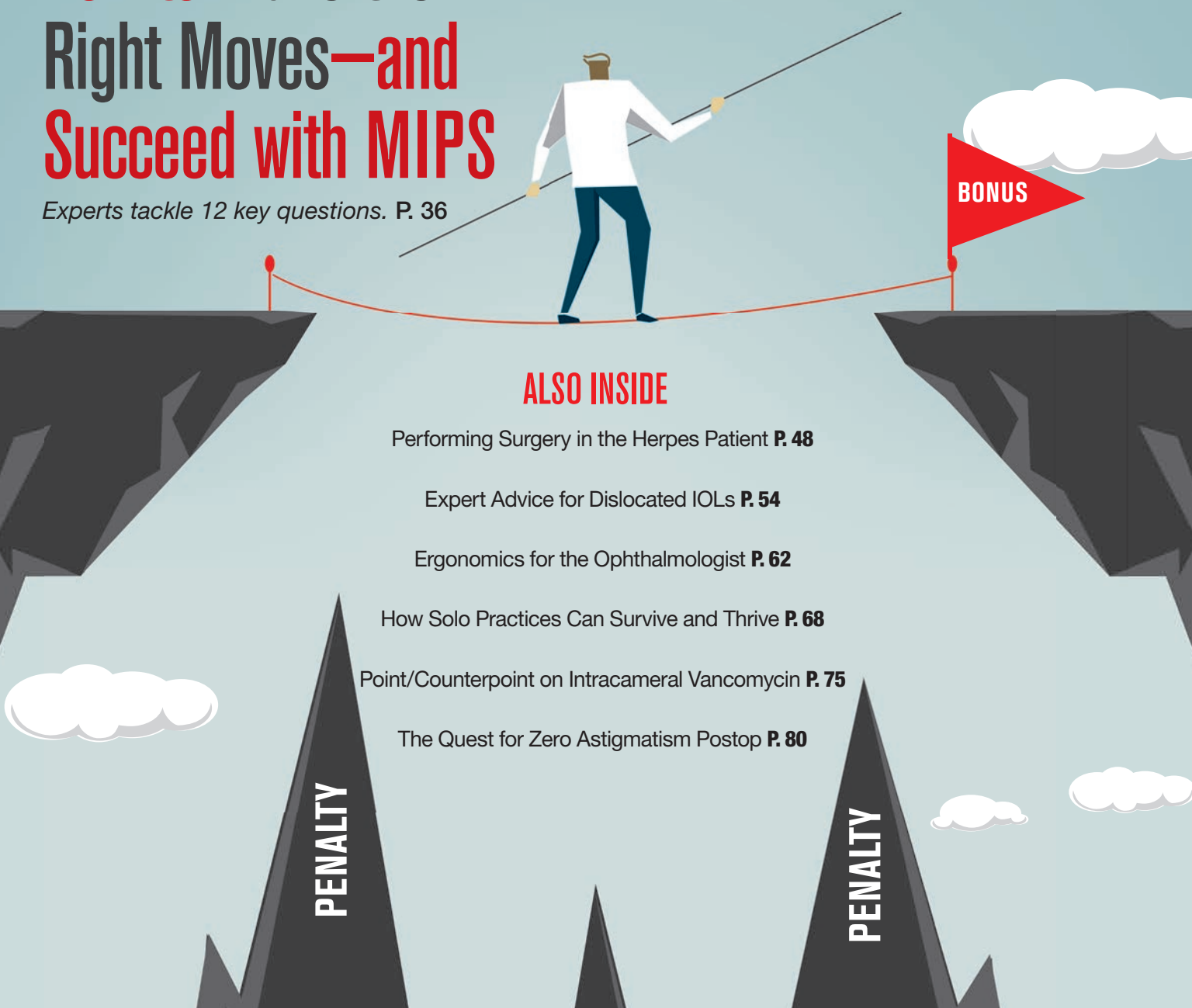
SURGEONS COPE WITH CYPASS WITHDRAWAL P. 4 • MORE THOUGHTS ON SULCUS IOLS P. 17
HOW TO HANDLE ABNs IN YOUR PRACTICE P. 20 • STRATEGIES FOR AVOIDING MALPRACTICE SUITS P. 26
GLAUCOMA: HOW TO RESPOND TO A FAILED TUBE SHUNT P. 98 • WILLS RESIDENT CASE REPORT P. 103

REVIEW® of Ophthalmology
OCTOBER 2018
reviewofophthalmology.com

How to Make the Right Moves—and Succeed with MIPS

Experts tackle 12 key questions. P. 36



ALSO INSIDE

Performing Surgery in the Herpes Patient **P. 48**

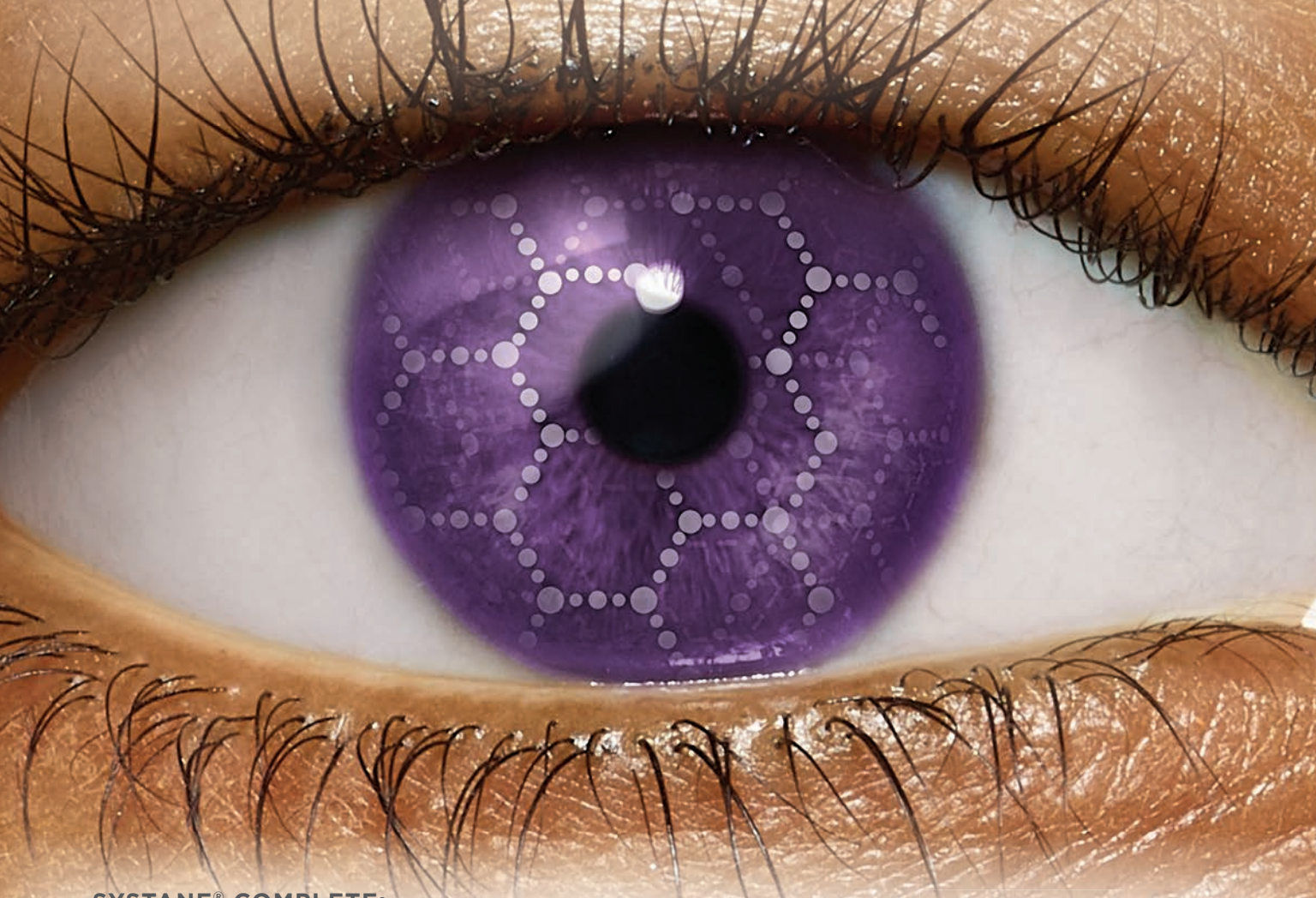
Expert Advice for Dislocated IOLs **P. 54**

Ergonomics for the Ophthalmologist **P. 62**

How Solo Practices Can Survive and Thrive **P. 68**

Point/Counterpoint on Intracameral Vancomycin **P. 75**

The Quest for Zero Astigmatism Postop **P. 80**



SYSTANE® COMPLETE:

OUR MOST ADVANCED SOLUTION.
ONE SIMPLE CHOICE.[1-2]

Our most innovative drop works to restore the tear film. It provides optimal relief by addressing **every major type of dry eye**:[1-7]

- ☑ **Evaporative Dry Eye**
- ☑ **Aqueous-deficient Dry Eye**
- ☑ **Mixed Dry Eye**

The Relief is Real™

With **advanced, lipid nano-droplet technology**, the lubricant is rapidly delivered across the ocular surface—resulting in **better coverage* to provide fast hydration and locking in moisture for long-lasting relief**[1-2,5,6,8]

TALK TO A REPRESENTATIVE TO LEARN MORE

*Compared to SYSTANE® BALANCE.

1. Ketelson H, Rangarajan R. Pre-clinical evaluation of a novel phospholipid nanoemulsion based lubricant eye drops. Poster presented at: The Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO); May 7–11, 2017; Baltimore, Maryland, USA. **2.** Data on file. Alcon; 2017. **3.** Fernandez KB, Epstein SP, Raynor GS, et al. Modulation of HLA-DR in dry eye patients following 30 days of treatment with a lubricant eyedrop solution. *Clin Ophthalmol*. 2015;9:1137-1145. **4.** Davitt WF, Bloomenstein M, Christensen M, Martin AE. Efficacy in patients with dry eye after treatment with a new lubricant eye drop formulation. *J Ocul Pharmacol Ther*. 2010;26(4):347-353. **5.** Korb D, Blackie C, Meadows D, Christensen M, Tudor M. Evaluation of extended tear stability by two emulsion based artificial tears. Poster presented at: 6th International Conference of the Tear Film and Ocular Surface: Basic Science and Clinical Relevance; September 22-25, 2010; Florence, Italy. **6.** Lane S, Paugh J, Webb JR, Christensen MT. An evaluation of the in vivo retention time of a novel artificial tear as compared to a placebo control. Poster presented at: The Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO); May 3-7, 2009; Fort Lauderdale, FL. **7.** Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II definition and classification report. *Ocul Surf.* 2017;15:276-283. **8.** Torkildsen G. The effects of lubricant eye drops on visual function as measured by the Inter-blink interval Visual Acuity Decay test. *Clin Ophthalmol*. 2009;3:501-506.

Alcon A Novartis Division

SAVE THE DATE

CME

Ophthalmology Update 2019

FEBRUARY 16-17, 2019

An interdisciplinary faculty of ophthalmic subspecialists will review the continuing progress in Cataract and Refractive Surgery, Glaucoma, Retina, Neuro-Ophthalmology, Pediatric Ophthalmology, Ocular Surface Disease, Cornea and Oculoplastics.

PROGRAM CHAIRS
Don O. Kikkawa, MD
Robert N. Weinreb, MD

LOCATION
Cape Rey Carlsbad
A Hilton Hotel
1 Ponto Road
Carlsbad, CA 92011
(760) 602-0800

EARLY BIRD SPECIAL
Registration cost: $95*

PROGRAM TIMES
Saturday, February 16
8:00am — 5:00pm
Reception to follow

Sunday, February 17
8:00am — 12:15pm

THREE WAYS TO REGISTER
www.reviewofophthalmology.com/update2019
Email: reviewmeetings@jhihealth.com | call: 855-851-9964

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity has been planned and implemented by Amedco LLC and Postgraduate Healthcare Education LLC. Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Credit Designation Statement – This activity has been approved for *AMA PRA Category 1 Credit*™.

Shiley Eye Institute
UC San Diego

Jointly provided by
AMEDCO PHE

Review of Ophthalmology®

*See event website for additional information.

REVIEW NEWS
Volume XXV • No. 10 • October 2018

Cataract/Glaucoma Surgeons Suffer CyPASS Withdrawal

In late August, Alcon surprised the ophthalmic world by withdrawing the CyPASS Micro-stent from the market due to issues with significant endothelial cell loss in a post-approval study called COMPASS-XT. Surgeons have been left wondering about the data that went into the decision, the mechanism behind the cell loss and how to handle existing glaucoma patients who already have the CyPASS in their eyes.

In the COMPASS-XT study, which was a three-year extension of the original two-year COMPASS study that was used to secure approval of the device, researchers studied the safety and efficacy in patients who underwent cataract surgery plus CyPASS implantation, compared to cataract surgery alone. The exact rates of cell loss still have not been shared by Alcon. "What we do know from the COMPASS study is that ECL was similar between the phaco-CyPASS arm and the phaco-only control arm," says Malik Kahook, MD, professor of ophthalmology and the Slater Family Endowed Chair in Ophthalmology at the University of Colorado School of Medicine. "We don't have access to the data beyond the two-year COMPASS trial data. Alcon recently reported that the ECL difference between control and study arms increased after the two-year time point. We don't know what the exact numbers are for either arm of the study at this time, though Alcon did share that the number of patients with severe ECL (>30-percent loss from baseline) was more than two times higher in the CyPASS arm. It will be of interest to all practitioners to get the specific numbers so we can better understand the issue at hand."

At this point, the mechanism by which the CyPASS induces the cell loss hasn't been explicitly defined either. Atlanta glaucoma specialist Reay Brown, who participated in the COMPASS study and presented the pivotal results at the annual meetings of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery, was completely surprised by the withdrawal. "It was a total surprise to me that this happened," he says. "I thought the cornea wouldn't have any problems at all. It's mystifying that you can put in an anterior-chamber IOL that's much bigger and seems to be more of a potential problem, and have those patients do very well, while this tiny device that seems very stable can cause the kind of endothelial cell loss that Alcon has seen in its five-year data."

Surgeons speculate that the problems may have something to do with devices that protrude too far outside the tissue in which they're implanted, which is just below the trabecular meshwork. "At this time, we have very little specific information from Alcon on the mechanism of ECL, and it is not clear if they have a firm understanding of the mechanism either," says Dr. Kahook. "What has been made public is that there is an association between devices that are positioned too far into the anterior chamber and the observed ECL over time. It is not clear if devices moved postoperatively, other than anecdotal reports by physicians on discussion boards. Anything beyond this would be pure speculation."

Sacramento glaucoma specialist, Richard Lewis, who consults for Alcon, says the revelations about endothelial cell loss need to be put into context. "The surgeons in the original COMPASS trial were good surgeons who were given a new device and instructed on approximately where to put it, but there wasn't really good guidance in terms of how far to put it into the eye," he says. "Some surgeons I've spoken to like to see the tip of the tube [poking out of the tissue] while others like to put it farther in. Fast forward to today; if we were to do the study now, we'd put the device flush with the tissue—there'd be no extension. But we didn't know that then. So, the data is a little bit misleading, because it was a brand-new device with a learning curve. Someone had to put the first set of devices in, and just as with iStent and Hydrus, all of us learned along the way as we did it.

"Also, no other device has been requested to perform a five-year follow-up of endothelial cells," Dr. Lewis continues. "You could argue that it's good that they did so, but perhaps if Alcon had known it was going to be followed for five years, greater precautions would have been

iDesign
Refractive Studio

EVERY TREATMENT IS A TRUE ORIGINAL

When you measure better, you treat better.

The ***iDESIGN***® Refractive Studio, the first and only topo-integrated, wavefront-guided technology, ensures every treatment is one-of-a-kind. Now you can measure and analyze the eye, inside+out, with next-level personalization.

Inside+Out

Treat more patients with the ***iDESIGN***® Refractive Studio indicated for the wavefront-guided LASIK treatment of monovision, myopia (with or without astigmatism), hyperopia (with or without astigmatism), and mixed astigmatism.

To make every treatment a true original, call your Johnson & Johnson Vision sales rep to learn more about the ***iDESIGN***® Refractive Studio.

INDICATIONS: The ***STAR S4 IR***® Excimer Laser System and the ***iDESIGN***® Refractive Studio is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes: 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision, with myopic astigmatism, up to -6.00 D spherical equivalent as measured by ***iDESIGN***® Refractive Studio, with cylinder up to -3.00 D, and a minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia; with an agreement between manifest refraction (adjusted for optical infinity) and ***iDESIGN***® Refractive Studio refraction as follows: Spherical equivalent: Magnitude of the difference is less than 0.625 D; Cylinder: Magnitude of the difference is less than or equal to 0.50 D; Cylinder Axis: If either the manifest cylinder entered into the ***iDESIGN***® Refractive Studio or the ***iDESIGN***® Refractive Studio cylinder selected for treatment is less than 0.50 D, there is no requirement for axis tolerance. When both cylinders have a magnitude of at least 0.50 D, the axis tolerance is linearly reduced from 15° (0.5 D) to 7.5° (7.0 D or greater) based on the average magnitude of both cylinders. With documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and with a successful preoperative trial of monovision or history of monovision experience.

See additional indications on next page.

Johnson & Johnson VISION

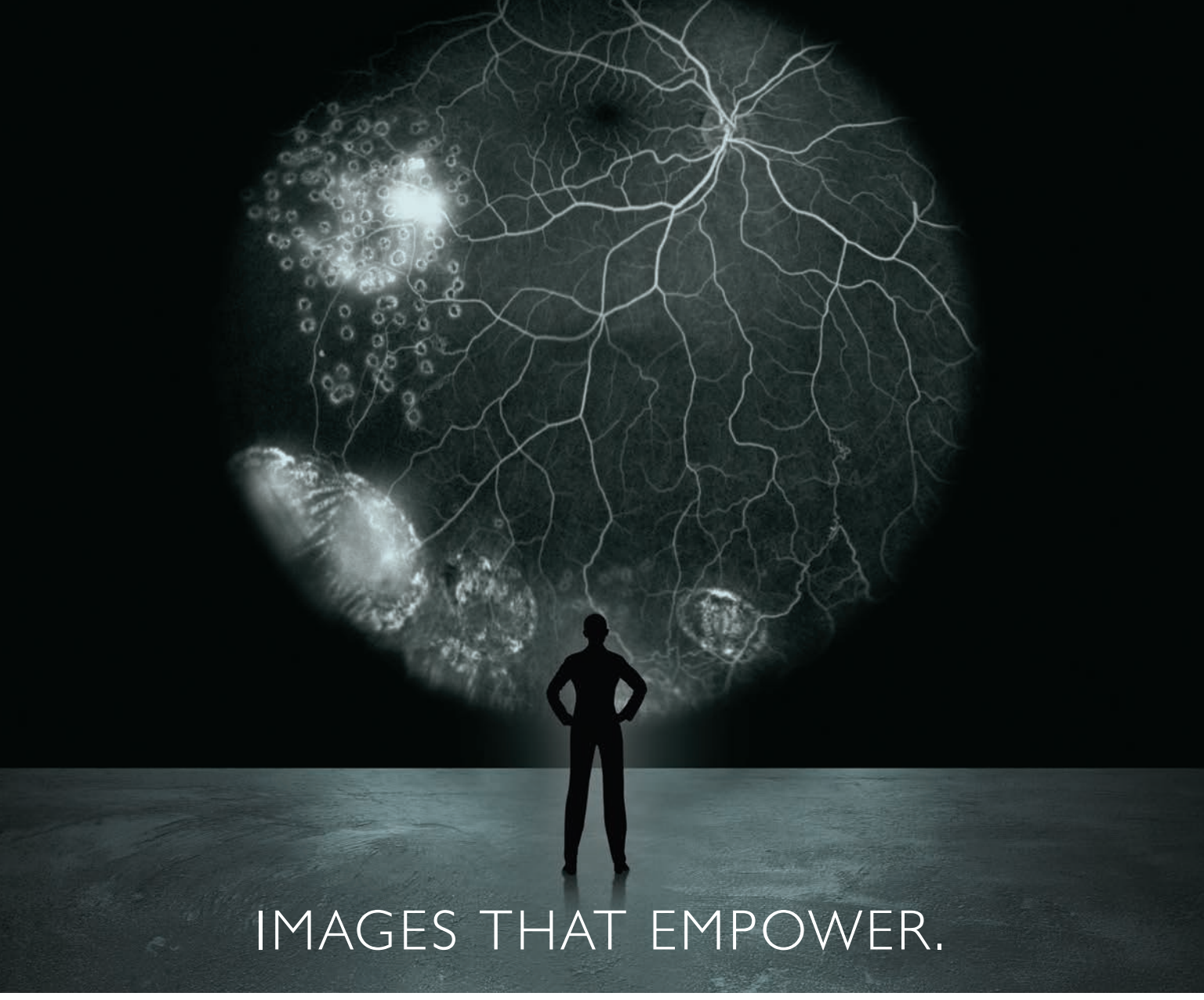
taken, and better training administered, before they enrolled these patients. Perhaps they could have gotten better surgical outcomes if they had these surgeons do five or 10 patients before they entered the study, so they could develop a better surgical skill set."

Surgeons are now left to manage current CyPASS patients, and are adopting their own systems for dealing with them until more official recommendations are released. "I put some CyPASS devices in the week before it was withdrawn," says Dr. Brown. "That led to a weird conversation a week later: 'Mrs. Jones, you're doing well with your CyPASS that I put in last week, and oh, by the way, it's been recalled.' But that's what you have to do. I then explain as much as I know to them. I'm monitoring them with endothelial cell counts. On a conference call shortly after the withdrawal was announced, Alcon's Steve Lane, MD, shared the impression that the more the CyPASS was exposed into the AC, the greater the endothelial cell loss. This leads to the question: Should we push the existing ones farther in? A few people on the call had experience doing that, and said it was difficult to push in farther, so they didn't advise it."

Though there haven't been any official recommendations, some surgeons are going back to the OR and trimming CyPASS stents that appear to be protruding too far, with some specifically saying you don't want more than one of the retention rings at the top of the device showing. "Right now, the guidelines of what should be trimmed are being worked out," Dr. Lewis says. He adds that the trimming procedure doesn't appear very involved. "I haven't done it yet, but I have one coming up in a few weeks," he says. "I told the patient it should just take a few minutes. The surgeon visualizes it, cuts it and is done."

Dr. Brown says he's hesitant to trim a device, though. "My own approach to something like this is, first, do no harm," he says. "I have patients who are now seven years out post-implantation who have no problems, and it makes it hard for me to do something that carries with it its own endothelial cell trauma. If you're going to trim the end of a tube, you're going to have some endothelial cell loss from that, as well. It's hard to know what to do at this point."

While surgeons await the ASCRS recommendations on the CyPASS situation, many of them say they're in mourning over a device that had a lot of potential. "I really hope it comes back," says Dr. Brown. "I think it filled a niche that was really important. It had enough efficacy to help patients who had real glaucoma damage, and you could use it at any point in the glaucoma cycle. I put it in several patients who had previously undergone tube shunts, trabeculectomy, angle surgery—basically every operation we have for glaucoma—and they did really well with the CyPASS. It had been the answer to a prayer." REVIEW



Welcome to a platform where every image is remarkably accurate. Reliably repeatable. Proven to enable confident clinical decision-making. And ready for the advanced image analytics necessary for success in a changing healthcare environment. It's a platform like none other. And now, one that's accessible for any practice.

Experience powerful images that empower you to do more for your patients and your practice. Experience Heidelberg Image Quality™.

To learn more, please call 800-931-2230 or visit HeidelbergEngineering.com.
For a live demonstration, please visit booth 2236 at AAO Chicago, October 27-30.

HEIDELBERG ENGINEERING

REVIEW Editorial Board

Contributors

CHIEF MEDICAL EDITOR
Mark H. Blecher, MD

CONTACT LENSES
Penny Asbell, MD

CORNEA / ANTERIOR SEGMENT
Thomas John, MD

GLAUCOMA MANAGEMENT
Peter Netland, MD, PHD
Kuldev Singh, MD

MEDICARE Q & A
Paul M. Larson, MBA

PEDIATRIC PATIENT
Wendy Huang, MD

PLASTIC POINTERS
Ann P. Murchison, MD, MPH

REFRACTIVE/CATARACT RUNDOWN
Arturo S. Chayet, MD

RETINAL INSIDER
Carl Regillo, MD, FACS
Emmett T. Cunningham Jr., MD, PHD, MPH

TECHNOLOGY UPDATE
Steven T. Charles, MD
Michael Colvard, MD

WILLS RESIDENT CASE SERIES
Jason Flamendorf, MD

Advisory Board

PENNY A. ASBELL, MD, NEW YORK CITY
WILLIAM I. BOND, MD, PEKIN, ILL.
ALAN N. CARLSON, MD, DURHAM, N.C.
Y. RALPH CHU, MD, EDINA, MINN.
ADAM J. COHEN, MD, DOWNERS GROVE, ILL.
UDAY DEVGAN, MD, FACS, LOS ANGELES
ERIC DONNENFELD, MD, ROCKVILLE CENTRE, N.Y.
DANIEL S. DURRIE, MD, KANSAS CITY, MO.
ROBERT EPSTEIN, MD, MCHENRY, ILL.
ROBERT D. FECHTNER, MD, NEWARK, N.J.
WILLIAM J. FISHKIND, MD, TUCSON, ARIZ.
JAMES P. GILLS, MD, TARPON SPRINGS, FLA.
HARRY GRABOW, MD, SARASOTA, FLA.
DOUGLAS K. GRAYSON, MD, NEW YORK CITY
THOMAS S. HARBIN, MD, MBA, ATLANTA
DAVID R. HARDTEN, MD, MINNEAPOLIS
KENNETH J. HOFFER, MD, SANTA MONICA, CALIF.
JACK T. HOLLADAY, MD, MSEE, HOUSTON
JOHN D. HUNKELER, MD, KANSAS CITY, MO.
THOMAS JOHN, MD, TINLEY PARK, ILL.
ROBERT M. KERSHNER, MD, MS, FACS, BOSTON
GUY M. KEZIRIAN, MD, PARADISE VALLEY, ARIZ.
TERRY KIM, MD, DURHAM, N.C.
TOMMY KORN, MD, SAN DIEGO
DAVID A. LEE, MD, HOUSTON
FRANCIS S. MAH, MD, PITTSBURGH
NICK MAMALIS, MD, SALT LAKE CITY
WILLIAM G. MARTIN, MD, OREGON, OHIO
MIKE S. MCFARLAND, MD, PINE BLUFF, ARK.
JEFFREY B. MORRIS, MD, MPH, ENCINITAS, CALIF.
MARLENE R. MOSTER, MD, PHILADELPHIA
ROBERT J. NOECKER, MD, FAIRFIELD, CONN.
ROBERT OSHER, MD, CINCINNATI
MARK PACKER, MD, BOULDER, CO.
STEPHEN PASCUCCI, MD, BONITA SPRINGS, FLA.
PAUL PENDER, MD, BEDFORD, N.H.
CHRISTOPHER J. RAPUANO, MD, PHILADELPHIA
AUGUST READER III, MD, SAN FRANCISCO
TONY REALINI, MD, MORGANTOWN, W.V.
KENNETH J. ROSENTHAL, MD, GREAT NECK, N.Y.
ERIC ROTHCHILD, MD, DELRAY BEACH, FLA.
SHERI ROWEN, MD, BALTIMORE
JAMES J. SALZ, MD, LOS ANGELES
INGRID U. SCOTT, MD, MPH, HERSHEY, PA.
JOEL SCHUMAN, MD, PITTSBURGH
GAURAV SHAH, MD, ST. LOUIS
DAVID R. STAGER JR., MD, DALLAS
KARL STONECIPHER, MD, GREENSBORO, N.C.
JAMES C. TSAI, MD, NEW YORK CITY
VANCE THOMPSON, MD, SIOUX FALLS, S.D.
FARRELL C. TYSON, MD, CAPE CORAL, FLA.
R. BRUCE WALLACE III, MD, ALEXANDRIA, LA.
ROBERT G. WILEY, MD, CLEVELAND
FRANK WEINSTOCK, MD, CANTON, OHIO

REVIEW of Ophthalmology®

BUSINESS OFFICES
11 CAMPUS BOULEVARD, SUITE 100
NEWTOWN SQUARE, PA 19073
SUBSCRIPTION INQUIRIES (877) 529-1746
(USA ONLY); OUTSIDE USA, CALL (847) 763-9630

BUSINESS STAFF
PUBLISHER
JAMES HENNE
(610) 492-1017 JHENNE@JOBSON.COM

REGIONAL SALES MANAGER
MICHELE BARRETT
(610) 492-1014 MBARRETT@JOBSON.COM

REGIONAL SALES MANAGER
MICHAEL HOSTER
(610) 492-1028 MHOSTER@JOBSON.COM

CLASSIFIED ADVERTISING
(888)-498-1460

VICE PRESIDENT OF OPERATIONS
CASEY FOSTER
(610) 492-1007 CFOSTER@JOBSON.COM

PRODUCTION MANAGER
SCOTT TOBIN
(610) 492-1011 STOBIN@JOBSON.COM

SUBSCRIPTIONS
$63 A YEAR, $99 (U.S.) IN CANADA,
$158 (U.S.) IN ALL OTHER COUNTRIES.
SUBSCRIPTIONS E-MAIL:
REVOPHTHALMOLOGY@CAMBEYWEST.COM

CIRCULATION
PO BOX 71, CONGERS, NY 10920-0071
(877) 529-1746
OUTSIDE USA: (845) 267-3065

SENIOR CIRCULATION MANAGER
HAMILTON MAHER
(212) 219-7870 hmaher@jhihealth.com

CEO, INFORMATION GROUP SERVICES
MARC FERRARA

SENIOR VICE PRESIDENT, OPERATIONS
JEFF LEVITZ

VICE PRESIDENT, HUMAN RESOURCES
TAMMY GARCIA

VICE PRESIDENT, CREATIVE SERVICES & PRODUCTION
MONICA TETTAMANZI

CORPORATE PRODUCTION DIRECTOR
JOHN ANTHONY CAGGIANO

VICE PRESIDENT, CIRCULATION
EMELDA BAREA

jmi

440 Ninth Avenue, 14th Floor
New York, N.Y. 10001

REVIEW OF OPHTHALMOLOGY (ISSN 1081-0226; USPS No. 0012-345) is published monthly, 12 times per year by Jobson Medical Information. 440 Ninth Avenue, 14th Floor, New York, N.Y. 10001. Periodicals postage paid at New York, NY and additional mailing offices. Postmaster: Send address changes to Review of Ophthalmology, PO Box 71, Congers, NY 10929-0071. Subscription Prices: US One Year $63.00, US Two Year $112.00, Canada One Year $99.00, Canada Two Year $181.00, Int'l One Year $158.00, Int'l Two Year $274.00. For subscription information call (877) 529-1746 (USA only); outside USA, call (845-267-3065. Or email us at revophthalmology@cambeywest.com. Canada Post: Publications Mail Agreement #40612608. Canada Returns to be sent to Bleuchip International, P.O. Box 25542, London, ON N6C 6B2.

The New DGH Technology SCANMATE FLEX

Enhance your practice's diagnostic capabilities with a portable, ophthalmic ultrasound platform. The Scanmate Flex, with USB interface to a Windows PC, provides any desired combination of A-Scan, B-Scan and UBM.

A-SCAN PROBE FOR AXIAL LENGTH MEASUREMENTS

Periodic axial length measurements have been identified as an essential procedure for monitoring the effectiveness of any myopia control program. The Scanmate Flex utilizes unique alignment and compression detection algorithms which provide audible feedback to the user. These exclusive features give real-time guidance for optimizing alignment and minimizing compression. You can be confident that your axial length measurements will be consistent, accurate and reliable.

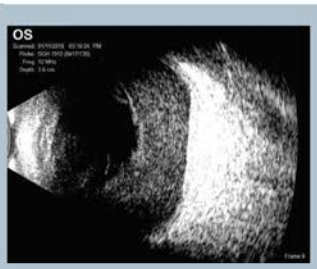
B-SCAN PROBE FOR IMAGES OF THE POSTERIOR SEGMENT OF THE EYE

This redesigned probe, new with the Flex, provides the best image quality and reliability available in a B-scan. The Flex B-scan provides class-leading images of the retina, even through opacities such as dense cataracts and blood that optical tools can't penetrate.

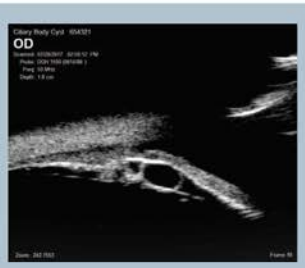
UBM PROBE FOR IMAGES OF THE ANTERIOR SEGMENT OF THE EYE

The UBM probe provides imagery of the anterior segment of the eye, including features behind the iris that optical devices can't see. This is particularly useful in diagnosing plateau iris and other pathologies hidden by the iris.

Scanmate Flex A-scan, showing the Flex user interface. The basic interface is the same for all three probe types.



Visualizing vitreous hemorrhaging with the Scanmate Flex B-Scan probe.



Visualizing ciliary cysts with the Scanmate Flex UBM probe.

Use of Scanmate Flex UBM probe for angle measurement.

Visit us at AAO 2018 Booth 2204

Contact us to learn how the Scanmate Flex can be customized to fit your practice's needs at an attractive price.

(800) 722-3883 • www.dghtechnology.com

DGH TECHNOLOGY, INC.

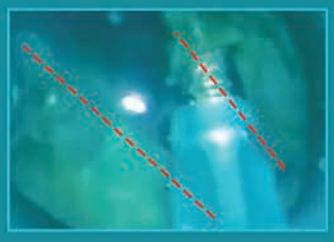
THE ULTRASOUND SPECIALIST

Serving Eye Care Professionals since 1982

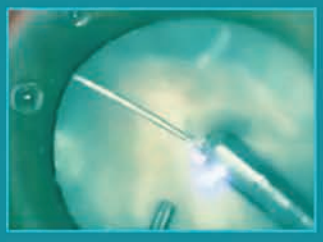
All DGH products are made in the USA.

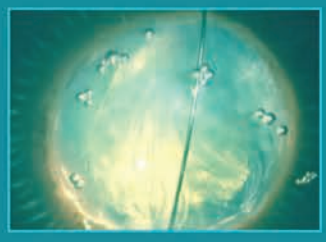
Keep the Zonules Intact!

Dissection Technique



Phaco





miLOOP

Preserving the Natural Lens Support System is Key to Improving Refractive Outcomes

Come hear an expert panel discuss how enhancing the ability to predict Effective Lens Position leads to increased confidence in recommending specialty IOLs for cataract surgery.

Try miLOOP at AAO
via private lab session

Join our Webinars
2018 Fall series

iantechmed.com

ianTECH

REVIEW® of Ophthalmology

October 2018 • Volume XXV No. 10 | reviewofophthalmology.com

Cover Story

36 | **MIPS & Ophthalmology: 12 Questions Answered**
Christopher Kent, Senior Editor
Update on the current CMS plan.

Feature Articles

48 | **Anterior Segment Surgery and Herpes**
Walter Bethke, Editor in Chief
Corneal experts break down the issues.

54 | **How to Manage Dislocated IOLs**
Michelle Stephenson, Contributing Editor
Treatment depends on the location of the IOL.

62 | **Ergonomics: How Not to Sacrifice Your Body**
Liam Jordan, Associate Editor
How to keep practicing painlessly.

68 | **Solo Practice: Can You (Still) Go it Alone?**
Kristine Brennan, Senior Associate Editor
Can solo practices thrive as PE and consolidation gather momentum?

75 | **Point/Counterpoint: Intracameral Vancomycin is Not Warranted for Cataract Surgery**
A good choice for endophthalmitis prevention?
Point: Harry W. Flynn Jr., MD; Anthony D. Anderson, PharmD, BCPS, and Stephen G. Schwartz, MD, MBA / Counterpoint: Richard Mackool, MD, and Paul Ernest, MD

80 | **Astigmatism: How Low Can You Go?**
Kristine Brennan, Senior Associate Editor
The drive to zero astigmatism in cataract surgery.

Departments

4 | Review News

14 | Editor's Page
Artificial Stupidity

17 | Letters to the Editor
Another Take on IOLs in the Sulcus

20 | Medicare Q & A
Financial Waivers: Using the ABN
What do when a service isn't covered.

26 | Refractive/Cataract Rundown
Malpractice: Minimizing Your Exposure
How to protect yourself, and what to do if something goes wrong.

90 | Retinal Insider
Regenerative Medicine: Science Fact
The possible future of cell replacement and regeneration.

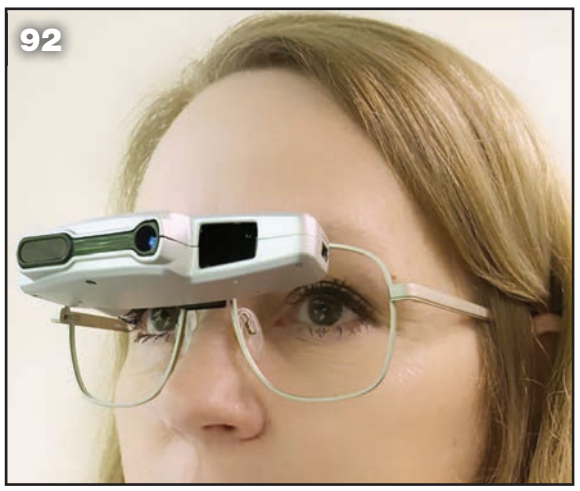
92 | Product News

94 | Research Review

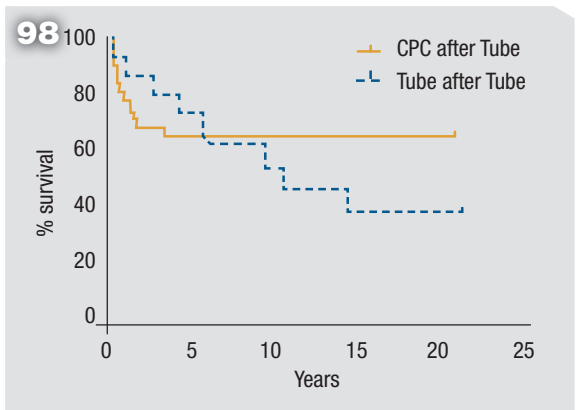
98 | Glaucoma Management
A Tube Shunt Fails: What's Next?
Choosing the next step when published evidence is minimal.

