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Retina Today

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Diversity and Inclusion

Where is the field of retina today?

With Guest Editors María H. Berrocal, MD
and Audina M. Berrocal, MD

RACIAL BIAS IN CLINICAL TRIALS:
WHAT YOU NEED TO KNOW

THE NEXT GENERATION
OF LEADERS IN RETINA

A WORD FROM MEMBERS OF
THE LGBTQ COMMUNITY





DON'T DELAY TREATMENT IN DME

HELP REDUCE INFLAMMATION IN DIABETIC MACULAR EDEMA (DME)

- Achieved clinically significant 3-line gains in BCVA^{1,*}
- Suppresses inflammation by inhibiting multiple inflammatory cytokines²

*BCVA = best-corrected visual acuity.

Indications and Usage **Diabetic Macular Edema**

OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of diabetic macular edema.

Retinal Vein Occlusion

OZURDEX® is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Posterior Segment Uveitis

OZURDEX® is indicated for the treatment of noninfectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

Contraindications

Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active

or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Glaucoma: OZURDEX® is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

Torn or Ruptured Posterior Lens Capsule: OZURDEX® is contraindicated in patients whose posterior lens capsule is torn or ruptured because of the risk of migration into the anterior chamber. Laser posterior capsulotomy in pseudophakic patients is not a contraindication for OZURDEX® use.

Hypersensitivity: OZURDEX® is contraindicated in patients with known hypersensitivity to any components of this product.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX® (dexamethasone intravitreal implant), have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored regularly following the injection.

Steroid-related Effects: Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

Adverse Reactions

Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of OZURDEX® for diabetic macular edema include: cataract (68%), conjunctival hemorrhage (23%), visual acuity reduced (9%), conjunctivitis (6%), vitreous floaters (5%), conjunctival edema (5%), dry eye (5%), vitreous detachment (4%), vitreous opacities (3%), retinal aneurysm (3%), foreign body sensation (2%), corneal erosion (2%), keratitis (2%), anterior chamber inflammation (2%), retinal tear (2%), eyelid ptosis (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: hypertension (13%) and bronchitis (5%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 28% of OZURDEX® patients versus 4% of sham patients. 42% of the patients who received OZURDEX® were subsequently treated with IOP-lowering medications during the study versus 10% of sham patients.

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6-month period).

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX® group and 12 months in the Sham group. Among these patients, 61% of OZURDEX® subjects versus 8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and 20 for Sham) of the studies.

Retinal Vein Occlusion and Posterior Segment Uveitis

Adverse reactions reported by greater than 2% of patients in the first 6 months following injection of OZURDEX® for retinal vein occlusion and posterior segment uveitis include: intraocular pressure increased (25%), conjunctival hemorrhage (22%), eye pain (8%), conjunctival hyperemia (7%), ocular hypertension (5%), cataract (5%), vitreous detachment (2%), and headache (4%).

Increased IOP with OZURDEX® peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received OZURDEX® required surgical procedures for management of elevated IOP.

Dosage and Administration

FOR OPHTHALMIC INTRAVITREAL INJECTION. The intravitreal injection procedure should be carried out under controlled aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

Please see Brief Summary of full Prescribing Information on adjacent page.

References: 1. Data on file, Allergan. 2. OZURDEX® Prescribing Information.

Ozurdex®
(dexamethasone intravitreal
implant) 0.7 mg

OZURDEX®

(dexamethasone intravitreal implant) 0.7 mg

Brief Summary—Please see the OZURDEX® package insert for full Prescribing Information.

INDICATIONS AND USAGE

Retinal Vein Occlusion: OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Posterior Segment Uveitis: OZURDEX® is indicated for the treatment of non-infectious uveitis affecting the posterior segment of the eye.

Diabetic Macular Edema

OZURDEX® is indicated for the treatment of diabetic macular edema.

CONTRAINDICATIONS

Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Glaucoma: OZURDEX® is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

Torn or Ruptured Posterior Lens Capsule: OZURDEX® is contraindicated in patients whose posterior lens capsule is torn or ruptured because of the risk of migration into the anterior chamber. Laser posterior capsulotomy in pseudophakic patients is not a contraindication for OZURDEX® use.

Hypersensitivity: OZURDEX® is contraindicated in patients with known hypersensitivity to any components of this product [see *Adverse Reactions*].

WARNINGS AND PRECAUTIONS

Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX®, have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments.

Patients should be monitored regularly following the injection [see *Patient Counseling Information*].

Steroid-related Effects: Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses [see *Adverse Reactions*].

Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

ADVERSE REACTIONS

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

Adverse reactions associated with ophthalmic steroids including OZURDEX® include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Retinal Vein Occlusion and Posterior Segment Uveitis

The following information is based on the combined clinical trial results from 3 initial, randomized, 6-month, sham-controlled trials (2 for retinal vein occlusion and 1 for posterior segment uveitis):

Adverse Reactions Reported by Greater than 2% of Patients

MedDRA Term	OZURDEX® N=498 (%)	Sham N=498 (%)
Intraocular pressure increased	125 (25%)	10 (2%)
Conjunctival hemorrhage	108 (22%)	79 (16%)
Eye pain	40 (8%)	26 (5%)
Conjunctival hyperemia	33 (7%)	27 (5%)
Ocular hypertension	23 (5%)	3 (1%)
Cataract	24 (5%)	10 (2%)
Vitreous detachment	12 (2%)	8 (2%)
Headache	19 (4%)	12 (2%)

Increased IOP with OZURDEX® peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received OZURDEX® required surgical procedures for management of elevated IOP.

Following a second injection of OZURDEX® (dexamethasone intravitreal implant) in cases where a second injection was indicated, the overall incidence of cataracts was higher after 1 year.

In a 2-year observational study, among patients who received >2 injections, the most frequent adverse reaction was cataract 54% (n=96 out of 178 phakic eyes at baseline). Other frequent adverse reactions from the 283 treated eyes, regardless of lens status at baseline, were increased IOP 24% (n=68) and vitreous hemorrhage 6.0% (n=17).

Diabetic Macular Edema

The following information is based on the combined clinical trial results from 2 randomized, 3-year, sham-controlled studies in patients with diabetic macular edema. Discontinuation rates due to the adverse reactions listed in the table below were 3% in the OZURDEX® group and 1% in the Sham group. The most common ocular (study eye) and non-ocular adverse reactions are as follows:

Ocular Adverse Reactions Reported by ≥ 1% of Patients and Non-ocular Adverse Reactions Reported by ≥ 5% of Patients

MedDRA Term	OZURDEX® N=324 (%)	Sham N=328 (%)
Ocular		
Cataract ¹	166/243 ² (68%)	49/230 (21%)
Conjunctival hemorrhage	73 (23%)	44 (13%)
Visual acuity reduced	28 (9%)	13 (4%)
Conjunctivitis	19 (6%)	8 (2%)
Vitreous floaters	16 (5%)	6 (2%)
Conjunctival edema	15 (5%)	4 (1%)
Dry eye	15 (5%)	7 (2%)
Vitreous detachment	14 (4%)	8 (2%)
Vitreous opacities	11 (3%)	3 (1%)
Retinal aneurysm	10 (3%)	5 (2%)
Foreign body sensation	7 (2%)	4 (1%)
Corneal erosion	7 (2%)	3 (1%)
Keratitis	6 (2%)	3 (1%)
Anterior Chamber Inflammation	6 (2%)	0 (0%)
Retinal tear	5 (2%)	2 (1%)
Eyelid ptosis	5 (2%)	2 (1%)
Non-ocular		
Hypertension	41 (13%)	21 (6%)
Bronchitis	15 (5%)	8 (2%)

¹Includes cataract, cataract nuclear, cataract subcapsular, lenticular opacities in patients who were phakic at baseline. Among these patients, 61% of OZURDEX® subjects vs. 8% of sham-controlled subjects underwent cataract surgery.

² 243 of the 324 OZURDEX® subjects were phakic at baseline; 230 of 328 sham-controlled subjects were phakic at baseline.

Increased Intraocular Pressure

Summary of Elevated IOP Related Adverse Reactions

IOP	Treatment: N (%)	
	OZURDEX® N=324	Sham N=328
IOP elevation ≥10 mm Hg from Baseline at any visit	91 (28%)	13 (4%)
≥30 mm Hg IOP at any visit	50 (15%)	5 (2%)
Any IOP lowering medication	136 (42%)	32 (10%)
Any surgical intervention for elevated IOP*	4 (1.2%)	1 (0.3%)

* OZURDEX®: 1 surgical trabeculectomy for steroid-induced IOP increase, 1 surgical trabeculectomy for iris neovascularization, 1 laser iridotomy, 1 surgical iridectomy Sham: 1 laser iridotomy

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6 month period).

Cataracts and Cataract Surgery

At baseline, 243 of the 324 OZURDEX® subjects were phakic; 230 of 328 sham-controlled subjects were phakic. The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX® group and 12 months in the Sham group. Among these patients, 61% of OZURDEX® subjects vs.

8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and 20 for Sham) of the studies.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies with OZURDEX® in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice, and malformations of the abdominal wall/intestines and kidneys in rabbits at doses 5 and 4 times higher than the recommended human ophthalmic dose (RHOD) of OZURDEX® (0.7 milligrams dexamethasone), respectively.

In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in mice. A dose of 0.75 mg/kg/day in the mouse is approximately 5 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m² basis. In rabbits, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.20 mg/kg/day, on gestational day 6 followed by 0.13 mg/kg/day on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A dose of 0.13 mg/kg/day in the rabbit is approximately 4 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m² basis. A no-observed-adverse-effect-level (NOAEL) was not identified in the mouse or rabbit studies.

Lactation

Risk Summary

Systemically administered corticosteroids are present in human milk and can suppress growth and interfere with endogenous corticosteroid production or cause other unwanted effects. There is no information regarding the presence of dexamethasone in human milk, the effects on the breastfed infants, or the effects on milk production to inform risk of OZURDEX® to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OZURDEX® and any potential adverse effects on the breastfed child from OZURDEX®.

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

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to determine whether OZURDEX® (dexamethasone intravitreal implant) has the potential for carcinogenesis or mutagenesis. Fertility studies have not been conducted in animals.

PATIENT COUNSELING INFORMATION

Steroid-related Effects

Advise patients that a cataract may occur after repeated treatment with OZURDEX®. If this occurs, advise patients that their vision will decrease, and they will need an operation to remove the cataract and restore their vision.

Advise patients that they may develop increased intraocular pressure with OZURDEX® treatment, and the increased IOP will need to be managed with eye drops, and, rarely, with surgery.

Intravitreal Injection-related Effects

Advise patients that in the days following intravitreal injection of OZURDEX®, patients are at risk for potential complications including in particular, but not limited to, the development of endophthalmitis or elevated intraocular pressure.

When to Seek Physician Advice

Advise patients that if the eye becomes red, sensitive to light, painful, or develops a change in vision, they should seek immediate care from an ophthalmologist.

Driving and Using Machines

Inform patients that they may experience temporary visual blurring after receiving an intravitreal injection. Advise patients not to drive or use machines until this has been resolved.

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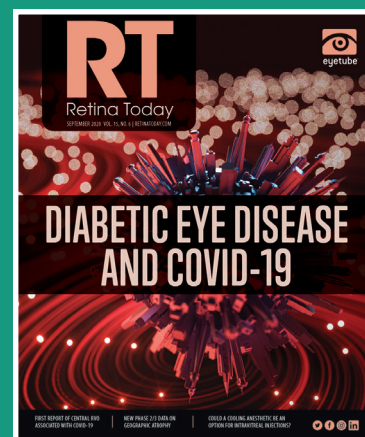
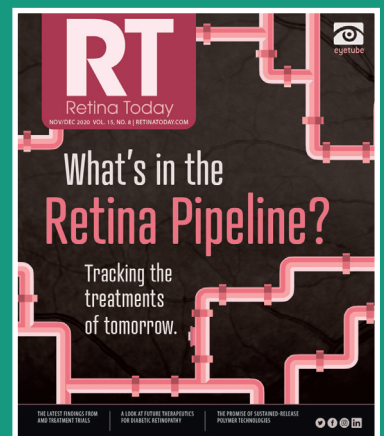
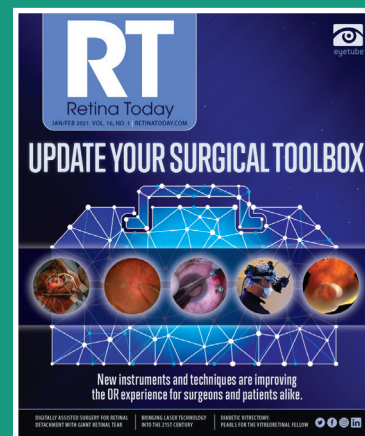
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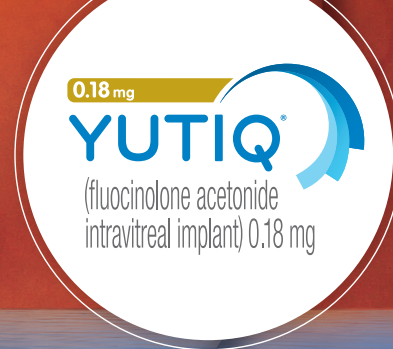
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Discover continuous calm in uveitis

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg:

- **Proven to reduce uveitis recurrence at 6 and 12 months^{1*}**
[At 6 months—18% for YUTIQ and 79% for sham for study 1 and 22% for YUTIQ and 54% for sham for study 2 ($P < .01$). At 12 months—28% for YUTIQ and 86% for sham for study 1 and 33% for YUTIQ and 60% for sham for study 2.]
- **Innovative Durasert® technology is designed for a sustained release of fluocinolone acetonide for up to 36 months with just 1 YUTIQ implant²**

For more
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Now With a Siliconized Needle

*Study design: The efficacy of YUTIQ was assessed in 2 randomized, multicenter, sham-controlled, double-masked, phase 3 studies in adult patients (N=282) with noninfectious uveitis affecting the posterior segment of the eye. The primary endpoint in both studies was the proportion of patients who experienced recurrence of uveitis in the study eye within 6 months of follow-up; recurrence was also assessed at 12 months. Recurrence was defined as either deterioration in visual acuity, vitreous haze attributable to noninfectious uveitis, or the use of prohibited medications.^{1,3}

INDICATIONS AND USAGE

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Ocular or Periocular Infections: YUTIQ is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.

Hypersensitivity: YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

Intravitreal Injection-related Effects: Intravitreal injections, including those with YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection.

Steroid-related Effects: Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

Risk of Implant Migration: Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

Please see next page for Brief Summary of full Prescribing Information.

References: 1. YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg full U.S. Prescribing Information. EyePoint Pharmaceuticals, Inc. October 2018. 2. EyePoint Pharmaceuticals Receives FDA Approval of YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg. Global Newswire. <https://www.globenewswire.com/news-release/2018/10/15/1621023/0/en/EyePoint-Pharmaceuticals-Receives-FDA-Approval-of-YUTIQ-fluocinolone-acetonide-intravitreal-implant-0-18-mg.html>. Accessed February 7, 2020. 3. Data on file.



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02/2021
US-YUT-2100009

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection
Initial U.S. Approval: 1963

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

1. INDICATIONS AND USAGE. YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

4. CONTRAINDICATIONS. **4.1. Ocular or Periocular Infections.** YUTIQ is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases. **4.2. Hypersensitivity.** YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product.

5. WARNINGS AND PRECAUTIONS. **5.1. Intravitreal Injection-related Effects.** Intravitreal injections, including those with YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection [see Patient Counseling Information (17) in the full prescribing information]. **5.2. Steroid-related Effects.** Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection. **5.3. Risk of Implant Migration.** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

6. ADVERSE REACTIONS. **6.1. Clinical Studies Experience.** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids including YUTIQ include cataract formation and subsequent cataract surgery, elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Studies 1 and 2 were multicenter, randomized, sham injection-controlled, masked trials in which patients with non-infectious uveitis affecting the posterior segment of the eye were treated once with either YUTIQ or sham injection, and then received standard care for the duration of the study. Study 3 was a multicenter, randomized, masked trial in which patients with non-infectious uveitis affecting the posterior segment of the eye were all treated once with YUTIQ, administered by one of two different applicators, and then received standard care for the duration of the study. Table 1 summarizes data available from studies 1, 2 and 3 through 12 months for study eyes treated with YUTIQ (n=226) or sham injection (n=94). The most common ocular (study eye) and non-ocular adverse reactions are shown in Table 1 and Table 2.

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

Ocular		
ADVERSE REACTIONS	YUTIQ (N=226 Eyes) n (%)	Sham Injection (N=94 Eyes) n (%)
Cataract ¹	63/113 (56%)	13/56 (23%)
Visual Acuity Reduced	33 (15%)	11 (12%)
Macular Edema	25 (11%)	33 (35%)
Uveitis	22 (10%)	33 (35%)
Conjunctival Hemorrhage	17 (8%)	5 (5%)
Eye Pain	17 (8%)	12 (13%)
Hypotony Of Eye	16 (7%)	1 (1%)
Anterior Chamber Inflammation	12 (5%)	6 (6%)
Dry Eye	10 (4%)	3 (3%)
Vitreous Opacities	9 (4%)	8 (9%)
Conjunctivitis	9 (4%)	5 (5%)
Posterior Capsule Opacification	8 (4%)	3 (3%)
Ocular Hyperemia	8 (4%)	7 (7%)
Vitreous Haze	7 (3%)	4 (4%)
Foreign Body Sensation In Eyes	7 (3%)	2 (2%)
Vitritis	6 (3%)	8 (9%)
Vitreous Floaters	6 (3%)	5 (5%)
Eye Pruritus	6 (3%)	5 (5%)
Conjunctival Hyperemia	5 (2%)	2 (2%)
Ocular Discomfort	5 (2%)	1 (1%)
Macular Fibrosis	5 (2%)	2 (2%)
Glaucoma	4 (2%)	1 (1%)
Photopsia	4 (2%)	2 (2%)

(continued)

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

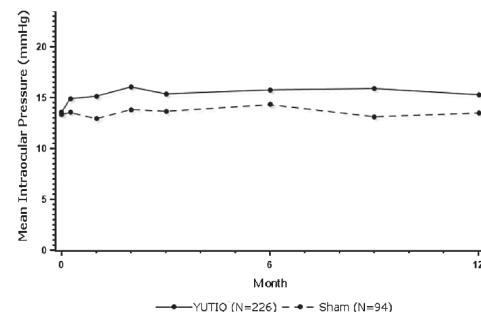
Ocular		
ADVERSE REACTIONS	YUTIQ (N=226 Eyes) n (%)	Sham Injection (N=94 Eyes) n (%)
Vitreous Hemorrhage	4 (2%)	0
Iridocyclitis	3 (1%)	7 (7%)
Eye Inflammation	3 (1%)	2 (2%)
Choroiditis	3 (1%)	1 (1%)
Eye Irritation	3 (1%)	1 (1%)
Visual Field Defect	3 (1%)	0
Lacrimation Increased	3 (1%)	0
Non-ocular		
ADVERSE REACTIONS	YUTIQ (N=214 Patients) n (%)	Sham Injection (N=94 Patients) n (%)
Nasopharyngitis	10 (5%)	5 (5%)
Hypertension	6 (3%)	1 (1%)
Arthralgia	5 (2%)	1 (1%)

1. Includes cataract, cataract subcapsular and lenticular opacities in study eyes that were phakic at baseline. 113 of the 226 YUTIQ study eyes were phakic at baseline; 56 of 94 sham-controlled study eyes were phakic at baseline.

Table 2: Summary of Elevated IOP Related Adverse Reactions

ADVERSE REACTIONS	YUTIQ (N=226 Eyes) n (%)	Sham (N=94 Eyes) n (%)
IOP elevation ≥ 10 mmHg from Baseline	50 (22%)	11 (12%)
IOP elevation > 30 mmHg	28 (12%)	3 (3%)
Any IOP-lowering medication	98 (43%)	39 (41%)
Any surgical intervention for elevated IOP	5 (2%)	2 (2%)

Figure 1: Mean IOP During the Studies



8. USE IN SPECIFIC POPULATIONS. **8.1 Pregnancy.** Risk Summary. Adequate and well-controlled studies with YUTIQ have not been conducted in pregnant women to inform drug associated risk. Animal reproduction studies have not been conducted with YUTIQ. It is not known whether YUTIQ can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. YUTIQ should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. **8.2 Lactation.** Risk Summary. Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production. Clinical or nonclinical lactation studies have not been conducted with YUTIQ. It is not known whether intravitreal treatment with YUTIQ could result in sufficient systemic absorption to produce detectable quantities of fluocinolone acetonide in human milk, or affect breastfed infants or milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for YUTIQ and any potential adverse effects on the breastfed child from YUTIQ. **8.4 Pediatric Use.** Safety and effectiveness of YUTIQ in pediatric patients have not been established. **8.5 Geriatric Use.** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

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THE CONVERSATION STARTS HERE



Diversity and inclusion have become hot-button issues recently, with the COVID-19 pandemic dredging up long-simmering tensions. In particular, the pandemic has put health care in the hot seat, demonstrating glaring disparities in COVID-19 infection and death rates among racial minorities.¹ Unfortunately, health care inequity is not a new concept, even in the field of retina, and many studies highlight treatment disparities and a lack of diverse representation in health care normative databases.²⁻⁵

On the flipside of that coin, diversity is also a work in progress in the health care workforce itself. A recent study in the *New England Journal of Medicine* examined the promotion of women in academic ophthalmology, and the findings weren't promising.⁶ Between 1979 and 2013, fewer women than expected were promoted to associate or full professor or department chair—and the gap didn't narrow between earlier (1979-1997) and later (1998-2013) cohorts. In fact, for promotion to full professor, it widened. Another recent study looked at racial disparities among ophthalmologists, finding that approximately 6% of practicing ophthalmologists are underrepresented minorities, compared with 33% of the general US population.⁷

So, we have a lot of work to do—and that work starts with an unabashed conversation about these disparities and

the steps necessary to close the gap. For this issue of *Retina Today*, we invited retina specialists from all walks of life to share what it's like to rise through the ranks as underrepresented minorities, and, wow, did they deliver.

We have a superb roundtable discussion with three new department chairs who agree that representation in retina leadership is crucial to increasing diversity for the profession as a whole. Elsewhere in the issue, several practices came together to discuss the benefits of a multicultural team, and two physicians tackled the hard conversation regarding microaggressions in clinical practice. Members of the LGBTQ community shared their experiences working their way through training and offered advice for others making the same journey. For a clinical perspective, Joseph M. Coney, MD, highlights the impact of racial disparities in clinical trials. Lastly, an international team of retina specialists provides a glimpse into their latest research.

