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REVIEW NEWS
Volume XXIV • No. 11 • November 2017

Shire Sues Allergan for Stifling Competition in Dry-eye Arena

Shire (Dublin, Ireland) filed an antitrust suit against Allergan (Dublin, Ireland) on October 2, 2017, alleging Allergan conducted unfair business practices in an effort to block Xiidra from Medicare Part D formularies and maintain Restasis' estimated 90 percent share of the Medicare market for chronic dry eye. Although Shire and Allergan are both headquartered in Dublin, Allergan has a U.S. location in Parsippany, N.J., and Shire does business in Lexington, Mass. Shire filed the federal complaint (Shire US v Allergan Inc. et al; No. 17-07716) in New Jersey District Court.

Shire claims that Allergan has squeezed Xiidra out of the Medicare market by offering Part D plans drastic discounts and/or rebates across a range of its pharmaceuticals, in addition to Restasis, in exchange for maintaining Restasis in a preferred-tier position on their formularies. "Through a combination of anticompetitive bundling and exclusive dealing arrangements, Allergan is coercing Part D plans representing over 70 percent of the Part D market for prescription DED medications to effectively exclude Xiidra from, or severely restrict Xiidra on, their formularies, while at the same time maintaining Restasis—Allergan's 15-year-old and clinically inferior drug—on a 'preferred' formulary tier," the complaint alleges.

Shire claims that Allergan has accomplished this shutout of Xiidra by offering Medicare Part D plans discounts and rebates spanning a portfolio of its drugs, so that when Shire offered multiple Part D plans substantial discounts and rebates to place Xiidra on their formularies, the plans declined. Shire alleges that Allergan's hold was so all-encompassing that one Medicare Part D representative advised, "You could give [Xiidra] to us for free, and the numbers still wouldn't work."

Shire contends that Allergan is anxious to preserve the larger market share of its "mature cash cow," Restasis, which it says netted Allergan $1.487 billion in sales for 2016 alone, producing more revenue than any other drug made by the company with the exception of Botox. While Restasis is approved for deficient tear production in dry-eye disease, Xiidra received a broader indication from the FDA, for the signs and symptoms of DED generally. Per goodrx.com, 30-day supplies of the drops have very similar average retail prices: $578.38 for Xiidra; $574.99 for Restasis.

Restasis was the only FDA-approved topical eye drop for the treatment of chronic dry eye from 2002 until 2016, when Xiidra was approved. Shire says that Xiidra claimed 20 percent of the prescription dry-eye market in its first six months of availability. Estimates place the chronic dry-eye population in the U.S. as high as 16 million people, although one million or fewer are thought to be receiving treatment.

An emailed request to Allergan for comment was unanswered, but Allergan spokesman Mark Marmur has stated that the lawsuit lacks merit, and that the manufacturer's pricing of Restasis to Medicare Part D and commercial plans flows solely from natural competition in the dry-eye market.

The antitrust complaint comes on the heels of Allergan's unorthodox decision to transfer its six patents related to Restasis to the St. Regis Mohawk tribe in New York State on the grounds that the tribe's sovereignty would protect the Restasis patents from *inter partes* review of their validity; legal challenges from other manufacturers seeking to formulate generic equivalents of Restasis have also been in play. The contenders include Teva Pharmaceuticals, Mylan Pharmaceuticals, Akorn and Apotex. The tribe got $13.5 million up-front for taking possession of the Restasis patents and licensing them back to Allergan and expected another $15 million annually for as long as the patents were valid.

On October 16, 2017, the U.S. District Court for the Eastern District of Texas invalidated four of the six Restasis patents. The decision also characterized Allergan's deal with the St. Regis Mohawk as the "renting" of tribal sovereignty to serve as a shield from IPRs. As a result, a compounded version of the drug from Imprimis has already appeared at a steeply discounted price compared to Restasis.

Does ALS Affect The Retina?

A combined team of ophthalmology and amyotrophic lateral sclerosis

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Ophthalmic Product Development Insights

Matthew Chapin & George Ousler

Establishing the Target Product Profile: Examples from the Anterior Segment

In the previous column, we discussed some points related to the development of the Target Product Profile, specifically those related to retina product development. This month, we'll continue that theme and look at a few areas that factor into the TPP for drugs designed for selected anterior segment indications. We can't cover all areas related to anterior segment in this brief piece, but we'll highlight a few pearls for new physician entrepreneurs to consider when thinking about the selection of a drug's indication.

Generally, when starting a development program, it's good to create at least two TPPs and compare them directly against profiles of the existing market leaders. One is a TPP with ideal criteria, and the second is the minimum acceptable profile, in which some elements may not be the best, but are still enough to support development and commercial feasibility. For example, the target may be once-daily dosing, but the minimally-acceptable dosing regimen may be twice daily. Similar thought processes can be used for the drug's indication, patient population, dosing frequency and duration, container closure and storage conditions (i.e., Will this product be stored at room temperature, or is cold-chain refrigeration— in which the different steps of the supply chain each involve refrigeration—acceptable?), clinical data for the package insert, and safety. Remember that for a topical ocular product, the comfort of the eye-drop formulation upon instillation may be a key aspect of the safety profile, as well. Products have battled in the marketplace based on patient comfort, but in the current reimbursement environment you have to consider if comfort alone would drive coverage by payers v. the standard of care.

When a new drug has a mechanism of action that can be applicable to multiple disease indications, or has various mechanisms of action, the selection of the lead indication(s) will drive the development program, the positioning and value proposition for the fundraising plan and its presentation. Is the plan to study one indication only, or to raise funds for multiple studies to be run either in parallel or sequence, across multiple indications, which may both build additional value and provide additional "shots on goal"? In our experience in talking with entrepreneurs, it's not always clear to them which indication to lead with, particularly since a product may have applications across multiple indications, each of which have defined clinical-regulatory pathways and unmet needs in the market that can potentially be addressed.

For example, with an anti-inflammatory drug, one has several major indications to consider. This is a general, high-level framework to use when considering them for such a situation:

• *Dry eye.* Currently, this is certainly the largest market for front-of-the-eye drugs. The success of Restasis and the introduction of Xiidra in 2016 have built considerable awareness of dry-eye disease in the general public, and of the value of dry-eye products in the world of pharmaceuticals and start-up companies. There's a very large opportunity for new products, especially if they feature different mechanisms of action that address alternative areas of the inflammation cascade and wound-healing response, and/or consist of therapies such as anti-apoptotics, anti-oxidants, secretagogues, mucogenics, mucomimetics, novel lipids, hormonal therapies and polymers. When developing a dry-eye product, it's important to consider mitigating clinical development risk. This includes targeting the proper subgroup of dry-eye disease, using validated endpoints and controlling environmental factors either through design or a clinical-controlled model approach. For example, there is a seasonal impact on disease signs and symptoms, and this may influence the timing of trials and introduce the need to build in tight control of operations and standardization across sites to maintain timelines and data precision.

Many dry-eye products are unpreserved, which raises different manufacturing considerations that impact time and cost for clinical supplies via utilizing blow fill seal manufacturing of unit-dose vials, alternative formulation technologies or container-closure approaches. These need to be considered early on.

• *Blepharitis.* One of the most common reasons for office visits is inflammation and discomfort of the eyelids. Interestingly, which side of the gray line of the lid margin you look at has large implications in terms of the actual disease to target and clinical-regulatory pathway to follow. When focusing on treating the posterior portion of the lid margin, the meibomian glands, the ultimate clinical endpoints are signs and symptoms similar to dry eye. Especially helpful for early studies, our group has focused on the imaging and categorization of different characteristics of the glands to help with patient selection, and on the evaluation of gland modulation. When moving to the anterior side of the lid margin, the signs and symptoms of blepharitis become redness and edema of the lid margins, discomfort and lid debris. For blepharitis, the current regulatory requirement is total clearing of these signs and symptoms. On a regulatory note, therapies in clinical trials must show superiority to lid scrubs, which are currently considered standard-of-care. Blepharitis is a large unmet need, and generally speaking, appears to be driven by an inflammatory process. When the first product—which may be a steroid—with a specific label for blepharitis gains approval, this should lay the groundwork for the evaluation of other agents and attract more interest in developing drugs for this indication. As with most product development programs, precise, validated clinical scales and standardized assessments across investigators in a multicenter trial will be two of the keys to success.

• *Postoperative inflammation.* Evaluating anterior chamber cells and flare, and pain following cataract or refractive surgery, has been a standard clinical-regulatory endpoint/pathway for the development of anti-inflammatories such as steroids and NSAIDs. This

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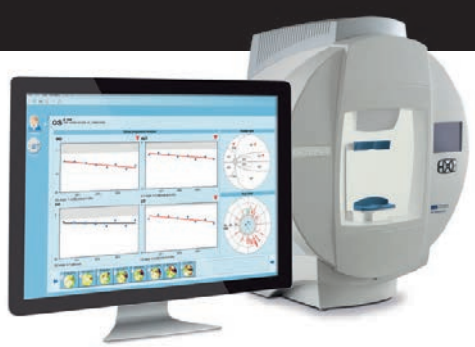

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well-established clinical-regulatory pathway (acute studies which focus on primary endpoints for the weeks after surgery), has been used for products like difluprednate, ketorolac, bromfenac, nepafanac, loteprednol and others. However, one has to balance the clinical unmet need in this area with the usefulness of the development pathway. Steroids and NSAIDs are standard in postop use, and have a high hurdle for showing superiority. But thanks to superior dosing regimens and/or sustained-release approaches, a higher percentage of patients with clearing, or speed to clearing, or a higher reduction in inflammation and pain—though relatively high hurdles—are areas that can be explored. In general, the studies are placebo-controlled. Naturally, the pharmacokinetics of the drug and formulation need to support penetration of the anterior chamber when compared to the ocular surface indications.

• *Allergy.* Don't forget allergy. Dominated by topical antihistamines, and now with generic and over-the-counter ketotifen available (it's currently the only long-acting antihistamine available OTC) and once-a-day products, the focus here is on novel mechanisms. There's still a large unmet need in a large proportion of patients with ocular allergy, with 30 to 40 percent of patients suffering from persistent allergic inflammation and showing an incomplete response to antihistamines. Steroids, of course, are still reserved for acute therapy in severe patients and cases non-responsive to antihistamines, due to their well-established side effects. There is opportunity, however, for the development of novel anti-inflammatories and agents with non-steroid mechanisms. A key attribute of allergy programs is the very rapid, precise and reproducible clinical trials utilizing the conjunctival allergen challenge (CAC) model that is validated and acceptable for use in both Phase II and Phase III U.S. trials, as well as trials in Japan, the second-largest market for allergy therapies. The CAC's precision for positive proof of concept and dose ranging, reproducibility, and then speed through Phase III is unique and attractive and several companies with novel anti-inflammatories have chosen to go after allergy as a lead, or at least as a parallel program to complement their clinical data set. Of note, the above CAC model is also ideal for rapid proof-of-concept testing to demonstrate effects on ocular surface inflammation and dose ranging, whether or not the goal is allergic conjunctivitis.

More severe chronic allergic diseases such as atopic keratoconjunctivitis and vernal keratoconjunctivitis can also be considered lead indications for targeted therapeutics. However, as they are orphan indications, they're more difficult to recruit for.

• *Uveitis.* Anterior uveitis is another of the more mainstream anterior segment inflammatory conditions worth considering. As there are multiple subgroups within this disease that can be targeted with specific anti-inflammatories, and generally due to the overall market size, we don't see many programs leading with anterior uveitis with broad anti-inflammatory products unless there is a specific mechanistic story that fits best for uveitis compared to the other main indications. But we mention it here to round out the list of key inflammatory indications for consideration.

The topic of class labeling is reserved for another discussion, but suffice it to say that there are opportunities for class labeling, and this requires showing efficacy across multiple indications, and is usually part of a life-cycle plan.

A Case Study

The ophthalmic program that pharmaceutical company ReGenTree is pursuing with Thymosin Beta 4 (Tβ4) serves as a good case study and example of a business structure for funding between a U.S. firm and an ex-U.S company that has a strategic interest in the product. RegeneRx (Rockville, Md.) had been developing its Tβ4 platform across indications in the eye, as well as systemic indications. Tβ4, a naturally occurring peptide, enhances wound healing and tissue remodeling by increasing cell migration, cell-to-cell and cell-to-matrix contacts, and antioxidant activity, and by reducing apoptosis and inflammation via downregulation of chemokines and cytokines. With these broad activities, Tβ4 has many potential applications.

After performing compassionate-use and investigator-led proof-of-concept evaluations in neurotrophic keratitis, RegeneRx chose to pursue dry eye as well. Neurotrophic keratitis would be a parallel program; NK is an orphan indication with a lower number of patients, but there are advantages to orphan indication status, and the pathology fits with the wound-healing properties of Tβ4. This approach potentially provides multiple 'shots on goal,' and demonstrates Tβ4's breadth of applications.

In 2015, RegeneRx partnered with the Korean clinical-stage development company GtreeBNT (Gtree) and formed the joint-venture ReGenTree, as a vehicle for funding and conducting the ophthalmic program in the United States. After reviewing more than 50 candidates in the early stage of human trials, Gtree concluded that a dry-eye indication would be the best fit for it because it determined that it could cover the investment of time and money required to develop an NDA in the United States. This led to Gtree reaching out to RegeneRx. Gtree also agreed to this deal given its strategic interest in eventually marketing a novel treatment globally, and its ability to attract funds from Korean-based venture capital firms for the funding of ReGenTree. The funding has financed Phase III studies, and Gtree plans to partner this product with a global pharmaceutical company for U.S./global rights.

Won Yang, president and CEO of GTree, explains the thought process behind the partnership. "We selected dry eye based on the total market potential for that indication," he says. "However, strategically, since wound healing is related directly to the primary mode of activity, we supported funding of a parallel program in neurotrophic keratitis. This structure leveraged GTree's access to investors in Korea, to identify and invest in a novel treatment from the U.S. that can also be eventually brought to the Korean market."

While this is not intended to be an exhaustive review, we hope we've elucidated the thought process involved when considering a drug's indications for the anterior segment and ocular surface. Specifically, when a drug has anti-inflammatory activity, the key is to be able to select from a range of ocular indications. The crucial factors in the selection of the lead indication(s) are: the specific molecular pathways targeted; formulation and manufacturing considerations; pharmacokinetics appropriate for the lead indication; and how different it is from the current standard of care for that indication. Examining the target profile (both the ideal and the minimal acceptable targets) and predict-

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ing how the product will differentiate itself from the competition will help drive its positioning in the minds of clinicians and payers, the plans for development and funding, and the designs of future studies.

Mr. Chapin is senior vice president of corporate development at Ora, and Mr. Ousler is vice president of dry eye. Ora provides a comprehensive range of development, clinical-regulatory and consulting services for developers, investors and buyers; preclinical and turnkey clinical trial services; assistance with regulatory submissions; and the integration of business development and fundraising support in ophthalmology. The authors welcome your comments or questions regarding product development. Please send correspondence to mchapin@oraclinical.com or gousler@oraclinical.com or visit www.oraclinical.com.

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researchers hope their retinal findings in patients with ALS eventually lead to a way to diagnose the disease earlier.

Henry Tseng, MD, PhD, a glaucoma specialist and assistant professor of ophthalmology at Duke University, is researching the mechanism of visual loss in glaucoma and how glaucoma relates to other neurodegenerative diseases. "Since I'm an eye doctor, people would ask me, 'Why are you studying ALS?'" Dr. Tseng says. "The answer is that one of the most exciting recent discoveries is that three glaucoma genes have also been linked to ALS. There seems to be something going on at the cellular level that may show a commonality between the diseases. This came as a total surprise to basic scientists and clinicians alike."

To try to build upon this finding, Dr. Tseng formed a joint research study with Richard Bedlack, MD, PhD, director of Duke's ALS clinic. "We didn't know if there were any ocular changes in patients with ALS, let alone glaucoma changes," Dr. Tseng avers. "That's why we undertook this study."

To make sure the study results carried weight, the researchers first examined the ALS patients to ensure there were no eye diseases that could cause retinal changes. They also made it a point not to use any exotic technology. "We didn't want to use a lot of research tools that clinicians can't use in their offices," Dr. Tseng says. Twenty-one ALS patients passed the exclusion criteria, and the results the researchers found surprised them.

"We found that, despite the patients having no eye diseases that could explain any retinal changes—especially thinning on OCT—these patients did, in fact, show differences," Dr. Tseng says. Specifically, they found statistically significant retinal nerve fiber layer thinning in the bilateral mean total RNFL thickness, temporal thickness, right superonasal thickness and left superotemporal thickness, as well as an overall trend toward RNFL thinning in all retinal sectors and the global mean retinal thickness *(See Table 1)*.

The upshot of the study is the strengthening link between the retina's neurons and others in the body. "This result suggests that it's possible that neurons in the eye have more in common with neurons such as the motor neurons affected by ALS at the cellular/molecular level than we thought," Dr. Tseng says. "Also, just like we do in glaucoma, ALS researchers are always looking for biomarkers for the disease, and the eye is the only place in the body where you can actually just look in and examine brain cells. This study shows that it may be possible to use the eye as a reliable biomarker for ALS, for diagnosing and potentially monitoring treatment and progression. Eventually, it would be great if we could study the possible clinical link between ALS and glaucoma, and perhaps get some clues as to why patients go blind." The study researchers only "briefly" looked at the possible association between RNFL thickness and ALS severity, but that could be the subject of future studies.

Future studies will include more patients, and hopefully lead to even stronger conclusions. "If we have other groups involved, we could get more patients," Dr. Tseng says. "The study could possibly be large enough to study whether specific eye diseases are associated with ALS." REVIEW

Table 1. Differences in RNFL Thickness Between ALS Subjects and a Normative Database

	Right Eye n = 20			Left Eye n = 19		
RNFL Sector	**Mean Difference (µm)**	**Standard Deviation (µm)**	**P-value**	**Mean Difference (µm)**	**Standard Deviation (µm)**	**P-value**
Global	-6.86	11.03	0.043	-8.15	11.34	0.007
Temporal	-6.59	10.34	0.012	-9.75	12.11	0.003
Nasal	-6.55	14.49	n.s.	-6.13	14.38	n.s.
Superonasal	-15.2	20.97	<0.001	-6.16	23.34	n.s.
Inferonasal	-1.00	0.00	n.s.	-3.26	18.01	n.s.
Superotemporal	-8.63	18.78	n.s.	-13.9	18.41	0.007
Inferotemporal	1.47	20.78	n.s.	-4.36	22.41	n.s.

Researchers report statistically significant RNFL thinning in the bilateral mean total RNFL thickness, temporal thickness, right superonasal thickness and left superotemporal thickness between ALS patients and normal controls. *Source:* https://doi.org/10.1371/journal.pone.0185242

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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.

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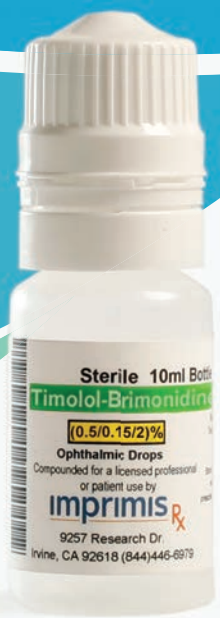

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November 2017 • Volume XXIV No. 11 | reviewofophthalmology.com

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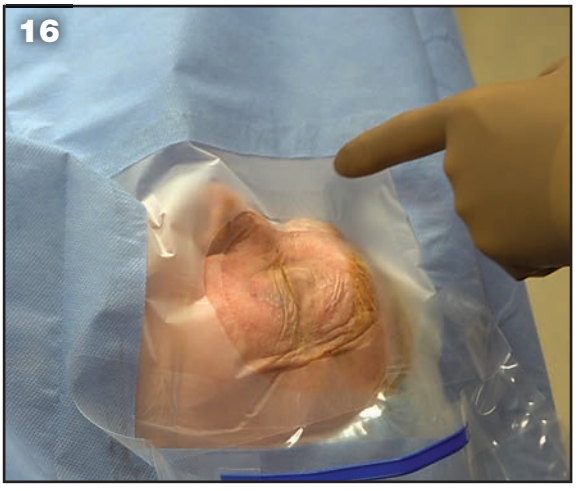

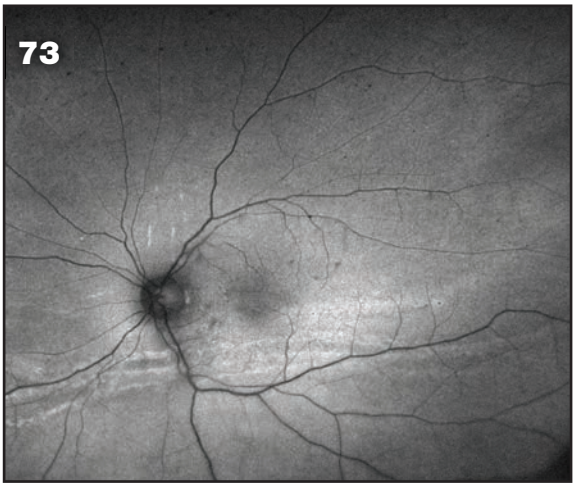

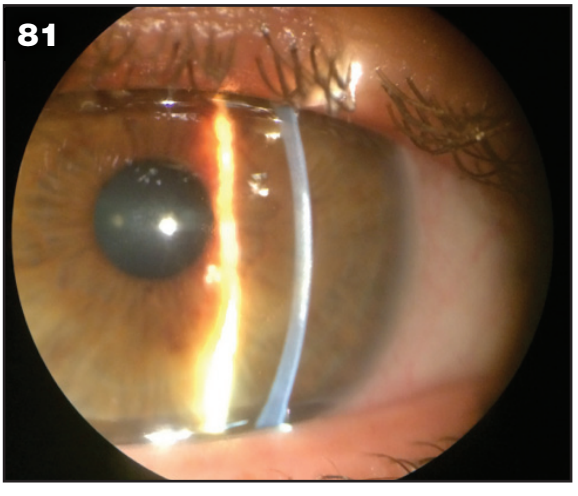

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IMPORTANT SAFETY INFORMATION

OMIDRIA (phenylephrine and ketorolac injection) 1% / 0.3% must be added to irrigation 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 2-24% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Use of OMIDRIA in children has not been established.

INDICATIONS AND USAGE

OMIDRIA is added to ophthalmic irrigation 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.

Reference: 1. OMIDRIA [package insert]. Seattle, WA: Omeros Corporation; 2016.

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

*Individual insurance coverage and policies may vary, and Omeros does not guarantee insurance coverage or payment. Omeros offers payments under the OMIDRIAssure "We Pay the Difference" program on behalf of qualifying patients. OMIDRIAssure is subject to change without notice.

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Three New Surgical Tools Make Their Debut

A new drape, a set of handheld tools and a device to clean the air over the table may make surgery safer and more comfortable.

Christopher Kent, Senior Editor

The evolution of surgical tools is an ongoing phenomenon, sometimes propelled by the advent of new materials, sometimes by frustration over the inadequacies of existing options, and sometimes in response to problems or opportunities created by other new technologies. One of the individuals at the forefront of this evolution is Robert H. Osher, MD, a professor in the department of ophthalmology at the University of Cincinnati College of Medicine, and Medical Director Emeritus at the Cincinnati Eye Institute in Ohio. Dr. Osher is a past recipient of the American Society of Cataract and Refractive Surgery's Charles D. Kelman Innovator's Award; he's participated in the design and development of numerous widely-used instruments, intraocular lenses, surgical tools and surgical techniques.

Here, Dr. Osher discusses three new developments in the field of cataract surgery that may help to make this operation easier and safer. Two of them were designed by Dr. Osher himself; the other is a device that he discovered in Europe and is eager to introduce to American surgeons. (Dr. Osher has no financial interest in any of these instruments.)

A Better Surgical Drape

Dr. Osher has a long history of being interested in the sterile field and the design of surgical drapes; he designed the first split-lid drapes, the first sterile-lid drapes and the first drape to cover the phaco machine, allowing the scrub tech to adjust the machine instead of the circulating nurse.

"There have still been a lot of problems with the standard set of drapes," Dr. Osher notes. "Patients would complain, 'It's really hot under here.' They'd say, 'I'm claustrophobic.' Or they'd say to the nurse, 'Please hold my hand,' but there was no way the nurse could get to the patient's hand. The drape would sometimes hang down over the patient's head so far that it would be lying on the phaco pedal; when I'd press on the pedal, the drape would turn the patient's head. The long drape also made it difficult for the anesthesiologist to get to the IV. In addition, I didn't like the cardboard feel of the current drapes; they weren't pliable or easy to work with. And patients would tell me that the worst part of the cataract surgery was when I removed the drape at the end, because of the strong adhesive. I was disturbed to see how red and irritated patients' skin would be as a result of removing the drape.

"I felt we should be able to do better," Dr. Osher says. "So a couple of years ago I approached the team at Beaver-Visitec International and told them I thought we could design a better drape. I suggested the use of a softer material, which the nurses appreciate, and we removed a lot of the adhesive that contacts the patient's skin so the drape can be removed easily. The patients don't even feel it now. We also placed translucent (not transparent) material over the unoperated eye, so patients can at least see forms and shapes and lights and they don't become claustrophobic.

"From the surgeon's perspective, it's a universal drape design, so it's good for the left or right eye," he continues. "It forms an inverted-D shape, so it's parallel to the brow and runs along the bridge of the nose. It comes down on the lower lid and then up

The *FIRST* and *ONLY* NSAID indicated to prevent ocular pain in cataract surgery patients[1]

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- Available in 5 mL bottle

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BromSite®
(bromfenac ophthalmic solution) 0.075%
Formulated with DURASITE® DELIVERY SYSTEM

Indications and Usage

BromSite® (bromfenac ophthalmic solution) 0.075% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.

Recommended Dosing

One drop of BromSite® should be applied to the affected eye twice daily (morning and evening) 1 day prior to surgery, the day of surgery, and 14 days postsurgery.

Important Safety Information

- **Slow or Delayed Healing:** All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including BromSite®, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- **Potential for Cross-Sensitivity:** There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including BromSite®. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.
- **Increased Bleeding Time of Ocular Tissue:** With some NSAIDs, including BromSite®, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. It is recommended that BromSite® be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.
- **Keratitis and Corneal Effects:** Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including BromSite®, and should be closely monitored for corneal health. Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days postsurgery may increase patient risk for the occurrence and severity of corneal adverse events.
- **Contact Lens Wear:** BromSite® should not be administered while wearing contact lenses. The preservative in BromSite®, benzalkonium chloride, may be absorbed by soft contact lenses.
- **Adverse Reactions:** The most commonly reported adverse reactions in 1% to 8% of patients were anterior chamber inflammation, headache, vitreous floaters, iritis, eye pain, and ocular hypertension.

Please see brief summary of Full Prescribing Information on the adjacent page.

NSAID=nonsteroidal anti-inflammatory drug.

References: 1. BromSite® [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2016. **2.** Hosseini K, Hutcheson J, Bowman L. Aqueous humor concentration of bromfenac 0.09% (Bromday™) compared with bromfenac in DuraSite® 0.075% (BromSite™) in cataract patients undergoing phacoemulsification after 3 days dosing. Poster presented at: ARVO Annual Meeting; May 5-9, 2013; Seattle, Washington. **3.** ClinicalTrials.gov. Aqueous humor concentration of InSite Vision (ISV) 303 (bromfenac in DuraSite) to Bromday once daily (QD) prior to cataract surgery. https://clinicaltrials.gov/ct2/show/results/NCT01387464?sect=X70156&term=insite+vision&rank=1. Accessed March 2, 2017. **4.** Si EC, Bowman LM, Hosseini K. Pharmacokinetic comparisons of bromfenac in DuraSite and Xibrom. *J Ocul Pharmacol Ther.* 2011;27(1):61-66. **5.** Bowman LM, Si E, Pang J, et al. Development of a topical polymeric mucoadhesive ocular delivery system for azithromycin. *J Ocul Pharmacol Ther.* 2009;25(2):133-139.

SUN OPHTHALMICS

BromSite® (bromfenac ophthalmic solution) 0.075%
Brief Summary

INDICATIONS AND USAGE
BromSite® (bromfenac ophthalmic solution) 0.075% is indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
Slow or Delayed Healing
All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including BromSite® (bromfenac ophthalmic solution) 0.075%, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Potential for Cross-Sensitivity
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including BromSite® (bromfenac ophthalmic solution) 0.075%. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

Increased Bleeding Time of Ocular Tissue
With some NSAIDs, including BromSite® (bromfenac ophthalmic solution) 0.075%, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

It is recommended that BromSite® be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Keratitis and Corneal Reactions
Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including BromSite® (bromfenac ophthalmic solution) 0.075%, and should be closely monitored for corneal health.

Post-marketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days postsurgery may increase patient risk for the occurrence and severity of corneal adverse events.

Contact Lens Wear
BromSite® should not be administered while wearing contact lenses. The preservative in BromSite®, benzalkonium chloride, may be absorbed by soft contact lenses.

ADVERSE REACTIONS
The following serious adverse reactions are described elsewhere in the Brief Summary:
- Slow or Delayed Healing
- Potential for Cross-Sensitivity
- Increased Bleeding Time of Ocular Tissue
- Keratitis and Corneal Reactions
- Contact Lens Wear

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

The most commonly reported adverse reactions in 1–8% of patients were: anterior chamber inflammation, headache, vitreous floaters, iritis, eye pain and ocular hypertension.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
There are no adequate and well-controlled studies in pregnant women to inform any drug associated risks. Treatment of pregnant rats and rabbits with oral bromfenac did not produce teratogenic effects at clinically relevant doses.

Clinical Considerations
Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of BromSite® during late pregnancy should be avoided.

Data
Animal Data
Treatment of rats with bromfenac at oral doses up to 0.9 mg/kg/day (195 times a unilateral daily human ophthalmic dose on a mg/m^2 basis, assuming 100% absorbed) and rabbits at oral doses up to 7.5 mg/kg/day (3243 times a unilateral daily dose on a mg/m^2 basis) produced no structural teratogenicity in reproduction studies. However, embryo-fetal lethality, neonatal mortality and reduced postnatal growth were produced in rats at 0.9 mg/kg/day, and embryo-fetal lethality was produced in rabbits at 7.5 mg/kg/day. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
There are no data on the presence of bromfenac in human milk, the effects on the breastfed infant, or the effects on milk production; however, systemic exposure to bromfenac from ocular administration is low. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for bromfenac and any potential adverse effects on the breast-fed child from bromfenac or from the underlying maternal condition.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 18 years have not been established.

Geriatric Use
There is no evidence that the efficacy or safety profiles for BromSite® differ in patients 65 years of age and older compared to younger adult patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis and Impairment of Fertility
Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (129 times a unilateral daily dose assuming 100% absorbed, on a mg/m^2 basis) and 5 mg/kg/day (540 times a unilateral daily dose on a mg/m^2 basis), respectively revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the bacterial reverse mutation, chromosomal aberration, and micronucleus tests.

Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively (195 and 65 times a unilateral daily dose, respectively, on a mg/m^2 basis).

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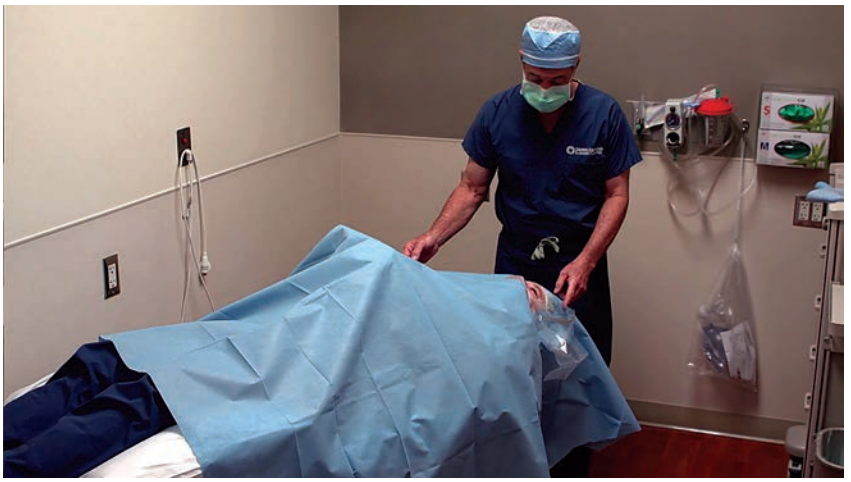
SUN-OPH-BRO-017-1 03/2017

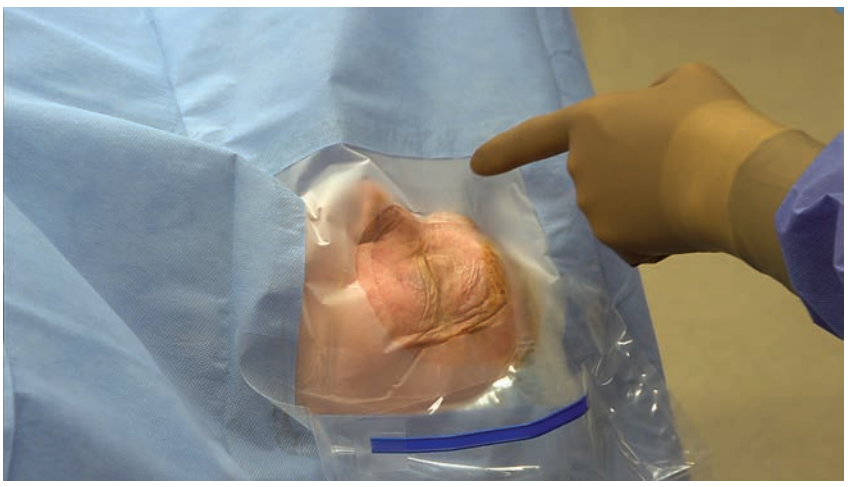
SUN OPHTHALMICS

along the temple on either eye, so it gives you beautiful exposure while at the same time acting as an effective barrier. Also, the length of the drape had been shortened to allow the anesthesiologist and nurses easy access to the patient, while making it less hot underneath for the patient and preventing the drape from catching on the foot pedal."

