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In This Issue

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News

TORIC POSTERIOR CHAMBER IOL APPROVED

By Cheryl Guttman Krader

ALISO VIEJO, CA :: **THE FDA APPROVAL of a toric IOL (model AT50T; Trulign Toric, Bausch + Lomb) is a significant event because this is the first implant available in the United States able to reduce residual refractive cylinder and provide improved uncorrected vision across a full range in cataract surgery patients with substantial pre-existing astigmatism, said Jay S. Pepose, MD, PhD.**

The IOL is a modification of the existing hinged-plate haptic silicone Crystalens AO platform that differs from the parent lens in only two ways—it has toric correction on the posterior surface of the biconvex optic and two

(See story on page 6)

Valeant to acquire Bausch + Lomb

$8.7 billion transaction catapults Canadian pharmaceutical company into a major player in the ophthalmic market

By Jennifer A. Webb

LAVAL, QUEBEC AND ROCHESTER, NY :: **VALEANT PHARMACEUTICALS** International Inc. will buy Bausch + Lomb (B+L) in an $8.7 billion all-cash deal that many analysts are viewing with cautious optimism.

The transaction transforms the 160-year-old, global eye-care company renowned for its pharmaceutical, vision care, and surgical segments into a division of Valeant, a company built by mergers and acquisitions—60 of which happened in the past 5 years.

Although Valeant had acquired some ophthalmology pieces—including pegaptanib sodium injection (Macugen) in its 2012 purchase of Eyetech Pharmaceuticals Inc. and two other products in its 2010 acquisition of Aton Pharma—the B+L deal catapults the younger company into a major player in the ophthalmic space.

"We're very excited to be getting into this space in a much larger fashion," said Laurie Little, vice president of investor relations for Valeant. "When we look at the operations and what B+L has accomplished over the years, we think it's a great fit with Valeant. We are very dedicated to the space; obviously we thought it would be built up a little slower, but this gives us a big leg up right away."

Valeant is buying the historic company from private equity firm Warburg Pincus, which acquired the company in 2007 for $4.58 billion after B+L had suffered through a series of missteps. In 1994, numerous accounting scandals rocked the company, followed by the 2006 worldwide recall of its ReNu with Moisture Loc contact lens solution, which was linked with more than 100 fungal keratitis cases. Under private ownership, B+L quietly settled nearly 600 lawsuits relating to that recall at a cost of about $250 million.

Yet, over the past 6 years, B+L was able to secure 10 quarters of top- and bottom-line growth and created a robust pipeline of new products. Of the $8.7 billion price tag, about $4.5 billion will go to an investment group led by Warburg Pincus and about $4.2 billion will be used to repay B+L's outstanding debt. The deal is expected to close in the third quarter, after customary regulatory approvals.

Fred Hassan, chairman of B+L's Board of Directors, will join Valeant's Board of Directors, and Dan Wechsler, executive vice president and president of B+L's global pharmaceuticals division, will join Valeant to lead the B+L division, which retains its name. B+L's chief executive officer, Brent Saunders, will work as an advisor in the transition before moving on to other interests.

Wechsler emphasized that B+L will remain intact, with no planned reduction of the head count of its North Ameri-

*(Continues on page 10 : **B+L sale**)*

VALEANT'S OPHTHALMIC ACQUISITIONS

2013
- Acquires **Bausch + Lomb**

2012
- Acquires **verteporfin** for injection (Visudyne) from QLT for treating predominantly classic subfoveal CNV due to AMD
- Acquires **Eyetech**, marketer of pegaptanib sodium injection (Macugen), first anti-VEGF inhibitor to be approved by FDA for treatment of wet AMD

2011

2010
- Acquires **Aton Pharma**, specialty pharmaceutical company focused on ophthalmology and certain orphan drug indications

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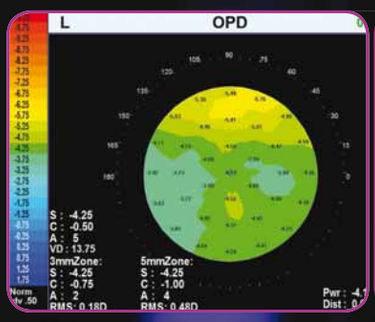

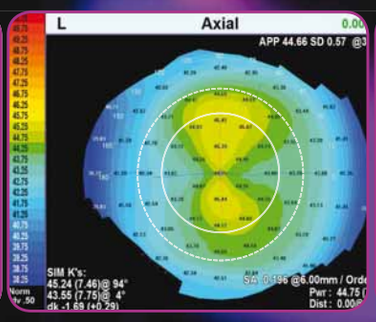

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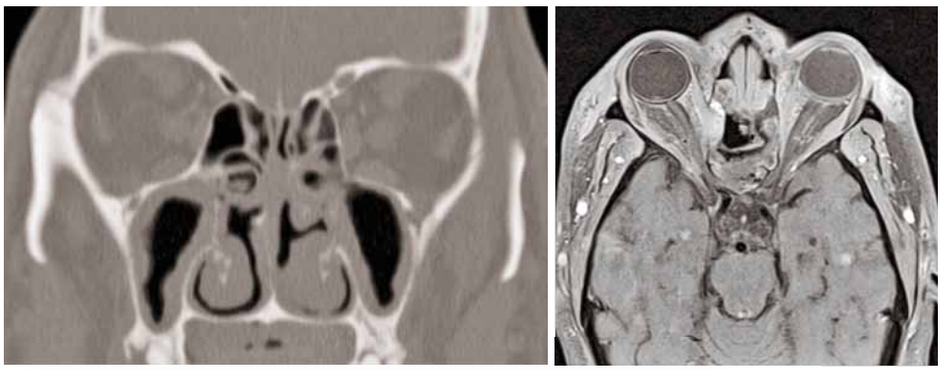

(Left) CT/CTA demonstrating extensive sinus disease. (Right) MRI status post-debridement showing enhancement of the orbits with involvement of the right intraconal and extraconal space, the right orbital apex, and the left extraconal space. **41**

InDispensable

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Special Report

ASCRS CATARACT NEWS

Online learning on demand

Hype or not, MOOCs have far-reaching effect on education

By Peter J. McDonnell, MD

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

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THE PAST PRESIDENT of my university likes to make the point that just about every business and profession in America today is dramatically different from the version that existed 25 years ago. Thanks to people like Steve Jobs, we shop online, ask our telephones to give us directions, watch the movies and TV shows we like whenever we feel like it, make dinner reservations by pushing three buttons, and no longer visit bookstores because they are almost nonexistent. Everything is faster, demonstrably better (except for TV shows like "Jersey Shore"), more efficient, and cheaper. But there was one industry, he maintained, that had refused to change.

CHANGING WITH THE TIMES?

He referred to the perceived failure of our nation's educational institutions (including the one he led) to change (or change enough) with the times. His point was that all too often, education today is provided in more or less identical fashion to how it was done 50 years or even 100 years ago. Students sit in lecture halls and listen to a professor speak about some topic of interest for an hour or so. They are also given reading assignments. Professors give occasional tests and grade the occasional paper written by their students. Students who seem confused are encouraged to visit the professor (in "elite" schools) or teaching assistant during "office hours" to ask questions and get some extra help.

Education today is not faster or demonstrably superior. It is now so expensive that student loan debt is at an all-time high.[1] The U.S. Department of Education says the federal student loan default rate is at its highest level in 14 years, and the New York Federal Reserve recently reported that more than five million student loan borrowers have at least one loan past due.

University presidents, who I believe as a group to be concerned sincerely about the poor and providing the benefits of education to all, paradoxically run an industry whose product they have increasingly priced beyond the reach of large segments of society.

ENTER MASSIVE OPEN ONLINE COURSES

So it's timely that A.J. Jacobs has reviewed the status of massive open online courses (MOOCs) in a balanced and interesting *New York Times* article, comparing and contrasting this model to our traditional campus-based educational system.[2] Millions of people from around the world are signing up to take these MOOCs, watching lectures by brilliant academicians from prestigious universities on their computers and reading assigned materials whenever they can find the time, as opposed to when the professors schedule the lecture.

Jacobs laments the relative lack of interaction with professors and fellow students. There is some opportunity to ask questions and discuss topics in online chat rooms, and some of these programs arrange for students in an area to get together to meet as a group with a local facilitator.

From a cost perspective, MOOCs win (big time). Spending a year on campus and warming seats in lecture halls runs $25,000 to $50,000 a year; many MOOCs are (I kid you not) free and others cost a tiny fraction of the bill to attend that same professor's college.

The part of the article that disappointed me was the lack of measurable results. For example, do people who make the effort to learn online, in general, learn as much as the students living in dorms?

Jacobs summarizes the state of the art of online higher education by giving MOOCs the grade of "B". They are not perfect, Jacobs asserts, but the following quotation suggests that we are seeing the emergence of a disruptive approach to education:

"As these online universities gain traction, and start counting for actual college course

Continues on page 9 : **Online learning**

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FDA approves B+L toric posterior chamber IOL

Approval signals first toric lens that provides improved uncorrected near, intermediate, distance vision

By Cheryl Guttman Krader; *Reviewed by Jay S. Pepose, MD, PhD*

TAKE-HOME

- ***A new toric IOL that provides improved vision across a natural range of focus (model AT50T; Trulign Toric, Bausch + Lomb) is a toric modification of the Crytalens AO IOL.***

ALISO VIEJO, CA ::

The FDA approval of a toric IOL (model AT50T; Trulign Toric, Bausch + Lomb [B+L]) is a significant event because this is the first implant available in the United States able to reduce residual refractive cylinder and provide improved uncorrected vision across a full range in cataract surgery patients with substantial pre-existing astigmatism, said Jay S. Pepose, MD, PhD.

The IOL is a modification of the existing hinged-plate haptic silicone Crystalens AO platform that differs from the parent lens in only two ways—it has toric correction on the posterior surface of the biconvex optic and two axis orientation marks on the anterior optic surface. The Trulign Toric IOL is available in three cylinder powers that correct 1.25, 2, and 2.5 D in the IOL plane (0.83, 1.33, and 1.83 D at the corneal plane). Like the parent lens, it will be available in spherical powers ranging from +.0 to +33 D.

Dr. Pepose

"It is the first option that allows U.S. surgeons to address two unmet clinical needs in cataract patients with a single procedure, the visual impact of residual uncorrected astigmatism and the desire for excellent distance and intermediate vision, as well as functional near vision," said Dr. Pepose, medical monitor for the FDA clinical trial, and founder and medical director, Pepose Vision Institute, St. Louis, MO.

"Toric IOLs were designed to correct for astigmatism," said Calvin Roberts, MD, executive vice president and chief medical officer, B+L. "However, that still leaves the surgeon with the challenge of choosing an IOL for a patient with astigmatism who wants a premium correction. Now we have the answer—a toric IOL that provides improved vision at near, intermediate, and distance. Our Trulign Toric IOL offers the best of both worlds and is an excellent option for the surgeon and the patient."

CLINICAL TRIAL RESULTS

The clinical trial inclusion criteria specified enrollment of patients with predicted postoperative corneal astigmatism between 0.83 and 2.5 D as determined by the IOL's toric calculator, best-corrected visual acuity (BCVA) of 20/40 or worse with or without glare, and the potential for BCVA of 20/32 or better. For the study, the toric calculator used a fixed value of 0.50 D for surgically induced astigmatism (SIA).

Patients with predicted postoperative cylinder between 0.83 and 1.32 D were randomly assigned to implantation of either the 1.25 D toric IOL (n = 76) or the spherical IOL (n = 82). In addition, 47 eyes with predicted postoperative cylinder of 1.33 to 1.82 D were enrolled to receive the 2 D toric IOL and 24 eyes with predicted postoperative cylinder of 1.83 to 2.5 D were entered into the 2.75 D toric IOL group.

Effectiveness data presented to the FDA were from an interim analysis conducted at the first datalock for 66 control patients and 133 toric IOL patients who reached study visit 4 (4 to 6 months postoperatively).

With data pooled for all eyes with the toric

(Continues on page 13 : ***Toric IOL*** *)*

HEADLINES YOU MIGHT HAVE MISSED

AS SEEN IN *Ophthalmology Times*' weekly eReport. Sign up at *http://www.modernmedicine.com/OphthalmologyTimes/enewssignup.*

POSITIVE RESULTS FOR AFLIBERCEPT

REGENERON AND BAYER HEALTHCARE reported positive top-line results for aflibercept injection (Eylea) from the phase III MYRROR study in myopic choroidal neovascularization (mCNV).
http://bit.ly/11BsWMe

TOPCON LAUNCHES AUTO REFRACTOR

TOPCON MEDICAL SYSTEMS HAS RELEASED its new KR/RM-800 auto refractor series. The KR-800 Auto Kerato-Refractometer and the RM-800 Auto Refractor incorporate the latest in design technology and ergonomics. The company begins delivering the new products at the end of June.
http://bit.ly/12uy6zJ

WAVETEC MAKES TECH STARTUP LIST

RED HERRING HAS CHOSEN WAVETEC VISION to receive the "Red Herring Top 100 North America Tech Startup" award. WaveTec was selected for its proprietary ORA System, which improves the precision of cataract surgery by offering customized premium lens placement to ensure patients have quality vision.
http://bit.ly/19a1FJx

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Anti-VEGFs equivalent in IVAN2, GEFAL trials

Bevacizumab, ranibizumab effective for improving vision in patients with age-related macular degeneration

By Lynda Charters; *Reviewed by Laurent Kodjikian, MD, PhD*

TAKE-HOME

Two anti-vascular endothelial growth factor drugs used to treat age-related macular degeneration seem to be equivalent for improving vision in two recent studies.

SEATTLE :: **BEVACIZUMAB (AVASTIN, GENENTECH)** and ranibizumab (Lucentis, Genentech)—two anti-vascular endothelial growth factor (VEGF) drugs used to treat age-related macular degeneration (AMD)—seem to be similarly effective for improving vision. Minor differences were found between the study drugs.

Researchers reported the findings of two large, multicenter, randomized trials—the Inhibit Vascular Endothelial Growth Factor in Age-Related Choroidal Neovascularisation (IVAN) Study and the French Study Group Avastin versus Lucentis for Neovascular AMD (GEFAL) trial—at the annual meeting of the Association for Research in Vision and Ophthalmology.

IVAN2 STUDY

The study confirmed the 1-year findings of the IVAN study and went a step further to compare continuous and discontinuous treatment regimens of intravitreal injections of the two drugs. In the discontinuous regimen, three monthly injections were administered, after which patients were treated based on the findings of monthly examinations during the rest of the 2-year study.


Dr. Kodjikian

"The key message is that the drugs are similarly efficacious, and the continuous therapy regimen has slightly better efficacy," said Simon Harding, FRCOphth, MD, chairman of Ophthalmology, Department of Eye and Vision Science, Royal Liverpool University Hospital, Liverpool, England.

An interesting finding in the IVAN2 study was that there were twice as many deaths in the discontinuous treatment group, compared with the continuous treatment group (20 versus 10, respectively), a difference that reached significance ($p = 0.01$). This difference represented a two-fold risk in mortality, according to Dr. Harding. The investigators were unable to explain why more deaths occurred in the discontinuous treatment group.

The investigators also conducted a meta-analysis that included the data from the IVAN Study and the Comparison of Age-Related Macular Degeneration Treatment Trial (CATT). The CATT data showed more systemic adverse events associated with bevacizumab compared with ranibizumab.

Dr. Harding suggested that monthly bevacizumab may be a good option considering the efficacy and safety as well as the substantially lower cost compared with ranibizumab.

GEFAL STUDY

The prospective, randomized, double-masked trial included 501 patients at 38 sites in France. Laurent Kodjikian, MD, PhD, professor and associate chairman of the Department of Ophthalmology, Croix-Rousse University Hospital, Lyon, France, reported the study outcomes for the GEFAL Study Group.

In this study, patients randomly assigned to bevacizumab and ranibizumab received three monthly loading dose injections. After this period, they were examined monthly and re-treated as needed based on changes in the visual acuity and findings on imaging.

The GEFAL results indicated that the two drugs were equivalent for visual acuity at the final evaluation. Each drug required a mean of about seven injections during the year of the study. Both drugs provided rapid and substantial decreases in macular thickness and fluid. Neither drug eliminated fluid from all eyes, although ranibizumab achieved more

retinas that were completely dry compared with bevacizumab. There was no significant difference in dye leakage on fluorescein angiography. Both drugs achieved a slight decrease in the area of choroidal neovascularization.

Finally, a similar number of systemic and ocular serious advents occurred with both drugs, according to Dr. Kodjikian.

When the GEFAL data were added into a meta-analysis of data that included data from the IVAN, CATT, and Avastin Versus Lucentis in Age-Related Macular Degeneration studies, the GEFAL results agreed with the findings of the previous studies.

"Adding the GEFAL results to the 1-year meta-analysis reinforces the initial findings, i.e., non-inferiority in visual acuity and more systemic serious adverse events with bevacizumab but no more artherothrombotic events or deaths," Dr. Kodjikian noted. "An individual data meta-analysis is required before drawing any firm conclusions. Bevacizumab for neovascular AMD should be used under a risk management plan." ■

LAURENT KODJIKIAN, MD, PHD

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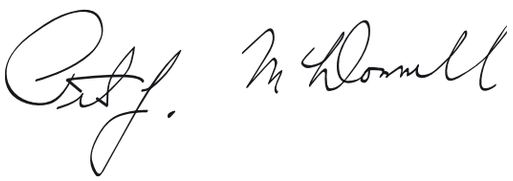
Dr. Kodjikian is a consultant for Novartis. The GEFAL study was totally financed by public grants.

ONLINE LEARNING

(Continued from page 4)

credit, they'll most likely have enormous real-world impact. They'll help in getting jobs and creating business ideas. They might just live up to their hype. For millions of people around the globe with few resources, MOOCs may even be life-changing." ■



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'The key message is that the drugs are similarly efficacious, and the continuous therapy regimen has slightly better efficacy.'

—Simon Harding, FRCOphth, MD

B+L agrees to pay fines over ISTA case

By Jennifer A. Webb

ROCHESTER, NY ::
ISTA PHARMACEUTICALS INC., purchased last year by Bausch + Lomb (B+L), pleaded guilty May 24 to civil and criminal charges that it offered kickbacks and improperly marketed unapproved uses of a drug prescribed by cataract surgeons to reduce post-surgery inflammation.

B+L agreed to pay about $34 million in civil and criminal fines after ISTA Pharmaceuticals pleaded guilty to conspiracy to offer kickbacks—such as wine tastings and speaker fees—to induce physicians to prescribe bromfenac (Xibrom) and conspiracy to promote it for unapproved uses. ISTA admitted encouraging physicians to prescribe bromfenac after LASIK and glaucoma surgeries, which are not FDA-approved uses. The allegations concern activity between January 2006 and March 2011.

The Justice Department, in a prepared statement, said some ISTA employees were told by management not to put in writing certain interactions with physicians regarding unapproved new uses, and not to leave printed materials in physician offices relating to unapproved uses. The department said certain ISTA employees, at their employers' direction, offered and provided physicians with free hyaluronidase (Vitrase) as an incentive for them to prescribe bromfenac.

Dan Wechsler, president of B+L's pharmaceuticals business, said his company was aware of the Department of Justice investigation when it acquired the pharmaceutical company in June 2012 for $500 million, and it has cooperated fully.

"We knew the value of the product and the people who came with it were well worth the investment," Wechsler said.

The settlement includes a $16.63 million criminal fine and a $15 million civil settlement linked to charges that ISTA's bromfenac marketing caused false claims to be submitted to government health-care programs. Keith Schenker, a former ISTA sales representative in New York who alerted authorities to the illegal practices, receives $2.5 million of the settlement amount as a "whistleblower."

U.S. Attorney William J. Hochul Jr., based in Buffalo, NY, said in the Justice Department statement that ISTA "offered doctors illegal inducements—such as a wine tasting, golf outings, and payments to attend what were in essence marketing sessions."

"Today's resolution sends a clear message that pharmaceutical companies cannot put profit ahead of people, by disregarding laws designed to protect the health of the American public," he said.

In addition to the fine, ISTA is prohibited from participating in federal health-care programs, such as Medicare and Medicaid. However, because ISTA's products—Bepreve, Bromday, Istalol, Prolensa, and Vitrase—all have been transferred to B+L, they are not affected by the settlement.

"There is, in effect, no impact on patients and doctors," Wechsler said. "Providing access to medicine is really important and these former ISTA products are still available to patients."

Laurie Little, vice president of investor relations for Valeant Pharmaceuticals International Inc., which announced its intent to acquire B+L 3 days after the ISTA allegations were resolved, said Valeant was aware of the pending settlement when J. Michael Pearson, its chairman and chief executive officer, approached B+L about a potential acquisition.

"It's behind us," Little said. "We move forward."

The settlement also requires B+L to maintain and strengthen its compliance and ethics program, something Little agreed is important to Valeant.

"No one currently employed by Bausch + Lomb was part of this, and we cooperated with the government to get it resolved," Wechsler said. "We're happy that we resolved this issue that was obviously pre-acquisition." ■

B+L SALE

(Continued from page 1)

can sales force and that doctors should not be impacted by the change in ownership from private equity firm Warburg Pincus.

"Valeant has said they are committed to our brand, customers, and patients," said Wechsler, who will hold titles of executive vice president and company group chairman, Ophthalmology and Eye Health. "One example of that is B+L employees will continue to carry B+L business cards."

Calvin W. Roberts, MD, chief medical officer for B+L, will join Valeant as chief medical officer of the ophthalmology and eye health division. Wechsler said that keeping Dr. Roberts on staff demonstrates Valeant's commitment to ophthalmology.

Little said she anticipates that more members of the B+L senior management team will be asked to join Valeant. Wechsler, who joined B+L in 2010, will oversee the integration of the two companies.

"We restored this company to growth and we restored the pipeline. I feel really proud of the people at B+L," Wechsler said. "All the teams all over the world have done a great job turning the company around."

Valeant announced it plans to recover $800 million in cost synergies—a number that surprised and concerned analysts, including Andrew Finkelstein of Susquehanna Financial Group and analysts with Stifel and Cleveland Research Co.

However, Wechsler said Valeant Chairman and CEO J. Michael Pearson wants those savings to come from existing Valeant properties as well as B+L.

Little cautioned that "it's early," adding, "We always take a look at everything. . . . Right now we're just moving forward with the three business units and integrating them. We like to say all of our assets are for sale but we don't have a huge history of divesting any."

