including besifloxacin, is different from that of aminoglycoside, macrolide, and β-lactam antibiotics. Therefore, besifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to besifloxacin. *In vitro* studies demonstrated cross-resistance between besifloxacin and some fluoroquinolones.
In vitro resistance to besifloxacin develops via multiple-step mutations and occurs at a general frequency of < 3.3×10^{-10} for *Staphylococcus aureus* and < 7×10^{-10} for *Streptococcus pneumoniae*.
Besifloxacin has been shown to be active against most isolates of the following bacteria both *in vitro* and in conjunctival infections treated in clinical trials as described in the INDICATIONS AND USAGE section:
*Aerococcus viridans**, CDC coryneform group G, *Corynebacterium pseudodiphtheriticum**, *C. striatum**, *Haemophilus influenzae*, *Moraxella catarrhalis**, *M. lacunata**, *Pseudomonas aeruginosa**, *Staphylococcus aureus*, *S. epidermidis*, *S. hominis**, *S. lugdunensis**, *S. warneri**, *Streptococcus mitis* group, *S. oralis*, *S. pneumoniae*, *S. salivarius**
*Efficacy for this organism was studied in fewer than 10 infections.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to determine the carcinogenic potential of besifloxacin have not been performed.
No *in vitro* mutagenic activity of besifloxacin was observed in an Ames test (up to 3.33 mcg/plate) on bacterial tester strains *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2uvrA. However, it was mutagenic in *S. typhimurium* strain TA102 and *E. coli* strain WP2(pKM101). Positive responses in these strains have been observed with other quinolones and are likely related to topoisomerase inhibition.
Besifloxacin induced chromosomal aberrations in CHO cells *in vitro* and it was positive in an *in vivo* mouse micronucleus assay at oral doses ≥ 1500 mg/kg. Besifloxacin did not induce unscheduled DNA synthesis in hepatocytes cultured from rats given the test compound up to 2,000 mg/kg by the oral route. In a fertility and early embryonic development study in rats, besifloxacin did not impair the fertility of male or female rats at oral doses of up to 500 mg/kg/day. This is over 10,000 times higher than the recommended total daily human ophthalmic dose.

14 CLINICAL STUDIES

In a randomized, double-masked, vehicle controlled, multicenter clinical trial, in which patients 1-98 years of age were dosed 3 times a day for 5 days, Besivance was superior to its vehicle in patients with bacterial conjunctivitis. Clinical resolution was achieved in 45% (90/198) for the Besivance treated group versus 33% (63/191) for the vehicle treated group (difference 12%, 95% CI 3% - 22%). Microbiological outcomes demonstrated a statistically significant eradication rate for causative pathogens of 91% (181/198) for the Besivance treated group versus 60% (114/191) for the vehicle treated group (difference 31%, 95% CI 23% - 40%). Microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

16 HOW SUPPLIED/STORAGE AND HANDLING

Besivance® (besifloxacin ophthalmic suspension) 0.6%, is supplied as a sterile ophthalmic suspension in a white low density polyethylene (LDPE) bottle with a controlled dropper tip and tan polypropylene cap. Tamper evidence is provided with a shrink band around the cap and neck area of the package.

5 mL in 7.5 mL bottle
NDC 24208-446-05

Storage:

Store at 15°-25°C (59°-77°F). Protect from Light. Invert closed bottle and shake once before use.

17 PATIENT COUNSELING INFORMATION

Patients should be advised to avoid contaminating the applicator tip with material from the eye, fingers or other source.
Although Besivance is not intended to be administered systemically, quinolones administered systemically have been associated with hypersensitivity reactions, even following a single dose. Patients should be advised to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.
Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Besivance or other antibacterial drugs in the future.
Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance.
Patients should be advised to thoroughly wash hands prior to using Besivance.
Patients should be instructed to invert closed bottle (upside down) and shake once before each use. Remove cap with bottle still in the inverted position. Tilt head back, and with bottle inverted, gently squeeze bottle to instill one drop into the affected eye(s).

Manufactured by: Bausch & Lomb Incorporated
Tampa, Florida 33637

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U.S. Patent Nos. 6,685,958; 6,699,492; 5,447,926

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9142605(flat)
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Digital contact lens information

Go beyond the paper

Going digital for your contact lens data (availability, parameters, pricing, etc.) can save time and gain you even better information than staying with paper.

"Have you seen the *Tyler's*? Anybody know where the *Tyler's* is? Who has the new one?" You're chuckling a little right now because you probably remember what it was like to run around the office trying to find a copy!

It has been quite a few years since I have had to do so, and the nostalgia of this article sparked my curiosity. Is there an online version of *Tyler's Quarterly* (TQ)? The search results excited me. A Web site! *http://lmgtfy.com/?q=tylers+quarterly* Excitement quickly turned to disbelief when I realized not only was this just a Web site designed to order TQ, but you actually have to print out a form and mail a check in to order it!

Technology has surpassed TQ. One no longer has to waste time running around the office looking for it. Paper cuts are becoming extinct as excessive page flipping is an activity we have replaced with a few keystrokes. The content contained between the pages of TQ has been digitized, revamped, enhanced and sent to the cloud.

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

ODspecs: *http://www.odspecs.com*
EyeDock: *http://www.eyedock.com/*
The Right Contact: *http://www.therightcontact.com*

These three Web sites offer content similar to TQ, but because they are in digital format, you gain a whole host of enhanced features, not to mention the ability to access them wherever you via computer or smartphone.

ODspecs

This site is an easy transition for a TQ user. It offers the user a very straightforward interface that by default breaks down products by manufacturer. Have a contact lens in mind but not quite sure of a certain parameter? You will be able to quickly and easily locate it on this Web site. The secondary ranking allows you to view products by categories. Want to compare power range of a daily disposable? This site will quickly allow you to do so. It also offers a very familiar vertex conversion chart. *Free*

EyeDock

Founded in 2002, EyeDock builds upon the basic framework of a contact lens database and envelops the data with advanced features and enhanced content. It is remarkably feature rich. Contact lens searches are accompanied by unique features such as ICD-9 diagnosis code search, topical ophthalmic medication searches, contact lens calculator (includes soft spheres and torics, GP bitoric, front toric, and back torics), oblique crossed cylinders, Park's 3 Step, vertexing and keratometry conversions, an ocular anatomy drawing tool, a vision simulator, a refraction tutorial and simulator, and a mobile app!

The advertisement-free environment comes at a cost. After a free 30-day trial, one may choose to continue with a subscription for $43 per year or $4 per month. This is a great deal when compared to the TQ subscription rate of $55 per year plus $44 per year for each additional subscription to the same address.

The Right Contact

This site was developed in 2007 and has been evolving ever since. It was initially designed as a desktop application but now lives in the cloud, accessed through both Web and mobile app. The site claims to house all the specific parameter information of over 2,000 contact lens products from over 150 different manufacturers.

The site brings all the great features of a searchable database to the eyecare professional. As stated by President Jason E. Compton, OD: "Digital products are the way of the future. Having the data at your fingertips not only saves chair time, but it may educate you on possibilities you didn't even think of." Looking for a lens with a specific Dk, base curve, and optic zone? The advanced search section will point you to the exact products and manufacturers to help meet your needs. In addition to the dozens of parameter categories, the results pages for each individual product are also packed with useful information like product images, fitting guides, FDA reports, recall data, package inserts, and much more.

The Right Contact also keeps up with the modern eyecare professional by frequently posting on social media outlets like Twitter (@therightcontact), Facebook (www.Facebook.com/RightContact), Google+ and LinkedIn.

The Right Contact.com also seems to have The Right Price for many optometrists: *Free*.

> These Web sites pack in more features and ease of use than a printed publication could achieve.

The Web sites highlighted here clearly pack in more features and offer an ease of use that a printed publication could never achieve. However, TQ reigns supreme in one specific area that is nowhere to be found on any of these sites: contact lens-compatible makeup list! I do hope that is not a deal-breaker and you spend some time at each of these sites. While you're online, drop us a line and let us know what you are using. *https://www.facebook.com/OptometryTimes* **ODT**

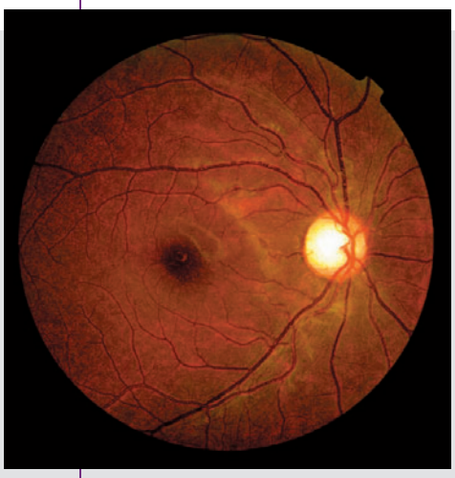


Figure 1. This optic nerve has a big cup and a corresponding big disc. This patient's intraocular pressure actually matched her age (12).