It's a robust offering, for sure, but it's just the tip of the iceberg. We hope this issue encourages all of our readers to make diversity and inclusion a part of their everyday conversations—and practice. ■

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WET AMD EYE

ANTI-VEGF

Therapy yields better long-term VA results when wet AMD detected with good VA¹

FELLOW EYE

20/79 VA

Mean VA of fellow eyes at wet AMD diagnosis according to real-world data¹

Over 60% of wet AMD “fellow eyes” lose too much vision¹—
even with frequent treatment visits

Detect Early. Treat Early.

ForeseeHome is a **remote monitoring** program for at-risk wet AMD fellow eyes that helps **detect conversion** at 20/40 or better in 83% of patients.²

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& Education

Benefits
Verification &
Authorization

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Monitoring

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Practice Workflow
Implementation

Remote Patient
Management

Vision Alert
Management



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FARICIMAB DEMONSTRATED EFFICACY WITH EXTENDED TREATMENT INTERVALS

In randomized clinical trials including patients with wet AMD or diabetic macular edema (DME), faricimab (Genentech/Roche) given at treatment intervals as great as 4 months demonstrated noninferiority to aflibercept (Eylea, Regeneron) given every 2 months.

Data from the four trials were presented in February at Angiogenesis, Exudation, and Degeneration 2021 and announced in a press release from Genentech.

Faricimab is a bispecific antibody that targets two pathways—angiopoietin-2 and VEGF-A—that drive retinal pathologies including AMD and DME. Inhibiting both pathways may improve vision outcomes for longer than with anti-VEGF monotherapy, thereby reducing the frequency of eye injections needed, according to the press release.

In the YOSEMITE and RHINE studies in patients with DME, faricimab given every 2 months or at personalized treatment

intervals of up to 4 months was compared with aflibercept given every 2 months. Both studies met their primary endpoints of noninferiority to aflibercept in visual acuity gains. Approximately half of patients eligible for extended dosing with faricimab could be treated every 4 months in the first year in the two studies.

In the TENAYA and LUCERNE studies, patients with wet AMD received faricimab given at fixed intervals of every 2, 3, or 4 months, based on their disease activity at weeks 20 and 24, or aflibercept every 2 months. Both studies met their primary endpoints of noninferiority to aflibercept in visual acuity gains.

In all four studies, approximately three-quarters of patients eligible for extended dosing with faricimab were able to be treated every 3 months or longer in the first year. Faricimab was generally well-tolerated in all four studies, with no new or unexpected safety signals identified.

CONTINUED DURABILITY OF GENE THERAPY FOR AMD REPORTED

A durable effect of treatment was seen across several cohorts of patients treated with RGX-314 (Regenxbio), a gene therapy candidate for the treatment of AMD. Updates for an ongoing phase 1/2 study and a long-term follow-up study were presented at Angiogenesis, Exudation, and Degeneration 2021. In addition, the initiation of a larger pivotal study of the therapy was announced.

RGX-314, administered using a subretinal delivery technique, has been generally well-tolerated at all dose levels, according to a press release from Regenxbio that summarized the meeting presentations.

In cohorts 4 and 5 of the phase 1/2 trial, at 1.5 years after RGX-314 administration, a durable treatment effect was observed with stable visual acuity, decreased retinal thickness, and reductions in anti-VEGF injection burden.

In long-term follow-up of cohort 3, a durable treatment

effect was demonstrated over 3 years, with mean improvement in vision and stable retinal thickness. At 3 years, three of the six patients in cohort 3 remain free of anti-VEGF injections, and four of the six had no anti-VEGF injections from 9 months to the 3-year mark. The treatment was well tolerated, with no new drug-related adverse events reported.

"I am excited about this data out to 3 years, which demonstrates that one-time treatment with RGX-314 has the potential to result in long-term stability to improvement of visual acuity outcomes and retinal anatomy, while alleviating treatment burden," Allen C. Ho, MD, said in the press release. Dr. Ho, one of *Retina Today's* medical editors, is an investigator in the RGX-314 clinical trials. "I look forward to further evaluating the effects of RGX-314 in ATMOSPHERE, the first pivotal trial of a gene therapy for the treatment of wet AMD," he added.

ATMOSPHERE, the first of two planned pivotal trials of the therapy, is active and enrolling patients, according to the Regenxbio press release. ■

ULTRA-WIDEFIELD IMAGING GUIDES COATS DISEASE TREATMENT



Fluorescein angiography-guided laser photocoagulation improved a patient's VA from 20/40 to 20/25.

BY MEHREEN ADHI, MD; MARIA REINOSO, MD; ARAVINDA K. RAO, MD; AND MALLIKA DOSS, MD

The advent of ultra-widefield multimodal imaging has significantly improved our understanding and management of peripheral retinal pathology. This is particularly useful in caring for patients with Coats disease.¹⁻⁵ This rare congenital condition is typically characterized by unilateral retinal vessel telangiectasias, light-bulb aneurysms, capillary nonperfusion and leakage in the temporal far periphery, and temporal macular exudation.¹ The case presented here highlights the utility of ultra-widefield multimodal imaging to guide not only the diagnosis of this retinal pathology but also its treatment.

CASE PRESENTATION

A 17-year-old male presented to the retina clinic with blurred vision and VA of 20/40 OS. He had a history of amblyopia in the left eye. The right eye was normal.

The dilated fundus examination and ultra-widefield color fundus photography of the left eye showed exudation in the temporal macula, extensive telangiectatic vessels with terminal bulb-like saccular aneurysmal dilatations in the temporal periphery, and a superotemporal hemorrhage (Figure 1A). Ultra-widefield fundus fluorescein angiography of the left eye showed multiple areas of temporal peripheral leakage and capillary nonperfusion (Figure 1B) consistent with a diagnosis of Coats disease.

The patient was treated with fluorescein angiography-guided laser photocoagulation in two separate sessions. Two months after the first session, ultra-widefield color fundus photography showed resolution of the superotemporal hemorrhage but worsening of exudation in the temporal macula (Figure 2A). Ultra-widefield fundus fluorescein angiography

also showed persistence of multiple areas of leakage and capillary nonperfusion (Figure 2B). This prompted a second session of imaging-guided laser photocoagulation.

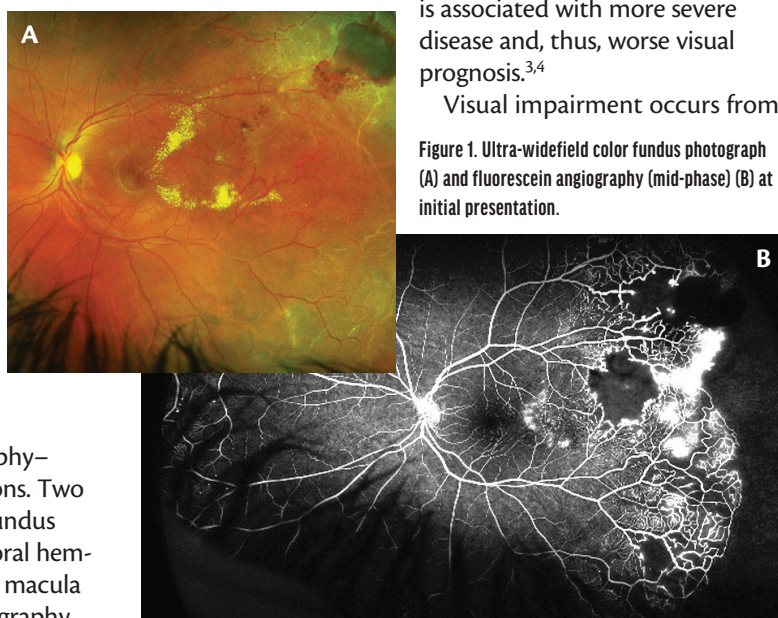
Three months after the second treatment, the patient's VA was 20/25 OS, and ultra-widefield color fundus imaging showed slight improvement in the temporal macular exudation with resolution of temporal aneurysmal dilatations (Figure 3A). Ultra-widefield fluorescein angiography showed considerable decrease in the temporal peripheral capillary nonperfusion and leakage (Figure 3B).

DISCUSSION

Coats disease typically affects young males, with diagnosis at a mean age of 6 years.² Younger age at presentation is associated with more severe disease and, thus, worse visual prognosis.^{3,4}

Visual impairment occurs from

Figure 1. Ultra-widefield color fundus photograph (A) and fluorescein angiography (mid-phase) (B) at initial presentation.



the accumulation of lipid exudates in the macula.¹ Exudation in the macula can be imaged using standard fundus photography and structural OCT. However, the characteristic features of Coats disease, including temporal peripheral retinal vessel telangiectasias and lightbulb aneurysms, can be seen only with ultra-widefield fundus photography. Furthermore, ultra-widefield fluorescein angiography captures the characteristic areas of peripheral temporal capillary nonperfusion and leakage that can help guide treatment with laser photocoagulation. Follow-up imaging with ultra-widefield fundus photography and fluorescein angiography is helpful to determine any changes to the areas of capillary nonperfusion and leakage following treatment.

In this case, after one session of laser photocoagulation,

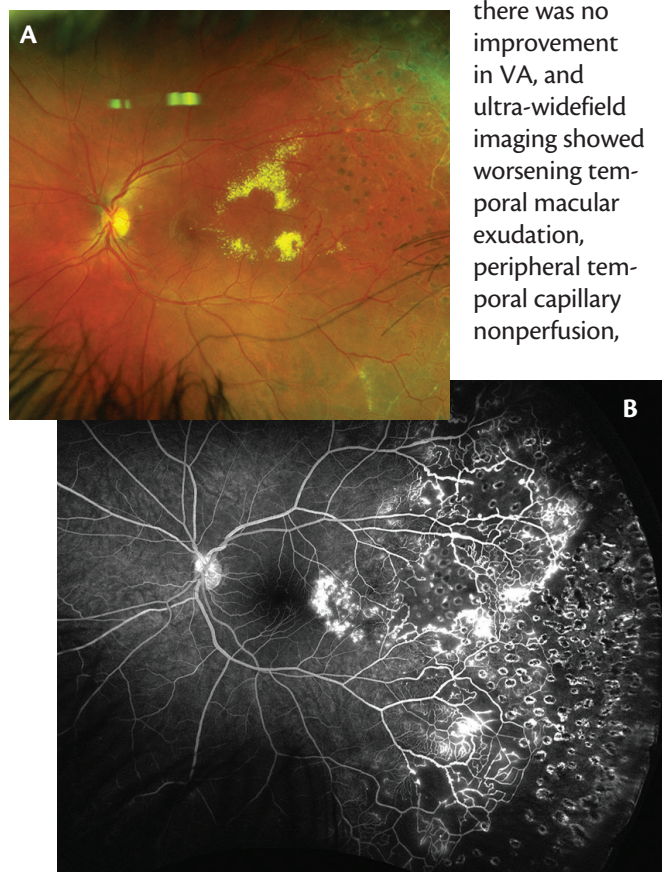


Figure 3. Ultra-widefield color fundus photograph (A) and mid-phase fluorescein angiography (B) 3 months after the second imaging-guided treatment session.

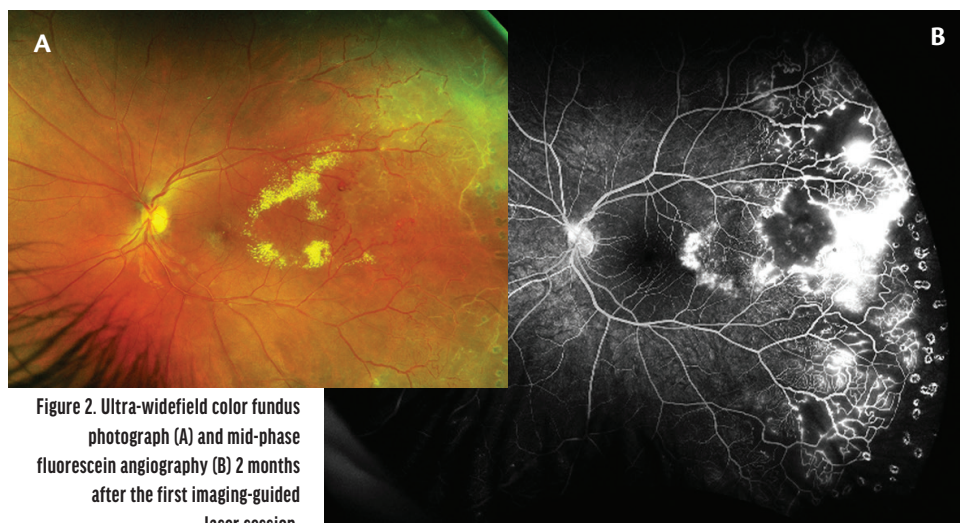


Figure 2. Ultra-widefield color fundus photograph (A) and mid-phase fluorescein angiography (B) 2 months after the first imaging-guided laser session.

there was no improvement in VA, and ultra-widefield imaging showed worsening temporal macular exudation, peripheral temporal capillary nonperfusion,

and leakage. This prompted a second session of imaging-guided laser photocoagulation with consequent improvement in VA.

This case emphasizes the benefit of using ultra-widefield imaging to guide optimal treatment in an adolescent male with Coats disease. Using the ultra-wide field of view, the areas of peripheral nonperfusion and leakage could be discretely identified and treated with laser photocoagulation. ■

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MOVING BEYOND PACHYCHOROID



It is a spectrum that is poorly defined and has no thematic focus.

BY RICHARD F. SPAIDE, MD

The great biologist Georges Cuvier¹ helped establish the field of paleontology and devised classification systems for animals that included the order *Pachydermata*, or thick skin. In this order he included horse, pig, elephant, rhinoceros, and hippopotamus because he thought they all had a thick skin. Later, substantial differences were found among these animals, most notable being that they did not have common ancestors. The attempted unifying principle, thick skin, proved illusory.

The choroids in patients with central serous chorioretinopathy (CSC) were found to be thick compared with normal eyes.² Curiously, the choroids in the fellow eyes were typically greater than normal eyes, and the same for eyes that had resolved CSC.

A link was made between choroidal vascular hyperpermeability seen during indocyanine green (ICG) angiography, a hallmark finding for CSC, and increased choroidal thickness. The choroid is also thicker for other diseases, such as Vogt-Koyanagi-Harada (VKH) disease.³

The term *pachychoroid*, *pachy* meaning thick, was developed to denote a thick choroid. Soon, pachychoroid as an entity was expanded to the pachychoroid spectrum that, in addition to pachychoroid, included entities such as pachychoroid pigment epitheliopathy, pachychoroid neovascularopathy, peripapillary pachychoroid syndrome, and focal choroidal excavation. Somehow, VKH was not included in the list of the pachychoroid spectrum.⁴

INCONSISTENCY IN THE LITERATURE

I recently conducted a literature review of the term pachychoroid and its spectrum.⁴ I found that the definitions of conditions within the pachychoroid spectrum varied substantially from one study to the next, even among those published by the same group. Among the 44 papers about pachychoroid examined, nearly half did not include a definition. For those that had a definition of pachychoroid, there were more than 18 different ones. Some were as simple as

The Euretina Lecture 2020

Dr. Spaide presented his keynote lecture, "Reconsidering Pachychoroid and What it Means" during the Euretina 2020 virtual conference.

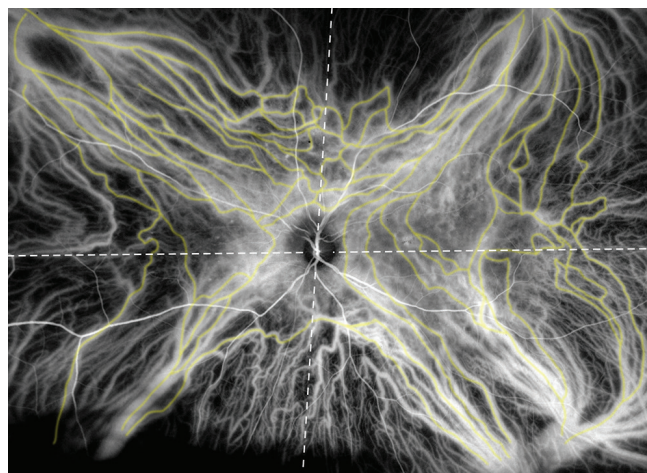


Figure 1. An ICG angiogram of a patient with CSC. Ordinarily, the venous drainage of the choroid is segmental and there would be watershed zones demarcated by the dashed white lines. This eye does not have watershed zones and there are intervortex venous anastomoses (some of which are highlighted in yellow) crossing over the watershed zones.

“choroidal thickening” or similar. In some, the definition was “choroidal thickening or dilated vessels or a history of CSC.” Other studies had specific choroidal thicknesses that the authors considered to be abnormal such as $\geq 200 \mu\text{m}$, $\geq 220 \mu\text{m}$, or $> 270 \mu\text{m}$, with or without the various modifiers such as dilated vessels or a history of CSC. Having a choroidal thickness in an extrafoveal location $50 \mu\text{m}$ greater than the subfoveal choroidal thickness was thought to be a diagnostic criterion.⁴

The lack of uniformity makes comparison between studies nearly impossible. But what about a choroidal thickness of $270 \mu\text{m}$, is that abnormal? What about $220 \mu\text{m}$ or $200 \mu\text{m}$? In a series of children between ages 3.5 and 14.9 years, Bidaut-Garnier et al found the average choroidal thickness was $342 \mu\text{m}$.⁵ Xiong et al found that in a group of myopes between ages 6 and 16 years, the mean subfoveal choroidal thickness was $303 \mu\text{m}$, and many had an extrafoveal location $50 \mu\text{m}$ thicker than the fovea.⁶ Thus, most children, including myopic children, would be considered to have pachychoroid by published definitions. The mean choroidal thickness in a group of 30-year-olds, as published by Tan et al, was $372 \mu\text{m}$, and Entezari et al found the mean subfoveal choroidal thickness in a group with a mean age of 34.6 years was $363 \mu\text{m}$.^{7,8}

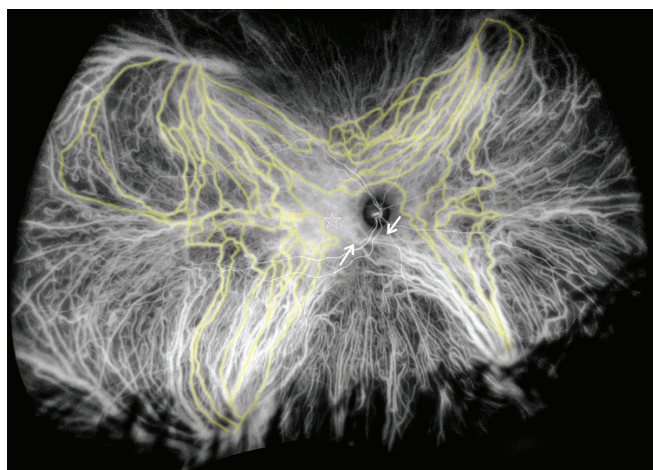


Figure 2. This patient has CSC. The ICG angiogram shows the venous drainage, with some of the intervortex venous anastomoses highlighted in yellow. There were vessels from the inferonasal vortex vein system that crossed over the expected vertical venous watershed zone (arrows) but, because there already is significant leakage in the submacular choroid (star), anastomoses could not be identified.

Many published studies found that mean subfoveal choroidal thickness did not dip below 300 μm until the mid-40s to early 50s. A cutoff of 200 μm , 220 μm , or 270 μm as a threshold for various pachychoroid definitions would imply most people would be considered to have pachychoroid.

AN INCOMPLETE SPECTRUM

Many diseases associated with a thick choroid—such as VKH, choroidal melanoma, lymphomatous infiltration, nanophthalmos, Behcets disease, sarcoidosis, and hypotony—are not included in the pachychoroid spectrum.⁴

The definition of pachychoroid has been changing. More recently, the diagnosis of pachychoroid could be made even if the choroid was not thin, despite the name. One characteristic thought to be important, but not mandatory, was choroidal vascular hyperpermeability seen during ICG angiography. However, many entities associated with hyperpermeability on ICG angiography are not currently listed as being pachychoroid disorders, such as hypertensive choroidopathy, trauma, lupus nephropathy, choroidal hemangioma, and Behcets disease, among many others.⁴

There is a huge variability in the definitions for each of the elements in the pachychoroid spectrum, if they are stated at all, and they have questionable sensitivity and specificity. Therefore, *pachychoroid* and *pachychoroid spectrum* are both incomplete and poorly defined. The terms lack thematic focus, particularly because an eye does not need to have a thick choroid to have pachychoroid. One should question the validity of the “spectrum” purported if there are many diseases that potentially could be included but are not.

CSC is one condition well-known to cause a thick choroid, likely as an epiphenomenon. Pathophysiologic changes that occur in CSC appear to be present in other

diseases, and these findings may help offer a pathophysiologic explanation. For example, a recent study using ICG angiography offered interesting findings in a series of eyes with either CSC or peripapillary pachychoroid syndrome (Figures 1 and 2).⁹ Ordinarily, the vortex vein systems empty the choroid in a quadrant fashion. The vortex veins in each quadrant course toward the vortex vein ampulla and exit the eye near the equator. Each system is independent of the others, and there is a watershed zone between them.¹⁰ In both CSC and peripapillary pachychoroid syndrome, large anastomotic connections were seen between the vortex vein systems—a finding that was uncommon in control eyes.¹⁰ In CSC eyes, these occurred in the central macular region; in peripapillary pachychoroid syndrome, they appeared around the nerve. The same pattern, large intervortex venous anastomoses, was present in eyes with CSC that progressed to neovascularization or polypoidal choroidal vasculopathy.¹⁰

FUTURE DIRECTIONS

The intervortex vein anastomoses fit into larger theories of venous congestion and overloading as mechanistic features leading to disease. The exciting aspect of venous overload choroidopathy as a mechanism of disease is the future possibilities. Theories, by their nature, suggest testable hypotheses. In medicine these testable hypotheses frequently lead to new treatments. The naming system and disease concepts involved in CSC and its related disorders are likely to undergo significant change and refinement in the near future with insights into the appropriate taxonomy and pathophysiology driving disorders of the choroid. These changes will likely create a new system that is more specific, less ambiguous, and related to underlying disease pathogenesis instead of epiphenomena. ■

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FOUR WAYS OUR PRACTICE CHANGED DURING COVID-19



Thinking outside the box and going the extra mile have become the norm for this Israeli clinic.

BY ANAT LOEWENSTEIN, MD

In March 2020, our world turned upside down. Until then, everyone, including retina specialists, was basking in the luxury of the predictable. We scheduled our patients as often as we considered necessary. To achieve good visual results, we knew we needed to follow meticulous monitoring and treatment routines, and so we did.

But with the COVID-19 pandemic, it became abundantly clear to the ophthalmology community that things needed to change. At first, we believed the upheaval would be short-lived, so we treated only the urgent patients. In some countries and institutes, this meant seeing patients with AMD and choroidal neovascularization who were being treated with anti-VEGF agents, but rescheduling patients with diabetic macular edema (DME), assuming the persistent edema in the latter group could wait a few weeks or months until the pandemic was over. We treated urgent cases of retinal detachment, of course, but did not perform elective cataract surgeries.