Dr. Osher says that the surgeons at the Cincinnati Eye Institute are now beginning to use the new drape. "I still use my split-lid drapes to cover the lashes," he notes. "They're enclosed in the package. I also continue to use a little wick to remove fluid from the lacrimal lake, and I still cover any exposed skin with a steri-strip on the lateral canthal angle. I'm very meticulous about draping, and I'm enthusiastic about having this new drape design."

The Visidrape Osher Half Body Aperture Drape is sold in shelf packs of 10 drapes and is available from Beaver-Visitec International (Waltham, Mass.) You can find more information in the product catalogue at beaver-visitec.com, or by calling BVI customer service (866-906-8080) or your local BVI sales representative.





The Visidrape Osher Half Body Aperture Drape is shorter than standard drapes, to improve patient comfort and surgical team access; the new material is more comfortable and less hot for the patient; the adhesive has been modified to eliminate patient discomfort when the drape is removed; and the new design allows some light to reach the unoperated eye, making patients less claustrophobic.

Sterilizing the Air

The Operio Mobile is a new instrument made by Toul Meditech in Sweden that's designed to sterilize the air around the operating field by creating a directed, laminar, nonturbulent, ultraclean air flow over the surgical site and/or sterile instruments. The unit circulates the ambient air through a HEPA filter to remove bacteria and particles, to help ensure that the surgical site and instruments remain sterile throughout the procedure. The direction of the air flow is easily controlled and the resulting sterile air zone is clearly shown via a "smart" visual indicator. The unit includes a sterile protective barrier that allows it to be placed close to the operating table and an integrated foldable instrument tray that can replace a standalone table, saving space in the OR. The unit is designed to be easily moved from room to room. (The company also makes a similar unit that hangs from the ceiling, which is not yet available in the United States.)

Dr. Osher, who has been using the first Operio instrument in the United States, discovered the technology at the 2016 European Society of Cataract and Refractive Surgeons meeting in Copenhagen. "We'd had several experiences at the Cincinnati Eye Institute that were of great concern to me," he says. "The surgical staff noticed an occasional piece of lint falling on the surgical field. Because most of the fibers were blue, we suspected they were coming from the surgical drapes.

"Then, right before attending the ESCRS meeting, one of my patients developed a corneal abscess after a fiber got caught in the stab incision," he continues. "We had to take the patient back to surgery, remove the fiber and give intracameral vancomycin. Fortunately, the patient did fine—but I didn't! It was traumatic for

The Operio Mobile, from Toul Meditech in Sweden, creates a directed, laminar, nonturbulent, ultraclean air flow over the surgical site, removing bacteria and particles from the air, to help ensure that the surgical site remains sterile throughout the procedure.

me; I'd never had anything like that happen in my career. It taught me that all airborne particulate matter is not benign, which is what I'd always thought.

"That's when I discovered the Operio at ESCRS," he says. "The model I saw is a mobile device that's very easy to use; it's like pulling up a monitor next to the eye. After we adjust the microscope and move the phaco machine closer to the patient, Operio is rolled into position either above the patient's head for a right eye, or on the right side of the patient's head for a left eye. It generates a laminar flow that sterilizes the field wherever it's pointing.

"I was so excited about the technology that they allowed me to bring a mobile unit back to the United States," he continues. "Operio was in the process of receiving FDA clearance, so I jumped at the chance to try the technology. Since then, we've been using it in practice, and we're also conducting a clinical study to see how effective the device actually is."

Dr. Osher says he's seen two remarkable things. "First, we've observed a total absence of particulate such as lint in the operative field since we began using Operio," he says. "Second, our study has found a dramatic reduction in the objective counts of 5-µm-size particles in the air—the size of bacteria. That's significant, because there have been plenty of articles over the years demonstrating that there are bacteria in the air. I remember a study by Stuart Brown, MD, years ago, which found bacteria growing on culture plates that were left open in the operating room."

Julia G. Schneider, MD, senior resident in ophthalmology at the University of Cincinnati Medical Center and Cincinnati Eye Institute, designed the study and is working on it with Dr. Osher. "We developed an *in-vivo* protocol designed to compare the presence of particulate matter ranging from 0.3 to 5 µm in size that are present in the operating room, with or without the Operio present," she explains. "This was done by using a specialized particle counter. We take readings in the OR outside the range of action of the Operio; within the sterile field prior to turning on the Operio; and finally within the sterile field after turning on the Operio. Patients are prepped and draped in the standard fashion and the surgery

The new No Fly surgical tools from Bausch + Lomb are designed to keep the surgeon from accidentally striking low-hanging instruments such as aberrometers. The line includes (from left to right): a Y-Hook; chopper; manipulator; tying forceps; capsule/foreign body forceps; fixation forceps; incision forceps; suturing forceps; a hydrodissection cannula; dye cannula; and a J cannula 2.0.

proceeds as usual.

"So far we've looked at 75 cataract procedures utilizing our protocol," she says. "The results have been very impressive. In all cases there's been a vast reduction in particulate matter measured within the sterile field after utilizing the Operio. In some cases, the particles of the measured size have been completely expunged." Dr. Schneider says they hope to have the study completed in October and publish it within the next six months.

Dr. Osher says he believes a tool like this could have implications for other areas of ophthalmology besides anterior segment surgery. "I'm especially interested in looking at using this type of sterilization during retinal injections," he notes. "I'm sure there will also be other applications for Operio outside of the OR.

"To me, deciding to use this instrument was a no-brainer," he concludes. "It's true that I only encountered one case of corneal abscess due to a fiber, but having now used the Operio many times and seeing the early results of our study, I'm a believer. I use it in every one of my cases, and it gives me a great sense of security. It makes me feel that I'm creating the safest possible field in which to perform surgery." For more information, contact Fran Carleton at Vitreq USA by phone (603) 347-5590 or email (csc@vitrequsa.com).

Helping Keep Handheld Tools Sterile

Dr. Osher says he developed the new Storz Ophthalmics line of No Fly surgical tools (Bausch + Lomb) in response to the evolution of devices that are placed under the operating microscope, close to the surgical field. "We've developed all kinds of devices that hang down from the microscope, including aberrometers, the Verion interface and the Callisto interface," he points out. "As these devices started to encroach upon the surgical field, I found myself occasionally clunking my handheld surgical tools against them, compromising their sterility. It didn't take a rocket scientist to think of making the instruments shorter so they wouldn't stick up and hit the microscope add-ons. *[See picture, facing page.]*

"There is a very brief learning curve to using the new tools, because you use fingertip control a little bit more," he admits. "But other than that, I don't see any downside to using these instead of the standard handheld instruments. I use them all the time, even if nothing is hanging down below the microscope."

The No Fly instruments currently available from Storz Ophthalmics include five types of No Fly forceps (tying, incision, fixation, capsule/foreign body, suturing), as well as a No Fly chopper, No Fly manipulator and No Fly Y-hook. (For more information, visit storzeye.com.) REVIEW

Making the Most of MACRA

By Kristine Brennan, Senior Associate Editor

What's happening now, and what you may need to consider for the future.

On January 1, 2017 the reporting period required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) officially began. MACRA repeals the Standard Growth Formula (SGR), which tied reimbursement rates to the growth rate of the GDP. Lobbying efforts held the SGR formula's cuts in abeyance every year except for 2002 when a 4.7-percent decrease in reimbursements passed, rendering the legislation a sword of Damocles over providers' heads after its adoption in 1997. Although CMS says that MACRA will spare doctors and other qualified providers from the SGR's long-delayed deep downward adjustments and will increase the flexibility of reporting requirements, this remains to be seen.

An overview of MACRA's requirements follows (with an emphasis on the Merit-based Incentive Payment System, or MIPS); the president of the AMA and two ophthalmologists comment on the pros and cons of the government's attempt to reward quality of care over volume of treatment.

The Quality Payment Program

The Quality Payment Program (QPP) is the cornerstone of MACRA. Most providers who participate in Medicare Part B are relegated to one of the QPP's two tracks: Advanced Alternative Payment Models (APMs) or the Merit-based Incentive Payment System (MIPS). Advanced APMs are a subgroup of Alternative Payment Models that reward clinicians for assuming some risk tied to patient outcomes. They include Next Generation ACOs; Comprehensive End-Stage Renal Disease Care and Oncology Care Models with two-sided risk; and

MIPS Category Weights

Legacy Program	New Category	Score Weight 2017 & 2018	Score Weight 2019 & beyond
Physician Quality Reporting System	Quality	60%	30%
Meaningful Use	Advancing Care Information (ACI)	25%	25%
(None)	Improvement Activities (IA)	15%	15%
Value-based Modifier	Cost	0%	30%

ACI may be reweighted to 15% if 75% of clinicians meet ACI threshold

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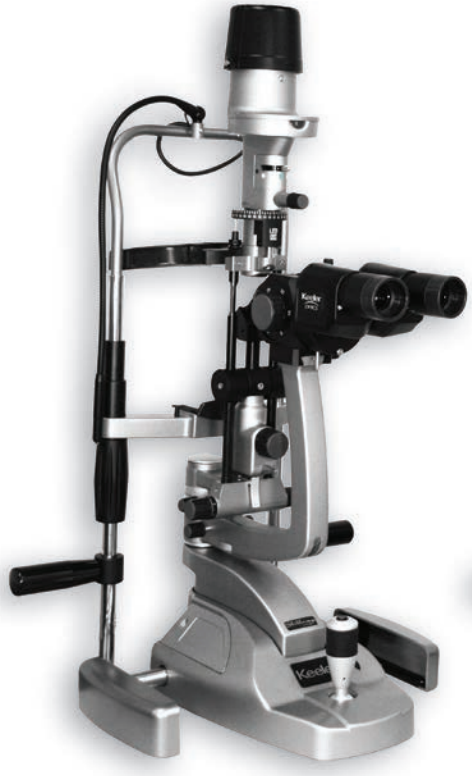

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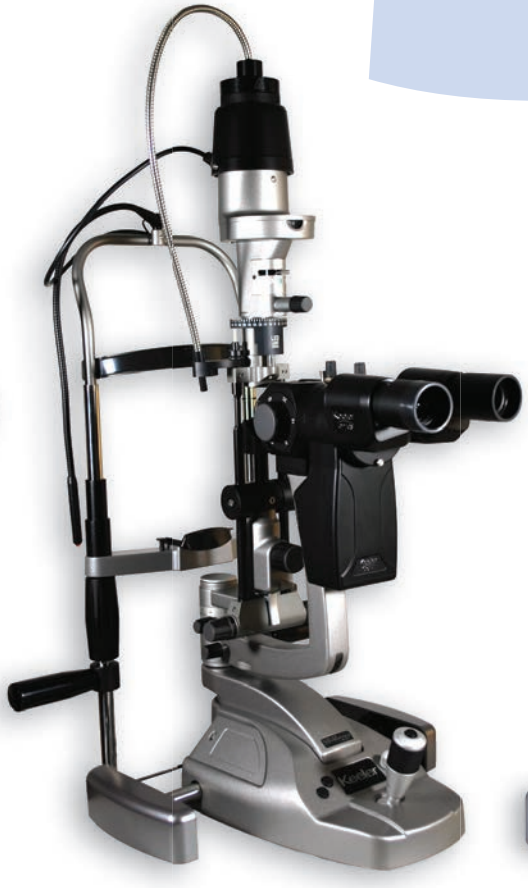

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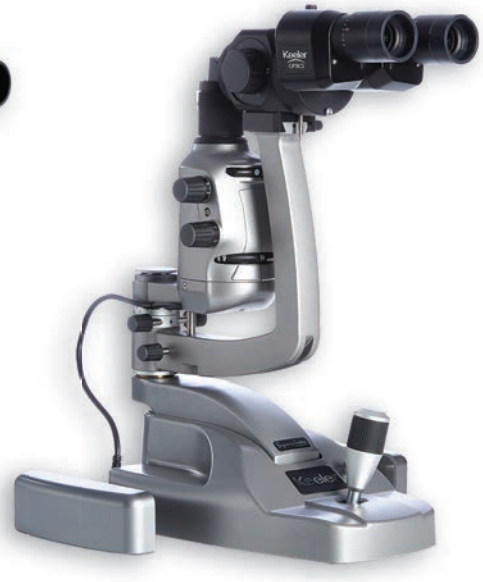

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Shared Savings Program ACOs-Track 2 and 3, as well as some comprehensive care models for primary care and joint replacements. Providers with sufficient advanced APM participation in 2017 will see a 5-percent increase in their Medicare reimbursements in 2019.

MIPS is the relevant branch of the QPP for the vast majority of ophthalmologists right now, but a major goal of MACRA is to foster a shift to advanced APMs. "Certainly, the most well-developed APMs are centered on primary care," says David O. Barbe, MD, president of the American Medical Association, via email. "Private industry insurers, and the primary-care specialties themselves took the lead in developing these models in the private sector many years ago. Most specialists, including ophthalmologists, do not fit neatly into the relatively few APMs that fit the QPP criteria for being designated as 'advanced' that would provide an exemption from MIPS. This is something that specialists are working to remedy, with new models being proposed to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) [chartered by the U.S. Department of Health and Human Services] for review of potential recommendation to the secretary of HHS for further development and adoption by Medicare," he says.

While most ophthalmologists must contend with MIPS, there are a few exceptions: If you're in your first calendar year of accepting Medicare Part B, 2017 MIPS reporting isn't required. If your Medicare Part B allowed charges are less than $30,000 per year or you see fewer than 100 beneficiaries, you fall below CMS's low-volume threshold and are also exempt from MIPS reporting. Absorbing the penalties of nonparticipation in MIPS or opting out of Medicare altogether are other options that may be viable for some ophthalmologists *(See sidebar.)*.

Only one dimension of MIPS reporting is new (Improvement Activities); the other three are legacies of the system that it replaces. "To the extent that ophthalmologists were comfortable with the old Physician Quality Reporting System (PQRS), they will be comfortable with the same measures being applicable to them under the Quality component of MIPS," says Dr. Barbe of the AMA. Brock K. Bakewell, MD, FACS, partner at Fishkind, Bakewell & Maltzman Eye Care in Tucson, Ariz., and adjunct associate professor of ophthalmology at the University of Utah, agrees, adding, "All of the previous quality elements from the PQRS have morphed into the MACRA system."

MIPS scoring replaces and consolidates the PQRS, the MU, and the VBM, while adding a new measure, Improvement Activities:

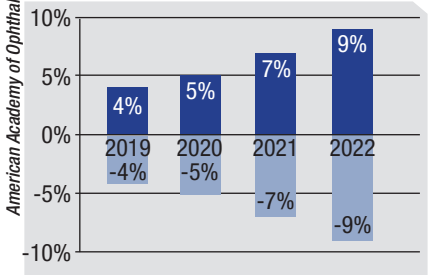
Quality (replaces PQRS): The Quality component accounts for 60 percent of the composite MIPS score for the 2017 reporting period. Providers must select at least six quality measures approved by CMS to report: One of the six must be an outcome or high-priority measure. Practice groups of 16 or more providers can earn 70 points; smaller groups can earn 60. Each can earn a 10-percent bonus score.

Advancing Care Information (replaces Meaningful Use): ACI is weighted at 25 percent of the total MIPS score for the 2017 period. There is a 50-point base score achievable only by having an electronic health records system in place, with 90 more possible performance points and 15 bonus points thereafter.

Resource Use (replaces VBM): This measure of costs is weighted at zero percent for 2017. Since CMS tabulates Resource Use from Medicare Part B claims, providers don't need to do any reporting. The proposed rule for CY 2018 would keep this component from factoring into the MIPS composite score for the 2018 reporting period as well.

Clinical Practice Improvement Activities: Weighted at 15 percent of the composite score, this new met-

MIPS Payment Adjustments



American Academy of Ophthalmology

Partial or full adjustment based on Final Composite Score Adjustments applied to Medicare FFS payments, including Part B drugs

Opting Out

If a tiny sliver of your business is Medicare Part B, you could opt out of MIPS altogether, but that choice is limited to a select few, according to Brock K. Bakewell, MD, FACS. "Most ophthalmologists can't do that because a significant amount of our insurance mix is Medicare," he says. "Some people with a practice where they do a lot of premium lens implants, LASIK and PRK may be willing to take the hit, especially if they're retiring soon, but younger practitioners are eventually going to have to go into the system unless they have a lot of procedures that are cash on the barrelhead. Your average ophthalmologist does some 65 percent of their practice with Medicare. It would be almost impossible to not participate in MACRA."

David B. Glasser, MD, also thinks that participating in the QPP is a fact of life for most ophthalmologists, and the decision to opt out must be carefully weighed. "Each practice needs to analyze the costs of participation in MIPS, including whether an EHR would need to be implemented. Those costs need to be weighed against the potential effect on revenue of simply opting out and taking the penalties, which increase to 9 percent by 2022," he notes. "But if Medicare is a small part of your revenue, it may be worth avoiding the administrative burden of reporting. Because the penalties are applied only to Medicare FFS revenue, part of the analysis must include an evaluation of payer mix."

ric requires providers to report on up to four CMS-approved activities. Measures to choose from include patient safety and practice assessment, coordination of care and emergency preparedness. They are worth up to 20 points apiece. The scoring on this domain offers some leeway for small or solo practices and providers in rural or designated HPSAs (health-professional shortage areas): Those providers can earn double points in this category, earning their 40 possible points by completing a single 20-point measure.

CMS set the 2017 "performance threshold" score for MIPS at 3 points, meaning that it takes a composite MIPS score of 3/100 points to avoid a downward adjustment in 2019 Medicare payments. Here is an outline of the scoring thresholds:

By 2022, the upward and downward MIPS adjustments are projected to reach 9 percent in each direction. Right now, the performance threshold to avoid penalties is easy to attain, but providers' raw Quality scores will be measured against population-based benchmarks to determine whether and to what degree providers can expect positive adjustments in 2019—and who will be penalized.

MIPS SCORES	≥70	positive adjustment of 4 percent for 2019; earns a 0.5 percent minimum bonus for exceptional performance
	4-69	a positive adjustment; does not qualify for bonus
	3	a neutral adjustment
	0	nonparticipation; a -4-percent adjustment

As Dr. Bakewell notes, even good ophthalmologists could find themselves among the losers because of the budget-neutral nature of MACRA. "You have to do better than the average, or you're potentially going to get cuts under MACRA that are not insignificant," he says. "If someone's getting a 9-percent bonus [in 2022], someone else is getting the same penalty. I think that configuring it so that there are winners and losers will create a hardship. We're already performing at a very high level. Our outcomes are excellent, so I think it's problematic to try to differentiate a specialty such as ophthalmology that is already at such a high level across the board."

That competition is further underscored by Physician Compare, which will list providers' MIPS scoring online sometime after the March 31, 2018 deadline for 2017 data submission. CMS describes Physician Compare as "a website designed to help consumers make informed choices about the health care they receive through Medicare."[1]

Could concerns about potential reputational damage from a surgeon's published score prompt him or her to shy away from higher-risk Medicare patients? "Quality measures do have the *potential* to disincentivize reporting on complications, or to encourage referring out cases with a higher probability of a poor outcome," acknowledges David B. Glasser, MD, assistant secretary for health policy, American Academy of Ophthalmology, and assistant professor of ophthalmology at Johns Hopkins University School of Medicine. "But I have to believe that physicians place the welfare of their patients above a number that makes up a small percentage of another number that may affect a percentage of their payments. On a more practical level, this risk can be mitigated by excluding high-risk cases from the denominator or by risk-adjusting for comorbidities. We have advocated for excluding all of the high-risk cases that were excluded under the old PQRS system," he says. *(For more proposals on how to improve MACRA implementation, see sidebar, p. 26.)*

Role of the IRIS Registry

The Intelligent Research in Sight registry is the first comprehensive clinical data registry for eye-disease cases. It's also a Qualified Clinical Data Registry (QCDR) for 2017 MIPS reporting, capable of optimizing MIPS quality reporting when IRIS is integrated with qualified EHR software. IRIS Registry use is worth MIPS points in the ACI and Improvement Activity domains. Practitioners with a certified EHR integrated with the IRIS Registry enjoy automatic quality reporting to CMS, and IRIS will optimize the measures reported to maximize their MIPs point values. IRIS Registry users without an EHR may enter quality data manually using the IRIS Registry web portal, and may be able to earn MIPS points in Improvement Activities performance.

For Advancing Care Information points, you must have a qualified EHR: This is an all-or-nothing proposition worth either 50 or zero points. IRIS Registry participation will net EHR users an additional five-point bonus in this category.

Dr. Glasser believes that making IRIS Registry use more valuable in MIPS scoring would create a more specialty-specific snapshot of what constitutes a high-quality clinical outcome in ophthalmic care. "More relevant outcomes like postoperative visual acuity and accuracy of IOL power selection cannot be extracted from claims data," he says. "That data does exist in the IRIS Registry. We would like to see CMS allow IRIS data to play a larger role in determining MIPS quality scores that are relevant to ophthalmology," he says.

MIPS and Smaller Practices

Lack of an EHR effectively prohibits solo providers and practices from earning any of their MIPS points from the ACI domain. "Small practices, particularly those without electronic health records, face a larger administrative burden in trying to achieve the maximum bonus under MIPS," says Dr. Glasser. "In 2017, only three points are necessary to avoid the penalty. Reporting a single quality measure or clinical practice improvement activity makes it very easy for any practice to avoid the penalty in 2017. For 2018, the penalty threshold is expected to increase to 15 points if the recommendations put forth by CMS in their proposed rule are carried forward in the final rule. Fifteen points remains an easy threshold to meet. After 2018, the penalty threshold is expected to increase substantially. That will be a more difficult hurdle to clear."

The proposed rule for 2018 speaks of small practices in supportive terms. "The support of small, independent practices remains an important thematic objective for the implementation of the Quality Payment Program and is expected to be carried throughout future rulemaking," it states.[2] The document outlines some measures intended to provide relief to solo practices, practices of 15 or fewer providers and those in rural or medically underserved areas. Chief among those is the proposed raising of the low-volume threshold from up to $30,000 in Medicare Part B allowed charges to a maximum of $90,000, and the Medicare Part B beneficiary patient volume from a maximum of 100 up to 200. CMS estimates that this measure would exempt an additional 390,000 providers from MIPS reporting requirements.

The proposed rule also contemplates offering small or solo practices a way to avoid penalties to their compos-

Making MACRA Better

Even MACRA skeptics say a replacement for the SGR Medicare payment formula was long overdue. "It put us at risk each year for potential cuts, but then Congress would always intervene," says Brock K. Bakewell, MD. "The threatened cuts were significant—in the area of 23 or 25 percent. That was untenable."

The final rule for MACRA in 2018 should be circulated soon, as the comment period on the proposed rule ended in August of 2017. David B. Glasser, MD, outlines some of the points raised by the American Academy of Ophthalmology during the comment period:

- Bonus and penalty payments should not be applied to Medicare Part B drug payments to physicians. Penalties applied to these payments would make it financially untenable to provide expensive anti-VEGF injections.
- Incentivize use of qualified clinical data registries (QCDRs) through MIPS. CMS already allows QCDRs like IRIS to submit data for the Quality and Clinical Practice Improvement Activities of MIPS, but limits the credit that can be obtained via a QCDR for the Advancing Care Information component. We propose that active engagement in a specialty QCDR should count for the entire ACI category, providing 25 points of the composite score based on the current weighting.
- In addition, we would like to see bonus points awarded for clinicians who use certified EHR technology for participation in a QCDR.
- Ophthalmology has many topped-out quality measures where performance is already high among most participants. Rather than removing all of them, some should be retained and awarded points for meeting threshold scores. In addition, the restriction on registries to develop no more than 30 QCDR quality measures should be removed.
- A change in the statute is needed to allow the secretary of HHS to delay implementation of the Resource Use category under MIPS beyond 2018, or to at least limit its weight to 10 percent in 2019 rather than 30 percent.
- Prolong the transition period to delay the implementation of the mean/median threshold for penalties under the Quality section of MIPS.
- Simplify and standardize the prior-authorization program for Medicare Advantage patients (not a MACRA-specific item).

ite score via "significant hardship exemptions," since not having an EHR, for example, cuts a provider's potential "perfect" score from 100 to 75 right off the bat. Moreover, the proposed rule delays the CY 2017 requirement that providers who use an EHR adopt a 2015-certified version in 2018, although it offers a 10-percent ACI bonus for those who trade up from a 2014-certified EHR in 2018. (Some APMs will still need to use a 2015-certified EHR for the next data-collection period, however.)

MIPS reporters can also see whether they qualify for technical assistance from CMS in on-ramping to the QPP. Priority goes to rural practitioners, those in medically underserved areas and those with low MIPS scores from CY 2017. More information on the technical assistance support available to small practices can be found at https://qpp.cms.gov/docs /QPP_Support_for_Small_Practices.pdf. A provision allowing virtual groups may also let smaller practices separated geographically pool their data for more robust scores.

Value and Motivation

The switch to value-based care is meant to reward efficient providers who document good outcomes, in an effort to phase out Medicare's longstanding fee-for-service environment. But this effort begs the question of what kinds of care and outcomes are valuable. "It is extremely difficult to measure quality through claims data alone," Dr. Glasser acknowledges. "A few things, like return to the operating room after cataract surgery, can be quantified by claims alone. But these events are extremely uncommon," he says.

Value-based care is the new law of the land, but whether pay-for-performance improves processes of care or health outcomes remains unclear.[3] Dr. Bakewell suspects that MACRA's more-stick, less-carrot approach will force physicians to focus on data entry over patient care, and will not inspire the best possible outcomes. "I'm not quite sure how you do this with ophthalmology because we do a lot of procedures, and you're going to end up captitating doctors if you move from fee for service. Capitation doesn't work because it's not a good motivator. It's like putting a doctor on a salary, where it won't matter if they do 100 cataracts or 1,000 cataracts—they're still going to be paid the same salary," he says.

"You're not free to charge what you feel you're worth. You could be the best doctor in the world for doing a certain procedure, but you're paid the same as everyone else in the Medicare system, unless your outcomes are superior; then maybe you get a little bonus, contingent on how well you document it," he continues.

"Doctors are very tired of regulatory burdens," Dr. Bakewell adds. "Physicians and their staff spend way too much time inputting data to EHRs. It's taking away from patient care and it's not emphasizing the right thing. The right thing is for doctors to be taking care of patients, not entering data."

Dr. Bakewell advocates gradual implementation to allow ophthalmologists to initiate MIPS reporting without penalty. "We want this to be eased in gradually. We want to keep the Resource Use element out of the final MIPS score for another three years, so that people can start to participate in MACRA without being penalized," he says. REVIEW

Dr. Bakewell and Dr. Glasser report no financial interests in connection with the topic discussed.

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Cataract Surgery with Co-existing Conditions

Christopher Kent, Senior Editor

Other ocular and systemic problems can complicate cataract surgery. Here's help.

Most individuals who develop cataracts do so later in life when they're likely to have other health problems as well. For that reason, cataract surgeons frequently find themselves operating on patients with problems such as corneal disease (e.g., Fuchs' dystrophy or keratoconus), glaucoma, macular degeneration, diabetic retinopathy or uveitis—among other possible issues. These co-existing conditions can complicate cataract surgery in significant ways. Cataract surgery can also be made more complex as a result of previous surgeries such as a vitrectomy, a glaucoma shunt implantation, a trabeculectomy or scleral buckling.

Making sure these issues don't cause intraoperative or postoperative problems may require taking extra precautions; adding another surgery; changing your surgical technique; postponing the operation; or simply being extra vigilant about what you say to the patient preoperatively. Here, experienced cataract surgeons offer strategies that can help prevent unnecessary problems when cataract patients present with some of the most common co-existing conditions.

Corneal Pathology: The Exam

Corneal disease is one of the most common co-existing conditions that can interact negatively with cataract surgery. On the one hand, pre-existing corneal problems can affect the accuracy of IOL calculations and undercut quality of vision following cataract surgery; on the other hand, the cataract surgery itself can make some endothelial problems worse.

These strategies can help to ensure a positive outcome:

• ***Don't forget to check for corneal issues preoperatively.*** "It's important to make sure you know what you're dealing with ahead of time," notes Nick Mamalis, MD, professor of ophthalmology, director of ocular pathology and co-director of the Moran Eye Center's Intermountain Ocular Research Center at the University of Utah in Salt Lake City. "If you're contemplating doing cataract surgery on a patient, you need to do a thorough examination of the cornea."

Vance Thompson, MD, founder of Vance Thompson Vision in Sioux Falls, S.D., and professor of ophthalmology at the Sanford School of Medicine at the University of South Dakota, agrees. "You'd be amazed how many patients I see who are frustrated that they didn't get the result they wanted from cataract surgery that was performed elsewhere, because they had co-existing anterior corneal

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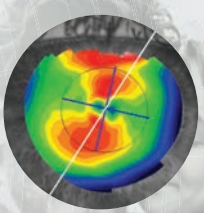

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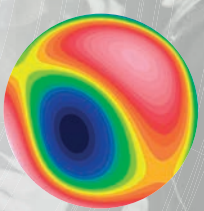

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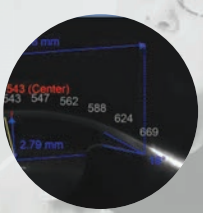

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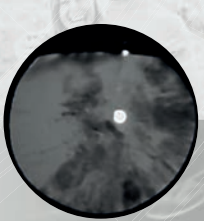
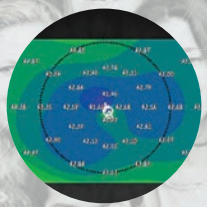


Lens Opacity

Cataracts



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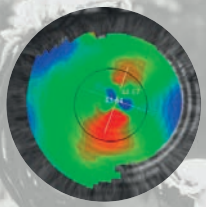

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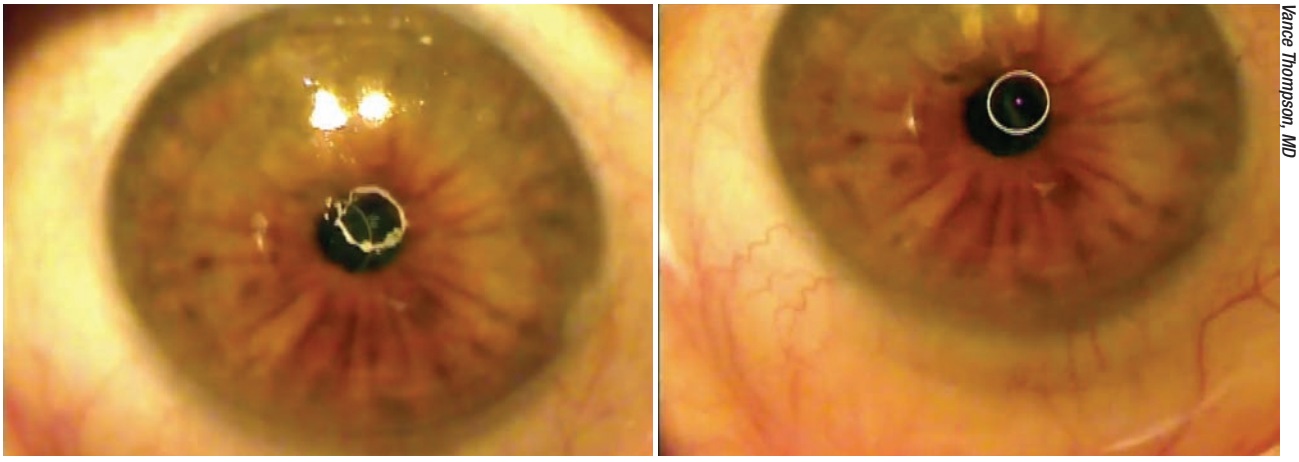

Vance Thompson, MD

Corneal problems should usually be addressed before performing cataract surgery. This patient had anterior basement membrane dystrophy but underwent cataract surgery without it being treated. After the cataract surgery, the patient was unhappy. Left: Before undergoing phototherapeutic keratectomy to address the ABMD, the reflection of the round illuminating light on the corneal surface is distorted, due to the rough corneal surface. Right: After epithelial scraping and lubricating drops the reflection is much smoother, just as the cornea will be after re-epithelialization and epithelial remodeling at about three months post-PK, resulting in much better vision.

pathology that went unnoticed," he says. "They're relieved that there's a reason for their frustration, but then they ask, 'Did I truly need the cataract surgery?' These are issues that you want to address before you perform cataract surgery."

