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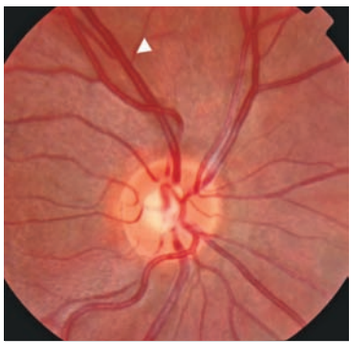
Clinical Diagnosis

BEYOND RNFL LOSS: WHAT OPTICAL IMAGING REVEALS



NEW YORK :: **ADVANCES** in imaging technology have helped answer numerous questions, but also created a new set of queries. Mark J. Kupersmith, MD, takes a deeper look at several imaging technologies that have improved optical imaging.

(See story on page 10 : Imaging)

Technology

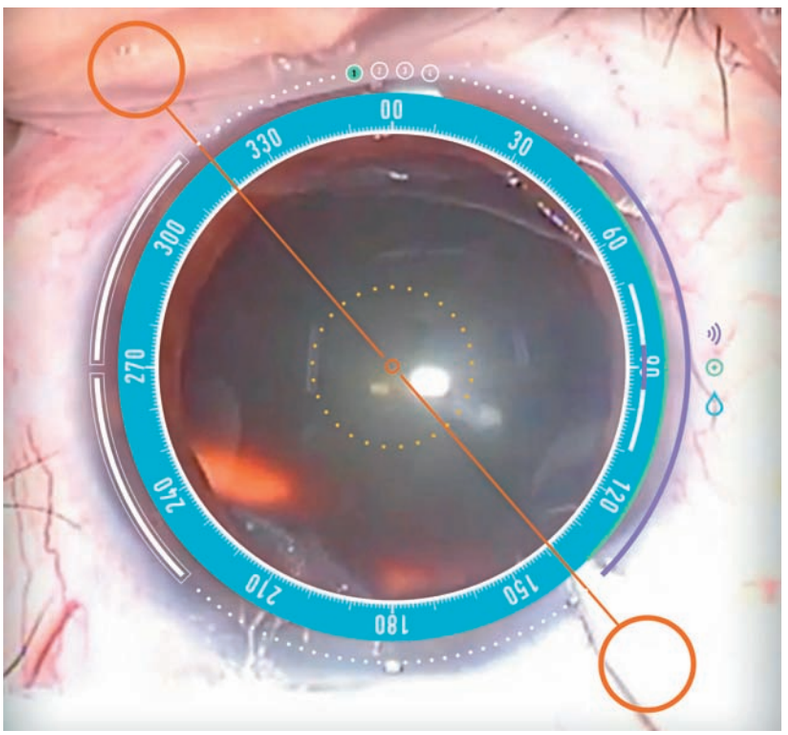
SINGLE-USE LENSES YIELD MULTIPLE DIAGNOSTIC GAINS

LONDON :: **A NEW LINE** of single-use anterior segment lenses for diagnostic, surgical, and therapeutic procedures offers a solution to many of the concerns associated with traditional single-use lenses: disease transmission and loss of therapeutic efficacy, said Professor John Marshall, PhD.

(See story on page 34 : Single-use lenses)

3-D guidance system improves cataract outcomes

Open-source platform enhances execution of four critical surgical steps



The surgical navigation platform features tagging (Holotag technology) that automatically projects surgical marks and measurements in three dimensions at the correct anatomical features, as technology (StereoCapture) tracks anatomical features optically in three dimensions.
(Image courtesy of Richard Awdeh, MD)

Watch as Richard Awdeh, MD, explains how the surgical navigation system works. Go to http://bit.ly/1DyhIND

By Cheryl Guttman Krader;
Reviewed by Richard Awdeh, MD

MIAMI ::
A NEW DIGITAL IMAGE guidance platform (Surgical Navigation System, Cirle) is a first-in-kind system for improving efficiency in cataract surgery and patient outcomes, according to its inventor, Richard Awdeh, MD. Using optical and digital technology, the system integrates preoperative data and images to provide intraoperative three-dimensional (3-D) image guidance through the oculars of the surgical microscope that enhances the accurate execution of four critical surgical steps:

- Cataract incision placement
- Capsulorhexis sizing and centration
- Toric IOL alignment
- Limbal relaxing incision placement

The system was designed to allow easy transfer of data from the clinic to the operating room and to be open source so that surgeons can use their existing diagnostic systems and microscope as well

(Continues on page 30 : Guidance)

UBM

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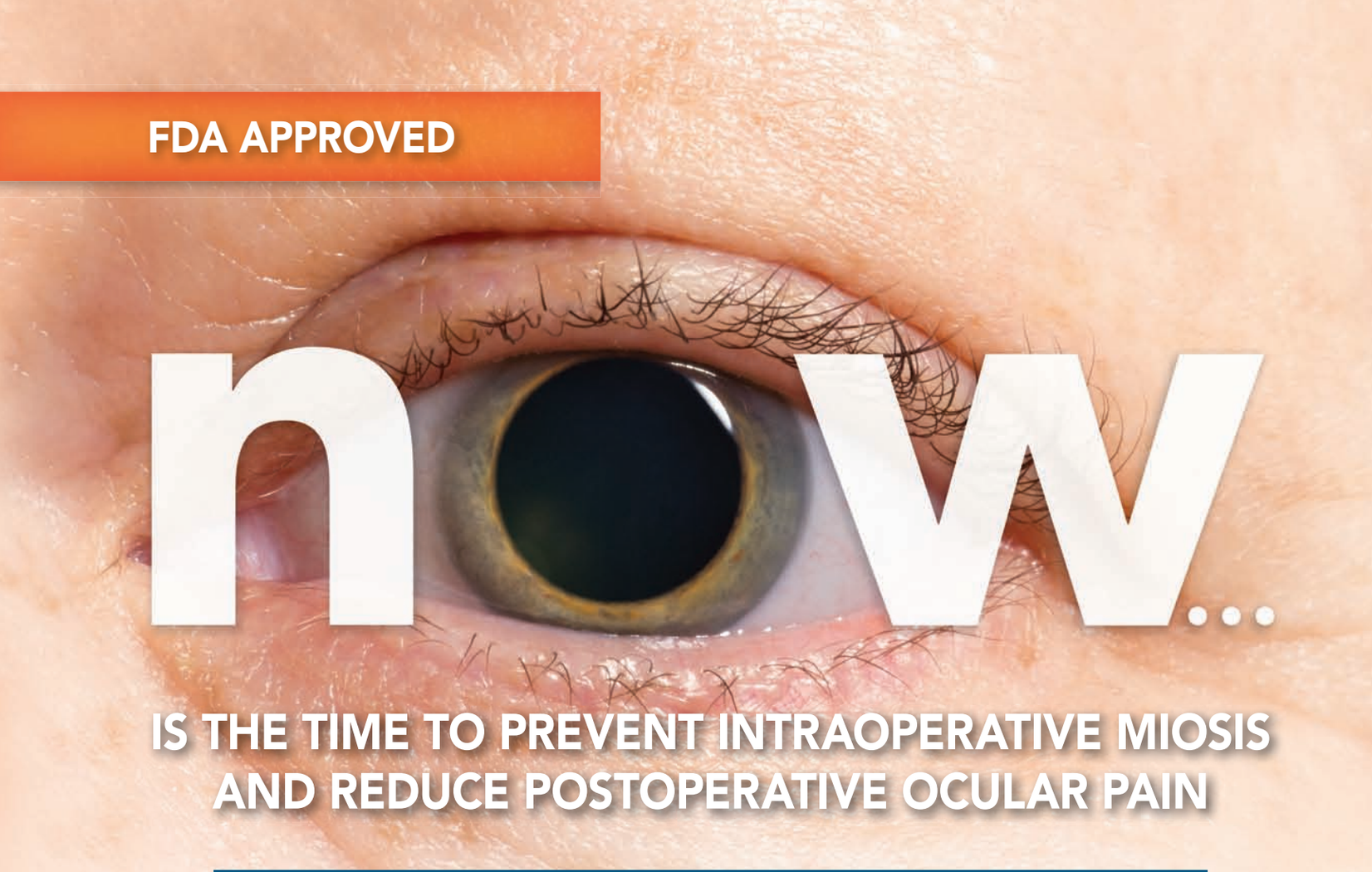

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WIDE OPEN

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Ignaz Semmelweiss: A physician-hero

History proves physicians should pursue truth, even in adversity

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*.

He can be reached at 727 Maumenee Building
600 N. Wolfe St. Baltimore, MD 21287-9278
Phone: 443/287-1511 Fax: 443/287-1514
E-mail: pmcdonn1@jhmi.edu

RECENTLY, I HAD my photo taken with Ignaz Semmelweiss. Not with the man himself, but with his statue. Although his is not a household name, the man is a physician-hero.

Born in 1818 in the city of Buda, Hungary, Semmelweiss became an obstetrician and worked in the First Obstetrical Clinic in Vienna, Austria. Two clinics in Vienna General Hospital alternated admitting pregnant women. Semmelweiss observed that the clinic managed by physicians differed from the clinic run by midwives in the frequency of "childbed fever." This condition—now known as puerperal fever—was much more common in the physician-run First Clinic than in the midwife-run Second Clinic.

The disease had a high mortality rate, and the death rate of pregnant women in the First Clinic was about 10% to 20%, compared with 2% to 4% in the Second Clinic.

Semmelweiss noted that physicians, not the midwives, examined patients at autopsy during the day, and he conjectured that something on the physicians' hands was responsible for causing the fevers and deaths. He experimented with having his doctors dip their hands into a solution of lime (calcium hydroxide) and showed that the rates of fever and death in the First Clinic quickly plummeted by 90% or more. He then ordered that the obstetrical instruments be immersed in the solution.

CHALLENGE TO ORTHODOXY

As word of his innovation spread, Semmelweiss expected that he would be congratulated and his intervention adopted broadly. Instead he was ignored, criticized, and ridiculed.

Many physicians, of course, were angry that he made them look bad by pointing out the high complication rate of physicians relative to the midwives, whereas others noted that he had no satisfactory explanation for his findings (Louis Pasteur would not propose his germ theory of disease until decades later). He was forced out of his hospital in Vienna.

Semmelweiss relocated to Hungary, where he repeated his study of the efficacy of lime, obtaining the same results and virtually eliminating the disease from his hospital.

His success in the clinics still did not translate into acceptance by his colleagues, and Semmelweiss became anxious and depressed. He reportedly used every conversation as an opportunity to rant against his fellow obstetricians who did not accept his findings.

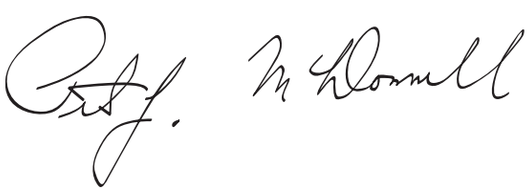
At the age of 47 he was placed in an insane asylum, and within 2 weeks, staff members beat him to death.

FLASH FORWARD

Today, we know about bacterial infection and that *Strep pyogenes* is the most common cause of puerperal sepsis. We accept the value of hand hygiene and instrument sterilization. Today, we are well schooled in the importance of honoring the results of clinical trials, whether or not the results and explanations conform to our expectations. Today, the statue of Semmelweiss stands in the beautiful campus of a fine medical school that bears his name (and where, incidentally, the first femtosecond laser-assisted cataract surgeries were performed).

The vindication, statues, and honors came too late for Semmelweiss to know of them. Time ultimately proved him a hero for fearlessly advancing some unpopular truths and saving the lives of many women when it would have been much better for his career to remain silent.

Standing under towering, century-old trees, Semmelweiss has a message for today's young physicians: The right thing is to pursue truth wherever it leads, even if it means challenging orthodoxy and comes at high personal cost. ■



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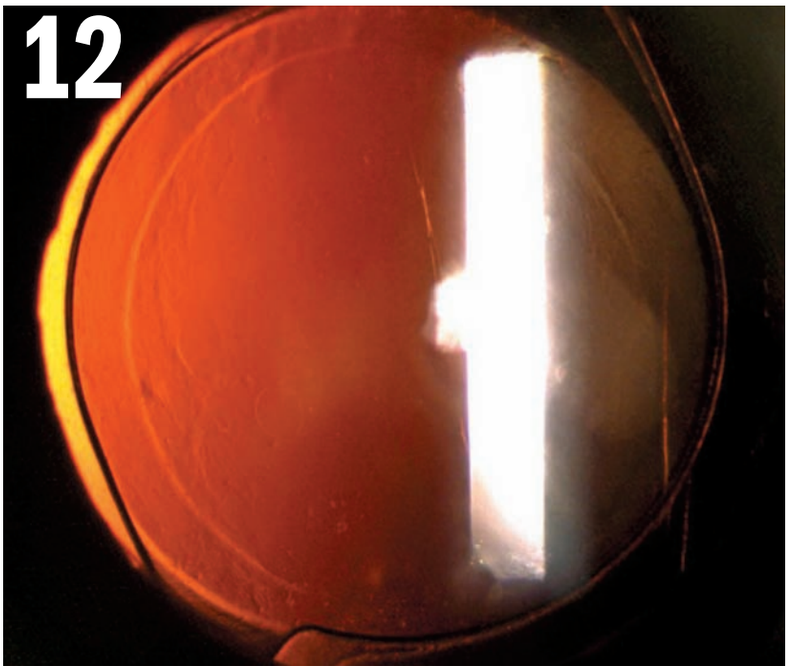

Clinical Diagnosis

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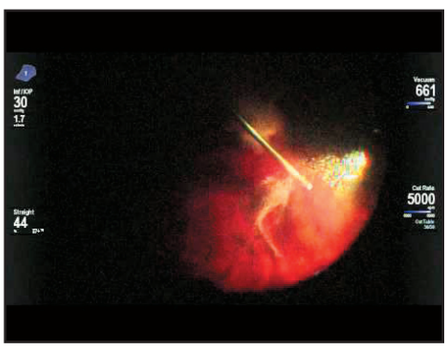

To watch a vitrectomy flow rate comparison go to http://bit.ly/1pb5Miq.
(Video courtesy of Pravin Dugel, MD)

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1. Conrad-Hengerer et al. *J Cat Refract Surg.* 2012; Conrad-Hengerer et al, JCRS 2012; 38(11): 1888-94.
2. Fabian E et al. New Phaco Fluidics Control: Case to Prevent Surge. Presented at ESCRS, Sept 2006, London, U.K.

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Actavis-Allergan deal fosters 'marriage of 2 great companies'

CEOs of both firms outline what the $66 billion acquisition means to ophthalmology

By Mark L. Dlugoss, *Group Content Director,* Ophthalmology Times

In November, Actavis announced it was acquiring Allergan in a $66 billion acquisition, thus thwarting a 7-month effort by Valeant Pharmaceuticals—and William Ackman, chief executive officer (CEO) of Pershing Square Capital Management—to acquire the multispecialty pharmaceutical company through a hostile takeover.

Though some industry observers may view Actavis as "a white knight" in its acquisition of Allergan, the principles involved view the deal as an opportunity to create one of the "most dynamic growth pharmaceutical companies in the world."

Brent Saunders, CEO of Actavis, and David E.I. Pyott, chairman and CEO of Allergan, outlined the details of the acquisition, what it means for both companies, and most importantly, to the eyecare market in an exclusive interview with *Ophthalmology Times*.


Saunders

"The combined companies will have pro forma revenue of about $23 billion dollars in 2015, and we'll be a leader in categories like ophthalmology, medical aesthetics, neurology, gastrointestinal, and women's health among other areas," Saunders said. "We're excited about creating one of the fastest-growing, most dynamic pharmaceutical companies in the world."

Saunders looks at the acquisition as a marriage of two great companies.

"Both companies are incredibly well run and both are committed to customer service, to innovation, and to our employees," he said. "When we put these two companies together, we're looking to really accelerate our commitment to innovation and customer service."

Pyott said the values of both companies are exactly the same, placing the primary focus on the customers—the physicians or the patients served by the physicians—and innovation. He added that Allergan would contribute solid assets to the combined company.

"I'm really looking forward to see how this combined management team really executes on this new genre of growth pharma and the dynamism," Pyott said, "which I think will be really a beacon for everybody in the pharmaceutical and medical device industry."

Saunders explained that when a deal of this magnitude is developed, there is something special about the company—and clearly that is the case with Allergan.

He added that one of the most impressive points about Allergan is the people and their capabilities—this is not about an acquisition and merging it under the Actavis umbrella. Saunders outlined that Actavis will preserve what made Allergan great and treat the situation as more of a merger than an acquisition.

"What you'll see us doing is putting our customers at the center of everything we do to . . . continue to provide excellent customer service, a commitment to education, and training for physicians and, of course, innovation," Saunders said.

SYNERGIES IN ACTION

Both executives see a synergy between the companies that makes the acquisition a solid fit. Saunders sees synergies in the area of revenue and enhancing Actavis' business capabilities.

He explained that Actavis has strengths in areas where Allergan was weak, and vice versa. As an example, Saunders alluded to the "geographic footprint" of the companies. In Western Europe where Allergan has great strength, Actavis did not have a strong presence. The same holds true in Latin America. Meanwhile in Eastern Europe, Actavis is stronger.

"Combined, we have not only a good presence, but we have more product flow," he said. "Our global position and our ability to service customers around the world only gets stronger."


Pyott

Pyott also sees plenty of synergies between the teams.

