OCTOBER 2021 # 57

the Ophthalmologist™

TAKEOVER #3: *The Power List*

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References
[1]US Patent NO: US8647383. [2]Data on file, BVI, 2019.

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Our Time to Shine

My message to all existing and future Power List champions

This special issue of The Ophthalmologist celebrates the Power List in general, but here I would like to focus on the latest, 2021 Power List, which highlighted the achievements of women in ophthalmology. I feel that this year's Power List played a crucial role in reminding us how much women can contribute to our healthcare system, to our patients, and to the scientific community.

While going over this list again now, I see all types of women coming from various backgrounds, cultures, ethnicities and ages. Each and every one on this list is a pillar of our ophthalmic community, whether she has a leadership role in industry, academia or medical center. What the list emphasizes to me, is the importance of celebrating our own achievements. A woman in a leadership role has successfully juggled through education, research, clinical work, and personal life – and it's worth shouting about from the rooftops.

This year's Power List is a very important step in women's empowerment. It gives credit and recognition not only to female leaders, but also to the promising physicians in their early careers.

I believe that all of us – regardless of gender – need to continue the path to equality by taking proactive measures, such as implementing mentorship programs in each organization, and raising awareness of gaps in salaries, female authorship, leadership in societies and journals, and faculty positions in academia. We should be actively reaching out to young women with careers in ophthalmology, guiding them in mastering networking and negotiation skills, and encouraging them to set professional goals aiming for excellence. We should also challenge existing policies in our institutions and facilitate change in them; it can be a research funding opportunity for young female ophthalmologists or implementation of anti-harassment policy.

As women at the top of our field, while trying to empower women in the early stages of their careers in ophthalmology, we must lead by personal example. We should express our wishes constantly, in an assertive manner if needed, recognize our potential, and do our best to fulfil it.

My final advice to young ophthalmologists, perhaps hoping one day to appear on The Ophthalmologist's Power List, is to try to find balance between work and personal life, to delegate commitments, and – most important of all – treat each other with empathy, generosity, and consideration.

Anat Loewenstein
Chair, Division of Ophthalmology, Tel Aviv Medical Center; Vice Dean, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

Reference

1. *"The Power List 2021," The Ophthalmologist (2021). Available at: https://bit.ly/2Z4Ceew.*

WHAT COULD SHE SEE THIS YEAR?

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

6,250 PATIENT CHARTS

Inspired by a real patient with DME.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with 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. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). 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.

TRUST THE #1 PRESCRIBED ANTI-VEGF FDA APPROVED FOR WET AMD, DME, AND MEfRVO*

*IBM Truven MarketScan data: number of injections administered from Q4 2018 through Q3 2019; Data on file.

Proven first-line efficacy

- **Powerful efficacy** and **robust anatomic outcomes** across all indications as shown in phase 3 clinical trials[1-8]
- A broad range of indications and **dosing flexibility** across several FDA-approved indications[1]

Demonstrated safety profile

- **Demonstrated safety** profile across 4 VEGF-driven retinal diseases: Wet AMD, DR, DME, and MEfRVO[1]

A legacy of clinical experience

- **9 years** of extensive real-world experience[1]
- **≈13 million** doses administered to **>1 million** eyes since launch (and counting)[9]

EYLEA® (aflibercept) Injection 4 U℠

A COMPREHENSIVE PATIENT SUPPORT PROGRAM TO HELP FACILITATE ACCESS TO EYLEA

- 82% of payers offer access to EYLEA first line, covering **>272 million** patients[9,†]
- As of June 30, 2020, EYLEA4U® has provided **>4.4 million** total support services to eligible patients prescribed EYLEA[9]

†Data represent payers across the following channels: Medicare Part B, Commercial, Medicare Advantage, and VA. Individual patient coverage is subject to patient's specific plan.

DISCOVER WHAT ELSE YOUR PATIENTS COULD SEE WITH EYLEA AT HCP.EYLEA.US

anti-VEGF, anti–vascular endothelial growth factor.

ADVERSE REACTIONS

- 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 and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg (0.05 mL) 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).

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019. **2.** Heier JS, Brown DM, Chong V, et al; for the VIEW 1 and VIEW 2 Study Groups. Intravitreal aflibercept (VEGF Trap-Eye) in wet age-related macular degeneration. *Ophthalmology.* 2012;119(12):2537-2548. doi:10.1016/j.ophtha.2012.09.006 **3.** Schmidt-Erfurth U, Kaiser PK, Korobelnik JF, et al. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. *Ophthalmology.* 2014;121(1):193-201. doi:10.1016/j.ophtha.2013.08.011 **4.** Brown DM, Schmidt-Erfurth U, Do DV, et al. Intravitreal aflibercept for diabetic macular edema: 100-week results from the VISTA and VIVID studies. *Ophthalmology.* 2015;122(10):2044-2052. doi:10.1016/j.ophtha.2015.06.017 **5.** Campochiaro PA, Clark WL, Boyer DS, et al. Intravitreal aflibercept for macular edema following branch retinal vein occlusion: the 24-week results of the VIBRANT study. *Ophthalmology.* 2015;122(3):538-544. doi:10.1016/j.ophtha.2014.08.031 **6.** Boyer D, Heier J, Brown DM, et al. Vascular endothelial growth factor Trap-Eye for macular edema secondary to central retinal vein occlusion: six-month results of the phase 3 COPERNICUS study. *Ophthalmology.* 2012;119(5):1024-1032. doi:10.1016/j.ophtha.2012.01.042 **7.** Holz FG, Roider J, Ogura Y, et al. VEGF Trap-Eye for macular oedema secondary to central retinal vein occlusion: 6-month results of the phase III GALILEO study. *Br J Ophthalmol.* 2013;97(3):278-284. doi:10.1136/bjophthalmol-2012-301504 **8.** Wykoff CC. Intravitreal aflibercept for moderately severe to severe non-proliferative diabetic retinopathy (NPDR): 2-year outcomes of the phase 3 PANORAMA study. Data presented at: Angiogenesis, Exudation, and Degeneration Annual Meeting; February 8, 2020; Miami, FL. **9.** Data on file. Regeneron Pharmaceuticals, Inc.

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

03/2021
EYL.21.02.0021

EYLEA® (aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY—Please see the EYLEA full Prescribing Information available on HCP.EYLEA.US for additional product information.

1 INDICATIONS AND USAGE
EYLEA is a vascular endothelial growth factor (VEGF) inhibitor 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), Diabetic Retinopathy (DR).

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections
EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation
EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity
EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in 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 EYLEA, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see 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 [*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.

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

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.
A total of 2980 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 (AMD). 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 (VIEW1 and VIEW2) for 24 months (with active control in year 1).
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

	Baseline to Week 52		Baseline to Week 96	
Adverse Reactions	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)	EYLEA (N=1824)	Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%	27%	30%
Eye pain	9%	9%	10%	10%
Cataract	7%	7%	13%	10%
Vitreous detachment	6%	6%	8%	8%
Vitreous floaters	6%	7%	8%	10%
Intraocular pressure increased	5%	7%	7%	11%
Ocular hyperemia	4%	8%	5%	10%
Corneal epithelium defect	4%	5%	5%	6%
Detachment of the retinal pigment epithelium	3%	3%	5%	5%
Injection site pain	3%	3%	3%	4%
Foreign body sensation in eyes	3%	4%	4%	4%
Lacrimation increased	3%	1%	4%	2%
Vision blurred	2%	2%	4%	3%
Intraocular inflammation	2%	3%	3%	4%
Retinal pigment epithelium tear	2%	1%	2%	2%
Injection site hemorrhage	1%	2%	2%	2%
Eyelid edema	1%	2%	2%	3%
Corneal edema	1%	1%	1%	1%
Retinal detachment	<1%	<1%	1%	1%

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

Macular Edema Following Retinal Vein Occlusion (RVO). The data described below reflect 6 months exposure to EYLEA with a monthly 2 mg dose in 218 patients following central retinal vein occlusion (CRVO) in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following branch retinal vein occlusion (BRVO) in one clinical study (VIBRANT).

Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

	CRVO		BRVO	
Adverse Reactions	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival hemorrhage	12%	11%	20%	4%
Intraocular pressure increased	8%	6%	2%	0%
Corneal epithelium defect	5%	4%	2%	0%
Vitreous floaters	5%	1%	1%	0%
Ocular hyperemia	5%	3%	2%	2%
Foreign body sensation in eyes	3%	5%	3%	0%
Vitreous detachment	3%	4%	2%	0%
Lacrimation increased	3%	4%	3%	0%
Injection site pain	3%	1%	1%	0%
Vision blurred	1%	<1%	1%	1%
Intraocular inflammation	1%	1%	0%	0%
Cataract	<1%	1%	5%	0%
Eyelid edema	<1%	1%	1%	0%

Less common adverse reactions reported in <1% of the patients treated with EYLEA in the CRVO studies were corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR). The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

	Baseline to Week 52		Baseline to Week 100	
Adverse Reactions	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium defect	5%	3%	7%	5%
Intraocular pressure increased	5%	3%	9%	5%
Ocular hyperemia	5%	6%	5%	6%
Vitreous detachment	3%	3%	8%	6%
Foreign body sensation in eyes	3%	3%	3%	3%
Lacrimation increased	3%	2%	4%	2%
Vision blurred	2%	2%	3%	4%
Intraocular inflammation	2%	<1%	3%	1%
Injection site pain	2%	<1%	2%	<1%
Eyelid edema	<1%	1%	2%	1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.
Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

6.2 Immunogenicity
As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.
In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
Adequate and well-controlled studies with 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 exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].
Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. 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 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

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 is not recommended during breastfeeding.
The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from 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 3 months after the last intravitreal injection of EYLEA.

Infertility
There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment.

8.4 Pediatric Use
The safety and effectiveness of EYLEA in pediatric patients have not been established.

8.5 Geriatric Use
In the clinical studies, 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.

17 PATIENT COUNSELING INFORMATION
In the days following 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 to seek immediate care from an ophthalmologist [*see Warnings and Precautions (5.1)*].
Patients may experience temporary visual disturbances after an intravitreal injection with 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

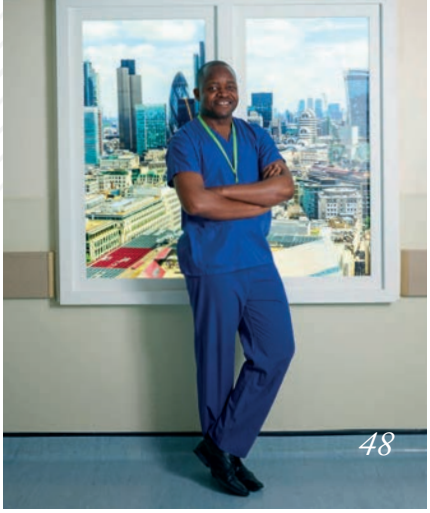
Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

Issue Date: 08/2019
Initial U.S. Approval: 2011

Based on the August 2019
EYLEA® (aflibercept) Injection full
Prescribing Information.

EYL.20.09.0052

Contents



On The Cover

Five women at the top of their profession discuss the circumstances that brought them there

the Ophthalmologist

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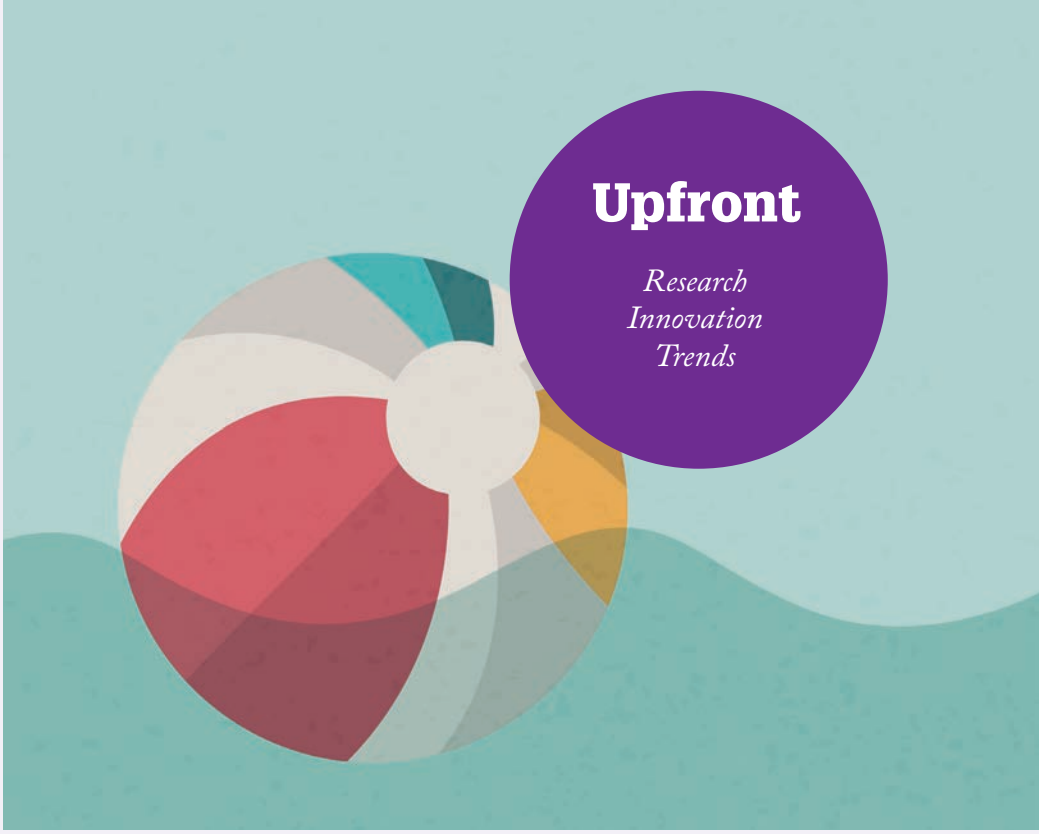

Lifting the Lid on Eye Pressure

Lower lid tightening surgery may increase the risk of ocular hypertension and glaucoma

Intraocular pressure (IOP) is a delicate biometric – even a small increase heightens the risk of developing glaucoma, and risk only increases with age. We also know that rates of lid malposition increase with age, so it is much more likely that a patient requiring surgery for lid malposition is at risk of glaucoma. But how does surgery on the lower-lid affect the pressure of the eye?

Clinical researchers from the UK have investigated the effect of lower-lid surgery with the lateral tarsal strip (LTS) technique on IOP – finding that the surgery was associated with a statistically significant increase in IOP, both immediately and, in some patients, three months after surgery (1). Lead authors for this work, Harpreet Kaur and Sarj Athwal, explain that impact of this finding "a prolonged period of increased intraocular pressure due to lid tightening could result in poor control of glaucoma, resulting in disease progression." They go on to explain the functional principle behind findings "Imagine holding an inflated beach ball in your hands. If you squeeze it and apply pressure on one end, you know that the external pressure has an effect on the internal pressure from the way the shape of the ball becomes distorted. We wanted to find out if the same thing happens to the eyeball when you tighten the eyelid against it by assessing whether the intraocular pressure changes."

This work has emphasized the importance of considering a patient's glaucoma when thinking about surgical options – it is possible that surgery could have detrimental effects on glaucoma risk and disease progression. Harpreet and Sarj highlight that "this is relevant not just to ophthalmologists, but all clinicians performing lid surgery for functional or aesthetic reasons such as plastic and maxillofacial surgeons."