• ***If corneal or retinal pathology exists, do your best to quantify the amount of blur each problem is responsible for.*** Dr. Thompson says estimating the contribution of other problems besides the cataract is a key factor when preparing to do cataract surgery on a patient with corneal or retinal pathology. "In terms of the cornea, issues such as anterior basement membrane dystrophy, anterior stromal scars or Salzmann's nodular degeneration can all affect best-corrected image quality," he says. "Today we have wonderful diagnostics such as the HD Analyzer which can quantify an image-quality reduction caused by the anterior segment—the tear film, cornea and/or lens. We can also quantify the irregularity in the cornea by measuring topography, measuring the irregularity index with tomography and measuring corneal higher-order aberrations. We can quantify lens density with the Pentacam or use the iTrace to get an idea of how much of the blur is coming from the lens and how much is coming from the cornea."

Of course, one of the main reasons to do this is to get the patient to understand that cataract surgery may not magically recreate the perfect vision of a younger person. "When explaining this to the patient, I still find it extremely helpful to simply grab the eye model or a white sheet of paper on a clipboard—with a nice dark felt-tipped pen, so that even a patient with blur can see what I'm drawing," says Dr. Thompson. "I'll explain that although the cataract is causing blur, we believe the retina and/or cornea are also causing blur, and we don't know for certain which one is causing the most blur. Then I explain that we have to treat the part of the eye that we think is causing the most blur—if it's treatable—and take the process in a stepwise fashion. Most important, these patients need to realize that they may not get everything they hoped for out of the cataract surgery.

"Patients are pretty smart," he notes. "They appreciate the explanation of what's going on inside their eyes, and the fact that you're testing to make the best determination you can. I've had some patients say, 'I think I'll let my vision get a little bit worse, so I can maybe have a little more confidence that cataract surgery is going to help me.' Mainly, it's important for them to be making an informed decision."

• ***Try using a gas-permeable contact lens to gauge how much any anterior corneal disease is contributing to reduced visual quality.*** "Even though I use all of this advanced technology, the tried-and-true test of putting on a gas-permeable contact lens to see how much irregularity it nullifies is extremely helpful when I have a patient with anterior corneal irregularities such as an elevated anterior stromal scar, Salzmann's nodular degeneration or anterior basement membrane dystrophy—all of which are fairly common," Dr. Thompson notes. "It even helps when the problem is dry-eye related.

"I may see a patient who's 58 years old with both an early cataract and anterior stromal pathology who's disappointed with his image quality," he continues. "Perhaps his best-corrected spectacle vision is only 20/30. If I'm trying to determine whether the problem is the cataract or the cornea, I can put on a gas-permeable contact

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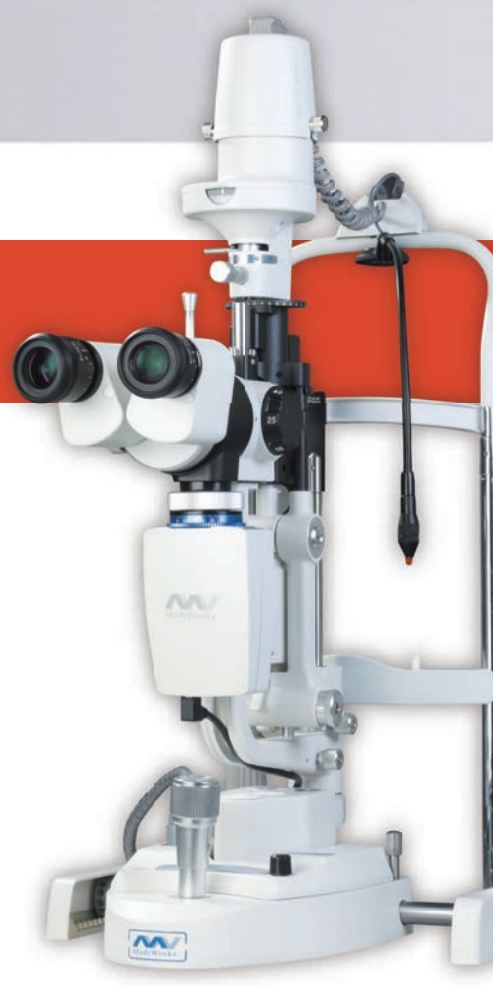

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lens and suddenly the patient is seeing 20/20. That tells me that all, or almost all, of the blur is coming from the cornea. In that situation, I'm going to do a corneal surgery. On the other hand, if I put on a gas-permeable contact lens and he's still only correctable to 20/30—and there's no retinal problem—that tells me that the blur is being caused by the lens, and I'm going to do cataract surgery, assuming the patient is ready for a surgical procedure. If the result is somewhere in between, then I have to make a judgment call about whether to treat the lens or the cornea. Either way, I've found that performing an over-refraction with a gas-permeable contact lens is still very valuable, despite all of the advanced technology we have."

Dr. Thompson notes that trying a gas-permeable contact lens won't help an issue such as corneal edema or deeper corneal pathology. "Those issues, however, are likely to be revealed by testing with today's instruments, or during the slit-lamp exam," he says.

• ***If Fuchs' dystrophy is an issue, perform additional testing.*** "One of the main corneal diseases that can affect cataract surgery—and be affected by cataract surgery—is Fuchs' endothelial dystrophy," notes Dr. Mamalis. "If the patient has a history of Fuchs' dystrophy, or you see guttata on examination, you should do specular microscopy and get an endothelial count to know what shape the cornea is in. If the patient has obvious corneal edema, you should also do pachymetry. The results can help guide you in terms of what you're going to do in the surgery. If the cornea is more than 600 µm thick, for example, you may want to consider doing a combined procedure, performing a DSEK or other corneal endothelial procedure along with the phaco."

Pathology & Surgical Options

Once you've evaluated the cornea, a number of factors need to be considered before proceeding with surgery:

• ***If the patient has corneal disease, determine whether it needs to be treated prior to cataract surgery.*** Bryan S. Lee, MD, JD, in private practice at Altos Eye Physicians in Los Altos, Calif., says that whether it's worth trying to correct a corneal problem before proceeding with cataract surgery depends on a combination of factors. "You need to determine how bad the corneal pathology is, how much it's independently affecting the patient's vision, and how it affects the IOL calculations," he says. "Another important consideration is the patient's goals. How important is uncorrected vision for that person?

Minimizing corneal irregularities before proceeding with cataract surgery can make the keratometry measurements and implant calculations more accurate.

"I see a lot of Salzmann's nodules," Dr. Lee continues. "In many cases these have been ignored because they may not affect best-corrected vision much if the patient wears glasses. But at the time of cataract surgery, they can make it difficult to do appropriate IOL selection and can cause irregular astigmatism, which can definitely limit the IOL options. So if I find Salzmann's nodules and see irregularity on the topography that's potentially going to affect the patient's vision or the IOL selection, I'll do a superficial keratectomy and take them off first.

"It's the same thing with pterygia," he continues. "Some patients have a pterygium that's relatively asymptomatic; they don't have a lot of foreign body sensation or redness. It's very stable. If that's the case, sometimes you can do the cataract surgery and not do anything about the pterygium. But if a patient has some irregular astigmatism on the topography because of the pterygium or is highly motivated to have good uncorrected vision afterward, you may want to remove it. If so, you'll need to give the cornea a couple of months to heal before you proceed with the cataract surgery."

Dr. Thompson notes that minimizing corneal irregularities before proceeding with cataract surgery can make the keratometry measurements and implant calculations more accurate. "If you perform the cataract surgery based on implant calculations that were influenced by corneal pathology, and the patient isn't happy with the image quality afterwards, then you'll need to treat the cornea," he points out. "At that point, the implant calculations you used will have been wrong for the eye the patient ends up with after you've treated the cornea. So, if the patient has a visually significant corneal problem, it's much better to take care of it before the cataract surgery. Then, let it heal well before you take the implant measurements."

• ***If the patient has Fuchs', limit your IOL options accordingly.*** "In this situation, you're not going to want to put in a presbyopia-correcting lens," notes Dr. Lee. "You may not even want to put in a toric lens if you feel there's a pretty high chance the patient may need a corneal transplant afterwards."

• ***If the patient may eventually need a corneal transplant, take that into account when choosing your IOL power.*** "If there's a good chance this patient's cornea is going to decompensate, you're going to need to do endothelial keratoplasty after-

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wards," Dr. Lee points out. "You may want to shift your target a little more myopic to compensate for the shift that would happen with a transplant."

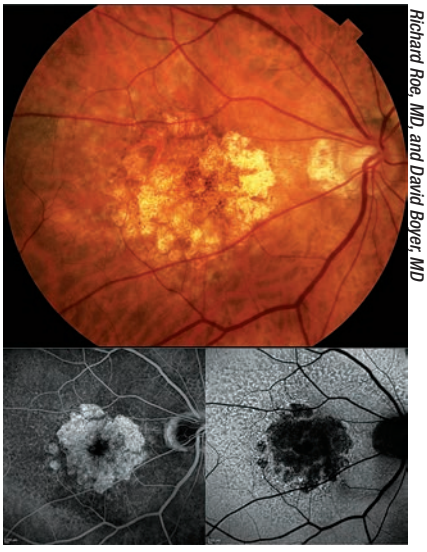
Corneal Pathology: The Surgery

As noted earlier, your surgical plan may need to be altered to manage the corneal problem, or to prevent the cataract surgery from worsening it:

• ***If the patient has Fuchs' dystrophy, adjust your surgical plan as necessary.*** "When dealing with Fuchs' dystrophy, it's a balance in terms of how bad the guttata are," notes Dr. Lee. "If the patient's symptoms appear to be caused as much by the cornea as by the cataract, we combine the cataract surgery with DMEK. If doing phaco alone, I use a dispersive viscoelastic and refill the anterior chamber with it more often. I also try to do the phaco as far away from the endothelium as possible."

"Cancelling the cataract surgery in this situation is probably not necessary," adds Dr. Mamalis. "As long as the corneal view is clear enough that you feel you can remove the cataract safely, I think you're OK to proceed."

• ***If the endothelium is fragile, change your OVD and lower your power level.*** "If you decide to proceed with cataract surgery in a patient with significant corneal endothelial disease, do everything you can to make the surgery as endothelium-friendly as possible," says Dr. Mamalis. "Instead of using my standard OVD, I'll use a cornea-protective OVD, maybe even something like DuoVisc, where you use two different OVDs during the surgery. First you use a very dispersive OVD to coat and protect the corneal endothelium; then you use a cohesive OVD. Steve Arshinoff, MD, has called this the 'soft-shell technique.' Then, of course, you want to make sure that you're using the lowest energy possible, and that you're doing your phacoemulsification as far away from the cornea as possible. Finally, at the conclusion of surgery, you want to be very careful not to allow the eye pressure to go up. Even a brief pressure spike can damage the corneal endothelium.



Richard Roe, MD, and David Boyer, MD

A color fundus photograph of a patient with geographic atrophy, with corresponding fluorescein angiogram (bottom left) and autofluorescence (bottom right) images. Although controversy exists regarding whether cataract surgery exacerbates the progression of dry macular degeneration, most studies suggest that it does not.

"These strategies would apply to any corneal endothelial disease," he adds. "Fuchs' is simply the most common."

Retinal Pathology

If your cataract patient may have retinal pathology:

• ***Examine the macula before surgery and consider getting a macular OCT.*** "You may not be able to obtain an adequate view of the macula if you have a cataract that's significant enough to affect the patient's vision," notes Dr. Mamalis. "However, you can get a very good OCT scan through a pretty dense cataract. That will allow you to know what's going on in the macula. Macular OCT is very helpful for assessing the status of the macula and ruling out macular diseases, and there are some subtle macular diseases that are tough to see without an OCT scan, such as an epiretinal membrane.

"We've started to rely on macular OCT more and more," he adds. "Our retina colleagues have started to recommend that we go ahead and do a preoperative macular OCT if there's any question about the condition of the macula. I know of some surgeons who do macular OCTs on everybody, but I think we have to use our clinical judgment in this setting. However, if there's any question, you want to be sure to rule out macular disease. A macular OCT prior to considering surgery is a good way to do that."

• ***Consider altering the IOL options you offer when the retina is not pristine.*** "In a cataract surgery evaluation, everyone wants to know their options," notes Dr. Thompson. "They wonder whether they should get a monofocal implant and wear glasses, or aim to replace both the clarity they lost and the reading ability they lost with one of the modern multifocal or extended-depth-of-focus lenses. Even though multifocals and EDOF lenses have been game changers, they still reduce contrast sensitivity somewhat, so if you put one of them in an eye that already has reduced contrast sensitivity, you're likely to make the problem worse. For that reason, we usually lean towards an aspheric monofocal implant in a patient with macular issues."

Dr. Mamalis agrees. "If your patient has significant macular disease or glaucoma with significant field loss, you really want to think seriously about whether that person is a good candidate for a multifocal lens," he says. "Any lens that breaks up the image as it comes in has the potential to decrease contrast sensitivity. If the patient already has a diseased macula with diabetic macular edema/ischemia, epiretinal membranes or macular degeneration, or significant

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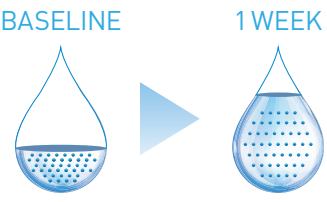

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visual field changes from glaucoma, decreasing contrast sensitivity further may not be a good idea."

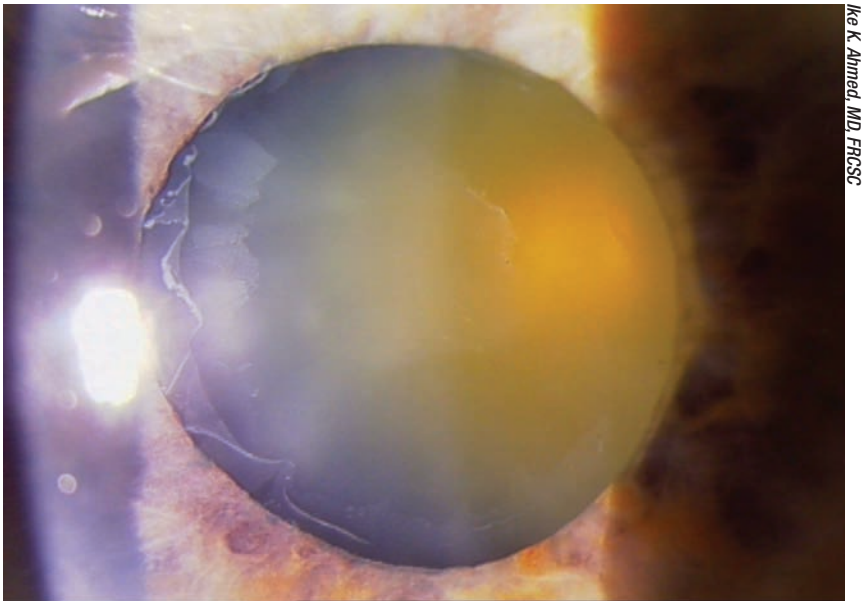
Glaucoma

If your cataract patient also has glaucoma:

• ***Consider performing MIGS during the cataract surgery.*** "I offer this option to any patient who's on a glaucoma drop with a definite diagnosis of glaucoma," says Dr. Lee. "In this situation, cataract surgery is not only an opportunity to improve the patient's vision but also to treat the glaucoma. I personally don't do trabeculectomies or tubes, but I tell patients that with the new MIGS procedures we can get better control of your eye pressure and maybe get rid of one or two of your drops at the same time. There's not much downside; some of these procedures can cause a little bleeding, but that's usually pretty mild and self-controlled. You don't have the risk of hypotony that you have with a trab or tube, and you don't have a lifelong risk of endophthalmitis. This is a great opportunity to help a patient with mild to moderate glaucoma at the time of cataract surgery."

• ***Consider altering your IOL options when the patient has glaucoma.*** "If a cataract patient has glaucoma, I generally have no problem putting in a toric lens," notes Dr. Lee. "I won't implant a multifocal lens, but I think it's reasonable to put in the Symfony extended-depth-of-focus lens if someone has very mild glaucoma. It doesn't reduce contrast sensitivity as much as a multifocal lens does."

"If it's well-controlled glaucoma and a very educated patient, and the patient's glaucoma specialist feels OK about it, then we may consider offering the patient the option of an EDOF lens," agrees Dr. Thompson. "Those lenses seem to reduce contrast sensitivity less than multifocality. But if the glaucoma is advanced, there's no way we're going to implant a multifocal or an EDOF lens. Furthermore, you have to keep in mind that even if a glaucoma patient doesn't have reduced contrast sensitivity now, that may change in the future because glaucoma is progressive."



Ike K. Ahmed, MD, FRCSC

Fibrillar material deposits on the anterior capsule that resemble a target are a sign of pseudoexfoliation. A cataract patient with pseudoexfoliation may have weak zonules, a potentially brittle capsule and pupils that don't dilate well. These patients also need to be warned that there's a risk of the need for additional surgery at some point in the future as a result of the lens possibly shifting or dislocating.

• ***If the patient has pseudoexfoliation glaucoma, change your surgical technique accordingly.*** "Pseudoexfoliation requires using a different approach when performing cataract surgery," says Dr. Mamalis. "In this patient you have potentially weak zonules, a potentially brittle capsule and pupils that don't dilate well, so you have to be prepared to address these issues."

Dr. Lee also warns these patients about possible postoperative problems. "I tell all these patients that there's a risk later on—even much later on—of the lens shifting or dislocating," he says. "That may require additional surgery."

"The good news is that in both open-angle and pseudoexfoliation glaucoma, very good studies have shown that just doing the cataract surgery itself will lower the intraocular pressure," notes Dr. Mamalis. "Removing the large crystalline lens—and if there is exfoliation, removing the exfoliation material—can lower the IOP postoperatively without any change in glaucoma medications."

• ***Beware of intraoperative and postoperative pressure spikes.*** "This is especially important if the glaucoma is moderate to advanced, where you find cupping, loss of nerve fiber layer and some visual field loss," says Dr. Thompson. "In this situation we're going to do everything we can to avoid large pressure fluctuations during the surgery. Furthermore, we need to think about the medications the patient will be on postoperatively, and we're going to be very type-A about getting the viscoelastic out."

Dr. Mamalis agrees. "Especially if a glaucoma patient has significant visual field loss, even a brief pressure spike could conceivably cause more vision

loss," he says. "That's why you have to do everything you can to prevent that postoperative spike in pressure. Be sure to get all of the viscoelastic out and watch the postoperative pressure very carefully."

Dr. Thompson adds that he likes to get a glaucoma specialist involved in these cases. "Even though we know that lens removal and replacement is a powerful glaucoma treatment by itself, it's not unusual for a glaucoma specialist to also do a MIGS procedure during the cataract surgery," he says. "That can help to blunt the possibility of a postoperative pressure rise, and may also help the patient get off drops."

• ***If the patient has a pre-existing glaucoma tube shunt or a trabeculectomy, adjust your surgical plan as necessary.*** For an in-depth discussion of these issues, see the Glaucoma Management column on page 67.

Macular Degeneration

Macular degeneration is a common co-existing problem in older patients:

• ***When macular problems are present, make sure the patient's expectations are realistic.*** "These patients may have tried every set of glasses and tear-film rehabilitation, and they see this as their last hope," notes Dr. Thompson. "You have to make the patient understand that the cataract is indeed visually significant, but the macula also has significant problems. That means that the cataract surgery won't solve all of the patient's visual issues."

He notes that the news isn't all bad. "It would be very rare for cataract surgery not to help at all," he points out. "It typically improves color perception, and since we know that both macular pathology and cataracts reduce contrast sensitivity, removing the cataract will typically improve that as well. So even though you may not improve Snellen vision in some patients, you can still increase their visual joy. They'll see colors better and end up with improved contrast sensitivity."

• ***Don't withhold surgery because of dry macular degeneration.*** "Macular degeneration is very common in the elderly, which is the population that usually gets cataracts," Dr. Mamalis points out. "There's been some controversy about whether cataract surgery exacerbates the progress of dry macular degeneration. A few studies have indicated that it may do so, but most others have not. Some researchers have suggested that a few patients may already have a pre-existing subretinal neovascularization that wasn't recognized, but is recognized after the surgery. However, if a patient doesn't have subretinal neovascularization or leakage of blood or fluid, there's no good evidence that cataract surgery will exacerbate the problem.

"Nevertheless, a thorough macular examination is im-

portant," he notes. "Certainly you want to make sure that there's no active subretinal neovascular leakage of blood or fluid prior to doing cataract surgery."

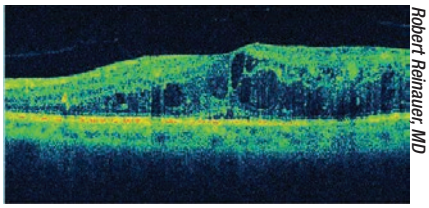
• ***If you find active leakage of blood or fluid, work with your retina colleagues to address that before surgery.*** "A retina specialist will give injections of anti-VEGF medications to reduce or eliminate active leakage," says Dr. Mamalis. "The retina doctor may also want to do an injection into the eye anywhere from a week to 10 days prior to the cataract surgery to make sure the surgery doesn't exacerbate any neovascularization. This is a situation in which you want to coordinate your surgery with your retina colleagues, because the right timing can allow you to maximize the value of those injections for your surgery."

Dr. Lee concurs. "Many of the retina specialists I work with want to do the injection about a week before the cataract surgery, but I leave it up to them," he says. "I just want to make sure we're all on the same page about the timing."

• ***If macular degeneration is present, adjust the IOL options accordingly.*** "If I see drusen, I won't put in a multifocal lens," says Dr. Lee. "A toric lens is fine, unless the person has horrible visual potential. It's difficult to come up with a clear rule regarding the extended-depth-of-focus Symfony lens; it depends on how mild the drusen are and how motivated the patient is. If the disease is really mild and the patient is motivated and really understands the risks and benefits, then I think you can put the Symfony lens in a patient with drusen. However, I would hesitate if the drusen start reaching the level of intermediate macular degeneration."

Diabetic Retinopathy

If your cataract patient is diabetic and has developed retinopathy, these strategies can help ensure an optimal outcome:



Robert Reinauer, MD

Optical coherence tomography reveals macular edema. Performing cataract surgery can exacerbate macular edema related to diabetic retinopathy, so any edema should be treated prior to performing cataract surgery.

• ***Be sure to address any macular edema or retinal neovascularization before proceeding with the cataract surgery.*** "Simply doing the cataract surgery can exacerbate diabetic macular edema," Dr. Mamalis points out. "This is another situation in which doing something like a macular OCT preoperatively is very important. If you find macular edema, you should treat it prior to surgery and make sure the macula is dried out before you proceed. You also want to make sure there's no obvious sign of neovascularization in the retina—on the disc or elsewhere—because the normal post-cataract inflammation and breakdown of the blood-aqueous barrier can exacerbate that neovascularization.

"For these reasons, when performing cataract surgery on a diabetic patient, make sure that macular edema and any proliferative diabetic retinopathy are controlled prior to going ahead with the surgery," he says. "This may mean postponing the surgery to give your retinal colleagues time to treat the retinal disease."

Dr. Thompson agrees. "We'd prefer to do cataract surgery when the patient's diabetes is under good control," he says. "We often enlist the advice of the retinal specialist who's taking care of their disease."

• ***Make sure the patient understands how diabetic retinopathy may affect the visual outcome.*** "Explaining this to the patient up front will help to ensure that the patient has realistic expectations," says Dr. Lee.

• ***If the patient is getting anti-VEGF injections for diabetic retinopathy, coordinate your schedule with the retina doctor.*** "This is similar to managing a cataract patient with macular degeneration," notes Dr. Lee. "If the patient is getting regular injections from a retina specialist, be sure to coordinate the timing of the surgery with him or her."

• ***Consider continuing postoperative NSAIDs for an extended period.*** "This patient population is at much higher risk for CME than the general population, even if they have no background changes and stable, treated disease," notes Dr. Thompson. "With a healthy eye, we might have the patient use a nonsteroidal anti-inflammatory drug postoperatively for a month, but with a diabetic patient we'll use it for three or four months. It's been proven to reduce the incidence of CME."

Vitrectomy or Scleral Buckle

Strategies that can help prevent a poor outcome in these situations include:

• ***Be especially careful about your IOL calculations if the patient has a scleral buckle.*** "The presence of a scleral buckle really doesn't change our surgical technique, but it can alter the patient's axial length," Dr. Mamalis points out. "It can make the calculation of IOL power more difficult, so you want to be very careful, especially if the patient is a high myope. You want to get the most accurate measurements you can when calculating the IOL power."

• ***If the patient has had a vitrectomy, warn him ahead of time about the increased risk of a follow-up surgery.*** "Because the retina surgeon has to go through the pars

plana, there's usually at least a little bit of zonular loss as a result," notes Dr. Lee. "I tell the patient to expect a higher risk of having a follow-up surgery after the initial cataract surgery, should I have any difficulty getting the cataract out. Depending on the patient's vision and history, I also say the same thing I say in any situation involving weak zonules: Even if the surgery goes perfectly, there's a chance that later on in life the lens could shift or move. I think a toric IOL is fine if the bag is stable, but you have to be careful with any presbyopia-correcting lens, given their history. That includes the Crystalens, because of the zonulopathy."

• ***If the patient has had a vitrectomy, remember that the patient's visual potential may still be unclear.*** "In this situation it may not be possible to determine the patient's visual potential, depending on how quickly the cataract formed post-vitrectomy," Dr. Lee points out. "I always remind patients that the retina is going to limit how good their vision is. I think patients understand that. On the other hand, if someone had enough time after the vitrectomy for vision to recover and become pretty good before the cataract developed, that's reassuring in terms of the person's retinal visual potential."

• ***If a cataract develops very quickly after a vitrectomy, it's possible there was damage to the posterior capsule.*** "Fortunately," says Dr. Lee, "damage to the back of the capsule during a vitrectomy is very rare, and if it happens you can often see unusual changes in the posterior capsule and know to avoid hydrodissection."

• ***If the patient has had a vitrectomy, remember that the capsular bag may move more during cataract surgery.*** "When the patient has had any prior retinal surgery, you want to examine the retina and make sure you don't see any ongoing issues," says Dr. Mamalis. "But if that surgery was a vitrectomy, you need to realize that it may change the dynamics of your cataract surgery. When you don't have solid vitreous behind the lens, the capsular bag tends to move a little bit more during the surgery—to trampoline, if you will. Fortunately, several of the newer phaco machines have become very good at minimizing the amount of trampolining and movement of the capsular bag during surgery."

"The lack of solid vitreous behind the capsule in combination with zonulopathy means that sometimes the capsule itself is a little floppy," agrees Dr. Lee. "You want to make sure that you're protecting the capsule with a second instrument. Also, sometimes you'll need to fill the bag with viscoelastic more often, to try to keep the capsule pushed back."

"A vitrectomy can also weaken the zonules," adds Dr. Mamalis. "We've encountered cases that we thought would be just a routine cataract, and as we go in to begin

Cataract Surgery and Systemic Problems

Systemic health issues can affect surgery in general and ocular surgery in particular. These strategies can help prevent trouble:

• ***Always be on the lookout for signs of a systemic condition.*** "Often, things going on in the body can be seen for the first time when we're doing an eye exam," notes Vance Thompson, MD, professor of ophthalmology at the Sanford School of Medicine at the University of South Dakota. "We should always be alert for signs of systemic trouble. They say the eyes are the window to the soul, but more to the point, they're the windows to the body."

Dr. Thompson adds that one of the nice things about cataract surgery is that a preoperative physical is required. "Often, that's what gets someone to go and see a family doctor or an internist or cardiologist," he says. "They can't get cataract surgery until they do. Those doctors often find things that end up saving the patient's life, or at least extending it."

• ***Make sure that any major health issues are under control before surgery.*** "In this era of doing cataract surgery through clear corneal incisions using topical anesthesia, without retrobulbar blocks or significant sedation, the patient's systemic health has become less of an issue than it was in the past," notes Nick Mamalis, MD, professor of ophthalmology, director of ocular pathology and co-director of the Moran Eye Center's Intermountain Ocular Research Center at the University of Utah in Salt Lake City. "For example, in the past we were very concerned about patients who were on anticoagulants; did we need to stop them? How would we cover them? Now that we're using topical anesthesia, that's become much less of an issue. Problems such as significant hypertension, heart failure, or lung disease such as chronic obstructive pulmonary disease are still an issue, but as long as they're sufficiently well-controlled that the patient can lie relatively flat for the 20 to 30 minutes that a procedure takes with topical anesthesia, these are much less of an issue than they were in the past."

• ***Remember to check for prior use of tamsulosin.*** As every cataract surgeon knows, the use of tamsulosin or related drugs is associated with floppy iris syndrome. "Patients don't always remember using these drugs in the past," notes Bryan S. Lee, MD, JD, in private practice at Altos Eye Physicians in Los Altos, Calif. "Even someone who just had a Foley catheter may have been given tamsulosin to wean them off, so you may have to dig into the patient's history."

—*CK*

the case we realize that the zonules are quite weak. You want to be sure that you have the ability to deal with this possibility. Have tools available that you can use during the surgery to support the capsular bag, such as capsular hooks and capsular tension rings, just in case."

Retinal Vein Occlusion

A history of retinal vein occlusion is a sign that addressing other problems may need to be factored into your plans:

• ***If the patient has had an RVO, make sure he's been evaluated for systemic problems.*** "A patient with this history should be evaluated for things like heart arrhythmias, carotid disease, hypertension, diabetes and other possible medical/systemic problems," says Dr. Thompson. "When a patient has had an RVO, we need to consider the possibility the there's something much bigger going on in the patient's body that needs attention."

• ***Make sure any macular edema is under control, and check for neovascularization.*** "Performing cataract surgery on a patient who's had a retinal vein occlusion is similar to surgery on a diabetic patient," says Dr. Mamalis. "If the patient has had a retinal vein occlusion—especially a central retinal vein occlusion—and there's any macular edema associated with this, you want to make sure that the macula is dry and there's no active edema at the time of the surgery.

"Patients who've had a central retinal vein occlusion may also develop anterior segment neovascularization as a result," he adds. "For that reason you want to carefully evaluate the iris and the angle preoperatively. Make sure there's no sign of neovascularization in either location."

• ***Try to quantify the patient's macular potential.*** "Sometimes this is not a lot different from working with a macular degeneration patient," notes Dr. Thompson. "The patient may have chronic macular changes that can affect image quality. So in order to get a sense of how much the cataract surgery will actually do for the patient, it helps to know how much visual degradation is being caused by the retina and how much is attributable to the lens."

• ***If the patient has had a retinal vein occlusion, enlist the help of a retinal specialist.*** "In this situation I always work with the input of a retinal specialist," says Dr. Thompson. "I find that most retinal specialists are more conservative than most cataract surgeons. Also, I find that a conservative retina specialist can be very valuable in helping to educate the patient that cataract surgery may not improve vision that much. This can be a very important part of getting informed consent when a patient with something as significant as an RVO is pushing for cataract surgery."