Unfortunately, the pandemic has lasted well beyond those first weeks and months, and we could not continue to postpone treatment for our nonurgent patients. We started to witness severe irreversible decreases in vision due to the lack of treatment from missed appointments.¹ Finding a way to treat all of our patients in the midst of the pandemic became our highest priority. The solution my department decided to adopt was to decentralize ophthalmic care based on a four-part strategy.

PART 1: ENSURING A SAFE ENVIRONMENT

First, we had to provide patients a safe and protective space by taking all necessary precautions and measures against COVID-19. We prescreened patients to ensure that none were experiencing fever or flu-like symptoms. Protective face masks and social distancing on the patients' part went without saying, and the latter was achieved by moving furniture and roping off chairs in our waiting rooms.



Figure 1. To reduce the risk of exposure, the ophthalmologist sits behind a protective shield when examinations require close contact with a patient.

We also provided personal protective equipment for our staff. In addition to wearing a face mask, our ophthalmologists sit behind a plastic shield that separates them from the patient during slit-lamp evaluations, laser treatments, and imaging studies (Figure 1).

We also reduced the patient load by increasing our clinic hours. We called patients the day before their scheduled appointments to ensure that they planned to come, and we did our best to convince reluctant patients to keep their appointments. Those who did not wish to attend were immediately rescheduled to avoid a future backlog.

Another aspect of ensuring a safe treatment environment was to reduce the length of appointments as much as possible. Our physicians began reviewing the patient's charts and imaging studies (accessible via the institution's electronic medical records database) before summoning the patient to the consultation room. The examination could then be carried out as soon as the patient was seated.

Some ophthalmologists suggested skipping visual acuity evaluations at each visit. To explore the ramifications of such a change, I conducted a small study to assess whether adding a visual acuity finding to the electronically available data led to significant changes in decision-making. The results revealed that visual acuity evaluations caused a change in

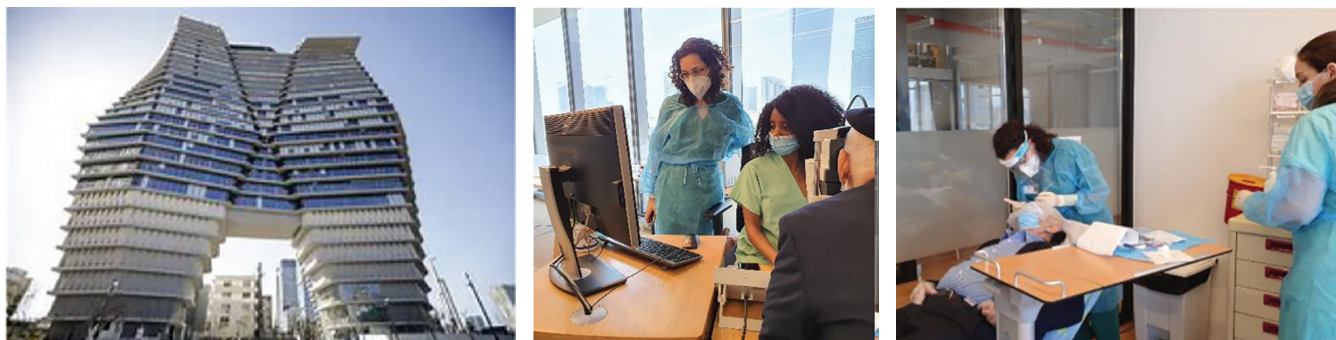


Figure 2. A remote clinic for treatment provides a safer location than the hospital.

management less than 10% of the time. We accepted that as a reasonable level of risk compared with the considerable gain in expediency.

We also considered other changes that could save time and yet carried no risk to patients with AMD: that is, switching patients to a longer-acting drug and changing their regimen to either a treat-and-extend or to a fixed regimen. With these regimens, we saw patients only on the day of injection rather than scheduling monitoring appointments.

PART 2: SEPARATING RETINA CARE

We also endeavored to isolate the ophthalmology visit from the high-risk hospital environment. We opened a clinic in a remote part of the city that allowed us to provide shorter waiting times and a more spacious setting (Figure 2). The office space—a generous donation of WeWork Israel—became available when many of their offices were vacated when people began working from home due to the COVID-19 pandemic.

PART 3: EMBRACING TELEMEDICINE

We also decided to establish an integrative telemedicine clinic. At each office visit, the physician evaluated the patient's suitability for a telemedicine visit for the next follow-up. This was especially useful for patients with external eye disease who could photograph themselves and send an image during the virtual visit. It was also helpful for patients who underwent OCT or other imaging studies at another location.

Importantly, we made arrangements at the hospital management level with the HMO payers to ensure that these visits were reimbursed.

PART 4: INSTITUTING IN-HOME CARE

Our most innovative step was establishing outreach to individual patients' homes. The mission was

to treat those patients with little or no access to health care, as well as patients who were too fragile or ill to leave their homes during the pandemic, all with the aim of preventing deterioration in vision.

Our patient selection strategy was meticulous: We located the patients who missed appointments, were very elderly, had systemic risk factors, or whose disease was one of medical priority (eg, choroidal neovascularization secondary to AMD as opposed to DME). We established a dedicated communication team that evaluated patients for these parameters.

After checking that the home setting was not a risk factor for endophthalmitis, we organized a mobile unit in which the ophthalmologist and a nurse or technician traveled to the patient's home and carried out the necessary injections (Figures 3 and 4).

No published studies have compared the incidence of infection after intravitreal injection in patients' homes versus the clinic setting, although a few studies have compared the impact of carrying out intravitreal injections in the OR compared with the clinic. Those studies concentrated on the incidence of endophthalmitis and, for the most part, showed no difference between locations.² As a point of clarification, most intravitreal injections in Israel are done in the clinic, not in a sterile environment.



Figure 3. In-home injections are offered to those who cannot attend the clinic.



Figure 4. With the right tools and training, ophthalmologists can perform in-home injections for the most high-risk patients.

THE RIGHT TOOLS FOR THE JOB

The unprecedented adjustments we have made highlight the benefits of many emerging treatment options. For example, we now have drugs with a longer duration of action. The FDA-approved anti-VEGF agent brolucizumab-dbl (Beovu, Novartis) can be administered every 3 months, although it remains under investigation regarding the risk of developing intraocular inflammation. Another promising option is faricimab (Roche), an inhibitor of VEGF and angiopoietin-2, which has met the primary endpoint in two phase 3 studies in DME; it is currently under regulatory consideration by the FDA and, if approved, can be administered every 3 or potentially even every 5 months.

An especially exciting development is the Port Delivery System (Roche). The phase 3 Archway trial demonstrated that a refill every 6 months was not inferior in efficacy to monthly ranibizumab (Lucentis, Genentech) injections in terms of improvement in visual acuity and reduction in central retinal thickness.

We look forward to adopting these longer-duration drugs and adding them to our armamentarium of treatments for patients with AMD or DME. However, these longer-acting drugs will require superior techniques for monitoring therapeutic response. Not all of our patients (albeit more than 50%) will be able to benefit from the longer intervals between injections.

Another exciting innovation is the development of at-home OCT (Notal Home OCT, Notal Vision), which has been evaluated in a few studies with successful imaging achieved in 93% of the enrolled eyes.³ Positive and negative agreement for detection of fluid, intraretinal fluid, and subretinal fluid in at least one of three consecutive spectral-domain OCT images was 97%/95%, 96%/94%, and 100%/98%, respectively, with the Notal Home OCT compared with commercial in-office OCT systems. As many as 95% of patients reported that it was easy to operate the device without assistance.

The analysis and depiction of fluid distribution and volume in a longitudinal case study of the Notal Home OCT illustrated the acute nature of wet AMD and the therapeutic response to anti-VEGF injections. The researchers concluded that the at-home OCT system met the requirements for self-controlled imaging by wet AMD patients with regard to image quality, field of view, and usability.

The expectation is that image analysis based on artificial intelligence can potentially support clinicians in the assessment and use of large amounts of data generated by daily at-home OCT imaging.³

KEY TAKEAWAYS

To provide the excellence in ophthalmic care to which we are committed, even in times of pandemic, we must be flexible. We must adapt to new situations, innovate, think outside the box, and dare to try something new.

How will the field of ophthalmology look after the COVID-19 pandemic is finally behind us? I believe our herculean and often exhausting efforts will bring ongoing changes to the ways we provide exceptional care to our patients—pandemic or not. ■

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Beovu[®]

(brolucizumab-dbl)
Injection



Dosage & Administration: BEOVU is administered by intravitreal injection. The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) monthly (approximately every 25-31 days) for the first 3 doses, followed by 1 dose of 6 mg (0.05 mL) every 8-12 weeks.

INDICATIONS AND USAGE

BEOVU[®] (brolucizumab-dbl) injection is indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

BEOVU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation or known hypersensitivity to brolucizumab or any of the excipients in BEOVU. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

AMD=age-related macular degeneration; BCVA=best corrected visual acuity; CST=central subfield thickness; ETDRS=Early Treatment Diabetic Retinopathy Study; IRF=intraretinal fluid; Q8=treatment every 8 weeks; Q12=treatment every 12 weeks; SRF=subretinal fluid.

Contact your local Novartis Sales Specialist or learn more at [BEOVUhcp.com](https://www.BEOVUhcp.com)

For patients with wet AMD¹

THEIR VISION IS A WORK OF ART

In 2 head-to-head trials vs aflibercept, BEOVU^{1,2}:

- **Achieved** similar mean change in BCVA at Week 48^{1*}
- **Started** eligible patients on Q12 immediately after loading, and **maintained** over half at Week 48 (56% and 51%)^{1,2†}
- **Demonstrated** greater CST reductions and fewer patients with IRF and/or SRF as early as Week 16, and at Week 48^{2‡}

In HAWK, superior CST reductions and reductions in the percentage of patients with IRF and/or SRF were achieved at Week 16 and Week 48. In HARRIER, *P* values are nominal and not adjusted for multiplicity.² Clinical significance has not been established. No conclusions of efficacy may be drawn.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachment

Intravitreal injections, including those with BEOVU, have been associated with endophthalmitis and retinal detachment. Proper aseptic injection techniques must always be used when administering BEOVU. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

Retinal Vasculitis and/or Retinal Vascular Occlusion

Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of BEOVU. Patients should be instructed to report any change in vision without delay.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

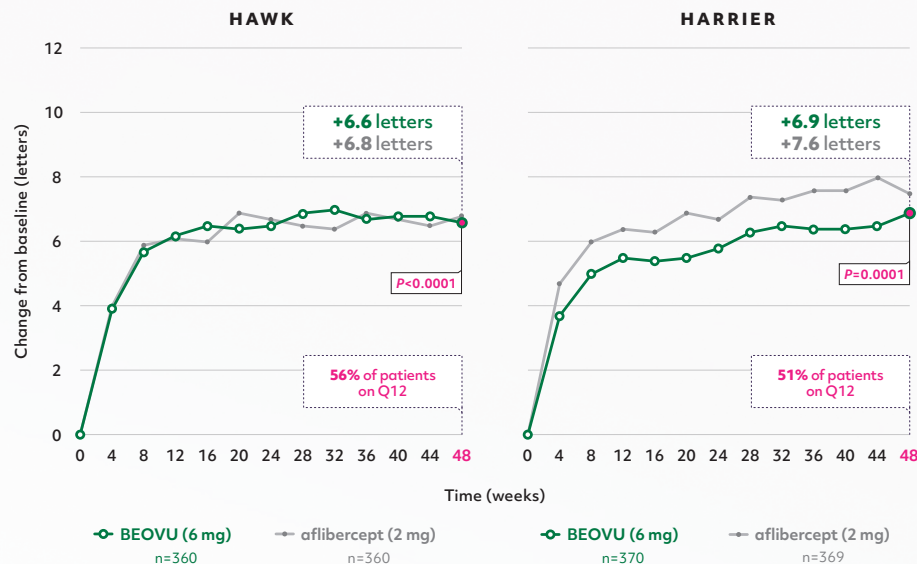
*The primary endpoint was to demonstrate efficacy in mean change in BCVA from baseline at Week 48, measured by ETDRS letters. BEOVU (Q8/Q12) demonstrated noninferiority in BCVA to aflibercept 2 mg (fixed Q8).¹

†In HAWK and HARRIER, respectively. All remaining patients were on Q8. Patients on BEOVU could be adjusted from Q12 to Q8 at any disease activity assessment.^{1,2}

‡CST reductions in patients on BEOVU vs aflibercept at Week 16 in HAWK (*P*=0.0008): -161.4 µm vs -133.6 µm; Week 48 (*P*=0.0012): -172.8 µm vs -143.7 µm. CST reductions in patients on BEOVU vs aflibercept at Week 16 in HARRIER (*P*<0.0001): -174.4 µm vs -134.2 µm; Week 48 (*P*<0.0001): -193.8 µm vs -143.9 µm. Percentage of patients with IRF and/or SRF on BEOVU vs aflibercept at Week 16 in HAWK (*P*<0.0001): 34% vs 52%; Week 48 (*P*=0.0001): 31% vs 45%. Percentage of patients with IRF and/or SRF on BEOVU vs aflibercept at Week 16 in HARRIER (*P*<0.0001): 29% vs 45%; Week 48 (*P*<0.0001): 26% vs 44%.²⁻⁴

Visual gains achieved with BEOVU were similar to aflibercept^{1,2}

Primary endpoint: Mean change in BCVA with BEOVU vs aflibercept from baseline to Week 48^{1,3,4}



The primary endpoint was to demonstrate efficacy in mean change in BCVA from baseline at Week 48, measured by ETDRS letters. Both studies confirmed the hypothesis of noninferiority at Week 48 with a margin of 4.0 letters.^{1,2}

RESULTS SEEN WITH over half of patients on Q12 at Week 48 (56% and 51%)¹

Study design: The safety and efficacy of BEOVU were assessed in 2 randomized, multicenter, double-masked, active-controlled, 2-year, Phase III studies in patients with wet AMD (N=1459). The primary endpoint demonstrated noninferiority in mean change in BCVA from baseline to Week 48 vs aflibercept as measured by ETDRS letters. Patients were randomized to receive either BEOVU 6 mg or aflibercept 2 mg (Q8 per label). Disease Activity Assessments (DAAs) were conducted throughout the trial at prespecified intervals. After 3 initial monthly doses, treating physicians decided whether to treat each patient on a Q8 or Q12 interval guided by visual and anatomical measures of disease activity, although the utility of these measures has not been established. Patients with disease activity at Week 16 or at any DAA could be adjusted to Q8 for the remainder of the study.^{1,2}

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Increase in Intraocular Pressure

Acute increases in intraocular pressure (IOP) have been seen within 30 minutes of intravitreal injection including with BEOVU. Sustained IOP increases have also been reported. Both IOP and perfusion of the optic nerve head must be monitored and managed appropriately.

Thromboembolic Events

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the BEOVU clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. Arterial thromboembolic events are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The ATE rate in the two controlled 96-week neovascular AMD studies (HAWK and HARRIER) during the first 96-weeks was 4.5% (33 of 730) in the pooled brolucizumab arms compared with 4.7% (34 of 729) in the pooled aflibercept arms.

ADVERSE REACTIONS

Serious adverse reactions including endophthalmitis, retinal detachment, retinal vasculitis and/or retinal vascular occlusion, increases in intraocular pressure, and arterial thromboembolic events have occurred following intravitreal injections with BEOVU.

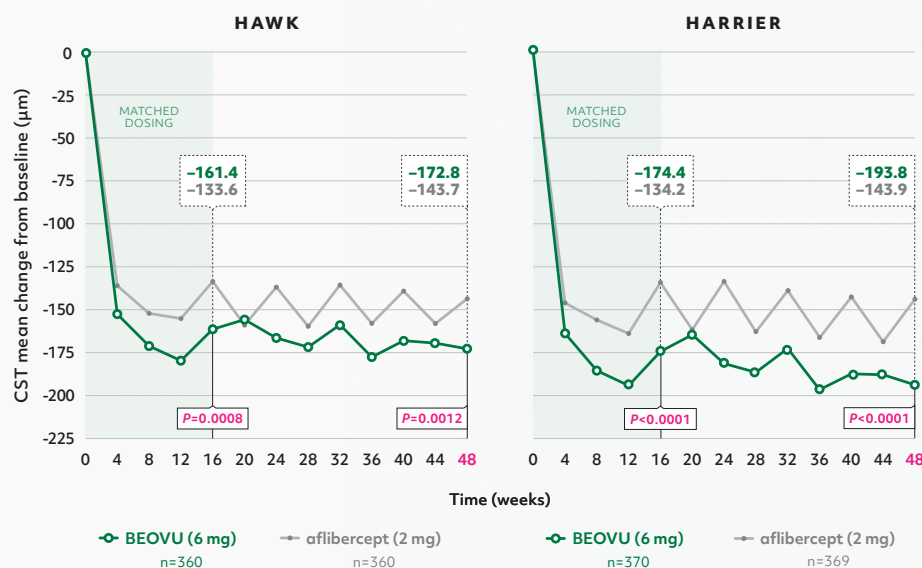
The most common adverse events (≥5% of patients) with BEOVU were vision blurred, cataract, conjunctival hemorrhage, vitreous floaters and eye pain.

REFERENCES: 1. Beovu [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020. 2. Dugel PU, Koh A, Ogura Y, et al, on behalf of the HAWK and HARRIER Study Investigators. HAWK and HARRIER: Phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. *Ophthalmology*. 2020;127(1):72-84. 3. Data on file. RTH258-C001 Clinical Study Report. Novartis Pharmaceuticals Corp; December 2018. 4. Data on file. RTH258-C002 Clinical Study Report. Novartis Pharmaceuticals Corp; December 2018. 5. Data on file. RTH258-C001 & RTH258-C002 CST. Novartis Pharmaceuticals Corp; September 2019.

Learn more at [BEOVUhcp.com](https://www.bEOVUhcp.com)

Greater CST reductions²

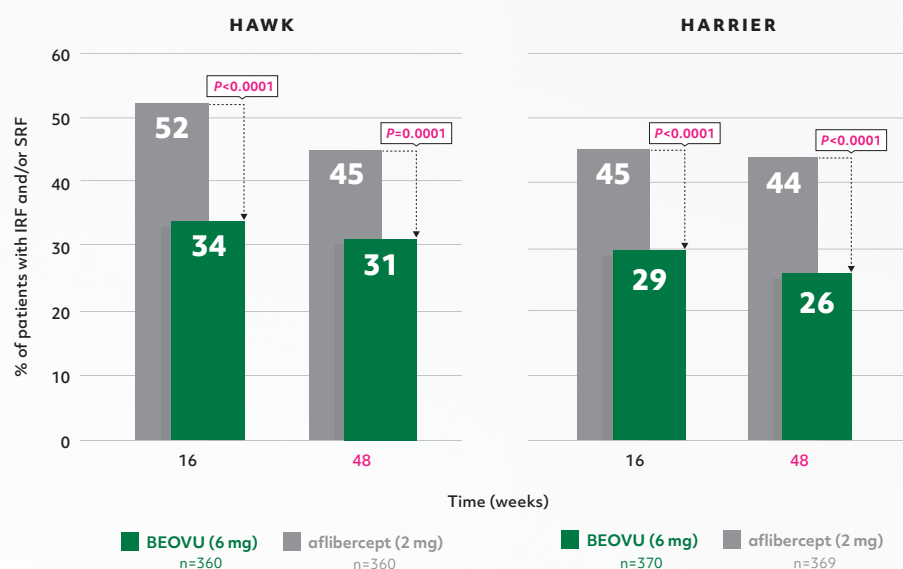
Secondary endpoint: CST reductions with BEOVU vs aflibercept from baseline to Week 48²⁻⁵



In HAWK, superior CST reductions were achieved at Week 16 and Week 48. In HARRIER, P values are nominal and not adjusted for multiplicity.² Clinical significance has not been established. No conclusions of efficacy may be drawn.

Fewer patients with IRF and/or SRF²

Secondary endpoint: % of patients on BEOVU with IRF and/or SRF vs aflibercept at Weeks 16 and 48^{3,4}



In HAWK, superior reductions in the percentage of patients with IRF and/or SRF were achieved at Week 16 and Week 48. In HARRIER, P values are nominal and not adjusted for multiplicity.² Clinical significance has not been established. No conclusions of efficacy may be drawn.

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS (cont)

As with all therapeutic proteins, there is a potential for an immune response in patients treated with BEOVU. Anti-brolucizumab antibodies were detected in the pre-treatment sample of 36% to 52% of treatment naive patients. After initiation of dosing, anti-brolucizumab antibodies were detected in at least one serum sample in 53% to 67% of patients treated with BEOVU. Intraocular inflammation was observed in 6% of patients with anti-brolucizumab antibodies detected during dosing with BEOVU. The significance of anti-brolucizumab antibodies on the clinical effectiveness and safety of BEOVU is not known.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following page.



BEOVU® (brolucizumab-dbil) injection, for intravitreal use
Initial U.S. Approval: 2019

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

1 INDICATIONS AND USAGE
BEOVU® is indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD).

4 CONTRAINDICATIONS
4.1 Ocular or Periocular Infections
BEOVU is contraindicated in patients with ocular or periocular infections.
4.2 Active Intraocular Inflammation
BEOVU is contraindicated in patients with active intraocular inflammation.
4.3 Hypersensitivity
BEOVU is contraindicated in patients with known hypersensitivity to brolucizumab or any of the excipients in BEOVU. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS
5.1 Endophthalmitis and Retinal Detachment
Intravitreal injections, including those with BEOVU, have been associated with endophthalmitis and retinal detachment [see Contraindications (4.1) and Adverse Reactions (6.1)]. Proper aseptic injection techniques must always be used when administering BEOVU. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [see Dosage and Administration (2.4) and Patient Counseling Information (17) in the full prescribing information].
5.2 Retinal Vasculitis and/or Retinal Vascular Occlusion
Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of BEOVU [see Contraindications (4.2) and Adverse Reactions (6.1)]. Patients should be instructed to report any change in vision without delay.
5.3 Increase in Intraocular Pressure
Acute increases in intraocular pressure (IOP) have been seen within 30 minutes of intravitreal injection, including with BEOVU [see Adverse Reactions (6.1)]. Sustained IOP increases have also been reported. Both IOP and perfusion of the optic nerve head must be monitored and managed appropriately [see Dosage and Administration (2.4) in the full prescribing information].
5.4 Thromboembolic Events
Although there was a low rate of arterial thromboembolic events (ATEs) observed in the BEOVU clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. Arterial thromboembolic events are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).
The ATE rate in the two controlled 96-week neovascular AMD studies (HAWK and HARRIER) during the first 96-weeks was 4.5% (33 of 730) in the pooled brolucizumab arms compared with 4.7% (34 of 729) in the pooled aflibercept arms [see Clinical Studies (14.1) in the full prescribing information].

