TRULIGN® TORIC
POSTERIOR CHAMBER INTRAOCULAR LENS

Bringing **astigmatism** AND **presbyopia** into focus.

TRULIGN® Toric IOL offers the critical advantages your patients need:

Full range of vision[1] | Excellent stability[2-4] | Minimized dysphotopsias[1]

LONG TERM **VISION** | FOR YOUR **PATIENTS** | FOR YOUR **PRACTICE**

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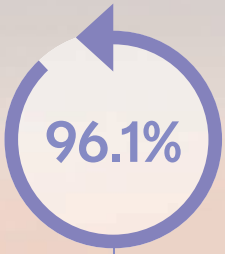
of Light,
100% of the Time



Exhibited IOL
Rotational Stability of ≤ 5°[2]

No Significant
Visual Disturbances[2]

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TRULIGN® TORIC
POSTERIOR CHAMBER INTRAOCULAR LENS

1. TRULIGN Toric IOL Directions for Use. **2.** Data on file, Bausch & Lomb Incorporated. Study 650. **3.** AcrySof IQ Toric Directions for Use. **4.** Tecnis Toric Directions for Use.

INDICATIONS FOR USE: The TRULIGN® toric posterior chamber intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision. WARNINGS: Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the risk/benefit ration before implanting a lens in a patient. Rotation of toric lenses away from their intended axis can reduce their effectiveness, and misalignment can increase postoperative refractive cylinder. The TRULIGN® Toric IOL should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye. Unlike most other IOLs, the TRULIGN® Toric IOL optic has hinges connecting it to the haptic; please see adverse events section below for more information. PRECAUTIONS: The safety and effectiveness of the TRULIGN® Toric intraocular lenses have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Long-term stability in the human eye has not been established; therefore postoperative monitoring after implant should be performed on a regular basis. Lens rotation less than 5° may not warrant reorientation. Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the TRULIGN® Toric IOL directions for use. ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. Vaulting is a post-operative adverse event where the TRULIGN® Toric IOL optic hinges move into and remain in a displaced configuration. If vaulting occurs, please see Directions for Use for a detailed listing of symptoms, information regarding diagnosis, potential causes, and sequelae. Physicians should consider the characteristics of each individual vaulting case prior to determining the appropriate treatment. Data on long-term follow-up after treatment of vaulting is not available. ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc. CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

REVIEW® of Ophthalmology

April 2017

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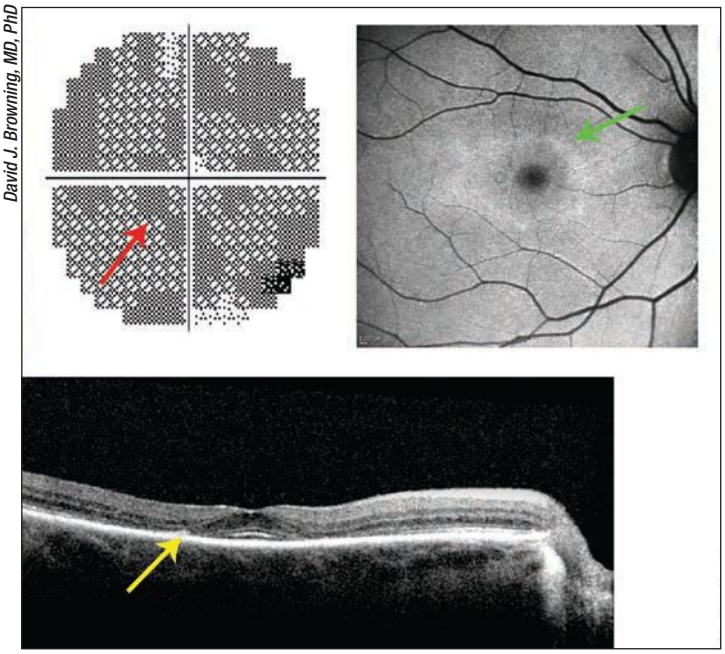
REVIEW NEWS
Volume XXIV • No. 4 • April 2017

Excess Hydroxychloroquine Dosing All Too Common

Hydroxychloroquine, the antimalarial long prescribed by rheumatologists to manage autoimmune conditions such as lupus and rheumatoid arthritis, is finding newer applications as an adjuvant to cancer chemotherapy and in diabetes mellitus management. Though its use is increasing, the association between long-term HCQ therapy and retinal toxicity is well-established. The American Academy of Ophthalmology has tried to mitigate retinal toxicity risk to patients, many of whom rely on HCQ therapy to prolong their lives and preserve function, by issuing guidance on safe dosing levels. However, a recent study[1] suggests that dosing guidance published by the AAO has had little impact on excess HCQ dosing.



David J. Browning, MD, PhD

Paracentral scotomata (top left, red arrow) in a 10-2 visual field test is a sign of toxic hydroxychloroquine dosing, as is an annulus of hyperautofluorescence (top right, green arrow) on blue fundus autofluorescence imaging. Other signs to look for are paracentral loss of the ellipsoid line and thinning of the outer nuclear layer (bottom, yellow arrow).

Lead author Rebekah A. Braslow, MD, of the Pritzker School of Medicine, University of Chicago and Division of Ophthalmology, NorthShore University Health System in Illinois, and colleagues undertook the study to find out what impact the American Academy of Ophthalmology's 2011 HCQ dosing guidance[2] has had on prescribing rheumatologists, and to help predict the long-term impact of the 2016 revision[3] of these guidelines. In 2011, the AAO recommended that patients receive no more than 6.5 mg of HCQ per kilogram of ideal body weight daily; in 2016, that recommendation was revised to 5 mg/kg/day based on actual measured body weight. Dr. Braslow and colleagues found, however, that many patients in the health-care system they studied continued to be prescribed HCQ at levels that may pose an undue risk to their retinal health.

The researchers performed a retrospective review of the medical records of the NorthShore University Health System. They identified 554 patients who'd been prescribed HCQ at least once between 2009 and 2016, and who'd also been seen by a staff ophthalmologist.

Ninety-two patients had been started on HCQ before the 2011 dosing guidelines; 462 started taking it after them. The researchers found that 54.3 percent of patients who started HCQ before the 2011 recommendations were exceeding the 2011 dosing threshold of 6.5 mg/kg/day per ideal body weight, compared with 49.4 percent who started HCQ therapy after the 2011 guidance. When the researchers applied the 2016 dosing guidelines of up to 5 mg/kg/day per actual weight using patient weights obtained from patient records, they found that 56 percent of the 527 patients still on HCQ therapy were getting excess doses. Many of the excess doses were within 50 mg of the lower dosing threshold established in 2016; but 43 percent of the current HCQ patients (224 of 527) were getting doses more than 50 mg/day above the recom-

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mended dose—some up to 450 mg/day more than the threshold amount.

The prevalence of retinal toxicity arising from HCQ is not insubstantial, with a 2014 study pegging it at 7.5 percent overall in patients on HCQ for a minimum of five years, spiking to nearly 20 percent after 20 years of daily therapy.[4] The retinal damage and vision loss that accompanies HCQ toxicity is irreversible and progresses for a period of time after discontinuing the drug. This complication leaves doctors and their patients with no recourse other than ophthalmologic monitoring of retinal toxicity once it develops, and the dilemma of whether to discontinue HCQ to slow and eventually arrest retinopathy and vision loss. Prior to modern screening techniques, a characteristic bull's-eye pattern of maculopathy was the first definitive sign of retinal toxicity, but it signifies later-stage damage to the RPE and photoreceptors. With spectral-domain optical coherence tomography, multifocal electroretinography and fundus autofluorescence imaging, more subtle early abnormalities are detectable.

Because the 2016 dosing threshold is based solely on a patient's weight instead of an ideal weight calculated using height, the authors note that the likelihood of a "safe" dose of HCQ increases correspondingly with weight, and that weight-based dosing reduces the disproportionate risk of excess dosing to thin patients. The authors suggest that a "screening referral" to an ophthalmologist isn't necessary when initiating therapy in patients, and that "the creative use of EMR to guide proper dosing" would be more helpful to non-ophthalmologists in determining a safe starting dose.

The American College of Rheumatologists released a position paper[5] in 2016 subsuming much of the AAO's latest guidance. According to Michael F. Marmor, MD, professor of ophthalmology, Byers Eye Institute, Stanford University, "The biggest problem is educating rheumatology. I have published a few alerts in rheumatology publications, but even their subspecialty journals have not embraced major editorial notice to the discipline." Dr. Marmor, who was not involved in the current study on HCQ dosing patterns, is the lead author of the AAO's 2011 HCQ dosing guidelines and the 2016 revision, and lectures widely on the topic of retinal toxicity.

He notes that rheumatology "is gradually coming around, teaching these new recommendations to trainees and educating the field." Dr. Marmor also thinks there is room for improvement on this topic in ophthalmology, however, adding, "Ophthalmologists often fail to follow these guidelines, so our field bears some responsibility for educating itself."

To step up HCQ dosing surveillance among all health-care providers, the authors recommend system-wide education and EMR-generated prompts and alerts to highlight potentially risky dosing. Dr. Marmor thinks that the idea of working warnings and dosing templates into EMR has merit, but it's not always feasible. "Alerts only work in systems that accept them. Some EMR is too complex, and notices

Correction

From Bausch + Lomb:

In the March 2017 issue of *Review of Ophthalmology*, a claim was presented on the cover tip advertisement for the Trulign toric IOL that stated: "Only one lens brings astigmatism AND presbyopia into focus." In light of recent FDA approvals, justification for this claim can no longer be maintained. Bausch + Lomb Incorporated regrets this oversight and has revised its advertising to reflect the current marketplace.

are hard to get accepted in large academic systems. Also remember that every drug has problems, and if 45 drug alerts pop up every time we see a patient, the effect will be to ignore them," he warns.

The study authors identify the commercially available form of HCQ (Plaquenil) as another contributor to excess dosing, since it only comes in 200-mg pills. They propose alternate-day regimens and the use of compounders as ways to fine-tune dosing. "A 50-mg tablet would be great," says Dr. Marmor, "except that there is no incentive for the drug industry to change an old drug." But he agrees that alternate-day doses are a simple solution. "That is a mild annoyance, but not an excuse to give an incorrect dosage," he says.

The latest study's authors conclude that the AAO's 2016 HCQ guidelines are not likely to influence dosing practices among prescribing rheumatologists absent "additional steps." Dr. Marmor emphasizes ophthalmologists' ongoing responsibility to stay informed and up-to-date on dosing protocols—and to spread the word.

"We are trying to expand awareness, and in our field of ophthalmology, we all have an individual responsibility to inform our colleagues in other fields about HCQ use, as well as about many other diseases that impact the eye," he says. REVIEW

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INDICATIONS AND USAGE

PROLENSA® (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

IMPORTANT SAFETY INFORMATION ABOUT PROLENSA®

- PROLENSA® contains sodium sulfite, a sulfite that may cause allergic type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.
- All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including bromfenac, may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including bromfenac. Use with caution in patients who have previously exhibited sensitivities to these drugs.
- There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. Use with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.
- Use of topical NSAIDs may result in keratitis. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including bromfenac, 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 suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.
- PROLENSA® should not be instilled while wearing contact lenses. The preservative in PROLENSA®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA®.
- The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

Please see brief summary of full Prescribing Information for PROLENSA® on adjacent page.

References: 1. PROLENSA Prescribing Information, April 2013. **2.** Data on file, Bausch & Lomb Incorporated. **3.** Baklayan GA, Patterson HM, Song CK, Gow JA, McNamara TR. 24-hour evaluation of the ocular distribution of (14)C-labeled bromfenac following topical instillation into the eyes of New Zealand white rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398.

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PROLENSA®
(bromfenac ophthalmic solution) 0.07%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to prescribe Prolensa safely and effectively. See full prescribing information for Prolensa.

PROLENSA (bromfenac opthalmic solution) 0.07%

Rx only
Initial Rx Approval: 1997

INDICATIONS AND USAGE

PROLENSA® (bromfenac ophthalmic solution) 0.07% is indicated for the treatment of postoperative inflammation and reduction of pain in patients who have undergone cataract surgery.

DOSAGE AND ADMINISTRATION

Recommended Dosing

One drop of PROLENSA ophthalmic solution should be applied to the affected eye once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.

Use with Other Topical Ophthalmic Medications

PROLENSA ophthalmic solution may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics. Drops should be administered at least 5 minutes apart.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Sulfite Allergic Reactions

Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Slow or Delayed Healing

All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including bromfenac, 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 bromfenac. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

Increased Bleeding Time

With some NSAIDs, including bromfenac, 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 PROLENSA ophthalmic solution 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 bromfenac, 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 post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.

Contact Lens Wear

PROLENSA should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

ADVERSE REACTIONS

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 following use of PROLENSA ophthalmic solution following cataract surgery include: anterior chamber inflammation, foreign body sensation, eye pain, photophobia and vision blurred. These reactions were reported in 3 to 8% of patients.

USE IN SPECIFIC POPULATIONS

Pregnancy

Treatment of rats at oral doses up to 0.9 mg/kg/day (systemic exposure 90 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and rabbits at oral doses up to 7.5 mg/kg/day (150 times the predicted human systemic exposure) produced no treatment-related malformations in reproduction studies. However, embryo-fetal lethality and maternal toxicity were produced in rats and rabbits at 0.9 mg/kg/day and 7.5 mg/kg/day, respectively. In rats, bromfenac treatment caused delayed parturition at 0.3 mg/kg/day (30 times the predicted human exposure), and caused dystocia, increased neonatal mortality, and reduced postnatal growth at 0.9 mg/kg/day.

There are no adequate and well-controlled studies in pregnant women. 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.

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

Nursing Mothers

Caution should be exercised when PROLENSA is administered to a nursing woman.

Pediatric Use

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

Geriatric Use

There is no evidence that the efficacy or safety profiles for PROLENSA differ in patients 70 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 (systemic exposure 30 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD] assuming the human systemic concentration is at the limit of quantification) and 5 mg/kg/day (340 times the predicted human systemic exposure), respectively, revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the 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 (systemic exposure 90 and 30 times the predicted human exposure, respectively).

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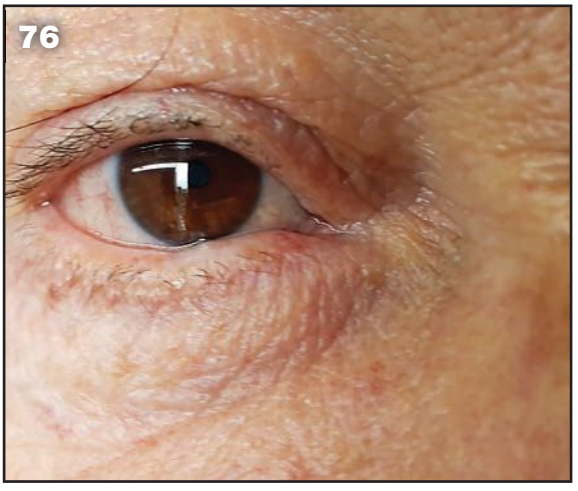

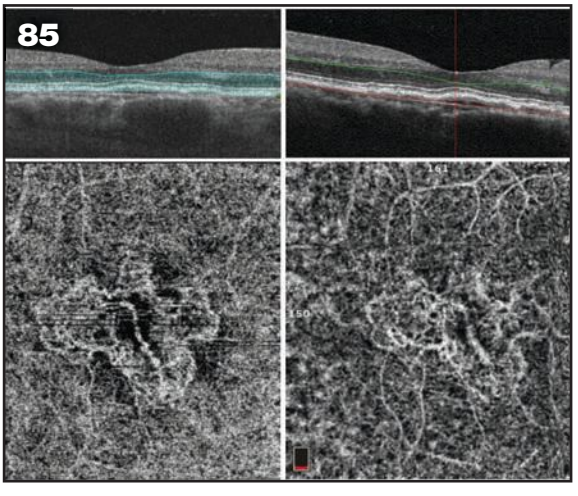

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Handheld Tablets and EMR In the Clinic

Managing electronic data during an exam can be done in a number of ways. Is a large-screen desktop the only way to go?

Christopher Kent, Senior Editor

Using electronic medical records can be a challenge for ophthalmologists, given the unique complexities of each ophthalmic subspecialty. But once that challenge has been accepted, an important question that has to be answered is how to manage digital patient data in the clinic. Given the availability of numerous computerized platforms for viewing and entering data, ranging from small, portable devices to large desktop units, many surgeons wonder which type of digital device makes the most sense in this setting.

Here, two surgeons who have used everything from smartphones to tablets to large-screen desktop units share their experiences and explain the reasons for their preference.

Using Tablets in the Clinic

"I like using handheld tablets," says John S. Jarstad, MD, an associate professor of clinical ophthalmology at Mason Eye Institute at the University of Missouri School of Medicine. "I know some doctors won't agree, but I think they're very convenient for the technicians compared to sitting at a desk and typing in data." Dr. Jarstad explains that he used electronic tablets in his previous practice for about three years before he moved to the University of Missouri School of Medicine. "We had an ophthalmology-specific EMR package when I was running my own practice, and we used the iPad in the clinic," he says. "It worked pretty well in our practice."

Dr. Jarstad says he likes many things about using electronic tablets in the clinic. "It was a little unwieldy to carry a tablet from room to room, so we didn't do that," he says. "We'd have the techs start the patients. They'd record the patient's chief complaint and history using the iPad; then they'd record the visual acuity and eye pressure and dilate the patient. Everything was ready for me when I walked into the room. The tech would hand me the tablet with the screen set up to show me the appropriate data. Then a scribe would input data as I did the exam. By the time the exam was finished, all of the drop-down menus had been completed by the technician. That system got us close to the efficiency we previously had with our paper charts."

Mounir Bashour, MD, PhD, FRCSC, FACS, is both an ophthalmologist and a biomedical engineer; he's currently a partner in LasikMD, an ophthalmologist-owned chain of LASIK centers in Canada. Dr. Bashour says he's worked with a number of electronic medical record programs, including some that used electronic tablets. "We did carry electronic tablets around with us in the office for a while," he says. "But eventually we ended up creating our own EMR software, and we're not using tablets today. Now we use large 27-inch touchscreens that let us make the most of our custom EMR; we have them in every room showing the patient's data, so we don't need to walk around with a smaller screen."

Benefits and Drawbacks

Drs. Jarstad and Bashour note a number of issues to consider when choosing whether or not to use electronic tablets in your clinic:

- ***The impact of screen size.*** "In ophthalmology, screen size is an issue because you don't want to be scrolling from screen to screen to see the data,"

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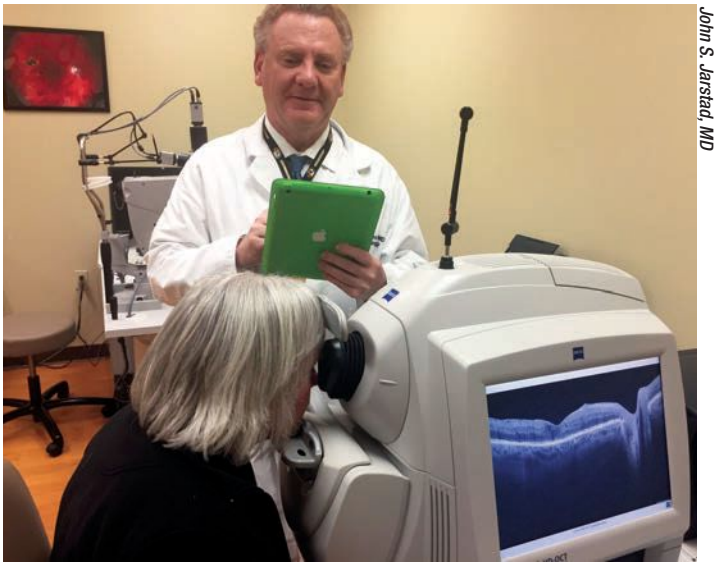
says Dr. Bashour. "Ideally, you want to be able to input all of your data on one screen. If you're scrolling forward four screens to enter data and then scrolling back three screens, that's not ideal." (Dr. Bashour notes that at home he uses a pen-based Microsoft Surface, which can be used as either a notebook or a tablet.)

Dr. Bashour points out another problem with a small screen: smaller type fonts. "I'm in my 40s and getting presbyopia, so I have to wear reading glasses to use the tablet because of the smaller type," he says. "That's not a problem if you're a young doctor, but it's an issue if you're a forty-something ophthalmologist."



John S. Jarstad, MD

Some surgeons find the portability of a handheld tablet offsets the disadvantage of a small screen—if the EMR program is designed for it.

Dr. Jarstad says he likes using the electronic tablets despite this concern. "Some of our rooms have two large-screen monitors, which lets us put all the visual fields and OCT scans and retina photos on one screen and all of the EMR data on the other," he says. "I appreciate that that's a nice way to manage the information. Using tablets we sometimes have to miniaturize everything so we can look at a whole series of visual fields at a glance, for example. That can be challenging for those of us with presbyopia. But I like using a tablet anyway."

• ***Your EMR template.*** The reality is that some EMR templates work better with a tablet than others. "To be honest, I don't yet know if our university's one-size-fits-all computer system will be able to adapt to what we need in ophthalmology, especially if we use handheld tablets," says Dr. Jarstad. "I've tried a number of EMR systems; many of them have drop-down menus and use pointing and clicking to highlight different things. That avoids the need for a lot of writing. In contrast, the current system here at the university requires quite a bit of data entry and typing."

Dr. Jarstad says their previous EMR system was set up to accommodate the small screen size. "It was organized into single pages that corresponded with each step of the exam," he notes. "There was a tab at the top that you could highlight with the pen or your finger, dropping down the menu you needed at that point. We had one screen for the technician's data; another for the slit lamp exam; one for the retina exam; and a place for the assessment and plan at the bottom. That was pretty efficient."

• ***Managing auto-shutdown.*** Another issue when using handheld electronic tablets is the security protocol that shuts down the screen after a few minutes of non-use. "That was a hassle," Dr. Jarstad says. "We had to input our password every time we walked into the room. But then we got devices that check your fingerprint, which is a big help. I highly recommend that. Otherwise, you're spending 25 or 20 seconds at every station entering your password."

• ***Weight and battery life.*** Dr. Jarstad notes that other issues are the weight of the device and how long the battery lasts. "The tablets we used were very big and heavy," he says. They had the highest capacity for data storage and a larger battery to last through an eight-hour day, so they were heavier than a typical iPad might be. Of course, these factors improve with every new iteration of these devices, but they still need to be considered when gearing up to use tablets in practice. You definitely don't want the battery to run out after four hours. We'd typically have a spare tablet charging at all times as a fallback, but most of the tablets we used had a robust enough battery to last through the clinic day."

• ***The possibility of theft.*** "Some systems that work with electronic tablets are really nice, but they still have issues, including that the tablets can be stolen," Dr. Bashour points out. "Theft is less likely if you put them in special cases with an alarm, but the alarm is sometimes triggered unintentionally."

Regarding theft of the tablets, Dr. Jarstad says he recalls one occasion when a patient left with an iPad. "It might have been an honest mistake," he notes. "In any case, it was useless without the password, and the patient returned it." He says no doctors or staff members took the iPads home when they were using them in his clinic, because those who were allowed access to the system from outside the office could do so on their home computer or smart device for charting or scheduling.

• ***Some uses are very appropriate for a tablet.*** Dr. Bashour says his practice still uses electronic tablets for

some things, including patient consent forms. "Tablets are convenient for that purpose," he says. "We just hand them to patients. They can read everything on the screen and sign directly on the electronic tablet; that's attached to their EMR record. Tablets are good for this because everyone's familiar with them. Almost everybody has one at home, so patients know how to use them."

• ***Surgeon comfort with a given device may relate to previous experience.*** Dr. Jarstad points out that a doctor's preference will be affected by what he or she used in training. "We become accustomed to practicing medicine the way we did as residents," he notes. "EMR in general is new to many of us. You just have to take the time to learn the system and practice with it; over time you get better and better at using it. If you're not willing to do that, the only solution is to hire young, smart technology-wise people who are good at using electronic devices."

What the Future May Hold

Will small, portable screens become more popular for clinic use in the future? "Tablets are useful if they fit the way you do things," says Dr. Bashour. "Meanwhile, their usefulness may change as computer technology evolves. Hopefully, things will become more simple; we may have artificial intelligence following us around—perhaps a small robot taking notes. That's a few years away, but it's coming."

Dr. Jarstad is looking forward to having voice-activated EMR systems. "In the future we'll have systems that will let us dictate our findings," he says. "They'll be more user-friendly and do more; they'll make it easier to input data and even code for us."

In the meantime, Dr. Jarstad still believes using an electronic tablet in the exam room has the potential to work well, no matter what your ophthalmic subspecialty. "I have a colleague who uses a tablet in his oculoplastics practice and swears by it," he says. "He can draw his findings regarding the eyelids and so forth, and he has templates for each area of concern. He swears by it and won't use any other system. I also have a retina colleague here at the university who uses it exclusively to make his retina drawings. So I think it can be done; it's just up to the personal preference of each physician." REVIEW

Drs. Jarstad and Bashour have no financial ties to any product discussed.

Donna McCune, CCS-P, COE, CPMA

Corneal Collagen Cross-Linking

This month, we look at reimbursement considerations for this increasingly popular procedure.

Q What is corneal collagen cross-linking?

A Corneal collagen cross-linking is a procedure that stiffens the cornea through a combination of exposure to ultraviolet light and eye drops containing riboflavin (vitamin B2). The procedure, as approved, begins with debridement of the epithelium followed by the application of riboflavin eye drops at frequent intervals for about half an hour to saturate the corneal stroma. Some surgeons, however, advocate cross-linking without epithelial debridement, called the "epi-on" technique. This epi-on technique avoids issues with epithelial healing and patient discomfort as short-term concerns.

After applying riboflavin, the cornea is exposed to UV light, causing the collagen fibrils to interconnect, thus increasing corneal rigidity. CXL has shown promise in clinical trials in several conditions. The idea is to intervene early to stiffen the corneal collagen matrix without affecting the corneal refractive index.

Q What are the clinical indications for this treatment?

A CXL is used to treat corneal ectasia from progressive conditions such as keratoconus, other corneal degeneration or a complication following keratorefractive surgery. UV light is effective at treating infections, so CXL has also been advocated for some types of corneal infection.

The American Academy of Ophthalmology Preferred Practice Pattern on corneal ectasia notes:

- *Young [age]… or postkeratorefractive surgery patients who … have unstable refractions should be evaluated for corneal ectasia.*
- *Signs of … ectasia include inferior steepening, superior flattening... [and others].*
- *It is impossible preoperatively to identify all patients at risk …*

Collagen cross-linking has the potential to reduce the risk … of ectasia (… in early stages) and stabilize the corneal contour.

Q What are the CXL approval parameters in the United States?

A In April, 2016, Avedro Inc., received approval from the U.S. Food and Drug Administration for Photrexa Viscous, Photrexa and the KXL System. Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% and Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146% are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus.

Q Is there a CPT code for the CXL procedure?

A Yes. Use Category III CPT code 0402T (*Collagen cross-linking of cornea including removal of the corneal epithelium and intraoperative pachymetry when performed*) to report this procedure. AMA released this code on July 1, 2015, and it was effective January 1, 2016.

Q Are there any procedures that may not be reported in conjunction with 0402T?

A Yes. 0402T may not be reported in combination with CPT codes 65435, 69990 or 76514.

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

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Q Will third-party payers consider CXL a covered procedure and reimburse for it?

A As with all Category III codes, payment is at the discretion of the payer and typically handled on a case-by-case basis. Payers may consider this experimental and investigational and therefore, non-covered.

Q Are there any published payment policies addressing CXL coverage?

A Not many. Aetna has a published policy titled Corneal Remodeling. This policy was slated for review in January, 2017. It includes the following information regarding the medical necessity of CXL:

"Collagen Cross-Linking for Keratoconus: Aetna considers epithelium-off photochemical collagen cross-linkage using riboflavin and ultraviolet A medically necessary for keratoconus and keratectasia. Photochemical collagen cross-linkage is considered experimental and investigational for all other indications because its effectiveness for other indications has not been established. Epithelium-on (transepithelial) collagen cross-linkage is considered experimental and investigational for keratoconus, keratectasia, and all other indications. Performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intraocular lens implantation) is considered experimental and investigational."[1]

Q Are payment rates for CXL published?

A Commercial payers determine their own unique reimbursement rates; rarely do they publish them. The Medicare Physician Fee Schedule doesn't publish reimbursement rates for Category III codes. Medicare does publish facility rates for ambulatory surgery centers and for hospital outpatient departments for Category III codes. In 2017, the national ASC reimbursement rate for 0402T is $418; for the HOPD it is $774. This includes all equipment and supplies used during the procedure.

"Use Category III CPT code 0402T (Collagen cross-linking of cornea including removal of the epithelium and intraoperative pachymetry when performed) to report this procedure. AMA released this code on July 1, 2015, and it was effective January 1, 2016."

Q May patients be charged for the procedure if insurance coverage is unlikely?

A Yes, patients may be asked to pay for the procedure as long as the patient is informed before the procedure. Explain to the patient why CXL is necessary, and that Medicare or other third-party payers will likely deny the claim. Ask the patient to assume financial responsibility for the charge. A financial waiver can take several forms, depending on insurance:

- An Advance Beneficiary Notice of Noncoverage is required for services where Part B Medicare coverage is ambiguous or doubtful, and may be useful where a service is never covered. You may collect your fee from the patient at the time of service or wait for a Medicare denial. If both the patient and Medicare pay, promptly refund the patient or show why Medicare paid in error.
- For Part C Medicare (Medicare Advantage), determination of benefits is required to identify beneficiary financial responsibility prior to performing non-covered services; MA Plans may have their own waiver processes.
- For commercial insurance beneficiaries, a Notice of Exclusion from Health Plan Benefits is an alternative to an ABN. The patient may be asked to pay in full for the procedure and should the payer provide coverage, the patient receives a refund.

Q If insurance provides reimbursement but the rate is extremely low, what recourse exists?

A Unfortunately, if you are a contracted provider with the payer, you are required to accept the allowed amount as payment in full. You may submit an appeal to the payer providing cost details and request additional funds. REVIEW

Ms. McCune is vice president of the Corcoran Consulting Group. Contact her at DMcCune@corcoranccg.com.

1. http://www.aetna.com/cpb/medical/data/1_99/0023.html accessed 20 March 2017.

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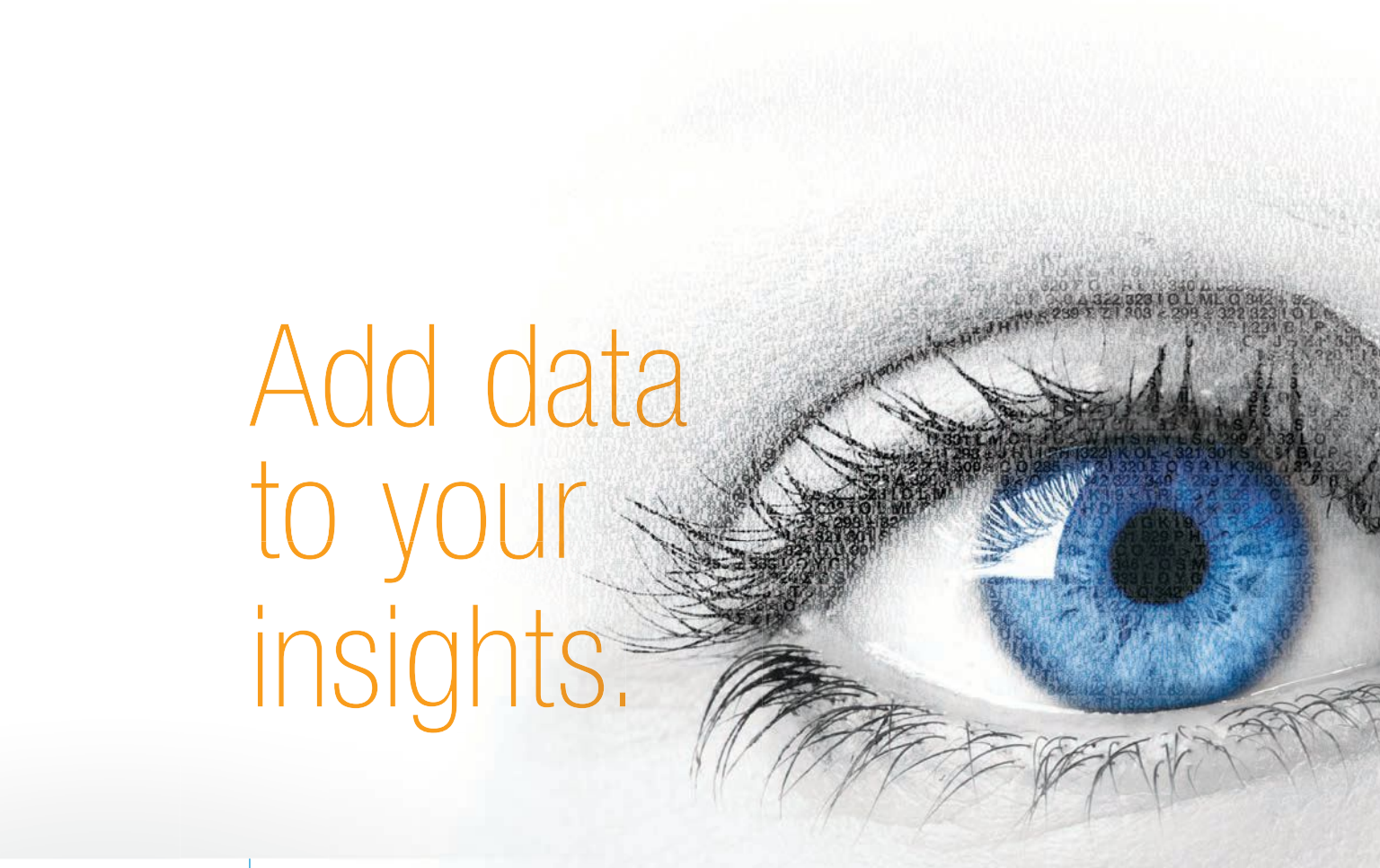

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The population is aging. More than 10,000 Americans turn 65 every day, and that will continue for the next 25 years.[1] The number of people diagnosed with age-related macular degeneration (AMD) in the United States is expected to more than double from 2.07 million to 5.44 million between 2010 and 2050.[2]

It's unknown if we have enough specialists to manage double the number of patients. No matter what, we're going to have huge dynamic shifts in ophthalmology and optometry in the United States.