Keratoconus

How a patient has chosen to manage this disease should be considered when choosing an implant:

• ***If a patient has keratoconus and is happy wearing an RGP contact lens, avoid a toric implant.***

"Using a toric lens is technically off-label, but some keratoconus patients do really well with a toric lens," notes Dr. Lee. "If you find consistent astigmatism measurements, I think a toric implant can be very beneficial. However, if you implant a toric lens, a rigid gas-permeable contact lens won't be a good option for the patient postoperatively because it will eliminate any corneal astigmatism, leaving the patient with iatrogenic, lenticular astigmatism.

"The reason this may be an issue for some patients is that an RGP lens can provide clarity and sharpness of vision, and some patients really love that," he continues. "I've had patients come in for a second opinion who were unhappy because they didn't realize that they weren't going to be able to wear an RGP contact lens anymore. Technically, they could, of course, but then they'd have to wear glasses to cancel out the IOL astigmatism. So if you're planning cataract surgery on a keratoconus patient who loves the clarity and sharpness of RGP lenses, that person should get a standard monofocal lens. On the other hand, if it's someone who mostly wears glasses or doesn't really like RGPs, then I think a toric implant will work well."

Setting Patient Expectations

Co-existing conditions can have a profound effect on intraoperative complications, visual outcomes and the possibility of needing further surgery down the road, making the patient's expectations especially important. To minimize the chance of a very unhappy patient:

• ***Make sure the patient understands that this is not standard cataract surgery.*** "It's really important to have a thorough informed consent conversation with the patient preoperatively," notes Dr. Lee. "You want to make sure patients understand what's different about their eye, and why you're making the recommendations that you are for their surgery and IOL selection. The paper they sign isn't really the issue—it's the conversation you have, and making sure they understand."

• ***Counsel patients with Fuchs' dystrophy carefully before the surgery.*** "You have to let the patient know preoperatively that he may have delayed or extended healing time," says Dr. Lee. "There's a risk of corneal decompensation and the possibility of needing a corneal transplant afterward."

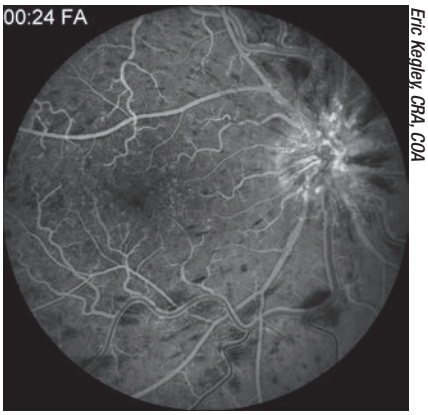
Dr. Mamalis notes that without this counseling, the patient is likely to blame the surgeon for a less-than-ideal outcome. "If the cornea was not quite decompensated before surgery and the vision wasn't too bad, these patients could still end up with corneal edema after your cataract surgery," he says. "If they do, they're going to blame you—you caused it. So you need to counsel these patients ahead of time that there's a good chance they'll need further

surgery such as DSEK later to replace endothelial cells."

• ***Make sure the patient understands that managing multiple problems can take much longer than simply having cataract surgery.*** "When a patient has two sources of visual limitation—and some may even have three—corneal, lens and macular pathology—it's important to educate the patient that dealing with these issues is going to be a stepwise process that takes much more time than cataract surgery alone," notes Dr. Thompson. "A patient might have a fair amount of corneal pathology, such as Salzmann's nodular degeneration from contact lens wear, or a thickened, hypertrophic peripheral cornea. In that situation, I'd want to address the corneal problem first. If it's visually significant anterior corneal pathology, I'd want to do a corneal scraping or a lamellar dissection, or a diamond burr smoothing, or a phototherapeutic keratectomy to smooth out the cornea, because often that will eliminate a lot of visual irregularity. Then, the patient may not even feel the need to have cataract surgery. However, you have to make it clear to the patient up front that instead of waiting a month to get new glasses after having nothing but cataract surgery, this could become a six- to nine-month journey if we go after the corneal pathology first and let things heal well, and then reassess the patient's vision."

• ***When you discuss these issues with the patient preoperatively, try to have a loved one in the room as well.*** "That's important because this discussion can become sensory overload," explains Dr. Thompson. "The patient may not remember everything you said if he's the only person in the room with you. So ideally, you should have a second set of ears."

• ***Be sure to note in the chart that you discussed these issues with the patient preoperatively.*** "You should be very specific in your medical record about what you found in your exam, and describe what you discussed with the patient as far as how the different parts of the eye may be contributing to reduced vision potential," says Dr. Thompson.



Eric Kegley, CRA, COA

Fluorescein angiography showing a central retinal vein occlusion. A patient with this history should be evaluated for possible medical/systemic problems. Then, before cataract surgery, make sure the macula is dry with no active edema and carefully evaluate the iris and the angle to ensure there's no sign of neovascularization.

Dr. Mamalis agrees. "I'll often write 'Discussed guarded prognosis with patient due to' whatever disease it is," he says. "I'll tell the patient, 'You have preexisting macular degeneration. We're going to remove your cataract and it's going to make your vision better. However, your vision may not be normal after the surgery; you may still have some decreased vision because of the retinal disease.' Or if it's a patient with exfoliation, I'll note that we discussed the possible increase in the risk of complications during surgery. If it's Fuchs' dystrophy, I'll note that we discussed the possible risk of worsening corneal edema and the possible need for further surgery."

Dr. Mamalis adds that it shouldn't be necessary to alter your informed consent document. "The informed consent should pretty much have everything in there already," he says.

• ***If you use electronic medical records, consider giving the patient a printout that includes the mention of your preoperative discussion.*** "With EMR we can give the patient a copy of what we said during the examination," says Dr. Mamalis. "We include the sentence that says we discussed the guarded prognosis with the patient."

Some Final Thoughts

In terms of the big picture, a few strategies are worth keeping in mind:

• ***Always do a thorough preoperative evaluation of the patient.*** "This is the most important thing," says Dr. Mamalis. "I know that in a busy clinic it's very difficult to make sure everything gets done, but when you're going to operate on a patient you need to get a thorough history and do a thorough examination. It's critical, because you want to know what you're dealing with ahead of time. You don't want any surprises when you're in the middle of surgery—or immediately after surgery."

• ***Plan ahead.*** "Whatever co-existing condition you're faced with, you want to have thought about it and planned for it before you do the surgery," Dr. Lee points out. "You shouldn't have to be solving foreseeable problems in the middle of a stressful situation when things are not going as planned in the OR. Think through the possibilities in a more controlled environment."

• ***Accept that sometimes you'll have to tell the patient you can't do what he's requesting.*** "Today, cataract surgery is so successful, and we're so used to being able to meet and exceed patients' expectations, that it can be difficult to have to tell a patient that something is not a good idea," observes Dr. Lee. "However, that's our job as the physician." REVIEW

Drs. Lee, Mamalis and Thompson have no relevant financial ties to any product mentioned.





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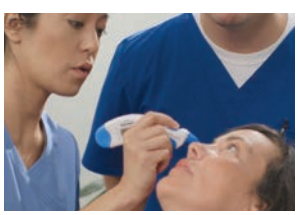


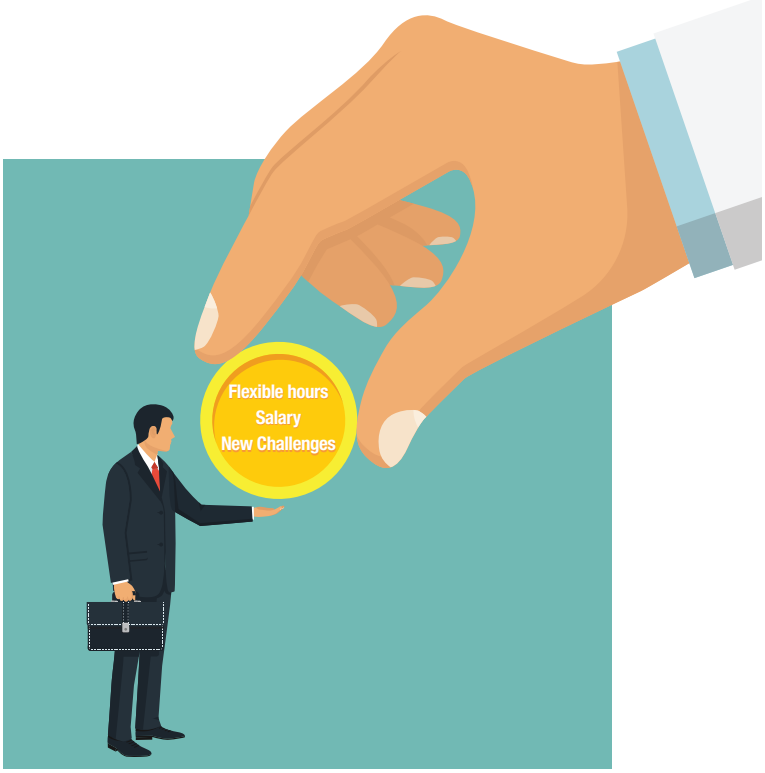
Staffing Essentials: Planning and Practice

Liam Jordan, Associate Editor

A look into getting the most out of your staff and how to retain them.

A machine is only as efficient as the sum of its parts. Like a machine, an ophthalmologist's practice needs many moving parts to work together to effectively and efficiently diagnose and treat its patients. From the patient's first contact with the front office, to the technicians who help diagnosis and treat whatever issues might arise, an ophthalmologist must know what to look for in his or her staff to streamline efficiency and create an excellent patient experience. A first-rate staff makes an ophthalmologist's life easier, taking away stress and bettering his or her business to create a well-oiled machine.

In this article, we'll discuss what to look for when hiring staff who will help improve your practice, as well as how to retain and reward that staff once you've assembled it.



Where Practices Go Wrong

Perhaps the best place to start is to analyze the missteps of some medical practices. Ravi Goel, MD, an ophthalmologist from Cherry Hill, N.J., identifies what he believes to be the biggest mistakes practices make when hiring or training staff. "I think the key is expectations—what a job entails and the demands that come with it. That's the biggest mistake or area for improvement," he says. "You need to be clear about your expectations right away, or you'll end up hiring someone who's not qualified, or not prepared for what you expect of them. If we're hiring, we want someone who's going to add to a clinical team and be happy there. Ultimately, we want them to enhance the team and make care more efficient for patients. If they're

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Dr. Sarah Martin, community outreach assistant director, leads students on outreach vision screenings and exams in the community and rural areas of Oregon. Acuity Pro donated two all in one systems for the mobile clinic, allowing for a clean, compact, and accurate means of testing visual acuity in all populations.

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not making your practice more efficient, they're not worth hiring.

"The bigger issue is how efficiently practices run because that directly impacts patients," Dr. Goel continues. "You absolutely need a team that provides an excellent patient experience."

For most practices, the patient experience starts with the staff on the "front line": the staff members who interact with patients every day, greet them, answer phones, set up appointments, file insurance claims, and generally help an ophthalmologist aid as many patients as possible. An invaluable staff will contribute something that's almost intangible to your practice and remove stress and roadblocks.

"Giving great clinical care and being a smart physician is assumed," Dr. Goel says. "Your patients assume that you are a good doctor, so you need to focus on the other areas they're exposed to. You need to give them an experience that leaves them happy and coming back. It's all about what the patient's experience is, and a lot of that is dependent on your team—your colleagues.

"The patient experience starts when they call you or look you up online. The most important person in your practice is the one who answers the phone. If that person doesn't treat a patient well, it's over. They'll go somewhere else," he says.

Dr. Goel has some thoughts on how to achieve this environment. "It has to be patient first," he says. "You want to create an environment where patients have excellent clinical care, and they ultimately leave the office that day feeling like they've had a great experience. Everyone who interacts with the patient that day affects the patient's attitude about the visit. I find that a lot of negative reviews are because of billing issues or issues with the front office that often have nothing to do with clinical care, and have more to do with the experience of the visit."

John Pinto, an ophthalmology business advisor, also weighs in on where practices can go wrong. "At the top of that list is poor selection, poor orientation/training and poor ongoing supervision," he says. "If you're not clear, you'll get undue perfectionistic expectations and oversights that'll result in stress and higher staff turnover." However, in terms of compensation, Mr. Pinto claims it actually isn't a huge issue. "Surprising to some, wages are way down on the list of factors that increase staff turnover."

Mark Packer, MD, FACS, president of Mark Packer MD Consulting in Boulder, Colo., highlights a different issue practices struggle with. "The biggest issue is losing staff to a competitor," he says. "Not necessary someone you view as a direct competitor, but it could just be someone in the region who has a more attractive package. It's not just financial—not just about the dollars. I've seen practices lose their most valuable technicians because something about another practice was more attractive, whether that's a potential for advancement, a lifestyle change, etc.

"The cost of losing a valuable tech is so much higher than it seems because getting someone to that level of skill and training them in the way you want things done is time-consuming," Dr. Packer adds. "There's a morale issue, too. Say someone you perceive as a leader leaves. There's going to be a certain level of morale exhaustion for those who looked up to him/her. So there are intangible losses too."

An Invaluable Staff

Avoiding these pitfalls and hiring the people that best fit your practice helps to create an efficient and invaluable staff. In regards to the traits of an invaluable staff, Dr. Packer says, "The number-one value is someone you can trust. It's the tech who comes up and says, 'Mr. Jones is here and he has this problem.' It's invaluable when you know they're absolutely right in what they're saying. They have to have the clinical experience and skills to make that call, obviously, but once they do, the trust will come almost naturally." Dr. Goel agrees. "Trust is a must—being able to entirely trust your techs when you see a patient takes the pressure off of you, making your life that much easier," he says.

"There's also a personality thing sometimes," Dr. Packer says. "Some people like to dramatize or minimize, and you want them to be in sync with you, so when a tech comes and says, 'You'd better see Mr. Johnson right now,' you know there's some real urgency behind it, not just an emotional or overreaction. That's so valuable. That kind of trust gets built up over a long period of time, which is also why it's a blow to lose someone you entirely trust. All those moments when they make the right calls and correct suggestions build toward that trust."

In an article discussing how to best build an eye-care team, authors Thulasiraj Ravilla and Gnanasekaran Chinnathambi state, "The selection process should probe not just the candidate's competency but also his or her motivation. The reality is that technical skills can be developed and improved over time, but it is much more challenging to change fundamental beliefs, attitudes and behavior. Thus the recruitment and selection process should ensure both competency and the right fit for the organization's values, but with a greater emphasis on the values (which are reflected in the organization's mission and vision)."[1]

However, sometimes staff turnover happens, and both Drs. Goel and Packer admit that while it is often a blow to the practice, there are some positives. "When people leave to go on to do something with research or at a different level (working in research when the company that sponsors the study hires them to be a clinical research associate, for example)—okay,

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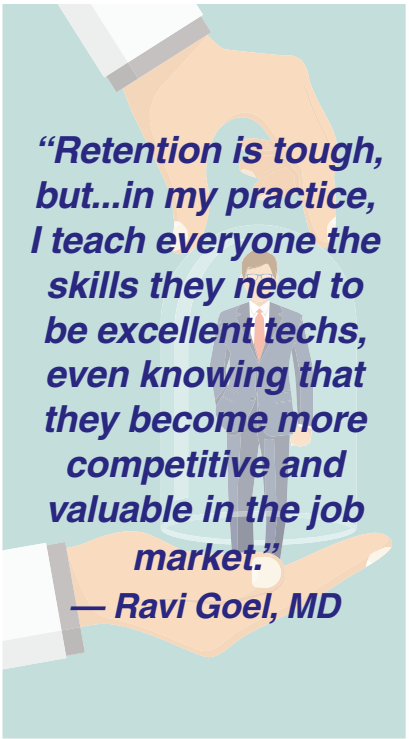
you lost someone," Dr. Packer says. "But you can look at it as if you're a training ground for people who want to go on that path. That's encouraging to staff. That can be a positive thing because it inspires people to do better where they are.

"They need to feel that they're on a path that is leading somewhere that they want to go," Dr. Packer adds. "It's intangible how you actualize that, but you can, by just talking to them about both your and their expectations, so their job isn't just a grind."

Like Dr. Packer, Dr. Goel says that although sometimes staff retention is tough to maintain, there are sometimes positives that come from it. "Retention is tough, but in my practice, I teach everyone the skills they need to be excellent techs, even knowing that they become more competitive and valuable in the job market," Dr. Goel says. "It really comes down to, would I rather have a tech that's highly skilled, but has a risk of leaving? Or would I rather have a tech who is not as skilled and wants to stick around? You want people who want to learn. They make the best staff. And sometimes it's not the worst thing if they leave. You shouldn't be afraid of someone leaving. What's worse is being afraid of someone staying who doesn't have the skills or the drive to learn those skills.

"On the flip side, when we acquire a tech from another practice, they're a gold mine," Dr. Goel continues. "We ask them what can we do to make things more efficient, what they liked most about their last practice, etc. If you use them as a resource, you'll often get some great advice from them, on not only what they did right, but also what to avoid. Tell me what we're doing wrong. How can we constantly improve our practice?" he asks. "Mr. Chinnathambi and Mr. Ravilla also agree that losing a member of staff is an opportunity to learn. "Employee retention should be a major concern for any organization," they state. "Individuals, once well trained and effective, may opt to move for better prospects. In that case, a formal exit interview is useful to inform management about her or his experiences within the organization and what might be improved. Above all else, the organization has to be concerned about employees' physical, mental, social and spiritual well-being."[1]



Keeping them Happy

So how do you retain your staff and keep them happy? According to Dr. Goel, it's about giving them a voice in your practice. "I find that the staff often want to feel like they're contributing to something. Oftentimes, they would rather take a lower wage as a trade-off for experience and the feeling that they're contributing to something and making a difference," Dr. Goel says. "Members of your team are happier if they're given a voice—if they feel they can contribute something to a practice to make it run more efficiently or improve the experience for a patient. They're more likely to stick around if you listen to them and value their clinical input. They feel a sense of investment in the practice, which is a very positive thing."

Corinne Z. Wohl, President of C. Wohl & Associates, a practice-management consulting firm, offers her advice on how to keep your best staff happy. "High morale and staff happiness are generated when employees feel respected for their work effort, appreciated as a team member and experience positivity in the workplace environment," she says. "Thorough communication from management and physician-owners via meetings and written announcements also adds to employees' confidence that they know what's happening in their organization. It's just another form of sharing, respect and teamwork that creates a happier work setting.

"Practices that prioritize building fun into their routines find increased staff happiness, too," she continues. "Things like playing email bingo, holding holiday-related contests, and providing thank-you lunches after a challenging clinic day are just a few ways to generate a positive team spirit and show sincere appreciation."

Dr. Packer also provides some concrete advice on how to facilitate a welcoming work environment to cultivate an invaluable and happy staff. "First of all, the compensation has to be competitive. You're not going to get good or happy people if you're paying them less than everyone else and working them harder," he says. "I know a lot of doctors are bottom-line-oriented and concerned because it's their livelihood, but you really can't afford to cut costs there if you want a reliable team that you can build a relationship with. That's the foundation.

"I think promoting people from within is huge," Dr. Packer continues. "In our practice, people from the front office have become techs,

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because they see what the techs do each day. Not everyone may have that ability, but it's worth exploring. Advancing through the practice can be a big morale boost for everyone.

"Beyond that, ask yourself, 'Is it exciting for these people to come to work every day? Do they like the environment? Do they feel there's potential for advancement? A future here? Can they learn more skills to achieve a higher level of compensation?' Some of that can be done through certification," Dr. Packer notes. "By continuing education, you can reward them for keeping their certifications active.

"They have to feel like they're part of something worthwhile. It's not just a job. They're not someone who could be replaced by a robot tomorrow," he says. "There's something about being there that's exciting and fun, whether it's the collegiality, working toward a common goal or being involved in clinical research.

"I think, intrinsically, most technicians give the doctors the benefit of the doubt—they trust and respect their expertise," Dr. Packer says. "I think they come in with a pretty positive attitude. It's yours to lose, but you don't have to. You can build on that. My favorite things are the new technologies, and training staff to use them. That can be exciting for everyone because you get to teach all of the new things you can use this technology for with your patients."

Advice from Your Staff

It's one thing to ask a doctor what staff value in a practice, but it's another to get the opinion of the staff directly. A staff member from an ophthalmology practice in Maryland discusses her experience at multiple practices. "I think it does start with the compensation, because that's how you're actually being valued," she says. "But I've never had a real problem with that. I think most doctors know the value of their staff and wouldn't try to cut corners there.

"Beyond that, it's nice to have some affirmation that what you're doing isn't going unnoticed—you're appreciated somehow," she continues, "whether it's recognition from the doctors themselves or the patients who are thrilled with their visit. That's probably the best feeling."

In terms of her previous practices, she says, "I recently left a practice because of a flexibility issue. I have to drop my son off at school on the weekdays, so I needed my hours to start at 10 o'clock, and the practice couldn't make it work. It's no one's fault, really, but I think being accommodating to your staff (up to a certain point) definitely goes a long way. The other practices I left were mainly due to lifestyle things—I moved back home for a year, and another year, after I got married, my husband and I bought a house down here. So there's another move and a new practice."

In another conversation with a staff member from an ophthalmology practice in New York, he highlighted a few more features that attracted him to his current practice. "When you're in an area with a high demand for techs, you sometimes get some recruitment going on," he says. "They try to really sell themselves to you, which is a good sign. They're passionate about their practice and want the best people they can get their hands on. This particular one offered me a flexible schedule, coupled with the technology they had available to them. It made for a tempting offer to work on some new technology I never had worked with before," he says. "So when they hired me, they immediately let me know my role and started training me on how to use this new technology, which was really exciting for me.

"Sometimes it's tough leaving a practice, though," he continues. "You really get to know the people you work with and appreciate the passion they have for what they're doing. It's reassuring to work for a doctor who isn't just going through the motions—someone who genuinely cares for patients and has a passion for his or her work. It can really be contagious." REVIEW

None of the contributors to this article have disclosed any financial interests.

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194843/ accessed 10 Oct 2017.

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Dysphotopsia: Not Just Black and White

Michelle Stephenson, Contributing Editor

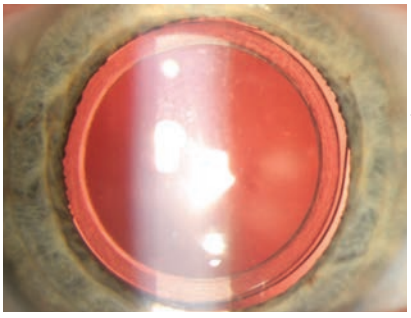
Both positive and negative dysphotopsias can occur after perfect cataract surgery.

Sometimes the squeaky wheel doesn't get the grease: Despite dysphotopsia being the leading cause of patient dissatisfaction after uncomplicated cataract surgery, surgeons say precious little has been done to address it. Recently, however, studies have emerged that have pinned down some of the chief causes of this frustrating effect of IOL implantation, and surgeons and industry are taking notice. Here's what we know about dysphotopsia and the steps you can take to help minimize or prevent it.

Positive Dysphotopsia

There are two types of dysphotopsia—positive and negative—that can occur after cataract surgery. "Dysphotopsia just means an unwanted image that patients see after cataract surgery. Positive dysphotopsia is unwanted light, such as a streak, starburst, flicker, fog or haze, and negative dysphotopsia is a black line or crescent in the far periphery of patients' vision," explains Jack Holladay, MD, MSEE, FACS, who lives in Bellaire, Texas.

Positive dysphotopsia is characterized by undesired light streaks, arcs, and flashes that emanate from obliquely incident sources of light. "The literature is clear that the chief cause of positive dysphotopsia is square-edge IOLs,



Samuel Masket, MD

Figure 1. First version of the Morcher 90S anti-dysphotopic IOL. The anterior capsulotomy fits into a peripheral groove in the IOL. Note the excellent centration.

which became popular in the mid-90s because of their ability to reduce the incidence or retard the development of posterior capsule opacification. We really didn't notice positive dysphotopsia until the advent of square-edge IOLs," says Samuel Masket, MD, who is in practice in Los Angeles.

He notes that another, less widely known cause of positive dysphotopsia is reflections from the internal back surface of the front of the IOL. This observation[1] is typically associated with high-index-of-refraction, low-radius-of-curvature IOLs. "The manufacturing sector eventually changed IOL design, putting more of the power on the front of the lens, which helped reduce internal reflection. Additionally, manufacturers altered the square edge of the IOL by making the front edge

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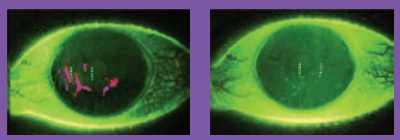

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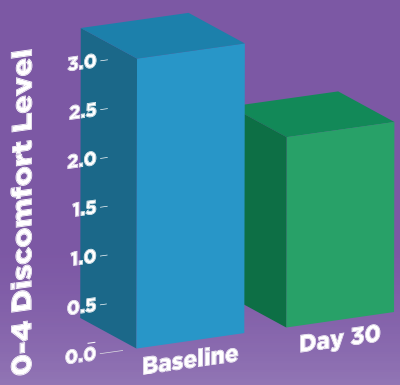


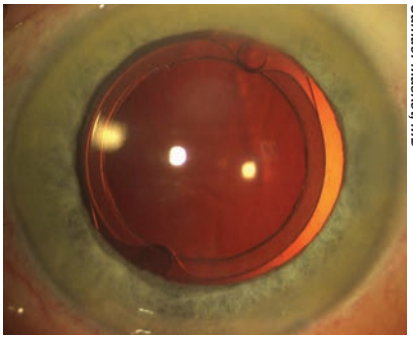
round or frosting the square edge. However, because positive dysphotopsia is due to internal reflection, altering the external edge of the lens seems unlikely to help," Dr. Masket explains.

According to Dr. Masket, all IOLs on the U.S. market today have square edges. He notes that because the index of refraction and the surface reflectivity of lenses can be associated with positive dysphotopsia, certain IOLs will show less of a tendency. "For example, silicone and copolymer lenses tend to have a much lower incidence of positive dysphotopsia than acrylic lenses, but any truncated-edge IOL, including oval lenses,[2] will be associated with positive dysphotopsia. So, it still exists, and my sense is that the manufacturing sector has paid closer attention to multifocality, asphericity and toricity of IOLs than to patient-generated complaints," he says.

Unfortunately, positive dysphotopsia typically doesn't resolve with time. However, making the pupil smaller pharmacologically, either with dilute pilocarpine or brimonidine, can often reduce symptoms. "If that fails, the best thing to do is offer the patient a lens exchange and choose a lens that has a lower index of refraction, or one that has less surface reflectivity. In our practice, we find that the STAAR Surgical three-piece copolymer lens (Collamer) offers us the best opportunity. Additionally, a silicone intraocular lens, typically the Bausch + Lomb LI61, will improve 80 to 90 percent of patients," Dr. Masket says.

Negative Dysphotopsia

According to Dr. Holladay, negative dysphotopsia became more common in the 1990s for three reasons: square optics were introduced, acrylic lenses (which have a higher index of refraction) were introduced, and surgeons began leaving an overlap of about 0.5 mm of the anterior capsule over the anterior edge of the optic of the lens.



Samuel Masket, MD

Figure 2. A modified Morcher 90S IOL. Note the peripheral groove and excellent centration. Fixation holes facilitate capture of the IOL within the anterior capsulotomy.

"These were all improvements in IOLs that reduced posterior capsular opacification, but there was a trade-off. We increased the incidence of negative dysphotopsia in exchange for reducing posterior capsular opacification," he says.

Negative dysphotopsia is an observation by a patient of a phenomenon similar to a horse blinder. There is a dark arc on the temporal side of the vision. "What causes it remains controversial today. Because of that controversy, it hasn't really been well approached by the manufacturing sector. Ray-tracing theoretical studies, particularly two studies from Jack Holladay, have indicated that IOL design, material, position and other factors could be causal. However, some of those parameters haven't matched the clinical picture," Dr. Masket adds.

According to one of Dr. Holladay's studies published earlier this year,[3] standard ray-tracing techniques showed that a shadow is present when there's a gap between the retinal images formed by rays missing the optic of the IOL and rays refracted by the IOL. Additionally, the ray tracing also showed a constriction and double retinal imaging in the extreme temporal visual field. This study found that, in a nominal acrylic pseudophakic eye model with a 2.5-mm diameter pupil, the maximum retinal field angle from rays refracted by the IOL was 85.7 degrees, and the minimum retinal field angle for rays missing the optic of the IOL was 88.3 degrees, which left a dark gap of 2.6 degrees in the extreme temporal field. "We also showed that there are patient factors that increase the risk of this, such as an extremely small pupil, a high intraocular lens power and a larger angle kappa," Dr. Holladay explains. "Angle kappa is the angle between the visual axis and the pupillary center. The bigger that is, or the more central your pupil is in the cornea away from the visual axis, the higher the chance of negative dysphotopsia." Secondary factors included the following: IOL edge design; material; diameter; decentration; tilt; and aspheric surfaces.

This study[3] explains in detail all of the factors associated with negative dysphotopsia, says Dr. Holladay. "In the simplest of terms, there is a gap between the rays refracted by the IOL and those missing the IOL, which leaves a crescent-shaped shadow on the retina. I don't believe anyone who has read this article still believes there is controversy as to the cause," he says.

Interestingly, and frustratingly, for the surgeon and patient, negative dysphotopsia only occurs after perfect surgery. "The posterior capsule is perfectly clean, the capsulorhexis perfectly overlaps the optic, and the lens is perfectly centered. It's like the perfect cases are the ones who are most likely to experience it," says Kevin M. Miller, MD, who is in practice in Los Angeles.

Dr. Masket agrees that these patients have a perfectly centered IOL underneath the continuous anterior capsulotomy. "Negative dysphotopsia occurs in as many as 15 percent of patients early after surgery, although the great majority improve over time, bringing the incidence down to about 3 percent at one year.[4] We've just completed a clinical study[5,6] that parallels our original work that indicates that negative dysphotopsia can be associated with any of the intraocular lenses

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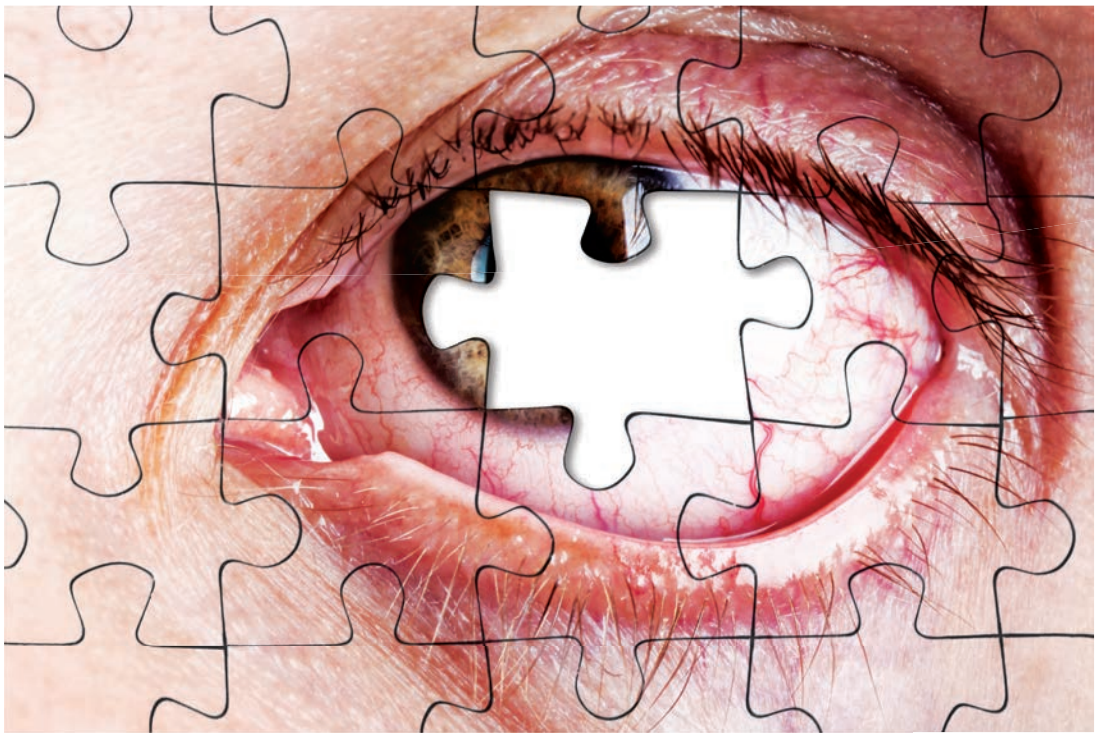

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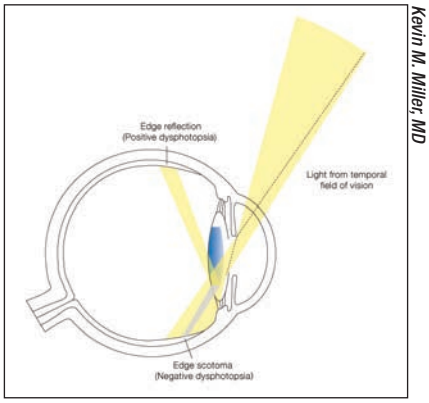
that are on the market in the United States, as long as that lens is well-centered in the capsular bag," Dr. Masket says.