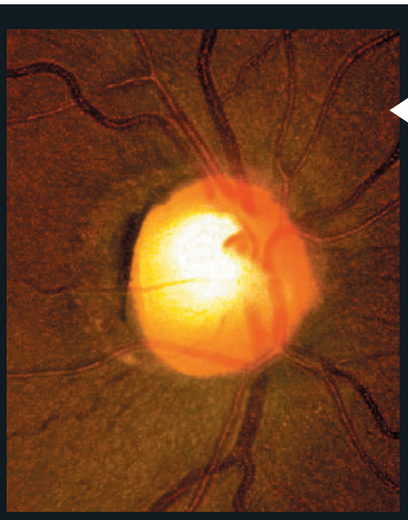
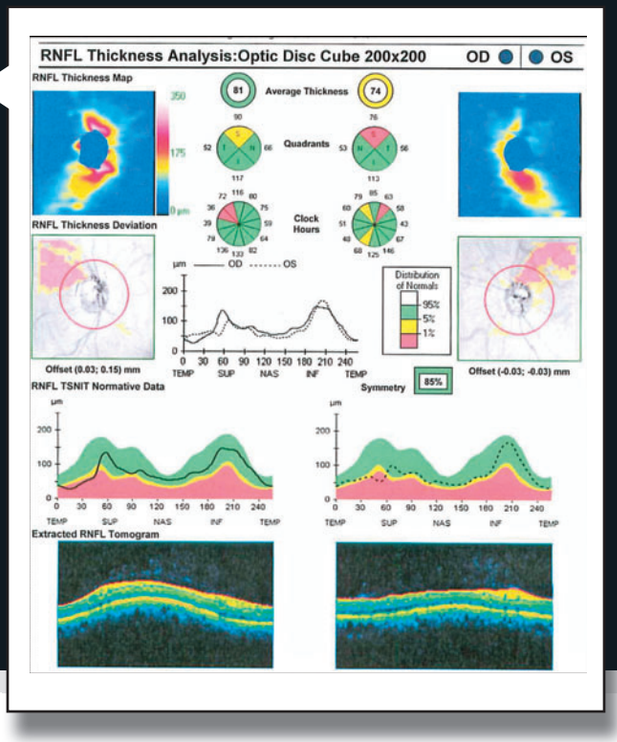


Figure 2. Temporal atrophy and pigmentary mottling with corresponding RNFL dropout.



Big optic cups

Do I get excited? Yes and no

Cup-to-disc ratio is certainly important in evaluating a patient for glaucoma. However, it's not the only clinical measurement to consider. Evaluate the overall size of optic discs. Optic disc hemorrhages may have corresponding retinal nerve fiber defects. Subtle areas of parapapillary atrophy are another indicator for the possible presence of glaucoma. Look beyond the optic disc cupping to gather additional information.

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

When I was a second-year optometry student, I took a quiz in which I was asked to evaluate a group of optic nerves and judge what their cup-to-disc ratios were. Three of my instructors gave their judgments, and I suppose they scored me based on how I compared to them. If you knew me as a student, you'd know that I had a little habit of freaking out and pacing up and down the hallway before quizzes, and this time was no different. So when the time came, I went in, looked at a dozen or so optic nerves, and gave my best guess as to their cup-to-disc ratios. Later, we were all given our scores as well as the cup-to-disc ratios that our instructors had come up with. You're going to think I'm lying, but for one particular patient, an instructor estimated a 0.9 vertical cup-to-disc ratio that another instructor had judged to be a 0.1. It was one of those shallow optic nerve heads with congenitally radial vasculature emanating from the center of a poorly defined cup. You know, one of those optic nerves that really deserves more of a description than a couple of numbers.

What I learned

As it turned out, I did OK on the quiz. Looking back now, I have come to learn several things from the experience. First, I promise you that I will never debate a cup-to-disc ratio with you. If my 0.3 is your 0.4, I don't care. I do care, however, that my 0.3s and your 0.4s are relatively consistent. Secondly, the experience of seeing optic nerves back to back to back in a short period of time was really the first time that it occurred to me that optic nerves really could have vastly different sizes.

We have all learned that a big optic disc can have a big cup (Figure 1) and still contain the 1 million or so ganglion cells it should. On the other hand, we also know that a small optic disc can have a relatively small cup and be glaucomatous. Those are the ones that scare me because it's easy to write down 0.3x0.3 and move on.

See **Optic cups** on page 16

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References: (1) Richer S, Stiles W, Statkute L, et al. Double-masked, placebo-controlled, randomized trial of lutein and antioxidant supplementation in the intervention of atrophic age-related macular degeneration: the Veterans LAST study (Lutein Antioxidant Supplementation Trial). Optometry. 2004;75:3-15. (2) SanGiovanni JP, Chew EY, Clemons TE, et al. The relationship of dietary lipid intake and age-related macular degeneration in a case-control study. AREDS Report No. 20. Arch Ophthalmol. 2007;125:671-679. (3) Chiu CJ, Taylor A. Nutritional antioxidants and age-related cataract and maculopathy. Experimental Eye Research. 2007;84:229-245.

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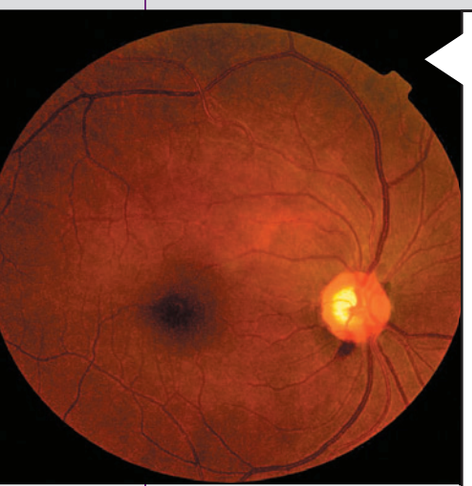

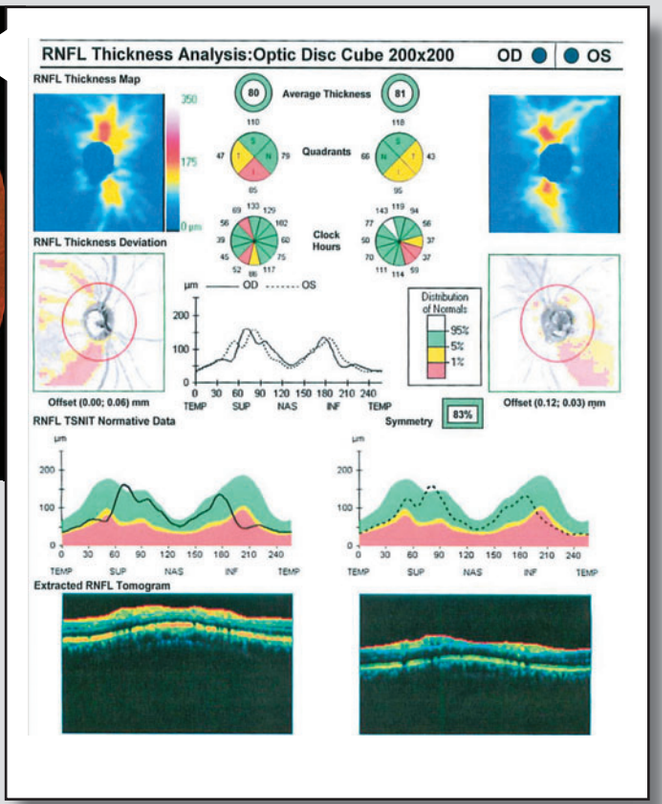

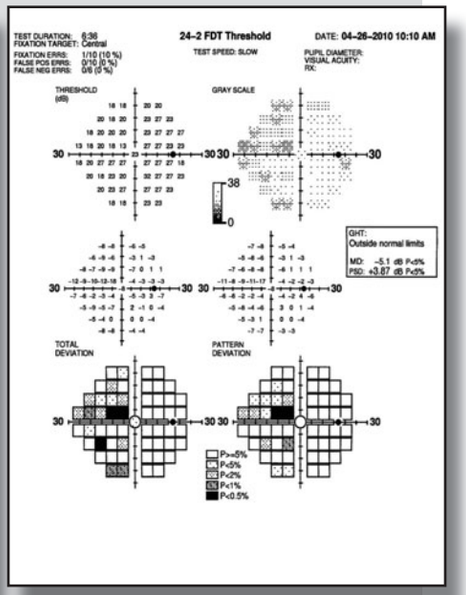

Figure 3. This patient with perimetric normal-tension glaucoma probably had a physiologically large cup to begin with. Note the inferior Drance hemorrhage with corresponding structural and functional loss.