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

- Hypersensitivity [see Contraindications (4.3)]
- Endophthalmitis and Retinal Detachment [see Warnings and Precautions (5.1)]
- Retinal Vasculitis and/or Retinal Vascular Occlusion [see Warnings and Precautions (5.2)]
- Increase in Intraocular Pressure [see Warnings and Precautions (5.3)]
- Thromboembolic Events [see Warnings and Precautions (5.4)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.
A total of 1088 patients, treated with brolucizumab, constituted the safety population in the two controlled neovascular AMD Phase 3 studies (HAWK and HARRIER) with a cumulative 96 week exposure to BEOVU, and 730 patients treated with the recommended dose of 6 mg [see Clinical Studies (14.1) in the full prescribing information].
Adverse reactions reported to occur in ≥ 1% of patients who received treatment with BEOVU pooled across HAWK and HARRIER, are listed below in Table 1.

Table 1: Common Adverse Reactions (≥ 1%) in the HAWK and HARRIER wet AMD Clinical Trials		
Adverse Drug Reactions	BEOVU (N = 730)	Active Control (aflibercept) (N = 729)
Vision blurred ^a	10%	11%
Cataract	7%	11%
Conjunctival hemorrhage	6%	7%
Vitreous floaters	5%	3%
Eye pain	5%	6%
Intraocular inflammation ^b	4%	1%
Intraocular pressure increased	4%	5%
Retinal hemorrhage	4%	3%
Vitreous detachment	4%	3%
Conjunctivitis	3%	2%
Retinal pigment epithelial tear	3%	1%
Corneal abrasion	2%	2%
Hypersensitivity ^c	2%	1%
Punctate keratitis	1%	2%
Retinal tear	1%	1%
Endophthalmitis	1%	< 1%
Blindness ^d	1%	< 1%
Retinal artery occlusion	1%	< 1%
Retinal detachment	1%	< 1%
Conjunctival hyperemia	1%	1%
Lacrimation increased	1%	1%
Abnormal sensation in eye	1%	2%
Detachment of retinal pigment epithelium	1%	< 1%
^a Including vision blurred, visual acuity reduced, visual acuity reduced transiently, and visual impairment. ^b Including anterior chamber cell, anterior chamber flare, anterior chamber inflammation, chorioretinitis, eye inflammation, iridocyclitis, iritis, retinal vasculitis, retinal vascular occlusion, uveitis, vitreous haze, vitritis. ^c Including urticaria, rash, pruritus, erythema. ^d Including blindness, blindness transient, amaurosis, and amaurosis fugax.		
6.2 Immunogenicity As with all therapeutic proteins, there is a potential for an immune response in patients treated with BEOVU. The immunogenicity of BEOVU was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to BEOVU in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to BEOVU with the incidence of antibodies to other products may be misleading. Anti-brolucizumab antibodies were detected in the pre-treatment sample of 36% to 52% of treatment naive patients. After initiation of dosing, anti-brolucizumab antibodies were detected in at least one serum sample in 53% to 67% of patients treated with BEOVU. Intraocular inflammation was observed in 6% of patients with anti-brolucizumab antibodies detected during dosing with BEOVU. The significance of anti-brolucizumab antibodies on the clinical effectiveness and safety of BEOVU is not known.		
8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy <u>Risk Summary</u> There are no adequate and well-controlled studies of BEOVU administration in pregnant women. Based on the anti-VEGF mechanism of action for brolucizumab [see Clinical Pharmacology (12.1) in the full prescribing information], treatment with BEOVU may pose a risk to human embryo-fetal development. BEOVU should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. All pregnancies have a background risk of birth defect, loss, and other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.		

Data

Animal Data

VEGF inhibition has been shown to cause malformations, embryo-fetal resorption, and decreased fetal weight. VEGF inhibition has also been shown to affect follicular development, corpus luteum function, and fertility.

8.2 Lactation

Risk Summary

There is no information regarding the presence of brolucizumab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are transferred in human milk and because of the potential for absorption and adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for at least one month after the last dose when stopping treatment with BEOVU.

8.3 Females and Males of Reproductive Potential

Contraception

Females

Females of reproductive potential should use highly effective contraception (methods that result in less than 1% pregnancy rates) during treatment with BEOVU and for at least one month after the last dose when stopping treatment with BEOVU.

Infertility

No studies on the effects of brolucizumab on fertility have been conducted and it is not known whether brolucizumab can affect reproductive capacity. Based on its anti-VEGF mechanism of action, treatment with BEOVU may pose a risk to reproductive capacity.

8.4 Pediatric Use

The safety and efficacy of BEOVU in pediatric patients has not been established.

8.5 Geriatric Use

In the two Phase 3 clinical studies, approximately 90% (978/1089) of patients randomized to treatment with BEOVU were ≥ 65 years of age and approximately 60% (648/1089) were ≥ 75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies. No dosage regimen adjustment is required in patients 65 years and above.

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FELLOWS' FOCUS

HOW TO APPROACH PEDIATRIC VITREORETINAL SURGERY



Tips on managing and performing surgery on our youngest patients.

AN INTERVIEW WITH YOSHIHIRO YONEKAWA, MD

BY MATTHEW STARR, MD

Pediatric vitreoretinal surgery is perhaps as challenging as it gets in ophthalmology. This interview focuses on how to approach and manage pediatric vitreoretinal surgery and provides pearls for vitreoretinal surgeons performing these delicate retina surgeries.

Matthew Starr, MD: How do you decide when to operate on a pediatric patient with vitreoretinal pathology? What are the most common types of pathologies you see?

Yoshihiro Yonekawa, MD: Deciding to operate or not is an important question when working with children. The stakes are high, and the surgeries should never be approached in a casual “just a vit” type of mindset.

The therapeutic goals are similar to those in adult surgeries: to improve or preserve vision, and in some cases to salvage the globe. However, the surgical and anatomic goals can be quite different. The decision tree is unique for each pediatric vitreoretinal diagnosis, but we ultimately want to improve the quality of life for the many years that these young patients have ahead of them.

There’s no dull moment in our ORs. This coming Monday in the OR, I’m working on kids with optic disc pit maculopathy, stage 4 retinopathy of prematurity, and siblings with von Hippel-Lindau disease, in addition to numerous adult patients. I personally take well over 100 children to the OR in a year, and all of my 19 surgical partners at Wills Eye Hospital and Mid Atlantic Retina operate on pediatric patients also.

Common pathologies that we routinely fix in our practice also include Coats disease, persistent fetal vasculature, familial exudative vitreoretinopathy, X-linked retinoschisis, rhegmatogenous retinal detachment, traumatic macular hole, combined hamartoma, retinoblastoma-related vitreous

hemorrhage and retinal detachment, trauma-associated complications, and many others.

Dr. Starr: Do you approach pediatric cases differently depending on the age of the child? How do you come up with your surgical plan when approaching a pediatric case?

Dr. Yonekawa: It’s important to consider the pediatric patient holistically. We need to consider not just the eye, but also the child’s age, maturity, family support, whether they play high-risk sports, and their systemic medical status and genetic conditions.

For example, if you have a pseudophakic 60-year-old with a superior retinal detachment, most surgeons in the United States would recommend a straight vitrectomy. However, kids with any rhegmatogenous detachment should be considered for a primary buckle, even if there’s proliferative vitreoretinopathy or vitreous hemorrhage. The younger they are, even more so. Sticklers, giant retinal tear, or self-injurious behavior? Then I would prophylactically laser the fellow eye. Will it be hard to examine the patient in clinic, or will the family have difficulty following up? I might consider a prophylactic buckle in the fellow eye depending on the etiology and pathology. Does the child play contact sports? I would counsel the family and patient about the risks and how to protect their eyes.

Here are a few specific examples of age-related considerations for surgical entry into the eye, which can make or break the case.

- We make pars plana incisions in adults at 3.5 to 4.0 mm from the limbus, but we must not do that in very young children. The pars plana may not be fully developed, and we could go right through the retina if we do that.
- For older kids, 3 to 4 mm is OK.
- For a neonate, 1 mm.

WE NEED TO CONSIDER NOT JUST THE EYE, BUT ALSO THE CHILD'S AGE, MATURITY, FAMILY SUPPORT, WHETHER THEY PLAY HIGH-RISK SPORTS, AND THEIR SYSTEMIC MEDICAL STATUS AND GENETIC CONDITIONS.

- If the retina is up against the lens or you have no view in an eye with a peripheral tractional detachment, go limbal, including the infusion.

Think carefully about each incision you make, and make sure to do a good examination under anesthesia first to determine the anatomy. In some eyes, the three cannulas may be in three totally different entry planes. You also may need to sit temporally or even nasally depending on where the pathology is located and where you can safely enter. Maximize your surgical creativity to tackle these cases optimally.

Dr. Starr: What are your rules to live by when performing pediatric vitreoretinal surgery?

Dr. Yonekawa: Preoperative rules:

- Whatever it is, make sure it's not retinoblastoma.
- Think about the entire patient holistically to optimize outcomes.
- Consider widefield fluorescein angiography depending on the differential diagnosis.
- Examine family members if you suspect inherited vitreoretinopathies.
- Make sure to examine the fellow eye well.
- Form a therapeutic alliance with the family.

Intraoperative rules:

- Never make an iatrogenic break in a tractional or exudative retinal detachment. You might lose the eye.
- Scleral buckles are your best friends.
- For vitrectomy cases in which separating the hyaloid is an essential step, use triamcinolone copiously as you will be fooled otherwise.
- No need for tamponade if it's a tractional retinal detachment (retinopathy of prematurity, familial exudative vitreoretinopathy, etc.). Just release the traction without creating breaks. The retinal pigment epithelium will pump the fluid out.
- Know when to *stop* operating. Less is more.

It's also important to communicate well with referring pediatric ophthalmologists. This alliance is key to aggressively address amblyopia and aphakia to optimize visual outcomes.

Dr. Starr: How do you see the future of gene therapy integrating with pediatric vitreoretinal surgery? Is there a specific delivery approach that you think may offer more promise than others?

Dr. Yonekawa: Gene therapy was science fiction a generation ago but is now an FDA-approved reality. Earlier treatment makes sense to optimize long-term outcomes, so I think we will gravitate toward intervening at younger and younger ages.

Gene therapy studies, including those for adult conditions, have been examining subretinal delivery via vitrectomy, subretinal delivery via suprachoroidal catheterization, intravitreal injection, and suprachoroidal injection. There are pros and cons to each of these approaches, but the less invasive ones will be advantageous in minimizing potential complications, assuming that the treatments are equally safe and efficacious.

Dr. Starr: What is your best piece of advice to fellows for performing pediatric vitreoretinal surgery?

Dr. Yonekawa: Helping kids and their families is very rewarding. There's nothing more satisfying than a pediatric vitreoretinal surgery that goes well. You'll often be met with hugs and happy tears of relief from mom and dad. The most common surgical pediatric pathology that young retina surgeons will encounter is rhegmatogenous retinal detachment. Buckle, buckle, buckle. And then buckle some more! ■

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The Next Generation of Leaders in Retina



New chairs in retina talk about their journeys to leadership, including hurdles, lessons learned, and future aspirations.

AN INTERVIEW WITH SOPHIE J. BAKRI, MD, MBA; R.V. PAUL CHAN, MD, MSc, MBA, FACS; AND SHLOMIT SCHAAL, MD, PhD, MHCM
BY MARÍA H. BERROCAL, MD, AND AUDINA M. BERROCAL, MD

This year, the editors of Retina Today chose to expand our usual women in retina issue to encompass diversity and inclusion more broadly, to allow more voices to be heard within these pages. To that end, our guest editors María H. Berrocal, MD, and Audina M. Berrocal, MD, moderated a roundtable with three new department chairs—Sophie J. Bakri, MD, MBA; R.V. Paul Chan, MD, MSc, MBA, FACS; and Shlomit Schaal, MD, PhD, MHCM—each of whom brings much-needed diversity to the leadership within their organizations. Here, we highlight excerpts from their conversation. You can hear the full conversation in the accompanying New Retina Radio Podcast.

— Rebecca Hepp, Editor-in-Chief

María H. Berrocal, MD: The field of retina has evolved a lot, and we see many more women in retina than when I started. Still, we should look at the study recently published in the *New England Journal of Medicine*.¹ When researchers compared the advancement of women through the ranks of academia to professorships and heads of department, they found that we are doing much worse in the past 20 years than in the 20 years prior.

Dr. M. Berrocal: It would be great to hear how you think we can overcome barriers to advancement and have more diverse departments, and the importance of this moving forward.

Sophie J. Bakri, MD, MBA: It is absolutely important. I consider diversity to be diversity of thought, which you get from people of different backgrounds bringing ideas to the table. Department chairs are role models, and if you want a



Listen Now
New Retina
Radio Podcast

Let's Talk Diversity
and Inclusion





Top: Audina M. Berrocal, MD; Shlomit Schaal, MD, PhD, MHCM; R.V. Paul Chan, MD, MSc, MBA, FACS. Bottom: Maria H. Berrocal, MD; Sophie J. Bakri, MD, MBA.

diverse pipeline, you have to have diverse role models and diverse mentors. If people look at the department chairs and see a lack of diversity, they think those positions are not attainable. It's important that the department chairs represent the future of ophthalmology and the people coming through our pipeline, which is the reason we need department chairs from all different backgrounds.

R.V. Paul Chan, MD, MSc, MBA, FACS: Yes, it's an active process. It doesn't change unless we're actively thinking about it, mentoring, and making conscious decisions about putting women on the podium and supporting underrepresented minorities in medicine. In ophthalmology, we are all consciously thinking about promoting diversity at every level, and there are a number of excellent programs that have been developed to help with these initiatives—for example, the AAO's Minority Ophthalmology Mentoring (MOM) program.² That has been a tremendous success over the years.

Something like 17% of all department heads in ophthalmology are women. But if you look further to underrepresented minorities, there are even less.

I agree with Dr. Bakri in saying that leadership should represent the future of our profession. Look at who are becoming doctors now. Over 50% of the medical students coming in are women, and there are growing numbers of Latinos and African Americans. We already know there are a lot of Asians, yet there aren't many Asian leaders. My dad, Guy H. Chan Jr, MD, FACS, was actually the first ophthalmology chair of Chinese descent in the United States, almost 40 years ago now.

We have a responsibility to future generations to mentor and give them examples and the tools to lead and serve.

Shlomit Schaal, MD, PhD, MHCM: My perception is that there has been progress. For example, when I became department chair in June 2016, there were only six women chairs, and I became the seventh; today there are 22 women chairs. We have women chair meetings and leadership groups, and we support each other. The key to progress is having this kind of group support.

Quite frankly, when I was offered the job as chair, I was scared, and I was afraid to take it. It was much more convenient for me to stay where I was and take care of my patients. The chairs that I knew were all men, and I didn't know if I would be good in this role.

One of the reasons I took the job is that a woman, the former dean at the University of Louisville, said to me, "What a wonderful opportunity." I will never forget those words from a woman leader. They gave me the courage to do it, while other people tried to discourage me.

Now, as the UMass Memorial Medical Group President, I have the opportunity to affect and influence the entire health care organization. If no one encouraged me and I hadn't taken the job as chair, I wouldn't be here today. This is the number one message: encourage, support, and believe in women, underrepresented minorities, and people born in other countries who speak different languages and come from other cultures and religions.

Audina M. Berrocal, MD: I think that happens to a lot of women in power positions. Many times, you don't have an example, somebody who supports you, who is not a male. The courage you had to take a job like that is going to change things because you're in power. The change comes from above, and people from different backgrounds open the door to other people who are different.

Dr. Chan: Diversity in any organization promotes better decision-making and better outcomes in general. When we look at residents, fellows, medical students, and even faculty, diversity is critical to evolve and build a better program and a better culture.

I'm a very new chair, and one of my priorities was to have a vice-chair for diversity and inclusion. I'm fortunate to have Jenny Lim, MD, in our department. Jenny is a retina specialist who has a lot of experience promoting young women. She's been a great partner with a lot of great ideas about how we can build our diversity initiatives.

If you don't see people who are succeeding or leading who you think you can model after, that can create a hurdle. Some of the most important people in my life, my mentors, were women. My mother, Nongnart Romayanda Chan, MD, was among the first fellows of William Richard Green, MD, at Wilmer Eye Institute, and I would hear stories about her time as an ophthalmologist in an era when there were not as many women in academic ophthalmology leadership. Joan Miller, MD, who is the chair at Harvard, started her tenure as chair not long before I first started my fellowship there. She has mentored and supported me throughout my career. You have to have mentors, faculty, and leadership who are diverse.

Dr. Schaal: One thing that I would add is that, in medicine, we have a responsibility to our patients. Here in Worcester, Massachusetts, we take care of a diverse population. In our clinic every day, we speak 72 languages with the help of interpreters. It's critical to have a workforce that looks like our patients, in color, shape, language, and culture, to increase the sense of belonging.

When patients come to the clinic and see a physician who looks like them or, better yet, speaks their language, they immediately have a sense of trust, increased belonging. We as leaders have an obligation to support as many caregivers as possible who are representatives of the populations we serve.

Dr. Chan: That is a great point. When we talk about this gap in health equity, it's fundamental that we have physicians and faculty who are representative of the population that we serve. It's been shown that people trust people who speak their own language and are from similar backgrounds.

Dr. A. Berrocal: One criticism you hear often when you're discussing diversity or trying to create a diverse faculty is that you're compromising quality to become diverse. What do you think of this argument?

Dr. Schaal: I hear it a lot in academic medicine. But diversity is an added value. It's not only how good you are as a

researcher, clinician, communicator, teammate, mentor, or author. Diversity is one extra thing that you have.

If I have someone who is a good clinician, a good scientist, and diverse, I think it's superior, because diversity is a value. If someone can increase the diversity of my team, that's a big plus for me.

Dr. M. Berrocal: If we are just focused on grades, we will only have very traditional applicants who will all likely look the same. Someone who comes from a more affluent background may get better board scores than someone who has to work two jobs to make it through medical school. Changing what we value is key.

Dr. Schaal: There is the concept of miles traveled. If you take my example, I traveled across the ocean, had to do all of my training twice and take my board exam twice, just to get to the same level as my peers. When I look at an underrepresented minority, it's about miles traveled, and that's how I try to evaluate our residents. What hurdles did they need to overcome? What mountains did they need to climb? What river did they need to cross to get here?

Dr. A. Berrocal: Some people who make objections to increasing diversity say that it penalizes the efforts of people who grew up in this country because we are giving an opportunity to someone who doesn't have the same scores or qualities.

Dr. Schaal: You should consider both and take both types of candidates. With the US Medical Licensing Examination scores going away, it's going to make our traditional decision-making much more difficult. But that's a very good change. Right now, we are making decisions according to scores. Without these scores in the future, we will be able to select people according to their miles traveled and the level of effort they put into getting here. For example, if someone took a year off to do research or gain experience in other ways, that sets them apart and shows their commitment to the profession.

Dr. A. Berrocal: Dr. Bakri, when you were offered your position, was it easy for you to say yes, or were you holding yourself back because of the few female chairs?

Dr. Bakri: I was appointed to my position through an internal search. That's the way the chair searches are typically done at Mayo Clinic—it is important for Mayo chairs to deeply understand the Mayo Clinic values and culture. Before I even got to the final three, the search committee knew everything about me from my peers and colleagues, and they knew all of the pluses and minuses. I went through the process intrigued as to what they wanted, and

WOMEN IN RETINA: A GLOBAL PERSPECTIVE

One expert shares her experiences as a retina specialist in Israel.

An interview with Anat Loewenstein, MD, MHA



Retina Today: What is it like as a leader in retina in your country, especially as a woman?

Being a leader is the only way to become independent in your thoughts and actions. Early on, I was really against differentiating between men and women in leadership,

and I thought that you should do the best you can at every point, regardless of gender. Now I understand that there are boundaries women face due to cultural and transitional issues. As a woman who has “made it” in a field that for many years was a boy’s club, I need to support women in their careers, young ophthalmologists or retina specialists, to help them achieve their potential.

RT: What hurdles did you have to overcome?

In my institute being a woman did not cause any significant issues. The director of the hospital did not consider gender as an obstacle and supported me in becoming a chair. I did face difficulties in some leadership positions in committees, boards, and advisory boards, which are mainly composed of men who tend to support each other and keep the same traditions.

RT: What advice would you give to aspiring women in retina?

The first piece of advice I would give is to make sure everything is balanced in their personal lives. Then they can devote all their time and energy to developing the field of retina. I would also advise that they share responsibilities both at home and at work—find people they trust and pass on some of their responsibilities. I would recommend they find a mentor, usually a woman, who can help them overcome challenging situations, such as not being promoted or not being entrusted with a leadership position.

ANAT LOEWENSTEIN, MD, MHA

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whether or not I was the person they wanted in terms of what I could do for the department, but also in terms of my phenotype.

And that I wasn’t sure about. I’m certainly different in many ways. When they called to offer me the position, I thought, “Well, they went for me, so then I guess they know what I have to offer, they know who I am.”

I had worked at Mayo Clinic for 15 years, and so they had input from all kinds of stakeholders in the department and the institution as a whole, and they were obviously ready for the change.

Dr. Schaal: As I’m listening to you talk, I hear you say, “Okay, well, if they said it’s OK, then it’s OK.” But you have the inner feeling of, “Am I good enough for this? Does a chair look like that?” There is always an internal voice that kind of holds you back, and maybe it comes from the way we were raised as little girls and what we were encouraged or not encouraged to do.

Recently, I was a candidate in the search for a president of the medical group here. There had never been a woman president of our medical group. As I was preparing for the interview with the search committee, I really thought that the other candidates were better because they fit the mold of what you think a successful president looks like.

Often, we hold ourselves back, and we need people from the side to say, “Yes, you can do it, you would be fantastic.”

Dr. Chan: I think we also have to take into account cultural considerations. As an Asian-American man—my parents were immigrants to this country—you’re told early on, do your work, keep your head down, don’t make a fuss, and, often, don’t ask for what you want. Just serve. There are a lot of cultural issues around this as well.

Dr. Bakri: Like you, Paul, I don’t like to ask for things. But as a department chair, you ask for things for others, which is much easier. You can deflect attention off yourself, empower others, give others roles and help them shine. That’s a good way of building a talent pipeline. When I go and ask for things, I’m not asking for myself, I’m asking for colleagues and other people in my department.

Dr. Schaal: That’s interesting, and I can tell you a quick related story. I had just graduated from a master’s in health care management, and there were many physician leaders in the class. We talked about salary and salary negotiations, and one of the physicians talked about his wife, who is a physician, who, when she negotiated for her salary, basically took whatever they gave her and didn’t ask for anything. But when he was negotiating, she said, “You should ask for this and ask for that.” We are used to fighting for others, and we’re comfortable with that. But we are not so comfortable saying “I deserve to be paid more, and you need to pay me equal or even more because I’m that good.” We still have a journey to get there.

