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November 15, 2013 VOL. 38, NO. 22
CLINICAL DIAGNOSIS | SURGERY | DRUG THERAPY

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Drug Therapy

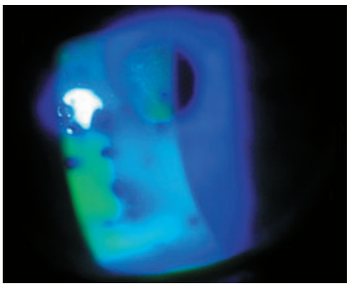
COMBINED THERAPY SHOWS PROMISE FOR DME PATIENTS

INDIANAPOLIS :: **ANTI-VASCULAR** endothelial growth factor agents alone may not provide the optimal response for all patients with diabetic macular edema, said Raj K. Maturi, MD, private practice, Midwest Eye Institute, and Department of Ophthalmology, Indiana University School of Medicine, Indianapolis.

*(See story on page 26 : **DME**)*

Special Report

NEW TECHNOLOGY ENTERING NEW ERA OF DRY EYE CARE



NEW YORK :: **RECENT TECHNOLOGICAL** advances are improving the diagnosis of dry eye disease and should enable more timely intervention that will help to reduce the morbidity of this common condition, according to Christopher E. Starr, MD, associate professor of ophthalmology, Weill Cornell Medical College, New York.

*(See story on page 11 : **Technology**)*

Sjögren's syndrome on the radar

How underdiagnosis of disorder can lead to significant morbidity, and even mortality

By Cheryl Guttman Krader;
Reviewed by Esen Akpek, MD

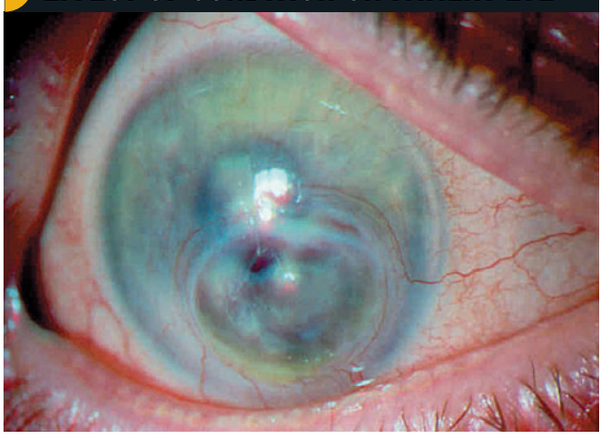
BALTIMORE :: **OPHTHALMOLOGISTS WHO SEE** patients with dry eye must maintain an index of suspicion for Sjögren's syndrome so that affected individuals are properly diagnosed and treated, said Esen Akpek, MD.

"Sjögren's syndrome is most often associated with dry eye and dry mouth," said Dr. Akpek, professor of ophthalmology and rheumatology; director, Ocular Surface Disease and Dry Eye Clinic, and associate director, Johns Hopkins Jerome L. Greene Sjögren's Syndrome Center, Wilmer Eye Institute at Johns Hopkins University School of Medicine, Baltimore.

"While those features are its most common early manifestations, Sjögren's syndrome is a multisystem autoimmune disease that can result in significant morbidity from joint and internal organ involvement as well as mortality through its association with lymphoma," Dr. Akpek said.

Early recognition and treatment are important for minimizing disease progression, Dr. Akpek noted. Unfortunately, although Sjögren's syndrome is one of the most common autoimmune diseases, it is also one of the most underdiagnosed.

EFFECT OF CONDITION ON PATIENT EYE



Slit lamp examination of a paracentral sterile corneal necrosis in a patient with Sjögren's syndrome and associated dry eye.

In addition, the presence of dry mouth or other systemic complaints associated with other tissue damage from Sjögren's syndrome may be a useful predictor. *(Image courtesy of Esen Akpek, MD)*

Lack of suspicion for Sjögren's syndrome—fueled by underappreciation of its true prevalence—is one reason why the disease is underdiagnosed or not diagnosed before the development of permanent tissue damage, Dr. Akpek said.

Affected patients often present to a primary eye-care provider because of their dry eye and do not receive the evaluation that would lead to a proper diagnosis.

"It is the responsibility of ophthalmologists and optometrists who see patients with dry eye complaints to raise the suspicion of Sjögren's syndrome and begin the work-up just as it would be done if the patient presented with uveitis," Dr. Akpek said. "Dry eye is

*(Continues on page 15 : **Sjogren's syndrome**)*

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with dry eye symptoms.

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Living in a bacterial world

Might malicious microbes make a mockery of modern medicine?

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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WHEN HALLOWEEN COMES EACH year the television networks advertise their many scary movie marathons. In these cinematographic masterpieces, shapely young women decide to walk around by themselves in the dark only to be attacked by chainsaw-wielding maniacs or crazy men wearing hockey masks.

Although I am personally not enamored of these films, they must meet an important need of my countrymen, considering that Hollywood spits out sequel after sequel.

A related genre of film is that in which the people are attacked by some natural predator, such as great white sharks in the Atlantic Ocean (*Jaws*) or giant snakes in the Amazon River of Brazil (*Anaconda*).

When I do watch these movies, having a pretty good idea that one or more of the protagonists is going to have something bad happen, the anticipation of the scary part results in a lot of boredom as the initial character development takes place. Is the giant man-eating snake about to leap out of the water and grab Ice Cube and JLo, or do I have to wait before the screams and excitement begin? Is that knocking at the door simply the local farmer, or is it the deranged mass-murderer?

ENTER DEADLY SUPER-BACTERIA

Well, that is how I am starting to feel about the long-heralded arrival of all the deadly superbacteria. I believe you know about these, as they are routinely given front-page attention on our newspapers and prominent coverage in television news. These are the germs that can't be stopped, we are told, because they have developed resistance to all the antibiotics at our disposal.

It's just a matter of time, we have been told for at least a decade, before these malicious microbes make a mockery of modern medicine.

According to the CDC, 2 million Americans now suffer infections each year from these bacteria, and 23,000 of us die.

There have always been infections that are difficult to treat (e.g., acanthamoeba or fungal keratitis), but that was no less the case 20 years ago than it is today. Bacterial infections are not (in my humble opinion) particularly more a concern today than they were a decade or two ago.

In a recent poll of *Ophthalmology Times* readers, we asked whether drug-resistant bacterial infections were a concern in their practices.

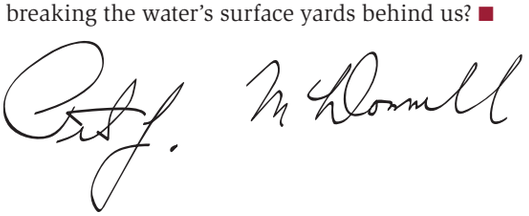
- **Fifty-nine percent of respondents described these "superbugs" as "not an issue."**
- **Eighteen percent reported them to be of minimal concern.**
- **Only 23% reported that they had experienced a significant encounter or encounters with the dread antibiotic-resistant organisms.**

So, roughly 4 in 5 ophthalmologists are like the movie-goer with the tub of popcorn on his or her lap, waiting for the ax-wielding miscreant who never seems to make an appearance.

Why the disconnect between the ominous warnings of these monstrous microorganisms and the experience of most ophthalmologists?

Is it the case that these malignant microbes simply fall victim to the very high levels of antibiotics we ophthalmologists can deliver topically to the cornea with our drops or intravitreally with our injections—even if they measure as being resistant in the lab when tested against the very low antibiotic concentrations achievable in the bloodstream?

Or, are we like the teenager in the movie who, lulled into a false sense of security, decides to go for a moonlight swim, unaware of the fin breaking the water's surface yards behind us? ■



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- *http://www.nytimes.com/2013/09/17/health/cdc-report-finds-23000-deaths-a-year-from-antibiotic-resistant-infections.html?_r=0*
- *http://download-latest-movie.blogspot.com/2012/09/anaconda-1997-720p-bluray-500mb-mkv.html*

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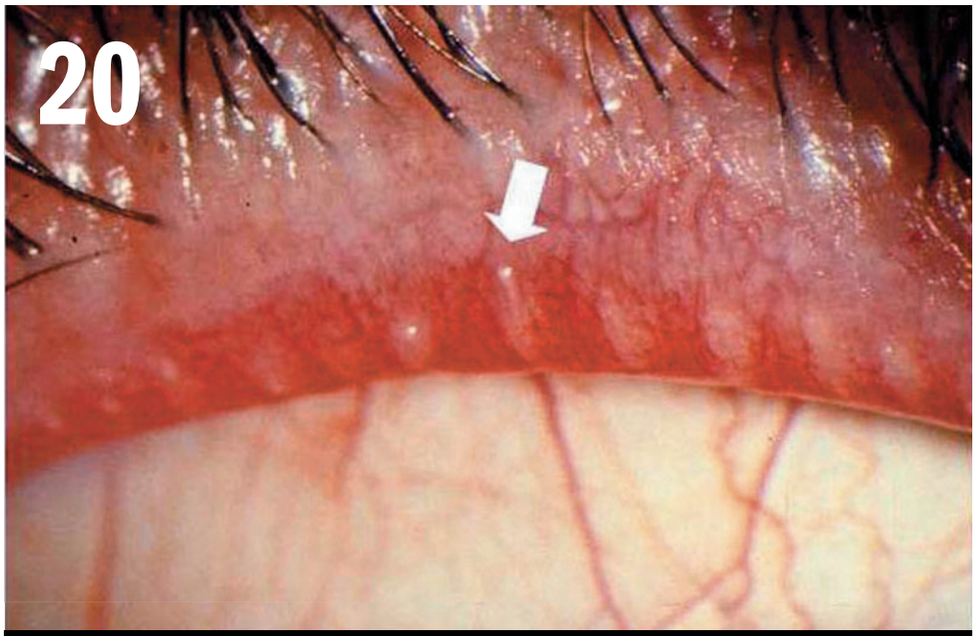
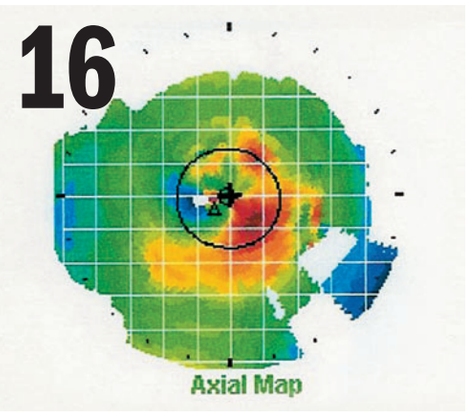
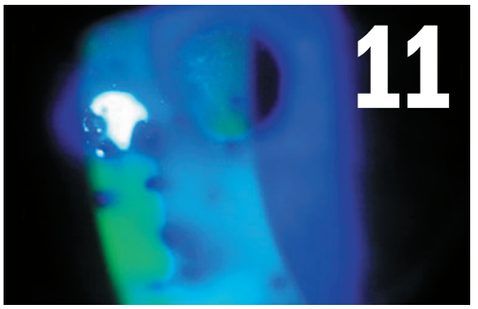


