CONTROLLING GLAUCOMA WITH CATARACT SURGERY, STENT IMPLANTATION

Several studies have shown IOP lowering associated with cataract surgery alone in patients with open-angle glaucoma. The addition of a Schlemm’s canal-based MIGS device can lower IOP even further without changing the safety profile of the procedure.

Daniel Laroche, MD, is using one micro-stent as his “go-to” device in patients with glaucoma and cataract. He explains that removal of the cataract opens Schlemm’s canal and expands the trabecular meshwork.

Continues on page 28:

Adult glaucoma

DEVICE TECHNOLOGY   Improving patient experience

Innovations can help physicians enhance outcomes

CLINICAL DIAGNOSIS   Get upper hand on nAMD

Treatment with brolucizumab yields better control

IMAGING   Color LED topography

Provides concise cornea measurement

Ophthalmology Times

CUTTING-EDGE ADVANCEMENTS

October 1, 2019

VOL. 44, NO. 16

CUTTING-EDGE ADVANCEMENTS

DIVING INTO DRY EYE:
KNOWING DETAILS LEADS TO EFFECTIVE THERAPY

DRY eye disease is far from being a single disease. Rather, it encompasses many different entities. To determine the proper approach to treatment, physicians must differentiate what type of ocular surface disease (OSD) the patient has. A host of mechanisms result in various contributing factors.

Harvey A. Fishman, MD, PhD, notes that regardless of the root cause, as the cornea becomes increasingly irritated it further dries out and normal function deteriorates. Tear production becomes compromised and inflammatory markers appear.

Continues on page 24:

Dry eye disease

Therapeutics

2019 SURVEY RESULTS

Gene Therapy

RESHAPING MEDICAL TREATMENT OF GLAUCOMA

Bascom Palmer tops in annual program survey

By Lynda Charters

The eagerly awaited results of the 2019 Ophthalmology Times Best Programs Survey are in, with the previously honored top institutions again achieving high rankings. Though many of the same 12 institutions from 2018 remained among the current year’s top 12 ophthalmic programs in the country, there also were some newcomers among the highest-ranked Best Residency and Best Clinical Care programs.

Ophthalmology Times extends congratulations to the teams of healthcare professionals involved in all of these programs. The survey that amassed these results was sent by Ophthalmology Times to chairpersons and residency directors across the country.

Continues on page 12:

Best Programs

OVERALL PROGRAM

CLINICAL CARE

RESIDENCY PROGRAM

RESEARCH PROGRAM

Wilmer holds steady in lead for best research

BEST programs

Surgery

INDICATIONS AND USAGE

XELPROS™ (latanoprost ophthalmic emulsion) 0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XELPROS is contraindicated in patients with a known hypersensitivity to latanoprost, or any other ingredients in this product.

Please see Important Safety Information on the back cover and brief summary of Full Prescribing Information inside.

XELPROS IS THE FIRST AND ONLY BAK-FREE FORMULATION OF LATANOPROST—DELIVERED WITH AN INNOVATIVE TECHNOLOGY1,2

Visit XelprosDelivered.com to learn more

Take the worry out of coverage with XELPROS Xpress™

Delivers XELPROS™ directly to patients at a low set price
Brief Summary of Prescribing Information for XELPROSTM (latanoprost ophthalmic emulsion) 0.005%, for topical ophthalmic use

XELPROSTM (latanoprost ophthalmic emulsion) 0.005%
See package insert for Full Prescribing Information.

INDICATIONS AND USAGE
XELPROS is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

CONTRAINDICATIONS
Known hypersensitivity to latanoprost, or any other ingredients in this product.

WARNINGS AND PRECAUTIONS
Pigmentation
XELPROS may cause changes to pigmented tissues. The most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as XELPROS is administered. After discontinuation of XELPROS, iris pigmentation is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Eyelash Changes
XELPROS may gradually change eyelashes and vellus hair in the treated eye, including increased length, thickness, pigmentation, and number of lashes. The changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
XELPROS should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

Macular Edema
XELPROS should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Herpetic Keratitis
XELPROS should be used with caution in patients with a history of herpetic keratitis. XELPROS should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Bacterial Keratitis
There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses
Contact lenses should be removed prior to administration of XELPROS and may be reinserted 15 minutes following administration.

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

Across multiple clinical trials conducted with XELPROS, the most frequently reported ocular adverse reactions were eye pain/stinging upon instillation and ocular hyperemia, reported in 55% and 41% of patients treated with XELPROS, respectively. Other adverse reactions reported (incidence ≥5%) were conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening. Less than 1% of patients discontinued therapy because of intolerance to the eye pain/stinging or to the ocular hyperemia.
DRUG INTERACTIONS
Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROS. If such drugs are used, they should be administered at least 5 minutes apart.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C
Reproduction studies have been performed in rats and rabbits. In rabbits, an incidence of 4 of 16 dams had no viable fetuses at a dose that was approximately 80 times the maximum human dose, and the highest nonembryocidal dose in rabbits was approximately 15 times the maximum human dose. There are no adequate and well-controlled studies in pregnant women. XELPROS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

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

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

PATIENT COUNSELING INFORMATION
Potential for Pigmentation
Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of XELPROS.

Potential for Eyelash Changes
Inform patients of the possibility of eyelash and vellus hair changes in the treated eye during treatment with XELPROS. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container
Instruct patients to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated emulsions.

When to Seek Physician Advice
Advise patients that if they develop an intercurrent ocular condition (eg, trauma or infection) or have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician’s advice concerning the continued use of the multiple-dose container.

Use with Contact Lenses
Advise patients that contact lenses should be removed prior to administration of the emulsion. Lenses may be reinserted 15 minutes following administration of XELPROS.

Use with Other Ophthalmic Drugs
Advise patients that if more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.

Rx Only
Distributed by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

© 2019 Sun Ophthalmics, a division of Sun Pharmaceutical Industries, Inc. All rights reserved.
XELPROS is a licensed trademark of Sun Pharma Advanced Research Company Ltd.
INDICATIONS AND USAGE
XELPROS™ (latanoprost ophthalmic emulsion) 0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
XELPROS is contraindicated in patients with a known hypersensitivity to latanoprost, or any other ingredients in this product.

WARNINGS AND PRECAUTIONS

Pigmentation: XELPROS may cause changes to pigmented tissues. The most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as XELPROS is administered. After discontinuation of XELPROS, iris pigmentation is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Eyelash Changes: XELPROS may gradually change eyelashes and vellus hair in the treated eye, including increased length, thickness, pigmentation, and number of lashes. The changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: XELPROS should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

Macular Edema: XELPROS should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Herpetic Keratitis: XELPROS should be used with caution in patients with a history of herpetic keratitis. XELPROS should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Bacterial Keratitis: There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses: Contact lenses should be removed prior to administration of XELPROS and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS
The most common ocular adverse reactions in clinical trials (incidence ≥5%) for XELPROS were eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening.

DRUG INTERACTIONS
Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROS. If such drugs are used, they should be administered at least 5 minutes apart.

Please see brief summary of Full Prescribing Information on the reverse side.

BAK=benzalkonium chloride.

DIVING INTO DRY EYE: KNOWING DETAILS LEADS TO EFFECTIVE THERAPY

DRY eye disease is far from being a single disease. Rather, it encompasses many different entities. To determine the proper approach to treatment, physicians must differentiate what type of ocular surface disease (OSD) the patient has. A host of mechanisms result in various contributing factors.

Harvey A. Fishman, MD, PhD, notes that regardless of the root cause, as the cornea becomes increasingly irritated it further dries out and normal function deteriorates. Tear production becomes compromised and inflammatory markers appear.

CONTROLLING GLAUCOMA WITH CATARACT SURGERY, STENT IMPLANTATION

Several studies have shown IOP lowering associated with cataract surgery alone in patients with open-angle glaucoma. The addition of a Schlemm’s canal-based MIGS device can lower IOP even further without changing the safety profile of the procedure.

Daniel Laroche, MD, is using one microstent as his “go-to” device in patients with glaucoma and cataract. He explains that removal of the cataract opens Schlemm’s canal and expands the trabecular meshwork.

Best programs

Bascom Palmer tops in annual program survey

Wilmer holds steady in lead for best research

By Lynda Charters

The eagerly awaited results of the 2019 Ophthalmology Times Best Programs Survey are in, with the previously honored top institutions again achieving high rankings. Though many of the same 12 institutions from 2018 remained among the current year’s top 12 ophthalmic programs in the country, there also were some newcomers among the highest-ranked Best Residency and Best Clinical Care programs. Ophthalmology Times extends congratulations to the teams of healthcare professionals involved in all of these programs. The survey that amassed these results was sent to chairpersons and residency directors across the country.

Continues on page 12: Best Programs
TECNIS SYMFONY® EXTENDED RANGE OF VISION IOL

INDICATIONS: The TECNIS Symfony® Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only. WARNINGS: Patients with any of the conditions described in the Directions for Use may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient’s eyesight. Lenses should not be placed in the ciliary sulcus. May cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL; fully inform the patient of this risk before implanting the lens. Special consideration should be made in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease. Inform patients to exercise special caution when driving at night or in poor visibility conditions. Some visual effects may be expected due to the lens design, including: a perception of halos, glare, or starbursts around lights under nighttime conditions. These will be bothersome or very bothersome in some people, particularly in low-illumination conditions, and on rare occasions, may be significant enough that the patient may request removal of the IOL. SERIOUS ADVERSE EVENTS: The most frequently reported serious adverse events that occurred during the clinical trial of the TECNIS Symfony® lens were cystoid macular edema (2 eyes, 0.7%) and surgical reintervention (treatment injections for cystoid macular edema and endophthalmitis, 2 eyes, 0.7%). No lens-related adverse events occurred during the trial.

TECNIS® MULTIFOCAL FAMILY OF 1-PIECE IOLs

INDICATIONS: The TECNIS Multifocal IOLs are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag. WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the Directions for Use that could increase complications or impact patient outcomes. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma. The lens should not be placed in the ciliary sulcus. Inform patients about the possibility that a decrease in contrast sensitivity and an increase in visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions. PRECAUTIONS: Prior to surgery, inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. ADVERSE EVENTS: The rates of surgical re-interventions, most of which were non-lens related, were statistically higher than the FDA grid rate for the ZLB00 (+3.25 D) lens model. The re-intervention rate was 3.3% for both the first and second eyes in the ZLB00 group.

ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

TECNIS and TECNIS Symfony are trademarks of Johnson & Johnson Surgical Vision, Inc.
©Johnson & Johnson Surgical Vision, Inc. 2019 | TecnisIOL.com | PP2019CT4953

See the Passion in Each Patient
18

Therapeutics

24 Diving into Dry Eye Can Help Solve Patients' Woes
Myriad mechanisms contribute to cause; knowing details leads to effective treatment

46

Surgery

35 Secrets to Success for Low Myopes
Pearls offer leads for helping challenging patients’ cases

58

Device Technology

46 Innovations Focus on Improved Patient Experience
Company poised to conduct additional trials, develop pipeline of technology

In This Issue 4 FOCAL POINTS 8 EDITORIAL 52 MARKETPLACE

What’s Trending

See what the ophthalmic community is reading on OphthalmologyTimes.com

1 10 Effective Habits of a Cataract Surgeon
OphthalmologyTimes.com/10habits

2 New for 2020 and Beyond: Dry Eye Disease Agents in Pipeline
OphthalmologyTimes.com/2020DEDpipeline

3 Quieting the Neuropathic Components of Ocular Pain
OphthalmologyTimes.com/NeuropathicPain

Digital App

Introducing the Ophthalmology Times app for iPad and iPhone. Download it for free today at OphthalmologyTimes.com/OTapp

eNewsletter


Video

Watch Josh Anderson, head of Alcon’s U.S. Surgical Retina Sales & Marketing, discuss how the NGENUITY 3D Visualization System creates an immersive surgical experience during the American Society of Retina Specialists annual meeting. ModernRetina.com/ASRS2019/JoshAnderson

Facebook

Like Ophthalmology Times at Facebook.com/OphthalmologyTimes
Sowing the seeds to develop ophthalmic care in war-torn Armenia

Eyecare initiative aims to prevent, treat blindness in residents of country’s rural regions

By Roger Ohanesian, MD; Special to Ophthalmology Times

I am a second-generation Armenian. In 1992, when Armenia took the responsibility as the main guarantor of security for Artsakh in its conflict with Azerbaijan, the Armenian government put out a call to all Armenian-American physicians to help treat casualties of war. For me, this was a reminder of the promise I had made to my grandfather at age 12—to return to the homeland when the need arose.

I had never been in a war zone before, and what I saw was shocking. Among the worst injuries were those from landmines and other explosives placed in playgrounds and schoolyards by Azerbaijani military who had overrun the country. I visited hospitals full of soldiers who were bilaterally blind due to severe injuries to their eyes, many of which had become infected. I did what I could through surgery and the dwindling amounts of medicines I brought. But as I left, I vowed to continue to return.

I started visiting Armenia twice a year, often bringing with me desperately needed equipment and medicines, as well as ophthalmologists with different specializations who could in turn train doctors in Armenia.

THE PROBLEM OF DIABETIC RETINOPATHY

Despite the horrors that I saw on those early trips, once the guns were silent it became clear that one of the biggest threats to eye health in this country was something with which ophthalmologists worldwide are very familiar: diabetic retinopathy (DR). This is a silent, blinding disease. Most people with diabetes have no symptoms until their vision is irreversibly damaged. While annual ophthalmic screening is recommended for all people with diabetes, less than half get screened yearly, even in the developed world.

Rates of diabetes and DR are similar in Armenia and the United States, but the impact on vision is more severe because those living in rural areas lack access to routine ophthalmic care. Many of these patients are seen only after they have retinal blood vessels leaking and bleeding within the eye. Without very rapid treatment, a burst blood vessel will destroy vision.

REACHING RURAL PATIENTS

In a country of 3 million, 2 million are poor and live in rural regions. They are often too poor to travel to the capital for free treatment. To get to them, the idea of a mobile eye hospital was conceived and executed with tremendous support of the Armenian diaspora. This 18-wheeled truck is equipped with two exam rooms, two different lasers, and a fully functional operating room with surgical microscopes and all the instruments needed to perform cataract, glaucoma, and retinal surgeries, and even corneal transplantation. This mobile eye hospital has been around the country seven times so far and treated more than half a million people. Our humanitarian organization has also built four regional eye centers so that people who cannot wait for the mobile eye hospital to arrive in their area.

Roger Ohanesian, MD, examines a patient in the cornea clinic with Anna Hovakimyan, MD, PhD, chief of the Corneal-Uveitis Clinic at the Malayan Ophthalmologic Center in Yerevan, Armenia, along with fellows and residents. (Photo courtesy of Roger Ohanesian, MD)

TAKE-HOME

» Lending expertise to people in need of eye care in poor and war-torn regions can prove to be a rewarding endeavor, offering surgeons a way to pay it forward.

Continues on page 6: Armenia
maximize
efficacy

minimize
concerns

In micro-invasive surgery, seek the micro-invasive option...

- 500,000+ Glaukos trabecular micro-bypass stents implanted and
  + peer-reviewed publications
- Lowest reported post-op mean IOP of any trabecular bypass stent
- Lowest reported rates of significant endothelial cell loss (ECL)
- Lowest reported rates of peripheral anterior synechiae (PAS)
- Stents are made of titanium, no nitinol (nickel) allergic responses

TransformMIGS.com  |  800.GLAUKOS (452.8567)

* In any trabecular bypass MIGS pivotal trial.
† Significant ECL defined as ≥30% ECL.

INDICATION FOR USE. The iStent inject® Trabecular Micro-Bypass System Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma. CONTRAINDICATIONS. The iStent inject is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retinoblastoma, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. WARNINGS. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. MRI INFORMATION. The iStent inject is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. PRECAUTIONS. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent inject have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, cataracts, or primary open-angle glaucoma that is not adequately controlled with current medical treatment. ADVERSE EVENTS. Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% vs. 4.2% for iStent inject vs. 4.2% for cataract surgery only); and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

ARMENIA

—which can take up to two years—can also receive timely treatment.

**MANAGING DR**

We have found that the best option for treating DR in patients living in rural areas is laser treatment because one round of therapy is usually enough to stop blood vessel leakage. The typical follow-up for lasered patients comes six months after the initial treatment, with touch-ups as required. This is a great way to prevent vision loss over the long term.

One of the most useful tools we have for the management of DR in Armenia has been the EyeArt AI Eye Screening System, which was donated to us by Eyenuk. It enables DR screening even with limited eye care resources. This system is a cloud-based screening software that uses artificial intelligence (AI) to autonomously detect DR by identifying the presence, size, position, and number of lesions within each eye.

The EyeArt System provides fully automated DR screening, including imaging, grading, and reporting in a single visit, without the need for eye dilation. Less than a minute after photographing the retina, we get a report, which is used to determine whether the patient needs to be treated right away or seen again in three, six, or 12 months. Those who require immediate treatment are sent to one of the four regional eye centers or the mobile eye hospital where laser treatment is available.

At publication, 8,147 patients have been screened in Armenia using the EyeArt System. The EyeArt AI Eye Screening System found 2,917 cases with referable diabetic retinopathy or macular edema. Those with vision-threatening DR or macular edema have been referred for additional treatment.

A higher prevalence of vision-threatening disease is expected in a country like Armenia, where a large population of diabetic patients do not have access to an ophthalmologist. That’s why the Eyecare Project is so important—until now there has been no systematic DR screening program available.

We all have something to offer the less fortunate, our own particular set of skills or knowledge base. My skills as an ophthalmologist can go exponentially further when I have the most advanced tools and equipment available to me.

Partnering with Eyenuk has allowed us to help numerous people keep their sight, and we will continue to screen and treat as many patients as possible.

Out our Armenian colleagues continue to screen patients throughout the year, not just when the Armenian Eyecare Project is in town. They are committed to eliminating preventable blindness in Armenia and teach that principle. In yearly conferences, they will teach that goal to neighboring countries and pass along what they have learned. This has been a good example of medical diplomacy, and it is working.