Wechsler said Pearson is committed to retaining all three divisions of B+L, including the surgical side—a new segment for Valeant, which has pharmaceutical products in dermatology, neurology, and branded generics. With the acquisition, Valeant's business will be about equally focused as one-third dermatology and aesthetics, one-third ophthalmology, and one-third neurology and "other."

*(Continues on page 13 : **Acquisition**)*

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Macular edema, including cystoid macular edema, has been reported. RESCULA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

*In pooled safety analyses of pivotal trials comparing RESCULA with timolol maleate 0.5%.[4]

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Rescula may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If two drugs are used, they should be administered at least five (5) minutes apart.

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WARNINGS AND PRECAUTIONS

Iris Pigmentation

Unoprostone isopropyl ophthalmic solution may gradually increase the pigmentation of the iris. The pigmentation change is believed to be due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. The long term effects of increased pigmentation are not known. Iris color changes seen with administration of unoprostone isopropyl ophthalmic solution may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. Treatment with Rescula solution can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula should be informed of the possibility of increased pigmentation.

Lid Pigmentation

Unoprostone isopropyl has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as unoprostone isopropyl is administered, but has been reported to be reversible upon discontinuation of unoprostone isopropyl ophthalmic solution in most patients.

Intraocular Inflammation

Rescula should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema

Macular edema, including cystoid macular edema, has been reported. Rescula should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Contamination of Tip and Solution

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses

Rescula contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS

Clinical Studies Experience

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

In clinical studies, the most common ocular adverse reactions with use of Rescula were burning/stinging, burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes, and injection. These were reported in approximately 10–25% of patients. Approximately 10–14% of patients were observed to have an increase in the length of eyelashes (≥ 1 mm) at 12 months, while 7% of patients were observed to have a decrease in the length of eyelashes.

Ocular adverse reactions occurring in approximately 5–10% of patients were abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder.

Ocular adverse reactions occurring in approximately 1–5% of patients were blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.

The most frequently reported nonocular adverse reaction associated with the use of Rescula in the clinical trials was flu-like syndrome that was observed in approximately 6% of patients. Nonocular adverse reactions reported in the 1–5% of patients were accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis.

Postmarketing Experience

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

Voluntary reports of adverse reactions occurring with the use of Rescula include corneal erosion.

There have been rare spontaneous reports with a different formulation of unoprostone isopropyl (0.12%) of chemosis, dry mouth, nausea, vomiting and palpitations.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C - There are no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, RESCULA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use - the safety and efficacy of RESCULA in pediatric patients have not been established.

It is not known whether RESCULA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RESCULA is administered to a nursing woman.

No overall differences in safety or effectiveness of RESCULA have been observed between elderly and other adult populations.

CLINICAL PHARMACOLOGY

Mechanism of Action

Rescula is believed to reduce elevated intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork. Unoprostone isopropyl (UI) may have a local effect on BK (Big Potassium) channels and ClC-2 chloride channels, but the exact mechanism is unknown at this time.

STORAGE AND HANDLING

Store between 2°–25°C (36°–77°F).

For more detailed information please read the Prescribing Information.

Marketed by:

Sucampo Pharma Americas, LLC
Bethesda, MD 20814

Revised 01/2013

References: **1.** RESCULA [package insert]. Bethesda, MD: Sucampo Pharmaceuticals, Inc; 2012. **2.** Data on file. CSR C97-UIOS-004. Sucampo Pharmaceuticals, Inc. **3.** Data on file. CSR C97-UIOS-005. Sucampo Pharmaceuticals, Inc. **4.** Data on file. Integrated summary of clinical safety. Sucampo Pharmaceuticals, Inc. **5.** McCarey BE, Kapik BM, Kane FE; Unoprostone Monotherapy Study Group. Low incidence of iris pigmentation and eyelash changes in 2 randomized clinical trials with unoprostone isopropyl 0.15%. *Ophthalmology*. 2004;111(8):1480-1488.

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TORIC IOL

(Continued from page 6)

IOL implanted, mean refractive cylinder was reduced 85% from baseline, and within each toric power group, mean residual cylinder was <0.5 D. Comparison between the eyes with the 1.25 D toric IOL implanted and those receiving the spherical control showed statistically significant differences favoring the toric eyes for % reduction in astigmatism and uncorrected distance visual acuity. Measurements to determine IOL rotation showed that the IOL had excellent stability, thanks to its rectangular-hinged haptics and round-to-the-right asymmetric polyimide loops. Mean rotation from day of surgery to follow-up at 4 to 6 months was between 1.365° and 2.245° for all three toric IOL groups. Overall, the IOL rotated <5° in 96.1% of eyes and by ≤10° 99.2% of all toric IOLs. No eye required secondary surgical intervention related to IOL rotation.

"These are outstanding and important results, because for every degree of misalignment of a toric IOL, there is a 3.3% reduction in its offset of astigmatism," said Dr. Pepose, also professor of clinical ophthalmology, Washington University School of Medicine, St. Louis.

Nearly 80% of eyes with the toric IOL implanted were within 0.5 D of intended MRSE and >95% were within 1 D of their target. Data for the new toric version of the accommodating IOL also support its equivalent accommodative effectiveness at intermediate and near compared with the parent lens. Mean monocular uncorrected visual acuity for eyes with the toric accommodating IOL implanted was 20/25 for distance, 20/22 for intermediate, and 20/39 for near.

"These results are very good and they are from monocular testing," he said. "With binocular implantation and summation, vision outcomes should be even better."

The Trulign toric IOL provides correction for astigmatism while delivering a broad range of improved vision for patients undergoing cataract surgery.

(Photo courtesy of Bausch + Lomb)

In the safety analysis, the toric accommodating IOL met all requirements of the ISO Grid of Safety and Performance Endpoints. No new concerns emerged relative to experience with the parent accommodating IOL. Significant increase in visual disturbances was reported by one toric IOL recipient (0.8%) and five patients who received the control IOL (7.8%).

"The FDA focuses particularly on visual disturbances with toric IOLs," Dr. Pepose said. "The single toric IOL patient in the study who reported a problem had developed moderate posterior capsular fibrosis. After having Nd:YAG capsulotomy, the symptoms resolved."

The same considerations that are important for achieving good results with toric monofocal IOLs apply when implanting the Trulign Toric lens. Attention must be given to the accuracy of preoperative measurements and issues that can confound them, including conditions that can affect the ocular surface, such as dry eye syndrome or contact lens use. Ideally, surgeons should also calculate a personalized SIA value for use in the toric IOL power calculations. ■

JAY S. PEPOSE, MD, PHD

E: *jpepose@peposevision.com*

Dr. Pepose is a consultant for Bausch + Lomb and served as medical monitor for the Trulign Toric IOL clinical trial.

ACQUISITION

(Continued from page 10)

Finkelstein also expressed concern in his May 28 research note about Valeant's "significant debt balance" and the fact that it is "more heavily leveraged than some of its peers." Little acknowledged the concern, but said Valeant did not need a "large war chest" for expensive research trials.

"We are slightly more leveraged, but I also would say we have an extremely strong and robust cash flow," she said. "If we didn't do another acquisition, our leverage would come down quickly. At the end of the day we feel our equity is a pretty precious commodity and obviously we have strong opinions that it will continue to increase."

"B+L acquisition appears a positive," Stifel said in its May 28 research note.

Finkelstein said the acquisition "makes sense and the financial parameters seem better than expected."

The deal comes at a time when B+L has resolved a looming Department of Justice lawsuit over marketing practices at ISTA Pharmaceuticals, which it bought in 2012 for $500 million. The settlement, reached May 24, requires B+L to pay a $33.5 million fine (see "B+L agrees to pay fines over ISTA case," Page 10). B+L made its bid to acquire ISTA after Valeant withdrew its hostile bid. Now, as Valeant acquires B+L, Little acknowledged the irony.

"It's the circle of life," she said.

Wechsler emphasized that the company's commitment to physicians and patients remains intact in this new "chapter."

"For our business, not a whole lot changes for B+L," he said. "We were held by Warburg Pincus, a private equity firm, and now we are held by Valeant, which has a lot of money, they have a great track record and they are dedicated to this business." ■

Worldwide attendance expected for 2013 Brazilian and Pan American Congress Ophthalmology

August event will bring together about 8,000 specialists to Rio de Janeiro

From Staff Reports

RIO DE JANEIRO ::
THE BEAUTIFUL COASTAL city of Rio de Janeiro will host the 2013 Brazilian and Pan American Congress Ophthalmology from Aug. 7 to 10.

The event, organized by the Brazilian Council of Ophthalmology (CBO) and the Pan American Association of Ophthalmology (PAAO), is a shared event at Riocentro Convention Centre.

"We expect more than 8,000 congressmen from all Americas," said Eduardo Dib, director of communication of the congresses.

With a scientific program in 18 classrooms with symposia, panels, and special events coordinated by professionals in Portuguese, Spanish, and English, the congresses have confirmed the participation of 500 speakers from 20 countries as well as 700 Brazilian ophthalmologists.

IVO PITANGUY, MD

One of the highlights of the event will be a presentation by renowned plastic surgeon Ivo Pitanguy, MD. Called "The Aging Process and Ideals of Beauty," the colloquium is part of the oculoplastics symposium.

"The population is aging and ophthalmologists need to be prepared to combine plastic-aesthetic knowledge with an ophthalmologic point of view," said Ana Luisa Hofling-Lima, MD, PhD, president-elect of PAAO and 2013 Pan-American Congress of Ophthalmology. "In other words, the surgeon must be able to restore functionality and beauty at the same time."

1ST WORLD EYE BANK SYMPOSIUM

Another highlight will be the World Eye Bank Symposium, organized by the World Alliance of Eye Banks along with the Pan American Association of Eye Banks (APABO). With lectures from Aug. 8 to 9, this event promises to be of interest not only to ophthalmologists, but also to health professionals in general.

"We will have space for 300 participants and we will discuss conduct standardization in eye banks in the world," said Luciene Barbosa de Souza, MD, international president of APABO. "An event of this magnitude taking place in Brazil is highly important, since the Brazilian transplant politic is unique and positioned as one of the best of the world."

GUESTS OF HONOR

Among the guests of honor at the Pan-American Congress are Alice McPherson, MD, of Houston, an accomplished educator, scholar, leader, and pioneer in the study of retina diseases. A professor of Baylor Medical School, her contributions to ophthalmology began with the pioneering scleral buckling procedures, cryotherapy, and xenon and laser therapy in the treatment of retinal diseases.

"She represents the modern woman in the Pan American Society of Ophthalmology," Dr. Hofling-Lima said.

Another guest of honor is David E.I. Pyott, chief executive officer/president of Allergan, a global company with multiple medical specialties, including ophthalmology, neuroscience, breast aesthetics, obesity intervention, and urology.

DETAILS

For more information regarding the 2013 Brazilian and Pan American Congress Ophthalmology, call: +55 11 3266-4000 or visit the website at *www.congressocbo.com.br.* ■

Some of the main themes of the meeting include:

- New technologies in cataract
- Gene therapy
- New drugs for age-related macular degeneration
- Minimally invasive cosmetic procedures
- New techniques of refractive surgery
- Refractive surgery complications
- Surgery for presbyopia
- Childhood strabismus
- Difficulty of access to assistive technology for people with disabilities
- Sports practice and visual impairment
- Work inclusion and disability
- Intra- and postoperative complications of congenital cataract
- Keratoconus diagnosis and treatment

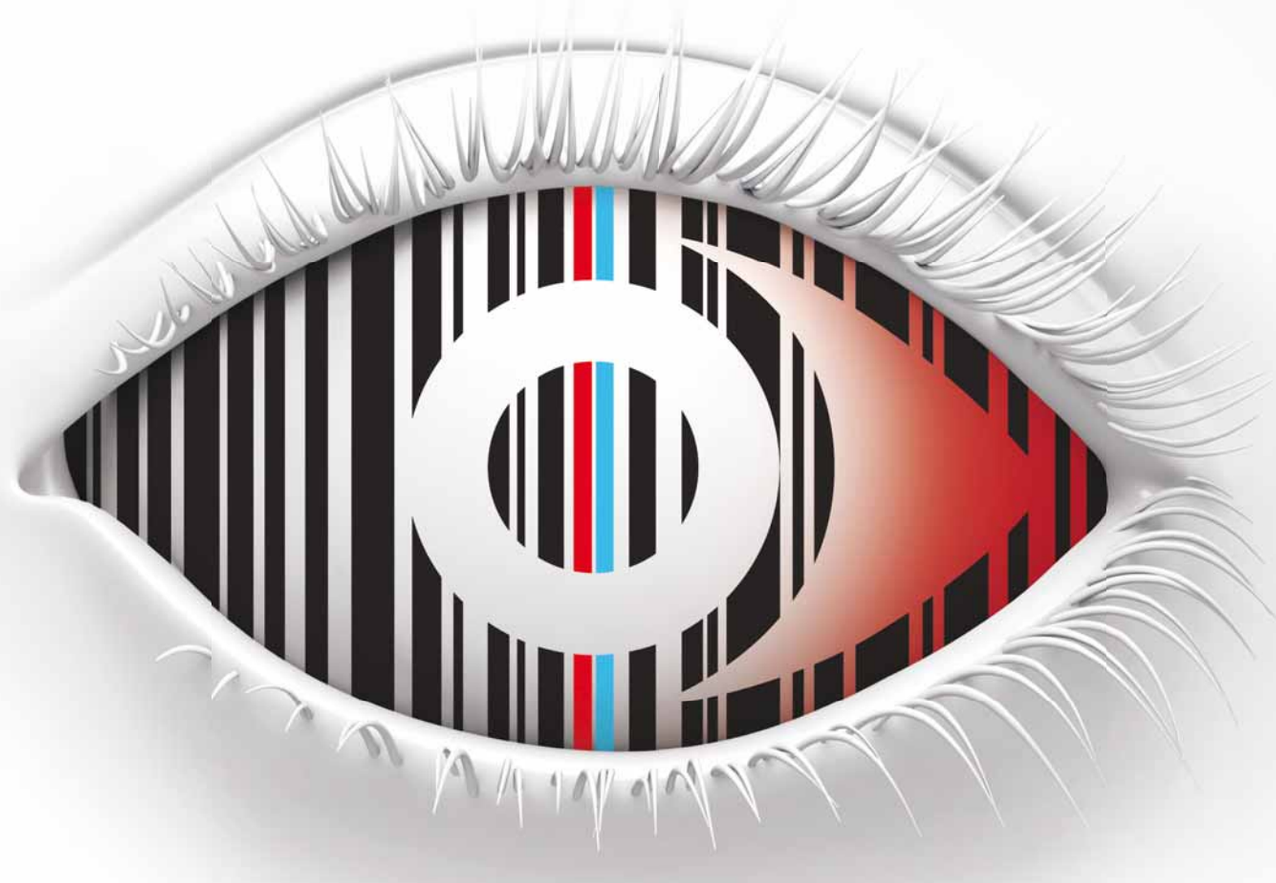
ON THE FAST TRACK

OWL HONORS THREE

OPHTHALMIC WOMEN LEADERS (OWL), an organization furthering the professional development and advancement of women in the eye-care industry, honored the recipients of three awards at a reception held during the annual meeting of the American Society of Cataract and Refractive Surgery. Those honored:

- **Visionary Woman Award:** Adrienne L. Graves, PhD, a visual scientist by training and a global industry leader in ophthalmology.
- **Rising Star Award:** Sheryl Stevenson, senior managing editor/content channel manager of *Ophthalmology Times*.
- **Catalyst Award:** Heather Ready, vice president of marketing at AcuFocus.

CORRECTION An incorrect model number was provided for a monofocal IOL mentioned in a recent article about the FDA approval of the Tecnis Toric IOL from Abbott Medical Optics ("Toric IOL expands options for pre-existing astigmatism," *Ophthalmology Times,* May 15, 2013, Page 10). The new lens "is based on the time-tested platform of the hydrophobic acrylic, monofocal aspheric Tecnis one-piece IOL (ZCB00) . . . ." Also, the recommended correction for the Tecnis Toric IOL is 1 to 3.62 D. *Ophthalmology Times* regrets the error.



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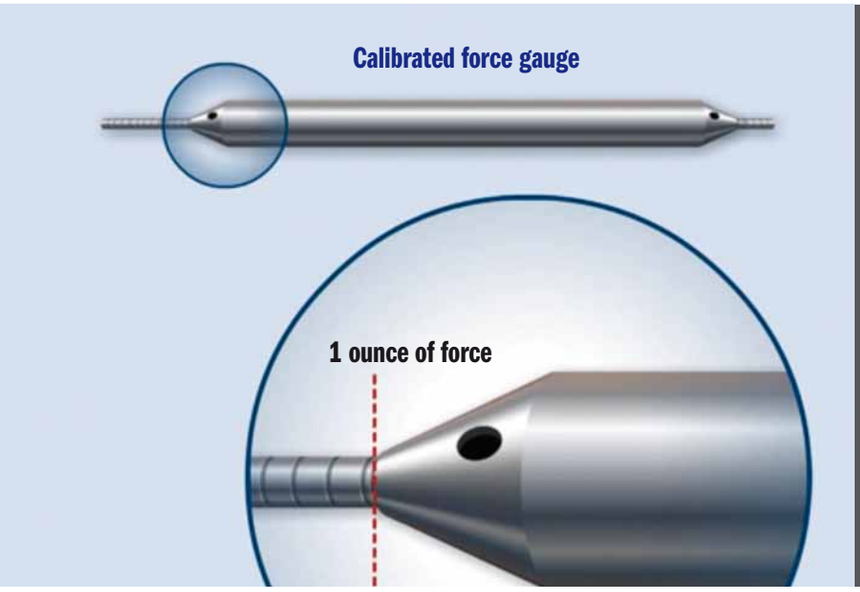

With a calibrated force gauge, 1 ounce of force is applied 0.5 mm from the limbus on the scleral side of the incision. *(Photo courtesy of Ocular Therapeutix)*

FORCE GAUGE FINDS MOST CATARACT WOUNDS LEAK

Companion studies show that 1 ounce or less of pressure may cause incisions to reopen

By Fred Gebhart; *Reviewed by John Hovanesian, MD, and Michael Raizman, MD*

take-home

- **Findings in several studies, based on a novel device designed to apply uniform pressure on the eye to evaluate wound leakage, demonstrated that cataract incisions might leak if patients squeeze or rub their eyes. While surgical technique clearly affects how well an incision seals, biplanar incisions appear to have a clear advantage with lower leak rates whether they are sutured or simply hydrated.**

SAN FRANCISCO ::

Many clinicians seem to believe that uncomplicated wounds in clear corneal cataract surgery do not leak. New data suggest otherwise.


Dr. Hovanesian

"The vast majority of surgical wounds—not just wounds without sutures—leak," said John Hovanesian, MD, Harvard Eye Associates, San Clemente, CA. "We found that a significant percentage of sutured wounds leak as well."

Dr. Hovanesian provided an evaluation of clear corneal wound integrity before and after suture placement under point pressure manipulation in the immediate postoperative period at the annual meeting of the American Society of Cataract and Refractive Surgery. Findings in the study, as well as those in a companion presentation by Michael Raizman, MD, Ophthalmic Consultants of Boston, were based on a novel device designed to apply uniform pressure on the eye to evaluate wound leakage.

"The gauge mimics the potential elevation in pressure that can occur after routine surgery if patients squeeze their eyes too hard or rub their eyes," Dr. Raizman said. "We wanted a way to apply a uniform force to every eye in the same way so we could objectively measure every patient in the same way. So far as we know, this is the first time a measured force has been applied to corneal cataract incisions in humans in this way."


Dr. Raizman

Presenting an evaluation of clear corneal cataract wound integrity and leakage during simulated patient manipulation in the immediate postoperative period, Dr. Raizman described a modified Dontrix gauge that can be used as a calibrated force gauge (CFG). The CFG can be sterilized and applies up to 1 ounce of pressure to the external surface of the eye in 0.25-ounce increments.

Using a CFG allowed researchers to apply a standardized amount of pressure and objectively assess the results across multiple eyes and patients in three different private practice clinical settings across the United States. Dr. Raizman noted that 1 ounce is the pressure most commonly cited in the ophthalmic literature resulting from patients squeezing or rubbing their eyes after ocular surgery.

The CFG was used in three successive studies. The first study was designed to determine the change in IOP that results from the application of 1 ounce of pressure posteriorly and temporal to the limbus in 30 healthy volunteers who were not undergoing cataract surgery.

The second study was designed to assess wound leakage in self-sealing, single-plane and biplane clear corneal incisions closed the stromal hydration. A third study was designed to compare wound leak rates before and after suture placement in both single-plane and biplane incisions.

Researchers also examined the effect of a hydrogel sealant (ReSure, Ocular Therapeutix) on wound leakage. The sealant is available in Europe but has not been approved for use in the United States. No data were presented on the hydrogel sealant because the product is currently under review by the FDA.

ESTABLISHING A BASELINE

The first step was to assess the effect of sim-

ulated blinking or rubbing on IOP. Researchers applied 1 ounce of force to the eyes of 30 healthy volunteers. The mean age of the volunteers was 32 years and 60% were female. The mean baseline IOP was 17.49 mm Hg, Dr. Raizman said, with a range of 10 to 22 mm Hg. During the application of 1 ounce of external pressure, the mean IOP rose to 43.44 mm Hg, with a range of 43.3 to 54 mm Hg. There were no adverse events of any grade reported.

STROMAL HYDRATION

The next study examined the effect of stromal hydration on wound leakage. A total of 29 patients and 30 eyes were studied following uncomplicated cataract surgery. A total of 14 eyes had single-plane incisions, 16 eyes had biplane incisions and there were no tri-plane incisions. All incisions were temporal and none were enlarged. The mean incision length was 2.5 mm, with a mean of 2.75 mm for single-plane incisions and 2.25 mm for biplane incisions.

All 30 eyes were treated with stromal hydration, Dr. Raizman said, and all had a negative Seidel test before any force was applied to the eye. Following the uniformly negative Seidel tests, increasing force was applied to each of the 30 eyes using the CFG. Twenty of the eyes (66.6%) leaked with 1 ounce or less of pressure. But nearly twice as many single-plane incisions leaked compared with biplane incisions, 43.3% versus 23.3%.