102 | Advertiser Index

103 | Wills Eye Resident Case Series



Second Treatment: Survival of Tube vs. CPC



AAO 2018 | MEET THE EXPERTS

Johnson & Johnson VISION

Brilliance BAR

Reserve a private session with a Brilliance Bar expert, and get answers to your most pressing surgical questions.

Leave armed with brilliant solutions to questions such as:

- How can you make your premium IOL patients' outcomes better?
- What phaco style is right for your technique?
- Should you incorporate laser surgery in your practice?
- How can you best optimize the ocular surface before surgery?

SATURDAY, OCTOBER 27			
10AM – 11AM	Zaina Al-Mohtaseb, MD Robert Maloney, MD	Preeya Gupta, MD	Ehsan Sadri, MD
11AM – 12PM	Elizabeth Davis, MD	Cynthia Matossian, MD	William Trattler, MD
12PM – 1PM	Rex Hamilton, MD	Paul Kang, MD	Devesh Varma, MD
1PM – 2PM	Daniel Chang, MD	Steven Dewey, MD	Sam Garg, MD
2PM – 3PM	Mark Blecher, MD	Nicole Fram, MD	Pulin Shah, MD

SUNDAY, OCTOBER 28			
10AM – 11AM	Christopher Blanton, MD	William Culbertson, MD	Blake Williamson, MD
11AM – 12PM	Sandy Feldman, MD Marc Odrich, MD	Dave Hardten, MD	Colman Kraff, MD
12PM – 1PM	Mark Kontos, MD	Ernesto Otero, MD	Michael Shapiro, MD
1PM – 2PM	Kendall Donaldson, MD	Francis Mah, MD	Laura Periman, MD
2PM – 3PM	Eva Liang, MD	Tal Raviv, MD	Gustavo Tamayo, MD

Reserve your private session with an expert at our AAO Brilliance Bar

WWW.BRILLIANCEBAR.COM

MORE *brilliant* TOGETHER #3708

While you're at AAO, visit our Speakers' Forum to hear expert booth talks

SAT & SUN | 10AM – 3PM | BOOTH #3708

REVIEW® of Ophthalmology

Artificial Stupidity

We're constantly bombarded with tales about the awesome power of computers to change our lives.

In 2016, at the University of Tokyo, IBM's resident artificial intelligence, Watson, accurately diagnosed a rare form of leukemia in a 60-year-old woman whose case had stumped the hospital's human experts for months. After just 10 minutes of perusing 20 million articles, Watson clinched the diagnosis. Treatment was started and the woman's cancer responded to it.[1]

In a similar vein, the government has been quick to embrace the power of computers in clinical and surgical practice, and has decreed that physicians should get on board with electronic health records or start suffering monetary penalties. This mandate, originally called "meaningful use" but now known as "Advancing Care Information" within the Merit-based Incentive Payment system, is touted as improving health care in several dimensions, such as quality, safety and efficiency, as well as improving care coordination and public health.[2]

So, imagine ophthalmologists' surprise three years ago when they learned about one particular aspect of the quality-based payment program at the time, as described by Chris Kent in this issue's cover story on MIPS:

"One problem that unfairly affected ophthalmologists in the past—especially retina specialists—is a thing called attribution," Jeff Grant [of HealthCare Management & Automation Systems] explains. "... Patients were 'attributed' to a particular doctor, based on factors such as how frequently the doctor was seeing the patient and whether the doctor was billing using evaluation and management codes. If you saw a patient often and used those codes—which retina specialists often do—then any Medicare charges associated with that patient were attributed to that doctor ... A retina patient might go to the hospital and have $20,000 worth of gastrointestinal surgery. Under this system, this cost was attributed to the retina specialist."

To be fair, attribution is just one boneheaded aspect of a system that ophthalmologists seem to be succeeding in overall. Also, Mr. Grant explains that, this year, efforts have been made to correct this glaring problem—though the results of the solution haven't been seen yet—but that still means it took three years to get a high-tech system to display a modicum of common sense.

Since the government likes to dole out penalties to get results, maybe penalties can work the other way too: Under a new system, let's call it the Watchdog Incorrect Payment System or WIPS, every time a physician gets the cost of a procedure wrongly attributed to him, the government will pay him 2 percent of what was billed.

A few months of this, and I bet the government's computer would get real smart, real fast.

—Walt Bethke, Editor in Chief

1. Feldman M. Watson proving better than doctors at diagnosing cancer. Available at https://www.top500.org/news/watson-proving-better-than-doctors-in-diagnosing-cancer/. Accessed 21 September 2018.
2. MIPS builds on meaningful use. Available at https://www.healthit.gov/topic/federal-incentive-programs/meaningful-use. Accessed 21 September 2018.

POWER TO PREVAIL

As demonstrated in phase 3 clinical trials evaluating BCVA,* as measured by ETDRS letters, in patients with Wet AMD, Macular Edema following RVO, DME, and by ETDRS-DRSS† in DR in Patients with DME,[1] as well as your clinical experience

Start with EYLEA for proven efficacy outcomes[1]

AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema;
DR = Diabetic Retinopathy; RVO = Retinal Vein Occlusion.

Dosing driving efficacy outcomes across all indications.[1]
Learn more at EYLEA.us/dose

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with

- Neovascular (Wet) Age-related Macular Degeneration (AMD): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months).
- Macular Edema following Retinal Vein Occlusion (RVO): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly).
- Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in Patients with DME: The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections, followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).

CONTRAINDICATIONS

- EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

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

Please see adjacent Brief Summary.

*Best-corrected visual acuity.
†Early Treatment Diabetic Retinopathy Study–Diabetic Retinopathy Severity Scale: an established grading scale for measuring the severity of DR.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. May 2017.

REGENERON

777 Old Saw Mill River Road, Tarrytown, NY 10591

10/2017
US-LEA-13945

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY—Please see the EYLEA package insert for full Prescribing Information.

1 INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of:

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

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see Dosage and Administration (2.7) and Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.7)*].

5.3 Thromboembolic Events. There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [*see Contraindications (4.3)*]
- Endophthalmitis and retinal detachments [*see Warnings and Precautions (5.1)*]
- Increase in intraocular pressure [*see Warnings and Precautions (5.2)*]
- Thromboembolic events [*see Warnings and Precautions (5.3)*]

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

A total of 2711 patients treated with EYLEA constituted the safety population in seven phase 3 studies. Among those, 2110 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

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

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

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

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, and endophthalmitis.

Macular Edema Following Retinal Vein Occlusion (RVO). The data described below reflect 6 months exposure to EYLEA with a monthly 2 mg dose in 218 patients following CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following BRVO in one clinical study (VIBRANT).

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

Adverse Reactions	CRVO		BRVO	
	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival hemorrhage	12%	11%	20%	4%
Intraocular pressure increased	8%	6%	2%	0%
Corneal epithelium defect	5%	4%	2%	0%
Vitreous floaters	5%	1%	1%	0%
Ocular hyperemia	5%	3%	2%	2%
Foreign body sensation in eyes	3%	5%	3%	0%
Vitreous detachment	3%	4%	2%	0%
Lacrimation increased	3%	4%	3%	0%
Injection site pain	3%	1%	1%	0%
Vision blurred	1%	<1%	1%	1%
Intraocular inflammation	1%	1%	0%	0%
Cataract	<1%	1%	5%	0%
Eyelid edema	<1%	1%	1%	0%

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

Diabetic Macular Edema (DME). The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 100	
	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium defect	5%	3%	7%	5%
Intraocular pressure increased	5%	3%	9%	5%
Ocular hyperemia	5%	6%	5%	6%
Vitreous detachment	3%	3%	8%	6%
Foreign body sensation in eyes	3%	3%	3%	3%
Lacrimation increased	3%	2%	4%	2%
Vision blurred	2%	2%	3%	4%
Intraocular inflammation	2%	<1%	3%	1%
Injection site pain	2%	<1%	2%	<1%
Eyelid edema	<1%	1%	2%	1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.

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

In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [*see Clinical Pharmacology (12.1)*], treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg.

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

8.2 Lactation

Risk Summary

There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 3 months after the last intravitreal injection of EYLEA.

Infertility

There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [*see Nonclinical Toxicology (13.1)*].

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

8.5 Geriatric Use. In the clinical studies, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

17 PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [*see Warnings and Precautions (5.1)*].

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

Issue Date: June 2017
Initial U.S. Approval: 2011

Based on the May 2017 EYLEA® (aflibercept) Injection full Prescribing Information.

REGENERON

Another Take on IOLs in the Sulcus

To the Editor:

I enjoyed reading the article, "The IOL in the Sulcus, When, Why & How," (July 2018) on sulcus placement of IOLs, and I'd like to contribute my take on this.

Sulcus placement is usually necessitated due to zonular instability or a capsular break, and I agree that a three-piece lens is mandatory when a sulcus placement is being contemplated. These lenses are 13 mm in length with a 10-degree forward angulation of the haptics.

In the early days of intraocular lenses, before in-the-bag implantation was emphasized, these lenses were widely used in routine cases, and were incredibly versatile, since they could be placed in the bag, in the sulcus, or at times (inadvertently) with one haptic in the bag and the other in the sulcus, all with reasonably good results.

In my experience, if I have a central posterior capsular break with an intact anterior capsular bag and an intact peripheral posterior capsular bag, I'm often able to place the Alcon MA30AC three-piece lens in the bag, rather than resorting to a sulcus-placement-with-optic-capture approach.

To implant the lens in this manner, I first place Provisc (sodium hyaluronate) to deepen the anterior chamber and bag and push back the intact or broken vitreous face. A Kuglen hook is useful for retracting the iris to make sure the peripheral posterior bag is intact 360 degrees or close to it. (If the posterior capsular bag is intact in some areas but absent in others, then caution should be the order of the day: Sulcus implantation is indicated.) After confirming the intact bag, I'll open the wound to 6 mm, preserving the same wound architecture that was used to make the initial 2.7-mm incision. I am averse to folding the lens in this scenario; I would rather make a larger incision and place the three-piece lens unfolded. This does add time to the case, and several sutures are needed to close the incision at the conclusion of the case.

The leading haptic then glides in underneath the anterior capsular flap, if possible, with the superior haptic rotated clockwise (as close to its junction with the optic as possible) with a Sinskey or Lester Hook, in order to "pop" the trailing haptic in.

Alternatively, a McPherson or microsurgical forceps (MST Techology) can be used to grab the haptic and bend it inferiorly and then release it underneath the capsular flap edge. Even with an open central posterior capsule, these maneuvers can be done without extending the capsular tear or causing the vitreous to move forward.

If the IOL can't be placed directly in the bag, but lands instead in the anterior chamber, one can manipulate it intracamerally to obtain in-the-bag positioning of both haptics. This is more apt to occur if the corneal incision is tight (slightly less than 6 mm), or if you choose to introduce the lens folded into the chamber.

If you attempt this in-the-bag placement but see a downward drift in the lens towards the vitreous, this means that you are anterior to the bag and that the peripheral posterior capsule-zonular complex where the haptic is being placed is not intact. Through your limbal incision, pop the optic in front of the anterior capsule and position the IOL haptics in the sulcus where the posterior capsular zonular complex is still intact (it must be intact both where the first haptic is being placed and 180 degrees away).

Keep in mind that the optic will generally remain well-centered if both haptics are properly positioned, even if you are unable to capture the optic behind the anterior capsular bag.

Wherever you decide to position the intraocular lens, be mindful of the effective lens position and adjust your lens power accordingly.

Lawrence Stone, MD
Chicago

Less stress. Pure success.

References: 1. Silverstein SM, Rana V, Stephens R, Segars L, Pankratz J, Shivani R, et al. Effect of phenylephrine 1.0%-ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg.* 2018;44(9):1103-1108. **2.** Rosenberg ED, Nattis AS, Alevi D, et al. Visual outcomes, efficacy, and surgical complications associated with intracameral phenylephrine 1.0%/ketorolac 0.3% administered during cataract surgery. *Clin Ophthalmol.* 2018;12:21-28. **3.** Bucci FA Jr, Michalek B, Fluet AT. Comparison of the frequency of use of a pupil expansion device with and without an intracameral phenylephrine and ketorolac injection 1%/0.3% at the time of routine cataract surgery. *Clin Ophthalmol.* 2017;11:1039-1043. **4.** Visco D. Effect of phenylephrine/ketorolac on iris fixation ring use and surgical times in patients at risk of intraoperative miosis. *Clin Ophthalmol.* 2018;12:301-305. **5.** Walter K, Delwadia N. Miosis prevention in femtosecond cataract surgery using a continuous infusion of phenylephrine and ketorolac. Presented at: 2018 American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) Annual Meeting; April 13-17, 2018; Washington, DC. **6.** Matossian C. Clinical outcomes of phenylephrine/ketorolac vs. epinephrine in cataract surgery in a real-world setting. Presented at: American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) Annual Meeting; April 13-17, 2018; Washington, DC. **7.** Al-Hashimi S, Donaldson K, Davidson R, et al. Medical and surgical management of the small pupil during cataract surgery. *J Cataract Refract Surg.* 2018;44:1032-1041. **8.** Gayton JL. E-poster presented at: 15th International Congress on Vision Science and Eye; 2017 Aug 10-11; London, UK. **9.** Katsev DA, Katsev CC, Pinnow J, Lockhart CM. Intracameral ketorolac concentration at the beginning and end of cataract surgery following preoperative topical ketorolac administration. *Clin Ophthalmol.* 2017;11:1897-1901. **10.** Waterbury LD. Alternative drug delivery for patients undergoing cataract surgery as demonstrated in a canine model. *J Ocul Pharmacol Ther.* 2018;34:154-160.

Visit us at AAO Booth 3772

OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

The data are compelling and consistent—OMIDRIA makes cataract surgery better for you and your patients

Published and presented clinical studies report that in post-launch (i.e., not included in current labeling), prospective and retrospective, double-masked and open-label, cohort and case-controlled, single- and multi-center analyses, the use of OMIDRIA, compared to the surgeons' standard of care, statistically significantly:

- Prevents Intraoperative Floppy Iris Syndrome (IFIS)[1]
- Reduces complication rates (epinephrine comparator)[2]
- Decreases use of pupil-expanding devices (epinephrine comparator)[2-7]
- Reduces surgical times (epinephrine comparator)[2,4,6,7]
- Prevents miosis during femtosecond laser-assisted surgery (epinephrine comparator)[5,8]
- Improves uncorrected visual acuity on day after surgery (epinephrine comparator)[2]
- Delivers NSAID to the anterior chamber and related structures better than routine preoperative topical drug administration, resulting in effectively complete postoperative inhibition of COX-1 and COX-2[9,10]

Separately reimbursed under Medicare Part B

Contact your OMIDRIA representative today or visit omidria.com to learn more

IMPORTANT SAFETY INFORMATION

OMIDRIA must be added to irrigating solution prior to intraocular use.

OMIDRIA is contraindicated in patients with a known hypersensitivity to any of its ingredients.

Systemic exposure of phenylephrine may cause elevations in blood pressure.

Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory drugs (NSAIDs), or have a past medical history of asthma.

The most commonly reported adverse reactions at ≥ 2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Please see the Full Prescribing Information for OMIDRIA at www.omidria.com/prescribinginformation.

You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

OMIDRIA®

(phenylephrine and ketorolac intraocular solution) 1% / 0.3%

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

Financial Waivers: Using the ABN

How to proceed when a patient needs a service that's not covered by Medicare and/or other insurance.

Some of the things ophthalmologists do for the benefit of their patients might not be covered by insurance. For Medicare Part B, the most commonly noncovered services are those that are: 1) refractive; 2) cosmetic; 3) screening; and 4) "routine" eye exams. Issuing a Medicare financial Advance Beneficiary Notice of Noncoverage in these situations is not required, although it's allowed.

How we document notices of noncoverage (other than telling patients verbally, "Your insurance doesn't cover it.") can be crucial when the payer is Medicare Part B. For other payers—including Medicare Part C, or Medicare Advantage—the principles are the same. It's often preferable, and sometimes mandatory, for us to issue one of these waivers as a way to document the conversation and obtain a signature. For Part B Medicare, the ABN is the proper form.

The Centers for Medicare & Medicaid (CMS) notes the following: "The Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, is issued by providers … physicians, practitioners, and suppliers to Original Medicare … beneficiaries in situations where Medicare payment is expected to be denied. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances." Guidelines for issuing an ABN properly are published by CMS, and can be found in the Medicare Claims Processing Manual.

Figure 1. Explaining Why Medicare Won't Pay

NOTE: If Medicare doesn't pay for the items or services below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the items or services below.

Items or Services	Reason Medicare May Not Pay:	Estimated Cost:
Screening diagnostic testing	The Medicare law, Social Security Act §1862(a)(1)(A), does not cover any service for screening that is not required by medical necessity "…for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."	$_____

Q When is an ABN required?

A When coverage for the service is uncertain (such that you can't determine in advance whether or not the beneficiary may be responsible for payment), issuance of the ABN is required. Some of the more common situations for this are when a test would potentially be covered but it's done in advance of an order for it (defined in that case as a screening), when an eligible diagnosis isn't present, and for durable medical equipment (DME) noncovered items purchased at the same time as DME-covered items.

If you're required to issue one but don't, without proof of the beneficiary's advance acceptance of financial responsibility, your office could be required to refund any payment from the beneficiary and can't pursue him for payment related to these services.

Q When is an ABN prohibited?

This article has no commercial sponsorship.

CENTURION® SURGEONS COMMAND THE OR

Surgeons everywhere have taken command of their procedures with the Centurion® Vision System. **Thank you for partnering with us to remove more than 2 million cataracts every year.**

Alcon A Novartis Division

Centurion® VISION SYSTEM

A You can't issue an ABN to circumvent National Correct Coding Initiative edits/bundles. It's also prohibited to abrogate assignment under your participation agreement with Medicare, and to use an ABN on a "universal" basis (the "blanket" ABN) when it's non-specific. Of course, issuing an ABN after-the-fact is also clearly improper.

Q Can I issue an ABN voluntarily?

A Yes. In some cases, such as when the service to be provided to the patient is relatively expensive, issuing an advance beneficiary notice is a good idea in order to be transparent in advance and to help address the patient's potential to experience "buyer's remorse" later on. CMS notes: "When the ABN is used as a voluntary notice, the beneficiary doesn't [need to] choose an option box or sign the notice."

Q What's the most current version of the ABN form?

A CMS gives this form the number CMS-R-131; the June 21, 2017 version is the most current one and you can see the "03/2020" version date at the bottom of the correct form. Importantly, older versions of the ABN are considered invalid if used now, so make sure that all old ones get destroyed so that they don't reappear later in your clinic.

Q Can I modify the three ABN choices the patient selects from? It doesn't seem to have "patient-friendly" language.

A While there are some things you can change (adding your name and logo, the particulars of what you are presenting, etc.), changing the three options' actual language is strictly prohibited. As a reminder, those three options are:

- Option 1. I want the _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment … I can appeal to Medicare …
- Option 2. I want the _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal to Medicare …
- Option 3. I don't want the _____ listed above. I understand with this choice I am not responsible for payment … I cannot appeal to Medicare …

If the beneficiary chooses Option 1, you must file a claim and append an appropriate modifier to the reported item(s) or service(s). Option 2 applies to situations where Medicare is precluded from paying for the item or service and the beneficiary does not dispute the point; you aren't required to file a claim. If the beneficiary chooses Option 3, there is no claim to file or charge to make; the service isn't provided because he said he doesn't want it.

Q How much information do I have to put into the boxes to explain why Medicare might not pay on the ABN form?

A For the answer, see the sample information in Figure 1 on p. 20.

Q Are there other requirements for an ABN?

A Yes. In addition to citing the relevant citation as noted above, an ABN must be one-page, single-sided, on

(*Continued on p. 105*)

iStent *inject*®

TRANSFORMING MIGS IN MORE WAYS THAN ONE.

Optimized Outflow: Two multi-directional stents designed to restore natural outflow

Clinically Proven: Significant IOP reduction across a wide range of clinical studies[1,2]

Procedural Elegance: Predictability and precision to meet the needs of your practice

Proven Safety: Safety profile similar to cataract surgery alone[1]

AAO BOOTH 1345

All with the exceptional customer support you've come to expect from Glaukos.

TransformMIGS.com | 800.GLAUKOS (452.8567)

INDICATION FOR USE. The iStent *inject*® Trabecular Micro-Bypass System Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma. **CONTRAINDICATIONS.** The iStent *inject* is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. **MRI INFORMATION.** The iStent *inject* is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent *inject* have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents. **ADVERSE EVENTS.** Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent *inject* vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). **CAUTION:** Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

REFERENCES: 1. iStent *inject*® Trabecular Micro-Bypass System: Directions for Use, Part #45-0176. **2.** Hengerer FH. Personal experience with second-generation trabecular micro-bypass stents in combination with cataract surgery in patients with glaucoma: 3-year follow-up. ASCRS 2018 Presentation.

GLAUKOS®
Transforming Glaucoma Therapy

Passionate About...

PATIENT CARE
Tono-Pen® Handheld Tonometers with **Ocu-Film® Tip Covers**,
trusted by clinicians for over 30 years.

IMPROVING GLAUCOMA CARE
Ocular Response Analyzer® G3 with **Corneal Hysteresis** + **IOPcc**,
a more objective predictor of glaucoma progression.

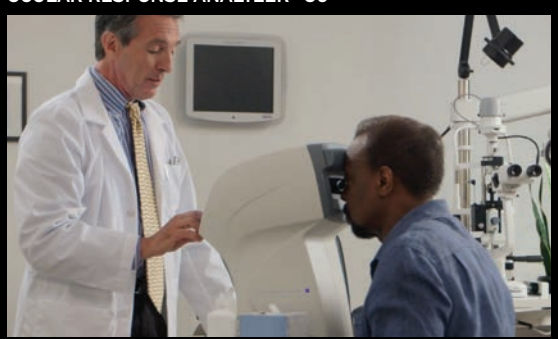
PATIENT EXPERIENCE
Digital and traditional refraction solutions for every practice,
featuring **Phoroptor® VRx**, the most advanced Phoroptor®.

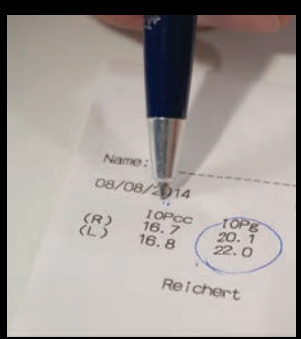
SEE AMERICAN INNOVATION AT AAO #3726

Reichert® TECHNOLOGIES
AMETEK®

reichert.com/aao

OCULAR RESPONSE ANALYZER® G3





Malpractice: Minimizing Your Exposure

Routine communication matters, but so does the human touch when things go wrong.

Kristine Brennan, Senior Associate Editor

A recent retrospective review in *Ophthalmology* examined 10 years of closed medical professional liability claims (90,743 total) against ophthalmologists and other specialties, and found that just 2.6 percent (2,325) of closed claims and 2.2 percent of paid claims (564/24,670) were filed against ophthalmologists. Ninety percent of ophthalmic liability claims that received verdicts were favorable to the ophthalmologist.[1] Cataract and corneal surgeries were the most prevalent and costly claims.

Another review looked at 159 litigated cornea and refractive surgery cases from 1964 to 2014. Ninety-three of these (58.5 percent) went to jury trials; 21.5 percent of the trials yielded plaintiff verdicts with a mean adjusted jury award of $588,896. Another 11.9 percent of those jury trials ended in settlements with a median adjusted indemnity of $782,533.[2] Below, a medical malpractice defense attorney who has represented ophthalmologists for nearly 30 years and an ophthalmologist who's run the malpractice gauntlet share their insights.

"You can talk to any doctor about what it feels like to be sued, and they will tell you it's a horrible experience that weighs on them every single minute of the day," says C. Gregory Tiemeier, Esq., of Tiemeier & Stich in Denver. Evidence that ophthalmologists incur a smaller share of med mal claims than many other medical specialties is cold comfort if you find yourself on the wrong side of that data. "The fact that you've been sued means that you've already lost," he observes.

"I still remember it like it was yesterday," says an ophthalmologist practicing on the East coast, recalling a wrong-IOL lawsuit brought by a patient several years ago. Despite a quick and favorable jury verdict, he says, "You never shake it off; you're always thinking about it in the back of your mind."

The Journal of Health Care Law and Policy cites a 1994 study of Florida physicians by Randall R. Bovbjerg and Kenneth R. Petronis which suggested that simply being sued—regardless of outcome—was associated with doubled odds of a subsequent claim.[3] A 2003 review of Ophthalmic Mutual Insurance Company LASIK- and PRK-related claims and suits found that a history of a prior claim or suit was second only to high surgical volume among the risk factors for future malpractice claims or lawsuits.[4]

As if that's not sobering enough, Mr. Tiemeier says that in his experience in Colorado, competitors will exploit a fellow ophthalmologist's misfortune for their potential gain. "You'll lose standing in your community because all the other doctors will know you've been sued. Colorado is really a hotbed of this because of we're one of the highest-penetration markets for LASIK and refractive surgery in the country. I see this more in ophthalmology than in any other medical specialty. Doctors will almost go out of their way to criticize the competition."

Changing Times

Despite his practice area's busy refractive-surgery market, Mr. Tiemeier says that anecdotally, he believes improvements in corneal topography and biometry have led to decreased malpractice claims arising from cataract and refractive procedures. "I really haven't had an ectasia case in over 10 years,"

PRESERVATIVE FREE • 100% PF • ZIOPTAN • COSOPT PF

100% PRESERVATIVE FREE

If you're attending
AAO 2018, visit us at

AKORN BOOTH #3700

ZIOPTAN®
(tafluprost ophthalmic solution) 0.0015%

www.ZIOPTAN.com

Cosopt PF
(dorzolamide HCl - timolol maleate ophthalmic solution) 2% / 0.5%

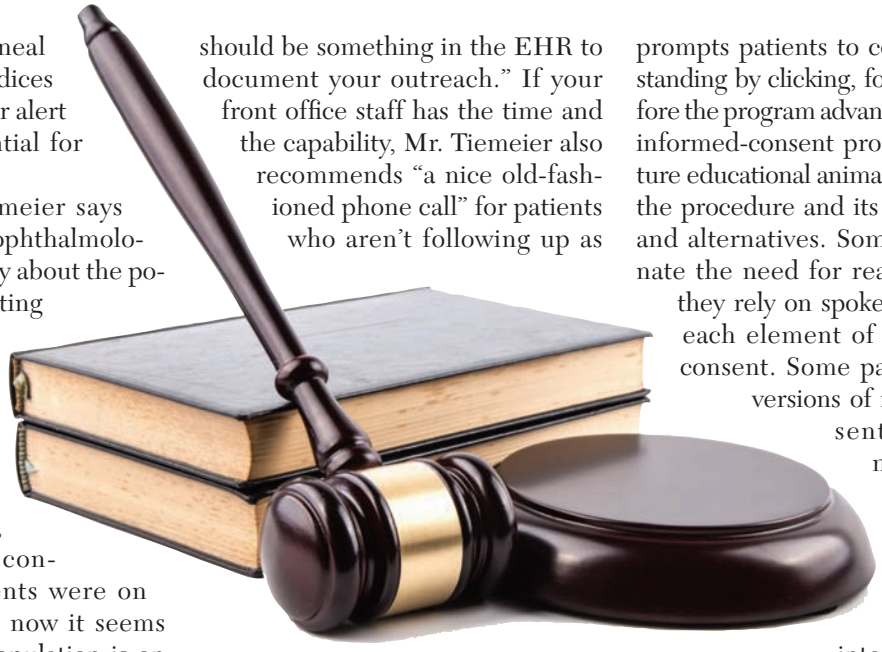
www.CosoptPF.com

he notes, "since corneal topographers have indices on them now to better alert doctors to the potential for ectasia."

Although Mr. Tiemeier says he used to counsel ophthalmologists more strenuously about the potential risks of operating on patients with a prior medical history of depression or anxiety, he now finds that advice less practical. "A long time ago, I told surgeons to consider whether patients were on antidepressants, but now it seems as though half the population is on similar medications, so that would eliminate too many patients," he says. He does, however, still warn surgeons to proceed cautiously with certain patients, including fellow doctors, lawyers, engineers and airline pilots. "They tend to have personality types prone to dissatisfaction with an objectively reasonable result," he opines.

There is some evidence supporting a relationship between preoperative mental health and satisfaction with the visual outcome of refractive surgery. Mr. Tiemeier cites a prospective study of active-duty military patients undergoing bilateral LASIK where preop levels of depression were positively correlated with dissatisfaction with visual quality at one and six months post surgery.[5]

Another behavioral factor that could lead to trouble is patient noncompliance. To protect against the possibility that a noncompliant patient may later allege that you abandoned them, Mr. Tiemeier urges ophthalmologists to keep at least a virtual paper trail. "Send them an email," he says of follow-up for no-shows. "Send reminders. There should be something in the EHR to document your outreach." If your front office staff has the time and the capability, Mr. Tiemeier also recommends "a nice old-fashioned phone call" for patients who aren't following up as recommended. The content of your office's phone messages and call-log notations must be specific, he says, using the example of glaucoma to illustrate. "When you call patients, don't just say something like, 'It's important to see your doctor,' he says. "Tell them instead, 'You have glaucoma: This can lead to sudden and irreversible vision loss and perhaps blindness if you don't continue to follow up and take your eye drops.' You need to make sure the patient understands the possible consequences of not coming in," he stresses, adding that your staff should log the substance of their messages whenever they leave voicemails for the patient.



Informed Consent

Informed consent is more than a piece of paper bearing the patient's signature. Ideally, the executed form commemorates the completion of a process during which the surgeon answers any questions the patient may have. Some surgeons stick with a traditional paper informed-consent form, while others find greater peace of mind in interactive electronic informed-consent software that prompts patients to confirm understanding by clicking, for instance, before the program advances. Electronic informed-consent products can feature educational animations depicting the procedure and its risks, benefits and alternatives. Some even eliminate the need for reading because they rely on spoken narration of each element of the informed consent. Some patients find e-versions of informed-consent documents more engaging and easier to understand, although others may feel uneasy interacting with a computer program or have concerns about privacy.[6] OMIC has a document bank of sample consent forms at omic.com/risk-management/consent-forms/, although you should consider your own practice's needs in adapting the language of any informed-consent template.

Whether your consent documents are digital or paper, Mr. Tiemeier recommends that you introduce them to the patient prior to the day of surgery. "Something that I see commonly in LASIK centers is that the surgeon doesn't see the patient until the day of surgery," Mr. Tiemeier says. "Although technically you can do that, I've never considered it a good idea. Whenever I see a lawsuit, this is one of the details that the patient is most concerned with. They'll testify, 'I didn't even see the doctor until the day of surgery, and the conversation consisted of, "Do you have any questions for me about the surgery?"and, "Did you read the consent form?" ' " Since the patient did review the consent form and the risks are written on it, the doctor has technically met their obligation to the patient. Can I defend it in the courtroom? Yes, but the doctor doesn't want to be in that

Visit Katena in Booth 1020 at AAO 2018

Extraordinary view - Great price!

Diamond series ophthalmic lenses

Exceptional optics

- Anti-reflective coating
- Low distortion & high resolution
- Superior small pupil performance

Ergonomic, durable design

- Lightweight construction
- “Sure Grip” handling ring
- Evaporated diamond hard coating (scratch resistance)

NEW!

Contact lenses: $150.00 *per lens*

Diagnostic lenses

K31-1002
3 mirror*

K31-1005
4 mirror*

Diagnostic & laser lens (PRP)

K31-1330
Retina 200

Bi-aspheric non-contact lenses: $125.00 *per lens*

Diagnostic lenses (slit lamp)

K31-2360
60D

K31-2355
78D

K31-2350
90D

Diagnostic & laser lenses

K31-2370
20D

K31-2365
28D

*3 mirror and 4 mirror lenses do not require anti-reflective or evaporated diamond coatings

katena
DESIGNED FOR SIGHT®

800-225-1195 • www.katena.com

KL-Adv-080218A-Rev 0

courtroom in the first place."

Mr. Tiemeier adds that because your informed-consent process will be scrutinized in the event of a claim, you should allow your patients time to review your informed-consent documents prior to the day of surgery whenever possible. That way, they won't be able to claim that they felt unduly pressured to sign at the ASC because the surgeon and staff were waiting; nor can they claim that any preoperative medications diminished their capacity to give informed consent. It may be worthwhile to send patients home with informed-consent documents and educational materials after talking with them about the proposed procedure during a preoperative visit, and then asking them if they have any more questions on the day of surgery. Document these discussions as specifically as possible: Record the questions asked and answered, rather than making a blanket statement that you answered the patients' questions.

"Although there is a high probability of successful outcomes for keratorefractive surgery, care should be taken to emphasize potential adverse events or complications that may occur and explain which may be transient and which may be permanent," reads the American Academy of Ophthalmology's preferred practice pattern for refractive errors and refractive surgery.[7] "The patient should be informed of the potential risks, benefits, and alternatives to and among the different refractive procedures before surgery. The informed-consent process should be documented, and the patient should be given an opportunity to have all questions answered before surgery. The surgeon is responsible for ensuring the patient's informed consent." The PPP goes on to enumerate possible risks and precautions.

Mr. Tiemeier says that a comprehensive informed-consent process is a matter of enumerating as many risks as possible within the limits of economic feasibility. "The answer is, the more you can do, the better," he explains. "There is no bright line where if you do this, you'll win; and if you don't, you'll lose. But as a businessman or businesswoman, you need to understand that it comes down to how much risk you're willing to take for the return you're going to get. In a lot of high-volume LASIK centers, patients are not going to see the surgeon until they're literally in the operating room minutes before the surgery. It's a very economical and efficient way of doing things, but it carries with it the risk of patient dissatisfaction if there's a bad outcome. That's why, with respect to the preoperative informed consent, more is better. You figure out where on that scale you can economically draw the line. The ideal would be to spend two or three hours with each patient, discussing every single aspect of LASIK and complications, for example. But you're never going to be able to stay in business if you do that," he acknowledges.

However you choose to approach your informed-consent process, you are ultimately responsible for ensuring it—not techs, not nurses and not preoperative counselors. There's legal precedent at the state level to back up this idea: a 2017 Pennsylvania Supreme Court decision (*Shinal v. Toms*, 2017 WL 2655387 (Pa. June 20, 2017) holds that ensuring informed consent is the "nondelegable" duty of the treating physician alone. Although *Shinal* is only binding in Pennsylvania, it could be persuasive in other jurisdictions.

If the Worst Happens

Some of the more memorable cases Mr. Tiemeier has defended include one that arose from a surgeon suffering a seizure while performing surgery. "I had another one where the anesthesiologist let the patient get too light during a corneal transplant. The patient woke up and moved when the doctor had just unroofed the eye. Everything avulsed forward, and the patient lost the eye," he recalls. More typical, however, are "wrong-axis, wrong-power or wrong-eye" claims, he says. The surgeon is ultimately responsible for making sure all the data is correct before proceeding, even if he or she didn't personally commit the alleged error. "Typically what happens is that patients sue the technician, the surgery center, and the optometrist in addition to the surgeon. Typically, the technician and optometrist are let out of the case or they settle out," he explains.

The ophthalmologist contacted for this article prevailed in a malpractice lawsuit arising from a mismatch between IOL and patient during cataract surgery performed at an ASC. The surgeon was working with some unfamiliar staff when the mismatch occurred despite performing his customary preop checks. "We gave them the correct lens power; we gave them the correct patient. All they had to do was pull the lens," he recalls. "They got the patient's name wrong, although another patient's similar name contributed to the mix-up, and they handed over the wrong IOL. We did everything in our power to prevent it; we did the same checks we do very single week. But unfortunately, one nurse was relieved and another nurse came in. There was a similar-name issue between patients, and a failure to double-check wristbands. We were in the middle of the case, and were asking for the lens and expecting the same checks and balances to be done that were normally done. But they weren't. You can only control other people so much," he observes. "I had a specific group I normally worked with in the ASC.

VisiPlug®: A visibly better plug to treat Dry Eye with no reportable instances since market release in 2003!

See you at AAO in Booth #2758.Stop by to see our complete line of products and special show pricing.

Available in both 0.4mm and 0.5mm

To order call 1-800-367-8327

Learn more at *www.lacrimedics.com*

Lacrimedics®

(800) 367-8327

E-mail: info@lacrimedics.com

www.lacrimedics.com

2620 Williamson Place, Ste. 113, DuPont, WA 98327

[1]Dramatization. Not a real patient. Actual results may vary. ©2018 Lacrimedics, Inc.

But people need breaks, and it just so happened that they added in a person who was not paying attention and who was subsequently fired."

The ASC paid the affected patient a settlement to avoid trial. When his patient decided to pursue a med mal claim against him after reaching a settlement with the ASC's insurer, the ophthalmologist decided to fight it, and was fortunate to have the support of his medical malpractice carrier.

