A TEAM OF investigators at the National Eye Institute (NEI) has determined that a protein associated with deposition of mineralized calcium in tooth enamel may be related to drusen deposits in patients with dry age-related macular degeneration (AMD).

“The protein is amelotin, which seems to be specific to dry AMD, and may potentially prove to be a therapeutic target in the disease,” said Dinusha Rajapakse, PhD, the first author of the study and a visiting research fellow at the NEI, in Bethesda, MD, working in the laboratory of Graeme Wistow, PhD, chief of the NEI Section on Molecular Structure and Functional Genomics and senior investigator of the study cited in Translational Research.¹

This finding may ultimately prove to be a boon for patients with dry AMD because, unlike wet AMD, there is currently no treatment available for the dry form of the disease.

Hydroxyapatite is a component of bone and

Discovery of protein in eye link to therapeutic options for dry AMD

Mineralized calcium in tooth enamel may be linked to drusen deposits

By Lynda Charters; Reviewed by Dinusha Rajapakse, PhD

Residual refractive errors may be preoperative culprits

By Lynda Charters; Reviewed by Scott M. MacRae, MD

REFRACTIVE SURGEONS HAVE a number of options from which to choose when considering presbyopia-correcting IOLs.

Trifocal IOLs continue to gain in popularity in Europe. One has been approved in the United States, the AcrySof IQ Pan-Optix trifocal IOL (Alcon). However, the downside with these IOLs is that surgeons must be attuned to the presence of residual refractive errors, which seems to be the issue associated with this technology. Those refractive errors can constitute a make or break for patients.

According to Scott M. MacRae, MD, it is mandatory to correct any residual refractive errors before attacking the presbyopia.

“After IOL implantation, when a patient is 20/happy, they see well at all distances; if they are 20/unhappy, I evaluate the residual refractive errors and, if found, try to refine them,” said Dr. MacRae, professor ophthalmology and visual sciences, Flaum Eye Institute University of Rochester, Rochester, NY. Sometimes there is no residual refractive error, and the unhappiness may result from the presence of retinal issues, such as cystoid macular edema, epiretinal membranes, cystoid macular edema; posterior capsular opacification; irregular astigmatism resulting from anterior basement macular dystrophy or dry eye; or unrealistic expectations.

“However, the one that we can treat the best is the residual refractive error,” he noted.

Continues on page 17: Refractive
The first FDA-approved pharmacologic treatment that targets the root pathogenesis of neurotrophic keratitis

Indication
OXERVATE is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

Important Safety Information

WARNINGS AND PRECAUTIONS
Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.

ADVERSE REACTIONS
The most common adverse reaction in clinical trials that occurred more frequently with OXERVATE was eye pain (16% of patients). Other adverse reactions included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, and increase in tears (1%-10% of patients).

For additional safety information, see accompanying Brief Summary of Safety Information on the adjacent page and full Prescribing Information on Oxervate.com/HCP.

Explore the breakthrough therapy at Oxervate.com/HCP
Brief Summary of Safety
Consult the full Prescribing Information for complete product information.

INDICATIONS AND USAGE
OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic keratitis.

DOSE AND ADMINISTRATION
Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration. If a dose is missed, treatment should be continued as normal, at the next scheduled administration. If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

Recommended Dosage and Dose Administration
Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

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 two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1-10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks. Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

Animal Data
In embryofetal development studies, daily subcutaneous administration of cenegermin-bkbj to pregnant rats and rabbits throughout the period of organogenesis produced a slight increase in post-implantation loss at doses greater than or equal to 42 mcg/kg/day (267 times the MRHOD). A no observed adverse effect level (NOAEL) was not established for post-implantation loss in either species. In rats, hydrocephaly and ureter anomalies were each observed in one fetus at 267 mcg/kg/day (1709 times the MRHOD). In rabbits, cardiovascular malformations, including ventricular and atrial septal defects, enlarged heart and aortic arch dilation were each observed in one fetus at 83 mcg/kg/day (534 times the MRHOD). No fetal malformations were observed in rats and rabbits at doses of 133 mcg/kg/day and 42 mcg/kg/day, respectively. In a pre- and postnatal development study, daily subcutaneous administration of cenegermin-bkbj to pregnant rats during the period of organogenesis and lactation did not affect parturition and was not associated with adverse toxicity in offspring at doses up to 267 mcg/kg/day. In parental rats and rabbits, an immunogenic response to cenegermin-bkbj was observed. Given that cenegermin-bkbj is a heterologous protein in animals, this response may not be relevant to humans.

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

Pediatric Use
The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older [see Clinical Studies (14)].

Geriatric Use
Of the total number of subjects in clinical studies of OXERVATE, 43.5% were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis and Mutagenesis Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj.

Impairment of fertility Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male and female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD). In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).
Surgery

1 Avoiding IOL refinements after presbyopia-correction surgery
Surgeons should consider focusing on correcting residual refractive errors before implanting a presbyopia-correcting IOL.

15 Trifocal IOL a key for premium cataract surgery practice
A newly FDA-approved option allows surgeons to meet patient expectations for spectacle independence.

21 Surgeon brings cataract care to underserved patients in the Caribbean
A depot steroid can make significant difference for patients in complicated situations by minimizing postoperative inflammation.

Clinical Diagnosis

23 Ferreting out undiagnosed glaucoma patients in the US
Lessons learned from abroad may reduce the rate of undiagnosed glaucoma in the United States.

Gene Therapy

25 Genetic analysis could predict myopia in children
Future research may lead to the development of a polygenic risk score to help clinicians accurately predict myopia in pediatric patients.

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29 OCT: Illuminating the retina layer by layer
New OCT technologies have isolated the white dot syndromes to distinct retinal layers.

Device Technology

31 Femtosecond laser-assisted RLE offering better outcomes
Pairing a refractive lens exchange with presbyopia-correcting IOL can offer improved patient satisfaction.

Therapeutics

32 Predictable, branded steroids offer control over surgery
Optimizing the ocular surface before surgery by choosing a consistent, predictable postoperative steroid can help surgeons achieve precision.
SPRING HAS ARRIVED, and as the flowers are blooming it is sparking thoughts of hope and renewal.

The Ophthalmology Times® team is continuing to offer the latest COVID-19 content, including videos, blogs, and podcasts. Visit us online at OphthalmologyTimes.com for the latest coverage.

Hope is a key driver for research, and on the cover of this issue, Dinusha Rajapaske, PhD, discusses work with colleagues at the National Eye Institute. The team determined that a protein associated with deposition of mineralized calcium in tooth enamel may be related to drusen deposits in patients with dry age-related macular degeneration. Leading our clinical diagnosis content, this finding may ultimately prove to be a real boon for patients with dry AMD.

Our surgery content examines options that refractive surgeons have today when considering presbyopia-correcting IOLs. Trifocal IOLs continue to gain in popularity in Europe, with one having been approved in the United States, the AcrySof IQ PanOptix trifocal IOL (Alcon). Scott M. MacRae, MD, offers some insight, noting that it is mandatory to correct any residual refractive errors before attacking the presbyopia.

Our special report in this issue focuses on innovations in cataract and presbyopia. Gerd U. Auffarth, MD, PhD, FEBO, discusses a small-aperture procedures in cornea and presbyopia. When paired with multifocal extended depth-of-field technology, the lens delivers extended depth of focus at near, far, and intermediate ranges while reducing halo and glare.

In August, the FDA granted approval for Alcon to market the AcrySof IQ PanOptix trifocal IOL. Surgeons who are using the lens, which is available in spherical and toric versions, agree that it is an important advance in presbyopia-correcting technology. Cathleen M. McCabe, MD, and Rosa Braga-Mele, MD, MEd, share their experiences with the IOL.

Our clinical diagnosis content also includes a look at how ophthalmologists can learn to detect undiagnosed glaucoma in the United States by learning practical lessons from overseas cases. Joshua Ehrlich, MD, MPH, discusses this trend. He points out that the bright spot is that globally a great deal of innovative work is being done, some of which might be applied favorably to the unmet need domestically.

Our gene therapy section includes an overview of research that finds that genetic analysis may predict myopia in children, possibly paving the way for a personalized medicine approach. Researchers note that successfully predicting risks of myopia in children can help clinicians recommend lifestyle changes such as more time outdoors, which can help mitigate or prevent the development of myopia.

In our imaging core, we look at new OCT technologies that have isolated the white dot syndromes to distinct retinal layers. Kathryn Peppe, MD, PhD, tells us that three considerations are key when diagnosing posterior uveitis.

We also examine device technology, with femtosecond laser-assisted RLE offering better outcomes for patients. R. Luke Keenetsch, MD, notes that when paired with presbyopia-assisted RLE, it can result in better results. As the technology surrounding IOLs has evolved, so have patients’ expectations regarding the best possible outcomes after refractive lens-based surgery.

In therapeutics, Inder Paul Singh, MD, explains how predictable, branded steroids can offer control over surgery. He explains that achieving the best surgical outcomes means putting as much effort into choosing a consistent and predictable postoperative steroid as into every other aspect of surgery. He points out that the bright spot is that globally a great deal of innovative work is being done, some of which might be applied favorably to the unmet need domestically.

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On the bright side...
Looking for the positive amid pandemic’s many negatives

Oh, the storm and its fury broke today
Crushing hopes that we cherish so dear
Clouds and storms will in time pass away
The sun again will shine bright and clear

Keep on the sunny side, always on the sunny side
— “Keep on the Sunny Side,”
a song written in 1899 by Ada Blenkhorn and J. Howard Entwhistle

O n the bright side...
Looking for the positive amid pandemic’s many negatives

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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WITH THE CORONAVIRUS pandemic and the government’s advisories to stay in our homes except for essential business or trips to the grocery store, the risk exists that we could become couch potatoes who are eating and drinking too much, exercising too little and becoming lonely and saddened. Determined to not allow this to happen to yours truly, I have resolved along the way to see the positive aspect to each new development in this saga.

TRAVEL RESTRICTIONS
It began when the association between infection and air travel became evident and many companies and universities (including mine) banned or severely restricted air travel. “There is a bright side to this,” I thought.

Because they would not be traveling around the world giving lectures and being visiting professors, I would be able to see a lot more of my brilliant faculty members in meetings and around the institute. I was really looking forward to this.

But then we were told that we should stop meeting in groups and that unless they were engaged in “essential work” such as patient care, faculty should stay at home. So no meetings with my faculty after all.

But keeping on the sunny side, at least I would see the happy smiling faces of my residents and clinical faculty members from time to time.

But then came the rule that we were to wear masks all the time at work, except perhaps when alone in our offices. So no smiling faces to see during the workday.