"Now, we have solid data about the kind of force needed and the leakage that results [from squeezing or rubbing eyes]. More than half of the eyes that leaked needed a 0.5 ounce or less of pressure to open the wound," Dr. Raizman said. "This gives us a reproducible approach to us what happens when you apply external force to the eye after cataract surgery."

LEAKY SUTURES

The next step was to test the effect of suturing on wound leakage. A total of 35 clear corneal incisions were closed using stromal hydration following uncomplicated cataract surgery. All of the wounds were challenged using the CFG and up to 1 ounce of pressure applied to the scleral side of the operative eye. Of the 35 wounds, 21 (60%) leaked with 1 ounce or less of force.

As in the previous study, biplane incisions were more stable than single-plane incisions, Dr. Hovanesian noted. All of the single-plane incisions leaked while fewer than half, 41.7%, of the biplane wounds leaked.

All 21 wounds that showed signs of leakage were closed with a 10-0 nylon suture. After suturing, the wounds were challenged a second time with the CFG and up to 1 ounce of pressure. Forty percent of the sutured, single-plane incisions leaked compared with 10% of the sutured, biplane incisions, a total leak rate of 23.8%.

"Even sutures don't completely seal the wound," Dr. Hovanesian said. "Incisions are subject to leakage around the point tension placed by the suture itself." ■

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The authors have financial interest in Ocular Therapeutix.

Science of incisions yields precision

Femtosecond laser allows for customizable, adjustable, fully repeatable astigmatic incisions

By Lynda Charters; *Reviewed by Eric D. Donnenfeld, MD*

SAN FRANCISCO ::

USE OF FEMTOSECOND LASER technology to create limbal relaxing incisions (LRIs) with intraoperative aberrometry to titrate the incisions provides reliable and customizable management of astigmatism during cataract surgery.

Dr. Donnenfeld

The low energy used allows greater adjustment of the incisions due to less primary effect from the incisions alone, said Eric D. Donnenfeld, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery.

"Refractive incisions are no longer an art form. They are a science," said Dr. Donnenfeld, a founding partner of Ophthalmic Consultants of Long Island and Connecticut, clinical professor of ophthalmology, New York University Medical Center, New York, and a trustee of Dartmouth Medical School.

Laser refractive cataract surgery arc incisions are fully customizable and adjustable. Surgeons can place the desired incisions that are the exact size, location, and depth required.

LRIs remain a challenge because of the unpredictable response, despite the scientific advances. Age, corneal diameter/curvature, pachymetry, corneal biomechanics, and IOP all play a role in the unpredictability of the effect of the LRIs.

take-home

- **The use of femtosecond laser technology to create limbal relaxing incisions with intraoperative aberrometry to titrate the incisions provides reliable and customizable management of astigmatism during cataract surgery.**

ARC INCISIONS ADJUSTABLE

An important feature with femtosecond laser arc incisions is that they are adjustable, Dr. Donnenfeld said. The full effect of the incision is not achieved until the incision is manually opened intraoperatively or postoperatively.

The response can be titrated by adjusting the line spot separation, energy, and the angulation of the incision, he explained.

Dr. Donnenfeld and his colleagues studied a consecutive series of 31 eyes with pre-existing corneal astigmatism and cataracts that received arcuate incisions during femtosecond laser cataract surgery and implantation of an IOL. A femtosecond laser (LenSx, Alcon Laboratories) was used for all procedures.

SERIES METHODOLOGY

The arcuate incisions were created using low energy; the 9-mm optical zone arcuate incisions were made at 85% of the corneal depth; 2.2 µJ/spots were placed and the layer separation was 5 µm.

After the IOL was implanted, the ORA (Optiwave Refractive Analysis) System (WaveTec Vision) was used to titrate the residual astigmatism by selectively opening the arcuate incisions.

The mean preoperative cylinder was 1.07 ± 0.38 D. The mean postoperative cylinder before the incisions were opened was 76± 0.36 D. After the first incision was opened, aberrometry showed that the mean cylinder was 0.38 ± 0.19 D; after the second incision was opened, the mean cylinder was 0.23 ± 0.14 D in 22 patients.

"Keratometric astigmatism was effectively reduced, with 84% of eyes having corneal astigmatism of less than 0.5 D postoperatively compared with 50% preoperatively," Dr. Donnenfeld said. "All patients had astigmatism below 1 D postoperatively compared [with] 71% preoperatively.

"The refractive astigmatism showed a similar trend, with 83% and 100% of the group achieving postoperative outcomes less than 0.5 D and less than 1 D, respectively, compared with 36% and 79% preoperatively," he said. "There was a 35% reduction of astigmatism resulting from creation of the incisions and an additional 48% effect from opening the incisions with intraoperative control."

NOVEL TECHNIQUE

The investigators concluded that femtosecond laser-assisted arcuate incisions are a novel technique that provides the precision of image-guided laser technology.

Using a femtosecond laser allows for customizable, adjustable, and fully repeatable astigmatic incisions. Intraoperative aberrometry may be used to titrate and improve results while the patient is in the operating room. ■

WaveTec Vision introduces VerifEye

TO IMPROVE UPON ON THE ACCURACY of its ORA System, WaveTec Vision introduced a new monitoring system that provides ophthalmic surgeons with continuous refractive information for more refined visual outcomes during cataract surgery.

Presented at the annual meeting of the American Society of Cataract and Refractive Surgery in April, the VerifEye upgrade enables surgeons to confirm that the eye is stable prior to the measurement, by providing streaming refractions in the preview screen.

The ORA System with VerifEye is designed to provide continuous assessment of the patient's eye, allowing for more precise measurements. VerifEye's advanced guidance results in increased confidence for surgeons and optimized outcomes for patients, according to the company.

"The data on VerifEye is exceeding our expectations," said Tom Frinzi, president and chief execuive officer of WaveTec, in a prepared statement. "Even the most experienced ORA surgeons are seeing a significant improvement in patient outcomes with VerifEye."

Robert Cionni, MD, of Salt Lake City, reports positive results with the ORA System.

"With the addition of VerifEye, we're now seeing LASIK-like results in cataract surgery," Dr. Cionni said. "Of the VerifEye cases we've done to date, 92% of patients were within 0.5 D of intended target, which is truly remarkable."

ERIC D. DONNENFELD, MD

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Dr. Donnenfeld is a consultant to Abbott Medical Optics, Alcon/LenSx, Bausch + Lomb, and WaveTec Vision.

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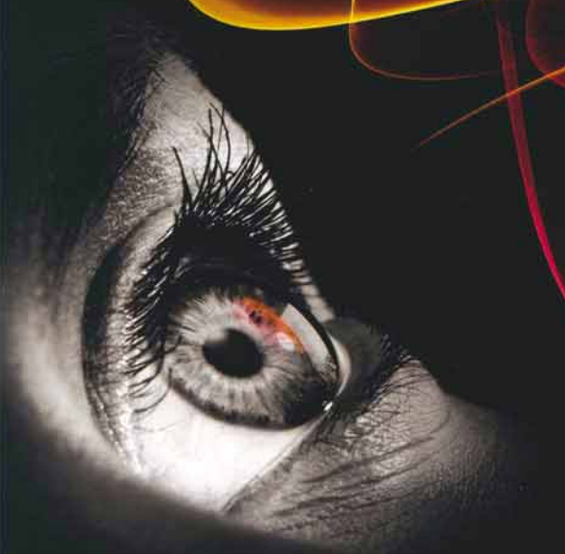

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ZIOPTAN is indicated for reducing elevated IOP in patients with OAG or OHT.

SELECT IMPORTANT SAFETY INFORMATION

ZIOPTAN has been reported to cause changes to pigmented tissues. The most frequently reported changes have been to the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as ZIOPTAN is administered. Pigmentation of the iris is likely to be permanent and may not be noticeable for several months to years, while pigmentation of the periorbital tissue and eyelash changes may be reversible in some patients. The long-term effects of increased pigmentation are not known.

ZIOPTAN may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, color, thickness, shape, and number of lashes. Eyelash changes are usually reversible on discontinuation of treatment.

ZIOPTAN should be used with caution in patients with active intraocular inflammation (eg, iritis/uveitis) because the inflammation may be exacerbated.

Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2α analogs. ZIOPTAN should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

In clinical trials of patients receiving either preservative-containing or preservative-free ZIOPTAN, the most common pooled adverse reaction observed was conjunctival hyperemia, which was reported in a range of 4% to 20% of patients.

Please see the adjacent Brief Summary of the Prescribing Information.

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Brief Summary of the Prescribing Information for ZIOPTAN.

INDICATIONS AND USAGE

ZIOPTAN is indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dose is 1 drop of ZIOPTAN in the conjunctival sac of the affected eye(s) once daily in the evening.

The dose should not exceed once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the intraocular pressure-lowering effect.

Reduction of the intraocular pressure starts approximately 2 to 4 hours after the first administration with the maximum effect reached after 12 hours.

ZIOPTAN may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than 1 topical ophthalmic product is being used, each 1 should be administered at least 5 minutes apart.

The solution from 1 individual unit is to be used immediately after opening for administration to 1 or both eyes. Since sterility cannot be maintained after the individual unit is opened, the remaining contents should be discarded immediately after administration.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

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

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with ZIOPTAN can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly. *[See Patient Counseling Information.]*

Eyelash Changes
ZIOPTAN may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, color, thickness, shape, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
ZIOPTAN should be used with caution in patients with active intraocular inflammation (eg, iritis/uveitis) because the inflammation may be exacerbated.

Macular Edema
Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2α analogs. ZIOPTAN should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

ADVERSE REACTIONS

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.

Preservative-containing or preservative-free tafluprost 0.0015% was evaluated in 905 patients in 5 controlled clinical studies of up to 24-months' duration. The most common adverse reaction observed in patients treated with tafluprost was conjunctival hyperemia which was reported in a range of 4% to 20% of patients. Approximately 1% of patients discontinued therapy due to ocular adverse reactions.

Ocular adverse reactions reported at an incidence of ≥2% in these clinical studies included ocular stinging/irritation (7%), ocular pruritus including allergic conjunctivitis (5%), cataract (3%), dry eye (3%), ocular pain (3%), eyelash darkening (2%), growth of eyelashes (2%), and blurred vision (2%).

Nonocular adverse reactions reported at an incidence of 2% to 6% in these clinical studies in patients treated with tafluprost 0.0015% were headache (6%), common cold (4%), cough (3%), and urinary tract infection (2%).

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

In postmarketing use with prostaglandin analogs, periorbital and lid changes, including deepening of the eyelid sulcus, have been observed.

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category C.
Teratogenic effects: In embryo-fetal development studies in rats and rabbits, tafluprost administered intravenously was teratogenic. Tafluprost caused increases in post-implantation losses in rats and rabbits and reductions in fetal body weights in rats. Tafluprost also increased the incidence of vertebral skeletal abnormalities in rats and the incidence of skull, brain, and spine malformations in rabbits. In rats, there were no adverse effects on embryo-fetal development at a dose of 3 µg/kg/day corresponding to maternal plasma levels of tafluprost acid that were 343 times the maximum clinical exposure based on C_{max}. In rabbits, effects were seen at a tafluprost dose of 0.03 µg/kg/day corresponding to maternal plasma levels of tafluprost acid during organogenesis that were approximately 5 times higher than the clinical exposure based on C_{max}. At the no-effect dose in rabbits (0.01 µg/kg/day), maternal plasma levels of tafluprost acid were below the lower level of quantification (20 pg/mL).

In a pre- and postnatal development study in rats, increased mortality of newborns, decreased body weights, and delayed pinna unfolding were observed in offsprings. The no observed adverse effect level was at a tafluprost intravenous dose of 0.3 µg/kg/day, which is greater than 3 times the maximum recommended clinical dose based on body surface area comparison.

There are no adequate and well-controlled studies in pregnant women. Although animal reproduction studies are not always predictive of human response, ZIOPTAN should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Women of childbearing age/potential should have adequate contraceptive measures in place.

Nursing Mothers
A study in lactating rats demonstrated that radio-labeled tafluprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ZIOPTAN is administered to a nursing woman.

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

ZIOPTAN™ (tafluprost ophthalmic solution) 0.0015%

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

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

Nightly Application
Patients should be advised to not exceed once-daily dosing since more frequent administration may decrease the intraocular pressure-lowering effect of ZIOPTAN.

Handling the Single-Use Container
Patients should be advised that ZIOPTAN is a sterile solution that does not contain a preservative. The solution from 1 individual unit is to be used immediately after opening for administration to 1 or both eyes. Since sterility cannot be maintained after the individual unit is opened, the remaining contents should be discarded immediately after administration.

Potential for Pigmentation
Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of ZIOPTAN.

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

When to Seek Physician Advice
Patients should be advised that if they develop a new ocular condition (eg, trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of ZIOPTAN.

Use with Other Ophthalmic Drugs
If more than 1 topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Storage Information
Patients should be instructed on proper storage of cartons, unopened foil pouches, and opened foil pouches *[see How Supplied/Storage and Handling]*. Recommended storage for cartons and unopened foil pouches is to store refrigerated at 2-8°C (36-46°F). After the pouch is opened, the single-use containers may be stored in the opened foil pouch for up to 28 days at room temperature: 20-25°C (68-77°F). Protect from moisture.

For more detailed information, please read the Prescribing Information.

Rx only.

Manufactured for:
Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

Manufactured by: Laboratoire Unither
ZI de la Guerie
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France

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Non-flared tip has designs on torsional ultrasound procedure

Mini tip provides high cutting efficiency while minimizing unwanted prolonged occlusion

By Cheryl Guttman Krader; *Reviewed by Khiun Tjia, MD*

SAN FRANCISCO ::

A RECENTLY INTRODUCED phaco tip designed specifically for torsional ultrasound phacoemulsification (0.9 Mini Tip, Alcon Laboratories) provides high cutting efficiency while minimizing the potential for unwanted prolonged occlusion.

The "mini tip" is a non-flared Kelman bent tip with an 800-µm outer shaft diameter and 570-µm shaft lumen size. Compared with the widely used mini-flared Kelman tip (Alcon), the new mini tip has the same lumen size and a slightly smaller outer diameter.

"The side-to-side, nonrepulsive cutting action of torsional ultrasound makes this technology more efficient than longitudinal ultrasound," said Khiun Tjia, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery. "However, when torsional ultrasound is performed using a flared tip, there is the possibility of unwanted prolonged occlusion and subsequent temperature increases, especially when operating on denser nuclei.

Dr. Tjia

take-home

- **A new non-flared Kelman bent tip for torsional ultrasound phacoemulsification retains the same high cutting efficiency of the mini-flared Kelman tip, but without the latter's propensity for inadvertent prolonged occlusion.**

"In fact, because clogging was happening too frequently with use of the mini-flared Kelman tip, my entire group had switched to a larger tapered tip that had less flare when performing 2.2-mm microcoaxial torsional phacoemulsification," said Dr. Tjia, consultant ophthalmologist, Isala Clinics, Zwolle, The Netherlands.

The new mini tip also avoids inadvertent prolonged occlusion because of its non-flared design. However, compared with the tapered tip, the mini tip has advantages of being more energy efficient and more suitable for 2.2-mm microcoaxial surgery because of its thinner shaft size, he noted.

Dr. Tjia evaluated the efficiency of microcoaxial torsional phacoemulsification using the mini tip and flared tips in groups of eyes matched by age, gender, and nuclear density. All of the procedures were performed by a single surgeon (Dr. Tjia) using the same phacoemulsification platform (Infiniti Vision System, Alcon), surgical technique, machine settings, and viscoelastic.

CDE ANALYSES

Analyses of cumulative dissipated energy (CDE) as a measurement of ultrasound efficiency showed statistically significant differences favoring the mini tip compared with the tapered tip in eyes with nucleus grade 1+ cataracts whether comparing mean CDE during the sculpting phase, quadrant removal, or total CDE. The difference between tips was even greater in nucleus grade 2+ eyes.

For the mini tip, mean total CDE values were 7.47 for grade 1+ eyes and 12.17 for grade 2+ eyes. Mean total CDE values for the grade 1+ and 2+ eyes operated on with the tapered tip were 10.77 and 20.17, respectively.

The groups were also compared for fluid use and surgical time, and there were no significant differences between the mini tip and tapered tip for these parameters in either the grade 1+ or grade 2+ eyes. The greater efficiency of the mini tip is explained by its greater cutting edge displacement compared with the flared tip, he noted.

"At 100% amplitude, maximum excursion for the mini tip is 135 µm but only 90 µm with the thicker tapered tip," he said.

With its thinner wall, the mini tip also has a slightly greater cutting edge displacement than the mini-flared Kelman tip. Data from a previous study where he compared CDE for procedures performed with the mini-flared tip and the tapered tip indicate the mini tip and mini-flared tip have similar efficiency. Because the new mini tip has a slightly smaller port size than the mini-flared Kelman tip, the mini tip may, in theory, have less holding force, he noted.

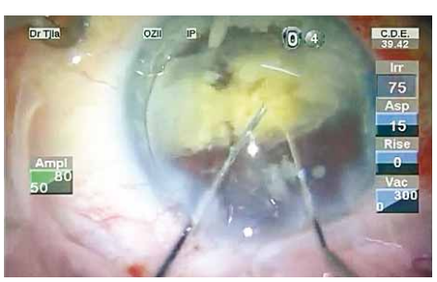
"However, this has not been a disturbing factor for me in clinical use," Dr. Tjia concluded. ■

Tip design comparison

STROKE	AT CUTTING EDGE
Tapered Kelman	90 µm*
Mini-Flared OZil 12	100 µm*
Mini-Flared Kelman	130 µm*
0.9 Mini Tip Kelman	135 µm*

** Rounded to the nearest 10 µm.*

VERY DENSE MATURE CATARACT



VIDEO Go to **http://bit.ly/10uji3K** to see how the new torsional phaco 0.9 mini tip provides enhanced efficiency and safety in a very dense mature cataract. *(Video courtesy of Khiun Tjia, MD)*

Table courtesy of Khiun Tjia, MD

Tell ***Ophthalmology Times*** your approach for cases of very dense mature cataract at **facebook.com/OphthalmologyTimes.**

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Dr. Tjia is a consultant to Alcon Laboratories.

Femtosecond cataract procedures effective after prior corneal surgery

Study finds that one platform delivers solid outcomes despite past refractive procedures

By Fred Gebhart; *Reviewed by Kerry Assil, MD*

SAN FRANCISCO ::

THE LATEST GENERATION OF FEMTOSECOND laser devices for cataract surgery deliver better precision, better safety, and better outcomes with previously untreated eyes.

However, are these systems effective for patients with prior corneal refractive surgery? New data suggest that at least one femtosecond laser platform (LensAR Laser System, LensAR Inc.) can deliver solid outcomes despite prior corneal refractive surgeries.

Dr. Assil

"I have performed approximately 500 procedures with the [system]," said Kerry Assil, MD, Assil Eye Institute, Santa Monica, CA. "The range of patients has included everything from uncomplicated eyes, to prior radial keratotomy (RK), astigmatic keratotomy (AK), buttonholed LASIK flaps, extremely high myopia and hyperopia, prior LASIK coupled with RK, patients with pterygia, and patients with mature, rock-hard cataracts. We have been quite happy with the results."

STUDY REVIEWED 33 EYES

Dr. Assil reviewed a cohort of patients, which included 33 eyes, that have undergone prior corneal refractive surgery in a presentation at the annual meeting of the American Society of Cataract and Refractive Surgery.

Concerns about the compatibility of femtosecond laser platforms with eyes that have undergone prior corneal refractive surgery and eyes with mild corneal opacities focus on three areas:

- The effect of docking the laser onto the eye.
- Imaging through non-uniform corneal tissue.
- Accurate placement of treatment pulses.

Surgical systems that require direct applanation distort the corneal shape as they compress and deform the cornea. The resulting optical distortion results in secondary alteration to both the imaging and laser pulse transmission.

"If there are additional pre-existing opacities or shape alterations, these distortions become even greater," Dr. Assil said. "The [laser system] overcomes this issue by using a fluid-filled patient interface, which eliminates all surface stria. The laser 'looks' through fluid overlaying the cornea, which addresses issues of artifactful measurements and stray laser pulses."

IMAGE DEFECTS MINIMIZED

The femtosecond laser platform minimizes image defects due to scarring and opacity by using infrared confocal illumination to look effectively through visual opacities. The system uses eight to 10 scans, each taken from a slightly different angle, which are combined into a single three-dimensional (3-D) image. Dr. Assil likened this to image processing and enhancement techniques used in computed tomography, in which multiple X-ray slices of the target tissue are combined to create a precise 3-D image to guide diagnostic and therapeutic decision-making.

The system utilizes variable rate scanning to provide automatic surface detection. Ray-tracing technology further reduces the influence of scars and other opacities to enhance further the 3-D reality of images.

"If there is a scar from a prior corneal incision, the scar may obscure the image from one angle," Dr. Assil said. "Images coming from other angles neutralize and negate the impact of that opacity. One very practical application is in visualizing the posterior capsule in dense cataracts. [This] is the only system, to my knowledge, that directly visualizes the posterior capsule even in denser cataracts. It does not extrapolate."

Auto-surface detection and highly accurate 3-D reconstruction offer multiple advantages. The combination enables precise laser delivery that allows for a capsulorhexis to within 250 µm of the pupillary margin. Knowing precisely where the posterior capsule lies enables safe treatment of denser nuclei. And there is no relative optical axis tilt, which enables reliably free-floating capsulorhexis.

"Auto-surface detection should not be overlooked," Dr. Assil added. "That is needed in order to be certain that every pulse of the laser is delivered directly to the desired location and nowhere else."

Of the 33 eyes reported in the study, all underwent treatment using this femtosecond laser as well as intraoperative aberrometry (WaveTec) (for proper IOL power selection)—26 eyes had prior LASIK, three had prior RK, one had prior RK with a buttonholed LASIK flap, two had steep central corneas, and one was post-hyperopic automated lamellar keratoplasty and AK. The mean patient age was 61 years and mean preoperative refractive error was 1.6 ± 1.38 D. Three-month, follow-up data were reported on 18 eyes and 1-month follow-up on all 33 eyes.

There was no significant change in IOP in any of the patients and a strong correlation between attempted correction and achieved correction with an R-squared of 0.941. Sixty percent of patients had uncorrected visual acuity of 20/20 or better at 1 month and nearly 80% were 20/40 or better. All of the eyes had best-corrected visual acuity of 20/40 or better and 75% were 20/20 or better. Residual refractive error was 0.25 D or less spherical equivalent (SE) error in 60% of eyes at 1 month, and more than 95% of eyes had 1 D or less residual SE error.