Optic cups

Continued from page 14

Going beyond big cups

We diagnose patients as having so-called "physiologic cupping" all the time when they just have big cups but no signs of glaucoma. These patients should almost always have big optic discs as well as big cups. Physiologic cupping is also one of the more exclusive of all the diagnoses we make (psychogenic amblyopia aside), and there are several aspects of these patients' optic nerves that we should be paying attention to besides the size of their cups.

We must take it a couple of steps further and evaluate the overall size of their optic discs.[1] I do this with my BIO and a 20 D lens because it gives me a qualitative view of the forest instead of the trees. I then document the disc as big, medium, or small. The rest I evaluate with a 78 D lens at the slit lamp (and a photo to see what I missed while the patient was tearing up and moving around). The quality of the neuroretinal rim has long been assessed with the ISNT rule—inferior retinal rim is thickest). However, I would argue that the ISNT rule is more of an ISNT guideline. Nonetheless, it is a meaningful and useful guideline to follow.

> When someone asks me to describe a particular optic nerve, I include the cup-to-disc ratio, but it's probably the last thing I bring up.

Optic disc hemorrhages raise big flags, especially in the presence of normal intraocular pressure.[1,2] These hemorrhages may have corresponding retinal nerve fiber defects which can be readily seen with a 78 D lens and a red-free filter. You don't have to have an OCT, HRT, or GDx to actually look at the retinal nerve fiber layer. This is also an exercise in which I use retinal photography because I can look at the forest and make use of the red free filter on my camera statically without having to contend with patient cooperation. Retinal nerve fiber defects may also point to subtle areas of parapapillary atrophy, another indicator for the possible presence of glaucoma (Figure 2).[1]

So, does a particular patient in question have glaucoma or physiologic cupping? I would argue that this question is a false dichotomy because there's no reason why someone couldn't simply have both (Figure 3). I'm a good boy and document cup-to-disc ratios. I see their qualitative (and somewhat quantitative) importance. If you see a big cup, it just gets you thinking, and that's a good thing. However, visual fields and OCTs aside, there's just so much more to an optic nerve than the size of its cup. When someone asks me to describe a particular optic nerve, I include the cup-to-disc ratio, but it's probably the last thing I bring up. **ODT**

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Obesity and the optometric practice

Obesity is connected to many ocular diseases, including those arising from diabetes

By Kimberly Reed, OD, FAAO

It wasn't too long ago that asking about a patient's body weight in an optometric practice would have been considered more than a little awkward. But with our increasing knowledge about the connection between overweight, obesity, and ocular disease, it's now becoming the standard of care to gather this data point. Still, it's a weighty topic for most patients as well as their healthcare providers, and as such it requires both patient and practitioner to fully appreciate the complexities of the issues.

Here, we will review the multifaceted etiologies to overweight and obesity, and explore the extensive connections among various ocular diseases and excessive adiposity.

Defining the terms

Although the concept of defining "fit" or "fat" using the body mass index (BMI) is flawed, it is still the most widely used metric to judge a person's weight status.[1] BMI is derived as a simple ratio of height and weight. But because of the wide variation in body composition, a person could technically be classified as overweight or even obese, yet have a very low body fat percentage and an associated low risk of systemic and ocular disease.

Waist circumference is a simpler measurement that is often used as an adjunct to or a substitute for BMI and is strongly correlated with risk of systemic disease.[2] However, at BMI levels above 35 kg/m^2, no additional predictive value is obtained with waist circumference.[1] Also, the idea of using a waist-to-hip circumference ratio is outdated and offers no predictive value for health hazards associated with obesity.[1]

What are the hazards associated with obesity?

Type II diabetes, hypertension, hyperlipidemia, hypercholesterolemia, and carotid artery disease are well-known associations with obesity.[3-8] Others include several types of cancer, respiratory diseases, and sleep apnea.

These systemic conditions pose additional threat to the ocular and visual system in the form of diabetic retinopathy, hypertensive retinopathy, vascular occlusive disease, optic neuropathy, glaucoma, and others.[9-13]

Diabetic retinopathy is the most common cause of blindness in middle-aged U.S. adults.[14] Because the majority of those cases arise from Type II diabetes, which is strongly associated with obesity,[8,15-16] most of these cases of blindness can be considered preventable. In fact, the Nurse's Health Study found that over 14 years, the risk of developing Type II diabetes was 100-fold higher in women with a BMI over 35kg/m^2, compared to those with BMI below 22kg/m^2.[7] The pathogenesis of macular edema (Figure 1) and vascular proliferation in diabetic retinopathy (Figure 2) is the result of many interrelated, complex processes resulting in retinal injury. A primary underlying mechanism is chronic hyperglycemia,[17] leading to dysregulation in blood flow, an accumulation of advanced glycation end products (AGEs) that damage cells and tissues, and an accumulation of sorbitol within the retinal cells.[18-19] Vascular proliferation is related to overexpression of vascular endothelial growth factor (VEGF)[20] and insulin-like growth factor-1 (IGF-1).[17,20] Once proliferative disease begins, severe vision loss is a very real risk. Primary prevention of diabetes means prevention of obesity and must include dietary and lifestyle habits integrated during childhood to minimize risk of vision loss due to diabetic retinopathy.

Other retinal vascular diseases associated with obesity include hypertensive/arteriosclerotic retinopathy (Figure 3) and vascular occlusive disease. While the association between obesity and all types of vascular disease is well-established,[21] the exact obesity-derived processes are less clear than that described for diabetes. This is due primarily to the frequent presence of comorbid disease.[22-23] Retinal vein occlusions (RVO) (Figure 4) are the second leading cause of vision loss from retinal vascular disease, second only to diabetic retinopathy. Obesity is a major risk factor for arteriosclerosis; arteriosclerosis, in turn, is a primary factor in branch vein occlusion.[24-25] Thus, retinal vein occlusion represents another at least partially preventable cause of vision loss in U.S. adults, if obesity is avoided.

Moreover, obesity is an independent risk factor for age-related macular degeneration[26-27] (Figure 5), and patients who have obesity as well as any of the associated systemic conditions are at even greater risk for vision loss, serious medical consequences, and even death.[28-33]

And patients suffer in many other ways, too. The psychological stigma attached to being overweight or obese can be profound; people from all walks of life—teachers, college admissions counselors, employers, nutritionists, and even doctors and nurses—may

See **Jumpline** on page 18

Take-Home Message

Obesity causes significant morbidity and mortality and is associated with some of the most common causes of vision loss. A full appreciation of its various causes and treatments is essential for today's primary care practitioner.

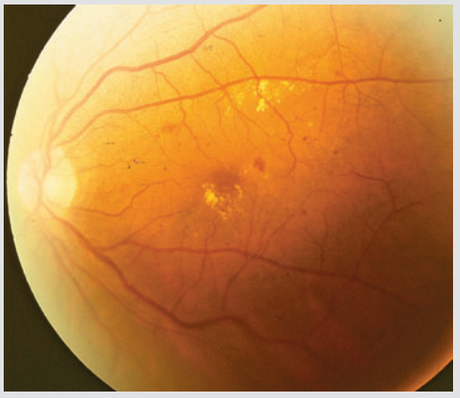

Figure 1. Non-proliferative diabetic retinopathy with clinically significant macular edema. Note the presence of hard exudates associated with retinal thickening at the macula, inferiorly. Multiple exudates and small dot hemorrhages surround the macula throughout the posterior pole.

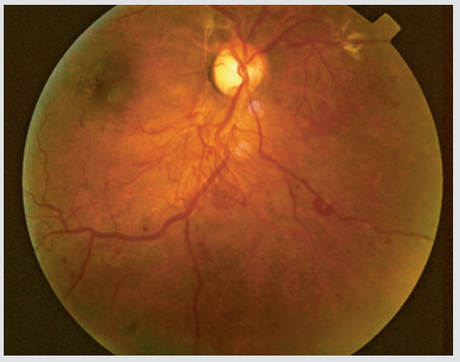

Figure 2. Proliferative diabetic retinopathy. Prominent neovascularization elsewhere (NVE) nasal and inferior to the optic disc; also note a retinal arterial macroaneurysm in the lower right quadrant of the photograph.