"My belief is it won't be a case of us and them, but us all together," Pyott said. "That's very exciting when organizations like this come together."

Actavis also plans to retain Allergan as a brand. Saunders said Actavis is spending time talking to its customers and understanding how to use both brand equities, in what order, and or under which label.

"The Allergan name and the Actavis name both have great value in different parts of the medical community," Saunders added.

As the two companies integrate, the policies and procedures should have seamless implications for the ophthalmic and eyecare markets.

"Over the long term, we're absolutely dedicated to supporting the eye health community," Saunders said, "[by] continuing to drive product innovation through research and development (R&D) and through bringing both products and perhaps devices in the future to help ophthalmologists and optometrists build their practices."

Saunders also emphasized that Actavis is steadfast in its commitment to R&D. One of the major issues within the eyecare communities during the Valeant takeover attempt was the argument of R&D (See "Focus on efficient R&D pays dividends for physicians, patients" *(http://bit.ly/1wIDPzw)* and "Future of ophthalmic innovation is through R&D partnerships" *(http://bit.ly/1JaXnSr)*. Saunders reassured physicians and researchers that R&D is important.

"R&D is the lifeblood of the industry," he said. "You will see us continue to invest in all the wonderful pipeline programs that are in the Allergan portfolio and [we] continue to look to add to them." ■

OphthalmologyTimes.com PODCAST

LISTEN TO Brent Saunders, CEO of Actavis, and David E.I. Pyott, chairman and CEO of Allergan, discuss the Actavis acquisition of Allergan and what it means to the eyecare market. The podcast also outlines Allergan's main points of resistance to the Valeant offer and what the future holds for Pyott following 17 years at the helm of Allergan.
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References: 1. PROLENSA® Prescribing Information, April 2013. **2.** Data on file, Bausch & Lomb Incorporated. **3.** Baklayan GA, Patterson HM, Song CK, Gow JA, McNamara TR. 24-hour evaluation of the ocular distribution of ^{14}C-labeled bromfenac following topical instillation into the eyes of New Zealand White rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398. **4.** BROMDAY® Prescribing Information, October 2012.

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Beyond retinal nerve fiber layer loss: What optical imaging can reveal

Advances in technology have helped answer numerous questions, while raising new queries

By Michelle Dalton, ELS;
Reviewed by Mark J. Kupersmith, MD

NEW YORK ::

These days, it is commonplace to use optical coherence tomography (OCT) to measure retinal nerve fiber layer (RNFL) thinning with optic nerve injury, due to glaucoma, optic neuritis, or ischemic optic neuropathy, and to determine disease progression and the effects of therapy.

Other methods of optical imaging, polarimetry and applied optics, are either less commonly used or in development.

These and other techniques "can show injury to peripapillary retinal axons and ganglion cells before the RNFL is thinned and can be used to increase the intensity of therapy or serve as an objective outcome or biomarker in treatment trials," said Mark J. Kupersmith, MD, as he discussed his interest in neuro-ophthalmology, and how far imaging has come since his resident days.


Dr. Kupersmith

"Like most neuro-ophthalmologists and glaucoma specialists, I am always interested in identifying changes in the optic nerve that can be used to monitor the effects of treatment, so-called biomarkers, or those that might suggest permanent injury that would not improve with an intensive or invasive therapy," said Dr. Kupersmith, director of neuro-ophthalmology, Institute of Neurology and Neurosurgery, Mount Sinai, New York, and chief of service of neuro-ophthalmology, New York Eye and Ear.

Through his work with many collaborators, Dr. Kupersmith has looked at diseases that cause optic nerve injury, including optic neuritis related to multiple sclerosis, or ischemic optic neuropathy, or optic nerve damage from chronic papilledema, among others.

"All of those disorders result in either one-time or progressive visual loss," Dr. Kupersmith said. "We're looking at therapies to try to prevent the subsequent vision loss when someone presents, or try to reverse the visual loss."

To date, no neuroprotective drug has been proven efficacious in humans. "But when they are available, the question is: How are you going to study it?" he asked. The answer is "imaging."

OPTIC NEURITIS

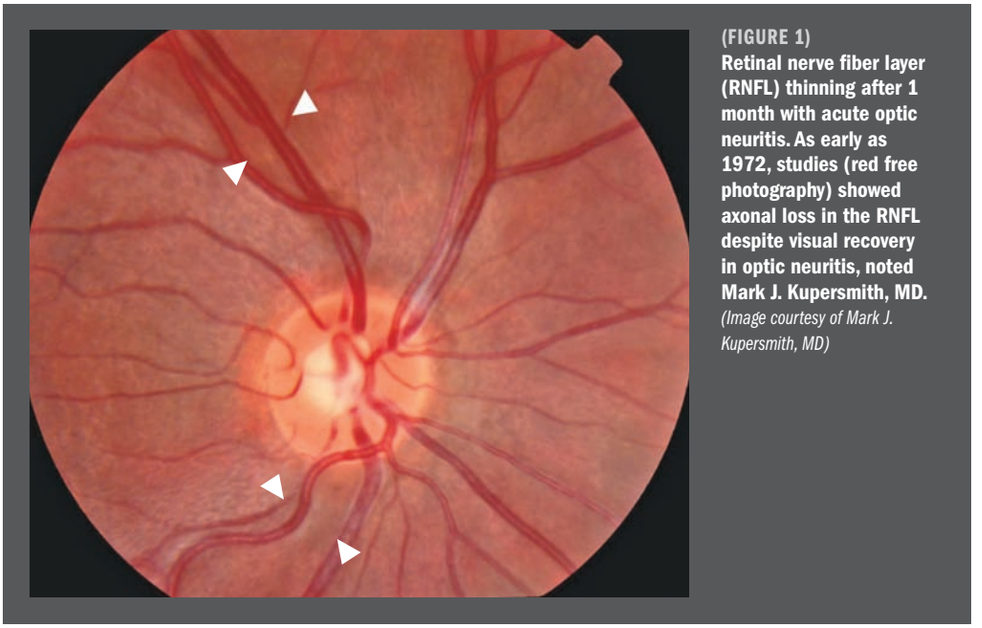
As early as 1972, studies (red free photography) showed axonal loss in the RNFL despite visual recovery in optic neuritis, Dr. Kupersmith noted.

"What would be predictive of having a bad outcome at presentation?" he asked. "We looked at the original optic neuritis treatment trial data, and we found there was nothing in the baseline vision studies that could distinguish those eyes that would recover from those that would to do poorly."

Optical imaging results confirmed evidence provided by vision studies—the 1-month time frame was crucial, as the amount of visual or residual vision loss or loss of RNFL at 1 month was predictive of the propensity for recovery.

By the end of that first month, "sometimes it seemed to be too late," he said.

Axonal loss may not be recognized early due to RNFL swelling.



(FIGURE 1)
Retinal nerve fiber layer (RNFL) thinning after 1 month with acute optic neuritis. As early as 1972, studies (red free photography) showed axonal loss in the RNFL despite visual recovery in optic neuritis, noted Mark J. Kupersmith, MD.
(Image courtesy of Mark J. Kupersmith, MD)

> 'We're looking at therapies to try to prevent the subsequent vision loss when someone presents.'
>
> — Mark J. Kupersmith, MD

"We realize now that if we look at OCT of the ganglion cell layer in the macula at baseline, it may look okay but by 2 weeks we can start to see the loss of ganglion cells in optic neuritis," Dr. Kupersmith said.

Spectral-domain OCT helped confirm the early loss in optic neuritis and his group found "a similar, but more profound loss in ischemic optic neuropathy."

SCANNING LASER POLARIMETRY

Scanning laser polarimetry (SLP) is based on a different type of biophysics than OCT, Dr. Kupersmith said.

"It's based on the fact that the nerve fiber layer is polarized, due to having intact neural filaments," he noted.

If a pathological process, such as ischemia, causes irreversible injury to a group of axons, "the peripapillary RNFL and affected retina could lose neural filaments acutely and, lo and behold, at presentation patients with anterior ischemic optic neuropathy show a loss of birefringence in the areas that are most affected," he said.

However, the SLP technology is somewhat outdated, he laments, and has not been updated because most clinicians, groups, and departments will only purchase one new imaging device, and the flexibility of the OCT outweighs the SLP, he said.

"SLP only looks at the nerve fiber layer, so it's limited to use in glaucoma and other optic neuropathies, and has fallen out of favor," he said. "Thus, the business decision is not to put money into furthering that technology."

Ideally, using this type of technology to notice a change in birefringence in optic neuritis or neuromyelitis optica would be helpful, but it is currently not possible with today's "crude technology," he noted.

TAKE-HOME

- ***Mark J. Kupersmith, MD, takes a look at optical imaging of the optic nerve beyond documenting retinal nerve fiber layer loss.***

EXPLORING IIH

Though an uncommon illness, idiopathic intracranial hypertension (IIH) is most common in women, especially those with obesity. After making "all kinds of adjustments on the imaging programs we use" on OCT, Dr. Kupersmith said his group found a dynamic shape changes of the neural canal that occurs in "the optic nerve that no one ever suspected was possible.

"Prior work in glaucoma suggested the increased pressure in the eye resulted in shape change of the optic nerve head only after patients lost a tremendous amount of neural and lamina tissue," he said. But with IIH, observing pressure arising from outside the eye, "it turns out the optic nerve head shape changes tremendously and quickly."

His group quickly developed some hypotheses on the relationship between the shape of the optic nerve head and how that reflects changes in intracranial pressure.

"There's a complex relationship between the pressure in the subarachnoid space behind the eye and the IOP that has implications for the changes in the optic nerve relative to glaucoma," he said.

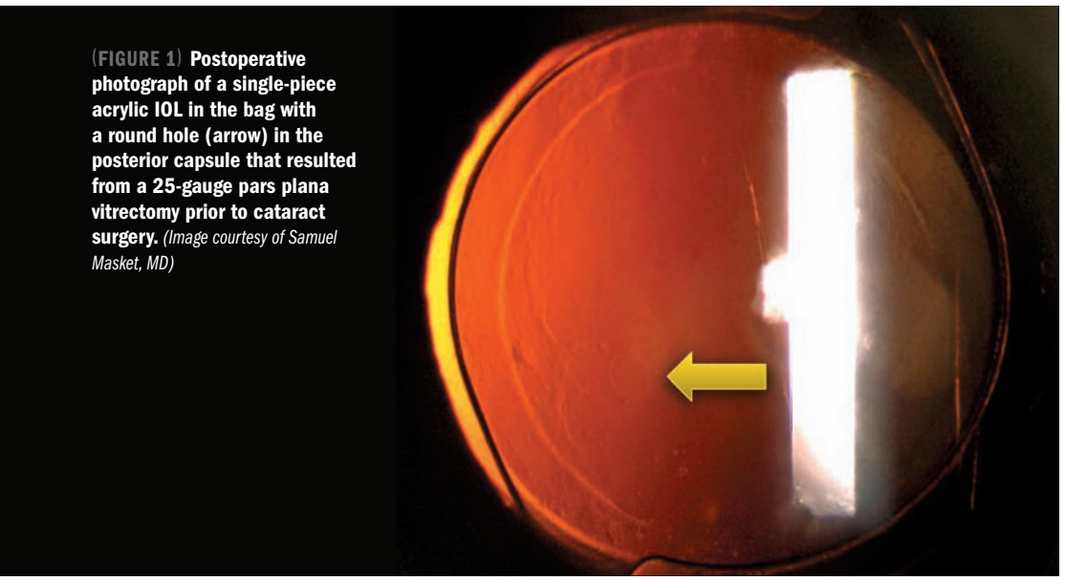
A new study will evaluate if patients with IIH and visual field loss will have early ganglion cell loss and if that relates to later visual loss or poor recovery. "Our study will investigate patients with moderate to severe loss due to papilledema in a randomized trial comparing surgeries and medication," Dr. Kupersmith said.

"I'm not a tech person. I'm not an OCT expert," he said. "I'm a clinician, and I have questions that relate to current and future care. I have to find the best way . . . to answer them, and optical imaging may provide some of the needed tools." ■

MARK J. KUPERSMITH, MD

E: *mkuper@chpnet.org*

This article was adapted from Dr. Kupersmith's presentation of the Hoyt Lecture at the 2014 meeting of the American Academy of Ophthalmology. Dr. Kupersmith did not indicate a proprietary interest in the subject matter.



(FIGURE 1) **Postoperative photograph of a single-piece acrylic IOL in the bag with a round hole (arrow) in the posterior capsule that resulted from a 25-gauge pars plana vitrectomy prior to cataract surgery.** *(Image courtesy of Samuel Masket, MD)*

APPLYING CATARACT SURGERY STRATEGIES IN SETTING OF OPEN POSTERIOR CAPSULE

How having an index of suspicion helps to guide appropriate surgical planning and decisions

By Cheryl Guttman Krader; *Reviewed by Samuel Masket, MD*

take-home

- **In patients who present with a cataract, certain histories should raise suspicion about existing damage to the posterior capsule or an increased risk for capsule rupture intraoperatively. Armed with that information, cataract surgeons can implement proper strategies for cataract removal and IOL implantation.**

LOS ANGELES ::

Cataract surgery in eyes with an open posterior capsule or that are at high risk for intraoperative rupture requires proper planning and specific careful techniques.

First, however, the onus on surgeons is to recognize these cases so that they will implement the appropriate strategies, said Samuel Masket, MD.

"Forewarned is forearmed, and therefore, cataract surgeons need to know when to have a high index of suspicion for an open posterior capsule," said Dr. Masket, clinical professor of ophthalmology, David Geffen School of Medicine, University of California, Los Angeles. "Not only will they have to change their surgical approach in these cases, but they should also involve a vitreoretinal specialist and will need to counsel the patient appropriately to set proper expectations."

Clues to an open posterior capsule come from the patient's history, and then documentation is sometimes possible using B-scan ultrasound. The presence of an open posterior capsule should be suspected in eyes with a mature cataract that developed rapidly after vitreoretinal surgery, intravitreal injection, or some incidental trauma.

"In cases where the cataract developed after a vitreoretinal procedure, surgeons should know that while the vitrectomy probe is likely to cause a round hole, sharp needle injury results in a laceration that will leave the posterior capsule unmanageable at the time of cataract surgery," Dr. Masket said.

Aside from the cases where there is injury to the posterior capsule, there is a 25% likelihood that the posterior capsule will be open in eyes with a posterior polar cataract.

In addition, eyes with posterior lenticonus have an elevated risk for intraoperative rupture of the posterior capsule and will also require special maneuvers.

PLANNING PRINCIPLES

Dr. Masket said that cataract surgeons operating in an eye known to have an open posterior capsule should reach out to a vitreoretinal colleague. If the problem developed during the course of a vitreoretinal procedure, the surgeon who operated in that case may wish to participate in the cataract procedure.

At the least, a vitreoretinal surgeon should be informed about a possible upcoming referral for managing posteriorly dislocated lens material.

"If I know there is a hole in the posterior capsule, I think it is best to do the cataract surgery in conjunction with a vitreoretinal colleague, and especially in the setting of a vitrectomized eye," Dr. Masket said. "In the latter situation, there is a strong likelihood the nucleus will drop, and then it will fall rapidly when there is no vitreous to cushion its descent."

In terms of specific considerations for the surgical technique, surgeons should anticipate performing optic capture to secure the IOL. Therefore, proper placement and size of the anterior capsulotomy is critical, and with that in mind, Dr. Masket recommended a few techniques.

"Rapid onset cataracts developing after damage to the posterior capsule are almost always white cataracts that would benefit greatly from

Continues on page 17 : **Posterior capsule**

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In search of the sutureless closure

Surgeon perspective: Sealant prevents fluid egress, maintains patient comfort, efficiency

By Stephen S. Lane, MD; *Special to* Ophthalmology Times

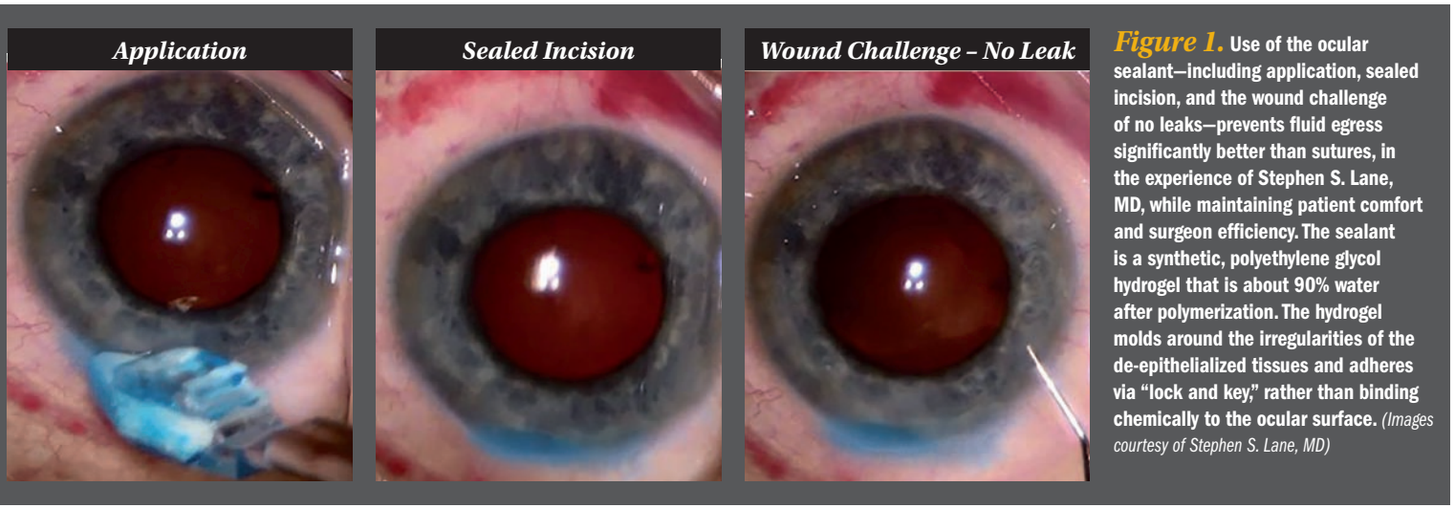

Figure 1. **Use of the ocular sealant—including application, sealed incision, and the wound challenge of no leaks—prevents fluid egress significantly better than sutures, in the experience of Stephen S. Lane, MD, while maintaining patient comfort and surgeon efficiency. The sealant is a synthetic, polyethylene glycol hydrogel that is about 90% water after polymerization. The hydrogel molds around the irregularities of the de-epithelialized tissues and adheres via "lock and key," rather than binding chemically to the ocular surface.** *(Images courtesy of Stephen S. Lane, MD)*

CLEAR CORNEAL incisions are gaining favor quickly among cataract surgeons because they are easy to perform, require less time, and have minimal effect on astigmatism. In addition, if performed correctly, they are generally self-sealing.