‘We have found that the best option for treating DR in patients living in rural areas is laser treatment.’ — Roger Ohanesian, MD

Based in Laguna Beach, CA, Dr. Ohanesian founded the Armenian Eyecare Project in 1994 as an initiative to eliminate preventable blindness.
OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

The data are compelling and consistent—OMIDRIA makes cataract surgery better for you and your patients

Published and presented clinical studies and manuscripts in press and/or in preparation report that in post-launch (i.e., not included in current labeling), prospective and retrospective, double-masked and open-label, cohort and case-controlled, single- and multi-center analyses, the use of OMIDRIA, compared to the surgeon’s standard of care, statistically significantly:

- Prevents Intraoperative Floppy Iris Syndrome (IFIS)2
- Reduces complication rates (epinephrine comparator)3
- Decreases use of pupil-expanding devices (epinephrine comparator)3-8
- Reduces surgical times (epinephrine comparator)3,5,7,8
- Prevents miosis during femtosecond laser-assisted surgery (epinephrine comparator)6,9
- Improves uncorrected visual acuity on day after surgery (epinephrine comparator)3
- Delivers NSAID to the anterior chamber and related structures better than routine preoperative topical drug administration, resulting in effectively complete postoperative inhibition of COX-1 and COX-210,11
- Decreases the incidence of CME, rebound iritis, and pain/photophobia when used with a post-op NSAID only (no steroid) compared to post-op steroids +/- NSAIDs (no OMIDRIA)12,15
- Reduces the need for opioids (i.e., fentanyl) during cataract surgery while decreasing pain scores14

OMIDRIA inhibits the release of inflammation-causing prostaglandins, preventing miosis and reducing postoperative pain15

OMIDRIA is separately reimbursed under Medicare Part B and by many Medicare Advantage and commercial payers.* Contact your OMIDRIA representative today or visit omidria.com to learn more.

*Based on currently available information and subject to change without notice. Individual plan coverage, policies, and procedures may vary and should be confirmed. Omeros does not guarantee coverage or payment.

IMPORTANT SAFETY INFORMATION
OMIDRIA must be added to irrigating solution prior to intraocular use.

OMIDRIA is contraindicated in patients with a known hypersensitivity to any of its ingredients.

Systemic exposure of phenylephrine may cause elevations in blood pressure.

Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory drugs (NSAIDs), or have a past medical history of asthma.

The most commonly reported adverse reactions at ≥2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Please see the Full Prescribing Information for OMIDRIA at www.omidria.com/prescribinginformation.

You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References:
Own your superpower
All physicians have unique traits that make them special

Then Bill walks into the room, spends a minute making small talk, and tells what Steve describes as “the stupidest corny joke in the world.”

Providing Some Comic Relief
The patient bursts into laughter and the fear and anxiety are put aside. The patient is now much more comfortable and he/she and the ophthalmologist can now get down to the business of figuring out the problem and how to address it.

“That’s the kind of thing that makes someone a great doctor,” he said.

“I see what you mean,” I replied. “It’s like a superpower.”

“Exactly,” Steve said.

“So, what is your superpower?” I asked.

Speaking Their Language
Steve explained that he was able to pick up new languages fairly readily, which is something I had already observed. In his city, there are large populations of elderly patients who were not born in the United States.

“I can greet patients and at least say something in Spanish, Italian, French, Portuguese, Hebrew, Tagalog, Turkish, and several other languages,” he said.

“It makes people who speak little or no English relax a bit when they come to see an American ophthalmologist who greets them in the language with which they grew up,” he continued. “You should see what happens when someone brings their Persian grandmother, who speaks no English, to my office and I say to her, in reasonably good Farsi: ‘Pardon me, ma’am. I do not speak Farsi.’”

Our system of medical education in the United States is excellent and we graduate each year about 450 ophthalmologists who are very talented diagnosticians and capable surgeons.

What will make some of them fabulously successful and “great” (to use Steve’s term) is their interpersonal skills that endear patients to them and increase the likelihood the patient will be as cooperative as possible, if for no better reason than they feel a rapport with the physician and want to please him or her.

These are the patients that will go back to their referring physicians and say: “Thank you for sending me to that doctor. I like him/her.”

And so we ask, dear reader: “What is your superpower?”

Know what I think makes our friend here a great doctor and not just a very good ophthalmologist?”

Steve explained that our colleague, Bill, has a busy referral practice in which he sees many complicated patients with severe eye problems.

As a result, the patients are extremely anxious and afraid they will go blind when they arrive at his office. The technician sees the patients and leaves them in the examination room waiting for the doctor, whom they have never met.

What will make some physicians ‘great’ are interpersonal skills that endear patients to them.
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Check out Xiidra-ECP.com

References:

©2018 Shire US Inc., Lexington, MA. 02421. 1-800-828-2038. All rights reserved. SHIRE and the Shire Logo are trademarks or registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates. Marks designated ® and ™ are owned by Shire or an affiliated company. S40448 0718
BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSSAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in ≤5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

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

Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenously (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg/day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg/day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.

Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421. For more information, go to www.Xiidra.com or call 1-800-828-2088. Marks designated ® and ™ are owned by Shire or an affiliated company. ©2018 Shire US Inc. SHIRE and the Shire Logo are trademarks or registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates. Patented: please see https://www.shire.com/legal-notice/product-patents. Last Modified: 01/2018 533769
Ophthalmology Times

OCTOBER 1, 2019  ■  VOL. 44, NO. 16

CONTENTS

Chief Medical Editor
Peter J. McDonnell, MD
Wilter Eye Institute Johns Hopkins University
Baltimore, MD

PHYSICIAN CONTENT EDITORS

Anterior Segment/Cataract
Cornea/External Disease
Ashley Behrens, MD
Wilter Eye Institute, Johns Hopkins University
Baltimore, MD

Kolene Singh, MD
Stanford University
Stanford, CA

Oculoplastics/Reconstructive Surgery
Robert Goldberg, MD
Johns Hopkins Eye Institute, University of Maryland
Baltimore, MD

Ocular Neuro-ophtalmology
Andrew G. Lee, MD
Blumenthal Eye Institute, Houston Methodist Hospital
Houston, TX

Pediatric Ophthalmology
Norman B. Medow, MD
Albert Einstein College of Medicine
Bronx, NY

Glaucoma
Robert D. Fechtner, MD
SUNY Upstate Medical University
Syracuse, NY

Jennifer Simpson, MD
University of California, Irvine
Irvine, CA

Practitioners
Joseph C. Noreika, MD
North Shore-LIJ Health System
Manhasset, NY

Frank Weinstock, MD
Boca Raton, FL

Refractive Surgery
William Cubertson, MD
Bausch & Lomb Eye Institute, University of Miami
Miami, FL

Peter S. Hersh, MD
University of Medicine & Dentistry of New Jersey
Newark, NJ

Jonathan H. Talano, MD
Harvard University
Boston, MA

Kazuo Tsuchiya, MD
Kure University School of Medicine
Tokyo, Japan

Retina/Vitreous
Stanley Chang, MD
Columbia University New York, NY

David Chow, MD
University of Toronto Toronto, Canada

Praveu A. Dugel, MD
Phoenix, AZ

Sharon Fekrat, MD
Duke University Durham, NC

Julia Haller, MD
Meds Eye Institute, Thomas Jefferson University Philadelphia, PA

Tarek S. Hassanein, MD
Oakland University Rochester, MI

Michael Ig, MD
Doheny Eye Institute Los Angeles, CA

Carol D. Regille, MD
Meds Eye Institute, Thomas Jefferson University Philadelphia, PA

Lawrence S. Singerman, MD
Case Western Reserve University Cleveland, OH

Uveitis
Emmet T. Cunningham Jr., MD
PhD
Stamford University
Stamford, CT

Chief Medical Editors Emeritus
Jack M. Dukoff, MD
New York University School of Medicine

David R. Guyton, MD
PhD
New York University School of Medicine

ASSOCIATE MEDICAL EDITORS

Dimitez Azar, MD
University of Illinois Chicago
Chicago, IL

Dimitri Azar, MD
Wilter Eye Institute Johns Hopkins University Baltimore, MD

Ernest W. Korneloff, MD
Harvard & Tufts Universities Boston, MA

Robert K. Maloney, MD
Los Angeles, CA

Kleiner Miller, MD
Massachusetts Eye & Ear Harvard University Boston, MA

Randall Olson, MD
University of Utah Salt Lake City, UT

Ophthalmology Times is a physician-driven media brand that presents cutting-edge advancements and analysis from around the world in surgery, clinical diagnosis, therapeutics, device technology, imaging, and gene therapy to elevate the delivery of progressive eye health from patient to patient.

Ophthalmology Times’ vision is to be the leading content resource for ophthalmologists.

Through its multifaceted content channels, Ophthalmology Times will assist physicians with the tools and knowledge necessary to provide advanced quality patient care in the global world of medicine.

CHIEF MEDICAL EDITOR

Peter J. McDonnell, MD
Wilter Eye Institute John Hopkins University
Baltimore, MD

AUDIO/VIDEO PRODUCTION

Mike Hennessy, Jr
President
Jack Lepping
Vice Chairman
Mike Hennessy, Sr
Senior Vice President, Business Operations

Corporate Development

Kelly Kemper, kkemper@MMHGroup.com

John Moricone
Senior Vice President, I.T.

John T. LiVecchi, MD
University of California, Irvine
Sharon Fekrat, MD
Boca Raton, FL

Frank Weinstock, MD
Boca Raton, FL

Refractive Surgery
William Cubertson, MD
Bausch & Lomb Eye Institute, University of Miami
Miami, FL

Peter S. Hersh, MD
University of Medicine & Dentistry of New Jersey
Newark, NJ

Jonathan H. Talano, MD
Harvard University
Boston, MA

Kazuo Tsuchiya, MD
Kure University School of Medicine
Tokyo, Japan

Retina/Vitreous
Stanley Chang, MD
Columbia University New York, NY

David Chow, MD
University of Toronto Toronto, Canada

Praveu A. Dugel, MD
Phoenix, AZ

Sharon Fekrat, MD
Duke University Durham, NC

Julia Haller, MD
Meds Eye Institute, Thomas Jefferson University Philadelphia, PA

Tarek S. Hassanein, MD
Oakland University Rochester, MI

Michael Ig, MD
Doheny Eye Institute Los Angeles, CA

Carol D. Regille, MD
Meds Eye Institute, Thomas Jefferson University Philadelphia, PA

Lawrence S. Singerman, MD
Case Western Reserve University Cleveland, OH

Uveitis
Emmet T. Cunningham Jr., MD
PhD
Stamford University
Stamford, CT

Chief Medical Editors Emeritus
Jack M. Dukoff, MD
New York University School of Medicine

David R. Guyton, MD
PhD
New York University School of Medicine

How to Contact Ophthalmology Times

Editorial
Millenium Place East
25155 Country Club Blvd.
North Doral, FL 33180
440/826-2800, FAX: 440/756-5227

Subscription Services
Tel: 888/527-7008 or
216/740-6477
FAX: 216/740-6417

Advertising
485 Route 1 South
Building F, Suite 210,
Iselin, NJ 08830-3009
732/596-0270, FAX: 732/596-0003

Production
131 W. First St.
Downtown, MN 55302-2065
651/346-0085
FAX: 218-740-2223, 218/740-6576

BEST OVERALL PROGRAM

The two top leaders from last year, Bascom Palmer Eye Institute at the University of Miami and the Wilmer Eye Institute at Johns Hopkins University, again snared the Number 1 and 2 spots, respectively, in the Best Overall Program category. This year, Wills Eye Hospital at Thomas Jefferson University, captured the Number 3 position and in so doing nudged Massachusetts Eye and Ear, Harvard University, into the Number 4 spot.

The other programs in the top 12 of Best Overall Program category are the W.K. Kellogg Eye Center, University of Michigan, in 5th place; University of Iowa, Carver College of Medicine, 6th place; Duke University Eye Center, Duke University Hospital, 7th place; Moran Eye Center, University of Utah, 8th place; Stein & Doheny Eye Institute, University of California, Los Angeles, 9th place; Casey Eye Institute, Oregon Health & Science University, 10th place; Dean McGee Eye Institute, University of Oklahoma, 11th place; and Storm Eye Institute, Medical University of South Carolina, 12th place.

All of these programs were the repeated their appearances in the 2018 Best Program Survey. The W.K. Kellogg Eye Center and Moran Eye Center both advanced two places higher than last year’s rankings.

THREE-FOLD MISSION

“Bascom Palmer is honored to receive these significant honors and rankings from Ophthalmology Times,” said Eduardo C. Alfonso, MD, director of the Bascom Palmer Eye Institute, and chairman, Department of Ophthalmology of the University of Miami Miller School of Medicine.

“In our mission to restore, preserve, and protect vision, our stellar team of ophthalmologists, vision researchers, ophthalmic technicians, nurses, and support staff are dedicated to providing superior eye care to each of our patients,” he added. “Everyone at Bascom Palmer is guided by the mission of our founder, Edward W. D. Norton, MD, who said: ‘The patient’s needs always come first.’”

BEST OVERALL PROGRAM

1. BASCOM PALMER EYE INSTITUTE
   University of Miami
2. WILMER EYE INSTITUTE
   Johns Hopkins University
3. WILLS EYE HOSPITAL
   Thomas Jefferson University
4. MASSACHUSETTS EYE AND EAR
   Harvard University
5. W.K. KELLOGG EYE CENTER
   University of Michigan
6. UNIVERSITY OF IOWA
   Carver College of Medicine
7. DUKE UNIVERSITY EYE CENTER
   Duke University Hospital
8. MORAN EYE CENTER
   University of Utah
9. STEIN & DOHENY EYE INSTITUTE
   University of California, Los Angeles
10. CASEY EYE INSTITUTE
    Oregon Health & Science University
11. DEAN MCGEE EYE INSTITUTE
    University of Oklahoma
12. STORM EYE INSTITUTE
    Medical University of South Carolina

PURSUIT OF EXCELLENCE

Peter J. McDonnell, MD, director and William Holland Wilmer Professor of Ophthalmology at the Wilmer Eye Institute expressed his congratulations to all the other excellent institutions recognized in this survey.

“The pursuit of excellence is the hallmark of the Wilmer Eye research program.”

“Our founder, Dr. Wilmer, established the Wilmer Eye Institute in 1925 with the belief that research, teaching, and patient care were so intimately interwoven that the pursuit of excellence in one area required the pursuit of excellence in all three areas,” Dr. McDonnell said.

“Consequently, we have always placed an emphasis on research regardless of whether it is conducted in the laboratory, in the clinic, or during the course of an epidemiologic study out in the ‘real world.’ The goal is to determine how we can better care for our patients,” he added. “Our residents and students participate in that research work, and we believe this is a key component of their educational experience.”

He went on to explain that Wilmer’s research has gone on to bear fruit.

“The largest licensing fees in the history of Johns Hopkins have come from ophthalmic surgical instruments developed at Wilmer,” Dr. McDonnell said. “In addition to partnerships with established pharmaceutical and device companies to bring our discoveries into the clinic, the Wilmer faculty teams have recently founded or co-founded 12 start-up companies for the purpose of translating exciting laboratory discoveries into new therapies that, if successful, will change how we care for patients.”

One example of these discoveries is a therapy for choroidal neovascularization in patients with age-related macular degeneration that would replace the currently used injection regimens that are extremely burdensome for both patients and physicians. Patients now receive injection every 1 to 2 months. The new therapy would require patients to return for injections once or twice a year. This therapy is currently undergoing testing in clinical trials.

Dr. McDonnell also mentioned that the Wilmer biomedical engineering research program has undergone substantial growth.

COMPREHENSIVE TEAM APPROACH

Vittorio Porciatti, DSc, professor, director and vice chair of research at Bascom Palmer’s Evelyn F. and William L. McKnight Vision Research Center, commented on the institute’s Number 2 ranking in the Best Research category.

“What makes Bascom Palmer unique in research is the appropriate mixture of clinicians, clinician-scientists, and basic scientists that foster cross-ferilization and allow the addressing of the full temporal spectrum of all eye diseases, that is, preclinical, translational between preclinical and clinical (the so-called tipping point), and manifest,” Dr. Porciatti said.

“These different stages need to be addressed with different strategies, which require different fields of expertise to achieve the goals of prevention of vi-
**Indication**

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

**Important Safety Information**

- **•** LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- **•** Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If LOTEMAX® SM is used for 10 days or longer, IOP should be monitored.
- **•** Use of corticosteroids may result in posterior subcapsular cataract formation.

**SM TECHNOLOGY™**

- Engineered with SM Technology™ for efficient penetration at a low BAK level (0.003%)\(^1,2\)
- ~2× greater penetration to the aqueous humor than LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%\(^3\)

Clinical significance of these preclinical data has not been established.

**Important Safety Information (cont.)**

- **•** The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those with diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- **•** Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- **•** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **•** Contact lenses should not be worn when the eyes are inflamed.
- **•** There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**References:**

1. LOTEMAX SM Prescribing Information. Bausch & Lomb Incorporated.

**SM TECHNOLOGY™**

- Engineered with SM Technology™ for efficient penetration at a low BAK level (0.003%)\(^1,2\)
- ~2× greater penetration to the aqueous humor than LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%\(^3\)

Clinical significance of these preclinical data has not been established.

**Important Safety Information**

- **•** 30% of LOTEMAX® SM patients had complete ACC resolution vs vehicle (15%) at Day 8 (N=371, P<0.0001)\(^1,2\)
- **•** 74% of LOTEMAX® SM patients were completely pain-free vs vehicle (49%) at Day 8 (N=371, P<0.0001)\(^1,2\)

\(^1\)Pooled analysis of Phase 3 clinical studies. **Study 1:** 29% LOTEMAX® SM (N=171) vs 9% vehicle (N=172). **Study 2:** 31% LOTEMAX® SM (N=200) vs 20% vehicle (N=199); P<0.05 for all.

\(^2\)Pooled analysis of Phase 3 clinical studies. **Study 1:** 73% LOTEMAX® SM (N=171) vs 48% vehicle (N=172). **Study 2:** 76% LOTEMAX® SM (N=200) vs 50% vehicle (N=199); P<0.05 for all.

**Bausch & Lomb**

© 2019 Bausch & Lomb Incorporated or its affiliates. All rights reserved. Printed in USA. LSM.0206.USA.19

**LOTEMAX® SM**

(loteprednol etabonate ophthalmic gel) 0.38%
BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use LOTEMAX® SM safely and effectively. See full prescribing information for LOTEMAX® SM.

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%

For topical ophthalmic use
Initial U.S. Approval: 1998

INDICATIONS AND USAGE
LOTEMAX® SM is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular surgery.

DOSEAGE AND ADMINISTRATION
Invert closed bottle and shake once to fill tip before instilling drops. Apply one drop of LOTEMAX® SM into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

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

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

Cataracts: Use of corticosteroids may result in posterior subcapsular cataract formation.

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

Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

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

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

Contact Lens Wear: Contact lenses should not be worn when the eyes are inflamed.