We also know that younger patients may be at greater risk than previously considered. The blue light emanating from digital devices could play a significant role in changing patterns of disease development. These highly visible-light-density-type wavelengths could affect the retina and increase the risk of blindness from the early onset or proliferation of AMD.

In many cases, once AMD is diagnosed in the first eye, we manage to save the other eye the majority of the time. That means we're taking a greater interest, following the patient more carefully and looking for key signs. This inevitably prompts the question: Why didn't we do that the first time around? Why didn't we try to save that first eye, and start looking for clues at a younger age?

One strategy to combat macular degeneration is through nutritional supplementation. AREDS2—published in 2013—is the largest study completed on the impact of nutritional supplements on AMD progression with various cohorts.[3] Since then, other significant studies have helped us further understand the role diet and nutritional supplements play. How can we reduce the risk of disease emergence and progression?

We put together an esteemed panel to discuss this issue in a way that will aid clinicians in their management of macular degeneration and understanding of the role of nutritional supplements.

AREDS2 Revisited: The Third Carotenoid

Dr. Karpecki: *In the AREDS2 study design, there was a belief that the addition of macular carotenoids, such as lutein and zeaxanthin, may aid in reducing the risk of disease progression. At the time, meso-zeaxanthin was not well-known. Since then, what have we learned about the role of meso-zeaxanthin?*

Dr. Beatty: AREDS2 showed us that supplementation with some macular pigment carotenoids does reduce the risk of disease progression and visual loss if you have non-advanced AMD. However, there were two problems with the AREDS2 study. First, the study formulation had high levels of zinc; some papers have since come out suggesting that, for certain AMD patients with a specific genetic background, the high levels of zinc in AREDS2 cause disease progression.[4] Second, there are three components to macular pigment: lutein, zeaxanthin and meso-zeaxanthin. All head-to-head trials have shown that including meso-zeaxanthin not only increases macular pigment centrally, where you most need it, but also enhances visual performance in patients who have early AMD.[5,6]

Dr. Sherman: I, and perhaps many others, started to pay close attention to meso-zeaxanthin when an article titled "Targeting AMD with a Critical Carotenoid" was published in *Review of Ophthalmology* in March 2011.[7] The paper was authored by arguably four of the world's experts in this area: Drs. Richard Bone, John Landrum, Stephen Beatty and John Nolan. The critical carotenoid identified was meso-zeaxanthin. Since I read that article, there have been some very important studies published with similar findings and conclusions.

Need for Meso-Zeaxanthin Supplementation

Dr. Karpecki: *One question that comes up around meso-zeaxanthin concerns its origin. Isn't it wholly derived, or could it be wholly derived, from retina lutein? And in a related point: Is there a need to supplement meso-zeaxanthin?*

Dr. Renzi-Hammond: I think that all of us would love to live in a perfect world, one where we advocate letting 'food be thy medicine and medicine be thy food.' If you can eat a sufficient amount of healthy food, that is ideally where you should be getting these dietary components. Where meso-zeaxanthin is concerned, if our general populous is not able to get enough basic lutein and zeaxanthin out of their diets, we're really sort of reaching if we believe they're going to go out and eat enough fish skin, for example, to acquire this byproduct of a molecular conversion. There is a pretty strong consensus that suggests meso-zeaxanthin is made from lutein, but one thing that we are absolutely unclear on with respect to carotenoid biosynthesis is whether all members of the population are able to conduct this conversion appropriately. Dietary supplementation with something like meso-zeaxanthin is going to be the only way to achieve the necessary levels unless you're relying on your own biochemistry to do the job. For most people, that's enough, but likely not for all.

Dr. Beatty: In a recent study, we showed meso-zeaxanthin is in trout flesh and a few kinds of fish skin, but these are not typical dietary staples.[8] I agree with Dr. Renzi-Hammond—there is a consensus that retina meso-zeaxanthin is derived in part from retina lutein. This is based on two older studies: one in primates and one in


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quails.[9,10] However, is it not true that all retina meso-zeaxanthin is derived from retina lutein? If you look at the quail study, the lutein only accounted for 50% of the meso-zeaxanthin found. Also take into account Paul Bernstein's research, which shows that you need all three macular carotenoids present in a 1:1:1 ratio to exert maximum antioxidant effect.[11] The lutein supplement given to the animals in the above studies probably contained some meso-zeaxanthin that researchers were unaware of, accounting for part of the meso-zeaxanthin detected. I think those studies really do need to be revisited. Even just two years ago, Dr. Karpecki's question would have been put very differently; we would have been much more affirmative that meso-zeaxanthin is derived from lutein. That's now been questioned. I suspect meso-zeaxanthin does derive, in part, from lutein in the retina. But, as Dr. Renzi-Hammond says, if it can be delivered prepared and pristine without any bioconversion necessary, which perhaps not all people can achieve, wouldn't that be the sensible thing to do?

Dr. Karpecki: *Do you have anything to add on the role of meso-zeaxanthin in the macula itself, its central location or its high concentration?*

Dr. Sherman: It appears that meso-zeaxanthin is found pretty much in one place, towards the center of the fovea. For some reason it's there, and it must have a purpose. Hence, if we want our fovea to work, it seems like we want a high level of meso-zeaxanthin, either in a diet or added as a supplement.

"Where meso-zeaxanthin is concerned, if our general populous is not able to get enough basic lutein and zeaxanthin out of their diets, we're really sort of reaching if we believe they're going to go out and eat enough fish skin, for example, to acquire this byproduct of a molecular conversion." *— Dr. Renzi-Hammond*

Lutein Absorption & the Literature

Dr. Karpecki: *The AREDS2 study results showed that beta-carotene actually inhibited the absorption of carotenoids like lutein and zeaxanthin in the cohort receiving carotenoids with beta-carotene. We've also heard that meso-zeaxanthin may inhibit the absorption of lutein because it's similarly a carotenoid. What are your thoughts on this, and are there any recent studies that validate your opinion?*

Dr. Beatty: In a study we just published in *Eye*, three groups of patients, all with early AMD, were supplemented with 20mg of lutein, 2mg of zeaxanthin and a few undeclared nanograms of meso-zeaxanthin vs. the MacuHealth formulation—which is 10mg of lutein, 10mg of meso-zeaxanthin and 2mg of zeaxanthin—vs. very high meso-zeaxanthin.[12] What was amazing was the serum lutein response was just as high in those supplemented with 10mg of lutein and 10mg of meso-zeaxanthin when compared with those supplemented with 20mg of lutein. In other words, supplemental meso-zeaxanthin did not inhibit the gastrointestinal absorption of lutein what-

soever. And we're talking about serum response, so there's no ambiguity here.

Dr. Renzi-Hammond: We've known for a very long time that high doses of beta-carotene will inhibit absorption in the gut. This is not something new to us. It's been an issue since the 1990s, when papers came out that documented this effect.[13-16]

Carotenoid Improvements on Macular Pigment

Dr. Karpecki: *What are the most important foods we should be telling our patients to consume to get the greatest carotenoid benefit from diet, and is that sufficient, or is the key really additional supplementation?*

Dr. Renzi-Hammond: Let's take our best-case scenario. We have a well-nourished patient who is eating a healthy diet, rich in fruits and vegetables, whole grains, fatty fish, and is low in dietary sources of saturated or trans fat. We like to believe that is enough, and for those who are otherwise leading a healthy lifestyle, it very well might be. One thing that is likely true is that the nutritional content of food is simply not what it was a long time ago. Foods are now frequently genetically modified, soil quality has changed, and we are exposed to a number of oxidative stressors, endocrine disruptors and other less-than-optimal chemical compounds we were not exposed to in the history of our species. The other issue to consider is that even a good diet is not a magic bullet. All things that we ingest are going to be better absorbed or more poorly absorbed depending on other factors present. An individual with high body fat percentage, for example, who might be trying to eat decent food but is not exercising, is potentially going to be storing a lot of these carotenoids in fat depots in the body and not absorbing what they should. We have the convenience diets that most of us rely on; 60% of the food we eat in the United States is processed. So, supplementation is becoming more necessary, given our lifestyles.

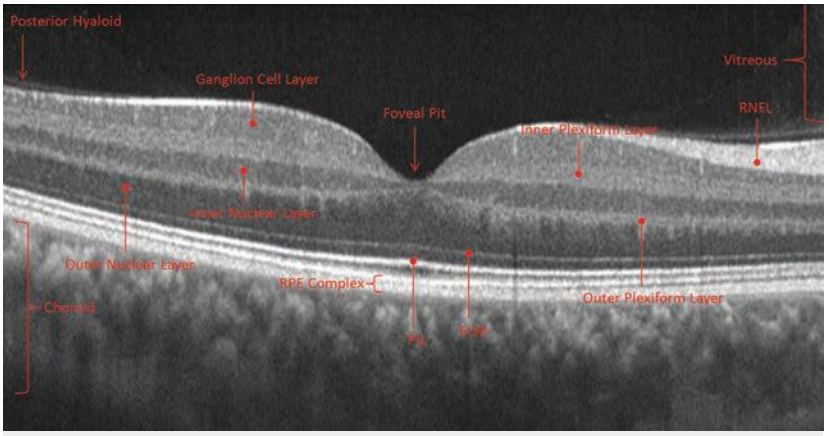
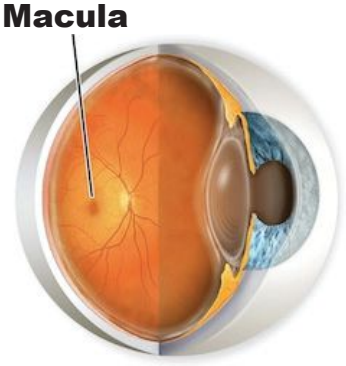


Photo by: Jerome Sherman, OD

In the eye, high concentrations of meso-zeaxanthin are contained within, and immediately around, the foveal pit, as visualized here by OCT.

Dr. Beatty: I want to echo everything Dr. Renzi-Hammond said. What is interesting is if you take a room full of well-fed people who have good diets and you supplement them, their macular pigment increases. And an increase in macular pigment does enhance your visual performance. A healthy diet rich in fruits and vegetables is absolutely fine, but we're living so much longer than we used to. Whether or not we need to supplement as a matter of routine to give us the tissue concentrations of certain nutrients to allow us to age



The Zinc Paradox

Dr. Karpecki: *Is there anything to the concern that some zinc oxide supplements may use greater than the recommended dietary allowance (RDA) level or a non-oxide version?*

Dr. Sherman: The National Eye Institute still continues to recommend 80mg of zinc per day even though the AREDS2 study demonstrated no difference between 80mg and 25mg. Does that make any sense? I think it makes sense to virtually no one and yet that's what many of us are still doing. In the AREDS1 study, the comparison was 80mg of zinc vs. 0mg. For those patients with a specific genetic profile—14% to 19% of the population—who were taking 80mg of zinc, many actually got worse. There's mounting evidence that 80mg of zinc is doing a lot of harm to at least that subgroup of people. So, dosage is critical. Paracelsus, the father of modern toxicology, noted more than 500 years ago that the right dose differentiates a poison and a remedy. And when the recommended daily allowance is about 10mg, why should we ever consider going to 80mg of zinc?

Dr. Beatty: If you go to the website of the Office of Dietary Supplements of the National Institutes of Health, you will see the RDA is 8mg for a woman and 10mg for a man, and the upper tolerable level is 40mg. In other words, 80mg is too much. It would seem to me that from a legal perspective—forget for a moment the scientific basis—you're exceeding the recommended dietary allowance. It just would seem counterintuitive to me to do that, which is why I use a formulation that contains 25mg of zinc.

gracefully and healthfully is the question. There's no evidence base to say you can get enough from your diet through your 80s because we've only been living to our 80s for 20 years.

Dr. Sherman: Findings from the CREST study may shed light on this issue.[17] Starting with seemingly normal individuals who had relatively low levels of the three carotenoids in their serum, researchers supplemented this group with lutein, zeaxanthin and meso-zeaxanthin, and demonstrated macular pigment improvements. However, it's simpler to show a change in subjects with relatively low levels of the carotenoids than it is to look at those who have very healthy diets and high carotenoid levels.

Dr. Beatty: In that study, we were afraid of having a ceiling effect, so we purposely chose subjects who had macular pigment of 0.5 or less. I think Dr. Renzi-Hammond would support me here in saying 0.5 isn't that low. We're not saying only people with appalling diets need supplementation, but also those with "lowish" macular pigment levels.

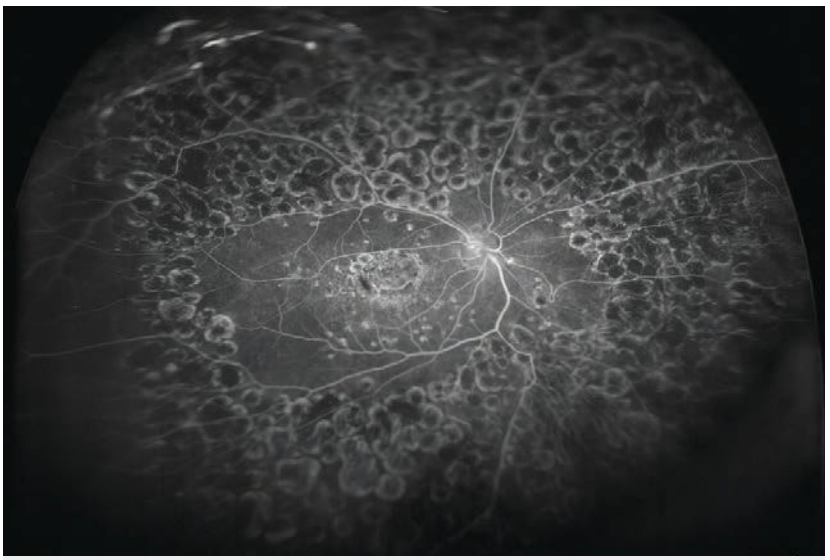
Dr. Renzi-Hammond: About 10 years ago, when my collaborators measured the optical density of the pigment, they found the average in the United States was right around 0.3.[18,19] We're in the process of completing a study looking at young, "healthy" adults, college students clicking away on all cylinders cognitively; and older adults—those aging well, and others manifesting signs of mild cognitive impairment. One finding that was sort of shocking: In the young, healthy adults who should not have been able to improve very much, as soon as retinal levels of these carotenoids began to change, we saw corresponding changes in cognitive function.

Dr. Beatty: The point Dr. Renzi-Hammond just alluded to is that having high levels of macular pigment does not mean you won't benefit from supplements. Even with a baseline score of 0.8, one can't assume that going up to 1.3 won't help; it does. We chose subjects who

> ***"A healthy diet rich in fruits and vegetables is absolutely fine, but there's no evidence base to say you can get enough from your diet through your 80s because we've only been living to our 80s for 20 years."*** *— Dr. Beatty*

The *Eye Care Provider* as a Neuroscientist

Photo by: Optos



Patients with type 2 diabetes are at an elevated risk for diabetic retinopathy and macular edema, as seen here on fluorescein angiography. Lifestyle changes, dietary alteration and nutritional supplementation can help limit the development and progression of diabetic eye disease.

were at 0.5 or less, and those given MacuHealth vs. the placebo exhibited improvements in visual function, especially contrast sensitivity.

Prevention Strategies

Dr. Karpecki: *Why would young, healthy patients with good vision want to maximize macular pigment?*

Dr. Renzi-Hammond: We focus a lot on the population that already has a condition, and we sort of ignore what's going on in the 75 years leading up to that state. Then we assume that we can intervene with nutrition and actually have some success. We're lucky to be in a field—vision science—where we can make a difference in a patient with disease. For the most part, though, the bulk of where we should be spending our energy is before they ever get to that point, to make every effort at prevention.

Dr. Sherman: Something else to think about: When does age-related macular degeneration begin? One could argue that it begins in utero because your genetic profile is already set. Age-related macular degeneration may start at age 0 and not really affect the patient until they are 65, 70 or 75.

Dr. Beatty: I firmly believe the reasons for supplementation in young people is twofold:

Dr. Karpecki: *Can you comment on the link between macular carotenoids and cognitive function?*

Dr. Renzi-Hammond: The retina is a wonderful prognostic indicator of what's going to happen to the rest of the central nervous system. When you see signs of hypertension, your patient might not have been diagnosed as hypertensive yet. When you see optic neuritis not linked to ocular disease, you're the first person who's going to be able to tell that patient, 'you need to go see a neurologist.' And, in my view, when we detect evidence of age-related macular degeneration, we might be also seeing signs of Alzheimer's disease. Eye care professionals, to me, are the one health care providers regularly looking at the central nervous system, with some ability to predict how the rest of the central nervous system is going to go. Dr. Beatty's group and my team have done studies where we have supplemented macular carotenoids and seen improvements in cognitive function. Other sites like the University of Illinois at Urbana-Champaign and Tufts University in Boston have seen the same thing. There's a confluence of evidence.

Dr. Beatty: We were involved in the Irish Longitudinal Study on Aging, and we measured macular pigment as well as the results of 12 tests of cognition on 5,000 subjects over 55 years of age.[20] Eleven of those 12 tests related positively and significantly to macular pigment levels. In other words: The more pigment you have at the back of your eye, the better your cognition.

one, for visual performance enhancement, which is demonstrable within months; and two, to protect against long-term chronic and cumulative damage, which cause AMD and contribute to Alzheimer's disease.

Role of Ocular Nutrition in U.S. Healthcare

Dr. Karpecki: *Looking at the U.S. system of overall healthcare, ACOs, the evolving role of optometry and the shortage of surgeons in ophthalmology, can you discuss what ocular nutrition means to the future of healthcare?*

Dr. Sherman: We do have some responsibility for the overall health of the patient. The vast majority of type 2 diabetes is completely preventable, and yet it's going to not only cause blindness and a multitude of deaths, it's going to bankrupt our entire healthcare system if we don't get a handle on it. Ophthalmologists and optometrists in the position to play a role in preventing macular degeneration, and also diseases like diabetes that are much more common in the entire population.

Dr. Renzi-Hammond: One thing we know is that when we start giving adults in the hospital oral nutritional supplements, readmission rates drop. The healthcare system spends less when we care about nutrition, and that's just with respect to critical care admissions. Right now, pharmacology is in many cases cheaper than nutrition, so if we could start looking at what we would save—the health economics of giving people better nutrition—then we would be in a much better position where prevention is concerned. I also feel that for a lot of folks in financial hardship, if you're working three jobs, poor nutrition doesn't stem from laziness or lack of awareness. The patient's mindset is not, 'I don't know that I should eat this food' but rather, 'I don't have the money, and I don't have the time.' If we can start nutritionally supporting this group of people in a different way, we're helping the percentage of the population that is most likely to get these sorts of degenerative diseases.

Dr. Beatty: We also need to talk about how to help the optometrist. Their practice revenue model has historically relied on refraction and corrective lenses. But optometrists are both vision specialists and *eye* specialists. If they want to avoid being squeezed by the ever-reducing cost of Internet sales, if they want to make a space for themselves that won't be occupied by busy ophthalmologists, this is the space: macular pigment and how it relates to visual function and brain function.

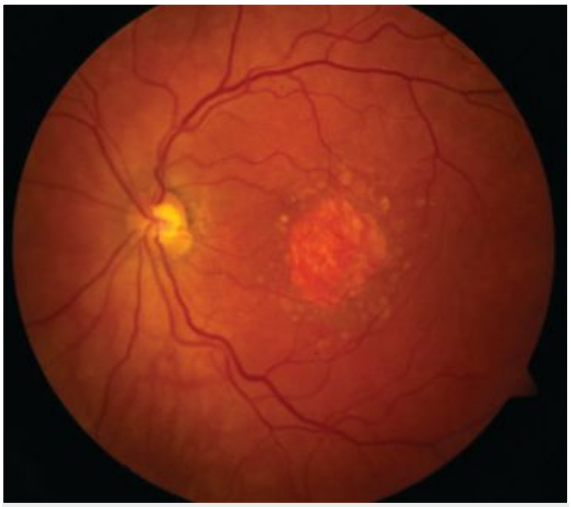
> ***"We have to start to feeling comfortable talking about lifestyle changes. An obese patient sits in the chair: They can't ignore that. Somebody who hasn't exercised in the last 12 years: They can't ignore that either. Patients can live a long life, in many cases, just by controlling lifestyle choices. And some of them are making terrible choices. Most eye care providers don't want to touch that, but they should."*** — Dr. Sherman

Talking to Patients

Dr. Karpecki: *What do I need to have at the tip of my fingers when reviewing ocular nutrition with patients who have macular degeneration or disease, and those who don't?*

Dr. Sherman: We have to start to feel comfortable talking about lifestyle changes. An obese patient sits in the chair: They can't ignore that. Somebody who hasn't exercised in

Photo by: National Eye Institute



Multiple clinical trials have indicated that nutritional supplementation with dietary carotenoids, particularly meso-zeaxanthin, can improve contrast sensitivity and enhance overall visual performance in patients with early age-related macular degeneration, as seen here.

the last 12 years: They can't ignore that either. Patients can live a long life, in many cases, just by controlling lifestyle choices. And some of them are making terrible choices, unfortunately. Most eye care providers don't want to touch that, but they should.

Dr. Renzi-Hammond: We need to understand how to be prescriptive. I know that if I can get my 90-year-old research subject to start lifting weights, she will beef up her bone mineral density and get a little bit of brain-derived neurotrophic factor, she'll grow some new neurons. How do I tell a 90-year-old woman to go pump some iron? If I just tell her, 'You need to go exercise,' she is probably not going to join a gym. We need to give our eye care professionals prescriptive tools: You should be able to say, 'Here's what you need to achieve in ocular nutrition: Take this daily with a meal. Here is a list of vegetables that are good for your eyes. Eat at least three a day.' Patients understand better how to change their behavior when instructions are clear, rather than the vague suggestion of, 'improve your diet.'

Dr. Beatty: I tell patients that supplementation has three roles in terms of the eye: one, to optimize your visual performance regardless of your age; two, to reduce the risk of progression of macular degeneration and potential vision loss; and three, to prevent disease. We know there is a lack of macular pigment decades before the onset of disease. But what I say, and it's borne out by AREDS2, is that this is not hypothetical; this is no longer a theory, this is a fact. It is good for you; you need to take these supplements. ◆

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How to Fight Insurance Companies—and Win

Christopher Kent, Senior Editor

Surgeons share strategies for getting what you and your patients need from insurers.

Many aspects of practicing medicine in today's world have little to do with the actual practice of medicine, and most physicians would not be sorry to see them disappear into the sunset. One of them is dealing with insurance companies. Although insurance is—in theory—a good thing for patients, outside of Medicare it's largely a for-profit industry. That means that while insurance can keep patients from being financially overwhelmed by an unexpected medical crisis, insurance companies have plenty of motivation to deny patient claims as often as possible and to negotiate contracts with doctors that squeeze practice budgets.

This certainly doesn't mean that dealing with insurers is all doom and gloom, but it does mean that any interaction is a negotiation. For that reason, you need to approach dealing with insurers strategically, both for your benefit and your patients'. Here, surgeons share what they've learned about interacting with insurers to get the best possible results for your practice and your patients.

The Trouble with Insurance

While most surgeons have encountered numerous situations in which insurers have balked at providing coverage, there are a few that come up frequently.

"The insurance companies have lots of guidelines, especially in terms of step therapy," says Mark Packer, MD, FACS, president of Mark Packer MD Consulting in Boulder, Colo. "We see that a lot with pharmaceuticals, where they place limits on the more expensive therapies; we can't prescribe Restasis or Xiidra until we've exhausted artificial tears and any other treatment options. We also see extensive guidelines for procedures that are performed frequently, like cataract surgery, and for procedures that may or may not really be medically indicated. The big one in the latter category is blepharoplasty, which can be performed to address a functional problem but may also be performed for cosmetic reasons. The insurers want to see a visual field test confirming a functional problem before they'll agree to pay for it.

"It's pretty clear that the prior authorization process that commercial insurers have is a cost-saving measure," he continues. "The companies want to have their person look at your chart and decide whether or not procedures X, Y and Z are actually indicated and within their guidelines. So we put together a dossier for a given patient which will hopefully convince

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the medical reviewer that our patient needs cataract surgery, a blepharoplasty, a prescription for Restasis or whatever it is."

"Today, Medicare is easier to deal with because we have a pretty good idea of what it will pay for," says Robert J. Noecker, MD, MBA, an assistant clinical professor at Yale University School of Medicine, clinical professor at Quinnipiac University, and in private practice at Ophthalmic Consultants of Connecticut in Fairfield. "It used to be that people would worry about leaving their commercial insurance, but today Medicare is the most transparent insurer. No one's getting rich off of it and Medicare patients understand exactly what they'll be paying for."

Denials for Drugs

One big insurance company hurdle that frustrates ophthalmologists is approval of the use of brand-name drugs. "We regularly get denials for medications like Xiidra and Restasis and brand name anti-inflammatories," says John A. Hovanesian, MD, a specialist in refractive surgery, cataracts, cornea and external disease at Harvard Eye Associates in Laguna Hills, Calif., and a clinical assistant professor at UCLA Jules Stein Eye Institute in Los Angeles. "In those situations we decide on a case-by-case basis whether it's worth pushing back. Unfortunately, the number of denials is increasing."

Dr. Noecker notes that this is especially problematic when patients need to use a drug on a chronic basis, such as topical drops for glaucoma. "There's a really big push toward fewer and fewer medications being covered," he says. "That's especially true for branded medications, but even the spectrum of things that used to have relatively low copays has shifted. As recently as last year, some branded medications cost the patient $30 or $40; today they cost $60 or $70. Some of them have been dropped from formularies altogether, while others have gone from $50 to $200. That's really disruptive for the patient.

"Some insurers won't allow two surgeries to be done at the same time. ... Doing the two surgeries separately increases patient risk."
— Robert Noecker, MD

"It's also challenging for the doctor," he continues. "It's a lot of work to figure out what works best for a given patient. Over a few visits you determine that one drug seems to work best for the patient in terms of side effects and efficacy. Then you have to throw all of that out the window because it's a new year and the drug that was working for the past five years now costs four times as much. We have to start from scratch to find an alternative medication that will be just as good as what the patient was using before. That means more work for both the doctor and the patient, and if the patient has glaucoma it increases the risk of progression. That's a serious problem, because if the patient gets worse while you're trying to find an alternative drug, you can't undo the damage; the vision loss is permanent."

Dr. Noecker notes that the setup is particularly unfair if a drug isn't covered by insurance at all. "When patients pay for a drug, they pay the full cash price," he points out. "The insurance companies get significant rebates, as much as 50 percent off, but patients don't get that. Why should the patient have to pay more than the insurance companies are paying? The system is crazy."

Three More Obstacles

Dr. Noecker notes three additional issues that he's found troubling when dealing with commercial insurers: First, some insurance companies are refusing to cover medications for cataract surgery on the second eye until some arbitrary amount of time has passed since the first surgery. "With many patients, we do one eye and plan to do the other eye a few weeks later," he says. "More and more insurance companies are saying, 'It's too soon—we won't pay for another bottle of antibiotic.' In reality, it's a new surgery for a new eye and these medications are the standard of care, so this is a big problem, even if we try to help the patient out with samples.

"We never used to see this," he continues. "Patients used to get whatever they needed to have a successful outcome. It's troubling when the patient has a very good surgery and we expect him to do well, and then he can't get the eye drops. That puts the patient at risk of an infection or prolonged inflammation, which can mean poorer vision and a slower rehab. It's a source of frustration for us and a source of anxiety for the patient."

Dr. Noecker says insurers are also being difficult about the newer glaucoma surgeries. "We're seeing increasing pushback when we try to use MIGS devices like the iStent, CyPass or Xen implants," he notes. "These things are available and FDA-approved and patients read about them, but we can't use them because the insurance won't cover them. Patients have to pay out of pocket if they want these newer, more advanced technologies. I've even seen insurers categorize canaloplasty as an 'experimental procedure,' although it's been in use for a decade."

A third issue Dr. Noecker notes is carrier unwillingness to pay for combined surgeries. "A patient may have both glaucoma and a cataract, but some insurers won't allow the two sur-

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Strategy: Get the Patient Involved

John A. Hovanesian, MD, a clinical assistant professor at UCLA Jules Stein Eye Institute in Los Angeles, points out that when fighting on behalf of individual patients with a commercial insurance carrier, the patients themselves may be the strongest leverage you have. "If the patient is articulate and willing to be his or her own advocate with the insurance carrier, it generally carries far more weight than your comments," he says. "After all, the patient is the insurance company's customer—you're not.

"Generally, when a claim is denied, the insurance company provides your office with a reference number," he says. "Just pass that information along to the patient. Tell the patient, 'I've taken this as far as I can. This is an opportunity to speak up for yourself.' Usually the patient just has to call the number on their insurance card to be connected to somebody who's an advocate."

Dr. Hovanesian says that some patients can be quite effective and persuasive. "They may tell the person at the insurance company, 'Look, I'm going to tell my employer not to work with you in the future. I'll file a complaint and ask that we change to a different carrier next year.' That kind of threat carries a lot of weight, because many employers do respond to employee complaints," Dr. Hovanesian notes. "If a company is evaluating insurance options at the end of the year and employees have complained about the current insurer, they're likely to look at others. Obviously, cost will factor into that decision, but in many cases there isn't a big cost difference between carriers."

Mark Packer, MD, FACS, president of Mark Packer MD Consulting in Boulder, Colo., agrees that a letter from the beneficiary to the insurer can be very helpful. "I haven't done this often with cataract surgery, because usually the more objective testing is sufficient," he says. "But with a denial for blepharoplasty it can really be an issue. Insurers just want to deny claims for blepharoplasty; that's their default. To get it approved you have to submit photos and visual fields, but even those may not show enough difference. After all, we have to do the visual fields au naturel and then with the eyelids taped up to show that there's a difference between the two, and that's hardly an exact science.

"So, when fighting a blepharoplasty denial, a letter from the patient is really helpful," he continues. "The patient might say, 'I was backing out of my driveway and I almost ran over my neighbor's kid, because when I look over my left shoulder, my eyelid is hanging down and there's nothing I can do. I can't let go of the steering wheel and hold my eyelid up with my fingers.' Stories like that can be really compelling for medical reviewers. The last thing they want to do is deny a blepharoplasty and then have the patient cause an accident."

Dr. Packer notes, however, that getting a letter from the patient doesn't make sense when the patient has Medicare. "It's hard to ask someone to write a letter in case I'm audited later," he says. "I wouldn't be comfortable doing that. For that reason, if a Medicare patient needs blepharoplasty you have to be even more careful about making sure that your objective testing fits the criteria. Because if you're audited, they will definitely be looking at those numbers. Blepharoplasty is a red flag for a Medicare auditor."

—CK

geries to be done at the same time," he says. "We have to choose which to do first, which is absurd. Which one should we say is more important: the patient's risk of going blind from glaucoma, or difficulty functioning because of the cataract? It's a bad thing that clinical decisions are being made based on insurance company dictates that are difficult to even understand. In a situation like this, doing the two surgeries separately increases patient risk. It's more expensive because it's two rounds of anesthesia and two trips to the surgery center, not to mention two sets of postoperative drops. And it doesn't even make sense for the insurance company: The company pays us more if the surgeries are separated than if we do them at the same time. So what's the rationale?

"This is illogical, and it creates a suboptimal decision-making process," he says. "We're no longer telling the patient what we think is best; we have to mitigate it, finesse it. The patient says, 'Is this the best thing for me, in your judgment?' And we have to say, 'No, this is what your insurance company will pay for.' Then we have to explain why we're doing something that's not optimal for the patient. It creates a conflict. We can't be the patient's advocate."

Dr. Noecker notes that, as frustrating as it can be to deal with insurance companies, patients get the worst of it. "Premiums are going up every year and deductibles are rising as well," he says. "Some patients have cataract surgery on one eye in December. When they go to get the second eye done in January, not only is the new year's deductible not met, but the costs to the patient may be higher for 2017. We can usually tell what's covered by insurance and what's not, but the details can be hard for us to predict with so many carriers and so many plans at each carrier. Patients can get hit with a pretty big bill for the uncovered part of the surgery."

Justifying Borderline Cataract

Another issue when dealing with insurance companies—including Medicare—is convincing them to cover a procedure when the patient's condition is considered borderline.