"Intraoperative complications were none," he said. "All capsulorhexes were free-floating, no notable capsular tags, no anterior radial tears, no capsular ruptures, no vitrectomies. Postoperatively, there was no reported corneal edema, excessive inflammation, excessive anterior chamber reaction, or incidence of cystoid macular edema at 1 or 3 months." ■

take-home

New data suggest that a femtosecond laser platform can provide better outcomes in eyes that have undergone prior corneal refractive surgeries.

KERRY ASSIL, MD
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Dr. Assil serves as a consultant for LensAR Inc.

Tool enables chopping, phaco

Dual-function instrument's versatility brings advantages to cataract surgery

By Cheryl Guttman Krader; *Reviewed by César Carriazo, MD*

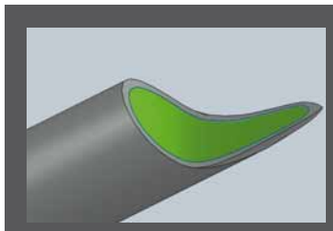
SAN FRANCISCO ::

THE TIP-CHOP IS a new instrument that combines the functions of a phaco tip and chopper in a single tool and makes surgery easier, safer, and more predictable, according to its inventor, César Carriazo, MD.

"In recent years, we have seen a number of innovations in phaco tips that include changes in diameter, shape, degree of inclination, materials, flow, and movement," said Dr. Carriazo at the annual meeting of the American Society of Cataract and Refractive Surgery. "In addition, cataract surgeons have hundreds, if not thousands, of instruments [from which] to choose for chopping the nucleus.

"The tip-chop is a novel instrument that serves dual functions and enables safer and more efficient surgery," said Dr. Carriazo, founder and scientific director, Carriazo Centro Oftalmologico, refractive and anterior segment ophthalmologist at Instituto Barraquer de America, Bogota, Colombia. "Furthermore, surgeons can enjoy its benefits with a minimal learning curve as the tip-chop is used similar to traditional tips and can be adapted to any surgeon's personal technique."

The tip-chop is designed in several iterations that are intended for use in different clinical situations according to nuclear density and whether the procedure is performed using all manual techniques or is a femto-cataract procedure.



The tip-chop is a new instrument that combines the functions of a phaco tip and chopper in a single tool. *(Photo courtesy of César Carriazo, MD)*

"In designing the tip-chop I wanted it to be versatile, and I believe it will be an ideal complement for femto-cataract surgery," Dr. Carriazo said.

Discussing the advantages of the tip-chop, Dr. Carriazo explained that because it can be used to lift and support the nucleus, it enables counterpressure techniques that optimize nuclear separation and subsequently reduce ultrasound energy use. In addition, because the instrument holds the nucleus to the tip, surgeons can work safely in the center of the cornea rather than performing phaco preferentially in the periphery of the nucleus.

Dr. Carriazo reported having used the tip-chop in 300 cases without encountering any complications. ■

take-home

- **A new instrument that serves as both a chopper and phaco tip is versatile, easy to use, and brings advantages to cataract surgery.**

CÉSAR CARRIAZO, MD

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Dr. Carriazo holds the patent on the instrument.

Special Report) **ASCRS CATARACT NEWS**

Laser aids in traumatic cataract cases

Surgeons can overcome capsulorhexis challenge, enabling faster, better visual rehabilitation

By Cheryl Guttman Krader; *Reviewed by Zoltan Z. Nagy, MD*

SAN FRANCISCO ::

FEMTOSECOND laser technology can enable the success of cataract surgery in eyes with traumatic cataract.

"Penetrating or blunt trauma leading to cataract and anterior capsular damage renders manual capsulorhexis more difficult and may increase the risk of posterior capsule damage that might exclude IOL implantation within the capsular bag," said Zoltan Z. Nagy, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery.


Dr. Nagy

"With the aid of a femtosecond laser, surgeons can reproducibly create a perfectly centered, regular, circular capsulotomy, making it possible to implant a posterior chamber IOL that will provide patients with faster and better visual rehabilitation," said Dr. Nagy, professor of ophthalmology, Semmelweiss University, Budapest, Hungary.

Dr. Nagy told attendees he performed his first case of femtosecond laser cataract surgery in an eye with traumatic cataract after using the same proprietary platform (LenSx, Alcon Laboratories) in about 1,000 routine cases.

FIRST CASE

The first traumatic cataract case involved a 28-year-old man who experienced penetrating trauma while working at home. He removed the foreign object himself, and when he presented for treatment in the emergency room, he had decreased vision, a 2-mm corneal laceration between 9 and 10 o'clock, and iris prolapse. The corneal wound was sutured, and an anterior capsule laceration was observed.

Dr. Nagy performed cataract surgery a few days later using the optical coherence topography-guided femtosecond laser to create a 4.75-mm capsulotomy. The capsular opening was positioned between two anterior capsule radial tears and made with start and end points 300 µm behind and 300 µm in front of the anterior capsule. In addition, the femtosecond laser was used to create a 3.2-mm main and 0.9-mm sideport corneal incision. The soft crystalline lens was removed with irrigation and aspiration. A three-piece hydrophobic acrylic IOL was implanted in the bag with lens power determined using the SRK/T formula and data obtained from the fellow eye.

At 2 weeks after surgery, the patient's refraction was +0.50 +0.50 D × 40º. Uncorrected visual acuity was 20/25 and corrected distance visual acuity was 20/20, and the endothelial cell count was stable. The IOL was well-positioned in the capsular bag with tilt and decentration values within acceptable limits, and it remained stable at a 1-year follow-up visit.

SECOND CASE

A second case involved a woman who presented with an anterior cortical cataract more than 10 years after sustaining a penetrating injury. She underwent femtosecond laser-assisted cataract surgery with a 4.5-mm capsulorhexis, 3.2-mm corneal incision, and 0.9-mm sideport incision. In this case, the laser was also used for nuclear liquefaction. After implantation of a three-piece acrylic IOL, the patient achieved good postoperative vision with minimal lens decentration and tilt. ■

ZOLTAN Z. NAGY, MD

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Dr. Nagy has published on his experience with femtosecond laser cataract surgery in traumatic cataracts (J Refract Surg. 2012;28:151-153). He is a consultant to Alcon Laboratories.

Using venturi, peristaltic pumps in different phaco modalities

Cataract technology provides surgeons with diverse applications without complications

By Lynda Charters; *Reviewed by Matteo Piovella, MD*

SAN FRANCISCO ::

A COMPARISON OF the venturi and peristaltic pumps in different phaco modalities demonstrated the superiority of a phacoemulsification system that incorporates both technologies.

Dr. Piovella

Matteo Piovella, MD, discussed this technology at the annual meeting of the American Society of Cataract and Refractive Surgery. One phaco platform (Whitestar Signature with Ellips FX, Abbott Medical Optics) seems to provide the best features of longitudinal and transverse procedures and achieves good outcomes, he noted.

Phacoemulsification procedures have improved continuously over the years, including reductions in turbulence and trauma in the eye, clearer corneas postoperatively in the short term, less endothelial cell loss over the long term, a lower incidence of serious complications, improved ability to manage challenging cases, and a better patient and surgeon experience.

The phaco technology has evolved from the traditional longitudinal ultrasound procedure to micropulse "cold" phaco/power modulation with pulse shaping to the newest generation of torsional and transverse ultrasound, according to Dr. Piovella.

ROOM FOR IMPROVEMENT

Having said that, there is room for improvement. Current areas of an ongoing study include modifications to the phaco tip, phacoenergy waveforms, tip-fragment interaction, understanding and enhancing cavitation, and interaction of mechanical and cavitation power.

In torsional phaco, the bent tip moves side to side, which increases the safety with less trauma than traditional phaco, and the contact with the nucleus is more constant compared with traditional phaco, resulting in a more efficient procedure. Maintaining suction can be challenging.

Continues on page 24 : ***Phaco modalities***

PHACO MODALITIES

(Continued from page 23)

Transverse phaco procedures result in reduced repelling forces, less chatter, and less wound friction. The Whitestar System decreases endothelial loss and can be performed with a straight or bent phaco tip, according to Dr. Piovella.

"The Whitestar System is the only commercially available phaco technology that blends longitudinal and transverse modes," Dr. Piovella said.

It provides constant emulsification, which reduces clogging of the phaco tip and allows the use of a straight or curved phaco tip. The goals are to optimize cutting and minimize heat and energy, he said.

A comparison of the Whitestar System with the Infiniti Vision System with Ozil Torsional technology (Alcon Laboratories) showed that the latter had a higher measured temperature rise and the shaft itself was the primary heat source in contrast to the Ellips Transversal Ultrasound, in which the hub region was the heat source.

The thermal rise at 1 second with the Ellips technology was 3.5° C compared with 9.9° C with the torsional procedure. In addition, the Ellips technology had an improved lens cut rate with 1.7 mm/second compared with 0.6 mm/second with the torsional procedure.

take-home

A comparison of the venturi and peristaltic pumps in different phaco modalities demonstrated the superiority of a phacoemulsification system (Whitestar Signature with Ellips FX, Abbott Medical Optics) that incorporates both technologies.

REDUCED SURGICAL TIME

Dr. Piovella demonstrated that with the peristaltic pump the mean surgical time in 75 eyes was 15.03 minutes and with the venturi Ellips FX in 79 eyes, it was 14.61 minutes compared with 15.96 minutes with the Venturi Ellips FX 21-gauge in 84 eyes.

The mean ultrasound time with the Venturi Ellips FX was significantly shorter compared with the peristaltic pump (43.97 versus 50.61 seconds, respectively). The mean ultrasound time with the Venturi Ellips FX in 79 eyes was shorter than that with the Venturi Ellips FX 21-gauge in 84 eyes (43.97 versus 57.28 seconds, respectively).

The mean effective phaco time was shorter with the Venturi Ellips FX 21-gauge compared with the Venturi Ellips FX (44.32 versus 45.07 seconds, respectively).

The mean endothelial cell count (ECC) also decreased less with the Venturi Ellips FX 21-gauge and the Venturi ELLIPS FX and were similar over 6 months postoperatively. Substantial reductions in the ECC were seen in the cases in which the peristaltic pump was used up to 1 year postoperatively, Dr. Piovella noted.

The Whitestar System is the only system to use peristaltic and venturi technology, which have different applications. Dr. Piovella pointed out that in phase one sculpting, the peristaltic pump is used. In phase two quadrant removal, the venturi pump is used; with premium IOL implantation with a small rhexis, the peristaltic pump is used. The venturi pump is used for epinuclear removal and for removal of an ophthalmic viscoelastic device; either pump can be used for cortex removal.

"Phaco machines with double pumps permit users of the peristaltic pump to adopt venturi pump without increasing the complication rate," he commented. ■

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Dr. Piovella is a consultant to Abbott Medical Optics.

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'PIZZA-PIE CHOP' INCREASES EFFICIENCY, SAFETY IN DENSE NUCLEI

LONG BEACH, CA ::
DWAYNE K. LOGAN, MD, in private practice at Long Beach, CA, serves a predominantly geriatric, managed-care patient population, in whom denser nuclei are common. He has modified his chopping technique to take advantage of the combined strengths of peristaltic, venturi, and transversal phacoemuslification to enhance safety and efficiency.

In an online exclusive to *Ophthalmology Times*, Dr. Logan describes his chopping technique, which he calls the "pizza-pie chop." Go to *http://bit.ly/17gX48w* to read more.

Differing methods, similar inflammation

From Staff Reports

SAN FRANCISCO ::
WHETHER A SURGEON USES A laser for cataract surgery or manual methods may not make much of a difference in terms of postoperative inflammation.

That at least is the experience of H. Burkhard Dick, MD, professor and chairman of ophthalmology and director of the University Eye Clinic Bochum, Bochum, Germany. Data presented showed significantly less ocular inflammation in patients who had laser surgery the day after the procedure compared with manual cataract surgery. But there was no difference in inflammation between the two groups on days 3 or 7.

Researchers compared inflammation rates and other surgical parameters as part of a randomized prospective trial on 152 eyes and 76 patients. Dr. Dick performed all of the cataract surgeries, capsulotomy, and fragmentation either by manual methods or using a laser system (Catalys, OptiMedica) with a fluid-filled interface and three-dimensional optical coherence tomography image guidance.

The biggest difference between the manual and laser surgeries was the effective phacoemulsification time (EPT). Laser procedures were much faster, typically less than 1 second EPT compared with several seconds for the manual procedure, Dr. Dick noted.

Inflammation results were much less concrete. On day 1 following surgery, the laser group had statistically significantly lower inflammation, 15.9 photon counts/msec, compared with the manual surgery group, 19.7 photon counts/msec, a 19% difference ($p = 0.008$). But the laser flare values were not statistically different from the manual flare values on days 3 or 7 following surgery ($p > 0.05$ for both days).

"The laser surgery group had a reduction in ultrasound energy and less inflammation on day 1," Dr. Dick said. "Inflammation on days 3 and 7 was no higher in patients who had manual surgery, but it was no lower, either." ■

For important safety information, please see adjacent page.

THE ACRYSOF ADVANTAGE

Alcon

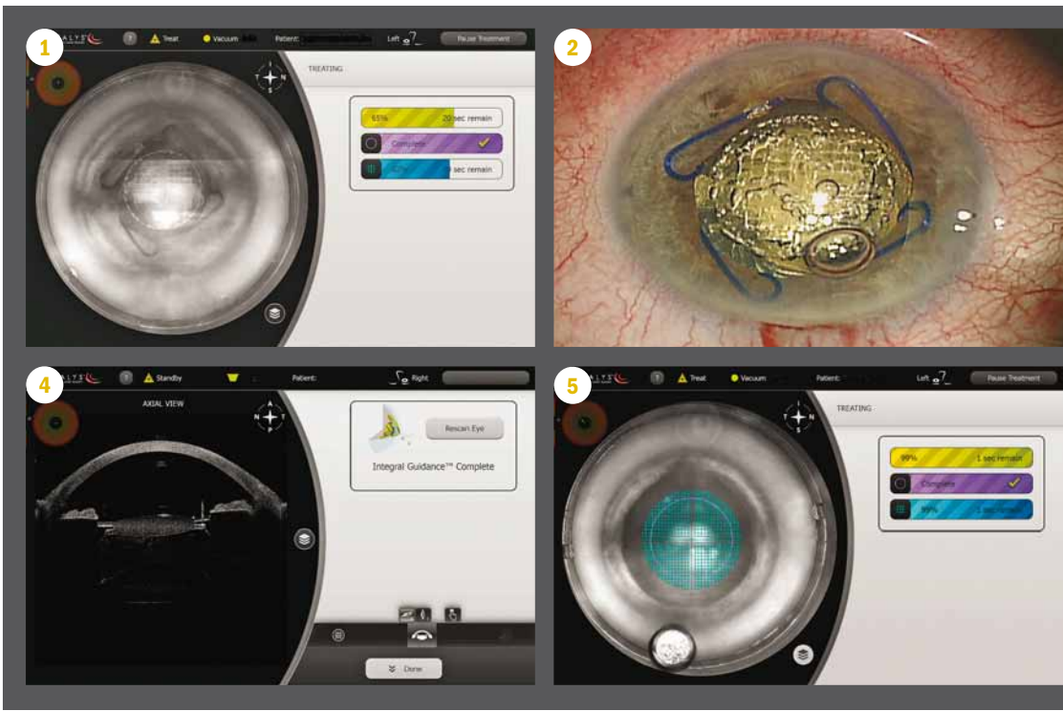
a Novartis company

Special Report) **ASCRS CATARACT NEWS**

Broad inclusion criteria applicable for femtosecond laser

Safety advantages associated with excellent results whether operating on routine cases or patients with co-morbidities

By Cheryl Guttman Krader; *Reviewed by Burkhard Dick, MD, PhD*



SAN FRANCISCO ::

FEMTOSECOND LASER CATARACT surgery using a proprietary system (Catalys Precision Laser System, OptiMedica) is associated with excellent results whether operating on routine cases or patients with co-morbidities.

In fact, it is in the complex cases where the laser may provide some of its greatest benefits, according to Burkhard Dick, MD, PhD, who presented findings from a large prospective review of his personal experience with the laser at the annual meeting of the American Society of Cataract and Refractive Surgery.

The series comprised the first 850 consecutive cases performed by Dr. Dick, professor of ophthalmology and chairman, Ruhr-University of Bochum, Bochum, Germany. They represented the entire spectrum of nuclear density, including 405 eyes with grade 4 cataract (LOCSIII scale) and 31 eyes with a mature intumescent cataract. Overall, 26% of cases presented with some co-morbidity or feature that could confound safety of conventional cataract surgery.

Within the series there were 53 eyes with glaucoma, 72 eyes with corneal pathology (Fuchs' dystrophy, corneal guttata, scars), 102 eyes with pupil issues (small pupils, intraoperative floppy iris syndrome), 50 eyes at risk for loose zonules due to pseudoexfoliation syndrome or history of pars plana vitrectomy, and 91 cases where patients were on anticoagulant medication.

take-home

Outcomes from use of a proprietary femtosecond laser system (Catalys Precision Laser System, OptiMedica) to perform cataract surgery in a series of 850 eyes, of which 25% have some comorbidity, are testament to its reliability and safety.


Dr. Dick

Summarizing outcomes, Dr. Dick noted that a complete capsulotomy was achieved in 99% of eyes, 40% of cases were completed with no ultrasound energy, and for the 836 eyes with grades 2 to 4 cataracts, mean effective phaco time was reduced by 96% compared with historical controls operated on with standard manual techniques. There were few complications.

"In our series where about one-fourth of eyes had some comorbidity, we would expect to encounter a much higher complication rate using a standard phaco technique," Dr. Dick said. "However, cataract surgery with this femtosecond laser has great safety thanks to the laser's precision, OCT guidance, and effective lens fragmentation that reduces ultrasound use."

The complications encountered included 2 tags in eyes with mature cataract where surgery was performed with ophthalmic viscoelastic device in the anterior chamber, 5 tags in eyes with a small pupil, and 9 cases of conjunctival alterations, all in patients on an anticoagulant.

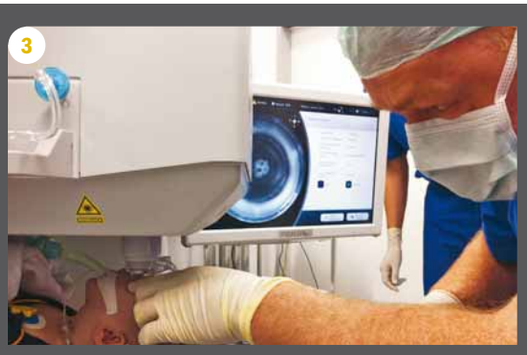
"The laser's Liquid Optics patient interface works well in all eyes, including pediatric cases and patients with strabismus or previous filtering surgery," Dr. Dick said. "It allows a gentle dock, increasing IOP by only about 10 mm Hg after application of the suction ring."

APPROACHING NEAR ELIMINATION OF ULTRASOUND

Despite achieving good results from the beginning, Dr. Dick aimed to refine his procedure over time. He first optimized the surgical technique and fragmentation pattern for lens softening and then switched irrigation and aspiration tips and phacoemulsification machine settings while adopting a new mindset about the need for routine phaco energy.

Each successive change led to a progressive decrease in ultrasound energy usage as shown by an analysis comparing three groups of 200 consecutive cases performed over time (mean LOCSIII scores 3.4 to 3.5). Dr. Dick noted using no ultrasound in 41% of cases 200 to 400, 72% of cases 700 to 900, and 91% of cases 1,200 to 1,400.

Dr. Dick also uses the laser to make precise corneal incisions, including to create the cataract surgery incisions and for astigmatic correction, and he has begun to apply the laser for performing posterior capsulotomy and the bag-in-the-lens technique. ■



1. Screenshot during a laser capsulotomy and lens fragmentation using the Catalys Precision Laser System.

2. Laser capsulotomy and fragmented cataractous lens after pupil dilation using a Malyugin ring.

3. Laser-assisted anterior capsulotomy in a pediatric cataract surgery under general anesthesia.

4. Screenshot of a 3-D spectral-domain OCT 2 months after femtosecond laser-assisted bag-in-the-lens implantation demonstrating a very well fixated and centered IOL.

5. Tight grid fragmentation of an advanced cataract in order to reduce the effective phacoemulsification time.

6. Perfectly laser-assisted capsulotomy in a fibrotic capsule with a tight lenticular fragmentation in an advanced cataract (same case as in Figure 5).

(Photos courtesy of Burkhard Dick, MD, PhD)

Novel model for patients

VIDEO Mercy Clinic Eye Specialists, Springfield, MO, recently installed two Catalys Precision Laser Systems (OptiMedica) at its surgery center. The practice is unique in the ophthalmic industry in that it is offering the femtosecond laser technology to all patients seeking cataract surgery at no additional charge to the patient. Shachar Tauber, MD, chairman of ophthalmology and director of ophthalmic research and telemedicine, discusses why Mercy Clinic Eye Specialists chose to implement its cataract surgery program in this manner, and how this novel model is received by patients. Go to **OphthalmologyTimes.com/MercyClinic** for more.

BURKHARD DICK, MD, PHD
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Dr. Dick is a consultant to Abbott Medical Optics, AcuFocus, Allergan, Aquesys, Bausch + Lomb, Calhoun Vision, Carl Zeiss Meditec, Domilens, Geuder, Morcher, Novartis, Oculus, Ophtec, Optical Express, OptiMedica, and PowerVision.

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Digital App

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

Facebook Poll

Do you perform refractions personally in your practice or employ an optometrist to do them? Tell us on Facebook at http://on.fb.me/12HATFL and see what your fellow ophthalmologists are saying.

Upgrade affords surgical time, efficiency

Investment in latest phaco equipment translates to improvements in OR, study finds

By Fred Gebhart; *Reviewed by Barry A. Schechter, MD*

SAN FRANCISCO ::

DEVICE MANUFACTURERS ARE continually developing and refining next-generation phacoemulsification systems. Improved safety, improved outcomes, and improved ease of use are the stated goals. Do these new systems deliver? Do they justify the investment in capital, time, and learning?