Managing MGD Slit lamp appearance of a patient with severe lid margin telangiectasia and meibomian gland dysfunction. *(Image courtesy of Esen K. Akpek, MD)*





Clinical Diagnosis

Drug Therapy

Special Report on page 11

DRY EYE

Technology

Practice Management

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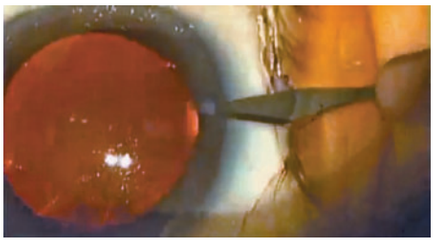

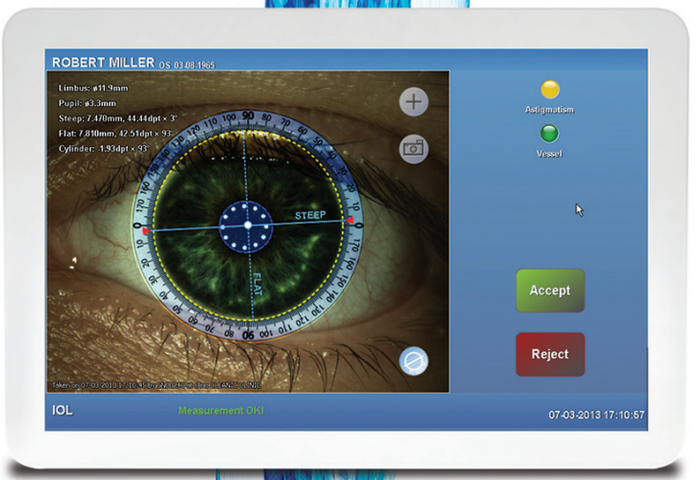

Pre-op

Image.

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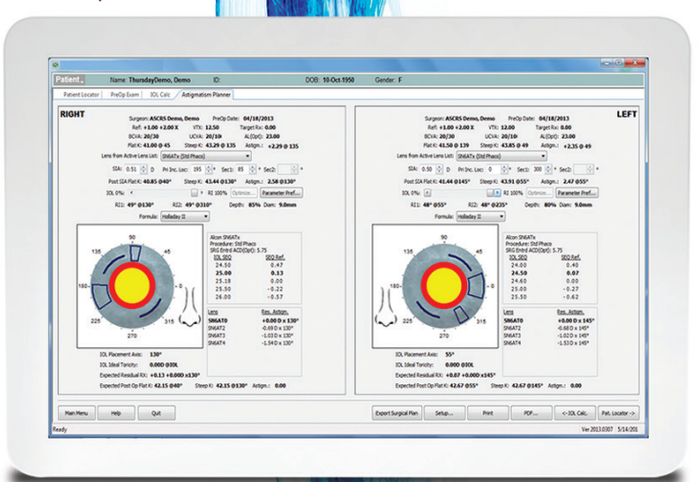
- Scleral vessels



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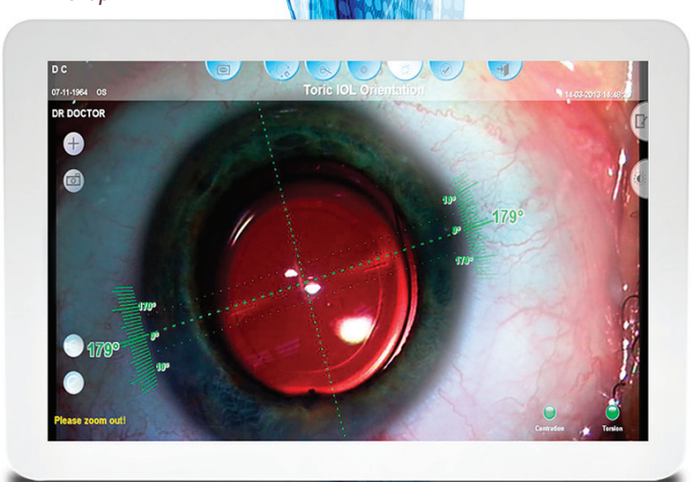

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ARVO gears up for 2014

Association's annual meeting theme promises 'Leading Eye and Vision Research'

***ARVO View* By Katrina Norfleet**

It is not too early for the vision science community to make plans for the 2014 meeting of the Association for Research in Vision and Ophthalmology (ARVO).

As the year winds down, the association also recognizes updates and achievements in translational research and opens up nominations for the ARVO Achievement Awards.

TRANSLATIONAL RESEARCH

Translational Vision Science & Technology (TVST)—the newest open-access, online and peer-reviewed journal published by ARVO—features articles on multidisciplinary research that bridge the gap between basic research and clinical care.

TVST has included articles in areas of low vision, genetic and ophthalmic imaging, as well as a special issue covering nanotechnology and regenerative medicine—*Vision Restoration: Regenerative Medicine in Ophthalmology*.

To read the articles, or submit a transcript, visit the *TVST* website at *tvstjournal.org*.

CLINICIAN-SCIENTISTS AWARDED

Congratulations to the 2014 Pfizer Camras Translational Research Award recipients. These early-career researchers have exhibited excellence in research and in fundamental scientific discoveries:

- **Rajendra Apte, MD, PhD (IM), Washington University School of Medicine: Dr. Apte's findings spawned a series of translational studies, which led to an age-related macular degeneration (AMD) drug development initiative and biomarker development for dry eye disease and AMD.**
- **Farhad Hafezi, MD, PhD (CO), Geneva University Hospitals and University of Southern California, Los Angeles: Dr. Hafezi was one of the core team of innovators who developed and brought to market the corneal collagen crosslinking method and transitioned this method from basic/pre-clinical studies to later arresting corneal degeneration caused by keratoconus in patients.**
- **Hendrik P.N. Scholl, MD, MA (RE), Johns Hopkins University School of Medicine: Dr. Scholl, one of the few retinal dystrophy experts in the world who is also an accomplished vitreoretinal surgeon, was recognized for his contributions to the understanding of the pathophysiology of blinding eye diseases.**

ACHIEVEMENT AWARDS

ARVO Achievement Awards are an opportunity to recognize members of the vision research community for their exceptional contributions to ophthalmology and visual science. Awards include the Proctor Medal and the Weisenfeld, Friedenwald, and Cogan awards, as well as the Joanne G. Angle Service and Kupfer Service awards.

Consider nominating a colleague for one or more of these prestigious awards before March 1, 2014.

There is no membership or geographical restrictions for nominees or nominators. Awards will be presented during the 2014 ARVO annual meeting.

To nominate a colleague or mentor, visit *arvo.org/awards*.

Key dates for 2014 ARVO Meeting

NOW: Hotel reservations open
NOW: Registration open
DEC. 6: Abstract submission closes
DEC. 6: Deadline for special interest group (SIG) session submissions

2014 ANNUAL MEETING

Under the banner of "Leading Eye and Vision Research," ARVO will host its 2014 annual meeting in Orlando, May 4 to 8.

Clinicians and researchers will come together to discover how eye and vision research is leading efforts in many related areas, including neuroscience, tissue imaging, and preventative health.

Abstract submissions are now being accepted through Dec. 6.

Learn more at *arvo.org/am*. ■

KATRINA NORFLEET *is assistant director of communications for the Association for Research in Vision and Ophthalmology. Readers may contact her at 240/221-2924 or knorfleet@arvo.org.*

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How patient satisfaction plays role in IOL selection

Each lens may be best suited to specific subset based on individual preferences, sensitivities

By Fred Gebhart; *Reviewed by Richard Chu, DO*

TAKE-HOME

- ***A patient satisfaction and quality-of-life survey found that three presbyopia-correcting IOLs provide better spectacle independence than monovision.***

FORT WORTH, TX ::

Ophthalmologists who might not be sure which IOL may be the best match for a particular patient have outside objective help.

Researchers presented what may be the first study to use patient satisfaction surveys to compare three FDA-approved presbyopic-correcting IOLs with validated test instruments.

Researchers used the National Eye Institute – Refractive Error Quality of Life – 42 (NEI-RQL-42) and the Subjective Vision Questionnaire (SVQ) to assess patient satisfaction with IOLs implanted for presbyopia.

The study, "Comparison of NEI-RQL-42 and SVQ quality of life measures after masked bilateral implantation of three FDA-approved presbyopia-correcting IOLs at 6-month follow-up," investigated patient perceptions of the three lenses.

Patients were similarly satisfied with the overall visual results following implantation of either the Crystalens AO (AT-50AO, Bausch + Lomb), ReSTOR 3.0 (SN6AD1, Alcon Laboratories), or Tecnis Multifocal (ZMA00, Abbott Medical Optics), said lead author Richard Chu, DO, medical director, Chu Eye Institute, Fort Worth, TX.

Dr. Chu

Other results have showed very good and objective outcomes for all three lenses. In terms of patient perceptions, each of the three lenses had its own strengths and weaknesses that made it more, or less, helpful for specific subsets of patients.

"The results supported what we suspected based on lens designs," Dr. Chu said. "Patients thought that the ReSTOR and Tecnis Multifocal had better near vision while the Crystalens had better distance vision and was better in terms of glare and halos, too."

The surprising part was that all three lenses did well in patient satisfaction scores, all three did well in terms of spectacle independence, and all three scored better than monovision using the same validated assessment instrument, he added.

LACK OF CORRELATION

A second surprising finding was the lack of correlation between objective measurements of surgical results with each of the three lenses and subjective patient preferences, Dr. Chu said.

A comparison of patient satisfaction scores on the NEI-RQL Distance Vision Subscale and the measured residual spherical correction 6 months following implantation showed no relationship between subjective satisfaction and objective results. The r^2 was less than 0.3 for all three lenses.

The idea of patient satisfaction surveys is not new, Dr. Chu said.

The novel element in this study was the use of familiar and standardized quality of life and patient satisfaction instruments. Most practices develop their own survey questions or procedures—which means results cannot be compared across different studies, products, patient groups, or practices.

"We chose these two instruments because they have been used in many other studies and have been well validated," Dr. Chu said. "The NEI-RQL, published in 2003, is more commonly used in America. The SVQ, which was published in Australia in 2004, is more familiar in other areas."

Both of these surveys were designed for LASIK, but they measure many of the same limitations, symptoms, and side effects of post-refractive surgery that we are interested in following IOL implantation. Since there is not a survey designed specifically to evaluate IOLs, these are the closest instruments available and the best validated, he noted.

THE PATIENT EXPERIENCE

One key message from the study is that patient perceptions of both their vision and specific side effects—such as glare and halos—are at least as important as objective measures.

Patients who value distance vision will probably be happier with a Crystalens or ReSTOR, which showed better satisfaction scores compared with Tecnis Multifocal (versus ReSTOR $p = 0.02$). Patients who value near vision will probably happier with a ReSTOR or Tecnis Multifocal, both of which showed better satisfaction scores compared with Crystalens ($p = 0.13$ for ReSTOR and $p = 0.04$ for Tecnis Multifocal).

