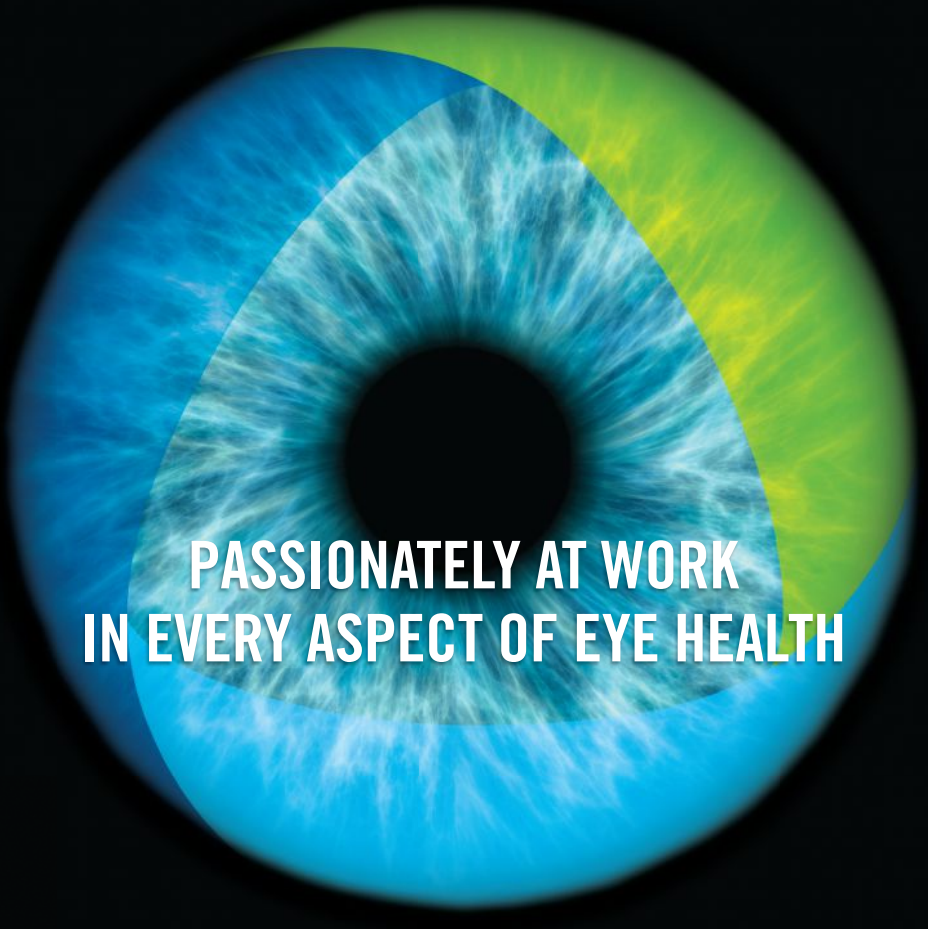

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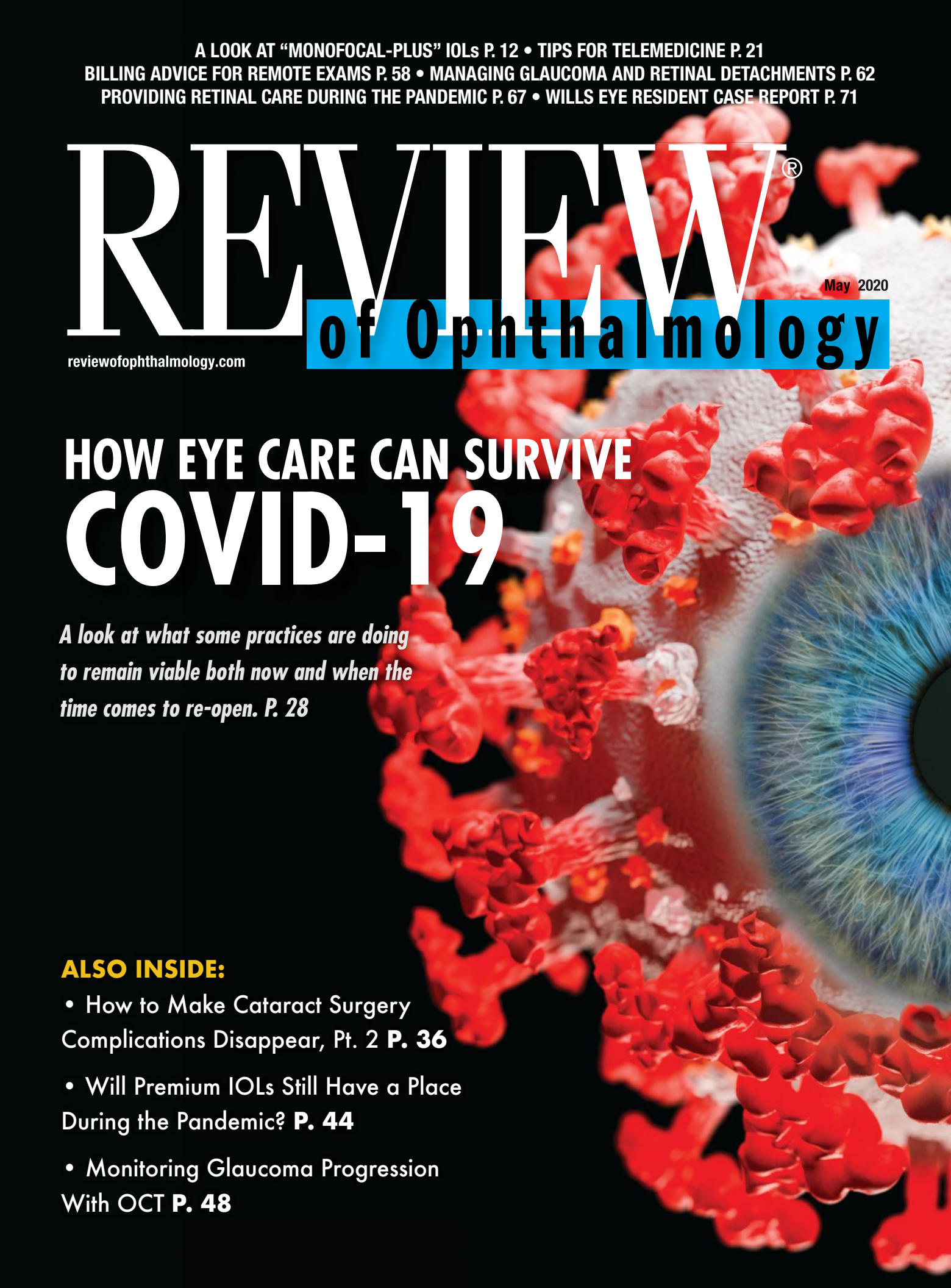
HOW EYE CARE CAN SURVIVE COVID-19

A look at what some practices are doing to remain viable both now and when the time comes to re-open. *P. 28*



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REFERENCE: 1. Samuelson TW, Sarkisian SR, Lubeck DM, et al. Prospective, randomized, controlled pivotal trial of an *ab interno* implanted trabecular micro-bypass in primary open-angle glaucoma and cataract. *Ophthalmology.* Jun 2019;126(6):811-821.

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Beovu Labeling to be Updated Due to Side Effects

Novartis recently completely its comprehensive product quality review of Beovu (brolucizumab), following a warning issued by the American Society of Retinal Specialists about a series of intraocular inflammation events—some of which led to severe vision loss. Throughout the month of March, Novartis conducted a safety review to investigate the adverse post-marketing cases. On April 8, 2020, the company announced its completion of the review, which included an assessment by an external, independent Safety Review Committee.

Novartis concluded that there is a confirmed safety signal of rare adverse events. One of the findings showed that retinal vasculitis, retinal artery occlusion or severe vision loss occurred in 8.75 to 10.08 out of 10,000 injections (between February 28 and March 27).[1]

The company says it will work with regulatory authorities to revise Beovu's safety and prescribing information to include these new vision-related side effects. Current clinical trials and Novartis-sponsored studies will receive updated informed consent forms, protocols and investigator brochures.

Vasculitis and severe vision loss on this scale have not been reported with Eylea (Regeneron), Avastin (Roche) or Lucentis (Novartis). Kevin J. Blinder, MD, of the Retina Institute in St. Louis, notes that "the results in the HAWK and HARRIER trials showed very few complications and a good safety profile. Beovu had an inflammatory rate of 4 percent, compared to 1 percent of aflibercept, and artery occlusions were about 1 percent, compared to less than 1 percent with aflibercept. The question is why was the complication rate in the trials lower? We never saw this severe occlusive vasculitis in the trials that we're seeing out in practice, post-approval.

"In the ASRS Research and Safety in Therapeutics (ReST) Committee case series, published in *Retina Times*, we had 26 eyes of 25 patients with retinal vasculitis, certainly higher and more severe than anticipated," continues Dr. Blinder. The *Retina Times* report[2] notes that 88 percent of reported cases occurred in women. None of the patients was treatment-naïve for other anti-VEGF agents and no eyes had a history of anti-VEGF-associated inflammation. One patient had a history of iritis. The study found no identifiable association with lot number. At the most recent follow-up, 13 eyes (50 percent) lost three lines of VA and/or were 20/200 or worse. Similar trends in visual acuity loss were noted in eyes with less than 60-days follow-up.

Dr. Blinder says that the manufacturing process may have played a role, but Novartis has not yet released conclusive findings on manufacturing.

One interesting finding from the trials included a potential immune reaction to Beovu. "In the trials, there was some pre-existing brolucizumab antibody formation in patients who weren't even injected yet," Dr. Blinder says. "Antibodies were present in 36 to 52 percent of the treatment-naïve patients. Once they had treatment, that went up to 53 to 67 percent of patients. Perhaps there's an immune reaction to Beovu that causes these severe complications, but we don't have any data to show that the ones that had this reaction were antibody-positive."

Fortunately, Dr. Blinder's practice hasn't seen any unusual inflammatory events, but Novartis' announcement of updated safety and prescribing information and this series of complications with Beovu has changed his utilization and practice patterns. "Retina specialists have to decide for themselves what their comfort levels are for using Beovu and discuss it with their patients," he says. "The risk may be justifiable in patients who are unresponsive or non-responders to all other treatments.

"Nevertheless, I think Beovu will still have a place in our armamentarium of treatment options for AMD," he says. "There are still many other ongoing trials with Beovu for other indications, so I think we need to see long-term if the incidence of this complication will go down."

Dr. Blinder notes that both the

Correction

In the April 2020 issue of *Review*, in the feature "Biometry and Formulas: Nailing the Outcome," Heidelberg Engineering's newest biometer, the Anterion, was incorrectly referred to as the Artemis. *Review* regrets the error.

Coronavirus: Survey on the State of Practice

In April, just before the Payroll Protection Plan and emergency loan program ran out of funds, *Review* conducted another e-survey to see how ophthalmologists were managing things during the pandemic. Here are some of the results from the 90 practices that responded:

- Most of the practices (70 percent) are either owned by an ophthalmologist or by a group of them.
- Sixty percent haven't laid off any staff, 6 percent have laid off half their staff, 15 percent say they've laid off three-quarters and 7 percent have laid off everyone (10 percent say they've laid off around 90 percent, however).
- In terms of staff furloughs, 32 percent haven't furloughed any staff, 22 percent have furloughed a quarter, 8 percent of the physicians have furloughed half, 16 percent have furloughed three-quarters and 13 percent have furloughed everyone.
- Eighty-one percent are seeing only urgent/emergency cases and 9 percent are completely closed to all patients. The rest are seeing a small mix of patients, but with many rescheduling their visits. Half of these consults are over the phone, 23 percent are secure video/image consults, 13 percent are phone "check-ins" not initiated by patients and 8 percent are via mobile apps.
- Seventy-seven percent say they're engaging in fewer than five telemedicine consults each day; 16 percent are doing 6 to 10 and 3 percent are doing 11 to 20. These consults are for such things as: red, irritated eyes; conjunctivitis; blepharitis; routine one-month postops with good vision; acute uveitis; RVO; glaucoma follow-ups; benign visual blurring; dry eyes; and floaters without flashes or vision loss.
- Surgeons are, understandably, divided as to when they'll be able to start seeing patients normally again. Ten percent were hoping for late April, 27 percent think it will be early May, 22 percent late May, 20 percent think it will be June, 9 percent say July or later, and 11 percent say they don't know.
- Twenty-two percent guess they'll be able to perform cataract surgery again in late May, 20 percent think it will be June and 13 percent think it will be July or later.
- To cover expenses, 39 percent of practices are dipping into their cash reserves, 24 percent have opened lines of credit, 8 percent are getting by with their collections and 6 percent say that private equity or a hospital is paying the bills. Twenty-four percent have made use of government loans or loans from other sources.

ASRS and Novartis have recommended that Beovu not be used in anyone who's had a history of inflammatory reaction to anti-VEGF therapy. "Bilateral injections are very questionable with Beovu, unless you have an extremely good reason to justify the risk," he adds. "Also, informed consent with a detailed discussion with the patient is extremely important."

If you continue to use Beovu, Dr. Blinder says examining the patient prior to every injection is important to detect any signs of intraocular inflammation. "Sometimes we do treatment-only visits for patients and don't do an examination or office visit. With this drug, it would be a good idea to look each time and check for inflammation in both the anterior and posterior segments. I would hold off on the injection if there are any signs of inflammation.

"It's really an unusual story," Dr. Blinder continues. "This drug had outstanding results in the registration trials, with great expectations post-approval. Hopefully, once all is said and done, we can still use it in our day-to-day practices." REVIEW

1. Gardner J. Eye drug side effects are real, Novartis confirms in new warning. BioPharmaDive. Accessed 22 April 2020. https://www.biopharmadive.com/news/novartis-beovu-safety-fda-eylea-regeneron/575816.
2. Hahn P, Arevalo JF, Blinder KJ, et al. Occlusive retinal vasculitis following intravitreal brolucizumab: An ASRS Research and Safety in Therapeutics (ReST) Committee Report. Retina Times 2020 [Epub]

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use LOTEMAX® SM safely and effectively. See full prescribing information for LOTEMAX® SM.

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38%

For topical ophthalmic use
Initial U.S. Approval: 1998

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once to fill tip before instilling drops. Apply one drop of LOTEMAX® SM into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

CONTRAINDICATIONS

LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, in mycobacterial infection of the eye and fungal diseases of ocular structures.

WARNINGS AND PRECAUTIONS

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

Cataracts: Use of corticosteroids may result in posterior subcapsular cataract formation.

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

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

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

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

Contact Lens Wear: Contact lenses should not be worn when the eyes are inflamed.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

USE IN SPECIAL POPULATIONS

Pregnancy: Risk Summary: There are no adequate and well controlled studies with loteprednol etabonate in pregnant women. Loteprednol etabonate produced teratogenicity at clinically relevant doses in the rabbit and rat when administered orally during pregnancy. Loteprednol etabonate produced malformations when administered orally to pregnant rabbits at doses 4.2 times the recommended human ophthalmic dose (RHOD) and to pregnant rats at doses 106 times the RHOD. In pregnant rats receiving oral doses of loteprednol etabonate during the period equivalent to the last trimester of pregnancy through lactation in humans, survival of offspring was reduced at doses 10.6 times the RHOD. Maternal toxicity was observed in rats at doses 1066 times the RHOD, and a maternal no observed adverse effect level (NOAEL) was established at 106 times the RHOD. The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies. Data: *Animal Data.* Embryofetal studies were conducted in pregnant rabbits administered loteprednol etabonate by oral gavage on gestation days 6 to 18, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations at 0.1 mg/kg (4.2 times the recommended human ophthalmic dose (RHOD) based on body surface area, assuming 100% absorption). Spina bifida (including meningocele) was observed at 0.1 mg/kg, and exencephaly and craniofacial malformations were observed at 0.4 mg/kg (17 times the RHOD). At 3 mg/kg (128 times the RHOD), loteprednol etabonate was associated with increased incidences of abnormal left common carotid artery, limb flexures, umbilical hernia, scoliosis, and delayed ossification. Abortion and embryofetal lethality (resorption) occurred at 6 mg/kg (256 times the RHOD). A NOAEL for developmental toxicity was not established in this study. The NOAEL for maternal toxicity in rabbits was 3 mg/kg/day. Embryofetal studies were conducted in pregnant rats administered loteprednol etabonate by oral gavage on gestation days 6 to 15, to target the period of organogenesis. Loteprednol etabonate produced fetal malformations, including absent innominate artery at 5 mg/kg (106 times the RHOD); and cleft palate, agnathia, cardiovascular defects, umbilical hernia, decreased fetal body weight and decreased skeletal ossification at 50 mg/kg (1066 times the RHOD). Embryofetal lethality (resorption) was observed at 100 mg/kg (2133 times the RHOD). The NOAEL for developmental toxicity in rats was 0.5 mg/kg (10.6 times the RHOD). Loteprednol etabonate was maternally toxic (reduced body weight gain) at 50 mg/kg/day. The NOAEL for maternal toxicity was 5 mg/kg. A peri-/postnatal study was conducted in rats administered loteprednol etabonate by oral gavage from gestation day 15 (start of fetal period) to postnatal day 21 (the end of lactation period). At 0.5 mg/kg (10.6 times the clinical dose), reduced survival was observed in live-born offspring. Doses ≥ 5 mg/kg (106 times the RHOD) caused umbilical hernia/incomplete gastrointestinal tract. Doses ≥ 50 mg/kg (1066 times the RHOD) produced maternal toxicity (reduced body weight gain, death), decreased number of live-born offspring, decreased birth weight, and delays in postnatal development. A developmental NOAEL was not established in this study. The NOAEL for maternal toxicity was 5 mg/kg.

Lactation: There are no data on the presence of loteprednol etabonate in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for LOTEMAX® SM and any potential adverse effects on the breastfed infant from LOTEMAX® SM.

Pediatric Use: Safety and effectiveness of LOTEMAX® SM in pediatric patients have not been established.

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in the chromosomal aberration test in human lymphocytes, or *in vivo* in the mouse micronucleus assay. Treatment of male and female rats with 25 mg/kg/day of loteprednol etabonate (533 times the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused preimplantation loss and decreased the number of live fetuses/live births. The NOAEL for fertility in rats was 5 mg/kg/day (106 times the RHOD).

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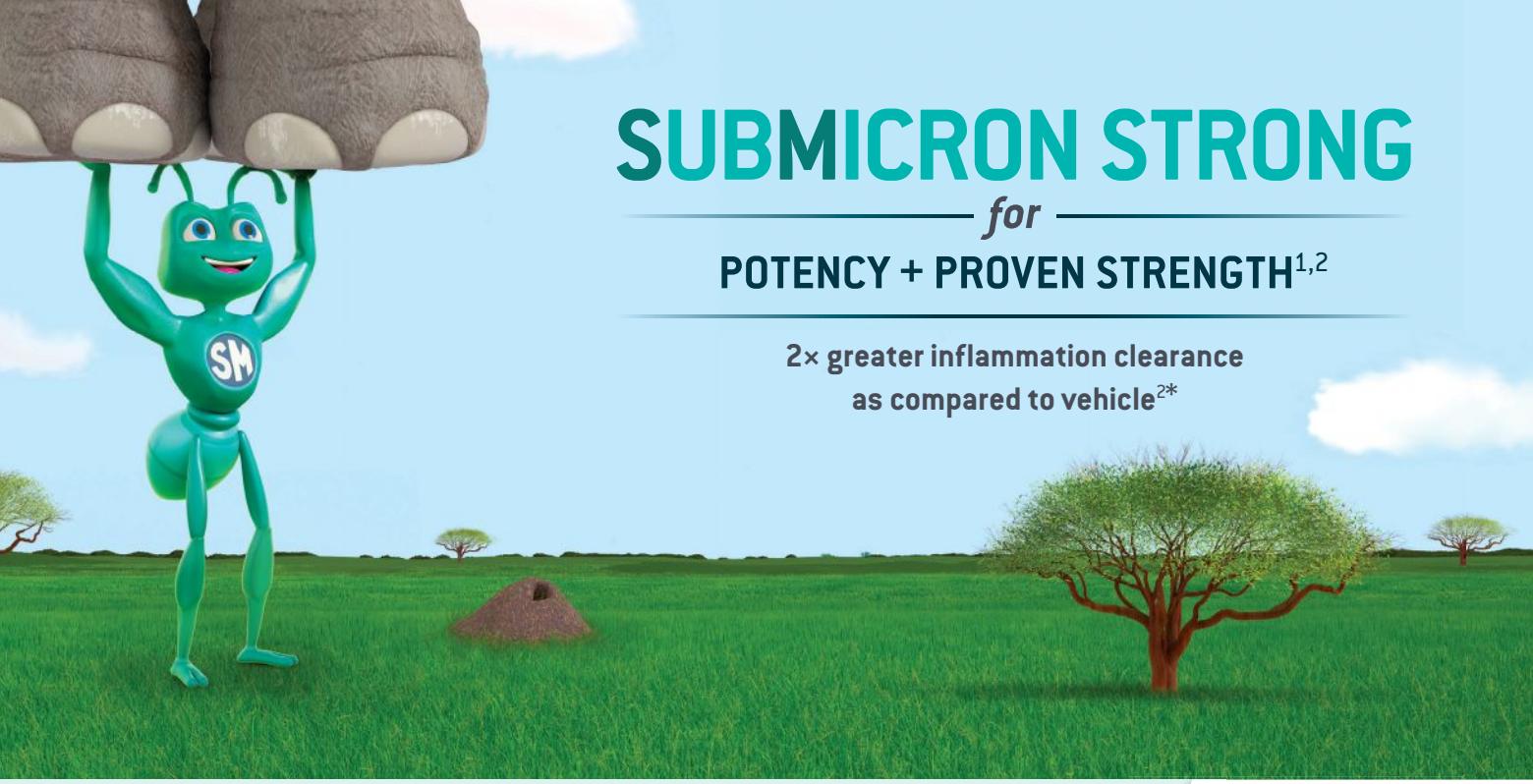

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SM TECHNOLOGY™

- **Engineered with SM Technology™ for efficient penetration at a low BAK level (0.003%)[1,3]**
- **~2× greater penetration** to the aqueous humor than LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%[3]

Clinical significance of these preclinical data has not been established.

LOTEMAX® SM
(loteprednol etabonate ophthalmic gel) 0.38%

SMALL & MIGHTY
SUBMICRON PARTICLES

*PROVEN STRENGTH

- **30% of LOTEMAX® SM patients had complete ACC resolution** vs vehicle (15%) at Day 8 (N=371, *P*<0.0001)[1,2†]
- **74% of LOTEMAX® SM patients were completely pain-free** vs vehicle (49%) at Day 8 (N=371, *P*<0.0001)[1,2‡]

†Pooled analysis of Phase 3 clinical studies. **Study 1:** 29% LOTEMAX® SM (N=171) vs 9% vehicle (N=172). **Study 2:** 31% LOTEMAX® SM (N=200) vs 20% vehicle (N=199); *P*<0.05 for all.

‡Pooled analysis of Phase 3 clinical studies. **Study 1:** 73% LOTEMAX® SM (N=171) vs 48% vehicle (N=172). **Study 2:** 76% LOTEMAX® SM (N=200) vs 50% vehicle (N=199); *P*<0.05 for all.

Indication

LOTEMAX® SM (loteprednol etabonate ophthalmic gel) 0.38% is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Important Safety Information

- LOTEMAX® SM, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.
- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If LOTEMAX® SM is used for 10 days or longer, IOP should be monitored.
- Use of corticosteroids may result in posterior subcapsular cataract formation.

Important Safety Information (cont.)

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those with diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infections.
- Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
- Contact lenses should not be worn when the eyes are inflamed.
- There were no treatment-emergent adverse drug reactions that occurred in more than 1% of subjects in the three times daily group compared to vehicle.

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 Prescribing Information on adjacent page.

References: 1. LOTEMAX SM Prescribing Information. Bausch & Lomb Incorporated. **2.** Data on file. Bausch & Lomb Incorporated. **3.** Cavet ME, Glogowski S, Lowe ER, Phillips E. Rheological properties, dissolution kinetics, and ocular pharmacokinetics of loteprednol etabonate (submicron) ophthalmic gel 0.38%. *J Ocul Pharmacol Ther.* 2019. doi: 10.1089/jop.2019;35(5):291-300.

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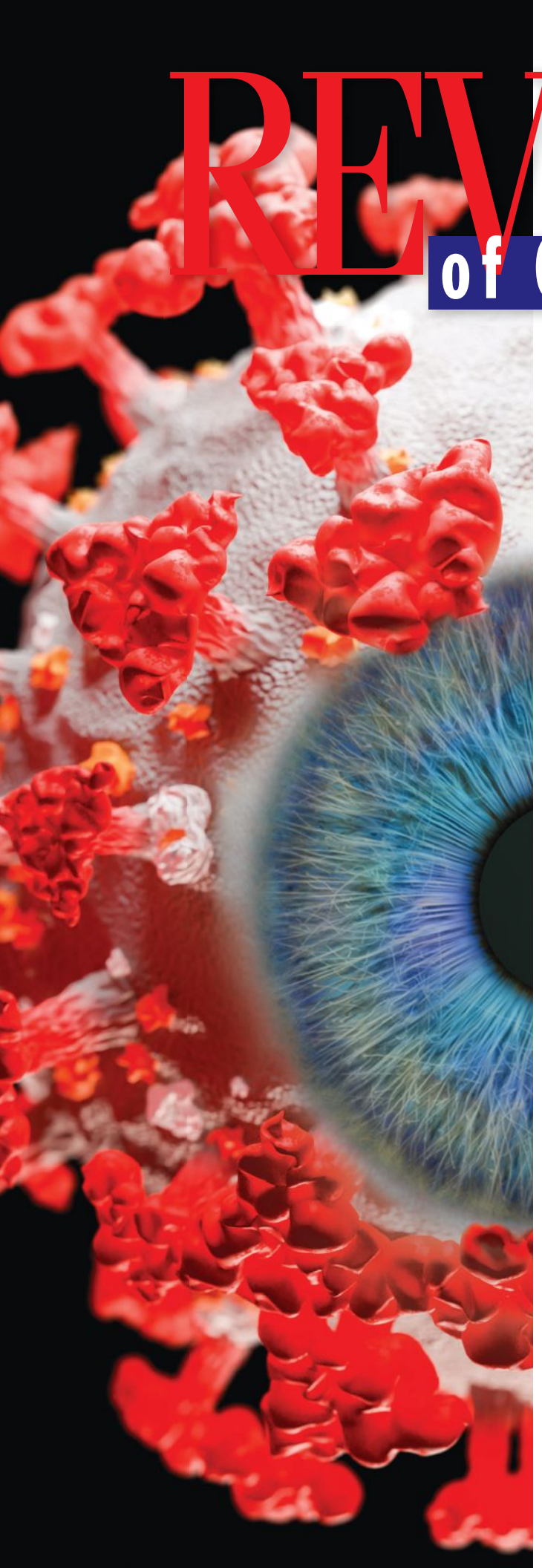

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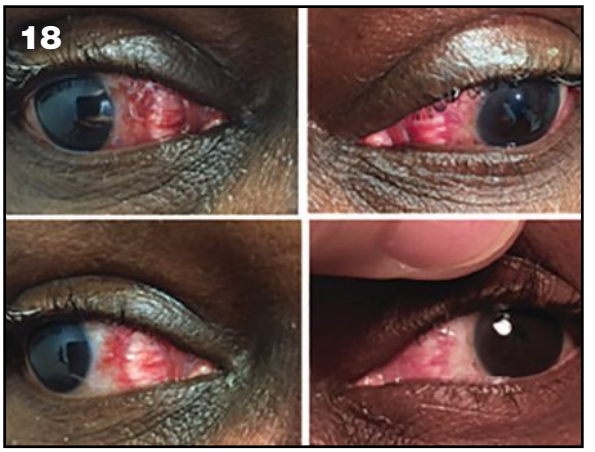

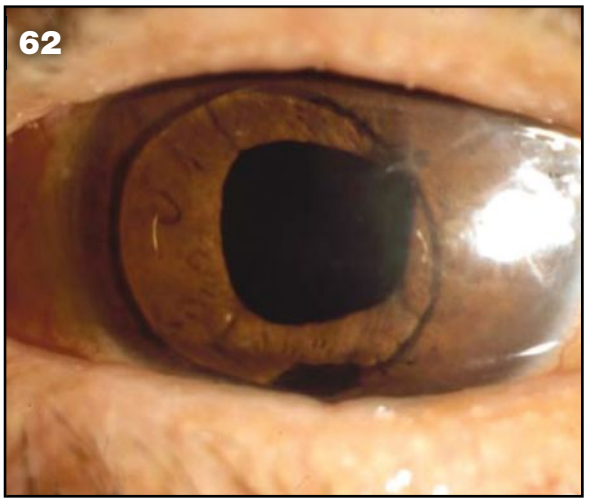

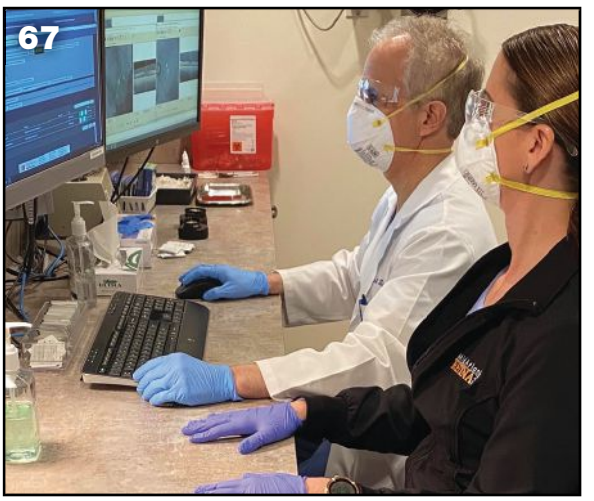

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OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis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

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

- **Prevents intraoperative floppy iris syndrome (IFIS)[3]**
- **Prevents iris prolapse[3]**

Compared to steroids*:

- **Reduces cystoid macular edema (CME)[4,5]**
- **Decreases breakthrough iritis[4]**
- **Reduces pain photophobia[4]**

*OMIDRIA used intraoperatively with postoperative NSAIDs (no steroids) when compared to postoperative steroids with or without NSAIDs (no OMIDRIA).

