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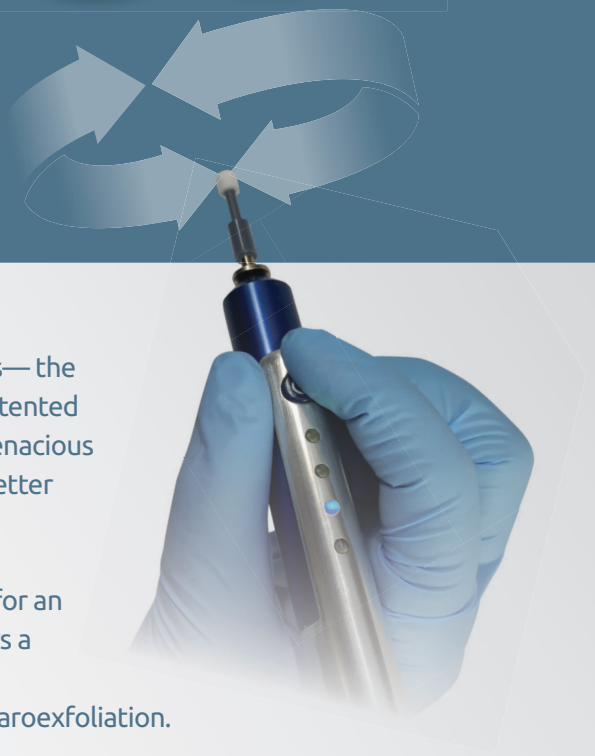

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REVIEW NEWS
Volume XXVI • No. 9 • September 2019

Medicare Proposes Another Cut In Cataract Reimbursement

Cataract surgery reimbursement may be cut by about 15 percent next year, according to the proposed rule changes to the 2020 Medicare physician fee schedule released in July by the Centers for Medicare and Medicaid Services.

Non-complicated cataract surgery (66984) may see a larger cut in reimbursement than complex cataracts (66982). The proposed Work Relative Value Unit (RVU) for complex cataracts is 10.25, compared to the current Work RVU of 11.08, a $47 reduction. For non-complicated cataracts, the proposed Work RVU is 7.35, compared to the current 8.52, a $97 reduction.[1]

After negotiations and efforts to retain reasonable reimbursement for cataract surgery, ASCRS and AAO agreed to the rate set by the AMA's Relative Value Scale Update Committee (RUC), which is responsible for describing the resources required to provide physician services. CMS takes RUC into account when developing RVUs. ASCRS notes that though it is a decrease, the rate is "equitable relative to payments of other physician services of similar time and intensity."[1]

"We're disappointed in the value that we got, but we're pleased it didn't go down further," says Michael Repka, MD, MBA, the vice chair for clinical practice at the Wilmer Eye Institute and the medical director for Governmental Affairs of AAO.

Reimbursement for cataract surgery has been progressively decreasing because ophthalmologists have gotten so good at it, says Douglas Grayson, MD, FACS, in practice at Omni Eye Services in New York. "Technology improved," he says. "Cataracts back in the 1990s used to be hour-long procedures, and now they can vary anywhere from five to ten minutes. So basically, they're paying for the time that it takes to do the surgery with some small factor added in for the complexity."

If the proposed rule changes go through, cataract surgeons may face a 15-percent cut in reimbursement.

Part of the decrease in valuation reflects the proposed rule's budget neutrality. "If cataract surgery goes down, those dollars get redistributed to other services in medicine," says Dr. Repka. "Oftentimes, those dollars end up in evaluation and management services, or the dollars go to primary care."

The random sample survey of AAO and ASCRS members required for RUC code revaluation showed a one-minute reduction in time to perform 66984 and one less postop visit, which Nancy McCann, ASCRS director of Governmental Relations, says always equates to some kind of reduction.[2] ASCRS and AAO demonstrated to the RUC cataract surgery's unique intensity to bring the reduction to 15 percent, as opposed to 50 percent.[2]

The proposed rule has a 60-day comment period. Ms. McCann says ASCRS will submit comments, but will support the recommended values along with the Academy. E/M values are also proposed to increase, a move both ASCRS and the surgical community oppose.[1] Ms. McCann hopes that if these increases are made they will be factored into cataract reimbursement, which may bring the reduction in 66984 to the $90 range.[2]

"The only way we've been able to keep up with progressive cuts over the years is by finding new sources or new ways to maximize reimbursement," explains Dr. Grayson. "At the end of the day, some doctors will say it's too bad and take less reimbursement and some will try to figure out ways around it."

Dr. Grayson anticipates increases in femto laser, multifocal lens and MIGS procedures such as iStent, Hydrus and Kahook goniotomy—glaucoma procedures done in

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REVIEW News

conjunction with cataract surgery—to make up for the deficit.

"Increased volume in cataract surgery is another concern, and they may audit more charts to make sure visual criteria are defined well enough and that patients truly need cataract surgery," Dr. Grayson says. "Certainly, they're going to look at MIGS more closely because that's an expensive ticket item for Medicare and for the primary insurers, because not only do they have to pay for the surgical procedure, they also have to pay for the device." Dr. Grayson notes that the iStent Inject device costs over a thousand dollars.

Dr. Grayson also says that decreased reimbursement may cause surgeons to reevaluate their schedules. "If you're not that great a surgeon, it might not be cost-effective to go to the OR and do five cataracts at a decreased reimbursement. You could actually do better in the office just seeing a bunch of patients."

Finding ways to streamline services and improve office efficiency is another way doctors might make up the reimbursement decrease, says Dr. Repka. "I expect that doctors will diversify and add some other services. Just be very careful about not charging for add-on services to try to recoup revenues, because those may or may not be legal, depending upon how they're framed and billed to the patient.

"We could have done more poorly than we did, but it's hard to spin a loss as a win, and I wouldn't try to," concludes Dr. Repka. "The good news is that this proposed rule did not have any other eye services that CMS considers possibly misvalued, which means we don't have to defend anything next year. So that, at least, is a good thing."

1. 2020 Medicare physician fee schedule (MPFS) proposed rule released. ASCRS. August 2019. http://ascrs.org/about-ascrs/news-about/2020-medicare-physician-fee-schedule-mpfs-proposed-rule-released
2. McCann N. ASCRS special report: Key information about the 2020 Medicare physician fee schedule proposed rule. ASOA. August 2019. https://asoa.org/news/ascrs-special-report-key-information-about-2020-medicare-physician-fee-schedule-proposed-rule

Iodine Safe vs. Viral Conjunctivitis

Researchers recently found that 5% povidone-iodine (PVP-I) used as a one-time treatment is safe and well-tolerated by patients with adenoviral conjunctivitis.[1]

A double-masked trial included 56 participants randomized to a one-time administration of PVP-I or preservative-free artificial tears. The team assessed visual acuity, and safety using corneal fluorescein staining, and tolerability using participant-rated overall ocular discomfort.

In the PVP-I group, the study authors discovered that corneal staining increased immediately post-administration but returned to baseline levels by day one. They noted no change in visual acuity between baseline and day one in either group. In the povidone-iodine group, they also found no change in participant-rated overall discomfort immediately post-administration or on day one, compared with baseline.

In the artificial tear group, on the other hand, they note that participant-rated overall discomfort was lower immediately post-administration but returned to baseline levels by day one. The investigators add that there was one adverse event in the povidone-iodine group within the first two days following drop adminstration that was unrelated to treatment. REVIEW

1. Shorter E, Whiteside M, Harthan J, et al. Safety and tolerability of a one-time, in-office administration of 5% povidone-iodine in the treatment of adenoviral conjunctivitis: The Reducing Adenoviral Patient Infected Days (RAPID) study. Ocul Surf. August 8, 2019 [epub ahead of print].

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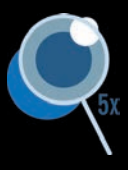

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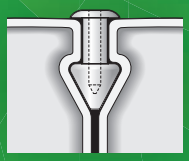

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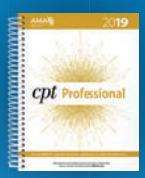

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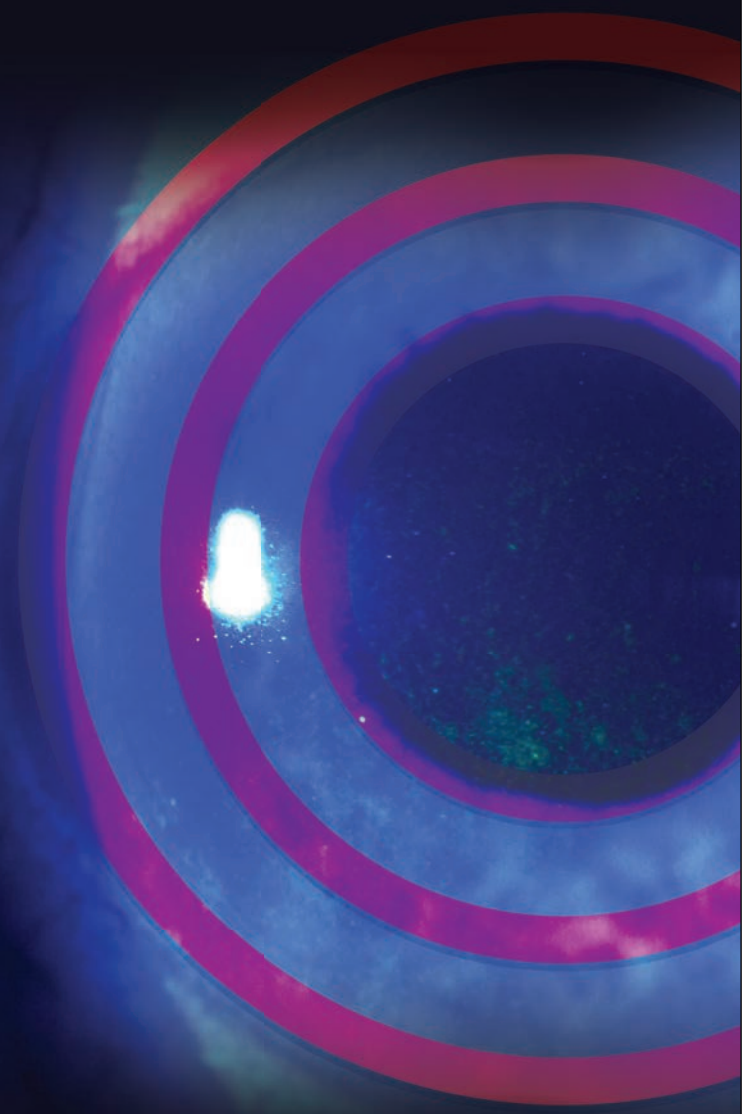

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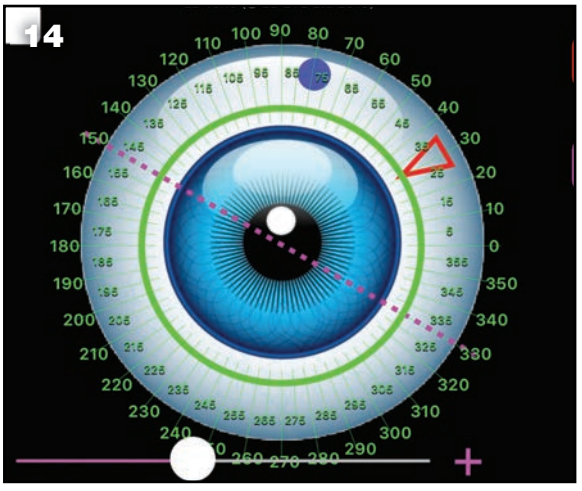

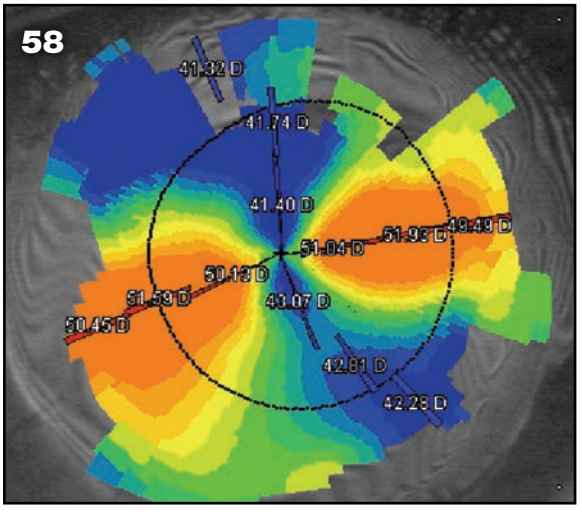

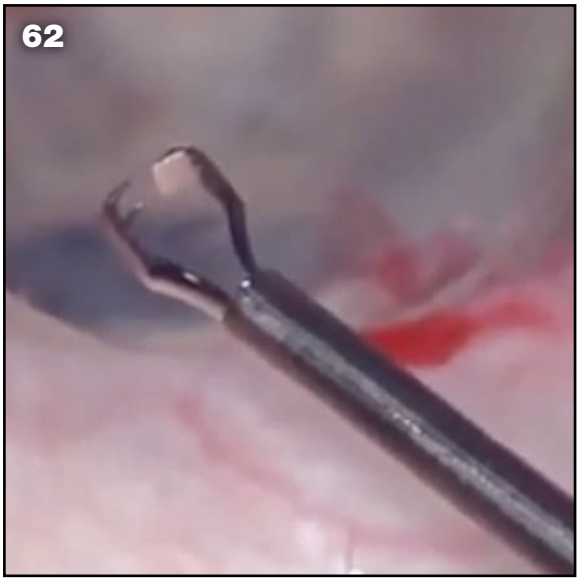

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Smartphone Apps for Cataract Surgery

A look at two IOL calculators and an axial marking tool you can use from your smartphone or tablet.

Christine Leonard, Associate Editor

It should come as no surprise that medical technology has found a platform on our mobile devices. Smartphone use in clinical practice is growing,[1] and applications that can save surgeons time and money are also helping improve patient outcomes. Here, we'll take a look at some of the recent advances.

Panacea IOL Calculator

The Panacea IOL and Toric Calculator is a multi-program ophthalmic application created by David Flikier, MD, medical director of the Instituto de Cirugía Ocular in San José, Costa Rica. Panacea considers two new corneal variables, the Gullstrand ratio (posterior-to-anterior corneal ratio) and corneal Q asphericity, which Dr. Flikier says increase predictability in normal cases and also allow for the calculation of abnormal corneas with objective data.

Dr. Flikier says he designed Panacea to be intuitive and easy to use. The app features 19 programs, including:

- "IOL Power and Toric Calculator." This includes calculators for surgically induced astigmatism, postop toric calculation, Holladay and SRK/T anterior chamber depth calculation and astigmatic keratotomy calculation;
- "Aphakic/Phakic Calculator." This allows both aphakic and phakic IOL calculation, posterior chamber intraocular phakic lens diameter and LASIK and PRK ablation thickness calculators; and
- "Optometric Formulas Calculator." This includes calculators for toric contact lenses, prism, vertex distance and abbe value.

"I'm very impressed with the Panacea software for IOL calculations," says Arturo Chayet, MD, of the Codet Vision Institute in La Jolla, California. "In my opinion it's the most complete, effective but underrated IOL calculator. I'm using it with great success."

Luis Lu, MD, senior member of Eye Consultants of Arizona and preceptor at Arizona State University and Hyatt Medical Education, International University, agrees. "I use the program to compare

David Flikier, MD

Figure 1. The Astigmatic Keratotomy Calculator in Panacea calculates the toric power of the anterior and posterior corneal surfaces; total corneal astigmatism, including that induced by corneal incisions; recommended arcuate keratotomy with graphs according to age, optic zone, arc and depth; and estimation of the necessary power at the corneal plane to achieve the desired residual astigmatism according to patient age.

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Filomena Ribeiro, MD

Predictability of Several IOL Formulas

SN60WF IOL outcomes (n=127)		
Methodology	SD	MAE
Panacea	0.38268	0.29186*
Barrett	0.40479	0.29012**
Olsen	0.41403	0.31860
RBF	0.42127	0.32253
Haigis	0.42943	0.33471**
SRK-T	0.44529	0.33633*

SA60AT IOL outcomes (n=193)		
Methodology	SD	MAE
Panacea	0.40922	0.31251
RBF	0.44125	0.33830
SRK-T	0.44421	0.33879
Barrett	0.44474	0.33767
Haigis	0.45974	0.35492
Olsen	0.46854	0.33867

CB00 IOL outcomes (n=105)		
Methodology	SD	MAE
Panacea	0.40732	0.30547*
Barrett	0.41617	0.31576
Olsen	0.41885	0.30420
RBF	0.44655	0.33738
Haigis	0.45301	0.35125
SRK-T	0.51346	0.38155*

SD=standard deviation; MAE=Mean Absolute Error
*p=0.006; **p=0.008; p values from within-group ANOVA with Sidak correction.

*p=0.002; p values from within-group ANOVA with Sidak correction.

Figure 2. Comparison of prediction error for SN60WF, SA60AT and PCB00 toric IOLs.[3]

the calculations done with the other fourth-generation formulas that are available," he says. "In normal corneas, in a few cases the calculation can change a little, but my main use is on those with previous corneal surgeries. I believe this 'fifth'-generation program should be used in conjunction with the other formulas to improve the outcome of the target refraction. Panacea can calculate the toricity well, perhaps because it includes factors or vectors not included in other programs."

Dr. Lu says the Panacea formula works well in all kinds of eyes, so long as the individual's posterior corneal power can be measured. This is where the advantage of Panacea lies, says Dr. Flikier. "To really get the advantage of Panacea, you need to introduce the posterior surface data through the Gullstrand ratio or posterior surface curvature," he explains.

While the app features several calculators and variables, "it does require the surgeon to be able to calculate the power, radius and axis of the anterior and posterior cornea," Dr. Lu says. One improvement he suggests is that "the data from the Pentacam, Galilei G4 or G5, IOLMaster 700 or any device capable of measuring the total corneal power be directly integrated into the program." He hopes that in the future more variables will be taken into account, such as aqueous index of refraction, vitreous index of refraction, lens tilt and retinal tilt.

A 2017 study comparing methodologies using estimated versus measured values of total corneal astigmatism for toric IOL power calculations found that the centroid prediction error, the error in the predicted mean of residual astigmatism for a series of patients, was 0.25 ±0.43 D at 173 degrees for the Panacea calculator.[2]

The latest results of a 2019 study headed by Filomena Ribeiro, MD, PhD, FEBO, director of the Ophthalmology Service of the Hospital da Luz Lisboa and professor of ophthalmology and biomedical engineering at the University of Lisbon, found Panacea calculated a mean absolute error of intended versus achieved refraction of 0.291 D for the Alcon SN60WF and 0.305 D for the Johnson & Johnson PCB00.[3]

Dr. Lu finds that his refractive outcomes have improved with Panacea. "Prior to this program, about 70 to 75 percent of my patients were within 0.5 D of the target refraction and 85 to 90 percent within 1 D. With the use of Panacea as a comparative formula, my results are 85 percent within 0.5 D."

The Panacea app is currently available for iPad, as well as for desktop Macs and PCs. Android and iPhone versions are in the works. For more information, visit panaceaiolandtoriccalculator.com.

iToric Patwardhan

The iToric Patwardhan is an axial marking tool that checks the accuracy of toric marking and suggests a new placement axis to reduce error in IOL placement. There's no need for a slit lamp or bubble marker. All the app requires is an Android smartphone with a good camera.

iToric Patwardhan was developed by Sourabh Patwardhan, FRCS, MD, medical director at India's Nandadeep Eye Hospital and Institute. Using the smartphone's built-in gyroscope, which can measure angular acceleration, iToric can pinpoint the exact orientation of a mark in space within 1 degree of precision.

After taking a photo of the eye, the surgeon can zoom in and align the cornea within the outer calibration circle in the app. Once the eye is centered, the user places the marks

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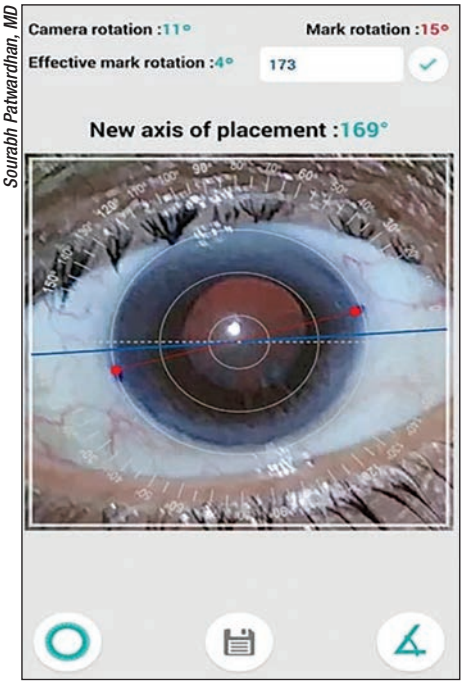

Sourabh Patwardhan, MD

Figure 3. The iToric Patwardhan app suggests a new axis of placement to be used intraoperatively.

on the cornea and enters the placement axis. The app will then suggest a new placement axis to correct any error in marking.

In Dr. Patwardhan's experience, the iToric resulted in a decrease of average residual cylinder from 32 to 22 percent and, in 87 toric IOL cases, none of them was more than 5 degrees away from its intended axis.

The quick workflow, high accuracy and opportunity to avoid additional calculations are the main advantages of the app, says Dr. Patwardhan. "Patients are much more comfortable with freehand pen marking," he notes. "Children are also more cooperative with this than with metal toric marking instruments."

Vinit Shah, MD, who practices at the Vinit Eye Clinic Retina and Laser Centre in Mumbai, India, agrees, saying, "iToric is very good in a busy operation theater where it might be difficult for surgeons to come out of the OT after every case to perform corneal marking at the slit lamp with bubble markers. This even helps the patient, as the process is fast and less cumbersome."

Zain Khatib, MD, in practice at the Khatib Eye Clinic, Mumbai, has been using iToric for more than two years. "You can capture a photograph and then align the marks with the calibration circles later," he says. "This is much more stable and easier to perform than working with real-time apps.

"Accuracy-wise, it's excellent," Dr. Khatib adds. "iToric almost matches the accuracy of a digital marking system."

A 2018 study supports this conclusion. Compared to manual marking methods, preoperative marking with smartphone gyroscope-assisted marking significantly improved accuracy.[4]

For a tutorial, watch this video: youtu.be/vHKrFGimkHw. Visit play.google.com/store/apps/details?id=com.itoric.app1 to download the app.