In spite of these benefits, wound leakage is more common than ophthalmologists may presume, with some reports showing incidence as high as 85%.[1-4] The inflow of ocular surface fluid through a fresh postoperative incision may allow bacteria to be introduced to the anterior chamber, and wound incompetence on the first postoperative day has been found to be a significant risk factor for endophthalmitis.[5]

WOUND INTEGRITY

Sutures have been considered the gold standard for incision closure, but 92% of surgeons responding to a survey by the American Society of Cataract and Refractive Surgery prefer a sutureless closure.[6]

This is likely due to the disadvantages of sutures which include:

- inflicting trauma on the cornea,
- time for suture placement in the operating room,
- induction of corneal astigmatism,
- extra office time for removal; and
- creating a possible nidus for infection, inflammation, and neovascularization.

In addition, the published wound leak with sutures is still almost 24%.[4]

A novel product (ReSure Sealant, Ocular Therapeutix) approved by the FDA last January was the first ophthalmic sealant for use in preventing fluid from leaking through the corneal incision following phacoemulsification. The sealant is a synthetic, polyethylene glycol hydrogel that is about 90% water after polymerization. The hydrogel molds around the irregularities of the de-epithelialized tissues and adheres via "lock and key," rather than binding chemically to the ocular surface.

The U.S. Pivotal Clinical Trial evaluated the safety and efficacy of the sealant on 488 eyes that exhibited leakage using a specialized pressure gauge at the time of cataract surgery.[7] These patients, from 24 ophthalmic clinics in the United States, were randomly assigned to receive either the sealant (n = 305) or a nylon suture (n = 183) at the main incision site.

Incision leakage was evaluated at 1, 3, 7, and 28 days postoperatively. The sealant demonstrated statistically significant superiority over sutures, with only 4.1% of eyes in the sealant cohort exhibiting leakage of the wound with provocation, compared with 34.1% in the suture group. The overall incidence of device-related adverse ocular events was also significantly lower for patients treated with sealant (1.6%) versus patients treated with sutures.

PERSONAL TECHNIQUE

Though there are a few ways to apply the hydrogel, what works for me is the following: after IOL placement, the eye is filled to a physiologic IOP through one of the paracentesis. The surgeon may want to underfill the eye slightly to avoid any leakage.

The incision site is then thoroughly dried with a sponge. Once the incision site is completely dry, pick up the mixing tray and hold it in view under the microscope. Add two drops of the diluent, consisting of water and buffer salts, to the blue deposit in one of the wells. This deposit contains the crosslinking agent, Trilysine, as well as the blue visualization aid to assist in application over the incision. Using the foam tip of the provided applicator, rapidly mix the solution with the white deposit, polyethylene glycol (PEG), for 3 to 5 seconds until the material is liquefied. At this point, the material must be applied within the next 8 seconds as polymerization on the ocular surface occurs quickly.

The same applicator sponge that was used to mix the product should be sufficiently saturated to apply it. Start in the middle of the incision, and apply the product in a figure-eight pattern to cover the incision entirely and with complete coverage over the peripheral margins. During application, it is important not to press on the wound with the applicator, but rather softly place the material over the incision.

Once the sealant has been allowed to polymerize completely for 20 seconds after application, inflate the eye through my side-port

Continues on page 17 : **Sutureless**

In the face of elevated IOP after monotherapy

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INDICATIONS AND USAGE: COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% is an alpha-adrenergic receptor agonist with a beta-adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP; the IOP-lowering of COMBIGAN® dosed twice a day was slightly less than that seen with the concomitant administration of 0.5% timolol maleate ophthalmic solution dosed twice a day and 0.2% brimonidine tartrate ophthalmic solution dosed three times per day.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: COMBIGAN® is contraindicated in patients with bronchial asthma; a history of bronchial asthma; severe chronic obstructive pulmonary disease; in patients with sinus bradycardia; second or third degree atrioventricular block; overt cardiac failure; cardiogenic shock; in neonates and infants (under the age of 2 years); in patients with a hypersensitivity reaction to any component of COMBIGAN® in the past.

WARNINGS AND PRECAUTIONS: COMBIGAN® contains timolol maleate; while administered topically, it can be absorbed systemically and systemic adverse reactions to beta-blockers may occur (eg, severe respiratory reactions including death due to bronchospasm in patients with asthma have been reported).

Sympathetic stimulation may be essential to support the circulation in patients with diminished myocardial contractility and its inhibition by beta-adrenergic receptor blockade may precipitate more severe failure. In patients with no history of cardiac failure, continued depression of the myocardium with beta-blocking agents over time can lead to cardiac failure. Discontinue COMBIGAN® at the first sign or symptom of cardiac failure.

Patients with chronic obstructive pulmonary disease (eg, chronic bronchitis, emphysema) of mild or moderate severity, bronchospastic disease, or a history of bronchospastic disease should not receive COMBIGAN®.

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS: (continued)

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

Although rare, timolol can increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.

Beta-blockers may mask the signs and symptoms of acute hypoglycemia and clinical signs (eg, tachycardia) of hyperthyroidism. Use caution in patients subject to spontaneous hypoglycemia or diabetics (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Carefully manage patients who may develop thyrotoxicosis to avoid abrupt withdrawal of beta-blockers that might precipitate a thyroid storm.

Ocular hypersensitivity has occurred with brimonidine tartrate ophthalmic solutions 0.2% (eg, increase in IOP).

Some authorities recommend gradual withdrawal of beta-blockers due to impairment of beta-adrenergically mediated reflexes during surgery. If necessary during surgery, the effects of beta-blockers may be reversed by sufficient doses of adrenergic agonists.

ADVERSE REACTIONS: The most frequent reactions with COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% in about 5% to 15% of patients included: allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, ocular burning, and stinging.

DRUG INTERACTIONS: Use caution in the co-administration of COMBIGAN® with: antihypertensives or cardiac glycosides; beta-blockers (concomitant use of two topical beta-blockers is not recommended); calcium antagonists (avoid co-administration in patients with impaired cardiac function); catecholamine-depleting drugs; CNS depressants /anesthetics; digitalis and calcium antagonists; CYP2D6 inhibitors; tricyclic antidepressants; and monoamine oxidase inhibitors.

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

[a]Includes preferred, approved, and tiers 1-4, with and without step-edits, and also includes prior authorization, based on 203,671,234 total lives.

1. Managed Markets Insight & Technology, LLC, database as of December 2013.

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BRIEF SUMMARY

Please see the **COMBIGAN®** package insert for full prescribing information.

INDICATIONS AND USAGE

COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% is an alpha adrenergic receptor agonist with a beta adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP; the IOP-lowering of **COMBIGAN®** dosed twice a day was slightly less than that seen with the concomitant administration of 0.5% timolol maleate ophthalmic solution dosed twice a day and 0.2% brimonidine tartrate ophthalmic solution dosed three times per day.

CONTRAINDICATIONS

Asthma, COPD: COMBIGAN® is contraindicated in patients with bronchial asthma; a history of bronchial asthma; severe chronic obstructive pulmonary disease.

Sinus bradycardia, AV block, Cardiac failure, Cardiogenic shock: COMBIGAN® is contraindicated in patients with sinus bradycardia; second or third degree atrioventricular block; overt cardiac failure; cardiogenic shock.

Neonates and Infants (Under the Age of 2 Years): COMBIGAN® is contraindicated in neonates and infants (under the age of 2 years).

Hypersensitivity reactions: Local hypersensitivity reactions have occurred following the use of different components of **COMBIGAN®**. **COMBIGAN®** is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

WARNINGS AND PRECAUTIONS

Potentiation of respiratory reactions including asthma: COMBIGAN® contains timolol maleate; and although administered topically can be absorbed systemically. Therefore, the same types of adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration. For example, severe respiratory reactions including death due to bronchospasm in patients with asthma have been reported following systemic or ophthalmic administration of timolol maleate.

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

In patients without a history of cardiac failure, continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of cardiac failure, **COMBIGAN®** should be discontinued.

Obstructive Pulmonary Disease: Patients with chronic obstructive pulmonary disease (e.g., chronic bronchitis, emphysema) of mild or moderate severity, bronchospastic disease, or a history of bronchospastic disease [other than bronchial asthma or a history of bronchial asthma, in which **COMBIGAN®** is contraindicated] should, in general, not receive beta-blocking agents, including **COMBIGAN®**.

Potentiation of vascular insufficiency: COMBIGAN® may potentiate syndromes associated with vascular insufficiency. **COMBIGAN®** should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

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

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

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

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

Ocular Hypersensitivity: Ocular hypersensitivity reactions have been reported with brimonidine tartrate ophthalmic solutions 0.2%, with some reported to be associated with an increase in intraocular pressure.

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

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

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

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. **COMBIGAN®:** In clinical trials of 12 months duration with **COMBIGAN®**, the most frequent reactions associated with its use occurring in approximately 5% to 15% of the patients included: allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, ocular burning, and stinging. The following adverse reactions were reported in 1% to 5% of patients: asthenia, blepharitis, corneal erosion, depression, epiphora, eye discharge, eye dryness, eye irritation, eye pain, eyelid edema, eyelid erythema, eyelid pruritus, foreign body sensation, headache, hypertension, oral dryness, somnolence, superficial punctate keratitis, and visual disturbance.

Other adverse reactions that have been reported with the individual components are listed below.

Brimonidine Tartrate (0.1%-0.2%): Abnormal taste, allergic reaction, blepharoconjunctivitis, blurred vision, bronchitis, cataract, conjunctival edema, conjunctival hemorrhage, conjunctivitis, cough, dizziness, dyspepsia, dyspnea, fatigue, flu syndrome, follicular conjunctivitis, gastrointestinal disorder, hypercholesterolemia, hypotension, infection (primarily colds and respiratory infections), hordeolum, insomnia, keratitis, lid disorder, nasal dryness, ocular allergic reaction, pharyngitis, photophobia, rash, rhinitis, sinus infection, sinusitis, taste perversion, tearing, visual field defect, vitreous detachment, vitreous disorder, vitreous floaters, and worsened visual acuity. **Timolol (Ocular Administration):** *Body as a whole:* chest pain; *Cardiovascular:* Arrhythmia, bradycardia, cardiac arrest, cardiac failure, cerebral ischemia, cerebral vascular accident, claudication, cold hands and feet, edema, heart block, palpitation, pulmonary edema, Raynaud's phenomenon, syncope, and worsening of angina pectoris; *Digestive:* Anorexia, diarrhea, nausea; *Immunologic:* Systemic lupus erythematosus; *Nervous System/Psychiatric:* Increase in signs and symptoms of myasthenia gravis, insomnia, nightmares, paresthesia, behavioral changes and psychic disturbances including confusion, hallucinations, anxiety, disorientation, nervousness, and memory loss; *Skin:* Alopecia, psoriasiform rash or exacerbation of psoriasis; *Hypersensitivity:* Signs and symptoms of systemic allergic reactions, including anaphylaxis, angioedema, urticaria, and generalized and localized rash; *Respiratory:* Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), dyspnea, nasal congestion, respiratory failure; *Endocrine:* Masked symptoms of hypoglycemia in diabetes patients; *Special Senses:* diplopia, choroidal detachment following filtration surgery, cystoid macular edema, decreased corneal sensitivity, pseudopemphigoid, ptosis, refractive changes, tinnitus; *Urogenital:* Decreased libido, impotence, Peyronie's disease, retroperitoneal fibrosis.

Postmarketing Experience: Brimonidine: The following reactions have been identified during post-marketing use of brimonidine tartrate ophthalmic solutions in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to brimonidine tartrate ophthalmic solutions, or a combination of these factors, include: bradycardia, depression, iritis, keratoconjunctivitis sicca, miosis, nausea, skin reactions (including erythema, eyelid pruritus, rash, and vasodilation), and tachycardia. Apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence have been reported in infants receiving brimonidine tartrate ophthalmic solutions. **Oral Timolol/Oral Beta-blockers:** The following additional adverse reactions have been reported in clinical experience with ORAL timolol maleate or other ORAL beta-blocking agents and may be considered potential effects of ophthalmic timolol maleate: *Allergic:* Erythematous rash, fever combined with aching and sore throat, laryngospasm with respiratory distress; *Body as a whole:* Decreased exercise tolerance, extremity pain, weight loss; *Cardiovascular:* Vasodilatation, worsening of arterial insufficiency; *Digestive:* Gastrointestinal pain, hepatomegaly, ischemic colitis, mesenteric arterial thrombosis, vomiting; *Hematologic:* Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura; *Endocrine:* Hyperglycemia, hypoglycemia; *Skin:* Increased pigmentation, pruritus, skin irritation, sweating; *Musculoskeletal:* Arthralgia; *Nervous System/Psychiatric:* An acute reversible syndrome characterized by disorientation for time and place, decreased performance on neuropsychometrics, diminished concentration, emotional lability, local weakness, reversible mental depression progressing to catatonia, slightly clouded sensorium, vertigo; *Respiratory:* Bronchial obstruction, rales; *Urogenital:* Urination difficulties.

DRUG INTERACTIONS

Antihypertensives/Cardiac Glycosides: Because **COMBIGAN®** may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with **COMBIGAN®** is advised. **Beta-adrenergic Blocking Agents:** Patients who are receiving a beta-adrenergic blocking agent orally and **COMBIGAN®** should be observed for potential additive effects of beta-blockade, both systemic and on intraocular pressure. The concomitant use of two topical beta-adrenergic blocking agents is not recommended. **Calcium Antagonists:** Caution should be used in the co-administration of beta-adrenergic blocking agents, such as **COMBIGAN®**, and oral or intravenous calcium antagonists because of possible atrioventricular conduction disturbances, left ventricular failure, and hypotension. In patients with impaired cardiac function, co-administration should be avoided. **Catecholamine-depleting Drugs:** Close observation of the patient is recommended when a beta blocker is administered to patients receiving catecholamine-depleting drugs such as reserpine, because of possible additive effects and the production of hypotension and/or marked bradycardia, which may result in vertigo, syncope, or postural hypotension. **CNS Depressants:** Although specific drug interaction studies have not been conducted with **COMBIGAN®**, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered. **Digitalis and Calcium Antagonists:** The concomitant use of beta-adrenergic blocking agents with digitalis and calcium antagonists may have additive effects in prolonging atrioventricular conduction time. **CYP2D6 Inhibitors:** Potentiated systemic beta-blockade (e.g., decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g., quinidine, SSRIs) and timolol. **Tricyclic Antidepressants:** Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with **COMBIGAN®** in humans can lead to resulting interference with the IOP-lowering effect. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines. **Monoamine oxidase inhibitors:** Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

USE IN SPECIFIC POPULATIONS

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

Brimonidine tartrate was not teratogenic when given orally during gestation days 6 through 15 in rats and days 6 through 18 in rabbits. The highest doses of brimonidine tartrate in rats (1.65 mg/kg/day) and rabbits (3.33 mg/kg/day) achieved AUC exposure values 580 and 37-fold higher, respectively, than similar values estimated in humans treated with **COMBIGAN®**, 1 drop in both eyes twice daily.

Teratogenicity studies with timolol in mice, rats, and rabbits at oral doses up to 50 mg/kg/day [4,200 times the maximum recommended human ocular dose of 0.012 mg/kg/day on a mg/kg basis (MRHOD)] demonstrated no evidence of fetal malformations. Although delayed fetal ossification was observed at this dose in rats, there were no adverse effects on postnatal development of offspring. Doses of 1,000 mg/kg/day (83,000 times the MRHOD) were maternotoxic in mice and resulted in an increased number of fetal resorptions. Increased fetal resorptions were also seen in rabbits at doses 8,300 times the MRHOD without apparent maternotoxicity.

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

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

Pediatric Use: COMBIGAN® is not recommended for use in children under the age of 2 years. During post-marketing surveillance, apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence have been reported in infants receiving brimonidine. The safety and effectiveness of brimonidine tartrate and timolol maleate have not been studied in children below the age of two years.

