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CLINICAL DIAGNOSIS | SURGERY | DRUG THERAPY

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Surgery

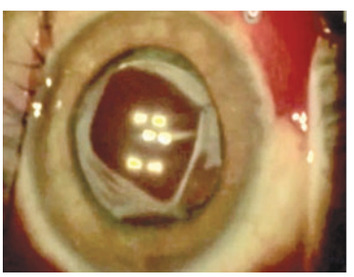
Y-FIXATION IMPROVES INTRASCLERAL IOL FIXATION OUTCOMES

SHIZUOKA, JAPAN :: **THE Y-FIXATION** technique is an effective method for sutureless IOL intrascleral fixation that is simpler and safer than alternative approaches for intrascleral IOL fixation, according to Toshihiko Ohta, MD.

(See story on page 16 : Y-fixation)

Surgery

TECHNIQUE ACHIEVES STABLE IOL RECENTRATION



CALGARY, ALBERTA :: **SCLERAL SUTURE FIXATION** of the entire IOL-capsular bag complex through the fibrotic rim of the continuous curvilinear capsulorhexis is an effective technique for achieving stable IOL recentration in cases of IOL-capsular bag subluxation.

In addition, the surgical technique offers advantages compared with other approaches for managing this late complication, according to Howard V. Gimbel, MD, MPH.

(See story on page 18 : IOL-bag complex)

Anti-factor D reduces GA progression 20%

Phase II clinical study results indicate monthly lampalizumab therapy may be successful treatment

By Michelle Dalton, ELS;
Reviewed by David F. Williams, MD, MBA

EDINA, MN ::
A PHASE II STUDY of a humanized monoclonal antibody fragment that binds factor D has shown a 20% reduction in slowing geographic atrophy (GA) progression over 18 months, according to David F. Williams, MD, MBA.

The MAHALO study of lampalizumab (formerly FCFD4514S, Genentech) also showed no unexpected or unmanageable serious adverse events, said Dr. Williams, who is a partner at Vitreo-Retinal Surgery, PA, Edina, MN, and an assistant clinical professor of ophthalmology, University of Minnesota, Minneapolis.

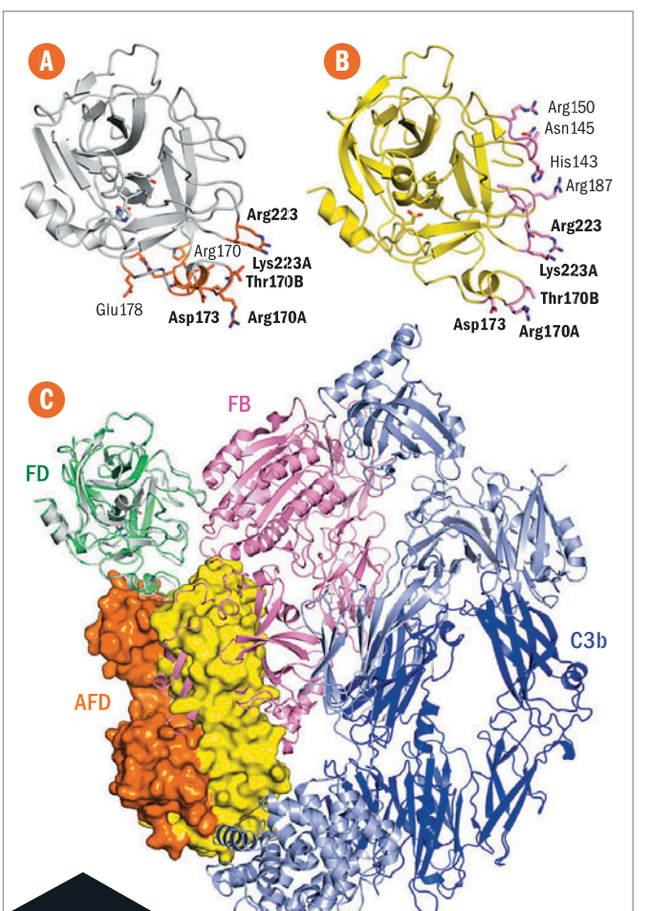
"The clinical implications of the phase II results, if confirmed in a future phase III trial, are profound," Dr. Williams said. "It would represent a seminal moment in ophthalmology—the first time that complement inhibition would show a positive therapeutic effect in an ophthalmic disease.

"This would herald a new era of treatment for a major unmet need—slowing GA progression due to age-related macular degeneration (AMD) and preserving visual function for people with a previously untreatable disease," he added.

ABOUT ANTI-FACTOR D

Lampalizumab, also known as anti-factor D, is a selective inhibitor of the alternative complement pathway. It is a humanized monoclonal antibody fragment that binds factor D, a rate-limiting enzyme in the pathway, Dr. Williams said.

(Continues on page 41 : Slows progression)



Mechanism of action

Anti-factor D (AFD) sterically prevents factor D (FD) from binding to C3bB proconvertase. A Residues in FD (white ribbon representation, from the FD-AFD complex) in contact with AFD (orange sticks). B Residues in FD (yellow ribbon representation, from the C3bBD complex) in contact with FB (pink sticks). C Modeling of a major steric clash between FB (pink) and the AFD HC (orange) and LC (yellow). Dark blue indicates the C3b *b*-chain, and light blue indicates the C3b *a*-chain. *J Biol Chem. 2012;287:12886–12892. (Reprinted with permission. ©2013 The American Society for Biochemistry and Molecular Biology)*

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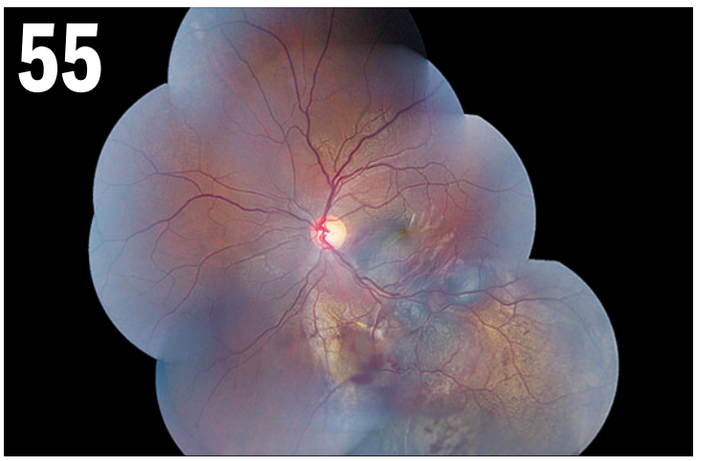
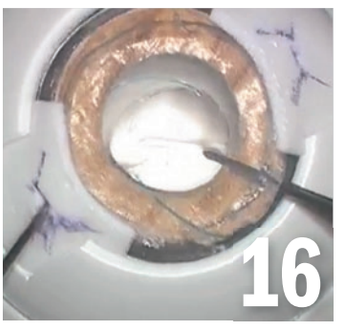
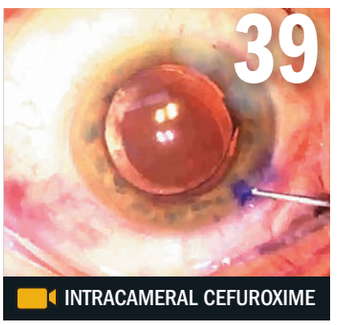
Ophthalmology Times

contents







Surgery

Drug Therapy

Technology

Practice Management

Clinical Diagnosis

Grand Rounds

In Every Issue

Special Report on page 30
PEDIATRICS

Life in the fast lane

Why a high CFF measure may have advantages for some species

By Peter J. McDonnell, MD

director of the Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and chief medical editor of *Ophthalmology Times*.

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CRITICAL FLICKER-FUSION FREQUENCY (CFF), as every ophthalmologist knows, is the lowest frequency at which a flickering light source is perceived to be constant (not flickering).

Humans average a CFF of 60 Hz, but other animals measure with very different capabilities.

Higher CFFs are thought to convey a survival advantage, as they permit faster reactions to threats and make it easier to catch prey.

According to a recent article by a professor in Dublin, Ireland, the CFF of a species correlates with metabolic rate and size.

All things being equal, in small species—like flies—the signals have very little distance to travel from the light-sensing neurons of the eye to the brain, so everything happens fast. Flies have a CFF of 250 Hz, making them so difficult for us humans—living in a world only one-fourth that speed—to swat those little guys.

The professor measured CFFs of a wide array of animals:

- **Eels (disgusting creatures) have a CFF of only 14 Hz.**
- **Hammerhead sharks are tied with people at 60 Hz.**
- **Ground squirrels lead all tested vertebrates at 120 Hz.**

This means that hammerhead sharks don't have trouble catching and biting people—as the media are always eager to report whenever that occurs somewhere in the world—because humans do not see images any faster than the sharks. Similarly, these data explain why it so rare for us to read about sharks successfully attacking ground squirrels.

Birds have CFFs of about 100 Hz, allowing them to zip through the air among tree branches without running smack into an obstacle.

For humans, when walking or running, a CFF of 60 Hz is quite adequate, but in a vehicle at high speed we apparently begin to suffer in terms of our ability to identify and react to objects with sufficient speed.

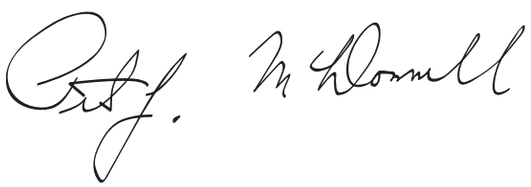
THE HUMAN FACTOR

An interesting fact about us primates is that we have cells in our lateral geniculates that respond to higher frequencies than 60 Hz, even though we are not conscious of this. Some believe that this may explain why certain people experience headaches and cognitive problems when exposed to the 120 Hz flicker of older fluorescent lighting.

A fascinating aspect of CFF is that the refresh rate on a television screen is usually set at 60 Hz, adequate for us human viewers to perceive smoothly transitioning video. One theory is that "dogs have a CFF of 80 Hz, which is probably why they do not seem to like watching television. To a dog a TV programme looks like a series of rapidly changing stills."

The lack of interest among dogs in watching television may relate to this scientific observation about CFF, but an alternative explanation exists. Clearly, most television shows are so moronic these days that sentient beings, like dogs, simply can't stand to watch.

Let's face it; since the end of season one of "House of Cards" (filmed largely in Baltimore, by the way), there's been nothing worth watching on TV. ■



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The 'Holy Grail' of emmetropia

Intraoperative aberrometry progressing alongside other cataract surgery advances

Cataract Corner **By Robert H. Osher, MD,** *Special to* Ophthalmology Times

TAKE-HOME

- ***Advances in intraoperative aberrometry are increasing the likelihood that, in the near future, ophthalmologists will be able to achieve emmetropia for all patients undergoing cataract surgery.***

A new intraoperative module (HOLOS IntraOp) attaches to any standard surgical microscope to assist surgeons in monitoring and confirming the accurate refractive status of a patient's eye throughout all phases of the surgical procedure.
(Photos courtesy of Clarity Medical Systems)

The steady stream of advances in cataract surgery have brought forth significant improvements in surgical techniques, in devices ophthalmologists implant, and in the vast array of tools available for improving modern cataract surgery safety and refractive outcomes.

Examples include newest-generation phacoemulsification, advanced technology IOLs, and the recent development of femtosecond cataract lasers. Each has contributed to the pursuit of our quest for emmetropia after cataract surgery.

We are now entering a new frontier in refractive cataract surgery with intraoperative refractive data being available for the first time to provide surgical guidance, as well as insurance against untoward refractive surprises. Early experience with intraoperative aberrometry has confirmed the clinical value of measuring refraction and providing the surgeon with this information during cataract surgery.

Finally—as the numbers of cataract patients that have previously undergone refractive cornea surgery increases—the challenge of obtaining accurate keratometry increases along with the associated risk of it confounding the preoperative surgical plan.

DEVELOPMENTS IN ABERROMETRY

Thankfully, intraoperative aberrometry is progressing alongside other cataract surgery advances—increasing the likelihood that, in the near future, we will be able to achieve emmetropia for all cataract surgical patients.

In the 1960s, Roland Shack and Benn Platt modified the aperture array developed by Johannes Franz Hartmann in 1900 to trace individual rays of light through the optical system of a large telescope. The Shack-Hartmann wavefront sensor revolutionized the accurate measurement of lower and higher order aberrations and is one of the most common forms of aberrometry in the market today.

As cataract surgery reaches new levels of success and safety, the potential need and value for a means of measuring aberrometry intraoperatively has become increasingly apparent.

Unfortunately, legacy aberrometer technologies, such as Shack-Hartmann systems, have not been able to support this application because of their bulky size. The technology is not compact enough to fit on an operating microscope and meet the ergonomic requirements of cataract surgery.

In 2010, WaveTec Vision overcame this critical deficiency by creating an intraoperative aberrometer using Talbot-Moire interferometry, which allows a somewhat smaller, less-cumbersome profile.

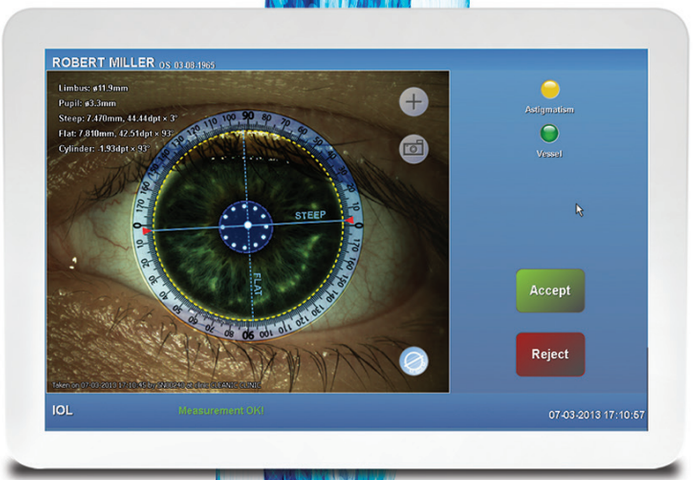
AT THE FOREFRONT

A new intraoperative device (*HOLOS* IntraOp, Clarity Medical Systems) will be released at the 2013 meeting of the American Academy of Ophthalmology (AAO) in New Orleans that moves beyond these legacy technologies with a next-generation form of wavefront technology.

The device—even more compact—uses a proprietary sequential scanning technology invented specifically for ophthalmic applications. The device provides a continuous stream of highly accurate refractive data that moves from a still camera (legacy technology) to a video camera overlaid on a live image of the patient's eye.

The manufacturer has recently secured

Continues on page 8 : ***Emmetropia***



Pre-op

Image.

Capture key diagnostic measurements, including:

- Dynamic keratometry
- Pupillometry, W2W, limbus
- Eccentricity of the visual axis

Simultaneously register the unique "fingerprint" of your patient's eye:

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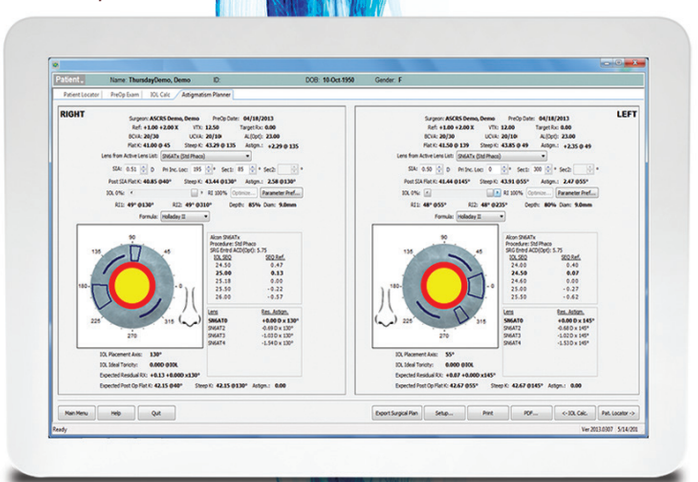
- Limbus
- Scleral vessels



Pre-op

Plan.

Conveniently and confidently determine a surgical plan targeting your desired outcome

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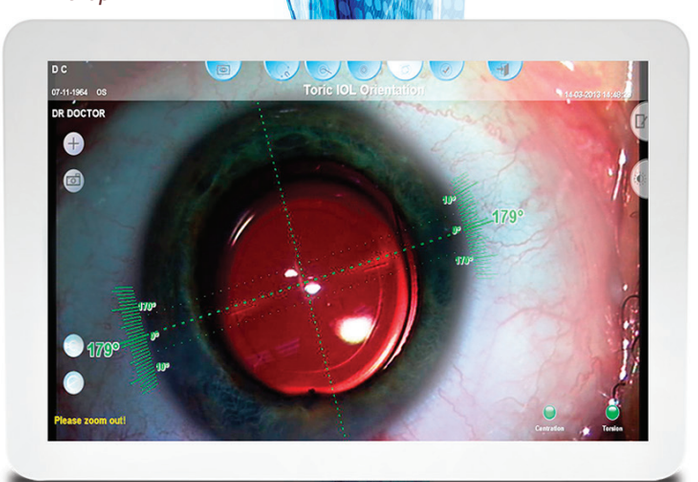
- Comprehensive astigmatism planner



Intra-op

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EMMETROPIA

(Continued from page 6)

patents on the ability to capture and display real-time refractive wavefront measurements during surgery.

The aberrometer attaches to any standard surgical microscope, and can adapt to a 150-, 175-, or 200-mm working distance—another unique feature for which the manufacturer has secured a patent.

A separate screen positioned conveniently for the surgeon's viewing displays continuous video of the data being captured.

The device is accurate in phakic, aphakic, and pseudophakic states, and is safe to keep running throughout the entire procedure—allowing the surgeon to glance up as needed at any point in the surgery to assess the refractive information. This all occurs without having to adjust either the microscope or the operating room lights, or interact with the device's touchscreen.

The measurement range spans 40 D.

CLINICAL APPLICATIONS

Real-time wavefront information has the potential to impact cataract surgery in a number of positive ways.

The technology's continuous, real-time aberrometer provides seamless, accurate refractive data to the surgeon throughout the surgery without adding to the surgical time. This is accomplished by capturing a live video of the eye while overlaying streaming qualitative and quantitative refractive data.

These data are also recorded for detailed review after the case.

> 'The value of real-time, scanning, continuous wavefront aberrometry is indisputable.'
>
> — Robert H. Osher, MD

During surgery, the device helps the surgeon actively manage astigmatism.

For example, the device can be used to guide the orientation of a toric lens to its optimal refractive position in real time (note that the astigmatic power may be minimized or eliminated at an axis that is different from the preoperative calculated axis).

The device can also be deployed to titrate a limbal relaxing incision as it is being performed, including with femtosecond laser-management astigmatism.

Additional applications include the assessment and quantification of surgically induced astigmatism.

Post-surgery, vast amounts of information can be mined from the integrated video and refractive movie, increasing understanding of surgical influences on final refractive outcomes.

GETTING THE BEST READINGS

As we embark on the journey of intraoperative aberrometry, the key elements needed to get the most value from our new tools will be explored.

The importance of physiologic IOP in achieving the accurate measurements will be one important key to success. During aphakia, it is necessary for the globe to be well inflated.

Pseudophakia is the second condition when control of pressure is important to achieve accurate refractive measures.

Achievement of physiologic IOP is important, since it is the biggest variable impacting effective lens position.

The device's continuous real-time refraction allows the surgeon to adjust IOP while monitoring the refractive results.

NEW HOPE

For most of my 35-year career in ophthalmology, I have been preaching the official "school of emmetropia," trying to convince my peers that emmetropia should be our end goal.

I presented and published the first papers emphasizing the goal of uncorrected vision. In the early 1980s, I performed the first refractive cataract surgery combining astigmatic keratometry with phacoemulsification to reduce astigmatism. Several years later, I performed the first hyperopic clear lensectomy in pursuit of the evasive emmetropia.

The value of real-time, scanning, continuous wavefront aberrometry is indisputable. Imagine the possibility of no longer depending entirely upon preoperative measurements, subject to operator error, in obtaining axial length and keratometry.