ADVERSE REACTIONS
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with the use of topical corticosteroids include decreased intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

USE IN SPECIAL POPULATIONS

Pregnancy: Risk Summary: There are no adequate and well controlled studies with loteprednol etabonate in pregnant women. Loteprednol etabonate produced teratogenicity at clinically relevant doses in the rabbit and rat when administered orally during pregnancy. Loteprednol etabonate produced malformations when administered orally to pregnant rabbits at doses 4.2 times the recommended human ophthalmic dose (RHOD) and to pregnant rats at doses 106 times the RHOD. In pregnant rats receiving oral doses of loteprednol etabonate during the period equivalent to the last trimester of pregnancy through lactation in humans, survival of offspring was reduced at doses 10.6 times the RHOD; and cleft palate, agnathia, cardiovascular defects, umbilical hernia, decreased fetal body weight and decreased skeletal ossification at 50 mg/kg (1066 times the RHOD). Loteprednol etabonate was associated with increased incidences of abnormal left common carotid artery, limb flexures, umbilical hernia, scoliosis, and delayed ossification. Abortion and embryofetal lethality (resorption) occurred at 6 mg/kg (256 times the RHOD). A NOAEL for developmental toxicity was not established in this study. The NOAEL for maternal toxicity in rabbits was 3 mg/kg/day. Embryofetal studies were conducted in pregnant rats administered loteprednol etabonate by oral gavage on gestation days 6 to 18, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations, including absent innominate artery at 5 mg/kg (106 times the RHOD); and cleft palate, agnathia, cardiovascular defects, umbilical hernia, decreased fetal body weight and decreased skeletal ossification at 50 mg/kg (1066 times the RHOD). Embryofetal lethality (resorption) was observed at 100 mg/kg (2133 times the RHOD). The NOAEL for developmental toxicity in rats was 0.5 mg/kg (10.6 times the RHOD). Loteprednol etabonate was maternally toxic (reduced body weight gain) at 50 mg/kg/day. The NOAEL for maternal toxicity was 5 mg/kg. A per-/postnatal study was conducted in rats administered loteprednol etabonate by oral gavage from gestation day 15 (start of fetal period) to postnatal day 21 (end of lactation period). At 0.5 mg/kg (10.6 times the clinical dose), reduced survival was observed in live-born offspring. Doses ≥ 5 mg/kg (106 times the RHOD) caused umbilical hernia/incomplete gastrointestinal tract. Doses ≥ 50 mg/kg (1066 times the RHOD) produced maternal toxicity (reduced body weight gain, death), decreased number of live-born offspring, decreased birth weight, and delays in postnatal development. A developmental NOAEL was not established in this study. The NOAEL for maternal toxicity was 5 mg/kg.

Lactation: There are no data on the presence of loteprednol etabonate in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for LOTEMAX® SM and any potential adverse effects on the breastfed infant from LOTEMAX® SM.

Pediatric Use: Safety and effectiveness of LOTEMAX® SM in pediatric patients have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic in vitro in the Ames test, the mouse lymphoma tk assay, or in the chromosomal aberration test in human lymphocytes, or in vivo in the mouse micronucleus assay. Treatment of male and female rats with 25 mg/kg/day of loteprednol etabonate (533 times the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused preimplantation loss and decreased the number of live fetuses/live births. The NOAEL for fertility in rats was 5 mg/kg/day (106 times the RHOD).

LOTEMAX is a trademark of Bausch & Lomb Incorporated or its affiliates. © 2019 Bausch & Lomb Incorporated

Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

LSM.0091.USA.19

Based on 9669600-9669700

Revised: 02/2019
sual loss, protection of existing vision, and restoration of lost vision,” he said. “Advanced technology leads the diverse fields and allows engineering of unique instrumentation and biomaterials that combine complementary disciplines and open new areas of investigation.”

**BEST RESIDENCY PROGRAM**

The standings in the Best Residency segment of the survey saw the three leaders, Bascom Palmer Eye Institute, Wills Eye Hospital, and Wilmer Eye Hospital, maintain their respective rankings from the previous year. The Moran Eye Center achieved a ranking that is six places higher than in 2018, from 12th to 6th place, and Massachusetts Eye and Ear moved up from 7th place in 2018 to 4th place in the current rankings.

A newcomer to the top 12 programs this year is the Cole Eye Institute of the Cleveland Clinic that currently fills the 11th spot.

**POSITIVE IMPACT ON OPHTHALMOLOGY**

Steven J. Gedde, MD, professor of ophthalmology, vice chair of education, and residency program director at Bascom Palmer, noted, that since the Institute’s inception in 1962, Bascom Palmer has been committed to training the next generation of leaders in ophthalmology.

“Each year, more than 500 well-qualified applicants apply for seven residency positions,” Dr. Gedde said. “That allows the institute to bring the best and the brightest into its residency training program. Additionally, 35 fellows train each year at the institute.

“The Bascom Palmer Eye Institute has made a tremendous positive impact on the field of ophthalmology through its training programs,” he added. “We have a depth of faculty in each subspecialty area, clinicians who are leaders in their field of expertise and superb teachers.”

Bascom Palmer creates an environment of learning that allows its physicians-in-training to realize their full potential. Upon completion of our training programs, all of its resident and fellow graduates provide outstanding patient care in their local communities, and many have joined academic institutions and are teaching others. This results in an exponential dissemination of knowledge and excellence in eye care, he added.

More than 45 graduates of Bascom Palmer’s training programs have be-
come ophthalmology department chairpersons at medical schools and teaching hospitals throughout the world, which speaks to the success of the program, he added.

“Bascom Palmer has solidified its commitment to ophthalmic education and training with the creation of its Global Center for Ophthalmic Education,” Dr. Gedde said. “The Center organizes international partnerships, collaborates with ophthalmic societies and institutions around the world and produces professional lectures and education events in South Florida, all of which have the common theme of advancing ophthalmic knowledge globally.”

Another component of Bascom Palmer’s graduate training is an innovative Master of Science in Vision Science and Investigative Ophthalmology (MVSIO) program, which is the first of its kind in the world. MVSIO offers comprehensive training in translational research, problem-based learning, management, and a skill set available only at Bascom Palmer as it prepares students for a PhD program in vision science and investigative ophthalmology, Dr. Gedde explained.

DEDICATION TO TRAINING
Fasika Woreta, MD, MPH, who is the director of the residency program at Wilmer Eye Institute and assistant professor of ophthalmology, commented on the makings of a great residency program.

“I believe what makes us a top residency program is the number of world-renowned faculty who are dedicated to resident education,” Dr. Woreta said. “We have 51 faculty members who are integrally involved in teaching our 15 residents, with 22 faculty members who dedicate time and support to this endeavor. In addition, our residency attracts the top medical students in the country who are amazingly talented and go on to be top leaders in our field.”

BEST CLINICAL CARE PROGRAM
Bascom Palmer Eye Institute and Wills Eye Hospital held on to the Number 1 and 2 positions from last year’s survey. Wilmer Eye Institute overtook the 3rd spot from Massachusetts Eye and Ear, which earned the 4th slot.

A number of programs advanced substantially in this years’ rankings. W.K. Kellogg Eye Center moved up four spots from Number 9 to Number 5. Both the Stein & Doheny Eye Institute and Moran Eye Center moved up two positions into the 6th and 9th spots, respectively. The Dean McGee Eye Institute and the U-W Department of Ophthalmology and Visual Sciences at the University of Wisconsin are new to the top 12 Clinical Care Programs this year and occupy the 11th and 12th places, respectively.

TREATMENT TECHNOLOGIES
“Patients with glaucoma, macular diseases, diabetic retinopathy, and other sight-stealing conditions can look forward to advances in treatment, as Bascom Palmer’s clinicians and scientists team up to share their knowledge and expertise,” Dr. Alfonso said. “Most recently, Bascom Palmer has successfully treated patients with gene therapy; developed new imaging techniques; produced the world’s first prosthetic 3-D eye, an innovative approach that could help millions of patients around the world who have undergone exenteration; and led national studies on the most effective surgical treatment for medically uncontrolled glaucoma,” he added. “The Artificial Intelligence and Computer Augmented Vision Laboratory has developed a novel artificial intelligence technology that augment patients’ visual loss from glaucoma, age-related macular degeneration, strokes, and retinitis pigmentosa using digital glasses.”

Bascom Palmer Eye Institute is scheduled this year to open the Lois Pope Center for Retinal & Macular Degeneration Research at its Palm Beach Gardens, FL, campus, which will be the most comprehensive retinal clinical research facility in the country.
INDICATIONS AND USAGE
VisionBlue® 0.06% is indicated for use as an aid in ophthalmic surgery by staining the anterior capsule of the lens.

DOSAGE AND ADMINISTRATION
Cataract surgery
VisionBlue® 0.06% is packaged in a 2.25 mL syringe to which a blunt cannula has to be attached. After opening the eye, an air bubble is injected into the anterior chamber of the eye to minimize dilution of VisionBlue® 0.06% by the aqueous. VisionBlue® 0.06% is applied onto the anterior lens capsule using a blunt cannula. Sufficient staining is achieved as soon as the dye has contacted the capsule. The anterior chamber is then irrigated with balanced salt solution to remove all excess dye. An anterior capsulotomy can then be performed.

DOSAGE

FORMS AND STRENGTHS
VisionBlue® (trypan blue ophthalmic solution) 0.06% is supplied in 2.25 mL syringes filled to a volume of 0.5 mL.

WARNINGS AND PRECAUTIONS
Excessive staining: It is recommended that after injection all excess VisionBlue® 0.06% is immediately removed from the eye by thorough irrigation of the anterior chamber.

ADVERSE REACTIONS
Adverse reactions reported following use of VisionBlue® 0.06% include discoloration of high water content hydrogen intraocular lenses [see Contraindications] and inadvertent staining of the posterior lens capsule and vitreous face. Staining of the posterior lens capsule or staining of the vitreous face is generally self-limited, lasting up to one week.

LEATHERY LENS?
PIECE OF CAKE.

IT’S BETTER WITH BLUE ON YOUR SIDE.

Very dense and mature cataracts can pose significant challenges. Fortunately, visualization doesn’t have to be one of them. The only FDA-approved cataract stain, VisionBlue®, has been proven in more than 6 million cases around the world – delivering the kind of safe and reliable results surgeons know they can count on when it matters most. See what your peers are saying about VisionBlue®, the leading Trypan Blue cataract stain, visit blueonyourside.com

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Compound eyed as treatment for neurotrophic keratitis

Complete corneal healing is a real possibility in most patients

By Lynda Charters; Reviewed by Giacolina Massaro-Giordano, MD

Cenegermin-bkbj 0.002% ophthalmic solution (Oxervate, Dompé Farmaceutici SpA), a recombinant form of human nerve growth factor, is the first such medical therapy to receive FDA approval to treat neurotrophic keratitis, a rare degenerative vision-threatening disease resulting in nerve malfunction and loss of corneal sensation. This drug is also the first topical biologic medication approved for use in ophthalmology.

The importance of the availability of such a treatment cannot be overemphasized. Before cenegermin was developed, surgery, artificial tears, or antibiotics may have been the only recourse for these patients, and in many cases there was no real long-term relief.

Cenegermin is a topical drug instilled onto the cornea and as such works to heal damage on the ocular surface. It also can promote tear production.

“The cornea is the first line of ocular defense,” said Giacomina Massaro-Giordano, MD. “Conneal innervation originates from the ophthalmic division of the trigeminal nerve. Nerve growth factor, a naturally occurring neurotrophin, is involved in the differentiation, growth, maintenance of neurons, and corneal integrity.”

Dr. Massaro-Giordano is co-director, Penn Dry Eye and Ocular Surface Center, and professor of Clinical Ophthalmology, Scheie Eye Institute University of Pennsylvania, Philadelphia.

Neurotrophic keratitis is classified based on the severity/stage of the disease, and treatment corresponds to the severity. However, diagnosis can be tricky because neurotrophic keratitis can mimic other ocular disorders. The presence of punctate keratopathy, epithelial irregularity, superficial neovascularization, and stromal scarring characterize stage I disease; a persistent defect of the epithelium characterizes stage II; and stromal involvement with corneal ulceration with possible perforation or stromal melting characterizes stage III. A step-ladder approach is needed to treat neurotrophic keratitis, according to Dr. Massaro-Giordano.

“While treatments are based on disease severity, the treatments are not mutually exclusive of one another, many times a combination of approaches is required,” she said.

**CLINICAL TRIALS**

The FDA approval of cenegermin-bkbj was based on the results of two pivotal trials (Europe and United States) in which patients with stage II and stage III neurotrophic keratitis were enrolled. The study’s primary efficacy measure was complete corneal healing, with “complete” defined as 0 millimeter of staining in the lesion area and no persistent staining in the rest of the cornea, Dr. Massaro-Giordano recounted.

In these eight-week, randomly selected multicenter studies, the safety and efficacy of cenegermin were assessed in 156 (Europe) 48 (United States) patients with neurotrophic keratitis. In one study, patients affected were randomized to cenegermin, an eye drop with a different concentration of cenegermin, or an eye drop without cenegermin. The second study randomly assigned the patients with disease to cenegermin or an eye drop without cenegermin. The designs of both studies required instillation of the drops six times daily in the eye with neurotrophic keratitis for 8 weeks.

The results showed that up to 72% of patients achieved complete corneal healing; and 80% of patients who achieved complete corneal healing had no recurrences 48 weeks after treatment, she reported. Dr. Massaro-Giordano was principal investigator of the study at the Scheie Eye Institute.

Eye pain, ocular hyperemia, ocular inflammation and increased lacrimation were the most common adverse reactions to cenegermin.

Dr. Massaro-Giordano treated the first patient in the United States with cenegermin drops in December 2018 after it was FDA approved in August of that year. Since then, in her clinical practice she reported that she has had positive results with the drops. Thus far, she has treated about 25 people with all three stages of neurotrophic keratitis. Most had stages I and II, and with the exception of one patient, most have improved. She also noted that she uses cenegermin in conjunction with other medications.

Dr. Massaro-Giordano reported the case of a 58-year-old man who had a nonhealing stage II neurotrophic ulcer as a result of a brain surgery. The cornea healed after treatment with cenegermin and his corneal lesion has remained closed to date. She said she is encouraged about the potential of the treatment.

“Cenegermin is a novel and needed treatment for neurotrophic keratitis,” she concluded. “Importantly, the mechanism of action of the drug targets the root pathology of the disease. Future studies are needed to determine other possible indications for this drug.”
Offered exclusively at a competitive cost through XELPROS Xpress™

Delivers XELPROS™ directly to patients without the need to worry about coverage

XELPROS is the first and only BAK-free formulation of latanoprost—delivered with LIPIXELLE™ technology

Visit ChooseXelpros.com to learn more.

INDICATIONS AND USAGE
XELPROS™ (latanoprost ophthalmic emulsion) 0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
XELPROS is contraindicated in patients with a known hypersensitivity to latanoprost, or any other ingredients in this product.

WARNINGS AND PRECAUTIONS
Pigmentation: XELPROS may cause changes to pigmented tissues. The most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as XELPROS is administered. After discontinuation of XELPROS, iris pigmentation is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Eyelash Changes: XELPROS may gradually change eyelashes and vellus hair in the treated eye, including increased length, thickness, pigmentation, and number of lashes. The changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: XELPROS should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

Macular Edema: XELPROS should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Herpetic Keratitis: XELPROS should be used with caution in patients with a history of herpetic keratitis. XELPROS should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Bacterial Keratitis: There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses: Contact lenses should be removed prior to administration of XELPROS and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS
The most common ocular adverse reactions in clinical trials (incidence ≥5%) for XELPROS were eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening.

DRUG INTERACTIONS
Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROS. If such drugs are used, they should be administered at least 5 minutes apart.

Please see brief summary of Full Prescribing Information on the adjacent page.
Brief Summary of Prescribing Information for XELPROSTM
(latanoprost ophthalmic emulsion) 0.005%,
for topical ophthalmic use
XELPROSTM (latanoprost ophthalmic emulsion) 0.005%
See package insert for Full Prescribing Information.

INDICATIONS AND USAGE
XELPROSTM is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

CONTRAINDICATIONS
Known hypersensitivity to latanoprost, or any other ingredients in this product.

WARNINGS AND PRECAUTIONS
Pigmentation
XELPROSTM may cause changes to pigmented tissues. The most frequently reported changes are increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as XELPROSTM is administered. After discontinuation of XELPROSTM, iris pigmentation is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Eyelash Changes
XELPROSTM may gradually change eyelashes and vellus hair in the treated eye, including increased length, thickness, pigmentation, and number of lashes. The changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
XELPROSTM should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation.

Macular Edema
XELPROSTM should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Herpetic Keratitis
XELPROSTM should be used with caution in patients with a history of herpetic keratitis. XELPROSTM should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

Bacterial Keratitis
There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses
Contact lenses should be removed prior to administration of XELPROSTM and may be reinserted 15 minutes following administration.

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

Across multiple clinical trials conducted with XELPROSTM, the most frequently reported ocular adverse reactions were eye pain/stinging upon instillation and ocular hyperemia, reported in 55% and 41% of patients treated with XELPROSTM, respectively. Other adverse reactions reported (incidence ≥5%) were conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening. Less than 1% of patients discontinued therapy because of intolerance to the eye pain/stinging or to the ocular hyperemia.

DRUG INTERACTIONS
Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROSTM. If such drugs are used, they should be administered at least 5 minutes apart.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C
Reproduction studies have been performed in rats and rabbits. In rabbits, an incidence of 4 of 16 dams had no viable fetuses at a dose that was approximately 80 times the maximum human dose, and the highest nonembryocidal dose in rabbits was approximately 15 times the maximum human dose. There are no adequate and well-controlled studies in pregnant women. XELPROSTM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

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

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

PATIENT COUNSELING INFORMATION
Potential for Pigmentation
Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of XELPROSTM.

Potential for Eyelash Changes
Inform patients of the possibility of eyelash and vellus hair changes in the treated eye during treatment with XELPROSTM. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container
Instruct patients to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated emulsions.

When to Seek Physician Advice
Advise patients that if they develop an intercurrent ocular condition (eg, trauma or infection) or have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician’s advice concerning the continued use of the multiple-dose container.

Use with Contact Lenses
Advise patients that contact lenses should be removed prior to administration of the emulsion. Lenses may be reinserted 15 minutes following administration of XELPROSTM.

Use with Other Ophthalmic Drugs
Advise patients that if more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.

Rx Only
Distributed by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

© 2019 Sun Ophthalmics, a division of Sun Pharmaceutical Industries, Inc. All rights reserved.
XELPROSTM is a licensed trademark of Sun Pharma Advanced Research Company Ltd.
PM-US-XPS-0070 03/2019
Novel integrin regulator a key for AMD treatment

Study of risuteganib meets primary efficacy endpoint

By Cheryl Guttmann Krader; Reviewed by Peter K. Kaiser, MD

A PHASE II study investigating intravitreal injection of risuteganib (Allegro Ophthalmics) in patients with intermediate nonexudative age-related macular degeneration (AMD) met its primary efficacy endpoint and found that the novel agent was associated with excellent safety, said Peter K. Kaiser, MD.

“Risuteganib is a small synthetic peptide that acts to regulate select integrin functions that appear to be involved in the pathogenesis of dry AMD,” said Dr. Kaiser, Chaney Family Endowed Chair in Ophthalmology Research and professor of Ophthalmology, Cole Eye Institute, Cleveland Clinic, Cleveland, OH.

Dr. Kaiser noted that the efficacy results from the phase II study are supported by additional functional endpoints that will be presented at future meetings.

“The safety of risuteganib in this study is consistent with the safety profile observed in more than 1,200 injections that have been given outside this study,” he said. “Currently, a larger study is being planned to confirm these phase II study findings.”