Patients who are bothered by glare might want to avoid Tecnis Multifocal, which showed significantly lower satisfaction scores at both 1 month and 6 months compared with Crystalens ($p < 0.01$ at 1 and 6 months) and ReSTOR ($p = 0.01$ at 1 month, $p = 0.04$ at 6 months). Glare scores improved for all three lenses from 1 to 6 months which suggests neuroadaptation.

All three lenses showed better spectacle independence at 1 month and 6 months than previously published monovision data.

"This study was really a way to quantify the patient experience with these three IOLs and get real world data in a quantifiable, analyzable manner," Dr. Chu said. "In objective measures, these lenses all do pretty well."

Lens selection really comes down to what the patient's needs and preferences are, he noted.

"If you have a patient who is sensitive to glare and halo, for example, the Tecnis Multifocal would be the lens to avoid in that patient," Dr. Chu said. "When new generations of lenses come out, we now know how to evaluate them in an apples to apples manner by using these same validated instruments." ■

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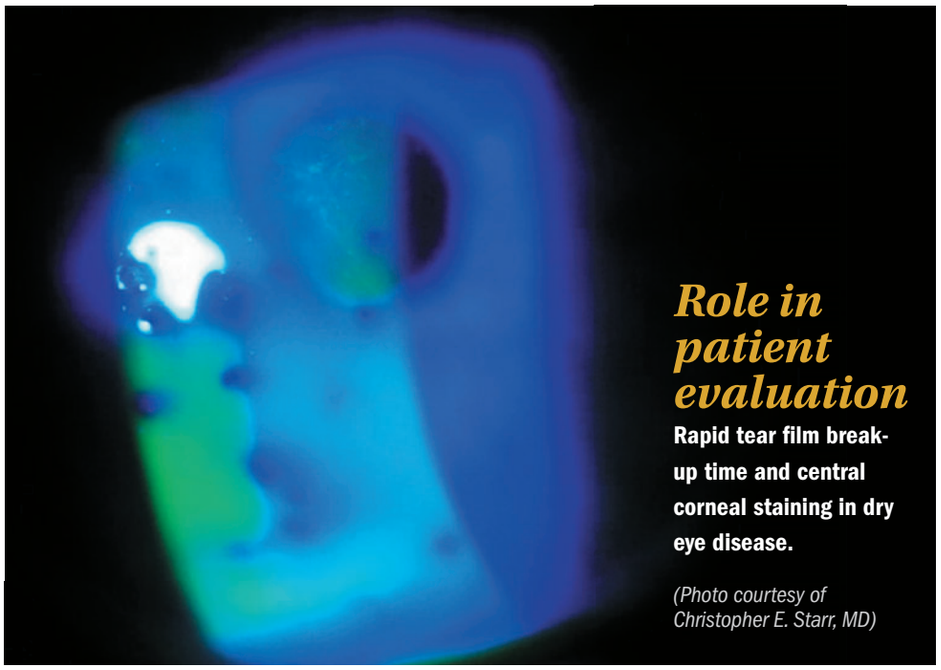
Dr. Chu has financial interests in Bausch + Lomb.



Role in patient evaluation

Rapid tear film breakup time and central corneal staining in dry eye disease.

(Photo courtesy of Christopher E. Starr, MD)

DIAGNOSTIC SYSTEMS LAUNCH NEW ERA IN DRY EYE CARE

Technology platforms have higher sensitivity, specificity than traditional techniques for patient treatment

By Cheryl Guttman Krader; *Reviewed by Christopher E. Starr, MD*

take-home

- **New diagnostic platforms for dry eye disease can help in determining the underlying cause and severity, which is useful for guiding treatment decisions.**

NEW YORK ::

Recent technological advances are improving the diagnosis of dry eye disease and should enable more timely intervention that will help to reduce the morbidity of this common condition, according to Christopher E. Starr, MD.

"New diagnostic tests for dry eye not only are increasing [ophthalmologists'] ability to identify affected patients correctly, but also our ability to offer appropriate treatment," explained Dr. Starr, associate professor of ophthalmology, Weill Cornell Medical College, New York.

"Using sensitive and specific objective testing takes the guesswork out of dry eye diagnosis—allowing clinicians to identify patients with significant disease who might otherwise have gone unnoticed or not treated aggressively enough," he added.

The value of some new dry eye diagnostic platforms relates to their ability to identify two features of the disease:

- **Hyperosmolarity, which is a core mechanism.**
- **Inflammation, which is a result of hyperosmolarity and a defining characteristic of dry eye disease.**

Dr. Starr

The currently available point-of-care device for measuring tear film osmolarity now plays a central role in his practice as a screening and follow-up tool, Dr. Starr said.

Patients are first seen by a technician who asks a series of questions to elicit any symptoms potentially associated with dry eye disease.

Patients with any of the following symptoms will then undergo tear osmolarity testing before the eyes are exposed to any drops or lights.

- **Grittiness on awakening**
- **Foreign body sensation**
- **Redness**
- **Tearing**
- **Burning**
- **Intermittent blurred vision**
- **Fluctuating vision**

"Validated standardized questionnaires, such as the Ocular Surface Disease Index, are useful for research studies, but a bit too time-consuming to be practical for daily patient care," Dr. Starr said. "We have developed a more streamlined approach to patient screening. Because we exclusively use an EMR for charting, a verbal, technician-driven, questionnaire is much faster and easier than scanning in the OSDI 45 times a day."

Dr. Starr added that bilateral measurement of film osmolarity takes about 1 or 2 minutes, making it a lot faster than the Schirmer test.

In addition, unlike the Schirmer test, testing tear film osmolarity is reimbursable.

Dr. Starr noted that the Schirmer test as well as tear film breakup time (TBUT) and ocular surface staining still have a valuable role in patient evaluation as they can help to further determine the etiology of dry eye disease (aqueous tear deficiency versus evaporative).

However, having the symptom and osmolarity information available from the technician's initial workup enables a directed, more efficient examination by the ophthalmologist and saves decision making time as well.

Continues on page 12 : ***Diagnostics***

Special Report) **DRY EYE**

Reviewing evidence in dry eye treatment

Disorder should be approached in a stepwise fashion based the severity of condition

By Fred Gebhart; *Deepinder K. Dhaliwal, MD, LAc*

PITTSBURGH ::

DRY EYE DISEASE IS more complex than many ophthalmologists realize.

It is defined less by the clinical sign of cornea staining and more by patient symptoms of discomfort, visual disturbances and tear film instability that can lead to damage of the ocular surface.

"Many clinicians think that if there's no corneal staining, it can't be all that serious," said Deepinder K. Dhaliwal, MD, LAc, associate professor of ophthalmology, director, Cornea and Refractive Surgery; director and founder, Center for Integrative Eye Care; director, UPMC Eye Center Monroeville; and medical director, UPMC LASER Vision Center, University of Pittsburgh Medical Center, Pittsburgh.

Dr. Dhaliwal

"The reality is that patients can and do can have dysfunctional tear syndrome with no clinical signs and lots of symptoms," Dr. Dhaliwal said.

One key message, she said, is that the current definition of dry eye is based largely on visual disturbance, ocular discomfort, and other symptoms of tear film instability and that patients can have significant damage to the ocular surface with subtle clinical signs.

Dry eye is a multifactorial disease of the tears and the ocular surface. The multiplicity of causal and contributor factors and the broad range of symptoms give rise to a diverse menu of treatments.

Potential choices range from artificial tears to various gels and ointments, moisture chamber spectacles, anti-inflammatory agents, tetracyclines, punctal plugs, autologous, serum bandage contact lenses, and systemic immunosuppressives to multiple types of surgery.

Regardless of the specific symptoms a patient might present, dry eye is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

The only effective way to treat dry eye is to deal with the root cause of the problem. That starts by focusing on patient education, eliminating drying medications—such as systemic antihistamines—and reducing environmental irritants.

take-home

- **An update is provided on the latest developments for an evidence-based approach in mild to severe dry eye disease.**

Dry eye is classified by stage:

- ***STAGE 1*** **is mild and/or episodic and usually occurs under stress. Visual symptoms are absent to episodic mild fatigue and there may be no clinical signs.**

- ***STAGE 2*** **is moderate episodic or chronic and can occur with or without stress. Visual symptoms are annoying and can sometimes limit activity.**

Continues on page 14 : ***Evidence***

DIAGNOSTICS

(Continued from page 11)

Tear osmolarity not only makes a diagnosis of dry eye, it also helps in assessing its severity.

Dr. Starr considers any patient with a hyperosmolar tear film or significant tear instability to be a candidate for immunomodulatory therapy with topical cyclosporine A 0.05% emulsion (Restasis, Allergan).

"Hyperosmolarity leads to ocular surface inflammation and the vicious progressive cycle of damage as outlined in the DEWS report," he said. "My aim is to inhibit that process by therapeutic intervention, and cyclosporine is the only FDA-approved anti-inflammatory medication for treating dry eye.

"Even if patients have minimal symptoms but significant signs, such as hyperosmolarity or staining, proper therapy with cyclosporine should be initiated," Dr. Starr added. "Similarly, anti-inflammatory treatment should be instituted in early stages of dry eye disease to prevent progression and potential ocular surface damage."

Dr. Starr said he also likes to utilize a short tapering course of loteprednol etabonatel 0.5% gel (Lotemax gel, Bausch + Lomb) in conjunction with topical cyclosporine in patients with significant inflammation.

He also considers off-label use of topical azithromycin 1% (Azasite, Merck) for patients with dry eye disease associated with meibomian gland dysfunction or other forms of blepharitis because of the macrolide antibiotic's anti-inflammatory activity.

OTHER CONSIDERATIONS

Artificial tears also have a role in the management of all patients with dry eye disease, and Dr. Starr said he monitors frequency of their instillation along with changes in tear film osmolarity to determine treatment response.

A system for ocular surface interferometry that characterizes the tear film's lipid layer (LipiView, TearScience) is also available in the United States for use in diagnosing dry eye. Though Dr. Starr does not have access to that technology yet, he hopes to have it soon. He believes it to be helpful for differentiating patients who have evaporative dry eye disease and for identifying patients who would benefit from treatment with the new thermal pulsation system for clearing meibomian gland obstruction (LipiFlow, TearScience).

Another platform that measures the level of matrix metalloproteinase-9 (MMP-9) in the tear film (InflammaDry, Rapid Pathogen Screening) is CE-marked and undergoing FDA review.