Certainly, much must be proven before ophthalmologists are completely accurate in selecting the ideal IOL power, placing it exactly on axis, and achieving zero residual astigmatism. I believe there is new evidence for hope that we are closing in on this desirable destination. ■

ROBERT H. OSHER, MD, *is professor of ophthalmology, College of Medicine, University of Cincinnati and medical director emeritus, Cincinnati Eye Institute, Cincinnati, OH. He did not indicate any proprietary interest. Readers may contact Dr. Osher at rhosher@cincinnatieye.com.*

Crizal® Prevencia™ and the Blue Light Hazard

Blue light plays a paradoxical role in health and vision. Not only is blue light essential for color perception, recent research has found that light in this band triggers critical physiological responses that include pupil constriction reflex and synchronization of the human biological clock. However, blue light may also be damaging to the eye, and the term "blue light hazard" has been coined to describe the danger this light presents to critical structures within the eye. Blue light can induce formation of damaging phototoxins, leading first to the death of critical retinal pigment epithelium (RPE) cells and then to photoreceptors. This damage is cumulative, and has been implicated in the development of retinal degenerative diseases such as age-related macular degeneration (AMD). The fact that blue light is both beneficial and harmful raises a critical question: Can we protect the eye from harmful blue light without simultaneously denying it the beneficial blue light? One way to accomplish this would be the creation of a lens that would selectively filter out the harmful wavelengths while transmitting the beneficial ones.

To determine if specific bands within the blue light spectrum were responsible for blue light's phototoxic effects, researchers from Essilor's Paris R&D laboratories joined forces with scientists from the Paris Vision Institute - one of the most important research centers in Europe on eye diseases—to develop a unique illumination system that allowed cultured swine retinal cells to be exposed to narrow bands of light. Using this test system, it was discovered that RPE phototoxicity was concentrated in a relatively narrow band, separate from the wavelengths necessary for the beneficial physiological effects of blue light. This finding paved the way for **selective photofiltration**: the creation of lenses that reduce the level of exposure to the harmful portion of the blue light spectrum, ranging from 415-455 nanometers (known as Blue-Violet light) while permitting the rest of the visible spectrum including beneficial blue light (known as Blue-Turquoise light), to enter the eye at a normal level. Thus, the eye's necessary visual and non-visual functions can be maintained while exposure to hazardous wavelengths is reduced.

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1. Covered under U.S. Patent No. 8,360,574. Additional U.S. and foreign patents pending.

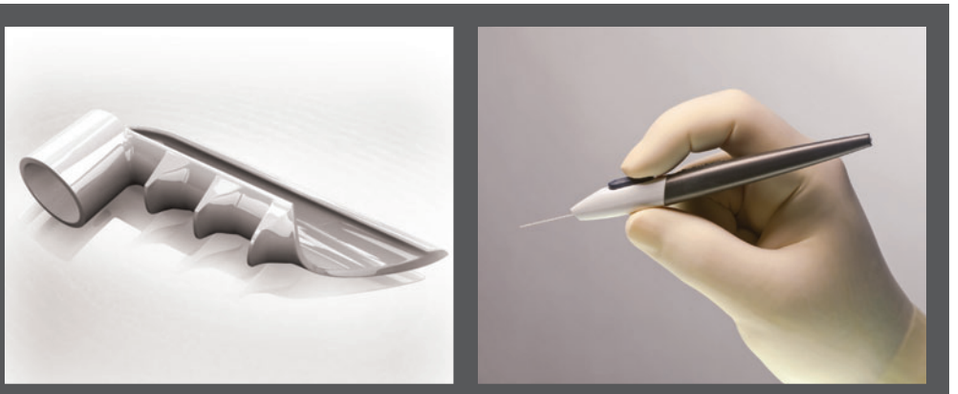
Triple procedure puts IOP on 'ICE'

Approach uses combination of treatments to maximize pressure-lowering benefit

By Nathan Radcliffe, MD; *Special to* Ophthalmology Times

TAKE-HOME

- ***A glaucoma specialist explains how he and colleagues have had excellent IOP-lowering success with a combination procedure called ICE: iStent, Cataract, and Endocyclophotocoagulation.***



The 1-mm-long trabecular micro-bypass stent (iStent, Glaukos) is inserted into the trabecular meshwork, creating a bypass between the anterior chamber and Schlemm's canal to address the issue of resistance to aqueous outflow. The stent is preloaded in a single-use, sterile inserter. *(Images courtesy of Glaukos)*

NEW YORK ::
THE PAST SEVERAL YEARS have brought an influx of glaucoma treatments—combination medications, laser therapies, and various surgical options. Of particular note has been the development of the microinvasive glaucoma surgery category with its ultrasafe risk profiles.

With the increase in low-risk options, it is inevitable that surgeons begin to investigate combinations of procedures to maximize pressure decreases while maintaining an excellent safety profile.

The causes of glaucoma are not entirely understood, but its most common manifestation is the buildup of aqueous humor in the eye, causing an increase of IOP that compresses and damages the optic nerve endings. Most glaucoma treatments are aimed at either decreasing the production of or improving the outflow of aqueous.

Although the mechanism of action is not yet elucidated, published literature demonstrates that phacoemulsification has a modest and sustained positive impact on IOP.[1]

WHAT IS 'ICE' PROCEDURE?

Some of my colleagues and I have had excellent success with a new combination procedure called ICE: iStent, Cataract Extraction, and Endocyclophotocoagulation (ECP).

The trabecular micro-bypass stent (iStent, Glaukos) has been found to create a positive synergy with cataract surgery, further reducing IOP while maintaining the same excellent safety profile.

The 1-mm-long stent is inserted into the trabecular meshwork, creating a bypass between the anterior chamber and Schlemm's canal to address the issue of resistance to aqueous outflow. In randomized trials comparing stent plus cataract surgery with cataract surgery alone, pressure reduction on fewer medication was clinically and statistically significantly better in patients who received the combined procedure versus those that received cataract surgery alone.[2]

In addition, the overall safety profile was similar to cataract surgery alone.

ECP addresses IOP from the opposite angle, by lowering the production of aqueous via ablation of the ciliary processes. Similar to the stent, a review of 808 patients who underwent either phacoemulsification alone or phacoemulsification combined with ECP showed greater benefit in the combined group with no increased risk of complications.[3]

A comparison of ECP performed through one incision versus two incisions in conjunction with cataract surgery shows that treatment of the entire 360° of ciliary processes provides better long-term control of IOP and less dependence on topical glaucoma medications.[4]

FINE-TUNING THE DETAILS

The existence of complimentary small-incision surgeries that address both inflow and outflow of aqueous seemed an intuitive combination, and my colleagues and I began fine-tuning the details of the procedure.

We found it most reasonable to begin with phacoemulsification followed by placement of the IOL.

While the stent could be placed before or after ECP, it makes the most sense to place the device directly following IOL placement while the viscoelastic is still in the eye, the angle is deep, and the view through the cornea has not been compromised by the manipulation required during ECP.

In general, I find that a small amount of additional viscoelastic helps to inflate the iridociliary sulcus to perform ECP.

While stent placement is generally done while visualizing the anterior chamber via gonioscopy, it is also possible to place it with the view provided by the endoscope.

Advantages of this approach include:

- **The ability to treat patients who are not adaptable to the gonioscope.**
- **Greater availability and increased comfort level with a gonioscopy.**
- **Saving time by not having to adjust the microscope.**

I first performed endoscopic stent placement when my operating room staff told me prior to a series of ICE procedures that I had only three gonioscopic lenses—not enough for my four cases. I felt confident that I could place the stent endoscopically and successfully proceeded with the procedure on the first case.

The endoscopic approach works best if you hold the endoscope in the left hand and place a

Continues on page 13 : ***'ICE' procedure***

For patients starting or changing PGA therapy

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Keep monotherapy.

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

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

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

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None

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C

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

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

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

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

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

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

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

OVERDOSAGE

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

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

NONCLINICAL TOXICOLOGY

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

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

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

PATIENT COUNSELING INFORMATION

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

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

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

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

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

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

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ALLERGAN®

'ICE' PROCEDURE

(Continued from page 10)

left-handed stent into the angle with the right hand. Both instruments are placed though the 2.75-mm temporal clear corneal incision, with the endoscope inserted first.

If a right-handed stent is placed using the right hand, the scope will only provide a view of the back of the stent inserter and placement, while not impossible, will be less facile. The implantation is very straightforward and withdrawing the endoscope slightly allows a nice broad view, while not letting it interfere with stent placement.

The presence of two instruments in the anterior chamber through the corneal main incision at one time can make it difficult to stabilize the eye.

On occasion, I have asked an assistant to stabilize the globe in the primary position so that manipulation of the instruments does not alter the position of the eye.

After stent placement, I gently tug backward on the inserter and watch to see that Schlemm's canal and the internal eye wall are drawn inward, indicating placement within the canal. After releasing the stent, I tap the device with the inserter to ensure it is well docked and visually check for blood reflux coming from the stent's heel.

After the stent is in place, I withdraw the inserter and place a viscoelastic cannula into the sulcus.

Looking through either the operating microscope or the endoscope, I watch to ensure that the posterior chamber has been adequately inflated to allow visualization.

When that is achieved, the viscoelastic cannula is removed and a standard one-site, 270° ECP is performed using the curved, 20-gauge probe.

PATIENT PROFILE

An ideal patient for this combined procedure was a 72-year-old male who had cataract extraction with ECP 3 years prior, before the stent was available.

His baseline IOP was 21 mm Hg, which was reduced to 16 mm Hg following the procedure. Preoperatively, he was taking 3 glaucoma medications and he remained on 2 medications for the following 3 years.

His other eye has now developed cataract alongside moderate glaucoma (IOP of 22 mm Hg) and I felt that we could combine the benefit he received previously from cataract extraction and ECP with that of the stent, while maintaining and excellent safety profile.

On the second eye, I performed the ICE procedure and 3 months following treatment, his IOP is now 16 mm Hg and he is on 1 medication.

Some of my cases have been more successful than this, and others have not and have moved on to other incisional glaucoma surgeries.

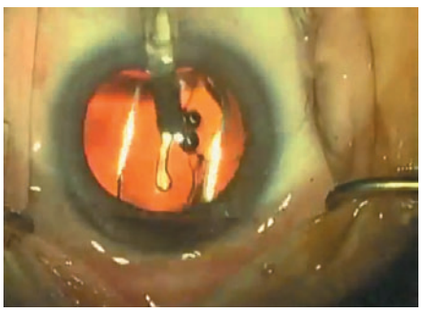
Though we are still evaluating clinical data, early results indicate an additional IOP-lowering benefit alongside a preserved favorable safety profile.

In more than 50 cases, my colleague, Parag Parekh, MD, of the Laurel Eye Clinic, and I have found none of the typical complications associated with filtration surgery and no incidences of hypotony.

Combined ICE procedures make sense for a variety of reasons. When you consider adding ECP to a planned cataract-stent procedure, there is no additional implanted material, no increase to facility cost, and only a modest increase to operating time

Additionally, the use of the endoscope in place of the gonioscope may provide surgeons a new approach that may expand the number of patients and situations when a stent can be provided. ■

WATCH THE 'ICE' PROCEDURE



VIDEO For a demonstration of the "ICE" procedure by Nathan Radcliffe, MD, go to **http://bit.ly/17BH5AD**. *(Video courtesy of Nathan Radcliffe, MD)*

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Dr. Stout appointed BCM chairman

HOUSTON ::

BAYLOR COLLEGE OF MEDICINE (BCM) has named Timothy Stout, MD, PhD, as its new ophthalmology department chairman.

A graduate of BCM, Dr. Stout had been serving as vice president for commercialization strategies and as a professor of ophthalmology and molecular genetics at Oregon Health and Sciences University, Portland.

"With a proven track record and excellent leadership skills, Dr. Tim Stout is the ideal choice to chair the ophthalmology department," said Paul E. Klotman, MD, president and chief executive officer of BCM. "He understands BCM and our strategic vision for the future in patient care, research, and education."

Dr. Stout received both his medical and doctorate degrees from BCM. His appointment is effective in December, as he will succeed Dan Jones, MD, who is retiring after serving as chairman for more than 30 years.

"I'm very much looking forward to returning home to Baylor and the Cullen Eye Institute," Dr. Stout said. "Danny Jones has set an incredible standard and I look forward to helping shape the future of the department." ■

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Y-fixation technique: Why not?

Surgeon explains how method offers IOL intrascleral fixation alternative with benefits

By Cheryl Guttman Krader; *Reviewed by Toshihiko Ohta, MD*

TAKE-HOME

- ***The Y-fixation technique is a method of sutureless IOL intrascleral fixation that requires less complicated manipulations and results in better closure than alternatives of its type.***

SHIZUOKA, JAPAN ::

THE Y-FIXATION technique is an effective method for sutureless IOL intrascleral fixation that is simpler and safer than alternative approaches for intrascleral IOL fixation, according to Toshihiko Ohta, MD.

The Y-fixation technique can be used when implanting an IOL in an aphakic eye without support for a posterior capsule (PC) IOL as well as for repositioning a subluxated PC lens, and it is applicable for 3-piece IOLs.

It is performed using a 24-gauge MVR knife first to create two Y-shaped half-thickness incisions in the sclera, 2 mm from the limbus, and then to form a scleral tunnel at the end of the Y-shaped incision.

"We expect to develop the Y-fixation technique further in the future," said Dr. Ohta, professor of ophthalmology, Juntendo University Shizuoka Hospital, Shizuoka, Japan. "However, our experience using it so far in numerous eyes demonstrates that it delivers anatomically and optically stable results."

HOW IT'S DONE

In the case of a dislocated IOL, vitrectomy is performed as needed and the IOL is brought forward. Then, one haptic tip is extracted into the scleral tunnel using a vitreous forceps and the step is repeated with the opposite haptic using a U-shaped hook or a push-and-pull hook held in one hand and vitreous forceps in the other.

Once the haptics are positioned within the scleral tunnel, a single 8-0 nylon suture is used to suture the scleral bed to prevent IOL shifting, and the sclera is sutured with 8-0 Vicryl.

When implanting an IOL into an aphakic eye, a forceps held in the left hand is used to grasp the leading haptic as it begins to extrude from the injector tip.

The haptic tip is pulled through the sclerotomy and externalized on the left side.

Next, the IOL is fully released as the injector is withdrawn, the trailing haptic is inserted into the anterior chamber with forceps, and the IOL is centered using a U-shaped hook or a push-and-pull hook.

Then, the tip of the haptic is grasped with the forceps, externalized through the sclerotomy, and the procedure is completed as described above.

LESS COMPLICATED MANIPULATIONS

Methods for sutureless intrascleral fixation of the IOL by securing the haptic to the inner surface of the sclera have been described by others, Dr. Ohta noted.

For example, in a technique by Gabor et al., a 24-gauge needle is used to create a straight sclerotomy.

Then, using a vitreous forceps, the haptics are brought into the ciliary sulcus through a parallel scleral tunnel.

Alternatively, Agarwal et al. introduced the glued IOL technique in which a 22-gauge needle is used to create a straight sclerotomy and fibrin glue is used to attach the extracted haptics within the scleral tunnel and to seal the scleral flaps and overlying conjunctiva.

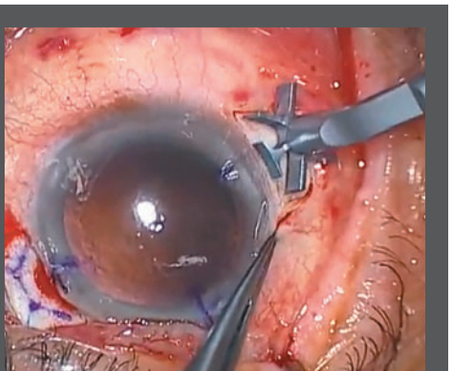
"In the technique by Gabor et al. it is difficult to extract the haptics, only a 3-piece IOL can be used, and the closure is problematic," Dr. Ohta said. "The technique by Agarwal also has problems with the closure, as well as with postoperative hypotony, and it necessitates creation of a lamellar scleral flap as well as the use of fibrin glue.

"Our technique avoids the need for a large lamellar scleral flap, while our approach for performing the sclerotomy with the MVR knife simplifies extraction of the haptic and greatly improves incision closure," Dr. Ohta continued. "In addition, the Y-fixation technique can be done with only one pair of vitreous forceps, whereas the other intrascleral fixation techniques require two."

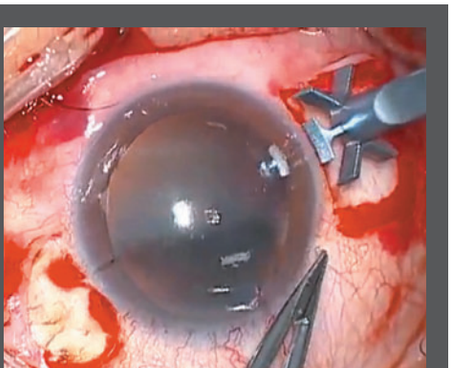
As shown in outcomes analyses, the Y-fixation technique also has benefits compared

Continues on page 21 : ***Y-fixation***

Go to **http://bit.ly/17v4Exe** to watch surgical practice of the Y-fixation technique using an artificial eye (Kitaro).



Go to **http://bit.ly/HrBqmB** to watch insertion of a 3-piece (7 mm) IOL (Santen Eternity) by Y-fixation technique.



Go to **http://bit.ly/17v4jL1** to watch insertion of a multifocal IOL (Alcon Laboratories) by Y-fixation technique.

(Videos courtesy of Toshihiko Ohta, MD)

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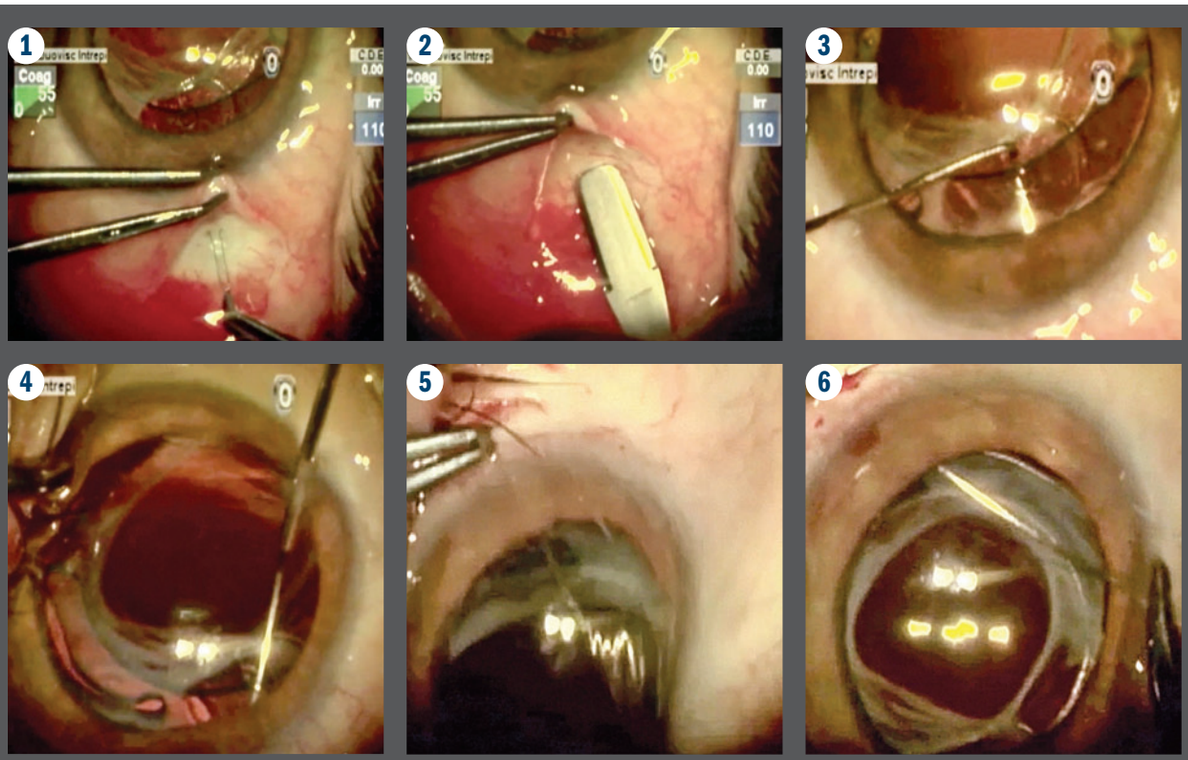
Managing subluxated IOL-bag complex

Fibrotic CCC rim serves as anchor for novel IOL-capsular bag repositioning technique

By Cheryl Guttman Krader; *Reviewed by Howard V. Gimbel, MD, MPH*



1 Broken Cionni ring suture being removed.

2 Reverse Hoffman tunnel for new Cionni ring suture.

3 Cionni eyelet engaged with new needle.

4 Needle captured with 26-gauge cannula.

5 Suture through fibrotic continuous curvilinear capsulorhexis (CCC).

6 Second needle of double-armed 9-0 prolene suture above the suture.

TAKE-HOME

- ***Multipoint scleral suture fixation through the fibrotic rim of a continuous curvilinear capsulorhexis results in stable recentration of a dislocated IOL-capsular bag complex.***

CALGARY, ALBERTA ::

SCLERAL SUTURE FIXATION of the entire IOL-capsular bag complex through the fibrotic rim of the continuous curvilinear capsulorhexis (CCC) is an effective technique for achieving stable IOL recentration in cases of IOL-capsular bag subluxation.