Symptoms will resolve with reverse optic capture, meaning that the optic portion of the lens is moved in front of the capsular bag into the ciliary sulcus, leaving the loops in the capsular bag. "There seems to be some relationship with the lens and the capsular bag, and that is the final common pathway," Dr. Masket adds, "although the cause of negative dysphotopsia is likely multifactorial and still somewhat enigmatic. For example, in our study, we found a preponderance of negative dysphotopsia in women and in left eyes. Those phenomena are mysterious to us."

He notes that making the pupil smaller, which helps positive dysphotopsia, actually makes negative dysphotopsia worse. "Dilating the pupil makes the symptoms better, but, unfortunately, dilation can induce glare and nighttime difficulties. So, pupil dilation is not an appropriate strategy for these patients," Dr. Masket says.

Patients can be offered spectacles that block the light coming from the side that is stimulating negative dysphotopsia. If the symptoms improve over time or the patient doesn't mind wearing glasses, then surgery doesn't need to be considered. "As far as surgical treatment, we strongly prefer reverse optic capture. In the case of a single-piece IOL, the haptics must remain in the bag, so we manipulate the capsulotomy to go under the edge of the optic rather than have it overlay the optic. This strategy requires that the anterior capsulotomy be the right size and well-centered. If it isn't, then we encourage lens exchange with a three-piece lens placed in the ciliary sulcus, and we suture-fixate the loops so the iris of the lens doesn't decenter. Reverse optic capture has eliminated or significantly improved the symptoms in nearly all of our patients. We've also used reverse optic capture for the second eye of patients who are very symptomatic in their first eye after surgery. We have employed this strategy for 21 cases, and none of those second eyes have had negative dysphotopsia,"[7] Dr. Masket says.



Kevin M. Miller, MD

Figure 3. Light entering an eye from the temporal field of vision crosses the pupil and encounters the flat edge of a high-index-of-refraction intraocular lens. Some of the light bounces off the edge, creating one of the positive dysphotopsias. Distal to the edge, a shadow is cast onto the nasal retina, creating a negative dysphotopsia.

For patients who have combined negative and positive dysphotopsia, he recommends exchanging the lens for a three-piece copolymer or three-piece silicone lens with reverse optic capture. "We've had excellent success with that technique," he notes.

Dr. Masket has designed an IOL specifically to prevent negative dysphotopsia. The design attempts to mimic the optical advantage of reverse optic capture while leaving the bulk of the IOL within the capsule bag. "The anti-dysphotopic IOL is manufactured in Germany by Morcher, and it has been used in limited clinical trials and modified as appropriate over time. Presently, 100 of the IOLs have been implanted, and none of those patients have had negative dysphotopsia at any time, providing proof of concept," he adds.

According to Dr. Miller, in the past, the best solution for patients with negative dysphotopsia was to exchange the lens for a round-edge lens, but currently none are available in the United States. "People have done other things, such as implant a piggyback lens. Anything that basically scatters light into the nasal retina where that shadow is will solve negative dysphotopsia. Time alone does that as well. As the capsular bag fibroses and as cells start to proliferate peripheral to the edge of the lens, you get more of a scattering effect. Many patients can just wait it out, and it usually gets better," he says.

Another treatment option is to orient the optic-haptic junction of an acrylic lens at 3 o'clock and 9 o'clock, so that the optic-haptic junction is horizontal. "The amount of negative dysphotopsia that patients experience goes from 25 or 30 percent down to 5 percent. The improvement is dramatic," he explains.

A recent study conducted by Bonnie Henderson, MD, and colleagues found that positioning the optic-haptic junction of an acrylic IOL inferotemporally resulted in a 2.3-fold decrease in the incidence of negative dysphotopsia after cataract surgery.[7] When implanted in the vertical position, acrylic IOLs seem to have a higher incidence of negative dysphotopsia than silicone IOLs.

In this study, patients had surgery with implantation of either a silicone IOL inferotemporally or vertically or a one-piece acrylic IOL with the optic-haptic junction inferotemporally or vertically. Other patients received acrylic IOLs bilaterally and inferotemporally without randomization. Patients were asked about negative dysphotopsia symptoms postoperatively.

The study included 418 eyes in 305 patients. A silicone IOL was implanted inferotemporally in 39 eyes and vertically in 60 eyes. An acrylic IOL was implanted with the optic-haptic junction inferotemporally in 163 eyes and with the junction vertical in 114 eyes. Forty-two eyes had bilateral inferotemporal implantation of an acrylic IOL. For the

(Continued on page 65)

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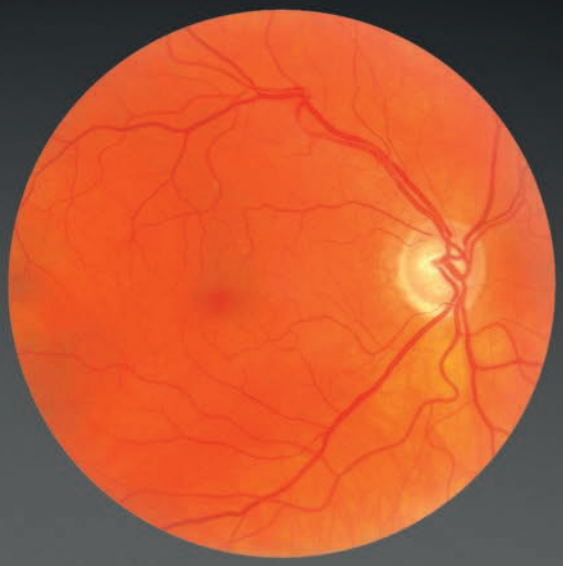

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Chasing Geographic Atrophy Treatments

By Kristine Brennan, Senior Associate Editor

There are a lot of potential therapeutic targets, but no clear winner has emerged.

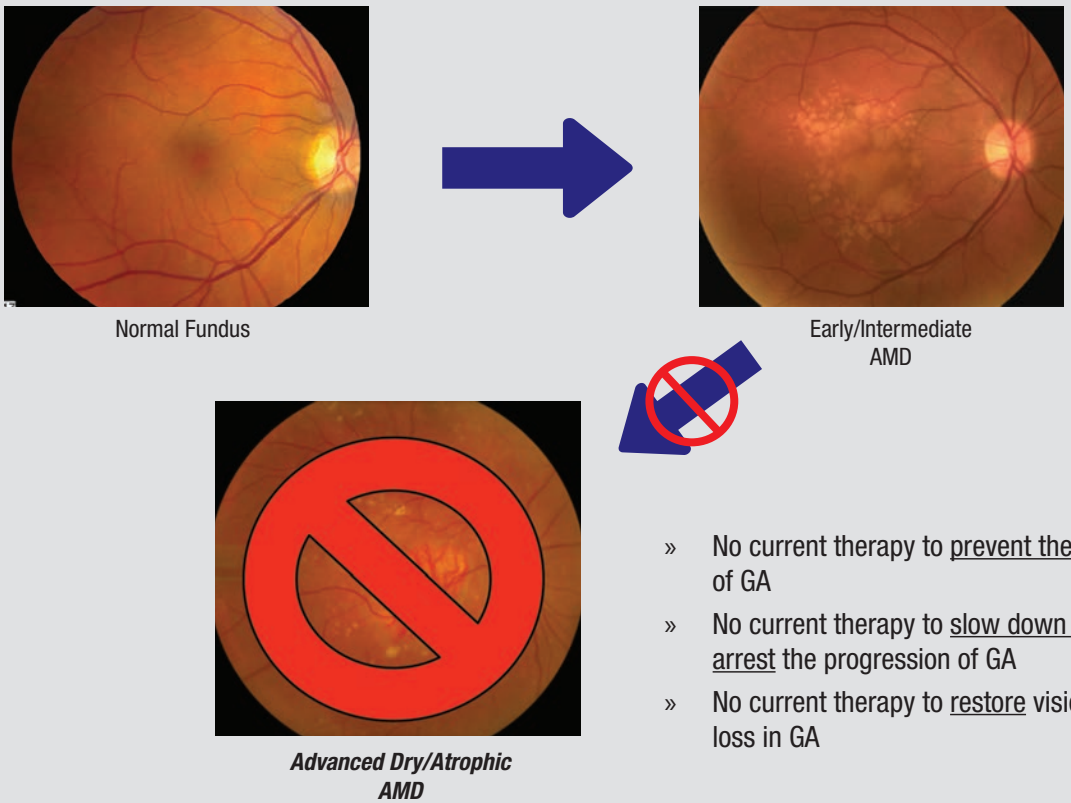
Late-stage age-related macular degeneration has been reported to occur in 8 percent of people aged 75 and older, a growing segment of the American population.[1] Although the exudative form of AMD is responsible for more vision loss than the atrophic form, so-called "dry" AMD has no known effective treatment. Two retinal specialists discuss their investigational efforts below, and provide an overview of some of the avenues researchers are taking to stop geographic atrophy (GA) in its tracks.

AREDS Supplementation

The AREDS study suggested that supplementing the diet of patients with early or intermediate AMD with vitamin C, vitamin E, beta-carotene and zinc could significantly reduce the risk of progressing to advanced AMD.[2] The AREDS 2 study indicated that replacing the beta carotene in the original AREDS formula with lutein and zeaxanthin may offer similar protection against developing advanced AMD.[3] The AREDS2 formulation may be safer for smokers and former smokers, as taking beta-carotene is associated with an increased risk of lung cancer in these patients. Commercial supplements such as PreserVision AREDS and PreserVision AREDS 2 (Bausch+ Lomb) are routinely recommended to patients who are at risk of progressing to advanced AMD, at least in part because there's currently nothing else to offer patients to avoid geographic atrophy.

"Even practitioners may sometimes be a little hazy with regards to what they tell their patients about the effects of the vitamins," acknowledges Wai T. Wong, MD, PhD, clinician-scientist, Unit on Neuron-Glia Interactions in Retinal Disease, National Eye Institute. "AREDS supplementation is given to patients with intermediate AMD who have large drusen in their maculas. The question remains, what exactly does it do for them? If you look very carefully at the trial data, what it actually shows is that AREDS supplements can reduce the risk of progressing from intermediate to wet AMD. It can reduce that rate by about one-quarter or one-third, depending upon the AREDS or AREDS2 formulation. But if you look at that data, it actually doesn't reduce the risk of progression from intermediate to atrophic AMD at all, just the risk of progression to wet AMD," he says. "Among patients who already have atrophic AMD and whose GA lesions are increasing in size, again, the data do not show that AREDS supplementation is helpful in slowing

State of Geographic Atrophy, 2017



Wai T. Wong, MD, PhD

This slide summarizes the current state of affairs regarding therapeutic options to prevent, treat, or repair cellular damage from geographic atrophy, the advanced stage of nonexudative or "dry" AMD. Fundus photos show a normal eye (top left) progressing to early/intermediate AMD with drusen (top right), to advanced AMD with geographic atrophy (bottom center).

down the growth in GA areas."

Even so, Dr. Wong continues to recommend AREDS supplementation for all patients at risk for developing wet AMD in the hope of sparing GA patients the "double whammy" of conversion from GA to wet AMD. "There's some theoretical evidence that it might be the case that if you have advanced atrophic AMD, the vitamins might decrease the risk of getting wet AMD," he explains. "However, that's not been directly tested in a large-enough study. Therefore, the main contribution of AREDS supplements is to reduce the risk of getting from intermediate AMD to wet AMD. It's still worth doing, however."

Lampalizumab

Dysregulation of the complement system—part of the body's defense system against invading pathogens—has long been implicated in RPE damage and photoreceptor cell death in AMD. Complement factors have been found at elevated levels in the bloodstreams of AMD patients[4] as well as in drusen.[5] Once activated, the complement cascade sets off a series of reactions that results in inflammation and cell death. Different complement proteins have been drug targets in the quest to combat GA, with no clear winners so far.

Lampalizumab (Genentech) is a monoclonal antibody fragment designed to alter the activation of complement factor D in order to throw a wrench into the workings of an inflammatory cascade. Dr. Wong likens the regulation of the complement factor cascade to a car with multiple gas pedals and brakes. "What lampalizumab is trying to do is bind up complement factor D, which is actually one of the positive regulators—one of the gas pedals that would drive forward towards complement activation," he explains.

In a Phase II study (MAHALO)[6] patients with geographic atrophy who received monthly injections saw a 20.4-percent reduction in the rate of growth of their areas of GA at 18 months; a subgroup of patients who

tested positive for a biomarker for complement factor I (CFI) experienced even greater reduction (44 percent) in the rate of change in their GA lesions.

"The study investigators didn't exclusively recruit subjects with a genotype thought to respond to the drug," notes Dr. Wong, who adds that these findings emerged in a post hoc analysis. "The Phase II results are in some sense promising, but inconclusive, because it's a relatively small study and the overall effect size is actually quite small. Only on post hoc analysis did they find that this treatment was more effective in a subset of patients with a certain complement gene makeup. So you're left wondering if this could have happened by chance. That is one question raised by the Phase II study," he says.

The Phase III trials, CHROMA (identifier: *NCT02247479*) and SPECTRI (identifier: *NCT02247531*), prospectively genotyped patients to see whether the CFI patients would be strong responders to lampalizumab in a larger sample. The CHROMA and SPECTRI trials are identically designed, multicenter, interventional studies enrolling 936 patients apiece, with 60 percent of the study arm positive for the CFI biomarker.

Genentech released the early results of SPECTRI[7] in September 2017: Lampalizumab given to the treatment arm once monthly or every six weeks failed to meet the study's primary endpoint, which was reduction in change in GA growth rate at 48 weeks. SPECTRI patients are no longer being dosed with lampalizumab, pending results from CHROMA, which are expected sometime in November 2017.

APL-2

In August 2017, Apellis Pharmaceuticals (Louisville, Ky.) announced the results of a Phase II study[8] of its own complement-factor inhibitor, APL-2, a drug also being investigated to treat a blood disorder called paroxysmal nocturnal hemoglobinuria. APL-2 is a complement factor 3 (C3) inhibitor.

The FILLY trial, a multicenter, randomized, single-masked, sham-controlled study, involved 246 patients. Study eyes received intravitreal injections of APL-2 either monthly or semimonthly for 12 months, and were monitored for six additional months. The primary endpoint was reduction in GA growth versus sham eyes from baseline to month 12 as measured by fundus autofluourescence photography. Compared to the sham eyes, the study eyes getting monthly APL-2 experienced a 29-percent reduction in the rate of GA lesion growth; the semimonthly APL-2 eyes showed a 20-percent reduction compared with sham eyes. Adverse events included an increased risk of onset of neovascular AMD, particularly in patients with wet AMD in the fellow eye. This was treated with standard anti-VEGF therapies.

During the subsequent six months of the FILLY trial, a post hoc analysis showed further reductions in the growth rate of GA in the monthly and semimonthly eyes: 47 percent and 33 percent, respectively. Apellis plans to conduct a Phase III trial in the near future.

Brimonidine

Brimonidine (Alphagan; Allergan) is a longstanding IOP-lowering therapy for glaucoma. Studies have suggested that topical brimonidine has a neuropotective effect in glaucoma, with less visual-field progression in treated eyes. This prompted Allergan to explore whether the drug is a viable treatment for the reduction of GA progression, according to William R. Freeman, MD, distinguished professor, vice chair and director of the Jacobs Retina Center at University of California, San Diego.

Brimo DDS, an intravitreal brimonidine delivery system based on the manufacturer's Ozurdex (dexamethasone) implant for DME and uveitis, is currently in trials for GA. Brimonidine, an alpha-2 adrenergic agonist, may have a protective effect on the retina by inducing the release of neurotrophic substances that protect the RPE and photoreceptor cells. The Brimo DDS implant allows a sufficient amount of brimonidine to reach the retina for possible therapeutic benefit, and may reduce treatment burden compared to intravitreal injections of free drug.

The Brimo DDS device currently being studied is a 25-gauge implant that researchers hope will have neuroprotective properties that will spare cells and preserve vision in dry AMD. "You could say that brimonidine is being repurposed, but it's never really been used for a retinal disease," says Dr. Freeman. "It appears to be a neurocytoprotectant, and I use that term because the retinal pigment epithelial cells, strictly speaking, are not neural cells, but brimonidine does seem to protect those. So the decision was made to try it in geographic atrophy."

Dr. Freeman presented the findings of the Phase IIa study of Brimo DDS Generation 1 (22-gauge) implant at last year's American Academy of Ophthalmology meeting in Chicago. "The Phase IIa study showed some evidence of efficacy," he says. "It is not published, but it shows a reduction in the rate of atrophy—the area of dead cells. Increases in that area are lower with brimonidine that's been delivered with this system. Depending on how you do the statistics, after 12 months, the reduction was statistically significant compared to sham.

"In the Phase IIb study, they're using an improved device," Dr. Freeman continues. In BEACON (Trial Identifier: *NCT02087085*), a randomized, triple-masked Phase IIb inter-

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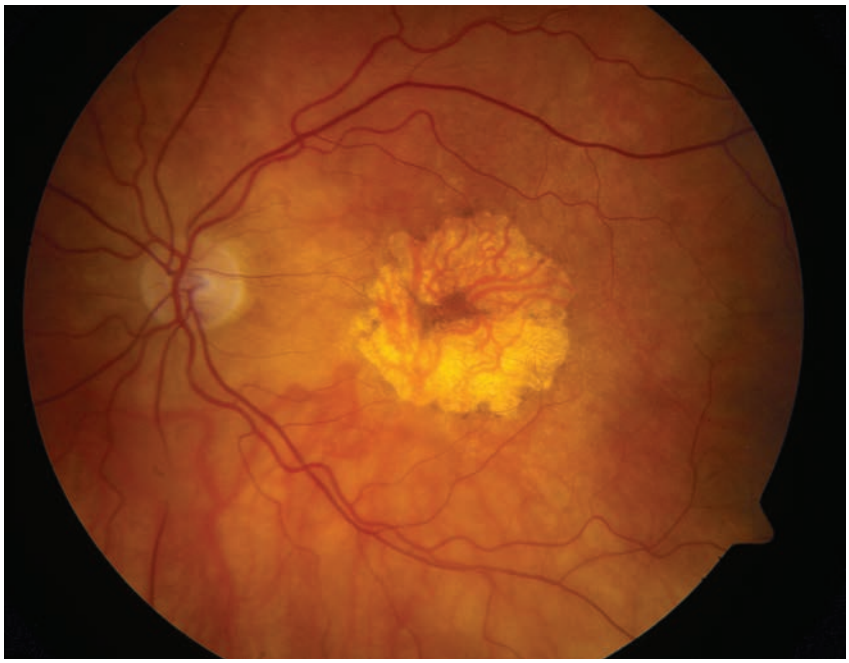
ventional study, the implant releases the drug faster so the implant doesn't last as long (three months versus six months in Phase IIa) but it gets higher levels of drug into the eye. "I can tell you that when you do these injections under topical lidocaine gel anesthesia, the patients feels essentially nothing because it's just 25 gauge," he says.

The BEACON study will test the new-generation Brimo DDS implant's safety and efficacy. The trial is ongoing but no longer recruiting. It will look at 311 patients in a multicenter, double-masked study to compare changes in GA lesions and BCVA in eyes treated with monocular 400-µg brimonidine implants replaced at three-month intervals through month 21 with patients whose eyes are given sham treatment with a needleless applicator (no implant) on the same schedule through month 21. The primary endpoint is change from baseline in atrophic lesion area in the eyes studied, to month 24.

"The lesion size is measured photographically and by autofluouresсence," Dr. Freeman, a BEACON investigator, explains. "Vision is in there, but not as the primary endpoint. You could be losing a big chunk of your vision that doesn't hit the center, so it's the area of absent cells. That progresses and you can see it over time, so at every visit photographs are taken."

While Dr. Freeman is unsure if or when Allergan will release interim data, he estimates that they'll have two-year data available in late 2018.



Theodore Leng, MD, MS

Color fundus photograph of an eye with central geographic atrophy. Proposed treatments for dry AMD have sought to regress drusen without giving rise to GA lesions, reduce the rate of GA growth, or to replace macular cells lost to GA.

Atorvastatin

AMD and atherosclerosis share some risk factors, such as age, smoking and hypercholesterolemia.[9] There is some evidence that cholesterol-lowering drugs may decrease the risk of developing AMD;[10] however, it has not been demonstrated that statins can retard disease progression.[11] A recent pilot study led by Harvard researchers treated patients with large drusen with high-dose oral atorvastatin to investigate if the treatment reduced these drusen.[12]

"This has not been proposed for treating people with GA," notes Dr. Wong, "but instead for people with intermediate AMD who are in danger of developing GA."

The small Phase II study of 26 AMD patients aged 55 and up investigated high-dose (80 mg/day) oral atorvastatin's ability to reduce drusen volume and improve visual acuity. Of the 23 patients who completed a 12-month minimum follow-up, 10 showed regression of drusen volume as measured by fundus photography and OCT, associated with a gain of 3.3 EDTRS letters over baseline (p=0.06). None of the cohort progressed to wet AMD. The study is small, and per the researchers, fails to take into account the genetic heterogeneity of dry AMD. The authors suggest that statins may be beneficial for some patients with large soft drusen, which are markers of high risk for progression to wet AMD. The patients who didn't respond to the atorvastatin regimen lost an average of 2.3 letters.

Further study would be needed to see if atorvastatin is a viable path to halting AMD from progressing to its vision-robbing later stages. "A study directly investigating the ability of atorvastatin to prevent GA onset has not been performed," notes Dr. Wong. "Prevention trials are usually very large and very expensive, and it is helpful to identify a very high-risk population so that the event rate of GA onset is sufficiently high to as to reveal a significant treatment effect. That's the challenge of developing outcome measures. A specific GA-prevention trial has never been done before, so the design implications are going to be novel.

"There's also a little debate about drusen," he continues. "Having lots of drusen generally means more risk, but GA actually forms from an acute

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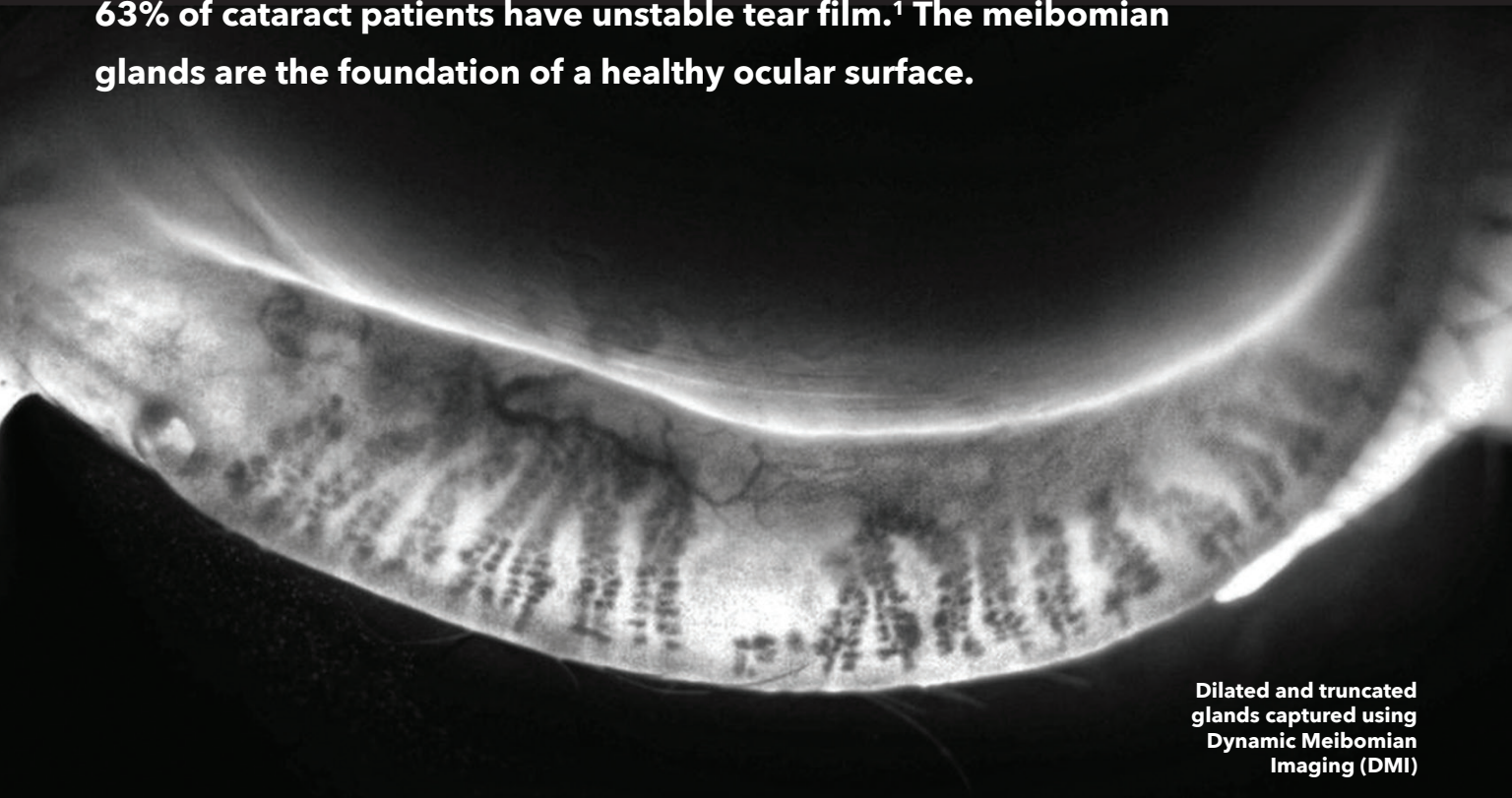

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1. Trattler WB, Reilly CD, Goldberg DF, et al. Cataract and Dry Eye: Prospective Health Assessment of Cataract Patients Ocular Surface Study , Presented at ASCRS 2011 [http://tinyurl.com/jurj3ra]

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collapse of all these drusen. Drusen build up, collapse, and the onset of GA ensues. So the disappearance of drusen is sometimes a bad sign. But what the investigators from Harvard think is that maybe the drug will cause the drusen to go away without the negative consequences, reducing the risk of GA onset. Part of the interest in cholesterol is that, in addition to complement genes appearing important to the control of AMD risk, lipid genes have also been found to have an important effect on controlling risk. We don't really know why, or what the mechanisms are, but looking at things like Lipitor is one way of broaching the question."

Photobiomodulation

Laser therapy as a proposed method of controlling drusen and heading off the visual complications of advanced AMD has not yet yielded clear or long-term benefits.[13] Although verteporfin photodynamic therapy was the standard of care for neovascularization before the advent of anti-VEGF therapy, there has been no counterpart for patients with dry AMD.

Graham F. Merry, MBBS, LMCC, and colleagues have been working with LED-sourced light treatments to regress drusen in patients diagnosed with dry AMD, and to correspondingly improve their visual function with these photobiomodulation treatments. The researchers believe that photobiomodulation therapy has anti-inflammatory properties and antioxidant properties that encourage phagocytosis in RPE cells, and can regress drusen without contributing to GA. Their recent study[14] looking at 42 eyes with dry AMD treated with three weekly sessions of photobiomodulation therapy for three weeks showed improvements in mean BCVA and contrast sensitivity, together with decreases in drusen volume and central thickness as measured via OCT and FAF.

"Blue Sky Right Now"

"If you want to break down all the GA trials, you can break them out into the prevention of progression to GA; trying to slow down the growth of GA; and, finally, bringing back whatever has been lost in GA," says Dr. Wong. "It's completely blue sky right now: We don't really have a lot in terms of established mechanisms to guide us."

"A lot of groups are trying different things, and success in any of these trials—even a small amount—will redirect the field."
—Wai T. Wong, MD, PhD

Oxidative stress has long been implicated in AMD. Cumulative oxidative stress may drive progressive retinal damage, and treatments that inhibit the production or effect of reactive oxygen species (ROS) are another investigative avenue. "Clearly, people who smoke, for instance, have an increased risk of advanced AMD, and that's well established," says Dr. Wong. "In 2010, we at the NEI had investigated an experimental compound administered as an eye-drop that acts as a free-radical scavenger in order to reduce oxidative stress.[15] That's one of the things investigators may continue to pursue. But so far, there's nothing that's demonstrated efficacy with respect to GA."

One therapeutic avenue he and his colleagues are actively investigating is the anti-inflammatory effect of a broad-spectrum tetracycline drug. "We're currently doing an oral minocycline study," says Dr. Wong. "In addition to acting as an antibiotic, it also has anti-inflammatory properties and it penetrates into the retina pretty well. We're doing the minocycline study in collaboration with two study sites in the U.K. There is also a concurrent study at the University of Virginia that is using another tetracycline medication. We're using minocycline; they're using doxycycline. The strategies are quite similar: to suppress the immune cells within the eye to see if that is helpful in slowing the growth of GA."

Stem-cell therapies represent a line of investigation that may one day lead to a way of replacing photoreceptor or retinal pigment epithelial (RPE) cells that have been destroyed by GA, rather than preventing or slowing GA. The proposed methods vary, according to Dr. Wong. "Different people have different ideas about the best way to replace the cells. Some people just inject embryonic stem cells or cells from other donor sources at various stages of differentiation, and let them float free until they settle down, where hopefully they'll take root, rather like sprinkling grass seed on a bare patch of lawn. Others differentiate the cells by growing them on a membranous scaffold so they're lined up like a sod patch that you can place exactly where they need to be. The plan is that the scaffold will dissolve over time, leaving behind a single layer of surviving RPE cells. These are the approaches that are being tried or planned," he reports.

He believes one thing is certain, however. "A lot of groups are trying different things, and success in any of these trials—even a small amount—will redirect the field. We've been barking up different trees, and the first one that bears fruit is going to re-orient the field in that direction." REVIEW

Dr. Wong is a clinician-scientist

with the NIH, and has no interests to disclose. Dr. Freeman has previously served as a consultant to Allergan, but is not personally remunerated as an investigator in the brimonidine trial described in this article.

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(Continued froom page 56)

acrylic IOL on the first postoperative day, the incidence of negative dysphotopsia was 6 percent for the inferotemporal IOL orientation, compared with 14 percent for the control group. The rate of persistent negative dysphotopsia decreased in both groups over time, and the difference was no longer statistically significant at one month postop. No negative dysphotopsia was observed with the silicone IOL.

The Future

According to Dr. Masket, not much attention has been paid to patient-reported outcomes with regard to dysphotopsia, despite the fact that dysphotopsia is the leading cause of patient dissatisfaction after otherwise uncomplicated cataract surgery.[8] However, that is changing. "There is now a group effort by the American Academy of Ophthalmology, the FDA and the manufacturing sector to develop a patient questionnaire to determine how patients perceive visual function with premium IOLs. Given that dysphotopsia, both negative and positive, has been problematic, it is likely that more attention will be directed to reducing these undesirable optical phenomena," he adds. REVIEW

Dr. Masket holds patents for IOL design and has a financial interest in the Morcher 90S IOL. Drs. Miller and Holladay don't have a financial interest in any product mentioned in the article.

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Should You Touch That Trab or Tube?

Successful cataract surgery sometimes involves working around a pre-existing trabeculectomy bleb or tube shunt. Here's help.

Herbert P. Fechter III, MD, PE, Augusta, Ga.

When performing cataract surgery on a patient who's been treated for glaucoma, you may have to work around a trabeculectomy or tube shunt. This raises concerns regarding how the surgery you're performing might affect the tube or trab, and hence the state of the patient's glaucoma.It also raises concerns regarding how the presence of the tube or trab may affect the outcome of the cataract surgery. In some cases you may even need to alter the tube or trab.