Dr. Starr said he intends to use it for diagnosis and follow-up when it becomes available, as studies show detection of elevated MMP-9 levels has very high sensitivity and specificity for diagnosing dry eye disease. ■

CHRISTOPHER E. STARR, MD

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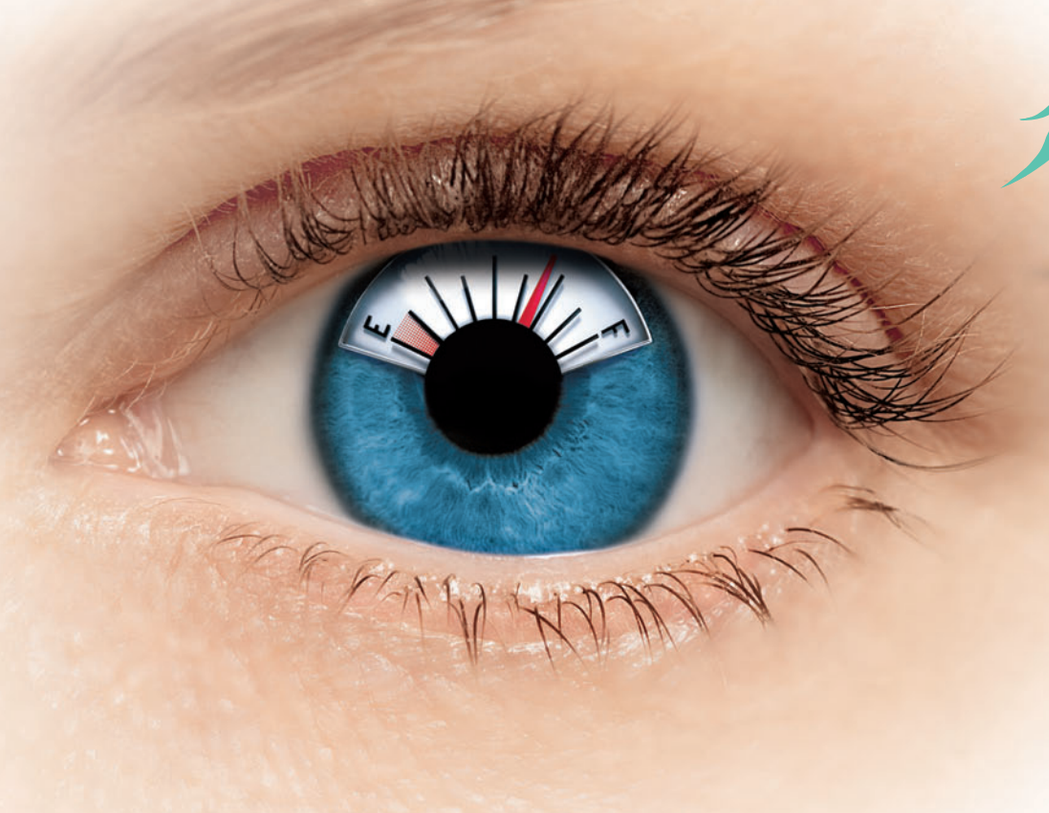
Dr. Starr is a consultant for Alcon Laboratories, Allergan, Bausch + Lomb, Merck, Nicox, Rapid Pathogen Screening, and TearLab.



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

Warnings and Precautions

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

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

ALLERGAN

EVIDENCE

(Continued from page 12)

Clinical signs may or may not be present, but if present, staining is mild and the tear meniscus is somewhat reduced.

> *STAGE 3* is severe frequent or constant without stress. Visual symptoms are annoying, chronic to constant and limit activity. Clinical signs are moderate to marked conjunctival staining and marked central corneal staining and filamentary keratitis

> *STAGE 4* is severe and constant and may be disabling. Visual symptoms are constant and may be disabling. Clinical signs include conjunctival injection and marked staining, severe punctate erosions, scarring ulcerations and almost immediate tear break-up time.

Treatment for dry eye is linked to the severity level, Dr. Dhaliwal said.

Stage 1 treatment is primarily education, environmental and dietary modifications, elimination of drying medications, artificial tears, gels or ointments, and eyelid therapy.

Environmental modifications are essential but not always easy. Patients should avoid drafts, which can be difficult if the workplace is directly under a heating or air conditioning vent. Computer screens may need to be repositioned so the patient can look down rather than straight ahead or up.

"Patients should not be using artificial tears every hour" Dr. Dhaliwal said.

That results in "dishpan" eyes, a condition like dishpan hands where all the natural oils have been washed away. Ophthalmologists need to treat the root cause of the dryness and not just tell patients to use artificial tears as often as they need. Get at the root cause of the disease, ocular surface inflammation.

Stage 2 dry eye needs more potent treatment, typically anti-inflammatories. Cyclosporine can be effective, but can take 6 weeks to 3 months to reduce inflammation.

Dr. Dhaliwal said she typically combines cyclosporine with a mild topical steroid for the first 2 to 4 weeks to get a more immediate anti-inflammatory response.

Punctal plugs can help maintain the tear film once inflammation has resolved. Secretagogues and moisture chamber spectacles can also help.

Level 3 treatments add autologous serum, contact lenses and permanent punctal occlusion.

Level 4 disease requires systemic anti-inflammatories. If medical treatment does not work, the patient may need lid surgery, tarsorrhaphy, or transplantation of mucus membrane, salivary gland or amniotic membrane.

Proper diagnosis and stepwise treatment is an effort to prevent patients progressing to level 3 or level 4 dry eye, Dr. Dhaliwal said.

In addition to counseling patients to take basic steps to remedy potential environmental, dietary and medication causes as well as avoiding overuse of artificial tears, clinicians can suggest other easy and affordable interventions.

In patients that have associated meibomian gland dysfunction (with rapid tear break-up time), oral omega 3 fatty acids and warm compresses/lid massage are helpful.

Dr. Dhaliwal educates her patients to create a simple yet effective warm compress by placing a cup of uncooked rice into a clean cotton sock and heating it in the microwave for 30 seconds or so. This should be placed over the eyes for 15 minutes twice daily.

Also, if patients have significant dry eye symptoms first thing in the morning, be suspicious of lagophthalmos in which case patients do well with lubricating ointment at bedtime. ■

DEEPINDER K. DHALIWAL, MD, LAC
P: *412/647-2200*
Dr. Dhaliwal did not indicate a financial interest.

SJOGREN'S SYNDROME

(Continued from page 1)

an inflammatory eye disorder just like uveitis and it doesn't matter that one affects the ocular surface and the other the inside of the eye."

Though there is a need for guidelines that might direct practitioners in identifying which patients deserve further evaluation, available studies indicate that presence of dry mouth or other systemic complaints associated with other tissue damage from Sjögren's syndrome, as well as a family history of autoimmune disease, are useful predictors.

The possibility of Sjögren's syndrome should be considered in any patient with clinically significant dry eye described by the presence of ocular surface staining, or a low Schirmer test score, or a high tear film osmolarity.

Then, a review of systems should be performed and patients should be asked about presence of dry mouth, joint pain, and a family history of autoimmune disease.

take-home

Since dry eye is an early presenting sign, eye-care providers need to maintain a high index of suspicion for Sjögren's syndrome in patients with clinically significant dry eye.

Any patient with these findings should have laboratory testing to diagnose Sjögren's syndrome.

A newer test is now available that identifies antibodies to salivary gland protein, carbonic anhydrase 6, and parotid secretory protein in addition to the traditional SSA, SSB, ANA and RF (Shen L et al. Novel autoantibodies in Sjogren's syndrome. *Clin Immunol.* 2012;145:251-255).

APPROACH TO MANAGEMENT

Patients whose dry eye is diagnosed with Sjögren's syndrome should be treated aggressively with anti-inflammatory treatment and followed at frequent intervals—even if their dry eye does not seem too severe, because they are at risk for developing extraglandular ocular complications.

"In a retrospective review of 183 patients with primary Sjögren's syndrome seen at our institution between 1999 and 2013, we found that one-third had extraglandular ocular findings," Dr. Akpek said. "Almost half of those patients had significant, vision-threatening disease, including corneal ulcer/infiltration, corneal melt/perforation, cicatrizing conjunctivitis, uveitis, optic neuritis, scleritis, and retinal vasculitis."

Patients with Sjögren's syndrome should also be referred to a rheumatologist for a full systemic evaluation and appropriate systemic treatment.

"Certain drugs used in the management of Sjögren's syndrome, such as hydroxychloroquine, can decrease the risk of lymphoma development," Dr. Akpek said. "Therefore, the ophthalmologist should always seek the collaboration of a rheumatologist in managing these patients." ■

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Dr. Akpek has received institutional research grants from Alcon Laboratories and Allergan and is a consultant for Nicox.

Special Report) **DRY EYE**

Minimizing ocular surface problems can maximize refractive results

Screening process reveals higher rates of dry eye, blepharitis than most physicians anticipate

By William B. Trattler, MD, and Jodi Luchs, MD, *Special to* Ophthalmology Times

TWO PROSPECTIVE STUDIES conducted recently both found that—though the majority of patients presenting for routine cataract surgery are asymptomatic—a large proportion of these patients do have clinically significant ocular surface disease.

If not addressed, tear film problems can lead to errors in IOL power selection, slow down healing and visual recovery, and reduce postoperative satisfaction and quality of vision, particularly in refractive cataract surgery with a premium IOL.

PHACO STUDY

The Prospective Health Assessment of Cataract Patients' Ocular Surface (P.H.A.C.O.) study was conducted at nine clinical sites across the United States.[1]

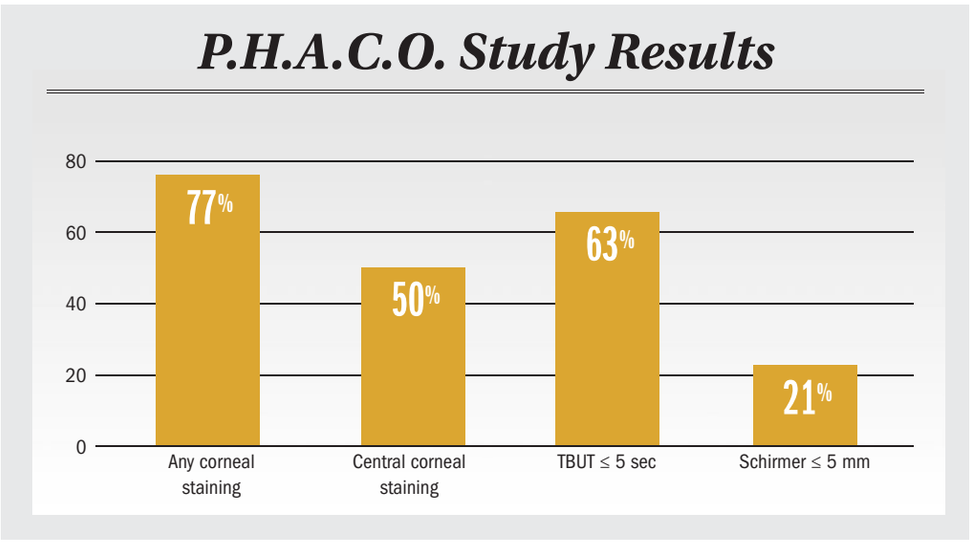
In all, 136 patients (272 eyes) presenting for routine cataract surgery were examined for signs and symptoms of dry eye prior to surgery. The average age was 70 (range 54 to 87) years. About 22% of the patients had been told at some point in the past that they had dry eyes.