IT'S CRITICAL TO HAVE A WORKFORCE THAT LOOKS LIKE OUR PATIENTS, IN COLOR, SHAPE, LANGUAGE, AND CULTURE, TO INCREASE THE SENSE OF BELONGING.

Dr. A. Berrocal: What do you think is needed to really promote diversity? Where are we in 2021, in our field?

Dr. Schaal: The most important thing is to keep discussing it and keep putting it as a priority. In our medical group, we call it the LEAD Initiative: Leadership, Engagement, Access, and Diversity. Every single month, we discuss diversity, and we involve the entire organization with diversity initiatives. When you hear other departments' efforts to promote diversity and health care equity, you think about it, too.

However, you have to not only talk and think about it, but also you have to have people in place, specifically in leadership positions, who are diverse and will promote the next generation of diverse people.

I know the statistics on diversity in leadership are grim. However, I believe that after all we've been through, specifically in the last year in this nation, people have really felt the inequities. We have the obligation to make that better, make the access to care easier, make the communication clearer, and regain the trust and the sense of belonging.

There's no quick remedy for that, so the three things I would say are, one, keep diversity as a top priority for your organization and your department; two, find leaders from diverse backgrounds; and three, connect with the patients and see how they respond to the changes that you make.

Dr. Bakri: I think it takes role models, leaders at the top, commitment, investment, and developing the talent pipeline with careful mentorship. All patients have to be able to relate to the entire care team. Not just the physicians, but the nurses, the technicians, everybody who takes care of patients. It's important to partner with the community, and partner with local schools, and hire from the community.

Dr. Chan: It also goes beyond the leadership in our departments or how our departments are built; we need programs like the American Society of Retina Specialists' Women in Retina program (WinR) and the AAO's MOM program. An additional factor that is incredibly important is philanthropy. We need endowments to help promote and recruit good people who are diverse and underrepresented in medicine.

Dr. M. Berrocal: This has been wonderful, and I want to thank you all for leading the way into a more diverse environment in retina and ophthalmology, which is so needed in these upcoming years. ■

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1) References CryoTreQ, Technical File STED 2.2.4 "Performance Specifications: In a water bath at a temperature of 37 °C, an ice ball will be formed with a layer thickness of 0.8 mm within 6 seconds".



Retina Around the World

Experts share the latest research and preferred techniques for macular holes, nonexudative macular neovascularization, myopic traction maculopathy, and more.

BY JUDY E. KIM, MD; LIHTEH WU, MD; TAMER H. MAHMOUD, MD, PHD; GIUSEPPE QUERQUES, MD, PHD;
KAZUAKI KADONOSONO, MD, PHD; GEMMY CHEUNG, MD; PAUL S. BERNSTEIN, MD, PHD; AND JOSE A. ROCA, MD



Despite the pandemic, our colleagues around the world continue to explore ways to improve the diagnosis and management of various retinal conditions. Because of COVID-19, perhaps the world has become smaller, as we share information in virtual settings. During the virtual 2020 annual meeting of the AAO, we gathered an international group of experts to share their knowledge and learn the latest research findings from various corners of the world. We are excited to share with you their summaries of the research they presented.

– Judy E. Kim, MD, and Lihteh Wu, MD

ART FOR MACULAR HOLES: OUTCOMES OF THE WORLD STUDY



By Tamer H. Mahmoud, MD, PhD

A multicenter international interventional study with 33 participating surgeons looked at 130 eyes that underwent autologous retinal transplant (ART) for repair of macular holes (MH) and MH retinal detachment (MHRD) to determine anatomic and functional outcomes.¹

Of the 130 eyes, 35 (27%) had primary and 76 (58%) had refractory MHs; 19 (15%) patients had an MHRD that was recurrent in 13 cases, 12 of which had undergone previous internal limiting membrane (ILM) peeling.

The mean maximum and minimum hole diameters were $1,470 \pm 160 \mu\text{m}$ and $840 \pm 94 \mu\text{m}$, respectively. Preoperative BCVA was approximately 20/500.

Grafts were 90% neurosensory retina without choroid, and most (70%) ranged in size from 0 to 1 disc diameter (DD). ARTs were positioned preretinal in 81% and subretinal in 19%. The mean follow-up was 8.6 ± 0.8 months.

In this study, we introduced the term *alignment of the*

neurosensory layers (ANL). When the graft is first placed, vertical lines appear on OCT between the graft and surrounding macular tissue. Within weeks, these lines gradually fade, details of the graft layers can be detected, and they align with similar layers in the surrounding host macular tissue (ie, plexiform to plexiform, nuclear to nuclear, etc.). This could suggest that the macular tissue recognizes the peripheral retinal tissue and may be trying to connect to corresponding layers, leading to integration of the transplant and, thus, better visual outcomes.

Anatomic closure was achieved in 89% of MHs and 95% of MHRDs. Visual acuity gains were substantial: 29% of eyes had at least a 5-line gain, and 43% had at least a 3-line gain. Better final VA was associated with MH closure ($P < .001$), reconstitution of the ellipsoid zone band ($P = .02$), and ANL on OCT ($P = .01$). Fifteen (12%) eyes had a final VA of 20/50 or better, most of which had refractory MHs. The mean preoperative and final BCVAs in this subgroup were, respectively, approximately 20/125 and 20/40 ($P < .001$). Two-thirds of eyes gained more than 3 lines and 40% more than 5 lines; in all of these eyes the holes closed.

With a better understanding of prognostic factors and the refinement of surgical techniques, anatomic closure can

be achieved in most large MHs, providing better visual outcomes. This study paves the way for further research into the role the peripheral retina may play in acquiring macular function and its potential in many macular diseases.

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TREATMENT-NAÏVE NONEXUDATIVE MNV IN AMD



By Giuseppe Querques, MD, PhD

AMD has been historically classified as exudative based on the presence of macular neovascularization (MNV). Treatment-naïve nonexudative MNV, by contrast, is characterized by a type 1 neovascular network without any sign of exudation. My colleagues and I coined the term *quiescent MNV* in 2013,¹ to refer to treatment-naïve MNV in AMD without intraretinal or subretinal exudation on repeated structural OCT imaging for at least 6 months. Roisman et al described subclinical MNV in AMD as type 1 MNV without evidence of exudation at the time of diagnosis.² We provided the specification of 6 months without exudation to distinguish quiescent MNV from a pre-exudative stage (an early stage when blood flow is sluggish) of an ordinary exudative type 1 MNV.³

In a series of 31 patients with treatment-naïve nonexudative MNV secondary to AMD,⁴ we characterized the natural history of the condition over a 6-month period and identified three groups: (1) a short-term activated MNV group (with exudation occurring before 6 months) and a quiescent MNV group (no exudation during a minimum 6-month follow-up) showing either (2) no activation (persistently quiescent) or (3) late activation during follow-up (long-term activated MNV).

Interestingly, the monthly MNV growth rate was significantly higher in the short-term activated MNV group (13.30%/month) than in the persistently quiescent MNV group (0.64%/month, $P < .001$) and the long-term activated quiescent MNV group (1.07%/month, $P < .001$). Moreover, the baseline perfusion density in the short-term activated MNV group was significantly greater than in the persistently quiescent MNV group ($P = .001$) and long-term activated MNV group ($P = .106$).

Of note, Capuano et al reported a protective role of quiescent MNV in the prevention of geographic atrophy progression and speculated that quiescent MNV may supply oxygen to the hypoxic outer retina and choriocapillaris.⁵ Arteriogenesis could be the main driving force of quiescent MNV, explaining the low rate of activation and the inclination to supply oxygen and nutrients to the outer retina.

In summary, we reported two different patterns for subclinical MNVs: subclinical MNV characterized by short-term

AT A GLANCE

- ▶ Autologous retinal transplant achieved anatomic closure in 89% of macular holes (MHs) and 95% of MH retinal detachments.
- ▶ Researchers have identified two patterns of subclinical nonexudative macular neovascularization (MNV): short-term activation and quiescent MNV.
- ▶ Vitrectomy including internal limiting membrane (ILM) peeling can allow surgeons to improve myopic retinoschisis in some cases.
- ▶ Recent findings with widefield indocyanine green angiography suggest that inter-vortex venous anastomoses are common in eyes with polypoidal choroidal vasculopathy and central serous chorioretinopathy.
- ▶ Examination of members of three unrelated families with a rare hereditary neurological condition confirmed that macular telangiectasia type 2 was present in nearly everyone over age 30.
- ▶ An inverted ILM technique for MH repair can induce glial cell proliferation, filling the MH and supporting closure.

activation that could represent a pre-exudative stage, and quiescent MNV characterized by a low growth rate and possible long-term activation. OCT angiography features may help to predict short-term activation for subclinical MNV. We recommend not treating quiescent MNV with intravitreal anti-VEGF injections until exudative changes develop.

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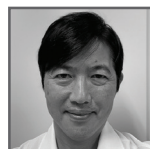
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TREATING MYOPIC TRACTION MACULOPATHY



By Kazuaki Kadonosono, MD, PhD

Myopic traction maculopathy, also known as retinoschisis,¹ is characterized by significant separation between the inner and outer retinal layers.² It is often seen in eyes with staphyloma, and there is a higher incidence in Asian populations.³ Prognosis for the natural course of the condition

tends to be poor. In one study, 3.8% of highly myopic eyes showed resolution of macular retinoschisis, but in most cases retinoschisis worsened and was accompanied by decreased visual acuity.⁴

Kobayashi and Kishi used OCT to study vitrectomy as a possible treatment for myopic traction maculopathy.⁵ However, it is difficult to determine an indication for vitrectomy for highly myopic eyes with traction maculopathy because the prognosis after surgery is unclear.

We studied highly myopic eyes with traction maculopathy and compared our surgical results based on the type of maculopathy identified using OCT. We identified four types of traction maculopathy: retinoschisis with subretinal fluid (SRF), retinoschisis without SRF, lamellar MH (LMH) retinoschisis, and retinoschisis with MH.

In our study, a significant improvement in visual acuity was seen after vitrectomy with ILM peeling and gas injection in retinoschisis with SRF and retinoschisis with MH; there was no significant improvement in visual acuity in eyes with LMH retinoschisis or retinoschisis without SRF.

A surgical technique for myopic traction maculopathy was recently developed. Long forceps specifically designed for highly myopic eyes are now available, allowing us to peel membranes more effectively. We can also use a promising new surgical technique in which LMH-associated epiretinal membrane is intentionally left around the foveal region.

In summary, vitrectomy including ILM peeling allows us to anatomically and functionally improve myopic retinoschisis in some cases. Myopic retinoschisis with subfoveal detachment seems well-suited to surgery, but more research is needed to determine the best course of treatment for other types of myopic retinoschisis.

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UPDATE ON POLYPOIDAL CHOROIDAL VASCULOPATHY



By Gemmy Cheung, MD

Polypoidal choroidal vasculopathy (PCV) is a subtype of wet AMD. Unfortunately, the differentiation of PCV from wet AMD relies on indocyanine green angiography (ICGA), a diagnostic modality that is not routinely used.

Recently, the PCV workgroup of the Asia-Pacific Ocular Imaging Society evaluated a set of diagnostic features based on OCT and color fundus photographs that may be helpful

to distinguish PCV from typical wet AMD in treatment-naïve eyes.¹ The combination of three OCT-based criteria of the retinal pigment epithelium (RPE)—sub-RPE ring-like lesion, en face OCT complex RPE elevation, and sharp-peaked pigment epithelial detachment—achieved an area under the receiver operating characteristic curve of 0.90 for identifying eyes with PCV. This set of practical diagnostic criteria can be easily applied in clinic to differentiate PCV from wet AMD without the need for ICGA.

However, ICGA remains an important tool for evaluating alterations in the choroid in eyes with PCV. Recent findings with widefield ICGA suggest that inter-vortex venous anastomoses are commonly present in eyes with PCV and central serous chorioretinopathy (CSCR).¹ Dynamic ICGA further revealed pulsatile flow within segments of these anastomotic vessels. These new findings based on ICGA suggest that a disturbance in choroidal perfusion pressure may play a role in the pathogenesis of PCV and CSCR.

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UPDATE ON MACTEL TYPE 2



By Paul S. Bernstein, MD, PhD

Recent advances in retinal imaging have revealed that macular telangiectasia (MacTel) type 2 is more common than originally described, and that, in its early stages, it has prominent nonvascular features such as retinal cavitations on OCT images.

The development of MacTel also has a significant genetic component, but its late onset and variable expressivity make identification of causative genes a challenge. A large genome-wide association study (GWAS) identified several loci linked to incidence of MacTel,¹ and our research group at the Moran Eye Center took advantage of the large families in Utah and Idaho to determine the frequency of MacTel in parents and siblings of MacTel patients.² We examined 52 of 71 living siblings and 11 of 12 living parents of 17 MacTel probands and found that 19% of first-degree relatives over age 30 years also had MacTel. This confirms that MacTel is indeed an inherited retinal disease, but with moderate genetic penetrance and multiple genes and environmental factors likely influencing the condition's expression.

In one multigenerational Utah MacTel family, all affected individuals also had a debilitating peripheral neuropathy (Figure 1). Whole exome sequencing revealed they had a C133Y mutation in SPTLC1, the causative gene for hereditary sensory and autonomic neuropathy 1 (HSAN1). Examination of unrelated HSAN1 families with the same variant in Pennsylvania and Australia confirmed that MacTel was

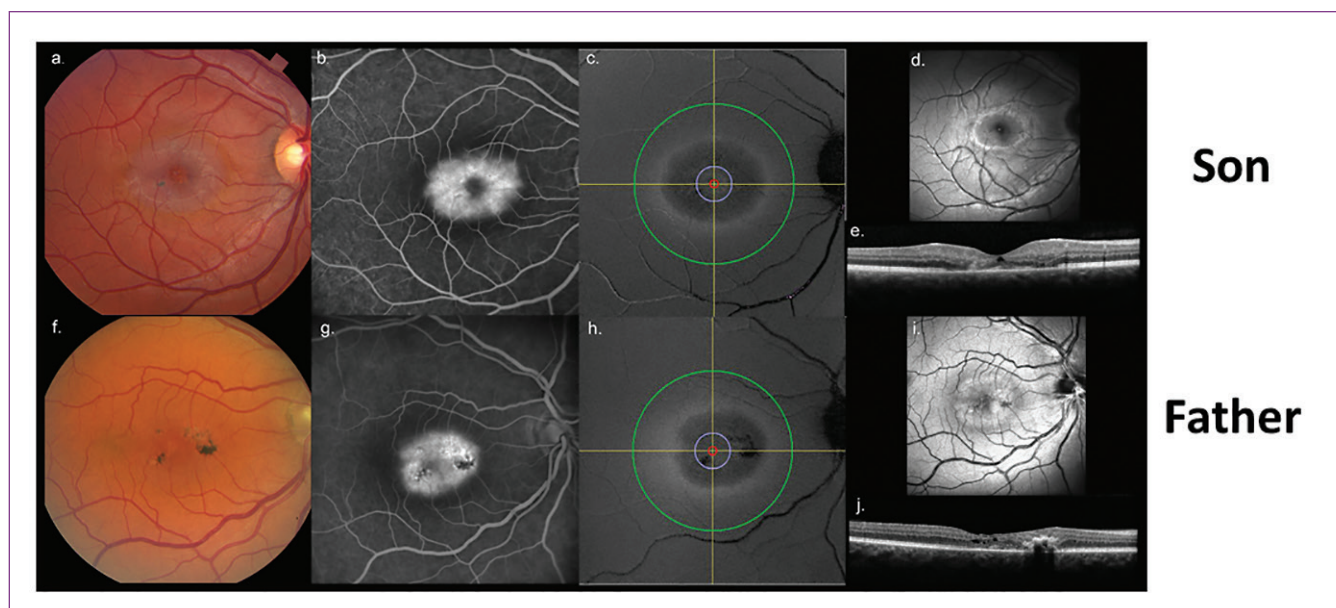


Figure 1. Father-son pair with HSAN1 and MacTel: color fundus photographs (A, F), late-phase fluorescein angiograms (B, G), macular pigment images showing the displacement of the foveal carotenoid pigment into a ring at the edge of the MacTel zone (C, H), blue light reflectance images (D, I), and OCTs (E, J).

present in nearly every member over age 30. We had identified the first highly penetrant genetic cause for MacTel.³

Although mutations in SPTLC1 are infrequent causes of MacTel (< 2% of cases), this finding provides valuable insights into novel pathways and treatments for MacTel. SPTLC1 encodes a subunit of serine palmitoyl transferase (SPT), the enzyme responsible for condensing serine with palmitoyl-CoA, the first step in synthesis of sphingolipids and ceramides. The C133Y-SPTLC1 mutation changes the substrate specificity of SPT to accept alanine instead of serine, which generates a series of deoxysphingolipids that are toxic to peripheral neurons and, presumably, the retina. We have found that many other MacTel patients also have low serine levels and high deoxysphingolipid levels, suggesting similar genetic or environmental abnormalities of serine and sphingolipid metabolism.

Neurologists already treat HSAN1 with high-dose serine supplements, and the MacTel Consortium researchers are gearing up to conduct comparable trials for MacTel.

Since then, various techniques and postoperative strategies have been introduced to improve anatomic and visual outcomes and patient comfort. The inverted ILM flap technique described by Michalewska et al was effective for treating full thickness MHs, particularly those over 400 μm , with a 98% success rate, whereas conventional vitrectomy with ILM peeling technique yielded only an 88% closure rate.²

My usual approach is to perform a three-port 25-gauge vitrectomy and posterior vitreous detachment assisted by triamcinolone. Then I stain the ILM with brilliant blue and peel the ILM around the hole, keeping the temporal ILM in place (Figure 2). This temporal ILM remnant is inverted and placed over the MH (Figure 3). Finally, fluid-air exchange is performed, and SF₆ at 20% is injected (Figure 4). I usually ask patients to maintain a facedown position for 3 to 5 days.

Peeling the ILM helps to relieve tractional forces acting on the fovea, enhancing the extensibility of the retina and Müller cell gliosis, both of which help in MH closure. The inverted ILM, which has Müller cell fragments, may induce glial cell proliferation, filling the MH and supporting closure. It may also work as a scaffold, encouraging the proliferation of myofibroblasts, fibrocytes, and RPE cells; creating a microenvironment that encourages correct photoreceptor positioning; and improving postoperative anatomic and functional outcomes.³ Rizzo et al reported a 97.5% single-surgery closure rate with this technique, with improvements in BCVA and multifocal electroretinography; their OCT images showed the appearance of a hyperreflective material filling the MH; gradually, this material contracted, inducing MH closure.⁴

Vitrectomy with the inverted ILM flap technique seems to be a safe and effective surgical approach for large MHs, improving both functional and anatomic outcomes. ■

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ILM FLAP IN MACULAR HOLE SURGERY



By Jose A. Roca, MD

In 1991, Kelly and Wendel described the role of pars plana vitrectomy and the removal of posterior hyaloid for the closure of MH, reporting an anatomic closure rate of 58%.¹

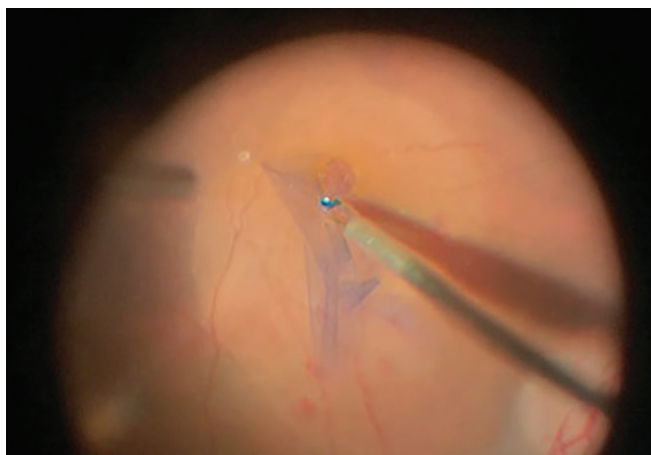


Figure 2. ILM peeling around the MH, leaving temporal ILM.

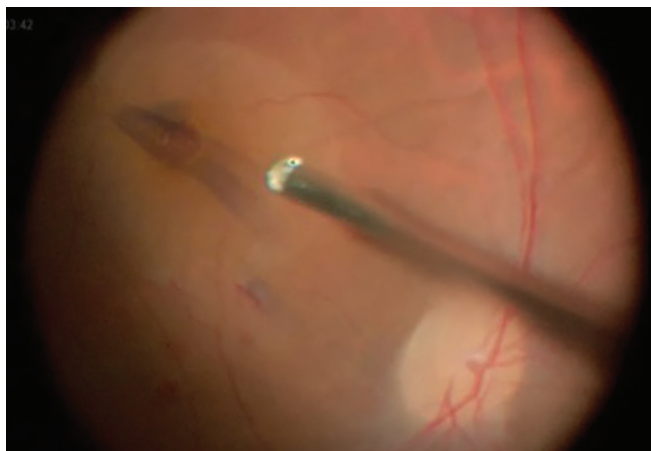


Figure 3. The temporal ILM is folded over the MH.

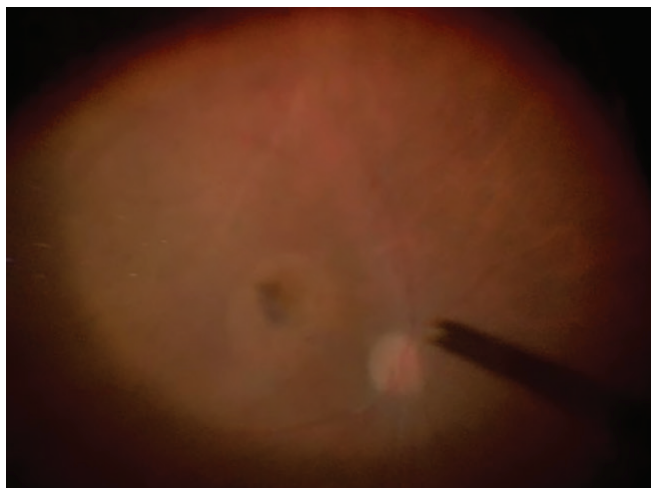


Figure 4. Fluid-air exchange with stained ILM over the MH.