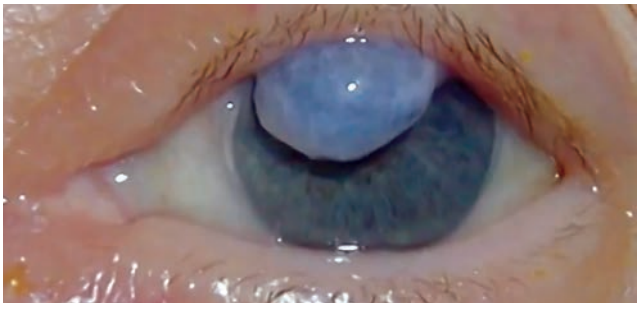
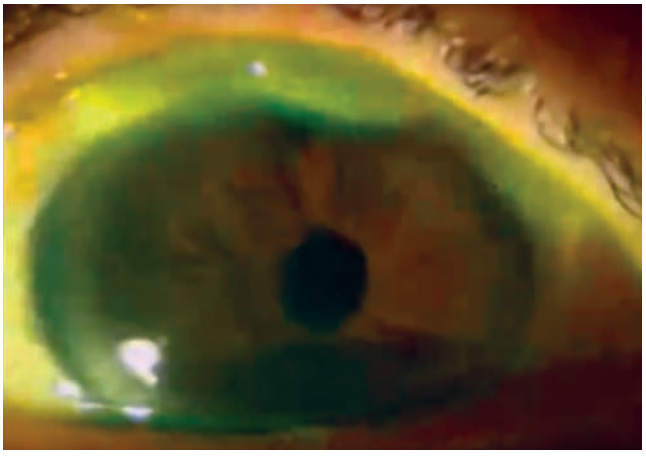
When deciding whether to touch a trab or tube during cataract surgery, you must first determine whether the glaucoma is safely and adequately controlled. If a tube or trab is working well, I usually perform cataract surgery using my standard technique. However, in some cases the presence of a tube or trab may require extra caution and/or additional steps on your part to ensure the best possible outcome. Here, I'd like to offer some suggestions for avoiding unwanted problems in this situation.

Managing a Bleb

When the eye has an existing bleb:

• ***If the bleb is problematic, revise it before proceeding with cataract surgery.*** For example, a bleb overriding the pupil will need revision prior to cataract surgery in order to reduce astigmatism, reduce irritation and clear an obstructed visual axis. In other, more subtle cases, such as an eye with bubble dysesthesia, a trabeculectomy revision would help to reduce the chronic pain symptoms associated with the bleb. *(See examples, below.)*

• ***Test a thin, avascular bleb for leaks.*** If a Seidel test reveals leakage, the bleb will need to be revised to

In some cases an overriding bleb (above) will need revision prior to cataract surgery to reduce astigmatism and irritation and clear an obstructed visual axis. In other more subtle cases, such as one with bubble dysesthesia (right), a trabeculectomy revision would reduce the chronic pain symptoms associated with the bleb.

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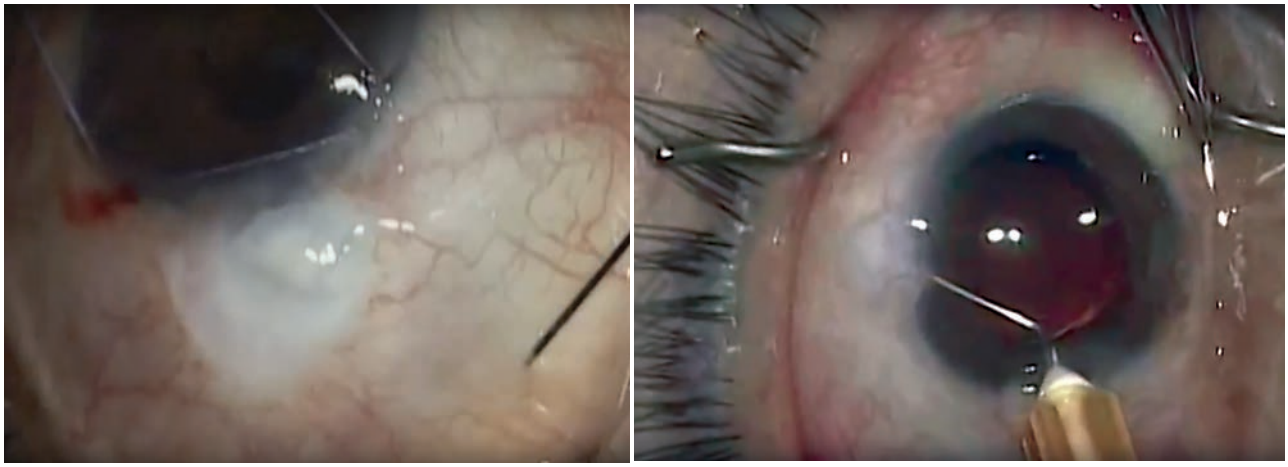


This thin, leaking bleb (left) was causing chronic hypotony and needed revision prior to cataract surgery. This thick, vascularized bleb (right) was associated with elevated pressure. After inserting the lens, I passed a 27-ga. needle across the anterior chamber, directed the needle tip through the prior sclerotomy site and separated the scarred-down tissue until I saw the bleb fill with aqueous.

prevent hypotony, choroidals, corneal decompensation and possible endophthalmitis. This might require the insertion of a tube shunt.

For example, a thin, leaking bleb *(above, left)* was causing chronic hypotony and needed revision prior to cataract surgery. I placed a drainage implant in the superotemporal quadrant and directed the tube toward the prior iridectomy site, using a 30-ga. needle to assist with tube positioning. I stained the thin, leaking bleb with dye to verify that I'd removed all of the epithelial cells and then covered the old trabeculectomy with healthy conjunctival tissue. Once the pressure was controlled, I was able to safely proceed with the cataract surgery.

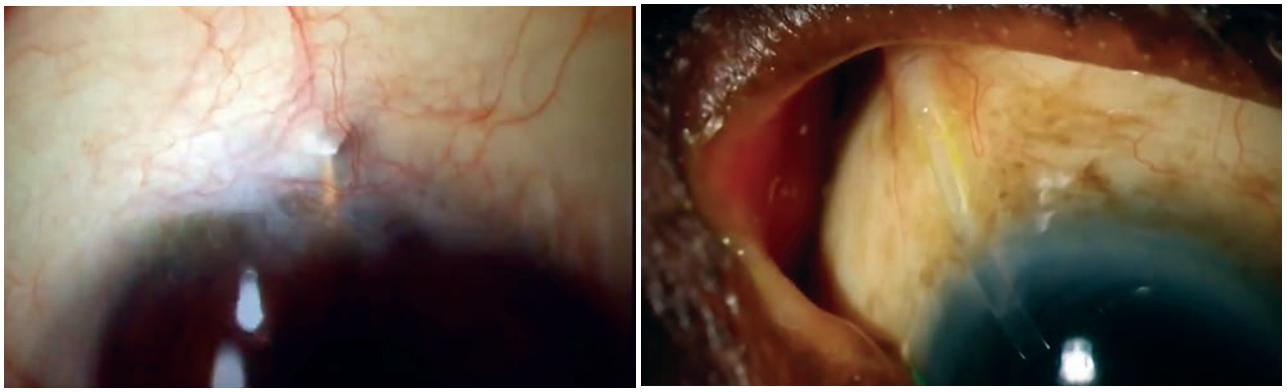
• ***Be careful to avoid overinflating a functioning bleb during hydrodissection.*** When performing surgery in the presence of a thin bleb, I use minimal infusion pressure to avoid distending and possibly rupturing the bleb. (Normal perfusion pressure can be used with thicker, more vascularized blebs.)

• ***If the bleb is thick and vascularized and pressure is elevated, modify the bleb during the cataract surgery.*** In a patient with a thick, vascularized bleb *(above, right)*, after inserting the lens I passed a 27-ga. needle across the anterior chamber and used it to rejuvenate the scarred bleb. I directed the needle tip through the prior sclerotomy site and separated the scarred-down tissue until I saw the bleb fill with aqueous. (An *ab externo* needling procedure—entering under the conjunctiva—has also been described by others in the literature, with moderate success in improving bleb function.)

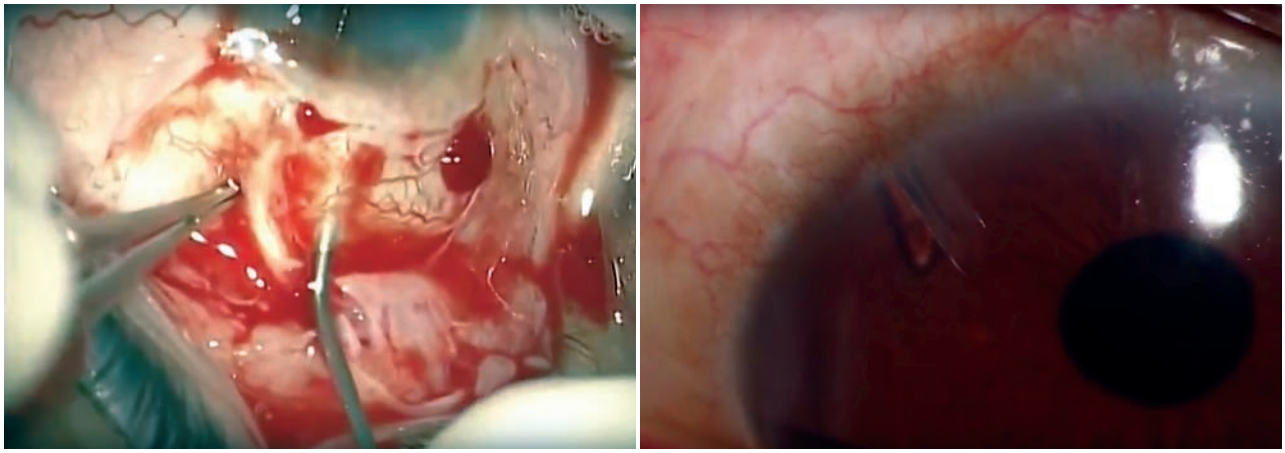
Working with a Tube Shunt

In eyes with a tube shunt:

• ***Look for hardware that's close to exposure.*** Eyes with imminent hardware exposure due to a superficial ExPress shunt or a tube inserted too close to the limbus *(examples below)* should be revised prior to cataract surgery to reduce the likeli-



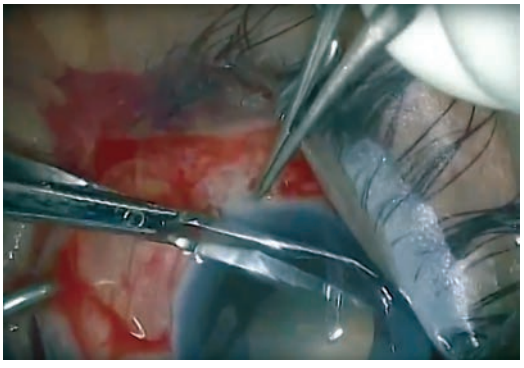
Eyes with imminent hardward exposure due to a superficial ExPress shunt (left), or a tube inserted too close to the limbus (right), should be revised prior to cataract surgery to reduce the likelihood of hypotony and endophthalmitis.



Before cataract surgery, this glaucoma patient's tube shunt barely entered the anterior chamber and was at risk for total occlusion. Left: At the conclusion of cataract surgery, after recreating the fornix-based peritomy to expose the tube, I constructed a new scleral tunnel using a bent 23-ga. needle, adjacent to the existing tube. I then withdrew the tube from the original entry site and directed it into the new scleral tunnel. Right: The more direct route provided extra slack, allowing the tube to protrude farther into the anterior chamber. The combined surgery improved the patient's vision and helped ensure that the tube will continue to function properly.

hood of hypotony and endophthalmitis. Correcting the exposure problem prior to cataract surgery will prevent postoperative complications. (A very thin patch graft can be covered with a new patch graft.)

• ***If a tube has pulled back, consider repositioning the tube at the conclusion of cataract surgery.*** For example, during the preoperative cataract exam of a patient with a glaucoma tube shunt implant, I noticed that the tube tip barely entered the anterior chamber and was at risk of total occlusion. I elected to reposition the tube at the conclusion of cataract surgery.



Long tubes can be trimmed during cataract surgery to help protect the corneal endothelium from repeated mechanical trauma.

To accomplish this, I recreated the fornix-based peritomy to expose the tube *(above)*. I then constructed a new scleral tunnel adjacent to the existing tube using a bent 23-ga. needle and withdrew the tube from the original entry site and directed it into the new scleral tunnel. Because the tube was now following a more direct route, extra slack was created and I was able to reposition the tube farther into the anterior chamber. (There was no need to re-ligate the tube, since the bleb surrounding the tube remained intact.) Finally, I reapproximated the conjunctiva to the limbus using two running 7-0 vicryl sutures and verified the proper position of both the tube and the IOL. The combined surgery improved the patient's vision, while also ensuring that the tube will continue to function properly.

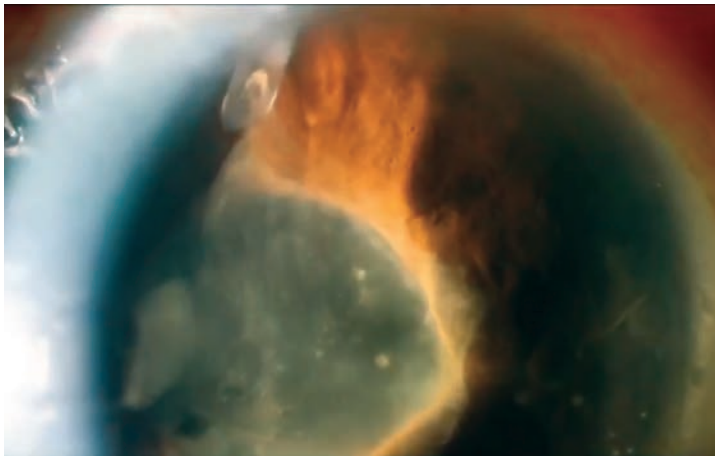
• ***If a tube is too far into the anterior chamber, consider shortening it during cataract surgery.*** Trimming a long tube can help to protect the corneal endothelium from repeated mechanical trauma. *(See example, below, left.)* In many cases I use microsurgical scissors to trim the tube after I insert the intraocular lens, prior to viscoelastic removal, although in some cases Bennett scissors may be the better tool to use. Once the tube has been trimmed, the cataract surgery can usually be completed using your standard technique.

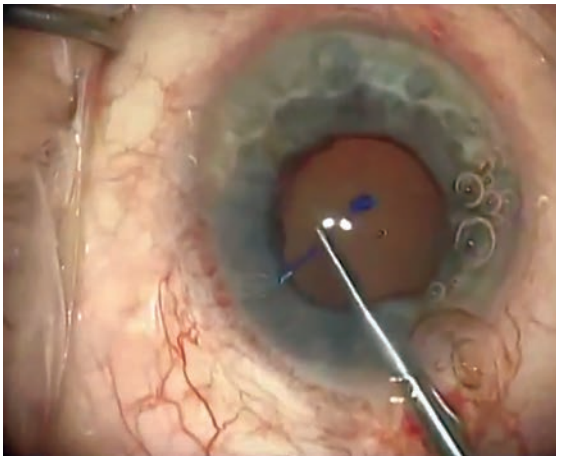
Managing Uveitic Disease

Certain types of glaucoma require special care when performing cataract surgery. For example, in eyes with uveitic glaucoma:

• ***Preoperative inflammation control is essential.*** Eyes with uveitic glaucoma are prone to developing posterior synechiae and fibrin membranes that can occlude the pupil following cataract surgery. For that reason, preoperative inflammation control is essential to ensure the best possible visual outcome in these eyes.

• ***If the eye has a tube shunt, consider temporarily plugging the tube during surgery.*** A tube plug can be used to reduce the likelihood of inflammation in uveitic glaucoma





Left: In eyes with uveitic glaucoma, preoperative inflammation control is essential to ensuring the best outcome. These eyes are prone to developing posterior synechiae and fibrin membranes that can occlude the pupil following cataract surgery. Right: In the most at-risk uveitic eyes that have a tube shunt, a tube plug can be used to reduce the likelihood of inflammation by preventing the reflux of inflammatory mediators into the anterior chamber. In this case I created a plug by tying a knot in a 4-mm segment of 3-0 prolene suture; I used the Utrata forceps to gently guide the plug into the tube orifice. I completed the cataract surgery and the lens implantation using my usual technique, and at the conclusion of the case I removed the plug using the Utrata forceps.

eyes that are at the greatest risk. I create a plug by tying a knot in a 4-mm segment of 3-0 prolene suture. I use Utrata forceps to gently guide the plug into the tube orifice; the plug prevents reflux of inflammatory mediators into the anterior chamber. *(See example, above, right.)* I then complete the cataract surgery and the lens implantation using my usual technique. At the conclusion of the case, I remove the plug using the Utrata forceps.

• ***Consider augmenting the usual topical prednisolone and NSAIDs with subconjunctival and oral steroids.*** These will help control postoperative inflammation in uveitic glaucoma eyes.

Managing Glaucoma in General

The following strategies are helpful in all eyes that have glaucoma:

• ***Use plenty of dispersive viscoelastic to protect the corneal endothelium and maintain a deep anterior chamber.*** Many glaucoma patients have compromised endothelial cells due to years of exposure to topical glaucoma medications and elevated intraocular pressure. These endothelial cells may be more prone to damage from phacoemulsification energy.

• ***If you need to place iris hooks, avoid the tube insertion site or conjunctival bleb site.*** My tubes usually enter the anterior chamber near the 12 o'clock position. I position my superior hook to avoid ensnarling the tube tip with iris tissue, and place my temporal hook posterior to the cataract incision site. For eyes with a prior trabeculectomy, I avoid placing a hook through a functioning bleb.

• ***Ensure inflammation control with enhanced steroid use.*** Eyes with prior glaucoma surgery are more prone to postoperative fibrin formation and cystoid macular edema following cataract surgery. For that reason, inflammation control is essential to achieving the best postoperative visual acuity.

• ***Take steps to prevent postoperative pressure spikes.*** Glaucomatous eyes usually have compromised outflow facility and are prone to pressure spikes, which are more harmful to a damaged nerve than a healthy one. Therefore, it's very important to minimize the risk of postoperative pressure spikes by thoroughly removing all viscoelastic. Also, consider prescribing acetazolamide postoperatively.

Look Before You Leap

When formulating an operative plan for performing cataract surgery on a glaucoma patient with a preexisting tube or trab, a thorough preoperative assessment of the patient's corneal health—including pressure control and inflammation, as well as tube placement and/or bleb function—is essential. In some patients it may be necessary to "touch" that trab or tube prior to or during cataract surgery to insure a good postoperative result. By revising an imperfectly functioning tube shunt or trabeculectomy, you may avoid future complications and help the patient achieve an optimal visual outcome. REVIEW

Dr. Fechter practices at Eye Physicians & Surgeons of Augusta. He has no financial disclosures relating to anything discussed in this article.

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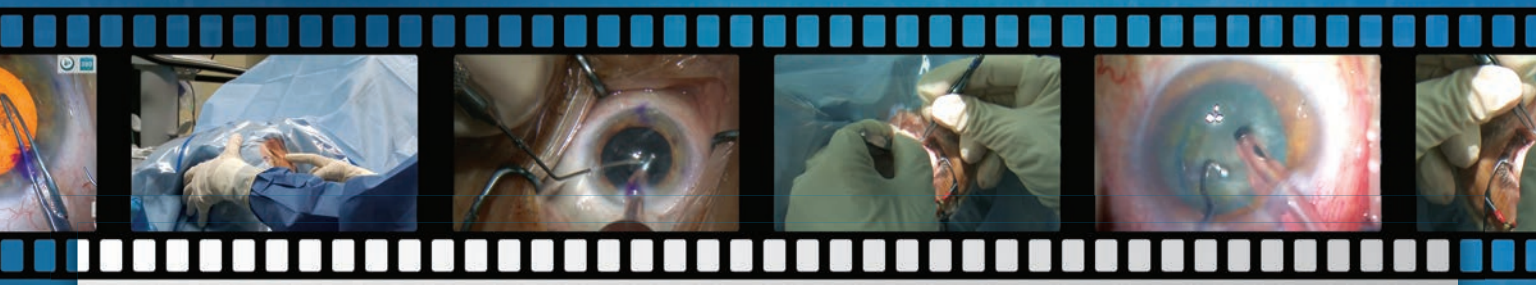

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Surgical Video by:
Richard J. Mackool, MD

Video Overview:
Determination of the correct IOL power for a highly myopic eye with posterior staphyloma is fraught with difficulty. Here I employ two methods that can permit measurement of both the spherical and astigmatic power of the desired IOL, including the degree of "retinal astigmatism" caused by the staphyloma. I demonstrate the use of both wavefront technology and the Aphakic Refraction Technique (manifest refraction) to calculate the power of the IOL that is then inserted on the day following cataract removal.

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Retinal Detachments in Patients with Uveitis

Co-existing inflammation always makes managing ocular pathologies tougher. Here's how to deal with it in cases of RD.

Alan G. Palestine, MD, Paula E. Pecen, MD, and Frank Siringo, MD, OD, Aurora, Colo.

The presence of intraocular inflammation complicates the management of retinal detachment and introduces several additional variables into our treatment decisions. Patients with uveitis may develop retinal detachment that's unrelated to their uveitis, or is a complication of it. There can be rhegmatogenous, tractional and serous aspects to the detachment—all occurring in an eye already compromised by inflammatory disease. The intraocular inflammation may interfere with visualization of the retina, and may be increased after surgery. Increased inflammation can also lead to additional complications such as proliferative vitreo-retinopathy, glaucoma and hypotony. Despite these challenges, these patients can be managed successfully. In this article, we'll discuss several ways to find the right approach.

The Scope of the Problem

Netherlands ophthalmologist Frank Kerkhoff and his colleagues found the incidence of rhegmatogenous retinal detachment in patients with uveitis to be approximately 3 percent.[1] This study included patients with viral retinitis, however, which, like syphilitic uveitis, has a relatively high rate of detachment.[2] However, the authors showed a 2-percent incidence of RRD in patients with non-infectious uveitis. There is a significantly higher incidence of PVR at the time of detachment diagnosis and a single-operation retinal reattachment success rate of approximately 60 percent, which is significantly lower than in patients without uveitis. Postoperative PVR developed in 37 percent of uveitis patients, compared to 9 percent of non-uveitis patients. The rate of RRD in infectious uveitis appears to be more than three times greater than in non-infectious uveitis. The final visual acuity results are also disappointing, with 67 percent of patients seeing worse than 20/200, including 11 percent having no light perception.

Is It Rhegmatogenous?

Although this might appear to be a simple question to answer, patients with uveitis, especially with intermediate and posterior uveitis, often develop multiple pinpoint retinal breaks due to peripheral vitreoretinal traction. When these occur in association with cataract and vitreous haze or debris, visualization of small breaks can be difficult. Assessment of the location of the detachment is helpful in searching for retinal breaks, as is careful examination with a three-mirror lens. Retinal detachments with small breaks in these patients are often inferior and low-lying, and may demonstrate multiple demarcation lines *(See Figures 1 and 2)*.

The presence of shifting fluid can indicate that the detachment isn't rhegmatogenous, but this can be misleading if the fluid is longstanding and viscous. In general, non-rhegmatogenous retinal detachment is much less common when the uveitis is controlled. Hence, a new detachment is most likely to be rhegmatogenous in a patient on chronic therapy for intermediate or posterior uveitis that's not currently active. A trial of one to two weeks of prednisone 1 mg/kg orally can be helpful to assess whether the fluid improves, with improvement suggesting a serous component to the detachment. This is also useful in getting the uveitis quieter in preparation

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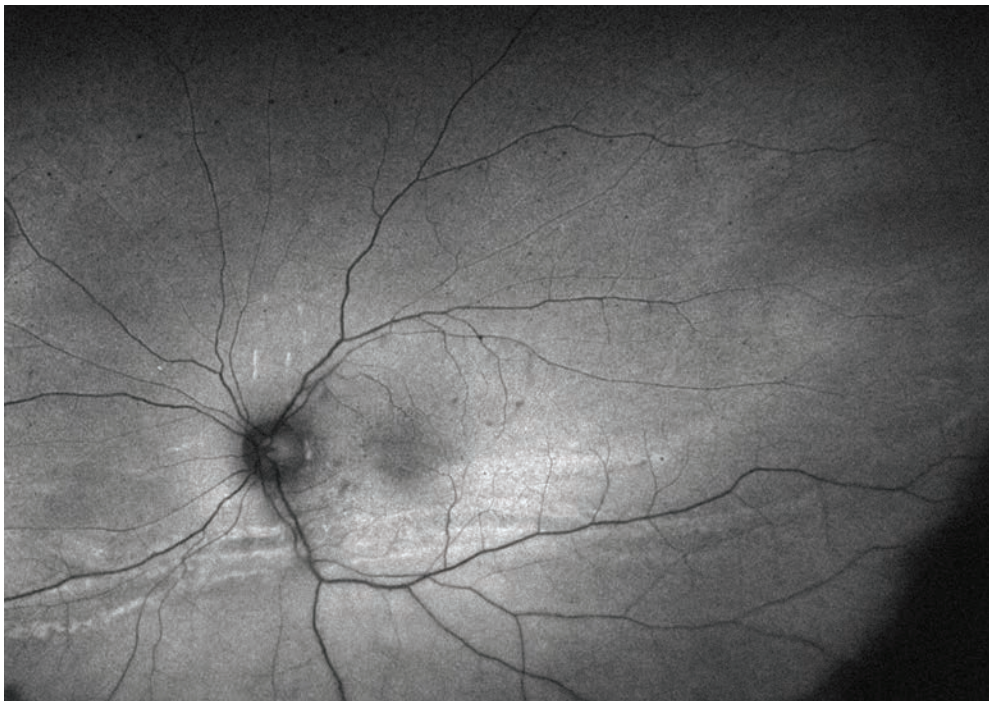

Figure 1. Fundus autofluorescence of the left eye of a patient with chronic panuveitis showing a low-lying retinal detachment with multiple demarcation lines.

for surgery. In patients with persistent fluid from serous non-rhegmatogenous detachment, surgical intervention with scleral buckling, vitrectomy and drainage of subretinal fluid can still result in resolution of the detachment.[3]

Perioperative Management

Even if a patient has a history of noninfectious uveitis, no recent activity and is not on chronic immunosuppression, it's still advisable to treat him with at least 30 mg oral prednisone daily for a few days prior to surgery. The dose can be adjusted based on the severity of the previous inflammation as well as accompanying conditions such as diabetes. This can be continued postoperatively for a few days, then tapered. Intraoperatively, administer 125 mg of intravenous methyl-prednisolone. If the patient isn't a known intraocular pressure steroid responder, 20 to 40 mg of subTenon's triamcinolone can be given at the end of the surgery, which will last for several months. Of course, the risk of steroid-induced ocular hypertension must be weighed against the risk of increased postoperative inflammation. The same regimen can be applied to patients with chronic inflammation on chronic immunosuppressive therapy who don't currently have inflammation.

It's been suggested that an eye should be quiet for at least three months prior to cataract surgery. However, we can't wait three months if there's a retinal detachment. Patients with uveitis and RRD have active inflammation 46 percent of the time.[1] If there's significant active inflammation preoperatively, a serious attempt to control the inflammation with systemic and periocular corticosteroids should be made. This puts the clinician in a difficult position: Surgery may need to be delayed for a few weeks to avoid operating on an inflamed eye, but this risks progression of the retinal detachment. Both choices increase the risk of PVR and the risk of a poor vi-

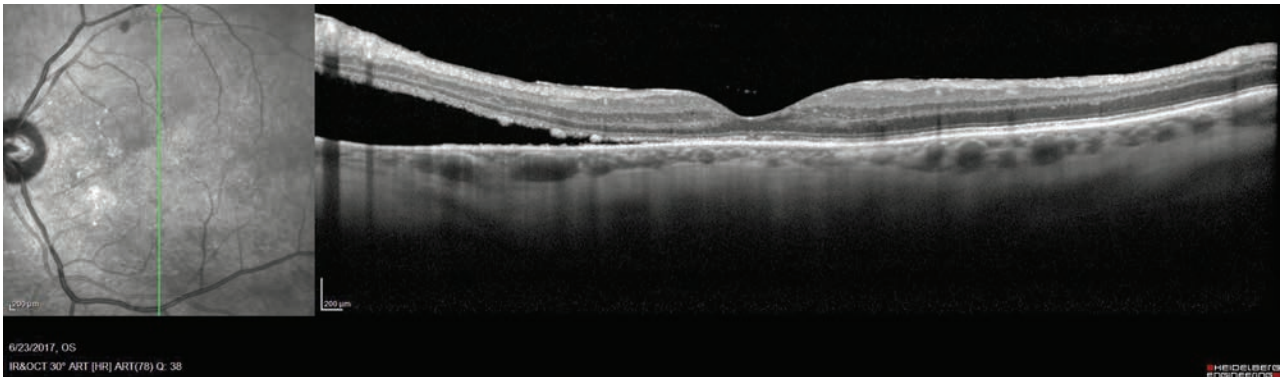

Figure 2. Spectral domain optical coherence tomography from the patient in Figure 1, showing inferior parafoveal retinal detachment.

sual outcome. Eyes with uveitis often have pre-existing visual compromise and this also needs to be considered when choosing to delay surgery.

In the case of infectious uveitis and RRD, control of the infection is a high priority, but the post-infection inflammation may persist for weeks after the infection has resolved. In addition to the human herpes viruses, toxoplasmosis and syphilis are associated with RRD. The latter two organisms, however, are less likely to be associated with the widespread retinal necrosis that follows infection by herpes-class viruses, and thus have a lower risk of RRD.

Surgical Options

Although vitrectomy and laser, combined with scleral buckling, will usually be the preferred surgical procedure, ancillary issues may complicate the overall surgical plan. Corneal and lenticular opacities often make visualization difficult. If a significant cataract is present, the choice of placing an intraocular lens versus performing a lensectomy warrants careful consideration. This is further complicated if there are significant synechiae. If the eye is relatively quiet, a simultaneous lens implant is often the preferred choice, as lensectomy precludes the future use of an intravitreal dexamethasone implant. However, visualization is paramount, and a lensectomy is an acceptable choice, especially in an eye with residual active inflammation.

For pinpoint breaks in the retina that can't be visualized intraoperatively, or through which subretinal fluid cannot be drained due to the small size of the retinal break, fluid should be drained through a drainage retinotomy. Endolaser should be applied around the retinotomy site, as well as in the area of the retinal detachment to cover any tiny breaks that may be missed in the periphery.

The choice of retinal tamponade is influenced by several factors. Silicone oil requires a second surgery for removal and will interfere with the function of a fluocinolone implant, if present. The use of intravitreal dexamethasone may also be suboptimal; it may not release drug properly if it remains initially within the silicone oil bubble rather than within the liquid vitreous. Intravitreal triamcinolone is difficult to use with silicone oil since it can obscure the postoperative view. In addition, the concern about the oil interface acting as a matrix for inflammatory membranes is an unanswered question. In patients with postviral retinal detachments, silicone oil is the preferred tamponade. In other patients, intraocular gas may be a better choice if the eye can be repaired in a single operation and there is no preoperative PVR.

Tractional components of retinal detachment, especially inferiorly in patients with pars planitis, need to be addressed by both scleral buckling and vitrectomy. This part of the surgery is complicated, since patients with RRD and uveitis are younger, may not have a posterior vitreous detachment and may have pre-existing epiretinal membranes. Significant anterior vitreous traction and membranes can be seen in patients with chronic uveitis, extending onto the pars plana and ciliary body. Furthermore, since ciliary body function is often already compromised in patients with chronic uveitis, there's a risk of hypotony related to postoperative formation of a cyclitic membrane.

Some patients with uveitis also have an associated scleritis. The scleral thinning makes scleral buckle placement difficult, if not impossible. As a result, the surgeon is often forced to alter the surgical plan to accommodate areas of scleral thinning that limit the placement of trocars.

Postoperative Inflammation

There are no systemic immunosuppressants that become fully effective within a few weeks, which means that the initial management of postoperative inflammation involves corticosteroids. Maximal use of oral, periocular, intravitreal and topical steroids may be required, as inflammatory mediators will increase the likelihood of PVR. Local steroid use such as the dexamethasone implant hasn't been shown to improve the prognosis of PVR; however, PVR will be accelerated by the presence of inflammatory cytokines. If the patient's uveitis wasn't adequately controlled preoperatively, it's important to initiate a long-term plan for uveitic control. This is especially important if additional surgeries are likely. In patients with infectious uveitis such as toxoplasmosis or cytomegalovirus, however, corticosteroids can lead to recurrent infection, which will further complicate the management of the inflammation. In these patients, it is essential to use sufficient antimicrobial agents throughout the postoperative course.

In summary, the management of rhegmatogenous retinal detachment in eyes with intraocular inflammation requires control of the inflammation before, during and after surgery, as well as understanding that the postoperative course and outcomes will be strongly influenced by the associated inflammatory process. REVIEW

Dr. Palestine is a professor of ophthalmology, and Drs. Pecen and Siringo are assistant professors of ophthalmology, at the University of Colorado School of Medicine in Aurora. Dr. Palestine may be contacted at alan.palestine@ucdenver.edu.