While experts debate what constitutes an abnormal tear film break-up time (TBUT), the typical values proposed as "abnormal" are <10 seconds or < 7 seconds.

However, most would agree that 5 seconds is too rapid. Surprisingly, the average TBUT in the PHACO study was 4.95 seconds, and 171 eyes (63%) had a TBUT of ≤ 5 seconds.

Most of the eyes (77%) had some corneal staining, but what was more concerning is that half of them had central corneal staining, which can certainly affect visual outcomes.

Although we generally view the Schirmer test as less useful for routine dry eye screening, one-fifth of the patients also had abnormally low Schirmer test scores (<5 mm) (Figure 1).



BLEPHARITIS STUDY

In another prospective study with very similar methodology, looking at the prevalence of blepharitis, we (along with Carlos Buznego, MD) enrolled a total of 200 eyes of 100 patients presenting for routine biometry prior to cataract surgery.[2]

Following an ocular surface examination, 59% of the patients in this study had a diagnosis of blepharitis. Sixty-one percent had a TBUT of ≤ 7 seconds.

As cornea and external disease specialists, we aren't all that surprised by the results in either of these studies. What is striking is that the majority of the patients were asymptomatic or minimally symptomatic.

Although this surprised us initially, it does explain why ocular surface disease so often goes undiagnosed preoperatively. The patients are not complaining about it; the surgeon is focused on the primary complaint (cataract); and no one is really thinking about treating the ocular surface.

But failing to identify and treat dry eye prior to cataract surgery can lead to reduced visual outcomes. Either rapid TBUT or corneal staining will significantly affect keratometry and topography, reducing the accuracy of preoperative IOL power calculations. Ocular surface disturbances can significantly alter the magnitude or axis of cylinder, affecting planning for limbal relaxing incisions or toric IOLs.

Moreover, once the cataract has been removed, visual fluctuations and quality-of-vision problems will become much more noticeable, even if the patient continues to be asymptomatic.

In the past, when patients expected to see 20/40 with glasses by 6 weeks, subtle ocular surface issues and even IOL power errors may not have mattered as much.

In today's environment, when patients undergo a 10- to 15-minute procedure under topical anesthesia and have the potential (with a premium IOL) for 20/20 distance and near acu-

Continues on page 18 : ***Ocular surface***

take-home

- **The majority of cataract patients likely have significant tear film disturbances that can affect their preoperative measurements and postoperative satisfaction with cataract surgery.**

If not addressed, tear film problems can lead to reduced postoperative satisfaction and outcomes. *(Figures courtesy of William B. Trattler, MD)*

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13-ADV-122 REV A

OCULAR SURFACE

(Continued from page 16)

ity within days of surgery, these subtle sources of error or visual compromises become much more relevant to successful management.

FIXING THE PROBLEM

Data suggest that cataract surgeons should have a high index of suspicion about dry eye and blepharitis and take steps to identify and treat these conditions prior to taking preoperative measurements for cataract surgery.

Short-term management of moderate dry eye or blepharitis to optimize the ocular surface for surgery is well within the skill set of any ophthalmologist. It does not require corneal training or specialized testing equipment, and it need not be time-consuming or disruptive to your preoperative flow.

Here are three steps that take only a few minutes preoperatively, but can save lots of chair time and headaches postoperatively:

1. **Look for dry eye with corneal staining, TBUT, and topography.**
2. **Look for blepharitis/meibomian gland disease (MGD) by examining the lid margins and applying pressure to express the meibomian glands.**
3. **If you see rapid TBUT, MGD or corneal staining, treat the patient for 1 to 2 weeks before the biometry appointment with cyclosporine, topical steroids, nonpreserved artificial tears, and potentially punctal plugs (dry eye) and/or with warm compresses and topical azithromycin (blepharitis/MGD).**

Alterations to the treatment regimen may be needed for longer-term management, but this regimen will get most patients in good enough shape for accurate biometry in a relatively short period.

IMPACT LARGE, SMALL

By routinely screening for ocular surface disorders—even in the absence of complaints—surgeons will be able to improve mean outcomes incrementally with premium IOLs across the board.

For patients for whom ocular surface disorders might have led to a less-than-satisfactory outcome—the wrong IOL power implanted, for example—the impact can be great.

We often see unhappy postsurgical patients referred for consultation who simply have dry eye or blepharitis. Once the tear film is stabilized, visual quality improves dramatically and dissatisfaction disappears.

In one of Dr. Trattler's recent multifocal IOL patients, preoperative measurements pointed to a 20-D multifocal IOL (Tecnis Multifocal, Abbott Medical Optics) as the best choice. However, the topography had a lot of missing data, suggesting an unstable tear film.

Dr. Trattler elected to treat the patient with cyclosporine and topical steroids. When measurements were repeated 1 week later, keratometry had changed significantly. The patient received a 21-D lens and a great result from surgery.

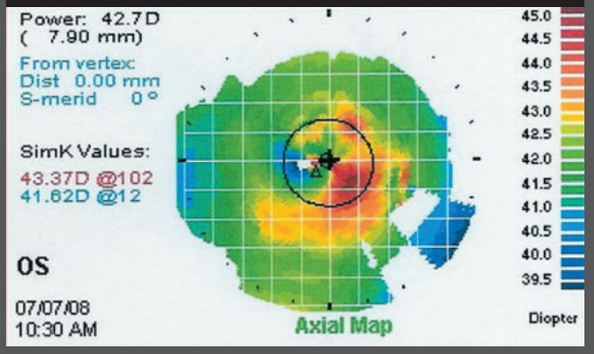
In another case, a 58-year-old male with visually significant cataract in the left eye, who was interested in a premium IOL, we observe how the topography changes with treatment over just 1 day and 1 week (Figure 2).

CONCLUSIONS

Ocular surface disease in the cataract population is more common than most people believe. The majority of cataract patients likely have significant tear film disturbances that can affect their preoperative measurements and postoperative satisfaction with cataract surgery.

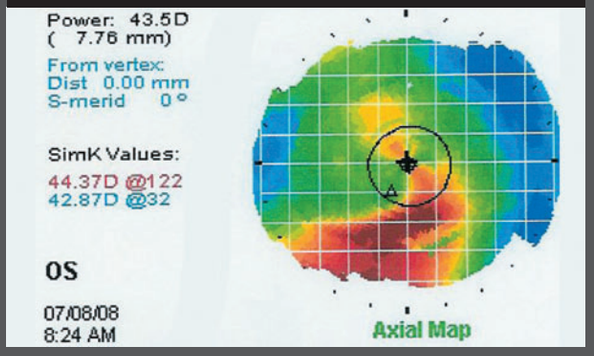
Given this, it is critical to have a high index of suspicion of dry eye and blepharitis. If ophthalmologists look for it even in asymptomatic patients, they can make the diagnosis and treat the ocular surface prior to surgery to maximize the chances of delivering the refractive results that patients expect. ■

Figure 2 Preoperative Topography



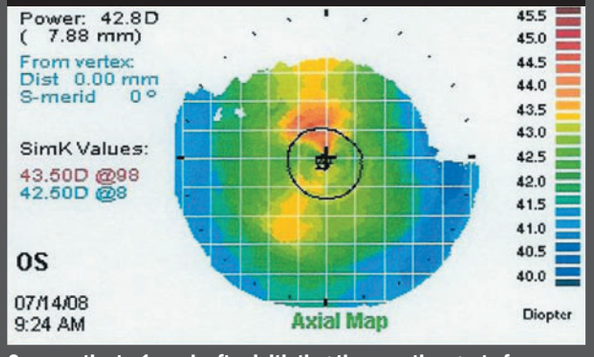
A 58-year-old male with visually significant cataract OS, interested in a premium IOL.

Preop Topography After 1 Day of Treatment



Same patient : 1 day after starting lubricating drops.

Preop Topography After 1 Week of Treatment



Same patient : 1 week after initiating therapeutic agents for dry eye. *(Images courtesy of William B. Trattler, MD)*

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What's trending in dry eye research

Ophthalmologists, vision scientists track latest therapeutic, diagnostic advances in disease

By George Ousler and Ora Staff

THE PAST YEAR HAS been filled with many clinical updates in the dry eye arena. Perhaps nowhere was this more prevalent than in studies presented by ophthalmologists and vision researchers at the annual meeting of the Association for Research in Vision and Ophthalmology.

In an effort to understand the natural progression of dry eye disease in patients with moderate dry eye better, McDonnell et al. presented the design and baseline characteristics of the Progression of Ocular Findings (PROOF) study (*McDonnell P et al. IOVS 2013;54:ARVO E-Abstract 4338*).

The multicenter, prospective, 5-year, observational, case-controlled study is currently ongoing and enrolled 217 patients with Level 2 dry eye and 51 patients with no history of dry eye. Both groups are being followed every 6 months with a primary study endpoint of the percentage of patients with progression of dry eye from baseline to month 60.

Study evaluations include Schirmer test, TFBUT, OSDI, corneal and conjunctival staining, and goblet cell density. The authors noted that significant decreases in goblet cell density and increases in blurred vision were evident in this dry eye population.

Researchers also sought to report the prevalence of dry eye disease in the elderly French population (*Muselier-Mathieu A, et al. IOVS 2013;54:ARVO E-Abstract 877*).

The MONTRACHET (Maculopathy Optic Nerve nutrition neurovascular and HEarT diseases) study included 1,024 subjects over the age of 75 years. The prevalence of dry eye was evaluated with both subjective criteria and objective criteria.

The study demonstrated that the prevalence of dry eye varies depending on the signs or symptom considered. For example, subjective criteria based on self-reported history of dry eye, use of topical medications, and OSDI scores of greater than 18 saw a dry eye prevalence of 17%, 11.9%, and 34%, respectively.

PHYSICAL ACTIVITY, SLEEP QUALITY

In a study designed to investigate the association among physical activity, sleep quality, and dry eye disease, the results indicated that both physical activity and sleep quality were associated with dry eye (*Kawashima M, et al. IOVS 2013;54:ARVO E-Abstract 940*). A high level of physical activity appears to lower the risk of dry eye, as more participants scored high in the physical activity in the non-dry eye group than in the dry eye group.

The researchers also concluded that poor sleep quality also appears to be an influencing factor of dry eye, particularly concerning dry eye symptoms.

SIGN, SYMPTOM ASSESSMENTS

Post-hoc data was presented from a prospective, two-center, randomized, double-masked, placebo-controlled phase II trial of MIM-D3 ophthalmic solution, a tyrosine kinase TrkA receptor agonist. In 150 patients with dry eye, those with greater or more rapid exacerbation of signs and symptoms from the CAE were more responsive to MIM-D3 (*Ousler G, et al. IOVS 2013;54:ARVO E-Abstract 4343)*.