Compared to epinephrine:

- **Decreases complication rates[6]**
- **Decreases use of pupil-expanding devices (PEDs)[6-11]**
- **Enables performance of surgery and postoperative care without the use of steroids—allowing NSAID-only anti-inflammatory therapy[4,5,7]**
- **Shortens surgical times[6,7,9,10]**
- **Reduces need for opioids (i.e., fentanyl) during surgery while decreasing VAS pain scores[12]**
- **Prevents miosis during femtosecond laser-assisted surgery[11,13]**
- **Improves uncorrected visual acuity on day after surgery[6]**

VAS = visual analog scale

OMIDRIA inhibits the release of inflammation-causing prostaglandins, preventing miosis and reducing postoperative pain[14]

OMIDRIA is separately reimbursed under Medicare Part B and by many Medicare Advantage and commercial payers.† Contact your OMIDRIA representative today or visit omidria.com to learn more.

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IMPORTANT SAFETY INFORMATION

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

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

Systemic exposure of phenylephrine may cause elevations in blood pressure.

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

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

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

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

References: 1. HCPCS quarterly update. CMS.gov. Available at: https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update.html. Accessed August 9, 2019. **2.** Omeros survey data on file. **3.** Silverstein SM, Rana V, Stephens R, et al. Effect of phenylephrine 1.0%-ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg.* 2018;44(9):1103-1108. **4.** Visco D, et al. Study to evaluate patient outcomes following cataract surgery when using OMIDRIA with postoperative topical NSAID administration versus a standard regimen of postoperative topical NSAIDs and steroids. Presented at: 28th Annual Meeting of the American College of Eye Surgeons (ACES), the American Board of Eye Surgery (ABES), and the Society for Excellence in Eyecare (SEE), Caribbean Eye Meeting; February 1-5, 2019; Cancún, Mexico. **5.** Walter K, Kauffman L, Hess J. Rate of pseudophakic cystoid macular edema using intraoperative and topical NSAIDs alone without steroids. Manuscript submitted for publication. 2019. **6.** Rosenberg ED, Nattis AS, Alevi D, et al. Visual outcomes, efficacy, and surgical complications associated with intracameral phenylephrine 1.0%/ketorolac 0.3% administered during cataract surgery. *Clin Ophthalmol.* 2018;12:21-28. **7.** Al-Hashimi S, Donaldson K, Davidson R, et al. Medical and surgical management of the small pupil during cataract surgery. *J Cataract Refract Surg.* 2018;44:1032-1041. **8.** Bucci FA Jr, Michalek B, Fluet AT. Comparison of the frequency of use of a pupil expansion device with and without an intracameral phenylephrine and ketorolac injection 1%/0.3% at the time of routine cataract surgery. *Clin Ophthalmol.* 2017;11:1039-1043. **9.** Visco D. Effect of phenylephrine/ketorolac on iris fixation ring use and surgical times in patients at risk of intraoperative miosis. *Clin Ophthalmol.* 2018;12:301-305. **10.** Matossian C, Teves N. Clinical outcomes of phenylephrine/ketorolac intraocular solution versus epinephrine in cataract surgery in a real-world setting. Manuscript submitted for publication. 2018. **11.** Walter K, Delwadia N, Coben J. Continuous intracameral phenylephrine-ketorolac irrigation for miosis prevention in femtosecond laser-assisted cataract surgery: reduction in surgical time and iris manipulation. *J Cataract Refract Surg.* 2019;45(4):465-469. doi: 10.1016/j.jcrs.2018.11.004. **12.** Donnenfeld E, Shojaei R. Effect of intracameral phenylephrine and ketorolac 1.0%/0.3% on intraoperative pain and opioid use during cataract surgery. Manuscript submitted for publication. 2019. **13.** Gayton JL. Effect of early phenylephrine and ketorolac injection 1% / 0.3% (Omidria®) usage on pupil diameter in traditional and femtosecond laser assisted cataract surgery. E-poster presented at: 15th International Congress on Vision Science and Eye; August 10-11 2017; London, UK. **14.** OMIDRIA [package insert]. Seattle, WA: Omeros Corporation; 2017.

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Dawn of the Monofocal "Plus" Era

Surgeons discuss their experiences with the two newest additions to the monofocal family.

Christine Leonard, Associate Editor

Though they often receive less attention than premium IOLs, monofocals continue to be the most commonly implanted type of lens in cataract surgery. "Conventional monofocal IOLs provide almost perfect uncorrected distance visual acuity with a minimal incidence of photic phenomena," notes Rita Mencucci, MD, and Eleonora Favuzza, MD, at the Eye Clinic in the department of neuroscience, psychology, pharmacology and child health at the University of Florence, in Italy.

Where traditional monofocals fall short, however, is in postoperative functionality, leaving most patients needing reading glasses for focal points other than pure distance.[1] Because of this, the latest trend in intraocular lenses appears to be the monofocal "plus," a new breed of monofocal that has a little something extra in its design to offer focusing power at intermediate distances.

There are currently only two available outside the United States: Johnson & Johnson Visions' Tecnis Eyhance and Santens' Xact Mono-EDOF. In this article, we'll take a look at the two latest additions to the monofocal family and how they're performing so far.

The New Breed

Premium IOLs such as EDOF and trifocal lenses can offer more spectacle independence for intermediate distances than monofocals, with trifocals also offering more near vision as well,[2] notes Dr. Mencucci. However, she says, "for the most part, they also have a higher incidence of visual disturbances than monofocal IOLs." Combining monofocals' low rate of dysphotopsias with an extended focusing range—creating a sort of hybrid monofocal—is just what this new breed aims to do.

"Both the Eyhance and the Xact Mono-EDOF offer true intermediate vision," adds Florian Kretz, MD, FEBO, medical director of the Augentagesklinik Rheine & Greven, in Greven, Germany.

Eyhance

The Tecnis Eyhance monofocal, currently available in Europe, is intended to offer improved intermediate vision. The Eyhance is available in powers of +5 D to +34 D, in 0.5-D steps. Made of UV-blocking hydrophobic acrylic, this one-piece biconvex lens features a 6-mm optic, with an overall diameter of 13 mm. The edge design is a frosted, continuous 360-degree posterior square edge.

"The new lens design is based on a continuous refractive optical surface that results in a progressive increase in power from the periphery to the center of the lens," explains Dr. Mencucci. "This local and continuous increase in power is achieved by a higher-order asphere that smoothly changes the shape of the central part of the lens. About 85 percent of the surface is indistinguishable from the surface of the Tecnis monofocal, enabling both IOLs to provide the same primary corneal spherical aberration correction (-0.27 microns for a 6-mm pupil). Therefore, the refractive IOL design in the Eyhance IOL enables intermediate vision while keeping distance image quality comparable to a standard monofocal aspheric IOL."

Early Eyhance Outcomes

Dr. Mencucci's team recently pub-

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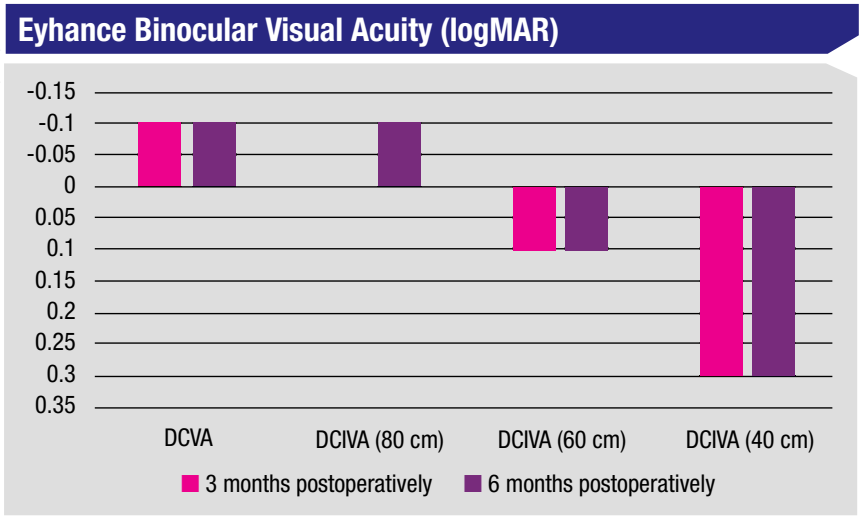
References: 1. Ngo W, Srinivasan S, Houtman D, Jones L. The relief of dry eye signs and symptoms using a combination of lubricants, lid hygiene and ocular nutraceuticals. *J Optom.* 2017 Jan-Mar;10(1):26-33. 2. Jones L, Downie L, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* Jul 2017;15:575-628.



Florian Kretz, MD, FEBO

This graph shows the postop binocular visual acuity (logMAR) of five patients implanted with the ICB00 Eyhance in a prospective, in-house study at Dr. Kretz's Augentagesklinik Rheine in Germany. Snellen equivalents: DCVA 20/16; DCIVA (80 cm) 20/16; DCIVA (60 cm) 20/25; DCIVA (40 cm) 20/40.

lished a paper in the *Journal of Cataract and Refractive Surgery* reporting their preliminary results with the Eyhance ICB00 IOL compared to the Tecnis ZCB00 monofocal IOL.[3] In the prospective case series, 80 eyes of 40 patients were evaluated at six months postoperatively and measured for monocular and binocular uncorrected and corrected (at 4 m) distance visual acuities; uncorrected intermediate visual acuity; and distance corrected, intermediate corrected (at 66 cm) and near (at 40 cm) visual acuities. The study also evaluated parameters such as photopic contrast sensitivity, binocular defocus curve, objective scatter index, and the incidence of halo and glare.

The researchers found that all patients reached high levels of uncorrected distance and corrected near visual acuity. The uncorrected intermediate visual acuity was significantly higher in the Eyhance ICB00 group. For monocular UIVA, the Eyhance achieved 0.28 logMAR ±0.11, (Snellen equivalent: 20/38 ±20/25) versus the monofocal ZCB00's 0.4 ±0.1 (20/50 ±20/25), $p<0.000$. For binocular UIVA, the Eyhance achieved 0.16 ±0.1 (20/28 ±20/25), versus the ZCB00's 0.27 ±0.06 (20/37 ±20/22), $p<0.21$.

Dr. Mencucci reports, "Regarding the defocus curve, the ICB00 IOL achieved a smoother profile along the entire curve with a less abrupt decrease in visual acuity, especially within the intermediate defocus range (up to -1.5 D, corresponding to 66 cm).

"There were no statistically significant differences in terms of photopic contrast sensitivity between the two IOLs," she continues. "Moreover, the optical quality measured with a 4-mm pupil using the AcuTarget HD Analyzer (Visiometrics), an Optical Quality Assessment System (OQAS) product based on double-pass technology, was similar."

In terms of spectacle independence, Dr. Mencucci says, "the implantation of the ICB00 IOL resulted in better spectacle independence for the intermediate distance than the ZCB00 IOL. In the Eyhance ICB00 group, only 20 percent of patients reported the need for correction to see at intermediate distances, whereas 90 percent of patients implanted with the ZCB00 IOL needed spectacles for intermediate.

"In our study, no statistically significant difference between Eyhance IOL and Tecnis ZCB00 IOL was detected, regarding glare and halo perception, assessed by the NEI-RQL-42 questionnaire glare subscale," Dr. Mencucci continues. "Up to now, no comparative studies of the Eyhance ICB00 and EDOF IOLs have been published. It would be interesting to compare the ICB00 outcomes with the results obtained with trifocal or EDOF IOLs, especially regarding intermediate visual outcomes and glare and halo perception."

As a newcomer to the IOL market, the Eyhance has yet to make its mark on monovision research and outcomes. "My experience at the moment is limited to bilateral emmetropic targets," Dr. Mencucci notes. "Nevertheless, it would be interesting to evaluate a 'light' monovision approach with this lens."

Currently, Dr. Mencucci is implanting the Eyhance in patients who aren't perfect candidates for multifocals or EDOFs. She adds that "there's almost no need for additional chair time [with Eyhance], making this IOL well-suited for high-volume cataract surgery. I would like to have an Eyhance toric platform available soon."

Xact Mono-EDOF

Santen's monofocal EDOF is available in powers of +10 to +30 D, in 0.5-D increments. The biconvex, aspheric, EDOF, diffractive, 6-mm, glistening-free optic is made of a blue-light-absorbing hydrophobic acrylic with an overall diameter of 12.5 mm. This lens isn't available in the United States.

"The Xact lens material is FDA-approved and it's actually the same as Bausch + Lomb's enVista material, just with a blue-light filter," notes Dr. Kretz, who led the first in-human clinical trial of the Xact Mono-EDOF. "Xact is yellow; enVista is clear. The

IN THE RACE AGAINST GLAUCOMA, **DURABILITY WINS**

Glaucoma demands outcomes that endure. Results from the largest MIGS pivotal trial to date have shown that the Hydrus® Microstent delivers the greatest improvement compared to cataract surgery alone for IOP reduction and medication elimination at 24 months.[1-4,*]

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material license was sold to Bausch + Lomb."

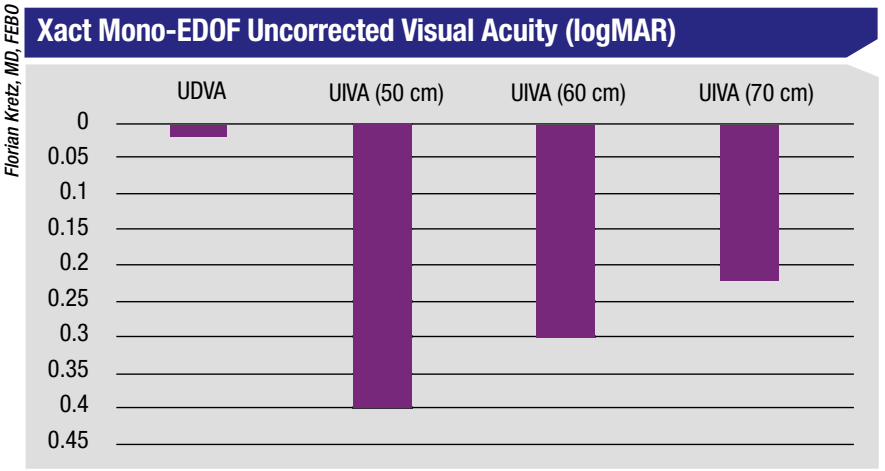
The 2002 clinical study in the United States with the early Santen/Advanced Vision Science model X-60 IOL enrolled 383 subjects, with 367 subjects available for examination at one year, 312 subjects available at two years and 281 available at three. Subsequent models—including the W-60R and the Mono-EDOF (ME4)—were minor modifications of the parent model X-60 and didn't warrant additional clinical testing. The percentage of patients who saw 20/40 or better at one year was 96.7 percent (n=320).[4]

Those familiar with the lens say the Xact's focus has a single peak, but it's broad—as opposed to the narrow peak of a traditional monofocal or the bimodular peak of a conventional diffractive EDOF—with no drop in modulation transfer function between far and intermediate distance. (*See the Xact MTF graph on page 48 in "Will Premium Options Still Have a Place?".*) In an optical bench study performed by Santen, the Xact IOL's design was found to minimize the occurrence of halos in night-time conditions.[5]

Instances of dysphotopsias with the Xact are comparable to conventional monofocals, making this lens a good option for patients who want an improved range of vision but who don't want to deal with the glare and halo typically found with premium IOL options, says Dr. Kretz. He adds that a low light distribution by the Xact's optics plays a major role in minimizing dysphotopsias while elongating the range of focus. "The Xact has four diffractive rings, but the add power is very low—only around 0.75 D," he notes. "With that small add power, it basically gives you intermediate focus because there are only four rings and the light distribution is so low."

Low light distribution has the benefit of higher light intensity, and it means the patients won't experience the typical levels of dysphotopsias found in premium IOLs, continues Dr. Kretz. "With a smaller area of distribution, and with a shorter defocus range due to the natural aberration of the cornea," he says, "patients don't see different images or halos, and they have only a little blur zone, which is just the glare they see at night. This glare isn't significantly different from a normal monofocal."

With the Xact, patients can expect good intermediate vision and a degree of spectacle independence, but to get truer vision, Dr. Kretz says monovision is another option. "You can decrease the level of monovision enough to 0.75 D to 1 D of defocus between both eyes," he says. "If the patient has a very high level of spherical aberration, that usually also increases the depth of focus on a monofocal, but the Xact doesn't offer true near vision. The limit is around 70 cm."



This graph shows the postop (120 to 180 days) uncorrected visual acuity (logMAR) of 20 patients implanted with an Xact Mono-EDOF in a prospective, in-house study at Dr. Kretz's Augentagesklinik Rheine in Germany. Snellen equivalents: UDVA 20/21; UIVA (50 cm) 20/50; UIVA (60 cm) 20/40; UIVA (70 cm) 20/33).

Early Xact Outcomes

"We did the initial trial at my clinic in Rheine, Germany, looking at the outcomes of the Xact Mono-EDOF IOL, compared to Santen's refractive monofocal W-60R, which they decided not to launch," says Dr. Kretz.

The pilot study included 12 eyes of six patients with visually significant cataract. Patients underwent bilateral implantation of the Xact Mono-EDOF (mean age: 69 years; mean preop BCVA: 0.3 logMAR [approximately equivalent to 20/40]). All patients had keratometric cylinder less than 1 D. At six months' follow-up, mean monocular UDVA was 0.02 logMAR (20/21), and mean BCVA was -0.09 logMAR (20/16). Monocular UIVA at distances of 50 cm, 60 cm and 70 cm were 0.4, 0.3 and 0.2 logMAR (20/50, 20/40 and 20/31), respectively. Mean BCDVA values were almost identical at the same distances.[6]

"The monocular depth of focus was around 1.5 D, with logMAR visual acuity of 0.3 or better in our defocus curve analysis," Dr. Kretz says. "Binocular defocus curves showed a focus depth around 1.75 D, with visual acuity better than 0.3 logMAR."

A Phase IV clinical study involving 39 eyes of 23 patients (mean age: 70 years) measured target and achieved spherical equivalent. Seven patients underwent monocular implantation of the Xact Mono-EDOF and 16 patients underwent bilateral implantation. Mean preoperative UDVA was 0.59 logMAR (20/78) and mean BCDVA was 0.33 logMAR (20/42). The target spherical equivalent was -0.14 D (range: -0.36 D to -0.14 D). With the IOLMaster, the research team achieved a mean spherical equivalent of -0.25 D (range: -1 D to +0.13 D), demonstrating a difference of 0.05 D (range: -0.4 to +0.93 D; A constant: 119.5).[6]

At six months' follow-up, patients' mean monocular UDVA was 0.12 logMAR (20/26). Monocular BCDVA was -0.05 logMAR (20/18). Those implanted bilaterally achieved a binocular UDVA of -0.01 logMAR (20/19) and BCDVA of -0.06 logMAR (20/17). Intermediate visual acuities without correction at six months for monocular implants at distances of 50 cm, 60 cm and 70 cm were 0.36, 0.28 and 0.23 logMAR (20/45, 20/38 and 20/34), respectively. Binocular values without correction at the same reading distances were 0.27, 0.17 and 0.13 logMAR (20/37, 20/29 and 20/27). Distance-corrected intermediate visual acuity values and uncorrected values were similar. The defocus range showed that patients maintained a visual acuity of 0.2 logMAR (20/31) with defocus ranging from -1.4 D to 1.1 D. Around ±0.5 D, patients maintained a visual acuity of 0.0 logMAR (20/20).

"One of the benefits of this lens is that it behaves similarly to a premium IOL but is a licensed monofocal," Dr. Kretz says. "Because of this, there's less need to counsel patients for any additional dysphotopsias and side effects, which makes the whole adaption process easier."

Dr. Kretz uses the Xact as his standard lens of choice for patients who have less than 1 D of corneal astigmatism. It's also his lens of choice for those with private insurance or insurance that covers the cost. "I'd like to have this mono-EDOF lens in a toric version," he says. "Santen is working on that, but it will come after they finish their toric monofocal." REVIEW

Dr. Mencucci has no financial disclosures. In terms of products mentioned, Dr. Kretz discloses research support from Acufocus and Santen.

1. Ribeiro F, Cochener B, Kohnen T, et al. Definition and clinical relevance of the concept of functional vision in cataract surgery. ESCRS Position Statement on Intermediate Vision: ESCRS Functional Vision Working Group. J Cataract Refract Surg 2020;46;Suppl 1:S1-S3.

2. Mencucci R, Favuzza E, Caporossi O, et al. Comparative analysis of visual outcomes, reading skills, contrast sensitivity, and patient satisfaction with two models of trifocal diffractive intraocular lenses and an extended range of vision intraocular lens. Graefes Arch Clin Exp Ophthalmol 2018;256:10:1913-1922.

3. Mencucci R, Cennamo M, Venturi D, et al. Visual outcome, optical quality, and patient satisfaction with a new monofocal IOL, enhanced for intermediate vision: Preliminary results. J Cataract Refract Surg 2020;46:3:378-387.

4. Xact Mono-EDoF Model ME4-IFU for CE Europe Material Specification. Santen/Advanced Vision Science. Accessed 3 April 2020. https://www.advancedvisionscience.com/wp-content/uploads/2019/04/280538-AXACT-ME4-IFU-FOR-CE-EUROPE-MATERIAL-SPECIFICATION-ART.pdf.

5. Xact mono-EDOF brochure. Sept 2019. Santen.

6. New concept monofocal IOL with continuous focus. ESCRS Euro Times Supplement November 2019. Accessed 25 March 2020. https://www.eurotimes.org/wp-content/uploads/2019/11/Santen_Monofocal_Supplement_November2019-Press-Quality.pdf.

Plication as a Muscle-Strengthening Procedure

This procedure can yield good results if you know how and when to use it, these surgeons say.

Maria Stunkel, MD, Lauren Mehner, MD, Charline Boente, MD, and Daniel Neely, MD, Ft. Wayne, Ind.

Strabismus is one of the most common ocular problems in children, affecting 5 percent of the preschool population.[1] It also affects a significant proportion of adults, both as an acquired condition as well as a lifelong condition necessitating continued symptomatic management. Though there are different approaches to treating the condition, we've found muscle plication to be effective in many cases. Here, we describe details of the technique, in addition to potential benefits of the procedure.

Plication vs. Resection

Surgical alternatives to rectus muscle resection have been available for over 100 years. The cinch technique, originally described in 1916, involves weaving a cable of suture (four strands of 3-0 nylon tied together to create an eight-strand cable) through a split muscle and tying the cable off to create a resection effect.[2] The technique gained limited popularity in the 1930s, but eventually fell out of favor. Muscle tucking was introduced in 1983 as a quick procedure that avoided cutting the extraocular muscle.[3] This procedure, however, has also fallen out of favor for rectus muscles, as the muscle-to-muscle suture fixation relaxes over time.[4] An alternate approach was introduced by Los Angeles surgeon Kenneth Wright in 1991: a modified rectus tuck where muscle is sutured to sclera, representing the plication procedure.[5] More recently, several authors have studied the effectiveness of the plication technique with favorable reviews.[6-11]

Several advantages of plication have been proposed: There's no risk of a lost muscle, since the muscle is never disinserted from the sclera; it preserves anterior ciliary circulation; and there's less tissue trauma and bleeding than in resection.[12,13] Additionally, the procedure's technique is arguably simpler than resection's and can possibly result in decreased operative time. One disadvantage, however, is that because the muscle is never disinserted from the sclera, plications can't be used to shift muscles for pattern strabismus (i.e., A- or V-pattern esotropia) or small vertical deviations in which the surgeon wishes to perform a vertical transposition of the horizontal rectus muscle(s) to address the vertical deviation.

Surgical Technique

The muscle plication surgical technique can be performed through either a fornix or limbal incision using surgical dose tables identical to those used for traditional resection, as described by Marshall Parks, MD, and co-authors.[14] Figure 1 outlines the steps of the plication procedure.

Using a 6-0 double-armed Vicryl (Ethicon) suture with a spatulated needle, a locking bite is placed at either pole of the muscle with an optional central locking bite for secure imbrication at the desired location, according to standard charts for resection. Each suture needle is then passed through partial-thickness sclera, just anterior to the poles of the muscle insertion. A wide, narrow-gauge hook, such as the Helveston Finder hook (Katena), is then placed under the muscle to create the plication fold. We prefer this particular hook, as it's not only thin but also has no knob at the end, making it easier to slide the instrument out after the plication suture is tied securely. The

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posterior portion of the muscle is advanced up to the original insertion by pulling on the two suture ends until the posterior suture line is flush with the insertion, thereby creating the appropriate resection effect.

To ensure success, it's imperative that no gap is left between the suture line and muscle insertion. Full approximation of the muscle fold segments at the muscle borders should be confirmed before the second locking knot is tied over the first double or triple-wrap suture throw. If any residual muscle gap is noted after the suture is tied, we recommend augmenting the plication with an additional suture throw at the pole of the muscle (muscle through partial-thickness sclera) to close the gap, as shown in Figure 2.

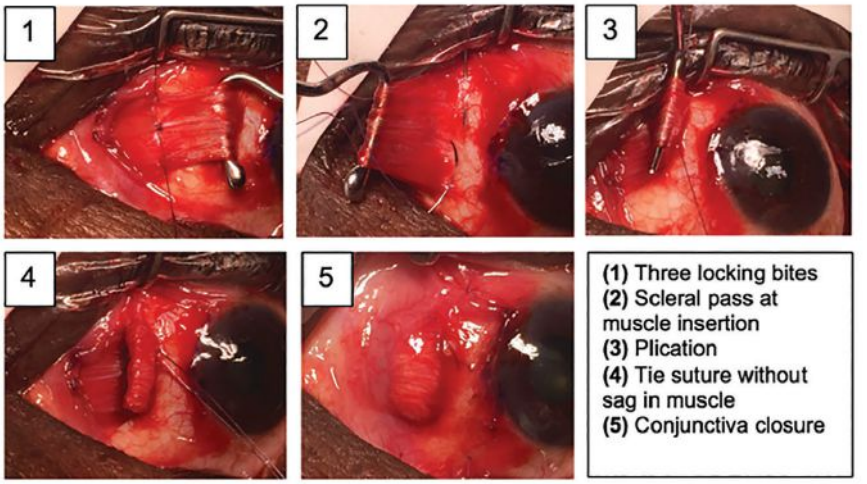


Figure 1. An annotated pictorial of the muscle plication procedure.

Postoperative Results

With plication, patients can expect postoperative alignment similar to that achieved with resection. In one study, surgeons compared 22 plication procedures to 31 resections and found an overestimation of surgical effect for exotropia at doses less than 4 mm and overestimation of effect for resection exceeding 7 mm.[6] Therefore, a typical range of 20 to 50 PD of exotropia led to similar results with plication or resection. The immediate postoperative result and the long-term result (119 days for plication and 966 days for resection) didn't vary significantly.

Other studies have found negligible differences between plication and resection for esotropia. A 2018 paper reviewed 88 plications for esotropia and 31 plications for exotropia with follow-up ranging from four weeks to 72 months.[11] All surgeries were combined with recession of the antagonist muscle. Surgical success, defined as ≤10 PD of undercorrection and of ≤4 PD overcorrection (measured between postoperative weeks four and 16), was found in 95.5 percent of plications for esotropia and 77.4 percent of plications for exotropia—this was similar when compared to resection for similar amounts. Re-operation rates between the two groups were also similar after as long as 72 months of follow-up.

Several studies cite similar surgical results for plication and resection up to a year following surgery.[8,10] However, there's sparse literature regarding success of the plication procedure several years out from the surgery. In a study by Boston surgeons Maan Alkharashi and David Hunter, they suggested that there's a decreased surgical success rate with rectus muscle plication.[15] Their study included 48 resections and 24 plications with surgical success defined as ≤10 PD deviation for horizontal muscles and ≤6 PD for vertical muscles. The success rates of 89 percent for resection versus 59 percent for plication were similar at six and 12 weeks of follow-up, as well as the final mean follow-up (19 ±13 months; range: three to 56 months). One could argue, however, that the quoted short-term success rate in this study varies from the favorable short-term success rates quoted in the aforementioned studies.[6-11] We've been pleased with the surgical result of plication at our institution, with some patients having a follow-up of up to five years. We are currently reviewing our long-term data for plication procedures.

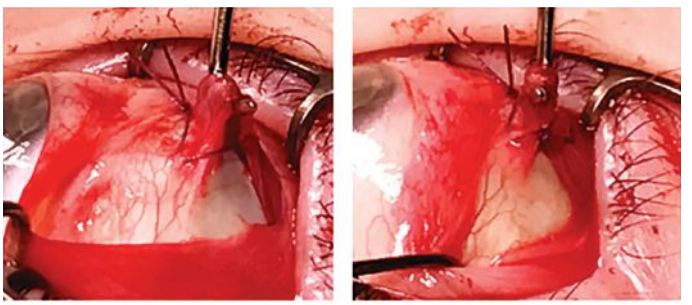


Figure 2. A sag in the muscle (left) can be corrected with an additional suture at the muscle pole (right).

Postoperative Healing

Some surgeons express concern regarding the appearance of the eye during wound healing, with a temporary visible "bump" of tissue after surgery. To date, we haven't encountered any patients with significant concerns regarding cosmesis or plication adversely effecting ocular surface healing. We use this approach for both adults and children with

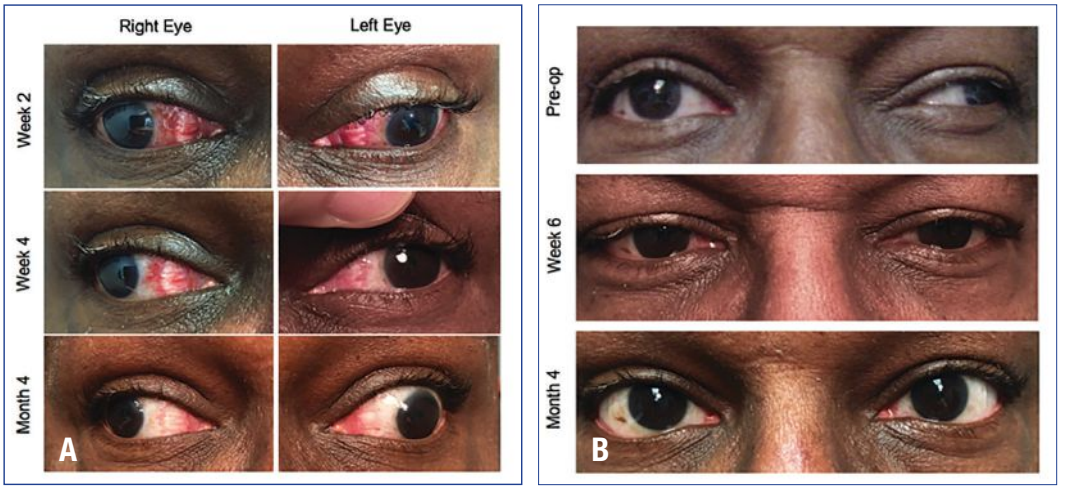


Figure 3. (A) Postoperative appearance following large medial rectus plications for 90 PD of exotropia; (B) Preoperative and postoperative comparison of healing.

strabismus. A randomized, prospective study evaluated an aggregated inflammatory score (congestion, chemosis, discharge, foreign body sensation and drop intolerance) in addition to scar visibility at one month, between patients undergoing resection or plication. It found similar results between groups.[9] Figure 3 shows the typical postoperative appearance of the eye following plication and a comparison of the preoperative appearance to the postop appearance after healing. Even with a large plication, the fold of muscle settles nicely several months following surgery. In our experience, patients and family members are generally not concerned about the appearance of the eye following plication. For patients who may be concerned about cosmetic appearance, we recommend a discussion regarding postop expectations, during which you let them know that a noticeable "bump" of tissue may be seen, but will settle several months after surgery. This timing coincides with that of our typical second postop visit three months following surgery.