Eye Pro

Eye Pro is a suite of programs for iOS that performs calculations such as post-LASIK biometry, vector astigmatism analysis and outcome analysis. Edmondo Borasio, MD, FEBO, Head of the Ophthalmology Department at Burjeel Day Surgery Center in Abu Dhabi and creator of the Borasio Edmondo Smith and Stevens (BESSt) formula,[5] developed Eye Pro in 2009, and he says it was the first ophthalmological app released for iOS. The current version includes standard biometry formulas like SRK/T and Hoffer Q, the BESSt formulas for post-refractive surgery patients,[5] and toric IOL and SIA calculators. It also includes an aggregate astigmatism plotter, optical formulas and converter programs for visual acuity notation, corneal to spectacle plane and Cartesian (x,y) to polar (r,θ) notation, which describes a point in terms of distance from and angle of rotation around a point.

"You can bring it with you to the operating theater to recheck biometries on the spot," says Dr. Borasio. "I also often use it in the clinic to perform post-laser refractive surgery biometries using BESSt 2 and Borasio Myopic/Hypermetropic Regressions (BMR/BHR),[6] or for toric IOL calculations and for converting visual acuity notations."

Surgeons say that Eye Pro's ability to analyze multiple patient data sets at once has helped them see important trends in their work. "Being able to see aggregate plots of pre-, post- and induced astigmatism and the centroid calculation was an eye-opener that helped me to modify my surgical technique based on my results," says Eduardo Viteri, MD, of Centro Oftalmológico Humana Vision, Ecuador. "I changed from a steeper axis to temporal incisions and was able to take into consideration the vector effect of my 2.2-mm incisions to decide on the IOL axis alignment."

For a series of cases, Dr. Viteri explains, "you can easily obtain the mean astigmatism and standard deviation, after conversion to Cartesian notation; plot two series simultaneously on the same plot—for example, pre- and postop; and plot the astigmatism centroid." The SIA plotter produces high-resolution, publication-level, double-angle polar plots, says Dr. Borasio.

Charles Diaper, MD, an oculoplastic surgeon with a general cataract practice in the National Health System in Scotland, says Eye Pro's astigmatism plotting and group outcome analysis came in handy when he needed to generate audit output data for his department to show they were matching national audit benchmarks for surgically induced

(Continued on page 19)

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Indication

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Important Safety Information

INVELTYS 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.

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.

Use of corticosteroids may result in posterior subcapsular cataract formation.

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.

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

Use 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 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.

In clinical trials, the most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

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

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US-INV-1900123

INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1%, for topical ophthalmic use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

INVELTYS is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

CONTRAINDICATIONS

INVELTYS 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.

WARNINGS AND PRECAUTIONS

Intraocular Pressure (IOP) Increase—Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, as well as 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—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—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 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—The preservative in INVELTYS may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation of INVELTYS and may be reinserted 15 minutes following administration.

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.

Clinical Trial Experience—Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The most common adverse drug reactions in the clinical trials with INVELTYS were eye pain and posterior capsular opacification, both reported in 1% of patients. These reactions may have been the consequence of the surgical procedure.

USE IN SPECIFIC POPULATIONS

Pregnancy—Risk Summary: INVELTYS is not absorbed systemically following topical ophthalmic administration and maternal use is not expected to result in fetal exposure to the drug.

Lactation—Risk Summary: INVELTYS is not absorbed systemically by the mother following topical ophthalmic administration, and breastfeeding is not expected to result in exposure of the child to INVELTYS.

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 thymidine kinase (tk) assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay.

For a copy of the Full Prescribing Information, please visit www.INVELTYS.com.

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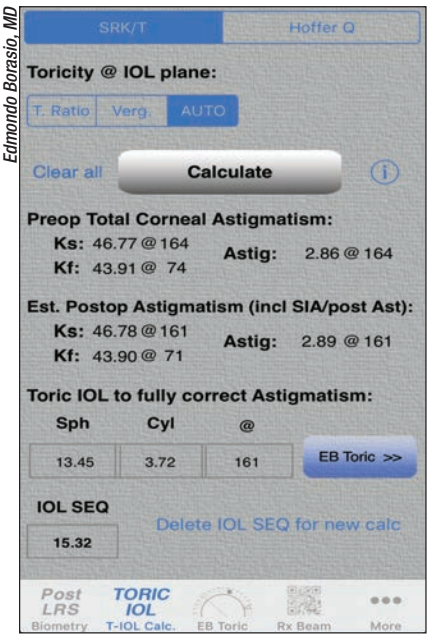
US-INV-1800055 December 2018

(Continued from page 16)
astigmatism. Dr. Diaper says his plots showed a change in incision width from 4.2-mm incisions to 2.2 mm, a decrease linked to a reduction in SIA,[7] which helped maintain his department "when management wished to constrain resources."

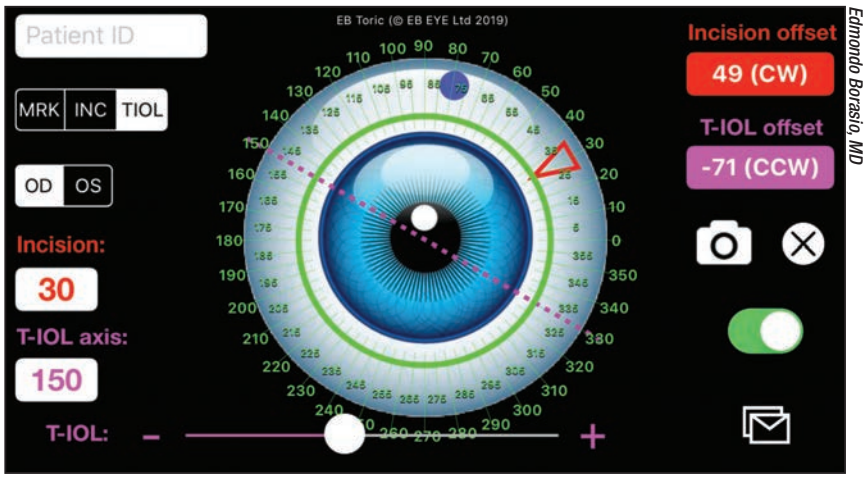
Both Dr. Viteri and Dr. Diaper find the app easy to use, but point out the ever-present possibility of data input error. "For individual cases, the data input is intuitive," Dr. Viteri says. "You just have to be careful. I suggest using a positive cylinder notation to avoid confusion."

Though the app's portability on iPads and iPhones is convenient, especially when the surgeon, as Dr. Diaper puts it, "is away from biometry machinery," Dr. Viteri says he'd like to be able to use Eye Pro on his computer to make data transfer easier. "It can be a little cumbersome to export and import the .cvs files to obtain the centroid and polar plots, but it's worth the effort," he says. "Having it on my computer would just make data transfer easier for aggregate vector analysis in astigmatic correction.



Edmondo Borasio, MD

Figure 4. The new EB Toric IOL Calculator supports different options for estimating astigmatism at the plane of the IOL, including custom/auto toricity ratio, custom/auto ELP, and a fully automated mode, recommended by Dr. Borasio.



Edmondo Borasio, MD

Figure 5. Screenshot of the EB Toric marking tool after gyroscopic realignment, which automatically rotates the photo an equal and opposite number of degrees in order to maintain a perfectly straight-on view of the eye. The surgeon then aligns the blue dot with the scleral mark and sets the location for the incision, marked by a red arrow. The toric IOL axis is imported directly from the EB Toric IOL Calculator. Data can also be entered manually if another calculator is used.

"It would be great to have Eye Pro integrated with Pentacam AXL to take the back of the cornea into consideration, avoid data input error and improve efficiency," continues Dr. Viteri. "I'd also like to be able to take or import anterior segment photographs for axial marking."

While Dr. Viteri doesn't use Eye Pro routinely, instead sticking with Goniotrans, a virtual angle conveyor for axial marking, and a Pentacam AXL for biometry and IOL calculation, he still considers Eye Pro a "must have" for cataract surgeons looking to improve their refractive results.

The latest release of the app contains three new features: a streamlined prescription app; a toric IOL calculator that supports posterior corneal astigmatism as well as Naeser/Savini Optimized Keratometry regressions and different options for estimating the astigmatism component at the IOL plane, including toricity ratio and effective lens position; and a new method of toric marking. The EB Toric marking tool employs a speculum and an ink mark applied anywhere on the sclera to orient the iPhone. A photo is taken, realigned by gyroscope, and digital marks can be added.

Comparing digital toric marking to direct marking, Dr. Borasio says it's fast, inexpensive, convenient and safe, since there's no need to unpack sterile instruments and there's no risk of corneal abrasions.

For more information or to download a free trial of the new release, visit eb-eye.com. REVIEW

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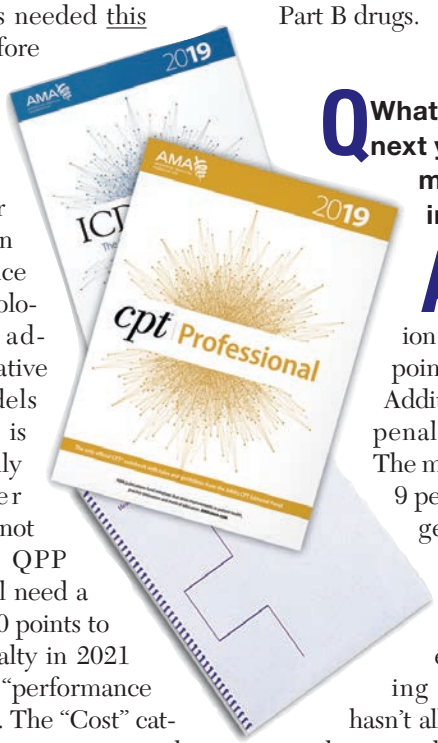
Paul M. Larson, MBA, MMSc, COMT, COE, CPC, CPMA

What's New for MIPS in 2020?

Some changes have been made to the Merit-based Incentive Payment System. Here's what you need to know.

Q I saw Medicare has released the 2020 Proposed Rule. Can you tell me if there are changes for the QPP/MIPS program next year?

A Yes—and they are significant, so planning is a key part of this. Let's review what is needed this year (2019) before moving on to next year. Participation in QPP is still as either a group or an individual. Since few ophthalmologists are in advanced alternative payment models (APM), MIPS is likely their only option under QPP. If you're not exempt from QPP this year, you'll need a minimum of 30 points to avoid the penalty in 2021 for your 2019 "performance year" activities. The "Cost" category is likely to impact any ophthalmologist who performs routine cataract surgery with IOL placement. If you aren't exempt and don't participate as either a group or individual in MIPS, and aren't part of an advanced APM, you would be penalized in 2021 the maximum 7 percent on all Part B services except office-administered Part B drugs.



Q What score do I need next year to avoid the maximum penalty in 2022?

A This is the biggest change, in my opinion. The bar is raised to 45 points for 2020 reporting. Additionally, the maximum penalty is now 9 percent. The maximum bonus is up to 9 percent too, but it's budget neutral, which has significantly affected what providers have been able to get each year. Even earning a 100-percent score hasn't allowed providers to get what was theoretically possible. Those doing claims-based reporting may have to work hard to achieve 45 points, although reaching the mid-30s and getting a much lower penalty is likely doable (it's why most doctors can avoid the maximum 7-percent penalty in 2019). Historically, those who report via a Registry have a much better chance to score higher than those doing claims-based reporting.

Q Are the categories being re-weighted again in 2020?

A Yes. "Cost" rises to 20 percent from the current level of 15 percent. "Quality" goes down to 40 percent from the current 45-percent level, continuing the downward trend. "Program Interoperability" (a.k.a., "PI," the EMR one) stays at 25 percent and Improvement Activities stays at 15 percent. In fact, CMS notes that by the 2022 performance year, Cost and Quality are each anticipated to be weighted at 30 percent.

Q What's going to happen to the Cost category of MIPS in 2020?

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1 McLaurin E, Cavet ME, Gomes PJ, Ciolino JB. Brimonidine ophthalmic solution 0.025% for reduction of ocular redness: A randomized clinical trial. Optom Vis Sci. 2018;95(3):264-271

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A Another big change is possible in the category of Cost. Many of you may remember the big change this year was the implementation of the Episode of Cost for Routine Cataract with IOL. Those doing routine, uncomplicated cases coded as 66984 for patients without certain concomitant diagnoses (such as age-related macular degeneration) are now scored in the Cost category. This Cost episode is proposed to continue for 2020 without change, but there is a proposal to modify one of the two other ways to be scored in this category (TPCC, or Total Per Capita Cost). While, historically, this hasn't affected many eye-care providers, it doesn't mesh well with how eye doctors practice and the proposed change was seen as unfair to those affected. The last way to get scored here (MPSB, or Medicare Spending Per Beneficiary) remains, but might possibly change in a more subtle way.

Q Has there been a proposal to change the EMR area of MIPS?

A Again, the answer is yes. This area is now known as Program Interoperability (PI). When MIPS started, it was known as "Advancing Care Information." Before that, we knew it as "Meaningful Use." This latest change isn't going to impact many ophthalmologists. CMS proposes to remove the "Verify Opioid Treatment Agreement" measure and make the "Query of Prescription Drug Monitoring Program" optional. CMS proposes to keep the small-practice exceptions here.

Q How about Improvement Activities (IA)? Any changes there?

A CMS proposes to survey doctors and groups about changes, but plans no changes other than to require half of the doctors in a group to participate for IA to count (instead of only one doctor, as the rule states now). If a provider is hospital-based, the threshold will be 75 percent of providers.

Other than the Quality weight changing to 40 as mentioned, the reporting thresholds are increasing to 70 percent for both claims-based reporters and those using Registries or direct EHR reporting.

The small practice doubling of IA scoring for those practices under 16 providers is slated to remain, as well, so you can still score 20 but yield 40 (the maximum) in 2020. CMS also proposes to begin developing a process for deciding how/when IA measures are removed.

Q What changes are afoot for the Quality area of MIPS?

A Other than the Quality scoring weight changing to 40 as mentioned, the reporting thresholds are increasing to 70 percent for both claims-based reporters and those using Registries or direct electronic health records reporting. For claims-based reporters, this is 70 percent of Part B patients, and for those with Registries or electronic health records systems it's 70 percent of all patients. The Centers for Medicare and Medicaid Services proposes to remove measures 192 (Complications within 90 days of Cataract/IOL that require additional surgery) and 388 (Unplanned rupture of posterior capsule requiring unplanned vitrectomy). The process for removing Quality measures continues so it's likely there may be fewer options for providers to choose from, or that scoring may become more difficult for those that remain in 2020.

Q What other changes should ophthalmologists be aware of?

A Cost and Quality reporting remains a full year, and PI and IA stay at 90 days (no change). Finally, we haven't covered everything. You can see the proposed 2020 changes for QPP and MIPS on the QPP Resource Library page at this link: https://qpp.cms.gov/about/resource-library. The downloadable document(s) that ophthalmologists will need for the 2020 billing year are near the top of the page right under the menu marked "Regulatory Resources."

CMS also proposed a new "MIPS Value Pathways" (MVP) system for 2021 but that won't change your 2020 reporting. REVIEW

Mr. Larson is a senior consultant at the Corcoran Consulting Group. Contact him at plarson@corcoranc-cg.com.

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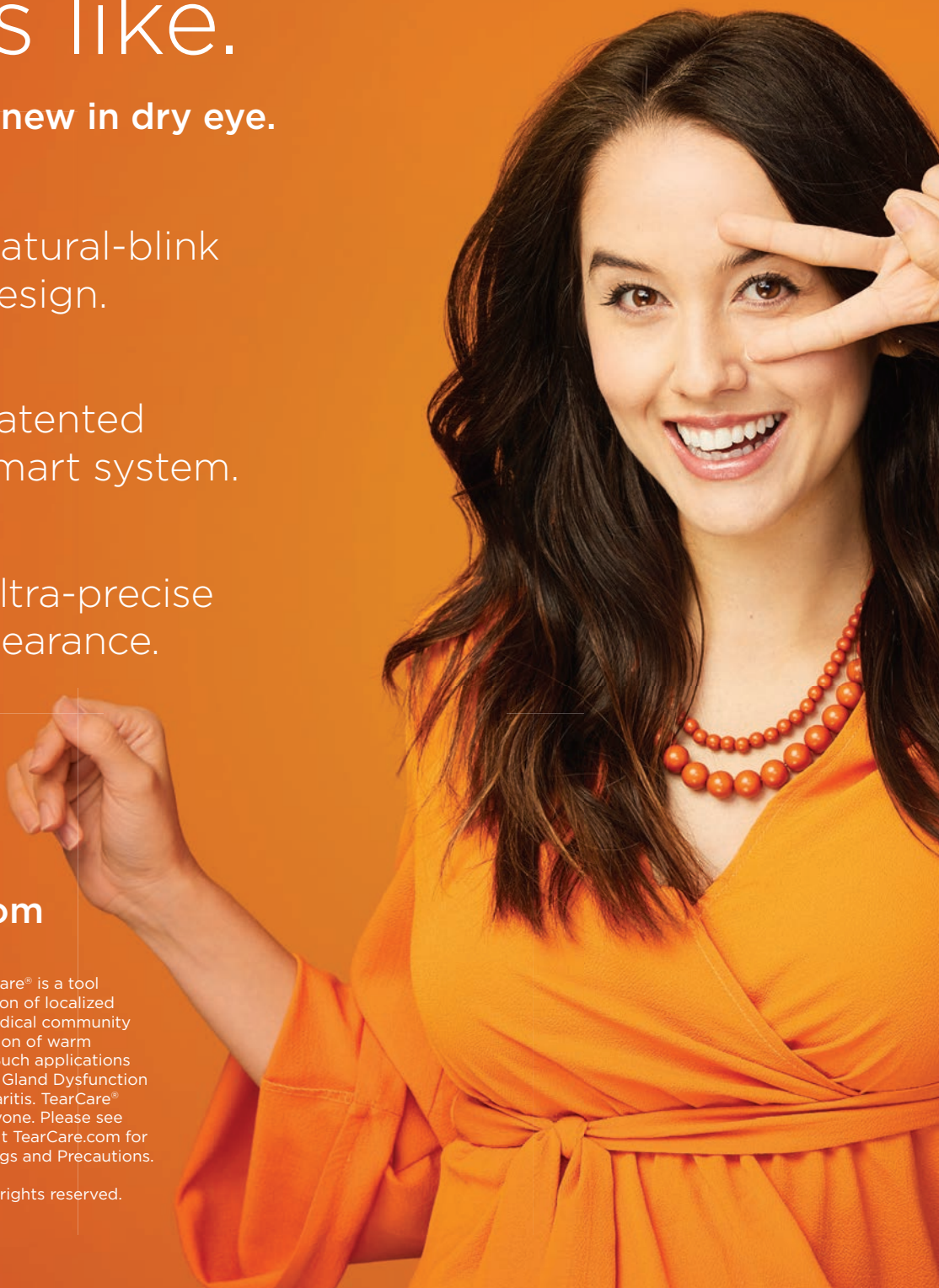

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Hypochlorous Acid Re-Imagined for Eye Care

How This Naturally Occurring Substance Can Elevate Eyelid Hygiene and Help Manage Dry Eye Symptoms

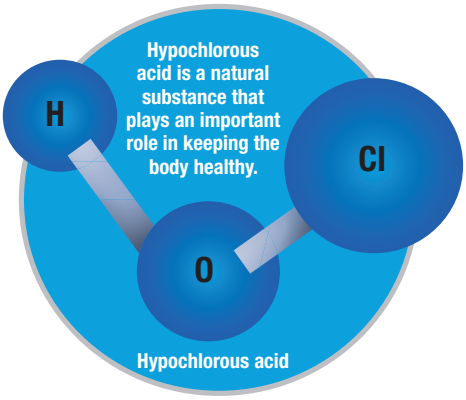
By Marguerite McDonald, MD, FACS

Eyelid hygiene is a crucial component of ocular health, especially for patients with conditions such as dry eye, blepharitis, or meibomian gland dysfunction. However, some older lid hygiene practices are not optimally effective, and many patients aren't compliant with their eyelid cleansing regimens. In fact, studies have shown that though 93% of eye care professionals recommend eyelid cleansing for this group,[1] only 19% of dry eye patients regularly cleanse their eyelids.[2] The groundbreaking Dry Eye Workshop II (DEWS II) report strongly advised that clinicians utilize newer, more efficacious hygiene solutions available on the market today to improve patient outcomes and compliance when it comes to lid hygiene, as opposed to more traditional strategies.[3]

One new way to elevate eyelid hygiene and help increase patient adherence involves the use of hypochlorous acid—a substance generated naturally in the body. Hypochlorous acid is produced in neutrophils and functions as an antimicrobial agent that destroys bacteria, serving as an important part of the immune system. Studies are finding that solutions containing hypochlorous acid not only possess powerful antimicrobial properties, but are well-tolerated for continuous use and yield minimal cytotoxic effects.[4-6]

The Need for Improved Lid Cleansing Approaches

The importance of appropriate lid hygiene was emphasized in the DEWS II report, offering foundational guidance from 150 worldwide experts in the areas of ocular surface care and disease management. The authors stressed the need to appropriately manage a variety of lid conditions that result in dry eye, particularly blepharitis. If used correctly, they determined, lid hygiene could reduce



lipid byproducts and lipolytic bacteria associated with these conditions.[3] The report also noted certain outdated lid hygiene practices that should be updated by eye care professionals, as well as a lack of patient compliance with best practices. For example, it revealed:[3]

- Though lid scrubs using diluted baby shampoo traditionally have been a widely accepted therapy,[7-9] one Level 1 study found that a dedicated lid cleanser had reduced ocular surface MMP-9 levels and improved lipid layer quality, and was better tolerated than diluted baby shampoo.[3,10] Baby shampoo also has been associated with reduced ocular surface MUC5AC levels, suggesting it might have an adverse effect on goblet cell function.[8]
- New, proprietary lid cleansing products that use a diversity of delivery mechanisms are recommend-

Eyelid Cleansing: Essential, But Often Overlooked

93% of eye care professionals recommend eyelid cleansing for certain patients[1]

ONLY 19% of dry eye sufferers regularly cleanse their eyelids[2]

ed over traditional lid cleansing strategies.[3] In recent years, many lid hygiene solutions have come to market as marked advancements over baby shampoo.