Dr. Packer is focused primarily on performing cataract surgery; he encounters this problem when a cataract is troublesome for the patient but doesn't meet basic criteria such as poor visual acuity. "Medicare carriers have a certain threshold at which they say, 'OK, cataract surgery is indicated,' " he notes. "For most of them it's a best corrected visual acuity of 20/50 or worse. There's usually also a stipulation that if the patient meets that threshold under conditions involving glare, that patient is covered—as long as glare is an issue for the patient.

"However, there are some subtleties about this that many surgeons don't fully understand," he continues. "Suppose a patient comes in and says, 'I'm having a lot of difficulty reading fine print these days, especially in dim light.' You find that the patient's best corrected acuity is 20/20; then you do a glare test and it's 20/60. You might conclude that because of the glare test, this patient can have cataract surgery. However, there's an important issue here: The patient didn't have a complaint relating to glare. Yes, the test showed diminished acuity in the face of glare, but that didn't correlate with the patient's chief complaint: trouble reading fine print.

"In order to invoke glare test acuity as the rationale for cataract surgery, there must be a complaint from the patient about glare," Dr. Packer explains. "The patient must be saying something like, 'I'm having a really hard time driving at night. Oncoming headlights really disturb my vision.' Or, 'On a bright sunny day, I have trouble seeing the edge of a curb when I'm walking down a city street.' You can only invoke the glare clause when the patient has some real-life complaint relating to glare. That's a point doctors often miss.

"The reason I bring this up is that, fundamentally, cataract surgery is done to improve quality of life and prevent things like motor vehicle accidents," he says. "It's not really done to improve visual acuity by some specific amount. Visual acuity is an artificial clinical test that's supposed to reflect something about how people see in the real world. That's why the most important thing is what the person is complaining about, and whether that complaint is attributable to the cataract. Also, beware if a patient says he has no complaint, regardless of his less-than-ideal best corrected visual acuity score. A Medicare auditor will want to know why you did the surgery if the patient said he was fine and had no complaint."

Dr. Packer adds that a technician is usually the one who writes down the patient's complaints, along with test scores. "Noting the nature of the patient's complaint is therefore a technician-training issue," he says. "Of course, it's ultimately the surgeon's responsibility, because it's the surgeon who will have to pay Medicare back if Medicare concludes the procedure wasn't justified."

Beyond Visual Acuity

Dr. Packer says that one tool that's effective at supporting the need for cataract surgery is a validated questionnaire. "The one that I've used most frequently, which we can perform in the office, is the VF-14," he says. "It's available online and not hard to find. It contains 18 questions with multiple answer options for each question, most ranging from 'never' to 'all the time.' The final score is a percentage, and it drops down from 100 percent as visual dysfunction increases. It can be very helpful in determining whether someone might benefit from cataract surgery. If the patient scores 99 percent, that's going to be a stretch because there's not much room for improvement. Seventy-five percent is a pretty good threshold, and there's good evidence that if a patient scores 75 percent on the VF-14 and then has

cataract surgery, he'll have a pretty high level of satisfaction afterwards.[1,2] The surgery will improve his visual function and he'll be glad he had it.

"The patient can do this questionnaire while dilating, sitting in the waiting room," he continues. "Then, when the doctor comes back in, the results are available. Or, the patient can fill it out as part of a patient information packet, done before the visit and submitted through your patient portal online.

"The VF-14 is particularly good in a Medicare-audit situation," he notes. "It provides hard evidence that cataract surgery was appropriate in cases where the BCVA was better than the threshold of 20/50. It's also helpful when making the case for a commercial insurer's medical reviewer. It can be very persuasive in either situation."

Dr. Packer says another test that's helpful for supporting the need for cataract surgery is contrast sensitivity. "Contrast sensitivity testing picks up reduced visual function far in advance of declines in best corrected visual acuity," he notes. "This can be done using a wall chart, but the best option is an instrument the patient looks into, like the ones at the motor vehicle bureau. In those, the illumination is controlled and you can dial in the patient's spectacle correction.

"These tests compare the patient's contrast sensitivity to a normative range at four or five different spatial frequencies," he continues. "Normally, if the patient scores 0.3 log units below the mean at any spatial frequency—it doesn't have to be at all spatial frequencies—that's a compelling argument that cataract surgery will improve vision."

Dr. Packer notes that you may have to explain to an insurance company's medical reviewer what the contrast sensitivity score means, either in a cover letter or over the phone. "Medical reviewers are not always familiar with the significance of contrast sensitivity," he says. "It's great to have a couple of peer-reviewed publications in your back pocket that you can cite to back up what you're saying.

"As long as I have convincing scores on the VF-14 and contrast sensitivity tests, I've always been able to get the cataract surgery covered after a denial," he says. "It's an extra effort, but it can make patients very happy. Obviously you want to do these tests as soon as you realize a patient is a borderline candidate; you don't want to have to bring them back in later to contest a denial. Make sure your technicians understand this."

"It helps to have a protocol in place for dealing with insurance companies."
— Robert Noecker, MD

Dr. Packer notes that you shouldn't send the extra supporting data in when you first ask for authorization. "When you first apply for approval, you're just going through a computer program," he says. "The computer won't even look at all of this, and it may create issues. So you want to wait for the appeal and then send this in, when you know that an actual person is going to look at it. And of course, if the patient meets the best corrected visual acuity criteria of 20/50 or worse, I can guarantee they'll do poorly on the VF-14 and have reduced contrast sensitivity, so there's no reason to put them through those additional tests."

Negotiating for Your Patients

Doctors suggests these strategies to increase the likelihood that you'll get your patients the treatment they need when an insurer denies the claim:

• ***Make contesting insurance company denials an acknowledged part of your practice.*** "I think it's important to say, 'Doing this is important for our practice and patients,' rather than just trying to deal with it once in a while," says Dr. Noecker. "It helps to have a protocol in place for dealing with insurance companies. Of course, there's no way to understand all the intricacies of every payer plan, but just understanding what will probably go through does make a difference. And it's important to know how to respond when claims are denied."

Dr. Packer says the number of denials a practice will receive depends partly on the demographics of the patient base. "Working people in the Midwest may be inclined to postpone coming in to see you until the cataract is clearly eligible for surgery," he says. "But if you're practicing in a big city on either coast, you'll probably see a lot of borderline eyes.

"If your practice receives a lot of denials, you may want to have a full-time person whose job is to talk to insurance companies all day long," he adds. "However, be forewarned that that employee will spend a lot of time on hold. I suspect that keeping callers waiting is an insurance company strategy to reduce costs. Such an employee will probably be able to do other kinds of work for you as well while they're listening to the on-hold music."

• ***If your medical decision is being influenced by insurance coverage, make sure patients know that.*** "Doctors are being made to look like the bad guys," says Dr. Noecker. "When we're forced to do two surgeries instead of one combined surgery, for example, I think we have to make it clear that it's the insurance company that's insisting on something other than our best judgment about what needs to be done."

• ***Don't hesitate to challenge a denial.*** "I believe in fighting the fight,

because if you give in on one thing it opens up the floodgates," says Dr. Noecker. "Of course, you have to decide how much time you want you and your staff to spend on this kind of thing. It's not financially beneficial to the practice; it's just the right thing to do. We have to let the insurance company know that this is what we've determined is best for the patient.

"In our practice we push back on everything," he continues. "Our staff automatically files requests for prior authorization forms. About two-thirds of the time, that's all we have to do—just sign the form and explain that this is standard of care, or that it's the best thing for this patient. Automatically filing for prior authorization is an extra step, but I look at it as a relatively trivial step.

"Sometimes you don't get an immediate approval and you have to go a little deeper," he says. "You may have to list the options the patient has tried and failed, or explain why the option the insurance company wants is inappropriate—what the risk to the patient is. Glaucoma is a blinding disease, and I have no problem saying that this patient needs this therapy and could have irreversible blindness if we make any missteps. I'm also happy to point out that the next step will be surgery if the patient can't get this medication. Insurers will find that surgery is a much more expensive undertaking than an eye drop."

Dr. Noecker acknowledges that the extra effort won't always pay off. "I'm pretty aggressive, but sometimes I do hit a wall," he says. "I typed 10 pieces of paperwork to get one patient covered for topical cyclosporine (Restasis), but her insurance plan would not allow it no matter what. I detailed how her dry eye was disabling her at home and at work, but the carrier wouldn't give in. Luckily, most of the time you can get what the patient needs if you go through the process."

• ***Persist until you talk to a medical director.*** "Often, I've had success after escalating the matter to a medical director at the insurance company," says Dr. Hovanesian. "At every insurance company that I've dealt with they have a process for escalating appeals that usually concludes with talking to a doctor. It's typically a phone call, so it doesn't require writing a letter. During that phone call you get to state your case.

"Usually, you don't end up talking to an ophthalmologist," he continues. "When you do, you're lucky because you can speak in shorthand and they understand your situation. Often these individuals are doctors who practice part time or don't practice at all, but they understand the physician's perspective and they'll usually grant a reasonable request. Actually, when the doctor is not an ophthalmologist, he may be even more likely to give in on a request because he won't have the knowledge of your specialty to make a good argument for denying the claim."

Dr. Hovanesian says that he argues for a claim to the point of talking to a medical director several times per year. "Sometimes just requesting a review with a medical director is enough to get a denial overturned," he says. "The representative will just say, 'OK. He's busy, we'll approve it.'

"I believe that when a patient needs a treatment and an insurance company is denying it, it's simply an insurance company strategy," he adds. "They're hoping to create enough barriers that you'll give up so they can avoid the expense of covering the treatment. By persisting, you show that the request is legitimate, and that you want the patient to receive proper, modern treatment. You also pave the way for future patients because you help to set a precedent with that insurer for what constitutes appropriate patient care."

Like Dr. Hovanesian, Dr. Noecker has noted that the medical director you end up speaking to is rarely an ophthalmologist, but Dr. Noecker be-

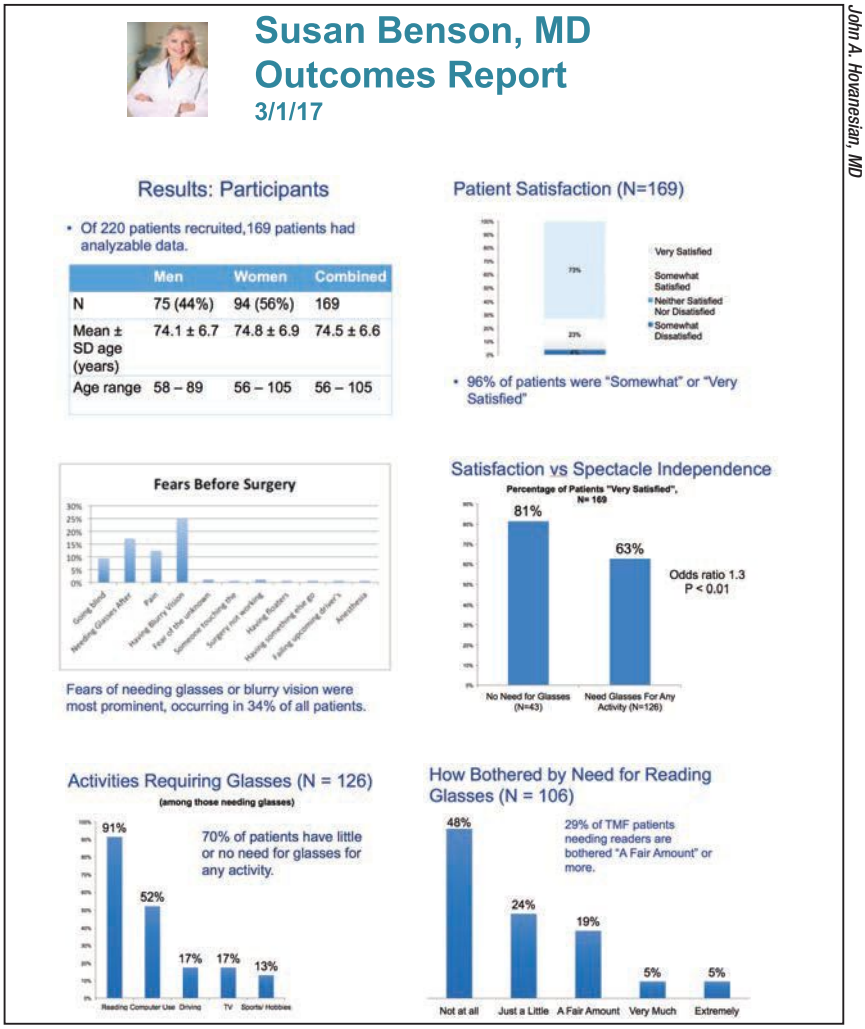
lieves that can be a bad thing. "Sometimes if the doctor doesn't have the ophthalmology background he'll just read from the carrier's manual, citing that what you're asking for isn't covered. Yes, sometimes the person is very reasonable; if I can show that I've documented everything, he'll say OK. But sometimes he won't budge. It's one more source of variability."

• ***With Medicare, be proactive to protect yourself.*** Dr. Packer notes that one of the big differences between commercial insurers and Medicare is that Medicare has no prior authorization process. "You just do the procedure and submit your charge to Medicare, and they generally pay it," he says. "However, doctors face the underlying threat that Medicare may someday come to audit you. If they review 10 of your blepharoplasties and determine that nine of them were not medically indicated, they're going to say that 90 percent of your blepharoplasties should not have been covered. If you've performed 1,000 blepharoplasties in the past 10 years, they'll demand to be repaid for 900 blepharoplasties. Medicare counts on the threat of an audit to keep people following their guidelines. It's all stick and no carrot."

How can a practice minimize the risk of a bad outcome should an audit occur? "You can conduct you own practice stress test," says Dr. Packer. "You can conduct an internal audit of your records, or better yet, hire somebody to come in. There are companies out there that will do a mock audit for you. They'll point out weaknesses, so if you're ever audited you won't end up paying needlessly for mistakes."

• ***When a drug or device is part of a claim, the manufacturer may be your best ally.*** "The manufacturer has a vested interest in the patient receiving its device or drug," notes Dr. Hovanesian. "For that reason, many companies have resources you can turn to, whether it's a drug company with patient-access programs and coupons, or a company like Omeros [maker of Omidria] with a drug that requires prior authorization to get it reimbursed. Omeros has created a reimbursement program that maximizes the likelihood of insurance company approval and minimizes the work required from physicians and staff. They assist in the process of verifying that a particular insurance company will cover it. And, if the insurance company doesn't end up covering it, they'll often provide a no-cost sample, so I can use Omidria and feel pretty confident that it will either be covered or the manufacturer will provide a sample." [To learn more about the Omeros program, visit omidria.com/reimbursement/omidriassure/.]

• ***Use preauthorization forms to help your patients.*** "Insurance companies are middlemen between patients and doctors," notes Dr. Noecker. "They want to maximize their profits, so they're going to encourage people to use whichever drug they've negotiated the best price on, for purely economic reasons. If your clinical analysis lines up with their economic motives, great. But if it doesn't, then a preauthorization form allows us to override the insurance company. Part of this is educating patients so they know about



John A. Hovanesian, MD

When negotiating a contract with an insurance company, having data that shows you provide excellent care can get you better terms. (Most practices don't provide this.)

this process, so they don't end up not getting the drug at all or paying an excessive amount of money for it."

• ***Help your patients reduce costs with vouchers.*** Dr. Noecker points out that many branded drug manufacturers provide practices with vouchers that can reduce the cost of medications for patients. "Vouchers put a cap on the cost of the medications, which can reduce the cost from $200 to $30 in some cases," he says. "As a result, it's sometimes cheaper to use the branded medications than the generics. That's especially true given the rising cost of some generics.

"The main issue with vouchers is remembering to use them," he adds. "In our office it's part of our surgical process; I have my surgical coordinator hand them out when our patients are getting their prescriptions. Vouchers help to keep costs predictable, but you have to take the time to explain to patients how to activate the card, and get the patient to take it to the pharmacy and present it when getting the prescription filled."

• ***Consider using third-party insurers to obtain some infrequently prescribed medications.*** "Some of the smaller manufacturers, like Akorn, have contracted with a third-party mail-order pharmacy," says Dr. Noecker. "Using this route takes a little bit of staff work, but the price will be half or a third of what patients might pay at their pharmacy. So if someone needs preservative-free timolol, for example, this can keep the patient from being hit with a gigantic bill."

• ***Be aware that patients may be convinced that Medicare supplement insurance pays for premium services.*** "I had a relative who thought that her Medicare supplemental insurance would pay for having femtosecond-laser-assisted cataract surgery," notes Dr. Packer. "Of course, it doesn't, and she'd been told that. It's just that with many patients the message doesn't quite get through.

Patients often believe they'll be covered, even if they've been told otherwise. Some believe it's worth a try because maybe the supplemental insurance will cover it.

"This is a good technician training item, because the patient will often mention this idea to the technician in passing," he continues. "That's the moment to nip it in the bud and make it clear that no insurance company covers FLACS or a premium implant. By the time patients mention this to someone in your office, they're usually easier to convince because they're specifically focused on this issue."

• ***Get involved in the political process.*** Dr. Noecker points out that ophthalmologists have been successful at changing some insurance company policies that put patients at risk. "There was a time when it was not uncommon for insurers to tell patients, 'We won't refill your glaucoma medication yet because we covered a month's supply and you're only three weeks in.' As every ophthalmologist knows, elderly patients often have trouble using drops correctly and end up finishing the bottle earlier than intended. If glaucoma patients are only receiving their drugs three out of four weeks, that can have profound consequences in terms of vision loss; it's a huge public health issue. But thanks to many physicians talking to their state congressmen, it's now the law in many states that insurers have to honor the refill, even if it comes in early.

"The point is that our political efforts can make a difference," he says. "Once you explain the situation to the politicians, they get it, but you have to call it to their attention. So I think it's really important to take action and remain engaged."

• ***Remind the patient that if all else fails, she can change insurance companies.*** "Sometimes you just can't get what you need from your carrier," says Dr. Noecker. "However, if worst comes to worst you can always choose a new one the next time you're up for insurance."

Should You Sign that Contract?

The other side of the insurance company coin is the contracts you sign with them that determine, among other things, your level of reimbursement. The following three strategies can make a big difference in how fair a deal you end up with:

• ***Negotiate to get the best possible terms in your contracts.*** "I'd say 75 percent of practices accept the contract they receive from insurance companies every year," says Dr. Hovanesian. "The doctors lower their heads in disappointment at how reimbursement is going down, but they sign and return the thing in disgust, and that's the end of it.

"Actually, there's absolutely no reason to accept the terms that come to you in a contract, as presented," he continues. "You should always negotiate to get the best deal you can. But when negotiating a payer contract—or anything else, for that matter—you have to understand the concept of leverage. What do you have that the other party wants? If you walk away from the table, what do they lose? You want to present yourself in the most favorable light so they'll want to have you on their panel."

• ***When negotiating, have data on your side.*** Dr. Hovanesian notes that it makes a big difference to have concrete data showing that your practice has top-notch doctors providing first-rate care. His practice uses a unique software system called MDbackline (which he helped to develop) that accumulates data about the practice. "The software automatically contacts patients after certain procedures, office visits and surgeries, to determine how they're doing," he says. "It gives them real-time guidance and advice based on their answers, and then it aggregates data on patient outcomes for us." *(See sample form, p. 36.)*

Dr. Hovanesian says using this program is advantageous for the practice in several ways: It helps to track whether patients are having complications; it collects surgical satisfaction data; and it aggregates outcome data that he can use to negotiate better contract terms. "We're seeing 2- or 3-percent better reimbursement from carriers because we have these data to present when we negotiate our contracts," he notes. "Most physicians do a good job, but they don't have the numbers to *prove* that they're doing a good job. With our very positive data in hand we can say to the insurance company, 'We deserve not only to be on your panel, but to be on your panel as a preferred provider with better reimbursement.' And we're getting that.

"The bottom line is that you have to approach a negotiation with the idea that you're selling something," he concludes. "You're selling yourself and your practice. Positive practice data will differentiate you from other companies that insurers contract with."

• ***Create a personal relationship with the insurance companies.*** Dr. Hovanesian says you'll do better with any insurance company if someone in your practice develops a personal relationship with someone at the company. "You don't build a relationship by just signing the contract the company sends you each year and returning it," he says. "You build a relationship by having contacts at the company that your people talk to, not only about the details of your contract, but about individual patient cases. The people who get the best results from insurance companies are those who know the people at the insurance companies. They know just whom to call when there's a problem; they know whom to call when there's a contract issue.

"You can hire a consultant to be a personal contact for your practice, or you can have an internal full-time per-

(continued on page 106)

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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.

Important Safety Information

- **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.
- Use of topical NSAIDs may result in keratitis. 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. Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular

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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.

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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

NSAID=nonsteroidal anti-inflammatory drug.

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SUN OPHTHALMICS

BromSite™ (bromfenac ophthalmic solution) 0.075% Brief Summary

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.

DOSAGE AND ADMINISTRATION
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.

Use with Other Topical Ophthalmic Medications
BromSite should be administered at least 5 minutes after instillation of other topical medications.

Dosage Forms and Strengths
Topical ophthalmic solution: bromfenac 0.075%.

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
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).

PATIENT COUNSELING INFORMATION
Slow or Delayed Healing
Advise patients of the possibility that slow or delayed healing may occur while using NSAIDs.

Concomitant Topical Ocular Therapy
If more than one topical ophthalmic medication is being used, advise patients to administer BromSite at least 5 minutes after instillation of other topical medications.

Concomitant Use of Contact Lenses
Advise patients not to wear contact lenses during administration of BromSite. The preservative in this product, benzalkonium chloride, may be absorbed by soft contact lenses.

Sterility of Dropper Tip/Product Use
Advise patients to replace the bottle cap after use and do not touch the dropper tip to any surface as this may contaminate the contents.

Advise patients to thoroughly wash hands prior to using BromSite.

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SUN OPHTHALMICS

Heading Off Preop Problems with OCT

Michelle Stephenson, Contributing Editor

Identifying retinal issues before cataract surgery can improve outcomes, especially for patients choosing premium IOLs.

Optical coherence tomography is widely used by ophthalmologists, and cataract surgeons agree that it has a role in cataract surgery evaluation. Some surgeons employ it for all routine cataract cases, while others only use it when specific IOLs are being implanted.

"I think, by and large, we are all finding more uses for OCT, and it has made its way into the evaluation of cataract patients," says Samuel Masket, MD, who is in practice in Los Angeles.

Steven Safran, MD, a surgeon from Lawrenceville, N.J., agrees. "I have been advocating for a long time for using OCT to evaluate patients for cataract surgery. It used to be that high-definition OCT was a retina surgeon's tool. I got an OCT Spectralis in 2008, and it became pretty clear to me at that point that this was something that all ophthalmologists needed to have. Without looking at the macula, you really have no idea what's going on there. In some respects, performing OCT is more important than performing topography. Looking at the retina with a 78-D lens is like a satellite image, while performing OCT is like having a Jeep on the ground," he explains.

OCT was shown to effectively diagnose macular changes preoperatively and postoperatively in a recent study.[1] This report was conducted to assess the ability of spectral-domain OCT to diagnose macular changes pre- and post-cataract surgery and to identify changes in central foveal thickness relative to age, gender and the presence of concomitant ophthalmic pathologies for six months following surgery.

In this prospective study, patients were evaluated by OCT within five hours before surgery and at 7, 30, 60, 90 and 180 days postoperatively, with respect to central foveal thickness and presence of maculopathy.

The study included 98 eyes of 98 patients. Patients' mean age was 71.4 years; preoperative mean visual acuity was 0.27 logMAR; and final mean visual acuity was 0.73 logMAR. Twenty-one patients had diabetes mellitus, 10 patients had age-related macular degeneration, three had epiretinal membrane and four had glaucoma. Sixty eyes had no other ophthalmic-related pathologies, with a mean preoperative central foveal thickness of 222 µm, which progressively increased up to postoperative day 60 when it reached a mean of 227.2 µm. No pseudophakic cystoid macular edema was seen. Mean central foveal thickness was statistically significantly different between patients with no other ophthalmic-related pathologies and diabetic patients, from 30 days postoperatively. Four eyes had a preoperative diagno-

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sis of age-related macular degeneration as measured by ophthalmoscopy. OCT was performed within five hours before surgery, and six additional patients were found to have age-related macular degeneration. Of the 98 total eyes, 10 were diagnosed with maculopathy only by OCT exam. Binocular indirect ophthalmoscopy was unable to detect such changes.

In this study, OCT diagnosed preoperative maculopathies in 21.4 percent of the patients and was found to be more effective than binocular indirect ophthalmoscopy, which diagnosed preoperative maculopathies in 11.2 percent of patients. Additionally, OCT showed a progressive increase in central foveal thickness in diabetics up to 180 days postoperatively, as well as greater central foveal thickness in male patients and in patients older than 70 years.

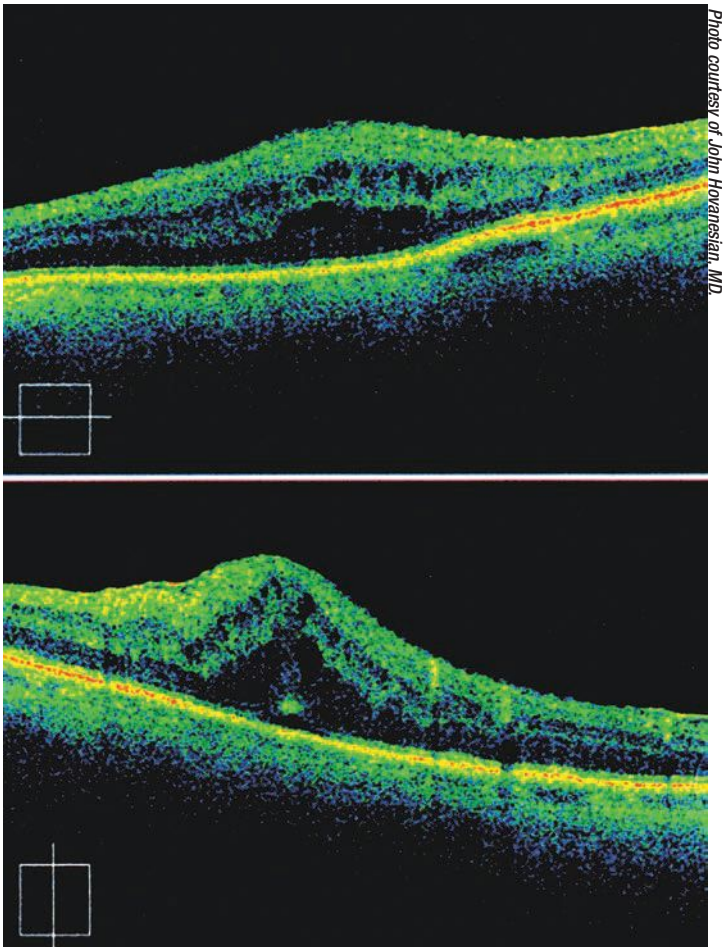

Photo courtesy of John Hovanesian, MD.

OCT image showing cystoid macular edema in a patient with diabetic retinopathy.

Premium IOLs

While OCT can be helpful in all patients, it's especially important in patients considering a premium IOL. "You are flying blind without having an OCT. I think that every patient who is going to undergo cataract surgery can potentially benefit from having a preoperative OCT evaluation of the macula, particularly if he or she is considering a so-called premium lens," Dr. Safran says. "I don't know if most surgeons are routinely using OCT, but I think that's the trend. Most surgeons who do diffractive multifocals certainly are."

Some IOLs, such as diffractive multifocals, are contraindicated in the setting of macular disease, so it is helpful for surgeons to have as much information as possible before implanting one of these lenses. "Patients will not be happy postoperatively if they pay a premium price for a premium lens and then have a less-than-desirable visual outcome because they have an epiretinal membrane or subretinal fluid that was present prior to surgery and not detected. It's not really defensible these days to simply say you didn't know, when you could easily obtain this information before making a specific IOL recommendation," he explains.

Dr. Safran also believes that OCTs are important when implanting standard lenses. "However, the stakes aren't as high for two reasons: One is that you are not asking patients to pay out-of-pocket for an outcome that you are promising but that you will never be able to achieve if there are macular issues. The other is that some of the so-called premium lenses are actually not as good as a monofocal lens from a visual-quality standpoint. Using multifocal IOLs in patients with macular disease may actually hurt them rather than help them. In fact, they might not be able to drive or read as well with this compromised function," he adds.

According to John Hovanesian, MD, who is in practice in Laguna Hills, Calif., today's cataract surgery patients are much more particular than previous generations about their outcomes. "They expect normal vision like they had when they were a much younger person," he says. "Unfortunately, these patients, whose average age is about 70 years old, often have co-morbidities that affect macular function, like epi-retinal membranes, early dry macular degeneration or other problems that can limit their visual potential. Some of these subtle findings are difficult or impossible to see when viewing the macula preoperatively through a cataract. OCT, which gives us a high-resolution cross-sectional image of the foveal region, can identify problems that would otherwise derail a satisfactory outcome for patients. This is particularly important when using multifocal lenses, where the lens itself degrades the optics of

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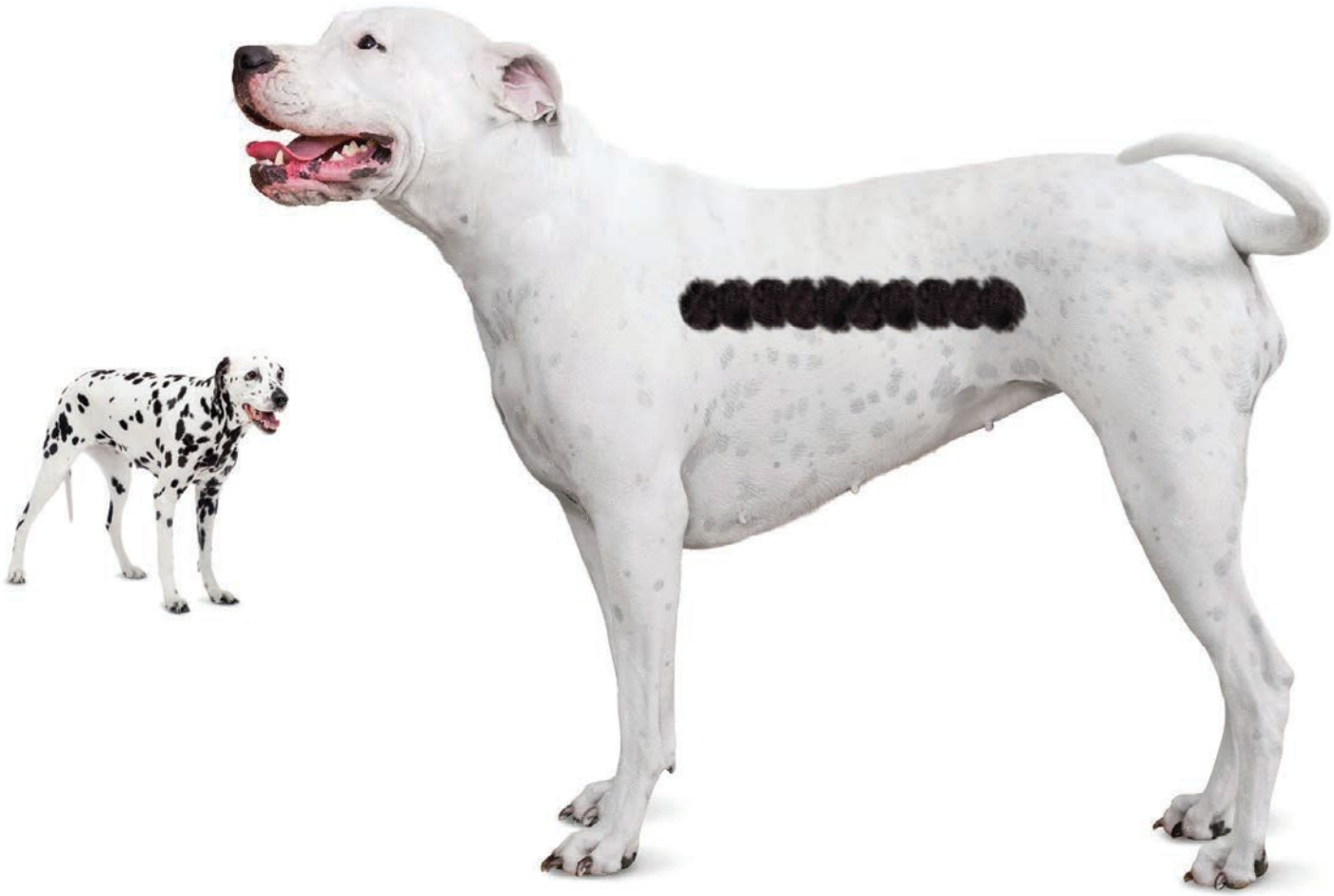

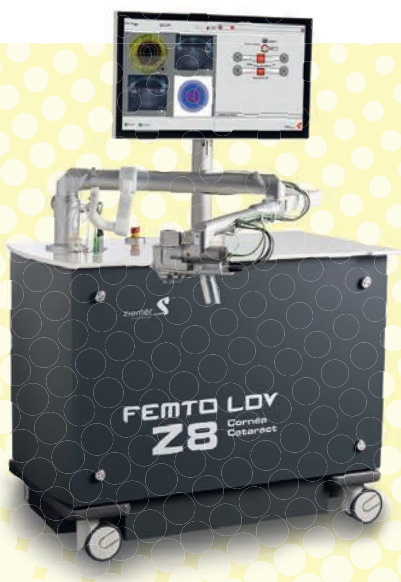

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the eye to a small degree in exchange for giving multiple depths of focus."