Other Benefits

Anterior segment ischemia (ASI) is a rare but potentially serious complication of strabismus surgery that can result from disinsertion of the rectus muscles disrupting the blood supply to the various anterior segment structures via the anterior ciliary arteries. Multiple studies have examined the effect of strabismus surgery techniques on anterior segment circulation in both primates and humans. These studies have demonstrated that plication procedures spare the anterior segment circulation as long as care is taken to avoid the anterior ciliary arteries, both superficial to the muscle tissue and in the sclera, when passing the needle.[12,13,16,17] Furthermore, one study found that postoperative iris-filling defects seen on iris angiograms were more common following vertical rectus muscle surgery that involved muscle disinsertion, consistent with the distribution of anterior ciliary and long posterior ciliary arteries providing anterior segment circulation.[13,17] Therefore, plications may be a safer alternative for certain muscle surgeries in patients at risk for ASI. This is especially pertinent for re-operations and multi-muscle surgeries such as those for nystagmus.[5,17]

Plications are also potentially reversible in the early postoperative period since no tissue is removed as in a traditional resection.[6] However, in his description of the technique, Dr. Wright cautions that any reversals need to be done within three days of the original surgery, prior to the muscle healing to the sclera.[5] Our personal experience confirms that the muscle can't be separated from sclera as early as one month postoperatively, and by three months or more, one cannot even find visible evidence that a plication has been performed *(as demonstrated in Figure 3)*. One group of researchers, however, described an adjustable plication procedure which may offer an additional option for those situations wherein early modification may be desired.[18]

In conclusion, muscle plication provides results comparable to resection as a strengthening procedure in strabismus surgery. Advantages include its procedural simplicity with short operative time, decreased risk of tissue trauma and bleeding, and decreased risk of lost or slipped muscle, since the muscle is never disinserted from the globe. Further, it may be beneficial in cases where anterior segment ischemia is a specific concern, as plications may preserve anterior segment circulation if done correctly. We feel that plication is a surgical equivalent to traditional resection in terms of alignment and cosmetic outcomes, and our patients have tolerated plication procedures very well to date. Muscle plication is an important skill to have on hand in the strabismus surgeon's toolkit. REVIEW

Drs. Stunkel and Mehner are completing their pediatric ophthalmology fellowship at Indiana University. In

(Continued on page 56)


Telemedicine in the Time of COVID-19

Telemedicine experts offer some tips for navigating distance doctoring during the pandemic.

Christine Leonard, Associate Editor

To mitigate transmission of the coronavirus, practice social distancing and keep their practices afloat financially during the pandemic and subsequent business shutdown, some practices are turning to telemedicine to continue seeing patients and provide non-emergency care. Transitioning to telemedicine during this stressful time may not be ideal for every practice, but those who have added, or are considering adding telemedicine to their practices may find it a good long-term investment. Telemedicine can offer patients—especially the elderly—peace of mind during the quarantine, experts say. You may even identify an early case of coronavirus during your virtual visit. Here, we'll discuss some of the logistics of telemedicine so you can decide if it's right for your practice.

Feeling the Impact

No matter which steps practices take regarding coronavirus safety—whether it's taking patients' temperatures as they enter, spacing out patients in the waiting room, turning away those with suspected coronavirus symptoms, proceeding as usual in less-affected regions or following the AAO's guidelines to stop all non-urgent, routine visits—they're all feeling the financial effects of reduced patient volume. Many have had to lay off or furlough staff. In coronavirus hotspot areas, like New York City, some practices have closed their doors.

"Routine visits across the country for ophthalmology have largely come to a halt," says Ingrid E. Zimmer-Galler, MD, associate professor of ophthalmology at Johns Hopkins and executive clinical director of the office of telemedicine. "That's why everyone's so interested in using telemedicine—we can reach out to patients that we otherwise can't see in the office."

Some telehealth companies are responding to the pandemic by offering their services to physicians free of charge. EHR tech company Modernizing Medicine has offered its platform, Modmed Telehealth, to current and future users,[1] and ImprimisRx recently announced an exclusive partnership with Doxy.me, another telehealth platform.[2]

"The real-time audio/video capabilities of telemedicine allow doctors to keep their doors virtually open, even though their offices might be shuttered," explains Nikola Ragusa, MD, FACS, an ophthalmologist at the Bronx Eye Center in New York and chief medical officer of the startup telemedicine app Pulse.

Dr. Ragusa says that interest in and use of telemedicine corresponds with the growing concern over the pandemic. Prior to the pandemic, he says, calls using his product ranged on average from about five to 10 per month per physician. Now, physicians are fielding about 30 calls per day. "This can generate close to $3,000 per practice per physician," he says. "It's probably not the typical revenue generated by patient visits, but it's something to help keep businesses afloat."

Paradigm Shifts

The pandemic will leave its mark on everyone around the country. One concern physicians have raised is the degree to which pandemic-era behavior and anxiety might impact future patient care. Kathryn Colby, MD, Louis Block professor and chair of the department of ophthalmology and visual science at the University of

Chicago Medicine & Biological Sciences, notes that "Just this morning in a virtual meeting, someone brought up the question: What if patients don't want to come back into the office after all this? After we say we're open for business, please come back, what if patients don't want to? Most ophthalmology patients are older and that would put them at a higher risk for infection. I think that once we have serological testing routinely available to demonstrate immunity, people will feel more comfortable resuming some of their daily activities."

Visits from a Distance

Pandemic-era telemedicine focuses more on practice management and routine cases than typical ophthalmic telemedicine, which has traditionally focused on remote monitoring and portable imaging, often in underserved regions.

"I have a retina practice, so it's very difficult for me to do my job with telemedicine visits when it comes to monitoring patients who have diabetic retinopathy or macular degeneration," says Dr. Zimmer-Galler. "You can't really do that with a simple video visit, but we can do a lot of follow-up on patients and determine who needs to come in."

When patients do need to come into the office, experts say it's a good idea to spread them out over the entire day, with just one patient in the office at a time. Using telemedicine for follow-up visits is another way to reduce patient volume.

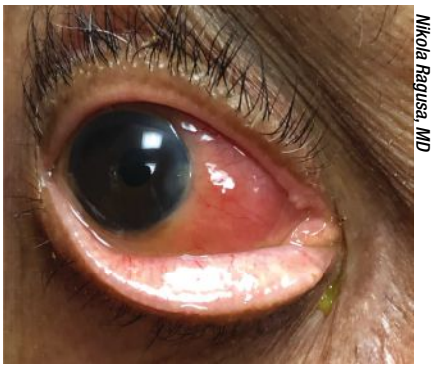
"One good thing to come out of this will be the use of telemedicine for a significant number of our postoperative exams," says Alan Aker, MD, who runs the Aker-Kasten Eye Center with his wife, Ann Kasten, MD, in Boca Raton, Florida. "Because of the pandemic, we've been forced to provide these postop checks via telemedicine. We've realized that following uneventful, well-performed surgery, patients who are doing well after the initial one-day visit can be screened by phone at the one-week and later visits. Any patient wishing to be seen, or who seems to be having an issue, can be scheduled. Eliminating a great number of routine but often cumbersome visits for our staff and our patients will enable us to streamline our postop visits. Our staff and our doctors will have more time to spend with those few patients who are having issues following surgery.

"Patients traveling long distances will benefit from this as well, saving travel time and the expense associated with that," he continues. "I see this as a very significant and positive change we will institute once the pandemic has passed. In addition, I think we'll begin to provide emergent telemedicine care for select patients. An example of this would be the patient who wakes with a subconjunctival hemorrhage and calls with great concern. These patients might prefer to be seen in person because of the concerns they have, but that could be handled on a case-by-case basis. As video is added to our systems for remote care, we can probably begin to provide more timely care and more compassionate care without the significant waits associated with being an 'add on' to our busy clinic schedules."

Here are some at-a-glance ways that users say telemedicine can help your practice during the pandemic.

• ***Keep your patients safe.*** Slit lamp exams are hotbeds for viral transmission. Additionally, senior patients and those with underlying health conditions will benefit from not having to come into the office or health-care facility.

• ***Triage.*** Telemedicine can help you check in on your follow-up patients as well as screen patients who call with concerns. "One of the big things we're trying to determine is who really does need to come in [to the office]," Dr. Zimmer-Galler says. "You want to make sure you're not missing someone who's had a change in vision and then their visit is postponed."



Nikola Ragusa, MD

An external photo taken with an iPhone 8 to show the quality of the image you can get with a video visit.

• ***Lower overhead.*** Reducing costs during this time is important. Telemedicine requires only internet access. "One telemedicine visit costs a practice around $5, versus the typical overhead of anywhere from $50 to $75 per [office] visit," says Dr. Ragusa.

• ***General exams.*** Telemedicine is more difficult for certain subspecialties, such as retina and glaucoma, but for less subspecialty-oriented issues that involve the front of the eye or the eyelids, televisits with video can be as effective as in-person exams. Dr. Zimmer-Galler says that benign problems such as a chalazion, sty, red eye and subconjunctival hemorrhage can be anxiety-provoking for patients, but adds that, "Those are things where you really could do as good an examination with a video visit as you can in person. Video visits add an extra element that you miss out on in a phone conversation, just by being able to see the patient."

• ***Patients accept it.*** "They're delighted with it," Dr. Zimmer-Galler says. "They like being able to see their providers. Once providers are more comfortable with telemedicine, I think they'll see that it's really not a bad way to go. More and more patients are going to expect these types of services, so I think we need to embrace it in ophthalmology once we get

past this emergency."

Dr. Ragusa adds that patients also enjoy being able to communicate with their doctor from their homes. "When I sign patients up, it's not like I'm getting non-stop calls," he says. "They just like the comfort of knowing they can reach me, and I like having the comfort of knowing I can reach them and check in, especially during this time, since many of my patients are elderly." Dr. Ragusa says he had a televisit with an elderly, febrile patient whom he suspected of having COVID-19. "She wasn't sure if she should go to the ER," he says, "but by the end of our call, she had significant shortness of breath and we decided she should go." She ended up testing positive for COVID-19.

Temporary CMS Changes

The temporary changes made by the Centers for Medicare and Medicaid Services have relaxed several telemedicine regulations. These changes will make telemedicine easier to incorporate and use on short notice and during the COVID-19 emergency. "We can do much more from a billing standpoint with the CMS updates for telemedicine visits at home," says Dr. Zimmer-Galler. "Prior to this emergency, CMS wasn't allowing any telemedicine video visits with patients at home. That's one of the big changes and what makes telemedicine more viable for ophthalmologists."

She adds that, "in order to meet all of the billing requirements in ophthalmology, you have to look carefully at the elements needed for the exam. You also still need to do your documentation in your electronic record and obtain patient consent."

Here are some important changes to health-care laws:

• ***1135 Waiver.*** According to the CMS, under the 1135 waiver, Medicare will pay for office, hospital and other visits through telehealth.[3] Clinicians can bill immediately for dates of services starting March 6, 2020.

• ***HIPAA requirements have been waived.*** CMS has waived HIPAA and site-of-service requirements. No penalties will be imposed. This means doctors and patients can communicate over platforms such as Facebook Messenger, FaceTime, Zoom, Skype and Google Hangouts. Be sure to document your virtual visit carefully. (*See sidebar on page 24.*) Though these options are available, experts recommend that if you're looking to stay with telemedicine after the pandemic, it's a good idea to use a HIPAA-compliant telemedicine service from the get-go. "What we don't want is for providers to get so caught up in all of this that they then forget about the HIPAA requirements once the waiver expires,"

Documentation and Coding for Telemedicine

Integrating telemedicine during the pandemic will boost your revenue, but if you don't follow the proper protocols, you may end up wrestling with payors. In your CPT book, telemedicine codes are identified by an asterisk. Here are some tips to keep in mind:

- **Use E/M codes.** CMS reimbursement requires E/M codes, but many ophthalmologists are used to using only the Eye Codes. Real-time audio and video telemedicine visits are covered under the E/M codes 99201-99215. This doesn't apply to tech code 99211 or Eye visit codes. The Academy's documentation requirements for outpatient evaluation and management visits can be downloaded at aao.org/practice-management/news-detail/coding-phone-calls-internet-telehealth-consult. Be sure to check this webpage frequently for updates and for a full list of all the codes and modifiers you'll need.

Here are the outpatient E/M codes with documentation requirement checklists:

  - 99202 for new patients.
  - 99212 or 99213 for an established patient.

- **POS and Modifiers.** For telemedicine, use POS 02. As of April 3, 2020, CMS says that place of service (POS) should be 11 for phone calls and e-visits; G-codes, and 99201-99215 via virtual telemedicine for Medicare Part B patients. Modifier -95 should be appended to 99201-99215, but not to phone calls, e-visits or G-codes. (Modifier -95 requires real-time audio and video.)
- **Document patient consent.** Patient consent must be documented for each real-time audio/video encounter.
- **Document the length of the encounter.** Be sure to record the start and end time of each virtual visit to justify coding.
- **Take a medical history.** Additionally, take history of present illness updates and update the patient's medical record.

A small, but important tip to remember:

- **Look presentable.** "You're going to be the focus of what the patient's looking at, so make sure you look presentable and smile—you're on camera," says Nikola Ragusa, MD, FACS, an ophthalmologist at the Bronx Eye Center in New York. "You need to make sure you're presenting yourself well so the patient is able to focus on the information you're giving him or her. Also, make sure you're enunciating clearly."

-CL

says Dr. Zimmer-Galler. "Take up telemedicine now as if these relaxed regulations weren't in place."

- ***State parity laws.*** Telehealth services will be billed under the Physician Fee Schedule at the same rates as in-person services. Medicare coinsurance and deductibles will still apply for these services. Health-care providers may reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.[4]
- ***Consulting across state lines.*** Licensure requirements have also been relaxed to allow telemedicine to span state lines.
- ***Accelerated and advance payments for Medicare.*** CMS also announced in late March an expansion of the accelerated and advance payments program for providers and suppliers during the pandemic. This means that practices can apply to their Medicare Administrative Contractors to receive their entire Medicare payment amount for a three-month period, calculated on historical payments. MACs will issue payment within seven days.[5]

Telemedicine and Patients

Today, almost all phones and tablets have high-quality cameras, which come in handy for virtual visits and examinations, but one concern some physicians have is the ability of their elderly patients to use technology for virtual visits. Dr. Ragusa finds that for the most part, the elderly aren't technologically inept. "They're used to FaceTiming with their grandchildren," he points out. "Many elderly patients are perfectly capable of using telemedicine."

Nevertheless, it's a good idea to have your patient's phone number on hand. "If you try to connect by video visit, but you're not able to make the video visit work, you want to make sure you have the patient's phone number so you can easily convert it to a phone visit," says Dr. Zimmer-Galler. "Add Modifier -52 for a phone visit, and you can still get reimbursed for that."

Dr. Zimmer-Galler says it's important to choose a telemedicine service that's easy for patients to use. Likewise, you want to start out with patients who are likely candidates for telemedicine. (Those who still use flip phones might not be the best choices when you're still learning how to navigate the new system.) Many integrated EHRs have telemedicine platforms built into them—but while that's easy on the provider's side, it's not so simple for many patients. "From the patient's side, you have to first be activated on the patient portal, then go through various steps to test your device to make sure it works," she says.

Additionally, it's important to let patients know upfront that a telemedicine visit is a bit different from an in-person visit, but a visit nonetheless. "I can't do all the things I would normally do," Dr. Zimmer-Galler says, "but you want patients to understand and not be surprised that they're getting a bill from a virtual visit. In medicine, we've traditionally provided so many services by phone for free that patients are used to us doing them for free. When you start billing for something that's outside the office, you just want patients to realize that it's really a visit."

The Virtual Eye Exam

To assist with the exam, Dr. Ragusa says you may be able to coordinate the virtual visit with a person the patient feels comfortable with—such as a home-health aid or a spouse. The other person may help position the camera for viewing external structures, lifting eyelids or visualizing a red reflex.[6]

"It takes practice," Dr. Ragusa says.

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Injector	RayOne	UltraSert	iTec
Nd:YAG rate	1.7%[1]	7.47%[7]	3.75%[7]
Miyata grade (Glistenings)	0[2] (None)	3[8] (High)	0[12] (None)
ABBE value	56[2]	37[9]	55[9]
Refractive index	1.46[3]	1.55[10]	1.47[12]
Mean decentration	0.08 mm[4]	0.78 mm[11]	0.27 mm[13]
Nozzle diameter	1.65 mm[5]	2.08 mm[5]	1.86 mm[5]
Injector steps	2[6]	3[10]	4[12]

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[1]Mathew RG et al. Opthalmic Surg Lasers Imaging. 2010; 41(6): 651-55, [2]Rayner. Data on file. White paper, [3]Ferreira T et al. J of Refract Surg. 2019; 35(7): 418-25, [4]Bhogal-Bhamra GK et al. J of Refract Surg. 2019; 35(1): 48-53, [5]Nanavaty M et al. J of Refract Surg. 2017; 43(4): 558-63, [6]www.rayner.com, [7]Cullin F et al. Acta Ophthalmol. 2014; 92(2): 179-83, [8]Werner L. J of Refract Surg. 2010; 36(8): 1398-1420, [9]Zhao H et al. Br J Ophthalmol. 2007; 91(9): 1225-29, [10]www.myalcon.com, [11]Humbert G et al. Fr J Opthalmol. 2013; 36(4); 352-61, [12]jnjvisionpro.com, [13]Baumeister M et al. J of Refract Surg. 2009; 35(6): 1006-12

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"Doing an eye exam with a smartphone instead of a slit lamp is strange. You'll probably fumble through the first few patients until you get an idea of how to do it. You have to be creative when checking vision, visual fields and obtaining pressure."

The AAO recommends performing the external exam, pupils, eye movements and alignment and pen light anterior segment with a camera. Patient selfie images for documentation can also be shared, but aren't separately billable. The AAO has printable instructions available online for patients testing their vision at home. Snellen charts for adults and children, as well as an Amsler grid, are available at aao.org/eye-health/tips-prevention/home-eye-test-children-adults.

For confrontation visual fields, Dr. Ragusa says he pulls back from the camera to demonstrate to the patient how to perform the test, so they can do it on themselves.

The biggest challenge by far is checking intraocular pressure. If patients are trained to use and have an iCare tonometer, at home, checking pressures is easy. If not, Dr. Ragusa asks patients to do rebound tonometry. "I ask if their eye feels soft like a grape, a little harder like a tomato or hard like an apple. Luckily, most patients say their eyes feel like grapes, which is about normal eye pressure. It's not a perfect method, but you have to get creative.

"[Remote eye exams are] problematic for patients with retinal issues complaining of increased floaters or decreased vision from something in the posterior pole," Dr. Ragusa admits. "They'll likely need a fundus exam in the office. But the beauty of telemedicine is that you're still able to triage them at home, offer them comfort and give patient education in these hard times."

Some Telehealth Options

Incorporating telemedicine into your practice—especially during this time—can help keep your practice afloat, minimize the risk of exposure for your patients and staff and allow you to reach vulnerable patient populations who can't make it to the office. Here are some telemedicine options:

• ***Modmed Telehealth*** is at the time of this writing, temporarily being offered at no charge, with all sign-up and utilization fees waived, to current and future users of Modernizing Medicine's electronic health records system, EMA. Modmed Telehealth features high-resolution, real-time audio/visual chat. Doctors and patients can virtually attend scheduled appointments with a new version of the PocketPatient app. The app is available for both iPhone (iOS12 and above) and Android (v. 7.0 and above). For information, visit modmed.com/telehealth.

• ***Doxy.me*** is a free telemedicine service with audio, video and text communication capabilities. The service is internet-based, with no software to download. It's compatible with Android and iOS and can be integrated with most EHRs or practice management software. Some of the features include a virtual waiting room, remote file sharing, image capture and prescription delivery through ImprimisRx's mail-order pharmacy. ImprimisRx's agreement with Doxy.me will provide all ImprimixRx ophthalmology, optometry and wellness practices with the clinic-level version of Doxy.me at no charge. Paid tiers offer additional security and encryption. The Professional tier is $35 per month, the Clinic tier is $50 per month, and the Basic tier is free. All tiers are HIPAA-compliant. For information, visit doxy.me.

• ***Pulse*** is a health-care startup telemedicine app designed specifically for private practices. The Pulse One app features HIPAA-compliant real-time audio/video chat and uses metadata to document patient consent, disclaimers and when the call took place, which is then compiled into a report for each visit. The developers say Pulse is designed to deploy in a few hours. For information, visit pulsett.com.

• ***Mend*** is a full-feature telemedicine suite with HIPAA-compliant audio and video aimed at increasing a practice's efficiency and profitability by reducing the number of missed appointments. Some features include SMS appointment reminders, online forms, patient self-scheduling, video and voice calling, survey and review options and automated workflow processes. Mend claims that its AI program can also predict no-shows and cancellations, "days and weeks before they happen." The program integrates with most EHR and practice management software. Monthly subscriptions per provider are $59; annual subscriptions, per provider per month, are $49. Custom quotes are also available. For information, visit mendfamily.com.

Though reaching for telemedicine at the current time may be motivated by panic about maintaining a semblance of normalcy during the maelstrom, physicians say that, in the calmer waters of the future, the habits practices develop now may carry forward. "I'm hopeful that once the emergency ends, we'll continue to be able to use telemedicine in a variety of ways," says Dr. Zimmer-Galler. REVIEW

1. Modernizing Medicine to launch telemedicine solution to provide real-time audio and video capabilities to help healthcare professionals care for patients. Modernizing Medicine. Press Release. March 16, 2020. https://www.modmed.com/press-release/video-telemedicine-solution/.
2. ImprimisRx announces exclusive agreement with Doxy.me to provide healthcare professionals with telemedicine services. Press Release. March 24, 2020. https://www.globenewswire.com/news-release/2020/03/24/2005411/0/en/ImprimisRx-Announces-Exclusive-Agreement-with-Doxy-me-to-Provide-Healthcare-Professionals-with-Telemedicine-Services.html.
3. Medicare telemedicine health care provider fact sheet. CMS. Accessed 30 March 2020. https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.
4. President Trump expands telehealth benefits for Medicare beneficiaries during covid-19 outbreak. CMS. Accessed 30 March 2020. https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak.
5. Fact sheet: Expansion of the accelerated and advance payments program for providers and suppliers during the covid-19 emergency. CMS.gov. Accessed 30 March 2020. https://www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf.
6. Coding for phone calls, internet and telehealth consultations. AAO. Accessed 7 April 2020. https://www.aao.org/practice-management/news-detail/coding-phone-calls-internet-telehealth-consult.

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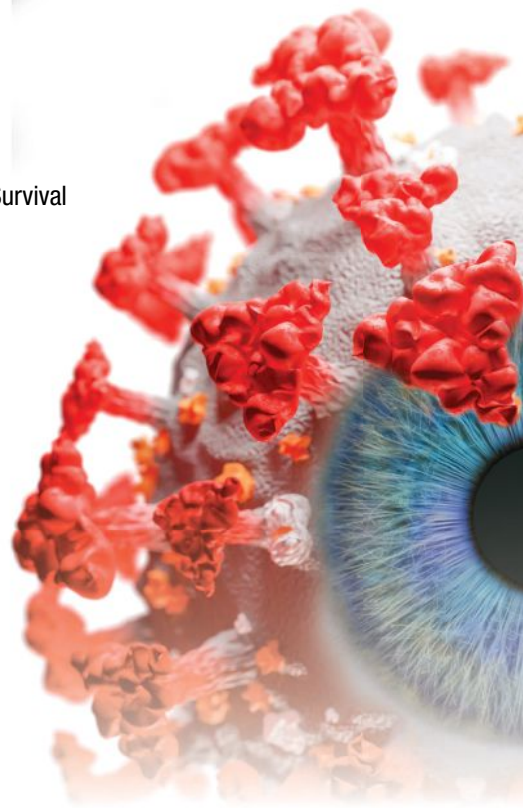

Finding a New Normal

Sean McKinney, Senior Editor

How general ophthalmologists shuttered by COVID-19 plan to reopen and adapt to an enduring public disease.

CMS announces a gaping cut in cataract reimbursements, eating a hole in the part of your net revenue that you had earmarked for retirement. Your partner goes out sick for six months. A tornado destroys the only office where you practice—fortunately, when no one is there. All of these setbacks can seem like more than you can handle. But none compare to the COVID-19 pandemic.

"I don't think any of us have ever envisioned a situation in which basically entire communities, nations and the world are very significantly shut down or constricted in activity all at the same time, or in short sequential time frames," says Minneapolis surgeon David Hardten, MD. "That's basically the situation we find ourselves in now. For anything else that happens to us in practice or in our professional or personal lives, there's always some sort of contingency plan that we can use to figure out a solution. But there's no contingency plan for this pandemic."

At least not yet. Cataract surgeons and comprehensive ophthalmologists venture into a brave new world this month, puzzling over how to recover from a month-long virtual shutdown caused by the virus. Here's how they're doing it.

Why Open Ophthalmology Now?

"Patients need ophthalmic care," says David W. Parke II, MD, explaining the rationale behind the decision to recommend reopening ophthalmology care after restricting scope of practice to emergent/urgent care and procedures for 30 days. The chief operating officer of the American Academy of Ophthalmology continues: "Much has been deferred because of COVID-19 for patient and ophthalmology office safety reasons. Some areas of the country are seeing decreases in new cases, and many in the public health community believe that careful loosening of economic lockdowns are prudent—on a local or state basis—so long as certain public health conditions are met."

Dr. Parke's call for opening ophthalmology came on April 17, one day after the White House released a plan for opening America that will be guided in large part by public health experts monitoring regional patterns of COVID-19. *(See "Reopening Ophthalmology and America, p. 30")*

Some cataract surgeons and comprehensive ophthalmologists, however, haven't been won over by the recent decisions to encourage the return of routine office visits and elective procedures. These besieged doctors are quick to point out that their op-

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portunity to increase patient flow will be controlled at highly-variable county or state levels, sometimes without their studied knowledge of the ever-changing numbers of open hospital beds, COVID-19 cases and symptoms and other factors that will need to be deemed acceptable to get ophthalmic care closer to normal.

"While it's helpful to have some further clarity on the road to slowly doing more work, I believe the pathway will continue to be tough to navigate, as the regional health-care COVID-19 impact will still leave a lot for each individual practice to figure out," says Dr. Hardten. "It will be based on our patient populations, the capacity of local hospitals, the patient demographics, the intensity of the eye-care needs of the practice and staff/provider challenges. Even though we have a strategy for inching forward as a practice, we're going to need to re-evaluate that strategy daily and make many changes in the next several months."

Marguerite McDonald, MD, FACS, a practitioner at OCLI Vision in the Long Island, New York, area, says, "Recent federal guidelines for the country's controlled re-opening have given all of us a glimmer of hope. But just a glimmer."

Peter Netland, MD, Vernah Scott Moyston Professor and ophthalmology department chair at the University of Virginia in Charlotte, says ophthalmology's sharp reduction in patient volume is "partly because we're receiving mandates to reduce patient care from states, other government agencies and medical societies, and partly because patients are electing to hold off on routine care until this settles down.

"Comprehensive ophthalmologists are losing their patient volume; so are subspecialty care doctors," Dr. Netland adds. "I'd say the average academic practice is probably losing two-thirds of its volume, in both clinics and the OR."

Reopening Ophthalmology and America

Recommendations to provide only emergent/urgent procedures and office-based care were released in an "essential practice guidance statement" by the American Academy of Ophthalmology on March 18, after the AAO agreed with every other major ophthalmology society on recommended procedures to respond to the COVID-19 pandemic. By April 15, according to an AAO membership survey conducted early in April, 95 percent of ophthalmic practices were seeing 25 percent or less of their pre-COVID-19 patient volume, and 81 percent were seeing 10 percent or less of their pre-COVID-19 surgical volume.

Within a matter of days, however, rays of hope splintered ophthalmology's dark outlook.

On April 16, the White House, under the advice of public health experts, released guidelines on "Opening Up America Again," permitting outpatient elective procedures and, eventually, inpatient elective procedures in areas that meet rigorous safety and COVID-19 management standards. These standards will be determined by local trajectories of cases and symptoms, testing and contact tracing capabilities, health-care system capacity and other factors. (*See* whitehouse.gov/openingamerica)

One day after the release of the White House guidelines, David W. Parke II, MD, AAO's chief executive officer, announced a revised recommendation by the academy that envisioned "more normal practice" in "local and regional areas . . . based on local and state governments, on public health authorities interpreting local patterns of disease, on testing availability, on institutional policies and ultimately on individual ophthalmologists."

Practices will be able to open according to the Phase One (elective outpatient procedures only) and Phase Two (elective outpatient and inpatient procedures) requirements of the White House under the direction of governors and, potentially, county-level officials.

Below is a link to the COVID-19 Dashboard by the Center for Systems Science and Engineering, which tracks numbers of deaths, cases and patients tested. This data will be among the many factors considered in decisions made to manage the phases of these guidelines.

gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6

"No Guidelines for This"

"This continuing situation we find ourselves in obviously changes and reduces our workload and increases our concern when we're in the environment, considering our risk of bringing an infection back to our loved ones when we go home," says Dr. Hardten. "You're counting on the people around you to be vigilant and to protect the patients and you. There are no guidelines for this. It's almost like we need to develop new eye-care triage guidelines in short order to replace those eye-care guidelines based on more than 30 years of comparisons and discussions about when it's right to remove a cataract, or when someone is healthy enough for anesthesia and many other considerations. We're basing our decisions on a new normal in terms of patient health, accessibility to care and our ability to provide that care, and we've only done it for the past few weeks."

