SEPTEMBER / OCTOBER 2023 # 69

the Ophthalmologist™

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The institutions advancing ophthalmology training around the world

16 – 26

Now Approved for Wet AMD

LASTING CONTROL, FEWER INJECTIONS[1-3]

As demonstrated by vision outcomes in PULSAR at Week 48—fewer injections vs EYLEA 2 mg

EYLEA HD achieved robust vision gains with fewer injections than EYLEA 2 mg at Week 48

The primary endpoint (noninferiority in mean change in BCVA [ETDRS letters] from baseline at Week 48) was met: 6.7 letters gained for EYLEA HD Q12W, 6.2 letters for EYLEA HD Q16W, and 7.6 letters for EYLEA 2 mg Q8W[1,2,*]

- Noninferiority was based on the LS mean difference between EYLEA HD Q12W vs EYLEA 2 mg Q8W and EYLEA HD Q16W vs EYLEA 2 mg Q8W: -1.0 (95% CI, -2.9 to 0.9) and -1.1 (95% CI, -3.0 to 0.7) letters, respectively, using a noninferiority margin of 4 letters
- Fewer mean number of injections: 6.1 for EYLEA HD Q12W and 5.2 for EYLEA HD Q16W vs 6.9 for EYLEA 2 mg Q8W[†]

*Following 3 initial monthly doses. FAS at baseline: EYLEA HD Q12W (n=335), EYLEA HD Q16W (n=338), EYLEA 2 mg Q8W (n=336). FAS; observed values (censoring data post ICE) at Week 48: EYLEA HD Q12W (n=299), EYLEA HD Q16W (n=289), EYLEA 2 mg Q8W (n=285).

†Patients who completed Week 48: EYLEA HD Q12W (n=316), EYLEA HD Q16W (n=312), EYLEA 2 mg Q8W (n=309).

PULSAR study design: Multicenter, randomized, double-masked study in which treatment-naïve patients with Wet AMD (N=1009; age range: 50-96 years, with a mean of 74.5 years) were randomized to receive EYLEA HD Q12W (n=335), EYLEA HD Q16W (n=338), or EYLEA 2 mg Q8W (n=336), following 3 initial monthly doses for each treatment group. In the EYLEA HD groups, patients could be treated as frequently as every 8 weeks based on protocol-defined visual and anatomic criteria starting at Week 16. The primary endpoint was the mean change in BCVA (ETDRS letters) from baseline at Week 48 for the EYLEA HD Q12W and Q16W groups vs EYLEA 2 mg Q8W, with a noninferiority margin of 4 letters.[1,2]

IMPORTANT SAFETY INFORMATION FOR EYLEA HD AND EYLEA

CONTRAINDICATIONS

- EYLEA HD and EYLEA are contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA HD or EYLEA.

WARNINGS AND PRECAUTIONS

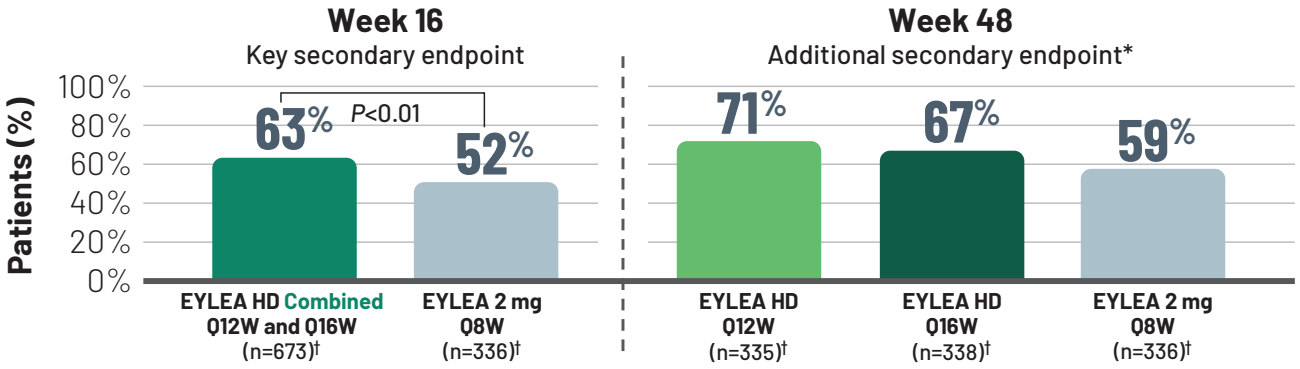
- Intravitreal injections, including those with aflibercept, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA HD or EYLEA. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA HD and EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA HD and EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA HD and EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).
  - EYLEA HD: The incidence of reported thromboembolic events in the wet AMD study (PULSAR) from baseline through week 48 was 0.4% (3 out of 673) in the combined group of patients treated with EYLEA HD compared with 1.5% (5 out of 336) in patients treated with EYLEA 2 mg. The incidence in the DME study (PHOTON) from baseline to week 48 was 3.1% (15 out of 491) in the combined group of patients treated with EYLEA HD compared with 3.6% (6 out of 167) in patients treated with EYLEA 2 mg.

Early, Superior Resolution of Retinal Fluid

EYLEA® HD (aflibercept) Injection 8 mg

Demonstrated superiority compared with EYLEA 2 mg at Week 16

Proportion of patients without retinal fluid (IRF and SRF) in the central subfield[2,3]



***Data limitations:** Proportions of patients with absence of retinal fluid (IRF and SRF) in the central subfield at Week 48 was a prespecified additional secondary endpoint. This endpoint was analyzed descriptively only and not adjusted for multiplicity. Clinical significance has not been established and conclusions regarding treatment effect cannot be drawn.

†Following 3 initial monthly doses. Absence of retinal fluid was determined by a central reading center on OCT. FAS; last observation carried forward (censoring data post ICE).

EXPLORE THE CLINICAL DATA AT EYLEAHDhcp.us

WARNINGS AND PRECAUTIONS (continued)

- EYLEA: The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

- EYLEA HD:
  - The most common adverse reactions (≥3%) reported in patients receiving EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage.
- EYLEA:
  - Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
  - The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA HD or EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® HD (aflibercept) 8 mg is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA® (aflibercept) 2 mg is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

Please see Brief Summary of Prescribing Information for EYLEA HD and EYLEA on the following page.

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; ICE, intercurrent event; IRF, intraretinal fluid; LS, least squares; OCT, optical coherence tomography; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks; SRF, subretinal fluid.

References: 1. EYLEA HD full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2023. **2.** Brown DM; on behalf of the PULSAR study investigators. Aflibercept 8 mg in patients with nAMD: 48-week results from the phase 3 PULSAR trial. Data presented at: Angiogenesis 2023; February 11, 2023. **3.** Data on file. Regeneron Pharmaceuticals, Inc.

08/2023
EHD.23.02.0012

EYLEA® HD (aflibercept) Injection 8 mg, for intravitreal use AND EYLEA® (aflibercept) Injection 2 mg, for intravitreal use
BRIEF SUMMARY OF PRESCRIBING INFORMATION

4. CONTRAINDICATIONS

4.1 Ocular or Periocular Infections EYLEA HD and EYLEA are contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation EYLEA HD and EYLEA are contraindicated in patients with active intraocular inflammation.

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

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments Intravitreal injections including those with aflibercept have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA HD or EYLEA. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see Dosage and Administration (2.6 EYLEA HD, 2.4 EYLEA) in the full Prescribing Information and Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA HD and EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.6 EYLEA HD, 2.4 EYLEA) in the full Prescribing Information*].

5.3 EYLEA HD, 5.4 EYLEA Thromboembolic Events There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA HD and EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

- **EYLEA HD:** The incidence of reported thromboembolic events in the wet AMD study (PULSAR) from baseline through week 48 was 0.4% (3 out of 673) in the combined group of patients treated with EYLEA HD compared with 1.5% (5 out of 336) in patients treated with EYLEA 2 mg. The incidence of reported thromboembolic events in the DME study (PHOTON) from baseline to week 48 was 3.1% (15 out of 491) in the combined group of patients treated with EYLEA HD compared with 3.6% (6 out of 167) in patients treated with EYLEA 2 mg.
- **EYLEA:** The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

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

- Hypersensitivity [*see Contraindications (4.3)*]
- Endophthalmitis and retinal detachments [*see Warnings and Precautions (5.1)*]
- Increase in intraocular pressure [*see Warnings and Precautions (5.2)*]
- Thromboembolic events [*see Warnings and Precautions (5.3 for EYLEA HD, 5.4 for EYLEA)*]

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

- **EYLEA HD:** A total of 1164 patients were treated with EYLEA HD and 503 patients were treated with EYLEA 2 mg in two clinical studies. The most common adverse reactions reported in ≥3% of patients treated with EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage.
- **EYLEA:** A total of 2980 adult patients treated with EYLEA constituted the safety population in eight phase 3 studies. Among those, 2379 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Neovascular (Wet) Age-Related Macular Degeneration (Wet AMD)

EYLEA HD: The data described below reflect exposure to EYLEA HD or EYLEA 2 mg in 1009 patients with Wet AMD, in 1 double-masked, controlled clinical study (PULSAR) for 48 weeks [*see Clinical Studies (14.1) in the full Prescribing Information*].

EYLEA: The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEW 1 and VIEW 2) for 24 months (with active control in year 1) [*see Clinical Studies (14.1) in the full Prescribing Information*]. Safety data observed in the EYLEA group in a 52-week, double-masked, phase 2 study were consistent with these results.

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

	PULSAR			VIEW 1 and VIEW 2		VIEW 1 and VIEW 2	
	ARs (≥1%) in at least one group			Baseline to Week 52		Baseline to Week 96	
Adverse Reactions	EYLEA HD q12 (n=335)	EYLEA HD q16 (n=338)	EYLEA 2q8 (n=336)	EYLEA (n=1824)	Active Control (ranibizumab) (n=595)	EYLEA (n=1824)	Control (ranibizumab) (n=595)
Conjunctival hemorrhage[a]	3%	2%	1%	25%	28%	27%	30%
Eye pain	-	-	-	9%	9%	10%	10%
Ocular discomfort/eye pain/eye irritation[a]	3%	3%	2%	-	-	-	-
Cataract[a]	4%	4%	4%	7%	7%	13%	10%
Vitreous detachment[a]	2%	3%	2%	6%	6%	8%	8%
Vitreous floaters[a]	1%	4%	3%	6%	7%	8%	10%
Intraocular pressure increased[a]	4%	4%	2%	5%	7%	7%	11%
Ocular hyperemia[a]	-	-	-	4%	8%	5%	10%
Corneal epithelium defect[a]	2%	2%	3%	4%	5%	5%	6%
Retinal pigment epithelial detachment[a]	1%	1%	2%	3%	3%	5%	5%
Injection site pain	-	-	-	3%	3%	3%	4%
Foreign body sensation in eyes[a]	1%	1%	2%	3%	4%	4%	4%
Lacrimation increased	-	-	-	3%	1%	4%	2%
Vision blurred[a]	4%	6%	7%	2%	2%	4%	3%
Intraocular inflammation[a]	1%	1%	1%	2%	3%	3%	4%
Retinal pigment epithelial tear	-	-	-	2%	1%	2%	2%
Retinal pigment epithelial tear/epitheliopathy[a]	2%	1%	2%	-	-	-	-
Injection site hemorrhage	-	-	-	1%	2%	2%	2%
Eyelid edema	-	-	-	1%	2%	2%	3%
Corneal edema	-	-	-	1%	1%	1%	1%
Retinal detachment[a]	1%	<1%	0%	<1%	<1%	1%	1%
Retinal hemorrhage	3%	3%	4%	-	-	-	-
Vitreous hemorrhage	<1%	1%	1%	-	-	-	-

Reported terms differ between the PULSAR and VIEW 1 and VIEW 2 studies, as indicated by dashes in the table.

[a]Represents grouping of related terms in PULSAR

Adverse drug reactions (ADRs) reported in <1% of participants treated with EYLEA HD were ocular hyperemia (includes adverse events of conjunctival hyperemia, conjunctival irritation, ocular hyperemia), lacrimation increased, eyelid edema, hypersensitivity (includes adverse events of rash, urticaria, pruritus), retinal tear, and injection site hemorrhage.

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA in VIEW 1 and VIEW 2 were hypersensitivity, retinal tear, and endophthalmitis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Risk Summary Adequate and well-controlled studies with EYLEA HD and EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposure (based on AUC for free aflibercept) was approximately 0.9-fold of the population pharmacokinetic estimated exposure in humans after an intravitreal dose of 8 mg for EYLEA HD and approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose of 2 mg for EYLEA [*see Data*].

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA HD or EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [*see Clinical Pharmacology (12.1) in the full Prescribing Information*], treatment with EYLEA HD or EYLEA may pose a risk to human embryofetal development. EYLEA HD and EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data *Animal Data* In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg. Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 0.9-fold of the population pharmacokinetic estimated systemic exposure (AUC) in humans after an intravitreal dose of 8 mg for EYLEA HD and approximately 6 times higher than systemic exposure (AUC) observed in adult patients after a single intravitreal dose of 2 mg for EYLEA.

8.2 Lactation Risk Summary There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA HD and EYLEA are not recommended during breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA HD or EYLEA and any potential adverse effects on the breastfed child from EYLEA HD or EYLEA.

8.3 Females and Males of Reproductive Potential Contraception Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 4 and 3 months after the last intravitreal injection of EYLEA HD or EYLEA, respectively.

Infertility There are no data regarding the effects of EYLEA HD or EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose 91 times higher (based on AUC of free aflibercept) than the corresponding systemic level estimated based on population pharmacokinetic analysis in humans following an intravitreal dose of 8 mg for EYLEA HD and at a dose approximately 1500 times higher than the systemic level observed in adult patients with an intravitreal dose of 2 mg for EYLEA. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [*see Nonclinical Toxicology (13.1) in the full Prescribing Information*].

8.4 Pediatric Use The safety and effectiveness of EYLEA HD in pediatric patients have not been established. The safety and effectiveness of EYLEA have been demonstrated in two clinical studies of pre-term infants with Retinopathy of Prematurity. These two studies randomized pre-term infants between initial treatment with EYLEA or laser. Efficacy of each treatment is supported by the demonstration of a clinical course which was better than would have been expected without treatment [*see Dosage and Administration (2.9), Adverse Reactions (6.1), Clinical Pharmacology (12.3) and Clinical Studies (14.6) in the full Prescribing Information for EYLEA*].

8.5 Geriatric Use In PULSAR, approximately 90% (604/673) of the patients in the HDq12 and HDq16 groups were 65 years of age or older and approximately 51% (343/673) were 75 years of age or older. In PHOTON, approximately 44% (214/491) of the patients in the HDq12 and HDq16 groups were 65 years of age or older and approximately 10% (50/491) were 75 years of age or older. In the clinical studies for EYLEA 2 mg, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

10 OVERDOSAGE Overdosing with increased injection volume may increase intraocular pressure. Therefore, in case of overdosage, intraocular pressure should be monitored and if deemed necessary by the treating physician, adequate treatment should be initiated.

17 PATIENT COUNSELING INFORMATION In the days following EYLEA HD or EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients and/or caregivers to seek immediate care from an ophthalmologist [*see Warning and Precautions (5.1)*]. Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA HD or EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

REGENERON®

Manufactured by: **Regeneron Pharmaceuticals, Inc.**
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 EHD.23.05.0127 08/2023

Who Owns Ophthalmology?

The patient remains the focus, of course – but shouldn't physicians "own" ophthalmology?

It says something of the quality and breadth of the discussions and seminars on offer at September's ESCRS 2023 in Vienna that my interest was piqued by a session ahead of the main event itself. Alongside the pre-congress Cornea and Glaucoma Days on September 7 was a debate titled "Who Owns Ophthalmology?" – surely a crucial question in any stakeholder's book.

With a growth in recent years in private equity (PE) firms entering the ophthalmology space, particularly in Europe, there has been a huge increase in cataract surgeries. Victor Chua, Senior Partner at Mansfield Advisors, illustrated that, by 2027, much of western Europe will see a rise of 26–30 percent in cataract surgeries, compared with 2019. In England, chiefly as a result of PE investment, ophthalmology is the only speciality that is back to pre-pandemic levels. In this respect, England is outperforming Europe – and it's rare, and quite refreshing, Chua noted, to see England or the UK at the top of any European ranking these days… Outsourced providers "have lower complication rates" than the NHS, he added – this is credited to "surgeon selection."