"Looking at surgical time as a measure of efficiency, there is sufficient improvement to justify the investment," said Barry A. Schechter, MD, director, cornea and cataract service, Florida Eye Microsurgical Institute, Boynton Beach, FL.

Dr. Schechter

"Yes, it is a little more expensive to put a new piece of machinery in the operating room (OR), but the cost is justified by the better efficiency and the probably better outcomes," he said. "Just by being more efficient you cause less trauma and should have fewer side effects."

Dr. Schechter offered a comparison of surgical time and efficiency using the latest phacoemulsification system (Stellaris, Bausch + Lomb) and an older-generation system (Millennium, Bausch + Lomb) in a presentation at the annual meeting of the American Society of Cataract and Refractive Surgery.

"We upgraded to the Stellaris system about 18 months ago," Dr. Schechter said. "After a period, our OR staff noticed that we seemed to be working more efficiently and getting through more cases with the same surgeons, the same support staff, the same patient population, and the same amount of time. They pointed out that things were moving more quickly in the OR than in the post-op area."

GREATER EFFICIENCY LEADS TO STUDY

What seemed to be increased patient throughput was not just with Dr. Schechter's patients. Two other high-volume surgeons at the facility also appeared to be working more efficiently. All three surgeons handled between 15 and 30 cases per week. The most direct way to answer the question about increased efficiency was a retrospective study.

Six surgery days were chosen at random for each of the three surgeons: 3 days using the Millennium system and 3 days using the Stellaris system. The Stellaris days were chosen from a period beginning 3 months after the new system was installed to allow for the surgical learning curve. Each surgeon had performed at least 45 procedures using the Stellaris before the study period began.

Each of the surgical days had at least 12 uncomplicated procedures—no limbal relaxing incisions, no vitrectomies, no capsular tension rings, or other intraoperative devices. There were no changes in surgical techniques, OR staff, IOLs implanted, incision size (2.8 or 3 mm), or viscoelastic substances between the two systems.

take-home

- **To learn if new technology increases efficiency in the operating room, one practice conducted a 3-month, retrospective study comparing surgical time and efficiency using a newer versus older phacoemulsification system.**

NEW TECHNOLOGY PERFORMED

Results of the comparison supported staff observations that the Stellaris is a more efficient platform. The mean time per procedure fell from a mean of 8.42 minutes with the Millennium to 6.58 minutes with the Stellaris, an absolute difference of 1.8 minutes or 22% ($p < 0.001$). The range of improvement varied from 19% at the low end (8.9 minutes to 7.2 minutes) to 25% at the high end (8.3 minutes to 6.2 minutes).

"Decreasing your surgical time by 22% is both statistically and clinically significant," Dr. Schechter said. "That is an impressive difference by any measure."

Each of the three surgeons showed a learning curve with less time required for surgery as the cumulative number of surgeries each performed increased. The learning curve was similar for the three surgeons. Operative time decreased by an average of 0.34 minutes for every 10 cases operated, then stabilized.

The actual surgical time for each case varied from about 3 minutes to 14 minutes, but how early or late any particular case fell in the series had little to do with the time it took. The case number accounted for only 8.5%, 11.8%, and 21.1% of the variability in time needed for the different cases performed by the three surgeons.

Dr. Schechter said advancements in technology and ergonomics are responsible for the increased efficiency of the Stellaris system. Sensors have been improved, he said, and the new software is more streamlined. There is also a longer stroke length on phacoemulsification, which provides more power and efficiency. The hand piece is lighter and more ergonomic, which causes less strain and fatigue during the day.

TECHNOLOGY ON OUTCOMES

One consideration that is not clear is the effect that the Stellaris system might have on surgical outcomes and patient satisfaction. The overall impression is similar outcomes and somewhat improved patient satisfaction compared with the Millennium, but there are no data. Yet.

A second retrospective study is planned to compare outcomes and patient satisfaction.

"We see a real potential for measurable benefit in patient outcomes, but we haven't proven it yet," Dr. Schechter said. "Everything we have seen says that reduced surgical time is associated with reduced post-surgical inflammation because there is less surgical trauma up front. Less trauma should translate into fewer side effects." ■

Have newer phaco technologies increased surgical efficiency in your operating room? Visit **facebook.com/OphthalmologyTimes** to weigh in.

BARRY A. SCHECHTER, MD
E: *info@DrBarrySchechter.com*

Dr. Schechter did not indicate any proprietary interest.

Form follows function

Balance eyewear function with eyewear fashion—the best possible vision in the best possible form

By Laurie L. Pierce LDO, ABOM

TAKE-HOME

- ***Identifying and purchasing frame styles to match the demographics of your patients/clients can be simplified by applying The Fashion Triangle as a model for following and tracking fashion trends.***

Optical professionals are curators of the rich history of eyewear. Frame fashions and trends have made huge leaps since early products such as the monocle, the lorgnette, the pince-nez, and other frame designs of the day.

At first, the purpose of eyeglasses was strictly to correct eyesight. Function, not fashion, drove the eyewear business. Optical merchants traveled from village to village showing early eyewear options. Marco Polo noted that, while on his visit to China, the people there wore eyeglasses as a look of distinction, even though they had no visual benefits.

So eyewear back then had no ophthalmic qualities, just an attitude. Today, history repeats itself. There is a niche clientele that wishes to wear eyewear for a look of distinction, the ultimate "attitude glasses."

As America boomed and prospered, the masses started to wear prescription eyewear. Form following function, eyewear trends continued to be mostly practical. (Think small, round eyewires.)

The Roaring Twenties glommed onto the

Continues on page 30 : ***Style***

In Brief

FROM STAFF REPORTS

Benefit of no-glare lenses

ESSILOR LAUNCHES NEW CONSUMER CAMPAIGN

DALLAS :: **ESSILOR OF AMERICA** has launched a national advertising campaign to consumers that outlines the benefits of its Crizal No-Glare Lenses. The multi-media campaign continues to roll out through the rest of the year in radio, print, and digital media.

The new Crizal ads introduce the critical health message about the need for everyday UV eye protection and showcase the Eye-Sun Protection Factor (E-SPF), an index that measures the total level of UV protection on a lens.

The television commercial virtually outfits viewers in a pair of glasses and engages them in adventure-filled activities, like whitewater rafting through the mountains, camel-back riding across the desert, or cruising through the city streets at night.

Through two different lenses, viewers are shown how Crizal lenses outperform ordinary lenses and provide the best clarity of vision by resisting the glare, scratches, smudges, dust, and water that appear in the viewers' vision throughout the voyage.

In other news, Essilor Vision Foundation, through its partnership with Special Olympics Opening Eyes program, provided more than 475 pairs of glasses to athletes at the Special Olympics Texas Summer in May.

Worldwide agreements

SAFILO ENTERS PACTS WITH MARC JACOBS, ESSILOR

PADUA, ITALY :: **SAFILO GROUP HAS** entered into a licensing agreement with Essilor and renewed its existing licence agreement with designer Marc Jacobs.

Safilo and Marc Jacobs International LLC renewed a licensing agreement for the design, manufacture, and worldwide distribution of Marc Jacobs and Marc by Marc Jacobs branded optical frames and sunglasses collections. The new agreement will run until Dec. 31, 2024.

Safilo and Essilor have entered a 10-year licensing agreement for the design, manufacture, and worldwide distribution by Essilor of polarized ophthalmic lenses under the Polaroid brand for use with eyewear products in general. ■

Be sure the fashion does not outweigh the function—the best possible vision in the best possible form.

STYLE

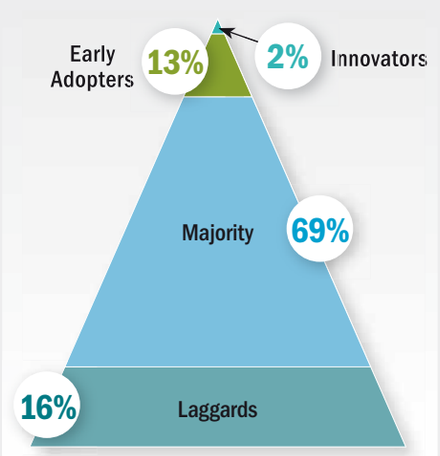
(*Continued from page 29*)

round frame design, making the look an instant classic that has stood the test of time. Contemporary frame designers, however, have reinvented the classic look by adding colored plastics and a semi-rimless look to update the visual effect. A perfectly round frame, whether metal or plastic, will always hold a place in the fashion world.

Next came the Fashion Fifties and the Sexy Sixties. Colored acetate/zyl came into the picture, and frame fashion trends started to pop with color and style. Although it must have been exciting to introduce new colors in eyewear, the plastics were very thick (5–7 mm stock), and the look was less attractive than contemporary colored zyl.

Today, acetates are color-layered to get the pop of color we want without a thick, obtrusive frame.

Figure 1
The Fashion Pyramid



Cut to the 1970s. Wait—there was no fashion then. Let's skip that era. The 1980s, however, were bigger than life.

In the new millennium, frame fashion trends take the best of the past and meld it with the present to create unique, fun, frame trends to which we can all relate. In the 21st Century, equally in fashion are bold, heavy Geek Chic zyls and disappear-on-your-face rimless—both extremes, both perfectly in style.

It is our job to help identify which of these looks speaks the loudest to our patients and clients.

When both extreme fashion trends are still in play, it leaves a lot of room for all the styles in between. Identifying and purchasing frame styles to meet today's fashion trends is not as difficult as you may think.

As in many fashion-related industries, there is a methodical way of knowing how fashion trends disseminate throughout a society. The Fashion Pyramid (Figure 1) is a great model to follow regarding how fashion trends trickle down.

THE FASHION PYRAMID

Think of a pyramid, like the food pyramid (or a base-up prism), with the top of the triangle (apex) being the most in-fashion haute couture trends, with other trends closely following.

INNOVATORS

The Innovators are the top 2% of the fashion triangle. This group of patients/clients are fashion-forward, trendsetters, and jet-setting type of people. The moment they see a fashion trend on another Innovator, they will dump it immediately and move on to the next fashion trend:

WOMEN INNOVATORS

Cat eyes (yes, with rhinestones, please), bright colors, and geometric shapes. The ultimate in women's frame fashion trends today are fun cat-eyes, and glamorous retro-fashions like Audrey Hepburn 1950s glam. Just turn to fashion magazines and you will see women with pin curls and finger-wave type hairstyles mirroring this glamorous time in history. And, tortoise shell colors and leopard prints are a must.

Ask yourself, are they *too* Peg Bundy or just Peg Bundy enough?

MEN INNOVATORS

Also retro in style. Think Martin Luther King, Jr. and Aristotle Onassis. Young college students are jumping on the fashion bandwagon more than ever. Add interesting materials, such as wood and buffalo horn, and we have a match made in heaven—retro styles with natural elements.

EARLY ADOPTERS

Similar to Innovators, Early Adopters are also trendsetters with fashion savvy. The difference here is that they will hold on to a fashion trend a little longer, taking great pride in the fact that they were among the first to wear the particular fashion.

This group of patients/clients will also wear the heavy "geek-chic" types of designs, as well as perfectly round metals and zyls. Additionally, they will match up interesting rimless styles with unique lens shapes and edge color treatments.

A great way to show our expertise with this group is to custom shape rimless designs to suit the individual's face shape and features. Simply draw a line on the demo lens from the cheekbone upward and outward to the outer edge of the eyebrow, and *oo la la*—a custom shape that is not too off the charts, but very distinct from mainstream shapes. A perfect combo for the Early Adopter.

(**Style tip:** *Most everyone looks good with a little upward temporal angle in a lens shape.*)

THE MAJORITY

The Majority (69%) of our patients/clients must see a frame fashion trend around them before they will embrace the style. They must see it on television, in the movies, in printed media, and on the streets. This group of people tends to hold on to their styles for a longer time, so we must be careful to present fashion trends that will last a couple of years.

The Majority of eyewear consumers today will still delight in classic rimless and short "B" dimension frame styles. Thick temples with extra designs are still on the mark for this fashion demographic. (*Optical note: Miss Optical Manners says there is no excuse for not having enough pantoscopic tilt for the best visual optics. If you plan to dispense frame fashions with thick temples, it is important to learn how to file the edges at an angle to give enough pantoscopic tilt, especially for PAL wearers.*)

Be sure the fashion does not outweigh the function—we aim for the best possible vision in the best possible form.

LAGGARDS

The Laggards are not interested in fashion trends; they are not part of this discussion. However, they are part of the fashion triangle and should be noted. Just talk stainless steel and spring hinges and they'll be happy. If you're lucky, you will have an engineer laggard, which will give you an opportunity to talk about index of refraction, ABBE value, and specific gravity . . . all in a day's work.

We are in a wonderful place regarding optics and frame fashion trends. New, innovative frame designers are introducing fresh, fun collections that bring back excitement and glamour to eyewear. In counterpoint, lens engineers are calculating enhanced lens designs to accommodate various frame fashion trends while keeping optics stable.

The result is Geek Chic at its best—a win-win for eyewear consumers and fashionistas. ■

LAURIE L. PIERCE, LDO, ABOM, *is an instructor in the opticianry program at Hillsborough Community College, Tampa, FL. Pierce also lectures extensively on optical theory and management topics at local, regional, and national conferences. In addition, Pierce is president of the Society to Advance Opticianry. She was named one of the most influential women in optical for 2010. Readers may contact Pierce at 813/253-7433 or lpierce@hccfl.edu*

The way it was . . . and at times, still is

Letter from the past reveals how eye surgery has changed, but complications still exist

Our Ophthalmic Heritage **By Norman B. Medow, MD, FACS**

TAKE-HOME

- ***The recent discovery of a letter from Ramón Castroviejo, MD, provides a glimpse into the state of ophthalmic care and socioeconomics from decades past. Dr. Castroviejo's research efforts in corneal transplantation led him to become one of the leaders of corneal transplants in the world.***

In 1965, President Lyndon Baines Johnson signed into law Medicare and Medicaid Amendments to the Social Security Act. The Medicare Amendment provided health care to those over 65 years of age, whereas the Medicaid Amendment provided health care to those whose income fell below the poverty level. The cost of part B (medical insurance) at that time, was $3 per month, a far cry from what it is today.

In 1951, prior to the Social Security Act, general practitioners charged $3 to $5 per office visit or upward of $14 for a specialist visit. General practitioners earned an average of $8,500 per year while specialists earned upward of $28,000 per year. The median family income in 1949 was just under $3,400 and by 1958 it had risen to $4,800. Fifty percent of families had some form of insurance before the Social Security Act became available; the other 50% had no insurance at all. Following the introduction of Medicare, physicians' incomes rose.

AN ERA GONE BY

I bring these statistics up because of a wonderful letter recently donated to the Museum of Vision of the Foundation of the American Academy of Ophthalmology by Linda and Jeffrey Nudelman. The Nov. 28, 1940 letter is from Ramón Castroviejo, MD, to Mr. Leonard Smith and it regards the possible surgery for his wife, Sara. The letter (printed here in its entirety) gives great insight into the mind and heart of the foremost corneal transplant surgeon of his era.

Dr. Castroviejo was born in Spain on Aug. 24, 1904. After graduating from the University of Madrid Medical School in 1927, he came to New York for a research fellowship in corneal diseases at Columbia Presbyterian Medical Center. His research efforts led him to become one of the leaders of corneal transplants in the world. In the early 1950s, Dr. Castroviejo moved his practice to the Hammond House at 9 East 91st St., where he practiced and operated until he retired in 1972. At this time, he moved back to Madrid, his hometown, where he died in 1987.

A LASTING IMPRINT

Dr. Castroviejo is to be remembered by all eye surgeons today. His instrument designs are still in use 50 years or more after he designed them. Dr. Castroviejo's original corneal transplant was a square or rectangular graft held in place with an ingenious suture that straddled the donor cornea and was kept in place for a number of weeks, while patients remained in bed with their heads immobilized by sand bags. Clear grafts did occur, but often with large degrees of astigmatism requiring a sclera-corneal contact lens.

Mrs. Smith did undergo a corneal transplant with Dr. Castroviejo and remained in the hospital for 9 weeks. After this, she had a repeat operation by Dr. Castroviejo and returned to Toronto, where she underwent two more corneal operations. Complication rates of corneal surgery at the time were high. Things have changed in many respects, but complications of ocular surgery still exist.

The more things change, the more they stay the same. ■

NORMAN B. MEDOW, MD, FACS, *is editor of the Our Ophthalmic Heritage column. He is director, pediatric ophthalmology and strabismus, Montefiore Hospital Medical Center, and professor of ophthalmology and pediatrics, Albert Einstein College of Medicine, Bronx, NY. He did not indicate a financial interest in the subject matter.*

November 28, 1940

Dear Mr. Smith:

I received your letter of November 15th in regard to Mrs. Sara Smith.

I consider the eyes of your wife very favorable for a corneal transplantation. She may come to New York at her earliest convenience. As soon as she arrives, she will be the first one to be operated, the moment material is available. During the past month I have performed over twenty corneal transplantations. This is the type of operation that I would have to perform on your wife. If she had been here, I could have operated on her with less than one week of delay.

However, I may say that sometimes we are not so lucky, and the good material needed for this type of operation does not present itself for several weeks. I would suggest that your wife comes to New York, and I will place her the first in my waiting list, to operate on her eye at the first opportunity.

She will have to stay in the hospital approximately two weeks, and two more weeks after she leaves the hospital, coming to my office for examination every two days.

Hospital expenses very from $6.00 to $20.00 per day, depending upon the type of room selected, pus $15.00 for the operating room, and .50 daily for nursing care.

My fees vary according to the financial status of the patients. Since I do my best for my patients, I expect them to do likewise towards me. To wealthy patients, I charge from $500.00 up for a corneal transplantation; a fee of $500.00 I consider fair, for a patient who without being wealthy, has comfortable means of life; $250.00 I consider a very modest fee for this type of operation. Anyhow, I trust the good faith of my patients and leave it up to them to decide in which financial status they should be included.

Sincerely yours,
Ramón Castroviejo, MD

Be bold and flexible when it comes to career planning

Identify core values of importance but realize they will probably change over time

The OWL Quarterly **By Molly Schar**

TAKE-HOME

- ***Three members of the nonprofit group Ophthalmic Women Leaders (OWL) offer insights into creating an individual strategic plan, developing key messages, and building relationships.***

IN A FAMOUS EXCHANGE between Lewis Carroll's title character in *Alice in Wonderland* and the Cheshire Cat, Alice wonders in which direction she should go and the Cat advises that it depends on Alice's desired destination.

"I don't much care where," says Alice.

"Then it doesn't matter which way you go," replies the Cat.

Unlike Alice, most of us do care about where we end up, even if we haven't identified a direct route to get there from our current positions.

GET CLEAR ON YOUR GOALS

"As you are moving forward in your career, it's important to be planning as you go along," said Marsha D. Link, PhD, an executive coach. "But before you develop a plan, define what success means to you. Without clarifying this, it will be difficult to identify what you want to achieve. Ask yourself: 'What do I want that I do not have now? What are my dreams?'"

Dr. Link

"Identify your 'true North,'" urged Ellen Troyer, MT, MA, chief executive officer and chief research officer for Biosyntrx Inc. "Don't be afraid to be brave and revolutionary as you consider not only what you want to do for yourself, but also what you want to contribute to the world around you."

Dr. Link agreed. "Your values will drive your plan. Identify the values that are most important to you to guide you in what to include in or exclude from your plan," she said.

Those values will probably change over time.

"Since I am now in the 'winter' of my career, I value different things than I did in mid-life," Dr. Link said. "My plan has evolved for each 'chapter' of my life."

Once you can articulate your goals and have identified your most important values, develop specific action plans to carry out your goals, including timelines for achieving milestones, Dr. Link advised.

Dr. Houtman

"Don't forget the importance of being mindful of new opportunities," added Diane M. Houtman, OD, FAAO, MBA, vice president of professional relations for Advanced Vision Research, an Akorn company. "I think in the early years of our careers, we sometimes don't even know what the possibilities might be. By being open to new opportunities and taking advantage of those opportunities, it widens the scope of where your career might eventually take you."

SEND THE RIGHT MESSAGE

With a good idea of where you want to be and how you're going to get there, look for ways to communicate your value to people who may be able to help you advance your goals.

Troyer

"Have passion for your work and the courage to make difficult decisions," Troyer said. "Dare to be radically vulnerable. Recognize the moments when opening yourself to people can be transformative. Share your story, it's important."

Develop an "elevator speech" that identifies your purpose and importance, what you have to offer, and language that expresses "who you are" in a clear and concise way, Dr. Link said.

Dr. Houtman takes a "major/minor" approach to positioning herself.

"I 'major' in the responsibilities of my current position and 'minor' in areas where I want to grow my expertise," she said.

MAKE GOOD CONNECTIONS

"Networking is really key to getting where you want to go," Dr. Houtman said. "Early in my career, I really thought that I could just work hard and do a good job and I would find myself in the next position I wanted to be in. It turns out it doesn't really work that way."

Effective networking is about giving in order to get, Dr. Link said.

"Figure out how you can help others get what they need," she said. "It is amazing to see how that behavior is reciprocated! Reaping the benefits of relationship-building takes time. Create a diverse network filled with 'lifters' by connecting with those people who are successful, willing to help others, and can relate to your goals."

"A great way to build your network is to take on assignments that are not in your job description, or to volunteer for causes you passionately believe in," said Troyer, who also advises the use of social media for network-building. "You can use social media to follow up on contacts made in person, to connect to new contacts through existing connections, and generally to reinforce your professional brand." ■

MOLLY SCHAR *is executive director of Ophthalmic Women Leaders (OWL), a membership organization focused on leadership development and advancement of women in ophthalmology. She can be reached at mschar@owlsite.org or 415/751-2401.*

DIANE M. HOUTMAN, OD, FAAO, MBA, MARSHA D. LINK, PHD, *and* **ELLEN TROYER, MT, MA,** *will further discuss the importance of intentionality in career planning during the Aug. 3 session "Brave Intentions: Creating a Brand That Gets You Where You Want to Go" as part of the Women in Ophthalmology Summer Symposium (www.wioonline.org).*

8 strategies for managing Graves' orbitopathy

Appropriate intervention and optimal timing are key to treatment strategy

By Lynda Charters; *Reviewed by Petros Perros, MD, FRCP*

TAKE-HOME

- ***Aside from treatment options for Graves' orbitopathy, the treatment strategy is also hugely important. The combination of options and strategy leads to optimal management.***

NEWCASTLE UPON TYNE, ENGLAND ::

Optimal management of Graves' orbitopathy extends beyond medical and surgical treatment options.