• Though lid hygiene is widely considered an effective therapy for MGD and blepharitis,[11] compliance with provider instructions is "notoriously poor."[3]

It's clear that modern approaches to managing lid hygiene, such as use of hypochlorous acid, are a more appropriate way to promote eyelid health than older methods using baby shampoo.

Expanding Access to Rx-Strength Solutions

Until recently, two types of eyelid cleansers were available to patients in the following ways, with these traits:

• *Cosmetics:* Not filed with the FDA, with large variation in ingredients and efficacy. Limited availability in retail stores, with most distribution in physician's offices and online.

• *Rx products:* Proven efficacy, but inconvenient due to prescription requirement and potentially very costly depending on insurance.

Realizing the need was great to provide patients with greater accessibility to prescription-strength daily eyelid cleansers, researchers embarked on developing such a product. The result is TheraTears® SteriLid® Antimicrobial Eyelid Cleanser and Facial Wash, now available at a variety of retail stores.

Hypochlorous Acid Reduces Ocular Skin Bacterial Load

One study demonstrated a

>99%

reduction in the staphylococcal load on periocular skin 20 minutes after a solution containing 0.01% pure hypochlorous acid was applied.[1]

Research has revealed the ability of hypochlorous acid to reduce the bacterial load on the surface of the periocular skin shortly after application.[1] Some solutions have even removed staphylococcal isolates resistant to multiple antibiotics.

1. Stroman DW, Mintun K, Epstein AB, et al. Reduction in bacterial load using hypochlorous acid hygiene solution on ocular skin. Clin Ophthalmol. 2017;13(11):707-14.

A Natural Opportunity for Hypochlorous Acid

In today's world, many patients actively seek out products with more natural characteristics. Embodying such qualities, hypochlorous acid is organically produced as part of the cytotoxic myeloperoxidase system in neutrophils.[12,13] This broad spectrum antimicrobial mimics the human system, and has been shown to cause rapid oxidation of nucleotides, inactivation of cell enzymes, disruption of cell membranes, and cell lysis when introduced to various microorganisms in vitro.[14-17]

From a clinical perspective, agents containing hypochlorous acid hold powerful antimicrobial properties that appear to be useful for ongoing use, exhibiting minimal toxic effects to cells in several studies.[4-6] In addition, hypochlorous acid exerts a broad range of anti-inflammatory and immunomodulatory activities, such as those involved in the pruritic cycle of certain dermatologic conditions.[18] For example, in atopic dermatitis, hypochlorous acid may decrease protease binding and modulate interleukins involved in the inflammatory cascade.[18]

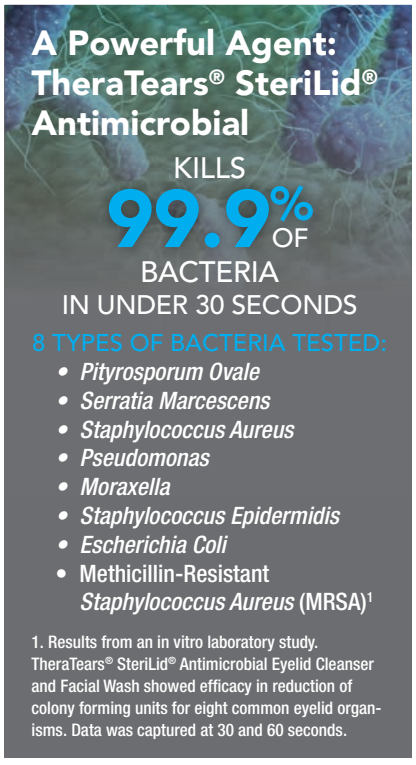
A Diversity of Clinical Uses for Hypochlorous Acid

Products with hypochlorous acid have received many FDA and EPA approvals across a broad range of medical markets including dermatology, ophthalmology, dentistry, and wound healing care. They are also widely used in veterinary and ostomy applications.

Clinically Advancing Lid Hygiene Practices

New products featuring hypochlorous acid offer leaps forward in the following clinical areas of eyelid hygiene:

Antimicrobial & Antifungal Efficacy: Research has documented the significant ability of antimicrobial agents such as hypochlorous acid to help maintain healthy skin—including near the eyelids—and to inhibit growth of pathogenic bacteria while promoting the proliferation of symbiotic bacteria.[19] It also has determined the swift, broad-spectrum fungicidal activity of 0.01% hypochlorous acid.[20] One literature review, which evaluated cases of fungal keratitis and endophthalmitis after Boston keratoprosthesis implantation during a 14-year period, noted the ability of 0.01% hypochlorous acid to reduce medically relevant yeast cells or mold conidia by 99.99% within 60



seconds, measured by an in vitro time kill assay.[20]

Tolerability: New hypochlorous acid daily eyelid cleansers designed to have low toxicity and pH-balanced formulas may prevent irritation of the delicate skin of the eyelids and eyelid margin.

Patient satisfaction: Rx-strength daily eyelid cleansers featuring non-irritating substances that are available at retail stores offer the possibility of high patient satisfaction and compliance due to greater comfort and easier access to effective eyelid cleansers.

A First in Daily Eyelid Cleansing

An innovation helping eye care professionals to advocate for daily eyelid hygiene, TheraTears® SteriLid® Antimicrobial Eyelid Cleanser and Facial Wash containing 0.01% hypochlorous acid is the first eyelid cleanser to be FDA accepted as a medical device. It has a rinse-free formula, eliminating the need to clean away a residue, and reflects patient-friendly pricing. In addition, the cleanser has a 24-month shelf life, opened or unopened.

My firsthand experience with TheraTears® SteriLid® Antimicrobial Eyelid Cleanser & Facial Wash is that it is easy and quick to use, non-irritating, and effective. It can be applied long-term without irritation. My patients are pleased with how their eyes and lids look and feel after using the product, and I see the slit-lamp improvements.

An eyelid cleanser such as TheraTears® SteriLid® Antimicrobial is especially important for dry eye, pre-operative, and MGD patients, patients who use eye makeup, and those who wear artificial lashes. The MGD Workshop[21] recommends eyelid cleansing twice daily as a treatment starting at the earliest MGD stages, and mentions the advantages of hypochlorous acid as an important and effective ingredient in cleansing solutions.

With the exception of blepharitis/MGD that is graded as trace, or trace to 1+, my first-line therapy for grade 2+ or greater starts with lid hygiene twice daily with an eyelid cleansing solution containing hypochlorous acid. In addition, I also use a host of other products mentioned in the DEWS II and MGD Workshop recommendations.

I have been very pleased with the results of new hypochlorous acid products. Not only are they effective, but they help improve daily eyelid hygiene compliance because patients look and feel better rapidly. Fortunately, we have therapeutic options now such as the TheraTears® system, designed to offer more complete relief of dry eye symptoms for patients.

Dr. McDonald practices at Ophthalmic Consultants of Long Island, Dry Eye Center of Excellence in Lynbrook, New York. *Dr. McDonald has received compensation for the preparation of this article from Akorn Consumer Health, manufacturers of TheraTears®SteriLid® Antimicrobial Eyelid Cleanser and Facial Wash.*

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» DEWS II

The groundbreaking Dry Eye Workshop II (DEWS II) report strongly advised that clinicians utilize newer, more efficacious hygiene solutions available on the market today to improve patient outcomes and compliance when it comes to lid hygiene, as opposed to more traditional strategies.[3]

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Reference: 1. Results from an in vitro laboratory study. TheraTears® SteriLid® Antimicrobial Eyelid Cleanser and Facial Wash showed efficacy in reduction of colony forming units for eight common eyelid organisms. Data was captured at 30 and 60 seconds.

M18-069-00

Diagnosing Ocular Surface Disease

Sean McKinney, Senior Editor

Take this systematic approach—but prepare to individualize your choices.

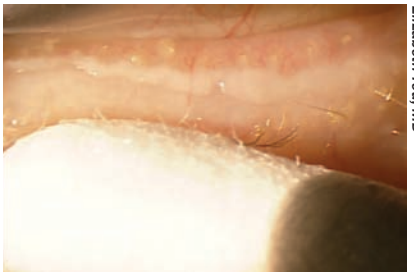
Guidelines for how to diagnose and characterize ocular surface disease have been available for years. Yet a 2019 survey by the American Society of Cataract and Refractive Surgery found that many surgeons don't know the guidelines, even though they realize the disease can affect surgical outcomes.[1]

"I think most of us want to diagnose OSD accurately but, frankly, the disease is more complex than a lot of us realize," says Kenneth Beckman, MD, a clinical assistant professor of ophthalmology at Ohio State University.

Performing cataract surgery on patients with unrecognized OSD can lead to refractive errors, OSD exacerbations and dissatisfaction with surgical outcomes.[1,2] Significant lid destruction[3] can occur in nonsurgical patients, and the disease can destroy more than half of the meibomian glands of otherwise healthy patients in their 20s.

OSD patients of all ages can develop photophobia, corneal scarring, intermittent blurred vision, pain, limited ability to perform daily activities, reduced vitality, poor general health and, in many cases, depression.[4,5]

Do you screen thoroughly enough to spare patients these problems? Find out how experts do so by balancing diagnostic protocols against the need to respond to unique patient problems.



Elizabeth Yeu, MD

Figure 1. Expressing meibum in patients with meibomian gland dysfunction can help remove bacteria and debris, as well as stimulate the glands. For a video showing Dr. Yeu performing meibomian gland expression, visit vimeo.com/3555159648

Overview of Disease Subtypes

Dr. Beckman has co-authored two of the five major reports offering recommendations on OSD and dry eye since 2017, including the ASCRS Cornea Clinical Committee's 2019 consensus-based algorithm for the preoperative diagnosis and treatment of OSD[1] and a "clinical guide" by the Cornea, External Disease, and Refractive Society (CEDARS) that combines the latest evidence-based approaches. Below is an overview of the five key CEDARS' disease subtypes:

• ***Subtype 1: Aqueous deficiency***. This primary manifestation is characterized by a reduction in lacrimal gland secretions, which form the bulk of the

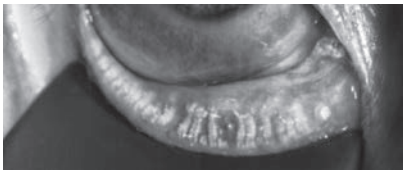
aqueous component of the tear film. Dr. Beckman says it may be caused by dysfunction or destruction of the lacrimal gland, or scarring and blockage of its ducts, which can prevent secretions from reaching the ocular surface. Injury, surgery, systemic conditions and topical agents can reduce corneal sensation, causing neurogenic inflammation that leads to decreased gland activity, he says.[6,7] You'll see a decreased tear lake, increased tear-film osmolarity and/or inflammation.[8,9]

• ***Subtype 2: Blepharitis/meibomian gland dysfunction (evaporative and nonevaporative).*** MGD can be asymptomatic or symptomatic.[10] Symptomatic cases may be restricted to the lids or be associated with MGD-related OSD that includes evaporative dry eye, according to the CEDARS report.[11] "Insufficient meibum flow leads to an abnormal lipid component and excessive tear evaporation," says Dr. Beckman.[6] "However, you may also see patients who have inflammation without tear evaporation."

• ***Subtype 3: Goblet cell deficiency/mucin deficiency.*** "This subtype is based on goblet cell disease, causing mucin deficiency," says Dr. Beckman. "These patients may have experienced a chemical burn, contact lens overwear, or have Stevens-Johnson Syndrome. Ocular medications such as glaucoma drops may cause goblet cell loss, decreasing mucins." Conjunctival tissue can be destroyed. "Tears evaporate too quickly," he observes. "Typically, evaporating tears make us think of lid margin disease. But not all evaporative disease is lid margin disease."

• ***Subtype 4: Exposure.*** "Exposure affects patients who can't completely close their eyes," says Dr. Beckman. "They could have an incomplete blink from previous ptosis surgery, or a history of Bell's palsy, trauma, scarring and Parkinson's disease. You may find normal tear production and TBUT, but the tears don't last between blinks."[12]

• ***Subtype 5: Dysfunctional Tear Syndrome/Co-conspirators.*** "The term 'co-conspirators' refers to conditions affecting the tear film and ocular surface that may either exacerbate dry eye or masquerade as dry eye," says Dr. Beckman. These could include superior limbic keratoconjunctivitis, medicamentosa, Thygeson's superficial punctate keratitis, mucus fishing syndrome, contact-chemical toxicity, allergic/atopic conjunctivitis, conjunctivochalasis, ocular allergy and glaucoma drops.



Elizabeth Yeu, MD

Figure 2. Example of moderately severe MGD with Grade 3 truncation and atrophy of the meibomian glands in a patient's right eye.

Overlapping Manifestations

Although subtyping can lead to an accurate diagnosis, Dr. Beckman and others note that overlapping manifestations will complicate your investigation. The following symptoms may be found in all of the subtypes: ocular discomfort; dryness; burning; stinging; grittiness; foreign body sensation; photophobia; and blurred or fluctuating vision. Also, aqueous deficiency can overlap with blepharitis/MGD and exposure-related OSD. Blepharitis/MGD can also overlap with goblet cell deficiency, which can additionally overlap with exposure-related disease.

"Individualizing your approach to every patient is critical," says Elizabeth Yeu, MD, a surgeon from Norfolk, Virginia who teamed with Dr. Beckman and others to write the CEDARS report. "There can be good concordance of signs and symptoms of dry-eye disease or there can be misalignment."

"Patients don't always present with the same symptoms," says Anat Galor, MD, associate professor of ophthalmology at the Bascom Palmer Eye Institute. "Individuals may report a variety of pain-related symptoms, such as sensations of dryness, burning or aching, or they can have visual complaints, such as poor or fluctuating vision. Different disease subtypes may underlie these symptoms."

Getting a thorough history is critical for a patient who complains of dry eyes. Besides using three leading questionnaires—SPEED, OSDI and DEQ5, all available online—ask patients if their eyes are affected by dry-eye symptoms, including pain, eye fatigue, light sensitivity, blurred vision, poor vision and night-time driving issues.

"I have a large dry-eye population, and I find a spectrum of patient complaints and underlying findings," says Dr. Galor. "A basic clinical exam is still the most important thing we can do."

She checks blink rate, lid closure of both lids, laxity and lid anatomy. She evaluates TBUT, performs ocular staining and probes for comorbidities, such as arthritis,[13] Sjögren's syndrome,[14] diabetes,[15] ocular allergies,[16] depression and anxiety.[17] Also important: Ocular and systemic medications. Antihistamines, beta blockers, antispasmodics, diuretics and some psychotropic drugs reduce lacrimal secretion and may increase the potential for subtypes of dry eye.[18] Remembering that tear secretion rates decrease in the elderly is also important.

Dr. Yeu listens carefully to patients, mindful that some experience more than one subtype and can be affected by nerve damage, such as neuropathy of the trigeminal nerve endings associated with diabetes or other corneal manifestations.[19] "They may be hyperesthetic or hypoesthetic," she adds.

When To Test Tear Osmolarity

Many doctors evaluate tear osmolarity, a biomarker of ocular surface health. The TearLab Osmolarity Sys-

tem measures concentrations that range from 300 mOsm/L or below (stable) to above 340 mOsm/L (severe instability). A difference between eyes greater than 8 mOsm/L also indicates instability, even for readings below 300 mOsm/L.

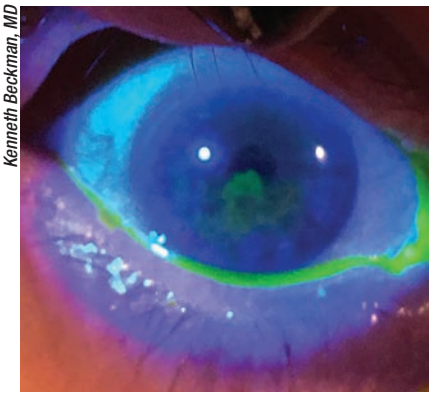
Dr. Beckman uses the test to triage patients early. "Besides identifying dry eye, osmolarity helps us grade severity," he says. Even though it doesn't differentiate by disease subtype, osmolarity can help monitor response to treatment. "Osmolarity is volatile," he notes. "A one-time normal reading doesn't rule out dry eye, just as a one-time normal blood sugar reading doesn't rule out diabetes. But consistent normal osmolarity alerts us to look for other causes of OSD symptoms."

Dr. Galor doesn't use osmolarity testing in clinical practice, although she values it in research, where she documents the osmolarity of study participants. In her practice, she evaluates tear stability via TBUT, and aqueous production via Schirmer's test. She also relies on InflammaDry (Quidel) to test for the presence of metalloproteinase 9 (MMP-9), an inflammation marker found on the ocular surface.

In appropriate individuals, she uses adjuvant imaging tests such as the LipiScan (Tear Science) to evaluate meibomian gland morphology (meibography). Dr. Galor also uses *in vivo* confocal microscopy–both the Confoscan CS4 (Nidek) and Heidelberg Retinal Tomograph with Rostock Corneal Module (HRT-RCM). One primary use is to evaluate nerve anatomy and whether inflammatory cells are present within the cornea.

Why Advanced Testing?

Dr. Yeu says meibomian gland dropout, congestion and atrophy are essential to evaluate on infrared meibography. These findings provide insight into the presence and potential chronicity of a patient's OSD, particularly



Kenneth Beckman, MD

Figure 3. Central corneal staining with fluorescein reveals severe aqueous deficiency.

in patients who are asymptomatic and may have otherwise "slipped through the cracks." As a surgeon who performs 1,800 cataract procedures a year, she sees many patients for surgical evaluations. Dr. Yeu examines many of them without the benefit of prior diagnoses suggestive of OSD because referring primary care practices provide limited insights.

"I need to determine if these patients have inflammatory or tear osmolarity issues, so we objectively test patient tears," she says. "I generally can't test tear osmolarity and Inflamma Dry during the first visit due to reimbursement issues, so I perform a tear osmolarity test during the initial visit and an InflammaDry test during the follow-up visit.

"It's better for me to find out if their MMP-9 is positive, especially if they've been treated with cyclosporine (Restasis) or lifitegrast (Xiidra). If they're still positive for MMP-9, that tells me the treatment they've been receiving is not enough, as is often the case, because one medication for a disease process is often not enough."

Positive and negative test results clarify the etiology and treatment options. Dr. Yeu trusts that a patient who has a positive InflammaDry finding will respond more favorably to an anti-inflammatory drop, including a steroid for acute cases and a steroid-sparing anti-inflammatory in chronic care.

"A negative osmolarity test result doesn't absolutely mean that the patient is negative for OSD," adds Dr. Yeu. "As Chris Starr, MD, and others demonstrated after completing one recent study, a negative tear osmolarity can also occur in OSD masqueraders and comorbidities, including MGD, allergic conjunctivitis and conjunctivochalasis."[20]

Dr. Beckman also documents his patients' tear osmolarity initially, then uses InflammaDry to get a quick read on his patients' status, even if he sees no obvious signs of disease.

"If you get a positive MMP-9, you're going to think this is an inflammatory condition," Dr. Beckman says. "If the test is negative, reflecting lower levels of this inflammatory marker, I may not treat as aggressively with anti-inflammatories. InflammaDry helps monitor the patient. You can see over time if the MMP-9 level normalizes."

Relying On Staining Too Much?

Dr. Yeu believes many ophthalmologists still rely too heavily on ocular surface staining as the sole way to diagnose OSD and dry eye, instead of performing a thorough ocular surface exam. "If patients sound like they have dry eye, the next step has classically been to seek out conjunctival and corneal staining," she observes. "But if you're going straight to the dye, then you are going to miss a whole lot of dry eye."

As an example, she describes patients who report fluctuating vision. "This symptom often hides aqueous deficiency, which often means they have MGD because they're not expressing enough meibum to stabilize their tear film," she says. "They may have allergies and may be taking daily doses of Benadryl or other antihistamines, which can have an extreme drying effect even after four days of use."