Continues on page 22 : ***Trending***

take-home

- **Research in dry eye disease continues to progress, fueled by studies in the area of therapies and diagnostics.**

Managing MGD still a challenge

Maintenance is an important determinant for the efficacy of any intervention

By Cheryl Guttman Krader; *Reviewed by Esen K. Akpek, MD*

BALTIMORE :: **RECOGNITION AND TREATMENT** of meibomian gland dysfunction (MGD) is important, because it is a common condition that can cause significant morbidity.

However, while a wide variety of therapeutic interventions are available for MGD, effective management remains a challenge.

Publication in 2011 of the proceedings from the International Workshop on Meibomian Gland Dysfunction ("MGD Workshop"), a project organized by the Tear Film Society and Ocular Surface Society, has raised awareness of MGD and the importance of identifying patients affected by what is considered to be the leading cause of dry eye.

Esen K. Akpek, MD, participated in the MGD Workshop as a member of the clinical trials committee, and she was also a co-author of a recently published Cochrane Database systematic review of interventions for chronic blepharitis.

"MGD is a chronic disease that can cause bothersome symptoms and serious corneal disease if there is progression to permanent gland atrophy," said Dr. Akpek, professor of ophthalmology and rheumatology, and director, ocular surface disease and dry eye clinic, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.

LID HYGIENE

"Lid hygiene measures definitely are effective treatment for MGD, and various other interventions, including pharmaceutical treatments, have been shown to work when evaluated over a short testing period," Dr. Akpek said. "However, effective management of MGD requires adherence to maintenance therapy, and that is probably why it is such a difficult therapeutic problem."

Lid hygiene measures using eyelid warming and mechanical lid hygiene to express MG secretions are widely considered effective for MGD even though there is no standard technique or studies comparing specific techniques for lid hygiene.

Nevertheless, it is generally agreed that patients should be advised about lid hygiene and followed for their compliance, Dr. Akpek said.

"There are some newer device-based approaches for addressing MG obstruction, including a thermal-pulsation device, intense pulsed light treatment, and gland probing," she said. "These interventions have been shown to lead to some improvement.

"However, any remission is not permanent, and these interventions are expensive and often not covered by insurance," she added.

OTHER THERAPIES

Artificial lubricant therapy has been more widely studied for treating aqueous tear deficiency than for evaporative tear deficiency that occurs with MGD. Based on available evidence, it may be reasonable to recommend use of higher-viscosity products to patients with MGD, Dr. Akpek said.

Topical lipid supplements in

Continues on page 22 : ***Manage MGD***

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TRENDING

(Continued from page 19)

What's more, patients who reported having dry eye for 5 to 10 years saw a significant reduction in fluorescein staining and experienced improvements in symptoms, as opposed to those patients who reported having dry eye for 1 to 5 years or >10 years (*Meerovich K, et al. IOVS 2013;54:ARVO E-Abstract 4340)*.

Positive data on thymosin beta 4 (Tβ4) was presented (*Sosne G et al. IOVS 2013;54:ARVO E-Abstract 6033*). In the physician-sponsored phase II study, 9 patients with severe dry eye were treated with Tβ4 eye drops (0.1%) or vehicle control 6 times daily over 28 days.

Dry eye sign and symptom assessments were evaluated throughout the study. Tβ4 drops were safe and well-tolerated and statistically significant differences in sign and symptom assessments were seen at various time points. The authors noted that further trials are warranted to assess optimal dosing regimens.

BIOMARKERS

One prominent clinical methodology theme for ocular inflammation was the measurement of biomarkers of disease with a focus on those found in tears. Several groups *(Hagan S et al. IOVS 2013;54:ARVO E-Abstract 955*; *Enriquez-De-Salamanca A et al. IOVS 2013;54:ARVO E-Abstract 2072; Dionne K et al. IOVS 2013;54:ARVO E-Abstract 4324; Lakshman N et al. IOVS 2013;54:ARVO E-Abstract 4325)* sought to indentify both normal and pathological values for cytokines in tears. Though there were some disagreements between studies on the quantitative metrics, it is clear that the tools to measure picogram quantities of signaling molecules accurately are up-and-coming.

TEAR FILM STABILITY

Other presentations focused on the importance of blink, mucin function, and dry eye tests of tear film stability.

Researchers examined the importance of considering lid contact time to differentiate dry eye and normal subjects *(Lafond A et al. IOVS 2013;54:ARVO E-Abstract 962)*. The authors found that dry eye subjects had significantly longer lid contact times and contact rates than normal subjects. The automated capture of blink and the relative ease of this technology allows for the tracking of spontaneous blink activity. Mucin function in dry eye was also the subject of multiple presentations.

Another presentation found that as the signs of dry eye worsen, soluble MUC16 values increase *(Watson M, et al. IOVS 2013;54:ARVO E-Abstract 4309)*.

Additionally, Saigal et al. presented data on the correlations of dry eye signs to signs, symptoms to symptoms, and both to objective tests of tear film stability. The authors reported the correlation of many signs and symptoms and quality-of-life variables (*Saigal S, et al. IOVS 2013;54:ARVO E-Abstract 4361)*. ■

GEORGE W. OUSLER III *is vice president of dry eye at Ora Inc., Andover, MA.*

MANAGE MGD

(Continued from page 20)

various formulations have been demonstrated to improve the signs and symptoms of MGD, probably by improving tear film stability. Topical antibiotics (azithromycin and metronidazole) and oral antibiotics (tetracycline derivatives) are also used and may provide benefit through both antimicrobial and anti-inflammatory actions.

Though there is some evidence of their efficacy, more solid proof from trials is missing, she said.

Lid scrubs containing tea tree oil, which eradicates Demodex, are also marketed for the treatment of MGD based on a suggested pathophysiologic role of infestation with these mites. Understanding of the relationship between Demodex and MGD is incomplete and there is a lack of good scientific evidence supporting use of tea tree oil scrubs for MGD treatment alone.

Tea tree oil also has antibacterial, antifungal, and anti-inflammatory properties that may be beneficial, and it has been shown to reduce symptoms of surface inflammation.

Topical corticosteroids have also been used as a treatment for MGD. Their use is controversial because of the potential for complications, but topical corticosteroids may be considered to have a role in managing acute inflammation, such as in patients with marginal hypersensitivity keratitis, or as an intralesional injection for chalazia.

Oral supplementation with essential fatty acids, including omega-3 and omega-6 fatty acids, is another popular recommendation for MGD management and also somewhat controversial, because there is conflicting evidence on the efficacy of these supplements and no clear information on necessary doses. ■

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Dr. Akpek has received institutional research grants from Alcon Laboratories and Allergan and is a consultant for Nicox. She was an unpaid member of the MGD Workshop.

New IOL technology yields lack of glistening formation

Surgeon's personal experience with lens also advantageous to explaining procedure to patients

By Lynda Charters; *Reviewed by Lawrence R. Goldberg, MD*

TAKE-HOME

- ***The absence of glistening formation is among the advantages associated with new IOL technology, relates one ophthalmologist.***

ST. PETERSBURG, FL ::

A new glistening-free, hydrophobic acrylic (enVista, Bausch + Lomb) seems to be a step forward in IOL technology in that it has major advantages and very few disadvantages, according to one ophthalmologist.

Though the IOL is relatively new to the market, Lawrence R. Goldberg, MD, is enthusiastic about its performance.

The hydrophobic acrylic IOL is designed to provide visual correction of aphakia in adults who have undergone removal of a cataractous crystalline lens with powers that range from 0 to +34 D. The lens is J-shaped, foldable, and very clear with no tint, which Dr. Goldberg prefers. Because this lens is not a premium IOL, it is covered by insurance.

Dr. Goldberg

By far the greatest benefit of this IOL is that it is glistening-free, according to Dr. Goldberg. He previously used the SN60WF IOL (Alcon Laboratories) almost exclusively in his practice, however, the major drawback of that IOL was the formation of glistenings.

From 10% to 15% of patients had a significant formation of glistenings throughout the lens, he noted.

"The glistenings were so extensive that it might affect contrast sensitivity even though the visual acuity was 20/20 to 20/25," he said.

ABSENCE OF GLISTENING FORMATION

With the introduction of the new hydrophobic acrylic IOL slightly over a year ago, Dr. Goldberg was impressed by the reported absence of glistening formation and began to use the lens in his practice in St. Petersburg, FL.

"I liked what I saw with my patients, and no glistenings have formed in the lenses," Dr. Goldberg said. "However, right now, it is too early to state that glistenings will never form because they usually form about 1 or 2 years after implantation in the SN50WF IOL."

Thus far, his patients have had no problems with the IOL postoperatively. The lenses have remained crystal clear. The IOL is stable in the bag, and all patients in a study sponsored by the manufacturer had 5° or less of IOL rotation between days 30 and 180 after implantation.

RESISTANT TO SCRATCHES AND ABRASIONS

Another advantage is that the lens is scratch- and abrasion-resistant, Dr. Goldberg noted.

"It is a tough lens that does not scratch or tear," he said. "The SN60WF IOL can tear occasionally, because it gets caught in the injector and I would have to pull it out."

Dr. Goldberg also has noted the occurrence of small cracks in the optic after uneventful injection of the SN60WF IOL into the capsular bag in a few patients.

"The enVista lens pops out of the injector smoothly," he said. "It has a harder surface and does not scratch or crack."

The IOL also has an aberration-free aspheric optic that enhances contrast sensitivity. Posterior capsular opacification should be minimal because of the IOL's 360° square posterior edge and step-vaulted haptics for direct contact with the capsular bag.

The IOL can be inserted through a 2.2-mm wound assist or a 2.4-mm in-the-bag incision during a standard phacoemulsification procedure. The only drawback to the hydrophobic acrylic IOL is that compared with other IOLs,

Continues on page 24 : ***Glistening-free***

GLISTENING-FREE

(Continued from page 23)

it unfolds slowly because it is a bit stiffer, according to Dr. Goldberg.

However, this is not a deal-breaker for him.

"Because it is stiffer, the IOL will hold up better in the event of a trauma if the injection process is not perfect," he said.

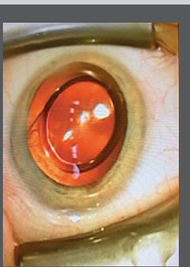
Dr. Goldberg also has first-hand experience with the lens, and he sees this as an advantage when explaining the cataract procedure. ■

Surgeon has lens implanted in his eyes

RESULTS ACHIEVED WITH the hydrophobic acrylic IOL (enVista, Bausch + Lomb) have impressed Lawrence R. Goldberg, MD, so much so that it was the lens of choice for his own bilateral cataract surgeries—especially because of the absence of glistening formation and positive feedback from colleagues.

Surgery on the right eye was performed July 19 and that on the left eye Aug. 13, 2013, to address a nuclear cataract and a posterior subcapsular cataract.

The cataract in the right eye was substantially worse, and the vision had decreased to about 20/40 without glare testing. The vision in the other eye was still 20/20.