Dr. Hardten notes that decisions may not be robust—or well thought out. "That's what really concerns me," he says. "Layered on top of our normal decision-making is our evaluation of whether patients' issues are significant enough to bring them out into this potentially lethal environment to give them care. Should we expose these patients to staff in the office, or expose our staff to these patients, many of

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whom are at risk for [complications from] COVID-19? Or should we wait another day, week, month or 18 months for a new vaccine or unil when the vast majority of people in our community are immune to this virus? We're faced with new questions with each patient on any given day, and we have to help patients make those decisions."

Dr. Hardten identifies some classic scenarios:

• The 62-year-old woman with borderline glaucoma. "You changed her medication three months ago because her IOP was high," he says. "How long should you wait before bringing her back?"

• A 53-year-old man who yanks on the cord of a gasoline-powered leaf blower and the cord slips from his grip and whips across his eye, rupturing the globe and leaving his lens hanging out. "You should probably have him come in, even though he'll be at great risk because the virus is everywhere," says Dr. Hardten.

• A patient has a pressure of 29 mmHg and a cup-to-disc ratio of 0.9 and is on maximal medicines. "Does he need that tube shunt now or do you wait?" asks Dr. Hardten. "And how long do you wait?"

• A patient is driving back and forth to work every day with 20/200 bilateral cataracts. "She shouldn't be driving now," he observes. "What would happen if you waited a month, two months or longer to bring her in? Is that really the best choice for her?"

He notes many gray areas lie between the obvious choices. "We're prioritizing patient care in a way we've never had to prioritize it," he says. "My advice is to think through these unusual scenarios and the questions you're facing and adapt them to what will work for you. Because there's no such thing as unusual anymore."

Like many other comprehensive ophthalmologists, David Hardten, MD, of Minneapolis, has recently spent more time talking to surgical candidates on the phone than doing anything else. "It's uncompensated time, but it can't be delegated," he says. "Some pretty complicated decisions have to be made."

Sticking by Your Staff

All ophthalmologists interviewed for this article agree: This is no time to deconstruct your most important infrastructure. Dr. Hardten and the others believe the real bricks and mortar of your practice are the people who make it hum. Without them, the patients won't come.

"The work force we have is extremely well-trained and tuned into our business needs, so we want to keep them thriving throughout this ordeal," he says. "We want them to be ready, willing and safe to come back to work when work is available. We've needed to furlough employees, but we're working very hard to keep engaged with them in different ways. Their hearts are in the work that they do. That's their passion."

Alan Aker, MD, who runs Aker-Kasten Eye Center with his wife, Ann Kasten, MD, in Boca Raton, Florida, couldn't agree more. He says their staff makes up a pillar of the practice that connects with the other pillar, loyal patients. Together, those two pillars keep the practice upright when threatened by the sudden ground shifts of negative change. Even when he was forced to close their clinic and ambulatory surgery center on March 13, Dr. Aker says he and Dr. Kasten committed to paying staff their salaries for 10 weeks.

"We value our staff and we're thankful we had the ability to con-

tinue to pay them," says Dr. Aker. "We explained we were concerned about the health of our elderly patients and all of our staff. Our instructions were for them to stay home as much as possible. A low number of our staff members came to work to contact patients whose surgery and clinic appointments were being canceled."

Dr. Netland also seeks to protect his investment in people. He describes how his group has changed the way staff members work together. "We're separating staff into smaller groups," he explains. "We don't want a situation in which everyone is rotating all the time with different people, because if one person turns out to be COVID-positive, we might have to quarantine a larger group of people."

Bryan S. Lee, MD, JD, in private practice at Altos Eye Physicians in Los Altos, California, and an adjunct clinical assistant professor of ophthalmology at Stanford University, operates the Peninsula Eye Surgery Center with 14 other surgeons. Because Northern California was one of the first areas in the country to order sheltering-in-place, he and the others stopped performing surgeries in mid-March.

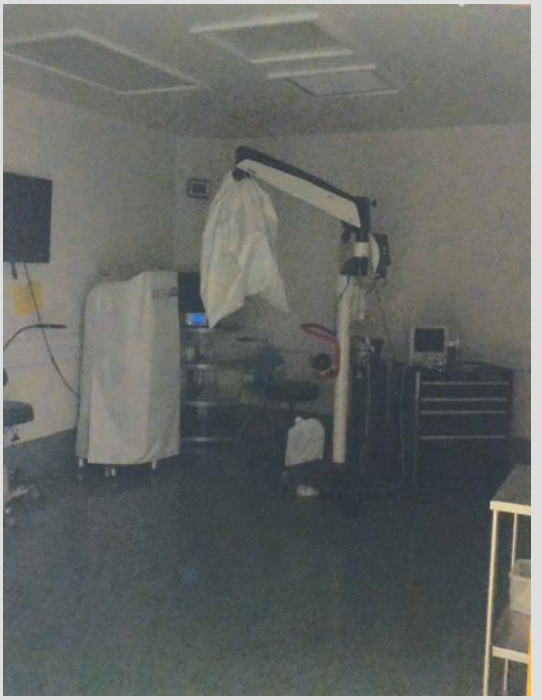
"My partners and I are doing our best to take care of our staff in the meantime," says Dr. Lee. "They are so important to us, and I try to keep up to date on how they're coping. I think the key is doing your best to take care of your employees. There's no way to move forward without them. Take advantage of every program that allows you to conserve cash, such as deferring mortgage payments if your bank allows you to do so without penalty. Other than that, all we can do is try to stay safe, because nothing else matters if you're not healthy."

Economic Reality

The challenge of taking care of staff in these times, of course, is that your budget won't support the expense if your revenue stream is running dry. Two loan programs offered under the $2.2 trillion Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that were designed to provide loans to private practices with fewer than 500 employees—the Paycheck Protection Program and Economic Injury Disaster Loan—ran out of funds two weeks after they were launched on April 4.

As *Review* was being printed, $310 billion in additional PPP funds and $60 billion in more EIDL funds were included in a $484 billion coronavirus relief package that was being signed into law. Although the PPP and EIDL target the payroll expenses of small businesses, the PPP has been the most coveted because eligible recipients may

ASCRS Goes Virtual: Turning the Lights Back on



ASCRS is trying to "turn on the lights" for ophthalmology with it's first-ever virtual meeting this month.

After the COVID-19 pandemic forced the American Society of Cataract and Refractive Surgery to cancel it's yearly meeting in Boston this month, the society forged ahead online with programmatic ingenuity, posting its usual assortment of clinical papers, posters and films, as well as two days of streaming education that will be available to meeting registrants for a year.

"ASCRS is working with its physician leaders, industry and the American Academy of Ophthalmology to make sure its members are as prepared as possible for reopening during this challenging time," says Steve Speares, ASCRS Executive Director. "Our 'Turning the Lights Back On' web portal will address contingencies as they arise and provide vetted solutions based on leading expert opinion. With no firm understanding yet of the general public's willingness to re-engage once restrictions have been lifted, nor the potential impact of future actions should infection rates show signs of increasing during the next year, ophthalmic associations will need to remain fluid in their planning. ASCRS' strength has always derived from its members' willingness to share their experiences and to educate one another, and ASCRS will work to provide practical guidance based on the approaches used and shared by its members."

Speares adds: "ASCRS recognizes that a reopening date does not mean a return to business as usual, and that special allowances will need to be made for staff and patient concerns as the restrictions begin to loosen." Former FDA Commissioner Scott Gottlieb, MD, will discuss COVID-19 and the roadmap to reopening as part of the annual ASCRS film festival. For a fee after the 2020 Annual ASCRS Meeting, yearlong access to the virtual meeting will be made available to those who don't register for the meeting.

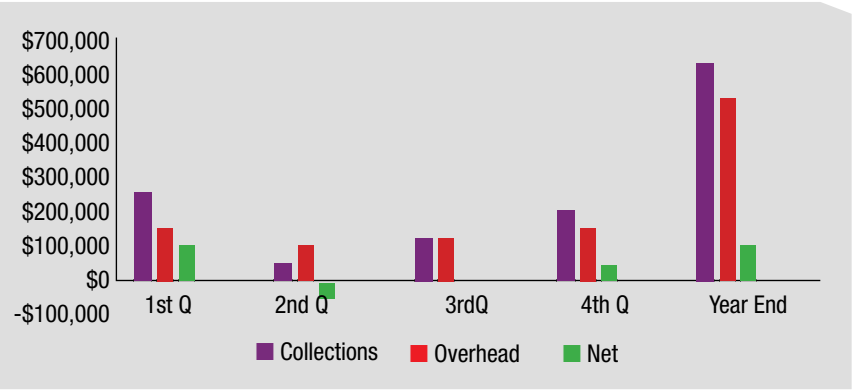
qualify for a loan of up to $10 million, determined by eight weeks of prior average payroll (capped at $100,000 per employee) plus an additional 25 percent of that amount for additional costs, such as utilities and rent. If you maintain your workforce, the U.S. Treasury Department will forgive the portion of the loan proceeds that are used to cover the first eight weeks of payroll and the 25 percent of additional expenses following loan origination.

Complete details on coronavirus relief options can be found at a user-friendly SBA website: sba.gov/funding-programs/loans/coronavirus-relief-options

Another source of relief is the expanded advanced and accelerated payments for Medicare Part A providers. Within seven days, an application to this program will provide you with up to 100 percent of your claims amount for the previous 180 days. The disadvantage of this program, though, is that the Centers for Medicare and Medicaid Services will begin recoupment of what it's paid to you by withholding payments on your future claims between 180 and 210 days, when the full amount owed must be repaid.

"This program will provide quick access to funds when you need the money," says Dr. Hardten, the only ophthalmologist interviewed who was using the program. "At some point, your income won't be coming in fast enough for you to earn net revenue while Medicare withholds every advanced and accelerated claim you've received during the the first 90 days of this program. Remember that the advance/accelerated claims will equal the normal amount of claims you were paid during the 180 days before the pandemic struck. So you'll have a gap in your income, because you won't be doing the same number of procedures you've already been paid for when you're filing new claims during those initial 90 days of the advance/accelerated program. To fill that gap, you have to establish an alternative, longer-term funding source or line of credit."

COVID-19's Potential Impact On a $1 Million Practice



As a service business with high fixed costs, any drop in revenue leverages profits sharply downward, according to management consultant John Pinto. "A practice normally collecting $1 million per year may generate just $625,000 in the 'Year of COVID-19,' " he says. "Even with efforts to reduce overhead, annual profits in this example fall from $400,000 to $100,000, showing only a comparatively modest impact. Many practices will experience a net loss for the year."

Challenging Your Budget

John Pinto, a national practice management expert with more than 40 years of experience helping practices manage cash flow and risk, says that the reduced revenues he expects because of the COVID-19 pandemic could be devastating to a practice that's relying only on income earned in 2020 to stay afloat.

"When you're in a business crisis like this, the crisis is only damaging to you to the extent that you do or don't have access to capital," says Pinto. "Let's look at a simple example. The doctor with a solo practice has a terrible skiing accident that puts him on his back for three months. If the practice doesn't have either insurance money or money in the bank to keep the practice alive for those three months, then the practice is going to go away. If the doctor has $2 million in the bank, then it doesn't matter if it's a three-month injury or a two-year injury. The practice is going to be able to come back. It's the same thing with the COVID-19 pandemic, which is the biggest business crisis most ophthalmologists will ever experience." (See "COVID-19's Potential Impact on a $1 Million Practice," above, which Pinto helped *Review* develop.)

Waiting for Rain

Most opthalmologists expect a crushing overflow of patients once the environment becomes safe enough for them to seek delayed cataract surgeries and other procedures.

"Once the crisis has passed, catching up with the backlog of patients could be a logistical challenge," says Dr. Netland. "If this goes on much longer, we'll have to reschedule 10,000 to 15,000 outpatient clinic visits, and we have a large number of 'elective surgery' cases that we need to reschedule. How we handle the recovery will depend on the final number. We're thinking about holding clinics on Saturdays and evenings, if necessary. Also, we'll need to add surgery time."

But until that day comes, it may be like awaiting for a long-delayed rainy season while the crops wither in the fields. Dr. McDonald, whose OCLI

(Continued on page 56)

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Overcoming Obstacles During Surgery (Part 2)

Christopher Kent, Senior Editor

In the second of a two-part series, surgeons share advice for dealing with problems that can arise during cataract surgery.

In Part 1 of this article (see the March 2020 issue of *Review*), surgeons offered their advice for dealing with uncooperative pupils; poor visualization through the cornea; no red reflex; and weak or missing zonular fibers. This month they address anterior capsule tears; posterior capsule tears; bleeding inside the eye; patient coughing; wound burns; and removing a very hard cataract.

Anterior Capsule Tears

"The key with capsule tears is to recognize that a tear has happened—and then not panic," says Nick Mamalis, MD, a professor of ophthalmology, director of ocular pathology and co-director of the Intermountain Ocular Research Center, part of the Moran Eye Center at the University of Utah in Salt Lake City. "Sometimes a tear happens without you seeing it, but you'll notice signs that something is amiss. If the chamber suddenly deepens or the nucleus refuses to rotate, that should tell you that something out of the ordinary is going on."

Daniel H. Chang, MD, a partner at Empire Eye and Laser Center in Bakersfield, California, agrees. "You should always maintain a high index of suspicion," he says. "If you do something during surgery and don't get the response that you expect, stop what you're doing and start looking for a problem. If a lens isn't chopping the way you think it should, or something isn't moving in the usual way, check to see if you have a tear in the bag. If you're using the phaco or I/A handpiece, maintain irrigation and don't come out of the eye. Maintain pressure inside the eye to prevent possible vitreal prolapse while you assess the situation and plan your approach."

Once you know a tear has occurred:

• ***Do NOT immediately pull out of the eye.*** "When you suspect there's a capsular tear, the first impulse will be to come off the foot pedal and take the phaco instrument out of the eye," Dr. Mamalis notes. "If you do that, the anterior chamber will shallow, the tear may extend and vitreous may come forward.

"The first thing we teach our residents is, if you suspect a capsular tear has occurred, stop doing the aspiration and phacoing and lighten up on the pedal, but do not come out of eye," he continues. "Instead, inject OVD through the paracentesis you've already made for your second instrument. Fill the anterior chamber with OVD, so that nothing shallows; then you can come out of the eye. That can help prevent a small capsular tear from becoming a large tear accompa-

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nied by vitreous loss.

"Once you have control of the anterior chamber, you can carefully assess the situation," he adds. "Check to see if there's a sign of a capsular tear or vitreous coming forward."

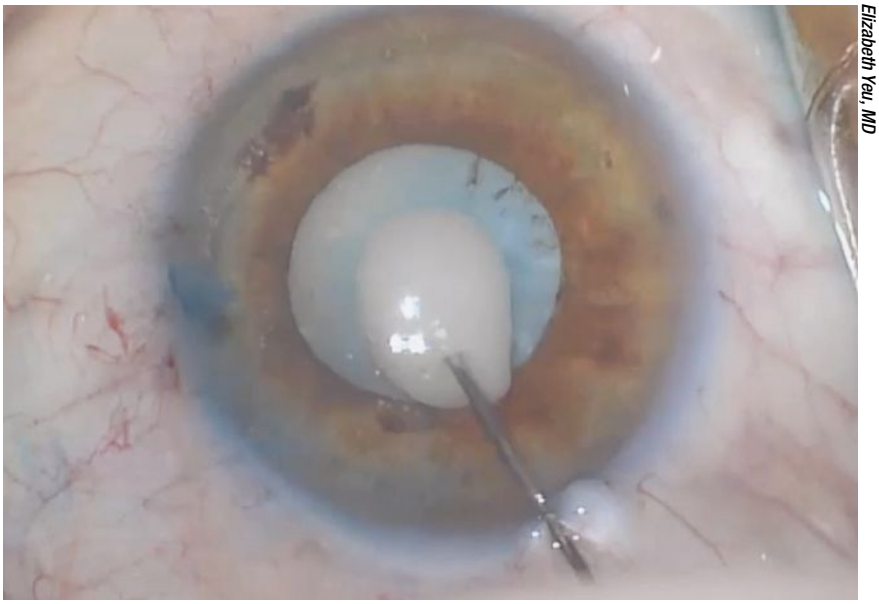
• ***Lower the infusion pressure.*** "Most surgeons will lower the infusion pressure if a radial tear is discovered," says Richard Mackool, MD, medical director at The Mackool Eye Institute and Laser Center in Astoria, New York, and senior attending surgeon at the Mt. Sinai New York Eye and Ear Infirmary and New York University Medical Center. "Having a lower pressure puts less stress on the posterior capsule, thereby making it less likely that the radial tear will extend into the posterior capsule."

• ***Don't stress the part of the bag with the tear.*** "Don't push nuclear pieces into that area," says Dr. Mamalis. "And as you're stripping cortex, strip it in the direction of the anterior capsular tear. Pulling away from it can cause it to extend."

"Do all subsequent nuclear divisions 90 degrees away from the location of the radial tear," adds Dr. Mackool. "Doing nuclear division 180 degrees away could actually cause the tear to widen."

Dr. Chang advises that when cleaning out the bag in the presence of a tear, do the torn section last. "When you're removing pieces of the cortex, try to pull toward the center and toward the direction of the tear, so you can minimize forces that may extend the tear," he says. "I take my time, and I usually leave the area with the tear for the last part of the I/A."

• ***Make sure you divide the nucleus in a manner that won't require separating the segments widely to achieve complete division.*** "This means that you have to sculpt the nucleus deeply," Dr. Mackool explains. "That's because the deeper you sculpt, the easier it is to separate and divide that region of the nucleus. If there's less resistance to the separation, getting the halves apart won't put as much stress on the tear."



Elizabeth Yeu, MD

White cataracts are under pressure and may need to be decompressed before proceeding with the capsulorhexis. The capsule may be fibrotic and/or fragile.

• ***Consider implanting a one-piece lens.*** "If I have an anterior capsular tear, I definitely prefer a one-piece lens to a three-piece lens because of the compression needed to get the haptics in the bag," says Dr. Chang. "One-piece lenses go in fairly compactly and open up slowly, so you can position the lens in the direction you'd like it to unfold. Also, one-piece lenses don't exert as much directional force as three-piece lenses do."

• ***Make sure the lens will unfold without stressing the tear.*** "When I insert the lens, I place it so that a haptic doesn't unfold into and extend the tear. I also prefer not to have the distal portion of the haptic span the area of the tear," says Dr. Chang. "If the anterior capsular tear hasn't already extended posteriorly, the force of the haptics shouldn't cause the tear to open any further."

Posterior Capsule Tears

"There are plenty of ways you can cause a posterior tear," notes Dr. Chang. "Regardless, if the hole or tear is relatively small and central, you may be able to convert it to a posterior capsulorhexis, which can stabilize the opening and allow for a posterior chamber IOL. After the eye heals, it's as if the patient has already had a YAG."

Dr. Mamalis concurs. "If you have the nucleus out of the eye and you're doing some cortical cleanup and you cause a small posterior capsule tear, you can often go ahead and put some OVD behind the tear, push the vitreous face away and carefully use your capsulotomy forceps to make a small round posterior capsulotomy in this area," he says. "However, this will only work if you don't have vitreous coming forward and it's just a small posterior tear."

If an anterior tear has extended into the posterior capsule, the advice is similar to that for an anterior tear.

"If the tear extends into the posterior capsule, the first thing to do is resist the impulse to remove the phaco or I/A handpiece from the eye," says Dr. Mackool. "If you do so and the posterior capsule bulges forward because of low IOP, that will increase the

Using a Snare to Divide the Nucleus

One tool that surgeons often rely on when faced with a very hard cataract is a snare, such as the MiLoop (Zeiss). This device lets the surgeon slip a loop around the hard nucleus and divide it by tightening the loop, slicing through the dense tissue.

Daniel H. Chang, MD, a partner at Empire Eye and Laser Center in Bakersfield, California, notes that using a snare to break up a hard nucleus can work better with a few simple strategies. "First, when you chop the nucleus, the lens tends to tilt forward because of the way the loop closes," he says. "I like to put a second instrument in my paracentesis to hold the lens back so it doesn't tilt too much while I chop. Be careful not to tear the rhexis during this process."

Richard Mackool, MD, medical director at The Mackool Eye Institute and Laser Center in Astoria, New York, agrees. "When using the currently available snares the nucleus tends to tilt upward during nucleus cleavage," he explains. "This can stress the zonular fibers significantly, so this should be done as a bimanual procedure. That can require significant dexterity."

Dr. Chang notes that he doesn't simply constrict the loop in one continuous motion. "While stabilizing the lens with a second instrument, I kind of jiggle the loop by constricting, then releasing, then constricting it," he explains. "This creates more of a sawing than chopping motion; it cuts through the lens with less bulk movement and displacement."

Dr. Chang says it's also important to realize that once you've engaged the loop around the hard lens, it's difficult to go back. "In most steps during cataract surgery, you can always pull out of the eye, but when you use a snare to cut the lens, you're hooked until you get that lens chopped," he notes. "There's no bail-out. You have to keep going and maintain good stabilization so you don't do something you don't want to do.

"Surgeons should get some training before using a snare in surgery," he adds.

Nick Mamalis, MD, a professor of ophthalmology at the University of Utah in Salt Lake City, agrees. "It might be worth sitting down with someone who's used this multiple times and have that surgeon walk you through your first few cases," he suggests. "You want to be very careful that the loop goes completely under the nucleus and isn't caught on anything before you pull in. If you don't have the loop completely under the capsule—and these eyes tend to have poor visualization—you may slip it in front of the capsule and go around to the zonules. Then when you pull it through, you end up making a mess of the whole lens-capsular bag and the zonules. Trypan blue can help by making it easier to see the edge of the capsule, so the loop goes where you want it to go."

—CK

risk of the tear extending and the vitreous coming forward. So stay in the eye with the phaco or I/A handpiece and the foot pedal in position one, which is infusion. Then, with your left hand, inject dispersive viscoelastic right against—and even through—the posterior capsule opening."

Dr. Mackool points out that doing this requires holding the syringe in one hand and using your thumb to depress the plunger while you hold the phaco or I/A tip in the correct spot with the other hand. "That maneuver needs to be practiced a little bit when you're not under pressure to do it perfectly," he says. "If you only do it when you discover you have a posterior capsule opening, you may never get good at it. So, I encourage surgeons to practice this at the end of I/A in a routine case, before injecting the IOL. Inject OVD through the sideport using your nondominant hand, in the manner I've just described. Do that regularly until you become facile at it. Then, when you really need to do it to prevent a problem, you can."

Norfolk, Virginia's Elizabeth Yeu, MD, an assistant professor in the department of ophthalmology at Eastern Virginia Medical School and medical director of the Virginia Surgery Center, adds that if a posterior tear necessitates placing a three-piece lens in the sulcus, she recommends using optic capture, with the haptics in the sulcus and the optic in the bag. "If I have a well-centered, 4.5- to 5-mm capsulorhexis, I'd use an optic capture," she says. "This is better than simply placing the lens in the sulcus. With optic capture, the lens power calculation remains the same, and you've done a great service for the patient because the lens will always remain centered. It eliminates any concern about recurrent iritis or UGH syndrome from the posterior chaffing of the iris or ciliary body. Also, if you just passively place a three-piece lens into the sulcus, decentration can definitely occur."

Dr. Yeu reiterates that it's important to prevent the chamber from shallowing if you have a posterior capsule tear. "If the chamber shallows in that situation," she says, "the vitreous will prolapse and come forward."

Bleeding Inside the Eye

"During intraocular anterior-segment surgery, bleeding that's problematic is virtually always from the iris root," says Dr. Mackool. "Bleeding from the iris itself, should it occur, is always minor. But the iris root has some large vessels, and they can really bleed.

"The treatment for that is to inject dispersive OVD right into the angle," he continues. "The OVD will contain the blood in that area. Then stop and wait five or 10 minutes. The blood remaining at the traumatized site will clot, and the bleeding will stop. Then inject more OVD and visco-express the blood from the eye, beginning near the clot."

Dr. Mamalis says that if he encounters bleeding he often uses a high-mo-

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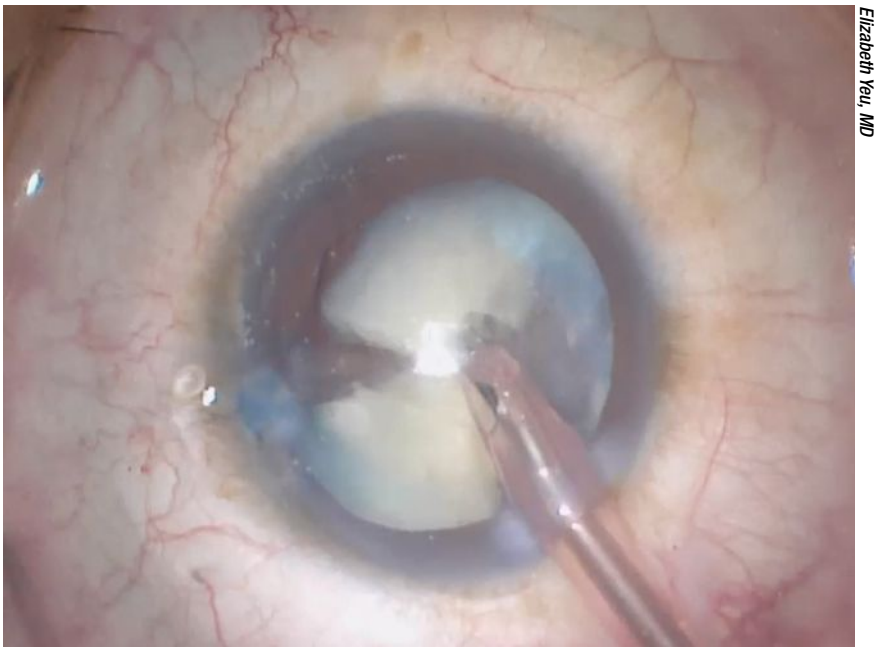
lecular-weight, cohesive OVD to try to tamponade it. "It's very uncommon to have bleeding that can't be controlled in this way," he notes. "Later, be sure to keep the eye well-pressurized when removing your instruments, so the bleeding doesn't resume."

Dr. Chang says that he helps prevent choroidal hemorrhaging by making sure that the head of the bed is elevated so the operative eye is the highest part of the body. "My patients never lie completely flat," he says. "Most of the time they're at least 10 or 15 degrees inclined, especially if the patient has a barrel chest or big abdomen. This minimizes the chance of posterior pressure and helps prevent choroidal issues."

"If you try to soldier on and ignore anything more than a tiny amount of bleeding, you're asking for big trouble," Dr. Mackool adds. "If you can't see what you're doing, you're very likely to traumatize other areas."



Elizabeth Yeu, MD

Nuclear densities of white cataracts differ from eye to eye. Some are brittle, crumbly and easy to crack (shown above). Traumatic cataracts and those in young eyes can be soft. Others, such as hypermature cataracts, may be thick and leathery.

The Patient is Coughing

Dr. Chang notes that patient coughing during the surgery can sometimes become a problem. "A little coughing during surgery isn't unusual," he says. "Sometimes patients choke on their own saliva, but they usually clear after a few coughs. However, every once in a while—especially with smokers—patients continue to cough and begin to valsalva, thus increasing pressure to the face and orbits.

"If the patient coughs against a soft eye, there's a chance they'll damage their choroidal circulation and bleed," he continues. "Therefore, when the patient coughs, the key is to maintain the intraocular pressure. How you do that will depend on where you are in the surgery, but the simplest way is to inject viscoelastic into the eye until you've reached at least physiologic pressure. Most surgeons' instinctive reaction is to pull out and let the patient cough. However it's important to stay in the eye and maintain pressure, because if you do pull out and let the patient cough for a while, the eye may not be in the same condition when they finish coughing. So either I pull out of the eye and inject viscoelastic, or I stay in the eye and maintain irrigation and pressure.

"The trickiest situation is if the patient coughs during the phacoemulsification step," Dr. Chang adds. "In that situation I try not to pull out of the eye; I set the handpiece on continuous irrigation so there's less likely to be any accidental damage. The primary goal is to maintain pressure in the eye until the coughing resolves."

Wound Burns

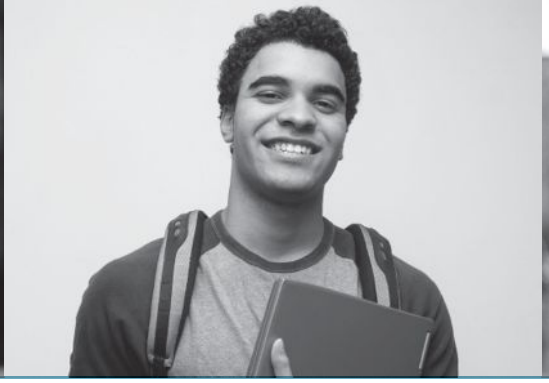
"A wound burn is a serious complication," says Dr. Mamalis. "It can happen in a matter of seconds if the circulation of BSS around the phaco tip is blocked. To prevent this, don't go directly to ultrasound when you first insert the phaco tip. Instead, irrigate a little bit to make sure that cohesive OVD isn't plugging the area around the tip. You should see the OVD being a little disturbed, indicating that flow is occurring. Once you're sure you have adequate irrigation and aspiration going on around the tip and sleeve, then go to phaco.

"Also, make sure the phaco tip and sleeve are properly sized to fit through the smaller wounds we're making today," he adds. "If the phaco handpiece and sleeve fit too tightly, you can get disruption of the flow of the BSS underneath the sleeve and around the phaco tip, resulting in a wound burn."

Removing a Hard Nucleus

"The key to dealing with hard lenses is patience," says Dr. Mackool. "Getting the nucleus out without causing any harm takes time. The very hard ones—the red or black ones—will give any surgeon fits. You have to be mentally prepared to fight that battle for several minutes.

"The hard part with a dense nucleus is disassembling it," he continues.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"You typically have to use some variant of the divide-and-conquer method. Once you've divided a hard lens in half you can usually chop each half into quarters, but dividing it in half is the most difficult part of the case. You have to use high magnification and sculpt the center of the nucleus down to one millimeter or less of thickness near the center, and get it almost that thin out toward the periphery. That takes several minutes."

With a hard nucleus, Dr. Mamalis says he likes to use a crater-and-chop technique. "Abhay Vasavada, MD, in Ahmedabad, India, has developed a nice technique in which you try to groove as much as you can in the center; then try to chop partially; then move a little bit deeper and chop again," Dr. Mamalis says. "The key thing is that you have to do multiple chops. You may want to break the hard nucleus into six or eight pieces."

Several surgeons have noted that a hard nucleus sometimes has a very leathery posterior plate. "You try to crack the plate, but instead of cracking, it bends as if it's a piece of shoe leather," Dr. Mamalis explains. "That can be very difficult to manage. You have to try to chip away at the nucleus anterior to that and save the posterior plate for the end. You may try to lift the lens up out of the capsular bag, but manipulating it can sometimes cause capsular tears."