An important consideration of this paper is that the study was designed to look at lower-lid post-surgery changes in IOP for healthy eyes. The authors point out that, while this is important and useful research, "there is a need for further research to assess and quantify the risk in patients with pre-existing glaucoma."

Reference

1. *H Kaur et al., J Plast Reconstr Aesthet Surg, S1748-6815, 00340 (2021). PMID: 34266805.*

INFOGRAPHIC

Think of the Children!

A UK survey highlights parents' uncertainty over their children's eyesight

ONLY 3 IN 10
UK adults are aware
THAT CHILDREN SHOULD GET
an eye test at age four to five

HALF OF ALL PARENTS
are unaware of eyecare recommendations for kids

BUSINESS IN BRIEF

The latest news in under 65 words

- Visus Therapeutics has appointed Tracy Valorie and Dwight Moxie to its Board of Directors. Valorie was previously Senior Vice President and General Manager, US Ophthalmology Rx and Surgical at Bausch + Lomb, and Moxie acted as Senior Vice President, General Counsel and Corporate Secretary at Revance Therapeutics.
- AbbVie and REGENXBIO are partnering to develop and commercialize RGX-314, a potential one-time gene therapy for the treatment of wet AMD, diabetic retinopathy, and other chronic retinal diseases. RGX-314 is currently being evaluated in patients with wet AMD in a pivotal trial using subretinal delivery, and in patients with wet AMD and DR in two separate Phase II clinical trials utilizing in-office suprachoroidal delivery.
- Ocuity, a UK-based medical technology start-up, hit its $2.5 million investment target in just 24 hours, thanks to crowdfunding. The company has developed and patented contactless optical technology for precise eye measurements, and it is now in the process of developing new optical diabetes screening and monitoring devices.
- Harrow Health is entering into an agreement with Wakamoto Pharmaceutical Co. Ltd to acquire US and Canadian commercial rights for drug candidate MAQ-100, a preservative-free triamcinolone acetonide ophthalmic injection for treating DME, non-infectious uveitis, and edema associated with retinal vein occlusion.
- RxSight has appointed Steve Everly as its Vice President of US Sales. Everly served as Johnson & Johnson Vision's Area Vice President, Surgical Sales Western US, responsible for all aspects of cataract, refractive and ocular surface product sales. The appointment follows new additions to the RxSight Board of Directors, namely Robert Palmisano, Robert Warner, and Julie Andrews.

Credit: Will H McMahan/Unsplash.com

Smoke Gets in Your Eyes

Cooking with wood or coal can increase the risk of cataracts and conjunctiva disorders

Can your cooking choices really impact your eyesight? Researchers from the University of Oxford, UK, and the Chinese Academy of Medical Science in Beijing, China, studied data gathered by the China Kadoorie Biobank (which followed almost 500,000 adults in China for 10 years) to examine their cooking habits and hospital admissions for major eye diseases. The study found that people who engaged in long-term use of solid fuels – such as coal and wood – had increased risk of various eye diseases compared with those who used "clean" fuels such as electricity or gas. These diseases included disorders of the sclera, cornea, iris and ciliary body (35 percent higher risk), conjunctiva disorders (32 percent higher risk), and cataracts (17 percent higher risk). People who had used solid fuels but switched to clean fuels during the follow-up period lowered their risk by several percentage points.

Reference

1. *KH Chan et al., PLoS Med, 18, e1003716 (2021). PMID: 34324491.*

54%

of parents have not booked an appointment for their children since the pandemic started

ALMOST ONE IN FOUR parents are unsure whether their kids' eyesight has deteriorated during the pandemic

PARENTS ARE urged to book an eye test **FOR CHILDREN TO** reduce the negative impact

Reference

1. *Orbis (2021). Available at: https://bit.ly/38ShCYo.*

Trust Your Gut

Shifting the balance of the gut microbiome can throw off the balance of the gut-eye axis

When asked to think of an ecosystem with over 1,000 different species, a tropical rainforest or a coral reef might spring to mind. A few of you may immediately think of the biological party platter that resides in your gut, which acts as a cozy home to trillions of microbes that keep us ticking over. Many people – and some doctors – would be forgiven for thinking that, because these microbes inhabit our intestines, their only impact is on gastrointestinal health. However, our gut microbiome is also crucial to the health of other organs of the body – including the eyes! This interaction, in which a balance exists between gut wildlife and healthy function and disease in the eyes, is called the gut-eye axis. A shift in the contents or health of the gut microbiome can throw off this balance, inducing or exacerbating ophthalmic diseases such as uveitis, AMD, diabetic retinopathy, or retinitis pigmentosa (RP).

A research team from Spain's University of Alicante have found that, in mice, retinal degeneration in RP is associated with specific changes in the gut microbiome (1). In particular, four common microbe genera – *Rikenella, Muribaculaceae, Prevotellaceae* UCG-001, and *Bacilli* – are missing in mice with retinal disease, whereas *Bacteroides caecimuris* is heavily enriched. This indicates that measuring shifts in microbiome composition could offer a simple biomarker of RP and other retinal diseases, as well as suggesting the gut-eye axis as a potential therapeutic target.

This research adds to previous evidence that the gut microbiome is important in a wide variety of disease states and warrants further research into the balance of the gut-eye axis.

Reference

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Saving Axons and Somas

Could the CaMKII enzyme help preserve vision in patients with retinal disease and eye injuries?

A recent study by researchers from the Icahn School of Medicine at Mount Sinai, New York, USA, looked at retinal ganglion cells degeneration caused by retinal disorder or injury, with a hope of finding treatments capable of preventing vision loss from optic nerve damage, diabetic retinopathy, and glaucoma (1). Scientists are hoping to use a key enzyme, called CaMKII – which has, for the first time, been shown to regulate the survival of retinal ganglion cells in the retina, whether normal or diseased – as a target for gene therapy aimed at preserving the axons and somas in retinal ganglion cells. So far, gene therapy has been used in animal models, where a more active type of CaMKII was introduced into the original retinal ganglion cells to boost their activity, regulating the cells' survival across many different pathologies.

Reference

1. *Z Guo et al., Cell, 184, 4299 (2021). PMID: 34297923.*

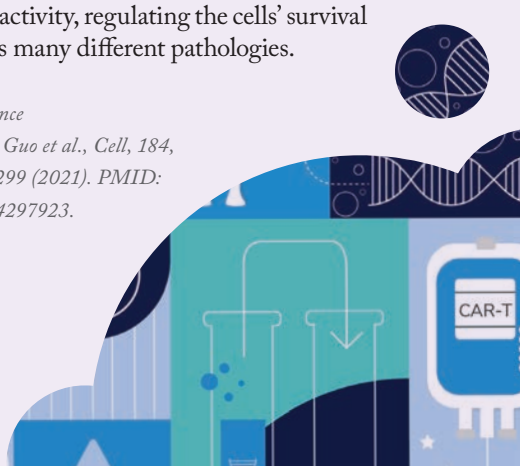
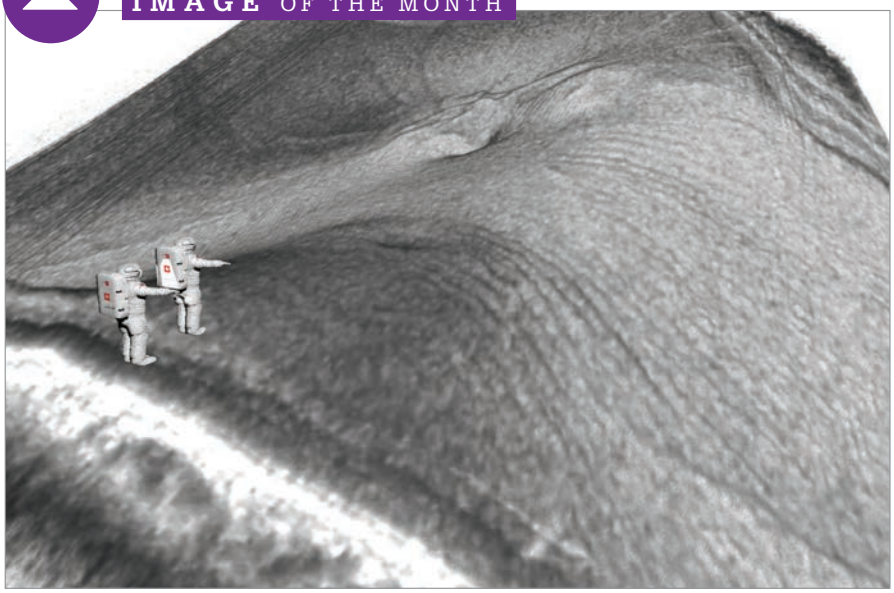


IMAGE OF THE MONTH



Deep Space Exploration

This month's image shows two astronauts exploring the deep canyons of a dome shaped maculopathy.

Credit: Peter Maloca,eye surgeon, Associate Professor at the University of Basel, and Group Leader Ophthalmic Imaging at the Institute of Molecular and Clinical Ophthalmology in Basel, Switzerland. He also works with Moorfields Eye Hospital in London, UK.

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

QUOTE OF THE MONTH

"You are much more likely to experience poor eye health if you come from a Black, Asian and minority ethnic background. Almost half of those with sight loss are economically disadvantaged, in households earning less than £300 [$413] a week, while people of south Asian & black African and Caribbean backgrounds are at much greater risk of developing glaucoma and diabetic retinopathy."

Bernie Chang, President of The Royal College of Ophthalmologists, UK

Credit: Mass Eye and Ear.

Good Vibrations

A vibrating wearable device helps visually impaired people avoid collisions

People who are visually impaired are now more independent and active than ever – but is there a way to also make them safer than ever? A randomized trial of 31 blind and visually impaired adults, conducted at Mass Eye and Ear in Boston, Massachusetts, USA, showed that a new wearable warning device reduced collisions by 37 percent compared with using a long cane, a guide dog, or both.

The device uses a wide-angle chest-mounted camera and two wristbands with a Bluetooth connection. Image-based data from the camera are used to calculate collision risk on the right, left, or head-on; when an obstacle is detected, the appropriate wristbands vibrate, letting the user know to move out of the way. Thanks to a novel computer vision algorithm that analyzes relative motion, the device can ignore nearby objects not on a collision course, making life on the go safer for people with vision impairments.

Reference

1. *S Pundlik et al., JAMA Ophthalmol, [Online ahead of print] (2021). PMID: 34292298.*

Protecting Eyes From the Friday Night Lights

Should visors be mandatory to reduce eye injuries in football?

The extreme physicality of football is clear to anyone – whether you're a spectator, stuck on the sidelines, or in the thick of the gridiron action – so injuries are guaranteed to occur at some point. But how dangerous is football to a player's eyes, and what can be done to reduce the risk of eye injuries?

To answer these questions, a research team from the University of Toronto, Toronto, Canada, have huddled up and formed a game plan – analyzing the NFL weekly injury reports for five seasons (2015–2020) to find out how the use of visors affects the rate and severity of eye injuries. Their research revealed that eye injuries are more common in players who don't wear visors – yet only 31.6 percent of players in those seasons actually wore visors (1).

The results support the American Academy of Ophthalmology (AAO) recommendations for football, which endorse using a polycarbonate eye shield – also known as a visor – to reduce risk of eye injury. Study lead author Arjan Dhoot says that, among NFL players, "eye pokes and gouges were the most common type of eye injury; other injuries include orbital fractures, corneal abrasions and eyelid lacerations." Although eye injuries aren't among the most common types of football injuries reported, it is clear that any of the injuries in this study could potentially threaten players' careers and devastate their day-to-day lives.

The major reason for players' reluctance to wear a visor is concern that it may reduce vision and impact performance – although previous research has shown that visors do not significantly affect reaction time or target detection. On the bright side, the study data indicate that visor use is increasing year on year, suggesting that teams and players may be paying more attention to the AAO recommendations.

How did this research topic come to fruition? Dhoot explains, "During the 2019–2020 NFL season, a star quarterback was kicked in the eye and still managed to throw a touchdown pass. This got us thinking – how prevalent are eye injuries in football? We found that this question had been answered for many other injuries, including knee and arm injuries, but no one had investigated [eye injuries] in football. A recent study had investigated them in the NBA (2), so we wanted to investigate the situation for the NFL."

So, given both the AAO recommendations of the AAO and the study outcomes, what are the barriers to widespread visor use in football? Dhoot says, "In recent times, we have seen hesitancy to uptake other forms of disease and illness prevention in the United States. I think, with time and long-term education, the visor can be a safe and reliable option to help prevent eye injuries in football at all levels."

And sports visors are no longer the boring plain plastic of years past. "The NFL recently partnered with Oakley to allow NFL players to use their PRIZM technology visors," says Dhoot. "These visors are stylish options for players that can help improve their performance."

The options include prescription lenses, UV protection, color recognition, and glare reduction – so no more using the Friday night lights as an excuse for missing that touchdown catch.

Although this study focused on NFL players, it is clear that similar uptake of visors can reduce eye injuries in players at all levels of the sport – and the research team state that this should be a focus of further research. The risk is even higher at non-professional levels due to the absence of the healthcare and resources NFL players have, which may mean that the same injury can have much more devastating consequences.

Dhoot concludes, "Many families are concerned about safety in football, so further studies investigating and promoting the use of visors may help reduce anxiety associated with football-related injuries. As well, future studies should investigate the association between visor usage and other injuries, including concussions. Finally, a survey should be conducted to gain better insight into NFL players' thoughts and attitudes about mandatory visor use and to explore reasons for visor use and non-use, giving insight into the positional and ethnicity differences in visor use reported in our study." Overall, it seems clear that visors would benefit football at all levels – but will football organizations be willing to make visors mandatory for the health of their players?

Faceoff Specialists

Leading the way in visor use is the National Hockey League (NHL), which has recently made visors mandatory for all players. A 2014 study found that the rate of eye injuries in the NHL was 2.48 per 10,000 exposures, whereas NFL rates are 1.05 per 10,000 exposures (3). The higher rate of injury in ice hockey is likely due to the speed of the puck, which is often deflected very close to players' faces (and is more likely to make contact with the eye than a much larger football), and the use of sticks that may also end up at eye level. Since the implementation of mandatory visor use, there has been a drop in eye injuries, which will hopefully inspire the NFL and other sports organizations to set similar policies.

References

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Keep Your Eye on the Ball

How visuomotor function separates the big hitters from those treading the Mendoza Line

A baseball leaves the pitcher's mound at almost 100 mph, reaching the batter in under half a second, with unpredictable movement through the air. Within this short timeframe, the batter must track and determine ball trajectory, decide to swing (or not), and adjust and drive with the bat to hit the ball. In short, a good eye is essential for a good hit rate.

Credit: Chris Chow/Unsplash.com

For the first time, researchers have shown that an experienced baseball player's visual tracking ability can be used to predict batting performance, with higher ocular tracking performance correlating with better batting capabilities (1). In contrast, non-athlete ocular tracking scores did not correlate to a better indication of batting ability – due to the nonvisual performance inefficiencies present in the non-athlete, which are "trained out" of the experienced baseball player.

Will MLB teams start screening strike-out swingers before they step up to the plate?

Reference

1. *R Chen, LS Stone, L Li, J Vis, 21, 3 (2021). PMID: 33651879.*

In My View

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

The Ocular Tumor Tsunami

What more can be done to avoid devastating waves of advanced eye cancers?