The safety and effectiveness of **COMBIGAN®** have been established in the age group 2-16 years of age. Use of **COMBIGAN®** in this age group is supported by evidence from adequate and well-controlled studies of **COMBIGAN®** in adults with additional data from a study of the concomitant use of brimonidine tartrate ophthalmic solution 0.2% and timolol maleate ophthalmic solution in pediatric glaucoma patients (ages 2 to 7 years). In this study, brimonidine tartrate ophthalmic solution 0.2% was dosed three times a day as adjunctive therapy to beta-blockers. The most commonly observed adverse reactions were somnolence (50%-83% in patients 2 to 6 years) and decreased alertness. In pediatric patients 7 years of age or older (>20 kg), somnolence appears to occur less frequently (25%). Approximately 16% of patients on brimonidine tartrate ophthalmic solution discontinued from the study due to somnolence.

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

OVERDOSAGE

No information is available on overdosage with **COMBIGAN®** in humans. There have been reports of inadvertent overdosage with timolol ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, shortness of breath, bradycardia, bronchospasm, and cardiac arrest. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

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SUTURELESS

(Continued from page 14)

incisions to reform the anterior chamber to normal pressure. Watch the incision site and use a sponge at the conclusion to gently press the edges of the posterior aspect of the wound, ensuring there is no leakage.

If I find that I did not apply an adequate amount of hydrogel on the incision, I use the second provided well to re-apply. The blue visualization agent dissipates within hours of application, and the remaining hydrogel sloughs off in the tears during re-epithelialization (typically 3 to 5 days), so there is no need for removal.

While it is not possible to "burp" the incision site to reduce pressure once the sealant is in place, it would still be possible to burp a paracentesis without impacting the sealed incision site.

I am using the sealant on any incision that does not self-seal with mild stromal hydration, as well as larger wounds up to 3.5 mm, and any situation with an incision size of 5 mm of less, when I would have otherwise used a suture. One example would be a patient undergoing Descemet's stripping endothelial keratoplasty with an incision size of 4.5 mm, which would typically require a suture.

While clear corneal incisions are superior in many regards, they are susceptible to leakage. Even after the use of standard closure methods—such as sutures and stromal hydration—many incisions leak when subjected to external forces, such as eye rubbing or improper eye drop application.

It has recently been shown that a suture causes greater astigmatism, at least transiently, than the sealant would.[8] This sealant prevents fluid egress significantly better than sutures, in my experience, while maintaining patient comfort and surgeon efficiency, and it is an excellent tool to have on hand. ■

take-home

Stephen S. Lane, MD, describes his technique for using an ocular sealant, as well as cases where he finds it useful and superior to sutures.

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STEPHEN S. LANE, MD, *is an adjunct professor of ophthalmology at the University of Minnesota, in practice at Associated Eye Care in St. Paul, MN, and a visiting faculty member of ORBIS International. Dr. Lane is a consultant to Ocular Therapeutix.*

POSTERIOR CAPSULE

(Continued from page 12)

capsulotomy performed using capsule stains or a femtosecond laser if one is available," he said.

The femtosecond laser facilitates capsulotomy in these eyes, adds precision for achieving the desired location and size, and can be used to create the corneal incisions.

However, laser treatment of the lens should not be performed since the gas bubbles that are generated would stress the already damaged capsule, Dr. Masket noted.

With the goals of minimizing the risk of posterior capsule blow-out and loss of nucleus into the posterior segment, surgeons should also avoid hydrodissection, choose phaco chop, and use a slow-motion phacoemulsification technique.

"Impaling the nucleus with the phaco tip and holding it with vacuum while subdividing the lens will be safer in these eyes than using a sculpting approach that pushes the lens posteriorly," Dr. Masket explained.

Dr. Masket also offered tips for proceeding if the posterior capsule ruptures during routine cataract surgery.

POSTERIOR CAPSULE RUPTURES

Recognition here is also key, and there are several classic clinical signs that posterior capsule rupture has occurred. They include the pupil snap sign in which the pupil abruptly narrows and then dilates, difficulty rotating the nucleus, a sudden increase in brightness or clarity of the red reflex, and frank sinking of the nucleus.

There are several options for managing posterior capsule rupture during cataract surgery. If the nuclear material has not dropped too far and surgeons believe they will be able to control it, they can try to elevate the piece into the anterior chamber by directing some an OVD beneath the dislocated material. Once it is brought forward, the fragment can be removed by phacoemulsification or by spooning it out after enlarging the incision.

"In performing these maneuvers, surgeons must continue to watch for vitreous in the anterior chamber, because if that occurs, phacoemulsification should be stopped until the vitreous is removed," Dr. Masket said.

Posterior assisted levitation, the "PAL" technique originally described by Charles Kelman, MD, is another option for managing posteriorly dislocated lens material.

The PAL technique involves posterior segment entry via the pars plana and injection of a viscoelastic agent behind the fragment followed by use of a spatula to elevate it into the anterior chamber.

A third approach is to ignore the nucleus, remove vitreous from the anterior segment, implant a posterior chamber lens in the ciliary sulcus using optic capture if the anterior capsulotomy permits, and refer the patient to a vitreoretinal surgeon for plars plana removal of the remaining lens material.

"I consider this the safest option, and it is the approach I generally recommend, although the decision may depend on the surgeon's geographic setting and patient access to a vitreoretinal surgeon," Dr. Masket said. ■

SAMUEL MASKET, MD

E: *avcweb@aol.com*

This article is based on Dr. Masket's presentation at the 2014 meeting of the American Academy of Ophthalmology. Dr. Masket has no relevant financial interests to disclose.

Newly approved drug aims to treat intraoperative miosis, reduce pain

Phenylephrine, ketorolac injection yields benefits during cataract surgery, IOL replacement

By Nancy Groves; *Reviewed by Eric D. Donnenfeld, MD*

NEW YORK ::

INTRACAMERAL phenylephrine and ketorolac injection 1%/0.3% (Omidria, Omeros Corp.)—approved by the FDA for its combined properties of maintaining pupil dilation and reducing pain—is expected to provide multiple advantages to both surgeons and patients during cataract surgery or IOL replacement.

"The goal is to maintain intraoperative mydriasis, to reduce inflammation at the time of surgery, and to reduce the pain associated with surgery," said Eric D. Donnenfeld, MD, who helped in the clinical trials for the product. Dr. Donnenfeld is a founding partner of Ophthalmic Consultants of Long Island and Connecticut and clinical professor ophthalmology, New York University Medical Center, New York.

Phenylephrine, acting as a mydriatic agent, contracts the radial muscle of the iris, while ketorolac inhibits both cyclooxygenase enzymes, providing a reduction in pain through a decrease in the production of prostaglandins.

"This product is in the perfect place at the perfect time, in that surgeons are looking for both better surgical outcomes and ways to make the procedure more comfortable for patients," Dr. Donnenfeld said. "We know that a well-dilated pupil improves operative results, reduces complications, and reduces total surgical and phacoemulsification time, so patients end up having more rapid return of visual acuity."

In addition, the availability of the new agent removes a step that previously was being performed in the operating room, that of compounding a medication that would prevent intraoperative miosis. According to Dr. Donnenfeld, this off-label activity places the patient and the surgeon at risk of formulation errors.

"In the current legal environment, my concerns are that using a compounded medication puts surgical centers and surgeons at risk when something of equal or better efficacy is available in an FDA-approved form," he explained.

Surgeons have routinely used intraoperative dilating agents, but the new product adds ketorolac for the first time as an intraoperative nonsteroidal.

"In the FDA trials, not only was dilation extraordinarily achieved but pain was also significantly reduced," Dr. Donnenfeld said.

He added that the new product also bridges a difference in perception between surgeons and patients. While ophthalmologists consider visual acuity the most important determinant of surgical success, to patients, comfort during and after surgery is often as important as the clinical outcome.

Dr. Donnenfeld predicted that when the new formulation becomes routinely used during cataract surgery and lens replacement, the reduction in pain will mean that fewer patients will be dissatisfied with the comfort of their procedure despite having attained excellent visual acuity.

The product may also have another benefit. It is known that prostaglandins cause intraocular miosis, and that nonsteroidals inhibit their production. Placing a nonsteroidal in the irrigating solution may reduce inflammation postoperatively as well as intraoperatively, Dr. Donnenfeld said, although this was not studied in the FDA trials.

"I view inflammation as a surgical iceberg, with the tip of the iceberg being pupillary miosis," he said. "If the pupil constricts, it also means that prostaglandins are being released into the eye and into the pain receptors, and it may increase the risk

Continues on page 20 : ***Regimen***

take-home

- **A recently approved intracameral phenylephrine and ketorolac 1%/0.3% product is expected to produce better surgical outcomes following cataract surgery or IOL replacement by preventing miosis and reducing intraoperative pain.**

What drug therapy means for preoperative regimen

THE APPROVAL OF intracameral phenylephrine and ketorolac injection 1%/0.3% (Omidria, Omeros Corp.) could have implications for preoperative management and potentially postoperative management as well, according to John R. Wittpenn, MD, Ophthalmic Consultants of Long Island. While the FDA study evaluated pain and maintenance of pupillary dilation pertaining to intraoperative use of Omidria, the findings hint at additional benefits.

"I think that Omidria in the intraoperative solution will negate the need for the preoperative nonsteroidals, and I'm hopeful, although there is no data yet, that it may even improve our postoperative course," Dr. Wittpenn said. "I suspect that we'll still need to use nonsteroidals to prevent macular swelling and speed up resolution of inflammation, but I'm hopeful that we'll be able to use them for shorter times and perhaps at lower doses."

The FDA study showed that intraoperative Omidria does as well at maintaining pupillary dilation and avoiding pain as all of the earlier studies looking at topical nonsteroidals.

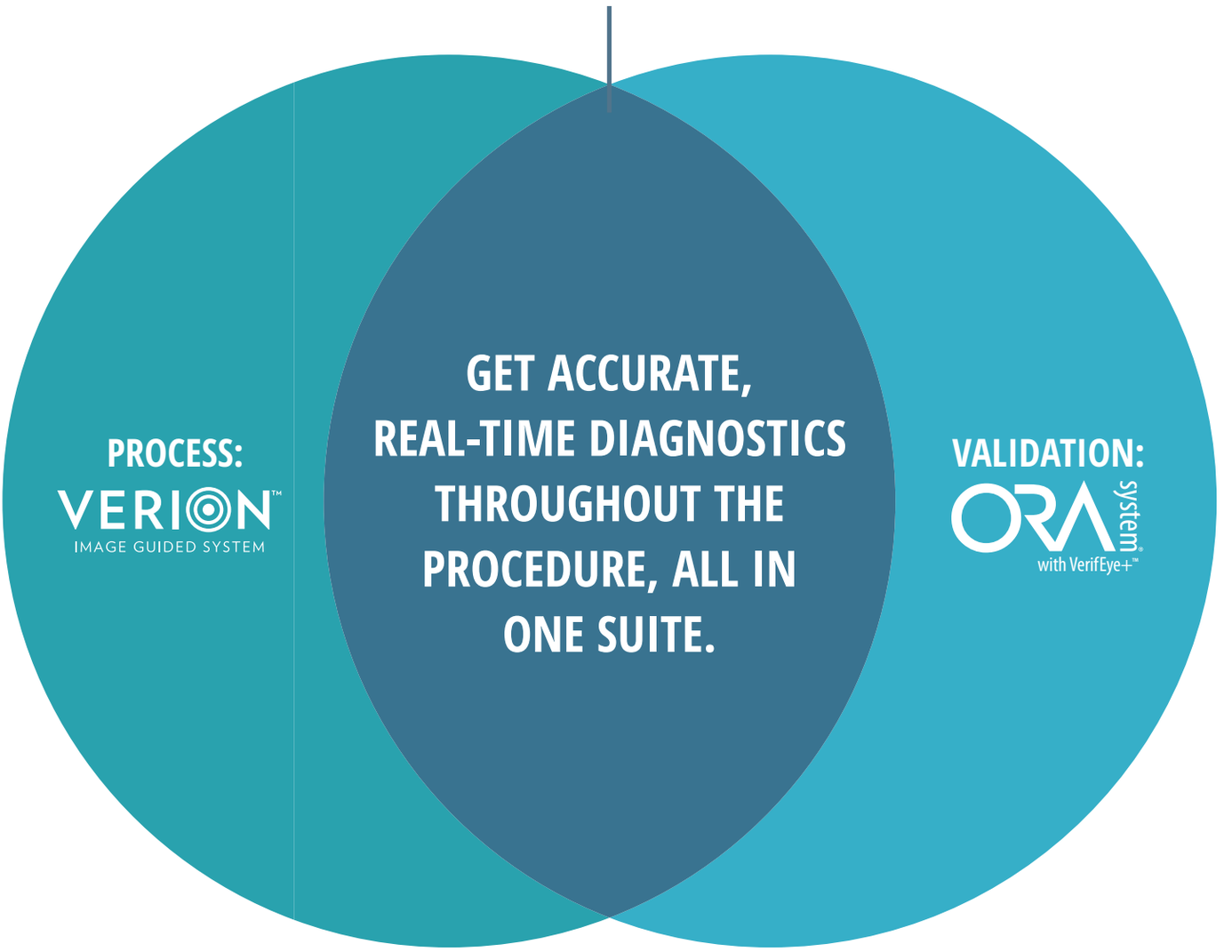
"I think the data is pretty clear in the FDA study that Omidria will certainly get us during surgery the same things we were attempting to get with the preoperative nonsteroidals used topically," he said.

The impact of Omidria on postoperative care has not yet been studied.

"That will be looked at in the future. I'm hopeful that we may find that the intraoperative use of the Omidria will reduce our need for nonsteroidals postoperatively in terms of either dosing frequency or even duration of use. Appropriate studies will need to be done once we have access to this new method of delivering a nonsteroidal into the eye," Dr. Wittpenn said. ■

—Nancy Groves

ARE YOU OPERATING WITH ALL THE RIGHT INFORMATION?



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THE CATARACT REFRACTIVE SUITE BY ALCON

REGIMEN

(Continued from page 18)

of cystoid macular edema. By reducing intraoperative surgically induced prostaglandin production, I think we can improve our surgical outcomes."

Leading up to FDA approval, the agent was evaluated in two phase III randomized, multicenter, double-masked, placebo-controlled clinical trials in 808 adult subjects undergoing cataract surgery or IOL replacement. In the group treated with the test product, mydriasis was maintained, while subjects treated with placebo experienced significant progressive constriction.

Pupil diameter was measured throughout the procedures. The results showed that following cortical cleanup, 23% of placebo-treated subjects and 4% of those treated with the combination product had a pupil diameter of less than 6 mm ($p < 0.0001$).

SECONDARY OUTCOME

To assess the secondary outcome, pain during the early postoperative period was evaluated with self-administered visual analog scales with a range of 0 to 100 mm. The results showed that pain 10 to 12 hours postoperatively was statistically significantly less in patients treated with the combination agent than in those treated with placebo.

Ocular adverse reactions such as eye irritation, posterior capsular opacification, increased IOP, and anterior chamber inflammation were similar between the two study groups.

"This is a welcome addition to the surgical armamentarium for refractive cataract surgery," Dr. Donnenfeld said. "It has everything we're looking for as surgeons. It improves outcomes, it reduces stress to the surgeon by maintaining pupillary dilation, it is compliant with operating room regulations of not using compound medications, and it makes the patient experience more comfortable while providing better visual outcomes." ■

ERIC D. DONNENFELD, MD
E: *ericdonnenfeld@gmail.com*
Dr. Donnenfeld is a consultant for Omeros Corp.

Pass-through Status:

The Centers for Medicare and Medicaid Services (CMS) has issued transitional pass-through payment status for Omidria. This reimbursement decision was based on CMS conclusion that Omidria substantially improves clinical outcomes compared with currently available treatments. Beginning Jan. 1, 2015, ASCs and other outpatient facilities can use a unique HCPCS billing code, C9447, to bill CMS for a separate payment for Omidria, outside the bundled APC payment. Transitional pass-through status typically remains in place for 2 to 3 years.

Confronting rock-hard cataract: How femtosecond laser brings benefits

Approach may allow for gentler surgery, reduce ultrasound energy for nucleus removal

By Cheryl Guttman Krader; *Reviewed by Juan F. Batlle, MD*

SANTO DOMINGO, DOMINICAN REPUBLIC :: **FEMTOSECOND LASER-ASSISTED** cataract surgery is not only feasible in eyes with rock-hard cataracts, but it can make the procedure safer and therefore may be the preferred technique, according to Juan F. Batlle, MD.

Dr. Batlle, who practices in Santo Domingo, Dominican Republic, noted that his professional time is divided between working at the Elias Santana Charity Hospital and private practice. For socioeconomic reasons, Morgagnian white cataracts and black cataracts are common among the patients he serves.

"Femtosecond laser pre-treatment of the lens in these cases allows for gentler surgery and reduces the amount of ultrasound energy needed for nucleus removal," said Dr. Batlle, director, Centro Laser, and director, Elias Santana Charity Hospital, Santo Domingo. "Then the patient is the winner. Gentle maneuvers protect the zonules and capsule, and reduced energy use means reduced likelihood of damaging the endothelium.

"I firmly believe that the future management of these 'catarocks' lies with the femtosecond laser-assisted cataract surgery technique, and as more femtosecond lasers become available, I expect the cost will fall so that my charity patients will also be able to benefit from its use," he said.