"My carrier said, 'We're not going to settle this,' " he recalls. "I was unwilling to have my name go down in a database for settling on something like this and to have it ruin my reputation and affect my ability to get more insurance or be a part of a hospital system, or to have it come up every time I got credentialed. My attorney thought the odds were in my favor, and I did not want it to affect my reputation, so I was willing to take my chances. We hunkered down and got an immediate favorable jury decision. I got lucky," he says.

Make Yourself Available

A maloccurrence often brings with it feelings of sadness and disbelief, but it's important to resist the impulse to hide from the affected patient, says Tiemeier. "Postoperatively, if there's a complication, you need to spend time with that patient. They are now a high-risk patient—a person who has a reasonably high probability of suing you.'

Although he ultimately did end up in court, the ophthalmologist who won his suit addressed the surgical error promptly. "As soon as I found out there was an improper lens, I told the patient exactly what happened and exchanged it immediately. That became part of the record, and I think it's one of the reasons that the decision went my way. And the patient ended up with 20/20 vision after the lens exchange," he says. "Even though the patient was 20/20 after the procedure, she said to me, 'You're a nice guy. But I lost work because of this, and so I'm going to have to sue you.'

"I said, 'Thank you very much for that information. I'm sorry you feel that way, but if there's anything else I can do for you, let me know.' " he continues.

Mr. Tiemeier says that measures like those taken by this surgeon can keep you out of court altogether in many instances. "It's a physician's lack of communication with the patient, and lack of the development of any type of rapport with the patient, that I believe most often leads to medical malpractice lawsuits," he says. "I can't prove this, but there are numerous studies showing that communication can deter lawsuits." One review of malpractice plaintiff deposition transcripts indicated that problematic doctor-patient relationships featured in 71 percent of the depositions reviewed, which totaled 3,787 pages of testimony: Deserting the patient came out on top of these relationship troubles, followed by devaluing the patient and/or family views; poor delivery of information and failure to understand the patient and/or family perspective.[8]

"Showing that you care about the patient makes an enormous difference," says Mr. Tiemeier. "The thing I hear over and over in plaintiff's depositions is, 'The doctor just ignored me after this happened. When I tried to get an explanation as to what happened, I couldn't even see him or her.' That is probably the most common comment I've heard from patients after they've had a complication."

As difficult as it may be, Mr. Tiemeier urges taking tangible steps to let your patient know that you're accessible in the aftermath of a maloccurrence or bad outcome. "One way is to let the front office know that if this particular patient calls, they're to get you immediately," he says. "Make sure you communicate well with the patient. Make sure that you're available to them and that you make the time to spend with them. Spending an hour with a patient may seem like a hell of a long time, but spending a day in a deposition with some attorney questioning you for seven hours is even more unpleasant. So decide what you want. I think that hour spent with the patient is very good inoculation against getting sued," he states.

One ophthalmologist Mr. Tiemeier met during an educational speaking engagement shared that she schedules an unhappy patient at the end of the day as her last patient, so she can spend unhurried time with him or her.

"I think that's a great idea," he says.

What you do and say once you're in the room with your patient is critical, Mr. Tiemeier adds. "You need to sit down with the patient and with the chart and say, 'This is what happened to you. I'm not sure why it happened, but this is what happened.' The doctor doesn't have to admit negligence, but it's okay—in fact it's a good idea—to say, 'I'm sorry that this happened.' Not 'I'm sorry I screwed this up,' but 'I'm sorry that this happened to you.' "

Mr. Tiemeier's next recommendation may seem counterintuitive. "Ask, 'Is this going to affect you financially?'" he says, adding that some ophthalmologists he has suggested this to have given him blowback, believing that this smacks of assuming financial responsibility for the patient's suffering. "Sometimes, all you need to do is fill out a form for them to send to their employer, or for them to send to their disability insurance carrier," he clarifies. "Showing that you care about the patient makes an enormous difference."

"Just try to offer assistance," concurs the ophthalmologist who was sued after doing an IOL exchange. "Admit that an error occurred. I didn't try to hide anything, and I admitted that there was an error. My feeling is that you have to be up-front. You have to be clear that something occurred; and you have to offer assistance in any way possible to remediate the situation. It was, fortunately, a correctable error in my case," he says, although he also says that he remains curious as to why the affected patient allowed him to do an IOL exchange if she really believed he was a negligent surgeon.

"The initial reaction is to want to pretend that it didn't happen or pretend that it wasn't his or her fault or to blame it on the patient," Mr. Tiemeier observes. "It's not something they'll necessarily verbalize, but I've detected that attitude many times in many surgeons. That is the opposite of what you need to do. If you have a complication with a patient, you need to fully embrace that patient. You need to do this as the surgeon—not the technician, not the optometrist, not the office manager but the surgeon," Mr. Tiemeier stresses.

The East coast ophthalmologist says he now performs procedures in his own facility, and has added even more checks and timeouts to his protocol over the years since the lawsuit. "You have to get past the ego-damaging aspects of this," he concludes. "You have to move forward after doing what you have to do to correct the situation. Show how much you care and express that you want the patient to do well, and try not to take it personally." REVIEW

1. Thompson AC, Parikh D, Lad EM. Review of ophthalmology medical professional liability claims in the United States from 2006 through 2015. Ophthalmol 2018;125:5:631-41.
2. Englehard SB, Shah CT, Sim AJ, Reddy AK. Malpractice litigation in cornea and refractive surgery: A review of the WestLaw database. Cornea 2018;37:5:537-41.
3.Roter D. The patient-physician relationship and its implications for malpractice litigation. J Health Care L & Pol'y 2006;9:2:304-14.
4. Abbott RL. Medical malpractice predictors and risk factors for ophthalmologists performing LASIK and PRK surgery. Trans Am Ophthalmol Soc 2003;101:233-68.
5. Morse JS, Schallhorn SC, Hettinger K, Tanzer D. Role of depressive symptoms in patient satisfaction with visual quality after laser in situ keratomileusis. J Cat Refract Surg 2009;35:2: 341-6.
6. Simon CM, Schartz HA, Rosenthal GE, et al. Perspectives on electronic informed consent from patients underrepresented in research in the United States: A focus group study. J Empir Hum Res Ethics 2018. doi: 10.1177/1556264618773883. [Epub ahead of print] Accessed 7 August 2018.
7. American Academy of Ophthalmology Preferred Practice Pattern Refractive Management/Intervention Panel. Refractive errors and refractive surgery preferred practice pattern. Ophthalmol 2018;125:1:P1-P104.
8. Beckman HB, Markakis KM, Suchman AL, et al. The doctor-patient relationship and malpractice: Lessons from plaintiff depositions. Arch Intern Med 1994;154:12:1365-70.

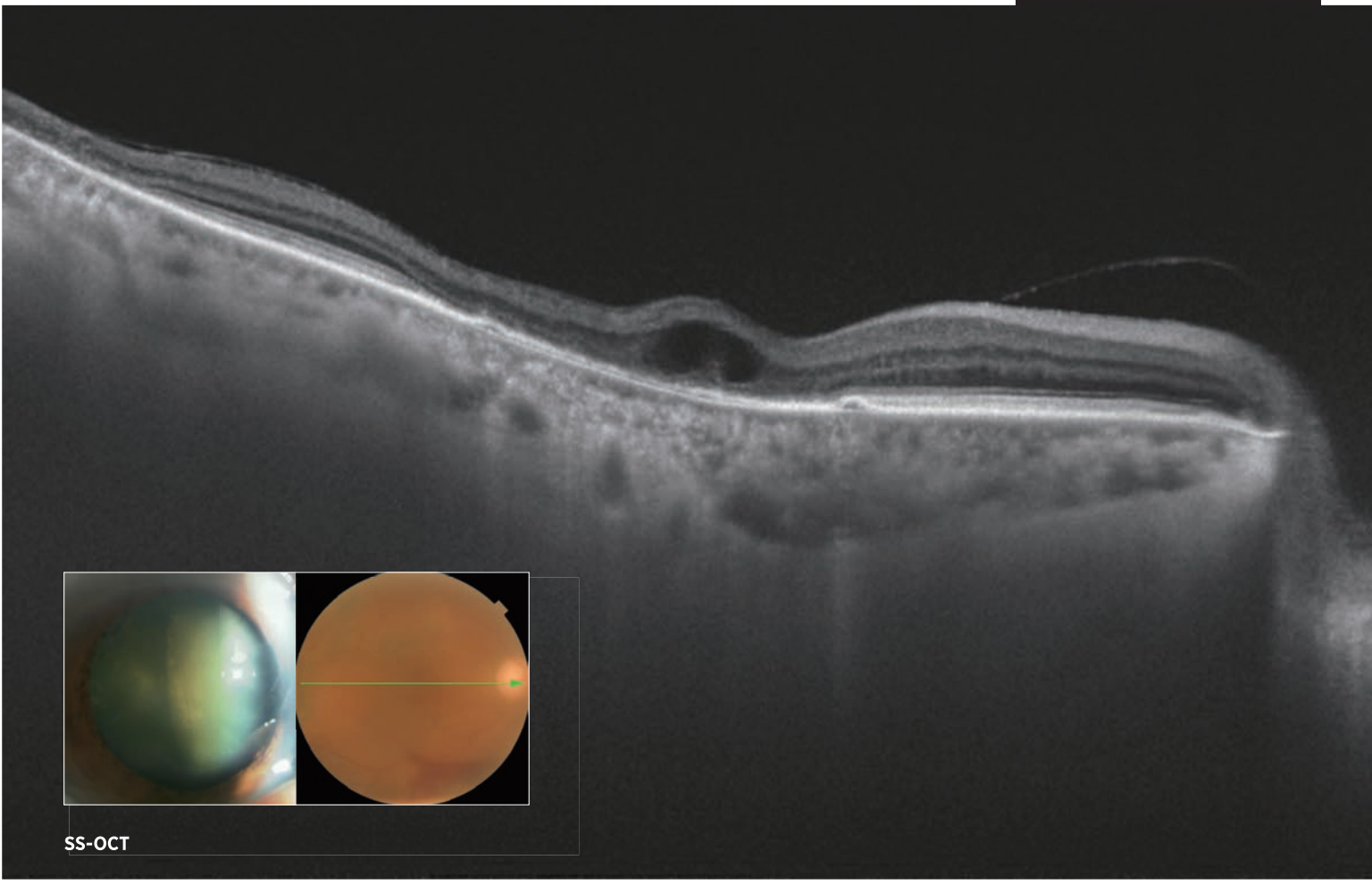
It’s time for Triton.

TOPCON

YOUR VISION. OUR FOCUS.

It's time to see through opacities.

FDA CLEARED



Contact your local Topcon Representative today or visit **newsgram.topconmedical.com/triton**.

See it live at AAO Booth #3745!

DRI OCT Triton™ Series

A Multimodal Swept Source OCT

MIPS & Ophthalmology: 12 Questions Answered

Christopher Kent, Senior Editor

The current CMS plan to adjust Medicare payments is off to a respectable start—with a few caveats.

The Merit-based Incentive Payment System, or MIPS, is the government's latest attempt to encourage doctors to adopt the best, most efficient and (hopefully) least-costly medical practices possible. Created as part of the Medicare Access and CHIP reauthorization Act (MACRA), MIPS is one of two payment tracks doctors can follow in the Quality Payment Program, which was implemented to replace the now-defunct sustainable growth rate system. (The other track in the QPP is the Advanced Alternative Payment Model, discussed below.)

MIPS adjusts Medicare reimbursements based on how physicians score in four categories: quality of care; cost of care; "promoting interoperability;" and improvement activities. Each category's score is given a relative weight; then the four resulting numbers are added up to a final score. If the final score falls above the threshold for a given year, the doctor receives a positive payment adjustment; a score below the year's threshold results in a payment penalty.

As with any complex system in which doctors must operate, understanding the system is essential to producing a positive result. Here, experts answer 12 key questions ophthalmologists are asking about the MIPS system and how they can best navigate it.

1 *How is MIPS impacting ophthalmologists so far?*

"Initial implementation of MIPS hasn't been as disruptive as some feared it would be," says Mark B. McClellan, MD, PhD, director of the Robert J. Margolis Center for Health Policy, and the Margolis Professor of Business, Medicine and Health Policy at Duke University. (Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration.) "Hopefully it's on track to provide better support for patients, helping them get the high-quality care they need, while avoiding unnecessary costs to the Medicare program and not being too burdensome for physicians. We still have a long way to go in all of those dimensions, but some of the recent regulatory modifications to MIPS have helped to prevent problems that might otherwise have occurred.

"Many measures are requiring less reporting than people expected," he continues. "Some of the measures have been revised with the goal of being more relevant to supporting good practice, and CMS has encouraged providers to focus on the measures they view as relevant. That helps to

The trail is clear.

Weaving along Hawaii's Na Pali Coast is the breath-taking Kalalau Trail. The trail is demanding...but in the end, its beauty is worth every step. Kalalau was early inspiration for us, today representing our innovative spirit and deep commitment to advancing the treatment of eye diseases. This is the journey we're all on at Kala and the one we can take together.

The technology in sight.

Our proprietary and barrier-breaking **AMPPLIFY**™ Drug Delivery Technology is designed to help us keep improving what's possible for eye care.

The vista awaits us.

Visit kalarx.com and let's get our journey underway.

kala
PHARMACEUTICALS

get better alignment between what providers are being asked to report and what they actually report on. For example, rather than ask doctors to go down a checklist of characteristics of their EHR system, there are fewer reporting measures related to electronic data, and the ones that remain are more focused on whether data is being shared among health-care providers the way it should be."

Michael X. Repka, MD, a professor of ophthalmology and a professor of pediatrics at the Johns Hopkins University School of Medicine, and medical director for government affairs at the American Academy of Ophthalmology, suggests that it's helpful to think of the participants in the program as falling into several categories, each of which may be having a completely different experience. "One category is ophthalmologists who are in big academic groups or multi-medical-specialty groups—in other words, groups that are not composed entirely of ophthalmologists," he explains. "They're working under a group-reporting option, so they don't actually do very much directly. That's the type of practice group I fall into; I rely on what the clinical practice association does in terms of more general medical performance measures, along with EHR use. [Dr. Repka notes that this is considered MIPS "group reporting," as opposed to an APM arrangement.] As far as I understand, ophthalmologists in academic-center situations or large multispecialty medical practices are doing well. They're potentially looking at up to a 2-percent bonus in 2019, based upon 2017 performance measurements. That will be a substantial amount of money.

"The majority of ophthalmologists in small-to-midsized practices who have EHR and participate in IRIS are reporting that they did fine in 2017," he continues. "As much as a 2-percent bonus is realistic for next year. Many of these practices may also be getting into the super-threshold bonus; that's the $500 million that's distributed among practices with high scores for the first five years of the MIPS program (scores above 70 in 2017). We think that the high performers participating in IRIS will get about 1 percent from the regular bonus pool and as much as another 1 percent from the 'super dollars.' Of course, the more practices that succeed and make it into that high-performance category, the smaller the bonuses will get.

"If you're hoping to make a living off of these bonuses," he adds, "you'll be disappointed. They're too small."

Jeff Grant, president and founder of HealthCare Management & Automation Systems, believes most ophthalmologists have accepted the new system. "They'd rather it not be there, but they've resigned themselves to the fact that this is the way it's going to be done," he says. "It's not going to go away. And I think most doctors understand that the number of tasks the staff has to perform has gone way down. Furthermore, I think they realize what a benefit IRIS has been for Academy members."

Potential Payment Adjustments, by Year*

Performance Year	Payment Year	Range of Possible Payment Adjustment
2018	2020	±5 percent
2019	2021	±7 percent
2020	2022	±9 percent
2021	2023	±9 percent

Exceptional performers will receive an additional positive adjustment taken from a pool of up to $500 million available each year from 2019 to 2024.

*cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRS-MIPS-and-APMs/MIPS-Scoring-Methodology-slide-deck.pdf

2 *How much of an advantage is it to have EHR and participate in IRIS?*

"In the current MIPS system, ophthalmologists have been lucky," says Mr. Grant. "Ophthalmologists have done exceedingly well. The biggest reason for that is the IRIS registry, supported by the American Academy of Ophthalmology. When IRIS first came along four or five years ago, back before we had MIPS, it only helped doctors with the quality-reporting portion. Today, IRIS has made it possible for providers to submit not just quality measures, but also data related to the old meaningful-use measures, now called 'promoting interoperability,' or PI. IRIS can extract the appropriate data from the EHR data and map it to that specific practice's reports, which is important because even if two practices have the same EHR product, they may enter the data a little bit differently. IRIS can account for that and then submit everything for them. It's been a fantastic tool.

"By way of comparison, consider the field of optometry," he says. "The American Optometric Association has struggled for several years to create something similar to IRIS, and it hasn't worked out nearly as well; I don't know why. But it makes me feel even better for ophthalmologists when I see what IRIS is able to do for them. IRIS has probably been the single best thing for ophthalmologists in regard to all of these federal programs, whether you're talking about PQRS or MIPS."

Mr. Grant says that when ophthalmologists have an issue with MIPS, it's usually related to things that are unique about their particular practice. "Maybe the practice isn't using EHR," he says. "That would be a big problem and make MIPS very difficult, because even if the practice submits

data through IRIS, IRIS can't extract the relevant MIPS data. The practice would have to come up with information on quality and the former meaningful-use measures on its own, and that can be problematic."

Mr. Grant notes that difficulties with the program caused by lack of an EHR system might soon become worse. "In order to avoid a penalty, a practice without EHR has to send quality measures via claims data," he says. "I have a couple of clients who've chosen not to use EHR and continue to send quality codes via claims. They've been relatively untouched—no penalties, no incentives. However, there's a proposed rule that just came out that would eliminate claims-based reporting for the quality measures. If that rule is implemented, a practice without EHR wouldn't have any way to submit their data; they'd have no way to prevent a penalty. The only option they'd have left would be to come up with some reporting mechanism using their software that generated numbers they could manually enter into the IRIS webport. That's possible, but again, how much time and expense would it involve?

"For now, they might decide that taking the penalty is better than spending the money," he concludes. "But as the penalties continue to increase in the coming years, the pain is going to increase. Those practices may change their minds two years down the road."

3 *How is bonus size determined?*

The "budget neutrality" built into the MIPS system, which adjusts the overall payments to ensure that the system only gives out a certain amount of money, has made the incentives and penalties unpredictable. "The physicians who do better on the MIPS measures are paid more at the expense of those who do worse," Dr. McClellan points out. "The measures reported are supposed to reflect differences in quality of care, but initially physicians were concerned that not reporting correctly might lead to a significant reduction in payments. What CMS is finding is that most physicians who do report are doing pretty well in the measures. In addition, there are many physicians who don't have to report as much because they have very small practices that don't see a lot of Medicare beneficiaries. The result is that the differences in payments that are emerging for physicians based on MIPS are not as large as expected. It looks like not too many physicians will face big penalties, and conversely, not too many will get large bonuses, either—at least for the next few years."

Mr. Grant notes that in the first year, it was publicized that doctors could earn up to a 4-percent bonus in 2019, based on their 2017 reporting. "It turned out that because a large number of practices did well, the largest incentive bonus was 2.02 percent," he says. "That's the most anyone got, and that includes some additional money that wasn't

part of the budget-neutrality deal."

Mr. Grant says many practices were surprised. "The fact that the bonus amount could be lower if a lot of practices met the criteria was not well publicized," he notes. "The possible bonus was actually 'up to' 4 percent. Next year, it's supposed to be 'up to' 5 percent. We won't know what it actually is until the reporting is done and they know how many practices reached certain levels and how many were poor performers.

"Of course," he continues, "many practices based their calculations on getting a 4-percent bonus. At the same time, some practices wanted to know what the maximum pain would be if they chose not to do this—especially doctors in their last three to five years of practicing. They're winding down and they don't want to go through all of these changes, so they have us try to figure out what the maximum penalty might be. It's now clear that if you base either calculation on the announced maximum benefit or penalty, your numbers will be off. We won't know what the maximum will actually be until the reporting for the year is done."

The number of doctors participating in MIPS is another key factor affecting the size of bonuses and penalties. "Different medical fields may be rooting for more or fewer exclusions from participation in MIPS in future years, because those changes will make the size of the bonuses rise or fall," Dr. Repka notes. "CMS has a sensitive job; it has to tread lightly and not hurt some people more than is reasonable, yet still encourage widespread participation. Currently, I believe that fewer than half of all potentially eligible Medicare-providing doctors are participating in MIPS because of various exclusions. If you think you're going to be a winner, then you need everyone possible to be in the program so you have more of a bonus pool distributed to the winners. On the other hand, specialties that don't have high scores are going to argue that we need more exclusions because the program is unfair. In general, ophthalmologists would like to see fewer exclusions, because we think we're doing very well."

> *"The fact that the bonus amount could be lower ... was not well publicized."*
> *—Jeff Grant*

4 *How is MIPS affecting reimbursements for the cost of Part-B drugs?*

Dr. Repka says that, contrary to what some thought might happen, MIPS penalties and bonuses will not be applied to the reimbursement of part-B drugs, a factor that could have profoundly impacted doctors such as retina specialists. "The reimbursement of part-B drugs is excluded right now from the application of the bonus and penalties," he explains. "In last year's guidelines, and in this year's proposed rule, it's been made clear that reimbursement of the practice for part-B drugs will not be affected by the penalty or bonus.

"Suppose you had a 5-percent penalty, and it included your part-B drug costs," he continues. "That would mean you were underwater before you even paid to have the drugs shipped to you. That expense for the part-B drugs used by the patient is included in the 'cost' category of MIPS, but that metric is only 10 percent this year, so it's still a very low number. Of course, if that category increases, the impact of part-B drug selection attributed to the retina surgeon could have serious negative effects, so we need to watch carefully as CMS rolls out these changes, and we have to continue to object to some of their methodologies for allocating expenses."

5 *What is the alternate payment model, and how might it help me?*

Dr. McClellan explains that within MACRA, the overall system that created the MIPS program, there are two big tracks that physicians can follow. "In MIPS you report on a set of measures relating to quality of care, data exchange, practice improvement and cost or value management. Based on those measures, your Medicare payment rates are adjusted up or down a bit. The other track is what Medicare is calling the Alternative Payment Model, or APM. In that track, physicians who participate agree to be part of a different payment approach that's typically more like a fee-per-member-per-month approach, similar to a medical-home payment model for a primary-care physician. It's designed to apply to physicians who primarily perform procedures. For those doctors, it's more of an episodic-payment model, like the advanced bundled-payments-for-care initiatives program that Medicare set up for major surgical procedures such as cardiac catheterization or joint replacement.

"These models are generally not available to ophthalmologists," he continues. "That's a concern for me because it means that ophthalmologists don't have as much opportunity to access the advantages of the APM model. Those advantages include not only the opportunity to get support for delivering care in ways that are potentially better or more efficient, they also include getting out of most of the MIPS reporting requirements, because the alternative payment models typically require reporting on a limited number of measures that are more outcome oriented. Also, some of these models allow physicians who substantially participate in them to get a significant bonus—a 5-percent addition

to their Medicare payment rate. But there currently aren't any APMs focused on ophthalmology care.

"Probably the only way ophthalmologists can participate in the APM model is if they're part of a large health-care organization that's become a Medicare accountable-care organization," he says. "In an ACO, all of the providers agree to be paid based on overall costs and some population-oriented outcome measures relating to the Medicare patients they primarily take care of. This works well for primary-care physicians and some specialists, such as those caring for diabetes or heart-disease patients. In those cases, there are some performance measures and relatively straightforward ways for them to coordinate care better with the primary-care doctors in the organization. But the kind of care provided by ophthalmologists, which typically involves discrete services like cataract surgery or macular-degeneration treatment, is harder to fit into that structure. Instead, we need APMs that focus on supporting ophthalmologists who treat these specialized problems better or at a lower cost."

Mr. Grant adds that some doctors consider having an ACO manage the reporting to be a significant benefit. "I haven't seen many doctors say that this is the only reason they're signing a contract with an ACO—so that they'll handle the MIPS reporting," he says. "But some have told me it was a major part of their decision to sign."

6 ***What is attribution, and why is it problematic?***

"One problem that unfairly affected ophthalmologists in the past—especially retina specialists—is a thing called attribution," Mr. Grant explains. "This was part of a cost-related component in the reporting. Patients were 'attributed' to a particular doctor, based on factors such as how frequently the doctor was seeing the patient and whether the doctor was billing using evaluation and management, or E&M, codes. If you saw a patient often and used those codes—which retina specialists often do—then any Medicare charges associated with that patient were attributed to that doctor, even if they were totally unrelated to what the doctor was treating. For example, a retina patient might go to the hospital and have $20,000 worth of gastrointestinal surgery. Under this system, this cost was attributed to the retina specialist. One of the unintended consequences of this was to make doctors hesitate to treat patients with more serious health issues, knowing that they could get hurt financially as a result.

"This problem was identified about three years ago," he continues. "It came from an aspect of the old quality program called the value-based modifier. The new cost program has attempted to fix that, and it has, to some extent.

"I don't believe that CMS wanted to cause doctors to push away patients with more severe problems," he adds.

The Rick Bay Foundation

for Excellence in Eyecare Education

www.rickbayfoundation.org

Support the Education of Future Healthcare & Eyecare Professionals

About Rick

Rick Bay served as the publisher of The *Review* Group for more than 20 years.

To those who worked for him, he was a leader whose essence was based in a fierce and boundless loyalty.

To those in the industry and the professions he served, he will be remembered for his unique array of skills and for his dedication to exceeding the expectations of his customers, making many of them fast friends.

Scholarships are awarded to advance the education of students in both ***Optometry*** and ***Ophthalmology***, and are chosen by their school based on qualities that embody Rick's commitment to the profession, including integrity, compassion, partnership and dedication to the greater good.

Interested in being a partner with us?

Visit www.rickbayfoundation.org

(Contributions are tax-deductible in accordance with section 170 of the Internal Revenue Code.)

THE RICK BAY FOUNDATION®
for Excellence in Eyecare Education

(The Rick Bay Foundation for Excellence in Eyecare Education is a nonprofit, tax-exempt organization under section 501(c)(3) of the Internal Revenue Code.)

"I'm sure these were unintended consequences. In any case, under the new MIPS system, last year cost was not even included in the bonus/penalty system. This is the first year it's been included, and for now, it's a small percentage of MIPS reporting. We'll see how that plays out as things unfold in the future."

7 *How will "Physician Compare" impact my practice?*

One controversial part of the MIPS program is "Physician Compare," which will publish online the measures that doctors report, theoretically helping potential patients to choose the best doctor. "Making quality measures available to the public has definitely produced mixed results," notes Dr. McClellan. "One major finding is that not many people actually look at the measures that are posted. That may be partly because it's inconvenient for people to spend the time and effort to find them online; but it's also that the things we measure for MIPS are not necessarily the things that matter most to patients.

"Right now, MIPS measures are focused on treatment processes and safety issues," he continues. "Obviously these things are important, but they're not things that most patients think about when they're choosing a doctor. If we move more toward measures relating to functional outcomes, more attention might be paid to the postings. Right now, that's not what the MIPS measures are focused on. So even though doctors may be unhappy if they come out looking less capable or patient-friendly than their competitors, the reality is that the measures that are available online now probably won't generate an enormous amount of public attention."

8 *Is a small practice at a disadvantage?*

"Those in small ophthalmology practices and those who don't have an

EHR system are likely having a harder time participating in MIPS successfully," says Dr. Repka. "However, this probably represents a small number of practices, and those practices have had some straightforward ways to avoid a penalty and remain neutral in terms of reimbursement. In 2017 measurements, you only had to accumulate three points to avoid a penalty. This year it's still easy to avoid the penalty with a few steps, which will be reflected in payment year 2020—as long as you remember to take those steps. However, penalty avoidance will get harder with each successive year, so that strategy is not going to be sustainable over time."

Mr. Grant says he doesn't believe a small practice will have a harder time managing MIPS than a large practice. "If it's a one-doctor practice, the doctor probably has a tech or two, and they'll have to change some of their habits," he says. "The doctor and staff at the front desk will have to do a few things differently. But that's equally true for a practice with 10 doctors and 20 techs. In addition, CMS thought that small practices might have a harder time managing the data, so this year they gave them some bonus points for being small. That's not a huge thing, but it's a help, and it shows that CMS is trying to come up with ways to help out."

9 *What about the possibility of opting out of MIPS?*

Mr. Grant says some practices are opting out of the system—at least for now—for several reasons. "Some practices have a very low Medicare volume," he points out. "They may calculate that the cost of having staff take the time to handle the data and do the reporting will be greater than the bonus they'll receive for doing it, especially if they don't have EHR and can't use IRIS. They might say, 'I'm going to spend $20,000 to save $20,000, or maybe only to save $10,000. It's not worth it.' On the other hand, the penalties for opting out will keep increasing, eventually reaching 9 percent. If a practice has a million dollars in Medicare payments, that would be $90,000 in penalties. I suspect it would be worthwhile to hire somebody to do the manual work to prevent the penalty at that point. So I think you'll see practices shifting their strategies as the penalty level goes up in the next few years."

10 *Is MIPS likely to actually accomplish something positive?*

Clearly, a system such as MIPS springs from good intentions, but whether it will end up having a positive impact is a different question. Among surgeons' concerns is the possibility that because of MIPS, doctors will avoid seeing patients as often as they should, or will refuse to treat more challenging patients to avoid being financially penalized.

"Causing surgeons to avoid treating high-risk patients, such as patients needing a very difficult retina-reattachment procedure that costs a lot and involves a lot of disposables, is a real risk any time you base reimbursements on outcome measures—if the system cannot accurately risk-adjust," says Dr. Repka. "The system is definitely moving toward outcome measures, such as what percentage of cataract surgery patients see 20/25 or better. The folks at CMS keep saying they know how to risk-adjust and compensate for this.

"At the moment, we're not sure they can do that very well," he continues. "In fact, we're pretty sure they can't do it well. So yes, the ability of CMS to risk-adjust is a concern, because we don't want to penalize surgeons who are providing care to patients with more serious problems. And we do not agree that what CMS is doing at present is adequate. I think they're trying to get this right, but I don't think they've been completely successful so far."

Not All EHR Products are MIPS-friendly

"Unfortunately, we've seen electronic health record products that don't handle some of the MIPS measures as well as they should," notes Jeff Grant, president and founder of HealthCare Management & Automation Systems. "The greatest problems seem to arise with the 'promoting interoperability,' or PI, measures, which used to be called 'meaningful use.' These measures have to do with the exchange of data. For example, you have to be able to send data to a provider that you've referred a patient to, and be able to receive data from that provider and import it into your EHR. Doing that is very problematic in some programs, depending on the way the vendor has the software set up.

"These EHR products are all certified," he notes. "They passed the government criteria, but users still struggle with some of these functions that are supposed to be part of the software. How can that be? I don't have a good answer for that question. It may be that the EHR certification process is not quite as detailed as it ought to be. It may not ask how efficient the system is, or whether it fits into a practice's normal flow. Some of the functions in some systems require a practice to go through some pretty convoluted steps. This can end up causing a doctor to decide not to bother trying to earn a bonus, and just focus on avoiding a penalty. After all, if you have to spend five or 10 minutes on every single patient to meet this measure, is it really worth it?"

—CK

"To do well in this system," notes Mr. Grant, "you'll have to learn to do only what you can justify and defend in your documentation. If you need to see a patient every week for three weeks, and that's clinically supported by other doctors and your professional society, then do it. CMS, however, decided that there were doctors seeing patients for visits that were not truly necessary, and that this caused a substantial amount of unneccesary expense to Medicare.

"I have no problem with trying to make doctors more mindful about that," he adds. "I'm a taxpayer, and I think the program needs to be run in an efficient way. But I don't want a doctor to not do something that's clinically relevant because he's concerned about having his hand slapped. Unfortunately, a system like this does have that potential."

Even if the system has a positive impact, is it worth participating in from the doctor's perspective? Dr. Repka says it depends how you look at it. "Some of the money doctors are forced to spend to participate successfully may really be contributing to improved quality of care," he points out. "Being able to benchmark and evaluate your practice, to look for outliers in performance and do these assessments quickly, is probably a real quality-improvement tool, as well as a potential money saver for the healthcare system. On the other hand, if you see this as an extra cost of doing business and think that you may not get back as much as you're putting in, you're also probably right. And exactly how much of the spending is really contributing to improved quality of care is unknown.

"My view," he concludes, "is that this is a program the AAO is trying to modify so that Academy members don't lose more than is necessary, and so the vast majority can succeed and be eligible for the bonus payments."

11 *What is CMS doing to improve MIPS?*

As doctors well know, the best-intentioned programs are often flawed, and MIPS is no exception. So a key concern is how CMS is working to uncover and correct issues that are causing unintended problems.

Mr. Grant says that one positive thing CMS has done is eliminate some pointless documentation requirements. "When meaningful use first came out, there's no question that it required doctors—especially specialists—to do things that were a bit silly," he says. "Some of the documentation requirements just didn't make sense. They were asking for minutiae that had nothing to do with the bigger picture.

"The current, first version of MIPS is far better than what doctors were dealing with before," he continues. "Most of what's required now makes more sense. Furthermore, CMS has made it about as easy as possible for a practice to avoid a penalty; for now, the requirements are very low. If you do just a couple of very nominal things, your practice ought to be able to avoid a penalty. If you want to get into this slowly, you can. If you want to go all-in and do everything you can to get the maximum incentive right from the start, you can do that, too."

Dr. McClellan notes that one of the challenges going forward will be to see if CMS can develop new kinds of payment approaches that could offer the same advantages to ophthalmologists that doctors in the APM models receive, helping to improve care and lower the total costs of treating specialized health problems while getting ophthalmologists paid better for doing so. "CMS is working on this," he says. "Medicare has a center within CMS called the Center for Medicare and Medicaid Innovation that focuses on developing new payment models," he explains. "To my knowledge, none of the current payment models is really focused on common ophthalmologic

conditions, even though this is a big part of Medicare spending. Maybe that's because things are going relatively well in terms of payment rates and quality-of-care access. This is a challenge for the clinical leaders in ophthalmology: Given the way that Medicare pays, is there a different payment approach that could be better aligned with getting good ophthalmologic outcomes for Medicare beneficiaries at a lower total cost of care? Ophthalmologists would know best about that.

"What's notable is that MIPS doesn't reward physicians for minimizing other types of spending," he continues. "Some of the major costs to the system come from physician decisions about things such as where a procedure is performed. The same procedure might be performed in a hospital outpatient department at a higher cost than in a physician's office, with similar—or possibly even greater—quality if it were done in the office. But under MIPS there's no real reward for physicians to take steps to get those costs down. Many of the APM models do take this into account, rewarding physicians for decisions that lower overall costs, but again, the current APM models aren't really designed for ophthalmologists.

"For example," he says, "the Innovation Center has developed a new payment model for oncologists that allows them to manage their cancer patients with team-based approaches to care, and more patient engagement, avoiding some of the costly complications from cancer treatment such as urgent hospital admissions. At the same time, those savings in hospital and other costs enable the practices to get paid significantly more. That, in turn, allows them to spend more money on resources that can help patients and prevent other complications. This model rewards them for finding less-costly drug treatments and other interventions, and it provides an additional payment opportunity that gets them out of the usual MIPS reporting requirements.

"What generally helps to move these alternate models forward is both sides working together," he adds. "That means that leaders in the clinical community can help by proposing ideas for how care could be improved and better supported with alternatives to fee-for-service payments. If ophthalmologists aren't happy with current MIPS programs, or if they want to have access to the additional payment bonuses that go along with the APMs, they need to help come up with new ideas and approaches to help make that a reality."

Dr. McClellan notes that in general, using measures to differentiate quality of care among physicians isn't an easy task. "It's a challenge because the measures that we have available that are feasible for physicians to report aren't always that useful as quality-of-care measures," he says. "They're not always that relevant to what really matters to physicians and their patients. So one of the issues with this program going forward will be whether it really is differentiating quality-of-care levels, and whether it really is encouraging better quality of care by rewarding it. CMS will continue to revise the program in the coming years as they try to address that."

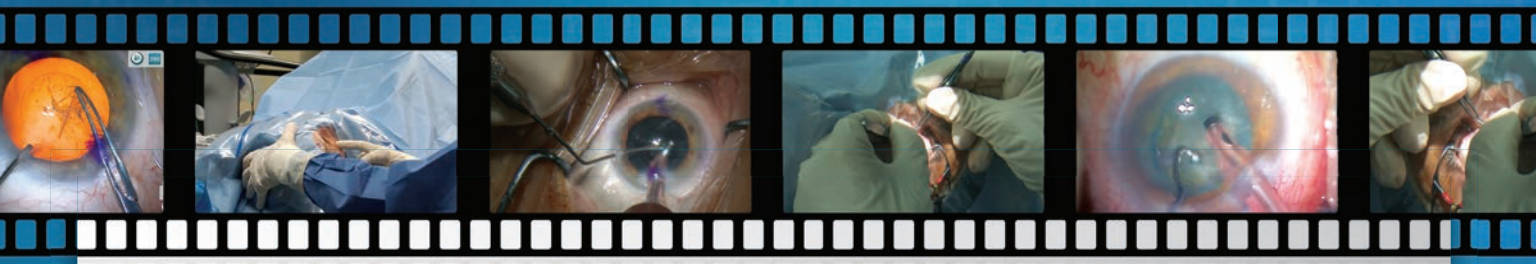
Mr. Grant notes that despite the improvements that have been made, many doctors still feel they have reason to complain. "You can't please everyone," he says. "But I believe CMS is listening, and I think MIPS is evidence that CMS is trying to make the program better and less onerous for providers, while still getting valid data out of it and trying to encourage habits that are reasonable. We'll see how it works out as they continue to tweak the system."