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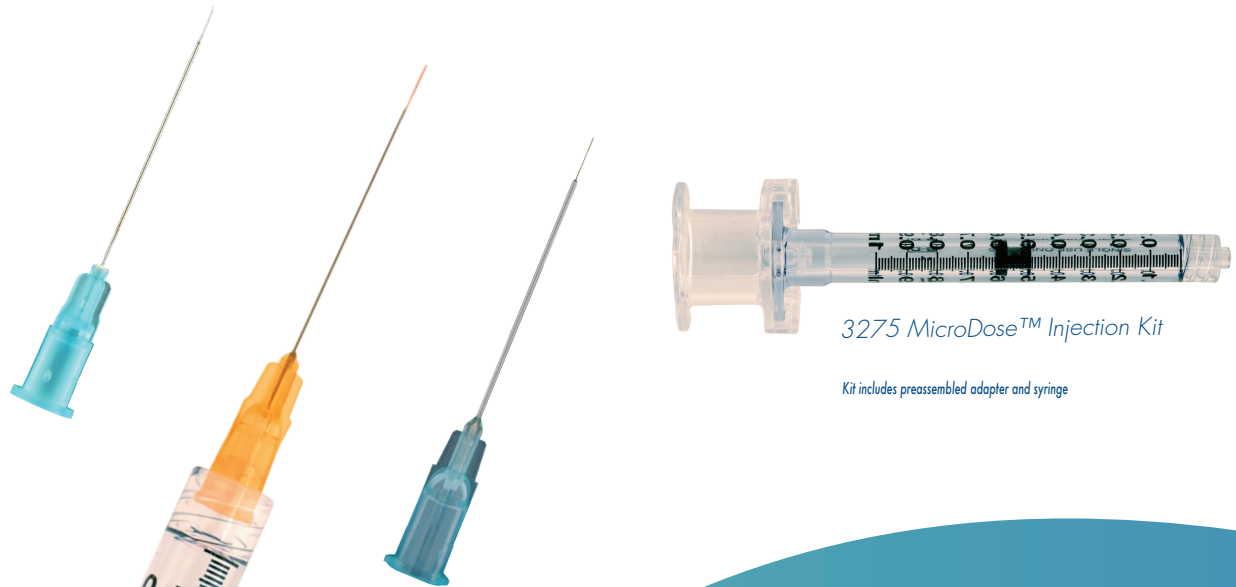
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A Word From Members of the LGBTQ Community

Retina specialists open up about what it's like to be a part of both this community and the field of retina.

Here, several physicians from the lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) community share their experiences seeking mentorship, navigating patient interactions, disclosing their sexual orientation to colleagues, and finding representation in leadership.

—Rebecca Hepp, Editor-in-Chief

OPEN FROM DAY 1



By Daniel Churgin, MD

Writing an article like this is complicated. Every time an LGBTQ person discloses their sexuality, it's intimidating and opens them to vulnerabilities. Putting this out there makes

me fearful about my practice, referrals, patients, and online reactions. In the spirit of holding a torch that has been passed down by others, here is my story.

Until now, no one has ever asked me about my experience as a gay ophthalmologist, but it's an important question because it's not often discussed. I came out as an undergraduate and was active in LGBTQ groups. To disclose or not to disclose is an ever-present question for LGBTQ applicants, regardless of the level of training. I decided to apply to medical school as openly gay, and, while there, I fought uphill battles to advocate for LGBTQ inclusion in our curriculum. Those in charge of the curriculum weren't exactly anti-LGBTQ, but we were invisible in the curriculum nonetheless.

When I decided to apply for ophthalmology in 2011, I started seeking LGBTQ mentors in the field, and I could find only *one*. It was important to me to learn from him, so I flew across the country to do a rotation with him. Support from your own community can be an enormous bolster, and his strong letter of support helped me to match successfully.

I made the decision, again, to be openly gay in my application to residency—a risky decision I didn't take lightly. I had a few awkward experiences on the interview trail, but mostly interviewers skipped over my sexuality. However, I vividly

remember one residency director who pulled me aside and told me that I would be at home and accepted in their residency as a gay man—a gesture that brought me to tears, privately, after my interview. I had 18 interviews, and almost everyone danced around my sexuality, except this one person.

As time went on and the acceptance of LGBTQ people in society increased, I became more vocal about being gay and made an effort to mention my same-sex partner during fellowship interviews. Over time, it had become a litmus test to make sure I was a good fit. I had an overwhelmingly positive experience, and the retina community was accepting.

I was open about my LGBTQ status when I applied for my first job as an attending, and I sought out a practice where diversity is celebrated as an advantage. In my practice, I am



Dr. Churgin, left, attends an event with his husband, Morgan.

openly gay, but I rarely talk about it with patients. I don't lie if patients ask, but I avoid talking about myself. Most of the time I am an invisible minority, still hiding to some degree—still a work in progress.

I have knowingly experienced outward discrimination due to being gay only once as a medical student. But how many times have I been the recipient of unspoken discrimination or microaggression? In my gut, I know I have experienced avoidance, bias, or being passed over for an experience.

To those who are LGBTQ and applying for retina positions: Be honest about who you are, and find a work family that celebrates you.

As for the patients, it can be hard to identify LGBTQ patients in ophthalmology. But, most importantly, if the patient discloses that they are in an LGBTQ relationship, following up with a positive remark such as, “That’s great, how long have you been together?” can be very empowering.

Another piece of advice: Don’t be afraid to ask about their experience because it will make them feel accepted, seen, and supported. It’s not off-topic, and it is important. Remember that when an LGBTQ person shares their sexuality with you, they are probably experiencing fear, and it is your opportunity to alleviate that fear.

Another way to support patients or colleagues is to address national events. During my third year of residency, the Pulse Nightclub shooting occurred in Orlando, and I was devastated by the slaughter of men and women within my community. The day after the shooting, a colleague came in early and plastered a rainbow flag on our door. I walked in and was speechless on seeing this act of solidarity.

Ophthalmology is not a place where people often discuss sexuality. Most of us live quiet, private lives. *Hidden* is a good term for most LGBTQ ophthalmologists. This atmosphere, I think, is why we don’t have an organization of LGBTQ ophthalmologists or any obvious LGBTQ representation in leadership and at academic meetings. I would love to see a shift

in this paradigm, and we need to organize a network of support. For the vast majority who aren’t a part of the LGBTQ community, hopefully these stories start a conversation.

BAY AREA SUPPORT



An Interview with Steve Sanislo, MD

I’ve been in the San Francisco Bay area for more than 25 years, so my experiences with LGBTQ situations are probably different from those of a lot of people because of the incredible tolerance here. Much of what I say here will no doubt vary from other people’s personal experiences.

Retina Today: As a member of the LGBTQ community, what has been your experience seeking mentorship in retina?

I basically had zero LGBTQ mentors. I’ve certainly had wonderful mentors, and I wouldn’t be as successful as I am had they not taken me under their wing—they just weren’t LGBTQ. In medical school, residency, and fellowship, I didn’t know anyone who was openly LGBTQ in ophthalmology, much less in retina. But for me personally, it wasn’t that important because in some ways I was compartmentalizing my existence.

I didn’t come out until after I was in my current academic position. It might have been different with different mentors or role models, people who were out in high-profile positions, so that I felt more comfortable being out myself.

But I had to accept who I was first. Once I accepted myself, I came out quickly and had wonderful experiences. At work, probably the first person I came out to was my mentor, and then some of my colleagues, and I honestly never had a negative reaction professionally. Once you have positive experiences, you want to make sure everyone knows because it’s so much better when you can be yourself.

RT: How has being gay affected your approach to patient interactions?

For a long time, that was the biggest area where I felt uncomfortable in my workplace—figuring out what to share with patients. The most awkward incidents were when patients tried to set me up with their daughters. After I was married, patients would ask about my wife, and I didn’t know how to handle that well. I would never talk about my personal life at that point in time, but if someone did bring up my “wife” I usually let it slide or even went along with it. But I always felt bad. It wasn’t the right thing to do, and it isolated me from the patients. When I finally started gently correcting them by stating I have a husband, not a wife, I was surprised with how people were OK with it.

In retina, we have so many older patients who have their own views, and I was worried they would feel differently about me. Honestly, I never experienced that.



DID YOU KNOW?

A recent Gallup survey found that 5.6% of American adults—an estimated 18 million people—identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ), a significant increase from the 4.5% recorded in 2017.¹ The researchers speculate that the rising numbers are due, in part, to society’s increasing acceptance of the LGBTQ community and younger generations choosing to live openly with a sexual orientation other than heterosexual. They also suspect the unwillingness of older generations to identify as LGBTQ means this percentage may actually be an underestimate.

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Eventually I started discussing my private life with patients regularly. I have seen some patients every month for 15 years now, so I know them well, and it's nice that they know me too. They might ask if I have kids, and I tell them I have two kids and what I do with my husband on the weekends. I can casually talk about my husband and family the same way a heterosexual person would, and I find that incredibly liberating to feel like I can have the same interaction with a patient that a straight person does.

RT: How do you feel the LGBTQ community is represented in retina meetings and leadership?

I don't think it is. I'm sure there are LGBTQ people on the podium at retina meetings and in leadership positions, but I don't know who they are.

But is it necessary? Maybe, in terms of role models for younger physicians. I remember a while back when a medical student asked for help with his application, and he asked if he should include his leadership positions in LGBTQ advocacy programs. Back then, I advised him against it. I felt that not everywhere is the Bay area, not all programs are inclusive, and I was worried one homophobic person on an application committee would reject him because of that.

But now, if I had a student ask the same thing I would say yes, you should. First—and most important—it's really essential to be yourself and be in an environment where people are OK with that. That outweighs the possibility that you might not get a position somewhere, and that's not a place where you want to be anyway. Second, I think the pendulum has actually swung in the opposite direction. Academic medical centers are valuing underrepresented minorities, including people who are LGBTQ. In some ways it can be an advantage to disclose that.

The more people can be open about who they are in their workplace, the better. You can feel wholly part of something—you don't have a feeling that you are holding back. I'm happy to see that things are changing a great deal. Nowadays, I have fellows and residents who are openly gay, and it's not an issue. It makes for a better situation for them.

A GLOBAL EXPERIENCE



By Wandsy Velez, MD

I have been in practice for 30 years now—10 in a multispecialty practice and 20 in a solo practice. I didn't disclose my sexual orientation when I was applying for a fellowship or when I was looking for a job because I didn't think it was relevant to my skills and knowledge as a retina surgeon.

Because I live on a small island with conservative religious beliefs, I disclose my orientation only to those I know or those I believe will not discriminate or judge me. These are often people from the United States.

At the same time, my partner for 20 years was not keen

on disclosing her orientation mostly because of family issues. I respected her wishes but also supported her once she was ready to open up to her family in her own time, which was just a few years ago.

In Puerto Rico, everyone in the lesbian community mostly knows each other, and now I see more lesbian and gay patients than ever before. Unfortunately, the same is not true with the transgender community. There is now one center in Puerto Rico, Centro Ararat, that serves the transgender community by offering the necessary hormone therapies and treating underlying disease.

To move our medical community further toward inclusion, we must ensure that our office personnel are highly educated about discrimination laws. We must also change our electronic health record systems and become more inclusive regarding gender.

The LGBTQ community is not well represented within the field of retina, but at 59 years young I am willing to challenge these stereotypes.

A BALANCING ACT



By Scott Walter, MD

In the competitive specialty of ophthalmology, and the hypercompetitive subspecialty of retina, the question has always been how much of yourself to put out there if it isn't relevant to your qualifications as a retina surgeon. Being open about your sexual orientation gives dimensionality to who you are as a person and may help others connect better with you; but it's also a liability, opening the door to potential discrimination.

At every stage of my schooling and career, I knew I had to be careful about how I expressed my sexual orientation in my applications. I carefully buried hints in my residency application, which only one faculty interviewer picked up on. But it really meant something when that person told me the institution was open-minded and was actively recruiting a gay faculty member; sure enough, that's where I matched. It was nice to join an institution that not only values diversity on paper but also would place someone like me in a position of authority and influence.

By the time I was applying for fellowships, I was engaged, and it was becoming more important to be out during the application process. I made a point of mentioning my fiancé to test the waters, to make sure I would be able to include my fiancé in the life of the department.

I was married by the time I was applying for retina jobs, and it was incredibly important to find a good fit for both of us. Most private retina practices understand that the spouse is an important factor, but few have experience with gay applicants. It was interesting to see how practices handled that. Those that went out of their way to make sure we would both be

Photo Courtesy of Kevin Caldwell



Dr. Walter and his husband, Bradley Harper, at the 2019 Retina Society meeting in London.

happy were obviously much more attractive to me than practices that were more hesitant to meet my husband.

Joining a practice out of fellowship isn't just another 2- or 3-year commitment—it's a marriage. You're joining a group with the intention of being a long-term partner, and you need to be sure there isn't any internal homophobia or prejudice that would jeopardize your happiness and the success of the partnership.

LEADING THE WAY

LGBTQ mentorship in retina is an important aspect that I underestimated as I worked my way through training. There weren't any visible LGBTQ people in the field of retina ahead of me. Of course I had many wonderful academic mentors throughout residency and fellowship, but I didn't have anyone as a social mentor in that respect, so I had to figure out a lot on my own.

But the truth is, I wasn't alone. When I matched in ophthalmology, a mutual friend introduced me to a gay medical student 2 years below me, and that friendship ultimately influenced him to apply to Bascom Palmer, where we both did our residency; he is also a successful retina surgeon now. Another retina fellow in my year was gay, and now we share many patients who snowbird between Connecticut and Florida, where he practices.

Mentorship and personal connections can be very powerful for advancing one's career. Whether it's securing a competitive residency position or building your own productive practice, it's helpful to learn from others who have gone before you. It's important to have visible LGBTQ mentors out there, so that people working their way through the ranks have someone to turn to for help.

CONNECTING WITH PATIENTS

In clinic, I focus primarily on what's happening in my patients' lives, not mine. When I've established a good rapport with my long-term patients, I usually come out naturally in the

course of conversation, and this openness often serves to further the doctor-patient relationship. Through my interactions with thousands of patients in my community, I am slowly weaving threads of LGBTQ awareness and acceptance into the social fabric of medicine and of society as a whole.

I have also come to realize that there are a lot of LGBTQ patients in retina. Sometimes we just don't see it unless we are a part of that community. A lot of older patients have lived their entire lives in the closet or don't express their sexual orientation freely. But many older patients have come out to me, and for them it's liberating to finally have a provider with whom they can identify. It's important to have providers out there who represent the diversity in our communities, and that goes for gender, race, sexual orientation, and every other category of diversity.

A LONG WAY TO GO

Women in ophthalmology have come so far now, and they've organized well to promote subsequent generations of women. As a result, they've become a visible contingent of the academic retina world. But we still have a long way to go on the LGBTQ side. I don't know of any openly LGBTQ leaders in retina, and it would be great to have a few of us who are frequent presenters at meetings and in positions of influence, whether in academia or in the American Society of Retina Specialists (ASRS) leadership. I have tried to participate in online fellows' forums and stay involved in state and local societies, as well as in ASRS. I'm not doing it specifically to be "the LGBTQ person," but I am there so that when someone's looking to connect, I'm visible enough that people can find me. ■

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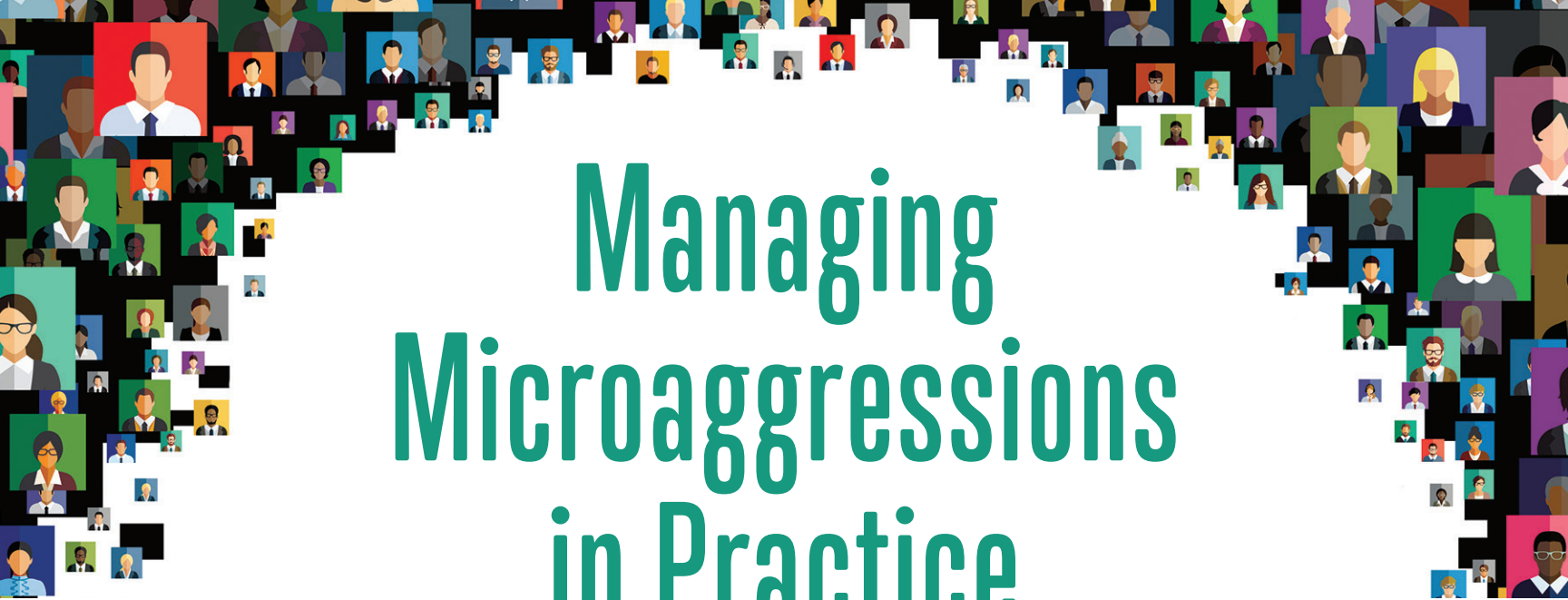
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Managing Microaggressions in Practice

Identify and address these often-unconscious slights to ensure an inviting and inclusive experience for both patients and colleagues.

BY NATHAN L. SCOTT, MD, MPP, AND HASENIN AL-KHERSAN, MD

Words matter. The wrong ones can leave lasting scars that affect one's overall health and diminish the joys of life. A substantial volume of literature has been dedicated to linking everyday discrimination to negative physical and mental health outcomes.¹⁻³

Blatant racism, sexism, and discrimination still exist, but as they have become less prominent, more insidious forms of discrimination have taken their place.

A recently popularized term for these daily impactful transgressions is *microaggression*. This term was coined in 1970 by Chester M. Pierce, MD, who defined microaggressions as minor yet damaging humiliations and indignities experienced by African Americans.⁴ More recently, the use of the term has been broadened to include snubs, slights, or insults directed toward minorities, women, or members of other historically stigmatized groups to implicitly communicate hostility.⁵ Academic literature breaks the term down further to encompass microassaults, microinsults, and microinvalidations.⁵

Microassaults are conscious and explicit "old fashioned" discrimination. They manifest as demeaning statements or actions, such as calling a person of Asian descent "oriental" or, in our field, suggesting that a female physician may not be as capable as a male counterpart.

Microinsults are often unconscious but similarly carry demeaning messages about a person's identity. An example would be applauding Black individuals for being "well-spoken," which carries the assumption that this is atypical.

Microinvalidations are also unconscious but reflect exclusions or dismissals of the recipient's feelings, thoughts, or reality. This category includes the common statement, "I don't see color," which tends to undermine the exceptionally different experience that people of color have in our society.

Importantly, most microaggressions do not come from a place of a malintent; in fact, they frequently manifest under the guise of comedy, as attempts to console or understand a colleague's or patient's struggle, or simply from poor word choice. This does not diminish their impact, nor does it make them excusable.

Thus, we must be intentional when we interact with one another because subconscious acts of racism and sexism can have lasting effects on both patients and colleagues.

It is important to note that some, including author and antiracist activist Ibram X. Kendi, PhD, have moved away from using the term *microaggression* altogether, noting that it fails to convey the damage these abuses can inflict. Although this may be true, this argument is beyond the scope of our article, and we feel that the term suffices for our message.

Addressing microaggressions is no easy task. Using examples from our own lives, in our separate sections below we highlight a framework to help you recognize and respond to microaggressions in the medical workspace. Recognizing a microaggression is the first step, but most people do not know what it is like to exist in a space where they do not feel valued. Recognition is not enough. Action is necessary.

IF FRIENDS OR COLLEAGUES ARE WILLING TO EDUCATE YOU ABOUT YOUR MICROAGGRESSIONS, THEY ARE ACKNOWLEDGING HOW CHALLENGING IT IS TO BE SELF-AWARE. THEIR CHALLENGE IS A GENUINE SYMBOL OF RESPECT AND ACCEPTANCE.

When microaggressions occur in practice, we support the use of the mnemonic GRIT outlined by Warner et al:⁶

- **Gather your thoughts.** Do not react with anger, and decide if it is the appropriate time and place to address the perceived microaggression.
- **Restate the comment.** Allow the person to clarify or realize the negative impact of their words.
- **Inquire to seek clarification.** Be nonjudgmental and address the comment or action without making it about the person.
- **Talk it out.** Discuss the impact on others and your personal perception of the comment or action.

It is just as important to know how to respond if *you* are called out for a microaggression. The most important step is to listen; give the other person a chance to explain their perspective. Do not become defensive. These interactions can be valuable teaching moments to help us confront our own internal biases.

Educating others about microaggressions can be a tiring task for those who experience them on a frequent basis. If friends or colleagues are willing to educate you about your microaggressions, they are acknowledging how challenging it is to be self-aware. Their challenge is a genuine symbol of respect and acceptance. The effort to educate is often reserved for the people we care most about.

VAGUE CONNOTATIONS



By Nathan L. Scott, MD, MPP

I was a third-year medical student—my first time on the medical wards. Admittedly, I was certainly not what one might call an all-star student. I was quiet, but not shy. I was confident in my abilities, but I deliberately tried to avoid seeming arrogant or overconfident. I had never received negative feedback on rounds, and I got along with my clinical teams and colleagues. Many had noted my unique ability to bond with patients. At lunch, I ate alone to escape the perpetual evaluations of medical school life.

During my mid-year feedback session, the program director started with a simple question: “How are things going?” I

told him that everything was great, and I was learning a lot. I really enjoyed my clinical teams and taking care of patients. His response? “You know, you’re a big strong guy. You should smile more.”

The feedback was genuine, and he explained that there was no negative feedback about my effort, attitude, or clinical knowledge, but that “there was concern.” To me, however, this was just another confirmation that I was different, that my appearance was intimidating, and that I needed to change my reserved demeanor to better fit the mold of the excitable, overeager medical student.

In translation, the microinsult I heard in that statement was, “You’re a Black man in medicine, so you need to make sure people don’t think you’re angry or unhappy.” I recounted the meeting with several of my minority mentors who not only confirmed my translation, but to my surprise (and dismay) also agreed with the feedback and premise—in our profession, Black physicians must work harder to ensure that other people don’t think they are angry. I did not address my concerns with my program director or my mentors.