APPLYING THE TECHNOLOGY

Though Dr. Batlle has been involved in the development of one of the available femtosecond laser platforms (Catalys Precision Laser System, Abbott Medical Optics), he noted his comments on the role of this technology for assisting in procedures involving mature cataracts would also apply to the other laser systems.

He cited a paper by Palanker et al. [*Sci Transl Med*. 2010;2:58ra85] in which it was reported that Catalys pre-treatment of the lens in a series of 29 eyes decreased the perceived hardness of a nuclear sclerotic cataract by two grades, from LOCS IV to LOCS II, and reduced ultrasound energy use (measured as cumulative dispersed energy) by almost 40% relative to a control group undergoing conventional cataract surgery.

Discussing other issues pertaining to the

Continues on page 22 : ***Rock-hard***

ROCK-HARD

(Continued from page 21)

use of femtosecond laser-assisted cataract surgery in cases of rock-hard cataract, Dr. Batlle noted that the first question surgeons need to consider is whether the laser's imaging technology will be able to visualize the posterior capsule so that the fragmentation can be done with an adequate safety zone.

In a clip from an intraoperative video of a case with a black cataract, Dr. Batlle showed how the optical coherence tomography system of the Catalys laser was able to detect the posterior capsule, which was not visible preoperatively on slit lamp exam.

He also pointed out that when operating on hard cataracts, surgeons should choose a fragmentation pattern that divides the nucleus into smaller pieces. Using the Catalys, he recommended creating 200 or 300 µm cubes. Hydrodissection should then be done particularly carefully, since there may be gas in the capsular bag.

Even with the use of a femtosecond laser for lens fragmentation, surgeons should be prepared to use additional techniques, such as the "onion-peeling" technique described by Lisa Arbisser, MD, to separate the hard, leathery posterior surface of the black nucleus as the laser will not cut through it.

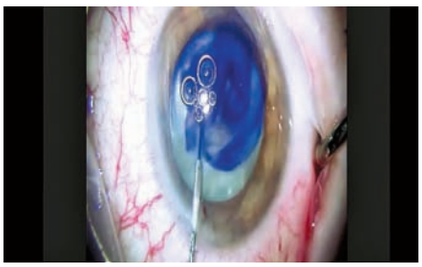
GENERAL TIPS FOR THE 'CATAROCK'

Sufficient pupil dilation is important when working in these difficult cases, whether operating with a manual or femtosecond laser-assisted cataract surgery technique. In eyes with small pupils, surgeons should first try topical phenylephrine, then subconjuntival epinephrine, and use of an ophthalmic viscosurgical device for viscodilation.

However, if the pupil cannot be opened to at least 3.5 to 4 mm, mechanical expansion with iris retractors or a Malyugin ring is needed. Use of a Malyugin ring to allow for femtosecond laser-assisted cataract surgery in eyes with small pupils has been reported in the literature.

Whether or not surgeons are performing femtosecond laser-assisted cataract surgery, Dr. Batlle advised making the capsulorhexis larger than average, up to 7 mm, and using trypan blue to enhance visualization of the anterior capsule in eyes with mature cataracts. ■

BLACK AND WHITE CATARACT



VIDEO With standard phaco in a white hypermature cataract, there is a risk of creating a runaway capsulotomy (i.e., "the Argentinian Flag"). Capsulotomy was completed safely in this eye using a femtosecond laser.
Go to **http://bit.ly/1BRhWy9**

VIDEO To watch surgery in a black cataract, go to **http://bit.ly/1sa4fdz**

(Videos courtesy of Juan F. Batlle, MD)

JUAN F. BATLLE, MD
E: *jbatlle@gmail.com*

This article was adapted from Dr. Batlle's presentation during the 2014 meeting of the American Academy of Ophthalmology. Dr. Batlle is a consultant to Abbott Medical Optics.

In practice: Integrating I/A handpiece, phaco into femtocataract surgery

Surgeon shares experience of adding instrumentation to regimen as technology continues to evolve

By Michelle Dalton, ELS; *Reviewed by Dee Stephenson, MD*

VENICE, FL ::

NEW TECHNOLOGIES—such as the femtosecond laser for cataract surgery—demand new instrumentation and "rethinking the most efficient and safest way to attain the safest surgery and best outcomes for the patient," said Dee Stephenson, MD, Stephenson Eye Associates, Venice, FL.

Dr. Stephenson

"[Surgeons] have to find the balance between femto power and phaco power," noted Dr. Stephenson, when considering the integration of femtocataract surgery into practice. "We need to know the total amount of energy that goes in the eye in order to do the safest procedure."

She quickly realized numerous (but minor) changes to her surgical technique would be needed, including the primary incision size and architecture, the side port incision, the size of her capsulotomy, determining which fragmentation pattern would be best, and needing new instruments (such as a sideport chopper, a zero phaco handpiece) that are specifically designed to work with the new system.

Dr. Stephenson uses the LensAR femtosecond laser, the Stellaris (Bausch + Lomb), and the ZeroPhaco I/A handpiece (Bausch + Lomb).

HANDPIECE DETAILS

The disposable I/A handpiece, with either 15° or 30° bevel needle, is designed for the removal of soft cataracts 1-2+ following femtosecond laser fragmentation without the use of ultrasonic energy, Dr. Stephenson said.

Pre-assembled with a standard infusion sleeve, the coaxial handpiece is designed to work with the Stellaris and Stellaris PC systems for lens removal using an I/A mode. The handpiece is used as replacement for the ultrasound phacoemulsification handpiece and is green-colored to avoid confusion with the I/A handpiece for cortical cleanup. In addition to the standard incision 2.4 mm, the ZeroPhaco I/A handpiece is also available for use in a microincisional cataract surgery 2.2mm incision, noted Bausch + Lomb in a prepared statement.

The company has made a "really nice silicone tip I/A—the capsule guard—that you can use without worrying if it touches the posterior capsule," Dr. Stephenson said. "Because the Stellaris has such great fluidics and chamber maintenance, you're in control the whole time, you can really utilize these micro-incisional instruments to do your micro-incisional surgery (MICS)."

ALTERED SETTINGS

Dr. Stephenson recommends setting the Stellaris to between 300 and 600 mm Hg for vacuum, with a bottle height of 140 cm.

"I prefer pressurized infusion of 50 cm of bottle height and an air pressure of 70 mm Hg," she said.

In her hands, Dr. Stephenson has "found chamber stability to be excellent, even in high vacuum settings," she said. Additionally, corneal clarity is similar to standard ultrasound phaco, there is good control of the fragmented lens during aspiration, and "testing which femto fragmentation pattern is best is highly recommended," she said. Currently, she prefers to use a dice pattern, followed by a cross pattern that still allows her to do a divide and conquer technique.

"With the femto, we're trying to make the nucleus softer so we can just aspirate it," she said. "It would be nice to find a happy medium to be able to utilize the energy in the most efficient way in both of those techniques.

"You have a learning curve with the femto laser, just like you do with any new technology," Dr. Stephenson said. "What I found in my transition to femto cataract surgery is to try and conquer one thing at a time. I first concentrated on my capsulotomy size and that I had a free floating capsule. Then I learned how to fragment the lens and what pattern was best in my hands."

Using a femtosecond laser also means the instruments feel different in the eye, "and once you learn those things then you can start to do the finesse. You can't do it all at once," she said.

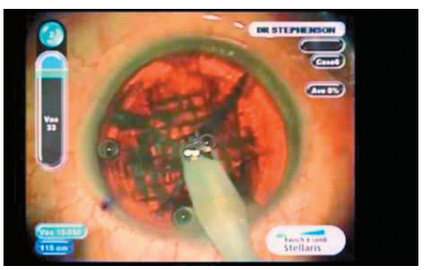
"I still hydro-dissect, and hydro-delineate, but I do it much slower," she said. "I'll watch the fluid wave and I kind of rotate the lens to release the gas so that my visualization is better."

She adds, "what I've been doing is using the ZeroPhaco hand piece after fragmentation. The tip is not sharp, so I find aspiration easy. I use my chopper to feed the cubes to the port," she said, noting she appreciates the varied sizes (one tip is designed for a 2.2 mm incision, another for a 2.4 mm incision).

Dr. Stephenson said the ability to switch from a standard cataract incision to a MICS incision is a benefit to having two different size tips.

"It works great on softer cataract grades 1-2.5, but once you're dealing with a grade 3 or 4, the ZeroPhaco handpiece may not work as well and you may spend more time in the eye than you realize, and you're using more fluid. The fluid is causing turbulence and this is energy. You may want to just use the standard phaco handpiece for the dense cataracts," she said. "With any new technology comes evolution of better and more efficient instruments and techniques. I believe in time we will only need aspiration for any grade of cataract." ■

I/A HANDPIECE



VIDEO Watch cataract surgery with the femtosecond laser handpiece.
Go to **http://bit.ly/1AZ18Vj**
(Video courtesy of Dee Stephenson, MD)

DEE STEPHENSON, MD
E: *eyedrdee@aol.com*
Dr. Stephenson is a consultant to Bausch + Lomb.

Dropless cataract surgery offers 'significant benefit' with low risk

Intravitreal transzonular injection improves compliance while maintaining good outcomes

By Michelle Dalton, ELS; *Reviewed by M. Stewart Galloway, MD*

CROSSVILLE, TN ::

INTRAVITREAL transzonular antibiotic/steroid combination concurrent with cataract surgery can provide a "significant benefit with minimum risk," said M. Stewart Galloway, MD, Cumberland Eye Care, Crossville, TN.

Use of intravitreal triamcinolone/moxifloxacin (TriMoxi, Imprimis Pharmaceuticals) following phacoemulsification with IOL implantation "is able to prevent postoperative inflammation, cystoid macular edema (CME), and endophthalmitis," Dr. Galloway said.

Dr. Galloway

It is common practice to deliver antibiotics topically, but with the antibiotic/steroid combination, the delivery is transzonular. The formulation is compounded, preservative-free triamcinolone acetonide and moxifloxacin delivered 15 mg/1mg/ml, with 0.2 ml injected transzonularly into the anterior vitreous, Dr. Galloway said, resulting in a total drug delivery of 3 mg triamcinolone and 0.2 mg of moxifloxacin.

"After the lens implant is in place, and prior to removing viscoelastic, you pass a cannula through the incision, over the anterior capsule, underneath the iris, and then penetrate the zonules into the anterior vitreous so the drug is delivered into the vitreous itself," Dr. Galloway said.

Unlike intracameral injections, which go into the anterior chamber, intravitreal triamcinolone/moxifloxacin is designed to be delivered to the posterior chamber, directly into the vitreous, he said.

In his retrospective chart review of 2,300 consecutive eyes that underwent phaco/IOL implantation with the use of intravitreal triamcinolone/moxifloxacin instead of topical antibiotic/steroids postoperatively, not one eye has developed endophthalmitis.

"There have been more than 14,000 eyes injected with [intravitreal triamcinolone/moxifloxacin]—not all at our center, of course—and while we can't say we have a zero rate of endophthalmitis, we can say it's zero thus far," he said.

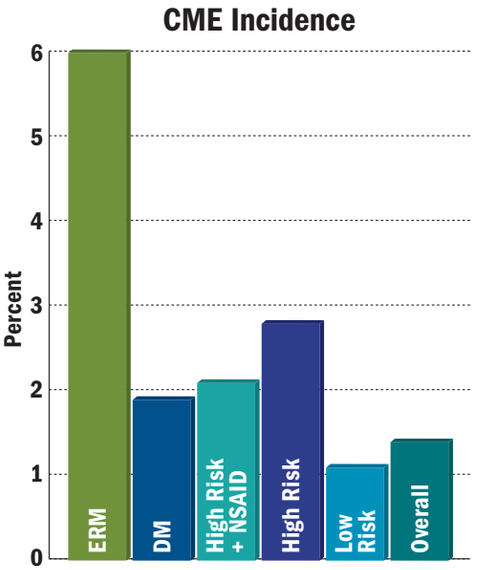
Dr. Galloway said he believes the reason intravitreal triamcinolone/moxifloxacin has yet to result in a single case of endophthalmitis is because when bacteria do enter the eye, they colonize in the vitreous.

"It's a nutrient-rich place, and that's where the bacteria grow and cause the problems," he said. "We put the antibiotic where the bacteria want to grow. We're not putting drops on the cornea and hoping they diffuse into the eye; we're not delivering them intracamerally and hoping some of it gets through to the vitreous."

He noted that a problem with intracameral injections is that "the drug is washed out of the eye in a fairly short time frame."

In rabbit eyes, conversely, "the moxifloxacin stays at therapeutic concentrations for at least 8 hours," he said. "The anti-inflammatory portion is detectable there for months afterward."

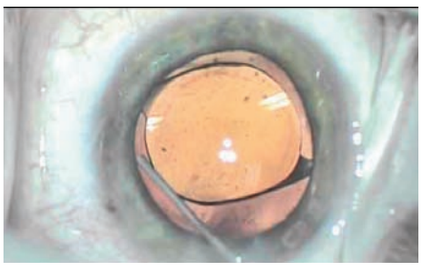
In Dr. Galloway's study, all patients were seen day of surgery (4 to 7 hours postoperatively). All patients were then seen between 3 and 4 weeks postoperatively, and then again at 6 months.



take-home

- **Use of an intravitreal transzonular injection can help with patient compliance.**

MAKING THE INJECTION



VIDEO Intravitreal triamcinolone/moxifloxacin is designed to be delivered to the posterior chamber, directly into the vitreous.

Go to **http://bit.ly/1vhBozV**

(Video/figure courtesy of M. Stewart Galloway, MD)

STUDY DETAILS

Of the original 2,300 patients, only 10 were lost to follow-up. The average age was 73 years (ranging from 34 to 95 years old). Almost one-fifth of the eyes/patients had diabetes, and 5% presented with epiretinal membrane (ERM).

Dr. Galloway said 19% of the patients received supplemental topical nonsteroidal anti-inflammatory drugs (NSAIDs) because of diabetes, ERM, or premium IOL implantation.

The rate of breakthrough inflammation requiring the addition of topical steroids during the postoperative period was 2%, but was "slightly higher at 3.5% in those with ERM, and 6.3% in those who developed CME," Dr. Galloway said. Mean IOP fell from 21.1 mm Hg on day of surgery to 14.1 mm Hg at weeks 3 to 4 postoperatively.

The overall CME rate in the study was 1.4%. The rate of CME in the diabetic subgroup was

Continues on page 27 : ***Dropless surgery***

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INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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

WARNINGS AND PRECAUTIONS

Potentiation of Vascular Insufficiency: ALPHAGAN® P may potentiate syndromes associated with vascular insufficiency. ALPHAGAN® P should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

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

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

DRUG INTERACTIONS

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

CNS Depressants: Although specific drug interaction studies have not been conducted with ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15%, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered.

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

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

ADVERSE REACTIONS

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

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

Alphagan® P 0.1%
(brimonidine tartrate ophthalmic solution) 0.1%

ALPHAGAN® P

(brimonidine tartrate ophthalmic solution)
0.1% and 0.15%

BRIEF SUMMARY

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

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CONTRAINDICATIONS

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

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

WARNINGS AND PRECAUTIONS

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

DRUG INTERACTIONS

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

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

OVERDOSAGE

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

NONCLINICAL TOXICOLOGY

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

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

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

PATIENT COUNSELING INFORMATION

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

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

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

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

Rx Only

Revised: 11/2011

Based on package insert 71816US15C

APC57BC13

Alphagan® P 0.1%
(brimonidine tartrate ophthalmic solution) 0.1%

Special Report) ADVANCEMENTS IN **CATARACT SURGERY**

Misaligned toric IOLs require prompt surgical management, repositioning

Ophthalmologists need to determine exact orientation, decide how lens should be shifted

By Cheryl Guttman Krader; *Reviewed by Randall J. Olson, MD*

IRVINE, CA ::

WHEN IOL MISALIGNMENT underlies a suboptimal outcome with a toric implant and the problem is identified in the early postoperative period, surgeons should not procrastinate about taking the patient back to the operating room for a repositioning procedure, said Roger F. Steinert, MD.

Dr. Steinert

"It is easy to open the capsular bag and rotate the IOL within the first several weeks after surgery," said Dr. Steinert, the Irving H. Leopold Professor and Chair, Department of Ophthalmology, University of California, Irvine. "So, if you identify that the IOL is in the wrong place, fix it."

CORRECTION STRATEGIES

Outlining the steps for correcting toric IOL misalignment, Dr. Steinert said the first task is to determine the exact orientation of the IOL. This is done at the slit lamp, and there are now two free smartphone apps (iHandy level and Axis Assistant) that can help to identify the axis.

The next step is to decide how the IOL should be shifted. While this may be done using the postoperative refraction and vector analysis that will take into account posterior and anterior corneal changes, use of an online tool developed by John Berdahl, MD, and David Hardten, MD, offers a much easier option. Available as a free download at *www.astigmatismfix.com*, the program requires input of the refractive data, but then it automatically does the mathematical calculations to determine exactly where the implant should be aligned in order to minimize final residual astigmatism.

take-home

New tools are facilitating repositioning of a misaligned toric IOL. The corrective procedure is best undertaken sooner than later.

"This program does the vector analysis for you, uses the refraction, which is the most accurate indicator of what it is you are trying to fix, and takes into account the effects of the posterior cornea and your incision," Dr. Steinert said.

To reposition the IOL, surgeons can use viscoelastic to viscodissect under the capsulorhexis and free the lens from the capsule. Presumably the axis for proper alignment will have been identified with manually placed ink markings.