Obesity

Continued from page 17

ascribe very negative attributes to obese people based solely on their weight.[34-38] Obesity carries with it a hefty financial burden, too. One study found that overall, overweight and obese persons spend an additional 25% in healthcare dollars due to their increased body fat. In 2008, the estimated annual medical cost of obesity in the U.S. was $147 billion.[39]

None of this is brand-new knowledge, though. Doctors and patients have known about the medical, financial and psychosocial hazards associated with obesity for years. Why, then, does the obesity problem keep growing? According to the Centers for Disease Control, 35.7% of the U.S. adult population is now classified as either obese or overweight. Some groups are affected more than others: non-Hispanic blacks have a 49.5% obesity rate. Let's look at some of the factors leading to overweight and obesity.

What causes it?

Energy regulation (food in, energy out)

From a very simple perspective, it is an undeniable fact that eating more food than is utilized in energy expenditure results in increased adiposity, or body fat. Americans eat more than we used to. And, the other truth is that as a society, we are moving far less than we used to. Watching television and playing with electronic devices play a larger role in our children's lives than bike riding and kickball did for ours. So, at the base of any solution to address the obesity epidemic must be eating more appropriate foods in more appropriate amounts and increasing physical expenditure in the right way. But it's not that simple, either. The real complexities begin when considering why some people are driven to eat more than they need, and why the effects of fat deposition in response to extra energy intake vary from person to person.

Genetic factors

There are definite genetic predispositions to overweight and obesity.[40] Some of these factors are inherited variants, such as the thermic response to food and activity, protein, and hormone synthesis, spontaneous physical activity, and metabolic rate.[41] The presence and retention of Brown adipose tissue (BAT) is also partly a heritable trait. BAT is a highly thermogenic substance thought to be found exclusively in infants, but adults probably have small amounts of BAT remaining. Lean people have more active BAT than obese people, and therefore will have a much higher metabolic rate (fat-burning rate) than their overweight counterparts.[42,43] Other genetic factors are specific genetic mutations, including Bardet-Biedel and Prader-Willi syndromes.[44] But not all overweight or obese people have overweight or obese parents, so other factors are surely at work.

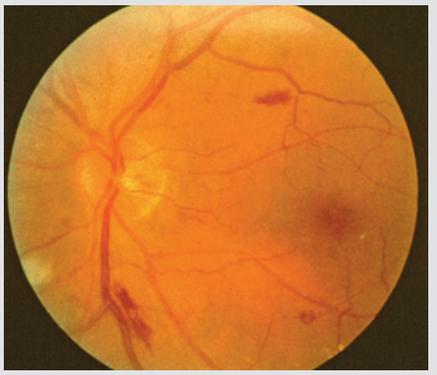

Figure 3: Hypertensive/ arteriosclerotic retinopathy. Flame-shaped (nerve fiber layer) hemorrhages are present. The artery-to-vein (A:V) ratio is reduced, and A/V nicking, created by arteriolar compression on the retinal venules, is seen in several locations. Photos courtesy Kimberly Reed, OD, FAAO.

Hormonal influences

Hormones have powerful, complex influences over our energy regulation, involving endocrine, neurobehavioral, psychological, and gastrointestinal systems.

Leptin is a protein, secreted primarily by fat (adipose) cells.[45] When more fat is deposited due to eating more food than is required, leptin levels increase, and in a normally regulated person, that increased leptin level works through complex signaling and feedback pathways to decrease appetite and increase energy expenditure. In obese people, these pathways are impaired, due at least in part to increased inflammation. Because not only do those adipose cells secrete leptin, they also secrete several pro-inflammatory substances that have effects on several different tissue and organ systems including hormonal signaling.[46] Leptin works in opposition to neuropeptide Y, another appetite-stimulating hormone secreted in the central nervous system.[47]

Ghrelin is a substance secreted primarily by the gut. When ghrelin levels increase due to an empty gut, the appetite is stimulated.[48] Ghrelin and neuropeptide Y also work in harmony to increase appetite.[49,50] Impaired signaling in these pathways leads to a lack of normal hunger-eating sensations in overweight and obese people.[51] Again, inflammation plays a role in dysregulation of these signals.

Adiponectin is a fat burner. Obese and overweight people have low levels of adiponectin.[52] Poor sleep habits, stress, and imbalanced dietary intake can cause adiponectin levels to drop.[53]

Sadly, once these hormones are dysregulated, the tendency is for more fat deposition, adding further to the dysregulation. This creates a vicious cycle that is difficult to break.

Neurobehavioral influences

One of the most exciting areas of research in obesity is in the area of neurobehavior.[54] This includes the endocannabinoid system—the hormones and substances that are secreted to provide a sense of well being, satisfaction, and satiation. Familiar behaviors leading to a robust endocannibinoid system are the "runner's high," yoga, and other mindfulness practices, and participating in pleasurable activities. In obese people, the endocannibinoid system is again dysregulated, causing profoundly strong reactions to the sight, smell, thought, or taste of palatable food. While lean people also respond positively to the taste or image of chocolate, for example, the reaction in an obese person is much greater—comparable to reactions that occur in individuals who are dependent on alcohol or drugs. What's more, these pathways can be trained, according to animal studies. Using highly palatable foods as a reward mechanism, frequently and/or over time, seems to cause a disrupted ability to measure and evaluate risk vs. reward—another shared characteristic between overeaters and alcohol- and drug-dependent individuals.[55]

How can we address obesity in the optometric practice?

Detection and management of the ocular manifestations associated with obesity (diabetic retinopathy, hypertensive/arteriosclerotic retinopathy, vein occlusions, etc.) is of immediate importance, and specific management strategies for these conditions are well described in other articles in this series.

Management of obesity is significantly more tricky because nutritional and lifestyle advice for weight management is not within the traditional role of the optometrist. However, as primary-care health providers, it is critical to start the process for addressing obesity, just as it would be for other conditions for which treatment is beyond the scope of primary-care optometry.

The first step is to address body weight,

See **Obesity** on page 20

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Rx only

Obesity

Continued from page 18

BMI, waist circumference, or whatever data point you are gathering as just that—a data point. Despite the highly emotionally charged value of body weight to most overweight and obese people, it is an important measure of wellness. Compassionate and non-judgmental statements such as, "As I'm sure you know, your height and weight aren't balanced for optimal health. According to research, achieving and maintaining a more balanced height-weight ratio is more likely to result in a longer, healthier life, as well as better ocular and visual health." This avoids the "You need to lose some weight" accusation and puts the patient's weight into perspective without adding judgment. You can also mention, if it seems graceful, that a lot of research is currently ongoing that addresses the difficulty that most people face when trying to stick to a reduced food intake plan. Knowing it's not just a personal failure or lack of willpower on their part will further enhance your compassionate communication with your patient.

But it can't stop there. Meaningful, specific recommendations need to be made for the patient's next steps. In most cases, a referral to a nutritionist or registered dietician is an appropriate next step. Generally, people who are overweight or obese are constantly aware of it and usually have a fair amount of guilt about it. Sometimes simply giving them an excuse to see a professional is a necessary step. That means you need to do your own research about what resources are available in your area. If you can, interview potential referral targets to find out specific philosophies and action plans so you can be informed if your patient has questions. In some cases, referral to a physician such as an endocrinologist, weight reduction specialist or surgeon, or a holistic/wellness practitioner is advisable. Advances are being made rapidly in weight management strategies, especially for extreme obesity, and patients may be good candidates for pharmaceutical or surgical intervention.

As our profession continues to evolve, we must stay informed of the rapidly expanding field of knowledge regarding systemic diseases that intersect our practices. Obesity causes significant morbidity and mortality and is associated with some of the most common causes of vision loss. A full appreciation of its various causes and treatments is essential for today's primary care practitioner.**ODT**

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Six months to life

Contact lenses in a pediatric population

By Weslie Hamada, OD

I am frequently asked by my patients at what age they should bring their children in for their first eye exams. That question is often followed by another asking how early can kids wear contact lenses.

The answer to the first question, of course, is 6 months of age for the first eye exam through the InfantSEE program. InfantSEE is a public health program created in partnership by Optometry Cares, the American Optometric Association (AOA) Foundation and by The Vision Care Institute of Johnson & Johnson Vision Care. The program provides a full exam and vision assessment by participating eyecare providers (ECP) at no cost for infants 6-12 months of age

The concept of seeing a patient at such a young age of 6 months seems daunting at first, but starting so early with patients is a fantastic practice builder. Not only are you establishing a good rapport with the patient early on in his development, you are also establishing a relationship with his parents, family members, and evetually network of friends. Growing up with these patients allows you learn about their hobbies, interests, habits, and lifestyles over time. Gaining a child's trust and confidence at an early age makes the contact lens discussion easier to address with both the child and the parents. Fitting contact lens depends on the individual child, of course, but it's never too early to start the discussion.