But here's the rub. Private providers in England and Wales are not obliged to train surgeons – "they get a bit of a free pass at the moment," admitted Chua. And the love affair with PE may not be all it is cracked up to be. The Ophthalmologist Power Lister, Guy Kezirian – President of SurgeonVision Consultants and, among other roles, President of Physician CEO – was on hand to rain on the PE parade. Based in the US, where the private model is far more advanced, he noted, "Private equity failures in ophthalmology recur about every 10 years – three times in my career!" The current high interest rates are going to see lots of PE companies fail, he added.

Rather than private equity, Kezirian advocates for the concept of physician equity – a private ownership model that is similar to PE but owned by the physicians. In PE, he explained, the doctors are working for the managers; with physician equity, "the managers are working for the doctors." Of course, success with this model requires business-savvy physicians – perhaps those who have had some formal business training – but the results are "ownership, financial benefits, and control." And, as much as anything, the physician has a relationship with the patient that "managers" don't.

Ultimately, of course, ophthalmology couldn't exist without the physician, said Kezirian – "so the physician should have ownership."

Julian Upton
Group Editor

SIGHT SCIENCES

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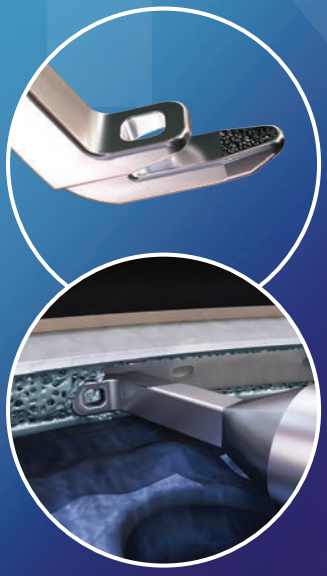

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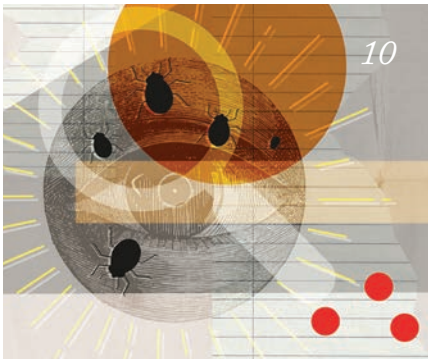
INDICATIONS FOR USE: The SION Surgical Instrument is a manually operated device used in ophthalmic surgical procedures to excise trabecular meshwork. The SION Surgical Instrument is a sterile, single use device. **CONTRAINDICATIONS**: Do not use the SION if there is inadequate corneal clarity, or poor visualization of angle structures or in any situations where the anterior chamber angle has been damaged (i.e., from trauma or surgery) or it may not be possible to pass the device through Schlemm's canal. SION is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow angle glaucoma, narrow inlets with plateau iris, peripheral anterior synechiae, traumatic, malignant, or uveitic glaucoma; it is also contraindicated in patients who have had previous argon laser trabeculoplasty, ab interno devices implanted in or through Schlemm's Canal, or prior incisional glaucoma surgery including trabeculotomy, goniotomy. **WARNINGS**: Always maintain direct microscopic and gonioscopic visualization of the instrument tip during the procedure to avoid inadvertently damaging intraocular structures. Avoid touching the SION tip to any surfaces as this may damage it. Do not use the SION tip to create a corneal incision. Visit **SIONsurgical.com/ifu** for the indications for use, contraindications, warnings, and potential adverse events.

Speak with your local Sight Sciences representative or email us at **glaucoma@sightsciences.com** to schedule a demo.

Contents



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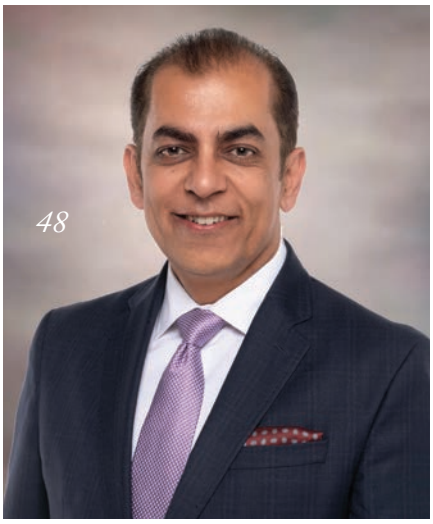

Practice Fundamentals

Sitting Down With...

the Ophthalmologist

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Feel free to contact any one of us:
first.lastname@texerepublishing.com

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Change of address info@theophthalmologist.com
Hayley Atiz, The Ophthalmologist, Texere Publishing Inc., 115 Broadway, FL 5, New York 10006, USA.

General enquiries
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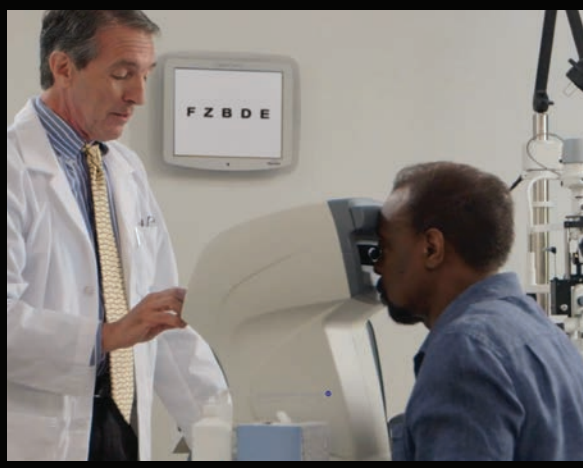

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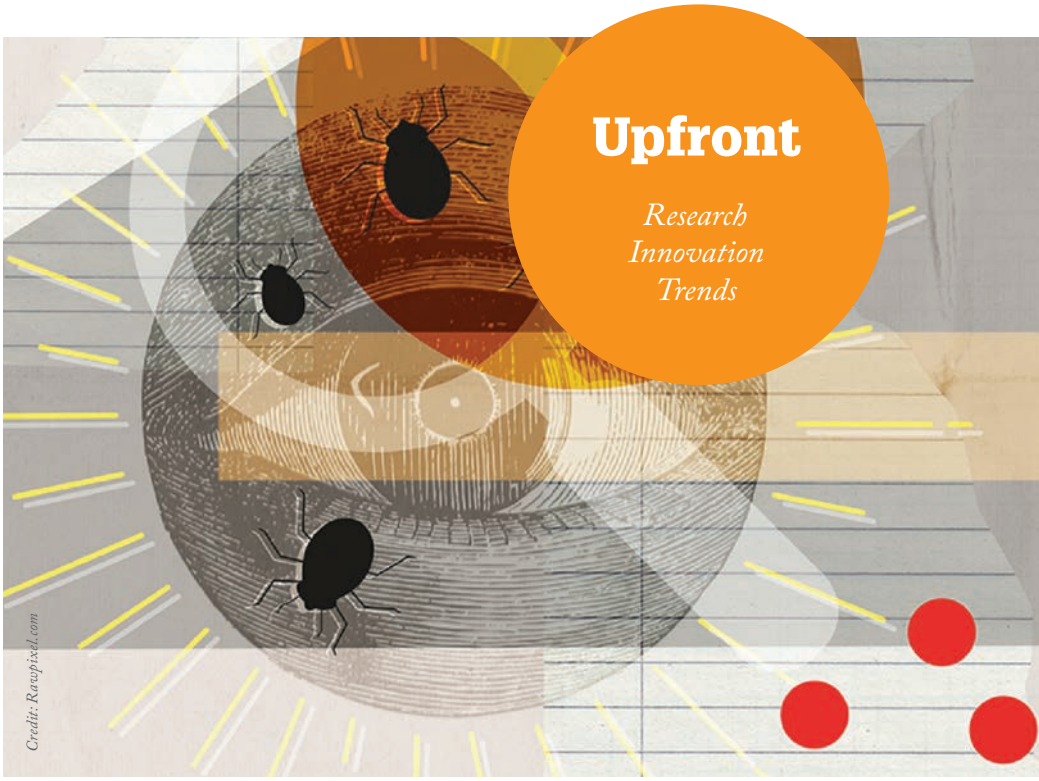

Credit: Rawpixel.com

Fall of the Mitey

The first FDA approval for Demodex blepharitis treatment

Demodex mites are the most common ectoparasite found on humans. An infestation of these miniscule parasites on a person's eyelashes can cause blockages in the oil glands at the base, leading to Demodex blepharitis, a condition characterized by eyelid inflammation, ocular irritation, redness, and dry eye disease. As people age, Demodex mites can become more prevalent. Patients suffering from chronic rosacea and immunodeficiency disorders have also been found to be more susceptible to infestation.

Studies investigating the prevalence of Demodex blepharitis from the presence of collarettes (1) – cylindrical deposits of waxy buildup found at the lid margin that can be detected by a routine slit-lamp examination – have indicated that the condition affects up to 45 percent of the US population (2). For patients living with the condition, associated psychosocial effects can include depression and anxiety (3).

Tarsus Pharmaceuticals launched its prescription eye drop, Xdemvy 0.25% – the first FDA-approved treatment for Demodex blepharitis (4) – at pharmacies across the US in August 2023. Administered with one drop in each eye, twice daily for six weeks, the lotilaner ophthalmic solution directly targets the Demodex mites, eradicating them by selectively inhibiting the GABA-Cl channels.

To support US patients' accessibility to Xdemvy, the company has developed Tarsus Connect – a suite of assistance programs to help provide financial support for eligible patients.

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"Biologic Velcro"

Researchers consider the biopolymer adhesive capabilities of plant-derived pectin for corneal wound healing

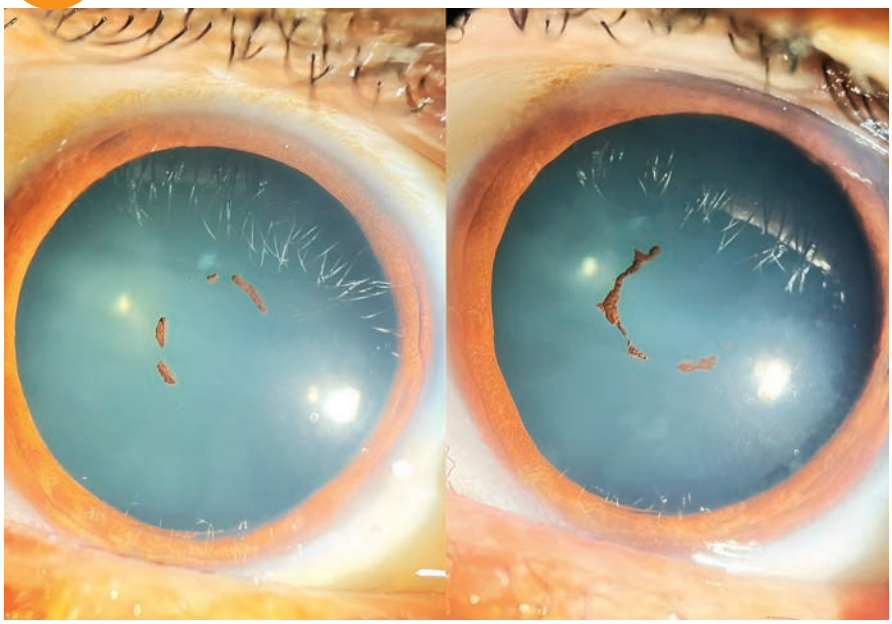
Pectin, a polysaccharide that functions as an adhesive between plant cells, is also one of the few polysaccharides with anti-inflammatory and immunomodulatory benefits. As well as being used in the food industry for its thickening, gelling and emulsification properties, pectin also has biomedical applications in drug delivery and tissue healing.

A new study investigates the potential for pectin as a biopolymer adhesive for corneal wound healing, particularly in post-routine corneal incisions – as a sealant to reduce wound leakage caused by variations in intraocular pressure – and in targeted drug delivery for traumatic injuries.

To assess the adhesive characteristics of pectin, the researchers used a bovine globe model as well as globes taken from Wistar rats. The pectin films – molded into tape form – were more adherent than control biopolymers (nanocellulose fibers, sodium hyaluronate, and carboxymethyl cellulose), and the adhesion strength got close to maximum within just seconds of contact, suggesting the potential for pectin to be used as an effective corneal incision sealant. Notably, the pectin films were able to resist anterior chamber pressure fluctuations from negative 51.3 ± 8.9 mm Hg to positive 214 ± 68.6 mm Hg. Biologic velcro indeed.

Credit: Rawpixel.com

IMAGE OF THE MONTH



A Case of TINU Syndrome

A case of tubulointerstitial nephritis and uveitis syndrome (TINU) - a rare oculorenal inflammatory condition first described in 1975 - in a patient with tubulointerstitial nephritis (TIN). Captured by Hammad Nasti, ophthalmologist at the Al-Kabir Eye Care Center in Srinagar, Jammu and Kashmir, India.

Credit: Credit: Hammad Nasti

Would you like your photo featured in Image of the Month? Send it to edit@theophthalmologist.com

QUOTE OF THE MONTH

"Although AI's current capabilities fall short of the hype, overcoming its challenges could unlock its potential in achieving the holy grail of personalized medicine. Yet, the question remains whether the rise of AI leads to the 'machinification' of medicine."

Siyin Liu is in Year Four of Specialty Training at UCL Institute of Ophthalmology, London, UK. He is the winner of this year's John Henahan Writing Prize (bit.ly/48tZ1Q3)

No Further PRoblems

Study shows effect of prophylactic ranibizumab (PR) on drusen volume, macular layer thicknesses, and progression of GA

"Impact of Prophylactic Ranibizumab to Prevent Neovascular Age-Related Macular Degeneration on Eyes With Intermediate Age-Related Macular Degeneration" is a new study published in ARVO's Translational Vision Science & Technology and conducted by a research group from an American multi-institutional team. Researchers compared the eyes of patients with intermediate age-related macular degeneration (AMD) injected with prophylactic ranibizumab (PR) every three months, with those given a sham injection to determine the effect of PR on drusen volume, macular layer thicknesses, and progression of geographic atrophy (GA) area over 24 months in the PREVENT trial. The results showed that PR given every three months did not appear to worsen the progressive retinal degenerative process as drusen volume, macular thinning or GA progression were not affected in eyes with intermediate AMD.

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In My View

Experts from across the world share a single strongly held opinion or key idea.

Responding to Short-Sightedness

An open letter to The Ophthalmologist

By Mark A. Bullimore, Adjunct Professor, University of Houston College of Optometry

I appreciate the recent article in The Ophthalmologist shining a light on myopia, the potential for slowing its progression, and thus reducing the risks of eye disease and visual impairment later in life (1). It is useful to see conflicting opinions amongst the contributors – something to be expected in an emerging field.

Three of the experts are clearly still riding the 0.01% atropine bandwagon, although one states that "0.01 percent atropine eye drops are effective in non-Asian children" while also concluding that "low-dose atropine 0.01 percent was not as effective in reducing axial length progression" as "highly aspheric lenslets (HAL), MiSight contact lenses, low dose atropine 0.05 percent, Biofinity +2.50 D lenses, Defocus Incorporated Multiple Segments (DIMS) eyeglasses, and orthokeratology lenses" (2).

My primary concern with the article is the disrespect shown to the eye care industry, which is driving the science of myopia control. One contributor makes a comment regarding "potential conflicts of interest" when it comes to "optical solutions." In their defense, they could be referring to manufacturers, prescribers, or both…

Another contributor states that opticians in their country "market different contact lenses as correcting peripheral hyperopic defocus, but again comprehensive data is lacking" and that "ophthalmologists have a skeptical attitude to these lenses due to somewhat questionable scientific evidence." He proceeds to selectively review portions of the literature, while acknowledging, but grossly overstating, the effect of age on rate of progression. He also states that "[o]ther studies on the efficacy of MiSight are by no means conclusive due to high dropout rates or other flaws in methodologies."

Absent from the discussion are the results of the pivotal three-year randomized clinical trial of the MiSight lens that resulted in its approval by the US Food and Drug Administration (FDA) (3, 4). Almost four years later, MiSight remains the only device or drug approved for the slowing of myopia progression in the US. The three-year trial showed that the lens slowed myopia by 0.73 D while it reduced axial elongation by 0.32 mm (3). This met a very high bar set by the FDA and approval would never have been granted were the results "by no means conclusive" with "flaws in methodologies."