It's imperative that patients understand co-morbidities that could affect their visual outcomes after their cataract surgery. "I'm a big fan of showing patients a picture of their OCT so they can see how theirs compares to a normal OCT. In my experience, patients with abnormal OCTs do not necessarily need to forgo premium cataract surgery. However, it alters their options," Dr. Hovanesian says.

If they should forgo a multifocal lens because of their macular issue, then they may be able to consider an accommodating lens, a toric lens, or advanced monovision. "As a general rule, I won't implant a presbyopia-correcting lens in a patient whose visual potential is less than 20/25, although there may be exceptions," he notes.

Dr. Hovanesian says that refractive cataract surgery is very popular in his practice in southern California. "About 75 percent of our patients choose to have some type of premium refractive option. I tell patients that in order for them to have perfect vision, everything in their eye has to be perfect, not just our surgery. Often, not everything is perfect, so I use OCT in all of my cataract patients," he adds.

According to Dr. Masket, there are two issues to consider when evaluating a cataract surgery patient. "One is determining the best lens device or the best surgical course for your patient. The other issue is what is and is not reimbursable. Many surgeons feel that before considering any type of multifocal or diffractive optic lens, which would include the new Symfony lens, one should be certain of macular health. Any disturbance, particularly to the macular surface where you might have vitreomacular traction or an epiretinal membrane, could lead to a less-than-desirable outcome. Vitreomacular traction can be missed by the anterior segment surgeon on routine examination of the posterior segment. I think many of us agree that, when considering any diffractive optic lens, it's a good idea to study the macula region with OCT," he says.

Dr. Masket says that he's not sure whether OCT is necessary in routine cataract surgery cases. "However, we know from the literature that, in dry macular degeneration, the condition will not be worsened by cataract surgery. However, if an occult neovascular membrane is missed, cataract surgery can worsen the course of wet AMD, so I always use OCT in any patients with macular degeneration to make certain that we are not missing a choroidal neovascular membrane. In these cases, we refer patients to a vitreoretinal specialist for the treatment of that lesion prior to cataract surgery. Treatment usually consists of an anti-VEGF drug injection," he adds.

The timing of cataract surgery is coordinated with the vitreoretinal specialist, in terms of giving the anti-VEGF injections at the appropriate intervals prior to the surgery. "Optical coherence tomography is of huge importance in any case of age-related macular degeneration," Dr. Masket says. "In the consideration of a diffractive optic, I think it's important to make sure that there is no surface disease that might be missed during the clinical examination. The reimbursement issue then comes into play because, for patients who have normal exams and are asymptomatic, obviously, the test is not and should not be reimbursable. The physician then must bear the time and expense of the test. It's okay, though: I think it's a very good ounce of prevention. My practice partner has taken to studying every cataract patient just to be certain that disease is not missed. We know, for example, if there is an epiretinal membrane or macular pucker, there is a greater likelihood of cystoid macular edema following surgery. We tend to pretreat these patients with steroidal and nonsteroidal agents for at least a week prior to cataract surgery," Dr. Masket says.

Reimbursement

Unfortunately, OCT can only be billed to insurance if the patient has existing macular disease. If it is used in routine cataract patients, it will need to be billed to the patient or not reimbursed. "We recognize the value of OCT in everyone, even if we don't get paid to do it," Dr. Hovanesian notes. "Part of our fee for refractive cataract surgery includes the use of a screening OCT for patients without existing macular disease. In other words, for patients who have exam findings and suspicion for macular disease, you can and should do an OCT, and you can and should bill for it. For patients in whom it is being used as a screening test, where no expectation of macular disease exists and you are doing it just to make sure there's nothing there, you can't bill insurance or Medicare for that. We do it for no charge because we want the information. It's part of doing the right thing for our patients and maintaining our reputation."

He adds that the Centers for Medicare and Medicaid Services is discussing global fees for cataract surgery, although nothing has been finalized. "A 'global fee' means that it would cover preoperative testing, intraoperative tests, and postoperative testing and care. So, a global fee would make it so that it would be on the surgeon if he or she wanted to do these extra tests. If these changes come to pass, clinicians will need to make even more decisions like this," he explains. REVIEW

Dr. Hovanesian is a consultant to Carl Zeiss Meditec, Bausch + Lomb, Alcon and Abbott Medical Optics. Dr. Safran and Dr. Masket do not have any financial interests to disclose.

1. Moreira CA, Moreira CA, Moreira ATR. Optical coherence tomography in patients undergoing cataract surgery. Arq Bras Oftalmol. 2015;78:4.

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What To Do If You Don't Like Surprises

Elizabeth Yeu, MD, Norfolk, Va.

How to get to the bottom of postop refractive errors and manage them effectively.

It can happen to anyone: You perform solid biometry and error-free cataract surgery, yet when you see the patient postop, there it is—a refractive error, also known as a postop refractive surprise. As surgeons, we've come to understand that these surprises can happen for any number of reasons, from biometry errors to patient factors that went undetected. In this article, I'll share my techniques for handling these unfortunate situations.

The Surprise-prone

Though you might say the patient at highest risk for an unexpected refractive error postop is the type-A person who expects everything to be perfect, there's not much you can do about that, so it's best to focus on factors you can control. Sometimes, you can see a refractive surprise coming, as long as you know what to look for.

First, note that the patient most at risk for a postop surprise is someone with a shorter (less than 22 mm) or longer than normal axial length (26 mm or more). Patients with higher levels of astigmatism—in the range of 3 D or more—as well as those for whom the ocular surface was providing a source of measurement error, are also at risk.

Additionally, inconsistent measurements among your devices can lead to a postop error. Such inconsistencies include differences in the magnitude and axis of K values, or the average K value differing among your biometry, topography and manual keratometry readings. If such a discrepancy exists among all those devices, your refractive outcome becomes a bit of a crapshoot.

Finally, if a patient has been wearing rigid gas-permeable contact lenses for a long time and hasn't been out of them for the appropriate length of time to let his corneas normalize, or he is a post-LASIK patient, he's at risk for a refractive surprise.

Minimizing Risk

Here are some things you can do preoperatively to lessen the risk of a postop surprise:

• ***Address the ocular surface.*** Make sure that you optimize the patient's ocular surface ahead of time. One of the biggest clues you can find that there may be a problem is on the placido disc image: Assess the quality of the pre-corneal tear film and the central corneal image capture. There should be sharp mires in the bull's-eye and no smudged or missing areas that would be suggestive of some level of

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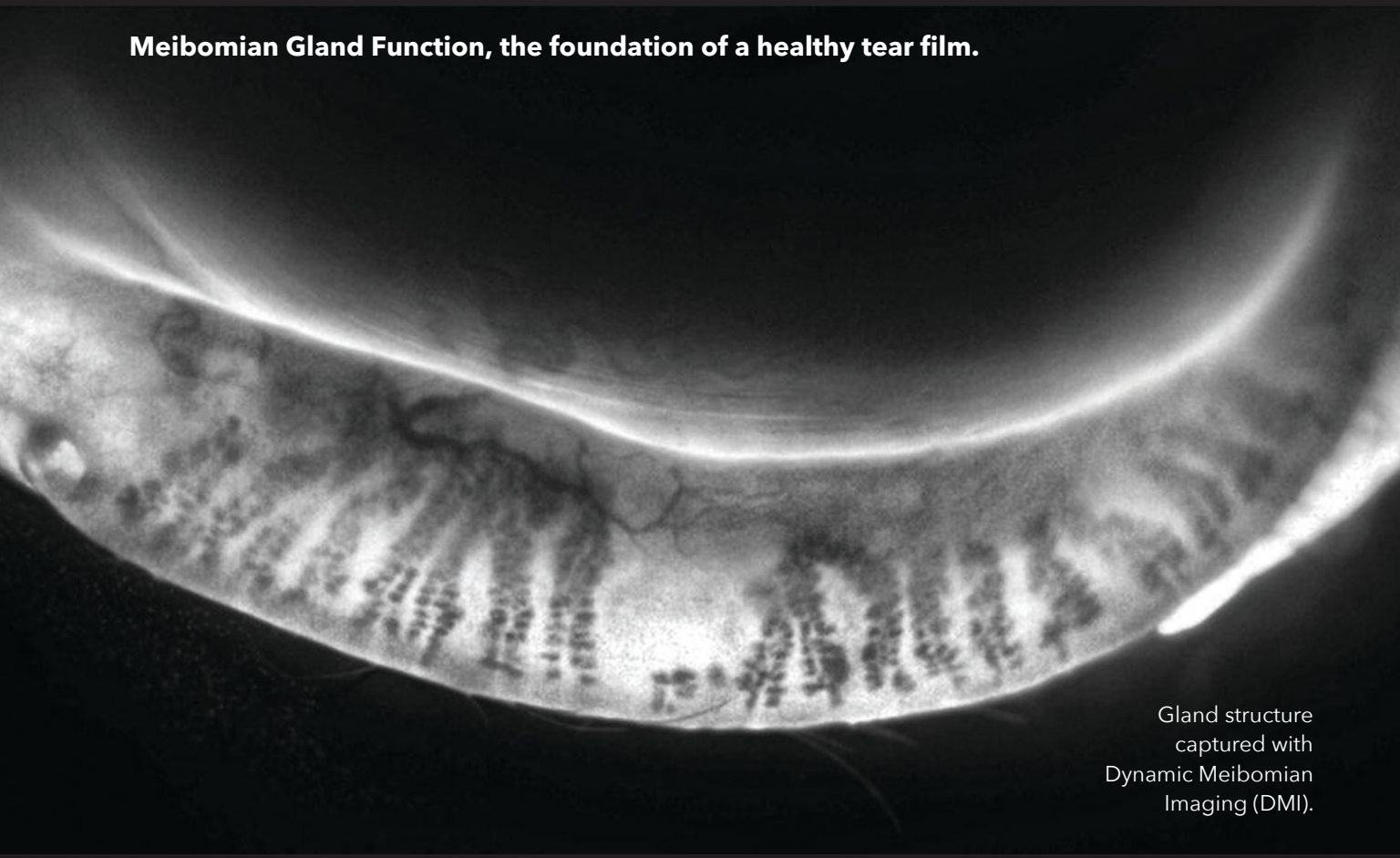
The leading cause of ocular discomfort and contact lens dropout is dryness.

Meibomian Gland Function, the foundation of a healthy tear film.



Gland structure captured with Dynamic Meibomian Imaging (DMI).

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ocular surface disease. Even though staining and a rapid tear breakup time are going to be most commonly the result of dry-eye disease, don't neglect the 10 to 15 percent of patients in whom this irregularity will be due to an epithelial condition, such as epithelial basement membrane disease or nodular degeneration. These irregularities can lead to inconsistent imaging that will really throw off measurement values, and a majority of what you see on topography won't be accurate in terms of the magnitude of the K readings.

If you don't have a placido-based topographer but instead use manual Ks and biometry, and those two technologies aren't consistent, that should alert you to the fact that you have to pay close attention to the ocular surface. The inconsistencies could be due to a lid effect or another issue, but you need to find the source. To do this properly, make sure to bring the patient back another day when she has no drops instilled in her eyes and repeat the imaging. This is especially necessary if you're trying to achieve a sharp refractive outcome.

• ***Measure the posterior corneal curvature.*** Being able to account for the effect of the posterior cornea, either with LED topography such as the Cassini or an online toric calculator that accounts for posterior corneal astigmatism such as the Barrett Toric Calculator, is key to a successful outcome. This will help you determine your astigmatic factor and decrease your residual postop error. Intraoperative aberrometry can also be helpful as a way to identify the total corneal astigmatism, especially if you don't have a lot of advanced preop diagnostic tools. At this point, the Alcon VerifEye has over 500,000 data points to use as a reference. It can also use the postop result in a patient's first eye to help refine the IOL selection process for his second. This can be very helpful, especially in the case of a post-LASIK patient.

• ***Counsel the patient.*** If you have one of these potentially challenging patients, spend some chair time preoperatively discussing how his particular situation might impact his postop result. Make sure he understands what your personal statistics are on this count. For me, for example, in an average eye I have a 92-percent chance of being within 0.5 diopter of the the spherical equivalent that I target. However, I tell him, if his eye falls outside that normal range with an axial length shorter than 22 mm preoperatively or he has had prior corneal refractive surgery, there may be upwards of a 20- to 30-percent chance that I won't be able to accurately hit the target I aim for in terms of the vision he wants postop.

Though you can't completely avoid having a dissatisfied patient, if you do the best preop diagnostics you can, and spend the time explaining things to the patient ahead of time, you can help reduce the risk that he'll be dissatisfied later.

What Went Wrong?

Determining the cause of the postop surprise can sometimes help you correct it and avoid similar surprises in the future.

In the postop period after you discover the postop refractive error, make sure the patient finishes his postop drop regimen and that any inflammation has quieted. Since he didn't hit his postop target, postpone the second eye's surgery, and explain why, saying, "We want to fully handle your first eye so that you're satisfied with its outcome before we move on to your other eye." Bring him back a good one to two weeks after he's finished his postop drops. If the patient needs a little handholding before then, don't hesitate to bring him back in the intervening time period just to reassure him that you'll be addressing the situation in due time.

You may be able to catch issues even during the postop medication period, however. For example, at the one-week exam, be sure to look at the ocular surface. If it looks like the patient's suffering from a toxic medicamentosa, or his ocular surface looks significantly worse, he may have been a marginally compensated dry eye patient to begin with, but now the toxicities of the medications are causing more ocular surface disease. If it's the one-week postop mark and he's still got some medication left, the first thing I'll do is switch him to a preservative-free formulation. If he's not at high risk for an issue with postop cystoid macular edema, I might take him off the topical NSAID or change him over to preservative-free ketorolac. In short, I do everything I can to get him onto a preservative-free formulation.

From a steroid standpoint, I'll get either a compounded preservative-free dexamethasone or move him over to Lotemax ointment at night or b.i.d. It's better to have transient blurred vision from the ointment than the potential toxicity from preservatives. This is especially true if it's a patient whose ocular surface was somewhat dry to begin with or who was already on other drops such as glaucoma medications, which can put him at risk for developing postop dryness.

In this ocular surface evaluation, look at the lids, the tear-film breakup time and vital dye staining. Of course I look at more than just staining, but I want to see how the surface looks during a certain timeframe compared to preoperatively. At least a third of my cataract patients will develop some transient exacerbation of their dry-eye disease.

Make sure to get a very good refraction, particularly if the patient had a toric IOL implanted, because you want to know exactly the refractive magnitude and axis of astigmatism. This will help you determine what to

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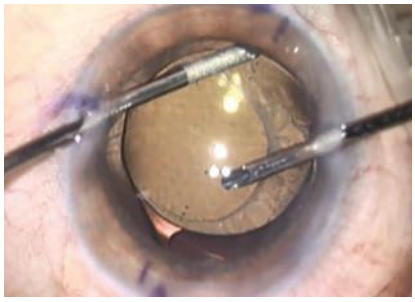
do with any astigmatic surprises after a toric IOL implantation.

Next, I perform all the normal imaging. I repeat the biometry and topography—including use of the Cassini. Then, I always get macular imaging, because I want to rule out any macular pathology, since you never know for sure unless you check. I also get another manifest refraction. I make sure that, in cases of postop refractive surprises, all of the refractive workup is performed by a LASIK technician. This is because we have certified ophthalmic medical technologists who do all of our LASIK evaluations who are more experienced, and their manifest refractions are simply more accurate than other techs'.

I review all of this data and the tech's notes before I walk into the exam room. From the notes I try to get a sense of the patient's level of satisfaction or anger, so I can be prepared to provide the emotional support the patient needs. It's at times such as these that your emotional quotient can be just as important—or more important—than your intelligence quotient for these unhappy patients. Talk to the patient and really listen to her complaint. Find out if she's achieving any point of clarity, if there's fluctuation in the vision, and whether or she's really bothered by potential side effects.

Regarding the presbyopia-correcting IOLs, we all know that there can be associated night vision symptoms, based on the advanced optic design of the extended depth of focus and multifocal IOLs. One point that's important to make here is that I don't specifically ask about side effects such as starbursts and halos. I don't want to put those ideas in patients' heads, but instead want them to voluntarily give me that information. If they do, then I know it's a true issue. All patients are aware of the potential for having night vision symptoms, and it goes without saying that these potential concerns should be fleshed out while I'm meeting with the patient preoperatively.



Bimanual I/A is great to use to manipulate and dial a toric IOL into position. Engage the IOL at the haptic-optic junction, on irrigation only, and gently rotate the IOL into position.

Dealing with the Error

The best option for dealing with a postop refractive error depends on the error itself and the lens the patient had implanted. An overarching theme, however, is that your choice is guided by three things: the severity of the refractive error; the level of the patient's dissatisfaction; and the patient's tolerance for waiting the requisite three months for full healing before you'd consider laser vision correction.

• ***Milder surprises.*** Take as an example a postop patient with a small amount of mixed astigmatism after cataract surgery. In this patient, her spherical equivalent is close to emmetropia and she has less than 1 D of residual astigmatism. This is the kind of patient for whom the best course of action is just making sure she's finished with her drops and her refraction remains consistent. Two or three months after cataract surgery, her error can easily be fixed with a relaxing incision.

In terms of a good nomogram for these incisions, I use the same nomogram that I'd use preoperatively, which is a fine-tuned version of the Koch nomogram that accounts for posterior corneal astigmatism. In general, I make my primary corneal relaxing incisions with femtosecond laser technology at 85-percent depth and a 9-mm optical zone.

For a postop relaxing incision, though, I may adjust my nomogram based on how the patient responded to any previous LRIs. Therefore, if my normal 40-degree arc, which corrects about 0.5 to 0.75 D of cylinder in my hands, didn't reduce the patient's astigmatism that much preoperatively, when I create my second arc I'll place it in the opposite axis 180 degrees away. I'll adjust the length based on the results of the initial LRI, making it longer or shorter as needed.

Also, when performing an LRI postop, I may place it a little more central than the first one. So, if I was in the 9-mm optical zone to begin with, I may reduce that to 8 mm, because the more central and deeper you go, the greater the relaxing effect on the cornea.

Also, if your surgery has flipped the astigmatic axis (for example, the toric IOL is at 90 and the patient's refractive astigmatism ends up being 1 D at 180 degrees), the patient will respond less favorably to an LRI at 180. At that point, the optical system just becomes too complicated, in my experience, because you'll be correcting astigmatism on the cornea that's steep in the exact opposite axis of the astigmatic correction in the IOL. This optical complexity can lead to a suboptimal visual outcome.

• ***Higher astigmatism.*** However, if the patient has an astigmatic error that's not just mixed astigmatism, or has an astigmatism value of 1.5 D or greater, this falls into the range that won't be well-served by performing an LRI. With a relaxing incision, any arc greater than 40 to 45 degrees is too large. It can destabilize the cornea, cause irregular astigmatism and intensify dry-eye issues. For me, then, if the astigmatic refractive error is 1.5 D or greater, I'm considering three



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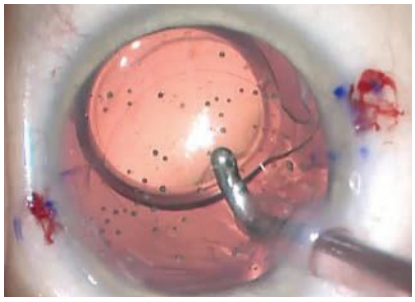
options: laser vision correction; possible rotation of the toric IOL; or IOL exchange.

To aid my decision on which route to take, I'll go to astigmatismfix.com and plug in the patient's manifest refraction and see if I can rotate the lens. If I find that I can move it more than 5 degrees from its current position and have an appreciable effect so that the net residual astigmatism is pretty low, I'll definitely take him to the OR in order to take care of that, fairly early in the postoperative period. Patients whose refraction can be corrected with repositioning of a toric IOL respond very favorably, with a greatly improved quality of uncorrected vision afterwards, if the IOL reposition results in a postop refractive astigmatism under 0.5 D. For multifocal lenses, however, in my experience anything over 0.25 D of residual refractive astigmatism actually leads to a decline of a line or more of vision, and should be corrected to optimize the patient outcomes.

• ***Considerations for LVC***. If the spherical and/or astigmatic errors are high, and the patient is willing to wait 90 days, you can successfully perform laser vision correction. This is a particularly attractive route if you or the patient aren't comfortable performing an IOL exchange.

The 90-day waiting period is crucial, because there have been cases in which the suction from the femtosecond flap-making laser actually burps the wound and causes decompression of the anterior chamber. You want stabilization of all those components. Also, though it's uncommon, some patients can have a greater level of fibrosis in their astigmatic relaxing incision(s), and the effects of their astigmatic correction can change between two weeks and three months postop. With this being the case, you want to reach a steady-state so that their refractive error remains consistent between visits.



With a toric IOL, sometimes an exchange isn't necessary and a simple rotation will suffice. When the toric IOL is in or just shy of the final position, shift the IOL, and get behind it in order to carefully aspirate out all of the visoelastic.

Since my cataract incision arcs are at a 9-mm zone, when I create a LASIK flap I make it 8.5 mm. This generally doesn't intersect or cause issues with the temporal wound, because the wound is fairly peripheral and has usually healed well.

The other important consideration when approaching LVC in these patients is whether the patient has a multifocal IOL. If you're treating a MF lens patient with custom LASIK, you'll notice that his refraction from the various image captures will be very inconsistent. This is because the aberrometer is trying to get a reading through the IOL's various rings. So, for my MF and EDOF lenses, I perform a straightforward, standard, non-wavefront-guided LASIK, based on a careful manifest refraction.

If the patient isn't one to wait, though, you can perform an IOL exchange sooner, or refer him to someone who can do the exchange.

Tips for Lens Exchanges

If you're going to perform a lens exchange, know that they can be readily done in the early postop period. Beyond the usual risk of infection, you can perform the exchange safely with no disturbance of the capsular bag, and with great outcomes. To help get the best results, though, here are some tips.

First off, if you're in the refractive-cataract surgery space but haven't performed a lens exchange yet, it's best to get comfortable with the mechanics of it.

To help become accustomed to the procedure of exchanging a lens, the next time you're in the OR with any cataract patient, once you inject the lens into the eye and dial it into the bag, take some time to practice using the Sinskey hook to deliver the haptics out of the bag and lift it a little bit into the sulcus and the anterior chamber just to get the feeling of what it's like to perform an exchange. This is helpful because the technique is very similar to that used in an actual IOL exchange in the early postop period.

When performing an actual lens exchange, if it's early on in the postop period, you can usually use your Sinskey hook to open your primary and secondary wounds pretty easily. For an exchange, I usually make a secondary paracentesis 180 degrees away from the first one, because it helps to come at the lens from different angles. This is especially true when you're trying to re-inflate the capsular bag; it just makes it a lot easier and less awkward in terms of positioning. Ultimately, I have paracentesis openings at 12'oclock and 6 o'clock; along with my temporal primary wound.

Generally, I don't use a dispersive viscoelastic, though I know there are others who do. I prefer a cohesive viscoelastic for the entire procedure. Early on in the case, you can generally leave it on the cannula and get under the optic-haptic junction to viscodissect the anterior capsule leaflet off of the optic-haptic edge. In some cases, however, you'll find that a little bit of fusion has occurred, and it may be difficult to achieve this viscodissection. In that case, it's easy to come out with the cannula and exchange it for a 27- or 30-ga needle. I engage under the anterior capsule, bevel down,

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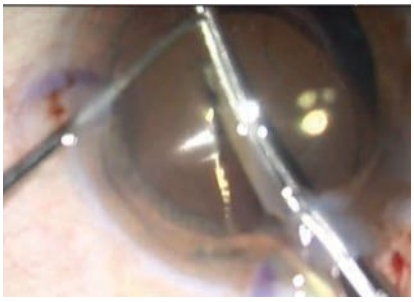
on a viscoelastic syringe, and gently inject along the optic surface to create enough space to separate the actual rhexis edge off the lens. I then quickly come back out and exchange the needle for the appropriate 27- or 30-gauge cannula—which is nice and blunt—and get back into the space.

At that point, I attempt to re-inflate the bag and, as I'm reinflating it, I try to inject the viscoelastic down the actual haptic itself to make sure I separate as much as I can. In many cases, the IOL I'm trying to remove is a one-piece acrylic, which has a terminal bulb on the haptics. These bulbs can develop little fibronectin bands that can keep the IOL stuck in the equator of the capsular bag. One important pearl here is that you can end up over-inflating the bag, which can create a posterior capsular rupture. So, as you do this maneuver, be cognizant of pushing/tapping the IOL down to release some of the viscoelastic that's stuck behind the optic, letting it come forward. Then, burp this viscoelastic out of the eye so that you actually have some potential space where you can deposit the fresh viscoelastic.

If it appears that the repeated movements involved with getting under the anterior capsule in different spots and reinflating the bag have opened it, use a Sinskey hook—or the instrument of your choice that has some form of hook—and see if you can rotate the lens. If the lens appears mobile, you have two options: You can get behind the lens with your hook, such as in the crook of the haptic-optic junction, and try to lift the IOL out of the bag and then dial the rest of the lens out; or you can actually pull the optic to one side enough to see where the actual shoulder of the haptic is so that you can then creep under the anterior capsule, engage that shoulder and lift it out of the bag. Once it's lifted out of the bag, you can get the optic with either a Sinskey hook or intraocular forceps, dial it, and then pull it up into the anterior chamber. Once it's in the chamber, make sure you have some viscoelastic to keep the IOL from touching the endothelium. In some cases, the terminal bulb of the haptic will not be mobilized, despite your best efforts. In that case, the haptic should be transected while the forceps gently pull the optic centrally, and intraocular scissors are used to transect the haptic as peripherally as safely possible.



IOLs can be explanted in different ways. Acrylic IOLs can very efficiently be stabilized with a Sinskey hook over the optic, capturing the optic nasally. Intraocular scissors can then be used to carefully transect the optic into two halves. Use plenty of viscoelastic over the optic, in order to protect the endothelium and create space between the optic and endothelium.

When you're ready, there are a couple of ways to remove the lens. Some surgeons choose to come across and actually fold the lens within the eye. I find this to be a little cumbersome, though, especially for a shorter eye. The technique that works for me involves stabilizing the lens, externalizing the haptic and ensuring that I have an adequately sized temporal wound. I usually have a 2.2-mm primary cataract wound that I'll extend to about 2.5 or 2.75 mm for an IOL exchange. I stabilize the optic with my second instrument, and I prefer to use intraocular scissors by MST to cut the optic in half. I then externalize and remove each half. At this point, some surgeons will even inject the replacement IOL into the bag in order to keep the bag protected. As long as you have good space within your temporal wound, chances are you won't burp the wound and lose viscoelastic in the process, and you'll have plenty of room to work inside the eye with your scissors and intraocular forceps while maintaining a very steady chamber.

• ***Thoughts on piggybacking lenses.*** A piggyback lens implantation can be done if you're simply correcting the spherical equivalent, because there are no piggyback lenses for astigmatic correction. That being said, I don't do piggyback lenses very often. Since the Staar silicone lens isn't available, we have few choices for a piggyback procedure. The Staar CQ2015 collamer lens is great because it's also got a rounded edge, but it doesn't come in the low powers I need for piggybacking. The Rayner lens, which is said to be a great piggyback option because it's non-acrylic and doesn't have a rounded anterior edge, isn't available in the United States.

The only other real options include the B+L LI61AO series and the AMO Sensar AR40 E series. The B+L series of lenses is nice because those are silicone three-piece lenses but, unfortunately, they have a square edge that can lead to chafing and chronic inflammation. If you're doing a piggyback operation and your primary lens wasn't acrylic, a good option is the Sensar, thanks to its rounded anterior edge, and the available low-power range.

In the end, no one likes a refractive surprise after cataract surgery. If you follow some of these tips, however, you can handle the surprise well and give your patient the outcome she wants. REVIEW

Dr. Yeu is a cornea, anterior segment and refractive surgery specialist, and an assistant professor of ophthalmology at East Virginia Medical School. She is a consultant for Cassini, Alcon and AMO.

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Sizing Up Optical Biometers

Kristine Brennan, Senior Associate Editor

Here's a rundown of optical biometers that can help make IOL planning efficient and accurate.

Since the advent of the first IOLMaster (Carl Zeiss Meditec; Jena, Germany) in 1999, optical biometry has helped fine-tune refractive results for cataract patients and keep patient flow moving. The no-contact approach to scanning ocular structures made rapid axial length measurements possible. Today's optical biometry systems can combine AL with keratometry, corneal topography and even wavefront analysis to collect data for IOL procedures and suggest which lens powers to use. A list of biometers and their features follows, along with some insights from surgeons who work with them.

IOLMaster 700

With the IOLMaster 700, Carl Zeiss Meditec AG did more than update the popular IOLMaster 500: The newest iteration uses swept-source OCT to visualize the full length of the eye, enabling the detection of unusual ocular geometry and crystalline lens tilt to assist with predicting the effective lens position. "For the first time, the examiner really sees what he is measuring. Because the IOLMaster 700 is an OCT machine, one sees the fovea, the lens and the cornea," notes Walter Sekundo, MD, PhD, professor and chairman, Department of Ophthalmology, Philipps University Hospital of Marburg in Germany.

Zeiss claims that the new IOLMaster can penetrate 99 percent of cataracts. A study[1] comparing AL, anterior chamber depth and K-value measurements obtained by the IOLMaster 700 and the IOLMaster 500 found that while the agreement between the two devices was excellent, only the IOLMaster 700 could measure through all 188 of the subject eyes. The same study indicated that when using formulae requiring white-to-white, there might be less agreement between the devices than with formulae that don't require this variable.

At 2,000 scans per second, the IOLMaster 700 measures axial length, anterior chamber depth, central corneal thickness and lens thickness quickly. Users can gather comprehensive data easily, according to Dr. Sekundo, who values the IOLMaster 700's simplicity. "Push the button once and you get everything you need," he says.

Zeiss says that the new IOLMaster's SS-OCT technology allows it to detect irregular eye geometry. One study showed that while it's not a substitute for a dedicated retinal OCT scan, the IOLMaster 700 may help pick up macular pathologies, particularly

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Patient's (top) and user's (bottom) views of the IOLMaster 700, a swept-source OCT device.

intraretinal fluid and macular holes, in patients seen for pre-cataract surgery biometry.[2]

The IOLMaster 700 includes Zeiss's "telecentric keratometry," producing highly repeatable, distance-independent corneal surface measurements. New capabilities include CCT and LT measurements. The biometer's Fixation Check feature alerts the user to a suboptimal scan if the resulting image doesn't show the foveal pit. "The examiner can check the position of the reference points, and either confirm or reject the exam," explains Dr. Sekundo, who adds, "With all laser interferometry biometry the examiner relies on the patient's good fixation."

For toric lens implantation, the IOLMaster 700 allows the surgeon to compare a reference image of the eye that uses blood vessels as landmarks to delineate the axis of the intraoperative eye. External marking is not necessary to achieve proper alignment. The device's onboard formulae include the Haigis Suite (Haigis, Haigis-L for post-refractive surgery eyes, and Haigis-T for torics); Hoffer Q, Holladay 2 and SRK/T. The IOLMaster 700 also has a built-in toric calculator, eliminating the need to use a lens manufacturer's calculator.

IOLMaster 700 users can continue to use the optimized IOL constants for more than 270 lenses from the User Group Laser Interface Biometry (ULIB) database.

Lenstar LS900

The Lenstar LS900 is an optical low-coherence reflectometry device. Manufacturer Haag-Streit says that the Lenstar, which made its debut in 2009, was the first optical biometer on the market able to measure crystalline lens thickness. The Lenstar LS900 also measures AL, corneal thickness, ACD, aqueous depth, corneal curvature, radii of the flat and steep meridians, axis of the flat meridian, WTW and pupil diameter.

For patient comfort, Lenstar's Automated Positioning System tracks eye movement to capture reliable measurements in one click. The user can select Dense Cataract Mode, and can also select for aphakic, pseudophakic or silicone oil-filled eyes before or after completing a scan. "What I like about the Lenstar is the ease of use. It just takes one click of the button to get K readings, topography, anterior chamber depth, lens thickness and axial length," says Edward Meier, MD, director of clinical research at Apex Eye in Cincinnati, Ohio.

A dual-zone keratometry measurement system with 32 closely spaced measurement points captures the spherical equivalent and axis. For extra

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[1]Blackie CA et al. Cornea 2009 (v0.1) p.1.

assurance when planning for toric or premium IOLs, the Pro version of the Lenstar LS900 comes with the option to add the T-Cone, a double-ring (1.65-mm and 2.3-mm diameter) placido disk topographer that measures a 6-mm optical zone. Another option is the EyeSuite IOL toric planner software, which includes the Barrett Toric Calculator. "The corneal measurements are so accurate you don't need to get separate K readings on another device for toric IOL planning," says Dr. Meier. "The other part that I like is that the EyeSuite software automatically populates the newest lens calculation methods, including Hill RBF, Barrett and Olsen."