How early is too early?

One of the main reasons why ECPs hesitate to recommend contact lenses to parents of young children is their belief that many children are not mature or responsible enough to care for contact lenses. Irresponsibility may lead to corneal infections or corneal infiltrative events (CIE). In fact, younger wearers have fewer contant lens complications than teenage contact lens wearers, according to the Contact Lens Assessment in Youth (CLAY) group. "Patient age, years of lens wear, use of multi-purpose care products, silicone hydrogels, and extended wear were all significantly associated with corneal infiltrative events with soft contact lens (SCL) wear. Use of SCLs in young patients aged 8 to 15 years was associated with a lower risk of infiltrative events compared with teens and young adults."[1]

Figure 1. Performing eye exams early in a child's life allows you to build a relationship of trust with this young patient.

Take-Home Message

Fitting children, even young children, with contact lenses can help you grow your practice and build a lifelong contact lens patient base. Build trust with children as they mature, and see how contact lenses can positively affect their lives. Know how and when to start fitting children, and know how to encourage safe and compliant lens wear.

Just like brushing teeth, washing hands, and proper hygiene, ingraining good habits at an early age may help with compliance. There is typically closer parental supervision with this younger age group, plus this patient base is generally more attentive than teenagers to doctors' instructions. Both of these factors may help contribute to better compliance and good contact lens care and hygiene, resulting in fewer corneal infiltrative events.

Who is a good contact lens candidate?

Examining a child's motivation level, maturity, and his own personal hygiene is important when deciding if he is a good contact lens candidate. Does he play sports or have hobbies that would benefit from wearing contact lens? Self perception and self esteem is also a very important factor when fitting a child in contact lenses. The Adolescent and Child Health Initiative to Encourage Vision Empowerment (ACHIEVE) Study found an increase in self perception with contact fitting in the pediatric population.[2] Researchers found that there was an increase in physical, social, and athletic competence in children fitted in contact lenses. In my practice, I have found that once I started fitting pediatric patients in contact lenses, there was a decrease in broken or last glasses among those patients. Therefore, ECPs should consider the social as well physical needs of a child when considering contact lenses.

Figure 2. Younger contact lens wearers tend to have fewer complications related to contact lenses than their teenaged counterparts.

How do I ensure compliance and safety for children and contact lens wear?

The question of safety with contact lens and children is normal concern of parents. As doctors, we always worry about that non-compliant patient. A study by Dumbleton concluded that the top non-compliant behaviors of contact lens wearers were lens replacement and recommended wear, lens storage case hygiene, and exposure to non-sterile water.[3] The CLAY study found that the use of multi-purpose solution tripled the risk of CIEs in patients wearing daily-wear lenses. As mentioned previously, the patients aged 8-15 years were associated with a lower risk of corneal infiltrative events than the teen group. Overall, the majority of the younger group was wearing daily replacement lenses. Daily replacement contact lenses are a great approach to address these concerns of non-compliance, giving piece of mind for the doctor, the parents, and the patient.

Dumbleton et al also found that patients were most compliant with daily replacement

lenses than a 2-week modality.[4] Using daily replacement lenses helps increase compliance and eliminate possible corneal toxicity from the use of contact lens care solution. It is recommended to schedule follow-up visits for first-time pediatric contact lens wearers more frequently than your established contact lens patients to help monitor the health of the eye and to review proper contact lens care. Be sure to emphasize to both the patient and parents to contact you as soon as any problems or questions arise.

dren for their first eye examination—this helps to establish a relationship with the next generation of patients. Asking your younger associate to examine children is a great way to introduce your patients to the associate while helping to build his or her own patient base. Growing up with the patients makes it easier to gain their trust and confidence. Make contact lenses fitting fun, and have a staff member who works well with young patients perform the contact lens training. Knowing that you can help improve con-

> Once I started fitting pediatric patients in contact lenses, there was a decrease in broken or last glasses among those patients.

Is there a place for pediatric contact lens fitting in my practice?

As doctors, we strive to provide the best care for all of our patients, including our pediatric population. Many of our young patients are very happy with their glasses, but there are many who are not. The Contact Lenses in Pediatrics (CLIP) Study found that children 8-11 years old who were fitted with 1-day replacement lenses had an overall quality of vision and comfort than spectacle wearers over a 3 month period.[5] Being able to provide contact lenses as an option for this patient base may help improve their quality of life in school, sports, and appearance.

Pediatric contact lens fitting also creates a niche in your practice. Parents of happy children make for one of your best referral systems. These children may have classmates or teammates who may also be interested in contact lenses, and your patient is the one to start the conversation with these groups, driving patients into your office. Gaining the confidence of a child and parent makes a patient for life and future generations to come.

Where do I start?

Start internally. Encourage your current patients to bring in their children for their first eye examination—this helps to establish a relationship with the next generation of patients. Asking your younger associate to examine children is a great way to introduce your patients to the associate while helping to build his or her own patient base. Growing up with the patients makes it easier to gain their trust and confidence. Make contact lenses fitting fun, and have a staff member who works well with young patients perform the contact lens training. Knowing that you can help improve confidence and have a positive effect on child's life is very rewarding. At the end of the day, seeing a child's smile and face light up makes our job worthwhile.**ODT**

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The cost of contact lens and lens care noncompliance

Patients may not be following your advice, so diligence is key

By Ernie Bowling, OD, FAAO
Chief Optometric Editor
Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Take-Home Message

Contact lens and lens care compliance depends on patients following the doctor's recommendations, yet not all of what is imparted to patients is being followed. Diligence is the watchword, in both patient education and looking for contact lens complications from noncompliance in contact lens-wearing patients.

A lot of us have bad habits. Whether it is gambling, smoking, eating or drinking to excess, or something much worse, it seems we all have demons to fight. This is especially true for our contact lens patients. While many, if not most, of our contact lens patients follow recommended wear schedules and disinfection regimens, some patients choose to ignore wear and care recommendations—even when educated that improper use can lead to serious problems, including sight-threatening infections.

There are a myriad of reasons: some patients do it to save money, others because they don't keep track of when they change their lenses, many because it just seems to be a waste to throw the lenses away "when they still feel fine and I see well," and others just don't care. Whatever the reason, we see noncompliance far too often. It is not a new problem. The first peer-reviewed article addressing contact lens compliance was published in 1986.[1]

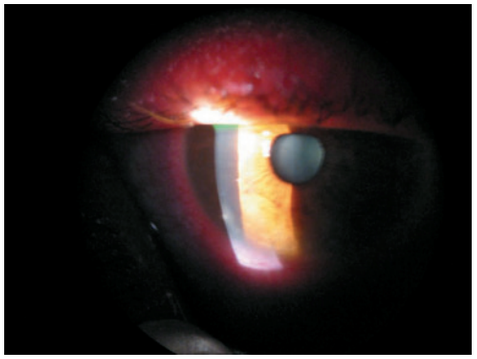

Figure 1. Peripheral corneal ulcer in contact lens wear.

Our contact lens patients aren't alone. Noncompliance is rampant in health care. The World Health Organization reports that only about 50% of people typically follow their doctor's orders when it comes to prescription drugs.[2] Studies have shown that noncompliance causes 125,000 deaths annually in the United States,[3] is responsible for 10% to 25% of hospital and nursing home admissions, and is becoming an international epidemic.[4]

Noncompliance with medications is one of the most costly health conditions afflicting Americans today. In 2011, medication non-adherence cost the U.S. healthcare system $317.4 billion in treating medical complications that could have been avoided if patients had complied with their medical therapy. That amount was higher than the total U.S. medical cost of treating diabetes, congestive heart failure, and cancer **combined**.[5]

Noncompliance, nonadherence

One might think that noncompliant behavior is a patient education problem or a breakdown in communication between the patient and doctor. Yet, this is not the case. Even clinical trials report average adherence rates of only 43% to 78% among patients receiving medications for chronic conditions.[6] One study showed that up to 1 in 8 patients admitted for acute myocardial infarction discontinued all prescribed medications for their condition within 1 month of being discharged from the hospital.[7] So, is it any wonder our contact lens patients don't comply with recommended wear, care, and lens replacement schedules?