Implicit in the comments is a blatant distrust of research funded by the eye care industry, although one assumes that they happily use surgical and diagnostic devices in their practice, while prescribing drugs and therapies to their patients – all developed by the eye care industry. They also appear to be ignorant to the fact that these FDA clinical trials are usually conducted at academic institutions and that the FDA conducts inspections to determine if the clinical investigators are conducting clinical studies in compliance with applicable statutory and regulatory requirements (5). In short, the level of rigor and oversight associated with industry-sponsored clinical trials usually far exceeds that of individuals and groups of investigators.

Returning to 0.01% atropine, a three-year randomized clinical trial was just published that could lead to its approval by FDA (6, 7). The trial showed 0.24 D slowing of progression and 0.13 mm slowing of axial elongation (6). I wonder whether the above criticism will be applied to these results with the same vigor or if the contributor will prefer to cite five-year studies conducted by independent clinicians in Europe and their fantastical findings (8, 9).

In closing, I am glad that opinions like those expressed in this recent article can be aired in The Ophthalmologist. At the same time, the publication is supported by the eye care industry and the herculean efforts needed to bring products to our patients and the level of rigor underlying these endeavors should be celebrated and not disparaged.

See references online at: top.txp.to/Bullimore/0923

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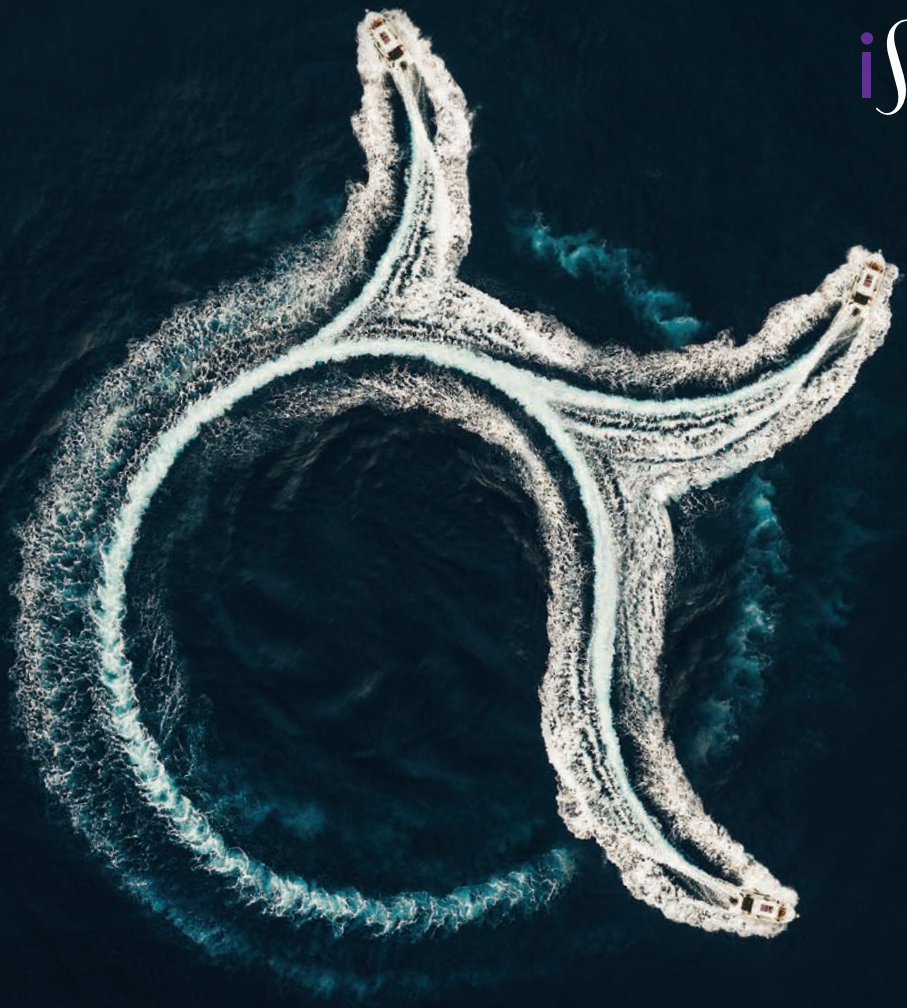

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REFERENCE

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Andy Corley is the Chair of the Board of RxSight, Inc. and owns equity interest in the company.

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RECOGNIZING GLOBAL EDUCATION IMPACT

We look at six institutions that are committed to developing and accelerating ophthalmology education and training around the world

Global ophthalmology is in the midst of an impressive pincer movement – on one flank, a shortage of ophthalmologists; on the other, an aging, expanding world population and a concomitant rise in age-related eye diseases. One response to this overwhelming maneuver is ophthalmology education that directly addresses widespread unmet needs and regional gaps in training.

The Ophthalmologist is proud to launch an annual initiative that recognizes the global educational impact of the institutions and programs that are leading the way in tackling health inequity. Our first Global Education Impact feature recognizes six institutions – a tour of the world from Mexico City to the Indian subcontinent, by way of long-established, state-of-the-art facilities in the US and UK. Find out how they are fostering cutting-edge technology, pairing local students and practitioners with expert mentors, and rolling out upskilling initiatives to the far corners of the world. Explore how they are focused on bringing new generations of ophthalmologists from diverse backgrounds and cultures into the profession, while facilitating treatment in the world's poorest areas.

Whatever their approach, all six institutions are united by the same ultimate aim: to ensure that everyone has access to quality eye care, regardless of location, age, or socioeconomic status.

Oftalmo University

Location: Mexico City
Established: 2017
Focus: Latin America (but with international ambitions)

Oftalmo University, Mexico City

Still in its relative infancy, Oftalmo University (OU) was set up in 2017 in Mexico City by a group of dedicated ophthalmologists who wanted to empower young eye care professionals to further their careers and become the best versions of themselves. "The inspiration behind the inception of Oftalmo University was to democratize access to high-quality ophthalmology education," says co-founder and CEO of the university, Ivo Ferreira Ríos. "We identified a pronounced void in specialized training, particularly in clinical and surgical subspecialties within ophthalmology, where access was inequitably distributed." By collaborating closely with leading training centers, OU serves as a "trailblazing entity" in the landscape of ophthalmological education, adds Ferreira Ríos. "We're not just an add-on; we're a disruptive center designed to revolutionize how ophthalmological education is delivered and accessed."

With this "pronounced void" clearly identified by the team, the OU leaders are now focused on myriad unmet needs within ophthalmological education, namely: accessibility, affordability, technological integration, hands-on experience, interdisciplinary training, cultural competency, continuous learning, research opportunities, global perspectives, and patient communication. Andres Benatti, a cornea and refractive surgeon with a specialism in LASIK surgery and a co-founder of the university, believes that addressing these needs is "critical for preparing a new generation of ophthalmologists, who are not only skilled but are also adaptable, empathetic, and ready to meet the challenges of a rapidly evolving healthcare landscape."

"We want to seize technology's tremendous potential to redefine how ophthalmology is taught and practiced."

Oliver Garcia Yañez, an ophthalmology mentor at the university, explains, "We have trained over 1,000 ophthalmologists from 16 predominantly Latin American nationalities, where universal learning opportunities for cataract surgery are limited and the need for surgery is high. The plan is to further expand this teaching strategy worldwide, promoting the benefits of this link that make it easier to learn cataract surgery." To facilitate communication and the exchange of information, the university offers all of its courses in English. It also provides transportation, airport accommodation, and campus facilities to its international students, smoothing the path for those arriving in a new country for the first time. "We also adapt to the student's educational level and the procedures followed in their home country," says Yañez. "These courses are fully personalized with the aim of ensuring that, when students return to their home country, they feel the benefit of applying what they have learned."

Ferreira Ríos adds that the university ensures accessibility to its education programs for individuals from diverse backgrounds and regions, including those with limited resources, through partnerships with both local and international ophthalmological companies.

The university recognizes technology as an essential component of its practices. "At OU, leveraging technology is not just an option, it's integral to our mission of democratizing ophthalmology education," says Lisandro Carnielli, an AI consultant and OU's Chief Technology Officer. Virtual learning environments, simulation technologies, social media outreach, and data analytics all substantially inform how the university teaches its students. "By incorporating these technologies, we're not only staying ahead of the curve but also ensuring that our students are equipped with the skills and knowledge they need to excel in the ever-evolving field of ophthalmology," she says. "We want to seize technology's tremendous potential to redefine how ophthalmology is taught

Ophthalmology student on campus

and practiced. Through innovations like artificial intelligence, virtual reality, and telemedicine, we aim to set new standards in personalized, interactive, and hands-on learning. These aren't just enhancements; they are disruptive methodologies designed to revolutionize ophthalmology education from the ground up."

Setting their sights on the future, the university's primary ambition is clear, says Andres Benatti: "To be a global catalyst for change in ophthalmology education, exponentially magnifying our impact far beyond the traditional scope of academia. At the core of this transformative vision is our commitment to scaling our reach internationally. We're not just about creating competent ophthalmologists; we're about developing community leaders in eye care who will transform local eye care across the globe."

As Oftalmo University continues to evolve, its focus is four-fold: global reach, technological prowess, disruptive educational methodologies, and, above all, community impact, says Carnielli. "We're not merely expanding; we're amplifying our influence, converting each student's success into community transformations. In this way, the impact of Oftalmo University is exponential – not just changing individual lives but reshaping entire communities through better eye care. And this, we believe, is the true measure of our future success."

International Centre for Eye Health

Location: London School of Hygiene & Tropical Medicine, UK
Established: 1980
Focus: International

London School of Hygiene & Tropical Medicine

Established in 1980 by Moorfields Hospital ophthalmology professor, Barrie R. Jones, as a way to address the global challenges of eye care, the International Centre for Eye Health (ICEH) recently celebrated 40 years of work in ophthalmological research, education, capacity strengthening, and technology. A collaborative network of clinicians, health economists, public health specialists, epidemiologists, statisticians, and evidence synthesis specialists, ICEH is based at the London School of Hygiene & Tropical Medicine (LSHTM).

Despite many fluctuations in the medical landscape since its establishment, ICEH's mission to improve eye health in low and middle income countries (LMICs) has remained its highest priority. "Very early on, it was clear that much more was needed in terms of education for public health in eye care," notes Andrew Bastawrous, ICEH Professor and co-founder of award-winning health social enterprise Peek Vision. "Equipping ophthalmologists and other eye care professionals with the skills to appropriately plan, conduct, and evaluate community programs is an essential part of improving eye health globally." To achieve this aim, the center works through various partnerships, particularly within LMICs, and has a large network of research collaborators and alumni, comprising many eye health leaders across the globe.

ICEH is now widely viewed as a leading center for education and training in global eye health. In collaboration with LSHTM, it runs a Master's (MSc) degree in Public Health for Eye Care, which enables ophthalmic professionals to develop evidence-based public health approaches towards reducing blindness and visual disability at local, national, and international levels. The center also manages an annual one-week short course aimed at ophthalmologists, optometrists, ophthalmic nurses, and program managers, introducing them to strategies to reduce blindness and visual impairments. ICEH also offers free online courses covering a range of topics, including glaucoma, retinopathy of prematurity, and diabetic eye disease. "Course content is designed for people working in all contexts, with an emphasis on LMIC settings; case studies used within our courses include examples from all regions, including low-resource areas," explains Bastawrous. "Our online courses have been accessed by over 40,000 people from 180 countries and territories, and our intensive MSc course has been taken by more than 750 eye health professionals from 100 countries."

ICEH alumni are already having a huge global impact, with many going on to hold global leadership positions in eye health. Some notable names are Jacquelyn O'Banion (Associate Professor and Director of Global Ophthalmology at Emory University, US), Oteri Okolo (National Eye Health Coordinator for the Federal Ministry of Health, Nigeria), and Shalinder Sabherwal (Director, Public Health and Projects, Shroff's Charity Eye Hospital network, India).

ICEH prides itself on its engagement with academic research. Every three months, it publishes the free, peer-reviewed Community Eye Health Journal (CEHJ), aimed at eye care professionals working in some of the hardest-to-reach LMICs. CEHJ is available as an app and in print, is produced in four different languages (English, French, Chinese, and Spanish), and sent out to over 20,000 readers worldwide.

The aforementioned Peek Vision also plays a significant role in ICEH's global work. Bastawrous explains: "Peek began life more than a decade ago as part of my PhD research project in rural Kenya with ICEH." Since spinning out in 2015, it continues to collaborate with ICEH on research, teaching, and dissemination of information. Current projects include the development of the Rapid Assessment of Avoidable Blindness (RAAB), aimed at driving action to prevent avoidable vision loss, and the School Eye Health Rapid Assessment tool (SEHRA) for improving school eye health programs.

ICEH's main goal remains reaching as many ophthalmologists and other eye health professions as possible, attempting to embed public health teaching into international ophthalmic education. "We intend to expand our online course portfolio to include additional topics and languages, and train more leaders in research globally," says Bastawrous. "We are always looking for exceptional students to join our MSc program. The benefits of the course for ophthalmologists in any country are vast, opening up new areas of practice and providing a global perspective on eye health, leading to extremely rewarding careers."

The University of Colorado School of Medicine Department of Ophthalmology

Location: Denver, US
Established: 1883
Focus: International

Anschutz Medical Campus, University of Colorado

The University of Colorado (CU) School of Medicine is consistently ranked as a leading medical school in the US; for example, placing eighth for primary care and 26th for research (out of 123 US institutions) in 2023's Best Medical School rankings compiled by US News & World Report (May 11, 2023). This was the sixth time CU made the top 10 for primary care in the Best Medical School rankings in the last eight years.

The School of Medicine's Department of Ophthalmology – established in 1883 – is held in similarly high esteem. The University of Colorado Health Eye Center is based at Sue Anschutz-Rodgers Eye Center, one of the largest state-of-the-art facilities in the US, and the department's 11 full-time faculty teaching members are prominent in research and teaching activities on an international scale.

Among these eminent educators is Power Lister Malik Y. Kahook, Professor of Ophthalmology, Slater Family Endowed Chair in Ophthalmology, Chief of the Glaucoma Service, and Co-director of the Glaucoma Fellowship at CU. Kahook is a noted innovator and inventor, with more than 40 patents granted, many of which have been licensed by companies for development and commercialization. Accordingly, he is heavily involved in promoting the use of cutting-edge technology in training at CU; for example, using AI for diagnostics and robotic-assisted surgery. "Our department has a leading AI team – headed by Jayashree Kalpathy-Cramer, Chief of Artificial Medical Intelligence in Ophthalmology – that is active in creating tools that can be used for the early diagnosis of eye diseases, as well as assist in longitudinal assessment to better treat these problems," he says.

The development of advanced simulators and virtual reality platforms to enhance ophthalmologists' surgical skills in complex procedures is another way in which CU is promoting advanced technology. "Several of our faculty members are involved in testing and improving both software and hardware to address these needs," says Kahook. And this technology is driving projects that are focused on the needs of low- and middle- income countries (LMICs), and how their access to solutions might be "enhanced with thoughtfulness" at the onset of each specific project.

Kahook is central to CU's ties with Orbis International – the global NPO focused on prevention and treatment of avoidable blindness through training, education, and advocacy, especially in LMICs – and Sidra Tree Foundation, which financially supports the efforts of NGOs focused on eye care. Serving on the boards of both Orbis and Sida Tree (and volunteering with the Orbis Flying Eye Hospital since 2018), he explains that CU's ophthalmology department is supporting and facilitating these nonprofits' efforts in teaching and supporting ophthalmic and optometric clinicians around the globe. "Many regions lack access to quality ophthalmology education and training programs, especially in low-resource areas," he explains. "We are attempting to address this by supporting online courses and telemedicine-based training to reach underserved populations." Kahook himself has been involved in some of the early testing of Orbis' and Fundamental VR's training simulator, with a view to supplying global trainees with lower-cost VR training systems. This particular platform is in its early stages, he explains, but should help "upskill trainees before and after they perform new procedures" and get them "up and running" more quickly and more safely.