LET THE BEARD GROW
Again, keeping on the sunny side, I realized this was a golden opportunity to grow a beard and mustache. Not a ridiculously large beard, but the manly kind of silver and white growth that Sean Connery sported when he played the Russian submarine captain in The Hunt for Red October. As all men know, the problem with growing such a beard or mustache is that it looks pretty bad until it has grown out adequately.

Under a mask, no one would see the early scraggly appearance and, when the period of mandatory mask use expired, the dashing end product would be revealed to all!

But then came the rule that hospitals like mine are banning facial hair in order to allow effective seals of the N95 masks to reduce the risk of viral transmission.

“So much for staying on the sunny side,” I thought as my secret plan to look like Sean Connery was dashed. A frown began to develop on my hairless face.

A GLIMMER OF HOPE?
But then today I received an email that revealed there is light at the end of the tunnel. The message was an invitation to speak at a meeting in London, England in August of this year. I have been to London and it is a beautiful city with wonderful people.

“But will the restrictions on travel and limitations on public gatherings be over by August?” I wondered as I read the invitation. Then I came to the sunny side of the message that cautioned against panic over the coronavirus and made a series of recommendations:

“Kindly follow some of the safety precautions like—wash your hands frequently for one hour, kindly include ingredient garlic or ginger in your food or along with the hot water which produces heat and acts as a barrier.”

Reading this list of protective measures restored the smile to my beardless and mustache-less visage.

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

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

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

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

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

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

References:
XIIDRA® (lifitegrast ophthalmic solution), for topical ophthalmic use

Initial U.S. Approval: 2016

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

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

4 CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation [see Adverse Reactions (6.2)].

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

• Hypersensitivity [see Contraindications (4)]

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

In five clinical studies of DED conducted with lifitegrast ophthalmic solution, 1401 patients received at least one dose of lifitegrast (1267 of which received lifitegrast 5%). The majority of patients (84%) had ≤ 3 months of treatment exposure. One hundred-seventy patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5%-25% of patients were instillation-site irritation, dysgeusia, and reduced visual acuity. Other adverse reactions reported in 1%-5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus, and sinusitis.

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

Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported [see Contraindications (4)].

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no available data on Xiidra use in pregnant women to inform any drug-associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation Day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocoele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD]), based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear [see Clinical Pharmacology (12.3) in the full prescribing information].

8.2 Lactation
Lifitegrast administered daily by IV injection to rats, from pre-mating through gestation Day 17, caused an increase in mean pre-implantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg/day, representing five, 400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg/day (40-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocoele was observed at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation Days 7 through 19. A fetal no observed adverse effect level (MDAEL) was not identified in the rabbit.

8.3 Pediatric Use

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low [see Clinical Pharmacology (12.3) in the full prescribing information]. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

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

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

Manufactured for:
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936
T2019-110

ECHOES OF HISTORY:
COVID-19 pandemic stirs memories, tests our mettle

Chief Medical Editor Peter J. McDonnell, MD, explores the history of physicians’ responses to plagues, the duties of doctors in the current coronavirus epidemic, as well as his own and his family’s past professional experiences.

OphthalmologyTimes.com/Coronavirus/Editorials/EchoesOfHistory

COVID-19: BELKIN Laser CEO offers company update

Daria Lemann-Blumenthal, CEO of the medical device company BELKIN Laser Ltd, provides an update on how the company’s operations have continued to progress amid the coronavirus pandemic.

OphthalmologyTimes.com/Coronavirus/BELKINlasertUpdate

Researchers find low risk of COVID-19 transmission in tears

While it currently is clear that the virus is transmitted in droplets spread through coughing and sneezing by infected patients, a new study has found that the virus does not seem to be present in the tears of those patients.

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PLUS COVID-19: Hospitals, practices set PPE policies for ophthalmic use

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COVID-19 pandemic may be a ‘black swan’ event for investors

Protecting portfolio from unexpected turns is no easy task in current landscape

Money Matters By John J., Traudy, and John S. Grande, CFPs

WHAT WE ARE experiencing now is an outlier to our normal risk/reward standard deviation. Some refer to it as a Black Swan event. It happens every so many years, as we all know. This latest event hit with a greater velocity and impact than any other time in our country’s history. We blinked and more than $7 trillion dollars was taken out of the markets’ value in little more than a week.

If you are reading this and you are a younger investor with five or more years to retirement, you can wait this out and keep dollar cost averaging. But what lessons are here if you think that this could happen right before, or just newly into your retirement? This risk is what we refer to as “sequence of return risk.” Translated into layman’s terms, “just God-awful bad luck and timing.”

Dealing with a crisis as we are all unfortunately doing now, is hard enough without the added stress of not knowing how it will impact a retiree’s income, and thereby, the quality of life. This downturn in the economy can be a great learning experience for investors looking forward as they watch the unthinkable happen. The questions you could be asking yourself now might be how you could be better prepared the next time sometime like this occurs, and how to use this movement in your favor.

Right now, top priority is staying safe and keeping those we love free of this insidious virus. Things will revert to the mean again in time, and as we have said in previous articles, we hope it is not business as usual. What have we learned?

Proper planning cannot be emphasized enough. Take this current crisis as an example. With a plan, you can instantly see how your probability of success is holding up.

If you are holding stocks, bonds, real estate, commodities, etc., there is no way that we know of to completely protect yourself from, at the very least, paper losses in your holdings during such an immediate and precipitous decline. You have probably heard the phrase, “all boats go lower in an outgoing tide.” It certainly seems that way. Sometimes, there is no place to hide. But this does not mean you cannot be prepared to lessen the blow by utilizing available investment strategies.

The first and most important strategy is to have a comprehensive financial/retirement plan that lays out when you will retire, how much you will be spending, how much you should be saving, and the minimal amount of risk you should accept in a well-diversified portfolio in order to achieve your stated goals.

You may have heard of the term “alpha” which, oversimplified, is attempting to get the best return for the risk taken. There is another kind of alpha that I believe you may not have heard of before—behavior alpha—referring to the avoidance of making emotional, spur of the moment decisions due to fear. When you have a financial plan to adhere to, you can consult with your advisor and perhaps be dissuaded from turning paper losses into real losses. If you had already had a plan that could be adjusted within the new “what-if” scenarios, then any possible panic might be better dealt with in a more logical manner.

What we are hearing every day during this crisis from our retired clients is how relieved they are that they have guaranteed, lifetime income as part of their retirement planning. This income takes pressure off drawing down on a depressed portfolio of equities, and gives peace of mind that income continues, no matter what the markets may temporarily be experiencing. It is prudent to consider covering your most essential expense needs through dependable, recurring income. In this way, the non-essential income can be tied more into portfolio balances as a percentage and adjusted as needed.

Also, there are investment instruments available that help hedge downside moves, albeit compromising a percentage of upside moves. When integrating these strategies with more traditional portfolios, the result is more peace-of-mind.

Proper planning cannot be emphasized enough. Take this current crisis as an example. With a plan, you can instantly see how your probability of success is holding up. Is it staying within the acceptable parameters or not? If not, what adjustments might be made? Without a plan, you are just guessing, not having any idea how a drop in the market truly affects your retirement.

EDITOR’S NOTE: The views depicted in this material are for information purposes only and should not be considered specific advice or recommendations for any individual. All investing involves risk, including the potential for loss. Past performance is not indicative of future results. No investment strategy can ensure a profit or protect against loss in a declining market.
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For more on Regeneron’s scientific efforts to help address COVID-19, please visit our website: www.regeneron.com/covid19

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When paired with multifocal IOL, IC-8 delivers extended depth of focus; reduces halo, glare

By Gerd U. Auffarth, MD, PhD, FEBO; Special to Ophthalmology Times*

The IC-8 small-aperture IOL (AcuFocus), which is CE marked and currently under investigation by the FDA, employs the pinhole camera effect to correct presbyopia.

By flattening the defocus curve on both the myopic and hyperopic sides, the IOL essentially creates a small amount of myopia, thereby extending the patient’s depth of focus and eliminating visual effects from corneal astigmatism or other irregularities.

This is a 1-piece hydrophobic acrylic ocular implant that comprises an embedded opaque annular mask with a central aperture. Aligned light rays converge through the 1.36-mm central aperture, while peripheral defocused and, often, aberrated rays are blocked from disrupting the image. As a result, patients experience a continuous range of vision from near to far, including the increasingly important intermediate range.

For most of us, the intermediate range (1.5 feet to 7 feet away) is a critical zone of activity. We eat the majority of our meals, work at our desks, and watch our large-screen media in this space. This distance represents the area where many people earn their living, including refractive surgeons.

Originally intended to be combined with a monofocal IOL, it has been found that when paired with a multifocal IOL, the IC-8 is better than previous alternatives at enhancing visual acuity at intermediate distances. As a result, this lens has the potential to benefit this underserved cohort. Likewise, patients who have undergone previous refractive procedures are becoming more common. As they proliferate, so does our necessity for techniques and technologies tailored to support their special needs.

The IC-8 has shown good outcomes in these “veteran” surgical patients.

Surgeons are only now beginning to appreciate the additional benefits made possible by combining the small-aperture lens with IOLs that function on completely different optical principles. Experimentation is ongoing, and this novel strategy may ultimately lead us to maximize the full potential of the IOL, providing patients with truly satisfying customized outcomes.

**Lenses Attributes**

Low-add multifocal lenses have been shown to improve intermediate visual acuity and offer surgeons the ability to further individualize patients’ visual outcomes, especially when mixed with another refractive technology. Combining a multifocal lens with a different type of lens can also act to minimize glare and halo, an intrinsic characteristic of low-add multifocal lens optics.

It is well known that most types of presbyopia-correcting IOLs—including multifocal refractive and diffractive, and even the newest trifocal technology—sacrifice distance vision to some extent in order to correct near vision and induce a variable amount of dysphotopsias.1 One study of the AcrySof ReSTOR +2.50 D IOL (Alcon) found it provided good intermediate and functional near vision for patients who did not want the higher potential for visual disturbances associated with the +3.00 D version of the same IOL but wanted more near vision than a monofocal IOL provides.2

Another prospective comparative investigation evaluated bilateral cataract surgery using the +3.00 D AcrySof IOL or a +4.00 D power of the implant.3 The +3.00 D IOL provided superior uncorrected distance visual acuity, significantly better uncorrected intermediate visual acuity at 40, 50, 60 and 70 cm, and functional reading acuity at 38.9 cm. Eyes with the +3.00 D IOL had better intermediate vision than those with the +4.00 D model without compromising distance and near visual acuity.