In addition, it offers advantages compared with other approaches for managing this late complication, according to Howard V. Gimbel, MD, MPH.

The fixation is performed using 9-0 or 10-0 Prolene double-armed sutures to anchor only the fibrotic CCC to the sclera using a modified Hoffman technique.

Depending on the situation, anywhere between 2 and 4 sutures may be passed to center the IOL-bag complex precisely.

"The formation of a fibrous membrane at the CCC margin is a well-described phenomenon that is seen in cases of anterior capsular phimosis," said Dr. Gimbel, medical director Gimbel Eye Centre, Calgary, Alberta, and professor and chairman of ophthalmology, Loma Linda University, Loma Linda, CA.

However, this IOL repositioning technique uses the strength of the fibrotic tissue to the surgeon's advantage, he noted.

Dr. Gimbel

"In fact, it is amazing how much traction the rim can withstand as the sutures are pulled in different directions to position the IOL-bag complex," Dr. Gimbel said.

"Alternative approaches for managing the development of a subluxated IOL-capsular bag complex include suturing of the haptics and capsule to the iris or sclera or removing the IOL and replacing it using different types of lenses and fixation techniques," he said.

However, suturing the entire IOL-capsular bag complex using the fibrotic CCC rim circumvents the various drawbacks of those techniques as it maintains in-the-bag IOL fixation while avoiding IOL exchange, the need for pupil enlarging techniques, suturing through the Soemmering's ring, and identification of the haptics, he explained.

Dr. Gimbel said the ideal situation for using the technique he described is when the fibrotic ring around the CCC rim is smaller than the IOL optic to provide a complete ring of fibrosis without the anterior capsule being adherent to the posterior capsule.

A measurement of the white-to-white corneal diameter is made in case a decision is made to convert to implantation of an anterior chamber IOL.

If there is vitreous prolapse, a two-port anterior vitrectomy is performed first using triamcinolone for staining.

When performing vitrectomy, the IOL may be stabilized using a single-armed 10-0 Prolene suture passed through the capsular membrane.

Continues on page 21 : ***IOL-bag complex***

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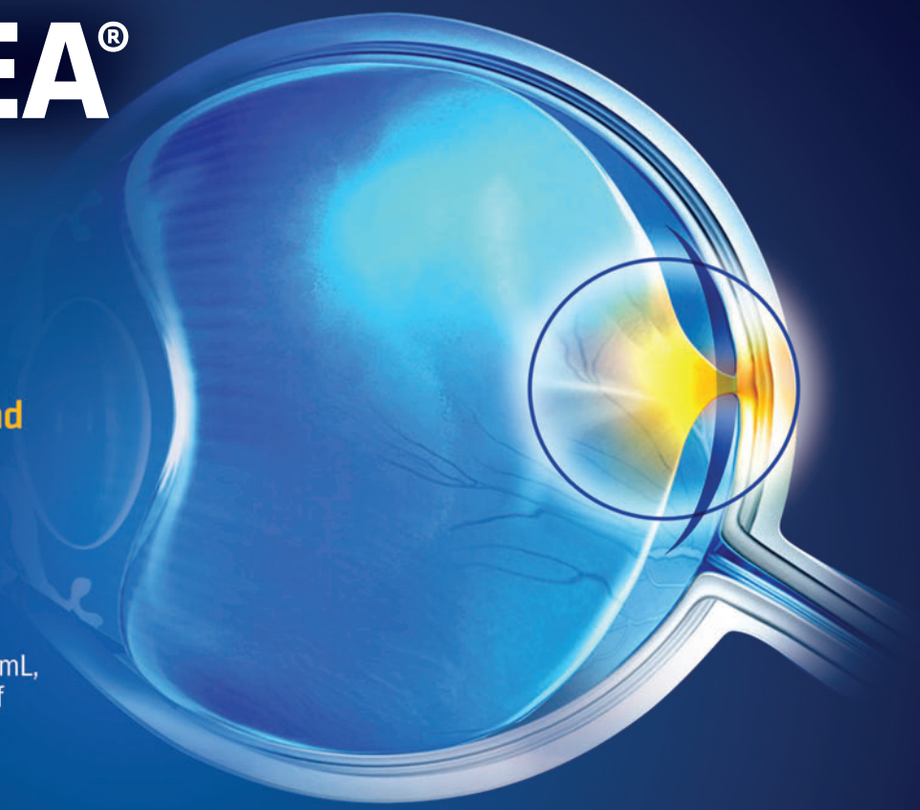

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Indication

JETREA® (ocriplasmin) Intravitreal Injection, 2.5 mg/mL, is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion (VMA).

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- A decrease of ≥3 lines of best-corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with JETREA® and 3.2% of patients treated with vehicle in the controlled trials. The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention. Patients should be monitored appropriately.
- Intravitreal injections are associated with intraocular inflammation/infection, intraocular hemorrhage, and increased intraocular pressure (IOP). Patients should be monitored and instructed to report any symptoms without delay. In the controlled trials, intraocular inflammation occurred in 7.1% of patients injected with JETREA® vs 3.7% of patients injected with vehicle. Most of the post-injection intraocular inflammation events were mild and transient. If the contralateral eye requires treatment with JETREA®, it is not recommended within 7 days of the initial injection in order to monitor the post-injection course in the injected eye.
- Potential for lens subluxation.
- In the controlled trials, the incidence of retinal detachment was 0.9% in the JETREA® group and 1.6% in the vehicle group, while the incidence of retinal tear (without detachment) was 1.1% in the JETREA® group and 2.7% in the vehicle group. Most of these events occurred during or after vitrectomy in both groups.
- Dyschromatopsia (generally described as yellowish vision) was reported in 2% of all patients injected with JETREA®. In approximately half of these dyschromatopsia cases, there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

Adverse Reactions

- The most commonly reported reactions (≥5%) in patients treated with JETREA® were vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, and retinal edema.

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

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BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

Please see the JETREA® package insert for full Prescribing Information.

1 INDICATIONS AND USAGE
JETREA is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion.

2 DOSAGE AND ADMINISTRATION
2.1 General Dosing Information
Must be diluted before use. For single-use ophthalmic intravitreal injection only. JETREA must only be administered by a qualified physician.

2.2 Dosing
The recommended dose is 0.125 mg (0.1 mL of the diluted solution) administered by intravitreal injection to the affected eye once as a single dose.

2.3 Preparation for Administration
Remove the vial (2.5 mg/mL corresponding to 0.5 mg ocriplasmin) from the freezer and allow to thaw at room temperature (within a few minutes). Once completely thawed, remove the protective polypropylene flip-off cap from the vial. The top of the vial should be disinfected with an alcohol wipe. Using aseptic technique, add 0.2 mL of 0.9% w/v Sodium Chloride Injection, USP (sterile, preservative-free) into the JETREA vial and gently swirl the vial until the solutions are mixed.

Visually inspect the vial for particulate matter. Only a clear, colorless solution without visible particles should be used. Using aseptic technique, withdraw all of the diluted solution using a sterile #19 gauge needle (slightly tilt the vial to ease withdrawal) and discard the needle after withdrawal of the vial contents. Do not use this needle for the intravitreal injection.

Replace the needle with a sterile #30 gauge needle, carefully expel the air bubbles and excess drug from the syringe and adjust the dose to the 0.1 mL mark on the syringe (corresponding to 0.125 mg ocriplasmin). THE SOLUTION SHOULD BE USED IMMEDIATELY AS IT CONTAINS NO PRESERVATIVES. Discard the vial and any unused portion of the diluted solution after single use.

2.4 Administration and Monitoring
The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include the use of sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a broad spectrum microbiocide should be administered according to standard medical practice.

The injection needle should be inserted 3.5 - 4.0 mm posterior to the limbus aiming towards the center of the vitreous cavity, avoiding the horizontal meridian. The injection volume of 0.1 mL is then delivered into the mid-vitreous.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., eye pain, redness of the eye, photophobia, blurred or decreased vision) without delay *[see Patient Counseling Information]*.

Each vial should only be used to provide a single injection for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, and injection needles should be changed before JETREA is administered to the other eye, however, treatment with JETREA in the other eye is not recommended within 7 days of the initial injection in order to monitor the post-injection course including the potential for decreased vision in the injected eye.

Repeated administration of JETREA in the same eye is not recommended *[see Nonclinical Toxicology]*.

After injection, any unused product must be discarded.

No special dosage modification is required for any of the populations that have been studied (e.g. gender, elderly).

3 DOSAGE FORMS AND STRENGTHS
Single-use glass vial containing JETREA 0.5 mg in 0.2 mL solution for intravitreal injection (2.5 mg/mL).

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS
5.1 Decreased Vision
A decrease of ≥ 3 line of best corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with JETREA and 3.2% of patients treated with vehicle in the controlled trials *[see Clinical Studies]*.

The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention. Patients should be monitored appropriately *[see Dosage and Administration]*.

5.2 Intravitreal Injection Procedure Associated Effects
Intravitreal injections are associated with intraocular inflammation / infection, intraocular hemorrhage and increased intraocular pressure (IOP). In the controlled trials, intraocular inflammation occurred in 7.1% of patients injected with JETREA vs. 3.7% of patients injected with vehicle. Most of the post-injection intraocular inflammation events were mild and transient. Intraocular hemorrhage occurred in 2.4% vs. 3.7% of patients injected with JETREA vs. vehicle, respectively. Increased intraocular pressure occurred in 4.1% vs. 5.3% of patients injected with JETREA vs. vehicle, respectively.

5.3 Potential for Lens Subluxation
One case of lens subluxation was reported in a patient who received an intravitreal injection of 0.175 mg (1.4 times higher than the recommended dose). Lens subluxation was observed in three animal species (monkey, rabbit, minipig) following a single intravitreal injection that achieved vitreous concentrations of ocriplasmin 1.4 times higher than achieved with the recommended treatment dose. Administration of a second intravitreal dose in monkeys, 28 days apart, produced lens subluxation in 100% of the treated eyes *[see Nonclinical Toxicology]*.

5.4 Retinal Breaks
In the controlled trials, the incidence of retinal detachment was 0.9% in the JETREA group and 1.6% in the vehicle group, while the incidence of retinal tear (without detachment) was 1.1% in the JETREA group and 2.7% in the vehicle group. Most of these events occurred during or after vitrectomy in both groups. The incidence of retinal detachment that occurred pre-vitrectomy was 0.4% in the JETREA group and none in the vehicle group, while the incidence of retinal tear (without detachment) that occurred pre-vitrectomy was none in the JETREA group and 0.5% in the vehicle group.

5.5 Dyschromatopsia
Dyschromatopsia (generally described as yellowish vision) was reported in 2% of all patients injected with JETREA. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

6 ADVERSE REACTIONS
The following adverse reactions are described below and elsewhere in the labeling:

- Decreased Vision *[see Warnings and Precautions]*
- Intravitreal Injection Procedure Associated Effects *[see Warnings and Precautions and Dosage and Administration]*
- Potential for Lens Subluxation *[see Warnings and Precautions]*
- Retinal Breaks *[see Warnings and Precautions and Dosage and Administration]*

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

Approximately 800 patients have been treated with an intravitreal injection of JETREA. Of these, 465 patients received an intravitreal injection of ocriplasmin 0.125 mg (187 patients received vehicle) in the 2 vehicle-controlled studies (Study 1 and Study 2).

The most common adverse reactions (incidence 5% - 20% listed in descending order of frequency) in the vehicle-controlled clinical studies were: vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, and retinal edema.

Less common adverse reactions observed in the studies at a frequency of 2% - < 5% in patients treated with JETREA included macular edema, increased intraocular pressure, anterior chamber cell, photophobia, vitreous detachment, ocular discomfort, iritis, cataract, dry eye, metamorphopsia, conjunctival hyperemia, and retinal degeneration.

Dyschromatopsia was reported in 2% of patients injected with JETREA, with the majority of cases reported from two uncontrolled clinical studies. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. Immunogenicity for this product has not been evaluated.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy: Teratogenic Effects
Pregnancy Category C. Animal reproduction studies have not been conducted with ocriplasmin. There are no adequate and well-controlled studies of ocriplasmin in pregnant women. It is not known whether ocriplasmin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The systemic exposure to ocriplasmin is expected to be low after intravitreal injection of a single 0.125 mg dose. Assuming 100% systemic absorption (and a plasma volume of 2700 mL), the estimated plasma concentration is 46 ng/mL. JETREA should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers
It is not known whether ocriplasmin is excreted in human milk. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, caution should be exercised when JETREA is administered to a nursing woman.

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

8.5 Geriatric Use
In the clinical studies, 384 and 145 patients were ≥ 65 years and of these 192 and 73 patients were ≥ 75 years in the JETREA and vehicle groups respectively. No significant differences in efficacy or safety were seen with increasing age in these studies.

10 OVERDOSAGE
The clinical data on the effects of JETREA overdose are limited. One case of accidental overdose of 0.250 mg ocriplasmin (twice the recommended dose) was reported to be associated with inflammation and a decrease in visual acuity.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No carcinogenicity, mutagenicity or reproductive and developmental toxicity studies were conducted with ocriplasmin.

13.2 Animal Toxicology and/or Pharmacology
The ocular toxicity of ocriplasmin after a single intravitreal dose has been evaluated in rabbits, monkeys and minipigs. Ocriplasmin induced an inflammatory response and transient ERG changes in rabbits and monkeys, which tended to resolve over time. Lens subluxation was observed in the 3 species at ocriplasmin concentrations in the vitreous at or above 41 mcg/mL, a concentration 1.4-fold above the intended clinical concentration in the vitreous of 29 mcg/mL. Intraocular hemorrhage was observed in rabbits and monkeys.

A second intravitreal administration of ocriplasmin (28 days apart) in monkeys at doses of 75 mcg/eye (41 mcg/mL vitreous) or 125 mcg/eye (68 mcg/mL vitreous) was associated with lens subluxation in all ocriplasmin treated eyes. Sustained increases in IOP occurred in two animals with lens subluxation. Microscopic findings in the eye included vitreous liquefaction, degeneration/disruption of the hyaloideo-capsular ligament (with loss of ciliary zonular fibers), lens degeneration, mononuclear cell infiltration of the vitreous, and vacuolation of the retinal inner nuclear cell layer. These doses are 1.4-fold and 2.3-fold the intended clinical concentration in the vitreous of 29 mcg/mL, respectively.

14 CLINICAL STUDIES
The efficacy and safety of JETREA was demonstrated in two multicenter, randomized, double masked, vehicle-controlled, 6 month studies in patients with symptomatic vitreomacular adhesion (VMA). A total of 652 patients (JETREA 464, vehicle 188) were randomized in these 2 studies. Randomization was 2:1 (JETREA:vehicle) in Study 1 and 3:1 in Study 2.

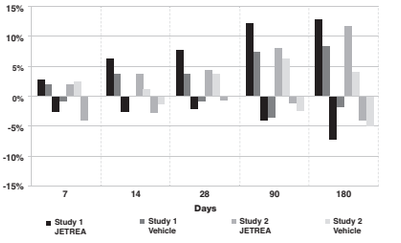
Patients were treated with a single injection of JETREA or vehicle. In both of the studies, the proportion of patients who achieved VMA resolution at Day 28 (i.e., achieved success on the primary endpoint) was significantly higher in the ocriplasmin group compared with the vehicle group through Month 6.

The number of patients with at least 3 lines increase in visual acuity was numerically higher in the ocriplasmin group compared to vehicle in both trials, however, the number of patients with at least a 3 lines decrease in visual acuity was also higher in the ocriplasmin group in one of the studies (Table 1 and Figure 1).

Table 1: Categorical Change from Baseline in BCVA at Month 6, Irrespective of Vitrectomy (Study 1 and Study 2)

Study 1			
	JETREA	Vehicle	Difference
	N=219	N=107	(95% CI)
≥ 3 line Improvement in BCVA			
Month 6	28 (12.8%)	9 (8.4%)	4.4 (-2.5, 11.2)
> 3 line Worsening in BCVA			
Month 6	16 (7.3%)	2 (1.9%)	5.4 (1.1, 9.7)
Study 2			
	JETREA	Vehicle	Difference
	N=245	N=81	(95% CI)
≥ 3 line Improvement in BCVA			
Month 6	29 (11.8%)	3 (3.8%)	8.1 (2.3, 13.9)
> 3 line Worsening in BCVA			
Month 6	10 (4.1%)	4 (5.0%)	-0.9 (-6.3, 4.5)

Figure 1: Percentage of Patients with Gain or Loss of ≥ 3 Lines of BCVA at Protocol-Specified Visits



16 HOW SUPPLIED/STORAGE AND HANDLING
Each vial of JETREA contains 0.5 mg ocriplasmin in 0.2 mL citric-buffered solution (2.5 mg/mL). JETREA is supplied in a 2 mL glass vial with a latex free rubber stopper. Vials are for single use only.

Storage
Store frozen at or below -4°F (-20°C). Protect the vials from light by storing in the original package until time of use.

17 PATIENT COUNSELING INFORMATION
In the days following JETREA administration, patients are at risk of developing intraocular inflammation/ infection. Advise patients to seek immediate care from an ophthalmologist if the eye becomes red, sensitive to light, painful, or develops a change in vision *[see Warnings and Precautions]*.

Patients may experience temporary visual impairment after receiving an intravitreal injection of JETREA *[see Warnings and Precautions]*. Advise patients to not drive or operate heavy machinery until this visual impairment has resolved. If visual impairment persists or decreases further, advise patients to seek care from an ophthalmologist.

Manufactured for:
ThromboGenics, Inc.
101 Wood Avenue South, 6th Floor
Iselin, NJ 08830

U.S. License Number: 1866

Version 1.0
Initial U.S. Approval: 2012
ThromboGenics U.S. patents: 7,445,775; 7,547,435; 7,914,783 and other pending patents.

05/13 OCRVMA0072 PI G

IOL-BAG COMPLEX

(Continued from page 18)

For the suture fixation technique, a dispersive viscoelastic (OcuCoat, Bausch + Lomb) is injected to maintain the anterior chamber and more instilled as needed. If two fixation sutures are to be used, 3-mm half-thickness scleral tunnel pocket incisions are created superiorly and inferiorly.

"I don't like the superior incision to be close to the visual axis, and therefore, the groove for the superior scleral pocket is made 2 mm posterior to the limbus," Dr. Gimbel said. "Inferiorly, the limbus is farther away from the visual axis and the corneal groove can be used to start the Hoffman tunnel."

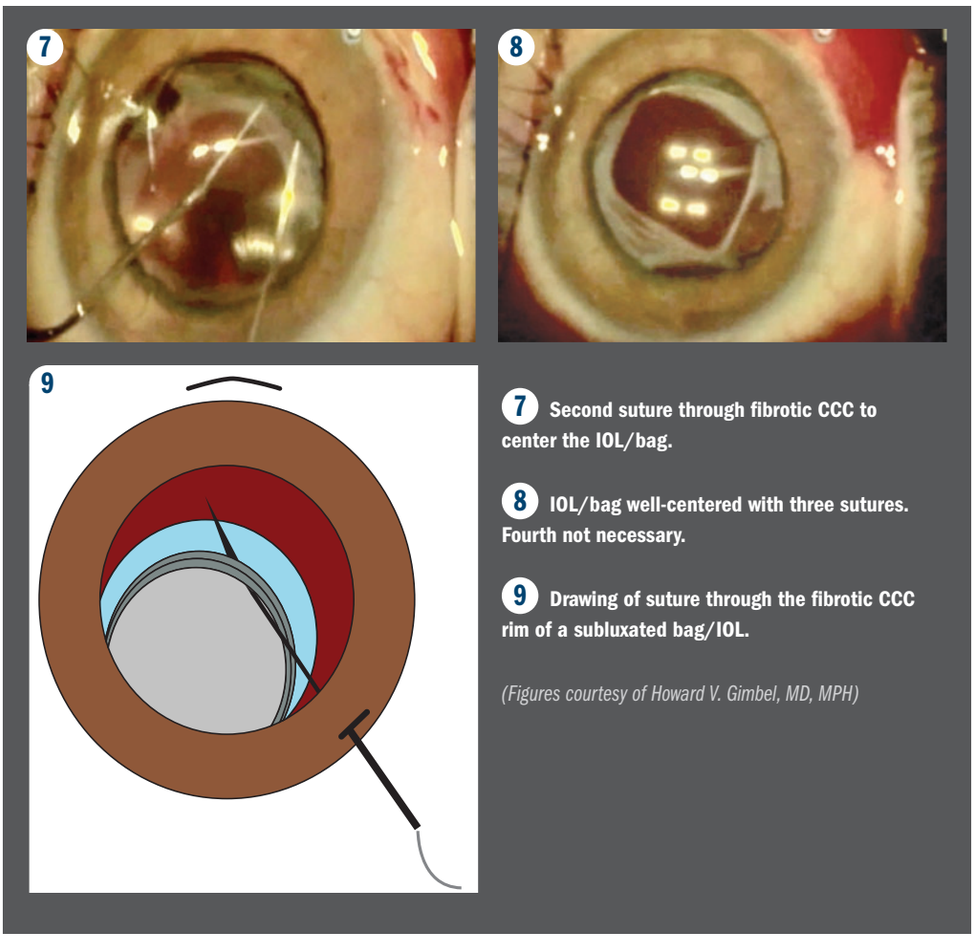
Once the scleral incisions are created, the first needle of a double-armed Prolene suture is passed through a paracentesis and the pupil, through the fibrotic CCC rim, behind the iris, and out through the superior scleral pocket, he explained.