Kahook and CU's support for training opportunities around the world goes beyond the promotion of cutting-edge technology. Fostering mentorship programs and global networks to connect experienced ophthalmologists with trainees is something Kahook is passionate about. He has mentored several visiting fellows through CU and Orbis and programs, such as the International Ophthalmological Fellowship Foundation. "Our past fellows have gone on to be leaders in their fields and have also engaged in teaching the next generation of learners in their respective countries," he says. Expanding subspecialty training opportunities, such as pediatric ophthalmology and retina specialties, to meet diverse patient needs is also a driver of CU's global education impact. "Our faculty, from neuro-ophthalmology to glaucoma, currently support multiple visiting fellows each year and also visit their home institutions to continue dialogue and foster a lasting relationship of learning."

Aravind Eye Care System

Location: India
Established: 1976
Focus: India

Aravind Eye Hospital, Madurai, India

Since its inception in 1976, the Aravind Eye Care System has placed much emphasis on ensuring that all patients are afforded the same quality of eye care, regardless of socioeconomic status. This ethos is also embedded into Aravind's training programs, which cater to all levels of ophthalmic personnel, including ophthalmologists, technicians, opticians, clinical assistants, outreach coordinators, and healthcare managers.

Aravind's mission is to eliminate needless blindness by providing large-volume, high-quality and affordable care. "Well-trained manpower is extremely important to achieve this mission," says R. Rathinam, Principal of the Postgraduate Institute of Ophthalmology at Aravind Eye Hospital, Madurai. The Institute offers postgraduate degree and diploma courses, fellowship programs, paramedical training and courses in administration and hospital management. Trainees at the Institute have the chance to participate in hands-on training, use state-of-the-art technology, tap into worldwide eye care resources, and interact with peers from around the world.

Aravind's commitment to tackling eye health on a large scale through education and training was evidenced when it joined forces with the Business Call to Action in 2012 to train 750 healthcare workers through an online system. The aim was to increase the number of yearly eye surgeries in India. By 2015, the number of eye surgeries performed each year had increased by 15 percent, from 350,000 to 400,000. Of these surgeries, 300,000 were provided at low or no cost to the country's most impoverished people. As part of the program, Avarind pledged to train 650 women from rural communities as certified mid-level ophthalmic professionals

"Aravind's paramedic staff are mostly young women, typically with a secondary education, from poor families in rural India."

(MLOPs) to "make ophthalmologists more productive" MLOPs, Aravind's paramedic staff, are mostly young women, typically with a secondary education, from poor families in rural India. They receive two years of in-house training from senior paramedic staff to become nurses, technicians, and counselors, taking paramedic positions in Aravind's hospitals and clinics. As of 2016, Aravind employed 2,200 MLOPs and 900 were in training.

"My life, My pride" is a well-being program for MLOPs at Aravind. It aims to prepare them "physically, emotionally, and psychologically" to maintain a balance between their personal and professional lives. Supported by the Aravind Eye Foundation, the program is designed to provide holistic training and includes activities such as individual

counseling and life skills development. According to the Aravind Eye Care System Activity Report 2022-2023 ,this MLOP program is currently being implemented at Aravind's Chennai facility.

Talking in 2021 about its involvement in eye care research and hospital capacity-building around the world, Dhivya Ramsamy, senior faculty member at Aravind, explained how its management consulting to other centers and hospitals had moved online since the pandemic, making them more convenient and accessible. "We have been able to see the hospitals increase volume, improve their data management, and serve more patients," Ramsamy explained. "One organization we worked with wanted to increase its surgical acceptance rate – the percentage who actually go through with cataract surgery. We strengthened their counseling and service design. For the entire cohort, we saw a 27 percent increase in surgeries. They got a 100-fold return on their investment in training."

Other continuing medical education (CME) programs offered by Aravind in the last two years months include a pediatric ophthalmology update, workshop on sterilization and aseptic techniques for ophthalmic operation theater, diagnostic skills transfer, surgical skills transfer and a dry lab for postgraduates. Organizational highlights from 2022-2023 include the establishment of seven new vision centers in rural areas, brining the total count of vision centers to 105. Aravind has also extended its support to governments and other organizations in establishing vision centers, including assisting the government of Bangladesh in setting up 45 centers.

Global Ophthalmology Fellowship, Emory Eye Center

Location: Georgia, US
Established: 2011
Focus: Ethiopia

University of Addis Ababa, Ethiopia

The Global Ophthalmology (GO)-Emery fellowship was established by Emory Eye Center in 2011. Fellows are given the opportunity to provide clinical care in Ethiopia's Addis Ababa and Menelik hospitals, as well as other outreach sites throughout Ethiopia. As part of the fellowship, and in line with delivering international care, fellows are expected to complete a research project aimed at improving eye care in vulnerable populations.

During their time in Ethiopia, fellows are exposed to public health approaches to eye care (such as the control and elimination of trachoma and onchocerciasis), as well as the management of cataract blindness with partner organizations. Additionally, they have the opportunity to get involved in public health campaigns, mass drug administrations, and cataract campaigns. This first-hand experience offers fellows a unique insight into the challenges of delivering eye care in low income countries whilst also developing their skill sets. The GO-Emory fellowship is unique in that it can be tailored for each individual fellow.

Last year, GO-E received a three-year, $90,000 grant from Vision2020 LINK USA to continue training ophthalmology residents from Ethiopia's Addis Ababa University (AAU), while bolstering much-needed screenings for retinopathy of prematurity (ROP) and diabetic retinopathy (DR). GO-E's co-director, Jacquelyn O'Banion, said, "The idea is to improve our outreach to underserved populations in Ethiopia while, at the same time, increasing the subspecialty expertise of the locally trained ophthalmologists. Now that the COVID-19 pandemic is beginning to retreat, we are looking forward to a more robust exchange of physicians between our two countries.

"The idea is to improve our outreach to underserved populations in Ethiopia while, at the same time, increasing the subspecialty expertise of the locally trained ophthalmologists."

She added, "Across the world, there are so many instances where treatable eye conditions deteriorate into blindness – sometimes because there simply isn't an ophthalmologist with the proper training to deliver it. When GO-E is able to train our colleagues from low-resourced countries like Ethiopia, we can stave off this trend – now, and in the future."

Although its activities are focused in Ethiopia, GO-E offers other international opportunities to encourage specific interests and career goals. The program also works with other international eye care organizations, such as the Himalayan Cataract Project, Orbis, the Carter Center, and Sightsavers International.

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Moorfields Education, Moorfields Eye Hospital and the University College London Institute of Ophthalmology

Location: London, UK
Established: 2014
Focus: International

Moorfields Eye Hospital, London

Since its founding in 1804, Moorfields has established a global reputation for delivering excellence in eye care, and continues to lead the charge when it comes to ophthalmic training. Of particular note is Moorfields Education, led by Michèle Russell, Joint Director of Education at both Moorfields Eye Hospital and the University College London (UCL) Institute of Ophthalmology. Moorfields Education is a collaboration with UCL that provides visionary education for clinical ophthalmic leaders through pioneering courses and programs, as well as offering both medical electives and fellowships.

Combining the UCL Institute of Ophthalmology's scientific expertise with Moorfields Hospital's work environment, Moorfields Education courses engage all stakeholders in the eye care sector, as well as the patients themselves, to consider the real-world practices that are making a difference to patients. The courses offer the opportunity to gain the necessary skills and training through the combined knowledge and expertise of hundreds of world-renowned leaders in vision and eye health.

Alongside learning from some of the biggest names in ophthalmology, program participants are afforded valuable practical experience with patients. Gus Gazzard, Moorfields' Director of Glaucoma, explained, "One of our great strengths is that not only are we very experienced with online and lecture-based teaching, but we are able to blend that with teaching with real patients. We have a large number of patients who are very keen to come back in, share their experiences, and to help train the next generation of clinicians."

Although situated in London, Moorfields' commitment to educating eye care professionals is not limited by borders. In tandem with the online courses that can be accessed and completed from anywhere, Moorfields opens its doors to international trainees and students. As Consultant Ophthalmologist and Professor of Retinal Neuroscience Omar Mahroo put it, "One of the reasons I find teaching [at Moorfields] so fulfilling is that we are fortunate to have students and trainees from all across the world. We feel that, through our teaching and our activities, we are not just benefiting the patients we manage but patients globally."

Beyond the substantive internal education and training that Moorfields undertakes, the Moorfields Eye Charity offers funding to projects to teach and build up the next generation of world-leading eye researchers and clinicians. Although the institution is one with an incredible history, Moorfields' focus is firmly on the future – providing the patients of tomorrow with the best possible eye care and investing in the training of the experts needed to make it happen.

Training the Next Generation

Can the pharma industry help upskill Allied Health Professionals (AHPs) working in ophthalmology?

Currently it can be argued that there is a lack of training and education programmes for ophthalmologists and AHPs working in ophthalmology about the latest advances in the presentation and management of key retina conditions such as age-related macular degeneration (nAMD) and diabetic macular odema (DMO).

There is often too little time allotted for training for Allied Health Professionals (AHP) at their hospitals and there are not enough accredited courses available.

Roche, pioneers in healthcare and one of the world's largest biotech companies – is no stranger to issues faced by those working in the area, keenly aware that training opportunities should be expanded to help upskill not only ophthalmologists but also AHPs working in ophthalmology. Aiming to tackle these gaps in training, Roche has begun to host multiple training programmes, both globally and in the UK.

One example is where the company has worked with Moorfields Eye Hospital in London to review and localise recommendations made by the Royal College of Ophthalmologists as part of their Ophthalmic Practitioner Training (OPT) Programme. This led to the development of a 12-month educational course for the Moorfields Medical Retina (MR) nursing teams, with an initial focus on virtual patient assessments, clinical audits, and patient communication and consenting. The aim of the project is to train the MR nursing teams so that they can become involved in the end-to-end patient pathway, relieving pressure on colleagues within the multidisciplinary team (MDT). According to Adam Mapani MBE, Nurse Consultant at Moorfields Eye Hospital NHS Foundation Trust and Honorary Teaching Fellow at UCL Institute of Ophthalmology: "This project has resulted in significant improvement in staff retention, patient and staff experience."

The company has also focused its attention on helping to educate and upskill those who are part of the wider MDT. Roche UK recently hosted a series of CPD approved regional medical education meetings for nurses and AHPs working in ophthalmology. The series of meetings were built in collaboration with a nurse/AHPs steering committee. Attended by over 330 nurses and AHPs, the meetings were delivered by appropriate local and national speakers, and were aimed at upskilling attendees' understanding of the nAMD and DMO disease areas, as well as the interpretation of diagnostic tests including Optical Coherence Tomography, and disease management and treatment regimes.

The positive impact of these meetings on attendees speaks for itself: "The ability to listen and interact with fellow AHPs from different trusts was invaluable," says Mike Horler, Consultant Optometrist Medical Retina and Head of Specialist Optometry at Sussex Eye Hospital. Jenny Nosek, a Specialist Nurse in Ophthalmology at Royal Shrewsbury Hospital who chaired a series of face-to-face Ophthalmic study days earlier in the year, adds, "In the challenging times that we currently work, these study days created an effective learning environment, embracing collaborative teamwork and cultivated a positive attitude."

Alongside venerable eye care institutions such as Moorfields, Roche is committed to training and educating AHPs and nurses within ophthalmology, but also the other diverse community of healthcare professionals that comprise the MDT, ensuring that all those across the entire ophthalmological spectrum are as well-trained as possible to meet the ever-increasing patient demand.

Roche is aiming to develop further courses to be run locally in the UK for AHPs throughout 2024.

Roche Products Ltd. has commissioned this feature and is responsible for the placement and information provided.

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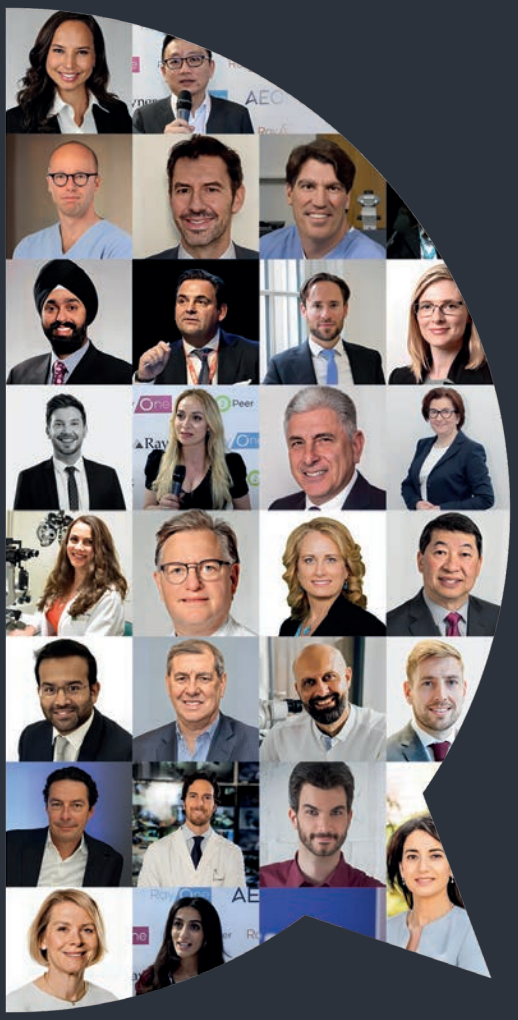

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Rising to the Responsibility

How Rayner has harnessed KOL-led education and digital technologies to rise to the responsibility of providing ophthalmic training

Ophthalmology is a field marked by rapid innovation. The consistent launching of new products, and development of procedural techniques have resulted in a space in which outcomes and efficiencies are improved, and overall patient satisfaction is enhanced on a near-daily basis. In this dynamic and evolving environment, providing ongoing education and development for everyone is key to ensuring patient safety and elevating standards of care. Rayner, understanding this responsibility, is working in collaboration with healthcare professionals to deliver effective training, establishing itself as a trusted partner, adding value to both the surgical team and the many processes they follow.

Although providing such training comes with several challenges – the two greatest being the time and resources required – Rayner has observed a high return on training and development investment, and coupled with a creative and resourceful team, finding innovative and effective solutions has been both fun and extremely rewarding. In particular, Rayner's solutions focus on two main areas: KOL-led scientific communications and digital technologies. As Chris Willis, Rayner's Vice President of Marketing explains, "Delivering impactful KOL-led scientific communications is a primary goal for myself and my team here at Rayner. To achieve this, we have chosen to encourage a peer-to-peer conversation on our technologies, led by KOLs, to increase awareness and practical application of our drugs, devices, and digital products, in all regions that we operate. These conversations were already taking place at congresses, educational meetings, and other in-person locations, but since the COVID-19 pandemic, much has changed. I believe we evolved with this change and delivered a dynamic platform that enabled this conversation to continue digitally."

The Peer2Peer platform is a substantial initiative and an excellent showcase of how harnessing these focus areas has led Rayner to innovative and effective solutions. A global KOL-led clinical digital education platform, Peer2Peer provides ophthalmic healthcare providers with on-demand, real-time learning and development opportunities and an ever-growing library of resources, including KOL webinars and interviews, clinical articles, live events, a dedicated e-newsletter, and the newly-launched "Peer2Peer: The Podcast" series featuring over 25 KOL-led episodes on numerous topics of current educational interest. Through this, and their other advancements in ophthalmology education, Rayner, not only invite you to benefit from their advancements but also demonstrate that, just like the rest of the field, ophthalmic training is in a healthy state of innovation and growth.

Rayner

www.rayner.com/Peer2Peer

the Ophthalmologist

POWER *List*

RISING *Stars*

For 10 years, The Ophthalmologist has been honoring the excellence of the most influential people in the field with its annual Power List – arguably the single biggest media event in the ophthalmology calendar.

This year, we expanded this celebratory roll-call with The Ophthalmologist Power List Hall of Fame, which highlights the legacy of Power List luminaries that have had the most significant impact on eye care.

Now, we extend the scope of the Power List to ophthalmologists and scientists at an earlier stage in their career.

The Ophthalmologist Power List Rising Stars program creates a connection between the community of doctors and scientists that have been rightly recognized for their impact on ophthalmology over many years and those individuals who are already making waves despite their relative youth.