The range of measurements that the Lenstar LS900 takes is required for modern IOL formulae. The Lenstar LS900 includes the following: Barrett Universal II; Barrett True-K; Haigis; HofferQ; Holladay 1; SRK/T; SRK II; Masket; Modified Masket; and Shammas No-history. In late 2016, the Lenstar LS900 also integrated the Hill RBF Method into its software, and previous adopters of the Lenstar LS900 received the update. The Hill RBF Method of IOL power prediction is based on machine learning using feature extraction and matching, and is designed to interpolate missing data and gain accuracy as it accrues experience. Holladay IOL Consultant Professional, Olsen and Okulix's ray-tracing methods are available via an additional software interface. Dr. Meier says that the Hill RBF method is his go-to for lens power calculation. "For toric strength and axis, I use the Barrett toric formula," he adds.

Dr. Meier says that the Lenstar LS900 simplifies toric IOL procedures. "I don't need to use a different machine to measure K readings if I'm planning on a toric lens implant," he says. The printout from EyeSuite gives me the lens power for as many formulae as I want to see. It also calculates toric lens power right on the printout. I can just look at the report and see if my patient would benefit from a toric implant, without having to calculate K's in my head."

Aladdin HW3.0

Topcon's new combination biometer and corneal topographer obtained FDA clearance for U.S. distribution in late February 2017. Topcon says the Aladdin HW3.0, a low-coherence interferometry biometer and placido topographer, can get the measurements needed for refractive cataract surgery with the manufacturer's goals of speed, accuracy and ease of use in mind.

"Ultrasound biometry still is ... the gold standard, but it requires a very well-trained person to perform it and get reliable data. Taking all the measurements in one instrument with a single touch makes our workflow more efficient."
—Jose A. Mendoza MD, MS

For Jose A. Mendoza MD, MS, in practice at Oftalmo Salud-Lima, Lima, Peru, the device helps keep patient flow moving while ensuring the accuracy of his IOL power predictions. "All of the important biometric measurements, for example, lens thickness, central corneal thickness and anterior chamber depth, are derived from interferometry, instead of a split beam as was used in prior versions," he says, adding that the new technology has aided IOL power calculation by more accurately predicting effective lens position.

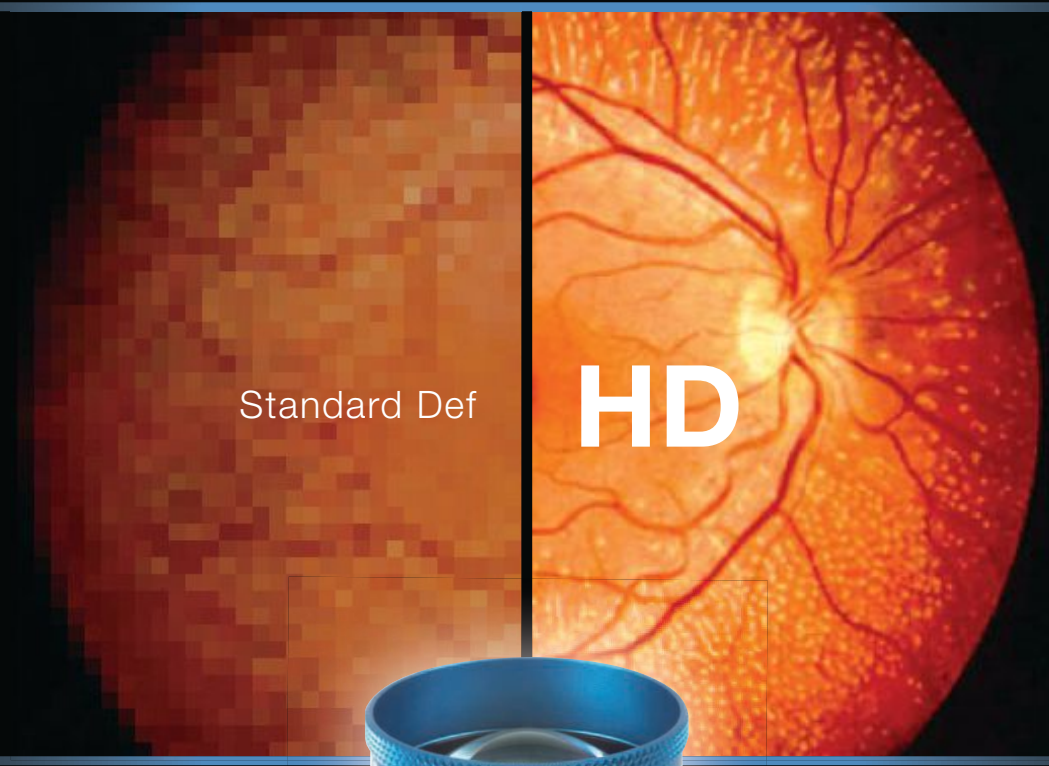
Three-zone keratometry at 3, 5, and 7 mm from the central cornea measures K's, and 24 placido rings map the cornea. The Aladdin's dynamic pupillometry allows users to see lens centration and the contraction and dilation of the pupil under photopic and mesopic conditions to assist in premium IOL selection. Zernike wavefront analysis evaluates higher-order aberrations and corneal surface anomalies like early-stage keratoconus. "The fact that Aladdin comes with a corneal topographer and also wavefront analysis helps us to decide which patients would be suitable for premium IOL implantation," says Dr. Mendoza.

The Aladdin biometer has demonstrated good agreement with the IOLMaster 500 in terms of AL, ACD and mean K-values.[3]

The Aladdin includes a built-in calculator that works with any commercially available toric IOL. The device's software features SRK/T, Holladay 1, Haigis, and Shammas No-history and the Camellin-Calossi formula for post-refractive surgery eyes. The Barrett IOL Suite and the Abulafia-Koch Regression Formula for toric lens selection are integrated into the device. "The new formulas it includes, such as the Barrett formula, provide an intuitive platform for the calculation of the cylindrical power and the placement axis of toric IOLs in astigmatic patients," says Dr. Mendoza. "The Toric IOL calculator and the simulation of the surgical outcome using this tool are really useful in our clinic, since we manage a lot of cataract patients with high astigmatism."

After taking measurements, users can save or print out an IOL report that identifies the lens power predicted to give the best refractive outcome. The Aladdin HW3.0 also generates the Measurement Report, a summary of all the data gathered

[See the **Def**-erence]



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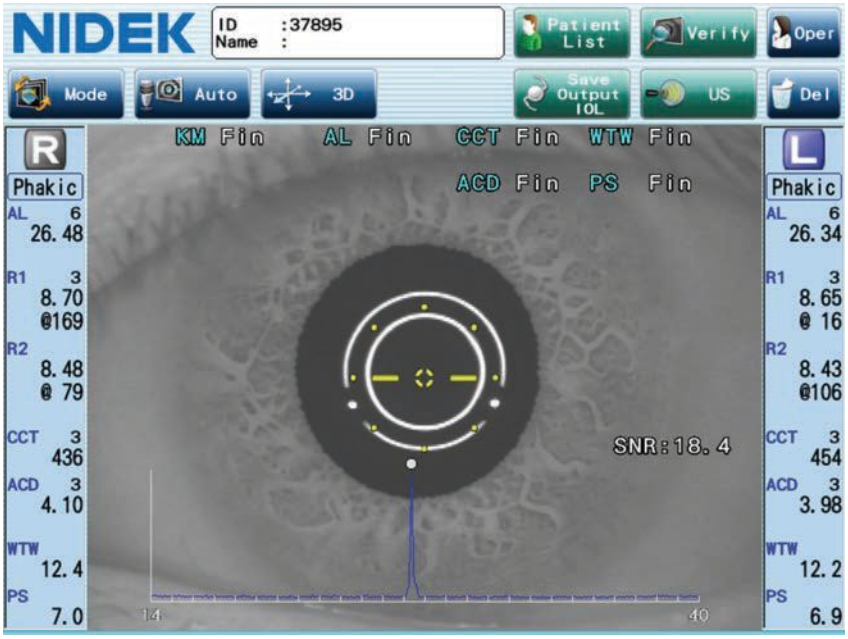

The AL-Scan has an auto-tracking feature that follows patients' eye movements along the X, Y and Z planes; auto-shot takes the scan at the moment of proper alignment.

for both eyes, as well as an Aladdin Report that alerts the user to any findings that could even subtly influence the performance of a premium IOL.

Dr. Mendoza says that in his busy practice, most cataract patients don't present for surgery until their cataracts are advanced; he reports the ability to scan through for axial length on about 30 percent more patients than before adopting the Aladdin HW3.0. "Since we started working with the new Aladdin, our surgical outcomes in hard-cataract patients are much better," he says. "Ultrasound biometry still is, as many colleagues think, the gold standard, but it requires a very well-trained person to perform it and get reliable data. Taking all the measurements in one instrument with a single touch makes our workflow more efficient."

AL-Scan

The AL-Scan measures axial length, anterior chamber depth, pupil size, WTW, central corneal thickness and keratometry in 10 seconds with ease, according to manufacturer Nidek. "The device is very easy to use, and technicians find it quick and very straightforward," says Sheraz Daya, MD, FACP, FACS, FRCOphth, medical director of the Centre for Sight in London. "Between the software and automated features, the device is very straightforward. There is less variation in terms of intra-user and inter-user variability."

Nidek says that preop measurements are easy for the patient as well as the operator of the AL-Scan, thanks to the biometer's 3D auto-tracking and auto-shot features: Auto-tracking follows the patient's eye movements along the X, Y and Z planes, while auto-shot takes the scan as soon as it senses correct alignment, for valid data with minimal fuss. Auto-tracking and auto-shot can facilitate collecting trustworthy data even from restless patients. "Auto-tracking improves usability; the technicians just love this feature," Dr. Daya notes.

Scheimpflug imaging captures CCT and ACD, which help to assess the depth of the cataract. Topography and keratometry with double mire rings reflected onto the cornea aid in evaluating for aberrations. The AL-Scan zeros in on optical landmarks in the eye to measure the angle from the steepest meridian. This axis determination aids the alignment of toric lenses.

Dr. Daya considers the AL-Scan a reliable source of multiple measurements using one device. "Three years ago we compared its performance to the IOLmaster 500 and found there was no difference in terms of measures and IOL calculations. It compared well to Pentacam keratometry. The device also has a built in ultrasound A-scan and a pachymeter," he says.

Surgeons can use the AL-Scan's constant-optimization feature to fine-tune IOL constants for results that can continually improve. The AL-Scan incorporates IOL formulae including Camellin-Calossi for post-refractive eyes; SRK/T, Shammas PL; Binkhorst, Regression; Regression II; HofferQ; Haigis and Holladay.

Nidek says that the AL-Scan has the ability to penetrate even dense cataracts by adjusting signal-to-noise ratio to amplify the signal, but the AL-Scan also offers an optional built-in ultrasound biometer to avoid moving patients to another machine if an A-scan is needed. "Although calculations can be performed with dense cataracts, there is the odd time when having the ultrasound device readily available is useful," Dr. Daya notes.

Argos

Relative newcomer Argos (Movu) attained FDA clearance in 2015. It uses swept-source OCT to get whole-eye scanning in a single 0.6-second capture, according to the manufacturer. The Argos measures AL, CCT, aqueous depth, ACD, LT, pupil size, WTW, K's and astigmatism.

Dense Cataract Mode allows the Argos to acquire data that other biometers may not get, according to Daniel Kim, MD, medical director of St. Mary's Eye & Surgery Center,

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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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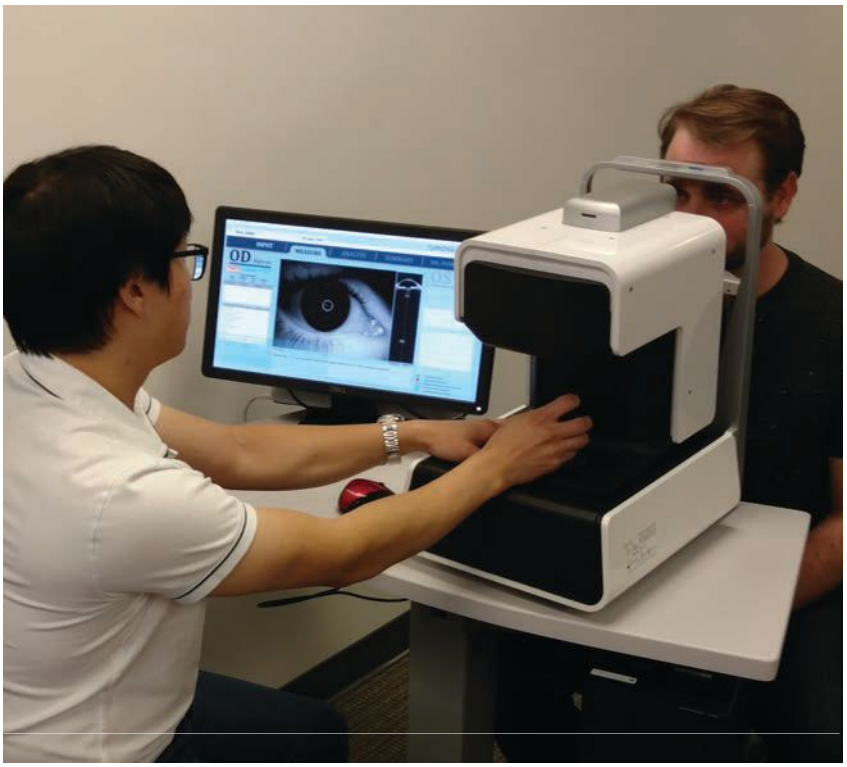

Manufacturer Movu says that the Argos acquires axial length, central corneal thickness, aqueous depth, anterior chamber depth, lens thickness, pupil size, white-to-white and keratometry quickly, making scans easy on patients.

Palisades Park, N.J. "Axial length acquisition rate is high, even in dense cataracts," he says. "There are fewer patients that need to be referred to A-scan." He also appreciates the speed at which the measurements are captured, adding, "A fast acquisition rate means that repeatability is great, and the patient does not need to be fixated for as long as with other biometers."

William B. Trattler, MD, Center for Excellence in Eye Care, Miami, Fla., also appreciates the Argos' ability to measure eyes with advanced cataracts. "The Argos biometer has made a significant impact to our practice in that it has dramatically reduced our need to perform ultrasound biometry," he says.

The Argos features an analysis mode that allows the surgeon to verify the results of collected measurements. "Analyze Mode allows our technicians to check the plausibility of the biometric values," Dr. Kim explains. "Having the OCT image available confirms that the measured parameters do actually align with correct boundaries. There are also indicators if the patient was not fixated during measurement, or of any other complications that would not necessarily be detected by biometers that do not provide a whole image of the eye."

The Argos' IOL power formulae include the Barrett Suite, Hoffer Q, Haigis, Holladay I, SRK/T and Shammas No-history.

"We like that the Argos has the Barrett Universal II formula as well as the Barrett True K formula integrated," says Dr. Trattler. "It also has a toric IOL calculator built in that can use these formulas, so we don't need to export our data to web-based planning software," he adds, noting that this helps avoid refractive surprises stemming from manual transcription errors.

Dr. Trattler says he combines data from the Argos with corneal mapping. "We typically use a placido disc topographer for evaluating the corneal shape, as well as the Cassini topography system, which we use for posterior corneal astigmatism measurements," he says.

Pentacam AXL

In addition to the Argos, the Pentacam AXL from Oculus has a valued role in Dr. Trattler's practice. "The Pentacam AXL is a very robust device that combines corneal imaging with axial length measurements," he says. "Its strength is the software, which can provide an incredible level of information about the anterior segment of the eye. The tomography software provides corneal shape images and corneal shape analysis. The integrated software can be used to determine whether a patient is an appropriate candidate for LASIK, if it's needed after cataract surgery," he says.

The Pentacam AXL combines the Scheimpflug imaging of the original Pentacam with a PCI biometer. The Pentacam AXL takes a succession of AL measurements, and the software selects the best one to render a three-dimensional image of the anterior segment.

The Pentacam's Scheimpflug camera technology allows it to assess corneal topography, taking into account irregularities and astigmatism of both the anterior and posterior corneal surfaces.

Another feature of the Pentacam AXL's software is the ability to estimate changes in the corneal shape incurred by previous PRK or LASIK, based on its current evaluation of the shape of the cornea. "The Pentacam AXL can provide an approximation of the patient's pre-LASIK level of myopia or hyperopia," Dr. Trattler explains.

The Pentacam AXL's combination of measurements, including CCT and WTW in addition to topography, keratometry and AL, are entered into the IOL calculation software automatically, so transcription errors aren't a con-

cern. The device will also measure the density of cataract and grade corneal opacities. "The Pentacam AXL can also evaluate the average angle depth, and is therefore useful for documenting and evaluating cases with narrow angle," says Dr. Trattler. "Another important aspect of the device is its assessment of corneal thickness. This is useful in patients who have Fuchs', so we can measure corneal thickness both before and after surgery to determine if the corneal thickness has returned to baseline postop."

The CCT measurement is also important for modern IOL power calculation; the Pentacam AXL's IOL power calculator includes formulae for normal eyes and post-refractive surgery eyes, among them Haigis, SRK/T, Holladay 1, Hoffer Q, Potvin-Shammas-Hill and Potvin-Hill. An integrated IOL database helps surgeons select the right lens at the correct power.

The Pentacam AXL generates multiple reports, including the Fast Scanning Report, which can alert the user to keratoconus and other corneal changes, as well as anterior chamber irregularities. The Pentacam AXL's Belin/Ambrósio Enhanced Ectasia Display function can detect ectatic conditions such as posterior keratoconus or post-LASIK ectasia.

The ability to measure irregularities on both corneal surfaces and wavefront analysis capability assist with premium IOL planning. The operator simply focuses on the center of the patient's pupil to get Oculus' Total Corneal Power Map. The Total Corneal Power Map calculates corneal power based on anterior and posterior astigmatism, which can help in planning toric IOL implantations. REVIEW

Dr. Sekundo is a consultant for Carl Zeiss Meditec AG. Dr. Daya is a consultant for Nidek. Dr. Kim is a consultant for Santec USA Corporation, parent company of Movu. Dr. Trattler is a consultant for Santec USA Corporation and Oculus. Drs. Meier and Mendoza report no relevant financial disclosures.

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Edited by
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Resident Training: The Aravind Experience

Haripriya Aravind, MS
Madurai, India

The chief of a busy cataract department details how she trains residents.

Residency training is crucial for the future of ophthalmology, as well as delivery of quality eye care. Therefore, the approach an institution takes to educate residents is important. Aravind Eye Care System in southern India has trained more than 800 residents over the past 35 years, and we feel our unique approach helps prepare them to serve our population of more than 1.3 billion. In this article, I'll highlight some unique aspects of our residency training that we feel make a difference in surgeons' education.

A Training Overview

In 2011, there were approximately 1,285 residency openings in India.[1] This includes the three-year master of surgery and diplomate of national board programs and the two-year diploma programs. For Aravind Eye Hospitals in particular, across our six tertiary eye-care centers, about 60 residents are enrolled in our residency program each year. Candidates are required to have completed their medical school prior to residency training. Medical school training is called MBBS, short for bachelor of medicine and bachelor of surgery.

Our microsurgical training curriculum is designed keeping in mind the knowledge, skill and attitude required to become a competent surgeon. Cataract surgery knowledge is acquired through reading suggested reference books, attending a set of lectures, submitting written assignments on important topics and watching instructional videos. A set of 15 lectures is covered within the first two weeks of commencement of their training. Skill development is through teaching of surgical steps, first at the wet lab, then through simulator practice and later through surgery on patients. The third critical aspect of the mindset toward surgery is covered by clarifying expectations at the very beginning of the surgical training and at every step of learning afterward, emphasizing that patients and their outcomes always come first, ahead of the residents' training. In terms of subspecialty training, during residency the residents pass through a rotation in various subspecialties such as retina, cornea, glaucoma, pediatric ophthalmology and oculoplastics. If they choose to undertake a fellowship, its a one- to two-year program which they undertake after the three-year residency program.

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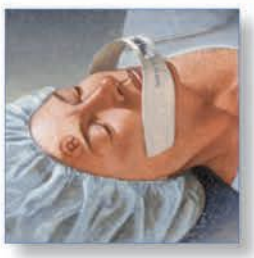

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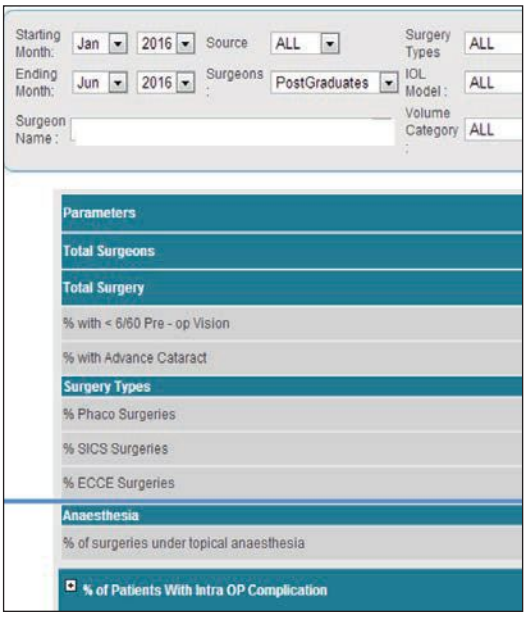
Cataract Instruction

Cataract surgical training is usually started by the fifth to eighth month of the residency program. Prior to that, the resident picks up skills in comprehensive ocular examination and preoperative evaluation of patients undergoing cataract surgery. One month is dedicated to the initial cataract surgical training, during which time the resident learns to perform extracapsular cataract extraction and manual small-incision cataract surgery. ECCE is a good technique for fostering an understanding of the anterior segment of the eye and for teaching suturing techniques. M-SICS is extremely popular in the developing world and is an effective technique employed to address cataract blindness in these settings. A dedicated trainer (medical consultant or senior anterior segment fellow) stays with the residents throughout the month. Near the end of their residency, the residents learn to perform phacoemulsification surgery.

On the first day of the month the trainee and trainer are oriented regarding the schedule and training program. In the initial few days, the residents are exposed to operation theater protocols, the central sterile supply department, patient flow in the OR, the surgical safety checklist and various local anesthetic techniques such as retrobulbar, sub-Tenon's and facial block. In the first week they also concentrate on wet lab practice and attend the scheduled lectures.

Wet-lab training includes:

- Orientation on use of operating microscope and surgical instruments and developing hand-eye coordination.
- Practice of various suturing techniques under the operating microscope using nylon sutures and sponge.
- Use of animal eyes (goat's eyes) and cadaver eyes (donor eyes unsuitable for corneal transplantation) are used to practice sclerocorneal tunnel construction, capsulorhexis and manual cortex aspiration using the Simcoe cannula.
- Use of the surgical simulator (Eye-Si) to learn surgical concepts such as hand-eye coordination, depth perception, control of hand tremors, capsulorhexis, hydro procedures, nucleus rotation and phacoemulsification.
- Instruction in phacoemulsification machine parts, machine connections, settings and foot pedal practice.
- Instruction in phacoemulsification technique (divide and conquer) using a goat-eye model. Here, about 70 percent of the lens matter from the goat eye's capsular bag is aspirated out and replaced with a frozen cataractous nucleus obtained from extracapsular cataract surgery. Learning phacoemulsification using this model is effective, as the surgeon is emulsifying an actual cataract.



Detail from Aravind's Cataract Surgery Outcome Monitoring system. With it, residents can compare their outcomes to those of their colleagues.

Surgical Training

Surgical training occurs between the second and fourth week, during which time each resident typically performs five extracapsular cataract extractions followed by 12 M-SICS procedures. We emphasize appropriate patient selection, which includes patients with immature cataracts and well-dilated pupils without coexisting risk factors. Initially, the residents only perform a few steps, and the rest of the case is done by the trainer. Then, after approximately five cases, they perform most of the surgery with assistance from the trainer. If a complication occurs, the rest of the surgery will be completed by the trainer while the trainee surgeon observes how the trainer manages the situation. After completion of the initial intense training, the resident performs about 10 surgeries over the next month, followed by once-weekly sessions in which the numbers are gradually increased. We find this system of consistent, intense hands-on experience early in the residents' career shortens the learning curve and improves skill and confidence. Even after they start performing independently, if they encounter a complication, a more experienced surgeon is called in to supervise or manage the case. Once they're competent with the surgical technique, they then attend an anterior vitrectomy and posterior capsule rupture management course to improve their complication-management skills.

Evaluation and Feedback

The residents maintain a detailed log of the preoperative findings, surgical events and postoperative evaluation of each surgery. The consultant signs the log book on a daily basis and provides the necessary feedback. The problems faced by the resident are discussed with the trainer both immediately after surgery and during wet-lab sessions. Feedback is also provided during postoperative examination in an effort to correlate cause and effect.'The trainer uses the OSCAR (Ophthalmology Surgical Competency Assessment Rubric) tool for each surgery to assess the competence of the trainee surgeon. Besides gauging the individual surgeon's learning curve with regard to each surgical step, the trainee surgeon also understands what s/he has to aim for in each step to become a more competent surgeon.

At the Aravind Eye Hospital, we have a data registry called the Cataract Quality Evaluation Registry. In the CATQA, information from each surgery such as demographics; preoperative, intraoperative and postoperative clinical pictures; preop and postop visual acuities; and refractive outcomes are entered into the database. This gives the residents a comprehensive view of their complication rates and visual outcomes over an extended period of time, and enables them to benchmark their performance with their peers and the rest of the institution. In addition, every quarter a senior cataract consultant reviews the data with each batch of residents and analyzes both the volume and quality of surgery performed by the residents and gives constructive feedback.

The average number of cataract surgeries performed by each resident over three years ranges from 700 to 900, most of which are M-SICS. Their complication rate is around 4 percent over the first 50 cases, decreasing gradually over the next 300 cases until it hits a level below 2 percent over the final 300 to 400.

In conclusion, a structured training curriculum with adequate wet-lab opportunities and timely feedback helps to develop residents who are confident and competent to perform quality cataract surgery. REVIEW

Dr. Aravind is chief of intraocular lens and cataract services at Aravind Eye Hospitals & Post Graduate Institute of Ophthalmology.

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Sixth Cranial Nerve Dysfunction in Children

The significance of sixth cranial nerve dysfunction, and how to catch it in time for management to be successful.

Carla J. Osigian, MD, Ta C. Chang, MD, and Kara M. Cavuto, MD, Miami

The sixth cranial nerve, or abducens nerve, is the most commonly affected cranial nerve in children presenting with acquired strabismus.[1,2] It innervates the lateral rectus muscle, which is responsible for abduction of the eye. Patients with sixth nerve dysfunction will present with impairment of the ipsilateral lateral rectus muscle function, characterized by a limited or complete absence of abduction of the affected eye. This results in an esodeviation due to the unopposed action of the antagonistic ipsilateral medial rectus muscle. Acquired cranial nerve dysfunctions are often more concerning in children than in adults, as they can frequently be a presenting sign of life-threatening pathology. In this article, we'll look at the anatomy of the sixth cranial nerve and provide tips for determining the cause of any dysfunction.

Anatomy

The sixth cranial nerve nuclei are located in the dorsal pons. Each nucleus contains the primary motor neurons for the ipsilateral lateral rectus muscle as well as the interneurons that travel through the medial longitudinal fasciculus to reach the contralateral third cranial nerve nucleus. Lesions or injury in this region will result in a complete ipsilateral horizontal gaze palsy, due to a deficit of abduction from the lateral rectus as well as an adduction deficit from the contralateral medial rectus. These lesions are usually also associated with ipsilateral facial nerve palsy (CN VII) due to the close proximity of these two nerves in the pons, as well as other brainstem signs such as hemiparesis and hemisensory loss.[3]

Each sixth cranial nerve nucleus issues sixth nerve fascicles that travel ventrally and laterally within the pontine tegmentum to exit at the pontomedullary junction. The nerve then enters the subarachnoid space and climbs vertically along the surface of the clivus. It subsequently travels over the petrous apex of the temporal bone to enter through the Dorello canal into the posterior cavernous sinus. Due to its long path along the subarachnoid space, the sixth nerve is particularly susceptible to damage due to traction forces of trauma and elevated intracranial pressure along this space.

Upon entering the posterior cavernous sinus, the sixth cranial nerve is joined by cranial nerves III, IV and V. It then enters into the substance of the cavernous sinus, where it runs lateral to the internal carotid artery and medial to the ophthalmic division of the trigeminal nerve. Due to the proximity of these structures, lesions occurring in the cavernous sinus often present with multiple cranial nerve palsies.

After exiting the anterior cavernous sinus, the sixth nerve then transverses the superior orbital fissure and enters the orbit through the annulus of Zinn to innervate the lateral rectus muscle.[3,4]

Etiology

Lesions causing dysfunction of the sixth cranial nerve can be congenital or acquired, and can occur anywhere along its path, from the nucleus in the dorsal pons to the lateral rectus muscle in the orbit. They are composed of:

- ***Congenital dysfunctions.*** When a child presents with a congenital esodeviation and abduction

This article has no commercial sponsorship.

Moderate angle esotropia in primary gaze with limited abduction on both right and left gaze, compatible with a diagnosis of bilateral sixth nerve palsy.

deficit, the most common cause is Duane syndrome, followed by isolated congenital sixth nerve palsy. Duane syndrome is characterized by anomalous co-contraction of the medial and lateral rectus muscles on adduction of the involved eye, which causes the globe to retract. Studies have shown the cause of this motility disorder might be a hypoplastic or absent sixth nerve nucleus, with an aberrant branch of the third cranial nerve innervating the lateral rectus muscle.[5] These two presentations may be difficult to differentiate, as the globe retraction feature of Duane syndrome may not be evident or may be difficult to elicit in infants. A distinguishing characteristic is that the deviation in primary position is usually much larger in sixth nerve palsy than it is in esotropic Duane syndrome.[6]

An isolated congenital sixth nerve palsy is rare, and, in most cases benign. It's thought to occur secondary to increased intracranial pressure associated with the birth process and usually resolves spontaneously.[6] It has also been associated with neurological conditions such as hydrocephalus and cerebral palsy.

• ***Acquired dysfunctions.*** The most common cause of an acquired sixth cranial nerve dysfunction in children is a neoplasm. This is followed by trauma, elevated intracranial pressure, inflammatory causes and postviral etiologies.[1,2,7-9]

- *Intracranial neoplasm.* Studies report that tumors and tumor removal surgery account for 20 to 45 percent of sixth nerve palsies in children.[1,2, 7-9] Tumors, either benign or malignant, can cause compression of the sixth nerve anywhere along its path and produce a unilateral or bilateral palsy. The most common tumors found in the pediatric population are posterior fossa tumors, such as brainstem glioma, medulloblastoma, ependymoma and cystic cerebellar astrocytoma. These patients usually present with other neurological symptoms such as ataxia and disturbance of gait along with sixth nerve palsies.[10]

- *Trauma.* Traumatic sixth nerve palsies can occur secondary to head trauma and skull base fractures. Approximately 12 to 42 percent of acquired sixth nerve palsies are of traumatic etiology.[1,8]

Trauma causes indirect pressure on the nerve, which is very susceptible to shearing forces as it passes over the apex of the petrous temporal bone and enters the cavernous sinus through the Dorello canal. These palsies may or may not improve over time, with maximum improvement typically occurring during the first six months after onset.[11]

- *Elevated intracranial pressure.* Elevated intracranial pressure can produce downward displacement of the brainstem, causing damage to the sixth nerves by pressure or traction of the nerves where they are tethered in the Dorello canal. Patients may also present with other signs of increased intracranial pressure such as headache, nausea, vomiting or papilledema. In children, this can occur secondary to a variety of underlying causes, including hydrocephalus, shunt failure, pseudotumor cerebri, posterior fossa tumors, neurosurgical trauma, venous sinus thrombosis, meningitis and Lyme disease.

- *Inflammatory and infectious disorders.* Pathologies such as meningitis, Lyme disease, varicella zoster and cytomegalovirus, among others, can cause inflammatory damage of the nerve along its course through the subarachnoid space. Chronic inflammation of the petrous bone in children with infections of the middle ear may cause an ipsilateral sixth cranial nerve palsy and facial pain, in a condition known as Gradenigo syndrome.[4]

Clinical Manifestations

Patients with sixth nerve palsy will present with dysfunction of the ipsilateral lateral rectus muscle, characterized by limited or no abduction of the affected eye on versions and ductions. When the nucleus is affected, patients will present with a complete horizontal gaze palsy. Other sixth nerve dysfunctions will present as an esodeviation on primary gaze, which increases with gaze towards the affected muscle. Characteristic features that differentiate an esotropia secondary to sixth nerve dysfunction from other types are the slowing of saccadic velocities of the affected lateral rectus muscle and weakness of the muscle on active force generation.

Older children with acquired sixth nerve palsies with good visual acuity may report binocular horizontal diplopia that worsens with gaze towards the paretic lateral rectus muscle. They will often have a compensatory head turn towards the side of the affected muscle to alleviate the double vision.[6] However, younger children may not complain of diplopia due to suppression abilities. If the child

presents soon after onset, suppression of the non-dominant eye has usually not been present long enough to produce suppression amblyopia, but a difference in visual acuity may be present later on.

Evaluation

The first aim of evaluation of these patients should be to identify the underlying cause of the sixth nerve palsy. Be sure to take a careful history, focusing on the presence of clinical features indicating a mass lesion and/or elevated intracranial pressure, such as focal neurologic complaints, headache, nausea and vomiting. The history should also include recent head trauma, infections, immunizations and other possible inciting factors. A complete neurologic examination should follow, evaluating for papilledema as well as any other neurologic abnormalities.