By Carol Shields, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University in Philadelphia, USA

Tsunami waves don't just suddenly appear at a coast they devastate; they are created with a ripple effect, starting with a major event, like an earthquake. We are now seeing a tsunami of ocular tumors, but our earthquake started in March 2020. When the pandemic began, the vast majority of patients stopped seeing their general ophthalmologists or other eye care professionals. The ripple effect? Fewer referrals to retina, oculoplastic, or pediatric ophthalmology specialists (the first ripple), and even fewer to ocular oncologists (the next ripple) – and this is the usual path that a patient takes to get to our practice. When this happens for an extended period, the ocular tumor cases that would normally be caught quite quickly are not addressed until they are very advanced.

Recently, we have been seeing a lot of advanced cases. Out of our usual 8–10 patients a week with uveal melanoma, an estimated 30 percent of them now have gigantic, out of control tumors. Before the pandemic, we were able to treat almost all of those patients, with perhaps one in 10 eyes being enucleated. Now, we are having to enucleate four to five eyes in a week. That is a huge increase. The same situation applies to children with retinoblastoma. Kids are coming in at a much later stage than they used to, and whereas before we'd treat them with chemotherapy, now – with many advanced cases – it's too risky, so we have to remove the eye.

I do think this is a temporary situation and it will get back to normal – but that makes it no more acceptable. Is there anything ophthalmologists in general, and ocular oncologists in particular, may be able to do differently in a similar situation? And what pandemic-induced solutions can ophthalmologists use day-to-day to improve patients' outcomes? My answers are using telehealth and hybrid/satellite offices.

Telehealth has been extremely important and useful in the past year and a half. Its universally accepted use is one of the very few good things that the pandemic has given us. It is vital that general ophthalmologists or retina specialists work closely and cooperate fully with an ocular oncologist who offers telehealth solutions, and that they consider referral of patients to the next level of care if they are not comfortable dealing with an issue themselves. In my opinion, the specialist offers experienced care to a patient and a degree of relief to the referring

"We are now seeing a tsunami of ocular tumors, but our earthquake started in March 2020."

physician. It is understood that clinicians might not know all the answers and might not have the necessary equipment to deal with every case, but they do know who can evaluated the patient with a questionable condition, and in a pandemic, this might have to be done remotely.

When a patient is referred to us by an eyecare professional, we prefer to see the patient in person and perhaps consider telehealth evaluation thereafter, if appropriate. The telehealth examination starts with the a virtual interview, where the technician takes a detailed history, a list of medications, interval changes, and then checks the vision and does a basic visual field test. All newly-taken images are uploaded to our protected system, where the specialist can review them – the images might be taken by the referring eyecare professional or at a satellite office that we staff with an ophthalmic photographer and single technician. Sometimes, the images are not of the quality that we are used to, but they are still helpful. After we have all the information collected, filed, evaluated, and described, we inform the patient of our findings and provide a printed correspondence. Monitoring visits are quite suitable to telehealth, as they can give the patient and also the referring ophthalmologist a real peace of mind – knowing that we are involved in the patient's care and overseeing their "tumor," even if they are unable to make it into the office.

I have seen patients from around the world – virtually, including a salmon fisher from northern Alaska, who couldn't come to Philadelphia for an in-person visit. Our team diagnosed his condition, prescribed treatment, and he never left his hometown – and he responded well. Another example is a woman from Uruguay who had a suspicious iris nevus; we managed her care via telehealth until growth was detected and she traveled to Philadelphia for treatment. The eventual outcome was good.

When COVID-19 struck, my colleagues and I noticed that even patients from our state did not want to come into the city. Probably because the center of Philadelphia is bustling, and Wills Eye Hospital has always been busy; the waiting room of the Ocular Oncology Service is usually full of people. We decided quite early on to open satellite offices outside of downtown Philadelphia with very few staff; most offices would only have a technician and a photographer, so patients only had to interact with two or three people in the office. And a specialist would be virtually brought in to see several patients efficiently, in a short time. The patients truly appreciate this system – they not only avoid the crowds, but are also spared long commutes and downtown parking charges.

These hybrid offices were something that retina specialists, both at Wills Eye and elsewhere – like Steven Houston at the Florida Retina Institute, US – had used even before the pandemic. For ocular oncologists, this hasn't been the case, as most of those are affiliated with universities, which may restrict the use of hybrid offices. The practice we run at Wills Eye is private, and we were able to open satellite offices at our own cost. And the cost is considerable; rent is an important consideration, which is why hybrid offices are usually relatively small spaces. You also have the initial purchase of all the equipment, and quality imaging equipment isn't cheap. We have considered it an investment into the future, but the cost of a good fundus camera, an external camera, OCT, and ultrasound equipment quickly adds up. Then there's the cost of a system that allows us to upload images to a server in real time, so we can see all the images at the same time they are taken. It's not cheap but, done right, it can make a big difference.

For the past 25-30 years, I have been answering emails from doctors all over the country and overseas, sending me images and descriptions and asking my opinion on diagnosis and treatment. It was often done informally, and the system wasn't always perfect. The pandemic pushed us all to formalize and improve this process, and a mixture of telehealth and satellite offices can now be used for patients who, for any reason, cannot come into our main office. Virtual visits are now approved by the governing bodies, and I can't see us going back. So much care and monitoring can be done virtually, and with the right protocols, approvals, and appropriate reimbursement, it will result in huge savings of time and money, both for the clinician and the patient.

"For the past 25-30 years, I have been answering emails from doctors all over the country and overseas, sending me images and descriptions and asking my opinion on diagnosis and treatment."

Currently, any patient who cancels a visit are offered an opportunity for telehealth or satellite/hybrid office visit, if available. All eye care providers should realize that ocular oncologists can perform effective examinations using telemedicine in its various forms – and we have taken full advantage of this silver lining of the pandemic's dark cloud.

Novel Uplifting Experience

Haroon Ilyas explains the practice-based workings of a non-surgical therapy for acquired ptosis in adults

Sponsored content by RVL Pharmaceuticals

Haroon Ilyas, MD, is an ophthalmic surgeon at Brandon Eye Associates - a comprehensive ophthalmology practice in Brandon, Florida, USA. Dr. Ilyas has been treating acquired ptosis in adult patients with Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1% a novel, non-surgical therapy from RVL Pharmaceuticals that received FDA approval in 2020. In this article, he explains how Upneeq works within his practice and how it has changed his diagnosis and treatment protocols.

The "before" times

Prior to Upneeq's approval, the status quo of diagnosing and treating patients with ptosis was most often to leave the problem unaddressed unless the patient complained or the condition was causing obvious impairment (1). Although patients may have cosmetic anxiety over their appearance, many assume that if their physician hasn't addressed the ptosis, it is not severe enough to warrant attention, let alone treatment. Additionally, until recently, the primary ptosis treatment available to me was surgical, so patients exhibited some reluctance, as did I.

Keeping good time

The timely detection and intervention of ptosis can minimize the duration of cosmetic and visual function consequences (2). It's also important to keep in mind that ptosis may be associated with neurologic or orbital diseases and consideration should be given to these conditions during diagnosis. Early to middle stages of acquired ptosis typically involve cosmetic concerns, with eyes appearing bored or sleepy; sometimes, there is asymmetry between ptosis levels in each eye. Late stages typically bring about more medical symptoms, including visual impairment, eye strain, brow ache, neck strain, and fatigue (although some of these may occur even in earlier stages). These symptoms can drastically affect my patients' daily living and therefore quality of life – activities such as watching TV, reading, or fine manual work can become much more difficult.

In its early stages, acquired ptosis may be confused with dry eye; presenting a diagnostic challenge. Due to dry eye's pervasiveness and shared symptoms of visual strain and fatigue, clinicians may misdiagnose ptosis complaints as dry eye and throw artificial tears and other dry eye therapies at the problem. This can lead to patients developing visual symptoms from their acquired ptosis in the more moderate to severe stages. Like with most ocular diseases, addressing ptosis as early as possible may avoid more significant symptoms. Clinicians may also appreciate the fact that acquired ptosis is a medical condition and addressing it may increase the overall complexity of the visit, while addressing the root of their patients' problems.

Talking about ptosis

Upneeq's ready availability has renewed my interest in finding acquired ptosis and treating it without surgery. Its accessibility has also made it much easier to discuss acquired ptosis with patients, and I have found that almost all patients are grateful to me for bringing awareness to the issue, explaining their symptoms, and acknowledging their cosmetic concerns. Because Upneeq often starts working within fifteen minutes of application, I will often trial it with patients on the spot so they can see the results for themselves. I also get them to take a selfie before the treatment (in which I ensure that they don't raise their brows to "hide" the ptosis) and a follow-up selfie an hour later to see the impact. Seeing is believing, of course, so I think that providing the patient a sample is important so that both the physician and the patient can see how the treatment worked for the patient. When I prescribe Upneeq I also make sure to tell my patients that they may have some adverse reactions and that in the clinical trials, the most common treatment emergent adverse reactions which occurred with an incidence 1 to 5% were: punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

Since prescribing Upneeq, I have started routinely taking MRD1 recordings in patients with acquired ptosis. This acts as a data point for both diagnosis and tracking progression of acquired ptosis. I now also pay much more attention to the possibility of acquired ptosis when I hear about fatigue or eye strain before offering lubricant eye drops. Upneeq has become my first-line treatment of acquired ptosis in adult patients who are candidates for the drop. It's important to keep in mind that Upneeq may not be right for all patients. Since Upneeq may impact blood pressure, I think physicians should tell patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to monitor their condition and call the clinic if it worsens.

Interestingly, my oculoplastic colleague was concerned that Upneeq would reduce the number of consultations she received. Contrary to this, her consultations have actually increased because of the practice's and patients' greater awareness of acquired ptosis – highlighting the importance of that awareness and its benefits for comprehensive practices.

Distribution and pricing

From a physician standpoint, the product's distribution model is the simplest I've seen in my career to date – mostly because it works outside of an insurance model. After I recommend it to a patient, my scribe sends the prescription to RVL Pharmacy and the company contacts the patient to ship it

out to them directly. That's it; there's no insurance and no callbacks for the physician. The great thing is that after diagnosing, discussing, prescribing, and treating with Upneeq, the patient takes over. If they are satisfied with their results, they order direct from RVL Pharmacy and we've had zero callbacks to our office – truly the first eye drop about which I can make that statement. Because it's a direct-to-patient billing model, it has been one of the few products that I enjoy prescribing because of the hands-off approach from a physician perspective after writing the prescription.

The ultimate cost of the medication depends entirely on the patient – not only their financial circumstances, but how they weigh the expense against the perceived benefit. Upneeq is indicated for daily use, however patients have ownership over how often they use the product. For example, I have many "weekend warrior" patients with ptosis who use the product when they plan to see other people and want to make their eyes look more open, but I also have patients who use the drop every day. Fortunately, the product comes in unit dose preservative free vials which allows people to work out a system of Upneeq treatment that best suits them, and overall, I think the price is very reasonable. We also make sure to instruct patients to not touch the tip of the container to their eye or any other surface to avoid contamination.

Positive results

In my experience, Upneeq works on both a functional and cosmetic level for patients with visual impairment symptoms from acquired ptosis – and many patients are happy with their results. I've been pleased with the outcomes for acquired ptosis patients in my practice, including patients with late-stage acquired ptosis.

For cataract patients going for premium lenses with diffractive technology, the amount of light coming into the eye makes a difference. Some of these patients also have acquired ptosis and addressing their eyelid position may improve vision (especially in lower light conditions). I had one patient in particular who had fairly significant cataracts and noticeably asymmetrical acquired ptosis between her eyes. Following her use of Upneeq, she was thrilled with the results – to the point where, after her successful cataract surgery (20/20 in both eyes), she talked about the improvement in the appearance of her eyelids as much as she did about her vision. It really shows how concerned patients can be about ptosis and the significance of now having a nonsurgical option.

IMPORTANT SAFETY INFORMATION

INDICATION

UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is indicated for the treatment of acquired blepharoptosis in adults.

WARNINGS AND PRECAUTIONS

- Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of ptosis with decreased levator muscle function and/or other neurologic signs.
- Alpha-adrenergic agonists as a class may impact blood pressure. Advise UPNEEQ patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use UPNEEQ with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.
- UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow angle glaucoma develop.
- Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

ADVERSE REACTIONS

Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

DRUG INTERACTIONS

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.
- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

Dr. Haroon Ilyas is a paid consultant of RVL Pharmaceuticals, Inc.

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THE PATH TO SUCCESS

Following the success of the 2021 Power List, five influential women discuss the career and life milestones on their way to positions of power in ophthalmology


1
3

Soosan Jacob

MEET THE PANEL

Aleksandra Jones, Editor of The Ophthalmologist, spoke to:

Julia Haller, Ophthalmologist-in-Chief at Wills Eye Hospital and Professor and Chair of Ophthalmology at the Sidney Kimmel Medical College at Thomas Jefferson University in Philadelphia, Pennsylvania, USA

Soosan Jacob, Director and Chief or Dr Agarwal's Refractive and Cornea Foundation, Senior Consultant of Cataract and Glaucoma Services at Dr Agarwal's Group of Eye Hospitals, based in Chennai, India

Anat Loewenstein, Chair of the Division of Ophthalmology at the Tel Aviv Medical Center and Vice Dean, Sackler Faculty of Medicine at the Tel Aviv University, Israel

Cynthia Roberts, Professor of Ophthalmology & Visual Sciences and Biomedical Engineering, and Chair for Research in Ophthalmology at Ohio State University in Columbus, Ohio, USA

Louisa Wickham, Clinical Director at Moorfields Eye Hospital NHS Foundation Trust in London, UK

Anat Loewenstein

Julia A. Haller

Cynthia Roberts

Louisa Wickham

WHAT WERE YOUR EARLY YEARS LIKE, AND WAS THERE ANYONE WHO PARTICULARLY INSPIRED YOU TO PURSUE YOUR STEM GOALS?

Soosan Jacob: I grew up in India, and my father was an army officer, and a military doctor. My early childhood was marked by transfers, changing schools every two years, making new friends – all of which brought with it advantages and disadvantages. I think it taught me resilience, ability to adapt to various situations and rise to the challenges I have faced. In some places, we would live very far from my schools, so there would be periods of a few years when I had school commutes taking three hours out of my day. As a child, you don't see it as a hardship, and they were fun times, as I had friends traveling with me.

In India, there were two sought after profession choices for a child: an engineer and a doctor. I wasn't very keen on engineering, so the other profession was a natural choice for me. I have an uncle who is an ophthalmologist, and he was a great, inspiring role model, so medicine – and ophthalmology in particular – followed me from quite an early childhood and really shaped me. My father was very persistent that I should do well in life; he was always extremely encouraging and kept a close eye on my well-being – something he does to this day with my children.

Anat Loewenstein: I had no other option open to me – ever since I was a child, I knew that I was going to be a physician. My grandfather was a doctor, and so was my mother; she was a cardiologist and practiced medicine until the day she died, aged 89. She actually found me a husband, as Julia Haller can confirm! My mother always emphasized to me and my brother, who is a general surgeon, that we need to do something that will really make a difference, and for that we have to excel in our fields – be the best in everything we did. When I suggested I could become a dancer, she responded that I would only be a mediocre dancer, and I should aim to be a great doctor instead. As early as aged seven, I remember reading her medical books and translating some of the text into Hebrew, and the need to excel in medicine has followed me since then, throughout my life.