12 *What's likely to happen in the years ahead?*

Monthly

MACKOOL ONLINE CME

CME SERIES | SURGICAL VIDEOS



To view CME video
go to:
www.MackoolOnlineCME.com

Episode 34:
"They Only Get to Move Once..."

Surgical Video by:
Richard J. Mackool, MD

Video Overview:
Over the next few months to finish out our year, will be present three rather complex cases. This month, our 57 year old patient is extremely anxious about having cataract surgery. She had uveitis and glaucoma in childhood for which a nasal thermal sclerectomy was performed at the age of 8. She subsequently developed a cataract, but opted to postpone surgery until the lens had become quite dense. She has a low endothelial cell count, possibly as a result of prior uveitis and/or intraocular surgery. Because of patient movement during the early stages of the procedure, we use tape to restrain head movement and I deliver a retrobulbar block to improve her ability to remain stationary.

MackoolOnlineCME.com MONTHLY Video Series

Richard J. Mackool, MD

Welcome to the third year of Mackool Online CME! With the generous support of several ophthalmic companies, I am honored to have our viewers join me in the operating room as I demonstrate the technology and techniques that I have found to be most valuable, and that I hope are helpful to many of my colleagues. We continue to edit the videos only to either change camera perspective or to reduce down time – allowing you to observe every step of the procedure.

As before, one new surgical video will be released monthly, and physicians may earn CME credits or just observe the case. New viewers are able to obtain additional CME credit by reviewing previous videos that are located in our archives.

I thank the many surgeons who have told us that they have found our CME program to be interesting and instructive; I appreciate your comments, suggestions and questions. Thanks again for joining us on Mackool Online CME.

CME Accredited Surgical Training Videos Now Available Online: www.MackoolOnlineCME.com

Richard Mackool, MD, a world renowned anterior segment ophthalmic microsurgeon, has assembled a web-based video collection of surgical cases that encompass both routine and challenging cases, demonstrating both familiar and potentially unfamiliar surgical techniques using a variety of instrumentation and settings.

This educational activity aims to present a series of Dr. Mackool's surgical videos, carefully selected to address the specific learning objectives of this activity, with the goal of making surgical training available as needed online for surgeons motivated to improve or expand their surgical repertoire.

Learning Objective:
After completion of this educational activity, participants should be able to:

- Demonstrate methods to improve patient cooperation during a complex surgical procedure

Satisfactory Completion - Learners must pass a post-test and complete an evaluation form to receive a certificate of completion. Your chosen sessions must be attended in their entirety. Partial credit of individual sessions is not available. If you are seeking continuing education credit for a specialty not listed below, it is your responsibility to contact your licensing/certification board to determine course eligibility for your licensing/certification requirement.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

Physicians - In support of improving patient care, this activity has been planned and implemented by Amedco LLC and Postgraduate Healthcare Education. Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team

Credit Designation Statement - Amedco designates this live activity for a maximum of .25 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Endorsed by:
Review of Ophthalmology®

Video and Web Production by:
JR Snowdon, Inc

Jointly provided by:
AMEDCO & PHE

Supported by an unrestricted independent medical educational grant from:
Alcon

Additionally Supported by:
Glaukos
MST
Crestpoint Management
Carl Zeiss Meditec

In Kind Support:
Sony Healthcare Solutions

"Doctors have been aware of the shift toward more paperwork, scrutiny and requirements for quality documentation for a long time," notes Dr. McClellan. "These trends are not new. And given that health-care costs keep going up as medical capabilities increase and the population keeps aging, there will be more and more pressure for payments to align with truly high-quality, efficient care. One result of that is that more transparency is coming.

"The challenge for the medical profession is, what do you want that transparency to be about?" he continues. "Are the MIPS measures the right measures? Are they measuring things that actually matter to patients? Are they measuring things that doctors really care about improving? Today, MIPS measures don't necessarily fit that description—they're more about the processes of care or features of the doctor's EHR capabilities. They're not really measuring the things that matter most to patients.

"The initial implementation of MIPS hasn't caused major disruptions in care, and some of the steps taken by CMS to reduce the measurement burden and help physicians manage this have been beneficial," he says. "However, we're definitely not done. There are still many opportunities to reduce the burden of reporting; reduce the administrative cost of payment by using better EHRs; shift the focus to measures that matter more to people; and create more efficiency in the health-care system when it comes to things like choice of drugs, choice of procedures and site of service of care. To make this happen, physicians need to take the lead in identifying the right ways to manage costs and effective ways to reduce the reporting burden. Doing so will help us make progress towards a health-care system that really is high-quality, innovative, easy to access and affordable."

Dr. Repka says he's hopeful for the future, despite the challenges. "In general, ophthalmology is likely to be a big winner in this program compared to other specialties, for a lot of reasons, some of which are inherent to ophthalmology," he says. "Ophthalmologists tend to be interested in technology and electronics, and a large percentage of practices were early adopters of EHR. On top of that, the IRIS registry has pooled the data together to make the effort fairly seamless, so you don't have to pay an employee to enter the data. Of course, it's possible to do that manually, but it's much more cumbersome.

"It's very reasonable for a payer to assess the services physicians provide for their insured," he continues. "A payer has that right. We know that's happening on the government side, and it will happen more and more on the commercial side, so it's not going away. The big issue is, if meeting these requirements takes up a lot of time, you don't really want the doctors having to manage this. This performance measurement needs to be a system that does not involve manual data collection. It should be as painless and invisible to the physician as it can be, and risk-adjusted. But beyond that, we want to make sure ophthalmologists can avoid the penalties, and if they want to spend the time and money, go after the bonuses. The bottom line is, we want ophthalmologists to succeed."

"No one is ever going to say, 'I love MIPS!' " adds Mr. Grant. "However, after practices start to receive substantial bonuses, they may not feel that the system is unreasonable. We'll see what happens one the incentives and penalties begin to appear." REVIEW

Dr. Repka consults on this topic for the AAO, but has no other relevant financial disclosures. Dr. McClellan and Mr. Grant have no financial ties to anything discussed in the article, although Dr. McClellan notes that he is an independent board member for Johnson & Johnson.

Anterior Segment Surgery and Herpes

Walter Bethke, Editor in Chief

Corneal experts break down the pre-, intra- and postop considerations.

Performing anterior segment surgery on a patient with a history of herpes flare-ups can be like walking through a minefield—any step could trigger disaster. Some patients need to have surgery, though, and the risk of not having the procedure outweigh those of a herpes recurrence. In this article, corneal specialists share their tips and tactics for managing these patients so you can minimize the chance of a flare-up that could complicate a good surgical outcome.

Herpes' Risks

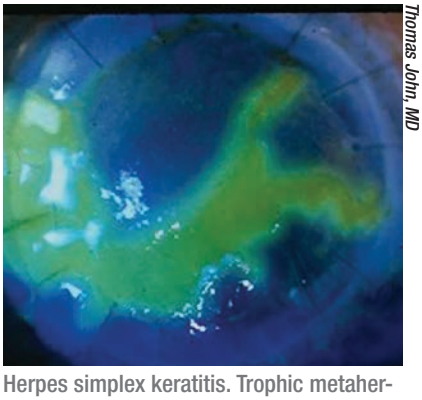
Surgeons explain what's at stake when operating on a patient with a history of herpes.

"One of the worries is more exuberant inflammation right after surgery," explains Asha Balakrishnan, MD, a corneal specialist in Encino, California, "because these patients are more pro-inflammatory. Also, we worry about them having any sort of reactivation that leads to visual decompensation and scarring in the cornea. Patients with reactivations can also develop keratitis, conjunctivitis or uveitis, each of which has its own sequellae. Also, sometimes, if a patient's herpes reactivates, it takes much longer to get the eye quiet, if it's possible. There are also intraocular pressure issues, because during a reactivation these patients are more likely to develop ocular hypertension."

Preop Considerations

Physicians say knowing the date of the last herpes flare-up is crucial when planning the surgery.

"If there's been no herpes simplex-related anterior segment activity for at least six months, you can consider doing cataract surgery," says Thomas John, MD, corneal specialist and clinical associate professor at Loyola University in Chicago. "If you're planning refractive surgery, there should be no herpes simplex-related ocular activity for at least a year, and you have to discuss the possible issues with the pa-

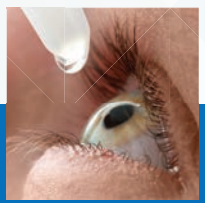


Thomas John, MD

Herpes simplex keratitis. Trophic metaherpetic epithelial defect in a corneal graft.

VISIT US AT AAO
BOOTH 3503

Autologous serum eye drops **made easy**.



Simple.

Vital Tears eye drops are easy to order and even easier to use.

Precise.

Available in your choice of dilution options in a 3 or 6 month supply.

Accessible.

300+ outpatient blood collection facilities. Direct delivery to your patient.

LEARN MORE AT **vitaltears.org** OR CALL **(800) 360-9592**

Vital Tears™

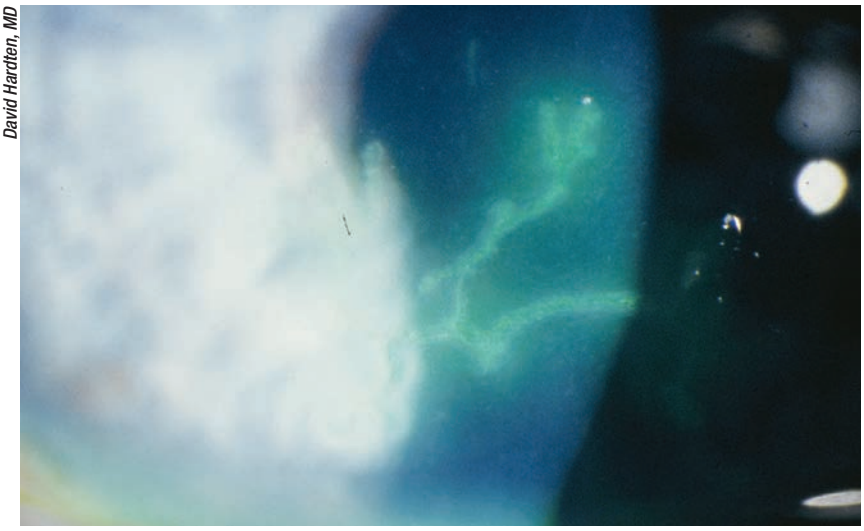
10560 N Ambassador Dr Suite 210
Kansas City MO 64153

tient; the patient must understand that if he gets a viral reactivation after the surgery, it can cause some issues with the vision. The patient must know this ahead of time, so it doesn't look like a complication of the surgery itself."

Some surgeons won't do excimer laser refractive surgery in these patients at all. "LASIK and PRK are elective," says Natalie Afshari, MD, chief of cornea and refractive surgery at UC-San Diego's Shiley Eye Institute. "The epithelium may have a hard time healing with PRK, and with LASIK there can be interface issues, so if a patient has a history of herpes, I won't do these procedures on him." She warns to be careful when doing PTK in certain corneal scar cases. "There are some scars that people don't realize are from herpes, and patients may get PTK to remove them," Dr. Afshari notes. "But then the problem is the epithelium doesn't heal afterward because it was a neurotrophic cornea, with decreased sensation, and the patient's problems can get even bigger. I actually tell my fellows during their exit interview to watch out for those HSV scars—you can't erase them like other scars because they don't have sensation."

In patients that you suspect may have had herpes flare-ups in the past, surgeons say a corneal sensation test can be helpful. "I like to perform it myself," says Dr. Balakrishnan. "I approach the eye from the side with a cotton-tipped applicator on which I've created a thin wisp of cotton by kind of working it with my fingertips. I use that wisp to see if the patient has any sensation. If you're patient, do it correctly by not hitting the lashes, and have a patient who's very focused and can sit still, this test can give you quite a bit of information about the cornea."

Dr. Balakrishnan says she'll consider refractive surgery, but whether she'll do it depends on several factors. "If we're talking about the kind of patient who has had a keratitis as a manifestation of the disease, I'd definitely proceed with caution with an excimer laser, and if someone has a history of recurrent herpetic keratitis, I'd strongly reconsider whether the surgery was a smart idea. But if the patient only had one episode and hasn't had it again for a long time, and it was never corneal, I'd perform it with antiviral coverage (detailed below). My concern with the excimer is, for someone who's had a herpes manifestation, we're really stimulating the tissue with that laser. It seems like the perfect situation for triggering a reactivation."



David Hardten, MD

Surgeons say the time elapsed since the last herpes flare-up and antiviral coverage are keys to minimizing complications after anterior segment surgery in herpes patients.

Dr. Balakrishnan notes that, since these patients may have had corneal involvement during their herpes outbreak, the effects could still be present. "Take the time to really get to know the course of the patient's disease," she says. "Pay attention to the corneal topographies in patients who have had prior herpetic keratitis. If you don't do a corneal map, or don't pay attention to it, these eyes might lead you into thinking that they have astigmatism that requires correction. However, it could be irregular astigmatism or something else that you need to address prior to surgery to enhance the visual outcome. I wouldn't just go by my IOLMaster or Lenstar Ks—I'd definitely perform topography. Before you implant something like a toric IOL, you want to make sure that the patient needs it and has the kind of regular astigmatism that the toric lens can address."

As with most preop regimens, the ocular surface requires attention. However, due to particular aspects of herpes, the surface may need more attention than usual.

"If a patient has a history of herpes keratitis, the corneal sensation will usually be decreased in that eye, and a decrease in corneal sensation can contribute to dry eyes," says Dr. John. "So, if the patient also has some other issue such as ocular-surface disease, you'll have compounding factors at work, all of which can have a deleterious effect on vision even in an otherwise uneventful cataract or refractive surgery. Though you should optimize the ocular surface as you would for any cataract patient, you also have to let them know that the vision post surgery might be affected. This can be due to either the inflammation itself or a reactivation of the herpes, and the postop course can be prolonged, as opposed to just having an uneventful cataract surgery and recovery. Postoperatively, these patients can run into issues with

FEMTOBILITY™ TOUR '18

FLACS
- Clear Corneal Incisions
- Arcuate Incisons
- Anterior Capsulotomy
- Lens Fragmentation

INTERMISSION

Cornea
- 2D and 3D z-LASIK
- Intracorneal Rings
- Instrastromal Pocket
- Lamellar Keratoplasty
- Penetrating Keratoplasty

Play the Femto Z8 Laser's greatest hits at your practice.

No other Femtosecond Laser plays the hits like a rock star Ziemer Z8. And now, during our Femtobility Tour '18, you can try one first hand. We'll train you and your staff, and you'll have plenty of time to see for yourself.

Our compact, mobile and ROI-friendly Femtos are ready to make house calls. So, schedule one at **ziemerusa.com/roadtrip** or contact Wayne Hopkins at **wayne.hopkins@ziemergroup.com** for details.

ziemer

a neurotrophic component that can delay the visual recovery, as well as the recovery of the ocular surface, which can make the patient a little bit less-satisfied with the postop course and visual recovery. So, use non-preserved artificial tears and punctal plugs, and even selective use of amniotic membrane if necessary, depending on the severity of the dry eye.

"The key is getting the patient to understand the potential risk of reactivation and how it could impact his or her daily activities. If their friend had cataract surgery and went back to work quickly, and that's their expectation, but suddenly they experience a herpes keratitis reactivation and have a prolonged postop treatment phase, they may be less than happy with the overall surgical experience. A well-informed patient is of paramount importance when it comes to patient satisfaction and ultimately a happy patient."

Antiviral Prophylaxis

Other than making sure the herpes has been quiet for a while, doctors say the other key to minimizing risk of complications is the use of antivirals.

"If the patient has a history of previous HSV, we often consider giving prophylactic acyclovir or another antiviral preoperatively," says Dr. Afshari. "This would be in the range of 400 mg b.i.d. preop, because of the chance of recurrence. Though not every surgeon administers an antiviral for their cataract patients with a history of herpes, those that do usually start it a week or two before the surgery—though some start a month before. The timing is similar for preop penetrating keratoplasty patients. There really hasn't been a clinical trial to let us know how soon to start. People just use the art of medicine."

Dr. Balakrishnan also bases the antiviral regimen on the intended surgery. "I'd start three to seven days before the procedure with q.d. Valtrex (valacyclovir) 1 g p.o., q.d.," she says. "If I'm a bit more concerned about the patient for some reason, I would use a therapeutic dose of t.i.d. maybe three days before, and continue that prophylactic dosing throughout their postop course. So, for a cataract patient, I'd keep them on prophylactic Valtrex for the entire time they're on topical steroids.

"If the surgery is to be a corneal transplant, because of the risk of herpetic keratitis, I'd probably start the therapeutic Valtrex two or three days before the surgery and continue a 10-day course of it, eventually bringing them down to a preventative dose until I felt comfortable tapering them down to their usual dose of preventative or trying to taper them off of it entirely." She says you can use a more aggressive regimen for patients who've had herpes flare-ups that had devastating visual consequences.

Dr. John describes his approach, which tries to balance the negative and positive effects of the steroids: "With cataract surgery, we use topical corticosteroids to decrease the postop inflammation, but we know steroid drops can contribute to HSV reactivation," he notes. "So, you want antiviral coverage when you use topical steroids. To accomplish this, usually you can use an antiviral medication along with the steroid, drop for drop, until the steroid dosage is once per day. At that point, you can stop the antiviral. Now, it's worth noting that certain antivirals, especially Viroptic, are often harsh to the corneal epithelium. This is especially true when compared to newer antivirals, like the topical ganciclovir 0.15% gel. More importantly, if you're concerned about the quality of the vision with the topical antivirals, you can put the patient on oral prophylaxis using antiviral agents like valacyclovir 500 mg p.o. b.i.d., or acyclovir 400 mg p.o. b.i.d. Currently, for cataract surgery, most surgeons prefer to start the topical corticosteroid drops either three days preop and continue it postop, while others start it one day preop and continue it postop. For prophylaxis in these patients, antiviral coverage with topical drops or oral medication is essential."

The location and severity of the herpes outbreak also play a role when deciding on the drug regimen. "I think stromal/uveitic manifestations are red flags," Dr. Balakrishnan says. "They require a more aggressive regimen. If the patient had a peripheral dendrite that's resolved and has had nothing since, or just had conjunctivitis, to me that's a little bit lower on the scale of worry, if you will. In those less-serious cases, I wouldn't necessarily pursue an aggressive preventative regimen."

Intraoperative Issues

Both the ephemeral threat of a recurrence and the concrete reality of a corneal scar cause surgeons to adjust their intraoperative approach.

"How to proceed intraoperatively depends on what type of herpes manifestation they've had," Dr. Balakrishnan says. "Did they have uveitis? If so, I'd take precautions for the uveitic patient, be careful about CME prevention and, in terms of a cataract procedure, I'd want to be inside the eye for as minimal a time as possible. I want to protect the endothelium in these patients. I'd keep the eye as full of viscoelastic as possible, direct the energy away from the cornea and use gentle maneuvers, and be careful near Descemet's detachments.

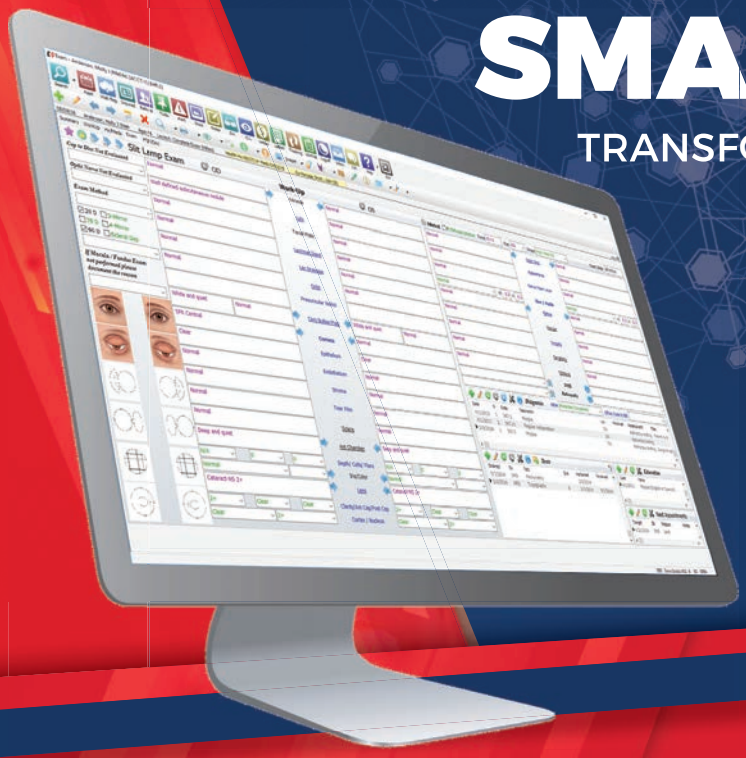
"In terms of incisions, you want them to be nice and clean," he continues. "One thing you want to consider is, if they've been uveitic in the past, you can't do subconjunctival injections. However, you could consider intravitreal injections, if necessary, to prevent CME or a recurrence of a more profound uveitis after you've been inside the eye.

"Regarding scarring," Dr. Balakrishnan adds, "retroillumination is important to do in the office to find

(Continued on p. 106)

SMART IS BETTER

TRANSFORM YOUR PRACTICE WITH ARTIFICIAL INTELLIGENCE



Our Advantage SMART Practice™ suite of All-in-One Solutions use real-time data from your clinic to optimize efficiency, improve outcomes, and increase revenue.

OPHTHALMOLOGY'S
EHR & PM Leader for
33 YEARS

EHR | PM | RCM | ASC | OPTICAL
ANALYTICS | PATIENT ENGAGEMENT
TELEHEALTH | ENTERPRISE PROVEN
2015 ONC CERTIFIED

In partnership with Corcoran Consulting Group

SEE IT LIVE. AAO 2018 ANNUAL MEETING. BOOTH 2232

WWW.COMPULINKADVANTAGE.COM/ONETAB | 800.456.4522

compulink

How to Manage Dislocated IOLs

Michelle Stephenson, Contributing Editor

Treatment depends on the location of the IOL.

Most cataract procedures are performed with no complications. The IOL is placed securely in the capsular bag, and it stays there for the duration of the patient's life. However, in some cases, the IOL can become dislocated to the point where a secondary intervention is required. In this article, expert surgeons share the techniques they use when faced with a dislocated lens.

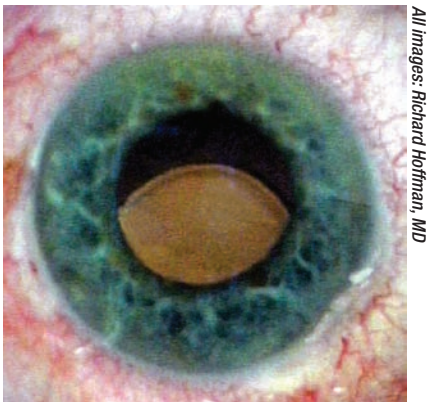
The Scope of the Problem

According to Richard Hoffman, MD, who is in practice in Eugene, Oregon, IOL dislocations can be divided into five categories:

- A lens that's decentered within an intact capsular bag.
- An IOL that's partially subluxed out of the capsular bag: One haptic is in the bag and one haptic is out, or a haptic is in and the optic and haptic are out.
- A lens that's in the sulcus, so there is a compromised capsular bag. The lens is in the sulcus, and that lens is decentered.
- An IOL that's in the capsular bag, and both are subluxed and decentered.
- An IOL that's completely dislocated and is sitting on the retina.

"Each of these can be approached using multiple techniques, so there isn't one best technique for all scenarios," Dr. Hoffman explains.

Uday Devgan, MD, who is in practice in Los Angeles and a professor at UCLA, notes that the operative report from the original cataract surgery can help determine whether there were complications. "Determine if the IOL was placed in the capsular bag, or perhaps in the ciliary sulcus. Loose zonules may have been noted during the original procedure. Was the case uneventful or was there a posterior-capsule rupture? Finally, note which type of IOL was placed and its dioptric power," he says. Videos of how to manage dislocated IOLs can be seen on Dr. Devgan's website: cataractcoach.com.



All images: Richard Hoffman, MD

Figure 1. Sunsetting three-piece IOL placed in the ciliary sulcus.

NEW EYES. NEW DATA. NEW CLARITY.

VISIT US AT AAO BOOTH #2226

Introducing Eyesuite 9 for Lenstar, featuring the exclusive Hill-RBF method now with nearly 4x more eyes in the database.

With expanded boundary models, Eyesuite 9 creates a one-stop shop for toric calculation, fully integrated into the system. This new release now offers three different toric options, for optimal refractive outcomes. And with the Lenstar LS 900 APS (Automated Positioning System), biometry measurements have never been easier or more accurate.

With Eyesuite 9, all eyes are on us. **Learn more at mylenstar.com.**

888-myLENSTAR
myLENSTAR.com

HAAG-STREIT USA

Decentered IOL in the Bag

Some IOLs are decentered but still in the bag. This can occur spontaneously or as a result of trauma. "The classic example of this is pseudoexfoliation syndrome," says Alan Crandall, MD, senior vice-chair of Ophthalmology and Visual Sciences, and director of glaucoma and cataract at the Moran Eye Center at the University of Utah.

For a decentered IOL within an intact capsular bag, Dr. Hoffman says the best approach is to viscodissect the bag open, which can be done many years after the initial surgery, and rotate the lens 90 degrees to center it. This can be accomplished using three or four paracenteses and a 25-gauge LASIK cannula attached to a vial of dispersive OVD. The hardest part of this procedure is getting the anterior capsule lifted off of the IOL optic for OVD injection; once the viscodissection is started, it's fairly straightforward to get the bag completely opened up and get the IOL recentered.

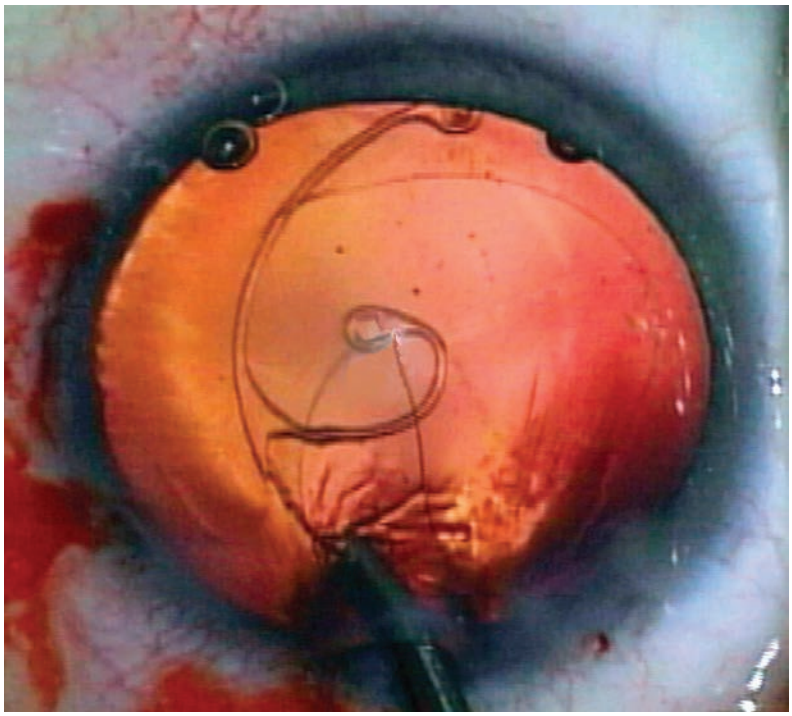


Figure 2. Ahmed segment with 9-0 Prolene suture being placed in the capsular bag following cataract extraction.

Partially Subluxed IOL

If an IOL is partially in the capsular bag and partially out of the capsular bag, Dr. Hoffman says he would viscodissect the bag open and then place the part of the IOL that's outside of the capsular bag within the capsular bag. The same technique described above is used to viscodissect the capsular bag open. The IOL can be rotated and centered if this is required for recentration.

An IOL in the Sulcus

If a three-piece lens is placed in the sulcus without any type of fixation, the lens will stay centered most of the time. On occasion, the IOL will work its way through the zonules and become decentered. "For these lenses, I will iris-fixate them with 9-0 or 10-0 Prolene," Dr. Hoffman explains.

He adds that management also depends on the presentation and type of IOL. If there's a single-piece lens in the sulcus, it typically needs to be replaced with a three-piece lens. "For patients with a subluxed IOL in front of a compromised bag, techniques vary," Dr. Hoffman says. "For example, I was just sent a patient who had a subluxed PMMA lens that was in the sulcus, and the posterior capsule was intact. I'm not sure why the surgeon put the lens in the sulcus. And for that patient, rather than fixate it to the iris or fixate it to the sclera, I was able to create a posterior capsulorhexis and then capture the optic through that rhexis to center it and stabilize it. So, if a patient has a lens in the sulcus and an intact anterior capsulorhexis, sometimes we can use the anterior capsulorhexis to capture and recenter the optic."

Decentered IOL and Bag

In-the-bag posterior chamber IOL dislocations can be managed by exchange with an anterior chamber IOL or by repositioning the posterior chamber IOL.[1]

For the scenario in which the IOL is in the capsular bag and the whole bag has come loose and subluxed, Dr. Hoffman says he will typically fixate the haptics of the IOL to the sclera using 9-0 Prolene.

In these cases, the lens does well for 12 to 14 years after routine cataract surgery, but then starts to sublux because of weakened zonules. "The lens will dislocate," Dr. Crandall says. "How to manage this depends on whether you see the patient before it is completely dislocated. If you see the patient after the lens has dropped all the way back, then you have to include the retinal service in the treatment. However, once the lens is brought up, a number of different techniques can be used to fixate the lens."

Dr. Crandall notes that his treatment of choice depends on the IOL that has been implanted and the patient's vision before surgery. "If the patient's vision was good, the IOL is not damaged and the bag is intact or has a capsular tension ring, I would identify the optic-haptic junction either

TONOMETRY REDEFINED

THE **INTELLIGENT** TONOMETER THE **ACCURATE** TONOMETER THE **CONSISTENT** TONOMETER THE **OBJECTIVE** TONOMETER THE **REPEATABLE** TONOMETER THE **INTELLIGENT** TONOMETER THE **ACCURATE** TONOMETER THE **CONSISTENT** TONOMETER THE **OBJECTIVE** TONOMETER THE **REPEATABLE** TONOMETER THE **ACCURATE** TONOMETER THE **CONSISTENT** TONOMETER

icare HOME

THE PATIENT CHOICE

icare ic100

THE PROFESSIONAL CHOICE

VISIT AAO 2018 **BOOTH #4600** AND MENTION **DEEP DISH** FOR SHOW SPECIAL!

Learn more: *info@icare-usa.com* or *www.icare-usa.com*

intraoperatively or preoperatively," he explains. "I would then mark 180 degrees from that, open up the conjunctiva, clear off back to 3 to 4 mm posterior, and then find the surgical limbus and go 2 mm posterior to that and make an incision into the sclera," he explains.

Then, he makes a lasso, lassoes the lens and the secures it to the sclera with 8-0 Gore-Tex, which is an off-label use, or with 9-0 or 10-0 Prolene sutures. He notes that there are a few different ways to accomplish this. One example is an *ab externo* scleral suture loop fixation technique.[2]

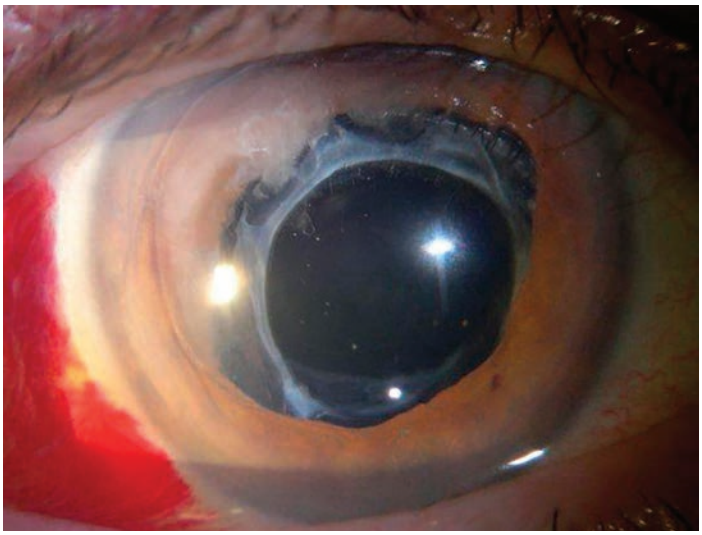


Figure 3. IOL with capsular tension ring subluxed into the anterior chamber following blunt trauma.

Garry Condon, MD, professor of ophthalmology at the Drexel University College of Medicine, Allegheny Program, in Pittsburgh, Pennsylvania, has described a simplified modification to the ab externo suture loop-fixation technique, designed to spare the superior conjunctiva and sclera in patients with significant pseudoexfoliative glaucoma, in case a future filtration surgery is needed.[3]

A description of Dr. Condon's technique: Under anesthesia, he creates a superotemporal 1-mm paracentesis with a diamond blade. Sodium hyaluronate 1% is injected through the paracentesis to provide anterior chamber stability and to keep the vitreous posterior during IOL manipulation. The surgeon then uses a diamond blade to create a 1-mm inferotemporal incision, through which two Grieshaber iris hooks are placed. This enhances temporal visibility of the decentered PC-IOL-capsular bag complex, even with poor pupil dilation.

The surgeon then uses Sharp Westcott scissors to create a 3-mm vertically oriented, temporal, conjunctival and Tenon's capsule dissection 2 mm posterior to the limbus. Then, a diamond blade is used to create a 3-mm, one-third-thickness scleral groove 2 mm posterior to the limbus. Next, at one end of the partial-thickness groove, a single 1-mm, full-thickness stab incision is made through the sclera.

The surgeon then passes a 9-0 polypropylene double-armed suture on a long curved needle (D8229, Ethicon) through the margin of the partial-thickness scleral groove opposite the stab incision, up through the optic-haptic portion of the IOL-capsular bag complex, and out the peripheral cornea. If the needle won't pass easily through the complex, the surgeon can apply counter traction with an intraocular microforceps to ensure successful passage of the needle. Then, a 30-degree iris hook is passed through the full-thickness scleral incision to retrieve the polypropylene suture anterior to the posterior capsule IOL-capsular bag complex.

The surgeon then cuts the needle so the suture can be tied at the scleral groove. To allow subsequent IOL centration, a slipknot is placed, and the same process is repeated at the nasal aspect to secure the fellow optic-haptic portion of the IOL-capsular bag complex. The nasal polypropylene suture needle pass and 1-mm stab incision for suture retrieval counter the temporal sites to prevent IOL tilt. The surgeon adjusts the suture tension on both haptics to center the IOL before securing and burying the knots. A single buried 8-0 polyglactin suture is used to close the conjunctiva. Also, limited 23-gauge pars

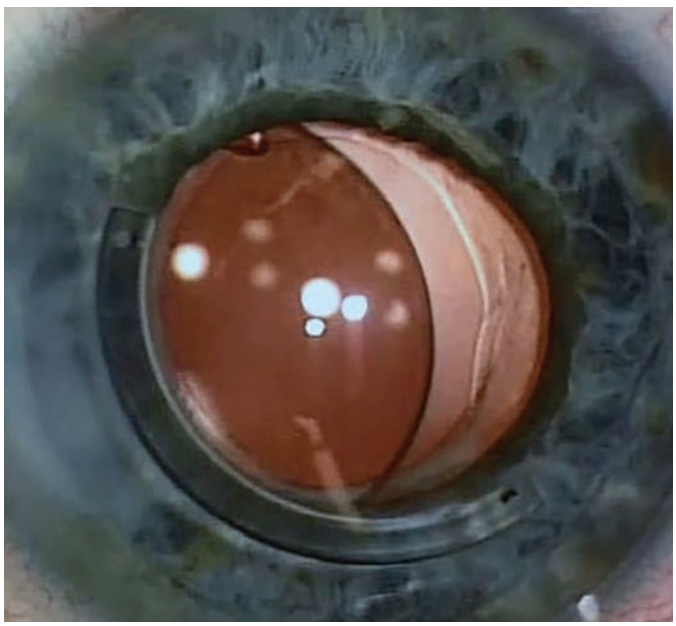
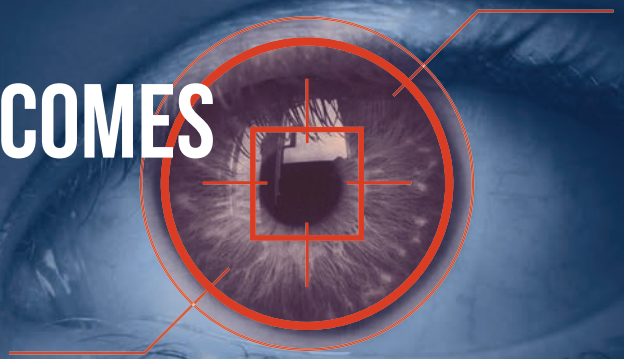


Figure 4. Pseudophakic eye with single intact segment and decentered piggyback IOL requiring iris fixation for recentration.

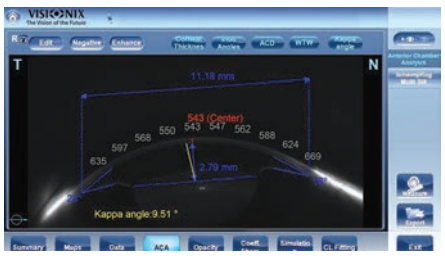
VISIONIX

FOCUS ON
BETTER SURGICAL OUTCOMES



THE POWER OF 3

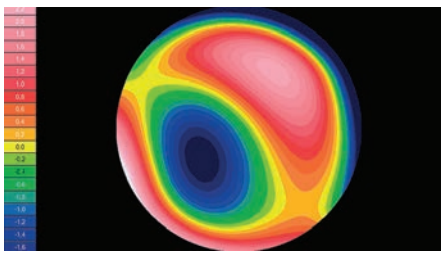
The Visionix VX130+ is the only instrument combining multi-slit Scheimpflug imaging, Shack-Hartmann wavefront aberrometry and Placido Ring corneal topography in a single instrument. This power gives you the most accurate anterior segment analysis available, in just 90 seconds, allowing you to focus on the critical needs of your patients.