Besides taking a careful history of such a patient, Dr. Yeu checks lid

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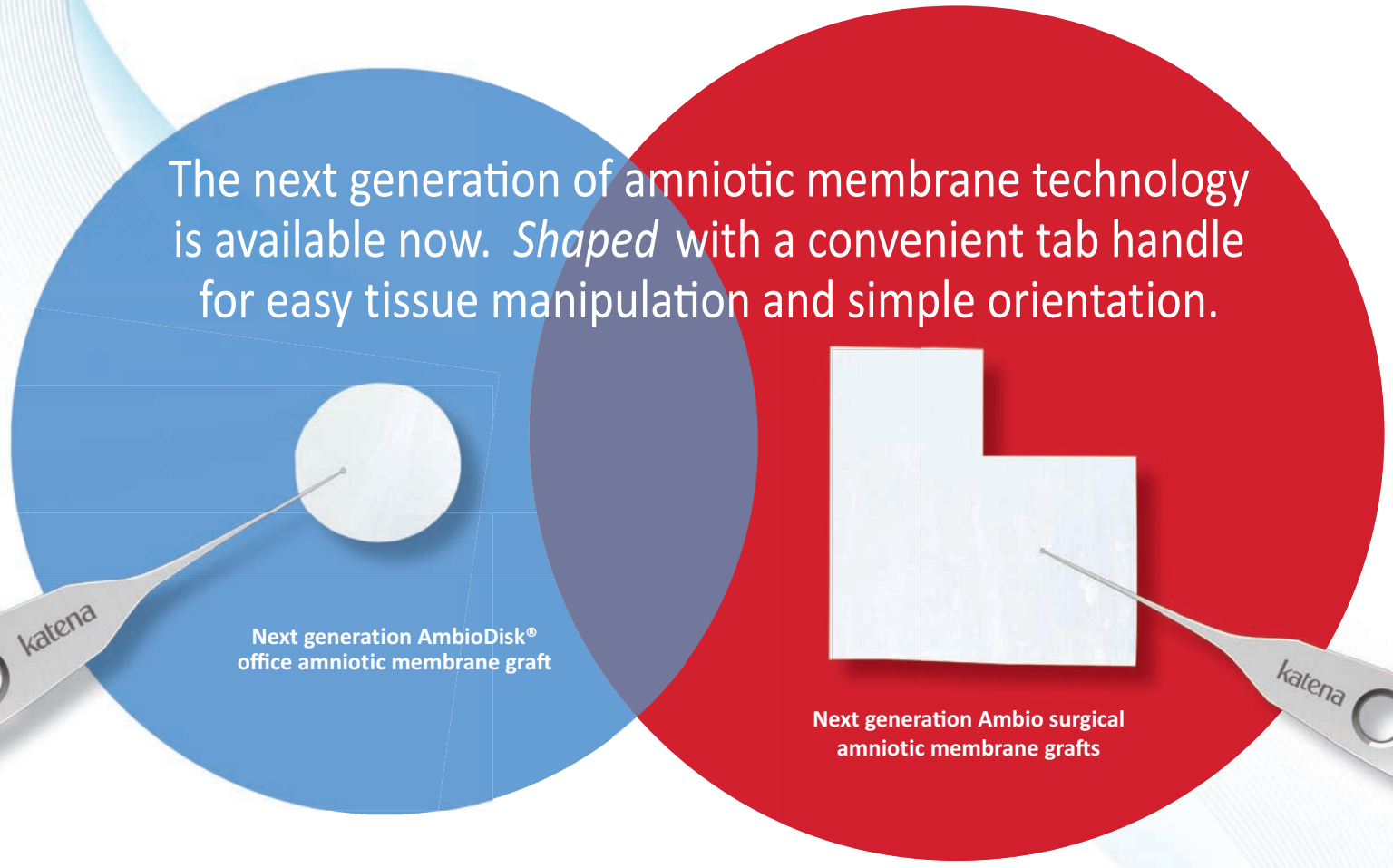

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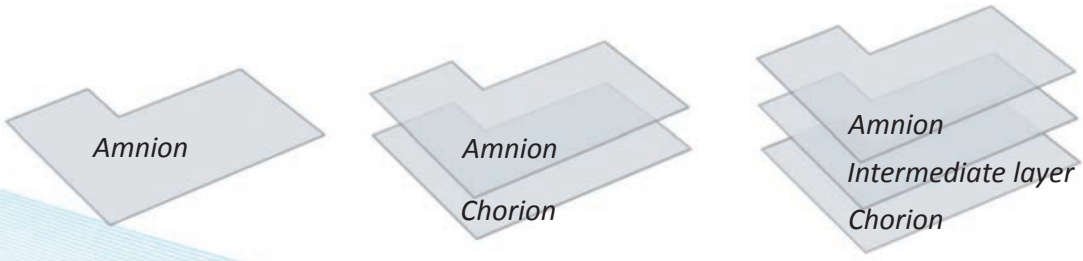

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Current Tests for Diagnosing and Monitoring Ocular Surface Disease

Either alone or in combination, these tests help diagnose a patient with OSD.

- ***Meibography:*** Imaging study developed to directly visualize the morphology of meibomian glands *in vivo*. Brands include the LipiScan Dynamic Meibomian Imager and LipiView II Ocular Surface Interferometer (Johnson & Johnson Vision) and the Keratograph 5M (Oculus). Also, the HD Analyzer and Tear Film Analzyer (Visionmetrics), which provide non-invasive objective vision fluctuation measurements.
- ***Osmolarity testing:*** The TearLab Osmolarity System measures osmolarity in a patient's tear film. The tear film is unstable when osmolarity, a biomarker of ocular health, is consistently above 340 mOsm/L and when an osmolarity reading in one eye is greater than 8 mOsm/L when compared to in the fellow eye.
- ***Schirmer's test:*** Determines if the eye is producing a sufficient amount of tears. This test is used when a person experiences very dry eyes or excessive watering of the eyes. Offered by a number of companies.
- ***Ocular surface staining:*** Used with a slit lamp to diagnose and measure the effects of OSD. Fluorescein can detect damage to the cornea. Lissamine Green, applied to the bulbar conjunctiva, stains dead and degenerating tissue and can detect early signs of disease.
- ***InflammaDry (Quidel):*** Detects elevated levels of MMP-9, an inflammatory marker that is consistently elevated in the tears of patients with OSD and dry eye.
- **In vivo *confocal microscopy:*** Helps detect changes in the corneal epithelium, immune and inflammatory cells, corneal nerves, keratocytes, and meibomian gland structures on a cellular level. Allows easy identification of conjunctival goblet cells, helping to detect corneal neuropathy and assess goblet cell and mucin deficiency in patients with OSD and dry eye. Current options are the Confoscan CS4 (Nidek) and the Heidelberg Retinal Tomograph with Rostock Corneal Module (HRT-RCM).
- ***Optical coherence tomography:*** Several commercially available OCT devices can help you determine whether the tear volume is reduced by noninvasively measuring the tear meniscus.
- ***Corneal topography:*** Irregular mires suggest an irregular ocular surface, which could reflect an issue with tears or the presence of a condition such as epithelial basement membrane dystrophy or subtle Salzmann's nodular dystrophy. In very dry eyes, topography may show missing mires or missing keratometry data.
- ***Tear-film breakup time:*** Options for this traditional test (using fluorescein tear-film breakup time measurements) now include the use of the Keratograph, which may improve discriminative ability for detecting dry eye.

margin health, including elasticity, signs of notching, capping of the glands, telangiectasia and secretion quality. "Not understanding signs and symptoms often creates a disconnect," she adds.

She also cautions against overlooking abnormal surface architecture.

"Conjunctivochalasis, anterior membrane dystrophy, Salzmann's nodules, pterygium and pinguecula are all mechanical elevations that break up the pre-corneal tear film," she points out. "If a patient doesn't have the ability to refresh the tear film, that is an issue. Alternatively, if a patient has poor sensation due to a neurotrophic component architecturally, the patient won't report any symptoms. This can be the source of problems or exacerbate OSD."

Staining Routinely

Dr. Beckman, who also closely checks lid margins and tests the meibomian glands for normal expression, stains the eyes of nearly every OSD suspect. "I look for aqueous deficiency, suggested by staining in the interpalpebral zone, which means the eye is exposed between the lids," Dr. Beckman says. "For evaporative disease, I typically look for rapid TBUT, a marker of that subset. I check for goblet cell/mucin deficiency. Commonly, we'll see conjunctival scarring in later stages. For exposure, I see how quickly the patient is blinking and if it's a complete blink. Staining typically shows around the inferior of the cornea because the lids aren't closing all the way and the inferior cornea is getting damaged."

Dr. Beckman says the CEDARS report showed staining patterns that are worth using as a reference. Superior staining, for example, should prompt you to look under the upper lid for signs of a foreign body or trichiasis. Other possibilities related to superior staining: floppy lid syndrome; superior limbic keratitis; blepharitis; conjunctival concretions; vernal keratoconjunctivitis; infectious keratitis; superior entropion; and atopic keratoconjunctivitis. "Superior staining also may prompt me to think of some of the co-conspirators, those conditions that can cause inflammation of the conjunctiva but don't result from dry eye," says Dr. Beckman.

He notes that while inferior staining often reflects exposure, "if you see inferior medial staining, leading to the punctum, the patient may have medicamentosa," he adds.

Individualizing Diagnostics

Our experts use the latest of today's diagnostic technologies, making choices that depend on availability and their preferences. All of them say the diagnostics they use provide the necessary rigor to reach definitive conclusions. "We now have a lot of tests," says Dr. Beckman. "You don't have to do everything. It's more important to be comfortable with what you're doing. Simple tests such as osmolarity, staining or Schirmer's are easy to do, cheap and can make a big difference." Dr. Yeu uses all available diagnostic tests, just not on the same day. (See "Current Tests for Diagnosing and Moni-

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toring Ocular Surface Disease" above.) An initial exam for a new patient who isn't a surgical referral should always include osmolarity and meibography, she says. "I'll do the InflammaDry test. I also monitor OSD once a year with topography. When necessary, I bring the patient back six months after ordering treatment to see if the MMP-9 went down."

Among today's diagnostic choices are scans, imaging studies and topographers that provide insights that weren't available to practitioners in the past. For example, meibography (LipiScan) offers images of glands that reveal just how extensive undetected disease is in young and old patients.

"You can see dilation of the meibomian gland over time, leading to atrophy and, eventually, loss of the glands," says Dr. Beckman. "Often, when these glands are lost, they don't regenerate. You see a thick pasty oil that's become almost like a cement coming out of the meibomian glands. We try to salvage them. The glands need treatment so they can start producing healthier oil, or the patients' eyes will dry out."

Dr. Yeu agrees meibography needs to be followed over time. "Significant insult to the meibomian gland can progress for years, causing significant dropout," she notes. "Atrophy and congestion that prevent expression of meibum contribute significantly to OSD. I've seen 20-something-year-olds with destruction involving more than half of their meibomian glands. But I've also seen healthy meibomian gland architecture in the presence of a patient's significant meibomian gland dysfunction.

In general, destruction of the meibomian gland is a secondary process that results from poor egress of meibum. Poor egress leads to congestion of the meibomian glands, which leads to pressure atrophy and destruction of the glands. We now know that assessing the health of the entire tear film really requires us to understand meibomian gland health in particular."

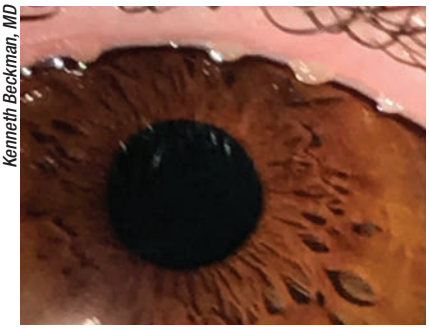
Kenneth Beckman, MD

Figure 4. Patients can develop severe MGD with plugging of the meibomian glands.

Cataract Surgery Candidates

With the recent ASCRS report on managing OSD in cataract surgery candidates,[1] more surgeons appreciate that OSD can complicate surgery. So how do the experts reduce the risk?

"Patients who are contemplating cataract and refractive surgery need to complete thorough testing to help us uncover OSD," says Dr. Yeu. She may stain the ocular surface with fluorescein to investigate the presence of abnormal morphology. Besides meibography, she also orders corneal topography and focuses on keratometry images. The views are important for evaluating the mires' appearance, not just the K-values, she notes.

"The appearance of the rings yields good information," she adds. "Irregular mires suggests an irregular ocular surface, either because of an issue with the tear film or the presence of conditions such as epithelial basement membrane dystrophy or subtle Salzmann's nodular dystrophy."

"For a very dry eye, you may discover mires and keratometry data—such as Atlas SimK values on an elevation map—that are dull or missing," she observes. "In the keratometry view, instead of seeing smooth rings, you may find mires that are warped or 'squiggly.' An irregular tear film can also present as irregular astigmatism, and it can even be misleading enough to take on a keratoconus-like appearance."

After diagnosing OSD, Dr. Yeu's response depends on the goals of her patients. "If they want to proceed with surgery, I begin treatment and postpone the surgery for five to seven weeks. This allows for a follow-up of dry-eye treatment and ocular surface preparation in two to four weeks after the initial visit."

Dr. Yeu often starts these patients on omega-3 capsules and prescribes interventional lid hygiene therapy, such as microblepharoexfoliation. "I won't consider these patients for surgery, specifically a refractive IOL option, unless they make an agreement with me that they will manage their disease aggressively before *and* after surgery," she says, noting that OSD symptoms may worsen three to six months after their procedures. "They may require a short course of acute treatments, such as steroids, or chronic steroid-sparing anti-inflammatory therapy," says Dr. Yeu. "Identifying and counseling patients preoperatively about any subtype of OSD is the key. Symptom questionnaires, topography readings and meibography help alert me to any issues."

If you don't treat preop OSD aggressively, Dr. Yeu offers these blunt words of advice: "Prepare for extreme postop IOL dissatisfaction. It's very important to see how patients will respond to treatment before surgery."

Meeting Refractive Challenges

Dr. Yeu says any OSD that responds poorly to aggressive treatment will limit her use of IOLs to spherical or toric monofocals. Premium IOLs split light, reduce contrast sensitivity and scatter light amid multiple points of vision. "These characteristics can disturb the vision of OSD patients," she says. "I will also not do corneal limbal relaxing incisions. I would rather patients be extremely satisfied with one focal point

(Continued on page 57)

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Knowledge and Tech: Treating Dry Eye, 2019

Christopher Kent, Senior Editor

As our understanding of the problem and options for addressing it increase, patients are benefiting.

Treating patients complaining of dry eye used to be a less-than-satisfying part of an ophthalmologist's job; the problem wasn't well understood and treatment options were limited. Today, that has changed dramatically. "Dry eye" is now understood to be a complex issue with multiple etiologies, and treatment options for the different aspects of the disease are proliferating. But as the field has expanded, the difficulty of staying on top of the latest developments has also increased.

Here, experts share the latest thinking about the group of concerns commonly labeled "dry eye" and offer advice for helping these patients achieve true, long-lasting relief.

Spotlight: Meibomian Glands

"In the old days, treating dry eye was just about supplementing inadequate tears using over-the-counter artificial tears," recalls Esen Akpek, MD, a professor of ophthalmology and rheumatology at Johns Hopkins University School of Medicine, and director of the Ocular Surface Disease and Dry Eye Clinic at the Wilmer Eye Institute in Baltimore. "Then came the idea of treating inflammation to improve the quantity and quality of tears; that approach became popular with the approval of Restasis.

"In the past five years, the focus has shifted again," she says. "Now we're much more aware of meibomian gland problems, and we know that pure aqueous tear deficiency is a lot less common than meibomian gland dysfunction. In fact, meibomian gland dysfunction and aqueous tear deficiency occur together in more than 80 percent of patients. The problem usually starts as meibomian gland dysfunction; over a period of decades, that causes an aqueous tear deficiency as well.

"Today we know that each component needs to be addressed separately," she adds. "As a result of this, we're trying to come up with better ways to diagnose meibomian gland dysfunction, and we now have better ideas about how to address the problem. Indeed, the majority of new dry-eye treatments are focused on addressing meibomian gland dysfunction."

Christopher J. Rapuano, MD, director of the cornea service at Wills Eye Hospital and a professor of ophthalmology at Sidney Kimmel Medical College at Thomas Jefferson University in Philadelphia, agrees. "I think about 80 percent of patients with ocular surface disease have a component of meibomian gland dysfunction that should be treated," he says. "Ignoring the meibomian gland problem—if it's

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there—is bad for patients and doctors."

Mark Milner, MD, FACS, an associate clinical professor at Yale University School of Medicine, notes that doctors have always been aware of meibomian gland dysfunction. "However, it was underdiagnosed for years," he says. "No treatments were approved for blepharitis, and getting insurance to pay for compounded or non-approved treatments was always difficult.

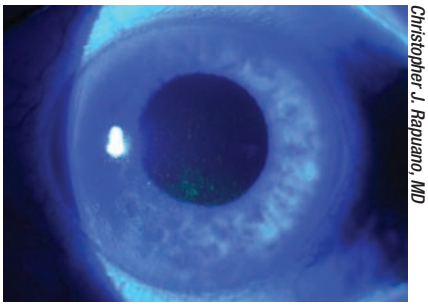
"Today we have more ways to diagnose it, with devices that can image the meibomian glands and thermal pulsation devices like LipiFlow, iLux, TearCare and eyeXpress that heat the lids and help you express the glands," he says. "As a result, we're starting to embrace this problem."

Dr. Akpek points out that meibomian gland dysfunction is actually an age-related problem. "It's like wear and tear on your teeth as you grow older," she says. "If you don't take care of your teeth, you develop dental plaques and caries. Eventually, you lose your teeth and need dentures. The same thing is true with the meibomian glands; if you don't care for them, they stop functioning correctly and symptoms of dry eye develop. Eventually the glands undergo permanent atrophy. So patients need to be caring for their meibomian glands on a regular basis.

"This idea of proactively taking care of your eyes is kind of new," she notes. "In fact, patients should ideally have home treatment modalities that keep the meibomian glands in good shape; they shouldn't have to come to the office for frequent treatments. Hopefully, these home treatments will end up being more impactful than just doing hot compresses with a rag."

Addressing Inflammation

Approved treatments such as Restasis and Xiidra have raised awareness of the importance of treating inflammation when managing dry eye, but many ophthalmologists have reported that their dry-eye patients don't always seem to get relief from these drops.



Christopher J. Rapuano, MD

Several years after LASIK, superficial punctate keratopathy is present in this eye over the central and inferior cornea.

Dr. Milner says he believes that this is partly because of a misconception about the nature of dry-eye disease. "Like glaucoma, dry eye often requires more than one treatment to resolve the problem," he says. "If a glaucoma patient has a pressure of 27 mmHg and needs to be at 17, one drop might only take him down to 22 mmHg. In that case, you wouldn't stop the drop; you'd add another drop.

"In contrast, I think most doctors expect these anti-inflammatory dry-eye drops to be a panacea," he continues. "If you use Restasis or Xiidra and the patient is 50 percent better, the problem isn't that the drops aren't working, it's that the patient needs more than one treatment. You might need to add punctal plugs, and maybe Azasite for the blepharitis, and maybe doxycycline for the meibomian gland dysfunction.

"About 85 percent of my patients have some success with Restasis and Xiidra," he says. "That means anything from mild success to 'This is a miracle drug.' The other 10 to 15 percent will say either that they didn't improve, or that the side effects such as burning were so bad that they couldn't tolerate it. We try to get around the burning problem by having the patient refrigerate the drops and/or use an artificial tear 10 minutes before and after. We educate them about the burning, and we may use a steroid off-label. Even so, the burning is still too much for some patients, so they stop."

In terms of adding other treatments, Dr. Milner says the CEDARS algorithm can be helpful. (To learn more about the CEDARS algorithm, check out "Three New Algorithms for Treating Dry Eye" in the October 2017 issue of *Review*.) "Let's say you start your patients on Restasis or Xiidra and they come back 40 percent better," he says. "If Schirmer's is still low, you can plug them. If their meibomian glands are still inflamed, you can do a LipiFlow, or Azasite off-label, or oral doxycycline. If Schirmer's is OK but there's still an evaporative problem, you might need an over-the-counter vitamin A ointment, used off-label, which may improve goblet cell health.

"The reality is, many patients need two or three different treatments," he concludes. "When a doctor says a dry-eye treatment wasn't successful, it probably was—it just didn't solve the entire problem."

Another question that arises regarding Restasis and Xiidra is whether they're useful if the core of a patient's dry-eye problem is meibomian gland dysfunction rather than aqueous deficiency. Dr. Milner says in his experience, Restasis and Xiidra do help to address meibomian gland dysfunction, although this use is off-label. "The inflammatory process in the meibomian glands is very similar to that in the lacrimal glands," he notes. "T-cells and inflammatory cells are part of the meibomian gland disease process as well, and recent evidence suggests these drugs can help.[1] But since this use is off-label, getting it covered by insurance has been difficult."

Dr. Rapuano has used Restasis to treat meibomian gland dysfunction, and he agrees that it helps. "I don't think it works as fast as when it's used to treat aqueous deficiency," he says. "It takes about three months to have a reasonable effect on aqueous deficiency, but it takes about six months

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for me to notice an improvement in meibomian gland dysfunction."

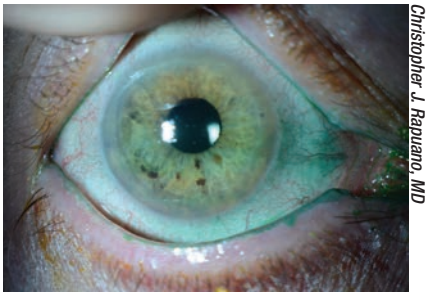
Restasis Plus Xiidra?

Patients often ask Dr. Rapuano for assistance in deciding between a treatment course involving Restasis or Xiidra. "I say, 'Restasis has been around for 14 or 15 years. It has a very good track record. It works a little bit more slowly, but it works very well. Xiidra's the new kid on the block; it's been around for a couple of years now. It tends to work a little faster, but it has a little taste issue and it can blur your vision. Both products work very well for most patients, but both of them can burn a little.' I haven't been as impressed with Xiidra for treating meibomian gland inflammation, but it seems to relieve dry-eye symptoms faster than Restasis," he notes. "That's the main thing going for it."

Dr. Milner says that many dry-eye experts have noted that Restasis and Xiidra appear to be synergistic, although there's no published data to support this claim. "The drugs work on different parts of the T-cell," he says. "Many dry-eye specialists are now using them concurrently, the way you might use a steroid and a nonsteroidal together because they work on different parts of the inflammatory process. I have hundreds of patients who will tell you they got partial relief with one of the drops; then, when we added the other one, they got complete relief. Furthermore, if we then take them off one of the drops, they regress a little bit. So they appear to need both.

"We have those patients use both drops twice a day," he adds. "I tell the patient to wait 10 or 15 minutes between the drops. If patients want to, they can alternate—Restasis in the morning and at dinner, Xiidra at lunch and bedtime. But most patients just do them twice a day separated by a few minutes."

Dr. Milner concedes that this raises a practical concern: getting insurance to cover both drops. "Many patients aren't on both," he says, "not because the drugs wouldn't work together, but because they can't get coverage. Insurance companies have no problem paying for two or three glaucoma drops, but they won't pay for two different dry-eye treatments. That shows a lack of understanding.



Christopher J. Rapuano, MD

Moderate lissamine green dye staining can be seen on the conjunctiva nasally in this patient complaining of severe dryness, but with minimal corneal fluorescent staining.

"We fight with the insurance companies, using information from our charts showing that these patients are doing better on both," he adds. "But it's a struggle. The insurance companies say they want to see a clinical trial showing the synergistic effect, and we don't have that so far. But in my opinion, these drugs do work together to help patients, so we're doing what we can to get both medications covered."

Artificial Tears

Dr. Akpek says artificial tears are still relevant. "For milder episodic cases of dry eye, artificial tears are therapeutic," she says. "They can even cure the problem, as long as the inciting factor has been eliminated. Unfortunately, by the time most patients come to see us, they don't have a mild case. Patients have already tried over-the-counter drops. Some are using them every 10 minutes, which is wrong, because it disturbs the normal homeostasis of the tear film."

"Artificial tears will always have a place," agrees Dr. Milner. "Many new formulas are coming out, such as Allergan's Refresh Optive Mega-3 tears, which may help with MGD. Freshkote isn't new, but it's now being re-marketed by Eyevance. The thing we like about Freshkote is that it's preservative-free, so it's usable with contacts."