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Lacrimal Obstruction: What Now?

An in-depth review of the relevant anatomy and treatment strategies for lacrimal obstruction.

Daniel Luther, MD, and Blair K. Armstrong, MD, Boston

Adult patients with acquired obstruction of the lacrimal drainage system present with tearing, a common complaint that can prove frustrating to patients and practitioners alike. Symptoms can be non-specific, unilateral or bilateral, constant or intermittent. Patients may complain of frank epiphora, eyelid crusting or simply blurry vision. Management varies depending on the level of obstruction, and all the acronyms for the therapies start to resemble alphabet soup. To help make things clearer, here is an overview of lacrimal surgical options for the adult patient with lacrimal obstruction.

Review of Anatomy

Epiphora results from obstruction at any level of the lacrimal drainage apparatus. After tears accumulate in the tear lake, they're actively drained through the lacrimal drainage system, a 35 to 37 mm tubular network beginning at the puncta *(See Figure 1A)* and terminating in the inferior nasal meatus. The lacrimal puncta are the gateway to the lacrimal drainage system; they open into the tubular canaliculi *(See Figure 1B)*, which drain into the lacrimal sac at the valve of Rosenmuller *(See Figure 1C)*. In most people, the inferior and superior canaliculi merge to form the common canaliculus before reaching the valve of Rosenmuller. The lacrimal sac extends downward and becomes the nasolacrimal duct, ultimately draining into the inferior nasal meatus at the valve of Hasner *(See Figure 1D)*. By conventional nomenclature, the puncta are considered the distal end of the lacrimal drainage system and the valve of Hasner is considered the most proximal structure.

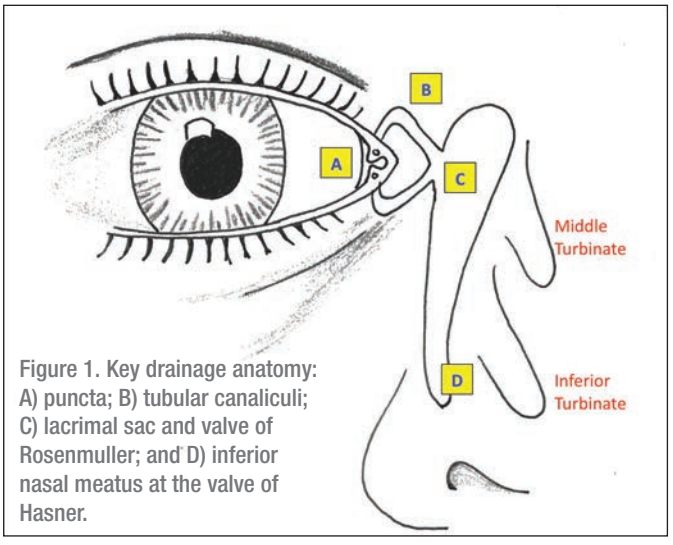

Figure 1. Key drainage anatomy: A) puncta; B) tubular canaliculi; C) lacrimal sac and valve of Rosenmuller; and D) inferior nasal meatus at the valve of Hasner.

Acquired nasolacrimal duct obstruction is most commonly due to inflammation and obstructive fibrosis, but may be secondary to more dangerous processes. Thus, careful history and clinical evaluation is essential to rule out etiology such as trauma, prior surgery, infection, systemic inflammatory conditions or neoplasms. When a cause can't be identified, the term primary acquired nasolacrimal duct obstruction (PANDO) is used. In one study, Nancy Tucker, MD, and her colleagues at Montreal's McGill University performed lacrimal sac biopsies in 150 patients undergoing DCR for clinically suspected PANDO. Histopathologic findings for 147 patients were consistent with inflammation

or fibrosis, and only three had identifiable underlying etiology (sarcoidosis, oncocytoma and lymphoma).

Locating the Blockage

Assuming a normal blink and anterior segment exam, patency of the lacrimal drainage system must be assessed. You can localize the obstruction by systematic testing. Palpation of the lacrimal sac can reveal distention or expression of fluid from the puncta, thus diagnosing obstruction, patent canaliculi and blockage proximal to the lacrimal sac or nasolacrimal duct. Further probing should be avoided to prevent iatrogenic scarring. Significant inflammation or infection of the sac can signify dacryocystitis due to stasis in the setting of nasolacrimal duct obstruction. Severe cases can be associated with preseptal cellulitis, orbital cellulitis or systemic infection, and these patients should be admitted for IV antibiotics. Incision and drainage may be necessary to control acute infection, and surgical correction of underlying nasolacrimal duct obstruction should be considered after treatment of the acute infection. (The presence of dacryocystitis is diagnostic and additional probing isn't necessary, particularly during acute infection.)

If the lacrimal sac is normal, patency can be further assessed using the fluorescein dye disappearance test (FDDT), Jones I test, Jones II test and/or lacrimal probing and irrigation. Radiographic techniques such as lacrimal scintillography and dacryocystography are options but are rarely employed clinically. There is no standard testing algorithm, and a poll of members of the American Society of Ophthalmic Plastic and Reconstructive Surgery showed a little less than half of the surgeons relied primarily on lacrimal irrigation, 21 percent used Jones Testing, 19 percent used the FDDT and 13 percent used Schirmer's testing.

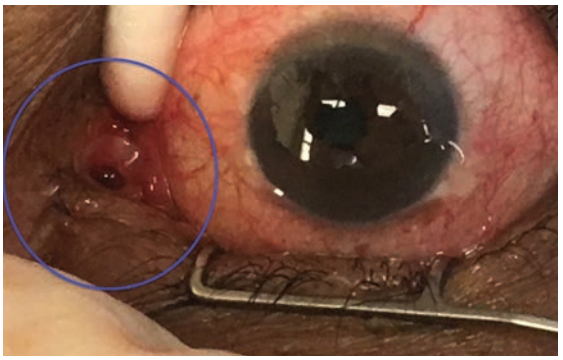

Figure 2. The Jones tube is designed for easy removal, since it's only held in place by friction and a small collar.

To perform the FDDT, instill one drop of fluorescein in the inferior cul-de-sac, wait five minutes, then reassess the patient. Minimal fluorescein in the tear lake indicates a patent drainage system, and retained fluorescein indicates impaired drainage. This is particularly useful in unilateral cases, where the asymptomatic eye can be used as a control. While useful conceptually, few clinicians perform Jones testing, and most rely on the FDDT and lacrimal irrigation alone. Lacrimal irrigation starts with punctal dilation, noting any signs of punctal stenosis. A lacrimal cannula is then carefully introduced through the punctum and into the canaliculus, stopping if any resistance is met. The canaliculus is patent if the cannula is easily advanced medially until a hard stop is reached at the nasal bridge (lacrimal fossa) but this can be additionally assessed with a Bowman probe. Once resistance is encountered, either during advancement or at the lacrimal fossa, the system is irrigated while observing both puncta carefully for reflux. Immediate reflux through the same punctum indicates distal canalicular obstruction, while reflux from the opposite canaliculus indicates blockage beyond the common canaliculus, most likely in the nasolacrimal duct. If fluid can be forced into the nasal passage with pressure, there is incomplete but functional obstruction of the lower lacrimal system. If fluid is easily passed into the nose without much pressure, the system is freely patent. However, irrigation applies pressure to the lacrimal system, and patency under non-physiologic conditions does not rule out partial obstruction.

Canalicular Obstruction

Once the obstruction is located, management consists of bypassing or recanalizing the site of obstruction. Distal obstructions involving the canaliculi can be particularly challenging, and often require completely circumventing the lacrimal drainage apparatus. Conjunctivodacryocystorhinostomy (CDCR) with placement of a glass Jones tube is the gold standard in management. This procedure connects the tear lake and the nasal cavity through a surgical ostomy, and relies on a glass tube to maintain a patent conduit over time. Success rates range as high as 90 percent, but patients may have difficulty tolerating and maintaining the Jones tube. By design, the Jones tube is easily removed to accommodate the frequent cleaning necessary to prevent blockage and biofilm development. It's held in place simply by friction and a small collar to prevent inward migration *(See Figure 2)*, and consequently tube dislocation and extrusion can occur in up to half of patients. Patients may also experience recurrent plugging, malposition, difficulty achieving the desired rate of tear outflow, and retrograde airflow when sneezing or using a CPAP.

The high rate of complications should be considered before CDCR, and alternate methods have been attempted in an effort to spare patients the burden of a Jones tube. In cases of distal obstruction with at least 8 mm of patent upper or lower canaliculus continuous with the punctum, canaliculo-DCR may be attempted. For this procedure, external dacryo-

cystorhinostomy is performed as described in the next section, followed by probing of the canaliculi to the point of blockage. The obstruction is resected, and the patent canaliculus is anastomosed directly into the lacrimal sac. Results are best with smaller obstructions and those located near or within the common canaliculus. Long-term success of this technically challenging procedure is rare and these cases often require subsequent CDCR with Jones tube.

As an alternative to bypassing the obstruction, a blocked canaliculus can be recanalized using trephination. For this procedure, a hollow tube with a cutting edge inside a protective stylus is advanced into the canalicular system. When an obstruction is encountered, the stylus is withdrawn and trephination is performed with gentle rotation of the instrument. This is continued until the instrument reaches the hard lacrimal fossa, taking extreme caution to avoid creation of a false passage along the way. Success rates may vary depending on the location of obstruction and surgeon experience. One recent study reported functional success of 78 percent and anatomical success of 84 percent at six months when combined with endoscopic DCR and silicone tube stenting. Anatomic success increased to 95 percent for surgeons with greater than five years of experience. This method has been performed as an initial surgical intervention or after a previously failed DCR.

Nasolacrimal Duct Obstruction

Dacryocystorhinostomy is the mainstay of treatment for nasolacrimal duct obstruction without canalicular involvement. DCR creates a channel between the lacrimal sac and nasal cavity, and can be performed externally or endonasally.

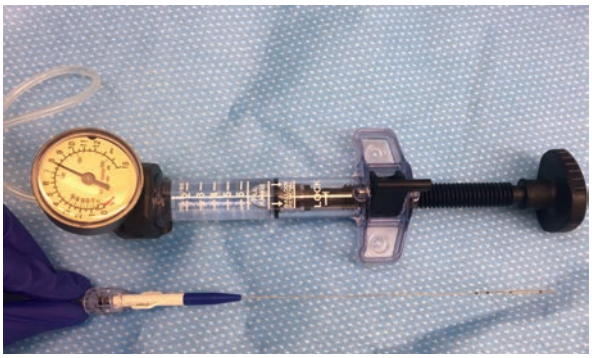

Figure 3. Balloon catheter dilation can be effective in some patients suffering from nasolacrimal duct obstruction.

The external DCR procedure begins with an initial incision at the level of the medial canthal tendon, which is extended 15 to 20 mm inferolaterally along the side of the nose. Blunt dissection is used to expose the periosteum, which is reflected to expose the intact lacrimal sac. After lifting the sac out of the lacrimal fossa, an ostomy is created in the lacrimal fossa to access the nasal mucosa, which is anastomosed to the lacrimal sac mucosa. A successful DCR connects a patent canalicular system to the nasal canal at the level of the lacrimal sac, bypassing any additional nasolacrimal duct obstruction proximally.

Endonasal DCR accomplishes the same task, but accesses the lacrimal sac through the nasal cavity. The endonasal approach offers certain advantages such as the absence of an external scar, lower complication rate, shorter operative time and complete preservation of the pump function by avoiding any manipulation of the orbicularis oculi. However, endonasal DCR is often more expensive and the equipment less readily available. Lower efficacy and higher recurrence rate with endonasal DCR has also been suspected. However, a recent Cochrane review suggests that success rates of mechanical endonasal DCR are comparable to external DCR in experienced hands (approximately 95 percent in both procedures) and that complications such as wound infection and postoperative bleeding may be less likely.

To Stent or Not to Stent

Monocanalicular or bicanalicular silicone tube stents may be placed during external or endonasal DCR surgery. Several methods have been attempted to prevent ostial closure, with limited efficacy. Success rates of DCR without stenting are excellent, and studies have failed to show any clear benefit of stenting. Furthermore, the practice is not entirely benign, and stent-related complications include prolapse, corneal abrasion, canaliculitis, adhesions, false passage creation during intubation and cheese wiring of the puncta.

Alternative Modalities

While DCR is the gold standard, other procedures aimed at recanalizing the nasolacrimal duct have been studied. Some success has been reported using balloon catheter dilation to treat acquired partial NLDO in patients *(See Figure 3)*. In a small, prospective study, 60 percent of patients reported subjective improvement, and 73 percent were objectively patent upon irrigation at six months. NLD probing with adjuvant mitomycin C has also been attempted, with one study reporting 84-percent patency at nine months. A group of Chinese surgeons reports using high-frequency electric cautery to recanalize the NLD, with a reported 87 percent success rate. While the evidence is far from conclusive, these minimally invasive techniques could offer patients additional options, pending further study.

Adult patients with tearing are challenging to evaluate, but a correct diagnosis is critical for guiding treatment. Surgical management is based on the level of obstruction, and thus a thorough understanding of lacrimal system

anatomy and physiology, combined with a good systematic evaluation, are indispensible. Keep in mind that a thorough history may reveal serious underlying pathology requiring additional workup and treatment beyond just the correction of tearing. REVIEW

Dr. Luther is a current second-year ophthalmology resident at Boston University. Dr. Armstrong is the director of oculoplastics, orbital and reconstructive surgery at Boston University, where she is also an assistant professor of ophthalmology.

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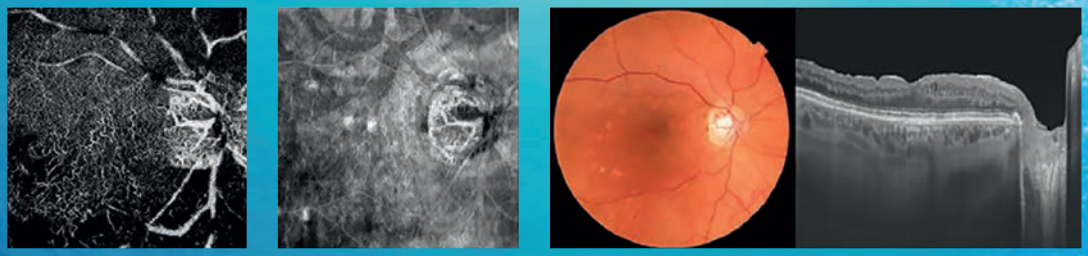

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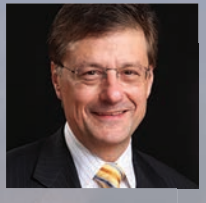

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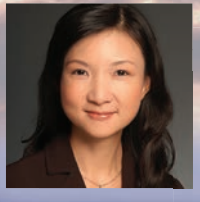

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How to Manage Pediatric Herpes Keratitis

Learn what makes cases of pediatric herpes keratitis unique—and use this knowledge to treat them appropriately.

Benjamin B. Bert, MD, FACS, Los Angeles

Any disease that can affect the clarity or refractive capability of the cornea in childhood can have devastating consequences as a result of refractive or deprivational amblyopia. Since herpetic keratitis can cause corneal scarring and irregular astigmatism, the goal is to treat it aggressively to prevent these sequelae during the amblyogenic period. Aggressive treatment is especially important since it is thought that children have a greater inflammatory response than adults, which can lead to faster development of scarring and corneal opacification. In this article, I'll cover the finer points of diagnosing and managing herpes keratitis in children.

Diagnosis

Making the diagnosis of herpes simplex virus keratitis in a young child is significantly more difficult than in an adult. At baseline, kids are more difficult to examine and require additional time. With the added discomfort of the infection and the photophobia that often accompanies it, the exam is often challenging. In addition, early findings of HSV ocular disease can be subtle and highly variable *(See Figures 1 to 3)*, ranging from a follicular conjunctivitis to punctate epithelial changes or a mild anterior chamber reaction. In order to make the diagnosis as early as possible you need to be patient and ensure that you examine the eye with sufficient light and magnification. Some children may not tolerate or be old enough for an exam at the slit lamp, so a handheld slit lamp can be especially beneficial. There are some situations in which an exam under anesthesia would be indicated to ensure an accurate diagnosis. These challenges continue in follow-up when assessing the child's response to treatment and the further clinical course of the disease.

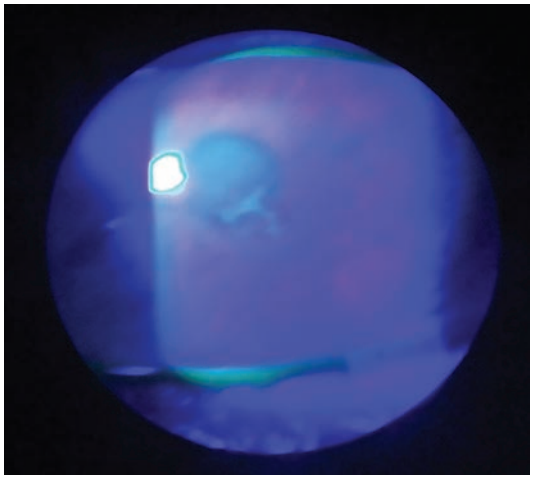

Figure 1. The findings in early HSV keratitis can be subtle, as noted by this lesion that doesn't have the full dendritic staining pattern but is highly suspicious.

Making the diagnosis of an HSV infection is even more important if the child is in the neonatal period, since the risk of fatal encephalitis or disseminated disease is much higher. The rate of HSV infection in the neonate is reported to be one out of 3,500 births.[1] Treating these patients as early as possible with intravenous antivirals has reduced morbidity from skin, eye and/or mouth infections (often called SEM disease). The rate of developmental delay in these SEM patients at 12 months of age has been reduced from 38 percent to less than 2 percent.[2]

Much of our understanding of and treatments for HSV keratitis are derived from the landmark Herpetic Eye Disease

Study. It's important to note, however, that HEDS only included patients who were 12 years of age or older.[3] Therefore, the study excluded patients in the amblyogenic period and those younger patients that may have an atypical presentation or greater inflammatory response to the virus.

Comparing studies of pediatric HSV keratitis patients and those included in HEDS shows some striking differences. In HEDS the recurrence rate of all forms of HSV keratitis was 32 percent,[3] while for pediatric patients in other studies it ranges from 33 to 80 percent.[4-10] Compiling all of the pediatric patients involved in the studies shows a cumulative recurrence rate of 51 percent. Thus, while one-third of adult patients will have a recurrence of their disease, more than half of pediatric patients will experience a recurrence without antiviral suppressive treatment.

The other major difference in HSV keratitis between pediatric and adult patients is in the rate of bilateral involvement. Studies in adults have consistently demonstrated that bilateral HSV ocular disease is a rare entity, often being reported in the low single digits, usually less than 3 percent.[11] Only a handful of older studies show a bilateral rate of disease approaching 10 percent.[12,13]

In the pediatric population, however, the reported occurrence rate of bilateral disease ranges from zero to 26 percent.[4-10] This is especially important to note, since many pediatric patients, 30 percent by some accounts,[14] are misdiagnosed. It's usually not until there is delayed resolution of the redness or notable disease progression that the condition is again investigated. This additional time without antivirals or topical steroids can be devastating, since visually significant scarring with induced irregular astigmatism can develop.

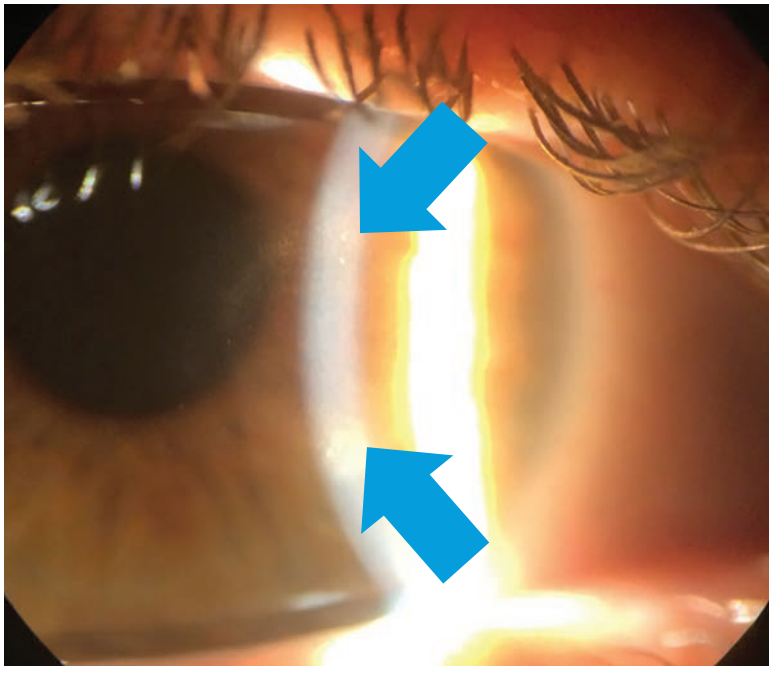

Figure 2. A Wessley immune ring is seen in this case of HSV disciform keratitis.

To summarize the key points of making the diagnosis in the pediatric population, the clinician should:

- be aware that there's a higher risk of recurrent disease;
- carry a high suspicion in cases of unilateral disease and not dismiss the possibility of HSV if bilateral disease presents; and
- know that a greater amount of inflammation and amblyogenic scarring from opacity and astigmatism can occur.

Treatment

Current treatment protocols for HSV keratitis are also derived from HEDS. But again, there are differences between an adult population and a pediatric one. One of the major findings in HEDS was that topical and oral antivirals were essentially equivalent in preventing progression from epithelial keratitis to stromal keratitis.[15] However, this is assuming that you have the proper concentration of a topical medication within the eye. It's fairly common for children to tear or cry after having a drop put into their eyes. This can dilute the medication and possibly reduce its effectiveness. For that reason, the recommendation in the pediatric population strongly leans towards using oral antivirals.[8]

- ***Treatment—active infection.*** In adults, the oral treatment protocol for HSV keratitis is acyclovir 400 mg by mouth five times per day.[16] For pediatric patients, adjustments for weight and other factors must be made. The range that was used in the study by Gary Schwartz, MD, and Edward Holland, MD, was 12 to 80 mg/kg/day in divided doses. However, even in their study, each dosing regimen was discussed with a staff pharmacologist to ensure proper treatment.[8] The treatment doses were then gradually tapered to an appropriate level to prevent recurrences.
- ***Treatment—suppression.*** HEDS demonstrated that using acyclovir 400 mg by mouth twice daily reduced recurrence rates from 32 percent to 19 percent and was most beneficial in those who had a history of previous recurrences.[17] For children the suppression dose was found to range between 12 to 20 mg/kg/day.[8] Reaching the appropriate suppression dose for each child did

involve some trial and error on the part of the investigators. While tapering the acyclovir down from the treatment dose, three out of their seven pediatric patients had recurrences. This required them to increase the dose back to treatment levels and then begin the tapering process again. They then tapered more slowly, exercising additional caution when they approached the dosage at which there was a recurrence previously.

A more recent study was conducted by Indiana University's Shaohui Liu, MD, PhD. She and her colleagues chose to use dosages in 100-mg intervals related to the commercially available acyclovir suspension 200 mg/5 ml. The dosages used were:

- infants (up to 18 months), 100 mg (2.5 ml) t.i.d for treatment or b.i.d. for prophylaxis;
- toddlers (18 months to 3 years), 200 mg (5 ml) t.i.d. (treatment) or b.i.d. (prophylactic);
- young children (3 to 5 years), 300 mg (7.5 ml) t.i.d. (treatment) or b.i.d. (prophylactic); and
- older children (6 years and older), 400 mg (10 ml) t.i.d. (treatment) or b.i.d. (prophylactic).[18]

However, the authors admit that the dosing will change as the child grows, referencing one case where a growth spurt led to a series of recurrences due to insufficient suppression of HSV. This, again, indicates that there is not a "one-dose-fits-all" approach to the pediatric population. Simplicity in dosing may increase patient compliance with the treatment, but you have to ensure that the dose is adequate for each child, as there will occasionally be outliers.

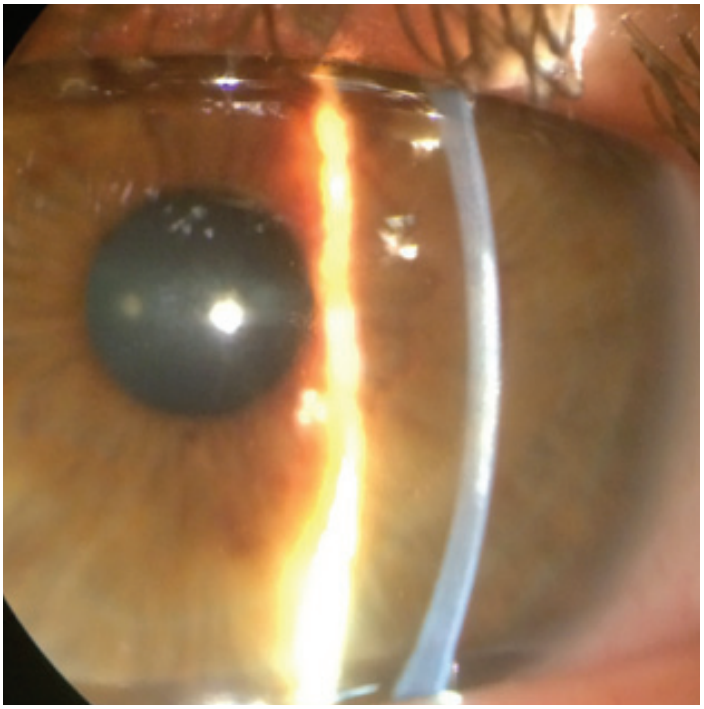

Figure 3. Stromal scarring as seen at the slit lamp secondary to HSV stromal keratitis.

- ***Treatment—topical corticosteroids.*** The treatment of stromal, endothelial and kerato-uveitic disease has long involved topical corticosteroids. However, treating a patient with topical corticosteroids while he or she has active epithelial disease remains contraindicated. In the pediatric population there is no study evaluating the dosage or duration of treatment. Many of the pediatric studies comment about topical corticosteroid treatment as being used "according to the severity of the disease,"[19] and then "adjusted according to the clinical response of each patient."[18] Again, the relied-upon information regarding the use of topical corticosteroids comes from the HEDS group. Keep in mind that HEDS only included patients 12 years of age or older.

In exploring the benefits and use of topical corticosteroids, the HEDS group performed a randomized, double-masked, placebo-controlled, multicenter trial. They looked at 106 patients treated with trifluridine 1% and a tapering regimen of a placebo or prednisolone phosphate for a 10-week period. The patients in the treatment arm started on prednisolone phosphate 1% eight times per day for one week, then tapering to six times per day for a week, then four times, then two times, then one time before cutting the concentration of the prednisolone phosphate to 0.125%. The taper was then continued at a rate of four times per day for a week, then two times per day for a week and then one time per day for two weeks, until the full 10-week taper was completed.

They demonstrated that the patients treated with topical corticosteroids had less progression of their disease and faster resolution. While some patients in the placebo group had delayed initiation of steroid treatment, they too benefited and showed delayed resolution—but equal vision compared to those in the treatment arm at six months follow-up.[20] The main consequence was that almost 10 percent of the patients that were in the treatment arm had activation of epithelial disease, despite suppressive treatment with trifluridine.

The authors concluded that steroids were safe, beneficial and could have delayed initiation with close monitoring in adults. Since it is understood that children have a higher rate of inflammation with activation of the infection, one has to question the wait-and-see approach with initiating topical corticosteroids in the pediatric population. This is certainly an area that would benefit from additional studies. For now, one can hy-

pothesize that treating the additional inflammation seen in the pediatric population aggressively and initiating corticosteroid treatment as early as possible (in conjunction with antivirals) for stromal, endothelial or kerato-uveitic disease could help improve these patients' conditions more rapidly and prevent any further sequelae. In the HEDS study, 67 percent of the patients in both arms had vision of 20/40 or better in the affected eye at six months. For the pediatric population, this still poses a significant risk of amblyopia and would further encourage the prompt use of topical steroids to reduce the time that it takes for the eye to recover and have the best vision possible.

Outcomes

The risk of developing amblyopia due to corneal opacity or irregular astigmatism is very real and something that needs to be monitored as closely as the patient's response to the treatment of the HSV keratitis itself. The largest recent study, by Mexico City's Juan Carlos Serna-Ojeda, MD, shows that 51.3 percent of the patient group developed central corneal opacities and 8.7 percent developed irregular astigmatism greater than 2 D. This resulted in 30.2 percent of their patients developing amblyopia.[19]

In the study by Dr. Liu, 54 percent of the patient group developed a central corneal opacity and 28 percent developed a change in their astigmatism of greater than 2 D. While they don't explicitly discuss the rates of amblyopia, they report that 26 percent had a best corrected visual acuity of 20/40 or worse.[17] The highest rate of amblyopia reported in recent studies was 66 percent.[10]

With a large portion of pediatric HSV patients developing amblyopia, it's important to monitor them frequently for any changes in their vision in addition to aggressively treating the infection. Frequent refractions and instituting early amblyopia treatment can help prevent the loss of BCVA. If there's a significant component of irregular astigmatism, then rigid gas-permeable lenses should be considered. Aggressive and early intervention was demonstrated in the study by Drs. Schwartz and Holland, in which no patients developed a loss of BCVA or even a difference in visual acuity between the affected and normal eye. There was one patient who required amblyopia and strabismus treatment, but achieved the same results in terms of best-corrected vision as the rest of his cohort.[8]

In those cases where medical management isn't sufficient and keratoplasty is needed, it's important to know that antiviral prophylaxis is exceedingly important. In another study by Dr. Serna-Ojeda, he and his colleagues treated pediatric patients with six months of oral acyclovir at a suppression dose level before proceeding with keratoplasty. They then continued the acyclovir at the suppression dose indefinitely. In their retrospective case review, with a median follow-up of 49 months, they had no graft failures.[21] The authors did mention that one of the biggest limitations to regaining vision was the amblyopia that had already developed. This leads to the common concern when considering a pediatric penetrating keratoplasty: the higher risk of graft failure in the younger patient versus the risk of continued amblyopia development.

Ultimately, though pediatric herpes keratitis can be challenging to diagnose and treat, the pediatric population benefits immensely from having the appropriate treatment initiated as soon as possible, since this limits the long-term sequelae of the disease. Current first-line treatment involves the use of oral antivirals and topical corticosteroids when appropriate. Close monitoring and follow-up is needed to assess the child's response to the prescribed treatment and to catch any changes to BCVA as early as possible. REVIEW

Dr. Bert is an assistant professor of ophthalmology at the Doheny Eye Center of UCLA, David Geffen School of Medicine.

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São Paulo, Brazil

Daniel Palanker, PhD
Stanford University
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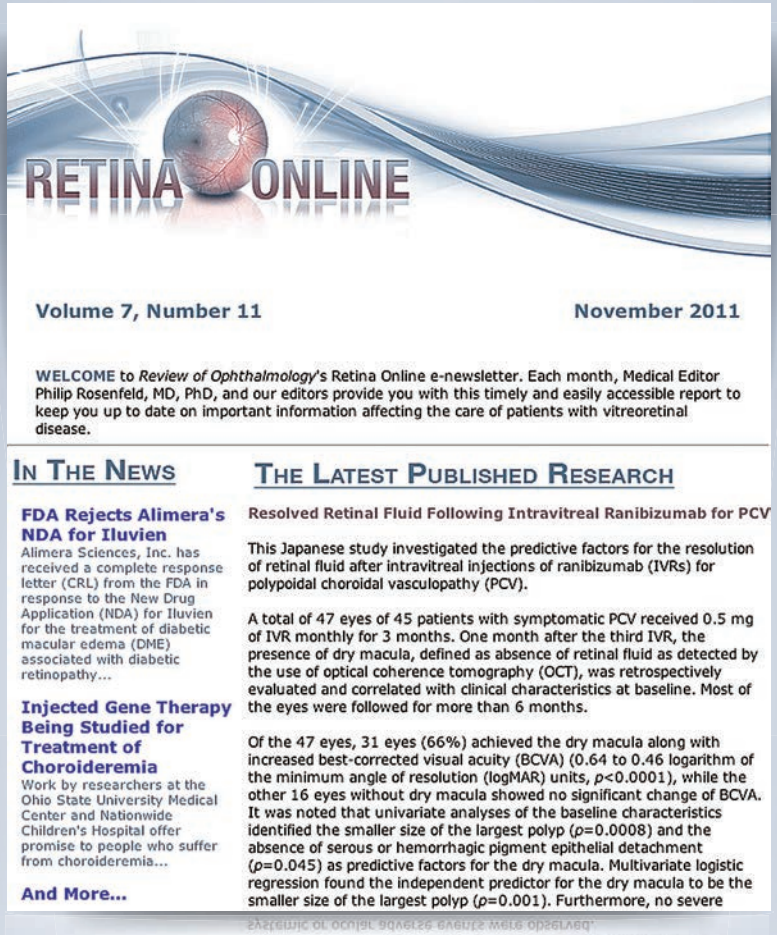

RETINA ONLINE

Volume 7, Number 11 November 2011

WELCOME to *Review of Ophthalmology*'s Retina Online e-newsletter. Each month, Medical Editor Philip Rosenfeld, MD, PhD, and our editors provide you with this timely and easily accessible report to keep you up to date on important information affecting the care of patients with vitreoretinal disease.