Then, the second needle is passed in a similar manner, beginning from above the CCC. The sutures are looped out of the tunnel, used to adjust IOL centration, tied, and cut.

"I like to capture just the fibrotic element of the capsule so as to avoid disturbing Soemmering's ring material in the capsule and causing it to spill out of the capsular bag," Dr. Gimbel said.

If vitrectomy has been needed, additional triamcinolone is injected and further vitrectomy performed to be sure all vitreous is removed from around the loose IOL-capsular complex.

"Not using a superior corneal groove minimizes the potential for inducing astigmatism, especially irregular astigmatism," Dr. Gimbel said.



7 Second suture through fibrotic CCC to center the IOL/bag.

8 IOL/bag well-centered with three sutures. Fourth not necessary.

9 Drawing of suture through the fibrotic CCC rim of a subluxated bag/IOL.

(Figures courtesy of Howard V. Gimbel, MD, MPH)

Dr. Gimbel has used this IOL repositioning technique in relatively few eyes over the past few years, he noted.

However, occasion to use it may increase in the future considering that advancing age is one of the risk factors for IOL-capsular bag complex subluxation.

"When posterior capsule IOLs first came into use, Professor Jan Worst told me that they were a ticking time bomb with respect to the possibility of posterior dislocation because lens opacification is the first part of the aging process that progresses to increasing zonular laxity," Dr. Gimbel explained. ■

HOWARD V. GIMBEL, MD, MPH

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Dr. Gimbel has no relevant financial interests to disclose.

Y-FIXATION

(Continued from page 16)

with IOL suture fixation methods for minimizing complications and providing better optical results.

CASE SERIES

In a series of 44 eyes managed with the Y-fixation technique, vitreous hemorrhage and temporary increase in IOP were the most common complications, each occurring at a rate of 9%.

The rate of vitreous hemorrhage in a comparator group of 38 eyes was 18% and significantly higher than in the Y-fixation series, while there was no significant difference between groups in the rate of temporary IOP elevation.

However, the incidence of IOL dislocation/tilt was also significantly higher in the sutured fixation group compared with the eyes operated on with the Y-fixation technique (18% versus 5%).

Consistent with the latter results, mean IOL astigmatism, calculated by subtracting corneal astigmatism from total astigmatism, was significantly less in eyes that underwent the Y-fixation procedure compared with eyes having a sutured IOL (0.51 versus 0.84 D).

"However, there was no significant difference in IOL astigmatism comparing the Y-fixation eyes with a control group having an in-the-bag IOL," Dr. Ohta concluded. ■

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Dr. Ohta has no relevant financial interests to disclose.

'Telling It Like It Is!' enhances already-robust lineup for 2014

Glaucoma, retina, neuro, practice management add diversity to successful Florida meeting

By Beth Thomas Hertz

SARASOTA, FL ::

THE FOURTH ANNUAL "Cataract Surgery: Telling It Like It Is!" meeting here Jan. 16 to 19, 2014, promises to cover more ground than ever—adding sessions on glaucoma, retina, optical coherence tomography, cornea, neuro-ophthalmology, and practice management.

"We are totally re-engineering this meeting to add other disciplines, while continuing to give attendees encyclopedic coverage of the field of cataract surgery through lectures and hands-on experience," said Robert H. Osher, MD, meeting chairman and professor of ophthalmology, University of Cincinnati, Cincinnati, OH.

Dr. Osher

"It is no surprise that we have sold out each of our three previous meetings given that we have an all-star faculty that provides the highest quality uncensored education at an affordable price," said Dr. Osher, who is also medical director emeritus of the Cincinnati Eye Institute, and editor of the *Video Journal of Cataract and Refractive Surgery*. "If you only go to one cataract meeting this year, this should be it."

MORE, MORE, MORE

After reading nearly 400 evaluations from the 2013 meeting, Dr. Osher decided to add "more faculty, more topics, and more fireworks! We want every attendee to depart Sarasota more confident about delivering the best possible surgical care."

Dr. Osher stressed that the top-notch faculty is what really sets this course apart.

Among faculty members returning from last year are Richard Mackool, MD; Ike Ahmed, MD; Warren Hill, MD; Michael Snyder, MD; Lisa Arbisser, MD; Robert Weinstock, MD; and Bill Fishkind, MD.

New faces will include Deepinder K. Dhaliwal, MD, directing the cornea sessions; Daniel Miller, MD, PhD, and Christopher Riemann, MD, offering retina; Steven Vold, MD, and Anup Khatana, MD, on glaucoma; Michael Hater, MD, on cataract; and John Pinto on practice management. This year's International Speaker is Fernando Trindade, MD, of Brazil, who has won multiple ASCRS Grand Prize Film Festival awards, Dr. Osher said.

The meeting does not offer CME credits (except for an Ophthalmic Mutual Insurance Co. seminar on risk management). This allows presenters to be open and unrestricted in what they discuss, Dr. Osher said.

"The censors are uninvited," he said. "We can teach the way we feel we should teach."

The meeting will feature more wet labs than previous years. In addition, it will continue to offer some of its most popular sessions, including "The Mike and Ike Show," a rapid-fire, challenging case session with videos from Drs. Ahmed and Snyder.

The popular new technology symposium will return, this year featuring head-to-head comparisons of femtosecond lasers, toric IOLs, microscopes, and more. Many companies will participate. A discussion of complications and how to manage them, and one on choosing IOLs, are other highly rated seminars that will return.

Preceding the meeting, on Wednesday, Jan. 15, from 6:30 to 8 p.m., Dr. Osher will again offer his optional Wednesday Night at the Movies, where he shares the best videos from the archives of the *Video Journal of Cataract and Refractive Surgery*. A buffet dinner is included at this event, which is held at the Hyatt Regency Sarasota Hotel.

"About 100 people typically attend this free pre-meeting night," Dr. Osher said.

Also new this year, Dr. Osher has partnered with the American Academy of Ophthalmology to improve the meeting's logistics.

"They are great meeting planners and are doing a great job organizing this one," Dr. Osher said. "They have helped us find a way to accommodate 500 attendees this year, up from about 400 last year. It is coming together very well. We are thrilled to partner with them."

He notes that the meeting offers an excellent value for the money (see "Meeting Logistics"), offering 12 hours a day of quality programming. ■

Meeting Logistics

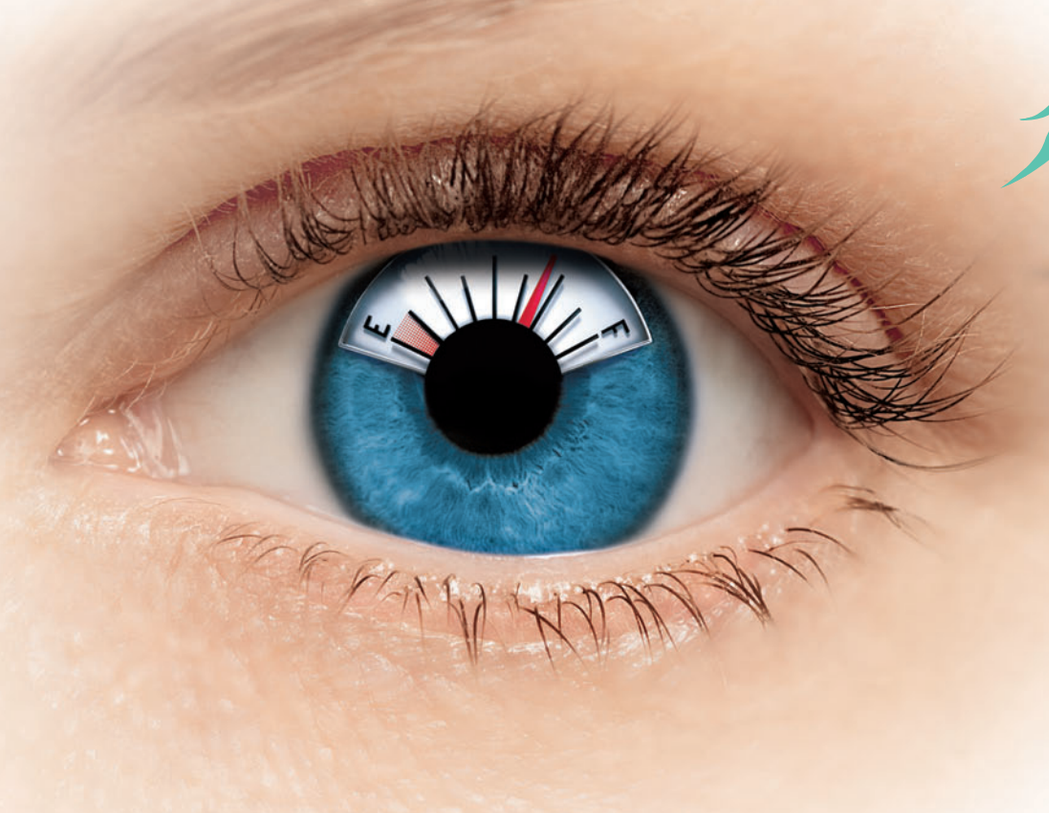
REGISTRATION FEES include general sessions, movie nights, tutorials, exhibits, New Technology Symposium, sponsored breakfasts, and lunches as noted on program agenda. Wet labs are an additional fee and are subject to class size limitations. For practicing physicians, the advance registration fee (register now to Dec. 18) is $550. The resident/fellow rate is $300. Onsite registration, if space allows, is $600.

ROOM BLOCKS have been reserved at the Ritz-Carlton, Sarasota and the Hyatt Regency Sarasota. The Wednesday Night at the Movies event will be held at the Hyatt Regency Sarasota; all other educational activities and events will be held at The Ritz-Carlton, Sarasota. The Hyatt Regency and the Ritz-Carlton are within easy walking distance of each other.

CONTACT The Ritz-Carlton at 941/309-2000 or *www.ritzcarlton.com/en/Properties/Sarasota/Contact/Default.htm*. Room rate: single/double deluxe room $269 plus tax. Rates guaranteed through Dec. 20. Complimentary amenities for meeting attendees over program dates: Wi-Fi in hotel room, use of the resort fitness center, and turndown service.

CONTACT the Hyatt Regency Sarasota on Sarasota Bay at 941/ 953-1234 or *http://www.sarasota.hyatt.com/en/hotel/home.html*. Room Rate: single/double room $189 plus tax. Rates guaranteed through Dec. 16. Complimentary amenities for meeting attendees over program dates: Wi-Fi in hotel room, and use of the resort fitness center. Note: When making a reservation at the Hyatt, attendees will be asked to provide their "Guest Type." Click on the drop-down menu and select "Attendee" from the list.

For more information about the meeting, visit ***http://www.cstellingitlikeitis.com.***



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Important Safety Information

Contraindications

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Warnings and Precautions

Potential for Eye Injury and Contamination: To avoid the potential for eye injury and contamination, individuals prescribed RESTASIS® should not touch the vial tip to their eye or other surfaces.

Use With Contact Lenses: RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion.

Adverse Reactions

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (upon instillation)—17%. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

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

ALLERGAN

Understanding convergence insufficiency

A look at orthoptics/vision therapy advances and why more prospective studies are needed

By Lynda Charters; *Reviewed by Jennifer Lambert, CO*

BOSTON ::

Convergence insufficiency is a common clinical entity with wide prevalence rates reported from less than 1% to 8.3%, said Jennifer Lambert, CO, who examined the most current research findings regarding various treatments for the disorder.

"Convergence insufficiency is . . . a near exodeviation of at least 10 to 15 prism D greater than the distance deviation," said Lambert, an orthoptist, Boston Medical Center and clinical instructor, Boston University School of Medicine. "Patients have remote near points and poor convergence amplitudes."


Lambert

Treatments range from pencil push-ups to computer-based programs and surgery for symptoms that include asthenopia, diplopia, blurring of letters at near, headache, and closing of an eye.

Four types of involuntary convergence are recognized: tonic, proximal, accommodative, and fusional. Vergence is stimulated by retinal blur and retinal disparity.

Initial knowledge about the vergence pathway indicated that the occipital cortex signals vergence premotor neurons in the midbrain reticular formation. More recent research shows that this is a biphasic response: a vergence "pulse" initiates the movement—i.e., proximal convergence—and the vergence "step" is longer and finishes the convergence action—i.e., fusional and accommodative convergence.

"Most current orthoptic treatments are designed to increase fusional convergence amplitudes," Lambert said. "However, research indicates the pulse phase responds more to training. The improvement is temporary with no improvement in the step phase."

SIX TRIALS

Regarding current treatments, the Cochrane Collaboration reviewed six trials that included 475 patients who underwent non-surgical treatment of convergence insufficiency, defined as an exophoria at near greater than distance.

All patients had decreased near points or decreased convergence amplitudes at near. Primary outcomes were the near point of convergence and convergence amplitudes at 12 weeks.

The six trials included were:

- **Birnbaum et al. (*J Am Optom Assoc.* 1999;70:225-232) evaluated home-based versus office-based therapy and included 60 men over age 40.**
- **The Convergence Insufficiency Treatment Trial [CITT] (*Br J Ophthalmol.* 2005; 89:1318-1323) evaluated base-in prism versus placebo reading glasses and included 72 patients aged 9 to 18 years.**

TAKE-HOME

- ***Recent randomized clinical trials have been advancing the understanding of current treatments for convergence insufficiency.***

- The second CITT study (*Arch Ophthalmol.* 2005; 123:14-24) evaluated home versus office therapy with an office-based therapy placebo group and included 47 patients aged 9 to 18 years.

- The third CITT study (*Optom Vis Sci.* 2005; 82:583-595) evaluated the same treatment as the second study and included 46 patients aged 19 to 30.

- The fourth CITT study (*Arch Ophthalmol.* 2008; 126:1336-1349) evaluated home-based pencil push-ups, home-based computer orthoptics and pencil push-ups, office-based computer orthoptics with home-based reinforcement, and office-based placebo with home-based reinforcement. There were 221 patients aged 9 to 17 who participated.

- Teitelbaum et al. (*Optom Vis Sci.* 2009; 86:153-156) evaluated base-in prism with progressive lenses versus progressive lenses only and included 29 patients older than age 45 years.

Results of the analysis indicated that in children there was no statistical significance of the base-in prism reading glasses for near point convergence, convergence amplitudes or the score of the Convergence Insufficiency Symptom Survey questionnaire. In adults, the base-in prism with a progressive lens was more effective for symptom relief.

Evaluation of the orthoptics/vision therapy showed office-based orthoptics was more effective than home-based orthoptics and office-based placebo.

No significant difference between home-based computer orthoptics and home-based pencil push-ups was found. Investigators found mixed results when they compared home-based pencil push-ups with office-based placebo. Home-based computer orthoptics were found to be more effective than office-based placebo, Lambert said.

The analysis also evaluated compliance with therapy in the CITT study performed in 2008. Patients receiving office-based therapies had a higher compliance rate than the home-based therapy cohort.

"Studies have shown that proximal and tonic vergence may be amenable to therapy," Lambert said. "Exercises such as jump vergence with base-out prism or sustained near work with base-out prism may be possible areas of study."

One study currently under way, conducted by the Pediatric Eye Disease Investigator Group, is evaluating home-based computer orthoptics versus home-based pencil push-ups.

"More prospective studies are needed to investigate other convergence types and their roles in convergence insufficiency," Lambert said. ■

JENNIFER LAMBERT, CO

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Lambert has no financial interest in any aspect of this report.

Glaucoma 360° covers every 'angle'

2014 meeting to encompass latest updates on disease, diagnosis and treatment, advances

By Jennifer A. Webb

TAKE-HOME

- ***Glaucoma 360° is designed to offer 3 days of the latest news in glaucoma from all perspectives.***

SAN FRANCISCO :: **OPHTHALMOLOGISTS OR THOSE** in the greater ophthalmic community who are seeking an all-encompassing meeting on all things glaucoma need look no further than Glaucoma 360°.

The 3-day event, Feb. 6 to 8, 2014, is designed to offer the latest news in glaucoma from all perspectives. It is the only meeting of its kind built to update glaucoma specialists quickly as well as those who work with or are treated by them.

The program also will interest those who:

- Treat patients with glaucoma;
- Research glaucoma pharmaceutical treatments;
- Invest in or contribute money toward glaucoma solutions or advise those who do;
- Invent glaucoma devices;
- Teach residents about glaucoma;
- Seek regulatory approval for glaucoma products.

Beginning with a black-tie gala and fundraiser benefiting the Glaucoma Research Foundation (GRF), the event includes a day of fast-paced and informative updates from every segment known to touch glaucoma, followed by a half-day course in which physicians may glean the latest clinical news and earn continuing medical education credits.


Dr. Graves

The event, now in its third year, was conceived by Adrienne Graves, PhD, who serves on the GRF Board of Directors and is the former president and chief executive officer (CEO) of Santen Inc., and Andrew G. Iwach, MD, GRF board chairman, and executive director, Glaucoma Center of San Francisco. Drs. Graves and Iwach now co-chair Glaucoma 360°, working with a broad-based board to uncover and invite those in the field who can contribute new ideas. *Ophthalmology Times* is a sponsor of the event.


Dr. Iwach

"The meeting covers a broad range of topics with experts in the field," said Andrew G. Iwach, MD, founder and co-chairman, Glaucoma 360°; GRF board chairman; and executive director, Glaucoma Center of San Francisco. "It is a changing field, and we are delighted and honored that we are able to assemble such an accomplished group, all dedicated to new developments in glaucoma."

ANNUAL GALA

Organizers hope attendees will come in Thursday to support the foundation and enjoy the gala, which will honor the contributions of William J. Link, PhD, managing director of Versant Ventures, who has been a leading provider of capital to ophthalmic startups, including glaucoma surgical device maker Glaukos. Dr. Link will receive the Catalyst Award.

GLAUCOMA RESEARCH FOUNDATION
GLAUCOMA 360

The gala also will honor singer Judy Collins, who has used her high profile to raise awareness of glaucoma and other social causes over several decades. Collins, who will receive the Visionary Award, also will perform at the dinner, which is held at the Palace Hotel, San Francisco.

"She's been an advocate for glaucoma (research) and is vocal about the fact that it's in her family," said Thomas M. Brunner, GRF president and CEO.

On top of the glam and sparkle of the reception and live auction, the dinner allows benefactors to meet researchers—up and coming, as well as those who are more established—and discuss their work. It also exposes scientists to those who suffer with glaucoma and can explain their hardships, Brunner said.

"The scientists we fund have told us many times they never really had a grant where the grantor is so involved in it, where they've had this wonderful opportunity to interact with patients who benefit from their research," he said. "They learn first hand what it's like to have glaucoma or low vision with glaucoma, and their frustration with the current treatments. We hope it will ultimately lead to products and devices that are going to benefit patients."

THE QUEST FOR A CURE

VIDEO Andrew G. Iwach, MD, Glaucoma Research Foundation board chairman, discusses Glaucoma 360°. Go to **http://bit.ly/1f24IJw.**
(Video courtesy of Glaucoma Research Foundation)

NEW HORIZONS FORUM

The New Horizons Forum the following day will feature an opening keynote address by Robert N. Weinreb, MD, as the inaugural Drs. Henry and Frederick Sutro Memorial Lecturer. Dr. Weinreb, chairman and distinguished professor of ophthalmology, University of California, San Diego, and director of its Shiley Eye Center and Hamilton Glaucoma Center, will speak on "Personalizing IOP to Manage Glaucoma."