Each candidate is nominated by one or more Power List alumni to create a shortlist. The shortlist is scrutinized and honed by The Ophthalmologist team to create a final list of 10 Rising Stars, who are following their own paths, building on the work of their mentors, and forging new connections to advance the world of ophthalmology.

Each year, we will follow our Rising Stars as their careers continue to soar – charting their journeys, discussing their achievements, and featuring their input as The Ophthalmologist embraces the next generation of experts and leaders. Are they the high-potential Power Listers of the future? You be the judge.

See the full profiles online: ***top.txp.to/Rising/Stars/2023***

Sally L. Baxter

Assistant Professor of Ophthalmology and Bioinformatics the University of California San Diego. Baxter is double board-certified in both ophthalmology and clinical informatics.

After her ophthalmology residency training at UC San Diego, Sally Baxter embarked on a National Library of Medicine-funded postdoctoral fellowship in Biomedical Informatics, also at UC San Diego, where she remains as faculty with joint appointments in ophthalmology and biomedical informatics.

"I practice comprehensive ophthalmology and do research in informatics, digital health, and AI," says Baxter. Much of her role involves looking at how to leverage data and generate insights – not only for clinical care, but also with health equity in mind. "Ever since I did my public health degree, I've been very interested in understanding health disparities between different populations and how we might narrow those, nowadays with large-scale data," says Baxter. She is also looking at how the use of large-language models like ChatGPT can help with responding to patient messages in the electronic health record (EHR) system. "I think we are one of the first sites to actually integrate large language models into point-of-care clinical practice."

Alongside her data research work, Baxter is focused on education, teaching ophthalmology residents cataract surgery, guiding them in research projects, and helping them along in their own career development. In the words of one of her mentors, Robert Weinreb, Baxter is "poised to broadly impact both clinical practice in ophthalmology and vision research."

Ticiana De Francesco

Adjunct Assistant Professor John Moran Eye Center, University of Utah, staff ophthalmologist at the Clínica de Olhos De Francesco, Brazil, and attending surgeon at the Hospital de Olhos Leiria de Andrade and Escola Cearense de Oftalmologia, Brazil

Ticiana De Francesco took early advantage of two glaucoma fellowships she was offered: a fellowship in San Paulo at the University of Campinas in 2019 and another at the University of Toronto in 2020, under the mentorship of Power Lister Ike Ahmed. Working with Ahmed in Canada particularly inspired De Francesco. She explains, "The most important thing that the fellowship brought me was to be encouraged to think differently and push myself beyond my limits."

Returning to Brazil, De Francesco now divides her time between her private practice and academia. Her future ambitions center around glaucoma, and she also hopes to make more space for women in ophthalmology, specifically in leadership positions. "Being a young Latin woman from Brazil, I hope I can inspire others to think differently and bring diversity into the ophthalmology field," she says.

Ike Ahmed comments: "In three short years, Ticiana has burst onto the global scene, becoming a leader in research, education, and innovation… She has become a highly skilled glaucoma and complex anterior segment surgeon, and published novel techniques in these areas. But most notably, she has become an inspiration to many young eye doctors around the world with her unique and humble style."

Li Lian Foo

Consultant with the Cataract and Comprehensive Ophthalmology Department and Myopia Program Lead, Singapore National Eye Centre

Li Lian Foo studied chemical engineering before she decided to embrace medical school. Since completing her ophthalmology training, Foo has been focusing on various childhood myopia control modalities, and how they might be used to slow down the rate of myopia progression in children. "Our main aim is to prevent high myopia amongst children in order to prevent potentially blinding-related complications later on in adulthood," Foo explains.

As an aspiring clinician-innovator, Foo hopes to use her skills – fueled by her combined engineering and medical background – to improve clinical care across Singapore, and bridge the bench-to-bedside gap. Rapidly evolving technology is key to achieving this, she says. "In my opinion, telemedicine and remote monitoring will likely become integrated in patient care, and this will ensure broader access to specialized treatment."

Recommending Foo as a Rising Star, The Ophthalmologist's two-time Power Lister, Seang-Mei Saw, told us, "I have had the privilege of mentoring Li Lian and have been consistently impressed with her dedication, intellect, and enthusiasm… I have no doubt she will continue to excel in her research endeavors in myopia and translate her findings to improve the outcomes of myopic children."

Arjan Hura

Board-certified and fellowship-trained refractive, cataract, and anterior segment surgeon at the Maloney-Shamie Vision Institute in Los Angeles, California

Ophthalmology was not initially on Arjan Hura's radar. In fact, when he applied to medical school, he planned on becoming a neurologist. It was only after shadowing multiple neuromuscular disease doctors and neurologists, and observing the limited treatment regimens – and limited ability to be hands-on with patients – that he realized neurology wasn't for him.

However, it was during his medical school's neuroscience lectures that Hura met Karl Golnik, a neuro-ophthalmologist who at the time was the Chairman for Ophthalmology at the University of Cincinnati. Hura was able to set up an unofficial two-week elective with Golnik over the winter break, and in these sessions Hura learned how to conduct a neuro-ophthalmic exam. "The first time Golnik taught me to use a slit lamp and I saw the optic nerve through a 90 diopter lens, hovering through the air in 3D, I just knew that ophthalmology was the field for me," he says.

As a refractive, cataract, and anterior segment surgeon at the Maloney-Shamie Vision Institute in Los Angeles, California, Hura is passionate about giving his patients a premium experience. His clinical interests focus on ways to reverse cataractogenesis, developing an IOL that is "as good as the natural human crystalline lens," and helping to advance laser correction at large. "These are the thematic elements that get me fired up and make me passionate about what I do on a day-to-day basis."

Pooja Khamar

Consultant and lead trainer in cataract and refractive services, and a clinician and a translational scientist at Narayana Nethralaya Eye Institute, Bangalore, India

For Pooja Khamar, ophthalmology was a calling. Growing up with an uncle who was a renowned retina specialist and an aunt who was a glaucoma specialist, a young Khamar gained an early introduction to both eye care and translational research. In the 1980s, her uncle achieved the rare dream of becoming a clinician-researcher in translational sciences, leaving an indelible mark on Khamar. When it came to embarking on her own career, she did so with a similar dream, one of making a lasting impact on ophthalmology through a combination of clinical and translational research.

A large portion of Khamar's research focuses on working towards a holistic medical approach, which she believes will form the backbone of ophthalmology's future. A particular highlight for Khamar is developing the first point-of-care stepwise diagnostic kit, the Bio-M Pathfinder Kit.

Paying tribute to her team and her mentors, Khamar says, "My career has not been a solo endeavor. [My mentors] are a large part of where, and who I am today." And this appreciation does not only flow one way. As Power List winner Damien Gatinel told us, "Khamar undoubtedly deserves the recognition she receives, and her remarkable journey is bound to inspire countless young clinicians to embark on similar dynamic roles in the field of medicine."

Radhika Rampat

Consultant ophthalmic surgeon at the Royal Free Hospital, Associate academic director of the Refractive Surgery Alliance (RSA) global fellowship network, and Chair of the American European Congress of Ophthalmic Surgery (AECOS) Green Working Group"

After pursuing a medical school internship in Mexico, Radhika Rampat undertook extended study in the US, working under the auspices of Gislin Dagnelie at the Wilmer Eye Institute. A place at the prestigious Academic Foundation Program (AFP) followed; she then joined the North Thames London deanery training program, where she rotated through The Royal Free, Western Eye, and Moorfields hospitals. A key turning point for her career was meeting Damien Gatinel, Head of the Anterior and Refractive Surgery Department of The Rothschild Foundation in Paris; she went to work with Gatinel as a research fellow in Paris. "Professor Gatinel really gave me that bug of being passionate about research and about refractive surgery," she says. Following this, Rampat completed two more years of corneal fellowships at Moorfields before moving to The Royal Free Hospital, where she currently serves as consultant ophthalmic surgeon.

Looking ahead, Rampat would like to establish herself in London, and she has a keen interest in promoting women in ophthalmology. "I'd like to show that you can have a successful career as well as having a family life. Nothing should be able to stop you from doing that, and you don't have to step on anybody else to move up the career ladder."

"Radhika is someone who is not afraid to get her hands dirty and to tackle the big problems facing ophthalmology: training for refractive surgeons, the digital changes coming our way, and then, critically, sustainability," says The Ophthalmologist's three-time Power Lister, Arthur B. Cummings. "She is an asset to ophthalmology and to moving our field forward across many fronts."

Eric Rosenberg

Cornea, cataract, and complex anterior segment surgeon Eric Rosenberg, SightMD, Clinical Assistant Professor at New York Medical College and Northwell, co-founder of the Digital Ophthalmic Society, and co-founder of MetaMed Media

Since receiving his medical degree, Rosenberg has gone on to become Clinical Assistant Professor at both New York Medical College and Northwell, and has co-founded both the Digital Ophthalmic Society, and MetaMed Media.

Among many career highlights, a few stand out particularly for Rosenberg. Namely, winning the complex case challenge symposium at ASCRS, becoming involved in the Digital Ophthalmic Society, and developing Metamed Media's Metaverse Platform – technology that is being used to "blow past geopolitical barriers and create a home that anybody can go to anywhere they are in the world." Although it is not going to replace in person meetings, the new platform allows for interaction from all around the world, regardless of busy schedules and time constraints, making it a particularly exciting venture, Rosenberg explains.

Rather than being fixed on an ultimate goal, Rosenberg is happy to see what direction his career will take. He says, "I want to be like my mentors. I want to help people to advance the field and shape it into what they see best fit."

Rahul Tonk

Cornea, cataract, and refractive surgeon, Assistant Professor, and Associate Medical Director at Bascom Palmer Eye Institute, Miami, USA

Rahul Tonk is a cornea, cataract and refractive surgeon at the Bascom Palmer Eye Institute in Miami, Florida, USA, where he also co-directs the cornea refractive surgery fellowship, serves as Associate Medical Director, and oversees operations at the Institute's satellite facility, the Lennar Foundation Medical Center.

Tonk was interested in medicine from early childhood, when his father gave him a very accessible book on anatomy, Charlie Brown's 'Cyclopedia of the Human Body. "I became fascinated with science and how the body worked, physiology and so forth, but I just didn't know where exactly to put that energy," he says. Going on to study Applied Economics and Management at Cornell University, he believed he'd take a different career path. That was until he went on a mission trip to Nicaragua in 2005, and had an opportunity to work in providing ophthalmic care and ophthalmology in very remote rural areas.

"The nature of restoring somebody's sight, especially people who are needlessly blind through cataract surgery, left an incredible impression on me," Tonk explains. It convinced him that he did in fact want to pursue a medical route, but at the same time, he didn't want to give up his interest in health economics, administration, and entrepreneurship. So, he started medical school on a dual degree program at Rutgers Medical School and Rutgers Business School. "It gave me a medical education, but also the opportunity to take curricula in all of those other varied interests of mine, which has been fantastic and has led to the type of work that I do now."

Siegfried Wagner

Vitreoretinal TSC Research Fellow at Moorfields Eye Hospital and Senior Research Fellow at University College London.

Siegfried Wagner came into ophthalmology in his penultimate year of university, having "never considered it before." But after studying rheumatology, infectious diseases, and neurology, he found that "the eye was really the only part of the body that could unite the immune system, the cardiovascular system, and the brain in such an elegant way." He went to work in an eye clinic in Cape Town, South Africa, and the experience really spurred his interest; he became fascinated by the pattern recognition aspects of ophthalmology, the research aspects, and the surgery.

In 2014, he moved to London for ophthalmology training and embarked on an NIHR Clinical Fellowship at Moorfields Eye Hospital, which gave him 25 percent protected research time and 75 percent clinical training. Next, Wagner began his PhD, which focused on using the retina and retinal imaging as a window into systemic health, looking particularly at prediction of people who go on to develop dementia, heart attack, stroke, and other conditions.

Today, in his TSC Fellowship at Moorfields, Wagner focuses on his vitreoretinal clinical training and three strands of research. "The first is a field we call oculomics, which is investigating retinal imaging in systemic disease, in particular cardiovascular and neurodegenerative disease," he says. "The second is mainly telemedicine, looking particularly into digital exclusion in synchronous and asynchronous telemedicine approaches." Third is his interest in artificial intelligence (AI) for retinal and other macular diseases.

These myriad interests serve Wagner's longer-term goal "to cultivate a greater role for ophthalmology and ophthalmic imaging into the general health of patients, into chronic disorders of aging, and other disciplines of medicine."

Dagny Zhu

Cornea, cataract, and refractive surgeon practicing as Medical Director and Partner at NVISION Eye Center in Rowland Heights, California, USA

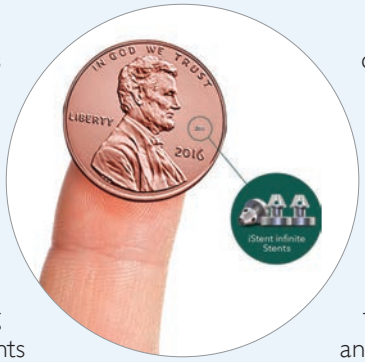
Dagny Zhu's first source of inspiration was her mother who, having immigrated to the US with a three-year-old Zhu, worked tirelessly to provide for the two of them. Her mother's work ethic and caring nature made a lasting impression on Zhu, motivating her to become a physician so that she could not only give back to her mother, but also to those around her.

Some career highlights for Zhu include being one of the first surgeons in Los Angeles to implant the PanOptix trifocal lens, winning Best Paper of the Session as a newly minted attendee to ASCRS, and being invited to speak on the Main Stage of Specialty Day for Refractive Surgery at the 2023 Academy of Ophthalmology (AAO) conference.

Although each of these strides have come as a result of Dagny Zhu's hard work and effort, she will be the first to tell you that there have been many people who have inspired her along her journey. This includes Marguerite McDonald, who not only paved the way for women in ophthalmology, but also served as an inspiration to many of Zhu's current mentors. Having a large social media following, Zhu herself now serves as a mentor and role model to the upcoming generation of medical students, trainees and residents – and her three-year-old son, Atlas – passing what she has gained to future generations.

ADVANCING INNOVATION IN MIGS

Glaukos' technology and products continue to transform the way ophthalmic surgeons manage chronic eye diseases.



Glaukos founded the MIGS category 20 years ago with the first-generation iStent. The iStent platform now has the longest-term body of evidence of any MIGS procedure. Due to its broad compatibility with other procedures, iStent remains the first choice for mild-to-moderate glaucoma management.

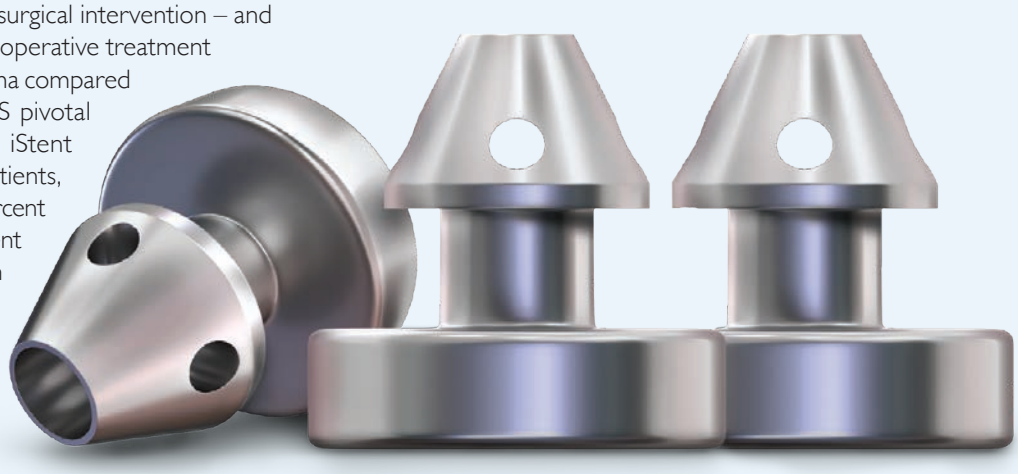
The standalone, implantable iStent infinite®* is the latest iteration of this ground-breaking technology. With three anatomically designed stents preloaded into an injector system, the device's powerful technology delivers foundational, 24/7, long-term control of IOP in patients with glaucoma who have failed prior medical and surgical intervention.