**Anchor with Small-Aperture Approach**

Unlike the aforementioned multifocal implants, the IC-8 IOL functions because of the pinhole effect. It reduces scattered light and permits only parallel rays to reach the macula. Depth of focus is extended and visual disturbances such as glare and halo are reduced. Small-aperture technology can even overcome problems with corneal asphericity and irregularities. Astigmatism up to 1.50 D can be corrected with the lens alone.4

The IC-8 IOL is typically implanted in the non-dominant eye, with a monofocal lens in the contralateral eye. To enhance acuity, the small-aperture IOL can be paired with other technologies such as a multifocal, a low-add trifocal, or even a trifocal lens. The basic idea is that using different types of implants can enhance the sharpness of vision at near, intermediate, and distance and minimize the side effects of the competing technologies.

**Small-Aperture Plus Extended Depth of Focus Technology**

The ongoing prospective, multicenter MOSAIC clinical trial was undertaken to evaluate visual outcomes from the combination of the IC-8 IOL and the Lentis MF20.6 Our group presented 5-month follow-up data on 13 patients with bilateral implantation of the IC-8 IOL with the Lentis LS-313 MF20 with +2.00 D of near add. We examined the following parameters:

- uncorrected and corrected (binocular) far, intermediate, and near visual acuity;
- defocus curves;
- Salzburg Reading desk test results; and
- photic phenomena (halo and glare simulator).

The MOSAIC trial included 26 eyes of 13 patients with cataracts (average age, 68.5 ± 10.8 years). The targeted refraction for the eyes implanted with the IC-8 IOL was -0.43 ± 0.18 D with an achieved refraction of 0.42 ± 0.41 D.

The achieved refraction was within ±0.50 D 62% of the time. The targeted refraction for the eyes implanted with the MF20 was -0.15 ± 0.16 D, and the achieved refraction was -0.33 ± 0.42 D. Eighty-five percent of the time, the achieved refraction was within ±0.50 D.

We found that patients implanted with the LS-313 MF20 had excellent binocular visual acuity at far distances, and visual acuity at near distances was excellent and maintained over 12 months of follow-up. One study of the AcrySof ReSTOR +2.50 D IOL (Alcon) found it provided good intermediate and functional near vision for patients who did not want the higher potential for visual disturbances associated with the +3.00 D version of the same IOL but wanted more near vision than a monofocal IOL provides.2

An evaluation of the implant with +2.00 D of near add compared with +3.00 D found superior visual outcomes from far distance to a near of about 25 cm with the latter lens. The +2.00 D demonstrated excellent visual results from a far distance to an intermediate distance of about 50 cm.4

**Take-home**

- When paired with multifocal extended depth-of-field technology, the IC-8 lens delivers extended depth of focus at near, far, and intermediate ranges while reducing halo and glare.

**Multi-Focal Extended Depth-of-Focus**

The Lentis Mplus LS-313 MF20 (Teleon; available in Europe but not in the United States) is a foldable, 1-piece, aspherical multifocal posterior chamber IOL that extends a patient’s depth of focus. Its refractive, and even the newest trifocal technology—sacrifices distance vision to some extent in order to correct near vision and induce a variable amount of dysphotopsias.1 One study of the AcrySof ReSTOR +2.50 D IOL (Alcon) found it provided good intermediate and functional near vision for patients who did not want the higher potential for visual disturbances associated with the +3.00 D version of the same IOL but wanted more near vision than a monofocal IOL provides.2

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DURYSTA™ (bimatoprost implant) 10 mcg

NOW APPROVED

INTRODUCING THE LATEST INNOVATION IN GLAUCOMA MANAGEMENT*: The first and only FDA-approved, biodegradable, intracameral implant indicated to reduce IOP in patients with open angle glaucoma or ocular hypertension via a sustained-release drug delivery system.1,2

INDICATIONS AND USAGE
DURYSTA™ (bimatoprost implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

IMPORTANT SAFETY INFORMATION
Contraindications
DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs’ Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet’s Stripping Automated Endothelial Keratoplasty [DSAEK]); absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; hypersensitivity to bimatoprost or to any other components of the product.

Warnings and Precautions
The presence of DURYSTA™ implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of DURYSTA™ should be limited to a single implant per eye without retreatment. Caution should be used when prescribing DURYSTA™ in patients with limited corneal endothelial cell reserve.

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including DURYSTA™ intracameral implant. DURYSTA™ 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.

Prostaglandin analogs, including DURYSTA™, have been reported to cause intraocular inflammation. DURYSTA™ should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Ophthalmic bimatoprost, including DURYSTA™ intracameral implant, has been reported to cause changes to pigmented tissues, such as increased pigmentation of the iris. Pigmentation of the iris is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. While treatment with DURYSTA™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering DURYSTA™, and patients should be monitored following the administration.

Adverse Reactions
In controlled studies, the most common ocular adverse reaction reported by 27% of patients was conjunctival hyperemia. Other common adverse reactions reported in 5%-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, and headache.

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


* IOP= intraocular pressure.
PRESBYOPIA

(Continued from page 12)

and intermediate distances, as well as functional vision at near. They had functional reading acuity at near and intermediate distances, and there was a low incidence of photic phenomena.

The combination of the small-aperture implant with a low-add multifocal lens such as the Lentis LS-313 MF20 is a good treatment option for patients who are motivated to achieve spectacle independence.

IMPLICATIONS AND CONCLUSION

Multifocal lens designs can exhibit pronounced peaks and troughs, but the IC-8 IOL provides uninterrupted functional vision over 3.00 D of defocus. The small-aperture principle has the ability to produce a high-quality, full range of vision without blurry zones and is more forgiving of refractive error misses or surprises.

The IC-8 IOL implant has been shown to provide good visual outcomes in post-LASIK and post-RK eyes. Patients with corneal irregularities can benefit from the technology’s ability to reduce aberrations.

When paired with multifocal extended depth-of-focus technology, the IC-8 delivers excellent extended depth of focus at near, far, and intermediate ranges while reducing halo and glare. It can enhance physicians’ ability to customize successful visual outcomes for each patient. Based on the simple, proven, and ancient understanding of the pinhole’s effect on light ray alignment, this IOL is a versatile tool to help patients who have undergone cataract surgery achieve their paramount postoperative visual goals.

REFERENCES


Patented. See: www.allergan.com/patents

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Trifocal IOL a key for premium cataract surgery practice

Option allows surgeons to meet patient expectations for spectacle independence

By Cheryl Guttman Krader, BS Pharm; Reviewed by Cathleen M. McCabe, MD

In August, the FDA granted approval for Alcon to market the AcrySof IQ PanOptix trifocal IOL. Surgeons who are using the lens, which is available in spherical and toric versions, agree that it is an important advance in presbyopia-correcting technology.

Cathleen M. McCabe, MD, chief medical officer, Eye Health America, and medical director, The Eye Associates, Bradenton, FL, said she began using the IOL as soon as it became available and estimates that she had already implanted it in several hundred eyes within the first six months.

“I think PanOptix is the lens we have been waiting for in the United States,” she said. “With the PanOptix, we can actually meet patient expectations for independence from glasses at all distances.”

Dr. McCabe noted that the patients she has implanted with the PanOptix have been very enthusiastic about their outcomes, and they are sharing their experience with family and friends.

“Happy and satisfied patients build the market and practices too,” she said. “Although the PanOptix has been available for a relatively short time, I am already seeing patients asking for it through word-of-mouth referral.”

In Canada, ophthalmologists have had access to the PanOptix IOL for more than three years.

Rosa Braga-Mele, MD, MEd, professor of ophthalmology, University of Toronto, Toronto, Ontario, Canada, has been using the lens since it came onto the market in her country and echoed the idea that the lens has been using the lens since it came onto the market.

Dr. Braga-Mele also observed that the refractive monovision, traditional multifocal IOLs and extended-depth-of-focus (EDOF) IOLs had a weakness at some point, Dr. Braga-Mele said. “In contrast, the PanOptix IOL delivers a blended range of vision with good vision at distance, intermediate, and near with- out glasses.”

Dr. Braga-Mele noted that with the toric version, ophthalmologists can correct a good range of astigmatism.

“They have excellent technology for accurate biometry and advanced formulas for IOL power calculation, including for toxicity. Refractive predictability with the PanOptix IOL has been excellent overall,” she said.

Dr. Braga-Mele also observed that the refractive

PLACE IN PRACTICE

Dr. Braga-Mele said that the PanOptix has become her go-to lens for patients wanting presbyopia correction. It is her lens of choice for patients who in the past she would have offered a bifocal multifocal IOL or an EDOF IOL, and she is offering the PanOptix to a broader pool of patients because of its superior range of vision.

Dr. McCabe pointed out that she has years of experience with various multifocal and accommodating presbyopia-correcting lenses, dating back to the days of the ReZoom and first ReSTOR IOLs.

“I have always tried to find the best solution to match each patient’s needs with the fewest side effects,” she said. “PanOptix is the first lens that gives a useable, functional range of vision.”

With the PanOptix IOL, preoperative counseling conversations with patients have changed for the better. Dr. McCabe observed that in the past she spent a lot of time explaining a variety of options to patients.

“I used to have to say that I could provide technology that would give good uncorrected vision at distance and intermediate and functional vision for near,” she said. “Or, I could offer better near vision with excellent distance vision and ‘okay’ intermediate vision.”

As a third choice, Dr. McCabe said she could try to mix and match technologies to achieve a full range of uncorrected vision.

“It’s a different situation now that I can use one lens that predictably gives excellent vision at distance, intermediate, and near,” she said.

Dr. McCabe also pointed out that in her discussion, she no longer has to distinguish between the intermediate and near focal points or offer surgery with different lenses in fellow eyes.

“I tell patients that I have a lens that will allow them to see up close without glasses and that gives them independence from glasses for their distance vision too,” she noted.

Surgical planning is also easier with the PanOptix because it eliminates mixing and matching and adjusting refractive targets. Both Dr. Braga-Mele and Dr. McCabe say they plan for emmetropia bilaterally when using the PanOptix IOL.

RELIABLE REFRACTIVE OUTCOMES

Dr. McCabe tells patients that 99% of patients in the FDA trial were so satisfied after surgery with the PanOptix IOL that they would want the same lens implanted again. In her practice, the few exceptions involve cases with a small refractive miss, and those can be solved with a touch-up procedure.

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TAKE-HOME

◗ The AcrySof IQ PanOptix trifocal IOL delivers a full range of good uncorrected vision, leads to high rates of patient satisfaction, and simplifies surgical counseling and planning.