Surgeons offer these additional pearls for removing a hard nucleus:

• ***Determine why the cataract is so mature.*** "Is it just because the patient decided not to seek care? Did the patient have a lot of intravitreal injections that sped up the formation of the cataract? Or did the patient have a vitrectomy in the past?" Dr. Yeu asks. "It's important to know this, because if the patient has a prior vitrectomy for example, the posterior capsule could be compromised."

• ***Make the rhexis larger.*** "If I know the cataract is very dense, I'll make my rhexis larger to provide more forgiveness and safety," says Dr. Chang. "I usually want it slightly over 5 mm, so it can overlap the lens 360 degrees, but if I'm dealing with a nuclear sclerosis that's 3+ or higher, I'd create a rhexis that approaches 6 mm to reduce the chance of tearing the anterior capsule if a large fragment wants to prolapse forward. An ounce of prevention is worth a pound of cure."

"It's crucial to protect the cornea during longer procedures."
–Richard Mackool, MD

• ***Don't try to use a femtosecond laser to break up the nucleus when it's very dense.*** "That simply won't work in this situation," Dr. Mackool explains. Dr. Yeu agrees. "Once the lens is rock hard and opaque," she says, "the laser often does a poor job and won't break up the lens nearly as well is it would in a softer nucleus."

• ***Use a larger phaco needle.*** "Instead of my usual 20-ga. needle, I'll go to a 19-ga.," says Dr. Chang. "Using a larger-bore needle makes nuclear disassembly and removal faster and more efficient, and it's safer for the patient. Of course, I use a slightly larger incision as appropriate.

"When an eye has a hard lens," he adds, "vision is generally poor, so any consequences of a larger incision, such as potential astigmatism induction, aren't as significant. These patients want the cataract out, and they want it out safely."

• ***Make sure the corneal endothelium remains coated with dispersive viscoelastic.*** "It's crucial to protect the cornea during longer procedures," notes Dr. Mackool. "When dealing with a dense nucleus you're running more fluid through the eye and using more ultrasound, so you have to keep the endothelium coated with dispersive viscoelastic to protect it from damage."

Dr. Mamalis notes that OVD also helps to keep the capsular bag taut. "Refilling the bag with OVD can help to keep it away from the hard nucleus you're trying to work with," he says. "That may prevent you from tearing the capsule or disrupting the zonules."

• ***Remember that the cataract may be under high internal pressure and require decompression.*** "A brunescent brown, black or red-tinted lens can have something resembling a white shell," notes Dr. Yeu. "In that situation the lens is under a lot of pressure, and needle decompression is going to be extremely important to help prevent the Argentinian flag sign. I use a 27-ga. needle and bevel down through my temporal wound (or through the paracentesis before the primary wound is created) after the eye is filled with viscoelastic. I enter right where I normally would with a cystotome. Then I draw back in order to get rid of some of the cortical material and some of the pressure that's built up inside the lens."

• ***Don't let the empty capsular bag flop around.*** "Hard lenses are large and the bag has been stretched over time," explains Dr. Yeu. "Once you remove the cortex the bag will be very floppy. Be aware of this and do everything you can to protect the posterior capsule. Use fluidics to minimize flapping and bouncing. One option is to refill the bag with viscoelastic. I normally use the Koch spatula to help manage this situation and hold the posterior capsule back." REVIEW

Dr. Chang is a consultant for Zeiss. Dr. Yeu is a consultant for Omeros. Drs. Mackool and Mamalis have no relevant financial ties to any product discussed.

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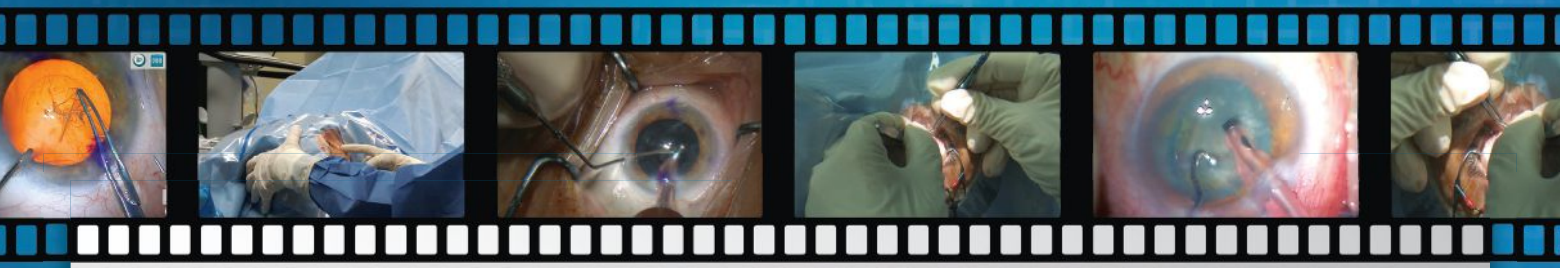

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Episode 53:
"Dense and Unusual Cataract in an Extremely Anxious Young Patient"

Surgical Video by:
Richard J. Mackool, MD

Video Overview:
Cataract-implant surgery was performed in a very highly myopic young woman with several disabilities, retinopathy of prematurity and an extremely dense cataract with an appearance that resembles spherophakia. Phacoemulsification, insertion of capsule retractors, a capsular tension ring and a 40 di-opter IOL were done in a necessarily deliberate manner. General anesthesia was avoided by the reas-suring support of the patient's mother who accompanied the patient into the operating room and maintained constant contact with her throughout the operation.

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Richard J. Mackool, MD

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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.

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

Learning Objective:

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

- demonstrate methods that reduce severe patient anxiety and distress during cataract surgery, and thereby reduce the risk of complications related to poor patient cooperation.

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Will Premium Options Still Have a Place?

Christopher Kent, Senior Editor

The pandemic-associated economic crunch could impact higher-cost options—but they might still be viable.

The COVID-19 pandemic is a double whammy for many ophthalmic products. Pandemic-based limits on "non-critical" visits and procedures have virtually eliminated the use of many cataract-surgery-related products. At the same time, the economic consequences of the pandemic could be devastating, making the more costly, optional offerings a hard sell after the crisis ends.

One group of items that could arguably be in trouble in this situation is premium intraocular lenses. Here, surgeons discuss the reasons lenses in this category may or may not be big sellers after this resolves; describe some new advanced-technology options that may rise to the top in an economically challenged future; and recap some basic guidelines for successfully offering these options under any circumstances.

The Effects of a Crisis

Samuel Lee, MD, a cornea and cataract surgeon at Sacramento Eye Consultants in California and a member of the clinical faculty at University of California Davis, believes the current crisis is likely to negatively impact the popularity of premium options. "People will have less disposable income," he points out. "Patients who might have budgeted $2,000 to $3,000 per eye for a premium lens upgrade may either reconsider and save that money for a rainy day or just cut their expenses because they lost money in the stock market or lost their job. Typically, the medical profession is fairly immune to recessions, but the first things to go are cosmetic and elective procedures."

On the other hand, some factors could actually result in increased interest in these options after the crisis:

• ***More people could end up wanting freedom from glasses and contact lenses.*** "The current crisis has generated a lot of fear of not having independence and freedom," notes Norfolk, Virginia's Elizabeth Yeu-Lin, MD, an assistant professor in the Department of Ophthalmology at Eastern Virginia Medical School and medical director of the Virginia Surgery Center. "I think that will really hit home in the next few months while we're restricted and stuck indoors, especially for individuals who rely heavily on glasses or contact lenses. As long as the economy is able to rebound after the crisis abates, that could lead to an uptick in LASIK and premium lenses."

• ***A pause in service availability leads to pent-up demand.*** Mark Packer, MD, president of Packer Re-

This article has no commercial sponsorship.

search Associates in Boulder, Colorado, sees reason to believe that rather than disappearing, demand for premium options may simply be in a holding pattern during the pandemic. "If you think about the rate at which cataract surgery is normally done, and the fact that it's at zero right now, there will be a lot of demand for it once the crisis is over," he says. "Meanwhile, the same number of people will still want to have freedom from glasses.

"I'm paying close attention to what's going on in China," he continues. "The largest hospital chain in the world is a Chinese group called Aier Hospitals. They closed down for about six weeks after the pandemic started, but then they gradually reopened. They're now doing a higher volume of all types of eye surgery than ever before, which appears to be about managing pent-up demand. Of course, they're using extreme personal protection protocols to minimize the risk of disease transmission while treating large numbers of patients, and I'm not sure if it would be possible to implement some of those protocols over here. People in the United States are more resistant to following orders from a doctor or the government. But I see their success as a hopeful sign. They're up and running, the demand is higher than ever, and they've been able to adapt to minimize the danger."

• ***Payment options could proliferate after the crisis abates.*** "How the economy will fare is hard to predict, but I think there will be a variety of mechanisms to help patients go ahead with those choices—people willing to make loans, and so forth," says Dr. Packer. "In a recovery period there are always people who are betting that something will work out in the long run, and to them it might be a perfect time to loan people money."

• ***The lenses are better than ever.*** "The latest generation of lenses has brought incremental but significant improvements that produce excellent vision and allow patients greater freedom than ever," notes Dr. Yeu. "The current trifocals are especially remarkable. We know from international data, supported by my own experience as an investigator in the FDA study, that trifocal lenses provide a high quality level of vision at multiple ranges. That translates to greater freedom for our patients."

Elizabeth Yeu-Lin, MD

Educating the patient about the advanced-technology options, and asking about the patient's goals and expectations, are key parts of successfully offering these options.

She also points out that the range of issues such as astigmatism that can be corrected keeps expanding. "Previously, we could only correct total corneal astigmatism of 1 D or more with monofocal toric lenses," she says. "Now, thanks to Bausch + Lomb's enVista lens, we can correct down to 0.8 D of corneal astigmatism. This is particularly fantastic for with-the-rule astigmatism patients, who generally possess less total WTR corneal astigmatism than what's observed in the anterior cornea."

Dr. Yeu adds that dysphotopsias are much less of an issue with the current lenses. "It's always a tradeoff between benefits and side effects," she notes. "Today, the overwhelming majority of patients are so pleased with the benefits afforded by the trifocal lenses and other current options that the mild to moderate amount of glare and halo they experience is seen as well worth the tradeoff. For example, the FDA trifocal study found that more than 99 percent of patients would have the same lens implanted again."

• ***Toric IOLs arguably can save patients money over the long run.*** "Studies have shown that a toric lens pays for itself pretty quickly over time because you don't need to purchase glasses to correct astigmatism," Dr. Packer points out. "That means there's a cost-effectiveness argument to be made for toric lenses.

"Unfortunately," he adds, "we can't make that same argument for presbyopia-correcting lenses, because reading glasses are cheap."

New Options on the Horizon

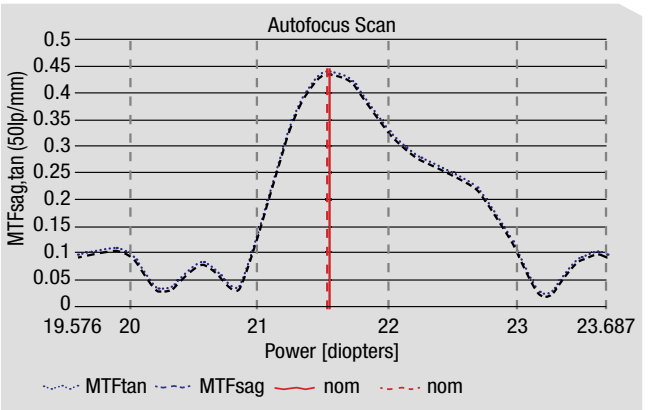
Often, new products emerge during a crisis that meet people's needs better than previous options. Dr. Packer notes that a recently developed new IOL design, referred to as enhanced monofocals, could end up becoming a major player in the marketplace, particularly if there's an economic crunch. (None have been approved in the United States to date.)

"These lenses simply increase the asphericity of a monofocal lens to provide more depth of focus," he explains. "Doing this gives you an additional

line of visual acuity at intermediate range, so if you're 20/20 at distance, you'd be around 20/25 or 20/30 at arm's length. This is a big deal because so many people use screens now, and screens are usually held at about arm's length. With the enhanced monofocal lens you won't need a pair of glasses to use your laptop or phone.

"This technology has several other important benefits," he continues. "First of all, because it's a monofocal, it doesn't cause the dysphotopsias associated with multifocal lenses and extended depth-of-focus lenses. These lenses have a single through-focus modulation transfer function peak in ISO bench testing, so they really are monofocals. On the MTF graph they just have an extended single peak, meaning they give you increased intermediate vision. *(See graphs, above.)* In contrast, the MTF graph for the Symfony lens has two peaks, so it's not classified as a monofocal.

Mono-EDoF ME4 (Xact, Santen)



ISO bench testing shows that the new "enhanced monofocal" lenses are true monofocals, with a broad but single focal peak, while still providing enhanced intermediate-range vision. As a result, they don't cause as many dysphotopsias as some multifocal and EDOF lenses proponents say.

"Patients with enhanced monofocals don't get halo or glare the way they might with a traditional diffractive or multifocal or EDOF lens," he continues. "I saw this first-hand when I was involved with the clinical trials of Santen's value-added monofocal in Europe. Among other things, we compared the dysphotopsias seen by these patients to dysphotopsias seen with other lenses. The Santen lens results were closer to a monofocal than to an EDOF or multifocal lens.

"A second important benefit is that ophthalmologists in Europe are adding just a small surcharge for this benefit," he continues. "They may add 100 or 200 Euros to the cost of a standard monofocal, instead of asking patients to pay thousands more for other advanced-technology lenses. These lenses don't cost any more to produce; any additional cost was in the research and development and any clinical trials, which are all one-time costs.

"Of course," he adds, "the profit margin isn't anything close to current premium lenses, but if you can do enough in volume, that extra 100 or 200 Euros starts to add up. That means patients get some of the advantages of the more expensive lenses at a very affordable cost. Plus, you don't have to deal with the much higher level of patient expectation that comes with higher cost." *(To learn more about these lenses, see "Dawn of the Monofocal Plus Era" on page 12.)*

If You're Just Starting Out

If you still haven't taken the plunge into offering advanced-technology lenses, and plan to start once the crisis has passed, some preparation is essential. "If you just start offering multifocals without any preparation, that's not a recipe for success," notes Dr. Lee.

Surgeons offer these tips:

• ***Don't offer these options unless you believe in them.*** Dr. Lee notes that most patients take their cue from the surgeon. "Sometimes patients will come in knowing what they want, but typically, patients will follow the surgeon's recommendation," he notes. "If the surgeon is hesitant about it, patients are less likely to go for it. If the surgeon is confident about the technology, patients will be much more receptive."

• ***Lower the cost of admission for your first couple of patients.*** "If you're just getting started with these implants, try to defer the surgeon fee for the refractive portion of the procedure," Dr. Lee suggests. "If you just tack on the cost of the lens implant, the patient is spending maybe $900 per eye; that's not a super high cost. Do that for one or two patients to get a feel for it. If you're charging $3,000 or $5,000 an eye on your first patient, and you choose the wrong patient and he ends up unhappy, it will leave a bad taste in your mouth."

• ***Ask about the patient's goals.*** "Typically, when patients come in for a cataract consultation, we'll have them watch a video and take a survey at home," says Dr. Lee. "That gives us an idea about their goals in terms of spectacle independence, and it tells us whether they have any interest in a refractive correction during the cataract procedure."

• ***Be careful about co-morbidities.*** "I won't place a light-splitting presbyopia-correcting lens—multifocal or EDOF—in a patient with any retinal problem that crosses the fovea, whether it's a subretinal elevation such as a foveal drusen or an epiretinal membrane," says Dr. Yeu. "If the eye has a peripheral, stable ERM, I might consider implanting an advanced-technology lens, but not if the ERM crosses the fovea.

"Ultimately," she says, "we should

always offer correction of corneal astigmatism with a monofocal option such as a toric lens implant, or femtosecond-laser astigmatic keratotomy, to patients with decent visual potential."

• ***Make sure you're getting accurate information from your measuring devices.*** "Learn to evaluate the keratometric values on placido topography and optical biometry to determine the quality of the images and the actual amount of astigmatism that needs to be corrected," advises Dr. Yeu. "That includes knowing how to distinguish between real astigmatism and astigmatism caused by a pathology such as dry-eye disease or anterior basement membrane dystrophy."

• ***Familiarize yourself with surgical techniques related to implanting these options.*** "Familiarize yourself with implanting and orienting toric lenses, and centering presbyopia-correcting lenses," says Dr. Yeu.

• ***Learn how to take care of the occasional unhappy patient.*** "There's a systematic process for deciphering whether a problem is the result of dry eye, refractive error or the lens itself," notes Dr. Yeu. "For example, if you've implanted a toric lens, it may simply need to be rotated. Of course, you have to be able to make whatever correction is necessary, or have a partner in the community who's willing to help you in that situation, such as another surgeon who's able to do laser vision enhancement as needed."

• ***Pay extra attention to dry eye, both before surgery and after.*** "I occasionally see patients coming in for a second opinion who are unhappy with their late-model presbyopia-correcting IOL," says Dr. Lee. "It often comes down to one foundational problem: dry eye. If there's a little dry eye present but you don't notice it during your initial preop testing, you may not get accurate measurements. The patient can end up with residual astigmatism and be walking around unhappy."

Just Diving In? Start With an Easy Patient

Samuel Lee, MD, a cornea and cataract surgeon at Sacramento Eye Consultants in California and a member of the clinical faculty at University of California Davis, notes that surgeons offering these high-tech options for the first time need to get off to a good start by avoiding patients who are more likely to be unhappy. "A less-complex patient is more likely to have an excellent outcome," he says. "A great outcome will make you enthusiastic about taking the time and effort to add this to your repertoire."

Elizabeth Yeu-Lin, MD, an assistant professor in the Department of Ophthalmology at Eastern Virginia Medical School and medical director of the Virginia Surgery Center, says she always takes the patient's personality into consideration. "One or two studies have demonstrated that there's a connection between a type-A personality and less satisfaction with advanced-technology lenses," she notes.[1,2] "So, I always talk to the patient about it. Sometimes you can get a sense that a patient isn't an ideal candidate, especially if they're extremely analytical and ask a lot of questions."

Dr. Lee agrees. "I'd choose a low-maintenance, spherical hyperope who has very consistent keratometry and biometry, as well as very little dry eye," he says. "Also, it's often the people who care the least about getting out of wearing glasses who have the happiest result. If someone is very adamant that this will be a failure if he has to wear any kind of glasses, you might not want to get involved with that set of expectations. I've also found that younger patients, in their 50s and 60s, tend to have better outcomes than patients in their 70s and 80s. So if you're interested in this, try to start out with a younger, low-maintenance, easygoing low hyperope, with no astigmatism and no dry eye. That will help you get an idea of whether you really want to adopt this technology."

—*CK*

Looking to the Future

"It's always hard to be offering what could be considered luxury items in a time of contraction," Dr. Packer admits. "Everyone wants to get down to basic needs. But there are still reasons to think outside of that box. We won't always be working in these circumstances. Remember that decisions you make now will have an impact five or 10 years from now."

Dr. Yeu says it's very important that surgeon education continues to expand so surgeons can move toward offering these high-tech options. "Surgeons just took a 15-percent hit on reimbursements for all routine cataract surgery procedures this year," she points out. "That's just the beginning. Reimbursements are going to continue to decline, which is reason enough to look for ways we can supplement our reimbursements. In addition, more and more patients today are coming in to the clinic desiring complete independence and freedom from glasses and contact lenses. And, as noted earlier, a crisis like the one we're going through could actually increase the number of patients who desire that level of independence and spectacle freedom." REVIEW

Dr. Yeu consults for Alcon, Johnson & Johnson Vision, Zeiss, Lensar and Bausch + Lomb. Dr. Packer is a consultant for Santen and Alcon. Dr. Lee reports no financial ties to any product discussed.

1. Henderson B, Sharif Z, Geneva I. Presbyopia Correcting IOLs: Patient Selection and Satisfaction. In: Bradley Randleman, Iqbal Ike K. Ahmed, eds. Intraocular Lens Surgery: Selection, Complications, and Complex Cases. Thieme Medical; 2015:72-77.
2. Rudalevicius P, Lekaviciene R, Auffarth GU, et al. Relations between patient personality and patients' dissatisfaction after multifocal intraocular lens implantation: Clinical study based on the five factor inventory personality evaluation. Eye (Lond) 2020;34:4:717-724.
3. Packer M. Clinical comparison and patient satisfaction with novel extended-depth-of-focus intraocular lens satisfying ISO 11979-2 optical standards for monofocal intraocular lenses. (Presenting Author). European Society of Cataract and Refractive Surgeons, Vienna, Austria, 22 September 2018.

Monitoring Glaucoma Progression with OCT

Chhavi Saini, MD, and Lucy Q. Shen, MD
Boston

Glaucoma specialists discuss how to get the most out of this technology.

Since glaucoma is a progressive disease, physicians are constantly searching for reliable tools to monitor it over time. Before the introduction of optical coherence tomography, determination of glaucoma progression relied heavily on clinical assessment of the optic nerve, comparison of disc photos over time and visual field analysis. Although these remain key elements of the glaucoma evaluation, they're still subjective and qualitative in nature, limiting their ability to detect progression reliably. In this article, we'll provide tips on how to use the OCT devices we're familiar with to monitor progression, and how to avoid artifacts and other errors that can lead you astray.

Anatomy and OCT

One major advantage of OCT is its ability to show detailed, quantitative information about the various retinal layers, which corresponds to tissue sections on a histology slide. Therefore, we'll discuss the various tissue structures affected by glaucoma progression and then provide practical tips for using OCT to monitor them.

Glaucoma is characterized by loss of retinal ganglion cells and their axons, and by the remodeling of the optic nerve head, which manifests as neuroretinal rim narrowing, optic disc excavation and displacement of lamina cribrosa. The ONH is formed by the axons of the retinal ganglion cells, blood vessels and glial tissue. The axons exit the eye through the neural canal opening and are supported by the lamina cribrosa (essentially a connective tissue structure), which comprises the floor of the physiologic cup. In 1979, Harry Quigley, MD, and William R. Green, MD, demonstrated that the increased optic disc cup size was caused by the loss of retinal ganglion cells and their axons.[1] In addition, the connective tissue in the ONH undergoes profound remodeling in glaucoma, leading to posterior deformation of the lamina cribrosa as well as expansion of anterior and posterior neural canal openings, as illustrated in an experimental monkey model of glaucoma.[2] In addition to cupping of the optic nerve, glaucoma patients often show sectorial loss of nerve fiber layer, which can be visualized with a red-free light.

The correlation between anatomic structures and volumetric spectral domain-OCT images of the optic nerve head was made clear in a study by Nicholas Strouthidis, MD, and his colleagues at Devers Eye Institute, Oregon, when they performed SD-OCT imaging of the optic nerve head in

This article has no commercial sponsorship.

monkeys and obtained thin histological sections of the same tissues.[3] With side by side comparison, they were able to show that the reflectance patterns imaged by SD-OCT corresponded precisely to the various retinal layers.

Commonly Used Devices

Currently, SD-OCT is the OCT device most commonly used in clinical practice. Spectral-domain units are made by several manufacturers; the devices differ in scanning protocols and segmentation algorithms, so their measurements are not easily interchangeable. The OCT devices we work with are the Cirrus HD-OCT (Carl Zeiss Meditec; Dublin, California), Spectralis (Heidelberg Engineering; Heidelberg, Germany), and RTVue-100 (Optovue; Fremont, California); we'll refer to them throughout the article. Some of their specifications and differences are summarized in Table 1 (pg. 52). In addition to SD-OCT devices, swept-source OCT, such as the DRI Triton (Topcon Corporation, Tokyo, Japan), is commercially available. This device images the peripapillary RNFL and inner retinal thickness in the macula in one wide-angle scan. While this type of scan may offer an advantage over SD-OCT in detecting glaucoma progression, its clinical utility has yet to be proven in large, prospective studies. Another swept-source OCT device, the Plex Elite 9000 from Zeiss, is available, but primarily for research purposes, as opposed to common clinical practice for glaucoma.

As was mentioned earlier, in terms of commonly used devices, there are some differences to be aware of. For example, it's been shown that RTVue gives a thicker peripapillary retinal nerve fiber layer thickness reading in comparison to the other two.[4] This could lead to misdiagnosis of glaucoma progression if a patient was imaged initially on an RTVue device but subsequently imaged with any other device.

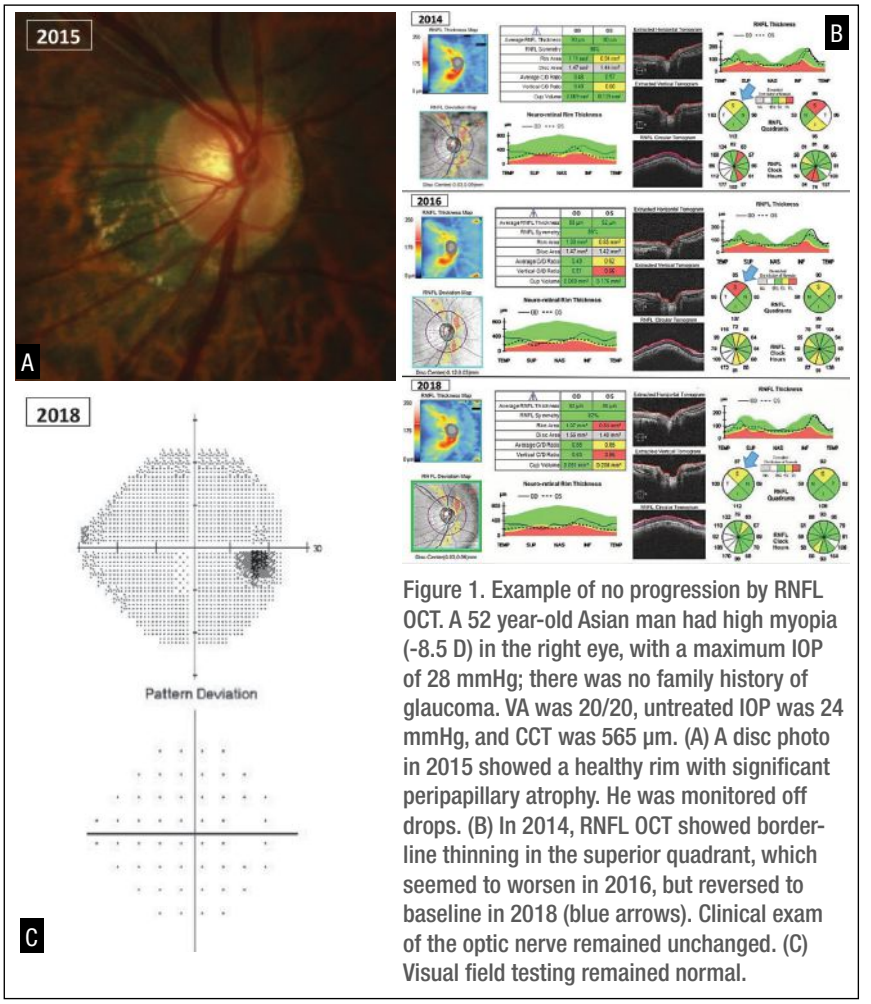


Figure 1. Example of no progression by RNFL OCT. A 52 year-old Asian man had high myopia (-8.5 D) in the right eye, with a maximum IOP of 28 mmHg; there was no family history of glaucoma. VA was 20/20, untreated IOP was 24 mmHg, and CCT was 565 µm. (A) A disc photo in 2015 showed a healthy rim with significant peripapillary atrophy. He was monitored off drops. (B) In 2014, RNFL OCT showed borderline thinning in the superior quadrant, which seemed to worsen in 2016, but reversed to baseline in 2018 (blue arrows). Clinical exam of the optic nerve remained unchanged. (C) Visual field testing remained normal.

On the other hand, each device has developed its own normative database, which aids in interpretation of scans. Therefore, it's important to be aware of device differences when assessing for progression.

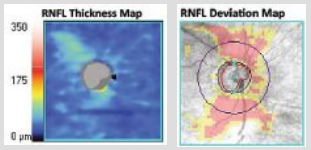
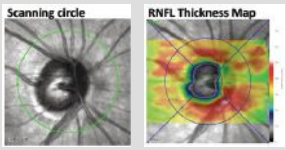
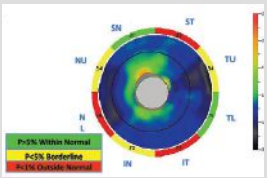
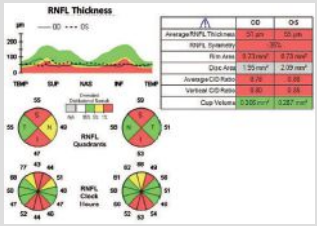
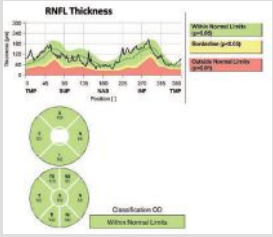
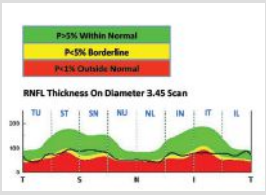
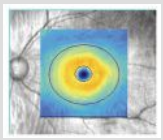
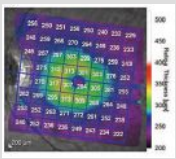
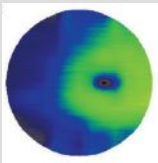
Each of the three SD-OCT devices we've worked with has its own benefits and drawbacks. For instance, while the Spectralis OCT has an eye tracking feature, the scanning time may be longer than some of the other devices' times. On the other hand, the Cirrus OCT and the RTVue OCT don't directly measure the retinal nerve fiber layer, but interpolate the thickness values from volume scans. There are also slight differences in axial resolution. Despite all this, the three devices have been reported to have equivalent performance. The decision on which device to obtain for your practice may be based on other factors, such as being shared with retina specialists, who prefer the Spectralis OCT, or if it's to be used in a high-volume clinic, for which the Cirrus OCT might be better-suited due to its shorter scanning time when generating RNFL measurements.

RNFL Thickness

Retinal nerve fiber layer thickness represents the ganglion cell axons before they enter the optic nerve. Loss of retinal nerve fiber layer can be observed in red-free photos and is quantified with OCT. The peripapillary RNFL thickness is by far the most popular OCT parameter used for glaucoma diagnosis and monitoring progression.