The hydrophobic acrylic IOL became the lens of choice for Dr. Goldberg's own bilateral cataract surgery. *(Photo courtesy of Lawrence R. Goldberg, MD)*

After undergoing surgery in the right eyes, Dr. Goldberg's eyeglass correction had gone from 5 D of hyperopia preoperatively (a similar correction was present in his left eye) to a spherical equivalent of plano 1 week postoperatively.

Due to significant anisometropia, Dr. Goldberg was unable to wear a temporary lens in his right eye along with his highly hyperopic lens in his left eye. He decided to have surgery 1 month later in his left eye despite the 20/20 corrected vision in that eye. Between surgeries, Dr. Goldberg noticed how much brighter vision was in the right eye with the IOL implanted compared with the fellow eye.

Dr. Goldberg no longer needs to wear glasses to correct the preoperative hyperopia. "My distance vision is great, even without glasses," he said. "I have a small amount of distance correction and I will add to the progressive lens power so that I don't have to take the glasses on and off for reading. However, I can still read a little without the glasses." ■

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Dr. Goldberg has no proprietary interest in the technology.

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Combined steroids, anti-VEGFs show promise in DME patients

Adding dexamethasone implant to bevacizumab resulted in lower subfield thickness, OCT volume

By Michelle Dalton, ELS; *Reviewed by Raj K. Maturi, MD*

TAKE-HOME

- ***For some patients with diabetic macular edema, treatment with anti-vascular endothelial growth factor agents may not be enough. Clinicians need to consider other options, including dexamethasone implants.***

INDIANAPOLIS ::

Anti-vascular endothelial growth factor (VEGF) agents alone may not provide the optimal response for all patients with diabetic macular edema (DME).

This was evident with only 50% of the subjects in the Diabetic Retinopathy Clinical Research Network's Protocol I monthly ranibizumab group achieving a 2-line improvement in visual acuity after 2 years.

Because steroids provide a different mechanism of action, combining steroids with anti-VEGFs "may be more efficacious than either treatment alone in those patients without a complete response," said Raj K. Maturi, MD, in private practice at Midwest Eye Institute and with the Department of Ophthalmology, Indiana University School of Medicine, Indianapolis.

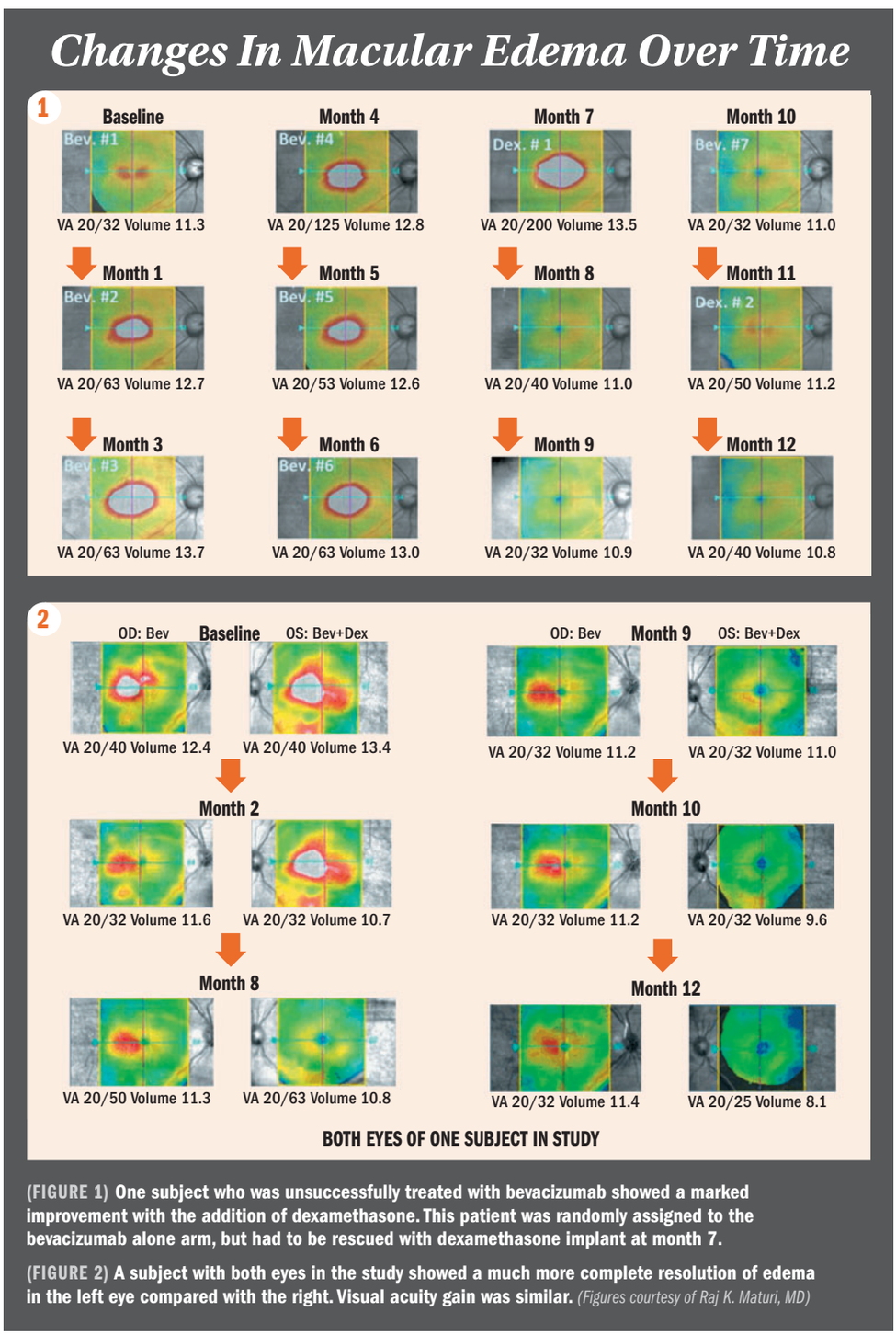
Dr. Maturi

Protocol I also found 40% were unable to achieve macular flattening at year 2, despite the protocol-mandated monthly evaluation and treatment, Dr. Maturi noted.

Protocol I (as well as the RISE/RIDE and RESTORE, the extension study for RISE/RIDE) "shows that if patients don't get the required treatment over time, they will lose out. If they don't come in consistently, they are losing out," Dr. Maturi said.

Optical coherence tomography (OCT) showed a continued thickening in a significant num-

Continues on page 28 : ***DME***



(FIGURE 1) One subject who was unsuccessfully treated with bevacizumab showed a marked improvement with the addition of dexamethasone. This patient was randomly assigned to the bevacizumab alone arm, but had to be rescued with dexamethasone implant at month 7.

(FIGURE 2) A subject with both eyes in the study showed a much more complete resolution of edema in the left eye compared with the right. Visual acuity gain was similar. *(Figures courtesy of Raj K. Maturi, MD)*

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DME

(Continued from page 26)

ber of subjects at 12 months in both the ranibizumab arms (0.3 and 0.5 mg).

POTENTIAL ROLE FOR STEROID COMBINATIONS

Dr. Maturi and colleagues—through a study supported by an Investigator Initiated Trial grant from Allergan—randomly assigned 40 eyes of 30 patients in a prospective, subject-masked, single-center study to evaluate the combination of dexamethasone and bevacizumab 1.25 mg (Group 1) versus bevacizumab 1.25 mg alone (Group 2).

In both groups, treatment was withheld if OCT was less than 250 µm and the acuity was better than 20/20. Both groups also received an initial bevacizumab injection.

Group 2 continued to receive monthly injections while Group 1 received dexamethasone intravitreal implant at month 1, 5, 10 and re-treated with bevacizumab at other visits.

The main inclusion criteria included a best-corrected visual acuity (BCVA) score between 24 and 78 letters and the presence of DME, defined as time domain equivalent OCT >250 µm.

Subjects with two eligible eyes had one eye randomly assigned to one treatment arm and the second eye to the other treatment arm. Ninety percent of those in Group 1 (n = 21) and 95% of those in Group 2 (n = 19) had type 2 diabetes.

There were more female (n = 17) than males, and the subject group was overwhelmingly Caucasian (n = 28).

At baseline, OCT central subfield thickness was slightly greater in Group 2.

Both groups gained about 5 letters, but it is the OCT changes that are "markedly different between the groups," Dr. Maturi said. "More patients in the combination group had macular flattening (OCT central thickness less than 250 µm) at 6 months with a change from baseline >25 µm (80% in the combination, versus 44% in the bevacizumab-alone groups)."

Additionally, the patients in the combination treatment group needed fewer supplemental treatments of bevacizumab.

"What we found was the overall edema resolution was much more complete in Group 1—volume is 10.4 mm^3 versus 11.3 mm^3 in the bevacizumab-only arm," Dr. Maturi said. "The dexamethasone intravitreal implant is most effective in the first 3 months after injection and less effective in the fourth month in reducing edema."

Monthly additions of bevacizumab during the subsequent 3 months "did not seem to have much affect on the duration of response," Dr. Maturi added.

For an example, see Figure 1 on Page 26 (a subject who was randomly assigned to Group 1, but her severe edema was unsuccessfully treated with anti-VEGFs and she required rescue with the dexamethasone implant).

In Figure 2 on Page 26, one patient with both eyes enrolled showed much better results in the combination arm than in the bevacizumab-only arm.

Dr. Maturi pointed out that the patients who had undergone the most bevacizumab injections prior to study enrollment gained the most vision when in the dexamethasone arm.

"There are some areas of caution with the use of dexamethasone (or other steroid)," Dr. Maturi said. "Steroids can cause an increase in IOP (6 of the 20 eyes in the steroid arm needed topical treatment for pressure control), and cataract progression can occur—almost half the eyes in the steroid group had progression of cataract.

However, these are known and manageable complications that the patient and physician are generally quite aware of, Dr. Maturi noted.

"Clinicians need to know that the anti-VEGFs don't work on everyone—about 30% will have continued edema despite 6 months or more of treatment," Dr. Maturi said. "We need to think about other options for these patients and dexamethasone implants are an excellent choice."

Dr. Maturi suggested these findings warrant a larger, phase III study. ■

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Dr. Maturi is a consultant for Allergan and Allergan provided financial support for the study and had no control on the results or submission. The statistical analysis was performed at the JAEB Center, Tampa, FL.

R-Tech RP study enrollment complete

By Rose Schneider

BETHESDA, MD ::
SUCAMPO HAS ANNOUNCED that its development partner, R-Tech Ueno Ltd., has completed the enrollment of a phase III study for its treatment of retinitis pigmentosa (RP).

R-Tech is conducting the clinical trial of unoprostone isopropyl ophthalmic solution 0.15% at 38 medical institutions in Japan.

The randomized, double-blind, placebo-controlled study will evaluate whether the treatment improves central retinal sensitivity as determined by Humphrey Field Analyzer in patients with RP.

The study's primary endpoint is the value of mean retinal sensitivity at four central points at 1 year.

The target sample size is 180 patients.