MECHANISM OF ACTION
Understanding the potential role of risuteganib as a treatment for dry AMD comes from a review of disease pathogenesis.

Dr. Kaiser noted that the retinal pigment epithelial (RPE) cells receiving continuous exposure to light leads to oxidative stress.

“Oxidative stress in part causes buildup of toxic byproducts in the form of drusen formation, thickening of Bruchs membrane, activation of the complement system, and eventually degeneration of the RPE and photoreceptors,” Dr. Kaiser said. “The inability of AMD patients to control this oxidative stress is related to mitochondrial dysfunction leading to increased levels of reactive oxygen species and subsequently integrin receptor deposition on cell surfaces that produces an amplification effect and ultimately the structural changes associated with dry AMD.”

Risuteganib regulates integrin function and has been shown in multiple preclinical studies to be anti-inflammatory via action on the complement 3 receptor and to reduce mitochondrial reactive oxygen species production, improve mitochondrial bioenergetics, prevent cellular apoptosis, and improve cell viability.

TAKE-HOME
★ Risuteganib regulates integrin function and has been shown in multiple preclinical studies to be anti-inflammatory via action on the complement 3 receptor and to reduce mitochondrial reactive oxygen species production, improve mitochondrial bioenergetics, prevent cellular apoptosis, and improve cell viability.

DRY AMD STUDY
In the double-masked phase II study, intermediate dry AMD patients were randomly assigned to receive intravitreal injections of risuteganib 1 mg or sham. The primary endpoint was percentage of patients achieving a BCVA improvement of ≥8 ETDRS letters.

Dr. Kaiser noted that natural history studies show that in general, vision does not improve in this population.

“The threshold of eight letters was chosen because a five-letter change in this patient population would be considered noise,” he explained. At the primary endpoint of the study, the percentage of patients achieving a ≥8 letter gain in BCVA was significantly higher in the risuteganib group than in the control group, 48% versus 7.1%.

The results are sparking a buzz among physicians and researchers alike.

“I am excited by the initial results from this phase II study,” Dr. Kaiser noted. “Having a potential treatment that addresses the unmet need in intermediate dry AMD would be beneficial for our patients who are currently not receiving any treatment.”

CONCLUSION
Dr. Kaiser concluded that integrin regulation “provides a promising new therapeutic target for researchers and clinicians who are looking for new approaches to the management of vitreoretinal disease.”

Questions? Visit us at AAO
iridex.com/glaucoma

Non-incisional glaucoma treatment with MicroPulse® Transscleral Laser Therapy
Achieves IOP reduction of 30% to 45%*
A success rate of 60% to 80%*
Versatile, repeatable, and for moderate, severe, and refractory glaucoma
Over 100,000 patients treated in more than 60 countries
Used in 38 of the 39 best U.S. hospitals for ophthalmology
Extended period IOP control with a durability of up to 72 months with 3 retreatments*

* Data on file at IRIDEX
1 As ranked by U.S. News and World Report.
© 2019 IRIDEX. All rights reserved. IRIDEX, the IRIDEX logo, Cyclo G6, and MicroPulse are trademarks or registered trademarks of IRIDEX.
Researchers find long-term statin use linked to lower POAG risk

Investigators find patients using drug for five years or more had reduced rate of glaucoma

By Lynda Charters

A TEAM OF researchers have conducted a study bringing the connection between statin use and the risk of primary open-angle glaucoma (POAG) into sharper focus.

Investigators from Brigham and Women’s Hospital have found that using statins for five or more years is linked to a lower risk for POAG.

Jae Hee Kang, ScD, assistant professor of medicine in the Channing Division of Network Medicine at Brigham and Women’s Hospital, was lead author of the study.

In vitro studies conducted in the 2000s indicated that statins may have the ability to decrease IOP and provide protection for the retinal ganglion cells against damage from glaucoma, according to the authors of a newly published study by Kang et al.1

“Our study suggests possible protective associations beyond cardiovascular conditions for long-term statin use,” Dr. Kang pointed out. “Statins may also strengthen neuroprotective mechanisms that prevent degeneration of cells in the optic nerve.”

The association between statin use and POAG had been investigated previously, but the results were inconclusive and contradictory. Only relatively short courses of statin use were investigated.

“Our primary a priori hypothesis was that longer duration of statin use is associated with a lower risk of POAG, and our secondary hypothesis was that higher cholesterol levels are associated with a higher risk of POAG,” Dr. Kang and her team reported.

Dr. Kang and her team tracked 136,782 healthy patients (113,702 women, 23,080 men) who were 40 years of age and older who did not have glaucoma. The patients were drawn from the Nurses’ Health Study (NHS) (patients followed from 2000 to 2014), Nurses’ Health Study 2 (NHS2) (patients followed from 1999-2015), and the Health Professionals Follow-up Study (HPFS) (patients followed from 2000 to 2014).

A review of the medical records confirmed the incident cases of POAG.

The study data regarding development of glaucoma, assessment of high cholesterol, total serum cholesterol, statin use, and use of other cholesterol-lowering drugs had been collected biennially from the patients.

The main outcomes measures were the multivariable adjusted relative risks (RR) and the 95% confidence intervals (CIs).

STUDY FINDINGS

A total of 886 confirmed cases of incident POAG were identified (522 women in the NHS, 208 men in the HPFS, and 156 women in the NHS2; mean patient age, 68.5 years) during 1,485,498 person-years of follow-up, the authors reported.

“Individuals who used statins for five or more years were more likely to have reported a history of elevated cholesterol levels, higher total serum cholesterol levels, and a higher prevalence of cardiovascular disease and risk factors,” the investigators said.

Dr. Kang’s team noted that longer statin use was not associated with known risk factors for glaucoma such as African American race/ethnicity or having a family history of glaucoma.

Importantly, they found that every 20 mg/dL increase in the total serum cholesterol value was associated with a 7% increase in the risk of development of POAG (RR, 1.07; CI, 1.02-1.11). This finding reached significance (P = 0.004).

They also reported that any self-reported history of elevated cholesterol levels was associated with a higher risk of development of POAG (RR, 1.17; CI, 1.00-1.37), and that a history of any use of statins was associated with a lower risk of development of POAG (RR, 0.85 CI, 0.73-0.99).

An important finding involved the longer use of statin, i.e., patients who used statins for five or more years had a 21% lower risk of development of POAG compared with patients who had never used statins (RR, 0.79; CI, 0.65-0.97).

TAKE-HOME

› A study suggests that patients who used statins for five years or more had a 21% lower chance of primary open-angle glaucoma.

‘Our study suggests possible protective associations beyond cardiovascular conditions for long-term statin use.’ — Jae Hee Kang, ScD

AGFAGE FACTOR

“The inverse association between use of statins for five years or longer and risk of POAG was stronger among those who were 65 years or older (RR, 0.70; CI, 0.56-0.87) than among those younger than 65 years (RR, 1.05, CI, 0.68-1.63),” the investigators said.

EFFECTS OF STATINS

This class of drugs may lower the risk of development of POAG by IOP-lowering and neuroprotective mechanisms.

“Statins affect the activities of myosin II adenylate triphosphatase and p kinase in the trabecular network that increase nitric oxide production and aqueous outflow facility, which may lead to some IOP lowering,” the investigators explained. “Greater production of nitric oxide also would increase the blood flow to the optic nerve.”

Additional neuroprotective effects that protect the retinal ganglion cells include anti-excitotoxic, anti-apoptotic, and anti-inflammatory effects.

“Among adults aged 40 years and older, higher serum cholesterol levels were associated with higher risk of POAG,” the investigators concluded. “Five or more years of statin use compared with no use of statins was associated with a lower risk of POAG.”

REFERENCE


JAE HEE KANG, ScD

P: 617/525-2022 E: nhjhk@channing.harvard.edu

Co-authors reported receiving personal fees from Allergan, Bausch + Lomb, Eyenovia, Grafton Optical, Novartis, Santen, and Thea.
TONOMETRY REVEALED

THE BEST OPTION FOR REMOTE IOP MEASURING OF GLAUCOMA PATIENTS

VISIT AAO BOOTH #2250 FOR SHOW SPECIAL!
Scan, email info@icare-usa.com or visit www.icare-usa.com to find out about reimbursement codes for HOME monitoring.

ALSO ASK ABOUT CENTERVUE COMPASS VISUAL FIELDS
Diving into dry eye can help physicians solve patients’ woes

Myriad mechanisms contribute to cause; knowing details leads to effective treatment

By Harvey A. Fishman, MD, PhD; Special to Ophthalmology Times

DRY EYE DISEASE (DED) is far from being a single disease. Rather, it encompasses many different entities. To determine the proper approach to treatment, physicians must differentiate what type of ocular surface disease (OSD) the patient has. A host of mechanisms result in various contributing factors.

Regardless of the root cause, as the cornea becomes increasingly irritated it further dries out and normal function deteriorates. Tear production becomes compromised and inflammatory markers appear. If a patient has underlying autoimmune/systemic concerns, the cycle is exacerbated.

BREAKING IT DOWN: MGD AND ROSACEA

Commonly, patients have DED in combination with meibomian gland dysfunction (MGD) and ocular rosacea. Because MGD is difficult to treat effectively, nonpharmacological treatments have been explored and are becoming more widely embraced. Intense pulsed light (IPL) is one such powerful solution that not only can treat the lid margins, but also the skin around the eyes that is contributing to the disease as well. IPL has been shown to dramatically reduce Demodex when studied via punch biopsy before and after treatment.

IPL PROTOCOL

In my practice, I take a comprehensive “holistic” approach to OSD. I consider everything from the gut microbiome—recommending an anti-inflammatory diet (e.g., omega-3 supplementation)—to devices like IPL and manual expression of the glands to prescription drops to scleral contact lenses for crippling disease.

My IPL protocol using the Optima device (Lumenis) combines those of Laura M. Periman, MD, and Rolando Toyos, MD, plus manual expression and BlephEx/lid debridement to create the “Fishman” Protocol. I treat the entire face, very much like one would for a cosmetic patient, and the upper and lower eyelids. The Optima sapphire-cool light-guide allows me to treat close to the eyelid margin to effectively eradicate Demodex.

Then, I perform manual expression with forceps and grade every single glad. I will use BlephEx (Scope Ophthalmics) or a similar device at the end to clean any dead mites off the lids. I refer to this as “the rub” step like with contact lens hygiene. If necessary, I will perform additional manual debridement. This rigorous protocol takes 20 to 30 minutes.

CONCLUSION

Patient selection is key for a successful IPL-based treatment. It is indicated for those who clearly have MGD, with evidence of facial and/or lid rosacea. In my experience, for these patients, there is no other technique that can rival IPL.

‘In my practice, I take a comprehensive ‘holistic’ approach to OSD.’
— Harvey A. Fishman, MD, PhD

DRY EYE SYMPTOMS

Are your patients suffering from dry eye? Symptoms of dry eyes and dry eye syndrome include:

- Burning sensation
- Itchy eyes
- Aching sensations
- Heavy eyes
- Fatigued eyes
- Sore eyes
- Dryness sensation
- Red eyes
- Photophobia
- Blurred vision

TAKE-HOME

For physicians, knowledge is power. Patient selection is key for a successful IPL-based treatment.

DEEPER IN THE OCULAR MICROBIOME

Demodex is associated with both facial and ocular rosacea. The parasite is a component of MGD, which in turn, is part of DED—it is a vicious cycle. In large numbers, Demodex itself becomes an inflammatory nidus for the eye, consuming bacteria called Bacillus oleronius. It is hypothesized that the interaction of the parasite and the lid’s bacterial load underlies eye lid margin inflammation. IPL has been shown to dramatically reduce Demodex when studied via punch biopsy before and after treatment. IPL lowers the inflammatory cytokine matrix metalloproteinase 9, a protease that literally “eats” the cornea. Questions remain around the exact mechanism at work and if IPL is definitively killing Demodex—I am in the process of gathering this evidence.

HARVEY A. FISHERMAN, MD, PhD
P: 650-322-4393

Dr. Fishman is the medical director, founder and head of Cataract Service and Advanced Therapeutics at Fishman Vision, Santa Cruz, CA. He is a consultant to Lumenis and 23&me, receives clinical funding from EyeDetec, is a non-paid medical advisory board member of iWold Medical, and co-founder of Therapeutics.
With a single injection at the end of cataract surgery, anti-inflammatory efficacy begins as early as day 1 and continues through day 30\(^*\)

- The percentage of patients who received DEXYCU\(^\text{®}\) (dexamethasone intraocular suspension) 9% (517 mcg) who had anterior chamber cell clearing on day 8 was 60% (n=94/156) vs 20% (n=16/80) in the placebo group\(^1\)
- The cumulative percentage of subjects receiving rescue medication of ocular steroid or nonsteroidal anti-inflammatory drug (NSAID) at day 30 was significantly lower in the DEXYCU (517 mcg) treatment group (20%; n=31/156) compared to placebo (54%; n=43/80)\(^1\)

\(^*\)DEXYCU was studied in a randomized, double-masked, placebo-controlled trial. Patients received either DEXYCU or a vehicle administered by a physician at the end of the surgical procedure. The primary endpoint was the proportion of patients with anterior chamber cell clearing (cell score=0) on postoperative day 8.

INDICATION AND USAGE
DEXYCU\(^\text{®}\) (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

Increase in Intraocular Pressure
- Prolonged use of corticosteroids, including DEXYCU, may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision
- Steroids should be used with caution in the presence of glaucoma

Delayed Healing
- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

Exacerbation of Infection
- The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures

ADVERSE REACTIONS
- Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections
- Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection

Cataract Progression
- The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts

ADVERSE REACTIONS
- The most commonly reported adverse reactions occurred in 5–15% of subjects and included increases in intraocular pressure, corneal edema and iritis

Please see brief summary of full Prescribing Information on adjacent page.
DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration
Initial U.S. Approval: 1958

BRIEF SUMMARY: Please see package insert for full prescribing information.

1 INDICATIONS AND USAGE
DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS

5.1 Increase in Intraocular Pressure
Prolonged use of corticosteroids including DEXYCU may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma.

5.2 Delayed Healing
The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids.

5.3 Exacerbation of Infection
The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of corneal steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungal invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection.

5.4 Cataract Progression
The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts.

6 ADVERSE REACTIONS
The following adverse reactions are described elsewhere in the labeling:
- Increase in Intraocular Pressure [see Warning and Precautions (5.1)]
- Delayed Healing [see Warnings and Precautions (5.2)]
- Infection Exacerbation [see Warnings and Precautions (5.3)]
- Cataract Progression [see Warnings and Precautions (5.4)]

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

The following adverse events rates are derived from three clinical trials in which 339 patients received the 517 microgram dose of DEXYCU. The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis. Other ocular adverse reactions occurring in 1-5% of subjects included, corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, blurred vision, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia, and vitreous detachment.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
There are no adequate and well-controlled studies of DEXYCU (dexamethasone intraocular suspension) in pregnant women. Topical ophthalmic administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice and malformations of abdominal wall/intestines and kidneys in rabbits at doses 7 and 5 times higher than the injected recommended human ophthalmic dose (RHOD) of DEXYCU (517 micrograms dexamethasone), respectively [see Data in the full prescribing information].

In the US general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation
Risk Summary
Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. There is no information regarding the presence of injected DEXYCU in human milk, the effects on breastfed infants, or the effects on milk production to inform risk of DEXYCU to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for DEXYCU and any potential adverse effects on the breastfed child from DEXYCU.

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

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

Manufactured for: EyePoint Pharmaceuticals US, Inc. Watertown, MA 02472
Breaking down the dorzolamide shortage; impact on patients

Shortages reveal how generic molecules are supplied in ophthalmology industry

By Nathan M. Radcliffe, MD; Special to Ophthalmology Times

AT A TIME when there are more treatment options than ever to manage glaucoma—including new minimally invasive procedures and agents for medical treatment—the shortage of a traditional glaucoma drug is reminding us just how precarious our reliance on generics has become. Our supply of dorzolamide, long a first-line glaucoma therapy used alone or in fixed combination with timolol, has recently proven unreliable.

The dorzolamide shortages have revealed a lot about how generic molecules are supplied. Dorzolamide has about six different manufacturers whose supplies were disrupted at various times. The companies have not offered the reasons for the shortages, nor has the FDA been able to explain why shortages of the same drug are occurring among different manufacturers. Generic manufacturers also seem to have very little accountability to patients and to the physicians who prescribe the medications. When manufacturing problems occur with branded drugs, most of the companies selling branded pharma are quick to inform doctors and patients of the reasons, when they expect to fix the problem, and what alternatives we can use in the interim.

When patients who take either dorzolamide or the fixed combination of dorzolamide and timolol try to fill their prescriptions, they are turned away at the pharmacy. Unable to get their medications, often patients do not understand that they need to return to their physician to get a replacement. As a result, this can be disruptive to care. Some patients are off the therapy until their next appointment.

Doctors spend years educating patients with glaucoma about the importance of complying with medical therapy. Amid a shortage, they may be prescribed a new medication that may not be covered or well tolerated.

This is where the lack of accountability and commitment from generic manufacturers of dorzolamide is most damaging. Patients rely on these medications to prevent glaucoma-related blindness, and the companies that profit from those prescriptions are not honoring that need with a commitment to their customers.

I want my patients with glaucoma to have consistent access to the medication I prescribe, without any disruption or negative experience at the pharmacy. This is essential to medical management of glaucoma. To avoid issues from dorzolamide’s availability today and in the future, I proactively stopped prescribing the drug to my patients when possible, either alone or in fixed combination.

Tasked with choosing an alternative medication, we have to make the right choice for each patient in the context of their glaucoma status, health, other medications, and prescription drug coverage.

The most logical alternative is brinzolamide (Azopt, Novartis), but coverage can present a roadblock. I have developed a decision tree for my office staff that lays out the options. Essentially, brimonidine 0.1% (Alphagan P, Allergan) is often a reasonable substitution for dorzolamide, while brimonidine-timolol (Combigan, Allergan) is an ideal substitution for dorzolamide-timolol shortages, assuming no brimonidine allergy.

Certainly, the dorzolamide shortage has helped physicians view branded pharmaceutical companies in a positive light, given their commitment to transparency and to therapy for patients with glaucoma.

With generic drugs undergoing price hikes and a variable supply, it is often easier for doctors to find a treatment solution with a brand name we trust for patients with glaucoma. It will be interesting to see how the current dorzolamide shortage plays out and if we continue to see a lack of transparency and accountability among generic drug manufacturers in the future.

NATHAN M. RADCLIFFE, MD
P: 212/966-3901
Dr. Radcliffe is a glaucoma specialist and professor at Icahn School of Medicine at Mount Sinai and New York Eye and Ear Infirmary of Mount Sinai, New York City. He is a consultant for several pharmaceutical companies, including Aerie Pharmaceuticals, Allergan, Bausch + Lomb, and Novartis.