- ***Scanning protocol and glau-***

Table 1. OCT Devices the Authors Have Used to Analyze Progression

	Cirrus HD-OCT (Carl Zeiss Meditec)	Spectralis OCT (Heidelberg Engineering)	RTVue-100 (Optovue)
Axial resolution	5 µm	7 µm	5 µm
Scanning speed	27,000 A-scans/sec	40,000 A-scans/sec	26,000 A-scans/sec
Manufacturer signal index (MSI) recommended threshold	Signal strength = 6 or 7 (max=10)	Quality = 15 (max=40)	Signal strength index = 39 (max=100)
RNFL scanning protocol	6x6 mm^3 cube centered on optic disc; RNFL thickness generated from 3.46-mm diameter circle	3.45 mm circle scan centered on optic disc	Radial and circular scans centered on optic disc; RNFL thickness generated from a 3.45-mm diameter circle
RNFL thickness map	OD 	OD 	OS 
Normative database and reporting			
Macular scanning protocol	6-mm^2 grid measures the macular GCIPL thickness with an elliptical annulus around the fovea	30° x 25° volumetric scan of 8x8-mm^2 grid oriented on foveal-BMO axis	7-mm^2 area of macula, with center shifted 0.75 mm temporally
Retinal layers measured in the macula	GCIPL measures ganglion cell layer and inner plexiform layer	Full thickness macula	GCC measures RNFL, ganglion cell layer and inner plexiform layer
Macular thickness map	OS 	OS 	OD 

Abbreviations: RNFL= retinal nerve fiber layer thickness; GCIPL= ganglion cell inner plexiform layer; GCC= ganglion cell complex

coma diagnosis. The various devices measure RNFL thickness in slightly different ways. In the Spectralis OCT, it's measured directly with a 3.46-mm diameter circular scan centered on the optic disc. In the case of the Cirrus OCT, the measurement of RNFL is generated from a 6 mm^3 cube scan centered on the optic disc. The RTVue device scans the optic nerve head with multiple radial and circular scans and generates the RNFL thickness map along a 3.45-mm diameter circle centered on the optic disc.

Each of the OCT devices provides the RNFL thickness curve on an age-adjusted normative database where green is considered normal, yellow is borderline and red is abnormal (RNFL values below the 99th percentile of normal database). Average RNFL thickness and the RNFL thickness in the inferior quadrant have been reported to be the most clinically relevant RNFL parameters for diagnosis, as well as progression.[5] RNFL thinning may be valuable in early diagnosis of glaucoma, as it may precede visual field loss. Even if the thickness curve remains in the green area, in certain cases we should still monitor for progressive thinning. This can lead to an early diagnosis of glaucoma, known

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as "green disease." Bascom Palmer's Mohamed Sayed, MD, and his fellow researchers demonstrated asymmetric thinning of RNFL in both eyes of glaucoma patients where all RNFL measurements were within the normal range for that age.[5,6] A difference greater than 9 µm in average RNFL thickness between the two eyes should alert the physician to early glaucomatous damage.[7] On the other hand, myopia can lead to abnormal thinning of RNFL measured on OCT with no progression of the thinned-out areas, known as "red disease," which isn't glaucoma *(Figure 1)*. (Additional details on other artifacts are provided in a section below.)

• ***Progression and structure-function correlations.*** To assess for progression with RNFL thickness obtained by OCT, we need to be aware of a few factors: thinning due to normal aging; the floor effect of this parameter; thinning suggestive of glaucoma progression, both globally and within a sector; and correlation of RNFL loss with visual field loss.

RNFL undergoes attrition with age in healthy eyes at a mean rate of -0.48 µm/year in Cirrus and -0.60 µm/year in Spectralis images. Glaucoma progression, on the other hand, has a faster rate of RNFL thinning, ranging from -0.98 µm/year for the Cirrus to -2.12 µm/year for the Spectralis. As glaucoma advances, RNFL measurement continues to decrease but it doesn't go to zero, which is known as the "floor effect." This is because the architectural support made up by Müller cells, astroglia, microglia and blood vessels doesn't degenerate completely with retinal ganglion cell axons. Average RNFL floor values range from 49.2 µm for the Spectralis, to 57 µm for the Cirrus *(See Table 1, pg. 52)*, to 64.7 µm for the RTVue. Once the RNFL thickness reaches the floor, progression can still occur, but it can't be detected by RNFL OCT. For that reason, the clinician should consider the use of macular OCT (discussed below) and HVF 10-2 to monitor progression in advanced glaucoma.

Progression analysis is provided by each OCT device; the method for analysis can be event- or trend-based.

Event-based analysis measures the difference between baseline and a follow-up measurement. A decrease of 5 µm or more in average RNFL thickness is suspicious for glaucomatous progression, while a decrease of 7 to 8 µm or more in a sector of RNFL thickness also suggests progression *(Figure 2)*.

Trend-based analysis identifies progression by monitoring the slope of RNFL thickness over time. Cirrus provides a glaucoma progression algorithm based on both event and trend, comparing RNFL thickness of individual pixels between baseline and follow-up images. Pixels are coded yellow if there is test-retest variability between a follow-up and baseline image while a red color indicates the same change evident on three consecutive scans. In Spectralis, the system looks for specific patterns in retinal structures to automatically position the retest scan in the same location; RNFL thickness change and trend reports are plotted over time to compare the rate of change. RTVue offers a trend-based analysis, which includes side-by-side global RNFL thicknesses, six sectorial thickness analysis and a regression line to determine the slope and standard error. Although progression analysis software can be a great tool, especially in a busy clinic, we should always review the original scans and the sectors, as subtle changes in a small area can be easily missed *(Figure 2)*.

Similar to the diagnosis of glaucoma, glaucoma progression detected on OCT should be assessed in the context of the clinical exam and visual field testing, although there is significant variability in structure-function cor-

How OCT Works

Optical coherence tomography provides quantitative, objective and high-resolution imaging of the optic nerve and retina, and has become a widely used diagnostic tool in the care of glaucoma patients. Here's a brief history of its development.

OCT uses low coherence interferometry, where light reflected from reflective boundaries and backscattering sites provides information on the time-of-flight delay. This delay is used to determine the location of the reflection sites.[1] It's a non-contact, non-invasive diagnostic tool, whose earlier version, known as time-domain OCT, had an axial resolution of 10 µm, a scanning speed of 400 A-scans per second and could provide two-dimensional imaging around the optic nerve in about two seconds.[2] Since then, significant technological improvements have been made, and now spectral-domain OCT, the most commonly used version today, has a scanning speed of up to 40,000 A-scans per second and performs three-dimensional imaging of the optic nerve and the posterior pole with an axial resolution of 5 µm.[3]

An even newer generation of OCT, known as swept-source OCT, measures tissue thickness by sweeping a narrow bandwidth light source through a broad range of frequencies and captures the reflected signals with a photo detector. SS-OCT not only allows us to scan a larger area (macula to disc in one scan) at a faster scanning speed of 100,000 A-scans per second, the longer wavelength of its light source also allows for imaging of deeper structures, such as the lamina cribrosa of the optic nerve head.[4]

1. Huang D, Swanson EA, Lin CP, et al. Optical Coherence Tomography HHS Public Access. Vol 254; 1991.
2. Hee MR. Optical Coherence Tomography of the Human Retina. Arch Ophthalmol 1995;113:3:325. doi:10.1001/archopht.1995.01100030081025
3. Leung CK shun, Ye C, Weinreb RN, et al. Retinal nerve fiber layer imaging with spectral-domain optical coherence tomography. A Study on diagnostic agreement with heidelberg retinal tomograph. Ophthalmology 2010;117:2:267-274. doi:10.1016/j.ophtha.2009.06.061
4. Takayama K, Hangai M, Kimura Y, et al. Three-dimensional imaging of lamina cribrosa defects in glaucoma using swept-source optical coherence tomography. Investig Ophthalmol Vis Sci 2013;54:7:4798-4807.

relation at different stages of glaucoma. Clinical trials indicate that, at an individual level, structural abnormality may precede functional abnormality in some, while the reverse is true in others. A broken-stick model has been used by glaucoma specialists to explain the non-linear structural functional relationship. A practical way to apply the broken-stick model is to rely on RNFL thickness to monitor progression in pre-perimetric and early-stage glaucoma with average RNFL thickness >83 µm, visual field mean deviation (MD) >-2.5 dB and visual field index (VFI) >93 percent and to rely mostly on VF in advanced glaucoma with average RNFL thickness <55 µm and visual field MD <-10 dB.[8,9] For mild to moderate glaucoma, we should use both OCT and VF measurements to monitor progression.

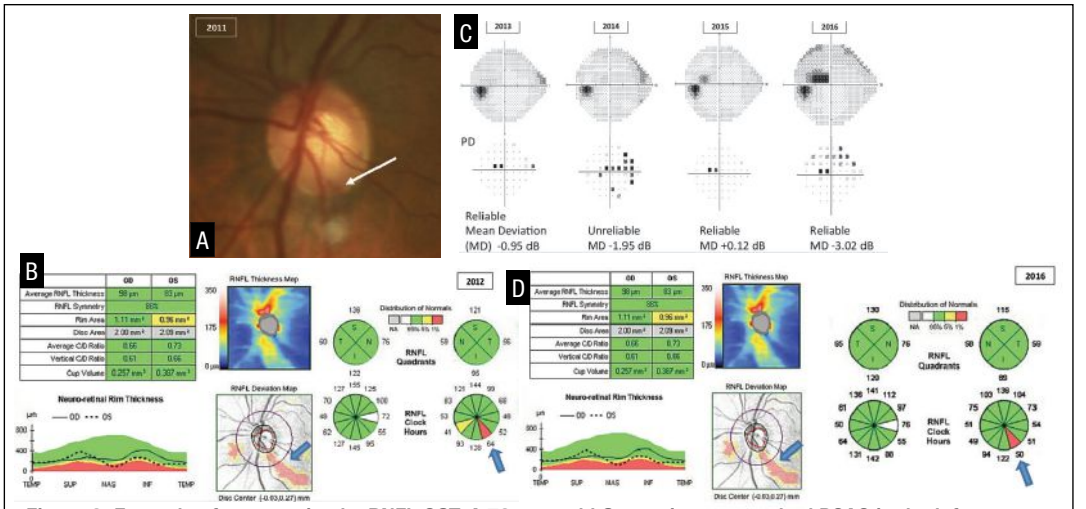

Figure 2. Example of progression by RNFL OCT. A 72-year-old Caucasian woman had POAG in the left eye, with a maximum IOP of 15 mmHg; there was no family history of glaucoma. In the left eye, VA was 20/20, IOP on medication was 10 mmHg, and CCT was 505 µm. (A) An inferotemporal disc hemorrhage (white arrow) occurred in 2011. (B) RNFL OCT in 2012 showed normal average thickness but significant thinning in the inferotemporal sector (deviation map and clock-hour map, blue arrows). (C) Superior paracentral loss was noted on the HVF pattern deviation probability plot in 2013. Since then, the patient had additional disc hemorrhages in the same area with IOP in the low teens range. Her VFs from 2013 to 2016 showed fluctuation and questionable progression. (D) RNFL OCT in 2016 showed worsening in the inferotemporal region, with the sector thickness decreasing from 64 µm in 2012 to 50 µm in 2016 (blue arrows), confirming progression. Patient was subsequently treated with SLT to prevent IOP fluctuation and has remained stable by OCT and VF.

• ***Artifacts.*** While OCT is helpful for monitoring the progression of glaucoma, we need to be aware of artifacts, which can lead to misinterpretation.

One type of artifact that can significantly affect RNFL measurement is segmentation error, in which the imaging software incorrectly identifies the anterior and posterior RNFL boundaries or delineates the RNFL layer incompletely. Per one study (though it was only in one device), this artifact is present in 11.46 percent of RNFL scans.[10] In addition, pathologic changes in the eye can affect RNFL measurements. Media opacities in the form of corneal haze, cataracts and vitreous debris may lead to a false decrease in RNFL thickness, while myelinated RNFL, epiretinal membrane, swelling of ONH and peripapillary retina can falsely increase RNFL measurements.

Another common artifact is decentration, which was reported in 27.8 percent of Spectralis scans.[10] If the scan isn't centered on the optic nerve head, RNFL appears thinner in some sectors and thicker in others. This and other artifacts may be more common in myopic eyes, which are elongated and often have peripapillary atrophy *(Figure 1)*. Hence, it's important for the clinician to review the actual scans along with the signal strength *(Table 1)*, before assessing for progression based on sectors or relying on progression analysis software. Fortunately, artifacts in OCT devices have decreased over time with improvements in technology.

The Macular Scan

Approximately half of the retinal ganglion cells reside in the macular region. Glaucoma can cause thinning of the macula early in the disease, especially the inferior macula, from which the retinal ganglion cells project to the inferotemporal region of the disc. Previous histology studies have shown that thinning of the macula, due to selective loss of retinal ganglion cells, occurs in glaucoma. Research has found that imaging the retinal thickness loss in the macula is a sensitive measure for detecting early glaucoma.[11]

• ***Diagnosis and scanning protocol for macular OCT.*** Each of the three OCT devices provides a different scan of the macula *(Examples appear in Table 1)*. Cirrus uses Ganglion Cell Analysis (GCA) to measure the thickness of the ganglion cell inner plexiform layer (GCIPL, ganglion cell layer + inner plexiform layer); the GCIPL and inferior GCIPL have the best diagnostic value for glaucoma. Spectralis performs a volume scan of macula, presents the thickness in an 8 x 8 mm

grid oriented on the fovea-to-disc axis and provides asymmetry analysis between the two eyes, which has shown utility in glaucoma diagnosis.[12] RTVue measures the GCC in a scan not centered on the fovea but shifted to include more of the temporal macula. In patients with focal thinning of the peripapillary RNFL, macular scans have diagnostic capability similar to RNFL thickness for detecting glaucomatous damage and aiding in the diagnosis of glaucoma.[13]

In contrast to the optic nerve and peripapillary area, where blood vessels are abundant, the macula is relatively devoid of large vessels. Similarly, disc size can be variable, while the macular region is comparatively uniform among patients. Hence, in individuals with large areas of peripapillary atrophy or high myopia, macular inner retinal layer is less affected than RNFL. In myopic patients, asymmetry between superior and inferior GCIPL thickness can occur in early glaucoma, and a difference of 5 µm is considered suspicious for glaucoma. Efforts are underway to develop normative databases for myopic individuals in order to improve the diagnostic capability of macular OCT.

• ***Progression monitoring with macular OCT.*** Average GCIPL thickness in normal subjects has been reported to be 82.1 ±6.2 µm, with the superonasal sector being the thickest and the inferior sector the thinnest.[14] Like the RNFL, macular GCIPL also undergoes attrition with aging at a rate of about -0.31 µm/year.[15] In addition to age, other factors that may influence macular retinal thickness are gender, central corneal thickness, axial length and RNFL thickness.

Average GCIPL thickness is about 75.2 ±6.8 µm in early glaucoma; it thins to 64.4 ±8.4 µm in moderate glaucoma and to 55.6 ±7.6 µm in advanced glaucoma.[16] An average GCIPL thickness change of more than 4 µm is suggestive of glaucomatous progression. In glaucoma progression, macular thickness change is visible as an arcuate defect on the thickness and progression-change maps. Macular parameters can also be affected by the floor effect, although this occurs later in the disease than is seen in the RNFL. In fact, studies have shown that in advanced glaucoma, when RNFL thickness is below 55 µm, change in GCIPL thickness can still correlate with functional damage measured by 10-2 VF. The floor effect in macular GCIPL measurements is observed at an average thickness of about 45 µm.

Macular GCIPL thickness has shown significant correlation with function, when VF loss is measured with 10-2 rather than 24-2 on Humphrey Standard Automated Perimetry (SAP). This is particularly true for average GCIPL and the inferior sector. In addition, built-in software can help clinicians monitor progression in macular OCT. Cirrus-HD OCT has Guided Progression Analysis, which is based on both event and trend. This analysis requires a minimum of four high-quality macular scans (two baseline and two follow-up). If a decrease in thickness is observed in the first follow-up scan the pixel is coded as yellow. If detected subsequently, the pixel is coded as red. The RTVue OCT provides the GCC map with additional parameters such as GLV (global loss volume) and FLV (focal loss volume), which can detect structural progression in early glaucoma.

Artifacts can also occur with macular OCT scans, similar to RNFL OCT. One common artifact is segmentation errors. In case of GCIPL, these may appear as segments of blue on the thickness map in the shape of a wheel, sometimes referred to as the propeller sign. Another common artifact is decentration of the scan, which may lead to the macula being incorrectly measured as too thick or too thin. Any measurement below 40 µm should alert the clinician to an artifact. In a patient with significant retinal pathology, such as macular degeneration, cystoid macular edema or epiretinal membrane, macular thickness shouldn't be used to monitor glaucoma. Thus, a detailed examination of the macula is necessary to rule out such pathology.

RNFL + Macular Scans

While macular scans have shown clinical utility in detecting early glaucoma, RNFL thickness changes are more readily detected due to the faster rate of RNFL loss in glaucoma progression. You should also be aware that "fluctuation" in thickness values can occur from scan to scan, and be sure to review a series of OCT images before confirming progression *(Figure 1)*.

In advanced glaucoma, when RNFL reaches the floor *(Table 1, Cirrus RNFL OCT example)*, macular OCT may be more useful. This can also apply to patients with myopia, who have variability in disc morphology and peripapillary atrophy. In both situations, we need to make sure that there's no other pathology affecting the macula before relying on it for monitoring progression. Newer OCT devices, such as swept-source OCTs, can combine macular and RNFL analysis, although the clinical utility for that hasn't been fully demonstrated.

The Optic Nerve Head Scan

Disc parameters measured by OCT haven't been widely accepted, probably due to variability of disc size, tilt, torsion, peripapillary atrophy and other potential artifacts. Cirrus and RTVue use an arbitrary reference plane; Spectralis, on the other hand, measures ONH with the minimum rim width at Bruch's membrane opening (BMO-MRW), which doesn't depend on an arbitrary reference plane. BMO-MRW measures the minimal thickness of the neuroretinal rim at the termination of Bruch's membrane. In addition, the

Glaucoma Module Premium Edition in Spectralis positions the scans according to foveal-BMO axis to minimize variability of disc position. Mean and inferotemporal BMO-MRW have a diagnostic capability comparable to RNFL and macular OCT. The utility of BMO-MRW to monitor for progression is yet to be established in large studies.

Another point to note is that current OCT technology can't image disc hemorrhage, which has been established as a clinical sign of glaucoma progression. Focal thinning of the RNFL measured by OCT and loss of visual field sensitivity—often in the paracentral region—follow the occurrence of a DH within one to two years *(Figure 2)*. Therefore, it's important to perform a detailed exam of the optic disc at every visit.

In conclusion, monitoring progression is an essential part of glaucoma care, and OCT has proven to be a quantitative and reliable tool for monitoring. However, it should be used in conjunction with clinical evaluation and visual field testing. Furthermore, different stages of glaucoma may require different monitoring tools. In early glaucoma, OCT of the RNFL and macula may be important for patients with normal or unreliable visual field tests. In moderate glaucoma, the correlation between OCT measurements and VF tests helps to confirm progression. In advanced glaucoma, we need to be aware of the floor effect in RNFL OCT measurements and consider the use of macular OCT and 10-2 visual field tests to detect progression. It's likely that as newer technology and better software develop, we'll use OCT not only to monitor glaucoma but also to gain a better understanding of why glaucoma occurs and how this disease process can vary among individuals, with OCT angiography possibly ushering in this new era. For now, when monitoring glaucoma progression, we should combine our clinical evaluation—paying special attention to disc hemorrhage—with a visual field assessment and a good understanding of OCT and its limitations. REVIEW

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Dr. Shen receives research support from Topcon. Dr. Saini has no financial interest in any product discussed.

1. Quigley HA, Green WR. The histology of human glaucoma cupping and optic nerve damage: Clinicopathologic correlation in 21 Eyes. Ophthalmology 1979;86:10:1803-1827.
2. Burgoyne CF, Downs JC, Bellezza AJ, Hart RT. Three-dimensional reconstruction of normal and early glaucoma monkey optic nerve head connective tissues. Investig Ophthalmol Vis Sci 2004;45:12:4388-4399.
3. Strouthidis NG, Grimm J, Williams GA, Cull GA, Wilson DJ, Burgoyne CF. A comparison of optic nerve head morphology viewed by spectral domain optical coherence tomography and by serial histology. Investig Ophthalmol Vis Sci 2010;51:3:1464.
4. Leite M, Rao H, Weinreb R, Zangwill L, Bowd C, Sample P, Tafreshi A, Medeiros F. Agreement among spectral-domain optical coherence tomography instruments for assessing retinal nerve fiber layer thickness. Am J Ophthalmol 2011;151:1: 85-92.
5. Kanamori A, Nakamura M, Escano MFT, et al. Evaluation of the glaucomatous damage on retinal nerve fiber layer thickness measured by optical coherence tomography. Am J Ophthalmol 2003;135:4:513-520.
6. Sayed MS, Margolis M, Lee RK. Green disease in optical coherence tomography diagnosis of glaucoma. Curr Opin Ophthalmol 2017;28:2:139-153.
7. Mwanza JC, Durbin MK, Budenz DL. Interocular symmetry in peripapillary retinal nerve fiber layer thickness measured with the cirrus HD-OCT in healthy eyes. Am J Ophthalmol 2011;151:3:514-521.e1.
8. Banegas SA, Anton A, Morilla A, et al. Evaluation of the retinal NFL thickness, the mean deviation, and the visual field index in progressive glaucoma. J Glaucoma 2016;25:3:e229-e235.
9. Lavinsky F, Wu M, Schuman JS, et al. Can macula and optic nerve head parameters detect glaucoma progression in eyes with advanced circumpapillary retinal nerve fiber layer damage? Ophthalmology 2018;125:12:1907.
10. Liu Y, Simavli H, Que CJ, et al. Patient characteristics associated with artifacts in spectralis optical coherence tomography imaging of the retinal nerve fiber layer in glaucoma. Am J Ophthalmol 2015;159:3:565-76.
11. Zeimer R, Asrani S, Zou S, et al. Quantitative detection of glaucomatous damage at the posterior pole by retinal thickness mapping: A pilot study. Ophthalmology.1998;105:2:224-231.
12. Asrani S. Novel software strategy for glaucoma diagnosis. Arch Ophthalmol 2011;129:9:1205.
13. Kim MJ, Park KH, Yoo BW, et al. Comparison of macular GCIPL and peripapillary RNFL deviation maps for detection of glaucomatous eye with localized RNFL defect. Acta Ophthalmol 2015;93:1:e22-e28.
14. Mwanza JC, Durbin MK, Budenz DL, et al. Profile and predictors of normal ganglion cell-inner plexiform layer thickness measured with frequency-domain optical coherence tomography. Investig Ophthalmol Vis Sci 2011;52:11:7872-7879.
15. Lee WJ, Baek SU, Kim YK, et al. Rates of ganglion cell-inner plexiform layer thinning in normal, open-angle glaucoma and pseudoexfoliation glaucoma eyes: A trend-based analysis. Investig Ophthalmol Vis Sci 2019;60:2:599-604.
16. Xu X, Xiao H, Guo X, et al. Diagnostic ability of macular ganglion cell-inner plexiform layer thickness in glaucoma suspects. Med (United States) 2017;96:51:e9182.

(Continued from page 34)

Vision practice is part of Spectrum Vision Partners, a four-state private equity practice, says her organization responded swiftly when the COVID-19 pandemic struck, furloughing her and all but a few clinicians at regional emergency centers. But she expects the practice to get back up to speed very slowly.

Practice planners wonder how many patients can be treated or receive surgery, given the need for COVID-19 precautions, social distancing, personal protective equipment, screening and other individualized attention that may reduce efficiency. In addition, many patients may not be eager to visit or have marginal cataracts removed until symptoms worsen, figuring they can ride out the pandemic. These factors, plus the bad economy, may suppress patient volume. "We may see a slow roll-out for all of those reasons," says Dr. McDonald. "Eventually we'll get there; then we'll face a log jam from the backlog of cases."

"Without sufficient patient volume to cover expenses, most practices can only go for a couple of months," admits Dr. Netland. "Clearly, the longer a crisis like this continues, the harder it is to continue covering your expenses. As a result, furloughing or reducing hours is happening in most practices around us. Academic centers may be able to hold out a little longer; we're a couple of weeks into this and we haven't had to furlough yet. We've reduced hours to some extent, but we've tried to keep everyone employed. Clearly if things continue, we'll have to adapt. We continue to evaluate this on a week-to-week basis."

A Sound Plan

Drs. Aker and Kasten in Boca Raton plan to buck the trend. They hope to reopen their surgical center and clinic at the end of May—and possibly perform eight to 10 surgeries on the last Wednesday or Thursday of the month, pending local officials' approval of elective procedures. He and his wife are examples of the surgeons John Pinto mentioned—those with protective capital reserves. Their resumption of operations will begin more than two months after they closed the eye center because they weren't able to provide elective surgeries or care. During the layoff, they retained all of their employees on full-time salaries and continued their health-care benefits. Much of the time, those employees, mostly working from home, lined up patients for a surgical schedule that could get up to 15 patients a day—about 65 percent of their peak volume.

Dr. Aker says he's also prepared for challenging financial times like these. "About 30 years ago, a financial advisor convinced me of the benefits of remaining debt-free. Since doing that we've always been very cash strong, with impressive balance sheets. No debt, no interest payments. As a result, we're in a very good position to be able to ride this out and care for our patients and staff."

Sooner or later, says Dr. Netland, reflecting on his many years in practice, others will join the ranks of Drs. Aker and Kasten as comprehensive ophthalmology recovers.

"One thing I've learned from living through pandemics such as AIDS, swine flu and others, is that this will pass eventually and things will get back to normal," he notes. "How long that will take is impossible to say. But in the meantime, I feel positive about the flexibility and responsiveness of the health-care system in responding to this crisis. We've been able to shift things pretty quickly and mobilize. The crisis has revealed problems with our supply chains, and recovering from this will take time. But I've been impressed by how effectively people have responded." REVIEW

(Continued from page 20)

the summer of 2020, Dr. Stunkel will be joining Mercy Hospital in Saint Louis and Dr. Mehner will be joining the University of Colorado in Denver.

Dr. Boente is an assistant professor of clinical ophthalmology and ophthalmology residency program director at Indiana University.

Dr. Neely is a professor of clinical ophthalmology at Indiana University and an international expert in the fields of pediatric ophthalmology and adult strabismus.

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1. Robaei R, Rose KA, Kifley A, Cosstick M, Ip JM, Mitchell P. Factors associated with childhood strabismus: Findings from a population-based study. Ophthalmol 2006;7:113.
2. Williams AT, Metz HS, Jampolsky A. The O'Connor cinch revisited. Br J Ophthalmol 1978;62:11:765-9.
3. Hamtil LW. A study in tucking extraocular muscles to correct strabismus. Ann Ophthalmol 1983;15:2:136-7.
4. Wright, KW, Ning, YJ. Pediatric Ophthalmology and Strabismus. New York: Oxford University Press, 2012.
5. Wright KW. Rectus strengthening procedures. In: Wright KW, ed. Color Atlas of Ophthalmic Surgery: Strabismus. Philadelphia: Lippincott, 1991.
6. Chaudhuri Z, Demer JL. Surgical outcomes following rectus muscle plication: A potentially reversible, vessel-sparing alternative to resection. JAMA Ophthalmol 2014;132:5:579-85.
7. Kühne J, Palmowski-wolfe A. Plication versus resection in horizontal strabismus surgery. Klin Monbl Augenheilkd 2019;236:4:442-445.
8. Sukhija J, Kaur S. Comparison of plication and resection in large-angle exotropia. J AAPOS 2018;22:5:348-351.
9. Sonwani P, Amitava AK, Khan AA, et al. Plication as an alternative to resection in horizontal strabismus: A randomized clinical trial. Indian J Ophthalmol 2017;65:9:853-858.
10. Kimura Y, Kimura T. Comparative study of plication-recession versus resection-recession in unilateral surgery for intermittent exotropia. Jpn J Ophthalmol 2017;61:3:286-291.
11. Huston PA, Hoover DL. Surgical outcomes following rectus muscle plication versus resection combined with antagonist muscle recession for basic horizontal strabismus. J AAPOS 2018;22:1:7-11.
12. Wright KW, Lanier AB. Effect of a modified rectus tuck on anterior segment circulation in monkeys. J Pediatr Ophthalmol Strabismus 1991;28:2:77-81.
13. Oltra EZ, Pineles SL, Demer JL, Quan AV, Velez FG. The effect of rectus muscle recession, resection and plication on anterior segment circulation in humans. Br J Ophthalmol 2015;99:4:556.
14. Parks MM, Mitchell PR, Wheeler MB. Concomitant esodeviations. In: Tasman W, Jaeger EA, eds. Duane's Foundations of Clinical Ophthalmology, vol 1. Philadelphia: Lippincott Williams & Wilkins, 2002:12.
15. Alkharashi M, Hunter DG. Reduced surgical success rate of rectus muscle plication compared to resection. J AAPOS 2017;21:3:201-204.
16. Park C, Min BM, Wright KW. Effect of a modified rectus tuck on anterior ciliary artery perfusion. Korean J Ophthalmol 1991;5:1:15-25.
17. Pineles SL, Chang MY, Oltra EL, Pihlblad MS, et al. Anterior segment ischemia: etiology, assessment, and management. Eye 2018;32:173-178.
18. Velez FG, Demer JL, Pihlblad MS, Pineles SL. Rectus muscle plication using an adjustable suture technique. J AAPOS 2013;17:5:480-483.

OCT's Usefulness in Severe Glaucoma

Researchers from Wills Eye Hospital in Philadelphia and Rutgers Robert Wood Johnson Medical School in New Brunswick, New Jersey, say that optical coherence tomography may still be useful in severe glaucoma cases.

The investigators note that retinal nerve fiber layer imaging done by OCT in glaucomatous eyes with advanced structural damage can reach a floor after which there is no further detectable thinning of the RNFL. They add that insurers are considering limiting coverage for OCT in "severe-stage glaucoma" as defined by CMS. However, CMS definitions of severe glaucoma are based primarily on visual field criteria, the authors say, adding that many of these patients may have preserved RNFL in other sectors.

In the study, researchers reviewed the records of patients with CMS-defined severe glaucoma, and collected data on such parameters as the average/sectoral RNFL thickness and the mean deviation of the visual fields. Previous estimates of RNFL floor and test-retest variability for Cirrus OCT were used to establish three threshold values for the RNFL.