Louisa Wickham: I was the first doctor in my family, and didn't have any medics around me, but my mother recalls me role playing medical scenarios in my childhood. When someone commented that I was a nurse, I would firmly correct them and emphasize that I was most definitely a doctor. Both my mother and grandmother were very strong women who worked throughout my childhood, which gave me great role models of high-achieving women being leaders in their fields. My school also had an ethos of encouraging girls to aim high, especially in science, which is not a common theme for schools, where girls are often encouraged to focus on humanities and arts. Throughout my education, I had a very keen interest in science, and I knew I wanted to be a doctor. Like Anat, I had one brief moment when I told my mother that perhaps I would choose another career, and she made me visit a friend of hers who was a physician, as she was certain that was what I ultimately wanted to do. I was always encouraged by her, and never regretted my decision of choosing medicine. I do think that ophthalmology is "the thinking person's surgery." It's a really beautiful mix of being surgical with the cerebral aspect of having to think about patients – so much manifests through the eyes, so we are constantly thinking of the big picture, not just the next surgery.

Cynthia Roberts:: My father was not only a trauma surgeon, but also a professor. We had professors coming to our home all the time when I was a child, so I was around academics from a very early age. I chose nursing as my undergraduate education, and worked as a nurse for four years, until I realized that it wasn't for me. I worked in a coronary intensive care unit, and I saw death and disaster every day, which was very hard for me emotionally.

Unfortunately, I wasn't exposed to ophthalmology, which obviously doesn't have a lot of mortality associated with it! Instead, I went back to school to study biomedical engineering, and I became interested in optometry applications in the early days of refractive surgery. I listened to my father, who taught me to take advantage of opportunities as they presented themselves; in fact, I'm still waiting for those opportunities to go away as they keep cropping up all the time! I feel that I have made important contributions to the field without being an ophthalmologist, and I've had an impact on patients' lives, on treatments, and physicians' understanding of some concepts affecting disease development and progression – the biomechanics of the eye.

AL: Indeed, a physician can help one patient with two eyes at a time, whereas a researcher or an entrepreneur can help

"I wanted to get up every day inspired by the thought that what I was doing really made a difference."

thousands of people with one finding.

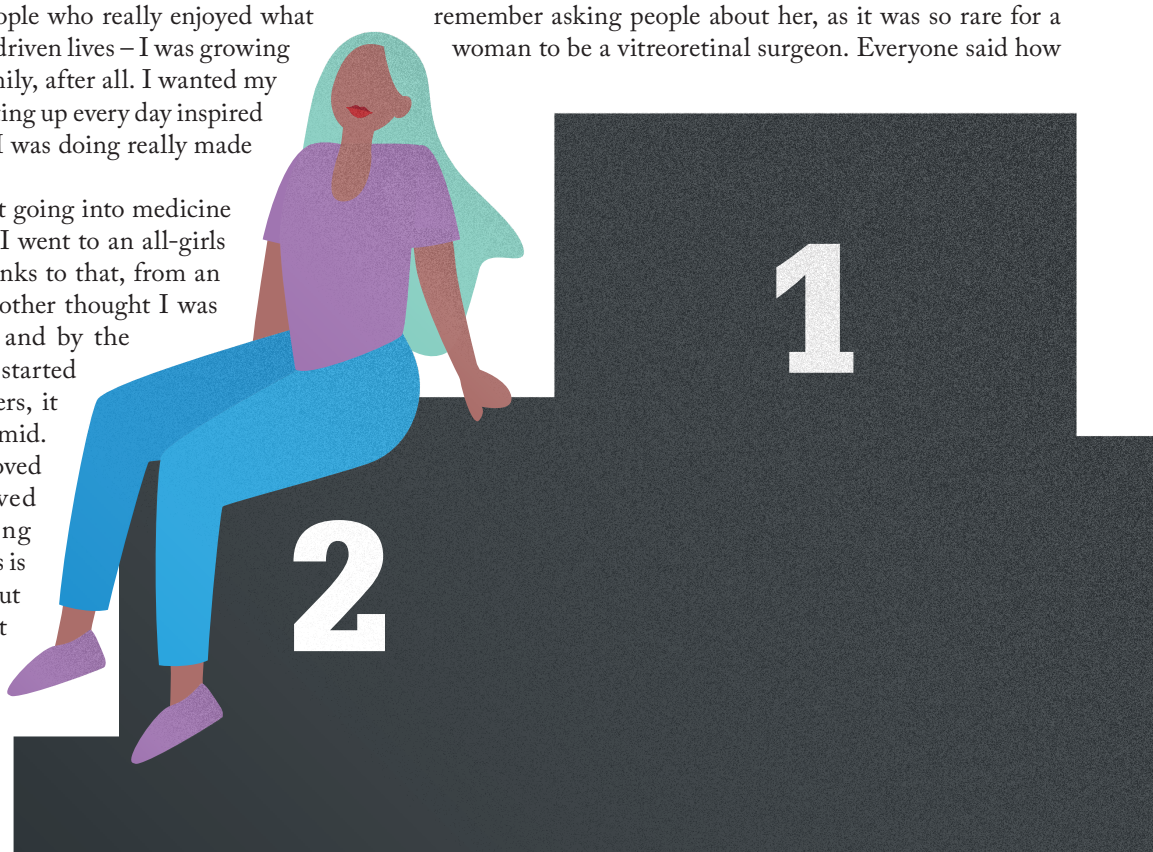
CR: I feel that I can convey complicated topics in a manner that people without the ophthalmic or engineering background will understand. Ophthalmologists and researchers like myself approach the same problems from different perspectives, and it's very important that we listen to each other to make progress. Many engineers start from equations, and I don't think that's the right approach – you have to start by speaking to the person or group you're aiming to help.

Julia Haller: I grew up with parents working in medicine: my father was a pediatric surgeon at Johns Hopkins, and my mother is an obstetrician. I originally gravitated towards non-scientific subjects, and I think I was eventually attracted to medicine because of its humanism, and interactions with people. It has also been intellectually stimulating. I saw my parents surrounded by people who really enjoyed what they did and had mission-driven lives – I was growing up in a Johns Hopkins family, after all. I wanted my life to be like that, too: getting up every day inspired by the thought that what I was doing really made a difference.

But originally, I thought going into medicine was too obvious a choice. I went to an all-girls school, and I feel that thanks to that, from an early age I never cared if other thought I was smarter than they were, and by the time I got to college and started interacting with male peers, it was too late to change my mid. I gradually found that I loved science classes, and loved finding out and knowing how the world worked. This is one of the great things about studying medicine: you get a real understanding of the things around you, and you have a skillset to interpret everything in a useful way. I have always liked fixing things, so I got drawn into surgery. After a couple of years of my medical school in Boston, I spent a summer at Hopkins, doing research with Stuart Fein, who was the Head of the Medical Student Program. He was an ophthalmology pied piper who led many students into the field, and I was one of them. At the time surgical fields were very male dominated, so when during my year of residency at Hopkins we had two women in one year for the first time, it was very unusual! When I went into retinal surgery and was admitted into the Vitreous Society, which is now the American Society of Retinal Surgeons, they only had one plaque template, so to this day my plaque says "To Dr Julia Haller in recognition of HIS contributions to the field of retinal surgery." Naturally, I have it proudly displayed in my office!

DID YOU ENCOUNTER INEQUALITY IN THE FIELD?

AL: When I started my career, it was a different world. I did my fellowship in retina at Hopkins, and in my second year, Julia [Haller] was going to be one of my bosses. I remember asking people about her, as it was so rare for a woman to be a vitreoretinal surgeon. Everyone said how



WHAT IS YOUR TAKE ON THE 2021 ALL-FEMALE POWER LIST?

JH: I think it was fabulous, a great idea and long overdue. Women have stories that are different, and so worth telling. It sets an example for those coming after us, and we need to urge them to aim high in every way we possibly can.

AL: If you asked me a few years ago, I would have said men and women were exactly equal and we did not need a separate list to acknowledge our achievements, but now I really see the hardships that women encounter. Due to my living in Israel and my position, I have not had to deal with a lot of them, but it's important to highlight them. The fact that you gave space to 100 women has meant that many more of them had the opportunity to appear on the list than would otherwise be possible.

LW: It will give encouragement to many women who hadn't been recognized previously. I also think that asking organizations to think more about the female nominations for this list might have given them an opportunity to re-examine themselves and not just nominate the usual people. It will probably make The Ophthalmologist aware of many more fantastic women in the field. With your huge readership, going to those people and asking them for contributions or to appear on panels will mean a lot to them.

CR: I think you would be surprised to know how many people look at the Power Lists to determine who they want on panels, as consultants, and involved in different projects. The all-female list will highlight women in general and perhaps we'll get a few more female presenters at the Academy meetings, moderators, and committee members.

SJ: It was an exceptional and proud moment. It's a great honor to be on the list, among such wonderful women. The list makes it clear how many powerful women there are in ophthalmology. That brings to focus what large role we play. I know the list isn't definite, and there are so many more capable, exceptionally talented women in the field, and I think people will be encouraged to put those women forward for future lists, and also for leadership positions.

brilliant she was, and I couldn't believe a woman could be that good at this profession, even though I was going into it! I thought she had to be very old, and it was such a surprise to find out that she was a young woman. I thought she probably hadn't done much research, and it turned out that she was one of the best retina researchers. So I assumed she would never let me touch a patient, and do a single vitrectomy, and on the first day with her in the OR, she said: "If I can do it, you can do it," and, despite trembling with nerves, I did five vitrectomies with her. All my conditioned predictions turned out to be wrong.

LW: When I started vitreoretinal surgery and went to national conferences, there were three women in a room of 200 men, so it was quite intimidating. But, when I did my fellowship, there were four women in five posts. I remember hearing comments before we started about how it was bound to be a disaster: "someone's going to get pregnant, then they will be off for a maternity leave, so how are we going to cope!" Actually, at the end of the fellowship, everyone commented about it being the most beautiful year they'd ever had, with everything beautifully organized. All the fellows ended up as consultants around the UK after their training.

SJ: It's so interesting to hear experiences from women all over the world, in typically male-dominated societies. India is also quite a male-dominated country, but Kerala, where I'm from, is a very matrilineal society, which places a lot of importance on women's education and equality. We don't really see men getting preferential treatment. Nevertheless, when I started out at medical school, women were forced to wear long saris – a five-yard sari would be draped around me, and I found it very difficult to deliver a small baby wearing that much fabric, making sure all the folds were still in place, and the baby wouldn't drop to the floor! Once, my friend bought a small bike, and she was the talk of the town, as it was the first time people saw a woman buy a bike. Despite all this, I felt that my male friends at medical school were very supportive and respectful.

CR: When I went from nursing, which was predominantly female, to engineering, it was quite a transition for me! I was once in class with one other woman and 83 men, and I remember the professor reading the list of names for the first time. It was Mr, after Mr, after Mr, and I knew that I wasn't

going to be happy if he called me a Mr, but he got both mine and the other woman's names right, even though her first name was gender neutral. It wasn't till much later, when I became a professor, that I realized that gender was specified on these lists all along!

I do hope that these days women who go into engineering do not experience some of the issues we faced. There has been a tremendous change over the past 30 years. When I began my career more than 30 years ago, it was hard for a woman to get attention. I had a strategy of saying things at meetings that I knew were true, but were also quite controversial. This would make people turn in their seats, heads would come up, and they listened closely to what I had to say. I would shock them first and then explain my thinking, and that's really how my career took off!

When I was pregnant with my first child, I hid it for as long as I could, as it wasn't well accepted. When I had my child, I was supposed to be off duty for the summer, but I was coming to work, bringing my son with me. One of the secretaries asked to see him, so I took him to the main office, and the director happened to be there. He looked at me and commented: "What's wrong with this picture?" before leaving the room. I never kept pictures of my children on my desk – it was like I didn't have any. Now, there are many women in biomedical engineering who work very closely with physicians all the time, so the perceptions have really changed. Men were an important part of this change; when I was in a graduate studies committee meeting, the chair was a man, and he let us know that we had to finish early as he had to pick his daughter up from day care. I'm glad he felt comfortable doing it, although I think if a woman said that, it would be perceived in a more negative way.

AL: When I was nominated to become chair of the department at the age of 40, the hospital director worried that I might be a bit too young as there were many more senior people in the department, but my gender never came to it. At the start of my career, I never felt that being a woman was a disadvantage. However, as I became more mature, and when I started following my daughter's career, I realized that to get very far as a woman – be it chair, head of a lab, head of a clinic of hospital – you have to work endlessly, and be really exceptional in the whole field. I think that for men who are as talented or as hard-working, it is easier to achieve these positions. We have all had to hide pictures of our children, not pick them up from school, and be absolutely exceptional in our fields, to get to where we are now.

I understand this much better now than I did when I was younger; I thought there was no glass ceiling, no limit to what any woman could achieve. Now I realize that we can break those ceilings, but only by being the exception rather than the norm, and having the best capacity for what we do. I don't have the capacity to become an exceptional engineer, so it is lucky that I chose a field where I could excel.

JH: I was well accepted in the ophthalmic community, but even now, when you look at panel discussions at events, there are many women in the audience – we have so many female physicians – but not as many on the panels. Some of our junior faculty put together a list of how many women gave presentations at retina meetings. What I noticed was that the more women there were on the organizing committee, the more women were asked to speak, and it's similar for minority groups, too. What we are doing for women is just part of what has to be done for underrepresented groups worldwide. We need to make ophthalmology reflective of the population.

LW: When I reflect on my fellowship – yes, I worked extremely hard, but so did the men who I worked with. We were all expected to put in the same number of hours. Thankfully, I think now it is more acceptable for both men and women to leave work early and pick children up. I have to see men paving the way for this as a positive thing. I hope it will make it easier for everyone.

My biggest mentors were men who really wanted me to succeed – I was able to "stand on the shoulders of giants." Bill Halewood, my mentor at Moorfields, was a phenomenally talented surgeon; always supportive and encouraging. It has often been the men with a more progressive view of the world who helped us throughout our careers, and I think it's important to recognize it. And now, hopefully, we can have the same impact on the women who will come after us!

AL: To add to the comment on discussion panels – all of us

sit on panels all the time now, almost daily! But I'm usually the only woman on a panel, occasionally there is one other woman there, who is also a renowned surgeon. It's similar with advisory boards, which still have too few women on them.

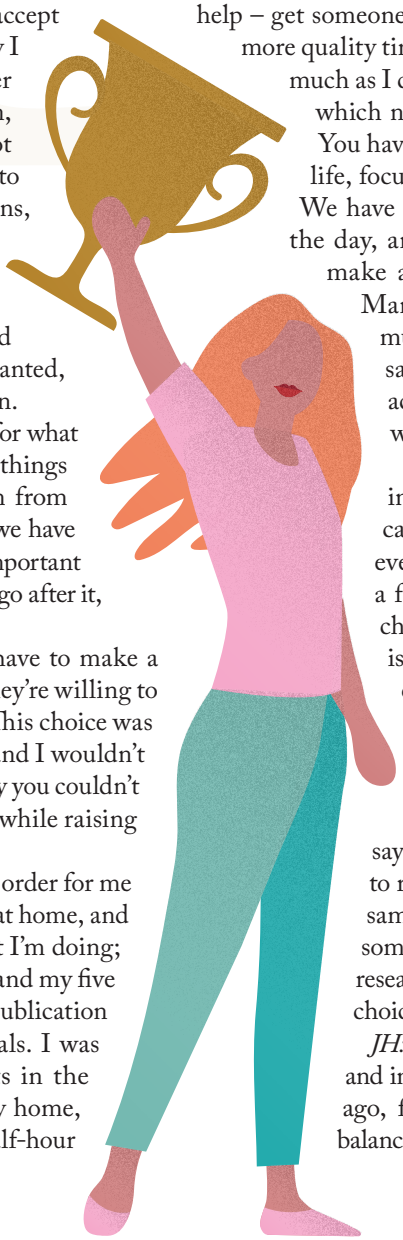
JH: I see your point about the hard work needed; there is a need to have "fire in your belly" to get far in our field as a woman. I often tell our residents and fellows about all the science that has emerged since we were their age, pointing to differences in psychology and conditioning of women and men. I wish I knew from the beginning of my career about what Sheryl Sandberg writes in her book, Lean In. A few years ago, a resident came to see me and said in passing: "Wish me luck, I'm on my way to negotiate my contract." I said absent-mindedly: "Just make sure you don't accept the first offer." She was stunned and asked why I said that, and it occurred to me that I failed her in not explaining previously that as a woman, she was bound to accept the first offer, and not negotiate, and that I had not encouraged her to read up on it. When I was leaving Johns Hopkins, the dean was debriefing me, and when told about a position I regretted not getting, he asked if I had put my hand up and said I was the right candidate… I then realized that I had not been emphatic enough about the things I wanted, and that this was something I still had to learn.