Dr. Graves noted this year's keynote speaker "epitomizes innovation in glaucoma. Dr. Weinreb has built interdisciplinary teams that have advanced our understanding of the pathophysiology of glaucoma, as well as its clinical detection and treatment. His contributions on both the basic and clinical side have been enormous."

The New Horizons Forum is designed to foster face-to-face interaction with experts so that those who have an idea for a new product or technique, for example, may connect

Continues on page 28 : ***Glaucoma 360°***

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President, Ellex Inc.

GLAUCOMA 360°

(Continued from page 26)

directly with people in industry or venture capital who can develop that idea, and with the regulatory officials who can advise them on the process.

Question-and-answer sessions follow every panel discussion and speaker, and audience members are encouraged to share insights or further explore a topic.

Breaks are planned as opportunities to approach key individuals on topics that relate to the work at hand.

In addition to a cocktail reception and breaks, attendees can look at lunch for key opinion leaders who will be seated at specific tables and ready for conversation.

Speakers and discussion leaders include William L. Rich III, MD, medical director of health policy, American Academy of Ophthalmology; Eliot Lazar, MD, president, elCON Medical (Buffalo, NY); Ronald L. Gross, MD, chairman and director of West Virginia University Eye Institute; Stuart B. Abelson, president and CEO, Ora Inc. (Andover, MA); Gary D. Novack, PhD, president, Pharmalogic (San Rafael, CA); J. Casey McGlynn, partner, Wilson Sonsini Goodrich and Rosati (Palo Alto, CA); Ike Ahmed, MD, FRCSC, assistant professor, faculty of medicine, University of Toronto; Alan S. Crandall, MD, senior vice chairman of ophthalmology and visual sciences, John A. Moran Eye Center/University of Utah, Salt Lake City; L. Jay Katz, MD, director, Glaucoma Services, Wills Eye Institute, Philadelphia; Ruth D. Williams, MD, president, Wheaton Eye Clinic (Wheaton, IL); and Richard L. Lindstrom, MD, founder, Minnesota Eye Consultants P.A. (Minneapolis).

"This year, we are trying to include emerging technologies that haven't been in trial yet," Brunner said. "It's something you can use to give hope to your patients. Some of them will be sharing unpublished or undisclosed data from their clinical trials and from their use of the product."

GLAUCOMA SYMPOSIUM CME

The final day of the event offers continuing medical education to ophthalmologists. The Glaucoma Symposium CME, in its 18th year, is presented by Glaucoma Research and Education Group in partnership with GRF, and is designed to offer physicians the latest updates on the most effective treatment options.

Michael V. Drake, MD, chancellor, University of California, Irvine, will deliver the 2014 Shaffer-Hetherington-Hoskins Lecture. The rest of the half-day meeting will include updates on glaucoma medications and laser treatment, complexities encountered with cataract surgery in glaucoma patients; reliability of glaucoma testing; and new surgical procedures.

"If there's something new going on in glaucoma," Brunner said, "this is the meeting where you're going to find out about it." ■

For more information about the Glaucoma 360° meeting program, visit ***http://bit.ly/qDliZK.***

Genetics aid AMD risk assessment

By Cheryl Guttman Krader

SAN DIEGO ::

INCLUSION OF CLINICALLY RELEVANT genetic markers improves the accuracy of predicting risk of progression to choroidal neovascularization (CNV) in patients with age-related macular degeneration (AMD) beyond a prediction based on only phenotypic risk factors, according to a recent cohort study.

"There have been many genetic, clinical, demographic, and environmental factors associated with progression to CNV in patients with AMD," said Lorah Perlee, PhD, vice president, scientific affairs, Sequenom Inc., San Diego.

"However, disease stage has been the most widely used method for anticipating risk of conversion," Dr. Perlee said.

The use of a CNV prediction model—combining genotype and phenotype—allows for greater stratification of individuals within the same grade of disease and allows for individualized risk assessment based on an individual's genetic predisposition, according to Dr. Perlee.

The analyses (*Ophthalmology.* 2013;120:1880-1892) used data from 2,415 participants in the Age-Related Eye Disease Study (AREDS). At baseline, 940 of the patients were free of disease and 1,475 had early or intermediate AMD.

During follow-up through 10 years, 603 subjects converted to CNV.

DNA specimens from all subjects were genotyped using single nucleotide polymorphisms in genes associated with the development of CNV, including CFH and related genes, C2, C3, FB, and ARMS2.

Phenotype was assessed at baseline using the AREDS simplified severity scale—the fundus grading system stratifying patients into five risk categories for progression to advanced AMD (grade 0 to 4) based on assessment of drusen and pigment abnormalities in both eyes.

The dataset was partitioned into a training set and a validation set, which were balanced with respect to progression, age gender, and smoking status.

Cox proportional hazards progression analysis was performed to assess individual disease-associated variables to generate predictive algorithms based on phenotype alone or including genotype.

In the validation testing, comparison of model accuracy for predicting CNV based on test sensitivity and specificity showed a statistically significant difference favoring the model, including genotype versus that based on phenotype alone.

The phenotype only model also provided only a single estimate for each risk category, Dr. Perlee added.

For example, all subjects in the highest risk category—grade 4—would be assigned a 65% probability of developing CNV after 10 years.

"Adding genotype resulted in greater stratification within each phenotype group, reflecting that risk of progression varies depending on an individual's genetic burden," Dr. Perlee said.

"Therefore, it is not surprising that we can find subjects with a grade 3 phenotype and a high genetic burden who have a higher risk of developing CNV than individuals with a grade 4 phenotype but a low genetic burden," Dr. Perlee added. ■

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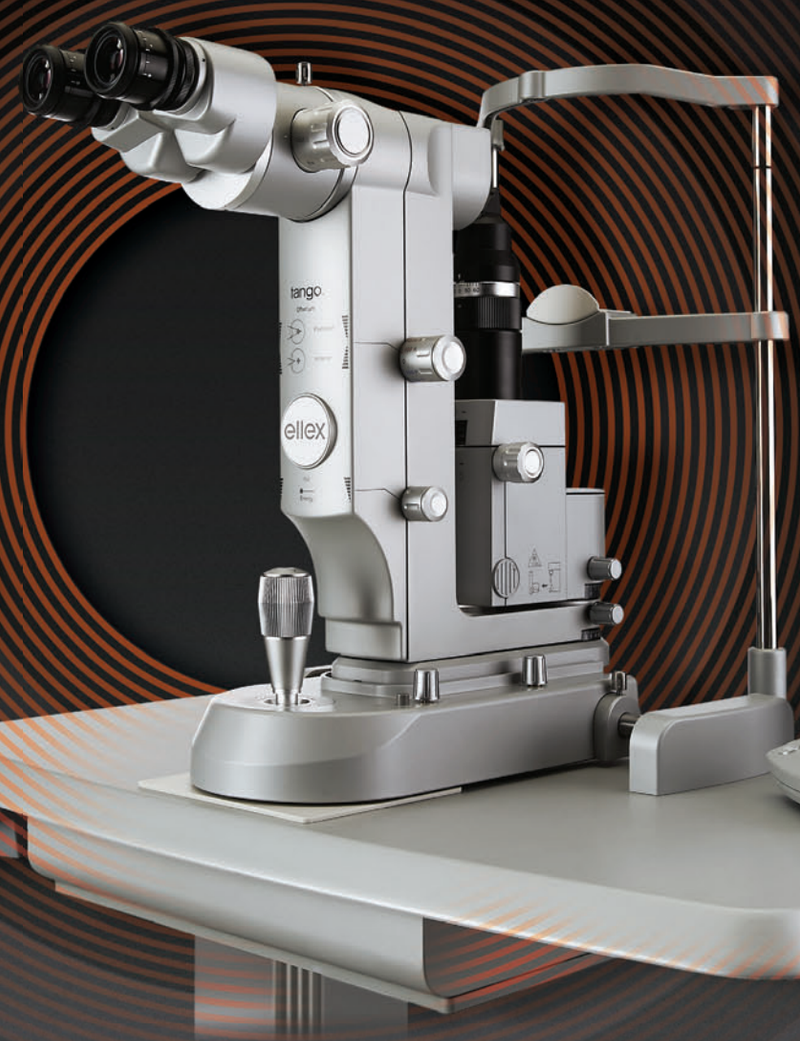

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HOW CHILDREN BENEFIT FROM 'OBAMACARE'

Crucial pediatric vision services are now covered under the new health-care law

By Rose Schneider, *Content Specialist,* Ophthalmology Times

WASHINGTON, DC ::

With children's vision-care benefits included in plans participating in the health insurance exchanges, millions of parents no longer have to avoid getting their child's vision checked or corrected due to cost concerns.

Because the Affordable Care Act—also known as "Obamacare"—has designated pediatric vision services as one of 10 essential health benefits, beginning in Jan. 2014, all individual and small groups with 50 or fewer employees have to provide those health plan benefits for children up to 19 years of age.

Effective Jan. 2016, coverage will expand to individual and small groups with 100 or fewer employees.

"(The pediatric vision provision) is a great thing," said Michael X. Repka, MD, medical director for governmental affairs, American Academy of Ophthalmology (AAO). "It means that children who have a vision problem will have coverage in any health-care plan . . . (and) it reverses many commercial plans which didn't cover refractive care."

Among the essential services the pediatric vision provision includes are routine comprehensive eye exams and follow-up care. These services were not typically covered previously by insurance plans, Dr. Repka said.

"Good vision is key to a child's physical development, school success, and well-being," he said. "The new (pediatric vision provision) makes it easy for parents to ensure that their children have a healthy start in life and aren't left behind due to sight problems."

take-home

The Affordable Care Act's provision stating vision services for children are essential will help increase the number of young people able to receive check-ups and follow-up care, which are crucial for their well-being.

BEFORE 'OBAMACARE'

Prior to the health-care overhaul, the Campaign for Children's Health Care conducted a study ("No Shelter from the Storm: America's Un-

Continues on page 34 : ***Vision plan***

Uninsured Children By Age, 2005

AGE	NUMBER UNINSURED	PERCENT OF AGE GROUP UNINSURED	AS PERCENT OF ALL UNINSURED CHILDREN
0-5	2,623,360	10.8%	29.0%
6-12	2,847,701	10.3%	31.5%
13-18	3,564,360	13.8%	39.4%
Total	9,035,420	11.6%	100.0%

Source: Analysis conducted by Mark Merlis for Families USA based on the Census Bureau's most recent Current Population Survey. Numbers may not add due to rounding.

*Access to Health Care And Unmet Health Care Needs Among Children, 2005**

	CHILDREN INSURED A YEAR OR MORE	CHILDREN UNSURED A YEAR OR MORE
Doctor Visits in the Past Year		
0 Visits	9.9%	31.1%
1 or more visits	90.1%	68.9%
Had at Least One Well-Child Visit in the Past Year		
Yes	74.0%	46.4%
No	26.0%	53.6%
Have a Usual Source of Care		
Yes	97.5%	67.0%
No	2.3%	30.3%
Delayed or Unmet Needs in the Past Year Due to Cost**	7.2%	3.47%
Unmet Dental Need	1.9%	10.0%
Unmet Vision Need	4.6%	23.3%
Unmet Prescription Need	1.5%	5.6%
Unmet Mental Health Need	0.6%	1.9%
Any Other Delayed or Unmet Medical Need	2.1%	20.0%

Source: Analysis conducted by the Urban Institute for families USA based on the 2005 National Health Interview Survey. Numbers may no add due to rounding.
** Sample includes children ages 2-17 only.*
***Delayed or unmet needs indude medical, dental, vision, prescription, mental health, and any other medical needs.*
Note: Numbers in Figure 1 on Page 34 are from this table.

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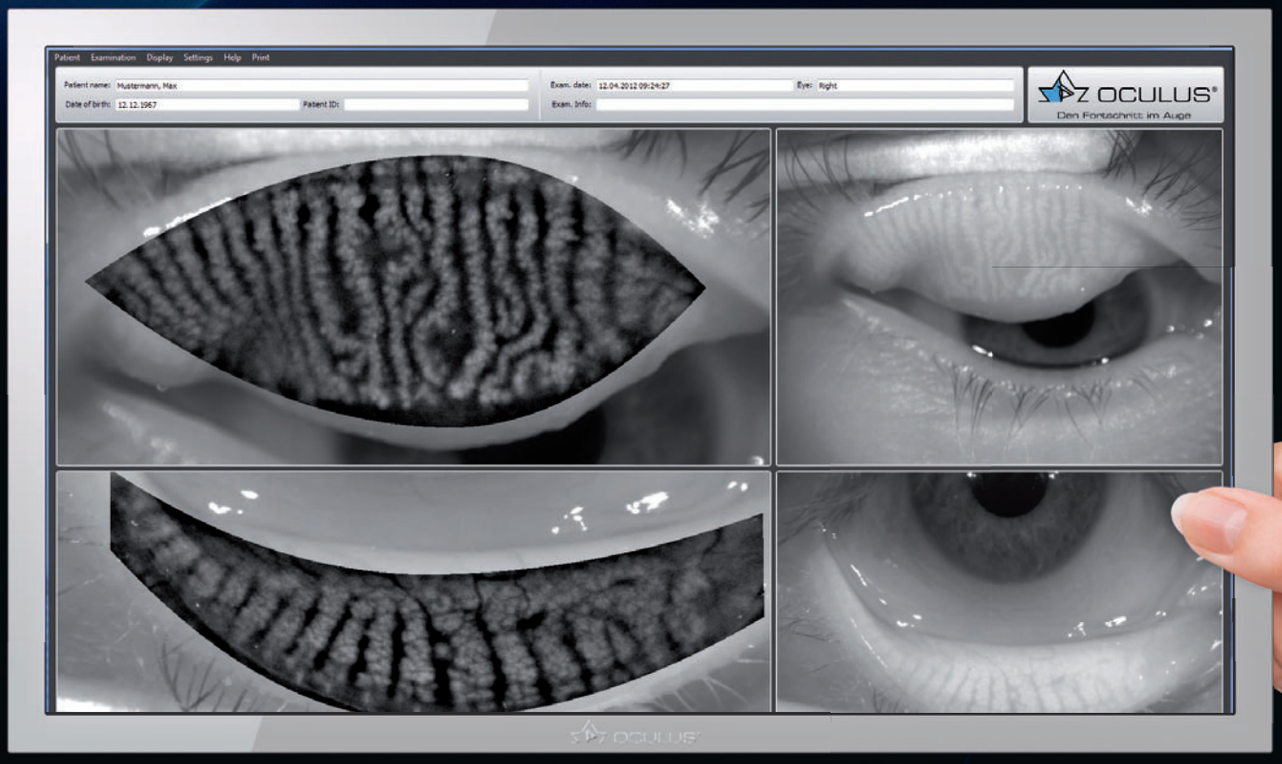

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Special Report 〉 **PEDIATRICS**

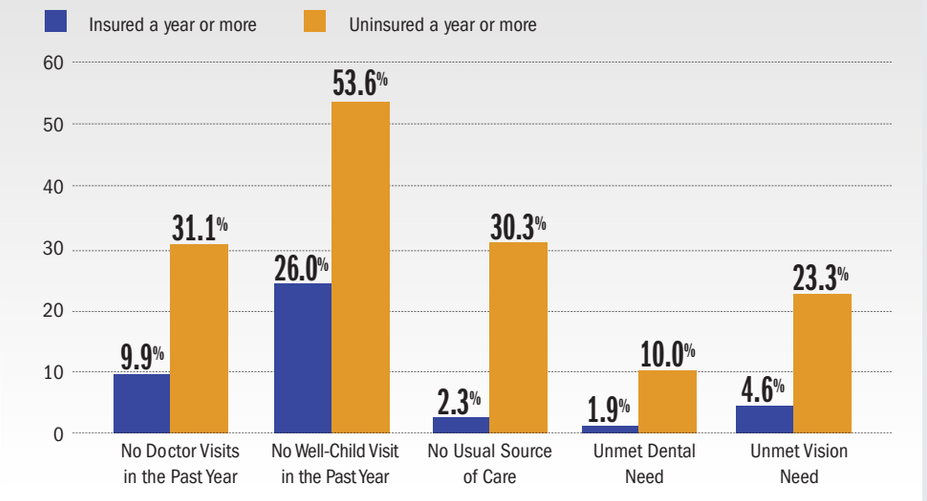
VISION PLAN

(Continued from page 30)

insured Children") and found that more than half of uninsured children have never had a well-child visit, which typically includes a vision screening. The study also found that 1.43 million uninsured children had an unmet vision-care need.

"Without coverage, many children make it to the doctor only when something urgent is needed and miss out on the benefits of ongoing well-child care," the 2006 study stated. "Without adequate preventative care, a child's health is at risk. Problems that could be prevented or detected early and corrected, can escalate into serious health problems that affect where the child can attend school regularly, participate in physical recreation activities with other children, or develop appropriate social and emotional skills for his or her age."

Unmet Health Care Needs Among Insured And Uninsured Children, 2005



(FIGURE 1) **Uninsured children are five times more likely than insured children to have an unmet vision-care need.** *(All tables in: Sullivan J. No Shelter from the Storm: America's Uninsured Children. Washington: Campaign for Children's Health Care, September 2006. Also available online at http://bit.ly/17BA56U)*

GROWING IMPORTANCE

Those statistics alone, Dr. Repka said, are why the vision services provision is so important for a child's well being.


Dr. Repka

"How are you going to know if (the child) has a problem?" he said. "Screening lets you know."

According to the AAO, screening is essential in facilitating the early detection and treatment of childhood vision impairments that may not be correctable later in life.

"(Screening) is a quick, efficient, and cost-effective method to identify patients who have indications of a vision problem or a potential vision problem. While screening cannot diagnose exactly what is wrong with a child's eyes, it can indicate whether the child should have a comprehensive eye examination with an ophthalmologist or an optometrist," the AAO stated.

Having access to screening is especially important with younger children who may be unable to communicate or recognize a problem, thus going undetected, Dr. Repka said.

The AAO recommends to parents that children should receive vision screenings at various stages, which can now be a reality for the millions who previously could not afford the price tag without insurance.

Those stages are:

- **All well-child visits from the time they are born until they are 3 years of age.**
- **Each year between 3 and 5 years of age.**
- **Every 1 to 2 years after age 5.**

While Dr. Repka acknowledged there is a risk factor of parents overutilizing the vision screenings now that they are covered, he said the issue is a risk that comes with any insurance benefit.

The pediatric vision provision, he said, is really "a great thing." ■

AAO will be hosting a presentation on the Affordable Care Act and health-care reform during its annual meeting on Monday, Nov. 18 in New Orleans.

MICHAEL X. REPKA, MD
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Dr. Repka has no financial interest in the subject matter.

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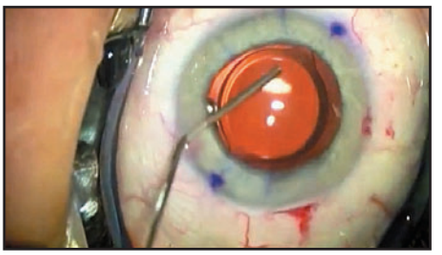

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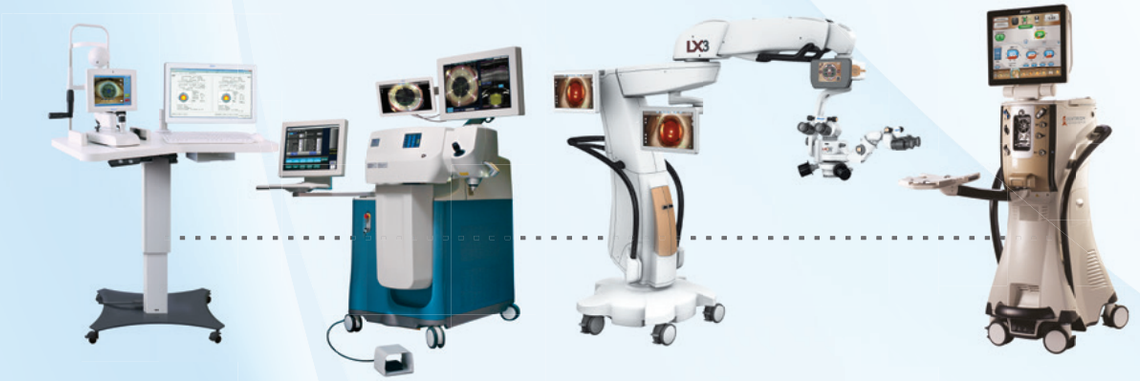

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Special Report 〉 **PEDIATRICS**

Strabismus alignment a surgical challenge

Patients with syndromic craniosynostosis may need combination of approaches

By Cheryl Guttman Krader; *Reviewed by Jane C. Edmond, MD*

HOUSTON ::

CHILDREN WITH SYNDROMIC craniosynostosis and strabismus are difficult to align.