A total of 129 eyes qualified (age: 71 ±12 y; mean deviation: –13.5 ±4.3 dB; average RNFL: 60.9 ±7.9 µm). A majority of eyes (66 percent) met "severe" glaucoma criteria, with defects in both hemifields; 34 percent met only paracentral-defect criteria. The proportion of eyes that had significant remaining average, superior, or inferior RNFL, estimated by thresholds 1 to 3, was 21 to 54 percent, 29 to 51 percent and 16 to 37 percent, respectively. At least one vertical quadrant had significant remaining RNFL in 35 to 66 percent of eyes, depending on the threshold used.

The researchers say that their data demonstrate that the presence of CMS-defined severe glaucoma doesn't exclude the potential utility of OCT for monitoring progression.

J Glaucoma 2020;29:4:241.
Kolomeyer NN, Mantravadi Anand V, Brody G, et al.

Impact of Glaucoma Surgery On the Cornea

Resarchers evaluated alterations in corneal biomechanical properties before and after conventional trabeculectomy and Ahmed valve implantation.

Thirty-nine eyes of 39 patients were evaluated retrospectively. Complete ophthalmic exams including evaluation of corneal biomechanical properties using the Ocular Response Analyzer were performed before and after six months postoperatively. The means four measurements—corneal hysteresis (CH), corneal resistance factor (CRF), Goldmann correlated intraocular pressure (IOPg) and corneal compensated intraocular pressure (IOPcc)—were recorded. Patients had undergone trabeculectomy or shunt surgery as the first surgical procedure and were on maximum glaucoma medication.

Twenty eyes of 20 individuals were in the trabeculectomy group and 19 eyes of 19 patients were in the Ahmed valve group. Some of the findings were:

- No significant differences were found between the two groups in terms of glaucoma drug usage, preop mean deviation of Humphrey visual fields; CH, CRF, IOPcc or IOPg ($p>0.05$).
- CH and CRF increased significantly after shunt surgery ($p<0.001$).
- In the trab group, postoperatively the CH increased ($p<0.001$), while CRF slightly decreased, though not statistically significantly ($p>0.05$).
- CH and CRF showed a greater increase after AGV surgery than after trabeculectomy surgery ($p<0.05$).
- No significant correlation was found between IOP changes and CH-CRF changes in conventional trabeculectomy or AGV groups ($p>0.05$).

Researchers found that surgical technique differences may have an impact on postoperative corneal biomechanical outcomes. They also determined that AGV surgery offered better corneal biomechanical results than standard trabeculectomy at six-month follow-up. REVIEW

Int Ophthalmol 2020; April 16 (epub).
Kaderli A, Demirok G, Tamer Kaderli S, et al.

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

Telemedicine Rules Relaxed for Pandemic

Since the pandemic has been declared a national emergency, billing for remote exams is now a lot easier.

Normally, Medicare's telemedicine policy is highly restrictive and it applies mostly to rural areas in Alaska and Hawaii. In the past, claims for telemedicine couldn't be processed and paid except in those locales, and even then, only with certain guidance on "place of service" and with certain code modifiers. Under the current COVID-19 public health emergency, however, Medicare has significantly relaxed those rules to allow for the safety of our patients, doctors, office staff and the U.S. public-at-large under "shelter in place" provisions.

Additionally, the government gave Ambulatory Surgery Centers instructions to be open only for emergency surgery, but in a very recent change, also allowed them flexibility to "become" hospitals temporarily or to contract with a hospital for surgical services in order to keep the beds available in the hospital for those needing them in the event of a shortage.

(Note: The codes and modifier advice has been fluid since the emergency declaration began, but is correct at the time of this writing.)

Q What rules did Medicare relax?

A There are two main ones for us in ophthalmology. First, when the president declared the Public Health Emergency, it was made retroactive to March 6, 2020, and HHS Secretary Alex Azar issued a series of "1135 Waivers" (https://tinyurl.com/ybaks4z2). These 1135 waivers apply to corresponding numbered sections of the Social Security Act and temporarily changed the conditions of licensure, EMTALA regulations and Stark self-referral sanctions, as well as some HIPAA considerations. More on each of those below.

Q How long will the rules remain relaxed?

A CMS has noted that these will "end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period." The waiver for EMTALA is worded slightly differently: It lasts until the "termination of the pandemic-related public health emergency."

Q What does the licensure waiver mean?

A CMS will allow providers to essentially practice across state lines so that care can be given by any provider already credentialed under Medicare to protect patients who need care from having to travel for it at their own risk. Additionally, CMS issued a Fact Sheet on the Emergency Declaration (https://tinyurl.com/udfcczq) that al-

This article has no commercial sponsorship.

lowed non-certified Part B providers to enroll and receive temporary Medicare billing privileges.

Q What about providers who had "opted out" of the Medicare system and want to help care for patients during the emergency?

A Even providers who had opted out of Medicare can terminate this status with Medicare, and they could thereby enroll in Medicare earlier than the normal period of disenrollment to be able to provide more care for the U.S. public. The termination provision of those providers remains once the disaster is over, however – they won't be "opted out" any longer.

In the same document immediately above, CMS has also waived revalidation Medicare actions until the emergency is declared over. Once it is over, revalidation should begin again—but there is no guidance on how quickly that would ramp up.

Q What about the relaxing of some of the Stark Law provisions? How does that affect me?

A The U.S. Department of Health and Human Services Office of the Inspector General (OIG) on March 17, issued a Policy Statement that noted that "physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health-care program beneficiaries may owe for telehealth services furnished consistent with the then applicable coverage and payment rules … ." This means you can (but don't have to) waive coinsurance and deductibles for telehealth services during the emergency. If the diagnosis is COVID-19-related, CMS has already stated that copays and deductibles are waived in order to not have cost stand in the way of proper care for potential COVID-19 patients; other private payers followed suit almost immediately.

Q What does the "1135 Waiver" mean with regards to HIPAA?

A Normally, telemedicine must be delivered via a secure system in order to be considered a valid service in terms of billing but also to protect a patient's "PHI" (protected health information). Under the 1135 Blanket waiver, for the duration of the emergency, the HHS Office of Civil Rights (OCR), which is normally in charge of HIPAA provisions, has noted in a press release that it will "exercise its enforcement discretion and will waive potential penalties for HIPAA violations against health-care providers that serve patients through everyday communications technologies during the COVID-19 nationwide public health emergency. This exercise of discretion applies to widely available communications apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID-19." HHS notes the following as acceptable media for this use: "… popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom or Skype."

They also note that offices are "encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications …" A consent (verbal) should be noted in the chart for the telemedicine exam.

HHS notes that the following are NOT acceptable for this purpose—even under the waiver because they

are "public facing": Facebook Live, Twitch and TikTok. Any similar technology would also be non-allowed.

Q How can I protect myself, my staff and patients yet deliver care for them appropriately?

A This is perhaps the biggest question of all. With social distancing and "stay at home" orders to shelter in place, some patients might actually need to be seen in the office. If this is a true ocular emergency that requires you to have the patient come to the office, your billing and coding is unaffected. Some patients you put off at first can't wait indefinitely; as a result, there's a new set of triage at play (who can wait and who can't) given the risk to the elderly and those with underlying medical conditions. If you do need to see someone, you can use your usual codes for exams and file and be paid as usual. Don't forget that first and foremost, your patients' welfare is primary, but also be safe yourself and make sure that you and your staff use appropriate protective gear. The Centers for Disease Control and Prevention have good, continuously updated coronavirus guidance on such matters.

Q If I determine that a patient needs care but it may not be safe to bring them into the office, how do I deliver care remotely?

A There are multiple options available: live on the phone; simultaneous audio/video; "store and forward" (pictures with follow-up later); and e-visits (via email, for example). There are also codes for doctor-to-doctor consultations, but those may be less common in eye care.

Q What billing codes apply to phone calls with patients made by doctors?

A Some things are not covered services under Medicare (they weren't before the emergency and remain so). For example, calling a patient to reschedule an appointment or merely to pass along a test result cannot be billed to Medicare or the patient. If your staff does these things, there is no mechanism for billing anyone.

In some cases, when your staff is reviewing the schedule and calls a patient, they may get the sense that a chat with the doctor is indicated. They should get consent for a telemedicine phone call and inform the patient that this will be billed. This should be documented in the chart; a written consent signed by the patient isn't required (verbal notice is acceptable as long as it is documented). If you then speak with the patient and determine that he needs some minor care adjustment but can otherwise avoid a trip to the office, depending on the amount of time you as the provider spend with the patient, there are four possible codes: G2012; 99441; 99442; and 99443.

Each of these codes imposes at least a five-minute provider time as well as other restrictions. (G2012 is not billable if there is a service related to the call rendered within 24 hours or at 'next available' appointment, for example or the service isn't billable at all.) Document your time in case the phone visit is questioned later. (See your CPT and HCPCS code books for details.) It's important to understand that CPT is created and revised by the AMA's CPT Editorial Panel and HCPCS is maintained by CMS, so CMS may not always follow what AMA recommends as a code, and will instead create another code for Medicare use.

In CMS' Interim Final Rule from March 30, 2020, CMS instructed to "report the POS code that would have been reported had the service been furnished in person." Your claim to Medicare would normally use "02" for this but the instruction means that eye-care providers will use "11" as the Place of Service (POS) during the emergency. No modifier is needed or desired on these codes for Part B. Normally, CPT phone-call codes (99441 to 99443) aren't paid by Medicare but coverage and payment is allowed under the pandemic emergency declaration. In this code series, 99443 has the highest time requirement for the provider to meet, so documenting that in the chart is key.

There's a separate group of phone call codes for qualified health-care professionals (QHP) and non-physician providers (98966 to 98698) that Medicare covers as well. The term "QHP" in this setting means that a nurse practitioner or a physician assistant had the conversation and bills for it. Medicare covers the service here as well.

Q What code applies if the doctor gets a digital image from a Medicare patient who asks for advice during this emergency?

A For Medicare, code G2010 applies. To bill for the service, you would obtain consent for the service to be billed and the doctor (not staff) would then review the image and reply to the patient via the same methodology. As above, the claim would include POS "11." No modifier is desired by Medicare.

Q We have a secure patient portal. What if the doctors or QHP email back-and-forth with the patient? Is that billable during the COVID-19 emergency?

A Yes. This was already payable before the emergency but it wasn't something we typically thought of.

Once the emergency is over, this might be something to consider as services are ramped up. CPT codes 99421 to 99423 apply here. Medicare covers and pays for the service. After consent for the service and billing, the doctor or QHP keeps track of how much time is involved in doing that over the next seven days and then tallies it up at the end of the week and bills one of the codes. 99421 has the lowest amount of time requirement and 99423 the highest. POS is "11." No modifier is used for Medicare.

Q I am a doctor and another doctor called me. She had an immunocompromised patient in the office with an eye condition. Rather than send the patient to me physically, she and I spoke with the patient present at her office. The other doctor felt we could minimize the exposure for the patient that way. After the discussion, I recommended some eye drops for the patient and didn't need to see the patient physically. Can I get paid for that?

A Yes. CPT codes 99446 through 99448 are for this service. You need the billing information, of course, but this is a payable service for Medicare during the emergency. Before billing, you should summarize your history and recommendations in a letter to the other doctor and send it for their files. Keep those notes in your records. Like the other codes, the time requirement varies: CPT 99446 has the lowest time and 99448 the highest. Be sure to document the consent and time, as above. On your claim, use POS "11"; no modifier is desired by Medicare.

Q What if a patient can avoid coming in physically but I need to use both audio and video to check on her? Can I bill for that?

A Yes. During the emergency declaration, when simultaneous audio and video are done and are medically supported, you can use Evaluation and Management codes 99212 to 99215 for established patients and 99201 to 99205 for new ones. Eye codes (92002 to 92014) aren't available to use for telemedicine.

For the level of service, CMS notes you can use the normal 2020 rules (history, exam and decision making) or an option which is similar to the proposed rules for 2021. CMS noted in the Interim Final Rule above that, "On an interim basis, we are revising our policy to specify that the office/outpatient E/M level selection for these services … via telehealth can be based on medical decision making (MDM) or time, with time defined as all of the time associated with the E/M on the day of the encounter; and to remove any requirements regarding documentation of history and/or physical exam in the medical record … ."

Claims should use place of service code "11" as in the case above, however, to ensure proper payment, The Centers for Medicare and Medicaid Services are recommending that modifier 95 be used for these codes, only to note that the services were delivered during the emergency declaration. Those rules on POS and the 95 modifier will expire when the officially declared state of emergency expires.

Finally, on a personal note: Please stay safe, everyone. We're all in this together. REVIEW

Mr. Larson is a senior consultant at the Corcoran Consulting Group and is based in Atlanta. He welcomes any comments or questions on the topic of this month's column. Please contact him at plarson@corcorancg.com.


Managing Glaucoma & Retinal Detachment

These two problems often coexist. A surgeon offers strategies for successfully managing the glaucoma in this situation.

Paul A. Sidoti, MD, New York City

Ophthalmologists who manage glaucoma know that retinal detachment and glaucoma often coexist. They share several risk factors, including high myopia and prior intraocular surgery. Furthermore, having had a retinal detachment may increase your chances of having glaucoma, and a retinal detachment, by itself, can lead to the disease. Managing glaucoma in these circumstances—especially with surgery—can be challenging. Here, I'd like to offer some strategies that can help that management succeed.

Mechanisms

We've known for a while that a history of detachment can be associated with glaucoma. A 1963 study of 530 retinal detachment patients, conducted by Bernard Becker, MD, found that 12.3 percent of them had glaucoma—half of it primary open-angle glaucoma.[1] A 1977 survey of 817 patients undergoing primary operations for retinal detachment, conducted by Charles Phelps, MD, and Thomas Burton, MD, found that 9.5 percent of them had glaucoma. (The glaucoma preceded the retinal detachment in 7.3 percent.)[2]

It's also clear that a retinal detachment, by itself, can lead to glaucoma. For example, retinal detachment can cause some photoreceptor outer segments to be released into the vitreous fluid; if the anterior hyaloid face has been disrupted by trauma or prior surgery, those segments can migrate into the anterior chamber and clog the trabecular meshwork. However, a more common scenario is that glaucoma develops, or is worsened, as a result of a surgical procedure that was used to repair a retinal detachment.

IOP elevation can occur following pars plana vitrectomy, scleral bucking surgery, injection of intravitreal silicone oil or gas, or even use of postoperative steroids. These can all contribute to pressure elevation, via a variety of mechanisms. Open-angle glaucoma can be triggered by anything that makes the trabecular meshwork not function well, such as trauma, or simply obstructs it, as can happen with emulsified silicone oil or blood cells. Steroids can cause elevated pressure, and volume expansion resulting from overfilling the eye with gas or silicone oil can leave the pressure too high. Inflammation can cause synechiae in the drainage angle, leading to closed-angle glaucoma. Or, injected gas or silicone oil can push the lens and iris forward, causing obstruction of the trabecular meshwork or pupillary block.

Let's consider the possible reasons each of these retinal detachment repair procedures may lead to a rise in pressure.

• ***Pars plana vitrectomy.*** The incidence or severity of glaucoma often increases in patients who have undergone pars plana vitrectomy; it's especially common when such patients have also undergone cataract surgery. Stanley Chang, MD, spoke about this in his 2006 Edward Jackson Lecture reprinted in the *American Journal of Ophthalmology*.[3] He proposed that the mechanism for this could be increased diffusion of oxygen from the vitreous into the anterior chamber, causing oxidative damage to the trabecular meshwork, which would in turn cause reduced aqueous outflow. To my knowledge, this explanation hasn't been proven,

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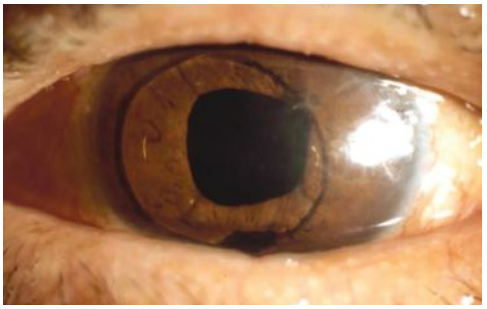
but it's a reasonable theory.

• ***Scleral buckle.*** A tight scleral buckle can compress vortex veins. This can lead to increased venous impedance; congestion, swelling and anterior rotation of the ciliary body; and anterior rotation of the lens-iris diaphragm, with iridotrabecular meshwork apposition. This can lead to angle closure with resulting elevation of the intraocular pressure.



Prolapse of silicone oil into the anterior chamber through a surgically enlarged pupil.

A tight scleral buckle can also trigger choroidal effusions. Choroidal effusions can be transient, resolving without treatment after days or weeks, but they can lead to the development of peripheral anterior synechiae. The result can be acute or chronic elevation of the pressure.

• ***Silicone oil injection.*** Silicone oil can be problematic, leading to open- or closed-angle glaucoma. If the oil migrates into the anterior chamber, it can obstruct aqueous outflow and/or cause trabecular endothelial damage and dysfunction, even in patients with an open angle. Overfill can cause pupillary block, requiring an inferior iridotomy or iridectomy. It can also lead to closed-angle glaucoma due to anterior displacement of the lens and iris. The angle closure may be asymmetric (more superior than inferior), and it can be exacerbated when the individual is in a supine position.

Clearly, the surgeon needs to avoid overfilling with the oil at the time of surgery; but even with the appropriate amount of oil, emulsified droplets will make their way into the anterior chamber over time and can lead to chronic trabecular obstruction and damage, with intraocular pressure elevation.

• ***Intravitreal gas injection***. Intravitreal gas also can lead to high pressure if you put in too much. The concentration of the gas will determine the rate and magnitude of its expansion; trouble can arise not only from initial overfill, but also if the rate of expansion exceeds the rate of aqueous outflow. As with silicone oil, overfill can cause pupillary block, requiring an iridotomy or iridectomy, or lead to closed-angle glaucoma because of anterior displacement of the lens and iris. Also, as with silicone oil, the resulting angle closure may be asymmetric (more superior than inferior), and it can be exacerbated when the individual is in a supine position.

Managing the Glaucoma

There are a number of ways to address the elevated pressure:

• ***First, address any causal mechanism relating to the retinal detachment or its treatment.*** It's important to begin addressing the glaucoma by first determining the mechanism that's caused it, because in many cases it may be possible to reverse that mechanism. For example, if the elevated pressure resulted from the treatment for the retinal detachment, you may be able to mitigate or undo the causal factor. Sometimes removing a little bit of gas will lower the pressure. You may be able to remove a tight scleral buckle or remove silicone oil from the anterior chamber. If steroids are the probable cause, see if you can wait a few weeks, while treating with glaucoma medications, to let the patient taper off of the steroid. The high pressure may resolve and you won't need to do any glaucoma surgery.

The cause could also be the detached retina itself (rather than the treatment used to address it). If the glaucoma has been triggered by photoreceptor outer segments clogging the trabecular meshwork, reattach the retina; remove any blood (if blood is contributing to the problem); and use Avastin or another anti-VEGF agent to address any neovascular component. If appropriate, perform a pars plana vitrectomy.

Admittedly, it's not always possible to undo an inciting factor; but it's important to make this your first-line approach to addressing the glaucoma.

• ***Try medications, topical and otherwise.*** Once you've done what you can to reverse causal mechanisms, move on to medications, laser and surgery to address the elevated pressure. Medications to consider should include: topical medications; miotics (including phospholine iodide) which can be useful in aphakic and pseudophakic patients; oral carbonic anhydrase inhibitors, especially as a temporizing measure; cycloplegia, to minimize anterior rotation of the lens-iris diaphragm; corticosteroids; and intravitreal anti-VEGF injections, if you need to control anterior segment neovascularization.

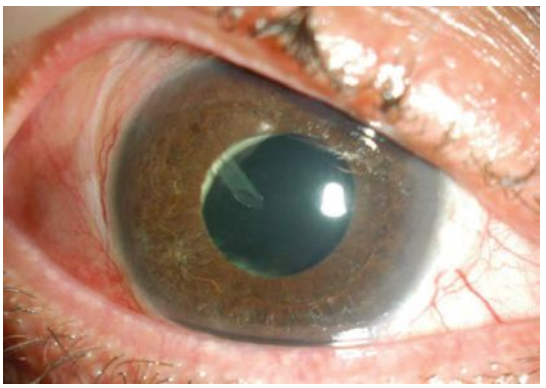
• ***Consider using laser.*** Panretinal photocoagulation, trabeculoplasty and cyclophotocoagulation (transcleral or endoscopic) are all worth considering. Certainly, PRP is a useful treatment for retinal disease, as a means to reverse neovascularization.

Some people resort to cyclophotocoagulation earlier; others wait and use it as a last resort.

• ***Incisional procedures.*** The basic categories here are angle surgery and external drainage procedures. Options include Trabectome and other types of Schlemm's canal surgery; trabeculectomy with mitomycin-C; variations on trabeculectomy, such as

subconjunctival MIGS procedures; and aqueous shunt surgery. Unfortunately, performing glaucoma surgery on a patient who has previously undergone retinal detachment surgery is always a challenge.

Note: It's worth considering performing glaucoma surgery at the time of vitreoretinal surgery if the patient already had a glaucoma problem before the retinal detachment. That's especially true if the patient's IOP isn't adequately controlled on maximal medication therapy, or if the pressure is adequately controlled on multiple medications, but the patient has moderate to severe disease. Aqueous shunt surgery often is the best procedure in that setting.



Ciliary sulcus aqueous shunt tube placement in a pseudophakic eye with intravitreal silicone oil.

Incisional Surgery: Pros & Cons

Let's look more closely at each incisional surgery option:

• ***Schlemm's canal surgeries***. Schlemm's canal surgeries such as an iStent, Kahook blade or Trabectome may be contraindicated because of the presence of silicone oil, angle neovascularization and/or extensive synechial angle closure. However, they can be reasonable options if your target IOP is mid-teens to low 20s; the disc and visual field damage is early to moderate; there's a fair amount of open angle; and silicone oil is not present in the anterior chamber. Conjunctival scarring doesn't preclude this option, and it has the advantage that it can be combined with cataract surgery. A potential downside is the possibility of steroid-induced pressure elevation postop.

• ***Trabeculectomy and its variations.*** Trabeculectomy is always worth considering when a patient has moderate to advanced disc damage and you need to achieve a very low target IOP, especially if the eye has mobile conjunctiva. However, it can be a less-than-ideal option if you're dealing with conjunctival scarring from a scleral buckle, for example, especially if the patient has had multiple prior surgeries such as vitrectomy or cataract surgery. Other factors to consider include anterior segment neovascularization; the presence of residual, emulsified silicone oil; and any chronic inflammation that's present. This type of surgery is also prone to failure following any future surgeries that might become necessary, due to episcleral scarring.

• ***Aqueous shunt surgery.*** This is often the preferable choice for addressing elevated pressure in this situation. You can use a tube shunt to manage all degrees of glaucoma severity, from early to advanced, and you can achieve very low pressures (although adjunctive medications are often required). Conjunctival scarring, except in its most severe stages, doesn't really interfere with doing the surgery or with its outcome. Also, tube shunts are pretty resilient. Even if the patient needs a subsequent operation, tube shunts can continue to work as well as they did when you initially implanted them.

Tube shunt surgery may be contraindicated if:

— the eye has extensive conjunctival scarring that precludes safe dissection for this surgery;

— multiple shunts were previously implanted in the eye; or

— silicone oil is present and must be retained, and anterior chamber or ciliary sulcus tube placement isn't possible (e.g., an aphakic eye with extensive anterior synechiae).

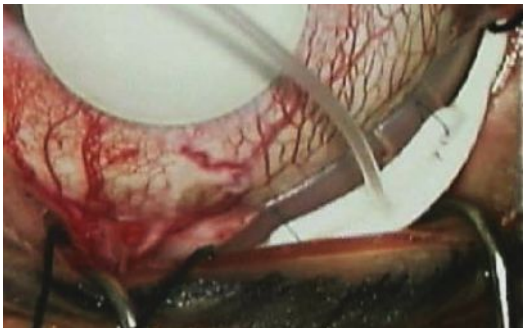
• ***Transscleral cyclophotocoagulation.*** I usually reserve this option for patients with very poor visual potential, those for whom trabeculectomy or an aqueous shunt are contraindicated for any of the reasons mentioned above, and those for whom a Schlemm's canal procedure isn't appropriate, either because you don't have an adequate view of the angle, or because you need to achieve a very low IOP. Downsides of this procedure as a stand-alone treatment include the difficulty of titrating the amount of laser administered. There's a risk of hypotony, which is irreversible after using the laser because there's nothing to reverse, unlike a tube or trab. Also, the risk of cystoid macular edema and visual problems is greater when large amounts of laser are administered.

One major advantage of this option is that it can be used as an adjunct to a functioning aqueous shunt if the pressure still isn't low enough. In that situation, you don't have to do extensive laser and you'll still improve the outcome. By using a limited amount of laser as an adjunct, you minimize the risk of inflammation and CME, and you may avoid the need to implant an additional shunt.

When Implanting a Shunt

Implanting an aqueous shunt in this situation requires careful preoperative assessment. For example, you need to consider the number, type and location of prior surgeries and the amount and location of conjunctival scarring. Are you dealing with scleral ectasia? Will you need to work around

a pre-existing filtering bleb or aqueous shunt? If you're faced with a scleral buckle, what type of tube shunt should you use? Where should you place it? Is the conjunctiva mobile? What's the status of the conjunctival fornices? Are they foreshortened? Do you see symblepheron formation? Is the patient phakic, aphakic or pseudophakic? What's the configuration of the anterior chamber and the anterior chamber angle?



Endplate of a Baerveldt implant sutured to a scleral encircling band.

• ***Placing the plate.*** If the patient is phakic or pseudophakic, it's preferable to place the plate in the superotemporal or inferonasal quadrant. If the patient is aphakic—especially if the patient has a large pupil—the inferonasal quadrant is often best if gas or silicone oil are present, or may be required.

• ***Working with a scleral buckle.*** When dealing with an existing scleral buckle, or when putting on a buckle at the time of the glaucoma surgery, a low-profile implant like a Baerveldt is a good choice. Its thin and flexible plate is preferred for inserting over a scleral encircling band. It's best to suture it directly to the upper surface of the scleral buckling element. If adjacent rectus muscles can be isolated, you can place the wings of the Baerveldt plate beneath the muscles. (This arrangement works well with narrow, low-profile encircling elements such as the MIRA #40 band.) You can place the plate above the muscles if the degree of scarring is too extensive; you also have the option of trimming the Baerveldt plate if extensive scarring makes placement difficult.

It's helpful to know the type and location of the scleral buckling element you're dealing with. Is it a complete encircling band, or just a segmental buckle? Has it migrated forward, or is it 10 mm back from the limbus? That information will help determine where and how you'll need to place your glaucoma drainage device. If it's 10 mm or more back, you can suture it to the encircling band. If the band has migrated forward and it's 5 mm or less from the limbus, you're probably going to have to secure your plate behind the buckle. (Often you can determine this before you get to the OR.)

The anterior edge of the plate should be 9 to 12 mm posterior to the limbus and sutured directly to the encircling band when possible. Avoid attempting to place it beneath the encircling band; the sclera is often very thin under the band, especially if the band has been on the eye long-term, and scleral perforation is a risk.

• ***Placing the tube.*** You can't place the tube between the iris and the cornea if the iris is pulled up to the cornea because of synechiae, which is not uncommon in these complex eyes. In that situation you want to put the tube either in the ciliary sulcus or through the pars plana, behind the lens implant and into the vitreous cavity. If it goes into the vitreous cavity, you'll need to have removed all of the vitreous gel to avoid occlusion of the tube. In pseudophakic patients, you can put the tube in the sulcus without doing a vitrectomy. (A more posterior location of the tube entry site may facilitate conjunctival closure.)

Tubes and Silicone Oil

When implanting a tube shunt in an eye that either already contains silicone oil, or into which you'll be placing silicone oil, you need to ask a number of questions: Is the patient phakic, aphakic or pseudophakic? How high is the intraocular pressure? Will you be removing the oil? (If so, you can put the tube in the vitreous cavity. If the oil has to stay in, you can't put the tube back in the posterior segment.) Can you wait for silicone oil removal at a future date, or do you need to put the tube in right away to reduce the pressure immediately? What's the status of the corneal endothelium? What's the status of the iris (pupil size, and location and size of iridectomies)? Is there silicone oil in the anterior chamber? If so, does it need to be removed prior to tube insertion?

A few specific issues to consider:

• ***Consider a two-stage procedure***. If you're going to remove the oil in six weeks, you can put the plate on at the time of surgery but hold off on inserting the tube. In a few weeks, when you go back to take the oil out, you can insert the tube.

Of course, in some patients, the oil never comes out. If you believe that's going to be the case with your patient, waiting to insert the tube wouldn't be a great strategy. You could still do the tube shunt surgery in two stages, but you won't be able to put the tube into the vitreous cavity. You'd wind up having to put the tube in the front of the eye (if there was a place for it).

• ***Don't allow anterior prolapse of the oil.*** You have to keep the tip of the tube away from the silicone oil, because if the oil gets into the tube, the implant won't work well. It also could drain oil out of the eye, which would interfere with good retinal tamponade. To prevent anterior prolapse of the oil, you need to avoid abrupt decompression of the eye. You have to be careful about how you put in the tube, so the

pressure doesn't drop precipitously. Intraoperatively, while the patient is supine, viscoelastic may help prevent forward movement of the silicone oil.

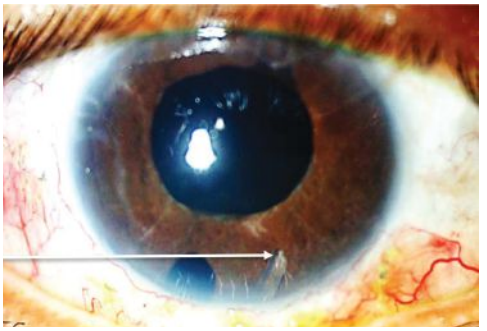
• ***Avoid allowing the tube tip to contact the silicone oil.*** For aphakic patients, keep the tip of the tube peripheral to the pupillary margin. The iris can act as a shield that protects the tube tip from the silicone oil. If the tube tip extends beyond the pupillary margin, the oil will have access to the tip of the tube. Avoid placing the proximal tube tip over iridectomies or iris defects.

• ***If you're doing the tube implant and retinal surgery concurrently, put the tube in first and infuse the oil last.*** If the oil goes in first and you make a hole to put the tube in, the pressure will often drop and oil will come forward into the front of the eye. Once that happens, it can be problematic to get the oil out of the anterior chamber.

• ***A Baerveldt shunt may be preferable to an Ahmed.*** In this situation I like to use non-flow-restricted devices. The Ahmed valve is a little bit unpredictable, and sometimes you wind up with a really low pressure. In an eye with silicone oil, that can be a problem.