TAKE-HOME

» With generic drugs undergoing price hikes and a variable supply, it is often easier for physicians to find a treatment solution with a trusted brand name for patients with glaucoma.
In the United States, more than 3 million Americans suffer from glaucoma. This is the second-leading cause of blindness worldwide. Now a new procedure is here to relieve the mechanism and symptoms of the disease and help prevent blindness.

Glaucoma is caused by damage to the optic nerve described as cupping. While there are known genetic risk factors, the only manageable symptom is elevated eye pressure. Elevated pressure damages the optic nerve and can result in vision loss and blindness if not treated properly.

Traditionally, most glaucoma patients use eye drops to lower pressure and relieve the stress on the optic nerve. Unfortunately, eye drops must be taken for as long as the patient lives, and as a result, managing the use of eye drops—which sometimes need to be administered multiple times during the day—can be cumbersome. Research has shown that as few as 50% of patients stay on their prescribed medicines past six months. Eye drops do not address the mechanism of glaucoma.

**IMPACT OF GLAUCOMA**

The most common form of glaucoma is primary open-angle glaucoma (POAG), and is characterized by reduced aqueous outflow resulting in elevated eye pressure. In patients over 50 years of age, the cataract, or enlarged lens, is the most common identifiable cause of glaucoma in my practice. Aqueous drainage depends on a functioning trabecular meshwork and a patent canal of Schlemm. The enlarged lens compresses Schlemm’s canal and creates pigment liberation by rubbing against the posterior iris. The pigment is trapped in the trabecular meshwork, further reducing flow and elevating pressure.

**SURVEY RESULTS**

In the Baltimore Eye Survey, the mean normal IOP in patients without glaucoma was about 15 mm Hg and the mean IOP in patients with glaucoma is 18 mm Hg.

For glaucoma patients with age-related cataract, it is essential to perform gonioscopy to identify increased pigment deposition, narrowing of the angle and compression of the angle structures to identify suitable candidates for potential combination glaucoma surgery.

Several randomized clinical studies have shown IOP lowering associated with cataract surgery alone in patients with open-angle glaucoma (Samuelson, Samuelson, Vold).

The addition of a Schlemm’s canal-based MIGS device can lower IOP even further without changing the existing safety profile of the procedure. There are three different FDA-approved MIGS stents currently available: the iStent, the iStent Inject, and the Hydrus Microstent.

Currently, the Hydrus is my “go-to” stent in patients with glaucoma and cataract. Removal of the cataract opens Schlemm’s canal and expands the trabecular meshwork. The Hydrus Microstent is multi-modal by creating a large opening through the trabecular meshwork and dilating and scaffolding the conventional pathway through which fluid exits the eye. It further enhances aqueous outflow through the trabecular meshwork.
THE HEAT IS ON!

Don’t be fooled. Heating devices for MGD expression shouldn’t cost $5,000, $10,000 or more. OCuSOFT®’s Thermal 1-Touch™ is only $2,650 and includes patient home care treatment for improved outcomes. Significantly, the Thermal 1-Touch™ eliminates costly treatment cartridges or other disposables drastically reducing cost per patient and making the Thermal 1-Touch™ with Digi-Lens™ technology practical for every office.

With Just 1-Touch™

Designed for office-based procedures, the Thermal 1-Touch™ offers preset modes and temperature settings and can treat all 4 eyelids simultaneously providing improved patient convenience. So, before you buy an in-office eyelid heating device... try OCuSOFT® Thermal 1-Touch™.

Contact OCuSOFT® and have a representative come by to demo TODAY!

Taking orders now for shipment
(800) 233-5469

© 2019 OCuSOFT Inc., Rosenberg, TX 77471
*Take-home products included
STENT

(Continued from page 28)

three mechanisms of action: trabecular meshwork bypass, expansion of Schlemm’s canal, and greater access to collector channels.

The bypass feature eliminates resistance to aqueous flow related to the effects of material build up in the trabecular meshwork, and the expansion of the canal over three clock hours of the circumference of the eye allows for optimal access to multiple collector channels.

Despite its complex design, the Hydrus Microstent is approximately the size of an eyelash

change in endothelial counts. Additionally, compared with phaco alone, Hydrus with phaco reduced the risk of incisional glaucoma surgery by 80% during the follow-up period.

There is a third study comparing the Hydrus to the iStent Trabecular Micro-bypass device in a prospective, multicenter randomized clinical trial. Recently published in Ophthalmology, the COMPARRE study demonstrated that the Hydrus is superior to two iStent devices in standalone surgery for reducing pressure and adjunctive medication use at 12 months.4

LASTING RESULTS

The effect appears to be durable for at least 24 months. The Hydrus maintained significant reductions in medications and IOP. More importantly, significantly fewer glaucoma operations were required in the Hydrus arm compared with two iStents arm after 2 years of follow up.

This study suggests that trabecular bypass with 3 clock hours of canal stenting—with its assured access to multiple collector channels—is in the right place. Canal stenting with Hydrus leads to a robust outflow of aqueous to the veins for several clock hours, as may be confirmed using a small injection of trypan blue. Several clock hours of blue dye are readily observed in aqueous veins after Hydrus implantation.

Alternatively, the aqueous veins may be blanched with BSS using the phaco tip. I also use it in my advanced glaucoma patients whom have not had glaucoma surgery and I have gotten very good results in these patients as well.

CLINICAL EVIDENCE

The clinical evidence for the Hydrus Microstent is convincing. Two prospective, multicenter, randomized controlled trials supporting the safety and effectiveness of the device have been published in Ophthalmology.5

In the HORIZON trial, the largest MIGS randomized study conducted to date, the Hydrus demonstrated significant reduction of IOP and medications in a wash out comparison for two years postoperative.

As presented at the recent American Society of Cataract and Refractive Surgery meeting, 3-year follow-up has shown that IOP reductions are maintained, with 73% of eyes in the Hydrus group remaining medication free with a safety profile similar to phacoemulsification alone, and no significant

—sufficiently that it is typically never felt or seen by the patient.

THE PROCEDURE

Inserting the Hydrus is an elegant procedure. It has an intuitive delivery system that is easy to learn. It is easy to confirm by visual inspection that you are in the right place. Canal stenting with Hydrus leads to a robust outflow of aqueous to the veins for several clock hours, as may be confirmed using a small injection of trypan blue. Several clock hours of blue dye are readily observed in aqueous veins after Hydrus implantation.

At times the stent has not been able to penetrate a thickened heavily pigmented trabecular meshwork. Also at times the iStent inject penetrated through both the inner and outer wall of the Schlemm’s canal and is actually implanted into sclera, reducing its efficacy. This has been confirmed by others with AS-OCT imaging of iStent.6

The Xen subconjunctival stent has not been full-proof in that the 45 μm small lumen will often get obstructed with subconjunctivally or intraluminally. Intraluminal obstruction cannot be overcome with needling or external revision of the Xen.

As we know, many glaucoma patients, despite intervention may progress to a more advanced disease stage.

SEEING RESULTS

Cataract surgery and implanting the Hydrus Microstent at an earlier stage will often serve to preserve the health of the patient’s collector channel and provide benefit from the beginning to the end of the disease. This could result in longer-term eye health.

Having performed over 70 of these procedures in patients with glaucoma, not only can I lower the IOP and dramatically reduce the amount of medications needed, but also improve vision from cataract extraction and refractive lens exchange.

This is currently my initial approach to patients with open-angle and angle-closure glaucoma over the age of 50. This does not apply to persons with other types of secondary glaucoma such a neovascular or uveitic.

CONCLUSION

In the future, use of Hydrus may not be limited to combination with cataract surgery.

In April 2017, the FDA granted Ivantis clearance to initiate a second IDE trial of the Hydrus Microstent. It was approved in 2018, based on results of the HORIZON trial.

The SUNSET trial will investigate the Hydrus in more challenging cases and will include 60 patients with advanced glaucoma for whom conventional therapies have proven unsuccessful.

Patients in this trial will undergo standalone glaucoma surgery without combined cataract surgery.

REFERENCES


5. Gillmann K1,2, Bravetti GE1,2, Mermod A1, Mansouri K1,2. A prospective analysis of iStent inject microstent positioning: Schlemm’s canal dilation and intraocular pressure correlations. J Glaucoma. 2019 May 1. doi: 10.1097/IJG.0000000000001273. [Epub ahead of print]
Understanding the surgical learning curve one case at a time

True success requires years of dedication, passion

By Uday Devgan, MD;
Special to Ophthalmology Times

THE PATH TO learning ocular surgery is a long and challenging one, but it is enjoyable and worth the investment to bring sight to our patients. True success requires years of dedication and the passion to consistently learn from every case and evolve your technique every year.

ACQUIRING SURGICAL SKILLS
During the years of residency and fellowship training, basic surgical skills are acquired relatively quickly and the fundamental techniques and procedures are learned. Because this part of the learning curve is the steepest, there is a frustration barrier that must be overcome to get your hands to do what you need. No one is born knowing how to suture with 10-0 nylon monofilament, so extensive practice in the wet lab is instrumental in learning.

Similarly, manual dexterity must be developed in both hands with particular attention paid to bring the non-dominant hand up to par with the dominant hand. Modern day cataract surgery is two-handed and the older, one-handed techniques are not as safe or efficient.

The blue line in our graph is the young doctor who cannot find the drive to push past the frustration barrier to become an ophthalmic surgeon. As such, this doctor will drop out of training, switch to a different medical specialty, or choose to be a medical ophthalmologist who does not perform surgery.

Completing residency training will allow the ophthalmologist to acquire a reasonable surgical skill set and to become a competent surgeon, but not to become a true expert with the highest level of surgical skill and judgment.

Who does not perform surgery.

Completing residency training will allow the ophthalmologist to acquire a reasonable surgical skill set and to become a competent surgeon, but not to become a true expert with the highest level of surgical skill and judgment.

Continues on page 32: Curve
The red line in our graph is the surgeon who is able to get past the frustration barrier and become a competent surgeon. But the passion and the drive to be better, simply is not there. This doctor will be stuck in this zone of mediocrity forever and will simply do the techniques that were learned back in residency training.

We have all seen the surgeons who continue to perform older, outdated procedures because that is what they learned decades ago and that is where their comfort level lies. The critical question to ask is, “Am I doing the best for my patients and am I living the surgery that I would want to receive?”

Becoming a true expert requires the surgeon to have a passion for ocular surgery and then to continue to learn independently for many years to come. Much more will be learned in the years after residency and fellowship compared to during the formal training.

**DRIVE TO GO GREEN**

The green line in our graph is the expert surgeon who has the drive and determination to learn from every single case and consistently evolve surgical techniques over the years. This surgeon embraces the very difficult cases and prepares diligently for them. This surgeon also has the passion to be the best and will maintain that passion for decades. This is the true expert.

Getting to the mountaintop is never easy, and would-be surgeons learn this from the first day. There is an incredible amount to learn in the first few years in practice. Having senior colleagues and partners are helpful in providing mentorship both in and out of the operating room. A large portion of surgical success is pre-operative planning and discussions with patients, as well as post-operative management.

Once we are able to push through this passion barrier, we will want to do more of the tough surgical cases because we will enjoy the challenge.

**CONCLUSION**

And then finally, when we are widely considered master surgeons and true experts in the field, we will still keep up with learning from every surgery and further advancing our skills.

We can all become true experts by channeling the passion that attracted us to ocular surgery. We must learn from each and every surgery that we perform.

As surgeons, we also need to keep up with the latest techniques and technologies through continuing medical education and collaboration with colleagues. We understand that our field keeps evolving from day to day and the way that we operate today may not be the preferred technique in the future.

When it comes time for me to have surgery on my body, be it cataract surgery, orthopedic surgery, or cardiac surgery, I want a true expert who has the passion to be the best. I’m sure you feel the same.
INDICATIONS AND USAGE

Warnings and Precautions

- Increased Bleeding Time – With some NSAIDs, including ILEVRO® 0.3%, there exists the potential for increased bleeding time. Ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.

- Delayed Healing – Topical NSAIDs, including ILEVRO® 0.3%, may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

- Increased Ocular Incidence of Keratitis
- Decreased Ocular Surface Disease
- Increased Risk for Corneal Effects
- Decreased Potency

Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5% to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For additional information about ILEVRO® 0.3%, please refer to the Brief Summary of Prescribing Information on the adjacent page.

For as little as $15, eligible patients can access proven efficacy for post-cataract-surgery pain and inflammation.2,4-6

- Ocular pain completely resolved in 84% to 86% of patients at day 141,3,5
- Inflammation completely cleared in 61% to 65% of patients at day 141,3,5

ILEVRO® Suspension is the only prodrug NSAID formulated for once-daily post-op use.2,4-6

- ILEVRO® Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.2
- Use of ILEVRO® Suspension more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk and severity of corneal adverse events.2

* Terms and Conditions: Limitations apply. Eligible, commercially insured patients may pay as little as $15 in out-of-pocket expenses for each 3-mL or 1.7-mL bottle of ILEVRO® 0.3%, with a maximum benefit per bottle of $285. This offer is not valid under Medicare, Medicaid, or any other federal or state program. See additional terms and conditions at www.copay.novartispharma.com.

† Study Design: Results from 2 randomized, multicenter, controlled, double-masked trials of adult patients undergoing cataract extraction. In Study 1, patients were randomized to receive either ILEVRO® Suspension (n=851), NEVANAC® Suspension (n=845), ILEVRO® Suspension vehicle (n=213), or NEVANAC® Suspension vehicle (n=213). In Study 2, patients were randomized to receive either ILEVRO® Suspension (n=540) or ILEVRO® Suspension vehicle (n=246).2,3


Information on the adjacent page.
ILEVRO* (nepafenac ophthalmic suspension) 0.3%, topical ophthalmic

1 INDICATIONS AND USAGE
ILEVRO* 0.3% is indicated for the treatment of pain and inflammation associated with cataract surgery.

2 CONTRAINDICATIONS
ILEVRO* 0.3% is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other nonsteroidal anti-inflammatory drugs (NSAIDs).

3 WARNINGS AND PRECAUTIONS
5.1 Increased Bleeding Time
With some NSAIDs including ILEVRO* 0.3%, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that orally applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with oculary surgery. It is recommended that ILEVRO* 0.3% be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

5.2 Delayed Healing
Topical NSAIDs including ILEVRO* 0.3%, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

5.3 Corneal Effects
Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration, or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including ILEVRO* 0.3% and should be closely monitored for corneal health.

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

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

5.4 Contact Lens Wear
ILEVRO* 0.3% should not be administered while using contact lenses.

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

6.1 Serious and Otherwise Important Adverse Reactions
The following adverse reactions are discussed in greater detail in other sections of labeling:
• Increased Bleeding Time [see Warnings and Precautions (5.1)]
• Delayed Healing [see Warnings and Precautions (5.2)]
• Corneal Effects [see Warnings and Precautions (5.3)]

6.2 Ocular Adverse Reactions
The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure (IOP), and sticky sensation. These reactions occurred in approximately 5% to 10% of patients.

Other ocular adverse reactions occurring at an incidence of approximately 1% to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing, and vitreous detachment.

Some of these reactions may be the consequence of the cataract surgical procedure.

6.3 Non-Ocular Adverse Reactions
Non-ocular adverse reactions reported at an incidence of 1% to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Teratogenic Effects
Pregnancy Category C: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 70 and 630 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 20 and 180 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses greater than or equal to 10 mg/kg were associated with dystocia, increased postimplantation loss, reduced fetal weights and growth, and reduced fetal survival.

Nepafenac has been shown to cross the placental barrier in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ILEVRO* 0.3% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects
Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of ILEVRO* 0.3% during late pregnancy should be avoided.

8.3 Nursing Mothers
Nepafenac is excreted in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ILEVRO* 0.3% is administered to a nursing woman.

8.4 Pediatric Use
The safety and effectiveness of ILEVRO* 0.3% in pediatric patients below the age of 10 years have not been established.

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

ACON® a Novartis Company
Distributed by:
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 USA
©2014, 2019 Novartis
* a trademark of Novartis
T2019-21
Secrets to success for low myopes

Pearls offer leads for helping challenging patients

By Cynthia Matossian, MD; Special to Ophthalmology Times

LOW TO MODERATE myopes are among the most challenging patients to satisfy with cataract surgery. They retain very good near vision when they remove their glasses, and activities such as smartphone browsing or reading remain happily undisturbed. They don’t intuitively understand that full distance correction with cataract surgery will cause them to lose these near abilities. Here are three secrets to succeeding with these patients:

1. SHOW THEM WHAT YOU MEAN BY “NEAR,” “INTERMEDIATE,” AND “FAR.”

I explain to the patient that if I help them see far—to the end of this room and through the window—then they will no longer be able to see what they’re used to seeing up close. Then, I physically hold the patient’s hand and stretch out their arm.

I tell them, “This is your middle range, where your fingertips are. I have lens options that can help you see far (out the window), and here in this middle distance. But as soon as you bend your elbow, and bring something toward your chest, that is considered near, and you may need glasses for near.”

Again, I physically demonstrate this by bending their elbow towards their chest.

Now, of course, I’m under-promising and over-delivering. I know the patient will most likely be able to see within that near range, but I want each patient to understand they may not be completely spectacle independent.

2. CONSIDER TWO DIFFERENT IOLS.

In low myopes, I have had great success with a personalized vision combination of an extended-depth-of-focus (EDOF) IOL (Tecnis Symfony, Johnson & Johnson Vision) in the dominant eye and a mid-add (+3.25) multifocal IOL in the nondominant eye.

This combination tends to provide the strong near vision they are accustomed to while minimizing the likelihood of night vision symptoms.

After the first eye surgery, I will ask the patient what they think of their near vision with the EDOF implant to see if they would like to have the same implant in the other eye.

I tell the patient that their near vision will be a little bit better once I’ve operated on both eyes. But if they want better near vision, we will stick with our plan to implant a mid-add multifocal in the second eye.

3. CUSTOMIZE THE CHOICE TO THE PATIENT.

Each patient is a wonderful, unique human being and each one has needs that are different from those of the person before or after them on the operating room schedule. Personalized attention really starts with me asking about their hobbies, lifestyle choices, and goals. I combine that with information about their ocular surface health and any comorbidities that affect visual quality or visual potential.

CONCLUSIONS

It is all about listening to the patient and really hearing them. As surgeons, we have to keep in mind that patients don’t know exactly what to tell us.

It is our job to use terminology they can understand and ask the right questions in order to help them figure out what they want and can expect post-cataract surgery.
A

analyses of data collected in phase III clinical trials investigating brolucizumab (Novartis) for the treatment of neovascular age-related macular degeneration (nAMD) provide further evidence that better disease control measured by less fluctuation of OCT-measured fluid is associated with better vision outcomes. The research demonstrated a link between stability of central subfield thickness (CST) and having a dry retina, according to Chirag D. Jhaveri, MD.