The presence of preservatives in many of the products is an issue. "Even if you try to direct patients to preservative-free drops, 99 percent of the time what they find and end up using isn't preservative-free," says Dr. Rapuano. "That can be a problem, because if they're using preserved tears more than three or four times a day, the preservatives are probably causing some of the ocular surface disease. In that case, the drops won't help as much as the patient wants, and they may make the problem worse.

"Patients with ocular surface issues should use preservative-free drops as much as possible," he says. "Likewise, if the patient has ocular surface disease and is on multiple glaucoma medications—which many of our patients are—you should try to get that patient switched to less-toxic glaucoma medications, or, ideally, preservative-free glaucoma medications."

Dr. Milner notes that many surgeons wonder why drops with preservatives should be recommended at all. "The ITF guidelines published in 2006 proposed recommending preserved tears for level-one disease, with non-preserved tears for levels two to four," he says.[2] "When asked, the task force said that they included preserved tears in level one because artificial tears are a billion-dollar industry, and it's unrealistic to expect people not to use preserved tears when they're a big part of that market. So, we just restrict our recommendation to level-one disease."

Devices for Treating MGD

Dr. Akpek says she has a low threshold for recommending an office-based

meibomian gland procedure. "If a patient is already doing warm compresses, and I've tried a combination of omega-3 acids and oral antibiotics for two to three months and the patient isn't getting better, then I'd definitely recommend one," she says. "Of course there are different options, and the treatment should be tailored to the patient's needs and the severity of meibomian gland dysfunction. We usually combine multiple treatments.

"Ironically, doctors often think that these modalities don't work," she notes. "That's because they're using them haphazardly. First of all, these are expensive instruments, so most people will acquire just one. Then they keep using the same treatment on every single patient, which is wrong. Do we use insulin on every single diabetic patient? No. We try different options, in a stepwise approach. That's what we should be doing with these patients.

"The second reason these modalities may not always work is that we don't have any guidelines to recommend which treatment should be done for which kind of finding, and how often they should be done, and what to do between treatments," she continues. "Most dry-eye specialists do the same thing on every single person despite different needs, different skin types, different severity of meibomian gland dysfunction and different etiologies of meibomian gland dysfunction. Then the treatment fails and gets a bad reputation. It's not that it doesn't work—we're just using it incorrectly."

Dr. Rapuano says he uses LipiFlow on some of his patients. "LipiFlow is a safe and easy treatment, although it's somewhat expensive and not covered by insurance," he notes. "That's why I put it pretty high up the treatment stepladder. However, if a patient asks about it, I explain how it works.

"It's important to remember that it's not a cure-all," he continues. "It makes things better, but it's not a substitute for hot compresses, ointments and other treatments. LipiFlow kick-starts the process by cleaning out the glands, but you have to keep them cleaned out or they're just going to clog up again."

Dr. Rapuano notes that the cost of LipiFlow has come down over the years. "When we first got LipiFlow about eight years ago, we charged about $1,800 for two eyes," he says. "Now we charge $650 or $700 for two eyes, which is less than half of the old cost. I believe that's mostly been possible because the cost of the disposable parts has really come down."

"I think all of these devices work well," says Dr. Milner. "It comes down to doctor preference. The important thing is that this device does two things. First, it has to heat the glands above the temperature required for the solid secretions to turn to liquid, the phase transition temperature. Normally, meibomian gland secretions are liquid at body temperature, but when the secretions become abnormal, the secretions become solid at body temperature. Once that happens, you have to heat the lids up—usually to 108 degrees—to convert it back to liquid. Then, either you or the device need to massage the glands to get the oils out.

"The mistake doctors make," he adds, "whether they're accomplishing this with IPL, LipiFlow, iLux, eyeXpress, MiBo Thermoflo or the TearCare system, is that they fail to keep the patient on an anti-inflammatory drop so the oil glands can be maintained at a healthy level with less inflammation. That's important. So don't just clean out the glands; keep treating them with the anti-inflammatories and maybe Azasite or doxycycline as well."

(Other tools that help address the signs and symptoms of patients suffering from meibomian gland dysfunction include devices such as BlephEx and NuLids that remove debris along the edge of the lashes; Cliridex, which kills Demodex; and Ocusoft and Sterilid, which help clean the surface of the lids.)

Additional Treatments

Many other options are also available:

• ***TrueTear.*** Dr. Rapuano says several of his patients like the TrueTear device. "It definitely creates tears," he says. "The company also claims that if you use it multiple times a day it trains your tear-producing glands to produce more tears on their own.

"Not too many patients have taken us up on using it," he notes. "We tell them about it, but it's expensive and it sounds unusual to some patients. Having said that, patients who have bought it and tried it have mostly really liked it. Furthermore, if your symptoms are making you miserable, that out-of-pocket expense may seem reasonable. So it could become more mainstream in the future. So far, it's not."

• ***Serum tears.*** Dr. Rapuano says serum tears seems to be gaining a little more traction as a dry-eye treatment. "You get your blood drawn, and it's sent to a special compounding pharmacy," he explains. "They make tears out of your serum, freeze it and mail it to you. We think it probably helps with aqueous-deficient blepharitis because it has anti-inflammatory components, but it's not likely to do much for conjunctivochalasis, floppy eyelid or pemphigoid."

Dr. Rapuano notes that using serum tears requires effort, and it has to be repeated every several months. "We used to save this option for severe patients, but now we're offering it to patients who are simply very unhappy," he says. "It's fairly expensive, and many insurances don't want to cover it, but some patients find it very helpful and thank us for suggesting it. These are patients who have already tried many things on the treatment stepladder. This is toward the top of that stepladder, but it's easy and safe and often successful. There are published papers that say it helps between 50 and 75 percent of patients.

"In the past serum tears were hard to get, but today, this option seems to be more readily available," he adds. "Still, it's not for everybody."

• ***Scleral lenses.*** Dr. Rapuano says this is another treatment option he used to reserve for severe patients. "The Prose lens is one of the original, best ones," he says. "Today there are several different Prose lenses, and lots of other scleral lens options.

"For patients with pretty advanced ocular surface disease, a scleral lens keeps a good tear coating on the eye," he explains. "The tears are captured under the lens, all day long. The lens designs have gotten better and better, and more optometrists are fitting them, so it's more mainstream now. It's fairly expensive, including the fitting, but it will last for years. Serum tears have to be recreated every several months, for example, and the TrueTear device requires the purchase of single-use components every month."

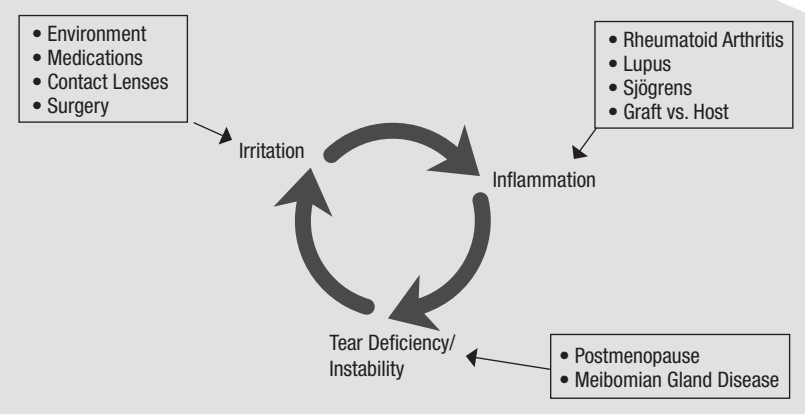
• ***Nerve regeneration.*** Another aspect of dry eye that's now possible to treat is loss of corneal nerve function. "We understand more than ever that neurotrophic keratitis can play a significant role in dry eye," says Dr. Milner. "In fact, DEWS II added the neurosensory component to their definition of dry eye. That validates the idea that we need to start looking at sensation as well.

"This is actually a two-way street," he continues. "Dry-eye patients often become neurotrophic because the neural feedback loop breaks down as a result of lacrimal gland inflammation. That inflammation causes a decrease in the quality and amount of tears. Neurotrophic patients, who don't have as much sensation, don't blink as much, so they get dry eye.

"Now, however, we're seeing a lot of new therapies that can help regenerate nerves," he says. "One therapy involves placing an amniotic membrane on the cornea for several days. Two recent studies [sponsored by TissueTech] found an increase in corneal nerve density and corneal sensation—i.e., nerve regeneration—after putting [Tissue-Tech's] Prokera amniotic membrane on the cornea for five or six days.[3,4] That improvement can last for nine months or more. [Dehydrated amniotic membrane such as Katena's AmbioDisk, is another option to consider in such cases.] In addition, Oxervate, from Dompe Pharmaceuticals, was recently approved. It's a recombinant nerve growth factor that helps regenerate nerves."

"Right now these treatments are being used for neurotrophic keratitis patients," he notes. "In the future, though, you might see some of them become accepted as treatments for dry eye."

Factors That Trigger Dysfunctional Tear Syndrome



Mark Milner, MD, FACS

A Helpful Dry-Eye Model

"In the end, dry eye is a carousel of inflammation," notes Dr. Milner. "I think of it as a cycle that has three parts. *[See illustration, facing page.]* Understanding this cycle leads to a much clearer understanding of treatment.

"The first part in the cycle is irritation," he explains. "If the eye becomes irritated, no matter what the cause, the result is an upregulation of T-cells and production of cytokines; that leads to inflammation, which is the second part of the cycle. That, in turn, leads to the third part of the cycle: tear deficiency and instability. Inflammation shuts down your lacrimal glands, and your meibomian glands become inflamed. Goblet cells are lost. That causes an unstable tear film, with a decrease in volume and quality. That then leads back to the first part of the cycle—more irritation. That leads to more inflammation, and the cycle continues.

"The beauty of seeing the process this way is that a dry-eye problem can begin at any point in the cycle," he continues. "For example, dry-eye triggers that jump onto the carousel at part one by causing irritation could include smoking, contact lenses, pollution, topical medications like glaucoma drops, refractive surgery such as LASIK or PRK, and cataract surgery. Irritants like these then lead to inflammation, the next part of the cycle.

"Other triggers can start the dry-eye cycle by causing inflammation first," he continues. "These would include Sjögren's, graft vs. host disease, Wegener's, rheumatoid arthritis, diabetes and so forth. These can cause inflammation, leading to the next part of the cycle: tear deficiency and instability.

"The dry-eye cycle can also be started at the point represented by part three: tear instability," he says. "These triggers can include menopause, because androgens, which are critical to tear production and meibomian gland secretion, are decreased; rosacea, which causes an unstable tear film; and oral medications that shut down your lacrimal glands. These can cause an unstable tear film, which leads to irritation, which leads to inflammation, and the cycle is underway."

Dr. Milner explains that treatment always requires three key things. "First, address the thing that's triggering the cycle, if you know what it is," he says. "If the trigger is anterior blepharitis, use antibiotics and lid wipes or lid sterilizers. If the trigger is contact lens wear, limit lens wear or change the fit. If the trigger is glaucoma drops, get off the drops or decrease the preservative. If the trigger is rheumatoid arthritis, get systemically treated.

"Second, no matter what the trigger is, treat the inflammation," he continues. "You won't break the cycle until you do this. That's where Restasis, Xiidra, and the new Cequa [Sun Pharma] come in. The third key thing is to treat the problem chronically. Use multiple medications if you need to, and treat it for long periods of time. The CEDARS algorithm can help you decide which specific tool and/or medication to use as your treatment."

A Treatment Stepladder

Dr. Rapuano has what he calls "treatment stepladders" for the two main diagnoses he addresses—aqueous deficiency and blepharitis. "When a patient has aqueous deficiency, the lowest level of the stepladder is what I call 'situational dry eye,' " he explains. "If a patient says his eyes get dry every time he drives in his convertible, artificial tears are fine. If a patient is using artificial tears more than three or four times a day, I switch the patient to preservative-free tears. If tear usage is more frequent than that, I switch the patient to a thicker preservative-free artificial tear such as Celluvisc, and may also start a tear gel at nighttime.

"If the patient still has a problem, I'd prescribe Restasis or Xiidra," he

continues. "The next step would be punctal plugs. Then I might try a short course of steroids. Rarely, we use bandage lenses. Finally we move to more heavy-duty options, like the TrueTear device, serum tears or scleral lenses.

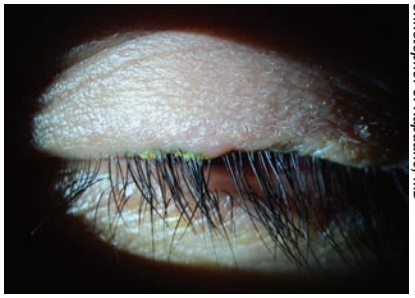
"To treat blepharitis we start with warm compresses and lid scrubs," he says. "Next, we might try a spray cleanser like the product Avenova. I also typically have the patient use an antibiotic ointment, such as erythromycin, at bedtime. You can keep moving up the ladder and try Azasite gel drops at night, although I've found that product difficult to get these days. If that's still not sufficient, you can try doxycycline or minocycline pills for about six weeks, sometimes longer. After that I'd try LipiFlow or IPL.

"In most cases I treat the patient for both types of problem, using options from both stepladders," he adds. "Meanwhile, if you find that the symptoms are related to another issue such as conjunctivochalasis, I'd treat everything else first. If the patient is still symptomatic, I'd excise the chalasis."

Strategies for Success

These tips can help you end up with a happy patient:

• ***Treat the right problem.*** Dr. Akpek says this comes down to two things: Listening carefully to the patient's complaint and doing a thorough exam. "There are subtle differences among the different conditions that may present as dry eye," she notes. "Some patients complain of lid redness; some complain of discharge; some complain of foreign body sensation; some complain of dryness or burning. Foreign body sensation and occasional excessive tearing could indicate conjunctivochalasis rather than dryness. If the patient complains of itching and redness, the problem might be Demodex, which can easily be eradicated. We need to listen carefully to the patient's complaint and attack that exact problem.



Christopher J. Rapuano, MD

Lid margin irregularity and moderate crusting can be seen in this eye with chronic blepharitis, which caused corneal staining and foreign body sensation.

"In addition, we need to do all the key tests," she says, "Schirmer's, corneal staining, osmolarity, conjunctival staining and a good slit-lamp exam of the surface. We need to check for conjunctivochalasis. If there really is an aqueous deficiency, that can be addressed by artificial tears, anti-inflammatories, or other modalities such as punctal plugs or serum tears. Patients with severe aqueous-deficient dry eye may have Sjögren's. Many dry-eye patients will have meibomian gland dysfunction that needs attention.

"The bottom line is that we have to pay attention to what the patient is saying, correlate that to our ocular surface and tear-film findings so we understand the exact problem, and then attack that," she concludes. "Then we need to try different treatment modalities in a stepwise manner, and be creative, based on what we find."

• ***Measure signs only after stressing the ocular surface.*** "There's a myth that patient symptoms and clinical findings don't correlate," notes Dr. Akpek. "On the contrary, there's a perfect correlation—if you measure the signs under conditions similar to those that are bothering the patient. For example, when patients complain that they can't see, it's not that they can't see to write a check; if you listen, they'll say that they can't see well long enough to read a book or do computer work. We don't test that in the clinic.

"To make a more accurate assessment of the patient's problem, sometimes you can take simple steps to recreate the stressed ocular surface that bothers the patient," she continues. "There are many ways to accomplish this. For example, you can ask the patient to stare at something for several minutes, by asking them to read and fill out the symptom questionnaire. Or, you can check the corneal staining after IOP measurement. Numbing the ocular surface to take that measurement will have the side effect of reducing blinking and tear secretion; that will worsen the corneal staining from baseline. Once you approximate the corneal stress the patient is encountering in daily life, your measurements will reflect the level of irritation that triggered the patient's complaint."

• ***Don't try only one treatment.*** "It's easy to offer one treatment to a dry-eye patient and then move on to other concerns," notes Dr. Rapuano. "I think doctors feel more comfortable treating problems for which they can offer a concrete solution. Furthermore, these are chronic conditions, patients are often pretty miserable, and managing them can take up a lot of chair time. On the other hand, we have a lot of treatment options we didn't have even 15 years ago."

• ***When deciding how to treat, think outside the box.*** "Right now we have Restasis, Xiidra and soon we'll have Cequa," notes Dr. Milner. "But when anti-inflammatories aren't enough, doctors get frustrated: What else can I do? Well, for one thing, there are a lot of great compounded medications you can use off-label. We've had great success with them. For example, the product Metrogel is a great treatment for facial rosacea dermatitis. We order a compound of its main ingredient, metronidazole, into an ophthalmic preparation for posterior blepharitis or meibomian gland dysfunction, because it reduces inflammation on the meibomian glands and the lids just like

Metrogel does on the face. If a patient can't tolerate oral doxycycline, we compound doxycycline drops. If you really want to help patients who aren't getting relief with the obvious treatments, think outside the box."

• ***Make sure your patients understand that these are chronic conditions.*** "Some patients will do the aggressive treatment you've prescribed, but when they get relief they decide that they're cured and stop the treatment," says Dr. Rapuano. "You have to drum into your patients that this is a chronic condition that they'll need to address their whole life."

• ***Let the patient know you're in this for the long haul.*** "We need to let these patients know that we're not going to throw in the towel if one treatment doesn't work," says Dr. Rapuano. "Tell them that you're going to try a treatment, and if it doesn't work you're going to keep trying options until you've improved their symptoms as much as possible. Patients want to know that you're not going to give up on them just because something doesn't work." REVIEW

Dr. Milner has financial interests with Allergan, Novartis, Shire, B+L, TearScience, Aldeyra, Eleven Biotherapeutics, Ocular Sciences, Kala, Eyevance and Refocus Group. He's a speaker and consultant for Allergan, Shire, TearScience, Dompe and Sun. Dr. Akpek has received research support from Allergan and W.L. Gore & Associates and is currently a consultant with Shire, Novaliq and Regeneron. Dr. Rapuano has consulted for Sun, BioTissue and Shire.

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The Latest in Retinal Surgical Instruments

Christine Leonard, Associate Editor

The design and function of vitrectomy cutters have come a long way. Here's a look at some of the most recent innovations.

"Retina is a rapidly changing field," says Rahul Reddy, MD, in practice in Phoenix, pointing to the diabetes pandemic, which has been steadily increasing surgeon caseloads. "As we look to the future, what we want is instrumentation that will allow us to get good outcomes and be as efficient as possible so we can help as many patients as possible."

Here's a look at some of the newest offerings available in vitreoretinal surgical instruments and how they may improve patient outcomes.

Stellaris Elite Bi-Blade

The newest addition to Bausch + Lomb's Stellaris Elite Vision Enhancement system is the 23-gauge Bi-Blade cutter. Released in July, the 23-gauge cutter joins its fellow 25- and 27-gauge Bi-Blade cutters, introduced in March 2018, as the most efficient option in the Bi-Blade portfolio, according to the company. Kevin Blinder, MD, professor of clinical ophthalmology and visual sciences at The Retina Institute, Washington University School of Medicine, says the Bi-Blade cutters are useful additions to the surgeon's toolbox.

The Bi-Blade cuts backwards and forwards to achieve a cut rate of 15,000 cpm. With its permanently open port and 100-percent duty cycle, the Bi-Blade allows for continuous aspiration and holding force and a consistent flow rate, he says. Consistent flow is crucial to vitrectomy procedures, since fluid acceleration is related to pressure variations and stress on the retina.[1]

Dr. Reddy says one advantage of the Bi-Blade is its predictability. "When we're working with instrumentation in the eye, it has to be very predictable," he says. "We're working with delicate tissues and there's no room for error. As we get closer to the retina, we want to know what those flow rates are doing, and we don't want the retina to get into our port, which could cause damage.

"When people talk about vitrectomy systems," he continues, "they tend to concentrate on a few concepts such as fluid efficiency, speed of vitreous removal and illumination. But I think what is just as important—if not more important

This article has no commercial sponsorship.

—is the idea of what I call 'fluidic predictability.' For me, that's the biggest advantage of the Stellaris Bi-Blade. I know exactly what it's going to do in every part of the eye. It's not volatile at the tip like some of the other systems I've used, so I'm confident that I can get close to the retina without complications occurring. It's very predictable."

Both Dr. Blinder and Dr. Reddy point out that the Bi-Blade is not just for vitreous—it's multifunctional. For thick diabetic membranes, Dr. Blinder advises backing down the cut rate on the Bi-Blade or dropping to the slow-cut mode so the cutter can function like a pair of small-gauge intraocular scissors. Dr. Reddy agrees, noting that using the cutter as scissors to treat surface pathology in the retina spares the cost of opening up another instrument.

"We've come a long way with our instrumentation. We're getting smaller and better and more efficient in general," says Dr. Reddy.

Dr. Reddy explains that with smaller-gauge surgery, "you're less likely to have catch when you remove instruments from port sites. They also don't leak as much, so there's less need for sutures, which increases our efficiency in the operating room and reduces complications." Smaller gauges also reduce postoperative inflammation, making for quicker visual recovery.[2]

He prefers the 27-gauge Bi-Blade for its efficiency, but says choice of gauge often comes down to surgeon preference and comfort. The introduction of the 23-gauge Bi-Blade accommodates surgeons who are used to 23-gauge cutters.

"My issue with 27-gauge in general is that it takes longer to get rid of the vitreous," says Dr. Reddy. "But out of all the 27-gauge instruments I've used, the Bi-blade appears to be the most efficient. That has been a bit of a surprise to me. I wasn't anticipating that."

Dr. Blinder's probe of choice is presently the 25-gauge Bi-Blade. "I like the size, the efficiency, and the wide range of instrumentation available," he says. "I also like the 27-gauge Bi-Blade, but I'm still awaiting a few more additions to the range of available accessories."

27G Ultra Short

The 27G Ultra Short vitrectomy kit (from DORC) was released in June of this year. It's designed to meet the challenges presented by smaller eyes and to optimize minimally-invasive procedures, says the company. The kit includes three probes, the One-Step cannula system, the Shielded TotalView Endoillumination Probe, and an 8,000 cpm two-dimensional cutter. The probes have a 20- to 26-percent shorter working length than standard 27-gauge instruments.

"It's hard to fit our regular instruments in small eyes with the current diameters of the non-contact systems," says Audina Berrocal, MD, professor of clinical ophthalmology and pediatrics at the Bascom Palmer Eye Institute. Dr. Berrocal is the first surgeon in the United States to use the 27G Ultra Short kit. "This instrumentation allows us to move around these very small eyes much more efficiently and without causing complications."