Ike K. Ahmed, Director of the Glaucoma & Advanced Anterior Segment Surgery (GAAS) Fellowship, has noted that "glaucoma is early only once, and surgeons have a time-limited opportunity to intervene early." iStent infinite® allows for earlier surgical intervention in glaucoma because of its favorable benefit-risk ratio. It is not restricted to mild-to-moderate patients – unlike some other implantable devices and previous-generation iStent technologies. iStent infinite® provides the versatility to treat a variety of patients, including those that are tough to treat. In a prospective, multi-center, 12-month pivotal trial, for example, patients with open-angle glaucoma who had failed prior medical and surgical intervention – and who had a significantly higher preoperative treatment burden with more severe glaucoma compared to other trabecular bypass MIGS pivotal trials – underwent standalone iStent infinite® implantation. Of these patients, 73.4 percent showed a ≥ 20 percent reduction in IOP, while 47.3 percent showed a ≥ 30 percent reduction in IOP. The device demonstrated sustained efficacy throughout the course of the study, as well as exceptional intraoperative and postoperative safety (1).

iStent infinite® is designed to maximize outflow while minimizing disruption to natural anatomy by occupying only 3% of Schlemm's canal, thereby leaving 97% untouched. Coupled with its patented multidirectional stent design, this helps bypass trabecular resistance and restore physiologic outflow. The device's injector system was evolved to allow an unlimited number of stent delivery attempts, giving surgeons confidence and peace of mind, no matter where they are in their learning curve.

Standalone glaucoma patients have limited micro-invasive options to treat their condition. Developed with these patients in mind, iStent infinite® addresses that gap in the treatment algorithm. It offers a safe, truly micro-invasive alternative to medications and more invasive glaucoma treatment procedures. And being the first FDA-cleared device that does not need to be implanted at the time of cataract surgery, iStent infinite® can also be used on phakic and pseudophakic patients.

It represents the beginning of the interventional glaucoma revolution!



"iStent infinite® is designed to maximize outflow while minimizing disruption to natural anatomy by occupying only 3% of Schlemm's canal, thereby leaving 97% untouched."

iPRIME and iAccess

In addition to the iStent platform, Glaukos' innovation in ophthalmic surgery continues apace with its iAccess and iPRIME technology.

The iAccess® Precision Blade was designed to open the trabecular meshwork over an area >90° to directly access Schlemm's canal. When medically necessary, precision goniotomy with iAccess® minimizes tissue disruption and is designed to preserve the eye's natural blood-aqueous barrier. It can preserve up to 95% more anatomy than other tissue removal procedures (technique dependent) and maintain the eye's natural blood aqueous barrier and mechanical pump (technique dependent).

Earning US FDA 510(k) clearance in 2022, Glaukos' iPRIME Viscodelivery System is designed to optimize the surgeon's control. A sterile, single-use minimally invasive viscoelastic fluid delivery device, iPRIME allows surgeons to deliver consistent and controlled amounts of viscoelastic to titrate where, when, and how much viscoelastic they deliver; to administer 2.7µL of viscoelastic with each activation (independent of catheter movement); and to possibly advance past an occlusion by delivering viscoelastic.

Commenting on iPRIME's FDA clearance, Thomas Burns, Glaukos Chairman and Chief Executive Officer, noted that the new technology "is consistent with our longstanding position on the value of truly minimally invasive therapy."

* *iStent infinite® is currently only available in the USA and Canada.*

INDICATION FOR USE. The iStent infinite® Trabecular Micro-Bypass System Model iS3 is an implantable device intended to reduce the intraocular pressure (IOP) of the eye. It is indicated for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed. CONTRAINDICATIONS. The iStent infinite is contraindicated in eyes with angle-closure glaucoma where the angle has not been surgically opened, acute traumatic, malignant, active uveitic, or active neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. WARNINGS. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization that could lead to improper placement of the stent and pose a hazard. MRI INFORMATION. The iStent infinite is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. PRECAUTIONS. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. Three out of 61 participants (4.9%) in the pivotal clinical trial were phakic. Therefore, there is insufficient evidence to determine whether the clinical performance of the device may be different in those who are phakic versus in those who are pseudophakic. ADVERSE EVENTS. The most common postoperative adverse events reported in the iStent infinite pivotal trial included IOP increase ≥ 10 mmHg vs. baseline IOP (8.2%), loss of BSCVA ≥ 2 lines (11.5%), ocular surface disease (11.5%), perioperative inflammation (6.6%) and visual field loss ≥ 2.5 dB (6.6%). CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

Reference

1. *Glaukos Data on File.*

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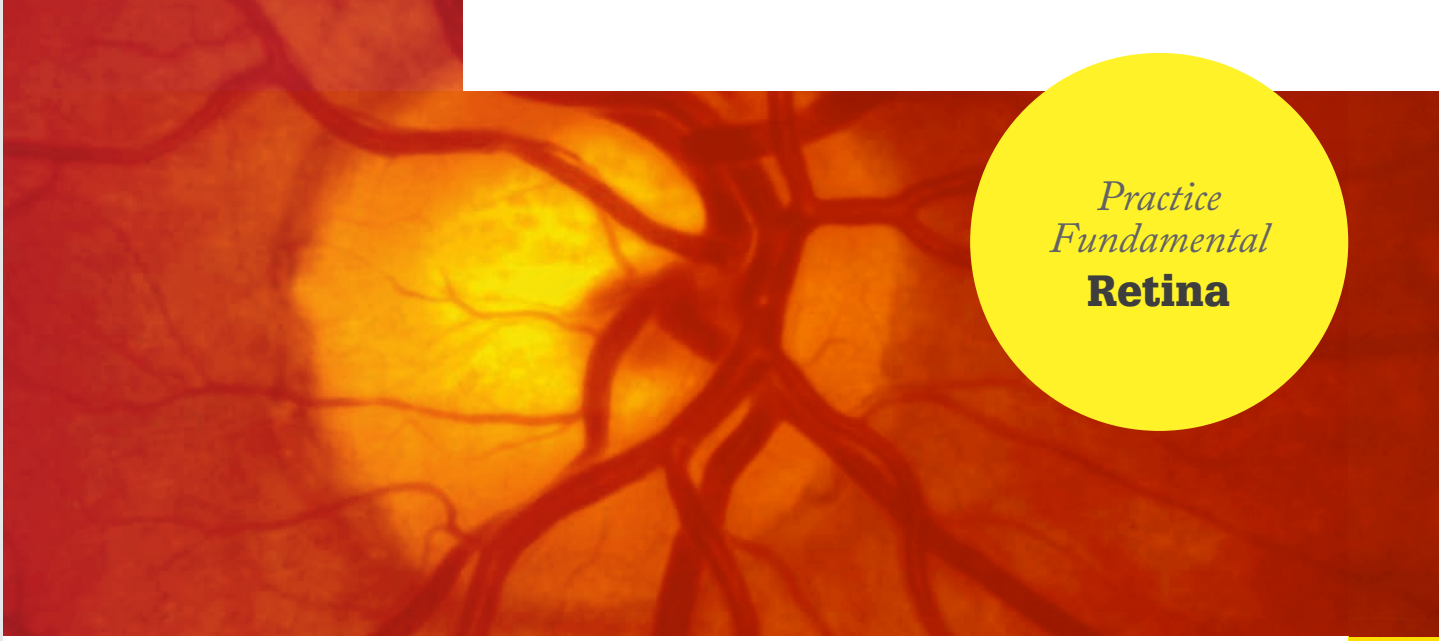

Crystal clear. A research team from Michigan State (*bit.ly/3ZM7Xwo*) have found that diabetes and other health conditions can lead to a buildup of crystallized cholesterol in the retina, which can contribute to the development of diabetic retinopathy. The team used scanning electron microscopy and immunohistochemistry to identify the crystal deposits, and claim that non-invasive evaluations could be performed by most optometrists for earlier diagnosis. According to Julia Busik, professor emeritus of physiology at Michigan State University: "Within 20 years of developing diabetes, every individual with either Type 1 or Type 2 diabetes will have some degree of retinopathy. Current treatment approaches are very invasive and are only directed at the very late stage of retinopathy."

Hagfish slime, anyone? Models of Bruch's membrane capture some of the membrane's properties but not all, so other approaches are needed. While studying in vitro models of Bruch's membrane to compare the natural aging process to AMD-related deterioration, researchers from Utah State University have found that hagfish slime proteins can be used to replicate the five-layered membrane. Hagfish produce slime either when they're attacked or stressed. The research team grew retinal cells on the slime protein to replicate how both AMD and aging affect Bruch's membrane.

Got the blues. A review of 17 randomized controlled trials – led by researchers at the University of Melbourne – found that blue-light filtering spectacles, thought to reduce eye strain, most likely make no difference (PMID: 37593770). The review also found little evidence to suggest that blue-light lenses protect the retina from damage. The authors evaluated change in visual fatigue score and critical flicker-fusion frequency, as well as other factors, such as "best-corrected visual acuity, contrast sensitivity, discomfort glare, proportion of eyes with a pathological macular finding, color discrimination, proportion of participants with reduced daytime alertness, serum melatonin levels, subjective sleep quality, and patient satisfaction with their visual performance."

First of hopefully many. Have you heard of posterior column ataxia with retinitis pigmentosa (PCARP)? The rare genetic condition has affected fewer than 20 patients in the last 50 years. Now, the first treatment designed to slow vision loss in patients with PCARP has been administered for a single patient facing the condition. Grace Hoyt, who is 13 years old, received the treatment at the University of Colorado School of Medicine and Children's Hospital Colorado. The treatment – an antisense oligonucleotide therapy – was given with permission from the FDA.

IN OTHER NEWS

Research from Anglia Ruskin University suggests that nanotechnology could be used to create 3D "scaffolding" on which to grow retinal pigment epithelial cells. (bit.ly/3F2I4i6)

Moorfields Eye Hospital and UCL Institute of Ophthalmology researchers have created RETFound, an open-source AI system for retinal scanning (freely available on GitHub).

Analysis published of the retinal landscape highlights novel investigation methods for identifying several retinopathies for a more "precise medicine" approach ((PMID: 37449599).

Study from the National Eye Institute and the University of Freiberg finds that Noelins play a crucial role in neural tissues such as the retina.

Relationship between dietary habits, dietary nutrient intake and AMD explored in Czech Republic study (PMID: 37451248)

Stopping The Unstoppable

SYFOVRE: the new FDA-approved treatment for geographic atrophy

The slow progression of geographic atrophy (GA) has made the identification of viable treatment options challenging. But by specifically targeting complement C3, the newly FDA-approved treatment SYFOVRE (pegcetacoplan injection) from Apellis provides control of the complement cascade, a critical component of the body's immune system. (1)

The approval follows positive results from the DERBY and OAKS studies, which compared the efficacy and safety of SYFOVRE with sham injections across a varied population of patients with GA. After a 24-month period, SYFOVRE was found to reduce the rate of GA lesion growth compared with sham.

We sat down with Caroline Baumal, Chief Medical Officer at Apellis, and CEO and cofounder Cedric Francois, to talk about what this new treatment means for the retina space – and for patients.

What inspired you to take on a disease as challenging as GA?

Francois: Well, there is an incredible unmet medical need; more than a million patients in the US alone are affected by this disease. It is typically something that patients start seeing or acquiring around the age of 70 and above. These are the last decades of life where you have the chance to watch your grandchildren or great grandchildren grow up. Going blind can have a dramatic and terrible impact on our lives, so giving even a couple of extra years of vision to people is incredibly inspiring.

What is notable about this new treatment?

Baumal: Cedric has already noted the impact that GA has on independence and the quality of life for our elderly patients. But then consider that, prior to the approval of SYFOVRE, there were no treatments for GA.

Following the FDA approval SYFOVRE is now available for all patients with GA, regardless of lesion location or whether one or both eyes are affected – and that's reflective of the broad and representative population enrolled in our clinical trials. I'm really pleased with the dosing flexibility of every 25-60 days, which allows us to treat patients mirroring the clinical study regimens. The approval of SYFOVRE is a genuine scientific breakthrough and provides an advance for patients who have been waiting a long time for a treatment.

Looking at the bigger picture, the approval of SYFOVRE is the first definitive proof that the natural progression of GA can be modified, essentially turning GA into a treatable disease. We can intervene at the level of C3 and C3b in the complement cascade to slow down the disease progression.

Francois: It's the first time after many

failures that we have a drug that can slow down the progression of GA lesions. We're going to look at further increasing efficacy over time; the aim is always to slow down progression of the disease as much as possible. We will also focus on convenience – in fact, we are already working on a pre-filled syringe that will make it easier for physicians to administer the product. But we will also try to find ways to reduce the frequency of the injections. Right now, we have very good efficacy with injections every two months – but perhaps we can go even lower.

Ultimately, there are two really important features that people need to know about. First, it has increasing effects over time, which is exceedingly rare. If you ask a physician to think about a drug that has an increasing effect over time, most won't come up with a single example. Second, the dosing flexibility Caroline mentioned – from 25–60 days between injections. Just think about the practicality of that; when a patient needs to book an appointment, you have a whole month to play with!

What were the main challenges during development and approval?

Francois: Where do I even start?! Whenever a therapeutic goes through development, there are numerous challenges that must be overcome – and you need a series of small miracles to make it happen. But two particular challenges stand out. When we started the phase III clinical trial, we had a small manufacturing issue that caused a big headache – and we had limited time to fix things. We discovered the problem in September 2018 but still managed to restart clinical trials in March 2019. Another key challenge was when the DERBY trial missed the primary endpoint in phase III. At the time, statisticians offered interesting feedback about an important imbalance; in short, we had aggressive patients in the active arm compared with the sham control. At the time, it was very clear that if we treated these patients longer, the imbalance would correct itself – but, two months into the trial, the patients in the drug arm were 20 percent worse than the control.

It was a challenge but also a lesson. We learned that the drug needed more time to overcome the deficit to show its maximum potential. Amazingly, at 24 months into DERBY and OAKS the difference between the groups had gone.

What lies beyond the FDA approval?

Baumal: The US FDA approval is just the beginning of what's possible for SYFOVRE. We continue to evaluate the long-term safety and efficacy of SYFOVRE in the GALE extension study, which is a three-year trial. Combined with the phase III DERBY and OAKS studies, GALE will allow us to better understand the efficacy and safety profile of SYFOVRE with up to five years of treatment. We are excited about this data and look forward to continuing to share information about this first-of-its-kind treatment with the medical community.

We are committed to bringing SYFOVRE to patients around the world as quickly as possible. In addition to our recent approval in the US, we are preparing for other approvals and launches; we have a marketing application that is currently under review in the European Union.

I am excited to be part of the team to bring SYFOVRE to patients as the first and only treatment for GA. As a retina specialist, I look forward to finally having a treatment to offer patients!

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2. *Apellis, "Apellis Provides Update on Review of Rare Safety Events with SYFOVRE® (pegcetacoplan injection) for Geographic Atrophy" (2023). Available at: bit.ly/3Yvjvna.*

SYFOVRE: SAFETY UPDATE

While SYFOVRE is exciting for the retinal space, recent concerns over safety events associated with the drug were voiced by the American Society of Retinal Specialists in July.

Apellis has been conducting a thorough evaluation following these reported events, the company states, including a review of the SYFOVRE manufacturing process. There were no changes in the formulation of the product between phase III clinical trials and commercial supply. Based on this review, the company adds, there were no new safety findings in the clinical trials upon secondary review.

Since launch, Apellis has confirmed a total of seven events of retinal vasculitis (four occlusive, three non-occlusive) as determined by the company's internal safety committee and external retina/uveitis specialists. Two of these events followed injections in April, two in May, and three in June. Apellis is also evaluating one reported event of retinal vasculitis, which the company has not confirmed.

CEO Cedric Francois comments, "The safety of patients has always been – and continues to be – our top priority at Apellis. Following 68,000 commercial vials distributed and 23,000 clinical trial injections to date, these events continue to be very rare. Additionally, as part of our ongoing review, we have seen no indication that drug product or manufacturing issues contributed to these events. We will continue to collaborate with the retina community to deliver a safe, effective treatment for GA…" (2).