SJ: Women often feel like they shouldn't ask for what they want, and they should patiently wait for things to come to them. This sometimes stops them from reaching their maximum potential. Of course, we have to work hard and excel in what we do, but it's important to remember to express what we need and want, go after it, and not just sit back and wait.

JH: I think that many women think they have to make a choice between career success and family, so they're willing to accept less so that they can have a family life. This choice was explicitly presented to me when I was young, and I wouldn't accept it; I thought that there was no reason why you couldn't be successful and rise to the top of your career while raising a family.

AL: I have a very strict idea on this issue – in order for me to be able to pursue my career, I need harmony at home, and I need the whole family to be happy with what I'm doing; that includes my husband, my three children, and my five grandchildren. When I was working on my publication record, I did a lot of toxicity studies in animals. I was doing electrophysiological studies on rabbits in the north of Israel, about an hour's drive from my home, after finishing my clinical work. I would do a half-hour dark adaptation for the rabbits, work for a couple of hours, and then drive home and get in around 8 pm. Then, my mentor decided that we had to switch to rats, which needed three hours of dark adaptation, and that meant that twice a week I wouldn't come home until midnight. My husband said that he couldn't cope with it, and I knew that I had to give that up – it was just too much for my family. That is the trade off – I can pursue my career, but I know that I need the family to be happy so I can put all my energy into my work.

LW: Women should always be honest about the choices we make throughout our career; sometimes your work-life balance needs to change for a while, and then when children are older, it will change again. Also, it's important to get help – get someone else to do the cleaning, so that you have more quality time to spend with the family. I outsource as much as I can, so I have more time for the nurturing, which nobody else can do for my family but me. You have to decide what adds value to your family life, focus on that, and get help with other things. We have to accept that there are only 24 hours in the day, and whenever we take something on, we make a choice about something we won't do. Many women are very organized and great at multitasking, playing different roles at the same time, which means sometimes we can achieve more in 24 hours than others, but we still only have 24 hours every day.



I try to be honest with younger women in the profession when they ask me about career and work-life balance; I tell them every woman can achieve success and have a family life, but we have to make our own choices over what is important to us and what isn't. That might mean that you're a great clinician, but you decide to leave research for five years, and then go back to it. You have to allow your career to go through different phases, and choose your own rhythm. It should always be OK for us to say that that's what we're going to do. We have to remember that just like not all men are the same, not all women want the same thing, so some won't feel the need to have a family or do research, and others will. As long as it's a positive choice, it should be fine.

JH: Barbara Judge, a British lawyer, entrepreneur and international banker, who died a few months ago, famously objected to the term "work-life balance," because it implied that work was separate

from "life." When you really love your job, it's part of your life – part of a mix.

LW: I agree. They say that if you do a job you love, you will never work a day in your life. People sometimes choose a profession based on the fact that it's "family friendly," but my advice is to always choose what you love, as it will keep you invigorated and enthused, and that's the most important thing about your job.

CR: Women sometimes talk about "having it all," and I really hate it, as it sounds selfish and entitled. You can't "have it all" and men wouldn't talk about it in those terms. You have to live to your fullest potential, whatever that is.

LW: At a national conference, we had a session with a theme of "How to do VR and still have a life." The topic was suggested by women, and we thought we would have a high female turnout, and actually many more men came. We shouldn't make an assumption that men don't want to have the option of leaving work early and picking up children, or doing something else they want to. It's very much a generational thing.

CR: In my engineering career, one of the biggest hurdles is having male colleagues who have never had to worry about home life. They have incredibly competent partners, who could've done anything – could've ran the world – and they ran their households. I'm often stuck with their husbands who are great at their jobs, but they have no real concept of life outside of it. It definitely is a generational thing, and the world is gradually moving in the right direction. Increasing involvement of women into our fields has allowed men to see what's possible.

SJ: In India, dynamics are different in different families, but I have always had the support of my husband in everything I've done. He's helped me along, given me suggestions on how to go about things, and never held me back from anything. It has been the same with my boss, Amar Agarwal, who has always encouraged me. Like Anat said, it's important to have peace at home and in your workplace, as it allows you to reach your natural potential. Like Louisa noted, you have to delegate what you can, and only do what you must – that will be more than enough. This applies to your home and your office, where you can often delegate work to your juniors, residents, who will be happy for the opportunity to participate in your work.

Having to give up on a family should never be a part of being a successful woman. You need support from those around you, including those in your life, and male and female colleagues. I have wonderful colleagues in my department who are always ready to step up and help when it's required. My daughter is actually sitting right here with me, as I wanted her to see the discussion with all these beautiful, powerful women, and I'd like her to know that it's possible to do well in your career and in your family life.

AL: I see this generational change in my daughter and two daughters-in-law. In all their families, there is a combined responsibility for providing for the family and making a home.

HOW DID YOU FIND THE RIGHT BALANCE BETWEEN CLINICAL PRACTICE AND RESEARCH?

JH: For research and teaching, you need the right environment, and patients often demand your full attention, and have to be taken care of immediately, so a very busy clinical career doesn't always lend itself well to bench research, although there are a few people out there who are organized enough and have support systems to be able to do it all.

Clinical research has allowed ophthalmology to become the most exciting field in medicine, with so many advances. We are lucky that we can go from bench to bedside, and often be on the bedside end of the research spectrum, and it's very satisfying to combine clinical care with enrolling patients into clinical trials. It has kept me interested in the field, and I think it feeds into my patient care as I'm able to offer patients the very latest treatments, and give them realistic hope in some very bad situations.

AL: I always felt that I shouldn't give up research because of clinical overload, and I was able to pursue it throughout my career. Rather than, for instance, seeing patients in the hospital in the morning, and privately in the afternoon, I chose to do work in research labs in my afternoons. I feel that this has made me much more effective in my clinical work, as I see complicated patients, and do complicated surgeries more often as a result of doing research. My mentors and department chairs always taught me to choose research that would enable me to find better treatments for my patients, knowing the latest innovations in the field. I wanted to pursue an academic career and not a clinical one first, so that it would give me more independence when I got to a high position, but I don't see pursuing research to be in conflict with clinical work – I see it as one influencing the other in a positive way.

SJ: Both research and clinical practice go hand in hand for me, too. I work in a hospital known internationally for its cutting-edge innovations and research, and it was that way already when I joined. This encourages staff to think about creative solutions when they see a difficult case in their clinical practice. The fact that the place you work in values innovative solutions really matters, as you should not feel like coming up with something new and creative is going to be frowned upon. Of course, there will always be a discussion about your new approaches – considering ethics and practicalities, but you should have the freedom to express yourself,

and be encouraged to pursue your choices. Ophthalmologists have to realize that text books keep changing, and that something that was the right approach a few years earlier, might soon be replaced by a new standard. When I see a patient, I wonder whether a less common approach might give them a better result.

LW: I've done it both ways: I took two years to focus on research in the middle of my training, which is quite common in the UK. It really got me thinking about things creatively. So much of what drives your interest in research and what gives you good ideas comes from seeing patients and getting frustrated about the lack of available options. Many great observers of clinical signs who put them together and find the connections fuel amazing research. When I started my career, the regulatory framework was more forgiving for people who pursued both research and clinical practice, and now – quite rightly – there is much more infrastructure and governance around it, which makes it more difficult to combine the two than some of us would like it to be. Currently, I have one day a week dedicated to research, on top of my clinical practice, and it allows me to keep things going. In an ideal world it would be more like 50/50, but then something else I love would have to give – it's not easy to achieve and keep the right balance

AL: Allocating time for research is crucial, which I learned already during my fellowship at Hopkins. When I became chair of the department, I devoted one day to research, one to organization, one to the clinic, one to the OR, and one to university work. I'm not able to keep it this way 100 percent of the time, but it's important to have this structure in place.

HOW DID LEADERSHIP OPPORTUNITIES COME YOUR WAY?

CR: When I joined the Department of Ophthalmology in Ohio, there were a lot of clinical trials going, but not much research similar to what I was doing, so overseeing it was a natural position for me to take. Then, I found myself to have been at the department longer than almost anyone else, so – again – a leadership position was quite natural. As I mentioned, my father told me to take advantages of opportunities presenting themselves, and I did.

It's really important for me to take an active role in training the next generation – they are the future. I spend a fair amount of time with ophthalmology residents, whose required component of residency is research, and even if they don't plan on taking an academic position, I tell them that they have to know what to incorporate into their practice when they finish their training. I've had former residents track me after several years at major meetings, like the AAO meeting, to ask my thoughts on some exhibits. Training future physicians, letting them know how important it is to be well versed in current literature, and to publish research, feels like a crucial part of being a leader.

JH: For me, it was a gradual process. At school, I was top of my class and a school president – a high achiever – and I always liked running things. I was also the first female chief resident at Wilmer. All these positions inevitably come with the impostor syndrome, but we have to fight it hard. Once you find that

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you're doing a good job in your current position, it's easier to go for the next one. Today, it might paradoxically be harder for young women, as they don't have to fight so hard. I felt like a pioneer, and that it was incumbent on me to work harder to stand for my gender, whereas if many opportunities come your way when you're younger, you can get overwhelmed and overloaded because you try to take on as many of them as possible and not say "no." I'm now at a point in my career where it's a challenge for me to say "no" and I have to figure out what the essential things are – where I can make the biggest difference.

I always have a To Do list. I often feel like I'm never getting through my work, but then I will find an old To Do list and say to myself: "Yes! I really found the time to do it all!" and I'm proud. Then I go back to my current list and see all the things left to do and find the energy to do the things that need to be done.

SJ: My siblings and I were all taught to be strong personalities, to never shirk from responsibilities, and to take challenges head on. The sort of discipline we saw in our parents really inspired us to take on leadership posts. My research and my innovations really helped me get many opportunities. Remember, all the effort you put in over the years – all the extra work you do over and above, and the extra experience matters a lot. If you keep on researching and publishing, people come to know about you. I have a YouTube channel where I post surgical videos, and it's extremely popular, with more than 10,000 subscribers. It has given me a lot of recognition, and people come up to me at conferences to tell me that they check the channel before they do surgery, to the point where their partners wonder whose voice it is they hear every morning before surgery. This recognition can lead to leadership positions, so make sure you show the world what you do and what you're capable of. Managing your team is also vital – how much time and importance you give to every single person, all the way up from your juniors.

LW: Becoming Medical Director of Moorfields has been a baptism of fire of sorts, but I go back to what Anat said about being able to make a difference for many more people, and not just one patient at a time – and that's what leadership means for me. The feeling you get when you develop a new pathway, reduce patients' waiting time or improve outcomes because you have trained the staff, organized everything, got the right funding, purchased equipment… it's really powerful.

I was Chief Surgeon at Moorfields throughout the first year of the pandemic – a time when leadership was really in the spotlight. How you led your organization through a period of huge uncertainty – particularly for ophthalmologists, as there's a lot of evidence that we get very up close and personal with our patients and are therefore potentially more at risk – showed what kind of a leader you were; whether you stayed in the hospital to help staff and patients. I think that's when female leadership really came to the fore, as I do consider female leaders to be more empathetic, more collaborative, and listening to others.

> "I feel that I have made important contributions to the field without being an ophthalmologist."

Since I became Medical Director, I've had nothing but support from my staff. No two days are the same; there are always new challenges. We are now in the process of building a new hospital, so there are many strategic decisions to make. I love it and consider it to be an amazing honor to have people's faith put in me. As a leader, you have to show authenticity and courage of conviction, which doesn't always make you the most popular person in the organization, but should earn you respect.

WHAT DO YOU THINK THE FUTURE HAS IN STORE FOR YOU?

JH: The COVID-19 pandemic has been such a challenging period to live through that I wouldn't have chosen it in a million years, but at the same time, we don't want to waste that crisis, and we have to use what we have learned in the past few months. We have been catapulted into teleophthalmology, and we learned how to streamline operations and have fewer people coming through the hospital.

I wrestle with a lot of unexpected opportunities that come up, and some of them involve moving out of ophthalmology and into medicine as a whole – such as taking on a deanship – or even moving into drug and device development. It's been interesting to serve on corporate boards, where I can look at ophthalmology from a different angle.

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- Decreases breakthrough iritis[4]
- Reduces pain[4]
- Reduces photophobia[4]

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

Compared to epinephrine:

- Decreases complication rates[6]
- Decreases use of pupil-expanding devices (PEDs)[6-10]
- Enables performance of surgery and postoperative care without the use of steroids—allowing NSAID-only anti-inflammatory therapy[4,5]
- Shortens surgical times[6,8-10]
- Reduces need for opioids (i.e., fentanyl) during surgery while decreasing VAS pain scores[11]
- Prevents miosis during femtosecond laser-assisted surgery[12]
- Improves uncorrected visual acuity on day after surgery[6]

VAS = visual analog scale

OMIDRIA inhibits the release of inflammation-causing prostaglandins, preventing miosis and reducing postoperative pain[13]

CMS confirmed that OMIDRIA qualifies for separate payment under the non-opioid pain management policy when used in ASCs. Contact your commercial and Medicare Advantage plans to determine OMIDRIA reimbursement. Reach out to your OMIDRIA representative today or visit omidria.com to learn more.†

†Based on currently available information and subject to change without notice. Individual plan coverage, payment, policies, and procedures may vary and should be confirmed by the facility. Omeros does not guarantee coverage or payment.

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

OMIDRIA must be added to irrigating solution prior to intraocular use. OMIDRIA is contraindicated in patients with a known hypersensitivity to any of its ingredients.

Systemic exposure to phenylephrine may cause elevations in blood pressure.

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

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

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

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

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(phenylephrine and ketorolac intraocular solution)
1% / 0.3%

things are going to happen that day. Sometimes it's a difficult challenge, but most things make me excited. I'm very optimistic about the future, and I think a lot about the breakthroughs that will happen over the next 10 years, and what difference they will make in addressing our patients' unmet needs. This thought keeps me going.

CR: I work a lot in interpretation of current ophthalmic devices and adding new analyses to provide quantitative metrics for physicians, and I consider ophthalmology to have been a little late in getting heavy technology involved, but now things are moving at a very rapid pace. We're at a crucial point of medicine and technology merging, so I'm really excited about the future and the students we are training.

AL: I have always been interested in early detection and monitoring of patients, and I now see self-monitoring as a huge opportunity. Home monitoring will be extremely important in retina, in ophthalmology, and in medicine in general, and I'm so happy that I've been involved in and leading this field for many years. I also see a great future in patients being in charge of their data, test results – having control over it all.