Urgent neuroimaging of infants and children with sixth nerve palsy depends upon whether the palsy is unilateral or bilateral and whether the palsy is isolated or accompanied by other neurologic abnormalities. Magnetic resonance imaging with and without gadolinium is the preferred modality of imaging to rule out an intracranial process, given the superior imaging capability of posterior fossa structures. Pay special attention to features such as a mass lesion, hydrocephalus, malformations and venous thrombosis. In adolescents, demyelination may be the cause, in which case MRI with fluid-attenuated inversion recovery imaging typically reveals T2 hyperintensities consistent with multiple sclerosis.[4]

If you find that the neuroimaging is normal, you can perform a lumbar puncture in order to measure the opening pressure in cases of suspected pseudotumor cerebri, or to measure the cerebrospinal fluid cell count, glucose and protein in cases of suspected meningitis. In addition, you can also perform serologic analysis, such as Lyme titers.[8]

Imaging Recommendations

Unilateral sixth nerve palsies in the absence of other neurological abnormalities are generally thought to be due to traumatic, postviral or idiopathic causes. However, recent studies looking exclusively at isolated palsies have found that tumors are actually the most frequent underlying cause in these patients, accounting for up to 30 percent of cases, followed by viral (19 percent) and traumatic (6 percent) etiologies.[12] Due to the variability of these findings, recommendations regarding immediate neuroimaging differ. If follow-up can be assured, some authors recommend following an isolated unilateral sixth nerve palsy without imaging until resolution, unless neurologic symptoms and signs develop, the angle of strabismus deteriorates or the palsy fails to improve after three months of observation.[12,13] On the other hand, in light of the high prevalence of associated intracranial lesions, the American Academy of Ophthalmology recommends obtaining an MRI in all children presenting with acquired sixth nerve palsy, even in the absence of other focal neurologic findings.[6] Of note, the development of a sixth cranial nerve palsy following minor head trauma is unusual, and the child should also undergo neuroimaging for the high suspicion of an accompanying compressive lesion.

In patients with non-isolated unilateral or bilateral sixth nerve palsies, the recommendations are more conclusive. Neuroimaging is indicated emergently in patients with the presence of bilateral palsies or patients with either unilateral or bilateral palsies presenting in association with other neurological abnormalities and/or papilledema.

Management

The treatment of sixth nerve palsies depends on the underlying cause. The goal of ophthalmological management in pediatric cases of sixth nerve palsy is to first and foremost identify the etiology and refer the patient for specialized treatment of the underlying pathology as needed.

Secondly, other key goals are to maintain binocular vision and promote visual development.

Careful and close follow-up with the patient with a nerve palsy, preferably by a trained pediatric ophthalmologist, is required to assess any changes in the patient's visual acuity levels and for proper sensorimotor evaluation of the patient. Spontaneous recovery may occur in patients with unilateral, isolated sixth nerve palsies. In younger patients, patching may be necessary to prevent or treat amblyopia. If a compensatory head posture allowing binocular fusion is present, patching may be optional unless there is a change in visual acuity or angle of deviation. Press-on prisms may be recommended to promote binocular vision and, in older patients, to alleviate diplopia in primary gaze. Some authors advocate the use of botulinum toxin injection of the ipsilateral medial muscle in order to cause temporary paralysis of the antagonist muscle.[14,15] This may decrease the angle of esotropia while preventing secondary contracture of the medial rectus muscle due to unopposed contraction.

In cases of nerve palsies that don't resolve after six months of management or observation, strabismus surgery may be indicated. Options for this surgical intervention include horizontal rectus muscle surgery—if the abduction function of the lateral rectus is partially preserved—or vertical rectus muscle transposition to the lateral rectus muscle if abduction is absent.

Counseling

Counseling patients and parents with cranial nerve palsies is often challenging, especially in cases of tumors. Many times, the psychological burden and stress, as well as follow-up with other specialties to treat the underlying pathology, will relegate ophthalmological evaluations to a lesser plane.

In any case, when faced with cases such as these, it's important to provide the patient's parents with the adequate information and reinforce the importance of continuous follow-up for visual development, as survival rates in children can be high depending on the pathology, and maximizing visual function is key for their future development. REVIEW

Dr. Osigian is an instructor at the Bascom Palmer Eye Institute, University of Miami Miller School of Medicine. Drs. Chang and Cavuto are assistant professors of clinical ophthalmology at Bascom Palmer.

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Stem the Tide of Excessive Tearing

Expert tips for diagnosing and managing patients who present with epiphora.

Jose Luis Tovilla Canales, MD, Osiris Olvera Morales, MD, and Adriana Velasco y Levy, MD, Valencia, Spain

Epiphora, or a watering eye, is one of the most common symptoms of many ocular pathologies and, as such, it can be a diagnostic challenge. The causes are often multifactorial and demand a thorough history and exam to ferret out. In this review, we'll explain the various causes of epiphora and the most effective ways to treat them.

Causes of Epiphora

Though most cases of epiphora are due to non-patency in the lacrimal outflow pathway, others, such as eyelid and adnexal disorders, and corneal and ocular surface pathologies, can also cause watering.[1]

It's important, then, to distinguish between the terms epiphora and pseudo-epiphora or hyperlacrimation.[1] True epiphora refers to watering due to obstruction in the lacrimal outflow pathway, while hyperlacrimation refers to excessive watering due to irritation of the corneal surface, as in cases of dry eye, corneal abrasion or corneal foreign body.[2]

Obstructions of the excretory lacrimal system can be either anatomical (referring to any structural pathology in the lacrimal outflow pathway that obstructs tear passage) or functional (where the lacrimal outflow pathway is anatomically normal with a patent syringing, but there's a failure of the lacrimal pump mechanism elsewhere).[2]

Pertinent Anatomy

The lacrimal system is divided into the secretory (tear production) and the excretory apparatus (where tears are drained from the eye into the lacrimal sac). Tears are produced by the main and accessory lacrimal glands. Tear quantity and composition are subject to regulatory control and may depend on weather conditions, as well as a healthy eyelid and ocular surface.

On the other end of the process, the excretory system is divided into a proximal and distal section. The proximal section includes the punctum, the canaliculus and the common canaliculus.[3-4] The distal lacrimal drainage system consists of the lacrimal sac and the nasolacrimal duct that finally opens into the lateral nasal wall below the inferior meatus.[3]

Spontaneous blinking (occurring at an average rate of eight to 12 per minute) also plays an important role in tear drainage. Eyelid closure begins at the lateral canthus in order to bring tears into the lacrimal drainage system. During this action, the inferior eyelid is displaced 0.5 mm more medially than the upper eyelid, so that the superior and inferior lacrimal puncta can get in touch. Once the tears are in the punctum and canaliculi, a pumping mechanism caused by the contraction of the palpebral orbicularis oculi muscle (particularly Horner's muscle) over the lacrimal sac helps to drain the tears into the inferior meatus.[4-5] For this reason, it's very important to evaluate the anatomy and physiology of the patient's eyelids during your exam, as laxity or malposition may be responsible for tearing.

Contrary to previously held beliefs, recent studies using high-speed video showed that the central portions of the upper and lower eyelids don't touch during spontaneous blinking.[6]

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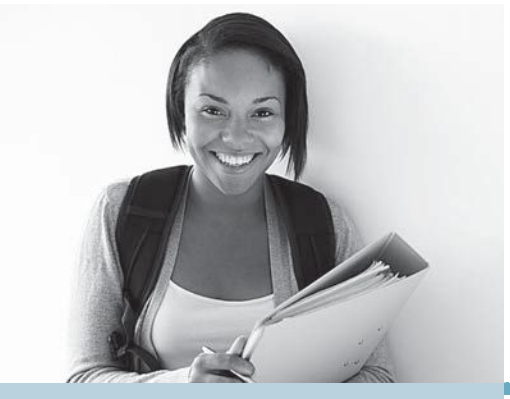

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Table 1. Causes of and Treatments for Epiphora[11]

Causes	Treatments
Punctal obstruction	Dilation, three-snip punctoplasty, silicone intubation
Canalicular obstruction	
Canalicular stenosis/ constriction	Silicone intubation.
Complete canalicular occlusion	Excision of occuded area and plastic repair of canaliculus
Canaliculitis	Antibiotics, warm compresses, curettage with canaliculotomy to remove concretions
Common canalicular obstruction/loss of canaliculi	Conjunctivodacryocystorhinostomy (CJDCR) with Jones tube placement
Nasolacrimal duct obstruction	Silicone intubation with or without dacryocystorhinostomy
With dacryocystitis	Antibiotics, allow acute infection to resolve, usually necessitates dacryocystorhinostomy
Recurrent NLDO	Dacryocystorhinostomy
Poor pump function/lid malposition	
Involutional ectropion	Horizontal eyelid tightening with lateral tarsal strip or modified lateral canthopexy
Involutional entropion	Retractor reinsertion with lateral tarsal strip or modified lateral canthopexy
Punctal ectropion	Medial spindle with or without horizontal eyelid tightening procedure
Ocular Surface Disorders	
Dry eye	Correct underlying problem. Consider artificial tears, punctual plugs, cyclosporine A, etc.
Conjunctivochalasis	Surgery. Removal of conjunctival folds

Diagnosis

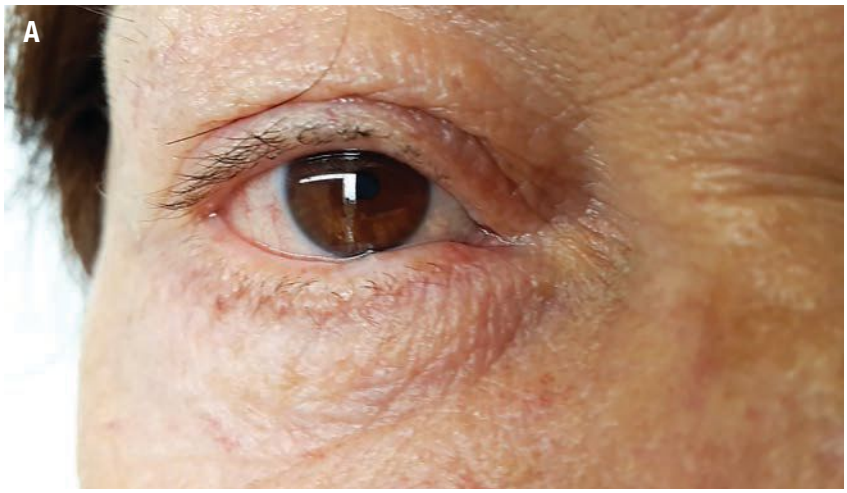
As mentioned earlier, tearing is multifactorial. Ophthalmologists need to differentiate tearing due to an excessive production of tears from tearing that results from an altered excretory system.

First, a detailed history of any systemic or topical medication, surgery, trauma, scarring and infection is mandatory. History of sinus disease, sinus surgery, mid-facial or ocular trauma, or history of nasolacrimal duct probing during childhood may all suggest obstructive problems. Associated symptoms such as pain, itching and burning are important to elicit, as they may provide further insight into the etiology.

During the slit lamp examination it's important to document the position and size of the lacrimal punctum, the height of the tear meniscus, evaluation of the eyelid margin (position, aspect of the meibomian glands, presence of trichiasis-distichiasis, blepharitis, etc.) and conjunctivochalasis. *(See Figure 1)* In addition, mucus secretion or blood in the tear film may indicate infection or malignancy, respectively. Laxity of the eyelids decreases the pump mechanism, so the snap-back and pinch tests have to be performed. *(See Figure 2)* Sometimes, using a skin tape in the office to simulate the effect of a lateral canthoplasty in the tearing patient may help to diagnose epiphora due to eyelid laxity.

Irrigation of the patient's lacrimal system will help the clinician determine the site of obstruction. You should suspect canalicular obstruction when you notice clear solution from any of the canaliculi while you're irrigating, but if regurgitation appears as a mucous secretion, diagnosis is a nasolacrimal duct obstruction. Some patients, however, may complain of a watery eye without any ocular or eyelid abnormality and with a patent lacrimal system during irrigation. This presentation is an entity known as functional epiphora.

Schirmer's tests 1 and 2,[8] tear breakup time,[9] ocular surface staining and tear meniscus height are some tests that help to highlight associated ocular surface abnormalities. *(See Figure 3)* The dye disappearance test is useful for differentiating hyperlacrimation from lacrimal drainage obstruction (whether functional or anatomical). In this test, you instill a drop of fluorescein 2%, or briefly place a fluorescein strip wetted by artificial tears, in the inferior fornix of each eye. You then evaluate the tear meniscus height with cobalt blue light after five minutes for the clearance of fluorescein and symme-



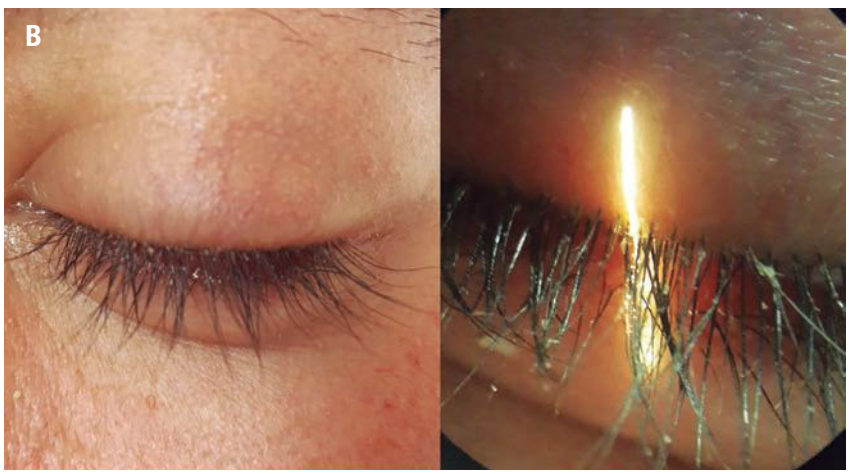


Figure 1A (top). Patient with epiphora. It's important to evaluate the position of the eyelids and lacrimal punctum, the aspect of the meibomian glands and eyelashes, as well as the presence of blepharitis and trichiasis (Figure 1B, bottom).

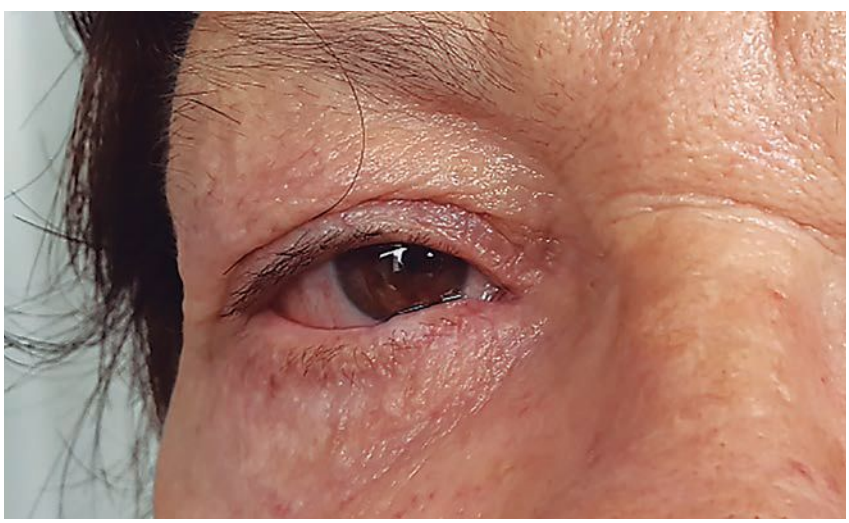


Figure 2. Eyelid laxity decreases the pump mechanism for lacrimal drainage. The snap back and pinch tests are very useful for determining whether this is the problem.

try of dye in both eyes.[4] *(See Figure 4)* In the pediatric patient in whom irrigation is not possible, the dye disappearance test may help diagnose an abnormal tear drainage system.[9]

Etiology and Treatments

An awareness of the exact cause of the patient's epiphora will allow you to select the right treatment. Here are the main etiologies to be aware of:

• ***Punctal stenosis.*** Punctal stenosis is a common cause of epiphora. It can be congenital, or acquired from infectious and inflammatory eyelid disorders, ocular surface disease, systemic or topical medications (antiviral, anti-glaucoma or anti-neoplastic medications), eyelid tumors or trauma.[11-13] It can appear as an isolated disorder or associated with canalicular stenosis, eyelid laxity or malposition. Also, tissue atrophy and involutional changes can cause the dense fibrotic structures of the punctum to be less resilient and the surrounding orbicularis fibers to become atonic, resulting in punctal stenosis.[14] *(See Figure 5)*

The basic principles in the treatment of punctal stenosis include creating an adequate opening while maintaining the position of the punctum against the lacrimal lake and preserving the lacrimal pump function.[15-16]

Repeated dilation of the stenotic punctum is a simple procedure that may provide temporary improvement in the patient's symptoms, but recurrences of stenosis are common unless additional procedures are performed.[16]

Different methods of punctoplasty have been used to augment punctal size, but the two-snip and three-snip punctoplasties have the best outcome. For recalcitrant cases, silicone intubation can be an effective method to help keep the punctum open.

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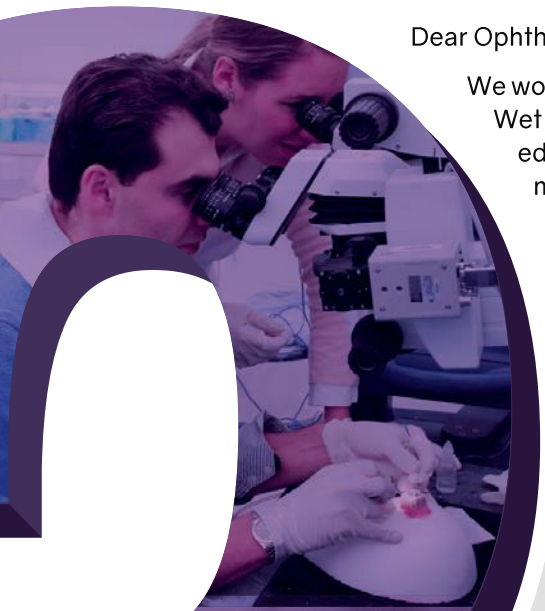

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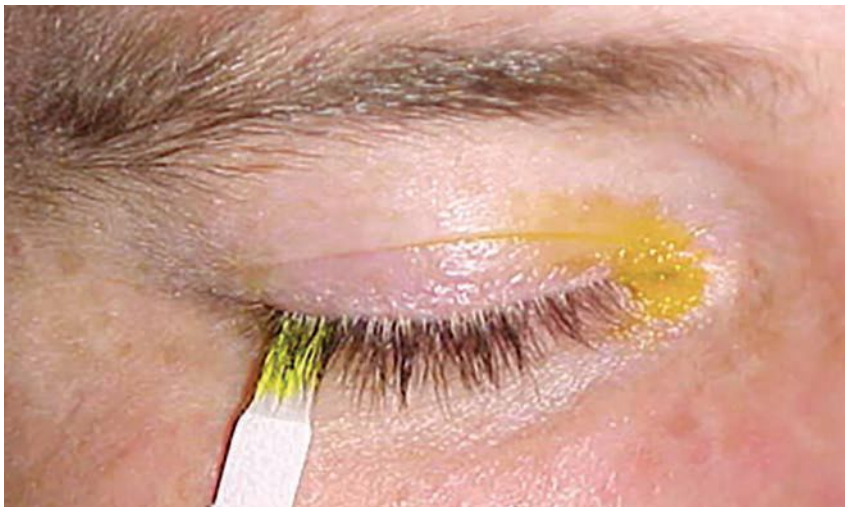

Figure 3. Schirmer's test 2 (with anesthetic).

• ***Canalicular stenosis.*** The frequency of canalicular obstruction has been reported to be between 16 and 25 percent in patients with epiphora. The most common symptom is intermittent or constant tearing. Canalicular obstructions can be anatomically classified as: proximal with involvement of the proximal 2 to 3 mm; mid-canalicular obstructions 3 to 8 mm from the punctum; and distal obstructions as defined by a membrane at the opening of the common canaliculus to the lacrimal sac.[18]

There are three types of canalicular stenosis: congenital; acquired; and involutional. Many causes have been associated with acquired canalicular stenosis, such as:

• inflammation, specifically blepharitis, canaliculitis, infection, ocular cicatricial pemphigoid, Stevens-Johnson syndrome, trachoma and ectropion;

• traumatic injury to the canaliculus, as in lacerations, chemical burns, thermal burns and radiotherapy;

• drug-induced, by medications such as docetaxel, paclitaxel, pilocarpine, timolol, dorzolamide, idoxuridine, trifluridine, fluorouracil, echothiophate iodide, dipivefrin, betaxolol, mitomycin-C, isotretinoin and verteporfin;

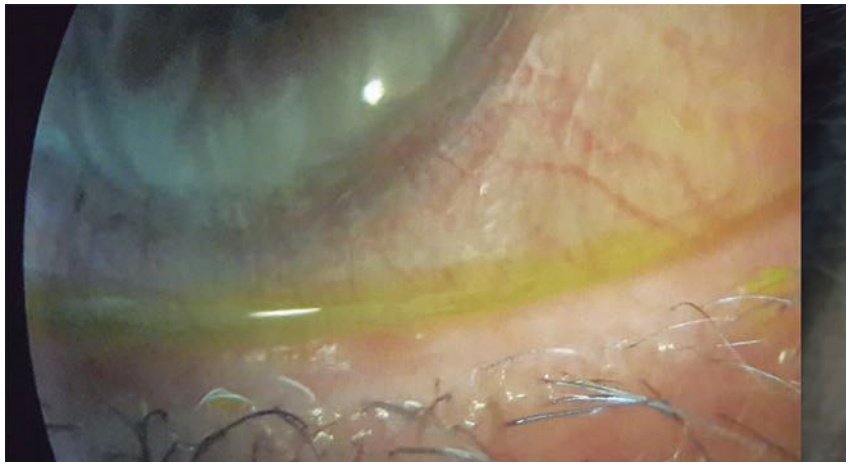

Figure 4. Dye disappearance test to differentiate hyperlacrimation from lacrimal drainage obstruction.

• systemic diseases, such as neoplasms, lichen planus and inflammatory bowel disease; and

• iatrogenic due to punctal plugs, cauterization, surgery, longstanding intubation or radiotherapy.[19]

The underlying causes of canalicular obstruction must be determined and addressed, as well as the site and extent of stenosis.[18]

One-snip punctoplasty and canalicular intubation (Mini Monoka) is a simple and effective method of treating punctal canalicular stenosis.[12] Silicone intubation (monocanalicular, bicanalicular, double bicanalicular) and probing are also effective methods.[21]

• ***Canaliculitis.*** Canalicular obstruction caused by a dacryolith often causes pain, redness, purulent discharge and intermittent tearing. Dacryoliths are usually associated with *Actinomyces israelii* or *Candida*. Patients under chronic topical medication with epinephrine are more prone to the formation of liths.

Treatment in the acute phase of canaliculitis primarily consists of a course of antibiotics and warm compresses. If obstruction doesn't clear with those interventions, a curettage with canaliculectomy and drainage of the dacryoliths with antibiotic irrigation of the lacrimal system may be required. Some authors advocate using silicon intubation at the same time but, personally, we don't think it is necessary.

• ***Partial and functional nasolacrimal duct obstruction.*** Functional NLD, by definition, is epiphora without a detectable lacrimal drainage system obstruction. The term "functional obstruction" is confusing, as it implies anatomically patent lacrimal passages with a physiological dysfunction.[19]

Different reasons have been cited in the literature, including partial NLD, which is patent upon positive-pressure irrigation through the

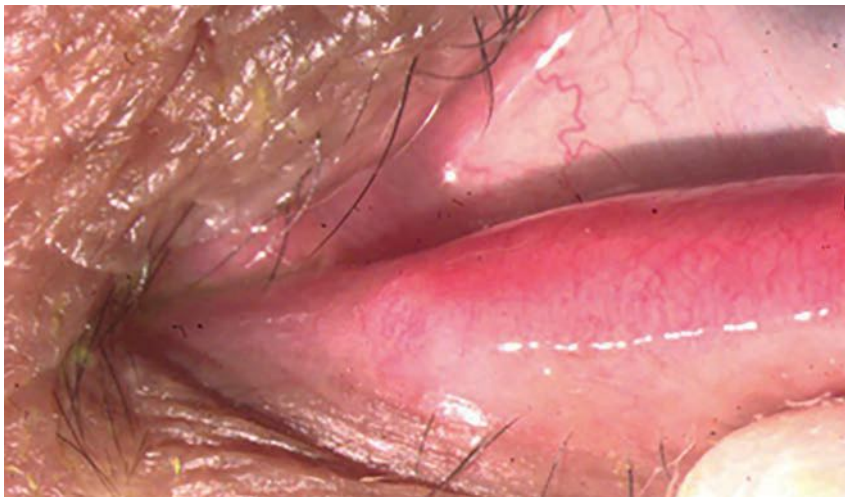

Figure 5. Stenosis of the lacrimal punctum.

canaliculus; lacrimal pump failure due to eyelid laxity, conjunctivochalasis and megalo-caruncle occluding the puncta, punctal apposition and subtle medial ectropion preventing punctal apposition to the lacrimal lake. Tearing without mucopurulent discharge is the most common presenting symptom.[18]

Management options for partial nasolacrimal duct obstruction include dacryocystorhinostomy, balloon catheter dilation with or without silicone intubation, silicone intubation (monocanalicular, bicanalicular, double bicanalicular) and probing.[21] We highly recommend bicanalicular intubation with silicon rods for these patients. We usually leave the tubes in position for three to four months.

The caruncle and bulbar conjunctiva can mechanically occlude the entrance to the lacrimal drainage system. Some patients with true epiphora due to functional lacrimal drainage obstruction have presented with enlarged caruncles. Studies have shown, however, that a caruncullectomy can alleviate epiphora in 77 percent of these patients.

Also worth noting is that a case of bulbar conjunctivochalasis occluding the lower punctum must be treated.[22-23]

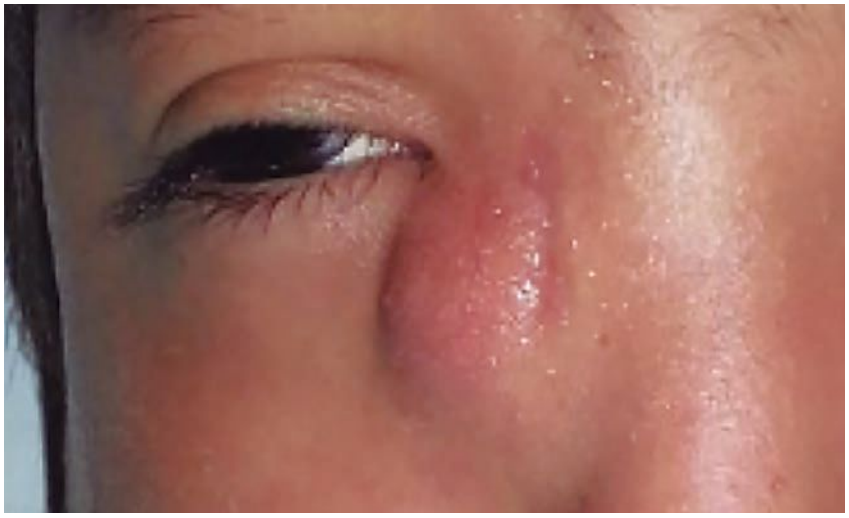

Figure 6. A young patient with acute dacryocystitis on the right side.

• ***Dacryocystitis.*** Lacrimal drainage obstruction at the union of the lacrimal sac and the nasolacrimal duct causes fluid to stagnate, with consequent tearing and mucous secretion. During the acute phase, patients present with a very painful mass in the lacrimal sac region. Sometimes the abscess can be drained with pressure, but in more severe cases a small puncture with a blade or a needle may be necessary to alleviate the pain. Systemic antibiotics and local compresses are recommended for the infectious phase. *(See Figure 6)*

Once the acute phase of dacryocystitis has been controlled, there is no recommended subsequent treatment other than a dacryocystorhinostomy, which can be performed via the traditional (external or transcutaneous) or the internal (endonasal) approach. The objective of this procedure is to create an anastomosis between the lacrimal sac and the nose, through a bony opening (10 to 15 mm) at the lacrimal bone. Success rates vary from 70 to 90 percent in different series. Usually, the surgeon stents the canaliculi, though it's been proven that this may not increase the success rate.

Though getting to the bottom of a patient's epiphora complaint can be a diagnostic challenge due to the multifactorial nature of the condition, a pertinent history, thorough examination and appropriate testing will help you pinpoint the cause—and the proper treatment—as quickly as possible.[10] REVIEW

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OCT Technology: Will We Be "Swept" Away?

A look at the differences between spectral-domain and swept-source OCT, and the potential clinical benefits of swept-source.

Emily D. Cole, BS, and Jay S. Duker, MD, Boston

As is sometimes the case with technology, just when we get comfortable using a device and begin to understand its secrets, limitations and how to best put it to use in our practices, a shiny new instrument arrives and demands our attention. Though this imaging modality has been around for some time, swept-source optical coherence tomography is one such example. It captures your attention, and though you may already use a spectral-domain device, you're left wondering if it's the next big thing to purchase. In this article, we'll break down the differences between spectral-domain and swept-source OCT to help make the picture a little clearer for you.

The State of the Art

Optical coherence tomography is based on the principle of low-coherence interferometry. Light is backscattered from the ocular tissue and compared to that of a reference beam. The superposition of both waves creates an interference pattern that's used to measure the light echoes versus the depth profile of the tissue *in vivo*.

Spectral-domain and the newer technology known as swept-source OCT are variations of Fourier-domain OCT, in which the interference patterns undergo a process known as Fourier transformation, which allows simultaneous measurement of all light echoes. Spectral-domain devices detect light echoes in the Fourier domain and measure the interference spectrum with a spectrometer and high-speed line scan camera. These systems are able to operate at increased speeds with enhanced sensitivity and signal-to-noise ratios. The sensitivity is enhanced by the ratio of axial resolution to imaging depth. SD-OCT devices are the current standard for ophthalmic instruments, with imaging speeds ranging from 25,000 to 85,000 A-scans per second.

SS-OCT is a variation of Fourier-domain OCT previously known as optical frequency domain reflectometry, which has recently been employed as tomography, and even more recently applied to OCT angiography. The hardware of SS-OCT differs from SD-OCT in several ways, including the light source, bulk optics components and photodetection device. The swept-source light source has a wavelength centered at ~1 µm that sweeps across a narrow band of wavelengths, while spectral-domain devices utilize a broadband light source. The laser frequency sweep labels different time delays, which are then detected by interference. To detect the light waves returning to the device, SS-OCT utilizes a point photodetector, while SD-OCT uses a spectrometer consisting of a diffraction grating, Fourier transform lens, and a detector array or a linescan camera. Although the light source of the SS system is more complex, the photodetector device is simpler in design and results in increased scanning speeds.