SCHEIMPFLUG

- Anterior and posterior corneal surface analysis
- Visualization of crystalline lens opacities
- Angle kappa

+



SHACK-HARTMANN

- Pre-op analysis of wavefront aberrations with the ability to separate corneal and lenticular/internal aberrations
- Post-op check on IOLs
- Axis alignment check on Toric IOLs
- Post-op analysis to improve surgical protocols

+

PLACIDO RING

- Anterior and posterior axial, tangential and refraction maps
- Anterior and posterior keratometry, eccentricity
- Elevation map

DEMO AT AAO BOOTH #3268 1-800-729-1959 | VISIONIXUSA.COM/VX130

Luneau Technology USA
224 James St. Bensenville, IL 60106 - USA - Ph. 800-729-1959 - **www.luneautechusa.com**

Luneau Technology USA

plana vitrectomy either early or at the conclusion of fixation may be necessary, depending on the extent of vitreous involvement with the dislocated IOL-capsular bag complex.

According to Dr. Crandall, another option is to go underneath, the same way as described above, but then dock the lens with a 26- or 27-ga needle inserted through a stab incision 180 degrees away. "Then, you pull that out and reverse it," he says. "This time, you go above the bag and just outside. Both options are easy and fast, and they work very well. Then, you've secured the IOL complex."

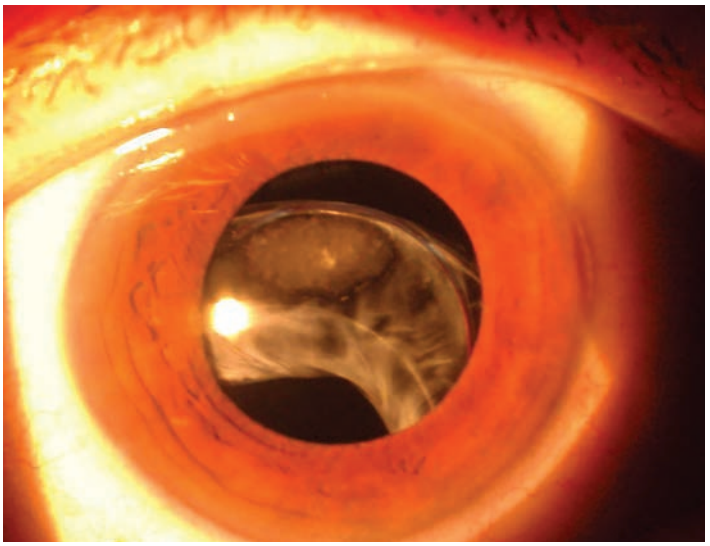


Figure 5. Subluxed IOL/capsular bag/capsular tension ring in a patient with pseudoexfoliation.

However, if the patient's preoperative vision wasn't good or the lens is damaged, the surgeon may need to do a lens replacement. "If it's an older PMMA lens, then you must make an incision that's at least 5, 5.5, or maybe 6 mm depending on the implant," Dr. Crandall advises. "Once the old lens has been removed, you can implant a lens like the Alcon CZ70BD, which is a large PMMA lens that has eyelets on it. You just put the lens in, and you've already got sutures through the eyelets. You pull them out posterior to the limbus. In this case, you've obviously made a large incision that will require sutures. It works well, but it's not the preferred technique because these eyes usually have some other issues, and you're risking glaucoma, infections, et cetera."

IOL Lying on the Retina

In cases where the IOL is completely dislocated onto the retina, Dr. Hoffman coordinates with a retina specialist. "If it was a three-piece lens, the retina specialist would do a vitrectomy and pull the lens up, and then I would iris-fixate it," he says. "But, I don't do that anymore because there's too much iridodonesis and pseudophacodonesis. The lens tends to move around a lot and sometimes causes chronic hyphemas or uveitis. So, in those situations, I now have the retina surgeon bring the lens up into the anterior chamber, and then I remove the lens. Then, I will scleral-fixate a new lens using a scleral incarceration technique. The latest one is the Yamane technique."

The Yamane technique for transconjunctival intrascleral fixation of an IOL was recently prospectively studied in 100 eyes of 97 consecutive patients with aphakia, dislocated IOL or subluxated crystalline lens who underwent posterior chamber sutureless implantation of an IOL.[4] This technique consists of making two angled incisions parallel to the limbus using 30-gauge, thin-wall needles. The haptics of an IOL are externalized with the needles and are cauterized to make a flange of the haptics; then, the flange is pushed back and fixed into the scleral tunnels. The IOLs are fixed with exact centration and axial stability.

Preoperatively, the mean best-corrected visual acuity was 0.25 logMAR units (around 20/35 Snellen), which significantly improved postoperatively to 0.11 (slightly worse than 20/25) at six months, 0.09 (slightly worse than 20/24) at 12 months, 0.12 (20/26) at 24 months, and 0.04 (slightly worse than 20/20) at 36 months.

Mean corneal endothelial cell density decreased from 2,341 cells/mm^2 preoperatively to 2,313 cells/mm^2, 2,240 cells/mm^2, 2,189 cells/mm2 and 2,244 cells/mm^2 postoperatively at six, 12, 24, and 36 months, respectively, and mean IOL tilt was 3.4 ±2.5 degrees. Postoperative complications included iris capture by the IOL in eight eyes (8 percent), vitreous hemorrhage in five eyes (5 percent), and cystoid macular edema in one eye (1 percent). No patients experienced postoperative retinal detachment, endophthalmitis or IOL dislocation.

According to Dr. Crandall, the surgeon should use whatever technique he is comfortable with. "If you have not performed some of these techniques, I think it's a good idea to watch another surgeon do them in person and not just on YouTube, because many subtleties of the techniques are edited out. Many of these subtleties can make the surgery much easier," he adds. REVIEW

1. Gross JG, Kokame GT, Weinberg DV; Dislocated in-the-bag intraocular lens study group. In-the-bag intraocular lens dislocation. Am J Ophthalmol 2004;137:4:630-635.
2. Chan CC, Crandall AS, Ahmed IK. Ab externo scleral suture loop fixation for posterior chamber intraocular lens decentration: Clinical results. J Cataract Refract Surg 2006;32:1:121-8.
3. Kirk TQ, Condon GP. Simplified ab externo scleral fixation for late in-the-bag intraocular lens dislocation. J Cataract Refract Surg 2013;39:3:489.
4. Yamane S, Sato S, Maruyama-Inoue M, Kadonosono K. Flanged intrascleral intraocular lens fixation with double-needle technique. Ophthalmology 2017;124:8:1136-1142.

IF YOUR FEMTOSECOND CATARACT LASER HASN'T EVOLVED,

IT'S PROBABLY EXTINCT

LENSAR Is a Different Breed, With the Broadest Range of Options for Managing Astigmatism and Superior Dependability

The intelligent LENSAR® Laser System with Streamline® IV is highly evolved to help you confidently and precisely manage astigmatism by guiding toric IOL placement and creating arcuate incisions—more options than any other femtosecond cataract laser. Further, LENSAR helps you maximize productivity, with 99.6% laser uptime and 99.4% surgery completion rates.[1] It's survival of the fittest—don't let your technology put you at risk for extinction.

Join the Evolution—Visit LENSAR.com, or visit us at Booth 1539.

Reference: 1. LENSAR, Inc. Data on file.

LENSAR
CATARACT LASER WITH AUGMENTED REALITY

Ergonomics: How Not To Sacrifice Your Body

Liam Jordan, Associate Editor

A guide to healthy, painless (for you) examinations and surgeries.

Ophthalmologists and professional athletes have more in common that you might think. Both need to maintain a level of physical ability, and stay on top of their nutrition, in order to be at their best. And, sometimes, both end up sacrificing their bodies for their professions. However, this doesn't have to be the case for the modern ophthalmologist. In this article, we'll take a look at how to optimize the ergonomics of a practice so that ophthalmologists can continue to perform surgery and diagnose patients without pain.

Preventative Measures

In a paper published in August of 2017, Santosh Honavar, MD, takes a thorough look at what he terms "modifiable risk factors" and some of the main physical struggles an ophthalmologist faces. According to Dr. Honavar, physical strains directly associated with the ophthalmic profession include stress on the shoulders, neck, back, arms and hands resulting from poor posture during examination and surgery. He also identified repetitive actions common to the surgical profession as some of these modifiable risk factors.[1]

One of the potential solutions to these problems is the ergonomic redesigning of workplaces.

Surgeons say there are many measures you can take both in the exam lane and in the operating room to ensure that you're not putting yourself at risk for years of pain and unnecessary stress. According to Dr. Honavar's research, a survey of U.S. ophthalmologists revealed that 52 percent of the 697 respondents reported neck, upper body or lower back pain, with 15 percent having to set aside their work as a result.[1]

John Jarstad, MD, director of cataract and refractive surgery at the University of Missouri School of Medicine, offers his advice on staying comfortable in order to avoid these risks. "As ophthalmologists, we sacrifice our bodies on behalf of our patients, and we have a very high rate of disability and back and neck pain as a result of using awkward angles and positions to complete an exam," he says. "Sometimes we operate at weird angles. In fact, when I was a child, my ophthalmologist had to retire due to low back pain and multiple disc operations.

"Now, thankfully, there are several things that can be done to prevent neck and back injuries," he says. "Those include positioning the microscope at a comfortable angle for yourself in the OR. Another tip is to

This article has no commercial sponsorship.

REVIEW® of Ophthalmology

ENRICH YOUR PRACTICE

Review of Ophthalmology delivers current and comprehensive information focusing on topics such as disease diagnosis, surgical techniques and new technologies.

The *Review* Group's *Ophthalmic Product Guide* brings you the latest products and technology on the market. Published every February and July.

The *Review* Group also distributes a variety of supplements, guides and handbooks with your subscription to *Review of Ophthalmology*. These publications are designed to keep you informed on what's new and innovative in the industry on topics ranging from cataract refractive surgery to ocular surface disease.

The *Review* Group also offers valuable continuing medical education sessions in both print and online formats, allowing a convenient way for you to earn CME credits. In addition, we also offer an impressive fleet of free e-newsletters—such as *Review of Ophthalmology Online* and *Review of Ophthalmology's Retina Online*—so you can keep up to date on breaking news and the latest research.

The *Review* Group offers eyecare practitioners quality informational resources dedicated to the growth and education of the profession. The *Review* Group offers a variety of print and online products to enrich your patient care and practice needs.

The *Review* Group also spearheads meetings and conferences, bringing together experts in the field and providing a forum for practitioners that allows you to educate, and learn from others in the profession. These meetings cover a broad range of topics in the form of educational or promotional roundtables and forums.

www.reviewofophthalmology.com

Jobson Medical Information LLC
The *Review* Group

The surgeon's typical posture during cataract surgery can wreak havoc with his neck and back over time, say physicians.

raise the patient up to eye level where you as a surgeon are comfortable so you don't have to hunch over."

Larry Patterson, MD, medical director of Eye Centers of Tennessee, offers similar advice. "One thing that's really important is raise up the patient's chair so you can move forward as far as you can without leaning forward," he says. "You want to stay in a neutral-spine position. Make the patient move forward, if possible. They're doing it once, but you'll be doing it up to 50 or 60 times a day, so it's better to make the patient strain for a small amount of time so you're not tense all day.

"When I'm doing cataract surgery, I tilt the patient's head about 30 degrees towards me and we tape it in place there," Dr. Patterson continues. "I have my microscope tilted back a bit as well, so I can sit there relaxed, leaning back a bit, and I can remain comfortable during the procedure."

Sandra Woolley, PhD, CPE, ergonomist and expert in occupational safety at the Mayo Clinic in Rochester, Minnesota, says an active doctor is a healthy doctor. "A healthy lifestyle is important," she says. "Set yourself and your equipment up for maximum comfort. Try to avoid non-neutral postures, repetitive activities and reduce your amount of static postures for long periods of time."

Aside from making good, healthy lifestyle choices outside of the office, ophthalmologists also have the opportunity to be more comfortable in their own offices and ORs by adjusting their equipment and office layout. "Make sure the computer monitor is sitting at eye level; hands are on the keyboard at elbow height or slightly lower; and feet are flat on the floor," Dr. Woolley says "For surgery, raise the bed so the patient comes up and you don't have to lean forward; bring the scope up so your head is in a neutral position and there's no backward extension. These may sound like silly little things, but they do add up."

Dr. Patterson also provides some insight into the ergonomics of his practice. "I think it's personal preference," he says. "Just go with what you're most comfortable with. Personally, I don't like those chairs that have back supports. They've just never really worked for me. When you're seeing patients and sitting at the slit lamp one person after another, get a chair and lamp that are comfortable for you."

Dr. Jarstad offers his advice how to get the most out of your equipment. "Be sure to lock your surgeon's chair so it doesn't roll away and cause an unusual posture," he says. "In the clinic, install the thickest carpet your installer has experience with. Then, try to have at least half an inch of pad under your carpet to take the stress off your knees and hip joints. This will help keep your back healthy. I tend to wear shoes with spongy, rubber-based soles and heels. I recommend visiting a podiatrist to get good orthotics or those spongy gel heel insoles for your shoes. This will take the pound-

ONLY

AzaSite®

(azithromycin ophthalmic solution) 1%

Now Available

If you're attending
AAO 2018, visit us at

AKORN BOOTH
#3700

AKORN

ing stress off your back if you have to spend hours walking on wood or hospital-grade linoleum floors each day."

Personal Routines

Aside from the ergonomics of an office, there are plenty of ways for ophthalmologists to stay in shape based on lifestyle choices.

"Like a number of us ocular professionals, growing up, I wasn't a jock," Dr. Patterson says. "We're academics. We're not all football or basketball stars, but I've since realized that I need to take care of myself as if I were an athlete. In med school, I started having back problems. And I would guess that ophthalmologists, by the nature of our work, have a high rate of back and neck problems. I started being more careful, but it wasn't until later in life that I started going to the gym regularly and thinking about nutrition.

"I have a personal trainer now," Dr. Patterson continues. "I get up each morning around 5:40 and meet him at the gym. We work out pretty hard for about an hour. I do that four times a week. I've been a relatively healthy eater, but now I'm trying to take that to another level. I'm 58 years old and I'm probably in better shape than I was when I was 20. It's not just your practice—it's you getting older.

"We as ophthalmologists deal with more older people than most other specialties," he continues. "We see both ends of the spectrum. We see the guy who's 65, smokes cigarettes, is overweight and has diabetes. On the other hand, we'll see a patient who's 80, never smoked, has remained active and was always careful about what he put in his body, and he's in terrific shape. They kind of give you hope looking forward. If anyone can see the effects of how you treat your body, it ought to be us. When you go to the grocery store at 80, you want to be able to walk around instead of being propelled. I have virtually no back issues right now because of these habits."

"You should be as comfortable as you would be at home reading a book. You need to get yourself into that mindset. Just because it's surgery doesn't mean everything has to be stressful."
—Larry Patterson, MD

Dr. Jarstad also weighs in, describing some of the routines he uses to stay on top of his health outside of the clinic. "I'd say, get an ab trainer or sit-up bench," he says. "They can range anywhere from $100 to $2,000. I was doing 400 sit-ups per day, but I've fallen back to 50 to 100 recently. It's important to strengthen your core because that really affects your posture. As you strengthen the opposing muscle group, the back muscles also get into shape. I also recommend walking, cycling, roller blading, skiing and water activities—anything that lets you be active and doesn't feel like a chore. You can enjoy it."

However, if you missed the boat and are already suffering from some sort of pain because of your practice, Dr. Woolley offers her advice. "I would say if you're having discomfort or pain, you need to go to your provider to take care of it at this point," she says. "You need to add stretching and exercise as a component, as well as whatever your physician recommends. Move around regularly. Don't get stuck standing or sitting, and eventually you'll start to feel the results."

Ergonomics vs. Outcomes

As to whether or not efficient ergonomics is related to good outcomes, Dr. Patterson says that ergonomics surely matters during surgery. "I used to have a tendency, when things got tense in surgery, to tighten up my shoulders, causing them to lift up a bit," he says. "It would put a little added stress on me. I would have one of the people in the OR tap me when I did that to remind me to loosen up. In surgery, if you're uncomfortable, whether it's a routine case or if something isn't going very well, I don't think there's any question that if you're stressed, uncomfortable in your back, neck or shoulders, you're not going to perform to the best of your ability.

"I've seen people hunched over their microscopes, and it just looks awkward and uncomfortable," Dr. Patterson adds. "That'll come back to bite them. They're going to have pain eventually if they have a high-volume surgical center. You should be as comfortable as you would be at home reading a book. You need to get yourself into that mindset. Just because its surgery doesn't mean everything has to be stressful."

Dr. Jarstad agrees that poor ergonomics will likely result in poorer results for your practice. "Remember, as an ophthalmologist, you're like a major league baseball or football player," he says. "Those teams provide nutritionists, physical therapists, sports psychologists, masseuses and many other perks to keep those athletes in top form day after day. Shouldn't you do the same?" REVIEW

1. Heads up, heels down, posture perfect: Ergonomics for an ophthalmologist. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5598171/ accessed 13 February 2018.

SURGICAL.

PREPARATION.

The Bruder Moist Heat Eye Compress Goes Beyond the Treatment of Dry Eye Disease

A thorough investigation of ocular surface health and addressing problems proactively are the first steps toward a successful surgery.

Help optimize the ocular surface prior to surgery and improve your surgical outcomes with the easy-to-use Bruder Moist Heat Eye Compress. This innovative therapeutic eye compress helps enhance patient outcomes by improving a compromised tear film layer.

Improve your surgical outcomes by offering the patented Bruder Moist Heat Eye Compress to your patients.

#1

#1 DOCTOR RECOMMENDED MOIST HEAT COMPRESS

Perfect for your Patients. Perfect for your Practice.
Learn more or request a sample at **www.bruder.com/prep**

Bruder Better. By Design.

www.bruder.com | 888.827.8337

Solo Practice: Can You (Still) Go It Alone?

Kristine Brennan, Senior Associate Editor

As PE and consolidation gather momentum, what's the future of the solo ophthalmology practice?

In case you missed it, ophthalmology has caught the eye of private-equity investors. "Even as late as 2016, private equity was just making a few rumblings in ophthalmology. Nobody really knew how prevalent it would become," says Derek Preece, MBA, principal and senior consultant with BSM Consulting in Orem, Utah. "There are market forces driving towards consolidation in ophthalmology, private equity being the primary force. But there are also other forces at work," he says. Does this mean that solo practices are destined to get squeezed out of ophthalmology?

Anjit Nemi, MD, MBA, doesn't think so. He's the owner and sole practitioner at Lotus Eye, where he focuses on cataract, refractive and comprehensive ophthalmology in Alpharetta, Georgia. "I did a combined MD/MBA at Tufts University, and I always had an entrepreneurial spirit," he says. "After finishing my cornea fellowship at Emory, I started work out West in a group practice. Within six months, I found myself not wanting to wake up on Monday mornings to go to work, and I thought, 'I went through 30 years of schooling and training—and I wake up on Mondays feeling this way?' " he recalls. "That forced me to realize that in order to practice the way I wanted to, I was going to have to do things my way. I did look at some practices that were for sale, but I decided that if I really wanted to do this, I'd have to build something from scratch the way I wanted it, rather than trying to rework something that already existed. That's what led me to start my own practice in the fall of 2008."

Mr. Preece notes that the term "solo practice" encompasses more than just the one-doctor model that Dr. Nemi has built. "There are couple of definitions of solo practice," he explains. "One is where you've got one doctor. Another is where you have one ophthalmologist who may have one or two optometrists working for him or her. The third definition of a solo practice is something I call solo ownership: This is where one doctor owns the practice, but might employ four or five ophthalmologists and several optometrists."

Regarding the future of solo ophthalmology practices of all types, Mr. Preece is cautiously optimistic. "Can small, independent practices still survive? Yes, especially in smaller towns," he says. "Many of the private-equity consolidators are mainly focused on big practices in big markets. So first of all, if you're a small practice in a town that isn't a suburb with a big populace, you're still going to be able to see your patients and continue on as you have

Acuity Pro™

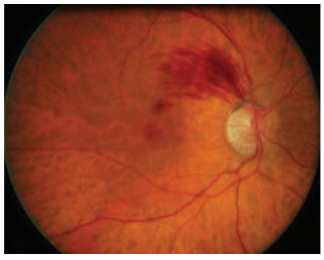
DIGITAL ACUITY SYSTEMS

"Acuity Pro grows with us"

- Vicki Leung, OD

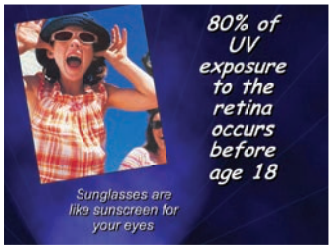
INCREASE REFRACTION SPEED AND ACCURACY

- Instantly change charts and randomize optotypes.
- Instantly switch from multi-row to single row to shorter single row.
- Create macros to customize sequences.



INCREASE SPEED OF PATIENT EDUCATION

Acuity Pro was the first digital chart to incorporate patient education libraries for rapidly switching from acuity testing to patient education. We include 50 common pathology images. You can add as many as you wish.



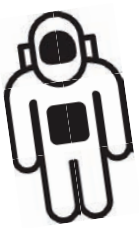
BRAND & MARKET YOUR PRACTICE FROM THE CHAIR

Educate while they wait. Our 200 included practice and product promotion slides are just the beginning. Create custom slides that speak to your patient population and promote your specialties and social media presence.

SLOAN / SNELLEN / NUMBERS / CONTRAST SENSITIVITY / HOTV / ALL ETDRS CHARTS / WHITE ON BLACK OPTION / VIDEO LIBRARY / SINGLE LETTER - SINGLE LINE - MULTI-LINE / 56 KEY CUSTOM REMOTE / MARCO INTEGRATION / INFINITE OR LIMITED RANDOMIZATION OPTIONS / ALL IN ONE SYSTEMS OR SOFTWARE ONLY / FREE SUPPORT/ NO ANNUAL FEES

DISASTER PROOF BY DESIGN - 580.243.1301 / ACUITYPRO.COM

VISIT US AT BOOTH 3167 AT AAO



USED ON BOARD THE INTERNATIONAL SPACE STATION AND IN OVER 20 COUNTRIES ON EARTH

been—albeit with some challenges."

Dr. Nemi notes that he founded his practice in the fall of 2008 surrounded by financial turbulence. "When I started my practice, it was during a time of economic uncertainty," he says. There was the housing-market collapse; the stock market crashed in September 2008. And there was an upcoming presidential election as we headed into a recession. So I was already starting out with the odds stacked against me. I had to build up from one patient a day, and I had to use a 'free' general medical EHR. Having built it up under those circumstances, I feel like my practice was battle-tested from the beginning," he says.

Because he cannot negotiate rates with private insurers in his state as a solo practitioner, Dr. Nemi joined a hospital-based group. In exchange for meeting the group's CME and quality requirements and agreeing to take call for the hospital, he can get the same fee schedule as the hospital's providers.

Anjit Nemi, MD, MBA

What circumstances might set solo ophthalmologists up to fight for their survival? What factors might work in their favor? What battles might lay ahead for solo ophthalmologists? Here are a few points of interest that Mr. Preece identifies, with insights from Dr. Nemi.

Location, Location, Location

Where you are on the U.S. map could determine your practice's future well-being, according to Mr. Preece, who says, "I think small practices are viable, certainly in the smaller towns, and potentially even in larger markets if they're able to keep access to their patients and keep up on technology."

Dr. Nemi, who's located in a large metropolitan area, says that he thrives in a larger market by thoughtfully controlling growth. "Being in Atlanta, I am seeing people acquire practices in other specialties such as gastroenterology and cardiology, for example," he says. "These are practices that had been around much longer than mine, and now they're all hospital owned. The reason I've just gone forward is that my practice is still in a growth phase. I've been able to control the overhead by carefully adding just one employee at a time whenever I thought the time was right. I don't feel compelled to open up multiple offices to make up any overhead or to reach a certain income level. I'm very satisfied with where I am right now.

"One of the reasons that some of these practices have gone to private equity is that some of them had really high overhead, and they saw the opportunity to get shares of PE and early buyout," Dr. Nemi notes. "I may not have that, but I feel like I'm going to be fine if I continue along the path that I'm following."

Finding Successors

Although it's not an issue on Dr. Nemi's radar right now, having your practice remain viable by eventually bringing younger partners aboard may prove difficult if the trend toward consolidation continues apace. "One challenge will be finding a successor doctor. When a doctor with a small practice gets towards retirement age, is he or she going to be able to find a replacement? My feeling is, yes, but it's not going to be as easy as it once was," says Mr. Preece. "The large, consolidated practices are going to be very appealing to young doctors as they exit training with 200-, 300- or 400,000 dollars of debt. The large practices are going to appeal to them because they seem stable and may be able to offer higher starting salaries, although potentially less long-term income. If you're coming out of school with hundreds of thousands of dollars of debt, you're really wondering, 'Am I going to make enough of a salary starting out to service my debt and buy a home and a car?' So there will be some challenges for smaller practices in recruiting doctors."

"My practice is turning 10 years old in October, so I don't think there's a scenario where a larger practice or PE can offer me anything that would be more lucrative than what I'm capable of doing at this point in my career," says Dr. Nemi. He acknowledges that things could've been a lot different when his practice was in its infancy. "For example, let's say I was a new cornea grad from Emory getting ready to start out practice, and larger opportunities had presented themselves."

Although he doesn't entirely rule out one day being pulled into consolidation, Dr. Nemi adds that the prior history of private equity—as related to him by older colleagues—serves as a somewhat cautionary tale. "A scenario could arise where an offer gets placed, saying, 'We like your quality of practice, in terms of the care you provide and your reviews, and we think you'd be a good practice to have in our portfolio: This is what we'd like to

offer you,' " he says. "I could conceive of that as an option, but there were earlier private-equity groups in the late 1990s and early 2000s, and a lot of those fizzled out, so who's to say this isn't another up-and-down cycle?

"I can't personally comment on it, because I wasn't practicing back then," Dr. Nemi continues. "But my dad was a general surgeon, and I do hear from my peers of that generation that when the ACOs and managed-care organizations came to prominence in the 1990s, a lot of people assumed that it was going to be the end of solo practice. But those people who stuck it out independently are still there."

Dealing with Insurers

It's no secret that larger practice groups have more clout with payers, so solo practices are intrinsically more vulnerable with regard to reimbursement. "One scenario where my practice wouldn't be fine is if Medicare were to say, 'We're going to reimburse solo practitioners 300 dollars per cataract, and group practices that meet our criteria in terms of size and accreditation will get the standard rate.' That's one way that I and other solo practitioners could be hurt," Dr. Nemi says.

"If the larger practices are able to get exclusive contracts with private insurance companies and potentially Medicare Part C companies, they might drive smaller practices out of business, because those smaller practices just won't have access to enough patients," cautions Mr. Preece. "A practice in a larger market that's heavily consolidated could lose patient flow—and that's a killer. Small or solo practices may lose patients as they become out of network for their patients, most of whom won't go out of network because they'd end up paying for much or all of the care they need."

Dr. Nemi has found an effective way to mitigate the risk of being stuck with unworkably low reimbursement rates that he says also helps to increase the flow of patients to his office. "With private insurances here in Georgia, if you're a solo practitioner, you cannot negotiate your rate. The people in larger groups can negotiate rates, whereas we're just given the standard rate," he explains. "But now, there are hospital-based groups—which I'm part of—that allow you to have access to the rates that the hospital is able to secure for its physicians. In exchange, you have to maintain certain quality parameters and CME credits. I also take call for some of the local hospitals." He notes that while it may be a bit unusual for a solo ophthalmologist to have a hospital affiliation, doing so accrues another benefit besides better reimbursement rates. "Taking call for the hospital has allowed me to generate greater patient flow into the office via referrals from the primary-care doctors while letting me align myself with an organization that has allowed me to get a better fee schedule," he says.

As Mr. Preece has mentioned above, a dearth of payer contracts, or anything else that stanches the flow of patients, is a practice-killer. What does the flow of patient traffic look like in a healthy practice? Mr. Preece says that it's a careful balance of demand and patient convenience. "In general, when a lot of patients want to see a doctor, that will increase the length of time it takes to get in to see him or her. However, inefficient patient flow and poor scheduling processes can also increase that time, so the lead time to get an appointment isn't always an indicator of a healthy practice," he says.

But as a rule of thumb, he says that he likes to see lead time for new patients that falls within a two-week window. "When a doctor gets his/her schedule consistently booked out further than about two weeks, the chance that new patients will look elsewhere for care begins to climb, so I advise doctors to try to arrange their schedules so they can see new patients within two weeks. Existing patients will tend to be willing to wait a little longer for their appointments," he advises.

"We generally book one week out," says Dr. Nemi. "However, we have an online appointment-booking module on our homepage which allows patients to see any available appointment openings in real time, just in case slots open due to cancellations or rescheduling."

Technical Support

A cash infusion from investors is undeniably helpful when it's time to purchase big-ticket diagnostic and surgical equipment—and the kind of online presence that allows Dr. Nemi's patients to grab open appointment slots. "In addition to having access to successor physicians and access to patients, keeping up technologically is another critical issue for small or solo practices," says Mr. Preece.

"At some point, the larger groups make a pitch to their patients about having the latest and greatest equipment that not everyone else has, and it's not just clinical machines," he continues. "It's IT; it's EMR technology; it's technology for patient portals. It's spending money on kiosks in the waiting room where patients can check in, or it's the ability to check in online. All of these require investment, and small practices will have a harder time making investments in technology. We could add to that personnel, because operating and maintaining some of these things requires personnel. They're going to have a harder time keeping up with technology that over time will become more and more of a prerequisite to keep attracting patients."

Add to this that some insurance companies already require ophthalmologists to have EMR and have strict reporting requirements in order to be on their panels, and the burdens of avoiding penalties and earning bonus-

es under MIPS and MACRA, and solo practices have their work cut out for them. There is also the risk of failing to keep up with federally mandated staff training on HIPAA, for example, simply due to the lack of a dedicated office administrator. "The smaller and solo practices don't have a training staff. Everyone's really busy doing their own job, and as things get more complicated in the ophthalmology space, employee training becomes more important. That's another area where solo practices can fall behind simply because they lack the resources to do all that," says Mr. Preece, whose company offers web-based employee training materials in addition to doing onsite consulting.

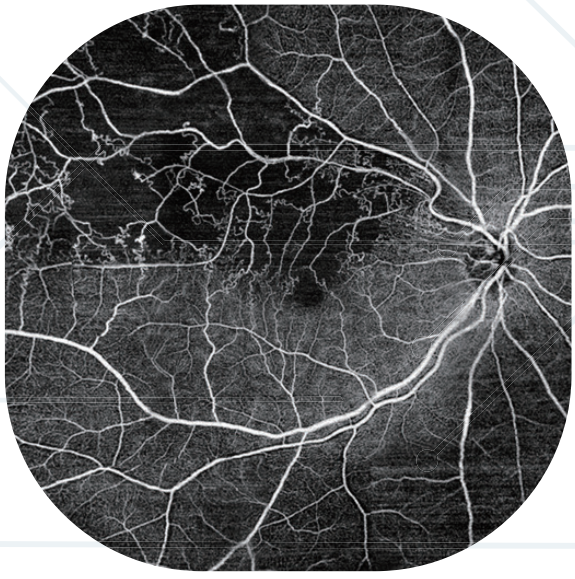
Dr. Nemi says that running a lean practice, by adding key support staff very slowly over time, has helped. "I have four full-time employees and one part time. When I started, it was just one employee besides me, and I've added staff gradually along the way," he says. He also credits choosing a hassle-free EHR system with keeping him on par with larger practice groups. "As a solo practitioner, if you incorporate the right technology, you can even outperform peers in larger practices," he says. "As I do my routine charting, the data on each patient is being extracted, so I'm not spending time after clinic doing administrative work, even though that might seem necessary to keep up with requirements."

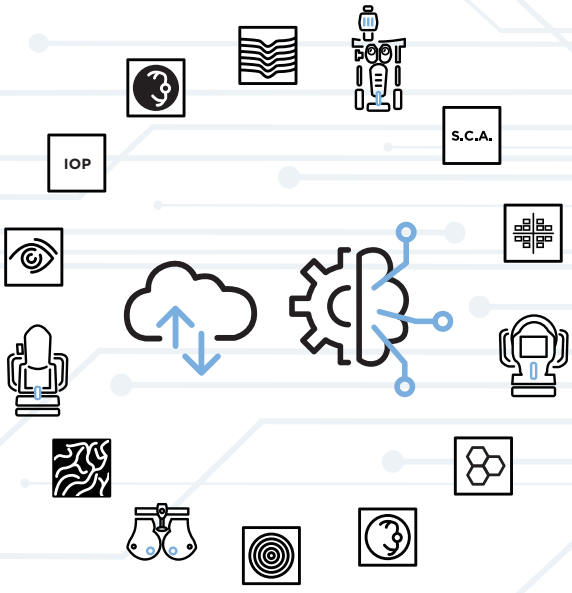
Chief among those requirements are the relatively new MIPS and MACRA reporting requirements. "For Medicare purposes, I think the biggest area to focus on is what was previously called meaningful use, now part of MIPS," Dr. Nemi continues. "The ability to meet those requirements in order to get the appropriate bonuses and to avoid penalties in terms of reimbursement is really a reflection of the type of EHR that you align yourself with. I have colleagues in successful group practices that are still on paper charts, and they're taking a major hit from Medicare in terms of penalties for not meeting meaningful-use requirements."

Although he believes that independent practices may be able to resist the rising tide of consolidation in less-saturated markets, Mr. Preece concurs with Dr. Nemi that EHR adoption is central to keeping up. "Over time, the deficit for smaller practices that haven't, and the gap between them and those that have kept up, will get wider and more expensive to overcome," he says.

Dr. Nemi plans on continuing to keep up, and says he feels no disadvantage when comparing his solo practice with larger ones. "I think that by not succumbing to peer pressure, working hard, taking good care of patients and being mindful of expenses and overhead, it is possible to be productive and profitable as a solo practitioner," he says. REVIEW

JOIN US AT AAO FOR A SYMPOSIUM





INNOVATIONS IN SWEPT SOURCE OCT

This symposium will review the latest clinical and technical advances in **SS-OCT** including the potential of **Artificial Intelligence** in ophthalmology.

Date: SUNDAY, OCTOBER 28

Registration: 5:00 PM - 6:00 PM
Cocktails and Hors d' oeuvres
(Complimentary Registration)

Presentation: 6:00 PM - 7:30 PM

Venue: Marriott Marquis
2121 S. Prairie Avenue Chicago, IL
Room: Great Lakes A & B

Moderator
Richard Spaide, MD
Vitreous Retina Macula
Consultants of New York

Speaker
Aaron Lee, MD, MSCI
eScience Institute University of
Washington Seattle, WA

Speaker
Carl Glittenberg, MD, FEBO
Global Medical Director Topcon Corporation

REGISTER Today!

Online: reviewofophthalmology.com/OCTReception1028
Call : 877-451-6513
Email : ReviewMeetings@jhihealth.com

BROUGHT TO YOU BY
REVIEW of Ophthalmology

SPONSORED BY
TOPCON UNIVERSITY

*OCT Angiography Image courtesy of Professor Yuichiro Ogura, Nagoya City University, Japan

Left your *Review of Ophthalmology* magazine at the office? No problem!

Read *Review* on the go from any mobile device!

Simply go to www.reviewofophthalmology.com and click on the digimag link to get your current issue.

Point/Counterpoint:

Intracameral Vancomycin and Cataract Surgery

Point: Intracameral vancomycin during cataract surgery is not a good choice for endophthalmitis prevention.

Harry W. Flynn Jr., MD, Anthony D. Anderson, PharmD, BCPS, and Stephen G. Schwartz, MD, MBA, Miami and Naples, Florida

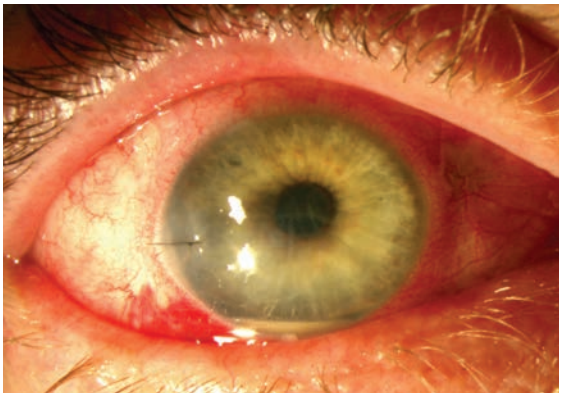
In 1995 the Centers for Disease Control and Prevention stated that vancomycin should not be used as prophylactic antibiotic; instead, it recommended that vancomycin be reserved for life-threatening or organ-threatening infections.[1] Despite that statement, vancomycin has been increasingly used in various specialties of medicine during and after surgery as prophylaxis. This was especially true a few years ago, but since then the use of prophylactic vancomycin has fallen in the United States. The majority of countries are not currently using intracameral vancomycin[2] because ophthalmologists recognize the potential complications (TASS, incorrect preparation, cystoid macular edema and contamination).