LW: The digital explosion that we're going to see over the next few years is bound to lead us into some unexpected directions. We have transformed more in the last six months than we would have done in six years otherwise. The pandemic has driven us to reimagine and re-examine how we deliver eye care. We now have to work out safe ways to deal with backlogs of patients. I'm intrigued to see how we change our environments and pathways. I see us working more closely with engineers and architects to develop new ways of seeing patients.

We have also been a lot more collaborative than in the past. Many organizations and institutions have been sharing knowledge and trying to ensure that we minimize health inequalities. We will continue to transform, and AI will be a big help in sifting through patients who are safe and picking those who we need to take a closer look at.

We have announced a project called Attend Anywhere for our A&E department, and a large number of our patients now have virtual consultations before they decide whether they need to come into the casualty department.

SJ: I don't think there's a limit on how much technology can advance with respect to helping to treat the eye, with all its biomechanical properties and layers, and visual and refractive properties. Another thing that I find very exciting is preventive ophthalmology – continuing to lower the bar for diagnosing a disease as early as possible and preventing it from advancing. It's extremely important. I also think that lasers are going to grow in importance in every field. I look forward to looking at every patient who comes in in a new way and wondering what I can change in my practice to make their eyes better. I just want to keep innovating.

Brian P. Smith
General Manager
Quidel Corporation–Eye Health

At this year's AAO, visitors, both virtual and in-person, can expect to learn about all the latest products Quidel has to offer the eyecare space. This includes the latest data on our flagship product, Inflammadry, the only affordable MMP9 test to detect inflammation on the ocular surface. In addition, we will introduce new product offerings addressing the current needs of our customers' practices and surgery centers. They are designed to ensure the safety of patients and staff so that clinics can remain open.

Over the past 18 months, we have had to adapt the way we conduct business with our customers. The "hybrid" approach to business has forced us to become more efficient working from home in our new virtual environment. It has also helped us expand our international business, both with our current distributors and new distribution relationships in existing and new markets.

Quidel is looking forward to getting back to a live in-person meeting at the AAO. We have spent many years building strong partnerships in this business and we are long overdue getting closer to "business as usual" in New Orleans. We plan to host a Dry Eye Roundtable featuring prominent KOLs in the industry discussing the most recent approach to OSD management as oulined in the 2019 ASCRS Guidelines. In addition, we will have several experts in the field at our booth to share successes in their practices. We will also offer live training sessions on Inflammadry and COVID-19-safe environment.

Booth number 1034

QUIDEL

Shawn P. Mullen
Global KOL and Strategic Management
Quidel Corporation–Eye Health

Quidel has been consistent with the strategy of expanding access to affordable testing, and we look forward to sharing more on these and other initiatives in the future! There continues to be both a strong need for COVID-19 testing, as well as for InflammaDry, the first and only MMP-9 test available to the ophthalmic community for ocular surface inflammation, and our QuickVue Adenoviral Conjunctivitis test that detects the presence or absence of the adenovirus. Quidel's products allow healthcare workers as well as corporate employees to quickly test and treat at the point of care, which leads to improved patient outcomes and provides numerous economic benefits to the healthcare system. The InflammaDry test has recently been included as one piece of the overall puzzle to ASCRS/ESCRS Pre-Operative OSD Algorithm – an essential test prior to an elective procedure.

In 2020, Quidel rose to the challenge and responded to the largest pandemic in modern history by being the first to market a rapid SARS-CoV-2 antigen test in the US, Sofia® SARS Antigen FIA. In March 2021, Quidel received approval for its QuickVue® At-Home OTC COVID-19 Test, unlocking a new market beyond the professional segment to include retail, employee, school, and home testing. Our rapid QuickVue COVID-19 tests and our newest OTC COVID-19 at-home tests are fast (under 10 minutes), accurate, and can be done at work or at home. Clinicians can also offer QuickVue test to patients to ensure that they are not contagious, so the practice can reopen and stay open with confidence.

Booth number 1034

QUIDEL

In Practice

Surgical Procedures
Diagnosis
New Drugs

What's Under the Ocular Surface Disease Umbrella?

Despite huge strides, there are still areas of OSD that are difficult to manage. Efforts should be made to diagnose conditions correctly, so that when a new treatment arrives – we are ready to use it.

By Elizabeth Yeu

How should we view ocular surface disease? In my opinion, it should be recognized as any imbalance of the tear film – and considered to be a broad umbrella that encompasses dry eye disease (DED), allergic conjunctivitis, Meibomian gland disease, and blepharitis. The symptoms of all those disorders can be so similar, when we consider signs reported by patients, such as redness and itching. This is why it's so important to take a closer look and find the differentiator for one of the above disorders.

Recently, the ATLAS study, conducted on patients diagnosed with Demodex blepharitis, showed that 80 percent of patients saw the disease and its symptoms as negatively affecting their daily life (1). These numbers are huge! Some blepharitis patients report that they might see a doctor up to six times before getting a clear

The ATLAS study findings (1)

The study used questionnaires to survey 311 patients pre-screened at eight sites taking part in phase 2b/3 Saturn-1 trial, showing three objective signs of Demodex blepharitis, such as the presence of Demodex mites, collarettes, and lid margin erythema.

Over 50 percent of patients reported having symptoms of blepharitis for at least four years, and 58 percent reported that they were never diagnosed despite making between two and six appointments with an eye care professional.

The emotional impact of the symptoms included patients being conscious of their eyes all day (47 percent), constantly worrying about their eyes (23 percent) and considering symptoms to be giving their eyes or eyelids a negative appearance (23 percent).

The majority of patients – 52 percent – reported experiencing itchy and/or dry eyes frequently or constantly in the month before taking the questionnaire.

47 percent of patients reported difficulty driving at night, and nearly a third reported the disease to add time to their daily hygiene routine.

A vast majority – 82 percent – of these blepharitis patients sought treatment, but many then discontinued it due to side effects or perceived ineffectiveness.

diagnosis. The study really highlights the need to detect and diagnose the condition sooner, with an effective therapy following.

Why do doctors so often fall short of diagnosing blepharitis? One of the reasons has been the lack of an effective therapeutic that would elevate the space. If you can't treat a disease, there is much less incentive to detect and diagnose it. This was the situation for dry eye disease a decade ago – and with the advent of effective medications, precise diagnosing has become much more common in the DED sphere.

The therapeutic

The results of the Saturn-1 trial, conducted by 15 different centers, show that we will most likely have the therapeutic, TP-03, available to us very soon (see box The Saturn-1 study findings). What we need now is greater awareness of blepharitis. At the recent ASCRS meeting in Lase Vegas, Nevada, USA (July 23-27, 2021), I saw a real buzz and a lot of blepharitis information projected from the podium and discussed among clinicians, but there is still a great need for education about the clinical diagnosis.

Many experts have been underdiagnosing the condition due to the lack of knowledge of how simple and quick this diagnosis can be. When I bring my patients to the slit lamp, the first thing I ask them to do is to look down, which enables me to check both lid margins, and look up – which allows me to look across the lower lid margin. This should be the first step in any examination – having a good macroscopic look at low magnification.

When I consider TP-03, what grabs my attention is that it reduces or gets rid of redness in a statistically-significant number (over 60 percent) of patients, even though it doesn't contain any anti-inflammatory agents (it gets rid of redness completely in one in five patients). This shows me that the therapeutic gets rid of the source of the redness, on top of removing collarettes.

The near future

Management of Demodex blepharitis is a second-level treatment, and it should be done at a second-tier visit, but it is currently pushed to visit three or four, mostly because specialists focus on things they can currently treat effectively. This condition has been the "low back pain" of ophthalmology, without a clear solution – with just homeopathic, minimally-effective therapies available, some of which required chronic management and came with uncomfortable side effects. Now we are so close to having an effective therapeutic, which can be used in a six-week cycle, with six to nine months before mite repopulation, there needs to be greater awareness and understanding of how to diagnose and manage the condition.

It's important to realize that currently only a fraction – eight to 10 percent – of patients under the umbrella of ocular surface disease symptoms are being adequately managed. Part of the issue is missing the correct diagnosis, so we have to look harder and make sure conditions are detected and diagnosed accurately, so that when a treatment is available – we are ready to use it straight away.

The Saturn-1 study findings (2)

The randomized, double-masked trial evaluated a novel therapeutic, TP-03, for patients with confirmed Demodex blepharitis, in 421 adults who had more than 10 collarettes on their upper eyelid, and at least mild erythema of the upper eyelid margin. Each patient enrolled in the study had at least 1.5 mites per lash on the upper and lower eyelids.

The trial found that the medication cured collarettes by day 43 in 81 percent of patients, with 43 percent of patients achieving complete collarette cure. 68 percent of patients using the therapeutic achieved Demodex mite eradication by day 43, with no mites present on eyelashes.

The trial also showed good tolerability of TP-03, with 93 percent of patients reporting neutral to high levels of comfort. No serious adverse effects were recorded, with mild effects such as pain, burning and stinging noted in under 12 percent of participants.

Elizabeth Yeu is Assistant Professor at Eastern Virginia Medical School and Cornea, and Cataract and Refractive Surgeon with Virginia Eye Consultants, Virginia, USA. She is the Chief Medical Advisor at Tarsus Pharmaceuticals.

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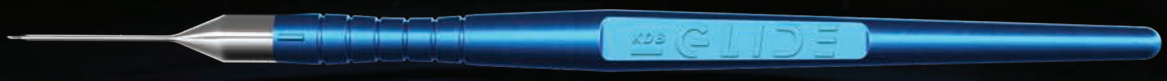

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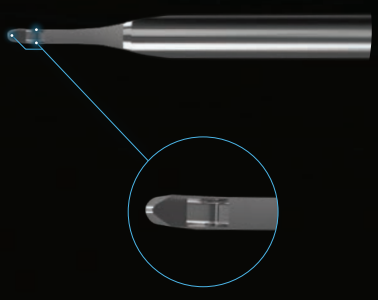
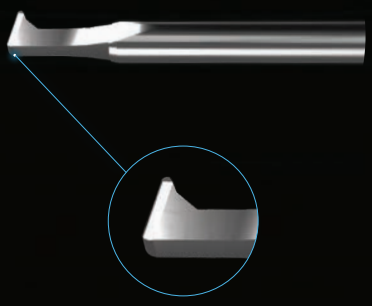


ROUNDED HEEL



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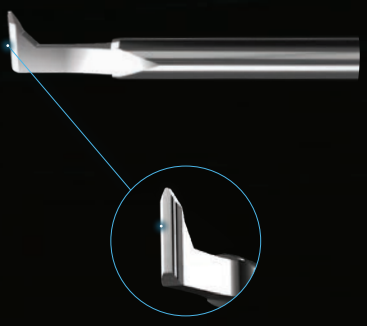

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Pressure Point

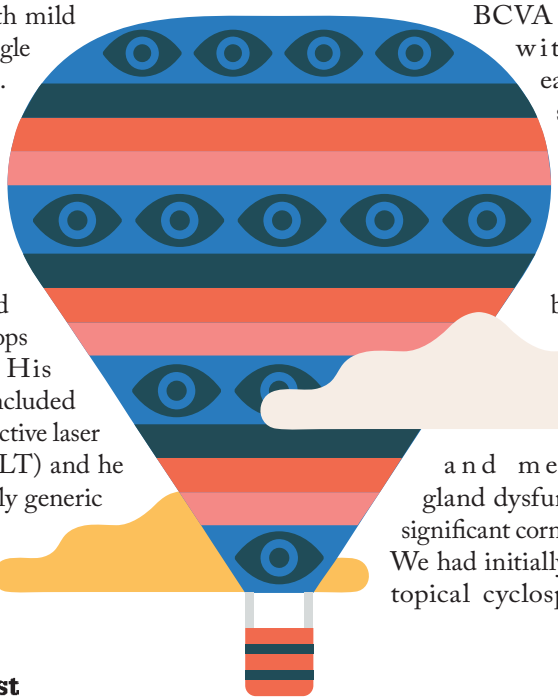
You can prescribe a patient a drug, but you can't make them compliant

By Paul Singh

Leading a horse to water, or prescribing a patient a medicine, is only one step in the process of treatment. Patient compliance – getting the horse to drink the water – is essential to ensuring that the prescription can actually have an effect. Compliance is a common problem across all fields of medicine, but is notorious in eye care, especially when looking at eye drops.

I'd like to share my experience of patient care following implantation of Durysta to reduce intraocular pressure (IOP), which I had previously used during its phase II and III trials. Last June, I finally got the chance to use the product in a real-world setting on a 68-year-old Medicare fee-for-service patient with mild peripheral open angle glaucoma (POAG). He was suffering with significant ocular surface issues, couldn't remember to take his topical medications, and would also skip drops to save money. His medical history included two sessions of selective laser trabeculoplasty (SLT) and he was back on a daily generic prostaglandin analog (PGA) and beta blocker for both eyes. A regular complaint was that his vision would fluctuate throughout the day and eye drops caused red and watery eyes; additionally, he admitted to mostly using his drops in the few days leading up to an appointment. Not all the news was bad, though! His Humphrey visual field tests were full and stable and he had a fairly healthy retinal nerve fiber layer (RNFL), minimal ganglion cell complex (GGC) loss, only slightly low corneal hysteresis, and central corneal thickness (CCT) in the 530s.

In-office IOP measurements were at target in the teens, but did fluctuate by around 4 mmHg between visits. His BCVA was 20/20 with a very early nuclear sclerosis lens change that was hard to detect due to poor tear film breakup time and meibomian gland dysfunction with significant corneal staining. We had initially prescribed topical cyclosporine and artificial tears – but, with the patient already struggling to use eye drops for glaucoma, adding extra drops to the list was fruitless.



"If a patient has a low likelihood of continuing a therapeutic regime due to compliance issues, that patient is not controlled."

This led me to ask, "Is this patient controlled? Should I continue with the course of treatment when compliance issues are so pervasive?"

One way to define patient control for glaucoma is to look at the patient's IOP, visual field, and disc stability alone – in which case, my patient could be considered controlled. But, in my opinion, if a patient has a low likelihood of continuing a therapeutic regime due to compliance issues – whether that be cost (which studies have shown can prevent initial

prescriptions from being refilled), side effects, ocular surface disease (OSD), forgetfulness, or other reasons – that patient is not controlled.

Taking compliance into account for my definition of controlled glaucoma has been a big philosophical change and it is a core tenet when I think of the term "interventional glaucoma." We have to remember that glaucoma is a progressive disease and it is often difficult to see changes early on. Intervention to maintain a high quality of life and substantial compliance to help preserve nerve structure and function are my goals.

Dry eye is common in glaucoma patient populations, but so is poor compliance with drops. This can lead to fluctuations in IOP – a risk factor for progression over time – and it is clear that untreated patients have much higher rates of disease progression.