"The treatment strategy is also hugely important," said Petros Perros, MD, FRCP, consultant endocrinologist, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, England.

Dr. Perros

Dr. Perros discussed eight strategic considerations for the medical management of patients with Graves' orbitopathy. He noted that there is a phase of disease activity in which acute inflammation is present that defines the window of opportunity for medical treatment. Medical treatments are effective only during the active phase, which can be difficult to determine.

1 Disease activity markers range from clinical markers, such as clinical activity score (CAS) and disease duration, to urinary and serologic biomarkers, such as thyrotropin receptor antibodies (TSHRAbs) to findings on imaging.

A Dutch study of possible predictive parameters found that simple clinical parameters, such as short disease duration, CAS, and restricted elevation, can predict a response to radiotherapy in about 82% of cases. When investigators evaluated the contribution of other biomarkers and imaging techniques, the percentage of responses increased only slightly to 89%, Dr. Perros recounted.

2 TSHRAbs are important in that they are the cause of thyrotoxicosis in Graves' orbitopathy. The question is whether TSHRAb levels are correlated with disease activity and severity, and data indicate highly variable results. However, TSHRAbs may predict the disease course. Patients with persistently increased levels have a poor clinical course in contrast to those with lower levels.

TSHRAbs can be used in the differential diagnosis of Graves' orbitopathy (i.e., these biomarkers are positive in most cases with euthyroid/hypothyroid Graves' orbitopathy, but they must be evaluated prospectively).

TSHRAbs are of limited value in the follow-up of Graves' orbitopathy. If there is difficulty reaching a definitive diagnosis, imaging or biopsy should be performed, Dr. Perros noted.

3 There is an association between dysthyroidism and severe Graves' orbitopathy. Studies have shown correlations between the Graves' orbitopathy severity and serum T3 and that hypothyroidism is associated with a worse ocular outcome.

4 Thyroid treatments include antithyroid drugs, radioiodine, and thyroidectomy (subtotal, total, or total thyroid ablation). Regarding thyroidectomy, the efficacy of total and subtotal thyroidectomy is equivalent. A comparison of total thyroid ablation (total thyroidectomy/radioiodine/intravenous steroids) and total thyroidectomy/intravenous steroids found that the Graves' orbitopathy outcome was the same. However, eyes treated with ablation improved faster and additional needed treatments were more effective.

An evaluation of radioiodine therapy found that 1 year post-treatment, there was an excess risk of orbitopathy developing de novo or worsening, and the risk was almost 25% higher in smokers. Steroids, when administered 1 or 2 days after radioiodine therapy, helped to prevent this risk. Smoking cessation is important to managing patients with Graves' orbitopathy, according to Dr. Perros.

5 Selenium as an antioxidant was found to have a response in patients with mild Graves' orbitopathy that was superior to placebo after 6 months. Fewer patients worsened.

6 Comparisons of oral and intravenous steroids for Graves' orbitopathy had varying results, with meta-analysis showing that intravenous steroids were significantly more efficacious. Another study, which evaluated three cumulative doses (range, 2.25 to 7.47 g) of intravenous methylprednisolone for moderate-to-severe Graves' orbitopathy and active Graves' orbitopathy, found that high-dose methylprednisolone was more efficacious. The 52% response rate, however, was much lower than in previous studies. Data point to serious morbidity/mortality with cumulative doses over 8 g.

7 Orbital radiation monotherapy was found in one study to be more effective in treated patients with moderate Graves' orbitopathy compared with sham-irradiation-treated patients; a second trial found no difference between the two arms; and one-third of patients with mild Graves' orbitopathy showed a definite benefit of orbital radiation. Considered together, the benefit of radiation was improved vertical motility. A study of the combination of oral steroids and orbital irradiation indicated that combination therapy is better than either treatment alone.

8 Rituximab, a new drug, has been evaluated in few patients but with good responses. The role of rituximab remains to be defined. ■

PETROS PERROS, MD, FRCP

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Dr. Perros has no financial interest in the subject matter. This article was adapted from Dr. Perros' keynote lecture during Oculofacial Plastic Surgery 2012 at the annual meeting of the American Academy of Ophthalmology.

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Functional tests add value for glaucoma detection

Newer perimetric methods seem to offer some advantages relative to SAP

By Cheryl Guttman Krader; *Reviewed by Robert L. Stamper, MD*

TAKE-HOME

- ***The search for new techniques to measure glaucoma-related functional damage is being driven in part by the various drawbacks of standard automated perimetry.***

SAN FRANCISCO ::

Although the perfect test for assessing glaucomatous functional damage is not yet available, newer perimetric methods seem to offer some advantages relative to standard automated perimetry (SAP) and utility in particular situations.

"SAP is difficult for patients to perform and time consuming," said Robert L. Stamper, MD, professor of ophthalmology and director of the glaucoma service, University of California, San Francisco. "Furthermore, the results of SAPs are highly variable, the testing platform is not easily portable, and SAP is not sensitive enough to detect the earliest glaucomatous damage as we know that between 25% and 35% of ganglion cells have to be lost before the first evidence of white-on-white perimetric damage is manifest."

SHORT WAVELENGTH AUTO PERIMETRY (SWAP), also known as blue-yellow perimetry, was first described almost a century ago. It became the subject of renewed interest during the 1990s based on evidence that a blue stimulus on a yellow background seemed to segregate out a subgroup of the parvocellular (P) ganglion cells.

"Compared [with] SAP, SWAP has a longer learning curve, greater variability, and takes 15% to 20% longer to complete, even with application of a SITA algorithm," he said. "Furthermore, SWAP is more sensitive to nuclear lens changes than SAP, and it is also affected by yellow-tinted IOLs.

"Additionally, while results from two longitudinal studies, which were conducted at academic institutions, suggested SWAP had higher sensitivity than SAP and detected progression earlier, those findings have not been borne out by more recent studies or experience in clinical practice," Dr. Stamper said.

FREQUENCY-DOUBLED PERIMETRY (FDP) tests a subset of the magnocellular (M) ganglion cells that are related to motion detection. Evaluations of FDP using the originally developed device showed the testing was relatively insensitive to refractive errors or ambient light levels, and had a minimal learning curve, high sensitivity and specificity (~90%), and good test/re-test reliability.

The currently available device based on frequency-doubling technology (FDT) (Humphrey Matrix, Carl Zeiss Meditec) is a more sophisticated platform. It uses an algorithm that allows relatively rapid visual field sensitivity testing and has both a screening program that performs well for detecting glaucoma and a threshold program that is as good as SAP for monitoring patients.

HIGH-PASS RESOLUTION PERIMETRY involves projection of rings of different sizes onto the visual field and is based on function of the parvocellular ganglion cells. This test has good sensitivity and specificity, is fast and easy to perform, and has good test/re-test reliability. It must be done using specialized lenses, but an ongoing patent fight is the main factor limiting its development for commercial availability.

MOTION AUTOMATED PERIMETRY (MAP) tests for the function of magnocellular ganglion cells. It is done with a laptop, and findings from initial testing at University of California, San Francisco and Moorfields Eye Hospital, London, suggest MAP has good patient acceptance and has features that can make it attractive as a screening tool.

MULTIFOCAL VISUAL EVOKED POTENTIAL testing (AccuMap, ObjectiVision) is an objective perimetry method based on analysis of an electroencephalogram of the visual cortex following retinal stimulation. It has been shown effective for discriminating patients with glaucoma from normal subjects, but long-term studies and change parameters are lacking. Like high-pass resolution perimetry, the technology for multifocal visual evoked potential testing has also been the subject of a patent dispute that may limit its commercial application. However, another company is currently working on developing similar technology.

Motion automated perimetry (MAP) tests for the function of magnocellular ganglion cells. Performed using a laptop, findings from initial testing suggest MAP has good patient acceptance and features that can make it attractive as a screening tool. *(Photo courtesy of Robert L. Stamper, MD)*

TWO TESTS MAY BE BETTER THAN ONE

Though refinements of some of the newer functional tests may improve glaucoma diagnosis and management in the future, use of tests in combination may bring advances, Dr. Stamper noted. For example, a 97% glaucoma detection rate was reported using SWAP and FDP together.

"However, the duration of testing using both functional assessments is much too long to be practical, and combining FDP with a structural test may be better," Dr. Stamper said. ■

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Dr. Stamper has no financial interest in the subject matter. This article was adapted from Dr. Stamper's presentation at Glaucoma 360°, presented by the Glaucoma Research Foundation in association with Ophthalmology Times.

CXL protocol a viable option

Reduced treatment time makes it practical as concurrent procedure with LASIK

By Cheryl Guttman Krader; *Reviewed by John Marshall, PhD, FMedSci, FRCPath*

LONDON ::

Accelerated corneal crosslinking (CXL) is a alternative to the original protocol for the treatment of corneal ectasia and a practical addition to LASIK as a means for preventing ectasia.

In accelerated CXL, both riboflavin imbibition time and UVA irradiation time are shortened relative to the original Dresden protocol. The riboflavin application time for accelerated CXL varies between 3 minutes and 7 minutes, depending on the riboflavin solution used, and UVA is delivered for just 3 minutes, but at a fluence of 30 mW/cm^2.

"The accelerated CXL technique delivers the same amount of UVA energy to the cornea as does the original Dresden technique, and interferometric biomechanics measurements show that it increases corneal strength to the same degree as the standard CXL protocol," said John Marshall, PhD, FMedSci, FRCPath, professor of ophthalmology, Institute of Ophthalmology, in association with Moorfields Eye Hospital, University College London.

Dr. Marshall

"However, there is no endothelial damage with accelerated CXL since riboflavin does not penetrate to the endothelium during the reduced soak time, and studies also show a trend for greater preservation of keratocytes using the accelerated versus the standard CXL technique," Dr. Marshall said. "The keratocytes are still not spared entirely during accelerated CXL, but disabling some of the keratocytes may be desirable to stop the repair process immediately after the procedure."

Interest in performing CXL routinely at the time of LASIK is based on recognition that cornea biomechanical stability is compromised by any surgical intervention.

"Surgery introduces instability into the system and leads to increases in age-related changes in corneal curvature over time," he said. "The aim of . . . CXL at the time of LASIK is to increase corneal stability. If I were to have LASIK, LASIK with simultaneous CXL is what I would choose."

Avedro has received the CE Mark for its CXL procedure performed immediately after LASIK (LASIK Xtra), and the procedure is also approved in Japan and Canada. It involves application of a 0.25% riboflavin solution (VibeX Xtra, Avedro) onto the stromal bed. The area is rinsed after 1 minute, and after repositioning the flap over the bed, the eye is irradiated for 75 seconds using the company's UVA device (KXL, Avedro).

"There is a little diffusion of the riboflavin back into the cap once the flap is replaced, so the CXL strengthens the cap, the interface, and the bed," Dr. Marshall said.

He noted that Minoru Tomita, MD, of Tokyo, evaluated LASIK Xtra in a bilateral eye-controlled study in which 24 patients with myopia had standard LASIK in the dominant eye and LASIK Xtra in the nondominant eye. During 6 months of follow-up, there were no statistically significant differences between groups in refractive outcomes and stability. ■

JOHN MARSHALL, PHD, FMEDSCI, FRCPATH

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Dr. Marshall is principal scientific advisor to Avedro. This article was adapted from his presentation at the 2012 meeting of the American Academy of Ophthalmology.

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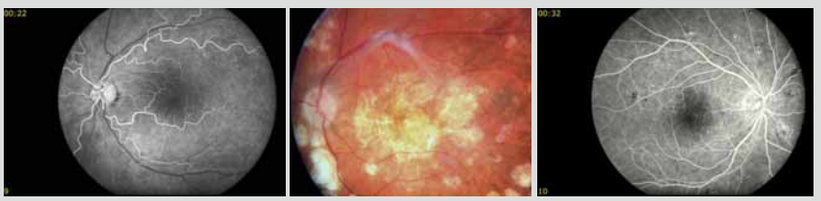

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HEATON EYE ASSOCIATES

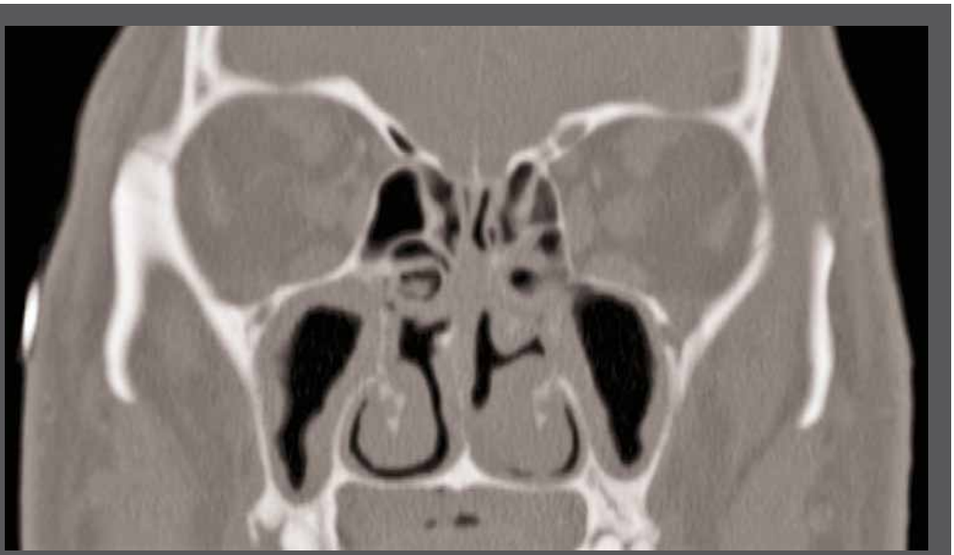
Patient has 1-week history of decreased vision OD

Man presents with binocular diplopia, right facial and periorbital pain: What is diagnosis?

By Brian E. Goldhagen, MD, Brian D. Alder, MD, Thomas J. Cummings, MD, and Michael J. Richard, MD

TAKE-HOME

- ***A 50-year-old black male presents to the emergency room with a 1-week history of decreased vision in his right eye, binocular diplopia, and right facial and periorbital pain. Two weeks prior to presentation, he had undergone a dental procedure, after which he had a complicated postoperative course. What is your diagnosis?***



(FIGURE 1) CT/CTA demonstrating extensive sinus disease.

A 50-year-old black male presents to the emergency room with a 1-week history of decreased vision in his right eye, binocular diplopia, and right facial and periorbital pain. Two weeks prior to presentation, he had undergone a dental procedure, after which he had a complicated postoperative course. He developed right facial swelling for which he was hospitalized and received IV clindamycin. After discharge, he developed recurrent nose bleeds requiring nasal packing.

The patient's medical history is remarkable for poorly controlled diabetes, hypertension, and hyperlipidemia. His surgical history is notable for toe amputation secondary to gangrene. He is pseudophakic but otherwise has no personal or family history of eye problems.

EXAMINATION

The patient's best corrected vision is 20/30 and 20/20 in the right and left eyes, respectively. His pupils are equal in the light and dark without a relative afferent pupillary defect. IOP, confrontational visual field testing, and color vision are all normal. Motility in the right eye is limited; it measures 40% in up-gaze, 20% in down-gaze, 80% in abduction, and 0% in adduction. Motility in the left eye is full. External exam reveals right ptosis and decreased sensation in the V1 and V2 right facial distribution. Slit lamp and dilated fundus exams are unremarkable, with healthy appearing optic nerves.

DIAGNOSTIC COURSE

The differential diagnosis for painful ophthalmoplegia in this patient is broad and includes: infectious (cellulitis and invasive sinus infection), inflammatory (idiopathic orbital inflammatory syndrome, Tolosa-Hunt syndrome, and autoimmune), vascular (cavernous sinus thrombosis and diabetic ophthalmoplegia), and neoplastic (primary lymphoproliferative and metastatic) etiologies. Given the patient's history, an infectious etiology is highly suspected. Further work-up is directed toward the diagnosis and treatment of possible infection.

An ENT consult is obtained. Their exam is remarkable for extensive right maxillary tooth decay and a 2 cm necrotic lesion of the right hard palate. Necrosis is also seen within the nasal cavity and has the appearance of invasive fungal sinusitis. CT imaging shows extensive sinus disease involving the bilateral maxillary, sphenoid, frontal, and ethmoid sinuses (Figure 1).

Given the concern for invasive fungal sinusitis, ENT performs extensive surgical debridement, including bilateral total maxillectomy, bilateral external ethmoidectomy, bilateral external sphenoidotomies, and right cheek soft tissue resection.

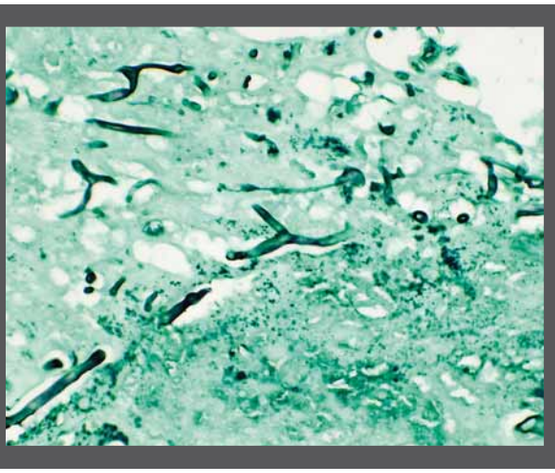
Pathology results are consistent with mucormycosis (Figure 2 on Page 42).

The patient is started on liposomal Amphotericin B as well as Zosyn for anaerobic coverage of dental decay. Micafungin is added for theoretical slowing of fungal tip growth.

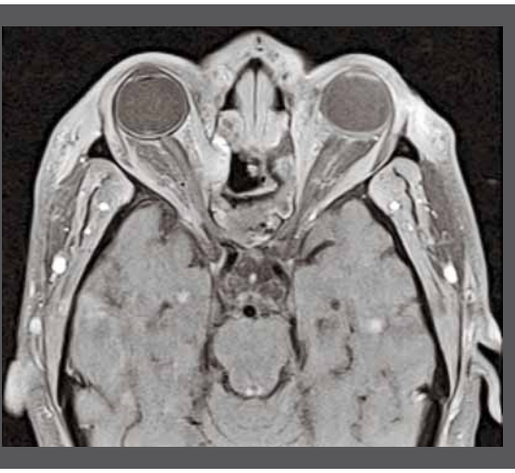
While the patient's right-sided multiple cranial neuropathies are thought to be due to invasive fungal infection, the exact location of involvement remains unclear. Lesions causing neuropathies of cranial nerve 3, 5, and 6 as in this patient may be localized to either the orbital apex or the cavernous sinus. ENT had seen no obvious periorbital involvement of the invasive fungal sinusitis during surgery. MRI with gadolinium is obtained, as it has been shown to be superior to CT in demonstrating invasive fungal disease.[1]

However, orbital apex changes are confounded by post-surgical changes from the recent ENT surgery. No cavernous sinus abnormality is seen. Thus, the exact anatomic location of the involvement is not able to be determined. The

Continues on page 42 : ***Grand Rounds***



(FIGURE 2)
Silver stain from necrotic palate/nasal biopsies showing the wide hyphae with an approximate 90° branch point characteristic of mucormycosis in the center of the image.



(FIGURE 3)
MRI status post-debridement showing enhancement of the orbits with involvement of the right intraconal and extraconal space, the right orbital apex, and the left extraconal space.
(Figures 1 and 3 courtesy of the authors. Figure 2 courtesy of Thomas J. Cummings, MD)

GRAND ROUNDS

(Continued from page 41)

decision is made to follow the patient closely with serial exams and MRI imaging.

On repeat examination, the patient's vision declined to 20/70 and 20/40. Pupil exam and color vision remain normal. Motility in the right eye has worsened to 10% in up-gaze, 10% in down-gaze, 20% in abduction, and 0% in adduction, while motility in the left eye remains full. Slit lamp examination and dilated fundus examination are unremarkable. Repeat MRI is now more concerning for bilateral apical orbital involvement as scattered and apical enhancement becomes more pronounced (Figure 3).

At this juncture, a decision on how to manage the patient's orbital involvement is of the utmost importance. With the patient's right orbit clearly affected with multiple cranial neuropathies and now evidence of involvement on MRI, the decision is made to proceed with exenteration of the right eye. Local irrigation and packing with amphotericin B is also performed.

Although the patient had tolerated the exenteration well, his course continues to decline. Over the ensuing several days, the patient develops respiratory decompensation and renal failure. He requires intubation and ultimately develops sepsis and dies.

DISCUSSION

Mucormycosis is ubiquitous and thrives in high glucose and acidic conditions. Rhino-orbital-cerebral mucormycosis sequentially involves the nose, sinuses, eyes, and brain. Approximately 70% of patients who have rhino-orbital-cerebral mucormycosis also have diabetes mellitus, most of whom have ketoacidosis at the time of presentation. Absence of the classical sign of a painful black necrotic eschar on the palate should not exclude the diagnosis. The diagnosis should be made as early as possible for the best prognosis and before this sign presents. Treatment involves multiple modalities: antifungal therapy, surgical debridement of involved tissues, and control of underlying disease condition.[2]

Surgical debridement is critical due to this fungus's aggressive nature and difficulty in its eradication by medical treatment alone.

In summary, our patient has invasive mucormycosis sinusitis with clear involvement of the right orbit and possible involvement of the left orbit based on MRI. We are then left with the medical and ethical question of how to proceed: should we exenterate, and if so, should we exenterate just the right eye or both?

Loss of an eye, and to an even greater extent, both eyes, would undoubtedly have a profound impact on our patient if he survives. On the other hand, if we decide to forgo exenteration and our patient dies, we will certainly be left with the question of whether exenteration might have saved his life. [3]

Ultimately, our patient undergoes exenteration of the right eye. Pathology, however, is without evidence of mucormycosis. Of course, the absence of evidence is not evidence of absence. Perhaps, there was poor sampling or sectioning, or perhaps the medical therapy was working. In fact, the vascular thrombosis seen on pathology was suggestive of eradicated disease.