IN THE NEWS

FDA Rejects Alimera's NDA for Iluvien
Alimera Sciences, Inc. has received a complete response letter (CRL) from the FDA in response to the New Drug Application (NDA) for Iluvien for the treatment of diabetic macular edema (DME) associated with diabetic retinopathy...

Injected Gene Therapy Being Studied for Treatment of Choroideremia
Work by researchers at the Ohio State University Medical Center and Nationwide Children's Hospital offer promise to people who suffer from choroideremia...

And More...

THE LATEST PUBLISHED RESEARCH

Resolved Retinal Fluid Following Intravitreal Ranibizumab for PCV

This Japanese study investigated the predictive factors for the resolution of retinal fluid after intravitreal injections of ranibizumab (IVRs) for polypoidal choroidal vasculopathy (PCV).

A total of 47 eyes of 45 patients with symptomatic PCV received 0.5 mg of IVR monthly for 3 months. One month after the third IVR, the presence of dry macula, defined as absence of retinal fluid as detected by the use of optical coherence tomography (OCT), was retrospectively evaluated and correlated with clinical characteristics at baseline. Most of the eyes were followed for more than 6 months.

Of the 47 eyes, 31 eyes (66%) achieved the dry macula along with increased best-corrected visual acuity (BCVA) (0.64 to 0.46 logarithm of the minimum angle of resolution (logMAR) units, $p<0.0001$), while the other 16 eyes without dry macula showed no significant change of BCVA. It was noted that univariate analyses of the baseline characteristics identified the smaller size of the largest polyp ($p=0.0008$) and the absence of serous or hemorrhagic pigment epithelial detachment ($p=0.045$) as predictive factors for the dry macula. Multivariate logistic regression found the independent predictor for the dry macula to be the smaller size of the largest polyp ($p=0.001$). Furthermore, no severe

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REVIEW® of Ophthalmology

Prognostic Value of Lid Tumor Staging

Researchers sought to identify the risk of metastasis for eyelid tumors by looking at the tumors' stages.

The investigators performed a systematic review of the literature using the terms "AJCC (American Joint Committee on Cancer)," "eyelid," "carcinoma" and "melanoma." The rates of local recurrence, regional nodal metastasis and distant metastasis appear in Table 1.

The researchers say that, overall, the risks of local recurrence and regional nodal and distant metastasis appeared to increase with increasing AJCC T category, though this wasn't statistically significant in all studies. Clinical T2b or greater T category was significantly associated with an increased risk of nodal metastasis of eyelid squamous cell carcinomas, sebaceous carcinomas, Merkel cell carcinomas, sweat-gland carcinomas and melanomas. Clinical T3 or greater T category was significantly associated with distant metastasis for eyelid carcinomas and melanomas. As a result, the investigators say that patients with T2b or larger tumors may be candidates for sentinel lymph node biopsy or close nodal surveillance.

Ophthal Plast Reconstr Surg 2017; 33:5:317-324.
Ford J, Thakar S, Thuro B, et al.

Diabetes and DMEK

Researchers reviewed a consecutive, single-center case series of Descemet's membrane endothelial keratoplasty to determine the effect of diabetes on both hosts and donors.

In 504 of 1,791 cases (28 percent) the donor had a history of diabetes, and the recipient had such a history in 14 percent of cases (250 corneas). For donors without diabetes vs. those with the disease, the preparation success rate was 99 percent versus 95 percent ($p<0.0001$), the air reinjection rate was 16 percent versus 18 percent ($p=0.19$), and the four-year graft replacement/failure rate was 7 percent versus 9 percent, respectively ($p=0.15$). The investigators say that endothelial cell loss wasn't associated with donor diabetes ($p=0.76$). For recipients without and with diabetes, in addition to the replacement/failure rate mentioned above, the median endothelial cell loss increased from 27 percent versus 29 percent at one month to 42 percent versus 48 percent at four years, respectively ($p=0.02$). Recipient use of insulin therapy was associated with poorer graft attachment and a higher air reinjection rate ($p=0.0023$).

The researchers say that although donor diabetes was associated with a fivefold increased risk of tissue preparation failure, it wasn't significantly associated with air reinjection, graft survival or endothelial cell loss in their study population. They add that this provides corneal surgeons with the reassurance that tissue prepared successfully from donors with diabetes is safe to use for DMEK.

Because recipient diabetes was associated with increased endothelial cell loss, the potential effect on longer-term graft survival merits further

Table 1. Recurrence and Metastasis of Lid Tumors

Cancer	Local Recurrence (%)	Regional Nodal Metastasis (%)	Distant Metastasis (%)
eyelid squamous cell carcinoma	7 to 10	1 to 9	0 to 0.8
eyelid sebaceous carcinoma	5 to 6	8 to 23	2 to 14
eyelid Merkel cell carcinoma	10	10 to 22	19 to 22
eyelid sweat gland carcinoma	14	5	0
eyelid melanoma	2	9	6

This article has no commercial sponsorship.

study, the investigators say.

Cornea 2017;36:10:1184–1188.
Price, MO, Lisek M, Feng M, Price FW

Reoperation Rate: RRD With Co-existing Macular Hole

Investigators examined surgical outcomes in individuals with coexistent macular hole and rhegmatogenous retinal detachment, as part of a retrospective case series. They looked at all individuals who underwent surgical repair of concomitant MH and retinal detachment in their facility between January 2014 and December 2016.

At least one retinal break was noted in all MHRD cases. Exclusion criteria included MHRD related to high myopia without peripheral retinal tears. Data collected included presence of proliferative vitreoretinopathy and classification at time of surgical repair. Outcomes evaluated included visual acuity comparisons, reoperation rate, final anatomic success and MH closure rate.

Over the study period, MHRD cases accounted for 17 (2.3 percent) of all 745 repaired RDs in the practice. Proliferative vitreoretinopathy was present in 53 percent of MHRD cases. Reoperation rates for MHRD were significantly higher than the practice average for all RD repairs (29 percent vs. 9.7 percent; p=0.01). Final anatomic success with RD was achieved in 100 percent of individuals. Internal limiting membrane peeling was performed in 15 of 17 individuals. The macular hole closure rate was 71 percent after initial surgery. Although 82 percent of individuals experienced equal or improved vision, only 24 percent of individuals achieved VA better than 20/80. Retinal detachment in the contralateral eye was noted in three of 16 individuals (19 percent) before initial presentation or during the follow-up period.

Investigators wrote that visual outcomes in MHRD cases were underwhelming because of high rates of PVR macula-off RRD and reoperation, and relatively low MH closure rates; therefore, they suggested aggressive surgical techniques to repair MHRD.

Ophthalmology Retina 2017; Sep 28. [Epub ahead of print].
Najafi M, Brown JS, Rosenberg KI, et al.

Autoregulation of ONH Blood Flow During Vitreous Surgery

Scientists examined whether hypertension and hyperlipidemia affected autoregulation of optic nerve head blood flow during vitrectomy, as part of a cohort study.

Seventeen eyes from 17 subjects with HTN and HL, and 19 eyes from 19 control subjects without systemic disorders underwent vitrectomy for treatment of epiretinal membranes or macular holes. Following standard 25-gauge microincision vitrectomy, the mean blur rate—an index of relative ONH blood flow—in the vascular area and MBR in the tissue area were measured using laser speckle flowgraphy. Measurements were conducted before, and five and 10 minutes after, an approximately 15-mmHg rise in intraocular pressure. The parameters represented relative values of optic nerve head blood flow (percent, compared to baseline). Scientists calculated the recovery rate of ONH blood flow using the equation: (MBR at 10 min. - MBR at 5 min.)/(MBR at baseline - MBR at 5 min.).

Ocular perfusion pressure in all subjects dropped five and 10 minutes after the increase in IOP. Vascular MBR in subjects with HTN and HL (75.5 ±14.8) was significantly lower than that in controls (86.7 ±12.1) 10 minutes after IOP elevation (p=0.019). The recovery rate of vascular blood flow was significantly lower in the HTN and HL groups than in the control group (p=0.002).

The researchers wrote that their results suggested that HTN and HL impaired autoregulation in the vascular component of ONH blood flow during vitrectomy.

Graefes Arch Clin Exp Ophthalmol 2017; Sep 23. [Epub ahead of print].
Hashimoto R, Sugiyama T, Ubuka M, et al.

Zonal Analysis for Peripapillary Choroidal Thickness in POAG

Researchers evaluated automatic peripapillary choroidal thickness measurements in a wide area around the optic disc and zones in individuals with primary open-angle glaucoma and healthy controls. They used a new swept-source optical coherence tomography device as part of a single-center, observational study.

Researchers enrolled 135 POAG individuals and 86 healthy subjects. They obtained 6-mm × 6-mm, three-dimensional scans of the optic disc using the SS-OCT Triton and generated a 26 × 26 cube-grid centered in the OD to automatically measure choroidal thickness. In addition, they established seven choroidal zones (superior-temporal, -central and -nasal; inferior-temporal, -central and -nasal; and optic nerve head).

PPCT was significantly thinner in the central-superior, nasal-superior and nasal-inferior zones of POAG subjects. Choroidal thickness was:

- in the central-superior zone, 124.61 ±54.95 µm in the POAG group vs. 156.17 ±80.89 µm in healthy controls (p=0.029);
- in the nasal-superior zone, 133.84 ±58.89 µm in the POAG group vs. 168.34 ±73.45 µm in healthy controls (p=0.012); and
- in the nasal-inferior zone, 113.45 ±49.93 µm in POAG vs. 137.47 ±65.96 µm in controls (p=0.049).

Compared with healthy subjects, glaucoma subjects presented with peripapillary choroidal thinning. The researchers say that the new SS-OCT could be a useful tool to evaluate choroidal thinning and aid in glaucoma diagnosis.

Jpn J Ophthalmol 2017; Oct. 11. (Epub ahead of print).
Pablo LE, Bambo MP, Cameo B, et al.

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Visiometrics Updates HD Analyzer

In early October, Visiometrics added a Touch Screen Package to its HD Analyzer, which measures visual quality to improve patient outcomes in cataract diagnosis, dry-eye treatment and refractive surgery. The touch screen will replace the laptop that's required for patient exams and is intended to increase ease of use and reduce the system's footprint; with the addition of the touchscreen, the system will be able to fit on a table.

Visiometrics says that the HD Analyzer's visual reporting is a good patient education tool, and that the device facilitates discussion of treatment plans and outcomes. The touch screen can be removed for patient discussions, making it easier to handle than the laptop version of the device.

The Touch Screen Package includes a Surface Pro tablet that comes loaded with Visiometrics HD Analyzer software, screen holders and an installation kit. It can be purchased with a new HD Analyzer system or as an upgrade to an existing system. It is currently only available to users in the United States.

For more information on Visiometrics' Touch Screen update, visit visiometrics.com/shop.

ThromboGenics Introduces 'Already-Diluted' JETREA

In late September, ThromboGenics released a new formulation of JETREA in the United States designed to eliminate the preparatory dilution steps before injection. At the point of administration into the eye, the strength, potency, composition and pharmaceutical form of the already-diluted formulation remain identical to the currently available formulation after dilution, the company says.

JETREA is the first and only pharmacological treatment in the United States for symptomatic vitreomacular adhesion. The product was introduced in 2013 and has been used to treat close to 30,000 patients globally.

ThromboGenics also announced that it regained the full global rights to JETREA from Alcon. In an announcement of the transaction, the company says that it was based on a mutual agreement that the unique characteristics of JETREA make ThromboGenics a "better fit for building a sustainable long-term business."

Following the agreement with Alcon/Novartis, ThromboGenics aquired cash that it will use to support its pipeline of novel and unique disease-modifying medicines for the treatment of diabetic eye disease.

For more information on this new formulation of JETREA, visit jetrea.com.

Zeiss Launches CLARUS 500

In late September, Zeiss announced the launch of its CLARUS 500 ultra-widefield fundus imaging system. Zeiss says that the new color system can aid in the diagnosis and documentation of ocular disease, ensuring confidence when evaluating the optic disc, nevi and lesions, when the color is important.

Zeiss says that the CLARUS 500 can capture a high-resolution image down to 7 µm with the ultra-widefield retinal camera. It also captures high-resolution fundus autofluorescence images in blue and green and infrared, as well as external eye images. The CLARUS 500 produces a 133-degree HD widefield image. These images are automatically merged to achieve a 200-degree ultra-wide field of view, allowing clinicians to easily review and compare high-quality images captured during

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a single exam.

Zeiss claims that the CLARUS 500 produces images in true color that closely resemble the coloration of the retina as seen through direct observation during clinical examination. This accurate coloration and resolution is important for evaluating focal change in rim tissue, nerve pallor, dry age-related macular degeneration RPE pigment changes and drusen.

For more information on Zeiss' Clarus 500, visit zeiss.com/meditec/us/products/ophthalmology-optometry/retina/diagnostics/fundus-imaging/clarus-500.html.

The FaceDownWalker

In hopes of alleviating his wife's post-vitrectomy discomfort, Wayde Faust, an inventor based in California, invented the FaceDownWalker, a mobility device that he says allows patients recovering from vitrectomy to stand, walk around and live a more active lifestyle, without risk of retinal detachment.

The FaceDownWalker transfers the weight of the head to a backpack, relaxing the muscles in the neck, chin and back, allowing for supervised, pain-free walks for extended periods of time. Wayde currently offers domestic shipping via UPS.

Mr. Faust's wife began using the walker after her own surgery. "When my wife was first told she would have to keep her head parallel to the floor for up to 10 days, depression and claustrophobia set in," he says. "I hated seeing her like that. So I came up with the FaceDownWalker. Once we got her in it, and I held her hand to lead her around the house, her attitude completely changed. It really did make a big difference during the recovery process."

For more information and testimonials on the FaceDownWalker, visit facedownwalker.com.

NIDEK Launches the TS-310 Tabletop Refraction System

NIDEK recently announced the U.S. launch of its new tabletop refraction system that integrates chart and refractor into a single unit. Nidek says the unit's compact, minimalist design allows easy installation and assimilation in the office.

The refraction system has a triple-performance combination of control box, refractor and chart unit. The control box has a 5.7-inch color LCD touch screen for ease of use. NIDEK says the product's compact design—it measures from 40 to 70 cm wide and 50 cm deep—allows for its integration into many offices.

The TS-310 uses the same high-resolution charts for both far and near testing. The clarity of the LCD allows measurement of visual acuity at 5 m and near visual acuity at 40 cm with the same accuracy as at the actual distances.

NIDEK also claims that because of the unit's compact design, it allows for either standing or sitting examinations, as well as examinations from either the right or left side of patients. The system doesn't require complex angle and distance adjustments, allowing any staff member to use it without expert knowledge.

For more information on NIDEK's TS-310, visit nidek-intl.com/product/ophthaloptom/refraction/ref_optometry/ts-310.html.

Bausch + Lomb's EnVista MX60E Intraocular Lens

Bausch + Lomb recently introduced the next-generation hydrophobic acrylic lens, providing improved material properties to enhance optic recovery following delivery.

The MX60E is a hydrophobic, acrylic, advanced-optic IOL with StableFlex technology designed to provide controlled unfolding, excellent stability and improved optical recovery. It also features AccuSet haptics, which provide extensive interaction with the capsular bag to aid in securing the lens position through its offset design and broad contact angle, the company says.

With this new addition, the enVista remains the first and only single-piece, hydrophobic acrylic IOL domestically available. Bausch + Lomb also claims that the lens has the potential for increased resistance to scratches and abrasions that may occur during loading and surgical manipulation. The company says its aberration-free design provides for excellent visual outcomes in a wide range of patients.

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A 25-year-old woman presents at Wills Eye Hospital with severe pain and blurred vision.

Michele Markovitz, MD, and Christopher Rapuano, MD

Presentation

A 25-year-old woman presented for emergent evaluation of severe pain, tearing and blurred vision in the right eye. She had been seen by an outside ophthalmologist one month prior and was diagnosed with a corneal ulcer. She was treated with moxifloxacin 0.5% every hour and trifluridine 1% nine times per day. Despite treatment, her symptoms progressed. She reported a history of soft contact lens wear; however, she denied wearing them in the months prior to presentation. There was no history of trauma to or foreign material in the eye. She reported hot tub use several months prior.

Medical History

The patient had an ocular history of corneal ulcer in the right eye four years prior to presentation which had resolved with topical antibiotics. She had no history of eye surgery. She had no other medical history and was not taking any other medications. She denied tobacco or alcohol use. A full review of systems was otherwise negative.

Examination

Visual acuity with correction was count fingers at one meter in the right eye and 20/25 in the left. External examination showed mild edema and reactive ptosis of the right upper eyelid. On slit-lamp examination, moderate injection and temporal chemosis were noted in the right eye. There was a 4 x 4-mm area of infiltrate with an overlying serpentine epithelial defect measuring 4 mm vertically x 2 mm horizontally at the superior and temporal infiltrate border. Scattered endoplaque with five areas of dense radial keratoneuritis were also seen *(See Figure 1)*. Examination of the left eye without staining showed multiple inactive scattered peripheral scars. Dilated funduscopic examination of both eyes was normal.

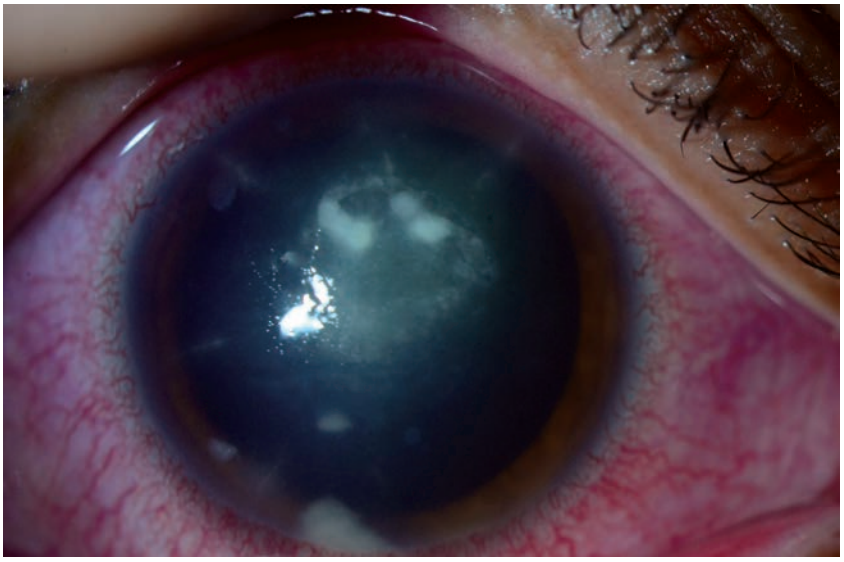

Figure 1. Anterior segment photograph of the right eye on presentation showing a multifocal infiltrate with anterior chamber reaction and dense radial keratitis.

What is your diagnosis? What further workup would you pursue? The diagnosis appears on the next page.

Workup, Diagnosis and Treatment

The differential diagnosis in this patient with a corneal ulcer and a history of contact lens use included infectious keratitis of bacterial, viral, fungal or parasitic etiology. In this case, given her refractory symptoms, the presence of radial keratoneuritis, and pain out of proportion to exam findings, there was high suspicion for *Acanthamoeba* keratitis.

Corneal scraping was performed and showed the presence of *Acanthamoeba* cysts. Bacterial and fungal cultures were negative. She was started on polyhexamethylene biguanide (PHMB) and propamidine isethionate every hour around the clock, moxifloxacin 0.5% every two hours while awake and cyclopentolate 1% every eight hours, all in the right eye.

After 10 days of treatment, the patient reported moderate improvement in her pain. Her vision was unchanged. Mild clinical improvement was noted, with improving epithelial defect and less dense infiltrate and radial keratoneuritis. After a long discussion with the patient, a novel, off-label therapy, oral miltefosine 50 mg every eight hours, was added to her regimen. After the addition of miltefosine, she demonstrated more rapid improvement in her clinical course (*See Figure 2*).

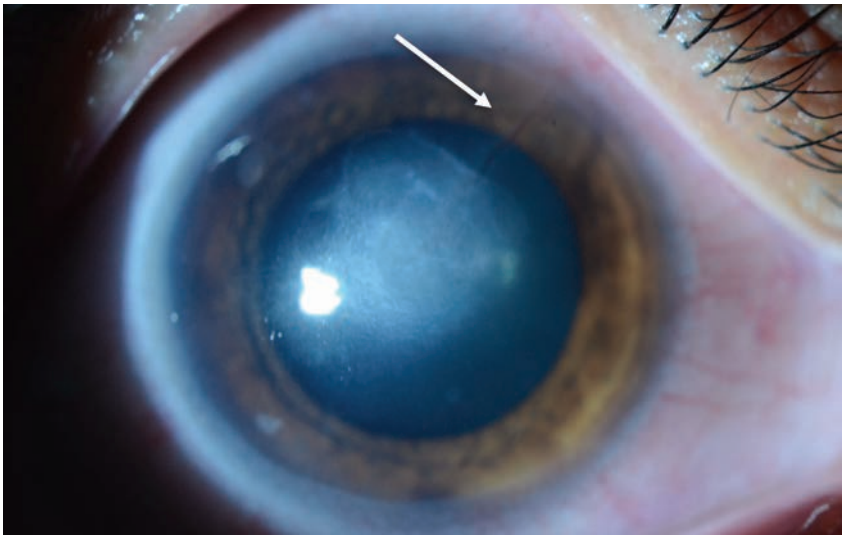

Figure 2. Anterior segment photograph of the right eye at eight weeks follow-up. There is resolution of the epithelial defect with less dense infiltrate and resolved radial keratitis. Superonasal neovascularization can be seen extending to the central cornea (arrow).

Discussion

Acanthamoeba is a ubiquitous, free-living protozoan found predominantly in soil and freshwater sources. First reported in 1973,[1] *Acanthamoeba* keratitis has been strongly associated with soft contact lens wear and contaminated water exposure. Infection can cause severe pain with sight-threatening sequelae. Data from 13 ophthalmologic institutions in the United States revealed that the annual incidence of AK markedly increased from 22 cases in 1999 to 170 cases in 2007.[2]

In early stages of AK, pseudodendritic or punctate corneal epithelial lesions, dot subepithelial infiltration or recurrent epithelial erosion can be seen.[3] The pseudodendritic appearance of the epithelial change causes frequent misdiagnosis as herpes simplex keratitis.[4] In a series of 59 patients with AK, 10 (17 percent) had radial keratoneuritis on presentation. Of the patients with stromal involvement, 32 percent had a ring infiltrate, 5 percent had a hypopyon, and 2 percent had keratic precipitates.[5] In more advanced stages, deep stromal ulcers may be present and exhibit pale or yellow-white purulent infiltration with a necrotic surface. In even later stages, corneal ulcers may develop thinning and perforation.[3]

AK is one of the most challenging ocular infections to manage. The disease stage at initial presentation is strongly associated with treatment outcome.[4] Current first-line treatment for AK involves topical therapy with biguanides (PHMB or chlorhexidine). Topical propamidine isethionate is also commonly used as a first- or second-line agent. A study of patients with AK treated at a tertiary-care eye hospital found that 53 percent required therapeutic grafts.[6] Unfortunately, the prognosis of penetrating keratoplasty for active AK remains poor.[7] Thus, it's necessary to enhance the rate of early detection and identify new, more effective anti-amoebic therapies to improve outcomes.

Miltefosine, an oral alkylphosphocholine drug, has shown early promise in the treatment of *Acanthamoeba* infections. Approved by the U.S. Food and Drug Administration for the treatment of visceral leishmanaisis, miltefosine is an antiprotozoal agent with *in vitro* activity against free-living amoebae, including *Naegleria fowleri*, *Balamuthia mandrillaris*, and

Acanthamoeba species. As of 2013, miltefosine has been available in the United States directly from the Centers for Disease Control and Prevention under an expanded-access investigational new drug protocol for use in the treatment of free-living amoeba infections.[8] There are currently five cases in the literature documenting the use of miltefosine in the treatment of systemic or disseminated *Acanthamoeba* infection.[9] Miltefosine has shown activity against AK in hamster and rat models.[10,11] To our knowledge, there are no reported cases documenting the use of miltefosine in the treatment of AK. In our patient, the addition of miltefosine 50 mg orally every eight hours for one month to the existing regimen of topical PHMB and propamidine isethionate appeared to result in a more rapid resolution of keratitis with respect to infiltrate size, density and clinical symptoms than expected for similar cases.

In summary, AK is a severe, sight-threatening infection that's often difficult to manage. This ubiquitous organism should be considered as a cause of keratitis in patients who don't respond to initial antibiotics, especially those with a history of soft contact lens use or contaminated water exposure. Clinicians must also be suspicious of AK in contact lens wearers diagnosed with HSV keratitis who aren't responding appropriately to therapy.

In this case report, we describe a patient with AK who was successfully treated with oral miltefosine in addition to topical agents. To our knowledge, this is the first case documenting miltefosine treatment of AK. This novel agent appears to show promise in the treatment of free-living amoebic infections such as AK, although further studies are needed to elucidate its role in treating this devastating corneal infection. REVIEW

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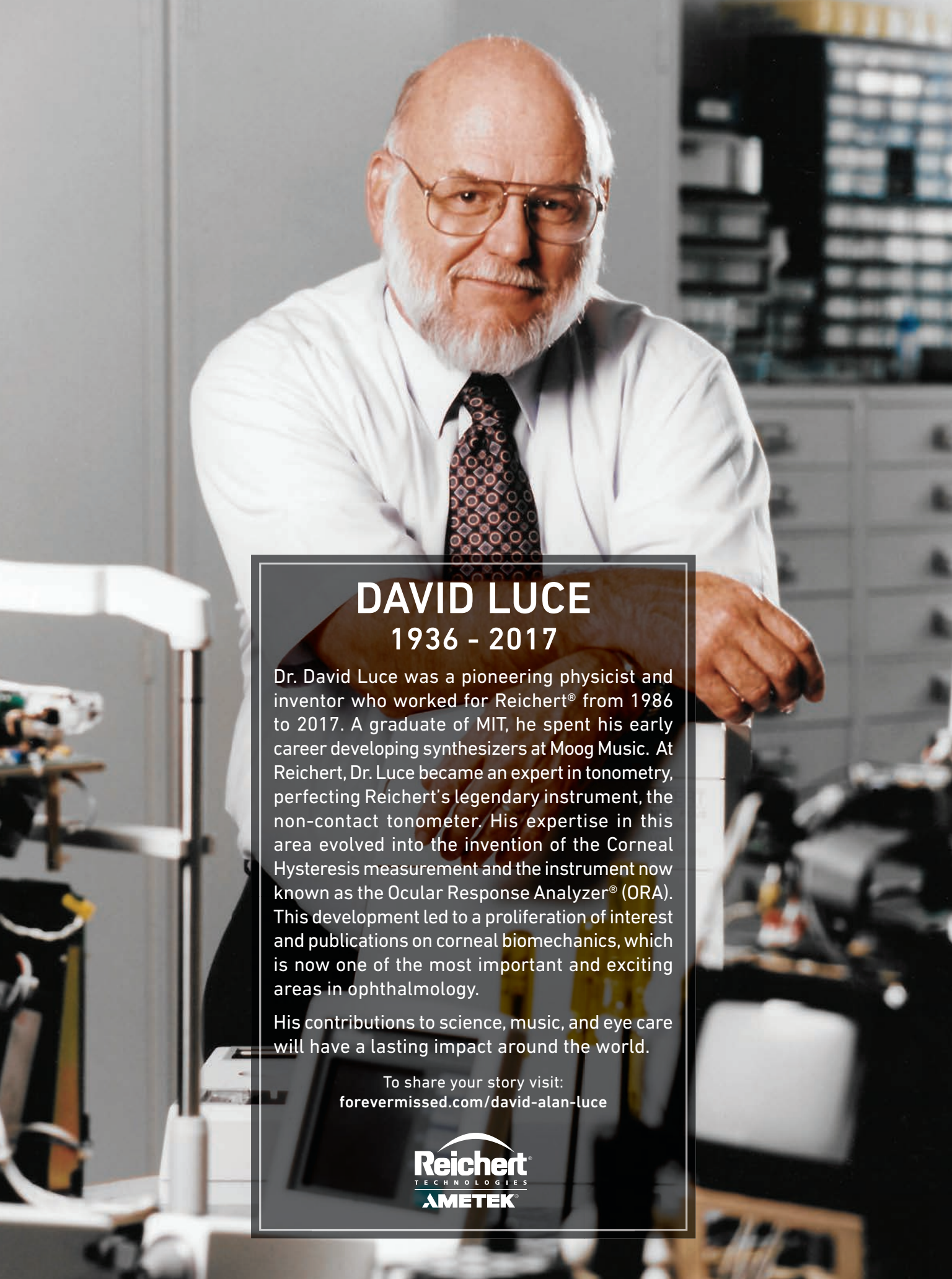

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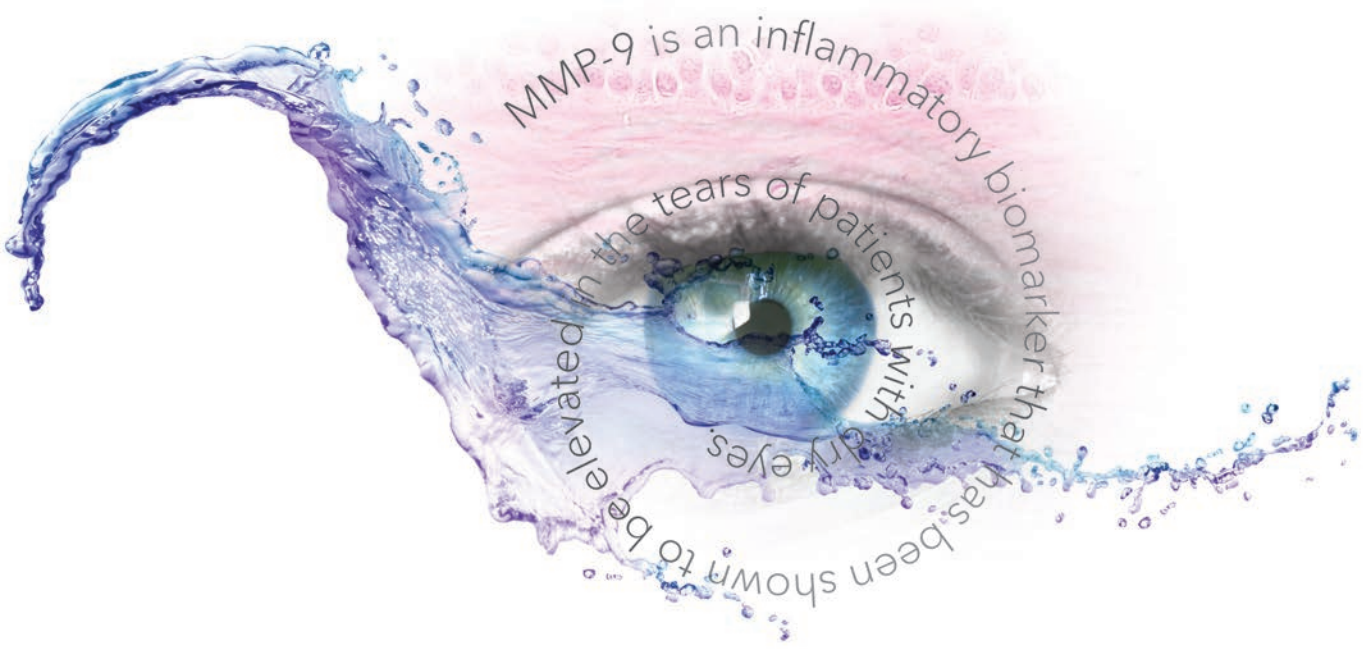

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