For that reason I prefer to use a tube that's completely ligated. You can use any of a variety of methods to control the pressure for the first few weeks, or you can do nothing and manage the patient with medications until the plate becomes encapsulated. Once the plate's encapsulated, you can open the tube.

One way to control the pressure during the first few weeks is to create an "orphan trabeculectomy," done without using mitomycin-C. Without the mitomycin, a trabeculectomy in this setting will generally fail within a few weeks. During that time the glaucoma implant plate is encapsulating. You can laser the stitches selectively, if necessary, to get a gradual reduction in pressure. (You don't want an abrupt pressure drop, or the oil might come forward.)



Inferior tube placement in an aphakic eye with silicone oil. Note the placement of the proximal tip over the iris, away from the peripheral iridectomy and peripheral to the pupillary margin.

Eventually the trabeculectomy will scar over and fail, but by then the tube is ready to take over controlling the pressure. This approach isn't used often because it's a significant amount of additional surgery compared to just fenestrating the tube, but in some patients, it may give you a little bit more control.

• ***If inserting the tube in the presence of silicone oil, use viscoelastic rather than an infusion to keep the chamber from shallowing.*** Using an infusion as an anterior chamber maintainer when inserting a tube isn't a good idea if there's pre-existing silicone oil in the eye. The fluid can end up going behind the oil and pushing it forward. However, you can use some viscoelastic to keep the chamber from abruptly shallowing as you enter the eye with the needle and try to position the tube.

• ***Controlled tube ligature release is helpful.*** I usually release the ligature at three to four weeks. You want to be careful about doing it sooner because of the risk that the plate isn't fully encapsulated. However, you don't want to wait much beyond the five-week mark. If you tie the tube with a 7-0 vicryl suture, by six weeks postop it will dissolve, opening the tube. If that happens between visits, the result will probably be an abrupt drop in pressure, often down to the single digits, as the fluid rushes out of the eye and fills the reservoir. Among other hypotony-related problems, that may cause the silicone oil to move forward into the anterior chamber.

To avoid that, I do a planned ligature release at three to four weeks. I discontinue aqueous suppressant medications several days beforehand, if the IOP isn't terribly high. Then I inject some viscoelastic into the anterior chamber at the slit lamp before I laser the ligature, to prevent hypotony and anterior chamber shallowing. Following ligature release, additional viscoelastic can be injected to maintain the anterior chamber depth and keep the pressure at a physiologic level.

Making the Best of It

The key point I hope you'll take home from this discussion is that glaucoma often is associated with retinal detachment. Sometimes it's pre-existing; sometimes it's related to the detachment itself, or to its treatment.

When you need to address elevated pressure in this situation, surgery may be required. If that's the case, Schlemm's canal surgeries may work in patients with early-to-moderate damage. If you need a more substantial drop in pressure, trabeculectomy is possible, but it's technically challenging in these patients. In most cases, an aqueous tube shunt is a better solution. REVIEW

1. Becker B, in discussion, Smith JL. Retinal detachment and glaucoma. Trans Am Acad Ophthalmol Otolaryngol 1963;67:731-732.
2. Phelps CD, Burton TC. Glaucoma and retinal detachment. Arch Ophthalmol 1977;95:3:418-22.
3. Chang S. LXII Edward Jackson lecture: Open-angle Glaucoma After Vitrectomy. Am. J. Ophthamol 2006;141:1033-1043.


Providing Retinal Care In the COVID-19 Era

How to best tap into government assistance, manage staff, carefully increase office visits and return to a more regular surgical schedule.

Sean McKinney Senior Editor

Timothy G. Murray, MD, MBA, President of the American Society of Retina Surgeons, knew he was insisting on seemingly unforgiveable—but necessary—medicine for his colleagues when he participated in the creation of a now-infamous virtual "ban" on routine patient visits and all surgeries except for emergent/urgent procedures during the first month of the COVID-19 outbreak. Now that the moratorium is over—with retinal specialists and other ophthalmologists planning a phased, regional return to work under the guidance of public health experts and local government leaders—he believes retinal specialists will be able to step up and meet pent-up demand for care without undermining efforts to flatten the regional curves of the deadly pandemic.

"Many of us practice medicine in small groups, following strict infection control measures and performing outpatient procedures," he says. "We have the needed flexibility, nimbleness and practice discipline to keep our patients and ourselves safe—and also cease operations or ramp back up up, as needed, in response to local epidemiological data and other inputs. Here, as COVID-19 continues its ever-branching and uneven penetration of the national patient population, Dr. Murray and other experts offer advice to help you resume—or prepare to resume—patient care, depending on your local circumstances.

The switch from doing procedures the old-fashioned way (top) to doing them with personal protective equipment to guard against COVID-19 infection (right) reflects a stark contrast in practice styles that won't change back any time soon.

Roger Barone

Effects of the Recent Slowdown

Many retinal surgeons cut chunks out of their schedules even before March 18, when the American Academy of Ophthalmology, representing the consensus of the American Society of Retinal Surgeons and all other major societies in ophthalmology, urged ophthalmologists to suspend routine patient visits and restrict their activities to emergent or urgent care/surgery. On April 17, however, after the release of White House guidelines on "Opening Up America Again," David W. Parke II, the chief operating officer of the AAO, announced in an emailed letter to

Mid Atlantic Retina

Gone are the days when Carl Regillo, MD, could comfortably read OCT scans (left), without worrying about getting an infection. The retinal specialist from Mid Atlantic Retina, and director of the Retina Service of Wills Eye Hospital, is shown (right) with certified ophthalmic technician assistant Jennifer Hagan, performing the same evaluation in the COVID-19 era.

all AAO members that it was "time to consider the process of reopening ophthalmology care," based on "local and state governments, on public health authorities interpreting local patterns of disease, on testing availability, on institutional policies and ultimately on individual ophthalmologists. While we closed routine practice nationally, we will open locally." (*See "Reopening Ophthalmology and America" on page 28.*)

"We needed to put those temporary restrictions in place to help get the disease somewhat more under control," says Dr. Murray, who is also founding director and CEO of Miami Ocular Oncology & Retina. "But that first month of significantly reduced care involved a lot of sacrifice that's left lasting effects. Some retina practices went weeks without seeing any patients. Some practices even closed. Our hope is that surgeons can get back on their feet by adapting to our new way of practicing. We hope to provide guidance targeted at returning to practice in the same way that we provided guidance regarding practicing during the earlier stages of pandemic."

Staying Stable

Jim Vander, MD, president of Mid Atlantic Retina, the Retina Service for Wills Eye Hospital, which has 18 locations in Pennsylvania, New Jersey and Delaware, says his independent private practice responded to the slowdown by submitting a successful application for a Paycheck Protection Program loan before the PPP's initial $349 billion offering ran out of funds in mid-April, two weeks after the loan program was launched.

The PPP is part of the $2.2 trillion Coronavirus Aid, Relief, and Economic Security Act (CARES Act), signed into law on March 27, which is designed to provide assistance to small and large businesses and displaced workers affected by the pandemic's nationwide shutdowns in March through May. An additional $310 billion allocation was approved by Congress to replenish the PPP as part of a $484 billion coronavirus relief bill fund for distressed businesses and individuals when this issue of *Review* was being printed.

Mid Atlantic qualifies for the PPP loan because it remains a private practice, as opposed to being a part of a private equity firm, which would't qualify for these loans. Mid Atlantic is categorized by the SBA as a "small business concern," which is usually (but not always) defined as having 500 or fewer employees. Like the president of any other small business affected by the pandemic, Dr. Vander plans to apply his practice's loan to the cost of payroll (except for employees earning more than $100,000 per year) and approved administrative expenses, paying for two month's worth of these costs. Under the loan terms, the portion of the PPP loan that meets payroll will be forgiven by the federal government and must meet 75 percent of the total loan value. The practice will need to repay the balance of any borrowed amount at 1-percent interest, beginning within six months and ending within two years.

Dr. Murray, the ASRS president, also secured a PPP loan to stabilize his practice's financial health. "I applied early, using my existing banking relationship," he says. "Luckily I was able to clear many of the hurdles associated with the PPP loan process and, in fact, my practice just received its PPP funding. Importantly, we're using a unique account for PPP funds to allow better tracking of all usages, especially focused on obtaining loan forgiveness at the conclusion of the loan term."

Tapping Federal Funds

If you plan to tap into future PPP or other CARES Act loan funds that may available, Drs. Murray and Vander recommend using a bank that's familiar with the needs of smaller clients, which typically include medical practices. Preferably, you should have an existing relationship with the lender. Mid Atlantic Retina benefited from the help of Bryn Mawr Trust, headquartered in Bryn Mawr, Pennsylvania, which Mid Atlantic has worked closely with for many years.

"These CARES Act programs are in Bryn Mawr Trust's wheelhouse," says Dr. Vander. "If you're a large bank that deals with large corporate customers, the PPP and other loan programs coming down from the federal government through the SBA may represent a whole different world and mindset. Our previous experience with very large national banks was a struggle after the financial collapse of 2009. These enormous institutions didn't seem to have the people and

systems in place to deal with a corporate structure and size like ours."

Easy Does it

John T. Thompson, MD, one of three partners at Retina Specialists, with offices in Towson, Frederick, and Columbia, Maryland, is not endorsing or participating in a federal assistance program. His practice's 30-member staff is working reduced hours, tackling administrative tasks. "At this point, we've shifted some clinical people to the front desk to help with a high volume of phone calls that are coming in from patients who need to discuss rescheduling issues and related matters," Dr. Thompson says.

Each of the practice's offices is also reducing costs by scheduling one physician at a time, Dr. Thompson notes. When the practice begins to get busier again, he expects the staff to be ready to help ramp up the volume of visits efficiently, having developed experience working with COVID-19 practice safeguards. "Each patient visit involves steps that require more time because of the need for screening, cleaning areas involved in the patient visit and taking other precautions," he notes.

Dr. Thompson admits finances are a concern and recommends adjusting your practice budget so that future revenues can compensate for the lower receivables during the recent slowdown. "Because of the way our medical billing works, we're fine right now. We're collecting for services provided two to three months ago," he says. "Soon, we'll need to contend with a substantial decrease in revenue from the clinical side of our practice. You need to keep in mind that most office-based practices have overhead that's 50 percent. So if your volume goes down by more than half, it essentially means you're barely covering your expenses."

One approach to avoiding cost over-runs is to furlough staff, with the intention of bringing them back when the practice gets busy again. Mid Atlantic Retina, which is preparing for a fiscally challenging second half of this year, has temporarily furloughed about 40 percent of the practice's employees while retaining their benefits during the recent slowdown. All retinal specialists began working three-quarters of their regular daily hours. Dr. Vander, the Mid Atlantic president, said the practice was still preparing for how and when to further open its practice when this publication was being printed.

"We do all of our work in 'outpatient facilities,' some ambulatory-surgery-center-based, and some hospital-based," Dr. Vander explained after the release of the White House guidelines and the Academy's conditional lifting of restrictions. "We're just discussing how to resume elective surgery and can't tell you anything definitive yet."

Patricia Blevins, RN

Drs. Ajay Kuriyan, MD, and David Xu, MD, at Wills Eye Hospital are shown performing a scleral buckle (left) and vitrectomy (right) with COVID-19 protection, including double N95 masks and eye protection, while Dr. Xu carefully avoids contact with the microscope.

New Systems

Specialists recommend introducing systems and protocols that improve efficiency, safety and quality of care under the unique circumstances of the pandemic. Dr. Vander says Mid Atlantic will continue to follow three priorities. "The first one, for which there is no flexibility, is safety," he says. "We make sure everyone is properly equipped and that our protocols are followed to protect our patients, employees, doctors and our families. Priority number two is managing the needs of our patients, and priority three is managing our finances. All three of these priorities are intertwined. We've established the types of patients who need to be seen for anti-VEGF injections and for new symptoms suggesting potentially acute problems, reflected by flashes and floaters, sudden pain and severe vision loss. We've verified that we have the materials and the protocols to see them and, based on that, determined the number of people that we need to keep employed onsite.

"We've also had a number of employees working from home," he ontinues. "Reducing the number of the people in the office has been important. It's not good for safety if you have too many people standing around and chatting. We've reduced the need

for personal protective equipment by reducing the number of people involved. We're starting to get a handle on the patient numbers—who is showing up and what those visits are like. We've structured the visits with the most efficiency and safety in mind. Going forward, we will have to bring some of those people back from furlough, and we hope to bring all of them back."

Managing Surgical Flow

Like most retinal practices, Mid Atlantic has had to limit surgeries to retinal detachments, infected eyes (endophthalmitis) and miscellaneous emergent cases such as trauma. Timely surgery has also been indicated for vitreous hemorrhage related to an acute retinal tear and a posterior vitreous detachment. When elective procedures are added to the mix, Mid Atlantic will continue with innovative protocols developed for surgery in the COVID-19 era. Wills Eye Hospital in Philadelphia, where Mid Atlantic performs operations, has dedicated an operating room to cases involving COVID-19-positive or presumed-positive patients, using a negative air flow environment, according to Dr. Vander. The anesthesia department has established protocols for managing the airways of vulnerable and COVID-19-positive patients. These safeguards will remain in place indefinitely, accommodating increased procedures while the virus remains far from eradicated, according to Dr. Vander.

"We also have a COVID-19-positive treatment room, separate from the OR, at Wills," says Dr. Vander. "So if we have to do a laser treatment or pneumatic retinopexy on a patient who is at high risk or known to be positive, we bring the patient directly into that room, wearing full protective gear during the encounter. A deep cleaning is done after the procedure. Our practice has contributed a laser and a cryotherapy unit for use in that room while we continue to deal with the virus. Only COVID-19-positive and presumed-positive patients will be treated in these rooms."

As time passes, Dr. Vander says the doctors at Mid Atlantic Retina will need to care for more patients who fit the description of high-risk or infected. "Soon the issue we'll have to wrestle with is how to deal with patients who were previously infected," he notes. "When can you let them back into your office? How do you handle the patient who has been exposed because of contact with an infected loved one? For example, how should we handle a man who gets a retinal detachment the day after his wife has been very symptomatic and has tested positive?"

Managing Office Visits

During March and April, Mid Atlantic Retina conducted injection visits and allowed for the care of the acute cases listed earlier. As ophthalmology practices stir back to life, Vander expects to care for more referral patients and will consider when to resume six-month and 12-month follow-up visits that have been postponed indefinitely.

To maintain social distancing and other precautions, Mid Atlantic will continue to minimize exposure to the staff and limit access to different rooms in the office. "We screen patients as they come to the door and typically allow only one or two patients in our waiting room," says Dr. Vander. "The patients appreciate that we're there for them and that there are no other patients around. When they approach the front desk, they're asked to continue walking to a room, which functions as their vision room, exam room and injection room. So there's a minimal amount of contact, physically, with the space, equipment and staff. All surfaces touched by the patient are assumed to be contaminated and are wiped down. We don't rely on gloves to protect against the virus because gloves are no better than your hands if you're touching everything with your gloves on."

Because of these approaches, patients get in and out of the practice faster than ever, says Dr. Vander. "If a back-up of patients develops, we ask the waiting patients to wait in their cars, and we send them a text message or call them on their cell and say, 'Okay it's your turn. Come on in.' "

To respond to the continuing shortage of personal protective equipment, the practice asks patients to wear their own masks, a request that's posted on the practice website and mentioned during all calls and reminders. "We don't feel confident in an ongoing supply to offer masks to patients routinely," Dr. Vander explains. "The priority is to get the health-care workers the masks first. I certainly don't want to take masks away from emergency rooms and hospitals that need them."

Time, Finances and Volume

Besides managing increasing office and OR activity, practices will need to focus on the calendar and their adjusted budgets. "The critical date for us will be two months from the date of our Paycheck Protection loan," says Dr. Vander.

Dr. Murray says his practice will carefully manage the cash flow from his practice's PPP loan. "My tumor practice has high overhead for the OR," Dr. Murray says. "If my volume went down, I'd be hurt without support. I do high-end specialty imaging, which most retina practices don't do. If volume should drop too far, that's when I think most people have to make the difficult decision to let their staffs go. That is, unfortunately, what I still need to tell my employees these days. I tell them that we're not out of the woods yet." REVIEW

A patient with a history of combined cataract surgery and endothelial transplantation presents with decreased vision.

Dilru C. Amarasekera, MD, and James P. Dunn, MD

Presentation

An 80-year-old male presented for evaluation of decreased vision in his left eye. His clinical course began four years prior when he underwent combined phacoemulsification cataract surgery and Descemet's stripping automated endothelial keratoplasty OS for what was described by an outside provider as a unilateral Fuchs' dystrophy. His recovery had been complicated by several episodes of recurrent graft rejection over the four years. He subsequently developed significant cystoid macular edema, believed to be a consequence of both recurrent inflammation and pseudophakia. For management of his CME, he received two injections of sub-Tenon's and 11 injections of intravitreal triamcinolone acetonide over four years. The patient then received an injection of intravitreal ganciclovir four months prior to his Wills Eye visit at an outside provider, with no improvement in his symptoms. He had subsequently developed new, painless, progressive, unilateral decreased vision, prompting referral to Wills Eye Hospital.

Medical History

The patient had an ocular history of unilateral corneal endothelial degeneration that required a combination phacoemulsification/DSAEK; cystoid macular edema; and steroid-induced glaucoma that had required the implantation of a tube shunt and an iStent OS. His medical history was notable for basal cell carcinoma. Family history was notable only for a sibling with diabetes. His ocular medications at presentation were brimonidine 0.2%-timolol 0.5%, sodium chloride 5%, difluprednate 0.05%, bromfenac 0.07% and cyclosporine 0.05% drops. His systemic medications were aspirin, vitamin B, saw palmetto, vitamin D and turmeric. He was retired with no recent travel or substance abuse history.

Examination

Ocular examination revealed visual acuity of 20/20 in the right eye and count fingers in the left. Pupillary examination showed a 1+ relative afferent pupillary defect OS. Intraocular pressure was 11 mmHg OD and 3 mmHg OS. Extraocular movements and confrontation visual fields were full bilaterally.

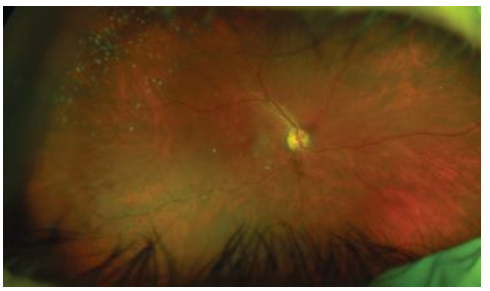


Figure 1. Right eye fundoscopy remarkable only for asteroid hyalosis and posterior vitreous detachment.

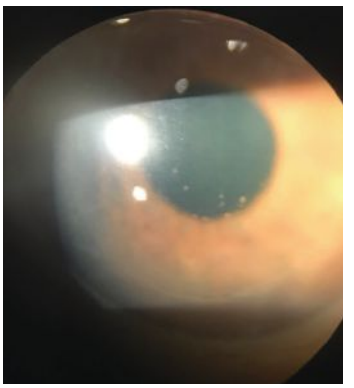


Figure 2. Left eye anterior segment evaluation revealing prior DSAEK with keratic precipitates localized to the inferior graft.

Anterior segment examination of the right eye was notable only for a posterior chamber intraocular lens with 1+ posterior capsule opacification, posterior vitreous detachment and asteroid hyalosis *(Figure 1)*. Examination OS *(Figure 2)* showed 1+ conjunctival injection. The cornea showed a DSAEK with trace endothelial folds and 1+ keratic precipitates localized to the inferior graft. There was no evidence of a rejection line. The anterior chamber was deep with 1 to 2+ flare, a well-positioned tube shunt at 11 o'clock and a centered PCIOL.

Posterior segment examination showed trace vitreous cell, macular thickening and attenuated blood vessels. Most notable was flat, granular, hemorrhagic retinitis in the temporal periphery and a chorioretinal scar superiorly *(Figure*

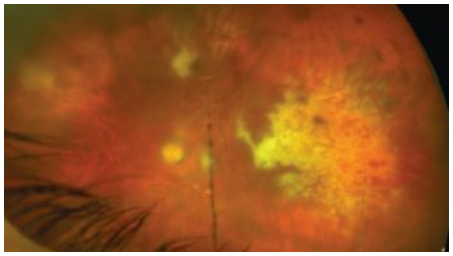


Figure 3. Left-eye fundoscopy with evidence of vitritis, temporal hemorrhagic retinitis, and superior chorioretinal scarring.

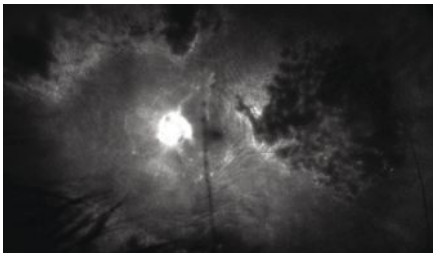


Figure 4. Fluorescein angiography consistent with granular, hemorrhagic retinitis and ischemia of the left eye.

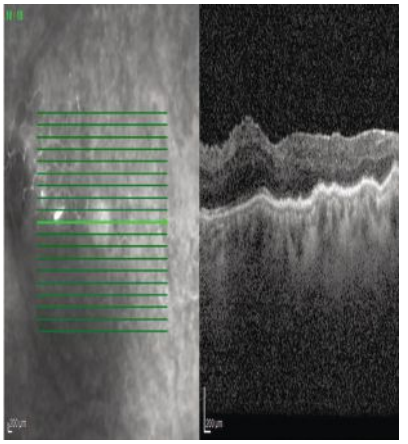


Figure 5. Optical coherence tomography showing retinal thickening consistent with macular edema and areas of retinal necrosis.

3). The optic disc appeared healthy.

Fluorescein angiography of the right eye was grossly normal. Optical coherence tomography of the right macula showed PVD and scattered drusen. A fluorescein angiogram of the left eye showed granular, hemorrhagic temporal retinitis *(Figure 4)*, and OCT of the macula showed retinal thickening consistent with macular edema as well as regions of necrotic-appearing retina *(Figure 5)*.

Based on this information, what's your diagnosis? The diagnosis appears below.

Workup, Diagnosis and Treatment

The differential for this patient's decreased vision and associated retinal findings was broad. The retina of the left eye appeared to have lesions that suggested retinal necrosis, and thus suspicion for an infectious etiology was high. Possible diseases included acute retinal necrosis, progressive outer retinal necrosis, cytomegalovirus retinitis, toxoplasmic retinitis and bacterial or fungal retinitis. Possible inflammatory causes included Vogt-Koyanagi-Harada disease, Behçet's disease and sarcoidosis.

An anterior chamber paracentesis was performed on the left eye with an aqueous sample sent for herpesviral and *Toxoplasma gondii* polymerase chain reaction testing. The aqueous tested positive for CMV at a titer of 1,100,000 IU/mL.

Treatment was promptly initiated for CMV retinitis in the setting of local immunocompromise. At Wills Eye Hospital he was treated with valganciclovir 900 mg twice a day for three weeks, then 900 mg once daily thereafter.

At six week follow-up the patient had mild improvement of his retinitis on fundoscopy. He was continued on a regimen of valganciclovir 900 mg daily and difluprednate 0.05% twice a day with plans for follow-up in two months.

Discussion

In an immunocompromised host, CMV, which circulates through the bloodstream following primary infection, may spread to the retina through the retinal vasculature. Individuals with HIV are known to have damaged vascular endothelium and decreased blood flow through the retina that predisposes them to develop subsequent retinitis.[1] Also, though it's rare, viral retinitis is a well-described complication of intraocular or periocular corticosteroid administration in patients without AIDS or iatrogenic immunosuppression.[2-4] In immunocompetent patients, the theorized mechanism of infection is less well-described, but is likely due to localized retinal immunosuppression following local steroid administration that enables opportunistic infections such as CMV.[2]

Our patient had undergone a prolonged treatment course for CME that included two sub-Tenon's steroid injections and 11 intravitreal steroid injections. The dose of steroids needed to cause local immunocompromise predisposing to viral retinitis varies significantly. Pleasanton, California, ophthalmologist Ako Takakura and her colleagues analyzed 30 reported cases of viral retinitis following intraocular or periocular corticosteroid administration and found that patients received doses ranging from 1.5 mg to 40 mg of differing forms of steroids prior to development of viral retinitis. The review also found that 85.7 percent of patients who developed viral retinitis had received only a single intravitreal steroid injection.[3]

Several studies have aimed to identify risk factors that place immunocompetent patients receiving intraocular steroid treatments at higher risk of developing viral retinitis. Several case reports have documented patients with known HIV with relative immune reconstitution and elevated CD4

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counts on highly active anti-retroviral therapy who developed CMV retinitis following administration of intraocular steroid injections. This suggests that this subset of patients may be at higher risk of developing viral retinitis despite CD4 counts well above the usual level associated with CMV retinitis.[3,4]

Dr. Takakura reviewed 30 cases with viral retinitis following regional steroid injections or implants, of which 23 (76.7 percent) were due to CMV. Diabetes was the most common risk factor. Two patients developed recurrence of CMV retinitis following treatment for immune recovery uveitis.[3] One study reported an incidence of CMV retinitis following intravitreal steroid injections of 3/334 (0.9 percent) in patients with an immune-altering condition, including one patient each with diabetes, HIV infection with prior CMV retinitis but CD4+ count >200 cells/mL, and chemotherapy. More frequent and higher doses of intravitreal steroids were also felt to be risk factors. The authors theorized that the persistent microangiopathy present in patients with diabetes mellitus both predisposed them to macular edema requiring steroid injection and facilitated entry of viruses such as CMV into the retina.[4]

While the foundation of management of CMV retinitis in the immunocompromised population involves immune reconstitution in combination with antiviral agents, no clear guidelines exist for treatment in the immunocompetent population. One study suggests that systemic therapy alone may be used for peripheral, non-sight-threatening lesions. The addition of intravitreal ganciclovir or foscarnet is recommended for patients with progression of disease despite systemic therapy or lesions near the macula or optic nerve.[5] Systemic agents typically include oral ganciclovir or intraveneous ganciclovir, foscarnet or cidofovir.

The patient described in this case suffered from a course of chronic, anterior uveitis of the right eye that was thought to be due to recurrent graft rejection. A study of ocular manifestations of CMV in immunocompetent patients described precipitates that are often small, non-granulomatous and stellate in shape, as well as the "circinate" precipitates that are characteristic of CMV. Affected patients also often notably have keratic precipitates superior to the corneal equator.[6,7] While our patient did have keratic precipitates localized to his DSAEK that could indeed represent recurrent graft rejection, it's possible that they represented the first manifestation of chronic infection.

In summary, viral retinitis is a rare but well-reported complication of intraocular or periocular corticosteroid use of which ophthalmologists should remain aware. Cases have been reported following even a single dose of intravitreal triamcinolone. Patients with a history of HIV are at increased risk of developing recurrent CMV retinitis despite immune reconstitution, as are previously uninfected diabetic patients, due to predisposing vasculopathy. Treatment regimens vary greatly but typically involve a combination of systemic and intravitreal antiviral medications. CMV is an inflammatory condition with various insidious and devastating anterior and posterior intraocular presentations, even in the immunocompetent population. REVIEW

1. Faber DW, Wiley CA, Lynn GB, Gross JG, Freeman WR. Role of HIV and CMV in the pathogenesis of retinitis and retinal vasculopathy in AIDS patients. Invest Ophthalmol Vis Sci 1992;33:8:2345-53.
2. Vertes D, Snyers B, De potter P. Cytomegalovirus retinitis after low-dose intravitreous triamcinolone acetonide in an immunocompetent patient: A warning for the widespread use of intravitreous corticosteroids. Int Ophthalmol 2010;30:5:595-7.
3. Takakura A, Tessler HH, Goldstein DA, et al. Viral retinitis following intraocular or periocular corticosteroid administration: A case series and comprehensive review of the literature. Ocul Immunol Inflamm 2014;22:3:175-82.
4. Shah AM, Oster SF, Freeman WR. Viral retinitis after intravitreal triamcinolone injection in patients with predisposing medical comorbidities. Am J Ophthalmol 2010;149:3:433-40.e1.
5. Port AD, Orlin A, Kiss S, Patel S, D'amico DJ, Gupta MP. Cytomegalovirus retinitis: A review. J Ocul Pharmacol Ther 2017;33:4:224-234.
6. Joye A, Gonzales JA. Ocular manifestations of cytomegalovirus in immunocompetent hosts. Curr Opin Ophthalmol 2018;29:6:535-542.
7. Chan NS, Chee SP, Caspers L, Bodaghi B. Clinical features of CMV-associated anterior uveitis. Ocul Immunol Inflamm 2018;26:1:107-115.

XIIDRA® (lifitegrast ophthalmic solution), for topical ophthalmic use
Initial U.S. Approval: 2016

BRIEF SUMMARY: Please see package insert for full prescribing information.

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation *[see Adverse Reactions (6.2)]*.

6 ADVERSE REACTIONS

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

- Hypersensitivity *[see Contraindications (4)]*

6.1 Clinical Trials Experience

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

In five clinical studies of DED conducted with lifitegrast ophthalmic solution, 1401 patients received at least one dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤ 3 months of treatment exposure. One hundred-seventy patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5%-25% of patients were instillation-site irritation, dysgeusia, and reduced visual acuity.

Other adverse reactions reported in 1%-5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus, and sinusitis.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Xiidra. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported *[see Contraindications (4)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Xiidra use in pregnant women to inform any drug-associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation Day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear *[see Clinical Pharmacology (12.3) in the full prescribing information]*.

Data

Animal Data

Lifitegrast administered daily by IV injection to rats, from pre-mating through gestation Day 17, caused an increase in mean pre-implantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg/day, representing five, 400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg/day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation Days 7 through 19. A fetal no observed adverse effect level (NOAEL) was not identified in the rabbit.

8.2 Lactation

Risk Summary

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low *[see Clinical Pharmacology (12.3) in the full prescribing information]*. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

8.4 Pediatric Use

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

8.5 Geriatric Use

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

Manufactured for:
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936

T2019-110

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

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

References:

1. Xiidra [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019. **2.** TFOS DEWS II Research Subcommittee. Report of the Research Subcommittee of the Tear Film & Ocular Surface Society Dry Eye WorkShop II (2017). *Ocul Surf.* 2017;15(3):269-649. **3.** FDA approves new medication for dry eye disease. FDA News Release. July 2016. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-dry-eye-disease. Accessed March 17, 2020. **4.** Food and Drug Administration. Electronic Orange Book. https://www.fda.gov/media/71474/download. Accessed March 17, 2020.

Indication

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

Important Safety Information

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

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

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

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

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