At the time, I didn’t know about the GRIT framework; looking back, that feedback session was the perfect scenario to gather my thoughts, restate what I was understanding the comment to mean, and inquire about exactly what the “concern” was. Talking, not only about mitigating concerns but also about what it is like to receive feedback with vague terminology, could have led to a more productive and impactful interaction for both me and my program director.

WHAT’S IN A NAME?



By Hasenin Al-khersan, MD

“What’s your name?”

I nervously glanced at my new classmates before turning back to answer my teacher: “Hasenin.”

The teacher’s face contorted into befuddlement. “What?” I replied again, this time more slowly, but I knew I wasn’t making any progress—three syllables might as well have been a hundred.

(Continued on page 48)



Racial Bias in Clinical Trials: What You Need to Know



Significant work is needed to ensure that patients of all demographics are equally represented in our data.

BY JOSEPH M. CONEY, MD

Racial bias in health care is one of the underlying factors preventing diversity in clinical research. Implicit and racial biases affect all medical subspecialties, as do other systemic problems such as institutional racism, patient distrust, and a lack of minority physicians treating underserved populations.

For example, Black women have a 41% higher mortality rate from breast cancer compared with White women,^{1,2} but they represent only 5% of clinical trial participants.³ Likewise, Black men have a 76% higher incidence rate and 120% higher death rate from prostate cancer compared with White men,⁴ yet more than 96% of participants enrolled in these studies are White.⁵

In our own field of retina, although Blacks and Latinos are more likely than Whites to be diagnosed with or go blind from diabetic retinopathy, they are underrepresented in our pivotal diabetic macular edema trials with less than 12% of participants being Black.^{6,7}

The FDA recently released new guidance for industry sponsors to enhance the diversity of trial populations,⁸ but a holistic approach is needed to drive lasting and sustainable change. Physicians and researchers alike must understand and address clinical research disparities and racial bias to achieve greater health equity for all patients, regardless of race, ethnicity, gender, age, or other demographics.

BARRIERS TO RECRUITMENT

As a retina specialist who has served my community for 15 years, I've experienced fair success in recruiting patients to participate in clinical trials; however, I'm not immune to

biases—none of us are. The key is recognizing our biases so that we can alter our behavior. In particular, I've noticed several barriers we need to overcome to help mitigate racial bias and improve minority representation in clinical research.

Implicit Bias

Most often, patients consider taking part in a trial because a physician asked them to participate.⁹ If a physician makes a snap judgment about a patient based on race,

AT A GLANCE

- ▶ Although Blacks and Latinos are more likely to be diagnosed or go blind from diabetic retinopathy, they constitute less than 12% of trial populations.⁶
- ▶ Of the 2,400 retina specialists in the United States, fewer than 100 identify as an underrepresented minority.
- ▶ Today, 30% to 50% of minorities distrust the COVID-19 vaccine and aren't considering vaccination.¹⁵
- ▶ Genentech's External Council on Advancing Inclusive Research seeks to ensure that clinical trial participants represent broader patient populations so that those with serious and life-threatening diseases have the opportunity to benefit from investigational medicines.

ethnicity, gender, or other demographics and concludes that the patient isn't an ideal candidate for a clinical trial, it's a lost opportunity to potentially help the patient and advance medical research. If we don't ask our minority patients to participate, they won't. Trial participation should be offered to everyone.

However, an invitation to participate is not sufficient on its own. We must also be aware of, and address, our own biases that, when left unchecked, can disrupt the physician–patient relationship. Without a foundation of trust between patients and physicians, noncompliance is likely. We must be conscious that some minority patients are inherently apprehensive and distrusting. We must listen to patients and address their concerns in a culturally competent manner.

Lack of Minority Physicians

Patients often prefer to see a doctor with whom they can identify.¹⁰ Although there are approximately 40 million Blacks (13% of the population) in the United States, only 5% of physicians and 2.9% of ophthalmologists are Black—and the disparity is even greater for non-White Hispanics.¹¹

Even more challenging, of the 2,400 retina specialists in the United States, fewer than 100 are an underrepresented minority. We desperately need stronger efforts to enroll more underrepresented minorities into medical school, assist with matriculation into competitive residencies and fellowships, expose students to subspecialty societies, and encourage early participation in advisory boards and research.

Patient Distrust

Long-standing social injustices and prejudices have led to skepticism among people of color regarding health care. Numerous research abuses, such as the Tuskegee Syphilis Study,¹³ the story of Henrietta Lacks and HeLa cells,¹⁴ and radiation studies on prisoners, have left deep-seated doubt in the minds of many about the safety and benefits of research.¹² This sentiment persists today, during the pandemic, as 30% to 50% of minorities distrust the COVID-19 vaccine and aren't considering vaccination.¹⁵

Cost and Time Commitment

Out-of-pocket travel costs, travel time to trial sites, medical follow-up appointments, unexpected bills,¹⁶ missing work, and childcare costs are among the concerns that restrict patients from trial participation. We should make every effort to ensure that all study patients have no out-of-pocket expenses while enrolled in a clinical trial.

SOLUTIONS: HOW TO MOVE FORWARD

Address Implicit Bias

As physician investigators, we need to examine our own biases. In addition, sponsors should have an “unmet

needs” dialogue with principal investigators to explain the importance of racial and ethnic diversity in trial participants. These dialogues should highlight disparities in disease prevalence, mortality data, and long-term disabilities within underrepresented groups. They should also emphasize that clinical trial recruitment must represent patients who will eventually, upon approval, be treated with the medication, and that efficacy and side effect data must reflect all races and ethnicities.

Increase Minority Enrollment in Medical Schools

Only a few years ago, I was the only African American retina specialist in the state of Ohio. In medical school, I was the only Black male in my class, and few of my fellow students and professors were people of color. To find my place, I quickly learned the value of mentors.

This is one of the reasons I strongly endorse initiatives such as the AAO's Minority Ophthalmology Mentoring program.¹⁷ We not only need to bring awareness of the field of ophthalmology to the next generation of students, but also to create an inclusive environment in which minorities can thrive. As a recipient of the Rabb-Venable Research Award from the National Medical Association,¹⁸ I know firsthand the difference these types of programs can make for a young medical professional.

Build Equity and Trust

Rebuilding trust within communities of color requires commitment from industry sponsors, policymakers, health care professionals, and patient advocates, among others. Outreach programs and support groups (eg, in churches and community centers) can help to increase the health literacy of minority patients and reinforce the importance of clinical trial participation.

Additionally, we must improve the informed consent process. Consent forms should be translated into the native languages of community patients and sent home with the patients for further review. A follow-up call afterward can address questions from the patient and family prior to the screening appointment.

Physicians have a responsibility to combat racial bias among staff members and colleagues. At my practice, our monthly meetings include a discussion of clinical trial recruitment strategies. It's important that we train our staff, make clinical study information accessible in exam rooms, and consider locating clinical trial sites near underserved areas.

Collaborate with Industry

In addition to making an impact in our local communities, we must also focus our attention on the regional and national landscape to reduce racial bias in clinical trials. Genentech's External Council on Advancing Inclusive Research, of which I've been a member for more than 2 years, seeks to ensure that trial

participants represent broader patient populations.

Our advisory council has helped Genentech shape its strategy and develop concrete recommendations to build more inclusive and equitable clinical trials.

The council has also provided guidance for sponsors working with principal investigators to make inclusion and exclusion criteria more inclusive (eg, by loosening strict HbA1C requirements). Moreover, because out-of-pocket costs can be a major factor preventing underrepresented minorities from participating in clinical trials, we have worked with Genentech to develop patient assistance programs and travel grants to reduce patients' cost burdens.

VISION FOR A MORE EQUITABLE FUTURE

I believe our health care future is bright and our drug pipeline is robust. We cannot afford to leave any patient behind and must be intentional about addressing the disparity gap in this country. Increasing the representation of minority patients in clinical trials is a step in the right direction, as it builds patients' trust in institutions, in their communities, and, most important, in you. ■

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(Continued from page 45)

"That's way too hard. I'm gonna call you Al." And he did, for the next 6 years.

That incident, burned vividly into my memory, is the earliest microaggression I can recall. At the age of 10, my family had just moved to rural northern Michigan, and it was my first day of school. Even at that age, I was already keenly aware of my identity as an Arab in post-9/11 America. Though my physical appearance may be culturally ambiguous, my name has always been foreign.

For a child, moments like these are demoralizing and invalidating. Any child with a "different" name can empathize with the feeling of waiting for a substitute teacher to butcher your name during roll call after admitting, "I'm going to definitely mess this next one up."

This scenario has since been played out hundreds of times throughout college and my medical training. Professors or colleagues who were hesitant to muster a second attempt at pronouncing my name often disengaged from me in classes or on the wards.

Fighting this perpetual battle is exhausting. I have learned three languages but, for some, three syllables seem insurmountable. And, as with most microaggressions, it can be difficult to advocate for yourself without feeling as if you are being difficult. Most of the people committing these slights are good people with good intentions, which makes confrontation complicated. Nonetheless, the impact of their actions is deeply felt.

These days, I choose my battles. When it matters most, I'm more adamant that others learn my name. If they continue to mispronounce it, I continue to correct them. But at other times I don't engage for the sake of my own well-being. I am constantly working on this balance, but I now know my name deserves respect like any other.

For the record, it sounds like it's spelled: "Ha-se-nin." ■

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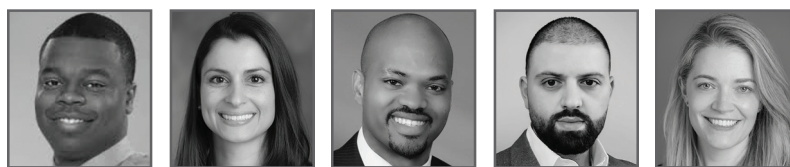
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Spotlight On Multicultural Retina Practices



Physicians from around the country share insights on caring for diverse populations.

**AN INTERVIEW WITH BASIL K. WILLIAMS JR, MD; NIKA BAGHERI, MD; MATTHEW A. CUNNINGHAM, MD;
ALBERT SHIRAKIAN; AND ALEKSANDRA RACHITSKAYA, MD**

The editors of Retina Today spoke with some of the most diverse retina practices across the country to find out how they handle cultural differences within their patient bases and the myriad benefits of fostering cultural diversity within their practices. Here's what they had to say.

—Rebecca Hepp, Editor-in-Chief

Retina Today: How does your practice address cultural differences among your patients?

Basil K. Williams Jr, MD: While we do not have a specific policy or set of guidelines in place to address cultural differences, we consider a number of factors in approaching the broad and diverse patient base in our practice. The goal is for the entire team, starting with receptionists and continuing with the technicians, photographers, and physicians, to approach each patient with curiosity, empathy, respect, and humility. With this approach, we seek out both potential and actual barriers to care and address them as needed.

Nika Bagheri, MD: The best way to provide superlative care to patients of all cultural backgrounds is to achieve diversity within your own organization, from the front desk staff to the office leadership. There also has to be internal education regarding cultural differences that may affect patient care. This could include having instruction sheets printed in multiple languages, recognizing the roles family members play in certain cultures, and appreciating the different fears patients may have about vision loss depending on their backgrounds.

Aleksandra Rachitskaya, MD: Healing is a complex process that requires patients to understand their disease and engage with their treatment. Thus, insight, awareness,

and understanding of the dangers of unconscious bias are paramount. My team and I try to do our part to improve patients' experiences by acknowledging and adapting to each patient's cultural background. Studies have shown that patients who share the same racial or ethnic background as their physician are more likely to have a better experience, as reflected by patient rating scores.¹

RT: How does a culturally diverse staff help your practice connect with your community?

Dr. Williams: I learned the value of representation early in my training. While shadowing a family practice physician during my first year of medical school, an older Black gentleman pulled me aside at the conclusion of his visit. Ensuring that no one else was within earshot, he told me how proud he was of me. Iterations of that scenario happened countless times with my Black patients throughout my training and continue in my current practice. I also noticed that speaking Spanish to members of the largely Cuban population in Miami during residency dramatically improved the patients' level of comfort and the rapport I had with them. Similarly, having a culturally diverse staff allows a deeper connection with the community at large, cultivating trust between physicians and patients that ultimately leads to better interactions and improved patient care and outcomes.

Dr. Bagheri: It is crucial when possible to hire staff with local ties and ideally to groom leadership from the same background as each individual office's distinct patient base. This will result not only in a stronger organizational culture, but also superior patient care. Studies have shown that underrepresented minority (URM) patients may achieve better outcomes when a treating facility includes URM physicians.²

Matthew A. Cunningham, MD: We maintain a culturally diverse staff, and we have found that it helps us connect with our patients and others in the community. It also helps us understand cultural topics or issues that we would not otherwise be aware of but that are beneficial to know as physicians.

Mr. Albert Shirakian: Ensuring that our patients' cultures and languages are represented in our practice provides them a level of comfort. Many who do not speak or read English feel comfortable coming into the clinic without a family member, knowing that familiar faces and a familiar language will be greeting them. This creates a friendly environment and great long-term relationships with our patients that resonate within the community.

Dr. Rachitskaya: We serve many patients for whom English is their second language. When I worked in Miami, I was amazed at how Spanish-speaking patients would prefer my broken and

grammatically challenged Spanish to English, even though these patients' own English was, in fact, significantly better than my attempts to communicate in their first language. I speak several languages, and I use my skills to build rapport, but in our practice we ensure that a professional translation service is available either in person or by phone for those who prefer it.

RT: What challenges have you encountered in caring for distinct ethnic populations?

Dr. Williams: The most difficult recurring challenge for me is bridging the language barrier between myself and members of distinct ethnic populations. We can provide patients with video-based translators in nearly every language available, but I often find it difficult to develop the same level of rapport with these patients because of the presence of an intermediary in the conversation.

Another challenge I've encountered is in dealing with patients whose cultural beliefs place an emphasis on holistic medicine over Western medicine. At times, this has led to the rejection of necessary medical or surgical treatments in favor of natural remedies.

Dr. Bagheri: In retina, one of the biggest issues is patient adherence to appointments and treatment plans. We have fantastic anti-VEGF medications to treat wet AMD, diabetic retinopathy, and other potentially blinding conditions. The Achilles heel of current anti-VEGF treatment, however, is the need for persistent and often continuous treatment, with functional visual benefits sometimes lagging behind anatomic ones.

Effectively communicating and achieving understanding of the need for adherence across cultural and language barriers can be a tremendous challenge. Some ethnic populations have respect for physicians but view doctor appointments as a symptom of illness: The more often you go, the sicker you must be. In other instances, there may be a culturally based reluctance to report symptoms that may be important for the treating provider to know, such as new distortion or vision loss between visits.

Dr. Cunningham: Although each individual is unique, it is important to be culturally sensitive to challenges that may be distinct to a culture or ethnic group. There may be an underlying distrust of the medical community, for instance based on a historical event such as the Tuskegee Syphilis Study. Often, seeing a health care professional from a similar cultural background in the clinic may put a patient at ease. Other patients may not believe their ocular condition is due to an underlying medical condition, such as diabetes mellitus.

In central Florida, Spanish is the second most common language, but many of our patients speak Vietnamese, Portuguese, or Creole. Having trained in Houston, I learned enough medical Spanish to complete an eye examination without assistance, but

IT IS CRUCIAL WHEN POSSIBLE TO HIRE STAFF WITH LOCAL TIES AND IDEALLY TO GROOM LEADERSHIP FROM THE SAME BACKGROUND AS EACH INDIVIDUAL OFFICE'S DISTINCT PATIENT BASE. THIS WILL RESULT NOT ONLY IN A STRONGER ORGANIZATIONAL CULTURE, BUT ALSO SUPERIOR PATIENT CARE.

I am fortunate to have other members of my health care team who can communicate with patients in these other languages.

We have faced recent challenges related to COVID-19. Many of our patients live in multigenerational households and rely on other family members for support with medical visits. During the pandemic, communication with some of these patients has become challenging. Virtual clinics have been helpful in these instances to allow the patient and family members to be present.

Mr. Shirakian: Distinct ethnic populations approach health care differently, with varied concerns and anxieties. It is our responsibility to try to deliver the highest quality care in a manner that is sensitive to these issues. This includes being vigilant that staff members and physicians are 100% respectful and considerate in addressing these concerns.

Dr. Rachitskaya: I am lucky to have a team that represents the diverse community we serve. It is common to hear different languages spoken as technicians greet patients. Retina specialists often see patients more frequently than any other medical provider. The patients share with my staff their life stories, their successes, and their fears. A patient's living situation, including support system or lack thereof, can affect access to care and compliance. Understanding the issues that patients face outside my office allows me to provide better care.

To improve patient–physician communication, I also try to engage family even if they might not be present for an appointment. Challenging situations might still arise. I remind myself that, however difficult the situation might be, I am here to take care of the patients and their conditions.

I would also note that it is a two-way street, and sometimes the patients might not be culturally sensitive to the caregivers. If there is discrimination or inappropriate behavior toward my staff, I try to address it the moment it happens and ensure that a patient is educated that such behavior is not acceptable at our institution.

RT: Can you share some success stories?

Dr. Williams: A Latino patient was referred to me for a conjunctival lesion concerning for ocular surface squamous neoplasia. He had missed multiple appointments because of his work schedule, and ultimately we extended our clinic hours to ensure that he was seen. Given his work and social situation, surgery was the most appropriate treatment. He was apprehensive about surgery, but his demeanor clearly eased after we had an extensive discussion in Spanish. He ultimately agreed to proceed with surgery and had an uncomplicated course.

A second success story involved an older White patient with ocular lymphoma. With COVID-19–related restrictions at the cancer center, he was not permitted to have family members with him in the treatment room. The patient was resistant to treatment during our initial discussion of his clinical diagnosis and recommendation for radiation treatment, given his age. A biopsy was needed to confirm the diagnosis, and he requested to have family input on his decision. We held a video conference with his daughter and repeated the discussion in its entirety, after which he left to weigh his decision with additional family support and input. The patient agreed to the biopsy, which confirmed the diagnosis of lymphoma, and underwent radiation for definitive treatment.

I consider these success stories not just because of the positive clinical outcomes but because they remind me of the importance of meeting the patient where they are and treating the patient as a whole person.

Dr. Cunningham: A Russian-speaking male in his 60s was referred for a retinal tear in his left eye. He spoke little English and was by himself. During his examination, I could tell he was apprehensive, scared, and confused. Despite using a translating app, I could tell he did not understand what was going on and why he needed laser treatment. At that moment, we found out that one of my billing

specialists was from Russia and spoke fluent Russian. I had her translate the exam findings and the risks, benefits, and alternatives to laser treatment. I immediately saw relief in his face, as he nodded in agreement. This story has replayed itself in dealing with patients from other cultures that speak a specific language.

Another success story at our practice has been with the use of telemedicine during the COVID-19 pandemic. We were one of the first retina groups to initiate a hybrid telemedicine platform. This has been especially helpful for our patients who reside in multigenerational households. We can limit their exposure while still reviewing all pertinent imaging and giving our impressions to the patient and family members on one video call. This has been extremely helpful.

Dr. Rachitskaya: Sometimes one person stopping and listening can make all the difference. I vividly recall an elderly gentleman under treatment for wet AMD. We saw him frequently, and on this particular visit he was extremely polite and appreciative, as always. However, something was off. He confided that day to my fellow, who was of the same gender and ethnic background, that he had been feeling depressed and had been having suicidal thoughts. We rushed him to the emergency room, possibly averting a catastrophe.

RT: What advice would you give to practices wishing to improve their cultural diversity?

Dr. Williams: From a practical standpoint, practices need to identify what diversity exists in their community and ensure that comparative data is available to assess progress. Hiring should focus on the broad definition of diversity, including, but not limited to, race, gender, nationality, religious background, and sexual orientation.

Improvements in practice-wide cultural diversity start on an individual level. When leadership and staff focus on improving their own understanding of cultural diversity, an environment that fosters a deeper understanding and acceptance of diversity is likely to result. Additionally, formal training and implementation of practice policies and guidelines can also improve the cultural competence of the staff. It is extremely important to foster an inclusive environment so that the culturally diverse team is retained.

Dr. Bagheri: Three simple rules:

1. Diversity is crucial at all levels of the organization, from the leadership on down.
2. Be flexible, and have each office location's staff and patient resources reflect the needs of the patient population.
3. Do not get satisfied or stagnant! Empower your team to give you feedback to constantly strive to be better at addressing cultural differences.

Dr. Cunningham: I believe a culturally diverse staff has significant advantages that go beyond simply connecting to patients from similar cultures. I would advise that every physician evaluate how they can make their staff a better reflection of their community at large. Also, we should all be offering professional development on the importance of diversity in the workplace.

Mr. Shirakian: Take the time to analyze the demographics of your patient base, referral sources, and local community to identify gaps that may amplify any discomfort a patient may feel during medical treatment. Ensuring that patients are comfortable and confident in explaining their chief complaints, during what may be a challenging time for them, will be remembered and appreciated for years to come.

Dr. Rachitskaya: Cultural diversity should not be an afterthought. It is important to be aware of the patient population being served and have a concrete plan on addressing these issues. ■

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THE ROLE OF SCLERAL BUCKLING IN 2021



Some retinal detachment patients would do better with this tried-and-true surgical approach.

BY BENJAMIN K. YOUNG, MD, MS, AND DAVID N. ZACKS, MD, PHD

Rhegmatogenous retinal detachment is a sight-threatening condition and one of the most common surgical problems encountered by vitreoretinal surgeons. Although each surgeon's specific technique may vary, the fundamental strategy for repair should always include the following:

- Finding all retinal breaks by careful intraoperative examination;
- Sealing the breaks with retinopexy, either cryo or laser; and
- Plugging the breaks with tamponade, internal (gas/oil) and/or external (scleral buckle).

The three techniques that incorporate each of these steps are often classified by their approach to tamponade: an internal approach with (1) pars plana vitrectomy (PPV) or (2) pneumatic retinopexy, and an external approach with (3) scleral buckle, which may be combined with PPV.

Scleral buckling, first described in 1949, predates PPV, first performed in 1971.^{1,2} Today, vitrectomy is by far the more popular technique to repair retinal detachments.³ A few reasons for scleral buckling's decline in popularity include greater operative time and comparative postoperative morbidity, including but not limited to postoperative pain, unpredictable refractive shifts, diplopia, ptosis, and intraocular injury during external fluid drainage.

So, in 2021, why should the vitreoretinal surgeon continue to stock scleral buckling equipment? Because, although vitrectomy has significant versatility, there are some clinical situations in which the scleral buckle, either alone or in combination with PPV, is the superior technique.

VITREOUS STATUS

Retinal breaks leading to detachments can be separated into two main categories: Either the vitreous remains

attached, or it is separated from the retina.