Continues on page 18 : IOL
IOL

(Continued from page 15)

outcomes with the IOL are predictable. She attributed its performance, in part, to the fact that it is built on the tried-and-true AcrySof IQ platform.

Although Dr. Braga-Mele said that is almost consistently achieving her target of emmetropia, vision outcomes with the PanOptix IOL seem to have some tolerance to residual sphere and cylinder.

There are some conditions that can impact the results of the IOL.

“Patients seem to do well with this lens if they have up to 0.5 D of hyperopia or myopia and up to 0.6 D of astigmatism,” she observed.

MAINTAINING AWARENESS OF LIMITATIONS

Because the PanOptix IOL is diffractive technology, some patients can still experience dysphotopsias.

Dr. McCabe says she explains that because the lens has a target-like design, some patients see rings around point sources of light following surgery. She goes on to say that the symptoms are relatively common early after surgery, but by six months, most patients are not bothered by them if they notice them at all.

“I acknowledge that a very small percentage of patients still consider this issue a problem,” Dr. McCabe pointed out. “Then, patients can decide for themselves if this is a potential compromise they are willing to accept for the benefit of having great vision at distance and near.”

Dr. Braga-Mele said that she also discusses dysphotopsias with patients, but that the PanOptix IOL seems to be associated with a little better profile than bifocal lenses when it comes to halo and glare.

Because it splits light to different foci, reduced contrast sensitivity is another issue to consider. Consequently, Dr. Braga-Mele and Dr. McCabe exclude patients as candidates for the lens if they have glaucoma or macular pathology affecting vision now or if there is a real risk for progression.

“If a patient has early diabetic retinopathy, age-related macular degeneration, or glaucoma, I consider the potential for it to worsen over time and reach a level where I think this technology would not have been the best choice,” Dr. McCabe explained. “In that setting, I would not implant the PanOptix IOL or any diffractive presbyopia-correcting lens.”

OPTIMIZING OCULAR SURFACE

Dr. Braga-Mele and McCabe both emphasized the importance of identifying pre-existing dry eye and corneal disease.

“Like all multifocal IOLs, outcomes with the PanOptix are sensitive to the condition of the ocular surface,” Dr. McCabe said. “I look carefully for dry eye and treat it preoperatively because dry eye affects the accuracy of surgical planning as well as quality of vision.”

She added that some patients may need additional encouragement and more intensive education postoperatively to maintain management for dry eye disease so that the quality of their vision is good.

Dr. McCabe explained that when patients express some dissatisfaction postoperatively, which is rare, she has found it helpful to ask if they notice fluctuation of their vision and if it seems better sometimes during the day than others.

“If patients report fluctuating vision, I use the information to help them understand why a healthy ocular surface is important for good quality vision,” she said.

Dr. McCabe also noted that she explains that the only thing that fluctuates during the day is the condition of their ocular surface.

“Their observation about fluctuation helps me understand their complaint about their vision and is a sign that if they follow the recommendations for treating their dry eye, their vision will stabilize at its better level,” she said.

Beyond dry eye, Dr. McCabe and Dr. Braga-Mele look for other ocular surface conditions/corneal pathology and determine whether they can be adequately treated preoperatively or are a reason for not recommending any multifocal IOL.

In August, the FDA granted Alcon permission to market the PanOptix IOL. The targeted design can be seen in image B. (Photos courtesy of Alcon)
Surgeons should be very aware that the possibility of IOL refinements may be necessary postoperatively,“ he concluded. “Rather than considering this a treatment failure, consider it as an anticipated refinement.”

Dr. MacRae summed up his pearls. First, rule out the potential for development of coma and less patient discomfort. Limbal relaxing incisions are effective in cases with mixed astigmatism of less than 1.25 D. In these cases, he advised against going too centrally (8 mm or less) on the cornea because of the potential for development of coma and less efficient wound healing.

**TAKE-HOME**

- Surgeons should focus on correcting residual refractive errors before implanting a presbyopia-correcting IOL.

**CONCLUSION**

Dr. MacRae pointed out that he could not overemphasize the understanding of the patient’s optics. One factor in the optics is the corneal topography. He recounted the case of a patient with anterior basement membrane dystrophy causing irregular astigmatism, who had undergone implantation of a multifocal IOL.

The patient was unhappy with her outcome and required a superficial keratectomy and PTK to improve her vision. Another patient had had contact lens-induced corneal distortion and, he noted, likely should not have received a multifocal IOL.

Some success was achieved with partial correction of the regular astigmatism. “However, cases such as this are difficult to correct, and multifocal IOLs are best avoided,” Dr. MacRae said.

Another factor is measurement of the postoperative manifest refraction. In Dr. MacRae’s practice, the technicians dig deep to identify as little as 0.75 D of hyperopia or 0.50 D of myopia. If this is uncovered, that amount of refractive error is put into a trial lens frame to allow the patient to test the impact of the refraction in the real world. A positive evaluation after that with a near card then determines if the refractive error correction solves the problem. If it is, a PRK or LASIK can be performed. If the patient is unsure, he or she uses a soft contact lens or spectacles containing the refractive error for a few weeks before a determination is made, he explained.

In addition to the multifocal IOLs, diffractive and extended-depth-of-focus IOLs also are particularly impacted by small amounts of residual refractive errors, especially astigmatism.

As noted, 0.75 D of astigmatism can wreak havoc with visual quality and performance, but when combined with subtle irregular astigmatism or posterior capsular opacification, large angle kappa, dry eye, and anterior basement membrane dystrophy, there is an additive effect that reduces image quality, he said.

“Surgeons should be very aware of this,” he advised. Dr. MacRae and colleagues performed a study at the University of Rochester in which they compared three multifocal IOLs (ReSTOR3D, ReSTOR3D, Micro F diffractive trifocal, FineVision; and Mplus refractive bifocal IOL, Ocufi) to the Acrysof monofocal IOL.

The investigators corrected the refractive errors and added increasing amounts of astigmatism to determine the through-focus image quality of the IOLs.

“We found that 0.75 D and 1 D of astigmatism dramatically reduced the image quality compared to the monofocal IOL,” he said. “Therefore, correcting even that small degree of astigmatism is important for these patients if they are symptomatic.”

**FOCUS ON FOCUS**

Dr. MacRae pointed out that between one and three months postoperatively, over 57% of eyes with premium IOLs may not have achieved the full benefit of the implants because of the bugabo, the residual refractive error.

The multifocal IOLs are particularly sensitive to residual refractive errors, in that 10.8% to 25% of eyes treated with a multifocal IOL required a re-treatment such as a lens exchange, LASIK, or PRK (Potvin et al. Clinical Ophthalmol 2016;10:365-71; Goes J Refract Surg 2008;24:243-50. doi: 10.3928/1081597X-20080301-05). Dr. MacRae pointed out.

**FOCUS ON FOCUS**

As noted, 0.75 D of astigmatism can wreak havoc with visual quality and performance, but when combined with subtle irregular astigmatism or posterior capsular opacification, large angle kappa, dry eye, and anterior basement membrane dystrophy, there is an additive effect that reduces image quality, he said.

“Surgeons should be very aware of this,” he advised. Dr. MacRae and colleagues performed a study at the University of Rochester in which they compared three multifocal IOLs (ReSTOR3D, ReSTOR3D, Micro F diffractive trifocal, FineVision; and Mplus refractive bifocal IOL, Ocufi) to the Acrysof monofocal IOL.

The investigators corrected the refractive errors and added increasing amounts of astigmatism to determine the through-focus image quality of the IOLs.

“We found that 0.75 D and 1 D of astigmatism dramatically reduced the image quality compared to the monofocal IOL,” he said. “Therefore, correcting even that small degree of astigmatism is important for these patients if they are symptomatic.”

**CORRECTING THE FOCUS**

What’s the best way? LASIK, PRK, and relaxing incisions are all good methods depending on the need.

Dr. MacRae performs LASIK in health eyes, and even older patients experience rapid visual recovery. PRK is useful to correct residual refractive errors in post-LASIK eyes. He noted that he likes to perform a mini-PRK for refinement, in which the epithelium with a 7-mm diameter is removed instead of removal of epithelium with a diameter of 8.5 mm, a 30% decrease. This approach allows quicker recovery by one day, less risk of an epithelial defect, and less patient discomfort.

Limbal relaxing incisions are effective in cases with mixed astigmatism of less than 1 D. In these cases, he advised against going too centrally (8 mm or less) on the cornea because of the potential for development of coma and less efficient wound healing.

**TAKE-HOME**

- Surgeons should focus on correcting residual refractive errors before implanting a presbyopia-correcting IOL.

**CONCLUSION**

Dr. MacRae summed up his pearls. First, rule out and correct any accompanying issues such as posterior capsular opacification and retinal problems as well as the refractive error.

“Most importantly, inform the patient preoperatively that the possibility of IOL refinements may be necessary postoperatively,” he concluded. “Rather than considering this a treatment failure, consider it as an anticipated refinement.”

Dr. MacRae has no financial interest in the topic of this report.
INDICATIONS
LUCENTIS® (ranibizumab injection) is indicated for the treatment of patients with:
- Neovascular (wet) age-related macular degeneration (wAMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

IMPORTANT SAFETY INFORMATION
- LUCENTIS is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab or any of the excipients in LUCENTIS. Hypersensitivity reactions may manifest as severe intraocular inflammation
- Intravitreal injections, including those with LUCENTIS, have been associated with endophthalmitis, retinal detachment, and iatrogenic traumatic cataract
- Increases in intraocular pressure (IOP) have been noted both pre-injection and post-injection with LUCENTIS
- Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause)

REFERENCES:
STRENGTH IN VISION

LUCENTIS has been extensively studied and FDA approved in 5 retinal indications.

- Fatal events occurred more frequently in patients with DME and DR at baseline treated monthly with LUCENTIS compared with control. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded.
- In the LUCENTIS Phase III clinical trials, the most common ocular side effects included conjunctival hemorrhage, eye pain, vitreous floaters, and increased intraocular pressure. The most common non-ocular side effects included nasopharyngitis, anemia, nausea, and cough.

Please see Brief Summary of LUCENTIS full Prescribing Information on following page.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Randomized, double-masked clinical trials conducted for the 5 LUCENTIS indications included the following: wAMD: MARINA, ANCHOR, PIER, HARBOR. DR and DME: RISE, RIDE. mCNV: RADIANCE. RVO: BRAVO, CRUISE.