Other reasons that intracameral vancomycin is not a good choice for antibiotic prophylaxis include:

• ***The rates of endophthalmitis without the use of intracameral antibiotics are very low.*** In fact, many studies have shown that those rates continue to decrease, thanks to the increasing skills of cataract surgeons, mandatory policies and procedures for sterile technique and preparation, and better intraoperative management of complications.[3]

• ***Intracameral antibiotics are not a panacea.*** In our own experience, we've seen a number of endophthalmitis cases over the past few years occurring after cataract surgery using intracameral antibiotics. Admittedly, these cases often involved moxifloxacin, which requires preparation by a compounding pharmacy. Also, moxifloxacin provides relatively poor coverage of *Staphylococcus*.[4]

• ***Widespread vancomycin use may contribute to the selection and development of vancomycin-resistant organisms.*** One of the consequences of the increasing utilization of vancomycin as a prophylactic agent in medicine is that there's been a worldwide increase in vancomycin-resistant organisms, which in turn has brought about the need for antibiotic stewardship programs in the United States and other countries.[5,6] To date, the widespread use of antibiotics in agriculture has been considered the primary source of increased antimicrobial resistance; there are no reported studies regarding the impact of intracameral or topical ophthalmic antibiotics on increased antibiotic resistance. Nevertheless, it's well known that the MIC-90s of gram-positive organisms have been increasing, impacting our ability to effectively treat gram-positive infections with vancomycin. Meanwhile, our patients may face life-threating infections which require vancomycin. For these reasons, the CDC has pressured hospitals and outpatient surgical centers to monitor and report their antibiotic usage, with added pressure from the



Endophthalmitis prevention is one key to successful cataract surgery. Some surgeons believe that the use of intracameral antibiotics adds more risk than benefit.

This article has no commercial sponsorship.

Centers for Medicare and Medicaid Services.

• ***Intracameral vancomycin increases costs to the health-care system.*** It is estimated that there are approximately 3 million cataract surgeries performed per year in the United States. The exact cost to the health-care system of using intracameral vancomycin is unknown, but those costs go beyond the cost of the drug itself to include the procurement, preparation, storage and distribution of the antibiotic. There's no question that these preparations add to the cost of surgery and require additional time for administration and documentation.

• ***There is currently no FDA-approved, ready-to-use intracameral antibiotic product in the United States.*** Outside the United States, there is an approved product containing cefuroxime, which has gained popularity in Europe and elsewhere. However, this antibiotic doesn't cover methicillin-resistant *Staphylococcus aureus* or methicillin-resistant *Staphylococcus epidermidis.* This product will not cover approximately 40 to 50 percent of *Staphylococcus* infections.

• ***Intracameral vancomycin can cause hemorrhagic occlusive retinal vasculitis.***[7,8] The most compelling argument against intracameral antibiotics is the risk of HORV. This devastating condition can occur at one week or more following uncomplicated cataract surgery and may result in extensive inflammatory vasculitis, frequent retinal detachment and generally very poor visual acuity outcomes. For this reason, the combined committee of the American Society of Cataract and Refractive Surgery and the American Society of Retina Specialists recommended caution with the use of intracameral vancomycin during cataract surgery, as noted in a report by Andre J. Witkin, MD et al. That report stated: "Surgeons should continue to weigh the relative merits of prophylactic intraocular antibiotic use in preventing endophthalmitis, with the additional knowledge that intraocular vancomycin is associated with HORV, a rare but potentially devastating disease. In addition, surgeons using vancomycin prophylaxis with sequential cataract surgery should be aware that in addition to delayed onset of symptoms up to three weeks, HORV may be asymptomatic in the first eye and a dilated fundus examination may be the only way to detect it. The risk of bilateral HORV therefore is higher if close sequential or immediate same-day bilateral surgery is performed."[7]

Most patients count on their cataract surgeon to make the correct decisions regarding their surgery. The entire issue of intracameral antibiotics is controversial, not just regarding vancomycin but with other antibiotics as well. There are significant complications associated with the use of any of these antibiotics. Our patients expect a perfect outcome, and in my opinion, the use of intracameral vancomycin increases the risk of adverse events during or after a procedure that already has a very low rate of endophthalmitis.

Dr. Flynn is the J. Donald M. Gass Distinguished Chair of Ophthalmology at the Bascom Palmer Eye Institute, University of Miami, Miller School of Medicine. Mr. Anderson is clinical pharmacist-infectious diseases consultant/antimicrobial stewardship director for the Sylvester Comprehensive Cancer Center at Bascom Palmer. Dr. Schwartz is a professor of clinical ophthalmology and medical director at Bascom Palmer.

Dr. Flynn and Dr. Anderson have no relevant financial disclosures. Dr. Schwatrz has previously received funding from Alimera and Welch Allyn not directly related to this topic.

1. CDC Bulletin. CDC issues recommendations for preventing spread of vancomycin resistance. Am J Health Syst Pharm 1995;52:12:1272-4.
2. Grzybowski A, Schwartz SG, Matsuura K, et al. Endophthalmitis prophylaxis in cataract surgery: Overview of current practice patterns around the world. Curr Pharm Des 2017;23:4:565-573. doi: 10.2174/1381612822666161216122230. PMID: 27981903.
3. George NK, Steward MW. The routine use of intracameral antibiotics to prevent endophthalmitis after cataract surgery: How good is the evidence? Ophthalmol Ther 2018 Jul 5 doi: 10.1007/s40123-018-0138-6. [Epub Ahead of Print].
4. Stringham JD, Relhan N, Miller D, Flynn HW Jr., Trends in fluoroquinolone nonsusceptibilities among coagulase-negative Staphylococcus isolates causing endophthalmitis, 1995-2016. JAMA Ophthalmol 2017;135:7:814-815. PIMD: 28617914. doi: 10.1001/jamaophthalmol.2017.1826.
5. Relhan N, Albini TA, Pathengay A, et al. Endophthalmitis caused by gram-positive organisms with reduced vancomycin susceptibility: Literature review and options for treatment. Br J Ophthalmol 2016;100:446-452. PMID: 26701686.
6. Relhan N, Pathengay A, Schwartz SG, Flynn HW Jr. Emerging worldwide antimicrobial resistance, antibiotic stewardship and alternative intravitreal agents for the treatment of endophthalmitis. Retina, Journal of Retinal and Vitreous Diseases 2017. 37:5: 811-818. DOI: 10.1097/IAE.0000000000001603. PMID: 28338559.
7. Witkin AJ, Chang DF, Jumper JM et al. Vancomycin-associated hemorrhagic occlusive retinal vasculitis: Clinical characteristics of 36 eyes. Ophthalmology 2017;124:5:583-595. PMID: 28110950.
8. Todorick B, Faia LJ, Thanos A et al. Vancomycin-associated hemorrhagic occlusive retinal vasculitis: A clinical-pathophysiological analysis. Am J Ophthalmol 2018;188:131-140.

Counterpoint: Intracameral vancomycin during cataract surgery is a good choice for endophthalmitis prevention.

Richard J. Mackool, MD, Astoria, New York, and Paul Ernest, MD, Jackson, Michigan

The use of an intracameral antibiotic during cataract surgery is now generally recognized as effective in reducing the incidence of postoperative endophthalmitis. Selection of the antibiotic however, requires analysis of both the efficacy of the drug as well as its safety profile. Simply put, we need to know the

OISX | OPHTHALMOLOGY INNOVATOR AWARDS DINNER GALA

WEDNESDAY, OCTOBER 24TH, 2018

MARRIOTT MARQUIS CHICAGO | CHICAGO, ILLINOIS

Over the past decade, OIS has been bringing together key leaders to collaborate and foster the development of ophthalmic innovation. To celebrate the history of OIS and to commemorate the 10th anniversary of the inaugural summit, the ophthalmology community is invited to come together and help us recognize those who have made a significant impact on innovation.

To attend the OISX Dinner Gala – complimentary with your OIS@AAO registration – visit www.ois.net/awards.

VOTE | PARTICIPATE | CELEBRATE

WWW.OIS.NET/AWARDS

TABLE I: Intracameral Antibiotics and Post-Cataract Endophthalmitis

Intracameral Antibiotics	Endophthalmitis Incidence
none	1:1,400[1]
cefuroxime or fluoroquinolone	1:5,000[1,2]
vancomycin	0:140,000[3]

relative morbidity associated with the use of the current antibiotic options—one of the fourth-generation fluoroquinolones (i.e., moxifloxacin, cefuroxime or vancomycin).

Here is a summary of what we know about intracameral antibiotics and endophthalmitis:

1. If an intracameral antibiotic is not used, the incidence of endophthalmitis is about 1:1,000 eyes;[1]

2. If either intracameral cefuroxime (ICC) or intracameral moxifloxacin (ICM) is used, the rate of endophthalmitis incidence declines to about 1:5,000;[1,2]

3. If intracameral vancomycin (ICV) is used, the incidence of endophthalmitis is astonishingly low. At our ASCs, we now have performed 140,000 consecutive cataract procedures with ICV, and have had no cases of endophthalmitis.[3] (Table I, above, summarizes this data.)

There are other factors to be considered in order to objectively compare morbidities with the available ICA options. These include:

• ***Vancomycin can cause HORV.*** Approximately 65 percent of eyes that develop HORV will have a final visual acuity of 20/200 or worse.[4] At our ASCs, we have identified two eyes with HORV in 140,000 consecutive cataract procedures. We therefore estimate the incidence of HORV to be approximately 1:70,000 eyes. If, as reported, 61 percent of these eyes will have a final visual acuity of 20/200 or worse, the incidence of final visual acuity of 20/200 or worse from HORV after ICV is 1:115,000.

• ***Approximately one out of three eyes developing endophthalmitis will have a final visual acuity of 20/200 or worse.***[1,5,6] The incidence of final visual acuity of 20/200 or worse from endophthalmitis after ICC or ICM is therefore approximately 1:15,000 eyes. (Table II, below, summarizes this data.)

The analysis, however, is a bit more complex. To wit:

1. Approximately 1 percent of patients may be allergic to cefuroxime or fluoroquinolones, and the administration of either drug to these patients may cause TASS. We are aware of a significant number of such cases occurring in a large U.S. cataract practice that began using intracameral moxifloxacin. Patients may not know that they are allergic to these medications, or may report an allergy to a second-generation fluoroquinolone which may be overlooked by medical personnel when planning surgery. Patients who have had an allergic reaction to vancomycin almost always report this when questioned.

2. The most common organism causing endophthalmitis is *Staphylococcus*, and this organism has demonstrated the ability to develop resistance to previous fluoroquinolone preparations. Because these drugs are commonly administered systemically, it's likely that the incidence of bacterial resistance to fourth-generation fluoroquinolones will increase. (NOTE: The concern that intracameral administration of any antibiotic will promote the development of resistance is unfounded. The latter requires continued antibiotic administration, a microbiologic fact that is widely recognized by experts in that field.)

3. In a similar vein, it's possible that the incidence of HORV may be increasing. The development of methicillin-resistant *Staphylococcus aureus* has resulted in the greater use of vancomycin by other specialists, and the population of sensitized patients may therefore be increasing. However, although cefuroxime and fluoroquinolones haven't been associated with HORV, cefuroxime has been associated with leukocytoclastic vasculitis in the skin, as has vancomycin. It may therefore be possible for cefuroxime to cause HORV.

4. Medicolegal concerns exist as a result of an FDA warning concerning the development of HORV after ICV. However, neither the FDA nor our national organizations (the American Society of Cataract and Refractive Surgery, and the American Academy of Ophthalmology) has recommended that vancomycin not be used for endophthalmitis prophylaxis, despite the fact that some ophthalmologists have published this opinion. We do not believe that legal concerns should carry any weight in these decisions. The best interest of our patients must always be our primary concern, and we are certain that our colleagues agree.

5. Bilateral HORV has occurred, and the consequences can obviously be catastrophic. This can be avoided, however, by delaying second-eye surgery for at least two weeks and by performing either a peripheral retinal examination or peripheral retinal

TABLE II: Visual Acuity of 20/200 or Worse Following Endophthalmitis after Intracameral Antibiotics

no intracameral antibiotics	1:3,000
cefuroxime or fluoroquinolone	1:15,000
vancomycin	1:93,000

photography on the first eye prior to surgery on the second eye.

6. There is some evidence that HORV may be dose related. In our series of 140,000 patients receiving ICV, administration was generally divided into three methods. Approximately 50,000 patients received ICV by the addition of 40 mg of vancomycin to the 500-cc BSS infusion source. Approximately 80,000 patients received vancomycin by the addition of 10 mg of the drug to 500 cc of BSS and injection of 1 mg of vancomycin into the anterior chamber at the conclusion of the procedure. An additional 10,000 eyes received vancomycin by the addition of 30 mg of the drug to 500 cc of BSS infusion solution. As stated above, none of these patients developed endophthalmitis.

In summary, an objective assessment of the morbidity associated with ICA, using a final visual acuity of 20/200 or worse as our marker, would indicate that the morbidity associated with ICV is significantly less than that associated with ICC or ICM. However, as with all things in medicine—particularly in the area of medications such as antibiotics—the development of increased antibiotic resistance and patient sensitivities must be carefully monitored, and prophylactic ICA administration adjusted accordingly. REVIEW

Dr. Mackool is medical director at The Mackool Eye Institute and Laser Center and senior attending surgeon at the Mt. Sinai New York Eye and Ear Infirmary and New York University Medical Center. Paul H. Ernest, MD, is an innovator, lecturer, author and laser-cataract surgeon at Specialty Eye Institute with 10 offices in Michigan and Ohio. He has performed more than 70,000 cataract surgeries and was the first to use the femtosecond laser for cataract surgery in Michigan. Neither Dr. Mackool nor Dr. Ernest has any relevant financial disclosures.

1. ESCRS Endophthalmitis Study Group. Prophylaxis of postoperative endophthalmitis following cataract surgery: Results of the ESCRS multicenter study and identification of risk factors. J Cat Refr Surg 2007; 3: 978-988.
2. Haripriya A, Chang DF, Ravindrian RD. Endophthalmitis reduction with intracameral moxifloxacin prophylaxis: Analysis of 600,000 surgeries. Ophthalmology 2017;124:6: 768-775.
3. Mackool R, Ernest P, unpublished data.
4. Witkin AJ, Chang DF et al. Vancomycin associated hemorrhagic occlusive retinal vasculitis. Ophthalmology 2017;124:5:583-595.
5. Al-Mezaine HS, Kangave D, Al-Assiri A, Al-Rajhi AA. Acute-onset nosocomial endophthalmitis after cataract surgery: Incidence, clinical features, causative organisms, and visual outcomes. J Cataract Refract Surg 2009;35:4:643-9.
6. Pathengay A, Flynn HW Jr, et al. Endophthalmitis outbreaks following cataract surgery: Causative organisms, etiologies, and visual acuity outcomes. Journal Cat Refr Surg 2012;38:7:1278-82.

Astigmatism: How Low Can You Go?

Kristine Brennan, Senior Associate Editor

Surgeons discuss the drive to zero astigmatism in cataract surgery.

Surgeons differ as to whether zero astigmatism is a feasible—or even uniformly desirable—goal of cataract surgery. Here, experienced surgeons discuss whether, when and how to pursue zero astigmatism in the setting of cataract surgery.

Arun Gulani, MD, founding director and chief surgeon of the Gulani Vision Institute in Jacksonville, Florida, thinks that although astigmatism can be useful in select cases, surgeons should strive to eradicate it most of the time."The attitude of the surgeon should be intolerant to astigmatism at any level. There's no such thing as a tolerable factor over zero," he states. "Not reaching that zero point is human, and could be an honest mistake or just arise from natural variations in healing between patients. But to not aim for it is unacceptable in this day and age."

Dr. Gulani, who teaches about astigmatism elimination in cataract surgery in the United States and abroad, adds that a substantial part of his practice involves correction of complications and providing second opinions for patients who've already undergone laser vision correction or premium cataract surgeries. "Astigmatism has been the most common residual refractive error that I've seen that could have been corrected by the surgeon," he says. "In recent studies, it's been documented to be the biggest reason for dissatisfaction following successful premium cataract surgery. It's also an element that can easily be corrected, but results in unhappy patients and disturbs patient/doctor relationships."

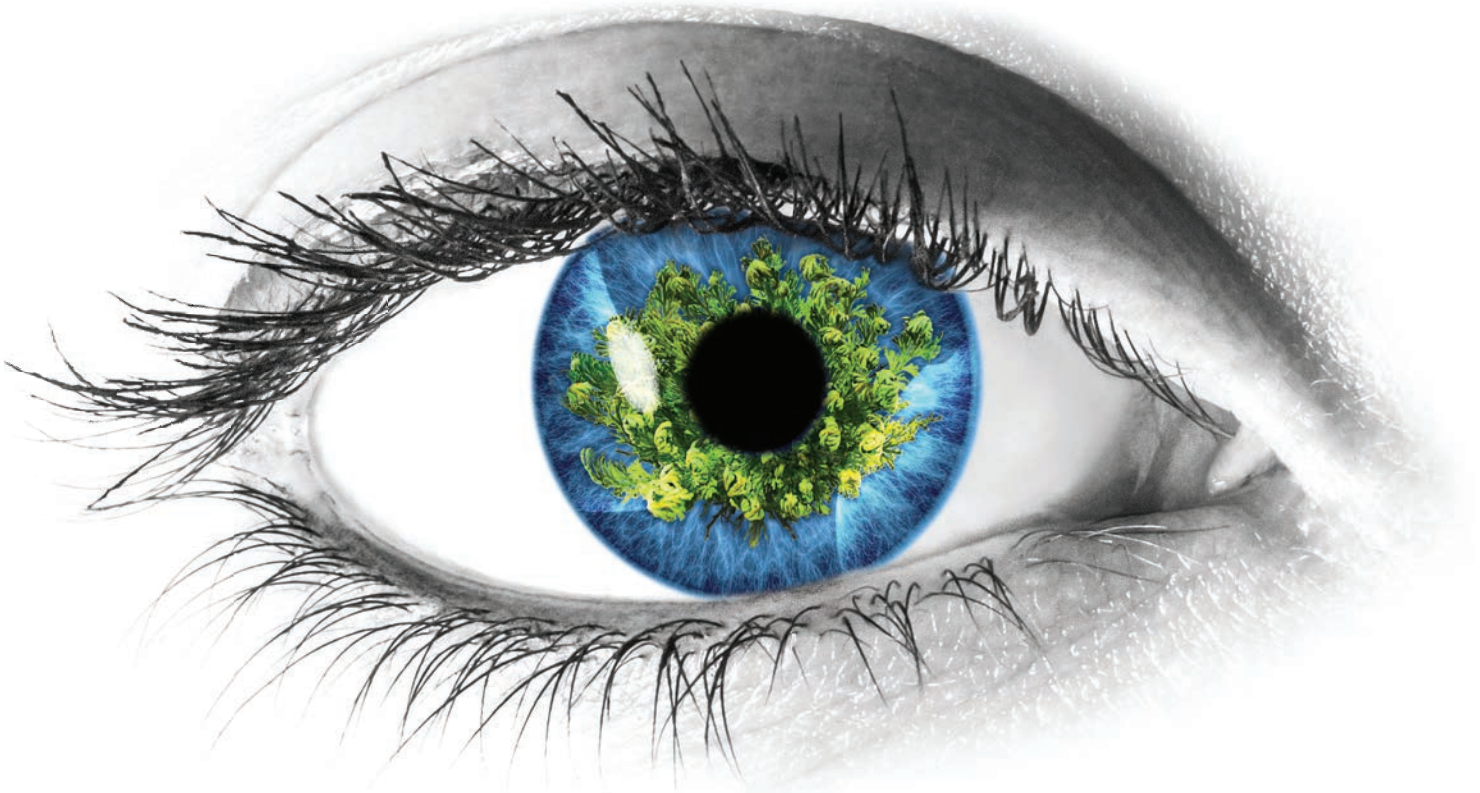
"Can we approach zero? Sure, but we can't guarantee zero," opines Natalie A. Afshari, MD, FACS, professor of ophthalmology and chief of the division of cornea and refractive surgery at the Shiley Eye Institute, University of California, San Diego, who thinks that promising zero astigmatism gives rise to unrealistic patient expectations.

Like Dr. Afshari, Jeremy Kieval, MD, a partner and director of cornea, cataract and refractive surgery at Lexington Eye Associates in Massachusetts, who also serves as an instructor of ophthalmology at Harvard Medical School, says that minimizing astigmatism as much as possible is important; but he also thinks we're too far from understanding all the potential contributing factors to completely eliminate it every time. "I think there are many factors, like dry-eye disease and age-related changes in the cornea, as well as postoperative changes and capsule contraction.

This article has no commercial sponsorship.

new!

thera tears EXTRA



HARNESS EXTRA POWER FROM A NATURAL WONDER

NEW TheraTears® Extra Dry Eye Therapy is **enhanced with trehalose** for superior relief

Trehalose is a natural disaccharide found in plants with moisture retention properties that help organisms survive in absence of water. In ophthalmic products, trehalose enhances active ingredients to help[1]:

- Protect corneal cells from desiccation
- Restore osmotic balance to the ocular surface
- Maintain the homeostasis of corneal cells

-2017 DEWS II Report

Learn about our complete line of dry eye therapy products at **theratears.com**

Reference: 1. Jones L, Downie L, Korb D, et al. TFOS Dews II Management and Therapy Report. The Ocular Surface Jul 2017; 575-628.

Additionally, the implanted lens creates some element of tilt. All of those things will contribute just minimally—a quarter- or a half-diopter—to astigmatism. I think that to really get down to zero, there will need to be a lot more understanding in terms of corneal biomechanics, dry-eye disease treatments, basement membrane dystrophy management and lens stabilization after cataract surgery. But, all those things being said, I think that the drive towards minimal astigmatism is absolutely reasonable and achievable," he says.

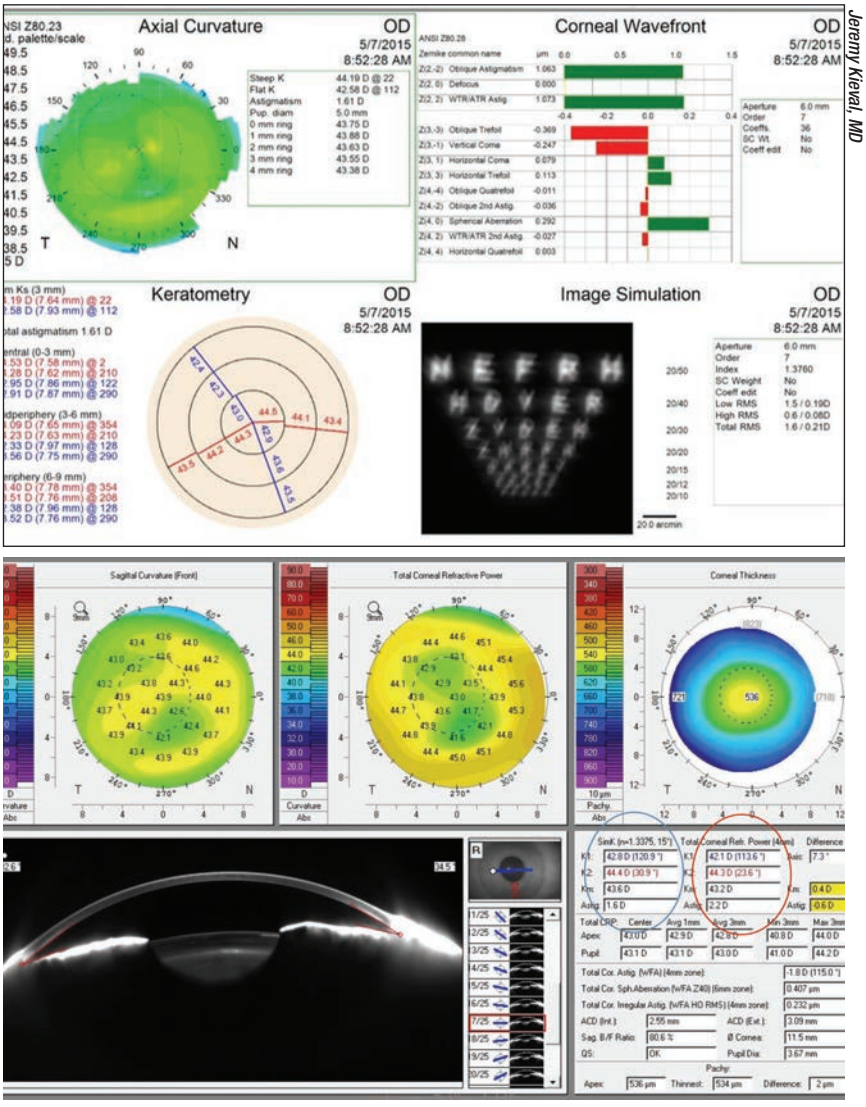
Is Astigmatism Always Bad?

Dr. Kieval adds, however, that the drive towards zero astigmatism may have a downside: forgetting those cataract patients who have successfully adapted to their astigmatism. "I've read articles over the years saying that zero astigmatism should be the standard of care," he says, "but I think that's a dangerously slippery slope when there are some elements of astigmatism that can be beneficial for patients.

"For example, you might have a patient with essentially zero spherical equivalent and 0.75 to maybe 1.25 D of astigmatism," Dr. Kieval continues. "Sometimes patients who have a zero spherical equivalent, but also a small amount of defocus from astigmatism, really love the effect that they get from their astigmatism, without understanding what it's doing and why. Many of these patients are able to read reasonably comfortably at a computer or even at nearer distances because of the depth of focus that they're getting from their astigmatism. Obviously, there are benefits to correcting it, but there are sometimes benefits to leaving it alone."

Dr. Kieval looks at the spectacle wear of patients with zero spherical equivalent and a little astigmatism to determine which ones might appreciate more aggressive astigmatism treatment. "Sometimes the way I determine which ones will do better with the correction and which ones won't is to ask, 'Do you wear glasses?' If they say, 'I never really wore glasses, but sometimes I'll put on a pair of reading glasses.' That tells me they're utilizing their astigmatism to get some depth of focus. If you correct that patient's astigmatism to zero, they may say, 'My distance vision is better, but I can't read anymore or see things up close like I used to,' and they might really be upset about that. The drive to zero astigmatism may not be the best thing for that particular patient," he explains. "The patient who has the same refractive error but says, 'I always wear glasses because my vision is blurry,' is the patient for whom I'll correct that astigmatism. They're going to do great, and they'll love it."

Daniel H. Chang, MD, of Em-



Jeremy Kieval, MD

Corneal topography (top) shows approximately 1.6 D of astigmatism. Scheimpflug imaging (bottom) shows that the simK (blue circle) agrees with the topography, but that the total corneal refractive power (red circle) measures 2.2 D of astigmatism, having accounted for the posterior corneal surface. Considering only the anterior corneal surface's contribution to astigmatism would have resulted in at least 0.6 D of astigmatism left uncorrected.

pire Eye & Laser Center in Bakersfield, California, isn't convinced that patients benefit from any amount of astigmatism. "Although it's commonly suggested that uncorrected astigmatism can help with near vision, I do not use this as a viable clinical strategy for improving depth of focus," he says. "Nevertheless, I'm not afraid to leave a little with- or against-the-rule astigmatism. I find that patients who are unhappy with their uncorrected visual acuity generally have a diopter or more of astigmatism at any axis: It is not a matter of whether 0.25 or 0.5 D of astigmatism lies in the original axis. Therefore, I generally shoot for zero astigmatism, whether it's with or against the rule; and I'm okay with flipping the axis for less than 0.5 D of astigmatic power. After all, the refractive variability of manifest refractions is around 0.4 D."

Dr. Kieval always strives for zero astigmatism for one segment of his patients. "Patients who are seeking correction with toric lenses, premium IOLs like presbyopia-correcting lenses and EDOF lenses are the patients we should all absolutely be striving to correct to zero astigmatism—or as close as possible, considering the limitations that exist," he stresses. "Obviously, those patients are paying a premium and they expect a premium level of vision. Presbyopia-correcting lenses can cause some loss of modulation transfer function and a loss of contrast sensitivity that can be worsened by any residual astigmatism. If their residual astigmatism is zero, they're going to get better contrast than if their residual astigmatism is 0.5 D. Is that going to be perceptible? Maybe not. But you want to give patients receiving those types of implants every benefit by striving for the best visual acuity they can have," he says.

Preop Workup

Just as a thorough preoperative workup is necessary to choose an IOL with the proper spherical power, it's also critical in order to treat astigmatism successfully. Many surgeons turn to corneal topography. "First we do refraction. Then we also do a corneal topography with Scheimpflug imaging using the Pentacam (Oculus)," explains Dr. Afshari. "That lets us see how much corneal astigmatism is there: Is it the regular bow-tie pattern, or is it irregular? The third step we do is an astigmatism check. We do an axial-length measurement and get the keratometry values during the preoperative visit."

Scheimpflug imaging is also crucial to Dr. Kieval's astigmatism treatment planning. "I rely heavily on Scheimpflug imaging for both magnitude and axis of astigmatism. I use the Pentacam, and I like the true net corneal power feature because it looks at the whole cornea by incorporating the posterior aspect of the astigmatism," he says. "But I obviously don't want to take measurements in a vacuum, and I want to see consistency between measurements. I look at topography primarily for the axis, to ascertain that there is a pattern of astigmatism. Our technicians do biometry, including manual keratometry. I just look for consistency, and as long as I see consistency, I tend to rely on the Scheimpflug imaging for magnitude and axis. The true net power is really the data point that I use to calculate the magnitude and axis, provided that it's consistent with my other measurements."

Dr. Gulani thinks that surgeons should use all of the modalities at their disposal to assess astigmatism as part of a comprehensive workup. "Before surgery, it's important to measure the astigmatism by refraction, keratometry, topography, wavefront, ray tracing, OPD or whatever technology is available to the doctor—even all of them if they're available—to ensure that the power and axis of astigmatism are as accurate as they can be," he says.

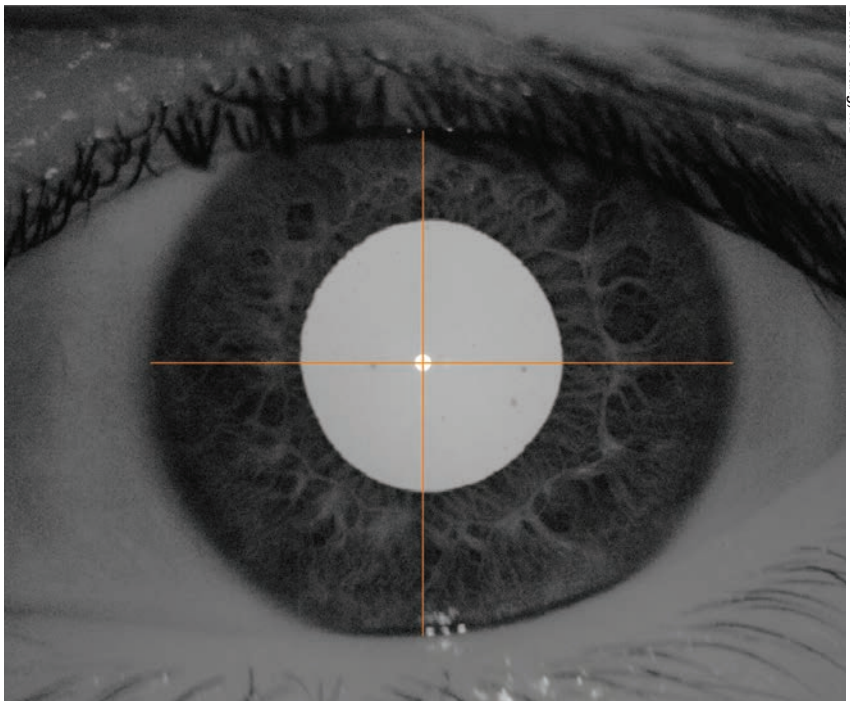
Dr. Chang uses his topographer to help assess the quality of his keratometry. "I use the IOLMaster 700 (Zeiss) to provide the mean K's, as well as astigmatic power and axis. I then use the Atlas topographer (Zeiss) to verify visually that what I'm getting on the IOLMaster 700 makes sense. The topography also gives me an overall map of the cornea, which is important because biometers will not show when there is irregular astigmatism. In essence, the topographer verifies whether the Ks from my biometer are any good," he says.

"I'll do at least two different measurements with the same device if I'm going to correct astigmatism—ideally on separate days," Dr. Chang continues. "I do this to look for fluctuations of the ocular surface, so I like to measure it on two separate days with the same device. If I have two devices and two different readings, I don't know if the K changed, or if it's just the different devices giving me different readings. After obtaining multiple measurements, I look at all of the readings to determine the power and axis that I plan to treat— for example, '1.25 D at 180 degrees'—which lets me determine my desired surgical approach."

Dr. Chang has devised a unique way to take his preop data into the OR once he's verified it. "After using my topography to guide my axis selection, I will use the pupil image taken by the topographer. I visualize the iris structures to translate my figures onto the eye at the time of surgery. It's a way to directly correlate my preoperative measurements with what I do intraoperatively. The IOLMaster 700 now prints an iris image as well, but my current workflow still involves the images from my topographer. I export it as a JPEG," he explains. "Then I mark a crosshair vertically and horizontally over

the corneal vertex, or the light reflex, which George Waring and I have described as the subject-fixated coaxial corneal light reflex. It's basically the fixation light that's reflected off the cornea. I place a line vertically and horizontally, and I take the image and digitally enhance it with Photoshop to maximize the contrast of the iris structures. At the surgery center, I put the patient in the slit lamp at the YAG laser. Using the preoperatively marked and enhanced pupil image, I then put a laser spot at 0° and 180° to reference the cardinal meridians. When I get the patient on the table, I then take a compass and mark the steep axis of astigmatism," he says.

Douglas D. Koch, MD, professor and the Allen, Mosbacher, and Law chair in ophthalmology at The Cullen Eye Institute, Baylor College of Medicine in Houston, combines topography and readings from two different biometers. "My standard workup is to use the Galilei (Ziemer) for topography, and both the IOLMaster 700 and the Lenstar (Haag-Streit). I'm also currently using the Cassini (Cassini), because it seems to be giving some interesting data about the posterior cornea that may prove to be quite accurate."



Daniel Chang, MD

Daniel H. Chang, MD, creates a JPEG of an image from his topographer, enhancing it in Photoshop to optimize his view of the unique iris structures, and adding crosshairs over the subject-fixated coaxial corneal light reflex. He references this enhanced image when marking the cardinal meridians and the steep axis of astigmatism on the day of surgery.

Overcorrect? Undercorrect?

Some surgeons believe certain patients benefit from a small amount of astigmatism, and that they may be dissatisfied if it's corrected to zero. A related issue is the question of whether to over- or undercorrect astigmatism to account for posterior astigmatism and/or a drift from with the rule to against the rule over time.

Dr. Kieval bases his decisions about adjusting for anticipated changes in astigmatism on the preop Scheimpflug imaging. "In terms of over- or undercorrecting, I don't feel like I need to use nomogram-like adjustments because I think that net-power data point on the Scheimpflug imaging is giving me the true power of the cornea. The only thing I will consider with regard to variance is the shift from with-the-rule to against-the-rule astigmatism with time and age. I'll account for that more in my younger patients, such as the early-onset cataract cases—the 40- and 50-year-olds. But it's not a dramatic accounting. If it's a pediatric case, like a teenager with a congenital cataract or posterior polar cataract, I tend to treat the astigmatism but try to leave about a half-diopter of with the rule to account for the drift that may occur over time. With the 30-year-olds and middle-aged patients, I try to leave about a quarter-diopter of with the rule to account for that drift. I think the drift can be variable, and it can be further managed later if it does occur," he says. "I think that astigmatism is dynamic. I would guess that 90 percent of our patients' astigmatism is static, and we can strive to treat that. But there's some element of astigmatism that appears to be dynamic, whether it's due to age, environment or other factors that can't be accounted for at this time."

Dr. Koch says that research suggests that this dynamic component of astigmatism that shifts from with the rule to against the rule appears to be slight and related to age.

Dr. Chang credits Dr. Koch's research regarding the posterior cornea with informing some of his decisions about treating astigmatism. "Primarily based on the work of Doug Koch at Baylor, we have become aware of the posterior-corneal component of astigmatism," he notes. "Depending on the axis, we should make a correction for total corneal astigmatism. As a rule of thumb, if the anterior corneal astigmatism is with the rule, I'll subtract 0.5 D; if it's against the rule,

I'll add 0.5 D. Then, I'll use LRIs or a toric lens with the appropriate astigmatic power."

With regard to the against-the-rule drift over time, however, Dr. Chang prioritizes immediate patient satisfaction over accommodating a gradual shift. "It's tough to account for a decade of drift," he says. "I really try to make the patient happy in the early postoperative period. If it drifts by 0.5 D over 10 years, they'll probably forgive me. I may leave a little with-the-rule astigmatism, but I definitely try to get close to zero on the day of surgery."

Dr. Gulani says that skilled surgeons may be able to use a patient's astigmatism to create a customized visual outcome. "In many cases, we can use astigmatism to our advantage by leaving natural astigmatism to help monofocal patients read with that refractive error," he says. "In some cases I have used astigmatism by flipping the axis using a toric lens implant, and then coming back to treat the corneal scar along that new flat axis using laser corneoplastique[1] and vice versa. Astigmatism should not only be corrected to zero levels for emmetropia; it can also be used to our advantage as an art. Understanding of astigmatism (both anterior- and posterior-corneal) and additionally, the mutual impact of coma and spherical aberration, is a must to successfully tread on the terrain of sure and happy patient endpoints."