Use of intraoperative aberrometry or other devices can also be used to confirm the accuracy of the IOL's position.

When dealing with an implant that rotated after it was initially implanted, surgeons may be concerned about whether or not it will stay in place after repositioning. Dr. Steinert said there are two options to consider for stabilizing the IOL.

One approach, which is probably the preferred technique, would be to insert a capsule tension ring, he said.

Alternatively, in eyes with a capsulorhexis <6 mm in diameter, surgeons can perform anterior capture of the optic, leaving the haptics in the capsular bag.

However, Dr. Steinert cautioned there is the potential for iris chafe by a sharp-edged optic. Therefore, before undertaking this technique, surgeons need to ascertain there is adequate clearance between the iris and anterior capsule. ■

ROGER F. STEINERT, MD
E: *steinert@uci.edu*

This article was adapted from Dr. Steinert's presentation at the 2014 meeting of the American Academy of Ophthalmology. Dr. Steinert is a consultant to Abbott Medical Optics and WaveTec Vision. He receives grant support from Abbott Medical Optics.

DROPLESS SURGERY

(*Continued from page 24*)

slightly higher at 1.9% and not significantly altered with the addition of topical NSAIDs. In the ERM subgroup, however, the CME rate was very significantly affected by the topical NSAID, decreasing from 8.5% without to 2.2 % with topical NSAIDs.

Dr. Galloway added he now routinely uses NSAIDs only on patients with ERMs and no longer uses them on diabetic patients without pre-existing maculopathy.

With the diabetic patient population, "if there's no maculopathy, then there's no reason to treat them differently than someone without diabetes," he said.

There are some disadvantages to the procedure—primarily that patients experience decreased immediate postoperative vision and floaters, due to the opaque nature of the drug.

There also may be an increased incidence of patients who experience foreign body sensation, "presumably due to a lack of topical anti-inflammatory drugs at the wound itself," he said.

PATIENT COMPLIANCE

By not relying on postoperative drops to control potential inflammation, Dr. Galloway said there's also no issue with patient compliance.

Calling the use of intravitreal triamcinolone/moxifloxacin "truly a dropless surgery, there's decreased patient cost as well, and a decrease in postoperative care," he said.

"There's enormous potential for this in Third World countries, where follow-up care is less than ideal," he said. ■

M. STEWART GALLOWAY, MD
E: *eyeguy@frontiernet.net*

This article is adapted from Dr. Galloway's presentation at the 2014 meeting of the American Academy of Ophthalmology. Dr. Galloway is a consultant to Imprimis Pharmaceuticals.

Special Report ADVANCEMENTS IN **CATARACT SURGERY**

Upgrades to laser cataract platform streamline surgical treatment process

Technologies work together to provide greater efficiency, increase patient eligibility

By Nancy Groves; *Reviewed by Eric D. Donnenfeld, MD*

LONG ISLAND, NY ::

THE ADVENT OF TWO NEW technologies for a laser cataract surgery platform (Catalys Precision Laser System, Abbott Medical Optics [AMO]) may provide greater efficiency for surgeons, while also expanding the number of people eligible for the procedure.

These technologies include the Cataract Operating System 3 (cOS3) and the Liquid Optics Interface 12, both from AMO. The cOS3 has more than 50 enhancements, many of which were developed in response to user feedback.

"It's a marked improvement, starting with the integral guidance system and moving right through to the actual treatment," said Eric D. Donnenfeld, MD, founding partner of Ophthalmic Consultants of Long Island and Connecticut and clinical professor of ophthalmology, New York University Medical Center, New York.

The interface is updated to become more intuitive throughout the procedure. The cOS3's template-based interface has been redesigned with expanded customization options that streamline planning and result in simpler treatment.

"The platform also has high-resolution streaming optical coherence tomography (OCT) so that you can see the anterior segment structures during the surgery," Dr. Donnenfeld said.

The stream is refreshed every .5-2 Hz for uninterrupted visualization of the eye throughout treatment.

The enhanced integral guidance system guidance system also calculates dimensions automatically.

"One of my favorite things is an automatic limbus offset," Dr. Donnenfeld said. "Instead of having four steps that have to be done by the surgeon to use the software, there are only two steps: confirming the ocular anatomy, then confirming all the incisions. You visualize all of the incisions that you're using during the procedure."

The cOS3 upgrade and the Catalys system's Liquid Optics technology work together to improve the docking process.

"It centers the docking and removes all forces from the eye during the treatment, which saves a lot of time," Dr. Donnenfeld said.

The non-applanating technology helps maintain corneal shape throughout the procedure.

"Another advantage of the Liquid Optics technology is that it increases the number of people eligible for laser cataract surgery by offering two patient interface sizes. You can now dock on some of these more difficult eyes," Dr. Donnenfeld said. "You have the flexibility to close the optimal interface for each laser cataract surgery patient, even those with smaller interpalpebral fissure widths."

Dr. Donnenfeld

The system is available with suction rings having 14.1 mm and 12.0 mm inner diameters; the 12.0 mm interface, used to treat patients with smaller eyes, is the smallest patient interface available.

take-home

- **Upgrades to a laser cataract surgery platform include features such as high-resolution video screening images that improve efficiency. In addition, a new interface with a smaller suction ring diameter expands the number of people who are candidates for laser cataract surgery.**

OTHER BENEFITS

Along with the upgrades, the Catalys system has maintained several advantages, such as no significant rise in IOP due to the non-applanating system. The average IOP increase is 10 mm Hg.

"Also, there are no folds in the cornea; the cornea is pristine so that the delivery to the capsule and the lens is the best I've ever seen of any of the treatments I've performed with other machines," Dr. Donnenfeld said. "Every single case I have ever performed has had a free-floating capsulate, and I use no ultrasound energy on the majority of my cataract surgeries."

In summary, laser cataract surgery with the Catalys system is more of a refractive procedure than ever before, he continued.

"Being able to center the lens optically will improve effective lens position as well as improve higher-order aberrations; incisions are more astigmatically neutral because they are more peripheral and reproducible," he said. "There are a lot of things that make the procedure better.

The cOS3 upgrade and the Catalys system's Liquid Optics technology work together to improve the docking process.
(Photo courtesy of Abbott Medical Optics)

"The cOS3 software is redesigned to simplify the user interface for a more intuitive procedure. There is very little learning curve involved with it," he added. "The surgeon is aware of the eye throughout the procedure because of the streaming OCT.

"The guidance system has new algorithms for automatic positioning for IOL placement; you can now center the capsulotomy on the lens, on the visual axis, or on the pupil," Dr. Donnenfeld concluded. "The new interface allows surgeons to treat eyes that were more difficult to treat before, and it has also sped up the treatment dramatically. The time of the procedure is one-third less than it was before." ■

ERIC D. DONNENFELD, MD

E: *ericdonnenfeld@gmail.com*

Dr. Donnenfeld is a consultant for Abbott Medical Optics. Abbott received FDA clearance for the Cataract Operating System 3 (cOS3) and the Liquid Optics Interface 12 in October 2014.

Postoperative Inflammation and Pain Can Make a Bad Impression

CHOOSE **DUREZOL® EMULSION** TO HELP RESOLVE INFLAMMATION AND PAIN[1]

BROAD MANAGED CARE COVERAGE[2]

INDICATIONS AND USAGE:
DUREZOL® Emulsion is a topical corticosteroid that is indicated for:
- The treatment of inflammation and pain associated with ocular surgery.
- The treatment of endogenous anterior uveitis.

Dosage and Administration
- For the treatment of inflammation and pain associated with ocular surgery instill one drop into the conjunctival sac of the affected eye 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.
- For the treatment of endogenous anterior uveitis, instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

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

Warnings and Precautions
- Intraocular pressure (IOP) increase – Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.
- Cataracts – Use of corticosteroids may result in posterior subcapsular cataract formation.
- Delayed healing – The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Bacterial infections – Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Viral infections – Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections – Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.
- Contact lens wear – DUREZOL® Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL® Emulsion. The preservative in DUREZOL® Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL® Emulsion.

Most Common Adverse Reactions
- Post Operative Ocular Inflammation and Pain – Ocular adverse reactions occurring in 5-15% of subjects included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.
- In the endogenous anterior uveitis studies, the most common adverse reactions occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis.

For additional information about DUREZOL® Emulsion, please refer to the brief summary of prescribing information on adjacent page.

For more resources for eye care professionals, visit MYALCON.COM/DUREZOL

References: 1. DUREZOL® Emulsion prescribing information. **2.** Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, March 2014.

Alcon®
a Novartis company

DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

THE RESULTS YOU WANT. THE RELIEF THEY NEED.

GUIDANCE

(Continued from page 1)

as their preferred IOLs.

"The [platform] was built with the goal of giving surgeons access to the data they care about at the time they need it so that they can deliver more accurate refractive results to their patients," said Dr. Awdeh, founder and chief executive officer, Cirle, Miami.

In developing the system, Dr. Awdeh collaborated with other practicing surgeons in order to create a system that would provide efficient and effective solutions for addressing surgeons' needs and at the same time would be easy to integrate into their existing environment.

"We thought about the sequence of steps performed for a typical case and tried to come up with creative ways to enable data transfer and accessibility, in a seamless and efficient manner," he said.

Dr. Awdeh

"We decided to create an open-source system to enable all surgeons the opportunity to have access to the technology regardless of the type of microscope or phacoemulsification machine they have in their practice," Dr. Awdeh said.

As a means to provide accurate and efficient data transfer, the Surgical Navigation Guidance Console features a built-in QR code reader that allows for uploading of the surgical plan.

A prototype of the system was presented at the Bausch + Lomb booth at the 2014 meeting of the American Academy of Ophthalmology in Chicago.

In addition to allowing for easy data input, the Surgical Navigation Guidance Console is used for selecting surgical preferences and monitoring key phacoemulsification parameters throughout the procedure. Those tasks are enabled with its large and highly intuitive touchscreen graphical user interface, Dr. Awdeh said.

take-home

A new digital image guidance platform (Surgical Navigation System, Cirle) for cataract surgery is an open-source system designed to enhance accurate execution of cataract incision placement, capsulorhexis sizing and centration, toric IOL alignment, and limbal relaxing incision placement.

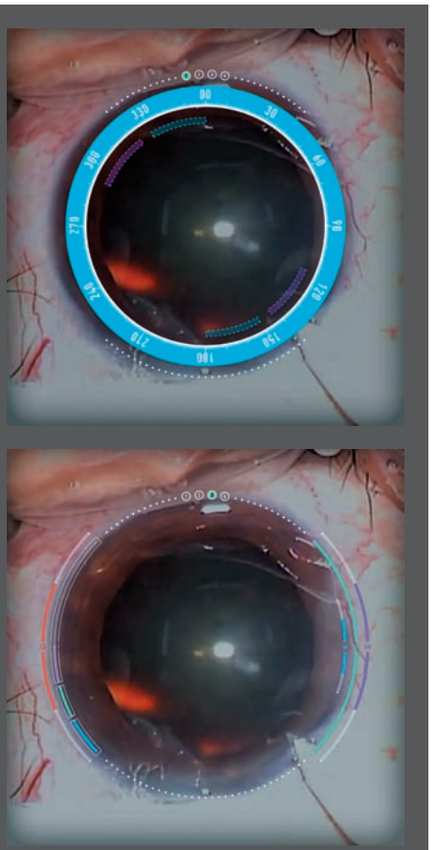
TAKING IT TO THE MICROSCOPE

The system is already compatible with a number of surgical microscopes marketed by Leica and Carl Zeiss Meditec, and that list will also be expanding. Its navigation overlays appear in both oculars as full color, 3-D images that are registered to the underlying anatomy of the eye.

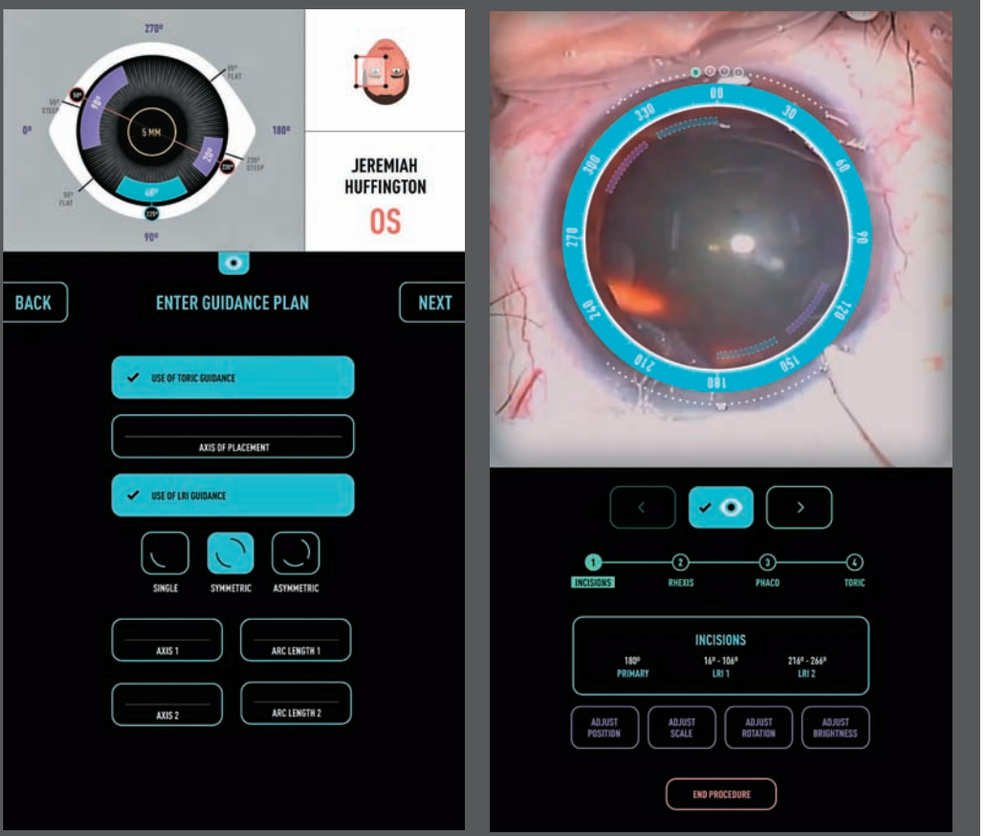
"The heads-up display design means surgeons do not have to move their head away from the microscope while operating, and with the stereo 3-D image, the display guides surgeons through each task at the appropri-

Special Report) ADVANCEMENTS IN **CATARACT SURGERY**

The surgical navigation platform both captures and delivers three-dimensional guidance into the microscope while surgeons operate. Technology (SightLine) is designed to provide important data in surgeons' line of sight in the microscope.



Navigation overlays appear in both oculars as full color, 3-D images that are registered to the underlying anatomy of the eye.



The easy-to-use interface intelligently guides surgical planning. Surgeons are able to import patient plans, edit surgical preferences, and have live intraoperative interaction on screen during surgery.

(Images courtesy of Richard Awdeh, MD)

ate anatomic level," Dr. Awdeh said. "So, the marks for surgical and astigmatic incisions are seen on the cornea, the capsulorhexis guidance is projected at the level of the anterior capsule, and lens alignment marks are seen at the IOL level."

MONITORING EASE DURING PHACO

For surgeons using the Stellaris Vision Enhancement System (Bausch + Lomb), the platform can also display key phacoemulsification parameters in the microscope oculars.

This feature brings surgeons increased monitoring ease during the entire phacoemulsification portion of the case, according to Dr. Awdeh.

Bausch + Lomb, a division of Valeant Pharmaceuticals, has acquired an exclusive license to this product in the United States. ■

Join the discussion about how surgical navigation is helping to improve cataract surgery outcomes at **Facebook.com/OphthalmologyTimes.**

RICHARD AWDEH, MD

E: *richard@cirle.com*

Dr. Awdeh discloses relevant financial interests in Cirle and Bausch + Lomb.

Levodopa for amblyopia explored as novel modality

Effect on visual acuity not significant, although patients experienced subtle, slow gains over time

By Vanessa Caceres; *Reviewed by Michael X. Repka, MD, MBA*

BALTIMORE ::

In children ages 7 to 12 with residual amblyopia, use of one medication—levodopa—did not lead to a meaningful improvement in visual acuity compared with placebo, said Michael X. Repka, MD, MBA.

There are a few medical therapies currently tried for amblyopia—including atropine, oral levodopa, and oral and intramuscular citicoline—although results with levodopa and citicoline have been mixed, said Dr. Repka, the David L. Guyton, MD, and Feduniak Family Professor of Ophthalmology, and professor of pediatric medicine, Johns Hopkins University School of Medicine, Wilmer Eye Institute, Baltimore.

Dr. Repka

All three agents are not currently approved by the FDA for the treatment of amblyopia, he added.

There are six trials that have analyzed the use of levodopa for amblyopia against placebo, but they have had varied results, Dr. Repka said.

One 2012 meta-analysis found that the drug compared with placebo was favorable by about 1 line.[1] However, the results are hard to follow from the various trials because of various treatment durations and treatment times that differed with respect to amblyopia.

ABOUT THE PEDIG STUDY

The Pediatric Eye Disease Investigator Group (PEDIG) that Dr. Repka participated in had the primary objective of comparing oral levodopa plus patching with oral placebo plus patching for residual amblyopia for older children.