The concept of SS-OCT was described in the mid-1990s, but development was limited by the performance of available laser technology, which has since improved with the release of commercially available short-cavity swept lasers with increased scanning speeds. Scanning speeds of up to a million A-scans per second have been achieved with swept-source systems. Increased scanning speeds yield a high-density scan with high resolution en face OCT images, but at the expense of worse signal-to-noise ratio. (There

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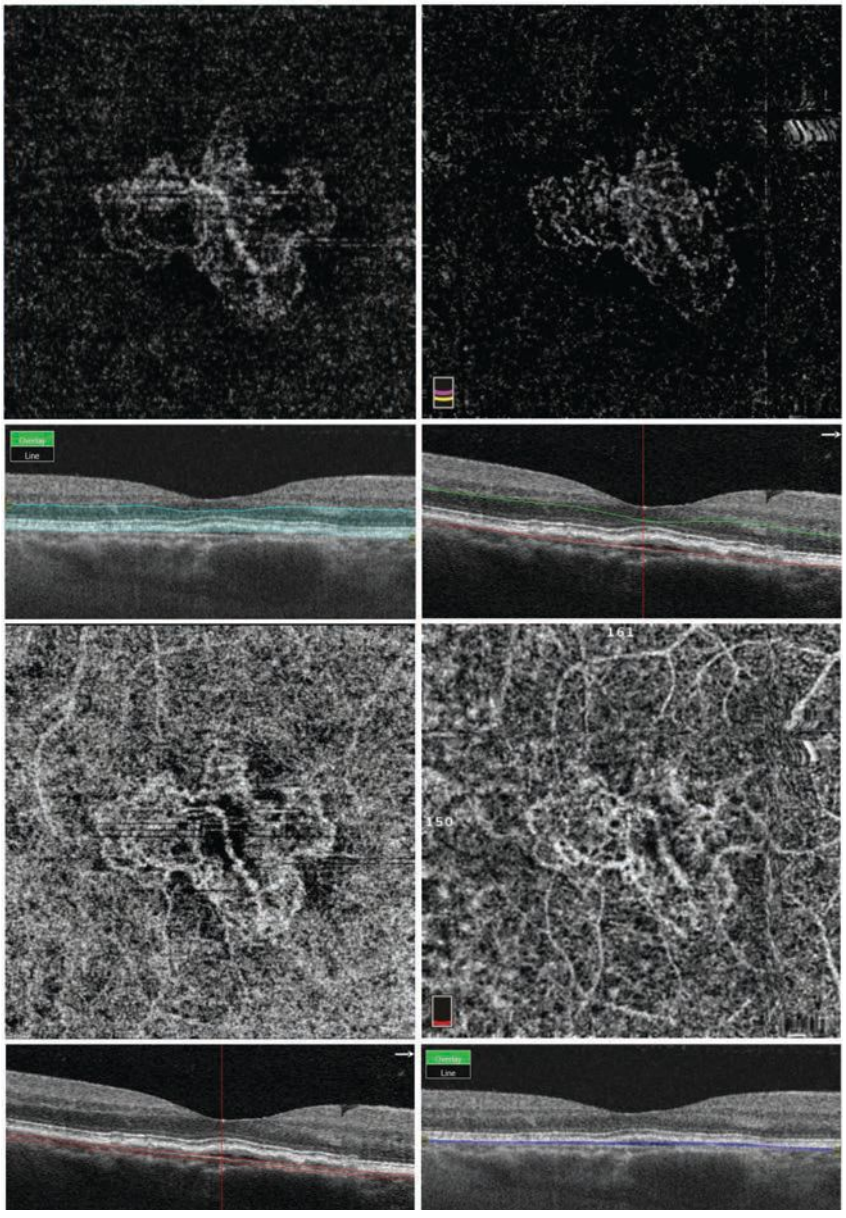

Figure 1. Same-day optical coherence tomography angiography imaging of choroidal neovascularization using swept-source and spectral-domain devices. The top two images are automated segmentation slabs of the outer retina with the corresponding structural cross-sectional OCT-B scan below each image. The bottom two images are automated segmentation slabs at the level of the choriocapillaris. These choriocapillaris images show significant projection artifact of the superficial and deep capillary plexuses due to inclusion of the retinal pigment epithelium in the segmentation slab, making it difficult to visualize the full extent of the neovascular membrane. The images on the left were imaged on the Topcon DRI Triton device, which is a 1050-nm swept-source device operating at a rate of 100,000 A-scans/second. The images on the right were imaged on the OptoVue RTVue XR Avanti, an 840 nm spectral-domain device operating at a rate of 70,000 A-scans/second.

are currently commercially available SS-OCT devices operating at a speed of 100,000 A-scans/second which will be described later in this article.) SS-OCT devices are more prevalent in clinical applications of OCT beyond ophthalmology, including cardiology, dermatology and gastroenterology.

In both spectral-domain and swept-source systems, the wavelength of the light source plays an important role in the visualization of retinal and choroidal structures, particularly at deeper locations beneath the RPE. Longer wavelengths are capable of improved visualization of the choriocapillaris and choroid, have improved immunity to ocular opacity, and may be useful for improved visualization of choroidal neovascularization, especially the sub-RPE components of the membrane. However, longer wavelengths have lower resolution compared to shorter ones. Therefore, there's a trade-off in resolution with increasing bandwidth. In shorter-wavelength systems, attenuation can become more severe in the presence of RPE clumping and drusen or thickened choroid, as in central serous chorioretinopathy.

Advantages and Disadvantages

SD-OCT devices are widely used to evaluate vitreous, retinal and choroidal pathology. Compared to spectral-domain OCT, however, SS devices improve the visualization of structures beneath the RPE due to decreased sensitivity roll-off and attenuation of the OCT signal in deeper structures, particularly the choroid. To overcome this limitation in SD devices, techniques such as enhanced depth imaging are used to better visualize the choroid and structures below the RPE in cross-sectional SD-OCT images. EDI involves image averaging in conjunction with setting the choroid adjacent to the zero-delay line. The zero delay is the axial range position of maximal sensitivity for signal detection.

Comparisons between swept-source and spectral-domain devices suggest that swept-source devices allow for improved visualization of the choroidal-scleral interface. However, with regards to choroidal thickness

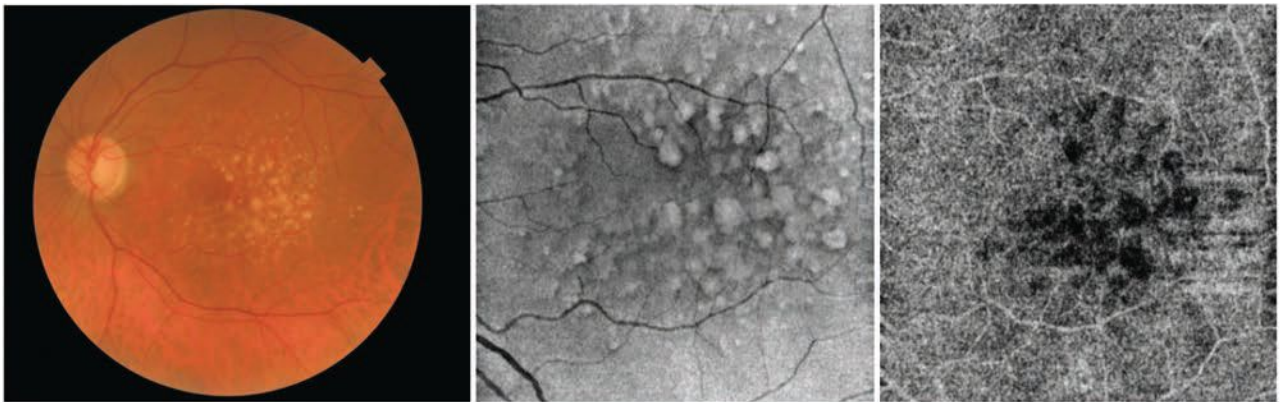

Figure 2. Multimodal imaging of drusen in a patient with non-exudative macular degeneration. The patient was imaged on the swept-source Topcon DRI Triton device. The first image is a color fundus photo taken by the Triton. The second image is the structural en face OCT-B scan, and the third image is an OCTA slab automatically segmented at the level of the choriocapillaris. The dark area underlying the drusen could be an area of low OCT signal secondary to attenuation due to overlying drusen, or areas of choriocapillaris flow impairment, but which one it is can't be determined based on this image alone.

measurements, there are conflicting results in published comparisons, possibly due to the different devices being compared. Though SS-OCT devices tend to have worse axial resolution than SD-OCT, image quality can be improved by software enhancements.

The overall simpler design of SS-OCT devices should enable them to be produced in a more compact form and at lower cost in the future, making them a viable option for further commercial development. Advances in laser technology have enabled the development of SS-OCT technology in recent years, but the current market acceptance of SS-OCT devices is limited by high costs, limited availability and a lack of normative data. Also, the clinical advantages of SS-OCT versus SD aren't clear; though SS offers improved visualization of the choroid and structures below the RPE, the clinical significance of this remains to be investigated.

Current SS-OCT Devices

• ***Topcon DRI OCT Triton.*** Currently, the Topcon Deep Range Imaging OCT Triton is commercially available in Europe and Asia but is only available for research purposes in the United States. It's an SS device that uses a 1050-nm wavelength light source, has a scanning rate of 100,000 A-scans per second and has an axial resolution of 8 µm. The Triton uses the OCT Angiography Ratio Analysis as its software-based angiography method, which utilizes amplitude information and keeps the full spectrum intact so that the axial resolution is preserved. The device has both conventional OCT, en face OCT and OCTA capabilities. The invisible wavelength of the light source allows patients to fixate on the target during scanning, which reduces involuntary eye movements. The eye-tracking capabilities also reduce motion artifact in these scans.

Combination scan protocols can be used with the Triton, which enable the simultaneous acquisition of a three-dimensional wide-field 12 x 9-mm image, thickness map and cross-sectional OCT-B. Precise localization of cross-sectional OCT-B scans can be obtained using fundus-guided acquisition, which allows the operator to manually select the scan area on the fundus image. The DRI OCT Triton is also unique in its multimodal imaging capabilities: It's able to acquire color fundus photos, fundus autofluorescence, red-free images and fluorescein angiography. Same-day FA and OCTA scans can be obtained on this device, making it ideal for comparing the two methods for visualizing retinal and

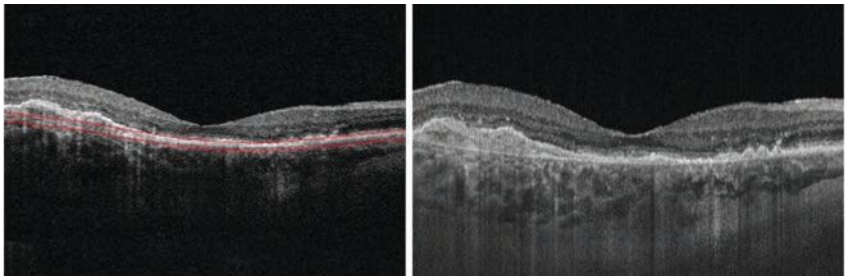

Figure 3. Cross-sectional OCT B-scans from a patient with neovascular age-related macular degeneration. The image on the left is from an 840-nm spectral-domain system operating at a rate of 68,000 A-scans/second, and the image on the right is from a prototype 1050-nm swept-source system at the Massachusetts Institute of Technology operating at a rate of 400,000 A-scans/second. The image from the prototype swept-source device demonstrates reduced signal attenuation and less sensitivity roll-off than that of the spectral domain system.

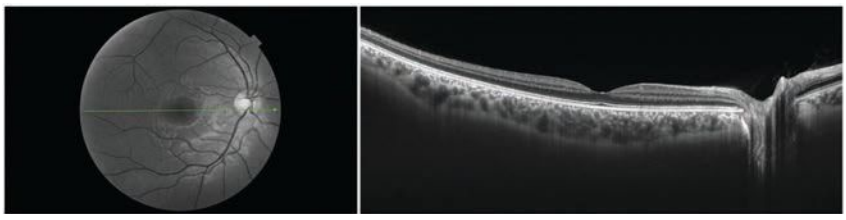

Figure 4. Cross-sectional OCT B-scan from the right eye of a 28-year-old healthy subject. The patient was imaged on the swept-source Topcon DRI Triton device. The image on the left is the red-free fundus image, with the green line corresponding to the cross-sectional OCT-B scan.

choroidal vasculature *in vivo*. Finally, improved vitreous visualization is possible with features known as Enhanced Vitreous Visualization and Dynamic Focus, which are designed to ensure uniform image quality with uniform focus across the imaging range.

• ***Zeiss Plex Elite 9000.*** This was unveiled in May 2016 and is an SS-OCT device introduced for clinical research use as part of the Advanced Retina Imaging Network, an international research effort. It will be available in Europe, the United States and select countries for research.

The Plex Elite 9000 makes use of a swept-source, tunable laser centered at 1060 nm and operating at a scan speed of 100,000 A-scans per second with an axial resolution of 6.3 µm. The major difference between the Cirrus HD-OCT system and the Plex Elite SS-OCT system is the use of a tunable laser-based swept source with a Class 1 laser light system and an updated interferometer. The software-based angiography method used in this device is the OMAGc method of processing angiographic data, which uses both phase and amplitude information. It has conventional cross-sectional OCT, en face OCT and OCTA capabilities.

This device also features mechanical eye-tracking capabilities and a 56-degree field of view. This device uses wider OCTA scan protocols than the currently available 3 x 3-mm and 6 x 6-mm scan patterns, and now includes 9 x 9-mm and 12 x 12-mm OCTA protocols. At first glance, the two commercially available swept-source devices appear similar, though differences in image processing software and acquisition scan protocols may lead to differences in the appearance of same-day images taken on the two devices.

• ***Research prototype devices.*** Prototype SS-OCT devices have been employed in the research setting for many years. These prototypes are typically tailored for the purposes of investigating a specific research question, and include such technology as anterior segment imaging, wide-field OCTA imaging or ultra high-speed SS-OCT imaging. Images from these prototypes can vary widely and typically require custom image processing software. Therefore, the only definitive similarities between the multiple prototypes that have been referenced in the literature are basic hardware components and the type of light source used.

Future of SS-OCT

OCTA is a relatively new imaging technique utilizing existing OCT technology to noninvasively visualize the retinal and choroidal microvasculature. In OCTA, multiple sequential OCT-B scans are acquired in rapid succession. These sequentially acquired OCT-B scans are compared; the decorrelation signal used to generate the image of the vasculature corresponds to regions of erythrocyte movement. It's possible that SS-OCTA devices may be able to visualize the choroid and choriocapillaris with less artifact, not only because of the type of OCT device used, but also because of the longer wavelength of the light source, the increased scanning speed and the reduction in motion artifact thanks to improved eye-tracking software.

Though currently available OCTA devices use SD-OCT systems, prototype swept-source devices have been used in the research setting to visualize changes in the choriocapillaris in diabetes and age-related macular degeneration. Both spectral-domain and swept-source devices have been used to qualitatively and quantitatively describe the microvascular morphology of choroidal neovascularization.

In the United States, swept-source devices will soon become commercially available, expanding the number of choices available to ophthalmologists when considering OCT systems. Swept-source OCT devices are able to operate at higher scanning speeds than

A Brief History of Optical Coherence Tomography

Early OCT devices contained time-domain technology that employed a moving reference arm and low-coherence light source. The first commercially available devices were introduced in 1996; over the past 20 years their clinical use has expanded widely. Compared to current devices, the Stratus time-domain OCT (Carl Zeiss Meditec, Dublin, Calif.) which first became available in 2002, scanned at comparatively low scan rates of ~400 A-scans per second, enabling visualization of features of retinal architecture including the nerve fiber layer. Spectral-domain systems were initially described in the literature in the mid 1990s, and the earliest images were published in 2002. The first commercially available SD-OCT was released in 2006. The development of anti-vascular endothelial growth factor agents for the treatment of a variety of posterior segment diseases led to more widespread use of OCT devices, since treatment response could be visualized and monitored.

—EC and JD

spectral-domain systems and, though their clinical superiority is still unclear, remain promising prospects for future imaging development. REVIEW

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QoL Questions: Measuring Happiness

The importance of valid questionnaires when treating patients who suffer from ocular allergy.

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Andover, Mass.

Hunter Doherty "Patch" Adams, MD, comedian and activist, once said, "The purpose of a doctor or any human in general should not be to simply delay the death of the patient, but to increase the person's quality of life." Physicians should take these words to heart, since patient satisfaction with the care and treatment we provide is an essential benchmark of therapeutic success. The collective impact of a disease and its treatment can have a significant effect on patients' quality of life, and on the broader economic burden of the disease.

This month, we discuss the quality of life aspects of ocular allergy and how this seemingly benign condition profoundly affects everyday life. This is also an opportunity to discuss the role of QoL questionnaires in broadening our understanding of disease, and to provide a brief primer on questionnaires used in the allergy space as tools for improving patient management.

While QoL questionnaires aren't routinely used in clinical practice, they're becoming an important component of clinical trials. Patient reported outcomes, or PROs, aren't simply symptom measures graded on different severity scales. In general, QoL questionnaires have domains for impact of the disease on sleep and mood; productivity; perception of physical appearance; interference with daily activities and social interactions; and satisfaction with treatments. The widespread implementation of the Ocular Surface Disease Index as an assessment of dry-eye disease is an example of a success story in which PROs are used not only as an endpoint in clinical trials to assess the efficacy of a therapeutic intervention, but have also crossed over into patient management.[1]

The Food and Drug Administration has provided extensive guidance on the development and implementation of PROs in clinical trials, recognizing that the patient's expectations and experience play important roles in the assessment of a therapeutic.[2,3] Perhaps just as important, evidence demonstrates a strong predictive value of patient's perception of his own status using these QoL tools.[4] In ocular allergy, we've been assessing QoL of patients by adapting questionnaires used in general allergy, rhinitis and asthma. Considering that allergic conjunctivitis is thought to impact 39 percent of the U.S. population,[5] and that there is significant comorbidity with other ocular diseases and with other allergic disorders, it behooves the practitioner to listen to his patients and to adopt as holistic approach as possible.

Questionnaires' Validity

Like all measures of disease and treatment, QoL questionnaires must be developed through rigid statistical analyses of their validity, to confirm that they're measuring what they say they're measuring. Psychometric tests must prove to have both convergent and discriminant validity, together defined as *construct validity*, to be effective tools. Construct validity is simply a determination that the measures of constructs that should be correlated or related to each other actually are (correspondence or convergence), and measures of constructs that theoretically shouldn't be related are not (discriminant). For example, if four queries on ocular allergy—fatigue, low productivity, itchy eyes and sneez-

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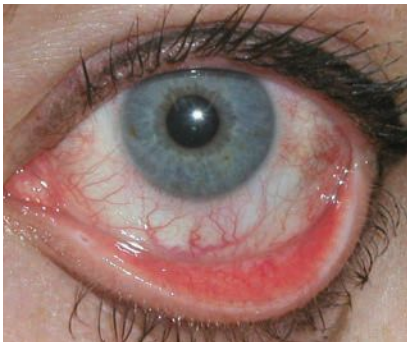
ing—are highly correlated, then these four items together show convergent validity (although the interrelationship isn't known to be due to ocular allergy per se), but not discriminant validity. To establish the latter, you need to show that these four related items are unrelated to other interrelated items, proving that they can discriminate and thus provide a measure of ocular allergy impact and not, for example, a parallel factor such as job satisfaction.

Although correlation testing assures us that the subsets are related to the domain in question and not to each other, how can we be sure that they are actually measuring ocular allergy burden? Other examples of validity testing are concurrent validity (how well this QoL tool correlates with other QoL tools); known-group validity (how it performs in a well-identified group of ocular allergy patients); clinical validity (its ability to discern the severity of allergy among patients); floor and ceiling effects (what percentage of patients rates the highest or lowest scores indicates the level of responsiveness); and scale-to-scale correlations (which determine if individual scales are measuring different attributes).[6]

Rhinoconjunctivitis

A validated disease-specific questionnaire, the Rhinoconjunctivitis Quality of Life Questionnaire, has been shortened to the miniRQLQ in order to measure the impact of allergies on other aspects of daily activities in adults with rhinoconjunctivitis. Using a seven-point scale, where 6 represents the greatest impairment and 0 represents the least, patients assess the impact of rhinoconjunctivitis in the five domains of activity (daily activities, work/school performance and sleep), practical problems (the need to rub the eyes and blow the nose repeatedly), and nasal, ocular and other symptoms. A clinically significant change in the mini-RQLQ score is defined as 0.70.[7]



Allergic conjunctivitis may impact 39 percent of the U.S. population.[5]

In one cohort of 447 allergic patients, 58.4 percent were recruited from primary care physicians, and the remainder from specialists. Of these, 44 percent reported moderate to severe ocular and nasal symptoms. Subjects reported that their ocular symptoms were better controlled than their nasal ones: 14.8 percent reported poorly controlled nasal symptoms compared to 5.8 percent with poorly controlled ocular symptoms. Conversely, of the 54 percent who reported having itchy/red eyes, 17.4 percent considered this symptom to be the worst in their spectrum of allergic signs and symptoms. Physicians, on the other hand, overestimate the burden of nasal congestion in their patients and underestimate the burden of sneezing, ocular symptoms, sinus pressure, sore throat, headache, snoring, nocturnal wakening, coughing and wheezing. Although this questionnaire didn't separate out ocular symptoms for their effect on activities, the presence of allergic symptoms significantly affected sleep in half of patients, with almost 80 percent of chronic allergy sufferers and 50 percent of seasonal sufferers complaining of insufficient sleep. The majority also reported an impact on daily activities and on work/school performance.[8]

Eye Allergy's Impact

The validity of one of the few tools developed specifically for ocular allergy, the Eye Allergy Patient Impact Questionnaire, was assessed for reliability as a measure of ocular allergy symptoms and their impact on health-related QoL, work productivity and treatment satisfaction.[9] After validity analyses, some of the 49 items were recommended for elimination to provide a more accurate tool with high internal and test-retest reliability. The final tool included 20 items: eight in the daily life impact; four in the psychosocial impact; five in the symptoms category; and three in the treatment satisfaction category. This questionnaire allowed for separation of patients with different eye allergy symptom severities, as rated by patients and clinicians, and provided evidence that the scales used in this tool are responsive to changes in eye allergies.[9]

A similar report narrowed the focus to ocular symptoms, presenting the results of the miniRQLQ, the Work Productivity and Activity Impairment Allergic Specific Questionnaire, and the Pittsburgh Sleep Quality Index in 1,009 allergic rhinitis patients in four European countries.[10] Results showed that the presence of ocular symptoms, found in 69 percent of this cohort, significantly reduced QoL work productivity and increased resource utilization, irrespective of nasal symptom severity. The presence of ocular symptoms had a greater impact on hours of work missed and impairment while working, with an additional half-day off of work in the previous three months due to allergies. Sleep quality was also significantly worse in these patients compared to AR patients without red itchy eyes. Lastly, the severity of ocular symptoms had a significant detrimental impact on all outcomes. These findings are remarkable, considering that allergic conjunctivitis is thought to be the poor cousin of allergic rhinitis in terms of the magnitude of disease burden in the United States and Europe.

A different study assessed sleep and mood disorders in dry eye and allergic

conjunctivitis in 715 outpatients in six clinics. The Pittsburgh Sleep Quality Index was again implemented along with another tool, the Hospital Anxiety and Depression Scale. While the main findings focused on the worst effects of dry eye on QoL measured within these domains, more than 35 percent of allergic conjunctivitis subjects reported sleep disorders (cutoff 5/6 on the PSQI), and 42 percent reported mood disorders (cutoff 9/10 HADS).[11]

Phone and Online Surveys

Telephone surveys are another tool for determining the degree of burden of a disease within a population. In 2012, 2,765 individuals were randomly selected from a pool of those diagnosed with nasal or ocular allergies, as well as 500 health-care providers in seven specialties. Subjects rated symptom distribution seasonally, with peaks in March through May and September. Nasal congestion was most commonly reported as the most bothersome symptom (39 percent), with red itchy eyes not far behind (34 percent). Twenty-nine percent of respondents reported that their daily life was significantly impacted, with workers indicating a 29-percent reduction in productivity when symptomatic. Providers reported that itchy eyes were the most common complaint that prompted patients to seek treatment.[5] In a European study of 1,482 allergic rhinitis patients, more than 80 percent reported some impairment of daily life when symptomatic. Notably, physicians once again rated symptoms as less severe than subjects rated their symptoms, affirming the need for these tools in determining disease burden and treatment.[12]

Ocular symptoms often tip the scales when it comes to detrimental effects on QoL. In a survey of 2,150 adolescents, the prevalence of rhinitis alone was 18.2 percent, and that of rhinitis and conjunctivitis was 20.5 percent. Rhinoconjunctivitis was more frequently associated with female sex, atopic history, household exposure to molds, passive smoke exposure and reported nearby truck traffic, along with higher levels of allergic sensitization. Asthma was found in 1.7 percent of subjects with no rhinitis or conjunctivitis, 5.1 percent in teens with rhinitis, and 10.7 percent in teens with rhinoconjunctivitis—a whopping twofold risk of asthma in adolescents with rhinoconjunctivitis compared to rhinitis alone. QoL was also worse: 10.7-percent impact in rhinoconjunctivitis versus 4.6 percent in rhinitis.[13] This means that teens are sicker, more allergic and more adversely affected when ocular allergies are present in addition to rhinitis. Another study that reviewed the use of PROs in rhinoconjunctivitis studies from 2012 to 2014 found that fatigue and malaise are common outcomes in adults and children with rhinoconjunctivitis, recommending a more whole-body approach to assessments of disease burden, rather than the more simplistic focus on the eyes and nose.[14] These symptoms are also associated with antihistamines, a reminder to be aware of potential iatrogenic QoL issues.

In a population-based study of 4,019 subjects who had undergone face-to-face interviews, 31.7 percent (1,276 patients) had allergic rhinitis, and 19 percent (763 patients) had ocular allergy. Of the group with ocular allergies, 52 percent also had allergic rhinitis. Again, compared to nasal symptoms, 51.7 percent of subjects rated ocular symptoms more troublesome. The impact of ocular symptoms on daily activities was "very important" or "moderate" in 38.8 percent of subjects, with blurry vision the most commonly reported in 47.8 percent. A total of 16.3 percent of subjects had sleep disturbances; work efficiency was reduced in 25.8 percent; and 12.9 percent of subjects had taken sick leave for up to three days because of ocular symptoms.[15]

In a telephone survey focusing on allergic conjunctivitis, 205 subjects responded. An overwhelming 83.9 percent reported also having nasal allergies, while fewer people (18 to 31 percent) reported suffering from food or skin allergies or asthma. Year-round allergies were reported in 38 percent of subjects. The second most bothersome symptom after itchy eyes was tearing and not redness.[16]

Treatment and QoL

Adding QoL endpoints to clinical trials or post-marketing comparative studies allows us to accumulate data on the real and perceived efficacy of treatments. Patients (n=540) rated intranasal treatments with fluticasone furoate, mometasone or fluticasone propionate equally in terms of efficacy and QoL parameters. Furthermore, in allergic patients who experienced both ocular and nasal symptoms (71.6 percent), the mean number of symptom-free days was fewer than in the overall population, indicating a more severe disease presentation in subjects with both nasal and ocular allergies. In this ocular subgroup, fluticasone furoate treatment resulted in a greater number of symptom-free days than mometasone-treated patients.[17]

Satisfaction with treatment is high on the list of outcomes rated in QoL questionnaires. Surprisingly, in the online U.S. survey, satisfaction was highest with immunotherapy (94 percent), although only 10 percent of subjects are treated this way.[18]

Cost to the patient is an important consideration, something that we as physicians sometimes forget. Of those subjects who preferred OTC medications, 72 percent noted that it was important that their medication be within their budget. For those using prescription meds, 69 percent and 65 percent, respectively, reported "covered by my prescription plan" and "'available at my lowest copay" as important criteria.[18] Cost may be one reason the 2013

survey found that as many as 71 percent of seasonal and 53 percent of perennial allergy sufferers didn't seek treatment from an eye specialist, and 40 percent didn't even purchase over-the-counter medications for allergy management. Nevertheless, 80 percent of those who did use drops rated them as effective all or most of the time.[16]

Staying Mindful

QoL tools help us to help our patients. We should remind ourselves to discuss with our patients more holistic health issues that may seem to have nothing to do with ocular signs and symptoms. Itchy and tearing eyes are making our patients miserable, and the collateral effects of these seemingly benign complaints have more far-reaching consequences for an individual's well-being and contribution to society. We as health practitioners owe it to our patients to be mindful of the psychological, emotional and societal effects of even non-vision-threatening ocular diseases such as ocular allergy. REVIEW

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Tube-in-tube: Glaucoma Drainage

A retrospective, noncomparative case series documented a new and simple technique of glaucoma tube extension that may have several advantages over previously described techniques. The study looked at three patients (one adult and two pediatric cases) with glaucoma tube retraction managed by the "tube-in-tube" technique. The follow-up duration ranged from one month to three years.

Here's a description of the technique, which uses minimal dissection: The anterior portion of the drainage tube is surgically exposed. The tube is then flushed with balanced salt solution. A new tube segment is obtained from either a glaucoma drainage device or a tube extender. Forceps are then inserted into one end of the tube with the tip closed. The tip is then opened to stretch the tube, creating adequate opening for a second tube insertion. To help withdraw the forceps, a non-toothed forceps may be required to maintain the two-tube segment fixation. The joined tube is stretched to check strength and flushed to ensure patency and a watertight interface. Depending on the surgical exposure and mobility of the pre-existing tube, either the original can be inserted into a stretched second tube or vice versa. The extended tube is then inserted into the anterior chamber using a 25-ga. tract to minimize leakage. Either an anterior chamber maintainer or viscoelastic is used to prevent intraoperative hypotony. The authors say that, depending on the state of the patient's pre-existing scleral graft, the surgeon can place a new graft, but this is usually not required. The surgeon then closes Tenon's and conjunctiva.

The surgeons say they noted adequate tube position and length in in all cases throughout the follow-up period. There was no tube migration. The intraocular pressures were significantly reduced and maintained in all cases, with no visual loss.

The study's authors say that this new "tube-in-tube" glaucoma drainage-device tube extension technique explored in their report is safe and simple to perform and may yield advantages over previously reported techniques. It can be used in both the adult and pediatric glaucoma populations and isn't limited to one type of drainage implant.

J Glaucoma 2017;26:93-95
Chiang M, Camuglia J, Khaw P.

Graft Detachment after Endothelial Keratoplasty

In a retrospective institutional cohort study, researchers from Forli, Italy, sought to identify risk factors associated with postoperative graft detachment after Descemet's stripping automated endothelial keratoplasty.

The study group included consecutive eyes that underwent primary DSAEK between January 2005 and October 2015 at Villa Serena-Villa Igea private hospitals. The control group included all eyes that underwent primary DSAEK during the same time period and did not go on to develop graft detachment. The main outcome was whether or not postoperative graft detachment occurred.

The main indications for surgery were Fuchs' endothelial dystrophy (525/1,212, 41 percent), pseudophakic bullous keratopathy (422/1,212, 35 percent) and a failed penetrating keratoplasty graft (190/1,212, 16 percent). Postoperative graft detachment occurred in 45 of 1,212 eyes (3.7 percent). Medically treated glaucoma, previous trabeculectomy, previous aqueous shunt procedure and failed PK were all associated with an increased risk of graft detachment in univariate analysis. No particular lens status at the time of graft implantation was significantly associated with graft detachment. The investigators conclude that previous penetrating keratoplasty and trabeculectomy are independent risk factors for postoperative graft detachment in primary DSAEK.

Cornea 2017;36:265-268
Nahum Y, Leon P, Mimouni M, Busin M.

Medicare Payments for Female vs. Male Ophthalmologists

Because of the growing number of women in ophthalmology, researchers conducted a retrospective review of the CMS database to look at the clinical activity of, and payments made to female ophthalmologists. The study specifically examined whether charges, as reflected in reimbursements from the Centers for Medicare & Medicaid Services to ophthalmologists, differ by sex and how any disparity relates to differences in clinical activity.

The study looked at the CMS database for payments to ophthalmologists from January 1, 2012 through December 31, 2013. After exclusion of J and Q codes, the total payments to and the number of charges by individual ophthalmologists were analyzed. The mean values were compared using a single-sample t-test, and the medians were compared by the nonparametric Wilcoxon rank sum test.

The study included 16,111 ophthalmologists (3,078 women, 19.1 percent; and 13,033 men, 80.9 percent) in 2012 and 16,179 ophthalmologists (3,206 women, 19.8 percent; and 12,973 men, 80.2 percent) in 2013. In 2012, the average female ophthalmologist collected $0.58 (95% CI, $0.53-$0.62; $p<0.001$) for every dollar collected by a male ophthalmologist; comparing the medians, women collected $0.56 (95% CI, $0.50-$0.61; $p<0.001$) for every dollar earned by men. Mean and median collections were similar in 2013 ($p<0.001$). The mean payment per charge was the same for men and women: $66 in 2012 and $64 in 2013. There was a strong association between collections and work products, with female ophthalmologists submitting fewer charges to Medicare in 2012 (median, 1,120 charges; difference -935; 95% CI, -1,024 to -846; $p<0.001$) and in 2013 (median, 1,141 charges; difference -937; 95% CI, -1,026 to -848; $p<0.001$) than male ophthalmologists. However, when corrected by comparing men and women with similar clinical activity, remuneration was still lower for women. In both years, women were underrepresented among ophthalmologists with the highest collections.

The authors conclude that remuneration from the CMS was disparate between male and female ophthalmologists in 2012 and 2013 primarily because of the submission of fewer charges by women. Further studies are necessary to explore root causes for this difference, with equity in opportunity and parity in clinical activity standing to benefit the specialty, the researchers say.

JAMA Ophthalmol 2017:135:205-213

Reddy A, Bounds G, Bakri S, Gordon L, et al.


What Causes a Sustained Post-injection IOP Rise?

A surgeon and his colleagues work to solve a mystery: why some patients develop chronic high IOP after anti-VEGF injections.

Malik Y. Kahook, MD, Denver

Anti-vascular endothelial growth factor injections for the treatment of age-related macular degeneration have become common. Of course, injecting anything into the eye carries risks such as endophthalmitis, but that's not the only concern.

Injecting fluid into the eye raises the intraocular pressure, which can go as high as 90 mmHg when a typical volume of anti-VEGF medication is injected. In a healthy eye, any pressure rise that occurs is short-lived. However, the intraocular pressure in some patients remains chronically high after an injection. A glaucomatous eye might have trouble managing the increased pressure caused by the injection, but many patients who have experienced this sustained pressure increase had not previously been diagnosed with glaucoma. As a result, the reason for their sustained pressure increase has been something of a mystery.

Here, I'd like to share some of my experience with these patients and some of the work my colleagues and I have done to try to elucidate what might be causing this pressure rise following anti-VEGF injections.

Case Histories

A few years ago I saw a 68-year-old Caucasian male patient who had been diagnosed with wet age-related macular degeneration in his right eye. He was given an injection of 1.25 mg of Avastin the day of his AMD diagnosis—the first such injection he'd ever received. He returned to the retina specialist two weeks later complaining of pain in that eye and blurred vision; his IOP in that eye was 56 mmHg. There was no vitreous or anterior chamber inflammation detected on the dilated exam, so it was apparently not a reaction to the drug. The patient was referred to me for further analysis.