The Role of LRIs

With the availability of toric IOLs for astigmatism correction, what's the role of limbal relaxing incisions in cataract surgery? Dr. Koch says they're alive and well in the United States. "In my practice, I use them in patients who have up to 1.4 to 1.5 D of with-the-rule astigmatism and in patients who have less than a half-diopter of against-the-rule astigmatism. The reason I have such a disparity between those two groups is because of the posterior-corneal effect. And there's also a little contribution from lens tilt; we know that lens tilt creates a little against-the-rule effect, along with the posterior cornea. Since our toric lenses correct a minimum of 1 D, if you take a patient with 1.5 D of astigmatism, they may easily have a quarter-diopter on the cornea, plus lens tilt," he explains. "If you put a toric lens in, you might flip the axis of their astigmatism, which would not be desirable because we know that eyes tend to drift against the rule. Therefore, I like to leave patients with a little bit of with the rule. For patients with against-the-rule astigmatism, again factoring in a little tilt and certainly the posterior cornea, a half-diopter or less on the cornea could easily add up to 0.7 or 0.8; and then if you put a 1-D toric in, you've just flipped their axis by about 0.2 D, which

would be ideal for them in the long term."

Dr. Gulani creates incisions using a femtosecond laser intraoperatively to treat astigmatism. "During surgery, the femtosecond laser can create accurate limbal relaxing—or astigmatic keratotomy—incisions, which can be created during, but opened during or after, cataract surgery," he says. "Of course, the modality of laser vision surgery is always available after premium cataract surgery to address and correct any residual astigmatism, right down to the zero-tolerance level. Not as accurate as laser vision surgery, but surely feasible and cost-effective, is an LRI at the slit lamp itself after cataract surgery for any residual astigmatism."

Dr. Kieval describes manual LRIs at the slit lamp as his own version of "postop enhancement" for small amounts of astigmatism. "I think that's different from what many people do," he says. "I treat that astigmatism with an LRI at the slit lamp even if it's 0.75 D, because I want to drive to zero. This is my preference because the incision in cataract surgery can be so variable in terms of inducing astigmatism that I really think it's better to wait for it to heal after cataract surgery before going after a small amount of astigmatism, just to ensure that it's residual. For higher amounts—1 D or more—it's much better to drive that astigmatism to zero with a toric lens."

Dr. Afshari says she finds herself using LRIs less frequently in recent years. "Now I do far fewer of them because of toric implants," she says. "That's one factor; another factor is if the patient's astigmatism is low enough that I can help it by the placement of my wound superiorly vs. temporally: I'll adjust my wound based on the steep axis to decrease the astigmatism, and get a little help from that wound."

Another surgeon who prefers a toric-IOL astigmatism solution is Dr. Chang. "The problem with LRIs is that you're never too sure of what you're going to get," he says. "I have found that while femtosecond-based LRIs provide far more precise cuts than manual incisions, variable corneal biomechanics can still can result in unexpected outcomes that will leave you scratching your head. Because I see a lot of variability with LRIs, I tend not to use them."

"What I really like are intrastromal relaxing incisions, which I can use to correct about a half-diopter. What's nice about them is that they don't cause any discomfort or dryness, and they can just give you a little, tiny correction that is sometimes just what you need with a premium IOL."
—Douglas D. Koch, MD

Dr. Gulani generally avoids manual LRIs for patients seeking premium results. "One cannot implant a premium lens implant and do an inaccurate manual LRI to complement it—though some cases of low-level astigmatism and high predictability, like a normal cornea, could justify this—but in most cases there are multiple astigmatic factors at work that will surprise the surgeon who thinks they were diligent enough," he says.

The Femto Factor

Astigmatic keratotomy by femtosecond laser gets mixed reviews. "I don't use femtosecond, but many colleagues like creating AKs with it, says Dr. Afshari. "It used to be that we'd do it more often, but now there are other options such as toric lenses and adjustment of the wound placement to help small amounts of astigmatism."

"I find myself doing a lot less femtosecond laser cataract surgery over the years, because I'm finding that the benefits have not outweighed the time and cost issues," says Dr. Kieval. "I currently feel that best management of astigmatism is achieved with a toric lens."

"The evidence does not clearly support that you get a better overall result or that you have improved safety," says Dr. Koch of FLACS. "The safety is comparable, but the evidence doesn't suggest that it's better. There are a couple of studies that suggest you may be a bit more accurate with femto with regard to the controlled capsulorhexis, but for astigmatism there are two issues: One is the toric IOL and its position. FLACS doesn't seem to improve the accuracy of the toric alignment. The other concern would be whether the incisions made by the femtosecond laser are better than those made with a diamond knife.

"What I really like are intrastromal relaxing incisions, which I can use to correct about a half-diopter," Dr. Koch continues. "What's nice about them is that they don't cause any discomfort or dryness, and they can just give you a little, tiny correction that is sometimes just what you need with a premium IOL. From that standpoint, I do like laser procedures, but the data are not in to support them, aside from than the fact that they do seem to work."

Wavefront Aberrometry

Dr. Chang says that he doesn't use the ORA Verif-Eye (Alcon) for intraoperative aberrometry. Dr. Koch only uses it for a limited number of cases. "I don't find it particularly helpful in most of my patients," he says. "The measurements we obtain in our office are so good that I don't feel the need to use wavefront very often in toric-IOL situations. There are cases in which I'll use it if my preoperative data are conflicting, and I also use it in post-LASIK eyes to help me with astigmatism correction sometimes, but I'm just not a strong advocate of the ORA, only because the cornea has been so modified by the time you get to that point in the operation that I don't think it can match the precision and the accuracy of the measurements that you get preoperatively in the clinic."

Dr. Afshari finds it helpful to compare wavefront aberrometry's readings with her preoperative data. "We do intraoperative aberrometry with the ORA," she says. "But beforehand, obviously, we determine how much of the astigmatism is corneal and how much is lenticular. Then, we see if all of the numbers match or are at least similar, and if the axes are similar. Sometimes you'll get a lot of astigmatism during the surgery, but when you check the topography from the Pentacam, you see very little astigmatism. In that case, you assume the astigmatism you're seeing intraoperatively is mainly lenticular. So we know that when we take that lens out, things should match more closely to the topography again."

The Toric Threshold

When should you use a toric lens for optimum astigmatism management? It depends on whom you ask. "For me the level of astigmatism at which I'll consider using a toric is around 1.25 or 1.5 diopters," says Dr. Afshari. "Before that, I'll often evaluate to see if I can do a little bit of wound adjustment to treat astigmatism. The posterior cornea contributing a little bit of against the rule is also a consideration."

But beyond a threshold amount of astigmatism, "It is a discussion with the patient," she says of the decision to use a toric IOL. "When I look at patients with around 1 D of astigmatism, many are fine with wearing glasses. They're used to them, or they like the eye protection, for example. Of course, the cost is another issue. When the astigmatism is a little higher, I really try to make sure that they know that a toric could be very helpful. I'll repeat that to them a couple of times."

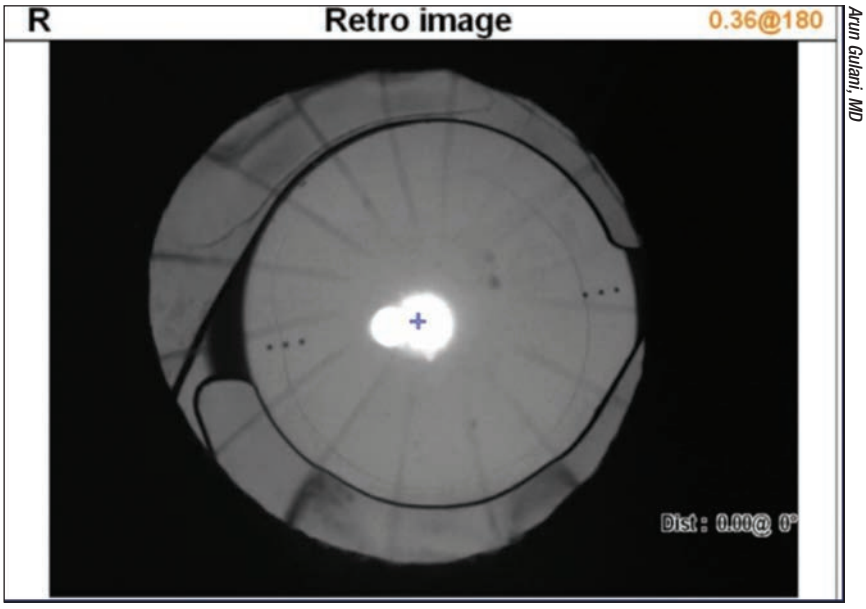
"I prefer a toric IOL solution for astigmatism," says Dr. Chang, who estimates that when treating presbyopia he implants about 55 percent toric vs. 45 percent nontoric

IOLs. "I think they're more reliable than incisional techniques," he says. Regarding his astigmatism threshold for toric implantation, he says, "I use IOLs to correct as little as 1 D of corneal astigmatism, so if patient has 1 D or more of estimated total corneal astigmatism (1.5 D or more of WTR or 0.5 D or more of ATR), I'll use a toric IOL. But if there is less than a diopter of total corneal astigmatism, I'll likely leave it uncorrected."

Dr. Koch's threshold for toric-IOL use also takes the posterior-corneal effect into account: "It would be around 1.5 diopters for with-the-rule, and about 0.5 against-the-rule," he says.

"Intraoperatively, I'm geared towards a toric-lens solution for astigmatism," says Dr. Kieval. "The most typical protocol if the patient has 1 D or more is to treat with a toric lens intraoperatively. If it's anything less than a diopter, I tend to try to operate on axis, and then treat any residual astigmatism with an LRI postoperatively in the office. If there's residual astigmatism, I'll manage it with a limbal relaxing incision afterward. The literature soundly supports the use of toric lenses over the intraoperative limbal relaxing incision. But I also think that I can treat low enough that if there's 0.75 D preoperatively, I can hope that an on-axis incision will be enough. If it's not enough because the patient really needs zero astigmatism, then I can enhance it with a limbal relaxing incision at the slit lamp, rather than doing that LRI at the time of surgery for somebody who has maybe 0.75 or 0.5 diopters of astigmatism."

Dr. Gulani decides to recommend toric lenses on a case-by-case basis. "As I always teach, there should be no mathematical cutoff point, but a clinical judgment about when to use a toric lens or when to use an LRI, either manual or femtosecond-laser-assisted. Given the accuracy and stability of toric lenses, I have a low threshold to use them in patients with astigmatism and associated cataracts, with inclusion of surgically induced astigmatism, which can vary between surgeons. In my mind, if the patient has more than even 0.6 D of astigmatism, a toric lens should surely be the first choice. With less than 0.65 D, I would still aim for a toric lens implant, calculating for any incisional astigmatism. Alternatively, one can certainly use a femtosecond laser. If monetary issues come up for the patient, a manual astigmatic keratotomy is also suitable, but the drive still has to be to relentlessly pursue zero astigmatism.



Arun Gulani, MD

Arun C. Gulani, MD, believes that some surgeons may avoid toric IOLs due to concerns about lens selection, alignment and staying power once placed. He says they can deliver great visual outcomes in skilled hands, however, even in complex eyes like the post-RK one shown here.

"Toric lenses are extremely accurate," Dr. Gulani continues. "I have used toric lenses not only in virgin eyes with astigmatism, but also in eyes with keratoconus, status post-RK, penetrating keratoplasty, corneal scarring and irregular cornea cases very successfully, to 20/20 outcomes. Given the accuracy of toric lens implants, I believe their utilization is low mainly because surgeons may not be confident in predicting the power or aligning the axis during and/or after surgery. Surgeons may be intimidated at three levels: accurate preoperative measurement; accurate placement during surgery; and concerns about persistent staying power of that 'accurately' placed lens implant on that axis," he says.

Dr. Gulani adds that some of the surgeons who call and email him perseverate on having the latest "magic bullet" technology for toric alignment. "Additionally, surgery is an art, and there are nuances like how to not thoroughly clean the underside of the anterior capsule along the axis, or how to ovalize the capsulorhexis in deep-chamber cases like status post-RK or keratoconus, and then also how to align the lens during surgery without additional and laborious steps." He uses the Gulani toric marker and alignment system (Bausch + Lomb).

"With nearly two decades of using toric lens implants in routine, complex and extreme cases, I have not had to rotate any implants post surgery to date," says Dr. Gulani.

Dr. Koch notes the recent study

showing that the Tecnis toric IOL (Johnson & Johnson Vision) tends to rotate in the eye more than AcrySof torics (Alcon),[2] but offers a pearl for stabilizing it. "I've found that when I'm using the J & J lens, it's helpful to spin the lens at least 180 degrees before I put it in its final location. Then I hold it down against the posterior capsule with some pressure using a Sinskey hook for a good count of three or four seconds," he explains. "That seems to stabilize it quite well. It doesn't completely eliminate postoperative rotation, but the incidence is now minimal for me."

Dr. Chang says that wound characteristics may influence whether or not toric IOLs rotate after cataract surgery. "When you're using toric lenses, you've got to be really meticulous in implanting them," he says. "Beyond marking the eye, unfolding the lens and aligning it in the eye, my biggest suggestion is to ensure that the wound is well sealed. A stable globe postoperatively provides a stable environment for the IOL, but if the eye becomes hypotonous, any force on the eye (squeezing, rubbing or pressure from an eye-drop bottle) can be transmitted through the eye wall, push on the lens and rotate it." Although he notes that you can always rotate the lens back into position postoperatively and even do a laser enhancement if the patient remains unhappy, ensuring that the wound is sealed may help avoid that. "Sealing the wound at the end of the case is good surgical technique, and it can ensure stable lens position as well as protect against endophthalmitis," he emphasizes.

Dr. Chang says that EDOFs are known to have refractive forgiveness for spherical error; but he says you can have that forgiveness for astigmatic error using these lenses, too. "However, you can't just throw the lens in and expect it to magically take care of astigmatism. If you end up slightly hyperopic, and you left-shift the defocus curve, the extended focal range will provide some refractive forgiveness for distant vision, even for astigmatism," he explains. "The tradeoff is that when you are slightly hyperopic, you lose a little bit of near vision in exchange. Therefore, it's still best to correct all of the astigmatism and hit plano."

"I encourage all eye surgeons to develop a zero tolerance for astigmatism," says Dr. Gulani. Embracing as many pearls as possible will help surgeons gain more confidence with torics and other astigmatism-management techniques, and get them "addicted to the beaming responses of their happy and gratified patients," he states.

Dr. Kieval strives for zero astigmatism to the extent he believes possible within the scope of current knowledge. "I think it's absolutely critical not to disrespect or disregard great cataract surgeons who aren't so refractive-minded and may not treat astigmatism or use toric lenses or manage astigmatism with LRIs. I don't think that's unreasonable, but I do think its unreasonable for those surgeons not to let patients know that there are other options. As we all know, many patients are seeking their absolute best visual acuity after their cataract surgery, so treating that astigmatism and trying to reduce it is really critical for them." REVIEW

Dr. Gulani reports that he is a consultant/speaker for Oculus, Marco, Ocular Therapeutix, EyePoint and Bausch + Lomb. Dr. Afshari reports no relevant financial interests. Dr. Kieval is a consultant and speaker for Johnson & Johnson Vision/AMO. Dr. Chang is a consultant to Zeiss for the IOLMaster, and a consultant to Johnson & Johnson Vision for Symfony EDOF lenses and other products. Dr. Koch is a consultant for Alcon, Johnson & Johnson Vision and Zeiss.

1. Gulani AC. Corneoplastique. Art of vision surgery. Indian J Ophthalmol 2014;62:1:3-11.
2. Lee BS, Chang DF. Comparison of the rotational stability of two toric intraocular lenses in 1273 consecutive eyes. Ophthalmology 2018;125:9:1325-31.


Regenerative Medicine: Science Fact

A look at one possible way researchers and physicians may expand the boundaries of regenerative medicine in the future.

Michael Trese, MD, Royal Oak, Mich.

The promise of regenerative medicine, including gene therapy, stem cell treatments and the repair or regeneration of a variety of tissues and organs has been discussed for more than two decades. Unfortunately, in desperate attempts to help themselves or those they care about, many patients have been harmed physically and financially by untested, experimental treatments proferred by despicable charlatans eager to take advantage of these indviduals. Fortunately, signs of change appeared last November when FDA Commissioner Scott Gottlieb issued a statement with two very important parts: First, he stated that the goal of rebuilding parts or complete organ systems "was no longer science fiction," but within the scope of modern medicine. Second, he stated that those who prey on patients will be policed and punished.[1]

Now, with Dr. Gottlieb ensuring patients' safety on one hand, and the approval of Luxturna (voretigene neparvovec-rzyl, Spark) and the existence of similar treatments in the pipeline on the other, patients may be entering an age where effective therapies are truly possible. In this article, I'll provide a brief review of the challenges of regenerative medicine and how researchers may be able to solve them.

The Research Landscape

To what extent is Dr. Gottlieb's optimism regarding tissue regeneration warranted for retinal diseases? First, after many years of the lay press announcing that gene therapy was just around the corner, we now have an approved gene therapy for Leber's congenital amaurosis in the form of Luxturna. Second, at the University of Southern California, stem cells are being introduced into the subretinal space in an effort to reactivate macular function.[2] Laboratory based, *in vitro* growth of retina cells, and indeed whole retina organ cultures, has been performed since at least 2012.[3] The thought is that these lab-grown tissues can be transplanted into diseased eyes in order to replace damaged tissue.

It may be that some organs/tissues are be more amenable to regenerative therapies, particularly the heart and liver; a stem-cell cardiac study is already underway in Japan.[4] The eye in general, and the retina in particular, present not only highly organized neuronal and vascular elements, but also complicated, highly connected structures that are necessary to produce vision. Restoring this complex organ to a complete functional level in various diseases will be a tall order, and is more challenging than getting patients to see the useful but limited visual percepts achieved with mechanical approaches such as retinal prostheses.

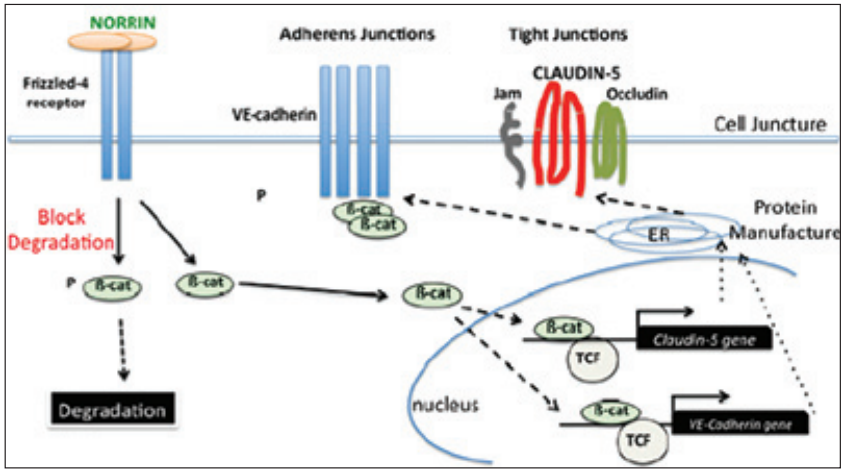
Signaling Systems

Is it possible to regenerate a system as complicated as the eye? It's likely possible, but doing so may require rethinking what constitutes regenerative medicine.

Introducing a primitive stem cell into a diseased adult eye might provide an environment or substrate that's only able to slow degeneration. That may be a reasonable solution for diseases of older adults, but what about diseases that take the vision of the young?

If we examine the development of the retina in fetal and infant life, we find that much is dictated by the growth environment provided by signaling systems. Though these systems are key to the eye's development, most physicians aren't used to thinking about them, especially as a therapeu-

This article has no commercial sponsorship.



Norrin binding to the Frizzled 4 receptor, triggering the production of two of the myriad of proteins associated with Wnt signaling: VE cadherin and Claudin 5.

tic target. Signaling systems, however, such as Wnt, NOTCH and Hedgehog, are vitally important to fetal and infant development. They produce a large number of substances, mostly proteins, that support proper growth of cells to form complex, interconnected structures. Wnt signaling, for example, is driven by the protein Norrin, which binds to the surface of endothelial and epithelial cells to produce many proteins that form an organized vascular and neuronal structure in the retina.

A congenital absence or underproduction of functional Norrin protein results in Norrie disease, which causes blindness in all children affected, as well as deafness and developmental delay in another large percentage of them. In many pediatric and adult retinal diseases, however, it may be possible to recreate this Norrin-driven Wnt signaling environment. Norrin-induced activation of the Wnt signaling system in adults may be able to effectively promote the growth of dormant autologous vascular and neuronal stem cells to regrow retinal capillaries and neurons in areas of capillary and neuronal loss by repairing these damaged cells. This would result in a reduction of VEGF-drive-restoring function, and avoid capillary loss and destructive laser therapy.

It's also worth noting that signaling systems vitally necessary in development may serve pathogenic roles as we age, with angiogenesis and cancer being just two examples. This is true for both the Wnt and Hedgehog signaling systems. For the Wnt signaling system, for example, pathologic angiogenesis is driven by Wnt proteins 3a, 7a and 10a.

There's much to learn about regenerative medicine. The proper cells, optimal environment and appropriate genetic manipulation will all play roles in discovering the next therapy. We hope that the realistic, ethical pursuit of regenerative therapy for both pediatric and adult retinal disease will enable cutting-edge therapies to become mainstays of treatment. REVIEW

Dr. Trese is a partner at Associated Retinal Consultants and chief of pediatric and adult retina at Oakland University William Beaumont School of Medicine in Auburn Hills, Michigan. His email address is mtrese@arcpc.net.

He is also a co-founder of Retinal Solutions, which is developing a regenerative therapeutic.

1. FDA Commissioner Scott Gottlieb, MD on regenerative medicine. November 16 2017. www.FDA.gov
2. Kashani A, Lebkowski JS, Rahhal FM, et al. A bioengineered RPE monolayer for advanced, dry AMD. Sci Transl Med 2018;10:435.
3. First mouse now human, lab grown eye tissue. https://phys.org/news/2012-11-mouse-human-lab-grown-eye-tissue.html. Accessed 7 September 2018.
4. 'Reprogrammed" stem cells approved to mend human hearts for the first time. https://www.nature.com/articles/d41586-018-05278-8. Accessed 7 September 2018.

Sun/SPARC Glaucoma Drug Approved

Sun Pharmaceutical Industries announced U.S. FDA approval for the New Drug Application of Xelpros (latanoprost ophthalmic emulsion) 0.005% for the reduction of elevated intraocular pressure in individuals with open-angle glaucoma or ocular hypertension. (Sun Pharmaceutical in-licensed Xelpros from SPARC in June 2015.) Xelpros—the first and only form of latanoprost that isn't formulated with benzalkonium chloride—was developed using SPARC's proprietary swollen micelle microemulsion technology. In randomized, controlled clinical trials of individuals with OAG or OH with a mean baseline IOP of 23 to 26 mmHg, Xelpros lowered IOP by a mean of 6 to 8 mmHg. For more information, visit MyXelpros.com.

New Heidelberg OCTA Module

The Spectralis expandable diagnostic imaging platform can now be upgraded with the OCT Angiography Module to perform noninvasive, layer-by-layer exams of flow in the vascular networks of the retina and choroid. The module can be added to new and existing Spectralis devices with the OCT2 Module. The multimodal imaging platform enables clinicians to compare OCT angiographies to other modalities such as structural OCT and dye-based angiographies as well as infrared, MultiColor and BluePeak images. To learn more, visit heidelbergengineering.com.

Alcon UV-absorbing-only IOLs

Alcon recently expanded its AcrySof intraocular lens portfolio with the introduction of multifocal and multifocal toric ultraviolet-absorbing IOLs, and the introduction of the AcrySof UV-absorbing monofocal IOL with the UltraSert Pre-loaded Delivery System. These lenses come without blue light filtering, which some surgeons dislike.

The new multifocal and multifocal toric options are the AcrySof ReSTOR +2.5 Multifocal UV-Absorbing IOL with Activefocus optical design and the AcrySof ReSTOR +2.5 Multifocal Toric UV-Absorbing IOL with Activefocus optical design. The unique optical design of the lenses is intended to deliver crisp, clear distance vision and a range of vision for patients who desire less dependence on glasses, the company says.

For more information on the new UV-absorbing-only intraocular lenses, visit myalcon.com.

New Laser Accessory

Following FDA 510(k) clearance, Iridex introduced its updated TruFocus LIO Premiere laser accessory to the U.S. market. The light combination and reflection viewing system, used with Iridex retina laser systems, is worn on the physician's head and combines a laser treatment beam from an Iridex laser source with the illumination beam of a binocular indirect ophthalmoscope into a mixed optical beam. The physician uses a handheld ophthalmic exam lens to view and treat the retina through the pupil. For more information, visit iridex.com.

Essilor Launches Wavefront Aberrometer

Essilor Instruments launched the WAM700+ wavefront aberrometer for anterior-chamber analysis and visual-needs assessment. Based on Shack-Hartmann wavefront technology, Essilor says the device is designed to be a fast, effective and space-saving fully automatic wavefront aberrometer. Built for ease

This article has no commercial sponsorship.

of navigation with a large touch screen, WAM700+ provides seven detailed measurements in 90 seconds for both eyes. The company says the device helps simplify screening for conditions such as cataract, glaucoma and keratoconus. For more information, visit essilorinstrumentsusa.com

The Falcon Takes Off

Ocutech recently released the VES Falcon Autofocus Bioptic Telescope for low-vision patients.

Ocutech says the VES Falcon is the world's only autofocusing bioptic for the visually impaired, and says it gives low-vision patients the most natural, hands-free magnified vision possible.

The device is described as using crisp, bright, high-contrast, wide-field 4X Keplerian optics to provide a 12.5-degree field of view, with a focusing distance as close as 13 inches. The Falcon runs for eight hours on a single charge, and weighs 3.2 oz., making it comfortable to wear, Ocutech says.

The suggested patient price for the Falcon is $3,900, excluding customization charges and professional fees. For more information, visit Ocutech.com. REVIEW

Are Intraop Antibiotics Necessary in PPV?

Researchers from Philadelphia say that prophylactic use of subconjunctival antibiotics may have no impact on the rate of endophthalmitis following pars plana vitrectomy.

In the retrospective, nonrandomized, comparative case series, researchers analyzed the outcomes of 18,886 consecutive cases of transconjunctival 23-, 25-, and 27-gauge PPV over a five-year period. They examined the impact of prophylactic intraoperative subconjunctival antibiotics on the development of acute infectious postoperative endophthalmitis.

Out of all the cases, 14,068 (74.5 percent) received intraoperative subconjunctival antibiotics, and 4,818 (25.5 percent) didn't. There were 16 cases of endophthalmitis (0.085%, 1/1,176). The incidence of endophthalmitis in eyes that received subconjunctival antibiotics was 0.078 percent (11/14,068 cases, 1/1,282), while the incidence in those that didn't receive subconjunctival antibiotics was 0.10 percent (5/4,818 cases, 1/1,000). There was no statistically significant difference between the two groups (p=0.598). Microbial culture was performed in 11 cases; six were culture-positive (5/8 cases that received subconjunctival antibiotics and 1/3 cases that did not).

The researchers say that, since prophylactic subconjunctival antibiotics weren't associated with a significantly reduced rate of post-PPV endophthalmitis, and since there is a constant concern about emerging multidrug-resistant bacteria, routine prophylactic subconjunctival antibiotics may not be justified.

Retina 2018;38:9:1848-1855.
Weiss S, Adam M, Gao X, et al.

Facedown Position Questioned for Macular Holes

Researchers compared clinical outcomes in eyes with macular hole managed by either facedown (FD) or no-FD (nFD) postoperative positioning protocols, as part of a prospective, randomized cohort study.

Eighty eyes of 80 consecutive individuals with MH that underwent vitrectomy surgery with internal limiting membrane peeling and gas tamponade were included. Forty eyes of 40 individuals kept in FD position for three days after surgery were assigned to the FD group, and 40 eyes of 40 individuals with nFD positioning were assigned to the nFD group. Researchers examined macular holes with swept-source optical coherence tomography images at one day, two days, three days, two weeks, one month and three months after surgery. They compared the MH closure rate and change in best-corrected visual acuity. Below are some of the findings:

- At postoperative day one, MHs were closed in 24 of 32 eyes with clear OCT images (75 percent) in the FD group, and 23 of 30 eyes with clear OCT images (77 percent) in the nFD group (p=0.97).
- At postoperative day two, MH closures were confirmed in 32 of 36 eyes (88.9 percent) in the FD group and in 31 of 33 eyes (94 percent) in the nFD group (p=0.84); results were unchanged at day three.
- At two weeks post-surgery, clear OCT images were acquired from all eyes in both groups, and MH closures were confirmed in 36 of 40 eyes (90 percent) in the FD group and in 37 of 40 eyes (92.5 percent) in the nFD group (p=0.91).
- Macular hole closures weren't achieved in eyes still open by day three post-surgery, and no eyes with confirmed MH closures by day three had reopenings by three months.
- The distribution of macular configurations at three months wasn't significantly different between the two groups (p=0.96).
- Researchers found no differences in improvement in best-corrected visual acuity (Early Treatment Diabetic Retinopathy Study letters gain) between the two groups at one month (p=0.22) and three months (p=0.45).

Researchers found that the nFD protocol neither delayed MH closures nor decreased the final closure rate

after vitrectomy surgery. As such, they suggested that using the prone position postoperatively seems to be unnecessary for all MH repair procedures.

Retina 2018; Sep 7. [Epub ahead of print]
Zhang Y, Chen X, Hong L, et al.

Evaluating Anterior Chamber Volume With SS-OCT

Scientists assessed changes in anterior chamber volume with swept-source optical coherence tomography after cataract surgery, in addition to factors that influenced the ACV changes, as part of a prospective cohort study.

Fifty-one individuals who underwent cataract surgery were enrolled. Their ACV, anterior chamber depth and angle widths were measured with SS-OCT before, and one day, one week and one month after surgery. Scientists looked for associations between changes in ACV and posterior vitreous detachments, and determined axial lengths. Here are some of their findings:

- Compared with preoperative volumes, ACV increased significantly at all three postoperative time points (all $p<0.001$).
- ACV was greater at one week than one day after surgery ($p<0.001$).
- AXL and posterior vitreous detachments were significantly associated with ACV changes one day post-surgery ($p=0.005$).
- Neither PVDs nor AXL affected ACV changes between one day and one week after surgery.
- ACV stabilized in the first week after cataract surgery.

The study researchers reported that absorption of irrigation fluid and balanced salt solution in the vitreous cavity contributed to ACV changes one week after surgery. Eyes with longer axial lengths and PVD tended to show less ACV changes one day after surgery.

Int Ophthalmol 2018; Sep 4. [Epub ahead of print].
Chen M, Hu H, He W, et al.

Vision Decreases May Predict Cognitive Decline

Researchers in the longitudinal, population-based Salisbury Eye Evaluation Study (conducted in Salisbury, Maryland), say that distance visual impairment appears to be associated with declining cognitive function.

The standardized size of visual acuity's effect on the cognitive score was larger relative to the reverse effect, demonstrating that acuity is likely the driving force in these dynamic associations.

In the study, researchers analyzed 2,520 adults aged 65 to 84 years, assessing them at baseline between September 1993 and August 1995 (round 1) and two years (round 2), six years (round 3), and eight years (round 4) later. They measured visual acuity using Early Treatment Diabetic Retinopathy Study charts, and the individual's cognitive status was assessed using the Mini-Mental State Examination (MMSE).

Of the 2,520 participants in the study, the mean age was 73.5 ±5.1 years; 1,458 (58 percent) were women, and 666 (26 percent) were black. There were 2,240 (89 percent), 1,504 (61 percent), and 1,250 remaining participants (50 percent) in the second, third, and fourth rounds of the study, respectively, with more than half of the loss being due to the death of the participants.

Both VA and MMSE score worsened over time. The mean biannual decline of VA was 0.022 logMAR (approximately one line during eight years; 95% CI, 0.018-0.026), and the mean biannual worsening of MMSE score was -0.59 (95% CI, -0.64 to -0.54; both $p<0.001$). Worse baseline VA was associated with worse baseline MMSE score ($r=-0.226$; 95% CI, -0.291 to -0.16; $p<0.001$). The rate of worsening VA was associated with the rate of declining MMSE score ($r=-0.139$; 95% CI, -0.261 to -0.017; $p=0.03$). Statistical models indicated that VA in the previous round was associated with an individual's MMSE score in the subsequent round ($\beta=-0.995$, $p<0.001$), and MMSE score in the previous round was associated with VA in the following round ($\beta=-0.003$, $p<0.001$). However, the standardized size of VA's effect on MMSE score ($\beta=-0.074$; SE, 0.015; $p<0.001$) was larger relative to the reverse effect ($\beta=-0.038$; SE, 0.013; $p<0.001$), demonstrating that visual acuity is likely the driving force in these dynamic associations.

The researchers say that visual impairment measured at distance was associated with declining cognitive function both cross-sectionally and longitudinally over time, with worsening vision having a stronger association with declining cognition than the reverse. Worsening vision in older adults may be adversely associated with future cognitive functioning, the investigators concluded, and they add that maintaining good vision may be an important interventional strategy for mitigating age-related cognitive declines. REVIEW

JAMA Ophthalmol. 2018 Sep 1;136:9:989-995
Zheng DD, Swenor BK, Christ SL, et al.

Macular Morphology and VA in Year Five of CATT

Investigators evaluated associations between morphologic features and five-year visual acuity in the Comparison of Age-related Macular Degeneration Treatments Trials.

CATT participant eyes with AMD-associated choroidal neovascularization and VA between 20/25 and 20/320 were eligible. Treatment was assigned randomly to ranibizumab or bevacizumab, and to three dosing regimens for two years, and at the ophthalmologists' discretion thereafter.

Main outcome measures included: VA, thickness and morphological features on optical coherence tomography, lesion size, and foveal composition on fundus photography and fluorescein angiography.

VA and image gradings were available for 523 of 914 participants (57 percent) alive at five years. At five years:

- Sixty percent of eyes had intraretinal fluid, 38 percent had subretinal fluid, 36 percent had subretinal pigment epithelium fluid and 66 percent had subretinal hyperreflective material.
- Mean (SD) foveal center thickness (in µm) was 148 (99) for retina, 5 (21) for SRF, 125 (107) for subretinal tissue complex, 11 (33) for SHRM and 103 (95) for RPE+RPE elevation.
- SHRM, thinner retina, greater CNV lesion area and foveal center pathology (all $p<0.001$) and IRF ($p<0.05$) were independently associated with worse VA.
- Adjusted mean VA letters was 62 for no pathology in the foveal center; 61 for CNV, fluid or hemorrhage; 65 for non-geographic atrophy; 64 for non-fibrotic scar; 53 for GA; and 56 for fibrotic scars.
- Incidence or worsening of eight pathological features (foveal GA, scar and CNV; SHRM, foveal IRF, retinal thinning, CNV lesion area and GA area) between years two and five were independently associated with greater VA loss between those years, and between baseline and year five.

Investigators found that associations between VA and morphologic features previously identified through year one were maintained or strengthened at year five. They also determined that new foveal scars; CNV; intraretinal fluid; SHRM and retinal thinning; development or worsening of foveal GA; and increased lesion size were important contributors to VA decline from year two to five.

Ophthalmology 2018; Sept. 3. [Epub ahead of print].
Jaffe GJ, Ying G-S, Toth CA, et al.

Disc Hemorrhage Treatment

Researchers assessed whether the use of antiplatelets/anticoagulants affected glaucoma progression in eyes with optic disc hemorrhage. A total of 119 eyes from 119 individuals with primary open-angle glaucoma in whom a DH was observed at least once during the follow-up period (mean follow-up duration: 6.2 years) were included in this retrospective, observational study.

Researchers identified the association between putative factors, including AP/AC use, and glaucoma progression. They assessed progression based on changes noted on serial optic disc and retinal nerve fiber layer photographs, or changes in the visual field.

Nineteen patients took AP/AC drugs daily [AP/AC-use group (AG)], while other participants didn't [no-use group (NG)]. The follow-up period to progression was significantly different between the two groups (61.2 ±23.5 months for the AG and 47.6 ±22 months for the NG; $p=0.016$). There was a greater cumulative probability of glaucoma progression in the NG group than in the AG group. Higher mean IOP during follow-up was a risk factor for progression, while AP/AC drug use protected against it.

J Glaucoma 2018; Sep 7. [Epub ahead of print].
Lee J, Sung KR, Kwon J, et al.

Neovascularization Masquerader on OCTA

Investigators reported that image artifacts due to retinal pigment epithelium hyperplasia overlying retinal pigment epithelial detachment in age-related macular degeneration can masquerade as neovascularization on optical coherence tomography angiography.

The hospital-based, retrospective and cross-sectional study included 22 eyes from 16 subjects with non-vascularized PED related to AMD. All subjects were examined by OCTA, spectral-domain OCT, fluorescein angiography and indocyanine green angiography. Investigators evaluated vascular flow signals (VFS) on the outer retinal slab of *en face* OCTA and cross-sectional OCTA images, and their correspondence with RPE hyperplasia. Findings included:

- Fifteen eyes (68.2 percent) showed VFS on both the outer retina slab of *en face* OCTA and cross-sectional OCTA, all corresponding with RPE hyperplasia overlying PED. Among them, 12 eyes with lump RPE hyperplasia outside the foveal avascular zone showed obvious VFS on the outer retina slab of OCTA, and three eyes with scattered RPE hyperplasia outside the FAZ showed VFS fragments.
- Four eyes had accompanying RPE hyperplasia inside the FAZ, and seven eyes without RPE hyperplasia overlying PED showed no corresponding VFS on the outer retina slab of OCTA.

Investigators determined that RPE hyperplasia overlying PED in AMD could masquerade as neovascularization on OCTA. They suggested that this RPE-hyperplasia-related image artifact should be considered when interpreting OCTA images.

Graefes Arch Clin Exp Ophthalmol 2018; Sept. 18. [Epub ahead of print].
Chen L, Zhang X, Yuhong Gan Y, et al.