5.3 Thromboembolic Events
Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intraocular injection. ATEs are as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

5.4 Fatal Events in Patients with DME and DR at baseline

6.1 Adverse Reactions

6.2 Clinical Studies Experience

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

The data below reflect exposure to 0.5 mg LUCENTIS in 440 patients with neovascular AMD in Studies AMD-1, AMD-2, and AMD-3; in 250 patients with diabetic macular edema (DME) in Studies AMD-4, AMD-5, and AMD-6 with 0.3 mg LUCENTIS in 250 patients with DME and DR at baseline (see Clinical Studies (7.4) in the full prescribing information). Safety data observed in Study AMD-4, D-0, 3-1, and in 224 patients with noC were consistent with these results. On average, the rates and types of adverse reactions in patients were not significantly affected by dosing regimen.

Table 1 shows frequently reported ocular adverse reactions in LUCENTIS-treated patients compared to control.

Table 1 Ocular Reactions in the DME and DR, AMD, and RVO Studies

6.3 Immunogenicity

As with all therapeutic proteins, there is the potential for an immune response against LUCENTIS. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to LUCENTIS and are highly dependent on the sensitivity and specificity of the assays.

The pre-treatment incidence of immunoreactivity to LUCENTIS was 0%–5% across all clinical studies. After multiple doses of LUCENTIS for 6 to 24 months, antibodies to LUCENTIS were detected in approximately 1%-9% of patients. Over 3 years, antibodies to LUCENTIS were detected in approximately 4%-10% of patients.

The clinical significance of immunoreactivity to LUCENTIS is unclear at this time. Among neovascular AMD patients with the highest levels of immunoreactivity, such antibodies were not associated with increased toxicity or visual impairment. Intraocular inflammation was not observed in patients with DME and DR at baseline, or RVO patients with the highest levels of immunoreactivity.

7.4 Postmarketing Experience

The following adverse reaction has been identified during post-approval use of LUCENTIS:

Ocular: Tearing of retinal pigment epithelium among patients with neovascular AMD.
Surgeon brings cataract care to underserved patients in the Caribbean

Steroid minimizes postoperative inflammation, eliminates patient compliance concerns

By Cathleen M. McCabe, MD; Special to Ophthalmology Times®

ACCORDING TO THE World Health Organization (WHO), cataracts cause one-third of worldwide blindness, affecting about 65.2 million people, as well as moderate-to-severe vision loss in 52.6 million others, 99% of whom live in developing countries.¹

With these statistics, those of us interested in “giving back” have our work cut out for us. In my case, that comes in the form of helping people with limited access to ophthalmic surgical care in less-developed areas around the world, including Kenya, Guatemala, Honduras, and the Caribbean. My most recent mission was to the island of St. Vincent, north of Trinidad and Tobago in the Caribbean.

For me, this is a familiar locale because almost every May since 2003, I have traveled there along with my family and a contingent of colleagues, including Indiana ophthalmic surgeon Eric Purdy, MD. The mission is partially supported by the Lions Club of Ft. Wayne, IN, as well as by ophthalmic companies that donate pharmaceuticals and supplies used during the week-long mission.

Over the years, we have established a reliable routine. We spend a day setting up a pop-up clinic and then another evaluating the surgical needs of the patients referred to us by the local ophthalmologists. Generally, about 250 patients present for screening and approximately 80 to 100 surgeries are scheduled.

We spend five days performing mostly cataract surgery, along with a few corneal cases.

When we first started going to St. Vincent, there was a handful of private ophthalmologists who referred patients to us, but there was no ophthalmologist dedicated to indigent patient care. This situation presented a problem because we had to lobby hard for the private ophthalmologists to provide follow-up care.

Today, there are four ophthalmologists who care for patients in need, including Orly Adams, MD, who was born and raised in St. Vincent and returned there to practice after being trained in Cuba and Mexico.

Dr. Adams and his colleagues perform the pre- and postoperative care, and we work with them on current medical trends in eye care as part of our educational support, which is a critically important element of the mission. These ophthalmologists help to decrease the load of patients waiting for surgery throughout the year, but unfortunately because they do not have sufficient access to equipment or dedicated operating room time, the number of cases they can complete throughout the year is about the same as the amount we complete there in a week.

POSTOP CONCERNS

Postoperative care is historically challenging in surgical mission work. In areas that lack good access to cataract surgery, the cataracts we remove tend to be very dense, which increases the patient’s risk of postoperative inflammation.

Typically, when our mission is complete, we simply have to hope that the patients will follow through with our instructions to apply topical steroid drops four times a day for four weeks to address that inflammation. Often, the only access they have to postoperative medications is what we give them, so if they run out, misplace the drops, or the bottle becomes contaminated, they may not have any way to replace them. In some cases, patients may not have the ability to properly store their drops.

Confusion can also arise because we distribute several different-looking bottles, as we are relying on whatever has been donated to us for the mission. Therefore, the local ophthalmologists who are caring for these patients in the postoperative period may have difficulty understanding exactly what regimen each patient is on, given the variability in what medications have been donated and distributed.

Even under the best circumstances in my own practice in Florida, with routine, uncomplicated cases that are not at a high risk of inflammation, my patients often find it challenging to instill their postoperative drops.

Some patients have difficulty physically manipulating the bottles, and others lose them, still others forget which drop to use and when. When you add these typical compliance challenges to the storage and access issues, and further consider that there

Continues on page 22: Caribbean
is often a language barrier, or even an inability to read the postoperative instructions in developing countries, it is easy to see that the challenges we normally face are multiplied for the patients we treat during a surgical mission.

Having several ophthalmologists in St. Vincent to help patients in need with postoperative care represents a major step forward. Another plus was having access to dexamethasone intraocular suspension 9% (Dexycu, EyePoint Pharmaceuticals Inc.), a sustained-release drug that is applied as a single intracameral injection at the end of surgery for postoperative inflammation control. Dexamethasone intraocular suspension 9% is a cohesive liquid steroid depot that is injected into the ciliary sulcus at the end of cataract surgery, where it delivers a tapering dose of dexamethasone for about three weeks.2

This approach alleviates patient adherence issues and the dosage errors that may be associated with topical steroid administration—a concern even in the best conditions—and still more challenging when we perform surgery on patients in developing countries.

Having a depot steroid such as dexamethasone intraocular suspension 9% is invaluable because I know with complete certainty that the patient received the dose they needed, that it was applied in the right place, at the right time, and that it would last for the necessary period of time. The fact that this is all within my control lends an irreplaceable level of security.

Eliminating uncertainty from the postoperative care equation by providing inflammation control in the form of a depot steroid can make a significant—even revolutionary—difference for patients in compromised and complicated situations, such as those in developing countries. All patients on our most recent trip were treated with dexamethasone intraocular suspension 9%, thanks to a donation from EyePoint Pharmaceuticals Inc.

When available, other surgeon-administered drugs that may replace standard postoperative drops, such as dexamethasone insert 0.4 mg (Dextenza, Ocular Therapeutics), phenylephrine 1%/ketorolac 0.3% intraocular solution (Omidria, Omeros), or non-FDA-approved compounded medications, could likewise be valuable in the setting of medical mission work, helping to limit the challenges of topical postoperative drug administration in the developing world.

**CONCLUSION**

These trips show how necessity really is the mother of invention. When I encounter a difficult case and don’t have all the resources I normally would, I look at the eye and the problem from a new perspective and can sometimes come up with a solution that I can potentially apply to my patients in the United States. Mission work in developing countries is a great reminder of the reality that exists outside my comfort zone and never fails to strengthen my surgical skills and test my resourcefulness. I always find that I return home with a greater appreciation of what it takes to be happy and productive in my own life.

**REFERENCES**


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Dr. McCabe is chief medical officer, The Eye Associates in Bradenton and Sarasota, FL. She is a speaker, consultant, and receives research support from EyePoint Pharmaceuticals, Inc.
Cost-effective community-based screening and opportunistic case detection are two important lessons learned by researchers outside the United States that may be beneficial for identifying patients with undetected glaucoma in the United States, according to Joshua R. Ehrlich, MD, MPH.

In the United States, individuals who are 80 years of age and older have a higher prevalence of glaucoma, about 8%, compared with younger patients between 40 and 50 years old, in whom the prevalence is less than 1%. Overall, in the U.S. population, between 4 and 5 million people have the disease.

Most worrisome is that an estimated 1.6 million of these people in the U.S. are unaware of their disease, which is a great problem, according to Dr. Ehrlich, assistant professor of Ophthalmology and Visual Sciences and co-director, Kellogg Eye Center for International Ophthalmology, University of Michigan, Ann Arbor, MI.

The bright spot in this picture is that globally a great deal of innovative work is being done, some of which might be applied favorably to the unmet need in the United States.

**Lessons Learned from China**

A Chinese study published in the Lancet (doi: https://doi.org/10.1016/S2214-109X(19)30201-3) looked at the cost-effectiveness and cost-utility of population-based glaucoma screening. Dr. Ehrlich explained that in most settings, population-based glaucoma screening has not been found to be cost-effective due to the relatively low prevalence of the disease in the general population and the high costs associated with screening.

However, most of the work in the area has been conducted in high-income settings, so there is less data on the cost-effectiveness of population-based glaucoma screening in low- and middle-income countries.

“This study found that a population-based screening program for glaucoma in China was very cost-effective in a model that included screening for both open-angle and angle-closure glaucoma and in both urban and rural settings,” he said.

Dr. Ehrlich also pointed out that “the findings were really driven by the high cost-effectiveness of screening for angle-closure glaucoma. In cities, the programs that included screening for angle-closure glaucoma alone or combined with open-angle glaucoma actually saved money for the health care system compared with no screening.”

This program proved to be cost-effective because of the high risk of blindness in untreated angle-closure glaucoma, which is highly prevalent in China. Another reason is that in China screening costs are comparatively low.

The takeaway messages for the United States are three-fold.

First, we should focus on those who are at the highest risk for having the disease, Dr. Ehrlich said.

“The two known factors that are most easily determined are ancestry and family history,” he said.

Second, he suggested, innovative ways can be sought to decrease costs. Two strategies are task shifting and use of tele-glaucoma.

And, third, the evidence must be evaluated. As cost-saving methods are adopted, better evidence is needed to determine if the cost-effective models are possible in specific populations or with specific approaches, and whether implementing these screening programs decreases the burden of vision impairment and vision-related disability, he said.

**Lessons Learned from India**

An Indian study performed at the Aravind Eye Care System also may provide lessons.

Continues on page 24: Glaucoma
Lessons learned testing for them. The reason for hydroxyapatite deposition remains unknown, but Dr. Wistow speculated that it may be the result of a “protective mechanism gone awry.” “It’s possible that these protein, lipid, and mineral deposits may help damaged RPE cells block blood vessels from growing into the retina, a problem that is one of the key features of wet AMD,” he said. “But when the mineral deposits get too extensive, they may also block nutrient flow to the RPE and photoreceptors, leading to retinal cell death.”