Surgeons often need to combine several approaches to address the multiple abnormalities in these patients, said Jane C. Edmond, MD, associate professor of ophthalmology and pediatrics, Baylor College of Medicine, Cullen Eye Institute, Houston.

Dr. Edmond

Patients with syndromic craniosynostosis characteristically have a V-pattern strabismus with a large exotropia on up gaze that diminishes in down gaze, she noted.

They have marked apparent overaction of the inferior oblique muscle(s) with possible underaction of the superior obliques, which causes a hypertropia, occuring ipsilateral to the coronal suture fusion.

"No one surgery is a perfect fit to treat all of these problems reliably, and surgeons should absolutely plan for the undercorrected," Dr. Edmond said.

MULTIFACTORIAL CAUSES

Causes for classic strabismus in children with syndromic craniosynostosis are multifactorial. Coronal synostosis causes ipsilateral orbital extorsion and superior lateral orbit elongation, leading to globe extorsion with upward offset of the medial rectus and downward offset of the lateral rectus.

As a result, the medial rectus behaves like an elevator in adduction, and as a corollary, the lateral rectus muscle may be acting as a depressor in abduction. This simulates inferior oblique overaction.

In addition, superior orbital rim retrusion may lead to superior oblique trochlea retrusion resulting in superior oblique underaction and secondary inferior oblique overaction.

Overelevation in adduction may also be secondary to anomalous insertions or agenesis of extraocular muscles, particularly the superior rectus and the superior oblique.

Therefore, Dr. Edmond cautioned surgeons to provide clear instructions to the radiologist when ordering imaging in these children.

"Do not rely on the radiologist alone to identify these problems of the extraocular muscles without a specific request, and learn to read your own scans preoperatively," she said.

MULTIPLE OPTIONS

Surgical procedures for addressing inferior oblique overaction strabismus include simple weakening of the muscle by myectomy or recession, which Dr. Edmond noted can provide good results in patients with isolated over-elevation in adduction.

However, it is not appropriate for more complex strabismus that is often found in patients with syndromic craniosynostosis.

Inferior oblique antero-positioning is an option for weakening treating the over-elevation in adduction. This procedure converts the inferior oblique to an antielevator in adduction, improves the V pattern by muscle weakening, and also improves excyclotorsion.

If done unilaterally it may induce anti-elevation syndrome, although that may be desirable, Dr. Edmond said.

Anterior and nasal inferior oblique transposition has also been performed in children with superior oblique agenesis, and it may be especially useful in patients with significant inferior oblique overaction.

This procedure converts the inferior oblique to an anti-elevator in adduction and an intorter. It improves the V pattern and excyclotorsion while also improving superior oblique underaction.

Vertical offsets of the medial and lateral recti is yet another option for surgical correction of the V pattern.

However, Dr. Edmond described it as a "wimpy" procedure and suggested it be used only as an adjunct and never as the primary method of correction of a V pattern in these patients.

"Vertical offset of the horizontal muscles reduces, but never eliminates, inferior oblique overaction or superior oblique underaction," she explained. "While it improves the V pattern some, it unfortunately increases excyclotorsion."

Superior oblique strengthening—a superior oblique tuck—offers one more option. Its benefits include reduction or elimination of over-elevation and underdepression in addition along with improvement of the V pattern and excyclotorsion.

However, it is suitable only for children with a normal superior oblique muscle, which may be missing in patients with syndromic craniosynostosis. ■

take-home

- **Achieving alignment of strabismus can be difficult in children with syndromic craniosynostosis as the causes are multifactorial.**

JANE C. EDMOND, MD

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Dr. Edmond did not indicate any proprietary interest in the subject matter.

Special Report 〉 **PEDIATRICS**

Glaucoma drugs in pediatrics not child's play

Why increased caution warranted with topical glaucoma medication use in children

By Cheryl Guttman Krader; *Reviewed by Yasmin Bradfield, MD*

MADISON, WI ::

THOUGH ALL CLASSES OF topical glaucoma drugs have a role in the management of pediatric glaucoma, patient selection is critical for reducing the potential for systemic side effects in this population, said Yasmin Bradfield, MD.

"The potential for systemic side effects must be kept in mind," said Dr. Bradfield, associate professor, Department of Ophthalmology and Visual Sciences, University of Wisconsin, Madison. "In general, the younger the child and the lower the body weight, the higher the risk."

Central nervous system (CNS) toxicity with alpha-2 agonists, and particularly brimonidine, is one of the most serious systemic concerns associated with topical glaucoma medication use in children.

The alpha-2 agonists are lipophilic and easily cross the blood-brain barrier into the brain, which is rich in alpha-2 receptors. Stimulation of these receptors leads to increased parasympathetic outflow and decreased sympathetic outflow.

Sedation, somnolence, respiratory depression, apnea, and coma within 30 to 60 minutes postdosing have all been reported in infants and toddlers treated with topical brimonidine.

Cardiovascular side effects—hypotension and bradycardia—can also occur and are mediated by both the central and peripheral actions of the medication.

RATE OF SIDE EFFECTS

"In one study investigating 83 children treated with topical brimonidine, the frequency of CNS side effects was highest among children younger than 6 years of age and those weighing less than 20 kg," Dr. Bradfield said.

"This information gives reason to be very cautious prescribing brimonidine to children less than 6 years old, and brimonidine is actually contraindicated in children younger than 2 years of age due to a lack of adequate research in that age group," Dr. Bradfield added.

Increased sensitivity in infants and very young children is hypothetically due to their smaller plasma volume combined with immaturity of metabolic and excretion pathways that together result in excessive drug plasma levels.

CNS penetration and drug activity is enhanced in youngsters due to their immature blood-brain barrier and increased receptor sensitivity.

"Following topical brimonidine administration, the plasma brimonidine level in a 1-month-old child can match that achieved with IV drug administration," she said.

Treatment of the systemic side effects of alpha-2 agonists involves discontinuation of medication and necessary supportive therapy. There are reports on use of naloxone to reverse the toxicity, but with varying success.

BETA BLOCKERS

Treatment with topical beta blockers is associated with risks of pulmonary and cardiac side effects, as well as masking of hypoglycemia. These medications are contraindicated in children with cardiac arrhythmias and asthma.

Caution is advised when treating a child whose diabetes is newly diagnosed and who is still undergoing insulin dose titration, and when treating neonates due to a high risk of apnea, Dr. Bradfield said.

Theoretically, the beta-1 selective antagonist, betaxolol, has a lower risk for causing pulmonary and cardiac side effects than the non-selective drug timolol. When using timolol, strategies to reduce systemic absorption include punctal occlusion, closing the eyelid for about 10 seconds after drop instillation, and even blotting excess medication from the eyelid.

OTHER THERAPIES

Among the carbonic anhydrase inhibitors, dorzolamide (Trusopt, Merck) specifically was found to be safe and well tolerated in children <6 years of age in a prospective, randomized, controlled multicenter study.

However, treatment duration was only 3 months. Possible risks with topical carbonic anhydrase inhibitors in infants include poor feeding and lack of weight gain, which may be a sign of metabolic acidosis.

Based on available data, prostaglandin analogues appear to be very safe in children, although there are rare reports of asthma exacerbations, due to increased inflammatory mediators.

A potential for development of cystoid macular edema has not been found in children, she said. ■

YASMIN BRADFIELD, MD

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Dr. Bradfield has no relevant financial interests to disclose.

Intracameral antibiotics use keeps endophthalmitis at bay

How postoperative infection rate dropped significantly with protocol in Northern California facility

By Fred Gebhart; *Reviewed by Neal H. Shorstein, MD*

TAKE-HOME

- ***Universal use of intracameral antibiotics can nearly eliminate postoperative endophthalmitis, relates one ophthalmologist.***

WALNUT CREEK, CA ::

Intracameral antibiotics work.

That is the key message from a study of more than 16,000 cataract surgeries performed by 14 ophthalmologists at a single Kaiser Permanente facility in Northern California.

Using intracameral cefuroxime in most patients produced a two-fold reduction in endophthalmitis. Extending intracameral antibiotics to 100% of patients produced a 22-fold reduction in postoperative infections.

Dr. Shorstein

"The take-home message for me is to use intracameral antibiotics in 100% of patients," said lead author Neal H. Shorstein, MD, ophthalmologist and associate chief of quality for Kaiser Permanente in Walnut Creek, CA. "Intracameral antibiotic injection works in the United States as it was demonstrated to work in the large European study several years ago."

KAISER FACILITY RESULTS

The Kaiser Permanente results were similar to results from a large multicenter trial in Europe published in 2006 and 2007.

The researchers reviewed 16,264 consecutive phacoemulsification surgeries performed by 14 different surgeons at the Kaiser Permanente facility in Walnut Creek, CA, from 2007 to 2011.

The study compared three different time periods:

- **No intracameral antibiotics.**
- **Intracameral cefuroxime in patients who were not allergic to the agent and did not have posterior capsule rupture.**
- **One-hundred percent use of either intracameral cefuroxime, moxifloxacin, or vancomycin.**

Before the use of intracameral antibiotics, there were nine cases of endophthalmitis in 2,878 surgeries, a rate of 3.13 per 1,000.

Internal quality review found that there was no identified environmental cause and no trends by surgeon, Dr. Shorstein noted.

Laboratory culture identified one case of coagulase negative *Staph*, one *Strep pneumoniae*, one *Strep viridans*, and six patients with clinically confirmed infection but no culture growth.

After results from the European trial were published, all 14 surgeons added intracameral cefuroxime to their usual antibiotic regimen except in patients with an allergy to a penicillin or cephalosporin, or posterior capsular rupture.

Five of the surgeons also switched from tobramycin drops postoperatively to gatifloxacin.

Three surgeons stopped prescribing eye drops altogether for patients with uncomplicated surgery who received intracameral cefuroxime. The practice change was instituted in September 2007.

The results were striking—nine cases of endophthalmitis in 6,278

Continues on page 40 : ***Endophthalmitis***

ENDOPHTHALMITIS

(Continued from page 39)

surgeries, a two-fold decrease from the initial period. However, the decrease to an infection rate of 1.43 per 1,000 was not statistically significant ($p = 0.09$).

Six of the nine infections occurred in patients who had not received intracameral cefuroxime, Dr. Shorstein noted.

Four had an allergy to cephalosporin, and two had posterior capsular rupture. Culture resulted in three cases of coagulase negative *Staph*, one methicillin-resistant *Staph aureus*, one *Enterococcus faecalis*, and four with no growth.

AN ADDITIONAL PRACTICE CHANGE

A second practice change was instituted in December 2009. All surgeons used an intracameral antibiotic in all patients, including those with posterior capsular rupture.

Cefuroxime remained the default agent, but moxifloxacin and vancomycin were added for patients who were allergic to cephalosporin and fluoroquinolones, respectively. There was no change in gatifloxacin prescribing.

"Then we found that we had only one infection in 7,108 surgeries, and it told us that using intracameral antibiotics in every single patient would give us the lowest endophthalmitis rate in our population of patients," Dr. Shorstein said.

"The real surprise was the degree of difference between these two study periods," he said. "We saw a ten-fold decrease from the period when we were using intracameral cefuroxime in most patients to when we were injecting an intracameral antibiotic by protocol in every single patient. That was a very pleasant surprise."

It was also a statistically significant surprise, Dr. Shorstein noted.

The ten-fold decrease in endophthalmitis compared with using intracameral endophthalmitis in some patients produced an infection rate of 0.14 per 1,000 ($p < 0.01$).

INSTITUTING PROTOCOL

"Instituting our protocol for 100% intracameral antibiotics produced an overall 22-fold decline in endophthalmitis," Dr. Shorstein said.

In the very few patients who received an injection and still went on to develop endophthalmitis, the final vision for each was 20/30, excluding a single patient with post-exudative age-related macular degeneration. There were no adverse events associated with the injections.

This antibiotic protocol is similar to surgical protocols that call for the use of antibiotic prophylaxis against surgical site infection not more than 60 minutes before the initial incision.

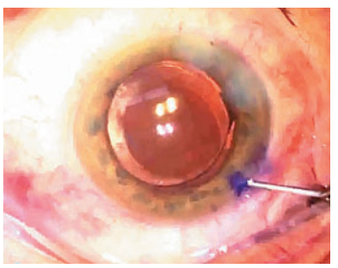
With regard to the concern for selecting out resistant organisms, intracameral antibiotic use is probably less likely to cause this, Dr. Shorstein noted.

Intracameral injection is a one-time use in a tissue that is largely isolated from the rest of the body as well as from the outside environment.

"I haven't seen any comparative studies," he said, "but my guess is that the risk of emerging resistance from this one-time, high-concentration application in a relatively confined environment is much lower than in the case of using multiple applications of a topical antibiotic.

"The injection of antibiotic is very easy," Dr. Shorstein concluded. "It is quick and there really isn't any additional skill set necessary to adopt this practice." ■

INTRACAMERAL CEFUROXIME



VIDEO For a video showing an intracameral cefuroxime injection, go to **http://bit.ly/Hx1Ena**. *(Video courtesy of Neal H. Shorstein, MD)*

Weigh in on intracameral antibiotics for endophthalmitis at **Facebook.com/OphthalmologyTimes.**

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Dr. Shorstein did not indicate any proprietary interest in the subject matter.

SLOWS PROGRESSION

(Continued from page 1)

Lampalizumab "blocks activation of the complement system through the alternative pathway, while preserving the host-defense response through the classical and mannose-binding lectin pathways," he said.

FOUR-ARM STUDY

MAHALO was a phase II study that included a phase Ib multidose safety run-in.

The four-arm study enrolled 129 patients randomly assigned 1:2:1:2 into monthly sham (n = 21) and 10 mg lampalizumab (n = 43) arms, and every other month sham (n = 21) and 10 mg lampalizumab (n = 44) arms, with the main inclusion parameter bilateral GA secondary to AMD in the absence of choroidal neovascularization, with the GA between 1 and 7 disc areas with a presence of hyperautofluorescence.

Dr. Williams

If the GA was multifocal, at least one lesion had to be greater than one-half disc area, Dr. Williams said.

Baseline best-corrected visual acuity (BCVA) had to fall between 20/50 and 20/400. The investigators used fundus autofluorescence to assess the changes in GA area from baseline to month 18.

> 'The next steps regarding a potential phase III study are still under consideration.' – *David F. Williams, MD, MBA*

For the analyses, the sham arms were pooled to increase the precision of the estimate, he said.

"Secondary endpoints were mean change in GA area with color fundus photography and mean change in baseline BCVA, though phase II was not powered to assess secondary endpoints," Dr. Williams said.

MORE ANALYSES

Additional analyses included segmenting the patients by baseline GA area to assess the effect of lesion size on area expansion over time.

At baseline, average visual acuity was about 20/100 with GA lesions averaging 3.4 disc areas (about 8.5 mm^2).

At 18 months, the lampalizumab monthly arm had a 20.4% reduction in progression relative to the pooled sham arm. This difference was seen beginning at month 6, Dr. Williams said, and was statistically significant at each subsequent time point.

Though the study was not powered to assess the efficacy of the compound on vision, the mean change in BCVA over time was assessed for safety signals.

"There were no safety concerns with lampalizumab relative to the pooled sham arm," he said.

NEXT STEPS

"The [monthly lampalizumab] reduction was remarkable," Dr. Williams said. "This is the first time any therapy has shown clinical trial evidence of efficacy in slowing GA progression."

In a specific subpopulation of GA patients treated monthly with lampalizumab that were identified using exploratory biomarkers, the GA progression rate was decreased by 44% ($p < 0.005$) at 18 months.

In the subset of patients positive for the exploratory biomarkers who presented with better vision (20/50 to 20/100), progression of the GA area was reduced by 54% ($p < 0.005$) at 18 months when treated with monthly lampalizumab.

From the patient samples collected in the MAHALO study, 57% of patients were positive for the exploratory biomarkers.

"The next steps regarding a potential phase III study are still under consideration," Dr. Williams said.

However, he said, more information on the biomarkers would be presented in the near future. ■

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Dr. Williams is a member of Genentech's advisory board.

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Cutting-edge technology debuts in European venues

Ophthalmic manufacturers launch new devices, innovations during 2013 EURETINA, ESCRS

By Rose Schneider, *Content Specialist,* Ophthalmology Times

TAKE-HOME

- ***Many new ophthalmic products and updated devices were presented during this year's EURETINA and ESCRS meetings.***

AMSTERDAM AND HAMBURG, GERMANY ::

An abundance of new products, technology upgrades, and devices were introduced this fall during the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Amsterdam, as well as EURETINA 2013 in Hamburg, Germany.

MULTIFOCAL IOL TECHNOLOGY

Abbott Medical Optics announced it will launch two new measurements (optical add powers) for the Tecnis multifocal IOL in Europe to provide more customized treatment options for cataract patients.

Photo courtesy of Abbott Medical Optics

The first multifocal IOL, +2.75 add power, is suited for patients who prefer intermediate vision activities, such as seeing an automobile dashboard.

The second multifocal IOL, +3.25 add power, is for patients favoring activities at longer reading distances, such as working at a computer, while still providing a full range of vision.

TREATMENT FOR FLOATERS

Ellex Medical Lasers Ltd. launched its Ultra Q Reflex technology, a YAG laser specifically for the treatment of vitreous strands and opacities.

The device is designed to overcome the issues associated with conventional YAG laser technology, and is designed for the treatment of floaters.

Continues on page 44 : ***Innovations***

INNOVATIONS

(Continued from page 43)

Incorporating Ellex's proprietary slit lamp illumination tower design, the device converges the operator's vision, the target illumination, and the treatment beam into the same optical plane. The device's illumination mirror—which briefly moves out of the laser pathway during firing—ensures that the laser beam is never obstructed, thus the system's illumination tower can be used coaxially, in addition to the typical off-axis position.

The device also ensures visibility of all ocular structures, and there is no risk of under-dosing or over-dosing the energy due to poor positioning of the illumination tower.

VISION TESTING SOFTWARE

Konan Medical USA Inc. unveiled the Chart2020 v5, an advanced vision testing software platform with a completely redesigned user experience that can be controlled with the Chart2020 Duo app for iPad with retina display.

Central to the software's user experience are SmartDocks, which enables users to quickly and easily access test libraries, sequences, system sequences, system settings, and Konan Wizards—a suite of guided, self-scoring tests.

Additionally, the software features global Sloan compliant optotypes for non-Western languages including Japanese, Korean, Russian, and Arabic, as well as Konan Kids, an optotype designed for children and illiterate adults.

RETINA LASER THERAPY

OD-OS presented study results that showed its combination of anti-vascular endothelial growth factor (VEGF) injections and navigated laser photocoagulation for diabetic macular edema proved superior to anti-VEGF therapy alone.

The prospective cohort study—conducted by Marcus Kernt, MD, of Ludwig Maximilians University, Munich—utilized the Navilas Navigated Laser System (OD-OS GmbH) in combination with ranibizumab anti-VEGF therapy versus standard ranibizumab monotherapy.

"(The laser) therapy demonstrated significant and stable visual gains in most patients," Dr. Kernt said. "These results were at least as good as with ranibizumab monotherapy at a significantly lower number of injections when compared to those who received (that) therapy alone. Importantly, the results after navigated laser therapy are also superior to results of previously reported studies which were based on conventional laser/anti-VEGF combinations with regard to reducing the injection burden."

PRELOADED IOL PRODUCT

Rayner Intraocular Lens Ltd. unveiled the C-flex Advance Aspheric, a preloaded IOL product.

The lens combines clinically proven benefits of the aberration-neutral C-flex aspheric IOL, with a mini incision and a preloaded IOL delivery system that eliminates handling of the acrylic lens in theater.

The lens also helps reduce the changes of IOL damage or contamination, and allows for an SIA neutral implantation through an incision size of 22 or 2.4 mm into the bag. The new lens is available in the power range +8 to +34 D in 0.5-D increments.

EXCIMER LASER PORTFOLIO

Schwind eye-tech-solutions expands its excimer laser portfolio with the Schwind Amaris 1050RS.