The 139 children who participated over more than 3 years came from 27 different centers; all were between the ages of 7 and 12. Patients had strabismus and/or amblyopia; they had patching for at least 2 hours daily for at least 3 months prior to enrollment.

"That period of patching could be longer, and in many cases, it was much longer," Dr. Repka said.

To participate in the study, patients could not have had any improvement over 6 weeks. The eligible range of visual acuity ranged from 20/50 to 20/400 for the eye that was examined, but the fellow eye had to be 20/25 or better.

Patients were randomly assigned at a 2:1 ratio (90 in the levodopa group and 49 in the placebo group) to receive levodopa 0.76 mg/kg with carbidopa 0.17 mg/kg three times a day. The carbidopa was given to reduce nausea associated with levodopa. Patients were treated for 16 weeks or longer, with a rapid initiation and taper of the drug.

Both study groups had similar characteristics, although there was more strabismus in the group receiving levodopa. Nearly all patients remained in the study for the entire duration, Dr. Repka said.

The mean change in visual acuity from baseline was 5.2 letters in the levodopa group and 3.8 letters in the placebo group, Dr. Repka said.

"The difference of 1.4 letters, after adjusting for disparities in visual acuity at entry, was not significant," he said.

Fifteen percent in the levodopa group improved 10 letters or more, compared with 4% in the patching group. Although more children improved in the levodopa group, that was not statistically significant, he added.

Looking at the 18-week outcome, a similar lack of treatment effect was found as in the primary analysis.

Investigators analyzed adverse effects of treatment by examining systemic symptoms, visual acuity in the fellow eye, ocular alignment, and stereoacuity; they found no changes in the latter two items.

Systemic effects, such as headaches, were reported at least once during treatment in 20% of the levodopa patients and 8% of the placebo group.

> 'The difference of 1.4 letters, after adjusting for disparities in visual acuity . . . , was not significant.' – *Michael X. Repka, MD, MBA*

"Nausea was reported in 7% of the levodopa group and 12% of the placebo group, so without the placebo, we would have wrongly concluded nausea was associated with the drug," he said. "It was more associated with placebo."

Although levodopa was not associated with a meaningful improvement over placebo, patients still seemed to experience a subtle-but-slow improvement over time, Dr. Repka said.

"We did not evaluate levodopa as an initial therapy," he said. "It could be effective in that setting." ■

TAKE-HOME

- ***A study of children with residual amblyopia did not find an advantage with the use of levodopa compared with a placebo group.***

Reference

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Join the discussion on research on new medical treatment modalities for amblyopia at **Facebook.com/OphthalmologyTimes**.

MICHAEL X. REPKA, MD, MBA

E: *mrepka@jhmi.edu*

This article was adapted from Dr. Repka's presentation at the 2014 meeting of the American Academy of Ophthalmology. Dr. Repka did not indicate any proprietary interest in the subject matter.

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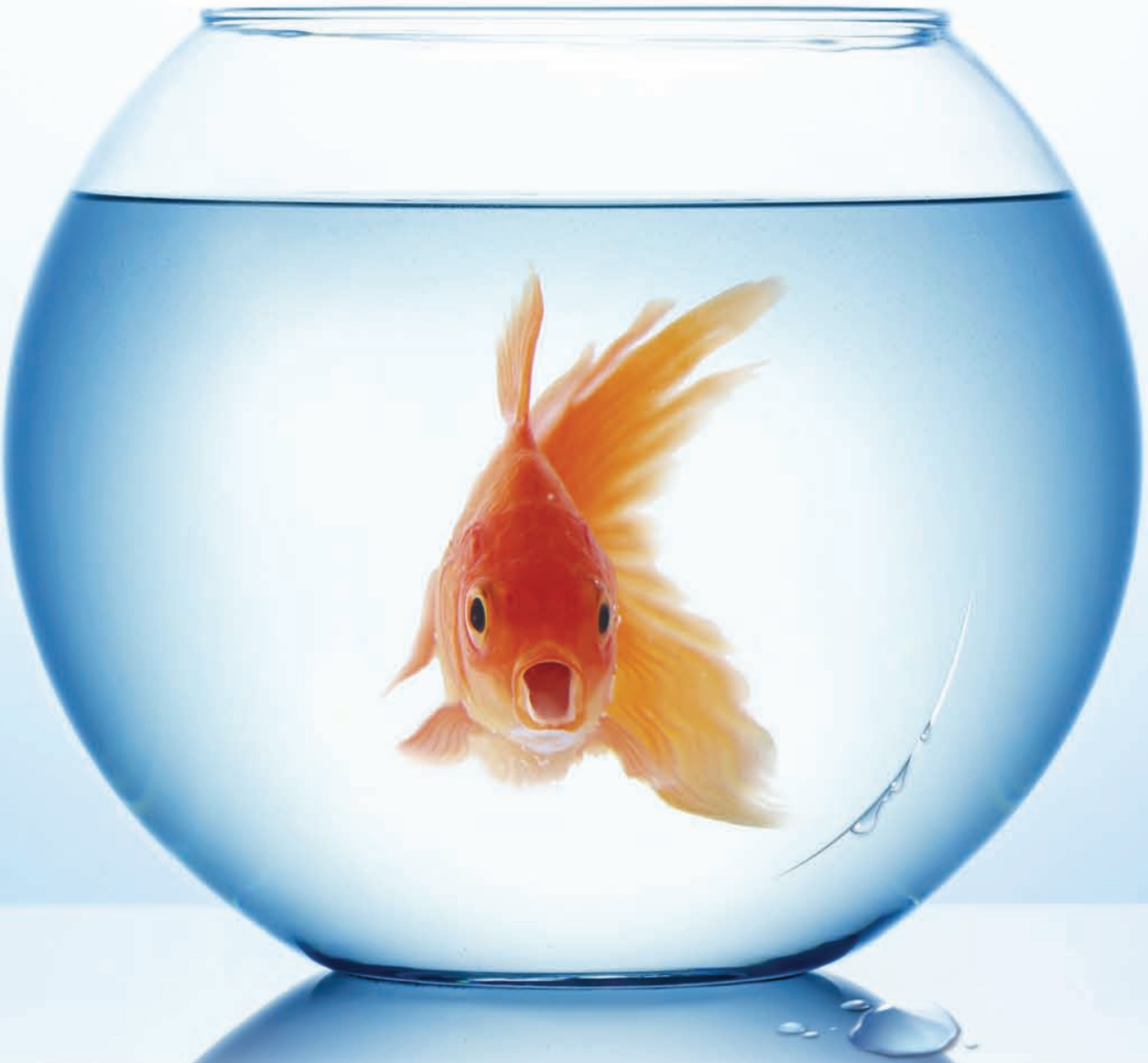

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How single-use lenses yield multiple diagnostic benefits

Disposable lens system may reduce risk of infection; serve as cost-effective choice in busy settings

By Nancy Groves; *Reviewed by Professor John Marshall, PhD*

LONDON ::

A line of single-use diagnostic and treatment lenses (Quantel Medical) offers clinicians the dual advantages of pristine optics with every use and a reduced risk of infection from improper cleaning and sterilization procedures.

These anterior segment lenses for diagnostic, surgical, and therapeutic procedures—which are packaged in a sterile pouch—offer a solution to many of the concerns associated with traditional single-use lenses: disease transmission and loss of therapeutic efficacy, said Professor John Marshall, PhD, Frost Professor of Ophthalmology, Moorfields Eye Hospital, London.

Dr. Marshall

"The optical quality of these lenses is as good as any classical lens with the added advantage that each time you do a procedure, effectively you have a brand new, perfect lens," Dr. Marshall said. "Whereas with a classical lens system, it's been cleaned, it's been wiped, it's been sterilized, and obviously the optical quality goes down as a function of use.

"If you take an average lens out of its container in an average clinic, you will see fingerprints, you will see scratches, and you will see dust," he said. "In theory, the lens has been cleaned or sterilized; in practice, that may or may not have happened."

In a busy hospital, such as Moorfields, there is a "horrendous problem" with lenses due to heavy usage, theft, and damage, and high costs for cleaning and sterilization—largely due to staffing requirements, Dr. Marshall added.

TAKE-HOME

- ***A new line of single-use lenses may reduce the risk of disease transmission and eliminate reductions in optical quality that occur over time with reusable lenses.***

(FIGURE 1) The single-use lens designs feature larger, flatter mirrors for a wider, improved field of view. A. The three-mirror lens. B. The four-mirror gonioscopy lens. C. The capsulotomy lens. D. The retina 180 lens is used to treat diabetic eye disease, particularly panretinal photocoagulation and age-related macular degeneration. *(Images courtesy of Quantel Medical)*

GROWTH IN SINGLE-USE MEDICAL PRODUCTS

Reducing the risk that disease can be transmitted through reusable medical products is a primary reason for growth in single-use items.

The so-called "mad cow disease" (bovine spongiform encephalopathy—BSE) scare in the United Kingdom and Europe during the 1990s—in which evidence suggested an association between BSE and a new human prion disease called variant Creutzfeldt-Jakob disease—made everyone aware of the almost total inability to sterilize instrumentation in the presence of prions, Dr. Marshall said.

As a result, there has been increasing pressure in the United Kingdom toward single-use devices for any neurological tissue, and legislation mandating their use appears likely.

"There was resistance initially, but as single-use instrumentation improved, that resistance has pretty much gone," he said.

There have also been numerous reports in the ophthalmic literature of outbreaks of epidemic keratoconjunctivitis associated with human adenovirus infections resulting from attendance at eye clinics, likely attributable to lax disinfection and sterilization procedures for reusable instruments. Though such outbreaks are far from everyday occurrences, the risk may be greater than that of BSE and high enough for at least some facilities to re-evaluate their infection control protocols and consider more widespread use of disposable lenses.

Continues on page 36 : ***Single-use lenses***

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  Use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.
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The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5 to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For additional information about ILEVRO® Suspension, please refer to the brief summary of prescribing information on adjacent page.

References: 1. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, June 2014. **2.** ILEVRO® Suspension prescribing information. **3.** NEVANAC® Suspension prescribing information.

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SINGLE-USE LENSES

(Continued from page 34)

The other main force behind the burgeoning interest in single-use lenses is the wear and tear that over time will reduce the image quality of reusable products. This is no longer a consideration with lenses used only once, he explained.

"Every time you do a treatment . . . , essentially you're using a new lens so the optics are absolutely perfect," Dr. Marshall said. "You aren't dealing with scratched optics or optics that have been dropped or chipped or optics that have been cleaned so many times that they've begun to fatigue and slightly yellow."

Transmission loss in aging reusable lenses also is a thing of the past.

"With these lenses, you have 100% of the laser output delivered, whereas with conventional lenses you're losing anywhere up to 20%, so you have to keep turning the energy up," he said.

VALUE IN TECHNOLOGY

Advances in technology have enabled the development of single-use lenses, such as those from Quantel, which have larger, flatter mirrors that result in a wider field of view, Dr. Marshall added.

"This is a completely novel technology in that it wouldn't have been possible until relatively recently to produce lenses of such high quality so inexpensively," he said. "That's a major technology pre-requirement.

"If you do an analysis of the cost effectiveness of these lenses, again it's a winner," Dr. Marshall said. "The number of procedures will determine exactly how much money you save, but even if you're only doing a relatively small number, you will still achieve savings on sterilization and cleaning."

An analysis performed by Sensor Medical Technology, which manufactures the lenses, compared the costs of using a four-mirror gonioscopy lens for 240 procedures a year with reusable and single-use lenses in two settings.

In a hospital, the costs of lenses, disinfecting materials, transportation to and from cleaning, disinfection, packaging, staff time, and cost per procedure was $11,042 for eight reusable lenses and $2,304 for the single-use lenses, a savings of $8,738.

In a private practice, the costs were $3,567.50 for two reusable lenses and $2,304 for single-use lenses, a savings of $1,263.50 per year with the single-use items.

Interest in single-use lenses is building outside of the United Kingdom as well, for the same reasons that hospitals such as Moorfields are switching to these products.

"A lot of people like the idea of a nice, fresh optic and use it as a sort of premium, having a personal optic for every treatment, as it were," Dr. Marshall said. "Other people are building on the idea of infection-free treatment." ■

JOHN MARSHALL, PHD
E: *eye.marshall@googlemail.com*

Dr. Marshall has served as a lecturer for Quantel Medical.

HOW TO

Sell sunwear successfully in ophthalmic clinics

Educating patients, physicians of benefits yields added value to dispensary services

By Rose Schneider, Content Specialist, *Ophthalmology Times*

While selling sunwear can seem intimidating or even off-putting for ophthalmologists, Joy L. Gibb, ABOC, said its practice is not only a great revenue-generator for physicians, but if handled correctly, can also increase patient satisfaction.

"You have to be committed to recommending, prescribing, and presenting sunwear to every patient," explained Gibb, president, Eyes of Joy Mobile Optical Service, Woods Cross, UT. "So many physicians feel uncomfortable 'selling' during the [patient] examination.

"Instead of considering it a 'sale,' it needs to be seen as a recommended product solution that will improve, protect, and retain the patient's vision and ocular health," she continued. "As eye-care professionals, we know the problems [of] cumulative ultraviolet (UV) exposure. It's our responsibility to explain those risks and offer solutions."

Because many ophthalmologists are hesitant to sell sunwear frames to patients, optical shops can lack the attention needed to ensure their success, said Bennett Romanoff, MD.

"The biggest fault of ophthalmologists is they are eye doctors, and they're

Continues on page 38 : ***Sunwear***

Getty Images/Cultura

In Brief

'Extreme glare'

SUNGLASS LINE TARGETS THOSE WITH PHOTOPHOBIA

ELK GROVE, CA :: **ZURICH HAS UNVEILED ITS NEW** eyewear line directed at those who are highly sensitive to sun glare, as well as those who are exposed to the sun for extended periods of time.

The new sunwear—Zurich Extreme Glare Sunglasses—provides protection to people with eyes suffering from various medical conditions including:

- Sensitive eyes
- Migraine headaches
- Albinism
- Dilated pupils
- Keratoconus
- Corneal abrasion
- Autoimmune diseases
- Eye and head surgery recovery
- Sensitive eyes from medication
- Medical conditions caused by surgery, such as cataracts, LASIK, corneal, and transplants
- Photophobia

"(The sunglasses) are the safest, most sensible and technologically advanced alternative to polarized lenses," the company said in a prepared statement.

Five-year forecast

REPORT: PHOTOCHROMIC INDUSTRY TO GROW 7.64%

DALLAS :: **A RECENT RESEARCH** report published by ReportsnReports.com has forecasted the photochromic lens industry to grow at 7.64% compound annual growth rate during 2014 to 2019.

Key market drivers—such as technological innovations in photochromic lenses, better marketing and promotion strategies, growing awareness on ultraviolet light exposure, and growing population—were discussed in the research.

The photochromic lenses market research also focused on market trends such as high sensitivity to economic cycles, increasing disposable income, risks vis-à-vis fluctuations in currency, and improved perception

Continues on page 38 : ***In Brief***

SUNWEAR

(Continued from page 37)

not too big into making their optical shops profit centers," said Dr. Romanoff, Romanoff Vision, Sylvania, OH.

To turn optical shops into profit centers, Gibb recommended ophthalmologists start by properly educating their patients on the importance of sunwear.

"Educating patients about the importance of UV protection and how sunwear can enhance their lifestyle and vision should be a part of every exam," Gibb said. "Patients come seeking solutions for their vision, how to retain what they have, and how they may be able to restore what may be diminished.

> 'We . . . do see the benefits in our optical shop as the result of doing this.'
>
> — Bennett Romanoff, MD

"We know that certain colors of lenses can help with vision and that UV protection can protect them from future problems," she explained.

This technique has proven highly successful for Dr. Romanoff, as he reported that in 2014, between 15% to 20% of his patients bought polarized sunwear, and 61% to 75% of them bought Transitions sunwear.

"It takes a little more time for ophthalmologists to educate their patients . . . but it is worth it in the optical shop," Dr. Romanoff said.

Committing to the right sunwear inventory is another important aspect that ophthalmologists should focus on if they want the practice's optical shop to be profitable, Gibb said.

"So many times the inventory is stacked with ophthalmic frames and only a few sunglasses," Gibb said. "Sunwear should be prominently displayed on your frame boards and highlighted in window displays. Have a great selection for both fashion and function.

"Make sure you have a nice variety of styles and prices available," she recommended.

Fashion and function should both be considered when deciding on inventory, Gibb said.

"Be sure to carry frames that can hold prescription lenses, but also have a few wrap frames for plano wearers," she said. "Wrap frames or wider temple pieces offer added protection for those who work outside where debris can enter the frame and injure the eye."

Pay attention to which frames are chosen, Gibb advised, to guarantee the optical shop has sunwear that patients actually want to purchase.

"Men tend to be brand loyal and will ask for sunwear brands by name," she said. "If you are repeatedly being asked for a certain line, you may want to consider putting it in. If you choose not to carry certain brands, at least be familiar with the product line so you can offer something comparable and be able to explain the differences and why you prefer the brands you offer."

ADVANTAGES OF OPHTHALMIC CLINICS

There are several unique opportunities that come with selling sunwear to patients in an ophthalmic clinic, Gibb pointed out.

"Sunwear should be recommended after surgical procedures, particularly those that improve vision and allow a patient to wear plano sunglasses," Gibb advised. "For someone who has had a significant correction in their lenses, the opportunity to wear large, fashionable sunglasses is exciting. Having the ability to wear a sunglass with interchangeable plano lenses with tints that will enhance specific activities can improve their quality of life and enjoyment of their outdoor activities."