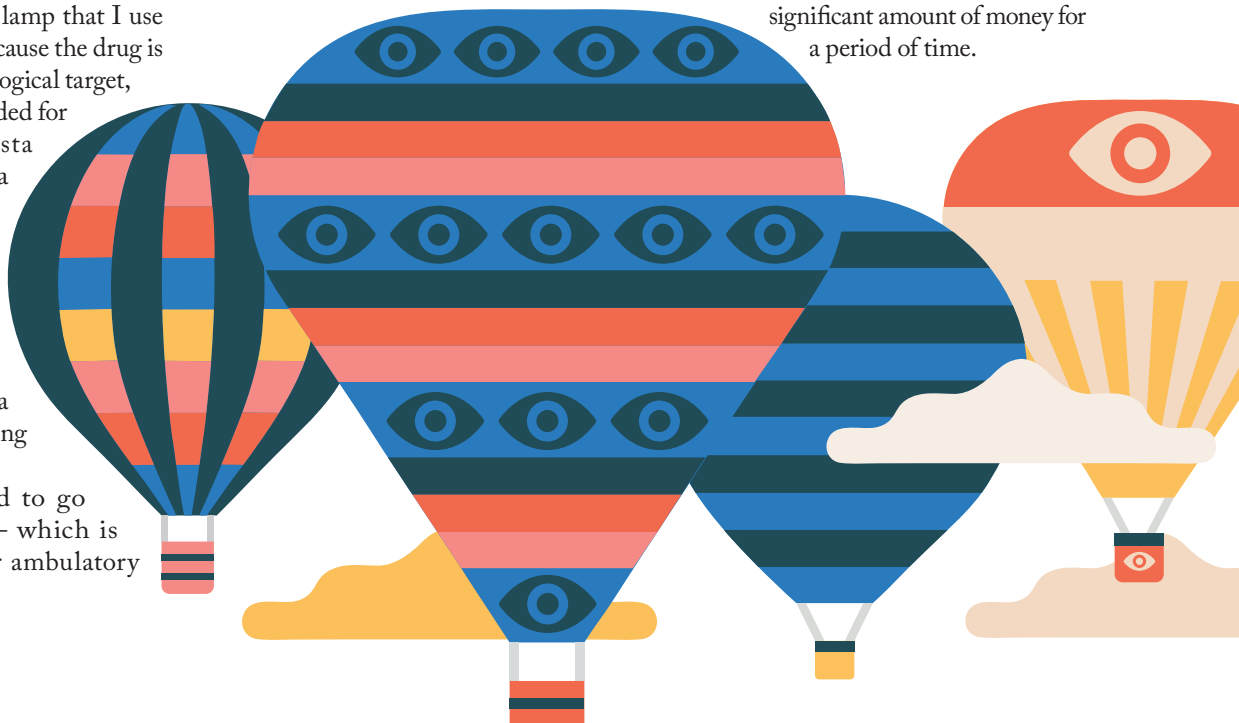
Due to the lack of compliance and the previous SLT treatments, I offered my patient MIGS – but the prospect of surgery made the patient apprehensive and he chose to wait. A short time later, Durysta was approved. I explained that the medication he was taking is now available as a dissolvable slow-release material that can be placed in the eye in-office using the same lamp that I use to check eye pressure. Because the drug is released nearer to the biological target, a much lower dose is needed for therapeutic effect. Durysta is also approved for a single administration, because its slow-release mechanism enables activity for four months. The IOP-lowering effect has a 33 percent chance of lasting for a year and a 25 percent chance of lasting two years.

The patient decided to go ahead with Durysta – which is inserted in an office or ambulatory surgical center with the patient in supine position at the slit lamp – in both eyes . For a procedure like this, aseptic conditions are crucial to avoid infection; we used betadine to clean the eye, sterile gloves, a technician to keep the patient's head stable, and had the patient fixate on one of the slit lamp knobs. I entered the eye anterior to the limbus just below three o'clock of the left eye and nine o'clock of the right eye, staying over the iris, and then depressed the button on the loader to release the implant. The patient couldn't believe that both eyes were implanted in the exam room without any discomfort. I'm routinely told, "Doc, that was easier than getting my eye pressure checked."

One pearl of wisdom I can offer to others is to press the injector button halfway until you see the implant partially exposed, then fully depress. This allows the fluid to absorb any air bubbles and ensures that the implant will be released completely free of the needle (double-press technique).

Patients don't tend to be bothered by IOP reduction lasting only four to six months – and a second injection has not been approved by the FDA at this time. The reason for patients' relaxed attitudes is that I present the therapy as a "drug holiday" – patients can take a break from the daily treatment regimen that is part and parcel of glaucoma management, thereby solving compliance issues for the duration of drug activity. Due to the high safety and benign nature of the insertion, the bar to acceptance and success is much lower than that of a surgical option. In fact, for this patient, there were no out-of-pocket costs because he had Medicare fee-for-service with a supplement. Even if he has to go back on drops, we at least saved him a significant amount of money for a period of time.

"We have to remember that glaucoma is a progressive disease and it is often difficult to see changes early on."



Another patient is now 10 months post-implant and his IOP is still in the 16–17 mmHg range – allowing him to stay off both PGA and beta blockers. I have been pleasantly surprised to see many patients maintain significant efficacy beyond six months and, likely due to compliance, able to remove more drugs than just the PGA. In fact, looking at our own data, over 90 percent of our patients have demonstrated efficacy beyond six months. A few have now seen a slight rise in IOP compared to topical medication, but most are still within the target range. I still feel comfortable observing those with IOPs 1–2 mmHg higher because I know there are no compliance issues to deal with and thus possibly less potential for fluctuation. The studies also demonstrate that IOP doesn't rise back to baseline immediately; there is a slow rise that provides time to see the patient again depending on the severity of their case.

On my patient's last visit, I told him that if his IOP is higher at his next visit, he may have to start taking the eye drops again. Surprisingly, he said, "Doc, now that I have had this time off from my glaucoma drops, my eyes feel so much better. I think I'm ready to have that glaucoma surgery you mentioned before." This kind of response is increasingly common from patients who initially refused MIGS-type procedures. After having a "drop-free holiday," patients express more openness to pursuing surgical interventions. It's almost as though Durysta has served as a mental bridge between drops and surgery – providing them with perspective on reducing the drop burden and appreciating the potential longer-term benefits of surgery.

After almost a year of implanting Durysta, we have found that patient acceptance is often based on their level of compliance issues. We have also had a wide range of patient types across mild, moderate, and advanced disease; we have implanted in patients with OSD, ocular hypertension, those on the way to a subconjunctival or tube procedure, and post-SLT or MIGS. Even with this diverse range of patients, we have not seen any adverse events to date in my practice.

We now have more options than ever before for surgeons and patients alike – and these safe and efficient interventions have forced me to reevaluate my processes. Can we now truly customize our therapy? Can we now combine technologies and mechanisms to help to maintain or improve quality of life while adequately controlling IOP? I have realized that, the earlier we intervene, and the higher the target IOP, the better the chance that less invasive options will succeed and keep patients functioning at a high level.

Paul Singh is President of The Eye Centers of Racine & Kenosha, Wisconsin, USA. Singh reports that he is a consultant for Ellex.

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INDICATIONS: The Light Adjustable Lens and Light Delivery Device system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag in adult patients with preexisting corneal astigmatism of ≥ 0.75 diopters and without preexisting macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS: The Light Adjustable Lens is contraindicated in patients who are taking systemic medication that may increase sensitivity to ultraviolet (UV) light as the Light Delivery Device (LDD) treatment may lead to irreversible phototoxic damage to the eye; patients who are taking a systemic medication that is considered toxic to the retina (e.g., tamoxifen) as they may be at increased risk of retinal damage during LDD treatment; patients with a history of ocular herpes simplex virus due to the potential for reactivation from exposure to UV light; patients with nystagmus as they may not be able to maintain steady fixation during LDD treatment; and patients who are unwilling to comply with the postoperative regimen for adjustment and lock-in treatments and wearing of UV protective eyewear. **WARNINGS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting an IOL in a patient with any of the conditions described in the Light Adjustable Lens and LDD Professional Use Information brochure. Caution should be used in patients with eyes unable to dilate to a pupil diameter of ≥ 7 mm to ensure that the edge of the Light Adjustable Lens can be visualized during LDD light treatments; patients who the doctor believes will be unable to maintain steady fixation that is necessary for centration of the LDD light treatment; and patients with sufficiently dense cataracts that preclude examination of the macula as patients with preexisting macular disease may be at increased risk for macular disease progression. **PRECAUTIONS:** The long-term effect on vision due to exposure to UV light that causes erythropsia (after LDD treatment) has not been determined. The implanted Light Adjustable Lens MUST undergo a minimum of 2 LDD treatments (1 adjustment procedure plus 1 lock-in treatment) beginning at least 17-21 days post-implantation. All clinical study outcomes were obtained using LDD power adjustments targeted to emmetropia post LDD treatments. The safety and performance of targeting to myopic or hyperopic outcomes have not been evaluated. The safety and effectiveness of the Light Adjustable Lens and LDD have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Patients must be instructed to wear the RxSight-specified UV protective eyewear during all waking hours after Light Adjustable Lens implantation until 24 hours post final lock-in treatment. Unprotected exposure to UV light during this period can result in unpredictable changes to the Light Adjustable Lens, causing aberrated optics and blurred vision, which might necessitate explantation of the Light Adjustable Lens. **ADVERSE EVENTS:** The most common adverse events (AEs) reported in the randomized pivotal trial included cystoid macular edema (3 eyes, 0.7%), hypopyon (1 eye, 0.2%), and endophthalmitis (1 eye, 0.2%). The rates of AEs did not exceed the rates in the ISO historical control except for the category of secondary surgical interventions (SSI); 1.7% of eyes (7/410) in the Light Adjustable Lens group had an SSI ($p < .05$). AEs related to the UV light from the LDD include phototoxic retinal damage causing temporary loss of best spectacle corrected visual acuity (1 eye, 0.2%), persistent induced tritan color vision anomaly (2 eyes, 0.5%), persistent induced erythropsia (1 eye, 0.3%), reactivation of ocular herpes simplex Infection (1 eye, 0.3%), and persistent unanticipated significant increase in manifest refraction error (≥ 1.0 D cylinder or MRSE) (5 eyes, 1.3%). **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. **Please see the Professional Use Information Brochure for a complete list of contraindications, warnings, precautions, and adverse events.**

Profession

Your career
Your business
Your life

The Best of Both Worlds

Combining the roles of clinician and researcher was not easy. But we can – and should – smooth the path for the next generation.

By Mariya Moosajee

Credit: Zoltan Tasi/Unsplash.com

I did my medical degree at St Mary's Hospital Medical School of Imperial College London in the UK, but I also always enjoyed basic sciences. And so, when an opportunity to get an additional degree in biochemistry and molecular genetics came along, I jumped at the chance. Back then, it was really exciting to study the Human Genome Project; I felt it was a huge privilege to be able to learn and understand such complicated science at such a young age and to witness the birth of this massive and hugely important endeavor. As part of that degree, I undertook a lab-based project, and I really enjoyed the practical skills, such as PCR and RNA extraction. Without fully realizing it, I had already begun my dual training to become a clinician scientist.

Looking back, I did feel a little bit like an outsider in both fields, and, because I was trying to do both, I faced soft discrimination. Thanks to my clinical training, I was used to getting to work at 7am – and it really suited me. So I did the same thing when I worked in the lab during my full-time science PhD in ophthalmic genetics. I would arrive before anyone else, and (understandably, I think) leave a little earlier, too. As a result, my fellow scientists told me that leaving before the supervisor was not "the done thing." Somehow, they had an image of clinicians as people who spent their days having coffee and lunches, and playing golf....

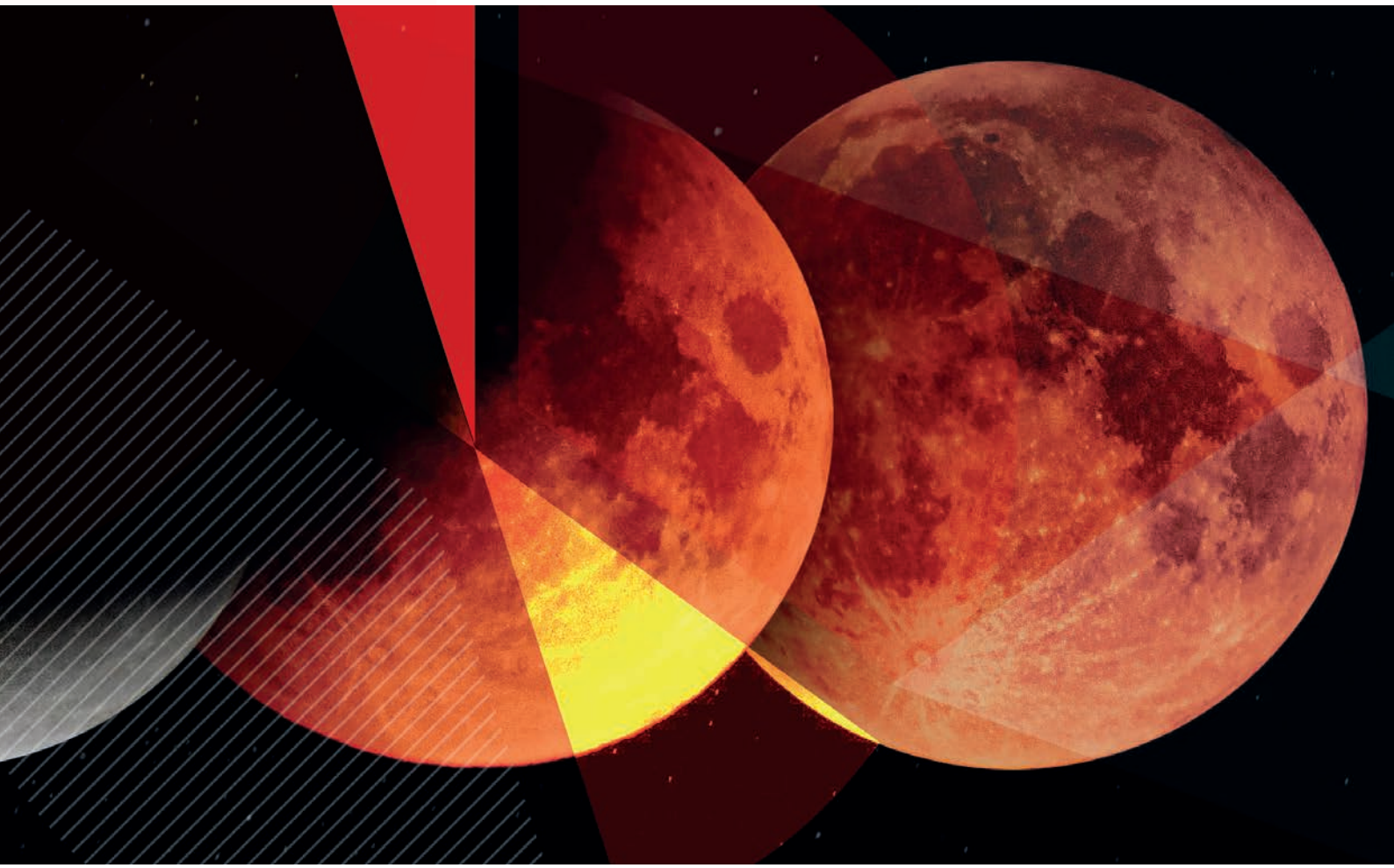
The need for role models

At the time, it wasn't easy to find good role models in my field – those people who would have an understanding of both paths, and how best to combine them. And so I forged my own path. I was quite naïve at the beginning and just did what interested me. I didn't know if it would be possible to combine the two careers successfully, but I knew I didn't want to give up on research. I enjoyed it immensely; I would spend my free afternoons going to the lab to work on my projects, even when I struggled for time. It wasn't until around seven years ago, when I really had to decide properly about my future as a consultant ophthalmologist, that I really believed that I could have a proper academic ophthalmology career. I decided that I could become a professor one day.

The fact that it was hard for me to find mentors who straddled both scientific research in academia and clinical practice has made me very conscious of showing my younger colleagues that this path is possible and realistic. I think the situation is changing, and these days it is much easier to find role models and mentors who have followed this path. In the UK, the Royal College of Ophthalmologists has paved the way for those who want to pursue a career in academic ophthalmology. I now sit on the Academic Committee at the University College London, which makes sure that there is clear signposting and support for those individuals who wish to pursue a combined career in clinical practice and scientific research.