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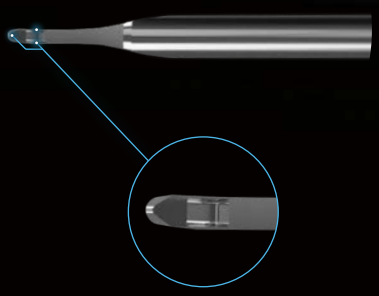
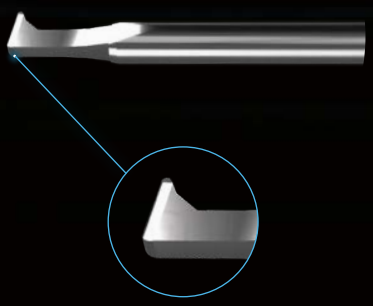
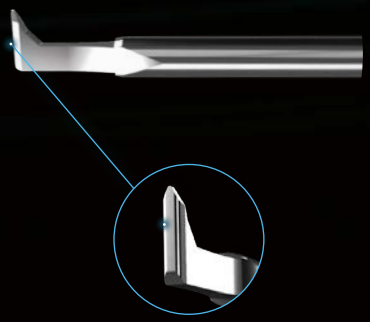


ROUNDED HEEL



TAPERED SIDES & FOOTPLATE



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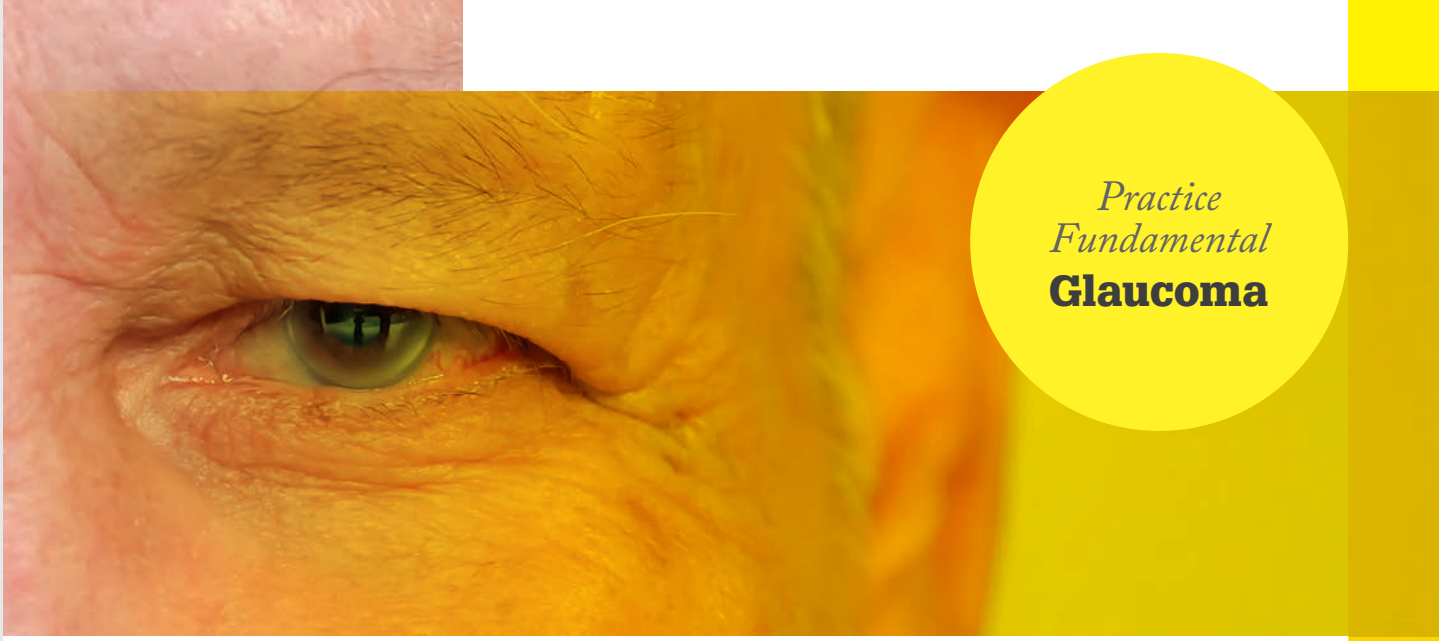


Practice Fundamental
Glaucoma

Age is just a number. A recent cohort study of 491 children, published in JAMA Ophthalmology, has analyzed primary intraocular lens implantation procedures to determine whether post-surgical glaucoma-related complications might be associated with the age of patients. While the study found that age at implantation, as well as implant location, were not linked to higher risk of complications, the authors recommend further research and monitoring into visual axis opacification (VAO), a frequent complication following pediatric lensectomy (PMID: 37347490).

Undetected diagnoses. "The prevalence of glaucoma in a 70-year-old Swedish population in the city area of Gothenburg," a recent study carried out at the University of Gothenburg by Lena Havstam Johansson and published in Acta Ophthalmologica (July 2023) has found that nearly five percent of 70-year-olds have glaucoma, with half of those diagnosed being unaware that they had the disease. The study has allowed newly diagnosed patients to begin treatment, and serves as a reminder that many individuals suffering from eye disease may not even know it.

Alternative POAG treatment. A new study in Graefe's Archive for Clinical and Experimental Ophthalmology offers a compelling alternative treatment for both primary open-angle glaucoma (POAG) and ocular hypertension (OHT). Researchers from the MERCURY-3 six-month randomized trial of Santen's latanoprost/netarsudil fixed-dose combination state that the primary efficacy endpoint of non-inferiority was assessed and met at month three of the trial (PMID: 37615697).

Mapping morphology. To assess how the morphology of connective and neural tissues in the optic nerve head differ with glaucoma severity, researchers conducted a cross-sectional study. ("Three-Dimensional Structural Phenotype of the Optic Nerve Head as a Function of Glaucoma Severity," JAMA Ophthalmol. 141, August 2023.) The researchers found that the majority of optic nerve head structural differences occurred in the early glaucoma stage, shedding new light on glaucoma's complex pathology.

Calculated G-RISK. Aiming to overcome the issue of glaucoma classification models struggling to replicate their impressive internal performance on external datasets, a research team tested and confirmed that the previously described G-RISK regression network for glaucoma is able to obtain excellent results in a number of challenging settings. The network was tested on 13 different data sources of labeled fundus images and surpassed the minimum sensitivity criteria recommended by Prevent Blindness America. ("A generalizable deep learning regression model for automated glaucoma screening from fundus images," Nature, June 13, 2023.)

IN OTHER NEWS

Pressure suppression. *Results of a recent study highlighted that early aqueous suppression (EAS) was associated with a lower final intraocular pressure (IOP) following Ahmed Glaucoma Valve (AGV) in uveitic glaucoma eyes; however, there were more medications in use at the final visit (PMID: 37567499).*

Phenotypic correlations. *Researchers investigating how phenotypic features of patients vary across genetic burden for primary open-angle glaucoma found that a higher polygenic risk was associated with more advanced disease (PMID: 37589995).*

Blocking the way. *To assess what extent systemic calcium blockers are associated with glaucoma, researchers conducted a cross-sectional study of over 400,000 adult UK Biobank participants. The results found that calcium blocker use was adversely associated with glaucoma prevalence and optical coherence tomography–derived inner retinal thicknesses, but not intraocular pressure. (PMID: 37676684).*

Cracking the (Genetic) Code

Is genotyping the answer to improving glaucoma management?

By Anthony Khawaja

Although glaucoma can cause irreversible, irreparable damage to vision, treatment can slow or halt disease progression, so early detection is important. Unfortunately, our current screening tests – if applied to a general population – don't work well enough; as a result, population screening for glaucoma is not currently recommended in some countries, including the UK and the US.

Using people's genetic codes to identify a subset of the population that will benefit from screening may be the solution to this problem. In the last decade, there has been huge progress in discovering many of the genetic variants that contribute to glaucoma risk. It was back in 2018 when we first realized that the great number of risk variants we had discovered could be considered collectively to predict – with surprising accuracy – whether someone would end up developing glaucoma. This approach of combining thousands of risk variants into a single number, a polygenic risk score, has become popular across many common diseases, including glaucoma.

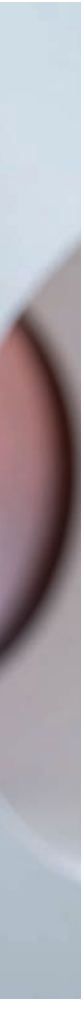
Instead of having to screen whole populations, genotyping enables targeted screening for those at a higher risk for glaucoma. Our current screening tests will perform much better when applied to a subset of the population with a higher prevalence of undetected glaucoma. In other words, there will be far fewer false positive referrals to secondary care if our current screening tests are applied to this enriched subset of the population.

A separate challenge in glaucoma care comes after diagnosis. At present, we cannot accurately predict which of our patients are at the highest risk of progressing and losing vision. If we could better predict this, we could ensure our limited healthcare resources are used optimally, focusing on the highest risk patients, but also saving costs, unnecessary treatment, and follow-up for those at lower risk.

It remains unclear whether the genetic variants which increase the risk of developing glaucoma also increase the risk of vision loss among patients with glaucoma. Instead of comparing people with glaucoma to people without glaucoma in the general population, we need more longitudinal genetic studies amongst cohorts of glaucoma patients, identifying the genetic variants that lead to worse disease.

A step in the right direction

This need was the motivation behind the Moorfields Glaucoma Bioresource – a project that involves recruiting glaucoma patients at Moorfields Eye Hospital, in collaboration with the NIHR BioResource (1). We can then combine our patients' genetic information with their clinical outcome data over time.



"A future where whole populations have genetic data available is increasingly looking like it will happen sooner rather than later."

The other way the Bioresource can help is by assessing how patients respond to different common treatments to enable tailoring of treatment options accordingly. There are multiple treatment options for glaucoma and it remains unclear which treatment would work best for individual patients.

There have been some really important randomized control trials, such as the LiGHT trial, that supports laser as an initial treatment for patients with ocular hypertension or primary open-angle glaucoma, and the TAGS study, which supports trabeculectomy as a reasonable first option for people with advanced glaucoma (2,3). However, these landmark studies only offer guidance on what may be best on average, rather than what would be optimal for individual patients.

We believe that the genetic code contains the answer to these challenges. For example, our genetic studies have suggested a substantial cause of higher intraocular pressure results from variation in pathways influencing Schlemm's canal and collector channels, and not, as one might expect, the trabecular meshwork. This finding, which challenges previous dogma, is striking as some of our treatment options only target the trabecular meshwork (for example, trabecular stents and selective laser trabeculoplasty). It may be that we can identify, using the genetic code, which glaucoma patients primarily have a problem in Schlemm's canal and collector channels and therefore might not do so well with trabecular meshwork treatment and ensure that they move onto a different type of treatment.

In addition to the Moorfields Glaucoma Bioresource – another major study we are looking at is the UK Biobank study, which includes the genetic testing of half a million people in the UK (4). We know who has glaucoma just by self report at the moment, but we are in the process of linking the UK Biobank to eye care electronic medical record (EMR) data from 15 centers around the country that use the Medisoft – a specialist ophthalmology EMR that efficiently documents disease progression and response to treatments. These 15 centers serve 15 of the 22 UK Biobank recruitment center regions and we therefore have estimates that we should get linked clinical data with UK Biobank data for over 10,000 patients with glaucoma.

Work in motion

When will it be feasible for the genetic testing detailed above to be available for our patients and communities? Many experts believe that it is "when" and not "if." A future where whole populations have genetic data available is increasingly looking like it will happen sooner rather than later. For example, the consumer company "23andMe" charges less than £150 for testing of markers across the whole genetic code (5). And now, they have started to report the polygenic risk score for glaucoma to their customers.

Most exciting is the current "Our Future Health" study that has commenced in the UK (6). They are recruiting and carrying out genetic testing for five million adults – over 10 percent of the adults in the country. I see a future where the NHS would hold the genetic information of all people centrally, allowing doctors to use small subsets of this information to inform personalized care. Glaucoma specialists, for example, would leverage the information to inform targeted population screening and risk stratification in the clinic.

Will this future form of personalized glaucoma care be limited to specialist centers with genetic expertise? I don't believe that ophthalmologists will need to be genetics experts to understand this information. All information can be summarized into one polygenic risk score number. It will simply be a case of understanding whether that number is low, medium, high, or very high to help doctors guide their risk stratification and which treatment option would be best.

This article was converted from an interview.

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Toward the Transformation of Glaucoma Treatment

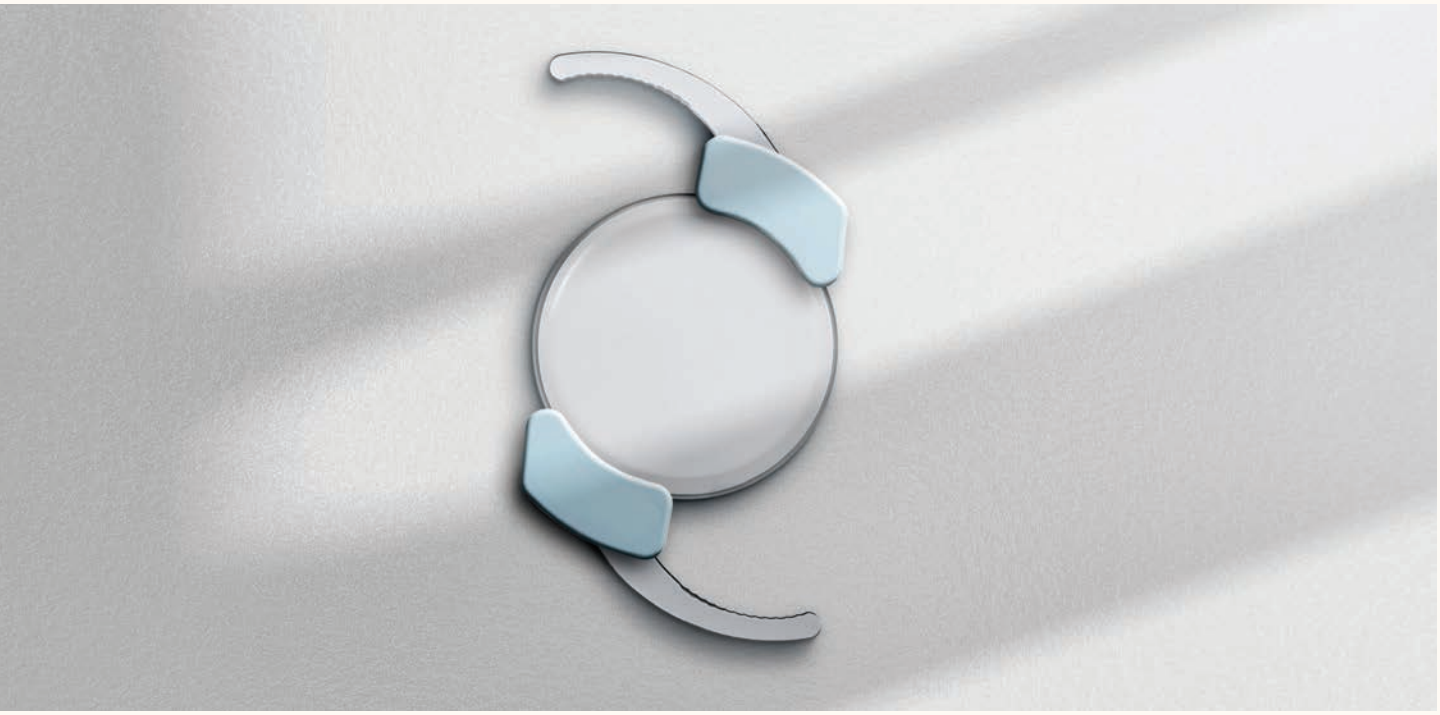
The story behind SpyGlass Pharma's innovative drug delivery platform for the treatment of glaucoma.