Something else to consider: Your contact lens patients may not be complying but believe they are. A group at the University of Texas questioned 162 established contact lens wearers regarding their lens care practices and knowledge of risk factors associated with lens wear. Some 86% of them believed they were compliant with contact lens wear and care, yet only 34% of those actually exhibited good compliance when questioned. Some 14% readily admitted being noncompliant.[8] Another study from the University of Waterloo of 501 silicone hydrogel contact lens wearers revealed that two thirds of those patients did not comply with manufacturer's recommended replacement frequency, and those patients wearing 2-week replacement lenses stretched the replacement interval of their lenses to a greater degree than those patients wearing 1-month replacement lenses. Failing to replace lenses when recommended and failing to rub and rinse lenses were associated with a higher rate of patient reported problems with contact lenses.[9]

These studies demonstrate that many patients are unaware that their contact lens wear and care practices are reflective of actual noncompliance.[1] To date, there is no single predictor for noncompliance among contact lens wearers,[10] and despite the introduction of daily disposables and 1-step multipurpose disinfection systems, compliance with contact lens wear is an ongoing clinical problem.[11]

Why comply?

The benefits of increasing patient compliance

See **Noncompliance** on page 26

$317.4 BILLION

Cost to the U.S. healthcare system in 2011 in treating medical complications that could have been avoided if patients had complied with their medical therapy.[5]

CONTACT LENS CARE

In one study, established contact lens wearers were questioned regarding their lens care practices and knowledge of risk factors associated with lens wear.[8]

86% of them believed they were compliant with contact lens wear and care, yet only

34% of those actually exhibited good compliance when questioned.

14% readily admitted being noncompliant.

Noncompliance

Continued from page 25

are clear. Although there are no definitive studies linking noncompliant behavior with increased risk of lens-related complications, high levels of lens case contamination leading to heavy biofilm formation, combined with the inappropriate use of contact lens care solutions is suspect.[11]

Loretta Szczotka-Flynn and a group from Case Western Reserve University in Cleveland found that "the presence of substantial bacterial bioburden on worn contact lenses was significantly associated with the development of a corneal infiltrative event (CIE)." In fact, other than smoking, they claim that bioburden is the only statistically significant risk factor for CIEs.[12]

The association between bacterial bioburden and CIEs is well-known.[16] CIEs result from some stimulus that causes direct infiltration of leukocytes into the cornea.[13] Contact lens- related CIEs are the end result of the ocular surface's normal defense mechanism as it encounters foreign substances. Overnight lens use[14] (a modifiable non-compliant behavior) and bacterial adhesion to contact lenses[15] significantly increase the risk of CIEs. There is a higher rate of CIEs observed during silicone hydrogel lens wear,[14] perhaps due to the fact certain silicone hydrogel lenses bind more microorganisms than do low-Dk lenses.[17]

Of lenses, cases, and solutions, lens cases represent the most common source of contamination and have been shown to include a host of pathogenic microorganisms, including bacteria, amoeba, and fungi.[18] From 24% to 81% of contact lens storage cases are contaminated with microbial biofilms, with the frequency of contamination increasing in wearers suffering from microbial keratitis.[19] Biofilm formation provides bacterial populations with resistance to antiseptics and antibiotics,[20] and thus increases the threat of bacterial infection. While contamination is required for an infection, it must be accompanied by some form of corneal compromise for an infection to occur. The most common compromising factor for contact lens corneal infections is overnight contact lens wear,[21] a modifiable risk factor.

A recent report from West Virginia University studied biofilms isolated from cases and lenses of patients with contact lens-related corneal disease. Of the 17 patients in the study, 7 were documented as having slept in their lenses or having lens overuse. The unexpected study outcome was that three bacteria, *Achromobacter*, *Stentrophomonas*, and *Delftia*, rather than *Pseudomonas* were the predominant bacteria associated with patients having contact lens-related corneal disease.[22] All three are Gram-negative bacteria like *Pseudomonas* and have a propensity to form biofilms.[23] Researchers claim that "the survival of these bacteria in contact lens specimens can be explained by their ability to form biofilms."[22]

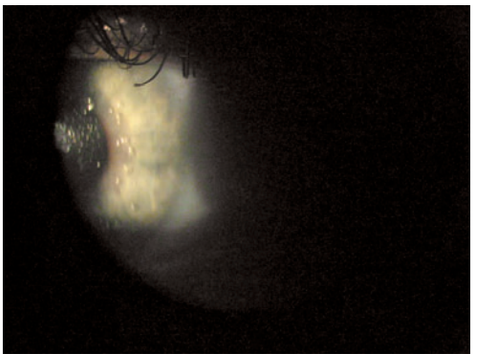

Figure 2. Deposits on overworn contact lens.

$58 MILLION

Overall annual direct and indirect cost of treating patients with both severe and nonsevere contact lens-related CIEs in the United States.[33]

$1,003 Cost of a NON-SEVERE contact lens-related CIE

$1,496 Cost of a SEVERE contact lens-related CIE

Looking back

Various hygiene related risk factors were evaluated in case-control studies of both the *Fusarium* and *Acanthamoeba* outbreaks of 2005. The practice of solution reuse or "topping off" (refilling the contact lens storage case without discarding used solution) has been suggested as a risk factor in both outbreaks in multiple studies[24,25] and is currently listed on the FDA Web site as an important contact lens warning to patients.[26] These studies also suggest that a number of other compliance-related practices may have had a role, including a lack of rubbing of contact lenses during the cleaning process, showering in contact lenses, and using lenses beyond their replacement date.[25,27] While noncompliant actions may have some clinical bearing in those outbreaks, "the magnitude of their contributions are likely substantially less than either the identified contact lens solution associations or yet to be identified environmental associations for these outbreaks."[28]

Exposure to water during contact lens wear or care has been repeatedly indicated as a significant risk factor for *Acanthamoeba* infection.[25,29] Most patients were aware of the risk of using tap water, yet "in contrast to risk factors that were easily identifiable by patients... such as sleeping in lenses or wearing lenses longer than recommended, almost one third of patients felt that swimming showed no effect on risk of infection and of those that knew ... 50 percent did so anyway."[8] Because some silicone hydrogel lenses show increased *Acanthamoeba* adherence to the contact lens surface,[30] eliminating exposure to water is imperative.

The cost of noncompliance

In the U.S. it has been estimated there are at least 35 million full-time contact lens wearers[31] and that the incidence of the most severe form of contact lens-associated corneal infiltrative event, microbial keratitis, is roughly 11 per 100,000.[32] A recent paper by Andrew Smith and Gary Osborn estimated the overall annual direct and indirect cost of treating patients with both severe and nonsevere contact lens-related CIEs in the U.S. at $58 million.[33] The authors estimated the cost per non-severe contact lens-related CIE (which they defined as needing primary care with a loss of 18 hours of work due to the condition) to be $1,003, while the cost of a severe contact lens-related CIE (defined as requiring specialized care and a loss of 34 working hours) to be $1,496.

Promoting compliance

How do we promote compliance in our patients? It is important for eyecare providers to make a concerted effort to individually address each patient's compliance, instead of simply making blanket recommendations. Do not assume your contact lens patients are practicing healthy contact lens wear and care. Spending time discussing contact lens wear and care with your patients at each visit will help you identify those patients who are more likely to be compliant, but even more importantly, those who may be noncompliant. New contact lens wearers are more likely to be compliant because they haven't had time yet to develop bad habits. Similarly, long-term wearers are more likely to lax into poor habits.[34]

Contact lens compliance ultimately depends on our patients following the doctor's recommendations. Educate the patient at each and every visit about why it is important to replace contact lenses as recommended, use the recommended contact lens care solution, and replace the contact lens case regularly. I give patients a copy of the Association of Optometric Contact Lens Educators *Healthy Soft*

See **Noncompliance** on page 28

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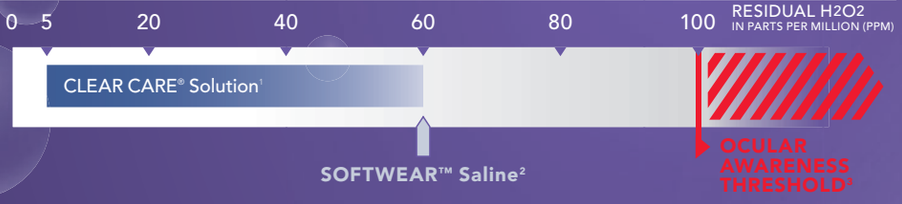

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Noncompliance

Continued from page 26

Contact Lens Habits handout as we discuss contact lens wear and care. It's generic, but it does have areas where you can enter the prescribed care solution and the prescribed lens replacement schedule.

For the ever-increasing number of patients using smartphones, there are applications to remind them about contact lens replacements and office visits. Online calendars allow users to establish recurring calendar appointments or tasks which can be used to remind your patients when to replace their contact lenses. Acuminder allows patients sign up for free text messages or e-mail reminders to change their lenses or schedule an appointment.