“Increased retinal thickness and fluid identified by OCT in any space in the retina in an eye with nAMD is an indication of active disease for which anti-VEGF therapy may be warranted,” said Dr. Jhaveri, private practice, Retina Consultants of Austin, Austin, TX, and clinical assistant professor of ophthalmology, Dell Medical School, the University of Texas at Austin. “Although fluid resolution correlates with vision improvement, the magnitude of the improvement is patient specific.”

According to Dr. Jhaveri, recent analysis of data from the CATT and IVAN trials found that fluctuation of CST in eyes with nAMD treated with anti-VEGF therapy was another factor predicting the vision outcome.

“The results of our post-hoc analysis of data from the brolucizumab trials parallel the finding from CATT and IVAN,” he said. “In addition, we showed that increasing fluctuation in fluid was associated with an increased proportion of visits where retina drying was not achieved.”

The analyses of CST fluctuation associations used data from 96 weeks of follow-up in the HAWK and HARRIER trials and included only patients who had more than three CST observations. HAWK randomized patients 1:1:1 to brolucizumab 3 mg, brolucizumab 6 mg, or aflibercept 2 mg, and HARRIER randomized patients 1:1:1 to brolucizumab 6 mg against aflibercept. All treatments were initiated with a loading phase in which patients received three doses at monthly intervals. Thereafter, brolucizumab was administered every 12 weeks with an option to adjust to dosing every eight weeks based on predefined disease activity assessments. After the loading phase, aflibercept was administered on a fixed schedule every eight weeks.

Retinal thickness fluctuation for each patient was quantified by calculating the standard deviation of the individual’s standardized CST. Patients were pooled from both studies and divided into quartiles based on CST fluctuation. Each quartiles included 444 patients, and they were defined by the following values: <27 μm, 27-44 μm, 44-68 μm, and ≥68 μm.

The data showed that the mean BCVA gain at the end of the study decreased progressively across the four quartiles moving from the group with the lowest CST fluctuation to the group with the highest variability (+10.3, +8.8, +6.9, and +2.1 letters, respectively).

“Mean gain from baseline among patients in the quartile with the greatest amount of fluctuation was eight letters less than in the reference group in the lowest quartile, which parallels the findings from the CATT and IVAN analysis,” Dr. Jhaveri said.

Dr. Jhaveri said that a separate analysis was done to investigate whether there was a correlation between fluid presence after the loading phase and CST variability. CST standard deviation from week 12 to week 96 was calculated for each patient and used to divide the population into new quartiles.

The analyses were done separately for HAWK and HARRIER patients. Results showed eyes in the quartile with the least CST variability had the least amount of visits with fluid. Those with the most fluctuations in CST had the most amount of visits with fluid.

“The findings indicate that a more stable retina with less CST variability is associated with a drier retina in addition to better BCVA gains,” Dr. Jhaveri said.

**TAKE-HOME**

- Study offers evidence that better disease control measured by less fluctuation of OCT-measured fluid is associated with better vision outcomes.

---

**Pooled treatment and study data from HAWK and HARRIER sensitivity analysis: Higher CST variability was associated with lower BCVA gains**

(Graphic courtesy of Chirag D. Jhaveri, MD)

By Cheryl Guttman Krader
PRED FORTE® is back

With the PRED FORTE® Savings Program, eligible patients could pay as little as*:

$50 for patients who are commercially insured or have Medicare Part D

For a 5 mL bottle of PRED FORTE®

Learn more at www.predforte.com

*This offer applies to PRED FORTE® only. Offer only valid for commercially insured patients and patients with Medicare Part D prescription drug insurance (including Medicare Advantage prescription drug plans), if the patient’s Medicare Part D prescription drug insurance does not cover PRED FORTE® or if the patient opts out of using their Medicare Part D prescription benefit in conjunction with this offer and the patient is responsible for the full cash payment for the prescription. Offer not valid for any uninsured patients, or patients with prescription coverage under any other federal or state health program such as Medicaid or TRICARE. Other limitations may apply. Offer for commercial patients expires on 4/30/2020. Offer for Medicare Part D patients expires on 12/31/2019. Offer applies only to prescriptions filled before the applicable program expires. This offer cannot be combined with any other programs, offers, or discounts, and may not be redeemed for cash. Allergan reserves the right to rescind, revoke, or amend this offer without notice at any time.
OCTA in glaucoma: Potential early-warning system

Technology compares each of the sequential scans with each other

By Lynda Charters; Reviewed by Robert L. Stamper, MD

Optical coherence tomography angiography (OCTA) may be as important a tool in the management of patients with glaucoma, according to Robert L. Stamper, MD.

The technology, which relies on the acquisition of sequential OCT B-scans and one cross-sectional layer of the retina, compares each of the sequential scans with each other. Any observed differences between the scans are considered to have resulted from movement because the tissue structure does not change. Most of the commercially available devices can shorten the scanning time to acquire about 70,000 B-scans per second during the three seconds required to obtain a scan.

Following acquisition, computerized motion-correction and eye-tracking are performed to ascertain that eye movements are not responsible for any movement perceived by the computer, he explained.

HOW IT WORKS

The concept is simple. When repeated photographs are taken in the same scene in which something is moving, the only thing that changes from one photograph to the next is the thing that is moving. “The clinician can then interpret this as what is assumed to be the presence of a blood-containing vessel,” explained Dr. Stamper, professor of ophthalmology and director emeritus of the Glaucoma Service, University of California San Francisco.

“We now can literally count the number of capillaries per unit of retinal area,” he said.

Wide acceptance

OCTA technology is used by retina specialists because it can visualize any retinal location. Certain forms of age-related macular degeneration are easily visualized with OCTA than with standard OCT, Dr. Stamper said.

In patients with diabetic retinopathy, the vascular changes in the macula can be observed before they are detected either clinically or by using standard OCT, he noted.

“This technology clearly identifies glaucomatous changes,” Dr. Stamper emphasized.

OCTA images show dropout of capillaries around the optic nerve head and in the peripapillary areas in the various stages of glaucoma, he explained. A recent advance in the technology is its ability to provide density measurements of the capillaries.

“We now can literally count the number of capillaries per unit of retinal area,” he said.

What is known

OCTA has reported previously advantages and has increased the knowledge of the effect of glaucoma on the eye, according to Dr. Stamper.

He noted that repeatable measurements can be obtained, the capillary density in the superficial macular area is known to be lower in glaucomatous eyes compared with age-matched controls, the peripapillary vessel density coincides with information provided on indocyanine green angiography images, the deep peripapillary microvascular dropout is correlated with the retinal nerve fiber layer thickness and location, and in the macular area the abnormalities observed in the foveal avascular zone correspond to paracentral visual field defects.

In addition, the optic nerve, peripapillary, and macular vessel densities can differentiate normal eyes from those with ocular hypertension.

“We are beginning to think we have an early-warning system for detecting early glaucoma,” Dr. Stamper said. “We can see decreases in capillary density that correspond with the locations of the visual field defects and this correlates with the findings on standard OCT images.”

Another interesting bit of information is that following trabeculectomy, the findings on OCTA do not change, which suggests that the ocular changes are permanent and do not improve with lowering of the IOP, he added.

Also, the deep layer of capillary dropout around the optic nerve is correlated with the subtle and not so-subtle changes in glaucoma.

Take-home

OCTA offers a new way of looking at various layers of retinal circulation in a variety of conditions, not just in glaucoma and macular disease.

Under investigation

Now that quantitative analyses of the vascular density are possible, the next step is determining which is better, the macular or peripapillary density.

Dr. Stamper questioned, “Does one come before another?”

Continues on page 40: OCTA

Image 494x418 to 518x442

Dr. Stamper shares his take-home message from his presentation, “OCT Angiography: Where Are We, What Do We Need To Learn?” Go to OphthalmologyTimes.com/Stamper2019
GETTING TO THE TOP TAKES FOCUS.

STAYING THERE YEAR AFTER YEAR REQUIRES GREAT VISION.

Bascom Palmer ranked #1 again.

Many of the most important innovations that have transformed global ophthalmology have come from one place – the Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine. In fact, Ophthalmology Times has once again ranked Bascom Palmer Best Overall Program, Best Clinical Care Program and Best Residency Program. Additionally, for the 18th time, Bascom Palmer is ranked #1 in Ophthalmology by U.S. News & World Report. While we are honored to be #1, it’s our patients who really come out on top.

Pictured on the cover of Ophthalmology, April 2019

Photographer: Brenda Fallas
Bascom Palmer Eye Institute

Co-author: Audina M. Berrocal, MD

Description: 7-year-old boy with an extremely rare free-floating vitreous cyst not associated with any ocular abnormality, trauma or systemic disease.

Bascom Palmer Eye Institute®
UNIVERSITY OF MIAMI HEALTH SYSTEM
bascompalmer.org
COLOR LIGHT-EMITTING DIODE (LED) technology can consistently measure anterior topography, aberrometry, and total corneal astigmatism, according to David P. Piñero, PhD.

But these measurements cannot be used interchangeably with those obtained through Scheimpflug imaging (Pentacam, Oculus), said Dr. Piñero of the University of Alicante, in Alicante, Spain.

One technology (Cassini Total Corneal Astigmatism) is a multispot (up to 700), multicolor (red, yellow, and green) LED tear film-reflection topography imaging system designed to avoid source mismatch and decrease artifacts caused by shadows.

The system uses ray tracing to process every three spots identified by the software and to define the relevant local elevation. Employing the reflection of seven infrared LEDs for second Pukinje imaging, it measures the center of the posterior corneal surface.

“This Cassini technology has shown its usefulness to measure the shape of the anterior corneal surface in different types of eye including keratoconus and scarred cornea,” Dr. Piñero said.

Several studies have evaluated the intrasession repeatability of some measurements the device provides.

“But I haven’t found any paper evaluating the intrasession repeatability of corneal asphericity or corneal high order aberrations provided by this device,” he said.

And he noted that papers by other authors, showed clinically relevant differences in keratometry and other parameters between the Cassini and other devices.

DIVING DEEPER

Dr. Piñero and colleagues set out to evaluate the intrasession repeatability of anterior corneal topographic and aberrometric measurements obtained by the Cassini and to compare it with those obtained by the Pentacam in healthy eyes.

They made this comparison in 35 healthy eyes of 35 patients, with an age range of 16 to 66 years at the University of Alicante. They obtained three consecutive measurements in each patient to assess the intrasession repeatability. Then they obtained one measurement in each patient with the Pentacam system.

They found that the within-subject standard deviation for keratometric readings was 0.02 mm with intraclass correlation coefficients readings of at least 0.992.

In addition, they found the intrasession repeatability for anterior astigmatic measurements was 0.16D, and for total astigmatic measurements it was 0.05D. The intraclass coefficient readings were 0.930-0.978.

They found a standard deviation of 0.06 mm for asphericity and 0.03 mm for corneal diameter, “which can also be considered as a good level of intrasession repeatability,” Dr. Piñero said.

When analyzing aberrometry repeatability, however, researchers found “something curious,” he said.

“We obtained very good correlation coefficients and intraclass correlation coefficients, and within subject standard deviations, for all this Zernike terms for the second order to the fourth order,” he said. “But when we analyzed one component of the secondary astigmatism and one component of the quadrafoil, we obtained a limited intrasession repeatability.”

He attributed this discrepancy to the very small amount of aberration; even a slight difference in a very small difference can appear to be a statistically significant variation, he said. “This is probably the reason, but we have to investigate more.”

On the other hand, the differences between the readings of the Cassini and Pentacam devices were statistically significant for keratometry, total astigmatism, asphericity, and in some Zernike terms.

“If we analyze the ranges of agreement between these two devices, we find, that for keratometry it was more than 0.06 mm which can be considered clinically relevant because this can have an impact, for example, in higher power calculation of more than 0.5 D,” he said.

There were differences in astigmatic corneal components of more than 0.69D, in asphericity of more than 0.35 mm. There was a trend for the Cassini of obtaining steeper values of curvature, as well as higher values of total corneal astigmatism. In Zernike terms, there were differences of 0.2 μm for the second order, 0.13 μm for the third order, and 0.01 μm for the fourth order.

OCTA

“OCTA offers an interesting new way of looking at various layers of retinal circulation in a variety of conditions, not just in glaucoma and macular disease,” Dr. Stamper explained. “We need to determine what has long been suspected, that the primary problem is not the intraocular pressure but a vasculopathy.

“Is OCTA a good method for identifying those patients? And if so, should those patients be treated differently from the treatment given to patients with standard high pressure?” he asked.

Because those questions are not yet answered, it is unclear if OCTA offers improvement and if we are evaluating the correct parameters, he noted.

“More work is needed,” Dr. Stamper concluded.
INNOVATION IN SIGHT

Novartis Ophthalmology is reimagining treatment and prevention, spanning every area of the eye, from the front to the back.

With gene therapies, next-generation pharmaceuticals, and new technologies in development, NOVARTIS IS COMMITTED TO OPHTHALMOLOGY PATIENTS.

Visit us at AAO NORTH, BOOTH 5645.

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

© 2019 Novartis

8/19
HRT-1378693
Reshaping medical treatment of glaucoma management

Future therapies require problem-solving strategies to achieve efficiency

By Lynda Charters; Reviewed by Christophe Baudouin, MD, PhD, FARVO

The best treatment for glaucoma would be efficient, well tolerated over the long and short term, easily used with minimal constrains, affordable, and having increased duration of effect to increase patient compliance. This is a tall order. One of the biggest problems that physicians face who treat patients with glaucoma is adherence to the treatment regimen. Poor adherence, according to Christophe Baudouin, MD, PhD, FARVO, has an estimated annual cost of $100 to $300 billion in the US, which translates to from 3% to 10% of health care spending. So, while uncontrolled IOP and visual field deterioration may be considered disease progression, in reality the patient simply may not be treated properly.

“This is an important issue; but patient education is not always the answer because from 25% to 40% of motivated patients have difficulties or fail to properly instill their drops, said Dr. Baudouin, professor of ophthalmology, head, Department of Ophthalmology III, Quinze-Vingts National Ophthalmology Hospital and director, Team S12, Chemokines and Glaucoma, Vision Institute, University Paris 6, Paris.

Recent developments in glaucoma have seen the introduction of preservative-free formulations designed to decrease side effects and drugs with increasing durations of effectiveness have decreased the number of instillations prescribed as have fixed combinations of drugs, gels, and polymers. However, new routes and delivery systems may represent the future of glaucoma therapy.

“We may have the choice of administering drugs over or under the conjunctiva or subconjunctivally or intraocularly with drugs implanted in the anterior chamber, intravitreally, or in Schlemm’s canal,” Dr. Baudouin commented.

**Delivery Challenges**

One such challenge is making sure the correct dose of a drug reliably reaches the targeted tissue.

“Only 10% of eye drops reaches the receptor,” he said.

Dr. Baudouin likened the eye a fortress in that all of the ocular structures are barriers to effective drug penetration.

“We must overcome this barrier to properly deliver a high or sustained medication dose,” he said.

**Nanotechnology One Approach**

Nanoparticles have been used for more than 10 years, examples of which are cyclosporine and the development of a latanoprost nanoeumulsion, both to increase the drug penetration and reduce the amount of the drug in the drop to reduce side effects.

The use of gold nanoparticles is also in the development stage to achieve the same goal. Latanoprost, timolol, and brinzolamide have been tested in nanocarriers with the goals of reducing the concentration and side effects, Dr. Baudouin explained.

Drug penetration has been enhanced using iontophoresis or electroporation with low-voltage current, using liposomes have been used, and brinzolamide have been tested in nanocarriers with the goals of reducing the concentration and side effects, Dr. Baudouin explained.

**Take-home**

Medical treatment of glaucoma is evolving to include internal and external drug delivery systems that will ensure patient compliance for long periods.

**Internal Delivery Systems**

In light of this, Dr. Baudouin and his team are involved in developing periocular or intraocular long-term delivery systems.

While this is not a revolutionary new approach, the development of ganciclovir (Vitrisept, Auritec Pharmaceuticals), an implant to treat cytomegalovirus retinitis, and then the introduction of the dexamethasone intravitreal implant (Ozurdex, Allergan) and fluocinolone acetonide intravitreal implant (Iluvien, Alimera Sciences) were major steps within this technology because of the slow release and duration of biodegradable drug delivery, respectively, that they provided.

More recently, Allergan developed an intracameral implant loaded with brimatoprost.

In an ongoing phase 1/11 study, the six-month results showed, according to Dr. Baudouin, that the loading dose worked quite well; the IOP reduction was slightly less than that achieved with a topical anti-glaucoma medication, but the patients were fully compliant, which is not the case in real life.

He emphasized that at six months, 71% of patients implanted with the device did not require rescue medication.

Regarding safety, no more side effects occurred with the implants compared with the topical medication if excluding the few transient side effects related to the procedure itself; 78% of patients indicated that they would undergo the procedure again.

Other intracameral implants include one containing latanoprost (PolyActiva) and one with travoprost XR (Envisia Therapeutics), both provided similar results to those of brimatoprost. Glaukos developed the iDose Travoprost, a non-degradable device implanted into the trabecular meshwork that should deliver the drug for a minimum of 1 year; the results are good compared to timolol but no side effects but the technique requires replacing the device after one year, according to Dr. Baudouin.

**External Delivery Systems**

Conjunctival rings containing brimatoprost, the He lios (ForSight Vision5) BIM ring, delivers the drug for six months after insertion in the fornix; a phase II study demonstrated that the device did not achieve noninferiority to timolol.

Because of the nature of such study where one eye received the ring, patient compliance was naturally much higher for instilling timolol in the fellow eye.

However, the safety profile was wanting: 28 dislodgements occurred in 15 patients and nine patients withdrew from the study because of the side effects compared with only one receiving timolol. The long-term results after readministration were stable, although the IOP was slightly higher compared with timolol.

Travoprost is contained in two new delivery systems, TODD (Amorphex Therapeutics) is a polymer...
FEEL THE THRILL

Break free from tradition. Unleash the power of the PanOptix® IOL.
implanted sub-tarsally in the superior lid intended to deliver drug for 180 days, and OTX-TP (Ocular Therapeutix) is a punctal plug that delivers drug for 90 days.

A phase IIb study of the latter device showed a greater IOP decrease at 90 days with timolol that likely resulted from punctal occlusion.

**CHALLENGES WITH NEW DELIVERY SYSTEMS**

Problems are present with internal and external approaches. The first concerns device performance. With the iDose, for example, the device must be removed or replaced at 1 year, but how many times is unknown.

Possible concerns exist for narrow angles. The intracameral implants can migrate. Extrusion can occur with rings and plugs. Patient tolerance of plugs or sub-tarsal polymers may be problematic.

Finally, are these implantations in-office or operating room procedures?

Another question revolves around detecting loss of efficacy.

For example, when the dexamethasone implants are no longer efficacious, macular edema may occur again with decreased visual acuity, but what is the clinical course in patients with an asymptomatic disease?

Dr. Baudouin reminded that 28% of patients with a BIM implant did not need rescue therapy after two years of a single implantation; however, there is no way to know if that is good or bad result as a careful follow-up will remain necessary to detect loss of efficacy and propose a new implantation.