According to Dr. Wistow, mechanistically, amelotin looks like a key player for the formation of these very specific hydroxyapatite spherules. “That’s what it does in the teeth, and here it is in the back of the eye,” he said. He pointed out that this underscores the need to develop drugs that can specifically block the function of amelotin in the eye, which may delay disease progression. “But we won’t know until we try it,” Dr. Wistow said.

However, this cannot be done until animal models are developed to test new therapies for dry AMD. Dr. Wistow’s laboratory is currently in the process of developing a new murine model for dry AMD. He also believes that the cell culture model, which mimics features of dry AMD, could potentially be useful for high throughput drug screening to find molecules that slow or prevent the development of soft drusen.

REFERENCE

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Dr. Rajapakse has no financial interest in this subject matter.

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Dr. Wistow has no financial interest in this subject matter.

In the Aravind program, when a patient is diagnosed with glaucoma, an ophthalmic clinician records information about the patient’s relatives and their glaucoma status.

The custom-designed system contains a great deal of automation and is programmed to ensure that the first-degree relatives are contacted by text message, automated messages, and phone calls. The software tracks the numbers of messages and calls and if the relatives have responded. The takeaway from this program is that in other contexts innovative strategies can be designed to at high risk of disease, and an emphasis on family history is one approach to doing so. Beyond that, there is a question about whether U.S. physicians can use technology-driven solutions to lower labor costs through automation and improve follow-up.

APPLYING LESSONS

“There are limitations as well as opportunities associated with implementing some of these lessons in the United States,” Dr. Ehrlich said.

He said cost-effectiveness may require a very targeted approach depending on ancestry and family history, for example, in order to identify people at-risk and develop more cost-effective programs in the United States. Another consideration is the high cost of examinations and testing in the United States compared with other countries. However, costs likely can be lowered by task shifting and use of tele-glaucoma.

Finally, U.S. families are dispersed widely compared to some other places. However, technological solutions, use of tele-glaucoma, and provider networks may offer opportunities for coordination of care. “Although these are limitations, they provide opportunity for innovation and for exciting new avenues to hopefully decrease the unacceptable burden of undiagnosed glaucoma in the United States,” Dr. Ehrlich concluded.
Clinicians may soon be able to use genetic information alone to determine the risk of myopia in very young children, according to researchers.

“A personalized medicine approach to detecting children at risk of myopia is now feasible, although currently the accuracy of polygenic risk scores (PRSs) is not yet good enough to warrant their use in clinical practice,” write Neema Ghorbani Mojarrad and colleagues at the University of Bradford in Bradford, UK.


Today, the best predictor of children at risk of myopia is a low hyperopic refractive error at an age before myopia typically manifests, so clinicians seeking to evaluate risks of myopia in young children typically rely on a screening regimen of cycloplegic autorefraction.

Successfully predicting risks of myopia in children can help clinicians recommend lifestyle changes such as more time outdoors, which can help mitigate or prevent the development of myopia.

However, the use of cycloplegic autorefraction is time- and resource-intensive, so Mojarrad and his team wanted to see if they could develop a PRS for evaluating risk based purely on genetic information.

To develop their PRS, the researchers conducted three genome-wide association studies (GWASs). Data used for the GWASs included 287,448 UK Biobank participants who had not undergone autorefraction, and 95,619 UK Biobank participants who had undergone noncycloplegic autorefraction.

In addition, researchers collected data on 328,917 individuals whose information had originally been compiled to study the relationship between genes and years of educational attainment and was downloaded from the Social Science Genetic Association Consortium (SSGAC) website.

The researchers then combined their data in a meta-analysis in order to increase the effective sample size. They generated a PRS for each participant using genotypes for 1.1 million variants.

Researchers validated their PRS by using it to predict rates of myopia in 1,516 women whose genome data and known rates of myopia were obtained from the Avon Longitudinal Study of Parents and Children (ALSPAC).

The PRS derived from the SSGAC GWAS provided limited predictive accuracy (R² = 0.14% where R² = 100% would be a completely accurate prediction). The autorefraction and non-autorefraction GWASs were also relatively inaccurate (R² = 7.1% compared to R² = 6.9%).

The researchers were able to improve the accuracy of the PRS by combining sets of traits. The best result came from combining the autorefraction and non-autorefraction GWASs (R² = 10.8%). Combining all three traits yielded even greater accuracy (R² = 11.2%).

The GWAS was unable to produce a PRS that was as accurate as the results obtained using cycloplegic autorefraction. Measured in terms of the area under the receiver operating characteristic (AUROC), where 0.5 is a useless model and 1.0 is a perfect model, the PRS had an AUROC of 0.67 while the cycloplegic autorefraction had an AUC of 0.87.

While they were unable to develop a suitably accurate alternative to cycloplegic autorefraction for predicting rates of myopia, Mojarrad and his team were able to conclude from their study that children can be categorized into three groups based on the risk of developing myopia. Those with a PRS in the top 25% were at 3-fold to 5-fold higher risk of myopia, and those in the top 10% were at 3.5-fold to 6-fold increased risk, whereas those in the top 5% were at 4.5-fold to 6.5-fold higher risk.

Researchers are hopeful that this information will aid clinicians in recommending lifestyle interventions or prescribing orthokeratologic or atropine treatment.

Mojarrad and his team are encouraged by the results of their study, and predict that future research may lead to the development of a PRS that will enable clinicians to accurately predict myopia in children, obviating the need for cycloplegic autorefraction.
As Demonstrated in Phase 3 Clinical Trials

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

• 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.

WARNINGS AND PRECAUTIONS

• 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 with the 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 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 of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.
IMPORTANT SAFETY INFORMATION AND INDICATIONS

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ADVERSE REACTIONS
• Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
• The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

INDICATIONS
EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

Please see Brief Summary of Prescribing Information on the following page.

1 INDICATIONS AND USAGE
EYLEA (aflibercept) is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of:

Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR).

1.4 CONTRAINDICATIONS

1.4.1 Ocular or Periocular Infections
1.4.2 Ocular or Periocular Inflammation

2.1 Adverse Reactions

2.2.1 OCULAR AND PERI OCULAR ADVERSE REACTIONS

2.3 Pharmacokinetics

2.4.6 Women of Reproductive Potential

2.4.7 Lactation

3.1 Animal reproduction studies

3.2 Human reproduction

3.2.1 Pregnancy

3.2.2 Lactation

3.3 Human fertility studies

3.4.2 Men with breast implants

6.2.2 Pregnancy categories

7.1 Intraocular Pressure

7.1.1 Effects on IOP

7.2.2 Localized injection site reactions

8.2.4 Veterinary Clinical Data

8.2.5 Human Clinical Data

8.3.1.1 Breastfeeding

8.3.1.2 Women of reproductive potential

8.4 Pediatric use

8.5.3 Intraocular inflammatory changes

8.5.4 Ocular or periocular adverse reactions

9.1 Preclinical Development

9.2 Clinical Trials

9.3.3 Intraocular Hemorrhage

9.3.4 Retinal Detachment

9.3.5 Other Ocular Adverse Reactions

9.3.6 Oral Hypertension

9.3.7 Other Systemic Adverse Reactions

9.3.8 Other Adverse Reactions

9.4 Preclinical Pharmacology

9.5.17.4 Clinical Trials

9.5.19.1 Clinical Trials with EYLEA in WET AMD Patients

9.5.3.5 Injection Site Pain

9.5.3.7 Vascular Endothelial Growth Factor (VEGF)

9.5.3.8 Retinal Detachment

9.6.2 Ocular Hypertension

9.6.4 Other Ocular Adverse Reactions

9.6.5 Other Adverse Reactions

9.7.2 Localized Injection Site Reactions

9.7.3 Other Systemic Adverse Reactions

9.7.4 Other Adverse Reactions

9.8.3.15 Cataract

9.8.3.17 Detachment of the Retinal Pigment Epithelium

9.8.3.19 Vision Blurred

9.8.3.21 Localized Ophthalmoscopic Changes

9.9.4.2 Intraocular Hemorrhage

9.9.4.4 Retinal Detachment

9.9.4.6 Other Ocular Adverse Reactions

9.9.4.8 Other Systemic Adverse Reactions

9.9.4.10 Other Adverse Reactions

10.11 NURSE’S DRUG GUIDE

10.12 Dose and Administration

10.14.2 Place of Administration

10.2.4 Intraocular Pressure

10.2.5 Localized Injection Site Reactions

10.2.6 Other Systemic Adverse Reactions

10.3.14.1 Injection site pain

10.3.14.3 Vascular Endothelial Growth Factor (VEGF)

10.3.14.5 Retinal Detachment

10.3.14.7 Other Ocular Adverse Reactions

10.3.14.9 Other Adverse Reactions

10.3.15.4 Intraocular Hemorrhage

10.3.15.6 Other Ocular Adverse Reactions

10.3.15.8 Other Systemic Adverse Reactions

10.3.15.10 Other Adverse Reactions

10.4.2 Injection site pain

10.4.4 Other Ocular Adverse Reactions

10.4.6 Other Adverse Reactions

10.5.4 Intraocular Hemorrhage

10.5.6 Other Ocular Adverse Reactions

10.5.8 Other Systemic Adverse Reactions

10.5.10 Other Adverse Reactions

10.6.4 Other Ocular Adverse Reactions

10.6.6 Other Adverse Reactions

10.7.4 Other Ocular Adverse Reactions

10.7.6 Other Adverse Reactions

10.8.4 Other Ocular Adverse Reactions

10.8.6 Other Adverse Reactions

10.9.4 Other Ocular Adverse Reactions

10.9.6 Other Adverse Reactions

10.10.4 Other Ocular Adverse Reactions

10.10.6 Other Adverse Reactions

10.11.4 Other Ocular Adverse Reactions

10.11.6 Other Adverse Reactions

10.12.4 Other Ocular Adverse Reactions

10.12.6 Other Adverse Reactions

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OCT: Illuminating the retina layer by layer

Three considerations are key when diagnosing posterior uveitis in patients

By Lynda Charters

When diagnosing posterior uveitis, three considerations are important when using optical coherence tomography (OCT), according to Kathryn Pepple, MD, PhD.

**OCT TYPE.** The first is the type of OCT system: spectral-domain (SD) or swept-source (SS). “Both are excellent for obtaining high-quality images of the retina and the retinal vasculature, but SS-OCT has some advantages over SD-OCT used for patients with uveitis,” Dr. Pepple commented.