Even with high rates of reported noncompliance, the incidence of severe complications associated with contact lens wear and care is relatively low and has remained constant for more than three decades, regardless of changes in lens material and the introduction of daily disposables and no-rub care solutions.[35-37] Current strategies to improve patient compliance are limited. Patient education is paramount, yet not all of what is being imparted to our patients is necessarily being followed. Diligence is the watchword, in both patient education and looking for contact lens complications from noncompliance in our contact lens-wearing patients. **ODT**

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In Brief

Adlens launches Adjustables variable focus eyewear

Oxford, United Kingdom—Adlens introduces Adjustables, its latest variable focus eyewear product.

Each lens consists of two wave-shaped plates that glide across each another to alter the power of each lens, correcting more than 90% of spherical errors (lens power –6.00 D to +3.00 D). Although the improved optics result in an optimized reading zone, Adjustables were designed for a range of applications, such as up-close work, computer use, yard work, and for managing fluctuating vision in diabetes patients or after eye surgery.

Along with enhanced optics, Adjustables offer an aesthetic pair of glasses. The brow bar is more ergonomic for a modern look, the nosepiece is adjustable for a comfortable fit, and the frame and temple arms were designed to give the glasses a lightweight feel. When they are released, Adlens Adjustables are available in black, blue, grey/black, and red/black, followed soon by a new range of colors.

Santinelli beefs up its line of dispensary tools, supplies

Hauppauge, NY—Santinelli International has used its 40th anniversary in business to re-launch its optical supplies product line. According to the company, Santinelli offers one-stop service for both dispensary and finishing needs.

The products for in-office labs include staples, such as nose pads, temple tips, and screws, but also features unique workshop items. One featured line is the Visionary Plier Collection, developed by Breitfeld & Schliekert, a German company known for craftsmanship and functional products.

"We are thrilled to provide our clients the ability to order a wide array of the optical tools and supplies they need to successfully run their practice," said Gerard Santinelli, president and chief executive officer. "

An e-catalog is available on the company's Web site: *www.santinelli.com.*

Marciano puts a new spin on sophisticated eyewear

New York—For fall, the Marciano optical collection from Viva International Group updates its signature style with colorful modern details.

The dramatic cat-eye silhouette of model GM 199 has satin metal finishes in gold, burgundy, and black. Transparent horn temple tips complement this simple elegant frame in shades of black, burgundy, and tortoise, as well as blue and green horn.

Retro-inspired model GM 201 offers rich jewel-tone horn colorations in teal, purple, brown, and black throughout. Acetate fronts, double-plated metal temples, and acetate temple tips set off the rectangular shape.

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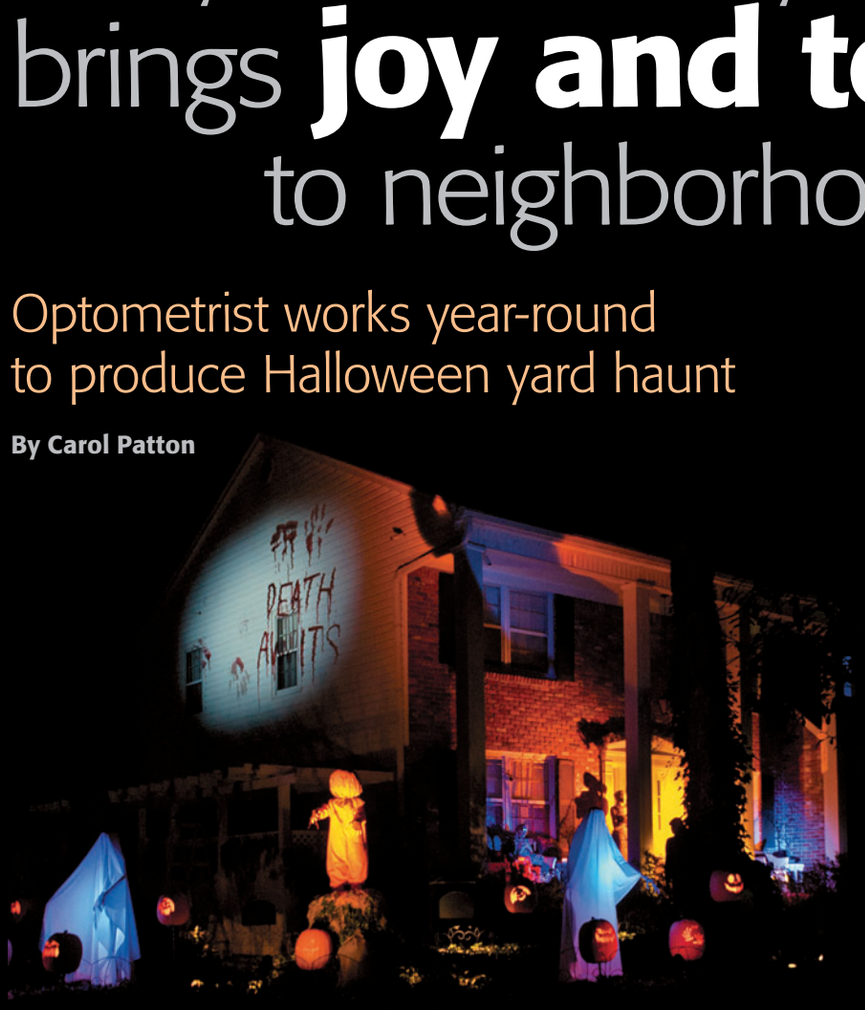
Eye doctor's hobby brings **joy and terror** to neighborhood

Optometrist works year-round to produce Halloween yard haunt

By Carol Patton



David Talley, OD, enjoys nothing more than scaring people.

Since 2008, Dr. Talley, who practices optometry in Memphis, TN, has created yard haunts. For 13 evenings prior to Halloween, the front and side yards of his corner, two-story house feature four different scare zones and four scare shows. The elaborate Hollywood-like scenes, which involve animatronics and video projection, attract more than 4,000 people each year who want to be scared out of their wits.

"I always loved Halloween," said Talley, who budgets roughly $8,000 a year for the elaborate holiday decorations. "Last year, it took my four neighbors, a certified electrician, and me about 320 hours to set everything up."

Scare tactics

One of the first scenes people see when they drive up to his house is a "Restless Rocker" on the front porch. The chair rocks by itself and emits ghostly sounds until people come within 3 feet of it. The rocking suddenly stops, then people hear somebody running through the bushes near the rocker and watch the bushes shake.

"It's as if the ghost jumped off the chair and ran away through the bushes," he said. "It's quite startling."

On the other side of the porch is a skeleton hunched over another chair whose head and eyes move as he tells the terrifying tale of how the Talley house became haunted.

The three other scare shows include "Flights of Fright," where ghosts and bats appear to be flying through the air; Shadow Theater's "Pick A Bone" presentation, where the window above some bushes start glowing and shadows morph into humans. He says people can see the silhouette of a human speaking on the phone, terrified about the ghosts in his house.

The last show is a graveyard zombie scene. As zombies come out of the ground, three are standing at the cemetery entrance holding three evil-looking pumpkins who sing a creepy song, "The Greatest Show Un-

Photos courtesy David Talley, OD

'For next year's haunt, I'm working on a werewolf scene.'

David Talley, OD

earthed," written by the band Creature Feature.

Now if that doesn't creep you out, maybe his scare zones will do the trick.

Through three upstairs windows, people watch ghosts floating around, which Dr. Tally said looks very real, adding that he named this zone, "Haunted Haven."

The "Trick or Treat" zone is based on a popular movie that bears the same name. It features a character named Sam, who resembles a 10-year old child, except that he's wearing an orange jumpsuit and burlap mask over his head.

Dr. Talley reproduced one of the movie's scenes where Sam, who is holding a box cutter, stands on a stump in front of a house that's not decorated for Halloween. After summoning his evil powers, several ghosts and 18 hand-carved, evil-looking pumpkins suddenly appear out of nowhere. Surrounding Sam are two glowing skeletal corpses wearing long sheets over their heads.

But if ghosts and skeletons aren't your brand of terror, there's always Bloody Mary. Her character is based on a story about a witch who ate children to stay young. But when the townspeople discovered the source of her midnight snacks, they burned her alive at the stake. But Mary had her revenge. She placed a curse on all humans—if anyone spoke her name three times into a darkened mirror, she would snatch their soul.

Dr. Talley built a 12 x 14-foot witch's shack. Outdoors is a cauldron sitting on top of a small fire with children's bones scattered nearby. The head of a ghost appears in the window, warning visitors to stay away. For those curious enough to peek into a side window, they see a mirror floating and hear Bloody Mary's name whispered once, twice, and on the third time, Bloody Mary appears, ready to grab their soul.