The new laser system operates at a rate of 1,050 Hz, giving a short ablation time of 1.3 seconds per D (myopia, without astigmatism, 12.5-mm vertex distance and 6-mm optical zone), which increases safety and patient comfort.

The corneal stroma is also exposed for shorter time, which minimizes the risk of drying out, while the length of time for which the patient has to fixate on the green light is further reduced.

Another feature of the laser is active 7D eye tracking in space and time.

Schwind also presented the PresbyMax Hybrid—an alternative to the existing PresbyMax types—for the treatment of presbyopia. The hybrid technique delivers a faster recovery of distance visual acuity, as well as high quality of distance vision.

FEMTOSECOND LASER PLATFORM

Ziemer Ophthalmic Systems announced an addition to its femtosecond laser line Femtro LDV Z Models—the Z8.

The new laser platform will be able to perform a large variety of cornea, presbyopia, and cataract procedures.

First clinical results were shown during ESCRS, and the laser platform is pending CE mark and FDA approval. ■

Photos courtesy of Ellex Medical Lasers Ltd. and Schwind eye-tech solutions

Contrast sensitivity test targets AMD

Diagnostic tool provides clinicians with standardized testing for retinal patients

New Product Focus **By Liz Meszaros;** *Reviewed by David W. Evans, PhD*

TAKE-HOME

- ***A new letter contrast sensitivity test may aid in the evaluation of patients with age-related macular degeneration and other retinal diseases.***

GREENVILLE, OH ::

PATIENTS WITH AGE-RELATED macular degeneration (AMD) and other retinal diseases may benefit from a new standardized letter contrast sensitivity test (Evans Letter Contrast Test, VectorVision).

"As baby boomers have moved into their older years, a lot of focus has been placed on AMD, diabetic retinopathy, and new treatments for these age-related diseases," said David W. Evans, PhD, founder of VectorVision, Greenville, OH, and inventor of the CSV-1000.

FILLING UNMET NEED

Until the new letter contrast sensitivity test was developed, Dr. Evans noted, there was no standardized test to evaluate patients who have poor vision—i.e., those with acuity worse than 20/50 to 20/70.

"That was the goal in developing this diagnostic tool—an accurate, standardized way to evaluate subtle changes in vision in patients who have poor vision," he said.

Dr. Evans has been involved in the development of this highly sensitive test for a number of years, based on requests from clinicians who dealt with age-related eye disease.

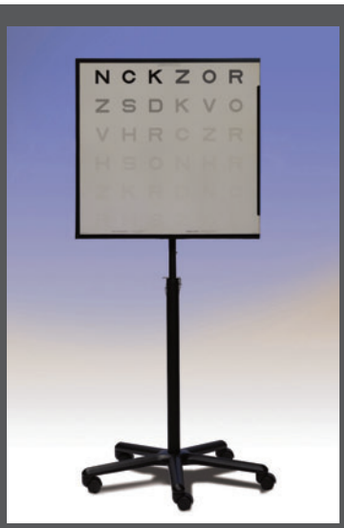
He established the current design after testing a number of versions.

Letter contrast sensitivity testing determines the lowest contrast level at which a letter can be correctly identified for a given size target, Dr. Evans explained.

Letter contrast sensitivity measures the patient's ability to see at different contrast levels, while acuity testing measures only one high level of contrast, black-on-white.

Acuity is a poor measure to determine the loss of vision with disease, or more importantly, the subtle improvements in vision with treatment, he noted.

The new letter contrast sensitivity test provides for a range of contrast sensitivity levels.



The development of the new letter contrast sensitivity test had the evaluation of patients with poor vision as its goal. *(Photo courtesy of VectorVision)*

This is achieved by using a letter size that was specifically chosen for evaluating the stabilization or the subtle changes in improvement in vision by patients with AMD following treatment.

The new, scientifically developed design of the test helps clinicians evaluate these patients in a standardized and comprehensive way, and it improves on current testing methods, Dr. Evans continued.

For example, the Pelli-Robson test for contrast sensitivity was developed

Continues on page 47 : ***Letter contrast***

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LETTER CONTRAST

(Continued from page 45)

with an arbitrary letter size and is not tested in a standardized lighting environment, he said.

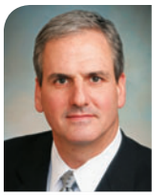
"We utilize a letter size that matches the ETDRS log scale at 20/630," Dr. Evans said. "This letter size is excellent from a testing standpoint, because it is the acuity level at which patients have their peak visual sensitivity under low-contrast conditions, based on visual psychophysics.

"We wanted to ensure that it would be technically sensitive for the patient, but would also be consistent with the ETDRS standard," he added.

ADVANTAGES OF TECHNOLOGY

One additional advantage of the new test is that it is used in a standardized lighting environment, in conjunction with an LED-based, auto-calibrated, back-lighting system (ESV3000, Good-Lite/VectorVision) that ensures uniform and consistent lighting for testing each patient.

"One of the problems with other large letter tests is that it is very difficult to test them in a standardized way," Dr. Evans said. "There is no guarantee that when a patient is re-tested, the test lighting will be the same as the previous test."



Dr. Evans

The new letter contrast sensitivity test is standardized, and because the LED backlighting auto-calibrates to a specific light level, clinicians now have a large-letter type of contrast test with standardized lighting, increasing test/re-test reliability, he said.

Other advantages include the fact that the test is produced through a silk-screen process on translucent styrene, not printed on plastic. This manufacturing process ensures that the test will not fade over time and affect the evaluation.

The test has been adopted for worldwide clinical trials evaluating novel treatments for retinal disease. Alcon Laboratories is currently using the test in an ongoing clinical trial.

"With the number of new drugs being introduced to treat retinal diseases, it is difficult to know which one is most effective," Dr. Evans said. "If we are waiting on a change in acuity to determine if a drug is effective, we may be missing information that could help patients preserve or recapture visual function.

"Acuity is not sensitive enough to detect small changes in vision," he said. "Unfortunately, acuity also changes very slowly with treatment. [The test] is a way to determine if patients are being helped by therapy, very quickly, and in a standardized way." ■

DAVID W. EVANS, PHD

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Dr. Evans has worked as a consultant and has participated in the development of study protocols and/or data analysis for clinical studies sponsored by Allergan, Autonomous Technologies, Novartis, Otsuka, Pharmacia, and VISX.

FDA issues guidance on medical apps

WASHINGTON, DC ::

FDA ISSUED FINAL guidance for developers of mobile medical applications ("apps") that outlines the agency's tailored approach to mobile apps.

The finalized FDA guidance on mobile medical apps focuses on two areas: apps that, due to their functionality and intended use, turn the mobile device into a medical device, and apps that act as accessories to currently regulated medical devices, according to Kyle Peterson, director, regulatory and corporate affairs for Calgary Scientific, Calgary, Canada.

Currently, mobile medical apps can diagnose abnormal heart rhythms, transform smartphones into a mobile ultrasound device, or function as the "central command" for a glucose meter used by a patient with insulin-dependent diabetes, for example.

FDA intends to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Drug and Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. In addition, FDA intends to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as they should.

FDA is focusing its oversight on mobile medical apps that:

- **Are intended to be used as an accessory to a regulated medical device—for example, an application that allows a health-care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system on a smartphone or a mobile tablet; or**

- **Transform a mobile platform into a regulated medical device—for example, an application that turns a smartphone into an electrocardiography machine to detect abnormal heart rhythms or determine if a patient is experiencing a heart attack.**

Mobile medical apps that undergo FDA review will be assessed using the same regulatory standards and risk-based approach that the agency applies to other medical devices.

The agency does not regulate the sale or general consumer use of smartphones or tablets nor does it regulate mobile app distributors such as the "iTunes App store" or the "Google Play store."

FDA received more than 130 comments on the draft guidance issued in July 2011.

Respondents overwhelmingly supported FDA's tailored, risk-based approach.

FDA has cleared about 100 mobile medical applications over the past 10 years—about 40 of those were cleared in the past 2 years.

"[Physicians] should examine any mobile medical apps they currently use to evaluate whether they are for diagnostic use or remotely connect to another medical device," Peterson explained.

Such apps will be regulated under the new guidance and physicians should know whether the app they use has passed through FDA review, he continued.

"If they are using an app that appears to fall into the regulated category and has not passed FDA review, at a minimum, they should be questioning the author to see if they agree that their app is regulated and what their plans are for compliance," Peterson continued. "If the app they're using impacts patient diagnosis, management, or treatment, and they are in doubt about its compliance, they can contact FDA for clarification." ■

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Release Date: November 1, 2013 | Expiration Date: November 1, 2014

Who Are Your Dry Eye Patients? Providing Optimal Management

Helene, a 62-year-old attorney, is referred for cataract surgery. She wears contact lenses and has recently noted decreased visual acuity. She is interested in presbyopia-correcting intraocular lens options so that she can eliminate her use of contact lenses altogether. Examination and medical history reveal signs and symptoms of undiagnosed dry eye disease, including 2+ blepharitis, Schirmer test <5 mm in each eye, punctate staining of the cornea with lissamine green, and elevated tear osmolarity. Further examination confirms the presence of a 2+ posterior subcapsular cataract in the right eye and a less advanced cataract in the left. What are the potential issues with cataract surgery in this patient with symptoms suggestive of dry eye disease?

For further details about Helene, including insight into her perioperative treatment and long-term management, check out our separate CME/CE activity at www.iche.edu/dryeyecase3

The Cataract Surgery Patient

Eye care professionals are often aware of the importance of dry eye disease (DED) management in the perioperative care of refractive surgery patients. Ocular dryness symptoms occur in as many as 48% of patients after refractive surgery, and the presence of these symptoms has a significant impact on patient satisfaction.[1] Addressing DED preoperatively can also improve the results of refractive surgery.[2]

The prevalence of undiagnosed DED is high in patients presenting for cataract surgery. In the Prospective Health Assessment of Cataract Patients Ocular Surface (PHACO) study, investigators found that, of 136 patients (272 eyes), only 22% reported previously receiving a diagnosis of DED. However, when these patients were tested, 62.9% had a tear break-up time (TBUT) of less than 5 seconds, 76.8% had positive corneal staining, 50% had central corneal staining, and 21.5% had a Schirmer score of 5 mm or less. These are all classic signs of DED.[3]

Cataract surgery itself also constitutes a risk factor for DED. With multiple topical medications prescribed preoperatively and postoperatively, as well as disruption of the ocular surface due to the incision, the cataract surgery episode can induce DED even in healthy eyes and exacerbate the condition in patients with existing DED. As a result, visual outcomes of cataract surgery can be diminished, especially in patients implanted with presbyopia-correcting intraocular lenses (IOLs).[4]

Dry Eye is a Chronic Condition

Effective management of DED during the perioperative period can help to make sure patients reap the optimum benefits of cataract surgery. Proper attention to the ocular surface can make the difference between a patient who reaches targeted visual acuity and one that is plagued with additional problems and reduced quality of life.

Diagnosing Dry Eye Disease

It is helpful to keep in mind the risk factors for DED: female gender, increasing age, use of a computer for work, concurrent use of topical medications containing benzalkonium chloride (BAK), postmenopausal use of estrogen-replacement therapy, comorbidities such as connective tissue disease, environmental factors, low dietary intake of omega-3 fatty acids, and numerous others.[5] In assessing patients for DED before cataract surgery, it should be considered that the symptoms and signs of DED can fluctuate or progressively worsen over time.[2] Therefore, a careful ophthalmic history, eliciting comments about past as well as current complaints of DED symptoms, is vital. A longitudinal study found that commonly used biomarkers of dry eye, including tear osmolarity, corneal staining,

LEARNING OBJECTIVES

- Describe recent guideline protocols for diagnosing dry eye disease (DED), classifying DED severity, and differentiating underlying etiologies of DED
- Describe the complications of DED in the setting of delayed diagnosis
- List the current recommendations for the treatment and follow-up of DED by level of severity and underlying etiologies

DISCLOSURES

Relationships are abbreviated as follows: E, Educational Planning Committee; G, Grant/research support recipient; A, Advisor/review panel member/educational planning committee; C, Consultant/Independent Contractor; SS, Stock shareholder; SB, Speaker bureau; PE, Promotional Event Talks; H, Honoraria; O, Other.

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Please go to www.iche.edu/dryeye3 to claim AMA credit. A complete set of references can be found online.

conjunctival staining, and meibomian gland grading, all varied at monthly examinations over a 3-month period (although tear osmolarity showed the least variability).[6]

Stabilizing the Dry Eye

Once DED is diagnosed in a cataract surgery candidate, a treatment plan should be formulated to bring the chronic condition of DED under control preoperatively and keep it that way postoperatively.

Inflammation plays an important role in the pathophysiology of DED.[2] In a healthy eye, the ocular surface and tear-secreting glands operate as an integrated unit to maintain the tear film. When this integrated functioning is disrupted, the inflammatory response initiated on the ocular surface leads to DED.[4,7]

In many cases, blepharitis associated with meibomianitis is also a part of DED leading to excessive tear evaporation due to lipid deficiency in the tear film.[5] Blepharitis can be addressed with lid hygiene and warm compresses.

When inflammation involves the ocular surface or there is a mixed etiology of DED, anti-inflammatory therapy is a key component of care. Anti-inflammatory therapies for moderate DED can include topical cyclosporine and corticosteroids; in severe cases, systemic anti-inflammatory treatment may be necessary.[5]

The Perils of Not Treating DED Perioperatively

Roberts and Elie performed a randomized, blinded study that demonstrated the development of dry eye symptoms after routine cataract surgery. In 30 female cataract surgery patients, half received treatment with topical cyclosporine for 1 month before and 1 month after surgery, while the other half received placebo. Symptoms were assessed with questionnaires preoperatively and at 1 week and 1 month postoperatively. In placebo-treated patients, 1 month following surgery, 87% reported needing artificial tear supplementation at least once daily, 80% experienced dry eyes at least occasionally, 73% reported foreign body sensation at least occasionally, 53% reported burning sensation at least occasionally, and 47% reported blurred vision at least once a day. The number of patients reporting these symptoms increased from the preoperative assessment. The cyclosporine-treated patients fared better; 1 month postoperatively, 53% reported no need for artificial tears, and greater numbers of treated patients reported "never" or "not usually" experiencing dryness, burning, and blurred vision compared with placebo-treated patients.[8]

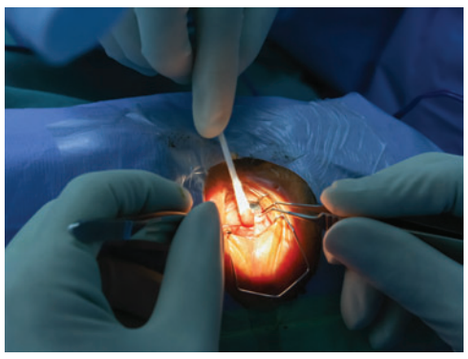

Image showing cataract surgery

DED can also negatively affect visual outcomes of cataract surgery with presbyopia-correcting IOLs. In a randomized, prospective study, patients undergoing bilateral cataract surgery with presbyopic IOL implantation who were treated with cyclosporine in one eye and an artificial tear in the other eye showed improvement in DED signs and better visual acuity outcomes in the cyclosporine-treated eye at 2 months postoperatively.[4]

Extending the DED treatment regimen to encompass the preoperative and postoperative periods helps to ensure that any exacerbation due to the trauma of surgery or toxicity from associated medications is kept to a minimum. Adequate lubrication can also help control postoperative symptoms. In fact, Bloomenstein reported that quality of vision was improved in patients who used artificial tears aggressively after cataract surgery and in the same dosing regimen as a postoperative refractive patient.[9]

Assessing Dry Eye

In order to recognize signs of DED and address the condition before cataract surgery is scheduled, conventional tests to assess the ocular surface, including TBUT with fluorescein, Schirmer test, lissamine green staining, tear meniscus height assessment, and meibomian gland grading, should be routinely performed. Corneal topography and tear osmolarity testing can also be valuable additions to the cataract DED diagnostic workup. Assessing corneal topography indices, Liu and Pflugfelder found that patients with aqueous deficiency have irregular corneal surfaces that may contribute to visual difficulties. They suggested that surface regularity and asymmetry indices can serve as objective diagnostic measures for identifying DED and assessing its severity.[10] Tear osmolarity is a relatively new objective diagnostic modality that has been shown to be more sensitive for diagnosing and grading the severity of DED than conventional measures.[4,11]

Patient Education Pearls

Because patient education is an important component of DED management, it may also be helpful to have the cataract surgery candidate fill out the Ocular Surface Disease Index (OSDI) questionnaire at a baseline visit and periodically thereafter to assess the severity of DED.[12] Explaining to the patient how he or she has scored on the questionnaire may help to demonstrate the need to improve his or her ocular surface health before cataract surgery can be considered.

The Continuum of Care

Because DED is a chronic condition that can worsen over time, and because cataract surgery can be an exacerbating factor, it is important to understand the management of DED in the cataract patient as an ongoing process, i.e., a continuum of care. The ocular surface must be made healthy before surgery is scheduled, possibly with a regimen including a topical corticosteroid and cyclosporine, and follow-up must continue for a longer and more intense period than the standard 90-day period of postoperative care for uncomplicated cataract surgery.

Conclusions and Final Clarifications

DED is often underdiagnosed in presurgical patients. All necessary diagnostic tests and DED treatment should begin before surgery is considered. It is important to remember that DED is a chronic condition, and patients will need continued monitoring and management to achieve excellent postoperative quality of vision and optimal levels of overall satisfaction.

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In-house financing programs can be rewarding alternative

How adopting new strategies for payment plans can grow business, deliver patient care

By Bob Richardson

TAKE-HOME

- ***An in-house financing program can help a practice grow in terms of the number of procedures performed, while saving money paid in third-party discounts, and even create new revenue streams as interest comes in on monthly payments.***

As the nation continues to transition out of the credit crisis that began in 2008, many medical practices are exploring new ways to move beyond survival mode and consistently grow their businesses again.

Though many patients still struggle with financial and credit issues, practices can adopt new payment plan strategies to serve this group and deliver the care they need, while growing their eye-care businesses.

FINANCING DILEMMAS

Though private insurance, Medicare, or Medicaid will cover the majority of essential, vision-saving procedures, financing issues can still present a barrier between physicians and their patients.

Some procedures or upgrades may not be covered, or potential patients may have trouble covering a co-payment.

Furthermore, third-party financiers have significantly reduced their approval rates, slashing the number of surgical leads physicians can accept.

With financing approval rates as they are, it is entirely possible that only 10% to 15% of interested patients can end up booking a surgery. Not to mention that the approval often comes with a 6% to 10% discount fee paid to the financier.

This is the great dilemma of the third-party financing paradigm.

It's not easy to turn down care for those in need, but when the numbers do not add up, physicians are left without a choice.

Making a serious impact on the business stream—while opening up more options to patients—requires looking past the third-party model and into more innovative solutions.

It's no wonder many ophthalmologists are beginning to take financing into their own hands—allowing them to choose whom they accept—and extend their own credit to finance procedures.

If executed correctly, an in-house financing program can grow the business in terms of the number of procedures performed, while saving money paid in third-party discounts, and even create new revenue streams as interest comes in on monthly payments.

> The process should begin with setting parameters on a number of key risk factors.

OPENING DOORS TO CARE

Let's take a look at a few ways ophthalmologists can use these resources as an avenue to provide care.

First off, we'll take the example of a patient seeking a $6,000 procedure—$3,000 of which covers hard costs—without coverage from insurance.

This patient has some money to put down, but simply cannot cover the entire payment out-of-pocket.

Rather than turn the patient away, the physician can formulate a payment plan that works for the patient while minimizing his or her own risks.

The paramount concern in this scenario is structuring a down payment that covers the hard costs and paying the rest over time, including interest.

That way, even if the patient immediate defaults on the payment plan right after the procedure—the worst of all worse-case scenarios—the practice's total loss is minimized.

However, physicians who are already utilizing this system—employing best practices—are reporting a 95% to 98% return rate on these kinds of payment plans, with interest paid on the remaining $3,000.

Though most physicians prefer to have all of their money up front, keep in mind this is net-new business.

Without the payment plan, the patient would have to be turned away.

Second, let's assume the patient has insurance, but has a $2,000 co-payment on the above procedure, and cannot pay out of pocket.

Since the insurance is already paying $4,000—covering hard costs, and then some—a payment plan can be used to cover the gap. Since hard costs are covered, the down payment can be more modest, but it is still prudent to collect something in case of a default.