One advantage is the longer imaging wavelength of the SS-OCT system that facilitates deeper evaluation into the choroid. “In the white dot syndromes, the deep choroidal tissues may be the location from which these syndromes emanate, and deeper visualization can be beneficial,” she said. SD-OCT can provide images of thesechoroid with use of the enhanced imaging procedure, she pointed out. Dr. Pepple is assistant professor, University of Washington, Mercer Island, WA.

A second advantage is that SS-OCT allows better visualization of the vitreous, because SS-OCT is faster, wider images can be obtained, which may be important for diseases in locations other than the macula.

**STRUCTURE VERSUS FLOW.** The second consideration is determined whether the image shows a structure or flow. OCT B-scans show structures; the newer flow imaging uses B-scan repeat imaging shows motion contrast to show retinal or choroidal blood flow. This then can be segmented into the different vascular layers in the deep capillary plexus of the retina and the deep capillary flow, and the slabs can be seen in the en-face view.

**LAYER SEGMENTATION AND EN-FACE VIEWS.** All previous en-face imaging and dye-based angio-graphy provide a topside view of a structure; in the case of the retina with its seven layers, the technologies provided views of all layers but clinicians could not discern which layer the imaged structures were in. “OCT revolutionized that and permitted viewing the retina and choroid via a side B-scan images. This information about the various layers revolutionized what we knew about various diseases. Now we have en-face slab images that allow removal of individual ‘pancakes’ to determine which pancake contains the pathology under study,” Dr. Pepple said.

**THE WHITE DOT SYNDROMES**

A close look at the images from the various white dot syndromes underscores the importance of being able to dissect the retinal layers and the information that dissection provides about the various diseases.

**MULTIPLE EVANESCENT WHITE DOT SYNDROME (MEWDS).** This disorder is characterized by multiple white dots that are accompanied by changes visible on OCT. The structural B-scans obtained from these patients when overlaid by slab images of the outer nuclear layer (ONL) or the ellipsoidal layer visualize the spots and corresponding dots seen in the two images. Dr. Pepple described that the spots are discontinuities in the external limiting membrane, while the dots are hyperreflective spots in the ONL. “The dots overlaying the spots suggest the presence of a contiguous lesion that is likely at the photoreceptor layer,” she said.

This information is in contrast to that suggested by indocyanine green angiography (ICGA) images that showed hypocyanescent lesions that were thought to be flow voids in the choriocapillaris or choroid. However, SS-OCT showed otherwise, i.e., there are no flow abnormalities and that MEWDS is a “photoreceptor-blockage.” “The dark spots on ICGA might be the result of photoreceptor blockage.”

**MULTIFOCAL CHOROIDITIS (MFC), PUNCTATE INNER CHORIOPATHY (PIC), CHOROIDAL NEOVASCULAR MEMBRANE (CVMN).** In the next retinal layer, MFC and PIC seem to affect the area under the retinal pigment epithelium (RPE), Dr. Pepple noted. “With active lesions, hyperactive dome-shaped hyperactive deposits can be seen under the RPE with discontinuities in the RPE resembling volcanos of inflammation in the RPE erupting into the outer retina,” she described.

Signal transmission through lesions increases into the choroid beneath. With resolution of the lesions and the dome-shaped deposit, small breaks are present in the RPE along with changes in the outer layers near the lesions.

OCTA flow images can identify flow in the hyperreflective lesions in the outer retinal slabs and show choroidal neovascular membrane (CVMN).

“Typically, these are associated with other findings of a CVMN on multimodal images but occasionally can identify flow in signals that were not apparent in typical modalities,” she advised.

**TAKE-HOME**

- New OCT technologies have isolated the white dot syndromes to distinct retinal layers.
- OCTA flow images can identify flow.
When viewing the choriocapillaris slab, evidence suggests that the choriocapillaris is a component of this disease with a decreased flow signal from acute lesions. Scars also can result in decreased flow.

**ACUTE MULTIFOCAL PLACOID PIGMENT EPITHELIOPATHY (AMPPE).** Structural OCT visualization of acute lesions shows hyperreflectivity and thinning of the ONL, changes in the RPE, and subretinal fluid in the hyperacute lesions. SD-OCTA flow images show defects in the choriocapillaris; the choriocapillaris lesion is shown to be larger than the outer retina and research has shown lesions can resolve over time.

ICGA shows that during active AMPPE inflammation, the hypocyanescent lesions are more widespread. When the disease is quiescent, the lesions mostly resolve but the damage in the outer retinal layer remains, with thinning of the layer and loss of some outer retinal bands.

**SERPIGNOUS CHORIORETINITIS.** “This disease is a much more damaging form of choriocapillaritis inflammation that seems similar to AMPPE, with thickening of the RPE, ONL hyperreflectivity, and loss of the ellipsoid bands on the retina and external limiting membrane,” Dr. Pepple said and noted that the most interesting findings in this disease concern choriocapillaris flow.

En-face choriocapillary imaging and quantitative monitoring have contributed substantially to the understanding of the disease. The lesions can respond to steroids. During an active flare of the disease, the lesions are shown to expand, but with treatment the lesions decreased. Dr. Pepple showed that “because the lesions are sharply demarcated, boundary analysis can actually detect the amount of damage inflicted by the flare and how much recovery was achieved with treatment.”

Dr. Pepple speculated that AMPPE and serpiginous chorioretinitis may be the same disease but with degrees of severity.

**BIRDSHOT RETINOCHOROIDOPATHY.** This disease occurs deeper in the choroid than the others. “The deep choroidal lesions can be visualized in some patients on color fundus imaging. Structural OCT images show many of the birdshot findings, including macular edema and thinning, loss of the outer retinal bands, and epiretinal membranes that cause complications over the long term,” she said.

Retinal OCTA can see changes in the retinal vasculature, including infrequent CVMN, capillary dilation and loops, and changes in the intercapillary distance. Enhanced-depth imaging OCT and SS-OCTA have illuminated the changes in choroidal structure in birdshot patients, including chronic choroidal thinning, active choroidal thickening, hyperreflective and hyporeflective foci, the controversial supachoroidal space and fluid, and increased choroidal reflectivity. SD-OCT has identified longitudinal changes. Preclinical deep choroidal lesions can be observed with SD- and SS-OCTA.

The newer technologies have shown that the white dot syndromes are localized in the various retinal layers, with MEWDS concentrated in the photoreceptors, CVMN in the subretinal and sub-RPE space, MCP/PIC in the outer retina, RPE, and choriocapillaris; AMPPE and serpiginous in the choriocapillaris; and birdshot in the choroid.

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Dr. Pepple has no financial interest in this subject matter.

The year 2020 is an important milestone for eyecare practitioners. Coming soon in *Ophthalmology Times®* and *Optometry Times®*—insights and information on 2020 and beyond.
Femtosecond laser-assisted RLE offering better outcomes

Pairing with presbyopia-correcting IOL can offer improved patient satisfaction

By Lynda Charters; Reviewed by R. Luke Rebenitsch, MD

The technology surrounding IOLs has evolved exponentially, and with that patients’ expectations regarding the best possible outcomes after refractive lens-based surgery have escalated.

In response to the use of multifocal and extended-depth-of-focus (EDOF) IOLs, femtosecond laser-assisted refractive lens exchange (RLE) may be the technology of choice to achieve even better outcomes, including correction of refractive errors and spectacle independence, with presbyopia-correcting IOLs.

“RLE is performed increasingly more often to address refractive errors, presbyopia, and to eliminate the need for a future cataract surgery,” said R. Luke Rebenitsch, MD, owner and medical director of ClearSight Center, Oklahoma City, OK. However, with that trend comes some downsides. Multifocal IOLs and extended-depth-of-focus IOLs are more sensitive to tilt and defocus than monofocal IOLs. To determine the potential benefit of femtosecond laser-assisted RLE with presbyopia-correcting IOLs, Dr. Rebenitsch and colleagues conducted a study to evaluate the visual and refractive outcomes postoperatively.

“The precise and automated nature of the femtosecond laser may positively impact the accuracy, safety, and patient satisfaction,” he said.

In support of that, Dr. Rebenitsch recalled a study (J Cataract Refract Surg. 2019;45:21-27) that compared the refractive and aberrometry outcomes obtained with a diffractive multifocal IOL using femtosecond laser-assisted surgery and phacoemulsification in 39 patients.

The study reported that while the visual results with monofocal IOLs were unaffected, a decrease in the internal aberrations was seen in the group treated with femtosecond laser-assisted surgery compared with phacoemulsification. The decrease was due to less tilt and the better effective lens position of the IOL in the eye.

**THE STUDY**

The study was a single-site retrospective chart review that included 590 eyes of presbyopic patients who wanted spectacle independence. One surgeon performed the RLEs.

Eyes were included if they had stable tear film, corneal higher-order aberrations (HOAs) under 0.4 μm at 4 mm. Total corneal astigmatism (TCA) less than 0.5 D was left untreated; TCA exceeding 0.5 D were considered for treatment, that is, by arcuate keratotomy or toric IOL.

Patients with residual refractive error who were unsatisfied with the visual quality underwent laser vision correction from 10 to 12 weeks after the RLE procedure.

The investigators used a combination of an EDOF IOL and a multifocal IOL. The ZLBOO was used to achieve distance and near vision in one eye and the EDOF IOL for distance and intermediate in the other eye.

“This would allow for seamless quality of vision from near to distance without any loss of quality,” Dr. Rebenitsch pointed out.

The LENSAR femtosecond laser system was used to in all eyes for femtosecond laser-assisted RLEs with or without arcuate keratotomy. When a toric IOL was used, initially the treatment axis was marked with the femtosecond laser using intrastromal corneal arcuate marks (IntelliAxis-C, LENSAR) or later anterior capsulotomy marks (IntelliAxis Refractive Capsulorhexis, LENSAR).

For presbyopia correction, the investigators implanted an intermediate add EDOF IOL (Tecnis Symfony, Johnson & Johnson Vision) (group 1, 475 eyes); for patients with excessive astigmatism, they used a bilateral EDOF toric IOL (Tecnis Symfony toric) with a near target in the non-dominant eye (group 2, 115 eyes).

Dr. Rebenitsch reported that in group 1, 91% of eyes achieved within ±0.5 D of the target refraction with an average manifest refraction spherical equivalent of about plano. In group 2, the astigmatism was reduced to an average 0.47 D compared with baseline (p = 0.001).

In group 1, 97% of eyes achieved an postoperative uncured distance visual acuity of 20/40 or better; in group 2, 94% did so.