---

**GLAUCOMA**

(Continued from page 42)

**AcrySof® IQ PanOptix® Family of Trifocal IOLs Important Product Information**

**CAUTION:** Federal (USA) law restricts this device to the sale by or on the order of a physician.

**INDICATIONS:** The AcrySof® IQ PanOptix® Trifocal IOLS include AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs and are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable visual acuity with a reduced need for eye glasses, compared to a monofocal IOL. In addition, the AcrySof® IQ PanOptix® Toric Trifocal IOL is indicated for the reduction of residual refractive astigmatism.

**WARNINGS/PRECAUTIONS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia and ensure that IOL centration is achieved. For the AcrySof® IQ PanOptix® Toric Trifocal IOL, the lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or starbursts, as well as other visual symptoms.

As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). As with other multifocal IOLs, patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure, available from Alcon, informing them of possible risks and benefits associated with the AcrySof® IQ PanOptix® Trifocal IOLS.

**ATTENTION:** Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

---

And the question arises about whether a repeat injection will modify ocular tissues and increase the effects over time; however, all of this remains unclear.

‘We may have the choice of administering drugs over or under the conjunctiva or subconjunctivally or intraocularly with drugs implanted in the anterior chamber, intravitreally, or in Schlemm’s canal.’

— Christophe Baudouin, MD, PhD, FARVO

In addition, can clinicians determine who are high and good responders? Are there lower pressure and higher responses to prostaglandins? Again, these questions remain unanswered.

With all of this in mind, Dr. Baudouin suggested that development of a follow-up algorithm and possibly self-monitoring of IOP may be good options.

**TISSUE REGENERATION**

Can tissues negatively impacted by glaucoma be regenerated?

Delivery of stem cells to the anterior chamber or the posterior eye may serve that purpose. Stem cells from bone marrow, adipocytes, or embryonic tissue, or induced pluripotent stem cells can be used.

Dr. Baudouin noted that when mesenchymal stem cells were injected into the trabecular meshwork in rats, the transplantation reduced the IOP for a short time. The stem cells also may be deleterious as shown by cases of blindness resulting from injection into the eye.

“The next steps may be a combination of different factors that may be useful to protect against glaucoma, gene therapy, and transfection of genes coding for trophic factors to make the retina secrete factors to self-protection against degeneration,” Dr. Baudouin explained.

A promising procedure, CRISPR-Cas9 gene editing, gene remodeling, has revolutionized biomedical research.

Mice treated with adenovirus-delivered CRISPR-Cas9 gene editing, gene remodeling, has revolutionized biomedical research.

CHRISTOPHE BAUDOUIN, MD, PhD, FARVO

E: cbaudouin@quanze-vingtfs.fr

This article was adapted from Dr. Baudouin’s presentation at the 2019 congress of the European Society of Cataract and Refractive Surgeons. Dr. Baudouin has no financial interest in any aspect of this report.
Gene therapy offering hope for retinal, corneal patients

Tests indicate change in functional vision during first year

By Cheryl Guttman Krader; Reviewed by Guylène Le Meur, MD

IN DECEMBER 2017, voretigene neparvovec-rzyl (Luxturna, Spark Therapeutics) became the first gene therapy with a recombinant adeno-associated virus vector for an ophthalmic disease. The story of its relatively short journey from preclinical development to regulatory approval gives hope for the future of gene therapy in ophthalmology, said Guylène Le Meur, MD.

“Currently, many other clinical trials are investigating gene therapy for various inherited retinal degenerations. There are almost 200 patients enrolled in these studies and approximately another 600 patients in studies of gene therapy for other retinal degenerative diseases,” said Dr. Le Meur, Department of Ophthalmology, Centre Hospitalier Universitaire de Nantes, Nantes, France.

“We can also expect to be seeing gene therapy arrive in the future for inherited corneal dystrophies,” Dr. Le Meur added.

Voretigene, which is given as a subretinal injection, is also the first pharmacologic therapy approved by the FDA for an inherited retinal dystrophy. Specifically, it is indicated for the treatment of adult and pediatric patients with vision loss caused by confirmed biallelic RPE65 mutations who have sufficient viable retina cells.

“The treatment is given in both eyes, with the second eye injected at least six days after the first, and immunosuppressive therapy with prednisone should be started prior to the injection and continued after,” Dr. Le Meur said.

Preclinical studies conducted in a canine model provided proof of concept that the gene therapy resulted in functional and structural recovery of the retina. Results from the first clinical trial investigating voretigene in patients with RPE65 Leber’s congenital amaurosis were published in 2008, and the paper describing the results of the phase III study was published in 2017.

The phase III study included 31 patients, of which about two-thirds were children. Participants were randomly assigned 2:1 to receive bilateral injection of the gene therapy or to a control group that were initially observed and then received delayed therapy after one year.

Change from baseline to one year in functional vision as measured by performance on a multi-luminance mobility test (MLMT) developed specifically for studying the efficacy of voretigene was investigated as the primary endpoint. Testing results showed that two-thirds of the treated patients were able to complete the course at the lowest illumination level whereas all of the untreated control patients failed to maneuver the course.

Additional testing showed a benefit of the treatment for improving full-field light sensitivity, and a recent publication showed the improvements are durable with follow-up to four years.

Voretigene was approved by the European Union in 2018, but due to stringent criteria pertaining to education and certification of the personnel involved with product storage, preparation, and administration, the gene therapy is currently only available in France and Germany.

IN DECEMBER 2017, voretigene neparvovec-rzyl (Luxturna, Spark Therapeutics) became the first gene therapy with a recombinant adeno-associated virus vector for an ophthalmic disease. The story of its relatively short journey from preclinical development to regulatory approval gives hope for the future of gene therapy in ophthalmology, said Guylène Le Meur, MD.

“Currently, many other clinical trials are investigating gene therapy for various inherited retinal degenerations. There are almost 200 patients enrolled in these studies and approximately another 600 patients in studies of gene therapy for other retinal degenerative diseases,” said Dr. Le Meur, Department of Ophthalmology, Centre Hospitalier Universitaire de Nantes, Nantes, France.

“We can also expect to be seeing gene therapy arrive in the future for inherited corneal dystrophies,” Dr. Le Meur added.

Voretigene, which is given as a subretinal injection, is also the first pharmacologic therapy approved by the FDA for an inherited retinal dystrophy. Specifically, it is indicated for the treatment of adult and pediatric patients with vision loss caused by confirmed biallelic RPE65 mutations who have sufficient viable retina cells.

“The treatment is given in both eyes, with the second eye injected at least six days after the first, and immunosuppressive therapy with prednisone should be started prior to the injection and continued after,” Dr. Le Meur said.

Preclinical studies conducted in a canine model provided proof of concept that the gene therapy resulted in functional and structural recovery of the retina. Results from the first clinical trial investigating voretigene in patients with RPE65 Leber’s congenital amaurosis were published in 2008, and the paper describing the results of the phase III study was published in 2017.

The phase III study included 31 patients, of which about two-thirds were children. Participants were randomly assigned 2:1 to receive bilateral injection of the gene therapy or to a control group that were initially observed and then received delayed therapy after one year.

Change from baseline to one year in functional vision as measured by performance on a multi-luminance mobility test (MLMT) developed specifically for studying the efficacy of voretigene was investigated as the primary endpoint. Testing results showed that two-thirds of the treated patients were able to complete the course at the lowest illumination level whereas all of the untreated control patients failed to maneuver the course.

Additional testing showed a benefit of the treatment for improving full-field light sensitivity, and a recent publication showed the improvements are durable with follow-up to four years.

Voretigene was approved by the European Union in 2018, but due to stringent criteria pertaining to education and certification of the personnel involved with product storage, preparation, and administration, the gene therapy is currently only available in France and Germany.

GENE THERAPY PIPELINE
Other gene therapy trials for Leber’s congenital amaurosis are ongoing. In addition, gene therapies are being developed for choroideremia, Stargardt disease, Usher syndrome, retinoschisis, retinitis pigmentosa, and achromatopsia.

Corneal dystrophies being targeted for gene therapy include lattice, Reis-Bucklers, Thiel-Behnke, and granular corneal dystrophy. ■

TAKE-HOME
The era of gene therapy in ophthalmology has begun. A treatment for patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy is now available and there are many ongoing studies of gene therapies for inherited and other retinal degenerative diseases.
Innovations focusing on improved patient experience

Company poised to conduct additional trials, develop pipeline of technology

By Steve Lenier

With a goal of becoming an innovator in minimally invasive glaucoma surgery (MIGS) and procedure-based dry eye treatments, Sight Sciences earlier this year completed a $56 million round of growth capital funding, which will be used to accelerate the growth of the company’s OMNI surgical system and its TearCare system in the United States.

The funding also will help develop a global commercial infrastructure to conduct additional clinical trials and to develop a pipeline of innovations.

Sight Sciences was founded by two brothers—Paul Badawi, who had a background in investing in medical device companies, and David Badawi, MD, an ophthalmologist.

In 2006, while attending the American Society of Cataract and Refractive Surgery annual meeting, they decided they could do some good for patients by innovating devices to treat the underlying disease state of prevalent diseases. They settled on glaucoma and dry eye as areas of focus, recognizing the unmet need in those diseases, and began to develop ideas.

In 2011, the brothers incorporated Sight Sciences, and began to raise funds to develop products and bring them to market.

Soon after, the commercial infrastructure was created, and the company moved toward a strong commercial focus.

The company’s overall goal is “treatment of the underlying disease state with innovative products that surgeons and eye-care providers want to use, therefore bringing these innovations to more patients,” said Shawn O’Neil, chief commercial officer.

The company’s focus in this area is evident through OMNI’s ability to target the three potential points of resistance in the conventional outflow pathway (Schlemm’s canal, the distal collector channels, and the trabecular meshwork) with a single, disposable device, whereas TearCare’s approach allows for eye-care professionals to deliver targeted heat to the meibomian glands with a personalized, open eye experience, allowing the patients to keep their eyes open and blink during the procedure, he noted.

A major feature of the OMNI system is that it can perform both viscodilation and trabeculotomy.

“When not only can you stretch the collector channels and Schlemm’s canal with viscodilation, you can also unroof the trabecular meshwork,” Dr. Baartman said. “And having both of those abilities in one tool really allows you to apply that tool to more surgical scenarios.”

Dr. Baartman explained that the labeling for certain procedures that OMNI is used for is not tied to a specific stage of glaucoma.

“There is more room for us as surgeons to utilize the technology in the best interest of the patient,” he added.

Dr. Baartman pointed out there are a number of tools and devices available for the treatment of meibomian gland dysfunction (MGD) and said there are unique ways he is able to use the system that differentiates it from other products.

Dr. Baartman, who treats a lot of patients who have both glaucoma and ocular surface disease, said the TearCare system is easy to use in these patients, as it does not require the cumbersome manipulation called for by some of the other devices in this space. He also said the system is uniquely comfortable for the patient.

Another advantage is that the system allows a physician more face-to-face time with the patient because the procedure is physician-directed, he noted.

As one final advantage in clinical practice, Dr. Baartman said he utilizes the system at one of his slit lamp cameras.

“I can actually videotape, or take photos of, the oil secretions as I am expressing them from the lids,” he said, adding that he can then review the images with the patients to help them better understand their condition and show the patients that their efforts are paying off, as positive reinforcement.

Diving Deeper: MIGS, Dry Eye

The OMNI Surgical System performs two procedures—the catheterization and transluminal viscodilation of Schlemm’s canal (up to 360º), and the cutting of trabecular meshwork.

The system enables access to Schlemm’s canal with a microcatheter through a single clear corneal incision, and is engineered with an internal reservoir that delivers a controlled amount of viscoelastic fluid.

The dual mechanisms of action are designed to allow the system to address the entire natural trabeculocanicular outflow pathway to reduce intraocular pressure in adult patients with open-angle glaucoma. The procedures can be done in conjunction with cataract surgery using the same corneal incision or as a stand-alone procedure.

The TearCare system is indicated for the application of localized heat for meibomian gland dysfunction (MGD), dry eye disease, or blepharitis, where the current standard recommendation is application of a warm compress to the eyelids.
Your Partners in Anterior Surgery Outcomes

AL-SCAN OPTICAL BIOMETER

- 6 measurements in 10 seconds (K, AL, PS, WTW, CCT, ACD)
- Easy to use: 3-D auto tracking and auto shot for all measurements
- Toric Assist function
- <NEW> Barrett Formula available with our optional software, NAVIS-EX

CEM-530 SPECULAR MICROSCOPE

- Easy to Use: 3-D auto tracking / auto shot / auto analysis
- Paracentral and Peripheral imaging for overall endothelial cell health of the cornea
- Manual Analysis function
- <NEW> Progression Analysis available with our optional software, NAVIS-EX

CONTACT US TODAY!
1-877-200-9892
Visit us at AAO Booth #6248

Follow Us Online!

June 21, 2019
19-0026
The personalized open-eye experience provides targeted and adjustable thermal energy to the meibomian glands by heating the lids via proprietary SmartLid technology.

This, along with the patients’ own blinking during the heating process, facilitates natural meibum expression.

A rechargeable software-driven SmartHub communicates with the SmartLids, which allows for the tailoring of the delivery and consistency of warming to the eyelid devices, which conform to the patient’s eyelids.

The TearCare technology also allows for the eye-care provider to precisely target individual glands depending on the patient’s need by manually clearing the warmed meibum.

In the procedure, patients actively contribute to their procedure success by blinking during the heating process and physicians are able to target precisely the glands that need the most effort to give the patients the best chance at an optimal outcome.

**ONGOING TRIALS**

The OMNI system is currently in a clinical trial that will evaluate the impact of ab-inferno trans-luminal viscoelastic delivery and trabeculotomy system with the LipiFlow thermal pulsation system with regard to safety and efficacy in relieving the patients’ signs and symptoms of dry eye disease.
and IOL formulae have significantly improved the refractive results of cataract surgery. “We still have to estimate the effective lens position, posterior corneal astigmatism, or surgically induced astigmatism (SIA),” he said. “In addition, many eyes are at higher risk for IOL power surprise, such as those with prior keratorefractive surgery or unusual keratometry or axial lengths.”

In a 2018 EUREQUO study of 280,000 patients cited by Dr. Chang, 27% of cataract surgeries failed to achieve within in a half diopter of the target refraction.

Dr. Chang predicted, that for eyes with astigmatism, an ophthalmologist fresh out of residency should be able to achieve better results with the LAL than the most experienced surgeons now get with the most advanced pre- and intraoperative technologies.

While refractive outcomes can be changed or enhanced with LASIK, many ophthalmologists do not perform keratorefractive surgery, requiring a patient who needs an enhancement to see a second surgeon. Even then, the patient must wait a few months until the refraction is stable before undergoing LASIK or PKR.

**Better Patient Experience**

In addition to improving the refractive accuracy, Dr. Chang hopes that adjustability will improve the patient experience.

Setting reasonable expectations and helping patients make decisions about their refractive goals during preoperative counseling can be difficult for both the patient and the surgeon.

Patients are sometimes overwhelmed by a bevy of unfamiliar terms and often intimidated by disclaimers that results of surgery may not meet their expectations.

The ability to try different pseudophakic refractive states should reduce preoperative anxiety and confusion, and improve patient satisfaction.

“If you wanted natural distance vision,” Dr. Chang said, “how would you know what the difference would be between plano and (-) 0.75 with an IOL? If you want to read without glasses, how could you appreciate the difference between being (-) 1.5 versus (-) 2.5? With an adjustable IOL, you can preview these different refractive targets once you have the IOL, and then have your preferred target delivered with an adjustment.”

Light-adjustable IOLs are a great way to deliver customized mini-monovision, Dr. Chang noted.

“In addition to achieving good distance vision in one eye, we can try out different amounts of myopia in the second eye,” he said. “We can let the patient decide postoperatively how much anisometropia is optimal for them, and how much they can comfortably tolerate. If they don’t like it, we can then reverse it.”

In theory, the ability to wait until after surgery to demonstrate different refractive options and targets should significantly reduce the amount of time that surgeons must spend preoperatively trying to describe these different options.

“The best thing is that patients will not have to understand concepts such as depth-of-focus, myopia, astigmatism, and anisometropia,” Dr. Chang concluded. “We can use trial lenses or even a soft contact lens trial to demonstrate postoperatively how increasing or decreasing myopia affects their uncorrected vision.”

The LAL is approved by the FDA and slated for commercial availability in the United States this month.

---

**The Sarasota Retina Institute Sarasota Vitreo-Retinal Update Course**

**February 13th, 14th & 15th, 2020**

*at The Ritz-Carlton on Sarasota Bay, Sarasota, Florida*

This course is targeted to practicing ophthalmologists interested in the diagnosis and management of vitreo-retinal and neuro-ophthalmologic diseases and ocular-oncology.

**Course Objectives:**

- Understand coming advancements in optical coherence tomography (OCT & OCTA) and how they will apply to the clinical practice and treatment of various retinal and optic nerve disorders.
- DRCNet: Current research in diabetic retinopathy, macular degeneration, and retinal vascular occlusions.
- Evaluation and treatment of eye tumors.
- Improve understanding of diseases that affect the optic nerve and visual pathways.
- Medical legal issues for retina.
- Macular degeneration treatment update and new developments.

**Ocular Imaging Workshop**

**Course Faculty:**

- Jody G. Abrams, M.D. .......................................................... Sarasota, FL
- Kevin J. Blinder, M.D. ......................................................... St. Louis, MO
- David S. Boyer, M.D. ......................................................... Los Angeles, CA
- Melvin C. Chen, M.D. ....................................................... Sarasota, FL
- Harry W. Flynn, Jr., M.D. ..................................................... Miami, FL
- Gregory S. Kosmorsky, D.O. ............................................. Cleveland, OH
- Marc H. Levy, M.D. ............................................................ Sarasota, FL
- Carol L. Shields, M.D. ......................................................... Philadelphia, PA
- Jerry A. Shields, M.D. ......................................................... Philadelphia, PA
- Thomas C. Spoor, M.D. ...................................................... Sarasota, FL

**Course Director:**

Jody G. Abrams, M.D. .......................................................... Sarasota, FL

**Registration:**

- Limited Enrollment .......................................................... $600 Physician’s Fee
- $300.00 Residents

**Early Enrollment Discount:**

- $550 Physician’s Fee ...................................................... $275.00 Residents (received by December 13, 2019)

**Bay Front Activities:**

- The Melvin C. Chen Tennis Tournament
- Near Beautiful Gulf Beaches
- Deep Sea Fishing
- Sailing and Tennis

**FMA Accreditation Program**

How Physicians Earn Quality CME

**Joint Provider by**

**FOR FURTHER INFORMATION CONTACT:**

Kathy Johnson (941) 921-5335 or e-mail: srikathy@hotmail.com

This activity has been approved for AMA PRA Category 1 Credit™
A DAY IN THE LIFE OF
AN OPHTHALMIC SURGEON

Expert Recommendations for Optimal Cataract and Refractive Outcomes

CME ONLINE MONOGRAPH

FACULTY

Eric D. Donnenfeld, MD (Chair)
Clinical Professor of Ophthalmology
New York University
Langone Medical Center
New York, New York
Founding Partner
Ophthalmic Consultants of Long Island and Connecticut
Garden City, New York

John Berdahl, MD
Cataract, Refractive, Glaucoma, and Corneal Surgeon
Vance Thompson Vision
Medical Director,
Dakota Lions Sight & Health
Sioux Falls, South Dakota

Preeya K. Gupta, MD
Associate Professor of Ophthalmology
Cornea & Refractive Surgery
Duke University Eye Center
Durham, North Carolina

Edward J. Holland, MD
Professor of Clinical Ophthalmology
University of Cincinnati
Director, Cornea Services
Cincinnati Eye Institute
Cincinnati, Ohio

Visiting https://tinyurl.com/optimalcataractoutcomes for online testing and instant CME certificate.