DORC says the Ultra Short compensates for typical size-related shortcomings of 27-gauge vitrectomy instruments with increased light output and probe rigidity. "We haven't had instruments that are short and stiff in 27-gauge before," she says. "It's not only the vitrector and light pipe, but also the trocars. They're shorter and valved perfectly for sutureless surgery. The only other short system out now is 25-gauge, but it doesn't come with short trocars that are valved. One of the greatest advances in vitreoretinal surgery has been valved trocars. They've reduced iatrogenic breaks, retina incarceration and suprachoroidal hemorrhages. They've also improved teaching, since they maintain intraocular pressure stability during surgeon changes. And, if all these things are true for adult eyes, they are also true for the eyes of

babies and kids with formed vitreous and thin sclerae that collapse easily."

Dr. Berrocal says that with larger-gauge instruments in small eyes, closing the sclera can be challenging. "The sclera is so thin that sometimes even after suturing, the eyes still leak," she says. That's where the Ultra Short comes into play.

"It allows me to do sutureless vitrectomy and leave patients phakic," Dr. Berrocal adds. "With this instrumentation, I can work on babies and kids too. When I tried the new system, I was able to do a traumatic retinal detachment repair and a lensectomy retinal detachment repair in eyes that measure 24 and 25 mm without a problem. Reaching the nerve to elevate the hyaloid wasn't an issue."

Stiffer probes are another key to successful small-gauge surgery, notes Dr. Berrocal. "I didn't come out of the eye with bent instruments, and I was able to do anterior and posterior work without a problem."

Dr. Berrocal says the 27G Ultra Short doesn't come with much of a learning curve. "It's the same technology but smaller," she explains. "It fits better in these small eyes where there's little room. It's also safer, especially for trainees."

As for the Ultra Short TDC probe, whose 8,000 cpm is half that of the full-size TDC (16,000 cpm), Dr. Berrocal says, "The TDC cutter is so efficient that even at this small gauge I didn't feel a difference from my usual 25- and 27-gauge surgery. The illumination was also great. No difference." For the trocar, however, Dr. Berrocal notes, "The diameter of the head of the trocar and the elevation of it could still be smaller and flatter."

One other thing she adds is that "the metal of the trocars inserted in the sclera have a nonpolished part that creates more friction, making it less likely to come out during surgery. It creates a better chance at stability. A clever idea."

Hypervit Dual Blade

The Hypervit Dual Blade vitrectomy probe (Alcon), available in 25- and 27-gauge, was introduced in July for a commercial release that's planned for later this year. Its open port and dual pneumatic cutting allow for a cut rate of 20,000 cpm. Rishi Singh, MD, a staff physician and Medical Director, Clinical Systems Office, at the Cole Eye Institute, says the Hypervit's high cut rate lowers the "sphere of influence" on tissue, which allows surgeons to get close to tissue without much vibration or movement. "It's been helpful with dense vitreous hemorrhages and tractional retinal detachments, where you want to get close to the retinal surface and avoid incarcerating tissue," he says. "The beveled tip also allows you to get much closer to the tissue. You can use it like scissors."

Dr. Singh says there isn't much adjustment needed when first using the Hypervit, but he recommends starting out at a low vacuum level. "It's a very powerful instrument," he says. "Start off the vacuum at 200, 250, 300 and increase proportionally. You can still maintain a reasonable duty cycle with the lower vacuum rate because the cut rate is so high.

"Be sure to check the intraocular pressure when you start using the Hypervit," Dr. Singh adds. "The duty cycle is strong and you want to make sure you're not cutting too much vitreous too quickly or reducing the IOP too rapidly. Watch your IOP infusion to make sure it's keeping up with you."

Hypersonic Vitesse

The Hypersonic Vitesse for the 23-gauge Stellaris Elite system (Bausch + Lomb) uses a piezoelectric ultrasound transducer to liquefy the vitreous at the port. The tip of the hypersonic vitrector vibrates at about 1.7 million vibrations per minute, creating smaller particles and less traction on the retina than traditional pneumatic cutters, the company says.

The first in-human study investigating the safety and performance of the 23-gauge Vitesse concluded that the hypersonic vitrector was effective in core vitreous removal in all tested cases and a "promising alternative" to current guillotine cutters.[3]

Dr. Blinder has tested the new vitrectomy system. "The Vitesse hypersonic vitrectomy (HV) technology represents a new and innovative approach to vitreous removal," he says. "HV received U.S. FDA 510(K) clearance in April, 2017, and has had a limited release to a few surgeons in the United States and other countries during an observational trial period. We recently published on our initial experience with 64 patients in the United States.[4]

"The rationale behind the devel-

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opment of HV was to replace the tube-inside-of-a-tube technology of the pneumatic cutters, simplify the technology with a hollow tube and an open port, and make the notion of duty cycle obsolete," he explains. "The initial animal model trials went well, and the human trials subsequently have been successful.[4,5] The low-power hypersonic vitrectomy probe has been utilized in a wide variety of cases, ranging from a dropped nucleus to a rhegmatogenous retinal detachment and removal of intraocular silicone oil. It's presently only available in 23-gauge, but there's active research on the smaller gauges of 25 and 27."

Dr. Blinder notes there's a significant learning curve and plenty of new terminology to become accustomed to. "Stroke length is the amplitude of axial oscillation," he says. "Varying the stroke length is one way to increase or decrease the rate of vitreous liquefaction in the eye. At the same time, the vacuum parameter can also affect the egress of vitreous out of the eye.

"These two parameters are controlled via the foot pedal in a dual yaw setting," Dr. Blinder continues. "This concept is probably the most difficult one in transitioning from the pneumatic vitrector. There's also a pulse mode that can be used to assist in vitreous removal. Thus, the transition from the lab setting to the operating room has been a smooth one."

Dr. Blinder feels that HV has a high potential for innovation. Changing the port opening or curving the probe itself for use in phakic eyes are just some of the possibilities. Dr. Reddy explains that a curved vitrectomy probe is only possible with hypersonic technology, since there are no moving blades within the needle. He's currently working on a prototype for a curved probe.

"With the Vitesse technology, we don't know what the limits are yet," says Dr. Reddy. "I really think it's going to be one of those stepping stones in retina where we are able to do things more efficiently than we've ever been able to do before, so we'll wait and see what happens with the Vitesse system."

FreeFlow Infusion System

The FreeFlow infusion system for retina surgery (Bausch + Lomb) was launched in July for the Stellaris Elite system. It offers a 40-percent increase of infusion flow compared to previous-generation infusion lines, says the company.

According to Bausch + Lomb, a larger inner lumen coupled with an infusion line going over the top of the trocar cannula, rather than inside of it, reduces resistance and makes the increased infusion flow possible. Additionally, the infusion line extends off the top of the cannula at a 30-degree angle, which provides better access to the eye and direct infusion with less torque, says the company.

Sunir Garg, MD, professor of ophthalmology at the Sidney Kimmel Medical College at Thomas Jefferson University, attending physician on the Retina Service at Wills Eye Hospital in Philadelphia, and partner at MidAtlantic Retina, says that having a higher flow rate is great. "The Bi-Blade cutters remove vitreous efficiently, and as a result we've needed better flow," he says.

"The FreeFlow lies flat on the globe, which is different than what we're used to," Dr. Garg adds. "So it takes a couple of cases to get the hang of it, but it works really nicely." REVIEW

Drs. Blinder, Reddy and Garg are consultants to Bausch + Lomb. Dr. Singh is a researcher for Alcon.

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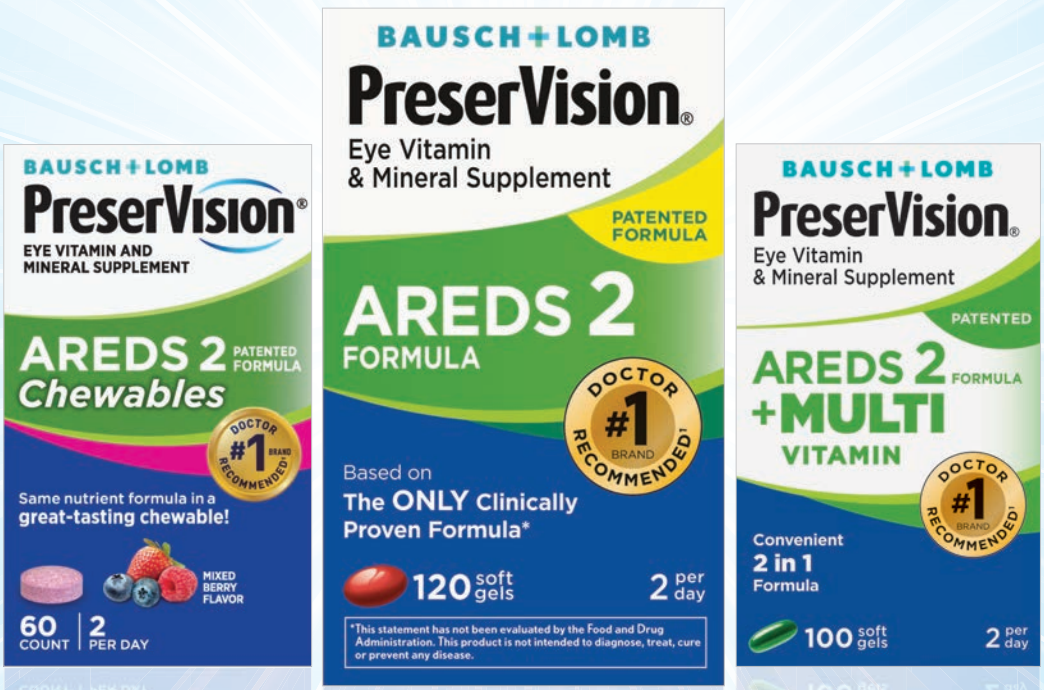

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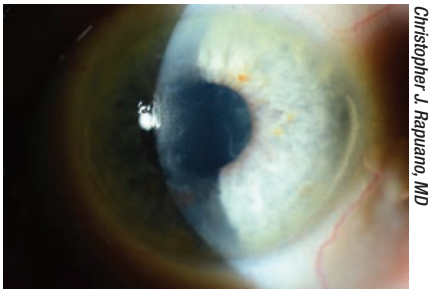
When and How to Treat EBMD

Michelle Stephenson, Contributing Editor

Expert advice on how to approach a treatment plan for the cases that warrant it.

Though epithelial basement membrane dystrophy isn't difficult to diagnose, deciding on the proper course of treatment for the cases that warrant it can be a challenge. In this article, cornea experts review their approaches to managing these cases, and how the type and severity of symptoms play into their decision-making process.



Christopher J. Rapuano, MD

Figure 1. Significant central epithelial basement membrane dystrophy changes can be seen in this eye, causing monocular "shadow vision."

When to Treat

Most patients with epithelial basement membrane dystrophy don't experience pain or visual symptoms and don't require treatment, but some cases will require your intervention. Symptoms range from corneal erosion to pain and diplopia, surgeons say.

"Epithelial basement membrane dystrophy can manifest with a few different symptoms," says Toronto's Raymond Stein, MD. "It can interfere with vision when the abnormal epithelial basement membrane appears over the pupil. The other, probably more common, symptom is that patients can have recurrent corneal erosions in which the epithelial cells slough off from the cornea, causing severe pain."

Christopher J. Rapuano, MD, Chief of Wills Eye Hospital Cornea Service in Philadelphia, agrees. "Patients with these two main symptoms will often complain of poor vision or 'double vision,'" he notes. "The irregularities can cause what I call 'shadow vision,' because patients see an image with a shadow next to it, as opposed to two equally distinct images. In addition to visual symptoms, this condition can also cause recurrent erosions. Pain from irregular, loose epithelium typically presents at nighttime or upon awakening in the morning. This is because epithelial basement membrane dystrophy causes the epithelial layer to not adhere properly. It can be painful for just a few seconds after waking up or it can cause a big scratch on the cornea that can be painful for days."

Michael B. Raizman, MD, who is in practice in Boston, says there is a third reason to treat. "I also treat when the

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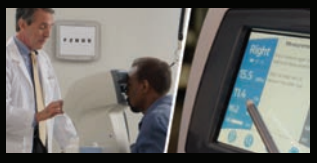

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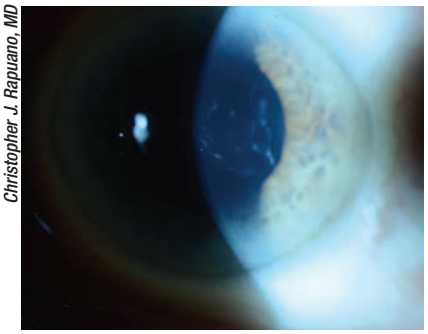
Christopher J. Rapuano, MD

Figure 2. Central epithelial basement membrane dystrophy changes can be seen in this eye, causing severe visual distortion.

basement membrane dystrophy affects my ability to calculate a lens implant power prior to surgery," he adds.

Dr. Rapuano adds that many patients have asymptomatic epithelial basement membrane dystrophy in the corneal periphery. "If they don't have painful episodes, you don't have to do anything about it," he says. "But, once they have visual symptoms or recurrent erosions, then we've got to go look for it. One way to do this is to instill fluorescein and then look for negative staining, where you put the fluorescein in and look with the cobalt blue light to see where the mild lumpy bumpiness is lifting the epithelium up off the cornea, and the yellow dye is kind of pulled off those areas. It basically highlights the epithelial basement membrane dystrophy problem. I would suggest that if you suspect an epithelial basement membrane dystrophy problem, but you really can't see it, put fluorescein in and look for negative staining. If there's negative staining in the visual axis, then it could be causing visual symptoms. If there's negative staining in a patient with recurrent erosions, then that might be an area where they had a recent erosion," he says.

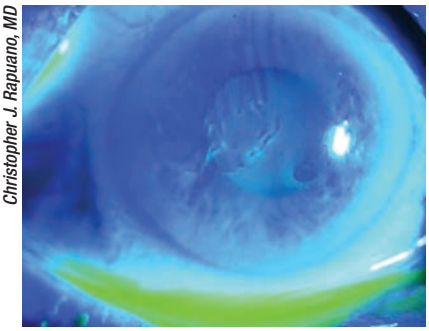
Christopher J. Rapuano, MD

Figure 3. Fluorescein dye has been placed in the eye. When viewed with a cobalt blue light, the negative staining pattern becomes quite apparent, revealing areas of elevated epithelium.

How to Treat

Visual complaints can be treated medically or by removing the affected part of the epithelium.

Dr. Raizman uses either a round blade, a spatula, a diamond burr or an excimer laser to remove the epithelium down to Bowman's layer. "If I'm removing the epithelium to improve the quality of vision or to create a smoother cornea to allow more accurate keratometry readings prior to surgery, I prefer to use a round metal blade, and I scrape off the epithelium without affecting Bowman's layer," he explains. "I generally remove between 5 and 7 mm of the epithelium centrally. I remove a little bit more when I'm doing this for lens calculations because the mid-periphery can affect my keratometry readings. If I'm doing it simply to let the patient see better, then, depending on the size of his or her pupil, sometimes I can get away with removing just 4 or 5 mm centrally. Additionally, the basement membrane dystrophy is occasionally associated with Salzmann's nodules, which are in the mid-periphery or even the periphery, and despite the nodules being out of the visual axis, they can disturb the tear film and may affect the vision or the keratometry measurement. So, I sometimes have to also remove nodules that are more peripheral. I also remove those with the blade."

Dr. Rapuano agrees. "If the vision is irregular from a 'lumpy bumpy' cornea right in the center, you can try lubrication, which doesn't usually do very much," he says. "Basically, you need to remove it. You can do a simple epithelial debridement, where you just scrape off all of the loose epithelium. This usually works well. Sometimes, a microscopic irregular basement membrane is left underneath the epithelium, and if you want to remove that, you can use a diamond burr polisher. Usually, I remove the epithelium, and then I sand down the cornea gently for five to 10 seconds. This removes any part of the microscopic basement membrane that's there. Then, I treat the patient with a bandage soft contact lens, antibiotic drops, lubrication, ice packs for the pain and pain pills—which may include narcotics. Then, I'll see patients the next day and then a couple of days later. Usually I'll take the contact lens out on day four or five, and the epithelial defect will be healed. But then they still use ointment every night for three to six months, just to let the epithelium tack down."

For patients with recurrent corneal erosions, Dr. Stein says he tries medical management first. "Typically, we use hypertonic salt solutions," he explains. "For example, I use a medication called Muro 128 (Bausch + Lomb), which comes in both drop and ointment forms. It draws water out of the epithelium and decreases epithelial swelling, which results in a decrease in corneal erosions. That's the mainstay of treatment."

Unfortunately, many patients have recurrent corneal erosions that start to interfere with their daily activities. "It's one thing to have an erosion once every six months, but if the erosions are occurring a number of times each month, and the pain is persistent for 15 to 30 minutes or

(Continued on page 57)

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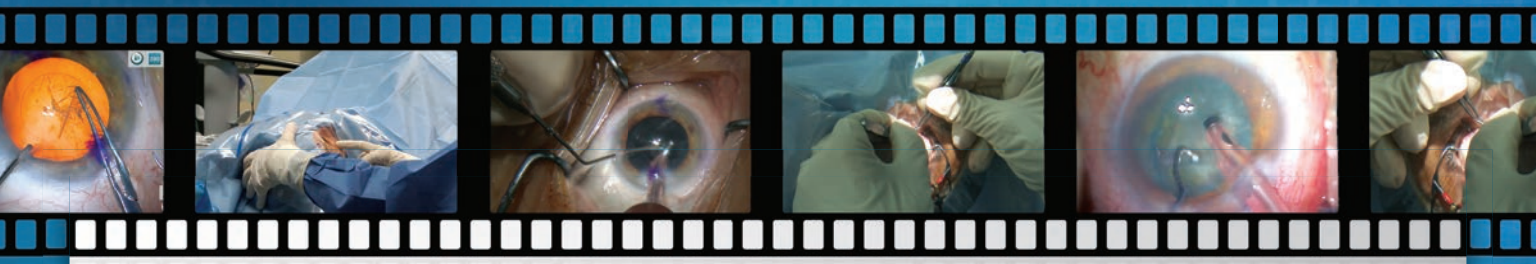

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(Continued from page 34)

with a monofocal IOL—distance, for example—instead of marginally satisfied or unhappy with multiple points of vision, especially after they've invested in an elective upgrade. This is a tough conversation to have, but it's the most important part of diagnosing and managing these patients."

Being Prepared

By incorporating this sage advice into your practice and adopting new and old tests appropriately, you can minimize the often undetected but deleterious effects of OSD on your patients. Your reward? Knowing that you're following the latest guidelines for diagnosing OSD and still retaining your individual practice style. REVIEW

Dr. Beckman reports relevant financial relationships with the following companies: Allergan, Alcon, TearLab, Takeda, Sun, Ocular Science, Eyevance, Kala Pharmaceuticals, eyeXpress, Johnson & Johnson, Bruder, NovoLog, Bausch+Lomb and Dompé. Dr. Galor is a consultant to Allergan, NovoLog and Dompé. Dr. Yeu reports relevant financial relationships with Alcon, Allergan, Bausch+Lomb/Valeant, Bio-Tissue, J & J Vision, Kala Pharmaceuticals, Merck, Novartis, Ocular Science, Ocular Therapeutix, OcuSoft, Oyster Point Pharma, ScienceBased Health, Shire, Sight Sciences, Sun Pharma, Surface Pharmaceuticals, Topcon, TearLab, TearScience and Zeiss.

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(Continued from page 54)

longer, then the patients need additional treatment, which is typically superficial keratectomy," says Dr. Stein. "In the operating room, with a lid speculum in place, under topical anesthesia, I use a Merocel spear and just touch the epithelium. If it's loose, it comes off very easily. If the epithelium is normal, it's quite adherent. We basically take off the epithelium that's really loose, and we'll often use a diamond polisher to polish the surface of Bowman's layer. This very quick procedure is followed by instilling an antibiotic drop and a non-steroidal drop and then fitting the patient with a bandage soft contact lens, which we keep in place typically for a few weeks. And with that treatment, there's a very high probability of permanent success. We've found that about 85 percent of patients don't have recurrent erosions after that. The remaining 15 percent could still have some erosions, but, in most cases, they're less severe and less frequent."

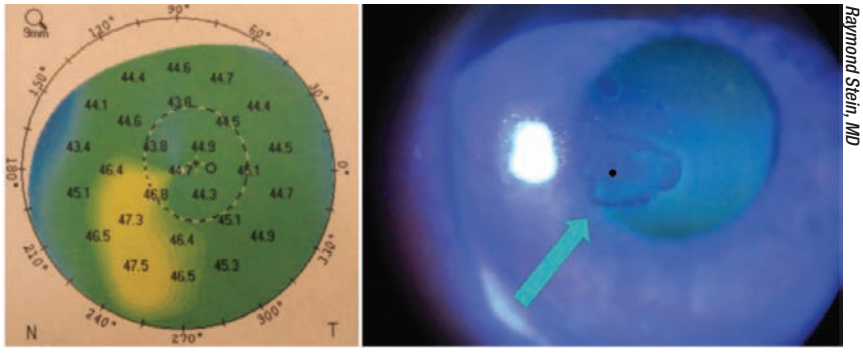


Figure 4. Pseudokeratoconus in a patient with epithelial basement membrane dystrophy. The irregular corneal epithelium induced topographic changes suggestive of keratoconus. Epithelial debridement improved the topographic irregularity.

For recurrent corneal erosions, Dr. Raizman also tries a simple debridement first. "However, in my experience, that is only effective about 50 percent of the time," he says. "I like anterior stromal puncture for erosions if the recurrent erosions are out of the visual axis. I prefer not to do puncture in the visual axis because the puncture creates scars that can be permanent. While those scars aren't often visually significant, they can be. Because the results are unpredictable, if there are erosions in the visual axis, I would prefer to use a diamond burr or an excimer laser to treat those. I think the excimer laser is safer because there is a more controlled removal of Bowman's layer and a more uniform removal. The downside is that

(Continued on page 64)

Hone Your Refractive Screening Process

Follow these tips to safeguard corneal health while ruling candidates in or out.

Sean McKinney, Senior Editor

Avoiding unexpected and unwanted results of refractive surgery can be just as important as striving to achieve ideal visual outcomes. More surgeons are coming to appreciate this today.