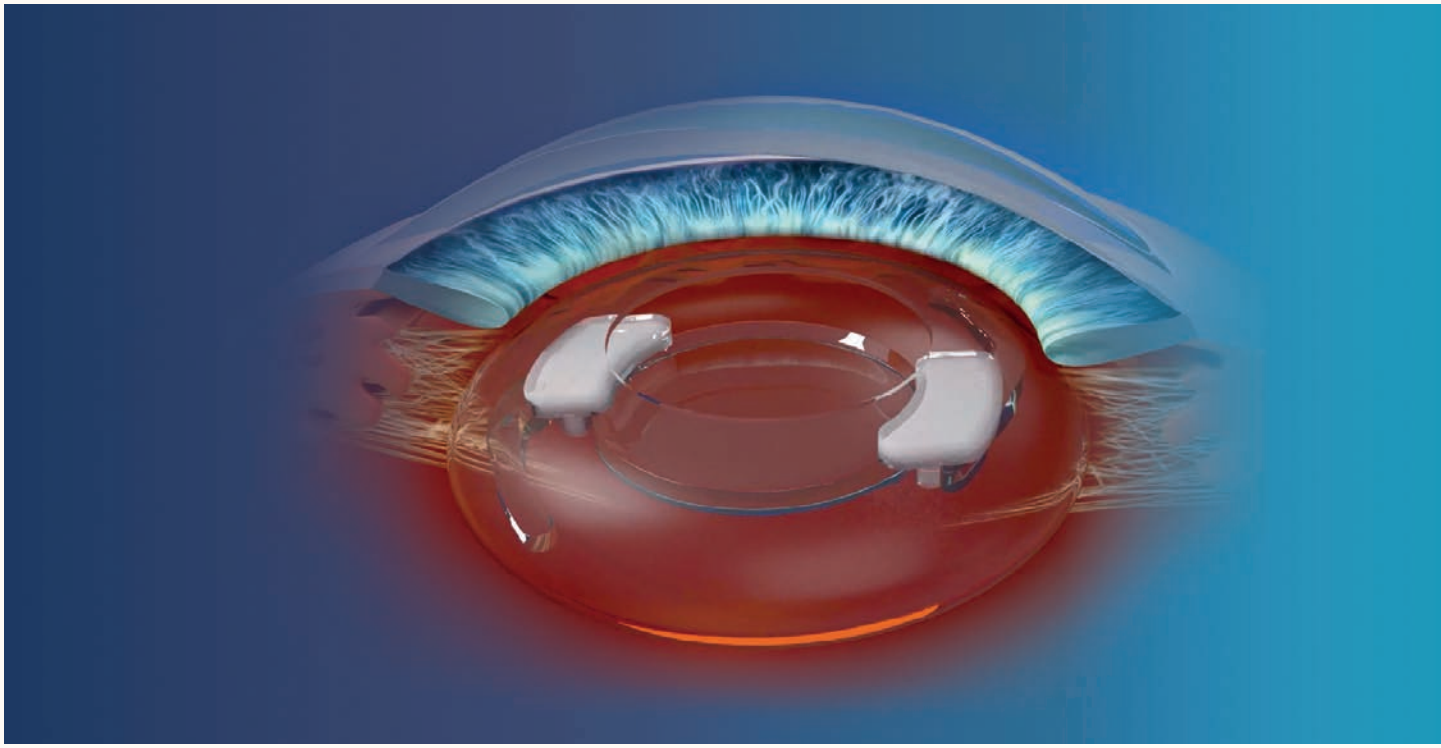
SpyGlass Pharma is aiming to revolutionize the field of glaucoma treatment with the development of its new, innovative drug delivery platform. Working by securing to the haptics of an intraocular lens (IOL), the SpyGlass platform is implanted into the capsular bag, with the IOL, at the time of routine cataract surgery. The initial product is designed to continuously elute bimatoprost therapy for multiple years to lower intraocular pressure (IOP) in patients with glaucoma or ocular hypertension (OHT).

CEO of SpyGlass Pharma, Patrick Mooney, says that although MIGS procedures are a great option for many patients with glaucoma, research suggests that 75 percent of cataract surgeons are not routinely performing MIGS procedures at the time of cataract surgery (1). In addition, claims data indicates that one in five cataract procedures in the United States today are done in patients with open-angle glaucoma or OHT (2). "By implanting at the time of cataract surgery, surgeons can continue using their tried and tested techniques without having to learn and adopt new skills," says Mooney.

SpyGlass' elegant technology not only benefits the surgeons conducting the procedure, but also the patient. Despite current therapeutics being effective at lowering IOP, medicines cannot work when patients don't take them. SpyGlass technology resolves the problem of patient non-adherence by delivering prostaglandin therapy consistently and continuously each day. As a result of bimatoprost being delivered from within the eye, the cumulative daily release needed to achieve a therapeutic effect is significantly lower than a single topical drop of bimatoprost, potentially making it a more effective treatment option for patients with glaucoma.

The clinical efficacy of the SpyGlass technology has been confirmed in its first-in-human (FIH) feasibility trial. In this trial, researchers enrolled 23 subjects who had a visually significant cataract and glaucoma. After being washed out of their topical medications and having their baseline IOP recorded, researchers randomized patients to receive cataract surgery and one of three doses of bimatoprost, via the SpyGlass drug delivery platform. Over a nine-month period, the trial found that, across all three doses, mean IOP-lowering was 45 percent from baseline. The visual results were also excellent and in line with best-in-class IOLs on the market today. Mooney confirms that SpyGlass is now proceeding with





their US phase I/II clinical trial that will test multiple doses of bimatoprost therapy in the SpyGlass system vs. control, marking a significant milestone for the company.

"The development of SpyGlass would not be possible without amazing team members with deep history and understanding of ophthalmic pharmaceuticals and medical devices," adds Mooney. SpyGlass was co-founded by Dr. Malik Y. Kahook and Glenn Sussman, both of whom are serial inventors and entrepreneurs with over 50 years of combined experience in the ophthalmic space. Together, Malik and Glenn spearheaded the innovation in ClarVista Medical which developed a modular IOL technology that was acquired by Alcon in 2017. SpyGlass' COO, James Dennewill, has over 20 years of industry experience and is a specialist in the development of products, people, and processes required to bring new technologies to market. Spyglass' Vice President of Regulatory Affairs, Nina Nguyen, also plays a key role in the company, bringing over 20 years of global regulatory affairs leadership in both the pharmaceutical and medical device industry, with relevant experience at Glaukos and Allergan. Mooney joined the company in 2021 as CEO and adds to the team's expertise with his experience of eye care that spans the surgical, vision-care and pharmaceutical spectrum, and which includes product launches in retina, glaucoma, dry eye as well as medical devices. Most recently, Mooney was Vice President and Head of the Ophthalmology Franchise at Novartis where he was responsible for the overall strategy and growth of US ophthalmic pharmaceuticals.

The wider team at SpyGlass, consisting of engineers, scientists, and an experienced clinical and regulatory team, are no less important. All have exhibited a proven track record of both innovating and commercializing key products that improve the standard of care for patients and surgeons.

In addition to addressing glaucoma patients at the time of cataract surgery, the SpyGlass system can also effectively elute both steroids and nonsteroidal anti-inflammatory drugs, used to address pain and inflammation post cataract surgery. Mooney says, "as SpyGlass technology allows for adjustments in daily elution and total payload, the team also sees an opportunity to address other chronic conditions such as uveitis and age-related macular degeneration."

"The SpyGlass drug delivery platform undoubtedly introduces an innovative and promising treatment option for glaucoma patients, and has the potential to establish itself as the gold standard of glaucoma treatment in the years to come."

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1. *CMS claims data (2022)*
2. *MarketScope, "2022 Glaucoma Surgical Device Market Report" (2022).*

Making An Impact

Sitting Down With… Dr. Rajesh Rajpal, Founder of See Clearly Vision Group and Chief Medical Officer of Johnson & Johnson Vision, Massachusetts, USA

Can you tell us a little about your career journey?

During my ophthalmology training, I liked the technological aspects of some sub-specialties. I was drawn to anterior segment – corneal and refractive – surgery. The bonus here is you get to have a real impact on patients undergoing cataract and LASIK surgery. Vision can improve relatively quickly in these patients; it's rewarding to interact with patients when they can – quite literally – see how quickly they are recovering.

My other passions are teaching, educating, and research. At Georgetown University I was fortunate to get involved with early clinical trials for laser technology. A real highlight was helping colleagues get certification on refractive surgery, in PRK or LASIK. I saw that working with industry is a great way of developing new technology. So, after transitioning to private practice and building up a network of refractive laser centers – which was very new at the time – I continued to research and collaborate with industry on new technologies. I'm proud to say we built a reputation of being able to take on complex cases.

All the while, I was still involved in clinical trials. I joined Avedro as Chief Medical Officer (CMO); the company was seeking FDA approval for cross-linking for keratoconus. I was one of the principal investigators on the study that led to FDA approval, and, in the long-term, reimbursement – which is essential for commercialization. After an IPO, we were acquired by Glaukos and I moved to J&J Vision. By continuing to practice and be a part of industry, I've had the privilege of helping more people through the scale of J&J Vision, which spans the entire eye health continuum from myopia management to contact lenses and dry eye, as well as cataract and refractive surgery.

Have any role models or mentors helped to shape the path you've taken?

At every stage of my career this has absolutely been the case. My mentors were the first ophthalmologists I worked most closely with; I modeled my career after them in many ways. Ophthalmologists tend to be very optimistic, positive people who make great teachers. Two who come to mind are my medical school advisor, Robert Weiunber, an excellent corneal specialist, and the head of my fellowship program, Peter Laibson.

I loved seeing them at work – how they spoke to patients, how they educated them, and of course, they were excellent surgeons. When I went into the business side of eye care, there were fewer role models, but there are many intelligent and creative people guiding the development of new technology and products. I've also worked with some great people in finance, who helped to teach me about building a company and the importance of developing the right team. My current position at J&J Vision now allows me to act as a mentor to colleagues who have also come into industry from an academic or clinical background.

How can industry meet the challenge of both chronic and preventable eye conditions?

Partnership is essential and I think our responsibility in the business world is to develop technology that is accessible. This is true from a cost perspective – where we need to make sure our breakthroughs are widely affordable wherever possible – and in terms of being proactive in getting involved in prevention. Myopia is a really good example here – it is a growing problem but it is preventable and we know it leads to so many other eye diseases.

At J&J, we continue to build on our 130-year legacy by pioneering in platforms, creating new categories, and elevating the existing ones. Innovating products is what we do, but our commitment to patient outcomes is the why. The quest for improved outcomes is what drives each innovation, product, and partnership.

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Part of our responsibility in the business world is to develop technology that is accessible. This is true from a cost perspective – We need to make sure our breakthroughs are widely affordable wherever possible, and be proactive in the prevention of diseases. Myopia is a good example – it's a growing epidemic that leads to so many other eye diseases,

but it is preventable. At J&J Vision we're creating solutions with contact lenses like ACUVUE Abiliti that help prevent myopia progression.

When it comes to the economics of treatment, we're developing a phacoemulsification machine, for example, which makes cataract surgery more efficient. We know cataract is one of the leading causes of preventable blindness, so if we can make treatment affordable worldwide then we can transform global eye health.

Our commitment to patient outcomes and presbyopia correction is reflected by advances in our TECNIS PC-IOL Portfolio Powered by InteliLight. These lenses are designed to provide the best contrast and low-light performance across the presbyopia-correcting IOL category with a combination of three proprietary technologies. We are also making significant investments in refractive surgery, like the recent debut of our ELITA Femtosecond Laser, which represents a generational leap in corneal refractive technology.

The J&J Vision R&D team regularly meets with optometrists and ophthalmologists to share our insights, learn the ever-evolving needs of patients and get feedback on our innovations during development. The industry has a responsibility to be involved in education and raising awareness. This can be achieved partially through academic research centers and clinical trials, making sure residents and fellows have access to technology. We must also encourage closer collaboration between optometrists and ophthalmologists. Both can partner successfully to help build better systems of care for patients – what could be more important than that?

Do you have any advice for new ophthalmology residents?

I am fortunate to speak frequently with residents, fellows, and students. I always tell them to "find and follow your passion." Eye care is so gratifying for both physician and patient – the feeling you get when you help someone see their loved ones clearly is so powerful. So, if you want to be a clinician, learn all you can. If you want to be the best surgeon, make sure you get the experience. If you enjoy technology, get involved in research and partner with industry. We partner with AAO, ASCRS, YoungMD Connect, and other organizations to offer opportunities such as educational workshops and events. I encourage those in training or clinicians who are interested in learning more about industry to engage with our clinical and medical affairs team through programs like these. That said, you also have to have something outside of work, so focus on your family and friends – because if you are happy and content outside of work, you will be the best doctor you can be.

"I am fortunate to speak frequently with residents, fellows, and students. I always tell them to 'find and follow your passion.' Eye care is so gratifying for both physician and patient – the feeling you get when you help someone see their loved ones clearly is so powerful."

What do you see on the horizon in terms of the detection and management of keratoconus?

In some ways keratoconus is similar to myopia – it has significant effects on a younger population. Those with irregular or asymmetric astigmatism must be watched very closely. Early detection is so important and today we have much better technology in topography and tomography to look at curvature and thickness of the cornea. But access is key – especially in a global setting. Eventually, telehealth and virtual testing that will allow early and remote diagnosis will be invaluable. In terms of treatment, there's a lot of discussion around removing or not removing the epithelium – or some hybrid of those two approaches. But removing the epithelium as an in-office procedure is only widely available in the USA. There are other types of cross-linking products on the way – aside from riboflavin or UV light – and it'll be interesting to see how they develop. Another option will be targeted treatment – really honing in on the most impacted area of the cornea. In the long term, with early detection, and more targeted treatment, we should see a decrease in the number of corneal transplants.

Outside of ophthalmology, what do you enjoy doing?

I love spending time with my family. One of the best things we do together is travel. Visiting other parts of the world is really fun and a hobby of mine. It's a great way of learning about different cultures and spending quality time connecting through new experiences.

oxervate®
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

Brief Summary of full Prescribing Information

Consult the full Prescribing Information for complete product information, available at www.oxervate.com/prescribing-information.

INDICATIONS AND USAGE

OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

General Dosing Information

Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

Recommended Dosage and Dose Administration

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

WARNINGS AND PRECAUTIONS

Use with Contact Lens

Contact lenses should be removed before applying OXERVATE because the presence of a contact lens (either therapeutic or corrective) could theoretically limit the distribution of cenegermin-bkbj onto the area of the corneal lesion. Lenses may be reinserted 15 minutes after administration.

Eye Discomfort

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment. The patient should be advised to contact their doctor if a more serious eye reaction occurs.

ADVERSE REACTIONS

Clinical Studies Experience

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

In two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1-10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

Lactation

Risk Summary

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

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older.

Geriatric Use

Of the total number of subjects in clinical studies of OXERVATE, 43.5 % were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis and Mutagenesis

Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj.

Impairment of fertility

Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male or female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD).

In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).

Dompé

For the treatment of all stages of neurotrophic keratitis (NK)

NOT JUST ANY SOLUTION

A RESOLUTION

Complete and long-lasting resolution of NK for most patients*[1-4]

- **Up to 72% of patients** achieved complete corneal healing in clinical trials*†[1-3]
- **80% of these patients** remained healed at 1 year (REPARO trial)*[4]

oxervate® (cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

* Resolution was evaluated in clinical trials as complete corneal healing, defined as the absence of staining in the lesion area and no persistent staining in the rest of the cornea after 8 weeks of treatment and as <0.5-mm lesion staining at 48-week follow-up.[1-3]

† Key study findings were after 8 weeks of treatment, 6 times daily. REPARO (Study NGF0212): 52 European patients with neurotrophic keratitis (NK) in 1 eye per group; 72% of patients completely healed; vehicle response rate 33.3%. Study NGF0214: 24 US patients with NK in 1 or both eyes per group; 65.2% completely healed; vehicle response rate 16.7%.[2,3]

Important Safety Information

WARNINGS AND PRECAUTIONS

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Eye Discomfort

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment. The patient should be advised to contact their doctor if a more serious eye reaction occurs.

ADVERSE REACTIONS

In clinical trials, the most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1% to 10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Lactation

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

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in pediatric patients 2 years of age and older is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in children.

INDICATION

OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) is indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

To report ADVERSE REACTIONS, contact Dompé U.S. Inc. at 1-833-366-7387 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the Brief Summary of full Prescribing Information for OXERVATE on the following page.

References: 1. OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. Boston, MA; Dompé U.S. Inc.; 2019. **2.** Bonini S, et al. *Ophthalmology*. 2018;125:1332-1343. **3.** Pflugfelder SC, et al. *Ophthalmology*. 2020;127:14-26. **4.** Data on File. Clinical Study Report (NGF0212). Dompé U.S. Inc., 2016.

See more clinical data
OXERVATE.com/hcp

Dompé