Earn up to 1.5 AMA PRA Category 1 Credits™

Accreditation Statement
This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of New York Eye and Ear Infirmary of Mount Sinai and MedEdicus LLC. The New York Eye and Ear Infirmary of Mount Sinai is accredited by the ACCME to provide continuing medical education for physicians.

AMA Credit Designation Statement
The New York Eye and Ear Infirmary of Mount Sinai designates this enduring material for a maximum of 1.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
Medical training has drained my brain. Not in the good way—that satisfying cognitive fatigue after hours of deep, engaged work. Just the opposite. My attention span is scattered. My focus is fuzzy. My brain is fried from the fire of incessant disruptions. My monkey mind meanders amok.

Purportedly, the average attention span for humans is now reportedly less than that of a goldfish. Goldfish-level attention feels aspirational for me nowadays.

Many of the reasons that residents suffer distress and burnout are evident and well-characterized. Causes include physical and emotional fatigue, the imbalance between effort and reward, and a lack of control. Now, in my last week of residency, I recognize another, more insidious culprit—years of distraction eroding my ability to focus. The struggle to concentrate and single task underlies much of my dissatisfaction, stress, and burnout.

Data is now validating my lived truth—the multitasking demanded in our work is a limited resource, short-term working memory shrivels under physiologic or emotional stressors. The greater the cognitive load, the more difficulty we experience when trying to pay attention, rehearse, and remember. Learning new information requires minimizing distracting—so-called extraneous cognitive load—to maximize the transfer of important information into long-term memory.

When we multitask, we actually shift our attention rapidly between multiple tasks. Our brains are built to single task. When we task-switch, we interrupt ourselves and lose time in the process. Often touted for hyper-efficiency, multitasking actually reduces productivity, increases mistakes, and contributes to information overload, according to a study in the *Journal of Experimental Psychology: Human Perception and Performance*.

Studies find that frequent multitaskers have reductions in grey matter in areas that control empathy and emotions and exhibit weakness in both working memory and long-term memory. We become increasingly distracted and may even be more prone to depression and anxiety. Multitasking restricts our available resources for attention and working memory.

Burnout emerges when the stresses of a job outstrip one’s ability to cope effectively. A systematic review of job burnout and cognitive functioning shows a clear correlation between burnout and a decline in three major cognitive functions—executive functions, attention, and memory. In medicine, the increasing cognitive load is a function not only of a mounting work load, but the complexity and pace of the work flow.

*By Rich Joseph, MD, MBA, and Elizabeth Harry, MD*
P.M. Medical Billing is the largest, oldest and most experienced 100% onshore medical ophthalmology billing service in the United States. By ensuring our clients receive the maximum reimbursements for claims, we enable you to focus on expanding, buying the best equipment, spending more time with individual patients, and making the money that you deserve. Our ultimate goal has been and always will be to maximize our clients’ revenue.

P.M. Medical Billing Provides:

- Integration Into Your Current Practice Management & EMR
- A Dedicated Account Manager (Not A Call Center)
- Certified Ophthalmic Coders, Billers & Techs
- Experts In Forensic Billing & A/R Clean Up
- A Full In House Credentialing Department
- Low Cost Practice Management Software
- End To End Medical Billing & Follow Up
- Best Collection Rates In The Industry
- Full Service Patient Billing
- 100% HIPAA Compliance
- Fee Schedule Analysis

Services Include:

- Expert Coders: Billing to Primary, Secondary & Tertiary insurance companies
- A/R Clean Up and analysis
- Patient Billing
- Posting of all Explanation of benefits
- Credentialing & Re-Credentialing
- Eligibility
- Fee Schedule Analysis
- Monthly Reports
- No long term commitment or contract required
- 100% HIPAA Compliant
- Stellar letters of reference

Call us today for your free, no obligation consultation

Ph: 855-EYE-BILL Ext. 802
Email: amay@focusedmedicalbilling.com
Web: www.focusedmedicalbilling.com

“Your’re focused on your patients, we’re focused on you”

Focused Medical Billing is a full service medical billing firm servicing all specialties of Ophthalmology. With our firm our focus is to maximize our client’s revenue and dramatically decrease denials by utilizing 30 years of Ophthalmology billing/coding experience and expertise. Our firm provides accurate clean claim submissions on first submissions with relentless A/R follow up to obtain a 98% collection rate that so many of our clients enjoy.

Services Include:

- Expert Coders: Billing to Primary, Secondary & Tertiary insurance companies
- A/R Clean Up and analysis
- Patient Billing
- Posting of all Explanation of benefits
- Credentialing & Re-Credentialing
- Eligibility
- Fee Schedule Analysis
- Monthly Reports
- No long term commitment or contract required
- 100% HIPAA Compliant
- Stellar letters of reference

Call us today for your free, no obligation consultation

Ph: 855-EYE-BILL ext. 802
Email: amay@focusedmedicalbilling.com
Web: www.focusedmedicalbilling.com

“Your’re focused on your patients, we’re focused on you”

Practice Management Systems We Work With:

- Nextech • NexGen • iMedicare
- MD Office • Medisoft • Advanced MD
- Azaiea • Cerner • OfficeMate
- Revolution • Management Plus • QRS
- Medware • Dr. Chrono • Centricity
- Intergy • Echo • Care Cloud • TCMS
- Epic • Eclinical • Allscripts • ADS
- and many more...

Email: info@pmbiller.com
Web: www.pmbiller.com
24 hours: 516-830-1500
1-888-PM-BILLING
(1-888-762-4554)

Our executive staff will be attending AAO 2019

We will be on-site and available to answer any billing questions you might have and explain how P.M. can benefit your practice.

Please contact us to arrange an appointment.

516-830-1500 • info@pmbiller.com • 516-780-2895

ADVERTISE TODAY!
PRODUCTS & SERVICES

BILLING SERVICES

ECBC
EYE CARE BILLING CONSULTANTS

SEE YOUR PROFITS MORE CLEARLY
- Ophthalmology & Optometry billing only
- New York City based
- 25 years of experience

eyecarebillingconsultants.com
contact@eyecarebillingconsultants.com
(646) 828-8889

DIGITAL IMAGING

The only independent FDA-cleared digital imaging company in the industry, FUNDUS PHOTO, Welcomes MERGE and ESCALON Imaging System Owners

Escalon Digital Imaging has partnered with Fundus Photo
Merge Eye Station is discontinued
We are here to help you transition your imaging systems

FDA Cleared, Study Certified, CMS Qualified
Easy to use - Easy to own

FUNDUS PHOTO, LLC
+1 314 533 6000 fundusphoto.com
Sustaining Member - Ophthalmic Photographers Society

PRACTICE FOR SALE

RALEIGH, NORTH CAROLINA

Solo Ophthalmology Practice for Sale
Rexwoodseye@gmail.com

Reach your target audience.
Our audience.

Ophthalmologists and allied eye care professionals. Contact me today to place your ad.

Joanna Shippoli
Account Manager
440-891-2615
jshippoli@mmhgroup.com

ADVERTISE NOW!

Combine Ophthalmology Times Marketplace print advertising with our online offerings to open up unlimited potential.

Place a recruitment ad in Ophthalmology Times — in print or online.

Joanna Shippoli
Account Manager | 440-891-2615
jshippoli@mmhgroup.com

Ophthalmology Times
CAREERS

NEW YORK

Fromer Eye Centers is the largest private ophthalmology practice in NYC. We have six state of the art medical offices as well as an optical, urgent eye care center and ambulatory surgery center. Our offices are located in the Bronx, Manhattan and Queens. We are currently recruiting for a full time BC/BE retina specialist as well as a pediatric specialist who would like to work in a busy multi-sub specialty practice with 10 MDs/9 ODs.

You can read more about our practice and our surgery center at www.fromereye.com and www.eyescny.com

We provide a comprehensive benefits package, base salary plus an incentive package.

Interested Candidates should send their CV to:

Michelle D. Jimenez | HR Manager
Fromer Eye Centers, 550 Park Avenue
New York, NY 10065
Main # 212.832.9228  ☐ Direct # 347.292.3497  ☐ Fax# 718.215.0224
mijimenez@fromereye.com

INTERNATIONAL

Live & Work in the South Pacific!
Be needed. Be appreciated.

- Seeking talented, kind, ethical, comprehensive ophthalmologist for US island of Saipan
- Part-time or Full-time. Locum tenens welcome.
- $350K with low low taxes, exotic travel nearby
- State-of-the-art clinic, excellent support staff

Visit www.MarianasEye.com/Jobs
Page password: eye@9
Or email: davidkhorram@gmail.com

Narrow your candidate search
to the best.

Place a recruitment ad in Ophthalmology Times—
in print or online.

Joanna Shippoli
Account Manager | 440-891-2615
jshippoli@mnhgroup.com

WE’RE GROWING. CARE TO JOIN US?

Eye Medical Clinic has the honor of being Silicon Valley’s founding ophthalmology practice. This year marks our 73rd anniversary in San Jose and the future is bright!

We’re adding physicians to our dedicated team to continue delivering the world-class care and five-star patient experience for which we’re known. We support your practice with:

- Best-In-Class Operations
- Higher Collection Rates
- Advanced Billing & Coding System
- Smoother Patient & Physician On-Boarding
- More Efficient Clinical Flow

We welcome all ophthalmology sub-specialities and seek motivated, community-engaged physicians with a patient-centered mindset and impeccable ethical standards. We’ll help you build your ideal mode of practice, while you maintain complete clinical control. You focus all your energy on the best possible care, and we’ll handle the rest.

Contact us at 408.869.3437 or Careers@EyeMedicalClinic.com

CAREERS
CAREERS

**SOUTH DAKOTA**

Sanford Eye Center is seeking a BC/BE Ophthalmologist to add to its current group of 5 ophthalmologists and 3 optometrists, with one physician focusing on pediatric patients.

- Ideal candidate would be a comprehensive ophthalmologist with fellowship training in glaucoma
- Call is 1:5
- Work 4.5 days per week
- Competitive compensation and comprehensive benefit package
- Excellent retention incentive & relocation allowance

Sioux Falls is one of the fastest growing areas in the Midwest. As the largest city in the state, it balances an excellent quality of life and strong economy with a safe, clean living environment. The cost of living is competitive and South Dakota has no state income tax. Sioux Falls offers amenities of a community twice its size such as fine dining, shopping, arts, sports and nightlife.

Check us out at practice.sanfordhealth.org

For More Information Contact: Deb Salava, Sanford Physician Recruitment at (605) 328-6993 or (866) 312-3907 or email: debra.salava@sanfordhealth.org

---

**VERMONT**

The Division of Ophthalmology at the University of Vermont College of Medicine, in alliance with the University of Vermont Medical Center, is seeking an academic neuro-ophthalmologist. This individual must have completed a board approved 3- or 4-year ophthalmology residency or a 3-year neurology residency and a clinical neuro-ophthalmology fellowship, and be board certified or board eligible, and eligible for medical licensure in the State of Vermont. The successful applicant will be appointed at the Assistant/Associate Professor level in the Clinical Scholar Pathway, commensurate with years of experience and accomplishments.

Duties will include providing clinical care to neuro-ophthalmology patients, teaching the principles of ophthalmology to medical students and undergraduate students in Allied Health programs, providing teaching experience for residents in training, developing basic and/or clinical research, and performing additional departmental and/or sectional administrative duties as assigned by the Chair of the Department of Surgery.

This is a full-time, 12 month, salaried, faculty appointment and carries with it attending staff privileges at The University of Vermont Medical Center. Salary is competitive and commensurate with ability and experience.

Located in Burlington, the University of Vermont Medical Center serves as Vermont’s only academic medical center. Burlington is a vibrant community located on the shores of Lake Champlain, between the Adirondack and Green Mountains. With year-round recreational opportunities, safe communities and excellent schools, this progressive community has been frequently cited as one of the most livable cities in the U.S.

The University is especially interested in candidates who can contribute to the diversity and excellence of the academic community through their research, teaching, and/or service. Applicants are requested to include in their cover letter information about how they will further this goal.

The University of Vermont is an Equal Opportunity/Affirmative Action Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, protected veteran status, or any other category legally protected by federal or state law. The University encourages applications from all individuals who will contribute to the diversity and excellence of the institution.

Interested individuals should apply online at https://www.uvmjobs.com/postings/32453 (position number 006035).

Inquiries may be directed to Dr. Brian Kim c/o Kristin Allard at Kristin.Allard@uvmhealth.org.
The high-stakes environment adds another layer of anxiety. In contrast, our brain works most efficiently when it can focus on a single task—even if boring or frustrating—for a longer period. Focus is foundational for job satisfaction. As originally described by psychologist Mihaly Csikszentmihalyi, “flow” is “a state in which people are so involved in an activity that nothing else seems to matter; the experience is so enjoyable that people will continue to do it even at great cost, for the sheer sake of doing it.”

Elements of flow include:

- present moment concentration on a singular task
- a clear objective with immediate feedback and intrinsically rewarding experience
- a sense of effortless, automatic performance
- an appropriate balance between perceived challenge and skill
- a sense of control
- an absence of time and self-consciousness

We might refer to this colloquially as being “in the zone.” This heightened sense of awareness of the here and now is inaccessible if distractions interfere. Excessive cognitive load is understandably perilous for patient safety. Do you remember entering the wrong medication for a patient while toggling between multiple patient charts on the electronic health record? Or perhaps you accidentally forgot to note that critical alert, perhaps when they are able to access flow in the operating room—one of the few times we have been there, tiptoeing along the precipice of medical error. Underappreciated, or perhaps less discussed, is how difficult it is to get “in the zone” while practicing medicine nowadays. Solutions to reduce cognitive load must target both the individual and the work itself. Techniques like meditation, breathing exercises, and other stress reduction techniques help to enhance working memory in high-demand environments. Learning how to manage stress and anxiety is a core competency for any professional in today’s frenzied work environment.

On a system level, we must devise mechanisms and tools to reduce extraneous cognitive load. Checklists, for example, help automate and streamline workflow and enhance patient safety. Storing patient data in one reliable location on the EHR would reduce the redundancy, and hence cognitive load. We should reduce the extraneous cognitive load on trainees by limiting the number of patient charts that can open simultaneously, restricting interruptions during dedicated education sessions, triaging alerts and nursing requests based on clinical severity, and using one dedicated platform to communicate about patient care with consulting services.

The National Physician Burnout, Depression and Suicide Report 2019, conducted by Medscape, discovered that the highest rates of burnout by specialty occurred among urology (54%), neurology (53%), physical medicine and rehabilitation (52%), internal medicine (49%), emergency medicine (48%), and family medicine (48%). Conspicuously absent are many fields—surgical specialties, in particular—with notoriously brutal hours that we would hypothesize experience more burnout than those with less hours on call, more sleep, and better “work-life balance.” To be clear, many surgeons are suffering from intense burnout. But perhaps when they are able to access flow in the operating room—one of the few remaining spaces that prioritizes and facilitates intense focus—this may confer some protective effect.

This begs the question: How do we create environments that support “deep work” for all physicians? For internists and others who primarily do cognitive work, consider designing workflows that batch the endless communications about patient care to free up protected blocks of time to think and devise the best possible care plans. For emergency medicine doctors, consider skill-based shifts, where one trainee is exclusively doing procedures, one is taking histories, and one is triaging patients based on acuity. For radiologists, one might be assigned to field requests for wet reads and imaging protocols such that the others may focus intensely on reading films.

Medicine is a heterogeneous profession with diverse personality types and a complex division of labor. The desire to experience flow in work is universal. Solutions that can enable us to spend time, energy, and focus immersed in the essence of our craft.

Editor’s Note: The full-length version of this article originally appeared in sister publication Medical Economics.
Register now for the 9th Annual New Horizons Forum, dedicated to speeding the development of new therapies and diagnostics for glaucoma patients.

Learn more at www.glaucoma360.org

New Horizons Forum

February 7, 2020
Grand Hyatt Hotel, 345 Stockton Street, San Francisco

Register online at www.glaucoma360.org

2020 OPENING KEYNOTE SPEAKER

DAVID W. PARKE, II, MD
Chief Executive Officer
American Academy of Ophthalmology (AAO)
“This latest time I upsized my phone, I realized I needed to do something about my poor vision.”
**Anterior blepharitis** means blepharitis on the outer eyelid margin, including the eyelashes.

**The POWER of the PULSE**

Advanced Doctor Treatment for Anterior Blepharitis

AAO Show Special - $1,495 for the AB Max™ Starter Kit

From one of the inventors of the first doctor’s treatment for Blepharitis—the AB Max™ is a new Doctor’s Treatment for Anterior Blepharitis with a Patented PULSE functionality specifically engineered to remove even the most tenacious scurf and debris, while gently massaging the outer eyelid margins for better patient outcomes!

AB Max™ is offering you the chance to trade in our competitor’s device for an AB Max™ in our new Trade UP program. This innovative product delivers a newly Patented PULSE action for more efficient and rapid outer eyelid debridement. AB Max™ offers Affordable and Advanced Anterior Blepharoesfoliation.

As part of the Trade UP program, when you purchase the new AB Max™ Starter Kit and you trade in our competitor’s device, AB Max™ will reimburse you the original purchase price with NO CHARGE boxes of AB Max™ Procedure Packs. This is a value of $299/box with 20 Procedure Packs @$14.95ea.

For example, if you originally paid $1,195, we would trade you four (4) boxes of AB Max™ Procedure Packs ($1,195/$299 = 3.99 boxes).

Contact us today to Trade IN and Trade UP to an AB Max™ at www.AB-Max.com or 1-800-721-8006.

Come See us at Booth #7358
WORKING TO EMPOWER A NEW ERA OF

PROACTIVE GLAUCOMA SURGERY

PROACTIVE
SURGERY

PREDICTABLE
POST-OP

SUSTAINABLE
TARGET IOP

DEVICE
INNOVATION

Go to AdvancingGlaucomaSurgery.com to hear your peers’ perspectives

Visit us at AAO booth 1139