Keep going

There is still a lot of work to be done in this area. Firstly, I think there should be a lot more flexibility in training programs. Everyone who goes through medical training knows that it is a challenging time – early starts and very late finishes,



not seeing your family for days, constant revisions and exams. Trainees are required to make a big effort and commit to their specialty, even before landing their residency. Then, they stay in their long training program, only allowed to leave it at certain periods to pursue other interests, and complete research degrees, for example. All the pressure makes it unnecessarily difficult for trainees to develop their own interests and find the flexibility to pursue other endeavors and build their CVs during their training. I tell my junior colleagues to find their niche and to find as much time to devote to it during their training as they can. I tell them to consider something that will better define them at the end of their residency and fellowship, be it work in education, leadership, management, or research. I believe it's the our responsibility – as senior consultants – to develop and encourage trainees to explore different options that will make them stand out in their future careers.

Now, I try to teach my trainees – clinicians and scientists – how to multitask successfully. We celebrate each other's successes, and share skills. During the pandemic lockdowns, I introduced fortnightly workshops for my lab group, where we would learn about various aspects of being a successful researcher; each member of the team would share a transferable skill that they mastered. It's important to give the next generation a broader view, beyond the experiment they're working on this week, or a technique they're currently mastering.

We've got to ask ourselves: how can we make it easier for the next generation? Personally, I have always tried to signal any issues and suggest potential improvements in any training environments I have been in, so that the people behind me would have better opportunities to improve their training or working conditions. I have great admiration for people who are always trying to think of ways to help rather than just take the easy option and say "no" – and I try to emulate that in my own professional (and personal) life.

Mariya Moosajee is Professor of Molecular Ophthalmology at University College London Institute of Ophthalmology; Group Leader of Ocular Genomics and Therapeutics at the Francis Crick Institute; and Consultant Ophthalmologist at Moorfields Eye Hospital and Great Ormond Street Hospital for Children, London, UK.

Earning a Place at the Table

How do you make a name for yourself in ophthalmology, when you're carrying a name that's already big in the field?

By Nikki Hafezi

When I first met my husband, I was working in the posterior segment field, working on a retinal prosthesis project in the US. I'd met Mark Humayun at the University of Southern California Eye Institute in Los Angeles, California, USA, and, thanks to my fundraising experience, I got the opportunity to work with his team at the Industrial Liaison Office for the Engineering Research Center (funded by the US National Science Foundation). Ever since then, I knew I wanted to stay in ophthalmology – a highly innovative field that I find incredibly fascinating to this day.

Farhad and I met at ARVO and, when we got together, we had to decide where "Team Hafezi" was going to live. As Farhad was already on his way to getting a professorship in Switzerland (and because he would have to begin his residency again if he moved to the US), we decided it would be easier for me to resume my career path in Europe. I was probably around five years too early in my career to be able to transfer it seamlessly to the University of Zurich in Switzerland. Having learned that, I decided to become better versed in European patent law; after I had earned a Master's degree in intellectual property, I started writing grant proposals – and their success really launched my career in Europe.

"When you develop a good relationship and get to know people well, you're able to work with them more easily and at a faster pace."

Breaking barriers

After my move to Switzerland, many of the people I met dismissed me as a "young wife" of Farhad who didn't have a professional career. It was very difficult and I was deeply offended. Frankly, I felt distraught a lot of the time. When Farhad's colleagues were referred to as doctor, professor, expert, or specialist, I would simply be "Nikki."

I had a choice: I could continue to get offended and try to fight the attitude – or I could use it to my advantage. I chose the latter. The English language naturally removes a lot of formality, but, in German, how you are addressed is a very big deal, and it can create certain barriers between people. The fact that people immediately call me "Nikki" breaks the formality down and allows me to develop meaningful working relationships more quickly. And when you develop a good relationship and get to know people well, you're able to work with them more easily and at a faster pace. And if younger residents or students are too intimidated to speak to Farhad about ideas they might have, they come to me; they see me as more approachable, and I'm more than happy to open communication channels, especially on topics, such as keratoconus and cross-linking. All of this has really helped "Team Hafezi."

Among equals?

As most women will know, being in a position of influence has some specific challenges for our gender. Now that I am a CEO of my own ophthalmic company – you can read more about that in When the Rubber Hits the Road (1) – I find myself being continually reminded of this fact. A few months ago, I was giving a presentation at a business meeting to a male audience within my age range. After I presented my topic, there was a question from the audience: "This all sounds great, but how will you have time to do it?" I didn't really understand, so I asked for clarification. The reply came: "Well, you have three children." I simply responded that I hadn't realized my children were part of the discussion, but I was very shocked to be asked this. Such moments bring a striking realization that things are still not equal, despite our best efforts.

Being married to an authority in a particular field, and carrying his name, brings with it even more challenges. Those with a similar experience may know that they have to work extra hard to feel like they deserve a place at the table. When I come to an ophthalmology meeting, those who don't know me don't know what to expect; they may wonder if I'm there thanks to my husband's career or because of my own. Many people also have preconceived notions of me before I start speaking, so I have to work harder to be treated fairly.

Different directions

As I'm not an ophthalmologist, I've always felt that I had to defend my education somehow; I haven't got a medical degree but instead have a diverse education and significant applicable of work experience (I did business studies, got a degree in intellectual property and law, and I did a lot of fundraising in my early career). Fortunately, I feel that people's perception of what background is useful in ophthalmology has changed over the past several years. For the slightly older generation in the field, the most prestigious way forward has been a medical career culminating in professorship and becoming chief of a department. But the residents I met over the past few years would much rather trade that for a more varied experience; they study law, economics or informatics, and aim to combine this with ophthalmology. Others get qualifications as skiing instructors, enjoy nature, and find the right work-life balance. Those residents are now becoming new leaders in the field – and they see a mixture of different types of experience as a real advantage. The same can be said about the industry – big players are also looking for people with varied backgrounds. Ophthalmology is now such a broad field that it cannot be limited simply to patient care. And that's why I'm now so proud of my background – and I have learned to use it to my advantage!

From the point of view of my career, I could view being married to Farhad as a strength or as a challenge to overcome. To be honest, I see the moment I met him as the most defining moment of my career – a pivotal point that gave me the opportunity to develop my own strengths within the field of ophthalmology.

Nikki Hafezi is the managing director of GroupAdvance Consulting GmbH and the CEO of EMAGine AG, Zug, Switzerland.

Reference

1. *N Hafezi, "When the Rubber Hits the Road," The Ophthalmologist (2021). Available at: https://bit.ly/2X1foE5.*

Leader's Digest

Sitting Down With… Adam Mapani, Honorary Clinical Teaching Fellow UCL Department of Clinical Ophthalmology and Nurse Consultant at Moorfields Eye Hospital, Medical Retina Department, London, UK

Why ophthalmology How did you envisage your career path?

I have always imagined myself in a career where I could make an impact on lives. Before embarking on my ophthalmology journey, I considered specializing in diabetes, with the ambition of becoming a diabetes nurse consultant.

So how did you end up in ophthalmology?

My parents came to the UK for my graduation in 2002 – and it coincided with them both having eyesight problems, for which I took them to an optician. All they needed was prescription glasses, which was a relief – and which made a lasting impression on me as a significantly positive experience that transformed their quality of life. It inspired me to pursue a career in ophthalmology, so that I would also be in a position to contribute to society and similarly transform other peoples' lives. My ambition was further ignited when I visited Moorfields Eye Hospital while accompanying a diabetic patient to a routine eye appointment.

What led to you becoming the first-ever nurse consultant in ophthalmology at Moorfields?

This followed a period of extensive training and development as an advanced nurse practitioner to become the lead medical retina nurse. From there, I set up the nurse-led clinics in the medical retina service. I nurtured and developed the medical retina team through training and education, and I forged strong support networks and mentorship from consultant colleagues and senior management. Having worked in the medical retina service for 11 years, July 2014 was a significant milestone in my career – the day I became the first-ever nurse consultant at Moorfields! I hope that being a pioneer in this role will inspire my nursing colleagues within and outside Moorfields to become future clinical leaders.

How did you get involved in training nurses and AHPs to deliver intravitreal injections?

When anti-VEGF injections were licensed by NICE in 2008, it placed an extra burden on the already-stretched medical retina service. There were so few trained ophthalmologists to deliver these new sight-saving therapies and meet the demands they created. I saw this crisis as an opportunity to use nurses and other allied healthcare professionals (AHCPs) to bridge the gap in service and demand. I began to advocate with policymakers to support this initiative with training for nurses and AHCPs. I was one of the first nurses to carry out intravitreal injections with the pioneering service established in 2012 at Moorfields. We successfully implemented the nurse-led intravitreal injection service across the Trust. This led to influencing policymakers at the national level and, to a certain extent, even globally.

I received an avalanche of inquiries about how we set it up. Colleagues worldwide wanted to know what we had done and how they could do it, too. Because of this huge level of interest, I developed a training program with my colleagues, both outlining our legacy and sharing our success story – demonstrating safety and positive patient experiences. Since establishing the course in 2014, we have trained more than 1,200 ophthalmic nurses and other AHCPs – this figure is at least two-thirds of the total number of practitioners who currently administer intraocular injections in the UK. The global outreach has given the course the international recognition needed to promote non-medical staff delivering injections. There is still work to be done in advancing practice outside the delivery of intravitreal injections – and nurses and AHCPs can play an integral role in other clinical pathways as well.

What other eye care projects have you taken part in?

My passion for eye care is driven by the fact that people's sight matters so much. Building on my many years of experience working in ophthalmology, combined with my connection to world-renowned clinical leaders, I decided that I wanted to work in Africa (to give back to Zimbabwe, my country of birth). My colleagues and I volunteered our time through Abalon Trust, an international eye charity that provides eye care in Africa and the Caribbean. I made trips as a volunteer at camps in Zimbabwe, Kenya, and Uganda delivering eye care to marginalized and underserved communities. I also wanted to make a difference to nurses in the communities in which I worked by empowering them through education and development.

Did the pandemic changed how you work?

The pandemic has significantly changed our work. In the first months, we had to adapt to new ways of working, restricting the number of patients we could see face-to-face and managing the psychological implications of the pandemic – mainly fears and anxiety – in staff, patients, and carers. When services resumed, we had a significant number of patients coming through our digital hubs. The backlog COVID-19 caused has now created extra demands in the service.

Tell us about your work promoting COVID-19 vaccinations in African communities in the UK?

I have had the privilege of working with African communities in the UK to address hesitancy and some of the myths associated with COVID-19 vaccines. Hesitancy about COVID-19 vaccines is disproportionately high in among Black, Asian and minority ethnic (BAME) groups despite the significant impact of COVID-19 in these populations. Coming from lived experience, I was uniquely placed to support the uptake of COVID-19 vaccines for people with links to African and Caribbean countries and the diaspora. Alongside senior BAME leaders in the National Health Service, pastors, and community leaders, we became a voice

challenging many of the myths around the COVID-19 vaccine. This was extremely important to prevent people in the most vulnerable communities from missing out on adequate COVID-19 protection.

How does it feel to receive the honors you've been given?

In 2020, I was truly humbled to be honored by the UK Prime Minister as an inspirational BAME leader – I was invited to 10 Downing Street (residence and office of the Prime Minister) in recognition of my work in ophthalmology. I was then overjoyed to learn that I had also been awarded an MBE by the Queen for my contribution to ophthalmology services. It is such an honor, especially among my many talented and deserving colleagues in the field.

What gets you out of bed in the morning these days?

The desire to make a difference and positively impact patients, colleagues, and wider society keeps me going!

The best part of my job is getting to know my patients, interacting with them, and delivering care that preserves their sight and makes a difference to their quality of life. I also have a zeal for problem-solving – while providing leadership and mentorship to my colleagues, both internally and externally. The worst part is when time with a patient is limited, making it more difficult to deliver care to a level that I feel is adequate. I am proud that through my international role as a guest key note speaker, and my leadership during the roll out of advanced practice, has made an impact to people's lives – inspiring many in the 15 countries that I have travelled to.

Do you have any personal missions for the next 10 years?

My passion for supporting others extends to mentoring. I am committed to the development of future leaders in eye care and patient care through mentorship, coaching, and leadership. I am now in my final year of my Executive MBA Studies at Warwick Business School, UK, and I hope to use what I've learned to provide better leadership.

What advice would you give to people who are following in your footsteps?

Find an early definition of success that is relative to you, find a mentor, and never compare your progression to others. My philosophy is, "Do what you love, and you will love what you do."

What makes you happy outside work?

Quality family time is very important to me. I like to work on my physical fitness through jogging, walking with my wife and daughters, or cycling. In my downtime, I listen to music and watch sports – football and rugby – and I am slowly learning to play golf!

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

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

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

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

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

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

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

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

(continued)

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

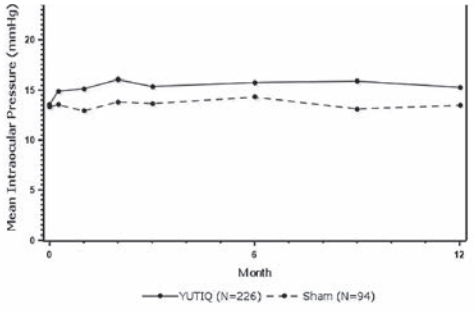
Ocular		
ADVERSE REACTIONS	**YUTIQ (N=226 Eyes) n (%)**	**Sham Injection (N=94 Eyes) n (%)**
Vitreous Hemorrhage	4 (2%)	0
Iridocyclitis	3 (1%)	7 (7%)
Eye Inflammation	3 (1%)	2 (2%)
Choroiditis	3 (1%)	1 (1%)
Eye Irritation	3 (1%)	1 (1%)
Visual Field Defect	3 (1%)	0
Lacrimation Increased	3 (1%)	0
Non-ocular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

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

Table 2: Summary of Elevated IOP Related Adverse Reactions

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

Figure 1: Mean IOP During the Studies



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

Manufactured by:
EyePoint Pharmaceuticals US, Inc., 480 Pleasant Street, Watertown, MA 02472 USA
Patented.

0.18 mg
YUTIQ®
(fluocinolone acetonide intravitreal implant) 0.18 mg

Discover continuous calm in uveitis[1]

YUTIQ is designed to deliver a sustained release of fluocinolone for up to 36 months for patients with chronic non-infectious uveitis affecting the posterior segment of the eye[1]

- Proven to reduce uveitis recurrence at 6 and 12 months[1]*
  At 6 months–18% for YUTIQ and 79% for sham for Study 1 and 22% for YUTIQ and 54% for sham for Study 2 (*P*<.01). At 12 months–28% for YUTIQ and 86% for sham for Study 1 and 33% for YUTIQ and 60% for sham for Study 2.
- Extended median time to first recurrence of uveitis[1,2]
  At 12 months–NE† for YUTIQ/92 days for sham in Study 1; NE for YUTIQ/187 days for sham in Study 2.
- Mean intraocular pressure (IOP) increase was comparable to sham[1,2]
  Study was not sized to detect statistically significant differences in mean IOP.

For more information, visit **YUTIQ.com**

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

†NE=non-evaluable due to the low number of recurrences in the YUTIQ group.

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CONTRAINDICATIONS

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

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

WARNINGS AND PRECAUTIONS

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

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

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

ADVERSE REACTIONS

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

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

References: 1. YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg full US Prescribing Information. EyePoint Pharmaceuticals, Inc. May 2021. **2.** Data on file.

EYEPOINT PHARMACEUTICALS

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