The prognosis of rhino-orbital-cerebral mucormycosis is poor with 62% mortality overall. The worst prognosis is in those patients with brain, cavernous sinus, or carotid involvement.[4]

CONCLUSION

Mucormycosis is an important diagnosis to have on a clinician's differential when encountering a poorly controlled diabetic patient with periorbital swelling, pain, ophthalmoplegia, or blurred vision. Early diagnosis and treatment is critical for the best prognosis of rhino-orbital-cerebral mucormycosis. In addition to antifungal therapy and controlling the underlying condition, surgical debridement is essential. However, the decision to exenterate or not to exenterate should not be taken lightly given the profound impact it will have on the patient's life. ■

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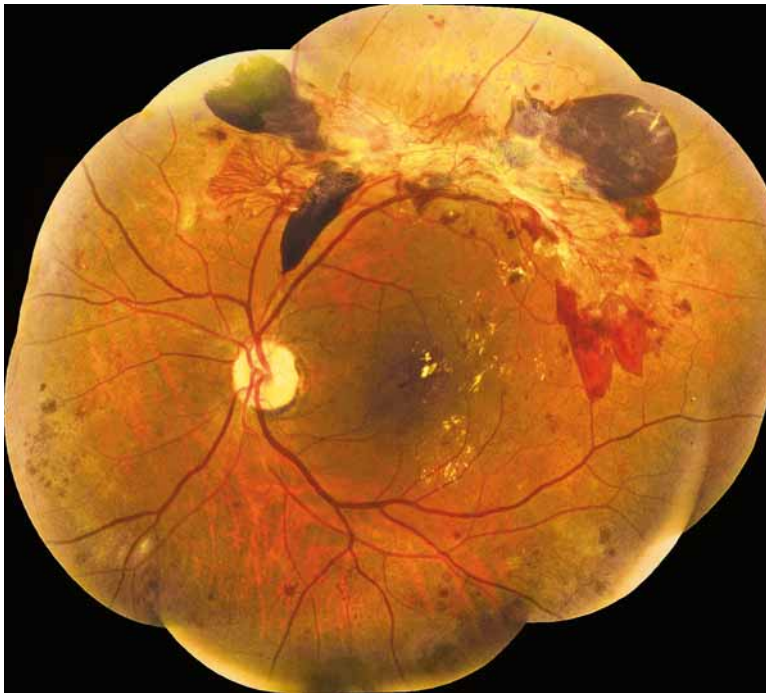
MANAGING RETINA PATIENTS



Proliferative diabetic retinopathy

By Mark E. Tafoya, OD, MD

The field of retina is exciting. It is continually changing. Opportunities abound. What's more, the treatment options we can offer our patients are forever increasing. When I was in optometry school and would diagnose a macular hole, I would tell the patient that nothing could be done and there was a chance that the same thing could happen in his fellow eye. But, now I can successfully surgically repair many macular holes.

In my office, I see people from all walks of life and of all ages. My patients span the gamut from premature newborns who are only days old all the way to great-grandparents who are in their early 100s. Retinal conditions affect all races. And here in Hawaii we have a melting pot of ethnicities represented. Retinal disease can also affect all socioeconomic groups. So the diversity in patients is very interesting to me.

In addition to the diversity of my patient base, my typical day at Pacific Retina Care is forever changing. One would think that I have set clinic days and set surgery days that were the same day every week. But because I am on call 24 hours per day and 7 days per week, I can be called in at any time and on any day. About one third of my surgical cases are unscheduled emergencies that I perform after clinic in the evening or on weekends. Because I treat every patient as an individual, even the encounter varies from patient to patient. Surprisingly, there is quite a variety of retinal diseases.

Out of all the patients I see, there are four most common categories of disease that I encounter.

Diabetic retinopathy

Diabetic eye disease is the most common condition that I encounter. All of us know that diabetes is of epidemic proportions. According to the American Diabetes Association (ADA), diabetes affects more than 25 million Americans.[1] Sadly, many patients with diabetes are undiagnosed; by the time the patient sees me, he or she has severe diabetic eye disease. The ADA

See **Retina** on Page 4

INSIDE:

Cataract

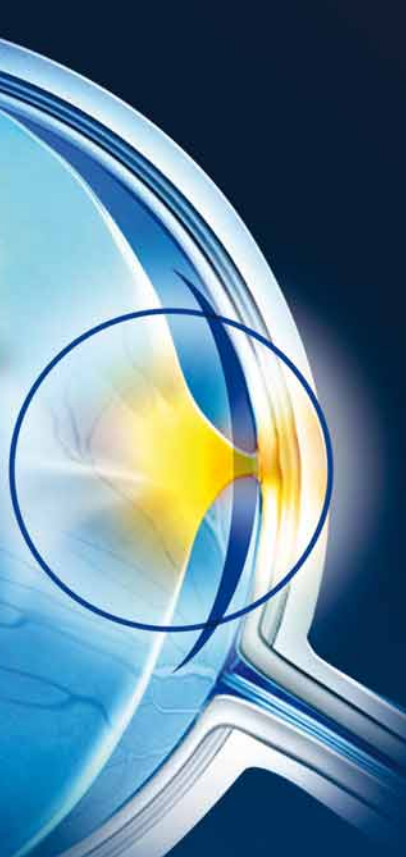
The cataract patient's journey

Cataract removal has been, and will likely remain for some time to come, a cornerstone of eye care and a major source of revenue for most ophthalmic practices.

Anyone who works in the eyecare field should have at least a passing understanding of how cataracts develop, the surgery that removes them, the postoperative routine, and the rapidly evolving technology of intraocular lenses (IOLs).

PAGE **10**

ONE INJECTION, EARLY INTERVENTION.



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The **FIRST** and **ONLY** pharmacologic treatment for symptomatic Vitreomacular Adhesion (VMA).[1]

Indication

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

Important Safety Information

Warnings and Precautions

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

Adverse Reactions

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

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

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Reference: 1. JETREA [package insert]. Iselin, NJ: ThromboGenics, Inc.; 2012.

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JETREA™
(ocriplasmin)
Intravitreal Injection, 2.5 mg/mL

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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

1 INDICATIONS AND USAGE

JETREA is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion.

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

Must be diluted before use. For single-use ophthalmic intravitreal injection only. JETREA must only be administered by a qualified physician.

2.2 Dosing

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

2.3 Preparation for Administration

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

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

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

2.4 Administration and Monitoring

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

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

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

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

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

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

After injection, any unused product must be discarded.

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

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Decreased Vision

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

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

5.2 Intravitreal Injection Procedure Associated Effects

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

5.3 Potential for Lens Subluxation

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

5.4 Retinal Breaks

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

5.5 Dyschromatopsia

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

6 ADVERSE REACTIONS

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

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

6.1 Clinical Trials Experience

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

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

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

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

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

6.2 Immunogenicity

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Teratogenic Effects

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

8.3 Nursing Mothers

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

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

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

10 OVERDOSAGE

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity, mutagenicity or reproductive and developmental toxicity studies were conducted with ocriplasmin.

13.2 Animal Toxicology and/or Pharmacology

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

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

14 CLINICAL STUDIES

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

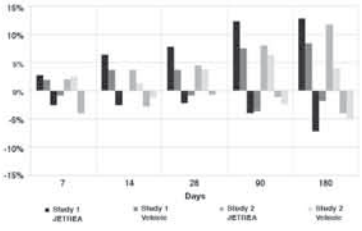
Patients were treated with a single injection of JETREA or vehicle. In both of the studies, the proportion of patients who achieved VMA resolution at Day 28 (i.e., achieved success on the primary endpoint) was significantly higher in the ocriplasmin group compared with the vehicle group through Month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

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

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

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

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



16 HOW SUPPLIED/STORAGE AND HANDLING

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

Storage

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

17 PATIENT COUNSELING INFORMATION

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

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

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U.S. License Number: 1866

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

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Retina

Continued from page 1

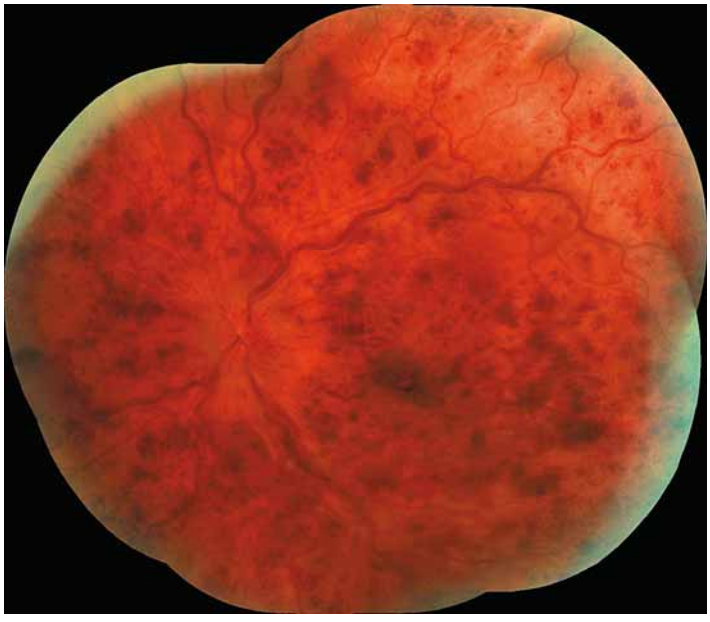
also says diabetes is the leading cause of new blindness in the U.S.[2]

In early diabetic retinopathy, we follow patients closely with dilated fundus exam, HD-OCT, fluorescence angiography, and B-scan imagery when indicated. As the disease progresses, patients may require closer monitoring, intravitreal injection, and laser treatment, all of which I perform in-office. If patients develop a non-clearing vitreous hemorrhage or tractional retinal detachment, then surgical intervention is offered. Also, macular edema can occur, which can be improved by anti-VEGF injections, steroids, or laser treatment.

The two main categories of diabetic retinopathy—proliferative and non-proliferative—differ in the formation of neovascularization. In proliferative disease, new blood vessels form at the optic nerve, elsewhere on the retina, or on the iris. These vessels are weak and leaky. Neovascularization of the retina leads to tractional retinal detachment. Neovascularization of the iris can cause a form of glaucoma. Either type of retinopathy can also involve macular edema.

Age-related Macular Degeneration

Age-related macular degeneration (AMD) affects 19 million Americans.[3] The majority has dry AMD. Currently, there is research on various treatments for dry AMD, but there are no FDA-approved treatments available at this time. More than 1.7 million patients have the wet form.[4] Wet AMD is characterized by leaking fluid or blood as a result of neovascularization. Fortunately, most cases of wet AMD have a positive outcome with anti-VEGF agents administered to the eye via intravitreal injection. I perform this procedure many times during the day to affected patients, often on a monthly basis.



Central retinal vein occlusion (CRVO)

There are many anti-VEGF medications available to choose from, such as Lucentis (ranibizumab, Genentech), Avastin (bevacizumab, Genentech), and Eylea (aflibercept, Regeneron). Information from the recent CATT Trial, which compared the use of Lucentis with Avastin head to head for the treatment of wet AMD, resulted in finding them to be equally effective when given monthly.[5] Eylea is the newest agent available, and it can be administered every other month rather than monthly. It has been found to be equally effective compared with monthly dosing of Lucentis for wet AMD.[5]

My goal for treating wet AMD is to get the macular region dry in OCT—no swelling due to intra- or sub-retinal fluid. I used clinical examination, HD-OCT, and fluorescein angiography to evaluate the response to these anti-VEGF agents. The field of retinal pharmacology is rapidly evolving. Several companies are currently testing their medication in the hopes that they can find a longer acting and more potent agent with an improved delivery vehicle. In the future, a combination of medications, each doing its own role, looks to provide the best promise for treating AMD.

Vascular occlusive disease

Retinal vein occlusion (RVO) is the second most common retinal vascular disease following diabetic retinopathy.[6] The spectrum of RVO includes central retinal vein occlusion (CRVO), hemi-retinal vein occlusion (HRVO), and branch retinal vein occlusion (BRVO). Patients with RVO often develop sudden painless loss of vision. Risk factors include hypertension, diabetes, age, anatomical predisposition, smoking, hyperlipidemia, hypercoagulable states, and glaucoma/elevated intraocular pressure.[7] VEGF plays a key role in the evolution and progression of RVO disease. Some of the highest levels of VEGF are often present in RVO patients. The mechanism of vision loss can be due to macular edema, neovascularization, and macular ischemia.[8] Neovascularization can

lead to neovascular glaucoma, vitreous hemorrhage, and tractional retinal detachment. Fortunately, there are more treatment options for RVO-associated macular edema today than in the past. Due to the high levels of VEGF present in this disease, anti-VEGF agents are quite effective. In addition, combination therapy, consisting of anti-VEGF injections, steroids, and laser, seems to provide the most effective mode of treatment in my office.

Anatomical disease

Treatments of retinal anatomical changes—retinal detachments, retinal tears, macular holes, and epiretinal membrane—most often involve surgery. However, the enzyme Jetrea (ocriplasmin) has been FDA approved for symptomatic vitreomacular adhesion (VMA). The ability to treat VMA with an injectable agent is attractive due to reduced risk compared with surgery. It has been shown to have a positive outcome in some patients. This new medication can be used in some macular hole cases and, if successful, the patient will avoid having to position face-down, as is the case after macular hole surgery.[9] Jetrea could also be used in cases of diabetic macular edema that show VMA.

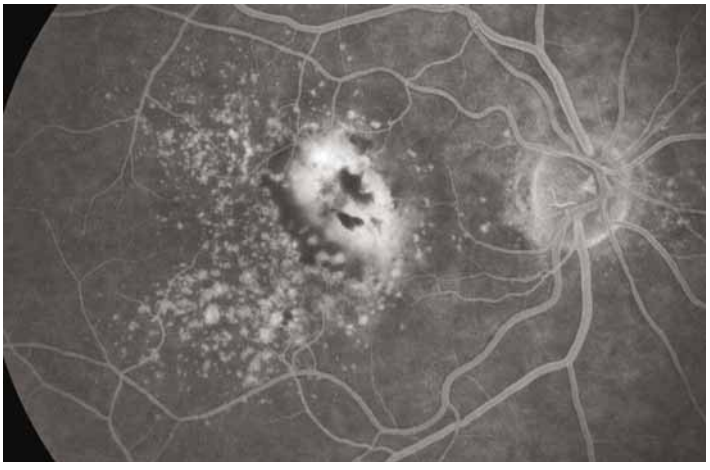
Working with an eyecare professional

Dr. Mark E. Tafoya relies on his assistants to help him manage retina patients in many ways, including:

- Taking a thorough case history, performing preliminary testing, performing all diagnostic testing, and scribing
- Preparing patients for treatment and assisting with procedures
- If surgery is required, educating patients in preparation for consent with the doctor; scheduling the case with the hospital; ensuring that all paperwork is prepared
- Facilitating communications with patients, hospitals, other doctors' offices, and pharmacies

Retinal detachments and retinal tears, if detected early, can be treated in-office with pneumatic retinopexy and laser/cryotherapy. The best case for pneumatic retinopexy is a patient with a single retinal break in the superior retina. These patients often recover faster than those that must go to surgery for vitrectomy with or without scleral buckle. Small-gauge instrumentation for vitrectomy has become available over the past 10 years, and I use it in every vitrectomy case that I perform. Small-gauge, disposable instruments and newer vitrectomy instruments have produced more efficient retinal surgery than when I was a resident and retina fellow. I am able to perform complex retinal detachment repairs, macular hole repairs, and epiretinal membrane removal in less time and with less trauma. Clearly, these new technologies and treatments lead to better outcomes and faster recovery times for our patients.

Retina is an exciting specialty. With the help of my assistants, I can effectively manage my patients and address their retinal needs.◗



Courtesy of Mark E. Tafoya, OD, MD

Wet age-related macular degeneration fluorescence angiography

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ADVANCE YOUR CAREER THROUGH CERTIFICATION

By Liz Meszaros

If you're an ophthalmic assistant or technician wondering about your career options, consider the many ophthalmic certification options open to you. Broader employment opportunities, enhanced job mobility, and increased earning power are just some of the benefits of becoming a certified ophthalmic assistant or technician. Public recognition and an enhanced acceptance by future managed healthcare systems are also benefits.

Your first step to becoming certified should be a visit to the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO) Web site, *www.jcahpo.org*. JCAHPO offers certification and continuing education to all ophthalmic allied health personnel. For everyone interested, this process involves 6 steps:

- **Fulfill required education and work experience**
- **Apply for initial certification**
- **Successfully complete the exam for initial certification**
- **Keep up with required continuing education credits**
- **Apply for re-certification every 3 years**
- **Advance to the next level of certification**

JCAPHO provides 3 levels of certification, with each requiring pre-set eligibility requirements and successfully passing an exam. The 3 levels begin with an entry-level certification and proceed to advanced-level certification:

Take-Home Message

Ophthalmic assistants and technicians can expand their career options by earning ophthalmic certifications. Diverse employment opportunities, enhanced job mobility, and increased earning power are just some of the benefits of becoming a certified ophthalmic assistant or technician.

Certified Ophthalmic Assistant (COA): This is the core level of certification. Some of the more common tasks performed by COAs include:

- **Measuring visual acuity**
- **Instilling ocular medications**
- **Taking medical and family histories**
- **Performing manifest refractometry**
- **Instructing patients about medications, tests, and procedures**
- **Coordinating patient flow**
- **Measuring IOP using applanation tonometry**
- **Taking part in telephone triage**
- **Measuring pinhole acuity**
- **Measuring, comparing, and testing the pupils**

Certified Ophthalmic Technician (COT): This intermediate level of certification is different from COA certification in that instead of 6 months to 1 year of training required for COA certification, COT certification is 1 to 2 years long. COTs have more responsibilities and technical skills than COAs, as well as more experience. In general, COTs have worked as either a COA for at least 1 year or graduated from training programs offered by the Commission on Accreditation of Ophthalmic Medical Programs (CoA-OMP), Certified Medical Assistant (CMA), or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredited training program.

Certified Ophthalmic Medical Technologist (COMT): Working at the highest levels of JCAHPO certification, the COMT can perform additional jobs including obtaining ophthalmic photographs, using ultrasound, and providing instruction and supervision of other ophthalmic personnel. COMTs have a higher level of responsibility and expertise than either COAs or COTs and are expected to have the ability to make clinical and technical judgments. Training generally lasts 2 or more years.

Go on to subspecialize

Once certified at any of these levels, ophthalmic healthcare providers can also become certified in subspecialty areas, such as ophthalmic surgical assisting (OSA). OSAs assist ophthalmologists through the entire surgical process, including pre-op, post-op, and follow-up patient care. OSAs are required to be knowledgeable in:

- **Pre-operative patient preparation**
- **Surgical instrument use**

See **Certification** on page 8

For more than 20 years, Liz Meszaros has been covering medical news. Reach her at lizm32@ptd.net.


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Certification

Continued from page 6

- **Aseptic technique**
- **Surgical procedures**
- **Surgical complications**
- **Surgical pharmacology.**

The JCAHPO has made available the subspecialty certification guidelines for OSA, which are available at *www.jcahpo.org/certification/osa.aspx*, as well as the "Ophthalmic Surgical Assisting Independent Study Course," available at *www.jcahpo.org/certification/osa.aspx*.

Specialty certifications are also available in the following subspecialties:

Registered ophthalmic ultrasound biometrist (ROUB): ROUB certificate holders specialize in A-scan biometry of the eye and assist ophthalmologists in the analysis of imaging for diagnostic and treatment purposes. They administer intraocular lens (IOP) power calculations, perform instrument settings, and must have a strong knowledge of the basic physics and keratometry of the eye and exam techniques and procedures related to biometry.

Certified diagnostic ophthalmic sonographer (CDOS): CDOS certificate holders perform critical tasks related to B-scan sonography in clinical settings under the supervision and direction of ophthalmologists. They must have superior knowledge of the anatomy and physiology of the eye and orbit, as well as the ability to perform sonographic exams to analyze the various components of the eye to help diagnose patients.

More about certification opportunities

For ophthalmic assistants and technicians interested in certification, a wealth of information is available from several sources. For example, to discover more about certification and requirements, go to the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO) Web site, *www.jcahpo.org/certification/coa.aspx* or *www.jcahpo.org/certification/cot.aspx*.

In addition, the 2013 edition of JCAHPO's "Criteria for Certification and Recertification" is available at *www.jcahpo.org/certification/pdfs/CriteriaforCert_FULL.pdf*.

Other informative Web sites:

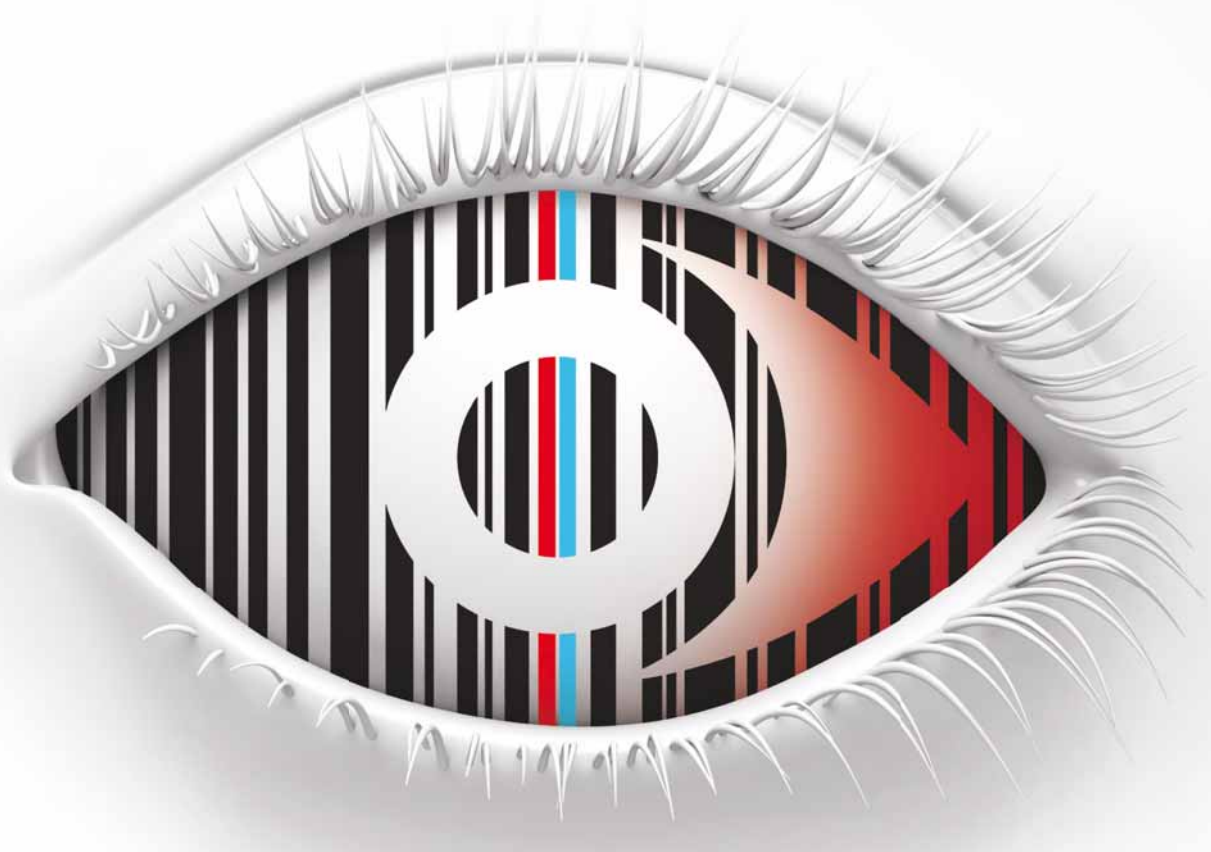
- **American Society of Ophthalmic Administrators** (ASOA): *www.asoa.org/coe*.
- **Association of Technical Personnel in Ophthalmology** (ATPO): *www.atpo.org/ATPO/Home/ATPO/Default.aspx*.
- **ACTIONed premier e-learning network for ophthalmic professionals:** *http://action.jcahpo.org/*.
- **Commission on Accreditation of Ophthalmic Medical Programs** (CoA-OMP): *www.coa-omp.org/*.
- **Discover Eye Careers:** www.discovereyecareers.org/.
- **JCAHPO/ATPO annual continuing education program:** www.jcahpo.org/ace2013/.