"I haven't had a postop case of ectasia in seven years," says Scott MacRae, MD, director of refractive services in the department of ophthalmology at the University of Rochester. "This problem is so rare because we've gotten to be so good at screening these patients."

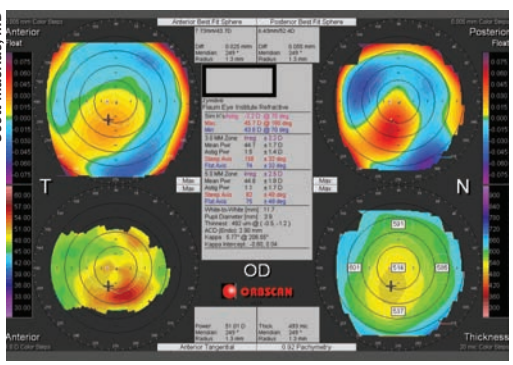
Dr. MacRae and other leading surgeons have learned that the key to steering clear of ectasia and other postop problems lies in how they approach the initial preop visit—specifically, how well they scrutinize the cornea, using corneal topography, keratometry, pachymetry and old-fashioned examination techniques. Here, they share strategies for selecting the right patients for surgery and the right surgical modality.

Getting Involved

"Preparing for refractive surgery is much more involved than doing the actual procedure itself," asserts Kendall E. Donaldson, MD, MS, professor of clinical ophthalmology, cornea/external disease/refractive surgery at the Bascom Palmer Eye Institute in Miami. "I'm not suggesting that refractive surgery, which needs to be carefully learned and perfected, is easy. But you have to spend more time on preop planning, evaluating all of the factors that could rule in or rule out surgery. We spend a few hours providing our fellows with instruction on surgical technique. But many more hours are spent on preop preparation."

Before preop screening can even begin, however, Stanford University's Edward E. Manche, MD, prioritizes the need to optimize the ocular surface. "You have to make sure you're imaging an eye that's healthy," he says. "The ocular surface needs to be pristine, unaffected by meibomian gland dysfunction, evaporative tear disorder, punctate epithelial erosions or other signs and symptoms of dry eye. Perform tomography and topography only after you've treated any of these conditions successfully. Sometimes, patients are also affected by corneal warpage related to contact lens wear. If so, instruct them to not wear soft contacts for a week before their screenings. For torics, have them go two weeks or a month. For RGPs, definitely a month. And for Ortho K, several months are needed to get the corneas into normal shape."

Dr. Manche's techs work up a history on the patient to address all issues. "We scan the patients, and I try to correlate abnormalities with the scans," he notes. "The way our clinic works, when I go in to see the patient, I want to do so with all of the data in front of me. Otherwise, it doesn't make for good flow."



Scott MacRae, MD

Figure 1. This case of keratoconus, as shown on an Orbscan scan, is characterized by inferior steeping, a crab claw appearance and a high posterior float of more than 0.055 mm.

Custom Fit Screening

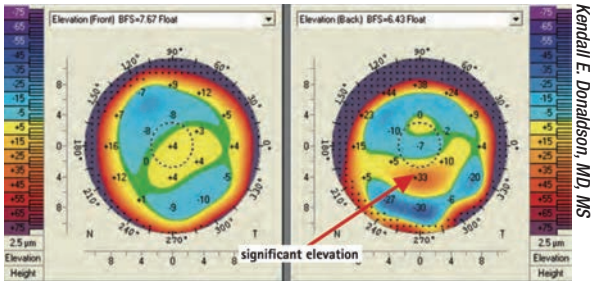
Dr. MacRae meets the preop challenge by making sure he uses a screening instrument that best fits the needs of each case. He relies frequently on an Orbscan (Bausch + Lomb), which works well for many patients. But if a patient has astigmatism or presents as a potentially complicated case, he switches to a multi-modality Galilei (Ziemer Ophthalmic Systems), which he has access to at the Flaum Eye Institute in Rochester.

Dr. MacRae say he values the data from the posterior cornea the Galilei provides. "But the most helpful part of the Galilei is that it has a toric component, so that allows you to compensate for patients with astigmatism," he observes. "The posterior float on the Orbscan can't be used to accommodate astigmatism, anteriorly or posteriorly, because it conducts a best-fit-sphere analysis. So with the Galilei, patients who would otherwise be excluded from consideration for refractive surgery are now included."

The Galilei also combines diverse state-of-the-art technologies—such as placido topography, dual Scheimpflug tomography and optical biometry—to offer a complete solution for refractive surgery planning. "All measurements are included in one device," he notes. "The device has also been found to be highly sensitive and specific in detecting keratoconus and forme fruste keratoconus."

Probabilities and Validation

Dr. Manche uses the placido-based Atlas 9000 Corneal Topography System (Zeiss) and Pentacam tomographer (Oculus) when screening potential refractive surgery candidates. The Atlas includes PathFinder II corneal analysis software, which provides probabilities for five corneal conditions by comparing topography exams to an extensive clinical database. Validation of PathFinder II with an independent data set has demonstrated greater than 90-percent sensitivity, specificity and accuracy in detecting normal versus abnormal corneas, he says. Color-coding of PathFinder II parameters also shows him when parameters are beyond normal limits and may contribute to specific classifications.



Kendall E. Donaldson, MD, MS

Figure 3. Note the contrast between the anterior topographic scan and the posterior scan, which shows significant elevation. The findings raise a red flag for a surgeon deciding if refractive surgery is appropriate for this patient.

"I'm a data hound, so I will get placido disc readings from the Atlas and the Pentacam," he says. "The Pentacam tomography map shows anterior and posterior elevations. I may see an indication of risk—that the patient is susceptible to ectasia, for example—based on the findings in the posterior area. In the Belin/Ambrosio Enhanced Ectasia Display embedded into the tomographer, you can see the summary data. If there are abnormal posterior or anterior findings, it can help determine if a patient is not a candidate for surgery. On the difference map, depending on the patient, you'll see white (proceed), yellow (some posterior deviation) and red (extreme risk of ectasia in the posterior wall.) So the testing allows you to ensure safety and rule out a patient based on extreme risk of ectasia."

Screening Principles

Dr. MacRae recommends applying some basic principles when screening all patients. "I do about 1,000 refractive surgery cases per year," he says. "We screen using the criteria most people use. If the posterior float is exceptionally high—more than 40 mµ on the Orbscan—that raises a red flag. For marked skewing, asymmetry, or marked thinning (less than 450 mµ), I'm concerned about that from the beginning."

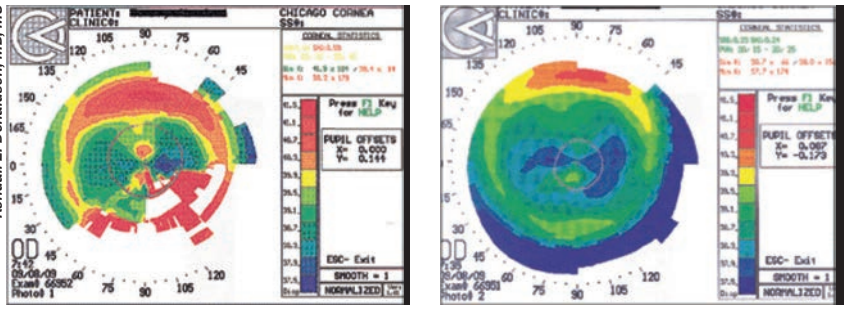
Dr. MacRae uses the "60-percent rule" to ensure he has enough corneal thickness with which to work. "At 600 mµ of corneal thickness, for example, 60 percent would be 360 mµ. So you can do a flap that is 100 microns deep. That means 140 mµ would be the deepest ablation you could do with LASIK because that would bring you to 360 mµ of residual tissue, or 60 percent of the corneal thickness.

Knowing this during screening can help you determine whether to perform PRK or LASIK, depending on refractive needs."

A high myope, such as -8 D, may push him toward recommending PRK only, he says. "For a 450-mµ cornea that's perfectly symmetrical, patients are usually safe candidates if they need only 1 or 2 D of treatment," he notes. "These patients can usually do well with PRK. You don't want to overreact to the 60-percent rule."

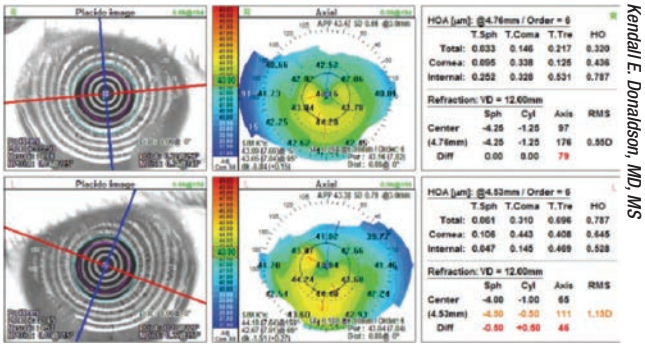
Another basic principle to consider is making sure your corneal topographer is at the right setting. Dr. MacRae says some surgeons choose a setting that's too sensitive. "I set my Orbscan setting at 1 D," he notes. "Others may put it at a half of a diopter, thinking that's better. Then, all of a sudden, they'll see these colors starting to stand out on the scan. Some experts, such as Steve Klyce, MD, recommend a setting as high 1.5 D."[2]

Kendall E. Donaldson, MD, MS



Figures 4-A and 4-B. The white sections within the map on the left reflect signs of dry eye, while the map on the right shows an eye with a healthy tear film. Your patient's eyes should be free of dry eye before screening for refractive surgery.

Figure 5. This patient has anterior basement membrane dystrophy, which will need to be resolved before screening for surgery. The placido rings on the topographic map are not intact, unlike the round shapes found in healthy eyes.



Kendall E. Donaldson, MD, MS

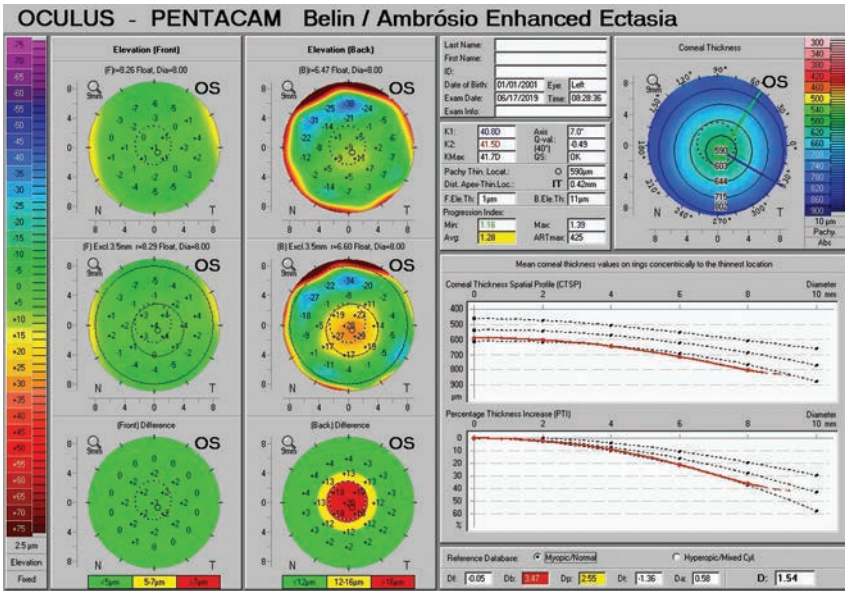


Figure 6. This map for the Pentacam Belin/Ambrosio Enhanced Ectasia Display shows an elevated posterior float that's bowed inward, a sign of corneal weakness not detected on placido scans that could lead to ectasia. A surgeon should opt for PRK instead LASIK or SMILE in these cases.

Tertiary Approaches

Dr. Donaldson offers pointed preop screening advice based on her work in a tertiary practice that receives many refractive surgery referrals. "We benefit from insights on the many factors that might rule out surgery—more so than the typical surgeon would in private practice," she notes. "My experience can help all surgeons keep in mind what to look for, even if 90 percent of their cases are good candidates, such as a 30-year-old with a -3 D sphere. ODs do 75 percent of our screening, so we never see bad patients. But we need to screen further before deciding how to proceed."

Dr. Donaldson relies on corneal topography, corneal tomography, keratometry, pachymetry and a thorough exam when screening her patients. Here are some important considerations she recommends keeping in mind:

- ***Anterior elevation map.*** Consider using keratometry to evaluate the shape of the cornea, looking for astigmatism and symmetry. "The corneas should be symmetrical," she says. "Any elevation steeper than 47.2 D is a red flag. You need to investigate for keratoconus." She also investigates when the manifest astigmatism in the patient's ophthalmic lens prescription doesn't match what she sees in topography. "The cause could be lenticular astigmatism," she points out. "Or it could involve some other situation that would make us think twice before proceeding with a procedure."
- ***Posterior elevation map.*** "Again, we're looking at the keratometry numbers and the shape—this time from the posterior perspective," says Dr. Donaldson. "The posterior aspect should match the anterior aspect. Anything that doesn't match is also a red flag for us."
- ***Pachymetry.*** "Any measurement of the cornea that is below 470 microns is a red flag," says Dr. Donaldson. "We are also looking for thin points. If the center of the cornea is too thin or you find thinness within a radius of 0.5 mm from the center, that should also raise a red flag."
- ***Underlying pathology***. "We make sure we check for ocular

(Continued on page 73)

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New Precision1 Contact Lens Debuts

In the coming year, you'll be able to prescribe a new daily disposable contact lens, Precision1, that its manufacturer, Alcon, says is ideally suited to the first-time contact lens wearer. Research cited by the company shows that 20 percent of new wearers drop out within the first year, and 57 percent don't inform their eye doctor when they do.

To help, Alcon developed Precision1 to negate what it identifies as the top three motivators of drop out: poor vision; poor comfort; and even the frustrations that arise from poor lens handling.

Precision1 uses a new silicone hydrogel material, verofilcon A, and includes a permanently adhered 'microthin' (2 to 3 µm) layer of moisture. Alcon says this feature, which it calls SmartSurface, improves comfort and supports a stable tear film. The lens has a water content of 51 percent at the core and greater that 80 percent at the anterior surface.

The company says the lens will be designed to be a mid-tier option between its Dailies Aqua Comfort Plus and Dailies Total1 lines of contact lenses. The lens will be available in a power range of -12 D to +8 D, with a 14.2-mm diameter and an 8.3 base curve. Precision1 will begin rolling out to select doctors in the United States in September, with widespread access anticipated for early 2020. For information, visit alcon.com.

New Prefilled Syringe for Aflibercept Approved by FDA

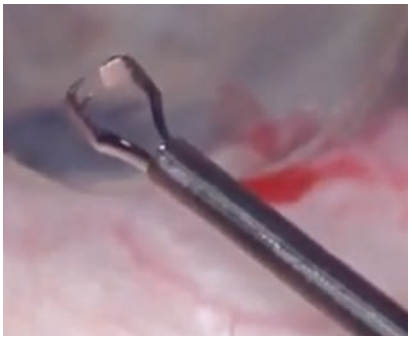
Regeneron Pharmaceuticals recnetly announced the U.S. Food and Drug Administration approved the Chemistry, Manufacturing and Controls Prior-Approval Supplement for the Eylea (aflibercept) Injection prefilled syringe.

The 2 mg, single-dose, sterilized prefilled syringe provides physicians with a new way to administer Eylea that requires fewer preparation steps compared with vials. The company says that it expects the prefilled syringe to be available to physicians this year.

For information on the prefilled syringe for aflibercept, visit https://investor.regeneron.com/news-releases/news-release-details/fda-approves-eylear-aflibercept-injection-prefilled-syringe.

Help for CyPass Patients

If you've got patients with Alcon CyPass glaucoma stents in their eyes that need revision, Microsurgical Technologies says its new instrument, the 19g Ahmed Micro Stent Cutter, might be of use.



Microsurgical Technologies' new cutting instrument is designed to snip already implanted CyPass Micro Shunts in an effort to possibly reduce endothelial damage related to the shunts.

MST says that it developed the cutter in collaboration with Toronto surgeon Ike Ahmed, MD, and says the unique design of the instrument enables surgeons to approach a micrstent coaxially, grasp and trim a stent in a single step using only one hand and make a clean cut of the stent's proximal end.

For information on the new cutting instrument, visit https://microsurgical.com/. REVIEW

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Richard Spaide, MD
Vitreous Retina Macula Consultants of NY

PANELISTS

Lama Al-Aswad, MD
NYU Ophthalmology Associates

Pearse Keane, MD
Moorfields Eye Hospital, London

Event Details

DATE

Sunday,
October 13, 2019

TIME

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Program:
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(Continued from page 57)

the laser is more expensive, and insurance usually won't pay for it, so patients have to pay out of pocket; there's a cost to the surgeon to use the laser that has to be passed on to the patient.

"The diamond burr is inexpensive, simple, and easy to use in the office setting," Dr Raizman continues. "However, if the burr is used too aggressively, you can remove more of Bowman's layer in some areas than others or even remove some stroma, and that can create irregular astigmatism and affect the patient's vision sometimes. But I should emphasize the burr is quite practical, and it's not hard to use it safely, so it's often a good choice for surgeons who don't have access to the excimer laser or for patients who can't afford it."

Dr. Raizman adds that while debridement is about 50-percent effective in these cases, the excimer laser is 90 to 95 percent effective for resolving the recurrent erosions with a single treatment. "I don't personally have enough experience with the diamond burr, but from the medical literature, it's probably equally as effective as the excimer laser," he says.

For recurrent erosions, Dr. Rapuano prefers a diamond burr treatment. "You can perform excimer laser phototherapeutic keratectomy, but I don't usually do that," he says. "I usually use the diamond burr, which I find to be as effective as the excimer laser and much faster, easier to schedule, and less expensive. However, if you've got some scarring on the anterior part of the cornea due to multiple erosions, then you can do excimer laser phototherapeutic keratectomy. In that case, I strip the epithelium off and then, instead of using a diamond burr to polish it, I use the excimer laser. The nice thing about the excimer is that it will polish a big area pretty uniformly."

Dr. Raizman says that while epithelial debridement is about 50-percent effective, the excimer laser is 90- to 95-percent effective for resolving the recurrent erosions with a single laser treatment.

Pearls

According to Dr. Stein, refractive surgeons should always be looking for epithelial basement membrane dystrophy. Most patients with this condition are asymptomatic, but it can have a significant impact on the outcome of refractive surgery. "If patients have epithelial basement membrane dystrophy, they are far better off having PRK than LASIK," he says. "If they have loose epithelium that goes undetected, and they have LASIK, the epithelium can slough off during the procedure, and the healing can be very delayed. So, it's important to rule out cases of epithelial basement membrane dystrophy in patients who are interested in laser vision correction. Often, the best way is the use of fluorescein dye and a blue light using the slit lamp to look for abnormal breakup in focal areas of the cornea. That's very suggestive of epithelial basement membrane dystrophy." He adds that all LASIK surgeons need to ask about patients' past history of corneal erosions.

Epithelial basement membrane dystrophy can also mimic other conditions. "These patients can have false ectasia or pseudokeratoconus, and it's very important that the surgeon identify that it's not keratoconus or pellucid marginal degeneration but is in fact epithelial basement membrane dystrophy," says Dr. Stein, "and they don't require corneal cross-linking. The rest of the cornea is totally normal, and these patients don't need corneal stiffening."

Dr. Raizman adds that he is referred a lot of patients with anterior basement membrane dystrophy for treatment prior to cataract surgery because the keratometry readings are a little bit irregular. "These patients often say that they don't really mind wearing glasses after their surgery," he says. "They're not necessarily looking for the best uncorrected vision after cataract surgery. And in that case, if the vision isn't significantly affected by the basement membrane dystrophy, there's not really a reason to do a debridement prior to your IOL calculations. But for patients who want the best possible uncorrected vision and are looking for a specific refractive outcome, those patients should have a debridement prior to measuring the cornea. My point is that it's not mandatory, so it doesn't have to be done on every patient. It depends on the patient's postop needs." REVIEW

None of the physicians quoted in the article have a financial interest in any of the products or procedures mentioned.

Interrupting Diabetic Retinopathy Treatment

Researchers report increasing interest in anti-VEGF therapy for treating proliferative diabetic retinopathy, since anti-VEGF therapy has been shown to be noninferior to panretinal photocoagulation, the heretofore standard treatment for achieving regression and stabilization of PDR. Their study shows, however, that interruptions in anti-VEGF treatment for PDR can result in marked progression of disease and potentially devastating visual consequences.

In a retrospective, multicenter case series, researchers analyzed 13 eyes of 12 patients with type 2 diabetes, aged 57 ±10 years. To reflect real-world conditions in which diabetic patients tend to "underuse eye care services and are prone to significant losses to follow-up" because of illness, financial hardship or noncompliance, the study sample included only those patients who were temporarily lost to follow-up and treated exclusively with anti-VEGF therapy for either PDR or nonproliferative diabetic retinopathy, with or without diabetic macular edema.

Baseline disease characteristics, cause and duration of treatment interruption, resulting disease progression, complications and outcomes were assessed. Reasons for treatment hiatus (median: 12 months) included intercurrent illness (31 percent), noncompliance (31 percent) and financial issues (15 percent). The authors report that 77 percent of eyes lost ≥3 lines of visual acuity on the Snellen chart, with 46 percent of eyes having a final visual acuity of hand motion or worse.

Though studies have shown closely-monitored anti-VEGF therapy is effective, especially for ischemic diabetic retinopathy and PDR, the study authors conclude that these controlled studies may give false assurance because anti-VEGF therapy is unable to reverse retinal ischemia or fully address diabetic retinopathy. Additionally, the real-world situations faced by diabetic patients lead to interruptions in treatment that negatively affect outcomes.

J Ophthalmol 2019;204:13-18.
Wubben TJ and Johnson MW. For the Anti-VEGF Treatment Interruption Study Group.