“As expected,” Dr. Rebenitsch said, “the uncorrected near visual acuity (UNVA) was excellent; 93% of eyes achieved an UNVA of 20/40 or better. In group 2, 83% achieved that level of UNVA.” A patient satisfaction survey indicated that 90% were completely or very satisfied with the visual results postoperatively, and 10% reported that they were somewhat satisfied. Over 90% indicated that they were completely happy or very happy that they underwent vision correction surgery; under 10% reported that they were somewhat happy. The vast majority, i.e., 97% said they would recommend the procedure to a friend or family member, according to Dr. Rebenitsch.

A caveat is that with RLE it is inherently more difficult to achieve patient satisfaction because patients have a clear lens, larger pupils, and higher expectations than those undergoing cataract surgery. We inform patients that they will need readers for fine print, although many do not need readers at all, Dr. Rebenitsch noted.

“Given the greater consistency of the procedure, I believe the femtosecond laser can assist in achieving even better outcomes in the group,” he said. “With 97% recommending this to family members, this has been the fastest growing part of our practice over the last three years.”

Dr. Rebenitsch concluded that patients can achieve positive refractive and visual outcomes after femtosecond laser-assisted RLE with presbyopia-correcting IOLs.

“This is potentially due to improved prediction of the effective lens position, easier centration, decreased internal HOAs, and improved toric alignment due to a reproducible capsulotomy and femtosecond capsular marks,” he said. “Improved patient satisfaction likely can be achieved by mixing multifocal and extended-depth-of-focus IOLs to achieve a fuller depth of focus as seen with the better near and distance uncorrected vision.”

**TAKE-HOME**

- Femtosecond laser-assisted refractive lens exchange with presbyopia-correcting intraocular lenses achieves excellent refractive and visual outcomes.

Dr. Rebenitsch is a consultant to Carl Zeiss Meditec and has received speaking fees from Staar Surgical and LENSAR.

R. LUKE REBENITSCH, MD
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Predictable, branded steroids offer control over surgery

Optimizing ocular surface before procedure can help surgeons achieve precision

By Inder Paul Singh, MD; Special to Ophthalmology Times*

We do so much to standardize surgery and minimize variability. To produce reliably positive outcomes, we focus first on the preoperative assessment and biome-etry, and then on using surgical tools and techniques that help us achieve micron-level precision. We optimize the ocular surface before surgery and refine our minimally invasive surgical techniques to improve postoperative recovery.

After surgery, we need to apply the same control-focused mindset in prescribing a postoperative steroid. There is enough variability in generic steroids to potentially affect healing and IOP, challenge compliance, and even erode patient satisfaction in the month following surgery. We cannot let that happen to our patients, and we should not diminish all of the careful work we have done up to that point.

NO TIME FOR GENERICS

To me, it is certainly not worth taking a chance with a generic steroid after surgery. Older generic drug formulations only needed to match the active ingredient of an original innovator or branded drug, not demonstrate equivalence. This included corticosteroids such as prednisolone acetate.1,2

Today, generic drops still may not be 100% bioequivalent to their branded counterparts. Manufacturers are only required to prove 80% bioequivalence, matching only in the active molecule while free to differ significantly in where they outsource the vehicle, inactive ingredients and bottle make and construction.

When good manufacturing processes are followed, the differences between branded and generic medications are minimal in ophthalmic solutions, where all of the active and inactive ingredients are dissolved. However, the common generic ophthalmic corticosteroids used today are formulated as suspensions, not solutions or emulsions.

Branded drugs rely on advanced vehicles that improve a drug’s therapeutic properties. It is almost impossible to accurately duplicate these important vehicles because they rely heavily on certain milling and other manufacturing processes that affect the particle size, coating, mixing, and other vehicle characteristics. A different vehicle and variation in the manufacturing process can cause several problems. The active molecule can settle in the new vehicle, so patients do not get the desired effect unless they shake the bottle, and patients have poor compliance with shaking the bottle postoperatively. In addition, differing pH levels can affect absorption. Buffering agents can be inadequate. The ocular surface problems and other side effects of benzalkonium chloride (BAK) preservative can be greater because some generics may use higher concentrations of BAK than the branded alternative.

In short, a drop’s efficacy, safety and tolerance are affected by the vehicle and other inactive ingredients that make up most of the bottle. This relationship can be used to our advantage, such as when brimonidine tartrate 0.1% (Alphagan P, Allergan) was developed by changing the inactive ingredients in the brimonidine tartrate 0.2% drop. The preservative was changed, thereby increasing the pH, giving us half the concentration of active medication with the same efficacy and fewer side effects. In addition, the concentration of bromfenac (Prolensa, Bausch +Lomb) was changed from 0.09% to 0.07% while maintaining efficacy by changing the pH of the vehicle. With generics, however, we do not consistently know how and from whom the manufacturer sources the inactive ingredients. There is no oversight of the bottle’s contents, so it is no surprise that efficacy and tolerability can vary.

It should be noted that in many cases, there is little or no savings in purchasing a generic steroid drop. Many generics are very close in price to branded counterparts, and manufacturers of new branded drugs typically offer coupons. Even if there is some small savings, to me it is not worth it to add potential unpredictability to the surgical recovery process.

We have tried to educate our patients to provide them with enough understanding of the differences between a branded and generic medication so they can make a better decision on their own if it is worth the cost to pay the potentially higher cost. Essentially, we place value on everything we purchase, so providing patients with this knowledge is crucial for them to make an informed decision.

AVOIDING PRESSURE SPIKES

In addition to sticking to the predictability of branded drops, it is important for me to factor IOP control into the selection of a steroid. I routinely perform not only cataract surgery, but also almost every type of glaucoma procedure.

I am concerned about pressure spikes in patients with glaucoma who undergo any kind of eye surgery, but I am most worried when they have surgery that does not address glaucoma. For example, in cataract surgery without a concomitant minimally invasive glaucoma surgery (MIGS), patients can get significant pressure spikes postoperatively.

Many years ago, a study by Aramaly showed a significant rise in pressure in 95% of primary open-angle glaucoma (POAG) patients treated with steroids.3 About 50% of POAG patients had an IOP above 40 mm Hg at two weeks. I have seen pressure rise within the first week in glaucoma patients on a certain steroids, such as difluprednate (Durezol, Novartis), an emulsion. We also know that almost all low-tension glaucoma patients are steroid responders. We always need to be aware of that risk.3

Loprednol is a molecule used to minimize that risk. I have long used loprednol for cataract surgery with or without MIGS, trabeculectomy, canaleoplasty, XEN (Allergan), Hydrus (Ivantis), and other MIGS procedures because I am very comfortable with both its efficacy and its comparatively low risk for pressure spikes. There used to be a misconception that because loprednol did not cause the same rate of pressure spikes as prednisolone, it was not as powerful as other steroids, but now we understand that this is not the case. It delivers the necessary efficacy with lower risk to IOP.4-6

UNIQUE FORMULATION, BID DOSING

After years of using loprednol postoperatively, I was very comfortable trying a new formulation comprised of loprednol nanoparticles with a mucus-penetrating surface coating (Invelys, Kala Pharmaceuticals), an ophthalmic suspen-
sion, which offers better penetration of the mucin layer and cornea as well as less elimination with tears. The vehicle keeps the nanoparticles with their proprietary coating equally distributed in solution, playing an important role in ensuring patients get the amount of medication they need.

The drop’s improved bioavailability of active medication in the anterior chamber makes it possible to get the same results with BID dosing I had with other suspension steroid formulations with QID dosing. In my opinion, we cannot underestimate the value of a BID drug versus a QID drug for improving compliance. As a glaucoma specialist, I always deal with eye drop compliance problems, from physical limitations to forgetfulness to ocular surface discomfort. Any time I can decrease the number of medications on the eye, I take that opportunity. BID dosing is simpler, so there’s less room for patient confusion and compliance errors.

Patients appreciate the convenience as well. We asked our patients, three months after cataract surgery when everything is healed, if any factor negatively affect their happiness with this experience. Their top problem was taking so many drops every day after surgery. Now they can use fewer drops. And there’s no tapering—just BID dosing until the bottle runs out. This makes the regimen is less confusing throughout recovery, and it is an especially welcome change when patients have the fellow eye done and can follow the same schedule for both eyes. In fact, simplifying the regimen to BID dosing has actually saved us 2 to 3 minutes of staff time normally spent verifying the tapering medications for the first eye and educating patients about the dosing schedule, which, in turn, improved office flow in general.

**BRANDED VERSUS GENERIC**

Last year, I saw a patient who had used generic prednisolone acetate after cataract surgery. She was happy at one week with 20/25 vision, but unhappy at two weeks with 20/60 vision. Prednisolone was reducing inflammation, but the generic formulation was aggravating the ocular surface and affecting her vision. (See Figure 1) Invellys had just been released, so I prescribed it after doing her second eye two weeks later. She was 20/20 and happy at one week, and the ocular surface looked much better compared to the prednisolone acetate eye.

It is not a direct comparison—these drops have two different active molecules—but the case illustrates just how destructive the generic vehicle can prove to be.

The detrimental effects of some generic formulations are not always so pronounced and may not always be clinically significant, but the possibility is always there. By carefully choosing a branded steroid, we get an approach that works clinically, improves compliance (which can make our patients happier), and also saves us time—all while delivering the reliable control over postoperative recovery that we all want. And when significant pharmacological advances come along to help our patients, we are not limited to older generic options.

**REFERENCES**


**FIGURE 1** When a patient used generic prednisolone after cataract surgery, the formulation aggravated the ocular surface, evidenced by significant corneal staining. The patient, who was on generic prednisolone acetate QID after surgery and at one week post op, was complaining of fluctuating vision, FB sensation, and glare. This is the reason why going to a BID drop with a good vehicle is important. (Photo courtesy of Inder Paul Singh, MD)
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* In any trabecular bypass MIGS pivotal trial.
† Significant ECL defined as ≥30% ECL.

INDICATION FOR USE. The iStent inject Trabecular Micro-Bypass System Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma.

CONTRAINDICATIONS. The iStent inject is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, disciform or congential anomalies of the anterior chamber (AC) angle, retinoblastic tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

WARNINGS. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

MRI INFORMATION. The iStent inject is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details.

PRECAUTIONS. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent inject have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudohyper trophy, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, aphakic eyes without concurrent cataract surgery or with complicated cataract surgery, eyes with nondilated IOP > 24 mmHg or unmedicated IOP < 24 mmHg or > 36 mmHg, or for implantation of more or less than two stents.

ADVERSE EVENTS. Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent inject vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BVCA loss ≥2 lines at ≥3 months (2.6% vs. 4.2%).

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.


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