Corporate certified ophthalmic assistant (CCOA): CCOA certificate holders are industry sales representatives who connect with administrators, physicians, and other healthcare personnel and work in the corporate segment of the eyecare field.

Another certification option is the Certified Ophthalmic Executive (COE). COE applicants must have at least 3 years of healthcare administration experience, 1 or more years of ophthalmic practice management experience, and a working knowledge of administrative duties in 7 content areas, including:

- **Basic ophthalmic knowledge**
- **Finance and accounting**
- **Business operations**
- **Marketing**
- **Risk management and regulatory compliance**
- **Human resources**
- **Management information systems**

COE applicants must complete the COE examination at a Pearson Vue Testing Center, of which there are approximately 5,000 throughout the country, or at the American Society of Ophthalmic Administrators (ASOA) Congress on Ophthalmic Practice Management held each spring.



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THE CATARACT PATIENT'S JOURNEY

Take a quick tour through this common surgery

By Frank Celia

Cataract removal is the most frequently performed surgery in the United States, with some 3 million patients undergoing the procedure each year.[1] It is also one of the most successful surgical procedures, producing very favorable visual outcomes and few adverse side effects. It has been, and will likely remain for some time to come, a cornerstone of eye care and a major source of revenue for most ophthalmic practices.

Anyone who works in the eyecare field should have at least a passing understanding of how cataracts develop, the surgery that removes them, the postoperative routine, and the rapidly evolving technology of intraocular lenses (IOLs). Following is a brief sketch of what today's patients with cataracts can expect.

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Symptoms and diagnosis

The lens of the human eye—a clear, flexible orb made mostly of water and protein—sits directly behind the iris and pupil. It focuses incoming light on the retina. Muscles around the lens cause it to change shape when we focus on objects near or far. For some unknown reason, around age 40, these muscles start to fail. This is why people in this age group and older have trouble reading small print, a refractive condition called presbyopia.

Another result of aging: proteins in the lens begin to clump together, causing some areas of the lens to become cloudy, creating a cataract. As the cataract grows, the cloudiness increases and vision declines. The surgeon breaks up this lens into pieces, removes them, and then inserts a clear plastic IOL, which will mimic the function of a natural lens.

Early cataracts may cause changes in vision that prompt a person to seek medical care. A cataract can be diagnosed during a routine eye examination or in the course of treatment for other ocular conditions. Changes will be gradual in the beginning. Sight may be cloudy or slightly blurry. Sunlight or lamplight may appear too bright or glaring. During nighttime driving, oncoming headlights may seem to contain more glare than previously. Colors may lose their luster.

Depending on the location of the growing cataract, near vision may actually improve somewhat in the early stages. However, this "second sight" is temporary, quickly replaced by vision impairment. Other differently positioned cataracts may induce few symp-

Take-Home Message

Cataract surgery, the most frequently performed surgery in the United States, is about as complication-free as a surgical procedure can get. Staying informed about this eyecare mainstay can help you better communicate to patients, thereby increasing your value to patients and employers alike.

toms early on, but then cause dramatic impairment after they become well developed. Strong multifocal spectacles, different lighting, and magnification may help alleviate early, pre-surgery symptoms.

Surgery—risks, results, complications

A cataract surgery procedure, free from complications, lasts only about 10 minutes. Most patients feel only slight discomfort afterward, and what little pain there is can be managed with over-the-counter medications such as acetaminophen. Most surgeons prescribe anti-inflammatory and antibiotic drops that the patient instills for about a week after surgery. Many patients recover all their vision in a few hours, but for others it may take up to a week before cloudy, blurry, or distorted vision subsides.

The most serious side effect associated with cataract surgery is infection, known as endophthalmitis, but it is extremely rare. Only about 1 eye in 1,000 becomes infected. However, because infection can cause blindness, it is still a risk eyecare practitioners take seriously. In addition to antibiotic therapy, patients are asked to avoid hot tubs and swimming pools, exposure to irritants such as grime, dust, or wind, and eye-rubbing.

If both of a patient's eyes have cataracts, the surgeon may wait 2 days to 2 weeks to perform the second surgery. Without complications, patients undergoing cataract surgery should take no more than a month to fully recover.

IOL options

Most patients will receive monofocal IOLs, that is, lenses that will produce only one kind of refraction, either distance correction

The most serious side effect associated with cataract surgery—endophthalmitis—is extremely rare. Only about 1 eye in 1,000 becomes infected. However, because infection can cause blindness, it is still a risk eyecare practitioners take seriously.

or near correction. Most patients must choose between the two. In rare cases, a combination of intermediate, near, and distance vision can be achieved by implanting a distance lens in one eye and a near lens in the other, creating monovision—vision that is not totally binocular (using both eyes at once). But, if the patient has no previous experience with monovision correction, it can be a difficult skill to learn in older age.

Several multifocal and one accommodative IOLs are approved for use in the U.S. These so-called premium lenses employ various optical strategies to give the patient some level of near, intermediate, and far vision. However, all the premium lenses currently available induce some degree of visual compromise and are known to produce side effects, such as nighttime glare and halos. Nevertheless, some patients are still willing to pay the $2,500 or so extra per surgery to reduce dependence on reading spectacles.

One of the most frequent questions new cataract patients ask is why Medicare and private insurance does not cover the cost of premium IOLs. The reason is due to the Centers for Medicare and Medicaid Services (CMS) regulatory ruling several years ago that the vision correction offered by premium lenses was tantamount to a refractive surgery procedure, such as LASIK, therefore surgeons could charge extra for it. In any case, premium IOLs require additional surgical expertise and follow-up care—and the lenses themselves are more expensive—eyecare practitioners earn that extra fee.

The next big IOL innovation expected to arrive in the U.S. is a premium toric lens that corrects for astigmatism. The technology has been available in Europe for some time and has produced favorable outcomes there. Several toric IOLs recently received FDA approval in the U.S.

Prevent Blindness America estimates there are more cataract cases worldwide than glaucoma, macular degeneration, and diabetic retinopathy combined.[1] Unlike those other diseases, the treatment for cataracts is well established and about as complication-free as a surgical procedure can get. No doubt, innovations will continue to occur, but the fundamental aspects of the surgery will likely remain constant. Staying informed about this eyecare mainstay can help you better communicate to patients, thereby increasing your value to patients and employers alike.

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IMPROVE PATIENT FLOW BY USING COMMUNICATION, FLEXIBILITY, CONSISTENCY

By Janet L. Carter, OD, FAAO

Take-Home Message

Streamlining the patient flow process can help build a high-performing practice. Implementing and enforcing three factors—communication, flexibility, and consistency—can enhance patient flow, thereby increasing the success and profitability of a practice.

All of us have experienced it: a day where the doctor just can't seem to run on time, the waiting room is full, and everyone is unhappy at having to wait. Few things are more frustrating for any optometric practice. Fortunately, with a little planning and a lot of patience, these days can be greatly reduced and your patients' experience enhanced.

Three things are required to improve patient flow and keep the practice on schedule: communication, flexibility, and consistency.

Communication begins when the patient makes the appointment. Your scheduler needs to clearly establish why the patient wants an appointment in order to allow the proper time. A patient might say, "I'm coming because I want the doc to check my glasses," when he or she really means, "I think my glasses need an adjustment." On the other hand, that statement could just as easily mean "I haven't had an eye examination in 5 years, and I am really not seeing well." A good EHR (electronic health records) system could help you here. Your EHR would allow you to quickly look up a patient's record to verify the most recent visit; that would tell you if a comprehensive eye examination is warranted. If the patient is new to your office, ask about his or her most recent eye examination and where it was done. I 've had patients tell me "Oh, I had an eye exam last week," only to uncover that the "examination" was really just a screening at the DMV.

If your scheduler knows exactly why patients are coming , then the scheduler can more easily advise the patients how long they should plan to be at your office so the patients can plan accordingly. Let the patient know ahead of time if the exam will require dilation; this avoids long conversations about it on the day of the appointment and may prevent the patient from rescheduling the dilation because of post-appointment plans. If the patient is interested in contact lenses, but has never worn them before, he or she will need to allow time to learn application and removal; if it's late in the day or if you are short-staffed, the patient may need a second visit for this. Knowing these things ahead of time can greatly reduce frustration for all concerned.

Planning ahead

The scheduler can also greatly assist patient flow by getting as much information as possible about vision plans or medical insurance prior to the appointment. Have a list handy of plans or procedures that may require pre-authorization so that it can be taken care of prior to the scheduled visit, thereby shortening wait times. Many practices e-mail required paperwork to patients in advance to be filled out ahead of time. Planning ahead is also very useful if you can note any special circumstances, such as language or mobility difficulties, right on the schedule. Many practices have one room that is wheelchair friendly, so such notes can insure that the proper room is available at the right time. Also, if you have a technician or optician who speaks a second language, you can be sure that person will be available when a particular patient needs assistance.

Good communication between the doctor and staff is also important. If I have a meeting or special event, I inform my staff ahead of time. That way they know it is important to me to finish on time and will schedule accordingly. Talk with the doctor and be sure you understand how much time to allow for specific types of appointments. If a patient calls and says he or she might be a little late, take a moment to ask the doctor's advice on possibly rescheduling. Try to show the doctor the schedule at the beginning of the day. Often, the doctor will recognize patient

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names as folks who might take a little longer to examine or require a little extra care. After you have been with the practice for a while, you might also recognize those names and schedule accordingly. If you are in a group practice, remember that every doctor is different. In that situation, you might need to vary the schedule based on the doctors' individual needs. This can be especially true if you have doctors who specialize in different clinical areas. A low-vision practitioner will have far different scheduling needs than someone who sees mostly young and healthy patients for routine vision care.

Flexibility keeps the pace brisk

Everyone involved in the practice needs to have the authority to change things up once as needed. For example, it's 9:35 and your 9:30 appointment hasn't shown, but the 10 o'clock patient just finished her paperwork. The technicians should feel free to get her started with pretesting. The 9:30 might not even show, but if the patient does eventually make it, he can expect a little longer wait in return for being tardy. Your tech can always tell the 10 o'clock patient that she might have to wait a little while after the pretesting to see the doctor. This creates a perfect opportunity for your tech to suggest the patient browse your optical during the wait. Always have at least one optician in the optical area to help unexpectedly early patients. Patients appreciate the chance to look at frames before being dilated or poked, plus it diverts the patients' attention from having to wait.

It is advantageous if you can have several waiting areas within your office space. That way, the tech can do pre-testing as patients are checked in, then direct them to wait for the doctor in a different area. Patients will then feel the appointment is in progress, and the perception of time waited may be less. Of course, always have interesting reading material or patient education videos in all the waiting areas. These secondary waiting areas can also be a useful place for patients to wait while they are dilating.

Optimal patient flow requires:

1. Communication
2. Flexibility
3. Consistency

Flexibility is also the key to setting your schedule for the day. Most practices have set times for examinations and briefer time slots in between for quicker checks such as emergencies and contact lens follow-ups. However, your scheduler should be empowered to change these around a bit without necessarily adding appointments as warranted. If, for example, you have a family of three coming in together, and there is an open quick check slot between the exam appointment times, move the examinations together and the quick check to the end of that combined time slot. It is often much easier for the doctor to see all the family members together, because health histories and the like can be discussed at the same time. Nothing will disrupt patient flower faster than having the doctor interrupt several family members' examinations by running to another room—or worse yet requesting the room be vacated—to see a contact lens check who was scheduled in between and doesn't have time on a busy workday to wait until the entire family is seen. Avoid that scenario by moving the quick check spot to later.

Consistency enforces perimeters

As important as it is for all staff involved with the patient to be flexible with timing and scheduling concerns, consistency is just as crucial to maintaining proper patient flow. Staff will feel more comfortable in being proactive and flexible by knowing there are consistent rules to guide them. This goes back to communication.

Ask your doctor to set guidelines for changing and rearranging appointments, and then stick to them. If the doctor will insist on rescheduling if a patient is late, know the drop dead time beyond which the patient cannot show up and be seen. In other words, if the doctor won't see patients who are more than 15 minutes late, the rule isn't 15 minutes for some people and 20 for others. Of course, this shouldn't apply to true emergencies. If the doctor knows that she can count on staff to enforce her rules, she will be more comfortable with giving staff the authority to be flexible within those boundaries. Keep in mind that to make the process work effectively, the doctor needs to be consistent in her own instructions.

All of your patients deserve the same consideration. Make sure that there aren't different sets of rules for different patients or staff. If everyone communicates this properly, your office will run smoothly and everyone will be happier.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD) and Macular Edema following Central Retinal Vein Occlusion (CRVO).

DOSAGE AND ADMINISTRATION

FOR OPHTHALMIC INTRAVITREAL INJECTION ONLY. EYLEA must only be administered by a qualified physician.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks (*see Clinical Studies*).

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (monthly).

Preparation for Administration

EYLEA should be inspected visually prior to administration. If particulates, cloudiness, or discoloration are visible, the vial must not be used. Using aseptic technique, the intravitreal injection should be performed with a 30-gauge x ½-inch injection needle.

The glass vial is for single use only. Remove the protective plastic cap from the vial. Clean the top of the vial with an alcohol wipe. Remove the 19-gauge x 1½-inch, 5-micron, filter needle from its pouch and remove the 1-mL syringe supplied in the carton from its pouch. Attach the filter needle to the syringe by twisting it onto the Luer lock syringe tip. Push the filter needle into the center of the vial stopper until the needle touches the bottom edge of the vial. Using aseptic technique withdraw all of the EYLEA vial contents into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle. Remove the filter needle from the syringe and properly dispose of the filter needle. **Note:** Filter needle is **not** to be used for intravitreal injection. Remove the 30-gauge x ½-inch injection needle from the plastic pouch and attach the injection needle to the syringe by firmly twisting the injection needle onto the Luer lock syringe tip.

When ready to administer EYLEA, remove the plastic needle shield from the needle. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top. To eliminate all of the bubbles and to expel excess drug, SLOWLY depress the plunger so that the plunger tip aligns with the line that marks 0.05 mL on the syringe.

Administration

The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include surgical hand disinfection and the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a topical broad–spectrum microbicide should be given prior to the injection.

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

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

Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before EYLEA is administered to the other eye.

After injection, any unused product must be discarded.

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

DOSAGE FORMS AND STRENGTHS

Single-use, glass vial designed to provide 0.05 mL of 40 mg/mL solution for intravitreal injection.

CONTRAINDICATIONS

EYLEA is contraindicated in patients with

- Ocular or periocular infection
- Active intraocular inflammation
- Known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as severe intraocular inflammation

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments (*see Adverse Reactions*). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (*see Dosage and Administration and Patient Counseling Information*).

Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA (*see Adverse Reactions*). Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (*see Dosage and Administration*).

Thromboembolic Events. There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence in the VIEW1 and VIEW2 wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA (*see Clinical Studies*). The incidence in the COPERNICUS and GALILEO CRVO studies during the first 6 months was 0% (0/218) in patients treated with EYLEA 2 mg every 4 weeks compared with 1.4% (2/142) in patients receiving sham treatment (*see Clinical Studies*).

ADVERSE REACTIONS

The following adverse reactions are discussed in detail in other sections of the labeling:

- Endophthalmitis and retinal detachments (*see Warnings and Precautions*)
- Increased intraocular pressure (*see Warnings and Precautions*)
- Thromboembolic events (*see Warnings and Precautions*)

The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Injection Procedure. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, increased intraocular pressure and vitreous detachment.

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

A total of 2042 patients treated with EYLEA constituted the safety population in four phase 3 studies. Among those, 1441 patients were treated with the recommended dose of 2 mg.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months (*see Clinical Studies*).

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

Adverse Reactions	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%
Eye pain	9%	9%
Cataract	7%	7%
Vitreous detachment	6%	6%
Vitreous floaters	6%	7%
Intraocular pressure increased	5%	7%
Conjunctival hyperemia	4%	8%
Corneal erosion	4%	5%
Detachment of the retinal pigment epithelium	3%	3%
Injection site pain	3%	3%
Foreign body sensation in eyes	3%	4%
Lacrimation increased	3%	1%
Vision blurred	2%	2%
Retinal pigment epithelium tear	2%	1%
Injection site hemorrhage	1%	2%
Eyelid edema	1%	2%
Corneal edema	1%	1%

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were retinal detachment, retinal tear, and endophthalmitis. Hypersensitivity has also been reported in less than 1% of the patients treated with EYLEA.

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The data described below reflect exposure to EYLEA in 218 patients with macular edema following CRVO treated with 2 mg dose in 2 double-masked, controlled clinical studies (COPERNICUS and GALILEO) for 6 months (*see Clinical Studies*).

Table 2: Most Common Adverse Reactions (≥1%) in CRVO Studies

Adverse Reactions	EYLEA (N=218)	Control (N=142)
Eye pain	13%	5%
Conjunctival hemorrhage	12%	11%
Intraocular pressure increased	8%	6%
Corneal erosion	5%	4%
Vitreous floaters	5%	1%
Conjunctival hyperemia	5%	3%
Foreign body sensation in eyes	3%	5%
Vitreous detachment	3%	4%
Lacrimation increased	3%	4%
Injection site pain	3%	1%
Vision blurred	1%	<1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were cataract, eyelid edema, corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD and CRVO studies, the pre-treatment incidence of immunoreactivity to EYLEA was 1% to 3% across treatment groups. After dosing with EYLEA for 52 weeks (wet AMD), or 24 weeks (CRVO), antibodies to EYLEA were detected in a similar percentage range of patients. Both in the wet AMD and in the CRVO studies, there were no differences in efficacy or safety between patients with or without immunoreactivity.

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

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category C. Aflibercept produced embryo-fetal toxicity when administered during organogenesis in pregnant rabbits at intravenous doses of 3 to 60 mg/kg. A series of external, visceral, and skeletal malformations were observed in the fetuses. The maternal No Observed Adverse Effect Level (NOAEL) was 3 mg/kg, whereas the fetal NOAEL was below 3 mg/kg. At this dose, the systemic exposures based on Cmax and AUC for free aflibercept were approximately 2900 times and 600 times higher, respectively, when compared to corresponding values observed in humans after an intravitreal dose of 2 mg. There are no adequate and well-controlled studies in pregnant women. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is unknown whether aflibercept is excreted in human milk. Because many drugs are excreted in human milk, a risk to the breastfed child cannot be excluded. EYLEA is not recommended during breastfeeding. A decision must be made whether to discontinue nursing or to discontinue treatment with EYLEA, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of EYLEA in pediatric patients have not been established.

Geriatric Use. In the clinical studies, approximately 85% (1728/2034) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 58% (1177/2034) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

Patients with Renal Impairment. Pharmacokinetic analysis of a subgroup of patients (n=492) in one Phase 3 study, of which 43% had renal impairment (mild n=120, moderate n=74, and severe n=16), revealed no differences with respect to plasma concentrations of free aflibercept after intravitreal administration every 4 or 8 weeks. No dose adjustment based on renal impairment status is needed for either wet AMD or CRVO patients.

PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, the patient should seek immediate care from an ophthalmologist (*see Warnings and Precautions*).

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations (*see Adverse Reactions*). Patients should be advised not to drive or use machinery until visual function has recovered sufficiently.

REGENERON

Manufactured by: Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
U.S. License Number 1760

Issue Date: September 21, 2012
Initial U.S. Approval: 2011

FOR THE TREATMENT OF WET AMD*

Permanent **J-code** has been issued for EYLEA® (aflibercept) Injection **effective January 1, 2013**

HCPCS Code	Description	Billing Units
J0178	Injection, aflibercept, 1 mg	2‡

‡With a per 1 mg descriptor, it is important to accurately indicate "2" billing units on the claim form for each 2 mg injection.

TIME BETWEEN TREATMENTS®†

More Information available at www.EYLEA.com

**Neovascular (wet) Age-related Macular Degeneration*

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA

- †EYLEA® (aflibercept) Injection is indicated for the treatment of patients with neovascular (Wet) Age-related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.
- EYLEA is indicated for the treatment of patients with Macular Edema following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly).

IMPORTANT SAFETY INFORMATION FOR EYLEA

- EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported during the post approval use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs in the VIEW 1 and VIEW 2 wet AMD studies in patients treated with EYLEA was 1.8% during the first year. The incidence of ATEs in the COPERNICUS and GALILEO CRVO studies was 0% in patients treated with EYLEA compared with 1.4% in patients receiving sham control during the first six months.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.
- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, increased intraocular pressure, and vitreous detachment.

Please see brief summary of full Prescribing Information on the following page.

REGENERON

11/2012 LEA-0065F-4

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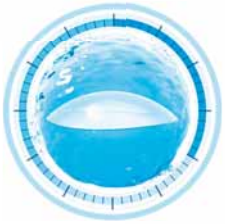

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