When the vitreous is separated from the retina, the detachment's causative break is typically either a horseshoe flap tear or an operculated hole. When the vitreous is still attached, the causative break is generally either an atrophic hole (often associated with lattice degeneration) or a retinal dialysis, in which the retina has torn at its insertion to the ora serrata, typically due to trauma.

We suggest that this classification of the vitreous should determine the choice of surgical technique, taking precedent over other factors such as lens status. When the vitreous is separated from the retina, the detachment is typically best repaired with PPV, as the vitreous and hyaloid face are easy to remove. Note that this does not necessarily mean a complete stage 4 posterior vitreous detachment (PVD) must be present; for example, an eye with a retinal detachment and a stage 3 PVD in which the vitreous is still adherent to the optic nerve head may still have a flap tear and thus benefit from vitrectomy. In that case, the PVD can simply be completed intraoperatively.

By contrast, if the vitreous is still attached to the retina, a significant disadvantage of vitrectomy is the difficulty in elevating the hyaloid face from the retina. These situations also tend to occur in younger patients, in whom the hyaloid face may be more adherent, increasing the difficulty of complete hyaloid removal even over attached retina. Leaving significant amounts of vitreous or hyaloid may increase the risk of proliferative vitreoretinopathy (PVR) and, ultimately, redetachment and/or poor visual outcome.³ Therefore, scleral buckling is an excellent technique in these cases. A further advantage of a scleral buckle in an eye with a formed vitreous without significant liquefaction is the ability to use the vitreous itself as a biotamponade to plug the breaks. This can obviate the need for external drainage or intraocular gas, thus leading to faster visual recovery.

Figure courtesy of Thomas Wubbien, MD, PhD, Kellogg Eye Center

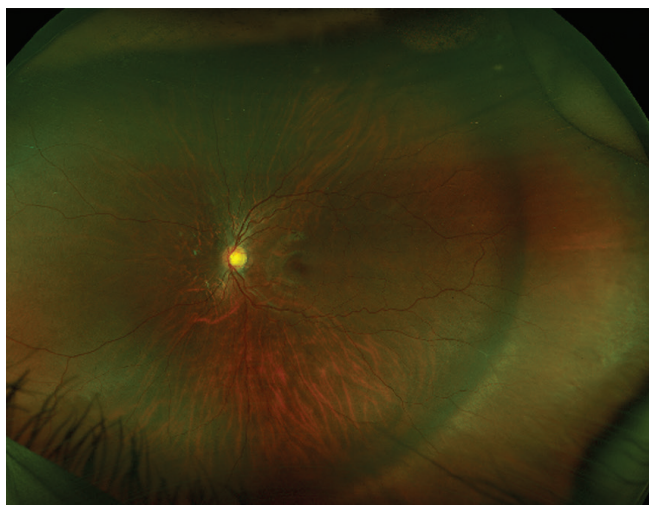


Figure. A 24-year-old woman who had a superior retinal detachment due to lattice with atrophic holes is now status-post scleral buckle.

So, although patient age often correlates with the use of a scleral buckle, this is because the vitreous tends to be attached and not significantly liquefied in younger patients. We do not consider age as an independent factor in the choice of technique, but rather as a surrogate for determining the extent of vitreous liquefaction, which can be difficult to assess clinically (Figure).⁴

THE PRESENCE OF PVR

Another situation in which a scleral buckle may be beneficial is in eyes with PVR. When PVR occurs, it tends to create anterior traction, which can be difficult to relieve with PPV and membrane peeling alone. When there is at least grade C PVR, we often prefer to perform a combined PPV with scleral buckle, which may obviate the need for potential large, circumferential retinectomies.

A notable exception is in an eye with a rhegmatogenous retinal detachment and attached vitreous, when the PVR is present only subretinally. In that situation, scleral buckling alone may be effective in primary reattachment.⁵

POSITIONING

Some patients, such as those with severe arthritis or other musculoskeletal disability, may be precluded from the head positioning required for optimal intraocular tamponade. These patients may benefit from a scleral buckle, which does not typically require intraocular tamponade.

LENS STATUS

In the age of minimally invasive, highly effective phacoemulsification, we no longer consider phakic status when devising the surgical strategy for retinal detachments. Although it may be of benefit to the patient to preserve the crystalline lens, and thus accommodation, the first priority

is maximizing the chance of primary reattachment of the retina. Therefore, if a patient has a clear crystalline lens but a PVD and flap tear or operculated hole, we typically recommend PPV.

For a pseudophakic retinal detachment, we almost always advocate for PPV, for three reasons:

1. Most pseudophakic retinal detachments have at least partial PVDs, as cataract extraction often changes the vitreous due to mechanical and biochemical factors.⁶
2. Most pseudophakes have a liquefied vitreous.
3. Pseudophakes can have very small retinal breaks that may be difficult to visualize with indirect ophthalmoscopy, even with optimal dynamic scleral indentation. The higher operative magnification from the surgical microscope, off-axial lighting with the light pipe, and ability to use active vacuum to tent up small breaks can make it easier to identify these very small breaks during vitrectomy.

CONCLUSIONS

The scleral buckle approach to retinal detachment repair is an essential tool in the retinal surgeon's armamentarium and should remain a foundational component of vitreoretinal surgical fellowship training. Scleral buckles have advantages over vitrectomy such as crystalline lens preservation, earlier visual rehabilitation, and absence of positioning requirements; however, vitreous status is the most important consideration in choosing a scleral buckle technique for primary retinal detachment. ■

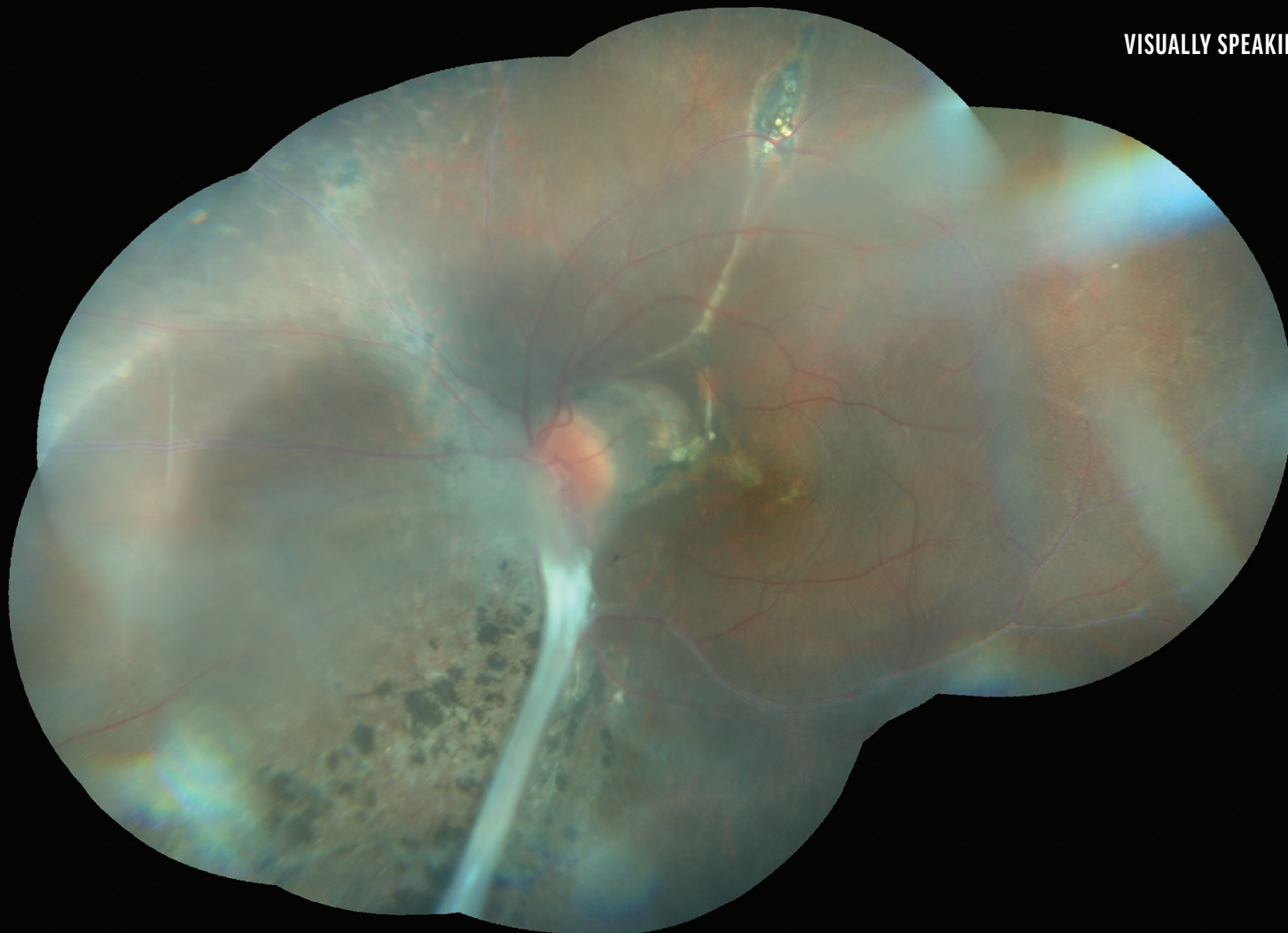
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A RARE DIAGNOSIS WITH LASTING EFFECTS

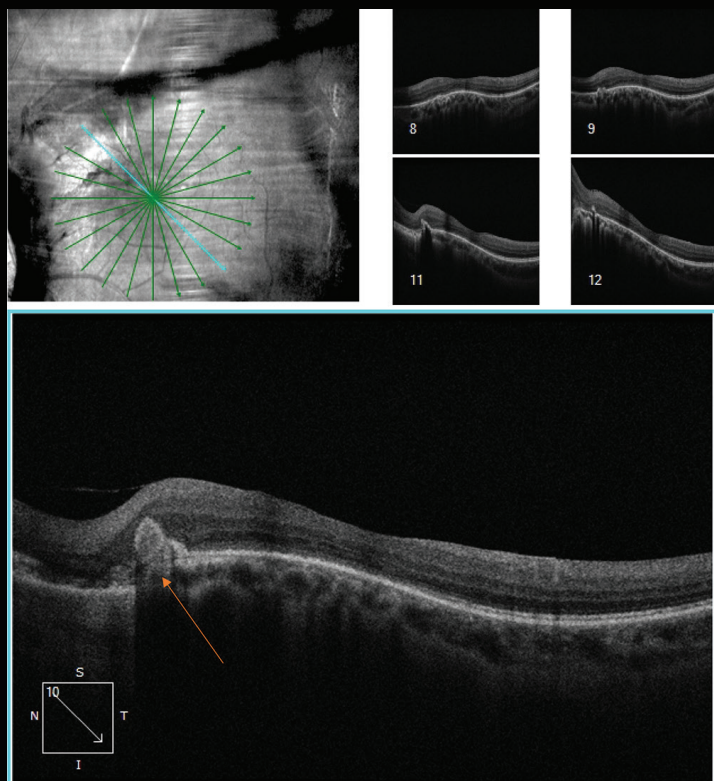
The long-term sequelae of *Toxocara* retinochoroiditis left this patient with poor vision in the affected eye.



BY EDUARDO ZANS, MD; EDITED BY MANISH NAGPAL, MBBS, MS, FRCS

A 26-year-old man presented with decreased vision in the left eye. His medical history included panuveitis due to *Toxocara* retinochoroiditis 1 year prior, which was confirmed by lab testing. At that time, his left eye was successfully treated topically with 1% atropine every 12 hours and 1% prednisolone every 6 hours for 2 weeks followed by a taper. In addition, the patient was prescribed oral albendazole 400 mg twice daily and prednisone 50 mg once daily for 2 weeks followed by a taper.

At presentation to our center, the patient was 1 month post-cataract surgery in the left eye, and VA was 20/20 OD and 20/100 OS. The examination in the right eye was normal. Indirect funduscopy in the left eye revealed a peripheral granuloma with consolidation and contraction of the lesion to the optic nerve, producing a peripheral elevated mass with retinal folds extending posteriorly (Main Figure). OCT of the macula showed involvement nasally with disruption of the retinal pigment epithelium layer (Figure, Next Page).



Because the patient was stable with no inflammatory signs in the anterior segment, he was prescribed artificial tears and followed closely.

DISCUSSION

Toxocara retinochoroiditis is usually diagnosed with a patient history of dog or cat exposure and clinical findings such as unilateral progressive vision loss, floaters, leukocoria, and funduscopy findings of peripheral granuloma (20%–40%), central posterior granuloma (25%–46%), and chronic endophthalmitis (25%).¹ Diagnosis is confirmed by laboratory testing. ■

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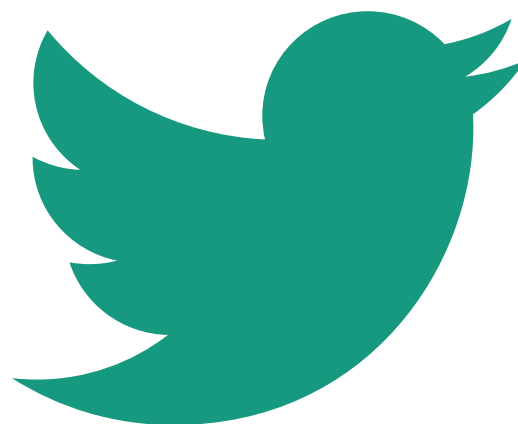
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METASTASES OF SURPRISING ORIGIN



A rare bilateral case of choroidal metastasis from prostate cancer.

BY HUSSAIN RAO, MS; ALLISON BRADEE, MD; SUNPREET RAKHRA, MD; DAVID CAMEJO, MD; AND KOMAL B. DESAI, MD

The choroid is the most common site for uveal metastasis, and choroidal metastasis is the most common intraocular malignancy. The vast majority of choroidal metastases are a result of primary tumors originating in the breast (40%–53%) or lung (20%–29%).¹ Prostate cancer metastasis to the choroid is exceedingly rare, representing approximately 2% of all choroidal metastases.² Prostate cancer more commonly metastasizes to sites such as bone, lymph nodes, and liver.³

CASE REPORT

A 70-year-old man with a history of metastatic prostate cancer was referred to ocular oncology for evaluation of decreased visual acuity and abnormal findings on fundoscopic examination. The patient's cancer was initially diagnosed 7 years earlier. At that time, he had mildly elevated prostate-specific antigen (PSA), and a prostate biopsy confirmed a diagnosis of prostatic adenocarcinoma. The patient subsequently underwent a modified radical prostatectomy that revealed poorly differentiated adenocarcinoma involving bilateral lobes with a Gleason score of 4 + 5 = 9. There was also evidence of perineural invasion and a positive left posterior margin.

Given these high-risk features, the patient underwent adjuvant radiation therapy. Despite treatment, his PSA continued to rise, and the patient developed bony metastasis, including to the orbital bone of his right eye. He was

treated with hormonal therapy, including leuprolide acetate (Lupron, Abbvie), enzalutamide (Xtandi, Astellas Pharma), and docetaxel (Taxotere, Sanofi-Aventis) without regression of disease.

Seven years after the initial diagnosis, the patient began noticing changes in his vision, including progressively worsening near and distance visual acuity, and he was evaluated by his primary ophthalmologist. His ocular history was significant for a retinal detachment in the left eye several years earlier that was treated with a scleral buckle. Ocular examination revealed VA of 20/60 OD and 20/40 OS with normal IOPs.

OCT of the maculae revealed bilateral choroidal masses with overlying subretinal fluid. Fundus photography demonstrated hypopigmented lesions in the macula bilaterally (Figure 1). Fluorescein angiography (FA) of the right eye demonstrated an area of hypofluorescence involving the fovea and temporal macula (Figure 2A). FA of the left eye

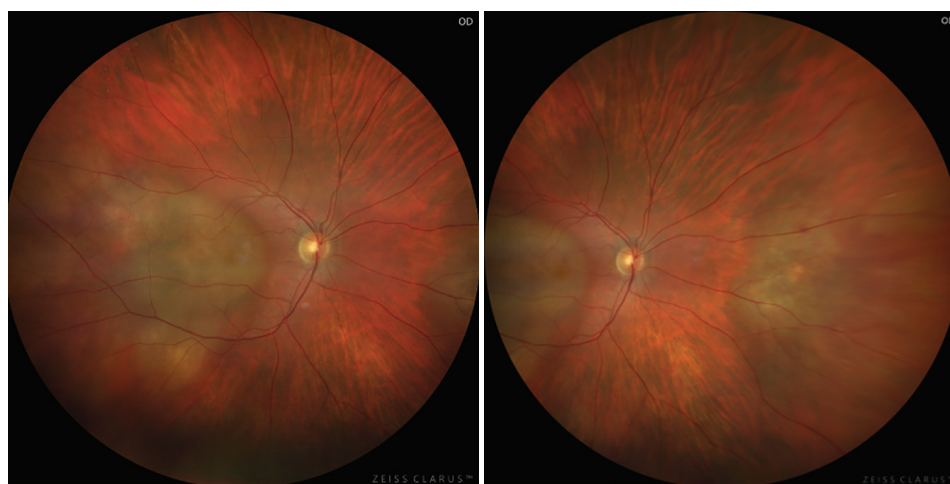


Figure 1. Fundus imaging revealed bilateral hypopigmented lesions in the macula.

demonstrated speckled hyperfluorescence in the temporal macula (Figure 2B).

The patient was diagnosed with bilateral choroidal metastases and referred to ocular oncology. Ocular oncology confirmed the diagnosis of choroidal metastasis with repeat fundus photos and FA demonstrating large amelanotic posterior pole lesions bilaterally.

Radiation oncology was consulted to create a plan for palliative external beam radiation therapy (EBRT) to prevent further vision loss. The patient received a total dose of 30 Gy in 10 fractions over the course of 14 days, and his visual symptoms began to improve. Three weeks after treatment, his VA had improved to 20/30 OD and 20/40 OS.

DISCUSSION

Prostate cancer is a common malignancy in men that often metastasizes to the bones, lymph nodes, lungs, and axial skeleton. Rarely, prostate cancer metastasizes to the choroid.² When it does, it is typically unilateral—not bilateral as seen in this case. Metastasis from prostate cancer typically presents as yellow-colored amelanotic lesions. Subretinal fluid and retinal epithelial mottling are typical.

Treatment for choroidal metastasis secondary to prostate cancer typically consists of hormonal therapy or EBRT.⁴⁻⁶ Hormonal therapy includes antiandrogens or luteinizing hormone-releasing hormone agonists. Current literature suggests that EBRT is an effective treatment modality, especially for those who have not responded to hormonal therapy, as seen in this case. ■

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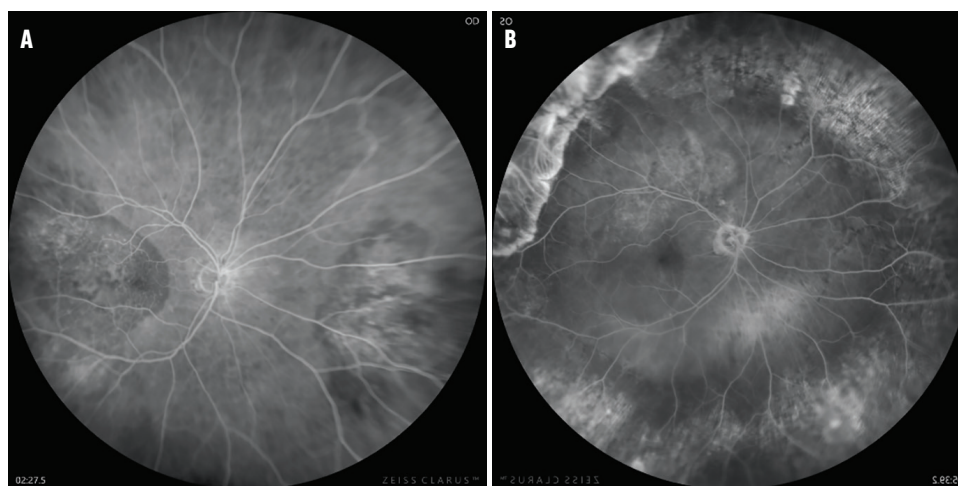


Figure 2. FA of the right eye (A) revealed an area of hypofluorescence involving the fovea and temporal macula, while the left eye (B) had speckled hyperfluorescence in the temporal macula.

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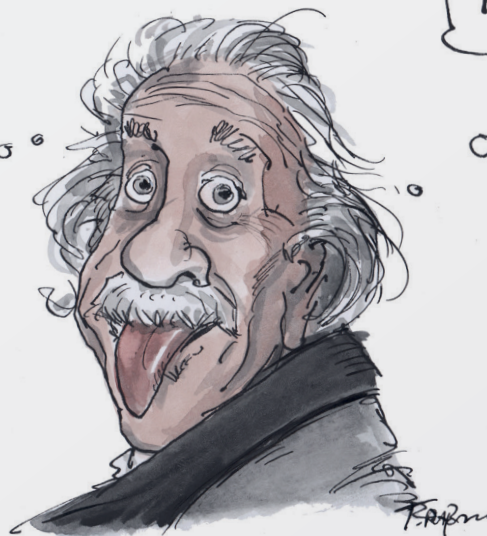
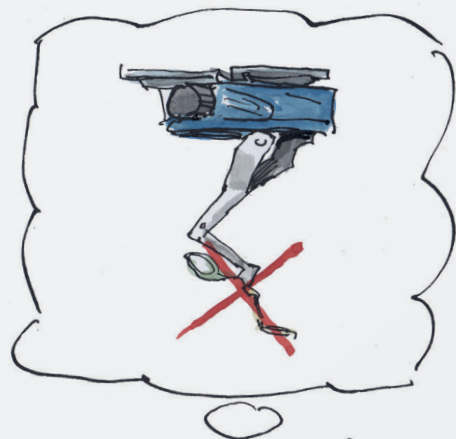
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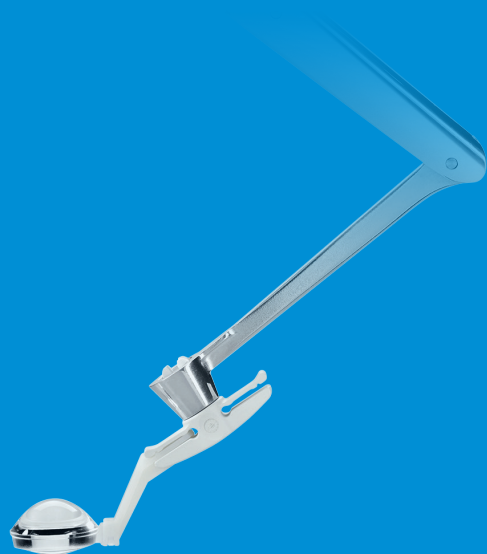
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