"There are no drugs currently approved for the treatment of RP anywhere in the world, and we believe that unoprostone isopropyl may be a promising candidate for this indication," said Ryuji Ueno, MD, PhD, chairman, chief executive officer, and chief scientific officer of Sucampo.

With the completion of the phase III trial enrollment, Dr. Ueno said R-Tech expects to complete the study by the end of 2014, with results available in early 2015.

"Upon successful results, Sucampo intends to work with regulatory authorities in the United States and the European Union to determine the incremental data that will be necessary to form application packages for each region," he said. "We look forward to the possibility of helping to meet the unmet needs of patients suffering from RP in these countries."

The study is being funded through an agreement between R-Tech and the Japan Science and Technology Agency.

Sucampo licensed from R-Tech the exclusive development and commercialization rights to the treatment globally except for Japan, China, Taiwan, and Korea.

Both the FDA and the European Medicines Agency have granted orphan drug designation to the treatment. ■

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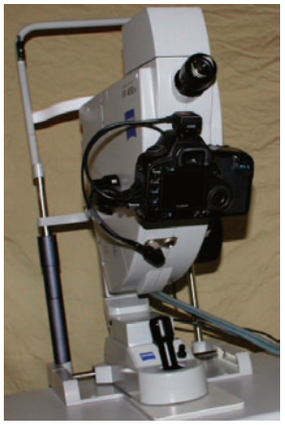

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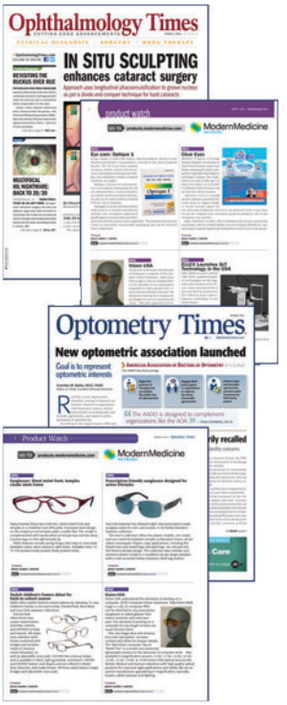

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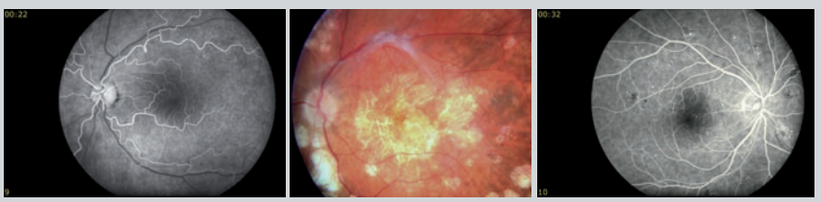

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Medicare fee schedule: Why it's déjà vu all over again

Proposed 24% decrease in physician payment rates not likely—if past is any indication

By Allen C. Ho, MD, Special to Ophthalmology Times

2014 Medicare Projected Payment Model

PROCEDURE	CPT CODE	UNITS	2013 CURRENT	2014		2013-2014 CHANGE	
				Proposed	Projected	Projected*	%*
Fundus photography	92250	CF[2]	$34.0230	$25.7109	$33.8529	-$0.1701	-0.5%
		RVUs	2.39	2.20		-0.19	-7.9%
		$/procedure	$81.31	$56.56	$74.48	$6.84	-8.4%

2013-2014 calculations use 2014 projected rates, with the 2014 anticipated CF at 99.5% of the 2013 CF. (Table courtesy of Allen C. Ho, MD)

TAKE-HOME

- ***Using recent history as a guide, will Medicare reduce physician payments by 24% in 2014?***

On July 8, 2013, CMS released the proposed Medicare Physician Fee Schedule (MPFS) for 2014. As currently proposed, the 2014 MPFS provides an overall decrease in physician payment rates of 24.4%.

At face value, these cuts seem drastic.

However, this should not cause immediate alarm.

Though this same scenario has played out over and over in recent years—and each year, Congress has taken action to prevent the drastic cuts—a historical review of this annual pseudo-rate cut and reprieve cycle serves as background to the forecast for 2014.

LEGACY OF SUSTAINABLE GROWTH RATE FORMULA

The sustainable growth rate (SGR)—enacted as part of the Balanced Budget Act in 1997—is a mechanism to update Medicare payment rates annually to ensure overall spending remains below a target "sustainable" level which is tied to gross domestic product (GDP). In essence, if growth in Medicare spending exceeds growth in GDP, an automatic cut in payment rates results.

The goal of the SGR concept was admirable. However, it has not worked out as planned.

The calculated rate cuts are so unrealistic that year after year Congress has enacted special measures to block the SGR forced reductions.

To understand this annual dance, it is necessary to understand a little bit about how Medicare payment rates are calculated.

Payment amounts for each CPT code are a calculation involving two key factors:

- **The relative value units (RVUs) of the work involved in each procedure.**
- **A dollar-based conversion factor (CF).**

Each procedure paid under the MPFS is assigned an RVU based on the resources associated with that service, whereas an annual CF[1] is used to convert the RVU to a payment amount.

HISTORICAL CHANGES TO THE CONVERSION FACTOR

The proposed 2013 CF as defined by the SGR was $24.7124. This was a 27% reduction from the 2012 CF of $34.0376.

Late last year, Congress intervened and provided an alternate CF of $34.0230 for all of 2013, a decrease of only 0.04%. As noted above, Congress has taken similar action in each of the past 10 years.

Last year, the action was taken before year end and applied to all of 2013, so there was no further drama.

In other years, the dance has been less smooth requiring multiple Congressional corrections for a single year.

However, the clear pattern is that Congress—often under direct pressure from physician groups—has consistently acted to prevent the drastic SGR payment cuts.

ANTICIPATED CHANGES TO CONVERSION FACTOR

The SGR proposed CF for 2014 is $25.7109. Without congressional action, this will result in a decrease of 24.4% from the 2013 CF of $34.0230.

Table 1 illustrates the impact of these CF changes on a common ophthalmic procedure, fundus photography. Using recent history as a guide, reimbursement experts estimate Congress will correct the 2014 CF so that it is no less than 99.5% of the current CF. That estimate is used in the *2014 Medicare Projected Payment Model* in Table 1.

Continues on page 34 : ***Medicare***

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WARNINGS AND PRECAUTIONS

Intraocular Pressure (IOP) Increase

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

Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing

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

Bacterial Infections

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

Viral Infections

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

Fungal Infections

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

Contact Lens Wear

Patients should not wear contact lenses during their course of therapy with LOTEMAX.

ADVERSE REACTIONS

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

The most common adverse drug reactions reported were anterior chamber inflammation (5%), eye pain (2%), and foreign body sensation (2%).

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C.

Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 times the maximum clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

There are no adequate and well controlled studies in pregnant women. LOTEMAX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment Of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (600 and 300 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

PATIENT COUNSELING INFORMATION

Administration

Invert closed bottle and shake once to fill tip before instilling drops.

Risk of Contamination

Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the gel.

Contact Lens Wear

Patients should be advised not to wear contact lenses when using LOTEMAX.

Risk of Secondary Infection

If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician.

FOR MORE DETAILED INFORMATION, PLEASE READ THE PRESCRIBING INFORMATION.

Bausch & Lomb Incorporated
Tampa, Florida 33637 USA
US Patent No. 5,800,807

MEDICARE

(Continued from page 32)

If the proposed 2014 CF were implemented, the effect on the payment amount for CPT code 92250 would be a decrease of 30%.

However, the change in RVU for this code is a decrease of just 7.9%. As shown in Table 1, the net projected effect is small: 8% decrease in the payment amount.

Despite this positive outlook, there is still reason for concern over both the proposed 2014 CF and the broken SGR formula.

There is a high likelihood that Congress will release an updated CF prior to January 2014, drawing sighs of relief from physicians across the country.

However, it does not appear Congress will be able to resolve the larger SGR issue at this time, so it is likely that we will be rehashing this discussion again 12 months from now. ■

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ALLEN C. HO, MD, *is professor of ophthalmology, Thomas Jefferson University Retina Service, and serves as director of retina research and attending surgeon, Wills Eye Hospital, Philadelphia. Readers may contact him at acho@att.net. He did not indicate any proprietary interest in the subject matter.*

Volunteer programs can revive physician passion

By Alison Ritchie

NEARLY EVERY PHYSICIAN WOULD agree that he or she originally pursued medicine to help others. But with changing requirements and regulations, it is easy to get caught up in the day-to-day tasks. One way to break free of that daily grind is to volunteer one's medical services, said Kate Fincham, director of program support for Health Volunteers Overseas (HVO).

"The most common comment made in our trip reports is people say, 'This trip reminded me of why I went into medicine in the first place,'" Fincham said. "That's because they're doing medicine. They're not doing insurance. They're not given only 10 minutes with a patient and told they're not allowed to take any longer than that. It does give them personal and professional fulfillment."

HVO is a non-profit organization, where medical professionals can volunteer their services across the globe. Its seven programs include a variety of subspecialties, including internal medicine, and it serves more than 25 counties in need. During a 2- to 4-week stay, HVO volunteers provide medical training and mentorship to healthcare providers in that country. Depending on the location, volunteers may be permitted to bring their spouse and their children.

Volunteers vary in their experience levels, from recent medical school graduates to physicians who have already retired from practice. For those who are just finishing up their residency, not only will volunteering look good on their curriculum vitaes, it may also help them further their own training.

"It is not uncommon for doctors at that part of their training to say that they came back more confident in their skills," she said. "They have to depend on themselves and not the machines."

Physicians with an established patient base may also see professional benefits.

"If someone is traveling with us for 2 weeks to 1 month, their patients find out about this," she said. "It's an opportunity for your patients to see you in a different light."

Several organizations, such as Doctors Without Borders, are available for those who would like to volunteer with a group of medical professionals or who would like to provide immediate disaster relief.

"Physicians will look back on it and say it's one of the best things they've ever done," Fincham said.

For a list of volunteer opportunities, visit the American College of Physicians website at *www.acponline.org*. ■

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Indications and Usage

- LOTEMAX® GEL is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery

Important Risk Information about LOTEMAX® GEL

- LOTEMAX® GEL is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures
- Intraocular pressure (IOP) increase—Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored
- Cataracts—Use of corticosteroids may result in posterior subcapsular cataract formation
- Delayed healing—Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation and occurrence of perforations in those with diseases causing corneal and scleral thinning. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification
- Bacterial infections—Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infection. In acute purulent conditions, steroids may mask infection or enhance existing infections
- Viral infections—Use of corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and exacerbate the severity of many viral infections of the eye (including herpes simplex)
- Fungal infections—Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use
- Contact lens wear—Patients should not wear contact lenses when using LOTEMAX® GEL
- The most common ocular adverse drug reactions were anterior chamber inflammation (5%), eye pain (2%) and foreign body sensation (2%)

Please see brief summary of full prescribing information on adjacent page.

*Ophthalmic corticosteroid.

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