Practice For Sale

Career Opportunities

OPHTHALMOLOGISTS
Danbury, CT

Ophthalmologists to share office with long standing Ophthalmologist in Danbury, CT. High quality equipment. $2,250 per month or adjoining office without equipment- $1,750 per month.

203-545-3539 or email mehrimd@aol.com

Products and Services


A Tube Shunt Fails: What's Next?

With limited published data to guide us, deciding how to proceed in this situation can be a challenge. Here's help.

Lauren S. Blieden, MD, Houston

One of the most difficult dilemmas in the management of eyes with complex glaucoma that have already had a tube shunt implant is what to do when the tube shunt fails. Assuming that we've exhausted medical options, we have to decide what the next step should be. Should we replace the tube shunt? Should we implant a second one? Should we perform an additional surgical or laser procedure?

These questions are not always easy to answer, and guidance in the literature is sparse. Here, to help you decide how to proceed when faced with one of these patients, I'd like to summarize the pros and cons of many of the options we have available at this point in time, and review the limited data available in the literature.

Defining "Failure"

There's no question that tube shunts often fail. In the literature, the reported rates of failure of a primary tube shunt vary from about 9 to 50 percent, depending on a number of factors, including which device was used, the definition of failure used in the study, the design of the study and how long the patients were followed after the procedure. Most of the retrospective studies in the literature show higher rates of tube shunt failure between the third and sixth years, with upwards of 30 to 50 percent of tubes failing during that period.

One of the reasons for the widely varying reports of success or failure in the clinical data is that there's no agreed-upon definition of tube-shunt "failure." Each research protocol or study chooses a specific target to help decide whether the treatments being tested are effective. That usually means picking a target pressure to achieve, or looking for a specific change in the optic nerve or visual field—something you can compare when you're looking over a group of data points. Since different studies choose different endpoints for different reasons, we end up with very different ranges of success and failure for similar protocols in different studies.

Not surprisingly, any marker you choose also has the potential to create a somewhat misleading conclusion. For example, if you set your "failure pressure" at 18 mmHg and a given patient ends up at 19 mmHg, that patient is considered to have failed, even if her glaucoma is under control and not progressing. (In other words, the tube shunt didn't really fail.) On the other hand, you could have patients with a pressure of 15 mmHg who are still progressing. Those patients would be counted as "successes" in that particular study, even though the patients' condition would continue to worsen.

Of course, a good randomized, prospective study of the different options would help provide a lot of answers, but up until now, nobody's really looked at this question prospectively. There was a trial sponsored by the Centers for Disease Control and Prevention that was designed to look at how different tube-shunt options compare, but the primary endpoint was a comparison of success between the interventions, not which worked best as a second surgical treatment. The American Glaucoma Society is sponsoring a trial, currently in the recruitment phase, to compare a second Baerveldt shunt to diode cyclophotocoagulation (the

This article has no commercial sponsorship.

After a Tube Fails: Success Rates of Follow-up Procedures in the Literature*

First author and year of publication	Number of patients	Mean follow-up (range), in months	Percentage of success	Definition of success
Cyclophotocoagulation				
Semchyshyn (2002)	21	26.9 (7–58)	72	IOP 5 to 21 mmHg; fail to lose light perception
Sood (2009)	9	19.8 (5–53)	66.7	IOP ≤22 mmHg
Francis (2011)	25	24	88	Reduction in IOP of 3 mmHg; discontinuation of nontolerated drops
Schaefer (2015)	32	62.8 (6–254)	65.6	IOP ≤18 mmHg
Additional Implant				
Burgoyne (2000)	22	35 (2–89)	86.4	IOP 6 to 21 mmHg; 20% reduction in IOP
Shah (2000)	21	35 (6–84)	62	IOP ≤21 mmHg; 25% reduction in IOP
Godfrey (2002)	18	20 (6–47)	83 at one year, 37 at three years	IOP ≤21 mmHg; 20% reduction in IOP
Smith (2009)	19	38.8 (12–80)	84.2	IOP 6 to 21 mmHg; 20% reduction in IOP
Sood (2009)	8	26.2 (11–42)	62.5	IOP ≤22 mmHg
Anand (2010)	43	33 (12–76)	83	IOP <21 mmHg; 25% reduction in IOP
Tung (2014)	43	39 (6–84)	81 at one year, 20 at three years	IOP ≤21 mmHg
Schaefer (2015)	15	132.1 (12–254)	40	IOP ≤18 mmHg
Capsule excision				
Valimaki (1997)	12	30 (8–75)	75	IOP 6 to 22 mmHg
Tsai (1999)	4	26.5 (13–55)	25	IOP 6 to 21 mmHg
Shah (2000)	12	25.2 (3–108)	42	IOP ≤21 mmHg; 25% reduction in IOP
Ibschitz-Tsimhoni (2005)	11	27.5 (13–47)	72.7	IOP 6 to 20 mmHg
Rosentreter (2010)	9	8.6	33	IOP <21 mmHg; 20% reduction IOP

* from Schaefer JL, et al. Br J Ophthalmol 2015;99:1718–1724. doi:10.1136/bjophthalmol-2015-306725

ASSISTs trial—AGS Second aqueous Shunt Implant vs. TranScleral Treatment Study). However, it will be a few years before that produces meaningful results.

For the purposes of this article, I'm defining primary tube-shunt failure as the inability to prevent progression of glaucoma in your patient using maximum tolerated medical options. In other words, despite the patient having a tube shunt and being on every medication you can reasonably prescribe, the glaucoma is still not controlled.

Managing Tube Number One

When we find that a patient with a tube shunt still has insufficiently controlled pressure, our first mission is to figure out why. To do that, we need to know whether the first tube shunt is still functioning. Is there fluid flowing into the reservoir or not? In some cases, the tube may still be functioning, but insufficient for getting the pressure down to your target range; in other cases, the shunt may have stopped working.

There are a couple of ways to determine whether the shunt is still working. One is to use an ultrasound B-scan to see if there's a hypoechoic shadow or border around the plate and the tube. A second option is to place a small-gauge needle on a syringe, prep the patient in a sterile manner, and then try to aspirate fluid from the reservoir over the plates; if you can't get anything out, then you know the tube is occluded. You can also push on the eye a little bit and see if the pressure drops and the reservoir comes up. (With the last two options, of course, you need to watch the anterior chamber carefully, because if the tube is actually working, you could theoretically collapse the anterior chamber by pulling or pushing out too much fluid.) The bottom line is, if there's fluid around the plate, the tube is functioning to some degree; it's just not working well enough to help that patient. In that situation you need to add another pressure-lowering option. (More on that below.)

If you've determined that the tube isn't working at all, you can either revise the tube to try to get it working again or replace it. One option is to try to flush out the tube in the OR using a 30-cc syringe. To do this, you pull the

Visual Outcomes: Cyclophotocoagulation (32 eyes) vs. Second Tube (15 eyes)

	Better vision (by ≥2 Snellen lines)	Same vision (within ±1 Snellen line)	Worse vision (by ≥2 Snellen lines)
CPC	1 (3 percent)	22 (77 percent)	6 (20 percent)
Tube	0	6 (40 percent)	9 (60 percent)

In this study conducted by Schaefer et al,[5] 11 of the 32 eyes in the CPC group (34.4 percent) required additional treatment following the secondary procedure, at a mean of 13.5 months (range: five to 40 months) despite the re-introduction of maximal tolerated medical therapy. Nine of 15 in the sequential GDD group (60 percent) underwent additional treatment, at a mean of 73.4 months (range: five to 173 months).

tube out of the eye and use a cannula loaded onto a large 30-cc syringe to forcefully irrigate the tube, in order to either expand or fracture the capsule of fibrous tissue that forms around the plate and tube. Another option is to try resecting the capsule from around the tube so that it's not restricting the volume the tube can hold.

This type of approach has been reported to have a success rate as high as 50 percent, but again, this depends on what the surgeons used for their definitions of success and how long they followed the patients. One published study compared the outcomes of resecting the capsule to putting in a second tube shunt.[1] The second-tube option did a better job of controlling the glaucoma, but the corneas in that group ended up failing more often. (The reality is, there's always a plus or minus to whatever treatment you choose for an eye that's sick enough to have needed a tube in the first place.)

Another option is to replace the first tube with a different type of tube. There's almost no published data regarding this approach, even though many surgeons report doing this. However, a very small series was recently published in which the surgeons removed failed Ahmeds and replaced them with Baerveldts. Two cases out of nine failed after five to eight years.[2] Given the small size of the series, of course, this isn't definitive information.

Moving to Step Two

If the first tube is still working but it's not adequate to control the glaucoma, then you have to try adding something else. Each option has some pros and cons:

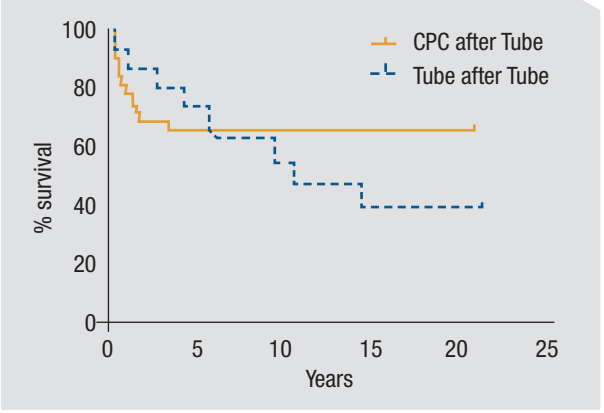
• ***Implanting a second tube.*** When the primary tube has failed, many surgeons would opt for adding a second tube. Most would place it in the opposite quadrant from the first tube, just because the tissue is usually much healthier there.

A second implant can definitely work, but it increases the risk of corneal edema and failure. In a retrospective study conducted by one group[3] there also seemed to be a risk of exposure of the first implant. We don't know if that was because of tissue manipulation, desiccation or some other factor. A second tube shunt certainly is not a panacea; additional interventions that were required after a second tube shunt have been reported because of tube erosion, corneal failure, endophthalmitis and hypotony.

Another key question is this: If you opt to implant a second tube, should you implant the same device or a different tube shunt? If an Ahmed isn't working, for example, some surgeons will switch to a Baerveldt or Molteno to see if they'll get a better result. Unfortunately, published data is scarce on the effectiveness of implanting the same device or trying one of the others; the surgeon has to use his or her best judgment regarding the cause of the first tube's failure and whether that suggests that a different device might work better.

When deciding whether to implant a second tube, another factor worth considering is the impact of having a second piece of hardware on the eye, in terms of vision. For example, diplopia can be an issue in this situation. Of course, many of these patients have very advanced disease, and some may only have one functioning eye. If the first shunt has failed, the eye is very sick by definition, so you're already dealing with a guarded prognosis.

Second Treatment: Survival of Tube vs. CPC



Kaplan–Meier analysis showing survival percentages for cyclophotocoagulation or a secondary tube over time. (Schaefer JL, et al. Br J Ophthalmol 2015;99:1718–1724.)

• ***Performing a trabeculectomy.*** Most surgeons wouldn't do a filtering procedure like a trabeculectomy with a tube

already in place. I haven't seen any published data on the success of such an approach, but the patient isn't likely to do well because the conjunctiva is already scarred. (Whether there's a role for a device like the Xen or InnFocus, which are bleb-creators, remains to be seen.)

• ***Performing a cyclodestructive laser procedure.*** This is an option that many surgeons would choose when a primary shunt has failed. In contrast to some of the other options, there's a lot of published data comparing implanting a second tube to the use of external diode cyclophotocoagulation (CPC) or endocyclophotocoagulation (ECP) after a tube shunt fails. *(For example, see table, facing page.)* If you look at visual outcomes when a CPC was used as the second intervention following a tube shunt, it maintained vision—plus or minus one line—far better than a second tube shunt did. I think that speaks volumes. CPC may be a better choice for preserving vision in these patients.

It's true that patients in some of the early studies required additional interventions, but many of those were actually extra CPC treatments. The reason for this was that when this option was first being investigated, surgeons were very conservative in the initial laser treatment, so they often undertreated. Up to that point, CPC had usually been reserved for eyes that were blind, or almost blind, because CPC was thought to create so much inflammation that it could put the eye at significant risk. In fact, we've learned that it's effective to start with a very conservative CPC and then follow up with additional treatments, as needed.

The group at the McGovern Medical School in Houston also retrospectively compared complications from a second tube shunt to complications from CPC; that data also favored CPC, in terms of avoiding serious complications, but the CPC group did require more interventions. The second-tube-shunt group had more serious complications, including three cases of endophthalmitis and more persistent corneal edema. This was also observed in the second-tube groups in some of the retrospective studies mentioned earlier.

There's less data regarding ECP as a second intervention. I usually do CPC—the external laser—unless I'm going into the eye to remove a cataract, or for some other reason; then I might try ECP. The one study I found on this showed that complications with ECP were limited, as you might expect, and the success rate at 12 months was 88 percent.[4] That's pretty consistent with what we saw with CPC. There's no data yet on using micropulse or SLT in this situation. I suspect that the impact of SLT might not be great enough to meet the needs of an eye in this situation.

Success Rates of Follow-up Procedures: Summary

Intervention	Reported success	Main complications
CPC	67 to 88 percent	Hypotony. Overall, there were lower complication rates but earlier failure.
Additional implant	37 to 86 percent	Corneal edema. Overall, there were fewer reoperations for IOP.
Capsule excision	25 to 75 percent	Lower rates of corneal decompensation; however, these were very small studies.

* Note: In many of the papers there were decreases in visual acuity, regardless of the type of intervention.

The Big Picture

The table on page 99, assembled by Jamie Schaefer, MD, et al, summarizes success rates for different follow-up procedures, reported in multiple studies. For CPC that's used after a primary tube shunt fails, the reported success rates ranged from 67 to 88 percent; the main complication was hypotony. Overall the CPC group had earlier failure, but lower complication rates, than the second-tube-shunt group. Additional tube shunt im-plants had a reported success rate of 37 to 86 percent; the most frequent complication seen with that option was corneal edema, but there was overall less reoperation for pressure, meaning that the glaucoma tended to be under control. For capsule excision, the reported rates of success were 25 to 75 percent, but those studies involved very small numbers of patients. Nevertheless, the rates of corneal decompensation were much lower. (I've summarized all of this in the table above.)

We don't yet have much information on the success rates of some of the newer procedures as follow-up to a tube shunt. One study did use the Trabectome in this situation, and out of 20 patients the survival rate was 84 percent at 12 months. There were no major complications (such as endophthalmitis), but three of the patients required additional glaucoma surgery.[6]

The new prospective, randomized trial designed to compare a second tube shunt to CPC mentioned earlier, the ASSIST study, sponsored by an American Glaucoma Society challenge grant and the Hermann Eye Fund in Houston, is currently enrolling patients. (Right now we're about a third of the way to being fully enrolled.) The lack of solid data regarding some of these questions was what prompted us to start this trial. It will be a multicenter international trial involving 33 sites. In terms of when to expect outcome data, completing the trial and analyzing the data will take a few years, because second tube shunts often fail three to five years out.

REVIEW Advertising Index

This advertiser index is published as a convenience and not as part of the advertising contract. Every care will be taken to index correctly. No allowance will be made for errors due to spelling, incorrect page number, or failure to insert.

REVIEW Glaucoma Management

Helping the Patient

What about my own experience? Initially I was doing a lot of second tubes in these patients, but when the retrospective data started coming out, I began opting more often for CPC. It's technically easier to perform, it's quicker, and the patient has a quicker recovery. Of course, we don't really know if the laser is the better option—yet.

When deciding how to proceed, you need to weigh the risks and benefits based on the patient sitting in front of you, looking for the least-offensive option to help that already sick eye.

These are difficult patients. Buying the patient as much time as possible is all you can really do, and every patient is different. There's no standard approach. Whenever we do any kind of invasive glaucoma surgery, we've already determined that the patient will go blind from glaucoma at some point, and a small risk associated with an intervention is almost always less than the risk of the person going permanently blind. (That being said, some risks are more serious than others. Glaucoma can blind a person over a period of years, but endophthalmitis can do it in a week.) When deciding how to proceed, you need to weigh the risks and benefits based on the patient sitting in front of you, looking for the least-offensive option to help that already sick eye. REVIEW

Dr. Blieden is an assistant professor at the Cullen Eye Institute, Baylor College of Medicine in Houston. She has no relevant financial disclosures, but is the director of the Data Collection Center for the ASSIST trial.

1. Shah AA, WuDunn D, Cantor LB. Shunt revision versus additional tube shunt implantation after failed tube shunt surgery in refractory glaucoma. Am J Ophthalmol 2000;129:4:455-60.
2. Zuo W, Lesk MR. Surgical outcome of replacing a failed Ahmed glaucoma valve by a Baerveldt glaucoma implant in the same quadrant in refractory glaucoma. J Glaucoma 2018;27:5:421-428.
3. Wang MY, Patel K, Blieden LS, et al. Comparison of Efficacy and Complications of Cyclophotocoagulation and second glaucoma drainage device after initial glaucoma drainage device failure. J Glaucoma 2017;26:11:1010-1018.
4. Francis BA, Kawji AS, Vo NT, Dustin L, Chopra V. Endoscopic cyclophotocoagulation (ECP) in the management of uncontrolled glaucoma with prior aqueous tube shunt. J Glaucoma 2011; 20:8:523-7.
5. Schaefer JL, Levine MA, Martorana G, et al. Failed glaucoma drainage implant: long-term outcomes of a second glaucoma drainage device versus cyclophotocoagulation. Br J Ophthalmol 2015;99:1718–1724.
6. Mosaed S, Chak G, Haider A, et al. Results of Trabectome surgery following failed glaucoma tube shunt implantation: Cohort study. Medicine (Baltimore) 2015;94:30:e1045.

A 23-year-old woman presents to the Wills Eye Emergency Room complaining of bilateral eye pain and redness.

Josh Uhr, MD, Matthew Palmer, MD, PhD, and James P. Dunn, MD

Presentation

A 23-year-old Caucasian female presented to the Wills Eye Emergency Room complaining of two days of bilateral eye pain, photophobia and redness. There was no change in vision. She had not had similar symptoms previously.

Medical History

The patient had no past ocular history. Past medical history was significant for a hospital admission two months prior to presentation for a week of weakness, nausea and vomiting. She was found to have an increased creatinine of 2.84 and granular casts on urinalysis, consistent with acute tubular necrosis. The creatinine increased to 4.00, and a kidney biopsy was performed showing tubular interstitial nephritis with eosinophilia. Medications at the time of admission included calcium carbonate, lactobacillus probiotic, acetaminophen as needed, the weight-loss supplement Apidexin, a multivitamin and over-the-counter nasal decongestants; none were considered to be the cause of the interstitial nephritis. The patient was started on prednisone 60 mg daily, which was quickly tapered over the following month. Family history was negative for renal or autoimmune diseases. Social history was non-contributory.

Examination

Ophthalmic examination revealed a visual acuity of 20/20-2 in the right eye and 20/20 in the left. Pupils were normal and intraocular pressures were 12 mmHg in both eyes. Motility and confrontational visual fields were full bilaterally.

The anterior segment examination revealed 1+ conjunctival injection with ciliary flush in both eyes. Diffuse fine keratic precipitates and 2-3+ cell and flare were observed in each eye. Pigment on the anterior capsule was also noted. Dilated fundus exam was normal without vitritis, chorioretinitis, macular or optic disc edema, or vessel sheathing in either eye.

What is your diagnosis? What further workup would you pursue? The diagnosis appears on p. 104.

Workup, Diagnosis and Treatment

Upon presentation to the Wills ER, details of the patient's recent admission were unavailable. Since she presented with a first episode of bilateral anterior uveitis, an initial uveitis workup was obtained, including syphilis antibody enzyme immunoassay, interferon-gamma release assay for tuberculosis, Lyme IgG/IgM antibody screen, HLA-B27 typing, angiotensin-converting enzyme and chest X-ray. All were normal.

The patient was started on prednisolone acetate 1% every two hours while awake and cyclopentolate 1% twice daily in both eyes. At follow-up, renal biopsy records were obtained, and she was diagnosed with tubulointerstitial nephritis and uveitis (TINU) syndrome *(Figure 1)*. Her anterior chamber reaction improved, and the topical steroids were tapered within two months. Several weeks after discontinuing her drops, the patient returned to the clinic and was found to have 3+ cell and flare in both eyes. Prednisolone drops were restarted four times daily. Three months later, both anterior chambers were quiet, and there were broken posterior synechiae from 6 to 7 o'clock in the left eye *(Figure 2)*. The remainder of the exam was normal. She was started on a slow topical steroid taper, which she was on at her most recent appointment.

During her treatment, the patient's IOP increased to a maximum of 22 mmHg bilaterally from a baseline of 12 mmHg. She was started on brimonidine tartrate 0.2%/timolol maleate 0.5% drops b.i.d. in each eye, and her IOPs remained controlled over successive follow-up visits.

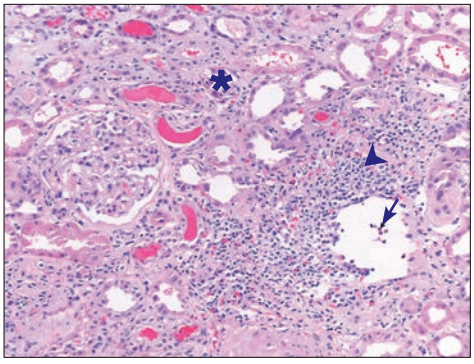


Figure 1. A representative photomicrograph of a renal biopsy (not from the patient in this report) demonstrating the features of interstitial nephritis. The inflammatory infiltrate is lymphocyte predominant (arrowhead) with some neutrophils (arrow). Interstitial edema and tubulitis (star) are also present.

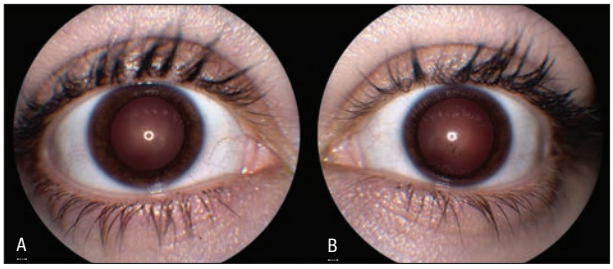


Figure 2. Anterior segment photos of the right (A) and left (B) eyes. The left eye demonstrates broken posterior synechiae on the anterior lens capsule at 6 to 7 o'clock, but both eyes are white and quiet three months after restarting topical prednisolone acetate 1% to manage a relapse of anterior uveitis.

Discussion

Uveitis is a collection of approximately 30 distinct diseases, all characterized by intraocular inflammation.[1] Disease course and management can vary widely by etiology, highlighting the need for an accurate diagnosis.

Uveitis is typically characterized by time course (acute or chronic), laterality, anatomic location (anterior, intermediate or posterior), morphology (e.g., paucifocal or multifocal), pathogen (e.g., toxoplasmosis, Lyme disease), and host/systemic disease factors (e.g., immunocompromised or immunocompetent). Even in cases in which a specific diagnosis cannot be made, it's more informative to call the disease "undifferentiated" and use the above characteristics to describe it rather than label it "idiopathic," as is often done.[1]

Our patient presented with undifferentiated bilateral acute anterior uveitis. The differential diagnosis for anterior uveitis is broad, including, but not limited to, HLA-B27-associated inflammatory bowel disease, psoriatic arthritis, TINU, sarcoidosis, Behçet's disease, viral etiologies (e.g., herpes simplex or herpes zoster), syphilis, tuberculosis and Lyme disease.[2] Further history in this case revealed a recent systemic illness, during which the patient was found to have an acute kidney injury. The workup consisted of a renal biopsy that revealed tubulointerstitial nephritis. In the setting of bilateral anterior uveitis with an otherwise negative uveitic workup, the findings were consistent with the diagnosis of TINU.

TINU, which usually occurs in adolescent females, is thought to be an autoimmune disorder, although its mechanism is unknown.[3] This disease is rare, representing 0.1 to 2 percent of cases seen in specialty uveitis clinics, although it's likely underdiagnosed.[4]

In addition to its low prevalence, making the diagnosis of TINU can be challenging because the signs and symptoms of acute interstitial nephritis are non-specific. In a review of 133 cases of TINU, researchers at Jules Stein Eye Institute at UCLA identified fever (53 percent), weight loss (47 percent), and fatigue/malaise (44 percent) as the three most common presenting symptoms.[5] Only 32 percent of patients initially presented with eye pain or redness. Finally, episodes of nephri-

tis don't usually occur simultaneously with uveitis. In the same review from UCLA, researchers found that only 15 percent of patients presented with concurrent interstitial nephritis and uveitis.[5] Twenty-one percent of patients had uveitis that preceded nephritis, and 65 percent had nephritis that preceded uveitis by at least one month, in some cases as much as eight months after the onset of renal disease.

The uveitis associated with TINU is limited to the anterior chamber in 80 percent of cases and is bilateral in 77 percent.[6] Posterior involvement, if present, can include mild vitritis, disc edema or macular edema. The disease is most often non-granulomatous. Panuveitis, unilateral uveitis and granulomatous uveitis have all been reported, however.[6] In a study of clinical features of patients with TINU at a medical center in Hokkaido, Japan, the authors report that the most common ocular findings at onset of uveitis were conjunctival injection, iridocyclitis and fine keratic precipitates. Five of nine patients had anterior vitreous cells, but only two had vitreous opacities. Six of nine patients had recurrence, with a trend towards more severe anterior inflammation and posterior segment involvement with recurrent episodes.[7]

TINU may have a genetic predisposition or be associated with certain HLA subtypes, but there's no consensus to date.[4] There is more evidence for an association with certain medications, in particular NSAIDs and antibiotics.[5] Interestingly, medications associated with TINU, including cidofovir, rifabutin, sulfonamides and bisphosphonates, appear to differ from those associated with drug-induced uveitis, which suggests that the mechanism for drug-induced uveitis may be different from that of TINU. Infections are also recognized to be associated with TINU, although less commonly than medications.[5]

Treatment of the uveitis in TINU most often consists of topical steroids and cycloplegics. Periocular steroid injections have also been used. Systemic steroids have been reported for uveitis alone but are typically reserved for patients with progressive renal failure. In cases in which systemic corticosteroids failed or weren't tolerated, disease control with immunomodulatory medications such as azathioprine, methotrexate, cyclosporine or mycophenolate mofetil have been reported.[5] Our patient has required oral steroids multiple times for control of interstitial nephritis. She experienced a recurrence of uveitis after discontinuing topical steroids, but her ocular inflammation is currently well controlled on prednisolone acetate 1% drops alone.

In conclusion, TINU is an uncommon but likely underdiagnosed cause of bilateral anterior uveitis with systemic manifestations, especially in young females. It's challenging to diagnose in part due to its rarity, but also because uveitis doesn't often correlate temporally with nephritis. Thorough history taking is critical to establishing the correct diagnosis. REVIEW

At Wills, Dr. Uhr is in the Department of Medical Education and Dr. Dunn is in the Retina Service. Dr. Palmer is with the Department of Pathology and Laboratory Medicine, University of Pennsylvania Perelman School of Medicine.

1. Jabs DA, Busingye J. Approach to the diagnosis of the uveitides. Am J Ophthalmol 2013;156:2:228-236.
2. González-López JJ, García-Aparicio ÁM, Sánchez-Ponce D, et. al. Development and validation of a Bayesian network for the differential diagnosis of anterior uveitis. Eye 2016;30:6:865-872.
3. Kim JE, Park SJ, Oh JY, et. al. Successful treatment of tubulointerstitial nephritis and uveitis with steroid and azathioprine in a 12-year-old boy. Korean J Pediatr 2016;59:S99-S102.
4. Okafor LO, Hewins P, Murray PI, et al. TINU syndrome: A systematic review of its epidemiology, demographics and risk factors. Orphanet J Rare Dis 2017;12:1:128.
5. Mandeville JT, Levinson RD, Holland GN. The tubulointerstitial nephritis and uveitis syndrome. Surv Ophthalmol 2001;46:3:195-208.
6. Aguilar MC, Lonngi M, de-la-Torre A. Tubulointerstitial nephritis and uveitis syndrome: Case report and review of the literature. Ocul Immunol Inflamm 2016;24:4:415-421.
7. Goda C, Kotake S, Ichiishi A, et. al. Clinical features in TINU syndrome. Am J Ophthalmol 2005;140:4:637-641.

(Continued from p. 22)

white paper and issued in advance of the service contemplated. The patient's questions must be answered in full before you ask her to sign. You must use blue or black ink, but you may also issue the ABN electronically (In this case, be sure to also offer the beneficiary a paper copy of what she signed.). As the issuer of the ABN, you must maintain a copy in your files (paper or electronic). You can't "pre-select" one of the three options for the beneficiary. Additionally, you can't use patients' old Medicare numbers or their new Medicare Beneficiary Identifier (MBI) numbers from the new cards that are currently being rolled out.

Of note, you can have an attachment page when the information in the required boxes might prevent a violation of the "one-page, single-sided" rule.

Q What about other payers?

A While patients think that being covered under a Medicare Advantage plan is the same as "regular" Medicare, in this instance there is a restriction. The official Advance Beneficiary Notice of Noncoverage is prohibited if Part C coverage is in play for a beneficiary; be sure to ask the individual Part C plans for their process and all of the required forms. Medicare Advantage plans might require an itemized list of individual ICD-10 and CPT codes and require you to submit the claims and use specific modifiers to properly assign patient responsibility. If you don't do as the plan requires, the beneficiary cannot be held liable and you could be forced to refund all of the money you received. Other private payers may have their own forms and processes for handling financial waivers. REVIEW

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

(Continued from p. 52)

out what you're able to see through a scar. You can often see more than you'd expect. If the scar is central, I note the density to make sure that I can operate through it. If it's peripheral, you're usually OK. In patients with significant scarring who are candidates for cataract surgery, in some cases you might consider PTK if it's a superficial scar, or potentially even a corneal transplant if it's extensive and really in the way. Scarring is definitely going to impact the patient's visual outcome as well as your surgery, so work around it as best as you can."

Postop Protocols

Most surgeons will keep the herpes patient on the antiviral medication during his postop course, but will alter the regimen based on different factors.

"For someone prone to more inflammation, such as a uveitic patient and perhaps a patient with past keratitis, I'd consider going to a Durezol—a little bit stronger medication—to keep down the inflammation," Dr. Balakrishnan avers. "And watch the pressure in these patients, because they're more likely to spike. I'd keep them on preventative Valtrex or, if they're higher-risk patients, consider doing a 10-day therapeutic course followed by tapering down to a q.d. course. These patients are more likely to have inflammation, pressure changes and to develop CME. You want to observe them closely. I usually don't let them go more than a week before seeing them in the immediate postop period.

"If, in the past, they only had dendritic keratitis, for instance, I'd be inclined to go the opposite way," she continues. "I'd probably keep them on a lower-potency steroid such as Lotemax or something a little stronger, and keep them on Valtrex q.d. For these patients, steroids aren't the treatment for that form of herpetic infection, so when you need to put them on steroids, you have to make sure that you balance it—you don't really need a heavy-hitting steroid."

Dr. Afshari notes there's a difference between cataract and corneal-transplant patients in terms of the postoperative medication course. "If it's a cataract patient, I'll often continue acyclovir, valacyclovir or pancyclovir a little while after the surgery," she says. "But, if it's a corneal transplant procedure, then I use one of these antivirals for months afterward. I may keep corneal-transplant patients on antibiotics a little longer. I'd give them some lubricating ointment to decrease the friction between the lid and the cornea. I'd also watch the epithelium more carefully, and sometimes will use amniotic membrane and a contact lens, or just a contact lens itself, to help the transplant patient in the initial stages of re-epithelialization. Really watch their corneas carefully, and know that you're not out of the woods even later on." REVIEW

UNITED STATES POSTAL SERVICE®

Statement of Ownership, Management, and Circulation (Requester Publications Only)

1. Publication Title	2. Publication Number	3. Filing Date
Review of Ophthalmology	0012-3458	09/06/18
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price (if any)
Monthly	12	$63.00

7. Complete Mailing Address of Known Office of Publication (Not printer) (Street, city, county, state, and ZIP+4®): Jobson Medical Information, 440 Ninth Ave, 14th Floor, New York, NY 10001 — Contact Person: Hamilton Maher; Telephone (Include area code): 212-274-7038

8. Complete Mailing Address of Headquarters or General Business Office of Publisher (Not printer): Jobson Medical Information, 440 Ninth Ave, 14th Floor, New York, NY 10001

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor (Do not leave blank)

Publisher (Name and complete mailing address): James Henne, Publisher, Reviews Group, Jobson Medical Information, 11 Campus Drive, Suite 100, Newtown Square, PA 19073

Editor (Name and complete mailing address): Walter C. Bethke, Editor-in-Chief, Jobson Medical Information, 11 Campus Drive, Suite 100, Newtown Square, PA 19073

Managing Editor (Name and complete mailing address): Christopher Kent, Managing Editor, Jobson Medical Information, 11 Campus Drive, Suite 100, Newtown Square, PA 19073

10. Owner (Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)

Full Name	Complete Mailing Address
Jobson Medical Information	440 Ninth Avenue, 14th Floor New York, NY 10001

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box. ☐ None

Full Name	Complete Mailing Address

12. Tax Status (For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months (Publisher must submit explanation of change with this statement.)

PS Form **3526-R**, July 2014 (Page 1 of 4 (See instructions page 4)) PSN: 7530-09-000-8855 **PRIVACY NOTICE:** See our privacy policy on www.usps.com.

13. Publication Title	14. Issue Date for Circulation Data Below
Review of Ophthalmology	August 2018

15. Extent and Nature of Circulation			Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies (Net press run)			25,539	23,576
b. Legitimate Paid and/or Requested Distribution (By mail and outside the mail)	(1)	Outside County Paid/Requested Mail Subscriptions stated on PS Form 3541. (Include direct written request from recipient, telemarketing, and Internet requests from recipient, paid subscriptions including nominal rate subscriptions, employer requests, advertiser's proof copies, and exchange copies.)	13,353	12,738
	(2)	In-County Paid/Requested Mail Subscriptions stated on PS Form 3541. (Include direct written request from recipient, telemarketing, and Internet requests from recipient, paid subscriptions including nominal rate subscriptions, employer requests, advertiser's proof copies, and exchange copies.)	0	0
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS®	86	52
	(4)	Requested Copies Distributed by Other Mail Classes Through the USPS (e.g., First-Class Mail®)	0	0
c. Total Paid and/or Requested Circulation (Sum of 15b (1), (2), (3), and (4))			13,439	12.790
d. Non-requested Distribution (By mail and outside the mail)	(1)	Outside County Nonrequested Copies Stated on PS Form 3541 (include sample copies, requests over 3 years old, requests induced by a premium, bulk sales and requests including association requests, names obtained from business directories, lists, and other sources)	11,431	10,345
	(2)	In-County Nonrequested Copies Stated on PS Form 3541 (include sample copies, requests over 3 years old, requests induced by a premium, bulk sales and requests including association requests, names obtained from business directories, lists, and other sources)	0	0
	(3)	Nonrequested Copies Distributed Through the USPS by Other Classes of Mail (e.g., First-Class Mail, nonrequestor copies mailed in excess of 10% limit mailed at Standard Mail® or Package Services rates)	225	10
	(4)	Nonrequested Copies Distributed Outside the Mail (Include pickup stands, trade shows, showrooms, and other sources)	0	0
e. Total Nonrequested Distribution (Sum of 15d (1), (2), (3) and (4))			11,656	10,355
f. Total Distribution (Sum of 15c and e)			25,095	23,145
g. Copies not Distributed (See Instructions to Publishers #4, (page #3))			444	431
h. Total (Sum of 15f and g)			25,539	23,576
i. Percent Paid and/or Requested Circulation (15c divided by 15f times 100)			53.55%	55.26%

* If you are claiming electronic copies, go to line 16 on page 3. If you are not claiming electronic copies, skip to line 17 on page 3.

UNITED STATES POSTAL SERVICE®

Statement of Ownership, Management, and Circulation (Requester Publications Only)

16. Electronic Copy Circulation	Average No. Copies Each Issue During Previous 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Requested and Paid Electronic Copies		
b. Total Requested and Paid Print Copies (Line 15c) + Requested/Paid Electronic Copies (Line 16a)		
c. Total Requested Copy Distribution (Line 15f) + Requested/Paid Electronic Copies (Line 16a)		
d. Percent Paid and/or Requested Circulation (Both Print & Electronic Copies) (16b divided by 16c × 100)		

☐ I certify that 50% of all my distributed copies (electronic and print) are legitimate requests or paid copies.

17. Publication of Statement of Ownership for a Requester Publication is required and will be printed in the October 2018 issue of this publication.

18. Signature and Title of Editor, Publisher, Business Manager, or Owner — Date: 9/5/18

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including civil penalties).

The Keeler[3] Trade In Program

Buy 3 // Trade 3 // Get 1 Free

The Power of 3. Purchase any 3 Keeler Slit Lamps and trade in 3 of your old Slit Lamps and we'll send you a 4th Keeler Slit Lamp absolutely free of charge.

KSL-H

(also in Digital Ready)

KSL-H-D

(full Digital)

KSL-Z

(also in Digital Ready)

KSL-H-D

(full Digital)

Keeler OPTICS

Keeler Instruments, Inc. • 3222 Phoenixville Pike, bldg. 50 • Malvern, PA 19355
Tel: (800) 523-5620 • Fax: (610) 353-7814 • email: keeler@keelerusa.com

Offer valid until December 31, 2018.

Contact Keeler or one of our authorized dealers for more information.

Approved & Available Soon

DEXYCU™

(dexamethasone intraocular suspension) 9%

Learn more at EyePointPharma.com

EYEPOINT™ PHARMACEUTICALS

480 Pleasant Street, Suite B300, Watertown, MA 02472

08/2018
DEX0003