See **Haunt** on page 38

Dr. Talley budgets about $8,000 a year for his Halloween yard haunt. Last year, his four-zone setup required 320 hours, 4 neighbors, and a certified electrician to create.

Haunt

Continued from page 37

Behind the scenes

Dr. Talley says his yard haunt requires a long list of technology that includes six projection systems, 26 different speakers, four computers, and video cameras strategically placed around his yard that capture people's gasps and horrified expressions. He purchased most of this equipment for his first yard haunt, which amounted to about $20,000.

Throughout the year, he attends workshops sponsored by the haunt industry at Universal Studios in Orlando and TransWorld, the haunt industry's annual trade show, to learn the art of terror. He also created a website to capture the highlights of each year's yard haunt, *www.thetelltalehouse*. His resume now includes skills in pneumatics, airbrushing, sculpting, computer programming, electrical wiring, and digital editing.

Although newspaper and TV reporters feature his yard haunt on Halloween, they never reveal his name or address to prevent larger crowds from coming, which would annoy his neighbors, he says.

"This is my hobby that brings me and thousands of others a lot of joy," Dr. Talley says. "For next year's yard haunt, I'm working on a werewolf scene."**ODT**

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(Requester Publications Only)
(Required by 39 USC 3685)

1. **Publication Title:** Optometry Times
2. **Publication Number:** 0890-7080
3. **Filing Date:** 9/30/13
4. **Issue Frequency:** Monthly
5. **Number of Issues Published Annually:** 12
6. **Annual Subscription Price (if any):** $49.00
7. **Complete Mailing Address of Known Office of Publication:**
131 West First Street, Duluth, St. Louis County, Minnesota 55802-2065
Contact Person: Wendy Bong **Telephone:** 218-740-7244
8. **Complete Mailing Address of Headquarters or General Business Office of Publisher:**
2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404
9. **Full Names and Complete Mailing Addresses of Publisher:**
Leonardo Avila, 485F US Highway 1S, Suite 210, Iselin, NJ 08830
Group Content Director: Mark L. Dlugoss, 24950 Country Club Blvd., North Olmsted, OH 44070
Content Channel Director: Gretchyn Bailey, 24950 Country Club Blvd., North Olmsted, OH 44070
10. **This publication is owned by:** Advanstar Communications Inc., 2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404. The sole shareholder of Advanstar Communications Inc. is: Advanstar, Inc., whose mailing address is 2501 Colorado Avenue, Suite 280, Santa Monica, CA 90404.
11. Advanstar Communications Inc. is a borrower under Credit Agreements dated June 6, 2013, with various lenders as named therein from time to time. As of June 6, 2013, the agent for the lenders is: Goldman Sachs Lending Partners LLC, Administrative Agent, 30 Hudson St, 4th Floor, Jersey City, NJ 07302.
12. **Does Not Apply**
13. **Publication Title:** Optometry Times
14. **Issue Date for Circulation Data Below:** Aug-2013
15. **Extent and Nature of Circulation**

		Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
A.	**Total Number of Copies**	37,463	36,532
B.	**Legitimate Paid and/or Requested Distribution**		
1.	**Outside County Paid/ Requested Mail Subscriptions Stated on PS Form 3541**	21,810	18,641
2.	**In-County Paid/Requested Mail Subscriptions Stated on PS Form 3541**	0	0
3.	**Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS**	1,833	1,942
4.	**Requested Copies Distributed by Other Mail Classes Through the USPS**	0	0
C.	**Total Paid and /or Requested Circulation** (Sum of 15b (1), (2), (3), and (4))	23,642	20,583
D.	**Non-requested Distribution**		
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2.	**In-County Non-requested Copies Stated on PS Form 3541**	0	0
3.	**Non-requested Copies Distributed Through the USPS by Other Classes of Mail**	0	0
4.	**Non-requested Copies Distributed Outside the Mail**	5,672	4,858
E.	**Total Non-requested Distribution** (Sum of 15d (1), (2), (3) and (4))	13,582	15,747
F.	**Total Distribution** (Sum of 15c and e)	37,225	36,330
G.	**Copies not Distributed**	238	202
H.	**Total** (Sum of 15f and g)	37,463	36,532
I.	**Percent Paid and/or Requested Circulation**	63.51%	56.66%

16. ☐ **Total circulation includes electronic copies.**
Report circulation on PS Form 3526-X worksheet.
17. **Publication of Statement of Ownership for a Requester Publication is required and will be printed in the October issue of this publication.Name and Title of Editor, Publisher, Business Manager, or Owner:**
Christine Shappell, Audience Development Director
Signature: Christine Shappell
Date: 09/30/13
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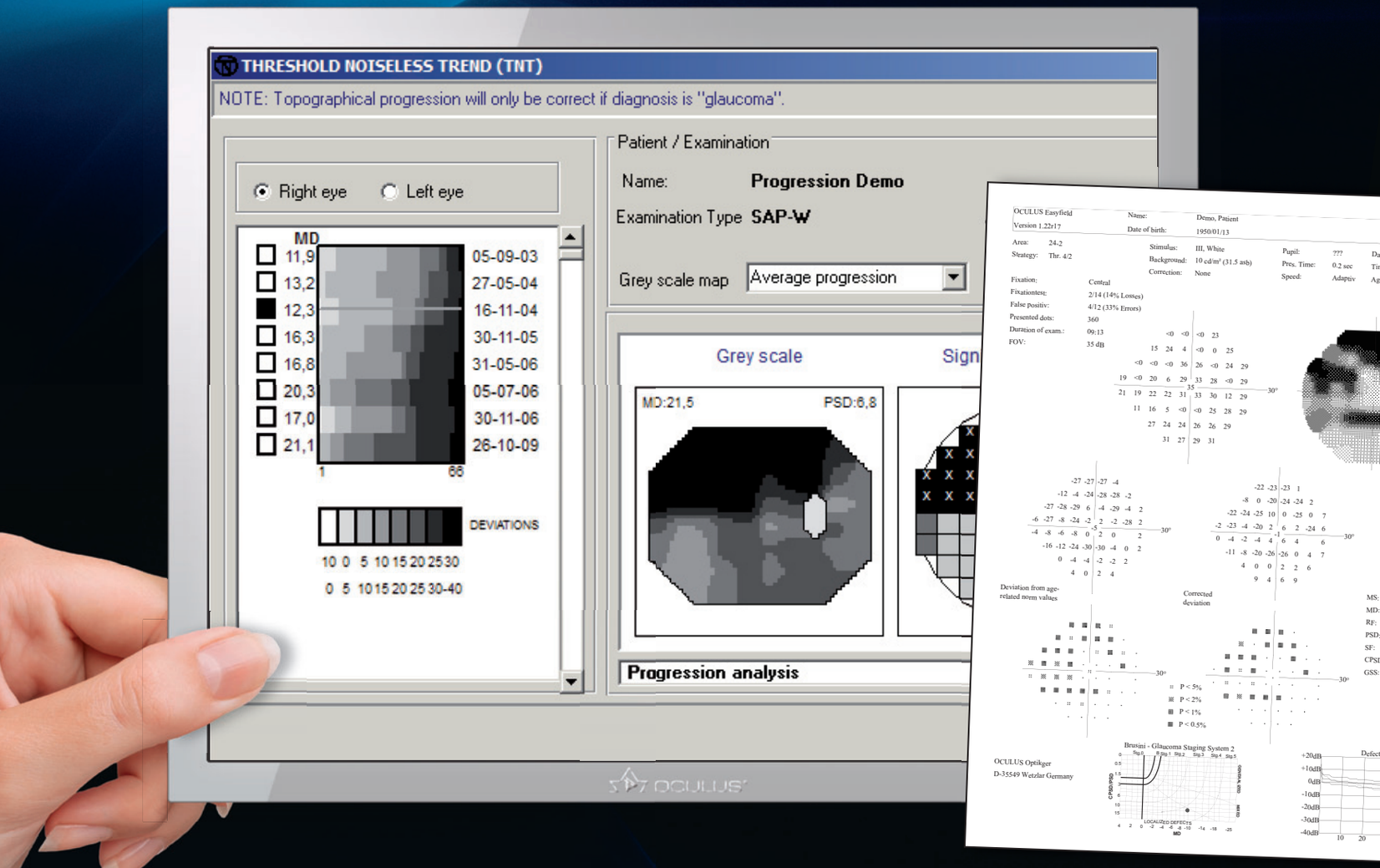

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