Also having the chance to show patients the characteristics of the sunwear in the chair—as opposed to being shown the frames by staff in the optical shop—can be highly beneficial to the patient, Gibb said.

"You can explain the benefits of a polarized lens, but showing [patients] a polarized lens demonstrator helps them fully understand how glare can be reduced," she said. "Those moments can give the patient the 'wow factor' and a better understanding of the value of their purchase."

Physicians can also find ease in knowing that they do not have to be aware of pricing logistics for the sunwear, Gibb said. Instead, ophthalmologists should focus on what they know best—how the features and characteristics of the frames help their patients' vision.

Ophthalmologists should make sure to write multiple prescriptions for sunwear as well, because the more prescriptions that are written, the more profitable the clinic's optical shop will become, she said.

"When doctors recommend a pair of sunglasses and then write a separate prescription for them, the patient feels more compelled to fill both prescriptions," Gibb added.

THE BOTTOM LINE

Above all else, both Gibb and Dr. Romanoff stressed the importance of commitment to ensure profit and patient satisfaction success.

"In the field of ophthalmology, and the field of medicine in general, we're getting pay cuts," Dr. Romanoff said. "(While selling sunwear) does take extra chair time and education, . . . patients really value the physician's expertise and opinions . . . rather than anyone else.

"We (really) do see the benefits in our optical shop as the result of doing this," he explained.

"When patients feel their needs and wants have been heard and met, they feel like they have an eye-care provider who genuinely cares for their vision, ocular health, and overall well-being," Gibb added. ■

Continues from page 37 : **In Brief**

of photochromic lenses among eyewear consumers.

To define the market circumstances in the next 3 to 4 years, the analysts conducted in-depth analysis of the impact of market drivers, challenges and trends featuring data on product segmentations, vendor shares, and growth rate by revenue, and evaluated the different buying criteria in the order of importance.

To calculate the market size, the report took into account revenue generated from sales of photochromic lenses to individual customers.

The Global Photochromic Lenses market 2015 to 2019 report was prepared based on an in-depth market analysis with input from industry experts.

The report covers the Asia-Pacific region, Europe, North America, and the Rest of World. It also highlights the Global Photochromic Lenses market landscape and its growth prospects in the coming years.

The report also includes a discussion on the key vendors operating in this market. ■

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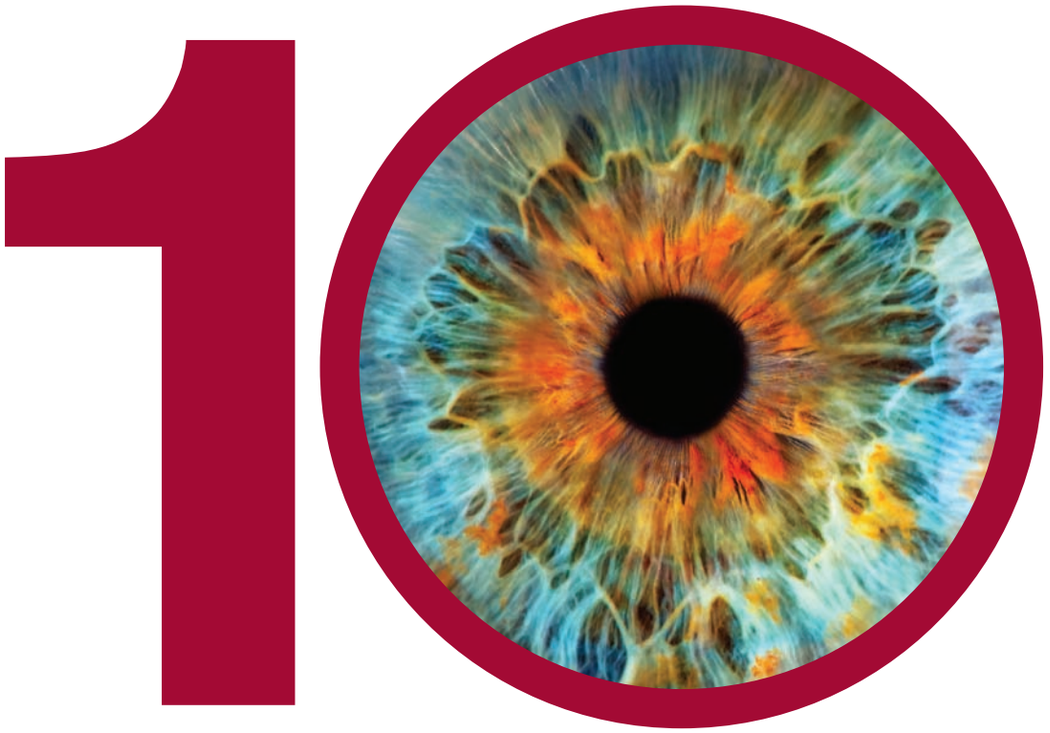

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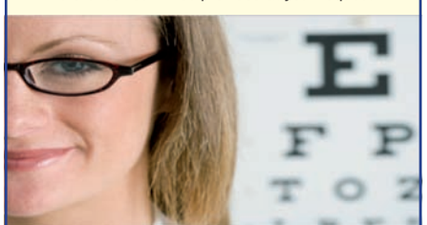

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Why modifier –59 modifications carry big reimbursement impact

Medicare: Substantial federal savings may result if appropriate use of modifier curtailed

coding.doc **By L. Neal Freeman, MD, MBA, FACS**

Over the past several years, numerous initiatives brought forth by Medicare—technically, the Centers for Medicare and Medicaid Services (CMS)—have created major changes in provider reimbursement. One such action is the development of a new set of specific modifiers that will impact claims previously submitted with modifier –59.

Modifier –59 is commonly known as the "Bundle Breaking Modifier." Although a tremendous number of bundling edits have been established through the National Correct Coding Initiative, it has been possible to break many of the bundles with the –59 modifier.

> 'Incorrect reporting of modifier –59 has been well documented. Some data show reporting error rates approaching 50%.'
>
> — L. Neal Freeman, MD, MBA, FACS

The CPT definition of modifier –59 is as follows:

"**59 Distinct Procedural Service**: Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M services performed on the same day. Modifier 59 is used to identify procedures/services, other than E/M services, that are not normally reported together, but are appropriate under the circumstances. Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual. However, when another already established modifier is appropriate it should be used rather than modifier 59. Only if no more descriptive modifier is available, and the use of modifier 59 best explains the circumstances, should modifier 59 be used."

The above definition encompasses a variety of circumstances ranging from "different session" to "separate injury," and therefore could be considered too broad. CMS believes this is the case, and has therefore taken action.

TAKE-HOME

- ***L. Neal Freeman, MD, MBA, FACS, takes a closer look at modifier –59, including some of the major concerns for which physicians (including ophthalmologists) should be aware, as it will affect claims.***

UNDERSTANDING SIGNIFICANCE OF MODIFIER -59

Identification of usage patterns for modifier –59 has been part of The Office of Inspector General's annual Work Plan many times recently. Incorrect reporting of modifier –59 has been well documented. Some data show reporting error rates approaching 50%. Medicare recognizes that substantial federal savings would result if inappropriate use of this modifier could be curtailed. The benefit to the program could easily reach hundreds of millions of dollars.

Incorrect unbundling is a form of fragmentation, hence double billing. Changes that are being implemented by CMS in reporting of modifier –59, by achieving greater detail, will likely eliminate some of the inappropriate reporting.

Beginning Jan. 1, 2015 (implementation date Jan. 5, 2015), these new modifiers should be reported, presuming one of the following specific scenarios applies:

XE ***SEPARATE ENCOUNTER***

Used to describe services that are separate because they take place during separate encounters.

XS ***SEPARATE STRUCTURE***

Used to describe services that are separate because they are performed on different anatomic organs, structures or sites.

XP ***SEPARATE PRACTITIONER***

Used to describe services that are distinct because different practitioners perform them.

XU ***UNUSUAL NON-OVERLAPPING SERVICE:***

Used to describe services that are distinct because they do not overlap the usual components of the main service.

CONCERNS FROM CMS PERSPECTIVE

CMS' biggest concern is not with separate encounter or separate structure indications. Rather, the agency believes the problem centers upon reporting distinct services when the work of one service has been designated as a subset of another service.

Medicare has instructed it will still accept the –59 modifier. However, certain codes may be rejected since the more specific modifier will be required for certain ser-

Continues on page 45 : ***Modifier –59***

Why specialty physicians need to view EHR systems differently

Consider role from both a liability protection and financial management perspective

By Robert Pollack, MD

SAN DIEGO ::

FOR SOME TIME, federal regulators and insurance companies have made the strong push for all physician groups—including ophthalmologists—to move toward digital practice management and electronic health record (EHR) systems. Eventually, it will mean the difference between being fully reimbursed or not.

Even without the mandate, there are great reasons to do so. For starters, the cost of paper management is significant. Surgical offices alone will spend an average of $2 to $3 annually to manage, retrieve, and store a single patient chart. Depending on the practice size, the hidden costs may be in the high five figures. With this daunting background, the right EHR system should not be seen as a necessary evil, but instead an efficient productivity tool that will save the specialty physician money over time.

One problem for such offices is that mainstream EHR platforms are not well suited for the needs of specialty physician practices. They are designed for family practice and internal medicine physicians who bill by the appointment instead of the procedure-oriented practice of surgeons.

Second, most EHR systems require the medical group to purchase and maintain at least one server on their premise thus causing the implementation costs to rise significantly. The hardware expense alone is at times too prohibitive for most surgeon groups, but add the appropriately trained IT and security personnel to run the servers, and the overhead is often unbearable.

FEATURES AND BENEFITS

The tech industry is beginning to respond and enabling specialty physicians to look at EHR platforms differently than before. The key is to seek out systems that were designed from the outset to meet the needs of this particular group of medical professionals. They include the following features and benefits:

- **Surgeon-specific EHR platforms that tie into existing office practices. Consider EHR platforms that can organize all patient documentation with one software package. The good ones also offer pre-made specialty templates as well as the ability to create new ones. Most importantly, the right EHR system should be specifically geared toward a specialty physician's day by managing scheduling, charting, labs, procedural notes, education, and billing. It should also give the office the ability to upload scanned documents and photos to a patient's online folder and thus eliminate paper charts.**

- **Surgeon-specific EHR platforms that are cloud-based. These systems eliminate the high up-front costs, complicated software installations, expensive servers, and annual upgrade fees associated with traditional offerings. Web-based platforms provide secure access to patient data with fully HIPAA-compliant data storage and disaster recovery for a monthly subscription and often times with 24/7 customer support. What's more, these systems afford specialty physicians access to patient records anywhere at anytime via a standard web browser, improving productivity and efficiency.**

- **Surgeon-specific EHR platforms that improve communication with patients and staff. These systems should enable specialty physicians and their staff to send and receive notifications and alerts, schedule and track appointments, and see summary data about the entire practice and procedures. Most will also offer automated appointment reminders to reduce patient no-shows, and many will enable staff to create mailing lists for patient birthdays and office events.**

REDUCING LIABILITY

There's an additional inherent advantage to EHR platforms that are cloud-based, and this is the reduction of liability exposure for the practice. With a server-based system, physicians must maintain encryption of data on the server and perform daily off-site backups. Failure to follow these policies can be seen as a violation of the federal statue and put specialty physicians and their entire practice at risk. The potential fines that can believed by the U.S. Department of Health and Human Services and the Office for Civil Rights can run anywhere from a few hundred thousand dollars into the millions of dollars.

HIPAA-compliant, cloud-based EHR systems eliminate this issue since data are not stored locally. Patient files are accessed by a web browser and remain secured and compliant on the cloud server with encryption and off-site data storage performed automatically. The benefits to lower liability risk for a specialty physician's practice cannot be overstated.

The move toward EHR and practice management software platforms is real and will happen. It's no longer a question of if, but when. Organizations, such as the American Medical Association, have recently called for an overhaul of EHR platforms in order to make usability a top priority.

One key way to do that is by offering systems that cater to specific medical practices. For specialty physicians, the shift cannot come soon enough. ■

TAKE-HOME

- ***The move toward specialty specific cloud-based EHR and practice management software platforms is real and will happen. It's no longer a question of if, but when. An overhaul of EHR platforms to offer systems that cater to specific medical practices is needed. For specialty physicians, the shift cannot come soon enough.***

Join the discussion on specialty physician-specific EHR platforms at **Facebook.com/OphthalmologyTimes.**

ROBERT POLLACK, MD, *is co-founder and chief medical officer of SupraMed and a board-certified plastic surgeon in private practice in San Diego. He can be reached at rpollack@supramed.com.*

MODIFIER –59

(Continued from page 43)

vices. Since the new modifiers are more specific than modifier –59, they will frequently be the appropriate choice. CMS has recommended "rapid migration" to use of the specific modifiers.

It is unknown whether the private payers will recognize the new modifiers. The best way to determine this is to review informational updates from the respective payers, and to contact them individually for any remaining questions.

OT L. Neal Freeman, MD, MBA, FACS, explains how Contractor Advisory Committee members act as a bridge to communication between providers and the Medicare contractor. To learn more, go to **http://bit.ly/1B23S41**

CLEARING UP UNCERTAINTIES

Another uncertainty exists for the circumstances in which the CPT manual specifically directs use of modifier –59. For example, in the wound closure section of the CPT manual, the following instruction appears:

"When more than one classification of wounds is repaired, list the more complicated as the primary procedure and the less complicated as the secondary procedure, using modifier 59."

The new modifier scheme might suggest otherwise, depending on specific circumstances. The answers to these apparent disparities will likely be worked out over time.

Questions regarding this change as it relates to Medicare are best directed to the physician's local Medicare contractor. The administration of the policy will probably vary between jurisdictions.

Physicians and their staff should stay constantly monitor changes in the National Correct Coding Initiative edit lists. The lists are dynamic, and many dollars are lost due to improper/inadequate reporting of related services.

It will be worthwhile to follow developments in this initiative. The financial impact of inadequate attention could be very sizable. ■

L. NEAL FREEMAN, MD, MBA, FACS

is president of CPR Analysts Inc. (www.cpranalysts.com.) He advises physicians nationally on coding, reimbursement, and practice management. Dr. Freeman is a practicing ophthalmic plastic surgeon and a certified specialist in physician coding. Readers may contact him at nfreeman@cpranalysts.com or 321/253-2166.

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VERION™ REFERENCE UNIT AND VERION™ DIGITAL MARKER IMPORTANT PRODUCT INFORMATION

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

INTENDED USES: The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides preoperative surgical planning functions that utilize the reference image and preoperative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION™ Digital Marker and other compatible devices through the use of a USB memory stick.

The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

CONTRAINDICATIONS: The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements.

Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.

The following contraindications may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

WARNINGS: Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker.

Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.

Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.

The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

LENSX® LASER IMPORTANT PRODUCT INFORMATION

CAUTION: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATION: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

RESTRICTIONS: Patients must be able to lie flat and motionless in a supine position. Patient must be able to understand and give an informed consent. Patients must be able to tolerate local or topical anesthesia. Patients with elevated IOP should use topical steroids only under close medical supervision.

CONTRAINDICATIONS: Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength. Descemetocele with impending corneal rupture. Presence of blood or other material in the anterior chamber. Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy. Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only). Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape. Corneal thickness requirements that are beyond the range of the system. Corneal opacity that would interfere with the laser beam. Hypotony or the presence of a corneal implant. Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease). History of lens or zonular instability. Any contraindication to cataract or keratoplasty. This device is not intended for use in pediatric surgery.

WARNINGS: The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

PRECAUTIONS: Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser. Discard used Patient Interfaces as medical waste.

AEs/COMPLICATIONS: Capsulotomy, phacofragmentation, or cut or incision decentration. Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure. Capsular tear. Corneal abrasion or defect. Pain. Infection. Bleeding. Damage to intraocular structures. Anterior chamber fluid leakage, anterior chamber collapse. Elevated pressure to the eye.

ATTENTION: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

CENTURION® VISION SYSTEM IMPORTANT PRODUCT INFORMATION

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

As part of a properly maintained surgical environment, it is recommended that a backup IOL Injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.

INDICATION: The CENTURION® Vision System is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert® IOL Injector Handpiece is indicated for use with the AcrySof® lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

WARNINGS: Appropriate use of CENTURION® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/COMPLICATIONS: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

ACRYSOF® IQ INTRAOCULAR LENSES – IMPORTANT PRODUCT INFORMATION

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

INDICATIONS: The AcrySof® IQ posterior chamber intraocular lens is intended for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. This lens is intended for placement in the capsular bag.

WARNING/PRECAUTION: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

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

ACRYSOF® IQ RESTOR® INTRAOCULAR LENSES — IMPORTANT PRODUCT INFORMATION

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

INDICATIONS: The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNING/PRECAUTION: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof® ReSTOR® lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

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

ACRYSOF® IQ TORIC INTRAOCULAR LENSES — IMPORTANT PRODUCT INFORMATION

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

INDICATIONS: The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNING/PRECAUTION: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggests that high astigmatic patients (i.e., > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric Cylinder Power IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

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

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Recommend the AcrySof® IQ Toric IOL for your astigmatic cataract patients.

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Improve outcomes for your astigmatic patients with real-time intraoperative guidance.[1]

ORA system® with VerifEye®

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1. Alcon data on file.

For important product information, please see adjacent page.

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