Finally, what if a procedure is already covered by insurance, but the patient is considering a lens upgrade?

If he or she cannot afford it at the moment, it makes sense to work with the patient to finance it, so the lens can be implanted during the procedure and save the trouble of a second surgery.

Once again allowing the patient to pay as he or she goes is not as ideal as getting all the money upfront, but in this particular instance, the financing route makes the upgrade possible, thus generating extra revenue.

All of the above solutions are also possible with third-party financing.

Keep in mind a third-party financier will often require 6% to 10% of the entire pay-

Continues on page 52 : ***In-house financing***

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IN-HOUSE FINANCING

(Continued from page 50)

ment, including that crucial down payment. Thus, if a $6,000 procedure requires a $3,000 down payment, the practice is required to pay out $240 to $600 to the financing company.

And that's only if the patient is approved for financing in the first place.

PROPER EXECUTION OF PROGRAM

Taking financing into one's own hands can help open the door to steadier bookings, but here's the truth. If not executed correctly, these programs can very quickly become more trouble than they are worth.

Without using best practices and an efficient billing system, administrative headaches and upkeep can snowball.

The good news is that modern technological tools not only can take care of structuring, tracking, and billing the financing plans, but also can aid in evaluating the risk of potential customers.

The very beginning of the process—evaluating a potential customer—is a critical first step and should begin with setting parameters on a number of key risk factors.

Modern automated software can run credit, banking, and fraud checks at the click of a mouse, and that mouse click may very well be the end of the evaluation for more safety-conscious doctors.

MEETING THE SET STANDARD

If all the results meet a pre-set minimum, then it is time to schedule the procedure and set the payment plan.

Those that meet the set standard will carry the smallest default risk, making this system a safe bet for those looking to book a few extra procedures a month.

However, in today's credit environment, this hard threshold generally represents only a small part of the picture, and can easily exclude many individuals who are more than capable of paying off their payment plans.

An administrator with override capabilities can make final approval decisions based on a number of factors much deeper than those mentioned above.

In these cases, the terms of the payment plan can be customized to include higher down payments and interest rates to account for a greater risk, all of which can once again be customized at the click of a button.

Physicians who relax their requirements slightly, and make exceptions for certain profiles will be able to approve more people (and thus book more patients), but may see a slightly higher default rate in the long run.

The level of acceptable risk is ultimately up to physicians and the needs of the practice. The important thing is utilizing an automated system to keep office staff from getting sucked into an administrative quagmire.

We've seen practices attempt to launch their own in-house financing plans, and organize all their payment plans on a spreadsheet.

They allocate time from one employee as a billing manager, spending a few hours each week tracking and collecting the payments.

Within the first month, they have 50 payment plans on the books.

However, out of those 50, about 5 to 10 default each month.

Suddenly the billing manager's workload has doubled, as he or she must spend hours making calls and attempting to collect the payments.

Given that he or she still has a day job, this extra task has now become a headache, and falls by the wayside as his or her daily work needs to get completed.

The result is that more payments slip through the cracks. All in all, this results in a loss for the business.

AUTOMATE THE PROCESS

Unfortunately, the above example is all too common, and it is no wonder many physicians have come to the conclusion that in-house financing is a bad idea, or at least out of their reach.

However, if the business utilizes an automated system to track and collect payments—along with a system to run banking, credit, and fraud checks, manage compliance issues, and automate the overall process—all of the above operational deficiencies can be mitigated.

Running the proper checks on potential customers can reduce missed payments.

Advanced loan servicing software can take care of all the billing and collecting duties required of an overworked billing manager.

With the proper tools and framework, many ophthalmologists now are seeing in-house financing as a realistic alternative to traditional methods, allowing them to say "yes" to more vision-saving procedures, while also growing their practices at a comfortable rate. ■

BOB RICHARDSON *is president of ExtendCredit.com. Readers may contact Richardson at 888/364-2808 or Bob.Richardson@extendcredit.com*

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Cracking the code for EHR success

How automated billing, coding substantially improves accuracy; minimizes risk of audits

By Shareef Mahdavi

TAKE-HOME

- ***Including checks and balances in ophthalmic practices' electronic health record systems can help ensure proper coding.***

WITH UPWARD OF 30% of ophthalmic exams coded incorrectly, the prospects of being audited—and of defending the coding choices—can weigh heavily on any practice or practice administrator.

Plus, incorrectly coding a visit (or tests done during that same visit) can cost a practice thousand of dollars in lost revenue.

Couple these two points with the increased attention directed at ophthalmologists with Meaningful Use, and it becomes even more imperative that a practice's electronic health record (EHR) system include a checks-and-balances section to ensure proper coding.

Some physicians remain skittish about implementing a system.

"The whole issue of change is always a concern," said Scott Peterson, chief information officer, The Eye Center of Central Pennsylvania, Lewisburg, PA. "We, like every other place that implements EHR, has that as an issue, and we were very aware of it.

"We made it very clear to our employees that we are all in on this together," Peterson said. "If it takes extra time working with them, then we will do whatever we need to do to make them successful. This is an investment in the future of the practice and investment in the future of the employees."

FINDING THE RIGHT FIT

From a technology standpoint, Peterson recommends practices look to software systems that fit with the practice—especially if there's an optical shop and/or optometry division, as well as an ophthalmic one, he said.

"Ophthalmology is such a unique specialty among the health-care industry," Peterson said. "As a practice, you have to choose a partner that truly understands exactly what is being done from the practice's standpoint."

Before The Eye Center—which operates more than 15 locations throughout central Pennsylvania—implemented its EHR, it was difficult to train staff to code uniformly, he added.

Jim Riggi, president of Medflow, an EHR provider, agreed.

If patients present with truly complex issues, often physicians may err on the side of caution and under-bill, he explained.

"They'll down-code something because of fear—fear of an auditor in their offices or fear of penalties," Riggi said.

That apprehension is likely to escalate once the new ICD-10 codes go into effect in October 2014.

Numerous websites note misinformation about ICD-10, including issues about:

- Cost.
- Documentation.
- Changes in payment models equating to less revenue.
- Overall confusion.

PREPARING FOR CODING CHANGES

For Charles Titone, MD, of East Carolina Center for Sight, Greenville, NC, some of those issues meant getting in front of the coding changes before they became an issue.

"Medflow has already built in an ICD-10 crosswalk, so I'll never need to worry about coding issues or lost revenue when the transition takes place," he said.

The practice's system streamlines Dr. Titone's testing, interpretation, and coding (via Corcoran Consulting, or C3), and his practice qualified for Meaningful Use reimbursement on its first attempt.

According to Medflow, the C3 software "relies on chart documentation in the electronic medical record (EMR) as the basis for accurate real-time coding recommendations."

Once data are entered, the program offers suggestions for coding and interacts with the EMR to provide coding for eye exams based solely on the entries.

Dr. Titone has said in today's technologically savvy world, it's almost mandatory that any EHR system flow seamlessly among tablets, telephones, and computer systems. With that necessary portability comes an increased need for certified compliance, however.

Dr. Titone believes some practices will lose "a lot of revenue" with the transition to ICD-10, and hence the need for software that is certified compliant.

> A 4% increase in revenue may not sound significant, but it could mean the difference between hiring another staff member or purchasing an additional piece of equipment.

Conversely, he cites a 20% increase in revenue once he began using the C3 module.

Even in smaller practices—those that might bill only $700,000 a year—increases of 4% are not uncommon, Riggi said.

Though a 4% increase in revenue may not sound significant, it could mean the difference between hiring another back-office staff member or purchasing an additional piece of equipment for the practice.

"There is not an individual in our organization who would want to go back [to the way we ran things before automating our health-records system]," Peterson said. "We see more patients today than we did when we were using a paper system."

And, he stressed, those additional patients are not adding any time to the physician's daily workload. ■

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Patient presents with macular hole after trauma

A 12-year-old boy has blurry vision in left eye after being hit with soda can. How to treat?

By Rebecca A. Shields, MD; *Edited by Jonathan S. Chang, MD, and Aleksandra V. Rachitskaya, MD*

TAKE-HOME

- ***A 12-year-old boy presents with full thickness macular hole 6 weeks after trauma to the left eye. What is the next treatment step?***

A 12-year-old boy presented to the Bascom Palmer Eye Institute emergency room with blurry vision in his left eye after being hit in the left eye with a soda can at school. Review of symptoms was negative. The patient's medical, surgical, and family histories were unremarkable.

EXAMINATION

On initial presentation, the patient's best-corrected visual acuity (BCVA) was 20/20 in the right eye and 20/200 in the left eye.

The pupils were pharmacologically dilated.

IOP was 13 mm Hg in the right eye and 8 mm Hg in the left eye.

Extraocular movements and confrontational fields were within normal limits.

The exam of the right eye was within normal limits. The external examination of the left eye revealed periorbital edema and ecchymosis.

Anterior segment examination revealed subconjunctival hemorrhage and microhyphema.

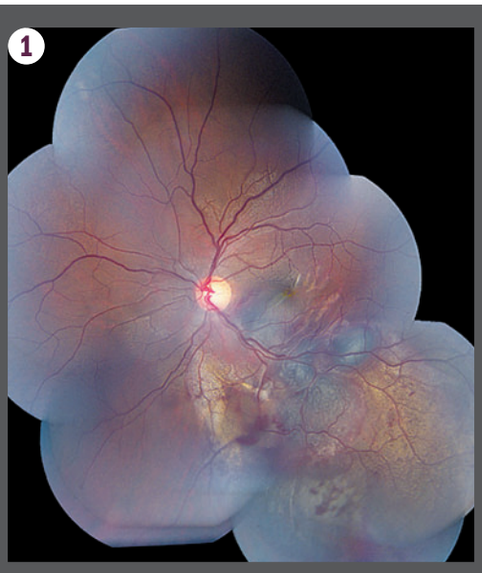
Posterior examination revealed extensive subretinal hemorrhage, choroidal rupture, commotio retinae, and vitreous hemorrhage (Figure 1).

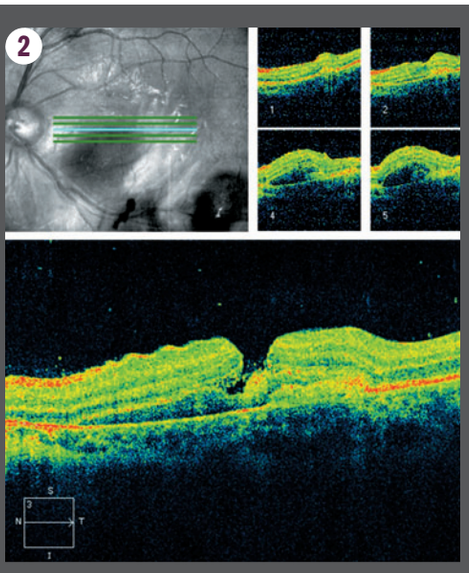
No retinal tear or detachment was noted. The patient was started on topical prednisolone acetate and atropine. He was instructed to wear a shield and to abstain from physical activities. Orbital fracture was ruled out via computed tomography scan.

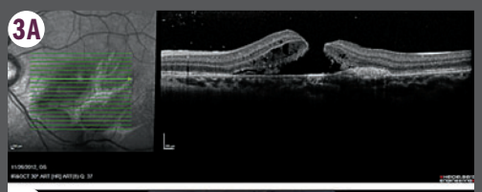
Optical coherence tomography (OCT) showed partial thickness macular hole, intraretinal thickening, and subretinal fluid (Figure 2).

The patient was followed closely with clinical exams and OCT imaging. Six weeks after the initial trauma, the patient was noted to have subjective blurring of central vision, best corrected visual acuity was 20/100.

OCT was obtained and showed full thickness macular hole and subretinal scar formation (Figures 3A and 3B). No vitreomacular traction was noted.







1 Fundus photo of the left eye at presentation reveals vitreous hemorrhage, subretinal and intraretinal heme, choroidal rupture, macular edema, and commotio retinae.

2 Ocular coherence tomography (OCT) of the left eye on presentation revealed partial thickness macular hole, retinal thickening, and subretinal fluid.

3 A. Six-week follow-up visit, OCT demonstrates full thickness macular hole, no vitreomacular traction, and subretinal scar formation. Visual acuity 20/200. B. Fundus photo of the left eye at 6-week follow-up demonstrates resolving vitreous hemorrhage, macular hole, subretinal hemorrhage, and commotio retinae. The macular hole corresponds to that seen on the OCT.

DIAGNOSTIC COURSE

Upon the diagnosis of the full thickness macular hole at the 6-week follow-up, observational management was selected.

The change in symptoms and previous OCT suggested the acute nature of the hole formation.

Continues on page 61 : ***Macular hole***

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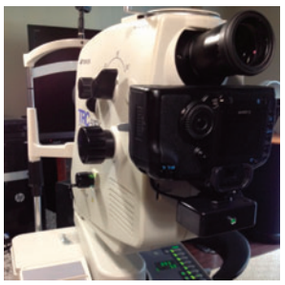

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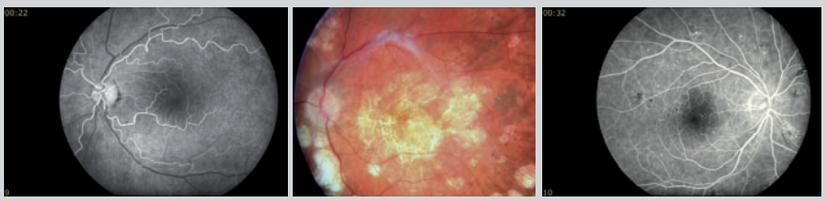

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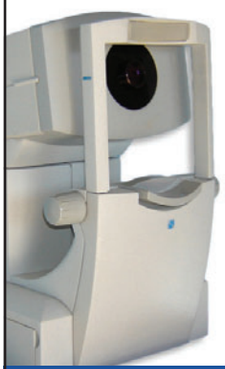

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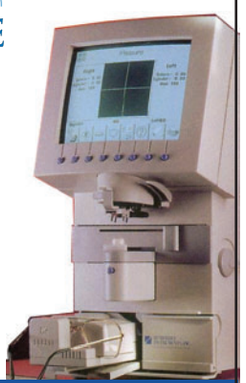

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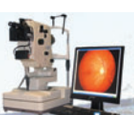

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Deadline to apply for a Fellowship is June 30, 2014.
Deadline to apply for a research grant is August 31, 2014.
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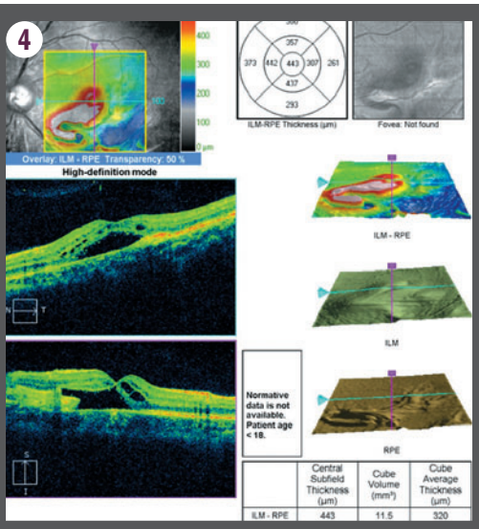
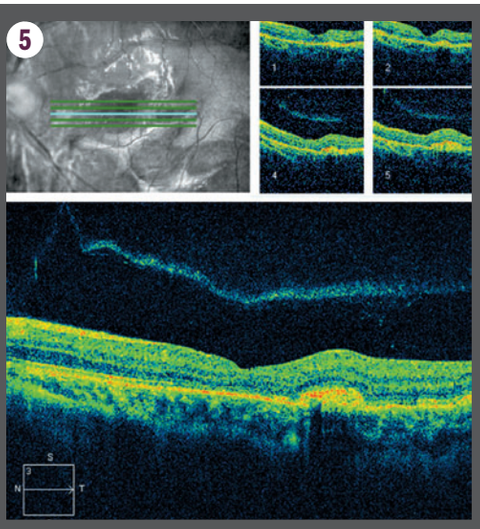
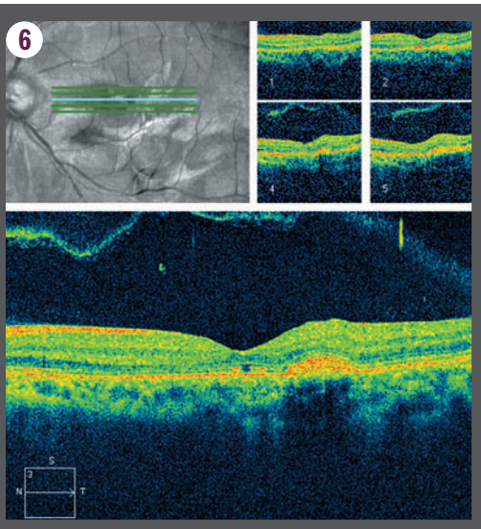


4 Ten-week follow-up visit, OCT demonstrates spontaneous resolution of full thickness macular hole with surrounding edema and intraretinal cyst formation.



5 Seven-month follow-up visit, OCT demonstrates spontaneous closure of the macular hole. Separation of the posterior hyaloid face is noted.



6 Nine-month follow-up visit demonstrates complete closure of the macular hole. Visual acuity improved to 20/30. *(Images courtesy of Rebecca A. Shields on behalf of Bascom Palmer Eye Institute Photography Department)*

MACULAR HOLE

(Continued from page 55)

At 10-week follow-up visit, the visual acuity improved to 20/60, and OCT began to demonstrate spontaneous resolution of the macular hole (Figure 4).

Observation was continued.

At 7 months follow-up visit, the patient's OCT demonstrated spontaneous closure of the macular hole with subretinal and intraretinal fluid (Figure 5).

The separation of the posterior hyaloid was clearly seen.

At 9 months follow-up visit, BCVA was 20/30 in the left eye. OCT demonstrated an irregular foveal contour but now with complete closure of the macular hole (Figure 6).

DISCUSSION

Traumatic macular holes were first described in the late 1800s. At that time, direct globe injury was believed to be the inciting event.

Modern theory remains unclear as to the specific mechanism of formation of traumatic macular holes. However, a number of hypotheses have been proposed.

Some researchers believe that tangential traction of the posterior hyaloid face may lead to development of holes. Others believe that sudden forces on the globe after blunt injury may place stress on the retina at points of vitreous attachment leading to traction and hole formation.

Recent studies in animals and surgical observation strongly support the belief that traction from the vitreous plays the largest role in hole formation. In spite of such discussion, a specific management algorithm has not yet been described and a complete understanding of the pathogenesis of disease has yet to be reported.

However, recent case reports of macular hole in the pediatric population often point to a traumatic etiology for disease development.

In previous reports, idiopathic macular holes have demonstrated great visual prognosis after vitrectomy surgery. A case series by Johnson, et al. in 2001 followed 25 cases of traumatic macular hole treated with vitrectomy.

However, in the study only one-third of these cases were pediatric cases. Twenty-four of the 25 cases had complete closure of the macular hole.

In 84% of the cases, visual acuity improved 2 or more lines, with 64% of patients achieving vision of 20/50 or better.

Such a report is strong evidence for early surgical management to promote best visual prognosis. However, a number of other case series suggest observational management can be used in traumatic macular holes, as they often will spontaneously close without further intervention, thus sparing morbidity associated with surgical intervention.

Our patient improved significantly with observation alone. Studies suggest that spontaneous closure of traumatic holes occurs following resolution of vitreofoveal adhesion and release of the posterior hyaloid. Others argue that inflammatory mechanisms enable a reformation and spontaneous closure of the macular hole.

The exact mechanism of resolution is not clear in our patient, however, as reported in many articles.Pediatric patients for a number of reasons are more likely to experience spontaneous closure and good visual prognosis—further proving a role for observation in traumatic pediatric patients before embarking on surgical intervention and postoperative care that requires positioning.

CONCLUSION

Spontaneous closure of traumatic macular holes is a rarely reported event. Surgical intervention can be spared in a group of patients with hole formation after blunt trauma.

Clinical decision making, however, should be made on a case by case case-by-case basis that considers the patient's age, mechanism of trauma, potential for visual prognosis, and long-term morbidity associated with surgical intervention. ■

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DESCRIPTION: Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

ACTION: The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphylococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

INDICATIONS: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

CONTRAINDICATIONS: This product should not be used in patients with a history of hypersensitivity to Bacitracin.

PRECAUTIONS: Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

ADVERSE REACTIONS: Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

DOSAGE AND ADMINISTRATION: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

HOW SUPPLIED: 3.5 g (1/8 Oz) sterile tamper proof tubes, NDC 48102-007-35.

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