The patient had no history of glaucoma in that eye, no family history of glaucoma, no prior surgery or trauma and no history of steroid use that might account for the high pressure. Slit lamp exam revealed slight corneal edema, but there was no sign of inflammation and no signs suggesting a secondary form of glaucoma such as pigment dispersion or pseudoexfoliation. In my exam, the pressure by Goldmann applanation was 53 mmHg and the angle was clear and open. The rest of the exam was essentially unremarkable. The possibility that this was injection-related was obvious, but the explanation for the lingering elevated pressure was not. This patient ended up getting an Ahmed valve several weeks later, and his wet macular degeneration treatment was changed, first to Lucentis and then to Eylea. The patient is doing well.

This experience inspired me to look further into this mystery, and I decided to conduct a chart review. A medical student, who became the first author on the paper we eventually published,[1] spent time in my clinic, as well as in the clinic of a referring retina specialist in our community. Looking at the charts of 215 patients who had received consecutive injections, what we found was remarkable. Thirty-three percent of patients with pre-existing glaucoma had a significant elevation of pressure after anti-VEGF injections that was sustained over time, compared to 3 percent of patients without pre-existing glaucoma—despite a lower mean number of injections ($p<0.001$). And

although we did see some pressure elevation following Lucentis injections, the rate was about three times higher in the Avastin group.

When the paper was published, I started getting phone calls from people around the country who were noticing this phenomenon. In 2009, John Carver, MD, reported a series of his own patients who were being treated monthly with Avastin for choroidal neovascularization, with two-year follow-up. Twelve percent of those eyes developed an unexpected IOP rise, usually to between 30 and 40 mmHg, that showed "remarkable resistance" to multiple topical drug therapies.

We decided to chart the locations of the cases we were hearing about. The main thing we noticed was that these cases were happening in clusters; the problem wasn't widespread, and in some cases it was present in some practices but not in others in the same city. The latter practices wondered why we were asking about it; they'd never seen it. This didn't help us draw any conclusions about the cause or mechanism that might be involved, but it did raise one possible association: Different practices in the same area often use different compounding pharmacies.

Digging Deeper

We wondered whether we could pin down the root cause of this, so we began systematically testing different hypotheses in the lab. Our first question was: Could this possibly be a toxicity issue? Although Lucentis was tested in the eye before approval by the U.S. Food and Drug Administration, Avastin was not.

We exposed trabecular meshwork cells to different levels of Avastin *in vitro*. The initial tests showed that Avastin could indeed be toxic to trabecular meshwork cells, but only at concentrations that were much higher than what we inject into the eye. Notably, we did not see this effect with Lucentis at high-dose molar equivalents. But given that we were only seeing toxicity with very high concentrations of Avastin, that didn't seem to be a likely explanation for this phenomenon.

A second hypothesis we pursued was the possibility that the concentration of Avastin in the injections was somehow being altered; that could mean that some patients were receiving more Avastin than the physician realized, potentially leading to toxicity. To test this hypothesis, we started buying vials of Avastin straight from our Genentech distributor, as well as compounded Avastin (in syringes) from different pharmacies around the country, hoping to see whether something about the compounding process was raising the concentration of Avastin.

Sustained Elevation of IOP after Intravitreal Injections of Anti-VEGF Agents[1]

Finding	All Eyes	Pre-existing Glaucoma	Bevacizumab only	Ranibizumab only	Bevacizumab and Ranibizumab
No. of eyes	215	21	101	96	18
Prevalence of IOP elevation	6 percent (n=13)	33 percent (n=7)	9.9 percent (n=10)	3.1 percent (n=3)	0 percent (n=0)
Median number of injections	9	6	7	12	11.5
Mean interval between injections (days)	70.2 (SD=54.6)	67.8 (SD=34.1)	86.6 (SD=73.0)	56.3 (SD=22.2)	51.8 (SD=17.0)

What we found was the opposite. The level of the Avastin protein in the compounded samples was lower than the level in the drug coming straight out of the vial. This meant there was a loss of protein during the compounding, storage and/or shipping. The cause wasn't clear—proteins could theoretically be altered by temperature, storage conditions, shipping trauma and other factors—but a lower concentration meant less likelihood of toxicity, not more.

Our third hypothesis was that the elevated pressure was caused by contamination; perhaps there was something else in the vial that we weren't accounting for. We performed a number of experiments, trying to do as many analyses as possible. We didn't find much, until we did microflow imaging—very fine, focused imaging of the fluid samples.

The difference between them was startling. The fluid taken straight out of the vial was basically clear, except for one tiny shard of glass near the bottom. (That's pretty typical at this level of imaging. It's a well-known phenomenon, and it's harmless.) In contrast, the samples from some of the compounding pharmacies were full of what looked like bubbles. We eventually determined that these were microscopic bits of silicone that were leaching from both the stopper and inside lumen of the syringe. This was not a subtle effect. There were millions of these bubbles, but they were very tiny—less than 10 µm in diameter. That's too small to be visible to the naked eye, but potentially large enough to block outflow through the trabecular meshwork.

How Did the Particles Get There?

One important question was: How did these microparticles end up being released into the fluid? To answer that question we studied some different repackaging processes to see how they might influence the amount of silicone leaching. We found that several things that could happen to the syringes had this effect:

- ***Long-term storage.*** Silicone leaching appears to be somewhat time-dependent. If you put this fluid in a syringe and leave it there for a long time, it increases the number of "bubbles" seen in the sample.
- ***Going through a freeze-thaw cycle.*** When mailing the drug, ice blocks are put into the boxes to keep the drug from warming too much. However, the syringes may touch the ice blocks, resulting in the fluid freezing; once you receive it and put it in the refrigerator, the fluid thaws. That freeze-thaw cycle causes millions of bubbles to leach off the plunger and the wall of the syringe.
- ***Shipping trauma.*** When a box is shipped, it may be thrown into a truck or onto a loading dock, and it could even be inadvertently knocked around at your practice after arrival. We found that every incidence of mechanical stress increased the amount of leachables seen in the fluid.

Other Explanations

It's important to note that silicone leaching might not be the only explanation for the chronic IOP rise seen in some patients (although it's almost certainly a key contributor to the problem in some cases). Other possible explanations include the mechanical impact of repeated increases in IOP following injections, which could be taxing the trabecular meshwork. And it's possible that the anti-VEGF drugs themselves directly impact the trabecular meshwork cells in some patients.

I believe these explanations are less likely to be correct, for a couple of reasons: 1) Many patients (as in the case history mentioned earlier) experience this chronic pressure rise starting immediately after their first injection. 2) No one has demonstrated that anti-VEGF drugs harm the trabecular meshwork. 3) If these explanations were correct, we'd expect to see a more even distribution of the problem. Nevertheless, other explanations for the problem can't be ruled out, including the possibility that other contaminants are present in the fluid besides the silicone "bubbles."

The other reason I suspect that silicone leaching is the most likely explanation is that we haven't seen a single case of chronic elevated pressure related to anti-VEGF injections since we started drawing up our

own medication straight from the vial, rather than using compounding pharmacies. Other practices in our area have also made the same change, and they report the same drop in the incidence of post-injection chronic pressure rise. In addition, I'm aware that some compounding pharmacies have changed their practices because of our publications, and the number of cases of this appears to be dropping, based on anecdotal reports.

Avastin vs. Lucentis

One question that's also worth considering is why this problem has been seen in connection with Avastin far more often than Lucentis. There are several differences between the two drugs that might help explain this. For one thing, Lucentis went through the rigorous process of getting FDA approval for use in the eye, including packaging standards. Avastin did not. (For example, Lucentis is drawn from a vial in the clinic; until recently, it was not available in a syringe.) Also, Lucentis was formulated specifically for use in the eye; Avastin was not.

In addition, the drugs themselves are somewhat different. Lucentis is what is called a Fab fragment; it's a portion of an immunoglobulin molecule, whereas Avastin is the entire molecule. The Avastin molecule looks like a letter Y; the leg or stem of the Y is what's called a fragment crystallizable, or Fc, region. Trabecular meshwork cells have a receptor for Avastin's Fc region that allows the cells to capture the Avastin molecule and internalize it, which is why Avastin can become toxic in high doses. In contrast, Lucentis doesn't have an Fc fragment. Some researchers have speculated that this difference might explain why post-injection chronic pressure elevation is seen more often with Avastin than Lucentis, but this is conjecture.

It may be that the few cases of this seen with injections of Lucentis are caused by one or more of the alternate explanations that have been offered. We know that when you inject things into the eye on a regular basis, a certain portion of patients will develop elevated IOP. This has been reported in the literature for a long time. If 1 or 2 percent of Lucentis patients develop chronic high pressure, it's possible that these patients had a predisposition for glaucoma that was simply not identified. Again, this is all speculation at this point. (I would add that Avastin, Lucentis and Eylea are all routinely used in my institution; I have no preference for one over the others from a safety standpoint, in the setting of proper handling and use.)

Addressing the Problem

What can we do to help ensure that our patients don't suffer from chronic elevated pressure following anti-VEGF injections? First of all, be vigilant about checking pressure in these patients. Patients who are receiving anti-VEGF injections should have their pressure checked at every visit. (This isn't always done.) They should be checked before the initial injection and also on subsequent visits prior to any further injections.

Be especially careful if the individual has pre-existing glaucoma. These individuals are especially susceptible to chronic pressure elevation because they already have a dysfunctional outflow system. In this situation:

- ***Check the patient's pressure both before and after injection.*** If a glaucoma patient is noted to have high pressure a half hour after an injection, you can ask that patient to stay a little longer and then check it again.
- ***If a glaucoma patient has a longer-lasting elevation in IOP after intravitreal injections, be sure to note it in the medical record.***
- ***Consider tapping the anterior chamber before the injection.*** If a patient has glaucoma, the surgeon can tap the anterior chamber by making a paracentesis to decrease the pressure in the eye before doing the injection. That minimizes the volume effect when you inject the drug.
- ***Consider pretreating with glaucoma medications.*** This also decreases the pressure so the volume effect won't be as massive.
- ***Consider increasing the glaucoma therapy to help stabilize the elevated pressure.*** This won't help in every case, but it should help some patients.
- ***Follow the patient closely.*** If the patient continues to have this problem—especially if your efforts to lower the pressure aren't working well—you may want to consider other approaches to addressing the macular degeneration.
- ***Give it a little time before resorting to surgery.*** We've had patients whose chronic elevated pressure did eventually clear. Unfortunately, that's not always the case; sometimes the only alternative is to do surgery to relieve the pressure.

Of course, some of these approaches won't prevent or resolve the problem if flow through the trabecular meshwork is being blocked by tiny silicone particles. But when dealing with a glaucoma patient, these strategies might help to decrease the pressure burden on the eye and limit pressure-related damage to the optic nerve. REVIEW

Dr. Kahook is The Slater Family Endowed Chair in Ophthalmology, professor of ophthalmology, chief of the Glaucoma Service and vice chair of clinical and translational research at the University of Colorado School of Medicine in Aurora, Colo. He is a consultant for and receives research support from Allergan and Alcon.

1. Good TJ, Kimura AE, Mandava N, Kahook MY. Sustained elevation of intraocular pressure after intravitreal injections of anti-VEGF agents. Br J Ophthalmol 2011;95:8:1111-4.

Equipment and Supplies / Career Opportunities

OPHTHALMOLOGY

Bassett Healthcare Network
Bassett Medical Center

Bassett Healthcare Network, a progressive health care network in central New York and major teaching affiliate of Columbia University is seeking a **General Ophthalmologist** to join a busy ophthalmology department based in the lovely village of Cooperstown. Glaucoma experience a plus!

Bassett Healthcare Network is an integrated health care system that provides care and services to people living in an eight county region covering 5,600 square miles in upstate New York. The organization includes six corporately affiliated hospitals, as well as skilled nursing facilities, community and school-based health centers, and health partners in related fields.

Key Benefits of this Position:

- Opportunities exist for both research and teaching if interested.
- Currently there are specialists in retina, cornea, pediatrics and oculoplastics.
- The support staff is well trained and experienced in both the clinic and operating room.
- Group employed model with competitive salary
- Comprehensive benefit package, including but not limited to medical, dental, CME, relocation assistance and paid malpractice insurance

Bassett Medical Center is located in Cooperstown, New York, a beautiful resort village on Otsego Lake. Home to the National Baseball Hall of Fame and Museum, the Glimmerglass Opera Company, and the Fenimore Art Museum, the area also boasts many cultural and four season recreational advantages including theater, music, museums, golf, sailing, hiking, and skiing.

EEO Employer

For confidential consideration, please contact:
Debra Ferrari, Manager, Medical Staff Recruitment,
Bassett Medical Center, One Atwell Road, Cooperstown, NY, 13326
phone: 607-547-6982; fax: 607-547-3651: email: debra.ferrari@bassett.org
or visit our web-site at www.bassettopportunities.org

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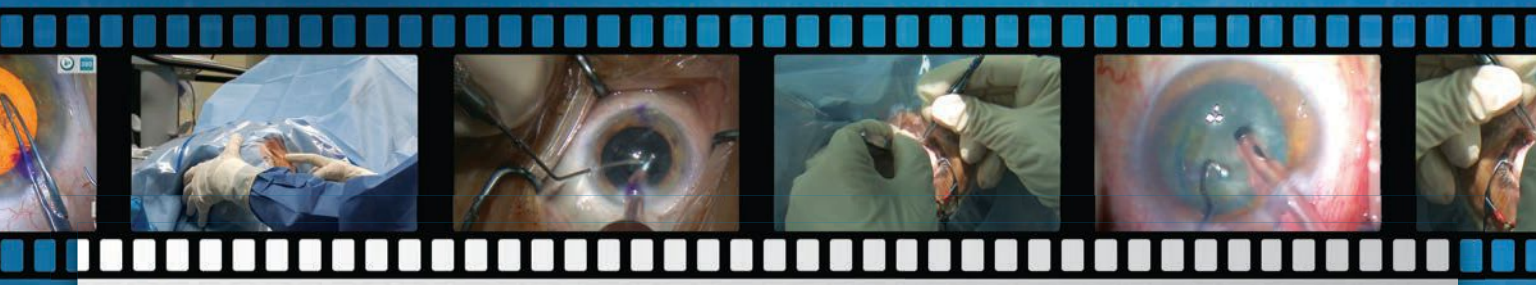

To view CME video
go to:
www.MackoolOnlineCME.com

Episode 16:
"Intraoperative Aberrometry"

Surgical Video by:
Richard J. Mackool, MD

Video Overview:
This patient has a dense cataract, low ocular rigidity and unreliable preoperative biometry. The use of a high flow rate of 55 cc/min* to remove nuclear segments, wavefront aberrometry, and methods to prevent contact of the IOL with the endothelium during the late stages of the procedure are demonstrated.

*Note that the OR technician was asked to set the aspiration flow rate (AFR) at 50 cc/min, but instead selected 55 cc/min. This small (10%) difference in AFR was of course insignificant.

MackoolOnlineCME.com MONTHLY Video Series

Richard J. Mackool, MD

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

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

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

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

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

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

Learning Objective:

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

- Apply phacoemulsification techniques that are useful for dense cataracts, wavefront aberrometry, and methods to maintain anterior chamber depth after IOL insertion in an eye with low ocular rigidity.

Accreditation Statement
This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Amedco and Postgraduate Healthcare Education, LLC (PHE). Amedco is accredited by the ACCME to provide continuing medical education for physicians.

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iDESIGN to Treat Mixed Astigmatism

The FDA recently approved a new indication for Abbott's Star S4 IR Excimer Laser System and iDESIGN Advanced WaveScan Studio System. The system is now approved to be used for LASIK patients with mixed astigmatism.

In clinical study of 149 eyes treated using the iDESIGN system, 91.9 percent of all eyes achieved uncorrected visual acuity of 20/20 or better without glasses at three months postop.

The iDESIGN system controls the procedure by generating a high-definition scan that measures and maps the irregularities of the eye that may impact visual acuity. Abbott says that iDESIGN then creates an accurate and personalized treatment plan based on these measurements.

The new approval allows for use in patients with mixed astigmatism measured by the iDESIGN system in which the magnitude of cylinder (1 to 5 D) is greater than the magnitude of sphere; who are 18 years of age or older; and who have stable refractions (a change of less than 1 D in sphere or cylinder for a minimum of 12 months prior to surgery).

For more information on Abbott's iDESIGN system, visit vision.abbott/us/systems/lasik/idesign-wavescan-studio-system.

FDA Approves Icare HOME

Icare USA recently announced that the Icare HOME tonometer has been approved by the FDA and is now available for use in the United States. Icare claims that the recent clearance will give doctors the ability to monitor their patients with more regularity and confidence, as patients are now able to measure their own IOP. Doctors can study IOP fluctuations throughout the day.

Icare highlights the ease of use for patients. The unit's Icare EyeSmart technology performs automatic OD/OS recognition. The company also says that the positioning is simple, thanks to red and green light signals that help patients correctly orient the tonometer. The Icare HOME also comes equipped with an automated measuring sequence that can take either a single measurement or a series of six.

Icare says that since the Icare HOME involves no puff of air and requires no drops, it's very convenient for patients to use.

For more information on the Icare HOME, visit icare-usa.com.

CooperVision's Clariti One-day Toric Contacts

In early March, CooperVision announced the release of a 90-pack configuration for its clariti one-day toric contact lenses. It says that these lenses provide astigmatic patients with the advantages of silicone hydrogel and the new convenience of one-day use. The clariti one-day toric is the only silicone hydrogel, one-day lens for astigmatism broadly available in the United States, the company states.

CooperVision also says these silicone hydrogel soft contact lenses feature high water content to support all-day comfort. It adds that the clariti one-day lenses have high oxygen transmissibility, allowing for 100 percent corneal oxygen consumption, which promotes ocular health.

The toric lens's power ranges include: plano to -9 D with cylinder options of -0.75 D, -1.25 D and -1.75 D in axes of 10, 20, 60, 70, 80, 90, 100, 110, 120, 160, 170 and 180 degrees; +0.25 D to +4 D with cylinder options of -0.75 D, -1.25 D and -1.75 D in axes of 20, 70, 90, 110, 160 and 180 degrees; and plano to -9 D with a cylinder power of -2.25 D in axes of 10, 20, 90, 160, 170 and 180 degrees.

For more information, visit coopervision.com.

This article has no commercial sponsorship.

A visitor to the United States develops a mysterious case of unilateral ocular pain and blurry vision.

Daniel J. Ozzello, MD, with Mark L. Moster, MD

Presentation

A 50-year-old female visitor to the United States from China presented to the neuro-ophthalmology clinic with one week of right-side periorbital and retrobulbar pain associated with blurry vision. She described the pain around her eye as a deep, dull pressure that worsened with movement of her head and eye movements.

Medical History

Her medical history was only significant for breast cancer treated 10 years prior with mastectomy and chemotherapy, without subsequent evidence of recurrence. She took no daily medications, had no medication allergies and didn't smoke, drink alcohol or use any illicit drugs. On review of systems she denied rashes or skin changes, joint pain, arthralgias or myalgias, paresthesias or sensory changes, balance difficulties or extremity weakness.

Examination

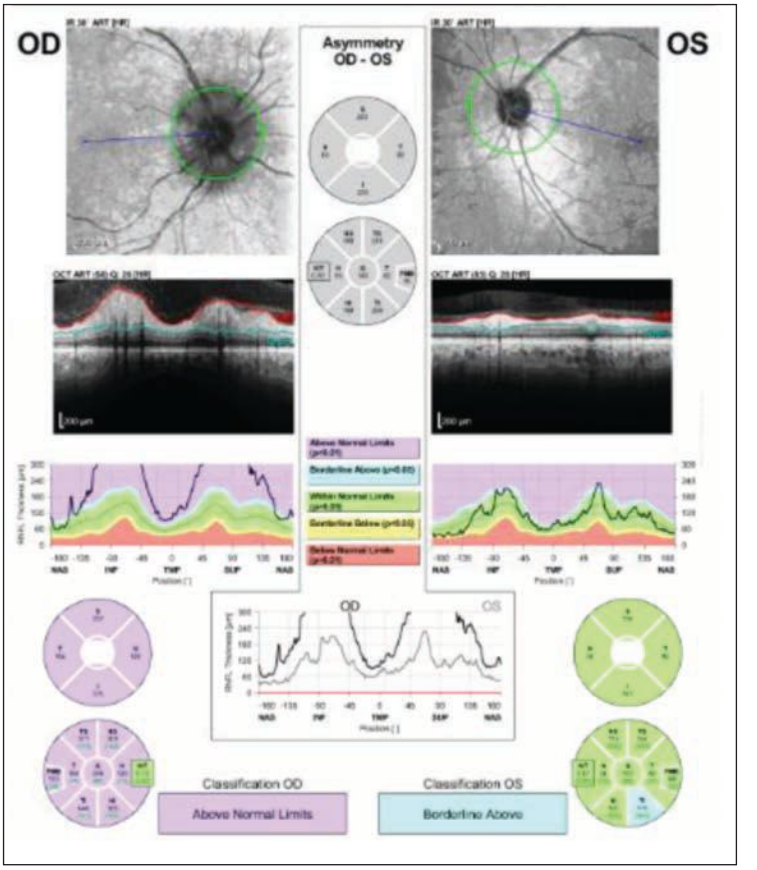


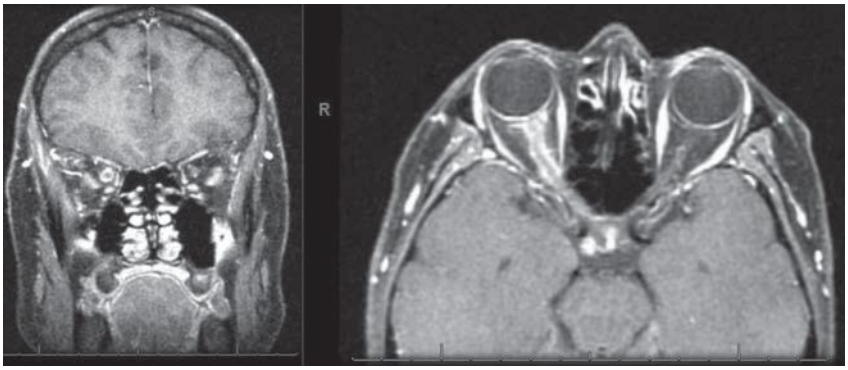
Figure 1. Spectral-domain OCT showing 360-degree RNFL thickening on the right and normal RNFL thickness on the left.

On examination her visual acuity was 20/25 OU, her pupils were equal in size and briskly reactive to light, and there was no relative afferent pupillary defect. Intraocular pressures were 18 and 16 mmHg in the right and left eye, respectively. Extraocular motility was full bilaterally, but associated with pain on the right. Color vision by Ishihara plates was within normal limits bilaterally. External examination revealed no periocular redness or swelling, and there was no relative proptosis by Hertel exophthalmetry. Anterior slit lamp examination was notable only for bilateral posterior subcapsular cataracts.

Dilated fundus examination revealed moderate, right-side disc edema without disc hemorrhages, but was otherwise normal. The left dilated fundus examination and optic nerve assessment were normal. Visual field testing by Humphrey perimeter showed blind spot enlargement in the right eye but was normal on the left. Spectral-domain OCT revealed thickening of the retinal nerve fiber layer on the right side and normal thickness on the left *(Figure 1)*.

What is your differential diagnosis? What further workup would you pursue? Please turn to page 104.

Diagnosis and Workup



Figures 2 and 3. T1-weighted post-contrast MRI shows circumferential enhancement of the optic nerve sheath along the length of the optic nerve in the right orbit with sparing of the nerve itself, creating a donut sign on coronal sections (left) and a tram-track sign on axial sections (right).

The differential diagnosis for the patient's pain with eye movements, enlarged blind spot and disc edema in her right eye was broad and included inflammatory (demyelinating optic neuritis, optic perineuritis, optic neuropathy related to systemic rheumatologic disease, idiopathic orbital inflammatory syndrome), infectious (tuberculosis, syphilis, Lyme, Bartonella) and infiltrative/neoplastic conditions (lymphoma, meningioma, glioma, metastatic disease). An MRI scan with and without contrast was ordered for further evaluation; it demonstrated enlargement and circumferential enhancement of the right optic nerve sheath. This was described radiographically as a positive "donut sign" and "tram-track" enhancement *(Figures 2 and 3)*. There was subtle streaking of the retrobulbar fat. The radiographic differential diagnosis included optic nerve sheath meningioma, acute optic neuritis, sarcoidosis, lymphoma and idiopathic orbital inflammatory syndrome. A CT scan of the orbits was subsequently performed to evaluate for calcifications in the optic nerve sheath that would suggest an optic nerve sheath meningioma, but none were found.

Serologic studies were also ordered, including basic metabolic panel, complete blood count, liver function studies, ACE, ANA, ANCA panel, Lyme antibody, RPR and FTA-antibody, and tuberculosis quantiferon gold test. A chest X-ray showed no lymphadenopathy. All of the above serologic studies returned normal except for the Lyme disease antibody panel, which was positive for Lyme IgM and negative for IgG, consistent with acute Lyme disease. A lumbar puncture revealed a normal opening pressure, cell count, protein and glucose levels, but was positive for CSF Lyme IgM. It was at this point that the patient recalled an odd, target-shaped rash four to six weeks earlier which had seemed unimportant to her at the time because it was self-limited.

With these radiologic and serologic results known, the patient was diagnosed with right optic perineuritis secondary to Lyme disease. She was admitted to the infectious disease service and started on IV ceftriaxone 2 g daily. She was also started on a course of oral corticosteroids with 60 mg of prednisone daily. Her pain with eye movement and visual blur improved rapidly with this regimen. Follow-up examination in the neuro-ophthalmology clinic two weeks after discharge also showed improvement of her disc edema. Two months thereafter, her disc edema had resolved, and a repeat MRI showed complete resolution of the optic nerve sheath enlargement and enhancement. Repeat visual field testing showed resolution of her blind spot enlargement on the right.

Discussion

Distinguishing optic perineuritis from demyelinating optic neuritis is important when selecting diagnostic studies, in therapeutic decision-making and in prognostic associations. Perineuritis may be clinically indistinguishable from typical demyelinating optic neuritis. The Optic Neuritis Treatment Trial demonstrated that treatment of demyelinating optic neuritis with intravenous corticosteroids hastened short term visual recovery, but long-term recovery wasn't significantly different from patients who weren't treated with corticosteroids.[1] In contrast, optic nerve perineuritis tends not to be self-limited and requires underlying conditions to be treated with or without supplemental corticosteroid therapy.[2] Furthermore, while optic neuritis is associated with multiple sclerosis and may be the first manifestation of this chronic neurologic condition, perineuritis does not have this association. It may, however, be an orbital manifestation of a systemic rheumatologic condition such as systemic lupus or polyangiitis with granulomatosis.[2] In patients such as ours, a targeted laboratory workup may help make the diagnosis; it may include ACE, ANA, ANCA panel, Lyme antibodies, syphilis studies and quantiferon gold for tuberculosis. Finally, if the laboratory workup is negative, optic perineuritis can be a manifestation of idiopathic orbital inflammatory syndrome, as inflammation along the optic nerve is present in 20 percent of cases.[3]

The clinical distinction between demyelinating optic neuritis and optic perineuritis can be challenging, therefore imaging is necessary to make the diagnosis. As noted above,

our patient received an MRI of the brain and orbits with and without IV contrast, which showed enlargement and circumferential enhancement of the optic nerve sheath. The neuroradiologist noted this to represent a positive "donut sign" with "tram-track" enhancement. The donut sign is seen on coronal sections of T1-weighted, post-contrast scans *(see Figure 2)*; the optic nerve sheath enhances peripherally around the optic nerve, while the nerve itself remains dark, giving a donut appearance.[4] On axial sections, the nerve is viewed longitudinally; the enhancing sheath is seen as two parallel lines separated by the non-enhancing nerve, which gives the appearance of tram tracks. Tram-track enhancement occurs when neoplastic or inflammatory lesions involve the optic nerve sheath and spare the optic nerve.[4] The differential diagnosis for this imaging sign is broad, as many neoplastic and inflammatory conditions can involve the optic nerve sheath. Optic nerve sheath meningiomas are the classic lesion that demonstrates tram-track enhancement.[4] However, this patient's symptoms and acuity of presentation were much more consistent with an inflammatory condition. The diagnosis of optic perineuritis secondary to Lyme disease couldn't be made until the clinical history, imaging and serologic studies were integrated.

Lyme disease is caused by the spirochete bacterium *Borrelia burgdorferia* and is the most common vector-borne illness in the United States.[5,6] While cases of Lyme disease have been reported in nearly every one of the continental United States, more than 93 percent of them have occurred in the Mid-Atlantic, New England and Great Lakes regions of the country.[5] The initial symptoms of Lyme disease include an influenza-like illness, myalgias and the target-like rash of erythema migrans. Of patients who go untreated during this initial stage, up to 15 percent will develop neurologic abnormalities and are diagnosed with neuroborreliosis. Neurologic manifestations are highly variable, including peripheral neuropathies, central nervous system and spinal cord disease and/or ocular involvement. Potential ocular disease is itself diverse, and includes conjunctivitis, episcleritis, perineuritis and chronic uveitis.[5] The Infectious Disease Society of America recommends 2 g IV ceftriaxone daily for 14 days (with anywhere from a 10- to 28-day course being acceptable) for the treatment of Lyme neuroborreliosis.[7] Cefotaxime and penicillin are other potential beta-lactam antibiotic choices, but both must be dosed multiple times per day. Finally, patients intolerant of beta-lactam antibiotics may be treated with oral doxycycline 200 to 400 mg per day in divided doses for 10 to 28 days.[7]

Optic perineuritis clinically mimics demyelinating optic neuritis, but prompt recognition of this entity is crucial for therapeutic decision-making as well as for potential association with systemic disease. The diagnosis of optic perineuritis most often requires a combination of clinical, imaging, and targeted serologic data. Especially in the Great Lakes and Mid-Atlantic regions and New England, Lyme disease should be considered as a possible cause of ocular and optic nerve sheath inflammation. REVIEW

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(continued from page 38)

son serve this function if you're a large enough practice," he continues. "This is one reason that larger practices often do better dealing with insurance companies; they have the resources to devote to developing friendly, personal contacts at each company. A solo practitioner probably won't be able to manage this; chances are it'll be a lesser priority for an administrator."

Fighting the Good Fight

"I'm happy to fight a denial," says Dr. Noecker. "I think that pushing back, standing up for yourself and your patient, is kind of a duty, and I think it does get results. I also think it's just wise. Accepting denials can become a slippery slope. You may concede one point and then put the patient on a medication you didn't want to use; then the patient has a bad reaction. In that situation, you're the one on the hook, not the insurance company.

"I'd say I get what I want from insurers about 80 percent of the time, without doing too much work," he adds. "My staff understands the protocol, and they take care of a lot of the process of asking the insurance company for what our patients need. Doctors have a tendency to just give up and do whatever the insurance company suggests, but at the end of the day, it's on us to do what we think is right for the patient. There are ways to push back; you just have to take the time to do it." REVIEW

Dr. Hovanesian is a consultant for Omeros and a co-owner of MDbackline software. Dr. Noecker is a consultant for Allergan, Alcon, Santen, Shire and Glaukos. Dr. Packer consults for Bausch + Lomb and Alcon.

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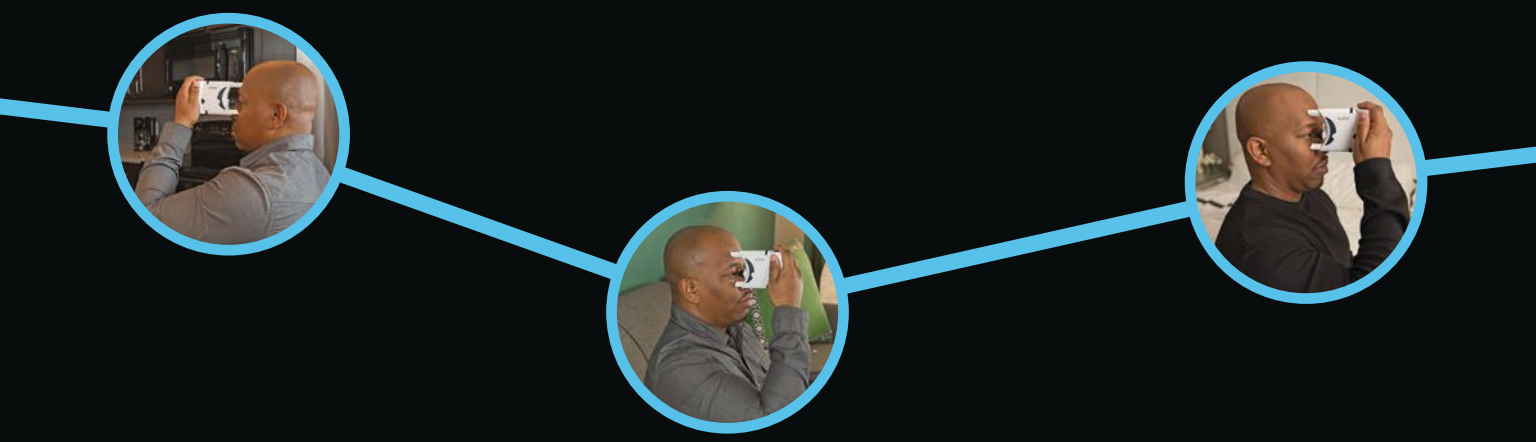

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