Impact of EBMD and SND on Biometry Measurements

In a retrospective case series, researchers from Duke University analyzed 39 eyes of 30 patients who were evaluated for cataract surgery with documented evidence of Salzmann's nodular degeneration (SND) or epithelial basement membrane dystrophy (EBMD) and who were also scheduled for surgical intervention for corneal irregularities before cataract surgery. The study found that SND and EBMD can adversely affect keratometry and biometry measurements for IOL selection. Here are some of the findings:

- ***The EBMD group (26 eyes).*** The difference in K measurements before and after intervention showed a mean K value increase ($p<0.001$). For biometry, the predicted IOL spherical power closest to a spherical equivalent of zero ($p<0.001$) changed in 21 of 26 eyes (8=0.5 D; 9=1.0 D; 4>1.0 D). For toric IOL-eligible eyes, there was a mean predicted cylinder power change of 1.2 D; recommended toric power changed for 16 of 24 eyes.
- ***The SND group (13 eyes).*** The difference in K measurements before and after intervention showed a mean K value increase ($p=0.023$). For biometry, the predicted IOL spherical power closest to a SE of zero ($p<0.041$) changed in 11 of 13 eyes (3=0.5 D; 3=1.0 D; 5>1.0 D). For toric IOL-eligible eyes, there was a mean predicted cylinder power change of 1.5 D; recommended toric power changed for 10 of 11 eyes.

The researchers conclude that EBMD and SND have significant effects on biometry measurements and IOL calculations, and that optimizing the ocular surface and being aware of the effects of these conditions are important steps in planning cataract procedures. REVIEW

J Cataract Refract Surg 2019;45:1119-1123.
Goerlitz-Jessen MF, Gupta PK, Kim T. De Salles MC, Amrén U, Kvanta A, and Epstein DL.

This article has no commercial sponsorship.


What We're Learning From the PTVT Study

The Primary Tube vs. Trabeculectomy Study is revealing useful data regarding tubes versus trabs in virgin eyes.

Steven J. Gedde, MD, Miami

Glaucoma surgery is generally undertaken when medical therapy and appropriate laser treatment fail to produce adequate intraocular pressure reduction. In recent years, the options for surgically managing glaucoma in that situation have greatly expanded with the introduction of the new "minimally invasive glaucoma surgeries," or MIGS. But despite being known for their excellent safety profile, MIGS haven't replaced the traditional glaucoma surgeries—trabeculectomy and tube shunt implantation. That's true because tube shunts and trabeculectomies are still the most effective ways to achieve the very low IOP that's required for some patients.

However, having two surgical options that are capable of producing very low pressures has caused some surgeons to wonder whether one might be superior to the other in different surgical situations. Here, I'd like to share some of what the Primary Tube vs. Trabeculectomy Study is revealing about performing these procedures on eyes that have not undergone previous incisional ocular surgery.

Comparing Tubes and Trabs

Glaucoma specialists continue to have different opinions regarding the best surgical approach for patients with medically uncontrolled glaucoma. Medicare claims data indicate that tube shunts are increasingly being used as an alternative to trabeculectomy. Surveys of the American Glaucoma Society membership have also demonstrated a growing preference for tube shunts over trabeculectomy in many clinical scenarios.

One clinical situation that's part of this debate is whether a tube shunt or trabeculectomy is preferable when operating on a "virgin" eye that hasn't undergone previous incisional surgery. In the most recent AGS survey, trabeculectomy has remained the most popular option as an initial procedure for eyes with POAG, but a growing number of glaucoma surgeons prefer the use of tube shunts as an initial glaucoma procedure. Until now, however, this surgical choice was being made with limited data.

The Primary Tube Versus Trabeculectomy (PTVT) Study was undertaken to provide that data. It's an investigator-initiated trial designed to compare the safety and efficacy of trabeculectomy with mitomycin-C to tube shunt surgery, when performed as an initial procedure in eyes that haven't had previous incisional ocular surgery.

Study Design

The design of the PTVT Study is similar to that of the Tube Versus Trabeculectomy (TVT) Study, an earlier trial that enrolled patients with prior cataract extraction and/or failed filtering surgery. In contrast, the PTVT Study recruited patients without prior incisional ocular surgery. Participants in the PTVT Study were 18 to 85 years old, with IOP ≥18 mmHg and ≤40 mmHg on maximum tolerated medical therapy. The vast majority of the subjects had primary open-angle glaucoma, and there were no significant differences between baseline demographic and ocular characteristics of the groups.

Reasons for exclusion included a narrow anterior chamber angle; secondary glaucomas such as neo-

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PTVT Study: Summary of Findings at Three Years

IOP reduction	IOP reduction was greater in the trabeculectomy group at all time points, and fewer adjunctive medications were required to achieve this.
Rate of surgical failure	The tube group had a higher failure rate at one year, but no significant difference between the groups was seen at three years.
Reasons for failure	In both groups the most common reason for treatment failure was insufficient IOP reduction. Failure because of a need for additional glaucoma surgery was more common in the tube group, while hypotony failures occurred exclusively in the trabeculectomy group.
Risk factors for failure	Lower preoperative IOP was predictive of failure, especially in the tube shunt group.
Medical therapy	The tube group required more adjunctive glaucoma medications postoperatively.
Complications	Many postoperative complications were observed in both groups, but most were self-limited. More complications occurred in the trabeculectomy group, especially during the first month after surgery.
Postoperative interventions	Postoperative interventions were performed with similar frequency in both groups.
Visual acuity	No significant difference in visual outcomes were seen between the groups.
Cataract formation	Cataract progression occurred at a similar rate in both groups.

vascular, uveitic, iridocorneal endothelial syndrome, epithelial downgrowth and steroid-induced glaucoma; severe posterior blepharitis; conjunctival scarring; a functionally significant cataract; and any anticipated need for additional ocular surgery.

As in the TVT Study, participants in the PTVT Study were randomized to a 350-mm^2 Baerveldt glaucoma implant or a trabeculectomy with MM-C, although the dosage of MM-C was lower than in the TVT Study. During the design phase of the study, we considered letting each glaucoma surgeon implant whichever tube shunt was preferred. However, the biostatisticians tasked with analyzing our data advised us to standardize the surgeries as much as possible.

It was a consensus opinion among the investigators in our study that the 350-mm^2 Baerveldt implant offered the highest efficacy among available implants due to its large surface area, and this has been supported by two landmark clinical trials—the Ahmed Baerveldt Comparison (ABC) Study and the Ahmed Versus Baerveldt (AVB) Study. So, a 350-mm^2 Baerveldt glaucoma implant was used in all patients randomized to the tube group. We also standardized other parts of the procedure, such as having the implant placed in the superotemporal quadrant with the tube in the anterior chamber, and a complete restriction of flow at the time of surgical implantation. We standardized aspects of the trabeculectomies as well. An MM-C dosage of 0.4 mg/ml for two minutes was used in all patients, and the surgery was performed superiorly.

Despite standardization of many aspects of each procedure, surgeons were allowed sufficient flexibility to perform both operations in a manner in which they were comfortable and proficient. For example, surgeons were allowed to decide whether a limbus- or fornix-based conjunctival flap was used. The method of tube ligation, the size of the trabeculectomy flap and the number of flap sutures were also left to the surgeon's discretion.

Sixteen clinical centers were involved in the study. Patients were randomly assigned to one of the two groups, with follow-up visits scheduled for one day, one week, one month, three months, one year, 18 months and two, three, four and five years postoperatively. The primary outcome measure was the rate of surgical failure, using criteria consistent with recommendations from the World Glaucoma Association.

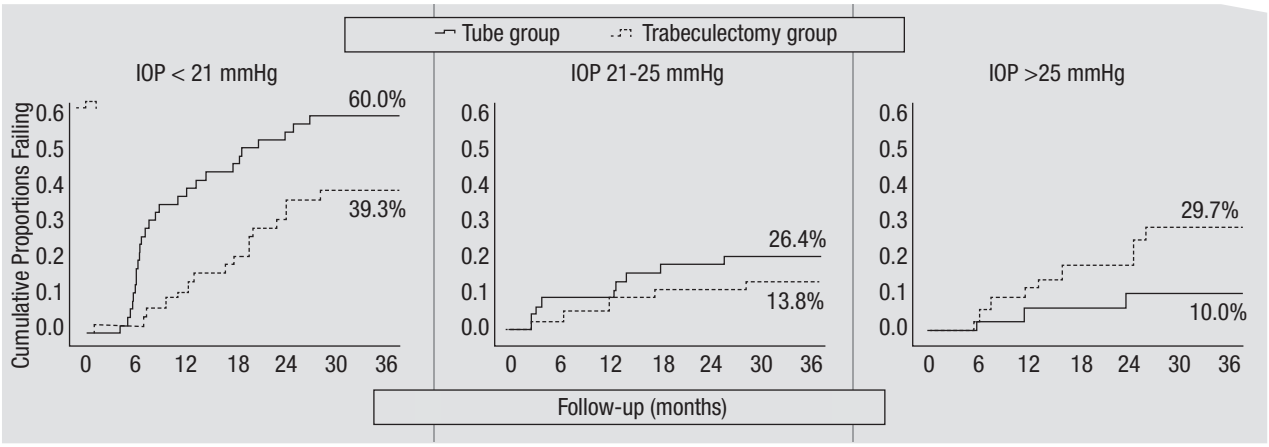
The Data (So Far)

Results from the PTVT Study at year three were presented at the 2019 Annual AGS Meeting. Highlights included:

• ***IOP reduction.*** The pressure reduction was greater in the trabeculectomy group at all time points, and that difference was statistically significant—with the exception of the 18-month and two-year time points. Furthermore, the greater degree of pressure reduction in the trabeculectomy group was achieved with fewer postoperative glaucoma medications. This clearly suggests that trabeculectomy with MM-C was more effective at reducing IOP than tube shunt implantation in this population.

• ***Rate of surgical failure.*** The primary outcome measure for the study was the rate of surgical failure, using Kaplan-Meier survival analysis. The rate of surgical failure increased over time, which came as no surprise; even glaucoma surgeries that are initially successful can eventually fail. At one year, the tube shunt group had a significantly higher failure rate

Probability of Surgical Failure Based on Preoperative IOP



than the trabeculectomy group. The cumulative probability of failure in the trabeculectomy group continued to trend somewhat lower than the tube group over time. However, the difference in failure rate between the groups was no longer statistically significant at three years.

• ***Reasons for failure.*** We found some differences in the reasons for surgical failure between the two study groups. The most common reason for failure in both groups was insufficient pressure reduction; either the pressure was above 21 mmHg at two consecutive visits, or it wasn't reduced 20 percent below baseline at two consecutive visits. Other reasons for failure included needing a reoperation for glaucoma or having hypotony. Interestingly, all of the hypotony failures occurred in the trabeculectomy group, while more reoperations were seen in the tube group.

• ***Need for adjunctive medical therapy.*** Patients who didn't fail were subdivided into complete or qualified successes. Complete successes didn't need postop adjunctive medical therapy; qualified successes were using glaucoma medications. The rate of complete success was significantly higher in the trabeculectomy group than in the tube shunt group. (That's an important consideration when managing a patient who can't tolerate medications, or a patient who is poorly compliant.)

• ***Baseline factors associated with surgical failure.*** We performed a risk factor analysis to identify baseline factors that were associated with failure in the study. The only significant predictor of failure was preoperative IOP. The patients with lower preoperative pressures had a higher risk of failure, and this was especially true in the tube group. *(See figure, above.)* In my opinion, this is one of the study's most interesting and important findings.

• ***Complications.*** In terms of complications, the PTVT Study's findings have been similar to what's been observed in other prospective glaucoma surgical trials, including the TVT, ABC and AVB studies. Postoperative complications are very common after traditional glaucoma surgery, whether it be a tube shunt or a trabeculectomy. Fortunately, most of these complications are self-limited and resolve without any specific intervention.

We did, however, find some differences between the types of complications occurring in the two treatment groups:

— Early postoperative complications, defined as those occurring in the first month after surgery, were more common in the trabeculectomy group than in the tube group.

— The rate of later postoperative complications (occurring after a month) wasn't significantly different between the two groups.

— The rate of serious complications, defined as those requiring a reoperation to manage the complication, and/or resulting in a vision loss of two or more lines of Snellen visual acuity, wasn't significantly different between the treatment groups.

— Overall, the rate of reoperation for complications trended higher in the trabeculectomy group compared to the tube group.

The complications data suggests that tube shunt surgery may have a slightly better safety profile than trabeculectomy with MM-C, at least during the first three years postop. If you combine all complications together, they were significantly more common in the trabeculectomy group than the tube group. However, the PTVT trial will continue out to five years, and the long-term data will be important for evaluating these two surgical procedures, in terms of both safety and efficacy.

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• ***Number of postoperative interventions.*** In my experience, postoperative management following tube shunt surgery tends to be less involved than postoperative management following trabeculectomy. However, in this study the number of postop interventions performed in the clinic, such as laser suture lysis or pulling a rip-cord suture, wasn't significantly different whether the patient received a tube or a trabeculectomy.

• ***Visual acuity.*** We didn't find any significant difference between the treatment groups with regard to visual acuity outcomes.

• ***Cataract formation.*** All of the patients in our study were phakic. After three years of follow-up, about a third of the patients in the study had undergone cataract extraction.

There's ample evidence in the literature to suggest that glaucoma surgery, whether it be trabeculectomy or tube shunt surgery, accelerates the development of cataract. This data suggests that cataract progression occurs at a similar rate among patients undergoing trabeculectomy or tube shunt surgery.

• ***Patient comfort.*** One of the complications we specifically asked patients about was dysesthesia, or patient discomfort. We found no significant difference in patient-reported dysesthesia between the two procedures.

Take-home Highlights (So Far)

What useful information can we take away from this study at the three-year follow-up mark?

• ***Preoperative IOP impacts the likelihood of success.*** When patients have lower levels of preoperative IOP—in our *post hoc* analysis the cutoff was less than 21 mmHg—trabeculectomy appears to be a more successful operation than tube shunt surgery. I suspect this is related to the titratability of trabeculectomy; it allows us to do laser suture lysis or use releasable sutures to titrate the pressure to lower levels in the early postoperative period. I think that's particularly valuable in patients who have initial low pressure.

• ***Both tube shunt surgery and trabeculectomy with MM-C are very effective at lowering IOP.***

Randomized clinical trials offer the highest level of evidence-based medicine, but caution should be used in extrapolating study results to dissimilar patients. We now have two trials that compared tube shunts and trabeculectomy .... Remember to apply the lessons learned only to the appropriate patient population.

Mean postoperative pressures were in the low teens in both groups throughout three years of follow-up; most patients ended up with pressures of 14 mmHg or less. MIGS procedures seldom achieve this degree of IOP reduction. As previously noted, traditional glaucoma surgeries are still an important part of our armamentarium.

• ***Your choice of tube or trabeculectomy may ultimately come down to safety vs. efficacy.*** There seems to be an inevitable tradeoff between safety and efficacy in glaucoma surgery. In our study comparing tube shunt implantation and trabeculectomy, the data suggests that trabeculectomy is more effective, but more likely to be associated with complications. A similar dichotomy was seen in the ABC and AVB studies; the Baerveldt implant was more effective, while the Ahmed valve was safer. Likewise, when comparing traditional glaucoma surgeries to MIGS, we find tube shunts and trabeculectomy are more efficacious, but MIGS are safer. So added efficacy seems to be achieved at the expense of reduced safety—at least with the existing glaucoma surgical options.

This shouldn't be surprising. Many of the complications that we contend with in glaucoma surgery are related to hypotony, such as anterior chamber shallowing and choroidal effusions, and sometimes more serious complications, including suprachoroidal hemorrhage and hypotony maculopathy. (Of course, it's possible that some future glaucoma surgery will be both highly effective and low-risk.)

A Few Final Thoughts

The purpose of a trial like the PTVT Study is to provide useful information that will help surgeons select the best glaucoma procedure for an individual patient. Data produced by the trial thus far hasn't demonstrated clear superiority of one of these procedures over the other.

However, there's another important consideration when choosing a glaucoma surgical procedure, one that was not addressed in the PTVT Study: the surgeon's experience and comfort with each procedure. All of the surgeons in the PTVT Study were proficient and experienced with both of the procedures being studied, but this may not be the case with

(Continued on page 73)

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(Continued from page 70)
all surgeons. A surgeon's familiarity with each operation is an important factor when deciding which surgery to perform.

One interesting question that our study may eventually help answer is how tube shunt and trabeculectomy function is impacted by subsequent cataract surgery. All eyes enrolled in our study were phakic, but a third of the patients had undergone cataract surgery by the three-year time point. Multiple studies have demonstrated that when performing cataract surgery in eyes with preexisting trabeculectomy filtering blebs, there's some risk of bleb failure. However, there's less information in the medical literature about how tube shunts fare with subsequent cataract removal. I believe the data coming from a prospective, randomized clinical trial will add significant new information to help answer this question. However, we're waiting for the five-year data to do a full statistical analysis relating to this question.

As noted earlier, glaucoma surgical practice patterns appear to be shifting away from trabeculectomy and toward implanting tube shunts. The TVT Study provided data to support this trend, as tube shunt surgery was found to be more successful, with a lower rate of early postop complications relative to trabeculectomy with MM-C among patients with prior cataract and/or failed glaucoma surgery. Notably, this efficacy result wasn't seen in the PTVT Study. However, it's important to realize that different patient populations were studied in the TVT and PTVT Studies.

Randomized clinical trials offer the highest level of evidence-based medicine, but caution should be used in extrapolating study results to dissimilar patients. We now have two trials that compared tube shunts and trabeculectomy with MM-C in different populations, and we're seeing somewhat different results. So remember to apply the lessons learned only to the appropriate patient population. REVIEW

Dr. Gedde is a professor of ophthalmology and vice chair of education at Bascom Palmer Eye Institute. He is a study chairman for the PTVT Study. He has no personal financial ties to any product mentioned, but notes that the PTVT Study was funded by grants from Johnson & Johnson Vision, the National Eye Institute and Research to Prevent Blindness.

(Continued from page 60)
surface disease, anterior basement membrane dystrophy, and (as mentioned previously) keratoconus," says Dr. Donaldson.

Guarding Against Risks

Dr. MacRae offers this advice to avoid surgical risks: "If you see a marked red zone inferiorly, nasally or temporally, that's another red flag, another sign of what we call skewing, where the bow tie is bigger down below than above," he says. "This represents a clear-cut case of keratoconus. No surgery can be done on this patient."

In a patient with Salzmann's nodular degeneration, a topographical representation of the cornea will reveal significant irregular astigmatism, another concern, he says.

If Dr. Manche encounters a subtle abnormality, he considers using PRK instead of LASIK. "It's also possible we'll choose IOL surgery," he notes. He also remains vigilant whenever his screening exam turns up two other key findings:

- A steep or a posterior slope that's bowed in. "Some people say the earliest sign of keratoconus is a bulge on the posterior cornea," he notes. "You might also see the anterior cornea bowed forward."
- A view going from the central to the peripheral cornea that reveals several suggestive indices, including those associated with thinning.

Pulling It All Together

In summary, Dr. Donaldson advises all refractive surgeons to keep the potential outcome of every case in mind. "When you're screening a patient for an elective procedure, you want to be extra careful and err on the conservative side," she says. "We have to ask ourselves: How well am I going to make this patient see? Am I going to flatten the tissue too much? Is the cornea too thin? Will underlying conditions cause long-term distortion?

"We want to keep them in the normal range of corneal fitness," she continues. "Remember to always calculate preoperatively what their corneas will look like postoperatively. We're looking at how LASIK will affect patients tomorrow and 10 years from now." REVIEW

Dr. Donaldson reports financial relationships with Alcon, Allergan, Johnson & Johnson Vision, Sun Pharmaceuticals, Shire, Bausch + Lomb, Kala Pharmaceuticals, EyeVance, Lumenis, Omeros and Carl Zeiss Meditech.

Dr. Manche is a consultant for Allergan, Avedro, J & J Vision and Carl Zeiss Meditec. He performs sponsored research for Allergan, Alcon, Avedro, Carl Zeiss Meditec and Presbia. He owns equity in Vacu-Site and RxSight. Dr. MacRae reports no financial relationships with relevant companies.

A PUBLICATION BY REVIEW of Ophthalmology

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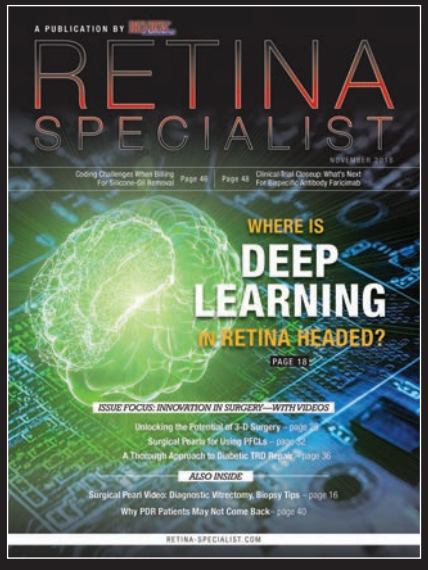

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xiidra® (lifitegrast ophthalmic solution) 5%

Rx Only

BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

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

DOSAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies 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 dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 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% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

Postmarketing Experience
The following adverse reactions have been identified during postapproval 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.

USE IN SPECIFIC POPULATIONS
Pregnancy
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 omphalocele 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.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg / day, representing 5,400-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 (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele 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 (NOAEL) was not identified in the rabbit.

Lactation
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. 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.

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

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.
Mutagenesis: Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.
Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

Shire

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.
For more information, go to www.Xiidra.com or call 1-800-828-2088.

Patented: please see https://www.shire.com/legal-notice/product-patents
Last Modified: 01/2018 S33769

xiidra® (lifitegrast ophthalmic solution) 5%

FIIRST IN CLASS

Xiidra is the only lymphocyte function-associated antigen-1 (LFA-1) antagonist treatment for Dry Eye Disease[1,2]

Xiidra, the first in a class of LFA-1 antagonists for Dry Eye Disease, is a prescription eye drop FDA-approved to treat both signs and symptoms of the disease.[1,3]

There's no substitute.[2,4] Check out patient resources, insurance coverage, and more at **Xiidra-ECP.com**

References:

1. Xiidra [Prescribing Information]. Lexington, MA: Shire US. **2.** TFOS DEWS II Research Subcommittee. Report of the Research Subcommittee of the Tear Film & Ocular Surface Society Dry Eye WorkShop II (2017). *Ocul Surf.* 2017;15(3):269-649. **3.** FDA approves new medication for dry eye disease. FDA News Release. July 2016. http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm510720.htm. Accessed July 12, 2016. **4.** Food and Drug Administration. Electronic Orange Book. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf. Accessed June 26, 2018.

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.

For additional safety information, see accompanying Brief Summary of Safety Information on the adjacent page and Full Prescribing Information on Xiidra-ECP.com.

Shire